The societal challenge
'Health, demographic change and well-being'

Work programme 2016-2017

INFO DAY
Zagreb
26 November 2015

Philippe Cupers
Deputy Head of Unit
DG Research and Innovation
Croatia started its participation to EU Health research programme with FP7 and continues in Horizon 2020.

Horizon 2020 should contribute to Commission priorities – importance of projects outcomes.

Horizon 2020 offers health research opportunities adapted to each step of the innovation cycle.

Horizon 2020 health research priorities are personalised medicine, biomonitoring, infectious diseases, child and maternal health, healthy ageing, e-health.

Collaborative research, multidisciplinarity, international cooperation, open to business.
Croatia and EU research programmes
Croatia participation to EU health research started in FP7
Zagreb region was the most successful in HR

FP7 Health Cooperation Programme (2007-2013)

CROATIA key figures
EC Contribution : 10,909,668
Total Costs : 14,309,342
Number of projects : 23
Number of participations : 28
Number of organisations : 19
Average amount by participations : 389,631
Croatian SMEs are successful participants.
Croatia mainly EU-active in clinical trials

Distribution by scientific area

- Clinical Trials: 2.7
- Brain and brain-related diseases: 2.1
- Omics: 1.6
- Other Chronic Diseases: 1.5
- Advanced therapies: 1.1
- Cancer: 1.1
- Infectious Diseases: 0.4
- Health Services: 0.1
- Coordination & Support: 0.1
- Toxicology & Drug Safety: 0.0
- Cardiovascular Diseases: 0.0
- Drug Discovery & Development: 0.0
- Diabetes and obesity: 0.0
Croatia continues its participation in H2020
Croatian institutions coordinate EU projects

Project OSTEOGROW
Regenerative medicine clinical trial of the therapeutic system OSTEOGROW for regenerating bone through harnessing a novel bone device to accelerate and enhance bone repair

Professor Slobodan Vukicevic
University of Zagreb
Laboratory for Mineralized Tissues
Centre for Translational & Clinical Research
University of Zagreb School of Medicine

H2020 contribution: about €5.7 m
Croatia participates to MS efforts in coordinating research on neurodegeneration

- 28 participating countries, including non-European (Canada)
- The JPND adopted its Research Strategy on 7 February 2012 (basic science, clinical research and healthcare research)
- 7 Calls published – more than €100 million invested
- Recent Call for European research projects on neurodegenerative diseases: risk and protective factors, longitudinal cohort approaches and advanced experimental models (co-funding with EU)

H2020 contribution: about €12 m
Health research in Horizon 2020 and in the Societal Challenge 1
Research and innovation is a priority for the EU ... ... but Horizon 2020 must deliver

- EXCELLENT research and innovation
- Projects must have an IMPACT
- Show ADDDED VALUE, be multidisciplinary and well-implemented

Reflected in the evaluation criteria
What are our intended outputs?

More healthy life years

Evidence based policy making
- Medicines for children
- Health Technology Assessment
- ATMP
- and many others...

Taking the lead in new areas of growth
- Personalised medicine

Responding to emergencies

Knowledge creation and exploitation
# Health research in Horizon 2020

## Collaborative health research (SC1)
- **Public-private partnership**
- **Frontier research**

## Support to innovation
- **Human Brain Project**
- **Modelling & predictive (neuro)sciences**
- **Research Education Innovation**

## Health research infrastructures
- **ESFRi European Strategy Forum on Research Infrastructures**
- **InnoFin EU Finance for Innovators**
- **Innovative Medicines Initiative**

## Loans for de-risking R&I
- **European Investment Bank**
- **The Juncker Plan for Investment in Europe**

## Deployment of innovative solutions
- **EDCTP**
- **EIT Health**
- **JPND**

---

**European**

**Human Brain Project**

**InnoLife**

**SME Instrument**

**ERC European Research Council**

**EASME Executive Agency for SMEs**

**jciamr Joint Programming Initiative on Ageing and Multiple Chronic Conditions**

**European Investment Bank**

**ESFRi European Strategy Forum on Research Infrastructures**

**InnoFin EU Finance for Innovators**

**The Juncker Plan for Investment in Europe**

**EDCTP**

**EIT Health**

**JPND**

**jciamr Joint Programming Initiative on Ageing and Multiple Chronic Conditions**

---

**Societal Challenges**

**Human Brain Project**

**InnoLife**

**SME Instrument**

**ERC European Research Council**

**EASME Executive Agency for SMEs**

**jciamr Joint Programming Initiative on Ageing and Multiple Chronic Conditions**

**European Investment Bank**

**ESFRi European Strategy Forum on Research Infrastructures**

**InnoFin EU Finance for Innovators**

**The Juncker Plan for Investment in Europe**

**EDCTP**

**EIT Health**

**JPND**

**jciamr Joint Programming Initiative on Ageing and Multiple Chronic Conditions**

---

**Societal Challenges**

**Human Brain Project**

**InnoLife**

**SME Instrument**

**ERC European Research Council**

**EASME Executive Agency for SMEs**

**jciamr Joint Programming Initiative on Ageing and Multiple Chronic Conditions**

**European Investment Bank**

**ESFRi European Strategy Forum on Research Infrastructures**

**InnoFin EU Finance for Innovators**

**The Juncker Plan for Investment in Europe**

**EDCTP**

**EIT Health**

**JPND**

**jciamr Joint Programming Initiative on Ageing and Multiple Chronic Conditions**

---

**Societal Challenges**

**Human Brain Project**

**InnoLife**

**SME Instrument**

**ERC European Research Council**

**EASME Executive Agency for SMEs**

**jciamr Joint Programming Initiative on Ageing and Multiple Chronic Conditions**

**European Investment Bank**

**ESFRi European Strategy Forum on Research Infrastructures**

**InnoFin EU Finance for Innovators**

**The Juncker Plan for Investment in Europe**

**EDCTP**

**EIT Health**

**JPND**

**jciamr Joint Programming Initiative on Ageing and Multiple Chronic Conditions**

---
Personalised medicine
Promoting healthy ageing
Human biomonitoring
Health ICT
Infectious Diseases
InnovFin
Maternal and child health
Personalised Medicine is defined as a medical model using characterization of individuals’ phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data) for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention

(Horizon 2020 Societal Challenge 1 Advisory Group Report)
Priority 'Personalised Medicine'

Strategic planning & coordination of national initiatives

A large number of research and innovation topics and coordination topics in the SC1 Work Programme 16-17

Implementation in SC1 Work Programme 2016-2017
Understanding health, well-being and diseases
• SC1-PM-01-2016: Multi omics for personalised therapies addressing diseases of the immune system
• SC1-PM-02-2017: New concepts in patient stratification
• SC1-PM-03–2017: Diagnostic characterisation of rare diseases
• SC1-PM-04–2016: Networking and optimising the use of population and patient cohorts at EU level

Treating and managing diseases
• SC1-PM-08–2017: New therapies for rare diseases
• SC1-PM-09–2016: New therapies for chronic 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
**Preventing diseases**
• SC1-PM-07–2017: Promoting mental health and well-being in the young

**Methods and data**
• SC1-PM-20–2017: Development of new methods and measures for improved economic evaluation and efficiency measures in the health sector

**Health care provision and integrated care**
• SC1-PM-21–2016: Implementation research for scaling-up of evidence based innovations and good practice in Europe and low- and middle-income countries
Coordination activities

- SC1-HCO-02-2016: Standardisation of pre-analytical and analytical procedures for in vitro diagnostics in personalised medicine
- SC1-HCO-03–2017: Implementing the Strategic Research Agenda on Personalised Medicine
- SC1-HCO-05–2016: Coordinating personalised medicine research
- SC1-HCO-06–2016: Towards an ERA-NET for building sustainable and resilient health system models
Priority 'Human biomonitoring'

Strategic planning & coordination of national initiatives

- Creating a European joint programme for monitoring and scientific assessment of human exposures to chemicals and potential health impacts
- Coordinating HBM initiatives in Europe at national and EU level with special focus on a two way dialogue between policy and science in support of evidence based policy making
- Implementation through a Joint Programme Co-Fund

Implementation in SC1 Work Programme 2016-2017

Preventing diseases
SC1-PM-05–2016: The European Human Biomonitoring Initiative
Priority 'Infectious diseases'

- **Collaborative research** – HIV/AIDS, Malaria and Tuberculosis; Neglected Infectious Diseases (NID); Emerging Epidemics; Antimicrobial drug resistance (AMR)

- **New financial instruments** - InnovFin Infectious Diseases – joint initiative between EC-EIB

- **Inducement prizes** – Horizon 2020 prize for better use of antibiotics

- **Global initiatives** - Global Research Collaboration for Infectious Disease Preparedness (GLOPID-R); Global Tuberculosis Vaccine Partnership (GTBVP)

- **Public–private partnerships** – IMI2

- **Public–public partnerships** – EDCTP2

- **Joint Programming Initiative on AMR** – JPIAMR – ERA-INFECT
Priority 'Infectious diseases'

Understanding health, well-being and diseases
• SC1-PM-02-2017: New concepts in patient stratification
• SC1-PM-04–2016: Networking and optimising the use of population and patient cohorts at EU level

Preventing diseases
• SC1-PM-06–2016: Vaccine development for malaria and/or neglected infectious diseases

Treating and managing diseases
• SC1-PM-09–2016: New therapies for chronic diseases
• SC1-PM-10–2017: Comparing the effectiveness of existing healthcare interventions in the adult population

Coordination activities
• SC1-HCO-04–2016: Towards globalisation of the Joint Programming Initiative on Antimicrobial Resistance
Priority 'Maternal and child health'

- Approximately 300,000 women died from preventable causes related to pregnancy and childbirth in 2013
- Maternal and perinatal conditions are the seventh contributors to the global burden of disease

Other Actions: Horizon Prize on reducing maternal and newborn morbidity and mortality – the Birth Day Prize

- The prize calls for a novel solution to improve the outcome of facility-based deliveries (of a clinical, technological or managerial nature, or a combination of these)
- Developed by European Commission and Bill & Melinda Gates Foundation
- More details and prize launch at the high-level conference "Together for the next generation" on 8 December in Brussels
Promoting healthy ageing

Health ICT

A large number of research and innovation topics, and coordination topics in the SC1 Work Programme 2016 - 2017
Priority 'ICT solutions for active & healthy ageing'

- Exploring new opportunities
- Catalyse Silver Economy
- IoT for Smart Living Environments (with ICT-LEIT)
- Scale up Innovative Care Services
- Complementing previous calls

- Ground-breaking R&D in Personalised Coaching (2017)
- EU – Japan Cooperation (2016)
- Smart Living Environments Large-scale pilot (2016)
- PPI for deployment and scaling up (2016)
- CSAs Standards & Silver Economy take-up (2016)
- Stimulate research and growth in SMEs (2016-17)
Priority 'ICT for health'

• More strategic patient-centred approach and health promotion

• Creating a body of evidence for IT technologies, support for SME's growth, IT skills for healthcare workforce

• New approaches in managing health, from well-being to personalisation

• Data and sharing data challenges

• Decrease of time to market, better adaptation to innovation and support to policy

• Contribution to WHO activities and US cooperation

The entire chain of innovation is needed, from research to support actions and specific instruments.
Active ageing and self-management of health

- SC1-PM-12–2016: PCP - eHealth innovation in empowering the patient
- SC1-PM-13–2016: PPI for deployment and scaling up of ICT solutions for active and healthy ageing
- SC1-PM-14–2016: EU-Japan cooperation on Novel ICT Robotics based solutions for active and healthy ageing at home or in care facilities

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-18–2016: Big Data supporting Public Health policies
- SC1-PM-19–2017: PPI for uptake of standards for the exchange of digitalised healthcare records
- SC1-PM-20-2017: Development of new methods and measures for improved economic evaluation and efficiency measures in the health sector
Coordination activities

- SC1-HCO-09–2016: EU m-Health hub including evidence for the integration of mHealth in the healthcare systems
- SC1-HCO-10–2016: Support for Europe’s leading Health ICT SMEs
- SC1-HCO-11–2016: Coordinated action to support the recognition of Silver Economy opportunities arising from demographic change
- SC1-HCO-12–2016: Digital health literacy
- SC1-HCO-13-2016: Healthcare Workforce IT skills
- SC1-HCO-14–2016: EU-US interoperability roadmap
- SC1-HCO-15-2016: EU eHealth Interoperability conformity assessment
- SC1-HCO-16-2016: Standardisation needs in the field of ICT for Active and Healthy Ageing
Other coordination activities

SC1-HCO-01-2016: Valorisation of FP7 Health and H2020 SC1 research results

SC1-HCO-07–2017: Global Alliance for Chronic Diseases (GACD)

SC1-HCO-08–2017: Actions to bridge the divide in European health research and innovation
Small and Medium Enterprises (SMEs)
SME instrument

Phase 1: Concept & Feasibility Assessment
- Feasibility of concept
- Risk assessment
- IP regime
- Partner search
- Design study

Phase 2: Innovation R&D activities
- Development, prototype, testing
- Miniaturisation/design
- Clinical trials
- Etc.

Phase 3: Commercialization
- Facilitate access to private finance
- Support via networking, training, knowledge sharing, dissemination

Lump sum:
- ~ 50,000 €
- ~ 6 months

EU funding:
- 1 to 5 million EUR
- 12 to 36 months

No direct funding
• SMEInst-05-2016-2017 – Supporting innovative SMEs in the healthcare biotechnology sector

• SMEInst-06-2016-2017 – Accelerating market introduction of ICT solutions for Health, Well-Being and Ageing Well
Public-private partnerships
Public-private partnership

IMI2:

- Covers the entire medical research and innovation value chain
- Strategic Research Agenda is based on the WHO Priority Medicine Report renewed in July 2013
- Involves pharmaceutical industries as well as others (diagnostics, imaging, animal health, ICT etc.)
- Supports World class research and innovation leading to breakthrough vaccines, medicines and treatments
Multi-lateral health research initiatives

[Logos and websites of various health research initiatives]

www.irdirc.org/
http://intbir.nih.gov/
http://ihec-epigenomes.org/
www.gacd.org/
https://icgc.org/
http://www.glopid-r.org/
EDCTP supports clinical trials and related research activities on PRDs, as well as capacity development for clinical trials and related research in sub-Saharan Africa.

EDCTP2:

- launched in December 2014
- almost €700 million EU co-funding, matching the same Member States contribution
- broader scope: including HIV, TB, malaria, neglected infectious diseases, all clinical phases, diagnostics and delivery optimisation
- longer duration: 10 years

EDCTP 2: ~€1.37 Billion
EC: €683 mio + MS €683 mio
Financial instruments
## InnovFin products overview

<table>
<thead>
<tr>
<th>SMEs</th>
<th>Midcaps</th>
<th>Large Caps</th>
<th>Thematic Finance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>InnovFin</strong> SME Guarantee</td>
<td><strong>InnovFin</strong> MidCap Guarantee</td>
<td><strong>InnovFin</strong> Large Projects</td>
<td><strong>InnovFin</strong> Energy Demo Projects</td>
</tr>
<tr>
<td><strong>InnovFin</strong> SME Venture Capital</td>
<td><strong>InnovFin</strong> MidCap Growth Finance</td>
<td></td>
<td><strong>InnovFin</strong> Infectious Diseases</td>
</tr>
<tr>
<td>SMEs and small Mid-Caps &lt; 500 Employees</td>
<td>Mid-Caps &lt; 3,000 Employees</td>
<td>Large Caps Typically &gt; 3,000 Employees</td>
<td>SPV, Mid-Caps and Large Caps</td>
</tr>
<tr>
<td></td>
<td>Intermediated SME/Mid-Cap Financing</td>
<td>Direct Corporate Lending</td>
<td>Project Finance and/or Direct Corporate Lending</td>
</tr>
</tbody>
</table>

---

InnovFin EU Finance for Innovators
• Broad range of products - standard debt instruments (i.e. senior, subordinated, and mezzanine) to risk sharing instruments (RSL) with forgiveness options

• EIB can only finance 50% of project costs

• Comprehensive due diligence (legal, financial, technical, etc.)

• EIB standard documentation under English or Luxembourgish law
Which projects can be supported?

- Projects which have passed pre-clinical stage and for which clinical validation is needed for further development
- Loan amount: min EUR 7.5 million, max EUR 75 million
- Loan maturity: up to 7 years
- Currency: EUR and local currency
- Pricing: commensurate to the risk incurred
Thank you for your attention

Find out more:
www.ec.europa/research/horizon2020
The European Commission, alongside the other European Institutions, stands united in solidarity with France

The EU 28 Member States unanimously agreed to the activation of the Mutual Assistance Clause 42.7 of the EU treaty