Clinical Study Results

This summary reports the results of only one study. Researchers must look at the results of many types of studies to understand if a study medication works, how it works, and if it is safe to prescribe to patients. The results of this study might be different than the results of other studies that the researchers review.

Sponsor: Pfizer Inc.

Vaccine Studied: Meningococcal group B vaccine (Trumenba®)

Protocol Number: B1971060

Dates of Study: 18 August 2021 to 06 September 2023

Title of this Study: Trial to Describe the Safety, Tolerability, and Immunogenicity of Trumenba® When Administered to Immunocompromised Participants ≥10 Years of Age

[A Phase 4, Open-Label, Single-Arm Trial to Describe the Safety, Tolerability, and Immunogenicity of Trumenba® When Administered to Immunocompromised Participants ≥10 Years of Age]

Date(s) of this Report: 24 June 2024

– Thank You –

If you or your child participated in this study, Pfizer, the Sponsor, would like to thank you or your child's participation.

This summary will describe the study results. If you or your child have any questions about the study or the results, please contact the doctor or staff at your study site.

Why was this study done?

What does it mean to be immunocompromised?

Being immunocompromised means your immune system isn't working as well as it should. This means you are at increased risk of severe infections caused by germs (bacteria). Conditions of your immune system, such as having your spleen removed, or if your spleen doesn't work properly is known as being 'immunocompromised'.

What is meningococcal disease?

Neisseria meningitidis (or *N. meningitidis*) is a type of germ. Meningococcus is its other name. *N. meningitidis* can cause meningococcal disease. It can cause infections of the blood, as well as inflammation around the brain and spinal cord known as "meningitis." People who get this illness are at risk for death, brain damage, loss of limbs, hearing loss, and other disabilities.

There are different types of *N. meningitidis*. Meningococcal type B disease is caused by the meningococcus B germ. There are different subtypes (strains) of the meningococcus B germ. In this study, the strains called A22, A56, B24, and B44 were looked at.

What is a vaccine and an antibody?

A vaccine can help prevent an infection or a disease. It works by helping the body fight off germs.

Antibodies are proteins that fight infections and help prevent diseases. After a person gets a vaccine, the body's response includes making antibodies. This is called an antibody response or immune response.

What is Trumenba®?

Trumenba (tru-men-bah) is a vaccine against the meningococcal germ type B. It works by helping the body to make antibodies to fight off the germ. Trumenba is given by injection.

What was the purpose of this study?

- This study aimed to collect additional data on the use of the licensed Trumenba vaccine for immunocompromised participants.
- The researchers wanted to find out about the safety of the Trumenba vaccine for immunocompromised adolescents and adults.
- Researchers also wanted to see whether Trumenba helped the body make antibodies to fight off the germ that causes meningococcal type B disease. This is called an antibody response or an immune response.

Researchers wanted to know:

How many participants had an immune response 1 month after Vaccination 2?

Did participants have any local reactions (redness, swelling, or pain) at the injection site within 7 days after Vaccination 1 or Vaccination 2?

Did participants have any systemic events (high temperature or fever, tiredness, headache, chills, vomiting, diarrhea, muscle pain, or joint pain) within 7 days after Vaccination 1 or Vaccination 2?

Did participants require any medication for a fever or pain within 7 days after Vaccination 1 or Vaccination 2?

What medical problems did participants have during the study?

Did participants have any medical problems that were not serious but required them to visit their doctor or go to a hospital during the study?

Were any participants diagnosed with a new long-term disease or medical condition during the study?

Did participants have any medical problems immediately after being given the vaccine?

Did any participant miss any days from school or work due to medical problems during the vaccination phase (from Vaccination 1 to 1 month after Vaccination 2)?

What happened during the study?

How was the study done?

First, a study doctor checked each participant to make sure they were able to join the study. This is known as a screening.

At the start of the study, the immunocompromised participants received the first Trumenba vaccine dose (Vaccination 1). Approximately 6 months later, participants received the second Trumenba vaccine dose (Vaccination 2).

During the study, the participants visited the study site 4 times. They visited twice to be vaccinated, and for a follow-up visit 1 month after each vaccination visit. They also received a telephone follow-up call 6 months after Vaccination 2. Researchers checked the participants' health during the study and asked them how they were feeling.

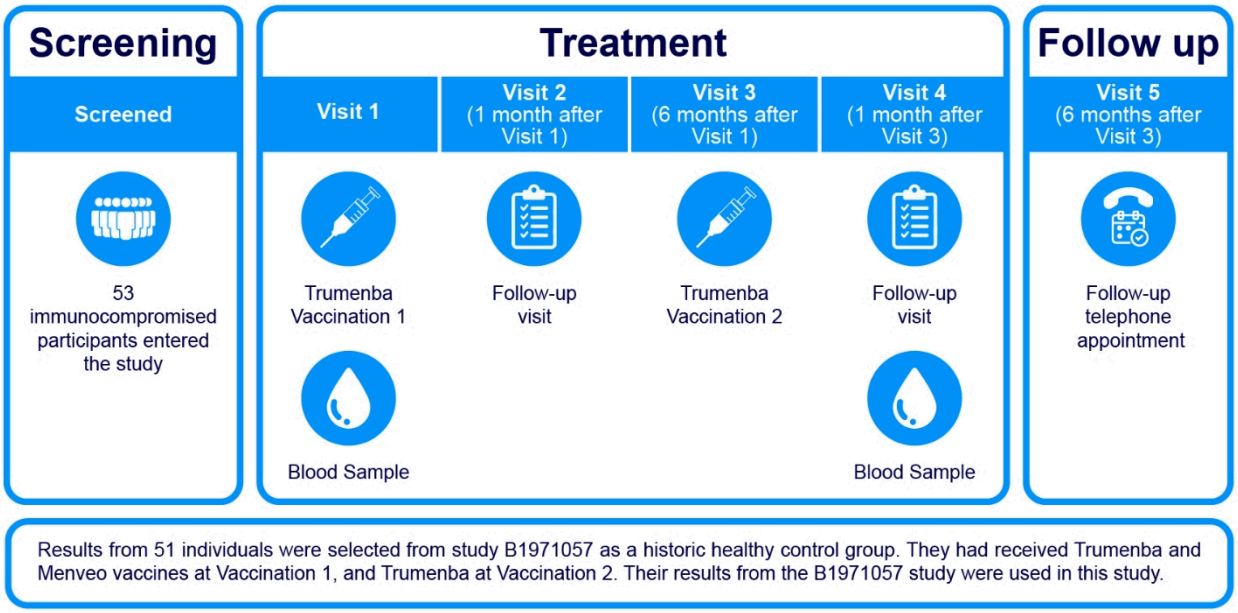
A group of healthy individuals who were not immunocompromised were selected for a comparison ("control") group. The researchers called this group the "historic healthy controls." These individuals did not actually take part in this study. They had been participants in an earlier study, B1971057. They had received their vaccinations in that study and their results from that study were used for comparison.

- Historic healthy controls were selected by chance from the B1971057 study, from participants who matched the gender and/or age of the immunocompromised participants in the present study. The historic healthy controls had received 2 doses of Trumenba 6 months apart, similar to the B1971060 study (immunocompromised participants). The historic healthy controls had also received a vaccine called Menveo at Vaccination 1. The Menveo vaccine is a licensed vaccine that is given as a single dose. It is used to protect against meningococcus types A, C, W, and Y but not type B.

The B1971057 study (historic healthy controls) took place before the COVID-19 pandemic. The study in this report, the B1971060 study (immunocompromised participants), took place during the COVID-19 pandemic.

A diagram showing what happened in this study is provided in Figure 1.

Figure 1. B1971060 Study Plan



The study participants and researchers knew what vaccine the participants received. This is known as an "open-label" study.

Where did this study take place?

The Sponsor ran this study at 10 locations in the Czech Republic, Poland, and Turkey.

When did this study take place?

It began on 18 August 2021 and ended on 06 September 2023.

Who participated in this study?

The study included participants who were immunocompromised and who did not receive prior meningococcal type B vaccine. Some participants had no spleen, or their spleen did not function. The spleen is an organ that fights invading germs in the blood. Some participants were missing some

proteins called “complement proteins” that usually help the immune system to work.

- A total of 30 men and boys participated
- A total of 23 women and girls participated
- All participants were between the ages of 10 and 69 years

In the historic healthy control group, a total of 30 men and boys and 21 women and girls participated; all participants were between the ages of 10 and 25 years.

Of the 53 immunocompromised participants who started this study, 53 (100%) received Vaccination 1 and 47 (88.7%) received Vaccination 2.

A total of 6 participants did not finish the study.

- Four participants left before the study was over by their choice or a doctor decided it was best for a participant to stop being in the study
- One participant could not be contacted
- One participant died

Of the 51 historic healthy controls, 51 (100%) had received Vaccination 1 and 47 (92.2%) had received Vaccination 2 in their study.

How long did the study last?

Study participants were in the study for around 12 months. The entire study took around 2 years to complete.

When the study ended in September 2023, the Sponsor began reviewing the information collected. The Sponsor then created a report of the results. This is a summary of that report.

What were the results of the study?

Researchers wanted to know if participants had an immune response to the 4 strains of meningococcal germs after Vaccination 2. To do this, the researchers collected blood samples from participants during the study. Then they measured the amount of antibody in these blood samples.

Researchers also wanted to know about the overall safety of the vaccine during the study. To do this, the researchers asked participants to keep a diary and record any symptoms they may have had for 7 days after each vaccination. This included details of how they were feeling, if there were any local reactions or systemic events, or if the participant had to take medication for fever or pain.

- A local reaction is something that happens around the skin area where the needle was inserted when giving the vaccine. This includes redness, swelling, and pain at the injection site.
- A systemic event is a reaction that is felt in the body as a whole. This can include things like fever, tiredness, headache, chills, vomiting, diarrhea, muscle pain, and joint pain.

The researchers also wanted to know if the participants had any medical problems during the study. Medical problems are discussed in the next section of this document.

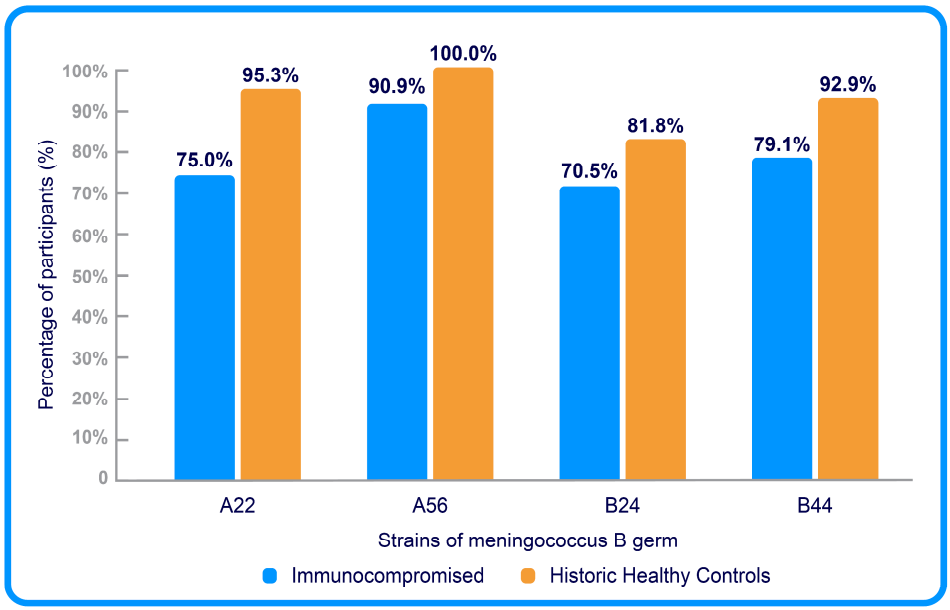
How many participants had an immune response 1 month after Vaccination 2?

Researchers looked at how many participants had an immune response to each strain of meningococcal germs. They measured the immune response 1 month after Vaccination 2.

The results are shown in Figure 2. One month after Vaccination 2, the numbers of participants with an immune response were:

- Between 31 out of 44 (70.5%) and 40 out of 44 (90.9%) immunocompromised participants.
- Between 36 out of 44 (81.8%) and 44 out of 44 (100%) historic healthy controls.

Figure 2. Percentage of participants with an immune response 1 month after Vaccination 2

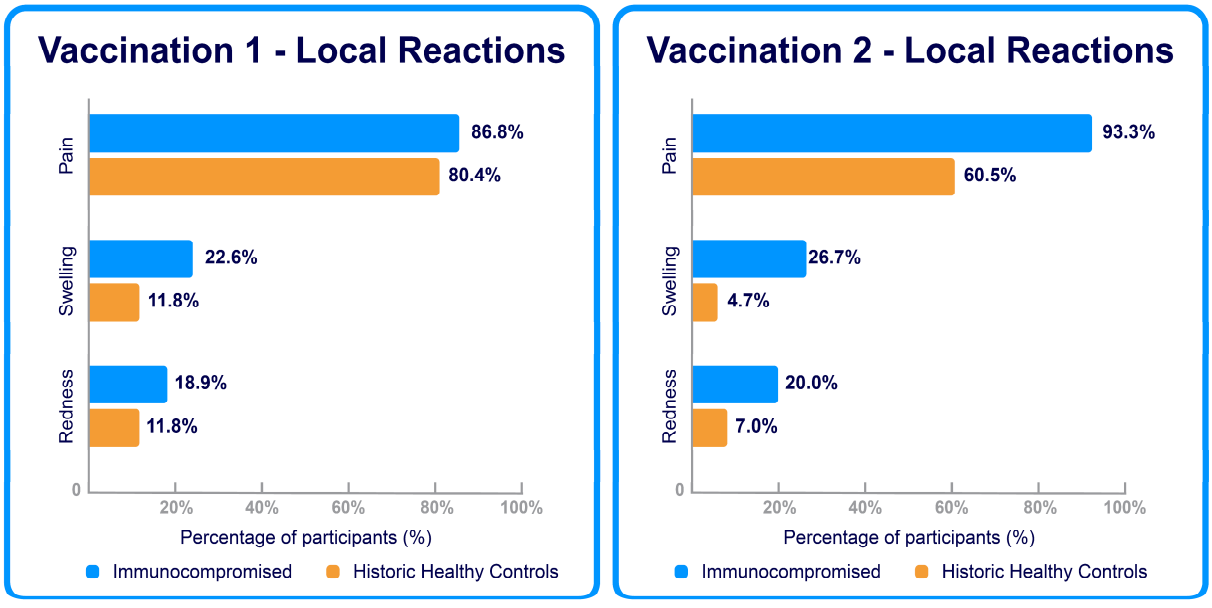


Did participants have any local reactions (redness, swelling, or pain) at the injection site within 7 days after Vaccination 1 or Vaccination 2?

The researchers looked at diary entries from the participants in the study. They counted how many participants had local reactions at the injection site within 7 days after Vaccination 1 and Vaccination 2.

The results are shown in Figure 3. The most common local reaction was pain, reported by 46 out of 53 (86.8%) immunocompromised participants and 41 out of 51 (80.4%) of historic healthy controls within 7 days after Vaccination 1. Pain was reported by 42 out of 45 (93.3%) immunocompromised participants and 26 out of 43 (60.5%) of historic healthy controls within 7 days after Vaccination 2.

Figure 3. Percentage of participants who had local reactions within 7 days after Vaccination 1 or Vaccination 2



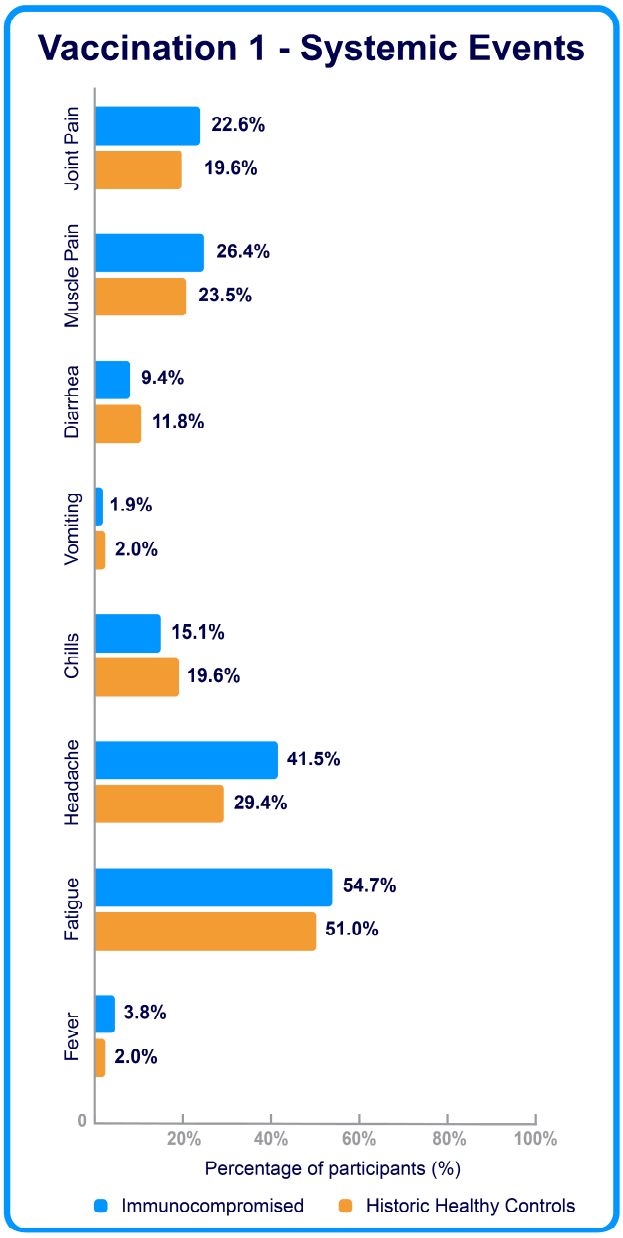
Did participants have any systemic events (high temperature or fever, tiredness, headache, chills, vomiting, diarrhea, muscle pain, or joint pain) within 7 days after Vaccination 1 or Vaccination 2?

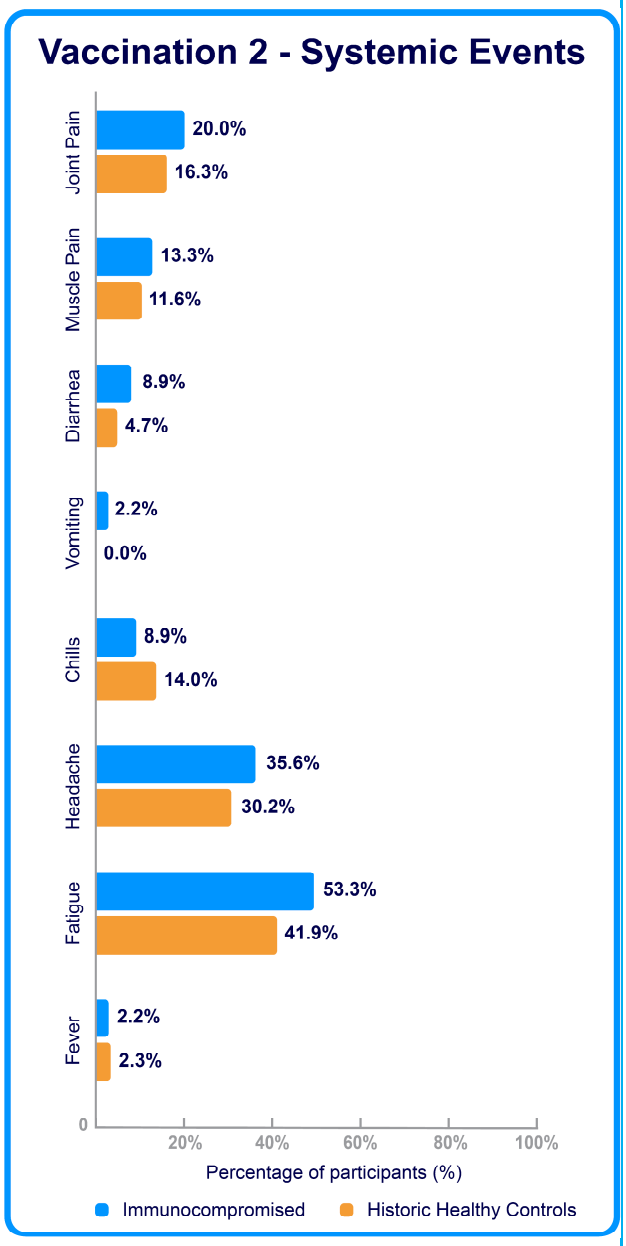
The researchers looked at diary entries from the participants in the study to see how many participants had systemic events within 7 days after Vaccination 1 or Vaccination 2.

The results are shown in Figure 4. The most common systemic events were:

- Fatigue, reported by 29 out of 53 (54.7%) immunocompromised participants and 26 out of 51 (51.0%) historic healthy controls within 7 days after Vaccination 1. Fatigue was reported by 24 out of 45 (53.3%) immunocompromised participants and 18 out of 43 (41.9%) historic healthy controls within 7 days after Vaccination 2.
- Headache, reported by 22 out of 53 (41.5%) immunocompromised participants and 15 out of 51 (29.4%) historic healthy controls within 7 days after Vaccination 1. Headache was reported by 16 out of 45 (35.6%) immunocompromised participants and 13 out of 43 (30.2%) of historic healthy controls within 7 days after Vaccination 2.

Figure 4. Percentage of participants who had systemic events within 7 days after Vaccination 1 or Vaccination 2



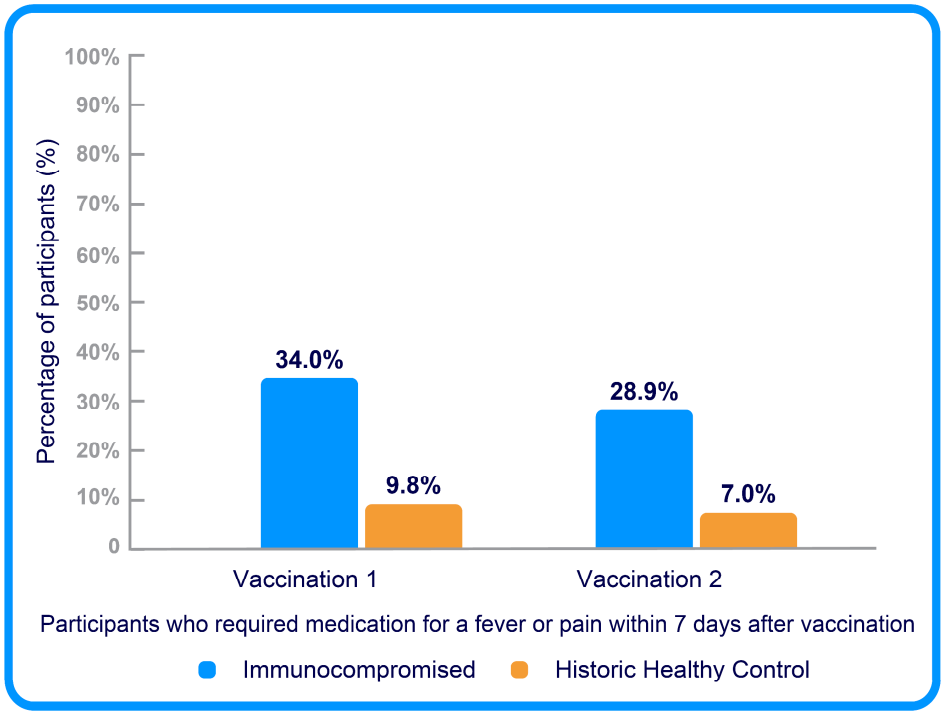


Did participants require any medication for a fever within 7 days after Vaccination 1 or Vaccination 2?

The researchers looked at diary entries from the participants in the study to see how many participants had taken any medication for a fever within 7 days after their vaccinations.

The results are shown in Figure 5. A total of 18 out of 53 (34.0%) immunocompromised participants and 5 out of 51 (9.8%) historic healthy controls required medication for fever or pain within 7 days after Vaccination 1. A total of 13 out of 45 (28.9%) immunocompromised participants and 3 out of 43 (7.0%) historic healthy controls required medication for a fever within 7 days after Vaccination 2.

Figure 5. Percentage of participants who required medication for a fever or pain within 7 days after Vaccination 1 or Vaccination 2



This does not mean that everyone in this study had these results. This is a summary of just some of the main results of this study. Other studies may have different results.

What medical problems did participants have during the study?

The researchers recorded any medical problems the participants had during the study. Participants could have had medical problems for reasons not related to the study (for example, caused by an underlying disease or by chance). Or, medical problems could also have been caused by a study vaccine or by another medicine the participant was taking. Sometimes the cause of a medical problem is unknown. By comparing medical problems across many groups in many studies, doctors try to understand what effects a study medication might have on a participant.

This study with immunocompromised participants took place during the COVID-19 pandemic. The historic healthy control group took part in the B1971057 study that took place before the pandemic. The researchers believe that this may have affected the number of medical problems reported by these 2 groups. The researchers also believe that the immunocompromised participants were more likely to have medical problems because their immune systems did not work as well as the immune systems of the historic healthy controls.

A total of 32 out of 53 (60.4%) immunocompromised participants in this study and 21 out of 51 (41.2%) historic healthy controls had at least 1 medical problem during the vaccination phase of this study. The vaccination phase was from Vaccination 1 to 1 month after Vaccination 2.

Participants with medical problems included:

- A total of 18 out of 53 (34.0%) immunocompromised participants and 9 out of 51 (17.6%) historic healthy controls had a medical problem within 30 days after any study vaccination.
- A total of 14 out of 53 (26.4%) immunocompromised participants and 5 out of 51 (9.8%) historic healthy controls had a medical problem within 30 days after Vaccination 1.
- A total of 6 out of 47 (12.8%) immunocompromised participants and 6 out of 47 (12.8%) historic healthy controls had a medical problem within 30 days after Vaccination 2.

No participants left the study because of medical problems. The most common medical problems in the vaccination phase – those reported by more than 5% of participants – are described below.

Below are instructions on how to read Table 1.

Instructions for Understanding Table 1.

- The **1st** column of Table 1 lists medical problems that were commonly reported during the study. All medical problems reported by more than 5% of participants are listed.
- The **2nd** column tells how many of the 53 immunocompromised participants who received Trumenba reported each medical problem. Next to this number is the percentage of the 53 immunocompromised participants who received Trumenba vaccination who reported the medical problem.
- The **3rd** column tells how many of the 51 historic healthy controls who received Trumenba reported each medical problem. Next to this number is the percentage of the 51 historic healthy controls who received Trumenba vaccination who reported the medical problem.
- Using these instructions, you can see that 3 out of the 53 (5.7%) immunocompromised participants who received Trumenba reported pain from “sickle cell anemia”. No historic healthy controls who received Trumenba reported pain from “sickle cell anemia”.

Table 1. Commonly reported medical problems by study participants		
Medical Problem	**Immunocompromised Participants (53 Participants)**	**Historic Healthy Controls (51 Participants)**
Pain from "sickle cell anemia" (an inherited condition that causes unusually shaped red blood cells)*	3 out of 53 participants (5.7%)	0
COVID-19	6 out of 53 participants (11.3%)	0
Tonsillitis (infection of the tonsils)	3 out of 53 participants (5.7%)	0
Common cold	2 out of 53 participants (3.8%)	4 out of 51 participants (7.8%)
Sinusitis (inflammation of the sinuses)	0	4 out of 51 participants (7.8%)

*Sickle cell anemia is a condition that some of the immunocompromised participants had at the start of the study.

Did study participants have any serious medical problems?

A medical problem is considered “serious” when it is life-threatening, needs hospital care, or causes lasting problems.

A total of 10 out of 53 (18.9%) immunocompromised participants had serious medical problems throughout the study. A total of 1 out of 51 (2.0%) historic healthy controls recorded a serious medical problem during their study. These included:

- A total of 5 out of 53 (9.4%) immunocompromised participants and no historic healthy controls within 30 days after Vaccination 1.
- No immunocompromised participants or historic healthy controls within 30 days after Vaccination 2.
- A total of 9 out of 53 (17.0%) immunocompromised participants and no historic healthy controls during the vaccination phase. The vaccination phase was from Vaccination 1 to 1 month after Vaccination 2.
- A total of 2 out of 44 participants (4.5%) immunocompromised participants and 1 out of 48 (2.1%) historic healthy controls had a serious medical problem during the follow-up phase. The follow-up phase was from 1 month after Vaccination 2 to 6 months after Vaccination 2.

Researchers believe that the immunocompromised participants had more serious medical problems than the historic healthy controls because their immune systems weren’t working as well as the immune systems of the historic healthy controls. Many of the serious medical problems were due to underlying medical conditions that the participants already had when they started the study. Researchers do not believe that any of the serious

medical problems reported by the participants were related to the study vaccine.

One immunocompromised participant died during the study when their heart suddenly stopped beating. Researchers believed that this participant's death was due to their underlying condition of sickle cell disease and was not related to the study vaccine.

Did participants have any medical problems that were not serious but required them to visit their doctor or go to a hospital during the study?

Researchers wanted to know how many participants had a medical problem that was not serious but required them to see a doctor or visit a hospital during the study. These types of problems were reported for 32 out of 53 (60.4%) immunocompromised participants and for 16 out of 51 (31.4%) historic healthy controls. This included:

- A total of 16 out of 53 (30.2%) immunocompromised participants and 5 out of 51 (9.8%) historic healthy controls within 30 days after any study vaccination.
- A total of 11 out of 53 (20.8%) immunocompromised participants and 3 out of 51 (5.9%) historic healthy controls within 30 days after Vaccination 1.
- A total of 6 out of 47 (12.8%) immunocompromised participants and 2 out of 47 (4.3%) historic healthy controls within 30 days after Vaccination 2.
- A total of 29 out of 53 (54.7%) immunocompromised participants and 15 out of 51 (29.4%) historic healthy controls during the

vaccination phase. The vaccination phase was from Vaccination 1 to 1 month after Vaccination 2.

- A total of 7 out of 44 participants (15.9%) immunocompromised participants and 5 out of 48 (10.4%) historic healthy controls during the follow-up phase. The follow-up phase was from 1 month after Vaccination 2 to 6 months after Vaccination 2.

The most common type of this problem was infections. Researchers believe that the difference in the number of problems for the immunocompromised participants and the historic healthy controls could have been due to the COVID-19 pandemic. The study took place during the COVID-19 pandemic. The study that the historic healthy controls took part in did not take place during the COVID-19 pandemic. Researchers also believe that the immunocompromised participants were more likely than the historic healthy controls to want to visit the doctor or hospital when they had infections.

Were any participants diagnosed with a new long-term disease or medical condition during the study?

Researchers wanted to know how many participants were diagnosed with a new long-term disease or medical condition during the study.

One immunocompromised participant was diagnosed with a new condition of high blood pressure. This was diagnosed within 30 days after Vaccination 2. The researchers did not believe that this condition was related to the study vaccine and believed that it was related to the participant being overweight.

Did participants have any medical problems immediately after being given the vaccine?

Researchers wanted to know how many participants had a medical problem immediately after receiving the study vaccination.

One participant in the historic healthy controls group reported a medical problem of fainting within 30 minutes of receiving Vaccination 1. The medical problem was not considered serious. Researchers believe that the fainting was related to the injection procedure but not to the study vaccine.

Did any participant miss any days from school or work due to medical problems during the vaccination phase (from Vaccination 1 to 1 month after Vaccination 2)?

Researchers wanted to know how many participants missed days of school or work due to medical problems, during the vaccination phase.

- Of the 32 immunocompromised participants who reported a medical problem, 9 participants (28.1%) missed days of school or work due to a medical problem.
- Of the 21 historic healthy controls who reported a medical problem, 6 historic healthy controls (28.6%) missed days of school or work due to a medical problem.

The medical problems that led to missed days of school or work were all considered not to be related to the study vaccine.

Where can I learn more about this study?

If you have questions about the results of your study, please speak with the doctor or staff at your study site.

For more details on your study protocol, please visit:

www.pfizer.com/research/research_clinical_trials/trial_results	Use the protocol number B1971060

The full scientific report of this study is available online at:

www.clinicaltrials.gov	Use the study identifier **NCT04893811**
www.clinicaltrialsregister.eu	Use the study identifier 2018-002588-24

Please remember that researchers look at the results of many studies to find out which medicines can work and are safe for patients.

Again, if you or your child participated in this study, **thank you** for volunteering. We do research to try to find the best ways to help patients, and you helped us to do that!