Reaching out: A meeting to advance clinical research preparedness for infectious disease outbreaks

20-21 September 2018
Pullman Hotel, Brussels, Belgium

Clinical research is vital to influence health outcomes and save lives in an infectious disease outbreak. To be effective, clinical research must be fast, flexible and integrated with the front line response. Globally, progress is being made to improve preparedness and deliver clinical research as a core part of outbreak response. However, there remain many challenges to rapid research deployment.

This meeting will examine bottlenecks to (rapid) deployment of clinical research in an infectious disease outbreak and what we can do to overcome them. Patient groups, researchers, regulators, funders and policy makers must work together to achieve this.

Practical solutions do exist. Clinical study protocols can be pre-positioned and pre-approved, regulatory and ethical approvals can be fast tracked, pre-funded clinical trial networks can respond, novel clinical trial designs can accelerate evaluation of treatment interventions, and good participatory practice with patients and local communities can make sure research processes are contextually and culturally appropriate.

Through presentations, panel discussions and audience debate, we will:

- Highlight the vital role of clinical research in an infectious disease (ID) epidemic or pandemic
- Provide insight into clinical trial networks in global regions
- Highlight the value of combining antimicrobial (AMR) clinical research with ID pandemic preparedness
- Illustrate the fundamental role of working in partnership with patients and the communities
- Show how regulators can ensure robust yet expedient review of clinical study protocols
- Demonstrate the value of novel clinical trial designs to evaluate therapeutic interventions

Practical workshops delivered by experts from different global regions will demonstrate how to approach research design, delivery and dissemination. Workshops include:

- How to work in partnership with patients and communities
- How to address common barriers to data sharing activities
- How to conduct robust, rapid ethical review of epidemic-relevant study protocols

The event will interest anyone involved in outbreak preparedness: clinicians, researchers, patient groups, regulators, public health, administrators, funders, and ethics advisory groups.

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Thursday 20 September

9h00 **Welcome and Opening remarks**
Herman Goossens, PREPARE Coordinator and Yazdan Yazdanpanah, GloPID-R chair

9h15 **PLENARY SESSION 1: BARRIERS AND SOLUTIONS TO CLINICAL RESEARCH DURING AN INFECTIOUS DISEASE OUTBREAK**

What is the benefit of integrating clinical research into an outbreak response? What are the challenges and solutions? What progress has been made? Panelists will present their experience and involvement in initiatives to deliver patient-centered clinical research in an infectious disease outbreak, highlighting key bottlenecks and ways to overcome them.

Chairs: Hugh Davies (Oxford National Health Service Research Ethics Committee) and Nina Gobat (PREPARE)

- Herman Goossens (PREPARE): Clinical research response: Preparing Europe for the next infectious diseases outbreak
- Peter Horby (PREPARE, ISARIC, ALERRT): Leaping the Barriers
- Alistair Nichol (PREPARE): Bottlenecks and solutions in pandemic research: lessons learned from PREPARE
- Catherine Hankins (McGill University Faculty of Medicine): Good Participatory Practice: meaningful engagement that strengthens the science

10h45 **Coffee**

11h15 **PLENARY SESSION 2: INTEGRATING RESEARCH AND RESPONSE**

Chair: John Marshall (CAPTIC, ISARIC) and Lennie Derde (PREPARE)

- Marion Koopmans (PREPARE, COMPARE): Bridging the gap between clinical research and public health in infectious disease outbreaks
- Steve Webb (PREPARE, APPRISE): Optimising trial design to evaluate therapeutic interventions during a pandemic
- Chris Butler (PREPARE): Answering patient-centered questions efficiently in primary care through response-adaptive platform trials: the ALIC4E study.
- Nicole Lurie (Harvard and Massachusetts General Hospital): Strengthening Research Response to Outbreaks: What Do We Need To Do Next?

13h00 **Lunch**

14h00 **BREAKOUT SESSION: WORKSHOPS 1-2-3 - REMOVING BOTTLENECKS TO CLINICAL RESEARCH**

Parallel session workshops that focus on key areas of research that can address common bottlenecks to delivering patient-centered clinical research in an infectious disease outbreak.

Workshop 1: Patients and the public as partners
Facilitated by Catherine Hankins, Adama Thorlee and Luisa Enria
This workshop will demonstrate how to involve patients and communities in the design and delivery of clinical research. Experience from different global regions will be shared to illustrate how meaningful patient involvement in clinical research can shift perception of sociocultural "barriers" to research participation. *Rapporteur: JP Byrne (PREPARE)*

Workshop 2: Data sharing in a public health emergency
Facilitated by George Haringhuizen (COMPARE), Carolina dos Santos Ribeiro (COMPARE)
This interactive workshop underscores the vital role of data and materials sharing in a public health emergency and how good data sharing practice can contribute to an efficient and effective response. Barriers and solutions to good practice in data sharing will be highlighted. Making use of actual incidents and cases, participants are challenged to give their opinion on regulatory and ethical dilemmas, discuss desired and feasible options, and vote for the best 'guiding statements' towards solutions. *Rapporteur: Sharon Abramowitz*

Workshop 3: Developing a framework of questions and considerations to reach out to all, promote and facilitate proper conduct of pandemic research
Facilitated by Hugh Davies (Oxford National Health Service Research Ethics Committee), Julian Sheather (Nuffield Bioethics), Heather Sampson (University of Toronto)
This workshop will take ethical guidelines developed by WHO and CIOMS and propose a framework of questions and considerations to guide regulators reviewing outbreak-related clinical studies and researchers designing them. *Rapporteur: Sarah Edwards (PANDORA-ID-Net)*

15h15 **Coffee**

15h45 Feedback from workshops

16h15 **PLENARY SESSION 3: KEYNOTE SPEAKER – DAME SALLY DAVIES**

17h00 **Close**

19h00 **Dinner for all delegates - La Manufacture**
We meet in the hotel lobby at 19h00 for a short walk to the restaurant

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Friday 21 September

9h00 **Welcome and summary of day 1**

9h10 **PLENARY SESSION 4: WORKING TOGETHER**

Stakeholders need to work together to make progress. Strong partnerships can help establish an effective environment for outbreak-relevant clinical research. In this session, we hear from stakeholders about how best to work together to remove barriers to clinical research.

Chair: Gail Carson (GloPID-R Secretariat, ISARIC, GOARN)

- Ilaria Capua (One Health Centre, University of Florida, former member of the Italian parliament): Disconnecting competence from science through populism
- Marco Cavaleri (European Medicines Agency): EMA perspective on preparedness for emergent infectious diseases
- Catherine Blewett (Health Research Authority, UK): Combined Ways of Working: How UK Regulators are working together to streamline clinical trial approvals
- Yazdan Yazdanpanah (GloPID-R): The funders' perspective

10h40 **Coffee**

11h10 **PLENARY SESSION 5: EBOLA**

Chair: John Amuasi (ALERRT)

- Jean-Jacques Muyembe (INRB): Ebola DRC – opportunities and challenges for clinical research
- Janet Diaz (WHO)/ Peter Horby (ALERRT): Clinical research in Ebola
- Francine Ntoumi (PANDORA-ID-Net) – PANDORA-ID-Net: Challenges in building capacities for prompt response to infectious diseases in Central Africa
- Eileen Farnon (ALERRT): Facilitating Rapid Ethics Review of Protocols during Outbreaks
- Luisa Enria (Bath University): Involving patients and the public in Ebola vaccine and treatment trials: Social Science and community engagement approaches

12h45 **Lunch**

13h45 **PLENARY SESSION 6: LOOKING AHEAD TO MAKE PROGRESS**

This interactive session will consolidate learning from the meeting: what progress has been made in being ready to deliver clinical research in an ID outbreak? What needs to happen to take this further? How can clinical research preparedness initiatives in different regions learn from each other and work together?

Facilitators: Nina Gobat (PREPARE), Gail Carson, (ISARIC, GOARN) J-P Byrne (PREPARE) Hugh Davies (Oxford National Health Service Research Ethics Committee)

15h15 **Close of meeting:** Alistair Nichol (PREPARE)

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