EC research and innovation
strategy and actions
for outbreak preparedness and response

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Unit "Fighting infectious diseases and advancing public health"

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Health Directorate
DG Research & Innovation
European Commission
EC research and innovation strategy: Objectives

**Overall**

- Improve prevention and early detection of infectious disease threats in Europe and globally
- Promote a 'One Health' approach

**Specific**

- Develop the pipeline of medical countermeasures against prioritised (and unexpected/unknown) pathogens
- Ensure that a comprehensive research response is swiftly launched in case of an outbreak
- Facilitate global collaboration
Research Priorities

'Drivers' of outbreaks (climate change, vectors, host and pathogen factors)

**One Health** (zoonoses - species barriers)

**Vector control, Vaccines**

Pathogen prioritization

Improved surveillance systems

Risk modelling/anticipation

Simple, point-of-care diagnostics and diagnostics 'platforms'

Syndromes definitions and differential diagnosis (e.g. Hemor. fever, flu-like)

Advance the **pipelines (vaccines/treatments)**

Clinical research during outbreaks (e.g. syndrome characterization, risk assessment, phase II/III clinical trials)

Research on disease management

**Social Sciences** (= communication, community impact/engagement)

Partnerships/coordination/knowledge transfer

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**Country-owned research capacity** (= human resources and infrastructure)
Main funding instruments under Horizon 2020 for preparedness research and response

- **Collaborative research** *(Countries, Sectors, Disciplines)*
  - SC1 (Health), SC2 (Bio-economy), SC6 (Societies), SC7 (Security), Research infrastructures

- **Innovative Medicines Initiative** *(IMI2)*
  - Public-private partnership between EC and pharma industry in Europe

- **European and Developing Countries Clinical Trials Partnership** *(EDCTP2)*
  - Partnership between 14 European and 14 African countries

- **InnoFin Infectious Diseases**
EC funding instruments for feeding the pipeline

Risk level
- Discovery, PoC
- Preclinic
- Clinical Phases 1-3
- Up-scaling Manufacturing
- Uptake Delivery

Resources required
- PUSH
- PULL

H2020 Grants
- SME-Instrument
- InnovFin ID
- EDCTP2
- IMI2

Discovery,
PoC

Preclinic

Clinical Phases 1-3

Up-scaling Manufacturing

Uptake Delivery
Specific instruments for response to an outbreak

- **Flexibility built into ongoing projects**
  Possibility for the EC or the participants to change research agenda in case of an outbreak

- **Flexible Financial Regulation**
  Foresees the possibility to award grants without a call for proposals in exceptional and duly substantiated emergencies
Outbreaks: Preparedness & Response

Prevention/Preparedness

Examples of Research Projects

Antigone (FP7), PreDEMics (FP7), Zika Projects (H2020)

Surveillance/Early Detection

Compare (H2020), Diagnostics projects for Zika (H2020), 3 Ebola Diagnostics projects (IMI2)

Control/Intervention

Silver (FP7), Enable (IMI2), Prepare (FP7), LAC preparedness network (H2020 Zika), Africa preparedness network (EDCTP2), Ebola, Zika projects, ZAPI, Ebola + programme (IMI2), Vaccine projects (other priority pathogens, influenza etc) (FP7, H2020, IMI2, EDCTP2, Prize), Social Sciences (TELL ME, E-com@EU, Ebola, Zika)

Health Systems/capacity building

EDCTP2, Ebola and Zika projects, PRD and NIDs projects
Some examples

• **COMPARE**
  - Aim for an enabling analytical framework and globally linked data and information sharing platform system for rapid identification, containment and mitigation of outbreaks
  - Combine sequence-based pathogen data and associated (clinical, epidemiological, etc.) data

• **PREPARE**
  - A European clinical research framework covering primary care and hospital care in the EU
  - Implements large inter-epidemic clinical studies and develops new diagnostic tests for diseases
  - Aim to ensure a rapid, coordinated deployment of clinical investigators within 48 hours of a severe infectious disease outbreak in Europe
Some examples (2)

- **SILVER**
  - Aimed to develop drug discovery programme to inhibit RNA viruses
  - Screened >700,000 cell-based assays, >700 promising hits, 20 tested for proof of concept analysis
  - Several licenced products

- **VIROGENESIS**
  - Virus discovery and epidemic tracing from high throughput meta-genomic sequencing
  - Addresses the challenge of advancing methodology that maximizes the use of Next-Generation Sequencing (NGS) data in biomedical and clinical settings.
  - Identified specific bioinformatics bottlenecks that prevent the effective use of NGS in clinical and epidemiological settings
Addressing Zika research gaps

• 3 EU funded consortia

• Addressing Zika research gaps
  • Clinical studies: prospective cohorts of pregnant women and newborns, adults with CNS involvement
  • Studies on natural history and clinical spectrum of disease, transmission modes, pathogenesis & immunological consequences of infection, diagnostics development, mathematical modelling, animal reservoirs, vector competence and control, social studies, ...
  • Harmonization of data collection & data sharing roadmap

• Develop LAC region preparedness research network
Participation in international initiatives

- Coalition for Epidemic Preparedness Innovations http://cepi.net/

- International Research Consortium on Animal Health http://www.star-idaz.net/

- Global Research Collaboration for IDs Preparedness http://www.glopid-r.org/
GLOPID-R : Global Research Collaboration for Infectious Disease Preparedness

• Brings together 25 major funders of preparedness research whose involvement is crucial for a comprehensive and rapid global outbreak response

• Specific objectives
  • Facilitate the exchange of information
  • Address scientific, legal, ethical and financial challenges
  • Implement a ‘One Health’ approach
  • Establish a strategic agenda for research response
  • Connect infectious disease research networks
  • Actively involve developing countries
Research alone is not enough!

- Data and sample sharing framework needed
- Regulatory: accelerating licensing without compromising safety
- Liability and insurance issues in pandemic setting
- Large-scale manufacturing, QA, access
- IP matters
- Infrastructure resources for rapid vaccine deployment
- Post-licensure commitments
- ...
Data sharing

• 3 EU funded consortia on Zika
  • Harmonise protocols & tools for data capture & management
  • Set up joint harmonised platforms for clinical research
  • Share data in real time between the 3 consortia
  • Prepare for sharing data with scientific community & public health officials

• GloPID-R working group
  • Aims to design a system for data sharing in public health emergencies to support the research response
    - Principles for data sharing in public health emergencies
    - Decision tree to identify data to be shared in particular context
    - Case studies to document data sharing experience
Thank you!