NOVARTIS

Clinical Trial Results Summary

A clinical trial to learn more about using vidoflufolastat (18F) to show prostate cancer that likely came back after treatment

Thank you!

Thank you to the participants who took part in the clinical trial for prostate cancer. Every participant helped the researchers learn more about the trial tracer **vidoflufolastat (18F)** or **[18F]CTT1057.**

Novartis sponsored this trial and believes it is important to share what was learned from the results of this trial with the participants and the public. We hope this helps the participants understand their important role in medical research.

Trial information

Trial number: CAAA405A12301

Novartis drug studied: vidoflufolastat (18F), also called [18F]CTT1057

Sponsor: Novartis

If you were a participant and have any questions about the results, please talk to the doctor or staff at the trial site.

This summary only shows the results of a single clinical trial. Other clinical trials may have different results.

What was the main purpose of this trial?

The purpose of this trial was to learn how well the trial tracer **vidoflufolastat (18F)** can show prostate cancer cells on **PET (positron emission tomography)** scan images in people whose prostate cancer likely came back after treatment. Everyone in this trial had prostate cancer that likely came back based on higher levels of **prostate-specific antigen (PSA)** on blood test results. PSA is a protein made in the prostate. This trial also learned about the safety of **vidoflufolastat (18F)**.

One way to confirm if prostate cancer came back, and where in the body, is to do imaging tests, such as a CT scan, bone scan, or PET scan. A PET scan using a radioactive tracer can be the best option to find cancer cells when tumors are very small. It is important for doctors to find all cancer cells that come back to decide on treatment options. To learn how well **vidoflufolastat (18F)** showed prostate cancer cells, researchers compared it to results from CT scans and PET scans using another tracer called **gallium (68Ga) gozetotide**.

Prostate cancer is cancer that starts in the prostate. The prostate is the organ in men that makes a fluid that mixes with sperm to make semen. Most prostate cancer cells have a protein on the surface called **prostate-specific membrane antigen**, or **PSMA**.

A **radioactive tracer** is a substance with a small amount of radioactivity attached to it. Doctors use a radioactive tracer with imaging tests to look at cells and activity in the body. After the tracer is injected into the blood, it travels through the body and attaches to cancer cells. The tracer gives off radioactive signals that the imaging test picks up to show cancer cells in scan images.

Vidoflufolastat (18F), also called **[18F]CTT1057**, is a trial radioactive tracer that attaches to PSMA on prostate cancer cells.

Gallium (68Ga) gozetotide is a radioactive tracer that attaches to PSMA. It is approved in some countries to be used in PET scans to show prostate cancer cells.

PET (positron emission tomography) is an imaging test (scan) that can show cells in the body that the radioactive tracer attached to. This can help doctors find specific cells, like cancer cells.

Trial tracer
Vidoflufolastat (18F), also called [18F]CTT1057

Pronounced as
vi-DO-flu-foh-la-stat 18F

The trial's purpose was to answer these main questions:

- How well did vidoflufolastat (18F), show prostate cancer cells that came back after treatment on PET scan images?
- What medical problems, also called adverse events, happened during this trial?

  ↳ An **adverse event** is any sign or symptom that participants have during a trial. Adverse events **may** or **may not** be caused by treatments in the trial.

How long was this trial?

The trial began in September 2021 and ended in November 2023. Each participant was in the trial for about 5 months.

Who was in this trial?

190 men whose prostate cancer likely came back were in this trial. Participants' ages ranged from 26 to 85 years. Their average age was 67 years.

The number of participants by race is shown below.

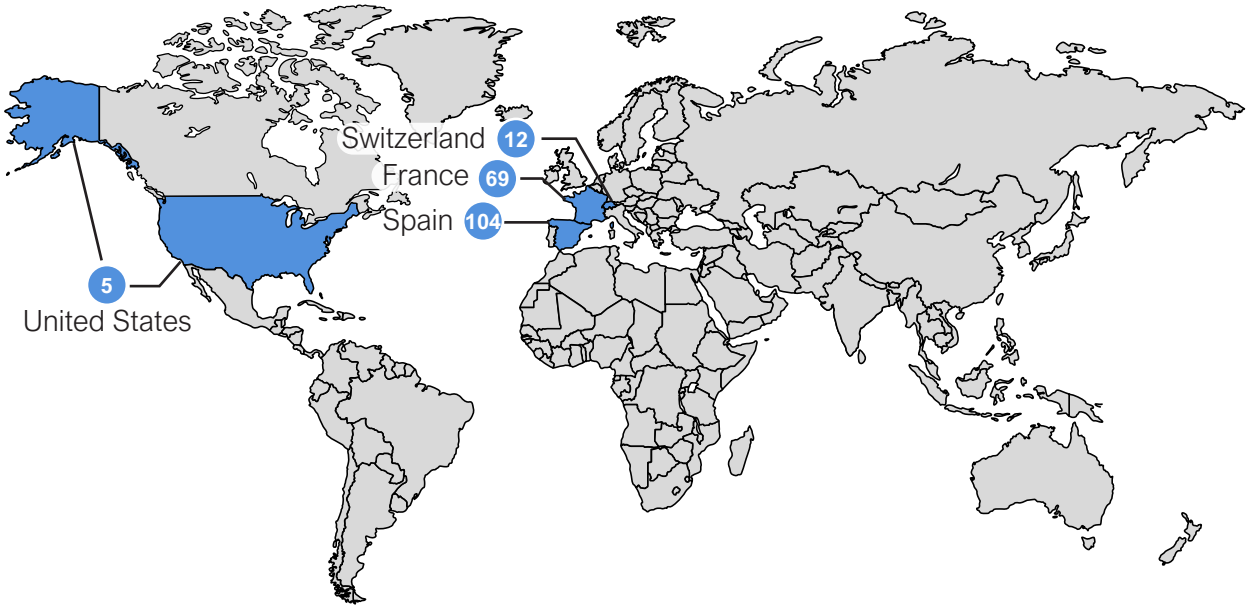
Race

2 Asian	4 Black or African American
180 White	4 Not reported

The participants could take part in this trial if they:

- Had prostate cancer that likely came back based on higher levels of PSA on blood tests
- Had not had surgery, other than to remove the prostate, in the previous 3 months
- Had not received hormone therapy to treat prostate cancer (also called androgen-deprivation therapy) up to 9 months before joining the trial

190 participants from 4 countries were in this trial. The map below shows the number of participants who took part in each country.



What tracers did the participants receive?

The tracers in this trial were:

- **Vidoflufolastat (18F)**, also called [18F]CTT1057, which was received as an injection in a vein.
- **Gallium (68Ga) gozetotide**, which was also received as an injection in a vein.

Researchers used a computer to randomly assign participants to receive one of the tracers first and the other tracer 2 weeks later.

The participants, researchers, and trial staff knew what tracers each participant received.

What happened during this trial?

Before PET imaging — Up to 1 month

Trial staff checked to make sure the participants could be in this trial. 11 participants left the trial before receiving any tracer.

During PET imaging — Up to 1 month

179 participants received one of these tracers, or both tracers 2 weeks apart. Participants may have only received one tracer, such as if they decided to leave the trial early:

- **Vidoflufolastat (18F)** and **gallium (68Ga) gozetotide**: 170 participants
- **Vidoflufolastat (18F)** only: 1 participant
- **Gallium (68Ga) gozetotide** only: 8 participants

About 1 to 2 hours after receiving each tracer, participants had PET scans.

After PET imaging — Up to 3 months

Trial staff checked participants for:

- Any medical problems for up to 2 weeks after their last tracer injection
- Prostate cancer using different tests, such as CT scans. If the trial doctor did surgery to remove or sample a prostate tumor up to 2 months after receiving **vidoflufolastat (18F)**, researchers also looked at those results.

Trial staff checked the participants' general health throughout the trial.

What were the main results of this trial?

How well did vidoflufolastat (18F) show prostate cancer cells that came back after treatment on PET scan images?

PET scan images with **vidoflufolastat (18F)** correctly showed prostate cancer cells in:

- 67% to 73% of areas that had prostate cancer cells based on other tests
- 67% to 75% of participants who had prostate cancer cells based on other tests

To learn this, **3 experts in PET scans** who were not part of the trial team looked at the images of **vidoflufolastat (18F)** PET scan for each participant. They recorded if they saw prostate cancer cells or not. Then, researchers compared the findings reported by each PET expert to results from other tests that showed prostate cancer.

The other test results included:

- Results from surgery to remove or sample prostate cancer, if any happened within 2 months of the **vidoflufolastat (18F)** PET scan
- Scan images, including PET scan images using **gallium (68Ga) gozetotide** and CT scans

In this trial, researchers calculated:

- **The percent of areas** that had prostate cancer cells correctly shown on PET scan images with **vidoflufolastat (18F)** out of all areas that had prostate cancer cells based on other tests
- **The percent of participants** who had prostate cancer cells correctly shown on PET scan images with **vidoflufolastat (18F)** out of all participants who had prostate cancer cells based on other tests

How well vidoflufolastat (18F) showed prostate cancer cells that came back after treatment based on results from PET experts

This table includes 161 participants who had results available.

	PET expert 1 vidoflufolastat (18F)	PET expert 2 vidoflufolastat (18F)	PET expert 3 vidoflufolastat (18F)
The percent of areas that had prostate cancer cells correctly shown on PET scan images with **vidoflufolastat (18F)** out of all areas that had prostate cancer cells based on other tests	68%	73%	67%
The percent of participants who had prostate cancer cells correctly shown on PET scan images with **vidoflufolastat (18F)** out of all participants who had prostate cancer cells based on other tests	68%	75%	67%

What medical problems, also called adverse events, happened during this trial?

Trial doctors keep track of all medical problems called **adverse events** that happen in trials, even if they think the adverse events are not related to the trial treatments.

Many trials are needed to know if a drug or treatment causes an adverse event.

This section is a summary of the adverse events that happened from the injection of the first tracer until 2 weeks after the injection of the last tracer.

An **adverse event** is:

- Any **sign or symptom** that the participants have during a trial
- Considered **serious** when it is life-threatening, causes lasting problems, the participant needs hospital care, or results in death

Adverse events **may** or **may not** be caused by treatments in the trial.

20 of 171 (12%) participants who received **vidoflufolastat (18F)** and 16 of 178 (9%) participants who received **gallium (68Ga) gozetotide** had adverse events within the 2 weeks after tracer injection. 1 participant had an adverse event that was considered serious. No participant left the trial due to an adverse event. No participants died. The researchers concluded there were no safety concerns for **vidoflufolastat (18F)** in this trial.

How many participants had adverse events?

	vidoflufolastat (18F) 171 participants	gallium (68Ga) gozetotide 178 participants
Had at least 1 **serious adverse event**	1 of 171 1%	0 of 178 0%
Had at least 1 **other adverse event**	20 of 171 12%	16 of 178 9%

What serious adverse events did the participants have?

1 participant had a serious adverse event within 2 weeks after receiving **vidoflufolastat (18F)**:

- **Trouble breathing** (dyspnea)

No other participants had serious adverse events.

What other adverse events did the participants have?

20 of 171 participants had other adverse events after receiving **vidoflufolastat (18F)**, and 16 of 178 participants had other adverse events after receiving **gallium (68Ga) gozetotide**.

The table below shows the other adverse events that happened in **2 or more** participants within 2 weeks after the injection of each tracer. Additional adverse events happened in fewer participants.

	vidoflufolastat (18F) 171 participants	gallium (68Ga) gozetotide 178 participants
Feeling weak or not having energy Asthenia	5 of 171 3%	0 of 178 0%
Possible sign of pancreas damage Lipase increased	3 of 171 2%	0 of 178 0%
COVID-19	2 of 171 1%	1 of 178 1%
High blood pressure Hypertension	0 of 171 0%	2 of 178 1%
Possible sign of pancreas damage Amylase increased	2 of 171 1%	0 of 178 0%

What was learned from this trial?

Researchers learned how well **vidoflufolastat (18F)** can correctly show prostate cancer cells in PET scan images in people whose prostate cancer likely came back after treatment. They also learned about the safety of **vidoflufolastat (18F)**.

The researchers concluded that:

- **Vidoflufolastat (18F)** correctly showed prostate cancer cells on PET scan images in 67% to 73% of areas
- **Vidoflufolastat (18F)** correctly showed prostate cancer cells on PET scan images in 67% to 75% of participants
- There were no safety concerns for **vidoflufolastat (18F)** in this trial

When this summary was written, the sponsor was considering next steps for the clinical development of **vidoflufolastat (18F)** in people with prostate cancer.

Where can I learn more about this trial?

More information about the results and adverse events in this trial can be found in the scientific summary of the results available on the Novartis Clinical Trial Results website **www.novctrd.com**

Follow these steps to find the scientific summary:

Go to **www.novctrd.com** → Click **Clinical Trial Results** → Accept the terms ☑ **I Accept** → Search for study number **CAAA405A12301**

For more information about this trial, go to any of these websites:

- clinicaltrials.gov – search using the number **NCT04838613**
- clinicaltrialsregister.eu – search using the number **2020-003959-16**

Other trials of **vidoflufolastat (18F)** may appear on the public websites above. When there, search for **vidoflufolastat (18F)**, AAA405, or [18F]CTT1057.

Full clinical trial title: Phase III study for evaluation of the diagnostic performance of [18F]CTT1057 PET imaging in patients with prostate cancer with rising PSA levels [biochemical recurrence (BCR)]

Novartis is a global healthcare company based in Switzerland that provides solutions to address the evolving needs of patients worldwide.

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