



## The VSV Ebola vaccine study: facts on the VSV-ZEBOV vaccine clinical study

*The purpose of this fact sheet is to provide targeted information efficiently. This text is not exhaustive and does not provide sufficient information for a volunteer considering participation in the clinical trial.*

**What is the purpose of this study?** The purpose of this research study is to test the safety of the VSV-Ebola vaccine and its ability to trigger an immune response against Ebola virus in 115 healthy adult volunteers.

**How is the study designed?** Participants will be randomly selected to receive either of two doses (10 or 50 million vaccine particles) of the VSV-Ebola vaccine OR placebo as a one-time injection. (Participants who are healthcare workers (HCW) that may deploy to Ebola-affected countries will not receive placebo.) Neither the participant nor study investigators will know which treatment the participant receives. All participants will be followed closely during the first 2 weeks and then periodically for six months to assess the vaccine's safety and ability to trigger immune responses against *Ebolavirus*.

**Who may consider participating in this study?** To maximize safety, the study is only open to adult volunteers aged 18 to 65 years. Females of childbearing potential should be neither pregnant nor nursing. All volunteers will have to be free of significant and active health problems (as determined by the information you provide, a physical exam and laboratory tests for "screening"). Those with a history of severe allergic reactions (including after vaccination), active hepatitis B or hepatitis C or HIV infection, or confirmed or suspected immunodeficient conditions (e.g., cancer, immunosuppressive therapy) will not be eligible to participate. If you have received an inactivated (or "killed") vaccine (including seasonal influenza!) in the 14 days, or a live vaccine within 30 days before screening, participation will have to be postponed. Thus if you wish to participate, you are advised to complete your vaccinations without delay. Other exclusion criteria will apply to minimize the risk of poor outcomes. As a precautionary measure common to all studies testing new vaccines or medications, to minimize potential risks, volunteers will be asked to use effective methods of contraception for 28 days following injection (men) or throughout the course of the study (women of childbearing age). In addition, volunteers will be asked to use barrier methods (latex condoms) during penetrative sexual intercourse, to avoid the sharing of needles, razors, or toothbrushes and to avoid open-mouth kissing in the 7 days after injection. Participation is not open to volunteers who live with someone immunodeficient, HIV-positive, pregnant or with an unstable medical condition.

**What will be required to participate in this study?** The first step will be to be thoroughly informed of the study, to take sufficient time to decide whether to participate, and, should participation be granted, to provide written consent.

The study includes 9 visits at the Clinical Trials Unit of the University Hospitals of Geneva (HUG) over a 6-month study period. The first visit will be an information and screening visit. If participation is granted, an interview and a physical exam will be performed and urine and blood will be collected. This will take 1 to 1 and a half hours. On the second visit, there will be a brief interview and blood samples will be taken. The vaccine (at 10 or 50 million vaccine particles) or the placebo (non-deployable volunteers only) will be injected into the arm. The participant will then be observed closely for 1.5 hours; the visit will take 2 hours total. In the 7 days following the injection, participants will be asked to record any symptoms into a diary. Study participation entails remaining in the Geneva area for 14 days following the injection.

Subsequent visits will take place on days 1, 2 or 3, 7, 14 and 28 after injection. Each will take approximately 20 to 30 minutes, the time needed for a short interview and urine, saliva and blood collection. On day 28, if as a deployable HCW you are abroad, the visit will include a short interview (15-20 minutes) by phone and blood sampling at a later stage. At 3 months after injection, a short interview is scheduled without blood collection. The final visit will occur approximately 6 months after the injection for an interview and blood draw. Some participants may be invited to return for a blood draw 12 months after injection to check whether vaccine responses persist.

**Which analyses will be performed for this study?** We will measure the inflammatory and immune responses (antibodies, cells) triggered by the VSV-Ebola vaccine and their impact on the body.

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**Who is conducting, organizing and funding this study?** This study is being conducted by the Center for Vaccinology and the Division of Infectious Diseases of the University Hospitals of Geneva (“HUG”). It is coordinated by the World Health Organization (WHO) and funded by the Wellcome Trust, a charitable foundation supporting advances in global health. The study vaccine was developed by the Canadian Government, is manufactured by NewLink Genetics and was donated to WHO. The study is sponsored by HUG.

**What are the advantages and disadvantages of this study?** There is no direct benefit from participating, as protection from the vaccine cannot be ensured. Benefits to society as a whole could be substantial should the vaccine prove to be safe and protective. The main disadvantages of the study are the time required to attend the visits, the described risks of vaccine side effects and blood draws and the possibility of yet unknown risks; financial compensation will be provided (see below).

**Will participants be informed of the results of the study?** At the end of the study, participants will receive a letter from the study team informing them of the study’s general findings. They will be told which vaccine dose they received, or whether they received placebo, and whether their immune system produced Ebola-specific antibodies. We will also inform them immediately should new information that may influence participation to this study become available.

**Will participation be confidential?** Yes. All information, including personally identifying information, is strictly confidential. Only the study’s research investigators, Swiss public health officials, authorized representatives of the vaccine manufacturer and members of the Cantonal Ethics Research Committee of Geneva are authorized to access participants’ medical charts. These personnel have an obligation to uphold patient confidentiality. The overall results of the study will be published in the scientific record (e.g., medical journal), but no name will appear in these publications, nor will any other personally identifying information. Study data will be made anonymous through random coding. Study data will be analyzed in Switzerland. Coded blood samples will be sent to research laboratories in Switzerland or in foreign countries. The laws of these countries require that patient data and biological samples be treated in the same confidential manner as in Switzerland. Biological samples will be stored in a coded manner for a maximum period of 15 years before being discarded.

**Will participation incur any cost to participants or their healthcare insurer?** No, all study visits and laboratory tests will be financed by the study.

**Will there be a financial compensation?** Volunteers will be compensated for their time, travel costs and inconvenience. Total compensation is 810 CHF. The first 540 CHF will be provided at the end of the Day 14 Visit and the remaining balance at the end of study (Visit 9). Should your participation end early, a *pro rata* amount of 90 CHF per visit realized will be provided.

**Would any damages resulting from this study be covered by an insurance policy?** The study sponsor (the University Hospitals of Geneva) is responsible for any damages that may result from this study. A comprehensive insurance policy with La Zurich is in place that will provide full compensation for any damages resulting from participation in this study.

**Has this study been assessed and approved by Swiss authorities?** The Ethics Committees of the Canton of Geneva (N° 14-221) and WHO (RCP-696), as well as Swissmedic (2014GT1010), have reviewed and approved this study and all related documents. Investigators will conduct the study according to International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidelines.