Meeting Objectives:

- Explore the design and implementation of clinical trials during the 2014-2015 Ebola outbreak.
- Examine the cultural, public health, and ethical context surrounding the respective designs of EVD clinical trials; highlight important takeaways for future trials in a similar emergency context.
- Discuss the scientific and public health gains from clinical trials during the EVD outbreak and identify lessons learned to improve a future international response to a public health emergency in a low-resourced country.
- Consider the role of the international bodies (governments, regulatory agencies, NGO’s, academicians, and others) in a rapid, robust, and sustained response.

9:45 a.m. Welcome by Committee Co-Chairs

- **Keith McAdam**, *Committee Co-Chair*, Emeritus Professor of Clinical and Tropical Medicine, London School of Hygiene and Tropical Medicine
- **Gerald Keusch**, *Committee Co-Chair*, Professor of Medicine and International Health, Boston University Schools of Medicine and Public Health

10:00 a.m. Opening Presentation: *Presentation and Q&A*

*Bringing the Divide: Connecting Clinician, Patient, and Researcher*

- **Ian Crozier**, Physician (*confirmed*)
SESSION I – PERSPECTIVES ON THE COMMUNICATION OF CLINICAL RESEARCH DURING AN EMERGENCY

(60min; 10min panelist presentations followed by 30min discussion and Q&A).

10:30 a.m.  

Objectives:
- Explore the role of public trust and rumor management in the communication and implementation of clinical trials.
- Examine how local understanding of existing clinical care and clinical research influence community acceptance of trials.

Moderator: Janice Cooper, Country Representative, Liberia Mental Health Initiative

Panelists:
- Kalipso Chalkidou, Founding Director, The National Institute for Health and Care Excellence (NICE) International Programme (*confirmed*)
- Heidi Larson, Senior Lecturer, London School of Hygiene and Tropical Medicine (*confirmed*)
- Melissa Parker, Medical Anthropologist, London School of Hygiene and Tropical Medicine (*invited*)

(Session II will consist of three panels and extend after lunch; speakers are encouraged to stay throughout the entire session)

Objectives:

- Discuss the considerations that were taken into account in the design of the trial (i.e. meeting scientific and ethical standards, health systems infrastructure, time to trial launch, public opinion, need of the affected population, etc.).
- Discuss any alternative trial designs considered leading up to implementation of the trial; explore why particular designs were selected.
- Explore the role of the trialist, if any, in selecting the interventions used in the EVD trials; discuss the considerations that go into advancing experimental compounds into clinical trials.
- Discuss the trial results, where available, and explore the scientific and public health value in the data derived from each study. What, if anything, would you do differently next time to achieve greater gains from trials?

Moderator: Janet Darbyshire, Emeritus Professor of Epidemiology, University College London (confirmed)

11:30 a.m. Overview Presentation: (20mins)
- Peter Smith, Professor, London School of Hygiene and Tropical Medicine (confirmed)

11:50 a.m. Panel 2A. Vaccine Trials Conducted During the Ebola Outbreak.
(60min; 10min panelist presentations followed by 40min discussion and Q&A).

- Johan van Hoof, Global Therapeutic Area Head, Infectious Diseases and Vaccines, Janssen Research & Development, LLC. – EBOVAC-Salone (confirmed)
- Ana Maria Henao-Restrepo, Medical Officer at the Initiative for Vaccine Research (IVR), Department of Immunization Vaccines and Biologicals, WHO – Guinea Ring Vaccine (confirmed)

12:50 p.m. LUNCH
1:50 p.m.  **Panel 2B. Therapeutic Trials Conducted During the Ebola Outbreak.**  
(85 min; 10 min panelist presentations followed by 45 min discussion and Q&A).

- **Trudie Lang**, Professor, University of Oxford *(confirmed)*;  
  **John Whitehead**, Emeritus Professor, Lancaster University – RAPIDE-BCV; TKM-Ebola *(confirmed)*  
- **Annick Antierens**, Medical Department, Médecins Sans Frontières *(confirmed)*  
- **Johan van Griensven**, Professor, Institute of Tropical Medicine – Antwerp, – Ebola-Tx *(confirmed)*  
- **France Mentre**, Professor of Biostatistics, Université Paris Diderot, Paris, France – JIKI *(confirmed)*

3:15 p.m.  **BREAK**

3:30 p.m.  **Panel 2C. Panel Reflections and Considerations for the Design of Clinical Trials.**  
(60 min; 10 min panelist presentations followed by 30 min discussion and Q&A).

**Objectives:**
- Discuss lessons learned and explore how future approaches to clinical trials in a public health emergency may be similar and/or different.  
- Identify innovative approaches to research in emergency contexts; consider options that facilitate flexible and accelerated approaches.  
- Consider whether adjustments to research standards in an outbreak are appropriate.

Panelists above and:
- **Jeremy Farrar**, Professor of Tropical Medicine at the University of Oxford and director of the Wellcome Trust *(invited)*  
- **Peter Smith**, Professor, London School of Hygiene and Tropical Medicine *(confirmed)*  
- **Geneviève Chêne**, Professor, University of Bordeaux *(confirmed)*
SESSION III – PUBLIC HEALTH CONTEXT

(30min; 10min panelist presentation followed by 20min discussion and Q&A).

4:30 p.m. **Objectives:**
- Explore strategies for how different stakeholders (ex: NGO’s, clinicians, health ministers, and international researchers) could work together to address a public health emergency.
- Consider how to best incorporate research into the public health response in the event of an outbreak in a low resource setting.
- In the context of a public health emergency in a low resource setting, examine where international organizations can best cooperate and invest to build sustainable in-country clinical research systems.
- Discuss lessons learned from other outbreak situations, ex. SARS, and explore how those experiences could have informed the Ebola response and reflect on the resultant implications of applying lessons learned in the future.

**Moderator:** David Peters, Professor, Johns Hopkins Bloomberg School of Public Health

**Presenters:**
- David Heymann, Professor, Chatham House *(confirmed)*

5:00 p.m. **ADJOURN**
Clinical Trials During the 2014-15 Ebola Outbreak

DRAFT AGENDA

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British Medical Association
BMA House
Tavistock Square
London WC1H 9JP
United Kingdom

Day TWO
March 23, 2016

SESSION IV – ETHICAL CONSIDERATIONS IN THE CONDUCT OF CLINICAL TRIALS DURING AN EMERGENCY

(60min; 10min presentations followed by 40min discussion)

10:00 a.m. Objectives:

- Explore how the ethical principles for clinical trial conduct are applied in a low resource outbreak setting, including:
  - Scientific validity and health value of the study
  - Fair subject selection and subject respect
  - Risk-benefit ratio; equipoise
  - Informed consent (vs. assent)
- Discuss how a public health emergency may impact the ethical considerations involved in clinical trial design and conduct – explore what, if any of the principles are inviolable.

Moderator: Olayemi Omotade, Professor of Paediatrics and Child Health, University of Ibadan

Panelists:

- François Hirsch, Director of Research, Head of Ethical Mission, INSERM (confirmed)
- Jonathan Montgomery, Professor of Health Care Law, University College London, Chair, Nuffield Council on Bioethics (confirmed)
- Carel IJsselmuiden, Executive Director, The Council on Health Research for Development (COHRED) Group South Africa (confirmed)
SESSION V – REGULATORY CONSIDERATIONS
(90min; 10min panelist presentations followed by 50min discussion and Q&A).

11:00 a.m.  **Objectives:**
- Discuss the standards of evidence needed to move an experimental product forward into clinical trials in an emergency situation; include the review of opportunities for accelerated pathways and discuss the balancing of risk and benefit.
- Reflecting on the recent regulatory experience with EVD clinical trials, explore how you might envision your country and the international community moving forward with the assessment, funding, and approval of clinical trials during the next outbreak.
- Explore the role of data sharing and confidentiality in the regulatory decision process.
- Discuss the role of the regulator in post-trial responsibility, including vaccine and therapeutic access upon trial completion.

**Moderator:** Michelle Mello, Professor of Law, Stanford University School of Medicine, School of Law

**Panelists:**
- **Guido Rasi,** Executive Director, European Medicines Agency (*invited*)
- **Dominique Martin,** Director General, French National Agency of Medicine and Health Products Safety (ANSM) (*invited*)
- **Karl Broich,** President, German Federal Institute for Drugs and Medical Devices (BfArM) (*invited*)

12:30 p.m.  LUNCH
SESSION VI – PREPARING FOR AND FINANCING CLINICAL TRIALS
(90min; 10min panelist presentations followed by 50min discussion and Q&A).

1:30 p.m. **Objectives:**
- Explore how the broader research community can work together during the interepidemic period to prepare for and improve the execution of clinical trials.
- Identify the biggest local and international road-blocks in determining and implementing clinical trials in West Africa. Discuss how international bodies be better situated to respond next time.
- Consider methods to develop a sustainable research system, ex. standard implementable clinical trial protocols, training local research staff, establishing regional health technologies and infrastructure.

**Moderator:** Fred Wabwire-Mangen, Associate Professor of Epidemiology and Public Health, Makerere University

**Panelists:**
- **Jimmy Whitworth**, Professor, London School of Hygiene and Tropical Medicine *(confirmed)*
- **Marguerite Koutsoukos**, Project Lead Ebola and HIV programs, GlaxoSmithKline (GSK) *(confirmed)*
- **Charlotte Watts**, Chief Scientific Adviser, Department for International Development (DFID) *(invited)*
- **Bruce Aylward**, Executive Director ad interim of the Outbreaks and Health Emergencies Cluster, WHO *(invited)*

3:00 p.m. **ADJOURN**
Clinical Trials During the 2014-15 Ebola Outbreak

DRAFT AGENDA

Second Committee Meeting
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Day THREE
March 24, 2016

SESSION VII – ETHICAL AND SCIENTIFIC CONSIDERATIONS FOR PRIORITIZING RESEARCH DURING OUTBREAKS

(60min; 10min panelist presentations followed by 40min Q&A).

10:00 a.m. Objectives:

- Explore what evidence is needed when evaluating potential treatment options to determine the most viable candidates for further development and advancement to clinical trials.
- Discuss how, in the context of an international emerging or re-emerging infectious disease event, clinical trials can best be prioritized.
- Explore the common goals and trade-offs in health care and clinical research.

Moderator: Alex John London, Professor, Carnegie Mellon University

Panelists:

- Katherine Littler, Policy Advisor, Wellcome Trust (confirmed)
- Miles Carroll, Head of Research Microbiology Service, Public Health England (PHE) (confirmed)

11:00 a.m. ADJOURN