NOVARTIS

Clinical Trial Results Summary

A clinical trial to learn more about using vidoflufolastat (18F) to show prostate cancer cells in PET scan images

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)**, also called **[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: CAAA405A12302

Novartis tracer 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 **vidoflufolastat (18F)** can show prostate cancer cells on PET scan images in people with prostate cancer. It also learned about the safety of **vidoflufolastat (18F)**.

One way to find cancer cells is to use an imaging test, such as PET with a radioactive tracer. However, current radioactive tracers may not correctly show all cancer cells in and around the prostate or in other parts of the body. It is important for doctors to find all cancer cells to decide on treatment options.

Prostate cancer is cancer that starts in the prostate. The prostate is the organ in men that makes the 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 (and tumors) in scan images.

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

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 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.

How long was this trial?

The trial began in September 2021 and ended in November 2023. Each participant was in the trial for about 3 months.

Who was in this trial?

195 men with prostate cancer were in the trial. Their ages ranged from 46 to 77 years. Their average age was 65 years.
The number of participants by race is shown below.

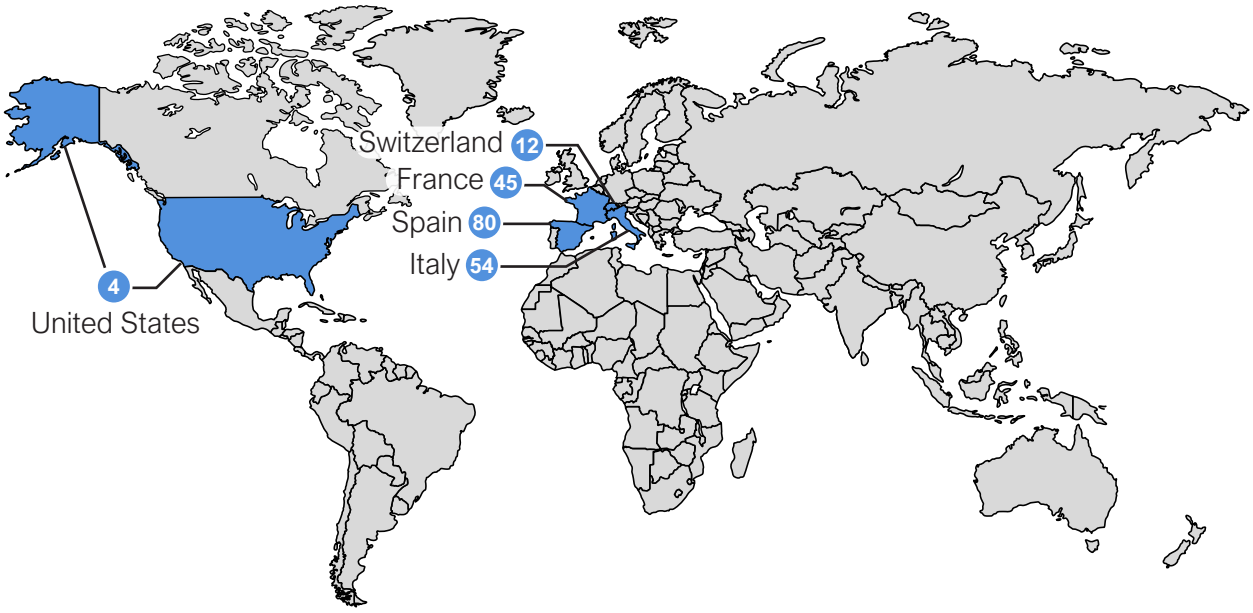
Race

1	Asian
192	White
2	Not reported

The participants could take part in this trial if they:

- Had recently been diagnosed with prostate cancer that had a high chance of spreading
- Were scheduled to have surgery to remove prostate cancer within 6 weeks after they would receive the trial tracer
- Had not received other treatments for prostate cancer

Trial participants were from 5 countries. The map below shows the number of participants who took part in each country.



What trial tracer did the participants receive?

The trial radioactive tracer was:

Vidoflufolastat (18F), also called [18F]CTT1057, which was received through an injection in a vein.

Each participant was going to have surgery to remove prostate cancer as part of their standard care.

The participants, researchers, and trial staff knew the trial tracer that each participant received. All participants received **vidoflufolastat (18F)**.

What happened during this trial?

Before 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 **vidoflufolastat (18F)**.

During imaging — **1 dose**

184 participants received 1 injection of **vidoflufolastat (18F)** into a vein in the arm. Each participant had a PET scan one and a half hours after receiving the trial tracer.

After imaging — **Up to 6 weeks**

Up to 2 weeks after the injection of **vidoflufolastat (18F)**, trial staff checked the participant for any medical problems.

Up to 6 weeks after imaging, all participants had surgery to remove prostate cancer as part of their standard care. During surgery, trial staff took tissue samples to check for cancer cells.

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 on PET scan images?

Based on tissues removed during surgery, PET scan images with **vidoflufolastat (18F)** correctly showed:

- Prostate cancer cells in 87% to 90% of participants
- Areas that had no cancer cells in 97% of participants

To learn this, **3 experts in PET scans** who were not part of the trial team looked at each participant's images and recorded if they saw cancer cells or not. Then, researchers compared the findings of each PET expert to the results from tissues removed during surgery.

In this trial, researchers calculated:

- **Sensitivity**, which is how well **vidoflufolastat (18F)** **correctly showed prostate cancer cells** on images compared to results from tissues removed during surgery
- **Specificity**, which is how well **vidoflufolastat (18F)** correctly showed **areas that had no cancer cells** compared to results from tissues removed during surgery

Sensitivity and specificity of vidoflufolastat (18F) based on the findings of each PET expert

This table includes the 172 participants who had a PET scan and results from tissues removed during surgery.

	PET expert 1 Vidoflufolastat (18F)	PET expert 2 Vidoflufolastat (18F)	PET expert 3 Vidoflufolastat (18F)
Sensitivity Percent of participants whose **vidoflufolastat (18F)** scans correctly showed prostate cancer cells on images out of participants who had cancer cells in tissues removed during surgery	87%	90%	87%
Specificity Percent of participants whose **vidoflufolastat (18F)** scans correctly showed areas that had no cancer cells on images out of participants who had no cancer cells in tissues removed during surgery	97%	97%	97%

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 **vidoflufolastat (18F)** until 2 weeks after the injection.

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.

2 of 184 participants had adverse events that were considered serious, and 23 participants had other adverse events. The 2 participants with serious adverse events left the trial due to these adverse events. No participants died. The researchers concluded there were no new safety concerns for **vidoflufolastat (18F)** in this trial.

How many participants had adverse events?

Participants who:	Vidoflufolastat (18F) 184 participants
Had at least 1 **serious adverse event**	2 of 184
Had at least 1 **other adverse event**	23 of 184
Left the trial due to an adverse event	2 of 184

What serious adverse events did the participants have?

2 participants had serious adverse events. The serious adverse events were:

- **Not enough blood flows to the heart** (myocardial ischemia)
- **Life-threatening infection** (sepsis syndrome)

What other adverse events did the participants have?

23 participants had other adverse events.

The table below shows the other adverse events that happened in **2 or more** participants. Additional adverse events happened in fewer participants.

	Vidoflufolastat (18F) 184 participants	
High blood pressure Hypertension	**5 of 184**	**3%**
Feeling dizzy Dizziness	**2 of 184**	**1%**
The feeling of being about to faint Presyncope	**2 of 184**	**1%**

What was learned from this trial?

Researchers learned how well **vidoflufolastat (18F)** can correctly show prostate cancer cells with PMSA in PET scan images in people with prostate cancer. They also learned about the safety of **vidoflufolastat (18F)**.

The researchers concluded that:

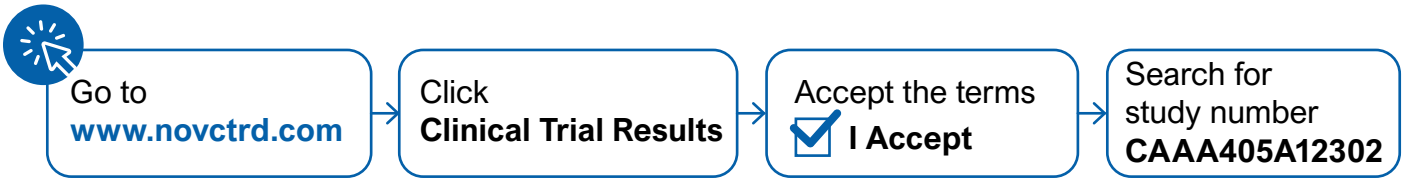
- **Vidoflufolastat (18F)** could show prostate cancer cells on participants' PET scan images
- There were no new safety concerns for **vidoflufolastat (18F)** in this trial

When this summary was written, the sponsor was considering next steps for the clinical program 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:



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

- **clinicaltrials.gov** – search using the number **NCT04838626**
- **clinicaltrialsregister.eu** – search using the number **2020-003958-67**

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 II/III study for evaluation of the diagnostic performance of [18F]CTT1057 PET imaging for the detection of PSMA positive tumors using histopathology as a standard of truth

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1-888-669-6682 (US) | +41-61-324 1111 (EU)

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