Plain Language Clinical Study

Summary

This summary reports the results of only one study. Researchers must look at the results of many types of studies to understand if a 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: Pfizer Inc.

Vaccine Studied: Group B Streptococcus 6-Valent Polysaccharide Conjugate Vaccine (GBS6)

Protocol Number: C1091002

Dates of Study: 14 January 2019 to 04 March 2024

Title of this Study: Trial to Evaluate the Safety, Tolerability, and Immunogenicity of a Multivalent Group B Streptococcus Vaccine in Healthy Nonpregnant Women and Pregnant Women and Their Infants

[A Phase 1/2, Randomized, Placebo-Controlled, Observer -Blinded Trial to Evaluate the Safety, Tolerability, and Immunogenicity of a Multivalent Group B Streptococcus Vaccine in Healthy Nonpregnant Women and Pregnant Women 18 to 40 Years of Age and Their Infants]

Date of this Report: 4 March 2025

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– Thank You –

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

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

Why was this study done?

What are Group B Streptococcus infections?

Group B Streptococcus (GBS) is a type of germ (bacteria) that may cause serious infection. There are 10 different "serotypes," or different types of GBS. However, 5 of the serotypes cause 97% of GBS disease worldwide. GBS infections are most common in infants less than 3 months old and older adults.

GBS is a common type of bacteria that many people carry in their bodies. Most of the time, it does not make people sick. However, if a pregnant person has GBS in her vagina or intestines, the baby may get infected during childbirth. GBS is not a sexually transmitted disease (STD).

In infants, GBS may cause life-threatening diseases including,

- An infection of the blood (sepsis)
- Infection of the lining covering the brain and spinal cord (meningitis)
- Infection of the lungs (pneumonia)

What is the GBS6 vaccine?

Group B streptococcus 6-valent polysaccharide conjugate vaccine (GBS6) is being studied. It is a vaccine designed to protect against the 6 GBS serotypes that cause most of the invasive disease in infants. It is given as an injection in the muscle.

Researchers wanted to see if the GBS6 vaccine can prevent invasive GBS infections in infants by vaccinating their mothers during pregnancy.

GBS6 vaccine contains small parts of the GBS bacteria that do not cause disease. These small parts are a type of sugar that help turn on the body's disease defense system, also called the immune system.

To fight GBS, the immune system makes specialized proteins called antibodies. Antibodies are special proteins that can recognize and help kill germs. Antibodies can help protect the body against GBS infections.

> When pregnant people get vaccinated, their immune system will make antibodies. A pregnant person can naturally pass these antibodies to their fetus. These antibodies may help to protect the infant from disease after birth.

The GBS6 vaccine was shown in a previous study to be safe in healthy men and nonpregnant participants. It also caused participants in the previous study to have antibodies against GBS that lasted at least 6 months after getting the GBS6 vaccination.

What was the purpose of this study?

Researchers think that giving GBS6 vaccine to pregnant participants could protect their infants against GBS infections. This is because a baby's immune system may not make enough antibodies when given a vaccine early in life.

The main purposes of the study were to learn:

- If the GBS6 vaccine, when given to pregnant participants, can protect their infants against GBS disease.
- If the GBS6 vaccine was safe in pregnant participants and their infants. The study also wanted to find out if pregnant participants had local or systemic reactions after getting the GBS6 vaccination.

Local or systemic reactions are responses that a person can have to a vaccine.

> Local reactions in this study are injection site reactions such as redness, swelling, or pain where the injection was given.
>
> Systemic reactions in this study are tiredness, headache, nausea, muscle pain, joint pain, vomiting, or diarrhea.

The participants in the study received either GBS6 vaccine or placebo. In this study, a placebo does not have any active ingredients in it but looks like the GBS6 vaccine.

Researchers wanted to know:

- **Was GBS6 vaccine safe for participants?**
- **What local or systemic reactions did the adult participants have?**
- **What medical problems did the adult participants have?**
- **What medical problems did the infants have?**

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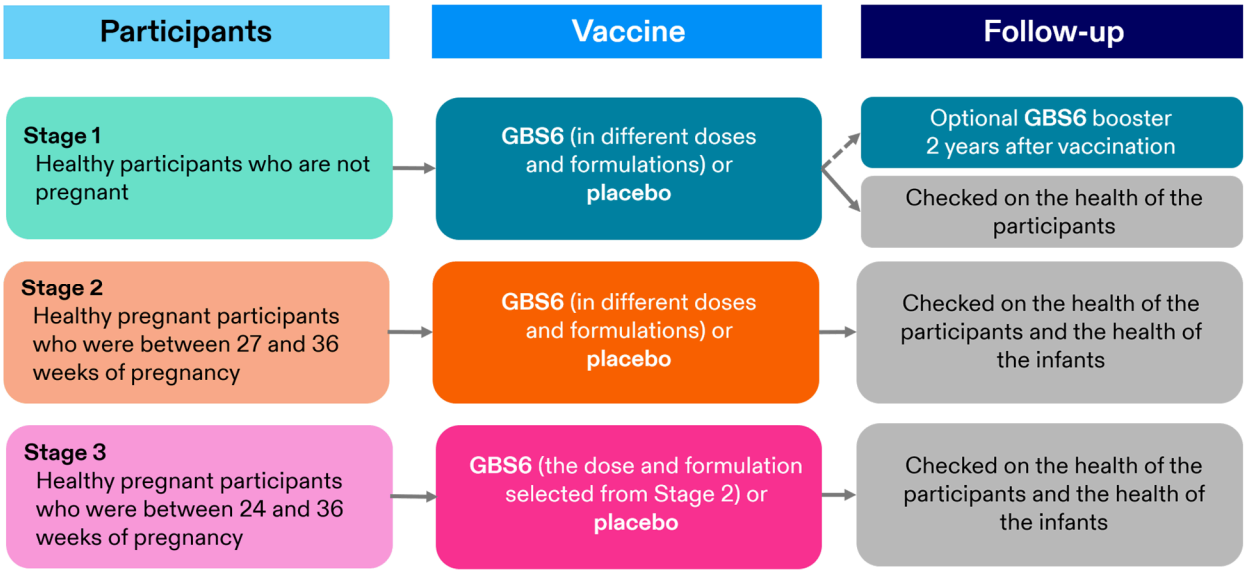
What happened during the study?

How was the study done?

The study was done in 3 stages. The figure below shows what happened in each stage. Figure 1 below shows the 3 stages in this study.

Figure 1. The 3 stages in this study



In all stages, study participants and researchers did not know who was given the GBS6 vaccine and who was given placebo. This is known as a "blinded" study. Study participants were assigned to each group by chance alone.

Researchers tested GBS6 vaccine in groups of study participants to find out more about the safety of the GBS6 vaccine.

Researchers then compared the results of study participants given GBS6 vaccine to the results of study participants given a placebo.

What happened in each stage is described below. Researchers collected information on all medical problems that all participants reported.

Stage 1

Stage 1 started first. Stage 1 compared 3 groups of healthy participants to learn more about the safety of the GBS6 vaccine. A total of 66 participants took part in Stage 1. The study included healthy women who were 18 to 40 years old and not pregnant.

Participants received the highest dose of GBS6 vaccine that was considered safe and well tolerated from a previous study. Two (2) different forms of GBS6 vaccine and a placebo were tested. The 2 forms of vaccine were GBS6 vaccine with aluminum phosphate ($AlPO_4$) and GBS6 vaccine without $AlPO_4$. Each participant received 1 dose of GBS6 vaccine or placebo.

The 3 groups in Stage 1 are shown in Figure 2 below.

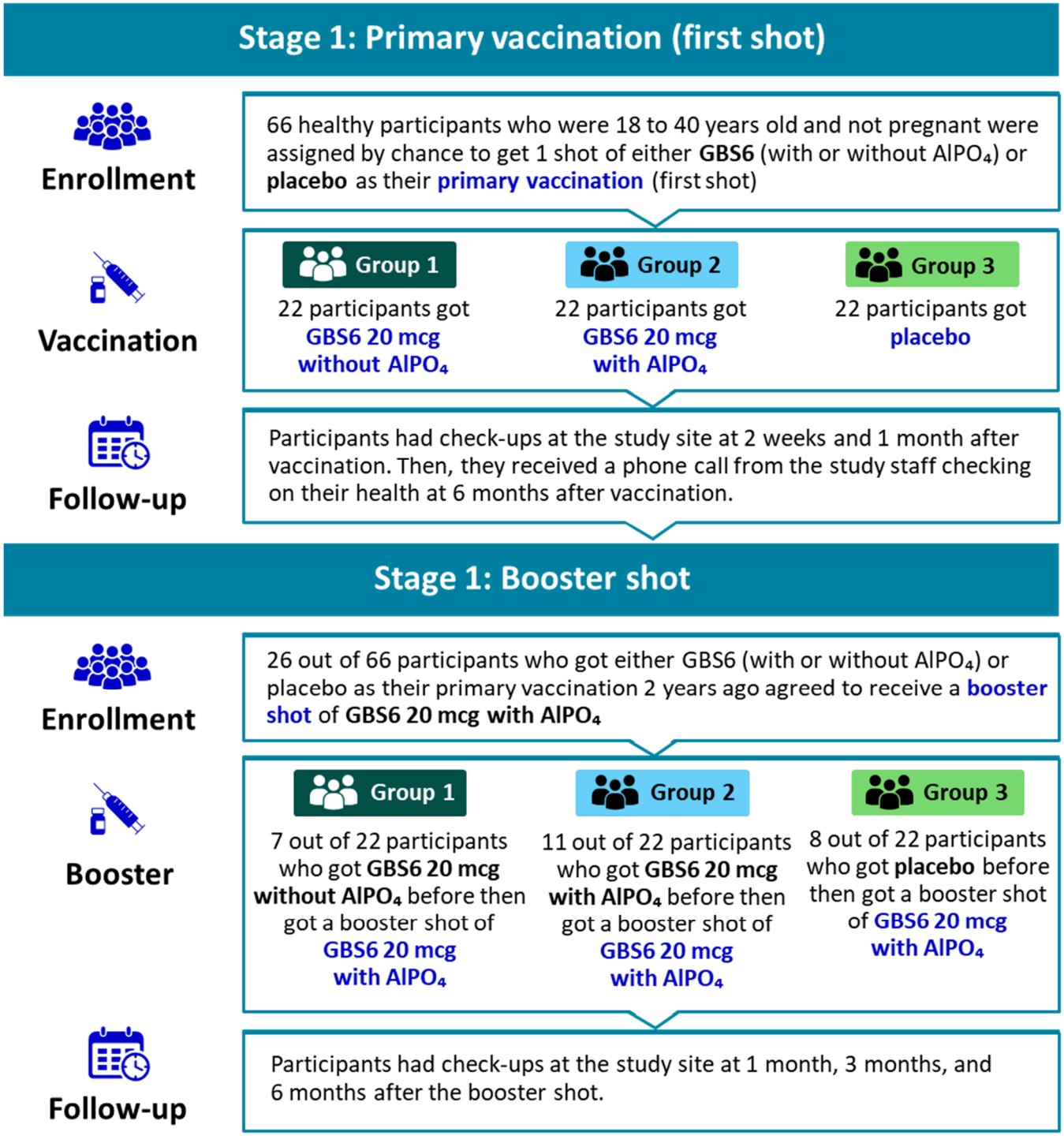
Participants were asked to:

- Keep a diary of any local or systemic reactions they had for 7 days after receiving GBS6 or placebo
- Return to the clinic for follow-up checkups 2 weeks and 1 month after receiving GBS6 or placebo
- Receive a call to check on their health 6 months after receiving GBS6 or placebo

Participants in Stage 1 could choose to receive a GBS6 vaccine booster 2 years after they received the GBS6 vaccine or placebo. There were 26 participants who received the booster. Participants had follow-up visits 1, 3, and 6 months afterwards. Participants who received the booster were asked again to keep a diary of any local or systemic reactions they had for 7 days after receiving GBS6 booster.

Figure 2 below shows what happened during Stage 1 of the study.

Figure 2. What happened in Stage 1?



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Researchers reviewed the results of Stage 1 and an earlier study to make sure it was safe to start Stage 2 of the study.

Stage 2:

Participants in Stage 2 were healthy women who were between 27 and 36 weeks pregnant. A total of 360 healthy pregnant participants took part in Stage 2, and there were 7 groups as shown in Figure 3 below.

The groups in Stage 2 did not start at the same time. Instead, the 5-mcg groups started first. Researchers reviewed the results of the first 42 participants in both the GBS6 5 mcg dose groups and placebo within 14 days after their vaccination to make sure it was safe to start the higher dose groups. They repeated this approach with each dose level before starting the next higher dose.

A total of 357 infants born to the participants in Stage 2 were also included in the study.

- 239 infants born to participants who received the GBS6 vaccine
- 118 infants born to participants who received placebo

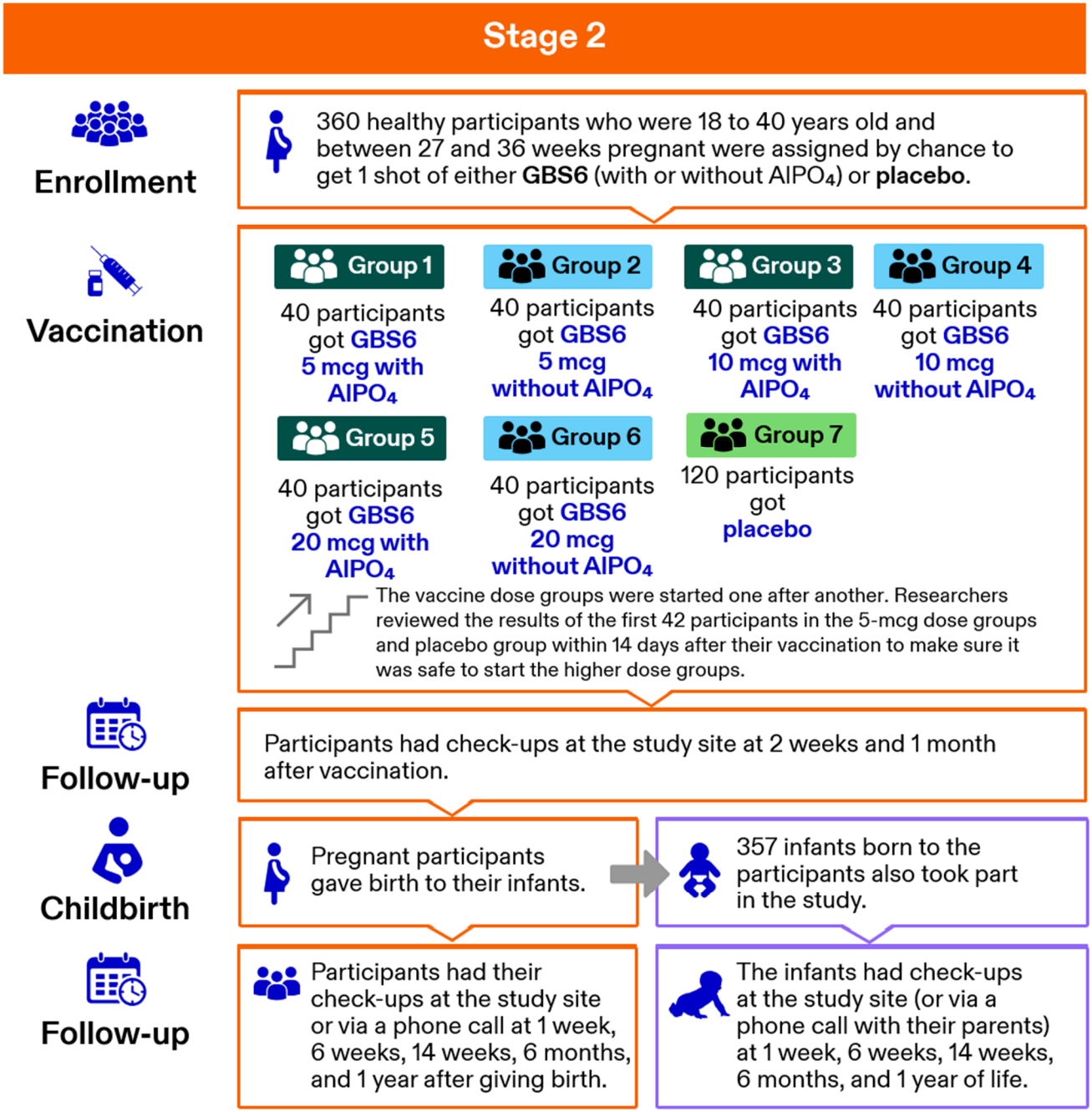
Participants were asked to:

- Keep a diary of any local or systemic reactions for 7 days after receiving the GBS6 vaccine or placebo
- Return to the clinic for follow-up checkups 2 weeks and 1 month after receiving the GBS6 vaccine or placebo
- Provide information on their experience giving birth
- Return to the clinic with their infants for follow-up checkups 6 weeks, 14 weeks, 18 weeks, and 1 year after giving birth
- Receive calls checking on their health and their infants' health 1 week and 6 months after giving birth

The results from Stage 2 were used to choose the dose of GBS6 vaccine to test in Stage 3.

Figure 3 below shows what happened during Stage 2 of the study.

Figure 3. What happened in Stage 2?



Stage 3

Stage 3 started after researchers reviewed the results of Stage 2. Based on the results from Stage 2, researchers chose the GBS6 vaccine 20-mcg dose without $AlPO_4$. Participants in Stage 3 were healthy women who were between 24 and 36 weeks pregnant. A total of 216 healthy pregnant participants took part in Stage 3, and there were 2 groups as shown in Figure 4 below.

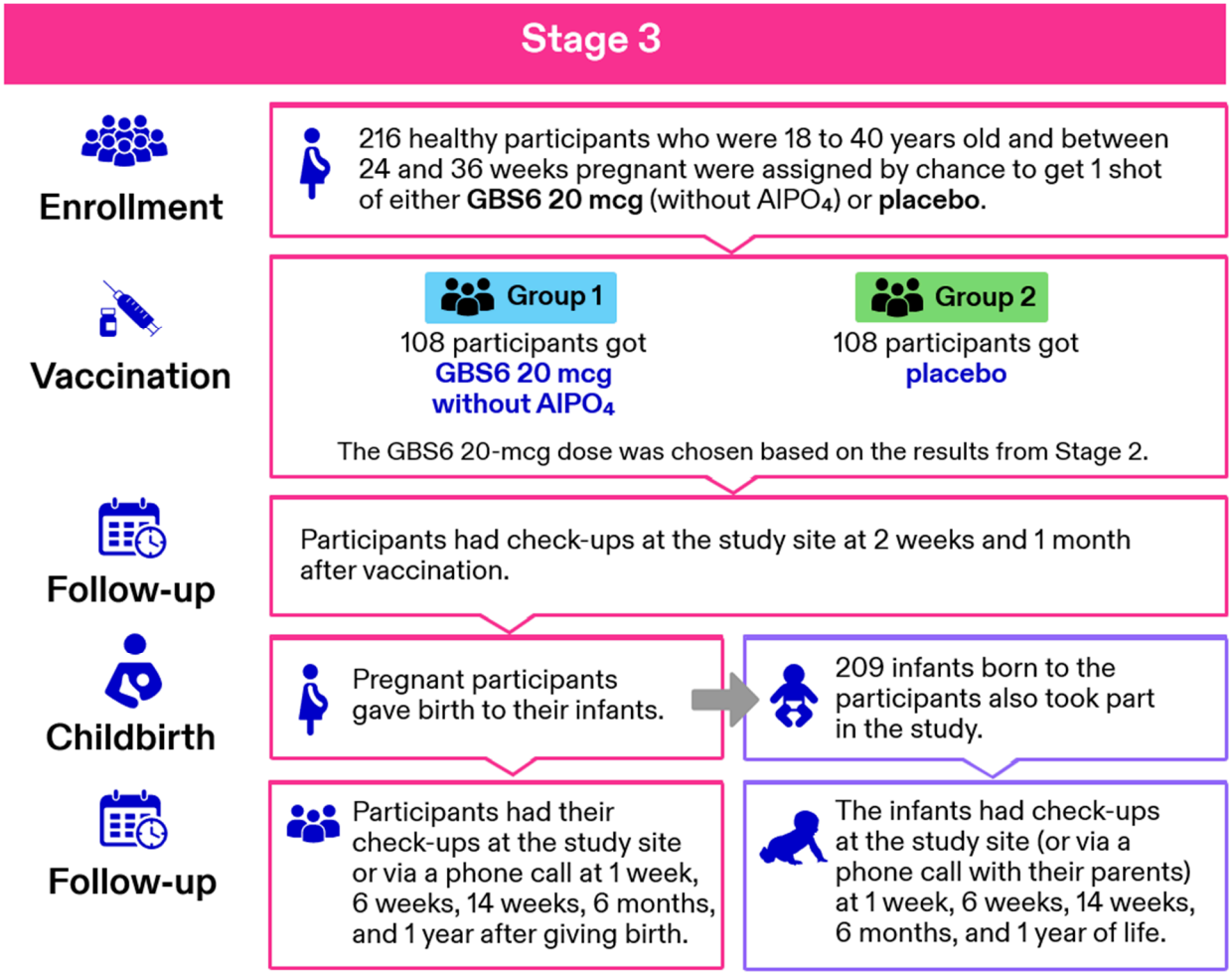
Participants in Stage 3 were asked to do the same things as participants in Stage 2.

A total of 209 infants born to the participants in Stage 3 were also included in the results.

- 104 infants born to participants who received GBS6 vaccine 20 mcg
- 105 infants born to participants who received placebo

Figure 4 below shows what happened during Stage 3 of the study.

Figure 4. What happened in Stage 3?



Where did this study take place?

The Sponsor ran this study at 20 locations in 3 countries in North America, Africa, and Europe.

When did this study take place?

It began on 14 January 2019 and ended on 04 March 2024.

Who participated in this study?

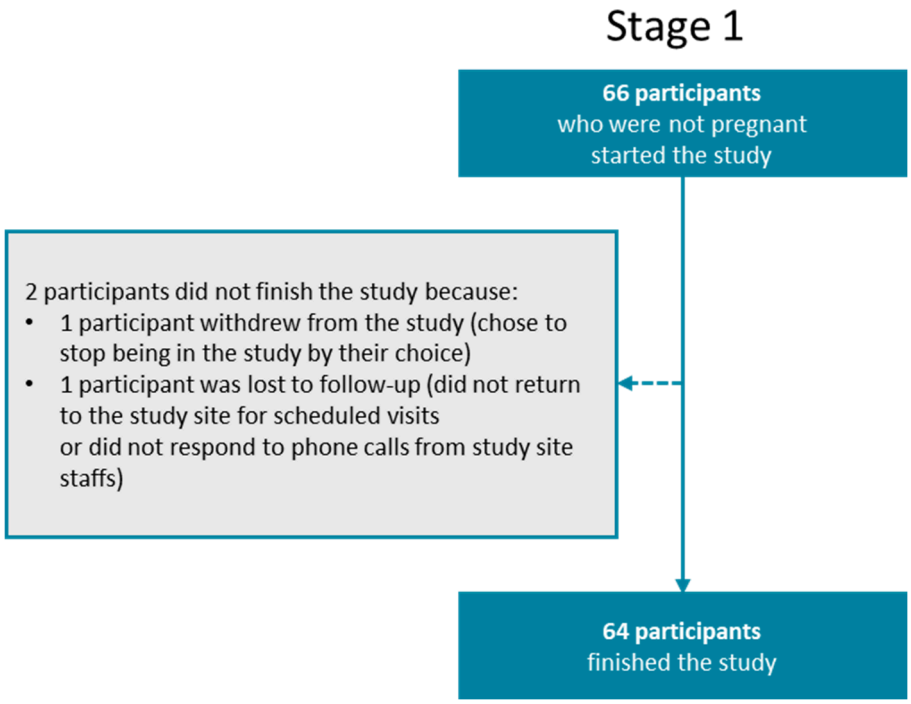
In Stage 1, the study included healthy women who were not pregnant. In Stages 2 and 3, the study included healthy pregnant participants and their infants after they gave birth.

- A total of 66 women who were not pregnant participated.
- A total of 576 pregnant people participated.
- A total of 566 infants participated.
- The women were between the ages of 18 and 40 years.

Participants who were not pregnant were in the study for up to 3 years. Pregnant participants were in the study until 12 months after delivery. Infants were in the study until they were a year old.

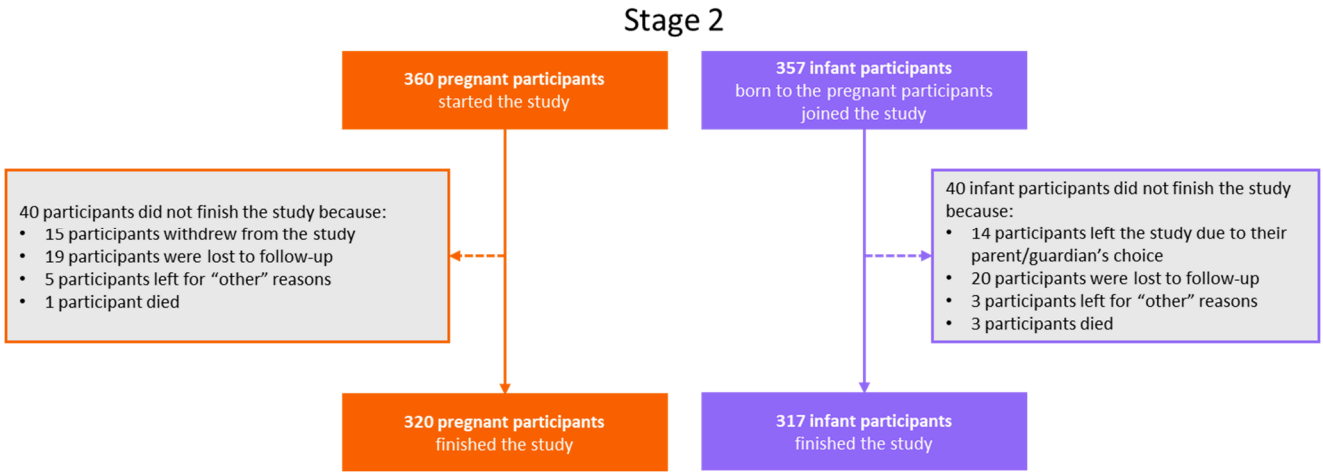
In Stage 1, of the 66 participants who started the study, 64 finished. Figure 5 below shows how many participants took part in Stage 1.

Figure 5. Number of participants who took part in Stage 1 of the study



In **Stage 2**, of the 360 participants who started the study, 320 finished. A total of 40 participants did not finish the study. Of the 357 infant participants in Stage 3, 317 finished. A total of 40 infant participants did not finish the study. Figure 6 below shows how many participants took part in Stage 2.

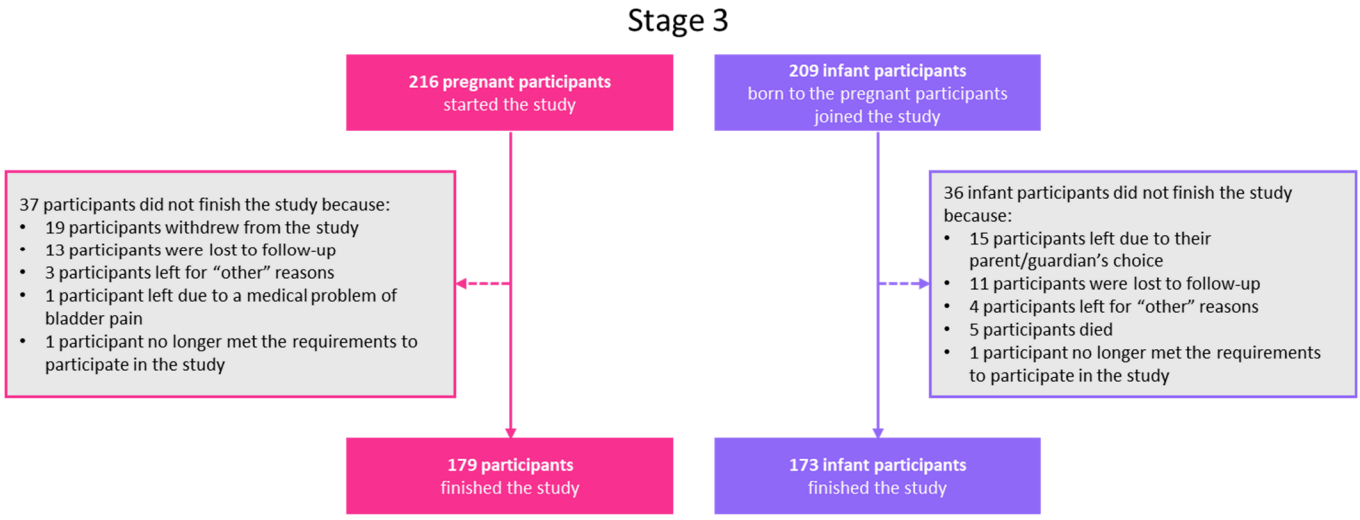
Figure 6. Number of participants who took part in Stage 2 of the study



None of the participants in Stage 2 left the study early due to a medical problem.

In **Stage 3**, of the 216 pregnant participants who started the study, 179 finished. A total of 37 participants did not finish the study. Of the 209 infant participants in Stage 3, 173 finished. A total of 36 infant participants did not finish the study. Figure 7 below shows how many participants took part in Stage 3.

Figure 7. Number of participants who took part in Stage 3 of the study



None of the infant participants left the study early due to a medical problem.

How long did the study last?

Study participants were in the study for up to 3 years. The entire study took about 5 years to complete. The study was completed as planned and did not end early.

When the study ended in March 2024, the Sponsor began reviewing the information collected. The Sponsor then created a report of the results. This is a summary of that report.

What were the results of the study?

Was GBS6 vaccine safe for participants?

Overall, the tested doses of GBS6 vaccine in nonpregnant and maternal participants were found to be safe. No safety concerns were found in infants of participants who received the GBS6 vaccine.

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 unknown 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 vaccine might have on a participant.

Researchers collected information about different types of medical problems participants had during the study. They collected information at each stage of the study. Below is the information researchers collected at each stage of the study.

Stage 1

How many participants in Stage 1 had a local or systemic reaction within 7 days of getting GBS6 vaccine, booster, or placebo?

Local or systemic reactions are responses that a person can have to a vaccine.

> Local reactions in this study are injection site reactions such as redness, swelling, or pain where the injection was given.
>
> Systemic reactions in this study are tiredness, headache, nausea, muscle pain, joint pain, vomiting, or diarrhea.

Figure 8 shows the number of participants in each vaccine group who had local or systemic reactions.

Figure 8. Number of participants in Stage 1 who had local or systemic reactions within 7 days after getting the GBS6 vaccine or placebo

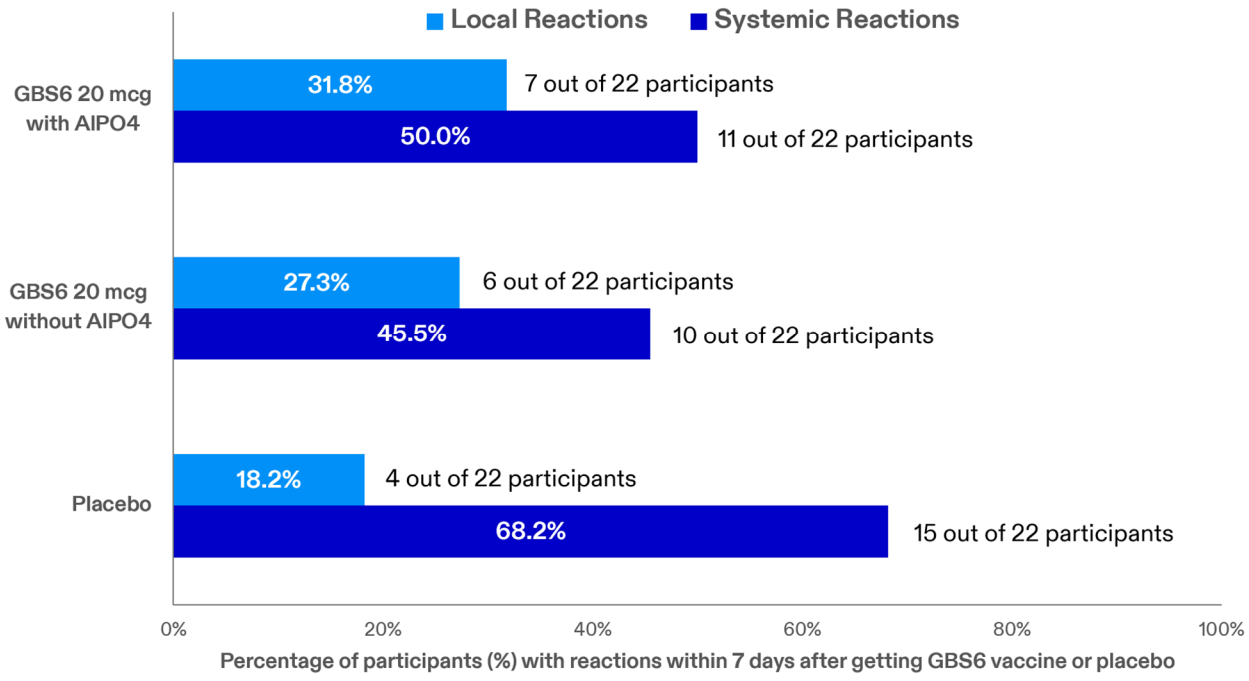
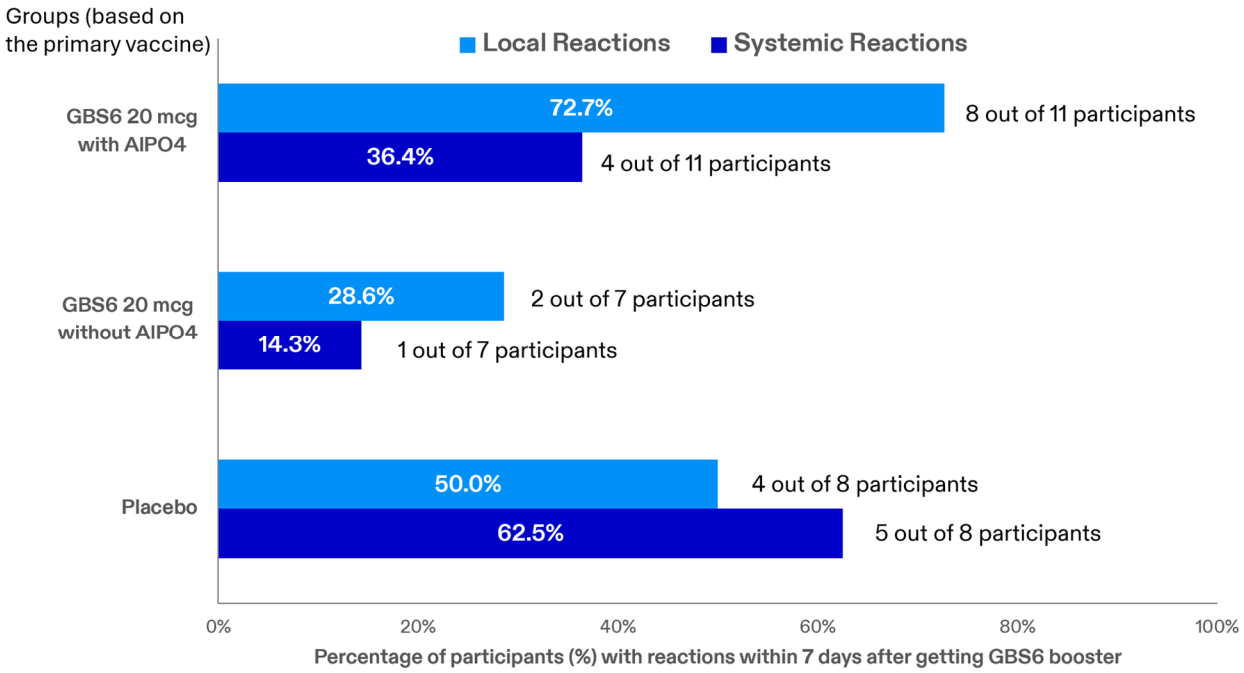


Figure 9 below shows the number of participants who had a local or systemic reaction within 7 days after receiving the GBS6 booster. The participants are grouped by what dose and formulation of the GBS6 vaccine they first received. Not everyone in Stage 1 chose to return about 2 years after the first shot to receive the booster.

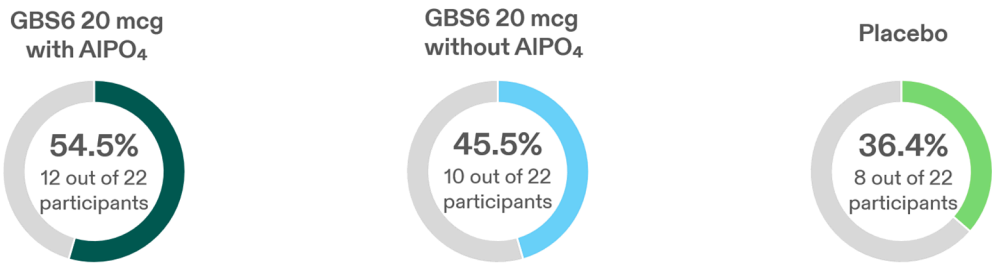
Figure 9. Number of participants in Stage 1 who had local or systemic reactions within 7 days after getting the GBS6 booster



How many participants in Stage 1 reported any medical problems within 1 month after receiving the GBS6 vaccine or placebo?

Figure 10 below shows the answer to this question.

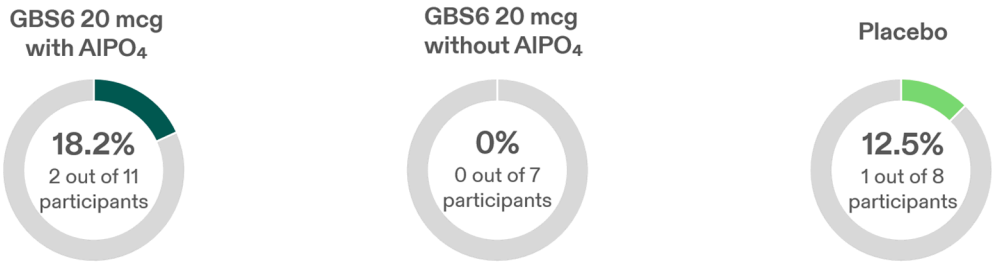
Figure 10. Number of participants in Stage 1 who reported any medical problems within 1 month after getting the GBS6 vaccine or placebo



How many participants in Stage 1 reported any medical problems within 1 month after receiving the GBS6 booster

Figure 11 below shows how many participants in Stage 1 reported any medical problems within 1 month after receiving the GBS6 booster. Medical problems were reported based on the first vaccination they received.

Figure 11. Number of participants in Stage 1 who reported any medical problems within 1 month after getting the GBS6 booster



How many participants reported medical problems that needed medical care within 6 months after getting GBS6 vaccine and 7 to 12 months after getting the booster in Stage 1?

Figure 12 and Figure 13 show the answer to this question.

Figure 12. Number of participants in Stage 1 who reported medical problems that needed medical care after getting GBS6 vaccine or placebo

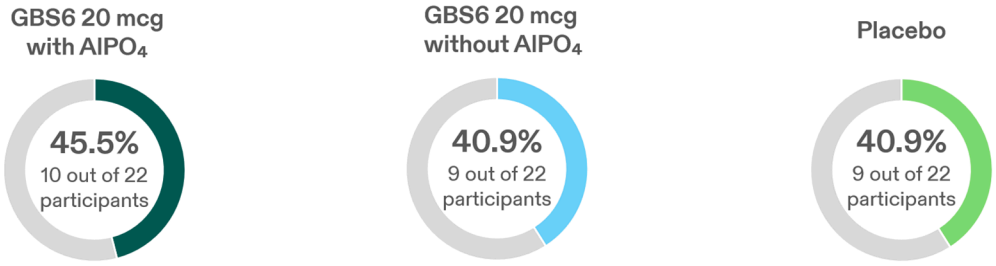
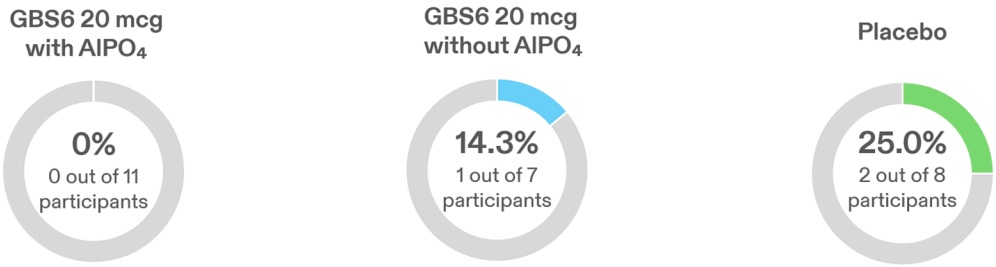


Figure 13. Number of participants in Stage 1 who reported medical problems that needed medical care after getting the GBS6 booster – grouped by primary vaccination groups:



Stage 2

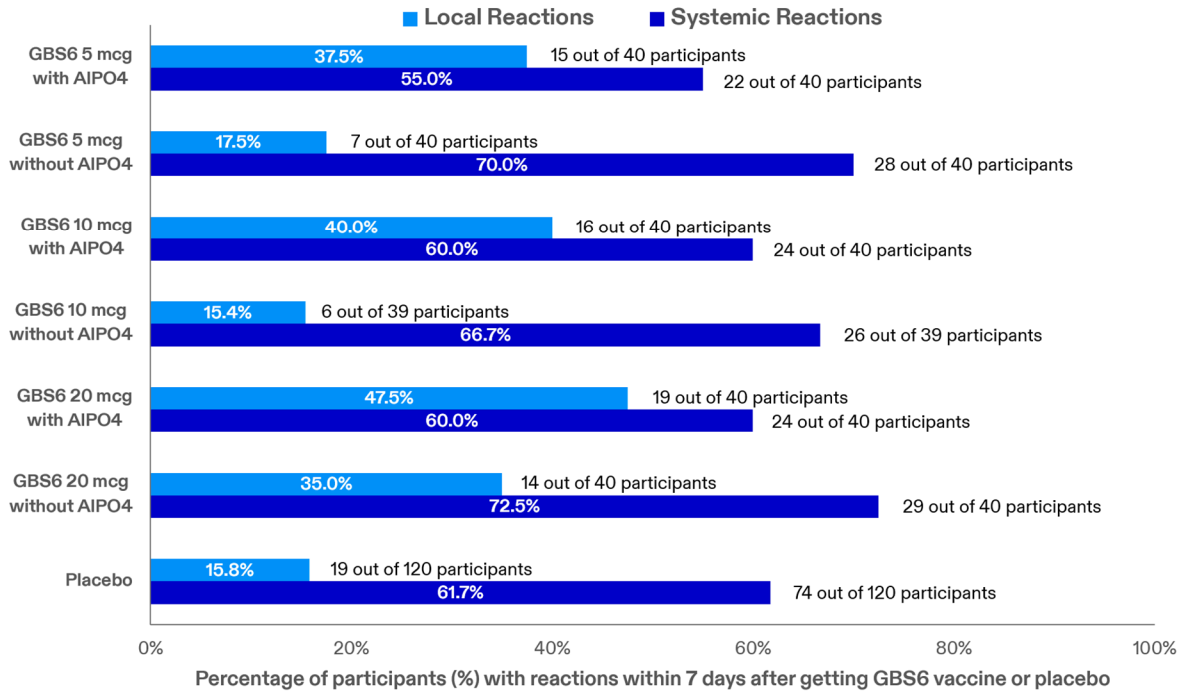
In the first 42 participants in each GBS6 vaccine dosing level or placebo, what were the unexpected laboratory test results within 2 weeks after receiving GBS6 vaccine or placebo in Stage 2?

Most of the laboratory test results were normal. Although there were a few minor unexpected laboratory test results, they were similar between the GBS6 vaccine and placebo groups.

How many pregnant participants had a local or systemic reaction within 7 days after getting GBS6 vaccine or placebo in Stage 2?

Figure 14 below shows the answer to this question.

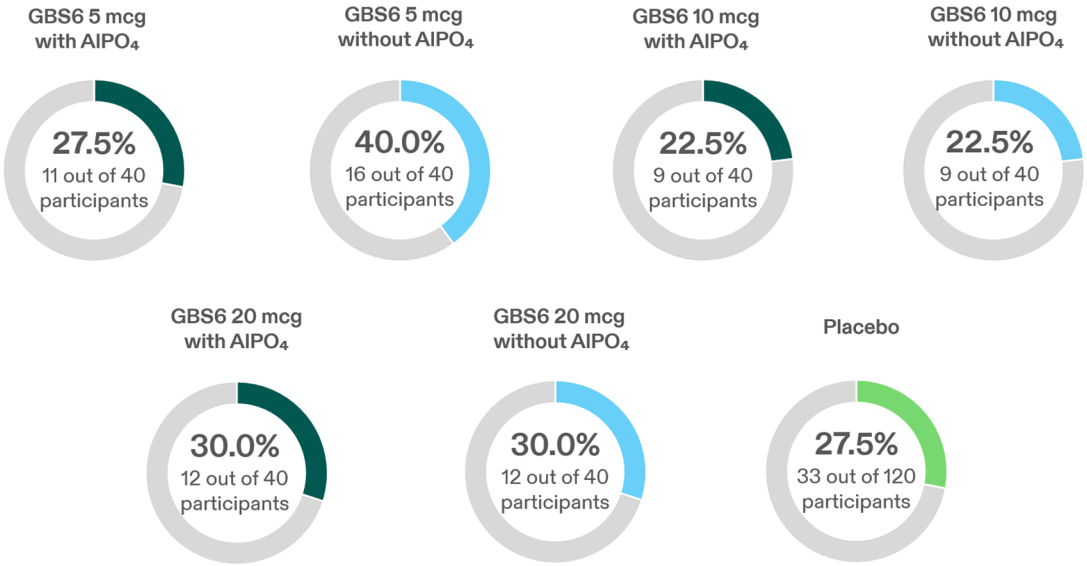
Figure 14. Number of participants in Stage 2 who had local or systemic reactions within 7 days after getting the GBS6 vaccine or placebo



How many pregnant participants had any medical problems within 1 month after receiving GBS6 vaccine or placebo in Stage 2?

Figure 15 below shows the answer to this question.

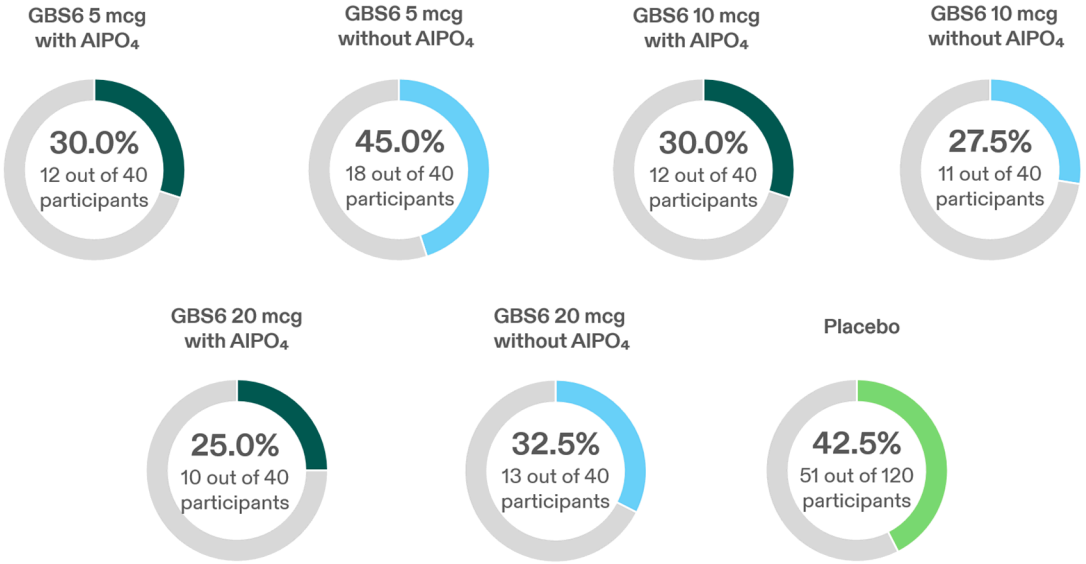
Figure 15. Number of participants in Stage 2 who had any medical problems within 1 month after getting the GBS6 vaccine or placebo



How many pregnant participants had medical problems that needed medical care or had pregnancy complications from the time they joined the study until 1 year after they gave birth in Stage 2?

Figure 16 below shows the answer to this question.

Figure 16. Number of participants in Stage 2 who had medical problems that needed medical care from the time they joined the study until 1 year after giving birth



A total of 89 participants in Stage 2 who got either GBS6 vaccine or placebo had pregnancy complications. The number of participants with pregnancy complications was similar between the GBS6 vaccine and placebo groups.

What were the delivery outcomes in Stage 2?

Researchers collected information on what happened when the participants in Stage 2 gave birth. Researchers recorded if the babies were born at full term, premature, stillbirths, or were delivered via cesarean section.

> Full-term labor is when the labor process starts at a normal time.
>
> Premature, or pre-term labor is when the labor process of giving birth starts early.
>
> Stillbirth is when a baby is born without any signs of life.
>
> A cesarean section (c-section) is when the baby is delivered through a surgical incision in the mother's abdomen.

There was 1 stillbirth reported in Stage 2. It was in the GBS6 5 mcg without $AlPO_4$ group. Table 1 below shows the other delivery outcomes.

Table 1. Delivery outcomes in Stage 2

GBS6 5 mcg with $AlPO_4$ (40 Participants)	GBS6 5 mcg no $AlPO_4$ (40 Participants)	GBS6 10 mcg with $AlPO_4$ (40 Participants)	GBS6 10 mcg no $AlPO_4$ (40 Participants)	GBS6 20 mcg with $AlPO_4$ (40 Participants)	GBS6 20 mcg no $AlPO_4$ (40 Participants)	Placebo (120 Participants)
Full term						
37 out of 40 participants (92.5%)	36 out of 40 participants (90.0%)	39 out of 40 participants (97.5%)	40 out of 40 participants (100%)	39 out of 40 participants (97.5%)	39 out of 40 participants (97.5%)	115 out of 120 participants (95.8%)
Pre-term						
3 out of 40 participants (7.5%)	3 out of 40 participants (7.5%)	1 out of 40 participants (2.5%)	0	1 out of 40 participants (2.5%)	1 out of 40 participants (2.5%)	2 out of 120 participants (1.7%)
C-section						
6 out of 40 participants (15.0%)	16 out of 40 participants (40.0%)	7 out of 40 participants (17.5%)	13 out of 40 participants (32.5%)	7 out of 40 participants (17.5%)	12 out of 40 participants (30.0%)	26 out of 120 participants (21.6%)

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Was there a difference in birth outcomes of infants in Stage 2 born to participants who got GBS6 or placebo?

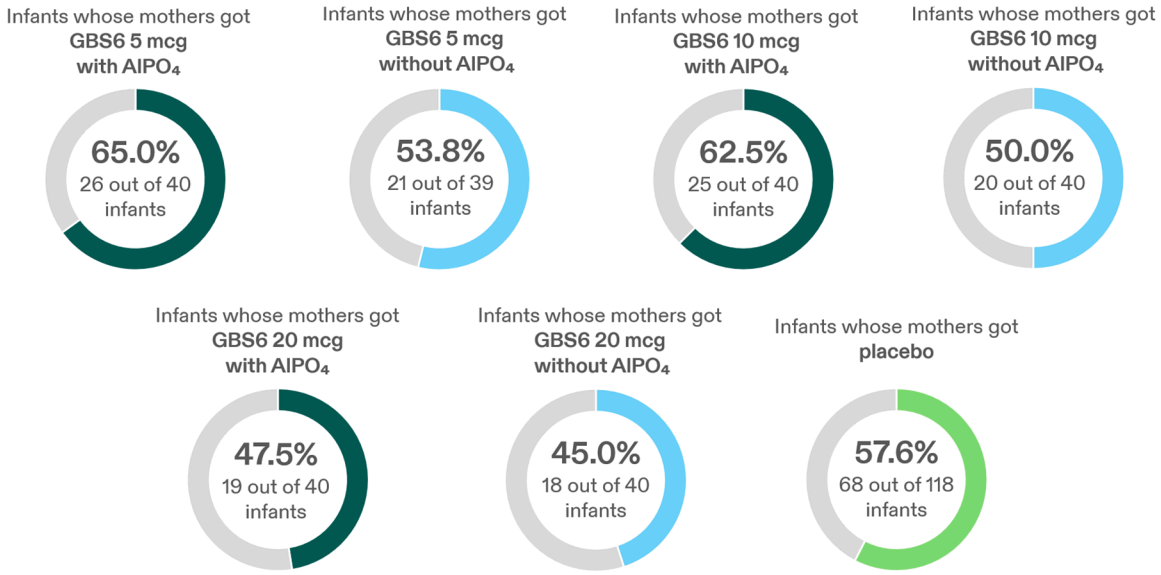
Researchers recorded information on the infants born in Stage 2. They recorded the length of the mothers' pregnancies, the infants' health within 5 minutes of being born, and if infants had any birth defects.

The results for birth outcomes were similar between the GBS6 and placebo groups.

How many infant participants had any medical problems within the first 6 weeks of life in Stage 2?

Figure 17 below shows the answer to this question.

Figure 17. Number of infants born to participants in Stage 2 with any medical problems within the first 6 weeks of life.



How many infant participants in Stage 2 had medical problems that needed medical care, major birth defects, developmental delays, or GBS infections within 1 year of their birth?

Birth defects, also called congenital disorders, are health conditions or physical abnormalities that an infant is born with. Birth defects can cause the infant to be disabled.

A **developmental delay** is when an infant does not reach certain milestones on time.

Figure 18 below shows how many infant participants in Stage 2 had medical problems that needed medical care within 1 year from birth. The infants were born to participants in Stage 2.

Figure 18. Number of infant participants in Stage 2 who had medical problems that needed medical care within 1 year from birth

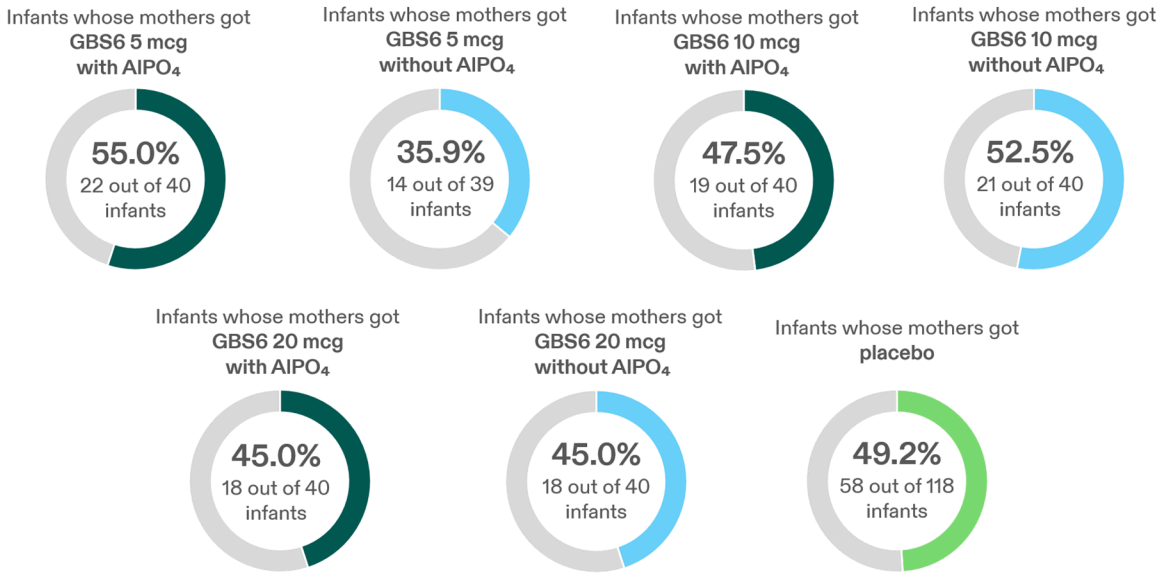


Table 2 below shows the number of infants with major birth defects or developmental delays within 1 year of birth. None of the infants in Stage 2 had any GBS infections.

Table 2. Number of infants with certain medical problems in Stage 2

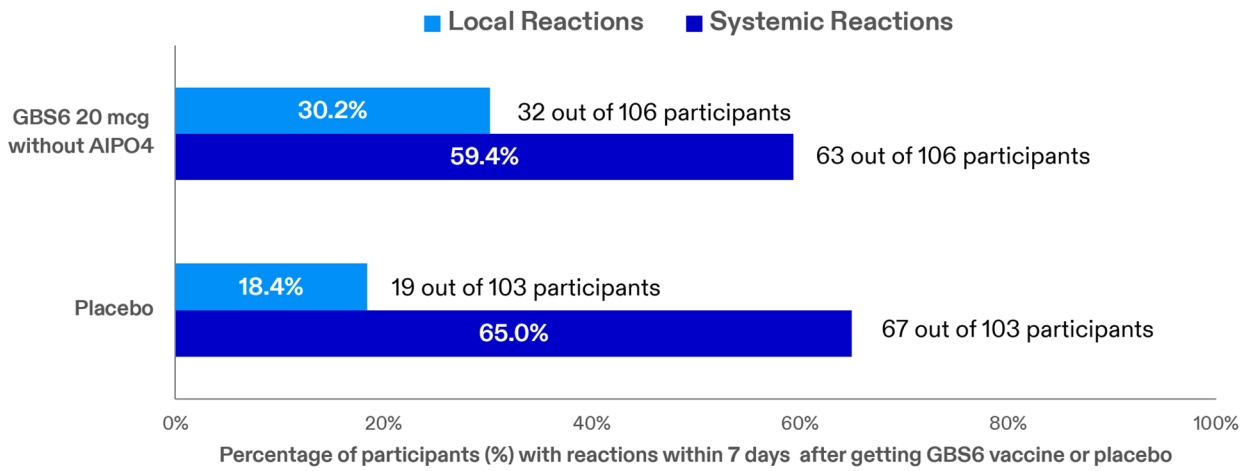
GBS6 5 mcg with $AlPO_4$ (40 Participants)	GBS6 5 mcg no $AlPO_4$ (39 Participants)	GBS6 10 mcg with $AlPO_4$ (40 Participants)	GBS6 10 mcg no $AlPO_4$ (40 Participants)	GBS6 20 mcg with $AlPO_4$ (40 Participants)	GBS6 20 mcg no $AlPO_4$ (40 Participants)	Placebo (118 Participants)
Major birth defect						
0	1 out of 39 participants (2.6%)	1 out of 40 participants (2.5%)	0	0	0	2 out of 118 participants (1.7%)
Developmental delay						
0	1 out of 39 participants (2.6%)	0	0	1 out of 40 participants (2.5%)	0	1 out of 118 participants (0.8%)

Stage 3

How many pregnant participants in Stage 3 had a local or systemic reaction within 7 days of getting the GBS6 vaccine or placebo?

Figure 19 below shows the answer to this question.

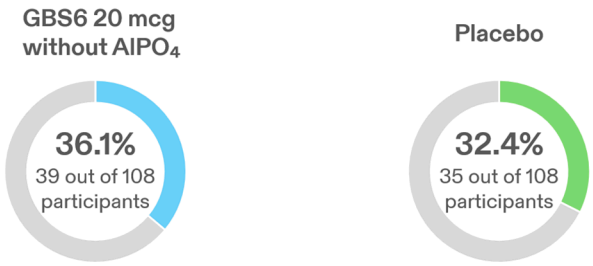
Figure 19. Number of participants in Stage 3 who had local or systemic reactions within 7 days of getting the GBS6 vaccine or placebo



How many pregnant participants in Stage 3 had any medical problems within 1 month of getting the GBS6 vaccine or placebo?

Figure 20 below shows the answer to this question.

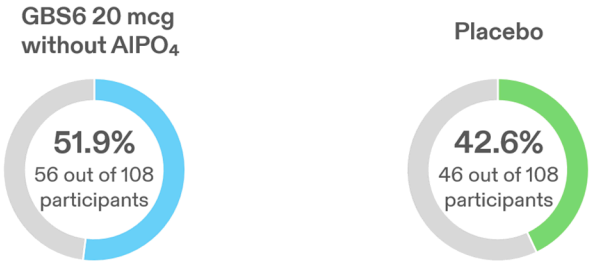
Figure 20. Number of participants in Stage 3 who had medical problems within 1 month of getting the GBS6 vaccine or placebo



How many pregnant participants had medical problems that needed medical care or had pregnancy complications from the time they joined the study until 1 year after they gave birth in Stage 3?

Figure 21 below shows the answer to this question.

Figure 21. Number of participants in Stage 3 who had medical problems that needed medical care from the time they joined the study until 1 year after giving birth



A total of 58 participants in Stage 3 who got either GBS6 vaccine or placebo had pregnancy complications. The number of participants with pregnancy complications was similar between the GBS6 vaccine and placebo groups.

What were the delivery outcomes in Stage 3?

Researchers collected information on what happened when the participants in Stage 3 gave birth. Researchers recorded if the babies were born at full term, premature, stillbirths, or were delivered via cesarean section.

> Full-term labor is when the labor process starts at a normal time.
>
> Premature, or pre-term labor is when the labor process of giving birth starts early.
>
> Stillbirth is when a baby is born without any signs of life.
>
> A cesarean section (c-section) is when the baby is delivered through a surgical incision in the mother's abdomen.

Table 3 below shows the delivery outcomes.

Table 3. Delivery outcomes in Stage 3

Outcome	GBS6 20 mcg no $AlPO_4$ (108 Participants)	Placebo (108 Participants)
Full term	95 out of 108 participants (88.0%)	99 out of 108 participants (91.7%)
Pre-term	8 out of 108 participants (7.4%)	6 out of 108 participants (5.6%)
Stillbirth	1 out of 108 participants (0.9%)	0
C-section	26 out of 108 participants (24.1%)	23 out of 108 participants (21.3%)

Was there a difference in birth outcomes of infants in Stage 3 born to participants who got GBS6 or placebo?

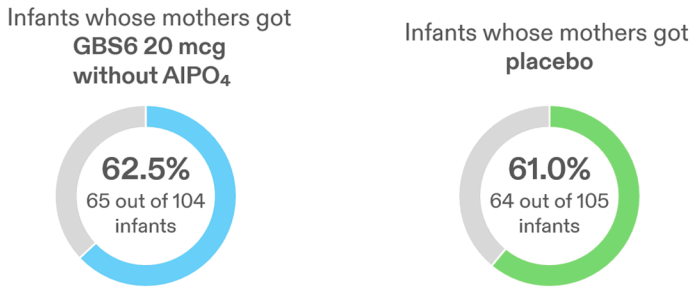
Researchers recorded information on the infants born in Stage 2. They recorded the length of the mothers' pregnancies, the infants' health within 5 minutes of being born, and if infants had any birth defects.

The results for birth outcomes were similar between the GBS6 and placebo groups.

How many infant participants had any medical problems within the first 6 weeks of life in Stage 3?

Figure 22 below shows the answer to this question.

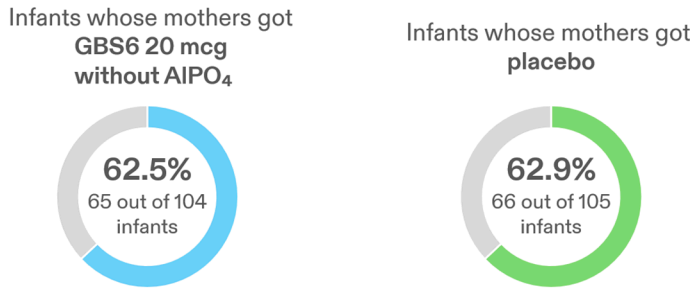
Figure 22. Number of infant participants born to participants in Stage 3 who had medical problems within the first 6 weeks of life



How many infant participants in Stage 3 had medical problems that needed medical care, major birth defects, developmental delays, or GBS infections within 1 year of their birth?

Figure 23 below shows how many infant participants in Stage 3 had medical problems that needed medical care within 1 year from birth. The infants were born to participants in Stage 3.

Figure 23. Number of infant participants in Stage 3 who had medical problems that needed medical care within 1 year from birth



None of the infants in Stage 3 had major birth defects. One (1) infant from the GBS6 20 mcg without $AlPO_4$ group in Stage 3 had a developmental delay. None of the infants in Stage 3 had any GBS infections.

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.

Stage 1

How many participants in Stage 1 had any serious medical problems during the study?

In Stage 1, none of the 66 participants (0%) had serious medical problems within 6 months after getting GBS6 vaccine or 7 to 12 months after getting the GBS6 booster.

Stage 2

How many pregnant participants in Stage 2 had any serious medical problems during the study?

Figure 24 below shows how many pregnant participants in Stage 2 had serious medical problems during the study - from the time they joined the study until 1 year after they gave birth.

Figure 24. Number of pregnant participants in Stage 2 with serious medical problems from the time they joined the study until 1 year after giving birth

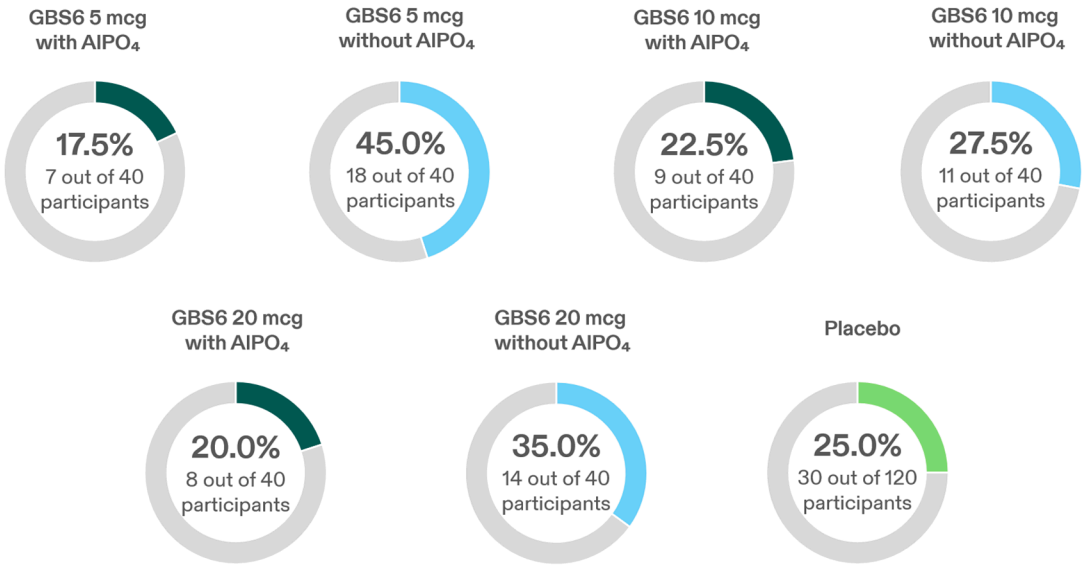


Table 4 below lists the most common serious medical problem among pregnant participants in Stage 2 – reported in more than 10 pregnant participants across all dose groups.

Table 4. Serious medical problems in pregnant participants in Stage 2

GBS6 5 mcg with $AlPO_4$ (40 Participants)	GBS6 5 mcg no $AlPO_4$ (40 Participants)	GBS6 10 mcg with $AlPO_4$ (40 Participants)	GBS6 10 mcg no $AlPO_4$ (40 Participants)	GBS6 20 mcg with $AlPO_4$ (40 Participants)	GBS6 20 mcg no $AlPO_4$ (40 Participants)	Placebo (120 Participants)
Fetal distress – signs that the fetus is not receiving enough oxygen						
4 out of 40 participants (10.0%)	7 out of 40 participants (17.5%)	3 out of 40 participants (7.5%)	9 out of 40 participants (22.5%)	4 out of 40 participants (10.0%)	6 out of 40 participants (15.0%)	11 out of 120 participants (9.2%)

How many infants born to participants in Stage 2 had any serious medical problems during the study?

Figure 25 below shows how many infants born to participants in Stage 2 had serious medical problems during the study – within 1 year of their birth, except for minor birth defects.

Figure 25. Number of infants born to participants in Stage 2 with serious medical problems within 1 year of their birth, except for minor birth defects

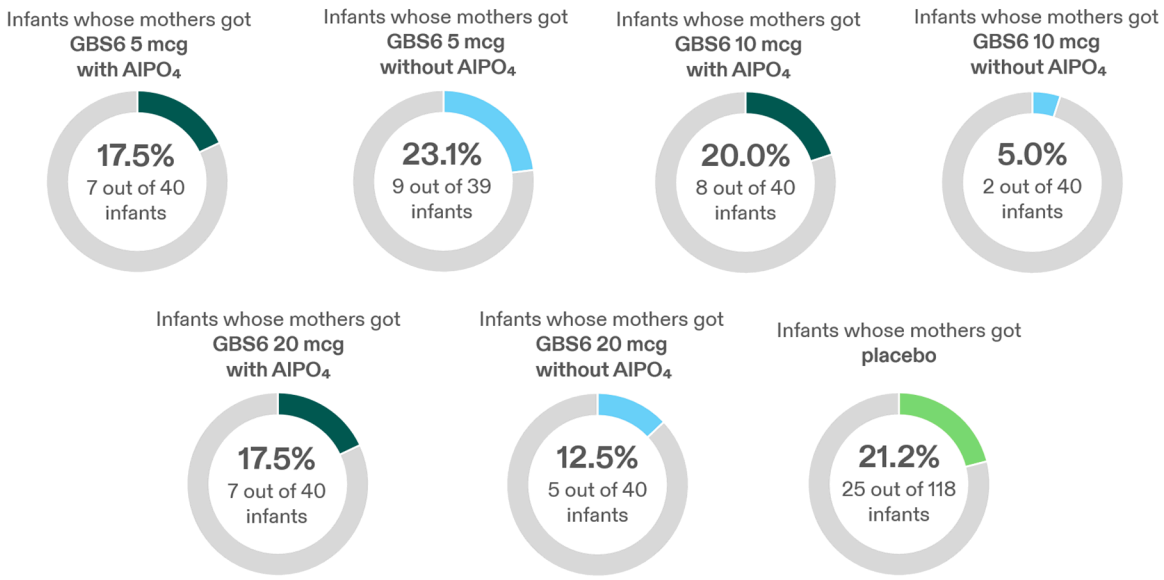


Table 5 below lists the most common serious medical problems among infant participants in Stage 2 – those reported in 10 or more infants born to participants overall.

Table 5. Serious medical problems in infant participants in Stage 2

GBS6 5 mcg with $AlPO_4$ (40 Participants)	GBS6 5 mcg no $AlPO_4$ (39 Participants)	GBS6 10 mcg with $AlPO_4$ (40 Participants)	GBS6 10 mcg no $AlPO_4$ (40 Participants)	GBS6 20 mcg with $AlPO_4$ (40 Participants)	GBS6 20 mcg no $AlPO_4$ (40 Participants)	Placebo (118 Participants)
Sepsis in newborn babies – a blood infection						
0	3 out of 39 participants (7.7%)	2 out of 40 participants (5.0%)	1 out of 40 participants (2.5%)	0	2 out of 40 participants (5.0%)	2 out of 118 participants (1.7%)
Jaundice in newborn babies – yellowing of the skin and whites of the eyes						
3 out of 40 participants (7.5%)	4 out of 39 participants (10.3%)	2 out of 40 participants (5.0%)	0	4 out of 40 participants (10.0%)	0	6 out of 118 participants (5.1%)

Stage 3

How many pregnant participants in Stage 3 had any serious medical problems during the study?

Figure 26 below shows how many pregnant participants in Stage 3 had serious medical problems during the study - from the time they joined the study until 1 year after they gave birth.

Figure 26. Number of pregnant participants in Stage 3 with serious medical problems from the time they joined the study until 1 year after giving birth

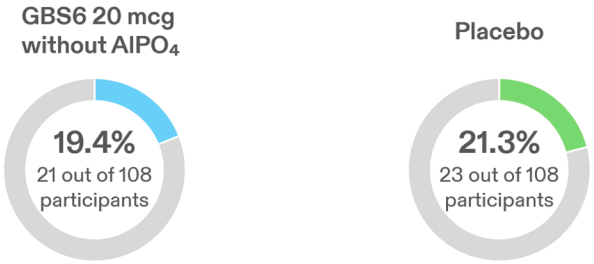


Table 6 below lists the most common serious medical problems among pregnant participants in Stage 3 – those reported in 5 or more pregnant participants.

Table 6. Serious medical problems in pregnant participants in Stage 3

	GBS6 20 mcg no $AlPO_4$ (108 Participants)	Placebo (108 Participants)
Fetal distress (signs that the fetus is not receiving enough oxygen)	9 out of 108 participants (8.3%)	14 out of 108 participants (13.0%)
High blood pressure during pregnancy	2 out of 108 participants (1.9%)	3 out of 108 participants (2.8%)

How many infants born to participants in Stage 3 had any serious medical problems during the study?

Figure 27 below shows how many infants born to participants in Stage 3 had serious medical problems during the study – within 1 year of their birth, except for minor birth defects.

Figure 27. Number of infants born to participants in Stage 3 with serious medical problems within 1 year of their birth, except for minor birth defects.

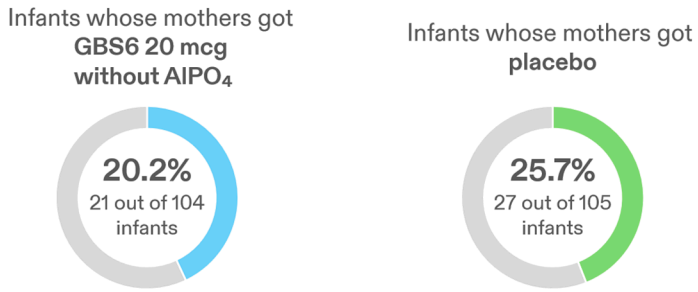


Table 7 below lists the most common serious medical problems among infant participants in Stage 3 – those reported in 5 or more infants born to participants.

Table 7. Serious medical problems in infants born to participants in Stage 3

	GBS6 20 mcg no $AlPO_4$ (104 Participants)	Placebo (105 Participants)
Sepsis in newborn babies – a blood infection	1 out of 104 participants (1.0%)	5 out of 108 participants (4.8%)
Low blood sugar in newborn babies	2 out of 104 participants (1.9%)	4 out of 108 participants (3.8%)
Breathing problems due to the lungs not being fully developed	3 out of 104 participants (2.9%)	2 out of 108 participants (1.9%)

Where can I learn more about this study?

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

For more details on your study protocol, please visit:

www.pfizer.com/research/research_clinical_trials/trial_results — Use the protocol number **C1091002**

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

www.clinicaltrials.gov — Use the study identifier **NCT03765073**

https://euclinicaltrials.eu — Use the study identifier **2020-005074-96**

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!

Pfizer