Designing a Vaccine efficacy trial during Public Health Emergencies

24 - 25 March 2016 in Chamonix-Mont-Blanc, France
Chair, Day 1 – John Edmunds, **Chair, Day 2** – Marc Brisson

This is the initial meeting of a series of efforts towards the development of a toolbox.

 The objectives of this meeting are as follows:

1.   To strengthen global collaboration and communication between disease content experts, epidemiologists, statisticians, modellers, and regulators to facilitate information and expertise sharing while designing and implementing clinical trials prior and during an outbreak.

2.   To propose a work plan and collaborative approaches leading to the design of models and evaluation of trial designs for top priority highly infectious pathogens listed by WHO (link).

3.   To engage discussions around designing a vaccine efficacy trial for the current Public Health Emergency on microcephalies and neurological disorders (link).

Day 1, Thursday, 24 March 2016 (Chair: John Edmunds)

Time	Presenter
08.30 – 08.50	**Welcome and Introduction**
	Marie-Paule Kieny – *Assistant Director General, Health Systems & Innovation, WHO*
08.50 – 09.05	Introductions of participants and declaration of interests
09.05 – 09.20	Objective of the meeting and expected outcomes
	Ana Maria Henao Restrepo, IVR, WHO
SESSION 1 – CHALLENGES AND OPPORTUNITIES AROUND VACCINE TRIAL DESIGNS	
09.20 – 10.00	**Challenges in designing a vaccine efficacy and effectiveness trials during epidemics**
	- Field perspective James Russell, Sierra Leone
	- Methodologists perspective Elizabeth Halloran, Univ. of Washington
	- Ethical Challenges Annette Kuesel, WHO
10.00 – 10.30	**Challenges in modelling infectious diseases during epidemics**
	- Challenges during epidemics (data access, off-target projections, uncertainties, …), Christl Donnelly, Imperial College
	- Challenges in modelling the emergence of novel pathogens, Monique Ambrose, UCLA
10.30 – 10.50	**Coffee Break**

10.50 – 11.10	**Opportunities to bridge infectious disease models and the design of vaccine trials v1**
	Anton Camacho, LSHTM ~ Real-Time Forecasting and Evaluation of Trial Success
11.10 – 11.30	**Opportunities to bridge infectious disease models and the design of vaccine trials v2**
	Steve E. Bellan, Univ. of Texas ~ The role of mathematical models to discuss ethics rationale for a study design
11.30 – 11.50	**Opportunities to bridge infectious disease models and the effectiveness of a design**
	Ira Longini, Univ. of Florida ~ Containing Ebola at the source with ring vaccination
11.50 – 12.10	**Discussion**
12.10 – 13.40	**Lunch**
SESSION 2 – DEFINING THE NEEDS FOR COLLABORATION	
13.40 – 14.20	**Regulatory Perspectives**
	Regulatory expectations from such collaboration in the choice of a design. - Philip Krause, FDA - Andrew Thomson, EMA
14.20 – 14.40	**Country Representative expectations and perspectives**
	Lourdes Garcia-Garcia, NIPH, Mexico
14.40 – 15.00	**Data Sharing**
	Katherine Littler, Wellcome Trust ~ Developing approaches to data sharing and repositories.
15.00 – 15.30	**Discussion**
15.30 – 16.00	**Coffee Break**
16.00 – 16.20	**Methodological expectations and perspectives**
	Ira Longini ~ Design and Analysis of Vaccine trial: Integrating disease dynamics and other considerations
16.20 – 19.00	**Group Session**
	Epi/Model/Methodo/Experts to discuss a given scenario/priority pathogen → Proposal of a Roadmap for Collaboration
19.00 -	**Dinner –** Restaurant la Télécabine

Day 2, Friday, 25 March 2016   (Chair: Marc Brisson)

09.00 – 12h00	**Break Session**
12h00 – 13h00	**Lunch**
SESSION 3 – TOWARDS A MECHANISM FOR COLLABORATION	
13.00 – 13.15	**How Zika Epidemiology will influence potential field trials of a vaccine ?** – *Fernando de la Hoz Restrepo, Univ. Nacional de Columbia*
13.15 – 13.30	**Zika Vaccine Evaluation and Deployment Strategy** – *Anna Durbin, Johns Hopkins Univ.*
13.30 – 13.50	**Sharing Early Zika Modelling Experiences** – *Alessandro Vespignani, Northeastern*
13.50 – 14.10	**Discussion**
14.30 – 15.00	**Coffee Break**
15.00 – 16.00	**Next Steps – Zika and other Top Priority Disease**
16.00 – 16.15	**Discussion**
15.30 – 16.00	**Conclusions**
	Ana Maria Henao Restrepo, IVR, WHO