The EU Framework Programme for Research and Innovation

HORIZON 2020

Horizon 2020 Health Challenge - Zika, Ebola & Antimicrobial Resistance

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Head of Unit, DG RTD
Fighting infectious diseases and advancing public health

UKRO Annual Conference, Glasgow 30 June 2016

https://ec.europa.eu/programmes/horizon2020
Overview

• Societal Challenge 1 (SC1) – Health, Demographic Change and Wellbeing work programme 2017
• Horizon Prizes
• Funding for infectious diseases under SC1
  • IMI2, EDCTP2, InnovfinID, JPIAMR
• EU research preparedness and response to outbreaks
  • Ebola
  • Zika
  • GLOPID-R
• UK participation in H2020 – SC1
• Next steps for WP 2018 – 2020
Health research: different programmes serving different communities & purposes

- Collaborative projects
- Public-private partnership with big pharma
- Grants for small businesses
- Loans for small and big R&I companies and universities
- Public-public partnerships with EU Member States & beyond
- Blue sky research
- Knowledge triangle: Higher education, business, R&I

HORIZON 2020

- IMI: Innovative Medicines Initiative
- SME Instrument
- InnovFin: EU Finance for Innovators
- ESFRI: European Strategy Forum on Research Infrastructures
- AAL Programme
- JPND Research
- ERC: European Research Council
- EIT Health
Personalised medicine (2014-2017)

Healthy ageing (2014-2017)


Infectious Diseases (2014-2017)

Human biomonitoring (2016-2017)

Maternal and child health (2016-2017)

2014-15: €1.3bn

2016-17: €1.4bn
## Timetable for Work Programme Updates 2017

<table>
<thead>
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<td>January</td>
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Personalised medicine in SC1 Work Programme 2017 (1)

Understanding health, well-being and diseases
• SC1-PM-02-2017: New concepts in patient stratification
• SC1-PM-03–2017: Diagnostic characterisation of rare diseases
• SC1-PM-07-2017: Promoting mental health and well-being in the young

Treating and managing diseases
• SC1-PM-08–2017: New therapies for rare diseases
• SC1-PM-10–2017: Comparing the effectiveness of existing healthcare interventions in the adult population
• SC1-PM-11–2016-2017: Clinical research on regenerative medicine

NB: Subject to approval by the Member States and the European Commission
Personalised medicine in SC1 Work Programme 2017 (II)

Active ageing and self-management of health
- SC1-PM-15–2017: Personalised coaching for well-being and care of people as they age

Methods and data
- SC1-PM-16-2017: In-silico trials for developing and assessing biomedical products
- SC1-PM-17-2017: Personalised computer models and in-silico systems for well-being
- SC1-PM-19-2017: PPI uptake of standards for the exchange of digitalised healthcare records
- SC1-PM-20-2017: Methods research for improved health economic evaluation

NB: Subject to approval by the Member States and the European Commission
SC1 Work Programme 2017 (III)
Other coordination activities

• SC1-HCO-03–2017: Implementing the Strategic Research Agenda on Personalised Medicine

• SC1-HCO-07–2017: Global Alliance for Chronic Diseases (GACD) prevention and management of mental disorders

• SC1-HCO-08–2017: Actions to bridge the divide in European health research and innovation

• SC1-HCO-17–2017: Support for large scale uptake of Digital Innovation for Active and Healthy Ageing

NB: Subject to approval by the Member States and the European Commission
Horizon Prizes still open
The Horizon Prize - Better use of Antibiotics is offering a cash reward of €1 million to the person or team who can most effectively develop a rapid test that will allow healthcare providers to distinguish at the point-of-care between patients with upper respiratory tract infections that require antibiotics and those that can be treated safely without them.

**Upper Respiratory Tract Infections** include pharyngitis, sinusitis, otitis and bronchitis.

**Who can join the contest?** Any single person and legal entity or groups of legal entities in EU Member States or in countries associated to Horizon 2020.

**Timeline:** Deadline for submissions: 17/08/2016 - Award decision at the end of 2016.

**Website:** [www.ec.europa.eu/horizonprize/antibiotics](http://www.ec.europa.eu/horizonprize/antibiotics)
Birth Day Prize

• The 'Birth day' Prize is an initiative of the European Commission which has committed €1 million, with the Bill & Melinda Gates Foundation pledging another €1 million and a further €500 000 donated by the MSD for Mothers programme of Merck Sharp & Dohme Corporation.

• Up to three prizes of a maximum of €1m

• The Prizes will be awarded for a novel solution to improve the outcome of facility-based deliveries (of a clinical, technological or managerial nature, or a combination)

• Open to any individual/legal entity or groups of legal entities in the world.

• Deadline for submission: 6 September 2017 at 17:00 CET

• More details: www.ec.europa.eu/horizonprize/birthday
INFECTIOUS DISEASES
Infectious Diseases R&I – Collaboration for innovative solutions – Implementation under SC1 1/2

1 – Collaborative research
- Implemented by DG RTD
- With the option to use emergency procedure without a call for proposals

2- SME instrument
- Implemented by DG RTD

3 - Horizon prize – Better Use of Antibiotics
Implemented by DG RTD

4- Public–Private partnership
- IMI – 2 www.imi.europa.eu
Infectious Diseases R&I – Collaboration for innovative solutions – Implementation 2/2

5- Public–Public partnership
- EDCTP2 [www.edctp.org](http://www.edctp.org)
- Joint Programme on AMR [www.jpiamr.eu](http://www.jpiamr.eu)
- ERA-INFECT [www.infect-era.eu](http://www.infect-era.eu)

6- INNOVFIN- Infectious Diseases
- Jointly implemented by EC and EIB [www.eib.org](http://www.eib.org)

7 – Global funders’ initiatives
- Global Collaboration for Infectious Disease Preparedness (GLOPID-R) [www.glopid-r.org](http://www.glopid-r.org)
The EC ecosystem for funding of Infectious Disease R&D under Societal Challenge 1

Risk level
- Discovery PoC
- Preclinical
- Phase 1/2a (Diagnostics/Devices: Validation)
- Phase 2
- Phase 3
- Commercial

"Valley of Death"

Resources required

PUSH ➔ "Valley of Death" ➔ PULL

FP7/H2020 Grants
EDCTP: PRD, NID
IMI-ND4BB
InnovFin ID
SME-Instrument
Horizon Prize
Innovation procurement

PUSH

"Valley of Death"

PULL

Research & Innovation

The EC ecosystem for funding of Infectious Disease R&D under Societal Challenge 1

FP7/H2020 Grants
EDCTP: PRD, NID
IMI-ND4BB
InnovFin ID
SME-Instrument
Horizon Prize
Innovation procurement

PUSH

"Valley of Death"

PULL

Research & Innovation
Current opportunities under the Innovative Medicines Initiative
IMI2 – Call 8:

IMI 2 Ebola and other filoviral haemorrhagic fevers (EBOLA+)
Programme: Future Outbreaks

- Broad scope
- Single stage, open call, with multiple submission deadlines:
  - 16 March 2016
  - 16 September 2016 currently open
  - 16 March 2017
  - 18 September 2017
  - 16 March 2018

- Total budget: up to EUR 70 million IMI financial contribution
- Expectation for contributing partner contributing at least 40% of total budget
- Available budget for next cut-off date: EUR 55 256 680
IMI2 – Call 9
Currently open for submission of short proposal
Submission deadline 26 July 2016 – 17:00:00 Brussels time

1. Addressing the **clinical burden of Clostridium difficile infection** (CDI): Evaluation of the burden, current practices and set-up of a European research platform (part of the IMI New Drugs for Bad Bugs (ND4BB) programme)

2. Development of **immune tolerance therapies** for the treatment of **rheumatic diseases**

3. **Data quality** in preclinical research and development

4. Next generation of **electronic translational safety**

5. Identification and validation of biomarkers for **non-alcoholic steatohepatitis (NASH)** and across the spectrum of **non-alcoholic fatty liver disease (NAFLD)**

6. Joint **influenza vaccine effectiveness** studies
EUROPEAN & DEVELOPING COUNTRIES CLINICAL TRIALS PARTNERSHIP (EDC TP)
THE EDC TP2 PROGRAMME (2014-2024)

Calls for proposals

Clinical Trials in Africa on PRDs

Capacity for Clinical Trials in Africa

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**PARTICIPATING STATES’ INITIATED ACTIVITIES**

- Administered by Participating States
- Selected and funded by Participating States
- Application of Participating States’ funding rules

**EDCTP2 CALLS FOR PROPOSALS**

- Administered by EDCTP
- Funded by the EU, Participating States and third parties
- Horizon 2020 rules for participation

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Third parties
(Private sector, PDPs, International Development Partners)

≥ € 683 M

≤ € 683 M

≥ € 500 M
**Diseases:** HIV/AIDS, TB, Malaria, NIDs, diarrhoeal disease, lower respiratory infections, 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
**CALLS FOR PROPOSALS FROM EDCTP SECRETARIAT**

1. **Clinical trials**  
   (Research & Innovation Actions, RIAs)  
   - Consortia of ≥ 2 European Participating States and ≥ 1 sub-Saharan African country  
   - Either full funding (RIA) (100% of costs) or cofunding (SRIA) (≤50%) with other funders (PSs and/or third parties)  
   - Broad non-prescriptive topics, bottom-up

2. **Fellowships**  
   (Training & Mobility Actions, TMAs)  
   - Grants to individuals: Career development, Senior, EDCTP-TDR  
   - 100% funding  
   - Individual institutions or consortia for ethics, training, networking and regulatory activities

3. **Capacity support**  
   (Coordination & Support Actions, CSAs)  
   - 100% funding  
   - (In 2016: 50% for Strategic CSA with cofunding from development agencies)
A new Finance Facility to stimulate investment in Infectious Disease R&D
A New Financial Instrument for Infectious Diseases R&D

- Jointly developed by the European Commission and European Investment Bank.
- Provides loans between EUR 7.5m and EUR 75m to innovative players active in developing vaccines, drugs, medical and diagnostic devices, and research infrastructures for combatting infectious diseases.
- No calls – demand-driven
- Launched 15 June 2015 in Riga during 'The First Innovative Enterprise Week'.
- 2 deals signed since launch
- Current budget 200 M Euro
Eligible Projects...

- Projects must have proven public health impact and potential market prospect.
- Projects must relate to pre-commercial stage investments in the field of infectious diseases (ID), i.e. the project develops and produces innovative vaccines, drugs, medical and diagnostic devices, and infrastructures in the field of infectious diseases.
- The product should have successfully completed the pre-clinical stage or the proof-of-concept stage (in case of medical and diagnostic devices)
- Research infrastructures that provide facilities, resources and related services to be used by the scientific community to conduct top-level research in the field of ID
Eligibility

Geography

• The Borrower must be established and operating in one or several of the Member States and H2020 Associated Countries. The Project and/or the IP development (e.g., clinical trials) can be undertaken outside Member States and H2020 Associated Countries.

Commitment

• Promoters, sponsors and/or operators must be willing to substantially co-fund the project with own funds for at least 25% of the identified project costs.
• Application & inquiries directly with the EIB:
  • innovfinIDFF@eib.org

• Further Information:
  • www.eib.org/innovfin
Co-operation between Member States: Joint programming on AMR

- Pulls together national research efforts, uses public resources better, and tackles key societal challenges
- 22 Countries BE, CH, CZ, DE, DK, EE, ES, FI, FR, GR, IL, IT, NL, NO, PL, RO, SE, TK, UK, Canada, Argentina and Japan
- Canada joined in 2014, Argentina and Japan joined in 2015, the initiative aims for a further global expansion
- Developed a strategic research agenda that sets out the AMR research priorities
- 11 countries in JPIAMR now have a national research strategy
- Launches transnational research calls
- **Next call expected early 2017**
EU response to Public Health Emergencies

Research a key component

Global collaboration essential

Calls for industry involvement
EC strategy for preparedness research and response during an outbreak

- **Longstanding funding of preparedness research**

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

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

- **Participation in GLOPID-R**
EBOLA
The Research Response to the Ebola Outbreak

2014/2015 West African Ebola epidemic
Reported cases by countries, as of 1 February 2015

- December 2014: EDCTP2 call on their scope
- November 2014: IMI2 call launching €215 million
- September 2014: EC mobilised €24.4 million
- May 2014: EC released €145 million
- 8 April 2014: WHO’s ‘Public Health Emergency of International Concern’
- March 2015: EDCTP2 call on Ebola research capacity development
- 11 January 2015: Ebola coordinators’ meeting
- 30 October 2014: Ebola research funders
Emergency Procedure Ebola Projects

€24.4m

EbolaVac
GlaxoSmithKline
Vaccine candidate ChAd3-EBOV

EVIDENT
Bernhard-Nocht Institute for Tropical Medicine, DE
Interactions between the Ebola virus and the host; genetics

REACTION
INSERM, FR
Favipiravir, antiviral licensed for flu

Ebola_Tx
Institute of Tropical Medicine Antwerp
Convalescent plasma from survivors

IF-EBOla
Institute of Research for Development, FR
Antibodies produced in horses
IMI2 Ebola+ Projects

IMI2 Ebola+ Projects

€101m – pharma industry
€114m – EC

FILODIAG
GNA Biosolutions
Ultra-fast diagnostics based on laser-heated nanoparticles

EBOVAC 1
LSHTM, Janssen
Phase 1 & 3 trials Janssen prime-boost vaccine

EBOVAC 2
Inserm, Janssen
Phase 2 trials Janssen prime-boost vaccine

Ebolamodrad
Public Health Institute Sweden
Portfolio of rapid diagnostic tools

Mofina
Public Health England, Altona
Mobile pan-filovirus nucleic acid test

VSV-EBOVAC
Sclavo Vacc. Assoc
In-depth immunogenicity VSV-ZEBOV

EBODAC
LSHTM, Janssen
Deployment & compliance

EBOMAN
Vibalogics, Janssen
Manufacturing challenges
EDCTP2 Ebola Projects

- CSA-Ebola-360: Building research capacity for infectious diseases in Sierra Leone
- CSA-Ebola-353: Capacity for phase 1 trials in Uganda
- CSA-Ebola-334: Strengthening Laboratory Capacities for Clinical Trials on infectious diseases in Liberia
- CSA-Ebola-337: Enhancing outbreak response capacity in Northern Uganda
- CSA-Ebola-355: Institutional capacity for health research in Sierra Leone
- CSA-Ebola-363: Vaccine trials and Ebola virus control

€1m
Outbreak

Understanding - EVIDENT mapped genetic evolution and mutation of virus

Treatment insights - EVIDENT found immune signature unique to Ebola fatalities

Patient care - Ebola_Tx found that plasma from survivors was not effective

Intervention - EbolaVac vaccine (GSK) in phase 2 trials in adults + children

Control
ZIKA
Zika Call 2016 (closed)

- 10 Feb 2016 – Call text pre-published online
- 15 Mar – Call published
- 28 Apr – Call deadline
- May – Evaluations
- 16 Jun – Grant agreement preparatory meeting
- August – Signature of grant agreements

18 projects submitted; 16 eligible.

5 projects passed thresholds.

NB This call has had an unprecedented level of cooperation between funders and is calling for collaboration between projects funded by EC as well as other GLOPID-R members.
As well as this €10 million call for Zika research there is:

- €40 million call for research on vaccine development for malaria and neglected infectious diseases, which includes the Zika virus

- €10 million for research infrastructures for vector control, including the mosquitos that spread Zika

- Under the ERA-NET programme under FP7: Prevention of infectious diseases in Latin America and the Caribbean
Lessons learned: Speed and sustainability are crucial

Zika
- **GloPID-R** responded on 1 December 2015, same day as PAHO warning. Months before declared emergency by WHO on 1 February 2016
- **EC responded with €10m Horizon 2020 call on Zika** - 10 Feb 2016 – Call text pre-published online, officially launched 15 March 2016

Yellow Fever
- 17 May 2016 **GloPID-R** began evaluating research needs
- The WHO have not declared an emergency situation, but are monitoring closely and will be holding a workshop.

But the crisis also highlighted the lack of preparedness e.g.
- The pipeline of vaccines, drug and diagnostics was weak
- Lack of understanding of the social context
- Improved health system and research capacity needed in LMIC
- Better surveillance, identification of risk factors and prevention are needed
- Regulatory, legal and ethical challenges must be addressed
Global Research Collaboration for Infectious Disease Preparedness

A network of research funders
A Novel Solution

GloPID-R: “Global Research Collaboration for Infectious Disease Preparedness”

- Facilitates an effective research response within 48hrs of a significant outbreak with pandemic potential, in order to save lives and economies worldwide
- The only initiative of its kind
How?

● GloPID-R:

  ● Brings together *funders* whose involvement is crucial for a comprehensive and rapid global outbreak response

  ● Identifies *existing weaknesses* that prevent a timely and efficient outbreak response

  ● Drives a process to *overcome gaps and obstacles*, identify concrete actions and build collaborative solutions
3 Priority Actions in 2016-2017

1. **Zika**  
   4 Working Groups:  
   - Etiology  
   - Diagnostics  
   - Vaccines  
   - Vector Control

2. **Data Sharing** - Develop a framework for data sharing during public health emergencies

3. **Response Plan** - Response modes and triggers for research actions
GloPID-R Members

- African Academy of Sciences
- Ministry of Science, Technology and Productive Innovation
- National Health and Medical Research Council
- Instituto Butantan
- Instituto Fiocruz
- Sao Paulo Research Foundation (FAPESP)
- Canadian Institutes of Health and Research (CIHR)
- International Development Research Centre (IDRC)
- European Commission - DG Research & Innovation
- INSERM - Institut national de la santé et de la recherche médicale
- Federal Ministry of Education and Research (BMBF)/PT-DLR
- Indian Council of Medical Research (ICMR)
- Ministry of Health
GloPID-R Members

Agency for Medical Research and Development

National Research Foundation of Korea

Consejo Nacional de Ciencia y Tecnología

Research Council of Norway (RCN)

South African Medical Research Council

Instituto de Salud Carlos III

Thai National Institute of Health, Department of Medical Sciences

Bill & Melinda Gates Foundation

U.S. Department of Health and Human Services

Wellcome Trust

Observer Status: Department for International Development (DFID)

Observer Status: World Health Organization
Country performance in SC1 Health up to February 2016

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## Top 15 organisations in SC1 Health up to February 2016

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<td>FRAUNHOFER GESELLSCHAFT ZUR FORDERUNG DER ANGEWANDTEN FORSCHUNG EV</td>
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</tr>
</tbody>
</table>
UK involvement – Health

• UK has received over €300 million (>£232m)

• Average success rate, all calls:
  o All countries = 6.0%
  o UK = 8.9%

UK involvement – Ebola

• For Ebola outbreak, UK received:
  o €1.8 million (£1.4m) from DG RTD
  o €62.6 million (£49.3) from IMI2
Participant portal – a non-stop shop

- Call topics
- NCPs
- Expert registration
- Documents
- Project officers' list for questions
- FAQs
- Rules for participation
- Upload project reports

http://ec.europa.eu/research/participants/portal
Process towards WP 2018-2020

- **2nd half 2015**: Foresight study
  - Report

- **January 2016**: Advisory Group Consultation
  - Advice report
  - Stakeholder consultation

- **June 2016**: Strategic priorities

- **Sept 2016**: Elaboration and adoption of the WP

- **1st half 2017**: Member States Consultation – ongoing process