



#InvestEUresearch



Horizon 2020 Work Programme for Research & Innovation 2018-2020

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

Christina Kyriakopoulou, Senior Scientific officer
Health Directorate, European Commission

Research and
Innovation



«Δεν υπάρχουν μυστικά για την επιτυχία ενός στόχου. Είναι το αποτέλεσμα της προετοιμασίας, της δουλειάς και της μάθησης από μια ανεπιτυχή προσπάθεια ώστε να επιτύχει την επόμενη φορά...»

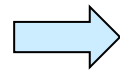
έρευνα
υγεία
χρόνιες-ασθένειες
σπάνιες-ασθένειες
καλή-επιτυχία
καινοτομία διάγνωση
θεραπεία
δημόσια-υγεία κλινικές-δοκιμές
νέες-τεχνολογίες
ψηφιοποιημένη-υγεία
εξατομικευμένη-ιατρική

Research and innovation – a growing priority for the EU

Horizon 2020 supports Commission priorities



- Jobs, growth & investment
- Digital single market
- EU – a stronger global actor



- 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
- Multidisciplinary and synergistic
- Address people's concerns

Three priorities



Health Research in Horizon 2020



BUDGET: € 3.276 billion

EC: €1.638 bn + EFPIA: €1.425 bn +
Associated Partners: €0.213 bn



- **30 November: Launch of Call 13** (16 topics) – EU contribution: € 124.5m + In-kind contribution from EFPIA & Associated Partners: € 113.5m

- supports health research and innovation, speeding up the development of innovative medicines, particularly in areas of unmet medical need

- covers the full spectrum of drug discovery and development

- facilitates collaboration between universities, research centres, the pharmaceutical and other industries; SMEs, patient organisations, and medicines regulators

- Strategic Research Agenda based on the WHO Priority Medicines Report renewed in July 2013

<http://www.imi.europa.eu/get-involved>

<http://www.imi.europa.eu/apply-funding>

<http://www.imi.europa.eu/apply-funding/general-overview/tips-applicants>

BUDGET: ~ € 1.37 billion
EC: € 683 m + MS: € 683 m



EDCTP

European & Developing Countries
Clinical Trials Partnership

- EDCTP2 Annual Work Plan 2018 to be adopted mid-2018:
EU-funded activities: € 115m + new Participating States: € 115m

- covers research accelerating clinical development of medical interventions to prevent or treat HIV/AIDS, tuberculosis, malaria and other infectious diseases

- includes the development of drugs, microbicides, vaccines, diagnostics and their delivery

- supports coordination of European national research programmes

- funds collaboration between EU, European countries and sub-Saharan African countries

www.edctp.org/see-work/strategy
www.edctp.org/funding-opportunities/calls

BUDGET (indicative): € 26 M*



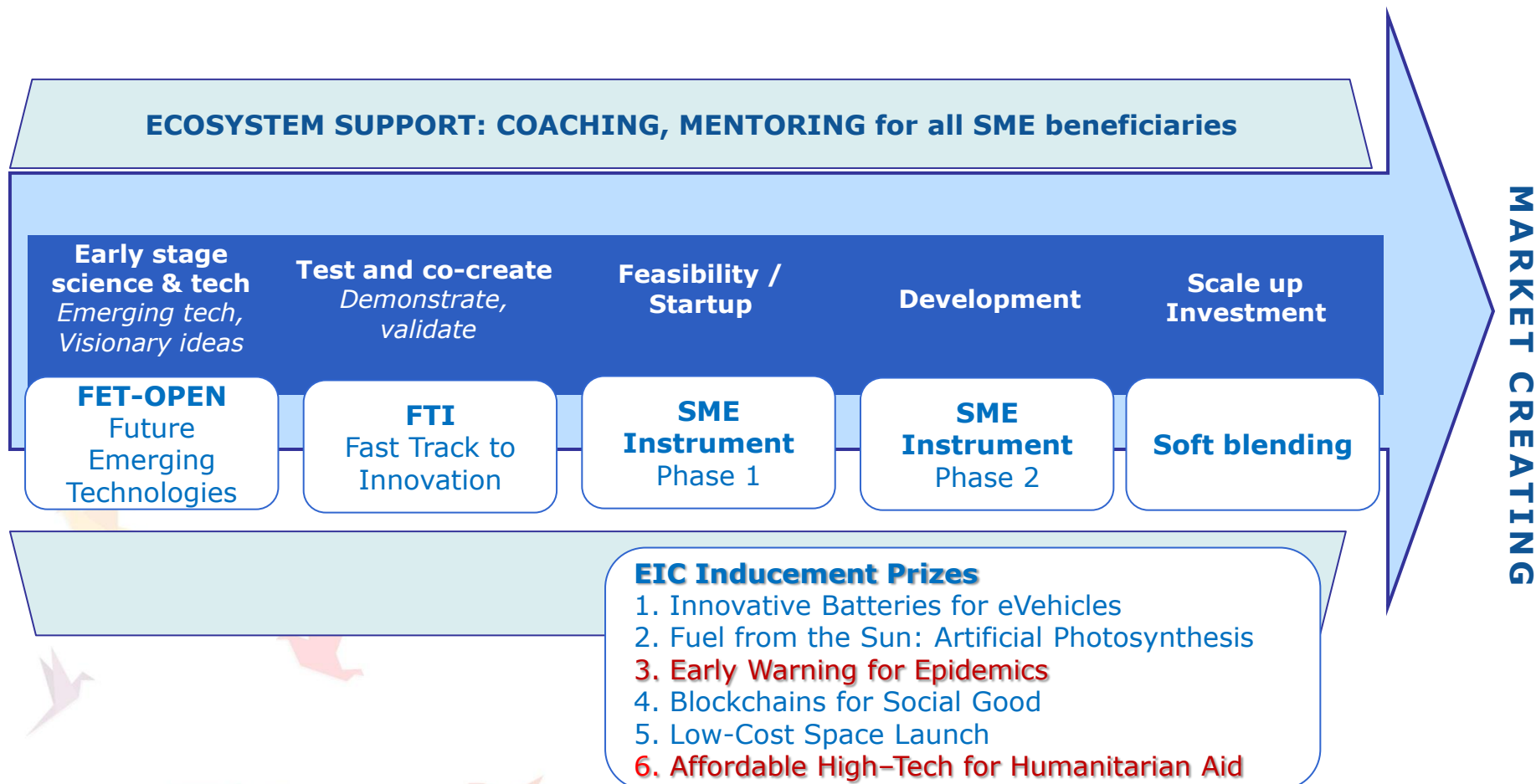
- **expected launch date of Call 2018: 5 February 2018** focused on: Smart solutions for ageing well ("open call").
- call addressing both the "private consumer" and "regulated" market (more flexibility → different types of project)
- strong involvement of end users: co-creation process with primary, secondary and tertiary end users in the whole project lifecycle Strong business and market orientation sought
- strong business and market orientation (short time to market: 2 years after the completion of the project)

<http://www.aal-europe.eu/get-involved/calls/>

*total budget project call 2018 (EC + MS); exact figures MS contribution will be available end 2017

European Innovation Council: pilot 2018-2020

€ 2.7 billion to support +5.000 SMEs and innovators



SME instrument



Phase 1

Concept & Feasibility Assessment

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

Lump sum:
~ 50.000 €
~ 6 months

Phase 2

Innovation R&D activities

- Development, prototype, testing
- Miniaturisation/design
- Clinical trials
- Etc.

Output-based payments:
1 to 5 M€
12 to 36 months

Phase 3

Commercialisation

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

No direct funding

Market



European Commission

EIC Prize Early warning epidemics



OPEN: 4th QUARTER 2017 | CLOSE: 1st QUARTER 2020

Early Warning for Epidemics

Prize value: €5 million

The challenge is to develop a scalable, reliable and cost-effective early warning system to forecast, monitor and ultimately prevent outbreaks of one or more vector-borne diseases.

[READ MORE >](#)

[Apply >](#)

Opening: 6 December 2017, managed by RTD, Directorate E.

Demonstration of the prototype at local level, taking into account any relevant societal factors in the chosen geographical area. It should be compatible for use with data coming from existing multi-disciplinary networks comprising health, humanitarian aid and emergency management actors, in order to leverage data and information from these networks, as well as to showcase the operational potential and added value of the solution.

EIC Prize Affordable High-Tech for Humanitarian Aid

Why?

- Need for more innovative and more cost-effective solutions to be used in a humanitarian aid context

When?

- to be launched on 30 November 2017 | deadline in January **2020**

What's at stake?

5 million EUR, for 5 categories, including Health

What is required?

- New solution, successfully and safely tested in a real (or similar) environment
- Solutions based on frugal application of advanced technologies:
 - Affordability and cost-effectiveness
 - Inclusiveness: engagement with end-users
 - Simplicity: solution responding to the needs of the affected populations
 - Quality and sustainability

More info: website to be made available at the time of the launch;

EC-Humanitarianaid-EICPrize@ec.europa.eu

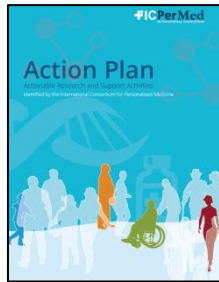
Horizon 2020 so far

- 2 biannual Work Programmes: WP 2014-2015, WP 2016-2017
- More than € 2.6 billion investment in Horizon 2020 projects

Horizon 2020 – what comes now

- first triennial Work Programme: WP 2018-2020
- the largest budget/year in the history of the EU Framework Programmes – ca. € 700 million/year for collaborative research (excluding IMI, EDTP, and the SME Instrument)
- Topics for 2020 in more detail will be published in mid-2018

Health collaborative research – 7 priorities for 2018–2020



Personalised medicine



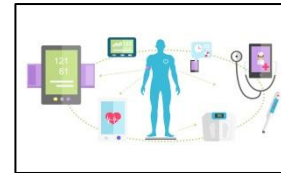
Decoding the role of
the environment for
health and
well-being



Infectious diseases and
improving global health



Innovative health
and care industry



Innovative health, and
care systems –
Integration of care



Digital transformation in
Health and Care



Trusted Big Data
solutions and
Cybersecurity for
Health and Care

7 priorities implemented via SC1 Work Programme 2018–2020 through 3 Calls for proposals

Call 'Better Health and care, economic growth and sustainable health systems'

Acronym: BHC & HCO

5 main priorities & 32 topics

Deadline single stage 2018 calls : 18 April 2018

Deadline two-stage 2019 calls : 04 Oct. 2018 & 16 April 2019

Call 'Digital transformation in Health and Care'

Acronyme: DTH

1 main priority & 13 topics

Deadline single stage 2018 & 2019 calls:

24 April 2018 & 24 April 2019

Call 'Trusted digital solutions and Cybersecurity in Health and Care'

Acronyme : DT-TDS

1 main priority & 3 topics

Deadline single stage : 24 April 2018

Other Actions 2018–2019

7 items

approx.
€ 2 billion



European
Commission

Priority 1 – Personalised medicine

- Personalised health and care solutions
- Improved health outcomes
- Chronic, rare and communicable diseases, including children, the ageing population and high-risk groups
- Understanding of the economic impact and the potential of personalised medicine to transform health systems

IMPACT: improved health outcomes for the citizens

POLICY DRIVERS + SUPPORT FO

[Council conclusions on Personalised Medicine](#)

[International Consortium on Personalised Medicine](#)

[European Reference Networks](#)



ICPerMed
INTERNATIONAL CONSORTIUM



European
Commission

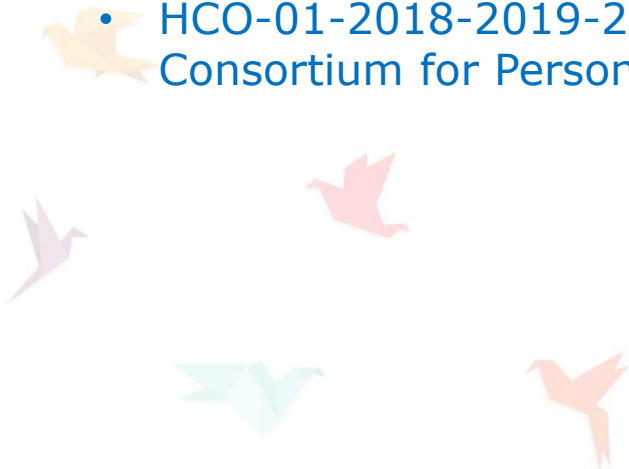
Personalised Medicine in Work Programme 2018–2019 (I)

- BHC-03-2018: Exploiting research outcomes and application potential of the human microbiome for personalised prediction, prevention and treatment of disease
- BHC-04-2018: Rare Disease European Joint Programme Cofund
- BHC-05-2018: International flagship collaboration with Canada for human data storage, integration and sharing to enable personalised medicine approaches
- BHC-01-2019: Understanding causative mechanisms in co- and multimorbidities
- BHC-02-2019: Systems approaches for the discovery of combinatorial therapies for complex disorders

Personalised Medicine in Work Programme 2018–2019 (II)

Coordination and support actions

- HCO-02-2018: Data integration and data-driven in-silico models for enabling personalised medicine - a European standardization framework
- HCO-04-2018: ERA-NET to support the Joint Programming in Neurodegenerative Diseases strategic plan (JPND)
- HCO-01-2018-2019-2020: Actions in support of the International Consortium for Personalised Medicine



Priority 2 – Innovative health and care industry

- Turning innovative knowledge and technologies into practical applications benefiting citizens, healthcare systems and businesses
- Innovative diagnostics and therapeutics, including advanced therapies
- Clear exploitation potential and socioeconomic benefits for patients and sustainable health systems
- Complementarity with the SME instrument, the Fast Track to Innovation and the Innovative Medicines Initiative (IMI)

IMPACT: to stimulate the healthcare industry

POLICY DRIVERS + SUPPORT FOR:

Upgrading the single market



Innovative health and care industry in Work Programme 2018–2019

- BHC-09-2018: Innovation platforms for advanced therapies of the future
- BHC-07-2019: Regenerative medicine: from new insights to new applications
- BHC-10-2019: Innovation Procurement: Next generation sequencing (NGS) for routine diagnosis

Coordination and support actions

- HCO-05-2018: Strengthening regulatory sciences and supporting regulatory scientific advice

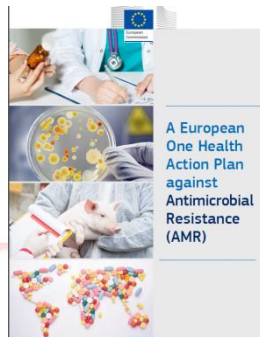
Priority 3 – Infectious diseases and improving global health

- Infectious diseases and the health of vulnerable groups
- 'One Health' approach
- Antimicrobial resistance, emerging and re-emerging infectious diseases and poverty-related and neglected diseases
- Maternal and newborn health, global collaboration on non-communicable diseases and on brain research

IMPACT: to prevent, detect and treat of priority diseases worldwide

POLICY DRIVERS + SUPPORT FOR:

GLPID-R
Global Research
Collaboration for
Infectious Disease
Preparedness



A European
One Health
Action Plan
against
Antimicrobial
Resistance
(AMR)

European One Health
Action Plan against
Antimicrobial Resistance


EDCTP
European &
Developing
Countries Clinical
Trials Partnership


**World Health
Organization**
Global Action Plan
on antimicrobial
resistance


GACD
GLOBAL ALLIANCE FOR CHRONIC DISEASES
AN ALLIANCE OF HEALTH RESEARCH FUNDERS
Global Alliance for
Chronic Diseases

Infectious diseases and improving global health in Work Programme 2018–2019 (I)

- BHC-15-2018: New anti-infective agents for prevention and/or treatment of neglected infectious diseases (NID)
- BHC-16-2018: Global Alliance for Chronic Diseases (GACD) - Scaling-up of evidence-based health interventions at population level for the prevention and management of hypertension and/or diabetes
- BHC-18-2018: Translational collaborative cancer research between Europe and the Community of Latin American and Caribbean States (CELAC)
- BHC-21-2018: Research on HIV, tuberculosis (TB) and/or hepatitis C (HCV) in patients with mono-, co-infections and/or comorbidities in the context of fostering collaboration with the Russian Federation

Infectious diseases and improving global health in Work Programme 2018–2019 (II)

- BHC-13-2019: Mining big data for early detection of infectious disease threats driven by climate change and other factors
- BHC-14-2019: Stratified host-directed approaches to improve prevention, treatment and/or cure of infectious diseases
- BHC-19-2019: Implementation research for maternal and child health



Infectious diseases and improving global health in Work Programme 2018–2019 (III)

Coordination and support actions

- HCO-06-2018: Establishment of an International Network of Social Sciences Research Centres to help address governance and other challenges in the preparedness for and the response to infectious threats
- HCO-08-2018: Creation of a European wide sustainable clinical research network for infectious diseases
- HCO-09-2018: Building international efforts on population and patient cohorts
- HCO-10-2018: Coordinating European brain research and developing global initiatives
- HCO-11-2018: Strategic collaboration in health research and innovation between EU and China

Priority 4 – Innovative health and care systems – Integration of care

- Personalised medicine, management of chronic diseases and health promotion
- Effective, accessible and sustainable health interventions and integrated care systems
- Development of Health technology assessment methods
- Development of sustainable and resilient health systems

IMPACT: better evidence for the development of more sustainable and resilient health systems, resulting in increased access to quality care for everyone and better health promotion

POLICY DRIVERS + SUPPORT FOR:

Upgrading the single market

Cross-border healthcare Directive



Innovative health and care systems – Integration of care in Work Programme 2018–2020

- BHC-23-2018: Novel patient-centred approaches for survivorship, palliation and/or end-of-life care
- BHC-26-2018: HTA research to support evidence-based healthcare
- BHC-22-2019: Mental health in the workplace
- BHC-25-2019: Demonstration pilots for implementation of personalised medicine in healthcare

Coordination and support actions

- HCO-12-2018: Innovation in healthcare – a CSA towards using pre-commercial procurement and public procurement of innovative solutions in healthcare systems

Priority 5

Priority 5 – Decoding the role of the environment, including climate change, for health and well-being

- Assessment of the impact of environment on health and well-being, and the related socio-economic impacts
- New testing and screening methods to identify endocrine disrupting chemicals
- The 'human exposome'
- European environment and health research agenda for the future

IMPACT: Improved risk assessment and mitigation measures

POLICY DRIVERS + SUPPORT FOR:



The 7th Environment
Action Programme (EAP)



Sustainable
Development Goals



The UNFCCC
Paris Agreement



REACH and EU related
policies

WHO Environment and Health Process
(since 1989)



**World Health
Organization**

REGIONAL OFFICE FOR
Europe



**European
Commission**

Decoding the role of the environment, including climate change, for health and well-being in Work Programme 2018–2019

- BHC-27-2018: New testing and screening methods to identify endocrine disrupting chemicals
- BHC-28-2019: The Human Exposome Project: a toolbox for assessing and addressing the impact of environment on health

Coordination and support actions

- HCO-13-2018: Setting the priorities for a European environment, climate and health research agenda



Priority 6

CALL – Digital transformation in Health and Care

- Better access to healthcare and sustainability of health and care systems
- To empower the participation of citizens and facilitate the transformation of health and care services to more digitised, person-centred and community-based care models
- eHealth and mHealth
- ICT for Active and Health Ageing

IMPACT: to maximise the potential of the digital economy in the health and care sectors

POLICY DRIVERS + SUPPORT FOR:



Connected Digital
Single Market



European Cloud
Initiative



European Free Flow
of Data initiative



Silver Economy
initiative

Digital transformation in Health and Care in Work Programme 2018–2020 (I)

- DTH-03-2018: Adaptive smart working and living environments supporting active and healthy ageing
- DTH-07-2018: Exploiting the full potential of in-silico medicine research for personalised diagnostics and therapies in cloud-based environments
- DTH-08-2018: Prototyping a European interoperable Electronic Health Record (EHR) exchange
- DTH-01-2019: Big data and Artificial Intelligence for monitoring health status and quality of life after the cancer treatment
- DTH-05-2019: Large scale implementation of digital innovation for health and care in an ageing society
- DTH-09-2019: Scaling up the univocal Identification of Medicinal Products
- DTH-10-2019-2020: Digital health and care services
- DTH-11-2019: Large Scale pilots of personalised & outcome based integrated care

Digital transformation in Health and Care in Work Programme 2018–2019 (II)

Coordination and support actions

- HCC-01-2018: Supporting investment in smart living environments for ageing well through certification
- HCC-03-2018: Support to further development of international cooperation in digital transformation of health and care
- HCC-04-2018: Digital health and care services – support for strategy and (early) adoption
- HCC-05-2018: Support to a Digital Health and Care Innovation initiative in the context of Digital Single Market strategy
- HCC-02-2019: Support for the large scale uptake of open service platforms in the Active and Healthy Ageing domain

Priority 7

CALL – Trusted digital solutions and Cybersecurity in Health and Care

- Multidisciplinary technologies and solutions in health and care with a focus on cybersecurity
- Secure and user-driven ICT-based solutions in early risk detection and interventions
- Aggregation of a variety of new and existing data sources

FOCUS AREAS

- Digitising and transforming European industry and services
- Boosting the effectiveness of the Security Union

POLICY DRIVERS + SUPPORT FOR:



Connected Digital Single Market



Big Data in healthcare



European Data Protection Regulation



Trusted digital solutions and Cybersecurity in Health and Care in Work Programme 2018–2019

- SU-TDS-02-2018: Toolkit for assessing and reducing cyber risks in hospitals and care centres to protect privacy/data/infrastructures
- SU-TDS-03-2018: Raising awareness and developing training schemes on cybersecurity in hospitals
- DT-TDS-01-2019: Smart and healthy living at home



Other actions for 2018–2019

- Subscription fee: Human Frontier Science Programme Organisation
- Studies, activities of the Scientific Panel for Health, conferences, events and outreach activities
- External expertise
- Grant to the Global Alliance for Chronic Diseases
- Expert group for the impact assessment of the planned Commission communication on infectious diseases
- Subscription fee: World RePORT international health research database
- Mobilisation of research funds in case of Public Health Emergencies

Topics for 2020

Better Health and care, economic growth and sustainable health systems (I)

Personalised medicine

- BHC-06-2020: Digital diagnostics – developing tools for clinical decisions integrating in vitro and in vivo diagnostics
- HCO-01-2018-2019-2020: Actions in support of the International Consortium for Personalised Medicine
- HCO-03-2020: Improving EU-13 participation in EU-supported health research programmes
- HCO-14-2020: ERA-NET Place holder 2

Innovative health and care industry

- BHC-08-2020: New therapies for Non Communicable Diseases
- BHC-11-2020: New, animal-free regulatory test methods for human safety testing at the horizon of 2030
- BHC-12-2020: Boosting the translation of results of health research into validated, innovative applications

Topics for 2020

Better Health and care, economic growth and sustainable health systems (II)

Infectious diseases and improving global health

- BHC-17-2020 : Global Alliance for Chronic Diseases (GACD) 2
- BHC-20-2020 : Using pre-commercial procurements and public procurement of innovative solutions in health care systems to: - reduce the risk of hospital-acquired infections and/or - improve integrated care
- HCO-07-2020 : ERA-NET Place holder 1

Innovative health and care systems - Integration of care

- BHC-24-2020 : Healthcare interventions for the management of the elderly multimorbid patient

Decoding the role of the overall environment for health and well-being

- BHC-29-2020 : Environment, climate change and health – novel mitigating measures for improving population health

Topics for 2020

Digital Transformation in Health and Care

- DTH-02-2020: Personalised early risk prediction, prevention and intervention, RIA
- DTH-04-2020: International cooperation in digital solutions and robotics for independent living
- DTH-06-2020: Accelerating the uptake of in-silico methods for testing medicines with dermatological use
- DTH-10-2019-2020: Digital health and care services
- HCC-06-2020: Support to eHealth Innovation ecosystems in Europe
- HCC-07-2020: Support for European eHealth Interoperability roadmap deployment
- HCC-08-2020: Scaling up innovation for active and healthy ageing
- HCC-09-2020: Supporting deployment of eHealth in developing countries for better health outcomes

Digital Transformation in Health and Care

- DT-ICT-12-2020: The smart hospital of the future
- DT-TDS-04-2020: Demonstrating the potential and benefits of a European Digital Health Infrastructure for Personalised Medicine

Call deadlines

Better Health and care, economic growth and sustainable health systems

BHC + HCO call topics
Calls open: 7 November 2017
Calls close: 18 April 2018

Digital transformation in Health and Care
Trusted digital solutions and Cybersecurity in Health and Care

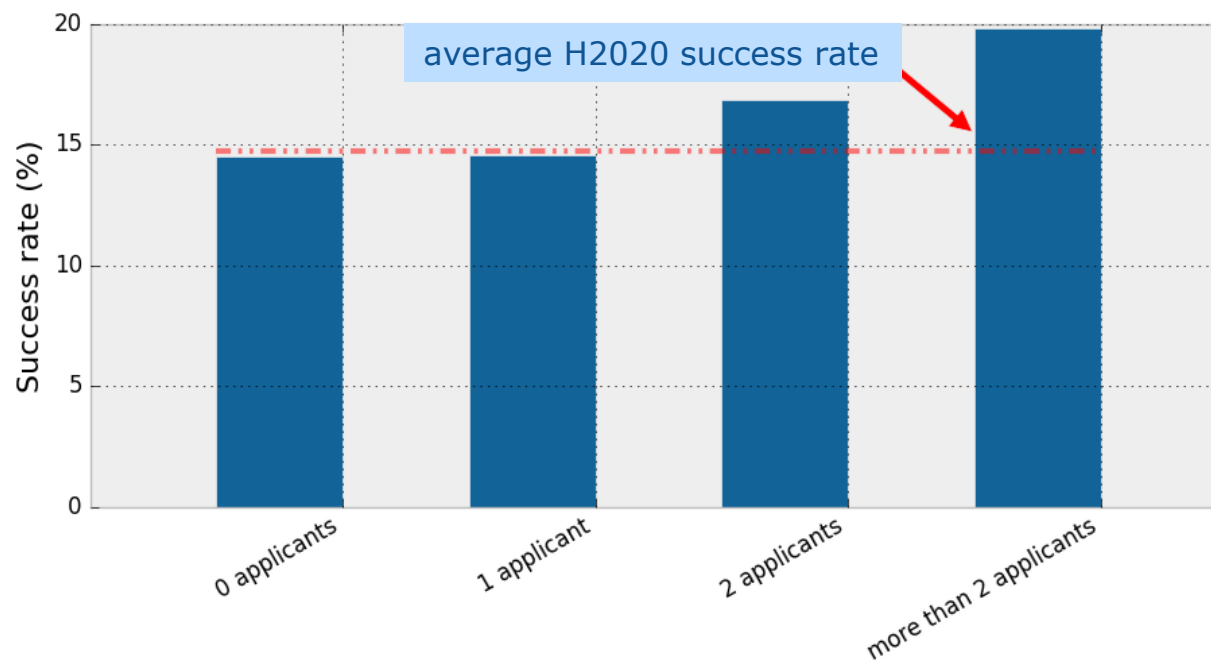
DTH, HCC, and SU-TDS call topics
Calls open: 7 November 2017
Calls close: 24 April 2018

Exception
BHC-15-2018
Lump Sum Funding: a pilot topic
Calls open: 7 November 2017
First stage: 6 February 2018
Second stage: 4 September 2018



Why International Collaboration?

Success rates of proposals with different numbers of applicants from non-associated countries



Note: Data for collaborative projects of Horizon 2020. Success rate is the ratio of mainlisted over eligible proposals.

Source: DG RTD - International Cooperation

Data: CORDA (JRC, EIT & art.185 not included), extraction date: 17/10/2017



International Cooperation main features of WP 2018-2020

General opening: all topics open to international cooperation!

- All SC1 topics are open to international cooperation
- EC contribution: 28 MS, 16 AC and 124 Third countries (General Annexes A.) + USA
- For some other TC: co-funding mechanism (CFM)
- Australia, Brazil, Canada, China, Hong Kong & Macau, India, Japan, Republic of Korea, Mexico, Russia, Taiwan

Topics targeting specific countries /regions (e.g. CELAC, Russian Federation, Canada, etc.)

- Lower overall participation of TC in WPs 2014-2016 if compared to FP7
- Need to get higher and more visible participation of TC in the last WP
- Stimulate cooperation on targeted areas that represent a burden for EU and TC (e.g. cancer for CELAC)
- Give a politically visible 'sign' of cooperation (science diplomacy)

Canada: SC1-BHC-05-2018

- International flagship collaboration with Canada for human data storage, integration and sharing to enable personalised medicine approaches
- Topic elaborated with the Canadian Institutes of Health Research
- At least one Canadian participant (to be co-funded by CIHR)
- RIA of € 4-6 million



CELAC and China: SC1-HCO-01-2018-2019-2020

- Actions in support of the International Consortium for Personalised Medicine
- Topic aimed at building links with third countries on collaboration in personalised medicine
- At least one CELAC in 2018 and at least one Chinese participant in 2019 (EU funding or country co-funding according to general rules)
- CSA of € 1,5-2 million



Disease endemic countries: SC1-BHC-15-2018

- New anti-infective agents for prevention and/or treatment of neglected infectious diseases (NID)
- The nature of the topic implies the participation of disease endemic countries
- At least one disease endemic country
- EU funding or country co-funding according to general rules
- RIA of € 5-10 million

NB: lump sum funding pilot scheme!

CELAC: SC1-BHC-18-2018

- Translational collaborative cancer research between Europe and the Community of Latin American and Caribbean States (CELAC)
- Discussion with CELAC representatives: some of the topics discussed within EU-LAC Health (FP7 CSA) used as input
- At least 2 different CELAC countries
- EU funding or country co-funding according to general rules
- RIA of € 2-4 million



Russian Federation: SC1-BHC-21-2018

- Research on HIV, tuberculosis (TB) and/or hepatitis C (HCV) in patients with mono-, co-infections and/or comorbidities in the context of fostering collaboration with the Russian Federation
- Co-developed with the Ministry of Education and Science of the Russian Federation
- At least one participant from Russian Federation (to be co-funded by Russia)
- RIA of € 2-3 million



International participation, in particular US, Canada, Japan, South Korea, China: SC1-HCC-03-2018

- Support to further development of international cooperation in digital transformation of health and care
- At least one third country (i.e. non-MS, non-AC) participant, in particular US, Canada, Japan, South Korea, China
- EU-funding or country co-funding according to general rules
- CSA of up to € 2 million



Topics with potential participation of third countries

- SC1-BHC-16-2018: Global Alliance for Chronic Diseases (GACD)
– Scaling-up of evidence-based health interventions at population level for the prevention and management of hypertension and/or diabetes
- SC1-HCO-11-2018: Strategic collaboration in health research and innovation between EU and China
- SC1- HCO-06-2018: Establishment of an International Network of Social Sciences Research Centres to help address governance and other challenges in the preparedness for and the response to infectious threats
- SC1-HCO-09-2018: Building international efforts on population and patient cohorts
- SC1-HCO-10-2018: Coordinating European brain research and developing global initiatives

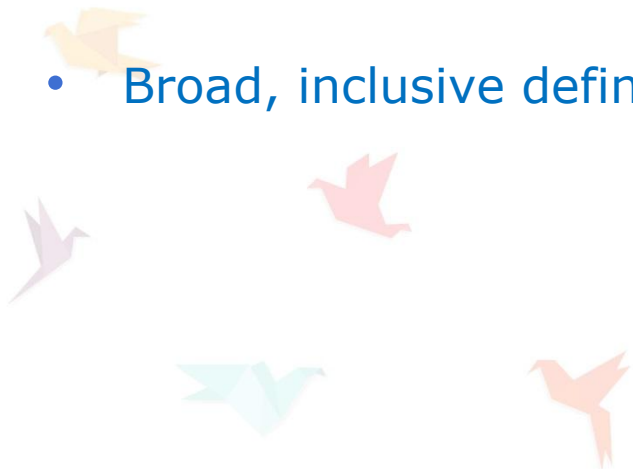
Clinical studies

- Application/definition
- Template – Essential information about clinical studies
- Do's and don'ts – key issues for evaluation
- Unit costs
- Status of recruitment sites
- Deliverables



Clinical studies – applicability/ definition

- **1** A 'clinical study' ... any clinical research involving a substantial amount of work related to the observation of, data collection from, or diagnostic or therapeutic intervention on multiple or individual **patients or study subjects**. It includes but is not limited to **clinical studies and clinical trials** in the sense of the EU Clinical Trials Directive (2001/20/EC) and the Regulation (EU 536/2014).
- Broad, inclusive definition!



Template

Essential information about clinical studies |

PURPOSE

- Providing structured information to experts for evaluation
- Giving applicants the chance to provide detailed information about clinical studies without page limitations
Reasons:
 - detailed but important information, e.g. about Scientific Advice Meetings, relevant (regulatory) guidelines, in- / exclusion- criteria, etc.
 - potentially high number of studies
- Providing necessary information to request 'unit costs'

Available under 'call documents'¹ and in submission system

¹http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/templ/h2020_tmpl-clinical-studies_2018-2020_en.pdf

Template

Essential information about clinical studies |

APPLICABILITY

- Use of template mandatory for certain single-stage and second-stage topics, **if** a clinical study is included
- But: no eligibility criterion, no disadvantage when information provided in other part of proposal
- Rather: more and more appreciated (applicants, evaluators) as an opportunity for structured information
- These topics are listed in the template itself



Template

Essential information about clinical studies |

SCOPE

- Ethical considerations have to be addressed in the respective separate section
- Risks and contingency plans have to be addressed in the respective section of the proposal (part B.3.2 and table 3.2.a) ... If contingency plans are not outlined in the proposal (and the grant agreement), **your grant agreement might be terminated and/or the EU contribution significantly reduced if a study cannot proceed as planned.**

"Extensions of project duration can generally not be granted in H2020. Significantly delayed key study milestones (e.g. 'first patient/first visit') might lead to the termination of the grant agreement."

Do's and don'ts – key issues for evaluation

- The **recruitment planning** has to be sufficiently detailed and realistic!
- **Contingency measures** have to be appropriate (ensuring that delays can be compensated) and realistic!
- If FIM / FIH (First in HuMan) application is intended in a clinical study, the descriptions of the '**FIM / FIH package**' (safety pharmacology / toxicology) has to be exhaustive, allowing experts to evaluate the risk of the project to (not) achieve the required ethics and regulatory approvals.
- If study medication is required sufficient information has to be provided allowing to evaluate if the planning is realistic.

Unit costs - conditions

- Requested in the proposal (and evaluated)
- Fixed methodology¹ (not beneficiary's own methodology!)
- Unit costs per patient/study subject **fixed for the entire duration** of the project. (No adjustments for inflation or wage increases during the time course of an action!)
- Indirect costs of the clinical study (25% of direct costs) eligible
- Can be combined with direct costs
- More detailed explanations and calculation table in the template²

¹ Commission Decision C(2016) 7553 final

(http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit%20costs_clinical_studies.pdf)

² http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/templ/h2020_tmpl-clinical-studies_2018-2020_en.pdf

Status of recruitment sites (I)

Clinical centres whose contribution is limited to subject recruitment or treatment may have status of:

- Full beneficiary → **always preferred!**

But: if obstacles for centres to become beneficiary (or linked third party), two other options remain:

- Use of in-kind contributions provided by third parties against payment (Art. 11 MGA) – **patient data are considered as in-kind contribution**
- Subcontractor (Art. 13 MGA)

Please note: It is not possible to reimburse recruitment sites based on Article 10 MGA (Purchase of goods, works or services)



Status of recruitment sites (II)

Use of in-kind contributions provided by third parties against payment (Art. 11 MGA)

- Third parties must be identified in DoA
- No profit, reimbursement of unit / actual **costs (!)**
- Requires prior agreement with beneficiary – prior to start of work, not necessarily prior to signature of GA
- Agreement might be 'ad-hoc'/specific to project
- 25% indirect costs can be claimed (by the third party itself, not by the beneficiary!) when actual or unit costs are used

Status of recruitment sites (III)

Subcontractor (Art. 13, MGA)

- **only task (!)** must be identified in DoA
- agreed 'price per patient/subject', profit possible
- best price/quality ratio, transparency and equal treatment
- public bodies: internal rules and applicable legislation related to public procurement
- no indirect costs for beneficiary! But with 100% reimbursement rate of direct costs, no more "shortfall" for linked beneficiary



Mandatory deliverables (I)

- 1.** 'First study subject approvals package', for each included CS (prior to enrolment of first study subject):
 - Final version of study protocol as submitted to regulators / ethics committee(s) (no need to change deliverable if later amendments)
 - Registration number of clinical study in a WHO- or ICMJE-approved registry
(Please note: Result posting for the study must be possible)
 - Approvals (ethics committees and national competent authority if applicable) required for invitation / enrolment of first subject in at least one clinical centre

Mandatory deliverables (II)

2. 'Midterm recruitment report', for each included CS: Deliverable to be scheduled for the time point when 50% of the study population is expected to have been recruited. The report shall include an overview of recruited subjects by study site, potential recruiting problems and, if applicable, a detailed description of implemented and planned measures to compensate delays in the study subject recruitment.



Mandatory deliverables (III)

3. Report on status of posting results in the study registry(s), for each included CS:

- Report on the status of the result posting including timelines when final posting of results is scheduled after end of funding period.

Includes now:

Please note the obligation to post results in the registry within 12 months of primary study completion in line with the WHO 'Joint Statement on public disclosure of results from clinical trials'

Open Research Data Pilot

- **Introduced** with H2020 as part of Open Science and Open Access policies of DG RTD.
- **Legal basis:** Art. 29.3 of the H2020 MGA
- A **default** as of 01 January 2017 for SC1 projects
- **'Opt-out' option** only for specific and well justified reasons
- **Principle:** 'As open as possible, as closed as necessary'
- **Type of Data concerned**
 - Data underlying scientific publications (raw/individual patient data (IPD) not concerned)
 - Additional data defined and agreed by the consortium in the data management plan (DMP) (avoiding potential IP and confidentiality infringements)

Open Research Data Pilot

- 'Opt-out' possible at any stage (but rarely justified):
 - during the application phase
 - during the grant agreement preparation (GAP) phase and
 - after the signature of the grant agreement
- **Costs** associated with open access to research data, can be claimed as eligible costs of any Horizon 2020 grant
- Participation in the ORD pilot is **not part of the evaluation of proposals**
- **First version of the DMP** (as a deliverable) must be submitted within the first 6 months of the project
- General [DMP template](#)* is available online, draft annotations specific for health research will be available in the near future
- The DMP needs to be updated over the course of the project whenever significant changes arise

*http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf

Participant portal – one-stop shop

- Call topics + all related documents
- **NCPs**
- Expert registration
- Legal & guidance documents
- FAQs
- Access to proposal submission system

RESEARCH & INNOVATION
Participant Portal

European Commission > Research & Innovation > Participant Portal > Home

HOME FUNDING OPPORTUNITIES HOW TO PARTICIPATE EXPERTS SUPPORT Search 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)
- 3rd Health Programme, Asylum, Migration and Integration Fund, Consumer Programme, COSME, Internal Security Fund Borders, Internal Security Fund Police, Justice Programme, Promotion of Agricultural Products Programme, Rights, Equality and Citizenship Programme and Research Fund for Coal & Steel

Non-registered users

- search for funding
- read the H2020 Online Manual & download the legal documents
- check if an organisation is already registered
- contact our support services or check our FAQs

Registered users

- submit your proposal
- sign the grant
- manage your project throughout its lifecycle
- register as expert advising the Commission

WHAT'S NEW? FUNDING OPPORTUNITIES HOW TO PARTICIPATE WORK AS AN EXPERT MY PERSONAL AREA INFORMATION AND SUPPORT

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

Participation of UK entities

- until the UK leaves the EU, EU law continues to apply to and within the UK, when it comes to rights and obligations; this includes the eligibility of UK legal entities to fully participate and receive funding in Horizon 2020 actions
- eligibility criteria must be complied with for the entire duration of the grant
- **if the United Kingdom withdraws from the EU during the grant** period without concluding an agreement with the EU ensuring in particular that British applicants continue to be eligible, you will cease to be eligible to receive EU funding (while continuing, where possible, to participate) or be required to leave the project on the basis of Article 50 of the grant agreement

Towards FP9

2017	
Q4	<ul style="list-style-type: none">• H2020 Work Programme 2018-2020 integrating main findings from the Interim Evaluation• Publication of Commission Communication about:<ul style="list-style-type: none">○ Overall conclusions on the evaluation results○ State of implementation of the FP7 ex-post HLEG recommendations○ Response to High Level Group recommendations○ Messages on Art. 185 and Art. 187 initiatives
2018	
Mid	Next Multiannual Financial Framework Commission proposal
	Commission proposal tabled for the next Framework Programme & accompanying Impact Assessment
2019	
	European Parliament elections, appointment of the new Commission
2021	
	Launch of the 9th Framework Programme



Thank you!

@EUScienceInnov

#InvestEUresearch

#EUHealthResearch

<http://ec.europa.eu/research/health>

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