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 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)

Develop and implement the European (EU) research and innovation policy agreed by the European Parliament and European Council.
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) + €80m contributions from Third Parties.

- +30 clinical trials on HIV/AIDS

- **to be renewed 2014** (EDCTP-2)

EDCTP- project portfolio 2012

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

- EC: 81%
- Ass countries: 8%
- ICPC - Eastern Europe and Central Asia: 4%
- ICPC - ACP - Africa: 4%
- ICPC - ACP - Caribbean: 0%
- ICPC - Latin America: 2%
- Other countries: 2%
- ICPC - Asia: 1%
HIV research under FP7 Cooperation programme - Health Theme - Organisation type

- Higher Education: 42%
- Research Organisation: 37%
- Private Company: 15%
- Public body: 4%
- Other: 2%
FP7 portfolio: HIV/AIDS collaborative research

€ 135 M
28 projects

HIV

**Prevention**

- **Training**
  - Basic science

- **Vaccines**
  - New vaccine (basic, preclinical, and phase I CT) inducing bNab
  - New routes of vaccination
  - Cutaneous and mucosal vaccines; CT phase I

- **Microbicidaes**
  - Discovery and development (phase I CT) of new (combined) microbicides
  - Platform for microbicides optimisation for novel formulations

**Treatment/Cure**

- **Drugs/vaccines**
  - Discovery and pre-clinical development of new drugs
  - Viral eradication/ control for functional cure

- **Clinical management**
  - Adherence with mobile phone technology to treatment in India
  - HIV drug resistance and its transmission

- **Public Health**
  - PK, PD studies new drugs formulation for paediatric use
  - Observational studies with cohorts for clinical management

**Diagnostics**

- **Therapeutic vaccine, Phase I and IIa CTs**

**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**

**HIV co-infection co-morbidities**

- **Platforms for vaccine and adjuvant development and testing; training for PRDs**
  - models to study HIV, TB, Mal & HCV and HIV+NID

- **New cohort and biomarkers for HIV-comorbidities**

- **Development validation diagnostic tool for HIV-syphilis**
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?

• **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 Framework Programme (CIP), EU contribution to the European Institute of Innovation and Technology (EIT)
Horizon 2020: ~ € 77 billion

H2020 builds on three priorities:

I Excellent science

II Industrial leadership

III Societal challenges
### Proposed funding
(million EUR, 2014-2020)*

<table>
<thead>
<tr>
<th>Societal challenges</th>
<th>Funding (million EUR)</th>
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<tbody>
<tr>
<td>Health, demographic change and wellbeing</td>
<td>7 472</td>
</tr>
<tr>
<td>Food security, sustainable agriculture and forestry, marine and maritime and inland</td>
<td>3 851</td>
</tr>
<tr>
<td>water research and the Bioeconomy</td>
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<tr>
<td>Secure, clean and efficient energy *</td>
<td>5 931</td>
</tr>
<tr>
<td>Smart, green and integrated transport</td>
<td>6 339</td>
</tr>
<tr>
<td>Climate action, environment, resource efficiency and raw materials</td>
<td>3 081</td>
</tr>
<tr>
<td>Inclusive, innovative and reflective societies</td>
<td>1 310</td>
</tr>
<tr>
<td>Secure societies</td>
<td>1 695</td>
</tr>
<tr>
<td>Science with and for society</td>
<td>462</td>
</tr>
<tr>
<td>Spreading excellence and widening participation</td>
<td>816</td>
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</tbody>
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* All funding figures in this presentation are subject to the pending Multiannual Financial Framework Regulation by the EP and the Council.
Innovative Medicines Initiative Initiative 2
www.imi.europa.eu

European Innovation Partnership on Active and Healthy Ageing
https://webgate.ec.europa.eu/eipa

Active and Assisted Living 2
www.aal-europe.eu

European & Developing Countries Clinical Trials Partnership (EDCTP2)
www.edctp.org
A new approach

Challenge-driven
Broad topics
Less prescriptive topic texts
Two-year work programme
Stronger focus on end users
## Next steps

<table>
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<th><strong>Adoption of work programme and publication of first calls for proposals</strong></th>
<th><strong>11 December 2013</strong></th>
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| **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: Understanding diseases: systems biology

Specific challenge: The development of new, improved understanding of the often very complex (bio)medicine approaches have the potential to open up a variety of biological and medical research directions. A collaborative approach is required to assemble the knowledge of biology, medicine, mathematics, computational and engineering approaches.

Scope: Proposals should focus on new avenues for phenotype studies in multifactorial diseases and/or drug discovery, optimisation and/or application of methods of biomedical and clinical data to produce or refine computational and mathematical approaches. These can be validated in well-phenotyped patient cohorts, taking potential thoroughly investigated.

The Commission considers that proposals requesting a maximum of EUR 4 and 6 million would allow this specific challenge to be addressed. Nonetheless, this does not preclude submission of proposals requesting larger amounts.

Expected impact: This will provide:
- Leverage of existing investments in Europe
- New directions for better disease detection
- Systems medicine tools and approaches that represent an improvement over current technologies

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) (PHC 4)
- 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)
**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) (PHC 28*)

* 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
Co-ordination activities
Support for European and International Initiatives

- European Innovation Partnership on Active and Healthy Ageing (2014)
- Global Alliance for Chronic Diseases (GACD) – Diabetes (2014)
- Joint Programming Initiative 'More Years, Better Life's (2014)
- Joint Programming Initiative on neurodegenerative diseases (JPND, 2014)
- Global Research Collaboration for Infectious Disease Preparedness (2014)
- European Reference Networks (2015)
Completing the European Research Area

- **Joint Programming Initiative on neurodegenerative diseases (JPND, 2014)**
- **Translational cancer research (2014)**
- **Systems medicine for clinical needs (2014)**
- **Rare diseases (2014)**
- **2015: Brain-related disorders, antimicrobial resistance, cardiovascular diseases**
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
Thank you!

DG Research and Innovation
Infectious Diseases unit
EDCTP
Cordis

http://ec.europa.eu/research
http://ec.europa.eu/research/health/infectious-diseases
http://edctp.eu