

## Protocol Plain Language Summary

### A clinical study of 9vHPV vaccine given to people ages 9 to 14 years (V503-069)

**Protocol Title:** A Phase 3 International, Multicenter, Open-label Study to Evaluate the Safety and Immunogenicity of 9vHPV Vaccine Administered as 2-dose Regimen with Extended Dosing Intervals in 9- to 14-Year Old Boys and Girls Compared with a Standard 3-dose Regimen in 16- to 26-Year Old Women

#### Why is this study needed?

**Human papillomavirus (HPV)** is a common virus that can cause an infection. Most people's immune system can clear HPV infection and it goes away without treatment. For some people, some HPV infections can last longer and may cause head and neck cancers and **anogenital diseases** years later, such as genital warts or cancer, including cervical and anal cancers.

Researchers found that a vaccine called **9vHPV vaccine** (also called the Human Papillomavirus 9-valent Vaccine, Recombinant) helps a person's body make HPV **antibodies** (proteins that the immune system creates to fight illness and infection). The 9vHPV vaccine protects against diseases caused by 9 types of HPV (6, 11, 16, 18, 31, 33, 45, 52, and 58), which are HPV types that cause most anogenital HPV diseases.

The 9vHPV vaccine is given to adults as 3 doses. It is usually given to children as 2 doses. These 2 doses are given 6 to 12 months apart. Researchers want to learn if giving a second dose of 9vHPV vaccine to children 2, 3 or 5 years after the first dose:

- Is safe
- Works as well to have children's immune systems make antibodies to each of the 9 HPV vaccine types compared to 3 doses of the HPV vaccine given to young women

#### Who will take part in this study?

About 700 healthy people will take part in this study. They will:

- Be children ages 9-15 years old or young women ages 16-26 years old
- Never have joined a clinical study for any HPV vaccine

#### What vaccines are being given?

Everyone in the study will get the **9vHPV** vaccine. The number of 9vHPV vaccine doses they will get depends on their assigned group.

#### How is this study designed?

People will be in the study between 1 month and 8 years. People will be assigned to a group based on their age and whether they already got 1 dose of the HPV vaccine before joining this study:

- **Group 1:** Children 10 to 15 years old who got 1 dose of 9vHPV vaccine at least 1 year before joining this study. They will get 1 dose of the 9vHPV vaccine on Day 1.
- **Groups 2-5:** Children 9 to 14 years old who have not gotten any HPV vaccine before joining this study will get 2 doses of the 9vHPV vaccine. They will get 1 dose on Day 1. Then, based on their age, each child will be assigned by chance to get the 2nd dose in:
  - 1 year (**Group 2**)
  - 2 years (**Group 3**)
  - 3 years (**Group 4**)
  - 5 years (**Group 5**)
- **Group 6:** Young women 16 to 26 years old who have not gotten any HPV vaccine before joining this study will get 3 doses of the 9vHPV vaccine. They will get a dose on Day 1, Month 2, and Month 6.

Each person will go to their study site to get the vaccine and stay at the study site for at least 30 minutes after the dose. Both the people in the study and the researcher will know what group a person is

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assigned to and how many doses they will receive during the study (open-label study). Each person will give blood samples, have a physical examination, and answer questions about their health during the study.

### What are the goals of this study and how will they be measured?

Main goals	How they will be measured
To learn if the children's immune systems respond by making antibodies to a second dose of 9vHPV vaccine given 2, 3 or 5 years after the first dose as well as the young women's immune systems respond to 3 doses of 9vHPV vaccine	The average level of antibody to each of the 9 HPV vaccine types in peoples' blood 1 month after the last dose
To learn if 9vHPV vaccine is safe when given 2, 3 or 5 years after the first dose	Percent of people who had: <ul style="list-style-type: none"> <li>• Certain <b>adverse events (AEs)</b> including pain, redness or swelling where they got the vaccine up to 5 days after any vaccine. AEs are health problems that happen or worsen during the study.</li> <li>• An AE anywhere in their body up to 15 days after they got any vaccine</li> <li>• A <b>serious AE (SAE)</b> during the study that the researcher thinks may be related to the vaccine. SAEs are serious health problems that happen or worsen during the study.</li> </ul>
To learn if the Group 1 children's immune systems respond by making antibodies to dose 2 of 9vHPV vaccine	The average level of antibody to each of the 9 HPV vaccine types in peoples' blood about 1 month after dose 2
Other goals	How they will be measured
To learn how the immune system responds to 9vHPV vaccine up to 3 years after the last dose of the vaccine (Groups 2-6)	The average level of antibody to each of the 9 HPV vaccine types in peoples' blood: <ul style="list-style-type: none"> <li>• 1 year after last dose</li> <li>• 2 years after last dose</li> <li>• 3 years after last dose</li> </ul> Percent of people who have antibodies to each of the 9 HPV vaccine types: <ul style="list-style-type: none"> <li>• 1 month after last dose</li> <li>• 1 year after last dose</li> <li>• 2 years after last dose</li> <li>• 3 years after last dose</li> </ul>

### What are the possible benefits and risks?

The 9vHPV vaccine may not prevent some people from getting HPV infection. More information about the benefits and risks for a person is in the Investigator Brochure, Protocol and Informed Consent documents.