Scoping Paper for

Horizon 2020 work programme 2018-2020

Societal Challenge 1: Health, demographic change and well-being

Important Notice: Working Document

This scoping paper will guide the preparation of the work programme itself. It is a working document not formally endorsed by the Commission, and its content does not in any way prejudge the final decision of the Commission on the work programme.

The adoption and the publication of the work programme by the Commission are expected in October 2017. Only the adopted work programme will have legal value.

Scoping paper for the Horizon 2020 work programme 2018-2020

Societal Challenge 1: Health, demographic change and well-being

1. Context

1.1. Current political context and the policy objectives to be supported (including the Juncker priorities and the 3 O's)

The headline goal of the 'Health, demographic change and well-being' societal challenge 1 (SC1) is better health and well-being for all. Its main policy objectives are in line with several Commission priorities and with the 3 O strategy (see table below). Beyond its importance for human well-being, health is also considered with its dimension of social policies and socio-economic convergence.

SC1 main policy objectives	Relevant Commission priorities	Relevant 3 O
To improve health and well-being outcomes	'A new boost for jobs, growth and investment'	Open innovation Open science
To promote active and healthy ageing		
To promote a more competitive European health industry and care sector		
To maximise the digital potential	'A connected Digital Single Market'	Open innovation Open science
To promote the EU as a global leader in the health area	'EU as a stronger global actor'	Open to the world Open science

In order to address these objectives, the SC1 implements a comprehensive strategy covering the whole innovation cycle. The SC1 supports multidisciplinary and translational approaches, aiming at the integration of new knowledge generated in pre-clinical, clinical and public health settings. It takes advantage of all Horizon 2020 instruments: Research and Innovation Actions (RIA), Innovation Actions (IA) and Coordination and Support Actions (CSA), Innovation Procurement (Pre-Commercial Procurement, PCP, and Public Procurement of Innovative Solutions, PPI), SME[1] instrument, public-public partnerships (ERA-NET Cofund, European Joint Programme Cofund, Article 185 TFEU[2]), public-private partnerships (Article 187 TFEU), prizes and loans (InnovFin Infectious Diseases).

It should be noted that the public-private partnership Innovative Medicines Initiative (IMI2), and the public-public partnerships European and Developing Countries Clinical Trials Partnership (EDCTP2) and Active and Assisted Living Programme (AAL JP2) as well as InnovFin Infectious Diseases have their own governance framework as defined in their respective legal basis where the Commission will ensure complementarity with relevant Horizon 2020 activities.

[1] Small- and medium-sized enterprises

[2] Treaty on the Functioning of the European Union

Many SC1 research priorities include an international dimension, mainly through multi-lateral initiatives (such as in the areas of rare diseases, chronic diseases and infectious diseases). Addressing social sciences and humanities, and sex differences and gender aspects are also requested where relevant. The SC1 integrates the principle of responsible research and innovation in all its activities, including ethics.

1.2. A very brief summary of the process for developing the scoping paper

This SC1 scoping paper has been developed mainly on the basis of the SC1 Advisory Group (AG) report and of the subsequent targeted stakeholder consultation (closing date 15 July 2016). In addition, the conclusions of several events[3] organised by DG RTD and DG CNECT have contributed to the priorities developed in this paper.

1.3. Main conclusions from the AG advice report and stakeholder consultations

The report of the SC1 Advisory Group summarised the current challenges and opportunities associated to SC1 in 'vertical', 'horizontal' and 'cross-cutting' themes, setting out the health research priorities for 2018-2020.

Europe faces rising and potentially unsustainable health and care costs, mainly due to the increasing prevalence of chronic diseases, to an ageing population requiring more diversified care and to increasing societal demands. Europe also experiences a decrease of research and innovation productivity in the health and care industry. The world, including Europe, is confronted with migration, climate change and new emerging infectious diseases influencing health and well-being. Finally, health inequalities and access to health and care also constitute major challenges for our societies. Europe needs smart, scalable and sustainable solutions building on the innovation opportunities in order to overcome these challenges, and must grasp every opportunity for leadership. Technology and innovation continue to offer new opportunities at an accelerating pace.

1.4. Gaps identified in gap analysis

The gap analysis has been conducted along the 7 SC1 sub-priorities identified in the Specific Programme implementing Horizon 2020.

The gap analysis shows that those 7 SC1 sub-priorities were to a large extent addressed by the calls 2014-2017. It is, however, necessary to ensure continuation and further support for some areas and to launch new topics with high potential for impact (including faster adoption of new solutions at scale).

2. Strategic orientations for 2018-2020 and translation into calls

2.1. Priorities identified

The strategic orientations will include the following **4 priorities, each of these being translated into specific calls.** Some of them may be implemented as part of a 'focus area' across societal challenges. Those priorities are interlinked and will support each other.

[3] Those events include 'Economic evaluation methods in healthcare' workshop (26 Jan 2016), 'Personalised medicine' conference (1-2 June 2016), the European Innovation Summit on Active and Healthy Ageing (March 2015) and the eHealth Week event (June 2016)

Priority 1: Better health and care, economic growth and sustainable health systems

This priority is expected to be the largest of SC1 2018-2020. It will aim at reconciling better health and healthy ageing with the need to develop sustainable health and care systems and growth opportunities for the health and care related industries. EU added value and impact of this priority are high, because research areas to be addressed under this priority will implement and provide an evidence-base for several global and EU policies, including the 2030 Agenda for Sustainable Development and its Sustainable Development Goals (SDGs, in particular the SDG3 on 'Good Health and Well-being'), the cross-border healthcare directive (and its support to the European Reference Networks), the Commission Communication on upgrading the single market (and its proposed health technology assessments initiative) and recent Council Conclusions on Personalised Medicine and on Pharmaceuticals. This priority will also contribute substantially to the Commission priorities on *'A new boost for jobs, growth and investment'* and *'A stronger global actor'*. It includes the following complementary research areas:

- ***Personalised medicine***

Objectives: Translation of new knowledge on disease aetiology and technological innovation into personalised health and care solutions. Areas of application include chronic, rare and communicable diseases. Targeted populations include children and ageing population, as well as adolescents and young adults, adults, minorities, and high-risk groups, all facing potential barriers to timely access to quality health and care. Relevant links with the priorities on 'Digital transformation in Health and Care' and 'Trusted Big Data solutions and Cybersecurity for Health and Care', the European Open Science Cloud and the European Reference Networks will be sought. Research under this priority will also attempt to develop an understanding on the economic impact and the health system transformation potential of personalised medicine.

Specific impacts: Strengthening the International Consortium on Personalised Medicine by: (i) establishing Europe as a global leader in personalised medicine research, (ii) supporting the personalised medicine science base through a coordinated approach to research, (iii) providing evidence to policy makers of the benefit of personalised medicine to citizens and healthcare systems.

- ***Innovative health and care industry***

Objectives: To support the most innovative stakeholders in Europe in the area of healthcare and ageing/well-being research in particular through two complementary funding schemes: SME-dedicated grants and loans (via the scaling-up of the InnovFin Infectious Diseases Pilot). This action is also relevant to the planned European Innovation Council. Note that IMI2 has its own governance structure and is complementary to this SC1 scoping paper.

Specific impacts: Exploiting the potential of the healthcare and ageing/well-being industry and contributing to growth and competitiveness and jobs in this sector.

- ***Improving global health***

Objectives: To address communicable and chronic diseases affecting global health including through preparedness. Taking a One-Health as well as a more personalised approach, this will include improving risk assessment and surveillance tools and approaches, the development of innovative medical countermeasures addressing in particular antimicrobial resistance and emerging and re-emerging infectious diseases, as well as , poverty-related and neglected diseases. Furthermore, maternal and newborn health, global research collaboration on dementia, upscaling interventions in specific diseases to low-and middle-income countries

populations and vulnerable populations of high-income countries and their connection to extensive migration waves. Relevant links exist to the EDCTP, the WHO (World Health Organisation) Global AMR action plan, the global coordination of emerging infectious diseases research, the Council Conclusions and the WHO Global Action Against Dementia, and further multi-lateral research initiatives.

Specific impacts: (i) To position the EU as a leading partner in the promotion of global health and well-being, (ii) to contribute to achieving SDG3, in particular by supporting research preparedness for epidemics and development of vaccines and medicines for communicable and non-communicable diseases that primarily affect developing countries, (iii) to implement the GloPID-R (Global Research Collaboration for Infectious Disease Preparedness) and GACD (Global Alliance for Chronic Diseases) agendas as well as the related G7 and WHO actions, (iii) to provide evidence for addressing migration-related health issues.

- ***Sustainable and evidence-based health and care systems***

Objectives: To develop new models for effective, accessible and sustainable health interventions and care systems (important in the context of personalised medicine development, management of chronic diseases and health promotion). This may include the further development of health technology assessment methods, and the evaluation of community and population-based intervention strategies, both retrospectively and prospectively, addressing also the important dimensions of organisational change, workforce skills, associated investment, new financing and business models, all of which suggest contributions from Social Sciences and Humanities disciplines.

Specific impacts: To provide better evidence for the development of more sustainable and resilient health systems, including through better and more coordinated health technology assessment, resulting in increased access to quality care for everyone and better health promotion.

- ***Innovative health and care delivery services – Integration of care***

Objectives: To promote the creation, the assessment and scaling-up of demand-driven open innovation health and care eco-systems for more effective approaches on key challenges, such as cancer, cardiovascular diseases, dementia, mental health and multi-morbidities. This may include aspects such as organisational, financing and business models, workforce training, hospital and telemedicine services, home care, self-care, patient centeredness and patient empowerment. This research line includes the integration of the care dimension, by the promotion of health literacy, and by better coordinating the primary and community care with the specific needs of the patient.

Specific impacts: (i) To provide a path to innovation and implementation of integrated care programmes, (ii) to provide evidence of benefits to the society, (iii) to focus on the user engagement, (iv) to address societal needs by high impact disruptive technologies, (v) to strengthen the procurement communities and the links between the demand (care authorities) and supply (technology providers) sides.

Priority 2: Decoding the role of the overall environment for health and well-being

This priority may contribute to the potential focus area "Building a low-carbon, climate resilient future"

The overall environment we live in has a strong impact on our health. Changes in this environment, such as climate change or environmental pollution, are affecting many sectors of the economy. Food production and consumption patterns are being transformed. Urbanisation is changing the ways we live and move. Migration is having a strong impact socially and economically. This priority takes an outwards looking perspective to assess how factors external to the human body and to health- and care systems impact health and well-being, including the related socio-economic impacts. It will contribute to the implementation of the Sustainable Development Goals, the agreement reached during COP21[4] and future COP agreements and the goals of the Parma Declaration on Environment and Health. It will develop a strategic approach to research and innovation needed to address these challenges, at the individual as well as at the systems level. The aim is to re-establish health and wellbeing as a strong driver for societal and political changes needed in support of a sustainable society. This priority will provide evidence enabling new approaches to disease prevention through actions cutting across different policy areas. It will be composed of two sub-priorities:

- ***The human exposome***

Objectives: To develop the 'human exposome', allowing the assessment of the totality of the life-long environmental influences that individuals are exposed to and their health impacts. This will require, *inter alia*, deciphering the biological pathways of how life-style, physical environments, and genes interact; harnessing of available data and collecting and managing new data; the development of cost-efficient sensors to monitor the environment and health data; and socio-economic analysis of the benefits of including the exposome approach into health assessments, health care and policy-making. A special focus will be given to research on the causal mechanisms between external exposure and health impact. With regards to the exposure to chemicals close collaboration with the European Human Biomonitoring Initiative (HBM4EUI) will be sought.

Specific impacts: (i) reinforcing the evidence base for preventive actions through new knowledge about the role of environment factors on human health; (ii) disclosing the causal effects of external exposures; and (iii) enhancing technological progress on new sensors combining exposure and health data measurements.

- ***Global changes and health***

Objectives: To assess how global changes (i.e. climate change and related changes in the agri-food sector or migration) may affect health, health and care systems as well as many sectors of the economy. The aim is to study the direct (e.g. heat waves, vector-borne diseases) and indirect **health impacts** of climate change, as well as other changes, and to develop policies or interventions to adapt to or limit these. Actions will take a cross-cutting, 'One Health' approach to assess the health impacts of changes related to climate change in other policy sectors as well as developing the optimal solution for overcoming a health problem, even if it lies outside the health area as such. This priority is relevant to the achievement of the

[4] 21st annual Conference of the Parties (COP) in Paris from November 30th to December 11th 2015 of The United Nations Framework Convention on Climate Change (UNFCCC)

Sustainable Development Goals and to the COP21 implementation priority. International cooperation will be called for when relevant.

Specific impacts: (i) provide evidence for the direct and indirect impact of climate change and other related changes on human health and well-being (ii) streamline health impact assessments across sectors and highlight the socio-economic importance of such assessments; iii) provide evidence on effective systems intervention to mitigate the impact of climate change and other related changes.

Priority 3: Digital transformation in Health and Care

This priority will address eHealth, mobile health (mHealth) and Information and Communication Technology) (ICT) for active and healthy ageing. It will complement work on eHealth policy, the legal framework for mHealth apps, and for demographic change and ageing well. The ultimate goal is managing health and wellbeing while empowering the participation of citizens and facilitating the transformation of health and care services to more person-centred and community-based care models, thereby ensuring better access to healthcare and the sustainability of health and care systems. It is relevant to the Commission priorities *'A new boost for jobs, growth and investment'* and *'A connected Digital Single Market'*, to the European Cloud Initiative and the European Free Flow of Data Initiative. This is seen as an area maximizing the potential of the digital economy in the health and care sectors.

- ***eHealth and mHealth***

Objectives: To support research and innovation in eHealth and mHealth and to accelerate the computerisation of medicine in order to satisfy the needs of all citizens of better health, better prevention and well-being and of the service providers and healthcare professionals in digitising diagnostics, treatments and other aspects of patient management. To support research and innovation in the highest impact disruptive IT technologies, such as *in silico* medicine and integration of technologies. To ensure the needs of interoperability and standardisation and to benefit from the European cloud-based infrastructures and international cooperation. To create an open health innovation and European wide upscale.

Specific impacts: A more digitised, predictive, personalised approach to diagnostics and treatments answering to the real needs in healthcare and public health. New possibilities in biomedical research and validation of research results and products in cloud-based infrastructures in order to accelerate benefit to patients and clinicians for decision making. Increased patient engagement and self-management of health for a better continuity of care, shifting to more person-centred and community-based care models. Overcoming the challenge of cross-border and within-border interoperability of electronic health records (EHRs) and scaling up markets through promotion of interoperability and standardisation.

- ***ICT for Active and Healthy Ageing***

Objectives: New personalised solutions building on progress in ICT such as artificial intelligence and the Internet of Things for prevention and engagement in active and healthy ageing based on the needs of citizens, the ageing society, and social and working life of older adults, support to de-institutionalising health and care, and the scaling up of markets underpinned by policy activities such as the Blueprint on digital transformation of health and care for the ageing society, the age-friendly housing initiative, and other activities in support of the Silver Economy.

Specific impacts: (i) Proven breakthrough ideas and digital solutions which substantially enhance better quality of life, independence and sustainability of health and care systems, (ii)

positioning Europe as a global leader in digital solutions for ageing well and strengthening the Silver Economy in Europe.

Priority 4: Trusted Big Data solutions and Cybersecurity for Health and Care

This priority may contribute to the potential Focus Areas on 'Digitising and transforming European industry and services' and 'Boosting the effectiveness of the Security Union'.

- ***Trusted Big Data solutions for health and care***

Objectives: To offer secure and user-driven ICT-based solutions and breakthroughs in early risk detection and interventions of key health and ageing related conditions and to enable adaptive aggregation and use of a variety of existing data sources such as medical records, registries, social platforms and other environmental, physiological and behavioural data, including data from large scale pilots on smart living environments and mobility.

Specific impacts: (i) to support prevention and self-empowerment of patients and older adults (ii) to provide timely, meaningful information and knowledge for personalised health and care services (iii) to promote and enable sustainable data sources and data reuse in health and care, (iv) to promote ICT-based solutions with health care as driver for social/economic change.

- ***Cybersecurity for health and care***

Objectives: To address research and innovation in the area of cybersecurity for assuring data privacy, security and/or protection of health and care data.

Specific impacts: To ensure secure data management and to develop trusted solutions adapted to the new future dynamic digital healthcare systems and that can make a difference in terms of getting industrially competitive eHealth products.

2.2. Calls linked to the priorities

Call working title *(indicate 'FA' if proposed as a focus area)*	**Brief description of the scope of the call including information if it is cPPP. If a focus area please show how the criteria have been met.**	**Possible contribution from and to other work programme parts (mandatory for focus areas)**
Call *'Better health and care, economic growth and sustainable health systems'*	The scope of the call may range from prevention, diagnosis, stratified approaches, integration of care, predictive toxicology, repurposing therapies, medical technologies including advanced therapies, cohorts and registries-based research, to systemic digital solutions for health and ageing well. It should translate new knowledge into innovative applications, accelerate large-scale uptake and deployment in different health and care settings, making health and care systems and services more accessible, responsive and efficient in Europe and beyond.	SC2: personalised nutrition (tbc)

Calls *'Decoding the role of the changing overall environment for health and well-being'* Possible contribution to the potential Focus Area on *' Building a low-carbon, climate resilient future '*	The scope of the call will range from research that advances the development of the human exposome, policy research, health promotion research, implementation research as well as methods research for health economic evaluation and health impact assessment. It will to establish clear links between different environmental factors as well as exposures and health and health systems impact. Important lines of research will be to identify effective adaptive responses and behaviours also at the systems level.	SC2: food security SC5: climate change SC6: migration
Call *'Digital transformation in Health and Care'*	The call will address eHealth, mHealth and ICT for active and healthy ageing through the full research and innovation cycle. The scope may range from in-silico medicine, biomedical research and applications within the European Cloud Initiative, computerised testing of biomedical products, decision support systems, mHealth, eHealth for developing countries, to innovative care services and intelligent living environments. From robotics, unobtrusive sensing, interoperability, standardisation, data integration to AI based technologies. It will build on international health innovation ecosystem initiatives.	
Call *'Trusted Big Data solutions and Cyber-security for Health and Care'* Possible contribution to the potential Focus Areas on *'Digitising and transforming European industry and services'* and *'Boosting the effectiveness of the Security Union''*	This call will address research on use of big data for improving health and care and innovative services building on state of the art technologies. It may encompass new trust and data models, analysis of behavioural and physiological patterns, early risk detection and disease prevention. It will provide integrated ICT solutions for smart living environments based on large scale IoT pilots. It will address new secure ways of data storage and safe exchange of data ensuring cybersecurity in future dynamic digital healthcare systems.	All SCs - LEIT-IoT-Cybersecurity