



Greek Info Day Horizon 2020 Societal challeng 1 'Health, demographic change and wellbeing'



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Presentation outline

- **What's new in H2020**
- **Where to focus -Health**
- **How to apply for funding**
- **Proposal submission –practical advice**
- **Guidance for applicants**

What is Horizon 2020



**The EU's 2014-20 programme
for research & innovation**

**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**

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

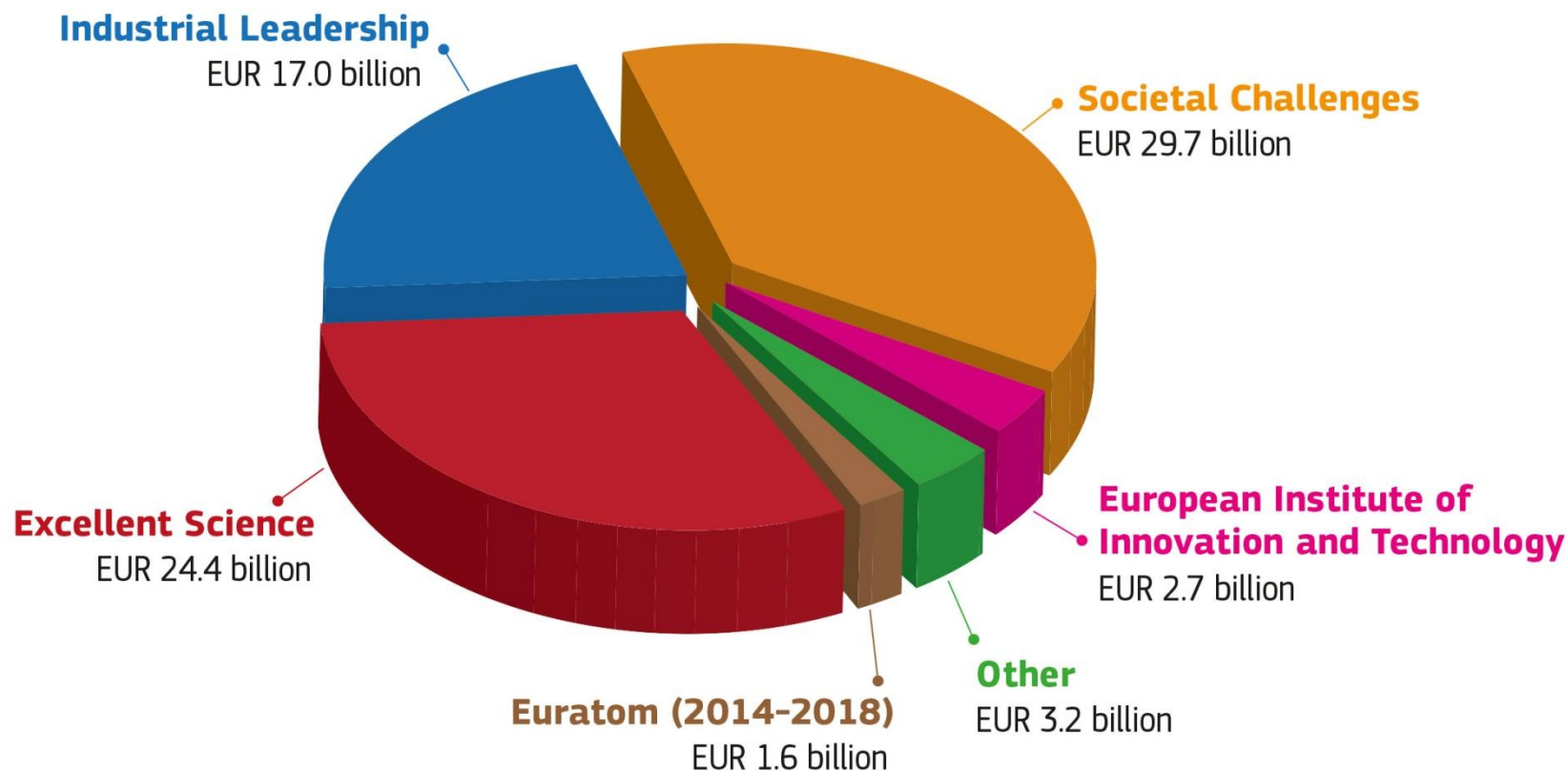
* The 7th Research Framework Programme (FP7), innovation aspects of Competitiveness and Innovation Framework Programme (CIP), EU contribution to the European Institute of Innovation and Technology (EIT)

Three priorities



€ 79 δισεκατομμύρια (τρέχ. τιμές) 2014-2020

HORIZON 2020 BUDGET (in current prices)



Excellent science

Proposed funding
(million EUR, 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

Industrial leadership

Proposed funding
(million EUR, 2014-2020)*

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

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

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
<i>Science with and for society</i>	<i>462</i>
<i>Spreading excellence and widening participation</i>	<i>816</i>

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

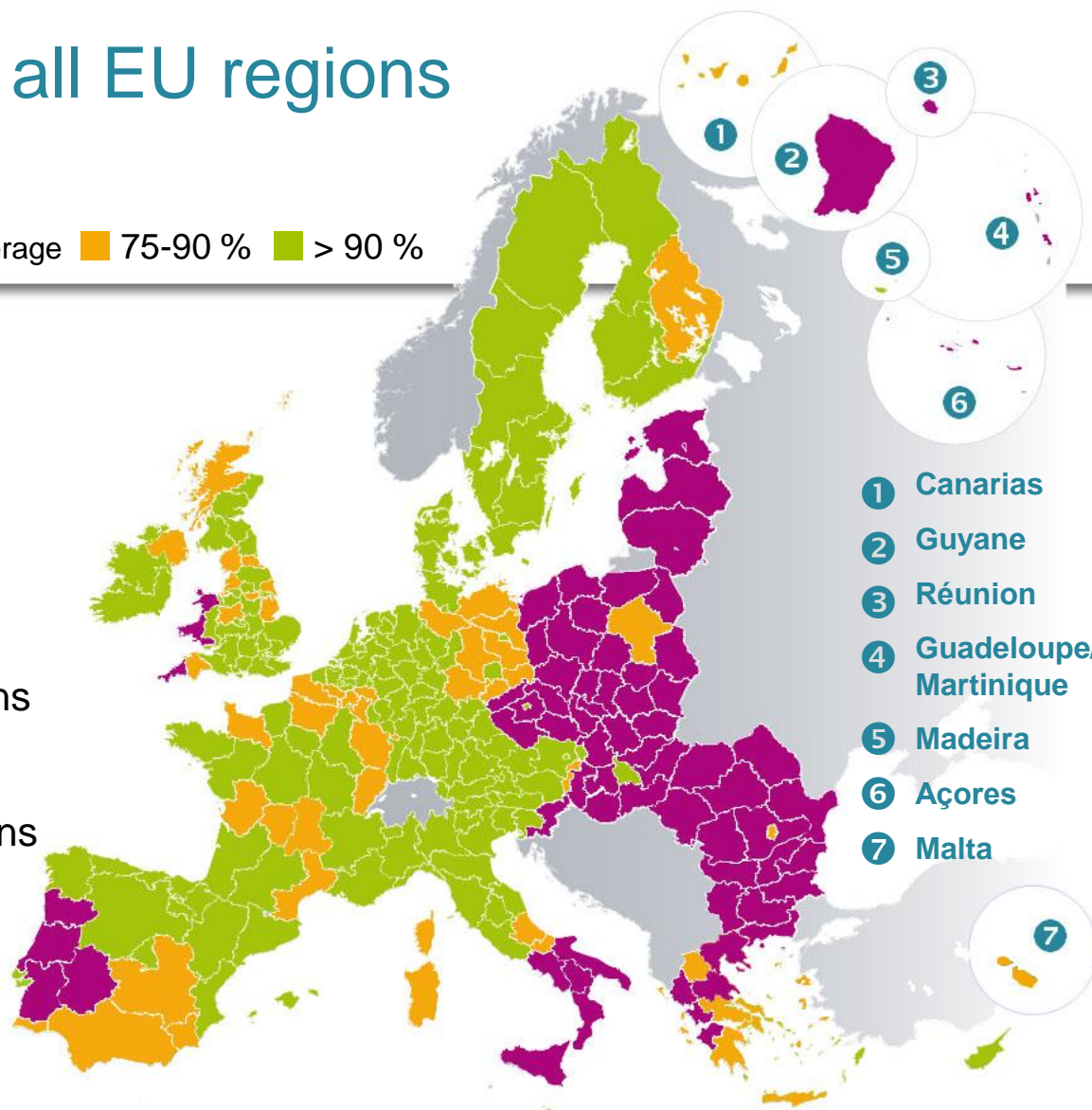
A fair system for all EU regions (eligibility simulation)

GDP/capita* ■ < 75 % of EU average ■ 75-90 % ■ > 90 %

*index EU27=100

3 categories of regions

- Less developed regions
- Transition regions
- More developed regions



Regional GDP figures: 2006-07-08
© EuroGeographics Association for the administrative boundaries

Different levels of measures to bridge European R&I divide

- **SC1 Work programme**
HCO 14 - New approaches to bridge the divide in European health research and innovation
- **Horizon 2020**
Spreading Excellence and Widening Participation
- **Cohesion policy**
Thematic objective 1: strengthening research, technological development and innovation + RIS3

**Take it
away**

€816 million

H2020: Spreading Excellence and Widening Participation

- **Principle of excellence: continue to allocate funding only to the best projects**
- **Accompanying measures in Horizon**
 - Teaming
 - Twinning
 - ERA chairs
 - Policy Support Facilities
 - COST - access to international networks



EXCELLENCE

Teaming for excellence

- Partnership between leading scientific institution and low performing RDI region/MS
- Creation of **centres of excellence** at low performing partner
- Stage 1 – Business Plan – **€0,2-0,5M**
- Stage 2 – start-up and implementation **€15-20M**
- Administrative costs, salaries (no infrastructure)
- Fitting with Smart Specialisation Strategies
- Expected funding from European Structural and Investment Funds



Twinning

- **Minimum 3 participants**
- **1 research institution from low performing region/MS + 2 internationally leading counterparts**
- **EU contribution ~€1M for activities such:**
 - staff exchanges, expert visits
 - short-term on-site or virtual trainings
 - workshops, conference attendance, joint summer school
 - outreach activities
 - dissemination



ERA Chairs

- To attract outstanding researchers to low performing regions/MS
- Covering ERA Chair holder and a number of team members
- Merit-based recruitment process
- EU contribution ~€2,5M



Horizon 2020

'Health, demographic change and wellbeing'

what's new?



Building on experience

FP7 'Health' – the largest multi-national fund...

- ...for collaborative research, global consortia, and public-private co-operation
- ...to fund excellent applied health and ageing research and innovation
- ...to bring together leading players from Europe and across the globe
- ...to tackle key European and global health challenges



Strategic Initiatives



Innovative Medicines Initiative 2
www.imi.europa.eu



**European Innovation Partnership
on Active and Healthy Ageing**
<https://webgate.ec.europa.eu/eipaha>



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



**European & Developing Countries
Clinical Trials Partnership (EDCTP2)**
www.edctp.org

A new approach



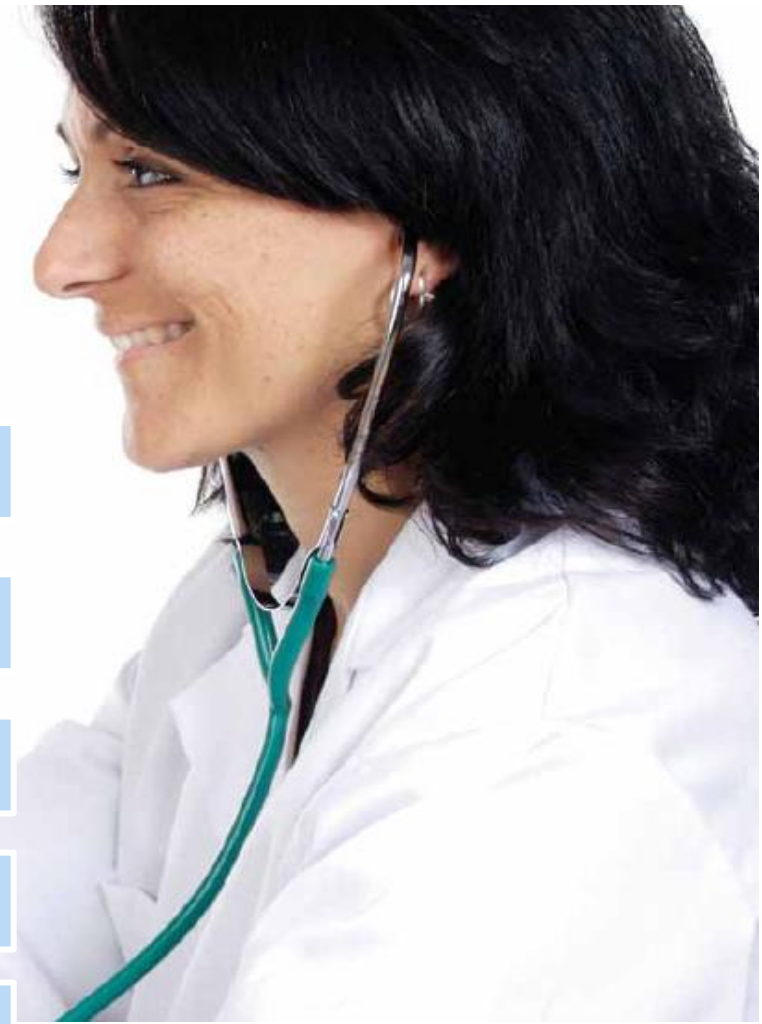
Challenge-driven

Broad topics

Less prescriptive topic texts

Two-year work programme

Stronger focus on end users



Horizon 2020

'Health, demographic change and wellbeing'

Where
to focus?



The challenges



- **Ageing population**
- **Increased disease burden**
- **Unsustainable and unequal health & care systems**
- **Health & care sector under pressure to reform**

Horizon 2020 - Societal Challenge 1



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

Do also look elsewhere! EU support of health related research & innovation is not limited to Societal Challenge 1

Horizon 2020

'Health, demographic change and wellbeing'

Where
to focus?



The Work Programme 2014/15 in brief

Call 'personalising health and care'

34 topics (15 in 2014, 17 in 2015, 2 open in both years)

Call for 'co-ordination activities'

16 topics (11 in 2014, 5 in 2015)

**€ 1,21
billion**

Next steps

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

NEW - SME instrument

Target group: Innovative SMEs

Only SMEs allowed to apply for funding

Single company support

Competitive, market-oriented, EU dimension

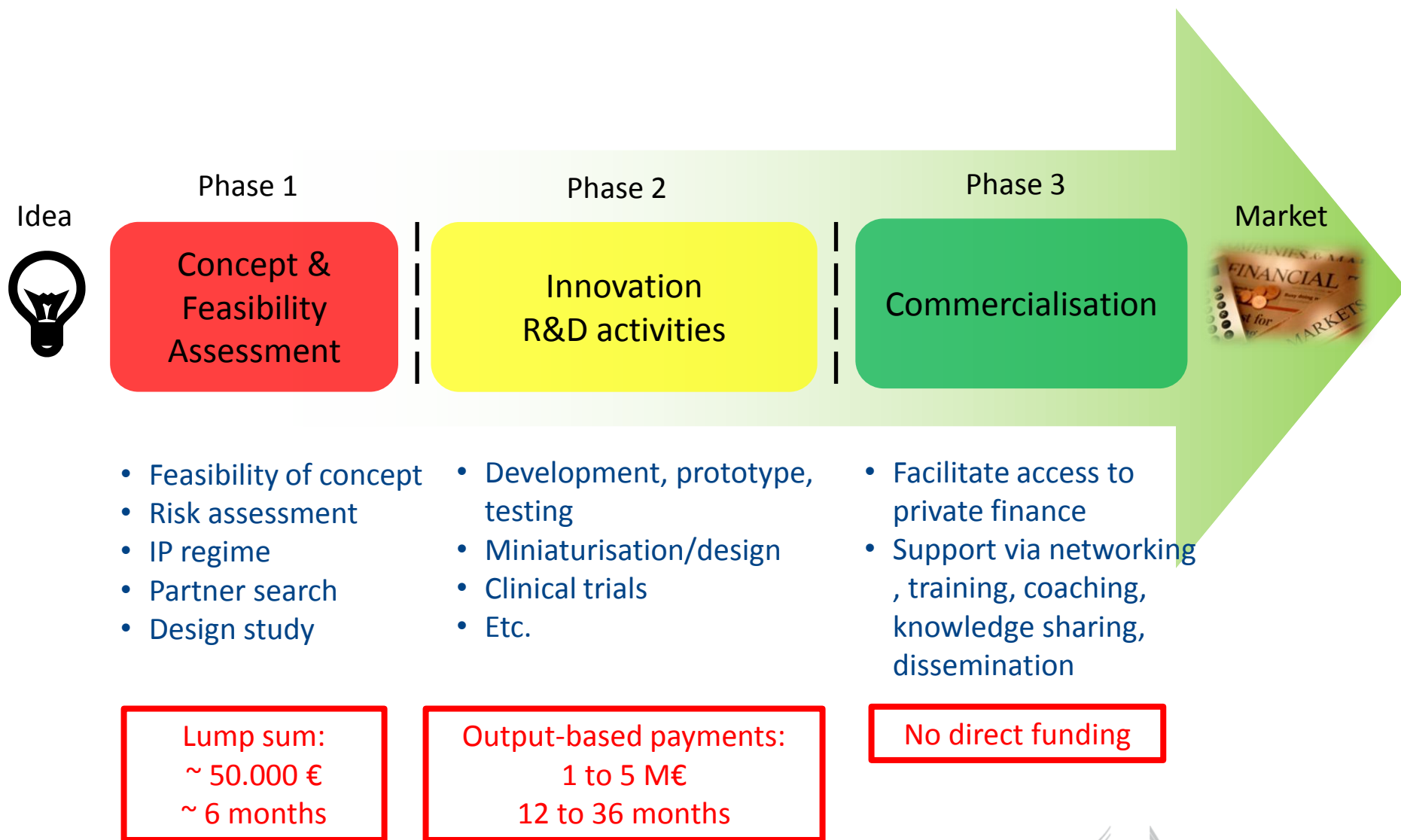
Open calls

Starting date: 2/3 cut off dates in 2014 for phase 1 & 2

70% funding (exceptions possible)

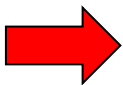


NEW - SME instrument



Recap: the 'Health, demographic change and wellbeing' challenge

Proposed funding 2014-2020 (million EUR)



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	3 081

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

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

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

The Commission considers that proposals requesting EUR 4 and 6 million would allow this specific. Nonetheless, this does not preclude submission of smaller amounts.

Expected impact: This will provide:

- Leverage of existing investments in Europe
- New directions for better disease detection
- Systems medicine tools and approaches to which represent an improvement over existing

Type of action: Research and Innovation action

'PHC 2 – 2015'

'Specific challenge'

'Scope'

'Expected impact'

'Type of action'

Unravelling health and 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)**

From "omics" ... to prevention

- **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)**

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

- ***In vitro* devices, assays and platforms (2014) (PHC 10)**
- ***In vivo* medical imaging technologies (2015) (PHC 11)**
- **Clinical validation of biomarkers (2014, 2015) (PHC 12)**
SME type of action

Topic of the SME instrument

PHC 12 – 2014 and 2015: Clinical validation of biomarkers and/or diagnostic medical devices

Scope

Identification

Qualification

Device validation

Biomarker validation

- All existing potential biomarkers (prediction, diagnostic, prognostic, monitoring, toxicity, end-point, etc.).
- Both in vivo and in vitro potential biomarkers are eligible.
- Preference will be given to the validation of disease-related biomarkers (*i.e.* diagnostic, susceptibility/risk, monitoring and prognostic biomarkers), but drug biomarkers are not excluded.
- Validation of the performance of new diagnostic devices (either in combination with the biomarker validation, or against existing standards).

Finding the cure ... **and evaluating existing treatments**

- **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)**

Adding more life to our years

- **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**

The citizen in the centre

- **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**

The citizen in the centre (2)

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

*** Topics with ICT focus**

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

Big Data for research

- **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*)**

CONDITION FOR THIS 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)



Co-ordination activities

Support for European and International Initiatives

- **European Innovation Partnership on Active and Healthy Ageing**
- **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**

Horizon 2020

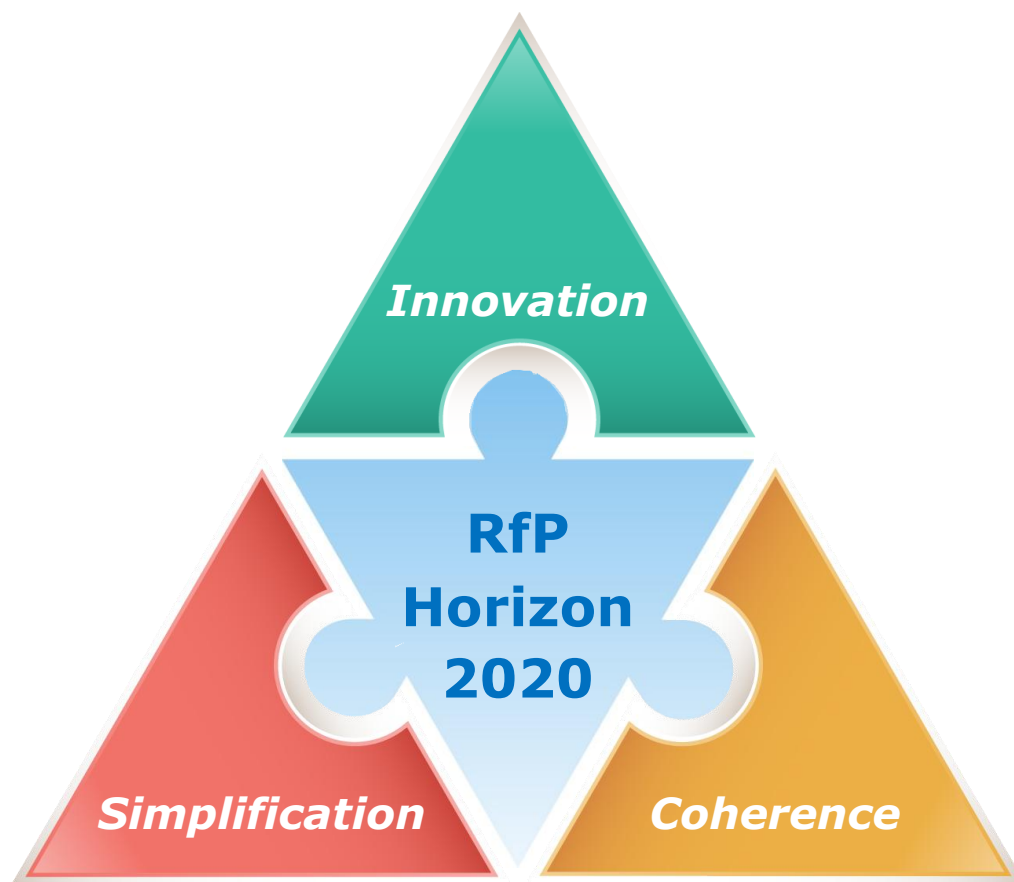
'Health, demographic change and wellbeing'

Applying for
funding: how
does it work?



Rules for participation: Three main objectives

**Innovation,
Simplification
and Coherence**



Forms of funding - I

WE KEEP

- ✓ Grants as main form of funding
- ✓ Standard collaborative actions
- ✓ Coordination and support
- ✓ Use of Grant Agreements
- ✓ Actual costs



Forms of funding - *II*

What is NEW

- ✓ **Grants to SME instrument**
- ✓ **Grants to Programme co-fund actions**
- ✓ **Specific provisions targeting innovation:**
 - pre-commercial procurement,
 - procurement of innovative solutions
 - and inducement prizes.
- ✓ **Enhanced use of other lump-sums, flat rates and unit costs.**

A single funding rate

FP7

Maximum reimbursement rates	Research and technological development activities (*)	Demonstration activities	Other activities
Network of excellence	50% 75% (**)		100%
Collaborative project(****)	50% 75% (**)	50%	100%
Coordination and support action			100% (***)

(*) Research and technological development includes scientific coordination.

(**) For *beneficiaries* that are *non-profit public bodies*, secondary and higher education establishments, *research organisations* and *SMEs*.

(***) The reimbursement of indirect eligible costs, in the case of coordination and support actions, may reach a maximum 7% of the direct eligible costs, excluding the direct eligible costs for subcontracting and the costs of resources made available by third parties which are not used on the premises of the *beneficiary*.

(****) Including research for the benefit of specific groups (in particular SMEs)

HORIZON 2020

One project = One rate

- ✓ For all beneficiaries and all activities in the grant.
- ✓ Defined in the Work Programme:
 - Up to 100 % of the eligible costs;
 - but limited to a maximum of 70 % for innovation projects (exception for non-profit organisations - maximum of 100%).



New funding model: what impact on the EU contribution?

An example

FP7	<i>Majority of HES & RTOs</i>	Direct costs	Indirect costs	Total costs	% EU contribution	EU contribution
Flat-rate	(60%)	100	60	160	75%	€ 120

HORIZON 2020	Direct costs	Indirect costs	Total costs	% EU contribution	EU contribution
100/25 Funding	100	25	125	100%	€ 125



A single set of rules



- Covering all H2020 research and innovation actions
- Keeping flexibility where needed.

Conditions for Participation

Minimum conditions

- ✓ **Standard collaborative actions**

At least three legal entities each established in a different Member State or an Associated Country;

- ✓ **ERC, SME instrument, programme co-fund, coordination and support, training and mobility actions:**

One legal entity established in a Member State or in an Associated Country.

Additional Conditions

- ✓ **In the work programme or work plan.**

No additional conditions in Health WP except for SME instrument

Time to grant: speeding up the process - I

A maximum TTG of 8 months

5 months

for informing all applicants
on scientific evaluation

3 months

for signature of GA

International cooperation

- A priority
- Key goal: enhancing and focusing international cooperation in terms of areas and partners
- Horizon 2020 is open to participation from across the world
- Wanted: more involvement of international partners!
- Targeted actions across the entire programme
- Horizon 2020 Regulation and Rules for Participation apply



General opening

- Horizon 2020 is **open to participation from across the world**
- **Automatic funding:**
 - Member States (including overseas departments and overseas territories)
 - Associated Countries
 - exhaustive list of countries in annex to work programme (but: no longer BRIC + Mexico in this list!)
- Participants from other countries only funded in **exceptional cases:**
 - when provision is made in the call text
 - bilateral agreement (e.g. Health challenge – NIH)
 - when the Commission deems it essential (case by case assessment)



Τα κριτήρια αξιολόγησης

ΤΥΠΙΚΑ ΚΡΙΤΗΡΙΑ ΑΝΑΘΕΣΗΣ

ΑΡΙΣΤΕΙΑ

ΑΝΤΙΚΤΥΠΟΣ

**ΠΟΙΟΤΗΤΑ ΚΑΙ
ΑΠΟΤΕΛΕΣΜΑΤΙΚΟΤΗΤΑ
ΤΗΣ ΔΡΑΣΗΣ**

- ✓ ERC δράσεις έρευνας αιχμής ~~Μόνο~~ Αριστεία
- ✓ Δράσεις Καινοτομίας ~~Μη~~ υψηλότερος συντελεστής στάθμισης για τον "αντίκτυπο"

Πρόταση αξιολογείται από τους εμπειρογνώμονες "όπως είναι"
και όχι όπως "θα μπορούσε να είναι" = δεν χρειάζεται διαπραγμάτευση



Horizon 2020

'Health, demographic change and wellbeing'

**Applying for
funding: proposal
submission**



Απλούστερη Πρόσβαση μέσα από την Διαδυκτιακή Πύλη Συμμετεχόντων

- **Μοναδικό Σημείο Εισόδου** από την Κλήση μέχρι την Υποβολή Πρότασης
- **Νέα εργαλεία έξυπνης αναζήτησης για τον χρήστη**, ακόμα και αν είναι νέος/α στο πρόγραμμα.



H2020 Calls

All call related documentation is published on the Participant Portal

<http://ec.europa.eu/research/participants/portal/page/home>



(A-Z) Sitemap About this site Contact Legal Notice English

RESEARCH & INNOVATION
Participant Portal

European Commission > Research & Innovation > Participant Portal > Home

HOME FUNDING OPPORTUNITIES HOW TO PARTICIPATE EXPERTS SUPPORT LOGIN REGISTER

Welcome to the Research and Innovation Participant Portal

About the Participant Portal:

The Participant Portal is your entry point for the electronic administration of EU-funded research and innovation projects. It hosts services for managing proposals and projects throughout their lifecycle.

The Participant Portal supports activities funded mainly by the following EU programmes:

- 7th Framework Programme for Research and Technological Development (FP7)
- Competitiveness and Innovation Framework Programme (CIP)

Using the Participant Portal:

As a guest user, browse the public pages to:

- search for funding opportunities
- download guidance and legal documents
- search for the participant identification code (PIC) of an organisation
- contact the FP7 support services and browse the FAQ for guidance on the Participant Portal tools

As a registered user, benefit from personalised services for proposal submission, negotiation, and project management.

WHATS NEW

FUNDING OPPORTUNITIES

HOW TO PARTICIPATE?

WORK AS AN EXPERT

ACCESS MY PERSONAL AREA

INFORMATION AND SUPPORT

RESEARCH ON EUROPA CORDIS OLAF

© European Communities

HORIZON 2020

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European
Commission



RESEARCH & INNOVATION

Participant Portal

BETA VERSION 4

Calls

Horizon 2020

COSME

Search Topics

Call Updates

Other Funding Opportunities

Previous Framework
Programmes (FP7 & CIP)

Stay informed

RSS feed

iCal

Email notification

HORIZON 2020 CALLS

FUNDING GUIDE

66 results

Filter options

Specific Programme:

- ☐ Excellent Science
- ☐ Industrial Leadership
- ☐ Societal Challenges
- ☐ Spreading excellence and widening participation
- ☐ Science with and for society

Type:

- ☒ Calls for proposal
- ☒ Calls for tender

Status:

- ☐ Open calls
- ☐ Closed calls
- ☐ Forthcoming calls

Sort by: ☒ Publication date ☐ Deadline ☐ Title ☐ Call ID

call for proposals
EXCELLENT SCIENCE
Developing new world-class
research infrastructures
H2020-RIDEV-2014/2015
PUBDATE 2013-12-11 DEADLINE 2014-03-12

call for proposals
INDUSTRIAL LEADERSHIP
Nanotechnologies, Advanced
Materials and KET support
H2020-NMK-2014/2015
PUBDATE 2013-12-11 DEADLINE 2014-03-12

call for proposals
SOCIETAL CHALLENGES
Sustainable Food Security
H2020-SFS-2014/2015
PUBDATE 2013-12-11 DEADLINE 2014-03-18

call for proposals
SOCIETAL CHALLENGES
Water Innovation: Boosting its
value for Europe
H2020-WATER-2014/2015
PUBDATE 2013-12-11 DEADLINE 2014-03-18

call for proposals
EXCELLENT SCIENCE
Marie Skłodowska-Curie
Innovative Training Network
H2020-MSCA-ITN-2014
PUBDATE 2013-12-11 DEADLINE 2014-04-08

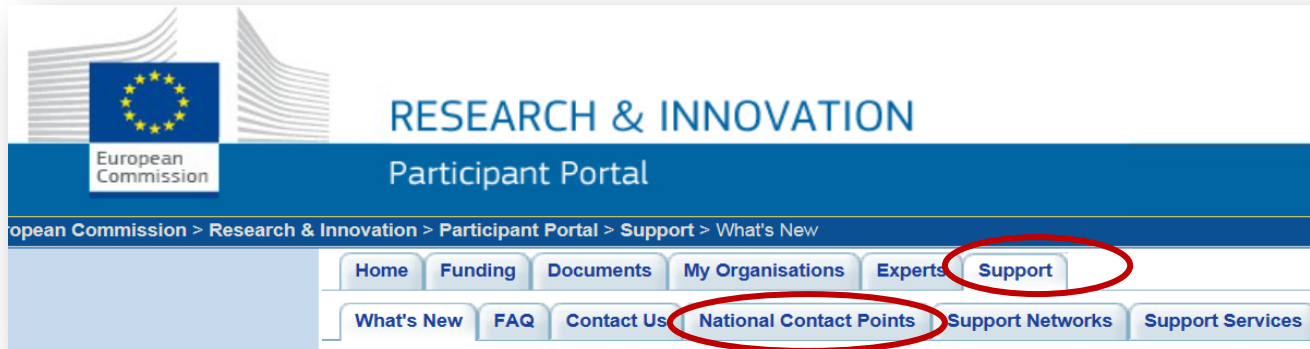
call for proposals
SOCIETAL CHALLENGES
Mobility for Growth
H2020-MG-2014/2015
PUBDATE 2013-12-11 DEADLINE 2014-03-18

call for proposals
EXCELLENT SCIENCE
FET Open - fostering novel
ideas
H2020-FETOPEN-2014/2015
PUBDATE 2013-12-11 DEADLINE 2014-03-18

call for proposals
INDUSTRIAL LEADERSHIP
Biotechnologies
H2020-BIOTEC-2014/2015
PUBDATE 2013-12-11 DEADLINE 2014-04-20




call for proposals
SOCIETAL CHALLENGES
Blue Growth: Unlocking the
potential of the oceans
H2020-BG-2014/2015
PUBDATE 2013-12-11 DEADLINE 2014-09-10

Find your project partners



<http://ec.europa.eu/research/participants/portal>



-  Publish your Profile
-  Publish your partner search
-  Find your project partners

<http://www.fitforhealth.eu>

Time to grant: speeding up the process - II

How to speed up the process

- ✓ **No detailed negotiations:**
each proposal evaluated 'as it is',
not as 'what could be';
- ✓ **Legal entity validated in parallel.**
- ✓ **No more paper:**
e-communication & e-signature of grants.





HORIZON 2020

**Thank you
for your attention!**

Find out more:
www.ec.europa/research/horizon2020

Provisional



Finding funding opportunities - proposal submission

Απλούστερη Πρόσβαση μέσα από την Διαδυκτιακή Πύλη Συμμετεχόντων

- **Μοναδικό Σημείο Εισόδου** από την Κλήση μέχρι την Υποβολή Πρότασης
- **Νέα εργαλεία έξυπνης αναζήτησης για τον χρήστη**, ακόμα και αν είναι νέος/α στο πρόγραμμα.



Evaluation: Remote evaluation throughout the process
Suggestion to abandon consensus meetings
Long feedback loops ("ESRs") slow down the process

Other eligibility conditions:

- * established in EU or associated country
- * one application/project (phase 1 or phase2) at a time

Funding over 7 years:

ca. 5,200 Phase 1 projects (fixed lump sum of 50K€)
ca. 1,700 Phase 2 projects with an average size of 1.5 M€
(or 2550 of an average size of 1 M€; 1250 of an average size of 2 M€)

Topic of the SME instrument

PHC 12 – 2014 and 2015: Clinical validation of biomarkers and/or diagnostic medical devices

Scope

Identification

Qualification

Device validation

Biomarker validation

- All existing potential biomarkers (prediction, diagnostic, prognostic, monitoring, toxicity, end-point, etc.).
- Both in vivo and in vitro potential biomarkers are eligible.
- Preference will be given to the validation of disease-related biomarkers (*i.e.* diagnostic, susceptibility/risk, monitoring and prognostic biomarkers), but drug biomarkers are not excluded.
- Validation of the performance of new diagnostic devices (either in combination with the biomarker validation, or against existing standards).

Topic of the SME instrument

Background

- Global market for diagnostics is in expansion (\$80 billion in 2013 worldwide), in particular for biomarkers (compound annual growth rate of 18.5%).
- 90% of the companies in the sector are SMEs.
- R&D bottleneck (around 25000 biomarkers identified each year that are in most cases not validated) and market failure with insufficient investments, as clinical validation is risky and valorisation of the diagnostic is poor (IVD is only 5% of medical product expenses).
- The Commission proposal for a regulation on *in vitro* diagnostic medical devices will change substantially the regulatory environment and will request clinical evidence.

Topic of the SME instrument

General Definitions

- A **biomarker** is a characteristic that is objectively measured and evaluated as an indicator of normal biologic processes, pathogenic processes, or pharmacologic responses to a therapeutic intervention (NHI Biomarkers Definitions Working Group; 2001)
- A **valid biomarker** is defined as “a biomarker that is measured in an analytical test system with well-established performance characteristics and for which there is an established scientific framework or body of evidence that elucidates the physiologic, toxicological, pharmacologic, or clinical significance of the test results (FDA. Guidance for industry - pharmacogenomic data submissions. 2005)

Topic of the SME instrument

Definitions (Regulation proposals)

- **"Performance of a device"** means the ability of a device to achieve its intended purpose as claimed by the manufacturer. It consists of the analytical and, where applicable, the clinical performance supporting the intended purpose of the device. (IVD & medical device regulation proposals)
- **"Analytical performance"** means the ability of a device to correctly detect or measure a particular analyte. (IVD regulation proposal)
- **"Clinical performance"** means the ability of a device to yield results that are correlated with a particular clinical condition or a physiological state in accordance with the target population and intended user. (IVD regulation proposal)