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HIV/AIDS research in Horizon 2020 and the work programme 2014-2015

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OUTLINE



FP7 cooperation health programme: HIV research

What's new in H2020

Where to focus

Disclaimer

Pending formal adoption by the EU of the Horizon 2020 legal texts, the content of the H2020 slides is not definitive and so should not be taken as such, nor used or referred to as such in any way or for any purpose



The role of the EC in health research and innovation

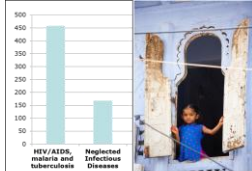
The European Union



Develop and implement the European (EU) research and innovation policy agreed by the European Parliament and European Council

The EU is the World's 3rd largest funder of research on poverty-related and neglected infectious diseases
G-Finder 2012

FP7 (2007-2013) financial commitment (€m)



The EU Framework Programmes and EDCTP

Since 1984

The EU Framework Programmes for Research and Innovation (FP) (current FP7)

↳ Collaboration between scientists from academia and industry from different countries around the world

Since 2003 (under FP6)

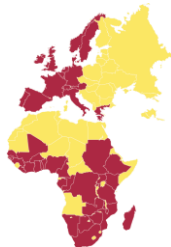
The European and Developing Countries Clinical Trials Partnership (EDCTP)

↳ Collaboration between European countries - aligning their research programmes and funding



The European and Developing Countries Clinical Trials Partnership (EDCTP)

- Established in 2003 as part of the EU response to MDGs
- Public-Public Partnership:** Joint initiative between 16 European States and EU
- Independent legal entity (EEIG).** Funding body (has its own calls for proposals) + convener (broker interactions between African and European research teams)
- Coordination of European national programmes for phase II + III clinical trials in Africa for HIV/AIDS, malaria, TB + capacity building
- EC contribution of 200 mill Euro + MS contribution of 200 mill Euro (in-kind) + C80m contributions from Third Parties.
- +30 clinical trials on HIV/AIDS
- to be renewed 2014 (EDCTP-2)



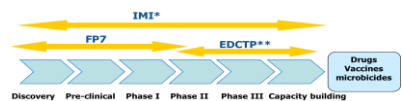
EDCTP- project portfolio 2012

http://www.edctp.org/fileadmin/documents/our_work/EDCTP_project_portfolio.pdf



Priorities in FP7 for HIV/AIDS research

- Basic research
- Vaccines
- Microbicides
- Drugs and other therapeutic interventions
- Capacity building and training
- Clinical management (optimisation of treatment)



Implementation modalities

- Large scale integrated projects
- Networks of excellence
- ERA-NET
- Small or medium-scale focused projects
- SME-targeted projects





HIV research under FP7 cooperation programme – HEALTH theme

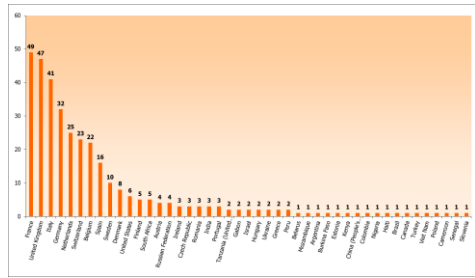
total: 28 cooperative projects - ~ € 135 million



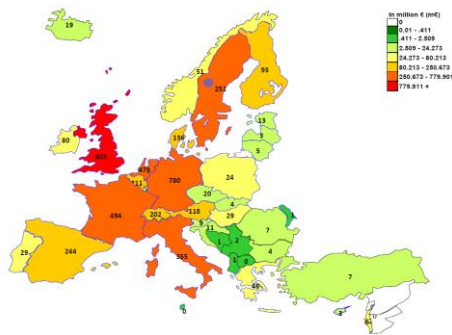
- Treatment/Therapeutic vaccines/Cure/Diagnostic/ (14 projects) € 70.7m
- Preventive vaccine/Microbicides (11 projects) € 58.3m
- Public Health/Policies (3 projects) € 5.4m



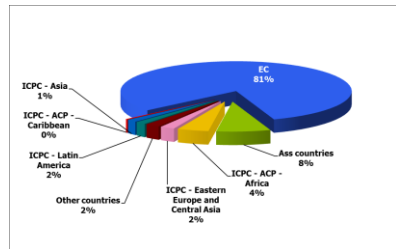
HIV research under FP7 Cooperation programme-Health Theme - Country participation



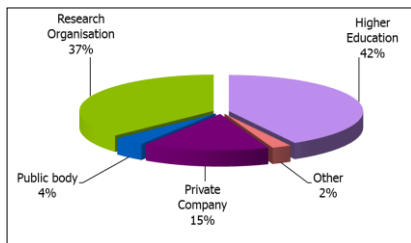
FP7 cooperation Health programme EC contribution by Member State



HIV research under FP7 Cooperation programme-Health Theme - Country group



HIV research under FP7 Cooperation programme-Health Theme - Organisation type



FP7 portfolio: HIV/AIDS collaborative research

€ 135 M
28 projects

	Training Basic science	Prevention	Treatment/Cure	
		Vaccines	Drugs/vaccines	
		Microbicides	Clinical management Public Health	
			Diagnostics	
HIV		New vaccine (basic preclinical, and phase I CT) Including iNab	Discovery and pre-clinical development of new drugs	Adherence with mobile phone technology to treatment in India
		Discovery and development (phase I CT) of new (combined) microbicides	Discovery and pre-clinical development of new drugs	PK, PD studies new drugs formulation for paediatric use
HIV co-infection co-morbidities*		New routes of vaccination Cutaneous and mucosal vaccines, CT phase I	Viral eradication/control for functional cure	HIV drug resistance and its transmission
		Platform for microbicides optimisation for novel formulations	Therapeutic vaccine, Phase I and IIa CTs	Observational studies with cohorts for clinical management
ERA-NET to harmonise and integrate European programmes on HIV/AIDS				
Roadmap for an HIV-TB scientific agenda				
		New vaccine, phase I CT for HIV+HCV		New cohort and biomarkers for HIV-co-morbidities
		Platforms for vaccine and adjuvant development and testing; training for PRDs		Development validation diagnostic tool for HIV-syphilis
		models to study HIV, TB, HAI & HCV and HIV-NID		

FP7 portfolio HIV/AIDS collaborative research outcome

Vaccines

development of several new vaccine candidate, of which 11 phase I or IIa CT
development of a novel transcutaneous route of vaccination

Microbicides

Development of novel candidates microbicides; 1 combination will go phase I CT
Development of a platform for microbicides optimisation and formulations (bottlenecks in microbicides development)

Drugs

Pre-clinical development of drug candidates tackling 4 novel targets; 1 candidate reached licence agreement with large pharma for clinical testing. 1 candidate into phase I/IIa CT

Diagnostics

Development and validation of 1 point-of-care diagnostic tool for testing HIV-Syphilis in new-born and pregnant women. Validation of a low-cost ELISA test

Treatment

Large network of cohorts: includes data > 270.000 HIV+ individuals; Standardised methods & protocols for data collection and sharing. Impact on WHO and EACS HIV treatment guidelines

Establishment of an European cohort for HIV-comorbidities

PK and PD studies (incl. 5 clinical trials) for new drugs formulations for pediatric use

Horizon 2020

what's new?

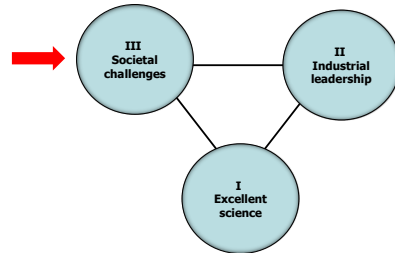
Horizon 2020 what's new?

- **A single programme** bringing together three separate programmes/initiatives*
- **Coupling research to innovation** – from research to retail, all forms of innovation
- **Focus on societal challenges** facing European society e.g. health and ageing, clean energy and transport
- **Simplified access**, for all companies, universities, institutes in all EU countries and beyond

□The 7th Research Framework Programme (FP7), innovation aspects of Competitiveness and Innovation Programme (CIP), EU contribution to the European Institute of Innovation and Technology (EIT)

Horizon 2020: ~ € 77 billion

H2020 builds on three priorities:



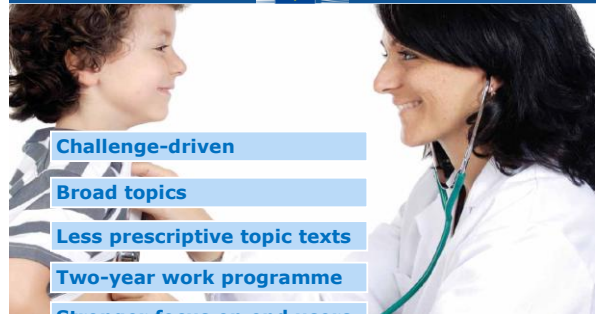
Societal challenges

Proposed funding
(million EUR, 2014-2020)*

Health, demographic change and wellbeing	7 472
Food security, sustainable agriculture and forestry, marine and maritime and inland water research and the Bioeconomy	3 851
Secure, clean and efficient energy *	5 931
Smart, green and integrated transport	6 339
Climate action, environment, resource efficiency and raw materials	3 081
Inclusive, innovative and reflective societies	1 310
Secure societies	1 695
Science with and for society	462
Spreading excellence and widening participation	816

□All funding figures in this presentation are subject to the pending Multiannual Financial Framework Regulation by the EP and the Council

A new approach



Challenge-driven

Broad topics

Less prescriptive topic texts

Two-year work programme

Stronger focus on end users

Next steps



Adoption of work programme and publication of first calls for proposals	11 December 2013
Submission deadlines for proposals	Two-stage: 11 March & 19 August All others: 15 April SME instrument: check Work Programme
Horizon 2020 national launch events	Until January 2014 Full list: http://ec.europa.eu/research/horizon2020
National info days	http://ec.europa.eu/research/participants/portal/page/nationalcontactpoint



Horizon 2020
SC1: 'Health, demographic change and wellbeing'
Where to focus?

The Work Programme 2014 2015



Call 'personalising health and care'
34 topics (15 in 2014, 17 in 2015, 2 open in both years)

Call for 'co-ordination activities'
15 topics (10 in 2014, 5 in 2015)

€ 1,21 billion



Personalising Health and Care



7 Focus Areas



- Understanding health, ageing & disease
- Effective health promotion, disease prevention, preparedness and screening
- Improving diagnosis
- Innovative treatments and technologies
- Advancing active and healthy ageing
- Integrated, sustainable, citizen-centred care
- Improving health information, data exploitation and providing an evidence base for health policies and regulation



Understanding the call topics example



PHC 2 - 2015 D Understanding diseases systems
Specific challenge: The development of an improved understanding of the often very complex (bio) medicine approaches have the potential to... of a variety of biological and medical research a collaborative approach is required to assemble (biology, medicine, mathematics, computational) medicine approaches.

Scope: proposals should focus on new avenues phenotypes in multifactorial diseases and on development/optimisation and/or application of of biomedical and clinical data to produce or refine computational and mathematical approaches. It validated in well-phenotyped patient cohorts, take potential thoroughly investigated.

The Commission considers that proposals require EUR 4 and 6 million would allow this space. Nonetheless, this does not preclude submission amounts.

Expected impact: This will provide:
- A review of existing investments in EU
- New directions for better disease detection
- Systems medicine tools and approaches which represent an improvement over existing approaches

Type of action: Research and Innovation action

'PHC 2 - 2015'

'Specific challenge'

'Scope'

'Expected impact'

'Type of action'





Understanding health, ageing & disease

- Determinants, risk factors and pathways of diseases (2014) (PHC 1)
- **Determinants and pathways of healthy and active ageing (2014) (PHC 1)**
- Systems medicine approaches (2015) (PHC 2)
- **Common mechanisms of diseases and potential co-morbidities (2015) (PHC 3)**



Effective health promotion, disease prevention, preparedness and screening

- Inter-sector cooperation for environment- and health-based interventions (2015) (PHC4)
- Translating -omics into stratified prevention and health promotion (2014) (PHC 5)
- **Evaluating existing screening and prevention programmes (2014) (PHC 6)**
- Control of infectious epidemics through rapid pathogen identification (2014) (PHC 7) (see also SC2)
- **Vaccine platforms for TB (2014) (PHC 8) and HIV (2015) (PHC9)**



PHC 9 - 2015) Vaccine development for poverty-related and neglected infectious diseases: HIV/AIDS

Scope

Focus on strengthening the capacity for discovery and early development of new vaccine candidates for HIV/AIDS by:

- i) establishment of platform for novel candidates discovery, selection, pre-clinical and early clinical testing
 - ii) tackling major bottleneck in vaccine development
 - iii) the vaccine development shall continue in the context of EDCTP-2
- To also address barriers and facilitators regarding the update and implementation of a new vaccine

Expected Impact:

- To increase the chance of discovery of an effective therapeutic or preventive vaccine with reduced costs
- To establish close links to the European and Developing Countries Clinical Trials Partnership (EDCTP-2)

Type of action: Research and innovation project



Improving diagnosis

- **In vitro devices, assays and platforms (2014) (PHC 10)**
- In vivo medical imaging technologies (2015) (PHC 11)

Innovative treatments and technologies

- Therapies for non-communicable diseases (2014) (PHC 13) and rare diseases (2015) (PHC 14)
- Clinical research on regenerative medicine (2014) (PHC15)
- Tools and technologies for advanced therapies (2015) (PHC 16)
- Comparing and establishing effectiveness of health interventions in the elderly (2014) (PHC 17) and in paediatric population (2015) (PHC 18)



Advancing active and healthy ageing

- Service robotics within assisted living environments (2014) (PHC 19*)
- Pilot projects on independent living with cognitive impairments (2014) (PHC 20*) (Innovation type of action)
- Early risk detection and intervention (2015) (PHC 21*)
- Promoting mental wellbeing in the ageing population (2015) (PHC 22)



* Topics with ICT focus



Integrated, sustainable, citizen-centred care

- New models for prevention oriented health and care systems (2014) (PHC 23)
- Piloting personalised medicine in health and care systems (2015) (PHC 24)
- Self-management of health and disease:
 - citizen engagement and mHealth for disease management (2014), (PHC 26*)
 - patient empowerment supported by ICT (2015) (PHC 27*)
 - based on predictive computer modelling (2015) (PHC28*)



* Topics with ICT focus



Integrated, sustainable, citizen-centred care

- Public procurement of innovative eHealth services (2015) (PHC 29*)
- ICT systems for integrated care (2015) (PHC 25*)
- eHealth sectorial inducement prize (2015)

Improving health information, data exploitation and providing an evidence base for health policies and regulation

- Digital representation of health data to improve diagnosis and treatment (2015) (PHC 30*)
- Foresight for health policy development and regulation (2014) (PHC 31)
- Advancing bioinformatics for clinical needs (2014) (PHC 32)
- Improve predictive human safety testing (2015) (PHC 33)
- eHealth interoperability (2014) (PHC 34*)

* Topics with ICT focus



CONDITION FOR 2014 PHC CALL

Publication date: 11 December 2013
(Opening date: PHC 12 – 2014/2015 only: 1st March 2014)

Deadline(s) (2014): 11 March 2014 (stage one of two stage call)
15 April 2014 (single stage call)
19 August 2014 (stage two of two stage call)

Eligibility and admissibility conditions*:

The conditions are described in **parts B and C** of the General Annexes to the work programme

Evaluation criteria, scoring and threshold*:

The criteria, scoring and threshold are described in **part H** of the General Annexes to the work programme

(exception: PHC 12, SME topic)



From EDCTP1 to EDCTP2

- **Broader scope:** HIV/AIDS, malaria and tuberculosis, other NIDs diseases. From phase I to IV clinical trials. Diagnostics, therapy, prevention
- **Extended duration of the programme to 10 years**, since a clinical trial programme typically lasts 8-15 years.
- **Larger budget**, the broader scope and extended duration require a higher budget in order to maximise the impact of the initiative. Currently planned EDCTP2 budget: €1366 million with calls over 10 years: matching EU contribution of up to €683 million
- **Better coordination, alignment and integration of relevant national** programmes to increase the cost-effectiveness of European public investments
- **Strengthened cooperation with sub-Saharan African countries**, in particular on building their capacity for conducting clinical trials in compliance with relevant laws
- **extended international cooperation with other public and private funders** (incl. BMGF and the pharmaceutical industry)



Experts

Appropriately qualified individuals may apply to work as experts in H2020 evaluations!

- **Application via Participant Portal**



**Call for experts published 22 November
Official Journal of the European Union C342/3**

<http://eurlex.europa.eu/JOHtml.do?uri=OJ%3AC%3A2013%3A342%3ASOM%3AEN%3AHTML>



34



Thank you!



DG Research and Innovation <http://ec.europa.eu/research>
Infectious Diseases unit <http://ec.europa.eu/research/health/infectious-diseases>
EDCTP <http://edcto.eu>
Cordis http://cordis.europa.eu/fp7/home_en.html

