3rd EBOVAC2

e-newsletter

October 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+ programme 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. The first dose, or 'prime', is intended to stimulate an initial immune response. The second dose is then 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 Vaccines & Prevention B.V as sponsor, French Institute of Health and Medical Research (Inserm) as coordinator, 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 the EBOVAC2 project, 2 clinical trials (Phase 2) are being conducted: one trial (EBL2001) in France and the United Kingdom and a second trial (EBL2002) in several countries in Africa, Burkina Faso, Uganda, Kenya, and Côte d'Ivoire.

In Africa

The aim of the EBL2002 trial in Africa was to test the vaccine in a total of 1,188 participants including healthy adults and the following population groups: elderly, HIV-infected adults, adolescents and children. The study on children aged 1-3 years has been cancelled (132 participants). Safety and immunogenicity data for this age group will be collected in 2 other studies with the programme. Consequently, the sample size was updated to 1,056 participants.

As of 17th October 2017, 1,857 participants have been screened and 1,049 have been randomized across Cohort 1(healthy adults), Cohort 2A (HIV-infected individuals), Cohort 2B (healthy adolescents), and cohort 3 (children aged 4-11 years)of which 919 have received the boost vaccination. Cohort 3 is stil on going with102 participants randomized and 30 screened.

Next step: A third vaccination will be administered to 90 participants in 4 selected sites will take place in Burkina Faso (2 sites), Kenya and Uganda (1 site).
The clinical trial protocol amendment 3 was submitted in August 2017 for the third dose sub-study. Regulatory approvals for this trial are expected end of October/early November 2018.

In Europe

The EBL2001 trial in Europe (UK, France) has been completed. 664 study participants (healthy adults) were screened, 423 were randomized (143 were randomized in reporting year 1 in 2015 and 280 in reporting year 2 in 2016), of which 290 received the boost vaccination. The sites' close-out visits are ongoing. Volunteers are currently switching to the long-term follow-up study.

Next annual meeting

The joint EBOVAC1 and EBOVAC2 annual meeting will take place in Amsterdam, the Netherlands from the 8th to the 10th January 2018. More than 80 people will attend and all partners will be represented. The annual meeting will be the opportunity to present the progress of the project work , the advancement of the clinical trials in the different countries and discuss successes and challenges met.

Focus: Interview with Dr Houreratou Barry, Principal Investigator, Centre Muraz, Burkina Faso

Centre MURAZ is member of the EBOVAC2 consortium and hosts a clinical trial site for a Phase 2 Ebola vaccine trial.

Can you briefly present Centre MURAZ?
Centre MURAZ is one of the oldest national health research institutions in Francophone West Africa. Its mission is to contribute, mainly in Burkina Faso, to the prevention, diagnosis and control of communicable and non-communicable diseases by promoting and carrying out health research, training and expertise in medical biology, social sciences and public health. These research activities are guided by an International Scientific Board.

What is the impact for the Centre MURAZ to be part of the EBOVAC2 project?
The impacts for Centre MURAZ to be part of the EBOVAC2 project can be summarized at two levels: Firstly, in terms of reinforcing the capacities of the Centre MURAZ by extending and renovating the clinic dedicated to the clinical trials with up-to-date equipment and training both clinical and laboratory staff in conducting vaccine trials and on some advanced laboratory techniques. After this trial, the new facility and the trained staff will enhance the capability of Centre MURAZ to conduct other future vaccine trials. Furthermore, the experience gained by the center and the staff is a great opportunity to develop future collaborations and grants.
Secondly, being a member of the EBOVAC2 consortium will enhance the visibility of Centre MURAZ in the national and international scientific world. The participation in this trial is also the contribution of the Centre and Burkina Faso in the fight against the Ebola disease.

How have you recruited volunteers?
The recruitment of volunteers consisted of a step-by-step approach with administrative and

community leaders first to get their approval, before proceeding with direct communication with target populations (healthy adults, elderly, People Living with HIV, parents of children to 17 years old). We held oral presentation meetings at universities, public health professional schools and at the community level. Posters were displayed in the city of Bobo-Dioulasso particularly at universities, schools and at health centres. Flyers were distributed during oral presentations, at the EBOVAC2 clinic and in the health centers of Bobo-Dioulasso.

This strategy led to the screening of 329 volunteers of which 183 were enrolled in the first two cohorts. Recruitment of cohort 3 started on September 2017 and is still ongoing.

What kind of difficulties did you meet?

The first difficulty was the risk of potential rumours and distortions of information about the trial. Since the city of Bobo-Dioulasso experienced two suspected cases of Ebola disease during the outbreak in 2014, the fear of the disease remained firmly anchored in the collective memory. Furthermore, the misconceptions related to the type of vaccine raised some questioning about the possibility of contracting Ebola through the vaccine that would be injected in volunteers. Therefore, the potential rumours was the first issue to be defeated by direct communication.

The second difficulty was the reluctance of the ethics committees to conduct such a trial in a country like Burkina Faso which did not experience any case of Ebola during the outbreak. Therefore, the ethics clearance took 8 to 9 months compared to the usual 3 months duration.

Specific training on clinical trials in research projects is going to be held in Centre Muraz in 2018. Can you give us more information?

As member of the Consortium, we are 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 not only for an effective conduct of the present trial but also to prepare sites for the effective conduct of future trials.

Furthermore, the training will help the young generation to take the lead on clinical trials in Africa. 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 is planned to take place in early 2018 at Centre MURAZ in Bobo-Dioulasso. The Participants from partner institutions will be invited to take part and specialists from partners' institutions will facilitate the training modules. These modules are mainly:

- Introduction to clinical trials;
- Clinical trials: ethics and regulations;
- Clinical trial Protocol;
- Socio-Anthropological aspects of clinical research in Africa;
- Key steps for clinical trial implementation;
- Clinical trial funding in West Africa: opportunities and constraints.

What is the future after EBOVAC2?

After EBOVAC2, other trials are upcoming and the most important is another Ebola vaccine trial. The network acquired by participating in this consortium will also be built on for future partnerships.

News release: WHO supports containment of rare virus on Uganda-Kenya border

20 October 2017 | GENEVA - WHO is working to contain an outbreak of Marburg virus disease (MVD) that has appeared in eastern Uganda on the border with Kenya. At least one person is confirmed to have died of MVD and several hundred people may have been exposed to the virus at health facilities and at traditional burial ceremonies in Kween District, a mountainous area 300 kilometres northeast of Kampala….Read more

Place to be: events coming soon

66th Annual Meeting of American Society of Tropical Medecine & Hygiene
5-9 November 2017 in Baltimore, Maryland, US
http://www.astmh.org/

Vaccines R&D 2017
13-15 November 2017 in Washington, DC, US
https://www.unitedscientificgroup.com/conferences/vaccines/

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