



IMI impact on: Ebola

13 June 2023

- 
- **How IMI EBOVAC projects have impacted Ebola research**

IMI impact on: Ebola

13.06.2023

15:00 Brussels time
Online event

The speakers:



Bailah Leigh
College of Medicine and
Allied Health Sciences,
Sierra Leone



Cynthia Robinson
Janssen Vaccines &
Prevention



Deborah Watson-Jones
London School of Hygiene &
Tropical Medicine, UK



Rodolphe Thiebaut
University of Bordeaux



Annik Willems
Janssen



Oussama Karroum
IMI, Event Moderator



IMI impact on: Ebola

Agenda

- Introduction and welcome
- How IMI EBOVAC projects have impacted Ebola research
- Q&A
- Closing remarks



The session will focus on projects supported by the Innovative Medicines Initiative, a partnership between the European Union and the European pharmaceutical industry.

IMI impact on: Ebola

Use the chat below



Ask questions and interact
with the speakers
(bottom of your screen)

The session is being **recorded**.
The recording will be posted on IHI's
website and Youtube channel.

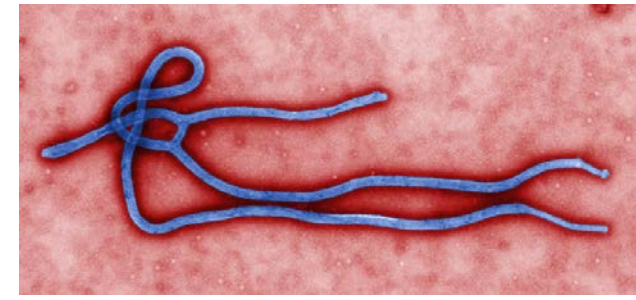


- **Setting the scene**
Rationale for EBOVAC/EBODAC



Prof. Deborah Watson-Jones
London School of Hygiene & Tropical Medicine

Ebola virus disease



By courtesy of Cynthia Goldsmith, CDC.

- Ebola virus disease is a deadly disease with a case fatality rate of 25-90% in past outbreaks¹
- Caused by an infection with RNA viruses within the genus *Ebolavirus*:
 - Ebola virus (species *Zaire ebolavirus*)
 - Sudan virus (species *Sudan ebolavirus*)
 - Taï Forest virus (species *Taï Forest ebolavirus*)
 - Bundibugyo virus (species *Bundibugyo ebolavirus*)
- Since 1976, 35 outbreaks with a cumulative total of about 34,935 cases and 15,385 deaths²
- Outbreaks predicted to become more frequent due to climate and environmental changes³

1. CDC. What is Ebola Virus Disease? <https://www.cdc.gov/vhf/ebola/about.html> 3. Redding et al. *Nat Commun* **10**, 4531 (2019).

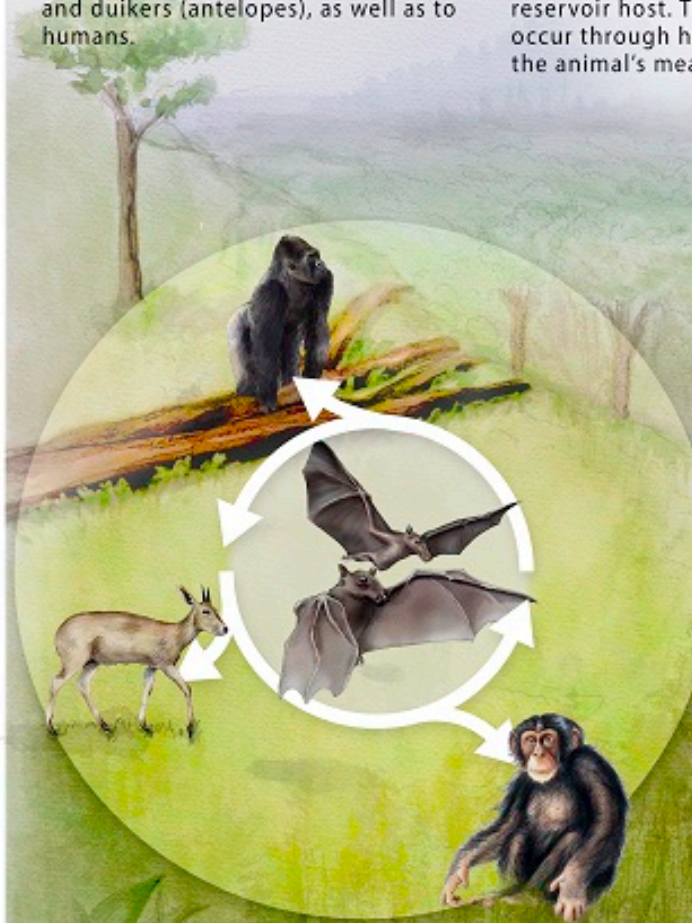
2. CDC. 2014-2016 Ebola Outbreak in West Africa.

Ebola Virus Ecology and Transmission

Ebola virus disease is a zoonotic disease. Zoonotic diseases involve animals and humans.

Animal-to-Animal Transmission

Evidence suggests that bats are the reservoir hosts for the Ebola virus. Bats carrying the virus can transmit it to other animals, like apes, monkeys, and duikers (antelopes), as well as to humans.



Spillover Event

A "spillover event" occurs when an animal (bat, ape, monkey, duiker) or human becomes infected with Ebola virus through contact with the reservoir host. This contact could occur through hunting or preparing the animal's meat for eating.



Human-to-Human Transmission

Once the Ebola virus has infected the first human, transmission of the virus from one human to another can occur through contact with the blood and body fluids of sick people or with the bodies of those who have died of Ebola.



Survivor

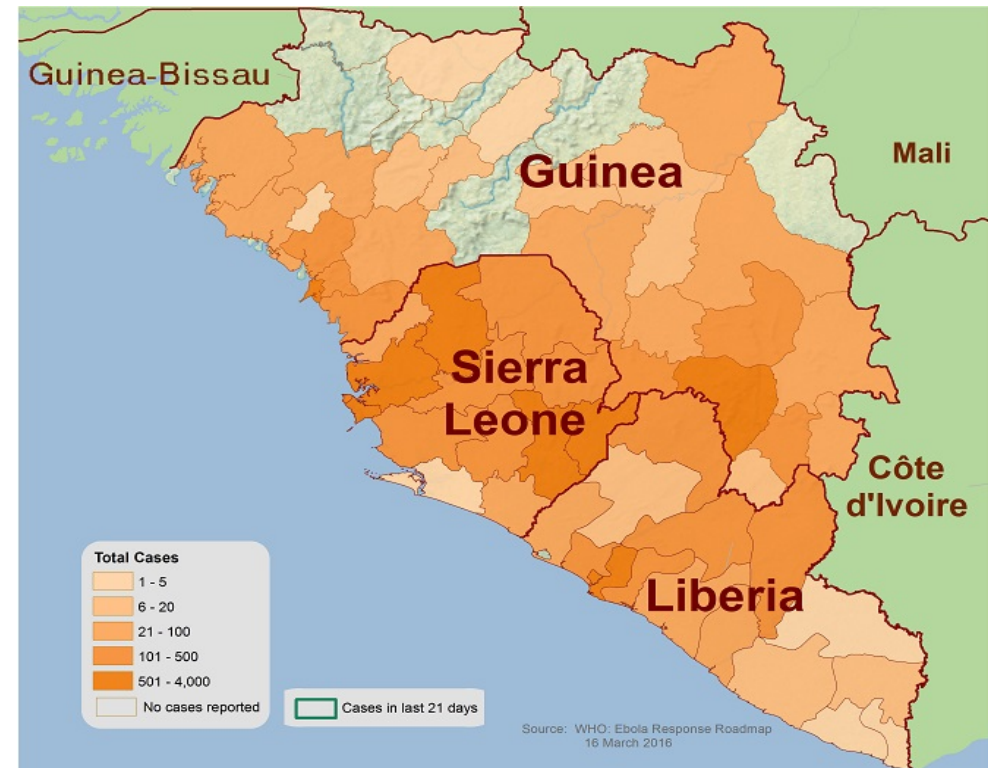
Ebola survivors face new challenges after recovery. Some survivors report effects such as tiredness and muscle aches, and can face stigma as they re-enter their communities.



2014-2016: Ebola outbreak in West Africa

The most severe Ebola epidemic in history

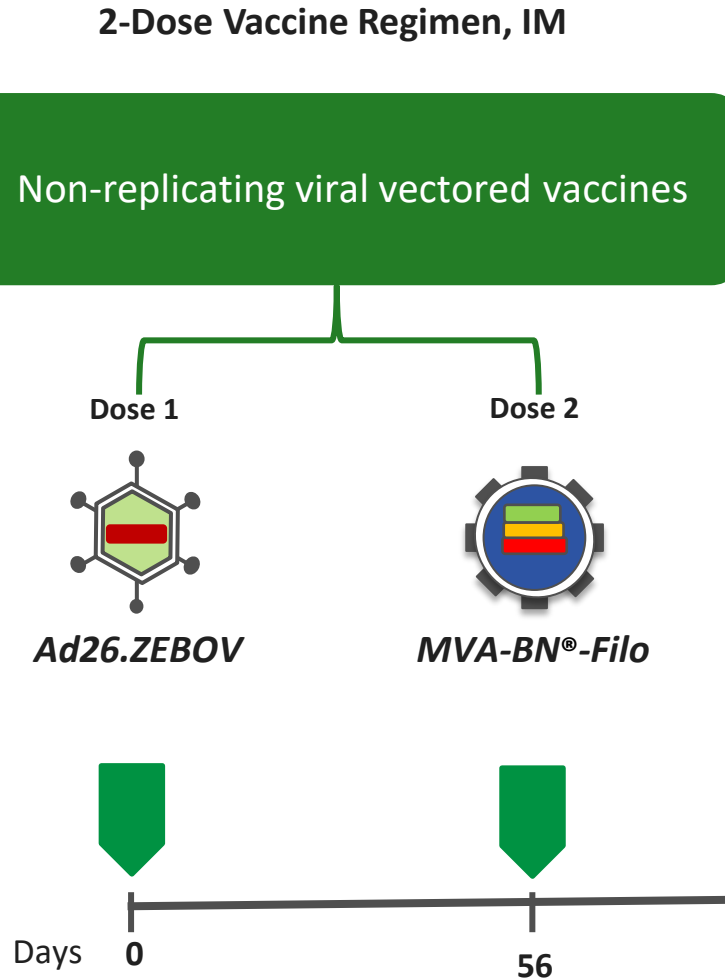
- December 2013 – Unidentified disease kills ‘patient zero’ in Guinea
- August 2014 – WHO declared Ebola a Public Health Emergency of International Concern (PHEIC)
- June 2016 – Outbreak ends
- **No vaccine/cure available at this time**
 - 28,652 reported cases
 - 11,310 deaths¹**
- **Critically urgent to develop and test a prophylactic vaccine against Ebola to protect people and prevent spread**



Source: US Centers for Disease Control and Prevention

¹CDC. 2014-2016 Ebola Outbreak in West Africa

Accelerated development of an Ebola vaccine



- August 2014 – Janssen accelerated Ebola Vaccine Program in response to Ebola outbreak
- **Two-dose heterologous regimen:**
 - 1: Ad26.ZEBOV (Janssen)
 - 2: MVA-BN-Filo (Bavarian Nordic)
- Protection in animal studies (56-day interval regimen) against Ebola Virus challenge
- Innovative Medicines Initiative 2 (IMI2) grants awarded to EBOVAC 1 and EBOVAC2 consortia in December 2014 and to EBOVAC3 consortium in June 2018.

IMI funded EBOVAC clinical trials (1)



Phase 1 study in EU

- Establish preliminary safety and immunogenicity (first-in-human study)
- Evaluate sequences and intervals between doses
- Investigate durability of immune responses

Phase 1 studies in Africa

- Confirm preliminary safety and immunogenicity data of first-in-human study in countries unaffected by the outbreak



Phase 2 studies in EU/Africa

- Expand safety experience on selected schedules
- Evaluate safety and immunogenicity in children, elderly, HIV+ (Africa)
- Safety and immunogenicity of booster dose in adults



Phase 3 study in Sierra Leone

- Staged approach to evaluate vaccine effectiveness if outbreak permissive
- Collect additional safety and immunogenicity data to bridge with NHP data
- Additional safety and immunogenicity in children
- Safety and immunogenicity of a booster dose in adults

IMI funded EBOVAC clinical trials (2)



PREVAC study site in Sierra Leone

- Safety and immunogenicity of two-dose Ad26.ZEBOV, MVA-BN-Filo vaccine regimen, rVSVΔG-ZEBOV-GP and two-dose rVSVΔG-ZEBOV-GP

Phase 2 booster study in children in Sierra Leone

- Safety and immunogenicity of a booster dose in previously vaccinated children

Phase 2 booster study in HIV+

- Safety and immunogenicity of a booster dose in previously vaccinated HIV+ adults



Phase 2 study in infants

- Establish safety and immunogenicity in infants (4-11 months old)

Phase 2 study in FLWs in DRC

- Safety and immunogenicity of a booster dose in previously vaccinated HIV+ adults
- Safety and immunogenicity of a booster dose given at either 1 or 2 years

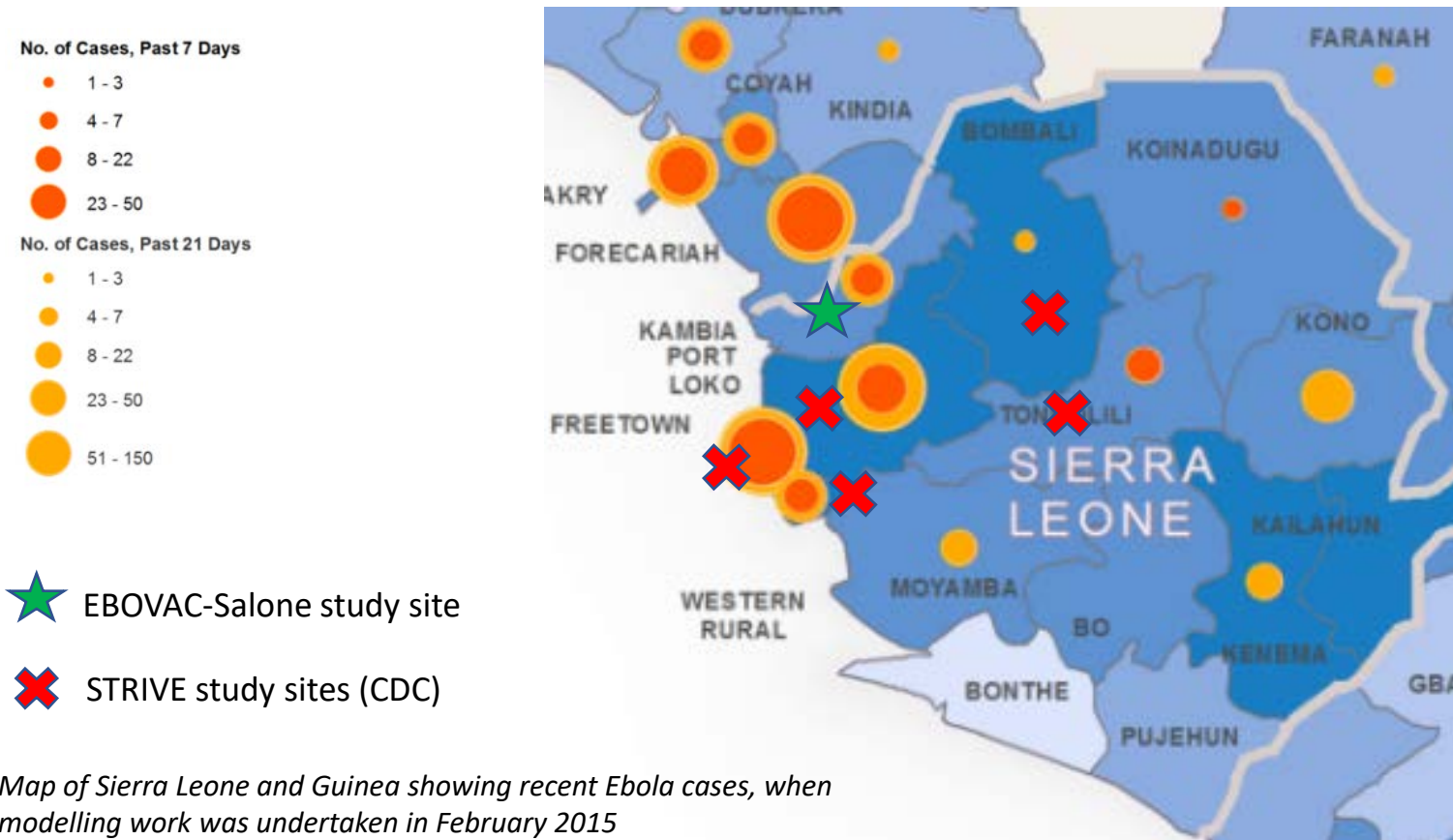
Long term follow-up of participants previously vaccinated in Sierra Leone

- Long-term follow-up of previously vaccinated adults and children
- Safety in children conceived by female participants up to 5 years of age

Selecting a study site in Sierra Leone

Selection of Kambia District, Northern Sierra Leone

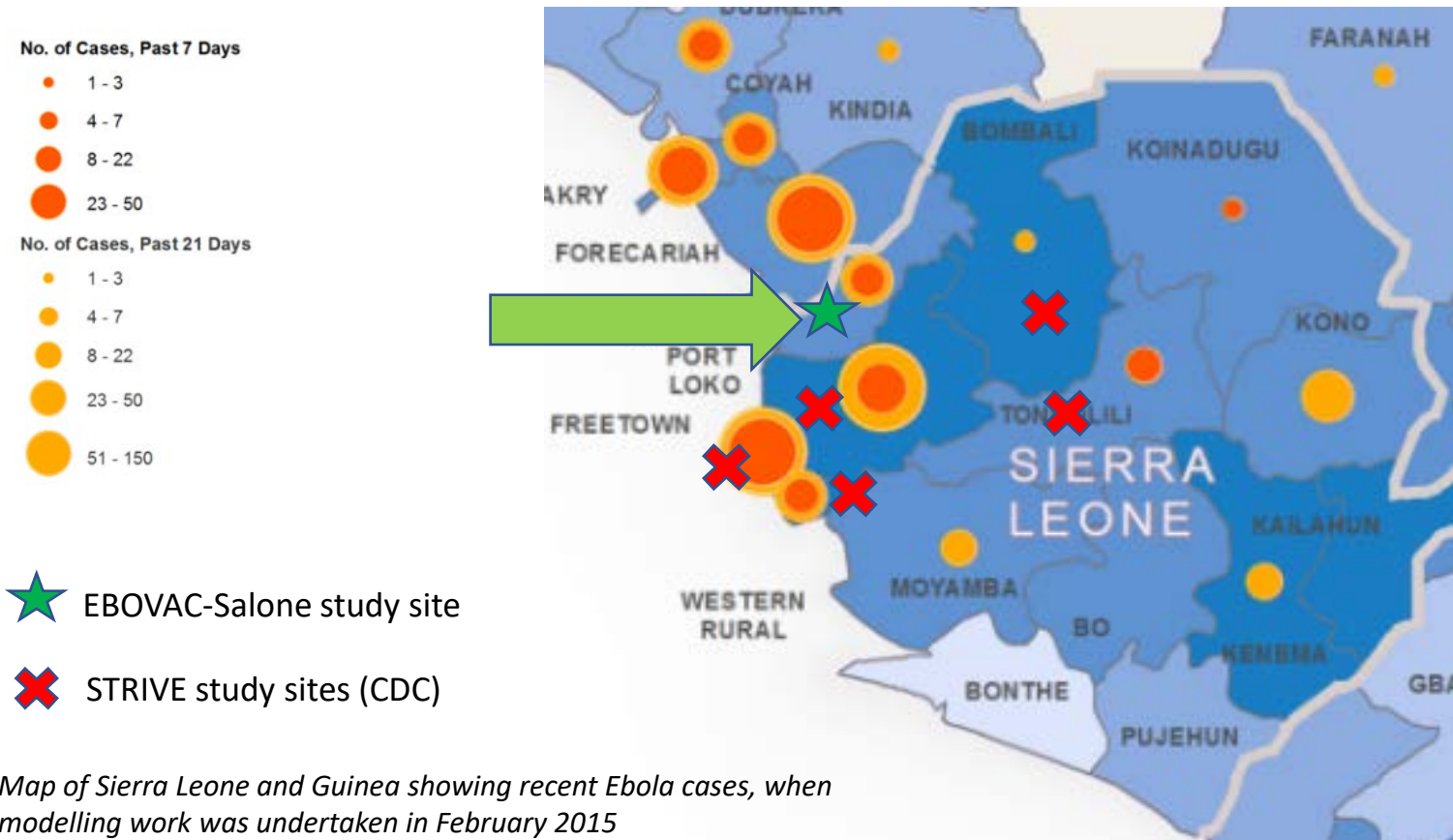
- Avoid communities hosting other Ebola vaccine trials
- Stakeholder and community support
- Likelihood of trial establishing vaccine effectiveness



Selecting a study site in Sierra Leone

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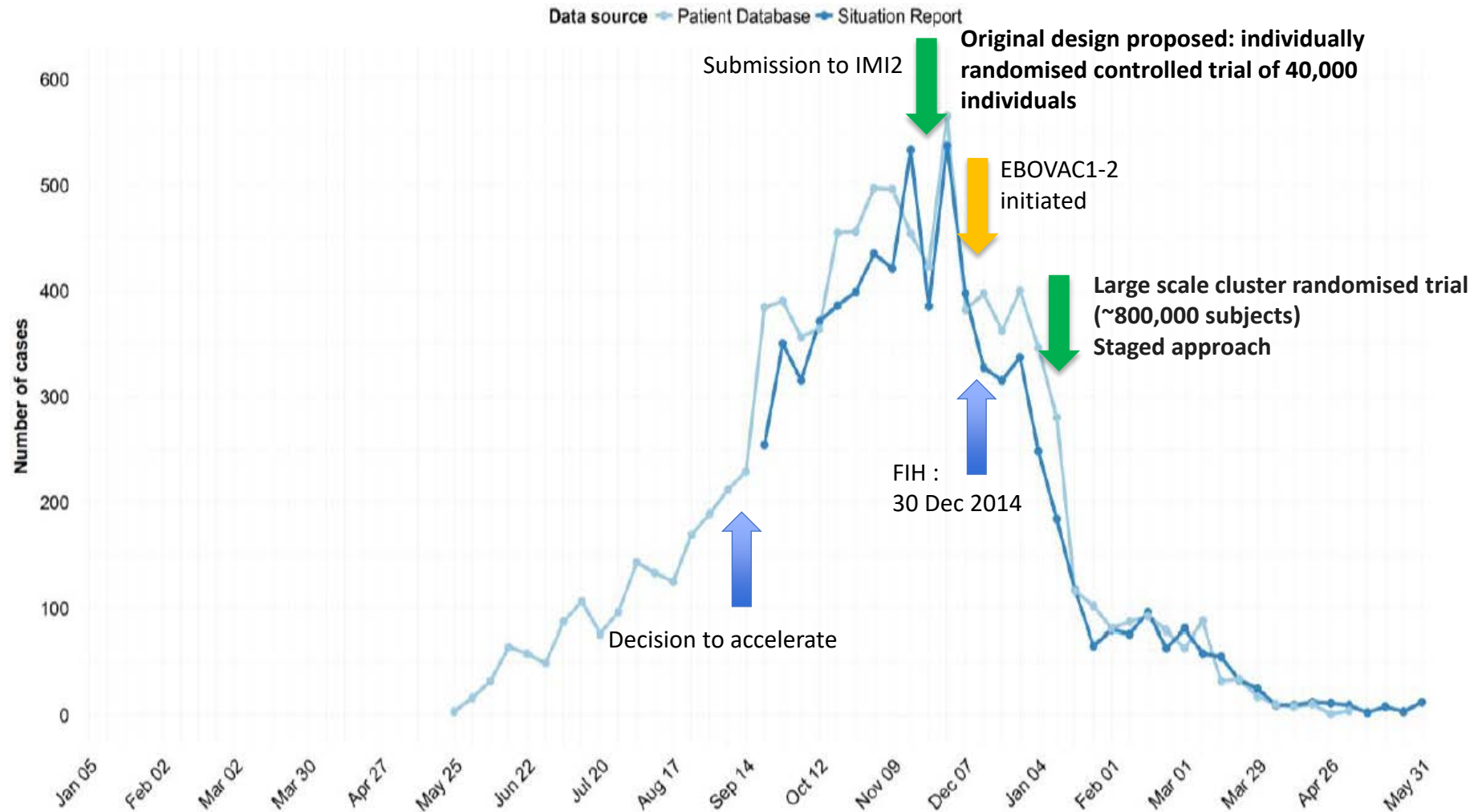
- Avoid communities hosting other Ebola vaccine trials
- Stakeholder and community support
- Likelihood of trial establishing vaccine effectiveness



Map of Sierra Leone and Guinea showing recent Ebola cases, when modelling work was undertaken in February 2015

Trial design and the epidemic

Initial study design of the Phase 3 study had to be adapted as epidemic unfolded



Source: LSHTM

Partnerships – EBOVAC1 and EBODAC

- Funding approved before many partnerships in place
- Not all ‘classical’ research partners

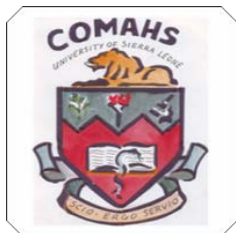
EBOVAC1 (consortium members and partners)

- London School of Hygiene & Tropical Medicine (coordinator)
- Inserm
- Janssen Vaccines & Prevention B.V
- College of Medicine and Allied Health Sciences (University of Sierra Leone)
- University of Oxford; Kavi (Kenya), MITU (Tanzania), MRC/UVRI (Uganda)
- GOAL



EBODAC (Ebola Vaccine, Deployment and Compliance) consortium members:
LSHTM, Grameen Foundation, World Vision

LONDON
SCHOOL of
HYGIENE
& TROPICAL
MEDICINE



EBOVAC2 and EBOVAC3

(consortium members and associated partners)

EBOVAC2

- Inserm (coordinator)
- Centre Muraz
- Janssen Vaccines & Prevention B.V.
- LSHTM
- University of Oxford
- Inserm Transfert



EBOVAC3

- LSHTM (coordinator)
- Janssen Vaccines & Prevention B.V.
- University of Antwerp
- University of Kinshasa
- COMAHS
- Inserm
- Coalition For Epidemic Preparedness Innovations (CEPI)

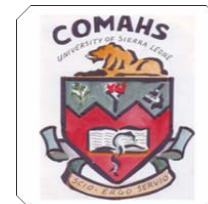


Inserm

InsermTransfert



LONDON SCHOOL of HYGIENE & TROPICAL MEDICINE



UNIVERSITE DE KINSHASA



Universiteit Antwerpen

CEPI



Thank you!



● IMI Impact on Ebola: Clinical Development Program



Cynthia Robinson, MD



IMI Impact on Ebola

- The challenge....



Vaccination site in Kambia, Sierra Leone

From this in 2014

Zabdeno [Share](#) [RSS](#)

ebola vaccine (Ad26.ZEBOV-GP [recombinant])

AUTHORISED
This medicine is authorised for use in the European Union.

Table of contents

- [Overview](#)
- [Authorisation details](#)
- [Product information](#)
- [Assessment history](#)

Overview

Zabdeno is a vaccine to protect adults and children aged one year and older against Ebola virus disease caused by *Zaire ebolavirus*. It is used with another Ebola vaccine called Mvabea as part of a vaccine regimen.

EMA Face sheet for Zabdeno®

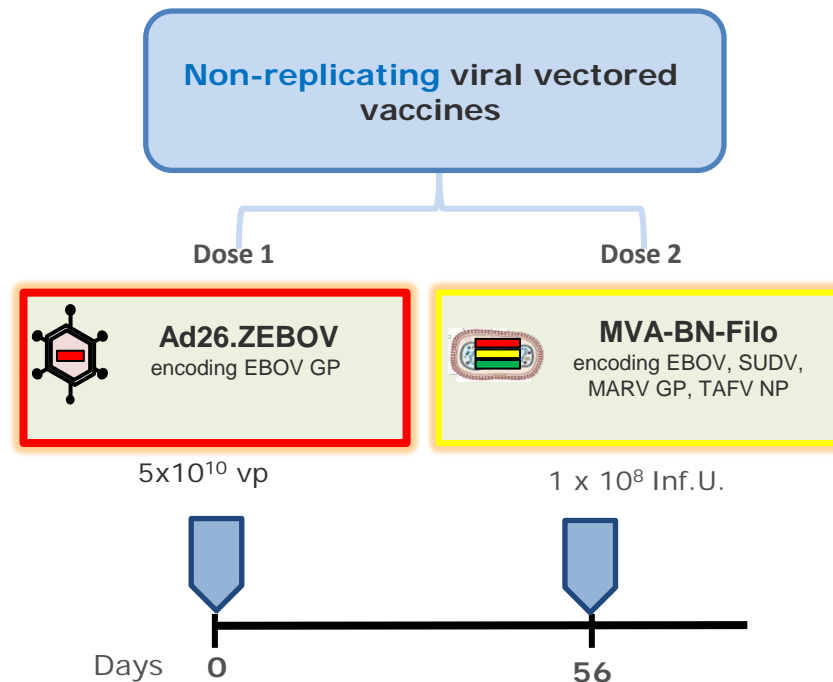
To this in 2020



Aim of the Clinical Program of the 2 dose vaccine regimen

- o The overall aim of the **EBOVAC** programme was to assess the safety, immunogenicity and efficacy of a novel 2-dose heterologous preventive vaccine regimen against Ebola Virus Disease.

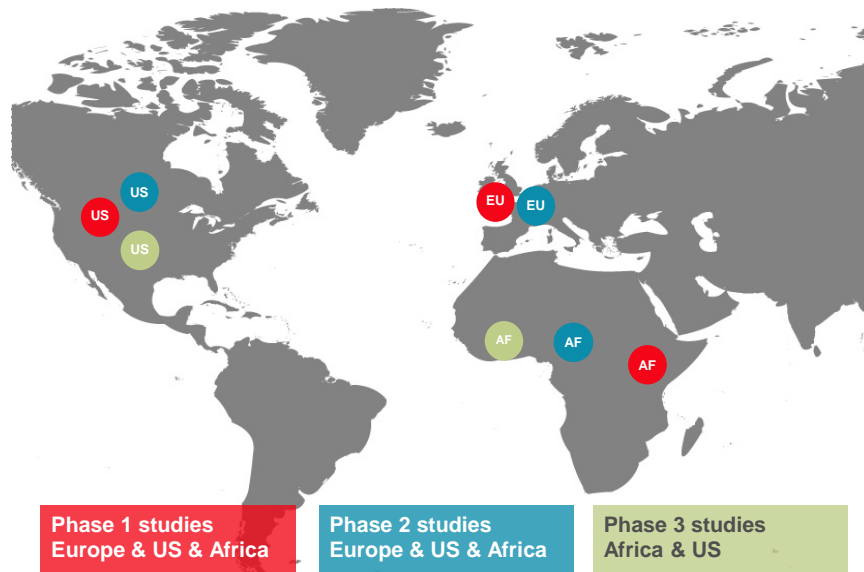
Primary vaccination: 2-Dose Vaccine Regimen,
given approximately 8 weeks apart



Both vaccines are
non-replicating in
humans

Robust Clinical Development

- **23 clinical trials sponsored by J&J or our partners** (Phase 1/2/3) in Europe, US and Africa
- Participants include [**adults** (18-50yrs), **older adults** (>50-70yrs), **HIV+ adults**, **children** (1-17yrs)], **infants** (4-11 months)
- **Phase 3 study in pregnant women ongoing in Rwanda**



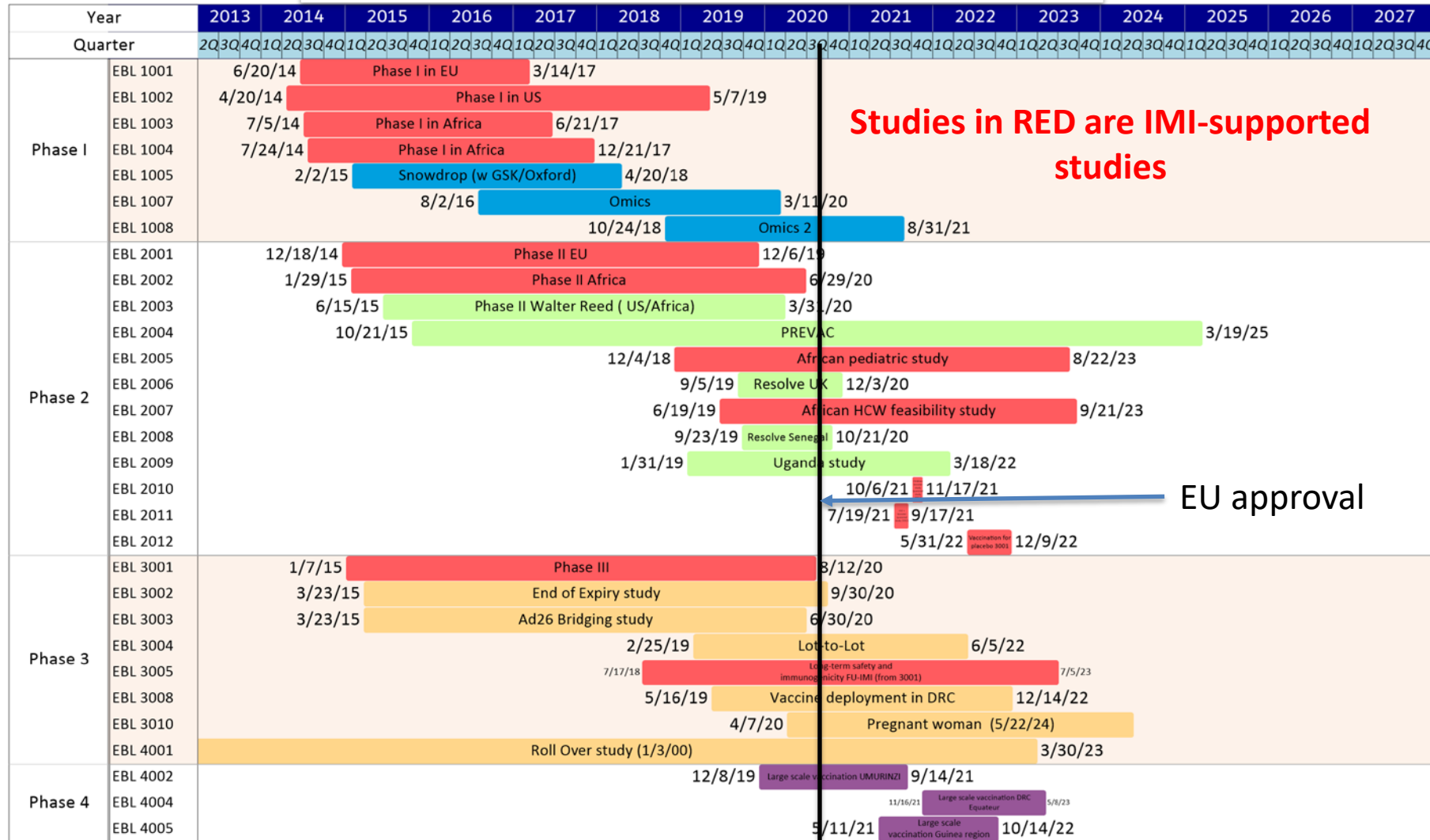
**And a cumulative experience of
> 260,000 vaccinations**

- Vaccination campaign in Rwanda (under emergency use authorization) with 216,229 participants
- Large scale study in DRC with 20,427 participants
- Large early access clinical trial in West-Africa > 8,400 participants in Sierra Leone to date (goal: up to 200,000 across West Africa)

EBOVAC studies figured prominently
in the successful licensing of the vaccine
by EMA July 2020

https://www.ema.europa.eu/en/documents/product-information/zabdeno-epar-product-information_en.pdf
https://www.ema.europa.eu/en/documents/product-information/mvabea-epar-product-information_en.pdf
WHO Weekly Epidemiological Record 4 JUNE 2021, 96th YEAR /No 22, 2021, 96, 197–216/<http://www.who.int/wer>

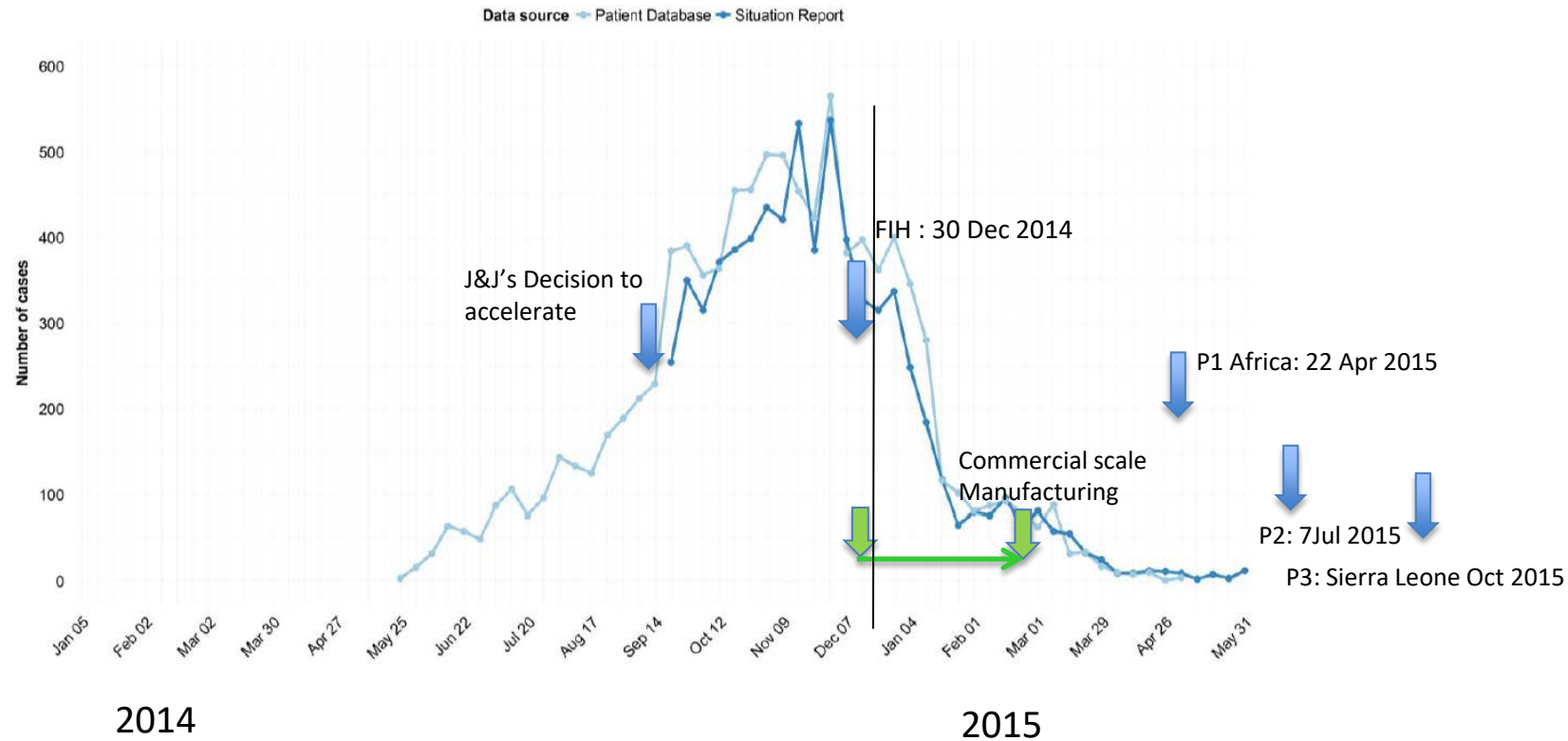
IMI Impact on Ebola: Clinical Program



Data from Planisware

C. Robinson

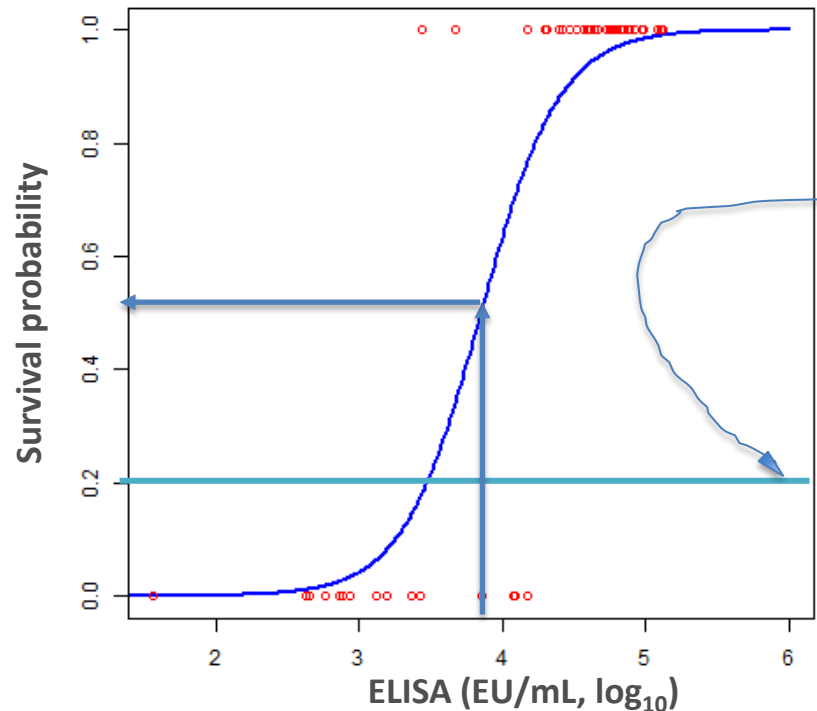
IMI Impact on Ebola: Pathway to Licensure



The Challenge...how to infer clinical benefit in the absence of an outgoing outbreak

FDA and EMA approved Immunobridging (IBr) Strategy: Inferring Clinical Benefit

'Animal Rule'



- Animal model used to determine clinical benefit of **human antibody concentrations**
- Calculate mean survival probability and **95% confidence interval** using a statistical method
- Clinical benefit demonstrated if lower limit of 95% CI is above **pre-specified success criterion of 20%** (strategy accepted by FDA and EMA)
- Animal model of Ebola is more aggressive than Ebola in humans:
 - Model can provide **evidence for clinical benefit**
 - Model **cannot quantify vaccine effectiveness**, as 1:1 translation gives **underestimation of clinical benefit**
 - Quantification of the actual **clinical effectiveness** must be determined **in a field study** (requirement of the Animal Rule)

- Immunobridging: Roozendaal R et al., npj Vaccines, 2020; 5, 112
- EMA Zabdeno, Public assessment report, https://www.ema.europa.eu/en/documents/assessment-report/zabdeno-epar-public-assessment-report_en.pdf



IMI Response to Ebola: **Pathway to Licensure**

Successful Immunobridging

Per Protocol Immunogenicity Analysis Set	Ad26.ZEBOV, MVA-BN-Filo (0,56)
N	1550
Mean Predicted Survival Probability (95.7% CI)	57.3% (41.2% ; 71.0%)

- The 95.7% CI lower limit of **41.2%** passes the pre-specified success criterion of 20%
 - Evidence for clinical benefit successfully demonstrated at final analysis
- In view of the stringency of the model, the point estimate cannot be used for absolute quantification of vaccine efficacy in humans.
- Estimate of clinical effectiveness and duration of protection to be demonstrated in subsequent studies (eg, EBL4006)



IMI Impact on Ebola: **Safety of the vaccine**

Safety

- Safety and tolerability were assessed by means of a diary card and investigator inquiry to collect local and overall body symptoms
- **Vaccine regimen is safe** and well tolerated **in adults**;
adverse events similar to the experience with other vaccines
- **Vaccine regimen is safe** and well tolerated **in children down to 1 year of age**;
adverse events generally similar to other pediatric vaccines
- **Vaccine regimen is safe** and well tolerated **in infants down to 4 months of age**

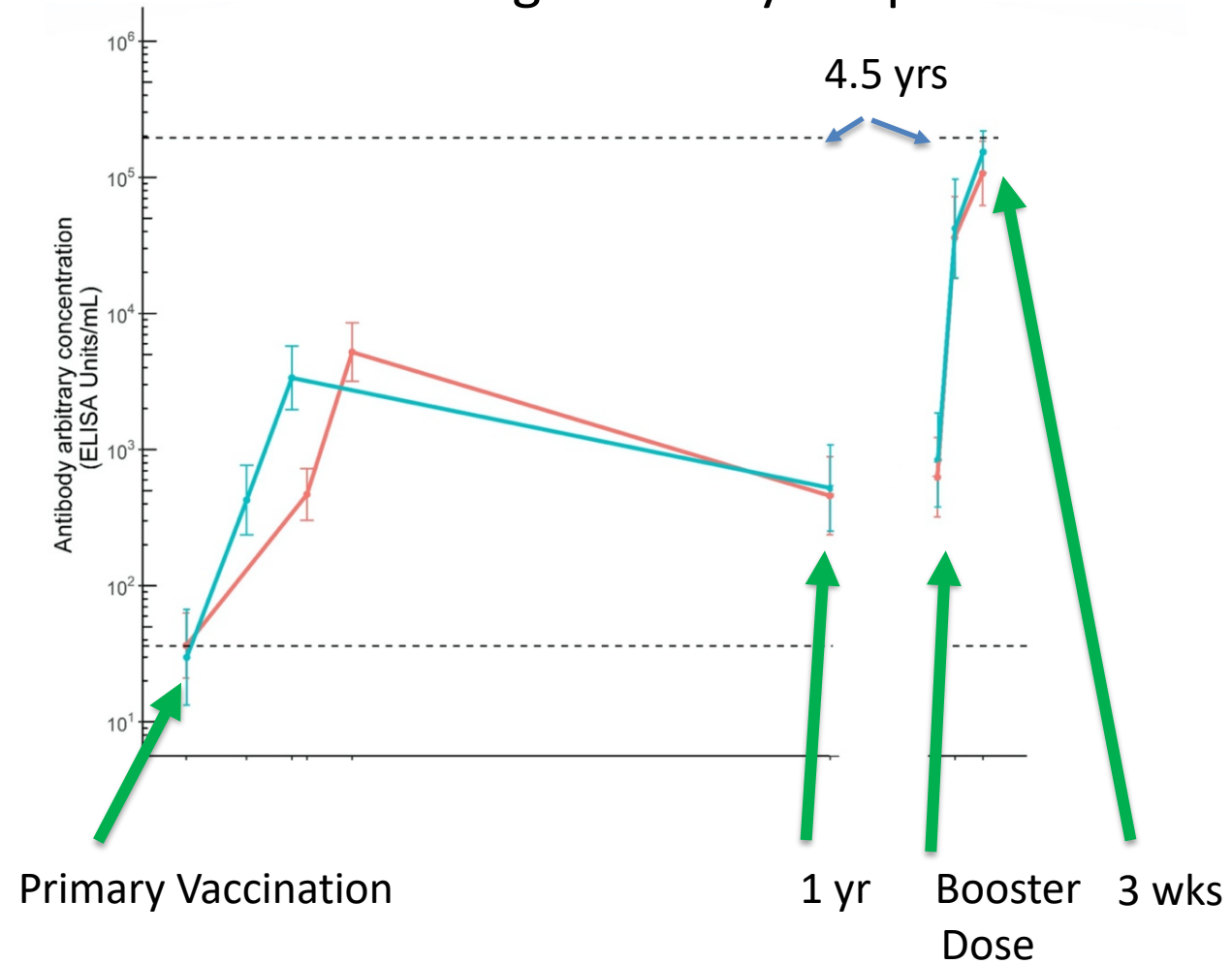
For more info, consult [hyperlink 1](#) and [hyperlink 2](#)

IMI Impact on Ebola: **Antibody response**

Persistence of Binding Antibody Response

Results in HIV+ Adults, who received another dose, ~4.5 years after the primary series

Submitted Choi et al LID, 2023



Vaccine provides a robust memory response years later



IMI Impact on Ebola: **Ongoing Impact**

Regulatory Approval Status

Zabdeno[®] (Ad26.ZEBOV), Mvabea[®] (MVA-BN-Filo) vaccine regimen indicated for active immunization to prevent disease caused by Ebola virus (Zaire) in individuals ≥ 1 year of age in the EU

EU Marketing Authorization obtained 01 July 2020 (EC Decision)

- Approval pathway: exceptional circumstances*)

WHO prequalification in April 2021

- Based on EMA dossier
- Parallel review with two National Regulatory Authorities in Africa

Approvals now in 5 African countries

- Ghana, Cote D'Ivoire, Uganda, Rwanda, ATU in DRC

For more info, please consult this [hyperlink](#)

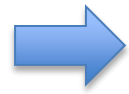


IMI Impact on Ebola: **Summary**



Private-public partnerships **critical** for successful registration of the vaccine

- Financial support
- Partners' contributions
- Unique set up of partnership



Ongoing partnerships' support **critical** for setting up the vaccine for its intended use

- Answering additional questions about vaccine



Lasting legacy of these commitments

- Safety data collected here benefits other vaccines like COVID
- Publications
- Capacity maintenance (training of personnel, attraction for new projects)
- Lessons learned for accelerated development
 - i.e. Immunobridging, community engagement



Thank you!



- **Additional benefits of the IMI investment for capacity strengthening**



Prof. Bailah Leigh
College of Medicine & Allied Health Sciences
Sierra Leone

Phase 1 trial sites

- Fast-tracked studies
- Oxford – many volunteers
- Kenya, Tanzania, Uganda sites
- Not affected by Ebola
- Chosen because of vaccine trial experience; allow fast set-up for these critical early phase trials
- Capacity-building was done through conduct of the studies with training etc.
- Raised awareness of West African outbreak



Challenges for EBOVAC in Ebola Virus Disease affected countries

Lack of infrastructure

Some sites had no suitable premises to host trial or laboratories

Lack of power/electricity and water

Some countries had little/no experience with vaccine trial research

- Research management skills needed strengthening in some sites
- Few staff experienced in leading vaccine trials

Human resources

- Shortage of health workers & scientists in countries
- Health workers were dying of Ebola
- In Sierra Leone - balance of priorities at Ministry of Health level: clinical vs. research



Kambia. Source: LSHTM



Kambia Town. Source: LSHTM

Challenges for EBOVAC in Ebola Virus Disease affected countries

Equipment & maintenance

- Technical support gap (e.g. skilled biomedical technicians)
- Maintenance/servicing of equipment challenging e.g. engineers came from far away (Ghana/Kenya)

Supply chain challenges & shipments

- Increasingly difficult in many Low and middle Income countries
- Remote location e.g. Boende; only accessible by air (or a boat trip of 10 days)

COVID pandemic

- Temporary closure of field work; supply shortages

Remote Locations

Boende in Democratic Republic of Congo (DRC)

- Remote site, only reachable by air (3,5 hours) or by a boat trip (10 days).



Research site in the DRC



Boende, Tshuapa Province, DRC



3,5 hours charter flight
from Kinshasa

Capacity building of the EBOVAC study sites

- IMI investment crucially important for site readiness
- Construction of buildings e.g. vaccine storage depot; set up of an emergency room in Kambia district hospital, Sierra Leone
- Set up of clinics in renovated rented buildings (e.g. Kambia, Mambolo, Sierra Leone) or in local hospitals (e.g. Boende, DRC)
- No power supply in some sites – generators and fuel supply chain established
- Installation of internet service
- Improvement in participant identification processes e.g. iris scanning

VACCINE DEPOT



EMERGENCY ROOM



KAMBIA CLINIC

REFERENCE HOSPITAL BOENDE



Expanding laboratory capacity in sites

KAMBIA RESEARCH LABORATORY



CLINICAL LABORATORY



IMMUNOLOGY/SEROLOGY LABORATORY



PCR LABORATORY



LIQUID NITROGEN PLANT

Training

Clinical staff

- Good Clinical Practice (GCP) & Protocol procedures
- Emergency medicine training & paediatric care training
- Methodology of vaccine trials, Centre Muraz, Burkina Faso

Pharmacy / cold chain

- Blinding and allocation concealment
- Sustaining the cold chain
- Vaccine monitoring and accountability

Laboratory

- Good Clinical Laboratory Practice (GCLP)
- Technical skills training (new assays: PCR, Luminex, Elispot, ELISA etc.)
- Sample transport, management and storage



By courtesy of Francois Guenet (INSERM).



Training (2)

Data

- Data management training & basic statistical software training

Qualitative research training

- E.g. study design, interview techniques, analysis

Research administration and logistics

- Stock management software training
- Administration, procurement and finance systems training

All training helped sites for future research e.g. for EBOVAC3

Ethics and regulatory review – how did the EBOVAC projects engage and support the process?

- Extensive communications with Ethics Committees & Regulatory authorities
- Expedited review processes for Ebola-related studies during outbreaks
- Engagement with the African Vaccine Regulatory Forum (AVAREF)
 - a platform for conducting joint reviews of clinical trial applications.
 - AVAREF assisted with regulatory and ethics review capacity in countries where EBOVAC trials were proposed
 - Face-to-face meeting with AVAREF in Tanzania for the phase 1 trials and in Ghana for Phase 3 trial in Sierra Leone to help with addressing questions on the protocols
- EBOVAC3 has also investigated experiences of ethics and regulatory bodies in Guinea, Sierra Leone and DRC during past Ebola outbreaks to improve preparedness for the next outbreak



EBOVAC3 workshop with Ethics Committees and Regulators of Sierra Leone and Guinea (7th – 8th March 2022, Conakry)

Conclusions

- IMI investment in EBOVAC/EBODAC projects has greatly assisted in capacity strengthening for future trials as well as allowing the EBOVAC studies and trials to be conducted at a very high standard and in contributing to vaccine strategies to prevent and control Ebola in the future.
- The EBOVAC/EBODAC projects have also built confidence in conducting vaccine trials and other research studies in these countries and, with that experience, many EBOVAC and EBODAC staff have gone on to do Masters and other post-graduate trainings.
- The laboratory and data management strengthening will be invaluable for research in infectious diseases and future outbreaks of emerging infections.



Thank you!



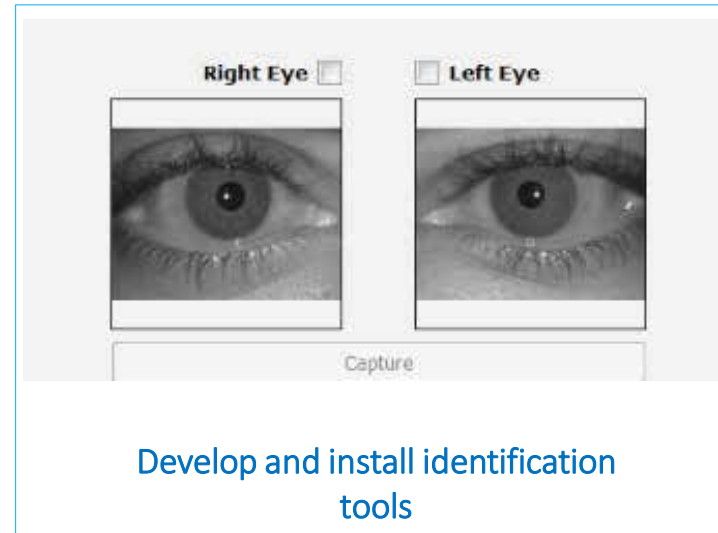
EBODAC Support to Vaccine Trials



Annik Willems
Program Leader, Janssen

EBODAC Support to Vaccine Trials

Ensuring the 2-dose Ebola vaccine regimen is well accepted & successfully deployed amongst communities in West-Africa



OUR MISSION:
Building a modular platform scalable for successful deployment of Ebola vaccines

Key Lessons

- Context matters: historical, political, social and economic factors that influence trust in vaccines
- Power, Fairness and Trust: developing engagement strategies grounded in local knowledge and experience
 - E.g. diversifying engagement to take into account power dynamics within communities and informal authority, i.e. there is not “one community”
- Motivations for joining: sacrifice and citizenship in a time of crisis; access to healthcare; curiosity and hope
- Translation challenges and opportunities between the social and clinical sciences



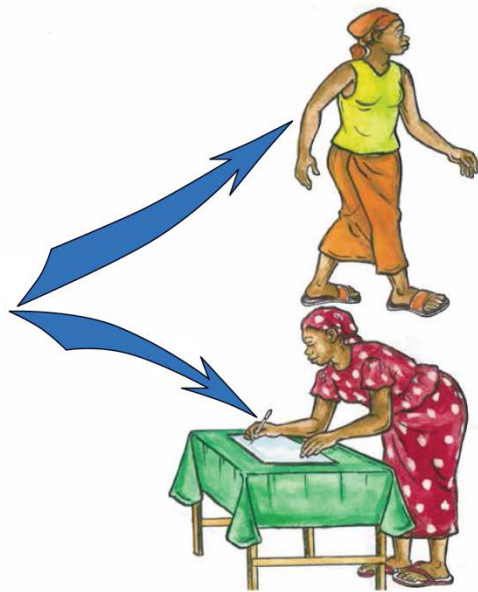
Beyond Crisis: Community preparedness

- Memories of Ebola have generated new ways for communities to prepare for future outbreaks
- Establishment of community-level systems to monitor and respond (e.g. informal border checks during Guinea Ebola outbreak in 2021)
- Social science research continues to explore these perspectives and how nuanced contextual understandings of social dynamics can contribute to develop better response strategies
 - E.g. The EBOVAC3 Social Science team works closely with a team of mathematical modellers to study contact patterns in Kambia town



During the consenting process,
a flip chart was used to explain the study

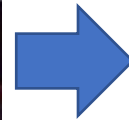
You have a choice



Biometric identification learnings

The biometric kit using iris scan and fingerprint has evolved into a handheld tablet using iris scanning, which our research shows can identify participants down to 3 years of age.

The technology has been used in large-scale Ebola vaccination program in Rwanda (Umurinzi) and supporting WHO's Covid-19 Solidarity vaccine trial.



Leapfrogging with technology: introduction of a monitoring platform to support a large-scale Ebola vaccination program in Rwanda

Paula Mc Kenna^a, Serge Masyn^a, Annik Willems^a, Anne De Paepe^a, Romain Rutten^a, Jean Baptiste Mazarati^b, Felix Sayinzoga^c, Etienne Karita^d, Jean Nepo Nduwamungu^d, Amelia Mazzei^d, Julien Nyombayire^d, Rosine Ingabire^d, Monica Amponsah^e, Seth Gogo Egoeh^e, and Nnamdi Ezeanochie^f

Human Vaccines & Immunotherapeutics, 2021

Overcoming the challenges of iris scanning to identify minors (1–4 years) in the real-world setting

[Serge Masyn](#)^{1,6}, [Anneleen Vuchelen](#)², [Eva Santermans](#)³, [Freya Rasschaert](#)⁴, [Allieu Bangura](#)⁵, [Wim Parys](#)¹ and [Romain Rutten](#)¹

BMC Res Notes. 2019

Mobile Training and Support System (MOTS) developed and piloted in Sierra Leone



Mobile training and support (MOTS) service—using technology to increase Ebola preparedness of remotely-located community health workers (CHWs) in Sierra Leone

Paula Mc Kenna¹, Geoffrey Babughirana², Monica Amponsah³, Seth Gogo Egoeh³, Evelyne Banura³, Robert Kanwagi², Bobbi Gray³

¹Johnson and Johnson Global Public Health, Disease Management Programs, Belgium; ²World Vision International, Dublin, Ireland; ³Grameen Foundation, Washington, DC, USA

Contributions: (I) Conception and design: P Mc Kenna; (II) Administrative support: G Babughirana, R Kanwagi; (III) Provision of study material or patients: M Amponsah, SG Egoeh, B Gray; (IV) Collection and assembly of data: E Banura, G Babughirana; (V) Data analysis and interpretation: P Mc Kenna, G Babughirana, E Banura, B Gray; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

Correspondence to: Paula Mc Kenna, PhD. Disease Management Program Leader, Johnson and Johnson Global Public Health, Disease Management Programs, Belgium. Email: pmckenna@its.jnj.com.

Background: The Ministry of Health in Sierra Leone has developed and operationalized the national Digital Health Strategy to guide integrated roll out of e-health/mobile health solutions. The goal is that “by 2023 an effective and efficient ICT enabled system supports delivery of quality, accessible, affordable, equitable, and timely healthcare services and moves Sierra Leone closer to achieving universal health

mHealth, 2019

Guidebook on community engagement, communications and technology in clinical trials during an outbreak

COMMUNITY ENGAGEMENT, COMMUNICATIONS AND TECHNOLOGY IN EBOLA CLINICAL TRIALS

20-21 FEBRUARY 2017

AKA



A guidebook on Community Engagement, Communications, and Technology for Clinical Trials in Outbreak Settings

London School of Hygiene & Tropical Medicine:
BETH SMOUT, WILL SCHULZ, HEIDI LARSON
Johnson & Johnson Global Public Health:
ANNIK WILLEMS, PAULA MC KENNA

Co-edited by the members of the eboDAC Consortium: London School of Hygiene & Tropical Medicine | Janssen Pharmaceutica NV | World Vision | Grameen Foundation



Document in open access available [here](#)



Deploying an approved vaccine will be especially sensitive to

Populations exposed for first time to relative new disease

Unfamiliar 2-dose regimen and need for repeat visit

Possible deployment during an emergency

The fear Ebola invokes

Post-traumatic stress suffered by those in outbreak areas

Unfamiliar targeting (i.e. high-risk individuals of different ages rather than children)



EBOLA VACCINE COMMUNICATION, COMMUNITY ENGAGEMENT AND COMPLIANCE MANAGEMENT (3C) GAP ANALYSIS TOOL

NOVEMBER 2019

For countries to assess their outbreak preparedness

Validated in the Democratic Republic of the Congo, Uganda and Senegal



Document in open access available [here](#)

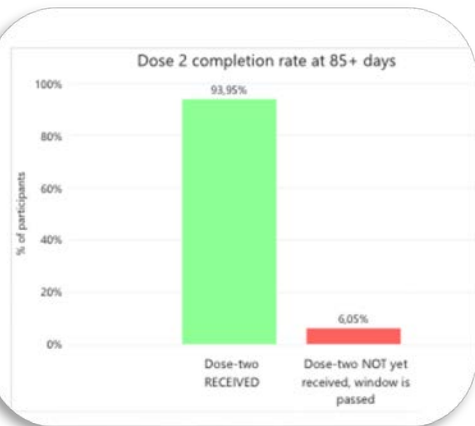
From Ebola to COVID-19



Rwanda Ministry of Health: Umurinzi Ebola vaccination campaign



~203,000
persons fully dosed



~94%
compliance

Enrolment 8990000644

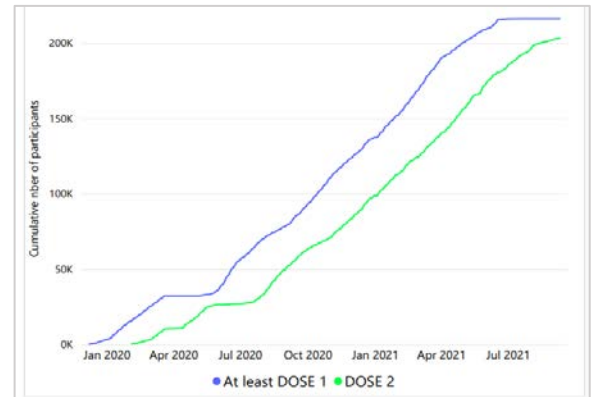
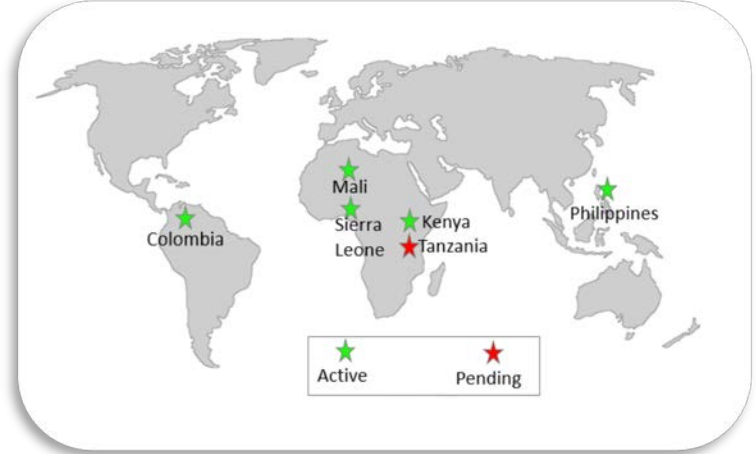
Capturing iris-pair Participant

CAPTURE

To scan the participant's right iris, press 'Capture' when ready

Declared as Digital Global Good

WHO Solidarity Covid-19 Vaccines Trial





Thank you!



The research side in EBOVAC projects



Prof. Rodolphe Thiébaud,
Univ. Bordeaux, France

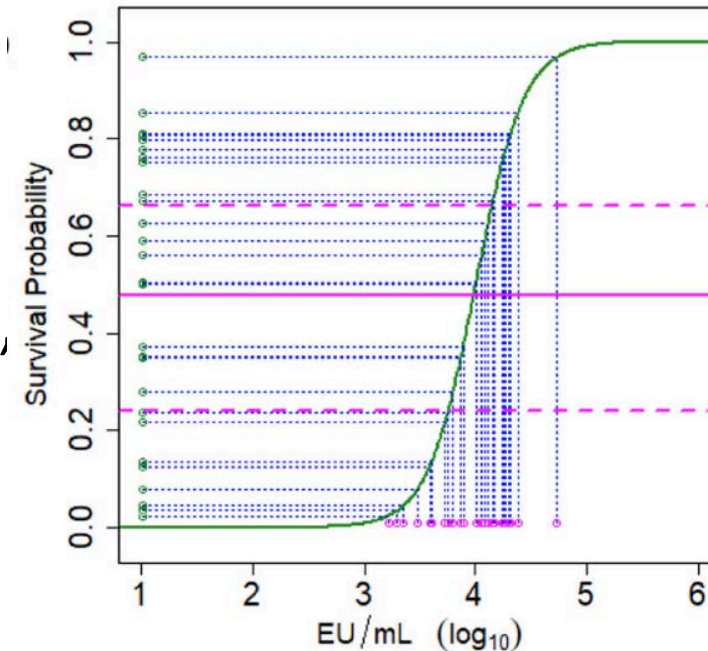
The research side in EBOVAC projects and beyond

- To keep fundamental research activities in the context of an accelerated vaccine development
 - To better understand the effect of the vaccine
 - To be ready to adapt the development
 - To learn beyond the developed vaccine

- Which research projects?
 - Non human primates studies
 - Immunological studies
 - Modelling studies

Non Human Primates studies

- Establish a model of Ebola virus disease
- Use data from Non Human Primate (NHP) to “immunobridge” human antibodies level to the NHP-challenge model



Immunological studies

1st dose Vaccine
(Ad26.ZEBOV)

2nd dose Vaccine
(MVA-BN-Filo)

Stimulate
innate response



Ebola vaccine

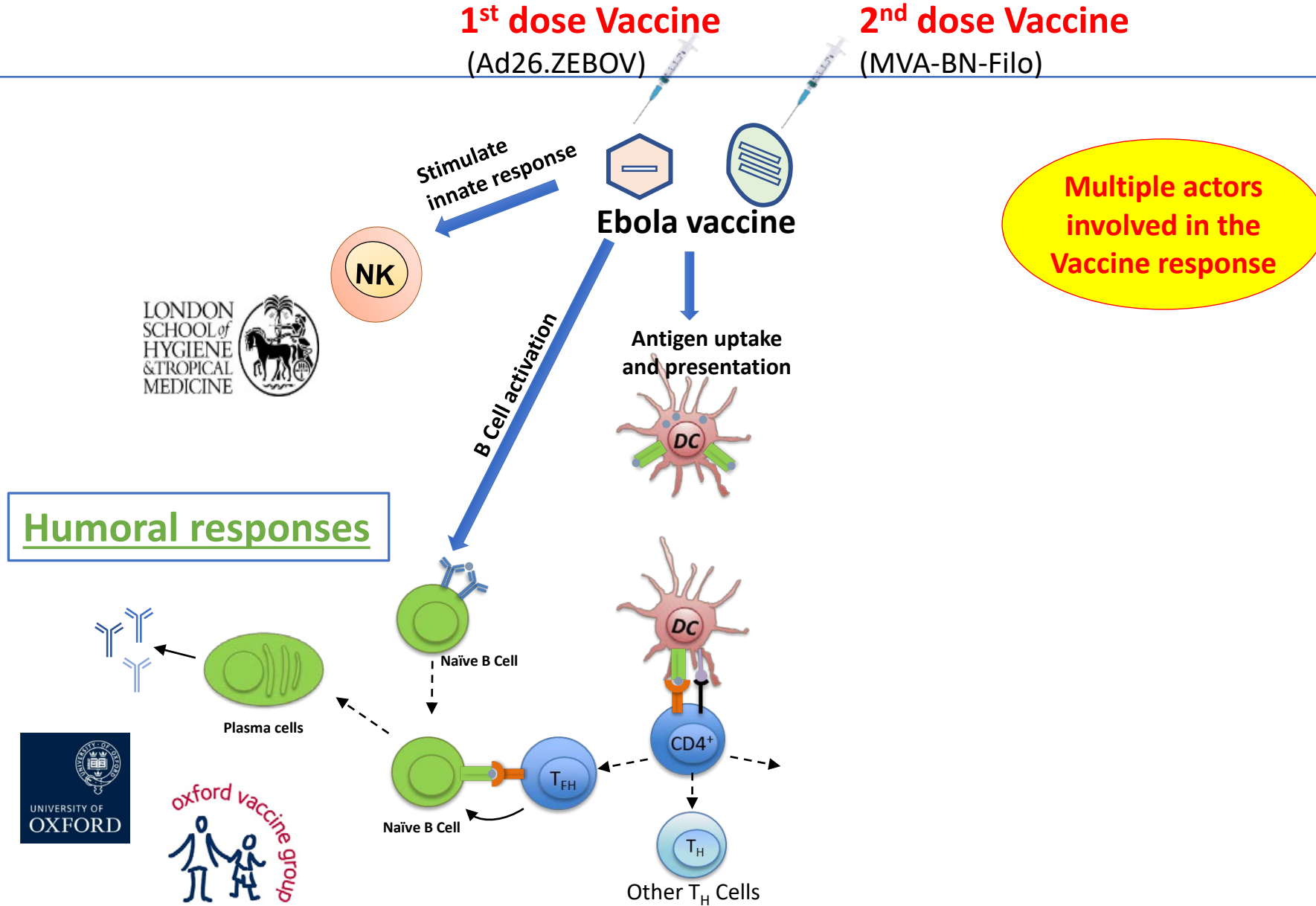
**Multiple actors
involved in the
Vaccine response**



Immunological studies

1st dose Vaccine
(Ad26.ZEBOV)

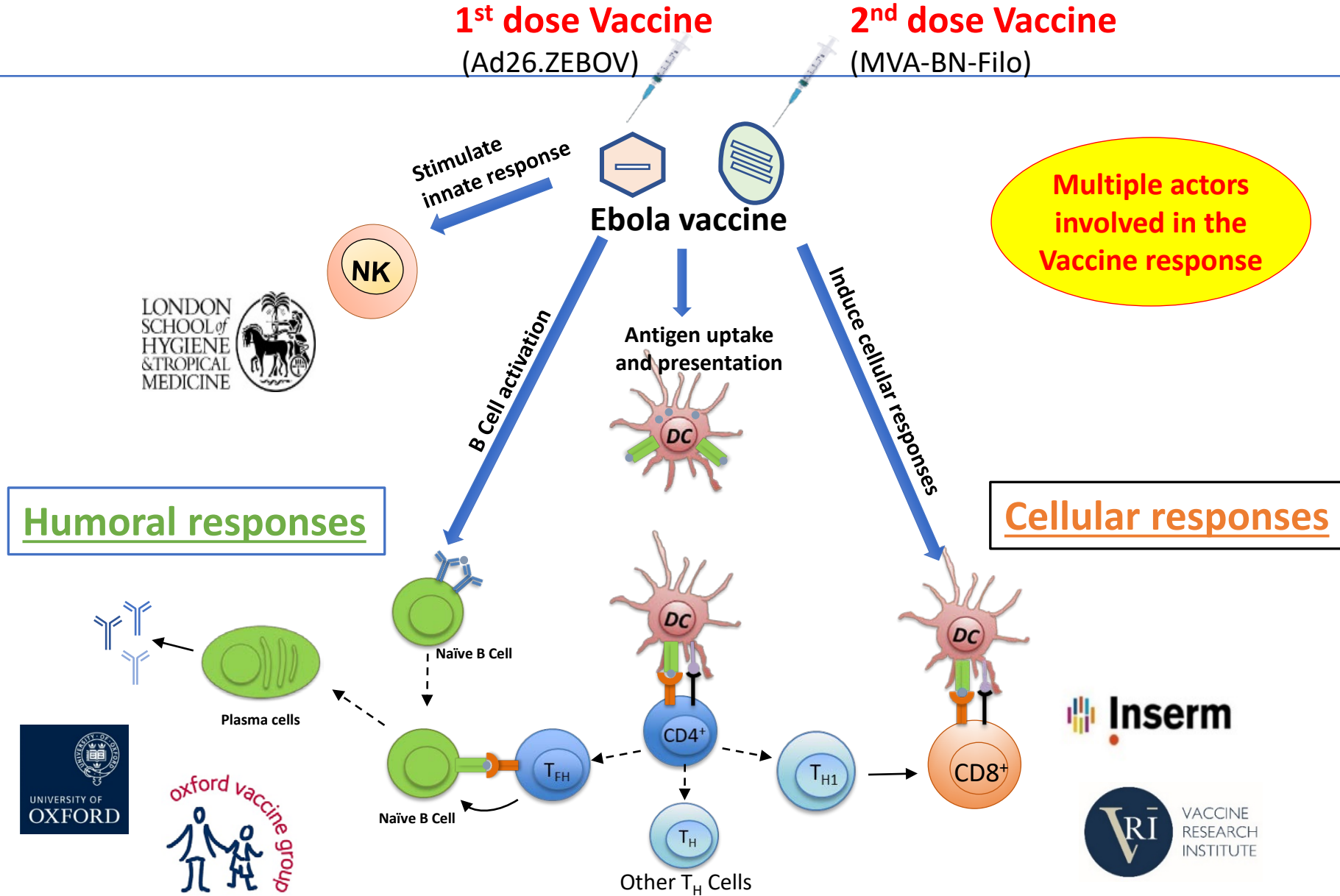
2nd dose Vaccine
(MVA-BN-Filo)



Immunological studies

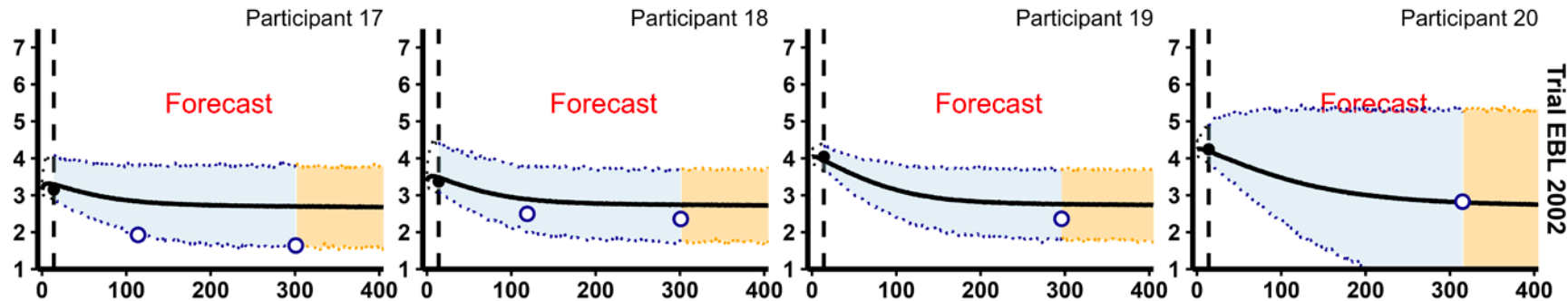
1st dose Vaccine
(Ad26.ZEBOV)

2nd dose Vaccine
(MVA-BN-Filo)



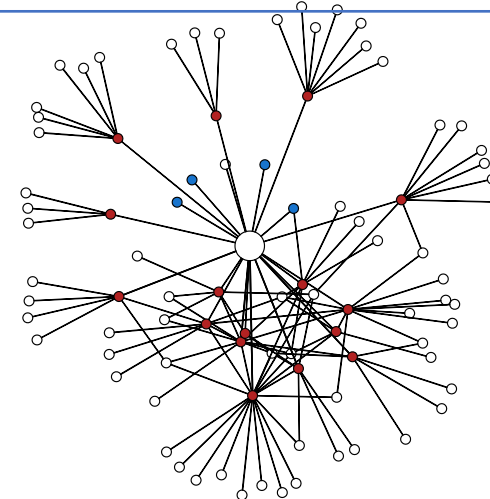
Modelling studies: response to vaccine

- Using mathematical modelling
- Prediction of the duration of the response to vaccine with phase 1 data
- Further confirmed by phase 2 data



Modelling studies: Ebola transmission

- Using mathematical modelling of Ebola transmission between hosts



- To assess the impact of different vaccination programs (e.g. ring vaccination versus mass vaccination) to control outbreaks of Ebola Virus Disease
- To maximise the power and optimise the design of any new study using model predictions

Concluding remarks

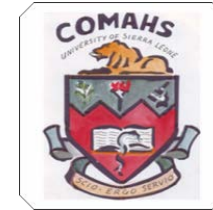
- An example of accelerated vaccine development program which was **crucial** for getting a vaccine ready to be used to **protect populations against Ebola Virus Disease**
 - With **Full involvement** from institutions to people in the field
 - With **Capacity building**
 - With **Innovation**
 - With **Multidisciplinarity**

eboVAC1

eboVAC2

eboVAC3

eboDAC
Ebola vaccine Deployment, Acceptance and Compliance



These projects have received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement Nos 115854 (EBOVAC1), 115861 (EBOVAC2), 800176 (EBOVAC3) and 115847 (EBODAC). This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and the European Federation of Pharmaceutical Industries and Association.



Q&A time



Use the **chat** below to ask questions to the speakers

Global Health EDCTP3 open call for proposals on Ebola

Research to rapidly evaluate interventions on Ebola outbreaks in sub-Saharan Africa

Proposals submitted under this call topic are expected to **advance knowledge on Ebola** virus disease.

Proposals should include one or more of the following areas:

- 1) Clinical development of therapeutics
- 2) Clinical development of point-of-care (POC) diagnostics
- 3) Social sciences research

Deadline date: 29 June 2023 at 17.00.00 (Brussels local time)

Further information can be found at: <https://www.globalhealth-edctp3.eu/>

To stay informed about the upcoming webinars, please visit:

ihi.europa.eu



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Innovative Health Initiative (IHI)



Thank you for your attention

