#InvestEUresearch

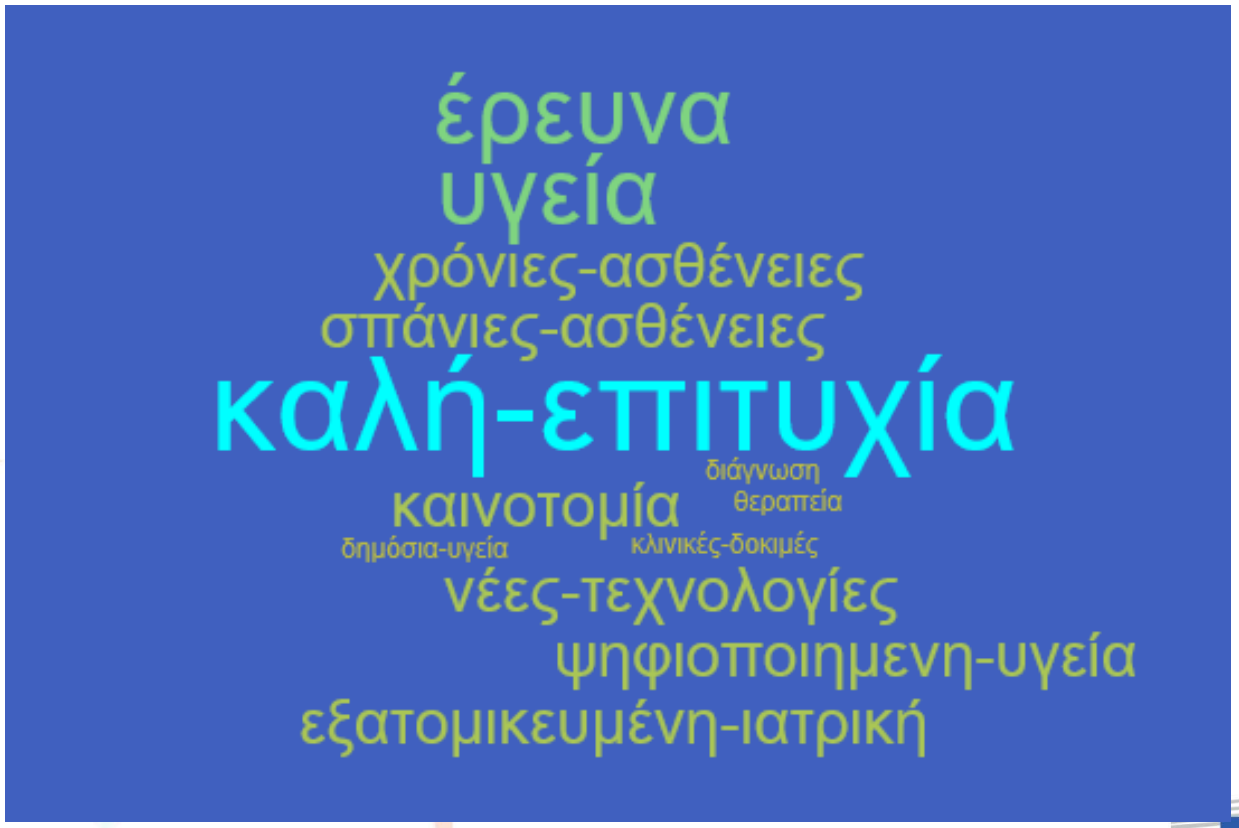
Horizon 2020 Work Programme for Research & Innovation 2018-2020

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

Christina Kyriakopoulou, Senior Scientific officer
Health Directorate, European Commission

Greek NCP info day, Athens 11 Sept 2018

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



European Commission

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

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

- 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

European Commission

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)

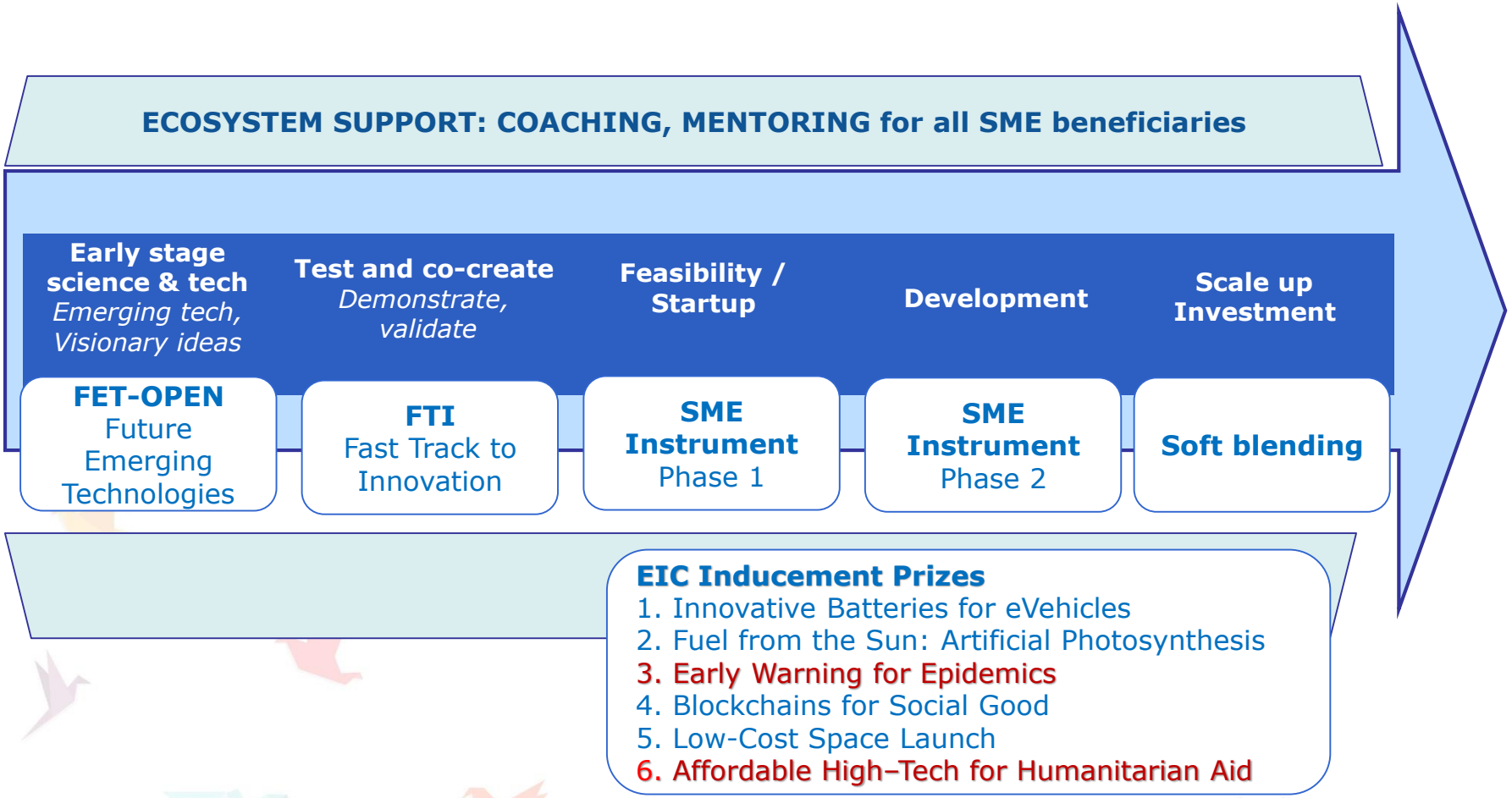
http://www.aal-europe.eu/get-involved/calls/

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

European Commission

European Innovation Council: pilot 2018-2020

€ 2.7 billion to support +5.000 SMEs and innovators



European Commission

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)
- Draft lines for WP 2020

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'
5 main priorities & 32 topics (15 topics in 2019)

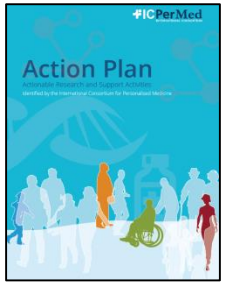
Call 'Digital transformation in Health and Care'
13 topics (6 in 2019)

Call 'Trusted digital solutions and Cybersecurity in Health and Care'
3 topics (1 in 2019)

Other Actions 2018–2019
8 items

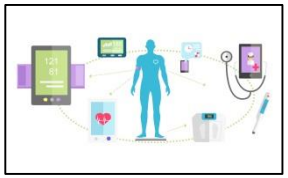
European Commission

Health collaborative research – 7 priorities for 2018–2020



Personalised medicine

Innovative health and care industry



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

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 mental[11] and any non-mental disorders through the integration of basic, pre-clinical and/or clinical research[12]. 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 expected[13], 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'**

European Commission

Participant portal –Call documents

Self-evaluation form

1. Excellence

- Clarity and pertinence of the objectives
- Soundness of the concept, and credibility of the proposed methodology
- Extent that the proposed work is beyond the state of the art, and demonstrates innovation potential (e.g. ground-breaking objectives, novel concepts and approaches, new products, services or business and organisational models)
- Appropriate consideration of interdisciplinary approaches and, where relevant, use of stakeholder knowledge and gender dimension in research and innovation content

Participant portal –Call documents

Self-evaluation form

2. Impact

- **The extent to which the outputs of the project would contribute to each of the expected impacts mentioned in the work programme under the relevant topic**
- Any substantial impacts not mentioned in the work programme, that would enhance innovation capacity, create new market opportunities, strengthen competitiveness and growth of companies, address issues related to climate change or the environment, or bring other important benefits for society
- Quality of the proposed measures to: (i) exploit and disseminate the project results (including management of IPR) and to manage research data where relevant ; (ii) communicate the project activities to different target audiences

Participant portal –Call documents

Self-evaluation form

3. Quality and efficiency of the implementation

- Quality and effectiveness of the work plan, including extent to which the resources assigned to work packages are in line with their objectives and deliverables
- Appropriateness of the management structures and procedures, including risk and innovation management
- Complementarity of the participants and extent to which the consortium as whole brings together the necessary expertise
- Appropriateness of the allocation of tasks, ensuring that all participants have a valid role and adequate resources in the project to fulfil that role

Frequently asked questions (FAQs)

Question : How can I be sure that my understanding of specific terms in the call topic is the same as that of the evaluators?

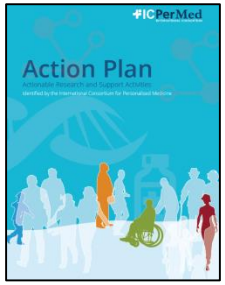
Answer: The European Commission uses independent experts to review all proposals received. Unless an explicit definition of a term is given in a topic description, or elsewhere in the work programme, you may assume that meanings of terms are understood by the evaluators as those which represent the general consensus of experts working in that domain at this time.

Frequently asked questions (FAQs)

Question : Topics sometimes include more than one 'expected impact'. Am I supposed to demonstrate that each of these expected impacts is likely to be achieved? Or can I focus on a selection? When listed as bullet points, are 'expected impact' statements mutually exclusive?

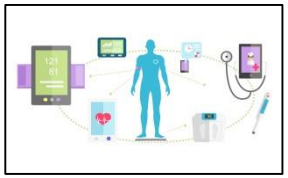
Answer: Applicants who in the opinion of the evaluators demonstrate the greatest likelihood of achieving the greatest level of impact as described in the topic description will be scored the most highly in the impact.

Health collaborative research – 7 priorities for 2018–2020



Personalised medicine

Innovative health and care industry



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

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 FOR:

Council conclusions on Personalised Medicine

International Consortium on Personalised Medicine

ICPerMed
INTERNATIONAL CONSORTIUM

Commission communication on Digital Health and Care

European Reference Networks

European Commission

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

Scope

- Identify and validate the causative mechanisms in co- and multimorbidities combining mental and non-mental disorders
- Integrate fundamental, pre-clinical and/or clinical research*
- Maximise the use of available data, registries, cohorts and biobanks
- Include different etiological models of comorbid conditions: from disease(s), treatment(s), risk factor(s) - common or correlated, or any other pathways

Title modified

Expected impact

- Elucidate the underlying pathophysiological mechanisms of co- and multimorbidities
- Enable new directions of clinical research to improve diagnosis, prevention, therapy and management of co- and multimorbidities
- Establish biomarkers for more accurate and earlier diagnosis as well as monitoring (where relevant)

Practical aspects

Research and Innovation Action, 70 M€ – 4-6 M€/proposal
Two stage submission Deadline: 02 October 2018, 16 April 2019

* Clinical trials are excluded

BHC-02-2019: Systems approaches for the discovery of combinatorial therapies for complex disorders

Scope

- Proof-of-concept of combinatorial therapies tailored to the needs of individuals or stratified patient groups
- Focusing on marketed/approved therapeutic interventions or currently in late stages of development
- Integrate multidimensional and longitudinal patient data using systems approaches

Expected impact

- New concepts for combinatorial therapies for complex diseases
- Improved cost-effectiveness in comparison to established clinical practice with monotherapies
- Enable the development of personalised medicine

Practical aspects

Research and Innovation Action, 50 M€ – 4-6 M€/proposal
Two stage submission Deadline: 02 October 2018, 16 April 2019

Frequently asked questions (FAQs)- topic SC1-BHC-02-2019

Question : Is it necessary to perform pre-clinical AND clinical studies? If this is the case, must the clinical studies also reach phase II?

Answer: The topic requests pre-clinical and clinical research. It also asks for validation in clinical studies. The term "clinical study" should be understood in its broad definition, as described in the template for clinical studies: A 'clinical study' is … 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).

The topic excludes clinical trials at their late stages of development meaning from stage III and further stages.

It is up to the applicants to decide whether to include clinical trials at the early stages of development.

SC1-BHC-30-2019: Towards risk-based screening strategies for non-communicable diseases

Scope

- Develop new or refined, targeted population-based screening interventions aiming at identifying populations or groups at high risk of developing disease
- Stratification by health risk factors and determinants

Expected impact

- Established risk-based screening strategies, which have demonstrated to be effective, affordable, acceptable to the population, cost-effective and suitable for implementation.
- Demonstrated potential to improve health outcomes and equity across Europe.

Practical aspects

Research and Innovation Action, 40 M€ – 4-6 M€/proposal
Two stage submission Deadline: 02 October 2018, 16 April 2019

SC1-BHC-31-2019: Pilot actions to build the foundations of a human cell atlas

NEW TOPIC

Scope

- Demonstrate the utility of an interdisciplinary technological/biological platform to generate and integrate data sets
- Primary focus on healthy tissues, though comparison between healthy and diseased tissues possible
- Should provide detailed plans for quality management of tissue procurement and data in compliance with the relevant EU legislation.

Expected impact

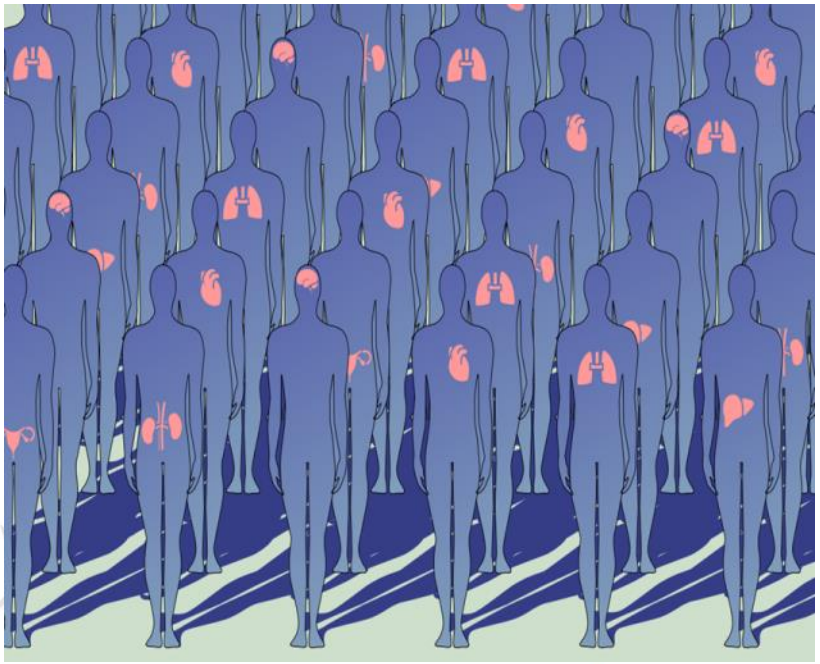
- Timely contribution of project results to the HCA
- Effective and sustainable biological and/or technological platforms.
- Competitive and sustainable European role in HCA
- Strong involvement of European technology SMEs
- Laying the groundwork for improving diagnosis and treatment of disease

Practical aspects

- Research and Innovation Action, 15 M€ – 3-5 M€/proposal – Duration of 2 years
- Proposals supported under this topic must strictly adhere to the values, standards and practices of the HCA
- Commission will ensure an overall coordination mechanism between the projects
- Proposals are expected to budget for the attendance of co-ordinators to regular meetings

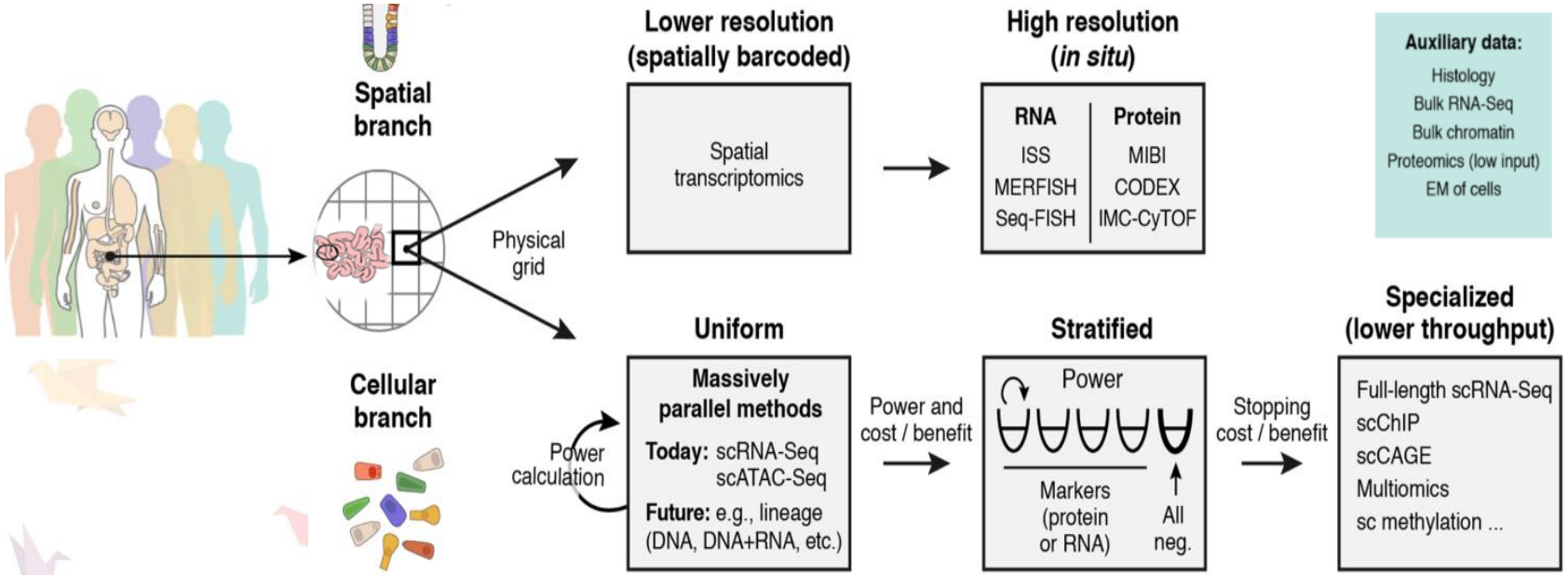
Single stage submission; Deadline: 16 April 2019

HUMAN CELL ATLAS



To create comprehensive reference maps of all human cells—the fundamental units of life—as a basis for both understanding human health and diagnosing, monitoring, and treating

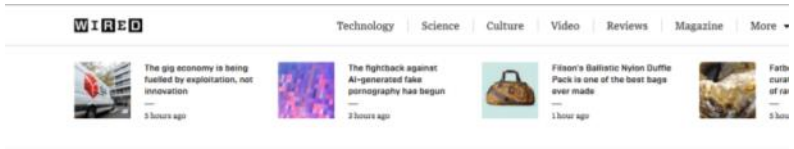
How to build an atlas



Human Cell Atlas: la mappa di tutte le cellule umane

Secondo gli scienziati coinvolti la nuova strategia aiuterà a capire meglio molti aspetti della biologia umana e della medicina, permettendo di migliorare la diagnosi, il monitoraggio e la cura delle malattie

Pubblicati su 20 ottobre 2016 da Francesca C



WIRED Health

Science is on a mission to map all

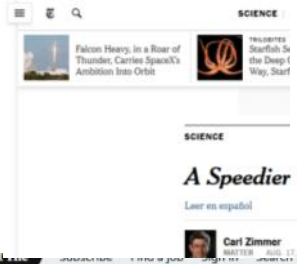
derstand how they

MEDICAL & BIOTECH

Human Cell Atlas Opens a New Window to Health and Disease

An international project is set to detail how every cell type in the body functions

By Sang Yup Lee on June 26, 2017



A Speedier Way to Catalog Human Cells (All 37 Trillion of Them)

Leer en español

Carl Zimmer

Vers un atlas des cellules humaines

Biologie - La Fondation Chan Zuckerberg lance une initiative visant à caractériser l'ensemble des types cellulaires de l'espèce humaine. C'est le Human Cell Atlas Project, « Atlas des cellules humaines ». Une équipe niçoise y participe.

HCA shared Values

- Transparency and open data sharing
- Quality
- Flexibility
- Community
- Diversity, inclusion and equity
- Privacy and ethics
- Technological innovation and excellence
- Computational innovation and excellence

Activities that could be supported

Biological networks	• Biobanks-tissue acquisition • Data generation for sub-atlases • Organoids and iPS cells
Technical Forum	• Technology development • Benchmark • training;
Data Coordination	• Software development • Support data portals • Data storage • Computational resources
Data Analysis	• Computational methods development • Software dissemination • Method comparison, testing, and training;

HCO-01-2018-2019-2020: Actions in support of the International Consortium for Personalised Medicine

Scope

Support the implementation of the IC PerMed Action Plan including actions such as:

- Support the building of PM networks with third countries (for the 2019 call: China).
- Develop new clinical trial designs for PM that facilitate the approval by regulatory and reimbursement authorities.

Expected impact

Support the implementation of the IC PerMed goals. Strengthen links between EU and China for personalised medicine healthcare approaches

Practical aspects

Coordination and support action, 4 M€ – 1.5-2 M€/proposal
Single-stage submission; Deadline: 16 April 2019

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

BHC-07-2019: Regenerative medicine: from new insights to new applications

Scope

- Translational research to develop regenerative processes towards the ultimate clinical goal of addressing an unmet clinical need of public health importance
- Not including devices or pharmaceuticals alone
- Focus on any stage or stages of the innovation chain from early testing of regenerative mechanisms to pre-clinical research, proof of concept to first-in-man trial

Expected impact

- Establish the basis of potential new regenerative therapies
- Strengthen Europe's position in translational regenerative medicine
- Address unmet needs of public health importance

Practical aspects

Research and Innovation Action, 50 M€ – 6-8 M€/proposal
Single-stage submission; Deadline: 16 April 2019

Frequently asked questions (FAQs)- topic SC1-BHC-07-2019

Question : is there a working definition of 'large patient group'?

Answer: The term 'large patient group' implies that proposals should address common, widespread diseases or conditions with respect to societal and economic burden, rather than addressing one specific rare disease.

SC1-BHC-10-2019: Innovation Procurement: Next generation sequencing (NGS) for routine diagnosis

Scope

- Promote the implementation of NGS tests in routine diagnostics for personalised medicine, from a technical, clinical, organisational and/or economic point of view.
- Develop and implement NGS standards and quality assurance schemes.
- Develop tools and methods for data collection, management, analysis and interpretation of NGS results.

Expected impact

Strengthen the implementation of personalised medicine and thus contribute to more effective healthcare systems.

Practical aspects

Pre-commercial procurement, 30 M€ – 9-11 M€/proposal
Single-stage submission; Deadline: 16 April 2019

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:

GLOPID-R
Global Research Collaboration for Infectious Disease Preparedness

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

European Commission

SC1-BHC-13-2019: Mining big data for early detection of infectious disease threats driven by climate change and other factors

Scope

- Develop the technology to enable the pooling, access, analysis and sharing of relevant data including next generation sequencing
- Provide innovative bio-informatics and modelling technologies that enable risk modelling and mapping
- Create analytical tools for early warning, risk assessment and monitoring of (re-) emerging infectious disease threats

Expected impact

Strengthening EU preparedness against (re-)emerging infectious diseases threats enabling the digital transformation of health and care while underpinning the European One Health action plan against antimicrobial resistance and contributing to achieving Sustainable Development Goals

Practical aspects

Research and innovation action, 30 M€ – 12-15 M€/proposal
Single- stage submission; Deadline: 16 April 2019

SC1-BHC-14-2019: Stratified host-directed approaches to improve prevention, treatment and/or cure of infectious diseases

Scope

- To test emerging concepts in drug and/or vaccine development to address the problem of antimicrobial drug resistance to optimize therapeutic, curative or preventive measures against infectious diseases.
- Utilization of knowledge on host factors, immune-modulators or host-pathogen interaction + use of cohorts and stratification of patients.
- Late pre-clinical and/or early clinical research to support proof-of-concept.

Expected impact

- Enrich the product development pipelines with novel, potentially more effective, targeted treatments, cures and/or preventive measures for IDs
- Contribute to the EU impact towards the Sustainable Development Goal 3.
- Contribute to the implementation of the European One Health Action Plan against Antimicrobial Resistance

Practical aspects

Research and innovation action, 95 M€ – 6-10 million EUR/proposal
Two stage submission; Deadline: 02 October 2018, 16 April 2019

SC1-BHC-19-2019: Implementation research for maternal and child health

Scope

- Implementation research that focus on first 1000 days of life (from conception to 2 years of age) to cover:
  - New health service delivery interventions (including introduction of new approved technologies), and/or scaling-up and/or uptake of existing interventions in new contexts
  - Integrating care: e.g. valuing interdependent relationship of mother & child, communicable and non-communicable diseases (e.g. diabetes), prevention & treatment, physical & mental health
- Consider contexts, equity, end-users
- Specific attention for collection of quality data
- Pre-clinical and clinical studies for product development: out of scope

Expected impact

- Evidence for policy: Guidance for ensuring routine quality care for pregnant women, neonates and children up to 2y of age
- EU Contribution towards the Sustainable Development Goals 2, 3, 5 and 10

Practical aspects

Research and innovation action, 25 M€ – 2-4 M€/proposal
Two stage submission; Deadline: 02 October 2018, 16 April 2019

SC1-BHC-32-2019: Towards a next generation influenza vaccine to protect citizens worldwide – an EU-India collaboration

NEW TOPIC

Scope

- Pre-clinical and/or early clinical research supporting proof of concept for next-generation flu vaccine(s).
- Candidate(s) should be suitable to different populations and to LMICs.
- Work should be included on human challenge model.

Expected impact

- Further the development of a flu vaccine effective against more strains and/or effective at the outset of a pandemic.
- Utilisation and/or improvement of human challenge influenza model.
- Reduction of burden of flu outbreaks, especially in Europe and India.
- India-specific impacts, to boost national initiatives by developing affordable biopharmaceuticals.

Practical aspects

- Research and innovation action, 15 M€ – 6-10 M€/proposal
- Minimum 3 participants from India – see http://www.dbtindia.nic.in/funding-mechanism/call/#
  Single-stage submission; Deadline: 16 April 2019

SC1-HCO-15-2019: Support for the functioning of the Global Research Collaboration for Infectious Disease Preparedness (GloPID-R)

Scope

- Administrative and organisational support to GloPID-R.
- Will include meeting organisation, information dissemination, communication (internal and external), support to Industry Stakeholder Group, Scientific Advisory Group, and Chairs of GloPID-R.
- Technical support on more specific issues.

Expected impact

- Effective operation of the network for at least 3 years.
- Reinforced international cooperation in funding of research in new and emerging infectious diseases.
- Improvements during outbreaks in areas such as data sharing, social science, clinical trial networks and others.
- Improved communication of GloPID-R activities.

Practical aspects

- Coordination and support action, 1M€ – Around 1 M€/proposal
- Single-stage submission; Deadline: 16 April 2019

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 propmotion.

POLICY DRIVERS + SUPPORT FOR:

Upgrading the single market

Cross-border healthcare Directive

BHC-22-2019: Mental health in the workplace

Scope

To develop effective interventions to promote mental health in the workplace and assess them for health outcomes and cost-effectiveness. Co-morbidities in mental and physical health should be addressed. Stigma, as well as social, cultural and gender aspects and ethics should be addressed where relevant.

Expected impact

- Broadened evidence base of effective interventions to promote mental health in the workplace, improved basis for policy making.
- Improved mental health and reduced sickness absence in the EU working population
- Positive impact on productivity and economic results of workplaces by improved policies and action to promote mental health

Practical aspects

Research and Innovation Action, 30 M€ – 2-4 M€/proposal
Two stage submission Deadline: 02 October 2018, 16 April 2019

BHC-25-2019: Demonstration pilots for implementation of personalised medicine in healthcare

Scope

- Demonstrate the benefit for patients as well as implementability and economic viability of personalised medicine in real life healthcare.
- Develop prediction, prevention or treatment solutions for diseases with high burden for society.
- Coordinate with national, regional or local authorities and help link different institutions (e.g. hospitals, public health authorities, payers, etc.).

Expected impact

- Evidence for personalised medicine as a new way of care organisation.
- Demonstration of the feasibility and the viability of personalised medicine in real-life settings and at a large scale.

Practical aspects

Innovation Action, 60 M€ – 18-20 M€/proposal

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' – the impact of life-long environmental influences
- A European environment and health research agenda

IMPACT: Improved risk assessment and mitigation measures, health and well-being as a driver for changes required to achieve a sustainable society

POLICY DRIVERS + SUPPORT FOR:

	Sustainable Development Goals
	UNEA Ministerial Declaration & Resolution on Environment and Health
	The UNFCCC Paris Agreement
	WHO Environment and Health Process (since 1989)
	The 7th Environment Action Programme (EAP)
	EU policies and regulations: Chemicals, (e.g. REACH Plant Protection Biocides), air/water quality, noise, occupational health

BHC-28-2019: The Human Exposome Project: a toolbox for assessing and addressing the impact of environment on health

Scope

- Agnostic or targeted approaches to identify and assess environmental risk factors
- Target a long standing policy/regulatory need –> proposals for preventive actions
- Use new technologies to collect, combine and analyse large data sets of environmental exposures and health impacts
- Connections with industry for sensors, omics, biomarkers

Expected Impact

- Innovation in environmental health sciences, in particular for exposure assessments and data management
- Enable researchers and policy makers to continuously include new knowledge in the policy making processes by using the toolbox to generate data and information
- Better predict disease risk by acquisition of new knowledge on the influence of external exposures on biological pathways at different life-stages

Practical aspects

- Research and Innovation action, 50M€ - 8-12M€/proposal
- Open data pilot
- International collaboration welcomed!
- **Collaboration agreement between successful proposals**
- Single-stage submission; Deadline: 16 April 2019

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

DTH-01-2019: Big data and Artificial Intelligence for monitoring health status and quality of life after the cancer treatment

Scope

how to better acquire, manage, share, model, process and exploit big data to effectively monitor health status of individual patients, provide overall actionable insights at the point of care and improve quality of life after the cancer treatment.

Expected impact

- Mapping comprehensive big data in a reachable and manageable way (for sharing and reusabillity);Creating a network of knowledge by linking heterogeneous data sources;
- Data driven analytics/simulation methods for forecasts of trajectories
- Better and faster means of high quality response to prevent or timely address development of new medical conditions and/or improve the quality of life; Improved patient couselling.
- Providing the evidence base for the development of policy strategies;
- Improving quality of life after cancer treatment, strengthening personal confidence and enhancing employability.

Research and Innovation action, 35 M€ - 3-5M€/proposal
Single-stage submission; Deadline: 24 April 2019

DTH-05-2019: Large scale implementation of digital innovation for health and care in an ageing society

Scope

- Contribute to the Scaling-Up Strategy of the European Innovation Partnership on Active and Healthy Ageing and Reference Sites;
- Target large-scale deployment of digital health and care solutions across different regions in Europe
- Specify, purchase and deploy ICT based solutions for active and healthy ageing in the health and care field
- Engage public and/or private procurers that have responsibilities and budget control in the relevant area of care or supply of services;

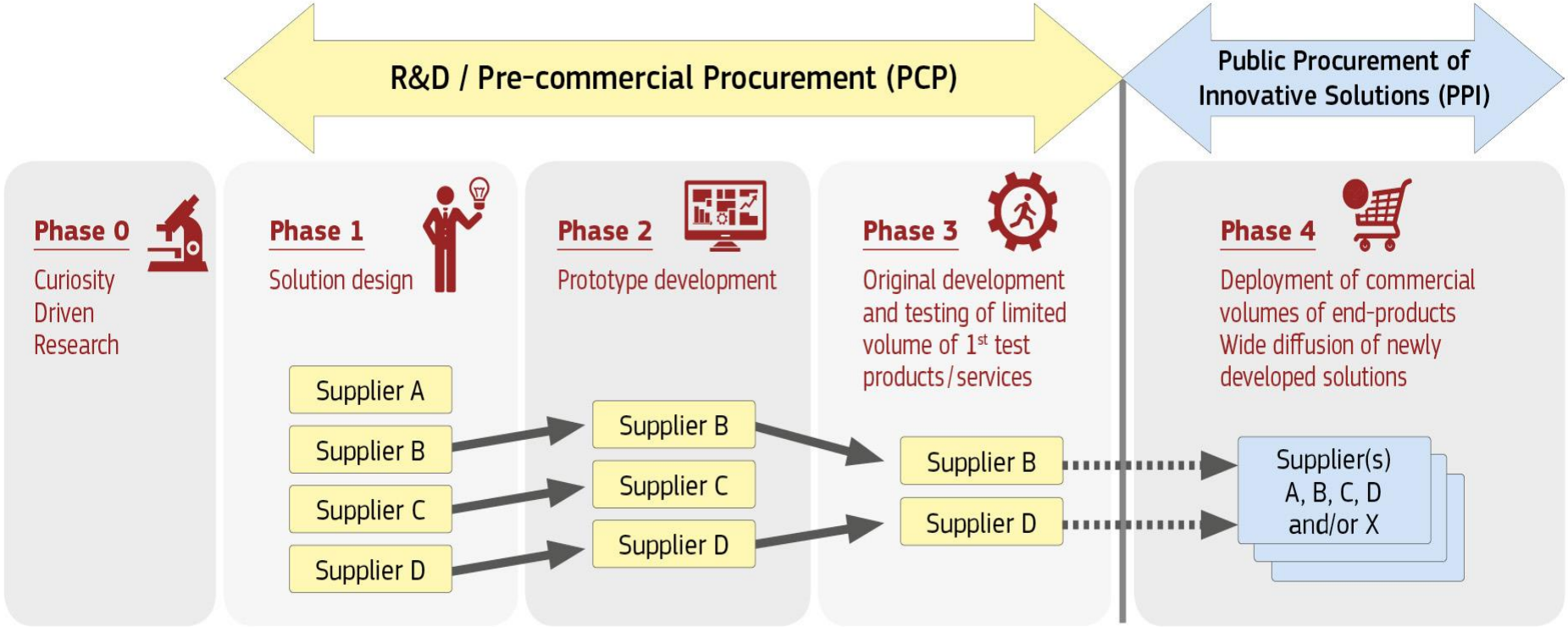
Expected impact

- Growing awareness on the successful use of public procurement to boost ICT innovation applied to active and healthy ageing, ultimately benefiting the growing ageing population across Europe;
- Contribution with data and experiences to addressing potential barriers (regulatory and other) to procurement of innovative solutions for active and healthy ageing.
- Support forward-looking, concerted public-sector investment strategies
- …

Public Procurement of Innovative solutions, 10 M€ - 2-5M€/proposal
Single-stage submission; Deadline: 24 April 2019

Innovation Procurement: PCP + PPI Complementarity

- **PCP** to steer the development of solutions towards concrete public sector needs, whilst comparing/validating alternative solution approaches from various vendors
- **PPI** to act as launching customer / early adopter / first buyer of innovative commercial end-solutions newly arriving on the market



DTH-09-2019: Scaling up the univocal Identification of Medicinal Products

Scope

- Foster the use and dissemination of the IDMP standards set to support the cross-border mobility of European patients by offering safer eDispensations across borders
- Support the standards implementation in national sources (and its possible linkage to a central EMA database) to allow the identification of locally available equivalent medicinal products and ensuring EU SPOR data can be safely used by the ePrescription/eDispensing systems
- Support integration with existing cross-border ePrescription services

Expected impact

- Improved quality of care resulting in enhanced patient safety; Extend the healthcare service provision continuum across borders for patients
- Better address adverse events/effects and safety issues by enhanced development of standard vocabulary
- Better health data access across Europe for patients and healthcare providers

Innovation action, 19 M€ – 5-8 M€/proposal
Single-stage submission; Deadline: 24 April 2019

DTH-10-2019-2020: Digital health and care services

Scope

- Support the health and care service provider to procure the development and testing of digital services and processes that can facilitate the transition to integrated care models across health and social services and country-specific cross-institutional set-ups, including decentralised procurement environments.
- Address key challenges like patient empowerment, self-management and safety, chronic disease management, diagnosing, hospital logistics, skills and independent living by applicable ICT domains e.g., telemedicine, mHealth, IoT, shared open source IT-based platforms,
- Early adoption and demonstration of the potential for scaling-up

Expected impact

- Established path to innovation, improved user and market engagement, strengthened procurement community, evidence of healthy innovation ecosystem, …
- Increased opportunities for solution uptake across wider international procurement markets by aiming at interoperable solutions across Europe

Pre-Commercial Procurement, 22 M€ – 5-6 M€/proposal
Single-stage submission; Deadline: 14 November 2018

DTH-11-2019: Large Scale pilots of personalised & outcome based integrated care

Scope

- Large-scale pilots for deployment of trusted and personalised digital solutions dealing with Integrated Care
- Ensuring secure and efficient sharing and processing of all data and information involved in the supply chain
- Flexibility and replicability of service delivery patterns to combine personalization and large scale adoption of services
- Improvement of quality of life for patients and also of working conditions of all health care and social care providers
- Efficiency gains in terms of resource utilization and coordination of care

Expected impact

- Progress towards a common vision of technical prerequisites and framework to ensure users trust with regard to health and social data and information in IT supported environment
- Contribute to an evidence-based minimum data set (clerical and clinical) on key points of integrated care pathway
- Harmonisation, certification, approval labelling ,reliable identification of adequate solutions, replicable business models for IT

Innovation action, 20 M€ – 4-6 M€/proposal
Single-stage submission; 24 April 2019

HCC-02-2019: Support for the large scale uptake of open service platforms in the Active and Healthy Ageing domain

Scope

- Analyse the use of open service platforms (OP) in the AHA domain, covering both open platforms and partly-open/proprietary platforms developed by industry, and also interactions between platforms
- Study the use of Ops by collecting and processing data from running and recently ended projects –including EU- and initiatives that use the referred platforms, with special focus on UniversAAL and Fiware
- Develop and implement a methodology that monitors OP development, adoption and spread across Europe with relevant KPI's, factors that support or hinder the uptake of open platforms in Europe

Impact

- Identification of the critical success factors of OP development, deployment, and spread;
- Evidence for the socioeconomic benefit of open service platforms;
- Engagement of required stakeholders to ensure data reliability
- Increased knowledge on the differences and synergies between open platforms regarding features and their interoperability on different levels (data / information / applications / services)

Coordination and support action, 1,5 M€ - Up to 1,5 M€/proposal
Single-stage submission; Deadline: 24 April 2019

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

DT-TDS-01-2019: Smart and healthy living at home

Scope

Pilots to build on open platforms, standardised ontologies, APIs and results from IoT-based smart living environments, service robotics and smart wearable & portable systems;

- Intelligent and personalised solutions for sustaining and extending healthy and independent living support to older individuals at risk of temporary or permanently reduced functionality and capabilities

OR

- Personalised early risk detection and intervention Innovative solutions for prevention and treatments based on early risk detection for people facing increased health and social risks

Expected impact

- European-led platforms for smart and healthy and independent living at home;
- Improved quality of life and health status for involved users and carers, with demonstrated added-value of underlying technologies

Innovation action, 60 M€ – 15-20 M€/proposal (SC1-ICT-LEIT)
Single-stage submission; Deadline: 14 November 2018

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

BHC + HCO call topics

Calls open: 26 July 2018

1st stage call closes: 2 October 2018

Single-stage and 2nd stage calls close: 16 April 2019

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

DTH and HCC call topics

Calls open: 16 October 2018
Calls close: 24 April 2019

Exceptions
DTH-10-2019 (PCP)
Call TDS
Calls open: 26 July 2018
Calls close: 14 November 2018

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

[1]http://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)

Open Research Data Pilot

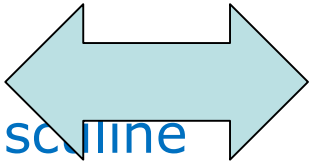
- 'Opt-out' possible at any stage (but rarely justified):
  - during the application phase
  - during the grant agreement preparation (GAP) phase and
  - after the signature of the grant agreement
- **Costs** associated with open access to research data, can be claimed as eligible costs of any Horizon 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

Definition of Terms

- **SEX:** biological qualities;
  male/female/intersex

- **GENDER:** cultural attitudes & behaviours;



  masculine
  feminine

- **WOMAN-MAN:** sex and gender plus other
  cultural factors interact in a person

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

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	• H2020 Work Programme 2018-2020 integrating main findings from the Interim Evaluation • Publication of Commission Communication about: ○ 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!

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#InvestEUresearch

#EUHealthResearch

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

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

European Commission