1. Summary for publication

1.1 Summary of the context and overall objectives of the action

The Ebola virus disease (EVD) epidemic has infected more than 28,000 people and killed more than 11,000 from March 2014 to December 2015, the vast majority of them in 3 West African countries: Guinea, Liberia and Sierra Leone (WHO Ebola Situation Report June 10, 2016). No therapy and no vaccine has been approved and made available yet for the treatment and prevention of EVD, but research led by a number of industrial, academic and non-profit stakeholders is ongoing. The EBOVAC1, EBOVAC2, EBODAC and EBOMAN projects, part of the Innovative Medicines Initiative's EBOLA+ programme supported by the European Commission and the European Federation of Pharmaceutical Industries (EFPIA), are in a series of trials and associated projects which aim to assess an experimental prime-boost preventive vaccine regimen against EVD. An Ebola vaccine will be a key tool to help protect from EVD.

The overall objective of the EBODAC project is to develop a communication and engagement strategy including the development of appropriate technology and tools to maximize the impact of Ebola vaccination in the targeted population. Complex social and cultural hurdles may prevent vaccine acceptance by the local population. When the Ebola vaccine will be deployed, ensuring adequate population coverage will be essential. Vaccination acceptance and compliance to the vaccination regimen composed of a heterologous booster dose will be a critical factor to high vaccination coverage. This includes the development of solutions for correctly identifying individuals returning for their second vaccination and reminding them of clinic visits.

EBODAC deliverables are the development and implementation of:

1. A communication and engagement strategy and tools that increase acceptance and compliance with Ebola vaccination and build trust in the vaccination strategy with the wider population,
2. A mobile technology platform to allow effective recall of vaccinees to receive the second vaccination in the context of a prime-boost vaccine regimen,
3. An identification tool that ensures that the right person will receive the second vaccination in the context of a prime-boost vaccine regimen.

1.2 Work performed from the beginning of the action to the end of the period covered by the report and main results achieved so far

EBODAC achievements match the Description of Action (DoA) in terms of objectives and approach and activities have been adapted to the specific context of the EBOVAC-Salone clinical trial in Sierra Leone. All three components of the EBODAC project: communication and engagement strategy and tools, mobile technology platform and identification tool have been developed, adapted to the clinical trial and made ready in time for start of trial in October 2015.

The communication and engagement strategy have been successfully developed and implemented for adults and have not encountered any significant barriers. Key stakeholders, community leaders and
participants have joined efforts with EBODAC and EBOVAC-Salone teams to make the trial happen. Potential barriers and opportunities for the clinical trial have been identified and communication has been adapted accordingly. Messages, communication materials and strategies have been updated following the evolution of the EBOVAC-Salone trial design. Following community meetings, volunteer sensitization efforts and a public lottery, 1686 people expressed their interest in volunteering for the clinical trial and 875 individuals attended the clinic for an initial screening visit. 445 subjects have received the first vaccination of the prime-boost regimen and 84% (376/445) of them returned to the trial clinic to receive the boost.

The mobile technology platform supports the clinical team to effectively recall participants to receive the second vaccine or attend clinic visits in the context of a prime-boost vaccine clinical trial and has been successfully deployed and adapted to the needs of a multilingual population with a high rate of illiteracy and a lack of familiarity with clinical trials. To date, 100% of Stage I participants and 97% of Stage II participants consented to be contacted through their mobile phone. For Stage I, 60% of calls where picked up, compared to 56% for Stage II. More than 96% of the messages is listened to by recipients for calls picked up in Stages I and II. The ability of the mobile platform to generate daily clinic reports for the clinical trial staff has also been of added value to the clinical team. An appointment scheduling application has been developed to allocate timeslots to each participant, which allows the clinic staff to efficiently manage the clinic capacity and prevents participants from long waiting hours at the clinic.

A biometric identification tool combining finger-print and iris scan has been chosen, accepted by study participants and successfully used to register and recognize clinical trial participants. A mobile version of the biometric identification tool using iris scan on a portable tablet is currently under development. The accuracy and feasibility assessment of using iris scanning in 1-4 year old children as unique biometric identification is currently ongoing.

Kambia is a rural region of a country with a sparse health care infrastructure and with a population with limited access to education and exhibiting a lack of trust in national and international structures and institutions. Considering the context of setting up a clinical trial during an Ebola epidemic in Kambia, an area which was particularly badly affected during the Ebola outbreak, the successful completion of stage 1 and stage 2 adults of the EBOVAC-Salone trial and successful implementation of the EBODAC solutions in this context should be considered a great achievement.  

1.3 Progress beyond the state of the art and expected potential impact (including the socio-economic impact and the wider societal implications of the action so far)

Communication and engagement strategies are often developed along with vaccination programs, but the specific context of a clinical trial in an outbreak setting was a unique situation with major challenges that have been successfully overcome. Lessons learnt from this experience, together with lessons learnt on the use of enabling technologies, will be shared during the EBODAC symposium organized in February 2017 and will be made publicly available afterwards through an online training tool.

External effects of EBODAC, along with EBOVAC1, encompass capacity building in Kambia by employing, training and giving experience to Sierra Leonean staff about clinical trials, community engagement, data entry, use of mobile, biometric identification and other technological tools, etc. Locally, EBODAC has employed 3 mobile technology workers, and 8 identification tool operators. With regard to the community engagement work, the Sierra Leone College of Medicine and Allied Health Sciences (COMAHS) hired 1 Community Liaison Officer and 4 Community Liaison Assistants and these are co-managed by the Communications Coordinator from EBODAC and the EBOVAC1 Communications Manager. World Vision hired 6 Community Liaison Facilitators.

Local capacity building efforts to prepare for trials in Sierra Leone and to train local Kambian staff will have impact on building research capacity in the country, together with the ability to conduct research in epidemic/outbreak conditions. The successful implementation of educational measures, communication strategies as well as of mechanisms ensuring proper handling of clinical data contribute to the facilitation of performing clinical trials in Sierra Leone.

1.4 Address (URL) of the action’s public website

http://www.ebovac.org/ebodac/