Summary:

IMI consultation workshop on preparedness for emerging diseases

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29.09.2016 • IMI Stakeholder Forum 2016 • Brussels, Belgium

Objectives of this consultation workshop

Workshop organised in collaboration with the European Commission and EFPIA

- To gather input from stakeholders
  - Views and vision on what it takes to establish a comprehensive strategy for medical countermeasures against emerging diseases
  - Identification of the needs and the missing pieces not already covered by existing efforts and initiatives
  - Which pieces should be supported by public funding?
  - Where can industry contribute?
  - What should be addressed by public-private partnership?
  - Is there scope for an IMI programme to address some of the gaps we face towards efficient preparedness for emerging diseases?

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Highlights of the discussion

Setting the scene - Key messages by organisation

- **WHO R&D blueprint**: we cannot repeat the Ebola experience, must have a preparedness strategy in the future; WHO has the mandate to define priorities
- **ECDC**:
  - Important research gaps identified for specific threats
  - importance to develop a code of conduct for collaboration respecting need for scientific independence
- **European Commission**: research priorities cover prevention, surveillance/early detection, intervention, and capacity building
  - Flexibility built into existing projects and financial regulation
- **CEPI (Coalition for epidemic preparedness innovations)**
  - Equity, call for financial support; need for understanding cost of not investing
  - Primary focus on vaccines

Highlights of the discussion

Key determinants of biopreparedness – Early detection and diagnostics

- Diagnostics are important and should not be restricted to certain type of assay nor setting nor pathogen
- Industry calls for standardised and well-characterised biobanks of clinical specimens, organisms; on the other hand, specimen collections are available in public organisations but lack of funding
- Need for laboratory capacity building
- Need to streamline and clarify regulatory pathways
- Data sharing, collecting and making available e.g. sequencing information

Highlights of the discussion

Key determinants of biopreparedness – vaccine and therapeutic development, clinical trial networks

- Need to streamline and clarify regulatory pathways, both for vaccine development and therapeutics
- Importance of moving from project mode to sustainable infrastructure
- Site preparedness, capacity building to establish networks for clinical trials
- Need to build in surge capacity to address outbreak situation
- One health approach important
- Gaps in epidemiology, biostatistics, and vaccinology (especially in low-income countries)

Deliverables - 1

Needs and gaps identified

- **Overarching challenge: lack of certainty on the pathogens to prepare for!** Implications for vaccines and therapeutics
- Diagnostics: huge potential for **collaboration between stakeholders**
  - To define better what the needs are in the field
  - Need for sustainable biobanks; agree on what specimens are needed, on protocols, on standards;
  - To develop regulatory pathways and identify means of accelerating ethics approval
- CEPI and other initiatives potential role for IMI should be further explored
- Therapeutics: More effort into elucidating disease mechanisms are needed; advanced therapies capacity could be increased; some of the CEPI mechanisms can be leveraged for therapeutics

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Deliverables - 2

Needs and gaps identified

- **Capacity building** in potentially affected countries is key and must be sustained; e.g. creation of centers of excellence by supporting institutions that have career development strategies in place
- More work needed in **social science**, to address acceptance and prepare for deployment, to improve communication and address vaccine hesitancy
- Care should be taken to avoid too many initiatives and duplication of efforts – objectives and responsibilities must be clear
- Public sector should take the lead in prioritisation and normative work/regulation
- Need for more effort of vaccine efficacy assay development