Oxford Vaccine Group
University of Oxford
Centre for Clinical Vaccinology and Tropical Medicine,
Churchill Hospital, Headington, Oxford OX3 7LE
Tel/Fax: 01865 611400 info@ovg.ox.ac.uk www.ovg.ox.ac.uk

Ebola Vaccine Registry Study

Participant information sheet and Informed Consent Form

Study Title: A Multi-country, Prospective, Clinical Safety Study of Subjects Exposed to the Candidate Ebola Vaccines Ad26.ZEBOV and/or MVA-BN-Filo

Short Study Title: A study to find out about the safety of adults and children who received the vaccine to prevent the Ebola Virus.

Sponsor: Janssen Vaccines and Prevention B.V.

Represented by: Oxford Vaccine Group
Centre for Clinical Vaccinology and Tropical Medicine (CCVTM)
Churchill Hospital
Oxford OX3 7LE
Tel: 01865 611400
Email: info@ovg.ox.ac.uk
Website: www.ovg.ox.ac.uk

Project Management, Site Monitoring and Local Oversight provided by:

PAREXEL, International/Clinical RM

Protocol Number: VAC52150EBL4001

IRAS ID: 202965

Study Doctor: Dr Matthew Snape

Please read this document carefully

You are invited to take part in a research study to follow-up participants who have previously received vaccines against Ebola Virus. The study is being run by the Oxford Vaccine Group which is a part of the University of Oxford. Taking part in a research study is voluntary. Before you decide whether to take part, it is important for you to understand what the study is about and what participation would involve. Please take time to read the information carefully, and discuss with others if you wish. If anything is unclear or you would like further information please contact the study team (details above).

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov* as required by US law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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Why is this study being done?

The study is being run by the Oxford Vaccine Group, which is a part of the University of Oxford, on behalf of the sponsor, Janssen Vaccines & Prevention B.V.

The purpose of this study is to collect long-term safety data from participants who received two experimental vaccines to prevent Ebola virus disease: Ad26.ZEBOV and MVA-BN-Filo. This may contribute to the future development of an Ebola vaccine.

Up to approximately 5,500 participants will take part in this worldwide study.

Who has reviewed and approved the study?

The Medicines and Healthcare products Regulatory Agency (MHRA) has independently reviewed this clinical trial. The study has also been reviewed and approved by the **South Central Oxford A Research Ethics Committee**. The Research Ethics Committee is an independent group of people responsible for reviewing clinical research, so as to protect your safety, rights, wellbeing and dignity.

How long will I be in the study?

You will be in this long-term safety follow-up study for about 5 years (60 months). This includes the time you have already spent in the previous clinical study for Ebola vaccines Ad26.ZEBOV and MVA-BN-Filo.

After un-blinding of the original study, if you received Ad26.ZEBOV and/or MVA-BN-Filo you will remain in this long-term safety follow up study. If you received placebo and have already been enrolled into this long-term safety follow-up study, you will be discontinued from further participation in this study.

What happens during the study?

The study is divided into two parts:

- **Baseline (Visit 1):** The study staff will approach you at or around the time that you are expected to complete the long-term follow-up part of the original Ebola vaccine clinical study, or as soon as possible afterwards. If you agree to participate in this study, participants would have to attend an appointment at the study centre to discuss the study in person and you will be asked to sign this informed consent form. Further details about this visit are provided in the section *'What is done at each visit?'*

- **Follow-up:** You will be contacted by phone by a study staff member every 6 months and asked about any significant changes in your general health. The information collected during the follow-up will be similar to the information collected during the long-term follow-up visits of the previous Ebola vaccine clinical study. If you are not reachable by phone or if there is a significant change in your general health you may be asked to come to the clinic for an in-person visit.

Below is a list of all the things that happen during the study. There is also a table later in this booklet to show what happens at each visit or phone call.

- Review of medical history
- Review of any significant changes in your general health, including any hospitalisation or other medically important events
- Review of medications if there is a significant change in your general health
- Review of any vaccinations you have received

What is done at each visit?

First, the study staff will complete the "Baseline Visit". The Baseline Visit is a visit at the study site and may take place at the same time as your last visit in the previous Ebola vaccine clinical study. If you have already completed the previous Ebola vaccine clinical study the study staff will ask you about any significant changes in your health since your last contact with the study staff.

After your Baseline Visit, a member of the study staff will contact you every 6 months by phone; in-clinic visits may be scheduled if needed. During the follow-up phone calls, a study staff member will ask you about any significant changes in your general health in the past 6 months, will review any medications you took if there were significant changes in your general health and review any vaccinations you have received.

The table below shows what is done at each study visit or phone call:

	Visit 1 (Study Site Visit)	Contact 2 (Phone Call*)	Subsequent Contacts (Phone Call*)	End of Study (Phone Call*)
	Baseline (Start of Data Collection)	Month 6	Every 6 Months	After 60 Months of Follow-up**
Informed consent	✓			
Review inclusion/exclusion criteria	✓			
Review significant changes in your general health	✓	✓	✓	✓
Review medications if there was a significant change in your general health	✓	✓	✓	✓
Review vaccinations	✓	✓	✓	✓

* In-clinic visits may be scheduled as needed

** Includes time spent in the previous clinical study for Ebola vaccines Ad26.ZEBOV and MVA-BN-Filo

What do I have to do?

While you are in the study you would be required to:

- Have means to be contacted by phone.
- Be available and willing to participate for the duration of the study.
- Be willing to provide verifiable identification.
- Give correct and accurate information about your medical history and current medical condition.
- Tell the study staff about any significant changes in your general health, including any hospitalisation or other medically important events. If this occurs in-between the 6 monthly phone calls, we would ask you to contact the study team if it is convenient to do so.
- Tell the study staff about any new medicine or drug you take during the study.
- Participate in all study phone appointments and study site visits (if needed).

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What are the possible side effects?

There may be risks with the use of Ebola vaccines Ad26.ZEBOV and MVA-BN-Filo that are not yet known. Sometimes during a study the study staff may learn new facts about the study vaccines. If new information is discovered about the vaccines, the study staff will tell you about it right away.

All vaccines can cause side effects. Problems that are not expected may arise and they may be life-threatening. If you have any side effects or problems during your participation in this study, you should let the study team know right away.

What are the benefits of taking part?

There are no clear benefits to you if you take part in this study. By taking part you may help future participants by potentially providing additional safety data on the vaccines under study.

What if something goes wrong?

We do not expect there to be any risk of injury to you as a result of the current study as, in this study, you will not receive any vaccines, study investigations or have samples taken. The purpose of the study is to monitor you for long-term safety data after you have been vaccinated in a previous study.

In the event of any injury shown to be caused by a vaccine administered to you or any procedure you underwent as part of the original study, compensation may be available. The details of this are available in the previous study documents.

Who is funding this study?

The study is being funded by Janssen Vaccines & Prevention B.V. No member of the study site staff is receiving direct financial benefit from conducting this study and the chief investigator has no direct financial involvement in the organisations which are involved in sponsoring or funding this research, that may give rise to a possible conflict of interest. The sponsor will fund the University of Oxford for conducting this study.

There is no required treatment or testing for this study. The sponsor will not pay for doctor visits, or other treatments or tests that are not part of this study.

Will I be compensated?

A reimbursement of £45 per visit will be provided if you are required to attend any in-clinic visits. This reimbursement allowance is calculated to account for an allowance to cover travel costs and the time required for a visit. Payments will be requested on completion of any in-clinic visits and are made by direct bank transfer. For this reason, we would require participants to provide their bank details and national insurance number at the Baseline Visit. It is important to note you will not be reimbursed for taking telephone calls during the study.

Would my taking part in this study be kept confidential?

Yes.

The Sponsor will use the information collected about you for the purposes of the study and for scientific research, such as study of your disease. The Sponsor may also use this information to apply for permission to sell the vaccine in some countries. The information will be stored both on paper and on computer, without identifying you by any personally identifiable details (including name, address, telephone number etc.) To protect your privacy, the information will be labelled with a code number. If the results of the study are published, your identity will be kept confidential. By signing the consent form, you are permitting the use of your information.

The study staff will keep your personal medical records and a list that links your name to your code number for at least 15 years.

Regulatory authorities, employees at the study site and representatives of the Sponsor will be able to access this list in order to compare and check the study information collected about you with information in your medical records. As far as the law allows, your medical records will not be made public. By signing this form, you are allowing direct access to your medical records by those who have legitimate reason to look at them.

The information collected may be sent to other members of the Sponsor's group of companies, to contractors working for them and to regulatory authorities. None of this information will contain your personally identifiable details. It may also be sent to some countries outside Europe that may not have the same level of data privacy protection as Europe. Data sent between Europe & the United States of America share the same level of data privacy protection. The Sponsor will protect

your privacy as far as the law allows and will keep and supervise the information collected about you only for as long as needed.

All information that is collected about you during the course of the study would be coded with a study number and kept strictly confidential. Any information about you that leaves the clinic would have your name and address removed so that you could not be recognised from it. Your information would be stored on a secure server, and paper notes would be held by the Oxford Vaccine Group in a locked filing cabinet. Once the study has completed, all documents would be archived in a secure facility for 15 years.

Who else can see my records during the study?

In order to ensure that the study is being conducted correctly, the following groups may inspect the study records without violating your confidentiality:

- Monitors who check that the study is being conducted to a high standard
- The research Sponsor (Janssen Vaccines & Prevention B.V.) and other designated members of the Sponsor's group of companies
- MHRA

You can arrange with the study staff to see the information collected about you, and you can ask for any mistakes to be corrected. If you decide to leave the study at any time, the Sponsor may still use your information collected up to that point, as the law allows.

Can I change my mind?

Your taking part in this study is voluntary. Should you volunteer and later change your mind (for whatever reason) it is your right to do so, and you would not need to provide an explanation to the study team or anyone else. Your decision will not affect your medical care.

If you decide to stop the study early, please contact the study team to inform them of your decision. The study staff will ask if there have been any significant changes to your general health since your last contact with the study staff. He/she may add that information to your study record. If you decide to stop the study early, you agree not to limit our use of your study information so far. The sponsor will not collect any new information from you.

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Can I be removed from the study early?

The study team and/or the study sponsor has the right to take you out of the study at any time with or without your agreement. These decisions will be made if, for example:

- It is in your best medical interest to stop your participation
- You do not follow instructions
- The study is cancelled.

After un-blinding of the original study, if you received placebo and have already been enrolled into this long-term safety follow-up study, you will be discontinued from further participation in this study.

May we contact your other doctors?

We would like your permission to contact the doctors you see regularly to let them know that you are taking part in this study. This may include consultants or specialists directly involved in your care if you were admitted to hospital, for example. While you are in the study, the study staff will ask about any significant changes in your general health. If you have any significant changes in your general health or if you stop the study early your other doctors may want to contact the study staff.

Where can I take advice on whether to take part?

We are happy to answer any questions you might have and contacting us does not commit you to taking part in the study. For independent advice you can contact **INVOLVE** (www.invo.org.uk) which is a government funded national advisory group supporting those considering involvement in research. Please feel free to discuss this study before deciding whether or not to participate.

What if I wish to complain?

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact:

Oxford Vaccine Group (telephone 01865 611400) or email **info@ovg.ox.ac.uk.**

You can also contact the University of Oxford Clinical Trials and Research Governance (CTRG) Office on 01865 572224 or email the head of CTRG, Heather House, at ctrg@admin.ox.ac.uk.

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Who do I contact for more information?

You are encouraged to ask the study team any questions about this study or this information sheet and informed consent form, and you should receive satisfactory answers to your questions.

Please contact the following if you have any questions about the study; if you want to know your rights as a research volunteer; if you want to tell us about any side effects; or if you want to make a complaint. Oxford Vaccine Group (telephone 01865 611400) or email info@ovg.ox.ac.uk.

Yours sincerely,

Dr. Matthew Snape
Chief Investigator
Consultant Vaccinologist and
Paediatrician
Honorary Senior Clinical Lecturer