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 vaccine works, how it works, and if it is safe to recommend for study participants. The results of this study might be different than the results of other studies that the researchers review.

Sponsor: Pfizer Inc.

Vaccine Studied: Meningococcal ABCWY vaccine (called MenABCWY or PF-06886992)

Protocol Number: C3511001

Dates of Study: 17 June 2020 to 24 July 2022

Title of this Study: A study of MenABCWY vaccine in healthy adolescents and young adults – if it was safe and produced antibody responses against a germ called *Neisseria meningitidis*

[A Phase 3, Randomized, Active-Controlled, Observer-Blinded Trial to Assess the Safety, Tolerability, and Immunogenicity of MenABCWY in Healthy Participants ≥10 to <26 Years of Age]

Date(s) of this Report: 22 December 2022

– Thank You –

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

This summary will describe the study results. If you 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 is *Neisseria meningitidis*?

Neisseria meningitidis (or *N meningitidis*) is a kind of germ (bacteria). Meningococcus is its other name. There are different types of this germ. For example, meningococcal type A disease is caused by the meningococcus A germ. Meningococcus A, B, C, W, and Y are the most common types.

N meningitidis can cause infections of the blood, as well as inflammation around the brain and spinal cord. People who get this illness are at risk for brain damage, loss of limbs, hearing loss, and other disabilities.

What is a vaccine and an antibody response?

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.

What is meningococcal ABCWY vaccine (MenABCWY)?

MenABCWY is an injectable study vaccine. It was not approved for general use at the time of this study. MenABCWY is composed of 2 other vaccines that are already used for the prevention of meningococcal disease:

- Nimenrix, which is used to prevent disease caused by meningococcus types A, C, W, and Y
- Trumenba, which is used to prevent disease caused by meningococcus type B

MenABCWY would combine protection against meningococcus types A, B, C, W, and Y into 1 vaccine.

What was the purpose of this study?

This study aimed to find out if MenABCWY was safe in healthy adolescents and young adults, and if it produced antibody responses against *N meningitidis*.

Researchers wanted to know:

1. **Did participants who received MenABCWY have antibody responses against meningococcus types A, C, W, and Y that were within a range considered to be comparable (noninferior) to those who received Menveo (another meningococcal vaccine similar to Nimenrix)?**
2. **Did participants who received MenABCWY have antibody responses against meningococcus type B that were within a range considered to be comparable (noninferior) to those who received Trumenba?**
3. **How many participants had redness, swelling, or pain at the MenABCWY or Trumenba injection site (or the skin area where the needle was injected) after they got study vaccine?**
4. **How many participants had headache, fatigue, use of fever-reducing medicines, muscle pain, joint pain, chills, diarrhea, fever, or vomiting after they got the study vaccine?**
5. **How many participants were diagnosed with a new long-term disease or medical condition during the study?**
6. **What medical problems did participants have during the vaccination phase (time from the first study vaccination through 1 month after the second study vaccination) of the study?**
7. **How many participants had medical problems that required going to the doctor or a hospital during the study?**
8. **How many participants missed days of school or work because of medical problems?**

What happened during the study?

How was the study done?

Researchers tested MenABCWY, compared to Menveo and Trumenba, with 8 groups of adolescents and young adults who joined the study. The researchers, participants, and their parents or guardians, if a child participant, did not know who received which vaccines; only the person preparing the vaccine for injection knew what vaccine was administered. Participants were first assigned to groups based on whether they had previously received a vaccine against meningococcal types A, C, W, and Y. They were then assigned to a study vaccine group by chance. Each participant was vaccinated a total of 2 times during the study to keep the study blinded (at visits 1 and 3). **Table 1** below shows the groups and the vaccines they received, along with the study visits.

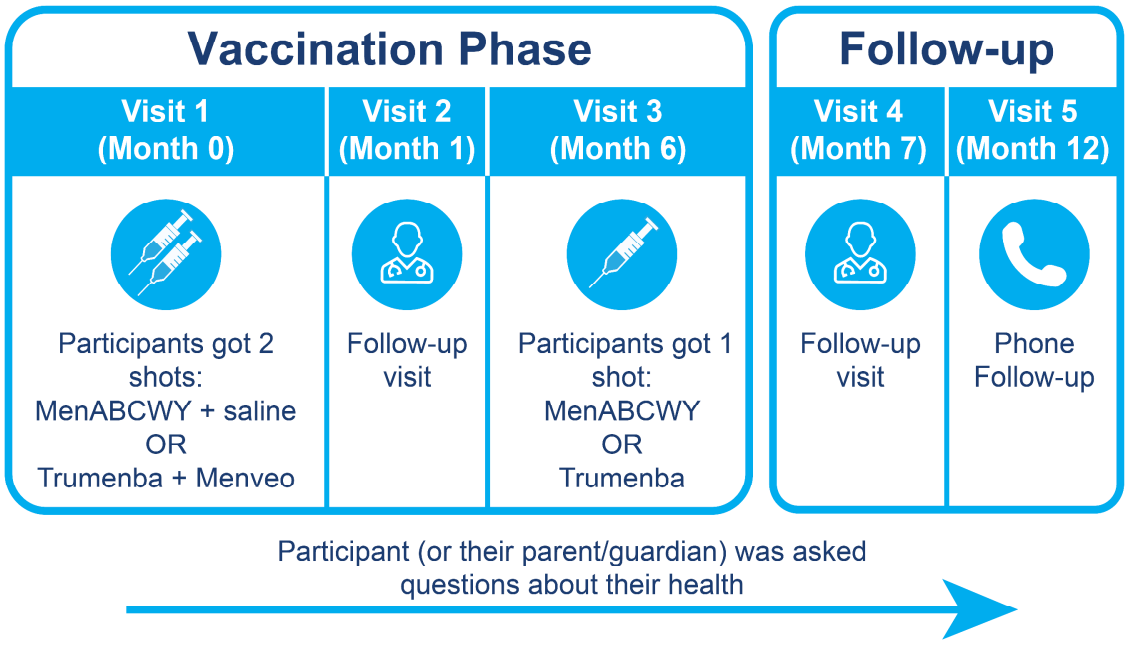
Table 1. Vaccine Groups and Study Visits

		Vaccination 1	Follow-up Visit 1	Vaccination 2	Follow-up Visit 2	Phone Follow-up
	Month	**0**	**1**	**6**	**7**	**12**
	Visit Number	**1**	**2**	**3**	**4**	**5**
Participants who never previously received ACWY-vaccine	Group 1 (554 participants)	MenABCWY + saline	Blood sample and safety assessment	MenABCWY	Blood sample and safety assessment	Safety assessment
	Group 2 (277 participants)	Trumenba + Menveo	Blood sample and safety assessment	Trumenba	Blood sample and safety assessment	Safety assessment
Participants who previously received	Group 3 (522 participants)	MenABCWY + saline	Blood sample and safety assessment	MenABCWY	Blood sample and safety assessment	Safety assessment

		Vaccination 1	Follow-up Visit 1	Vaccination 2	Follow-up Visit 2	Phone Follow-up
ACWY-vaccine	Group 4 (260 participants)	Trumenba + Menveo	Blood sample and safety assessment	Trumenba	Blood sample and safety assessment	Safety assessment
Participants who never previously received ACWY-vaccine	Group 5 (551 participants)	MenABCWY + saline	Safety assessment	MenABCWY	Safety assessment	Safety assessment
	Group 6 (56 participants)	Trumenba + Menveo	Safety assessment	Trumenba	Safety assessment	Safety assessment
Participants who previously received ACWY-vaccine	Group 7 (151 participants)	MenABCWY + saline	Safety assessment	MenABCWY	Safety assessment	Safety assessment
	Group 8 (60 participants)	Trumenba + Menveo	Safety assessment	Trumenba	Safety assessment	Safety assessment

Figure 1 below shows what happened during the study.

Figure 1. What happened during the study?



Where did this study take place?

The Sponsor ran this study at 82 locations in Czech Republic, Denmark, Hungary, Poland, and the United States.

When did this study take place?

It began 17 June 2020 and ended 24 July 2022.

Who participated in this study?

The study included participants who were assessed as healthy by study doctors, and who were at least 10 years old but younger than 26 years old when the study started.

Of the 2431 participants who started the study, 2413 participants received a study vaccine.

- There were 1176 boys/men and 1236 girls/women.
- All participants were 10 to 25 years old when they started the study, with an average age of 16 years.

Overall, 2061 participants finished the study. 370 participants did not finish the study; the most common reason was that the participant was lost to follow-up (stopped coming to study visits and could not be contacted by the study staff).

How long did the study last?

The participants were in the study for about 1 year. The entire study took about 2 years to finish.

When the study ended in July 2022, 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?

The researchers measured the amount of antibodies against *N meningitidis* in the participants' blood samples. They compared the amount of antibodies found in participants who received MenABCWY + saline to those who received Trumenba + Menveo.

Did participants who received MenABCWY have antibody responses against meningococcus types A, C, W, and Y that were within a range considered to be comparable (noninferior) to those who received Menveo?

1 month after Vaccination 1 and Vaccination 2, researchers saw a rise in antibodies against meningococcus types A, C, W, and Y among the participants. They found out that the participants who received MenABCWY had comparable (noninferior) antibody responses against *N meningitidis* to participants who received Menveo.

Did participants who received MenABCWY have antibody responses against meningococcus type B that were within a range considered to be comparable (noninferior) to those who received Trumenba?

1 month after Vaccination 2, researchers saw a rise in antibodies against meningococcus type B among the participants. They found out that the participants who received MenABCWY had comparable (noninferior) antibody responses against *N meningitidis* to participants who received Trumenba.

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.

Participants kept a diary to record how they were doing within 7 days of getting vaccine at Vaccination visits 1 and 2.

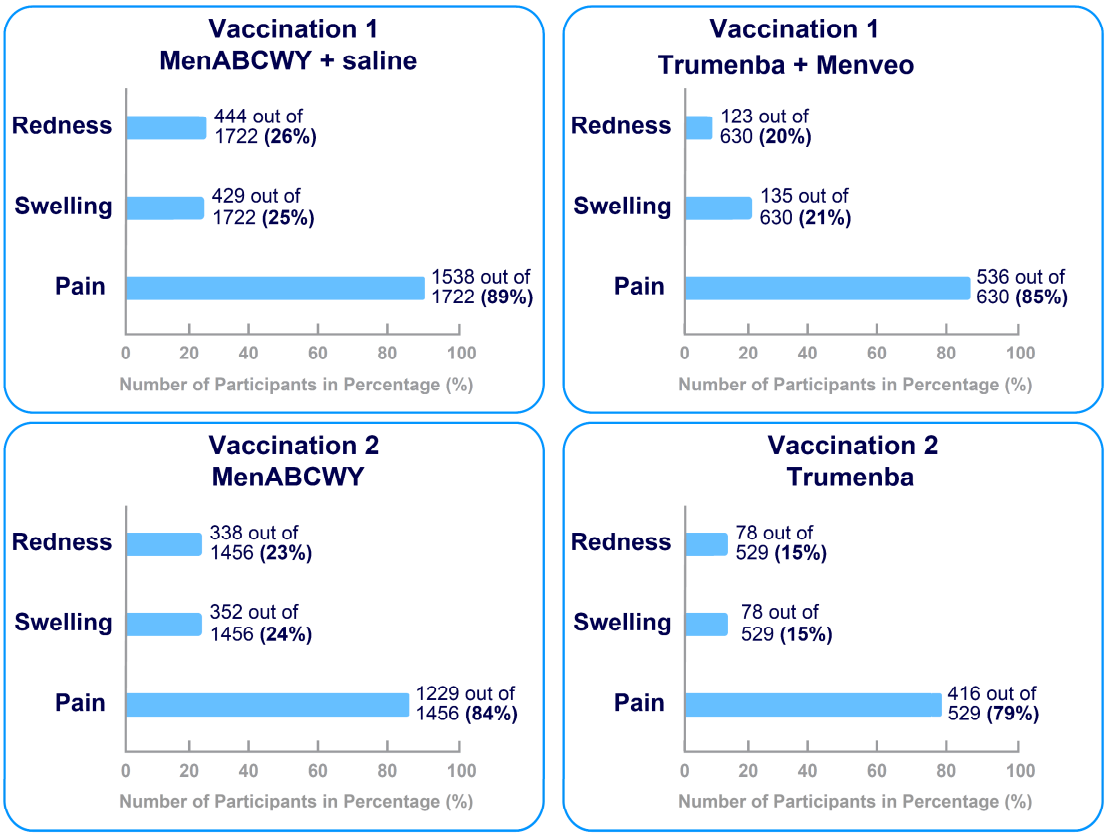
Researchers checked the records of 2412 participants who had diary entries (the researchers did not receive diary entries for 35 participants).

How many participants had redness, swelling, or pain at the MenABCWY or Trumenba injection site after they got study vaccine?

A total of 1634 out of 1728 (95%) of participants who received MenABCWY + saline and 581 out of 635 (91%) of participants who received Trumenba + Menveo had at least one of the following: redness, swelling, or pain at the MenABCWY or Trumenba injection site (or the skin area where the needle was injected) within 7 days of any study vaccination.

The charts below in **Figure 2** show that pain at the injection site was the most common reaction after both Vaccination 1 and Vaccination 2.

Figure 2. How many participants had redness, swelling, or pain at the MenABCWY or Trumenba injection site within 7 days of Vaccination 1 or 2?



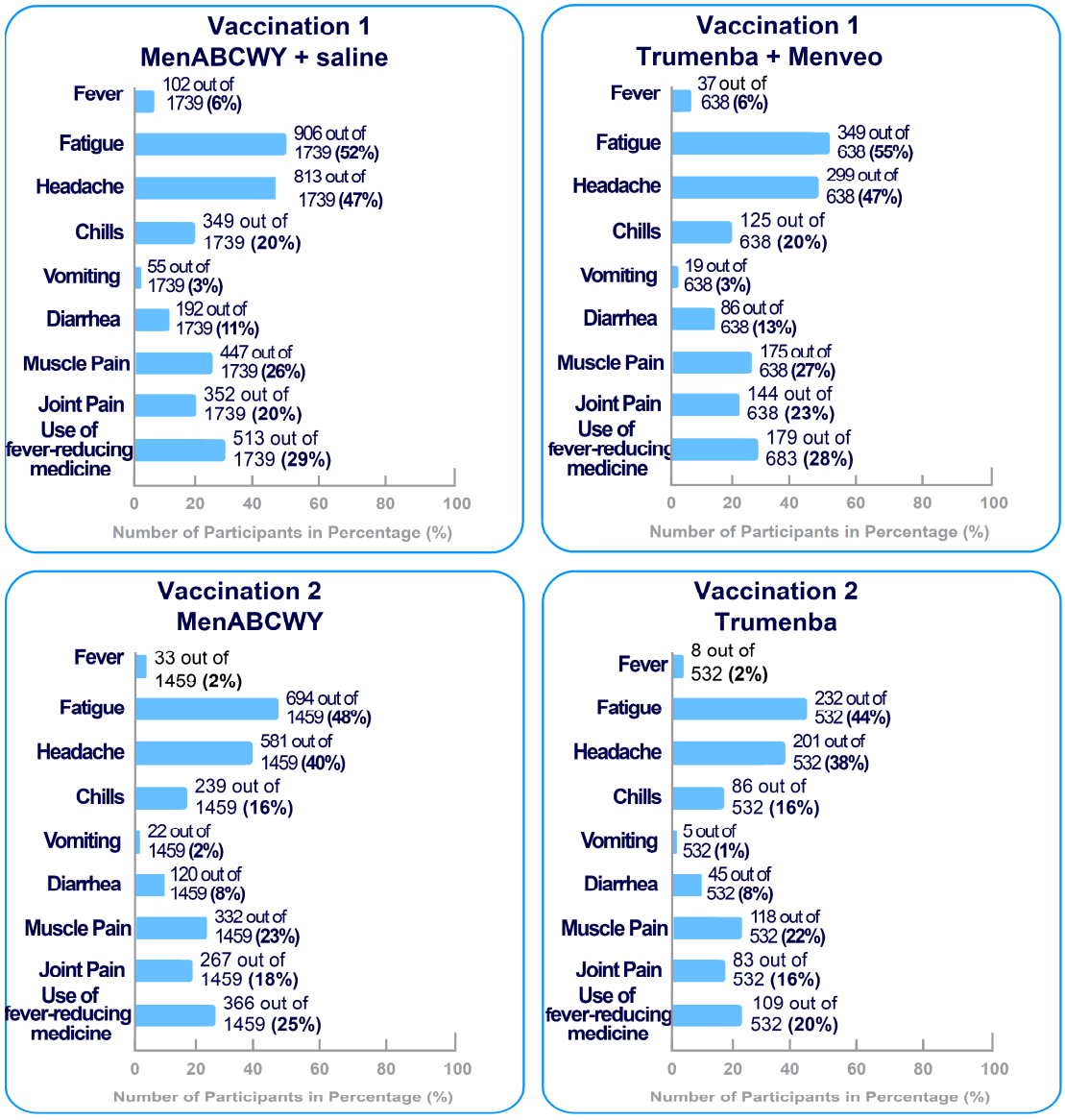
How many participants had headache, fatigue, use of fever-reducing medicines, muscle pain, joint pain, chills, diarrhea, fever, or vomiting after they got study vaccine?

1427 out of 1748 (82%) of participants who received MenABCWY + saline and 527 out of 646 (82%) of participants who received Trumenba + Menveo had at least one of the following: headache, fatigue, muscle pain, joint pain, chills, diarrhea, fever, or vomiting within 7 days of any study vaccination. 671 out of 1748 (38%) of participants who received MenABCWY + saline and 225 out of 646 (35%) of

participants who received Trumenba + Menveo used fever-reducing medicines within 7 days of any study vaccination.

The charts in **Figure 3** below show that headache and fatigue were the most common symptoms.

Figure 3. How many participants had fever and other symptoms within 7 days of Vaccination 1 or 2?



How many participants were 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. Researchers looked at the records of 2412 participants.

25 out of 1763 (1%) participants who received MenABCWY + saline were diagnosed with a new long-term disease or medical condition. 2 out of 649 participants (less than 1%) who received Trumenba + Menveo were diagnosed with a new long-term disease or medical condition. None of the new long-term diseases or medical conditions were considered to be related to the study vaccines.

What medical problems did the participants have during the study?

The researchers recorded any medical problems the participants had during the study. The participants could have had medical problems for reasons not related to the study (for example, caused by an underlying disease or by chance). 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 vaccine might have on a participant.

What medical problems did participants have during the vaccination phase of the study?

In this study, 368 out of 1763 (21%) participants in the MenABCWY + saline group and 132 out of 649 (20%) participants in the Trumenba + Menveo group had a medical problem.

Three (3) participants in the MenABCWY + saline group left the study because of medical problems that were not related to the study vaccines. In the Trumenba + Menveo group, 1 participant left the study because of a medical problem that was not related to the study vaccines, and 1 participant left the study because of a medical problem (mild skin rash that lasted about 1 month and resolved without treatment) that was considered to be related to the study vaccines.

The table below describes the most common medical problems – those reported by at least 1% of participants in either group.

Below are instructions on how to read Table 2.

Instructions for Understanding Table 2.

- The **1st** column of Table 2 lists the most common medical problems reported during the vaccination phase of the study (time from the first study vaccination through 1 month after the second vaccination). It lists all medical problems reported by at least 1% of participants in either group.
- The **2nd** and **3rd** columns tell how many of the participants in each group had a medical problem. Next to this number is the percentage of participants in either group who had the medical problem.
- Using these instructions, you can see that 69 out of 1763 participants (4%) who received MenABCWY + saline had COVID-19. 19 out of 649 (3%) participants who received Trumenba + Menveo had COVID-19.

Table 2. Most common medical problems reported by study participants (at least 1% of participants in either group)

Medical Problem	MenABCWY + Saline (1763 participants)	Trumenba + Menveo (649 participants)
COVID-19	69 out of 1763 participants (4%)	19 out of 649 participants (3%)
Infection of the nose, throat, or upper airways	25 out of 1763 participants (1%)	11 out of 649 participants (2%)
Sore throat	19 out of 1763 participants (1%)	8 out of 649 participants (1%)
Common cold	4 out of 1763 participants (less than 1%)	7 out of 649 participants (1%)

How many participants had medical problems that required going to the doctor or a hospital during the study?

In this study, 340 out of 1763 (19%) participants in the MenABCWY + saline group and 119 out of 649 (18%) participants in the Trumenba + Menveo group had a medical problem that required going to the doctor or a hospital. Three (3) of these medical problems were considered to be related to the study vaccines:

- 1 participant in the MenABCWY + saline group had a sensation of swelling to the tongue
- 1 participant in the MenABCWY + saline group had a hematoma (blood pooling under the skin) at the injection site
- 1 participant in the Trumenba + Menveo group had a severe headache that started on Day 1 after receiving Vaccine 1, and lasted 2 days

How many participants missed days of school or work because of medical problems?

A total of 88 participants out of 1763 (5%) participants in the MenABCWY + saline group and 29 out of 649 (4%) participants in the Trumenba + Menveo group missed days of school or work because of a medical problem. None of these missed days were for medical problems that were considered to be related to the study vaccines.

Did the participants have any serious medical problems?

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

No participants died during the study.

How many participants had a serious medical problem during the study?

A total of 11 participants out of 1763 (1%) participants in the MenABCWY + saline group and 4 out of 649 (1%) participants in the Trumenba + Menveo group had a serious medical problem. None of these serious medical problems were considered to be related to the study vaccines. Depression requiring hospitalization was the most common serious medical problem, which was reported by 2 participants in the MenABCWY + saline group.

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 **C3511001**

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

www.clinicaltrials.gov	Use the study identifier **NCT04440163**
www.clinicaltrialsregister.eu	Use the study identifier **2019-004313-13**

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

Again, if you participated in this study,
thank you for volunteering.
We do research to try to find the

best ways to help participants, and you helped us to do that!