



EU funded research to enhance Humanitarian Health

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Overview

- Seventh Framework Programme for Research & Development (FP7)
- Horizon 2020
- European & Developing Countries Clinical Trials Partnership (EDCTP 2)
- Global Research Collaboration on Infectious Disease Preparedness (GloPID-R)

A large banner with a blue and white space-themed background. On the left, a transparent globe of Earth is shown with a bright light source behind it, creating a lens flare effect. The background is filled with stars and abstract blue and white light trails.

Seventh Framework Programme for Research & Development (FP7) (2007-2013)

FP7 Health Theme: key priorities for infectious diseases



- **Emerging infectious diseases:** *Influenza and other emerging diseases (incl vector-borne diseases)*
- **Anti-microbial resistance**
- **Poverty-related diseases:** *HIV/AIDS, Tuberculosis, malaria*
- **Neglected Infectious diseases:** *protozoal, helminth, bacterial diseases*



FP7 funding on HIV/AIDS, Malaria and Tuberculosis

FP7 PROGRAMME	THEME	HIV/AIDS	Malaria	TB	Multiple diseases	Total
COOPERATION	HEALTH	130,1	75,5	88,4	23,8	317,7
	ICT	2,8	2,9	0,0	1,4	7,1
	ENVIRONMENT	0,0	3,5	0,0	1,7	5,2
	NMP	0,0	3,1	0,0	0,0	3,1
	SPACE	0,0	0,5	0,0	0,0	0,5
IDEAS	European Research Council	32,1	19,5	15,0	3,0	69,6
CAPACITIES	Infrastructures	0,0	8,5	0,0	18,4	26,9
	REGPOT	0,0	0,0	1,0	0,0	1,0
	SME	1,4	0,0	0,4	1,3	3,1
PEOPLE	Marie-Curie Actions	6,8	8,9	9,0	1,7	26,3
Total support in € million		173,1	122,4	113,7	51,2	460,4



FP 7 – Ebola research

Using the flexibility of existing Emerging Epidemics projects

- ANTIGONE: Emergence + transmissibility + pathogenicity of zoonotic pathogens
 - Discovered soluble Ebola proteins responsible for damage to vessel wall;
 - Reallocate funding to additional studies on therapeutic strategies to alleviate the septic shock-like syndrome caused by EBOV; to understand how people in West Africa come into contact with ebola virus and ebola-like virus e.g. role of domestic animals, fruit bat populations, risk factors.
- PREDEMICS: risk patterns of zoonotic pathogens for surveillance, control, intervention and preparedness
 - Analysis of inter- and intra-host virus evolution, source and time of introduction, Patterns of transmission
- PREPARE : Streamline Europe's clinical research response to future epidemics
 - Preparedness questionnaire to hospitals around Europe
 - Contribution to draft clinical trial protocols
- TELL ME: models for improved risk communication during infectious disease crises
 - Analysis of Ebola-related Twitter messages - 5 top influencers on Ebola topic

A graphic for the Horizon 2020 program. It features a central, glowing globe of Earth with a bright light source behind it, creating a lens flare effect. The background is a deep blue space with stars and a faint, glowing blue structure resembling a DNA helix or a network of connections. The text "HORIZON 2020" is written in a large, bold, yellow font at the top right. Below it, "EU's Programme for Research & Innovation" is written in a smaller, yellow font, and "(2014-2020)" is written in a larger, bold, yellow font at the bottom right.

HORIZON 2020
EU's Programme for
Research & Innovation
(2014-2020)



What is Horizon 2020?

The EU's 2014-20 programme for research & innovation with a budget of 79 billion euro

A core part of Europe 2020, Innovation Union & European Research Area

Three priorities:

1. Excellent science (24,4 bn €)
 2. Industrial leadership (17,0 bn €)
 3. Societal challenges (29,7 bn €)
- + Other activities (5,9 bn €)





How does it work ? (1)

- The policy for research is described in the Horizon 2020 documents (available on CORDIS web site).
- A work programme is prepared by the EC staff, based on consultation (Advisory Group, Programme Committee...).
- Then EC publishes calls for proposals to invite researchers to submit collaborative proposals for research projects.
- Researchers form consortia and prepare proposals.
- One or two-stage submission & evaluation process.
- Panels of independent experts (peer review) identify best projects, which are selected by the EC.
- After finalisation of a grant agreement, a project is normally funded for 2-5 years, with regular reporting.





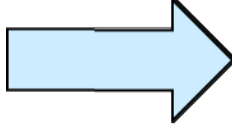
European
Commission

From CALL to GRANT

**Publication
of the calls**

Time to prepare
the proposal

**Submission
of proposals**



Evaluation

**Signature grant
agreement**

Finalisation
of the grant

**Information on
the outcome of
the evaluator**





Exceptional procedure - **Ebola**

- Use of provisions in Financial Regulation (art 128) and its Rules of application (art 190) **to award grants without a call for proposals** *"in exceptional and duly substantiated emergencies"*
- Spontaneous expressions of interest – intention to submit proposal
- To all such EoI, Commission acknowledged receipt and provided link to electronic submission system with deadline 6 October 2014



Exceptional procedure - Ebola

- 8 proposals received, 1 inadmissible (submission after deadline)
- Evaluation by 7 independent high-level experts
- 5 of 7 proposals passed all thresholds → shortlisted
- Allocated budget: **€ 24.4 million**
- GA preparation ongoing, signature expected 28 November 2014
- Start of the projects - 1 November 2014



Exceptional procedure - Ebola

Shortlisted proposals

EbolaVac: coordinator GlaxoSmithKline (BE), EU contribution € 15.2 million

- Phase II clinical trials in EU & Africa to establish **safety** of most advanced vaccine candidate ChAd3-EBOV. (trials expected to start in November in Switzerland and in January in Mali, Cameroon, Ghana and Nigeria)

REACTION: coordinator INSERM (FR), EU contribution € 2.6 million

- Safety and efficacy of favipiravir (licensed for influenza) in animal model and in phase II clinical trial (trials expected to start in December)

Ebola_Tx: Prins Leopold Instituut for Tropische Geneeskunde (BE), EU contribution € 2.9 million

- Safety, efficacy and feasibility of plasma from survivors of ebola infection (trials expected to start in December in Guinea)

EVIDENT: Bernhard-Nocht Institut für Tropenmedizin (DE), EU contribution € 1.8 million

- Host-pathogen interaction, transmissibility of virus in various body fluids and understanding mutations of virus

IF-EBOLa: Institut de Recherche pour le Developpement (F), EU contribution € 2.9 million

- Safety and efficacy of passive immunotherapy by deploying horse serum containing antibodies against ebola (testing expected to start mid-2015 in Guinea and Sierra Leone)



Innovative Medicines Initiative (IMI 2) – fast track procedure for Ebola research

- ❑ The EU Commission and the EU pharmaceutical industry launched a **€280 million call for proposals** to boost research on Ebola under the Innovative Medicines Initiative.
- ❑ **€140 million from Horizon 2020** and €140 million from the pharmaceutical companies (members of the EU Federation of Pharmaceutical Industries and Associations - EFPIA).
- ❑ The call for proposals will use a **new fast-track procedure** to get successful projects up and running early next year.
- ❑ Topics in the call address **vaccine development** Phase I, II, and III; **Manufacturing capability**; **Stability of vaccines during transport and storage**; **Deployment and compliance of vaccination regimens** as well as **Rapid diagnostic tests**.



European & Developing Countries Clinical Trials Partnership (EDCTP)





EDCTP: mission & objectives

Background

- Established in 2003 by a co-decision of the European Parliament and Council
- Funding from EC matched by EU Member States, Switzerland and Norway

Mission

- To reduce the burden of **poverty related diseases** and generally improve the health of people living in developing countries

Objectives

- To accelerate R&D of new or improved interventions for poverty related diseases through the **coordination** of EU Member States' national programmes working in **partnership** with sub-Saharan African countries in collaboration with like-minded organisations





EDCTP2 Participating States (PSs)

13 European Countries

Austria, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain and United Kingdom

11 African Countries

Cameroon, Rep of Congo, Ghana, Mozambique, Niger, Senegal, South Africa, Tanzania, The Gambia, Uganda, Zambia

Countries that can receive funding

- All sub-Saharan African countries
- All EU MSs and Associated (H2020) Countries





What EDCTP funds

Diseases: poverty related diseases (HIV/AIDS, Tuberculosis, Malaria), neglected infectious diseases, 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



A wide banner with a dark blue, starry space background. On the left, a transparent globe of the Earth is shown, with a bright light source behind it creating a lens flare effect. The text "Global Research Collaboration for Infectious Disease Preparedness (GloPID-R)" is written in a bold, yellow, sans-serif font on the right side of the banner.

Global Research Collaboration for Infectious Disease Preparedness (GloPID-R)





WHY GloPID-R ?

Severe epidemics are not restricted to single nations or regions, but have the potential to threaten the population of the entire planet;

'Preparedness Research' on (Re-)Emerging Infectious Diseases (development of diagnostics, epidemiology, clinical trials etc.) requires a rapid international research response;

Unlike the public health response (coordinated by WHO), there is currently no forum for the coordination of an international research response to such outbreaks;

Joint work in 'peacetime' on regulatory, financial and administrative bottlenecks for preparedness research will prepare the ground for successful collaboration in the case of an outbreak.





What is GloPID-R ?

- A network of research funders - launched in Brussels in February 2013;
- The goal is to facilitate an effective research response within 48 hours of a significant infectious diseases outbreak with pandemic potential;
- Governance 'GloPID-R Charter' adopted 30 September 2014 in Montreal, Canada;
- The GloPID-R founding members are funders from EU, France, Spain, U.S., Canada, South Africa, Brazil, Korea, Thailand, Australia;
- Interim chair from the European Commission, interim vice chairs from Brazil, Canada, France and South Africa;
- **Funding organisations from other countries are invited to join.**





Objectives OF GloPID-R ?

GloPID-R aims to facilitate a global research response to a significant outbreak of an infectious disease through research and policy development during inter-epidemic periods by:

- Facilitating exchange of information between funders.
- Connecting the existing and future research networks in this area.
- Addressing scientific, logistical, legal, regulatory, ethical and financial challenges.
- Establishing a strategic agenda to address these challenges.
- Aiming to involve developing countries.





**GloPID-R's goal is
not to coordinate a public health response and it is
not a new funding organisation**

GloPID-R aims to make the work of its members more effective through collaboration and by jointly addressing the barriers to research.

GloPID-R will closely collaborate with public health and veterinary services, industry, regulatory agencies and patient groups.





Ongoing activities and next steps

Collaboration on Ebola Virus disease research;

Development of the Strategic agenda for research response: A first round of discussions took place in Montreal in fall 2014 and work will continue in the coming months;

The GloPID-R secretariat, selected from the first Horizon 2020 call and funded by the European Commission, will be operational in December 2014;

Next GloPID-R 2015 meeting will take place in South Africa-details to be confirmed later.

