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:	Comirnaty® (Pfizer-BioNTech RNA-based COVID-19 Vaccine), also known as BNT162b2
Protocol Number:	C4591007
Dates of Study:	24 March 2021 to 08 December 2023
Title of this Study:	A Study to Learn If BNT COVID-19 Vaccine Is Safe and Can Prevent COVID-19 in Healthy Children [A Phase 1, Open-Label Dose-Finding Study to Evaluate Safety, Tolerability, and Immunogenicity and Phase 2/3 Placebo-Controlled, Observer-Blinded Safety, Tolerability, and Immunogenicity Study of a SARS-CoV-2 RNA Vaccine Candidate Against COVID-19 In Healthy Children]
Date of this Report:	31 May 2024

– Thank You –

If you or your child 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 or your child have any questions about the study or the results, please contact the doctor or staff at your or your child's 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 is BNT162b2?

BNT162b2 (also called Comirnaty®) is an injectable vaccine that may help 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 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.

BNT162b2 is the original "monovalent" COVID-19 vaccine. This vaccine was designed to protect against the original strain of the COVID-19 virus. BNT162b2 will be called "**BNT**" in this summary.

While this study was ongoing, health authorities in many countries authorized or approved the use of different COVID-19 vaccines in children of different age groups.

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 prevent disease.
- An **immune response** is the body's ability to find and fight off germs that cause disease.

Primary dose or doses of a vaccine are the first doses needed to have an immune response against a disease. But, a person's immune protection from a disease can fade over time. A **booster shot** is the extra dose of a vaccine after receiving the primary dose or doses. A booster shot 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 phases: Phase 1 and Phase 2/3. The main goals of each phase were as follows:

- **Phase 1**: Researchers studied different BNT dose levels in a small group of children to see which dose level was safe and made the most antibodies against COVID-19.
- **Phase 2/3**: This phase has 2 parts:

  Selected-Dose Testing Part: Researchers studied the selected BNT dose level for each age group from Phase 1 in a larger number of children to see whether it could help participants have an immune response to the COVID-19 virus. Safety of the selected BNT dose level and how well it could work against COVID-19 were also studied.

Troponin I Testing Part: Researchers further checked how safe BNT was in another group of participants 5 years to under 16 years old. In this part, researchers checked whether participants had high troponin I levels after getting BNT.

Troponin I is a protein in the blood that can rise when there is a heart injury.

Researchers wanted to know:

- **Did participants have an immune response to the COVID-19 virus after getting BNT?**
- **Did BNT help to prevent COVID-19 in participants?**
- **How many participants had local reactions within 7 days after getting BNT?**
- **How many participants had systemic symptoms within 7 days after getting BNT?**
- **What medical problems did participants have during the study?**

In this study, **local reactions** include the following:

- For participants 2 years to under 12 years old, any pain, redness, or swelling at the injection site (arm).
- For participants 6 months to under 2 years old, any tenderness, redness, or swelling at the injection site (thigh).

Systemic symptoms include the following:

- For participants 2 years to under 12 years old, any fever, tiredness, headache, chills, vomiting, diarrhea, muscle pain, or joint pain.
- For participants 6 months to under 2 years old, any fever, loss of appetite, sleepiness, or irritability.

What happened during the study?

How was the study done?

Phase 1

Researchers tested different BNT dose levels in a small group of participants 6 months to under 12 years old.

Participant age	What dose of BNT they got
5 years to under 12 years old	BNT 10, 20, or 30 mcg
2 years to under 5 years old	BNT 3 or 10 mcg
6 months to under 2 years old	BNT 3 mcg

Vaccination started from the oldest age group. Vaccination in the younger groups started only after a safe dose was determined in the older groups. In each age group, vaccination started with the lowest dose. Study doctors checked on the safety of participants before the next higher doses were tested in other groups of participants.

Phase 1 was “open-label,” meaning participants and researchers knew the dose level each participant got.

Based on the safety information gathered and the participants' immune response, researchers selected the most suitable BNT dose level to be further studied in Phase 2/3.

Phase 2/3

Selected-Dose Testing Part

Researchers tested the selected BNT dose levels from Phase 1 in a larger number of participants aged 6 months to under 12 years old. Researchers then compared the results of participants who got the selected BNT dose level to the results of those who got a placebo. A placebo looks like BNT, but it does not have any active ingredients in it.

For each age group, the selected BNT dose levels and which study vaccine they got are shown below:

Participant age	Selected BNT dose level from Phase 1	What study vaccine they got
5 years to under 12 years old	10 mcg	BNT 10 mcg or placebo
2 years to under 5 years old	3 mcg	BNT 3 mcg or placebo
6 months to under 2 years		

For each age group, participants were assigned at random (by chance, like flipping a coin) to get either BNT or a placebo. There was a 2 in 3 chance of getting BNT and 1 in 3 chance of getting placebo in each age group.

This part is "observer-blinded," meaning only the study staff who prepared and gave the vaccine knew at first which vaccine each participant got. The

participants and researchers were later informed of whether participants got either BNT or placebo.

Troponin I Testing Part

Researchers tested BNT in participants 5 years to under 16 years old.

Participant age	What study vaccine they got
12 years to under 16 years old	BNT 30 mcg
5 years to under 12 years old	BNT 10 mcg or placebo

- All participants 12 years to under 16 years old got BNT 30 mcg, the approved BNT dose level for this age group. BNT was given in an open-label manner to this group.
- Participants 5 years to under 12 years old were assigned at random to get either BNT 10 mcg or placebo. Their assigned vaccine was given in an observer-blinded manner like in the Selected-Dose Testing Part.

As part of the study, participants who got placebo in Phase 2/3 (in both the Selected-Dose Testing and Troponin I Testing parts) were offered to get BNT after their vaccination with placebo. This means that all participants had the chance to get BNT in the study.

In both Phase 1 and Phase 2/3, the participants had health checks done throughout the study. They also had blood samples taken so study doctors could measure the amount of COVID-19 antibodies in participants' blood and further check on their health.

At first, researchers planned to give only 2 doses ("shots") of BNT. However, the study plan was changed to give an additional 3rd dose of BNT to all participants. This was because while the study was ongoing, a new Omicron variant emerged, and new information has shown that a 3rd BNT dose may offer high levels of protection against COVID-19.

The BNT dose level for the 3rd dose depended on the participants' age at the time of the 3rd dose vaccination. At the time of the 3rd dose:

Participants who were under 5 years old got **BNT 3 mcg**. The 3rd dose was given as an addition to the primary doses, making it a 3-dose primary vaccination series. The 3rd dose was given at least 8 weeks after Dose 2.

Participants who were 5 years to under 12 years old got **BNT 10 mcg**, and those 12 years old or older got **BNT 30 mcg**. The 3rd dose was given as a booster shot at least 5 months after Dose 2 for these age groups.

Where did this study take place?

This study ran at 119 locations in 6 countries.

- Brazil
- Finland
- Mexico
- Poland
- Spain
- USA

When did this study take place?

It began on 24 March 2021 and ended on 08 December 2023.

Who participated in this study?

The study included healthy children 6 months to under 16 years old who had not received any COVID-19 vaccine before.

Phase 1 included participants from 6 months to under 12 years old who did not have COVID-19 when they joined the study.

5 years to under 12 years old (out of 48 participants vaccinated)	2 years to under 5 years old (out of 48 participants vaccinated)	6 months to under 2 years old (out of 16 participants vaccinated)
• 24 boys and 24 girls participated. • 8 participants completed the study, and 40 others did not.	• 28 boys and 20 girls participated. • 21 participants completed the study, and 27 others did not.	• 10 boys and 6 girls participated. • 8 participants completed the study, and 8 others did not.

The most common reason for not completing the study was because participants got a COVID-19 vaccine outside of the study or they joined another BNT study.

> While this study was ongoing, health authorities in many countries authorized or approved the use of different COVID-19 vaccines in children of different age groups. This led to people having easier access to COVID-19 vaccines, including BNT.

> Because of the easier access to COVID-19 vaccines, some of the participants left the study early or got a COVID-19 vaccine outside of the study.

Phase 2/3 included participants 6 months to under 16 years old.

Selected-Dose Testing Part

5 years to under 12 years old (out of 4647 participants vaccinated)	**2 years to under 5 years old** (out of 3543 participants vaccinated)	**6 months to under 2 years old** (out of 2177 participants vaccinated)
• 2240 participants completed the study, and 2407 others did not. • 2388 boys and 2259 girls participated.	• 1622 participants completed the study, and 1921 others did not. • 1774 boys and 1767 girls participated. Two (2) participants got the wrong BNT dose level and were not included in this count.	• 974 participants completed the study, and 1203 others did not. • 1076 boys and 1100 girls participated. One (1) participant got the wrong BNT dose level and was not included in this count.

The most common reason for not completing the study was because the participants or their parents/guardians decided to leave the study by their choice or because they joined another BNT study.

Troponin I Testing Part

12 years to under 16 years old

(out of 506 participants vaccinated)

- 443 participants completed the study, and 63 others did not.
- 271 boys and 216 girls participated. The 19 participants who did not meet certain study requirements were not included in this count.

5 years to under 12 years old

(out of 778 participants vaccinated)

- 583 participants completed the study, and 195 others did not.
- 406 boys and 372 girls participated.

The most common reason for not completing the study was because the participants or their parents/guardians decided to leave the study by their choice.

How long did the study last?

Participants were in the study for at least 13 months. Participants were in the study for different lengths of time depending on which phase they joined. The entire study took about 2 years and 8 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 December 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?

In summary, study results showed the following:

- **3 doses of BNT 3 mcg** may help protect children 6 months to under 5 years old against COVID-19. BNT 3 mcg was about 73% effective compared to a placebo in preventing COVID-19 in this age group.
- **2 doses of BNT 10 mcg** may help protect children 5 years to under 12 years old against COVID-19. BNT 10 mcg was about 85% to 88% effective compared to a placebo in preventing COVID-19 in this age group.
- Local reactions and systemic symptoms experienced by participants after getting each age-appropriate BNT dose (**BNT 3 mcg** for 6 months to under 5 years old and **BNT 10 mcg** for 5 years to under 12 years old) were mostly mild to moderate in severity and short-lived.
- Age-appropriate BNT doses (**BNT 3 mcg** for 6 months to under 5 years old and **BNT 10 mcg** for 5 years to under 12 years old) were safe and well tolerated.

Did participants have an immune response to the COVID-19 virus after getting BNT?

Results from the Phase 2/3 Selected-Dose Testing Part were used to answer this question.

To find out if there was an immune response to the COVID-19 virus, researchers measured participants' levels of antibodies against the COVID-19 virus before getting a BNT dose and,

- 1 month after getting BNT Dose 2.
- 1 month after getting BNT Dose 3.

Researchers then compared the results of participants from this study to the results of a selected group of participants from another study called **C4591001**, who were participants 16 years to 25 years old and had 2 shots of BNT 30 mcg. Results of these participants from C4591001 were used as reference for the comparison as these participants from C4591001 had an immune response to the COVID-19 virus.

Participants 6 months to under 5 years old:

- After **2 doses of BNT 3 mcg**, participants 6 months to under 2 years old had an immune response to COVID-19 that was **as good as** that seen in C4591001 participants. But, participants 2 years to under 5 years old did not have an immune response to COVID-19 that was as good as that seen in C4591001 participants.
- After **3 doses of BNT 3 mcg**, participants 6 months to under 2 years old and participants 2 years to under 5 years old had an immune response to COVID-19 that was **as good as** that seen in C4591001 participants.

What do these results mean?

The researchers have decided that these results are not likely due to chance.
Combining these results, the emergence of a new Omicron variant, and new information showing better protection against COVID-19 after 3 BNT doses, the researchers believe that 3 doses of BNT 3 mcg may help protect children 6 months to under 5 years old against COVID-19.

Participants 5 years to under 12 years old:

- After **2 doses of BNT 10 mcg**, participants 5 years to under 12 years old had an immune response to COVID-19 that was **as good as** that seen in C4591001 participants.

What does this result mean?

The researchers have decided that these results are not likely due to chance. This result means that in children 5 years to under 12 years old, 2 doses of BNT 10 mcg may help protect against COVID-19.

Did BNT help to prevent COVID-19 in participants?

To find out if BNT was effective in preventing COVID-19, researchers compared how many participants had COVID-19 between those who got BNT and placebo at any time:

- **from 7 days after Dose 2 of BNT or placebo to before Dose 3 (booster shot)** was given in participants 5 years to under 12 years old.
- **from 7 days after Dose 3 of BNT or placebo** in participants 6 months to under 5 years old.

Researchers checked the results for 2 sets of participants:

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

In participants 5 years to under 12 years old, BNT was **88.2%** effective compared to placebo in preventing COVID-19 from 7 days after Dose 2 to before Dose 3 (booster shot) in those without past COVID-19 infection, and **85.7%** effective in those with or without past COVID-19 infection.

In participants 6 months to under 5 years old, BNT was **73.2%** effective compared to placebo in preventing COVID-19 from 7 days after Dose 3 in those without past COVID-19 infection, and **72.5%** effective in those with or without past COVID-19 infection.

What do these results mean?

The researchers have decided that these results are not likely due to chance. In this study, the first 2 doses of BNT 10 mcg helped to give protection against COVID-19 in participants 5 years to under 12 years old, while 3 doses of BNT 3 mcg helped to give protection against COVID-19 in participants 6 months to under 5 years old.

How many participants had local reactions within 7 days after getting BNT?

To answer this question, researchers checked the electronic diary records of participants in this study.

Phase 1

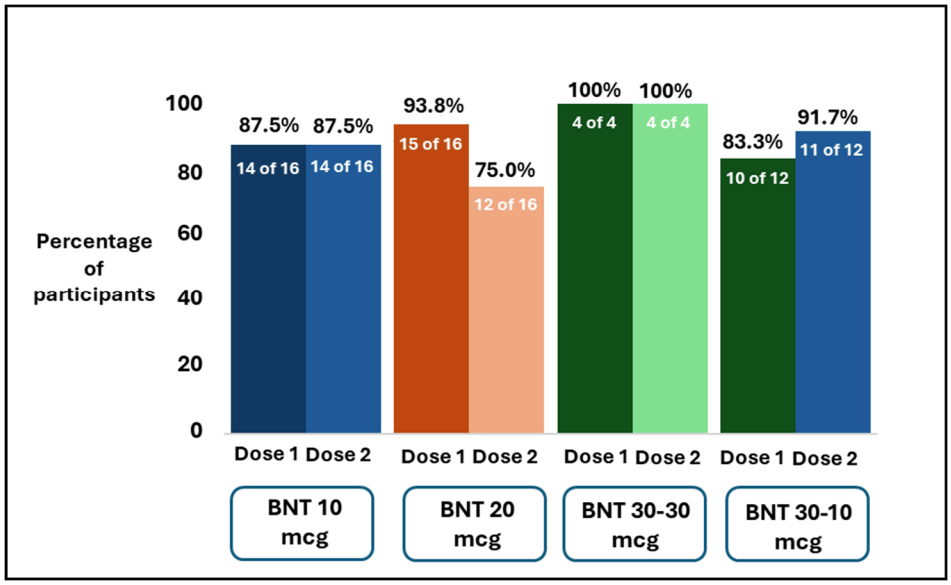
Participants 5 years to under 12 years old

After Doses 1 and 2

Figure 1 on the next page shows the percentage of participants 5 years to under 12 years old who had local reactions (any pain, redness, or swelling at the injection site) within 7 days of getting Doses 1 and 2 of BNT 10, 20, or 30 mcg.

Participants who got higher BNT dose levels had more local reactions, including the first few participants (4 participants) who got 2 doses of BNT 30 mcg (BNT 30-30 mcg in Figure 1). Because of this, the remaining participants (12 participants) who were supposed to get BNT 30 mcg were reassigned to get BNT 10 mcg for Dose 2 (BNT 30-10 mcg in Figure 1). BNT 30 mcg was no longer tested in any of the participants under 12 years old.

Figure 1. How many participants 5 years to under 12 years old had any local reactions within 7 days after Doses 1 and 2 of BNT 10, 20, or 30 mcg?



After Dose 3 (booster shot): BNT 10 mcg

A total of 38 participants from this group got a 3rd BNT dose in this study.

- A total of 34 out of 38 participants (89.5%) had local reactions within 7 days of getting BNT 10 mcg for Dose 3.
- Pain at the injection site was the most commonly reported local reaction after each of the 3 doses. Most of these local reactions were mild or moderate in severity, and most lasted from 1 to 2 days.

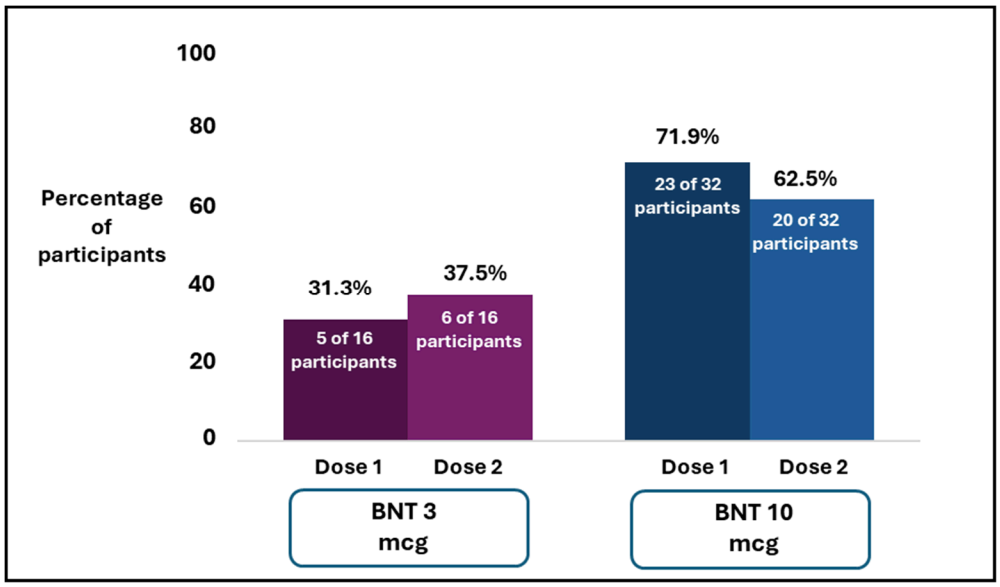
Participants 2 years to under 5 years old

After Doses 1 and 2

Figure 2 on the next page shows that, within 7 days of getting Doses 1 and 2 of BNT 3 or 10 mcg, a higher percentage of participants in the

BNT 10 mcg group had local reactions (any pain, redness, or swelling at the injection site) than in the BNT 3 mcg group.

Figure 2. How many participants 2 years to under 5 years old had any local reactions within 7 days after Doses 1 and 2 of BNT 3 or 10 mcg?



Pain at the injection site was the most commonly reported local reaction after each of the 2 doses in both dose levels. Most of these local reactions were mild or moderate in severity, and most lasted from 1 to 2 days.

After Dose 3: BNT 3 or 10 mcg (depending on participant's age at the time of 3rd dose)

A total of 39 participants from this group got a 3rd BNT dose in this study. A higher percentage of participants in the BNT 10 mcg group had local reactions than in the BNT 3 mcg group.

- A total of 10 out of 26 participants (38.5%) who got BNT 3 mcg for their 3rd dose had local reactions within 7 days after they got Dose 3.

- A total of 11 out of 13 participants (84.6%) who got BNT 10 mcg for their 3rd dose had local reactions within 7 days after they got Dose 3.

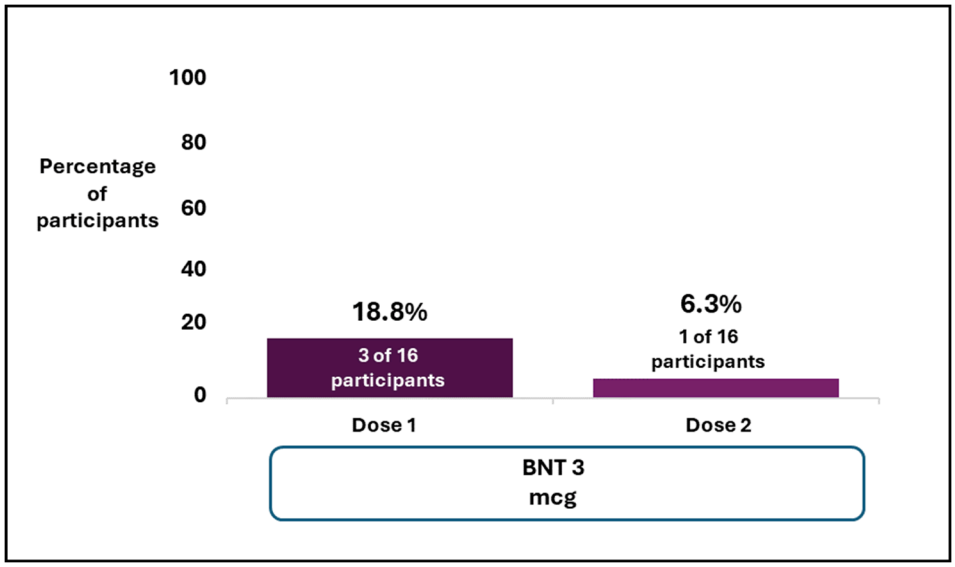
Pain at the injection site was the most commonly reported local reaction after Dose 3 in both dose levels. Most of the local reactions were mild or moderate in severity, and most lasted from 1 to 3 days.

Participants 6 months to under 2 years old

After Doses 1 and 2

Figure 3 below shows the percentage of participants 6 months to under 2 years old who had local reactions (any tenderness, redness, or swelling at the injection site) within 7 days of getting Doses 1 and 2 of BNT 3 mcg.

Figure 3. How many participants 6 months to under 2 years old had any local reactions within 7 days after Doses 1 and 2 of BNT 3 mcg?



Redness and swelling at the injection site were the only local reactions reported in the group. All local reactions were mild or moderate in severity, and most lasted from 1 to 4 days.

After Dose 3: BNT 3 mcg

A total of 15 participants from this group got a 3rd BNT dose in this study.

- A total of 4 out of 15 participants (26.7%) had local reactions within 7 days of getting BNT 3 mcg for Dose 3.

Tenderness at the injection site was the most commonly reported local reaction after Dose 3. All local reactions were mild in severity, and most lasted from 1 to 2 days.

Phase 2/3: Selected-Dose Testing Group

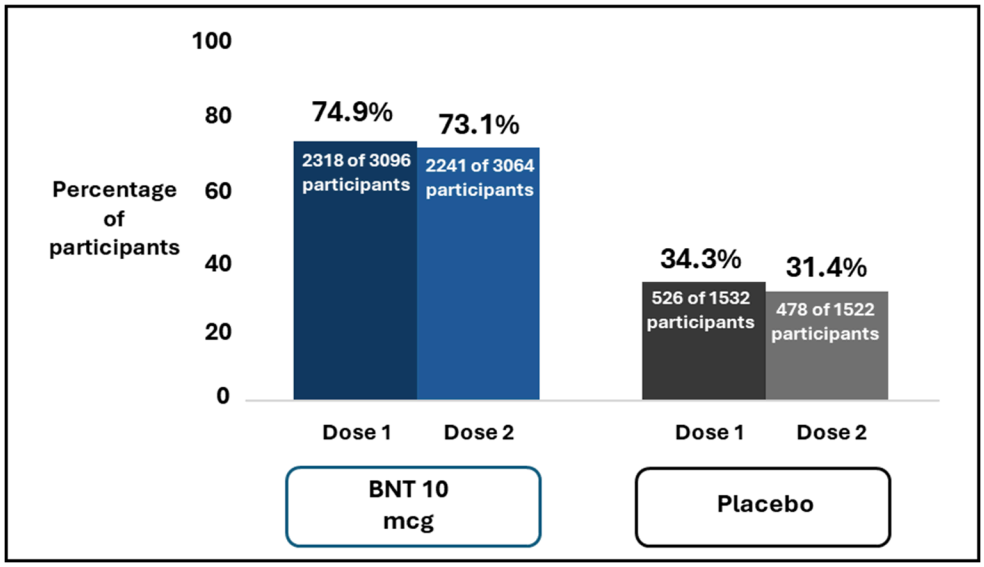
Participants 5 years to under 12 years old

Enrollment of participants 5 years to under 12 years old in Phase 2/3 had been completed before the decision to add a 3rd dose (booster shot) was made. Because of this, discussion in this section has 2 parts: results for the original 2-dose plan and results after the addition of a 3rd dose as a booster shot for this age group.

After Doses 1 and 2 in the original 2-dose plan

Figure 4 below shows that, within 7 days of getting Doses 1 and 2 of BNT 10 mcg or placebo, a higher percentage of participants who got BNT 10 mcg had local reactions (any pain, redness, or swelling at the injection site) than those who got a placebo.

Figure 4. How many participants 5 years to under 12 years old had any local reactions within 7 days after Doses 1 and 2 of BNT 10 mcg or placebo?



Pain at the injection site was the most commonly reported local reaction after each of the 2 doses. Most of the local reactions were mild or moderate in severity, and most lasted from 1 to 2 days.

After Dose 3 (booster shot): BNT 10 or 30 mcg (depending on participant's age at the time of 3rd dose)

- A total of 1611 out of 2265 participants (71.1%) who got BNT 10 mcg for their 3rd dose had a local reaction within 7 days after they got Dose 3. Among participants who got 3 doses of BNT 10 mcg, the percentage of participants who had local reactions was similar after each dose.

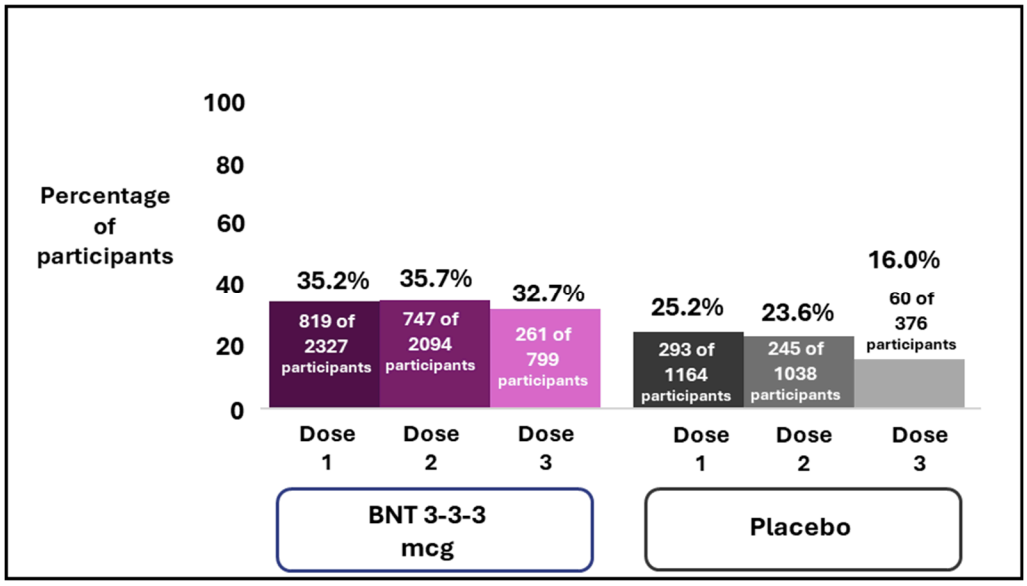
- A total of 118 out of 138 participants (85.5%) who got BNT 30 mcg for their 3rd dose had a local reaction within 7 days after they got Dose 3. Among those who got BNT 10 mcg for Doses 1 and 2, then BNT 30 mcg for Dose 3 as an age-appropriate dose, a higher percentage of participants had local reactions following the BNT 30 mcg dose than after each of the first 2 BNT 10 mcg doses.

Pain at the injection site was the most commonly reported local reaction after Dose 3 of BNT 10 or 30 mcg. Most of the local reactions were mild or moderate in severity, and most lasted from 1 to 2 days.

Participants 2 years to under 5 years old

Figure 5 below shows that, within 7 days of getting each of Doses 1 to 3 of BNT 3 mcg or placebo, a higher percentage of participants who got BNT 3 mcg had local reactions (any pain, redness, or swelling at the injection site) than those who got a placebo.

Figure 5. How many participants 2 years to under 5 years old had any local reactions within 7 days after Doses 1 to 3 of BNT 3 mcg or placebo?

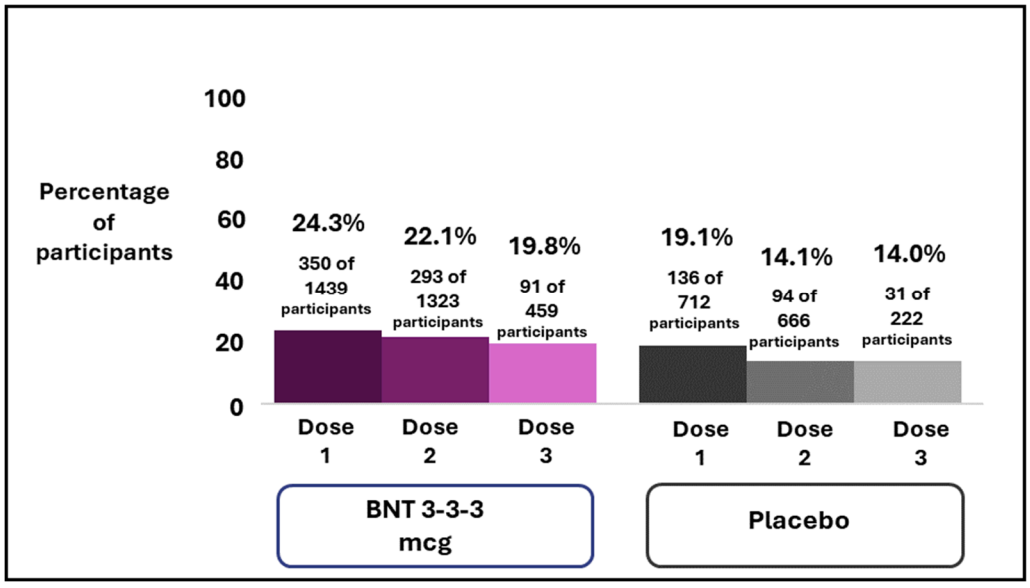


- Pain at the injection site was the most commonly reported local reaction after each of the 3 doses. Most of these local reactions were mild or moderate in severity, and most lasted 1 day.
- Participants who turned 5 years old at the time of Dose 3 got BNT 10 mcg for their 3rd dose (BNT 3-3-10 mcg). Among these participants, a higher percentage of participants had local reactions following the BNT 10 mcg dose than after each of the first 2 BNT 3 mcg doses.

Participants 6 months to under 2 years old

Figure 6 below shows that, within 7 days of getting Doses 1 to 3 of BNT 3 mcg or placebo, a higher percentage of participants who got BNT 3 mcg had local reactions (any tenderness, redness, or swelling at the injection site) than those who got a placebo.

Figure 6. How many participants 6 months to under 2 years old had any local reactions within 7 days after Doses 1 to 3 of BNT 3 mcg or placebo?



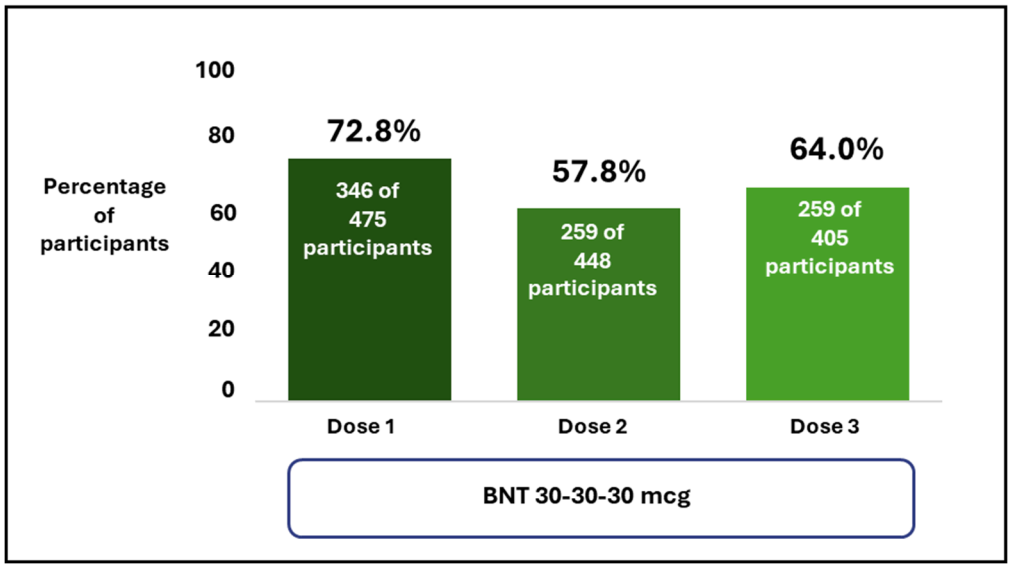
Tenderness at the injection site was the most commonly reported local reaction after each of the 3 doses. Most of the local reactions were mild or moderate in severity, and most lasted from 1 to 2 days.

Phase 2/3: Troponin I Testing Group

Participants 12 years to under 16 years old

Figure 7 below shows that, within 7 days of getting each of the 3 doses of BNT 30 mcg, the percentages of participants who had local reactions (any pain, redness, or swelling at the injection site) were generally similar after each dose.

Figure 7. How many participants 12 years to under 16 years old had any local reactions within 7 days after Doses 1 to 3 of BNT 30 mcg?



Pain at the injection site was the most commonly reported local reaction after each of the 3 doses. Most of the local reactions were mild or moderate in severity, and most lasted from 1 to 2 days.

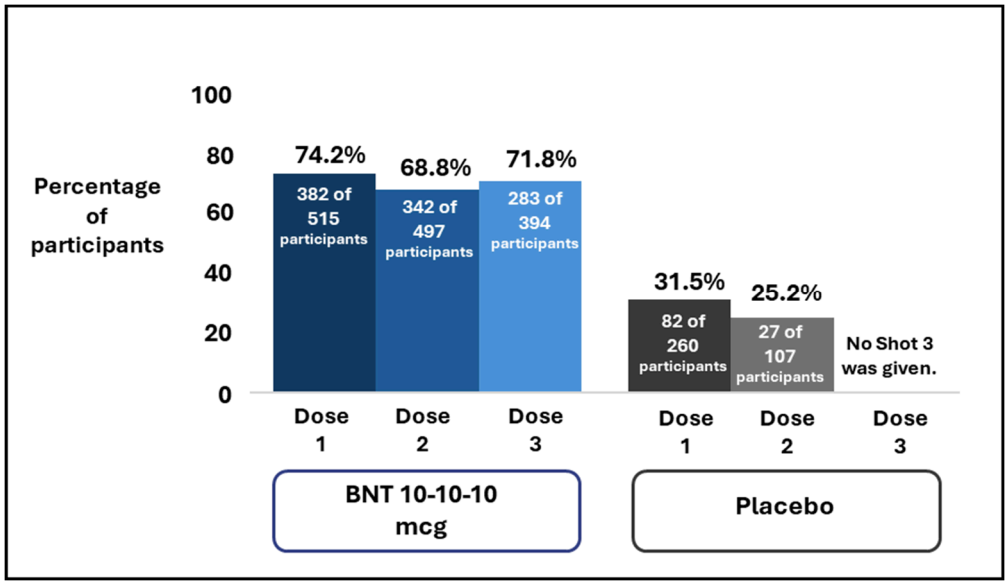
Participants 5 years to under 12 years old

Figure 8 on the next page shows that, within 7 days of getting each dose of BNT 10 mcg or placebo, a higher percentage of participants who got

BNT 10 mcg had local reactions (any pain, redness, or swelling at the injection site) than those who got a placebo.

> Participants in the placebo group did not receive a 3rd dose of placebo as BNT 10 mcg had already been approved as a COVID-19 vaccine for children 5 to 11 years old at the time of the study.

Figure 8. How many participants 5 years to under 12 years old had any local reactions within 7 days after Doses 1 to 3 of BNT 10 mcg or Doses 1 and 2 of placebo?



Pain at the injection site was the most commonly reported local reaction after each of the doses. Most of the local reactions were mild or moderate in severity, and most lasted from 1 to 2 days.

How many participants had systemic symptoms within 7 days after getting BNT?

To answer this question, researchers checked the electronic diary records of participants in this study.

Phase 1

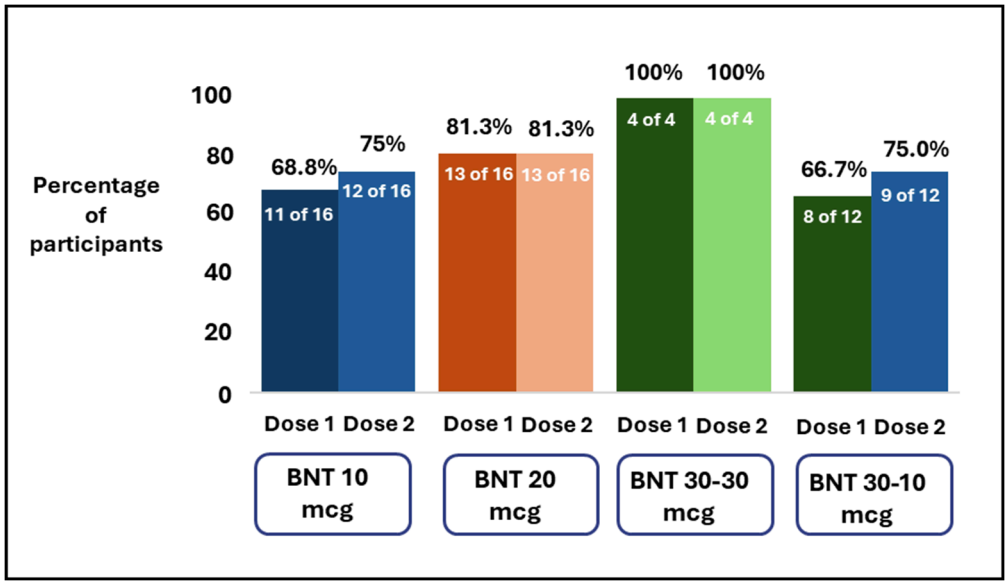
Participants 5 years to under 12 years old

After Doses 1 and 2

Figure 9 on the next page shows the percentage of participants 5 years to under 12 years old who had systemic symptoms (any fever, tiredness, headache, chills, vomiting, diarrhea, muscle pain, or joint pain) within 7 days of getting Doses 1 and 2 of BNT 10, 20, or 30 mcg.

Participants who got higher BNT dose levels had more systemic symptoms, including the first few participants (4 participants) who got 2 doses of BNT 30 mcg (BNT 30-30 mcg in Figure 9). Because of this, the remaining participants (12 participants) who were supposed to get BNT 30 mcg were reassigned to get BNT 10 mcg for Dose 2 (BNT 30-10 mcg in Figure 9).

Figure 9. How many participants 5 years to under 12 years old had any systemic symptoms within 7 days after Doses 1 and 2 of BNT 10, 20, or 30 mcg?



Tiredness was the most commonly reported systemic symptom after each dose. Most of these systemic symptoms were mild or moderate in severity, and most lasted 1 day.

After Dose 3 (booster shot): BNT 10 mcg

A total of 38 participants from this group got a 3rd dose in this study.

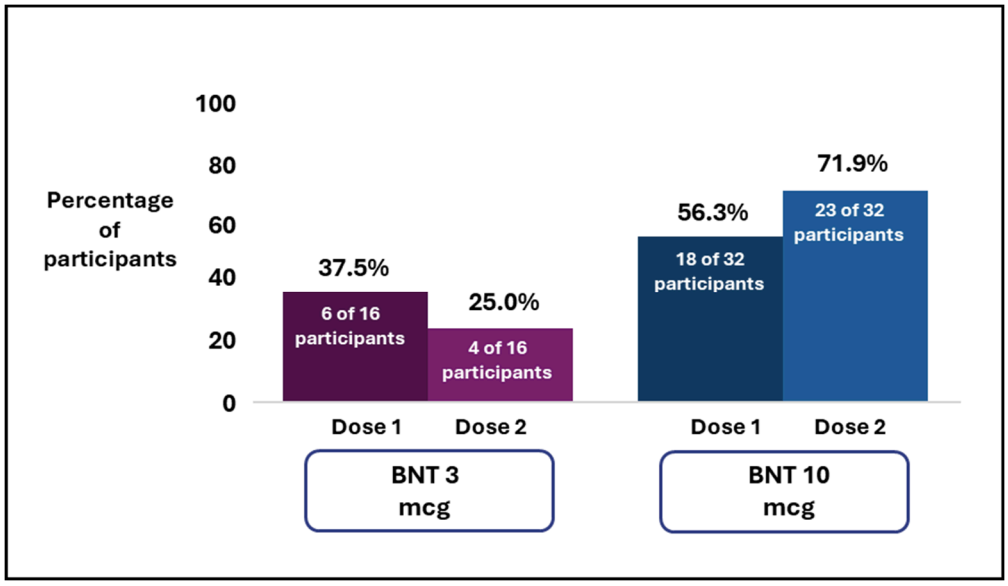
- A total of 18 out of 38 participants (47.4%) had systemic symptoms within 7 days of getting BNT 10 mcg for Dose 3.
- Tiredness was the most commonly reported systemic symptom after each dose. Most of the systemic symptoms were mild or moderate in severity, and most lasted from 1 to 3 days.

Participants 2 years to under 5 years old

After Doses 1 and 2

Figure 10 below shows that, within 7 days of getting Doses 1 and 2 of BNT 3 or 10 mcg, a higher percentage of participants in the BNT 10 mcg group had systemic symptoms (any fever, tiredness, headache, chills, vomiting, diarrhea, muscle pain, or joint pain) than in the BNT 3 mcg group.

Figure 10. How many participants 2 years to under 5 years old had any systemic symptoms within 7 days after Doses 1 and 2 of BNT 3 or 10 mcg?



Tiredness was the most commonly reported systemic symptom after each of the 2 doses in both dose levels. All systemic symptoms were mild or moderate in severity, and most lasted from 1 to 2 days.

After Dose 3: BNT 3 or 10 mcg (depending on participant's age at the time of 3rd dose)

A total of 39 participants from this group got a 3rd dose in this study. A higher percentage of participants in the BNT 10 mcg group had systemic symptoms than in the BNT 3 mcg group.

- A total of 8 out of 26 participants (30.8%) who got BNT 3 mcg for their 3rd dose had systemic symptoms within 7 days after they got Dose 3.
- A total of 7 out of 13 participants (53.8%) who got BNT 10 mcg for their 3rd dose had systemic symptoms within 7 days after they got Dose 3.

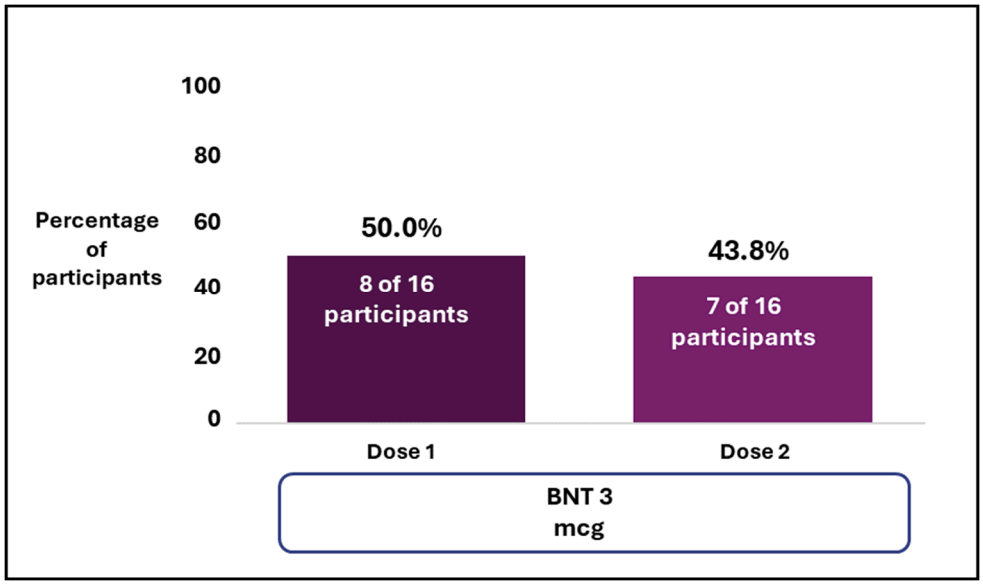
Tiredness was the most commonly reported systemic symptom after Dose 3 in both dose levels. Most of the systemic symptoms were mild or moderate in severity, and most lasted from 1 to 2 days.

Participants 6 months to under 2 years old

After Doses 1 and 2

Figure 11 on the next page shows the percentage of participants 6 months to under 2 years old who had systemic symptoms (any fever, loss of appetite, sleepiness, and irritability) within 7 days of getting Doses 1 and 2 of BNT 3 mcg.

Figure 11. How many participants 6 months to under 2 years old had any systemic symptoms within 7 days after Doses 1 and 2 of BNT 3 mcg?



Irritability was the most commonly reported systemic symptom in the group. All systemic symptoms were mild or moderate in severity, and most lasted from 1 to 3 days.

After Dose 3: BNT 3 mcg

A total of 15 participants from this group got a 3rd BNT dose in this study.

- A total of 4 out of 15 participants (26.7%) had systemic symptoms within 7 days of getting BNT 3 mcg for Dose 3.

Irritability was the most commonly reported systemic symptom after Dose 3. Most of the systemic symptoms were mild or moderate in severity, and most lasted from 1 to 3 days.

Phase 2/3: Selected-Dose Testing Group

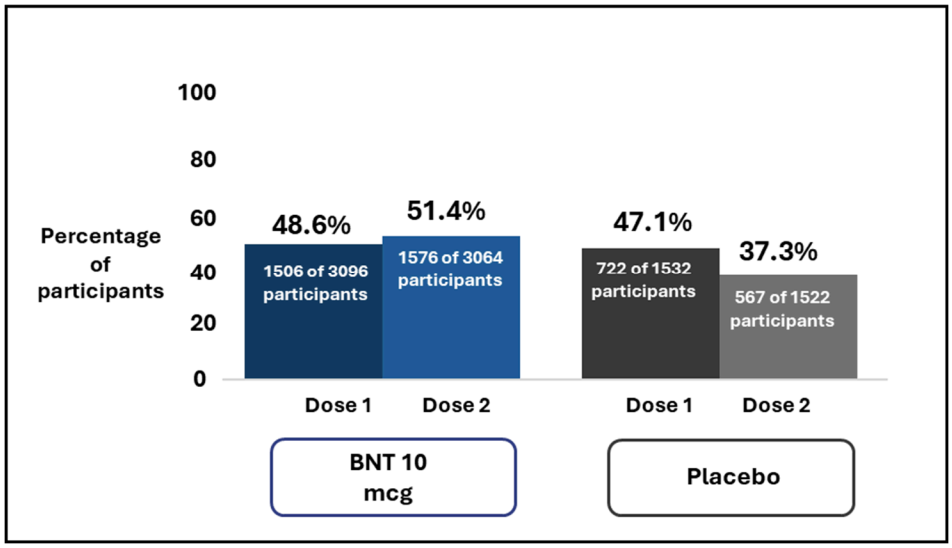
Participants 5 years to under 12 years old

Enrollment of participants 5 years to under 12 years old in Phase 2/3 had been completed before the decision to add a 3rd dose (booster) was made. Because of this, discussion in this section has 2 parts: results for the original 2-dose plan and results after the addition of a 3rd dose as a booster shot for this age group.

After Doses 1 and 2 in the original 2-dose plan

Figure 12 below shows that, within 7 days of getting Doses 1 and 2 of BNT 10 mcg or placebo, a higher percentage of participants who got BNT 10 mcg had systemic symptoms (any fever, tiredness, headache, chills, vomiting, diarrhea, muscle pain, or joint pain) than those who got a placebo.

Figure 12. How many participants 5 years to under 12 years old had any systemic symptoms within 7 days after Doses 1 and 2 of BNT 10 mcg or placebo?



Tiredness was the most commonly reported systemic symptom after each of the 2 doses. Most of the systemic symptoms were mild or moderate in severity, and most lasted from 1 to 2 days.

After Dose 3 (booster shot): BNT 10 or 30 mcg (depending on participant's age at the time of 3rd dose)

- A total of 1180 out of 2265 participants (52.1%) who got BNT 10 mcg for their 3rd dose had a systemic symptom within 7 days after they got Dose 3. Among participants who got 3 doses of BNT 10 mcg, the percentage of participants who had systemic symptoms was similar after each dose.

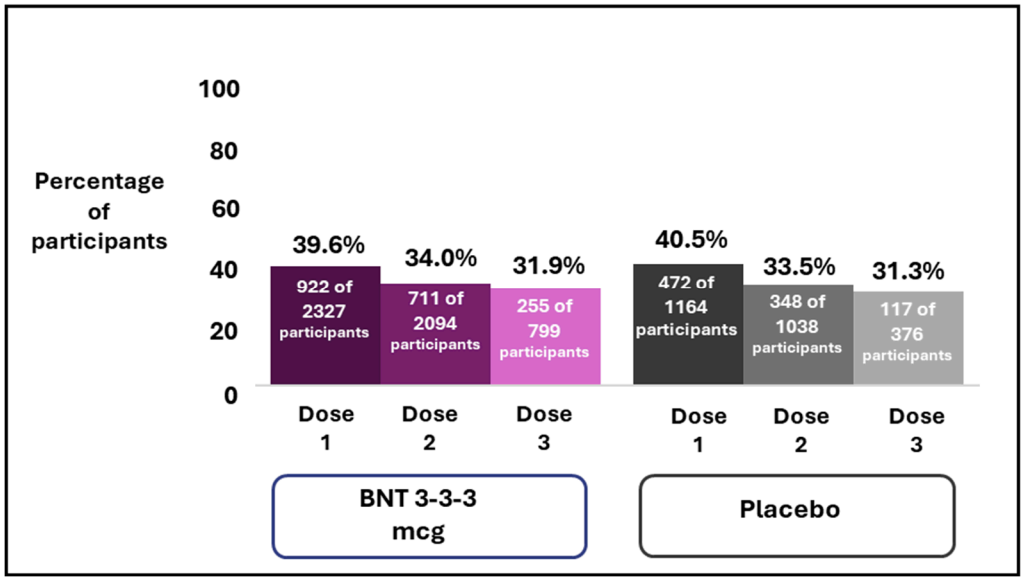
- A total of 94 out of 138 participants (68.1%) who got BNT 30 mcg for their 3rd dose had a systemic symptom within 7 days after they got Dose 3. Among those who got BNT 10 mcg for Doses 1 and 2, then BNT 30 mcg for Dose 3 as an age-appropriate dose, a higher percentage of participants had systemic symptoms following the BNT 30 mcg dose than after each of the first 2 BNT 10 mcg doses.

Tiredness was the most commonly reported systemic symptom after each of the 3 doses. Most of the systemic symptoms were mild or moderate in severity, and most lasted from 1 to 2 days.

Participants 2 years to under 5 years old

Figure 13 on the next page shows that, within 7 days of getting Doses 1 to 3 of BNT 3 mcg or placebo, the percentage of participants who had systemic symptoms (any fever, tiredness, headache, chills, vomiting, diarrhea, muscle pain, or joint pain) was similar between those who got BNT 3 mcg and those who got a placebo.

Figure 13. How many participants 2 years to under 5 years old had any systemic symptoms within 7 days after Doses 1 to 3 of BNT 3 mcg or placebo?

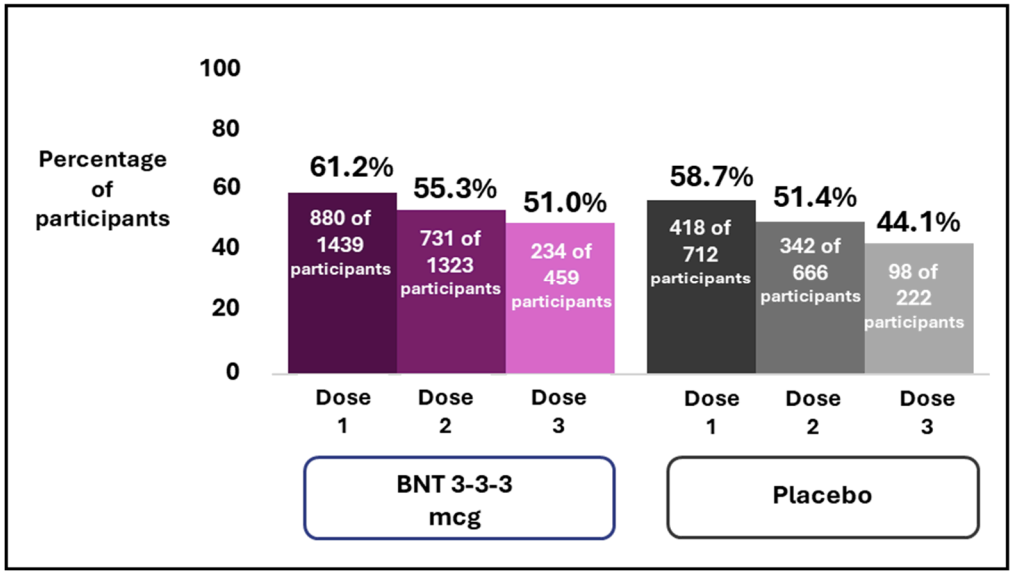


- Tiredness, diarrhea, fever, and headache were the most commonly reported systemic symptoms after each of the 3 doses. Most of these systemic symptoms were mild or moderate in severity, and most lasted 1 to 2 days.
- Participants who turned 5 years old at the time of Dose 3 got BNT 10 mcg for their 3rd dose (BNT 3-3-10 mcg). Among these participants, a higher percentage of participants had systemic symptoms following the BNT 10 mcg dose than after each of the first 2 BNT 3 mcg doses.

Participants 6 months to under 2 years old

Figure 14 below shows that, within 7 days of getting Doses 1 to 3 of BNT 3 mcg or placebo, the percentage of participants who had systemic symptoms (any fever, loss of appetite, sleepiness, and irritability) was similar between those who got BNT 3 mcg and those who got a placebo. Participants experiencing systemic symptoms decreased after each dose for both BNT and placebo groups.

Figure 14. How many participants 6 months to under 2 years old had any systemic symptoms within 7 days after Doses 1 to 3 of BNT 3 mcg or placebo?



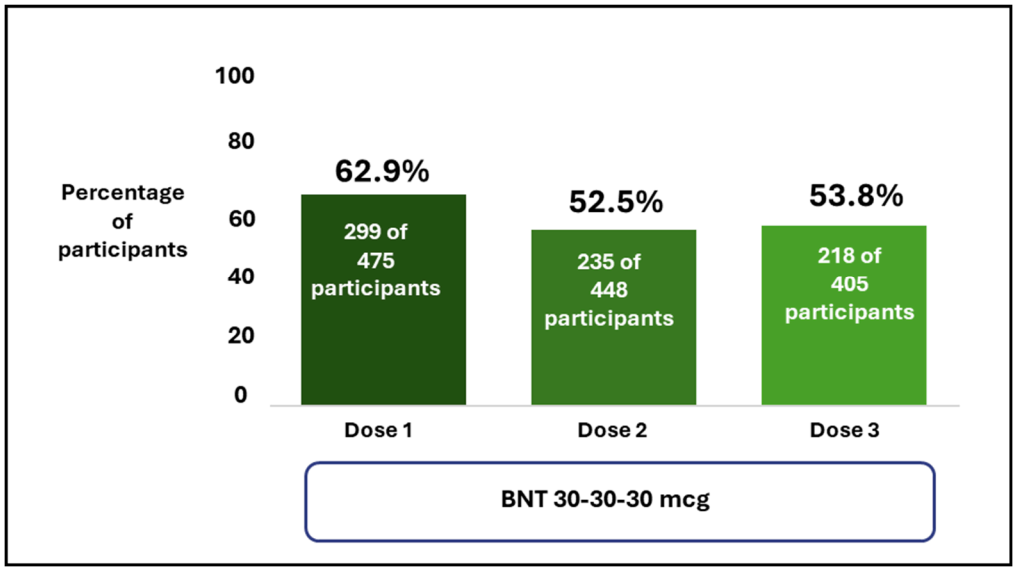
Irritability was the most commonly reported systemic symptom after each of the 3 doses. Most of the systemic symptoms were mild or moderate in severity, and most lasted from 1 to 2 days.

Phase 2/3: Troponin I Testing Group

Participants 12 years to under 16 years old

Figure 15 below shows that, within 7 days of getting Doses 1 to 3 of BNT 30 mcg, the percentages of participants who had systemic symptoms (any fever, tiredness, headache, chills, vomiting, diarrhea, muscle pain, or joint pain) were generally similar after each dose.

Figure 15. How many participants 12 years to under 16 years old had any systemic symptoms within 7 days after Doses 1 to 3 of BNT 30 mcg?



Tiredness was the most commonly reported systemic symptom after each of the 3 doses. Most of the systemic symptoms were mild or moderate in severity, and most lasted 1 day.

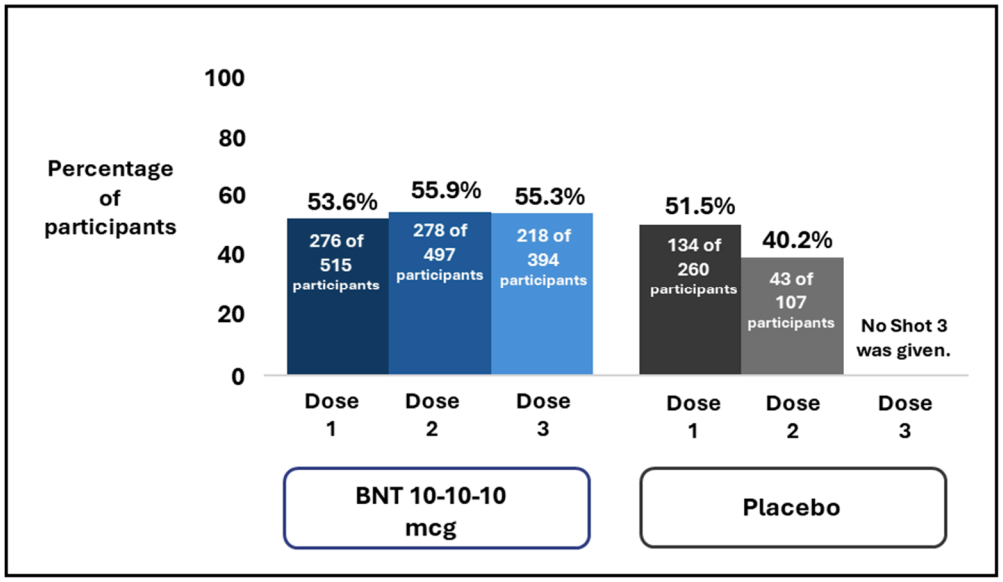
Participants 5 years to under 12 years old

Figure 16 on the next page shows that, within 7 days of getting each dose of BNT 10 mcg or placebo, the percentage of participants who had

systemic symptoms (any fever, tiredness, headache, chills, vomiting, diarrhea, muscle pain, or joint pain) was similar between the BNT 10 mcg and placebo groups after Dose 1. A higher percentage of participants had systemic symptoms after Dose 2 of BNT 10 mcg than those who got Dose 2 of a placebo.

> Participants in the placebo group did not receive a 3rd dose of placebo as BNT 10 mcg had already been approved as a COVID-19 vaccine for children 5 to 11 years old at the time of the study.

Figure 16. How many participants 5 years to under 12 years old had any systemic symptoms within 7 days after Doses 1 to 3 of BNT 10 mcg or Doses 1 and 2 of placebo?



Tiredness was the most commonly reported systemic symptom after each of the doses. Most of the systemic symptoms were mild or moderate in severity, and most lasted 1 to 2 days.

In summary, in participants 6 months to under 12 years old who were given 2 or 3 doses of BNT:

- Local reactions and systemic symptoms within 7 days after getting each age-appropriate BNT dose (**BNT 3 mcg** for 6 months to under 5 years old and **BNT 10 mcg** for 5 years to under 12 years old) were mostly mild to moderate in severity and short-lived.

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 treatment 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.

Phase 1

How many participants had medical problems from Dose 1 to 1 month after Dose 2?

Participants 5 years to under 12 years old

The following number of participants had at least 1 medical problem from Dose 1 to 1 month after Dose 2:

- Seven (7) out of 16 participants (43.8%) who got BNT 10 mcg.
- Five (5) out of 16 participants (31.3%) who got BNT 20 mcg.
- Two (2) out of 4 participants (50%) who got BNT 30 mcg.
- Three (3) out of 12 participants (25%) who got BNT 30 mcg (Dose 1) and BNT 10 mcg (Dose 2).

The most commonly reported medical problems during this period were pain at the injection site and pinworm infection, which were reported in at least 2 participants in any vaccine group (BNT 20 mcg).

No other medical problems were reported in more than 1 participant in any group. No participant left the study because of a medical event.

Participants 2 years to under 5 years old

The following number of participants had at least 1 medical problem from Dose 1 to 1 month after Dose 2:

- Four (4) out of 16 participants (25.0%) who got BNT 3 mcg.
- Twelve (12) out of 32 participants (37.5%) who got BNT 10 mcg.

The most commonly reported medical problems during this period were pain at the injection site (reported in 2 participants in BNT 3 mcg) and abdominal pain (reported in 2 participants in BNT 10 mcg).

No other medical problems were reported in more than 1 participant in any group. No participant left the study because of a medical event.

Participants 6 months to under 2 years old

Two (2) out of 16 participants (12.5%) who got BNT 3 mcg had at least 1 medical problem from Dose 1 to 1 month after Dose 2. One of these participants had runny nose, and the other one had hives.

No participant left the study because of a medical event.

How many participants had medical problems from Dose 3 to 1 month after Dose 3?

Participants 5 years to under 12 years old

Six (6) out of 38 participants (15.8%) who got BNT 10 mcg for Dose 3 (booster shot) had at least 1 medical problem from Dose 3 to 1 month after Dose 3.

- No medical problems were reported in more than 1 participant.
- No participant left the study because of a medical event.

Participants 2 years to under 5 years old

Three (3) out of 27 participants (11.1%) who got BNT 3 mcg for their 3rd dose had at least 1 medical problem from Dose 3 to 1 month after Dose 3.

- There were 2 participants from the BNT 3 mcg group who reported vomiting. No other medical problems were reported in more than 1 participant.
- No participant left the study because of a medical event.

None of the participants who got BNT 10 mcg for their 3rd dose had any medical problem during this period.

Participants 6 months to under 2 years old

One (1) out of 15 participants (6.7%) who got a 3rd dose of BNT 3 mcg had at least 1 medical problem from Dose 3 to 1 month after Dose 3. This participant had a speech disorder.

No participant left the study because of a medical event.

Phase 2/3: Selected-Dose Testing Group

How many participants had medical problems from Dose 1 to 1 month after Dose 2?

Participants 5 years to under 12 years old

Similar percentages of participants had at least 1 medical problem during this period between the BNT 10 mcg and placebo groups. The following participants had at least 1 medical problem from Dose 1 to 1 month after Dose 2.

- Three hundred thirty-three (333) out of 3109 participants (10.7%) who got BNT 10 mcg.
- One hundred fifty (150) out of 1538 participants (9.8%) who got placebo.

One (1) participant stopped taking part in the study because of medical problems. This participant had fever and low levels of neutrophils (a type of white blood cell).

Table 1 below lists the most common medical problems reported in participants 5 years to under 12 years old in the Phase 2/3 Selected-Dose Testing Group. These medical problems were reported in 0.5% or more of participants in any vaccine group.

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 in 0.5% or more of participants are listed.

- The **2nd** column tells how many of the 3109 participants given BNT 10 mcg reported each medical problem. Next to this number is the percentage of these participants who reported the medical problem.
- The **3rd** column tells how many of the 1538 participants given a placebo reported each medical problem. Next to this number is the percentage of these participants who reported the medical problem.
- Using these instructions, you can see that 21 out of the 3109 participants (0.7%) who got BNT 10 mcg reported swelling of lymph nodes. A total of 4 out of the 1538 participants (0.3%) who got a placebo reported the same medical problem.

Similar instructions apply to all tables that follow.

Table 1. Commonly reported medical problems by participants 5 years to under 12 years old from Dose 1 to 1 month after Dose 2 – Phase 2/3 Selected-Dose Testing Group

Medical Problem	BNT 10 mcg (3109 Participants)	Placebo (1538 Participants)
Swelling of lymph nodes	21 out of 3109 participants (0.7%)	4 out of 1538 participants (0.3%)
Vomiting	14 out of 3109 participants (0.5%)	4 out of 1538 participants (0.3%)

Table 1. Commonly reported medical problems by participants 5 years to under 12 years old from Dose 1 to 1 month after Dose 2 – Phase 2/3 Selected-Dose Testing Group

Medical Problem	BNT 10 mcg (3109 Participants)	Placebo (1538 Participants)
Pain at the injection site	31 out of 3109 participants (1.0%)	5 out of 1538 participants (0.3%)
Tiredness	9 out of 3109 participants (0.3%)	8 out of 1538 participants (0.5%)
Fever	6 out of 3109 participants (0.2%)	9 out of 1538 participants (0.6%)
Infection of the outer ear canal	9 out of 3109 participants (0.3%)	7 out of 1538 participants (0.5%)
Headache	15 out of 3109 participants (0.5%)	7 out of 1538 participants (0.5%)

Participants 2 years to under 5 years old

In this age group, similar percentages of participants between the BNT 3 mcg and placebo groups had at least 1 medical problem from Dose 1 to 1 month after Dose 2. The following participants had at least 1 medical problem during this period.

- Three hundred nine (309) out of 2350 participants (13.1%) who got BNT 3 mcg.
- One hundred fifty-two (152) out of 1173 participants (13.0%) who got placebo.

Table 2 below lists the most common medical problems reported in participants 2 years to under 5 years old in the Phase 2/3 Selected-Dose Testing Group. These medical problems were reported in 1% or more of participants in any vaccine group.

Table 2. Commonly reported medical problems by participants 2 years to under 5 years old from Dose 1 to 1 month after Dose 2 – Phase 2/3 Selected-Dose Testing Group

Medical Problem	BNT 3 mcg (2350 Participants)	Placebo (1173 Participants)
Vomiting	41 out of 2350 participants (1.7%)	13 out of 1173 participants (1.1%)
Diarrhea	22 out of 2350 participants (0.9%)	13 out of 1173 participants (1.1%)
Fever	38 out of 2350 participants (1.6%)	23 out of 1173 participants (2.0%)
Hay fever	14 out of 2350 participants (0.6%)	12 out of 1173 participants (1.0%)
Cough	22 out of 2350 participants (0.9%)	14 out of 1173 participants (1.2%)

Participants 6 months to under 2 years old

In this age group, similar percentages of participants between the BNT 3 mcg and placebo groups had at least 1 medical problem from Dose 1 to 1 month after Dose 2. The following participants had at least 1 medical problem during this period.

- Three hundred eleven (311) out of 1447 participants (21.5%) who got BNT 3 mcg.
- One hundred forty-three (143) out of 718 participants (19.9%) who got placebo.

Table 3 below lists the most common medical problems reported in participants 6 months to under 2 years old in the Phase 2/3 *S*elected-Dose Testing Group. These medical problems were reported in 1% or more of participants in any vaccine group.

Table 3. Commonly reported medical problems by participants 6 months to under 2 years old from Dose 1 to 1 month after Dose 2 – Phase 2/3 Selected-Dose Testing Group

Medical Problem	BNT 3 mcg (1447 Participants)	Placebo (718 Participants)
Diarrhea	31 out of 1447 participants (2.1%)	17 out of 718 participants (2.4%)
Vomiting	27 out of 1447 participants (1.9%)	15 out of 718 participants (2.1%)
Teething	18 out of 1447 participants (1.2%)	7 out of 718 participants (1.0%)

Table 3. Commonly reported medical problems by participants 6 months to under 2 years old from Dose 1 to 1 month after Dose 2 – Phase 2/3 Selected-Dose Testing Group		
Medical Problem	**BNT 3 mcg (1447 Participants)**	**Placebo (718 Participants)**
Fever	39 out of 1447 participants (2.7%)	14 out of 718 participants (1.9%)
Hand-foot-and-mouth disease	16 out of 1447 participants (1.1%)	11 out of 718 participants (1.5%)
Ear infection	10 out of 1447 participants (0.7%)	8 out of 718 participants (1.1%)
Fall	5 out of 1447 participants (0.3%)	7 out of 718 participants (1.0%)
Irritability	15 out of 1447 participants (1.0%)	6 out of 718 participants (0.8%)
Runny nose	20 out of 1447 participants (1.4%)	5 out of 718 participants (0.7%)

How many participants had medical problems from Dose 3 to 1 month after Dose 3?

Participants 5 years to under 12 years old

The following number of participants had at least 1 medical problem from Dose 3 (booster shot) to 1 month after Dose 3:

- Three hundred one (301) out of 3363 participants (9%) who got BNT 10 mcg for Dose 3.

- Thirty-four (34) out of 236 participants (14.4%) who got BNT 30 mcg for Dose 3.

Most of the medical problems reported in both groups were either local reactions/systemic symptoms due to vaccination (like pain at the injection site, tiredness, fever, headache, nausea, and vomiting), or medical problems commonly seen in this age group.

No participant left the study because of a medical problem.

Participants 2 years to under 5 years old

The following number of participants had at least 1 medical problem from Dose 3 to 1 month after Dose 3:

- Thirty-nine (39) out of 863 participants (4.5%) who got BNT 3 mcg.
- Twenty-six (26) out of 405 participants (6.4%) who got placebo.

Most of the medical problems reported in both groups were either local reactions/systemic symptoms due to vaccination (like vomiting, diarrhea, or fever), or medical problems commonly seen in this age group.

No participant left the study because of medical problems during this period.

Participants 6 months to under 2 years old

The following number of participants had at least 1 medical problem from Dose 3 to 1 month after Dose 3:

- Fifty (50) out of 483 participants (10.4%) who got BNT 3 mcg.
- Eighteen (18) out of 237 participants (7.6%) who got placebo.

Most of the medical problems reported in both groups were either local reactions/systemic symptoms due to vaccination (like vomiting, diarrhea, or fever), or medical problems commonly seen in this age group.

Phase 2/3: Troponin I Testing Group

How many participants had medical problems from Dose 1 to 1 month after Dose 2?

Participants 12 years to under 16 years old

A total of 26 out of 487 participants (5.3%) who got BNT 30 mcg had at least 1 medical problem from Dose 1 to 1 month after Dose 2. No participant left the study because of a medical problem during this period.

- The most commonly reported medical problem during this period was COVID-19. This was reported in 6 participants (1.2%).
- Most of the medical problems reported in this group were medical problems commonly seen in this age group (like cough and common colds).

Participants 5 years to under 12 years old

The following number of participants had at least 1 medical problem from Dose 1 to 1 month after Dose 2:

- Thirty-seven (37) out of 518 participants (7.1%) who got BNT 10 mcg.
- Twenty-one (21) out of 260 participants (8.1%) who got placebo.

The most commonly reported medical problem during this period was infection of the nose, throat, and airways. This was reported in:

- Four (4) participants (0.8%) in the BNT 10 mcg group.
- Three (3) participants (1.2%) in the placebo group.

No participant left the study because of a medical problem during this period. Most of the medical problems reported in this group were either local reactions/systemic symptoms due to vaccination or medical problems commonly seen in this age group.

How many participants had medical problems from Dose 3 to 1 month after Dose 3?

Participants 12 years to under 16 years old

A total of 6 out of 433 participants (1.4%) who got BNT 30 mcg had at least 1 medical problem from Dose 3 (booster shot) to 1 month after Dose 3. No participant left the study because of a medical problem during this period.

Most of the medical problems reported in this group were medical problems commonly seen in this age group (like cough and common colds).

Participants 5 years to under 12 years old

A total of 79 out of 620 participants (12.7%) had at least 1 medical problem from Dose 3 (booster shot) to 1 month after Dose 3 of BNT 10 mcg, regardless of their vaccine assignment at the start of the study.

The most commonly reported medical problem during this period was pain at the injection site, which was reported in 24 participants (3.8%).

Most of the medical problems reported in this group were either local reactions/systemic symptoms due to vaccination or medical problems commonly seen in this age group. No participant left the study because of a medical problem during this period.

How many participants had high troponin I levels?

Overall, in the Troponin I Testing group, the percentage of participants with high troponin I levels at the start of the study and after getting BNT was low.

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.

Phase 1

How many participants had serious medical problems from Dose 1 to 6 months after Dose 2 and Dose 3 to 6 months after Dose 3?

All participants 6 months to under 12 years old

None of the participants in any of the age or dose groups had serious medical problems or died during Phase 1 of the study.

Phase 2/3: Selected-Dose Testing Group

How many participants had serious medical problems from Dose 1 to 6 months after Dose 2?

Participants 5 years to under 12 years old

The following number of participants had at least 1 serious medical problem from Dose 1 to 6 months after Dose 2:

- Eight (8) out of 3109 participants (0.3%) who got BNT 10 mcg.
- Two (2) out of 1538 participants (0.1%) who got placebo.

No serious medical problems were reported in more than 1 participant. One (1) participant had a serious medical problem of mini stroke. This serious medical problem was severe and was thought by the study doctors to be related to BNT. This serious medical problem lasted for 7 days.

Participants 2 years to under 5 years old

The following number of participants had at least 1 serious medical problem from Dose 1 to 6 months after Dose 2:

- Eleven (11) out of 2350 participants (0.5%) who got BNT 3 mcg.
- Ten (10) out of 1173 participants (0.9%) who got placebo.

The most common serious medical problems reported in the group were appendicitis and dehydration, both of which were reported in 2 participants from the BNT 3 mcg group.

One (1) participant had serious medical problems of severe fever and moderate calf pain that were thought by the study doctors to be related to BNT. The fever lasted 5 days, while the calf pain lasted 4 days.

Participants 6 months to under 2 years old

The following number of participants had at least 1 serious medical problem from Dose 1 to 6 months after Dose 2:

- Twenty-four (24) out of 1447 participants (1.7%) who got BNT 3 mcg.
- Seventeen (17) out of 718 participants (2.4%) who got placebo.

The most common serious medical problems reported in the group are listed in Table 4 below. These serious medical problems are those reported in at least 2 participants in any vaccine group.

Table 4. Commonly reported serious medical problems by participants 6 months to under 2 years old from Dose 1 to 6 months after Dose 2 – Phase 2/3 Selected-Dose Testing Group

Medical Problem	BNT 3 mcg (1147 Participants)	Placebo (718 Participants)
Infection of the airways	3 out of 1147 participants (0.2%)	3 out of 718 participants (0.4%)
Respiratory syncytial virus (RSV, a type of virus that causes cold-like symptoms)-related infection of the airways	5 out of 1147 participants (0.3%)	1 out of 718 participants (0.1%)
Stomach flu	3 out of 1147 participants (0.2%)	0 out of 718 participants (0%)

Table 4. Commonly reported serious medical problems by participants 6 months to under 2 years old from Dose 1 to 6 months after Dose 2 – Phase 2/3 Selected-Dose Testing Group

Medical Problem	BNT 3 mcg (1147 Participants)	Placebo (718 Participants)
Viral stomach flu	2 out of 1147 participants (0.1%)	0 out of 718 participants (0%)
Lung infection	2 out of 1147 participants (0.1%)	0 out of 718 participants (0%)
Bluish discoloration of the skin	0 out of 1147 participants (0%)	2 out of 718 participants (0.3%)

None of these serious medical problems were thought by the study doctors to be related to BNT.

How many participants had serious medical problems from Dose 3 to 6 months after Dose 3?

Participants 5 years to under 12 years old

The following number of participants had at least 1 serious medical problem from Dose 3 (booster shot) to 6 months after Dose 3:

- Twelve (12) out of 3363 participants (0.4%) who got BNT 10 mcg for Dose 3.
- Four (4) out of 236 participants (1.7%) who got BNT 30 mcg for Dose 3.

Appendicitis and asthma were reported in 2 participants each. No other serious medical problems were reported in more than 1 participant.

Participants 2 years to under 5 years old

The following number of participants had at least 1 serious medical problem from Dose 3 to 6 months after Dose 3:

- Three (3) out of 863 participants (0.3%) who got BNT 3 mcg.
- None of the participants who got placebo.

No serious medical problems were reported in more than 1 participant. None of the serious medical problems were thought by the study doctors to be related to BNT.

Participants 6 months to under 2 years old

One (1) out of 483 participants in the BNT 3 mcg group had a serious medical problem from Dose 3 to 6 months after Dose 3. This participant had RSV-related infection of the airways, which was thought by the study doctors to be not related to BNT.

None of the 237 participants from the placebo group had any serious medical problems during this period.

Phase 2/3: Troponin I Testing Group

How many participants had serious medical problems from Dose 1 to 6 months after Dose 2?

Participants 12 years to under 16 years old

One (1) out of 487 participants (0.2%) who got BNT 30 mcg had at least 1 serious medical problem from Dose 1 to 6 months after Dose 2. This

participant had miscarriage and ovarian cyst, both of which were thought by the study doctors to be not related to BNT.

No other participant had any serious medical problems during this period.

Participants 5 years to under 12 years old

One (1) out of 518 participants (0.2%) from the BNT 10 mcg group had a serious medical event from Dose 1 to 6 months after Dose 2. This participant had asthma, which was thought by the study doctors to be not related to BNT.

None of the 260 participants from the placebo group had any serious medical problems during this period.

How many participants had serious medical problems from Dose 3 to 6 months after Dose 3?

Participants 12 years to under 16 years old

No participant had any serious medical problems from Dose 3 (booster shot) to 6 months after Dose 3 of BNT 30 mcg.

Participants 5 years to under 12 years old

Two (2) out of 620 participants (0.3%) had serious medical problems from Dose 3 (booster shot) to 6 months after Dose 3 of BNT 10 mcg.

- One (1) participant had a choking episode that resulted in “respiratory arrest” (a condition wherein the inability to breathe causes lack of oxygen in the body).
- One (1) participant had a blood disorder called “sickle cell anemia,” which affects the red blood cells.

None of these serious medical problems were thought by the study doctors to be related to BNT.

No participant died in any age or dose groups during Phase 2/3.

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 **C4591007**

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

www.clinicaltrials.gov	Use the study identifier **NCT04816643**
www.clinicaltrialsregister.eu	Use the study identifier **2020-005442-42**

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!