Agenda

Rapporteur: Elisabeth Heseltine

Monday 11 May 2015

8:00-9:00 Registration

Session 1: Introduction
Chair: John Mackenzie (Curtin University, Australia)

9:00-9:15 Welcome: Margaret Chan, Director-General, World Health Organization (WHO)
and Objectives of meeting, expected outcomes: Marie-Paule Kieny, Assistant-Director General, Health Systems and Innovation (WHO)

9:15-9:35 Keynote lecture: The Ebola response/getting to zero (20 min), Bruce Aylward (WHO)

9:35-10:15 Country perspectives on R&D during the Ebola epidemic (10 min each)
• Wiltshire Johnson (Pharmacy Board, Sierra Leone)
• Stephen Kennedy (Ministry of Health, Liberia)
• Mandy Kader Konde (CEFORPAG, Guinea)

Discussion (10 min)

10:15-10:45 Coffee break

SESSION 2: Main lessons learnt on R&D in the 2014-15 EVD outbreak in West Africa. Main challenges, and factors that facilitated implementation of research activities in the affected countries
Chair: Nicole Lurie (HHS/ASPR, USA)

10:45-11:30 What were the known facts, pipelines and major challenges to Ebola R&D when the international emergency was declared in August 2014, and what has been achieved since then?

This presentation and discussion will identify crucial knowledge gaps at the start of the outbreak, e.g., in immunopathogenesis, appropriate animal models, use of in vitro data, natural history of disease; and map out the current (May 2015) achievements in filling these gaps.

Peter Jahrling (NIH/NIAID, USA): Addressing knowledge gaps in countering Ebola Virus Disease (20 min)

Panel discussion (25 min) moderated by Peter Jahrling:
WHO Ebola Research and Development Summit
WHO Executive Board Room

Sina Bavari (USAMRIID, USA), Inger Damon (CDC, USA), Stephan Günther (BNI, Germany), Mandy Kader Konde (CEFORPAG, Guinea), Janusz Paweska (NICD, South Africa)

11:30-12:00 Robin Robinson (BARDA, USA): Developing an integrated R&D agenda: prioritizing, developing and funding considerations (30 min)

12:00-12:10 Discussion (10 min)

12:10-13:00 Lunch break (50 min)

13:00-13:40 What are the decisive actions that helped to advance R&D? (10 min each)

From Recommendations to Actions: Lessons learnt in Ethics from the Ebola R&D, Aissatou Toure (Institut Pasteur, Senegal)

The role of the Scientific and Technical Advisory Committee (STAC-EE) in prioritising experimental interventions, Fred Hayden (University of Virginia, USA)

The VEBCON consortium for vaccine evaluation, Maxime Agnandji (CRM, Gabon)

Consultation on innovative Personal Protection Equipment (PPE), Adriana Velasquez-Berumen (WHO)

13:40-14:10 Round table (30 min) moderated by Robin Robinson: What processes should be in place to facilitate prioritising interventions and the R&D agenda in the future.
May Chu (OSTP/EOP, USA), Russ Coleman (DoD, USA), Jean-François Delfraissy (INSERM, France), Steve Landry (BMGF, USA), Samba Sow (CVD, Mali)

Session 3: National and International Coordination of R&D activities, sharing of results and implementation of networks and collaborations
Chair: Janusz Paweska (NICD, South Africa)

14:10-14:55 How were regulatory coordination efforts and timelines adjusted to expedite R&D?

AVAREF-facilitated joint reviews of clinical trial applications (15 min), Mimi Darko (FDA, Ghana)

Short presentations (5 min each):

Assisted review of Phase 3 trial protocol, Kabiné Souaré (Ministry of Health, Guinea)

International Collaborative Efforts Supporting the WHO Emergency Use Assessment and Listing (EUAL) of Diagnostics Procedure, Robyn Meurant (WHO)

Preparation of standards reagents, Philip Minor (NIBSC, UK)

Discussion (15 min)
WHO Ebola Research and Development Summit
WHO Executive Board Room

14:55-15:30 Data sharing and access to early information on epidemiology and results of clinical trials.

Introduction (10 min): Piero Olliaro (WHO/TDR)

Panel discussion (25 min) moderated by Piero Olliaro:
Amadou Sall (Inst Pasteur, Senegal), Philippa Easterbrook (WHO), Bronwyn MacInnis (Broad Inst, USA), Calum Semple (LSTM, UK)

15:30-16:00 Coffee break

16:00-16:30 Country level and international level coordination. Technology-specific and general coordination

Panel discussion (30 min) moderated by Brian Greenwood (LSHTM, UK):
Nyankoye Haba (NBTS, Guinea), Wiltshire Johnson, (Pharmacy Board Sierra Leone), Libby Higgs (NIH/NIAID, USA), Line Matthiessen (EC), Marie-Paule Kieny (WHO)

16:30-17:50 Establishing, sustaining and using networks/platforms for effective R&D responses to global public health threats

The experience of the European Mobile Lab network, Stephan Günther (BNI, Germany) (15 min)

The ‘Global Research Collaboration for Infectious Disease Preparedness' (GloPID-R), and the new European Commission’s Emergency research funding mechanism, Line Matthiessen (EU) (20 min)

Coordinated platform for evaluation of therapeutics, Peter Horby (Oxford University, UK) (15 min)

Panel discussion (30 min) moderated by John Mackenzie (Curtin University, Australia):
Akin Abayomi (African Voices Conference), Rob Fowler (SHSC, USA), Johan van Griensven (ITM-Antwerp, Belgium), Adam Levine (Brown University, USA), Lucy Ward (DoD, USA)

17:50-18:15 General Discussion and wrap-up of Day 1

18:45 Cocktail reception at Starling Hotel (transportation will be provided from WHO to Hotel Starling, and from Hotel Starling to Cornavin train station)
SESSION 4: Improving the planning and execution of research activities before and after global public health threats.

Chair: David Kaslow (PATH, USA)

The time available between public health threats provides an opportunity to convene scientists and other relevant stakeholders to involve them in the development of innovative approaches that address a broad range of R&D questions in the context of global public health threats. Critical activities might include the establishment of research platforms/networks for the coordinated conduct and requirements of studies, identifying sources and mechanisms for the coordinated and rapid funding of research, and agreeing on coordinated central mechanisms that can provide timely reviews of studies, and ethical and regulatory guidance, among others tasks.

9:00-9:35 Agreeing a priori on the characteristics of priority products for development (5 min each)

The experience of Team B, Mike Osterholm (University of Minnesota, USA)

Setting Target Product Profiles (TPPs) for vaccines against diseases of epidemic potential through the WHO PDVAC, David Kaslow (PATH, USA)

The experience of setting up TPPs for in vitro diagnostics, Arlene Chua (MSF, Switzerland)

Discussion (20 min)

9:35-10:30 Developing consensus on generic approaches, innovative methods and protocols so that these are available and promptly reviewed and endorsed when outbreaks happen

Perspectives (discussion on clinical trial designs including prior approval of protocols):

Trudie Lang (Oxford University, UK): How do we design trials in disease outbreaks that enable a rapid answer within the realities on the ground? (10 min)

Libby Higgs (NIH/NIAID, USA): An innovative adaptive trial design to assess efficacy and safety of investigational therapeutics during infectious disease outbreaks: the MCM RCT (10 min)

Gail Carson (ISARIC): Accelerating access to R&D results to inform the response to outbreaks (10 min)

General discussion (25 min) moderated by David Kaslow (PATH, USA)

10:30-11:00 Coffee break

11:00-11:20 Keynote address: Preparing and integrating communication, advocacy and community engagement efforts required to mount an effective R&D response, Cheikh Niang (Diop University, Senegal) (20 min)
SESSION 5: Integrating R&D efforts into broader public health response measures in future outbreaks/public health threats

Chair: Helen Rees (University Witwatersrand, South Africa)

Vaccine research preparedness and research implementation in the context of an on-going epidemic. How do we prepare the future, what have we learnt for current experiences? What are the gaps, how do we undertake research in the middle of the immediate need for a lifesaving response to an outbreak?

11:20-11:30 Framing and expediting recommendations, Helen Rees, co-chair of SAGE Working Group on Ebola vaccines (10 min)

11:30-12:25 Completing the development pathway for products that have shown promise during the 2014 Ebola virus outbreak, but could not be fully evaluated due to the diminishing number of EVD cases

Introduction to key regulatory issues, Luciana Borio (FDA, USA) and Enrica Altieri (EMA) (15 min)

Discussion (40 min) moderated by Margareth Sigonda (NEPAD): Enrica Altieri (EMA), Luciana Borio (FDA, USA), Gregory Glenn (Novavax), Swati Gupta (Merck), Wiltshire Johnson (Pharm Board, Sierra Leone), Michael Pfeiderer (PEI, Germany), Moncef Slaoui (GSK), Matthias Stahl (WHO), Paul Stoffels (J&J)

12:25-13:25 Lunch break

13:25-14:15 Improving the transition from research to access for successful interventions

Outlining the key components, contributions and challenges to collaborative vaccine deployment plans, Jean-Marie Okwo-Bele (WHO), on behalf of countries and partners (10 min)

Integrating investments into Ebola vaccines procurement, preparedness; and deployment and into immunization programme recovery and strengthening, Seth Berkley (GAVI) (10 min)

Panel discussion (30 min) on “Potential roadmap and blueprint for transitioning vaccines from development to deployment in the context of an Ebola or other emerging disease outbreak”, moderated by Helen Rees: Gregory Glenn (Novavax, USA), Swati Gupta (Merck Sharp & Dohme, USA), Adam MacNeil (CDC, USA), Eric Midboe (DoD, USA), Doreen Mulenga (UNICEF), Moncef Slaoui (GSK, Belgium), Camille Soumah (EPI Guinea), Paul Stoffels (J&J, USA)

14:15-14:45 New R&D funding models to support the development of products where the market is inexistent, unknown or unreliable.

Panel discussion (30 min) moderated by John-Arne Rottingen (NIPH, Norway): Gregory Glenn (Novavax, USA), Swati Gupta (Merck Sharp & Dohme, USA), Bernard Pécoul (DNDi, Switzerland), Robin Robinson (BARDA, USA), Margareth Sigonda (NEPAD), Moncef Slaoui (GSK, Belgium), Paul Stoffels (J&J, USA), Angela Wittelsberger (IMI, EC)
14:45-15:15  Coffee break

SESSION 6: Bringing it all together: setting up a process for identifying, agreeing and implementing a blueprint for R&D preparedness in the context of global public health threats
Chair: Mike Levine (Univ Maryland, USA)

15:15-15:35  Keynote address (20 min)  (Mike Levine)

15:35-17:00  General discussion and Next Steps