



# PLAIN LANGUAGE SUMMARY OF CLINICAL STUDY RESULTS

**Study Sponsor:** Gilead Sciences

**Gilead Study Number:** GS-US-611-6464

**Date of Study:** December 2023 to February 2024 (the study closed earlier than planned)

**Short Study Title:** Study of Obeldesivir in Children and Adolescents With COVID-19

**Date of this Plain Language Summary:** August 2024

The information in this summary does not include any information available after this date.

## Thank you

Thank you to the participants who contributed to the clinical study for **obeldesivir**, also known as **GS-5245**. In addition, thank you to the parents and caregivers of the participants.

Gilead Sciences sponsored this study. We believe it is important to share the results with study participants and the general public.

If you participated in the study and have questions about the results, please speak with a doctor or staff member at the study site.

Always talk to a doctor or a healthcare provider before making any treatment changes.



## What was the purpose of the study?

The study was to learn more about obeldesivir in children and adolescents (pediatric participants) below 18 years of age.

The purpose of the study was to find out how safe and effective obeldesivir was in these participants who had **risk factors** of becoming very sick from COVID-19. The researchers also wanted to see how the study drug obeldesivir was taken up, broken down, and removed from the body of the participants.



### Some examples of **risk factors** included:

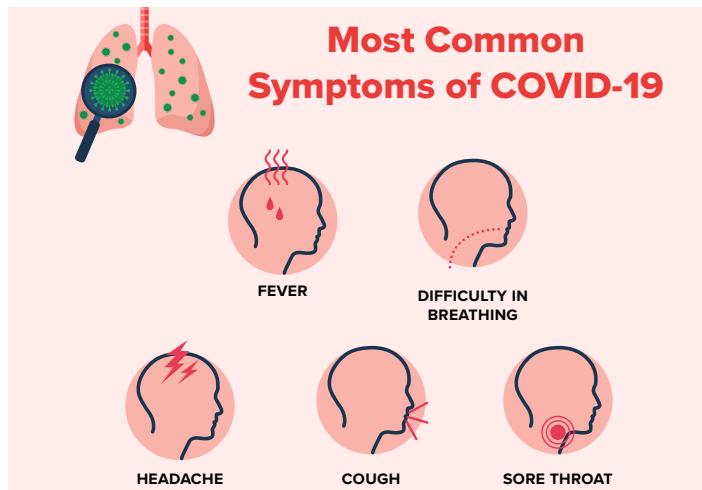
- Overweight or obesity
- Diabetes (a condition with increased amount of sugar in the blood)
- Heart, kidney, liver, or lung-related conditions
- Weakened immune system
- Brain-related disorders
- Birth defects
- Other medical conditions

## What is COVID-19?

COVID-19 is a respiratory disease caused by a virus called severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2). The virus was the cause of the spread of COVID-19 disease around the world starting in late 2019. COVID-19 may affect the lungs and multiple other organs. The symptoms can be mild to very bad and may even lead to death in some people. The most common symptoms are shown below. Some other symptoms may include muscle or body aches, extreme tiredness, runny nose, feeling sick to the stomach (nausea), vomiting and diarrhea. COVID-19 has caused millions of deaths worldwide. It can affect people of all ages.

Currently, there are very few treatment options available for COVID-19 in children. Some options are available in the injection form. This may require going to a hospital or staying there for a few days to get the medicine as a slow injection into a vein (intravenous infusion). So, there is a need for a treatment that can be taken orally (by mouth) at home which can help children and adolescents with COVID-19.

Obeldesivir is a pill (tablet). In this study, the researchers wanted to check if obeldesivir could be a treatment option for COVID-19 in children and adolescents.



### The main questions the researchers wanted to answer in this study were:

- How much obeldesivir **breakdown product** was found in participants' blood after taking the medicine?
- How many participants had unwanted medical events during the study, if any?
- How many participants had **abnormalities in their laboratory test results** during the study?
- What side effects did participants have during the study, if any?



**Breakdown product:** The substance formed after the drug breaks down in the body.

**Abnormalities in laboratory test results:** Test results that fall outside the normal range.



## Who took part in the study?

The study was planned to enroll at least 52 participants in different parts of the world. However, only 3 participants from the United States were enrolled since the study was stopped early.

Pediatric participants took part in the study if they:



Were less than 18 years of age and met the required criteria for weight



Had a positive COVID-19 test result



Had one or more risk factors that could increase the chance of getting very sick from COVID-19

All 3 participants that enrolled in the study were male, white, and of Hispanic or Latino ethnicity.

### Participant breakdown by age Number (%) of participants



**Children**  
(6 to less than 12 years of age)

**2 (67%) participants**



**Adolescents**  
(12 to less than 18 years of age)

**1 (33%) participant**



## What happened during the study?

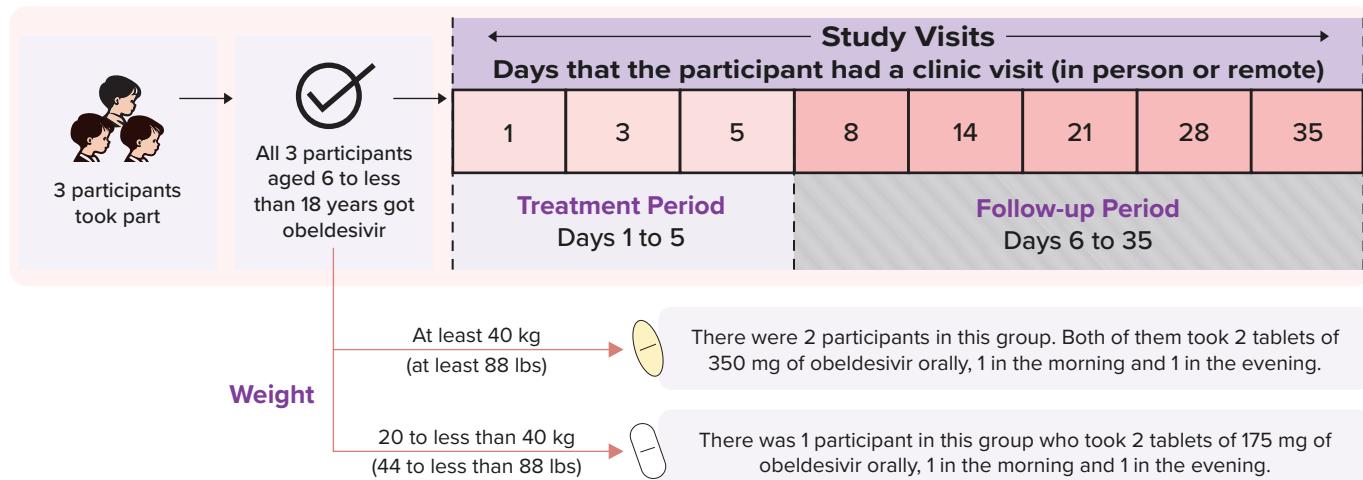
This was a **single-arm, open-label** study.



**Single-arm:** This means all participants received the same drug, obeldesivir.

**Open-label:** This means the participant's parent or caregiver, doctors, and study staff knew the treatment the participants took.

The figure below shows how the study was done.



The study planned to include 52 participants in 7 groups based on their age and weight. However, the study was stopped early after the enrollment of 3 participants in 2 groups. The decision to stop the study early was not because of safety concerns or how obeldesivir worked.

Gilead chose to stop the enrollment early because the other 2 obeldesivir studies in the adult participants did not meet their main goals. However, obeldesivir was safe, well-tolerated, and reduced the levels of virus in the blood of participants in both the studies.



## What were the results of the study?

This is a summary of the main results of this study. The individual results of each participant might be different and are not present in this summary. A detailed presentation of the results can be found on the websites listed at the end of this summary.

### How much obeldesivir breakdown product was found in participants' blood after taking the medicine?

As the study was stopped early, there was not enough information for researchers to make any conclusions.

### How many participants had unwanted medical events during the study, if any?

None of the participants had any serious or any other **unwanted medical events** during the study.

An **unwanted medical event** is any unwanted sign or symptom that participants may have during the study. This may or may not be caused by the study treatment.



#### An unwanted medical event is considered “serious” if it:

- results in death
- is life-threatening
- is considered by the study doctor to be medically important
- causes lasting problems
- requires hospital care
- causes a birth defect

### How many participants had abnormalities in their laboratory test results during the study?



The researchers did laboratory tests in participants before and after taking obeldesivir. They checked if the changes in laboratory test values were abnormal, meaning they were out of the normal range.

None of the participants had any laboratory test abnormalities during the study.



## What side effects did the participants have during the study?

None of the participants had any **side effects**, or stopped treatment or died because of any side effects, during the study.

Unwanted medical events can happen to the study participants when they take study treatments. In this summary, “**side effects**” are defined as unwanted medical events that the study doctors thought might be caused by the study treatment.

The results from several studies are usually needed to help decide if a treatment actually causes a side effect.

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## How has this study helped researchers?

The researchers learned about the safety of obeldesivir in the enrolled pediatric participants.

The results from several studies are needed to help decide which treatments work and are safe. This summary shows only the main results from this one study with only 3 participants. Other studies may provide new information or different results.

Gilead Sciences plans to have more clinical studies with obeldesivir in other types of viral infections.



## Where can I learn more about this study?

You can find more information about this study on the websites listed below.

Organization (Website)	Study Identifier
Europe Medicines Agency ( <a href="https://euclinicaltrials.eu">euclinicaltrials.eu</a> )	EU CT number <a href="#">2023-503282-27</a>
United States National Institutes of Health (NIH) ( <a href="https://www.clinicaltrials.gov">www.clinicaltrials.gov</a> )	ClinicalTrials.gov ID <a href="#">NCT05996744</a>
<a href="https://www.gileadclinicaltrials.com">www.gileadclinicaltrials.com</a>	<a href="#">GS-US-611-6464</a>

Please note that information on these websites may be presented in a different way from this summary.

**Full Study Title:** A Phase 2/3 Single-Arm, Open-label Study to Evaluate the Safety, Pharmacokinetics and Efficacy of Obeldesivir in Pediatric Participants With COVID-19

To learn more about clinical trials in general, please visit this [page](#) on [www.clinicaltrials.gov](https://www.clinicaltrials.gov) website

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## Thank you

Clinical study participants belong to a large community of people who take part in clinical research around the world. They help researchers answer important health questions and find medical treatments for patients.

