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

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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

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Research Priorities

Outbreak Preparedness & Response

Prevention/ Preparedness

'Drivers' of outbreaks (climate change, vectors, host and pathogen factors)
One Health (zoonoses - species barriers)
Vector control, Vaccines

Surveillance/ Early Detection

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)

Control/ Intervention

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)

Health Systems/ capacity building

Partnerships/coordination/knowledge transfer

↓

Country-owned research capacity
(= human resources and infrastructure)

Main funding instruments under Horizon 2020 for preparedness research and response

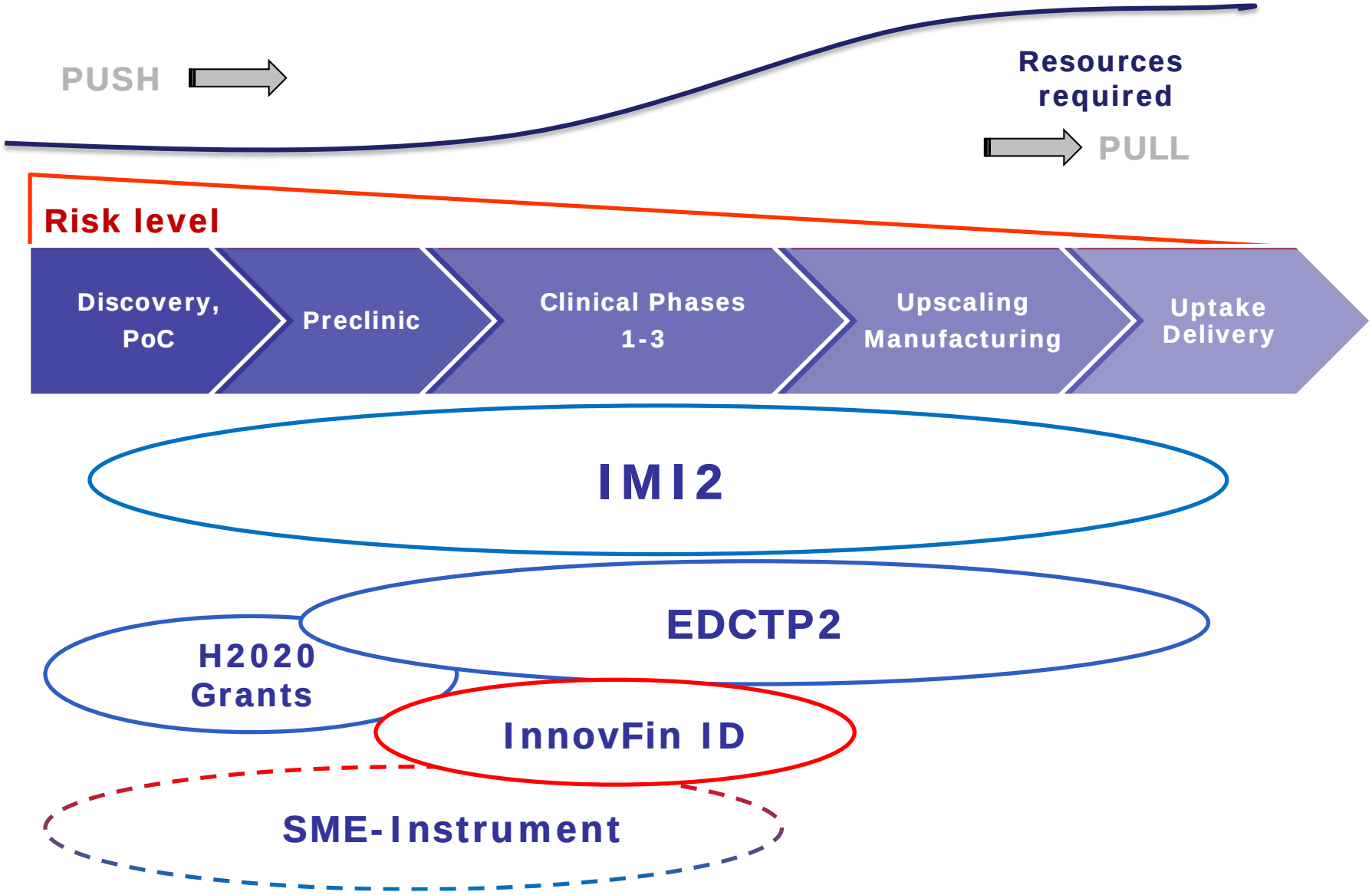
- ***Collaborative research*** *(Countries, Sectors, Disciplines)*
  - *SC1 (Health), SC2 (Bio-economy),SC6 (Societies), SC7 (Security), Research infrastructures*

- ***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*

- InnoVFin Infectious Diseases

EC funding instruments for feeding the pipeline



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

Examples of Research Projects

Outbreaks: Preparedness & Response

Prevention/ Preparedness

→ 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

REDe Research Capacity Network

Preparedness Latin American Network ZikaPLAN

ZIKAction

ZIKAlliance A Global Alliance for Zika Virus Control and Prevention

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Participation in international initiatives

- Coalition for Epidemic Preparedness Innovations

http://cepi.net/

CEPI
New vaccines for a safer world

- International Research Consortium on Animal Health

http://www.star-idaz.net/

STAR-IDAZ
International Research Consortium on Animal Health

- Global Research Collaboration for IDs Preparedness

http://www.glopid-r.org/

GLOPID-R

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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

GLOPID-R

Research and Innovation

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

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