



EU-funded Health Research

HORIZON 2020

The graphic features the word "HORIZON" in large, white, sans-serif capital letters. The letter "O" is replaced by a realistic, glowing globe of the Earth. The word "2020" follows in the same font. The background is a vibrant blue with a lens flare effect emanating from behind the globe, suggesting a horizon or a bright light source.

**PolSCA meeting
25 November 2013
Brussels**

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Health Research Directorate
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Predictive, Preventive and Personalised medicine - an introduction



Personalised medicine to address significant challenges...

- Ageing population, increasing pressure on European healthcare systems
- Increasing disease burden; only non-communicable diseases worldwide will cause an output loss of €35 trillion over the next two decades
- Gap between the EU and global innovation leaders such as the US, Japan and South Korea
- Biomedical companies are finding drug development in Europe economically challenging and are moving their operations from the region, mainly to Asia

...and benefit from opportunities

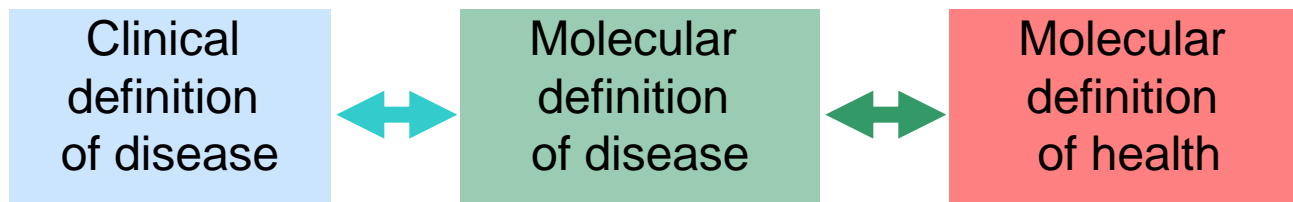


"Take them until further testing shows they really aren't effective."

- **Stratified and subsequently personalised medicine can deliver better outcomes for patients and potential cost savings**
- **Recent studies suggest cost savings of 37% for breast cancer and 46% for CVD when a stratified approach is taken**
- **But the building blocks are many and linked, requiring clinical trials, a better understanding of the fundamentals of disease, and efforts to translate results to the clinic**

Healthcare opportunities: making medical treatments more personalised

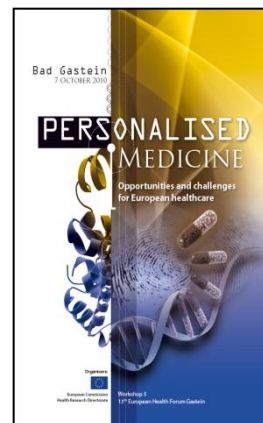
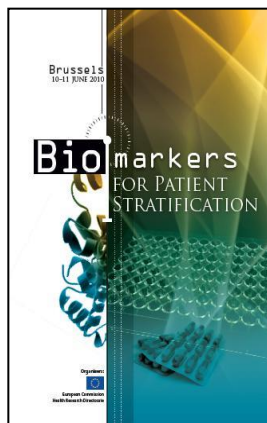
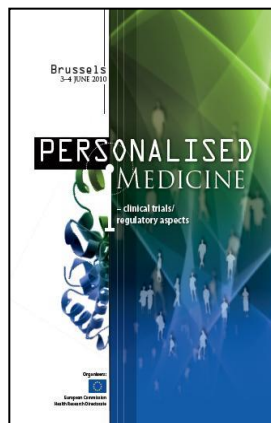
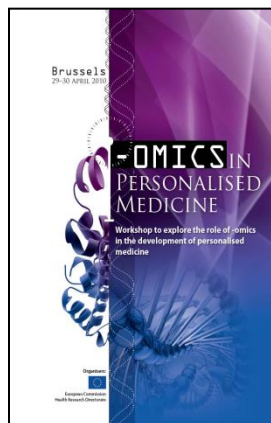
- **Avalanche of new –omics and molecular information following the sequencing of the human genome**
- **Translation of – omics from basic to clinical research can bring us better understanding of health and disease**



Need innovative approaches for changing the focus from treatment and cure to **prediction and **prevention****

Personalised Medicine EU workshops & conference

- **Vision for Europe 2020: identify bottlenecks for PM implementation into clinical practise**
- **2010: Preparatory workshops (-omics, biomarkers, clinical trials/regulatory, uptake)**
- **2011: European Perspectives in PM conference (Brussels)**



Outcome of our stock taking exercise: key challenges for research (1/2)

- **Generating knowledge and developing the right tools**

- Adaptations of new research tools for use in clinical settings
- Standards for data and sample collection and analytical procedures
- Linking clinical data with molecular profiles and development of novel algorithms to explore complex signatures

- **Translating knowledge to medical applications**

- Development of new approaches and methodologies for identification and validation of biomarkers
- Qualification and clinical validation of all types of biomarkers
- Better use of biomarkers in existing therapies
- Adapted clinical trial methodologies for stratified and/or small populations



Outcome of our stock taking exercise: key challenges for research (2/2)

- **Breaking barriers and speaking the same language**
 - Collaboration and discussion between different disciplines and stakeholders
 - Integration of new knowledge in education and training curricula
- **Understanding the economic impacts and aspects**
 - Studies on impact for patients and on the economic viability of personalised approaches in health care systems
 - Methodologies for Health Technology Assessment
 - Comparative cost effectiveness and other pharmaco-economic studies on personalised medicine approaches



Staff Working Document on
*Use of '-omics' technologies in the development of personalised
medicine (published 31 Oct 2013)*

- the potential for, and issues with, the use of '-omics' technologies in personalised medicine, and the related EU research funding,
- recent developments in EU legislation for placing medicinal products and devices on the market,
- factors affecting the uptake of personalised medicine in health care systems.



Available on:

http://ec.europa.eu/health/human-use/advanced-therapies/index_en.htm

Where we are going: R&I in Horizon 2020 (2014-2020)

Disclaimer

Pending formal adoption and publication by the EU of the Horizon 2020 legal texts, the content of these 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



What is Horizon 2020

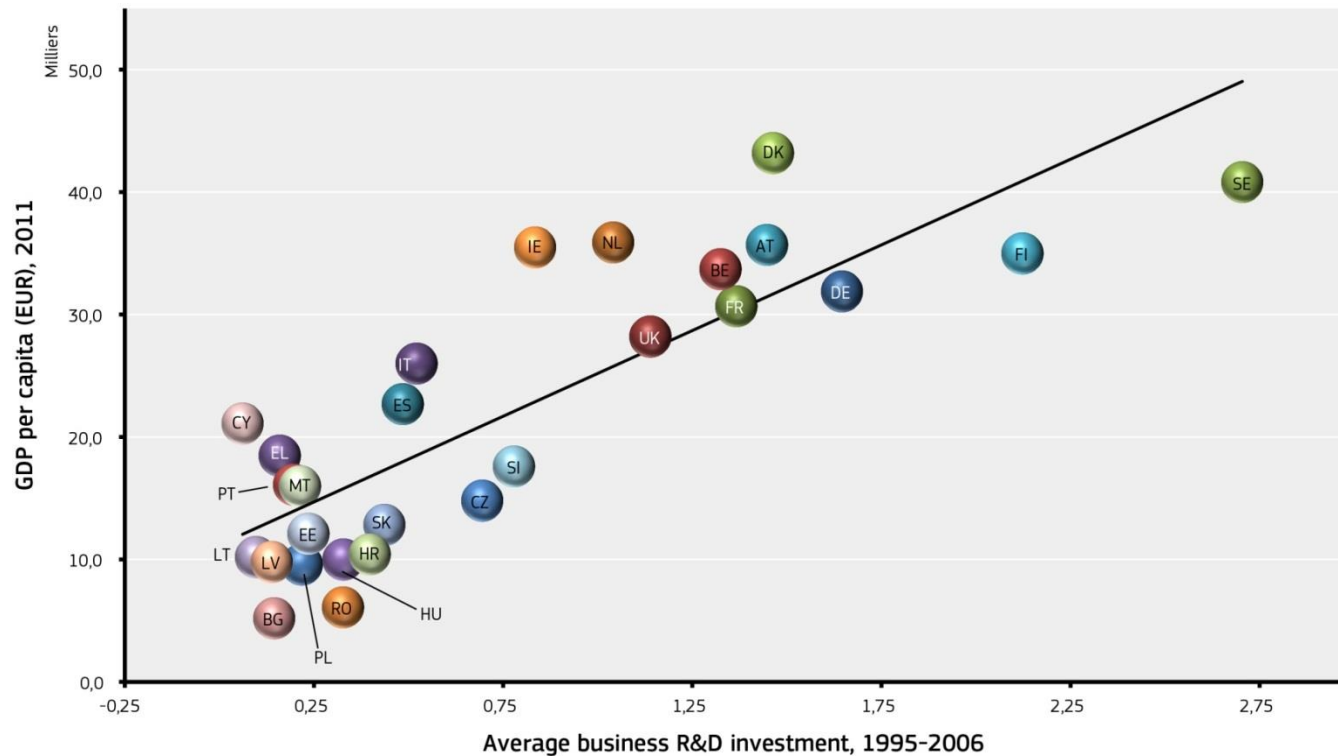
- **€70 billion for EU research and innovation from 2014-2020**
- **A core part of Europe 2020, Innovation Union & European Research Area:**
 - **Responding to the economic crisis to invest in future jobs and growth**
 - **Addressing people's concerns about their livelihoods, safety and environment**
 - **Strengthening the EU's global position in research, innovation and technology**





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Investment in R&D is part of the solution to exit from the economic crises

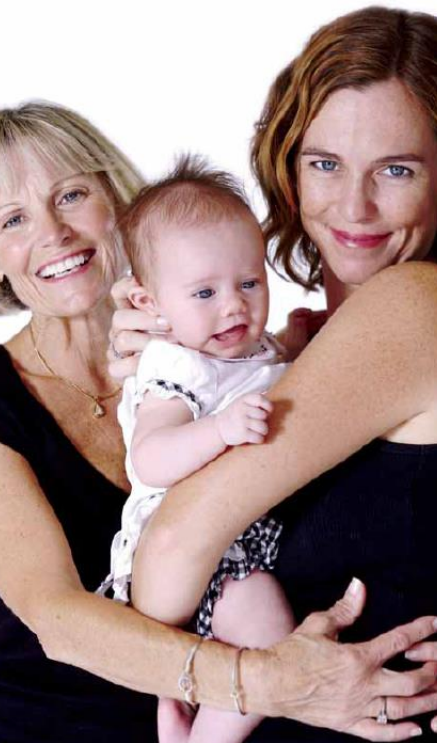


Source: DG Research and Innovation - Economic Analysis Unit - Eurostat data.

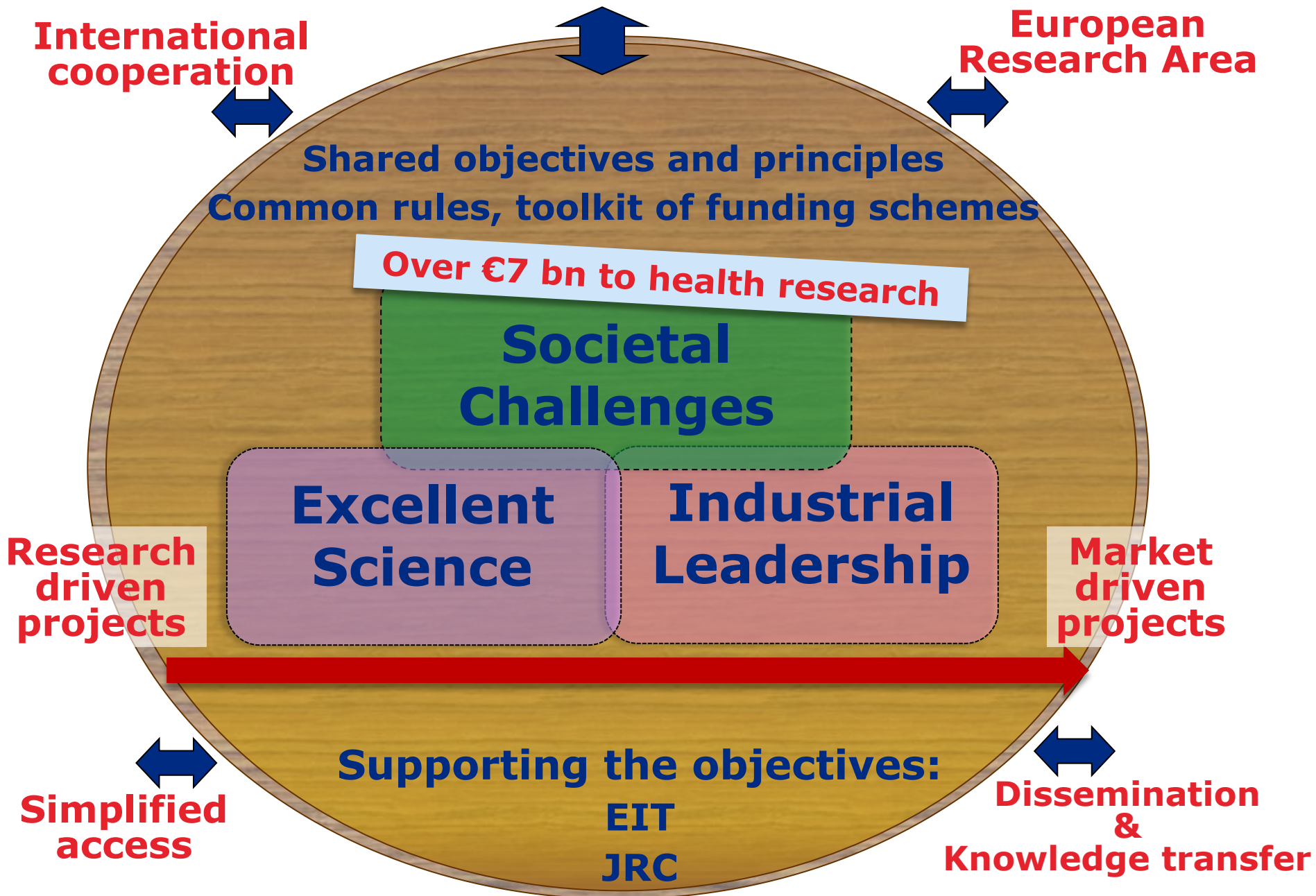
Note: Luxembourg has a GDP per capita of 82100 EUR (2011) and an average business R&D of 1.45 (1995-2006). It is not displayed on the graph.

Funding excellent breakthrough research and innovation

- **Translating science to benefit citizens**
- **Improve health outcomes**
- **Support a competitive healthcare sector**
- **Test and demonstrate new healthcare models, approaches and tools**
- **Promote healthy and active ageing**



Europe 2020 priorities



Priority 1. Excellent science

- **Why:**
- World class science is the foundation of tomorrow's technologies, jobs and wellbeing
- Europe needs to develop, attract and retain research talent
- Researchers need access to the best infrastructures



Proposed funding (€ million, 2014-2020)*

<i>European Research Council (ERC)</i> Frontier research by the best individual teams	13 095
<i>Future and Emerging Technologies</i> Collaborative research to open new fields of innovation	2 696
<i>Marie Skłodowska-Curie actions (MSCA)</i> Opportunities for training and career development	6 162
<i>Research infrastructures (including e-infrastructure)</i> Ensuring access to world-class facilities	2 488

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

Priority 2. Industrial leadership

- **Why:**
- Strategic investments in key technologies (e.g. advanced manufacturing, micro-electronics) underpin innovation across existing and emerging sectors
- Europe needs to attract more private investment in research and innovation
- Europe needs more innovative small and medium-sized enterprises (SMEs) to create growth and jobs

Proposed funding (€ million, 2014-2020)

<p><i>Leadership in enabling and industrial technologies (LEITs)</i> (ICT, nanotechnologies, materials, biotechnology, manufacturing, space)</p>	<p>13 557</p>
<p><i>Access to risk finance</i> Leveraging private finance and venture capital for research and innovation</p>	<p>2 842</p>
<p><i>Innovation in SMEs</i> Fostering all forms of innovation in all types of SMEs</p>	<p>616 + complemented by expected 20% of budget of societal challenges + LEITs and 'Access to risk finance' with strong SME focus</p>

Priority 3. Societal challenges

- **Why:**
- Concerns of citizens and society/EU policy objectives (climate, environment, energy, transport, etc) cannot be achieved without innovation
- Breakthrough solutions come from multi-disciplinary collaborations, including social sciences & humanities
- Promising solutions need to be tested, demonstrated and scaled up

Proposed funding (€ million, 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
<i>Science with and for society</i>	462
<i>Spreading excellence and widening participation</i>	816

* Additional funding for nuclear safety and security from the Euratom Treaty activities (2014-2018)

Simplification: Rules for Participation

- **A single set of rules:**
 - Adapted for the whole research and innovation cycle, covering all research programmes
 - Aligned to the Financial Regulation, coherent with other new EU Programmes
- **One project – one funding rate**
 - Simplified reimbursement of real direct costs at 100% rate (except for innovation actions, where a 70% maximum will apply for profit making entities)
 - Indirect eligible costs: a flat rate of 25% of direct eligible costs
- **Simple evaluation criteria**
 - Excellence – Impact – Implementation (Excellence only, for the ERC)
- **New forms of funding aimed at innovation**
 - pre-commercial procurement, inducement prizes, dedicated loan and equity instruments
- **International participation**
 - facilitated but better protecting EU interests

Simplification: Rules for Participation

- **Simpler rules for grants**
 - broader acceptance of participants' usual accounting practices for direct costs, flat rate for indirect costs, no time-sheets for personnel working full time on a project, possibility of output-based grants (lump sums for projects in specific areas)
- **Fewer, better targeted controls and audits**
 - Lowest possible level of requirements for submission of audit certificates without undermining sound financial management
 - The FVC threshold of 500 kEur only for coordinators but no more for beneficiaries
 - Audit strategy focused on risk and fraud prevention as the Guarantee Fund will cover all actions under H2020
- **Improved rules on intellectual property**
 - Balance between legal security and flexibility
 - Tailor-made IPR provisions for new forms of funding
 - A new emphasis on open access to research publications

Beyond the Rules: further simplified provisions in the Grant Agreement and implementing procedures to facilitate access to Horizon 2020 (e.g. common IT platform).

New 'SME instrument'

~5 billion EUR in H2020

Inspired by the US model "SBIR"

Challenge driven, bottom up

A single company can be funded

3 phases:

Concept and feasibility assessment

R&D, demonstration, market replication

Commercialisation

What else is

- New balance sheet requirements, fewer audits
- Simpler rules
- Indirect cost rate
- New forms of funding and innovation and focused funding for SMEs
- Successful projects up and running more quickly



Horizon 2020 and personalised medicine



Integrated approach to address key research challenges

**Breaking barriers
& speaking the same
language**

**"cross-disciplinarity",
education & training**

**Generating knowledge
& developing the right
tools**

**standards, clinical
bioinformatics, adaptation
of tools**

**Translating knowledge
to medical applications**

**disease taxonomy,
biomarker validation,
clinical trials**

**Understanding the value
& economic aspects**

**health care pilots, HTA,
comparative
effectiveness, value chain**

An integrated approach with 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

+ co-ordination activities

Unravelling health and disease

- **Improving our understanding of the causes underlying health, healthy ageing and disease**
 - Genetic, epigenetic and non-genetic factors
 - Systems medicine approaches
 - Understanding co-morbidities



In biomarkers we trust ... and in novel diagnostic tools

- **Bringing new diagnostic tools and technologies to patients; validating existing biomarkers**
 - In vitro devices, assays and platforms
 - In vivo medical imaging technologies
 - Clinical validation of biomarkers
 - SME focus



Finding the cure ... and evaluating existing treatments

- **Developing new therapies and technologies; evaluating treatments for specific populations**
 - Therapies for non-communicable diseases and rare diseases
 - Tools and technologies for advanced therapies
 - Clinical research on regenerative medicine
 - Comparing and establishing effectiveness of health interventions in the elderly and children



The citizen in the centre

- **Piloting novel and personalised healthcare models and approaches; focusing on self-management of health and disease**
 - Piloting personalised medicine in healthcare
 - New models for prevention oriented health and care systems
 - Integrated care and self-management of health and disease
 - Public procurement and eHealth
 - eHealth sectorial inducement prize

citizen 

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

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Letting Big Data drive research

- **Improving health data handling; providing evidence base for health policies and regulation**
 - Digital representation of health data to improve diagnosis and treatment
 - Foresight for health policy development and regulation
 - Advancing bioinformatics for clinical needs
 - Improve predictive human safety testing
 - eHealth interoperability
 - Inducement Prize

Opportunities - summary

- Improving diagnosis: PHC 10-11 (+ PHC12 – SME topic)
- Advancing active and healthy ageing: PHC 19-22
- Integrated, sustainable, citizen-centred care: PHC 23-29
- Improving health information... PHC 30-34

- Co-ordination:
 - HCO 1 (EIP Active and Healthy Ageing)
 - HCO 2 (JPI More Lives, Better Lives)

- Details: draft work programme 2014/2015

http://ec.europa.eu/research/horizon2020/pdf/work-programmes/health_draft_work_programme.pdf

Horizon 2020 and partnering

Public private partnerships:

- Through Joint Technology Initiatives or other formal structures (Art. 187)
- Through contractual agreements, which provide inputs for work programmes
- Only when criteria met, e.g. clear commitments from private partners

Public public partnerships:

- Through « ERA-Nets » for topping up individual calls/actions (replacing current ERA-Net, ERA-Net Plus, Inco-Net, Inno-net)
- Through participation in joint programmes between Member States (Art. 185)
- Supporting agendas of Joint Programming Initiatives when in line with Horizon 2020
- Only when criteria met, e.g. financial commitments of participating countries

European Innovation Partnerships:

- Not funding instruments, but for coordination with broader policies and programmes

Strategic initiatives



**Innovative Medicines Initiative 2:
Public Private Partnership for better and
safer medicines**



**European & Developing Countries
Clinical Trials Partnership:
with a focus on neglected diseases**



**Ambient and Assisted Living:
Joint Programme focusing on market
oriented research and SMEs**

IMI 2: broader objectives

- **Mission: create an even more powerful research and innovation machine – with broader objectives and a wider range of activities and partners**
- **Key objectives:**
 - **pave the way for breakthrough vaccines, medicines and treatments needed in the near future**
 - **Enable top quality research and innovations with great public health benefits and commercial possibilities**
 - **Open consultation on IMI2 Research Agenda**
 - **<http://efpia.eu/documents/48/63/SRA-PUBLIC-CONSULTATION>**





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Open Access in EU funded research

Open Access in EU funding programmes

- **Serving research and innovation, improving return on investment**
- **Allow benefits of science to be exploited by all (researchers, industry, citizens) and equal access in all EU countries**
- **Give free access to results of publicly-funded research**
- **Drive down the costs for dissemination without sacrificing quality**



Proposal for Horizon 2020

OA pilot in FP7

Best effort to provide OA

7 areas (incl. health)

Peer-reviewed publications

Allowed embargos: 6/12 m

OA Publishing costs

Eligible while projects run

OA mandate in H2020

Obligation to provide OA

All areas

Peer-reviewed publications

Allowed embargoes: 6/12 m


Plus: 'pilot' for research data

OA Publishing costs

Eligible while projects run

Plus (*tbc*): possibility to cover later publications under conditions to define

Horizon 2020: Work Programme timeline



Main call identifier	Sub-call	Type of call	Deadline(s)
H2020-HCO-2014/2015	H2020-HCO-2014	single stage	15/04/2014
	H2020-HCO-2015	single stage	21/04/2015
H2020-PHC-2014/2015	H2020-PHC-2014	single stage	15/04/2014
	H2020-PHC-2014-two-stage	2 stages	11/03/2014 and 19/08/2014

Find a partner for you project

- **Get in touch with your national contact point:**
<http://ec.europa.eu/research/participants/portal/page/nationalcontactpoint>
- **Fit for Health:**
<http://www.fitforhealth.eu>
- **Health competence:**
<http://www.healthcompetence.eu>
- **IMI partnering platform:**
<http://www.imi-partnering.eu>



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Thank you for your attention!