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 prescribe to patients. The results of this study might be different than the results of other studies that the researchers review.

Sponsor:	BioNTech SE
Sponsor Agent:	Pfizer Inc.
Vaccine Studied:	BNT162b2 RNA-Based COVID-19 Vaccines (also known as PF-07302048 or Comirnaty®)
Protocol Number:	C4591020
Dates of Study:	01 April 2021 to 01 December 2021
Title of this Study:	A Phase 3 Study to Evaluate the Safety, Tolerability, and Immunogenicity of Multiple Formulations of BNT162b2 Against COVID-19 in Healthy Adults [A Phase 3, Randomized, Observer-Blind Study to Evaluate the Safety, Tolerability, and Immunogenicity of Multiple Formulations of the Vaccine Candidate BNT162b2 Against COVID-19 in Healthy Adults 18 Through 55 Years of Age]
Date(s) of this Report:	02 December 2022

– Thank You –

If you participated in this study, Pfizer, the Sponsor Agent, 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 COVID-19?

COVID-19 is known as "Coronavirus disease 2019", which is caused by a virus called severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). People can catch COVID-19 from an infected person who has the virus, even if the person has no symptoms.

COVID-19 can cause a wide range of symptoms, such as fever, chills, cough, loss of taste or smell, and trouble breathing. Most people with COVID-19 have mild to moderate symptoms. But in some people, COVID-19 can be more severe, and they may need hospital care.

What is BNT162b2 vaccine?

> A vaccine can help the body to fight off germs.
>
> After a person gets a vaccine, the body's immune system makes antibodies, which are proteins that fight off infections and help to prevent a disease. This is called an "immune response".

BNT162b2 (also called Comirnaty®) is an injectable vaccine that helps the body's immune system to defend against COVID-19.

- It does not contain a whole virus or any part of the virus that can cause COVID-19.
- It is made up of a part of the virus's genetic code called RNA (or "ribonucleic acids"). This RNA teaches the body's own cells to make "spike proteins". These spike proteins may help the body to produce antibodies to fight against COVID-19.

What was the purpose of this study?

Researchers tested 3 different versions (also known as formulations) of BNT162b2: **freeze-dried**, **frozen-liquid**, and **ready-to-use (RTU)** BNT162b2.

> **What is a "freeze-dried" vaccine?**
>
> The vaccine was first frozen before the water content was removed. Then, the remaining contents of the vaccine went through a drying process.
>
> **What is a "ready-to-use (RTU)" vaccine?**
>
> The RTU vaccine is the same as the freeze-dried vaccine before the water content was removed.

Researchers think that the **freeze-dried** or **RTU** BNT162b2 could make storage easier at normal refrigerator temperatures compared with the **frozen-liquid** BNT162b2.

The study had 2 parts. The main purposes of each part were:

- **Part 1:** Researchers wanted to find out if **freeze-dried** BNT162b2 and **frozen-liquid** BNT162b2 produced similar immune responses against COVID-19. They also wanted to learn about the safety of both versions of BNT162b2.
- **Part 2:** Researchers wanted to learn about the safety of **frozen-liquid** BNT162b2 and **RTU** BNT162b2.

Researchers wanted to know:

In Part 1:

1. **Did participants who received the freeze-dried BNT162b2 have similar immune responses against COVID-19 compared with those who received the frozen-liquid BNT162b2?**

In Parts 1 and 2:

2. **How many participants had redness, swelling, or pain at the injection site within 7 days of receiving each vaccination?**
3. **How many participants had fever, tiredness, headache, chills, vomiting, diarrhea, or muscle or joint pain within 7 days of receiving each vaccination?**
4. **How many participants had a medical problem during the study?**
5. **How many participants had a serious medical problem during the study?**

What happened during the study?

How was the study done?

Researchers tested 3 versions of BNT162b2 in this study.

The study had 2 parts, which ran separately. Each participant joined 1 part of this study and received 1 version of BNT162b2. BNT162b2 (30 micrograms or mcg) was given in 2 doses at 3 weeks apart.

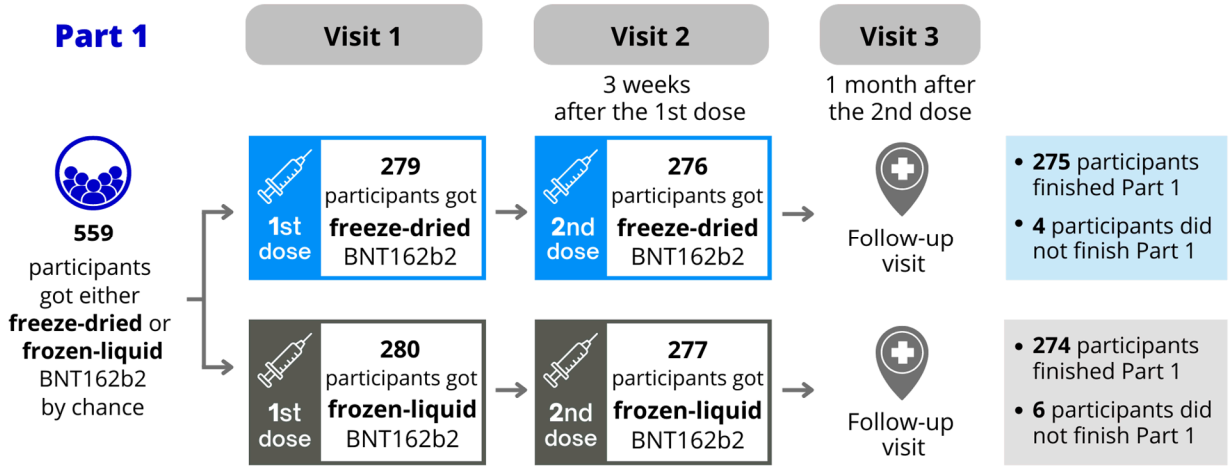
In both parts, the healthcare workers who injected the vaccine knew which version of BNT162b2 the participants got. The researchers and participants did not know. This is called an "observer-blinded" study. Being "blinded" allows researchers to study each version of BNT162b2 fairly.

Part 1:

Participants who joined Part 1 were assigned to receive either **freeze-dried** or **frozen-liquid** BNT162b2 by chance.

Figure 1 below shows what happened during Part 1.

Figure 1: What happened during Part 1?



Researchers compared the results of participants who got **freeze-dried** BNT162b2 with the results of participants who got **frozen-liquid** BNT162b2.

Part 2:

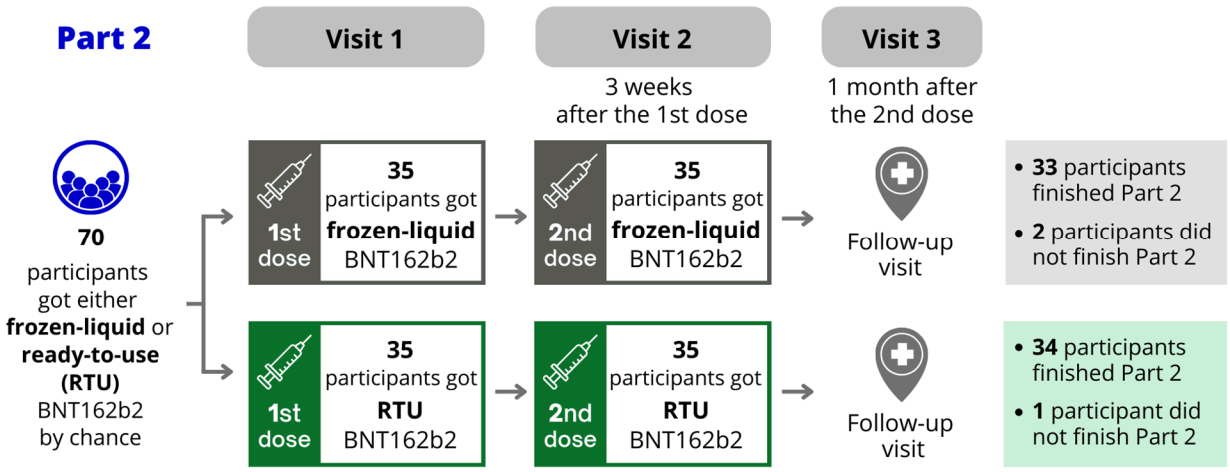
Participants who joined Part 2 were assigned to receive either **frozen-liquid** or **RTU** BNT162b2 by chance.

The difference between the 2 **frozen-liquid** versions in Part 1 versus Part 2 is the size of the "carrier" part of the vaccine. This "carrier" delivers the RNA that helps the body to make spike proteins.

> These spike proteins may help the body to produce antibodies to fight against COVID-19.

Figure 2 below shows what happened during Part 2.

Figure 2: What happened during Part 2?



Researchers compared the results of participants who got **frozen-liquid** BNT162b2 with the results of participants who got **RTU** BNT162b2.

Parts 1 and 2:

On Visits 1 and 3, the following samples were taken from participants:

- Blood samples to test for antibodies against the virus that causes COVID-19.
- Nasal swab samples to test for presence of the virus that causes COVID-19.

Throughout the study, participants were asked how they were feeling and if they received other types of vaccines.

Where did this study take place?

This study was run at 20 locations in the United States.

When did this study take place?

It began 01 April 2021 and ended 01 December 2021.

Who participated in this study?

The study included participants who:

- were assessed as healthy by the study doctors.
- were between 18 and 55 years old at Visit 1 of the study.
- did not have prior COVID-19.
- had not gotten any vaccine for COVID-19 before this study.
- had not taken any medicines that prevent COVID-19.

Part 1:

Overall, 559 participants took part: 290 men and 269 women. They were between 18 and 55 years old.

- A total of 549 out of 559 participants (98%) finished Part 1.
- A total of 10 out of 559 participants (2%) did not finish Part 1.

Figure 1 above shows the number of participants in Part 1.

Part 2:

Overall, 70 participants took part: 32 men and 38 women. They were between 18 and 55 years old.

- A total of 67 out of 70 participants (96%) finished Part 2.
- A total of 3 out of 70 participants (4%) did not finish Part 2.

Figure 2 above shows the number of participants in Part 2.

Across the 2 parts, the most common reason for not finishing the study was because participants could not be reached for follow-up.

How long did the study last?

Each participant was in Part 1 or 2 for about 2 months. The entire study took about 8 months to complete.

When the study ended in December 2021, the Sponsor Agent began reviewing the information collected. The Sponsor Agent then created a report of the results. This is a summary of that report.

What were the results of the study?

1 Did participants who received the freeze-dried BNT162b2 have similar immune responses against COVID-19 compared with those who received the frozen-liquid BNT162b2?

Researchers measured the levels of antibodies against COVID-19 about 1 month after the 2nd dose of BNT162b2 in Part 1.

The researchers found that:

- The levels of antibodies seen in participants who received **freeze-dried** BNT162b2 were lower than those seen in participants who received **frozen-liquid** BNT162b2.
- When given as 2 doses, **freeze-dried** BNT162b2 was not as good as **frozen-liquid** BNT162b2 in producing immune responses against COVID-19. The researchers have decided that these results are not likely due to chance.

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 of BNT162b2 may have different results.

What medical problems did participants have during the study?

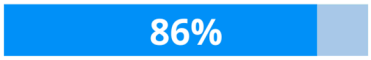
The researchers recorded any medical problems the participants had during the study. Participants could have had medical problems for reasons not related to the study (for example, caused by an underlying disease or by chance). Or, medical problems could also have been caused by a study vaccine or by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

2 How many participants had redness, swelling, or pain at the injection site within 7 days of receiving each vaccination?

> The point on the arm where the vaccine was injected is called "injection site".

Known medical problems seen within 7 days of BNT162b2 vaccination are: redness, swelling, or pain at the injection site. These are also called "injection site reactions".

In **Part 1**, the percentage of participants who had any injection site reactions within 7 days of receiving either dose of BNT162b2 was slightly lower in the **freeze-dried** BNT162b2 group than in the **frozen-liquid** BNT162b2 group.



240 out of 279 participants (86%) who got **freeze-dried** BNT162b2.

262 out of 280 participants (94%) who got **frozen-liquid** BNT162b2.

Most of the injection site reactions were mild to moderate in intensity and went away after about 1 to 2 days. Pain was the most common injection site reaction after each dose of **freeze-dried** or **frozen-liquid** BNT162b2.

In **Part 2**, the percentage of participants who had any injection site reactions within 7 days of receiving either dose of BNT162b2 was slightly higher in the **frozen-liquid** BNT162b2 group than in the **RTU** BNT162b2 group.

31 out of 35 participants (89%) who got **frozen-liquid** BNT162b2.

28 out of 35 participants (80%) who got **RTU** BNT162b2.

Most of the injection site reactions were mild to moderate in intensity and went away after about 1 to 2 days. Pain was the most common injection site reaction after each dose of **frozen-liquid** or **RTU** BNT162b2. None of the participants who received **frozen-liquid** BNT162b2 had redness or swelling at the injection site.

3 How many participants had fever, tiredness, headache, chills, vomiting, diarrhea, or muscle or joint pain within 7 days of receiving each vaccination?

Known medical problems seen within 7 days of BNT162b2 vaccination are: fever, tiredness, headache, chills, vomiting, diarrhea, or muscle or joint pain.

In **Part 1**, the percentage of participants who had any fever, tiredness, headache, chills, vomiting, diarrhea, or muscle or joint pain within 7 days of receiving either dose of BNT162b2 was slightly lower in the **freeze-dried** BNT162b2 group than in the **frozen-liquid** BNT162b2 group.

236 out of 279 participants (85%) who got **freeze-dried** BNT162b2.

263 out of 280 participants (94%) who got **frozen-liquid** BNT162b2.

Most of these medical problems were mild to moderate in intensity and went away after about 1 to 2 days. Tiredness and headache were the most common of these medical problems after each dose of **freeze-dried** or **frozen-liquid** BNT162b2.

In **Part 2**, the percentages of participants who had any fever, tiredness, headache, chills, vomiting, diarrhea, or muscle or joint pain within 7 days of receiving either dose of BNT162b2 were similar between the **frozen-liquid** and **RTU** BNT162b2 groups.

28 out of 35 participants (80%) who got **frozen-liquid** BNT162b2.

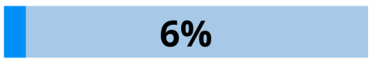
27 out of 35 participants (77%) who got **RTU** BNT162b2.

Most of these medical problems were mild to moderate in intensity and went away after about 1 to 3 days. Tiredness and headache were the most common of these medical problems after each dose of **frozen-liquid** or **RTU** BNT162b2.

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

Researchers checked how many participants had a medical problem within 1 month after the 2nd dose of BNT162b2.

In **Part 1**, the percentages of participants who had at least 1 medical problem were similar between the **freeze-dried** and **frozen-liquid** BNT162b2 groups.



16 out of 279 participants (6%) who got **freeze-dried** BNT162b2.

21 out of 280 participants (8%) who got **frozen-liquid** BNT162b2.

The most common medical problems happened in 2 participants in either group: headache and back pain. The study doctors did not think these medical problems were related to BNT162b2.

All other medical problems happened in 1 participant each in either group.

Overall, 2 participants left Part 1 because of a medical problem they had during the study.

- One (1) participant who received **freeze-dried** BNT162b2 left because of tiredness, which the study doctors thought was related to BNT162b2.
- One (1) participant who received **frozen-liquid** BNT162b2 left because of diarrhea, which the study doctors did not think was related to BNT162b2.

In **Part 2**, the percentages of participants who had at least 1 medical problem were similar between the **frozen-liquid** and **RTU** BNT162b2 groups.

4 out of 35 participants (11%) who got **frozen-liquid** BNT162b2.

4 out of 35 participants (11%) who got **RTU** BNT162b2.

All medical problems happened in 1 participant each in either group. None of the participants left Part 2 because of a medical problem they had during 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.

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

Researchers checked how many participants had a serious medical problem within 1 month after the 2nd dose of BNT162b2.

None of the participants in Part 1 or 2 had a serious medical problem. No participant died during the study.

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 **C4591020**

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

www.clinicaltrials.gov	Use the study identifier **NCT04816669**
www.clinicaltrialsregister.eu	Use the study identifier **2020-002641-42**

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

Again, if you 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!