

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 1017 have received the boost vaccination. **All cohorts are now complete**. A subset of 90 subjects of cohort 1 received a third dose vaccination. The sub-study was conducted in 4 sites in Burkina Faso, Kenya and Uganda.

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.

On February 22nd of 2018 the EBL2001 safety database was locked. The next milestone will be the lock of the immunological database which will conclude the data release plan for the EBL2001 clinical trial. This next step is expected to take place before August 2018.

EBOVAC2 Training: Conducting clinical trials in Africa



As partner of the Consortium the Centre Muraz was 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 training took place from January 23 -26 2018 at Centre MURAZ, Bobo-Dioulasso, Burkina Faso. The aim of this course was to strengthen the capacity of the African research centres to prepare the sites for an effective conduct of clinical trials.

35 participants (MDs, investigators, biologists, MSc & PhD students) attended the training. From the evaluation made, it appears that trainees enjoyed the training and found it very useful. They specifically enjoyed the case studies and group discussions as well as the profile of speakers. 73% of the participants judged that the quality the training was very good and 27% good. Some of them mentioned that the training could last 5 days instead of 4 to further



develop specific aspects of clinical research such as epidemiology and statistical analysis. It could be also interesting to have the participation of countries affected by the epidemic.



Dr Houreratou Barry, Centre Muraz PI EBOVAC2 and Pr Rodolphe Thiebaut EBOVAC2 Coordinator were interviewed by local media.

See TV report and article:

RTB TV: http://www.rtb.bf/2018/01/jt-de-20h-du-25-

janvier-2018/

Lefaso.net: http://hauts-

bassins.lefaso.net/spip.php?article461&rubrique1

A second training in English will be organized for the East African partners.

Place to be: events coming

Health Leaders Research Congress - 24–25 April 2018 https://healthleadersresearch.com/

ASM Clinical Virology - West Palm Beach, Florida, May 6–9, 2018 https://www.asm.org/index.php/2018-clinical-virology-symposium

5th International One Health Congress - Saskatoon, June 2018 https://onehealthplatform.com/cnt/article/welcome-website-5th-international-one-health-congress

ISV 2018 - Atlanta, Georgia, 28–30 August, 2018 https://isvcongress.org/

Vaccine Congress - Budapest, 16–18 September 2018 https://www.elsevier.com/events/conferences/vaccine-congress

ESCV 21st Meeting - Athens, Greece, 23–26 September 2018 http://www.escv2018.com/?c=4&Ing=1

ID Week 2018 - San Francisco, California, 3–7 October, 2018 http://www.idweek.org/

IMI scientific symposium - Brussels, 22–23 October 2018

http://www.imi.europa.eu/news-events/events/imi-10th-anniversary-scientific-symposium-october-2018

IMED 2018 - Vienna, 9–12 Nov 2018 http://imed.isid.org/

ASTMH 67th Annual Meeting - New Orleans, Louisiana USA, October 28–November 1, 2018 http://www.astmh.org/annual-meeting/future-meetings

Events to be confirmed

- 4th West African Sub-regional conference
- 4th Africa Conference on Emerging Infectious Diseases and Biosecurity
- International Symposium on Filoviruses

EBOVAC2 Partners













EBOVAC2 Funding







This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement no. 115861. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA. www.imi.europa.eu