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Novartis

Generic Drug Name

Spartalizumab (PDR001) and sabatolimab (MBG453)

Trial Indication(s)

Acute myeloid leukemia and high risk myelodysplastic syndrome

Protocol Number

CPDR001X2105

Protocol Title

Phase 1b, multi-arm, open-label study of PDR001 and/or MBG453 in combination with decitabine in patients with acute myeloid leukemia or high risk myelodysplastic syndrome

Clinical Trial Phase

Phase 1

Phase of Drug Development

Phase 3 (spartalizumab) and phase 1 (sabatolimab)

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Study Start/End Dates

Study Start Date: July 06, 2017 (Actual)
Primary Completion Date: September 08, 2023 (Actual)
Study Completion Date: September 08, 2023 (Actual)

Study Design/Methodology

This was a phase 1b, multi-arm, open-label study composed of six arms:

- Arm 1: Evaluation of a fixed dose of the standard of care agent decitabine, in combination with a fixed dose of spartalizumab
- Arm 2: Evaluation of a fixed dose of the standard of care agent decitabine in combination with an escalating dose of sabatolimab
- Arm 3: Evaluation of a fixed dose of the standard of care agent decitabine in combination with a fixed dose of spartalizumab and an escalating dose of sabatolimab
- Arm 4: Evaluation of an escalating dose of sabatolimab
- Arm 5: Evaluation of a fixed dose of spartalizumab in combination with an escalating dose of sabatolimab
- Arm 6: Evaluation of a fixed dose of the standard of care agent azacitidine in combination with an escalating dose of sabatolimab

This study was conducted in adult patients with acute myeloid leukemia (AML), intermediate or high-/very high-risk myelodysplastic syndrome (MDS), or MDS/myeloproliferative neoplasm (MPN) including chronic myelomonocytic leukemia (CMML).

Centers

11 centers in 8 countries: Australia(1), Spain(1), United Kingdom(1), Finland(1), United States(3), Netherlands(1), France(1), Germany(2)

Objectives:

The primary objective of the trial was to characterize the safety and tolerability of 1) MBG453 as a single agent or in combination with PDR001 or 2) PDR001 and/or MBG453 in combination with decitabine or azacitidine in AML and intermediate or high-risk MDS patients or MDS/MPN including CMML, and to identify recommended doses for future studies.

The secondary objectives were:

- To evaluate the preliminary anti-tumor activity of MBG453 as a single agent or in combination with PDR001 or PDR001 and/or MBG453 in combination with decitabine or azacitidine
- To characterize the pharmacokinetics of PDR001, MBG453 and decitabine or azacitidine
- To assess immunogenicity (IG) following one or more intravenous infusions of PDR001 and/or MBG453

Test Product (s), Dose(s), and Mode(s) of Administration

For this study, the term “study drug” refers to spartalizumab, sabatolimab, decitabine, and azacitidine.

“Study treatment” refers to all combinations given during the course of the trial (sabatolimab with spartalizumab, decitabine together with spartalizumab or sabatolimab, the combination of both spartalizumab and sabatolimab, or azacitidine together with sabatolimab).

“Study arm” refers to treatment with:

- decitabine with spartalizumab (Arm 1)
- decitabine with sabatolimab (Arm 2)

- decitabine with combined spartalizumab and sabatolimab (Arm 3)
- single agent sabatolimab (Arm 4)
- sabatolimab in combination with spartalizumab (Arm 5)
- azacitidine with sabatolimab (Arm 6)

Decitabine was administered according to standard clinical practice. A standard dose of decitabine (20 mg/m^2) was given intravenously every day for five consecutive days on days 1 to 5 out of a 28-day cycle, followed by spartalizumab or sabatolimab, or both. In order to minimize the risk of toxicity from concomitant administration with decitabine, spartalizumab infusion was administered on day 8 and sabatolimab infusions administered on day 8 and day 22 out of a 28-day cycle.

Azacitidine was administered according to standard clinical practice. A standard dose of azacitidine (75 mg/m^2) was given subcutaneously or intravenously every day for seven consecutive days on days 1 to 7 out of a 28-day cycle, followed by sabatolimab. In keeping with standard clinical practice, the alternative schedule of 75mg/m^2 for five consecutive days on days 1 to 5, followed by a two day break, then two consecutive days on days 8 to 9 was alternatively permitted. Sabatolimab infusions were administered on day 8 and day 22 out of a 28-day cycle.

Sabatolimab (100 mg/1 mL or 400 mg/4 mL liquid in vial) and spartalizumab (100 mg powder for solution for infusion) were administered via intravenous (i.v.) infusion over 30 minutes. When given in combination, both study drugs were administered on the same day.

Statistical Methods

Pharmacokinetics (PK) parameters were calculated using non-compartmental methods available in Phoenix WinNonlin 8.3.

The Full Analysis Set (FAS) and Safety Set (SS) were defined in the same way and comprised all participants who received at least one dose of any study treatment. Participants were analyzed according to the study treatment received, where treatment received was defined as the treatment most frequently taken between study day 1 and the end of Cycle 1 (the first 28 days of dosing) for Arm 4, or Cycle 2 (the first 56 days of dosing) for Arms 1, 2, 3, 5, 6, the onset of a dose-limiting toxicity (DLT) or treatment discontinuation, whichever occurred first.

The Dose-Determining Set (DDS) included all participants from the FAS who met the minimum exposure criterion and had sufficient safety evaluations, or who experienced a DLT during Cycle 1 (the first 28 days of dosing) for Arm 4 or Cycle 2 (the first 56 days of dosing) for Arms 1, 2, 3, 5, or 6.

The Pharmacokinetic analysis set (PAS) included all participants who provided an evaluable PK profile. A profile was considered evaluable if all of the following conditions were satisfied:

- Participant received the planned treatment,
- Participant provided at least one primary PK parameter.

The Immunogenicity prevalence set included all participants in the FAS with a determinant baseline immunogenicity (IG) sample or at least one determinant post-baseline IG sample.

The Immunogenicity incidence set included all participants in the Immunogenicity prevalence set with a determinant baseline IG sample and at least one determinant post-baseline IG sample.

IG analysis sets were defined separately for sabatolimab and spartalizumab.

Analyses were descriptive; no hypothesis testing was performed for this final clinical study report (CSR).

Study Population: Key Inclusion/Exclusion Criteria

Inclusion Criteria:

1. Written informed consent must be obtained prior to any screening procedures
2. Male or female patients ≥ 18 years of age who present with one of the following:

Arms 1-3:

● Relapsed/refractory AML following ≥1 prior therapies who have relapsed or exhibited refractory disease (primary failure) and are deemed by the investigator not to be candidates for standard therapy, including re-induction with cytarabine or other established chemotherapy regimens for patients with AML (patients who are suitable for standard re-induction chemotherapy or hematopoietic stem cell transplantation and willing to receive it are excluded)

● Newly diagnosed AML patients who are suitable for treatment with decitabine (patients who are suitable for standard induction chemotherapy or hematopoietic stem cell transplantation and willing to receive it are excluded)

● Intermediate or high risk MDS or MDS/MPN including CMML (patients who are suitable for standard re-induction chemotherapy or hematopoietic stem cell transplantation and willing to receive it are excluded)

Arms 4-5:

● Refractory / relapsed AML following ≥1 prior therapies (Arms 4a & 5a)

● Intermediate or high risk MDS or MDS/MPN including CMML who have failed hypomethylating agent therapy (Arms 4b & 5b)

(Note: hypomethylating agent failure is defined as progressive disease on hypomethylating agent therapy or lack of clinically meaningful response as deemed by investigator after at least 4 cycles of hypomethylating agent therapy.)

Arm 6:

● Newly diagnosed AML patients who are suitable for treatment with azacitidine (patients who are suitable for standard induction chemotherapy or hematopoietic stem cell transplantation and willing to receive it are excluded) (Arm 6a)

● Intermediate or high-risk MDS or MDS/MPN including CMML (patients who are suitable for standard induction chemotherapy or hematopoietic stem cell transplantation and willing to receive it are excluded) (Arm 6b)

3. Patient has an Eastern Cooperative Oncology Group (ECOG) performance status ≤ 2

4. Patient must be a candidate for serial bone marrow aspirate and/or biopsy according to the institutions guidelines and be willing to

undergo a bone marrow aspirate and/biopsy at screening, during and at the end of therapy on this study. Exceptions may be considered after documented discussion with Novartis.
5. Arms 1-3: Patients must be fit for standard treatment with decitabine as determined by the investigator and as per local decitabine package insert.
6. Arm 6: Patients must be fit for standard treatment with azacitidine as determined by the investigator and as per the local azacitidine package insert.

Exclusion Criteria:
1. Arms 1-3 or Arm 6: Patients who have received prior hypomethylating agent treatment for AML or MDS.
2. Patients with active, known or suspected autoimmune disease. Patients with vitiligo, type I diabetes, residual hypothyroidism only requiring hormone replacement, psoriasis not requiring systemic treatment or conditions not expected to recur should not be excluded.
3. History of, or current drug-induced interstitial lung disease or pneumonitis grade ≥ 2.
4. Patients who discontinued prior PD-1 or PD-L1 directed therapy due to a treatment related toxicity should not be included in the PDR001 containing arms of the study. Patients previously exposed to anti-PD-1/PD-L1 treatment who are adequately treated for skin rash or with replacement therapy for
endocrinopathies should not be excluded.
5. Systemic antineoplastic therapy (including cytotoxic chemotherapy, alphainterferon, kinase inhibitors or other targeted small molecules, and toxinimmunoconjugates) or any experimental therapy within 14 days or 5 half-lives, whichever is shorter, before the first dose of study treatment.
6. Systemic chronic corticosteroid therapy (>10 mg/day prednisone or equivalent) or any immunosuppressive therapy within 7 days of first dose of study treatment. Topical, inhaled, nasal and ophthalmic steroids are allowed.

Other protocol-defined inclusion/exclusion criteria may apply.

Participant Flow Table

Arms 1 and 2

	PDR001 400mg Q4W + Decitabine ND AML	PDR001 400mg Q4W + Decitabine R/R AML	PDR001 400mg Q4W + Decitabine HR/V HR MDS	MBG453 240mg Q2W + Decitabine ND AML	MBG453 240mg Q2W + Decitabine R/R AML	MBG453 400mg Q2W + Decitabine ND AML	MBG453 400mg Q2W + Decitabine R/R AML	MBG453 800mg Q4W + Decitabine ND AML	MBG453 800mg Q4W + Decitabine R/R AML	MBG453 240mg Q2W + Decitabine HR/V HR MDS	MBG453 400mg Q2W + Decitabine HR/V HR MDS	MBG453 400mg Q2W + Decitabine IR MDS	MBG453 800mg Q4W + Decitabine HR/V HR MDS	MBG453 800mg Q4W + Decitabine IR MDS	MBG453 240mg Q2W + Decitabine CMML	MBG453 400mg Q2W + Decitabine CMML	MBG453 800mg Q4W + Decitabine CMML
Arm/Group Description	Arm 1: PDR001 in combination with decitabine 20mg/m2 in newly diagnosed acute myeloid	Arm 1: PDR001 in combination with decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 1: PDR001 in combination with decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in newly diagnosed acute	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in newly diagnosed acute	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in newly diagnosed acute	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in chronic myelomonocytic leukemia	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in chronic myelomonocytic leukemia	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in chronic myelomonocytic leukemia

	leukemia			myeloid leukemia		myeloid leukemia		myeloid leukemia									
Started	1	12	3	3	9	12	11	7	9	9	4	5	6	2	1	3	1
Completed	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Not Completed*	1	12	3	3	9	12	11	7	9	9	4	5	6	2	1	3	1
Progressive Disease	0	8	1	3	7	7	7	2	4	5	0	0	2	0	1	1	1
Adverse Event	1	2	0	0	0	0	0	2	0	0	0	1	0	0	0	0	0
Death	0	1	0	0	0	2	1	1	0	0	1	0	0	0	0	0	0
Physician Decision	0	1	2	0	0	1	1	2	5	3	2	3	3	1	0	2	0
Subject/guardian decision	0	0	0	0	2	2	2	0	0	1	1	1	1	1	0	0	0
Completed planned cycles	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

*Discontinued from treatment

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Arms 3, 4 and 5

	MBG453 160mg Q2W + PDR001 + Decitabine R/R AML	MBG453 240mg Q2W + PDR001 + Decitabine ND AML	MBG453 240mg Q2W + PDR001 + Decitabine R/R AML	MBG453 400mg Q2W + PDR001 + Decitabine ND AML	MBG453 400mg Q2W + PDR001 + Decitabine R/R AML	MBG453 160mg Q2W + PDR001 + Decitabine HR/VHR MDS	MBG453 240mg Q2W + PDR001 + Decitabine HR/VHR MDS	MBG453 400mg Q2W + PDR001 + Decitabine HR/VHR MDS	MBG453 400mg Q2W R/R AML	MBG453 1200mg Q2W R/R AML	MBG453 400mg Q2W HR/VHR MDS	MBG453 1200mg Q2W HR/VHR MDS	MBG453 1200mg Q2W IR MDS	MBG453 80mg Q2W + PDR001 R/R AML	MBG453 240mg Q2W + PDR001 R/R AML	MBG453 240mg Q2W + PDR001 HR/VHR MDS
Arm/Group Description	Arm 3: MBG453 160 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in newly	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in newly	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 3: MBG453 160 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in high-/very high-risk myelo dyspla	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in high-/very high-risk myelo dyspla	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in high-/very high-risk myelo dyspla	Arm 4: MBG453 400 mg Q2W in relapsed/refractory acute myeloid leukemia	Arm 4: MBG453 1200 mg Q2W in relapsed/refractory acute myeloid leukemia	Arm 4: MBG453 400 mg Q2W in high-/very high-risk myelodysplastic syndrome	Arm 4: MBG453 1200 mg Q2W in high-/very high-risk myelodysplastic syndrome	Arm 4: MBG453 1200 mg Q2W in intermediate-risk myelodysplastic syndrome	Arm 5: MBG453 80 mg Q2W in combination with PDR001 400 mg Q4W in relapsed/refractory acute myeloid leukemia	Arm 5: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W in relapsed/refractory acute myeloid leukemia	Arm 5: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W in high-/very high-risk myelodysplastic syndrome

		diagnosed acute myeloid leukemia		diagnosed acute myeloid leukemia		stic syndrome	stic syndrome	stic syndrome								
Started	3	2	2	2	3	3	2	1	10	6	3	5	2	1	5	5
Completed	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Not Completed*	3	2	2	2	3	3	2	1	10	6	3	5	2	1	5	5
Progressive Disease	2	0	0	2	3	0	1	0	4	5	2	3	1	1	4	4
Adverse Event	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	1
Death	0	2	0	0	0	0	0	0	4	0	0	0	0	0	1	0
Physician Decision	1	0	0	0	0	0	1	1	0	0	1	1	1	0	0	0
Subject/guardian decision	0	0	1	0	0	3	0	0	1	0	0	1	0	0	0	0
Completed planned cycles	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0

*Discontinued from treatment

Arm 6, HMA only and Total

	MBG453 240mg Q2W + Azacitidine ND AML	MBG453 400mg Q2W + Azacitidine ND AML	MBG453 800mg Q4W + Azacitidine ND AML	MBG453 240mg Q2W + Azacitidine HR/VHR MDS	MBG453 240mg Q2W + Azacitidine IR MDS	MBG453 400mg Q2W + Azacitidine HR/VHR MDS	MBG453 400mg Q2W + Azacitidine IR MDS	MBG453 800mg Q4W + Azacitidine HR/VHR MDS	MBG453 800mg Q4W + Azacitidine IR MDS	MBG453 400mg Q2W + Azacitidine CMML	MBG453 800mg Q4W + Azacitidine CMML	Decitabine 20mg/m2	Azacitidine 75 mg/m2	Total
Arm/Group Description	Arm 6: MBG453 240 mg Q2W in combination with azacitidine 75 mg/m2 in newly diagnosed acute myeloid leukemia	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in newly diagnosed acute myeloid leukemia	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in newly diagnosed acute myeloid leukemia	Arm 6: MBG453 240 mg Q2W in combination with azacitidine 75 mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 6: MBG453 240 mg Q2W in combination with azacitidine 75 mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in chronic myelomonocytic leukemia	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in chronic myelomonocytic leukemia	Hypomethylating agent (HMA) only: decitabine 20mg/m2	Hypomethylating agent (HMA) only: azacitidine 75 mg/m2	
Started	6	14	6	3	2	14	5	17	2	5	5	5	4	241
Completed	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Not Completed*	6	14	6	3	2	14	5	17	2	5	5	5	4	241

Progressive Disease	6	9	4	2	1	7	0	3	0	3	2	0	0	118
Adverse Event	0	0	1	0	0	0	0	0	1	0	0	0	0	11
Death	0	1	0	0	0	1	1	0	0	0	0	2	2	20
Physician Decision	0	4	1	1	1	3	4	11	0	1	3	3	2	66
Subject/ guardian decision	0	0	0	0	0	2	0	2	1	1	0	0	0	23
Completed planned cycles	0	0	0	0	0	1	0	1	0	0	0	0	0	3

*Discontinued from treatment

Baseline Characteristics

Arms 1 and 2

PDR001 400mg Q4W + Decitabine ND AML	PDR001 400mg Q4W + Decitabine R/R AML	PDR001 400mg Q4W + Decitabine HR/VHR MDS	MBG453 240mg Q2W + Decitabine ND AML	MBG453 240mg Q2W + Decitabine R/R AML	MBG453 400mg Q2W + Decitabine ND AML	MBG453 400mg Q2W + Decitabine R/R AML	MBG453 800mg Q4W + Decitabine ND AML	MBG453 800mg Q4W + Decitabine R/R AML	MBG453 240mg Q2W + Decitabine HR/VHR MDS	MBG453 400mg Q2W + Decitabine HR/VHR MDS	MBG453 400mg Q2W + Decitabine IR MDS	MBG453 800mg Q4W + Decitabine HR/VHR MDS	MBG453 800mg Q4W + Decitabine IR MDS	MBG453 240mg Q2W + Decitabine CMML	MBG453 400mg Q2W + Decitabine CMML	MBG453 800mg Q4W + Decitabine CMML

Arm/ Group Description	Arm 1: PDR001 in combination with decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Arm 1: PDR001 in combination with decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 1: PDR001 in combination with decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in chronic myelomonocytic leukemia	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in chronic myelomonocytic leukemia	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in chronic myelomonocytic leukemia
Number of Participants [units: participants]	1	12	3	3	9	12	11	7	9	9	4	5	6	2	1	3	1
Baseline Analysis Population																	

Description																	
Age Continuous (units: years) Analysis Population Type: Participants Mean ± Standard Deviation	70.0	58.3±19.54	72.3±9.29	71.3±2.52	63.7±14.78	75.7±6.64	65.2±10.40	73.0±5.69	64.9±13.21	65.8±11.86	63.8±27.38	68.8±10.45	71.3±10.52	70.5±4.95	63.0	75.0±6.08	68.0
Age, Customized (units: participants) Analysis Population Type: Participants Count of Participants (Not Applicable)																	
18 - < 65 years	0	5	0	0	3	0	3	0	4	4	1	1	1	0	1	0	0
65 - < 85 years	1	7	3	3	6	10	8	6	5	4	3	4	4	2	0	3	1
>= 85 years	0	0	0	0	0	2	0	1	0	1	0	0	1	0	0	0	0
Sex: Female, Male (units: participants) Analysis Population Type: Participants Count of Participants (Not Applicable)																	
Female	1	6	0	3	4	3	5	3	2	3	1	2	4	1	0	1	1
Male	0	6	3	0	5	9	6	4	7	6	3	3	2	1	1	2	0

Race/Ethnicity, Customized
(units: participants)
Analysis Population Type: Participants
Count of Participants (Not Applicable)

Caucassian	0	8	3	3	7	11	8	7	7	5	4	5	6	2	1	3	1
Asian	0	0	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0
Black	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Other	0	1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Unknown	1	3	0	0	2	1	3	0	2	0	0	0	0	0	0	0	0

Arms 3, 4 and 5

MBG453 160mg Q2W + PDR001 + Decitabine R/R AML	MBG453 240mg Q2W + PDR001 + Decitabine ND AML	MBG453 240mg Q2W + PDR001 + Decitabine R/R AML	MBG453 400mg Q2W + PDR001 + Decitabine ND AML	MBG453 400mg Q2W + PDR001 + Decitabine R/R AML	MBG453 160mg Q2W + PDR001 + Decitabine HR/VHR MDS	MBG453 240mg Q2W + PDR001 + Decitabine HR/VHR MDS	MBG453 400mg Q2W + PDR001 + Decitabine HR/VHR MDS	MBG453 400mg Q2W R/R AML	MBG453 1200mg Q2W R/R AML	MBG453 400mg Q2W HR/VHR MDS	MBG453 1200mg Q2W HR/VHR MDS	MBG453 1200mg Q2W IR MDS	MBG453 80mg Q2W + PDR001 R/R AML	MBG453 240mg Q2W + PDR001 R/R AML	MBG453 240mg Q2W + PDR001 HR/VHR MDS

Arm/ Group Description	Arm 3: MBG453 160 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 3: MBG453 160 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 4: MBG453 400 mg Q2W in relapsed/refractory acute myeloid leukemia	Arm 4: MBG453 1200 mg Q2W in relapsed/refractory acute myeloid leukemia	Arm 4: MBG453 400 mg Q2W in high-/very high-risk myelodysplastic syndrome	Arm 4: MBG453 1200 mg Q2W in high-/very high-risk myelodysplastic syndrome	Arm 4: MBG453 1200 mg Q2W in intermediate-risk myelodysplastic syndrome	Arm 5: MBG453 80 mg Q2W in combination with PDR001 400 mg Q4W in relapsed/refractory acute myeloid leukemia	Arm 5: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W in relapsed/refractory acute myeloid leukemia	Arm 5: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W in high-/very high-risk myelodysplastic syndrome
Number of Participants [units: participants]	3	2	2	2	3	3	2	1	10	6	3	5	2	1	5	5
Baseline Analysis																

Population Description																
Age Continuous (units: years) Analysis Population Type: Participants Mean ± Standard Deviation	65.7±8.14	68.5±3.54	74.0±2.83	71.0±4.24	65.3±9.07	72.0±3.61	74.5±0.71	78.0	71.3±9.79	57.5±19.36	65.0±15.52	68.4±7.40	72.5±2.12	69.0	66.4±14.84	71.8±5.72
Age, Customized (units: participants) Analysis Population Type: Participants Count of Participants (Not Applicable)																
18 - < 65 years	2	0	0	0	2	0	0	0	2	3	2	1	0	0	1	1
65 - < 85 years	1	2	2	2	1	3	2	1	8	3	1	4	2	1	4	4
>= 85 years	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Sex: Female, Male (units: participants) Analysis Population Type: Participants Count of Participants (Not Applicable)																
Female	1	0	1	0	1	3	0	0	5	0	2	2	1	0	2	3

Male	2	2	1	2	2	0	2	1	5	6	1	3	1	1	3	2
Race/Ethnicity, Customized (units: participants) Analysis Population Type: Participants Count of Participants (Not Applicable)																
Caucasian	2	2	2	2	1	2	2	0	8	5	3	4	1	1	4	2
Asian	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1
Black	0	0	0	0	0	0	0	1	0	0	0	1	1	0	1	0
Other	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Unknown	0	0	0	0	1	1	0	0	2	1	0	0	0	0	0	2

Arm 6, HMA only and Total

	MBG453 240mg Q2W + Azacitidine ND AML	**MBG453 400mg Q2W + Azacitidine ND AML**	**MBG453 800mg Q4W + Azacitidine ND AML**	**MBG453 240mg Q2W + Azacitidine HR/VHR MDS**	**MBG453 240mg Q2W + Azacitidine IR MDS**	**MBG453 400mg Q2W + Azacitidine HR/VHR MDS**	**MBG453 400mg Q2W + Azacitidine IR MDS**	**MBG453 800mg Q4W + Azacitidine HR/VHR MDS**	**MBG453 800mg Q4W + Azacitidine IR MDS**	**MBG453 400mg Q2W + Azacitidine CMML**	**MBG453 800mg Q4W + Azacitidine CMML**	**Decitabine 20mg/m2**	**Azacitidine 75 mg/m2**	**Total**
Arm/Group Description	Arm 6: MBG453 240 mg Q2W in combination	Arm 6: MBG453 400 mg Q2W in combination	Arm 6: MBG453 800 mg Q4W in combination	Arm 6: MBG453 240 mg Q2W in combination with azacitidin	Arm 6: MBG453 240 mg Q2W in combination with azacitidin	Arm 6: MBG453 400 mg Q2W in combination with azacitidin	Arm 6: MBG453 400 mg Q2W in combination with azacitidin	Arm 6: MBG453 800 mg Q4W in combination with azacitidin	Arm 6: MBG453 800 mg Q4W in combination with azacitidin	Arm 6: MBG453 400 mg Q2W in combination with azacitidin	Arm 6: MBG453 800 mg Q4W in combination with azacitidin	Hypomethylating agent (HMA) only: decitabin	Hypomethylating agent (HMA) only: azacitidin	

	with azacitidine 75 mg/m2 in newly diagnosed acute myeloid leukemia	with azacitidine 75 mg/m2 in newly diagnosed acute myeloid leukemia	with azacitidine 75 mg/m2 in newly diagnosed acute myeloid leukemia	e 75 mg/m2 in high-/very high-risk myelodysplastic syndrome	e 75 mg/m2 in intermediate-risk myelodysplastic syndrome	e 75 mg/m2 in high-/very high-risk myelodysplastic syndrome	e 75 mg/m2 in intermediate-risk myelodysplastic syndrome	e 75 mg/m2 in high-/very high-risk myelodysplastic syndrome	e 75 mg/m2 in intermediate-risk myelodysplastic syndrome	e 75 mg/m2 in chronic myelomonocytic leukemia	e 75 mg/m2 in chronic myelomonocytic leukemia	e 20mg/m2	e 75 mg/m2	
Number of Participants [units: participants]	6	14	6	3	2	14	5	17	2	5	5	5	4	241
Baseline Analysis Population Description														
Age Continuous (units: years) Analysis Population Type: Participants Mean ± Standard Deviation														
	72.5±7.20	75.7±5.31	78.0±6.26	69.3±5.69	78.5±6.36	74.4±10.33	64.0±7.78	68.3±12.18	55.5±14.85	68.8±9.86	65.4±7.27	74.6±5.22	42.8±7.63	69.2±11.5
Age, Customized (units: participants) Analysis Population Type: Participants Count of Participants (Not Applicable)														

18 - < 65 years	1	0	0	1	0	1	2	4	1	1	2	0	1	51
65 - < 85 years	5	13	5	2	2	12	3	11	1	4	3	5	3	180
>= 85 years	0	1	1	0	0	1	0	2	0	0	0	0	0	10
Sex: Female, Male (units: participants) Analysis Population Type: Participants Count of Participants (Not Applicable)														
Female	2	8	3	1	0	8	2	7	1	1	0	0	1	95
Male	4	6	3	2	2	6	3	10	1	4	5	5	3	146
Race/Ethnicity, Customized (units: participants) Analysis Population Type: Participants Count of Participants (Not Applicable)														
Caucassian	5	12	5	3	2	13	5	16	1	5	5	5	4	203
Asian	0	0	0	0	0	0	0	1	1	0	0	0	0	8
Black	0	0	0	0	0	0	0	0	0	0	0	0	0	4
Other	0	0	0	0	0	1	0	0	0	0	0	0	0	3
Unknown	1	2	1	0	0	0	0	0	0	0	0	0	0	23

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Primary Outcome Result(s)

Arm 1: Number of participants with Adverse Events (AEs) and Serious Adverse Events (SAEs) during the on-treatment period

Description	Number of participants with AEs (any AE regardless of seriousness) and SAEs, including changes from baseline in vital signs, electrocardiograms and laboratory results qualifying and reported as AEs. The on-treatment period is defined from the day of first administration of study treatment up to 30 days after the date of its last administration.
Time Frame	Up to approximately 1.9 years
Analysis Population Description	All patients from Arm 1 who received at least one dose of study treatment.

	PDR001 400mg Q4W + Decitabine ND AML	PDR001 400mg Q4W + Decitabine R/R AML	PDR001 400mg Q4W + Decitabine HR/VHR MDS
Arm/Group Description	Arm 1: PDR001 in combination with decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Arm 1: PDR001 in combination with decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 1: PDR001 in combination with decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome
Number of Participants Analyzed [units: participants]	1	12	3
Arm 1: Number of participants with Adverse Events (AEs) and Serious Adverse Events (SAEs) during the on-treatment period (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
AEs	1 (100%)	11 (91.67%)	3 (100%)
Treatment-related AEs	1 (100%)	8 (66.67%)	3 (100%)
SAEs	1 (100%)	11 (91.67%)	3 (100%)
Treatment-related SAEs	0 (%)	3 (25%)	1 (33.33%)

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Arm 2: Number of participants with Adverse Events (AEs) and Serious Adverse Events (SAEs) during the on-treatment period

Description	Number of participants with AEs (any AE regardless of seriousness) and SAEs, including changes from baseline in vital signs, electrocardiograms and laboratory results qualifying and reported as AEs. The on-treatment period is defined from the day of first administration of study treatment up to 30 days after the date of its last administration.
Time Frame	Up to approximately 3 years
Analysis Population Description	All patients from Arm 2 who received at least one dose of study treatment.

	MBG453 240mg Q2W + Decitabine ND AML	**MBG453 240mg Q2W + Decitabine R/R AML**	**MBG453 400mg Q2W + Decitabine ND AML**	**MBG453 400mg Q2W + Decitabine R/R AML**	**MBG453 800mg Q4W + Decitabine ND AML**	**MBG453 800mg Q4W + Decitabine R/R AML**	**MBG453 240mg Q2W + Decitabine HR/VHR MDS**	**MBG453 400mg Q2W + Decitabine HR/VHR MDS**	**MBG453 400mg Q2W + Decitabine IR MDS**	**MBG453 800mg Q4W + Decitabine HR/VHR MDS**	**MBG453 800mg Q4W + Decitabine IR MDS**	**MBG453 240mg Q2W + Decitabine CMML**	**MBG453 400mg Q2W + Decitabine CMML**	**MBG453 800mg Q4W + Decitabine CMML**
Arm/Group Description	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in newly diagnosed acute	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in relapsed/ refractory acute myeloid leukemia	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in newly diagnosed acute	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in relapsed/ refractory acute myeloid leukemia	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in newly diagnosed acute	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in relapsed/ refractory acute myeloid leukemia	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in high-/very high-risk myelod	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in high-/very high-risk myelod	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in intermediate-risk myelodysplasti	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in high-/very high-risk myelod	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in intermediate-risk myelodysplasti	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in chronic myelomonocytic	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in chronic myelomonocytic	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in chronic myelomonocytic

	myeloid leukemia		myeloid leukemia		myeloid leukemia		ysplastic syndrome	ysplastic syndrome	c syndrome	ysplastic syndrome	c syndrome	leukemia	leukemia	leukemia
Number of Participants Analyzed [units: participants]	3	9	12	11	7	9	9	4	5	6	2	1	3	1
Arm 2: Number of participants with Adverse Events (AEs) and Serious Adverse Events (SAEs) during the on-treatment period (units:	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**

partici pants)														
AEs	3 (100%)	9 (100%)	12 (100%)	11 (100%)	7 (100%)	9 (100%)	9 (100%)	4 (100%)	5 (100%)	6 (100%)	2 (100%)	1 (100%)	3 (100%)	1 (100%)
Treat ment-related AEs	3 (100%)	8 (88.89%)	8 (66.67 %)	6 (54.55%)	6 (85.71 %)	6 (66.67%)	9 (100%)	4 (100%)	3 (60%)	6 (100%)	2 (100%)	1 (100%)	3 (100%)	1 (100%)
SAEs	3 (100%)	8 (88.89%)	10 (83.33 %)	8 (72.73%)	5 (71.43 %)	7 (77.78%)	7 (77.78%)	3 (75%)	4 (80%)	3 (50%)	2 (100%)	0 (%)	3 (100%)	1 (100%)
Treat ment-related SAEs	1 (33.33 %)	1 (11.11%)	1 (8.33%)	0 (%)	2 (28.57 %)	0 (%)	1 (11.11%)	2 (50%)	2 (40%)	1 (16.67%)	1 (50%)	0 (%)	0 (%)	0 (%)

Arm 3: Number of participants with Adverse Events (AEs) and Serious Adverse Events (SAEs) during the on-treatment period

Description	Number of participants with AEs (any AE regardless of seriousness) and SAEs, including changes from baseline in vital signs, electrocardiograms and laboratory results qualifying and reported as AEs. The on-treatment period is defined from the day of first administration of study treatment up to 30 days after the date of its last administration.
Time Frame	Up to approximately 4.4 years
Analysis Population Description	All patients from Arm 3 who received at least one dose of study treatment.

	MBG453 160mg Q2W + PDR001 + Decitabine R/R AML	**MBG453 240mg Q2W + PDR001 + Decitabine ND AML**	**MBG453 240mg Q2W + PDR001 + Decitabine R/R AML**	**MBG453 400mg Q2W + PDR001 + Decitabine ND AML**	**MBG453 400mg Q2W + PDR001 + Decitabine R/R AML**	**MBG453 160mg Q2W + PDR001 + Decitabine HR/VHR MDS**	**MBG453 240mg Q2W + PDR001 + Decitabine HR/VHR MDS**	**MBG453 400mg Q2W + PDR001 + Decitabine HR/VHR MDS**
Arm/Group Description	Arm 3: MBG453 160 mg Q2W in combination with	Arm 3: MBG453 240 mg	Arm 3: MBG453 240 mg Q2W in combination with	Arm 3: MBG453 400 mg	Arm 3: MBG453 400 mg Q2W in combination with	Arm 3: MBG453 160 mg Q2W in	Arm 3: MBG453 240 mg Q2W in	Arm 3: MBG453 400 mg Q2W in

	PDR001 400 mg Q4W and decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	PDR001 400 mg Q4W and decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	PDR001 400 mg Q4W and decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome
Number of Participants Analyzed [units: participants]	3	2	2	2	3	3	2	1
Arm 3: Number of participants with Adverse Events (AEs) and Serious Adverse Events (SAEs) during the on-treatment period (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
AEs	3 (100%)	2 (100%)	2 (100%)	2 (100%)	3 (100%)	3 (100%)	2 (100%)	1 (100%)

Treatment-related AEs	2 (66.67%)	0 (%)	2 (100%)	1 (50%)	2 (66.67%)	1 (33.33%)	2 (100%)	1 (100%)
SAEs	2 (66.67%)	2 (100%)	2 (100%)	2 (100%)	2 (66.67%)	3 (100%)	2 (100%)	1 (100%)
Treatment-related SAEs	0 (%)	0 (%)	0 (%)	0 (%)	1 (33.33%)	0 (%)	0 (%)	0 (%)

Arm 4: Number of participants with Adverse Events (AEs) and Serious Adverse Events (SAEs) during the on-treatment period

Description	Number of participants with AEs (any AE regardless of seriousness) and SAEs, including changes from baseline in vital signs, electrocardiograms and laboratory results qualifying and reported as AEs. The on-treatment period is defined from the day of first administration of study treatment up to 30 days after the date of its last administration.
Time Frame	Up to approximately 1 year
Analysis Population Description	All patients from Arm 4 who received at least one dose of study treatment.

	MBG453 400mg Q2W R/R AML	**MBG453 1200mg Q2W R/R AML**	**MBG453 400mg Q2W HR/VHR MDS**	**MBG453 1200mg Q2W HR/VHR MDS**	**MBG453 1200mg Q2W IR MDS**
Arm/Group Description	Arm 4: MBG453 400 mg Q2W in relapsed/refractory acute myeloid leukemia	Arm 4: MBG453 1200 mg Q2W in relapsed/refractory acute myeloid leukemia	Arm 4: MBG453 400 mg Q2W in high-/very high-risk myelodysplastic syndrome	Arm 4: MBG453 1200 mg Q2W in high-/very high-risk myelodysplastic syndrome	Arm 4: MBG453 1200 mg Q2W in intermediate-risk myelodysplastic syndrome
Number of Participants Analyzed [units: participants]	10	6	3	5	2
Arm 4: Number of participants with Adverse Events (AEs) and Serious Adverse Events (SAEs) during the on-treatment period (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**

AEs	10 (100%)	6 (100%)	3 (100%)	5 (100%)	2 (100%)
Treatment-related AEs	2 (20%)	3 (50%)	2 (66.67%)	3 (60%)	2 (100%)
SAEs	9 (90%)	4 (66.67%)	1 (33.33%)	2 (40%)	1 (50%)
Treatment-related SAEs	1 (10%)	1 (16.67%)	0 (%)	0 (%)	0 (%)

Arm 5: Number of participants with Adverse Events (AEs) and Serious Adverse Events (SAEs) during the on-treatment period

Description	Number of participants with AEs (any AE regardless of seriousness) and SAEs, including changes from baseline in vital signs, electrocardiograms and laboratory results qualifying and reported as AEs. The on-treatment period is defined from the day of first administration of study treatment up to 30 days after the date of its last administration.
Time Frame	Up to approximately 0.6 years
Analysis Population Description	All patients from Arm 5 who received at least one dose of study treatment.

	MBG453 80mg Q2W + PDR001 R/R AML	**MBG453 240mg Q2W + PDR001 R/R AML**	**MBG453 240mg Q2W + PDR001 HR/VHR MDS**
Arm/Group Description	Arm 5: MBG453 80 mg Q2W in combination with PDR001 400 mg Q4W in relapsed/refractory acute myeloid leukemia	Arm 5: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W in relapsed/refractory acute myeloid leukemia	Arm 5: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W in high-/very high-risk myelodysplastic syndrome
Number of Participants Analyzed [units: participants]	1	5	5
Arm 5: Number of participants with Adverse Events (AEs) and Serious Adverse Events (SAEs) during the on-treatment period (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**

AEs	1 (100%)	5 (100%)	5 (100%)
Treatment-related AEs	0 (%)	2 (40%)	4 (80%)
SAEs	0 (%)	5 (100%)	3 (60%)
Treatment-related SAEs	0 (%)	1 (20%)	1 (20%)

Arm 6: Number of participants with Adverse Events (AEs) and Serious Adverse Events (SAEs) during the on-treatment period

Description	Number of participants with AEs (any AE regardless of seriousness) and SAEs, including changes from baseline in vital signs, electrocardiograms and laboratory results qualifying and reported as AEs. The on-treatment period is defined from the day of first administration of study treatment up to 30 days after the date of its last administration.
Time Frame	Up to approximately 4.3 years
Analysis Population Description	All patients from Arm 6 who received at least one dose of study treatment.

	MBG453 240mg Q2W + Azacitidine ND AML	**MBG453 400mg Q2W + Azacitidine ND AML**	**MBG453 800mg Q4W + Azacitidine ND AML**	**MBG453 240mg Q2W + Azacitidine HR/VHR MDS**	**MBG453 240mg Q2W + Azacitidine IR MDS**	**MBG453 400mg Q2W + Azacitidine HR/VHR MDS**	**MBG453 400mg Q2W + Azacitidine IR MDS**	**MBG453 800mg Q4W + Azacitidine HR/VHR MDS**	**MBG453 800mg Q4W + Azacitidine IR MDS**	**MBG453 400mg Q2W + Azacitidine CMML**	**MBG453 800mg Q4W + Azacitidine CMML**
Arm/Group Description	Arm 6: MBG453 240 mg Q2W in combination with azacitidine 75 mg/m2 in	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in	Arm 6: MBG453 240 mg Q2W in combination with azacitidine 75 mg/m2 in high-	Arm 6: MBG453 240 mg Q2W in combination with azacitidine 75 mg/m2 in	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in high-	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in high-	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in chronic	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in chronic

	newly diagnosed acute myeloid leukemia	newly diagnosed acute myeloid leukemia	newly diagnosed acute myeloid leukemia	/very high-risk myelodysplastic syndrome	intermediate-risk myelodysplastic syndrome	/very high-risk myelodysplastic syndrome	intermediate-risk myelodysplastic syndrome	/very high-risk myelodysplastic syndrome	intermediate-risk myelodysplastic syndrome	myelomonocytic leukemia	myelomonocytic leukemia
Number of Participants Analyzed [units: participants]	6	14	6	3	2	14	5	17	2	5	5
Arm 6: Number of participants with Adverse Events (AEs) and Serious Adverse Events (SAEs) during the on-treatment period (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
AEs	6 (100%)	14 (100%)	6 (100%)	3 (100%)	2 (100%)	14 (100%)	5 (100%)	17 (100%)	2 (100%)	5 (100%)	5 (100%)
Treatment-related AEs	6 (100%)	12 (85.71%)	6 (100%)	3 (100%)	2 (100%)	14 (100%)	3 (60%)	15 (88.24%)	2 (100%)	4 (80%)	4 (80%)

SAEs	3 (50%)	10 (71.43%)	4 (66.67%)	1 (33.33%)	0 (%)	5 (35.71%)	2 (40%)	12 (70.59%)	1 (50%)	3 (60%)	1 (20%)
Treatment-related SAEs	2 (33.33%)	1 (7.14%)	0 (%)	1 (33.33%)	0 (%)	3 (21.43%)	0 (%)	4 (23.53%)	1 (50%)	0 (%)	0 (%)

Arm 1: Number of participants with Dose-Limiting Toxicities (DLTs)

Description	A dose-limiting toxicity (DLT) is defined as an adverse event or abnormal laboratory value of Common Terminology Criteria for Adverse Events (CTCAE) grade ≥ 3 assessed as having a suspected relationship to the study drug and as being unrelated to disease, disease progression, inter-current illness or concomitant medications that occurs within the first 28 days of treatment with single agent MBG453 or 56 days of treatment in any of the combination treatment arms. Other clinically significant toxicities may be considered to be DLTs, even if not CTCAE grade 3 or higher.
Time Frame	56 days
Analysis Population Description	All patients Arm 1 who either met the minimum exposure criterion defined in the protocol and had sufficient safety evaluations, or experienced a DLT during the first 56 days of treatment.

	PDR001 400mg Q4W + Decitabine ND AML	**PDR001 400mg Q4W + Decitabine R/R AML**	**PDR001 400mg Q4W + Decitabine HR/VHR MDS**
Arm/Group Description	Arm 1: PDR001 in combination with decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Arm 1: PDR001 in combination with decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 1: PDR001 in combination with decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome
Number of Participants Analyzed [units: participants]	1	10	3
Arm 1: Number of participants with Dose-Limiting Toxicities (DLTs) (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
	0 (%)	1 (10%)	0 (%)

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Arm 2: Number of participants with Dose-Limiting Toxicities (DLTs)

Description	A dose-limiting toxicity (DLT) is defined as an adverse event or abnormal laboratory value of Common Terminology Criteria for Adverse Events (CTCAE) grade ≥ 3 assessed as having a suspected relationship to the study drug and as being unrelated to disease, disease progression, inter-current illness or concomitant medications that occurs within the first 28 days of treatment with single agent MBG453 or 56 days of treatment in any of the combination treatment arms. Other clinically significant toxicities may be considered to be DLTs, even if not CTCAE grade 3 or higher.
Time Frame	56 days
Analysis Population Description	All patients Arm 2 who either met the minimum exposure criterion defined in the protocol and had sufficient safety evaluations, or experienced a DLT during the first 56 days of treatment.

	MBG453 240mg Q2W + Decitabine ND AML	**MBG453 240mg Q2W + Decitabine R/R AML**	**MBG453 400mg Q2W + Decitabine ND AML**	**MBG453 400mg Q2W + Decitabine R/R AML**	**MBG453 800mg Q4W + Decitabine ND AML**	**MBG453 800mg Q4W + Decitabine R/R AML**	**MBG453 240mg Q2W + Decitabine HR/VHR MDS**	**MBG453 400mg Q2W + Decitabine HR/VHR MDS**	**MBG453 400mg Q2W + Decitabine IR MDS**	**MBG453 800mg Q4W + Decitabine HR/VHR MDS**	**MBG453 800mg Q4W + Decitabine IR MDS**	**MBG453 240mg Q2W + Decitabine CMML**	**MBG453 400mg Q2W + Decitabine CMML**	**MBG453 800mg Q4W + Decitabine CMML**
Arm/Group Description	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in newly diagnosed	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in relapsed/ refractory acute myeloid leukemia	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/ m2 in newly diagnosed	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in relapsed/ refractory acute myeloid leukemia	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/ m2 in newly diagnosed	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in relapsed/ refractory acute myeloid leukemia	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/ m2 in high-/very high-risk	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/ m2 in high-/very high-risk	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/ m2 in intermediate-risk myelod	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/ m2 in high-/very high-risk	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/ m2 in intermediate-risk myelod	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in chronic myelomonocytic	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in chronic myelomonocytic	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in chronic myelomonocytic

	acute myeloid leukemia		acute myeloid leukemia		acute myeloid leukemia		myelodysplastic syndrome	myelodysplastic syndrome	ysplastic syndrome	myelodysplastic syndrome	ysplastic syndrome	leukemia	leukemia	leukemia
Number of Participants Analyzed [units: participants]	3	9	8	8	6	7	8	3	5	4	1	1	2	1
Arm 2: Number of participants with Dose-Limiting Toxicities (DLTs) (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
	1 (33.33 %)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)

Arm 3: Number of participants with Dose-Limiting Toxicities (DLTs)

Description A dose-limiting toxicity (DLT) is defined as an adverse event or abnormal laboratory value of Common Terminology Criteria for Adverse Events (CTCAE) grade ≥ 3 assessed as having a suspected relationship to the study drug and as being unrelated to disease, disease

progression, inter-current illness or concomitant medications that occurs within the first 28 days of treatment with single agent MBG453 or 56 days of treatment in any of the combination treatment arms. Other clinically significant toxicities may be considered to be DLTs, even if not CTCAE grade 3 or higher.

Time Frame: 56 days

Analysis Population Description: All patients Arm 3 who either met the minimum exposure criterion defined in the protocol and had sufficient safety evaluations, or experienced a DLT during the first 56 days of treatment.

	MBG453 160mg Q2W + PDR001 + Decitabine R/R AML	**MBG453 240mg Q2W + PDR001 + Decitabine ND AML**	**MBG453 240mg Q2W + PDR001 + Decitabine R/R AML**	**MBG453 400mg Q2W + PDR001 + Decitabine ND AML**	**MBG453 400mg Q2W + PDR001 + Decitabine R/R AML**	**MBG453 160mg Q2W + PDR001 + Decitabine HR/VHR MDS**	**MBG453 240mg Q2W + PDR001 + Decitabine HR/VHR MDS**	**MBG453 400mg Q2W + PDR001 + Decitabine HR/VHR MDS**
Arm/Group Description	Arm 3: MBG453 160 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 3: MBG453 160 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome
Number of Participants Analyzed [units: participants]	2	1	1	2	2	1	2	1

Arm 3: Number of participants with Dose-Limiting Toxicities (DLTs) (units: participants)	Count of Participants (Percentage)	Count of Participants (Percentage)	Count of Participants (Percentage)	Count of Participants (Percentage)	Count of Participants (Percentage)	Count of Participants (Percentage)	Count of Participants (Percentage)	Count of Participants (Percentage)
	1 (50%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (100%)

Arm 4: Number of participants with Dose-Limiting Toxicities (DLTs)

Description	A dose-limiting toxicity (DLT) is defined as an adverse event or abnormal laboratory value of Common Terminology Criteria for Adverse Events (CTCAE) grade ≥ 3 assessed as having a suspected relationship to the study drug and as being unrelated to disease, disease progression, inter-current illness or concomitant medications that occurs within the first 28 days of treatment with single agent MBG453 or 56 days of treatment in any of the combination treatment arms. Other clinically significant toxicities may be considered to be DLTs, even if not CTCAE grade 3 or higher.
Time Frame	28 days
Analysis Population Description	All patients Arm 4 who either met the minimum exposure criterion defined in the protocol and had sufficient safety evaluations, or experienced a DLT during the first 28 days of treatment.

	MBG453 400mg Q2W R/R AML	MBG453 1200mg Q2W R/R AML	MBG453 400mg Q2W HR/VHR MDS	MBG453 1200mg Q2W HR/VHR MDS	MBG453 1200mg Q2W IR MDS
Arm/Group Description	Arm 4: MBG453 400 mg Q2W in relapsed/refractory acute myeloid leukemia	Arm 4: MBG453 1200 mg Q2W in relapsed/refractory acute myeloid leukemia	Arm 4: MBG453 400 mg Q2W in high-/very high-risk myelodysplastic syndrome	Arm 4: MBG453 1200 mg Q2W in high-/very high-risk myelodysplastic syndrome	Arm 4: MBG453 1200 mg Q2W in intermediate-risk myelodysplastic syndrome
Number of Participants Analyzed [units: participants]	7	6	3	5	2

Arm 4: Number of participants with Dose-Limiting Toxicities (DLTs) (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)

Arm 5: Number of participants with Dose-Limiting Toxicities (DLTs)

Description	A dose-limiting toxicity (DLT) is defined as an adverse event or abnormal laboratory value of Common Terminology Criteria for Adverse Events (CTCAE) grade ≥ 3 assessed as having a suspected relationship to the study drug and as being unrelated to disease, disease progression, inter-current illness or concomitant medications that occurs within the first 28 days of treatment with single agent MBG453 or 56 days of treatment in any of the combination treatment arms. Other clinically significant toxicities may be considered to be DLTs, even if not CTCAE grade 3 or higher.
Time Frame	56 days
Analysis Population Description	All patients Arm 5 who either met the minimum exposure criterion defined in the protocol and had sufficient safety evaluations, or experienced a DLT during the first 56 days of treatment.

	MBG453 80mg Q2W + PDR001 R/R AML	**MBG453 240mg Q2W + PDR001 R/R AML**	**MBG453 240mg Q2W + PDR001 HR/VHR MDS**
Arm/Group Description	Arm 5: MBG453 80 mg Q2W in combination with PDR001 400 mg Q4W in relapsed/refractory acute myeloid leukemia	Arm 5: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W in relapsed/refractory acute myeloid leukemia	Arm 5: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W in high-/very high-risk myelodysplastic syndrome
Number of Participants Analyzed [units: participants]	0	3	5
Arm 5: Number of participants with Dose-Limiting Toxicities (DLTs) (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
	(NaN%)	1 (33.33%)	0 (%)

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Arm 6: Number of participants with Dose-Limiting Toxicities (DLTs)

Description	A dose-limiting toxicity (DLT) is defined as an adverse event or abnormal laboratory value of Common Terminology Criteria for Adverse Events (CTCAE) grade ≥ 3 assessed as having a suspected relationship to the study drug and as being unrelated to disease, disease progression, inter-current illness or concomitant medications that occurs within the first 28 days of treatment with single agent MBG453 or 56 days of treatment in any of the combination treatment arms. Other clinically significant toxicities may be considered to be DLTs, even if not CTCAE grade 3 or higher.
Time Frame	56 days
Analysis Population Description	All patients Arm 6 who either met the minimum exposure criterion defined in the protocol and had sufficient safety evaluations, or experienced a DLT during the first 56 days of treatment.

	MBG453 240mg Q2W + Azacitidine ND AML	**MBG453 400mg Q2W + Azacitidine ND AML**	**MBG453 800mg Q4W + Azacitidine ND AML**	**MBG453 240mg Q2W + Azacitidine HR/VHR MDS**	**MBG453 240mg Q2W + Azacitidine IR MDS**	**MBG453 400mg Q2W + Azacitidine HR/VHR MDS**	**MBG453 400mg Q2W + Azacitidine IR MDS**	**MBG453 800mg Q4W + Azacitidine HR/VHR MDS**	**MBG453 800mg Q4W + Azacitidine IR MDS**	**MBG453 400mg Q2W + Azacitidine CMML**	**MBG453 800mg Q4W + Azacitidine CMML**
Arm/Group Description	Arm 6: MBG453 240 mg Q2W in combination with azacitidine 75 mg/m2 in newly diagnosed acute myeloid leukemia	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in newly diagnosed acute myeloid leukemia	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in newly diagnosed acute myeloid leukemia	Arm 6: MBG453 240 mg Q2W in combination with azacitidine 75 mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 6: MBG453 240 mg Q2W in combination with azacitidine 75 mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in chronic myelomonocytic leukemia	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in chronic myelomonocytic leukemia
Number of Participants Analyzed [units:	6	10	4	2	2	14	4	15	2	5	4

participants]											
Arm 6: Number of participants with Dose-Limiting Toxicities (DLTs) (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (50%)	0 (%)	0 (%)

Arm 1: Number of participants with dose reductions and dose interruptions of PDR001 and decitabine

Description	For patients who did not tolerate the protocol-specified dosing schedule of the study drugs, dose adjustments either through reduced dose or longer treatment interval could be permitted in order to allow the patient to continue study treatment. Dose reductions were not permitted for PDR001.
Time Frame	Up to approximately 1.8 years
Analysis Population Description	All patients from Arm 1 who received at least one dose of study treatment.

	PDR001 400mg Q4W + Decitabine ND AML	**PDR001 400mg Q4W + Decitabine R/R AML**	**PDR001 400mg Q4W + Decitabine HR/VHR MDS**
Arm/Group Description	Arm 1: PDR001 in combination with decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Arm 1: PDR001 in combination with decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 1: PDR001 in combination with decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome
Number of Participants Analyzed [units: participants]	1	12	3

Arm 1: Number of participants with dose reductions and dose interruptions of PDR001 and decitabine (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
PDR001, at least one dose reduction	0 (%)	0 (%)	0 (%)
PDR001, at least one dose interruption	0 (%)	4 (33.33%)	2 (66.67%)
Decitabine, at least one dose reduction	0 (%)	1 (8.33%)	0 (%)
Decitabine, at least one dose interruption	0 (%)	5 (41.67%)	0 (%)

Arm 2: Number of participants with dose reductions and dose interruptions of MBG453 and decitabine

Description	For patients who did not tolerate the protocol-specified dosing schedule of the study drugs, dose adjustments either through reduced dose or longer treatment interval could be permitted in order to allow the patient to continue study treatment.
Time Frame	Up to approximately 2.9 years
Analysis Population Description	All patients from Arm 2 who received at least one dose of study treatment.

	MBG453 240mg Q2W + Decitabine ND AML	**MBG453 240mg Q2W + Decitabine R/R AML**	**MBG453 400mg Q2W + Decitabine ND AML**	**MBG453 400mg Q2W + Decitabine R/R AML**	**MBG453 800mg Q4W + Decitabine ND AML**	**MBG453 800mg Q4W + Decitabine R/R AML**	**MBG453 240mg Q2W + Decitabine HR/VHR MDS**	**MBG453 400mg Q2W + Decitabine HR/VHR MDS**	**MBG453 400mg Q2W + Decitabine IR MDS**	**MBG453 800mg Q4W + Decitabine HR/VHR MDS**	**MBG453 800mg Q4W + Decitabine IR MDS**	**MBG453 240mg Q2W + Decitabine CMML**	**MBG453 400mg Q2W + Decitabine CMML**	**MBG453 800mg Q4W + Decitabine CMML**
Arm/Group	Arm 2: MBG453 240	Arm 2: MBG453 240 mg	Arm 2: MBG453 400	Arm 2: MBG453 400 mg	Arm 2: MBG453 800	Arm 2: MBG453 800 mg	Arm 2: MBG453 240	Arm 2: MBG453 400	Arm 2: MBG453 400	Arm 2: MBG453 800	Arm 2: MBG453 800	Arm 2: MBG453 240	Arm 2: MBG453 400	Arm 2: MBG453 800

Description	mg Q2W in combination with decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Q2W in combination with decitabine 20mg/m2 in relapsed/ refractory acute myeloid leukemia	mg Q2W in combination with decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Q2W in combination with decitabine 20mg/m2 in relapsed/ refractory acute myeloid leukemia	mg Q4W in combination with decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Q4W in combination with decitabine 20mg/m2 in relapsed/ refractory acute myeloid leukemia	mg Q2W in combination with decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	mg Q2W in combination with decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	mg Q2W in combination with decitabine 20mg/m2 in intermediate-risk myelodysplastic syndrome	mg Q4W in combination with decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	mg Q4W in combination with decitabine 20mg/m2 in intermediate-risk myelodysplastic syndrome	mg Q2W in combination with decitabine 20mg/m2 in chronic myelomonocytic leukemia	mg Q2W in combination with decitabine 20mg/m2 in chronic myelomonocytic leukemia	mg Q4W in combination with decitabine 20mg/m2 in chronic myelomonocytic leukemia
Number of Participants Analyzed [units: participants]	3	9	12	11	7	9	9	4	5	6	2	1	3	1
Arm 2: Number of participants with dose reductions and dose interruption	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**

s of MBG453 and decitabine (units: participants)														
MBG453, at least one dose reduction	1 (33.33%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (16.67%)	0 (%)	0 (%)	0 (%)	0 (%)
MBG453, at least one dose interruption	2 (66.67%)	2 (22.22%)	3 (25%)	2 (18.18%)	3 (42.86%)	0 (%)	4 (44.44%)	4 (100%)	1 (20%)	3 (50%)	0 (%)	1 (100%)	2 (66.67%)	0 (%)
Decitabine, at least one dose reduction	0 (%)	1 (11.11%)	0 (%)	0 (%)	1 (14.29%)	0 (%)	1 (11.11%)	0 (%)	0 (%)	1 (16.67%)	0 (%)	0 (%)	1 (33.33%)	0 (%)
Decitabine, at least one dose interruption	2 (66.67%)	2 (22.22%)	3 (25%)	1 (9.09%)	5 (71.43%)	1 (11.11%)	3 (33.33%)	3 (75%)	3 (60%)	3 (50%)	0 (%)	1 (100%)	3 (100%)	1 (100%)

Arm 3: Number of participants with dose reductions and dose interruptions of MBG453, PDR001 and decitabine

Description	For patients who did not tolerate the protocol-specified dosing schedule of the study drugs, dose adjustments either through reduced dose or longer treatment interval could be permitted in order to allow the patient to continue study treatment. Dose reductions were not permitted for PDR001.
Time Frame	Up to approximately 4.3 years
Analysis Population Description	All patients from Arm 3 who received at least one dose of study treatment.

	MBG453 160mg Q2W + PDR001 + Decitabine R/R AML	MBG453 240mg Q2W + PDR001 + Decitabine ND AML	MBG453 240mg Q2W + PDR001 + Decitabine R/R AML	MBG453 400mg Q2W + PDR001 + Decitabine ND AML	MBG453 400mg Q2W + PDR001 + Decitabine R/R AML	MBG453 160mg Q2W + PDR001 + Decitabine HR/VHR MDS	MBG453 240mg Q2W + PDR001 + Decitabine HR/VHR MDS	MBG453 400mg Q2W + PDR001 + Decitabine HR/VHR MDS
Arm/Group Description	Arm 3: MBG453 160 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 3: MBG453 160 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome
Number of Participants Analyzed [units:	3	2	2	2	3	3	2	1

participants]								
Arm 3: Number of participants with dose reductions and dose interruptions of MBG453, PDR001 and decitabine (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
MBG453, at least one dose reduction	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
MBG453, at least one dose interruption	0 (%)	0 (%)	0 (%)	2 (100%)	2 (66.67%)	1 (33.33%)	1 (50%)	1 (100%)
PDR001, at least one dose reduction	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
PDR001, at least one dose interruption	1 (33.33%)	0 (%)	0 (%)	1 (50%)	2 (66.67%)	1 (33.33%)	1 (50%)	0 (%)
Decitabine, at least one dose reduction	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (100%)
Decitabine, at least one	1 (33.33%)	0 (%)	1 (50%)	2 (100%)	2 (66.67%)	1 (33.33%)	1 (50%)	1 (100%)

dose
interruption

Arm 4: Number of participants with dose reductions and dose interruptions of MBG453

Description	For patients who did not tolerate the protocol-specified dosing schedule of the study drugs, dose adjustments either through reduced dose or longer treatment interval could be permitted in order to allow the patient to continue study treatment.
Time Frame	Up to approximately 0.9 years
Analysis Population Description	All patients from Arm 4 who received at least one dose of study treatment.

	MBG453 400mg Q2W R/R AML	MBG453 1200mg Q2W R/R AML	MBG453 400mg Q2W HR/VHR MDS	MBG453 1200mg Q2W HR/VHR MDS	MBG453 1200mg Q2W IR MDS
Arm/Group Description	Arm 4: MBG453 400 mg Q2W in relapsed/refractory acute myeloid leukemia	Arm 4: MBG453 1200 mg Q2W in relapsed/refractory acute myeloid leukemia	Arm 4: MBG453 400 mg Q2W in high-/very high-risk myelodysplastic syndrome	Arm 4: MBG453 1200 mg Q2W in high-/very high-risk myelodysplastic syndrome	Arm 4: MBG453 1200 mg Q2W in intermediate-risk myelodysplastic syndrome
Number of Participants Analyzed [units: participants]	10	6	3	5	2
Arm 4: Number of participants with dose reductions and dose interruptions of MBG453 (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
MBG453, at least one dose reduction	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
MBG453, at least one dose interruption	2 (20%)	0 (%)	0 (%)	0 (%)	0 (%)

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Arm 5: Number of participants with dose reductions and dose interruptions of MBG453 and PDR001

Description	For patients who did not tolerate the protocol-specified dosing schedule of the study drugs, dose adjustments either through reduced dose or longer treatment interval could be permitted in order to allow the patient to continue study treatment. Dose reductions were not permitted for PDR001.
Time Frame	Up to approximately 0.5 years
Analysis Population Description	All patients from Arm 5 who received at least one dose of study treatment.

	MBG453 80mg Q2W + PDR001 R/R AML	MBG453 240mg Q2W + PDR001 R/R AML	MBG453 240mg Q2W + PDR001 HR/VHR MDS
Arm/Group Description	Arm 5: MBG453 80 mg Q2W in combination with PDR001 400 mg Q4W in relapsed/refractory acute myeloid leukemia	Arm 5: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W in relapsed/refractory acute myeloid leukemia	Arm 5: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W in high-/very high-risk myelodysplastic syndrome
Number of Participants Analyzed [units: participants]	1	5	5
Arm 5: Number of participants with dose reductions and dose interruptions of MBG453 and PDR001 (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
MBG453, at least one dose reduction	0 (%)	0 (%)	0 (%)
MBG453, at least one dose interruption	0 (%)	1 (20%)	1 (20%)
PDR001, at least one dose reduction	0 (%)	0 (%)	0 (%)
PDR001, at least one dose interruption	0 (%)	1 (20%)	1 (20%)

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Arm 6: Number of participants with dose reductions and dose interruptions of MBG453 and azacitidine

Description	For patients who did not tolerate the protocol-specified dosing schedule of the study drugs, dose adjustments either through reduced dose or longer treatment interval could be permitted in order to allow the patient to continue study treatment.
Time Frame	Up to approximately 4.2 years
Analysis Population Description	All patients from Arm 6 who received at least one dose of study treatment.

	MBG453 240mg Q2W + Azacitidine ND AML	MBG453 400mg Q2W + Azacitidine ND AML	MBG453 800mg Q4W + Azacitidine ND AML	MBG453 240mg Q2W + Azacitidine HR/VHR MDS	MBG453 240mg Q2W + Azacitidine IR MDS	MBG453 400mg Q2W + Azacitidine HR/VHR MDS	MBG453 400mg Q2W + Azacitidine IR MDS	MBG453 800mg Q4W + Azacitidine HR/VHR MDS	MBG453 800mg Q4W + Azacitidine IR MDS	MBG453 400mg Q2W + Azacitidine CMML	MBG453 800mg Q4W + Azacitidine CMML
Arm/Group Description	Arm 6: MBG453 240 mg Q2W in combination with azacitidine 75 mg/m2 in newly diagnosed acute myeloid leukemia	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in newly diagnosed acute myeloid leukemia	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in newly diagnosed acute myeloid leukemia	Arm 6: MBG453 240 mg Q2W in combination with azacitidine 75 mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 6: MBG453 240 mg Q2W in combination with azacitidine 75 mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in chronic myelomonocytic leukemia	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in chronic myelomonocytic leukemia
Number of Participants Analyzed [units: participants]	6	14	6	3	2	14	5	17	2	5	5

Arm 6: Number of participants with dose reductions and dose interruptions of MBG453 and azacitidine (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
MBG453, at least one dose reduction	1 (16.67%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
MBG453, at least one dose interruption	4 (66.67%)	5 (35.71%)	1 (16.67%)	0 (%)	0 (%)	4 (28.57%)	0 (%)	6 (35.29%)	0 (%)	0 (%)	2 (40%)
Azacitidine, at least one dose reduction	0 (%)	1 (7.14%)	1 (16.67%)	0 (%)	0 (%)	0 (%)	0 (%)	3 (17.65%)	0 (%)	0 (%)	0 (%)
Azacitidine, at least one dose interruption	3 (50%)	7 (50%)	4 (66.67%)	0 (%)	0 (%)	4 (28.57%)	0 (%)	7 (41.18%)	0 (%)	0 (%)	2 (40%)

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Arm 1: Dose intensity of PDR001

Description	Dose intensity of PDR001 was calculated as: Actual Cumulative dose (mg) / (Duration of exposure in weeks/4)
Time Frame	Up to approximately 1.8 years
Analysis Population Description	All patients from Arm 1 who received at least one dose of study treatment.

	PDR001 400mg Q4W + Decitabine ND AML	PDR001 400mg Q4W + Decitabine R/R AML	PDR001 400mg Q4W + Decitabine HR/VHR MDS
Arm/Group Description	Arm 1: PDR001 in combination with decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Arm 1: PDR001 in combination with decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 1: PDR001 in combination with decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome
Number of Participants Analyzed [units: participants]	1	12	3
Arm 1: Dose intensity of PDR001 (units: mg/4 weeks)	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**
	395.29 (395.29 to 395.29)	400.00 (228.6 to 407.3)	354.67 (312.2 to 400.0)

Arm 1: Dose intensity of decitabine

Description	Dose intensity of decitabine was calculated as: Actual Cumulative dose (mg/m2) / (Duration of exposure in weeks/4)
Time Frame	Up to approximately 1.8 years
Analysis Population Description	All patients from Arm 1 who received at least one dose of study treatment.

	PDR001 400mg Q4W + Decitabine ND AML	PDR001 400mg Q4W + Decitabine R/R AML	PDR001 400mg Q4W + Decitabine HR/VHR MDS

Arm/Group Description	Arm 1: PDR001 in combination with decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Arm 1: PDR001 in combination with decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 1: PDR001 in combination with decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome
Number of Participants Analyzed [units: participants]	1	12	3
Arm 1: Dose intensity of decitabine (units: mg/m^2/4 weeks)	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**
	98.83 (98.83 to 98.83)	92.09 (77.3 to 101.0)	87.02 (72.5 to 104.8)

Arm 2: Dose intensity of MBG453

Description	Dose intensity of MBG453 was calculated as: Actual Cumulative dose (mg) / (Duration of exposure in weeks/4)
Time Frame	Up to approximately 2.9 years
Analysis Population Description	All patients from Arm 2 who received at least one dose of study treatment.

	MBG453 240mg Q2W + Decitabine ND AML	**MBG453 240mg Q2W + Decitabine R/R AML**	**MBG453 400mg Q2W + Decitabine ND AML**	**MBG453 400mg Q2W + Decitabine R/R AML**	**MBG453 800mg Q4W + Decitabine ND AML**	**MBG453 800mg Q4W + Decitabine R/R AML**	**MBG453 240mg Q2W + Decitabine HR/VHR MDS**	**MBG453 400mg Q2W + Decitabine HR/VHR MDS**	**MBG453 400mg Q2W + Decitabine IR MDS**	**MBG453 800mg Q4W + Decitabine HR/VHR MDS**	**MBG453 800mg Q4W + Decitabine IR MDS**	**MBG453 240mg Q2W + Decitabine CMML**	**MBG453 400mg Q2W + Decitabine CMML**	**MBG453 800mg Q4W + Decitabine CMML**
Arm/Group Description	Arm 2: MBG453 240 mg	Arm 2: MBG453 240 mg Q2W in combination with	Arm 2: MBG453 400 mg	Arm 2: MBG453 400 mg Q2W in combination with	Arm 2: MBG453 800 mg	Arm 2: MBG453 800 mg Q4W in combination with	Arm 2: MBG453 240 mg Q2W in combin	Arm 2: MBG453 400 mg Q2W in combin	Arm 2: MBG453 400 mg Q2W in combin	Arm 2: MBG453 800 mg Q4W in combin	Arm 2: MBG453 800 mg Q4W in combin	Arm 2: MBG453 240 mg Q2W in combin	Arm 2: MBG453 400 mg Q2W in combin	Arm 2: MBG453 800 mg Q4W in combin

	Q2W in combination with decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	decitabine 20mg/m2 in relapsed/ refractory acute myeloid leukemia	Q2W in combination with decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	decitabine 20mg/m2 in relapsed/ refractory acute myeloid leukemia	Q4W in combination with decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	decitabine 20mg/m2 in relapsed/ refractory acute myeloid leukemia	ation with decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	ation with decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	ation with decitabine 20mg/m2 in intermediate-risk myelodysplastic syndrome	ation with decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	ation with decitabine 20mg/m2 in intermediate-risk myelodysplastic syndrome	ation with decitabine 20mg/m2 in chronic myelomonocytic leukemia	ation with decitabine 20mg/m2 in chronic myelomonocytic leukemia	ation with decitabine 20mg/m2 in chronic myelomonocytic leukemia
Number of Participants Analyzed [units: participants]	3	9	12	11	7	9	9	4	5	6	2	1	3	1
Arm 2: Dose intensity of MBG453 (units: mg/4 weeks)	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**
	419.13 (79.9	473.24 (373.3 to 497.8)	797.17 (678.	781.40 (533.3 to 861.5)	746.67 (482.	800.00 (711.1 to 829.6)	458.18 (298.2	646.58 (589.5	746.67 (622.2	726.83 (488.9	680.40 (673.7	464.68 (464.68	553.09 (448.0	784.44 (784.44

to 480.0)	1 to 845.3)	9 to 809.6)	to 480.0)	to 726.1)	to 800.0)	to 800.0)	to 687.1)	to 464.68)	to 689.2)	to 784.44)

Arm 2: Dose intensity of decitabine

Description	Dose intensity of decitabine was calculated as: Actual Cumulative dose (mg/m2) / (Duration of exposure in weeks/4)
Time Frame	Up to approximately 2.9 years
Analysis Population Description	All patients from Arm 2 who received at least one dose of study treatment.

	MBG 453 240mg Q2W + Decitabine ND AML	**MBG453 240mg Q2W + Decitabine R/R AML**	**MBG 453 400mg Q2W + Decitabine ND AML**	**MBG453 400mg Q2W + Decitabine R/R AML**	**MBG 453 800mg Q4W + Decitabine ND AML**	**MBG453 800mg Q4W + Decitabine R/R AML**	**MBG453 240mg Q2W + Decitabine HR/VHR MDS**	**MBG453 400mg Q2W + Decitabine HR/VHR MDS**	**MBG453 400mg Q2W + Decitabine IR MDS**	**MBG453 800mg Q4W + Decitabine HR/VHR MDS**	**MBG453 800mg Q4W + Decitabine IR MDS**	**MBG453 240mg Q2W + Decitabine CMML**	**MBG453 400mg Q2W + Decitabine CMML**	**MBG453 800mg Q4W + Decitabine CMML**
Arm/Group Description	Arm 2: MBG 453 240 mg Q2W in combination with decitabine 20mg/m2 in	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in relapsed/ refractory acute myeloid leukemia	Arm 2: MBG 453 400 mg Q2W in combination with decitabine 20mg/m2 in	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in relapsed/ refractory acute myeloid leukemia	Arm 2: MBG 453 800 mg Q4W in combination with decitabine 20mg/m2 in	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in relapsed/ refractory acute myeloid leukemia	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in high-/very high-	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in high-/very high-	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in intermediate-risk	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in high-/very high-	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in intermediate-risk	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in chronic myelomonocytic	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in chronic myelomonocytic	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in chronic myelomonocytic

	newly diagnosed acute myeloid leukemia		newly diagnosed acute myeloid leukemia		newly diagnosed acute myeloid leukemia		risk myelodysplastic syndrome	risk myelodysplastic syndrome	myelodysplastic syndrome	risk myelodysplastic syndrome	myelodysplastic syndrome	leukemia	leukemia	leukemia
Number of Participants Analyzed [units: participants]	3	9	12	11	7	9	9	4	5	6	2	1	3	1
Arm 2: Dose intensity of decitabine (units: mg/m^2/4 weeks)	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**
	82.89 (54.4 to 103.5)	97.61 (73.9 to 104.6)	97.79 (79.2 to 105.7)	97.82 (81.6 to 105.1)	91.67 (69.4 to 100.3)	99.03 (83.7 to 101.6)	86.12 (56.8 to 106.4)	86.96 (64.4 to 88.9)	92.85 (80.8 to 102.0)	79.37 (48.3 to 106.3)	71.20 (54.6 to 87.8)	95.84 (95.84 to 95.84)	73.47 (68.6 to 84.9)	97.03 (97.03 to 97.03)

Arm 3: Dose intensity of MBG453 and PDR001

Description Dose intensity of MBG453 and PDR001 was calculated as: Actual Cumulative dose (mg) / (Duration of exposure in weeks/4)

Time Frame	Up to approximately 4.3 years
Analysis Population Description	All patients from Arm 3 who received at least one dose of study treatment.

	MBG453 160mg Q2W + PDR001 + Decitabine R/R AML	MBG453 240mg Q2W + PDR001 + Decitabine ND AML	MBG453 240mg Q2W + PDR001 + Decitabine R/R AML	MBG453 400mg Q2W + PDR001 + Decitabine ND AML	MBG453 400mg Q2W + PDR001 + Decitabine R/R AML	MBG453 160mg Q2W + PDR001 + Decitabine HR/VHR MDS	MBG453 240mg Q2W + PDR001 + Decitabine HR/VHR MDS	MBG453 400mg Q2W + PDR001 + Decitabine HR/VHR MDS
Arm/Group Description	Arm 3: MBG453 160 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 3: MBG453 160 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome
Number of Participants Analyzed [units: participants]	3	2	2	2	3	3	2	1
Arm 3: Dose intensity of MBG453	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**

and PDR001 (units: mg/4 weeks)								
MBG453	320.00 (290.9 to 320.0)	450.00 (420.0 to 480.0)	428.00 (376.0 to 480.0)	705.82 (653.1 to 758.6)	746.67 (400.0 to 783.2)	314.39 (240.0 to 320.0)	413.40 (373.8 to 453.0)	622.22 (622.22 to 622.22)
PDR001	400.00 (365.7 to 400.0)	400.00 (400.0 to 400.0)	363.56 (327.1 to 400.0)	361.37 (342.4 to 380.4)	373.33 (228.6 to 391.6)	392.98 (266.7 to 400.0)	344.50 (311.5 to 377.5)	400.00 (400.00 to 400.00)

Arm 3: Dose intensity of decitabine

Description	Dose intensity of decitabine was calculated as: Actual Cumulative dose (mg/m2) / (Duration of exposure in weeks/4)
Time Frame	Up to approximately 4.3 years
Analysis Population Description	All patients from Arm 3 who received at least one dose of study treatment.

	MBG453 160mg Q2W + PDR001 + Decitabine R/R AML	**MBG453 240mg Q2W + PDR001 + Decitabine ND AML**	**MBG453 240mg Q2W + PDR001 + Decitabine R/R AML**	**MBG453 400mg Q2W + PDR001 + Decitabine ND AML**	**MBG453 400mg Q2W + PDR001 + Decitabine R/R AML**	**MBG453 160mg Q2W + PDR001 + Decitabine HR/VHR MDS**	**MBG453 240mg Q2W + PDR001 + Decitabine HR/VHR MDS**	**MBG453 400mg Q2W + PDR001 + Decitabine HR/VHR MDS**
Arm/Group Description	Arm 3: MBG453 160 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in newly	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in newly	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 3: MBG453 160 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome

		diagnosed acute myeloid leukemia		diagnosed acute myeloid leukemia				
Number of Participants Analyzed [units: participants]	3	2	2	2	3	3	2	1
Arm 3: Dose intensity of decitabine (units: mg/m^2/4 weeks)	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**
	94.25 (56.4 to 100.2)	111.86 (100.5 to 123.2)	78.99 (54.5 to 103.5)	85.29 (76.4 to 94.2)	90.30 (58.8 to 94.6)	93.09 (84.2 to 98.0)	84.88 (75.2 to 94.6)	78.81 (78.81 to 78.81)

Arm 4: Dose intensity of MBG453

Description	Dose intensity of MBG453 was calculated as: Actual Cumulative dose (mg) / (Duration of exposure in weeks/4)
Time Frame	Up to approximately 0.9 years
Analysis Population Description	All patients from Arm 4 who received at least one dose of study treatment.

	MBG453 400mg Q2W R/R AML	**MBG453 1200mg Q2W R/R AML**	**MBG453 400mg Q2W HR/VHR MDS**	**MBG453 1200mg Q2W HR/VHR MDS**	**MBG453 1200mg Q2W IR MDS**
Arm/Group Description	Arm 4: MBG453 400 mg Q2W in relapsed/refractory acute myeloid leukemia	Arm 4: MBG453 1200 mg Q2W in relapsed/refractory acute myeloid leukemia	Arm 4: MBG453 400 mg Q2W in high-/very high-risk	Arm 4: MBG453 1200 mg Q2W in high-/very high-risk	Arm 4: MBG453 1200 mg Q2W in intermediate-risk

			myelodysplastic syndrome	myelodysplastic syndrome	myelodysplastic syndrome
Number of Participants Analyzed [units: participants]	10	6	3	5	2
Arm 4: Dose intensity of MBG453 (units: mg/4 weeks)	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**
	800.00 (600.00 to 800.0)	2400.00 (2240.0 to 2400.0)	800.00 (800.0 to 811.6)	2400.00 (2356.1 to 2434.8)	2407.19 (2400.0 to 2414.4)

Arm 5: Dose intensity of MBG453 and PDR001

Description	Dose intensity of MBG453 and PDR001 was calculated as: Actual Cumulative dose (mg) / (Duration of exposure in weeks/4)
Time Frame	Up to approximately 0.5 years
Analysis Population Description	All patients from Arm 5 who received at least one dose of study treatment.

	MBG453 80mg Q2W + PDR001 R/R AML	**MBG453 240mg Q2W + PDR001 R/R AML**	**MBG453 240mg Q2W + PDR001 HR/VHR MDS**
Arm/Group Description	Arm 5: MBG453 80 mg Q2W in combination with PDR001 400 mg Q4W in relapsed/refractory acute myeloid leukemia	Arm 5: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W in relapsed/refractory acute myeloid leukemia	Arm 5: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W in high-/very high-risk myelodysplastic syndrome
Number of Participants Analyzed [units: participants]	1	5	5
Arm 5: Dose intensity of MBG453 and PDR001 (units: mg/4 weeks)	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**
MBG453	160.00 (160.00 to 160.00)	480.00 (264.6 to 480.0)	480.00 (361.3 to 483.5)
PDR001	400.00 (400.00 to 400.00)	400.00 (317.7 to 400.0)	400.00 (329.4 to 400.0)

Arm 6: Dose intensity of MBG453

Description	Dose intensity of MBG453 was calculated as: Actual Cumulative dose (mg) / (Duration of exposure in weeks/4)
Time Frame	Up to approximately 4.2 years
Analysis Population Description	All patients from Arm 6 who received at least one dose of study treatment.

	MBG453 240mg Q2W + Azacitidine ND AML	MBG453 400mg Q2W + Azacitidine ND AML	MBG453 800mg Q4W + Azacitidine ND AML	MBG453 240mg Q2W + Azacitidine HR/VHR MDS	MBG453 240mg Q2W + Azacitidine IR MDS	MBG453 400mg Q2W + Azacitidine HR/VHR MDS	MBG453 400mg Q2W + Azacitidine IR MDS	MBG453 800mg Q4W + Azacitidine HR/VHR MDS	MBG453 800mg Q4W + Azacitidine IR MDS	MBG453 400mg Q2W + Azacitidine CMML	MBG453 800mg Q4W + Azacitidine CMML
Arm/Group Description	Arm 6: MBG453 240 mg Q2W in combination with azacitidine 75 mg/m2 in newly diagnosed acute myeloid leukemia	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in newly diagnosed acute myeloid leukemia	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in newly diagnosed acute myeloid leukemia	Arm 6: MBG453 240 mg Q2W in combination with azacitidine 75 mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 6: MBG453 240 mg Q2W in combination with azacitidine 75 mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in chronic myelomonocytic leukemia	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in chronic myelomonocytic leukemia
Number of Participants Analyze	6	14	6	3	2	14	5	17	2	5	5

d [units: participants]											
Arm 6: Dose intensity of MBG453 (units: mg/4 weeks)	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**
	439.39 (409.6 to 525.7)	767.16 (425.6 to 800.0)	794.37 (533.3 to 800.0)	480.00 (480.0 to 527.1)	581.12 (480.0 to 682.2)	731.88 (617.9 to 829.6)	800.00 (752.9 to 800.0)	788.27 (445.0 to 845.3)	797.97 (795.9 to 800.0)	751.13 (738.5 to 796.4)	770.52 (702.2 to 800.0)

Arm 6: Dose intensity of azacitidine

Description	Dose intensity of azacitidine was calculated as: Actual Cumulative dose (mg/m2) / (Duration of exposure in weeks/4)
Time Frame	Up to approximately 4.2 years
Analysis Population Description	All patients from Arm 6 who received at least one dose of study treatment.

	MBG453 240mg Q2W + Azacitidine ND AML	**MBG453 400mg Q2W + Azacitidine ND AML**	**MBG453 800mg Q4W + Azacitidine ND AML**	**MBG453 240mg Q2W + Azacitidine HR/VHR MDS**	**MBG453 240mg Q2W + Azacitidine IR MDS**	**MBG453 400mg Q2W + Azacitidine HR/VHR MDS**	**MBG453 400mg Q2W + Azacitidine IR MDS**	**MBG453 800mg Q4W + Azacitidine HR/VHR MDS**	**MBG453 800mg Q4W + Azacitidine IR MDS**	**MBG453 400mg Q2W + Azacitidine CMML**	**MBG453 800mg Q4W + Azacitidine CMML**
Arm/Group Description	Arm 6: MBG453 240 mg Q2W in	Arm 6: MBG453 400 mg Q2W in	Arm 6: MBG453 800 mg Q4W in	Arm 6: MBG453 240 mg Q2W in combinatio	Arm 6: MBG453 240 mg Q2W in combinatio	Arm 6: MBG453 400 mg Q2W in combinatio	Arm 6: MBG453 400 mg Q2W in combinatio	Arm 6: MBG453 800 mg Q4W in combinatio	Arm 6: MBG453 800 mg Q4W in combinatio	Arm 6: MBG453 400 mg Q2W in combinatio	Arm 6: MBG453 800 mg Q4W in combinatio

	combination with azacitidine 75 mg/m2 in newly diagnosed acute myeloid leukemia	combination with azacitidine 75 mg/m2 in newly diagnosed acute myeloid leukemia	combination with azacitidine 75 mg/m2 in newly diagnosed acute myeloid leukemia	n with azacitidine 75 mg/m2 in high-/very high-risk myelodysplastic syndrome	n with azacitidine 75 mg/m2 in intermediate-risk myelodysplastic syndrome	n with azacitidine 75 mg/m2 in high-/very high-risk myelodysplastic syndrome	n with azacitidine 75 mg/m2 in intermediate-risk myelodysplastic syndrome	n with azacitidine 75 mg/m2 in high-/very high-risk myelodysplastic syndrome	n with azacitidine 75 mg/m2 in intermediate-risk myelodysplastic syndrome	n with azacitidine 75 mg/m2 in chronic myelomonocytic leukemia	n with azacitidine 75 mg/m2 in chronic myelomonocytic leukemia
Number of Participants Analyzed [units: participants]	6	14	6	3	2	14	5	17	2	5	5
Arm 6: Dose intensity of azacitidine (units: mg/m^2/4 weeks)	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**
	478.05 (421.0 to 524.2)	490.51 (361.1 to 560.0)	460.33 (337.3 to 558.0)	442.82 (316.0 to 510.6)	504.16 (496.4 to 512.0)	457.93 (260.4 to 544.7)	519.73 (448.4 to 535.3)	481.69 (326.9 to 581.1)	522.94 (496.5 to 549.4)	501.92 (462.0 to 517.1)	499.45 (486.8 to 530.8)

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Secondary Outcome Result(s)

Arm 1: Best Overall Response (BOR) based on Cheson 2003 for AML

Description	Best overall response (BOR) was calculated based on local investigator assessment per Cheson 2003. BOR is the best response recorded from the start of the treatment until treatment failure/relapse. In case of “no response” as best response evaluation, “treatment failure” was considered best overall response. If any alternative cancer therapy was taken while on study, any subsequent assessments were excluded from the best overall response determination.
Time Frame	Up to approximately 1.8 years
Analysis Population Description	All patients from Arm 1 with AML who received at least one dose of study treatment and had a valid assessment for the outcome measure.

	PDR001 400mg Q4W + Decitabine ND AML	PDR001 400mg Q4W + Decitabine R/R AML
Arm/Group Description	Arm 1: PDR001 in combination with decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Arm 1: PDR001 in combination with decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia
Number of Participants Analyzed [units: participants]	1	10
Arm 1: Best Overall Response (BOR) based on Cheson 2003 for AML (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
Complete Remission (CR)	0 (%)	3 (30%)
Morphologic CR with incomplete blood count recovery (CRi)	0 (%)	1 (10%)
Partial Remission (PR)	0 (%)	0 (%)
>Relapsed from CR, CRi or PR	0 (%)	3 (30%)
Treatment Failure (TF)	1 (100%)	6 (60%)

Unknown	0 (%)	0 (%)

Arm 2: Best Overall Response (BOR) based on Cheson 2003 for AML

Description	Best overall response (BOR) was calculated based on local investigator assessment per Cheson 2003. BOR is the best response recorded from the start of the treatment until treatment failure/relapse. In case of “no response” as best response evaluation, “treatment failure” was considered best overall response. If any alternative cancer therapy was taken while on study, any subsequent assessments were excluded from the best overall response determination.
Time Frame	Up to approximately 2.9 years
Analysis Population Description	All patients from Arm 2 with AML who received at least one dose of study treatment and had a valid assessment for the outcome measure.

	MBG453 240mg Q2W + Decitabine ND AML	**MBG453 240mg Q2W + Decitabine R/R AML**	**MBG453 400mg Q2W + Decitabine ND AML**	**MBG453 400mg Q2W + Decitabine R/R AML**	**MBG453 800mg Q4W + Decitabine ND AML**	**MBG453 800mg Q4W + Decitabine R/R AML**
Arm/Group Description	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia
Number of Participants Analyzed [units: participants]	3	8	8	10	6	8
Arm 2: Best Overall Response (BOR) based on Cheson 2003 for AML (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**

Complete Remission (CR)	2 (66.67%)	0 (%)	4 (50%)	0 (%)	1 (16.67%)	0 (%)
Morphologic CR with incomplete blood count recovery (CRi)	0 (%)	2 (25%)	0 (%)	2 (20%)	0 (%)	2 (25%)
Partial Remission (PR)	0 (%)	0 (%)	0 (%)	0 (%)	1 (16.67%)	0 (%)
>Relapsed from CR, CRi or PR	2 (66.67%)	2 (25%)	4 (50%)	0 (%)	1 (16.67%)	0 (%)
Treatment Failure (TF)	1 (33.33%)	6 (75%)	4 (50%)	6 (60%)	4 (66.67%)	6 (75%)
Unknown	0 (%)	0 (%)	0 (%)	2 (20%)	0 (%)	0 (%)

Arm 3: Best Overall Response (BOR) based on Cheson 2003 for AML

Description	Best overall response (BOR) was calculated based on local investigator assessment per Cheson 2003. BOR is the best response recorded from the start of the treatment until treatment failure/relapse. In case of “no response” as best response evaluation, “treatment failure” was considered best overall response. If any alternative cancer therapy was taken while on study, any subsequent assessments were excluded from the best overall response determination.
Time Frame	Up to approximately 4.3 years
Analysis Population Description	All patients from Arm 3 with AML who received at least one dose of study treatment and had a valid assessment for the outcome measure.

	MBG453 160mg Q2W + PDR001 + Decitabine R/R AML	**MBG453 240mg Q2W + PDR001 + Decitabine ND AML**	**MBG453 240mg Q2W + PDR001 + Decitabine R/R AML**	**MBG453 400mg Q2W + PDR001 + Decitabine ND AML**	**MBG453 400mg Q2W + PDR001 + Decitabine R/R AML**
Arm/Group Description	Arm 3: MBG453 160 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W and	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400 mg Q4W and	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in

	relapsed/refractory acute myeloid leukemia	decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	relapsed/refractory acute myeloid leukemia	decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	relapsed/refractory acute myeloid leukemia
Number of Participants Analyzed [units: participants]	3	1	2	2	3
Arm 3: Best Overall Response (BOR) based on Cheson 2003 for AML (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
Complete Remission (CR)	0 (%)	0 (%)	1 (50%)	0 (%)	0 (%)
Morphologic CR with incomplete blood count recovery (CRi)	0 (%)	0 (%)	0 (%)	1 (50%)	2 (66.67%)
Partial Remission (PR)	1 (33.33%)	0 (%)	0 (%)	0 (%)	0 (%)
>Relapsed from CR, CRi or PR	1 (33.33%)	0 (%)	0 (%)	1 (50%)	2 (66.67%)
Treatment Failure (TF)	2 (66.67%)	0 (%)	1 (50%)	1 (50%)	1 (33.33%)
Unknown	0 (%)	1 (100%)	0 (%)	0 (%)	0 (%)

Arm 4: Best Overall Response (BOR) based on Cheson 2003 for AML

Description	Best overall response (BOR) was calculated based on local investigator assessment per Cheson 2003. BOR is the best response recorded from the start of the treatment until treatment failure/relapse. In case of “no response” as best response evaluation, “treatment failure” was considered best overall response. If any alternative cancer therapy was taken while on study, any subsequent assessments were excluded from the best overall response determination.
Time Frame	Up to approximately 0.9 years
Analysis Population Description	All patients from Arm 4 with AML who received at least one dose of study treatment and had a valid assessment for the outcome measure.

	MBG453 400mg Q2W R/R AML	MBG453 1200mg Q2W R/R AML
Arm/Group Description	Arm 4: MBG453 400 mg Q2W in relapsed/refractory acute myeloid leukemia	Arm 4: MBG453 1200 mg Q2W in relapsed/refractory acute myeloid leukemia
Number of Participants Analyzed [units: participants]	7	5
Arm 4: Best Overall Response (BOR) based on Cheson 2003 for AML (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
Complete Remission (CR)	0 (%)	0 (%)
Morphologic CR with incomplete blood count recovery (CRi)	0 (%)	0 (%)
Partial Remission (PR)	0 (%)	0 (%)
>Relapsed from CR, CRi or PR	0 (%)	0 (%)
Treatment Failure (TF)	4 (57.14%)	5 (100%)
Unknown	3 (42.86%)	0 (%)

Arm 5: Best Overall Response (BOR) based on Cheson 2003 for AML

Description	Best overall response (BOR) was calculated based on local investigator assessment per Cheson 2003. BOR is the best response recorded from the start of the treatment until treatment failure/relapse. In case of “no response” as best response evaluation, “treatment failure” was considered best overall response. If any alternative cancer therapy was taken while on study, any subsequent assessments were excluded from the best overall response determination.
Time Frame	Up to approximately 0.5 years
Analysis Population Description	All patients from Arm 5 with AML who received at least one dose of study treatment and had a valid assessment for the outcome measure.

	MBG453 80mg Q2W + PDR001 R/R AML	MBG453 240mg Q2W + PDR001 R/R AML
Arm/Group Description	Arm 5: MBG453 80 mg Q2W in combination with PDR001 400 mg Q4W in relapsed/refractory acute myeloid leukemia	Arm 5: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W in relapsed/refractory acute myeloid leukemia
Number of Participants Analyzed [units: participants]	1	4
Arm 5: Best Overall Response (BOR) based on Cheson 2003 for AML (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
Complete Remission (CR)	0 (%)	0 (%)
Morphologic CR with incomplete blood count recovery (CRi)	0 (%)	0 (%)
Partial Remission (PR)	0 (%)	0 (%)
>Relapsed from CR, CRi or PR	0 (%)	0 (%)
Treatment Failure (TF)	1 (100%)	4 (100%)
Unknown	0 (%)	0 (%)

Arm 6: Best Overall Response (BOR) based on Cheson 2003 for AML

Description	Best overall response (BOR) was calculated based on local investigator assessment per Cheson 2003. BOR is the best response recorded from the start of the treatment until treatment failure/relapse. In case of “no response” as best response evaluation, “treatment failure” was considered best overall response. If any alternative cancer therapy was taken while on study, any subsequent assessments were excluded from the best overall response determination.
Time Frame	Up to approximately 4.2 years
Analysis Population Description	All patients from Arm 6 with AML who received at least one dose of study treatment and had a valid assessment for the outcome measure.

	MBG453 240mg Q2W + Azacitidine ND AML	MBG453 400mg Q2W + Azacitidine ND AML	MBG453 800mg Q4W + Azacitidine ND AML
Arm/Group Description	Arm 6: MBG453 240 mg Q2W in combination with azacitidine 75 mg/m2 in newly diagnosed acute myeloid leukemia	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in newly diagnosed acute myeloid leukemia	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in newly diagnosed acute myeloid leukemia
Number of Participants Analyzed [units: participants]	6	12	5
Arm 6: Best Overall Response (BOR) based on Cheson 2003 for AML (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
Complete Remission (CR)	1 (16.67%)	2 (16.67%)	0 (%)
Morphologic CR with incomplete blood count recovery (CRi)	1 (16.67%)	0 (%)	1 (20%)
Partial Remission (PR)	0 (%)	3 (25%)	1 (20%)
>Relapsed from CR, CRi or PR	2 (33.33%)	4 (33.33%)	0 (%)
Treatment Failure (TF)	4 (66.67%)	5 (41.67%)	3 (60%)
Unknown	0 (%)	2 (16.67%)	0 (%)

Arm 1: Best Overall Response (BOR) regardless of confirmation based on Cheson 2006 for MDS

Description	Best overall response (BOR) was calculated based on local investigator assessment per Cheson 2006. BOR is the best disease response recorded from the start of the treatment until final disease progression/relapse. If any alternative cancer therapy was taken while on study, any subsequent assessments were excluded from the best overall response determination.
Time Frame	Up to approximately 1.8 years
Analysis Population Description	All patients from Arm 1 with MDS who received at least one dose of study treatment and had a valid assessment for the outcome measure.

	PDR001 400mg Q4W + Decitabine VHR MDS	PDR001 400 mg Q4W + Decitabine HR MDS
Arm/Group Description	Arm 1: PDR001 in combination with decitabine 20mg/m2 in very high-risk myelodysplastic syndrome	Arm 1: PDR001 in combination with decitabine 20mg/m2 in high-risk myelodysplastic syndrome
Number of Participants Analyzed [units: participants]	1	1
Arm 1: Best Overall Response (BOR) regardless of confirmation based on Cheson 2006 for MDS (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
Complete Remission (CR)	1 (100%)	1 (100%)
Bone marrow CR (mCR)	0 (%)	0 (%)
>mCR with Hematologic Improvement	0 (%)	0 (%)
Partial Remission (PR)	0 (%)	0 (%)
>Relapse from CR or PR	0 (%)	0 (%)
Stable Disease (SD)	0 (%)	0 (%)
>SD with Hematologic Improvement	0 (%)	0 (%)
Disease Progression (PD)	0 (%)	0 (%)
Unknown	0 (%)	0 (%)
>Unknown with Hematologic Improvement	0 (%)	0 (%)

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Arm 2: Best Overall Response (BOR) regardless of confirmation based on Cheson 2006 for MDS and CMML

Description	Best overall response (BOR) was calculated based on local investigator assessment per Cheson 2006. BOR is the best disease response recorded from the start of the treatment until final disease progression/relapse. If any alternative cancer therapy was taken while on study, any subsequent assessments were excluded from the best overall response determination.
Time Frame	Up to approximately 2.9 years
Analysis Population Description	All patients from Arm 2 with MDS and CMML who received at least one dose of study treatment and had a valid assessment for the outcome measure.

	MBG453 240mg Q2W + Decitabine VHR MDS	**MBG453 240 mg Q2W + Decitabine HR MDS**	**MBG453 400mg Q2W + Decitabine HR MDS**	**MBG453 400mg Q2W + Decitabine IR MDS**	**MBG453 800mg Q4W + Decitabine VHR MDS**	**MBG453 800 mg Q4W + Decitabine HR MDS**	**MBG453 800mg Q4W + Decitabine IR MDS**	**MBG453 240mg Q2W + Decitabine CMML**	**MBG453 400mg Q2W + Decitabine CMML**	**MBG453 800mg Q4W + Decitabine CMML**
Arm/Group Description	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in very high-risk myelodysplastic syndrome	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in high-risk myelodysplastic syndrome	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in high-risk myelodysplastic syndrome	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in very high-risk myelodysplastic syndrome	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in high-risk myelodysplastic syndrome	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in chronic myelomonocytic leukemia	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in chronic myelomonocytic leukemia	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in chronic myelomonocytic leukemia
Number of Participants Analyzed [units: participants]	1	8	4	5	3	2	2	1	3	1

Arm 2: Best Overall Response (BOR) regardless of confirmation based on Cheson 2006 for MDS and CMML (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
Complete Remission (CR)	1 (100%)	0 (%)	1 (25%)	0 (%)	1 (33.33%)	1 (50%)	0 (%)	0 (%)	0 (%)	0 (%)
Bone marrow CR (mCR)	0 (%)	3 (37.5%)	2 (50%)	0 (%)	1 (33.33%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (100%)
>mCR with Hematologic Improvement	0 (%)	2 (25%)	1 (25%)	0 (%)	1 (33.33%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Partial Remission (PR)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (100%)	0 (%)	0 (%)
>Relapse from CR or PR	0 (%)	1 (12.5%)	0 (%)	0 (%)	0 (%)	1 (50%)	0 (%)	0 (%)	0 (%)	0 (%)

Stable Disease (SD)	0 (%)	4 (50%)	1 (25%)	4 (80%)	1 (33.33%)	1 (50%)	2 (100%)	0 (%)	3 (100%)	0 (%)
>SD with Hematologic Improvement	0 (%)	0 (%)	0 (%)	1 (20%)	1 (33.33%)	0 (%)	0 (%)	0 (%)	1 (33.33%)	0 (%)
Disease Progression (PD)	0 (%)	1 (12.5%)	0 (%)	1 (20%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Unknown	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
>Unknown with Hematologic Improvement	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)

Arm 3: Best Overall Response (BOR) regardless of confirmation based on Cheson 2006 for MDS

Description	Best overall response (BOR) was calculated based on local investigator assessment per Cheson 2006. BOR is the best disease response recorded from the start of the treatment until final disease progression/relapse. If any alternative cancer therapy was taken while on study, any subsequent assessments were excluded from the best overall response determination.
Time Frame	Up to approximately 4.3 years
Analysis Population Description	All patients from Arm 3 with MDS who received at least one dose of study treatment and had a valid assessment for the outcome measure.

	MBG453 160mg Q2W + PDR001 + Decitabine VHR MDS	**MBG453 160 mg Q2W + PDR001 + Decitabine HR MDS**	**MBG453 240mg Q2W + PDR001 + Decitabine HR MDS**	**MBG453 400mg Q2W + PDR001 + Decitabine HR MDS**
Arm/Group Description	Arm 3: MBG453 160 mg Q2W in combination with	Arm 3: MBG453 160 mg Q2W in combination with	Arm 3: MBG453 240 mg Q2W in combination with	Arm 3: MBG453 400 mg Q2W in combination with

	PDR001 400 mg Q4W and decitabine 20mg/m2 in very high-risk myelodysplastic syndrome	PDR001 400mg Q4W and decitabine 20mg/m2 in high-risk myelodysplastic syndrome	PDR001 400 mg Q4W and decitabine 20mg/m2 in high-risk myelodysplastic syndrome	PDR001 400 mg Q4W and decitabine 20mg/m2 in high-risk myelodysplastic syndrome
Number of Participants Analyzed [units: participants]	1	1	2	1
Arm 3: Best Overall Response (BOR) regardless of confirmation based on Cheson 2006 for MDS (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
Complete Remission (CR)	0 (%)	0 (%)	2 (100%)	0 (%)
Bone marrow CR (mCR)	0 (%)	0 (%)	0 (%)	1 (100%)
>mCR with Hematologic Improvement	0 (%)	0 (%)	0 (%)	1 (100%)
Partial Remission (PR)	0 (%)	0 (%)	0 (%)	0 (%)
>Relapse from CR or PR	0 (%)	0 (%)	1 (50%)	0 (%)
Stable Disease (SD)	1 (100%)	1 (100%)	0 (%)	0 (%)
>SD with Hematologic Improvement	0 (%)	0 (%)	0 (%)	0 (%)
Disease Progression (PD)	0 (%)	0 (%)	0 (%)	0 (%)
Unknown	0 (%)	0 (%)	0 (%)	0 (%)
>Unknown with Hematologic Improvement	0 (%)	0 (%)	0 (%)	0 (%)

Arm 4: Best Overall Response (BOR) regardless of confirmation based on Cheson 2006 for MDS

Description	Best overall response (BOR) was calculated based on local investigator assessment per Cheson 2006. BOR is the best disease response recorded from the start of the treatment until final disease progression/relapse. If any alternative cancer therapy was taken while on study, any subsequent assessments were excluded from the best overall response determination.
Time Frame	Up to approximately 0.9 years
Analysis Population Description	All patients from Arm 4 with MDS who received at least one dose of study treatment and had a valid assessment for the outcome measure.

	MBG453 400mg Q2W VHR MDS	MBG453 400 mg Q2W HR MDS	MBG453 1200mg Q2W VHR MDS	MBG453 1200 mg Q2W HR MDS	MBG453 1200mg Q2W IR MDS
Arm/Group Description	Arm 4: MBG453 400 mg Q2W in very high-risk myelodysplastic syndrome	Arm 4: MBG453 400 mg Q2W in high-risk myelodysplastic syndrome	Arm 4: MBG453 1200 mg Q2W in very high-risk myelodysplastic syndrome	Arm 4: MBG453 1200 mg Q2W in high-risk myelodysplastic syndrome	Arm 4: MBG453 1200 mg Q2W in intermediate-risk myelodysplastic syndrome
Number of Participants Analyzed [units: participants]	2	1	1	4	2
Arm 4: Best Overall Response (BOR) regardless of confirmation based on Cheson 2006 for MDS (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
Complete Remission (CR)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Bone marrow CR (mCR)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
>mCR with Hematologic Improvement	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Partial Remission (PR)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
>Relapse from CR or PR	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)

Stable Disease (SD)	1 (50%)	1 (100%)	0 (%)	3 (75%)	2 (100%)
>SD with Hematologic Improvement	0 (%)	0 (%)	0 (%)	1 (25%)	1 (50%)
Disease Progression (PD)	1 (50%)	0 (%)	1 (100%)	1 (25%)	0 (%)
Unknown	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
>Unknown with Hematologic Improvement	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)

Arm 5: Best Overall Response (BOR) regardless of confirmation based on Cheson 2006 for MDS

Description	Best overall response (BOR) was calculated based on local investigator assessment per Cheson 2006. BOR is the best disease response recorded from the start of the treatment until final disease progression/relapse. If any alternative cancer therapy was taken while on study, any subsequent assessments were excluded from the best overall response determination.
Time Frame	Up to approximately 0.5 years
Analysis Population Description	All patients from Arm 5 with MDS who received at least one dose of study treatment and had a valid assessment for the outcome measure.

	MBG453 240mg Q2W + PDR001 VHR MDS	**MBG453 240 mg Q2W + PDR001 HR MDS**
Arm/Group Description	Arm 5: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W in very high-risk myelodysplastic syndrome	Arm 5: MBG453 240 mg Q2W in combination with PDR001 400mg Q4W in high-risk myelodysplastic syndrome
Number of Participants Analyzed [units: participants]	1	4
Arm 5: Best Overall Response (BOR) regardless of confirmation based on Cheson 2006 for MDS (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
Complete Remission (CR)	0 (%)	0 (%)

Bone marrow CR (mCR)	0 (%)	0 (%)
>mCR with Hematologic Improvement	0 (%)	0 (%)
Partial Remission (PR)	0 (%)	0 (%)
>Relapse from CR or PR	0 (%)	0 (%)
Stable Disease (SD)	1 (100%)	2 (50%)
>SD with Hematologic Improvement	0 (%)	1 (25%)
Disease Progression (PD)	0 (%)	2 (50%)
Unknown	0 (%)	0 (%)
>Unknown with Hematologic Improvement	0 (%)	0 (%)

Arm 6: Best Overall Response (BOR) regardless of confirmation based on Cheson 2006 for MDS and CMML

Description	Best overall response (BOR) was calculated based on local investigator assessment per Cheson 2006. BOR is the best disease response recorded from the start of the treatment until final disease progression/relapse. If any alternative cancer therapy was taken while on study, any subsequent assessments were excluded from the best overall response determination.
Time Frame	Up to approximately 4.2 years
Analysis Population Description	All patients from Arm 6 with MDS and CMML who received at least one dose of study treatment and had a valid assessment for the outcome measure.

MBG453 240mg Q2W +	MBG453 240 mg Q2W +	MBG453 240mg Q2W +	MBG453 400mg Q2W +	MBG453 400 mg Q2W +	MBG453 400mg Q2W +	MBG453 800mg Q4W +	MBG453 800 mg Q4W +	MBG453 800mg Q4W +	MBG453 400mg Q2W +	MBG453 800mg Q4W +

	Azacitidine VHR MDS	Azacitidine HR MDS	Azacitidine IR MDS	Azacitidine VHR MDS	Azacitidine HR MDS	Azacitidine IR MDS	Azacitidine VHR MDS	Azacitidine HR MDS	Azacitidine IR MDS	Azacitidine CMML	Azacitidine CMML
Arm/Group Description	Arm 6: MBG453 240 mg Q2W in combination with azacitidine 75 mg/m2 in very high-risk myelodysplastic syndrome	Arm 6: MBG453 240 mg Q2W in combination with azacitidine 75 mg/m2 in high-risk myelodysplastic syndrome	Arm 6: MBG453 240 mg Q2W in combination with azacitidine 75 mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in very high-risk myelodysplastic syndrome	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in high-risk myelodysplastic syndrome	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in very high-risk myelodysplastic syndrome	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in high-risk myelodysplastic syndrome	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in chronic myelomonocytic leukemia	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in chronic myelomonocytic leukemia
Number of Participants Analyzed [units: participants]	2	1	2	8	6	3	7	9	2	5	5
Arm 6: Best Overall Response (BOR) regardless of confirmation based on Cheson 2006 for MDS	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**

and CMML (units: participants)											
Complete Remission (CR)	0 (%)	0 (%)	1 (50%)	2 (25%)	1 (16.67%)	0 (%)	1 (14.29%)	0 (%)	0 (%)	2 (40%)	2 (40%)
Bone marrow CR (mCR)	2 (100%)	0 (%)	0 (%)	0 (%)	0 (%)	3 (100%)	1 (14.29%)	5 (55.56%)	1 (50%)	1 (20%)	2 (40%)
>mCR with Hematologic Improvement	1 (50%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (33.33%)	0 (%)	2 (22.22%)	0 (%)	1 (20%)	1 (20%)
Partial Remission (PR)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (11.11%)	1 (50%)	0 (%)	0 (%)
>Relapse from CR or PR	0 (%)	0 (%)	0 (%)	2 (25%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (20%)	0 (%)
Stable Disease (SD)	0 (%)	0 (%)	1 (50%)	5 (62.5%)	4 (66.67%)	0 (%)	4 (57.14%)	3 (33.33%)	0 (%)	2 (40%)	1 (20%)
>SD with Hematologic Improvement	0 (%)	0 (%)	0 (%)	2 (25%)	4 (66.67%)	0 (%)	2 (28.57%)	0 (%)	0 (%)	1 (20%)	0 (%)
Disease Progression (PD)	0 (%)	1 (100%)	0 (%)	1 (12.5%)	1 (16.67%)	0 (%)	1 (14.29%)	0 (%)	0 (%)	0 (%)	0 (%)

Unknown	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
>Unknown with Hematologic Improvement	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)

Arm 1: Best Overall Response (BOR) with confirmation based on Cheson 2006 for MDS

Description	Best overall response (BOR) was calculated based on local investigator assessment per Cheson 2006. BOR is the best disease response recorded from the start of the treatment until final disease progression/relapse. The responses of Complete Remission (CR), Partial Remission (PR), bone marrow CR, and Stable Disease (SD) were to be confirmed in the evaluation of best overall response. If any alternative cancer therapy was taken while on study, any subsequent assessments were excluded from the best overall response determination.
Time Frame	Up to approximately 1.8 years
Analysis Population Description	All patients from Arm 1 with MDS who received at least one dose of study treatment and had a valid assessment for the outcome measure.

	PDR001 400mg Q4W + Decitabine VHR MDS	**PDR001 400 mg Q4W + Decitabine HR MDS**
Arm/Group Description	Arm 1: PDR001 in combination with decitabine 20mg/m2 in very high-risk myelodysplastic syndrome	Arm 1: PDR001 in combination with decitabine 20mg/m2 in high-risk myelodysplastic syndrome
Number of Participants Analyzed [units: participants]	1	1
Arm 1: Best Overall Response (BOR) with confirmation based on Cheson 2006 for MDS (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
Complete Remission (CR)	1 (100%)	1 (100%)
Bone marrow CR (mCR)	0 (%)	0 (%)

>mCR with Hematologic Improvement	0 (%)	0 (%)
Partial Remission (PR)	0 (%)	0 (%)
>Relapse from CR or PR	0 (%)	0 (%)
Stable Disease (SD)	0 (%)	0 (%)
>SD with Hematologic Improvement	0 (%)	0 (%)
Disease Progression (PD)	0 (%)	0 (%)
Unknown	0 (%)	0 (%)
>Unknown with Hematologic Improvement	0 (%)	0 (%)

Arm 2: Best Overall Response (BOR) with confirmation based on Cheson 2006 for MDS and CMML

Description	Best overall response (BOR) was calculated based on local investigator assessment per Cheson 2006. BOR is the best disease response recorded from the start of the treatment until final disease progression/relapse. The responses of Complete Remission (CR), Partial Remission (PR), bone marrow CR, and Stable Disease (SD) were to be confirmed in the evaluation of best overall response. If any alternative cancer therapy was taken while on study, any subsequent assessments were excluded from the best overall response determination.
Time Frame	Up to approximately 2.9 years
Analysis Population Description	All patients from Arm 2 with MDS and CMML who received at least one dose of study treatment and had a valid assessment for the outcome measure.

MBG453 240mg Q2W + Decitabine VHR MDS	MBG453 240 mg Q2W + Decitabine HR MDS	MBG453 400mg Q2W + Decitabine HR MDS	MBG453 400mg Q2W + Decitabine IR MDS	MBG453 800mg Q4W + Decitabine VHR MDS	MBG453 800 mg Q4W + Decitabine HR MDS	MBG453 800mg Q4W + Decitabine IR MDS	MBG453 240mg Q2W + Decitabine CMML	MBG453 400mg Q2W + Decitabine CMML	MBG453 800mg Q4W + Decitabine CMML

Arm/Group Description	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in very high-risk myelodysplastic syndrome	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in high-risk myelodysplastic syndrome	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in high-risk myelodysplastic syndrome	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in very high-risk myelodysplastic syndrome	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in high-risk myelodysplastic syndrome	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in chronic myelomonocytic leukemia	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in chronic myelomonocytic leukemia	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in chronic myelomonocytic leukemia
Number of Participants Analyzed [units: participants]	1	8	4	5	3	2	2	1	3	1
Arm 2: Best Overall Response (BOR) with confirmation based on Cheson 2006 for MDS and CMML (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
Complete Remission (CR)	1 (100%)	0 (%)	0 (%)	0 (%)	1 (33.33%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)

Bone marrow CR (mCR)	0 (%)	2 (25%)	3 (75%)	0 (%)	1 (33.33%)	1 (50%)	0 (%)	0 (%)	0 (%)	0 (%)
>mCR with Hematologic Improvement	0 (%)	1 (12.5%)	2 (50%)	0 (%)	1 (33.33%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Partial Remission (PR)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (100%)	0 (%)	0 (%)
>Relapse from CR or PR	0 (%)	1 (12.5%)	0 (%)	0 (%)	0 (%)	1 (50%)	0 (%)	0 (%)	0 (%)	0 (%)
Stable Disease (SD)	0 (%)	1 (12.5%)	1 (25%)	3 (60%)	0 (%)	0 (%)	2 (100%)	0 (%)	2 (66.67%)	1 (100%)
>SD with Hematologic Improvement	0 (%)	1 (12.5%)	0 (%)	1 (20%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (33.33%)	0 (%)
Disease Progression (PD)	0 (%)	3 (37.5%)	0 (%)	1 (20%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (33.33%)	0 (%)
Unknown	0 (%)	2 (25%)	0 (%)	1 (20%)	1 (33.33%)	1 (50%)	0 (%)	0 (%)	0 (%)	0 (%)
>Unknown with Hematologic Improvement	0 (%)	0 (%)	0 (%)	0 (%)	1 (33.33%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)

Arm 3: Best Overall Response (BOR) with confirmation based on Cheson 2006 for MDS

Description	Best overall response (BOR) was calculated based on local investigator assessment per Cheson 2006. BOR is the best disease response recorded from the start of the treatment until final disease progression/relapse. The responses of Complete Remission (CR), Partial Remission (PR), bone marrow CR, and Stable Disease (SD) were to be confirmed in the evaluation of best overall response. If any alternative cancer therapy was taken while on study, any subsequent assessments were excluded from the best overall response determination.
Time Frame	Up to approximately 4.3 years
Analysis Population Description	All patients from Arm 3 with MDS who received at least one dose of study treatment and had a valid assessment for the outcome measure.

	MBG453 160mg Q2W + PDR001 + Decitabine VHR MDS	**MBG453 160 mg Q2W + PDR001 + Decitabine HR MDS**	**MBG453 240mg Q2W + PDR001 + Decitabine HR MDS**	**MBG453 400mg Q2W + PDR001 + Decitabine HR MDS**
Arm/Group Description	Arm 3: MBG453 160 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in very high-risk myelodysplastic syndrome	Arm 3: MBG453 160 mg Q2W in combination with PDR001 400mg Q4W and decitabine 20mg/m2 in high-risk myelodysplastic syndrome	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in high-risk myelodysplastic syndrome	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in high-risk myelodysplastic syndrome
Number of Participants Analyzed [units: participants]	1	1	2	1
Arm 3: Best Overall Response (BOR) with confirmation based on Cheson 2006 for MDS (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
Complete Remission (CR)	0 (%)	0 (%)	0 (%)	0 (%)
Bone marrow CR (mCR)	0 (%)	0 (%)	2 (100%)	1 (100%)
>mCR with Hematologic Improvement	0 (%)	0 (%)	2 (100%)	1 (100%)
Partial Remission (PR)	0 (%)	0 (%)	0 (%)	0 (%)

>Relapse from CR or PR	0 (%)	0 (%)	1 (50%)	0 (%)
Stable Disease (SD)	0 (%)	0 (%)	0 (%)	0 (%)
>SD with Hematologic Improvement	0 (%)	0 (%)	0 (%)	0 (%)
Disease Progression (PD)	0 (%)	0 (%)	0 (%)	0 (%)
Unknown	1 (100%)	1 (100%)	0 (%)	0 (%)
>Unknown with Hematologic Improvement	0 (%)	0 (%)	0 (%)	0 (%)

Arm 4: Best Overall Response (BOR) with confirmation based on Cheson 2006 for MDS

Description	Best overall response (BOR) was calculated based on local investigator assessment per Cheson 2006. BOR is the best disease response recorded from the start of the treatment until final disease progression/relapse. The responses of Complete Remission (CR), Partial Remission (PR), bone marrow CR, and Stable Disease (SD) were to be confirmed in the evaluation of best overall response. If any alternative cancer therapy was taken while on study, any subsequent assessments were excluded from the best overall response determination.
Time Frame	Up to approximately 0.9 years
Analysis Population Description	All patients from Arm 4 with MDS who received at least one dose of study treatment and had a valid assessment for the outcome measure.

	MBG453 400mg Q2W VHR MDS	**MBG453 400 mg Q2W HR MDS**	**MBG453 1200mg Q2W VHR MDS**	**MBG453 1200 mg Q2W HR MDS**	**MBG453 1200mg Q2W IR MDS**
Arm/Group Description	Arm 4: MBG453 400 mg Q2W in very high-risk myelodysplastic syndrome	Arm 4: MBG453 400 mg Q2W in high-risk myelodysplastic syndrome	Arm 4: MBG453 1200 mg Q2W in very high-risk myelodysplastic syndrome	Arm 4: MBG453 1200 mg Q2W in high-risk myelodysplastic syndrome	Arm 4: MBG453 1200 mg Q2W in intermediate-risk myelodysplastic syndrome
Number of Participants Analyzed [units: participants]	2	1	1	4	2

Arm 4: Best Overall Response (BOR) with confirmation based on Cheson 2006 for MDS (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
Complete Remission (CR)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Bone marrow CR (mCR)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
>mCR with Hematologic Improvement	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Partial Remission (PR)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
>Relapse from CR or PR	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Stable Disease (SD)	0 (%)	0 (%)	0 (%)	1 (25%)	2 (100%)
>SD with Hematologic Improvement	0 (%)	0 (%)	0 (%)	0 (%)	1 (50%)
Disease Progression (PD)	2 (100%)	0 (%)	1 (100%)	2 (50%)	0 (%)
Unknown	0 (%)	1 (100%)	0 (%)	1 (25%)	0 (%)
>Unknown with Hematologic Improvement	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)

Arm 5: Best Overall Response (BOR) with confirmation based on Cheson 2006 for MDS

Description	Best overall response (BOR) was calculated based on local investigator assessment per Cheson 2006. BOR is the best disease response recorded from the start of the treatment until final disease progression/relapse. The responses of Complete Remission (CR), Partial Remission (PR), bone marrow CR, and Stable Disease (SD) were to be confirmed in the evaluation of best overall response. If any alternative cancer therapy was taken while on study, any subsequent assessments were excluded from the best overall response determination.
Time Frame	Up to approximately 0.5 years

Analysis Population Description: All patients from Arm 5 with MDS who received at least one dose of study treatment and had a valid assessment for the outcome measure.

	MBG453 240mg Q2W + PDR001 VHR MDS	MBG453 240 mg Q2W + PDR001 HR MDS
Arm/Group Description	Arm 5: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W in very high-risk myelodysplastic syndrome	Arm 5: MBG453 240 mg Q2W in combination with PDR001 400mg Q4W in high-risk myelodysplastic syndrome
Number of Participants Analyzed [units: participants]	1	4
Arm 5: Best Overall Response (BOR) with confirmation based on Cheson 2006 for MDS (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
Complete Remission (CR)	0 (%)	0 (%)
Bone marrow CR (mCR)	0 (%)	0 (%)
>mCR with Hematologic Improvement	0 (%)	0 (%)
Partial Remission (PR)	0 (%)	0 (%)
>Relapse from CR or PR	0 (%)	0 (%)
Stable Disease (SD)	0 (%)	0 (%)
>SD with Hematologic Improvement	0 (%)	0 (%)
Disease Progression (PD)	0 (%)	3 (75%)
Unknown	1 (100%)	1 (25%)
>Unknown with Hematologic Improvement	0 (%)	1 (25%)

Arm 6: Best Overall Response (BOR) with confirmation based on Cheson 2006 for MDS and CMML

Description	Best overall response (BOR) was calculated based on local investigator assessment per Cheson 2006. BOR is the best disease response recorded from the start of the treatment until final disease progression/relapse. The responses of Complete Remission (CR), Partial Remission (PR), bone marrow CR, and Stable Disease (SD) were to be confirmed in the evaluation of best overall response. If any alternative cancer therapy was taken while on study, any subsequent assessments were excluded from the best overall response determination.
Time Frame	Up to approximately 4.2 years
Analysis Population Description	All patients from Arm 6 with MDS and CMML who received at least one dose of study treatment and had a valid assessment for the outcome measure.

	MBG453 240mg Q2W + Azacitidine VHR MDS	MBG453 240 mg Q2W + Azacitidine HR MDS	MBG453 240mg Q2W + Azacitidine IR MDS	MBG453 400mg Q2W + Azacitidine VHR MDS	MBG453 400 mg Q2W + Azacitidine HR MDS	MBG453 400mg Q2W + Azacitidine IR MDS	MBG453 800mg Q4W + Azacitidine VHR MDS	MBG453 800 mg Q4W + Azacitidine HR MDS	MBG453 800mg Q4W + Azacitidine IR MDS	MBG453 400mg Q2W + Azacitidine CMML	MBG453 800mg Q4W + Azacitidine CMML
Arm/Group Description	Arm 6: MBG453 240 mg Q2W in combination with azacitidine 75 mg/m2 in very high-risk myelodysplastic syndrome	Arm 6: MBG453 240 mg Q2W in combination with azacitidine 75 mg/m2 in high-risk myelodysplastic syndrome	Arm 6: MBG453 240 mg Q2W in combination with azacitidine 75 mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in very high-risk myelodysplastic syndrome	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in high-risk myelodysplastic syndrome	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in very high-risk myelodysplastic syndrome	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in high-risk myelodysplastic syndrome	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in chronic myelomonocytic leukemia	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in chronic myelomonocytic leukemia
Number of Participants Analyze	2	1	2	8	6	3	7	9	2	5	5

d [units: participants]											
Arm 6: Best Overall Response (BOR) with confirmation based on Cheson 2006 for MDS and CMML (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
Complete Remission (CR)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (14.29%)	0 (%)	0 (%)	1 (20%)	2 (40%)
Bone marrow CR (mCR)	0 (%)	0 (%)	0 (%)	2 (25%)	0 (%)	0 (%)	1 (14.29%)	3 (33.33%)	0 (%)	2 (40%)	1 (20%)
>mCR with Hematologic Improvement	0 (%)	0 (%)	0 (%)	2 (25%)	0 (%)	0 (%)	0 (%)	1 (11.11%)	0 (%)	2 (40%)	1 (20%)
Partial Remission (PR)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (11.11%)	0 (%)	0 (%)	0 (%)

>Relapse from CR or PR	0 (%)	0 (%)	0 (%)	2 (25%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (20%)	0 (%)
Stable Disease (SD)	2 (100%)	0 (%)	1 (50%)	3 (37.5%)	2 (33.33%)	1 (33.33%)	0 (%)	2 (22.22%)	1 (50%)	1 (20%)	0 (%)
>SD with Hematologic Improvement	1 (50%)	0 (%)	0 (%)	2 (25%)	2 (33.33%)	0 (%)	0 (%)	1 (11.11%)	1 (50%)	1 (20%)	0 (%)
Disease Progression (PD)	0 (%)	1 (100%)	0 (%)	1 (12.5%)	2 (33.33%)	0 (%)	2 (28.57%)	0 (%)	0 (%)	1 (20%)	2 (40%)
Unknown	0 (%)	0 (%)	1 (50%)	2 (25%)	2 (33.33%)	2 (66.67%)	3 (42.86%)	3 (33.33%)	1 (50%)	0 (%)	0 (%)
>Unknown with Hematologic Improvement	0 (%)	0 (%)	1 (50%)	0 (%)	2 (33.33%)	1 (33.33%)	1 (14.29%)	0 (%)	0 (%)	0 (%)	0 (%)

Arm 1: Overall Response Rate (ORR) based on Cheson 2003 for AML

Description	Tumor response was based on local investigator assessment per Cheson 2003. ORR per Cheson 2003 is defined as the percentage of participants with a best overall response of Complete Response (CR), Morphologic CR with incomplete blood count recovery (CRi) or Partial Response (PR).
Time Frame	Up to approximately 1.8 years
Analysis Population Description	All patients from Arm 1 with AML who received at least one dose of study treatment and had a valid assessment for the outcome measure.

	PDR001 400mg Q4W + Decitabine ND AML	PDR001 400mg Q4W + Decitabine R/R AML
Arm/Group Description	Arm 1: PDR001 in combination with decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Arm 1: PDR001 in combination with decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia
Number of Participants Analyzed [units: participants]	1	10
Arm 1: Overall Response Rate (ORR) based on Cheson 2003 for AML (units: Percentage of participants)	**Number** **(95% Confidence Interval)**	**Number** **(95% Confidence Interval)**
	0 (0 to 97.5)	40.0 (12.2 to 73.8)

Arm 2: Overall Response Rate (ORR) based on Cheson 2003 for AML

Description	Tumor response was based on local investigator assessment per Cheson 2003. ORR per Cheson 2003 is defined as the percentage of participants with a best overall response of Complete Response (CR), Morphologic CR with incomplete blood count recovery (CRi) or Partial Response (PR).
Time Frame	Up to approximately 2.9 years
Analysis Population Description	All patients from Arm 2 with AML who received at least one dose of study treatment and had a valid assessment for the outcome measure.

	MBG453 240mg Q2W + Decitabine ND AML	MBG453 240mg Q2W + Decitabine R/R AML	MBG453 400mg Q2W + Decitabine ND AML	MBG453 400mg Q2W + Decitabine R/R AML	MBG453 800mg Q4W + Decitabine ND AML	MBG453 800mg Q4W + Decitabine R/R AML
Arm/Group Description	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in newly diagnosed	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in newly diagnosed	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in newly diagnosed	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia

	acute myeloid leukemia		acute myeloid leukemia		acute myeloid leukemia	
Number of Participants Analyzed [units: participants]	3	8	8	10	6	8
Arm 2: Overall Response Rate (ORR) based on Cheson 2003 for AML (units: Percentage of participants)	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**
	66.7 (9.4 to 99.2)	25.0 (3.2 to 65.1)	50.0 (15.7 to 84.3)	20.0 (2.5 to 55.6)	33.3 (4.3 to 77.7)	25.0 (3.2 to 65.1)

Arm 3: Overall Response Rate (ORR) based on Cheson 2003 for AML

Description	Tumor response was based on local investigator assessment per Cheson 2003. ORR per Cheson 2003 is defined as the percentage of participants with a best overall response of Complete Response (CR), Morphologic CR with incomplete blood count recovery (CRi) or Partial Response (PR).
Time Frame	Up to approximately 4.3 years
Analysis Population Description	All patients from Arm 3 with AML who received at least one dose of study treatment and had a valid assessment for the outcome measure.

	MBG453 160mg Q2W + PDR001 + Decitabine R/R AML	**MBG453 240mg Q2W + PDR001 + Decitabine ND AML**	**MBG453 240mg Q2W + PDR001 + Decitabine R/R AML**	**MBG453 400mg Q2W + PDR001 + Decitabine ND AML**	**MBG453 400mg Q2W + PDR001 + Decitabine R/R AML**
Arm/Group Description	Arm 3: MBG453 160 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in newly	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in newly	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia

		diagnosed acute myeloid leukemia		diagnosed acute myeloid leukemia	
Number of Participants Analyzed [units: participants]	3	1	2	2	3
Arm 3: Overall Response Rate (ORR) based on Cheson 2003 for AML (units: Percentage of participants)	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**
	33.3 (0.8 to 90.6)	0 (0 to 97.5)	50.0 (1.3 to 98.7)	50.0 (1.3 to 98.7)	66.7 (9.4 to 99.2)

Arm 4: Overall Response Rate (ORR) based on Cheson 2003 for AML

Description	Tumor response was based on local investigator assessment per Cheson 2003. ORR per Cheson 2003 is defined as the percentage of participants with a best overall response of Complete Response (CR), Morphologic CR with incomplete blood count recovery (CRi) or Partial Response (PR).
Time Frame	Up to approximately 0.9 years
Analysis Population Description	All patients from Arm 4 with AML who received at least one dose of study treatment and had a valid assessment for the outcome measure.

	MBG453 400mg Q2W R/R AML	**MBG453 1200mg Q2W R/R AML**
Arm/Group Description	Arm 4: MBG453 400 mg Q2W in relapsed/refractory acute myeloid leukemia	Arm 4: MBG453 1200 mg Q2W in relapsed/refractory acute myeloid leukemia
Number of Participants Analyzed [units: participants]	7	5
Arm 4: Overall Response Rate (ORR) based on Cheson 2003 for AML (units: Percentage of participants)	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**
	0 (0 to 41.0)	0 (0 to 52.2)

Arm 5: Overall Response Rate (ORR) based on Cheson 2003 for AML

Description	Tumor response was based on local investigator assessment per Cheson 2003. ORR per Cheson 2003 is defined as the percentage of participants with a best overall response of Complete Response (CR), Morphologic CR with incomplete blood count recovery (CRi) or Partial Response (PR).
Time Frame	Up to approximately 0.5 years
Analysis Population Description	All patients from Arm 5 with AML who received at least one dose of study treatment and had a valid assessment for the outcome measure.

	MBG453 80mg Q2W + PDR001 R/R AML	**MBG453 240mg Q2W + PDR001 R/R AML**
Arm/Group Description	Arm 5: MBG453 80 mg Q2W in combination with PDR001 400 mg Q4W in relapsed/refractory acute myeloid leukemia	Arm 5: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W in relapsed/refractory acute myeloid leukemia
Number of Participants Analyzed [units: participants]	1	4
Arm 5: Overall Response Rate (ORR) based on Cheson 2003 for AML (units: Percentage of participants)	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**
	0 (0 to 97.5)	0 (0 to 60.2)

Arm 6: Overall Response Rate (ORR) based on Cheson 2003 for AML

Description	Tumor response was based on local investigator assessment per Cheson 2003. ORR per Cheson 2003 is defined as the percentage of participants with a best overall response of Complete Response (CR), Morphologic CR with incomplete blood count recovery (CRi) or Partial Response (PR).
Time Frame	Up to approximately 4.2 years
Analysis Population Description	All patients from Arm 6 with AML who received at least one dose of study treatment and had a valid assessment for the outcome measure.

	MBG453 240mg Q2W + Azacitidine ND AML	MBG453 400mg Q2W + Azacitidine ND AML	MBG453 800mg Q4W + Azacitidine ND AML
Arm/Group Description	Arm 6: MBG453 240 mg Q2W in combination with azacitidine 75 mg/m2 in newly diagnosed acute myeloid leukemia	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in newly diagnosed acute myeloid leukemia	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in newly diagnosed acute myeloid leukemia
Number of Participants Analyzed [units: participants]	6	12	5
Arm 6: Overall Response Rate (ORR) based on Cheson 2003 for AML (units: Percentage of participants)	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**
	33.3 (4.3 to 77.7)	41.7 (15.2 to 72.3)	40.0 (5.3 to 85.3)

Arm 1: Overall Response Rate (ORR) based on Cheson 2006 for MDS

Description	Tumor response was based on local investigator assessment per Cheson 2006. ORR per Cheson 2006 is defined as the percentage of participants with a best overall response of Complete Response (CR), Bone marrow CR (mCR) or Partial Response (PR). ORR was calculated taking into consideration the best overall response regardless of confirmation and with confirmation. In the latter case, the responses CR, mCR and PR were to be confirmed in the evaluation of best overall response.
Time Frame	Up to approximately 1.8 years
Analysis Population Description	All patients from Arm 1 with MDS who received at least one dose of study treatment and had a valid assessment for the outcome measure.

	PDR001 400mg Q4W + Decitabine VHR MDS	PDR001 400 mg Q4W + Decitabine HR MDS
Arm/Group Description	Arm 1: PDR001 in combination with decitabine 20mg/m2 in very high-risk myelodysplastic syndrome	Arm 1: PDR001 in combination with decitabine 20mg/m2 in high-risk myelodysplastic syndrome
Number of Participants Analyzed [units: participants]	1	1

Arm 1: Overall Response Rate (ORR) based on Cheson 2006 for MDS (units: Percentage of participants)	Number (95% Confidence Interval)	Number (95% Confidence Interval)
Regardless of confirmation	100 (2.5 to 100)	100 (2.5 to 100)
With confirmation	100 (2.5 to 100)	100 (2.5 to 100)

Arm 2: Overall Response Rate (ORR) based on Cheson 2006 for MDS and CMML

Description	Tumor response was based on local investigator assessment per Cheson 2006. ORR per Cheson 2006 is defined as the percentage of participants with a best overall response of Complete Response (CR), Bone marrow CR (mCR) or Partial Response (PR). ORR was calculated taking into consideration the best overall response regardless of confirmation and with confirmation. In the latter case, the responses CR, mCR and PR were to be confirmed in the evaluation of best overall response.
Time Frame	Up to approximately 2.9 years
Analysis Population Description	All patients from Arm 2 with MDS and CMML who received at least one dose of study treatment and had a valid assessment for the outcome measure.

	MBG453 240mg Q2W + Decitabine VHR MDS	MBG453 240 mg Q2W + Decitabine HR MDS	MBG453 400mg Q2W + Decitabine HR MDS	MBG453 400mg Q2W + Decitabine IR MDS	MBG453 800mg Q4W + Decitabine VHR MDS	MBG453 800 mg Q4W + Decitabine HR MDS	MBG453 800mg Q4W + Decitabine IR MDS	MBG453 240mg Q2W + Decitabine CMML	MBG453 400mg Q2W + Decitabine CMML	MBG453 800mg Q4W + Decitabine CMML
Arm/Group Description	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in very high-risk myelodyspl	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in high-risk myelodyspl	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in high-risk myelodyspl	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in intermediate-risk myelodyspl	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in very high-risk myelodyspl	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in high-risk myelodyspl	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in intermediate-risk myelodyspl	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in chronic myelomono	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in chronic myelomono	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in chronic myelomono

	astic syndrome	astic syndrome	astic syndrome	astic syndrome	astic syndrome	astic syndrome	astic syndrome	cytic leukemia	cytic leukemia	cytic leukemia
Number of Participants Analyzed [units: participants]	1	8	4	5	3	2	2	1	3	1
Arm 2: Overall Response Rate (ORR) based on Cheson 2006 for MDS and CMML (units: Percentage of participants)	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**
Regardless of confirmation	100 (2.5 to 100)	37.5 (8.5 to 75.5)	75.0 (19.4 to 99.4)	0 (0 to 52.2)	66.7 (9.4 to 99.2)	50.0 (1.3 to 98.7)	0 (0 to 84.2)	100 (2.5 to 100)	0 (0 to 70.8)	100 (2.5 to 100)
With confirmation	100 (2.5 to 100)	25.0 (3.2 to 65.1)	75.0 (19.4 to 99.4)	0 (0 to 52.2)	66.7 (9.4 to 99.2)	50.0 (1.3 to 98.7)	0 (0 to 84.2)	100 (2.5 to 100)	0 (0 to 70.8)	0 (0 to 97.5)

Arm 3: Overall Response Rate (ORR) based on Cheson 2006 for MDS

Description Tumor response was based on local investigator assessment per Cheson 2006. ORR per Cheson 2006 is defined as the percentage of participants with a best overall response of Complete Response (CR), Bone marrow CR (mCR) or Partial Response (PR). ORR was

calculated taking into consideration the best overall response regardless of confirmation and with confirmation. In the latter case, the responses CR, mCR and PR were to be confirmed in the evaluation of best overall response.

Time Frame: Up to approximately 4.3 years

Analysis Population Description: All patients from Arm 3 with MDS who received at least one dose of study treatment and had a valid assessment for the outcome measure.

	MBG453 160mg Q2W + PDR001 + Decitabine VHR MDS	MBG453 160 mg Q2W + PDR001 + Decitabine HR MDS	MBG453 240mg Q2W + PDR001 + Decitabine HR MDS	MBG453 400mg Q2W + PDR001 + Decitabine HR MDS
Arm/Group Description	Arm 3: MBG453 160 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in very high-risk myelodysplastic syndrome	Arm 3: MBG453 160 mg Q2W in combination with PDR001 400mg Q4W and decitabine 20mg/m2 in high-risk myelodysplastic syndrome	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in high-risk myelodysplastic syndrome	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in high-risk myelodysplastic syndrome
Number of Participants Analyzed [units: participants]	1	1	2	1
Arm 3: Overall Response Rate (ORR) based on Cheson 2006 for MDS (units: Percentage of participants)	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**
Regardless of confirmation	0 (0 to 97.5)	0 (0 to 97.5)	100 (15.8 to 100)	100 (2.5 to 100)
With confirmation	0 (0 to 97.5)	0 (0 to 97.5)	100 (15.8 to 100)	100 (2.5 to 100)

Arm 4: Overall Response Rate (ORR) based on Cheson 2006 for MDS

Description: Tumor response was based on local investigator assessment per Cheson 2006. ORR per Cheson 2006 is defined as the percentage of participants with a best overall response of Complete Response (CR), Bone marrow CR (mCR) or Partial Response (PR). ORR was calculated taking into consideration the best overall response regardless of confirmation and with confirmation. In the latter case, the responses CR, mCR and PR were to be confirmed in the evaluation of best overall response.

Time Frame: Up to approximately 0.9 years

Analysis Population Description	All patients from Arm 4 with MDS who received at least one dose of study treatment and had a valid assessment for the outcome measure.

	MBG453 400mg Q2W VHR MDS	MBG453 400 mg Q2W HR MDS	MBG453 1200mg Q2W VHR MDS	MBG453 1200 mg Q2W HR MDS	MBG453 1200mg Q2W IR MDS
Arm/Group Description	Arm 4: MBG453 400 mg Q2W in very high-risk myelodysplastic syndrome	Arm 4: MBG453 400 mg Q2W in high-risk myelodysplastic syndrome	Arm 4: MBG453 1200 mg Q2W in very high-risk myelodysplastic syndrome	Arm 4: MBG453 1200 mg Q2W in high-risk myelodysplastic syndrome	Arm 4: MBG453 1200 mg Q2W in intermediate-risk myelodysplastic syndrome
Number of Participants Analyzed [units: participants]	2	1	1	4	2
Arm 4: Overall Response Rate (ORR) based on Cheson 2006 for MDS (units: Percentage of participants)	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**
Regardless of confirmation	0 (0 to 84.2)	0 (0 to 97.5)	0 (0 to 97.5)	0 (0 to 60.2)	0 (0 to 84.2)
With confirmation	0 (0 to 84.2)	0 (0 to 97.5)	0 (0 to 97.5)	0 (0 to 60.2)	0 (0 to 84.2)

Arm 5: Overall Response Rate (ORR) based on Cheson 2006 for MDS

Description	Tumor response was based on local investigator assessment per Cheson 2006. ORR per Cheson 2006 is defined as the percentage of participants with a best overall response of Complete Response (CR), Bone marrow CR (mCR) or Partial Response (PR). ORR was calculated taking into consideration the best overall response regardless of confirmation and with confirmation. In the latter case, the responses CR, mCR and PR were to be confirmed in the evaluation of best overall response.
Time Frame	Up to approximately 0.5 years
Analysis Population Description	All patients from Arm 5 with AML who received at least one dose of study treatment and had a valid assessment for the outcome measure.

	MBG453 80mg Q2W + PDR001 R/R AML	MBG453 240mg Q2W + PDR001 R/R AML
Arm/Group Description	Arm 5: MBG453 80 mg Q2W in combination with PDR001 400 mg Q4W in relapsed/refractory acute myeloid leukemia	Arm 5: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W in relapsed/refractory acute myeloid leukemia
Number of Participants Analyzed [units: participants]	1	4
Arm 5: Overall Response Rate (ORR) based on Cheson 2006 for MDS (units: Percentage of participants)	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**
Regardless of confirmation	0 (0 to 97.5)	0 (0 to 60.2)
With confirmation	0 (0 to 97.5)	0 (0 to 60.2)

Arm 6: Overall Response Rate (ORR) based on Cheson 2006 for MDS and CMML

Description	Tumor response was based on local investigator assessment per Cheson 2006. ORR per Cheson 2006 is defined as the percentage of participants with a best overall response of Complete Response (CR), Bone marrow CR (mCR) or Partial Response (PR). ORR was calculated taking into consideration the best overall response regardless of confirmation and with confirmation. In the latter case, the responses CR, mCR and PR were to be confirmed in the evaluation of best overall response.
Time Frame	Up to approximately 4.2 years
Analysis Population Description	All patients from Arm 6 with MDS and CMML who received at least one dose of study treatment and had a valid assessment for the outcome measure.

	MBG453 240mg Q2W + Azacitidine VHR MDS	MBG453 240 mg Q2W + Azacitidine HR MDS	MBG453 240mg Q2W + Azacitidine IR MDS	MBG453 400mg Q2W + Azacitidine VHR MDS	MBG453 400 mg Q2W + Azacitidine HR MDS	MBG453 400mg Q2W + Azacitidine IR MDS	MBG453 800mg Q4W + Azacitidine VHR MDS	MBG453 800 mg Q4W + Azacitidine HR MDS	MBG453 800mg Q4W + Azacitidine IR MDS	MBG453 400mg Q2W + Azacitidine CMML	MBG453 800mg Q4W + Azacitidine CMML
Arm/Group	Arm 6: MBG453 240 mg	Arm 6: MBG453 240 mg	Arm 6: MBG453 240 mg	Arm 6: MBG453 400 mg	Arm 6: MBG453 400 mg	Arm 6: MBG453 400 mg	Arm 6: MBG453 800 mg	Arm 6: MBG453 800 mg	Arm 6: MBG453 800 mg	Arm 6: MBG453 400 mg	Arm 6: MBG453 800 mg

Description	Q2W in combination with azacitidine 75 mg/m2 in very high-risk myelodysplastic syndrome	Q2W in combination with azacitidine 75 mg/m2 in high-risk myelodysplastic syndrome	Q2W in combination with azacitidine 75 mg/m2 in intermediate-risk myelodysplastic syndrome	Q2W in combination with azacitidine 75 mg/m2 in very high-risk myelodysplastic syndrome	Q2W in combination with azacitidine 75 mg/m2 in high-risk myelodysplastic syndrome	Q2W in combination with azacitidine 75 mg/m2 in intermediate-risk myelodysplastic syndrome	Q4W in combination with azacitidine 75 mg/m2 in very high-risk myelodysplastic syndrome	Q4W in combination with azacitidine 75 mg/m2 in high-risk myelodysplastic syndrome	Q4W in combination with azacitidine 75 mg/m2 in intermediate-risk myelodysplastic syndrome	Q2W in combination with azacitidine 75 mg/m2 in chronic myelomonocytic leukemia	Q4W in combination with azacitidine 75 mg/m2 in chronic myelomonocytic leukemia
Number of Participants Analyzed [units: participants]	2	1	2	8	6	3	7	9	2	5	5
Arm 6: Overall Response Rate (ORR) based on Cheson 2006 for MDS and CMML (units: Percentage of participants)	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**
Regardless of confirmation	100 (15.8 to 100)	0 (0 to 97.5)	50.0 (1.3 to 98.7)	25.0 (3.2 to 65.1)	16.7 (0.4 to 64.1)	100 (29.2 to 100)	28.6 (3.7 to 71.0)	66.7 (29.9 to 92.5)	100 (15.8 to 100)	60.0 (14.7 to 94.7)	80.0 (28.4 to 99.5)

With confirmation	0 (0 to 84.2)	0 (0 to 97.5)	0 (0 to 84.2)	25.0 (3.2 to 65.1)	0 (0 to 45.9)	0 (0 to 70.8)	28.6 (3.7 to 71.0)	44.4 (13.7 to 78.8)	0 (0 to 84.2)	60.0 (14.7 to 94.7)	60.0 (14.7 to 94.7)

Arm 1: Progression-free survival (PFS)

Description	Progression-free survival (PFS) is defined as time from start of treatment to date of death due to any cause or Progression Disease/relapse. PFS was censored at the date of the last adequate assessment before administration of the new anti-cancer therapy, if a subject had not had an event. Tumor response was based on local investigator assessment per Cheson 2003 (AML) and Cheson 2006 (MDS). PFS was analyzed using Kaplan-Meier estimates as defined in the protocol.
Time Frame	Up to approximately 2.2 years
Analysis Population Description	All patients from Arm 1 who received at least one dose of study treatment.

	PDR001 400mg Q4W + Decitabine ND AML	**PDR001 400mg Q4W + Decitabine R/R AML**	**PDR001 400mg Q4W + Decitabine HR/VHR MDS**
Arm/Group Description	Arm 1: PDR001 in combination with decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Arm 1: PDR001 in combination with decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 1: PDR001 in combination with decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome
Number of Participants Analyzed [units: participants]	1	12	3
Arm 1: Progression-free survival (PFS) (units: months)	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**
	NA (NA to NA)[1]	3.9 (1.1 to 6.1)	16.7 (13.4 to NA)[1]

[1] Not estimable due to insufficient number of participants with events.

Arm 2: Progression-free survival (PFS)

Description	Progression-free survival (PFS) is defined as time from start of treatment to date of death due to any cause or Progression Disease/relapse. PFS was censored at the date of the last adequate assessment before administration of the new anti-cancer therapy, if a subject had not had

an event. Tumor response was based on local investigator assessment per Cheson 2003 (AML) and Cheson 2006 (MDS and CMML). PFS was analyzed using Kaplan-Meier estimates as defined in the protocol.

Time Frame	Up to approximately 3.3 years
Analysis Population Description	All patients from Arm 2 who received at least one dose of study treatment.

	MBG453 240mg Q2W + Decitabine ND AML	**MBG453 240mg Q2W + Decitabine R/R AML**	**MBG453 400mg Q2W + Decitabine ND AML**	**MBG453 400mg Q2W + Decitabine R/R AML**	**MBG453 800mg Q4W + Decitabine ND AML**	**MBG453 800mg Q4W + Decitabine R/R AML**	**MBG453 240mg Q2W + Decitabine HR/VHR MDS**	**MBG453 400mg Q2W + Decitabine HR/VHR MDS**	**MBG453 400mg Q2W + Decitabine IR MDS**	**MBG453 800mg Q4W + Decitabine HR/VHR MDS**	**MBG453 800mg Q4W + Decitabine IR MDS**	**MBG453 240mg Q2W + Decitabine CMML**	**MBG453 400mg Q2W + Decitabine CMML**	**MBG453 800mg Q4W + Decitabine CMML**
Arm/Group Description	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in newly diagnosed acute myeloid	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in relapsed/ refractory acute myeloid leukemia	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in newly diagnosed acute myeloid	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in relapsed/ refractory acute myeloid leukemia	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in newly diagnosed acute myeloid	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in relapsed/ refractory acute myeloid leukemia	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in chronic myelomonocytic leukemia	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in chronic myelomonocytic leukemia	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in chronic myelomonocytic leukemia

	leukemia		leukemia		leukemia									
Number of Participants Analyzed [units: participants]	3	9	12	11	7	9	9	4	5	6	2	1	3	1
Arm 2: Progression-free survival (PFS) (units: months)	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**
	14.7 (1.6 to NA)[1]	3.7 (1.6 to 6.2)	6.4 (1.5 to 25.6)	3.5 (1.0 to NA)[1]	10.6 (2.5 to NA)[1]	3.0 (1.4 to NA)[1]	10.5 (0.8 to NA)[1]	NA (NA to NA)[1]	13.4 (1.9 to NA)[1]	24.2 (23.3 to NA)[1]	NA (NA to NA)[1]	12.3 (NA to NA)[1]	6.9 (4.9 to NA)[1]	7.6 (NA to NA)[1]

[1] Not estimable due to insufficient number of participants with events.

Arm 3: Progression-free survival (PFS)

Description	Progression-free survival (PFS) is defined as time from start of treatment to date of death due to any cause or Progression Disease/relapse. PFS was censored at the date of the last adequate assessment before administration of the new anti-cancer therapy, if a subject had not had an event. Tumor response was based on local investigator assessment per Cheson 2003 (AML) and Cheson 2006 (MDS). PFS was analyzed using Kaplan-Meier estimates as defined in the protocol.
Time Frame	Up to approximately 4.7 years
Analysis Population Description	All patients from Arm 3 who received at least one dose of study treatment.

	MBG453 160mg Q2W + PDR001 + Decitabine R/R AML	MBG453 240mg Q2W + PDR001 + Decitabine ND AML	MBG453 240mg Q2W + PDR001 + Decitabine R/R AML	MBG453 400mg Q2W + PDR001 + Decitabine ND AML	MBG453 400mg Q2W + PDR001 + Decitabine R/R AML	MBG453 160mg Q2W + PDR001 + Decitabine HR/VHR MDS	MBG453 240mg Q2W + PDR001 + Decitabine HR/VHR MDS	MBG453 400mg Q2W + PDR001 + Decitabine HR/VHR MDS
Arm/Group Description	Arm 3: MBG453 160 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 3: MBG453 160 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome
Number of Participants Analyzed [units: participants]	3	2	2	2	3	3	2	1
Arm 3: Progression-free survival (PFS) (units: months)	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**
	6.5 (4.1 to NA)[1]	1.6 (1.1 to NA)[1]	NA (NA to NA)[1]	15.7 (8.0 to NA)[1]	7.3 (3.8 to NA)[1]	7.6 (NA to NA)[1]	4.9 (NA to NA)[1]	21.8 (NA to NA)[1]

[1] Not estimable due to insufficient number of participants with events.

Arm 4: Progression-free survival (PFS)

Description	Progression-free survival (PFS) is defined as time from start of treatment to date of death due to any cause or Progression Disease/relapse. PFS was censored at the date of the last adequate assessment before administration of the new anti-cancer therapy, if a subject had not had an event. Tumor response was based on local investigator assessment per Cheson 2003 (AML) and Cheson 2006 (MDS). PFS was analyzed using Kaplan-Meier estimates as defined in the protocol.
Time Frame	Up to approximately 1.3 years
Analysis Population Description	All patients from Arm 4 who received at least one dose of study treatment.

	MBG453 400mg Q2W R/R AML	MBG453 1200mg Q2W R/R AML	MBG453 400mg Q2W HR/VHR MDS	MBG453 1200mg Q2W HR/VHR MDS	MBG453 1200mg Q2W IR MDS
Arm/Group Description	Arm 4: MBG453 400 mg Q2W in relapsed/refractory acute myeloid leukemia	Arm 4: MBG453 1200 mg Q2W in relapsed/refractory acute myeloid leukemia	Arm 4: MBG453 400 mg Q2W in high-/very high-risk myelodysplastic syndrome	Arm 4: MBG453 1200 mg Q2W in high-/very high-risk myelodysplastic syndrome	Arm 4: MBG453 1200 mg Q2W in intermediate-risk myelodysplastic syndrome
Number of Participants Analyzed [units: participants]	10	6	3	5	2
Arm 4: Progression-free survival (PFS) (units: months)	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**
	1.6 (0 to 2.1)	2.3 (1.0 to NA)[1]	3.2 (1.8 to NA)[1]	3.3 (1.8 to NA)[1]	9.1 (6.5 to NA)[1]

[1] Not estimable due to insufficient number of participants with events.

Arm 5: Progression-free survival (PFS)

Description	Progression-free survival (PFS) is defined as time from start of treatment to date of death due to any cause or Progression Disease/relapse. PFS was censored at the date of the last adequate assessment before administration of the new anti-cancer therapy, if a subject had not had an event. Tumor response was based on local investigator assessment per Cheson 2003 (AML) and Cheson 2006 (MDS). PFS was analyzed using Kaplan-Meier estimates as defined in the protocol.

Time Frame	Up to approximately 0.9 years
Analysis Population Description	All patients from Arm 5 who received at least one dose of study treatment.

	MBG453 80mg Q2W + PDR001 R/R AML	MBG453 240mg Q2W + PDR001 R/R AML	MBG453 240mg Q2W + PDR001 HR/VHR MDS
Arm/Group Description	Arm 5: MBG453 80 mg Q2W in combination with PDR001 400 mg Q4W in relapsed/refractory acute myeloid leukemia	Arm 5: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W in relapsed/refractory acute myeloid leukemia	Arm 5: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W in high-/very high-risk myelodysplastic syndrome
Number of Participants Analyzed [units: participants]	1	5	5
Arm 5: Progression-free survival (PFS) (units: months)	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**
	NA (NA to NA)[1]	1.9 (0 to NA)[1]	4.4 (1.9 to NA)[1]

[1] Not estimable due to insufficient number of participants with events.

Arm 6: Progression-free survival (PFS)

Description	Progression-free survival (PFS) is defined as time from start of treatment to date of death due to any cause or Progression Disease/relapse. PFS was censored at the date of the last adequate assessment before administration of the new anti-cancer therapy, if a subject had not had an event. Tumor response was based on local investigator assessment per Cheson 2003 (AML) and Cheson 2006 (MDS and CMML). PFS was analyzed using Kaplan-Meier estimates as defined in the protocol.
Time Frame	Up to approximately 4.6 years
Analysis Population Description	All patients from Arm 6 who received at least one dose of study treatment.

	MBG453	MBG453	MBG453	MBG453 240mg	MBG453 240mg	MBG453 400mg	MBG453 400mg	MBG453 800mg	MBG453 800mg	MBG453 400mg	MBG453 800mg

	240mg Q2W + Azacitidine ND AML	400mg Q2W + Azacitidine ND AML	800mg Q4W + Azacitidine ND AML	Q2W + Azacitidine HR/VHR MDS	Q2W + Azacitidine IR MDS	Q2W + Azacitidine HR/VHR MDS	Q2W + Azacitidine IR MDS	Q4W + Azacitidine HR/VHR MDS	Q4W + Azacitidine IR MDS	Q2W + Azacitidine CMML	Q4W + Azacitidine CMML
Arm/Group Description	Arm 6: MBG453 240 mg Q2W in combination with azacitidine 75 mg/m2 in newly diagnosed acute myeloid leukemia	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in newly diagnosed acute myeloid leukemia	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in newly diagnosed acute myeloid leukemia	Arm 6: MBG453 240 mg Q2W in combination with azacitidine 75 mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 6: MBG453 240 mg Q2W in combination with azacitidine 75 mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in chronic myelomonocytic leukemia	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in chronic myelomonocytic leukemia
Number of Participants Analyzed [units: participants]	6	14	6	3	2	14	5	17	2	5	5
Arm 6: Progression-free survival (PFS) (units: months)	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**
	7.4 (5.6 to NA)[1]	6.4 (2.2 to 10.6)	4.1 (1.2 to NA)[1]	11.1 (1.1 to NA)[1]	13.2 (NA to NA)[1]	11.5 (4.8 to 18.8)	NA (NA to NA)[1]	11.3 (4.9 to NA)[1]	26.9 (NA to NA)[1]	7.4 (3.8 to NA)[1]	5.9 (4.6 to NA)[1]

[1] Not estimable due to insufficient number of participants with events.

Arm 1: Time to progression (TTP)

Description	Analysis of time to progression (TTP) is based on patients with Complete Remission (CR), regardless of confirmation. TTP is defined as the time between date of first documented CR to the date of first documented Disease Progression (PD)/relapse or death due to any cause during the CR or Partial Remission (PR), whichever occurs first. If a patient had not had an event, TTP was censored at the last adequate response assessment date. TTP was analyzed using Kaplan-Meier estimates as defined in the protocol.
Time Frame	Up to approximately 2.2 years
Analysis Population Description	All patients from Arm 1 who received at least one dose of study treatment and had CR (regardless of confirmation).

	PDR001 400mg Q4W + Decitabine ND AML	**PDR001 400mg Q4W + Decitabine R/R AML**	**PDR001 400mg Q4W + Decitabine HR/VHR MDS**
Arm/Group Description	Arm 1: PDR001 in combination with decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Arm 1: PDR001 in combination with decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 1: PDR001 in combination with decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome
Number of Participants Analyzed [units: participants]	0	3	2
Arm 1: Time to progression (TTP) (units: months)	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**
		3.0 (1.5 to NA)[1]	NA (7.8 to NA)[1]

[1] Not estimable due to insufficient number of participants with events.

Arm 2: Time to progression (TTP)

Description	Analysis of time to progression (TTP) is based on patients with Complete Remission (CR), regardless of confirmation. TTP is defined as the time between date of first documented CR to the date of first documented Disease Progression (PD)/relapse or death due to any cause during the CR or Partial Remission (PR), whichever occurs first. If a patient had not had an event, TTP was censored at the last adequate response assessment date. TTP was analyzed using Kaplan-Meier estimates as defined in the protocol.
Time Frame	Up to approximately 3.3 years

Analysis Population Description: All patients from Arm 2 who received at least one dose of study treatment and had CR (regardless of confirmation).

	MBG453 240mg Q2W + Decitabine ND AML	MBG453 240mg Q2W + Decitabine R/R AML	MBG453 400mg Q2W + Decitabine ND AML	MBG453 400mg Q2W + Decitabine R/R AML	MBG453 800mg Q4W + Decitabine ND AML	MBG453 800mg Q4W + Decitabine R/R AML	MBG453 240mg Q2W + Decitabine HR/VHR MDS	MBG453 400mg Q2W + Decitabine HR/VHR MDS	MBG453 400mg Q2W + Decitabine IR MDS	MBG453 800mg Q4W + Decitabine HR/VHR MDS	MBG453 800mg Q4W + Decitabine IR MDS	MBG453 240mg Q2W + Decitabine CMML	MBG453 400mg Q2W + Decitabine CMML	MBG453 800mg Q4W + Decitabine CMML
Arm/Group Description	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in relapsed/ refractory acute myeloid leukemia	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in relapsed/ refractory acute myeloid leukemia	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in relapsed/ refractory acute myeloid leukemia	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in chronic myelomonocytic leukemia	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in chronic myelomonocytic leukemia	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in chronic myelomonocytic leukemia
Number of	2	0	4	0	1	0	1	1	0	2	0	0	0	0

Participants Analyzed [units: participants]														
Arm 2: Time to progression (TTP) (units: months)	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**
	13.4 (3.7 to NA)[1]		16.9 (9.1 to NA)[1]		1.3 (NA to NA)[1]		13.4 (NA to NA)[1]	NA (NA to NA)[1]		21.5 (NA to NA)[1]				

[1] Not estimable due to insufficient number of participants with events.

Arm 3: Time to progression (TTP)

Description	Analysis of time to progression (TTP) is based on patients with Complete Remission (CR), regardless of confirmation. TTP is defined as the time between date of first documented CR to the date of first documented Disease Progression (PD)/relapse or death due to any cause during the CR or Partial Remission (PR), whichever occurs first. If a patient had not had an event, TTP was censored at the last adequate response assessment date. TTP was analyzed using Kaplan-Meier estimates as defined in the protocol.
Time Frame	Up to approximately 4.7 years
Analysis Population Description	All patients from Arm 3 who received at least one dose of study treatment and had CR (regardless of confirmation).

	MBG453 160mg Q2W + PDR001 +	**MBG453 240mg**	**MBG453 240mg Q2W + PDR001 +**	**MBG453 400mg**	**MBG453 400mg Q2W + PDR001 +**	**MBG453 160mg Q2W +**	**MBG453 240mg Q2W +**	**MBG453 400mg Q2W +**

	Decitabine R/R AML	Q2W + PDR001 + Decitabine ND AML	Decitabine R/R AML	Q2W + PDR001 + Decitabine ND AML	Decitabine R/R AML	PDR001 + Decitabine HR/VHR MDS	PDR001 + Decitabine HR/VHR MDS	PDR001 + Decitabine HR/VHR MDS
Arm/Group Description	Arm 3: MBG453 160 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 3: MBG453 160 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome
Number of Participants Analyzed [units: participants]	0	0	1	0	0	0	2	0
Arm 3: Time to progression (TTP) (units: months)	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**
			NA (NA to NA)[1]				8.1 (NA to NA)[1]	

[1] Not estimable due to insufficient number of participants with events.

Arm 4: Time to progression (TTP)

Description	Analysis of time to progression (TTP) is based on patients with Complete Remission (CR), regardless of confirmation. TTP is defined as the time between date of first documented CR to the date of first documented Disease Progression (PD)/relapse or death due to any cause during the CR or Partial Remission (PR), whichever occurs first. If a patient had not had an event, TTP was censored at the last adequate response assessment date. TTP was analyzed using Kaplan-Meier estimates as defined in the protocol.
Time Frame	Up to approximately 1.3 years
Analysis Population Description	All patients from Arm 4 who received at least one dose of study treatment and had CR (regardless of confirmation).

	MBG453 400mg Q2W R/R AML	MBG453 1200mg Q2W R/R AML	MBG453 400mg Q2W HR/VHR MDS	MBG453 1200mg Q2W HR/VHR MDS	MBG453 1200mg Q2W IR MDS
Arm/Group Description	Arm 4: MBG453 400 mg Q2W in relapsed/refractory acute myeloid leukemia	Arm 4: MBG453 1200 mg Q2W in relapsed/refractory acute myeloid leukemia	Arm 4: MBG453 400 mg Q2W in high-/very high-risk myelodysplastic syndrome	Arm 4: MBG453 1200 mg Q2W in high-/very high-risk myelodysplastic syndrome	Arm 4: MBG453 1200 mg Q2W in intermediate-risk myelodysplastic syndrome
Number of Participants Analyzed [units: participants]	0	0	0	0	0
Arm 4: Time to progression (TTP) (units: months)	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**

Arm 5: Time to progression (TTP)

Description	Analysis of time to progression (TTP) is based on patients with Complete Remission (CR), regardless of confirmation. TTP is defined as the time between date of first documented CR to the date of first documented Disease Progression (PD)/relapse or death due to any cause during the CR or Partial Remission (PR), whichever occurs first. If a patient had not had an event, TTP was censored at the last adequate response assessment date. TTP was analyzed using Kaplan-Meier estimates as defined in the protocol.
Time Frame	Up to approximately 0.9 years

Analysis Population Description	All patients from Arm 5 who received at least one dose of study treatment and had CR (regardless of confirmation).

	MBG453 80mg Q2W + PDR001 R/R AML	MBG453 240mg Q2W + PDR001 R/R AML	MBG453 240mg Q2W + PDR001 HR/VHR MDS
Arm/Group Description	Arm 5: MBG453 80 mg Q2W in combination with PDR001 400 mg Q4W in relapsed/refractory acute myeloid leukemia	Arm 5: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W in relapsed/refractory acute myeloid leukemia	Arm 5: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W in high-/very high-risk myelodysplastic syndrome
Number of Participants Analyzed [units: participants]	0	0	0
Arm 5: Time to progression (TTP) (units: months)	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**

Arm 6: Time to progression (TTP)

Description	Analysis of time to progression (TTP) is based on patients with Complete Remission (CR), regardless of confirmation. TTP is defined as the time between date of first documented CR to the date of first documented Disease Progression (PD)/relapse or death due to any cause during the CR or Partial Remission (PR), whichever occurs first. If a patient had not had an event, TTP was censored at the last adequate response assessment date. TTP was analyzed using Kaplan-Meier estimates as defined in the protocol.
Time Frame	Up to approximately 4.6 years
Analysis Population Description	All patients from Arm 6 who received at least one dose of study treatment and had CR (regardless of confirmation).

	MBG453 240mg Q2W + Azacitid	MBG453 400mg Q2W + Azacitid	MBG453 800mg Q4W + Azacitid	MBG453 240mg Q2W + Azacitidin	MBG453 240mg Q2W + Azacitidine IR MDS	MBG453 400mg Q2W + Azacitidin	MBG453 400mg Q2W + Azacitidine IR MDS	MBG453 800mg Q4W + Azacitidin	MBG453 800mg Q4W + Azacitidine IR MDS	MBG453 400mg Q2W + Azacitidine CMML	MBG453 800mg Q4W + Azacitidine CMML

	ine ND AML	ine ND AML	ine ND AML	e HR/VHR MDS		e HR/VHR MDS		e HR/VHR MDS			
Arm/Group Description	Arm 6: MBG453 240 mg Q2W in combination with azacitidine 75 mg/m2 in newly diagnosed acute myeloid leukemia	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in newly diagnosed acute myeloid leukemia	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in newly diagnosed acute myeloid leukemia	Arm 6: MBG453 240 mg Q2W in combination with azacitidine 75 mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 6: MBG453 240 mg Q2W in combination with azacitidine 75 mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in chronic myelomonocytic leukemia	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in chronic myelomonocytic leukemia
Number of Participants Analyzed [units: participants]	1	2	0	0	1	3	0	1	0	2	2
Arm 6: Time to progression (TTP) (units: months)	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**
	25.0 (NA to NA)[1]	9.0 (8.5 to NA)[1]			NA (NA to NA)[1]	6.5 (3.7 to NA)[1]		NA (NA to NA)[1]		13.1 (NA to NA)[1]	NA (NA to NA)[1]

[1] Not estimable due to insufficient number of participants with events.

Arm 1: Duration of Response (DOR)

Description	Analysis of DOR is based on responders only (regardless of confirmation). DOR is defined as: • For AML patients: the time from the date of first documented onset of CR, CRi or PR to the date of relapse or death due to AML. • For MDS patients: the time from the date of first documented onset of CR, mCR or PR to the date of PD/relapse or death due to MDS. If the event occurred after the administration of any new anti-cancer therapy, DOR was censored at the date of the last adequate assessment before administration of the new anti-cancer therapy. In case a subject did not have an event, DOR was censored at the date of the last adequate assessment before administration of the new anti-cancer therapy. DOR was analyzed using Kaplan-Meier estimates as defined in the protocol.
Time Frame	Up to approximately 2.2 years
Analysis Population Description	All patients from Arm 1 who received at least one dose of study treatment and were responders: participants with CR, CRi or PR for AML and participants with CR, mCR or PR for MDS.

	PDR001 400mg Q4W + Decitabine ND AML	**PDR001 400mg Q4W + Decitabine R/R AML**	**PDR001 400mg Q4W + Decitabine HR/VHR MDS**
Arm/Group Description	Arm 1: PDR001 in combination with decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Arm 1: PDR001 in combination with decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 1: PDR001 in combination with decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome
Number of Participants Analyzed [units: participants]	0	4	2
Arm 1: Duration of Response (DOR) (units: months)	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**
		2.7 (1.6 to NA)[1]	NA (11.3 to NA)[1]

[1] Not estimable due to insufficient number of participants with events.

Arm 2: Duration of Response (DOR)

Description	Analysis of DOR is based on responders only (regardless of confirmation). DOR is defined as: • For AML patients: the time from the date of first documented onset of CR, CRi or PR to the date of relapse or death due to AML. • For MDS/CMML patients: the time from the date of first documented onset of CR, mCR or PR to the date of PD/relapse or death due to MDS/CMML. If the event occurred after the administration of any new anti-cancer therapy, DOR was censored at the date of the last adequate assessment before administration of the new anti-cancer therapy. In case a subject did not have an event, DOR was censored at the date of the last adequate assessment before administration of the new anti-cancer therapy. DOR was analyzed using Kaplan-Meier estimates as defined in the protocol.

Time Frame	Up to approximately 3.3 years
Analysis Population Description	All patients from Arm 2 who received at least one dose of study treatment and were responders: participants with CR, CRi or PR for AML and participants with CR, mCR or PR for MDS/CMML.

	MBG 453 240mg Q2W + Decitabine ND AML	**MBG453 240mg Q2W + Decitabine R/R AML**	**MBG 453 400mg Q2W + Decitabine ND AML**	**MBG453 400mg Q2W + Decitabine R/R AML**	**MBG 453 800mg Q4W + Decitabine ND AML**	**MBG453 800mg Q4W + Decitabine R/R AML**	**MBG453 240mg Q2W + Decitabine HR/VHR MDS**	**MBG453 400mg Q2W + Decitabine HR/VHR MDS**	**MBG453 400mg Q2W + Decitabine IR MDS**	**MBG453 800mg Q4W + Decitabine HR/VHR MDS**	**MBG453 800mg Q4W + Decitabine IR MDS**	**MBG453 240mg Q2W + Decitabine CMML**	**MBG453 400mg Q2W + Decitabine CMML**	**MBG453 800mg Q4W + Decitabine CMML**
Arm/Group Description	Arm 2: MBG 453 240 mg Q2W in combination with decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in relapsed/ refractory acute myeloid leukemia	Arm 2: MBG 453 400 mg Q2W in combination with decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in relapsed/ refractory acute myeloid leukemia	Arm 2: MBG 453 800 mg Q4W in combination with decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in relapsed/ refractory acute myeloid leukemia	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in chronic myelomonocytic leukemia	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in chronic myelomonocytic leukemia	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in chronic myelomonocytic leukemia

Number of Participants Analyzed [units: participants]	2	2	4	2	2	2	4	3	0	3	0	1	0	1
Arm 2: Duration of Response (DOR) (units: months)	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**
	17.9 (12.7 to NA)[1]	2.3 (1.7 to NA)[1]	17.1 (12.3 to NA)[1]	NA (NA to NA)[1]	NA (1.3 to NA)[1]	NA (NA to NA)[1]	16.1 (7.9 to NA)[1]	NA (NA to NA)[1]		21.5 (NA to NA)[1]		4.7 (NA to NA)[1]		3.0 (NA to NA)[1]

[1] Not estimable due to insufficient number of participants with events.

Arm 3: Duration of Response (DOR)

Description	Analysis of DOR is based on responders only (regardless of confirmation). DOR is defined as: • For AML patients: the time from the date of first documented onset of CR, CRi or PR to the date of relapse or death due to AML. • For MDS patients: the time from the date of first documented onset of CR, mCR or PR to the date of PD/relapse or death due to MDS. If the event occurred after the administration of any new anti-cancer therapy, DOR was censored at the date of the last adequate assessment before administration of the new anti-cancer therapy. In case a subject did not have an event, DOR was censored at the date of the last adequate assessment before administration of the new anti-cancer therapy. DOR was analyzed using Kaplan-Meier estimates as defined in the protocol.
Time Frame	Up to approximately 4.7 years
Analysis Population Description	All patients from Arm 3 who received at least one dose of study treatment and were responders: participants with CR, CRi or PR for AML and participants with CR, mCR or PR for MDS.

	MBG453 160mg Q2W + PDR001 + Decitabine R/R AML	MBG453 240mg Q2W + PDR001 + Decitabine ND AML	MBG453 240mg Q2W + PDR001 + Decitabine R/R AML	MBG453 400mg Q2W + PDR001 + Decitabine ND AML	MBG453 400mg Q2W + PDR001 + Decitabine R/R AML	MBG453 160mg Q2W + PDR001 + Decitabine HR/VHR MDS	MBG453 240mg Q2W + PDR001 + Decitabine HR/VHR MDS	MBG453 400mg Q2W + PDR001 + Decitabine HR/VHR MDS
Arm/Group Description	Arm 3: MBG453 160 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 3: MBG453 160 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400 mg Q4W and decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome
Number of Participants Analyzed [units: participants]	1	0	1	1	2	0	2	1
Arm 3: Duration of Response (DOR) (units: months)	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**
	6.6 (NA to NA)[1]		NA (NA to NA)[1]	21.4 (NA to NA)[1]	1.6 (0.7 to NA)[1]		16.4 (NA to NA)[1]	17.0 (NA to NA)[1]

[1] Not estimable due to insufficient number of participants with events.

Arm 4: Duration of Response (DOR)

Description	Analysis of DOR is based on responders only (regardless of confirmation). DOR is defined as: • For AML patients: the time from the date of first documented onset of CR, CRi or PR to the date of relapse or death due to AML. • For MDS patients: the time from the date of first documented onset of CR, mCR or PR to the date of PD/relapse or death due to MDS. If the event occurred after the administration of any new anti-cancer therapy, DOR was censored at the date of the last adequate assessment before administration of the new anti-cancer therapy. In case a subject did not have an event, DOR was censored at the date of the last adequate assessment before administration of the new anti-cancer therapy. DOR was analyzed using Kaplan-Meier estimates as defined in the protocol.
Time Frame	Up to approximately 1.3 years
Analysis Population Description	All patients from Arm 4 who received at least one dose of study treatment and were responders: participants with CR, CRi or PR for AML and participants with CR, mCR or PR for MDS.

	MBG453 400mg Q2W R/R AML	MBG453 1200mg Q2W R/R AML	MBG453 400mg Q2W HR/VHR MDS	MBG453 1200mg Q2W HR/VHR MDS	MBG453 1200mg Q2W IR MDS
Arm/Group Description	Arm 4: MBG453 400 mg Q2W in relapsed/refractory acute myeloid leukemia	Arm 4: MBG453 1200 mg Q2W in relapsed/refractory acute myeloid leukemia	Arm 4: MBG453 400 mg Q2W in high-/very high-risk myelodysplastic syndrome	Arm 4: MBG453 1200 mg Q2W in high-/very high-risk myelodysplastic syndrome	Arm 4: MBG453 1200 mg Q2W in intermediate-risk myelodysplastic syndrome
Number of Participants Analyzed [units: participants]	0	0	0	0	0
Arm 4: Duration of Response (DOR) (units: months)	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**

Arm 5: Duration of Response (DOR)

Description	Analysis of DOR is based on responders only (regardless of confirmation). DOR is defined as: • For AML patients: the time from the date of first documented onset of CR, CRi or PR to the date of relapse or death due to AML. • For MDS patients: the time from the date of first documented onset of CR, mCR or PR to the date of PD/relapse or death due to MDS. If the event occurred after the administration of any new anti-cancer therapy, DOR was censored at the date of the last adequate assessment before administration of the new anti-cancer therapy. In case a subject did not have an event, DOR was censored at the date of the last adequate assessment before administration of the new anti-cancer therapy. DOR was analyzed using Kaplan-Meier estimates as defined in the protocol.

Time Frame	Up to approximately 0.9 years
Analysis Population Description	All patients from Arm 5 who received at least one dose of study treatment and were responders: participants with CR, CRi or PR for AML and participants with CR, mCR or PR for MDS.

	MBG453 80mg Q2W + PDR001 R/R AML	MBG453 240mg Q2W + PDR001 R/R AML	MBG453 240mg Q2W + PDR001 HR/VHR MDS
Arm/Group Description	Arm 5: MBG453 80 mg Q2W in combination with PDR001 400 mg Q4W in relapsed/refractory acute myeloid leukemia	Arm 5: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W in relapsed/refractory acute myeloid leukemia	Arm 5: MBG453 240 mg Q2W in combination with PDR001 400 mg Q4W in high-/very high-risk myelodysplastic syndrome
Number of Participants Analyzed [units: participants]	0	0	0
Arm 5: Duration of Response (DOR) (units: months)	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**

Arm 6: Duration of Response (DOR)

Description	Analysis of DOR is based on responders only (regardless of confirmation). DOR is defined as: • For AML patients: the time from the date of first documented onset of CR, CRi or PR to the date of relapse or death due to AML. • For MDS/CMML patients: the time from the date of first documented onset of CR, mCR or PR to the date of PD/relapse or death due to MDS/CMML. If the event occurred after the administration of any new anti-cancer therapy, DOR was censored at the date of the last adequate assessment before administration of the new anti-cancer therapy. In case a subject did not have an event, DOR was censored at the date of the last adequate assessment before administration of the new anti-cancer therapy. DOR was analyzed using Kaplan-Meier estimates as defined in the protocol.
Time Frame	Up to approximately 4.6 years
Analysis Population Description	All patients from Arm 6 who received at least one dose of study treatment and were responders: participants with CR, CRi or PR for AML and participants with CR, mCR or PR for MDS/CMML.

	MBG453 240mg Q2W + Azacitidine ND AML	MBG453 400mg Q2W + Azacitidine ND AML	MBG453 800mg Q4W + Azacitidine ND AML	MBG453 240mg Q2W + Azacitidine HR/VHR MDS	MBG453 240mg Q2W + Azacitidine IR MDS	MBG453 400mg Q2W + Azacitidine HR/VHR MDS	MBG453 400mg Q2W + Azacitidine IR MDS	MBG453 800mg Q4W + Azacitidine HR/VHR MDS	MBG453 800mg Q4W + Azacitidine IR MDS	MBG453 400mg Q2W + Azacitidine CMML	MBG453 800mg Q4W + Azacitidine CMML
Arm/Group Description	Arm 6: MBG453 240 mg Q2W in combination with azacitidine 75 mg/m2 in newly diagnosed acute myeloid leukemia	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in newly diagnosed acute myeloid leukemia	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in newly diagnosed acute myeloid leukemia	Arm 6: MBG453 240 mg Q2W in combination with azacitidine 75 mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 6: MBG453 240 mg Q2W in combination with azacitidine 75 mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in chronic myelomonocytic leukemia	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in chronic myelomonocytic leukemia
Number of Participants Analyzed [units: participants]	2	5	2	2	1	3	3	8	2	3	4
Arm 6: Duration of Response (DOR) (units: months)	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**

15.0 (4.2 to NA)[1]	8.5 (5.2 to NA)[1]	NA (2.4 to NA)[1]	6.7 (NA to NA)[1]	NA (NA to NA)[1]	14.6 (12.1 to NA)[1]	NA (NA to NA)[1]	9.4 (3.7 to NA)[1]	NA (NA to NA)[1]	15.4 (5.6 to NA)[1]	5.0 (2.8 to NA)[1]

[1] Not estimable due to insufficient number of participants with events.

Arms 1, 3 and 5: Maximum observed serum concentration (Cmax) of PDR001

Description	Pharmacokinetic (PK) parameters were calculated based on PDR001 serum concentrations by using non-compartmental methods. Cmax is defined as the maximum (peak) observed concentration following a dose.
Time Frame	Pre-infusion and 1, 168, 336 and 648 hours after end of infusion on Cycle 1 Day 1 and Cycle 3 Day 1. The duration of the infusion was 30 minutes. 1 cycle=28 days
Analysis Population Description	Patients in the pharmacokinetic analysis set (PAS) who had an available value for the outcome measure at each timepoint. PAS consists of all patients who received one of the planned treatments and provided at least one primary PK parameter. For each arm, patients receiving the same study treatment at the same dose are pooled together.

	PDR001 400 mg Q4W + Decitabine 20 mg/m2	**MBG453 160 mg Q2W + PDR001 400 mg Q4W + Decitabine 20 mg/m2**	**MBG453 240 mg Q2W + PDR001 400 mg Q4W + Decitabine 20 mg/m2**	**MBG453 400 mg Q2W + PDR001 400 mg Q4W + Decitabine 20 mg/m2**	**MBG453 80 mg Q2W + PDR001 400 mg Q4W**	**MBG453 240 mg Q2W + PDR001 400 mg Q4W**
Arm/Group Description	Arm 1: PDR001 400 mg Q4W in combination with decitabine 20mg/m2	Arm 3: MBG453 160 mg Q2W in combination with PDR001 400mg Q4W and decitabine 20mg/m2	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400mg Q4W and decitabine 20mg/m2	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400mg Q4W and decitabine 20mg/m2	Arm 5: MBG453 80 mg Q2W in combination with PDR001 400mg Q4W	Arm 5: MBG453 240 mg Q2W in combination with PDR001 400mg Q4W
Number of Participants Analyzed [units: participants]	15	6	6	6	0	9
Arms 1, 3 and 5: Maximum observed serum concentration (Cmax) of PDR001 (units: µg/mL)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Cycle 1 (n=13,6,4,4,0,8)	83.9 ± 23.6	93.5 ± 25.1	93.5 ± 47.3	85.5 ± 9.53		84.0 ± 16.5

Cycle 3 (n=8,1,2,4,0,3)	126 ± 19.6	101	149 ± 58.0	110 ± 12.3	113 ± 23.9

Arms 1, 3 and 5: Time to reach maximum serum concentration (Tmax) of PDR001

Description	Pharmacokinetic (PK) parameters were calculated based on PDR001 serum concentrations by using non-compartmental methods. Tmax is defined as the time to reach maximum (peak) concentration following a dose. Actual recorded sampling times were considered for the calculations.
Time Frame	Pre-infusion and 1, 168, 336 and 648 hours after end of infusion on Cycle 1 Day 1 and Cycle 3 Day 1. The duration of the infusion was 30 minutes. 1 cycle=28 days
Analysis Population Description	Patients in the pharmacokinetic analysis set (PAS) who had an available value for the outcome measure at each timepoint. PAS consists of all patients who received one of the planned treatments and provided at least one primary PK parameter. For each arm, patients receiving the same study treatment at the same dose are pooled together.

	PDR001 400 mg Q4W + Decitabine 20 mg/m2	**MBG453 160 mg Q2W + PDR001 400 mg Q4W + Decitabine 20 mg/m2**	**MBG453 240 mg Q2W + PDR001 400 mg Q4W + Decitabine 20 mg/m2**	**MBG453 400 mg Q2W + PDR001 400 mg Q4W + Decitabine 20 mg/m2**	**MBG453 80 mg Q2W + PDR001 400 mg Q4W**	**MBG453 240 mg Q2W + PDR001 400 mg Q4W**
Arm/Group Description	Arm 1: PDR001 400 mg Q4W in combination with decitabine 20mg/m2	Arm 3: MBG453 160 mg Q2W in combination with PDR001 400mg Q4W and decitabine 20mg/m2	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400mg Q4W and decitabine 20mg/m2	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400mg Q4W and decitabine 20mg/m2	Arm 5: MBG453 80 mg Q2W in combination with PDR001 400mg Q4W	Arm 5: MBG453 240 mg Q2W in combination with PDR001 400mg Q4W
Number of Participants Analyzed [units: participants]	15	6	6	6	0	9
Arms 1, 3 and 5: Time to reach maximum serum concentration (Tmax) of PDR001 (units: hours)	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**
Cycle 1 (n=13,6,4,4,0,8)	1.68 (1.37 to 3.20)	1.64 (1.52 to 3.82)	1.73 (1.53 to 2.00)	1.64 (1.53 to 1.80)		1.59 (1.45 to 2.98)

Cycle 3 (n=8,1,2,4,0,3)	1.57 (1.48 to 2.92)	1.75 (1.75 to 1.75)	1.84 (1.65 to 2.03)	1.63 (1.00 to 1.82)	2.07 (1.50 to 3.23)

Arms 1, 3 and 5: Area under the serum concentration-time curve from time zero to the time of the last quantifiable concentration (AUClast) of PDR001

Description	Pharmacokinetic (PK) parameters were calculated based on PDR001 serum concentrations by using non-compartmental methods. The linear trapezoidal method was used for AUClast calculation.
Time Frame	Pre-infusion and 1, 168, 336 and 648 hours after end of infusion on Cycle 1 Day 1 and Cycle 3 Day 1. The duration of the infusion was 30 minutes. 1 cycle=28 days
Analysis Population Description	Patients in the pharmacokinetic analysis set (PAS) who had an available value for the outcome measure at each timepoint. PAS consists of all patients who received one of the planned treatments and provided at least one primary PK parameter. For each arm, patients receiving the same study treatment at the same dose are pooled together.

	PDR001 400 mg Q4W + Decitabine 20 mg/m2	MBG453 160 mg Q2W + PDR001 400 mg Q4W + Decitabine 20 mg/m2	MBG453 240 mg Q2W + PDR001 400 mg Q4W + Decitabine 20 mg/m2	MBG453 400 mg Q2W + PDR001 400 mg Q4W + Decitabine 20 mg/m2	MBG453 80 mg Q2W + PDR001 400 mg Q4W	MBG453 240 mg Q2W + PDR001 400 mg Q4W
Arm/Group Description	Arm 1: PDR001 400 mg Q4W in combination with decitabine 20mg/m2	Arm 3: MBG453 160 mg Q2W in combination with PDR001 400mg Q4W and decitabine 20mg/m2	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400mg Q4W and decitabine 20mg/m2	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400mg Q4W and decitabine 20mg/m2	Arm 5: MBG453 80 mg Q2W in combination with PDR001 400mg Q4W	Arm 5: MBG453 240 mg Q2W in combination with PDR001 400mg Q4W
Number of Participants Analyzed [units: participants]	15	6	6	6	0	9
Arms 1, 3 and 5: Area under the serum concentration-time curve from time zero to the time of the last quantifiable concentration (AUClast) of PDR001 (units: day*µg/mL)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**

Cycle 1 (n=15,6,5,6,0,8)	817 ± 284	948 ± 483	826 ± 489	950 ± 307	1020 ± 377
Cycle 3 (n=9,1,3,4,0,5)	1450 ± 487	1940	2020 ± 1320	1430 ± 613	1100 ± 486

Arms 2 to 6: Maximum observed serum concentration (Cmax) of MBG453

Description	Pharmacokinetic (PK) parameters were calculated based on MBG453 serum concentrations by using non-compartmental methods. Cmax is defined as the maximum (peak) observed concentration following a dose.
Time Frame	Pre-infusion and 1, 168, 336 and 648 hours after end of infusion on Cycle 1 Day 1 and Cycle 3 Day 1. The duration of the infusion was 30 minutes. 1 cycle=28 days
Analysis Population Description	Patients in the pharmacokinetic analysis set (PAS) who had an available value for the outcome measure at each timepoint. PAS consists of all patients who received one of the planned treatments and provided at least one primary PK parameter. For each arm, patients receiving the same study treatment at the same dose are pooled together.

	MBG453 240 mg Q2W + Decitabine 20 mg/m2	**MBG453 400 mg Q2W + Decitabine 20 mg/m2**	**MBG453 800 mg Q4W + Decitabine 20 mg/m2**	**MBG453 160 mg Q2W + PDR001 400 mg Q4W + Decitabine 20 mg/m2**	**MBG453 240 mg Q2W + PDR001 400 mg Q4W + Decitabine 20 mg/m2**	**MBG453 400 mg Q2W + PDR001 400 mg Q4W + Decitabine 20 mg/m2**	**MBG453 400 mg Q2W**	**MBG453 1200 mg Q2W**	**MBG453 80 mg Q2W + PDR001 400 mg Q4W**	**MBG453 240 mg Q2W + PDR001 400 mg Q4W**	**MBG453 240 mg Q2W + Azacitidine 75 mg/m2**	**MBG453 400 mg Q2W + Azacitidine 75 mg/m2**	**MBG453 800 mg Q4W + Azacitidine 75 mg/m2**
Arm/Group Description	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2	Arm 3: MBG453 160 mg Q2W in combination with PDR001 400mg Q4W	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400mg Q4W	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400mg Q4W	Arm 4: MBG453 400 mg Q2W	Arm 4: MBG453 1200 mg Q2W	Arm 5: MBG453 80 mg Q2W in combination with PDR001 400mg Q4W	Arm 5: MBG453 240 mg Q2W in combination with PDR001 400mg Q4W	Arm 6: MBG453 240 mg Q2W in combination with azacitidine 75 mg/m2	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2

				and decitabine 20mg/m2	and decitabine 20mg/m2	and decitabine 20mg/m2							
Number of Participants Analyzed [units: participants]	22	32	24	6	6	6	12	13	0	9	11	33	28
Arms 2 to 6: Maximum observed serum concentration (Cmax) of MBG453 (units: µg/mL)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Cycle 1 (n=21,31,24,4,6,6,12,13,0,9,9,33,25)	59.9 ± 14.1	101 ± 30.5	214 ± 49.3	41.9 ± 13.8	58.6 ± 15.8	99.3 ± 22.6	99.1 ± 21.0	318 ± 66.1		66.0 ± 18.3	62.1 ± 11.4	105 ± 33.7	208 ± 53.7
Cycle 3 (n=15,23,17,2,3,4,3,6,0,5,10,26,17)	79.3 ± 19.7	159 ± 49.8	244 ± 61.7	40.2 ± 15.5	120 ± 56.1	168 ± 30.0	162 ± 45.2	527 ± 180		104 ± 18.1	95.4 ± 24.2	164 ± 54.5	247 ± 71.9

Arms 2 to 6: Time to reach maximum serum concentration (Tmax) of MBG453

Description	Pharmacokinetic (PK) parameters were calculated based on MBG453 serum concentrations by using non-compartmental methods. Tmax is defined as the time to reach maximum (peak) concentration following a dose. Actual recorded sampling times were considered for the calculations.
Time Frame	Pre-infusion and 1, 168, 336 and 648 hours after end of infusion on Cycle 1 Day 1 and Cycle 3 Day 1. The duration of the infusion was 30 minutes. 1 cycle=28 days
Analysis Population Description	Patients in the pharmacokinetic analysis set (PAS) who had an available value for the outcome measure at each timepoint. PAS consists of all patients who received one of the planned treatments and provided at least one primary PK parameter. For each arm, patients receiving the same study treatment at the same dose are pooled together.

MBG453 240 mg	**MBG453 400 mg**	**MBG453 800 mg**	**MBG453 160 mg**	**MBG453 240 mg**	**MBG453 400 mg**	**MBG 453 400**	**MBG 453 1200**	**MBG453 80 mg**	**MBG453 240 mg**	**MBG453 240 mg**	**MBG453 400 mg**	**MBG453 800 mg**

	Q2W + Decitabine 20 mg/m2	Q2W + Decitabine 20 mg/m2	Q4W + Decitabine 20 mg/m2	Q2W + PDR001 400 mg Q4W + Decitabine 20 mg/m2	Q2W + PDR001 400 mg Q4W + Decitabine 20 mg/m2	Q2W + PDR001 400 mg Q4W + Decitabine 20 mg/m2	mg Q2W	mg Q2W	Q2W + PDR001 400 mg Q4W	Q2W + PDR001 400 mg Q4W	Q2W + Azacitidine 75 mg/m2	Q2W + Azacitidine 75 mg/m2	Q4W + Azacitidine 75 mg/m2
Arm/Group Description	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2	Arm 3: MBG453 160 mg Q2W in combination with PDR001 400mg Q4W and decitabine 20mg/m2	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400mg Q4W and decitabine 20mg/m2	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400mg Q4W and decitabine 20mg/m2	Arm 4: MBG453 400 mg Q2W	Arm 4: MBG453 1200 mg Q2W	Arm 5: MBG453 80 mg Q2W in combination with PDR001 400mg Q4W	Arm 5: MBG453 240 mg Q2W in combination with PDR001 400mg Q4W	Arm 6: MBG453 240 mg Q2W in combination with azacitidine 75 mg/m2	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2
Number of Participants Analyzed [units: participants]	22	32	24	6	6	6	12	13	0	9	11	33	28
Arms 2 to 6: Time to reach maximum serum concentration (Tmax) of MBG453 (units: hours)	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**
Cycle 1 (n=21,31,24,4,6,6,12,13,0,9,9,33,25)	1.63 (1.13 to 3.12)	1.72 (1.35 to 3.33)	1.59 (1.03 to 3.02)	1.71 (1.47 to 2.93)	1.67 (1.45 to 2.00)	1.63 (1.42 to 3.43)	1.71 (1.58 to 3.37)	1.68 (1.42 to 3.48)		1.58 (1.45 to 3.53)	1.57 (1.50 to 3.00)	1.62 (0.43 to 165.18)	1.62 (1.08 to 3.30)

Cycle 3 (n=15,23,17,2,3,4,3,6,0, 5,10,26,17)	1.68 (0.42 to 3.25)	1.72 (1.42 to 3.20)	1.50 (0.58 to 2.08)	2.49 (1.63 to 3.35)	1.70 (1.62 to 2.05)	1.56 (1.00 to 1.58)	1.58 (0.98 to 3.52)	1.54 (1.43 to 3.20)		2.17 (0.50 to 3.23)	1.53 (1.42 to 1.58)	1.60 (1.48 to 2.15)	1.60 (1.47 to 2.25)

Arms 2 to 6: Area under the serum concentration-time curve from time zero to the time of the last quantifiable concentration (AUClast) of MBG453

Description	Pharmacokinetic (PK) parameters were calculated based on MBG453 serum concentrations by using non-compartmental methods. The linear trapezoidal method was used for AUClast calculation.
Time Frame	Pre-infusion and 1, 168, 336 and 648 hours after end of infusion on Cycle 1 Day 1 and Cycle 3 Day 1. The duration of the infusion was 30 minutes. 1 cycle=28 days
Analysis Population Description	Patients in the pharmacokinetic analysis set (PAS) who had an available value for the outcome measure at each timepoint. PAS consists of all patients who received one of the planned treatments and provided at least one primary PK parameter. For each arm, patients receiving the same study treatment at the same dose are pooled together.

	MBG453 240 mg Q2W + Decitabine 20 mg/m2	**MBG453 400 mg Q2W + Decitabine 20 mg/m2**	**MBG453 800 mg Q4W + Decitabine 20 mg/m2**	**MBG453 160 mg Q2W + PDR001 400 mg Q4W + Decitabine 20 mg/m2**	**MBG453 240 mg Q2W + PDR001 400 mg Q4W + Decitabine 20 mg/m2**	**MBG453 400 mg Q2W + PDR001 400 mg Q4W + Decitabine 20 mg/m2**	**MBG453 400 mg Q2W**	**MBG453 1200 mg Q2W**	**MBG453 80 mg Q2W + PDR001 400 mg Q4W**	**MBG453 240 mg Q2W + PDR001 400 mg Q4W**	**MBG453 240 mg Q2W + Azacitidine 75 mg/m2**	**MBG453 400 mg Q2W + Azacitidine 75 mg/m2**	**MBG453 800 mg Q4W + Azacitidine 75 mg/m2**
Arm/Group Description	Arm 2: MBG453 240 mg Q2W in combination with decitabi	Arm 2: MBG453 400 mg Q2W in combination with decitabi	Arm 2: MBG453 800 mg Q4W in combination with decitabi	Arm 3: MBG453 160 mg Q2W in combination with PDR00	Arm 3: MBG453 240 mg Q2W in combination with PDR00	Arm 3: MBG453 400 mg Q2W in combination with PDR00	Arm 4: MBG453 400 mg Q2W	Arm 4: MBG453 1200 mg Q2W	Arm 5: MBG453 80 mg Q2W in combination with PDR00	Arm 5: MBG453 240 mg Q2W in combination with PDR00	Arm 6: MBG453 240 mg Q2W in combination with azacitid	Arm 6: MBG453 400 mg Q2W in combination with azacitid	Arm 6: MBG453 800 mg Q4W in combination with azacitid

	ne 20mg/m2	ne 20mg/m2	ne 20mg/m2	1 400mg Q4W and decitabine 20mg/m2	1 400mg Q4W and decitabine 20mg/m2	1 400mg Q4W and decitabine 20mg/m2			1 400mg Q4W	1 400mg Q4W	ine 75 mg/m2	ine 75 mg/m2	ine 75 mg/m2
Number of Participants Analyzed [units: participants]	22	32	24	6	6	6	12	13	0	9	11	33	28
Arms 2 to 6: Area under the serum concentration-time curve from time zero to the time of the last quantifiable concentration (AUClast) of MBG453 (units: day*µg/mL)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Cycle 1 (n=22,32,24,4,6,6,12,13,0,9,10,33,28)	416 ± 108	697 ± 275	2270 ± 911	232 ± 67.8	323 ± 223	700 ± 169	666 ± 210	2430 ± 832		448 ± 195	434 ± 122	801 ± 235	2190 ± 839
Cycle 3 (n=15,23,17,2,3,4,12,13,0,5,10,26,19)	692 ± 244	1400 ± 592	2930 ± 1600	275 ± 148	1410 ± 909	1470 ± 426	1280 ± 334	4900 ± 1990		811 ± 203	893 ± 300	1400 ± 462	3640 ± 1950

Arms 1 to 3: Maximum observed serum concentration (Cmax) of decitabine

Description	Pharmacokinetic (PK) parameters were calculated based on decitabine serum concentrations by using non-compartmental methods. Cmax is defined as the maximum (peak) observed concentration following a dose.
Time Frame	Pre-infusion, right after completion of infusion and 1 hour after completion of infusion on Cycle 1 Day 1 and Cycle 3 Day 1. The duration of the infusion was 1 hour. 1 cycle=28 days
Analysis Population Description	Patients in the pharmacokinetic analysis set (PAS) who had an available value for the outcome measure at each timepoint. PAS consists of all patients who received one of the planned treatments and provided at least one primary PK parameter. For each arm, patients receiving the same study treatment at the same dose are pooled together.

	PDR001 400 mg Q4W + Decitabine 20 mg/m2	MBG453 240 mg Q2W + Decitabine 20 mg/m2	MBG453 400 mg Q2W + Decitabine 20 mg/m2	MBG453 800 mg Q4W + Decitabine 20 mg/m2	MBG453 160 mg Q2W + PDR001 400 mg Q4W + Decitabine 20 mg/m2	MBG453 240 mg Q2W + PDR001 400 mg Q4W + Decitabine 20 mg/m2	MBG453 400 mg Q2W + PDR001 400 mg Q4W + Decitabine 20 mg/m2
Arm/Group Description	Arm 1: PDR001 400 mg Q4W in combination with decitabine 20mg/m2	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2	Arm 3: MBG453 160 mg Q2W in combination with PDR001 400mg Q4W and decitabine 20mg/m2	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400mg Q4W and decitabine 20mg/m2	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400mg Q4W and decitabine 20mg/m2
Number of Participants Analyzed [units: participants]	15	22	32	24	6	6	6
Arms 1 to 3: Maximum observed serum concentration (Cmax) of decitabine (units: ng/mL)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Cycle 1 (n=15,16,32,20,6,6,4)	136 ± 144	99.7 ± 80.5	135 ± 150	164 ± 218	104 ± 69.2	177 ± 169	124 ± 26.3
Cycle 3 (n=7,11,22,14,1,2,4)	290 ± 407	225 ± 323	112 ± 77.3	279 ± 676	84.9	186 ± 74.2	186 ± 53.8

Arms 1 to 3: Time to reach maximum serum concentration (Tmax) of decitabine

Description	Pharmacokinetic (PK) parameters were calculated based on decitabine serum concentrations by using non-compartmental methods. Tmax is defined as the time to reach maximum (peak) concentration following a dose. Actual recorded sampling times were considered for the calculations.
Time Frame	Pre-infusion, right after completion of infusion and 1 hour after completion of infusion on Cycle 1 Day 1 and Cycle 3 Day 1. The duration of the infusion was 1 hour. 1 cycle=28 days
Analysis Population Description	Patients in the pharmacokinetic analysis set (PAS) who had an available value for the outcome measure at each timepoint. PAS consists of all patients who received one of the planned treatments and provided at least one primary PK parameter. For each arm, patients receiving the same study treatment at the same dose are pooled together.

	PDR001 400 mg Q4W + Decitabine 20 mg/m2	MBG453 240 mg Q2W + Decitabine 20 mg/m2	MBG453 400 mg Q2W + Decitabine 20 mg/m2	MBG453 800 mg Q4W + Decitabine 20 mg/m2	MBG453 160 mg Q2W + PDR001 400 mg Q4W + Decitabine 20 mg/m2	MBG453 240 mg Q2W + PDR001 400 mg Q4W + Decitabine 20 mg/m2	MBG453 400 mg Q2W + PDR001 400 mg Q4W + Decitabine 20 mg/m2
Arm/Group Description	Arm 1: PDR001 400 mg Q4W in combination with decitabine 20mg/m2	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2	Arm 3: MBG453 160 mg Q2W in combination with PDR001 400mg Q4W and decitabine 20mg/m2	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400mg Q4W and decitabine 20mg/m2	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400mg Q4W and decitabine 20mg/m2
Number of Participants Analyzed [units: participants]	15	22	32	24	6	6	6
Arms 1 to 3: Time to reach maximum serum concentration (Tmax) of decitabine (units: hours)	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**
Cycle 1 (n=15,16,32,20,6,6,4)	1.13 (0.95 to 1.58)	1.10 (0.97 to 2.13)	1.28 (0.97 to 4.12)	1.18 (1.00 to 2.28)	1.29 (1.25 to 1.37)	1.20 (1.02 to 1.45)	1.25 (1.08 to 1.30)
Cycle 3 (n=7,11,22,14,1,2,4)	1.17 (1.03 to 1.45)	1.15 (1.00 to 1.30)	1.21 (0.00 to 2.55)	1.13 (1.00 to 1.48)	1.17 (1.17 to 1.17)	1.17 (1.02 to 1.32)	1.10 (1.00 to 1.25)

Arms 1 to 3: Area under the serum concentration-time curve from time zero to the time of the last quantifiable concentration (AUClast) of decitabine

Description	Pharmacokinetic (PK) parameters were calculated based on decitabine serum concentrations by using non-compartmental methods. The linear trapezoidal method was used for AUClast calculation.
Time Frame	Pre-infusion, right after completion of infusion and 1 hour after completion of infusion on Cycle 1 Day 1 and Cycle 3 Day 1. The duration of the infusion was 1 hour. 1 cycle=28 days

Analysis Population Description: Patients in the pharmacokinetic analysis set (PAS) who had an available value for the outcome measure at each timepoint. PAS consists of all patients who received one of the planned treatments and provided at least one primary PK parameter. For each arm, patients receiving the same study treatment at the same dose are pooled together.

	PDR001 400 mg Q4W + Decitabine 20 mg/m2	**MBG453 240 mg Q2W + Decitabine 20 mg/m2**	**MBG453 400 mg Q2W + Decitabine 20 mg/m2**	**MBG453 800 mg Q4W + Decitabine 20 mg/m2**	**MBG453 160 mg Q2W + PDR001 400 mg Q4W + Decitabine 20 mg/m2**	**MBG453 240 mg Q2W + PDR001 400 mg Q4W + Decitabine 20 mg/m2**	**MBG453 400 mg Q2W + PDR001 400 mg Q4W + Decitabine 20 mg/m2**
Arm/Group Description	Arm 1: PDR001 400 mg Q4W in combination with decitabine 20mg/m2	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2	Arm 3: MBG453 160 mg Q2W in combination with PDR001 400mg Q4W and decitabine 20mg/m2	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400mg Q4W and decitabine 20mg/m2	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400mg Q4W and decitabine 20mg/m2
Number of Participants Analyzed [units: participants]	15	22	32	24	6	6	6
Arms 1 to 3: Area under the serum concentration-time curve from time zero to the time of the last quantifiable concentration (AUClast) of decitabine (units: hr*ng/mL)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Cycle 1 (n=15,16,32,20,6,6,4)	145 ± 153	104 ± 88.6	139 ± 132	182 ± 235	120 ± 79.6	179 ± 173	133 ± 30.5
Cycle 3 (n=7,11,22,14,1,2,4)	315 ± 445	231 ± 307	120 ± 82.1	291 ± 681	97.5	214 ± 106	195 ± 45.2

Arm 6: Maximum observed serum concentration (Cmax) of azacitidine

Description	Pharmacokinetic (PK) parameters were calculated based on azacitidine serum concentrations by using non-compartmental methods. Cmax is defined as the maximum (peak) observed concentration following a dose.
Time Frame	Pre-infusion or subcutaneous (SC) injection, right after completion of infusion or 30 minutes after SC injection, 2 and 4 hours after completion of infusion or SC injection on Cycle 1 Day 1 and Cycle 3 Day 1. 1 cycle=28 days
Analysis Population Description	Patients in the pharmacokinetic analysis set (PAS) who had an available value for the outcome measure at each timepoint. PAS consists of all patients who received one of the planned treatments and provided at least one primary PK parameter. For each arm, patients receiving the same study treatment at the same dose are pooled together.

	MBG453 240 mg Q2W + Azacitidine 75 mg/m2	**MBG453 400 mg Q2W + Azacitidine 75 mg/m2**	**MBG453 800 mg Q4W + Azacitidine 75 mg/m2**
Arm/Group Description	Arm 6: MBG453 240 mg Q2W in combination with azacitidine 75 mg/m2	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2
Number of Participants Analyzed [units: participants]	11	33	28
Arm 6: Maximum observed serum concentration (Cmax) of azacitidine (units: ng/mL)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Cycle 1 (n=9,20,17)	1290 ± 1260	1560 ± 1430	587 ± 337
Cycle 3 (n=8,21,17)	698 ± 378	1440 ± 1180	807 ± 382

Arm 6: Time to reach maximum serum concentration (Tmax) of azacitidine

Description	Pharmacokinetic (PK) parameters were calculated based on azacitidine serum concentrations by using non-compartmental methods. Tmax is defined as the time to reach maximum (peak) concentration following a dose. Actual recorded sampling times were considered for the calculations.
Time Frame	Pre-infusion or subcutaneous (SC) injection, right after completion of infusion or 30 minutes after SC injection, 2 and 4 hours after completion of infusion or SC injection on Cycle 1 Day 1 and Cycle 3 Day 1. 1 cycle=28 days
Analysis Population Description	Patients in the pharmacokinetic analysis set (PAS) who had an available value for the outcome measure at each timepoint. PAS consists of all patients who received one of the planned treatments and provided at least one primary PK parameter. For each arm, patients receiving the same study treatment at the same dose are pooled together.

	MBG453 240 mg Q2W + Azacitidine 75 mg/m2	MBG453 400 mg Q2W + Azacitidine 75 mg/m2	MBG453 800 mg Q4W + Azacitidine 75 mg/m2
Arm/Group Description	Arm 6: MBG453 240 mg Q2W in combination with azacitidine 75 mg/m2	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2
Number of Participants Analyzed [units: participants]	11	33	28
Arm 6: Time to reach maximum serum concentration (Tmax) of azacitidine (units: hours)	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**
Cycle 1 (n=9,20,17)	0.55 (0.22 to 0.87)	0.41 (0.17 to 0.65)	0.62 (0.28 to 1.97)
Cycle 3 (n=8,21,17)	0.50 (0.03 to 0.90)	0.43 (0.28 to 0.65)	0.53 (0.25 to 0.80)

Arm 6: Area under the serum concentration-time curve from time zero to the time of the last quantifiable concentration (AUClast) of azacitidine

Description	Pharmacokinetic (PK) parameters were calculated based on azacitidine serum concentrations by using non-compartmental methods. The linear trapezoidal method was used for AUClast calculation.
Time Frame	Pre-infusion or subcutaneous (SC) injection, right after completion of infusion or 30 minutes after SC injection, 2 and 4 hours after completion of infusion or SC injection on Cycle 1 Day 1 and Cycle 3 Day 1. 1 cycle=28 days
Analysis Population Description	Patients in the pharmacokinetic analysis set (PAS) who had an available value for the outcome measure at each timepoint. PAS consists of all patients who received one of the planned treatments and provided at least one primary PK parameter. For each arm, patients receiving the same study treatment at the same dose are pooled together.

	MBG453 240 mg Q2W + Azacitidine 75 mg/m2	MBG453 400 mg Q2W + Azacitidine 75 mg/m2	MBG453 800 mg Q4W + Azacitidine 75 mg/m2
Arm/Group Description	Arm 6: MBG453 240 mg Q2W in combination with azacitidine 75 mg/m2	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2

Number of Participants Analyzed [units: participants]	11	33	28
Arm 6: Area under the serum concentration-time curve from time zero to the time of the last quantifiable concentration (AUClast) of azacitidine (units: hr*ng/mL)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Cycle 1 (n=9,20,17)	1650 ± 1470	1890 ± 1670	869 ± 441
Cycle 3 (n=8,22,19)	969 ± 457	1720 ± 1420	1100 ± 548

Arms 1, 3 and 5: Number of participants with anti-PDR001 antibodies

Description	PDR001 immunogenicity was evaluated in serum samples. Anti-drug antibodies (ADA) status was defined as follows: • ADA-negative at baseline: ADA-negative sample at baseline and PDR001 PK concentration at the time of sample collection is less than the drug tolerance level • ADA-positive at baseline: ADA-positive sample at baseline • ADA-inconclusive at baseline: ADA-negative sample at baseline and PDR001 PK concentration at the time of sample collection is greater than or equal to the drug tolerance level or missing • ADA-negative post-baseline: ADA-negative sample at baseline and at least 1 post-baseline sample, all of which are ADA-negative samples • Treatment-induced ADA-positive: ADA-negative sample at baseline and at least 1 treatment-induced ADA-positive sample • Treatment-boosted ADA-positive: ADA-positive sample at baseline and at least 1 treatment-boosted ADA-positive sample • ADA-inconclusive post-baseline: patient who does not qualify for any of the above definitions
Time Frame	Baseline (before first dose) and post-baseline (assessed throughout the treatment, up to 1.8 years in Arm 1, 4.3 years in Arm 3 and 0.5 years in Arm 5).
Analysis Population Description	Patients who received at least 1 dose of PDR001 and had a determinant baseline immunogenicity (IG) sample and at least 1 determinant post-baseline IG sample for assessing anti-PDR001 antibodies. For each arm, patients receiving the same study treatment at the same dose are pooled together.

	PDR001 400 mg Q4W + Decitabine 20 mg/m2	**MBG453 160 mg Q2W + PDR001 400 mg Q4W + Decitabine 20 mg/m2**	**MBG453 240 mg Q2W + PDR001 400 mg Q4W + Decitabine 20 mg/m2**	**MBG453 400 mg Q2W + PDR001 400 mg Q4W + Decitabine 20 mg/m2**	**MBG453 80 mg Q2W + PDR001 400 mg Q4W**	**MBG453 240 mg Q2W + PDR001 400 mg Q4W**
Arm/Group Description	Arm 1: PDR001 400 mg Q4W in combination with decitabine 20mg/m2	Arm 3: MBG453 160 mg Q2W in combination with PDR001 400mg Q4W and	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400mg Q4W and	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400mg Q4W and	Arm 5: MBG453 80 mg Q2W in combination with PDR001 400mg Q4W	Arm 5: MBG453 240 mg Q2W in combination with PDR001 400mg Q4W

		decitabine 20mg/m2	decitabine 20mg/m2	decitabine 20mg/m2		
Number of Participants Analyzed [units: participants]	15	5	4	5	1	8
Arms 1, 3 and 5: Number of participants with anti-PDR001 antibodies (units: participants)	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**
ADA-negative at baseline	10 (66.67%)	3 (60%)	3 (75%)	5 (100%)	1 (100%)	7 (87.5%)
ADA-inconclusive at baseline	4 (26.67%)	2 (40%)	0 (%)	0 (%)	0 (%)	1 (12.5%)
ADA-positive at baseline	1 (6.67%)	0 (%)	1 (25%)	0 (%)	0 (%)	0 (%)
ADA-negative post-baseline	1 (6.67%)	0 (%)	0 (%)	0 (%)	0 (%)	3 (37.5%)
ADA-inconclusive post-baseline	12 (80%)	4 (80%)	3 (75%)	4 (80%)	1 (100%)	4 (50.0%)
Treatment-induced ADA-positive	2 (13.33%)	1 (20%)	1 (25%)	1 (20%)	0 (%)	1 (12.5%)
Treatment-boosted ADA-positive	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)

Arms 2 to 6: Number of participants with anti-MBG453 antibodies

Description: MBG453 immunogenicity was evaluated in serum samples. Anti-drug antibodies (ADA) status was defined as follows: • ADA-negative at baseline: ADA-negative sample at baseline and MBG453 PK concentration at the time of sample collection is less than the drug tolerance level • ADA-positive at baseline: ADA-positive sample at baseline • ADA-inconclusive at baseline: ADA-negative sample at baseline and MBG453 PK concentration at the time of sample collection is greater than or equal to the drug tolerance level or missing • ADA-negative post-baseline: ADA-negative sample at baseline and at least 1 post-baseline sample, all of which are ADA-negative samples • Treatment-induced ADA-positive: ADA-negative sample at baseline and at least 1 treatment-induced ADA-positive sample • Treatment-boosted ADA-positive: ADA-positive sample at baseline and at least 1 treatment-boosted ADA-positive sample • ADA-inconclusive post-baseline: patient who does not qualify for any of the above definitions

Time Frame: Baseline (before first dose) and post-baseline (assessed throughout the treatment, up to 2.9 years in Arm 2, 4.3 years in Arm 3, 0.9 years in Arm 4, 0.5 years in Arm 5 and 4.2 years in Arm 6).

Analysis Population Description	Patients who received at least 1 dose of MBG53 and had a determinant baseline immunogenicity (IG) sample and at least 1 determinant post-baseline IG sample for assessing anti-PDR001 antibodies. For each arm, patients receiving the same study treatment at the same dose are pooled together.

	MBG453 240 mg Q2W + Decitabine 20 mg/m2	MBG453 400 mg Q2W + Decitabine 20 mg/m2	MBG453 800 mg Q4W + Decitabine 20 mg/m2	MBG453 160 mg Q2W + PDR001 400 mg Q4W + Decitabine 20 mg/m2	MBG453 240 mg Q2W + PDR001 400 mg Q4W + Decitabine 20 mg/m2	MBG453 400 mg Q2W + PDR001 400 mg Q4W + Decitabine 20 mg/m2	MBG453 400 mg Q2W	MBG453 1200 mg Q2W	MBG453 80 mg Q2W + PDR001 400 mg Q4W	MBG453 240 mg Q2W + PDR001 400 mg Q4W	MBG453 240 mg Q2W + Azacitidine 75 mg/m2	MBG453 400 mg Q2W + Azacitidine 75 mg/m2	MBG453 800 mg Q4W + Azacitidine 75 mg/m2
Arm/Group Description	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2	Arm 3: MBG453 160 mg Q2W in combination with PDR001 400mg Q4W and decitabine 20mg/m2	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400mg Q4W and decitabine 20mg/m2	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400mg Q4W and decitabine 20mg/m2	Arm 4: MBG453 400 mg Q2W	Arm 4: MBG453 1200 mg Q2W	Arm 5: MBG453 80 mg Q2W in combination with PDR001 400mg Q4W	Arm 5: MBG453 240 mg Q2W in combination with PDR001 400mg Q4W	Arm 6: MBG453 240 mg Q2W in combination with azacitidine 75 mg/m2	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2
Number of Participants Analyzed [units: participants]	21	31	23	5	4	6	12	13	1	9	11	33	27

Arms 2 to 6: Number of participants with anti-MBG453 antibodies (units: participants)	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**
ADA-negative at baseline	18 (85.71%)	27 (87.1%)	17 (73.91%)	3 (60%)	4 (100%)	4 (66.67%)	10 (83.33%)	12 (92.31%)	1 (100%)	8 (88.89%)	10 (90.91%)	25 (75.76%)	23 (85.19%)
ADA-inconclusive at baseline	3 (14.29%)	2 (6.45%)	2 (8.7%)	1 (20%)	0 (%)	0 (%)	1 (8.33%)	1 (7.69%)	0 (%)	1 (11.11%)	0 (%)	4 (12.12%)	3 (11.11%)
ADA-positive at baseline	0 (%)	2 (6.45%)	4 (17.39%)	1 (20%)	0 (%)	2 (33.33%)	1 (8.33%)	0 (%)	0 (%)	0 (%)	1 (9.09%)	4 (12.12%)	1 (3.7%)
ADA-negative post-baseline	0 (%)	0 (%)	0 (%)	0 (%)	1 (25%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
ADA-inconclusive post-baseline	20 (95.24%)	28 (90.32%)	20 (86.96%)	4 (80%)	1 (25%)	6 (100%)	8 (66.67%)	10 (76.92%)	1 (100%)	8 (88.89%)	8 (72.73%)	28 (84.85%)	23 (85.19%)
Treatment-induced	1 (4.76%)	2 (6.45%)	1 (4.35%)	1 (20%)	2 (50%)	0 (%)	3 (25%)	3 (23.08%)	0 (%)	1 (11.11%)	3 (27.27%)	2 (6.06%)	4 (14.81%)

ADA positive													
Treatment-boosted ADA positive	0 (%)	1 (3.23%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)

Post-Hoc Outcome Result(s)

All-Collected Deaths

Description	On-treatment and post-treatment safety follow-up (FU) deaths were collected from: (1) first dose of study medication to 150 days after last dose of MBG453 or PDR001 or (2) 30 days after last dose of decitabine or azacitidine, whichever is the latest. Survival FU deaths were collected from: (1) 151 days after last dose of MBG453 or PDR001, or (2) 31 days after last dose of decitabine or azacitidine, until end of study. All deaths refer to the sum of on-treatment and post-treatment safety FU deaths plus survival FU deaths.
Time Frame	On-treatment and safety FU deaths: up to 2.2 years (Arm 1), 3.3 years (Arm 2), 4.7 years (Arm 3), 1.3 years (Arm 4), 0.9 years (Arm 5), 4.6 years (Arm 6) and 4 months (HMA only). The same timeframe is applicable to the survival FU deaths.
Analysis Population Description	All patients who received at least one dose of study treatment.

Arms 1 and 2

PDR001 400 mg Q4W + Decitabine R/R AML	PDR001 400mg Q4W + Decitabine R/R AML	PDR001 400 mg Q4W + Decitabine HR/V	MBG453 240 mg Q2W + Decitabine	MBG453 240mg Q2W + Decitabine R/R AML	MBG453 400 mg Q2W + Decitabine	MBG453 400mg Q2W + Decitabine R/R AML	MBG453 800 mg Q4W + Decitabine	MBG453 800mg Q4W + Decitabine R/R AML	MBG453 240 mg Q2W + Decitabine HR/V	MBG453 400 mg Q2W + Decitabine HR/V	MBG453 400 mg Q2W + Decitabine IR MDS	MBG453 800 mg Q4W + Decitabine HR/V	MBG453 800 mg Q4W + Decitabine IR MDS	MBG453 240mg Q2W + Decitabine	MBG453 400mg Q2W + Decitabine	MBG453 800mg Q4W + Decitabine

	NDAML		HRMDS	NDAML		NDAML		NDAML		HRMDS	HRMDS		HRMDS		CMML	CMML	CMML
Arm/Group Description	Arm 1: PDR001 in combination with decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Arm 1: PDR001 in combination with decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 1: PDR001 in combination with decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 2: MBG453 240 mg Q2W in combination with decitabine 20mg/m2 in chronic myelomonocytic leukemia	Arm 2: MBG453 400 mg Q2W in combination with decitabine 20mg/m2 in chronic myelomonocytic leukemia	Arm 2: MBG453 800 mg Q4W in combination with decitabine 20mg/m2 in chronic myelomonocytic leukemia
Number of Participants Analyzed [units: participants]	1	12	3	3	9	12	11	7	9	9	4	5	6	2	1	3	1
On-treatment and post-treatment safety FU deaths (n=1,12,3,3,9,1	1	6	1	1	7	5	9	4	6	1	0	1	1	0	1	1	1

2,11,7,9,9,4,5,6,2,1,3,1)																	
Survival FU (n=0,6,2,2,2,7,2,3,3,8,4,4,5,2,0,2,0)		2	2	0	1	2	0	1	0	5	1	1	0	0		0	
All deaths (n=1,12,3,3,9,12,11,7,9,9,4,5,6,2,1,3,1)	1	8	3	1	8	7	9	5	6	6	1	2	1	0	1	1	1

Arms 3, 4 and 5

	MBG453 160mg Q2W + PDR001 + Decitabine R/R AML	**MBG453 240mg Q2W + PDR001 + Decitabine ND AML**	**MBG453 240mg Q2W + PDR001 + Decitabine R/R AML**	**MBG453 400mg Q2W + PDR001 + Decitabine ND AML**	**MBG453 400mg Q2W + PDR001 + Decitabine R/R AML**	**MBG453 160mg Q2W + PDR001 + Decitabine HR/VHR MDS**	**MBG453 240mg Q2W + PDR001 + Decitabine HR/VHR MDS**	**MBG453 400mg Q2W + PDR001 + Decitabine HR/VHR MDS**	**MBG453 400mg Q2W R/R AML**	**MBG453 1200mg Q2W R/R AML**	**MBG453 400mg Q2W HR/VHR MDS**	**MBG453 1200mg Q2W HR/VHR MDS**	**MBG453 1200mg Q2W IR MDS**	**MBG453 80mg Q2W + PDR001 R/R AML**	**MBG453 240mg Q2W + PDR001 R/R AML**	**MBG453 240mg Q2W + PDR001 HR/VHR MDS**
Arm/Group Description	Arm 3: MBG453 160 mg Q2W in combination with PDR001 400	Arm 3: MBG453 240 mg Q2W in combinati	Arm 3: MBG453 240 mg Q2W in combination with PDR001 400	Arm 3: MBG453 400 mg Q2W in combinati	Arm 3: MBG453 400 mg Q2W in combination with PDR001 400	Arm 3: MBG453 160 mg Q2W in combination with	Arm 3: MBG453 240 mg Q2W in combination with	Arm 3: MBG453 400 mg Q2W in combination with	Arm 4: MBG453 400 mg Q2W in relapsed/refractory acute myeloid	Arm 4: MBG453 1200 mg Q2W in relapsed/refractory acute myeloid	Arm 4: MBG453 400 mg Q2W in high-/very high-	Arm 4: MBG453 1200 mg Q2W in high-/very high-	Arm 4: MBG453 1200 mg Q2W in intermediate-risk	Arm 5: MBG453 80 mg Q2W in combination with PDR001 400	Arm 5: MBG453 240 mg Q2W in combination with PDR001 400	Arm 5: MBG453 240 mg Q2W in combination with

	mg Q4W and decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	on with PDR001 400 mg Q4W and decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	mg Q4W and decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	on with PDR001 400 mg Q4W and decitabine 20mg/m2 in newly diagnosed acute myeloid leukemia	mg Q4W and decitabine 20mg/m2 in relapsed/refractory acute myeloid leukemia	PDR001 400 mg Q4W and decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	PDR001 400 mg Q4W and decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	PDR001 400 mg Q4W and decitabine 20mg/m2 in high-/very high-risk myelodysplastic syndrome	leukemia	leukemia	risk myelodysplastic syndrome	risk myelodysplastic syndrome	myelodysplastic syndrome	mg Q4W in relapsed/refractory acute myeloid leukemia	mg Q4W in relapsed/refractory acute myeloid leukemia	PDR001 400 mg Q4W in high-/very high-risk myelodysplastic syndrome
Number of Participants Analyzed [units: participants]	3	2	2	2	3	3	2	1	10	6	3	5	2	1	5	5
On-treatment and post-treatment safety FU deaths (n=3,2,2,2,3,3,2,1,10,6,3,5,2,1,5,5)	2	2	0	1	2	1	0	0	10	3	0	2	0	1	5	2
Survival FU (n=1,0,2,1,1,2,2,1,0,3,3,3,2,0,0,3)	1		0	1	0	0	1	0		1	2	0	0			0

All deaths (n=3,2,2,2,3,3, 2,1,10,6,3,5,2, 1,5,5)	3	2	0	2	2	1	1	0	10	4	2	2	0	1	5	2

Arm 6 and HMA only

	MBG453 240mg Q2W + Azacitidine ND AML	**MBG453 400mg Q2W + Azacitidine ND AML**	**MBG453 800mg Q4W + Azacitidine ND AML**	**MBG453 240mg Q2W + Azacitidine HR/VHR MDS**	**MBG453 240mg Q2W + Azacitidine IR MDS**	**MBG453 400mg Q2W + Azacitidine HR/VHR MDS**	**MBG453 400mg Q2W + Azacitidine IR MDS**	**MBG453 800mg Q4W + Azacitidine HR/VHR MDS**	**MBG453 800mg Q4W + Azacitidine IR MDS**	**MBG453 400mg Q2W + Azacitidine CMML**	**MBG453 800mg Q4W + Azacitidine CMML**	**Decitabine 20mg/m2**	**Azacitidine 75 mg/m2**
Arm/Group Description	Arm 6: MBG453 240 mg Q2W in combination with azacitidine 75 mg/m2 in newly diagnosed acute myeloid leukemia	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in newly diagnosed acute myeloid leukemia	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in newly diagnosed acute myeloid leukemia	Arm 6: MBG453 240 mg Q2W in combination with azacitidine 75 mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 6: MBG453 240 mg Q2W in combination with azacitidine 75 mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in high-/very high-risk myelodysplastic syndrome	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in intermediate-risk myelodysplastic syndrome	Arm 6: MBG453 400 mg Q2W in combination with azacitidine 75 mg/m2 in chronic myelomonocytic leukemia	Arm 6: MBG453 800 mg Q4W in combination with azacitidine 75 mg/m2 in chronic myelomonocytic leukemia	Hypomethylating agent (HMA) only: decitabine 20mg/m2	Hypomethylating agent (HMA) only: azacitidine 75 mg/m2
Number of Participants Analyzed [units: participants]	6	14	6	3	2	14	5	17	2	5	5	5	4

On-treatment and post-treatment safety FU deaths (n=6,14,6,3,2,14,5,17,2,5,5,5,4)	2	8	4	1	0	4	1	4	0	1	0	2	0
Survival FU (n=4,6,2,2,2,10,4,13,2,4,5,3,4)	2	0	0	0	0	0	0	0	0	0	1	1	2
All deaths (n=6,14,6,3,2,14,5,17,2,5,5,5,4)	4	8	4	1	0	4	1	4	0	1	1	3	2

Safety Results

Time Frame	On-treatment and post-treatment safety follow-up: from (1) first dose of study medication to 150 days after last dose of MBG453 or PDR001 or (2) 30 days after last dose of decitabine or azacitidine, whichever is the latest, up to 2.2 years (Arm 1), 3.3 years (Arm 2), 4.7 years (Arm 3), 1.3 years (Arm 4), 0.9 years (Arm 5), 4.6 years (Arm 6) and 4 months (HMA only). Deaths in survival period: from (1) 151 days after last dose of MBG453 or PDR001, or (2) 31 days after last dose of decitabine or azacitidine, until end of study (maximum 4.6 years).
Additional Description	Deaths in the survival period are not considered Adverse Events (AEs). No AEs were collected in the survival period.
Source Vocabulary for Table Default	MedDRA (26.1)
Collection Approach for Table Default	Systematic Assessment

NOVARTIS

All-Cause Mortality

Arms 1 and 2

	PDR001 400 mg Q4W + Decitabine 20 mg/m2 AML N = 13	PDR001 400 mg Q4W + Decitabine 20 mg/m2 MDS N = 3	MBG453 240 mg Q2W + Decitabine 20 mg/m2 AML N = 12	MBG453 400 mg Q2W + Decitabine 20 mg/m2 AML N = 23	MBG453 800 mg Q4W + Decitabine 20 mg/m2 AML N = 16	MBG453 240 mg Q2W + Decitabine 20 mg/m2 MDS N = 9	MBG453 400 mg Q2W + Decitabine 20 mg/m2 MDS N = 9	MBG453 800 mg Q4W + Decitabine 20 mg/m2 MDS N = 8	MBG453 240 mg Q2W + Dec 20 mg/m2 CMML N = 1	MBG453 400 mg Q2W + Dec 20 mg/m2 CMML N = 3	MBG453 800 mg Q4W + Dec 20 mg/m2 CMML N = 1
Arm/Group Description	Arm 1: Safety data up to 150 days after last dose of PDR001 or 30 days after last dose of decitabine, whichever is the latest	Arm 1: Safety data up to 150 days after last dose of PDR001 or 30 days after last dose of decitabine, whichever is the latest	Arm 2: Safety data up to 150 days after last dose of MBG453 or 30 days after last dose of decitabine, whichever is the latest	Arm 2: Safety data up to 150 days after last dose of MBG453 or 30 days after last dose of decitabine, whichever is the latest	Arm 2: Safety data up to 150 days after last dose of MBG453 or 30 days after last dose of decitabine, whichever is the latest	Arm 2: Safety data up to 150 days after last dose of MBG453 or 30 days after last dose of decitabine, whichever is the latest	Arm 2: Safety data up to 150 days after last dose of MBG453 or 30 days after last dose of decitabine, whichever is the latest	Arm 2: Safety data up to 150 days after last dose of MBG453 or 30 days after last dose of decitabine, whichever is the latest	Arm 2: Safety data up to 150 days after last dose of MBG453 or 30 days after last dose of decitabine, whichever is the latest	Arm 2: Safety data up to 150 days after last dose of MBG453 or 30 days after last dose of decitabine, whichever is the latest	Arm 2: Safety data up to 150 days after last dose of MBG453 or 30 days after last dose of decitabine, whichever is the latest
Total Number Affected	7	1	8	14	10	1	1	1	1	1	1
Total Number At Risk	13	3	12	23	16	9	9	8	1	3	1

Arms 3, 4 and 5

	MBG453 160mg Q2W+PDR001 400mg Q4W+Decitabine 20mg/m2 AML N = 3	MBG453 240mg Q2W+PDR001 400mg Q4W+Decitabine 20mg/m2 AML N = 4	MBG453 400mg Q2W+PDR001 400mg Q4W+Decitabine 20mg/m2 AML N = 5	MBG453 160mg Q2W+PDR001 400mg Q4W+Decitabine 20mg/m2 MDS N = 3	MBG453 240mg Q2W+PDR001 400mg Q4W+Decitabine 20mg/m2 MDS N = 2	MBG453 400mg Q2W+PDR001 400mg Q4W+Decitabine 20mg/m2 MDS N = 1	MBG453 400 mg Q2W AML N = 10	MBG453 1200 mg Q2W AML N = 6	MBG453 400 mg Q2W MDS N = 3	MBG453 1200 mg Q2W MDS N = 7	MBG453 80 mg Q2W + PDR001 400 mg Q4W R/R AML N = 1	MBG453 240 mg Q2W + PDR001 400 mg Q4W AML N = 5	MBG453 240 mg Q2W + PDR001 400 mg Q4W MDS N = 5
Arm/Group Description	Arm 3: Safety data up to 150 days after last dose of MBG453 or PDR001 or 30 days after last dose of decitabine, whichever is the latest	Arm 3: Safety data up to 150 days after last dose of MBG453 or PDR001 or 30 days after last dose of decitabine, whichever is the latest	Arm 3: Safety data up to 150 days after last dose of MBG453 or PDR001 or 30 days after last dose of decitabine, whichever is the latest	Arm 3: Safety data up to 150 days after last dose of MBG453 or PDR001 or 30 days after last dose of decitabine, whichever is the latest	Arm 3: Safety data up to 150 days after last dose of MBG453 or PDR001 or 30 days after last dose of decitabine, whichever is the latest	Arm 3: Safety data up to 150 days after last dose of MBG453 or PDR001 or 30 days after last dose of decitabine, whichever is the latest	Arm 4: Safety data up to 150 days after last dose of MBG453	Arm 4: Safety data up to 150 days after last dose of MBG453	Arm 4: Safety data up to 150 days after last dose of MBG453	Arm 4: Safety data up to 150 days after last dose of MBG453	Arm 5: Safety data up to 150 days after last dose of MBG453 or PDR001	Arm 5: Safety data up to 150 days after last dose of MBG453 or PDR001	Arm 5: Safety data up to 150 days after last dose of MBG453 or PDR001
Total Number Affected	2	2	3	1	0	0	10	3	0	2	1	5	2
Total Number At Risk	3	4	5	3	2	1	10	6	3	7	1	5	5

Arm 6, HMA only and survival period

	MBG453 240 mg Q2W + Azacitidine 75 mg/m2 AML N = 6	MBG453 400 mg Q2W + Azacitidine 75 mg/m2 AML N = 14	MBG453 800 mg Q4W + Azacitidine 75 mg/m2 AML N = 6	MBG453 240 mg Q2W + Azacitidine 75 mg/m2 MDS N = 5	MBG453 400 mg Q2W + Azacitidine 75 mg/m2 MDS N = 19	MBG453 800 mg Q4W + Azacitidine 75 mg/m2 MDS N = 19	MBG453 400 mg Q2W + Azacitidine 75 mg/m2 CMML N = 5	MBG453 800 mg Q4W + Azacitidine 75 mg/m2 CMML N = 5	Decitabine 20 mg/m2 N = 5	Azacitidine 75 mg/m2 N = 4	Deaths in Survival period (All arms)
Arm/Group Description	Arm 6: Safety data up to 150 days after last dose of MBG453 or 30 days after last dose of azacitidine, whichever is the latest	Arm 6: Safety data up to 150 days after last dose of MBG453 or 30 days after last dose of azacitidine, whichever is the latest	Arm 6: Safety data up to 150 days after last dose of MBG453 or 30 days after last dose of azacitidine, whichever is the latest	Arm 6: Safety data up to 150 days after last dose of MBG453 or 30 days after last dose of azacitidine, whichever is the latest	Arm 6: Safety data up to 150 days after last dose of MBG453 or 30 days after last dose of azacitidine, whichever is the latest	Arm 6: Safety data up to 150 days after last dose of MBG453 or 30 days after last dose of azacitidine, whichever is the latest	Arm 6: Safety data up to 150 days after last dose of MBG453 or 30 days after last dose of azacitidine, whichever is the latest	Arm 6: Safety data up to 150 days after last dose of MBG453 or 30 days after last dose of azacitidine, whichever is the latest	HMA only: Safety data up to 30 days after last dose of decitabine	HMA only: Safety data up to 30 days after last dose of azacitidine	Deaths collected in the survival follow-up period (starting from Day 151 after last dose of MBG453 or PDR001, or Day 31 days after last dose of decitabine or azacitidine). No AEs were collected during this period.
Total Number Affected	2	8	4	1	5	4	1	0	2	0	27
Total Number At Risk	6	14	6	5	19	19	5	5	5	4	137

Serious Adverse Events

Time Frame	On-treatment and post-treatment safety follow-up: from (1) first dose of study medication to 150 days after last dose of MBG453 or PDR001 or (2) 30 days after last dose of decitabine or azacitidine, whichever is the latest, up to 2.2 years (Arm 1), 3.3 years (Arm 2), 4.7 years (Arm 3), 1.3 years (Arm 4), 0.9 years (Arm 5), 4.6 years (Arm 6) and 4 months (HMA only). Deaths in survival period: from (1) 151 days after last dose of MBG453 or PDR001, or (2) 31 days after last dose of decitabine or azacitidine, until end of study (maximum 4.6 years).
Additional Description	Deaths in the survival period are not considered Adverse Events (AEs). No AEs were collected in the survival period.
Source Vocabulary for Table Default	MedDRA (26.1)
Collection Approach for Table Default	Systematic Assessment

Arms 1 and 2

	PDR001 400 mg Q4W + Decitabine 20 mg/m2 AML N = 13	**PDR001 400 mg Q4W + Decitabine 20 mg/m2 MDS N = 3**	**MBG453 240 mg Q2W + Decitabine 20 mg/m2 AML N = 12**	**MBG453 400 mg Q2W + Decitabine 20 mg/m2 AML N = 23**	**MBG453 800 mg Q4W + Decitabine 20 mg/m2 AML N = 16**	**MBG453 240 mg Q2W + Decitabine 20 mg/m2 MDS N = 9**	**MBG453 400 mg Q2W + Decitabine 20 mg/m2 MDS N = 9**	**MBG453 800 mg Q4W + Decitabine 20 mg/m2 MDS N = 8**	**MBG453 240 mg Q2W + Dec 20 mg/m2 CMML N = 1**	**MBG453 400 mg Q2W + Dec 20 mg/m2 CMML N = 3**	**MBG453 800 mg Q4W + Dec 20 mg/m2 CMML N = 1**
Arm/Group Description	Arm 1: Safety data up to 150 days after	Arm 1: Safety data up to 150 days after last	Arm 2: Safety data up to 150 days after	Arm 2: Safety data up to 150 days after	Arm 2: Safety data up to 150 days after	Arm 2: Safety data up to 150 days after	Arm 2: Safety data up to 150 days after	Arm 2: Safety data up to 150 days after	Arm 2: Safety data up to 150 days	Arm 2: Safety data up to 150 days	Arm 2: Safety data up to 150 days after last

	last dose of PDR001 or 30 days after last dose of decitabine, whichever is the latest	dose of PDR001 or 30 days after last dose of decitabine, whichever is the latest	last dose of MBG453 or 30 days after last dose of decitabine, whichever is the latest	last dose of MBG453 or 30 days after last dose of decitabine, whichever is the latest	last dose of MBG453 or 30 days after last dose of decitabine, whichever is the latest	last dose of MBG453 or 30 days after last dose of decitabine, whichever is the latest	last dose of MBG453 or 30 days after last dose of decitabine, whichever is the latest	last dose of MBG453 or 30 days after last dose of decitabine, whichever is the latest	after last dose of MBG453 or 30 days after last dose of decitabine, whichever is the latest	after last dose of MBG453 or 30 days after last dose of decitabine, whichever is the latest	dose of MBG453 or 30 days after last dose of decitabine, whichever is the latest
Total # Affected by any Serious Adverse Event	12	3	11	18	13	8	8	5	0	3	1
Total # at Risk by any Serious Adverse Event	13	3	12	23	16	9	9	8	1	3	1
Blood and lymphatic system disorders											
Anaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Febrile neutropenia	5 (38.46 %)	3 (100.00 %)	9 (75.00 %)	8 (34.78 %)	6 (37.50 %)	7 (77.78 %)	3 (33.33 %)	3 (37.50 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Leukocytosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Splenomegaly	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Thrombocytopenia	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cardiac disorders											
Acute coronary syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Acute myocardial infarction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Angina pectoris	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Atrial fibrillation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Atrial tachycardia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Atrioventricular block	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Atrioventricular block complete	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33 %)	0 (0.00%)
Cardiac failure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cardiac failure acute	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cardiac failure congestive	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cardiovascular insufficiency	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Palpitations	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pericarditis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Eye disorders											
Diplopia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Optic nerve disorder	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Retinal detachment	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Uveitis	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastrointestinal disorders											
Abdominal distension	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Abdominal pain	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	2 (22.22%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Anal fissure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Anal fistula	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Colitis	0 (0.00%)	0 (0.00%)	1 (8.33%)	2 (8.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Constipation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Diarrhoea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastric haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastrointestinal haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gingival bleeding	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haematochezia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Large intestine polyp	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Melaena	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Nausea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	1 (12.50 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neutropenic colitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oesophagitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oral pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rectal haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	1 (33.33 %)	0 (0.00%)
Small intestinal obstruction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Stomatitis	0 (0.00%)	0 (0.00%)	1 (8.33%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Subileus	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33 %)	0 (0.00%)
Terminal ileitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Toothache	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Upper gastrointestinal haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33 %)	0 (0.00%)
Vomiting	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (12.50 %)	0 (0.00%)	1 (11.11 %)	1 (12.50 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)
General disorders and administration site conditions											
Chest pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Chills	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Disease progression	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fatigue	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)
General physical health deterioration	1 (7.69%)	0 (0.00%)	1 (8.33%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Influenza like illness	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Malaise	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Mucosal inflammation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Mucosal ulceration	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Non-cardiac chest pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oedema peripheral	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Peripheral swelling	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Physical deconditioning	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pyrexia	2 (15.38%)	0 (0.00%)	0 (0.00%)	3 (13.04%)	4 (25.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	1 (100.00%)
Hepatobiliary disorders											
Biliary colic	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Cholecystitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hepatitis	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Immune system disorders											
Haemophagocytic lymphohistiocytosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Infections and infestations											
Abdominal sepsis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Abscess	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Abscess limb	1 (7.69%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Adenovirus infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Anal abscess	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Anal infection	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Anorectal infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Arthritis bacterial	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Aspergillus infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Atypical pneumonia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Bacteraemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bacterial pyelonephritis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bacterial sepsis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bacteriuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bronchopulmonary aspergillosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cellulitis	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	1 (33.33 %)	0 (0.00%)
Clostridium difficile colitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
COVID-19	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
COVID-19 pneumonia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Device related infection	1 (7.69%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Diverticulitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ear infection bacterial	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Encephalitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Endocarditis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Enterococcal bacteraemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33 %)	0 (0.00%)
Escherichia sepsis	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Fungal infection	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fungal sepsis	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastroenteritis norovirus	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastroenteritis viral	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Influenza	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Klebsiella sepsis	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lower respiratory tract infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Myelitis	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neutropenic sepsis	2 (15.38 %)	0 (0.00%)	0 (0.00%)	2 (8.70%)	3 (18.75 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Osteomyelitis	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Otitis externa	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Parainfluenzae virus infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Periorbital cellulitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Peritonitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Pharyngitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumococcal sepsis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumonia	2 (15.38 %)	0 (0.00%)	1 (8.33%)	4 (17.39 %)	3 (18.75 %)	0 (0.00%)	2 (22.22 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumonia fungal	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumonia staphylococcal	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pseudomonal sepsis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pseudomonas infection	2 (15.38 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pyelonephritis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Respiratory tract infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33 %)	0 (0.00%)
Sepsis	4 (30.77 %)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Septic shock	1 (7.69%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Serratia sepsis	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sinusitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33 %)	0 (0.00%)
Staphylococcal sepsis	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Stenotrophomonas infection	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Systemic mycosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tooth abscess	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Upper respiratory tract infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urinary tract infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33 %)	0 (0.00%)
Vascular device infection	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Viral upper respiratory tract infection	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Wound infection	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Injury, poisoning and procedural complications											
Fall	1 (7.69%)	0 (0.00%)	1 (8.33%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33 %)	0 (0.00%)
Fat embolism	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Femoral neck fracture	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Femur fracture	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fracture	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Head injury	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Infusion related reaction	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Procedural pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Subdural haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Transfusion reaction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Transfusion related complication	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Investigations											
Body temperature increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gamma-glutamyltransferase increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Influenza A virus test positive	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
SARS-CoV-2 test positive	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Troponin increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Metabolism and nutrition disorders											
Hyperglycaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyponatraemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tumour lysis syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Musculoskeletal and connective tissue disorders											
Arthritis	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Back pain	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Intervertebral disc degeneration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Joint effusion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Muscular weakness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Myositis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)											
Acute myeloid leukaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Central nervous system leukaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Chronic myelomonocytic leukaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)
Colorectal adenoma	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Malignant neoplasm progression	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Metastases to meninges	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nervous system disorders											
Encephalitis autoimmune	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haemorrhage intracranial	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Headache	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lethargy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Subarachnoid haemorrhage	1 (7.69%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Syncope	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Transient ischaemic attack	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Psychiatric disorders											
Confusional state	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)
Hallucination	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)
Mental status changes	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Suicide attempt	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Renal and urinary disorders											
Acute kidney injury	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Renal colic	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Respiratory, thoracic and mediastinal disorders											
Acute pulmonary oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dyspnoea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dyspnoea exertional	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Epistaxis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hiccups	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypoxia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Immune-mediated lung disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Interstitial lung disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lung disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Organising pneumonia	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Painful respiration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pleural effusion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumonitis	2 (15.38 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Pulmonary embolism	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Respiratory distress	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Respiratory failure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (100.00 %)
Skin and subcutaneous tissue disorders											
Acute febrile neutrophilic dermatosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rash	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rash maculo-papular	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin haemorrhage	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vascular disorders											
Deep vein thrombosis	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Embolism	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haematoma	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33 %)	0 (0.00%)
Hypotension	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	1 (12.50 %)	0 (0.00%)	1 (33.33 %)	0 (0.00%)
Thrombophlebitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Arms 2, 3 and 4

	MBG453 160mg Q2W+PDR001 400mg Q4W+Decitabine 20mg/m2 AML N = 3	MBG453 240mg Q2W+PDR001 400mg Q4W+Decitabine 20mg/m2 AML N = 4	MBG453 400mg Q2W+PDR001 400mg Q4W+Decitabine 20mg/m2 AML N = 5	MBG453 160mg Q2W+PDR001 400mg Q4W+Decitabine 20mg/m2 MDS N = 3	MBG453 240mg Q2W+PDR001 400mg Q4W+Decitabine 20mg/m2 MDS N = 2	MBG453 400mg Q2W+PDR001 400mg Q4W+Decitabine 20mg/m2 MDS N = 1	MBG453 400 mg Q2W AML N = 10	MBG453 1200 mg Q2W AML N = 6	MBG453 400 mg Q2W MDS N = 3	MBG453 1200 mg Q2W MDS N = 7	MBG453 80 mg Q2W + PDR001 400 mg Q4W R/R AML N = 1	MBG453 240 mg Q2W + PDR001 400 mg Q4W AML N = 5	MBG453 240 mg Q2W + PDR001 400 mg Q4W MDS N = 5
Arm/Group Description	Arm 3: Safety data up to 150 days after last dose of MBG453 or PDR001 or 30 days after last dose of decitabine, whichever is the latest	Arm 3: Safety data up to 150 days after last dose of MBG453 or PDR001 or 30 days after last dose of decitabine, whichever is the latest	Arm 3: Safety data up to 150 days after last dose of MBG453 or PDR001 or 30 days after last dose of decitabine, whichever is the latest	Arm 3: Safety data up to 150 days after last dose of MBG453 or PDR001 or 30 days after last dose of decitabine, whichever is the latest	Arm 3: Safety data up to 150 days after last dose of MBG453 or PDR001 or 30 days after last dose of decitabine, whichever is the latest	Arm 3: Safety data up to 150 days after last dose of MBG453 or PDR001 or 30 days after last dose of decitabine, whichever is the latest	Arm 4: Safety data up to 150 days after last dose of MBG453	Arm 4: Safety data up to 150 days after last dose of MBG453	Arm 4: Safety data up to 150 days after last dose of MBG453	Arm 4: Safety data up to 150 days after last dose of MBG453	Arm 5: Safety data up to 150 days after last dose of MBG453 or PDR001	Arm 5: Safety data up to 150 days after last dose of MBG453 or PDR001	Arm 5: Safety data up to 150 days after last dose of MBG453 or PDR001
Total # Affected by any Serious Adverse Event	2	4	4	3	2	1	9	4	1	3	0	5	3
Total # at Risk by any	3	4	5	3	2	1	10	6	3	7	1	5	5

Serious Adverse Event													
Blood and lymphatic system disorders													
Anaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (14.29 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Febrile neutropenia	1 (33.33 %)	4 (100.00%)	3 (60.00 %)	3 (100.00%)	1 (50.00 %)	0 (0.00 %)	4 (40.00 %)	1 (16.67 %)	0 (0.00 %)	1 (14.29 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Leukocytosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Splenomegaly	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Thrombocytopenia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Cardiac disorders													
Acute coronary syndrome	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Acute myocardial infarction	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Angina pectoris	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (14.29 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Atrial fibrillation	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Atrial tachycardia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Atrioventricular block	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Atrioventricular block complete	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Cardiac failure	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Cardiac failure acute	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Cardiac failure congestive	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (14.29 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Cardiovascular insufficiency	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Palpitations	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pericarditis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Eye disorders													
Diplopia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Optic nerve disorder	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Retinal detachment	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Uveitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Gastrointestinal disorders													
Abdominal distension	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Abdominal pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (40.00 %)
Anal fissure	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Anal fistula	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Colitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Constipation	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Diarrhoea	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	1 (20.00 %)
Gastric haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Gastrointestinal haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Gingival bleeding	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Haematochezia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Large intestine polyp	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Melaena	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Nausea	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Neutropenic colitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Oesophagitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Oral pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Rectal haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Small intestinal obstruction	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Stomatitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Subileus	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Terminal ileitis	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Toothache	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Upper gastrointestinal haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vomiting	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
General disorders and administrati													

on site conditions													
Chest pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (14.29 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Chills	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Disease progression	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Fatigue	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	1 (20.00 %)
General physical health deterioration	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Influenza like illness	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Malaise	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Mucosal inflammation	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Mucosal ulceration	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Non-cardiac chest pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Oedema peripheral	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Peripheral swelling	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Physical deconditioning	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pyrexia	1 (33.33 %)	0 (0.00 %)	1 (20.00 %)	1 (33.33 %)	1 (50.00 %)	0 (0.00 %)	3 (30.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (40.00 %)	0 (0.00 %)
Hepatobiliary disorders													
Biliary colic	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Cholecystitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hepatitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Immune system disorders													
Haemophagocytic lymphohistiocytosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Infections and infestations													
Abdominal sepsis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Abscess	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Abscess limb	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Adenovirus infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Anal abscess	0 (0.00 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Anal infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Anorectal infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Arthritis bacterial	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Aspergillus infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Atypical pneumonia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Bacteraemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Bacterial pyelonephritis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Bacterial sepsis	0 (0.00 %)	1 (25.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Bacteriuria	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Bronchopulmonary aspergillosis	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Cellulitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Clostridium difficile colitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
COVID-19	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

COVID-19 pneumonia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Device related infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Diverticulitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Ear infection bacterial	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Encephalitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Endocarditis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Enterococcal bacteraemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Escherichia sepsis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Fungal infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Fungal sepsis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Gastroenteritis norovirus	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Gastroenteritis viral	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Influenza	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (14.29 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Klebsiella sepsis	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Lower respiratory tract infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Myelitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Neutropenic sepsis	1 (33.33 %)	0 (0.00 %)	2 (40.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Osteomyelitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Otitis externa	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Parainfluenzae virus infection	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Periorbital cellulitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Peritonitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pharyngitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pneumococcal sepsis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pneumonia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	1 (16.67 %)	0 (0.00 %)	1 (14.29 %)	0 (0.00 %)	1 (20.00 %)	2 (40.00 %)
Pneumonia fungal	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Pneumonia staphylococcal	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pseudomonal sepsis	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pseudomonas infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pyelonephritis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Respiratory tract infection	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Sepsis	1 (33.33 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Septic shock	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Serratia sepsis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Sinusitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Skin infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Staphylococcal sepsis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Stenotrophomonas infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Systemic mycosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Tooth abscess	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Upper respiratory tract infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Urinary tract infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vascular device infection	0 (0.00 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Viral upper respiratory tract infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Wound infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Injury, poisoning and procedural complications													
Fall	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Fat embolism	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Femoral neck fracture	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Femur fracture	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Fracture	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Head injury	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Infusion related reaction	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Procedural pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Subdural haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Transfusion reaction	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Transfusion related complication	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Investigations													
Body temperature increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Gamma-glutamyltransferase increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Influenza A virus test positive	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
SARS-CoV-2 test positive	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Troponin increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Metabolism and nutrition disorders													
Hyperglycaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hyponatraemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Tumour lysis syndrome	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Musculoskeletal and connective tissue disorders													
Arthritis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Back pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Intervertebral disc degeneration	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Joint effusion	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (14.29 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Muscular weakness	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Myositis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Neoplasms benign, malignant and unspecified													

(incl cysts and polyps)													
Acute myeloid leukaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Central nervous system leukaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Chronic myelomonocytic leukaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Colorectal adenoma	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Malignant neoplasm progression	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Metastases to meninges	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Nervous system disorders													
Encephalitis autoimmune	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Haemorrhage intracranial	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Headache	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)

Lethargy	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Subarachnoid haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Syncope	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Transient ischaemic attack	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Psychiatric disorders													
Confusional state	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hallucination	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Mental status changes	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Suicide attempt	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Renal and urinary disorders													
Acute kidney injury	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Renal colic	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Respiratory, thoracic and													

mediastinal disorders													
Acute pulmonary oedema	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Dyspnoea	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Dyspnoea exertional	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Epistaxis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hiccups	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypoxia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Immune-mediated lung disease	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Interstitial lung disease	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Lung disorder	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Organising pneumonia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Painful respiration	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pleural effusion	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pneumonitis	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Pulmonary embolism	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Respiratory distress	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Respiratory failure	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Skin and subcutaneous tissue disorders													
Acute febrile neutrophilic dermatosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Rash	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Rash maculo-papular	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Skin haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vascular disorders													
Deep vein thrombosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Embolism	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Haematoma	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

NOVARTIS

Hypotension	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Thrombophlebitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Arm 6 and HMA only

	MBG453 240 mg Q2W + Azacitidine 75 mg/m2 AML N = 6	MBG453 400 mg Q2W + Azacitidine 75 mg/m2 AML N = 14	MBG453 800 mg Q4W + Azacitidine 75 mg/m2 AML N = 6	MBG453 240 mg Q2W + Azacitidine 75 mg/m2 MDS N = 5	MBG453 400 mg Q2W + Azacitidine 75 mg/m2 MDS N = 19	MBG453 800 mg Q4W + Azacitidine 75 mg/m2 MDS N = 19	MBG453 400 mg Q2W + Azacitidine 75 mg/m2 CMML N = 5	MBG453 800 mg Q4W + Azacitidine 75 mg/m2 CMML N = 5	Decitabine 20 mg/m2 N = 5	Azacitidine 75 mg/m2 N = 4
Arm/Group Description	Arm 6: Safety data up to 150 days after last dose of MBG453 or 30 days after last dose of azacitidine , whichever is the latest	Arm 6: Safety data up to 150 days after last dose of MBG453 or 30 days after last dose of azacitidine , whichever is the latest	Arm 6: Safety data up to 150 days after last dose of MBG453 or 30 days after last dose of azacitidine , whichever is the latest	Arm 6: Safety data up to 150 days after last dose of MBG453 or 30 days after last dose of azacitidine , whichever is the latest	Arm 6: Safety data up to 150 days after last dose of MBG453 or 30 days after last dose of azacitidine , whichever is the latest	Arm 6: Safety data up to 150 days after last dose of MBG453 or 30 days after last dose of azacitidine , whichever is the latest	Arm 6: Safety data up to 150 days after last dose of MBG453 or 30 days after last dose of azacitidine , whichever is the latest	Arm 6: Safety data up to 150 days after last dose of MBG453 or 30 days after last dose of azacitidine , whichever is the latest	HMA only: Safety data up to 30 days after last dose of decitabine	HMA only: Safety data up to 30 days after last dose of azacitidine
Total # Affected by any Serious Adverse Event	3	10	5	1	8	13	3	1	4	4
Total # at Risk by any Serious Adverse Event	6	14	6	5	19	19	5	5	5	4

Blood and lymphatic system disorders										
Anaemia	2 (33.33%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Febrile neutropenia	3 (50.00%)	2 (14.29%)	2 (33.33%)	1 (20.00%)	1 (5.26%)	7 (36.84%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	1 (25.00%)
Leukocytosis	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Splenomegaly	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Thrombocytopenia	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cardiac disorders										
Acute coronary syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Acute myocardial infarction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Angina pectoris	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Atrial fibrillation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Atrial tachycardia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Atrioventricular block	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Atrioventricular block complete	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cardiac failure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (50.00%)
Cardiac failure acute	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)
Cardiac failure congestive	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cardiovascular insufficiency	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Palpitations	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pericarditis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Eye disorders										
Diplopia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Optic nerve disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Retinal detachment	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)
Uveitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastrointestinal disorders										
Abdominal distension	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Abdominal pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Anal fissure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Anal fistula	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Colitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Constipation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Diarrhoea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastric haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastrointestinal haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gingival bleeding	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haematochezia	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Large intestine polyp	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Melaena	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Nausea	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neutropenic colitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oesophagitis	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oral pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rectal haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Small intestinal obstruction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Stomatitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Subileus	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Terminal ileitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Toothache	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Upper gastrointestinal haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)
Vomiting	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
General disorders and administration site conditions										
Chest pain	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Chills	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Disease progression	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fatigue	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
General physical health deterioration	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Influenza like illness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Malaise	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Mucosal inflammation	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Mucosal ulceration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Non-cardiac chest pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oedema peripheral	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Peripheral swelling	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Physical deconditioning	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pyrexia	0 (0.00%)	2 (14.29%)	2 (33.33%)	0 (0.00%)	3 (15.79%)	2 (10.53%)	1 (20.00%)	0 (0.00%)	2 (40.00%)	1 (25.00%)
Hepatobiliary disorders										
Biliary colic	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cholecystitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hepatitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Immune system disorders										
Haemophagocytic lymphohistiocytosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Infections and infestations										
Abdominal sepsis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Abscess	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Abscess limb	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Adenovirus infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Anal abscess	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Anal infection	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Anorectal infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Arthritis bacterial	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Aspergillus infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Atypical pneumonia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)
Bacteraemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bacterial pyelonephritis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bacterial sepsis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bacteriuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bronchopulmonary aspergillosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cellulitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Clostridium difficile colitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
COVID-19	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
COVID-19 pneumonia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Device related infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Diverticulitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)
Ear infection bacterial	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Encephalitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Endocarditis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Enterococcal bacteraemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Escherichia sepsis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fungal infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fungal sepsis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastroenteritis norovirus	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastroenteritis viral	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Infection	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Influenza	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Klebsiella sepsis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lower respiratory tract infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Myelitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neutropenic sepsis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Osteomyelitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Otitis externa	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Parainfluenzae virus infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Periorbital cellulitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Peritonitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pharyngitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Pneumococcal sepsis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumonia	1 (16.67%)	4 (28.57%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumonia fungal	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumonia staphylococcal	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pseudomonal sepsis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pseudomonas infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pyelonephritis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Respiratory tract infection	0 (0.00%)	1 (7.14%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (50.00%)
Sepsis	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Septic shock	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Serratia sepsis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sinusitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Staphylococcal sepsis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Stenotrophomonas infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Systemic mycosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tooth abscess	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Upper respiratory tract infection	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urinary tract infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Vascular device infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Viral upper respiratory tract infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Wound infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Injury, poisoning and procedural complications										
Fall	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fat embolism	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Femoral neck fracture	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Femur fracture	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fracture	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Head injury	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Infusion related reaction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Procedural pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Subdural haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Transfusion reaction	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Transfusion related complication	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Investigations										
Body temperature increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gamma-glutamyltransferase increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Influenza A virus test positive	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
SARS-CoV-2 test positive	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Troponin increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)
Metabolism and nutrition disorders										
Hyperglycaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyponatraemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tumour lysis syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Musculoskeletal and connective tissue disorders										
Arthritis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Back pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Intervertebral disc degeneration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Joint effusion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Muscular weakness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Myositis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)										
Acute myeloid leukaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Central nervous system leukaemia	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Chronic myelomonocytic leukaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Colorectal adenoma	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Malignant neoplasm progression	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Metastases to meninges	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nervous system disorders										
Encephalitis autoimmune	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haemorrhage intracranial	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Headache	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lethargy	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Subarachnoid haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Syncope	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Transient ischaemic attack	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Psychiatric disorders										
Confusional state	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hallucination	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Mental status changes	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Suicide attempt	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Renal and urinary disorders										
Acute kidney injury	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Renal colic	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Respiratory, thoracic and mediastinal disorders										
Acute pulmonary oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)
Dyspnoea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)
Dyspnoea exertional	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Epistaxis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hiccups	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypoxia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Immune-mediated lung disease	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Interstitial lung disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lung disorder	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Organising pneumonia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Painful respiration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pleural effusion	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumonitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pulmonary embolism	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Respiratory distress	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Respiratory failure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Skin and subcutaneous tissue disorders										
Acute febrile neutrophilic dermatosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rash	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rash maculo-papular	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vascular disorders										
Deep vein thrombosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Embolism	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haematoma	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypotension	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Thrombophlebitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Other (Not Including Serious) Adverse Events

Time Frame On-treatment and post-treatment safety follow-up: from (1) first dose of study medication to 150 days after last dose of MBG453 or PDR001 or (2) 30 days after last dose of decitabine or azacitidine, whichever is the latest, up to 2.2 years (Arm 1), 3.3 years (Arm 2), 4.7 years (Arm 3), 1.3 years (Arm 4), 0.9 years (Arm 5), 4.6 years (Arm 6) and 4 months (HMA only).

	Deaths in survival period: from (1) 151 days after last dose of MBG453 or PDR001, or (2) 31 days after last dose of decitabine or azacitidine, until end of study (maximum 4.6 years).
Additional Description	Deaths in the survival period are not considered Adverse Events (AEs). No AEs were collected in the survival period.
Source Vocabulary for Table Default	MedDRA (26.1)
Collection Approach for Table Default	Systematic Assessment
Frequent Event Reporting Threshold	5%

Arm 1 and 2

	PDR001 400 mg Q4W + Decitabine 20 mg/m2 AML N = 13	**PDR001 400 mg Q4W + Decitabine 20 mg/m2 MDS N = 3**	**MBG453 240 mg Q2W + Decitabine 20 mg/m2 AML N = 12**	**MBG453 400 mg Q2W + Decitabine 20 mg/m2 AML N = 23**	**MBG453 800 mg Q4W + Decitabine 20 mg/m2 AML N = 16**	**MBG453 240 mg Q2W + Decitabine 20 mg/m2 MDS N = 9**	**MBG453 400 mg Q2W + Decitabine 20 mg/m2 MDS N = 9**	**MBG453 800 mg Q4W + Decitabine 20 mg/m2 MDS N = 8**	**MBG453 240 mg Q2W + Dec 20 mg/m2 CMML N = 1**	**MBG453 400 mg Q2W + Dec 20 mg/m2 CMML N = 3**	**MBG453 800 mg Q4W + Dec 20 mg/m2 CMML N = 1**
Arm/Group Description	Arm 1: Safety data up to 150 days after last dose of PDR001	Arm 1: Safety data up to 150 days after last dose of PDR001 or 30	Arm 2: Safety data up to 150 days after last dose of MBG453	Arm 2: Safety data up to 150 days after last dose of MBG453	Arm 2: Safety data up to 150 days after last dose of MBG453	Arm 2: Safety data up to 150 days after last dose of MBG453	Arm 2: Safety data up to 150 days after last dose of MBG453	Arm 2: Safety data up to 150 days after last dose of MBG453	Arm 2: Safety data up to 150 days after last dose of MBG453 or 30	Arm 2: Safety data up to 150 days after last dose of MBG453	Arm 2: Safety data up to 150 days after last dose of MBG453 or 30

	or 30 days after last dose of decitabine, whichever is the latest	days after last dose of decitabine, whichever is the latest	or 30 days after last dose of decitabine, whichever is the latest	or 30 days after last dose of decitabine, whichever is the latest	or 30 days after last dose of decitabine, whichever is the latest	or 30 days after last dose of decitabine, whichever is the latest	or 30 days after last dose of decitabine, whichever is the latest	or 30 days after last dose of decitabine, whichever is the latest	days after last dose of decitabine, whichever is the latest	or 30 days after last dose of decitabine, whichever is the latest	days after last dose of decitabine, whichever is the latest
Total # Affected by any Other Adverse Event	12	3	12	23	16	9	9	8	1	3	1
Total # at Risk by any Other Adverse Event	13	3	12	23	16	9	9	8	1	3	1
Blood and lymphatic system disorders											
Anaemia	1 (7.69%)	2 (66.67%)	3 (25.00%)	9 (39.13%)	6 (37.50%)	5 (55.56%)	3 (33.33%)	2 (25.00%)	1 (100.00%)	2 (66.67%)	1 (100.00%)
Bone marrow failure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Coagulopathy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Disseminated intravascular coagulation	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Febrile neutropenia	0 (0.00%)	1 (33.33%)	1 (8.33%)	2 (8.70%)	2 (12.50%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haemorrhagic diathesis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)
Leukocytosis	2 (15.38%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	1 (6.25%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Leukopenia	0 (0.00%)	0 (0.00%)	1 (8.33%)	3 (13.04%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Lymph node pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lymphadenitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lymphadenopathy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lymphadenopathy mediastinal	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neutropenia	3 (23.08%)	1 (33.33%)	5 (41.67%)	9 (39.13%)	7 (43.75%)	6 (66.67%)	2 (22.22%)	1 (12.50%)	1 (100.00%)	2 (66.67%)	1 (100.00%)
Pancytopenia	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Splenomegaly	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	1 (100.00%)	1 (33.33%)	0 (0.00%)
Thrombocytopenia	3 (23.08%)	2 (66.67%)	4 (33.33%)	8 (34.78%)	8 (50.00%)	6 (66.67%)	2 (22.22%)	1 (12.50%)	1 (100.00%)	2 (66.67%)	1 (100.00%)
Thrombocytosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	2 (22.22%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cardiac disorders											
Acute myocardial infarction	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Angina pectoris	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Aortic valve stenosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Arrhythmia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Atrial fibrillation	0 (0.00%)	0 (0.00%)	1 (8.33%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	1 (33.33%)	0 (0.00%)
Bradycardia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Cardiac failure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cardiomyopathy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Coronary artery disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Diastolic dysfunction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Mitral valve incompetence	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Myocardial ischaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Palpitations	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pericardial calcification	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pericardial effusion	1 (7.69%)	2 (66.67%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sinus tachycardia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Supraventricular tachycardia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tachycardia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ventricular arrhythmia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Congenital, familial and genetic disorders											
Cerebrovascular arteriovenous malformation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Ear and labyrinth disorders											
Deafness	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Deafness bilateral	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ear congestion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ear discomfort	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ear haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ear pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
External ear pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tinnitus	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (100.00%)
Vertigo	1 (7.69%)	0 (0.00%)	0 (0.00%)	2 (8.70%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vertigo positional	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Endocrine disorders											
Adrenal insufficiency	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypothyroidism	0 (0.00%)	2 (66.67%)	1 (8.33%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Primary hypothyroidism	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Eye disorders											

Anisocoria	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blindness	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cataract	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Conjunctival haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Conjunctival irritation	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dry eye	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Eye haemorrhage	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Eye irritation	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Eye pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Eyelid disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Eyelid oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Glaucoma	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ocular hyperaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Retinal detachment	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Retinal haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Retinopathy	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Uveitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vision blurred	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Visual field defect	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Visual impairment	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vitreous floaters	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastrointestinal disorders											
Abdominal discomfort	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Abdominal distension	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Abdominal hernia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Abdominal pain	2 (15.38%)	0 (0.00%)	2 (16.67%)	1 (4.35%)	1 (6.25%)	1 (11.11%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Abdominal pain lower	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Abdominal pain upper	1 (7.69%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (100.00%)
Aerophagia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Anal erythema	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Anal fissure	1 (7.69%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Anal incontinence	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Aphthous ulcer	0 (0.00%)	0 (0.00%)	1 (8.33%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ascites	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Colitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Constipation	4 (30.77%)	2 (66.67%)	4 (33.33%)	5 (21.74%)	2 (12.50%)	3 (33.33%)	3 (33.33%)	3 (37.50%)	0 (0.00%)	1 (33.33%)	0 (0.00%)
Dental caries	0 (0.00%)	0 (0.00%)	1 (8.33%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Diarrhoea	4 (30.77%)	2 (66.67%)	6 (50.00%)	7 (30.43%)	5 (31.25%)	3 (33.33%)	4 (44.44%)	2 (25.00%)	1 (100.00%)	1 (33.33%)	0 (0.00%)
Dry mouth	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	1 (6.25%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dyspepsia	0 (0.00%)	1 (33.33%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dysphagia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Faecaloma	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Flatulence	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	1 (11.11%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastric haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastrointestinal haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastrooesophageal reflux disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gingival bleeding	0 (0.00%)	0 (0.00%)	1 (8.33%)	2 (8.70%)	2 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)
Gingival pain	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Gingival swelling	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Glossodynia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haematochezia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haemorrhoids	1 (7.69%)	1 (33.33%)	1 (8.33%)	1 (4.35%)	1 (6.25%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haemorrhoids thrombosed	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)
Hypoaesthesia oral	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ileus	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Large intestine polyp	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lip dry	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lip erythema	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lip swelling	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lip ulceration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Melaena	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Mouth haemorrhage	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Mouth ulceration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nausea	8 (61.54%)	1 (33.33%)	5 (41.67%)	6 (26.09%)	7 (43.75%)	3 (33.33%)	4 (44.44%)	4 (50.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Odynophagia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oesophageal pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oral disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oral mucosa haematoma	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oral mucosal erythema	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oral pain	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	1 (11.11%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Palatal swelling	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pancreatitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Periodontal disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Proctalgia	2 (15.38%)	0 (0.00%)	1 (8.33%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rectal haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)
Rectal polyp	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Regurgitation	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Stomatitis	1 (7.69%)	0 (0.00%)	0 (0.00%)	2 (8.70%)	1 (6.25%)	0 (0.00%)	1 (11.11%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tongue discomfort	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tongue haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Tongue ulceration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Toothache	0 (0.00%)	1 (33.33%)	0 (0.00%)	1 (4.35%)	1 (6.25%)	1 (11.11%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vomiting	4 (30.77%)	0 (0.00%)	2 (16.67%)	4 (17.39%)	4 (25.00%)	1 (11.11%)	1 (11.11%)	1 (12.50%)	0 (0.00%)	1 (33.33%)	0 (0.00%)
General disorders and administration site conditions											
Administration site extravasation	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Administration site rash	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Asthenia	0 (0.00%)	0 (0.00%)	1 (8.33%)	2 (8.70%)	4 (25.00%)	2 (22.22%)	0 (0.00%)	1 (12.50%)	1 (100.00%)	2 (66.67%)	1 (100.00%)
Catheter site haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Catheter site inflammation	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Catheter site pain	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Catheter site pruritus	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Catheter site swelling	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Catheter site vesicles	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Chest discomfort	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Chest pain	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Chills	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Device related thrombosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Face oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Facial pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fatigue	4 (30.77%)	2 (66.67%)	5 (41.67%)	8 (34.78%)	7 (43.75%)	0 (0.00%)	4 (44.44%)	3 (37.50%)	0 (0.00%)	1 (33.33%)	0 (0.00%)
Gait disturbance	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
General physical health deterioration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Generalised oedema	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Induration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Inflammation	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Influenza like illness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Infusion site extravasation	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Injection site bruising	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Injection site haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Injection site inflammation	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Injection site pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Injection site rash	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Injection site reaction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lithiasis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Localised oedema	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Malaise	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Medical device pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Mucosal dryness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Mucosal inflammation	0 (0.00%)	0 (0.00%)	1 (8.33%)	1 (4.35%)	0 (0.00%)	1 (11.11%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nodule	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Non-cardiac chest pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (22.22%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oedema	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oedema peripheral	0 (0.00%)	2 (66.67%)	2 (16.67%)	2 (8.70%)	5 (31.25%)	0 (0.00%)	6 (66.67%)	3 (37.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Peripheral swelling	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (8.70%)	0 (0.00%)	1 (11.11%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Physical deconditioning	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Puncture site erythema	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pyrexia	2 (15.38%)	0 (0.00%)	2 (16.67%)	1 (4.35%)	2 (12.50%)	0 (0.00%)	1 (11.11%)	2 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Swelling face	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hepatobiliary disorders											
Autoimmune hepatitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bile duct stone	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Biliary colic	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cholecystitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hepatic lesion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hepatitis	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hepatomegaly	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (100.00%)	0 (0.00%)	0 (0.00%)
Hepatosplenomegaly	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperbilirubinaemia	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Jaundice	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (100.00%)	0 (0.00%)	0 (0.00%)
Periportal oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Immune system disorders											

Drug hypersensitivity	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Graft versus host disease in skin	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypersensitivity	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Immune system disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Infusion related hypersensitivity reaction	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Seasonal allergy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Infections and infestations											
Abscess limb	1 (7.69%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Abscess oral	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Anal abscess	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Anal infection	2 (15.38%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Atypical pneumonia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bacteraemia	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bacterial disease carrier	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bacterial infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Bacterial sepsis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blastocystis infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bronchiolitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bronchitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (100.00%)	0 (0.00%)	0 (0.00%)
Bronchopulmonary aspergillosis	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Candida infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Catheter site infection	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cellulitis	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (18.75%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Chronic sinusitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Clostridium difficile infection	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Conjunctivitis	0 (0.00%)	1 (33.33%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
COVID-19	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cystitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cytomegalovirus infection reactivation	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Device related bacteraemia	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Diverticulitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Encephalitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Enterococcal infection	1 (7.69%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Escherichia bacteraemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Escherichia infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Escherichia urinary tract infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Folliculitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fungaemia	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fungal infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fungal skin infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Furuncle	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastroenteritis	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastroenteritis viral	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)
Gingivitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haematoma infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Helicobacter infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Herpes simplex	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)
Herpes zoster	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Influenza	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Joint abscess	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Latent tuberculosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lip infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Localised infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lower respiratory tract infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	1 (6.25%)	0 (0.00%)	2 (22.22%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lower respiratory tract infection viral	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Medical device site pustule	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Metapneumovirus infection	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Mucosal infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nail infection	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nasopharyngitis	0 (0.00%)	0 (0.00%)	1 (8.33%)	1 (4.35%)	0 (0.00%)	1 (11.11%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oesophageal candidiasis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Onychomycosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ophthalmic herpes simplex	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oral candidiasis	1 (7.69%)	0 (0.00%)	0 (0.00%)	2 (8.70%)	0 (0.00%)	1 (11.11%)	2 (22.22%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (100.00%)
Oral herpes	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)
Oral infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Orchitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Osteomyelitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Osteomyelitis chronic	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Otitis externa	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Parainfluenzae virus infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Paronychia	0 (0.00%)	0 (0.00%)	2 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Parotitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Periodontitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Periorbital cellulitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pharyngitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Picornavirus infection	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Pneumonia	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (18.75%)	0 (0.00%)	2 (22.22%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumonia fungal	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumonia pseudomonal	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumonia viral	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Post procedural infection	1 (7.69%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pseudomonas infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pyelonephritis acute	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Respiratory syncytial virus infection	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)
Respiratory tract infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	1 (100.00%)	0 (0.00%)	0 (0.00%)
Rhinitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sepsis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sinusitis	2 (15.38%)	0 (0.00%)	0 (0.00%)	2 (8.70%)	1 (6.25%)	1 (11.11%)	1 (11.11%)	1 (12.50%)	0 (0.00%)	1 (33.33%)	0 (0.00%)
Skin candida	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin infection	1 (7.69%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Soft tissue infection	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Staphylococcal abscess	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Stoma site infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Subperiosteal abscess	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Superinfection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tonsillitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tooth abscess	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tooth infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Upper respiratory tract infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	1 (100.00%)	1 (33.33%)	1 (100.00%)
Urethritis	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urinary tract infection	0 (0.00%)	0 (0.00%)	1 (8.33%)	1 (4.35%)	1 (6.25%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urinary tract infection bacterial	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vascular device infection	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Viral infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Viral upper respiratory tract infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vulvovaginal candidiasis	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Wound infection	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Injury, poisoning and procedural complications											
Animal scratch	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ankle fracture	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Arthropod bite	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Avulsion fracture	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bone fissure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Contusion	0 (0.00%)	0 (0.00%)	1 (8.33%)	2 (8.70%)	2 (12.50%)	1 (11.11%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Craniofacial fracture	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Extra-axial haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Extradural haematoma	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Eye contusion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fall	1 (7.69%)	0 (0.00%)	2 (16.67%)	5 (21.74%)	3 (18.75%)	0 (0.00%)	1 (11.11%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gingival injury	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Head injury	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Humerus fracture	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Immunisation reaction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Infusion related reaction	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Joint injury	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Limb injury	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lumbar vertebral fracture	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Meniscus injury	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Overdose	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Periorbital haemorrhage	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Post procedural discomfort	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Post procedural haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Post procedural urine leak	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Procedural headache	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Procedural pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Procedural pneumothorax	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Road traffic accident	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Skin abrasion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin injury	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin laceration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Spinal compression fracture	0 (0.00%)	0 (0.00%)	1 (8.33%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Stoma site ulcer	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Subcutaneous haematoma	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Subdural haematoma	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)
Synovial rupture	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Thermal burn	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Thoracic vertebral fracture	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tooth fracture	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Transfusion reaction	0 (0.00%)	0 (0.00%)	1 (8.33%)	2 (8.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Transfusion related complication	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Traumatic haematoma	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Wound dehiscence	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Investigations

Activated partial thromboplastin time prolonged	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Alanine aminotransferase increased	1 (7.69%)	1 (33.33%)	3 (25.00%)	0 (0.00%)	0 (0.00%)	2 (22.22%)	1 (11.11%)	3 (37.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Amylase increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Aspartate aminotransferase increased	0 (0.00%)	1 (33.33%)	0 (0.00%)	2 (8.70%)	0 (0.00%)	1 (11.11%)	1 (11.11%)	2 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Aspergillus test positive	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Base excess decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood albumin decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood alkaline phosphatase increased	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	1 (100.00%)	1 (33.33%)	0 (0.00%)
Blood bilirubin increased	0 (0.00%)	1 (33.33%)	0 (0.00%)	1 (4.35%)	1 (6.25%)	1 (11.11%)	0 (0.00%)	3 (37.50%)	0 (0.00%)	1 (33.33%)	1 (100.00%)
Blood calcium decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood cholesterol increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood creatine increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood creatinine increased	0 (0.00%)	0 (0.00%)	2 (16.67%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)

Blood folate decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood glucose increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood lactate dehydrogenase decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood lactate dehydrogenase increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood magnesium decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood pH decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood phosphorus decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood phosphorus increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood pressure increased	0 (0.00%)	0 (0.00%)	2 (16.67%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood thyroid stimulating hormone decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood thyroid stimulating hormone increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood uric acid increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Clostridium test positive	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Coagulation factor XIII level decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
C-reactive protein increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (8.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ejection fraction decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Electrocardiogram QT prolonged	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Epstein-Barr virus test positive	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fluid balance positive	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gamma-glutamyltransferase increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (8.70%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	1 (100.00%)	0 (0.00%)	0 (0.00%)
General physical condition abnormal	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Glomerular filtration rate decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Glycosylated haemoglobin increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Human metapneumovirus test positive	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lipase increased	1 (7.69%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	1 (6.25%)	2 (22.22%)	0 (0.00%)	2 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Liver function test abnormal	1 (7.69%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Lymphocyte count decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neutrophil count decreased	0 (0.00%)	1 (33.33%)	0 (0.00%)	2 (8.70%)	1 (6.25%)	1 (11.11%)	1 (11.11%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neutrophil count increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
N-terminal prohormone brain natriuretic peptide increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Platelet count decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (8.70%)	0 (0.00%)	1 (11.11%)	1 (11.11%)	2 (25.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)
Prostatic specific antigen increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Protein urine present	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Prothrombin time shortened	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Red blood cell count increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
SARS-CoV-2 test positive	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Serum ferritin increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Smear site unspecified abnormal	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Troponin T increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Viral test positive	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vitamin B12 decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Vitamin B6 decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vitamin D decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Weight decreased	0 (0.00%)	1 (33.33%)	1 (8.33%)	0 (0.00%)	2 (12.50%)	0 (0.00%)	2 (22.22%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Weight increased	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
White blood cell count decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (22.22%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
White blood cell count increased	1 (7.69%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
White blood cells urine positive	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Metabolism and nutrition disorders											
Cachexia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Decreased appetite	1 (7.69%)	3 (100.00%)	2 (16.67%)	7 (30.43%)	7 (43.75%)	2 (22.22%)	3 (33.33%)	2 (25.00%)	0 (0.00%)	2 (66.67%)	0 (0.00%)
Dehydration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gout	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)
Hyperglycaemia	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	3 (18.75%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperkalaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperlipidaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypernatraemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Hyperphosphataemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypertriglyceridaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	1 (11.11%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperuricaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	1 (33.33%)	0 (0.00%)
Hypervolaemia	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (12.50%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypoalbuminaemia	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (12.50%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypocalcaemia	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (100.00%)
Hypokalaemia	5 (38.46%)	2 (66.67%)	3 (25.00%)	5 (21.74%)	1 (6.25%)	0 (0.00%)	3 (33.33%)	2 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypomagnesaemia	2 (15.38%)	0 (0.00%)	1 (8.33%)	2 (8.70%)	3 (18.75%)	1 (11.11%)	0 (0.00%)	3 (37.50%)	0 (0.00%)	1 (33.33%)	0 (0.00%)
Hyponatraemia	2 (15.38%)	2 (66.67%)	0 (0.00%)	2 (8.70%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypophagia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypophosphataemia	1 (7.69%)	1 (33.33%)	0 (0.00%)	1 (4.35%)	1 (6.25%)	2 (22.22%)	1 (11.11%)	2 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Malnutrition	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Metabolic acidosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pseudohyponatraemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Steroid diabetes	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tumour lysis syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Vitamin D deficiency	0 (0.00%)	1 (33.33%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vitamin K deficiency	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Musculoskeletal and connective tissue disorders											
Arthralgia	1 (7.69%)	1 (33.33%)	1 (8.33%)	3 (13.04%)	4 (25.00%)	0 (0.00%)	4 (44.44%)	1 (12.50%)	0 (0.00%)	2 (66.67%)	0 (0.00%)
Arthritis	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Back pain	0 (0.00%)	0 (0.00%)	2 (16.67%)	2 (8.70%)	2 (12.50%)	2 (22.22%)	2 (22.22%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bone lesion	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bone pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bone swelling	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Flank pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gouty arthritis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Groin pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haemarthrosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Joint contracture	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Joint range of motion decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Joint swelling	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Limb mass	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Muscle spasms	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	2 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Muscle twitching	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Muscular weakness	1 (7.69%)	1 (33.33%)	1 (8.33%)	1 (4.35%)	1 (6.25%)	2 (22.22%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	1 (33.33%)	0 (0.00%)
Musculoskeletal chest pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Musculoskeletal pain	1 (7.69%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Myalgia	1 (7.69%)	1 (33.33%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	1 (11.11%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Myopathy	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)
Myositis	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neck pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	3 (18.75%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nodal osteoarthritis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Osteoarthritis	0 (0.00%)	0 (0.00%)	1 (8.33%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Osteopenia	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Osteoporosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (8.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pain in extremity	1 (7.69%)	1 (33.33%)	1 (8.33%)	1 (4.35%)	2 (12.50%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Pain in jaw	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Plantar fasciitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Polymyalgia rheumatica	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sacral pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Seronegative arthritis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Spinal osteoarthritis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Spinal pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Synovial cyst	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tendon pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tenosynovitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)											
Acute myeloid leukaemia	0 (0.00%)	0 (0.00%)	1 (8.33%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Angiolipoma	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Angiomyolipoma	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Basal cell carcinoma	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Chloroma	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Leukaemia cutis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Leukaemic infiltration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Melanocytic naevus	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Meningioma	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Renal hamartoma	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nervous system disorders											
Amnesia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Axonal neuropathy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)
Balance disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Burning sensation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Carpal tunnel syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cerebral haemorrhage	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cerebral ischaemia	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cognitive disorder	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dizziness	1 (7.69%)	0 (0.00%)	1 (8.33%)	3 (13.04%)	2 (12.50%)	1 (11.11%)	3 (33.33%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Dysgeusia	0 (0.00%)	1 (33.33%)	0 (0.00%)	1 (4.35%)	2 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Encephalopathy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Facial nerve disorder	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Headache	3 (23.08%)	0 (0.00%)	3 (25.00%)	0 (0.00%)	5 (31.25%)	2 (22.22%)	5 (55.56%)	2 (25.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)
Hypoaesthesia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypogeusia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypotonia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Intensive care unit acquired weakness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Intracranial aneurysm	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lethargy	3 (23.08%)	0 (0.00%)	1 (8.33%)	1 (4.35%)	1 (6.25%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neuralgia	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neuropathy peripheral	0 (0.00%)	1 (33.33%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nystagmus	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Paraesthesia	1 (7.69%)	0 (0.00%)	2 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Parosmia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Peripheral sensory neuropathy	1 (7.69%)	0 (0.00%)	1 (8.33%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Presyncope	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Restless legs syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Retinal migraine	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sciatica	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Seizure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Somnolence	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Syncope	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Taste disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tremor	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Psychiatric disorders											
Agitation	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Anxiety	1 (7.69%)	1 (33.33%)	1 (8.33%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)
Confusional state	1 (7.69%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Delirium	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Depressed mood	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Depression	0 (0.00%)	2 (66.67%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Disorientation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hallucination	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hallucination, olfactory	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Insomnia	1 (7.69%)	2 (66.67%)	2 (16.67%)	3 (13.04%)	3 (18.75%)	1 (11.11%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Mania	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Mood altered	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nightmare	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Restlessness	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sleep disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (8.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Renal and urinary disorders											
Acute kidney injury	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (8.70%)	2 (12.50%)	1 (11.11%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Anuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cystitis noninfective	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dysuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	1 (6.25%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haematuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (12.50%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Hydronephrosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Micturition urgency	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nephrolithiasis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nocturia	0 (0.00%)	1 (33.33%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pollakiuria	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Polyuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Renal colic	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)
Renal failure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Renal impairment	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Renal mass	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Renal pain	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tubulointerstitial nephritis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urethral pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urinary incontinence	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urinary retention	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urinary tract pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Reproductive system and breast disorders											
Benign prostatic hyperplasia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pelvic pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Prostatic haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Prostatomegaly	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Scrotal erythema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Scrotal oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Testicular swelling	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Respiratory, thoracic and mediastinal disorders											
Chronic obstructive pulmonary disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (100.00%)	0 (0.00%)	0 (0.00%)
Cough	1 (7.69%)	1 (33.33%)	3 (25.00%)	4 (17.39%)	1 (6.25%)	1 (11.11%)	3 (33.33%)	2 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dysphonia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dyspnoea	3 (23.08%)	1 (33.33%)	1 (8.33%)	3 (13.04%)	4 (25.00%)	1 (11.11%)	2 (22.22%)	1 (12.50%)	1 (100.00%)	1 (33.33%)	0 (0.00%)
Dyspnoea exertional	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Epistaxis	2 (15.38 %)	0 (0.00%)	1 (8.33%)	6 (26.09 %)	4 (25.00 %)	5 (55.56 %)	1 (11.11 %)	1 (12.50 %)	0 (0.00%)	1 (33.33 %)	0 (0.00%)
Haemoptysis	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (8.70%)	0 (0.00%)	0 (0.00%)	1 (11.11 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypoxia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	2 (12.50 %)	0 (0.00%)	1 (11.11 %)	1 (12.50 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Laryngeal inflammation	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Laryngeal oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lung infiltration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nasal congestion	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (37.50 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oropharyngeal pain	1 (7.69%)	1 (33.33%)	1 (8.33%)	2 (8.70%)	2 (12.50 %)	1 (11.11 %)	1 (11.11 %)	1 (12.50 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Paranasal sinus discomfort	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Paranasal sinus inflammation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pharyngeal erythema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pleural effusion	3 (23.08 %)	1 (33.33%)	0 (0.00%)	2 (8.70%)	3 (18.75 %)	1 (11.11 %)	1 (11.11 %)	1 (12.50 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pleuritic pain	3 (23.08 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumonitis	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Productive cough	1 (7.69%)	1 (33.33%)	0 (0.00%)	1 (4.35%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pulmonary congestion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Pulmonary embolism	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pulmonary mass	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pulmonary oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	1 (6.25%)	1 (11.11%)	1 (11.11%)	2 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Respiratory distress	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Respiratory failure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (100.00%)
Rhinalgia	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rhinitis allergic	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rhinorrhoea	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (13.04%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)
Rhonchi	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sinus disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sinus pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tachypnoea	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	2 (12.50%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Throat lesion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Upper-airway cough syndrome	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Wheezing	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Skin and subcutaneous tissue disorders											
Actinic keratosis	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Acute febrile neutrophilic dermatosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Alopecia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blister	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood blister	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cutaneous vasculitis	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Decubitus ulcer	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dermatitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dermatitis acneiform	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Diffuse alopecia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dry skin	0 (0.00%)	2 (66.67%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ecchymosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Eczema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (12.50%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Erythema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Hyperhidrosis	1 (7.69%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ingrowing nail	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nail bed inflammation	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nail discolouration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Night sweats	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Onychomadesis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Papule	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Petechiae	1 (7.69%)	0 (0.00%)	0 (0.00%)	2 (8.70%)	1 (6.25%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pruritus	1 (7.69%)	1 (33.33%)	1 (8.33%)	2 (8.70%)	1 (6.25%)	1 (11.11%)	1 (11.11%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Purpura	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rash	2 (15.38%)	1 (33.33%)	3 (25.00%)	4 (17.39%)	1 (6.25%)	2 (22.22%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rash erythematous	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rash macular	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rash maculo-papular	0 (0.00%)	2 (66.67%)	1 (8.33%)	1 (4.35%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rash papular	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (100.00%)	0 (0.00%)	0 (0.00%)
Rash pruritic	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Seborrhoeic dermatitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sensitive skin	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin atrophy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin discolouration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)
Skin hyperpigmentation	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin induration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin irritation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin lesion	1 (7.69%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin mass	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin ulcer	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	2 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urticaria	0 (0.00%)	0 (0.00%)	1 (8.33%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vascular disorders											
Aortic arteriosclerosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Arteriosclerosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Circulatory collapse	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Deep vein thrombosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)
Embolism	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Flushing	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haematoma	0 (0.00%)	0 (0.00%)	2 (16.67%)	0 (0.00%)	1 (6.25%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)
Haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hot flush	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypertension	1 (7.69%)	0 (0.00%)	0 (0.00%)	3 (13.04%)	2 (12.50%)	0 (0.00%)	1 (11.11%)	1 (12.50%)	0 (0.00%)	1 (33.33%)	0 (0.00%)
Hypotension	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (8.70%)	2 (12.50%)	0 (0.00%)	1 (11.11%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Orthostatic hypotension	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)
Pallor	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Peripheral arterial occlusive disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Peripheral embolism	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Phlebitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	1 (11.11%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)
Superficial vein thrombosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Thrombophlebitis	0 (0.00%)	0 (0.00%)	1 (8.33%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Thrombosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Varicose vein	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Venous thrombosis limb	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Arms 3, 4 and 5

	MBG453 160mg Q2W+PDR001 400mg Q4W+Decitabine 20mg/m2 AML N = 3	**MBG453 240mg Q2W+PDR001 400mg Q4W+Decitabine 20mg/m2 AML N = 4**	**MBG453 400mg Q2W+PDR001 400mg Q4W+Decitabine 20mg/m2 AML N = 5**	**MBG453 160mg Q2W+PDR001 400mg Q4W+Decitabine 20mg/m2 MDS N = 3**	**MBG453 240mg Q2W+PDR001 400mg Q4W+Decitabine 20mg/m2 MDS N = 2**	**MBG453 400mg Q2W+PDR001 400mg Q4W+Decitabine 20mg/m2 MDS N = 1**	**MBG453 400 mg Q2W AML N = 10**	**MBG453 1200 mg Q2W AML N = 6**	**MBG453 400 mg Q2W MDS N = 3**	**MBG453 1200 mg Q2W MDS N = 7**	**MBG453 80 mg Q2W + PDR001 400 mg Q4W R/R AML N = 1**	**MBG453 240 mg Q2W + PDR001 400 mg Q4W AML N = 5**	**MBG453 240 mg Q2W + PDR001 400 mg Q4W MDS N = 5**
Arm/Group Description	Arm 3: Safety data up to 150 days after last dose of MBG453 or PDR001 or 30 days after last dose of decitabine, whichev	Arm 3: Safety data up to 150 days after last dose of MBG453 or PDR001 or 30 days after last dose of decitabine, whichev	Arm 3: Safety data up to 150 days after last dose of MBG453 or PDR001 or 30 days after last dose of decitabine, whichev	Arm 3: Safety data up to 150 days after last dose of MBG453 or PDR001 or 30 days after last dose of decitabine, whichev	Arm 3: Safety data up to 150 days after last dose of MBG453 or PDR001 or 30 days after last dose of decitabine, whichev	Arm 3: Safety data up to 150 days after last dose of MBG453 or PDR001 or 30 days after last dose of decitabine, whichev	Arm 4: Safety data up to 150 days after last dose of MBG453	Arm 4: Safety data up to 150 days after last dose of MBG453	Arm 4: Safety data up to 150 days after last dose of MBG453	Arm 4: Safety data up to 150 days after last dose of MBG453	Arm 5: Safety data up to 150 days after last dose of MBG453 or PDR001	Arm 5: Safety data up to 150 days after last dose of MBG453 or PDR001	Arm 5: Safety data up to 150 days after last dose of MBG453 or PDR001

	er is the latest	er is the latest	er is the latest	er is the latest	er is the latest	er is the latest							
Total # Affected by any Other Adverse Event	3	4	5	3	2	1	8	6	3	7	1	4	5
Total # at Risk by any Other Adverse Event	3	4	5	3	2	1	10	6	3	7	1	5	5
Blood and lymphatic system disorders													
Anaemia	0 (0.00 %)	1 (25.00 %)	3 (60.00 %)	0 (0.00 %)	2 (100.00%)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	1 (33.33 %)	3 (42.86 %)	0 (0.00 %)	2 (40.00 %)	2 (40.00 %)
Bone marrow failure	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Coagulopathy	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Disseminated intravascular coagulation	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Febrile neutropenia	0 (0.00 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Haemorrhagic diathesis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Leukocytosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100.00%)	1 (20.00 %)	0 (0.00 %)
Leukopenia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Lymph node pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Lymphadenitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Lymphadenopathy	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Lymphadenopathy mediastinal	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Neutropenia	1 (33.33 %)	1 (25.00 %)	1 (20.00 %)	2 (66.67 %)	2 (100.00%)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	2 (28.57 %)	0 (0.00 %)	2 (40.00 %)	0 (0.00 %)
Pancytopenia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Splenomegaly	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Thrombocytopenia	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	1 (33.33 %)	2 (100.00%)	0 (0.00 %)	1 (10.00 %)	1 (16.67 %)	0 (0.00 %)	1 (14.29 %)	0 (0.00 %)	2 (40.00 %)	1 (20.00 %)
Thrombocytosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Cardiac disorders													
Acute myocardial infarction	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Angina pectoris	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Aortic valve stenosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Arrhythmia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Atrial fibrillation	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Bradycardia	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Cardiac failure	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Cardiomyopathy	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Coronary artery disease	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Diastolic dysfunction	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Mitral valve	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

incompetence													
Myocardial ischaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Palpitations	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pericardial calcification	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pericardial effusion	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Sinus tachycardia	0 (0.00 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Supraventricular tachycardia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Tachycardia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Ventricular arrhythmia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Congenital, familial and genetic disorders													

Cerebrovascular arteriovenous malformation	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Ear and labyrinth disorders													
Deafness	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Deafness bilateral	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Ear congestion	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Ear discomfort	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Ear haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Ear pain	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
External ear pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Tinnitus	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vertigo	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Vertigo positional	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Endocrine disorders													
Adrenal insufficiency	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Hypothyroidism	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Primary hypothyroidism	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Eye disorders													
Anisocoria	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blindness	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Cataract	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Conjunctival haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	1 (14.29 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Conjunctival irritation	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Dry eye	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Eye haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Eye irritation	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Eye pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Eyelid disorder	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Eyelid oedema	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Glaucoma	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Ocular hyperaemia	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Retinal detachment	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Retinal haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Retinopathy	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Uveitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vision blurred	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Visual field defect	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Visual impairment	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vitreous floaters	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Gastrointestinal disorders													
Abdominal discomfort	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Abdominal distension	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Abdominal hernia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Abdominal pain	1 (33.33 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	2 (33.33 %)	1 (33.33 %)	1 (14.29 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Abdominal pain lower	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Abdominal pain upper	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Aerophagia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Anal erythema	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Anal fissure	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Anal incontinence	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Aphthous ulcer	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Ascites	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Colitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Constipation	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	1 (50.00 %)	1 (100.00%)	2 (20.00 %)	2 (33.33 %)	1 (33.33 %)	1 (14.29 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Dental caries	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Diarrhoea	1 (33.33 %)	1 (25.00 %)	2 (40.00 %)	2 (66.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	4 (66.67 %)	0 (0.00 %)	3 (42.86 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Dry mouth	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Dyspepsia	0 (0.00 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Dysphagia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Faecaloma	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Flatulence	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Gastric haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Gastrointestinal haemorrhage	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Gastrooesophageal reflux disease	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Gingival bleeding	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Gingival pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (14.29 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Gingival swelling	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Glossodynia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Haematochezia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (50.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Haemorrhoids	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Haemorrhoids thrombosed	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypoaesthesia oral	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Ileus	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Large intestine polyp	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Lip dry	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Lip erythema	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Lip swelling	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Lip ulceration	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Melaena	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Mouth haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (40.00 %)
Mouth ulceration	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Nausea	2 (66.67 %)	2 (50.00 %)	0 (0.00 %)	2 (66.67 %)	1 (50.00 %)	0 (0.00 %)	1 (10.00 %)	3 (50.00 %)	1 (33.33 %)	1 (14.29 %)	0 (0.00 %)	1 (20.00 %)	2 (40.00 %)
Odynophagia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Oesophageal pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Oral disorder	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Oral mucosa haematoma	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (50.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Oral mucosal erythema	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Oral pain	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Palatal swelling	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pancreatitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Periodontal disease	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Proctalgia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Rectal haemorrhage	0 (0.00 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Rectal polyp	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Regurgitation	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Stomatitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Tongue discomfort	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Tongue haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Tongue ulceration	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Toothache	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vomiting	1 (33.33 %)	0 (0.00 %)	1 (20.00 %)	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)

General disorders and administration site conditions													
Administration site extravasation	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (50.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Administration site rash	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Asthenia	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Catheter site haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Catheter site inflammation	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Catheter site pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Catheter site pruritus	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Catheter site swelling	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Catheter site vesicles	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Chest discomfort	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Chest pain	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	1 (14.29 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Chills	0 (0.00 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Device related thrombosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Face oedema	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Facial pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Fatigue	1 (33.33 %)	2 (50.00 %)	1 (20.00 %)	0 (0.00 %)	1 (50.00 %)	0 (0.00 %)	1 (10.00 %)	1 (16.67 %)	0 (0.00 %)	3 (42.86 %)	0 (0.00 %)	3 (60.00 %)	0 (0.00 %)
Gait disturbance	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
General physical health deterioration	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Generalised oedema	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Induration	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Inflammation	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Influenza like illness	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (50.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Infusion site extravasation	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (50.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Injection site bruising	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Injection site haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Injection site inflammation	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Injection site pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Injection site rash	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Injection site reaction	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Lithiasis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Localised oedema	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Malaise	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Medical device pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Mucosal dryness	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Mucosal inflammation	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	1 (14.29 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Nodule	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Non-cardiac chest pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (14.29 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Oedema	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Oedema peripheral	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	3 (30.00 %)	0 (0.00 %)	0 (0.00 %)	1 (14.29 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (20.00 %)	0 (0.00 %)	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Peripheral swelling	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Physical deconditioning	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Puncture site	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

erythema													
Pyrexia	0 (0.00 %)	0 (0.00 %)	2 (40.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	1 (100.00%)	0 (0.00 %)	3 (60.00 %)
Swelling face	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hepatobiliary disorders													
Autoimmune hepatitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Bile duct stone	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Biliary colic	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Cholecystitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hepatic lesion	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hepatitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hepatomegaly	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hepatosplenomegaly	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hyperbilirubinaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Jaundice	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Periportal oedema	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Immune system disorders													
Drug hypersensitivity	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Graft versus host disease in skin	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypersensitivity	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Immune system disorder	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Infusion related hypersensitivity reaction	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Seasonal allergy	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Infections and infestations													

Abscess limb	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Abscess oral	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Anal abscess	0 (0.00 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Anal infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Atypical pneumonia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Bacteraemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Bacterial disease carrier	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Bacterial infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Bacterial sepsis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blastocystis infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Bronchiolitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Bronchitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (50.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Bronchopulmonary aspergillosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Candida infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (50.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	1 (20.00 %)
Catheter site infection	0 (0.00 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Cellulitis	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Chronic sinusitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Clostridium difficile infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (14.29 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Conjunctivitis	0 (0.00 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
COVID-19	0 (0.00 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Cystitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Cytomegalovirus infection reactivation	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Device related bacteraemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Diverticulitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	1 (14.29 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Encephalitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Enterococcal infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Escherichia bacteraemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Escherichia infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Escherichia urinary tract infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Folliculitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Fungaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Fungal infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Fungal skin	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

infection													
Furuncle	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Gastroenteritis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Gastroenteritis viral	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Gingivitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Haematoma infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Helicobacter infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Herpes simplex	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Herpes zoster	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Influenza	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Joint abscess	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Latent tuberculosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Lip infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Localised infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Lower respiratory tract infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Lower respiratory tract infection viral	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Medical device site pustule	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Metapneumovirus infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Mucosal infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Nail infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Nasopharyngitis	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Oesophageal candidiasis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (50.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Onychomycosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Ophthalmic herpes simplex	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Oral candidiasis	0 (0.00 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Oral herpes	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Oral infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Orchitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (14.29 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Osteomyelitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Osteomyelitis chronic	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Otitis externa	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Parainfluenzae virus infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Paronychia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Parotitis	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Periodontitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Periorbital cellulitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pharyngitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Picornavirus infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pneumonia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pneumonia fungal	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pneumonia pseudomonal	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pneumonia viral	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Post procedural infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pseudomonas infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Pyelonephritis acute	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Respiratory syncytial virus infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Respiratory tract infection	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Rhinitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Sepsis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Sinusitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Skin candida	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Skin infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Soft tissue infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Staphylococcal abscess	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Stoma site	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

infection													
Subperiosteal abscess	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Superinfection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Tonsillitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Tooth abscess	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Tooth infection	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Upper respiratory tract infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Urethritis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Urinary tract infection	0 (0.00 %)	1 (25.00 %)	1 (20.00 %)	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (14.29 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Urinary tract infection bacterial	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Vascular device	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

infection													
Viral infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (50.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Viral upper respiratory tract infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vulvovaginal candidiasis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Wound infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Injury, poisoning and procedural complications													
Animal scratch	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Ankle fracture	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Arthropod bite	0 (0.00 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Avulsion fracture	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Bone fissure	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Contusion	0 (0.00 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Craniofacial fracture	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Extra-axial haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Extradural haematoma	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (50.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Eye contusion	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Fall	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Gingival injury	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Head injury	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Humerus fracture	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Immunisation reaction	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Infusion related reaction	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Joint injury	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Limb injury	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Lumbar vertebral fracture	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Meniscus injury	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Overdose	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Periorbital haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Post procedural discomfort	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Post procedural haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Post procedural urine leak	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Procedural headache	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Procedural pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Procedural pneumothorax	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Road traffic accident	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Skin abrasion	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Skin injury	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Skin laceration	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Spinal compression fracture	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Stoma site ulcer	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Subcutaneous haematoma	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Subdural haematoma	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Synovial rupture	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Thermal burn	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Thoracic vertebral fracture	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Tooth fracture	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Transfusion reaction	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Transfusion related complication	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Traumatic haematoma	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Wound dehiscence	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Investigations													
Activated partial thromboplastin time prolonged	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Alanine aminotransferase increased	1 (33.33 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	3 (42.86 %)	0 (0.00 %)	1 (20.00 %)	2 (40.00 %)
Amylase increased	0 (0.00 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Aspartate aminotransferase increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (50.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	3 (42.86 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Aspergillus test positive	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Base excess decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blood albumin decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blood alkaline phosphatase increased	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (14.29 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blood bilirubin	0 (0.00 %)	1 (25.00 %)	1 (20.00 %)	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

increased													
Blood calcium decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blood cholesterol increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blood creatine increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blood creatinine increased	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (14.29 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blood folate decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blood glucose increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Blood lactate dehydrogenase decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100.00%)	0 (0.00 %)	0 (0.00 %)
Blood lactate	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

dehydrogenase increased													
Blood magnesium decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blood pH decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blood phosphorus decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blood phosphorus increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blood pressure increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blood thyroid stimulating hormone decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Blood thyroid stimulating hormone increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (14.29 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blood uric acid increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Clostridium test positive	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Coagulation factor XIII level decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
C-reactive protein increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	1 (14.29 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Ejection fraction decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Electrocardiogram QT prolonged	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Epstein-Barr virus test positive	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Fluid balance positive	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Gamma-glutamyltransferase increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
General physical condition abnormal	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Glomerular filtration rate decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Glycosylated haemoglobin increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Human metapneumovir	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

us test positive													
Lipase increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (14.29 %)	0 (0.00 %)	1 (20.00 %)	1 (20.00 %)
Liver function test abnormal	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Lymphocyte count decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Neutrophil count decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (50.00 %)	1 (100.00%)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Neutrophil count increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
N-terminal prohormone brain natriuretic peptide increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Platelet count	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	3 (42.86 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)

decreased													
Prostatic specific antigen increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Protein urine present	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Prothrombin time shortened	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Red blood cell count increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
SARS-CoV-2 test positive	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Serum ferritin increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Smear site unspecified abnormal	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Troponin T increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Viral test positive	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vitamin B12 decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vitamin B6 decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vitamin D decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Weight decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Weight increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
White blood cell count decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
White blood cell count	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

increased													
White blood cells urine positive	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Metabolism and nutrition disorders													
Cachexia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Decreased appetite	1 (33.33 %)	1 (25.00 %)	2 (40.00 %)	1 (33.33 %)	0 (0.00 %)	1 (100.00%)	1 (10.00 %)	2 (33.33 %)	1 (33.33 %)	1 (14.29 %)	0 (0.00 %)	0 (0.00 %)	2 (40.00 %)
Dehydration	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Gout	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hyperglycaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (50.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Hyperkalaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hyperlipidaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (14.29 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypernatraemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hyperphosphataemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Hypertriglyceridaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (14.29 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Hyperuricaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypervolaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypoalbuminaemia	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	2 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypocalcaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Hypokalaemia	1 (33.33 %)	0 (0.00 %)	2 (40.00 %)	3 (100.00%)	1 (50.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (14.29 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Hypomagnesaemia	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Hyponatraemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (50.00 %)	0 (0.00 %)	1 (10.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	1 (20.00 %)
Hypophagia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypophosphataemia	1 (33.33 %)	1 (25.00 %)	0 (0.00 %)	1 (33.33 %)	1 (50.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	1 (14.29 %)	0 (0.00 %)	2 (40.00 %)	0 (0.00 %)
Malnutrition	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Metabolic acidosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pseudohyponatraemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Steroid diabetes	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Tumour lysis syndrome	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vitamin D deficiency	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vitamin K deficiency	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Musculoskeletal and connective tissue disorders													
Arthralgia	0 (0.00 %)	1 (25.00 %)	2 (40.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	2 (33.33 %)	1 (33.33 %)	1 (14.29 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Arthritis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Back pain	0 (0.00 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	1 (50.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Bone lesion	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Bone pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Bone swelling	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Flank pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	1 (14.29 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Gouty arthritis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Groin pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Haemar throsis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Joint contract ure	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Joint range of motion decreas ed	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Joint swelling	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Limb mass	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Muscle spasms	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Muscle twitchin g	0 (0.00 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Muscul ar weakne ss	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	1 (16.67 %)	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Muscul oskelet al chest pain	0 (0.00 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Muscul oskelet al pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Myalgia	0 (0.00 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Myopathy	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Myositis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Neck pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Nodal osteoarthritis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Osteoarthritis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Osteopenia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Osteoporosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pain in extremity	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pain in jaw	0 (0.00 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Plantar fasciitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Polymyalgia rheumatica	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (50.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Sacral pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Seronegative arthritis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Spinal osteoarthritis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Spinal pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (14.29 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Synovial cyst	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Tendon pain	0 (0.00 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Tenosynovitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)													
Acute myeloid leukaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Angiolipoma	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Angiomyolipoma	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Basal cell carcinoma	0 (0.00 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Chloroma	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Leukaemia cutis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Leukaemic infiltration	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Melanocytic naevus	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Meningioma	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Renal hamartoma	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Nervous system disorders													
Amnesia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Axonal neuropathy	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Balance disorder	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Burning sensation	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (14.29 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Carpal tunnel	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

syndrome													
Cerebral haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Cerebral ischaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Cognitive disorder	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Dizziness	1 (33.33 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100.00%)	0 (0.00 %)	2 (33.33 %)	0 (0.00 %)	2 (28.57 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Dysgeusia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Encephalopathy	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Facial nerve disorder	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Headache	0 (0.00 %)	1 (25.00 %)	0 (0.00 %)	2 (66.67 %)	0 (0.00 %)	1 (100.00%)	1 (10.00 %)	1 (16.67 %)	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Hypoaesthesia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Hypogeusia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypotonia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Intensive care unit acquired weakness	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Intracranial aneurysm	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Lethargy	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Neuralgia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Neuropathy peripheral	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Nystagmus	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Paraesthesia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Parosmia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Peripheral sensory neuropathy	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Presyncope	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Restless legs	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

syndrome													
Retinal migraine	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Sciatica	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Seizure	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Somnolence	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Syncope	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Taste disorder	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Tremor	0 (0.00 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Psychiatric disorders													
Agitation	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Anxiety	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (14.29 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Confusional state	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Delirium	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Depressed mood	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Depression	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (14.29 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Disorientation	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hallucination	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hallucination, olfactory	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Insomnia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	1 (20.00 %)
Mania	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Mood altered	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Nightmare	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (50.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Restlessness	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Sleep disorder	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Renal and urinary disorders													
Acute kidney injury	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Anuria	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Cystitis noninfective	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Dysuria	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Haematuria	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hydronephrosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Micturition urgency	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Nephrolithiasis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Nocturia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pollakiuria	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Polyuria	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Renal colic	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Renal failure	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Renal impairment	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Renal mass	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Renal pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Tubulointerstitial nephritis	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Urethral pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Urinary incontinence	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Urinary retention	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Urinary tract pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Reproductive system and breast disorders													
Benign prostatic hyperplasia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pelvic pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Prostatic haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Prostatomegaly	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Scrotal erythema	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Scrotal oedema	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Testicular swelling	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Respiratory, thoracic and mediastinal disorders													
Chronic obstructive pulmonary disease	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (14.29 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Cough	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	1 (20.00 %)
Dysphonia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Dyspnoea	0 (0.00 %)	1 (25.00 %)	2 (40.00 %)	0 (0.00 %)	1 (50.00 %)	0 (0.00 %)	2 (20.00 %)	0 (0.00 %)	0 (0.00 %)	2 (28.57 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Dyspnoea exertional	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Epistaxis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)

Haemoptysis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypoxia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Laryngeal inflammation	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Laryngeal oedema	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Lung infiltration	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Nasal congestion	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Oropharyngeal pain	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	1 (50.00 %)	0 (0.00 %)	1 (10.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Paranasal sinus discomfort	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Paranasal sinus inflammation	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (50.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pharyngeal erythema	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Pleural effusion	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pleuritic pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pneumonitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Productive cough	1 (33.33 %)	1 (25.00 %)	0 (0.00 %)	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pulmonary congestion	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pulmonary embolism	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pulmonary mass	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pulmonary oedema	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Respiratory distress	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Respiratory failure	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Rhinalgia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Rhinitis allergic	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Rhinorrhoea	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Rhonchi	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Sinus disorder	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Sinus pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Tachypnoea	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Throat lesion	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Upper-airway cough syndrome	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Wheezing	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Skin and subcutaneous tissue disorders													
Actinic keratosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Acute febrile neutrophilic dermatosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Alopecia	0 (0.00 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blister	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blood blister	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (50.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Cutaneous vasculitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Decubitus ulcer	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Dermatitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Dermatitis acneiform	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Diffuse alopecia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Dry skin	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Ecchymosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (50.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Eczema	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Erythema	0 (0.00 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hyperhidrosis	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Ingrowing nail	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Nail bed inflammation	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Nail discoloration	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Night sweats	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Onychomadesis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Papule	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Petechiae	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Pruritus	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Purpura	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Rash	2 (66.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (50.00 %)	0 (0.00 %)	1 (10.00 %)	1 (16.67 %)	0 (0.00 %)	1 (14.29 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Rash erythematous	0 (0.00 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Rash macular	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (14.29 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Rash maculo-papular	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	1 (50.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Rash papular	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Rash pruritic	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Seborrhoeic dermatitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Sensitive skin	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Skin atrophy	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Skin discoloration	0 (0.00 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Skin disorder	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (14.29 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Skin haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Skin hyperpigmentation	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Skin induration	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Skin irritation	0 (0.00 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Skin lesion	0 (0.00 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Skin mass	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Skin ulcer	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Urticaria	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vascular disorders													
Aortic arteriosclerosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Arteriosclerosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Circulatory collapse	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Deep vein thrombosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Embolism	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Flushing	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Haematoma	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hot flush	0 (0.00 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypertension	0 (0.00 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypotension	0 (0.00 %)	2 (50.00 %)	0 (0.00 %)	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Orthostatic	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

hypotension													
Pallor	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)
Peripheral arterial occlusive disease	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (14.29 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Peripheral embolism	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Phlebitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Superficial vein thrombosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Thrombophlebitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (50.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Thrombosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Varicose vein	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Venous thrombosis limb	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Arm 6 and HMA only

	MBG453 240 mg Q2W + Azacitidine 75 mg/m2 AML N = 6	MBG453 400 mg Q2W + Azacitidine 75 mg/m2 AML N = 14	MBG453 800 mg Q4W + Azacitidine 75 mg/m2 AML N = 6	MBG453 240 mg Q2W + Azacitidine 75 mg/m2 MDS N = 5	MBG453 400 mg Q2W + Azacitidine 75 mg/m2 MDS N = 19	MBG453 800 mg Q4W + Azacitidine 75 mg/m2 MDS N = 19	MBG453 400 mg Q2W + Azacitidine 75 mg/m2 CMML N = 5	MBG453 800 mg Q4W + Azacitidine 75 mg/m2 CMML N = 5	Decitabine 20 mg/m2 N = 5	Azacitidine 75 mg/m2 N = 4
Arm/Group Description	Arm 6: Safety data up to 150 days after last dose of MBG453 or 30 days after last dose of azacitidine , whichever is the latest	Arm 6: Safety data up to 150 days after last dose of MBG453 or 30 days after last dose of azacitidine , whichever is the latest	Arm 6: Safety data up to 150 days after last dose of MBG453 or 30 days after last dose of azacitidine , whichever is the latest	Arm 6: Safety data up to 150 days after last dose of MBG453 or 30 days after last dose of azacitidine , whichever is the latest	Arm 6: Safety data up to 150 days after last dose of MBG453 or 30 days after last dose of azacitidine, whichever is the latest	Arm 6: Safety data up to 150 days after last dose of MBG453 or 30 days after last dose of azacitidine, whichever is the latest	Arm 6: Safety data up to 150 days after last dose of MBG453 or 30 days after last dose of azacitidine , whichever is the latest	Arm 6: Safety data up to 150 days after last dose of MBG453 or 30 days after last dose of azacitidine , whichever is the latest	HMA only: Safety data up to 30 days after last dose of decitabine	HMA only: Safety data up to 30 days after last dose of azacitidine
Total # Affected by any Other Adverse Event	6	14	6	5	19	19	5	5	5	4
Total # at Risk by any Other Adverse Event	6	14	6	5	19	19	5	5	5	4
Blood and lymphatic system disorders										
Anaemia	3 (50.00%)	4 (28.57%)	3 (50.00%)	2 (40.00%)	8 (42.11%)	10 (52.63 %)	3 (60.00%)	2 (40.00%)	2 (40.00%)	3 (75.00%)
Bone marrow failure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Coagulopathy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Disseminated intravascular coagulation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Febrile neutropenia	1 (16.67%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haemorrhagic diathesis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Leukocytosis	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (50.00%)
Leukopenia	0 (0.00%)	2 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (10.53%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lymph node pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lymphadenitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lymphadenopathy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lymphadenopathy mediastinal	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neutropenia	3 (50.00%)	3 (21.43%)	2 (33.33%)	1 (20.00%)	5 (26.32%)	8 (42.11%)	3 (60.00%)	2 (40.00%)	2 (40.00%)	1 (25.00%)
Pancytopenia	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Splenomegaly	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Thrombocytopenia	2 (33.33%)	3 (21.43%)	4 (66.67%)	1 (20.00%)	5 (26.32%)	11 (57.89%)	2 (40.00%)	2 (40.00%)	2 (40.00%)	1 (25.00%)
Thrombocytosis	1 (16.67%)	0 (0.00%)	0 (0.00%)	2 (40.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cardiac disorders										
Acute myocardial infarction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Angina pectoris	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Aortic valve stenosis	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Arrhythmia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Atrial fibrillation	0 (0.00%)	1 (7.14%)	2 (33.33%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	1 (20.00%)	0 (0.00%)
Bradycardia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cardiac failure	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)
Cardiomyopathy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Coronary artery disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Diastolic dysfunction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Mitral valve incompetence	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Myocardial ischaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Palpitations	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pericardial calcification	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pericardial effusion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sinus tachycardia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Supraventricular tachycardia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tachycardia	1 (16.67%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ventricular arrhythmia	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Congenital, familial and genetic disorders										

Cerebrovascular arteriovenous malformation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ear and labyrinth disorders										
Deafness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Deafness bilateral	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ear congestion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ear discomfort	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ear haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ear pain	0 (0.00%)	2 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
External ear pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tinnitus	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vertigo	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vertigo positional	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Endocrine disorders										
Adrenal insufficiency	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypothyroidism	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Primary hypothyroidism	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Eye disorders										
Anisocoria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blindness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cataract	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Conjunctival haemorrhage	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Conjunctival irritation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dry eye	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Eye haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Eye irritation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Eye pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Eyelid disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Eyelid oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Glaucoma	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ocular hyperaemia	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Retinal detachment	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Retinal haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Retinopathy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Uveitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vision blurred	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	2 (40.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Visual field defect	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)
Visual impairment	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vitreous floaters	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastrointestinal disorders										
Abdominal discomfort	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Abdominal distension	1 (16.67%)	1 (7.14%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Abdominal hernia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Abdominal pain	1 (16.67%)	3 (21.43%)	1 (16.67%)	0 (0.00%)	1 (5.26%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Abdominal pain lower	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Abdominal pain upper	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Aerophagia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Anal erythema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Anal fissure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Anal incontinence	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Aphthous ulcer	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ascites	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Colitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Constipation	5 (83.33%)	9 (64.29%)	3 (50.00%)	4 (80.00%)	13 (68.42%)	11 (57.89%)	3 (60.00%)	3 (60.00%)	2 (40.00%)	1 (25.00%)
Dental caries	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Diarrhoea	2 (33.33%)	4 (28.57%)	4 (66.67%)	0 (0.00%)	8 (42.11%)	0 (0.00%)	2 (40.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)
Dry mouth	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dyspepsia	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	3 (15.79%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dysphagia	0 (0.00%)	1 (7.14%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Faecaloma	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Flatulence	0 (0.00%)	2 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Gastric haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)
Gastrointestinal haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastrooesophageal reflux disease	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gingival bleeding	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gingival pain	2 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gingival swelling	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Glossodynia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haematochezia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haemorrhoids	2 (33.33%)	2 (14.29%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haemorrhoids thrombosed	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypoaesthesia oral	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ileus	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)
Large intestine polyp	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lip dry	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lip erythema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lip swelling	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lip ulceration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Melaena	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Mouth haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (10.53%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Mouth ulceration	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Nausea	3 (50.00%)	8 (57.14%)	3 (50.00%)	3 (60.00%)	8 (42.11%)	12 (63.16%)	3 (60.00%)	1 (20.00%)	1 (20.00%)	0 (0.00%)
Odynophagia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Oesophageal pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oral disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oral mucosa haematoma	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oral mucosal erythema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oral pain	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Palatal swelling	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pancreatitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Periodontal disease	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Proctalgia	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rectal haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rectal polyp	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Regurgitation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Stomatitis	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	2 (10.53%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tongue discomfort	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tongue haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tongue ulceration	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Toothache	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	3 (15.79%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)
Vomiting	0 (0.00%)	3 (21.43%)	1 (16.67%)	1 (20.00%)	5 (26.32%)	7 (36.84%)	1 (20.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)

General disorders and administration site conditions										
Administration site extravasation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Administration site rash	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Asthenia	0 (0.00%)	1 (7.14%)	1 (16.67%)	0 (0.00%)	1 (5.26%)	3 (15.79%)	0 (0.00%)	1 (20.00%)	2 (40.00%)	2 (50.00%)
Catheter site haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Catheter site inflammation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Catheter site pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Catheter site pruritus	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Catheter site swelling	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Catheter site vesicles	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Chest discomfort	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Chest pain	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Chills	1 (16.67%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	2 (10.53%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Device related thrombosis	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Face oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Facial pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fatigue	2 (33.33%)	7 (50.00%)	0 (0.00%)	3 (60.00%)	6 (31.58%)	6 (31.58%)	3 (60.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Gait disturbance	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
General physical health deterioration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Generalised oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Induration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Inflammation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Influenza like illness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)
Infusion site extravasation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Injection site bruising	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Injection site haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Injection site inflammation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Injection site pain	1 (16.67%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Injection site rash	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Injection site reaction	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lithiasis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Localised oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Malaise	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Medical device pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Mucosal dryness	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Mucosal inflammation	0 (0.00%)	1 (7.14%)	1 (16.67%)	0 (0.00%)	1 (5.26%)	1 (5.26%)	0 (0.00%)	1 (20.00%)	1 (20.00%)	0 (0.00%)

Nodule	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)
Non-cardiac chest pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oedema	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)
Oedema peripheral	2 (33.33%)	2 (14.29%)	2 (33.33%)	1 (20.00%)	6 (31.58%)	4 (21.05%)	0 (0.00%)	1 (20.00%)	2 (40.00%)	1 (25.00%)
Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	1 (5.26%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Peripheral swelling	0 (0.00%)	2 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Physical deconditioning	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Puncture site erythema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pyrexia	2 (33.33%)	5 (35.71%)	1 (16.67%)	0 (0.00%)	3 (15.79%)	4 (21.05%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Swelling face	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hepatobiliary disorders										
Autoimmune hepatitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bile duct stone	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Biliary colic	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cholecystitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hepatic lesion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hepatitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hepatomegaly	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Hepatosplenomegaly	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperbilirubinaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Jaundice	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Periportal oedema	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Immune system disorders										
Drug hypersensitivity	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Graft versus host disease in skin	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypersensitivity	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Immune system disorder	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Infusion related hypersensitivity reaction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Seasonal allergy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Infections and infestations										
Abscess limb	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Abscess oral	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Anal abscess	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Anal infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Atypical pneumonia	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bacteraemia	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bacterial disease carrier	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bacterial infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Bacterial sepsis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blastocystis infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bronchiolitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bronchitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bronchopulmonary aspergillosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Candida infection	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Catheter site infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cellulitis	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	2 (10.53%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Chronic sinusitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Clostridium difficile infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Conjunctivitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
COVID-19	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cystitis	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cytomegalovirus infection reactivation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Device related bacteraemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Diverticulitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Encephalitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Enterococcal infection	0 (0.00%)	1 (7.14%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Escherichia bacteraemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Escherichia infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Escherichia urinary tract infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Folliculitis	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fungaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fungal infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fungal skin infection	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Furuncle	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastroenteritis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastroenteritis viral	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gingivitis	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haematoma infection	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Helicobacter infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Herpes simplex	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Herpes zoster	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Influenza	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Joint abscess	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Latent tuberculosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lip infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Localised infection	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lower respiratory tract infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lower respiratory tract infection viral	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Medical device site pustule	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Metapneumovirus infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Mucosal infection	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nail infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nasopharyngitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oesophageal candidiasis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Onychomycosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ophthalmic herpes simplex	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oral candidiasis	0 (0.00%)	1 (7.14%)	1 (16.67%)	0 (0.00%)	1 (5.26%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oral herpes	0 (0.00%)	1 (7.14%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	2 (10.53%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oral infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Orchitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Osteomyelitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Osteomyelitis chronic	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Otitis externa	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Parainfluenzae virus infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Paronychia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Parotitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Periodontitis	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Periorbital cellulitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Pharyngitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Picornavirus infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumonia	0 (0.00%)	1 (7.14%)	1 (16.67%)	1 (20.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumonia fungal	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumonia pseudomonal	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumonia viral	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Post procedural infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pseudomonas infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pyelonephritis acute	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Respiratory syncytial virus infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Respiratory tract infection	1 (16.67%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rhinitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sepsis	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sinusitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin candida	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (15.79%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Soft tissue infection	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)
Staphylococcal abscess	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Stoma site infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)
Subperiosteal abscess	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Superinfection	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tonsillitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tooth abscess	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tooth infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Upper respiratory tract infection	0 (0.00%)	1 (7.14%)	1 (16.67%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urethritis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urinary tract infection	0 (0.00%)	1 (7.14%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Urinary tract infection bacterial	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vascular device infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Viral infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Viral upper respiratory tract infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vulvovaginal candidiasis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Wound infection	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Injury, poisoning and procedural complications										
Animal scratch	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ankle fracture	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Arthropod bite	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Avulsion fracture	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bone fissure	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Contusion	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Craniofacial fracture	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Extra-axial haemorrhage	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Extradural haematoma	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Eye contusion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fall	0 (0.00%)	3 (21.43%)	1 (16.67%)	0 (0.00%)	2 (10.53%)	1 (5.26%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gingival injury	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Head injury	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Humerus fracture	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Immunisation reaction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Infusion related reaction	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Joint injury	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Limb injury	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lumbar vertebral fracture	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Meniscus injury	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Overdose	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Periorbital haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Post procedural discomfort	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Post procedural haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Post procedural urine leak	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Procedural headache	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Procedural pain	0 (0.00%)	1 (7.14%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Procedural pneumothorax	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Road traffic accident	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin abrasion	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin injury	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin laceration	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (5.26%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Spinal compression fracture	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Stoma site ulcer	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Subcutaneous haematoma	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Subdural haematoma	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Synovial rupture	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Thermal burn	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Thoracic vertebral fracture	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tooth fracture	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Transfusion reaction	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	1 (5.26%)	3 (15.79%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Transfusion related complication	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Traumatic haematoma	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Wound dehiscence	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)
Investigations										
Activated partial thromboplastin time prolonged	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Alanine aminotransferase increased	2 (33.33%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Amylase increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Aspartate aminotransferase increased	1 (16.67%)	1 (7.14%)	0 (0.00%)	1 (20.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Aspergillus test positive	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Base excess decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood albumin decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood alkaline phosphatase increased	0 (0.00%)	1 (7.14%)	2 (33.33%)	1 (20.00%)	3 (15.79%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Blood bilirubin increased	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	3 (15.79%)	2 (10.53%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Blood calcium decreased	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood cholesterol increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood creatine increased	0 (0.00%)	1 (7.14%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood creatinine increased	0 (0.00%)	3 (21.43%)	1 (16.67%)	0 (0.00%)	1 (5.26%)	3 (15.79%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Blood folate decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood glucose increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)
Blood lactate dehydrogenase decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood lactate dehydrogenase increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood magnesium decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood pH decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood phosphorus decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood phosphorus increased	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood pressure increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood thyroid stimulating hormone decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood thyroid stimulating hormone increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Blood uric acid increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Clostridium test positive	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Coagulation factor XIII level decreased	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
C-reactive protein increased	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ejection fraction decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Electrocardiogram QT prolonged	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Epstein-Barr virus test positive	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fluid balance positive	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gamma-glutamyltransferase increased	0 (0.00%)	1 (7.14%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)
General physical condition abnormal	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Glomerular filtration rate decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Glycosylated haemoglobin increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Human metapneumovirus test positive	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lipase increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Liver function test abnormal	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Lymphocyte count decreased	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neutrophil count decreased	1 (16.67%)	3 (21.43%)	1 (16.67%)	1 (20.00%)	3 (15.79%)	1 (5.26%)	2 (40.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neutrophil count increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
N-terminal prohormone brain natriuretic peptide increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Platelet count decreased	2 (33.33%)	1 (7.14%)	2 (33.33%)	2 (40.00%)	5 (26.32%)	1 (5.26%)	2 (40.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Prostatic specific antigen increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Protein urine present	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Prothrombin time shortened	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Red blood cell count increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
SARS-CoV-2 test positive	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Serum ferritin increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Smear site unspecified abnormal	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)
Troponin T increased	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Viral test positive	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vitamin B12 decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Vitamin B6 decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vitamin D decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Weight decreased	0 (0.00%)	4 (28.57%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	3 (15.79%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Weight increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
White blood cell count decreased	0 (0.00%)	1 (7.14%)	1 (16.67%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
White blood cell count increased	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
White blood cells urine positive	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Metabolism and nutrition disorders										
Cachexia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Decreased appetite	1 (16.67%)	5 (35.71%)	0 (0.00%)	2 (40.00%)	3 (15.79%)	2 (10.53%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dehydration	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gout	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperglycaemia	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (5.26%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	2 (40.00%)	0 (0.00%)
Hyperkalaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperlipidaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypernatraemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperphosphataemia	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypertriglyceridaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	1 (5.26%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Hyperuricaemia	0 (0.00%)	1 (7.14%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	2 (10.53%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypervolaemia	1 (16.67%)	1 (7.14%)	1 (16.67%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypoalbuminaemia	0 (0.00%)	2 (14.29%)	0 (0.00%)	1 (20.00%)	1 (5.26%)	2 (10.53%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypocalcaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	1 (25.00%)
Hypokalaemia	0 (0.00%)	3 (21.43%)	0 (0.00%)	1 (20.00%)	3 (15.79%)	1 (5.26%)	1 (20.00%)	0 (0.00%)	2 (40.00%)	1 (25.00%)
Hypomagnesaemia	0 (0.00%)	1 (7.14%)	0 (0.00%)	1 (20.00%)	2 (10.53%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyponatraemia	0 (0.00%)	0 (0.00%)	1 (16.67%)	2 (40.00%)	2 (10.53%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)
Hypophagia	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypophosphataemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (40.00%)	5 (26.32%)	2 (10.53%)	2 (40.00%)	1 (20.00%)	0 (0.00%)	1 (25.00%)
Malnutrition	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Metabolic acidosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pseudohyponatraemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Steroid diabetes	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tumour lysis syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Vitamin D deficiency	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vitamin K deficiency	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Musculoskeletal and connective tissue disorders										

Arthralgia	0 (0.00%)	2 (14.29%)	1 (16.67%)	0 (0.00%)	7 (36.84%)	2 (10.53%)	0 (0.00%)	1 (20.00%)	1 (20.00%)	1 (25.00%)
Arthritis	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Back pain	0 (0.00%)	4 (28.57%)	0 (0.00%)	1 (20.00%)	2 (10.53%)	4 (21.05%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bone lesion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bone pain	1 (16.67%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	3 (15.79%)	1 (5.26%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bone swelling	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Flank pain	0 (0.00%)	1 (7.14%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gouty arthritis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)
Groin pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haemarthrosis	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Joint contracture	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Joint range of motion decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Joint swelling	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Limb mass	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Muscle spasms	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (10.53%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Muscle twitching	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Muscular weakness	0 (0.00%)	2 (14.29%)	0 (0.00%)	1 (20.00%)	2 (10.53%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Musculoskeletal chest pain	1 (16.67%)	2 (14.29%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Musculoskeletal pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Myalgia	0 (0.00%)	1 (7.14%)	0 (0.00%)	1 (20.00%)	1 (5.26%)	4 (21.05%)	1 (20.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)
Myopathy	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Myositis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neck pain	0 (0.00%)	3 (21.43%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)
Nodal osteoarthritis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Osteoarthritis	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Osteopenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Osteoporosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pain in extremity	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	2 (10.53%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pain in jaw	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Plantar fasciitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)
Polymyalgia rheumatica	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sacral pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Seronegative arthritis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Spinal osteoarthritis	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Spinal pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Synovial cyst	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tendon pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tenosynovitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)										

Acute myeloid leukaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Angiolipoma	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Angiomyolipoma	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Basal cell carcinoma	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Chloroma	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Leukaemia cutis	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Leukaemic infiltration	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Melanocytic naevus	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Meningioma	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Renal hamartoma	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nervous system disorders										
Amnesia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Axonal neuropathy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Balance disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Burning sensation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Carpal tunnel syndrome	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cerebral haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cerebral ischaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cognitive disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dizziness	0 (0.00%)	2 (14.29%)	1 (16.67%)	1 (20.00%)	8 (42.11%)	6 (31.58%)	1 (20.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)

Dysgeusia	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (40.00%)	2 (10.53%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Encephalopathy	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Facial nerve disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Headache	2 (33.33%)	2 (14.29%)	0 (0.00%)	1 (20.00%)	2 (10.53%)	4 (21.05%)	1 (20.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)
Hypoaesthesia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypogeusia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypotonia	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Intensive care unit acquired weakness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Intracranial aneurysm	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lethargy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neuralgia	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neuropathy peripheral	0 (0.00%)	1 (7.14%)	1 (16.67%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nystagmus	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Paraesthesia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Parosmia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Peripheral sensory neuropathy	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Presyncope	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Restless legs syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Retinal migraine	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sciatica	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Seizure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Somnolence	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Syncope	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	1 (20.00%)	0 (0.00%)
Taste disorder	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tremor	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (10.53%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Psychiatric disorders										
Agitation	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Anxiety	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	1 (5.26%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Confusional state	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Delirium	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Depressed mood	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Depression	0 (0.00%)	2 (14.29%)	0 (0.00%)	0 (0.00%)	2 (10.53%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Disorientation	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hallucination	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)
Hallucination, olfactory	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Insomnia	0 (0.00%)	2 (14.29%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	1 (5.26%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Mania	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Mood altered	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nightmare	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Restlessness	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sleep disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Renal and urinary disorders										
Acute kidney injury	0 (0.00%)	0 (0.00%)	1 (16.67%)	1 (20.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	3 (60.00%)	0 (0.00%)
Anuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)
Cystitis noninfective	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dysuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (10.53%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haematuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hydronephrosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Micturition urgency	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nephrolithiasis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nocturia	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pollakiuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)
Polyuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Renal colic	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Renal failure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Renal impairment	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Renal mass	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Renal pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tubulointerstitial nephritis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urethral pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Urinary incontinence	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urinary retention	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urinary tract pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Reproductive system and breast disorders										
Benign prostatic hyperplasia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pelvic pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Prostatic haemorrhage	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Prostatomegaly	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Scrotal erythema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Scrotal oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Testicular swelling	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Respiratory, thoracic and mediastinal disorders										
Chronic obstructive pulmonary disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cough	0 (0.00%)	2 (14.29%)	1 (16.67%)	1 (20.00%)	3 (15.79%)	3 (15.79%)	2 (40.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dysphonia	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dyspnoea	0 (0.00%)	2 (14.29%)	1 (16.67%)	0 (0.00%)	6 (31.58%)	6 (31.58%)	1 (20.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)
Dyspnoea exertional	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Epistaxis	1 (16.67%)	1 (7.14%)	2 (33.33%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	1 (25.00%)
Haemoptysis	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Hypoxia	1 (16.67%)	1 (7.14%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Laryngeal inflammation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Laryngeal oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lung infiltration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)
Nasal congestion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (10.53%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oropharyngeal pain	0 (0.00%)	0 (0.00%)	2 (33.33%)	1 (20.00%)	1 (5.26%)	1 (5.26%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Paranasal sinus discomfort	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Paranasal sinus inflammation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pharyngeal erythema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pleural effusion	0 (0.00%)	3 (21.43%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (10.53%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)
Pleuritic pain	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumonitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Productive cough	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pulmonary congestion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pulmonary embolism	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pulmonary mass	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pulmonary oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Respiratory distress	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Respiratory failure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)
Rhinalgia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rhinitis allergic	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rhinorrhoea	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rhonchi	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sinus disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sinus pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tachypnoea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Throat lesion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Upper-airway cough syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	2 (40.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Wheezing	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin and subcutaneous tissue disorders										
Actinic keratosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Acute febrile neutrophilic dermatosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Alopecia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blister	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood blister	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cutaneous vasculitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Decubitus ulcer	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dermatitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Dermatitis acneiform	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Diffuse alopecia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dry skin	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ecchymosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Eczema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Erythema	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperhidrosis	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (10.53%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ingrowing nail	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nail bed inflammation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nail discolouration	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Night sweats	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Onychomadesis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Papule	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Petechiae	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pruritus	1 (16.67%)	1 (7.14%)	1 (16.67%)	1 (20.00%)	0 (0.00%)	4 (21.05%)	1 (20.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)
Purpura	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rash	1 (16.67%)	1 (7.14%)	1 (16.67%)	1 (20.00%)	2 (10.53%)	5 (26.32%)	1 (20.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)
Rash erythematous	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rash macular	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Rash maculo-papular	2 (33.33%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	4 (21.05%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)
Rash papular	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rash pruritic	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Seborrhoeic dermatitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sensitive skin	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin atrophy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin discolouration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin disorder	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin hyperpigmentation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin induration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin irritation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin lesion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (10.53%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin mass	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin ulcer	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urticaria	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)
Vascular disorders										
Aortic arteriosclerosis	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Arteriosclerosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Circulatory collapse	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Deep vein thrombosis	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Embolism	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Flushing	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haematoma	1 (16.67%)	0 (0.00%)	3 (50.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haemorrhage	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hot flush	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypertension	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypotension	0 (0.00%)	1 (7.14%)	1 (16.67%)	0 (0.00%)	1 (5.26%)	1 (5.26%)	1 (20.00%)	1 (20.00%)	1 (20.00%)	0 (0.00%)
Orthostatic hypotension	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pallor	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Peripheral arterial occlusive disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Peripheral embolism	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Phlebitis	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)
Superficial vein thrombosis	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Thrombophlebitis	0 (0.00%)	2 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Thrombosis	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Varicose vein	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Venous thrombosis limb	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Conclusion:

- Sabatolimab was found to be safe and tolerable as a single agent and in combination with HMAs and/or spartalizumab in MDS/AML
- The recommended phase 2 dose (RP2D) for sabatolimab in combination with HMA in AML/MDS was established to be 400 mg Q2W or 800 mg Q4W based on the pharmacokinetics/pharmacodynamics (PK/PD), as well as efficacy and safety results
- Sabatolimab showed encouraging efficacy in combination with HMAs and addresses an unmet medical need
- The safety profile of the sabatolimab in combination with HMAs in general was consistent with the safety profile observed with HMAs alone, with no significant additive hematological toxicity requiring monitoring beyond standard recommendations for HMAs
- The benefit risk profile of sabatolimab + HMA combinations tested in this study were positive supportive of further development in MDS/AML

Date of Clinical Trial Report

6-Aug-2024