

The societal challenge 'Health, demographic change and well-being' Work programme 2016-2017



Athens
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DG Research and Innovation





The societal challenge of health, demographic change and wellbeing

Ageing population

Increased disease burden

Unsustainable and unequal health and care systems

Health and care sector under pressure to reform

Horizon 2020 - Societal Challenge 1

What do we do?

- Support health R&I from bench to bedside
- Encourage transformation of knowledge into innovative
 - ✓ prevention
 - ✓ diagnosis
 - ✓ treatment modalities and healthcare systems in Europe and around the globe



Our guiding principles:

- Open innovation
- Open science
- Openness to the world

Research and innovation – a growing priority for the EU

Horizon 2020 must deliver



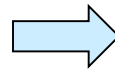
- You should perform EXCELLENT research and innovation
- Your project must have an IMPACT
- Show ADDED VALUE, be multidisciplinary and well-implemented

Reflected in the
evaluation
criteria

Horizon 2020 should support Commission priorities

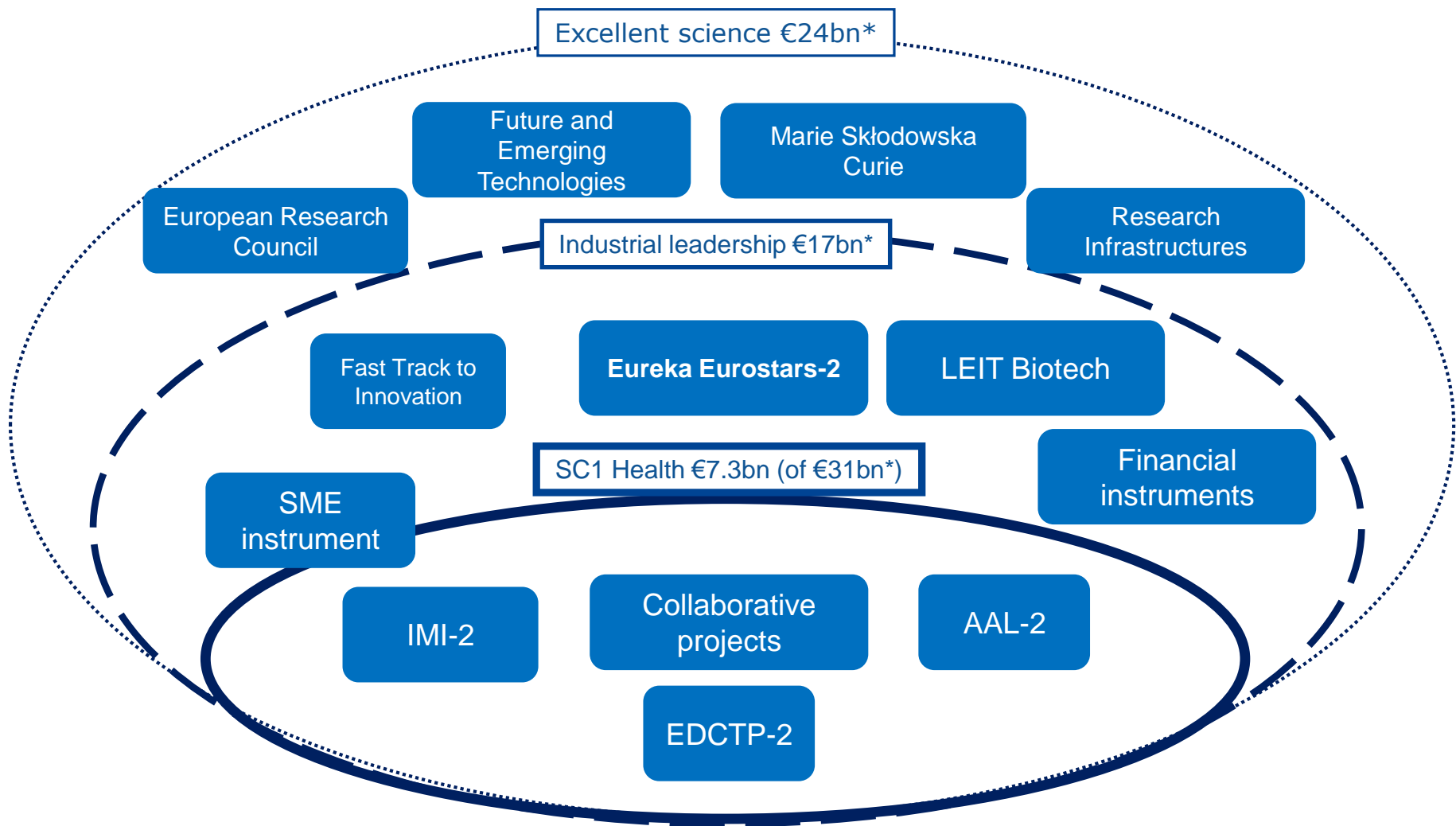


- Jobs and growth
- Societal challenges
- European industrial leadership and competitiveness
- EU international excellence



- Couple research to innovation
- Provide evidence-base for addressing societal challenges, supporting EU policies and better regulation
- Strengthen research capacities and innovation strategies across all Member States
- Multidisciplinarity and synergies
- Address people's concerns

Health Research in H2020



* Figure to be updated following EFSI investments in 2015



innovative
medicines
initiative

THE INNOVATIVE MEDICINES INITIATIVE

The Innovative Medicines Initiative (IMI) is Europe's largest public-private initiative aiming to speed up the development of better and safer medicines for patients.

IMI supports collaborative research projects and builds networks of industrial and academic experts in order to boost pharmaceutical innovation in Europe.

IMI is a joint undertaking between the European Union and the pharmaceutical industry association EFPIA.



IMI 2: ~€3.2 billion
EC: €1.6b+ EFPIA €1.4b + other
(€0.2b)

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



European & Developing Countries Clinical Trials Partnership

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.



EDCTP 2:
~€1.37 Billion
EC: €683 mio + MS
€683 mio

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

H2020: Collaborative research

A young boy with curly hair is looking towards a female doctor. The doctor is wearing a white lab coat and a green stethoscope, and she is smiling. The background is plain white.

Challenge-driven

Broad, less 'prescriptive', topics

Two-year work programme

Stronger focus on end-users

The SC1 Work Programme 2016-17 in brief

Call 'Personalised Medicine'

21 topics (34 in 2014-2015): 10 in 2016, 10 in 2017,
1 open in 2016 & 2017

including 'coordination activities'

15 topics (17 in 2014-2015): 12 in 2016, 3 in 2017

€ 935
million

SME Instrument : 2 Topics

Other Actions: 12 items

(incl. InnovFin ID & "Birth Day Prize")

Focus Area Digital Security: 1 Topic

Focus Area Internet of Things: 1 Topic

Main research priorities for 2016-2017



Personalised medicine



Promoting healthy ageing



Human biomonitoring



Health ICT



Infectious Diseases

InnovFin



Maternal and child health

Calendar for Horizon 2020 Work Programme 2016-2017 (2017 indicative)

- 18 September 2015: SC1 Info Day – Brussels
- 13 October 2015: adoption of WP 2016-2017 by the Commission
- 14 October 2015: publication of WP 2016-2017
- Call 2016 deadlines : 19.01.2016, 16.02.2016, 13.04.2016 (mainly single-stage)

CSAs- deadline 16.02.2016 or 13.04.2016

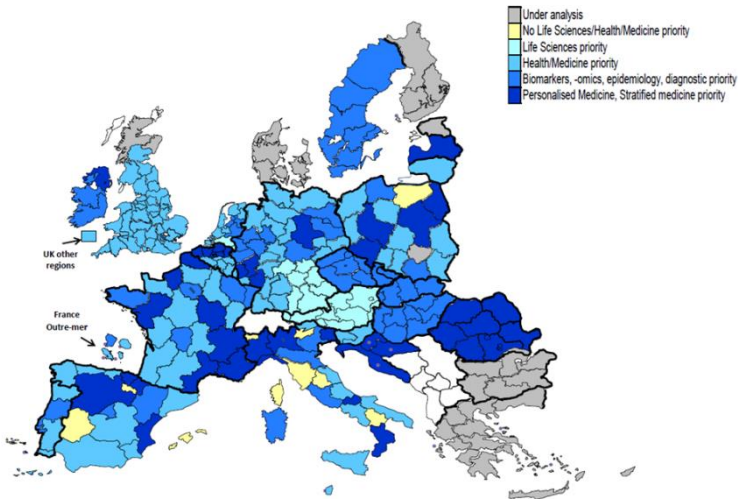
Majority R/I actions single stage - deadline 13.04.2016

Developing personalised medicines at EU level

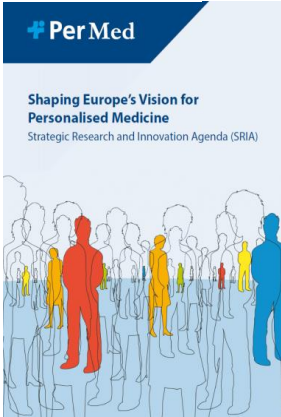


Strategic planning & coordination of national initiatives

Implementation in SC1 Work Programme 2016-2017



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



Personalised medicine in SC1 Work Programme 2016-2017 (I)

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

Personalised medicine in SC1 Work Programme 2016-2017 (II)

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

Personalised medicine in SC1 Work Programme 2016-2017 (III)

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

SC1-PM-2-2017: New concepts for patient stratification

Challenge:

- Despite the major advances in understanding disease in the post-genomic era, still a majority of all drugs are effective in only a limited number of patients. From a clinical perspective, implementing knowledge-based decisions on what therapeutics to use for which patients and, if relevant, in which combinations, are extremely challenging.

Scope:

- Proposals should deliver novel concepts for disease-mechanism based patient stratification to address the needs for stratified or personalised therapeutic interventions. The proposals should integrate multidimensional and longitudinal data and harness the power of -omics, including pharmacogenomics, systems biomedicine approaches, network analysis and. of computational modelling. The new concepts of stratification should be validated in pre-clinical and clinical studies taking into account sex and gender differences. Applicants are encouraged to actively involve patient associations. The proposals should consider regulatory aspects of clinical practice and commercialisation opportunities. Proposals should focus on complex diseases having high prevalence and high economic impact.

Expected Impact:

- New models for patient stratification to inform clinical decision making..
- Increased cost-effectiveness of the novel concepts in comparison to already established practices.
- Increased research and innovation opportunities in this innovative industries-driven field, particularly small or medium-sized enterprises (SMEs).

European human biomonitoring initiative

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



Preventing diseases

SC1-PM-05-2016: The European Human Biomonitoring Initiative





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

Infectious diseases in SC1 WP 16-17 (I)

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

Infectious diseases in SC1 WP 16-17 (II)

Other Actions: InnovFin Infectious Diseases (InnovFin ID) Pilot

A New Financial Instrument for Infectious Diseases R&D:

- Jointly developed by the European Commission and European Investment Bank
- Launched on 15 June 2015 in Riga during 'The First Innovative Enterprise Week'
- Established under InnovFin - EU Finance for Innovators
- 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

<http://www.eib.org/innovfin>



InnovFin
EU Finance for Innovators





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

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



Promoting healthy ageing



Health ICT



A large number of research and innovation topics, and coordination topics in the SC1 Work Programme 2016 - 2017



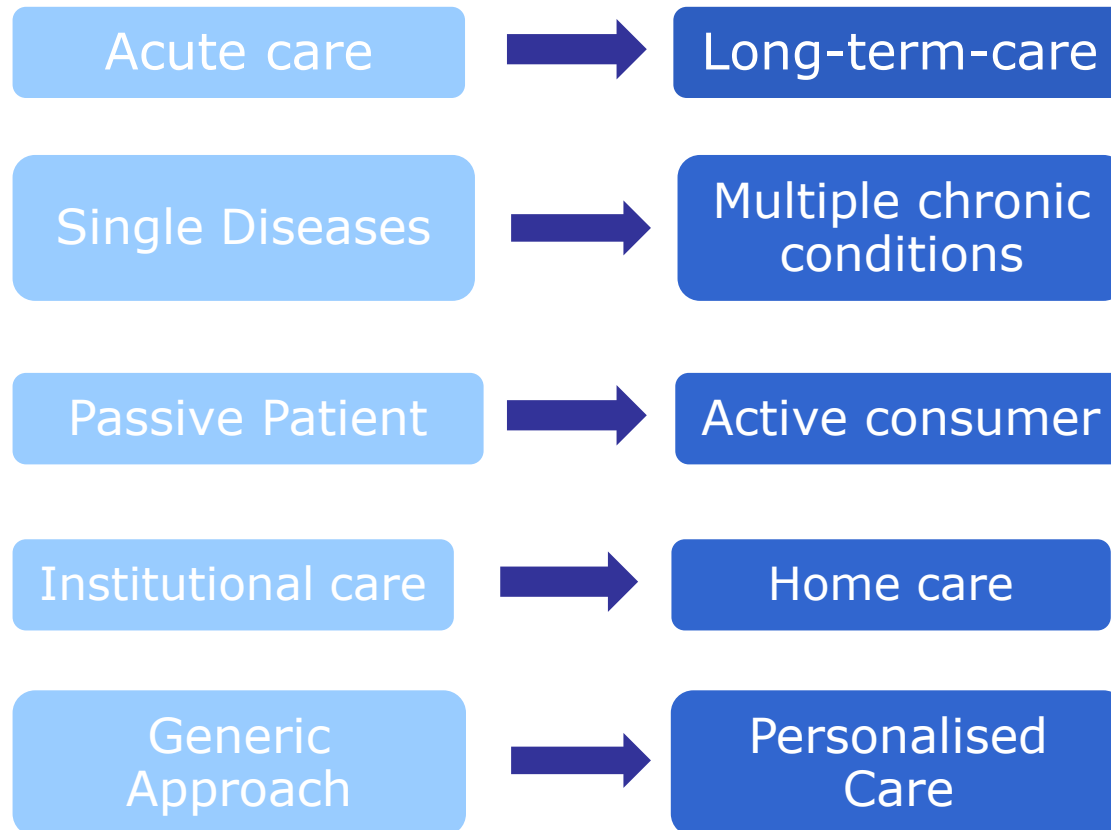
Horizon 2020
Health, Demographic Change and Well-being
Open Info day
18 September 2015, Brussels, 15:00-17:30, room JENK

**ICT for Health, demographic change and
well-being – Work Programme 2016-17**



Health and Well-being Unit (H1)
Digital Social Platforms Unit (H2)
DG Communications Networks, Content and Technology
European Commission

Transforming Health and Care



How to get there

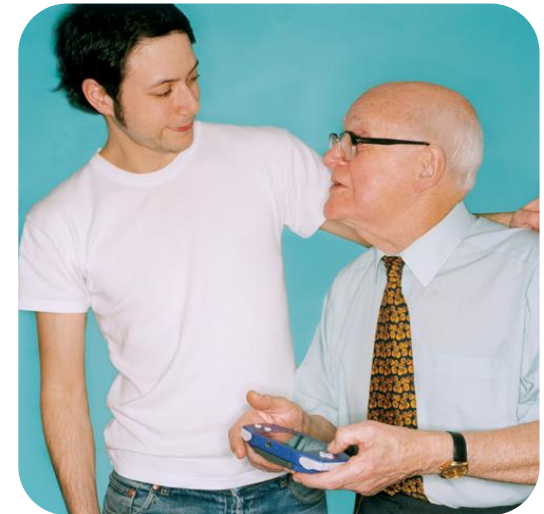
Digital
Single
Market

Smarter,
innovation
friendly
Policies

Creating
scale,
partnerships
and return of
investments

Investing in
Research
and
Innovation
(H2020)

European
Innovation
Partnership
on Active
and Healthy
Ageing



eHealth
Action plan
2012-2020
mHealth
Green paper
and follow-up

1.9 Billion €
2014-2020

Longer Term Research Areas

- **Service robotics within smart living environments**
- **Early risk detection & intervention linked to ageing**
- **Advanced ICT for Integrated Care**
- **Self-management of health and disease based on predictive computer modelling used by the patient**
- **Digital representation of health data to improve disease diagnosis and treatment**

Applied Research

- **Open Service Platforms
(Open Source IoT middleware for service, device,
data integration)**
- **Self-management of health and disease: citizen
engagement and mHealth**
- **eHealth Interoperability**

Draft H2020 WP 2016/2017 SC1- ICT for Health and Well-being - Overview

CSAs: EU mHealth Hub; Support for Health ICT SMEs; Digital Health literacy; Healthcare Workforce IT skills; EU/US Interoperability roadmap; EU eHealth Interoperability conformity;

PCP: Empowering the patient

SME Instrument: Accelerating market introduction of ICT solutions for SC1

RIA: Big Data; Digital Security; Simulation /modelling on wellbeing; In silico trials

Horizon Prize: Food scanner *)

*) Horizon Prize instrument (not under SC1)

SC1-PM-18–2016: Big Data supporting Public Health policies

Challenge:

- How to use Big Data for supporting healthy life and preventing diseases.
- Insight for understanding human systems to develop personalized medicine.

Scope:

- Develop integrating solutions for acquiring, managing, sharing, modelling, processing and exploiting Big Data to support public health authorities in long-term policy making and increase the ability to provide actionable insights at the point of care.

Expected Impact:

- Creation of network of knowledge by linking data sources for public health strategy.
- Turning large amounts of data into actionable information to authorities for planning public health activities and implementation of an approach "health in all policies".

SC1-PM-18–2016: Big Data supporting Public Health policies

Deadline, Budgets

- Submission Deadline: 16/02/2016 (17.00.00 Brussels local time)
- Research and Innovation Action
- Cumulative threshold: 10 (3/3/3)
- Total Budget: 10 million €

Horizon 2020: more opportunities for SMEs

- **Integrated approach** – around 20% of the total budget for societal challenges and LEITs to go to SMEs
- **Simplification** of particular benefit to SMEs (e.g. single entry point)
- A **new SME instrument** will be used across all societal challenges as well as for the LEITs
- A dedicated activity for research-intensive SMEs in **'Innovation in SMEs'**
- **'Access to risk finance'** with a dedicated SME scheme (debt and equity facility)

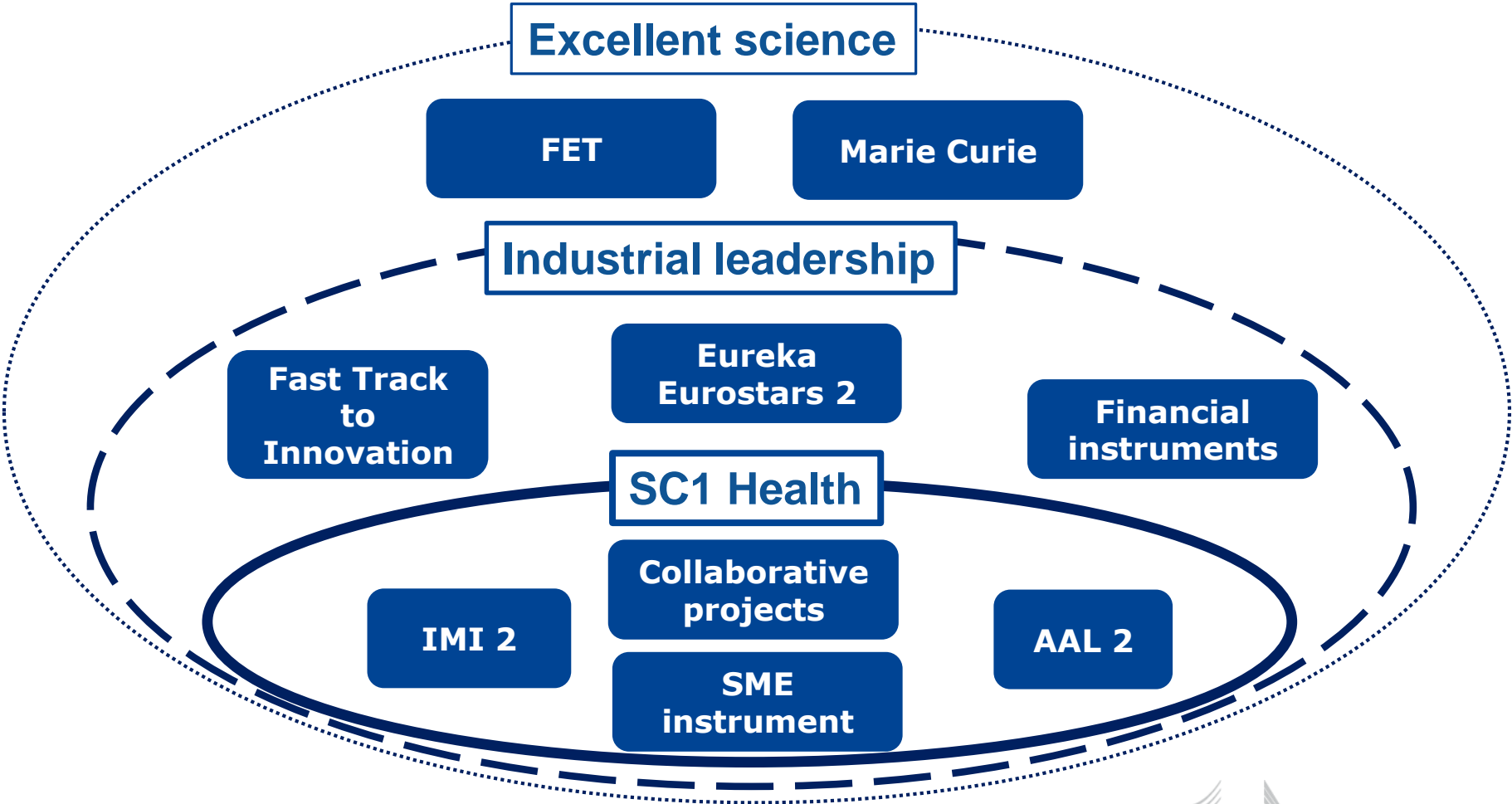


SME instrument in SC1 work programme 2016-2017



- 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

Funding for Health SMEs in H2020



SME instrument

- Inspired by the US Small Business Innovation Research (SBIR) program
- Piloted by the Health Directorate in 2012/13
- **Single company support possible**
- Only EU SMEs allowed to apply for funding
- Competitive, market-oriented, EU dimension
- Several cut-off dates i.e. submission deadlines per year
- Resubmission is possible

SME instrument: 3 phases

Idea



Phase 1

Feasibility Assessment

- Feasibility of concept
- Risk assessment
- IP regime
- Partner search
- Design study

€50,000
~ 6 months

Phase 2

Innovation / R&D project

- Clinical trials
- Development, prototyping, scaling-up
- Miniaturisation, design
- Etc.

€1 to 5 million
~36 months
100% / 70% funding rate

Phase 3

Commercialisation

- Facilitate access to private finance
- Support via networking, training, coaching, knowledge sharing, dissemination

No direct funding

Market



SME instrument topics (1/2)

SMEInst-05-2016-2017: Supporting innovative SMEs in the healthcare biotechnology sector

1) Clinical research for the validation of biomarkers and/or diagnostic medical devices (PHC 12)

- 25/11/2015: phase 1 & 2 cut-off
- 18/01/2017: phase 2 only cut-off

2) Cell technologies in medical applications

- 2016: 4 cut-offs in phase 1 & 2
- 2017: 4 cut-offs in phase 1 & 2

Overall budget: €80 million

Funding rate: 100%

SME instrument topics (2/2)

SMEInst-06-2016-2017: Accelerating market introduction of ICT solutions for Health, Well-Being and Ageing Well

- 2016: 4 cut-offs in phase 1 & 2
- 2017: 4 cut-offs in phase 1 & 2

Overall budget: €30.5 million
Funding rate: 70%

Identify opportunities

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European Commission

RESEARCH & INNOVATION

Participant Portal

European Commission > Research & Innovation > Participant Portal > Home

HOME FUNDING OPPORTUNITIES HOW TO PARTICIPATE EXPERTS SUPPORT Search PP LOGIN REGISTER

Horizon 2020 Funding

Starting from 1/1/2014

On this site you can find and secure **funding** for projects under the following EU programmes:

- **2014-2020** Horizon 2020 - research and innovation framework programme
- **2007-2013** 7th research framework programme (FP7) and Competitiveness & Innovation Programme (CIP)
- Research Fund for Coal & Steel, COSME, 3rd Health Programme, Consumer Programme

Non-registered users Registered users

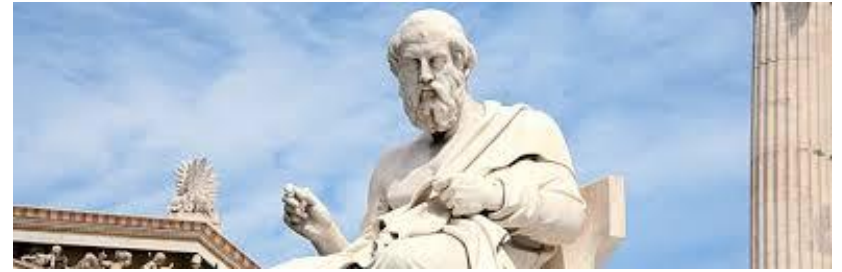
Tip! Use the keyword search on the Participant Portal



Cross-cutting items

**Social sciences and humanities
(SSH)**

Why SSH in SC1



- Social Sciences investigate the processes that govern the behaviours of individuals and groups
- Humanities and Social Sciences are a **key part of the research and innovation spectrum** and it is important they are integrated in research and innovation programmes
- Health and wellbeing **cannot be achieved by health and medical research alone**

How to include / assess SSH

- Some **specific SSH areas** that might be considered for health research are: **ethics, vulnerability, inequality and legal matters**
- SSH needs to be **initiated upstream**, and not simply considered as an add-on => Help achieving impact through SSH
- Important to check: a) the level of interaction between STEM and SSH; b) the level of **rigour of application** of SSH c) and, in the scope, the areas that go beyond health economics
- Evaluators → look for evaluators who have a **broader knowledge** (economics, statistics, psychology, anthropology and behavioural science)
- Importance to **disseminate** more information on good practices in embedding SSH

Examples in health research (1)

The variability between patients in responses to the same treatment is one of the most challenging health care problems:

- Need to unravel the mechanisms of how peoples' expectations affect immune and endocrine responses and related health outcomes, through the use of multidisciplinary methods in experimental studies (Social Sciences, Biomedical and Life Sciences, Neuroscience and Humanities)

Examples in health research (2)

How healthy ageing individuals manage to stabilise their quality of life and health in real life:

- To examine the determinants of healthy instead of ill ageing and the factors stabilising instead of declining health, through evidence standard for real life instead of laboratory outcomes, with results on the level of individuals instead of populations (gerontology, clinical and experimental psychology, ethnology, psychotherapy, robotics)



Cross-cutting items

International cooperation

Global challenges call for global responses

- Engaging in international cooperation is essential to attract talent, access knowledge and markets, thus increasing EU competitiveness
- Horizon 2020 is a vehicle to work together with the best worldwide



International Cooperation Strategy

Enhancing and focusing EU
international cooperation in research
and innovation

Horizon 2020

Open to the World

General opening

Horizon 2020 is fully open to participation of entities from across the globe

Targeted opening

Many topics are flagged as being specifically relevant for international cooperation, identifying upfront the targeted area and partner country or region

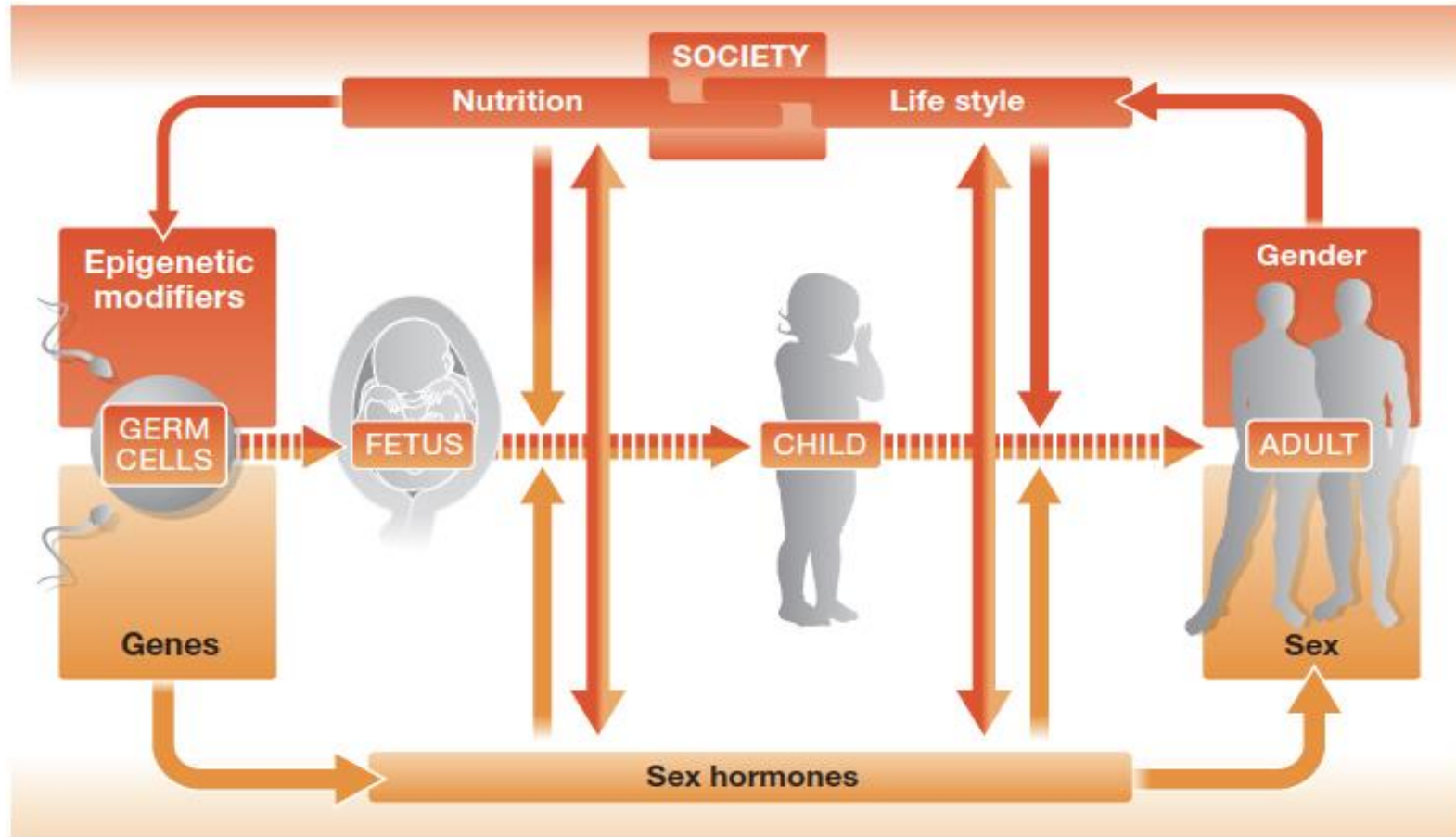


Cross-cutting items

Gender

Sex and Gender interact

Regitz-Zagrosek, V. (2012). Sex and Gender Differences in Health. *EMBO Reports*, 13 (7): 596- 603





Cross-cutting items

Communication



Communicating H2020 projects

Increased importance of communication

- Communication plan and work package in the proposal and the grant agreement (GA **article 38.1**)
- Promote your project and its results beyond the projects own community
- Communicate your research in a way that is understood by non-specialist, e.g. the media and the public
- Inform EC/ Agency in advance of communication activities expected to have a major media impact

Communication ≠ Dissemination

Dissemination (GA article 29) is a separate obligation (e.g. through scientific articles and conferences)



Cross-cutting items

Ethics

Ethics

- Ethics issues to be carefully considered in proposals
- Check on EU guiding principles
- Ethics evaluation of all proposals included in priority lists
- Ethics requirements to be implemented in funded projects





HORIZON 2020

**Thank you
for your attention**

Find out more:

www.ec.europa.eu/research/horizon2020

<http://ec.europa.eu/research/participants/portal/desktop/en/home.html>