



Horizon 2020 Work Programme for Research & Innovation 2018-2020

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

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Participant portal – one-stop shop

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



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



Finding the appropriate call

On the EC Participant Portal

DOs

DONTS

- Use large concept 'keywords': Don't Use too specific • NCD, infectious diseases, prevention, diagnostic...)
- Read the table of content of the WP: topic titles
- Consider other SC programmes
- Look at IMI, ERANET, EIC
- Consider bottom up programmes (ERC, MC, FET...)

- 'keywords' (e.g. diabetes)
- Adapt to the specificity of the programme



Understanding the call topic: example

SC1-BHC-01-2019: Understanding causative mechanisms in co- and multimorbidities combining mental and non-mental disorders

Specific Challenge: The increasing number of individuals with co-and multimorbidities poses an urgent need to improve management of patients with multiple co-existing diseases. A better understanding of their causative mechanisms is needed to develop early diagnosis, efficient prevention and monitoring, and better treatments adapted to co- and multimorbid patients throughout their life course. Furthermore, there are many different etiological models of comorbid conditions (e.g., direct causation model or a consequence of treatment). In this context, capturing and measuring patient's complexity in the context of co- and multimorbidities is crucial for adequate management of these conditions and requires innovative approaches.

Scope: Proposals should identify and validate causative mechanisms (e.g. molecular, genetic, correlative, drug-drug interaction) of co- and multimorbidities combining mental¹¹ and any non-mental disorders through the integration of basic, pre-clinical and/or clinical research¹². Applicants should prove the relevance of the identified mechanisms for co-morbid development. Where pertinent, development of biomarkers and other technologies for diagnosis and monitoring of comorbid conditions in patients is encouraged. A purposeful exploitation of existing data, biobanks, registries and cohorts is expected¹³, but does not exclude generation of new data. Sex and gender aspects, age, socio-economic, lifestyle and behavioural factors and any other non-health related individual attributes should be taken into consideration. SME participation is strongly encouraged.

The Commission considers that proposals requesting a contribution from the EU of between EUR 4 and 6 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected Impact:

- New directions for clinical research to improve prevention, diagnosis, prognosis, therapy development, and management of co- and multimorbidities.
- Whenever relevant identified biomarkers for more accurate and earlier diagnosis, prognosis as well as monitoring of patients' condition.

Type of Action: Research and Innovation action

'SC1-BHC-01-2019'

'Specific challenge'

Scope'

'Expected impact'

'Type of action'



Preparing the proposal: the idea

DOs

- Does the idea respond to the topic?
- Will it achieve the impacts listed in the topic?
- Be specific regarding the impact listed in the topic
- Integrate cross-cutting issues from the beginning
- Involve the enduser/patients/medical staff from the concept



- Don't stretch your idea to answer the scope of the topic
- Don't submit in several topics if slightly relevant



Preparing the proposal: the consortium

DOs

- The right expertise for the right tasks
- Include multidisciplinary teams, for the benefit of the proposal
- Include expertise for crosscutting issues: in ethics, SSH, data management, CT, IPR...
- Involvement of the end-user in the consortium (patients, medical staff...)

DONTs

- Size does not matters!
- Don't overload one or two partners: balance consortium



Cross-cutting issues

- Social Sciences and Humanities (SSH): vulnerability, inequality, legal matters,...
- **Gender dimension:** different risks factors, different interventions, also considering behavior of patients
- **Ethical aspects** relevant for the feasibility/scientific credibility of a project/clinical study (e.g. unacceptable placebo-control)
- **International cooperation:** if an international partner/organization non eligible for funding is foreseen in the proposal, its essentiality for the project needs to be justified (if they are essential and cannot sign the grant eventually, the project will stop)





Participant portal –Call documents

Evaluation criteria

- **1. Excellence**
- 2. Impact
- 3. Quality and efficiency of the implementation







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



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Three priorities

Excellent science

Industrial leadership

Societal challenges



Health Research in Horizon 2020



Health collaborative research – 7 priorities for 2018–2020



Innovative health and care industry



Personalised medicine



Innovative health, and care systems -Integration of care



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



Digital transformation in Health and Care



Infectious diseases and improving global health



Trusted Big Data solutions and Cybersecurity for Health and Care



European Commission

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

Call 1 'Better Health and care, economic growth and sustainable health systems' 5+1 main priorities & 21+3 topics (linked to next Call)

Call 2 'Digital transformation in Health and Care' 8+3 topics (In previous call)

Call 3 'Trusted digital solutions and Cybersecurity in Health and Care' 2 topics

Other Actions 2018–2019-2020

7 items open for 2020





Priority 1 – Personalised medicine

- Aim: delivering personalised health and care to benefit patients and citizens
- Focus: complex disorders, human microbiome, rare diseases and data sharing for enabling personalised medicine, economic models, reinforcing international and regional collaboration

POLICY DRIVERS + SUPPORT FOR:

Council conclusions on Personalised Medicine

International Consortium on Personalised Medicine

European Reference Networks







Call 1 Better health and care...

Priority Area 1.1 Personalised Medicine

 SC1-BHC-06-2020: Digital diagnostics – developing tools for supporting clinical decisions by integrating various diagnostic data
 [Research & Innovation Action (RIA), single-stage, deadline 7 April 2020, €8-15m per proposal, budget for topic €40m]

Coordination & support actions

 SC1-HCO-01-2018-2019-2020: Actions in support of the International Consortium for Personalised Medicine (ICPerMed)
 [CSA, deadline 7 April 2020, €1.5-2m per proposal, budget for topic €4m]
 SC1-HCO-03-2020: Bridging the divide in health research and innovation – boosting return on investment
 [CSA, deadline 7 April 2020, €1.5-2m]

Call 1Better health and care...Area 1.1Personalised Medicine

SC1-HCO-17-2020: Coordinating and supporting research on the human microbiome in Europe and beyond
 [CSA, deadline 7 April 2020, €1.5-2m]

ERA-NET Cofund

SC1-HCO-14-2020: : Sustained collaboration of national and regional programmes in cancer research [ERA-NET Cofund, deadline 7 April 2020, >€5m]

SC1-HCO-16-2020: Sustained collaboration of national and regional programmes in research on brain-related diseases and disorders of the nervous system
 [ERA-NET Cofund, deadline 7 April 2020, >€5m]

Commission

Priority 2 – Innovative health and care industry

- Aim: turn innovative knowledge and technologies into practical applications benefiting citizens, healthcare systems and businesses
- Focus: regenerative medicine, advanced therapeutics and regulatory science
- Complementarity with the SME instrument, the Fast Track to Innovation and the Innovative Medicines Initiative (IMI)



Upgrading the single market





Call 1 Better health and care...

Area 1.2 Innovative Health and Care Industry

SC1-BHC-08-2020: New interventions for noncommunicable diseases

[**RIA**, <u>two-stage evaluation</u>, first deadline 24 Sept 2019, €4-6m per proposal, budget for topic €40m]

SC1-BHC-11-2020: Advancing the safety assessment of chemicals without the use of animal testing
 [RIA, deadline 7 April 2020, €10-20m per proposal, budget for topic €60m]





- Call 1 Better health and care...
- Area 1.2 Innovative Health and Care Industry

Coordination and support actions

 SC1-HCO-18-2020: Developing methodological approaches for improved clinical investigation and evaluation of high-risk medical devices
 [CSA, deadline 7 April 2020, €1-2m]

 SC1-HCO-19-2020: Reliable and accessible information on cell and gene-based therapies
 [CSA: deadline 7 April 2020, €1.5-2m]





Priority 3 – Infectious diseases and improving global health

- Aim: fighting infectious diseases and the growing threat of antimicrobial resistance; addressing the needs of the most vulnerable and the global increase in chronic diseases
- Focus: emerging infectious diseases, poverty and neglected diseases, stratified host-directed approaches to communicable diseases, maternal and child health, global collaboration on non-communicable diseases (cohorts, brain research, hypertension, diabetes, cancer)

POLICY DRIVERS + SUPPORT FOR:



Call 1 Better health and care ...

Area 1.3 Infectious diseases & improving global health

 SC1-BHC-17-2020: Global Alliance for Chronic Diseases (GACD) - Prevention and/or early diagnosis of cancer
 [RIA, deadline 7 April 2020, €1-3m per proposal, budget for topic €20m]

SC1-BHC-33-2020: Addressing low vaccine uptake [RIA, deadline 7 April 2020, €2-3m per proposal, budget for topic €9m]

SC1-BHC-34-2020: New approaches for clinical management and prevention of resistant bacterial infections in high prevalence settings [RIA, deadline 7 April 2020, €10-15m per proposal, budget for topic €25m] Call 1. Better health and care ... Area 1.3 Infectious diseases & improving global health

 SC1-BHC-35-2020: Creation of a European wide sustainable network for harmonised large-scale clinical research studies for infectious diseases
 [RIA, deadline 7 April 2020, €25-30m per proposal]

SC1-HCO-07-2020: ERA-NET Cofund to support the Joint
 Programming Initiative on Antimicrobial resistance
 (JPIAMR)
 [ERA-NET Cofund, deadline 7 April 2020, >€5m]



- Call 1. Better health and care ...
- Area 1.3 Infectious diseases & improving global health

SC1-BHC-20A-2020: Pre-commercial procurement (PCP) for integrated care solutions [PCP, deadline 7 April 2020, €5-6m per proposal]

SC1-BHC-20B-2020: Public procurement of innovative solutions (PPI) for diagnostics for infectious diseases
 [PPI, deadline 7 April 2020, €3-5m per proposal]





Priority 4 Innovative health and care systems – Integration of care

- Aim: develop effective, accessible and sustainable health interventions and integrated care systems
- Focus: mental health in the workplace, novel approaches for palliative care, implementation of personalised medicine, HTA, innovation in health care

POLICY DRIVERS + SUPPORT FOR:

Upgrading the single market

Cross-border healthcare Directive





- Call 1 Better health and care ...
- Area 1.4 Innovative health and care systems -Integration of care
- SC1-BHC-24-2020: Healthcare interventions for the management of the elderly multimorbid patient
 [RIA, two-stage evaluation, deadline 24 September 2019, €4-6m per proposal, budget for topic €50m]
- SC1-BHC-37-2020: Towards the new generation of clinical trials – trials methodology research [RIA-LS, deadline 7 April 2020, €4-6m per proposal]

Coordination and support actions

SC1-HCO-20-2020: Coordination of clinical research activities of the European Reference Networks [CSA, deadline 7 April 2020, €1.5-2m per proposal]

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

- Aim: improving the risk assessment of environment on health and well-being, and the related socio-economic impact and developing mitigation measures.
- Focus: new testing/screening methods to identify endocrine disrupting chemicals, the development of the 'human exposome' (to allow the assessment of lifelong environmental influences on individuals) and to set the priorities for a new research agenda

POLICY DRIVERS + SUPPORT FOR:



WHO Environment and Health Process (since 1989)





Call 1 Better health and care ...

- Area 1.5 Decoding the role of the environment, including climate change, for health and well-being
- SC1-BHC-29-2020: Innovative actions for improving urban health and wellbeing - addressing environment, climate and socioeconomic factors
 [RIA, two-stage evaluation, deadline 24 September 2019, €4-5m per proposal, budget for topic €35m]

 SC1-BHC-36-2020: Micro- and nano-plastics in our environment: Understanding exposures and impacts on human health
 [RIA, deadline 7 April 2020, €4-6m per proposal, budget for topic €25m]



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 communitybased care models
- eHealth and mHealth
- ICT for Active and Healthy Ageing

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

POLICY DRIVERS:



Connected Digital Single Market



European Cloud Initiative



European Free Flow of Data initiative





- Call 1 Better health and care ...
- Area 1.6 Supporting the Digital transformation in Health and Care
- SC1-DTH-12-2020: Use of Real-World Data to advance research on the management of complex chronic conditions [RIA, deadline 7 April 2020, €4-6m, budget for topic €41m]

SC1-DTH-13-2020: Implementation research for scaling up and transfer of innovative solutions involving digital tools for people-centred care

[RIA, <u>two-stage evaluation</u>, deadline 24 September 2019, €3-4m, budget for topic €20m]
Coordination and support action

SC1-HCC-10-2020: Health research and innovation cloud: capitalising on data sharing initiatives in health research [CSA, deadline 7 April 2020, €2-3m]

Call: Digital transformation in Health and Care

Call 2 Digital transformation in Health and Care

- SC1-DTH-02-2020: Personalised early risk prediction, prevention and intervention based on Artificial Intelligence and Big Data technologies
 [RIA, single-stage, deadline 22 April 2020, €4-6m per proposal, budget for topic €32m]
- SC1-DTH-04-2020: International cooperation in smart living environments for ageing people (esp. Canada & Japan)
 [RIA: deadline 22 April 2020, €2-4m per proposal, budget for topic €8m]

SC1-DTH-06-2020: Accelerating the uptake of computer simulations for testing medicines and medical devices [RIA: deadline 22 April 2020, €6-8m per proposal, budget for topic €32m]

Call: Digital transformation in Health and Care

Call 2 Digital transformation in Health and Care

SC1-DTH-14-2020: Pre-commercial Procurement for Digital Health and Care Solutions [PCP: single-stage, deadline 22 April 2020, €4-5m per proposal, budget for topic €9m]

SC1-HCC-06-2020: Coordination and Support to better data and secure cross-border digital infrastructures building on European capacities for genomics and personalised medicine [CSA, deadline 13 November 2019, €4m]



Call: Digital transformation in Health and Care

Call 2 Digital transformation in Health and Care

- SC1-HCC-07-2020: Support for European eHealth Interoperability roadmap for deployment
 [CSA, deadline 13 November 2019, €3m)
- SC1-HCC-08-2020: Scaling up innovation for active and healthy ageing [CSA, deadline 22 April 2020, €1.5-2m]
- SC1-HCC-09-2020: Supporting the development of eHealth in low and middle income countries in Africa
 [CSA, deadline 22 April 2020, €1.5-2m]



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 :



Connected Digital Single Market



Big Data in healthcare



Call: Trusted digital solutions and Cybersecurity in Health and Care

Trusted digital solutions and Cybersecurity in Health and Care

- DT-TDS-04-2020: AI for genomics & personalised Medicine [RIA: single-stage, deadline 22 April 2020, €10m per proposal, budget for topic €35m]
- DT-TDS-05-2020: AI for Health Imaging
 - [**RIA**: single-stage, <u>deadline 13 Nov. 2019</u>, €8-10m per proposal, budget for topic €35m]





Call deadlines

Better Health and care, economic growth and sustainable health systems

> BHC + HCO + DTH-12 and HCC-10 call topics Calls open: 4 July 2019 Calls close: 7 April 2020

Digital transformation in Health & Care

Trusted digital solutions and Cybersecurity in Health & Care

Other DTH, HCC & TDS-04 topics Calls open: 19 November 2019 Calls close: 22 April 2020

Exceptions BHC-08, BHC-24-, BHC-28 & DTH-13-2020 Two Stage call Call open: 4 July 2019 1st stage closes: 24 September 2019 2nd stage closes: 7 April 2020 Exceptions HCC-06, HCC-07 & TDS-05 Call open: 9 July 2019 Closes: 13 November 2019



Clinical studies – applicability/ definition

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

Broad, inclusive definition!



Template Essential information about clinical studies

PURPOSE

- Providing <u>structured</u> information <u>to experts for evaluation</u>
- Giving applicants the chance <u>to provide detailed information</u> 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 '<u>unit costs</u>'

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



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)





Thank you!

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http://ec.europa.eu/research/health http://ec.europa.eu/research/participants/portal

