Summary of Clinical Study Results

This study summary is an overview of the study results. It's intended to help the people who took part in the study understand the results. This study summary:

- Does not replace your healthcare professional's advice;
- Is not a recommendation of how to use the studied medicine*;
- Is not prescribing advice; and
- Does not mean that the studied medicine, or the studied use of the medicine, has been shown to be safe or to work.

You should always talk to a healthcare professional about any treatment decisions. If you participated in this study and have questions about it or the study results, please speak with the study staff.

This study may include treatment plans, medicines, or uses of medicines that have not been approved by your government health authority. The information in this study summary:

- Is from this study only;
- May be different from information in other studies; and
- Does not reflect all information about the studied medicine.

Different studies may be designed to look at different questions or may reach different results. Researchers must look at results from many types of studies to understand if a studied medicine works for a specific use and to learn about its safety.

When a government health agency approves a new medicine, or a new use of a medicine, this is described in the medicine's approved labeling. If the medicine or use explored in this study gets approved, information from this study may or may not be included in the medicine's approved labeling. Check with your healthcare professional, your country's health agency, or your country's MSD office for any approved labeling for this medicine in your country.

*In this statement, the word "medicine" includes drugs, vaccines or other preventative agents.

Thank you!

Thank you to those who took part in this study and to their families and caregivers. You helped researchers learn more about V116.

Summary of Clinical Study Results

A clinical study of V116 in adults 50 years of age and older who had pneumococcal vaccine before (V116-006)

What is a clinical study?

A clinical study is a type of research designed to learn more about how the body responds to medicines, vaccines, or other treatments.

Researchers look at the results of many clinical studies to understand which treatments work and how they work. It takes lots of people in many clinical studies all around the world to advance medical science. This summary only shows the results from this one clinical study. Other clinical studies may show different results.

What were the goals of this clinical study?

Researchers wanted to learn about the safety of a study vaccine called V116 and if it works to make an immune response in adults 50 years of age and older who have had a pneumococcal vaccine before. **Immune response** is the body's response to infections and illnesses by making **antibodies** (proteins) that fight against germs.

V116 is a study vaccine designed to help prevent **invasive pneumococcal disease** (**IPD**) and **pneumonia**. IPD is a group of infections caused by pneumococcal bacteria (germs). There are many different types of pneumococcal bacteria, called **serotypes**. The V116 vaccine contains small parts of 21 serotypes. These parts are not live bacteria and will not cause an infection, but will help the body make antibodies to fight those serotypes.

The main goals of this study were to learn:

- If V116 works to make an immune response in adults aged 50 and older who previously received a pneumococcal vaccine
- If it is safe to give V116 to adults 50 years of age and older who previously received a pneumococcal vaccine and if they tolerate V116

What kind of clinical study was this?

This was a randomized, phase 3 study with 3 groups. Groups 1 and 2 were double-blind. Group 3 was open-label:

- **Randomized** means that researchers assigned people by chance to a treatment group
- A **phase 3** study learns about a study treatment in a large number of people
- **Double-blind** means neither the people in the study nor the researchers knew which treatment a person received
- **Open-label** means both the people in the study and the researchers knew which study treatment a person received

When did this clinical study start and end?

This study started in July 2022 and ended in May 2023.

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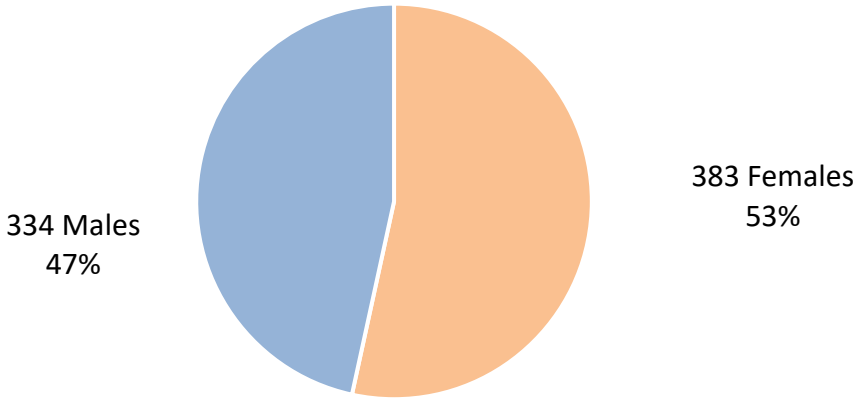
Who took part in this clinical study?

717 people were in this study. They were between 50 and 91 years old. The average age was 68 years. The graph below shows how many males and females took part:



A person **could** be in this study if they:

- Were at least 50 years old
- Had already received at least one pneumococcal vaccine one year or more before joining the study
- Did not have IPD in the past 3 years

7 people did not finish the study. The table below shows the reasons:

Reason people did not finish the study	Number of people
They decided to stop taking part in the study	4
They were not given the study vaccine because they were accepted into the study by mistake	2
The researchers were unable to contact them	1

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712 people received study treatment. The clinical study took place in 9 countries. The table below shows the number of people who received treatment and their location:

Country	Number of people
Canada	75
France	4
Israel	99
Italy	31
Japan	63
South Korea	100
Spain	50
Taiwan	67
United States	223
Total	**712**

What treatments were studied?

People received one of these as an injection (shot):

- **V116** - the study vaccine, that has 21 serotypes
- **PCV15** - a pneumococcal vaccine that has 15 serotypes
- **PPSV23** - a pneumococcal vaccine that has 23 serotypes

This study compared two pneumococcal vaccines (PCV15 and PPSV23) to V116.

What happened during this clinical study?

People were placed into 1 of 3 groups based on the pneumococcal vaccine they had already received before they joined the study:

- Group 1: people who had received only PPSV23 before joining the study
- Group 2: people who had received only PCV13 before joining the study
- Group 3: people who had received only PCV15 or PCV20 or another eligible combination of pneumococcal vaccines

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The table below shows the study treatment that each group received.

Group	Study treatment
Group 1 (who had received prior PPSV23 only)	People were assigned by chance to receive either: • V116 (2 out of 3 chance) • PCV15 (1 out of 3 chance)
Group 2 (who had received prior PCV13 only)	People were assigned by chance to receive either: • V116 (2 out of 3 chance) • PPSV23 (1 out of 3 chance)
Group 3	All people received V116

Researchers watched people for about 30 minutes after they received the vaccine. People returned to the study site about one month after they received the vaccine for a follow-up visit. Researchers also followed up with people by phone up to about 6 months after they received the vaccine. During the study, people gave blood samples and had physical examinations.

Overall results of this clinical study

Did V116 work to make an immune response?

To answer this question, researchers measured the antibody level for each serotype in V116 in people's blood samples. They measured this 30 days after people received the study vaccine.

Researchers learned that V116 caused an immune response to each of the 21 serotypes in the vaccine.

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How many people had certain adverse events or serious adverse reactions?

In this study, researchers wanted to know if certain **adverse events (AEs)** happened after people received a vaccine. Researchers also wanted to know if any **serious adverse reactions** happened during the study.

People in the study used an electronic diary to record if they had **certain AEs** up to 5 days after receiving a vaccine. These AEs included:

- **Problems (AEs) in the body where the vaccine was given**, including:
  - Redness
  - Pain
  - Swelling
- **Problems (AEs) somewhere else in the body**, including:
  - Feeling weak and tired
  - Headache
  - Muscle pain
  - Fever

What is an adverse event and adverse reaction?

Adverse events are health problems that happen or worsen during a clinical study. Adverse events **may or may not** be caused by the treatment a person received in a study.

Adverse reactions are adverse events that the researchers believe **could be related to the treatment** a person received in a study.

An adverse event or reaction is **considered serious** when it:

- Is life-threatening
- Causes lasting problems
- Requires hospital care
- Results in death

Number (%) of people who had certain AEs or serious adverse reactions					
	Group 1 Received V116 (Out of 230 people)	**Group 1 Received PCV15** (Out of 117 people)	**Group 2 Received V116** (Out of 174 people)	**Group 2 Received PPSV23** (Out of 85 people)	**Group 3 Received V116** (Out of 105 people)
AE in the body where the vaccine was given	92 (40%)	56 (48%)	75 (43%)	46 (54%)	46 (44%)
AE somewhere else in the body	48 (21%)	25 (21%)	45 (26%)	20 (24%)	26 (25%)
Serious adverse reaction (AE that could be related to the treatment)	1 (less than 1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

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What adverse reactions did people have during this study?

In addition to adverse events, researchers also looked at adverse reactions (serious and non-serious) that happened during the study.

This summary only provides information on the adverse reactions recorded during this study. Other studies may record different adverse reactions.

What serious adverse reactions did people have during this study?

At each visit, researchers asked if the person had any serious adverse reactions.

There was **1 serious adverse reaction** reported during the study. One person in Group 1 who received V116 had a skin infection where the injection was given that resolved.

There were no deaths during this study.

What is an adverse reaction and when is it serious?

Adverse reactions are health problems that happen or worsen during a study that researchers believe **could be related to the** treatment a person received in a study.

An **adverse reaction** is considered **serious** when it:

- Is life-threatening
- Causes lasting problems
- Requires hospital care
- Results in death

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What were the most common non-serious adverse reactions?

The table below shows the most common **non-serious adverse reactions** that happened in at least 5% (5 out of every 100) of people in any group up to 1 month after they received the vaccine.

Non-serious adverse reactions	**Number (%) of people**				
	Group 1 received V116 (Out of 230 people)	**Group 1 received PCV15** (Out of 117 people)	**Group 2 received V116** (Out of 174 people)	**Group 2 received PPSV23** (Out of 85 people)	**Group 3 received V116** (Out of 105 people)
Pain in the body where the injection was given	82 (36%)	51 (44%)	72 (41%)	40 (47%)	46 (44%)
Feeling weak and tired	31 (14%)	20 (17%)	32 (18%)	12 (14%)	23 (22%)
Headache	16 (7%)	11 (9%)	18 (10%)	10 (12%)	9 (9%)
Swelling in the body where the injection was given	20 (9%)	10 (9%)	8 (5%)	14 (17%)	11 (11%)
Redness on the body where the injection was given	19 (8%)	9 (8%)	14 (8%)	8 (9%)	8 (8%)
Muscle pain	17 (7%)	4 (3%)	17 (10%)	8 (9%)	9 (9%)

What did researchers learn from this study?

The results from this study helped researchers learn more about V116.

Are there plans for future clinical studies?

Researchers may continue to do studies to learn more about V116.

Where can I find more information about this clinical study?

To learn more about this clinical study, visit:

- ClinicalTrials.gov at Study Record | ClinicalTrials.gov
- European Union clinical register at Clinical Trials register - Search for V116-006

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For questions about this summary, contact the clinical study sponsor, Merck, Sharp & Dohme LLC (Rahway, NJ, USA), at: ClinicalTrialsDisclosure@merck.com

Full study title: A Phase 3 Clinical Study to Evaluate the Safety, Tolerability, and Immunogenicity of V116 in Pneumococcal Vaccine-Experienced Adults 50 Years of Age or Older

Who sponsored this clinical study?

Merck Sharp & Dohme LLC (Rahway, NJ, USA) sponsored this study.

Protocol number: V116-006

EU Clinical Trial Number: Not applicable

Other identifiers:

EudraCT number: 2021- 006679-41
NCT number: NCT05420961
JRCT: jRCT2071220025

Date: 12-Apr-2024

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