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.
Vaccines Studied:	PF-07302048 (BNT162 RNA-Based COVID-19 Vaccines) BNT162b1 and Comirnaty® (BNT162b2)
Protocol Number:	C4591001
Dates of Study:	29 April 2020 to 10 February 2023
Title of this Study:	A Study to Learn If RNA Vaccines (BNT162b1 and BNT162b2) Are Safe and Can Prevent COVID-19 in Healthy Participants [A Phase 1/2/3 Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals]
Dates of this Report:	03 November 2023

– 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 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 is COVID-19?

"Coronavirus disease 2019" (or COVID-19) is caused by a virus called **s**evere **a**cute **r**espiratory **s**yndrome **co**rona**v**irus **2** (SARS-CoV-2). People can catch COVID-19 from an infected person who has the virus, even if that 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 are BNT162b1 and BNT162b2?

BNT162b1 and BNT162b2 (also called Comirnaty®) are injectable vaccines that may help the body's immune system to defend against COVID-19.

- These vaccines do not contain a whole virus or any part of the virus that can cause COVID-19.
- They are made up of a part of the virus's genetic code called RNA (or "ribonucleic acid"). The RNA teaches the body's cells to make "spike proteins" or part of the spike protein, which may help the body to produce antibodies to fight against COVID-19.

BNT162b1 and **BNT162b2** are the original "monovalent" COVID-19 vaccines. These "monovalent" vaccines contain RNA that targets the original strain of the COVID-19 virus.

Some participants received **BNT162b2$_{SA}$**, a vaccine that targets the "Beta variant" of COVID-19 virus. This Beta variant is a different strain of COVID-19 virus first found in South Africa.

When a person first gets a vaccine, a protective **immune response** is triggered in the body. This means that the body's immune system is activated to make **antibodies**.

- **Antibodies** are proteins that can fight off infections and help to prevent disease.
- An **immune response** is the body's ability to find and fight off germs that cause disease.

A person's immune protection from a disease can fade over time.

- A **booster dose** is the extra dose of a vaccine after receiving the first dose or series of doses.
- A booster dose can help the immune system maintain or "**boost**" the level of protection against a disease.

What was the purpose of this study?

This study had 2 parts, which included 3 phases. The main goals of this study were as follows:

- **Part 1 is called "Phase 1"**. This part aimed to see if vaccines (BNT162b1 or BNT162b2) given at different dose levels are safe for a small group of adult participants. This part also wanted to find out the preferred vaccine and dose for Part 2.

  Based on the Phase 1 results, 30 micrograms (called µg) BNT162b2 was selected as the vaccine for the next part.

- **Part 2 is called** "**Phase 2/3**". This part aimed to see if 30 µg BNT162b2 is safe and can help to prevent COVID-19 in a larger group of participants (children and adults).

Researchers wanted to know:

- **Did BNT162b2 vaccine help to prevent COVID-19?**
- **Did BNT162b2 and BNT162b2$_{SA}$ produce immune responses against the COVID-19 virus?**
- **What medical problems did participants have during the study?**

What happened during the study?

How was the study done?

Phase 1 − First 2 doses

Researchers tested different doses of 2 vaccines (BNT162b1 and BNT162b2) on a small group of study participants. This was done to find out if these BNT162 vaccines are safe and to select the vaccine and dose level for the next part of the study.

Researchers then compared the results of study participants who got BNT162b1 or BNT162b2 to the results of study participants who got a placebo. A placebo does not have any active ingredients in it.

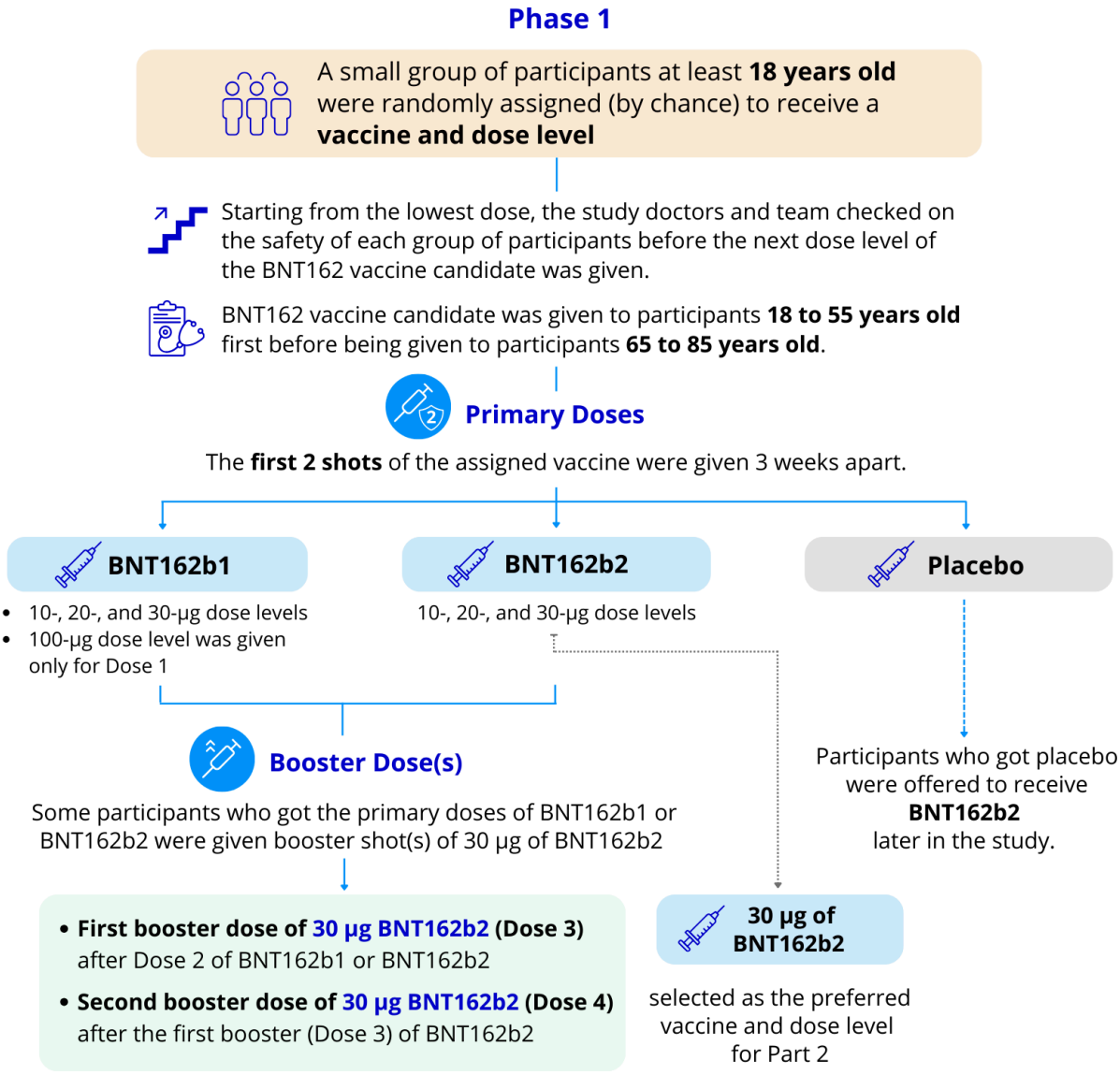
A group of study participants were assigned by chance to receive 2 doses of BNT162b1 or placebo. Another group of study participants were assigned by chance to receive 2 doses of BNT162b2 or placebo.

Dose levels tested in Phase 1:

- BNT162b1 and BNT162b2 were given in 10, 20, and 30 µg.
- BNT162b1 was also given in 100 µg, but it was decided not to give the 100-µg dose level to participants for Dose 2 because of reactions seen after Dose 1. These participants later got Dose 2 at the 10-µg dose level.
  Results of participants who got 100 µg BNT162b1 are not included in this summary.

Figure 1 below shows what happened in Phase 1.

Figure 1. What happened during Phase 1 of the study?



Based on the Phase 1 results, **30 µg BNT162b2** was selected as the vaccine for the next part of the study.

Phase 2/3 – First 2 doses

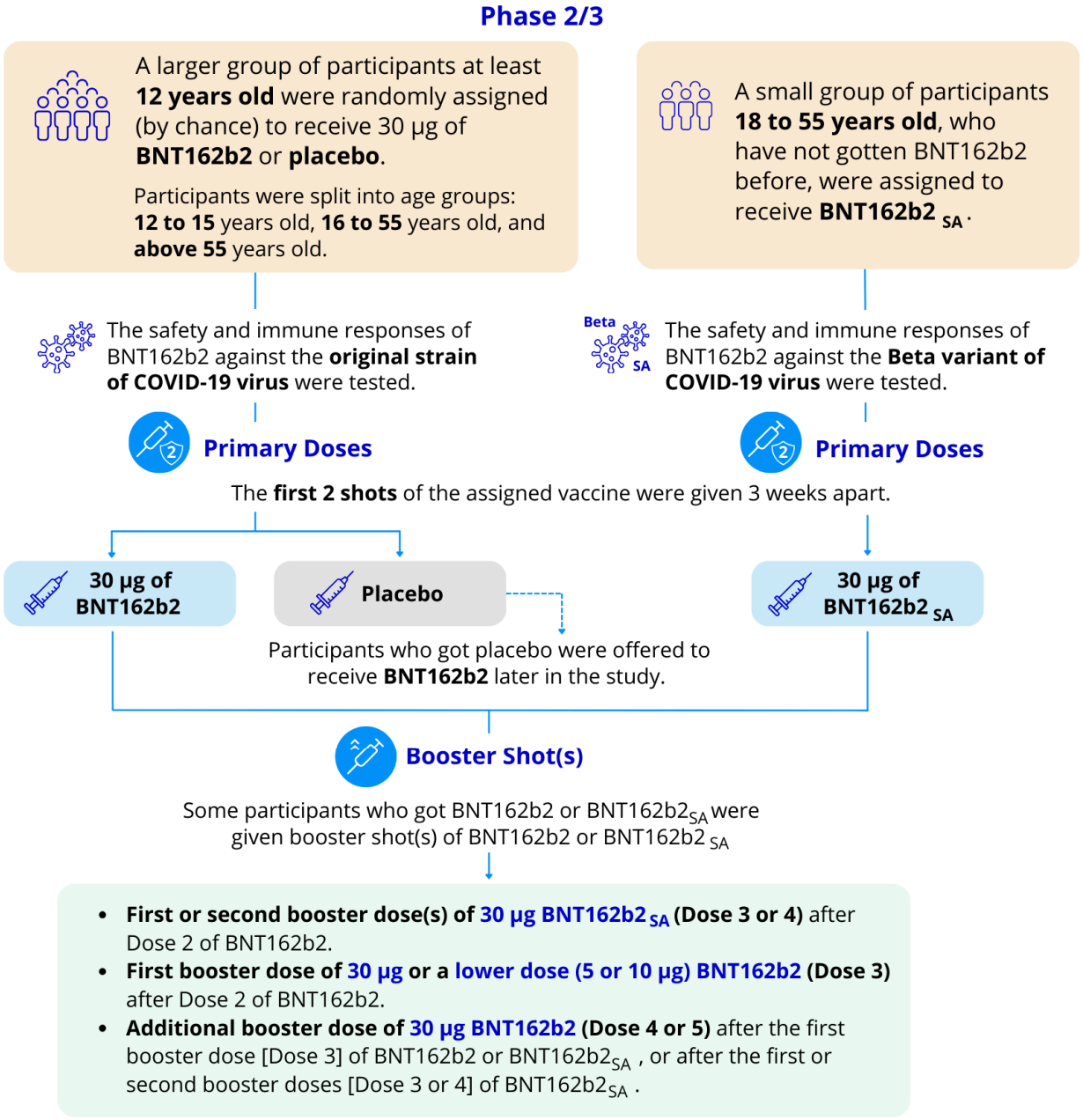
Researchers tested BNT162b2 (30 µg) in the first 360 participants enrolled in Phase 2/3. This group is called the "Phase 2" participants. Then, researchers tested BNT162b2 (30 µg) on a larger group of study participants in Phase 2/3. This was done to find out if BNT162b2 is safe and can help to prevent COVID-19.

- Researchers then compared the results of study participants who got BNT162b2 to the results of study participants who got placebo.
- Study participants were assigned by chance to receive 2 doses of BNT162b2 or placebo.

A small group of participants, who had not gotten BNT162b2 before, were assigned to receive BNT162b2$_{SA}$ in Phase 3.

Figure 2 below shows what happened in Phase 2/3.

Figure 2. What happened during Phase 2/3 of the study?



Participants who got placebo in Phase 1 and Phase 2/3

After it had been shown that the BNT162b2 can help in preventing COVID-19, participants who got doses of placebo at the start were offered to receive BNT162b2 at a later point in the study. This depended on the participant's and study doctor's decision.

Booster doses in Phase 1 and Phase 2/3

Some participants received 1 or 2 booster doses of BNT162b2 or BNT162b2$_{SA}$ after their first 2 doses of BNT162 vaccine.

How were the study vaccine and booster doses given?

All phases where participants got the first 2 doses of BNT162b1, BNT162b2, or placebo started as "observer-blinded". This means that the healthcare staff who prepared and gave the vaccine knew which vaccine and dose were given, but the study participants and researchers did not know. The study later became "open-label" with respect to the first vaccine given to participants. This means that the study participants and researchers knew which vaccine and dose were given.

For a small group of participants who had not gotten BNT162b2 before, the first 2 doses of BNT162b2$_{SA}$ were given open-label in Phase 3.

The booster doses were given "open-label" in the study for those assigned to receive:

- 1 booster dose of BNT162b2 (Dose 3) after the first 2 doses of BNT162b2 or BNT162b2$_{SA}$.
- 1 additional booster dose of BNT162b2 (Dose 4 or 5) after the booster dose(s) of BNT162b2 or BNT162b2$_{SA}$.

For another small group of participants, who were reassigned to receive either BNT162b2 (30 µg or a lower dose of 5 or 10 µg) or BNT162b2$_{SA}$ (30 µg) as Dose 3 (booster), they did not know their booster assignment ("observer-blinded").

Where did this study take place?

This study ran at 153 locations in 6 countries.

- Argentina
- Brazil
- Germany
- South Africa
- Turkey
- USA

When did this study take place?

It began 29 April 2020 and ended 10 February 2023.

Who participated in this study?

The study included healthy children and adults aged 12 years and older who have not had COVID-19 infection and have not received a COVID-19 vaccine before they joined this study.

- A balanced number of men and women participated in Phase 1 and Phase 2/3.
- In **Phase 1**, participants were between the ages of 19 and 82 years.
- In **Phase 2/3**, participants were between the ages of 12 and 91 years.

Phase 1: Two doses of BNT162b1, BNT162b2, or placebo

- Of the **195** participants who started Phase 1, all participants (100%) received a study vaccine.
- No participants (0%) left the study during the blinded part of Phase 1.

Phase 2/3: Two doses of BNT162b2 or placebo

- Of the **46,406** participants who started Phase 2/3, 46,297 (99%) received a study vaccine.
- A total of 1156 participants (3%) left the study during the blinded part of Phase 2/3. The most common reason was because they could not be reached for follow-up.

Phase 3: Two doses of BNT162b2$_{SA}$

- A total of **333** participants, who had not received BNT162b2 before, were assigned to receive BNT162b2$_{SA}$ in Phase 3. Of these participants, 330 (99%) received BNT162b2$_{SA}$.
- A total of 102 participants (31%) did not finish the study. The most common reason was because they could not be reached for follow-up.

How long did the study last?

Study participants were in the study for up to 26 months. They were in the study for different lengths of time depending on which phase they joined. The entire study took about 33 months to complete.

The Sponsor Agent began reviewing the information collected while the study was ongoing. The Sponsor Agent created reports of the results after each review. When the study ended in February 2023, the Sponsor Agent reviewed the information that was not reported before. The Sponsor Agent then created a report of the results. This is a summary of all the reports that were created.

What were the results of the study?

Did BNT162b2 vaccine help to prevent COVID-19?

This section describes the main results from Phase 2/3 after the first 2 doses of BNT162b2 or placebo.

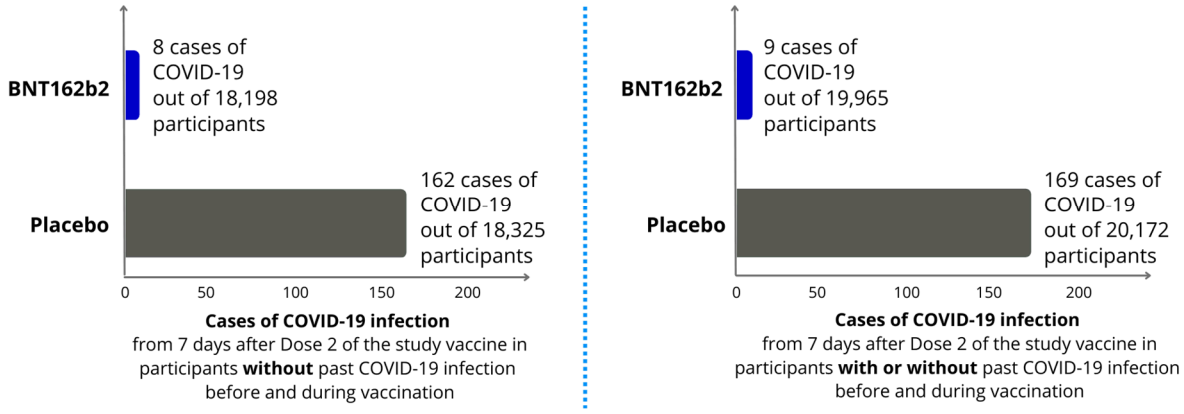
Researchers compared how many participants got COVID-19 at any time from 7 days after Dose 2 of BNT162b2 or placebo to the end of the monitoring period on 03 December 2020.

Researchers checked the results for 2 sets of participants:

- Those without COVID-19 infection before and after vaccination.
- Those with or without COVID-19 infection before and after vaccination.

The charts below in Figure 3 show how many participants got COVID-19 from 7 days after Dose 2 of the study vaccine.

Figure 3. How many participants got COVID-19 from 7 days after Dose 2 of the study vaccine?



Compared to a placebo, BNT162b2 was **95%** effective in preventing COVID-19 from 7 days after Dose 2 to the end of the monitoring period. The results were similar for the 2 sets of participants − those without past COVID-19 infection before and after vaccination, and those with or without past COVID-19 infection before and after vaccination.

The researchers have decided that these results are not likely due to chance. In this study, the first 2 doses of BNT162b2 at 30 µg gave protection against COVID-19 in participants aged 16 years and older. This was regardless of past COVID-19 infection.

Did BNT162b2 and BNT162b2$_{SA}$ produce immune responses against the COVID-19 virus?

To find out if there was an immune response against the COVID-19 virus, researchers measured the levels of antibodies against the COVID-19 virus at 1 month after receiving BNT162b2 or BNT162b2$_{SA}$.

For participants who **received BNT162b2 before** and did not have past COVID-19 up to 1 month after Dose 3 (booster), researchers found that:

- The immune responses against the original strain of COVID-19 virus seen 1 month after **Dose 3** (booster) of **BNT162b2** were as good as the immune responses seen at 1 month after **Dose 2** of **BNT162b2** in the same participants.
- The immune responses against the Beta variant of COVID-19 virus seen 1 month after **1 booster dose** of **BNT162b2$_{SA}$** were as good as the immune responses against the original strain of COVID-19 virus seen 1 month after **Dose 2** of **BNT162b2** in the same participants.

For participants who **did not receive BNT162b2 before** and did not have past COVID-19 up to 1 month after Dose 2, researchers found that:

- The immune responses against the Beta variant of COVID-19 virus seen 1 month after **Dose 2** of **BNT162b2$_{SA}$** were as good as the immune responses against the original strain of COVID-19 virus seen 1 month after **Dose 2** of **BNT162b2**.

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 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.

This section describes the medical problems that happened in participants who received at least 1 dose of a study vaccine.

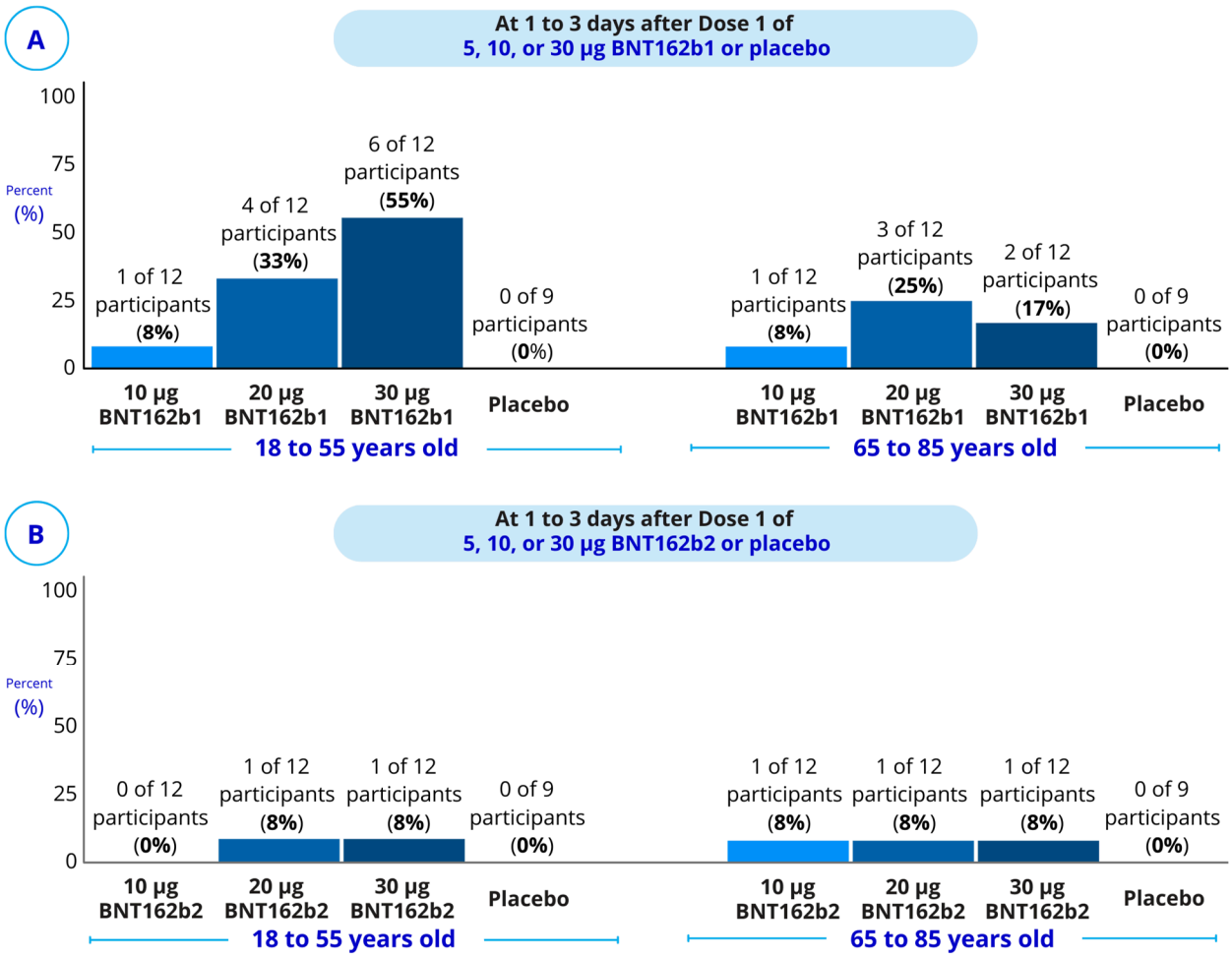
How many participants had abnormal blood test results during Phase 1?

In Phase 1, at 1 to 3 days after Dose 1 of BNT162b1 or BNT162b2, a few participants had a temporary drop in the number of **lymphocytes** (a type of white blood cells that help fight diseases).

- For these participants, lymphocyte count went back to normal by 6 to 8 days after Dose 1 of BNT162b1 and BNT162b2.
- None of the participants had low lymphocytes at 6 to 8 days after Dose 2 of BNT162b1 and BNT162b2.

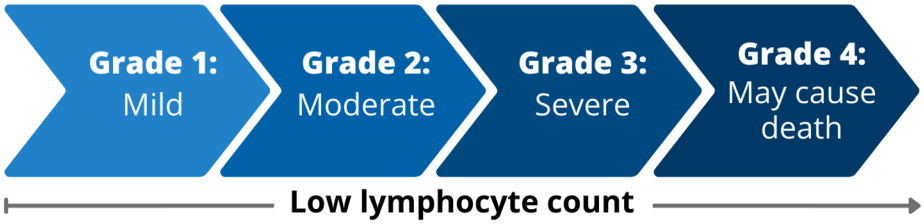
The charts in **Figure 4** below show how many participants in each age group had a temporary drop in lymphocyte count at 1 to 3 days after Dose 1 of BNT162b1 (Figure **4-A**) or BNT162b2 (Figure **4-B**).

Figure 4. How many participants had a temporary drop in lymphocyte count 1 to 3 days after Dose 1 of BNT162b1 or BNT162b2 in Phase 1?



Researchers checked how severe was the temporary drop in lymphocyte count and its worst grade during Phase 1 after participants got BNT162b1 or BNT162b2. **Figure 5** shows the grading scale and severity of low lymphocyte count.

Figure 5. Grading scale and severity of low lymphocyte count



The tables below show few participants had a temporary shift in lymphocyte count from normal or low lymphocytes Grade 1 to Grade 2 or higher at 1 to 3 days after Dose 1 of BNT162b1 (**Table 1**) or BNT162b2 (**Table 2**).

BNT162b1:

Table 1. Temporary drop in lymphocyte count at 1 to 3 days after Dose 1 of BNT162b1 in Phase 1

18 to 55 years old	65 to 85 years old
A shift from normal to Grade 3 as the worst grade in: • 1 of 12 participants (8%) in the 10-µg group. • 2 of 12 participants (17%) in the 20-µg group. • 1 of 11 participants (9%) in the 30-µg group.	A shift from normal to Grade 3 or 4 as the worst grade in: • 1 of 12 participants (8%) in the 10-µg group (a shift from normal to Grade 4). • 1 of 12 participants (8%) in the 30-µg group (a shift from normal to Grade 3).

There was no shift from normal count or a lower grade low lymphocytes to Grade 2 or 4 by 6 to 8 days after Dose 1 or 2 in either age group.

BNT162b2:

Table 2. Temporary drop in lymphocyte count at 1 to 3 days after Dose 1 of BNT162b2 in Phase 1	
18 to 55 years old	**65 to 85 years old**
A shift from normal to Grade 2 as the worst grade in: • 1 of 12 participants (8%) in the 20-µg group. • 1 of 12 participants (8%) in the 30-µg group.	A shift from normal or Grade 1 to Grade 2 or 3 as the worst grade in: • 1 of 12 participants (8%) in the 10-µg group (a shift from normal to Grade 3). • 1 of 12 participants (8%) in the 30-µg group (a shift from Grade 1 to Grade 3). • 2 of 12 participants (17%) in the 20-µg group (a shift from normal to Grade 2).

In the **18 to 55 years old** group, there was no shift from normal count or a lower grade low lymphocytes to Grade 2 or higher at 6 to 8 days after Dose 1 or Dose 2.

In the **65 to 85 years old** group, there was no shift from normal count or a lower grade low lymphocytes to Grade 2 or higher at 6 to 8 days after Dose 1. At 6 to 8 days after Dose 2, a shift from Grade 1 to Grade 2 was seen in 1 of 12 participants (8%) in the 30-µg group and 1 of 9 participants (11%) in the placebo group.

How many participants had redness, swelling, or pain at the injection site within 7 days after vaccination? − Phase 1 and Phase 2/3

Redness, swelling, or pain at the injection site are common medical problems seen after vaccination. These are called "**injection site reactions**".

All participants in Phase 1 and some participants in Phase 2/3 were asked to fill in their electronic diary (e-diary) 7 days after getting a study vaccine. This section includes the injection site reactions recorded in participants' e-diaries during the study.

Summary for Phase 1 and Phase 2/3:

- Injection site reactions within 7 days after getting BNT162b1 or BNT162b2 were well tolerated and went away after a short time.
- Most of these injection site reactions were mild or moderate in severity.
- Pain at the injection site was the most common of these reactions after getting BNT162b1 or BNT162b2.

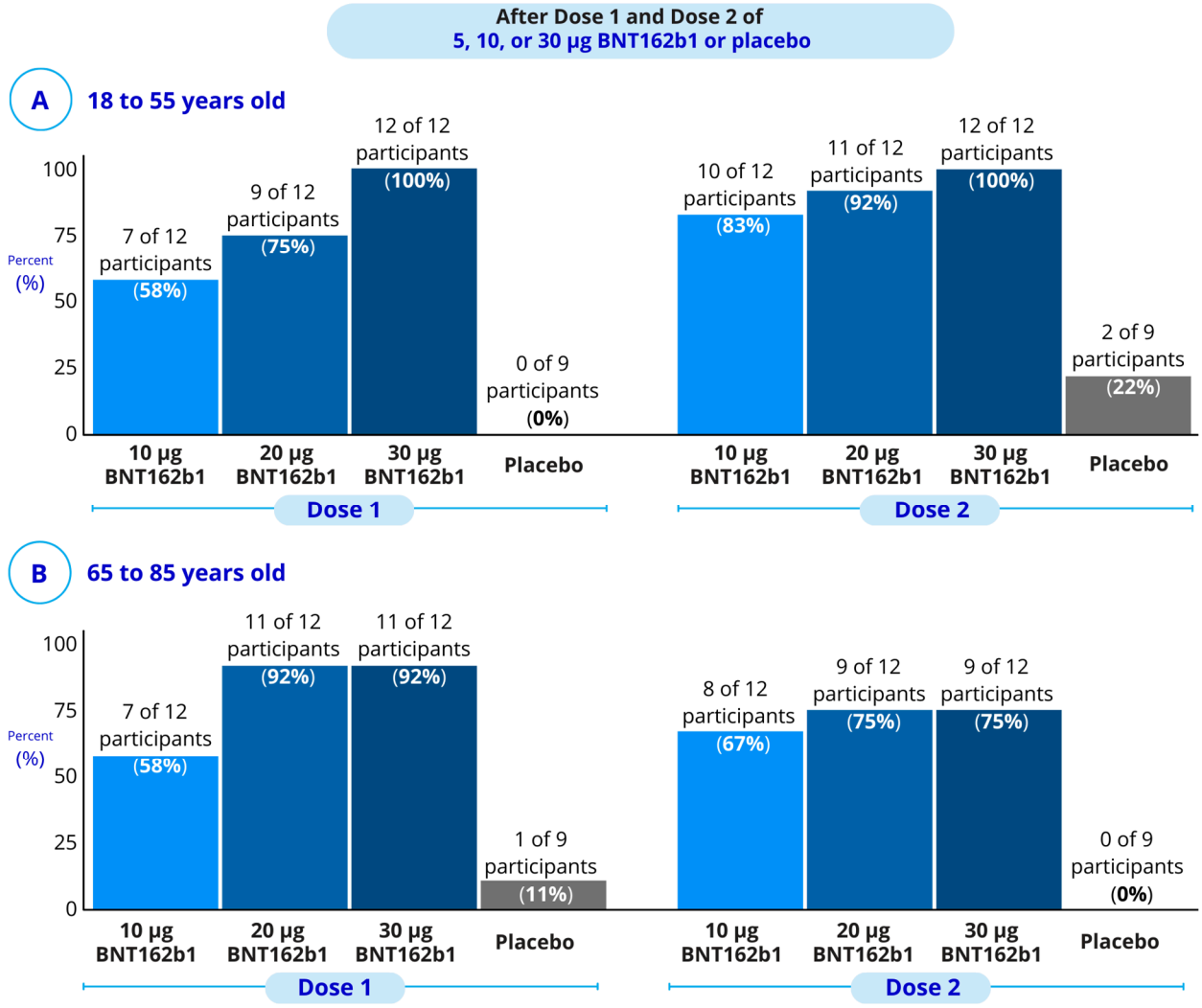
The sections below describe the injection site reactions that happened after the first 2 doses and the booster doses.

Phase 1:

Two doses of BNT162b1 or placebo in Phase 1

Figure 6 shows how many participants had any injection site reactions after each dose of **BNT162b1** or **placebo** in Phase 1.

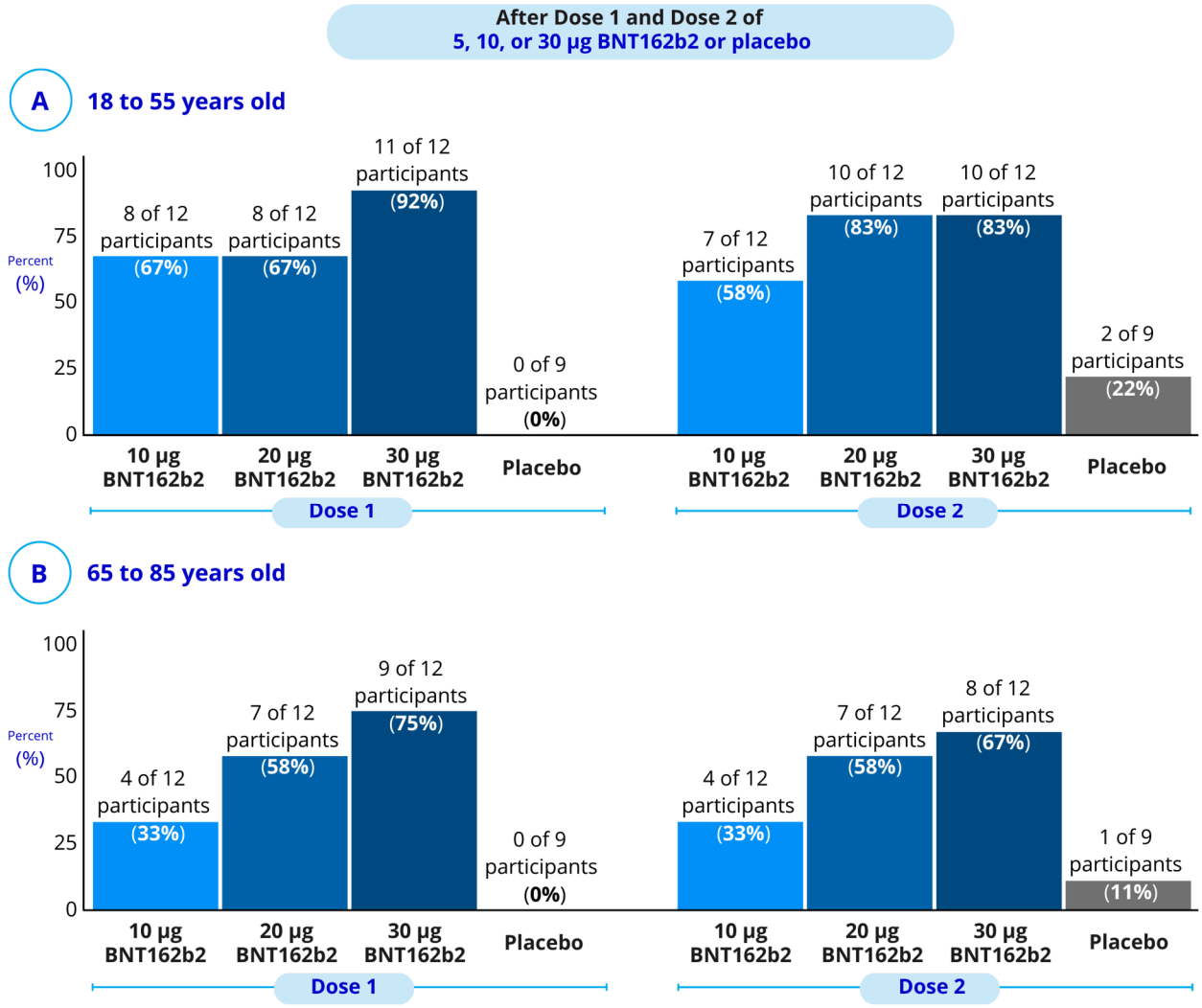
Figure 6. How many participants had any injection site reactions within 7 days after each dose of BNT162b1 or placebo in Phase 1?



Two doses of BNT162b2 or placebo in Phase 1

Figure 7 shows how many participants had any injection site reactions after each dose of **BNT162b2** or **placebo** in Phase 1.

Figure 7. How many participants had any injection site reactions within 7 days after each dose of BNT162b2 or placebo in Phase 1?



Phase 2/3:

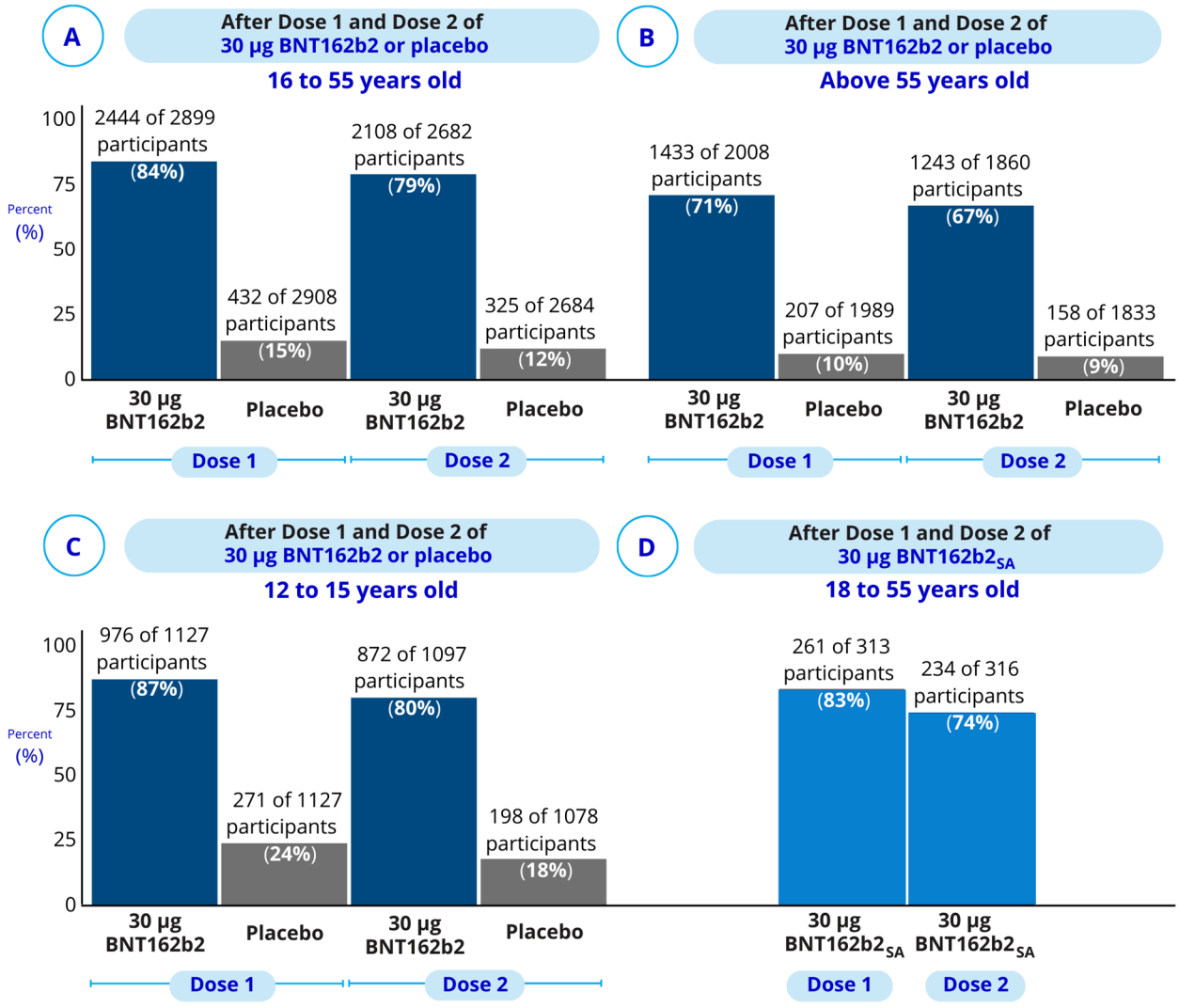
Results for Phase 2 participants (the first 360 participants enrolled in Phase 2/3 part of the study) were similar to those seen in the total participants in Phase 2/3.

Two doses of 30 µg BNT162b2 or placebo in Phase 2/3 and 30 µg BNT162b2$_{SA}$ in Phase 3

The charts in **Figure 8** show how many participants had any injection site reactions after each dose of:

- **BNT162b2** or **placebo** in Phase 2/3 (Figures **8-A**, **8-B**, and **8-C**).
- **BNT162b2$_{SA}$** in Phase 3 for those who had not gotten BNT162b2 before they received 2 doses of **30 µg BNT162b2$_{SA}$** (Figure **8-D**).

Figure 8. How many participants had any injection site reactions within 7 days after each dose of 30 µg BNT162b2 or placebo in Phase 2/3 and 30 µg BNT162b2$_{SA}$ in Phase 3?

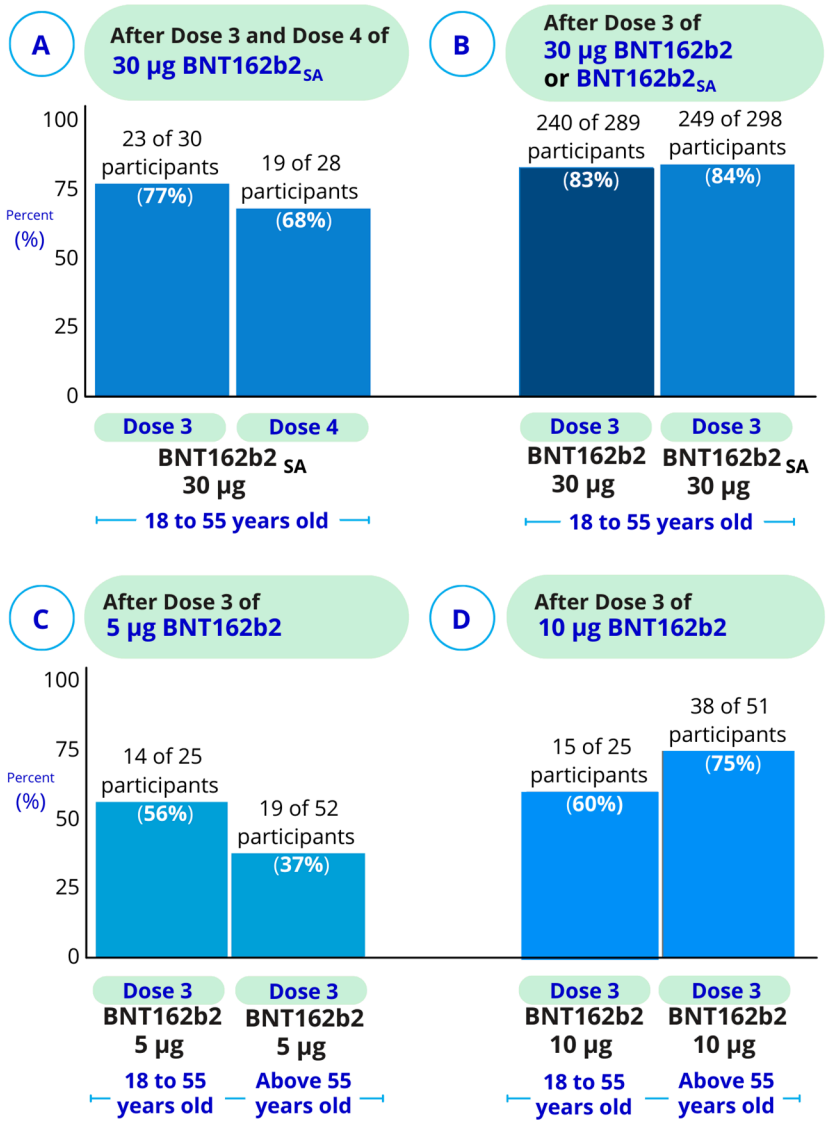


Booster dose(s) of 30 µg BNT162b2, 30 µg BNT162b2$_{SA}$, or 5 or 10 µg BNT162b2 in Phase 3

The charts in **Figure 9** show how many participants had any injection site reactions after each booster dose of BNT162b2 or BNT162b2$_{SA}$ for those who got 2 doses of BNT162b2 before they were reassigned in Phase 3 to receive:

- 2 booster doses of **30 µg BNT162b2$_{SA}$** (Figure **9-A**).
- 1 booster dose of **30 µg BNT162b2 or BNT162b2$_{SA}$** (Figure **9-B**).
- 1 lower booster dose of **5 or 10 µg BNT162b2** (Figures **9-C** and **9-D**).

Figure 9. How many participants had any injection site reactions within 7 days after the booster dose(s) of 30 µg BNT162b2, 30 µg BNT162b2$_{SA}$, or 5 or 10 µg BNT162b2 in Phase 3?



The injection site reactions seen in these groups of participants are similar to those seen in the larger group of participants in Phase 2/3.

How many participants had fever, tiredness, headache, chills, vomiting, diarrhea, muscle pain, or joint pain within 7 days after vaccination? − Phase 1 and Phase 2/3

Fever, tiredness, headache, chills, vomiting, diarrhea, or new muscle or joint pain are common medical problems seen after vaccination. These are called "**systemic events**", which are responses affecting the body.

All participants in Phase 1 and some participants in Phase 2/3 were asked to fill in their e-diary 7 days after getting a study vaccine. This section includes the systemic events recorded in participants' e-diaries during the study.

Summary for Phase 1 and Phase 2/3:

- Systemic events within 7 days after getting BNT162b1 or BNT162b2 were well tolerated and went away after a short time.
- Most of these systemic events were mild or moderate in severity.
- Tiredness and headache were the most common systemic events after BNT162b1 or BNT162b2.

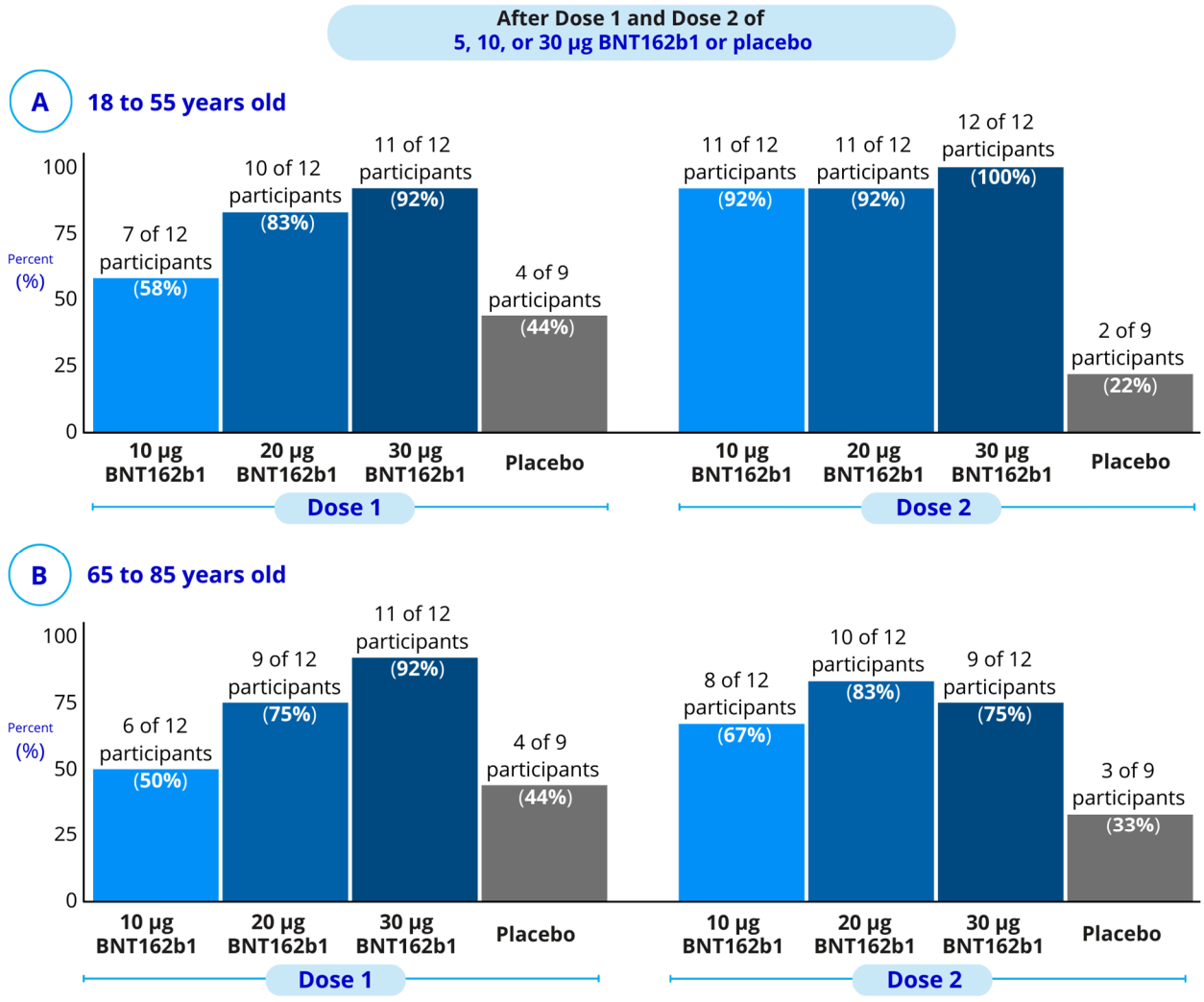
The sections below describe the systemic events that happened after the first 2 doses and the booster doses.

Phase 1:

Two doses of BNT162b1 or placebo in Phase 1

Figure 10 shows how many participants had any systemic events after each dose of **BNT162b1** or **placebo** in Phase 1.

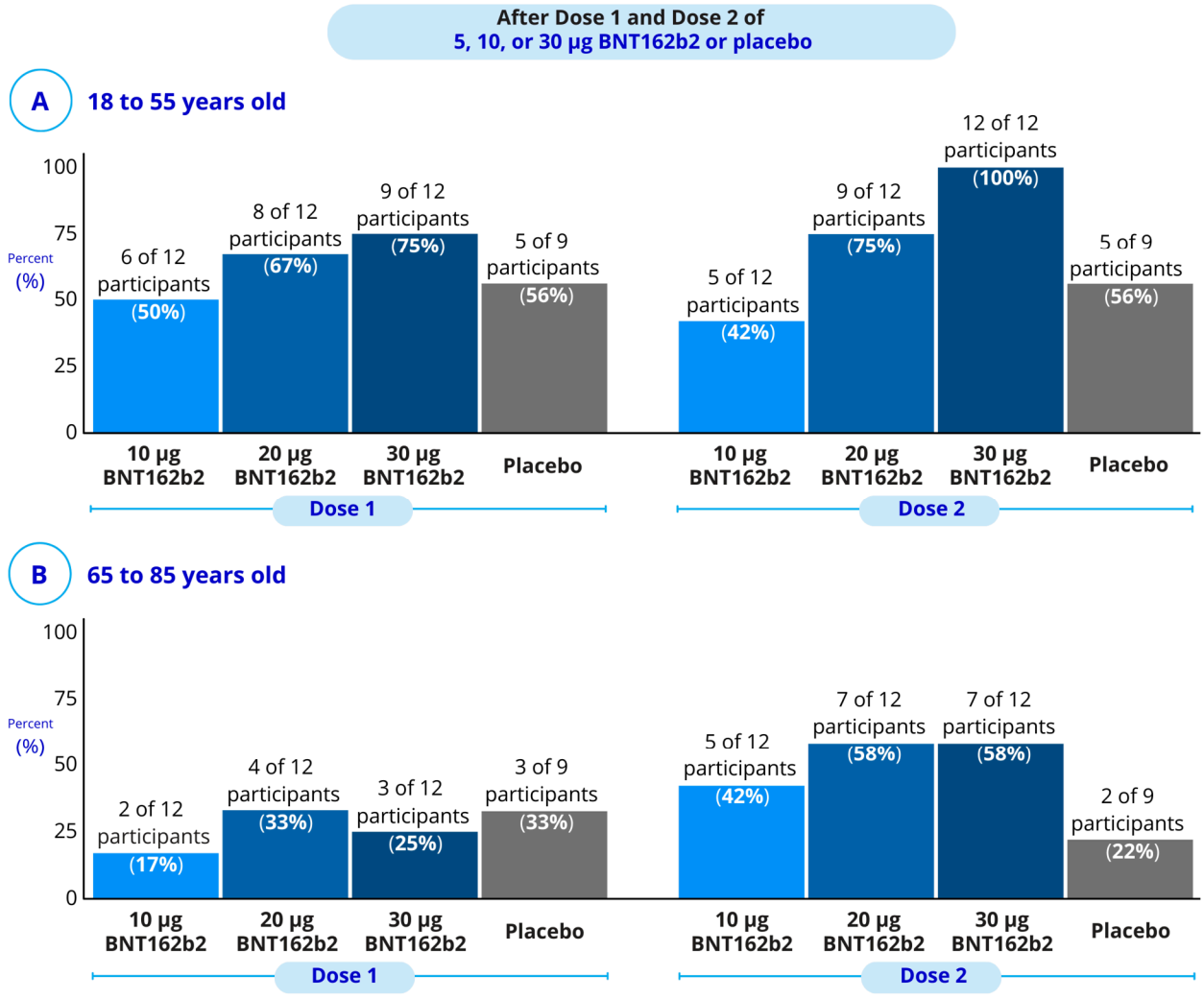
Figure 10. How many participants had any systemic events within 7 days after each dose of BNT162b1 or placebo in Phase 1?



Two doses of BNT162b2 or placebo in Phase 1

Figure 11 shows how many participants had any systemic events after each dose of **BNT162b2** or **placebo** in Phase 1.

Figure 11. How many participants had any systemic events within 7 days after each dose of BNT162b2 or placebo in Phase 1?



Phase 2/3:

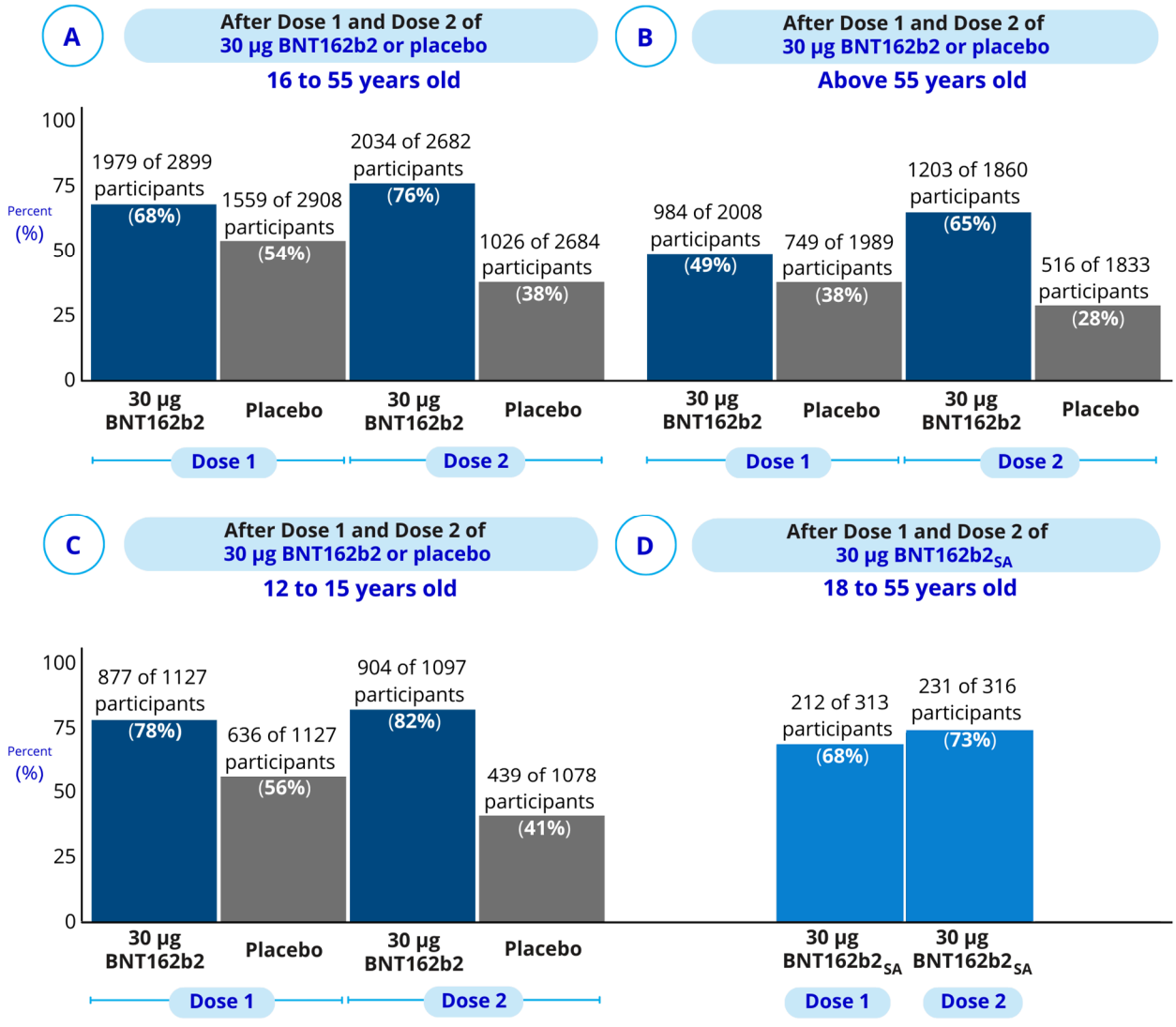
Results for Phase 2 participants (the first 360 participants enrolled in Phase 2/3 part of the study) were similar to those seen in the total participants in Phase 2/3.

Two doses of 30 µg BNT162b2 or placebo in Phase 2/3 and 30 µg BNT162b2$_{SA}$ in Phase 3

The charts in **Figure 12** show how many participants had any systemic events after each dose of:

- **BNT162b2** or **placebo** in Phase 2/3 (Figures **12-A**, **12-B**, and **12-C**).
- **BNT162b2$_{SA}$** in Phase 3 for those who had not gotten BNT162b2 before they received 2 doses of **30 µg BNT162b2$_{SA}$** (Figure **12-D**).

Figure 12. How many participants had any systemic events within 7 days after each dose of 30 µg BNT162b2 or placebo in Phase 2/3 and 30 µg BNT162b2$_{SA}$ in Phase 3?

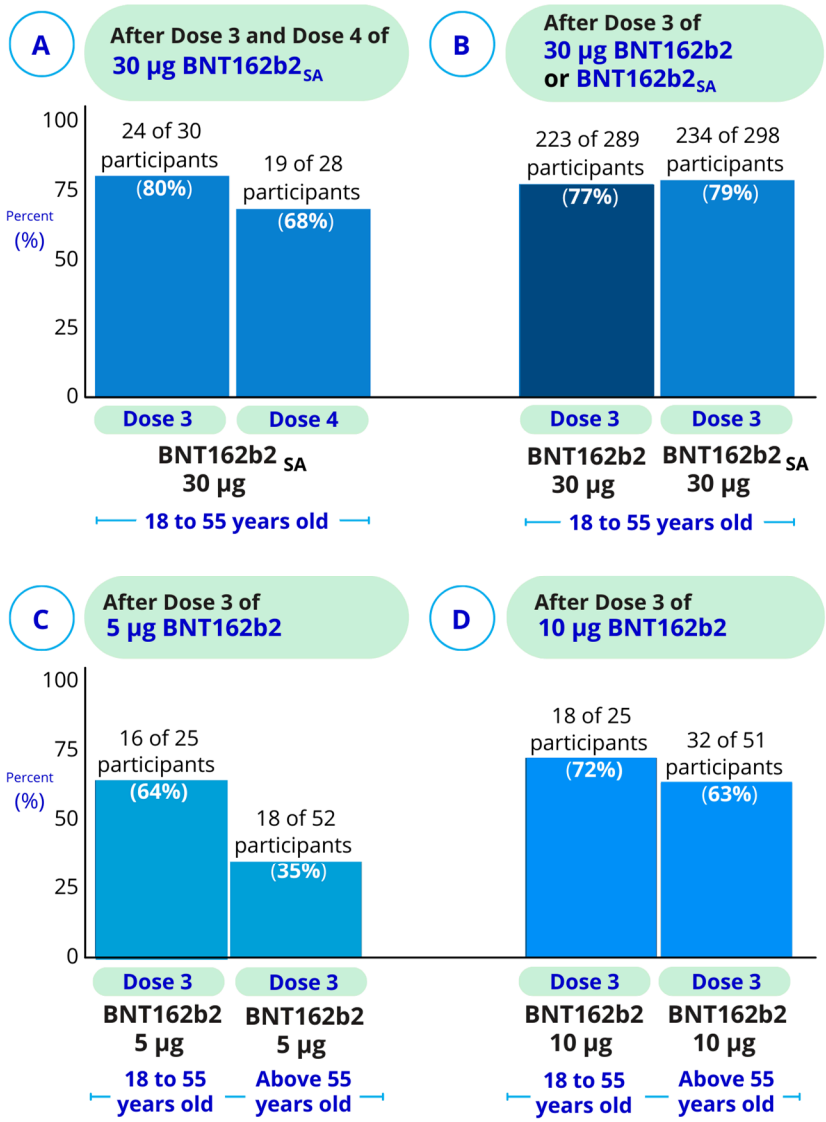


Booster dose(s) of 30 µg BNT162b2, 30 µg BNT162b2$_{SA}$, or 5 or 10 µg BNT162b2 in Phase 3

The charts in **Figure 13** show how many participants had any systemic events after each booster dose of BNT162b2 or BNT162b2$_{SA}$ for those who got 2 doses of BNT162b2 before they were reassigned in Phase 3 to receive:

- 2 booster doses of **30 µg BNT162b2$_{SA}$** (Figure **13-A**).
- 1 booster dose of **30 µg BNT162b2 or BNT162b2$_{SA}$** (Figure **13-B**).
- 1 lower booster dose of **5 or 10 µg BNT162b2** (Figures **13-C** and **13-D**).

Figure 13. How many participants had any systemic events within 7 days after the booster dose(s) of 30 µg BNT162b2, 30 µg BNT162b2$_{SA}$, or 5 or 10 µg BNT162b2 in Phase 3?



The systemic events seen in these groups of participants are similar to those seen in the larger group of participants in Phase 2/3.

How many participants had medical problems within 1 month after Dose 2 or the booster doses? − Phase 1 and Phase 2/3

This section includes the medical problems seen within 1 month after Dose 2 or the booster doses.

Phase 1:

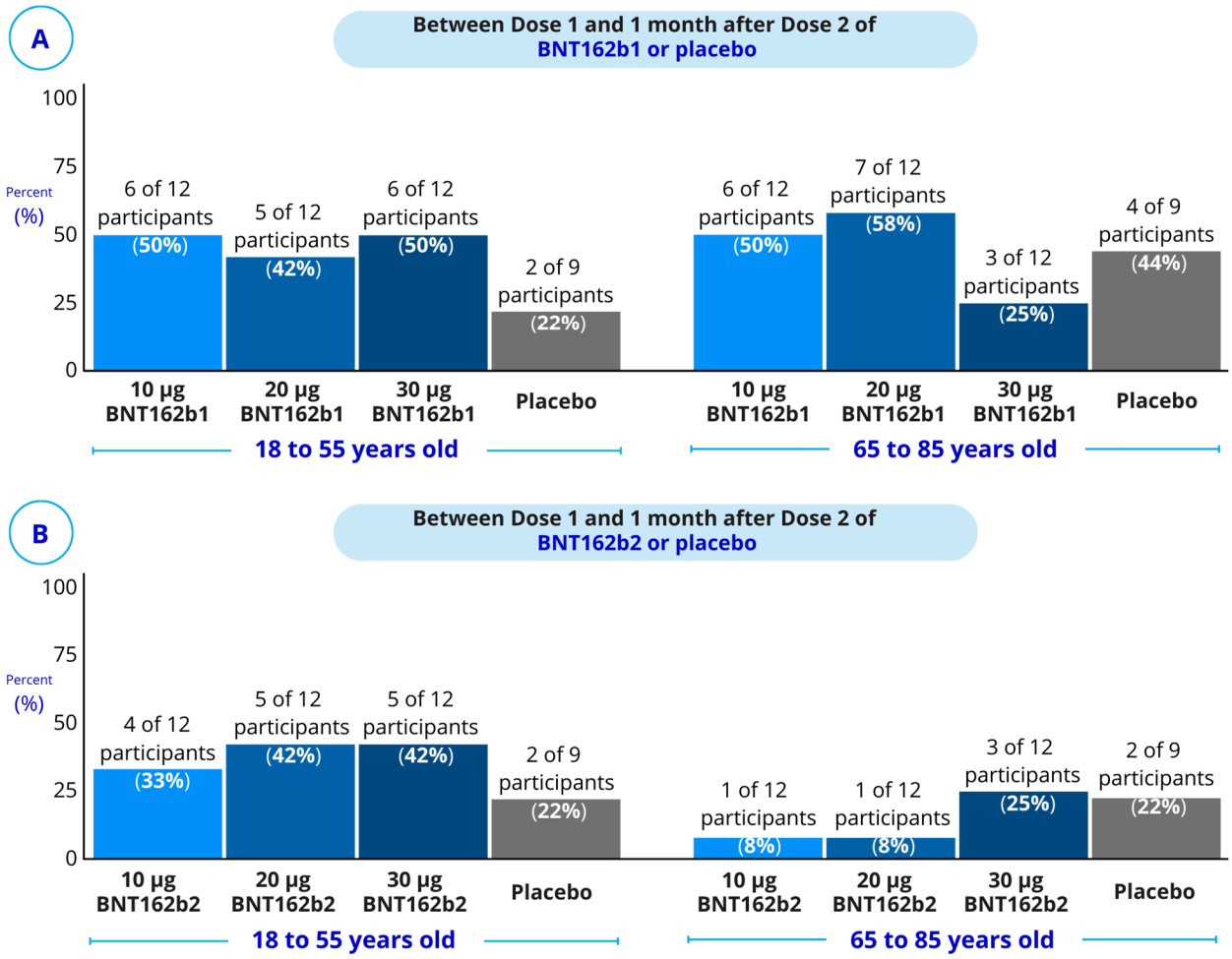
Two doses of BNT162b1, BNT162b2, or placebo in Phase 1

Summary:

- All tested doses (10, 20, and 30 µg) for BNT162b1 and BNT162b2 in Phase 1 were well tolerated, except for BNT162b1 at 100 µg. The 100-µg dose was stopped after Dose 1 because of injection site reactions or systemic events.
- BNT162b2 at 30 µg was the selected vaccine for Phase 2/3 of this study.
- No participants left Phase 1 of the study because of medical problems.
- Most of the medical problems were mild or moderate in severity.
- Between Dose 1 and 1 month after Dose 2 of BNT162b1 or BNT162b2, no single medical problem happened in more than 2 participants in any dose group.

Figure 14 shows how many participants had a medical problem between Dose 1 and 1 month after Dose 2 of **BNT162b1, BNT162b2,** or **placebo** in Phase 1.

Figure 14. How many participants had a medical problem between Dose 1 and 1 month after Dose 2 of BNT162b1, BNT162b2, or placebo in Phase 1?



Phase 2/3:

Results for Phase 2 participants (the first 360 participants enrolled in Phase 2/3 part of the study) were similar to those seen in the total participants in Phase 2/3.

Two doses of 30 µg BNT162b2 or placebo in Phase 2/3

Summary:

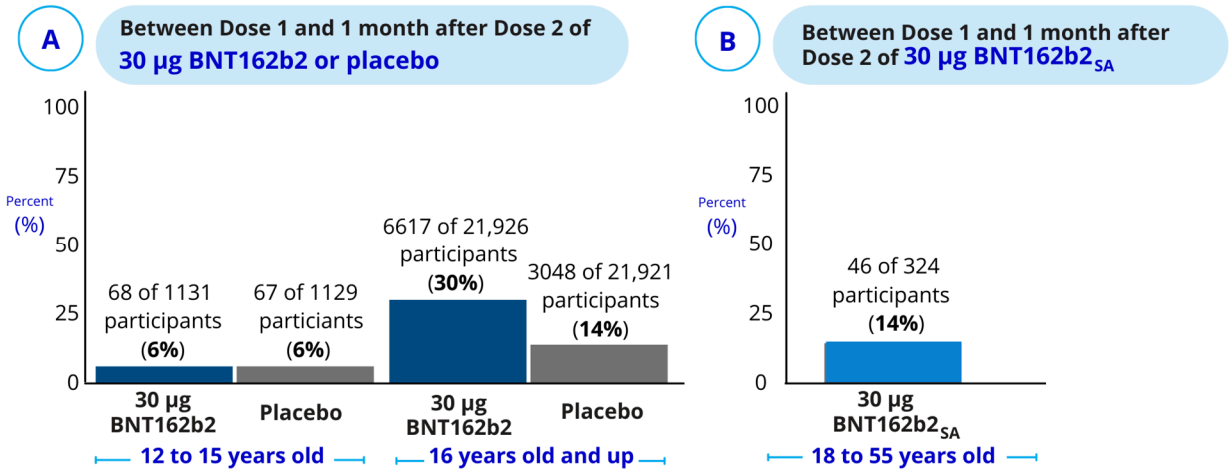
- BNT162b2 at 30 µg was well tolerated and its safety results were similar to those seen in earlier phases.
- Few participants in the BNT162b2 and placebo groups left during the blinded part of Phase 2/3 of the study because of medical problems.
    - 32 of 21,926 participants (less than 1%) in the BNT162b2 group
    - 36 of 21,921 participants (less than 1%) in the placebo group
- Most of the medical problems were mild or moderate in severity.
- Most of the medical problems seen in the BNT162b2 group involved injection site reactions or systemic events.

Two doses of 30 µg BNT162b2 or placebo in Phase 2/3 and 30 µg BNT162b2$_{SA}$ in Phase 3

The charts in **Figure 15** show how many participants had a medical problem between Dose 1 and 1 month after:

- Dose 2 of **BNT162b2** or **placebo** in Phase 2/3 (Figure **15-A**).
- Dose 2 of **30 µg BNT162b2$_{SA}$** in Phase 3 for those who had not gotten BNT162b2 before they received 2 doses of **30 µg BNT162b2$_{SA}$** (Figure **15-B**).

Figure 15. How many participants had a medical problem between Dose 1 and 1 month after Dose 2 of 30 µg BNT162b2 or placebo in Phase 2/3, and between Dose 1 and 1 month after Dose 2 of 30 µg BNT162b2$_{SA}$ in Phase 3?



No single medical problem happened in more than 1% of participants aged 12 to 15 years old in either vaccine group.

Table 3 describes the most common medical problems that happened in at least 1% of participants aged 16 years and older in either vaccine group during Phase 2/3. These medical problems happened at any time between Dose 1 and 1 month after Dose 2 of BNT162b2 or placebo.

Below are instructions on how to read Table 3.

Instructions for Understanding Table 3.

- The **1st** column of Table 3 lists medical problems that were commonly reported after the first 2 doses of the study vaccine in Phase 2/3. All medical problems reported by at least 1% of participants in either vaccine group are listed.
- The **2nd** column tells how many of the 21,926 participants had each medical problem after getting BNT162b2. Next to this number is the percentage of the 21,926 participants who had the medical problem after getting BNT162b2.
- The **3rd** column tells how many of the 21,921 participants had each medical problem after getting a placebo. Next to this number is the percentage of the 21,921 participants who had the medical problem after getting a placebo.
- Using these instructions, you can see that 274 out of the 21,926 participants (1%) had nausea after getting BNT162b2. A total of 87 out of the 21,921 participants (less than 1%) had nausea after getting a placebo.

Table 3. What were the commonly reported medical problems between Dose 1 and 1 month after Dose 2 of 30 µg BNT162b2 or placebo in Phase 2/3?		
Medical problem	**BNT162b2 (30 µg)**	**Placebo**
Nausea	274 out of 21,926 participants (1%)	87 out of 21,921 participants (less than 1%)
Diarrhea	248 out of 21,926 participants (1%)	188 out of 21,921 participants (1%)
Injection site pain	2915 out of 21,926 participants (13%)	397 out of 21,921 participants (2%)
Fever	1517 out of 21,926 participants (7%)	77 out of 21,921 participants (less than 1%)
Tiredness	1463 out of 21,926 participants (7%)	379 out of 21,921 participants (2%)
Chills	1365 out of 21,926 participants (6%)	120 out of 21,921 participants (1%)
Pain	628 out of 21,926 participants (3%)	61 out of 21,921 participants (less than 1%)
Muscle pain	1239 out of 21,926 participants (6%)	168 out of 21,921 participants (1%)
Joint pain	268 out of 21,926 participants (1%)	102 out of 21,921 participants (1%)
Headache	1339 out of 21,926 participants (6%)	424 out of 21,921 participants (2%)

Table 4 lists the most common medical problems that happened in at least 1% of participants who had not gotten BNT162b2 before they received 2 doses of 30 µg BNT162b2$_{SA}$. These medical problems happened at any time between Dose 1 and 1 month after Dose 2 of 30 µg BNT162b2$_{SA}$.

Table 4. What were the commonly reported medical problems between Dose 1 and 1 month after Dose 2 of 30 µg BNT162b2$_{SA}$ in Phase 3?

Medical problem	BNT162b2$_{SA}$ (30 µg), 2 doses
Nausea	4 out of 324 participants (1%)
Tiredness	10 out of 324 participants (3%)
Injection site pain	6 out of 324 participants (2%)
Chills	4 out of 324 participants (1%)
Fever	4 out of 324 participants (1%)
Muscle pain	6 out of 324 participants (2%)
Joint pain	4 out of 324 participants (1%)
Headache	8 out of 324 participants (3%)

Booster dose(s) of 30 µg BNT162b2, 30 µg BNT162b2$_{SA}$, or 5 or 10 µg BNT162b2 in Phase 3

The charts in **Figure 16** show how many participants had a medical problem within 1 month after the last booster dose of BNT162b2 or BNT162b2$_{SA}$ for those who got 2 doses of BNT162b2 before they received booster dose(s) in Phase 3:

- 2 booster doses of **30 µg BNT162b2$_{SA}$** − between Dose 3 and 1 month after Dose 4 (Figure **16-A**)
- 1 booster dose of **30 µg BNT162b2 or BNT162b2$_{SA}$** − between Dose 3 and 1 month after Dose 3 (Figure **16-B**)
- 1 lower booster dose of **5 or 10 µg BNT162b2** − between Dose 3 and 1 month after Dose 3 (Figures **16-C** and **16-D**)

Figure 16. How many participants had a medical problem within 1 month after the last booster dose of 30 µg BNT162b2, 30 µg BNT162b2$_{SA}$, or 5 or 10 µg BNT162b2 in Phase 3?

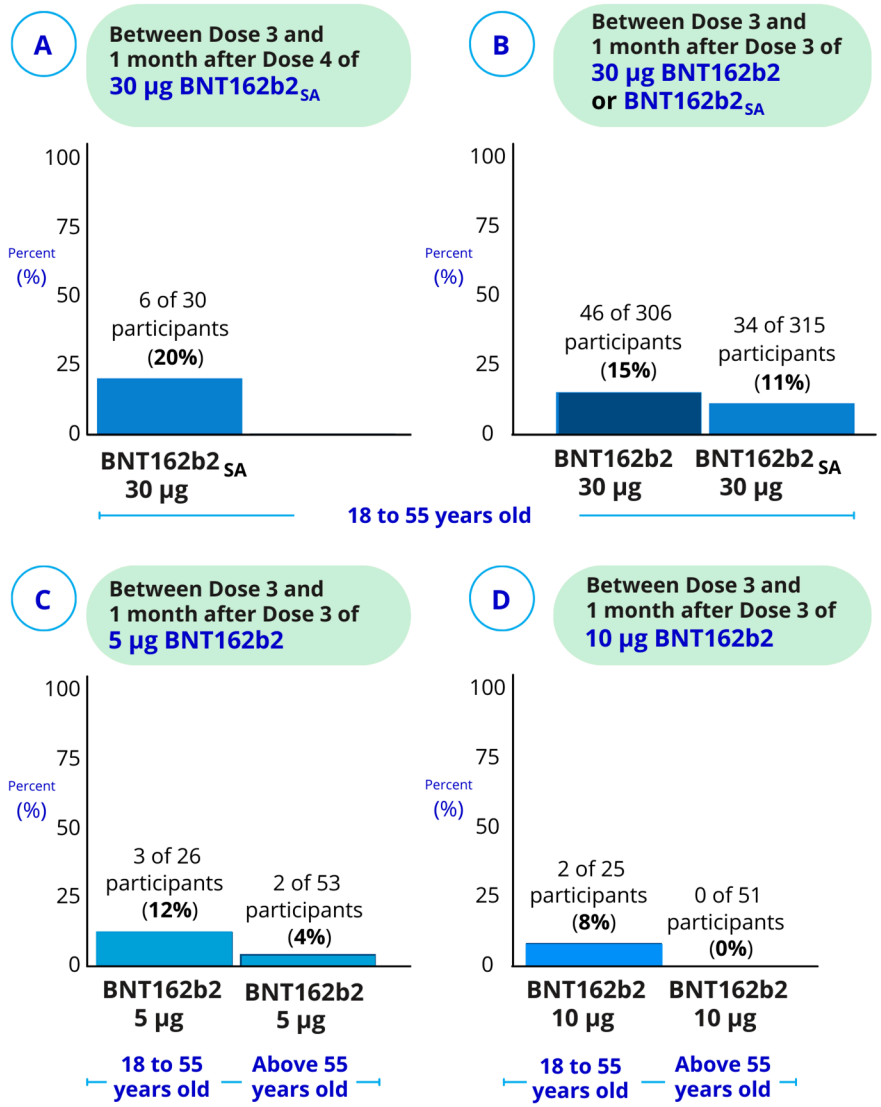


Table 5 lists the most common medical problems that happened within 1 month after the last booster dose of **30 µg BNT162b2** or **BNT162b2$_{SA}$** in participants who got 2 doses of BNT162b2 before. These medical problems happened in at least 5% of participants in any group who received booster dose(s) in Phase 3:

- 1 booster dose of **BNT162b2** or **BNT162b2$_{SA}$** − between Dose 3 and 1 month after Dose 3
- 2 booster doses of **BNT162b2$_{SA}$** − between Dose 3 and 1 month after Dose 4

Table 5. What were the commonly reported medical problems between Dose 3 and 1 month after the last booster dose of 30 µg BNT162b2 or BNT162b2$_{SA}$ in Phase 3?

Medical problem	Reassigned to get 1 booster dose (between Dose 3 and 1 month after Dose 3)		Assigned to get 2 booster doses (between Dose 3 and 1 month after Dose 4)
	BNT162b2 (30 µg)	BNT162b2$_{SA}$ (30 µg)	BNT162b2$_{SA}$ (30 µg)
Swollen lymph nodes	16 out of 306 participants (5%)	6 out of 315 participants (2%)	2 out of 30 participants (7%)
Joint pain	0 out of 306 participants (0%)	1 out of 315 participants (less than 1%)	2 out of 30 participants (7%)

Booster dose of 5 or 10 µg BNT162b2 in Phase 3

Table 6 lists the most common medical problems that happened in at least 1% of participants in any of the lower booster dose groups. These medical problems happened at any time between Dose 3 and 1 month after Dose 3 of **5 or 10 µg BNT162b2** (lower booster dose) in Phase 3 among those who got 2 doses of BNT162b2 (30 µg) before.

Table 6. What were the commonly reported medical problems between Dose 3 and 1 month after Dose 3 of 5 or 10 µg BNT162b2 (lower dose booster) in Phase 3?

Medical problem	BNT162b2 (5 µg)		BNT162b2 (10 µg)	
	18 to 55 years old	Above 55 years old	18 to 55 years old	Above 55 years old
Swollen lymph nodes	0 out of 26 participants (0%)	0 out of 53 participants (0%)	1 out of 25 participants (4%)	0 out of 51 participants (0%)
Backflow of food from stomach up into the food pipe	1 out of 26 participants (4%)	0 out of 53 participants (0%)	1 out of 25 participants (4%)	0 out of 51 participants (0%)
Tiredness	0 out of 26 participants (0%)	1 out of 53 participants (2%)	0 out of 25 participants (0%)	0 out of 51 participants (0%)
Cut or wound in the skin	1 out of 26 participants (4%)	0 out of 53 participants (0%)	0 out of 25 participants (0%)	0 out of 51 participants (0%)
Loss of too much fluid from the body	0 out of 26 participants (0%)	1 out of 53 participants (2%)	0 out of 25 participants (0%)	0 out of 51 participants (0%)

Table 6. What were the commonly reported medical problems between Dose 3 and 1 month after Dose 3 of 5 or 10 µg BNT162b2 (lower dose booster) in Phase 3?				
Medical problem	**BNT162b2 (5 µg)**		**BNT162b2 (10 µg)**	
	18 to 55 years old	**Above 55 years old**	**18 to 55 years old**	**Above 55 years old**
Arm or leg pain	1 out of 26 participants (4%)	0 out of 53 participants (0%)	0 out of 25 participants (0%)	0 out of 51 participants (0%)
Feeling dizzy	0 out of 26 participants (0%)	1 out of 53 participants (2%)	0 out of 25 participants (0%)	0 out of 51 participants (0%)
Change in the sense of taste	0 out of 26 participants (0%)	1 out of 53 participants (2%)	0 out of 25 participants (0%)	0 out of 51 participants (0%)

Booster dose of 30 µg BNT162b2 in Phase 2/3

Table 7 shows how many participants had a medical problem between Dose 3 and 1 month after Dose 3 of **30 µg BNT162b2** (booster) in Phase 2/3.

Table 7. How many participants had a medical problem between Dose 3 and 1 month after Dose 3 of 30 µg BNT162b2 (booster) in Phase 2/3?	
Age group	**BNT162b2 (30 µg)**
12 to 15 years old	153 out of 825 participants (19%)
16 years and older	3818 out of 22,470 participants (17%)

Additional booster dose of 30 µg BNT162b2 in Phase 2/3

Table 8 shows how many participants had a medical problem between Dose 4 or 5 and 1 month after Dose 4 or 5 of **30 µg BNT162b2** (additional booster) in Phase 2/3.

Table 8. How many participants had a medical problem between Dose 4 or 5 and 1 month after Dose 4 or 5 of 30 µg BNT162b2 (additional booster) in Phase 2/3?

Previous Vaccine Group				
BNT162b2 (30 µg)	**BNT162b2$_{SA}$ (30 µg)**	**BNT162b2 (5 µg)**	**BNT162b2 (10 µg)**	**BNT162b2$_{SA}$ (30 µg, 2 doses)**
17 out of 182 participants (9%)	17 out of 196 participants (9%)	0 out of 33 participants (0%)	1 out of 38 participants (3%)	1 out of 15 participants (7%)

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.

How many participants had serious medical problems within 1 to 6 months after Dose 2 or the booster doses? − Phase 1 and Phase 2/3

This section includes the serious medical problems seen within 1 to 6 months after Dose 2 or the booster doses.

Phase 1:

Two doses of BNT162b1, BNT162b2, or placebo in Phase 1

Between Dose 1 and 6 months after Dose 2 of **BNT162b2** or **placebo**, 2 participants had a serious medical problem in Phase 1:

- 1 of 24 participants (4%) in the BNT162b2 20-µg group had inflamed appendix.
- 1 of 24 participants (4%) in the BNT162b2 30-µg group had inflamed nerves.

Researchers do not believe that any of the serious medical problems were related to the study vaccine.

No participant in the BNT162b1 10, 20, and 30-µg dose groups or placebo group had a serious medical problem in Phase 1.

Phase 2/3

Results for Phase 2 participants (the first 360 participants enrolled in Phase 2/3 part of the study) were similar to those seen in the total participants in Phase 2/3.

Two doses of 30 µg BNT162b2 or placebo in Phase 2/3

Table 9 shows few participants had a serious medical problem in Phase 2/3 between Dose 1 and 6 months after Dose 2 of **BNT162b2** or **placebo**.

Table 9. How many participants had a serious medical problem between Dose 1 and 6 months after Dose 2 of 30 µg BNT162b2 or placebo in Phase 2/3?

Age group	BNT162b2 (30 µg) Only at the Start of the Study	Placebo at the Start Then BNT162b2 (30 µg) Later in the Study	Placebo Only at the Start of the Study
12 to 15 years old	13 out of 1131 participants (1%)	13 out of 1014 participants (1%)	2 out of 1129 participants (less than 1%)
16 years and older	428 out of 21,910 participants (2%)	353 out of 20,267 participants (2%)	291 out of 21,911 participants (1%)

No single serious medical problem happened in at least 1% of participants in any group.

12 to 15 years old:

None of the participants in this age group had serious medical problems that were related to the study vaccine.

16 years and older:

For those in this age group that got BNT162b2 at the start of the study, 3 participants had 1 serious medical problem each that lasted temporarily.

Researchers believe these serious medical problems may be related to the study vaccine.

- 1 participant had irregular heartbeat.
- 1 participant had shoulder injury.
- 1 participant had numbness or tingling of the arms or legs.

For those in this age group that got placebo at the start then BNT162b2 later in the study, 3 participants had 1 serious medical problem each that lasted temporarily. Researchers believe these serious medical problems may be related to the study vaccine.

- 1 participant had narrowing or blockage of the portal vein by a blood clot. The portal vein is a blood vessel that brings blood to the liver from the gut.
- 1 participant had a mini stroke or temporary blockage of blood flow to the brain.
- 1 participant had muscle pain.

Two doses of 30 µg BNT162b2$_{SA}$ in Phase 3

A total of 4 out of 324 participants (1%) had a serious medical problem between Dose 1 and 6 months after Dose 2 of **30 µg BNT162b2$_{SA}$** for those who had not gotten BNT162b2 before they received 2 doses of **30 µg BNT162b2$_{SA}$**. No single serious medical problem happened in more than 1 participant in this group. Researchers do not believe that any of the serious medical problems were related to the study vaccine.

Booster dose(s) of 30 µg BNT162b2 or BNT162b2$_{SA}$ in Phase 3

Table 10 below shows few participants had a serious medical problem after their booster dose(s) in Phase 3:

- 1 booster dose of **30 µg BNT162b2 or BNT162b2$_{SA}$** − between Dose 3 and 6 months after Dose 3.
- 2 booster doses of **30 µg BNT162b2$_{SA}$** − between Dose 3 and 5 months after Dose 4.

Table 10. How many participants had a serious medical problem within 5 or 6 months after the last booster dose of 30 µg BNT162b2 or BNT162b2$_{SA}$ in Phase 3?

Reassigned to get 1 booster dose (between Dose 3 and 6 months after Dose 3)		**Assigned to get 2 booster doses** (between Dose 3 and 5 months after Dose 4)
BNT162b2 (30 µg)	**BNT162b2$_{SA}$ (30 µg)**	**BNT162b2$_{SA}$ (30 µg)**
2 out of 306 participants (1%)	2 out of 315 participants (1%)	1 out of 30 participants (3%)

No single serious medical problem happened in more than 1 participant in these groups. Researchers do not believe any of the serious medical problems were related to the study vaccine.

Booster dose of 5 or 10 µg BNT162b2 in Phase 3

Table 11 shows 1 participant had a serious medical problem between Dose 3 and 6 months after Dose 3 of **5 or 10 µg BNT162b2** (lower booster dose) in Phase 3 among those who got 2 doses of BNT162b2 (30 µg) before. Researchers do not believe the serious medical problem was related to the study vaccine.

Table 11. How many participants had a serious medical problem between Dose 3 and 6 months after Dose 3 of 5 or 10 µg BNT162b2 (lower dose booster) in Phase 3?

BNT162b2 (5 µg)		BNT162b2 (10 µg)	
18 to 55 years old	Above 55 years old	18 to 55 years old	Above 55 years old
0 out of 26 participants (0%)	1 out of 53 participants (2%) had back pain	0 out of 25 participants (0%)	0 out of 51 participants (0%)

Booster dose of 30 µg BNT162b2 in Phase 2/3

Table 12 shows few participants had a serious medical problem between Dose 3 and 1 month after Dose 3 of **30 µg BNT162b2** (booster) in Phase 2/3.

Table 12. How many participants had a serious medical problem between Dose 3 and 1 month after Dose 3 of 30 µg BNT162b2 (booster) in Phase 2/3?

Age group	BNT162b2 (30 µg)
12 to 15 years old	2 out of 825 participants (less than 1%)
16 years and older	65 out of 22,470 participants (less than 1%)

No single serious medical problem happened in at least 1% of participants in either age group.

12 to 15 years old:

None of the participants in this age group had serious medical problems that were related to the study vaccine.

16 years and older:

In this age group, 2 participants had 1 serious medical problem each that researchers believe may be related to the study vaccine:

- 1 participant had a miscarriage.
- 1 participant had inflamed heart tissue.

Additional booster dose of 30 µg BNT162b2 in Phase 2/3

Table 13 shows 1 participant had a serious medical problem between Dose 4 or 5 and 1 month after Dose 4 or 5 (additional booster) of **30 µg BNT162b2** in Phase 2/3. Researchers do not believe the serious medical problem was related to the study vaccine.

Table 13. How many participants had a serious medical problem between Dose 4 or 5 and 1 month after Dose 4 or 5 of 30 µg BNT162b2 (additional booster) in Phase 2/3?				
Previous Vaccine Group				
BNT162b2 (30 µg)	BNT162b2$_{SA}$ (30 µg)	BNT162b2 (5 µg)	BNT162b2 (10 µg)	BNT162b2$_{SA}$ (30 µg, 2 doses)
0 out of 182 participants (0%)	1 out of 196 participants (1%) had muscle weakness	0 out of 33 participants (0%)	0 out of 38 participants (0%)	0 out of 15 participants (0%)

How many participants died? – Phase 1 and Phase 2/3

No participant died during Phase 1.

In Phase 2/3, the follow-up time after getting BNT162b2 for participants who got BNT162b2 at the start of the study and those who got placebo at the start then later got BNT162b2 was about 18 to 24 months. This follow-up time was longer than the follow-up time after getting placebo for those who got placebo at the start of the study before receiving any BNT162b2, most of whom were allowed to know their vaccine assignment around 4 to 6 months after Dose 2 of placebo.

The following participants who got at least 1 primary dose of BNT162b2 or placebo died during Phase 2/3:

- 85 out of 23,141 participants who got **BNT162b2** at the start of the study.
- 62 out of 21,371 participants who got **placebo** at the start then later got **BNT162b2**.
- 23 out of 23,141 participants who got **placebo** at the start of the study and before receiving any **BNT162b2**.

They died from different causes, and researchers do not believe that the deaths were caused by BNT162b2.

In Phase 3, no participant died among those who had not gotten BNT162b2 before they received at least 1 dose of BNT162b2$_{SA}$.

Where can I learn more about this study?

If you or your child 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 **C4591001**

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

www.clinicaltrials.gov	Use the study identifier **NCT04368728**
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 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!