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:	Pfizer Inc.
Vaccine(s) Studied:	Influenza Modified RNA (modRNA) Vaccine
Protocol Number:	C4781001
Dates of Study:	13 September 2021 to 26 May 2023
Title of this Study:	Study on Use of a Modified RNA Vaccine for Influenza in Healthy Participants [Substudy A Final Report - A Phase 1/2 Randomized Study to Evaluate the Safety, Tolerability, and Immunogenicity of a Modified RNA Vaccine Against Influenza in Healthy Individuals.]
Date(s) of this Report:	11 January 2024

– Thank You –

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

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

Why was this study done?

What is influenza?

Influenza is also known as the flu. It is caused by a virus that infects the respiratory system. This includes the nose, throat, and lungs. Symptoms include runny or stuffy nose, sore throat, cough, headache, fever, chills, and muscle pain or body aches. Many people with influenza will have mild illness. Some people can become seriously ill and may die.

What is a vaccine?

A vaccine can help prevent an infection or a disease. It works by helping the body fight off germs. One of the ways to prevent influenza is to be vaccinated.

Antibodies are proteins that fight germs and infections to help prevent disease. After a person gets a vaccine, the body's response includes making antibodies. This is called an antibody response.

What is an influenza vaccine?

Hemagglutinin (HA) is a protein that is made by the influenza virus that is important for how the virus works. The influenza virus can mutate (change) the form of HA it makes. This means each year different strains (types) of the influenza virus may become widespread worldwide.

There are 2 main groups of influenza virus, Group A and Group B. Within these 2 main groups, there are lots of different types of the virus. The study vaccines contain ribonucleic acid (RNA) that is found in different Group A and/or Group B influenza viruses. RNA, or ribonucleic acid, is present in all living cells and it helps the cell make proteins. It is also present in some viruses where it carries genetic information rather than

deoxyribonucleic acid (DNA). DNA is used in human cells to carry genetic information.

Each year, the World Health Organization (WHO) tries to predict what influenza strains are likely to be most common that year. The vaccines are then made to target these or similar strains.

What vaccines were tested in this study?

In this study, the investigational influenza vaccines were administered to participants at the start of the study (Vaccination 1). Some participants received another dose 8 weeks later (Vaccination 2). Only a small number of participants opted to have Vaccination 2.

The investigational vaccines used in this study were:

- The monovalent influenza modRNA vaccines (mIRV) targets an A or a B strain
- The bivalent influenza modRNA vaccine (bIRV) targets an A and B strain
- The quadrivalent influenza modRNA vaccine (qIRV) targets 2 A and 2 B strains

These are all injectable study vaccines and not approved for use at the time of this study.

Some participants also received licensed quadrivalent influenza vaccine (QIV). The licensed QIV vaccine used in this study is approved by health authorities when 1 dose is administered. If 2 or more doses are given annually then this vaccine is also considered investigational.

What was the purpose of this study?

The main purpose of this study was to see if new types of influenza vaccine used in this study are safe in healthy participants aged 65 years and older.

Researchers wanted to know:

- **Did participants have any local reactions (any, redness, swelling, or pain at the injection site) within 7 days of being given the vaccines?**
- **Did participants have any systemic events (any, high temperature or fever, tiredness, headache, chills, vomiting, diarrhea, muscle pain, or joint pain), or require any medication for pain or a fever within 7 days of being given the vaccines?**
- **Did participants have any abnormal laboratory test results within 7 days of being given the vaccines?**
- **Did participants have any abnormal electrocardiogram (ECG) results that show abnormal electrical activity in the heart within 7 days of being given the vaccines?**
- **Did participants have any medical problems or serious medical problems after being given the vaccines?**

What happened during the study?

How was the study done?

There were 4 main vaccine groups in this study. Participants were assigned to a modRNA vaccine and QIV by chance alone. This a bit like flipping a coin.

At Vaccination 1, the researchers tested the following vaccines on groups of elderly participants:

- Different doses of mIRV A or B
- Different doses of bIRV
- qIRV
- Licensed QIV

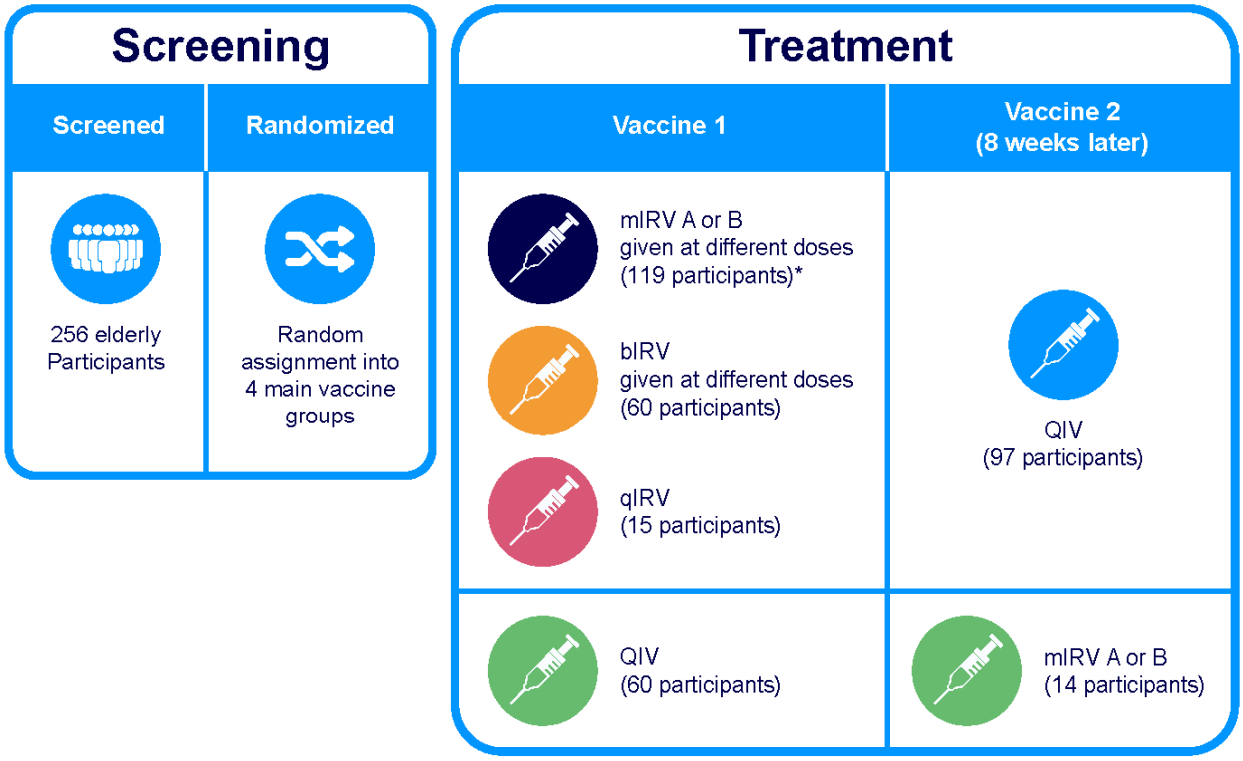
The participants and researchers did not know who took which vaccine at Vaccination 1. This first part of the study is known as the “blinded” phase.

At Vaccination 2, the participants and researchers knew what vaccines were given to each participant. This is known as an open label phase. This was because the vaccine given depended on the previous vaccine used:

- Participants who had previously been given any of the modRNA influenza vaccines were offered the licensed QIV.
- Participants who had previously been given QIV, were given mIRV A or B at a specific dose. This dose was one of the doses tested at Vaccination 1.

This is shown in Figure 1.

Figure 1: Study Design



*: While 121 participants were randomized to mIRV A or B, 2 participants did not receive the vaccine and therefore 119 participants were vaccinated.

At Vaccination 1 and Vaccination 2, participants were asked to record details of any local reactions or systemic events they had in an electronic study diary they were given. They were also asked if they had taken any medication for fever or pain. This information was collected for 7 days after each vaccination.

To look at the safety and tolerability of the vaccines, the researchers looked at whether there were any "local" reactions to the vaccine. A local reaction is something that is seen at the site where the injection of the vaccine was given and can include pain at the injection site, swelling, and/or redness. The researchers also looked at whether there were any "systemic events"

or reactions to the vaccine. Systemic means something that affects the whole body or specific parts of it like the head or joints. Systemic events were reactions that participants may have had after they had been given the vaccine. This included having a fever or high temperature, tiredness, headache, vomiting, diarrhea, chills, new or worsening muscle pain, and new or worsening joint pain.

The researchers also collected blood samples from participants for testing. They also rans some electrocardiogram (ECG) tests. An ECG machine looks at the electrical activity in the heart. The researchers also asked participants about their health and how they were feeling.

Researchers then compared the results of participants in each vaccine group. The researchers did this to learn how the vaccines acted in the body.

Where did this study take place?

The Sponsor ran this study at 20 locations in the United States (US).

When did this study take place?

It began 13 September 2021 and ended 26 May 2023.

Who participated in this study?

The study included healthy participants who were aged 65 years or older.

For Vaccination 1:

- A total of 117 men participated
- A total of 137 women participated
- All participants were between the ages of 65 and 85 years

For Vaccination 2:

- A total of 58 men participated
- A total of 53 women participated
- All participants were between the ages of 65 and 81 years

Of the 256 participants who started the study, 254 received Vaccination 1. Fewer than half of the participants in most groups opted to receive Vaccination 2. This meant there were 111 participants who received Vaccination 2. Few participants left the study after either Vaccination 1 or Vaccination 2. Reasons for leaving the study were because they no longer wanted to continue in the study or a doctor thought this was best for the participant.

How long did the study last?

Study participants were in the study for about 8 months. The entire study took over 20 months to complete.

When the study ended in May 2023, 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?

What was the safety and tolerability of the vaccines?

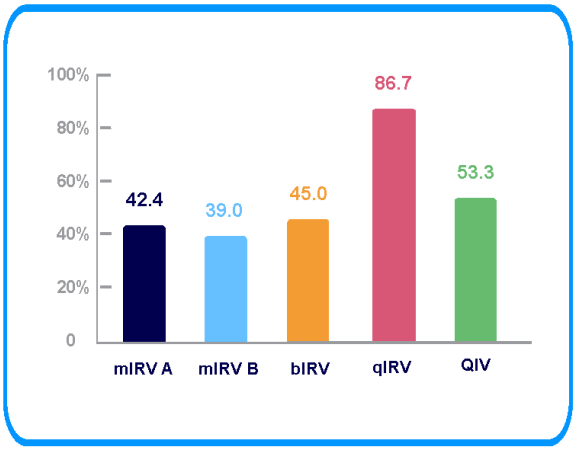
Not all participants who were vaccinated completed the study diary. This meant that safety information on local reactions and systemic events was not available for some participants.

The researchers also asked participants about any medical problems they had after the vaccinations. Medical problems are discussed in the next section of this document.

Did participants given the vaccines have any local reactions within 7 days of the vaccinations?

- The percentage of participants who reported any local reactions within 7 days of the vaccines given in Vaccination 1 are shown in Figure 2. Local reactions were pain at the injection site, swelling, and/or redness.

Figure 2: Percentage of Participants With Any Local Reactions within 7 days of Vaccination 1

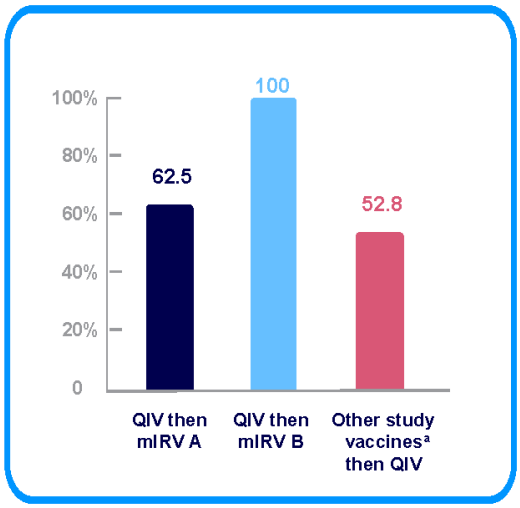


  - Of the 3 types of local reaction, pain at the injection site was the most common local reaction in any vaccination group. It was reported by most participants who had a local reaction. Few participants reported redness or swelling after Vaccination 1.

- For Vaccination 2, data on local reactions were limited and available for 47 participants.

- Results are shown in Figure 3, but caution is needed in interpreting the results due to low numbers of participants.

Figure 3: Percentage of Participants With Any Local Reactions within 7 days of Vaccination 2



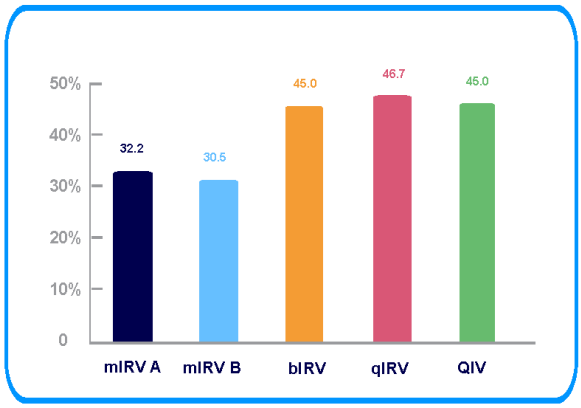
a: Other study vaccines were mIRV B, bIRV, and qIRV

- Of the 3 types of local reaction, pain at the injection site was the most common local reaction in any vaccination group. It was reported by most participants who had a local reaction. Few participants reported redness after Vaccination 2 and even fewer participants reported swelling.

Did participants given the vaccines have any systemic events within 7 days of the vaccinations?

- Participants who reported any systemic events within 7 days of Vaccination 1 are shown in Figure 4. Systemic events were high temperature or fever, tiredness, headache, chills, vomiting, diarrhea, muscle pain, or joint pain, or the requirement for any medication for pain or a fever.

Figure 4: Percentage of Participants With Any Systemic Events within 7 days of Vaccination 1

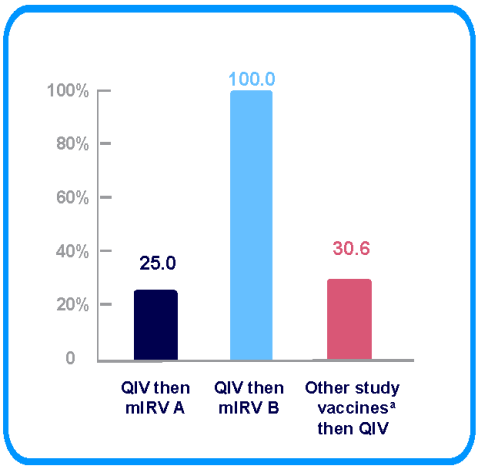


Of the different types of systemic event, tiredness was the most common systemic event in any vaccination group. It was reported by almost a third of participants who had a systemic event. After tiredness, headache was the next most common systemic reaction. Few participants reported vomiting, diarrhea, chills, muscle pain, or joint pain. There were few participants who took medication for pain or fever.

- For vaccination 2, data on systemic events were limited and available for 47 participants.

- Results are shown in Figure 5, but caution is needed in interpreting the results due to low numbers of participants.

Figure 5: Percentage of Participants With Any Systemic Events within 7 days of Vaccination 2



a: Other study vaccines were mIRV B, bIRV, and qIRV.

- Of the different types of systemic event, tiredness was the most common systemic event in any vaccination group. It was reported by a third of participants who had a systemic event. After tiredness, headache was the next most common systemic event. Less than a fifth of participants took medication for pain or fever.

Did participants given the vaccines have any abnormal laboratory test results within 7 days of Vaccination 1?

- Changes in laboratory test results after vaccination were minimal.
- There were 2 participants with a change in one of their laboratory test results considered severe.
- None of the changes in laboratory test results caused any symptoms or required a visit to a doctor or hospital.

Did participants given the vaccines have any abnormal ECG results that showed abnormal electrical activity in the heart within 7 days of Vaccination 1?

- There were no new abnormal ECG findings seen in participants after receiving vaccinations in this study.

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 treatment 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 medication might have on a participant.

A total of 50 out of 254 (19.7%) participants in this study had at least 1 medical problem. There were no participants who left the study because of medical problems.

The most common medical problems – those reported by more than 1 participant 1 to 4 weeks after Vaccination 1 – are described below. All reported medical problems were similar to those that might be expected in participants aged 65 years and over.

Below are instructions on how to read Table 1. These instructions can also be used for Table 2.

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 by more than 1 participant are listed.
- The **2nd** column tells how many of the 59 participants given mIRV A reported each medical problem. Next to this number is

the percentage of the 59 participants who reported the medical problem.

- The **3rd** column tells how many of the 60 participants given mIRV B reported each medical problem. Next to this number is the percentage of the 60 participants who reported the medical problem.
- The **4th** column tells how many of the 60 participants given bIRV reported each medical problem. Next to this number is the percentage of the 60 participants who reported the medical problem.
- The **5th** column tells how many of the 15 participants given qIRV reported each medical problem. Next to this number is the percentage of the 15 participants who reported the medical problem.
- The **6th** column tells how many of the 60 participants given QIV reported each medical problem. Next to this number is the percentage of the 60 participants who reported the medical problem.
- Using these instructions, you can see that 0 out of the 59 participants given mIRV A reported low iron in blood. A total of 2 out of 60 participants (3.3%) given mIRV B reported low iron in blood. There were 3 out of 60 participants (5.0%) given bIRV who reported low iron in blood and 1 out of 15 participants (6.7%) given qIRV who reported low iron. There were 0 out of 60 participants given QIV who reported low iron in blood.

Table 1. Commonly reported medical problems by study participants 1 to 4 weeks after Vaccination 1

Medical Problem	mIRV A (59 Pts)	mIRV B (60 Pts)	bIRV (60 Pts)	qIRV (15 Pts)	QIV (60 Pts)
Low iron in blood	0	2 out of 60 pts (3.3%)	3 out of 60 pts (5.0%)	1 out of 15 pts (6.7%)	0
Increased inflammation (CRP)	0	2 out of 60 pts (3.3%)	3 out of 60 pts (5.0%)	0	0
Stomach acid irritating the food pipe lining (GERD)	0	0	1 out of 60 pts (1.7%)	0	2 out of 60 pts (3.3%)
Nausea	0	2 out of 60 pts (3.3%)	0	0	0
Fall	0	2 out of 60 pts (3.3%)	1 out of 60 pts (1.7%)	0	0

bIRV = bivalent influenza modRNA vaccine; CRP = C-reactive protein; GERD = gastro-esophageal reflux disease; mIRV = monovalent influenza modRNA vaccine; modRNA = modified RNA; pts = participant(s); qIRV = quadrivalent influenza modRNA vaccine; QIV = quadrivalent influenza vaccine

Fewer than half of the participants (111 out of 254 participants, 43.7%) received Vaccination 2. The most common medical problems – those reported by more than 1 participant 2 to 4 weeks after Vaccination 2 – are described in Table 2.

All reported medical problems were expected in participants aged 65 years and over.

Table 2. Commonly reported medical problems by study participants 2 to 4 weeks after Vaccination 2

Medical Problem	mIRV A then QIV (37 Pts)	mIRV B then QIV (21 Pts)	bIRV then QIV (32 Pts)	qIRV then QIV (7 Pts)	QIV then mIRV A (11 Pts)	QIV then mIRV B (3 Pts)
Possible or suspected COVID-19	0	0	2 out of 32 pts (6.3%)	0	0	0
Positive COVID-19 test	1 out of 37 pts (2.7%)	0	2 out of 32 pts (6.3%)	0	0	0

bIRV = bivalent influenza modRNA vaccine; COVID-19: coronavirus 2019 pandemic; mIRV = monovalent influenza modRNA vaccine; modRNA = modified RNA; pts = participant(s); qIRV = quadrivalent influenza modRNA vaccine; QIV = quadrivalent influenza vaccine

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.

A total of 4 participants (1.6%, or 4 out of 254 participants) had serious medical problems during the study. These events were:

- 1 participant in the mIRV B group fractured their hip after Vaccination 1
- 1 participant in the bIRV group fractured a rib after Vaccination 1
- 1 participant in the QIV group felt suicidal after Vaccination 1
- 1 participant in the qIRV group had a very bad cold sore and needed hospital care after Vaccination 2

Researchers did not believe any of the serious medical problems reported by participants were related to study medications.

There were no participants who died during the study.

Where can I learn more about this study?

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

For more details on your study protocol, please visit:

www.pfizer.com/research/research_clinical_trials/trial_results	Use the protocol number C4781001

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

www.clinicaltrials.gov	Use the study identifier **NCT05052697**

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

Again, if you participated in this study, **thank you** for volunteering. We do research to try to find the best ways to help patients, and you helped us to do that!

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 medication 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(s) Studied: Influenza Modified RNA (modRNA) Vaccine

Protocol Number: C4781001

Dates of Study: 14 February 2022 to 27 January 2023

Title of this Study: Study on Use of a Modified RNA Vaccine for Influenza in Healthy Participants

[Substudy B Final Report - A Phase 1/2 Randomized Study to Evaluate the Safety, Tolerability, and Immunogenicity of a Modified RNA Vaccine Against Influenza in Healthy Individuals]

Date(s) of this Report: 23 January 2024

– Thank You –

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

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

Why was this study done?

What is influenza?

Influenza is also known as the flu. It is caused by a virus that infects the respiratory system. This includes the nose, throat, and lungs. Symptoms include runny or stuffy nose, sore throat, cough, headache, fever, chills, and muscle pain or body aches. Many people with influenza will have mild illness. Some people can become seriously ill and may die.

What is a vaccine?

A vaccine can help prevent an infection or a disease. It works by helping the body fight off germs. One of the ways to potentially help prevent influenza is to be vaccinated.

Antibodies are proteins that fight germs and infections to help prevent disease. After a person gets a vaccine, the body's response includes making antibodies. This is called an antibody response.

What is an influenza vaccine?

Hemagglutinin (HA) is a protein that is made by the influenza virus that is important for how the virus works. The influenza virus can mutate (change) the form of HA it makes. This means each year different strains (types) of the influenza virus may become widespread worldwide.

There are 4 types of influenza viruses, types A, B, C, and D. Influenza A and B viruses cause seasonal epidemics of disease in humans. Within these 2 main types, there are lots of different varieties of the virus. The study vaccines contain ribonucleic acid (RNA) that is found in different type A and/or B influenza viruses. RNA is present in all living cells and it helps the cell make proteins. It is also present in some viruses where it carries

genetic information rather than deoxyribonucleic acid (DNA). DNA is used in human cells to carry genetic information.

Each year, the World Health Organization (WHO) tries to predict what influenza types are likely to be most common that year. The vaccines are then made to target these or similar types.

What vaccines were tested in this study?

Investigational influenza vaccines were administered to participants at the start of the study (Vaccination 1). Some participants received another dose 21 days later (Vaccination 2). Other participants were only due to receive 1 dose of the vaccine, or 2 doses at the same time.

The investigational vaccines used in this study were:

- The 4-part (quadrivalent) influenza modRNA vaccine (qIRV) that targets 2 type A and 2 type B
- The 2-part (bivalent) influenza modRNA vaccine (bIRV A) that targets type A only
- The 2-part (bivalent) influenza modRNA vaccine (bIRV B) that targets type B only

These are all injectable study vaccines and were not approved for use at the time of this study.

Some participants also received licensed 4-part (quadrivalent) influenza vaccine (QIV). The licensed QIV vaccine used in this study is approved by health authorities when 1 dose is administered. If 2 or more doses are given annually then this vaccine is also considered investigational.

What was the purpose of this study?

The main purpose of this study was to see if new types of influenza vaccine used in this study were safe and well tolerated in healthy participants.

Researchers wanted to know:

- **Did participants have any local reactions (any redness, swelling, or pain at the injection site) within 7 days of being given the vaccines?**
- **Did participants have any systemic events (any high temperature or fever, tiredness, headache, chills, vomiting, loose stools, new or worsening muscle pain, or new or worsening joint pain), or require any medication for pain or a fever within 7 days of being given the vaccines?**
- **Did participants have any abnormal laboratory test results within 2 days of being given the last vaccination?**
- **Did participants have any abnormal electrocardiogram (ECG) results that showed abnormal electrical activity in the heart within 2 days of being given the last vaccination?**
- **Did participants have any medical problems or serious medical problems after being given the vaccines?**

What happened during the study?

How was the study done?

There were 2 parts in this study. Part 1 was an initial enrollment where participants were able to join the study and were vaccinated. Part 2 was an

expanded enrollment where more participants joined the study and were vaccinated. Part 1 included participants who were 65 to 85 years old. Part 2 included participants who were 65 to 85 years old and also participants who were 18 to 64 years old.

There were 17 different vaccine groups in this study. Not all groups were enrolled at the same time. Participants were enrolled in the initial enrollment and then more participants were enrolled in the expanded enrollment period. Participants 18 to 64 years of age were only enrolled in the expanded period. Even within these periods, different vaccine groups were enrolled over different time points.

Below is the summary of the vaccine groups enrolled in the initial and expanded enrollment periods by age group.

Initial enrollment – 2 vaccine doses
This included Part 1 participants aged 65 to 85 years who received 2 vaccine doses separated by 21 days. The following vaccines were tested:

- qIRV (dose level 1) – 2 doses given 21 days apart
- QIV then bIRV A (dose level combination 1) 21 days later
- QIV then bIRV A (dose level combination 2) 21 days later
- QIV – 2 doses given 21 days apart.

Initial enrollment – 1 vaccine dose or 2 vaccines at the same time

This included Part 1 participants aged 65 to 85 years who received 1 dose of the vaccine, or 2 doses at the same time. The following vaccines were tested:

- QIV then bIRV A (dose level combination 1) in the opposite arm

- QIV then bIRV A (dose level combination 2) in the opposite arm
- qIRV (dose level 2, dose combination 1)
- QIV
- bIRV A (dose level combination 1) then bIRV B (dose level combination 1) in the opposite arm
- qIRV (dose level 2, dose combination 2)
- qIRV (dose level 3)

Expanded enrollment – 65 to 85 years old

This included Part 2 participants who were 65 to 85 years old. The researchers tested the following vaccines:

- qIRV (dose level 1)
- qIRV (dose level 2, dose combination 1)
- QIV
- qIRV (dose level 1) – 2 doses given 21 days apart.

Expanded enrollment – 18 to 64 years old

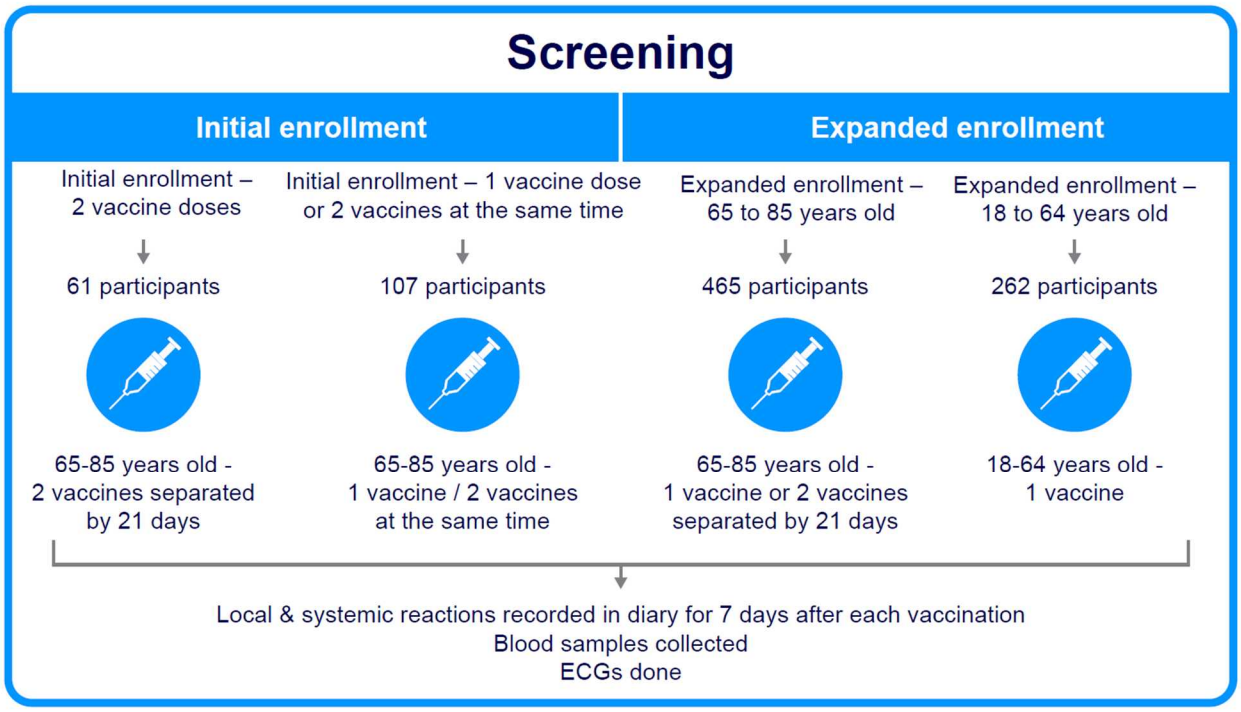
This period included Part 2 participants who were 18 to 64 years old. The researchers tested the following vaccines:

- qIRV (dose level 1)
- qIRV (dose level 2)

The study participants did not know which vaccine they were given, but the researchers knew who was given each vaccine. This is known as a "single-blinded" study. Study participants were assigned to a vaccine

group within each enrollment period by chance alone. The design of the study is shown in Figure 1.

Figure 1: Study Design



Participants were asked to record details of any problems they experienced after Vaccination 1 and Vaccination 2 (if they had a Vaccination 2). They were also asked if they had taken any medication for fever or pain. This information was collected for 7 days after each vaccination.

To look at the safety and tolerability of the vaccines, the researchers looked at whether there were any “local” reactions to the vaccine. A local reaction is something that is seen at the site where the injection of the vaccine was given and can include pain at the injection site, swelling, and/or redness. The researchers also looked at whether there were any “systemic events” or reactions to the vaccine. Systemic means something that affects the whole body or specific parts of it like the head or joints. Systemic events

were reactions that participants may have had after they had been given the vaccine. These could have included having a fever or high temperature, tiredness, headache, vomiting, loose stools, chills, new or worsening muscle pain, and new or worsening joint pain.

The researchers collected blood samples from participants for testing. They also ran some electrocardiogram (ECG) tests. An ECG test looks at the electrical activity in the heart. Blood sample collection and ECGs were done 2 days after vaccination. The researchers also asked participants about their health and how they were feeling.

Researchers then compared the results of participants in each vaccine group. The researchers did this to learn how the vaccines acted in the body.

Where did this study take place?

The Sponsor ran this study at 49 locations in the United States (US).

When did this study take place?

It began 14 February 2022 and ended 27 January 2023.

Who participated in this study?

In total for this study, 902 healthy participants were enrolled and 895 participants received at least one vaccine.

- A total of 403 men participated and received a vaccine
- A total of 492 women participated and received a vaccine
- All participants were between the ages of 18 and 85 years

Of the 895 participants who received at least one vaccine, 51 participants left the study before the study was finished.

Reasons for leaving the study were because the participant no longer wanted to continue in the study, a doctor thought this was best for the participant, the participant refused further study procedures, were lost to follow-up, or “other” reason.

How long did the study last?

Study participants were in the study for approximately 8 months. The entire study took around 11 months to complete. During the study, there was a pause for a safety check when a participant had an abnormal test result. When researchers were satisfied that it was safe to continue, the study resumed.

When the study ended in January 2023, 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?

What was the safety and tolerability of the vaccines?

Not all participants who were vaccinated completed the study diary. This meant that safety information on local reactions and systemic events was not available for some participants.

The researchers also asked participants about any medical problems they had after the vaccinations. Medical problems are discussed in the next section of this document.

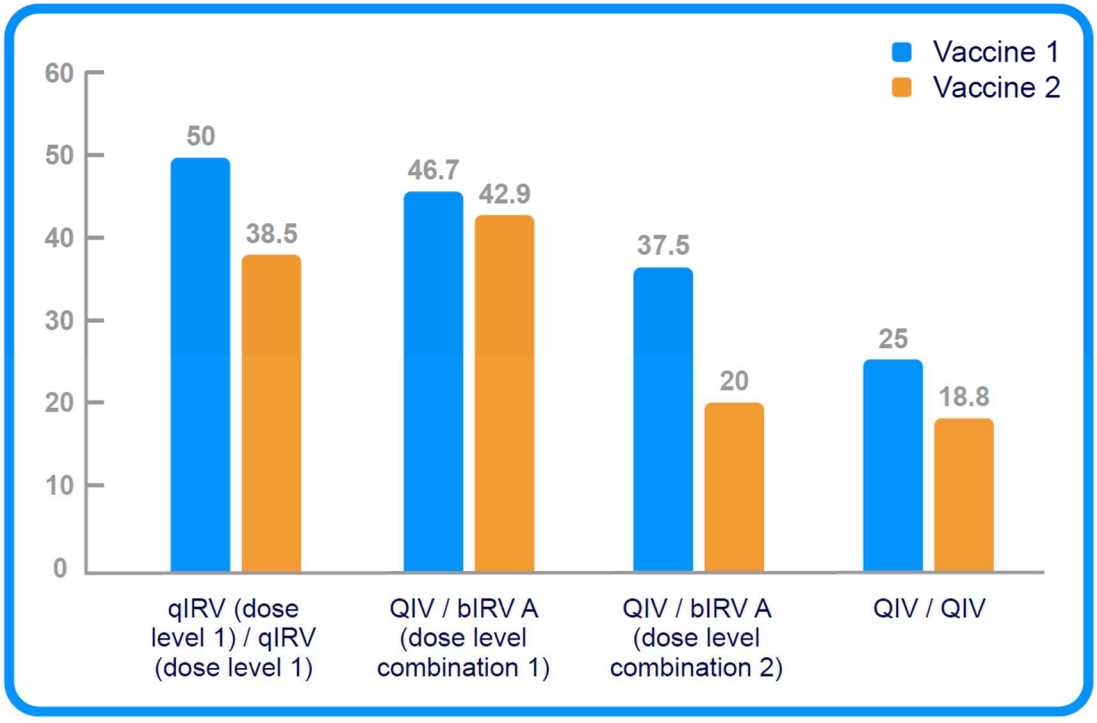
Did participants have any local reactions within 7 days of being given the vaccines?

A local reaction was pain at the injection site, swelling, and/or redness.

Initial enrollment – 2 vaccine doses

- The percentage of participants who reported any local reactions within 7 days of each vaccination are shown in Figure 2.

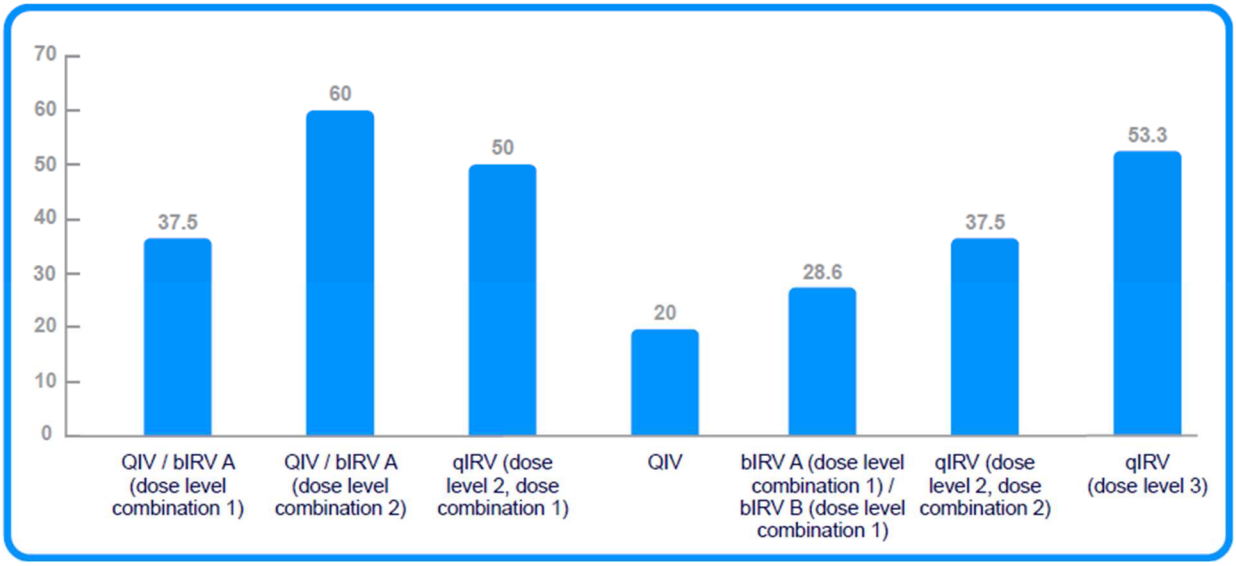
Figure 2: Percentage of Participants in Initial Enrollment – 2 Vaccine Doses With Any Local Reactions Within 7 Days of Each Vaccination



Initial enrollment – 1 vaccine dose or 2 vaccines at the same time

- The percentage of participants who reported any local reactions within 7 days of vaccination are shown in Figure 3.

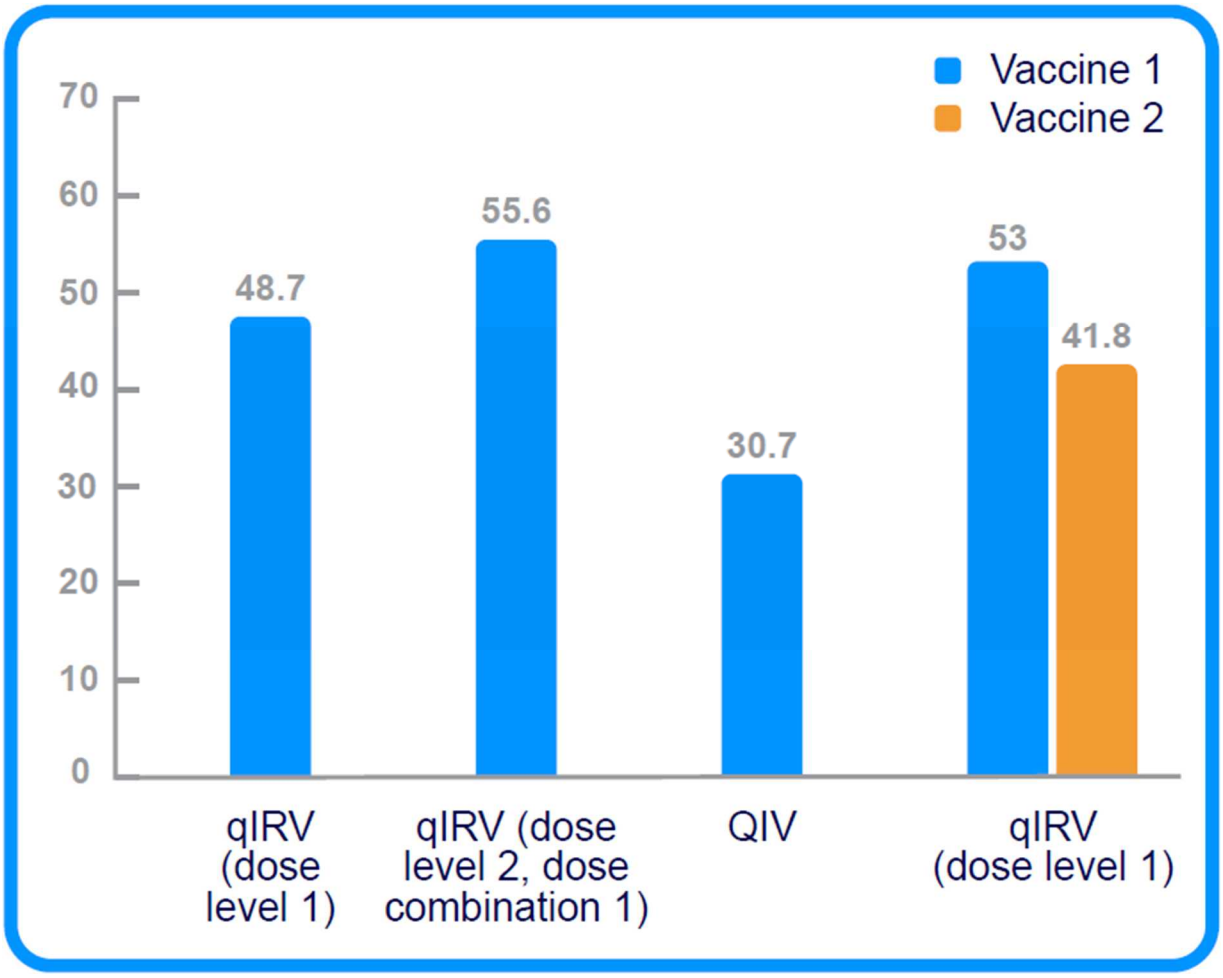
Figure 3: Percentage of Participants in Initial Enrollment – 1 Vaccine Dose or 2 Vaccines at the Same Time With Any Local Reactions Within 7 Days of Vaccination



Expanded enrollment – 65 to 85 years old

- The percentage of participants who reported any local reactions within 7 days of each vaccination are shown in Figure 4.

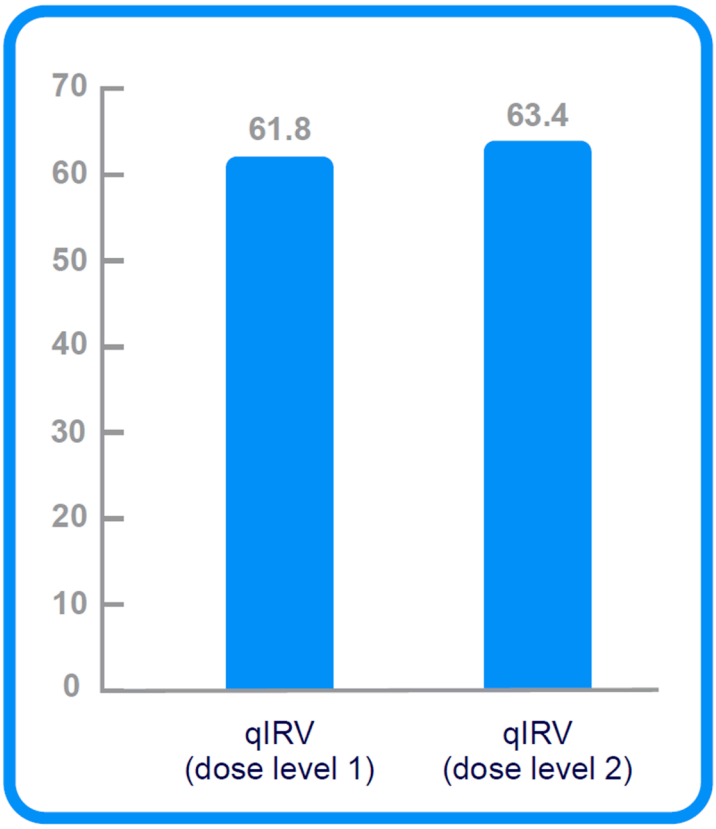
Figure 4: Percentage of Participants in Expanded Enrollment – 65 to 85 Years Old With Any Local Reactions Within 7 Days of Each Vaccination



Expanded enrollment – 18 to 64 years old

- The percentage of participant who reported any local reactions within 7 days of each vaccination are shown in Figure 5.

Figure 5: Percentage of Participants in Expanded Enrollment – 18 to 64 Years Old With Any Local Reactions Within 7 Days of Each Vaccination



In both the initial and expanded enrollment periods, pain at the injection site was the most common local reaction in any vaccination group. It was reported by most participants who had a local reaction. Few participants reported redness or swelling after vaccinations.

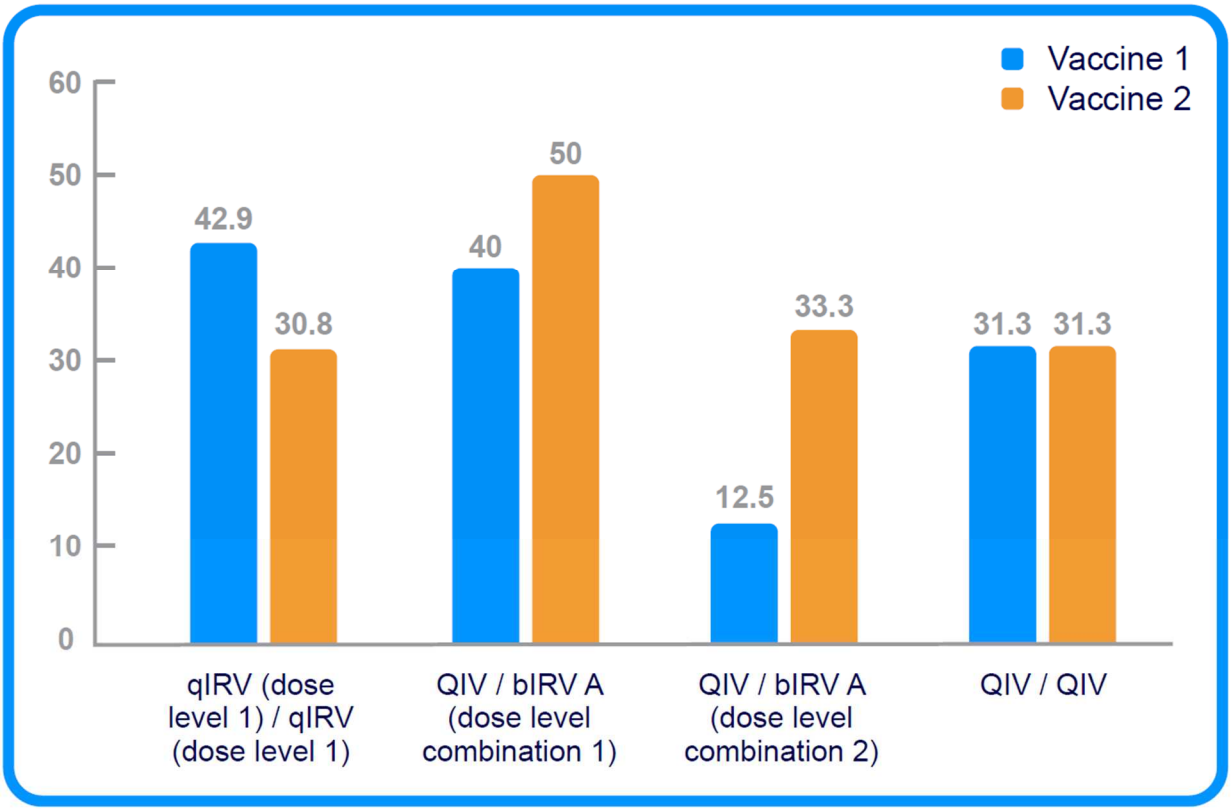
Did participants given the vaccines have any systemic events within 7 days of being given the vaccines?

Systemic events were fever or high temperature, tiredness, headache, vomiting, loose stools, chills, new or worsening muscle pain, or new or worsening joint pain.

Initial enrollment – 2 vaccine doses

- The percentage of participants who reported any systemic events within 7 days of each vaccination are shown in Figure 6.

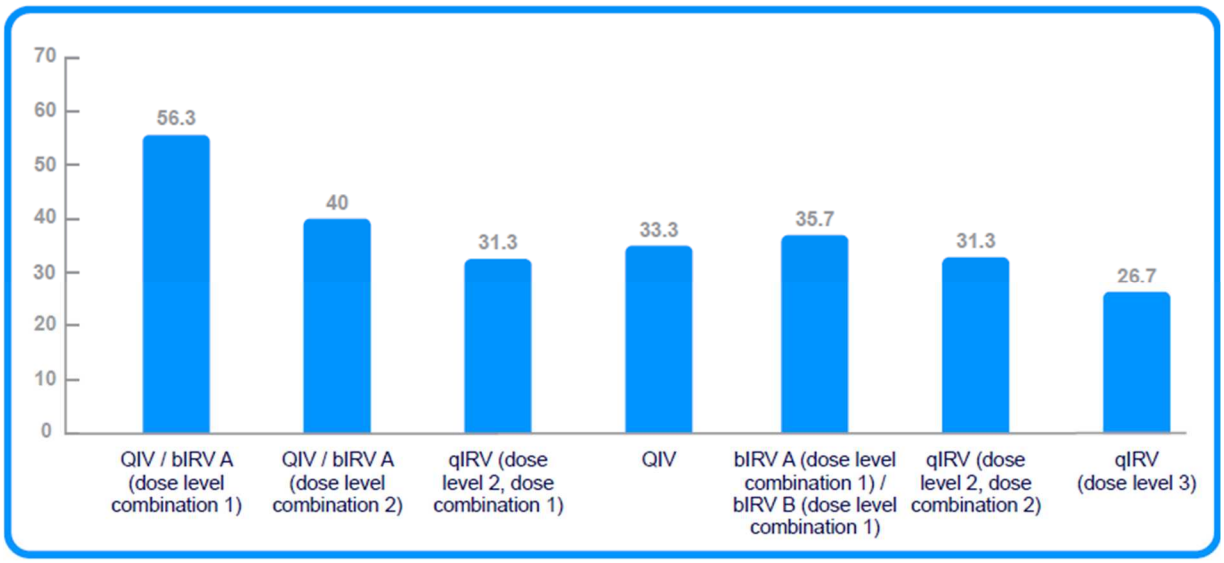
Figure 6: Percentage of Participants in Initial Enrollment – 2 Vaccine Doses With Any Systemic Events Within 7 Days of Each Vaccination



Initial enrollment – 1 vaccine dose or 2 vaccines at the same time

- The percentage of participants who reported any systemic events within 7 days of vaccination are shown in Figure 7.

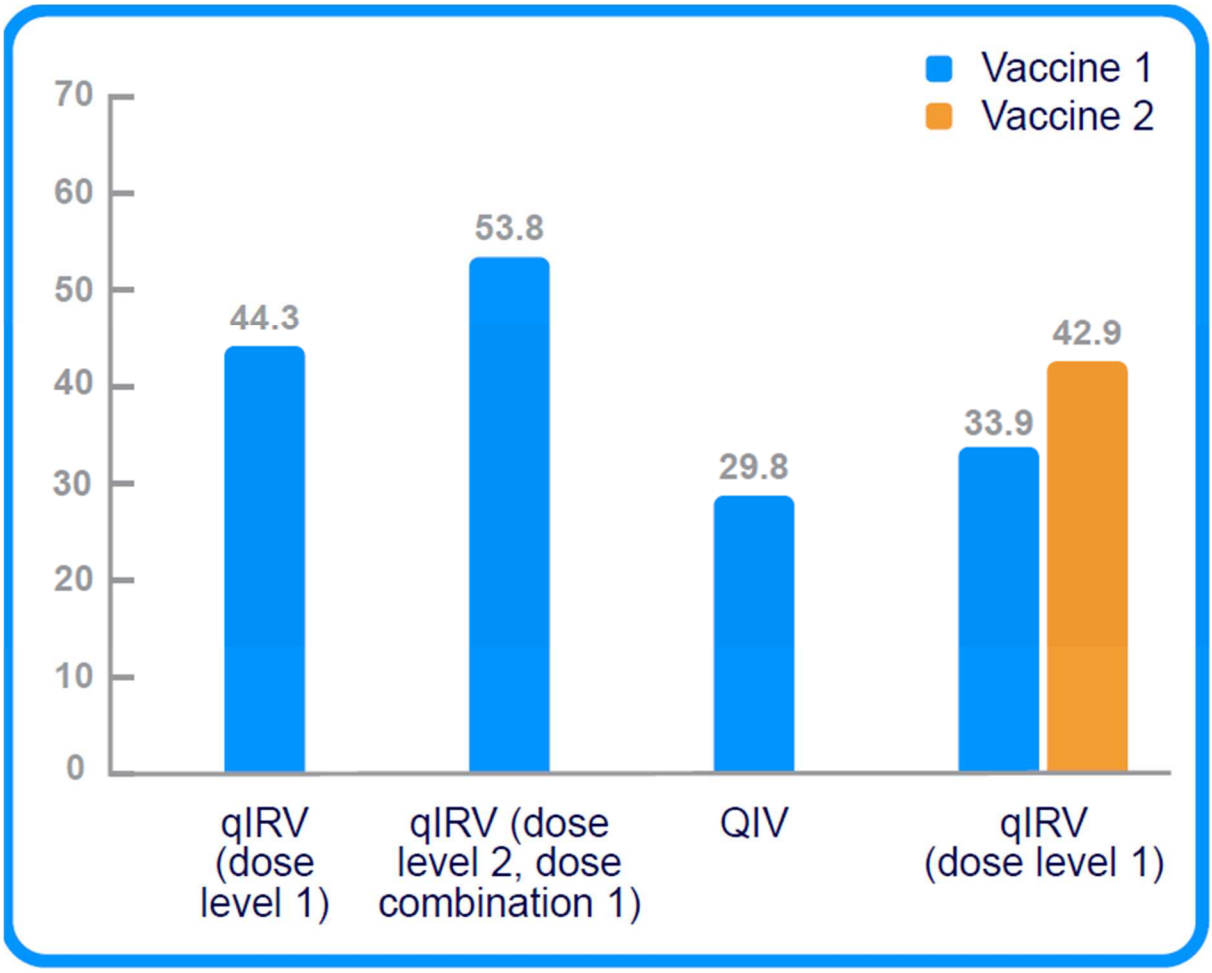
Figure 7: Percentage of Participants in Initial Enrollment – 1 Vaccine Dose or 2 Vaccines at the Same Time With Any Systemic Events Within 7 Days of Vaccination



Expanded enrollment – 65 to 85 years old

- The percentage of participants who reported any systemic events within 7 days of each vaccination are shown in Figure 8.

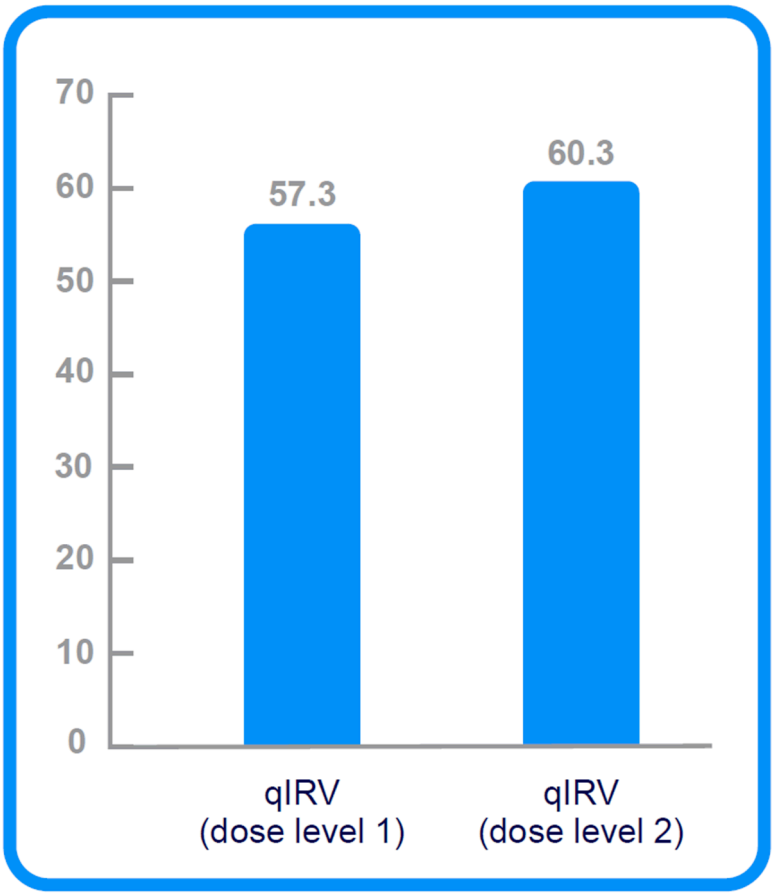
Figure 8: Percentage of Participants Expanded Enrollment – 65 to 85 Years Old With Any Systemic Events Within 7 Days of Each Vaccination



Expanded enrollment – 18 to 64 years old

- The percentage of participants who reported any systemic events within 7 days of vaccination are shown in Figure 9.

Figure 9: Percentage of Participants in Expanded Enrollment – 18 to 64 Years Old With Any Systemic Events Within 7 Days of Vaccination



In both the initial and expanded enrollment periods, tiredness was the most common systemic event in any vaccination group. After tiredness, headache was the next most common systemic reaction. Few participants reported fever or high temperature, vomiting, loose stools, chills, new or worsening muscle pain, or new or worsening joint pain. There were few participants who took medication for pain or fever.

Did participants given the vaccines have any abnormal laboratory test results within 2 days of receiving the last vaccine?

- Changes in laboratory test results after vaccination were minimal.
- None of the changes in laboratory test results caused any symptoms or required a visit to a doctor or hospital.

Did participants given the vaccines have any abnormal ECG results that showed abnormal electrical activity in the heart within 2 days of receiving the last vaccine?

- There were no new abnormal ECG findings seen in participants vaccinated during the initial enrollment or in participants aged 18 to 64 years after receiving the study vaccines.
- One (1) participant in the 65 to 85 year old group in expanded enrollment had an abnormal ECG finding. The participant had received qIRV (dose level 2, dose combination 1). A safety check was carried out for the study and researchers decided it was safe for the study to continue.

This does not mean that everyone in this study had these results. This is a summary of just some of the main results of this study. Other studies may have different results.

What medical problems did participants have during the study?

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

Fifty-four (54) of 895 (6%) vaccinated participants in this study had at least 1 medical problem. No participants left the study because of medical problems.

No medical problems were experienced by more than 1 participant in the initial enrollment or in participants aged 18 to 64 years.

Medical problems experienced by more than 1 participant in the 65 to 85 year old group in the expanded enrollment were:

- loose stools (2 participants who received the qIRV vaccine)
- positive COVID-19 test (4 participants who received the qIRV vaccine and 2 participants who received the QIV vaccine)
- fall (2 participants who received the qIRV vaccine).
- injection site pruritus (2 participants who received the qIRV vaccine)

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.

Four participants (0.5%, or 4 out of 895 participants) had serious medical problems.

- One (1) participant in the initial enrollment who had 2 vaccines at the same time. This participant received the QIV vaccine and the bIRV A vaccine and reported gallstones.
- One (1) participant who was in the 65 to 85 year olds in the expanded enrollment received the qIRV vaccine reported swelling and pain in both knees.
- One (1) participant who was in the 18 to 64 year old group in the expanded enrollment and received the qIRV vaccine reported infection of the lungs (pneumonia), blood poisoning (sepsis), and a viral infection.
- One (1) participant who was in the 18 to 64 year old group in the expanded enrollment and received the qIRV vaccine reported hip fracture.

Researchers believed that these serious medical problems were not related to the study vaccines.

No participants died during the study.

Where can I learn more about this study?

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

For more details on your study protocol, please visit:

www.pfizer.com/research/ research_clinical_trials/trial_results	Use the protocol number **C4781001**

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

www.clinicaltrials.gov	Use the study identifier **NCT05052697**

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

Again, if you participated in this study, **thank you** for volunteering. We do research to try to find the best ways to help patients, and you helped us to do that!