



FURTHERING THE RESEARCH AGENDA FOR WORLD HEALTH

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Barbara Kerstiëns, MD, MPH
European Commission, DG Research & Innovation

Outline

- I. Research - part of outbreak preparedness and response
- II. EC strategy and funding instruments
- III. Participation in international initiatives
- IV. Beyond research
- V. Challenges
- VI. EU added value

I. Research part of response

Ebola 2014-2016



- Magnitude
 - 28,646 cases – incl. 11,323 deaths (39.5%)
- Health system impact
 - 881 confirmed health worker infections, 513 deaths
 - Disruption of basic health services, e.g. vaccination
- Socio-economic impact
 - 16,000 orphans
 - Long term sequelae and stigma
 - Cost of response > \$3.6 billion
 - \$2.8 billion in lost GDP for 2014-2016 period
- **Absence of**
 - Rapid diagnostics, treatment, prophylactic vaccination

I. Research part of response

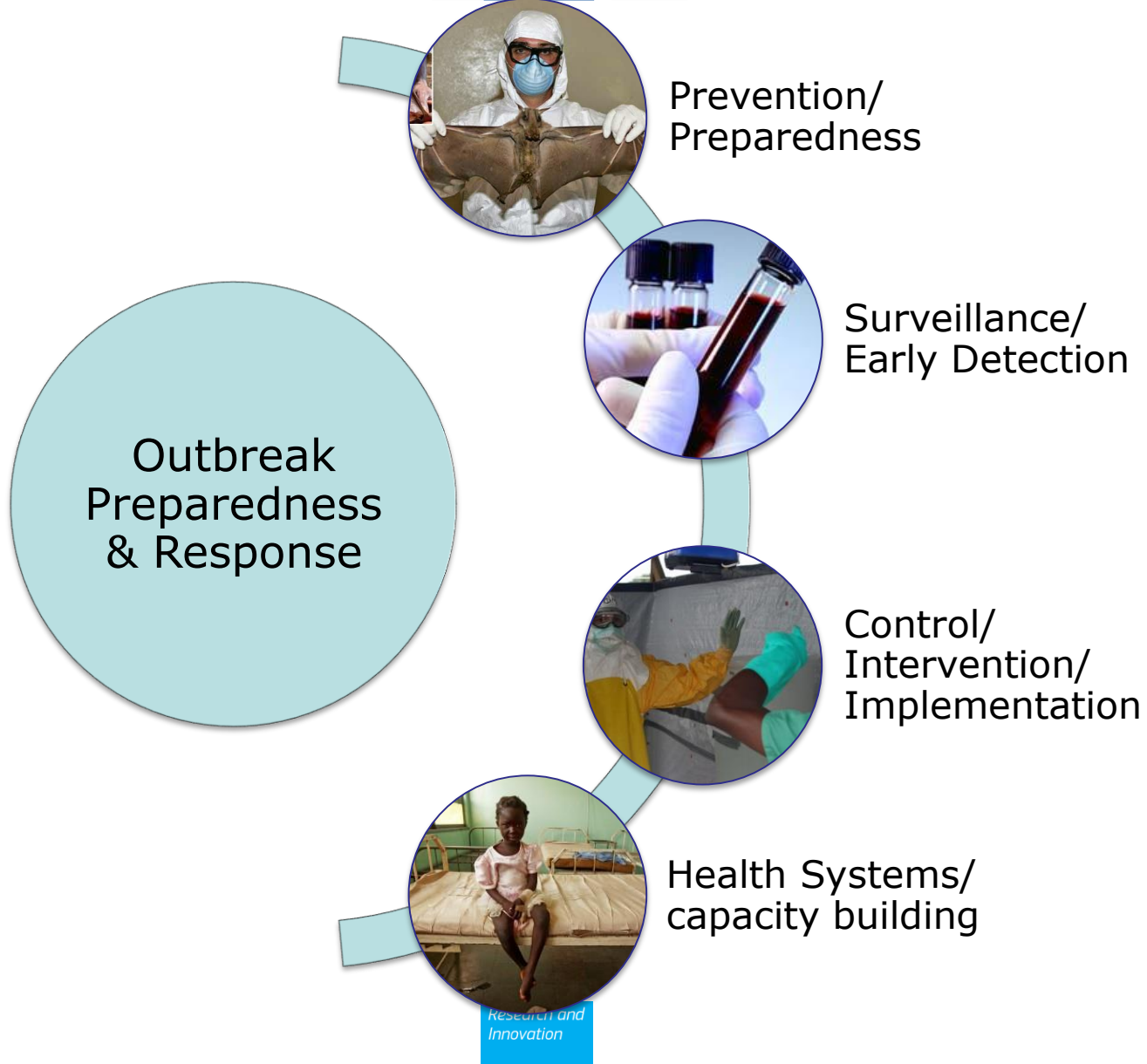
SARS 2002-03



- Magnitude
 - 8,096 infections, 774 deaths (9.6%)
 - Health workers accounted for a fifth of all cases globally
 - 26 countries affected
- Socio-economic impact
 - Travel and tourism affected
 - Global cost of roughly \$80 billion: to medical expenses, travel and related services, consumer confidence and investment
- **New disease**
 - Understanding of transmission mode, pathogenesis, etc.
 - No diagnosis, treatment or vaccine

"(...) multinational, collaborative, and coordinated surveillance, research, and containment measures greatly limited the spread of Sars-CoV."

Research needs



II. EC research strategy & instruments



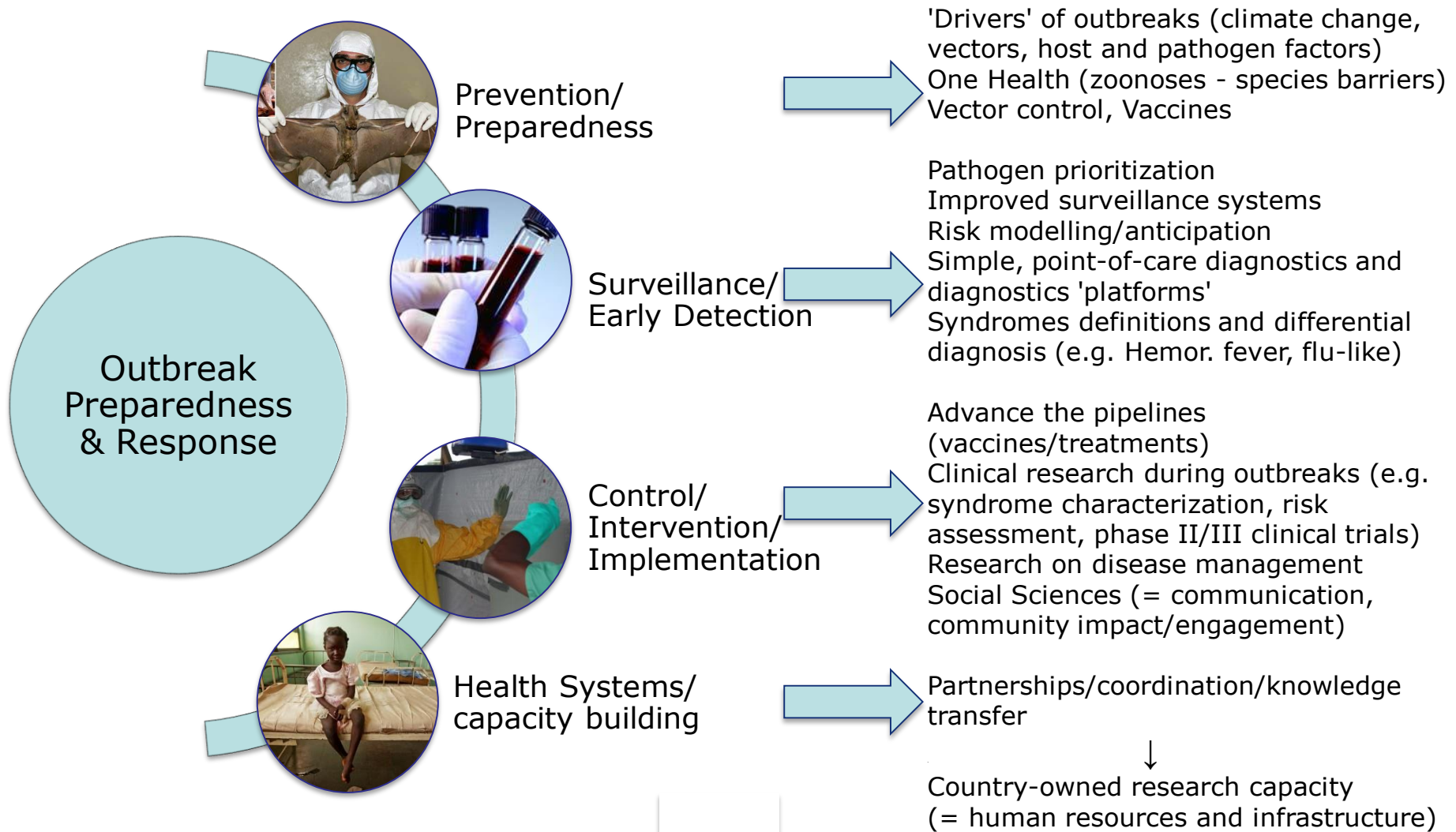
Overall objectives

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

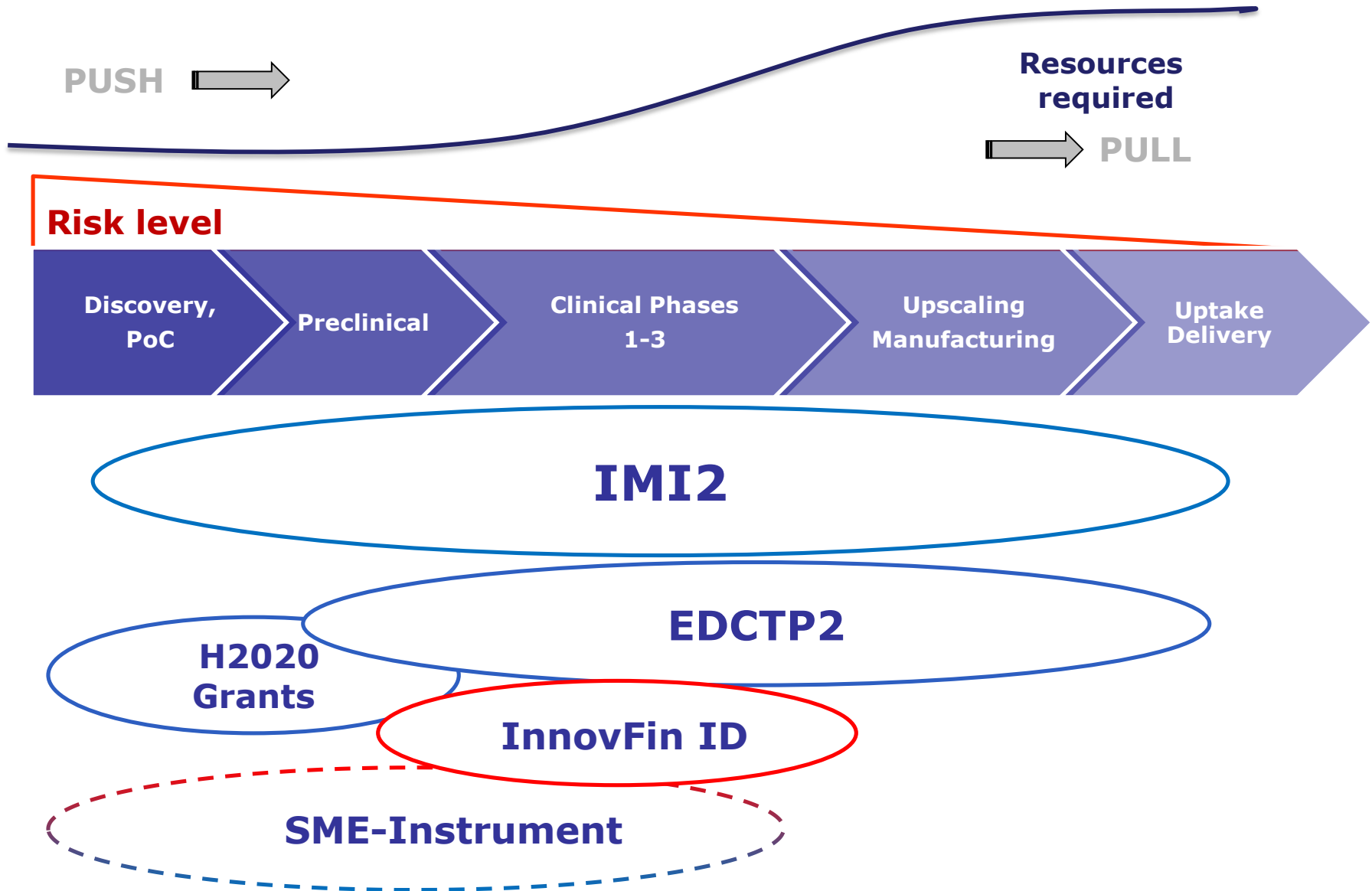
Specific objectives

- 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



EC funding instruments for feeding the pipeline





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*



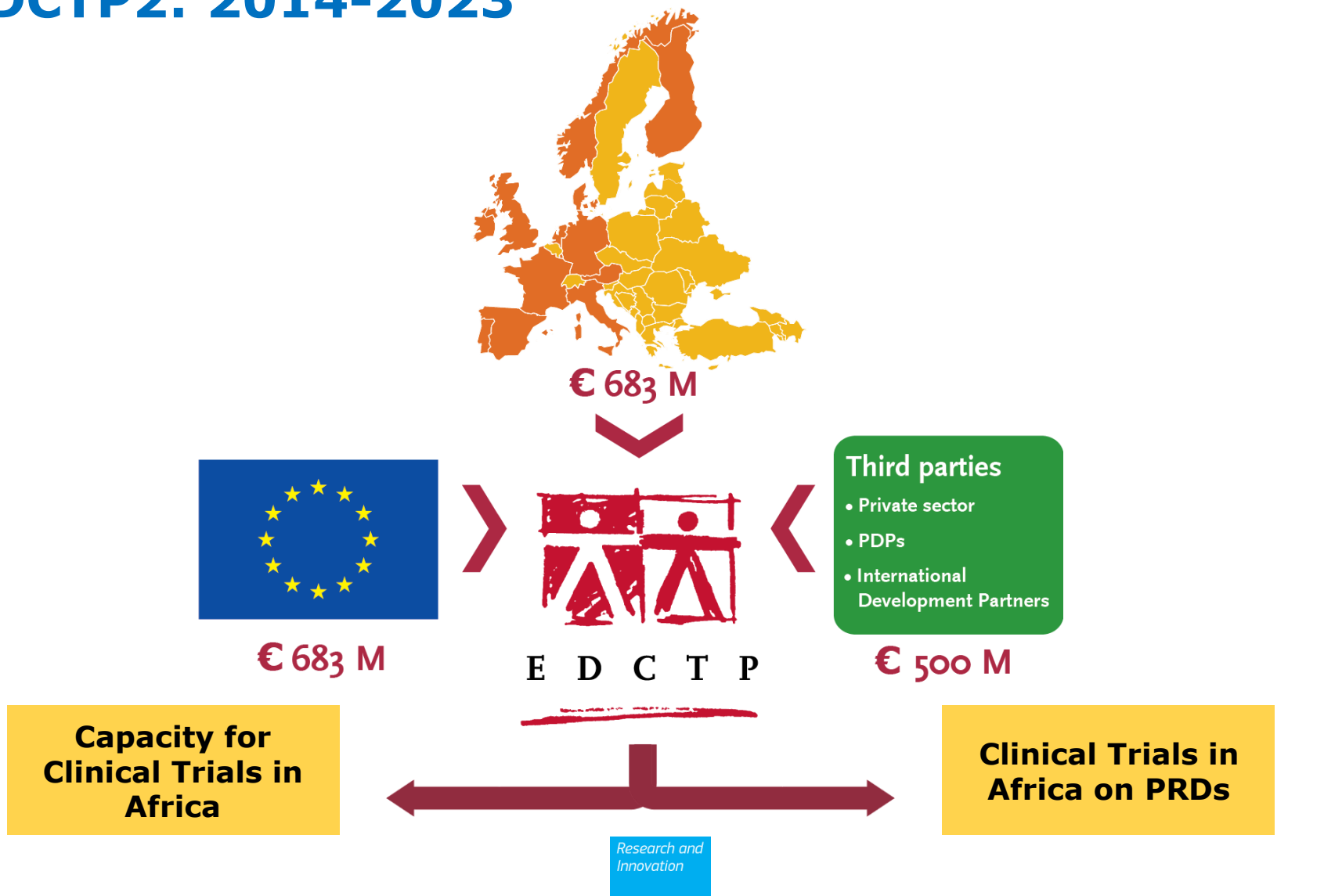
- **InnovFin**
Infectious Diseases

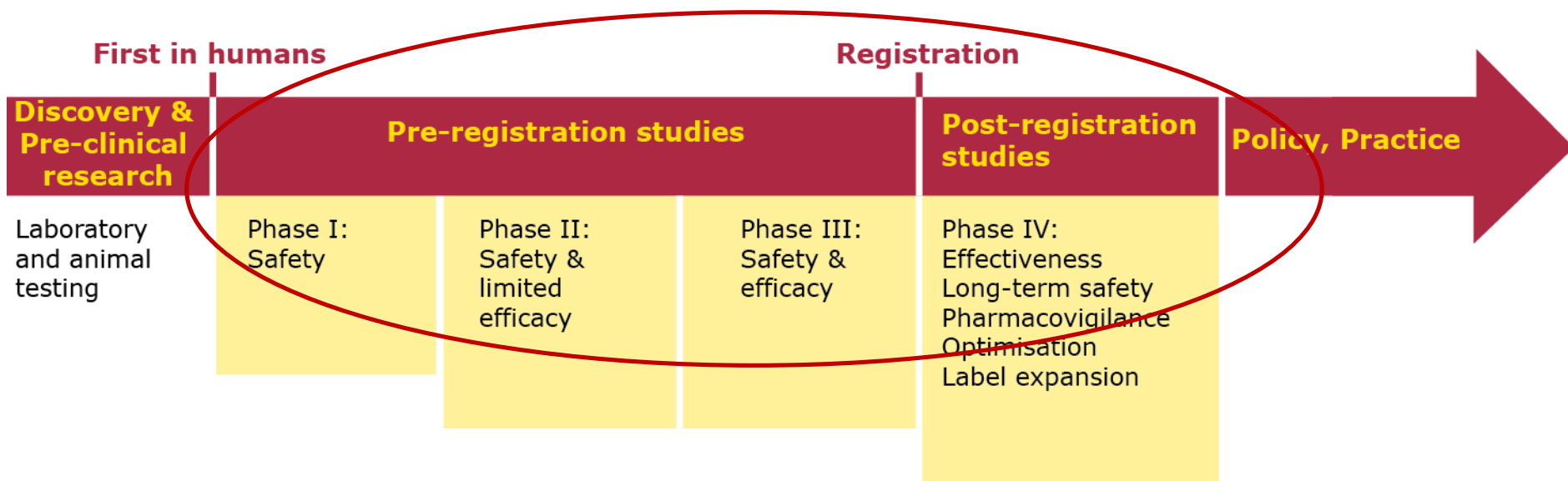


European and Developing Countries Clinical Trials Partnership (EDCTP)



EDCTP2: 2014-2023





Diseases: HIV/AIDS, TB, Malaria, NIDs, emerging infectious diseases of particular relevance for Africa, including Ebola

New tools and interventions: Diagnostics, drugs, vaccines and microbicides

Capacity Development: Fellowships, Networks, Ethics, Regulatory

- **Innovative Medicines Initiative (IMI)**

- Europe's largest public-private initiative
- Aims to speed up development of better and safer medicines for patients



- **InnovFin ID**

- Provides loans between €7.5m and €75m
- To innovative players in development of vaccines, drugs, medical devices, and research infrastructure for combatting infectious diseases
- For projects that have completed pre-clinical stage and for which clinical validation is needed for further development

Instruments for swifter research 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

- **Article in the Financial Regulation providing flexibility**

Foresees the possibility to award grants without a call for proposals in exceptional and duly substantiated emergencies

Some examples

Ebola research response



- **Budget**

- €189 Mn
- + €100.8 Mn EFPIA contribution

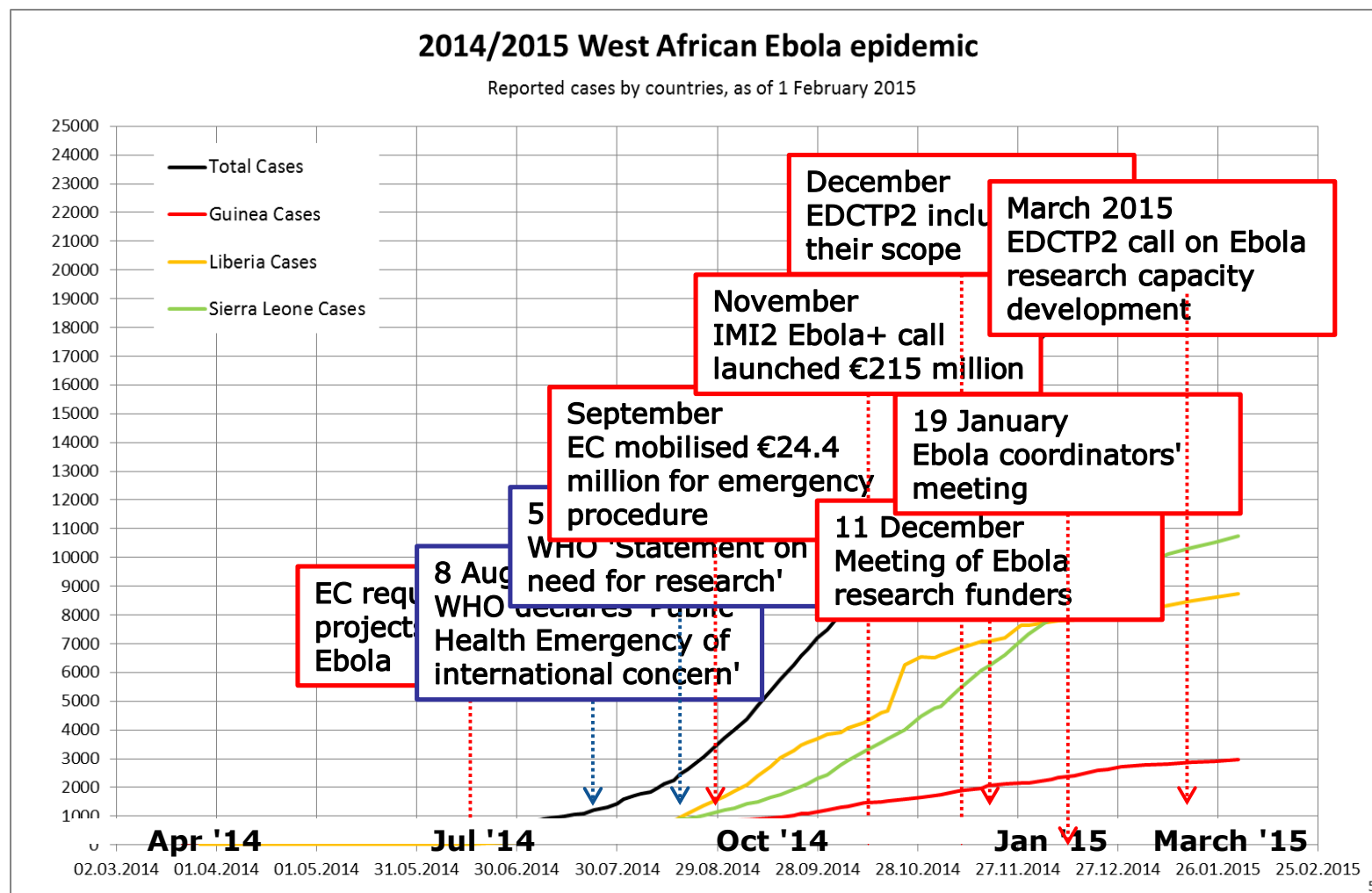
- **Combination of different instruments**

- H2020 : €24.4 Mn
- IMI : €113.9 Mn
- EDCTP : €1 Mn
- FP7 : €49.7 Mn

- **Covering wide range of needs**

- Vaccine development (6)
- Therapeutics (3)
- Diagnostics (3)
- Basic research (3)
- Preparedness (3)
- Social sciences (3)

EU Research Response to the Ebola Outbreak



Addressing Zika research gaps (H2020)



- 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



Research and
Innovation



Building capacity and tools



- COMPARE (H2020)

- Aims 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.)** information



- PREPARE (FP7)

- 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
- Aims to ensure a **rapid, coordinated deployment clinical investigators** within 48 hours of a severe infectious disease outbreak in Europe

III. Participation in international initiatives



- Global Research Collaboration for IDs Preparedness
<http://www.glopid-r.org/>



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



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



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 Members

23 research funders worldwide,
with active engagement of developing countries



Observer Status: World Health Organization (WHO)

IV. Beyond research



- 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
- ...

VI. Challenges



I. Big data and data sharing

- Great efforts underway
- Need appropriate tools and technologies
- Need for operational and legal framework

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

Key principles for data sharing in a public health emergency

GL  PID-R

Timely

Ethical

Equitable

Accessible

Transparent

Fairness

Quality



II. Involvement and capacity of affected countries

- Cf. EDCTP strong capacity building aspect
- EDCTP governance by 14 European and 14 African Participating States, through the General Assembly

V. EU added value



- EU level data collection and analysis
 - Cf. ECDC risk assessments, EFSA scientific opinions
 - Gathering of best researchers, across Europe and internationally – e.g. Zika consortia
- International exposure of EU funded researchers
 - Publication in higher impact journals
 - GloPID-R Zika research workshop in São Paulo, to foster collaboration between research groups
- Rapid mobilisation of funds
 - Complementarity with other funders

