4th EBOVAC2

e-newsletter

December 2017

Welcome to the EBOVAC2 e-newsletter!

EBOVAC2: Getting up to date

The EBOVAC2 project is one of 8 projects funded under the IMI Ebola+ program that was launched in response to the Ebola virus disease outbreak. Through several clinical trials conducted in Europe and Africa, the EBOVAC1 and EBOVAC2 projects will assess the safety, tolerability and immunogenicity of different schedules of a vaccine regimen against Ebola.

How? To expedite the development of a novel prophylactic Ebola vaccine regimen, several clinical trials have been carried out in parallel and coordinated by two separate teams: EBOVAC1 (Phase 1 and Phase 3 large scale safety and immunogenicity studies) and EBOVAC2 (Phase 2 studies).

What? The vaccine regimen used in the Phase 2 studies involves two different vaccine candidates given a few weeks apart, Ad26.ZEBOV developed by Janssen Vaccines & Prevention B.V., part of the Janssen Pharmaceutical Companies of Johnson & Johnson, and MVA-BN.Filo developed by Bavarian Nordic and licensed to Janssen. The first dose, or 'prime', is intended to stimulate an initial immune response. The second dose then is designed to 'boost' the level of the body's immune response further. The EBOVAC2 consortium also aims to work out the best timing for each of the vaccine doses so volunteers will therefore receive different vaccination schedules. This strategy offers the advantage of potentially identifying the optimal schedule for improved and, especially, longer lasting immunity.

Who? The consortium brings together industrial and academic stakeholders: Janssen as the regulatory sponsor and project lead, French Institute of Health and Medical Research (Inserm) as coordinator, and the University of Oxford (UOXF), London School of Hygiene & Tropical Medicine (LSHTM), Centre MURAZ (CM) and Inserm Transfert (IT).

Learn more information about EBOVAC2 on our website www.ebovac2.com

Conducting clinical studies

In Africa

The aim of the EBL2002 trial in Africa is to test the vaccine in a total of 1056 subjects including healthy adults and population groups including the elderly, HIV-infected adults, adolescents and children. In total, 1885 participants have been screened and 1075 have been randomized across cohort 1(healthy adults), cohort 2A (HIV-infected individuals), cohort 2B (healthy

adolescents aged 12 to 17 years) and cohort 3 (children aged 4 to 11 years) of which 996 have received the boost vaccination.

Cohort 3 is now complete : the 132 volunteers have been randomized. Cohort 4 (children aged 1 to 3 years) has been eliminated, safety and immunogenicity data for this age group will be collected in 2 other studies within the program.
Next step : The third vaccination sub- study for 90 subjects is about to begin in 4 sites in Burkina Faso, Kenya and Uganda. The enrollment on this study will start as soon as the clinical trial protocol amendement 3, submitted in August 2017 is approved.

In Europe

The EBL2001 trial in Europe (UK, France) has been completed. 423 study participants have been randomized (143 were randomized in reporting year 1 and 280 in reporting year 2), of which 290 have received the boost vaccination. The site closed out visits are ongoing. Volunteers have now switched to the EBL4001 roll over study.

Annual meeting is coming

The joint EBOVAC1 and EBOVAC2 annual meeting will take place in Amsterdam, on 9-10 January 2018. More than 80 participants will attend the meeting and all partners will be represented. The annual meeting will be the opportunity to present the progress of the clinical trials in the different countries and discuss successes and challenges met by the consortium.

EBOVAC2 Training : Conducting clinical trials in Africa

As partner of the Consortium the Centre Muraz is in charge of organizing the session "Training of young health professionals of the Sub-Region in methodology of research and conduct of clinical trials". The aim of this course is to strengthen the capacity of the African research centres to prepare sites for the effective conduct of clinical trials.

Two training sessions are planned: one in French for the West African partners and the second in English for the East African partners.

The first training session on clinical research will be organized together with Centre Muraz, Inserm and Janssen and is planned to take place from **January 23 -26 2018 at Centre MURAZ in Bobo-Dioulasso.**

The training modules will mainly focus on:
- Introduction to clinical trials
- Clinical trials: ethics and regulation
- Clinical trial Protocol
- Socio-anthropological aspects of clinical research in Africa
- Key steps for clinical trial implementation
- Clinical trial funding in West Africa

Link to register

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EBOVAC2 Partners

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