EN

Annex 4

Horizon Europe Programme (HORIZON)

Work Programme 2021-2022

4. Health

Table of contents

Introduction

The promotion of social cohesion and inclusiveness and the health and well-being of its people are central aims of the European Union's policies and programmes, including this Health Cluster of Horizon Europe. With the **European Pillar of Social Rights**, the EU set the direction towards a fairer, inclusive and more social Europe for all European citizens based on a European social model that is fit for the challenges of the 21st century, also providing people with equal opportunities. Further efforts should be devoted to develop **an economy that works for people** by supporting Member States in making innovative high-quality health technologies and health care both available and affordable for citizens as well as to rendering health care systems more accessible and sustainable, including through the digital transformation of health and care. On the one hand, this entails that citizens can rely on effective health care services that address their medical needs and reduce the burden on them, their families and communities; on the other hand, people should be assisted in promoting their own health and preventing diseases. The **EU4Health programme** is proposed to be an investment instrument in making sure that the EU remains the healthiest region in the world, has tools available to address health challenges at national and EU level including new emerging health threats. To ensure maximum synergies between these programmes in order to reach maximum public health impact, Horizon Europe will focus on creating new knowledge, while the EU4Health programme will focus on making the best possible use of this new knowledge for the benefit of citizens and health systems. In particular, **Europe's Beating Cancer Action Plan** will support Member States in improving cancer prevention, control and care. The COVID-19 crises underlined that supporting cooperation and coordination among the Member States at Union level is essential to improve the prevention and contain the spread of epidemic outbreaks across borders, to strengthen immunisation against vaccine-preventable diseases, to control other cross-border health threats and risk factors, and to safeguard the health and well-being of people in the Union. This includes, as part of the **European Green Deal**, to take a One Health approach in tackling the impact of environmental degradation, pollution, biodiversity loss and climate change on citizens' health and well-being as well as on health care systems and their ability to adapt rapidly to changing health care needs and conditions, due to global change. Unleashing the full potential of digital tools and data-enabled research and innovation will be crucial for making **Europe fit for the digital age** and increasing productivity and supporting sustainability of health-related industry and SMEs in the EU, including the related convergence of pharmaceutical, digital and medical technologies. This will also underpin the digital transformation of health and care supported by data-driven manufacturing of tailor-made products and mainstreaming of personalised health care services, resulting in significant gains in health outcomes and health economies.

Research and innovation actions under this cluster will be key to address the health-related challenges by advancing knowledge and capabilities, improving our understanding of health and diseases, developing innovative methodological and technological solutions to better manage health and diseases, and designing sustainable approaches for the digital transformation and delivery of integrated, person-centred and equitable health and care services with improved accessibility and health outcomes supported by needs-driven innovation and reliable supply

chains in Europe. However, it will also depend on the actors on the ground – those receiving, supporting and delivering health and care services in local communities, regions and countries – to accept, support, take-up, scale-up and implement the recommendations and innovative solutions developed through research and innovation to achieve desired impacts. Research and innovation actions supported under this cluster should therefore mobilise researchers from academic institutions, research organisations, small and medium enterprises, and large companies, as well as citizens and patients, patients associations, providers of health and care services and regulatory instances. To maximise the benefits of EU investments and support the EU in achieving its goals, the cluster health will promote and foster synergies with public health policies at national and regional level, with other EU programmes and policies. It will benefit from participation of health-related European research infrastructures which can offer tailored research support services to activities across all destinations under the health cluster.

Destination 1 – Staying healthy in a rapidly changing society

Research and innovation under this Destination will provide new evidences, methodologies and tools for understanding the transition from health to disease, preventing diseases and promoting health.

Across all stages of life (birth, infancy, childhood, adolescence, pregnancy, mature and late adulthood) and in all health conditions, needs, and socio-economic position, citizens will have access to personalized health solutions, including solutions to help achieve and maintain healthier behaviours and lifestyles as well as wellbeing.

Specific measures will also be developed to educate and empower citizens of all ages and throughout their life, to play an active role in the self-management of their own health and self-care, to the benefit of an active and healthy ageing.

Dialogue and coordination between stakeholders and policy makers as well as integration across different settings will be needed to develop more effective cross-sectoral solutions for health promotion and disease prevention and deliver improved evidence-based health for all.

Key to achieving these objectives is the availability and accessibility of health data from multiple sources, including real-world health data, which will require appropriate support by research and data infrastructures and AI solutions.

Expected impacts:

Proposals for topics under this Destination should set out a credible pathway to contributing to the following expected impacts of the Horizon Europe Strategic Plan:

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- Promotion of healthier lifestyles, behaviours and environments to enable citizens stay healthy throughout the life; Innovative evidence-based services, policies and guidelines for health promotion and disease prevention;
- Accessible, equitable and effective co-designed digital solutions for promoting health and preventing disease;
- Strong collaborations across sectors and with other Horizon Europe clusters to transform the healthcare system from reacting to illness, to proactively promoting health and preventing disease.

This first Horizon Europe Work Programme will address major societal challenges linked to Commission priorities such as diet and health (obesity), demographic change, mental health and digital empowerment in health literacy. In 2022 it will also call for improving usage of cohorts through International Cooperation and health to disease transition, in particular for chronic diseases.

The following calls in this Work Programme contribute to this Destination:

Call	Budgets (EUR million)Deadline(s)
HORIZON-HLTH-STAYHLTH-2021-01 Staying Healthy (2021)	
HORIZON-HLTH-STAYHLTH-2022-01-two-stage Staying healthy (Two stage - 2022)	
HORIZON-HLTH-STAYHLTH-2022-02 Staying healthy (Single stage, 2022)	
HORIZON-HLTH-STAYHLTH-2022-03 Partnerships in Health (2022)	
Estimated total budget	

Call - Staying Healthy (2021)

HORIZON-HLTH-STAYHLTH-2021-01

Conditions for the Call

Indicative budget(s)[1]

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million)	Number of projects expected to be funded
Opening: na				
Overall indicative budget				

Proposals are invited against the following topic(s):

HORIZON-HLTH-STAYHLTH-2021-01-01: Prevention of obesity through the life course

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.

[1] The Director-General responsible for the call may decide to open the call up to one month prior to or after the envisaged date(s) of opening.
The Director-General responsible may delay the deadline(s) by up to two months.
All deadlines are at 17.00.00 Brussels local time.
The budget amounts are subject to the availability of the appropriations provided for in the general budget of the Union for years 2021 and 2022.

Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2021**

Action type: RIA

The proposals under this topic should aim to address several of the following expected outcomes:

- Improved knowledge of basic biological pathways (genetic and epigenetic blueprints) conferring susceptibility to and protecting against overweight/obesity.
- Development, adoption and impact of implementation of evidence-based clinical guidelines, best practices, strategies, policy recommendations and/or new policies to prevent overweight/obesity and their comorbidities throughout the life course.
- Piloting prevention campaigns to tackle overweight/obesity, including improving integration of health care education and raising awareness for health care providers and citizens.
- A robust outcomes framework and tool-kit for standardised collection of economic and cost data related to the prevention and treatment of overweight/obesity and its comorbidities at population level across European regions and countries.
- Empower the citizens to make evidence based lifestyle choices that will enable them to avoid becoming overweight/obese.
- Coordinated, pan-European, multidisciplinary preventive strategies to fight overweight/obesity.

Scope:

Obesity is one of the most serious public health challenges of the 21st century. Although health has improved in the EU over the last decades, the prevalence of obesity has tripled in many countries of the EU. It is known that once individuals become overweight or obese, they also develop related diseases (diabetes, cardiovascular disease, cancer). Overweight and obesity are largely preventable. In the current pandemic, the issue of overweight/obesity has become even more prominent, highlighting the need for prevention of overweight/obesity.

Increased efforts in research and innovation are critical for developing and testing the impact of tools, initiatives, interventions, strategies, programmes, policies and their implementation to prevent overweight/obesity. The use of best practices, harmonisation guidelines and/or standard operating procedures developed at various levels (from local to national) in the EU and beyond, will be the foundation for new research.

Cultural diversity, urban/rural dichotomy, socio-economic status, age groups, sex and gender differences should be investigated, where relevant. Strong collaborations across sectors and

with other European projects dealing with issues such as agriculture, food, environment, etc. are welcome. Proposals should engage citizens, authorities (for example municipalities and health authorities) and institutions (schools, canteens, hospitals, work places, shopping malls, sports centres), local producers, etc. in the development of their actions to ensure acceptability and deployment.

- The proposals should address several of the following research bottlenecks: A comprehensive understanding of the genetic/molecular/microbiome/neuroinmune predisposing factors determining uncontrolled “weight gain".
- Identification of pre-obesity biomarkers (genetic, laboratory, imaging, etc.) and their association to lifestyle and environmental interventions aiming at obesity prevention and tailored to specific target populations.
- Mapping existing implementation research activities to prevent overweight/obesity, outcomes analyses and identification of best practices.
- Mapping of information from available scientific literature and identification of the relationship between the risk for overweight/obesity and the biology of obesity, lifestyle habits, exposures to co-morbidities and/or all of their combinations.
- Developing recommendations for what constitutes an appropriate healthy diet for different age and health groups.
- Understanding the links between overweight/obesity and sedentary behaviour, quality, quantity and types of food/drinks and, physical activity.
- Designing a creative and engaging programme to reach the optimal balance between diets and physical activity for the prevention of overweight/obesity.
- Analysing stress and work-life balance, mental health (including psychological problems), screen-time dependency, drugs and side effect of drugs, on overweight/obesity.
- Addressing inequality aspects of overweight/obesity at multiple levels, taking into account vulnerable groups, gender and socio-economic factors.
- Setting up pilots to assess the cost-effectiveness analysis of obesity management strategies and the impact of inactions, taking into account co-morbidities and value based care system.
- Developing a system for monitoring population indicators relevant to overweight/obesity by extending European Core Health Indicators.

Selected projects under this topic are strongly encouraged to participate in joint activities as appropriate. These joint activities could take the form of clustering of projects, participation in workshops etc. The proposals will also be expected to demonstrate support to common coordination and dissemination activities. Applicants should plan the necessary budget to cover those activities without the prerequisite to define concrete common actions at this stage. The

details of these coordination activities will be defined during the grant preparation phase with the Commission.

HORIZON-HLTH-STAYHLTH-2021-01-02: Towards a molecular and neurological understanding of mental health and mental illness for the benefit of citizens and patients

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2021**

Action type: RIA

- Significant advancements regarding the molecular and neurological understanding of how genetic, epigenetic and environmental risk factors (including psychosocial experiences, diet, infections and other exposures) interact to drive the transition from mental health to mental illness[2] throughout the life course.
- Identification and/or validation of different types of combination (bio) markers for at least one of the following purposes:
    - development of quantitative, clinical measures of mental and brain health
    - identification of signatures conferring susceptibility to and protection against mental illnesses
    - establishment of more objective diagnostic and monitoring criteria (complementing current symptom-based criteria) to improve patient outcomes and reduce the stigma associated with mental illness

[2] This may include acute, chronic and relapsing-remitting mental disorders and consortia are encouraged to also study the molecular/neurological changes brought about by interventions and associated with remission

  - prediction of treatment response for better and more scientifically-guided use of currently available interventions for different population groups.

- New disease pathways and drug targets to boost the development of new or repurposed classes of safer and more effective medications[3] for the prevention and treatment of mental illnesses (including relapse prevention), thus stimulating innovations within the European pharmaceutical industry.

- Establishment of the molecular and neurological effects of non-pharmacological strategies[4] for improving mental health outcomes.

- Development and adoption of international clinical guidelines, best practices and policy recommendations for person-centred and timely prevention of mental illnesses as well as enhanced trust, engagement and adherence to effective, evidence-based strategies for mental health promotion.

Scope:

Mental illnesses represent a huge and growing burden for Europe, both at individual and societal level. There is an enormous stigma and they often remain undetected as diagnoses largely depend on symptom-based criteria without any biological markers linked to causative mechanisms. A deeper molecular and neurological understanding of the interplay between genetic, epigenetic and environmental risk factors[5] is critical for the development of objective biomarkers and evidence-based interventions that will significantly improve mental health outcomes.

Accordingly, the proposed research is expected to address the following:

- **Take stock** of advances in for example neuroendocrinology, immunopsychiatry, stem cell biology, optogenetics, nanomedicine, -omics (genomics, epigenomics, transcriptomics, proteomics, metabolomics, lipidomics, microbiomics[6], exposomics), electrophysiological monitoring, neuroimaging and e-health and m-health tools for the identification and/or validation of different types of biomarkers for mental health and mental illness.

- **Analyse** complex and heterogeneous big data via computational modelling and artificial intelligence tools to come up with a systems-level multiscale understanding of how genetic, epigenetic and environmental risk factors interact to drive the transition from mental health to mental illness as well as how such molecular and neurological changes could be reversed.

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3 Going beyond monoaminergic neurotransmitter systems by targeting novel pathways and addressing also the challenge of getting drugs pass through the blood-brain barrier

4 Including but not limited to: neurostimulation, neurofeedback, psychotherapy, diet, exercise, lifestyle, mindfulness or a combination of them.

5 This may also include a bridging of scales from molecules to neural circuits for a better mechanistic understanding of molecular and neural circuit alterations in mental illnesses

6 For example, the role of the microbiota-gut-brain axis in mental health and mental illness

- **Provide new approaches** for timely [7] and effective pharmaceutical and non-pharmaceutical interventions and conduct person-centred clinical studies. These may also include longitudinal and cross-sectional studies, making use of data from biobanks and health registries to assess the effects of different intervention strategies.

Proposals may cover different stages in the continuum of the innovation cycle (from basic and translational research to the validation of findings in real-world settings) and ensure strong involvement of end-users. Sex and gender differences as well as age should be duly taken into account. International cooperation is encouraged and the proposed research is expected to be multidisciplinary including both medical sciences and social sciences and humanities.

HORIZON-HLTH-STAYHLTH-2021-01-03: Supporting digital empowerment and health literacy - Placeholder

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2021**

Action type: CSA

HORIZON-HLTH-STAYHLTH-2021-01-04: A roadmap for personalised prevention

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.

[7] Determining also windows of opportunity for when preventive actions are most effective

Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2021**

Action type: CSA

The proposal should include a strategy for measurement of the progress towards the following expected outcomes:

• Exploitation of a Strategic Research and Innovation Agenda by the research community, research funders and policy makers.

• Coordinated, harmonised and comprehensive approach to personalised prevention research across Europe.

• Awareness and adoption of personalised prevention strategies by healthcare systems

• Evidence based policy decisions for insurers and authorities implementing personalised prevention strategies

Scope:

The progress in medicine over the past decades has been impressive. Nevertheless, many promising advancements have not yet been taken up in the healthcare practice. Thanks to personalised approaches and the development of targeted interventions, several medical conditions which until recently were very serious or even fatal, can now be cured, attenuated or turned to a chronic condition. However, more could be achieved if we could identify early on individuals at higher risk of developing a particular condition, before symptoms occur. As an indicator, two thirds of chronic diseases are thought to be preventable.

Personalised prevention therefore holds many promises and would allow for a paradigm shift in the provision and management of healthcare if efforts are co-ordinated and concentrated at the European and global levels. A number of successful individual preventive approaches are already deployed, for example in the field of cancer. However, more insight is needed on the underlying human biology taking stock of the rich data accumulated from the biomedical sciences. Most importantly, better co-ordination is essential to foster and accelerate the development and adoption of personalised prevention strategies for the years to come. It will also be important to assess the value of increased healthy life years as well as the value of prevention in terms of savings in the healthcare system.

Accordingly, the proposals should cover the following activities:

• Literature mapping and research gap analysis, including of existing preventative research programmes in Europe and beyond.

• A Strategic Research and Innovation Agenda on personalised prevention throughout the life course to inform the candidate Partnership on Personalised Medicine and the funders (at all levels).

• Identification of key stakeholders for personalised prevention.

• Analysis of how personalised prevention can be most effectively and efficiently delivered, as well as cost effective.

• Identification of the existing bottlenecks and analysis of evidence and examples of successful implementation of personalised prevention approaches for transferability.

• Robust communication strategy to maximise the impacts of the findings and the uptake of personalised prevention strategies

The CSA should engage with related initiatives (e.g. IC Permed) and provide input for the candidate EU partnership on personalised medicine.

Call - Staying healthy (Two stage - 2022)

HORIZON-HLTH-STAYHLTH-2022-01-two-stage

Conditions for the Call

Indicative budget(s)[8]

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million)	Number of projects expected to be funded
Overall indicative budget				

Proposals are invited against the following topic(s):

[8] The Director-General responsible for the call may decide to open the call up to one month prior to or after the envisaged date(s) of opening.
The Director-General responsible may delay the deadline(s) by up to two months.
All deadlines are at 17.00.00 Brussels local time.
The budget amounts are subject to the availability of the appropriations provided for in the general budget of the Union for years 2021 and 2022.

HORIZON-HLTH-STAYHLTH-2022-01-two-stage-01: Boosting mental Health in Europe in times of change

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2022**

Action type: RIA

- New and/or improved knowledge leading to the development and adoption of clinical guidelines, best practices and policy recommendations to mitigate the mental health burden and help cope with the (combined) effects of a transforming Europe (e.g. the socio-economic consequences of the Covid-19 pandemic, climate change, energy transition, demographic and migration factors and exponential technological advancements).
- Anticipation of new and emerging risks to mental health associated with this transformation.
- Improved (cost-) effectiveness and uptake of large-scale comprehensive strategies for promotion and prevention in mental health, targeting key settings and the most vulnerable populations.
- Individuals are empowered to make informed decisions about their mental health care (including self-management and self-care) as well as to find appropriate support that is targeted to their needs and available. Stigma is reduced.

Scope:

Against the backdrop of a transforming Europe and in the midst of a global pandemic, the EU is committed to lead the transition to a healthier planet and a new digital world. The health and wellbeing of its individuals is a prerequisite to achieve this aspiration.

On the one hand, extreme weather and environmental disasters have risen dramatically over the last decade. Links between these events and serious mental health problems, including anxiety, depression, post-traumatic disorder and suicide, have been reported. Moreover, several new words such as "eco-anxiety", "ecoparalysis" and "ecological grief" have been coined to express the acute and/or chronic effects on mental health caused by climate and environment change.

On the other hand, digital technologies and the achievement of the Digital Single Market – one of Europe's key priorities – are transforming our economy, our industries as well as our culture and lifestyle. Digitalisation, including ICT-enabled technologies such as robotics and artificial intelligence, are penetrating much faster into societies than in the past and affect us all. Accordingly, the "Fourth Industrial Revolution"' is changing workplaces, working practices, the workforce and how we perceive work as well as the way we live. However, the exponential incorporation of technology in our daily lives has caused profound changes in the way we communicate and is likely to have significant impact (both positive and negative) on mental health and intellectual/cognitive ability, in particular of the youth. Digital platforms can provide mental health support as well as increase social inclusiveness. However, digital technologies also introduce new risks, for example, continuous connectivity, cyberbullying and exposure to inappropriate or fake content.

Accordingly, the proposed research should aim to achieve:

- A comprehensive knowledge base of how Europe's transformations can influence mental health in a fast-evolving society, especially in the most vulnerable populations, by consolidating data from relevant sources and/or acquiring new one.

- Develop and implement (pilot and/or scale-up) interventions, which promote wellbeing and prevent mental illness to help cope with and mitigate the stress of a changing society, including digital life, climate change and/or other factors highlighted in the "Expected outcomes". The interventions should target relevant settings (e.g. workplaces, schools) and the most vulnerable populations (e.g. children and adolescents, the elderly, people with pre-existing conditions and comorbidities and other high-risk groups such as socio-economic disadvantaged groups, migrants, etc.). Integration of care and coordination among different settings from community to healthcare is desirable. The interventions should be assessed in terms of health outcomes, (comparative) cost-effectiveness, implementation facilitators and barriers. Depending on the aspects covered by the proposed research, desired outputs may include, but are not limited to:

    - Evidence based guidelines for healthcare professionals on the promotion of mental wellbeing and prevention of mental illness related to ICT and climate and environment change (including screening methods).

    - Evidenced based pedagogical practices for education professionals to foster mental health promotion in a schools and/or via eLearning.

    - Consultation during school time to educate students (e.g. on coping with change) and to detect students at risk early.

- Educational material and campaigns targeting the most vulnerable groups.
- Studies on mental occupational health in the workplace, in particular in small and medium-sized enterprises, e.g.: i) understanding the impact of 24-hour digital economy on workers' well-being, also in terms of managerial control mechanisms, work-life balance and privacy and developing/piloting new methods to protect and support workers' well-being in this respect; ii) designing information and training campaigns for workers to integrate the already visible impacts of digitalisation-induced changes into the professional risk assessment processes; iii) developing return-to-work programmes, also exploring innovative collaboration between mental health services, (life-long) education, and employment sectors. This will ensure appropriate support to better integrate individuals affected by mental ill health in the workforce and the society.

- Inform policy makers and regulators on i) the prevalence and burden of mental ill health related to a transforming society (e.g. digital technologies, climate change, etc); ii) the effects of digitalisation, climate change and transition to "green jobs" on occupational mental health; iii) the (comparative) cost-effectiveness of public mental health policies.

Research should be multidisciplinary, including medical, social sciences and humanities. It is important to consider aspects such as (associated) behavioural patterns, stigma and novel social dynamics as well as different socioeconomic, cultural and geographical contexts. Sex and gender-related issues must be taken into account. All data should be disaggregated by sex, age and other relevant variables. International collaboration is encouraged.

Proposals should strongly consider involving end-users (including civil society organisations) and/or strategic partners by design and during the course of the project. Possible end-users and strategic partners could include local or regional authorities, community services, employers, schools, insurance companies, civil society organisations, among others.

HORIZON-HLTH-STAYHLTH-2022-01-two-stage-02: The Silver Deal: "A comprehensive engagement on the challenges of the ageing population"

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.

Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2022**

Action type: RIA

Project results are expected to contribute to most of the following outcomes:

1. To deliver a comprehensive engagement in different areas and across sectors for advanced solutions and new opportunities addressing in general the changing population and in particular the needs and demands of older people to live healthier, longer active and independent lives. This action should have the potential to coordinate existing initiatives and ongoing efforts, to reshape existing patterns into innovative approaches, to facilitate mutual learning and to develop a joint agenda on risks and opportunities for our changing society.

2. To anticipate, manage and reduce implications of demographic changes on health care systems, long term care, public spending and the world of work. To promote work-life-balance/fit, wellbeing, quality of life and staying healthy for the silver generation for which it is more challenging to adapt or to learn novel healthier behaviours or active lifestyles. To promote musculoskeletal health through targeted evidence-based programmes focusing on physical activity and individual participation. To facilitate also retirement transitions or final work-life phases during which the silver generation is particularly vulnerable and could benefit from health promotion interventions, including nutrition.

3. To combat anxiety and mental disorders related to novel and rapid societal changes. This includes the identification and validation of emotional and cognitive parameters, sex and gender interconnections, educational programmes from young age, strengthening people's autonomy and enhancing health literacy.

4. To combat loneliness, social isolation and poverty in the silver generation. To include the elderly population as full active participants of society, which means to go further than protecting the elderly from dying, and to break the solidified situation that the elderly is prevented from living. This supports modern, active and healthy ageing as well as the dignity and self-confidence of the silver generation in their homes and in the changing society in general.

5. To enable solutions for the silver generation that struggles with innovation such as the modern internet information flood and application. To reduce the risk of the current rapid digitalisation in health care that could build out the people who are most in need. To enhance the cognitive accessibility and ability to deal with complex systems, novel information and unfamiliar technologies. To find opportunities for the silver generation that does not want to consume innovative products on a daily basis (such as clothes, devices, apps, highly processed novel foods, plastic cups for coffee to go, etc.).

6. To deliver effective and preventive health services to tackle multi-morbidities, frailty, biologically reduced capacities, impairments, dementia and/or neurodegeneration. This should include medical research, novel tech-based solutions, assistive devices, the validation of early markers for lifetime developments, the facilitation of the elderly's self-assessment and the monitoring of functional, cognitive and physical capacities during ageing.

7. To assist cities and rural environments providing the right infrastructure for the changing society, in particular the silver generation to be engaged and physically active, including age-friendly environments, increased community engagements and healthy lifestyle behaviour changes.

8. To ensure equitable access to novel, cost-effective, integrated and people centred high-quality health care including prevention measures, diagnostic screenings, interventions and therapies.

9. To bridge the inter-generational gap in the changing society, to manage conflicts and tensions between generations and to protect against other structural, personal or cultural violence. To identify and deal with ethical dilemmas associated with increased lifespan.

11. Ensure integration of age-friendly, smart innovative solutions, such as connected wearables, ambient sensors, social robots, assistive technologies, diagnostic screenings, self-monitoring devices, robotics into the daily life of ageing population, by engaging all relevant stakeholders, public authorities, health care providers, citizens.

Scope:

* Deliver affordable, advanced solutions and assistive technologies for the variety of problems and challenges of demographic changes, in particular for the silver generation but also with a view on inter-generational issues. The ageing of the population together with the accelerating impact of digitalisation, the increasing mental and chronic disorders, the potential nutrition and food supplements and difficult work-life-balance require specific advanced knowledge and solutions to keep an active and healthy lifestyle.

* Build enhanced understanding and knowledge by analysing impact, complexity and severity of disorders of the silver generation in connection with specific lifestyles, active societal participation, changing societies and social issues.

* Provide new approaches for effective health services around people's needs for health and social care, strengthened disease prevention, rehabilitation and high-quality health care and for staying active and healthy. In future, more efforts are needed concerning prevention and person-centred approaches. The fragmentation of services should be addressed to get integrated, holistic and coordinated interventions along the continuum of care without any single-disease focus. This includes the promotion of active, healthy and sustainable lifestyle behaviours for the most often linked mental and physical functions.

* Coordinate existing initiatives and ongoing efforts with the intention to facilitate mutual learning, to reduce the patchiness, to change ineffective patterns and to develop a more

comprehensive, common policy approach for the benefit of our ageing society. Proposals should avoid networking without output and provide appropriate indicators to measure its progress and impact.

HORIZON-HLTH-STAYHLTH-2022-01-two-stage-03: Personalised blue print of chronic inflammation in Health-to-disease transition

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2022**

Action type: RIA

The proposed research should aim to achieve an optimal combination of several of the following targeted outcomes:

- Understanding of the individual's abnormal chronic inflammatory events triggering the health-to-disease transition in chronic diseases, taking into account the person's genotype, phenotype, life-style and/or life stressors
- Delivery of objective personalised indicators for the health-to-disease transition linked to chronic systemic inflammation, in order to guide better prevention strategies for chronic diseases
- Evidence-based discovery of (pre)-disease multimodal biomarkers underlying chronic systemic inflammation, as predictors of health and disease risk for better health outcomes
- Actionable recommendations for personalised interventions to tackle chronic inflammation and maintain the healthy state, improve people's health and reduce the risk for chronic diseases

Scope:

Personalised approaches for disease prevention seek to determine the predisposition to disease and deliver timely and targeted prevention. Understanding the risk factors that trigger the health-to-disease transition is essential for delivering personalized preventive measures to reduce the chronic diseases burden.

A large body of clinical evidence has accumulated over the past decade demonstrating that chronic systemic inflammation is a process implicated in chronic diseases/disorders (i.e. autoimmune, metabolic, mental, neurodegenerative, chronic inflammatory diseases etc.). Inflammation is a physiological process helping the body to heal against harmful entities, such as infections, injuries, and toxins. When the inflammatory response is dysregulated it can lead to an unresolved chronic, local or systemic inflammation which in combination with the person's genotype, phenotype, life-style and/or life stressors is likely to be involved in driving the health-to-disease transition, leading to the onset of chronic diseases.

The topic will support proposals of multidisciplinary nature involving all relevant stakeholders and may cover different stages in the continuum of the innovation path (from translational research to validation of the findings in human studies etc.), as relevant.

The projects should develop and implement data-driven, personalised approaches to elucidate the chronic inflammation drivers that may determine the transition from health to pre-symptomatic and early stages of chronic diseases/disorders. The human studies and human data utilised/generated should be compatible to an age range as representative as possible to the (pre)-disease onset of the diseases to be studied, in order to boost the fast translation of the research results into proof-of-concept studies.

The topic will support proposals that aim at developing of personalised diagnosis and/or prevention strategies linked to chronic systemic inflammation and assess different types of interventions or their combinations i.e. pharmacological, non-pharmacological, nutritional supplements, diet and life-style modifications, as relevant. Sex and gender differences should be investigated, wherever relevant.

The proposals should address several of the following research bottlenecks:

- Integrate the state-of-the-art knowledge and the data from relevant retrospective human studies, including medical/clinical and life-style data linking chronic systemic inflammation to the health-to-disease transition

- Leverage the advances in multi-omics (i.e. genomics, metabolomics, nutrigenomics, microbiomics etc.) and the power of data-driven analytical tools to assess chronic systemic inflammation during health-to-disease transition

- Understand at the systems-level of the human biology and physiology underlying chronic inflammation in connection to the tissues/organ dysregulation, organ cross-talk and homeostasis breakdown triggering the health-to-disease transition, taking into account the person's genotype, phenotype, life-style and/or life stressors

- Leverage the power of proven robust sensor, minimally-invasive devices and/or mobile apps technologies for the personalised and dynamic monitoring of the health status and the transition to chronic diseases

- Pilot proof-of-concept human studies to assess the beneficial effect of diverse prevention and/or interventions strategies aiming to improve health outcomes and to reduce and/or revert the (pre)-disease state linked to chronic systemic inflammation.

The proposal(s) should adhere to the FAIR principles and adopt wherever relevant, data standards and data sharing/access good practices developed by existing European health research infrastructures.

*The Commission will ensure an overall coordination mechanism in between the projects funded under this topic to catalyse the exchange of knowledge, as well as the development and adoption of best practices. Successful proposals will also be encouraged to exchange with other relevant proposals funded under other topics to ensure the synergies in cross-cutting subjects of common interest.

HORIZON-HLTH-STAYHLTH-2022-01-two-stage-04: AI tools to predict the risk for chronic diseases and/or their progression

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2022**

Action type: RIA

The proposed research should aim to achieve the following expected outcomes:

- Validated disease risk algorithms taking into account the personal characteristics/situation/history and empower citizens to manage their health

- Robust, trustworthy and privacy-preserving AI tools to predict and assess the risk for and/or progression of chronic non-communicable diseases and deliver improved health outcomes for the citizens

- Evidence-base recommendations for the development of AI-based personalised prevention strategies for chronic diseases, superior to the standard-of-care

- Quantitative indicators for the identification and follow-up of individuals with high risk for the development and/or risk for progression of chronic diseases

Scope:

It is widely recognised that health systems must put more emphasis on prevention and adopt a person-centred approach. Artificial intelligence along with the increased availability of health data hold great potential to enable progress towards personalised prevention strategies by utilising AI tools either on their own and/or in combination with other relevant state-of–the-art technologies to enable risk prediction and early detection of chronic diseases.

The topic will support multidisciplinary research and build on broad stakeholder engagement and support projects developing novel robust AI tools to enable timely personalised prevention approaches for chronic diseases/disorders.

The projects should aim at developing and testing AI tools to predict and assess the risk for developing a disease and/or the risk of disease progression once it is diagnosed, taking into account the individuals' (or groups) genotypes, phenotypes, including life-style, life-stressors and behavioural characteristics. Sex and gender aspects should be considered, wherever relevant.

The AI tools may include a broad range of technological solutions on their own and/or in combination with other relevant state-of-the-art technologies (i.e. AI algorithms, mobile apps and sensors, robotics, e-health tools, telemedicine etc.)

The projects should implement proof-of-concept studies to test and validate the performance of their AI tools in the real-world setting and compare their performance to the established practices..

The applicants should ensure that the AI tools developed are driven by relevant end-users/citizens/healthcare professional needs. Therefore, the proposals are expected to introduce concrete measures for the involvement of the end-users throughout the AI development process and not only in the last phases. SME(s) participation is encouraged with the aim to strengthen the scientific and technological basis of SME(s) and valorise their innovations for the people's benefit.

The proposals should address the following research bottlenecks currently encountered in the field:

- Leverage of existing high-quality health-relevant data from multiple sources (i.e. cohorts, electronic health records and registries, taking into account the individuals'

genotypic/phenotypic, medical, life-style, behavioural data etc.) and/or generation of new high-quality health data necessary for the rigorous development of the AI disease-risk tools

- Develop the adequate performance metrics to assess the technical robustness of the developed AI disease-risk tools and in particular their accuracy, reliability, reproducibility and generalisability. The projects should assess the possible inherent bias introduced to the AI tools originating from the data quality used for their development
- Develop the criteria to assess the effectiveness of the AI disease-risk tools in terms of improving health outcomes to enable personalised prevention strategies.
- Implement proof of concept and/or feasibility studies to validate the AI tools in a relevant end-users environment and/or real-world setting and assess their performance in comparison to the standard-of-care

The proposals are expected to establish standard operating procedures to ensure that the health data are curated and are FAIR according to established international standards and to ensure the highest data quality as an input to the AI tools. Special attention should be given to the harmonisation of data collection and standardisation of protocols, as well as to the adoption of common formats and standards.

Integration of ethics and health humanities perspectives to ensure an ethical approach to the development of AI solutions. In relation to the use and interpretation of data, caution should to be paid to systematically control for gender and ethnic bias and/or discrimination when developing and using data the AI tools.

The proposals aiming to develop AI solutions of high technology readiness level are encouraged to deliver a plan for the regulatory acceptability of their technologies. The early interaction with the relevant regulatory bodies is recommended.

* The Commission will ensure an overall coordination mechanism between the projects funded under this topic to catalyse the exchange of knowledge, as well as the development and adoption of best practices. Successful proposals will be also encouraged to exchange with other relevant proposals funded under other topics to ensure synergies in cross-cutting subjects of common interest.

Call - Staying healthy (Single stage, 2022)

HORIZON-HLTH-STAYHLTH-2022-02

Conditions for the Call

Indicative budget(s)[9]

[9] The Director-General responsible for the call may decide to open the call up to one month prior to or after the envisaged date(s) of opening.
The Director-General responsible may delay the deadline(s) by up to two months.

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million)	Number of projects expected to be funded
Overall indicative budget				

Proposals are invited against the following topic(s):

HORIZON-HLTH-STAYHLTH-2022-02-01: Population cohorts for health research (international cooperation dimension)

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2022**

Action type: CSA

Call - Partnerships in Health (2022)

HORIZON-HLTH-STAYHLTH-2022-03

All deadlines are at 17.00.00 Brussels local time.
The budget amounts are subject to the availability of the appropriations provided for in the general budget of the Union for years 2021 and 2022.

Conditions for the Call

Indicative budget(s)[10]

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million)	Number of projects expected to be funded
Overall indicative budget				

Proposals are invited against the following topic(s):

HORIZON-HLTH-STAYHLTH-2022-03-01: European Partnership Fostering an ERA for Health research - Placeholder

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2022**

Action type: Co-Funded Partnership

[10] The Director-General responsible for the call may decide to open the call up to one month prior to or after the envisaged date(s) of opening.
The Director-General responsible may delay the deadline(s) by up to two months.
All deadlines are at 17.00.00 Brussels local time.
The budget amounts are subject to the availability of the appropriations provided for in the general budget of the Union for years 2021 and 2022.

Destination 2. Living & working in a health-promoting environment

The environment we live and work in has direct or indirect beneficial or adverse impacts on human health and well-being. It is a major determinant of health and well-being, estimated to account for almost 20% of all deaths in Europe. Opinion surveys have shown that European citizens are concerned about the impact of pollution on their health. The factors causing these impacts on both physical and mental health and well-being are not all identified nor their effects comprehensively understood and accounted for to support evidence-based decision-making. This is true for, e.g. certain types of pollution and the impact of climate change. Furthermore, agreed methodologies to estimate health-related costs of exposure to environmental stressors are lacking. Therefore, the workprogramme aims at filling knowledge gaps in the understanding of the environmental, occupational and socio-economic risk factors for health and well-being and improving economic assessments. These risk factors include, among others, indoor and outdoor air pollution, chemicals, non-ionizing radiation, urbanisation, climate and other environmental changes, socio-economic inequalities, and changing working environments. The results will support the EU's environment and health policies and overarching policy frameworks such as the European Green Deal, the future 8th Environment Action Programme, the EU Strategic Framework on Health and Safety at Work as well as the European Environment and Health Process (EHP). Strong collaborations across sectors and with other Horizon Europe clusters dealing with issues such as agriculture, food, environment, climate, mobility, security, urban planning, social inclusion and gender will be needed to ensure that maximal societal benefits are reached.

This Destination will address mainly two Key Strategic Orientations: (i) 'Restoring Europe's ecosystems and biodiversity, and managing sustainably natural resources' by improving the understanding of pollution on health and thereby contributing to clean and healthy air, water and soil; and (ii) 'Making Europe the first digitally led circular, climate-neutral and sustainable economy' through research on health impacts of climate change and pollution, thereby impacting climate change mitigation and adaptation policies and contributing to smart and sustainable transport.

Expected impacts:

Proposals for topics under this Destination should set out a credible pathway to contributing to the following expected impacts:

- Living and working environments are health-promoting, sustainable and equitable thanks to better understanding of environmental, occupational, social, structural and economic determinants of good health and well-being;

- Knowledge base necessary to identify and assess the risks and benefits for health of living and working environments in order to enable the design of health-promoting and disease preventive policy actions and dissemination of best practices in line with EU commitments and citizens' demands;

- Solid scientific evidence and uptake of research results into relevant environmental, occupational, social, economic, fiscal and health policies at the EU, national and regional level, including overarching policy frameworks such as the European Green Deal, the future 8th Environment Action Programme, the EU Strategic Framework on Health and Safety at Work and the European Environment and Health Process led by the World Health Organization;
- New and improved health interventions, technologies, tools and services for care and health;
- Strong collaborations across sectors and with other Horizon Europe clusters dealing with issues such as agriculture, food, environment, climate, mobility, security, urban planning, social inclusion and gender ensuring that maximal societal benefits will be reached;
- Improved international cooperation, including at science-policy level, to address global environment and health challenges

The following calls in this Work Programme contribute to this Destination:

Call	Budgets (EUR million)Deadline(s)
HORIZON-HLTH-ENVHLTH-2021-02 Environment and health (2021)	
HORIZON-HLTH-ENVHLTH-2021-03 Partnerships in Health (2021)	
HORIZON-HLTH-ENVHLTH-2022-04 Environment and health (Single Stage - 2022)	
HORIZON-HLTH-ENVHLTH-2022-05-two-stage Environment and health (Two Stage - 2022)	
Estimated total budget	

Call - Environment and health (2021)

HORIZON-HLTH-ENVHLTH-2021-02

Conditions for the Call

Indicative budget(s)[11]

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million)	Number of projects expected to be funded
Overall indicative budget				

Proposals are invited against the following topic(s):

HORIZON-HLTH-ENVHLTH-2021-02-01: Health risks related to exposure to electromagnetic fields (EMF)

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

[11] The Director-General responsible for the call may decide to open the call up to one month prior to or after the envisaged date(s) of opening.
The Director-General responsible may delay the deadline(s) by up to two months.
All deadlines are at 17.00.00 Brussels local time.
The budget amounts are subject to the availability of the appropriations provided for in the general budget of the Union for years 2021 and 2022.

Expected Outcome: **Year of the topic: 2021**

Action type: RIA

- Increased number of high-quality studies on exposure to EMF, in particular relevant to new generation radiocommunication networks (e.g. 5G networks), providing information on their occurrence including in occupational settings;

- FAIR[12] data on causal associations between level and duration of exposures and health effects in living and working environment, considering also vulnerable groups, particularly children, for risk assessments, risk management and risk communication by competent public health authorities;

- Quality criteria and standards (CEN/ISO[13]) for the analytical methodologies to be developed for the assessment of EMF, including 5G, exposure and impact on human health and the environment;

- Guidance and case studies for exposure prevention and reduction measures of exposures of general public, including occupational settings, where relevant, by technological and non-technological means;

- Supporting evidence for the implementation of the Council Recommendation 1999/519/EC on the limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz) as well as Directive 213/35/EU on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields), in particular the implementation of article 1.4 of the Directive;

- New communication channels to address citizens' concerns and inform about risk-preventing behaviours

Scope:

Digital technologies and electronic communication services are a critical enabler for attaining the sustainability goals of the European Green Deal in many different sectors. The use of new generation radiocommunication networks, e.g. 5G, the fifth generation of mobile phone technology promise higher data transfer rates and increased network capacity compared with previous generations. While digitalisation presents new opportunities, e.g. distance monitoring of air and water pollution and health outcomes, it also presents potential risks. Europe needs a digital sector that puts sustainability at its heart: when deploying new technologies, the potential risks related to human health should also be assessed, in addition to the significant benefits.

There has been an exponential increase in the use of wireless personal communication devices (mobile phones, WiFi or Bluetooth-enabled devices etc.) by almost all citizens and in the supporting infrastructures. The number of other applications using EMF have also increased

[12] FAIR data are data, which meet principles of findability, accessibility, interoperability, and reusability.
[13] https://www.cencenelec.eu/news/brief_news/Pages/TN-2017-057.aspx

such as security scanners, smart meters and medical equipment. This has resulted in an increase in manmade electromagnetic radiation in our surroundings.

The International Commission on Non-Ionizing Radiation Protection (ICNIRP) issues guidelines for limiting exposure to electric, magnetic and electromagnetic fields. EU member states are subject to Council Recommendation 1999/519/EC and the Directive 2013/35-EU, which follows basic rules on EMF exposure evaluation provided by ICNIRP guidelines. Nevertheless, there is some concern over the possible impact on health and safety from potentially higher exposure to EMF, e.g. arising from the deployment of 5G technology. Increased exposure may result from, for instance, the additional use of higher frequencies, and from the potential aggregation of different signals, especially in cities.

Research activities under this topic shall provide forward-looking information on potential hazards and risks of EMF exposures through innovative monitoring techniques, experimental evidence and modelling. Exposures of the general population and specific groups at risk such as children and workers should be monitored using innovative technologies and compared to exposure patterns, e.g. generated by the use of previous generations of mobile phone technologies. It should be shown how exposures to EMF changes over time due to the introduction of new technologies, supporting infrastructure, radiofrequency bands and applications. Evidence of local and systemic biological effects and health impacts across the lifecycle should be produced using *in vitro* and *in vivo* approaches, respecting the 3Rs[14] principle, and taking into account combined exposures and changing patterns of device use. Case studies on solutions for exposure reduction based on acquired evidence should, be undertaken. Furthermore, efficient communication methods and tools for engaging citizens in preventive actions and addressing their concerns should be proposed and tested.

Gender aspects should be considered, where appropriate.

HORIZON-HLTH-ENVHLTH-2021-02-02: Indoor air quality and health

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.

[14] Replacement, reduction and refinement

Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2021**

Action type: RIA

- Identification and FAIR[15] monitoring data of air pollutants, including both chemical and microbiological (including viral) determinants, and their main sources for relevant and representative indoor environments and settings in Europe;
- Digital solutions to monitor indoor air quality;
- An accessible evidence base of risk factors associated to human health impacts related to the main indoor air determinants;
- Proposals for indoor air quality standards for the main determinants identified to support regulatory measures and improve regulatory monitoring;
- Innovative cost-effective, environment-friendly technologies to improve indoor air quality and reduce disease burden, including guidelines for interventions and actions to improve indoor air quality supporting health promotion and disease prevention in various sectors, e.g. construction and transport, and in various socio-economic settings;
- Science-based evidence to support the Zero-Pollution Action Plan of the European Green Deal.

Scope:

Air quality is primarily monitored in outdoor locations, often for regulatory targets compliance purposes. However, people spend the majority of their lives in indoor environments: at home, in the workplace, in schools, inside vehicles and other modes of transport etc. Whereas improving outdoor air quality leads to general improvements of indoor air quality as well, certain sources of air pollution not covered by ambient air quality standards can dominate in some indoor environments. In the current pandemic situation, the issue of good indoor air quality has become even more prominent, encompassing issues such as the need of good ventilation of indoor spaces.

In addition to identifying determinants for indoor air quality, it is important to assess their health impacts in the levels reached indoors to facilitate setting of purposeful indoor air quality standards. The mere presence of a determinant may not mean harmful health effects and some (biological) determinants may even have beneficial health effects.

Applicants should propose activities that advance the understanding of the indoor air quality and related health and safety issues in one or several of the following areas:

[15] FAIR data are data, which meet principles of findability, accessibility, interoperability, and reusability

- Identification and characterisation of sources and dispersion of chemical and biological indoor air pollution [16], e.g. indoor air microbiome and allergens, viral pathogens, household chemicals, biocides in building materials, particulate matter, radon as well as emerging pollutants;

- Development and application of technologies enabling cost-effective monitoring of indoor air quality (e.g. air quality sensors) and user-friendly alert systems;

- Development and application of effect-based test systems for the detection of synergistic effects of different biogenic particles and substances as well as additional chemical substances such as volatile organic compounds;

- Investigation of differences and modes of interaction between indoor and outdoor air quality at relevant and representative locations;

- Investigation of body burdens resulting from multipollutant (real life scenario) exposures and pathways indoors and associated health effects, with specific focus on vulnerable population groups and sensitive life stages and dose-response studies facilitating the setting of purposeful quality standards;

- Development of guidelines for interventions in specific settings and cost-effective technologies to improve indoor air quality.

Gender aspects should be considered, where appropriate.

HORIZON-HLTH-ENVHLTH-2021-02-03: Health impacts of climate change, costs and benefits of action and non-action

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.

[16] All chemical exposure data resulting from the selected projects shall be shared via IPCHEM (https://ipchem.jrc.ec.europa.eu/RDSIdiscovery/ipchem/index.html).

Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2021**

Action type: RIA

- FAIR[17] data on (positive and negative) health impacts of climate change, including on impact on groups with higher risk of vulnerabilities such as older persons;
- Predictive and early warning systems for direct and indirect health impacts caused by climate-change induced events, e.g. changes in biodiversity, disruption and shift of ecosystems, fragmentation and destruction of habitats, spread and transmission of vector-borne and other infectious diseases as a result of global warming and flooding, emergence of new pathogens, heat waves, changes in UV exposure;
- User-friendly tools for integrated risk assessments and cost-benefit assessments of climate change mitigation and adaptation actions to support decisions across policy sectors;
- Guidelines for adaptation and innovation of health systems and public health and occupational health practices to minimise climate-change related health risks in cost-efficient and effective ways;
- Predictive modelling for health impacts of climate change;
- Scientific evidence to support EU and global climate policies and actions as well as the Zero-Pollution Action Plan;
- Support for EU Observatory for Climate and Health.[18]

Scope:

The European Green Deal refocused the European Commission's commitment of tackling climate and environmental-related challenges. It also aims to protect, conserve and enhance the EU's natural capital, and protect the health and well-being of citizens from environment-related risks and impacts. In addition to aiming for climate neutrality by 2050, the Commission will adopt a more ambitious EU strategy on adaptation to climate change. This is essential, as climate change will continue to create significant stress in Europe in spite of the mitigation efforts.

The World Health Organization estimates that climate change is expected to cause at least 250 000 additional deaths per year globally between 2030 and 2050[19]. Climate change, together

17 FAIR data are data, which meet principles of findability, accessibility, interoperability, and reusability. Data can include exploitation of information and data from European data infrastructures and programmes such as Copernicus, European Space Agency and the GEO initiative.

18 https://climate-adapt.eea.europa.eu/observatory/evidence/indicators_intro https://climate-adapt.eea.europa.eu/observatory/evidence/indicators_intro

19 https://www.who.int/news-room/fact-sheets/detail/climate-change-and-health

with other natural and human-made health stressors, can influence human health and pattern of disease in numerous ways. Some existing health threats will intensify and new health threats will emerge, with variable impact on various socio-economic groups.

Climate and global changes are disrupting the epidemiology of infectious diseases, causing new threats to human and animal health. Innovative surveillance tools are further required to ensure a timely response to emerging threats, to feed and strengthen early warning systems and to enable monitoring and evaluation of interventions, as well as to predict and propose the best combination thereof. This may include mathematical modelling with Big Data and AI, remote sensing and the use of drones, citizen sciences and the search for biomarkers of exposure or virulence.

Applicants should carry out activities along one or several of the following lines of research:

i. Identification, monitoring and quantification of direct and indirect health impacts and related risk factors correlated to climate change, especially in vulnerable population groups such as children;

ii. Examine the relationships between changes in environmental pollution induced by climate change and subsequent impacts on interrelated ecosystems with influence on human health;

iii. Study the implications of climate change on health systems or working conditions and develop adaptation measures;

iv. Advance Eco-health[20] and One Health[21] approaches for understanding of climate induced health threats, such as transmission of pathogens and spread of zoonotic pathogens;

v. Develop forecast models and early warning systems for health impacts of climate change in Eco-health or One Health context when relevant;

vi. Development of suitable indicators and backward-looking monitoring mechanisms to assess the health-relevant outcomes of climate policies and actions;

vii. Develop tools for health impact and cost-benefit assessment of climate-change adaptation and mitigation measures and apply these in policy relevant case studies;

viii. Investigate health co-benefits of adaptation and mitigation policy measures outside the health sector.

International cooperation is encouraged with the specific target to support international climate policies.

[20] Ecohealth is a field of research, education, and practice that adopts systems approaches to promote the health of people, animals, and ecosystems in the context of social and ecological interactions

[21] The One Health concept recognises that human health is tightly connected to the health of animals and the environment, for example that animal feed, human food, animal and human health, and environmental contamination are closely linked

Gender aspects should be considered, where appropriate.

Call - Partnerships in Health (2021)

HORIZON-HLTH-ENVHLTH-2021-03

Conditions for the Call

Indicative budget(s)[22]

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million)	Number of projects expected to be funded
Overall indicative budget				

Proposals are invited against the following topic(s):

HORIZON-HLTH-ENVHLTH-2021-03-01: European Partnership on Assessment of Risk of Chemicals (PARC) Placeholder

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

[22] The Director-General responsible for the call may decide to open the call up to one month prior to or after the envisaged date(s) of opening.
The Director-General responsible may delay the deadline(s) by up to two months.
All deadlines are at 17.00.00 Brussels local time.
The budget amounts are subject to the availability of the appropriations provided for in the general budget of the Union for years 2021 and 2022.

Expected Outcome: **Year of the topic: 2021**

Action type: Co-Funded Partnership

Call - Environment and health (Single Stage - 2022)

HORIZON-HLTH-ENVHLTH-2022-04

Conditions for the Call

Indicative budget(s)[23]

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million)	Number of projects expected to be funded
Overall indicative budget				

Proposals are invited against the following topic(s):

HORIZON-HLTH-ENVHLTH-2022-04-01: Methods for assessing health-related costs to environmental stressors

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.

[23] The Director-General responsible for the call may decide to open the call up to one month prior to or after the envisaged date(s) of opening.
The Director-General responsible may delay the deadline(s) by up to two months.
All deadlines are at 17.00.00 Brussels local time.
The budget amounts are subject to the availability of the appropriations provided for in the general budget of the Union for years 2021 and 2022.

Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2022**

Action type: RIA

- EU-wide accessible evidence base and methodologies for efficient and transparent public policies and budget allocations;
- Stakeholder consensus on the most relevant population health and quality of life metrics, including DALYs (Disability Adjusted Life Years) or QALYs (Quality Adjusted Life Years)[24];
- Guidelines for harmonised and more integrative methodology for socio-economic assessments in Europe based on experts elicitation and the joint output of selected projects;
- Methods for assessment of imbalance between costs and benefits (Benefits for industry and costs for society) of environmental pollution;
- More regular and consistent use of outputs from economic and health modelling exercises in policy impact assessments and policy evaluation at EU and national levels;
- Information on how national contexts can impact on health-related costs of the same environmental and occupational exposure.

Scope:

Due to paucity of data, lack of standards and differences in methods, policy-makers face challenges when devising pollution mitigation measures and having to assess the health costs emerging from exposures to environmental stressors or the benefits from clean environments. Deaths and disabilities resulting from pollution carry a quantifiable economic cost to society, but there are significant uncertainties in the cost estimates methodologies. There is also paucity of data to evaluate the economic benefits of clean environments.

Impact Pathway Analysis[25] and Health Impact Assessment (HIA)[26] are methodologies, which can be useful in linking scientific knowledge with environmental-economic analysis for informing policy action in diverse sectors such as transport, energy, chemicals, occupational health etc.

[24] While introducing relevant changes, it should be ensured that metrics respect the UN Convention on the Rights of Persons with Disabilities.

[25] http://arirabl.org/untitled/

[26] Health Impact Assessment (HIA) has been defined by WHO European Centre for Health Policy as a combination of procedures or methods by which a policy, programme or project may be judged as to the effects it may have on the health of a population.

The main aim of the research will be to improve the calculation of the socio-economic costs (or benefits) of health impacts associated to environmental stressors, advance methodological approaches and foster acceptance. The following specific activities should be considered:

- Exploitation of latest evidence of exposure-response functions and causation resulting from published medical and scientific research and the accumulated data from the past 10-20 years, including results published based on EU-funded research projects;
- Identification of data gaps as regards environment and health risk factors and health-related tangible and intangible costs and recommendations on priorities for new data collections;
- Advancement of methodological rigor and consistency in accounting for morbidity and mortality, disabilities, linking valuation of statistical life and/or life-years with quality adjustments within a unified framework, adapted to the needs and circumstances in Europe;
- Application of experimental approaches addressing the potential link of quality of life and the burden of disease indicators as well as more integrative impact indicators (e.g. reflecting subjective well-being, health, work-life balance, education, housing, etc.);
- Enhancement of the understanding of the role of discounting and other methods for weighing present and future costs and benefits;
- Development of innovative tools; methods and models for health impact assessments;
- Undertaking of expert elicitation and stakeholder consultations on tools, models, methods and assessments developed;
- Development of case studies involving public authorities comparing the costs of action and non-action in at least 3 different EU countries.

Projects resulting from this call will be invited to share and discuss their case studies amongst themselves and with relevant stakeholders at the EU level, and necessary resources should be allocated to this task.

Call - Environment and health (Two Stage - 2022)

HORIZON-HLTH-ENVHLTH-2022-05-two-stage

Conditions for the Call

Indicative budget(s)[27]

[27] The Director-General responsible for the call may decide to open the call up to one month prior to or after the envisaged date(s) of opening.
The Director-General responsible may delay the deadline(s) by up to two months.
All deadlines are at 17.00.00 Brussels local time.

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million)	Number of projects expected to be funded
Overall indicative budget				

Proposals are invited against the following topic(s):

HORIZON-HLTH-ENVHLTH-2022-05-two-stage-01: The role of enviromental pollution in non-communicable diseases

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2022**

Action type: RIA

- FAIR[28] data on causal associations between environmental (including occupational) risk factors and health outcomes taking into account vulnerable population groups and specific exposure situations;

The budget amounts are subject to the availability of the appropriations provided for in the general budget of the Union for years 2021 and 2022.

[28] FAIR data are data, which meet principles of findability, accessibility, interoperability, and reusability. Data can include exploitation of information and data from European data infrastructures and programmes such as Copernicus, European Space Agency and the GEO initiative.

- User-friendly tools for national authorities to derive national data on the impacts of pollutants on health and the cost-of inaction;
- Guidelines to mitigate pollution effects on health and well-being allowing policy-makers and other stakeholders, e.g., urban planners, NGOs and citizens, to take action to prevent pollution-related illnesses and impairments, and choose healthier lifestyles and behaviours;
- Case studies showing the applicability of the data, tools and guidelines to take preventive actions and raise political awareness;
- Supporting materials for training courses on pollution and health impacts to inform the variety of actors impacting our daily life e.g. doctors, engineers, teachers, urban planners etc.;
- Recommendations for updates of limit values for different classes of pollutants in the environment at EU, national and regional levels;
- Foundations for the establishment of a European-wide open database on aeroallergen information
- New indicators for health impact assessments;
- Targeted evidence-based communication actions for fact based risk and benefit communication and improving citizen awareness of pollution, offsetting dissemination of misinformation;
- Evidence to support the Zero-Pollution Action Plan and Chemical Strategy for Sustainability of the European Green Deal.

Scope:

The European Green Deal set out by the European Commission recognises that manmade environmental pollution is an increasing threat for human health and wellbeing. The global burden from NCDs has consistently increased over the last decades, being now estimated to account for 70% deaths, globally (World Health Organization). The growing burden of chronic diseases will also be a challenge for Europe's healthcare systems, these diseases already account for an estimated 70-80% of healthcare costs. Currently, around 50 million European citizens suffer from two or more chronic conditions and most of these people are over 65.[29] In Europe, 90% of deaths attributable to the environment result from non-communicable diseases, including cancers, cardiovascular diseases, stroke, chronic obstructive pulmonary disease, mental, behavioural and neurological disorders, diabetes, kidney disease and asthma.[30] While early childhood deaths have declined, the years lived with disability have increased, particularly with chronic disease. This increase cannot be fully explained by genetic predispositions and

29 European Commission 2020 Report on the Impact of Demographic Change
30 EEA 2020 report on Healthy environment, healthy lives: how the environment influences health and well-being in Europe

environmental and lifestyle factors play a major role. A 2018 assessment attributed 16% of total global mortality to pollution-related disease. Based on the most recent WHO environmental burden of disease data, annually, 13% of deaths (630 000) in the EU are attributable to environmental stressors.

The proposed research should strengthen the knowledge base available to policy-makers regarding pollution-disease associations and causal mechanisms at different phases of the life course, taking advantage of latest molecular technologies to elucidate biological pathways from exposure (including combined exposures) to disease. The work should take advantage of data from various sources such as pollution-related databases and disease registries, epidemiological studies and biobanks, environmental and human biomonitoring data. All exposure routes should be considered where relevant (water, food, inhalation, dermal).

The focus should be on issues where causality should be strengthened due to the current paucity of data or where there is a call from policy-makers to improve the evidence base, such as links between (the applicants should focus on one of the three aspects):

i. Environmental pollution such as agricultural chemicals and human neurodevelopmental and neurodegenerative diseases and related impairments;

ii. Air pollution, especially in the urban environment, taking into account its various components, e.g. ultrafine particles and interactions with pollen, and human health;

iii. Waste (e.g. pharmaceuticals, illicit drugs, e-waste, plastics), heavily contaminated environments, exposures and adverse health outcomes, including endocrine-disrupting effects;

The research design should take into account, where appropriate, vulnerable groups, socio-economic factors and exposures in the workplace. Tools for systematic mining and assessment of the knowledge generated and translation into best practices should be developed. Cross-sectoral interventions shall be identified with highest potential for remediating pollution and improving human health and well-being at short/medium term and case studies undertaken. The case studies should also allow for the development of best practices in communication related to risk and prevention and identification of training needs amongst various stakeholders.

Gender aspects should be considered, where appropriate.

Projects resulting from this call will be invited to share and discuss their case studies amongst themselves and with relevant stakeholders at the EU level, and necessary resources should be allocated to this task.

Destination 3. Tackling diseases & reducing disease burden

Health care providers are able to effectively tackle diseases (infectious diseases, including poverty-related and neglected diseases, non-communicable and rare diseases) and reduce the disease burden on patients thanks to an increased understanding of diseases, the use of more effective and innovative health technologies and a better ability and preparedness to manage epidemic outbreaks.

To further advance, there is an urgent need for research and innovation to develop new prevention measures, public health interventions, diagnostics, vaccines, therapies, alternatives to antibiotics, as well as to improve existing prevention strategies to create tangible impacts, taking into account sex/gender-related issues. This will require international cooperation to pool the best expertise and know-how available worldwide, to access world-class research infrastructures and to leverage critical scales of investments on priority needs through a better alignment with other funders of international health research and innovation cooperation. The continuation of international partnerships and cooperation with international organisations is particularly needed to combat infectious diseases, including antimicrobial resistances, to respond to major unmet needs for global health security, including the global burden of non-communicable diseases, and to strengthen patient safety.

This Destination will address mainly two Key Strategic Orientations: (i) 'Promoting an open strategic autonomy by leading the development of key digital and enabling technologies, sectors and value chains' by providing innovative health technologies and better ability and preparedness to manage epidemic outbreaks; and (ii) 'Creating a more resilient, inclusive and democratic European society' through contribution of research and innovation to global health security, including combating infectious diseases, reduction of the global burden of non-communicable diseases, and strengthening patient safety.

Expected impacts:

Proposals for topics under this Destination should set out a credible pathway to contributing to the following expected impacts:

- Health burden of diseases in the EU and worldwide is reduced through effective disease management, including through the development and integration of innovative diagnostic and therapeutic approaches, personalised medicine approaches, digital and other people-centred solutions for health and care. In particular, patients are diagnosed early and accurately and receive effective, cost-efficient and affordable treatment, including patients with a rare disease, due to effective translation of research results into new diagnostic tools and therapies.

- Premature mortality from non-communicable diseases is reduced by one third (by 2030), mental health and well-being is promoted, and the voluntary targets of the WHO Global

Action Plan for the Prevention and Control of NCDs 2013-2020 are attained (by 2025), with an immediate impact on the related disease burden (DALYs)[31,32, 33].

- Health care systems benefit from strengthened research and innovation expertise, human capacities and know-how for combatting communicable and non-communicable diseases, including through international cooperation. In particular, they are better prepared to respond rapidly and effectively to health emergencies and are able to prevent and manage communicable diseases transmissions epidemics, including within healthcare settings.

- Citizens benefit from reduced (cross-border) health threat of epidemics and AMR pathogens, in the EU and worldwide[34 , 35]. In particular, the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases are contained and hepatitis, water-borne diseases and other communicable diseases are being combated[36].

- Patients and citizens are knowledgeable of disease threats, involved and empowered to make and shape decisions for their health, and better adhere to knowledge-based disease management strategies and policies (especially for controlling outbreaks and emergencies).

- The EU benefits from high visibility, leadership and standing in international fora on global health and global health security, especially in partnership with Africa.

The following calls in this Work Programme contribute to this Destination:

Call	Budgets (EUR million)Deadline(s)
HORIZON-HLTH-DISEASE-2021-04 Tackling diseases (2021)	
HORIZON-HLTH-DISEASE-2022-06-two-stage Tackling diseases (Two Stage - 2022)	

31 WHO Global Action Plan for the Prevention and Control of NCDs 2013-2020 (resolution WHA66.10).https://www.who.int/nmh/events/ncd_action_plan/en/ against the 2010 baseline):

32 Including for instance the following voluntary targets (against the 2010 baseline): A 25% relative reduction in the overall mortality from cardiovascular diseases, cancer, diabetes, or chronic respiratory diseases; Halt the rise in diabetes and obesity; An 80% availability of the affordable basic technologies and essential medicines, including generics, required to treat major non-communicable diseases in both public and private facilities.

33 Disability-adjusted life year (DALY) is a quantitative indicator of overall disease burden, expressed as the number of years lost due to ill-health, disability or early death.

34 WHO global action plan on antimicrobial resistance, 2015.

35 EU One Health Action Plan against AMR, 2017.

36 SDG 3 target 3.3

HORIZON-HLTH-DISEASE-2022-07 Tackling diseases (Single Stage - 2022)	
Estimated total budget	

Call - Tackling diseases (2021)

HORIZON-HLTH-DISEASE-2021-04

Conditions for the Call

Indicative budget(s)[37]

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million)	Number of projects expected to be funded
Overall indicative budget				

Proposals are invited against the following topic(s):

HORIZON-HLTH-DISEASE-2021-04-01: Comparative effectiveness research for healthcare interventions in areas of high public health need

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

[37] The Director-General responsible for the call may decide to open the call up to one month prior to or after the envisaged date(s) of opening.
The Director-General responsible may delay the deadline(s) by up to two months.
All deadlines are at 17.00.00 Brussels local time.
The budget amounts are subject to the availability of the appropriations provided for in the general budget of the Union for years 2021 and 2022.

Expected Outcome: **Year of the topic: 2021**

Action type: RIA

- Identification of healthcare interventions (pharmacological, non-pharmacological and technological), including preventive and rehabilitative actions, that work best for specific population groups from the point of view of safety, efficacy, patient outcomes, adherence, quality of life, accessibility, added value, and cost-effectiveness

- Case studies on implementation of the interventions in a new healthcare setting, preferably within communities where there is a high incidence of the disease or condition in Europe and beyond

- Improved clinical guidelines on the optimal treatment of patients, including harmonisation and standardisation of care for high burden diseases or conditions throughout Europe; Considerations include individualised needs of patients or situations where there may be a lack of available evidence

- Effective use of state-of-the-art information, data, technologies, tools and best practices by the scientific and clinical communities to develop sustainable interventions; Delivery of more accurate information on available healthcare interventions to patients, prescribers, and payers via communication platforms

- Establishment of open access databases and/or integration of them with the existing open access infrastructures for storage and sharing of collected data according to FAIR principles

Scope:

Effective healthcare for diverse population groups in Europe is challenging and complex. There are, for example, specific needs for delivering effective preventive actions and therapeutic treatments to a rapidly growing elderly population, which is also subject to frequent comorbidities and associated poly-pharmacy. The paediatric population has also its specific needs in specially adjusted therapeutics and, similarly to the elderly population, is often excluded from many clinical trials that generate the evidence base for healthcare interventions. Other population groups that represent ever-growing strata of the European population with limited

access to quality healthcare and under-representation in clinical studies include women, low-income groups, and refugees. Intersectionality within these groups also needs consideration.

Projects are expected to address the following:

- Compare the use of currently existing (pharmacological as well as non-pharmacological) healthcare interventions in specific population groups (or selected subgroups). While there is no restriction on diseases or conditions, preference will be given to proposals focusing on interventions with high public health relevance, i.e. interventions addressing diseases

or conditions that are particularly frequent, have a high negative impact on the quality of life of the individual and/or are associated with significant costs where savings can be achieved.

- End users (patients, care providers, etc.) should be involved in the design of the study. Additionally, proposals should take into account the diversity of health systems in different regions of Europe as to make sure that findings can be generalised.
- Consider issues of particular relevance for the target populations, for example, poly-pharmacy, vaccine efficacy, compliance, age and gender specificities. Given the focus on existing interventions, proposals will aim to contribute to decisions about the discontinuation of interventions that are less effective or cost-effective than others.
- Assess for the chosen populations clinical and safety parameters, as well as health and socio-economic outcomes (e.g. quality of life, patient mortality, morbidity, costs, and performance of the health system). Agreed core outcome sets (COS) should be used as endpoints in conditions where they already exist, in other cases efforts should be made to agree on such COS.
- Clinical trials, observational studies, creation of large-scale databases and performing meta-analyses may be considered for this topic. Regarding databases, sustainability after the project's end also needs to be considered. The proposed research needs to take into account sex and gender aspects.

HORIZON-HLTH-DISEASE-2021-04-02: Building a European innovation platform for the repurposing of medicinal products

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2021**

Action type: RIA

- New effective therapeutic options addressing unmet medical needs, both for communicable and non-communicable diseases.
- More cost-effective treatments that would reduce in the longer term the financial burden on healthcare systems and payers.
- New models of sustainable collaboration between the public sector and the pharmaceutical industry, with a global dimension.
- Further harmonisation of the EU pharmaceutical regulatory landscape increasing the efficiency of medicinal products repurposing based on a data-driven approach.

Scope:

Development of therapeutics is a lengthy process that requires a large amount of efforts and financial resources. It is often burdened by delays and barriers that account for an average of almost 15 years until a promising candidate molecule becomes an approved medicine. It is therefore of paramount importance to define strategies that facilitate the reduction of timeframes, decrease costs and improve the success rate of this complex and lengthy process. One efficient strategy towards this direction is the repurposing of already approved medicinal products and repositioning of investigational products, beyond their original indication. This approach has already proved successful[38] in several instances, but its potential is far from having been fully exploited.

Proposals are expected to address the following:

- Elaborate a repurposing model with a harmonized and sustainable dimension in the EU, attracting investments and taking a position of leadership at global level. This model should integrate the financial, legal, regulatory, and intellectual property aspects of the repurposing approach.
- Provide a robust selection mechanism for prioritising repurposing projects, based on recognized unmet medical needs and sound preliminary data
- Leverage and pool existing high quality data assets in the EU repurposing landscape, also by using in silico and AI approaches.
- Resolve the fragmentation and lack of ownership of the repurposing approach that greatly impedes the efficient exploitation of its potentials, networking existing projects and initiatives.
- Propose a model to enhance and coordinate EU collaboration among relevant stakeholders e.g. academia, non-profit organisations, patients, health-care professionals, regulators,

[38] Notable examples are thalidomide and sildenafil.

health technology assessment bodies, payers, industry, and European Research Infrastructures.

- Special attention should be given to investigator-driven projects.

HORIZON-HLTH-DISEASE-2021-04-03: Clinical development of health technologies relevant in sub-Saharan Africa

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2021**

Action type: RIA

Place Holder:

The aim of this topic is to bridge the gap between Horizon 2020 and Horizon Europe in clinical development of interventions for diseases of poverty affecting particularly sub-Saharan Africa. The supported research activities should contribute to global health, build clinical trials capacity, and reduce the infectious disease burden in sub-Saharan Africa. In addition, a potential CSA topic is proposed for 2021, which should allow the European & Developing Countries Clinical Trials Partnership (EDCTP) secretariat to continue the coordination and communication activities in collaboration with the European and African States.

Expected outcomes:

- Advanced clinical evaluation of vaccines, diagnostics, and treatments
- Increased clinical research capacity and strengthened infrastructure for clinical research and implementation in sub-Saharan Africa

- Strengthened surveillance capabilities and systems to detect infectious disease outbreaks at an early stage and strengthened laboratory systems to rapidly confirm diagnoses
- Improved epidemic/pandemic preparedness

Scope:

The aim of this topic is to bridge the gap between the European and Developing Countries Clinical Trials Partnership (EDCTP2) of Horizon 2020 and the potential EU – Africa Global Health Partnership foreseen for Horizon Europe.

The European and Developing Countries Clinical Trials Partnership (EDCTP) has established itself as the focal point of cooperation between the EU and sub-Saharan Africa in infectious disease research. To continue these investments after the end of EDCTP2 there is a need to further support research on the major infectious disease threats facing sub-Saharan Africa – HIV, TB, malaria, lower respiratory tract infections, and diarrhoeal disease – as well as emerging and re-emerging infections, antimicrobial resistance, and the infectious disease impacts of the climate crisis.

The scope can be further defined in collaboration with EDCTP.

HORIZON-HLTH-DISEASE-2021-04-04: Advancing innovative Artificial Intelligence (AI)-based solutions for treatment

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2021**

Action type: RIA

- Safe and evidence-based clinical decision support tool for affordable treatment including home-based care

- Predict patients' (long-term) prognosis and response, including side effects, to a personalised specific treatment
- Clinically validated AI solutions included into clinical guidelines
- Harmonising the type of therapies proposed to patients
- Information communication package to the patients about the disease and the proposed treatment.

Scope:

Applying trustworthy-AI [39] in healthcare contexts can generate a multitude of benefits, including effective disease management by optimised personalised treatments and assessment of health outcomes.

Projects should focus on implementing clinical studies to validate AI-based solutions at late stages of (pre)clinical development comparing their benefit versus state-of-the-art treatments in non-communicable diseases that pose a major health, societal and economic threat and burden for people. The proposals should pay special attention to the usability, performance and safety of the developed AI solutions, and above all their clinical evaluation in view of their inclusion into current clinical guidelines for personalised treatments following current EU regulatory framework.

Early end-users inclusion is highly required in order to ensure uptake of trustworthy-AI solutions in clinical settings.

Solutions could also provide more accurate prognosis for, and response to, a personalised specific treatment, including side effects.

Proposals should integrate an information communication package about the disease and the proposed treatment adapted to the diversity of patients.

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.

HORIZON-HLTH-DISEASE-2021-04-05: One Health AMR - Placeholder

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.

[39] High Level Group on Artificial Intelligence, set up by the European Commission, Ethics Guidelines for Trustworthy AI, document made public on 8 April 2019

Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2021**

Action type: CSA

HORIZON-HLTH-DISEASE-2021-04-06: EU Wide Clinical Trials Network - public health emergencies- Placeholder

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2021**

Action type: CSA

Call - Tackling diseases (Two Stage - 2022)

HORIZON-HLTH-DISEASE-2022-06-two-stage

Conditions for the Call

Indicative budget(s)[40]

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million)	Number of projects expected to be funded
Overall indicative budget				

Proposals are invited against the following topic(s):

HORIZON-HLTH-DISEASE-2022-06-two-stage-01: Towards improved palliation and/or end-of-life care

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2022**

Action type: RIA

[40] The Director-General responsible for the call may decide to open the call up to one month prior to or after the envisaged date(s) of opening.
The Director-General responsible may delay the deadline(s) by up to two months.
All deadlines are at 17.00.00 Brussels local time.
The budget amounts are subject to the availability of the appropriations provided for in the general budget of the Union for years 2021 and 2022.

- Reduced health-related suffering and improved well-being and quality of life of patients in need of palliative and end-of-life care and their professional and family caregivers.
- Early and better access, higher quality and (cost-) effectiveness of palliative or end-of-life care services.
- Reduced societal, healthcare and economic burden related to increasing demands of palliative or end-of-life care services.
- Improved clinical guidelines and policy with respect to pain management, psychological and spiritual support, palliative or end-of-life care of patients.
- Improved guiding of the palliative care decision-making process through an information driven management of patients with the end-stage disease.

Scope:

In aging societies, the complexity of health conditions related to life-threatening and chronic diseases, acute and chronic pain, late or long-term side effects as consequences of diseases and their treatments affect quality of life of patients and their families and pose an immense societal and economic burden. Palliative[41] and end-of-life care approaches improve quality of life of patients and professional and family caregivers through the prevention and relief of suffering by means of early identification, assessment and treatment of pain and other problems, physical, psychosocial and spiritual. Although a variety of interventions are in use, they are often not adequately validated or adapted to the specific needs of patients affected by complex diseases or their co- or multimorbidities. Therefore, a need exists to strengthen the evidence base for available patient-centred effective interventions improving quality of life and outcomes of patients in the domains of palliative and end-of-life care.

Proposals are expected to address the following:

- Demonstrate the effectiveness and cost-effectiveness of newly proposed or specifically adapted pharmacological and/or non-pharmacological interventions[42] to improve well-being and quality of life of patients suffering from life-threatening diseases[43] (including disabilities). Whenever relevant, serious late and long-term side effects of disease treatments or symptoms that occur at the end of life of patients should be considered.

- Prove the feasibility of integrating the proposed interventions in current pain management, palliative and/or end-of-life care regimes and healthcare systems across Europe. The complex human, social and ethical aspects that are necessarily managed by those care

41 https://www.who.int/cancer/palliative/definition/en/

42 Randomised clinical trials or observational studies should be considered for this topic. Proposals should give a sound feasibility assessment, including an appropriate patient selection and realistic recruitment plans, justified by available publications and/or preliminary results.

43 Proposals focused on cancer-related research are not in the scope of this topic. The survivorship, palliation and end-of-life care of cancer patients are (will be) covered by topics proposed within the Mission on Cancer annex to the Work Programme (specific link to the mission topics will be included).

regimes and healthcare systems should be reflected from patients' as well as their professional and family caregivers' perspectives. The views and values of patients and their caregivers (including families, volunteers, nurses and others) should also be appropriately taken into account in patient-centred care decisions.

- Identify and analyse relationships between sex, gender, age and socio-economic factors in health and any other relevant factors (e.g. ethical, familial, cultural considerations, including personal beliefs and religious perspectives, etc.) that could affect health equity[44] to the proposed interventions.
- Analyse the barriers and opportunities to re-invigorating and enhancing timely social inclusion and active engagement of patients in need of palliative and end-of-life care and their carers.
- Provide guidelines for patient-centred communication as well as standards for evidenced based communication trainings for caregivers.
- When relevant, provide policy recommendations with respect to pain management, psychological and/or spiritual support, palliative or end-of-life care of patients or afflicted by late and long-term side effects of treatments.

HORIZON-HLTH-DISEASE-2022-06-two-stage-02: Pre-clinical development of the next generation immunotherapies

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2022**

Action type: RIA

[44] https://www.who.int/topics/health_equity/en/

- Increased success rate in the pre-clinical validation of new immunotherapies for communicable and non-communicable diseases or disorders with unmet medical needs.
- Increased knowledge of mode of action of novel immunotherapies and/or combinatorial treatments.
- Availability of new targeted and/or personalized models (in vitro and in vivo) and protocols for the development of new immunotherapies.
- Evidence-based safety and efficacy guidelines for immunotherapies as compared to existing approaches.
- Advanced formulation strategies and/or proof-of-clinical concept for enhanced delivery of new immunotherapies as single or combinatorial treatments.

Scope:

Immunotherapy is defined as a treatment able to stimulate or restore the ability of the immune (defence) system to fight infection, disease or disorder.

Immunotherapy has proved to be a valuable medical solution notably when preventive treatments are not available. Passive and active immunotherapies are covered by this topic, which is aiming at the pre-clinical to first-in human development of new immunotherapies for unmet needs. The proposals should build on existing knowledge in the field, when available, in order to save time and to avoid spilling resources, and could take advantage of artificial intelligence and existing databases.

New immunotherapies are needed in order to improve and diversify the health standards of care of several communicable or non-communicable diseases[45] that cannot be effectively tackled with the current available treatments.

Projects are expected to address the following research gaps for the development of new effective and safe immunotherapies:

- Preclinical development and study of new immunotherapeutic agents in vitro and in relevant animal model(s) of the disease(s). This includes understanding of the therapy's agent(s) mode of action, its toxicity, the development of related potency assay, and its/their validation in vitro and in vivo. A robust regulatory and HTA strategy should be in place at the start of the project.
- Off-the-shelf therapies, including the cell-based therapies, will be considered as assets during the evaluation.

[45] Excluded from the scope are the preventive vaccines, the immunotherapies for rare diseases and the repurposing of drugs as they are covered by other topics in the HE research programme 2021-2022. Research on cancer immunotherapies is excluded as it will be covered by the Mission on Cancer.

- Proposals could include proof-of-concept/first-in-human studies for testing the new therapies, with a clear regulatory and clinical path [46](explained in the related applicants' template for proposals including clinical trial) and should address as appropriate the therapy-related adverse effects. Proposals should take sex, gender, age and socio-economic factors into account. Phase II studies or higher phases trials will not be supported.

- Leverage the development of standardised framework of assays and data usage for a robust assessment of the safety and efficacy.

- In case treatments are already available for the proposed targeted disease(s), a justification of the need for development of a new immunotherapy treatment is requested, as well as a cost-effectiveness assessment as compared to available treatments.

- The proposed action should include a pathway of the necessary steps to ensure sustainable production and uptake by health systems and access to patients.

HORIZON-HLTH-DISEASE-2022-06-two-stage-03: Vaccines 2.0 - using knowledge on host-pathogen interactions and novel technologies for the development of next generation of vaccines

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2022**

Action type: RIA

[46] Template for essential information for proposals including clinical studies https://ec.europa.eu/research/participants/data/ref/h2020/other/legal/templ/h2020_tmpl-clinical-studies_2018-2020_en.pdf

- Increased knowledge of pathogens and the immune system for infectious diseases where vaccine efficacy needs to be improved.
- Increased number of innovative manufacturing technologies and GMP manufacturing capacity for the production of second generation of vaccines.
- Diversified portfolio of vaccine candidates ready for testing in clinical trials.
- Increased number of preventive interventions tested in early stages of clinical studies.
- Improved prevention outcome for infectious diseases.
- Validation of new biological compounds and vaccine technologies.

Scope:

Infectious diseases, including antimicrobial resistant (AMR) infections, remain a major threat to health in the EU and to global health security. The availability of accessible and affordable new, improved vaccines would provide the most cost-effective preventive measure against the health threat of epidemics and AMR pathogens. Vaccines against diseases, such as AIDS, tuberculosis (TB), malaria, neglected tropical diseases, hepatitis and water-borne diseases are essential to achieve the WHO targets to control the spread of infectious diseases. First generation vaccines against some of the pathogens have proven to be suboptimal and not effective enough to eradicate the diseases. Many viruses of pandemic potential are variable in their surface antigen composition, and novel technologies are required to develop efficient vaccines against each new variant efficiently and in a short timeframe.

To ensure that novel, effective and affordable vaccines against all major infectious diseases become a reality, it is essential to sustain a diverse and modernised vaccine development pipeline. This collaborative research and innovation action aims to diversify and accelerate the global vaccine R&D pipeline, and to strengthen the current leading role of EU in technological development and vaccine research & innovation. The action is intended to cover those pathogens, which lack sufficiently efficacious vaccines, but where earlier efforts have already produced vaccine candidates.

Projects are expected to address the following:

- Innovation and integration of expertise and capabilities, including alignment of preclinical and clinical models, biomarker studies and new vaccine approaches from discovery or late stage development to GMP production and early clinical development of promising preventive candidates.
- Application of iterative processes (including cross learning and back-translation steps) to allow exploitation and integration of novel findings between clinical, preclinical and discovery.
- Some of the following elements: deciphering mechanisms of protection of candidates, new approaches to antigen discovery, evaluation of vaccines in novel platforms and

technologies, innovative vaccine manufacturing approaches, relevant animal models, evaluation of alternative vaccine delivery routes.

- Effective, evidence-based decision-making for progression of vaccine candidates based on transparent and objective portfolio management. Regulatory requirements should be considered.

- Sex, gender, age and socio-economic factors should be taken into account whenever relevant.

HORIZON-HLTH-DISEASE-2022-06-two-stage-04: Development of effective therapies for rare diseases with an unmet medical need

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2022**

Action type: RIA

The proposals under this topic should aim to address several of the following expected outcomes:

- Effective integration of the state-of-the-art knowledge on the rare diseases and targets mechanisms, to guide the therapeutic development for group(s) of rare diseases with commonalities

- Robust preclinical models, methods and/or technologies to increase the confidence in the targets selection and to accurately design and implement the safety and efficacy studies

- Validated biomarkers defining robust surrogate and clinical endpoints in the therapy development pipeline

- Novel therapeutic interventions and/or orphan medicinal products for people living with a rare disease with no approved therapeutic option

Scope:

Despite the considerable amount of knowledge that has been accumulated and the new orphan medicines developed in recent years, the number of available therapies for rare diseases remains low, as fewer than 6% of rare diseases have an approved treatment option.

The joint evaluation[47]of the regulations on orphan medicinal products and paediatric medicines concluded that those regulations have boosted the development for new therapies for rare diseases but have not yet adequately managed to direct R&D development in areas of greatest unmet medical need. Therefore there is an urgent need for EU support for the development of novel therapies for rare diseases, where there is no approved therapeutic option available.

The topic will support proposals aiming to explore the accumulated state-of-the-art knowledge and results in the rare diseases to enable the robust development of novel therapeutic interventions in group(s) of rare diseases with no approved therapeutic option. The proposals should not focus on a single disease (for example with a unique Orphacode) but on group(s) of rare diseases with commonalities, such as shared biological features, possibly across different medical areas within the rare diseases landscape[48].

The therapies to be developed may include a broad family of therapeutic interventions such as, small molecule(s), advanced therapy medicinal products, repurposing existing therapies, including non-pharmacological interventions and/or their combinations, as relevant. Sex and gender aspects should be considered, wherever relevant. To ensure that the needs of people living with a rare disease are adequately addressed, the involvement of patient representatives in all phases of the research is strongly encouraged. Rare infectious diseases and rare cancers therapies development will not be considered in this call.

The topic will support proposals that focus on rare diseases with an unmet medical need and no approved therapeutic option and may cover different stages in the continuum of the innovation path (i.e. translational, preclinical, clinical research, validation in the clinical and/or real-world setting etc.), as relevant. SME(s) participation is encouraged with the aim to strengthen the scientific and technological basis of SME(s) and valorise their innovations for the benefit of people living with a rare disease.

The proposals should address several of the following research bottlenecks, currently encountered in the field of the rare diseases therapy development:

- Establish multidisciplinary collaborations by integrating disciplines, technological developments and regulatory advances with the aim to understand the

[47] https://ec.europa.eu/health/sites/health/files/files/paediatrics/docs/orphan-regulation_eval_swd_2020-163_part-3.pdf

[48] Medical areas such: neurology, immunology, dermatology, endocrinology-metabolism etc.; see EMA therapeutic areas; https://www.ema.europa.eu/en/human-regulatory/research-development/prime-priority-medicines

pathophysiology/heterogeneity of the rare diseases concerned. Furthermore, develop/utilise relevant preclinical models to guide the development and implementation of safe and effective therapies

- Integrate harmonised data from multiple sources (i.e. natural history studies/clinical trials, multi-omics, medical imaging, registries etc.) and/or leverage the advances in artificial intelligence/mobile sensors for defining and testing clinical endpoints and patient-centred reported outcomes into the therapy development pipeline

- Leverage the power of preclinical models, biomarkers, companion diagnostics and/or in-silico trials in order to establish a robust link in between the targets and the rare diseases under study and monitor the safety and efficacy of the proposed interventions

- Implement proof-of-concept preclinical studies and/or clinical studies[49] to demonstrate the effectiveness of the therapeutic interventions under study

The proposals shall involve rare diseases i.e. a disease affecting not more than five in 10.000 persons in the European Union. Proposals that plan to run clinical trials should demonstrate that they have already taken into account scientific advice[50] or protocol assistance from EMA. In particular, the proposals planning the clinical development of orphan medicinal products should demonstrate that they have been granted approval for an orphan designation at the latest on the date of the call deadline.

The proposals should adhere to the FAIR principles and take stock, wherever relevant, of the data standards, harmonisation guidelines and data sharing/access good practices developed by existing European health research infrastructures. The proposals should take stock, wherever relevant, of the data integration harmonised procedures and of good practices for analytical methods and/or preclinical models developed by the European Joint Programme on Rare Diseases (EJP RD) and other relevant EU-funded consortia. Proposals utilising data from registries may adopt when relevant, the European standards, such as the "set of common data elements"[51] developed by the European Platform on Rare Disease Registration. In addition, synergies should be sought with the European Reference Networks, whenever relevant.

Projects funded under this topic will contribute towards the goals of the International Rare Diseases Research Consortium (IRDiRC) that supports the development of 1000 new therapies for rare diseases by 2027 and where relevant may take stock of the IRDiRC the Orphan Drug Development Guidebook[52].

Call - Tackling diseases (Single Stage - 2022)

HORIZON-HLTH-DISEASE-2022-07

49 Template for essential information for proposals including clinical studies
50 https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-advice-protocol-assistanc
51 https://eu-rd-platform.jrc.ec.europa.eu/set-of-common-data-elements_en
52 https://irdirc.org/orphan-drug-development-guidebook-materials/

Conditions for the Call

Indicative budget(s)[53]

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million)	Number of projects expected to be funded
Overall indicative budget				

Proposals are invited against the following topic(s):

HORIZON-HLTH-DISEASE-2022-07-01: GLOPID R secretariat

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2022**

Action type: CSA

[53] The Director-General responsible for the call may decide to open the call up to one month prior to or after the envisaged date(s) of opening.
The Director-General responsible may delay the deadline(s) by up to two months.
All deadlines are at 17.00.00 Brussels local time.
The budget amounts are subject to the availability of the appropriations provided for in the general budget of the Union for years 2021 and 2022.

Destination 4. Ensuring access to innovative, sustainable & high-quality Healthcare

The COVID-19 crisis resurfaced needs for more resilient health systems, be it to epidemics/pandemics, but also to environmental crisis and crisis of economic nature. Therefore, solidifying the foundations of our health systems will be one of the biggest challenges in the economic recovery-bound future. It will also be a time for opportunity, for generating evidence and developing more flexible and dynamic health systems that are prepared to deal with future crisis. More so, systems that have the right tools to cope with ongoing trends and changes such as demographic, epidemiological, technological, environmental and socioeconomic transitions.

Under this destination, research and innovation aims at supporting health care systems in their transformation to ensure fair access to sustainable health care services of high quality for all citizens. Planned activities will support the development of innovative solutions in the various dimensions of health and care systems (e.g. governance, financing, human and physical resources, health service provision, and patient empowerment). Ultimately, these activities will provide decision-makers with new evidence, but also methods, tools and technologies for uptake into their health and care systems. Consequently improving governance of the European health and care systems, supporting healthcare professionals and providers and allocating resources according to citizens' health needs and preferences, while ensuring fiscal sustainability to assure those needs can be met on the long-term.

Expected impacts:

Proposals for topics under this Destination should set out a credible pathway to contributing to the following targeted impacts of the Horizon Europe Strategic Plan:

1. Health and social care services and systems have improved governance and are more effective, efficient, accessible, resilient, trusted and sustainable, both fiscally and environmentally, with health promotion and disease prevention at their heart, by shifting from hospital-centred to community-based, people-centred and integrated health care structures and successfully embedding technological innovations that meet public health needs, while patient safety and quality of services is increased.

1. Health care providers are trained and equipped with the skills and competences suited for the future needs of health care systems that are modernised, digitally transformed and equipped with innovative tools, technologies and digital solutions for health and care. They save time and resources by integrating and applying innovative technologies, which better involve patients in their own care, by reorganising workflows and redistributing tasks and responsibilities throughout the health care system, and by monitoring and analysing corresponding health and care activities.

1. Citizens play a key role in managing their own health and care, informal carers (i.e. unpaid carers) are fully supported (e.g. by preventing overburdening and economic stress) and specific needs of more vulnerable groups are recognised and addressed. They benefit from improved access to health care services, including financial risk protection, timely access

to quality essential health care services, including safe, effective, and affordable essential medicines and vaccines.

1. Health policy and systems adopt a holistic approach (individuals, communities, organisations, society) for the evaluation of health outcomes and value of public health interventions, the organisation of health and care, and decision-making.

The following calls in this Work Programme contribute to this Destination:

Call	Budgets (EUR million)Deadline(s)
HORIZON-HLTH-CARE-2021-05 Ensuring access to innovative, sustainable and high-quality health care (2021)	
HORIZON-HLTH-CARE-2022-08 Ensuring access to innovative, sustainable and high-quality health care (Single Stage - 2022)	
HORIZON-HLTH-CARE-2022-10 Partnerships in Health (2022)	
Estimated total budget	

Call - Ensuring access to innovative, sustainable and high-quality health care (2021)

HORIZON-HLTH-CARE-2021-05

Conditions for the Call

Indicative budget(s)[54]

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million)	Number of projects expected to be funded
Opening: na				
Overall indicative budget				

Proposals are invited against the following topic(s):

HORIZON-HLTH-CARE-2021-05-01: Enhancing quality of care and patient safety

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.

[54] The Director-General responsible for the call may decide to open the call up to one month prior to or after the envisaged date(s) of opening.
The Director-General responsible may delay the deadline(s) by up to two months.
All deadlines are at 17.00.00 Brussels local time.
The budget amounts are subject to the availability of the appropriations provided for in the general budget of the Union for years 2021 and 2022.

Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2021**

Action type: RIA

- Context specific knowledge and evidence on effective and affordable interventions ensuring patient safety;
- Harmonised or standardised patient-centred procedures and practice guidelines for improving patient safety developed in partnership with empowered patients;
- Innovative approaches for integration of harmonised and standardised practices with personalised treatment schemes;
- Quality assured processes to bridge inter-sectorial gaps in the clinical pathways of patients to improve patient safety;
- Improved rigour of guideline development, mode of implementation and evaluation of impact;
- Better trained health care professionals to be able to identify, evaluate and address risks for patient safety;
- Greater acceptance of and adherence to recommendations by health care professionals and patients/citizens.

Scope:

Patient safety remains an issue of increasing concern for EU health systems. The Commission estimates (COM (2008) 836) that between 8% and 12% of patients admitted to hospitals in the EU suffer from adverse effects of health care.

Overall, the most common types of in-hospital adverse effects are operative/surgical related, medication or drug related, and health care – associated infections, half of them being preventable (Schwendimann et al., 2018). According to the OECD (Health Working Papers No. 106, 2018), more than 7 million admissions in the OECD countries result from safety lapses in primary and ambulatory care. Diagnostic errors persist throughout all settings of care and contribute to increased risks and harms from the treatment (Erin P. Balogh et al., 2015). Therefore, it is necessary to develop and implement coherent quality improvement and patient safety strategies in Europe. Harmonisation and standardisation of health care processes (Guidelines and Standard Operating Procedures) along the continuum of care contribute to improve quality and safety of health services, minimise the risk of errors and at the same time ensure the quality and comparability of health data. It is also a mean to address inequities in health care delivery.

Only proposals contributing to improved patient safety along the continuum of care in Europe may be funded under this topic. Each proposal should take into consideration the already existing EU-funded initiatives in this area and should address in a coherent manner at least 3 (three) of the following items, but may also contain other research and innovations activities for improving patient safety:

- To address knowledge gaps on improved quality of care and patient safety, including through harmonisation and standardisation of health care delivery, optimizing inter-sectoral clinical pathways and decision-making processes and tools across regions and countries.
- Development and piloting of harmonised evidence-based interventions in a uniform way within health care institutions in different regions and countries. The issue should be addressed in case studies at hospital, primary and outpatient care levels, and it should also take into consideration the diverse health care landscape across Europe.
- Research on translation of international standards and clinical guidelines into national practice for improved quality of care and patient safety. To provide context-specific evidence on facilitators and barriers for transferring identified good practices across regions and countries.
- Comprehensive comparison of practices related to clinical guidelines in European countries, including the regulatory basis underpinning guidelines in each health system, the guideline development process, mechanisms of quality control, implementation modalities, and evaluation of produced recommendations.
- Innovative approaches for integration of harmonised and standardised practices with personalised treatment plans.

The proposal should present a clear strategy for empowering and involving patients and caregivers in addressing the selected item(s), giving attention to both PROMs (Patient-Reported Outcome Measures) and PREMs (Patient-Reported Experience Measures). The research design, including the expected results, should carefully analyse and tackle the sex and gender dimension. The proposed evidence-based interventions, including clinical guidelines and standards, should meet health care providers' needs and goals to increase patient safety and health care quality.

HORIZON-HLTH-CARE-2021-05-02: Data-driven decision-support tools for better health and care delivery and policy-making

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.

Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2021**

Action type: RIA

- Better use of health relevant data (incl. collection, storage and analysis), planning algorithms and Artificial Intelligence (AI) in support of health and care decision-making processes;
- Evidence-informed deliberative processes for transparent decision- and policy-making;
- Increased capacity of policy-makers, health planners, caregivers (formal and informal), and citizens to make better informed health decisions and communicate about those decisions;
- Improved integrative and participative decision-making processes that take in consideration diverse values and perspectives;
- Interoperable and reusable tools for public health policy-making and health and care delivery.

Scope:

An ever-increasing amount of data is at the disposal of decision- and policy-makers, which, if analysed, pooled and used, could lead to novel approaches in health and care delivery and policy-making, consequently improving quality of life, health equity and producing better health outcomes. Collection, access to and use/reuse of data is still very fragmented across national health systems. The availability and use of qualitative health data has huge potential for the implementation of data-driven innovation and it provides new opportunities for developing, monitoring, evaluating interventions and feedback into health policy strategies.

Within the scope of this topic, research and innovation actions should aim at optimising or transforming health and care processes organisation and delivery in a transparent way. The development of innovations, including tools, processes and services, should be done together with end-users (i.e. citizens, health professionals and policy makers), and represent both a

support-base and scientific evidence for data-driven innovation. Input data should be FAIR (meet the principles of Findability, Accessibility, Interoperability and Reusability) and based on domain-relevant community/quality standards. Part of the action can be focused on creating, agreeing and piloting the use of standards for data formatting. Data-driven algorithms should be explainable, unbiased and inclusive. Caution needs to be paid to systematically control for gender and racial bias and/or discrimination bias, when developing and using data and algorithms. Proposals may choose to focus on advancing skilled combination of big data and 'thick data'. The actions should ensure that the novel ideas are accompanied by frameworks/guidelines for new forms of collaboration and incentivising mechanisms/tools in order to support implementation of the innovations in the public sector. The tools should aim to improve health outcomes and quality of life, not only to lower health care costs.

Actions should pursue a multi-disciplinary approach and integrate health care research, health services research, innovation, health economics, implementation science and data science to ensure more equitable, innovative and sustainable health and care systems.

Building on health and care data, research and innovation can support projects in, but are not limited to, the following:

- Developing interactive policy and visualisation tools (i.e. through creation of digital twins /virtual models) that help scan/survey populations, systems and services as a whole, to help policy-makers make data-driven decisions. These can be foreseen to be used solely in health and care or constitute health-relevant inputs for other sectorial approaches, and promote multi-disciplinary knowledge exchange;

- Scenario tools that help logistics planning and management, capacity, utilisation of health services and allocation of resources and infrastructures (i.e. beds and wards, human resources, health goods, among others);

- New models for estimation of health resources and services needs using existing/available data and establishing governance models for the (secondary) use of health data;

- Understanding and foresight on availability of and access to (also taking in consideration reimbursement mechanisms) health and care technologies (i.e. pharmaceuticals, vaccines, medical devices, etc.) and interventions;

- Developing digital and e-governance solutions for facilitation of citizens' interaction with the health and care systems, including feedback mechanisms, guidance on health and care pathways, supporting patients in making healthcare decisions and treatment adherence;

- Creating toolkits and solutions with indicators to better assess outputs from end-user involvements including of patient-reported outcomes measures (PROMs) and patient-reported experience measures (PREMs), as well as use of digital technologies in health and care (including interaction between patients and health care providers) for measurement/evidence of impact.

Individual proposals are not expected to address all expected outcomes. More so, this topic intends to cover the different areas above mentioned, not in one single proposal, but in different proposals that cover at least a relevant area. Evaluation will select proposals in a portfolio approach manner, in order to ensure that the majority of the topics pointed out and use-case/sector-specific areas are included in the portfolio of proposals selected and that there is no (complete) overlap in the selected proposals.

Applicants are encouraged to establish dynamic relations and synergies with the following areas, where applicable:

- Decision-making processes and tools, including social innovation;
- Monitoring and evaluating budgetary impact of health and care interventions (i.e. innovative solutions, digital services and health and care models);
- Health technology assessment and cost-effectiveness analysis;
- Artificial intelligence/deep learning tools in social medicine to determine causal factors of disease/conditions and develop interventions;
- Data sharing between different institutions;
- European Health Data Space (EHDS);
- Open source and/or common building blocks used in Connecting Europe Facility (CEF) (e.g. eDelivery, eID);
- Standards and mechanisms to allow for interoperability between primary and secondary use of data;
- Privacy-preserving protocols for secondary use of data for public health policy-making and research;
- Federated/distributed access or data processing protocols for data-driven decision-support tools for better health and care delivery and policy-making.

Projects involving earth observation, positioning, navigation or timing data, services or technologies must make use of Copernicus and/or Galileo/EGNOS data, services and technologies. Other programmes or systems may additionally be used.

HORIZON-HLTH-CARE-2021-05-03: Personalised medicine and infectious diseases: understanding the individual host response to viruses (e.g., SARS-CoV-2)

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.

Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2021**

Action type: RIA

- Enhanced understanding of risk factors, symptoms expression, disease progression and clinical outcomes in relation to host and viral characteristics, and host-pathogen interaction (i.e., the mechanistic understanding of the interplay between host and virus).
- Characterized diversity of host response at the level of genetic patterns, molecular pathways and physiological mechanisms, in relation to a large number of variables that inform disease predisposition, disease progression, symptoms expression and clinical outcomes.
- Deep characterization of the dynamics of the immune responses to the chosen virus(es), identifying factors critical for viral control and immune protection. This will provide solid science base for the development of personalised therapeutic interventions and vaccines in the future.
- Potential biomarkers in the broad sense*A biomarker has been defined as a characteristic that is objectively measured and evaluated as indicator of normal biologic processes, pathogenic processes, or pharmacologic responses to therapeutic interventions* (NIH working group (Clin. Pharmacol. Ther. Vol. 38 n°.3 (2001))

Guidance on preventive measures and early identification of patients at risk of developing severe symptoms.

Scope:

Proposals are expected to characterize the host response and host-pathogen interaction to a virus (or viruses) at the level of genetic patterns, physiological mechanisms and molecular pathways involving different organs and systems to identify factors that predispose to different clinical symptoms, different progression of the viral disease and different clinical outcomes. Ideally,

the study should include patient follow-up to identify conditions (including long-term ones) that may appear after the patient has recovered from the viral disease.

In all cases, the above research should include deep immunological phenotyping of the host response, including the use of animal models if relevant. The latter should cover the dynamics of the innate and adaptive immune responses to the chosen virus(es) (comprising immunity duration, the effect of potential subsequent infections, etc.) including, if relevant the association of HLA assets of patients with protective or harmful immune responses. Ultimately, this research should inform disease progression and the development of personalised prophylactic and therapeutic strategies.

The analysis should address the effect of differences in age, sex, gender, ethnicity, chronic conditions, comorbidities, treatments offered and other relevant characteristics. The sample should be geographically representative of Europe.

The data used should be well standardized following the best available international practices and standards. Equally, sample collection and processing should be done following recognised standard operating procedures. All data should be treated in accordance with GDPR and ethical principles.

If the project focuses on COVID-19, it is strongly encouraged to build links with successful projects from the second Horizon2020 expression of interest "Pan-European COVID-19 Cohorts".

In case the project focuses on COVID-19, special attention should be given to links with the newly established European COVID-19 research data sharing platform[55] and collaboration with the existing network of H2020 COVID-19 projects will be encouraged.

Collaboration with the 1 + Million Genomes initiative[56] is encouraged where relevant.

The Commission considers that proposals requesting a contribution from the EU of between EUR 6-8 million would allow these specific challenges to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

HORIZON-HLTH-CARE-2021-05-04: Health and Care procurement innovation network

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.

[55] https://www.covid19dataportal.org/
[56] https://ec.europa.eu/digital-single-market/en/european-1-million-genomes-initiative

Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic:** 2021

Action type: CSA

- Optimal, cost-efficient and flexible innovation procurement strategies for public/private procurers and decision makers at a regional, national and EU level, taking into account the ongoing changes in the organisational procedures of healthcare structures caused by the covid-19 pandemic.
- Mainstreaming health and care-related Innovation Procurement best practices by procurers and decision makers in procurement organisations in their respective policy and investment strategies, as well as scaling up of cross-border collaborations among health and care procurers to maximise scale and minimise risk in research and deployment of innovative solutions.
- Contribute to the creation of more widely scalable markets across Europe for innovative solutions for health and social care.
- Create a common understanding / innovation procurement roadmap that reflects the priorities of stakeholders involved in the demand side of health and care innovations (i.e. procurement agencies, healthcare providers, payers (i.e. health insurers), public authorities, healthcare professionals, citizens, etc.).

Scope:

This CSA intends to create a network of public[57] and private procurers that are responsible for deploying health and care innovations across the EU, in order to identify potential areas of interest for innovation procurement and support the European Commission in building needs-driven investment opportunities.

This network should assemble a critical mass of European procurers with a strong track record, processes and resources for deploying innovative solutions in health and social care, as well as less experienced ones (due, for example, to budget constraints, lack of expertise or language barriers) who are interested to venture into this area. Through collaboration and experience

[57] Public procurers are organisations that are contracting authorities or contracting entities according to the definition of those terms in the EU public procurement directives 2014/24/EU, 2004/25/EU, 2009/81/EC.

sharing, the network should offer the opportunity to less experienced procurers in health innovation to build up capacity on innovation procurement.

The aim of this initiative is to help procurers coordinate Innovation Procurement initiatives in the area of health/care across Europe and build the capacity of its members, by disseminating innovation procurement instruments, exchanging best practices, preparing areas for future collaborative actions on innovation procurement and addressing potential regulatory hurdles within specific contexts.

These goals are particularly relevant in light of the Covid-19 pandemic, which highlighted issues such as the timing, financing and coordination of cross-border/emergency procurement in the EU, supply chain diversity and security or the contribution of digital solutions to the safety of patients, health professionals and citizens. The ongoing pandemic has demonstrated that new critical challenges for health and care systems may arise in the future, which will need to be addressed properly and swiftly, sometimes with innovative tools and flexible approaches.

Successful proposals should present a credible plan for a network that will:

- create a sustainable mechanism for decision-makers in the health care sector to enable and facilitate the use of Innovation Procurement as a tool to tackle current and future challenges faced by the procurers involved;

- develop a holistic innovation procurement action plan for key health and care challenges ahead, that is adaptable to the procurement strategies of most public organizations in the health and care sector in Europe and covering all stages of Innovation Procurement implementation (from the identification of a need until evaluation of the procurement's impact);

- facilitate and coordinate the procurement of R&D (including pre-commercial procurement) and the procurement of innovative solutions addressing existing public needs in the health / care sector by involving all relevant stakeholders in each stage of procurement implementation;

- set the ground for mainstreaming (cross-border) Innovation Procurement implementation in Europe's health sector (EU-funded or not), while engaging, in an appropriate way, other stakeholders who are important for Innovation Procurement activities in the health care area, such as: patients, healthcare providers, industry, policy makers (local, regional and/or national authorities) as well as investors (e.g. private investors, National Promotional Banks and Economic Development Agencies etc.).

The CSA should be composed primarily by beneficiaries that are public or private procurers that are interested in the purchase of health and care innovations. In addition, beneficiaries can

also include health authorities or innovation procurement competence centres that support these health and care procurers in implementing innovation procurements[58].

Proposals should not promote a silo mentality but should interconnect different types of procurers with their counterparts in other countries across Europe and with the wider healthcare/eHealth ecosystem and an enlarged group of stakeholders critical to the success of Innovation Procurement activities. Applicants should demonstrate that they have the in-house expertise and can engage key decision makers from their organisation (procurement departments, clinical, academic & research departments) who would provide the backbone for such an innovation procurement policy and coordination mechanism to operate effectively (e.g. leverage funds and externa expertise, recruit stakeholders, develop/adapt strategies, provide policy recommendations, facilitate emergency procurement procedures).

Activities supported by this CSA should include the following aspects:

- open market consultation with the industry across Europe on the current state of the art for the shared unmet needs for innovative solutions identified by the procurers, including on technical and service readiness;
- develop cooperation models for PCP and PPI implementation that overcome potential differences in legal public procurement framework for the participating procurers in health and social care;
- market analysis and proposed solutions to overcome potential barriers (standardisation, certification, regulatory requirements, intellectual property rights, contracting models, payment/reimbursement models);
- consultations with relevant stakeholders, end-users (consumer organisations, reimbursement bodies) to prepare for a future market uptake of the solutions;
- measures ensuring the sustainability of outcomes beyond the lifespan of the proposed project and their integration into the procurement strategies of participating organisations, taking into account acceptance with users and professionals as well as health economics considerations.

Call - Ensuring access to innovative, sustainable and high-quality health care (Single Stage - 2022)

HORIZON-HLTH-CARE-2022-08

[58] Innovation procurement competence centres are organisations /organisational structures that have been assigned the task by their government and have a mandate according to national law to encourage wider use of pre-commercial procurement (PCP) and public procurement of innovation (PPI) that includes among others providing practical and/or financial assistance to public procurers in the preparation and/or implementation of PCP and PPI procurements

Conditions for the Call

Indicative budget(s)[59]

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million)	Number of projects expected to be funded
Overall indicative budget				

Proposals are invited against the following topic(s):

HORIZON-HLTH-CARE-2022-08-01: Pre-commercial procurement for environmentally sustainable and low-carbon health and care systems

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2022**

Action type: PCP

[59] The Director-General responsible for the call may decide to open the call up to one month prior to or after the envisaged date(s) of opening.
The Director-General responsible may delay the deadline(s) by up to two months.
All deadlines are at 17.00.00 Brussels local time.
The budget amounts are subject to the availability of the appropriations provided for in the general budget of the Union for years 2021 and 2022.

- Market-ready sustainable innovative solutions (materials, technologies and systems/practices), support for their certification and commercialisation at a larger scale (EU/international) to ensure their validation in multiple countries and health and care settings;

- Harmonised approaches for environmental sustainability at EU level, including the promotion of sustainable procurement practices;

- Secure, interoperable digital health and care solutions, complying with relevant ethical and privacy protection standards, which are proven to improve health outcomes and equal access to care, as well as reduce pollution and expenses for health systems and citizens;

- Uptake and transfer of best solutions/practices; through competitive procurement procedures;

- Higher awareness of environmentally sustainable health practices among health practitioners, medical professionals and patients, within and outside health and care settings;

- Maximally efficient use of resources, without compromising the quality or safety of care for patients;

- Reduced environmental impact of the health and care sectors, through decreased carbon emissions, reduced waste and discharges, and efficient resource management.

Scope:

Health and care sectors, including materials suppliers and diagnostic laboratories, etc., contribute significantly to Europe's carbon footprint, and to the generation of large amounts of plastic and other waste, including waste containing toxic chemicals. Across the EU, there are about 15,000 hospitals that require energy for power generation, heating, lighting, ventilation, air conditioning, electrical equipment, transport and supplies.

Together with their supply chains, hospitals are estimated to account for roughly 5% of EU carbon dioxide emissions per year. Hospitals and other care establishments are also considered as hotspots for the discharge of pharmaceuticals and diagnostic chemicals as well as disinfectants and antimicrobial resistant pathogens into the waste water system. They also use large amounts of single-use products, including some plastic products that contain toxic substances (certain plasticisers).

It is clear that good hygiene and safety is vital in the settings described, but it may be possible to reduce the environmental impact of the activities by reducing resource use and introducing more efficient or “greener” materials, technologies and systems/practices. To address the challenges, this topic looks into pre-commercial procurement for environmentally sustainable and low-carbon health and care systems.

Pre-commercial procurement (PCP) actions in the area of health and care gather relevant public and private procurers to address their common needs through the cross-border public procurement of R&D for demand-driven innovative solutions. Specific guidance on PCP actions and minimum eligibility requirements can be found in General Annex I[60] of the Horizon Europe work programme.

A wide variety of settings are potentially relevant for the implementation of these innovative solutions, these can include but are not limited to primary healthcare settings, hospitals, specialised centres, and long-term health and care facilities. The involvement of end-users and the use of cross-sectorial approaches are highly recommended in the area of health. They can lead to more impactful proposals, especially if combined with cost-effectiveness/cost-benefit analyses in comparison with the status quo.

Research and innovation, demand-driven solutions and interventions can focus on a variety of challenges. Below there are some areas identified, but proposals are not limited to these, as long as solutions focus on challenges and opportunities that are specific to the health and care sectors.

- **Reducing health and care (including long-term care) sectors' carbon footprint**, through improving energy consumption and usage in heating, lighting, ventilation, air conditioning, electrical (including diagnostic) equipment, transport, supply chain, among others.

- **Adopting green healthcare solutions** (e.g. alternatives to plastics and single-use devices) and **reducing production of waste and contamination of the environment** due to health and care sectors by improving waste and waste water management, decreasing the use and disposal of hazardous chemicals, including through the use of alternative substances and technologies, and reducing the quantity of disposable equipment/materials used, including through the disinfection and re-use where safe and practicable of medical equipment, personal protection equipment (PPE) and consumables, not only in treatment but also in diagnostic procedures;

- Transfer of the concepts **"climate-neutral digital solutions" and "climate-smart" technologies to health and care settings**, as foreseen for example within the Pharmaceutical Strategy for Europe ("take advantage of digitalisation and make sure that innovation and emerging science and technology caters to the therapeutic needs of patients while reducing the environmental footprint"). Data-driven solutions should be explainable, unbiased and inclusive.

Within this topic, it is possible to foresee the transfer and adaptation of solutions and/or interventions from other sectors to health and care, as well as uptake of environmentally sustainable and low-carbon emission approaches within health and care systems. It is open both to proposals requiring improvements mainly based on one specific solution/technology field,

[60] Link not yet available

as well as to proposals requiring end-to-end solutions that need combinations of different types of innovation.

Applicants are encouraged to consider how their proposals can contribute in the context of the Green Deal for Europe, and to take into account the principles of the Circular Economy Action Plan[61] and of the Pharmaceutical Strategy for Europe[62]. Some specific activities that can be addressed include green public procurement practices[63] as well as some of the actions in the Strategic Approach to Pharmaceuticals in the Environment[64] and relevant actions to decrease impact of the health sector in climate change.

Proposals should demonstrate sustainability of the action beyond the life of the project. Activities covered could include cooperation with policy makers to reinforce relevant national policy frameworks and with stakeholders for standardisation purposes or in order to leverage additional national funds for procuring solutions.

HORIZON-HLTH-CARE-2022-08-02: Innovation procurement (PCP) for building the resilience of health and care systems in the context of recovery

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic:** 2022

Action type: PCP

61 Circular Economy Action Plan https://ec.europa.eu/environment/circular-economy/index_en.htm
62 Pharmaceutical Strategy for Europehttps://ec.europa.eu/health/human-use/strategy_en
63 Following the principles of Green Public Procurement or other relevant national/regional strategies is encouraged, see http://ec.europa.eu/environment/gpp/index_en.htm
64 Strategic Approach to Pharmaceuticals in the Environmenthttps://ec.europa.eu/environment/water/water-dangersub/pdf/strategic_approach_pharmaceuticals_env.PDF

- Contribute to mitigating the economic and social impact of the coronavirus pandemic and similar future health emergencies by making the EU health sector more sustainable, competitive, resilient and better prepared.

- Reinforce EU strategic autonomy and strengthen the security of the supply chain in the health care sector by procuring the competitive development of market-ready sustainable innovative solutions (materials, technologies and systems / practices) that are made in Europe and can improve the preparedness and resilience of health and care systems;

- Facilitate the commercialisation of innovative solutions at a large scale (EU/international) by providing fist customer references for the validation and first pilot deployment in multiple countries and health and care settings;

- Bring to the market secure, interoperable digital health and care solutions; complying with relevant ethical and privacy protection standards, which are proven to improve health outcomes and access to care;

- Facilitate the uptake and transfer of good practices and the best solutions the market can deliver to improve the resilience of health and care systems;

Scope:

Pre-commercial procurement (PCP) can boost innovation in health and care systems, while building the capacity of providers and increasing resilience and preparedness in the context of cross-border public health emergencies. Through the competitive development of a range of breakthrough innovations for a concrete healthcare challenge, PCP can strengthen the security of the supply chain in the health care sector. At the same time, these instruments can support the economic recovery of the EU by providing incentives to the EU health and technology industry (especially spin-offs, start-ups and SMEs) to innovate and commercialise their products or services at a larger scaler than they normally would. Fostering the development of such innovative solutions in Europe can reinforce EU strategic autonomy in strategic health technologies and lead to the creation of new markets for the EU industry, thereby contributing to EU growth, employment and competitiveness. At the same time, joint/collaborative demand-side initiatives can help create economies of scale and early adoption of innovations by the health sector. Advances in this area can help EU health and care systems build resilience and respond to public health threats better than if they would act individually.

Pre-commercial procurement actions in the area of health and care gather relevant public and private procurers to address a common, unmet need through the cross-border public and private procurement of R&D for demand-driven innovative solutions. Specific guidance on PCP actions and minimum eligibility requirements can be found in General Annex I[65] of the Horizon Europe work programme.

Proposals should therefore be based on clearly identified user needs and well-structured work plans, explaining how the procured R&D will contribute to the expected outcomes. In addition,

[65] Link not yet available

proposals should clearly state the expected health benefits of the solutions that will be developed during the course of the project. In this context, applicants should also consider aspects of accessibility and affordability of the solution, efficiency of the technology when implemented in the relevant contexts and how it contributes to health systems resilience.

This topic prioritises areas of health care such as health promotion, preparedness, prevention, surveillances and rapid response to cross-border health threats. Promoting coordination, cooperation and common standards in the procurement of innovation in health and care (including emergency procurement) should be at the heart of any proposal submitted as well as facilitating the digital and green transition of EU health systems.

A wide variety of settings are potentially relevant for the implementation of such innovative solutions, such as: primary healthcare settings, hospitals, specialised centres, and long-term health and care facilities. The involvement of end-users and the use of cross-sectorial approaches are essential in the area of health. They can lead to more impactful proposals, especially if combined with cost-effectiveness/cost-benefit analyses in comparison with the status quo.

Within this topic, it is possible to foresee the transfer and adaptation of solutions and/or interventions from other sectors to health and care, as well as uptake of environmentally sustainable and low-carbon emission approaches within health and care systems. It is open both to proposals requiring improvements mainly based on one specific solution/technology field, as well as to proposals requiring end-to-end solutions that need combinations of different types of innovation.

Proposals should demonstrate sustainability of the action beyond the life of the project. Activities covered could include cooperation with policy makers to reinforce relevant national policy frameworks and with stakeholders for standardisation purposes or in order to leverage additional national funds or private investment for procuring solutions.

Synergies with the Structural Reform Support Program and the European Structural and Investment Fund are encouraged (e.g. for wider deployment of the developed solutions).

HORIZON-HLTH-CARE-2022-08-03: Innovation procurement (PPI) for building the resilience of health and care systems in the context of recovery

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.

Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic:** 2022

Action type: PPI

- Market uptake of innovative solutions and transfer of best practices in Innovation Procurement which will contribute to the preparedness and resilience of health and care systems;
- Large-scale deployment – across EU borders – of market-ready sustainable innovative solutions (materials, technologies and systems/practices) that are relevant for the preparedness and resilience of health and care systems, through competitive procurement procedures;
- Mitigation of the economic and social impact of the coronavirus pandemic and similar future health emergencies by making the EU health sector more sustainable, competitive, resilient and better prepared.

Scope:

Public procurement of innovative solutions (PPIs) can boost the wider market uptake of high impact innovations in health and care systems, while building the capacity of providers and increasing resilience and preparedness in the context of cross-border public health emergencies. This can support the economic recovery of the EU by providing incentives to the EU health and technology industry (especially spin-offs, start-ups and SMEs) to innovate and by providing business opportunities to deploy innovative products or services at a larger scale than they would normally have. By acting as early adopters of such innovative solutions, procurers can open up new growth markets for the EU industry, thereby contributing to EU growth, employment and competitiveness. At the same time, joint / collaborative demand-side initiatives can help create economies of scale and scale up the wider adoption of innovations by the health sector. Advances in this area can help EU health and care systems build resilience and respond to public health threats better than if they would act individually.

The actions supported will target large-scale deployment of health and care solutions across different regions in Europe. The scope of this topic is to engage public and/or private procurers from each participating country (at national, regional or local level) that have deployment responsibilities and budget control in the relevant area of care or supply of services. Procurers will specify, purchase and deploy solutions addressing their shared unmet needs, while engaging also together in a supply and demand side dialogue, in order for the deployed solutions to deliver sustainable, new or improved health and care services and outcomes, always taking

into account patient feedback. Specific guidance on PPI actions and minimum eligibility requirements can be found in General Annex I[66] of the Horizon Europe work programme.

Proposals should therefore be based on clearly identified user needs and well-structured work plans, explaining how the procurement of the innovative solutions will contribute to the expected outcomes. In addition, proposals should clearly state the health benefits of the solutions that will be developed during the course of the project. In this context, applicants should also consider aspects of accessibility and affordability of the solution, efficiency of the technology when implemented in the relevant contexts and how it contributes to health systems resilience.

This topic prioritises areas of health care such as health promotion, preparedness, prevention, surveillances and rapid response to cross-border health threats. Promoting coordination, cooperation and common standards in the procurement of innovation in health and care (including emergency procurement) should be at the heart of any proposal submitted as well as facilitating the digital and green transition of EU health systems.

Activities covered should include cooperation with policy makers to reinforce the national policy frameworks and mobilise substantial additional national budgets for the PPIs, searching support and collaborating with respective coordination and networking projects. Likewise, awareness raising, technical assistance and/or capacity building beyond the project to mainstream PPI implementation and removing obstacles for introducing the innovative solutions to be procured into the market could be included.

A wide variety of settings are potentially relevant for the implementation of such innovative solutions, for example primary healthcare settings, hospitals, specialised centres, and long-term health and care facilities. The involvement of end-users and the use of cross-sectorial approaches are necessary in the area of health. They can lead to more impactful proposals, especially if combined with cost-effectiveness analyses in comparison with the status quo.

Within this topic, it is possible to foresee the transfer and adaptation of solutions and/or interventions from other sectors to health and care, as well as uptake of environmentally sustainable and low-carbon emission approaches within health and care systems. It is open both to proposals requiring improvements mainly based on one specific solution/technology field, as well as to proposals requiring end-to-end solutions that need combinations of different types of innovation.

Synergies with the Structural Reform Support Program and the European Structural and Investment Fund are encouraged.

HORIZON-HLTH-CARE-2022-08-04: Better economic foresight, financial planning and procurement/contractual strategies for health systems

Conditions related to this topic

[66] Link is not yet available

Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2022**

Action type: RIA

- Evidence-based and socially equitable health and care financial decisions;
- New approaches to health systems financial planning;
- Financing mechanisms that provide flexibility to stretched health budgets;
- Alternative procurement/contractual methodologies that allow for concession power from the demand side;
- Evidence–based evaluation of the impact of personal risk behaviour on healthcare costs
- Cost-effective spending strategies based on the optimisation of benefits packages without negatively affecting health outcomes;
- Improved systems and tools to remunerate/incentivise health and care workforce.

Scope:

In 2017 alone, spending on health care in the European Union stood at 9.6% of gross domestic product, ranging from over 11% in France and Germany to less than 6% in Romania. In most countries, inpatient care services made up the bulk of health spending, while spending on pharmaceuticals also accounted for a large share of health expenditure in some countries.[67]

Due to an increasingly older EU population with greater needs and higher expectations regarding health and care provision, public health threats with relevant repercussions for society

[67] Health at a Glance: Europe 2018 - STATE OF HEALTH IN THE EU CYCLE

and the uptake of innovative and digital solutions to improve healthcare, demand as well as budgetary pressures for health and care have and will keep increasing.

Therefore, research and innovation should tackle the challenges of financing health and care by addressing one or more of the following:

- **Economic modelling and foresight of health system's performance and sustainability** – modelling effectiveness, access, resilience and sustainability indicators in order to benchmark EU health systems versus each other and EU average; foresight at global, European, country and regional level; application of economic modelling and assessment to different indicators; inform where to invest and when;

- **Economics of financing health systems** – development of new models for primary care and secondary care financing, new incentive mechanisms and outcomes-based financing in order to avoid perverse incentives and promote good performance;

- **Financing of preventive healthcare** – novel models and financial incentives for effective health promotion and disease prevention at primary care level, financial incentives for stronger co-operation between primary care and public health services, long-term financing models for local/municipality-run promotion programmes in order to ensure that the funding of preventive care is not displaced due to its long-run timescales; also assessment of personal health risk behaviour and its potential impact on health costs;

- **Cost-effective healthcare delivery with focus on optimisation of benefits packages** – spending efficiently and delivering cost-optimized high quality services, for the projected benefits package can ensure that patients have access to the highest value for money.

- **New/improved cost-effective transparent procurement methodologies** – procurement (including innovation procurement) by health systems is a problematic area. On the one hand, there is a great deal of variation between the prices that different health system actors pay for the same item, which suggests there is potential for improvement. However, solutions such as centralised purchasing may have competition implications that could affect the supply chain and lead to shortages unless properly defined. There is therefore a need to understand these trade-offs and develop new procurement models that can potentially solve them, as well as ways of assessing and mitigating unintended consequences of the suggested practices;

- **Innovative purchasing methodologies** – new strategies for contracting provision of care (public sector hired services) as well as solutions to better assess capacity, to assess markets, and cost-effectiveness of contracting-out services. This can help align the incentives of providers with those of patients and the public good.

- **New/improved remuneration/non-financial incentives systems' structures and tools for better design of remuneration/non-financial incentives for human health resources** – foster better health and care planning, avoid overconsumption of health and care services and waste, minimise differentiation between services and minimise cream

skimming of patients. It can also comprise better ways of monitoring, assessing cost-effectiveness of models/mix-models, development of case studies on what does and does not work, including implementation of positive results.

Individual proposals are not expected to address all expected outcomes. More so, this topic intends to cover the different areas above mentioned, not in one single proposal, but in different proposals that cover at least one of the areas. Evaluation will select proposals in a portfolio approach manner, in order to ensure that the majority of the areas are included in the portfolio of proposals selected.

Research and innovation in these areas should take into account the impact of public health emergencies and threats on the sustainability, financing, as well as the effective and efficient functioning of EU health systems, by taking into account relevant factors (for example cross-border emergency procurement coordination, quality of supplies, access to and diversification of supply chains for medical products and solutions).

Applicants are highly encouraged to involve public authorities (i.e. ministers of finances and health, procurement agencies/procurers and agencies responsible for the management of health services contracts, public health and health policy institutes, health administrations, among other) in the proposals.

Call - Partnerships in Health (2022)

HORIZON-HLTH-CARE-2022-10

Conditions for the Call

Indicative budget(s)[68]

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million)	Number of projects expected to be funded
Opening: na				
Overall indicative budget				

Proposals are invited against the following topic(s):

[68] The Director-General responsible for the call may decide to open the call up to one month prior to or after the envisaged date(s) of opening.
The Director-General responsible may delay the deadline(s) by up to two months.
All deadlines are at 17.00.00 Brussels local time.
The budget amounts are subject to the availability of the appropriations provided for in the general budget of the Union for years 2021 and 2022.

HORIZON-HLTH-CARE-2022-10-01: European Partnership on Transforming Health and Care Systems - Placeholder

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2022**

Action type: Co-Funded Partnership

Destination 5. Unlocking the full potential of new tools, technologies and digital solutions for a healthy society

Technology is a key driver for innovation in the health and care sector. It can provide better and more cost-efficient solutions with high impact, tailored to the specific health and care needs of patients. However, novel therapies, technologies and approaches face specific barriers and hurdles in piloting, implementation and scale-up before reaching the patient and including societal issues such as technology acceptance or public outreach. In addition, several emerging disruptive technologies and the availability of vast amounts of data and digitalisation offer big opportunities for transforming health and care and promoting health and well-being of citizens. Unlocking these opportunities depends on the capacity to collect, combine and make sense out of vast amounts of data, on the availability of appropriate regulatory frameworks and data infrastructures that will both safeguard the rights of the individual and of society, and stimulate innovation to develop impactful solutions. European Health Data Space will promote health-data exchange and support research on new preventive strategies, as well as on treatments, medicines, medical devices and outcomes. Due consideration of aspects of safety, effectiveness, appropriateness, accessibility, comparative value-added and fiscal sustainability as well as issues of ethical, legal and regulatory nature will be crucial in order to translate these innovations into health policies, health and care systems, and clinical practice.

Expected impacts:

Proposals for topics under this Destination should set out a credible pathway to contributing to the following expected impacts of the Horizon Europe Strategic Plan:

- Europe's scientific and technological expertise and know-how, its capabilities for innovation in new tools, technologies and digital solutions, and its ability to take-up, scale-up and integrate innovation in health and care is world-class.
- Researchers, innovators and health care providers use health data and Artificial Intelligence (AI) supported decision-making in a secure and ethical manner, respecting individual integrity and underpinned with public acceptance and trust.
- Citizens benefit from targeted and faster research resulting in safer, more efficient, cost-effective and affordable tools, technologies and digital solutions for improved (personalised) disease prevention, diagnosis, treatment and monitoring for better patient outcome and well-being, in particular through increasingly shared health resources (interoperable data, infrastructure, expertise, citizen/patient driven co-creation). [69]

The following calls in this Work Programme contribute to this Destination:

69 Commission Communication on the digital transformation of health and care.

Call	Budgets (EUR million)Deadline(s)
HORIZON-HLTH-TOOL-2021-06 Tools and technologies for a healthy society (2021)	
HORIZON-HLTH-TOOL-2022-11 Tools and technologies for a healthy society (Single Stage - 2022)	
HORIZON-HLTH-TOOL-2022-12-two-stage Tools and technologies for a healthy society (Two Stages - 2022)	
Estimated total budget	

Call - Tools and technologies for a healthy society (2021)

HORIZON-HLTH-TOOL-2021-06

Conditions for the Call

Indicative budget(s)[70]

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million)	Number of projects expected to be funded
Overall indicative budget				

Proposals are invited against the following topic(s):

HORIZON-HLTH-TOOL-2021-06-01: Smart medical devices and their surgical implantation for use in resource-constrained settings

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

[70] The Director-General responsible for the call may decide to open the call up to one month prior to or after the envisaged date(s) of opening.
The Director-General responsible may delay the deadline(s) by up to two months.
All deadlines are at 17.00.00 Brussels local time.
The budget amounts are subject to the availability of the appropriations provided for in the general budget of the Union for years 2021 and 2022.

Expected Outcome: **Year of the topic: 2021**

Action type: RIA/IA

- Sustainable smart medical devices suitable for minimally-invasive implantation
- Surgical procedures adapted for smart active implants, compatible with resource-constrained clinical settings

Scope:

"Smart" technologies, i.e. micro-electronic sensor-/actuator systems provide novel functionalities to surgically-implanted active medical devices. "Smart" active implants open up therapeutic avenues for a wide range of medical handicaps, complex chronic conditions and lesions, thanks to their integrated diagnostic capabilities, and may help addressing hitherto unmet medical needs. Among the challenges involved in the development of these devices are e.g. miniaturization, sensor robustness, or wireless power supply, etc. Such devices require specific surgical implantation procedures, dependant on the type of device and on the intended use, with the successful surgical implantation and activation of such smart medical implants, being crucial steps for their functioning. The device targeted and its intended use is open for applicants to choose (e.g. orthopaedic, neural, cardiovascular, metabolic, etc.), but shall at the start of the proposed work be at a TRL of 4 and will necessitate appropriate tailored surgical procedures and interventions. Surgical conditions account for app. 30% of the global burden of disease and have a huge social and economic impact. However, of the 300 million surgical interventions undertaken every year only around 6% occur in low-income countries, where a third of the world's population lives. There is therefore a strong need for high-quality, affordable surgical intervention for implanting "smart" active medical devices suitable for resource-limited or -constrained clinical settings. To address this gap, the sustainability of both the medical device and the applied surgical intervention, including the necessary equipment and operating skills, are essential elements. Implantation procedures should be fully compatible with resource-constrained environments and minimally-invasive approaches should be favoured. Hence, R&I activities should comprise medical device design, regulatory work, clinical stages and developmental iterations, reaching a TRL of at least 7, and involve key medical specialists (e.g. surgeons) and/or other healthcare professionals, developers, patients and relevant regulatory bodies as appropriate.

Proposals shall meet the essential requirements as defined in the new EU legal framework on medical devices.

HORIZON-HLTH-TOOL-2021-06-02: Next generation advanced therapies to treat prevalent and high burden diseases with unmet needs

Conditions related to this topic

Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2021**

Action type: RIA

- Assay development for the valorisation and/or assessment of efficiency, delivery, safety, potency or mode of action of novel advanced therapy interventions based on either pluripotent stem cells, genome editing or RNA and which are aligned with regulatory standards
- Established pre-clinical efficacy of novel advanced therapies involving pluripotent stem cells, genome editing or RNA which are compliant with the appropriate regulatory requirements
- Several new advanced therapies based on pluripotent stem cells, gene editing or RNA are ready for testing in clinical trials for major diseases

Scope:

The recent development of advanced therapies has been hampered by the lack of robust research on certain key parameters e.g. safety, upscaling, immunity, potency assays, cost-effectiveness, and early on in development. This topic aims to ensure that the next wave of advanced therapies based on either pluripotent stem cells, gene editing or RNA, are established in a timely fashion and in accordance with the appropriate regulatory standards for further clinical testing. This topic will support preclinical research platforms for disorders with high prevalence and burden[71] that tackle the following bottlenecks currently encountered in the field and ensure that promising advanced therapies could reach the market within the next decade. Supported activities should include at least one of the following:

[71] As defined by www.who.int/medicines/areas/priority_medicines/en/

- Method development for the production and differentiation of pluripotent stem cells (defined as cells that can give rise to cells from all three embryonic germ layers[72]), to include defining appropriate potency assays. Complimentary activities to assess mode of action, safety, in vivo validation or upscaling procedures could be considered.

- Development and validation of biological assays and methods that can demonstrate efficacy, delivery, specificity, and safety (including off-target effects) of genome editing products in the targeted cells and tissues (e.g. base editing, prime editing, talens, zinc-finger nucleases, CRISPR).

- Development and validation of novel RNA-based therapeutics targeting non-communicable diseases. Complimentary activities to assess mode of action, delivery, safety in vivo validation or upscaling procedures could be considered.

- Study, analysis and tackling of immune responses generated by any of the above-mentioned advanced therapies in vivo, facilitating regulatory approval for next phase of research and development.

HORIZON-HLTH-TOOL-2021-06-03: Innovative tools for use and re-use of health data (in particular electronic health records and/or patient registries)

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2021**

Action type: RIA

- Novel solutions improving the quality, the interoperability and the re-use of health data and metadata from repositories across Member States, in particular electronic health

[72] Definition: Embryonic stem cells and induced pluripotent stem cells are pluripotent stem cells. www.nature.com/subjects/pluripotent-stem-cells

records and/or patient registries, in compliance with FAIR data management principles, and with national and EU legal and ethical requirements.

- Novel solutions using text mining, natural language processing and deep learning techniques to improve the accessibility and interoperability of health information from unstructured data existing in multiple and fragmented clinical repositories, to catalyse the integration of that data with electronic health records and/or patient registries and link them with other relevant data sources.

- Robust digital tools to improve the standardization of clinical data, especially data coming from different clinical services / sites and/or from multiple countries, and to make them accessible to clinicians and to researchers. Improvement of health data analytics by exploiting multiple data sources (in particular electronic health records (EHR) and/or patient registries).

- Availability of more and better standardised "meta" knowledge (meta data, ontologies and reference repositories) enabling findability and re-use of health data.

Scope:

Health data exists in many forms and multiple fragmented repositories; there is still significant room for improvement in the way both structured and unstructured health data is stored, analysed and interpreted. Sharing and analysing data from multiple countries in a safe and legally compliant manner remains a challenge. Powerful analytic tools are already helping providers to use structured data in increasingly impactful ways. On the other hand, the heterogeneity, diversity of sources, quality of data and various representations of unstructured data in healthcare increases the number of challenges as compared to structured data.

Advances in artificial intelligence and machine learning, however, have the potential to transform the way clinicians, providers and researchers use unstructured data.

Proposals should focus on developing robust novel solutions improving the quality, the interoperability, the machine-readability and the re-use of health data and metadata in compliance with FAIR data management principles, with a particular focus on electronic health records (EHR) and/or patient registries, to make these data more accessible to clinicians and to researchers. The purpose is to allow unlocking the potential of health data and information by enhancing its use and re-use which will improve the delivery of care and advance health research. Proposals should develop innovative natural language processing tools, including associated machine learning and deep learning, to improve the accessibility, the interoperability, the translation, the transcription, and the analysis of health data (e.g., to predict risks) with the purpose to extract health information from unstructured data contained in different clinical and medical sources and to bring that data into EHRs or patient registries in a structured form. Innovative solutions should facilitate a better integration between EHR and other data and data sources in accordance with data protection legislation. The innovative solutions should also address missing data in EHR and/or patient registries and their related metadata, to reduce bias and improve the quality of conclusions.

Proposals are also invited to develop AI-powered virtual assistants that will improve EHR and/or patient registries usability, and contribute to improved disease prevention, early detection, diagnosis, treatment and enhanced health research in particular in relation to personalised medicine (e.g., prediction of disease risk). Furthermore, as a result, more efficient and cost-effective healthcare procedures and workflows will be developed.

The use of open standards is encouraged. To guarantee their adoption, the developed solutions should be quick and easy to use by researchers and clinicians, therefore active involvement of end-users from the onset is encouraged when relevant.

Proposers should focus on health data (in particular EHR and/or patient registries) coming from a number of EU Member States and EEA countries which constitute a sample as representative of the European healthcare landscape as possible.

The proposals should duly take into account requirements stipulated in the European in-vitro diagnostics and medical devices regulation.

Patient advocacy groups/patients/citizens should be involved to ensure adequate consideration of patient needs and to underpin acceptance by patients and other data subjects.

Novel solutions must comply with national and EU legal (privacy) and ethical requirements.

Proposals are expected to build on and contribute to existing European and international data standards, specifications and schemas for health data. Developing data interoperability standards, trust and harmonization of GDPR's interpretation across the EU for the sharing and processing of personal health data should support establishing a sound health data culture in view of the European Health Data Space.

Appropriate links and interaction with relevant ongoing research infrastructure efforts concerning EU health data are encouraged.

SME participation is encouraged.

Call - Tools and technologies for a healthy society (Single Stage - 2022)

HORIZON-HLTH-TOOL-2022-11

Conditions for the Call

Indicative budget(s)[73]

[73] The Director-General responsible for the call may decide to open the call up to one month prior to or after the envisaged date(s) of opening.
The Director-General responsible may delay the deadline(s) by up to two months.
All deadlines are at 17.00.00 Brussels local time.
The budget amounts are subject to the availability of the appropriations provided for in the general budget of the Union for years 2021 and 2022.

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million)	Number of projects expected to be funded
Opening: na				
Overall indicative budget				

Proposals are invited against the following topic(s):

HORIZON-HLTH-TOOL-2022-11-01: Optimising effectiveness in patients of existing prescription drugs, with the use of biomarkers, for major diseases (except cancer)

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2022**

Action type: RIA

- Patient stratification using clinically validated biomarkers for personalised medicine.
- Available companion diagnostics
- Better and more cost effective use of existing drugs, with better efficiency and less adverse effects in patients

Scope:

The applicants should perform the clinical validation of qualified biomarkers (not limited to molecular biomarkers) that will enable the identification of appropriate patients to ensure an effective and efficient use of existing pharmaceuticals in the treatment of major diseases and conditions. The relevant biomarkers should allow providing the right medicinal product, at the right dose and the right time, according to the concept of personalised medicine. This topic refers to medicines that are already on the market and not to the validation of biomarkers for the development of new medicinal products. It addresses broadly prescribed medicines for major diseases and conditions, such as, but not limited to, cardiovascular diseases. A condition is that preliminary studies or publications have demonstrated that the pharmaceuticals considered are efficient in less than 50% of the population treated. This topic excludes cancer and rare disease treatments. The applicants should consider existing guidelines, standards and regulations, as appropriate. Synergies with relevant European Research Infrastructures are encouraged.

HORIZON-HLTH-TOOL-2022-11-02: New methods for the effective use of real-world data and/or synthetic data in regulatory decision-making and/or in health technology assessment

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2022**

Action type: RIA

- Optimised data-driven methodologies for the effective use of real-world data (including omics data)[74], and/or synthetic data from digital twins and advanced computational

[74] Real world data is an umbrella term for data regarding the effects of health interventions that are not collected in the context of highly-controlled RCTs. Instead, RWD can either be primary research data collected in a manner which reflects how interventions would be used in routine clinical practice or secondary research data derived from routinely collected data

methods (such as modelling & simulation or approaches based on machine learning / artificial intelligence) by health regulatory bodies and/or HTA bodies, for the assessment of medicinal products and/or digital health innovations.

- In addition to the methodological solutions, produce robust evidence showcasing the value of real-world data and/or synthetic data for healthcare regulatory decision-making and/or for health technology assessment, aimed at increasing the usability of this data in different use cases.

- Derive recommendations for optimised guidelines for health regulatory authorities and bodies (e.g., medicines agencies, HTA bodies, notified bodies for medical devices) for the development and assessment of medicinal products and/or medical devices including digital health innovations.

- Capacity building including training to enable data-driven decision making across Europe.

Scope:

With the emerging use of real-world data (RWD), synthetic data by the pharmaceutical industry and medical devices industry, regulators and health technology assessment (HTA) bodies need to perform targeted validation of claims through independent analysis. The principal aim of this topic is to address the data needs of health regulatory bodies and HTA bodies across the EU, as outlined in the recently published "HMA-EMA Joint Big Data Taskforce Phase II report: 'Evolving Data-Driven Regulation'" and its associated DARWIN (Data Analysis and Real World Interrogation Network) project.

To harness the potential of RWD and synthetic data from digital twins and advanced analytical models, and make them actionable for health regulatory decision-making and for health technology assessment, targeted research is needed on the evidentiary value of these data for a number of relevant use cases. In addition, methods need to be developed to increase the usability of such data by different stakeholder groups. Doing so will contribute to the European Health Data Space and maximise the positive impact of DARWIN in driving up the quality of evidence and decisions on the development and use of medicines and digital health innovations.

Access to and analysis of RWD, synthetic data can inform regulatory decision-making throughout the product lifecycle, and namely: 1) support product development (e.g. scientific advice, PRIME), 2) support authorisation of new medicines and digital health innovations and 3) monitor the performance of medicines and digital health innovations on the market (effectiveness and safety) and ultimately, if knowledge is fed into decision-making, enable a 'learning healthcare system'.

Successful proposals are expected to build a comprehensive approach to address the following objectives:

(https://www.ema.europa.eu/en/documents/presentation/presentation-session-1-use-real-world-data-pre-authorisation-what-can-it-answer-peter-mol_en.pdf)

1. **"Evidentiary value of RWD, and/or synthetic data in a number of relevant use cases"**

- Develop a set of evidentiary standards to be pre-specified and used in the analysis of real-word evidence and/or synthetic data applied to different types of regulatory advice and health technology assessment and decisions on the safety and efficacy/effectiveness of medicines and digital health innovations (e.g. in complement to clinical trial data in an authorisation application, or for extension of indications, post marketing surveillance, amendment to product information or regulatory actions on the marketing authorisation due to safety concerns). This includes validating the use of advanced analytical methods for regulatory decision-making and/or health technology assessment.

- Establish methods and processes to enable continuous learning from pre-authorisation procedures and authorisation applications on the use of RWD and/or synthetic data.

- Address aspects that would enable moving towards a standard data quality framework reproducible across different types of RWD and/or synthetic data sources, with a characterisation of the data collection, management and reporting and an empirical data quality validation. In this regard, it will be important to closely monitor the work in the context of the European Health Data Space.

1. **“RWD (Real World Data), and/or synthetic data use together with clinical trials data for efficacy and safety assessment”**

- Enhance the performance and efficiency of large randomised clinical trials and new models of clinical trials by developing standardised processes and methods to access RWD (e.g., facilitating the detection of various types of health outcomes during the treatment period of a double-blinded trial by linkage to appropriate electronic health care record databases, etc.).

- Define methodological standards for the regulatory acceptability of RWD, and/or synthetic data in the context of clinical trials augmented with RWD, and/or synthetic data.

3. **“Define and develop advanced analytical methods (including AI) and computational models”**

- Test the ability of machine learning methods to help identify relevant RWD, and/or synthetic data to match with and interpret clinical trials.

- Develop machine learning techniques that can help standardise and curate RWD and make them interoperable.

- Assess and validate how machine learning methods can be systematically harnessed to screen a large amount of data, including unstructured data, in many electronic databases to identify factors affecting efficacy and safety of treatments and/or digital health innovations. The cross-border interoperability dimension should be taken into account.

Successful proposals must involve researchers who are specialised in the use of real-world data and/or synthetic data to evaluate medicinal products and/or healthcare digital innovation products and services. Proven experience with national healthcare product regulatory bodies and/or medical device notified bodies is essential to determine what research questions need to be answered so as to bring medicinal and digital innovations to healthcare systems. Involving citizens and patients' representatives in the work is recommended where relevant.

The proposals should include capacity-building efforts to address inequalities of health regulatory processes across Europe. This should comprise training activities and the sharing of best practices.

In addition to national competent authorities, proposals could consider the involvement of the European Medicines Agency (EMA) as an added value in order to provide an effective interface between the research activities and regulatory aspects and/or to translate the research results into validated test methods and strategies fit for regulatory purpose. Additionally, the EMA will review all successful proposals and may join the projects in which their expertise would be best fitted and based on policy priorities.

Call - Tools and technologies for a healthy society (Two Stages - 2022)

HORIZON-HLTH-TOOL-2022-12-two-stage

Conditions for the Call

Indicative budget(s)[75]

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million)	Number of projects expected to be funded
Overall indicative budget				

Proposals are invited against the following topic(s):

[75] The Director-General responsible for the call may decide to open the call up to one month prior to or after the envisaged date(s) of opening.
The Director-General responsible may delay the deadline(s) by up to two months.
All deadlines are at 17.00.00 Brussels local time.
The budget amounts are subject to the availability of the appropriations provided for in the general budget of the Union for years 2021 and 2022.

HORIZON-HLTH-TOOL-2022-12-01: Computational models for new patient stratification strategies

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2022**

Action type: RIA

The proposals should aim to achieve an optimal combination of several of the following expected outcomes:

- Effective health-relevant data integration solutions for evidence-based classification of the clinical phenotypes
- Robust data-driven computational tools available for researchers and/or health care professionals to define clinically relevant sub-groups of patients
- Computer-aided patient stratification strategies to guide personalised diagnosis and/or personalised therapy development adopted by the end users
- Evidence-based guidelines for stratification-based patient management superior to the standard-of-care for the health care professionals
- Validated clinical decision support systems for improved clinical outcomes in personalised medicine

Scope:

In the era of big and complex data, the challenge remains to "make sense" of the massive amount of data accumulated in health research and care. Computational approaches hold great potential

to enable new patient stratification strategies superior to the established clinical practice, which in turn are a prerequisite for the development of effective personalised medicine approaches.

The proposals may include a broad range of solutions, such as computational disease models, computational systems medicine approaches, machine learning algorithms, Virtual Physiological Human and/or digital twin technologies and/or their combinations, as relevant. The topic covers different stages in the continuum of the innovation path (i.e. translational, pre-clinical, clinical research, validation in the clinical and real-world setting, etc.), as relevant to the objectives of the proposals.

The topic will support the development of the computational models driven by the end users' needs and the proposals should address an optimal combination of several of the following research bottlenecks:

- The establishment of interdisciplinary research by bridging disciplines and technologies (disease biology, clinical research, data science, computational and mathematical modelling of diseases, advanced statistical and/or AI/machine learning methods, Virtual Physiological Human and/or digital twin technologies)
- The development of new computational models for the integration of complex health-relevant data from multiples sources, including structured and unstructured data
- The development and optimisation of robust and accurate computational models with respect to improved clinical outcomes
- The demonstration, testing and clinical validation of such models with respect to their utility to improve the standard-of-care
- The development of new patient stratification strategies guided by computational models and the validation of the new concepts of stratification in pre-clinical and/or clinical studies

The proposals should adhere to the FAIR principles and adopt data quality standards, data integration operating procedures and GDPR-compliant data sharing/access best practices developed by the European research infrastructures, if relevant. In addition, the proposals are encouraged to adopt best practices of international standards used in the development of computational models.

Proposals aiming to develop computational models of high technology readiness level are encouraged to deliver a plan for the regulatory acceptability of their technologies. The early interaction with the relevant regulatory bodies is recommended (i.e. the EMA qualification advice for new technologies etc.) for the proposals contributing to the development of new medicinal products, improvement of the effectiveness of marketed products and the development of medical devices. The proposals aiming to validate their models as high-risk medical devices in the relevant clinical environment are encouraged to deliver a certification implementation plan.

The Commission will ensure an overall coordination mechanism between the projects funded under this topic to catalyse the exchange of knowledge as well as the development and adoption of best practices. Proposals are expected to budget for the attendance to regular meetings. In addition, the proposals will be encouraged to exchange with other successful proposals developing AI algorithms and in-silico models under other relevant topics.

Destination 6. Maintaining an innovative, sustainable & globally competitive health industry

The health industry is a key driver for growth and contributes to employment through high-value jobs and a positive trade balance, and has the capacity to provide health technologies to the benefit of patients and providers of health and care services in Europe and worldwide. The relevant value chains involve a broad variety of key players from supply, demand and regulatory sides. Therefore, there is a need for research and innovation encompassing and integrating various health technologies (medical technologies, pharmaceuticals, biotechnologies, digital health technologies) to strengthen the single market. In addition, the path of innovation in health is long and complex. The development of novel health technologies is generally associated with high risks.

Under Destination 6, the work programme will support those activities of the "Orientations towards the first Strategic Plan for Horizon Europe" that aim at:

- Novel methodologies and metrics adapted to new tools, technologies, digital solutions and interventions for their assessment, validation and translation into health care practice, including ethical aspects, their societal impact and integration into regulatory frameworks, and for allowing swift access by health care providers, patients and healthy citizens.
- Regulatory authorities supported with better methodologies and interdisciplinary approaches to assess new health technologies and interventions.
- Safe and clinically validated tools, technologies and services developed and delivered by European health industry that meet the needs of citizens, patients, health care providers and systems.
- Greener pharmaceuticals and health technologies.

Expected impacts:

Proposals for topics under this Destination should set out a credible pathway to contributing to the following expected impacts:

1. Health industry in the EU is more competitive, sustainable and growing, providing high-value jobs and contributing to economic growth, in particular SMEs, by tapping into new markets and providing European leadership in breakthrough health technologies and innovations.

2. Health industry in the EU, in particular SMEs, gain the ability to grow and reach a critical mass to develop innovative products and services and to tap into international value chains and international markets.

3. Citizens, health care providers and health systems benefit from a swift uptake of innovative health technologies and services offering significant improvements in health outcomes, while health industry in the EU benefit from decreased time-to-market.

4. Health industry is working more efficiently along the value chain from the identification of needs to the scale-up and take-up of solutions at national, regional or local level, including through early engagement with patients, health care providers, health authorities and regulators ensuring suitability and acceptance of solutions.

The following calls in this Work Programme contribute to this Destination:

Call	Budgets (EUR million)Deadline(s)
HORIZON-HLTH-IND-2021-07 A competitive health-related industry (2021)	
HORIZON-HLTH-IND-2022-13 A competitive health-related industry (2022)	
Estimated total budget	

Call - A competitive health-related industry (2021)

HORIZON-HLTH-IND-2021-07

Conditions for the Call

Indicative budget(s)[76]

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million)	Number of projects expected to be funded
Overall indicative budget				

Proposals are invited against the following topic(s):

HORIZON-HLTH-IND-2021-07-01: Green pharmaceuticals

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

[76] The Director-General responsible for the call may decide to open the call up to one month prior to or after the envisaged date(s) of opening.
The Director-General responsible may delay the deadline(s) by up to two months.
All deadlines are at 17.00.00 Brussels local time.
The budget amounts are subject to the availability of the appropriations provided for in the general budget of the Union for years 2021 and 2022.

Expected Outcome: **Year of the topic: 2021**

Action type: RIA

- Greener manufacturing process for active pharmaceutical ingredients and medical products to avoid shortages of medicines.
- Sustainable and competitive manufacturing process for pharmaceuticals.

Scope:

This topic is part of an EU strategic approach to pharmaceuticals in the environment, in particular as regards the promotion of greener pharmaceuticals and greener manufacturing (COM(2019) 128 final ;Section 5.2). The purpose of this topic is to help maintaining and bringing back pharmaceutical ingredients manufacturing process in the EU, while using the full potential of the climate transition and digitalisation. The applicants should consider both product quality, with less impurities to ensure the safety of the population, and European environmental manufacturing standards.

Proposals are expected to address the followings:

- Propose innovative manufacturing technology that are greener, low in energy consumption and emissions, using less solvent or recycling solvents;
- Propose methods for eliminating impurities in pharmaceuticals process;
- Explore innovative uses of digital transformation or robotic for competitive methods of production;
- Research and innovation to support the development of "greener" pharmaceuticals that degrade more readily to harmless substances in waste water treatment plants and the environment;
- Research on the eco-toxicity and environmental fate of pharmaceuticals, in particular those that are not yet subject to environmental risk assessment.

HORIZON-HLTH-IND-2021-07-02: New payment models for cost-effective and affordable health innovations/new models of pricing

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.

Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2021**

Action type: RIA

- Adoption of new payment models for health technologies, including pharmaceuticals;
- Accelerated uptake of innovative health technologies in health systems;
- Affordability of innovative health technologies both on short and longer terms;
- Equitable access to effective health technologies.
- Sustainable innovation

Scope:

Applicants are requested to propose new value-based pricing and reimbursement models that can help ensure equitable access to effective affordable and sustainable health technologies, including medicines, while supporting innovation and industrial competitiveness. The research should tackle the issue globally and be based on a multidisciplinary approach combining economic science, political science and sociology. The proposal should not be limited to the study of cost-effectiveness analyses and thresholds in decision-making. They should also address long term intended and unintended consequences of pricing and reimbursement decisions as well as the consideration of climate change mitigation. Moreover, they should consider the potential limitation of no-coverage decision for products with high budgetary impact. Applicant consortia should include regulators and public entities that are in charge of attributing value tags to health technologies, negotiating with health technology manufacturers and/or reimbursing medical costs.

The proposals are expected to address the following:

- Affordability of health innovations;
- Variety of pricing/payment schemes in the EU;
- Cost-effectiveness and budget impact (including life-time indirect medical costs);

- Impact of payment schemes (e.g. pay-for-performance / multi-annual instalments) on long term competition in health technology markets, in particular the pharmaceutical market;
- Potential influence of post-launce evidence-generation plans agreed with regulators and downstream decision makers (HTAs, payers) on the payment models;
- Transparent and comprehensive assessment of technology and medicine development costs, taking into account public investments and incremental character of some innovations (e.g. new indications);
- Development, integration and harmonisation of tools that allow for validation and revision of clinical evidence and cost-effectiveness, and long-term financial planning for effective and transparent decision-making;
- New methods for definition of cost-effectiveness thresholds, integration of greener production and environmental impact, rational applications in real world contexts, comparative analysis of influence in decision-making and influence in the formulation of prices of technologies.
- Potential equity issues derived by payment models and the measures for their mitigation

HORIZON-HLTH-IND-2021-07-03: Uptake of Technical specifications for "Quality and Reliability of Health and Wellness Apps" – promoting a trusted 'mhealth label' in Europe

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2021**

Action type: CSA

- Promotion and uptake of technical specifications for health and wellness apps by all involved actors

- Setting up of a digital ecosystem around a trusted mHealth label
- Accelerate uptake of mHealth solutions by health and care systems/authorities
- Increased levels of trust towards the use of health apps by the wider public, consumers, patients and health & care professionals
- Enhanced market conditions for mHealth that facilitate economies of scale for suppliers of technology and services
- Contribution to promoting common pan-European principles for validation and certification

Scope:

Europe is experiencing a fast growing market for Health and Wellness Apps. At the same time, concerns about the quality and reliability of apps have risen (for example, many health and wellness apps are being published on app stores without clinical evidence supporting the claimed benefits that they will deliver)[77]. CEN[78], together with CEN/TC 251, ISO and IEC, is developing a new Technical Specification for 'Quality and Reliability of Health and Wellness Apps' together with a CEN/ISO 82304-2 health app quality label (capturing medical safety, usability, safety of personal data and technical quality of health apps).

The objective of the Technical Specification is to define quality and reliability criteria, which support app developers to design and users of apps to select better apps.

The specification is intended for use by manufacturers of health apps as well as by app checkers in order to communicate the quality and reliability of a health app.

However, once developed, there will be a need to bring together app developers, health and care system representatives, users (citizens/patients, health and care providers) and certification bodies in order to promote and stimulate the use and up-take of the health app quality label, building a digital ecosystem around a trusted mHealth label to support the integration and use of Health and Wellness Apps in the health and care system.

Projects are expected to address the following:

- Set up a structured dialogue on the uptake of the Technical Specifications between app developers, health and care system representatives, app stores, medical societies, patient organisations, users (incl. health and care professionals) and certification bodies, building a digital ecosystem around a trustable mHealth label.

[77] https://ec.europa.eu/digital-single-market/en/news/green-paper-mobile-health-mhealth

[78] http://www.ehealth-standards.eu/quality-reliability-for-health-and-wellness-apps/due to be completed in 2020

- Co-create, develop and implement an action plan on the promotion of the mHealth label in the health and care system.
- Implement concrete actions on the integration and use of secure and qualitative Health and Wellness Apps, using the new label, in specific health and care settings, covering the entire European Union.
- Support and set-up an inclusive dissemination strategy to promote the use of the health app quality label (cfr. EU energy labels and EU Nutri-Score nutrition label) taking into account the different levels of digital health literacy among the involved actors.

Call - A competitive health-related industry (2022)

HORIZON-HLTH-IND-2022-13

Conditions for the Call

Indicative budget(s)[79]

Topics	Type of Action	Budgets (EUR million)	Expected EU contribution per project (EUR million)	Number of projects expected to be funded
Overall indicative budget				

Proposals are invited against the following topic(s):

HORIZON-HLTH-IND-2022-13-01: Enhancing Cybersecurity of connected Medical Devices

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.

[79] The Director-General responsible for the call may decide to open the call up to one month prior to or after the envisaged date(s) of opening.
The Director-General responsible may delay the deadline(s) by up to two months.
All deadlines are at 17.00.00 Brussels local time.
The budget amounts are subject to the availability of the appropriations provided for in the general budget of the Union for years 2021 and 2022.

Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2022**

Action type: RIA

- Stakeholders apply measures to identify and address cybersecurity risks and gaps in connected medical devices.
- Stakeholders adopt and use newly developed risk benefit analysis schemes and capabilities for cybersecurity of connected medical devices.
- Stakeholders adopt and use newly developed methodologies and toolboxes for ensuring cybersecurity of connected medical devices by design.
- Stakeholders adopt and use newly developed fit for purpose guidance covering challenges posed by connected medical devices, including software.
- Assessment of the applicability (and revision) of current guidance, the MDCG 2019-16 - Guidance on Cybersecurity for medical devices[80], to connected medical device, including software.

Scope:

The proposals are expected to help strengthening cybersecurity maintaining the performance of medical devices while preserving or enhancing safety, security and data confidentiality and integrity. The applicants should tackle the cybersecurity issue of connected medical devices and *in vitro* diagnostic medical devices, in particular those that are connected to the internet, allow remote access to data and exchange private or proprietary data. They should also consider the implications of Regulation (EU) 2017/745[81] on medical devices and Regulation (EU) 2017/746[82] on *in vitro* diagnostic medical devices regarding qualification and classification of software. In their proposals, applicants should consider to maximise synergies with other on-going initiatives/activities and integrate knowledge generated in current and past national, European and international projects.

[80] https://ec.europa.eu/docsroom/documents/41863
[81] OJ L 117, 5.5.2017, p. 1–175
[82] OJ L 117, 5.5.2017, p. 176–332

Proposals are expected to address the followings:

- Systematic review of current standards/guidelines/best practices applied to cybersecurity of connected medical devices, with the final objective to identify and specify gaps and requirements based on evidence.
- Propose risk benefit analysis schemes for cybersecurity of connected medical devices, taking into account several novel technological developments (e.g. 5G networks, big data, artificial intelligence, cloud computing, augmented reality, blockchain) and interconnection architectures.
- Explore, develop and validate novel methodologies and toolboxes for ensuring cybersecurity of connected medical devices by design.
- Identify representative case studies, evaluate the applicability of existing guidance MDCG 2019-16 - Guidance on Cybersecurity for medical devices and make recommendations to (better) address specificities of the connected medical device, including software, of different risk classes.

HORIZON-HLTH-IND-2022-13-02: Scaling up multi-party computation, data anonymisation techniques and synthetic data generation

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2022**

Action type: RIA

- European standards for health data (including medical imaging data) and strong European contribution to global standards for health data.
- GDPR compliant guidelines and rules for data anonymization

- Large uptake of advanced secure data processing tools by innovators to support researchers, clinicians and health systems at large.
- Reinforcement of the role of cross-border health data hubs as facilitators of innovations, in the respect of GDPR.
- Better data tools and services for wellbeing, prevention, diagnosis, treatment and follow-up of care.
- More opportunities for GDPR compliant data driven health research and innovation.

Scope:

Because the sensitivity of health data is a barrier to their access, which hinders the development of innovative products and services, the proposals should aim at scaling up multi-party computation, data anonymization techniques and synthetic data generation..

To ensure privacy, the data analytics should be conducted in a distributed way among processors that grants third parties access to analysis outcomes but not to the underlying data. The developers should make use of distributed testing data sources at large scale, with a view to improving the speed and robustness of multi-party computation solutions for innovators. The aim is to allow secure GDPR-compliant data processing for research, and clinical purposes.

The proposals should consider the use of synthetic, i.e. artificially generated, data as they allow researchers and developers to test, verify and fine-tune algorithms in large-scale data experimentations without re-identifiable personal data.

In addition, the proposed anonymization techniques will have to be sophisticated and robust enough to tackle the challenge of anonymized data sets that still make it possible to trace back to individuals.

The proposed solutions should help the development of secure, interoperable and trustable cross-border health data hubs that can facilitate the provision of the required testing environments for innovators. This should support the uptake of new data tools, technologies and digital solutions for health and care.

Integration of national/regional health data hubs/repositories/research infrastructures should be considered as appropriate.

Projects are expected to address the following:

- Consolidate and scale up multi-party computation and data anonymization techniques and synthetic data generation to support health technology providers, in particular SMEs.
- Support the development of innovative AI based and distributed tools, technologies and digital solutions for the benefit of researchers, patients and providers of health services, while maintaining a high level of data privacy.

- Advance the state-of-the-art of de-identification techniques, to tackle the challenge of anonymised datasets that can be traced back to individuals.
- Develop innovative anonymisation techniques demonstrating that effective data quality and usefulness can be preserved without compromising privacy.
- Explore and develop further the techniques of creating synthetic data, also dynamically on demand for specific use cases.
- Widen the basis for GDPR-compliant research and innovation on health data.

HORIZON-HLTH-IND-2022-13-03: Development and procurement of new antimicrobials

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2022**

Action type: Innovation partnership

- Availability of new antimicrobials in particular new antibiotics or their alternatives to the patients.
- Response to antimicrobial resistance.
- Catalysing market-based reforms by providing a pull incentive for antimicrobial development, while reconciling these incentives with responsible use.
- .
- Solving market failure, i.e. de-link profitability from sales volume.
- Strengthened antimicrobial R&D.

Scope:

The aim is to establish an innovation partnership as a pull incentive for new antimicrobials where there is an unmet medical need and a market failure. This would allow for the combination of development of new antimicrobials and procurement elements tailored to public health needs. It would catalyse the integration of science, technology and development with public health needs in new medicines.

The innovation partnership process takes place in three phases:

- The **competitive phase** takes place at the very beginning of the procedure, when the most suitable partner(s) are selected on the basis of their skills and abilities. The contracts establishing the innovation partnership are awarded using the criteria of the best price-quality ratio proposed.
- In the next phase, the partner(s) will develop the new solution in collaboration with the contracting authority. This **research and development phase** can be divided into several stages during which the number of partners may be gradually reduced, depending on whether they meet predetermined criteria.

In the **commercial phase**, the partner(s) provide the final results. Proposals of this topic should follow the specific requirements for Innovation partnership

Proposals are expected to address the followings:

- Emerging health threats, particularly that of Antimicrobial resistance (AMR), and identification of relevant public health needs in new antibiotics development.
- Market failures and the challenges of availability and accessibility of therapeutics.
- Development and purchase of new antimicrobials.
- Requirements of the innovation partnership process.

HORIZON-HLTH-IND-2022-13-04: Setting up a European Smart Health Innovation Hub

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.

Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.
Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2022**

Action type: CSA

Projects are expected to contribute to the following outcomes:

- Accelerating adoption of digital tools for empowering patients and citizens to monitor their health status independently;
- Building a strong ecosystem of innovators, including, for example, SMEs, Research and Technology Organisations (RTOs), accelerators, incubators, European Digital Innovation Hubs (EDIH), European Reference Sites of the EIP-AHA [83] and Knowledge Hubs, involving end-users
- Making European digital health companies, especially SMEs and mid-caps more sustainable and resilient through enhanced adoption of their innovations by public and private entities;
- Building a repository of digitally-enabled innovative solutions addressing all health related sectors, areas and segments, with particular focus on self-management and prevention.

Scope:

The EU has supported innovation of digital tools for better and more personalised treatment and self-monitoring of citizens and patients throughout Europe. However, adoption and deployment of digital health solutions in practice, both in the public health system and by private players remains low.

Building on the recommendations from the report of the Strategic Forum for Important Projects of Common European Interest[84], coordination and support is needed to i) create a pan-European operational network as a mechanism (a European Smart Health Innovation Hub) that can assess and promote Smart Health initiatives; ii) stimulate the demand-side and the uptake of Smart Health products and services; and iii) support the development of Smart Health products and services.

83

84 https://ec.europa.eu/docsroom/documents/37824

The coordination and support action addresses the need to bring together different actors, working on innovative digital health solutions and to reinforce their collaboration, exchange and efforts on scaling-up digital health solutions across Europe.

Various repositories of digital health solutions, which are already deployable, exist across different projects and initiatives. It is necessary to integrate them into a European Digital Health Smart Innovation Hub, which will serve as a European reference platform for scalable digital health solutions, both for public organisations and private actors.

Projects are expected to address the following:

- Promote transfer and exchange of best practices (such as twinnings) between different actors, such as SMEs, mid-caps, accelerators, incubators, RTOs, DIHs, EDIH, Reference Sites of the EIP-AHA and Knowledge Hubs – working on innovation of digital health solutions to exchange innovative practices, including training to end-users, e.g. citizens, patients, health and care providers,
- Promote scalability of digital innovation solutions by organising market places and pitching events to public health organisations and private actors,
- Integrating existing repositories into a sustainable European repository, serving as a reference of ready to market solutions (supply side) and public and private organisations adopting them (demand side), as well as best practices,
- Reinforce the European Smart Health ecosystem by enhancing collaboration and networking between the different actors working on digital health innovation across Europe.

HORIZON-HLTH-IND-2022-13-05: Uptake of European Electronic Health Record Exchange Format

Conditions related to this topic	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Award criteria	The criteria are described in General Annex D.
Legal and financial set-up for grants	The rules are described in General Annex G.
Financial and operational capacity and exclusion	The criteria are described in General Annex C.

Procedure	The procedure is described in General Annex F.

Expected Outcome: **Year of the topic: 2022**

Action type: CSA

- A validated and scalable infrastructure prototype based on the European Electronic Health Record Exchange Format (EEHRxF) functional and technical specifications and compliant with its principles, that significantly improves the development of interoperable cross-border digital health solutions for use by citizens, researchers, health services and the workforce across borders in the EU Digital Single Market, and supports tools and services related to the European Health Data Space.

- A set of representative, assessed and documented use case applications, demonstrating delivery of value for different target users, in a variety of medical domains and registries, involving advanced digital technologies such as AI.

- Specific contributions to further refine and validate the requirements, specifications and guidelines for the exchange of data relevant to the EEHRxF information domains (images, image reports, laboratory results, discharge letters etc.) at national and cross-border levels.

- A Pan-European ecosystem of early adopters comprising "all" digital health innovation stakeholders, involving both supply and demand sides, its Terms of Reference, Governance and Operations rules and procedures, as well as a well-defined framework for exploitation and further capacity building (including support such as training material, dedicated tools, guidelines, mentorship and collaboration programs for designers, developers, healthcare professionals, individuals, policy makers etc.)

- Improved level of accessibility, control and portability of health data for people, including donation for research, across Europe and jurisdictions.

- Strengthened interoperability of electronic health records and other health information across-borders and inter-institutional interoperability solutions;

- Substantiated recommendations for policy makers regarding potential evolutions of the above and their extension to other uses cases.

The proposal should provide appropriate indicators to measure the progress and achievement of the outcomes.

Scope:

Interoperability of Electronic Health Record is key for the exchange and the portability of health data in view of better health outcomes and treatments. The EU has supported projects to ensure cross-border sharing of health data and, in 2019, adopted a Recommendation on EEHRxF. There is a need to continue supporting the uptake of new use cases (i.e. Laboratory Results,

Medical Imaging and reports, and Hospital Discharge Reports) and take on board possible new requirements. For this, it is also important to bring together policy actors and stakeholders.

Projects are expected to address the following:

- Elaborate and implement an Action Plan for establishing and developing a scalable infrastructure for digital health innovation based on the EEHRxF principles and the functional and technical specifications of its information domains (i.e. medical imaging, discharge letters, laboratory results etc.). Extensions to the latter should be considered whenever deemed necessary. This infrastructure must provide a REST API[85] to third-party developers, which should comprise a coherent set of functionality that significantly improve the development and deployment of interoperable cross-border digital health solutions. It should specifically allow individuals accessing and providing their own (electronic) health records across national borders. The infrastructure must ensure compliance with the General Data Protection Regulation[86], the Network and Information Systems Directive[87] and the operation in a European Digital Single Market, including compliance with relevant regulatory governance frameworks. It should build on the Commission Recommendation on the European EHR exchange format[88] and outcomes of related activities and projects[89]. It should be guided by strong and systemic contributions for better data and better computational approaches to advance disease prevention and personalised medicine.

- Elaborate and implement an Action Plan for leveraging the above EEHRxF-based infrastructure to demonstrate feasibility of real-life interoperable digital platforms and solutions for use by citizens, researchers, health services and the workforce across borders in the EU Digital Single Market. Emphasis should be given to specific fields of high societal relevance and high prevalence. Omics type of information associated to the use and exchange of health datasets and artificial intelligence should be strongly considered with special regard to analysis and corresponding further health-related data. Integration with population-based patient registries such as cardiovascular disease, congenital anomalies, diabetes, rare diseases, and cancer are highly recommended. Relevant activities of the eHealth Network[90] should be taken into account. For all relevant data (e.g. from hospitals, doctors or user-generated) ethics and legal issues should be considered

85 https://joinup.ec.europa.eu/collection/api4dt

86 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation): http://eur-lex.europa.eu/eli/reg/2016/679/oj

87 Directive (EU) 2016/1148 of the European Parliament and of the Council of 6 July 2016 concerning measures for a high common level of security of network and information systems across the Union: http://eur-lex.europa.eu/eli/dir/2016/1148/oj

88 https://ec.europa.eu/digital-single-market/en/news/recommendation-european-electronic-health-record-exchange-format

89 E.g. from the H2020 topics PHC 34 – 2014, HCO-14-2016, HCO-15-2016, SC1-DTH-08-2018, SC1-HCC-07-2020.

90 https://ec.europa.eu/health/ehealth/policy/network_en

appropriately. Local, regional, national and cross-border aspects (to cover e.g. differences in languages and terminologies) should be given adequate consideration.

- Elaborate and implement an Action Plan for promoting and ensuring adoption of the EEHRxF-based infrastructure for digital health innovation by establishing and developing a Pan-European ecosystem of digital health stakeholders, involving both supply and demand sides, and reinforcing collaboration and networking between the different actors working on digital health innovation across Europe around that infrastructure. The latter should include innovation initiatives related to clinical research, clinical trial integration, outcomes-based research, monitoring or decision aids for individuals, and business analytics, as well as application designers and developers, SMEs, innovation hubs, national authorities and policy makers, professionals networks e.g. rare disease network, health professionals and patient associations, and standardisation bodies.

- Elaborate and implement an Action Plan for building capacity and enabling further exploitation of the infrastructure for digital health innovation through trainings to potential developers, dedicated tools, best practices guidelines, mentorship and twinning programs (including SMEs).

- The above should be aligned with other EU programmes and initiatives, specifically the European Health Data Space (EHDS) and the Digital Europe Programme (DEP).

Other Actions – Not implemented through regular Open Calls for Proposals [Placeholders - Not from CPS]

OA1 Call for tenders for: Studies, conferences, events and outreach activities- Placeholder

Year of the topic: 2021 and 2022

Action type: Call for tenders

OA2 CEPI 3 - Contribution to the Coalition for Epidemics Preparedness Initiative - Placeholder

Year of the topic: 2021 and 2022

Action type: Framework Partnership Agreement to Named Beneficiary

OA3 GACD Contribution to the Global Alliance on Communicable Diseases - Placeholder

Year of the topic: 2021

Action type: Operating Grant

OA4 European registry for human pluripotent stem cell lines

Year of the topic: 2021

A contribution for 5 years will be made to ensure the continued registration of human Pluripotent Stem Cell (hPSC) lines in a European registry. The aim is to gather and make available detailed information on the different hPSC lines derived in Europe and beyond, thereby also avoiding needless creation of new cell lines. This registry operates through an internet website that will continue to provide high quality data about the lines (e.g. cell characteristics), details regarding their source and contact information regarding their location.

Legal entities: FRAUNHOFER GESELLSCHAFT ZUR FOERDERUNG DER ANGEWANDTEN FORSCHUNG E.V.

Type of Action: Grant to identified beneficiary - Coordination and support actions

Indicative budget: EUR *** million from the 2021 budget

OA5 Responding to Public Health Emergencies - Placeholder

Year of the topic: 2021 and 2022

Action type: RIAs/IAs and CSAs based on Calls for Expression of Interest

OA6 Contribution to EDCTP – Depending on progress of the Institutional Partnership Placeholder

Year of the topic: 2021

Action type: CSA

OA7 Operating grant for the Human Frontier Science Program Organization

Action type: Operating Grant - Subscription

An annual subscription to the international Human Frontier Science Program Organization (HFSPO)[91] will allow researchers from EU non-G7 Member States to fully benefit from the Human Frontier Science Program (HFSP) and contribute to the implementation of the Union's strategy for international cooperation in research and innovation.

Duration: 12 Months

Legal Entity: HFSPO (***)

Type of Action: Subscription – Operating grant

Indicative budget: EUR *** million from the 2021 budget and *** million from the 2022 budget.

Indicative timetable: 2021 and 2022

Placing to be decided - Support to cross-fertilisation of the NCP Health network of contact points - Placeholder

Year of the topic: 2021

Action type: CSA

[91] The European Commission is a member of the HFSP Organization (HFSPO) and has funded HFSP under previous Framework Programmes