



2nd EBOVAC2 e-newsletter

June 2017



www.ebovac2.com

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 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 sponsor, 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 1,188 subjects including healthy adults and population groups including the elderly, HIV-infected adults, adolescents and children. So far, 1698 participants have been screened and 943 have been randomized across Cohort 1 (healthy adults), Cohort 2A (HIV-infected individuals) and Cohort 2B (healthy adolescents), of which 866 have received the boost vaccination.

In Europe

The EBL2001 trial in Europe (UK, France) aims to vaccinate a total of 630 subjects (healthy adults). So far, 423 study participants in Europe have been randomized (143 were randomized in reporting year 1 and 280 in reporting year 2), of which 290 have received the boost vaccination.

From a scientific perspective

Thanks to the finalisation of Cohort 1, the first results in EBOVAC2 on the immune response to the vaccine were obtained by the Oxford Vaccine Group (UOXF) in a subcohort of 30 participants in the UK. During last year, UOXF has been characterising the B cell response to Ad26.ZEBOV/MVA.BN.Filo and has shown strong plasma cell responses and also identified their phenotypes. The group has also begun preliminary analysis of the antibody VH-gene response post Ad prime and MVA boost and initial isolation of monoclonal antibodies has been achieved.

Towards clustering activities

Central Information Repository

A Central Information Repository (CIR) has been developed and deployed on a commercial, EU-based cloud infrastructure, and made available consortium wide.

The main objective of such a tool is to encourage information and data-sharing across the Ebola+ projects which could be beneficial in the future for research purposes or in an outbreak setting.

The solution provides controlled access to named members of the consortium, with key users identified across the eight Ebola+ projects. More than 50 users, from all eight Ebola+ projects, have been provided usernames and passwords and offered training. The solution is based on CKAN, the leading open-source application of its type. The configuration of the system was developed at Janssen, in collaboration with its external partner CMAST (BE). Users are able to upload documents, presentations, meeting minutes, reports and multiple forms of data. Access to these resources can be restricted by the uploader per project or organization. To ensure uploaded resources are easy to locate, the system provides a simple interface to include meta-data with every data entry.

Recruitment strategies best practices

The Communication team decided to collect information about clinical trial recruitment strategies from each EBOVAC1 and EBOVAC2 trial site. The main objective is to describe communication strategies used to recruit volunteers in different countries, settings and populations to better understand the needs for clinical trial recruitment and identify key challenges in this area. The second objective is to share experiences of recruitment strategies between Ebola+ projects and externally so that the experiences can be of benefit to future clinical trial recruitment campaigns.

Inside EBOVAC2

Annual meeting 2017

The joint EBOVAC1 and EBOVAC2 annual meeting took place in Windsor, UK from 14-16 November 2016. More than 80 people attended and all partners were represented. The annual meeting was the opportunity to present the progress of the clinical trials in the different countries and discuss successes and challenges met.

EBOVAC2 team news

Congratulations to Prof. Nicolas Meda, Centre Muraz, who was named Minister of Health of Burkina Faso on the 20th February 2017!

Communications

EBOVAC2 report on BBC News - *March 8th*

Victoria Derbyshire reporter Catrin Nye went to visit the Oxford Vaccine Group looking for volunteers who participated in the EBL2001 study. Prof. Andrew Pollard (Professor of Paediatric Infection and Immunity and Oxford Vaccine Group PI for EBOVAC1 and EBOVAC2) and study volunteers were interviewed.

Watch here : <http://www.bbc.co.uk/news/uk-39202974>

EBOVAC1 consortium reports that Investigational Ebola Vaccine Regimen Induces Durable Immune Response 1 Year After Vaccination - *March 14th*

Based on final Phase 1 data published in *JAMA: The Journal of the American Medical Association*, the prime-boost Ebola vaccine regimen induced an antibody response that persisted in 100 percent of healthy volunteers to at least 1 year following vaccination. The results are from the EBOVAC1 study EBL1001 conducted by the Oxford Vaccine Group in the UK.

Please find the [article](#)

EBOVAC2 report on VOA Afrique – *June 3rd*

33rd edition (in French) of "Your health your future" was devoted to the research and experimentation of vaccines against Ebola. Pr Rodolphe Thiebaut, coordinator of the Ebovac2 project has been interviewed with others guests: Dr Marie-Paule Kieny, WHO Deputy Director for Health Systems and Innovations, Dr. Armand Nghemkap answered questions from the auditors. Program broadcast on Saturday 3 June 2017 and broadcast on Sunday 4 June and Wednesday 7 June 2017.

Listen here <https://www.voaafrique.com/a/3862792.html>

News Ebola

WHO Press releases

"1 June 2016 | Brazzaville - Today WHO declares the end of Ebola virus transmission in the Republic of Guinea. Forty-two days have passed since the last person confirmed to have Ebola virus disease tested negative for the second time. Guinea now enters a 90-day period of heightened surveillance to ensure that any new cases are identified quickly before they can spread to other people."

"9 June 2016 | Monrovia - Today the World Health Organization (WHO) declares the end of the most recent outbreak of Ebola virus disease in Liberia. This announcement comes 42 days (two 21-day incubation cycles of the virus) after the last confirmed Ebola patient in Liberia tested negative for the disease for the second time. Liberia now enters a 90-day period of heightened surveillance to ensure that any new cases are identified quickly and contained before spreading."

Last reports on Ebola outbreak Democratic Republic of the Congo :

"On 28 May 2017, no new confirmed or probable EVD cases were reported. The last confirmed case was reported on 11 May 2017. Four new suspected cases were reported, 3 from Muma, 1 from Ngabatata in Likati Health Zone. Seven cases previously reported as suspected cases have now been re-classified as 'not a case' following laboratory analysis.

Currently there are a total of two confirmed cases, three probable and 14 suspected cases. The confirmed and probable cases were reported from Nambwa (two confirmed and two probable) and Ngayi (one probable). The suspected cases have been reported from seven health areas (Nambwa, Muma, Ngayi, Azande, Ngabatata, Mobenge and Mabongo). The outbreak currently remains confined to Likati Health Zone.

As of 28 May, 101 contacts remain under follow up for signs and symptoms of Ebola. The previously undertaken modelling to determine the risk of further cases was updated with newly available onset dates for the confirmed / probable cases. Results suggest the risk of further cases is low but not negligible, and decreases with each day without new confirmed/probable cases; as of the reporting date, 67% of simulated scenarios predict no further cases in the next 30 days."

Previous reports

"On 9 May 2017, WHO was informed of a cluster of undiagnosed illness and deaths including haemorrhagic symptoms in Likati Health Zone, Bas Uele Province in the north of the Democratic Republic of the Congo (DRC), bordering Central African Republic. Since 22 April, nine cases including three deaths have been reported. Six cases are currently hospitalized."

"On 10 May 2017, a multidisciplinary team led by the MoH and supported by WHO and partners was deployed to the field and are expected to reach the affected area on 12 or 13 May 2017 to conduct an in depth field investigation."

"On 11 May 2017, the Ministry of Health (MoH) of DRC informed WHO that of the five samples collected from suspected cases, one tested positive by RT-PCR for Ebola virus subtype Zaire at the Institut National de Recherche Biomédicale (INRB) in Kinshasa. Additional specimens are currently being tested and results, including sequencing, are awaited to describe the outbreak."

"On 24 May, 2017 WHO and partners request \$10.5M for Ebola response. Funding is urgently needed to ensure that WHO and partners can effectively support to Government in a rapid responses to the Ebola outbreak in Democratic Republic of the Congo.

Places to be

International Summer School ISPED

Statistical analysis of big data in systems immunology

3-7 July 2017 in Bordeaux, France

<http://bss-publichealth.u-bordeaux.fr/fr/>

9th IAS Conference on HIV Science

23-26 July 2017 in Paris, France

<http://www.ias2017.org/>

3rd African Conference on Emerging Infectious Diseases and Biosecurity

16-18 August 2017 in Accra, Ghana

<http://www.getafrica.org/>

Scientific Colloquium on Heterologous Prime Boost Vaccination

29 September 2017 in Leuven, Belgium

<http://onehealthplatform.com/node/643>

66th Annual Meeting of American Society of Tropical Medicine & 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



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