Cluster 1 – Health

Topics WP 2023-2024

Draft Vs.2.1

This file contains draft topics of the Health Cluster WP by Destinations for information of the Health Programme Committee – February 2022[1]

Contents

[1] Nota Bene - Topic codes are used for interaction within the Health Cluster Group and the Health Programme Committee. They do not prejudge of final numbering or call structure.

Destination 1. Staying healthy in a rapidly changing society

Topics 2023

HORIZON-HLTH-2023-STAYHLTH-1.01: The Silver Deal - Person-centred health and care throughout the EU

Single-stage

Action type: RIA

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several impacts of destination 1 "Staying healthy in a rapidly changing society". To that end, proposals under this topic should aim for delivering results that are directed at, tailored towards and contributing to most or all of the following expected outcomes:

1. Citizens, businesses and public institutions will better anticipate and manage the implications of demographic, social and technological changes on health care systems, long-term care, public spending and the world of work. Mental and physical wellbeing, quality of life and healthy lifestyles will be promoted, with a range of interventions and integrated approaches, including nutrition and physical activity, adaptation of work and workplace, health-promoting age-friendly working, home and community environments, better equality of access to health and care services enabled by community-based and integrated care solutions, also digitally enabled.

2. Primary health care and health promotion services will be better equipped to early identify people at risk of developing non-communicable diseases (NCDs) and multi-morbidities, and they will have cost-effective intervention tools to help prevent progression of diseases and promote healthy lifestyles and mental wellbeing among the elderly.

3. Physical health, mental wellbeing and health literacy will be enhanced among older people in order to reinforce their resilience vis-à-vis the increasing inequality of access to health and care, societal changes and digitalization of society and health systems. Older people will be empowered to take an active role in the management of their own physical and mental health through better health literacy, educational programmes, trainings and platforms, also digitally enabled. Vulnerability, loneliness, isolation and limited social interaction of the ageing population will be reduced by improved health literacy and better connectedness.

4. Citizens, all relevant stakeholders, public authorities, cities and rural environments, as well as health care providers will be engaged to ensure the introduction to and the integration of age-friendly, mental and physical health promoting innovative solutions into the daily life of the ageing population. Such solutions could include, but are not limited to: integrated care solutions, connected wearables, ambient sensors,

social robots, assistive technologies, diagnostic screenings, self-monitoring devices and robotics.

5. Citizens and patients will get effective, preventive, integrated and people-centred high-quality health and care services to tackle or prevent multi-morbidities, frailty, biologically or mentally reduced capacities, impairments, dementia and/or neurodegeneration. This should include biomedical research and innovation on older age related diseases and treatments, novel tech-based solutions, assistive devices, the validation of early markers for lifetime developments, digital nutrigenomics, the facilitation of the elderly self-management and the monitoring of functional, cognitive and physical capacities during ageing.

The proposals should provide appropriate indicators to measure performance and progress towards the relevant expected outcomes.

Scope:

In 2021, the European Commission adopted a Green Paper on Ageing[2] and published a Long-term care report[3], calling for an EU wide policy action to address demographic change, including by a new EU Care Strategy[4]. In the last five decades, life expectancy at birth has increased by about ten years for both men and women. The demographic profiles of EU regions vary widely, notably between urban and rural areas, with some places ageing significantly. Today's median age in Europe is 42.5[5]. This has implications for economic growth, fiscal sustainability, health and long-term care, wellbeing and social cohesion. In addition, the COVID-19 pandemic's disproportionate impact on older people – in terms of hospitalisations and deaths - has highlighted some of the challenges an ageing population poses on health and social care. On the other hand, the ageing population is also an asset of knowledge and experience. Ageing thus provides new opportunities for creating new jobs, fostering social fairness and boosting prosperity, for instance in the 'silver' and care economies.

In the context of the UN 2030 Agenda for Sustainable Development and the UN Decade for Healthy Ageing, the EU must develop a holistic approach to staying healthy and active in a changing society. The EU has adopted Council Conclusions on Mainstreaming ageing in Public policies[6], *Council Conclusions* on the Human rights and participation of *older people* in the *digital* era[7] and the Green Paper on Ageing. The EU launched on 15 December 2021 the "Healthier Together" – EU Non-Communicable Diseases Initiative[8] that includes five strands: cardiovascular diseases, diabetes, chronic respiratory diseases, mental health and neurological disorders, and health determinants. Currently the European Commission is

[2] https://ec.europa.eu/info/sites/default/files/1_en_act_part1_v8_0.pdf
[3] https://ec.europa.eu/social/main.jsp?catId=738&langId=en&pubId=8396
[4]https://www.europarl.europa.eu/legislative-train/theme-promoting-our-european-way-of-life/file-european-care-strategy
[5] https://ec.europa.eu/info/sites/default/files/1_en_act_part1_v8_0.pdf
[6] https://data.consilium.europa.eu/doc/document/ST-6976-2021-INIT/en/pdf
[7] https://data.consilium.europa.eu/doc/document/ST-11717-2020-INIT/en/pdf
[8] https://ec.europa.eu/health/non-communicable-diseases/overview_en

working on a new EU Care Strategy[9], striving to enable better health and care for our growing ageing societies, and exploit the potential of the Silver Economy[10].

The EU population is vulnerable and the resilience of citizens should be reinforced vis-à-vis rapid societal changes, increasing digitalization of society and health and care systems. New cost-effective, integrated solutions for elderly care systems and services should be taken into account. Informing policy makers about the importance of addressing health challenges, such as frailty, balance disorders, falls prevention, muscular-skeletal disorder prevention, early detection of diseases, dementias, multi-morbidities, social and mental isolation is of utmost importance.

Whilst primary care is crucial for people at high risk of developing NCDs, the sector currently does not have the optimal tools to fully exploit its potential for early detection and more effective interventions for promoting health and preventing NCDs. New tools and care models are needed that reinforce primary care in preventive health care through better early detection linked with improved risk management, digital technologies, occupational health aspects, patient participation and empowerment, incentives, wellbeing and integrated, community-based sustainable health and care approaches. In order to advance research, innovation and implementation, this action should build further on past initiatives funded under Horizon2020 and avoid duplication of past Research and Innovation results. The participation of small and medium-sized enterprises (SMEs), as well as of European, national and regional authorities and civil society is encouraged, in order to: 1) strengthen the scientific and technological expertise of SMEs in the health and care domain; 2) strengthen the European Health- and Age-Tech; and 3) improve the uptake of digitally enabled health and care solutions in the EU.

The proposed research and innovation should focus on most or all of the following aspects:

- Consolidate effective and digitally enabled person-centred 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 as people age. Promote holistic independent-living, prevention and integrated care solutions, with a focus on the physical and mental health of older people, building on use cases and applications, resulting from past and ongoing actions, such as the EU-funded large-scale pilots on Active and Healthy Ageing[11], or EU-funded R&I actions on frailty, chronic diseases and dementia.

- Provide new approaches for effective and person-centred health services and care around people's needs for increased physical and mental resilience vis-à-vis the

[9] https://www.europarl.europa.eu/legislative-train/theme-promoting-our-european-way-of-life/file-european-care-strategy

[10] A new multi-policy approach is recommended by the "Silver Economy Study": the ageing population promises more economic growth and jobs. https://ec.europa.eu/digital-single-market/en/news/silver-economy-study-how-stimulate-economy-hundreds-millions-euros-year

[11] https://www.opendei.eu/healthcare-sector/

influence of commercial determinants of health, societal changes and digitalization of society, including health systems, also through improved digital health literacy.

- The applicants should ensure that the developed solutions, technologies and adopted policies are driven by the needs of citizens and patients of old age and ensure their involvement. Co-creation, co-design and particular consideration of the diversity of the needs, mental and physical abilities, living and socio-economic conditions as well as life-situations of older people are required, including provision of formal/informal training for carers and the workforce.

- Deliver enhanced collaboration and a multi-policy approach for the adoption of affordable, advanced solutions and assistive technologies for the variety of problems and challenges of demographic changes, in particular for the ageing population. Build on advancements made in European[12] and in international cooperation in the domain, such as EU-Japan[13] and EU-Canada.[14]
- Support solutions that are close-to-market (TRL 6-7 or higher) in one of the health areas associated with ageing mentioned above and that have already received, or are about to receive, the conformity assessment (CE marking) to proceed to large scale testing, piloting and deployment operations in health and care areas related to older people.

- Support market innovation (from lab-to-fab) for further developing and maturing innovative solutions that have already been validated in lab environments with the aim to help accelerate developments and achieve conformity assessment (CE marking) and towards a broader use in the EU.

- In order to improve the broad and sustainable uptake of results, the proposal should ensure cross-regional collaboration, exchange of best practices (Twinnings) and coordination with existing initiatives on European, national and regional level and make use of reference architectures, solutions for interoperability, use cases and data schemes, if available. Such initiatives include the European Innovation Partnership on Active and Healthy Ageing (EIP on AHA)[15], the Reference Sites Collaborative Network (RSCN)[16], the Active and Assisted Living Programme (AAL)[17], More Years Better Lives (MYBL)[18], AI-Testing and Experimentation Facility in Health[19], EC funded Horizon2020 projects and others. The proposal should also build further on the achievements of the EC-funded large-scale pilots on Active and Healthy Living[20].

[12] https://digital-strategy.ec.europa.eu/en/policies/eip-aha and http://www.aal-europe.eu/
[13] International cooperation EU-Japan: Digital health and ageing Smart living environments for ageing people. September 2021; DOI: 10.2759/13059; Luxembourg: Publications Office of the European Union: ISBN 978-92-76-38187-7
[14] https://idih-global.eu/
[15] https://digital-strategy.ec.europa.eu/en/policies/eip-aha
[16] http://www.rscn.eu/
[17] http://www.aal-europe.eu/
[18] https://jp-demographic.eu/
[19] https://digital-strategy.ec.europa.eu/en/activities/testing-and-experimentation-facilities
[20] https://www.opendei.eu/healthcare-sector/

- Coordinate existing national and regional initiatives and ongoing efforts with the intention to assess their performance and outcomes, inform and involve policy makers, facilitate mutual learning, reduce the fragmentation, change ineffective patterns and develop a more comprehensive, common policy approach for the benefit of the European ageing society.

This topic addresses consortia including innovative technology providers, including SMEs, and/or organisations that can offer the range of activities required to address the objectives of the topic; the latter could for example be based on Digital Innovation Hubs, digital health accelerators and knowledge hubs, Centres offering Pilot Lines or similar technology, business and/or knowledge transfer organisations. The innovative technology providers can be either members of the applicant consortium or selected through open calls organised by the consortium using financial support to third parties. The support offered could include access to product development, accelerator, incubator and technical services and capabilities such as testing and experimentation facilities together with expertise, prototyping, design, engineering or pilot manufacturing services as necessary, as well as providing support for medical certification and clinical validation. Any use of third party grants must result in minimal administrative burden for participants, and allow the fastest possible launch and progress of the project.

The proposal(s) should be highly integrated, ambitious, go beyond simple networking and provide appropriate indicators to measure progress, impact and adoption in the EU. Dissemination and involvement of policy makers, both at national and regional level, as well as civil society organisations in an EU wide geographical balanced matter is essential, as the results of this action are expected to have an EU wide impact. Joint activities could include joint workshops, the exchange of knowledge, the development and adoption of best practices and adoption strategies on regional, national and European level. The details of these joint activities will be defined during the grant preparation phase with the European Commission.

HORIZON-HLTH-2023-STAYHLTH-1.02: Towards a holistic support to children and adolescents' health and care provisions in an increasingly digital society

Single-stage

Action type: RIA

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several impacts of destination 1 "Staying healthy in a rapidly changing society". To that end, proposals under this topic should aim for delivering results that are directed at, tailored towards and contributing to most or all of the following expected outcomes:

1. Children, adolescents and their parents/carers are educated, empowered and use digital tools for managing their own health (physical and mental) and well-being (including social), in full respect of the privacy of individuals.

2. Children and adolescents monitor their health risks, adopt healthy lifestyles at home, at school and in the community and interact with their doctors and carers (receiving and providing feedback). The impact of COVID on psychiatric conditions in the young population becomes visible and manageable.

3. Thanks to better co-creation, training and (digital) health literacy, children, adolescents, parents and carers across the EU access, adopt and use person-centred, widely disseminated, digitally enabled health and care solutions, with specific focus on children and adolescents' wellbeing.

4. Children, adolescents and their parents/carers are digitally empowered to allow the transition from a disease-based approach to a preventive and systems approach with a greater involvement of non-health sectors directly affecting risk factors, determinants of health, including environment, food, safety and physical activity.

The proposal should provide appropriate indicators to measure the progress towards the relevant expected outcomes.

Scope:

The aim is to promote healthier societies in line with the HealthyLifestyles4All Initiative[1], and the Communication of the Commission on enabling the Digital Transformation of Health and Care[2] [3]. Laying the ground for a healthy life starts already in childhood. Therefore, the objective is to develop solutions that foster healthy lifestyles in early age but with a perspective to have a long-term impact.

Digital technologies pose risks but can also be a driving force for empowering citizens in taking an active role in the management of their own health and well-being, as well as supporting innovations for coordinated person-centred care models. Children and adolescences are becoming highly skilled in using digital tools, growing up in an increasingly digitised world and there is an opportunity to provide them and their parents with advanced person-centred solutions to help them manage their health conditions, mental health and promote healthy lives and disease prevention. In addition, it is vital to promote better health literacy among children, adolescents and their parents/carers, including with the help of digital tools.

The proposed research and innovation should focus on several aspects:

1. Develop innovative, privacy preserving tools and technologies, such as (but not limited to) activity trackers, sensors, platforms and robotics, Massive Open Online Courses (MOOCs), to help children and adolescents to better monitor and manage

their physical and mental health (including addressing potential effects of social media and psychiatric impact of COVID), as well as lead healthy, social and active lifestyles and prevent diseases.

2. Help children and adolescents navigate the healthcare systems, interact with their doctors, formal and informal carers, as well as better manage their own health at home, in the community and at school, taking into account specific youth psychiatric risk factors as well as the geographic, social and economic determinants of digital health literacy inequities.
3. Stimulate the adoption of person-centred approaches and digitally enabled solutions for better health and care of children and adolescents, by including stakeholders from all the relevant sectors (including but not limited to education, leisure, social innovation, healthcare, Medtech, media and citizens) in the co-creation, design, planning and adoption of the tools.
4. Provide evidence-based guidance for children and adolescents in finding a healthy balance between an inactive digitised time spending and a more active non-digitized lifestyle in support of their overall health on short- and long-term basis.

In all instances, gender as well as demographic, geographic and socio-economic aspects should be duly taken into account.

Proposals should be highly integrated, ambitious, go beyond simple networking and provide appropriate indicators to measure progress and impact. The long-term impact of COVID on psychiatric conditions should be made transparent for specific risk factors.

Selected projects under this topic are strongly encouraged to participate in joint activities as appropriate. These joint activities could, for example, take the form of clustering of projects and involve joint coordination and dissemination activities such as the participation in joint workshops, the exchange of knowledge, the development and adoption of best practices and adoption strategies on regional, national and European level. The details of these joint activities will be defined during the grant preparation phase with the Commission.

[1] https://sport.ec.europa.eu/healthylifestyle4all
[2] https://digital-strategy.ec.europa.eu/en/policies/ehealth
[3]https://digital-strategy.ec.europa.eu/en/library/communication-enabling-digital-transformation-health-and-care-digital-single-market-empowering

HORIZON-HLTH-2023-STAYHLTH- 1.04: Improving population level screening strategies and programmes for non-communicable diseases

Single-stage

Action type: CSA

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several impacts of destination 1 "Staying healthy in a rapidly changing society". To that end, proposals under this topic should aim for delivering results that are directed at, tailored towards and contributing to most or all of the following expected outcomes:

- Healthcare providers and public health authorities have access and implement recommendations on best practices, analysis of the potential of new methods and can integrate specific screenings into a lifelong monitoring scheme for individuals.
- Member States receive recommendations that are used for the identification of risk groups to ensure detection at the right time or more frequent testing and which individuals are less at risk and do not need certain tests.
- Individuals at high risk of developing particular diseases have better access to screening programmes at appropriate age and frequency.
- Individuals at low risk of developing particular diseases will not need to undergo certain screenings or less often.
- Operators of screening programmes for different age groups and different disease areas gain insight and implement existing practice of various other programmes.
- Health authorities adjust their strategies to optimise use of funds for screening programmes.

Scope:

Early diagnosis of disease by (sub-) population wide screening programmes is an important factor in reducing disease burden, improve health and save lives. Many screening efforts are undertaken in different countries, from perinatal screenings to screening for particular cancer types (breast, cervical, colon).

Progress is being made in several fields that can be translated into new screening programmes in the future. This is particularly evident in the areas of rare diseases, cancer and complex diseases. Further development is to be expected in the frame of projects funded under the Cancer Mission and the new partnerships for rare diseases and for personalised medicine.

The purpose of this coordination and support action is to assess and modernise evidence-based, tested and ready to implement non-communicable diseases (NCDs) screening strategies. This should be prepared and supported by the health authorities, the research community and the relevant stakeholders by analysing the existing opportunities for rolling out new and/or refined population-based screening programmes for NCDs across the EU and exploring the current and future needs for new programmes.

The focus will be on exploring new avenues for screening and making recommendations for coordination among the authorities and actors involved in screening programmes at different ages and for different disease areas. Furthermore, to recommend ways to expand screening to new disease areas using the evidence base and experience from other screening programmes, in particular those from the screening of cancers such as breast, cervical and colorectal cancer.

At the same time, perinatal and neonatal screening programmes are also a key tool for detecting diseases, which through early detection can benefit children's development.

Screening programmes need to be cost-effective at the population level and take into account ethical aspects. Ideally, there should be a treatment available for the detected diseases, or a way to manage the disease and minimise harm. Screening programmes should take into account and integrate state of the art scientific and technological developments in different areas, such as genomics and artificial intelligence.

In order to make progress in the area of prevention, this action will start from an analysis of the needs to develop and implement population-based screening in areas other than those already in place.

Accordingly, the proposed action is expected to deliver on all of the following items:

- Uniting actors from across the spectrum relevant to screening programmes, researchers, healthcare professionals, health insurances, government agencies, patients' organisations etc., to create recommendations for health screening programmes for citizens across their lifespan.
- Mapping current screening programmes for NCDs and proposing ambitious and cost-effective population screening strategies, developing evidence-based guidelines for screening and diagnosis and assess the feasibility of developing accompanying quality schemes to facilitate implementation of such screening and diagnosis measures. Identifying the best sequence for particular screenings, for which target groups (e.g. men without smoking history at risk for aneurysms), at which age and for which segments of the population. Also, the issue of opportunistic vs. population based screening should be looked at.
- Healthcare providers and public health authorities exchange best practices, analyse the potential of new methods and options for integrating specific screenings into a lifelong monitoring scheme for individuals.
- Gathering and analysing existing evidence on current methodologies and promising new developments, as well as identifying potential knowledge gaps in the areas needed for development of new, harmonised screening programmes.
- Developing recommendations for countries on how to identify risk groups to ensure detection at the right time or more frequent testing and which individuals are less at risk and do not need certain tests.
- Assessment of performance of polygenic risk scores across diseases and geographical areas (national and regional programmes). Special attention should be given to vulnerable population groups, covering also gender specific differences.

This CSA should have a duration of at least four years in order to align optimally with other related initiatives. Proposals should consider the involvement of the European Commission's Joint Research Centre (JRC) whose contribution could consist of providing a trialled and tested methodology for the development of European guidelines on screening and diagnosis and quality assurance schemes.

The action will create synergies with relevant initiatives, including the Cancer Mission and the new European partnerships on rare diseases and on personalised medicine. Coordination should also be achieved with the 'Healthier Together' - EU Non-Communicable Diseases Initiative[21].

[1] https://ec.europa.eu/health/non-communicable-diseases/overview_en

Topics 2024

HORIZON-HLTH-2024-STAYHLTH- 1.05: Personalised prevention for non-communicable diseases - addressing areas of unmet needs using multiple data sources

2-stage

Action type: RIA

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several impacts of destination 1 "Staying healthy in a rapidly changing society". To that end, proposals under this topic should aim for delivering results that are directed at, tailored towards and contributing to most or all of the following expected outcomes:

- Citizens have access and use effective personalised prevention schemes and health counselling that takes into account their individual characteristics and situation.
- Health professionals use effective, tried and tested tools to facilitate their work when advising both patients and healthy individuals.
- Public health programme owners gain insight into the specificities and characteristics of clusters within the population through stratification. This can then be used to facilitate the screening of high-risk population groups and improve the programmes, update them to identify target groups and design effective strategies for optimal solutions and interventions.
- Companies explore opportunities for new product and service developments to cater to the needs of the healthcare service and individuals.
- Society benefits from reduced economic and health burden from avoidable sickness, disease and premature death.
- National programmes make better use of funds, infrastructure and personnel in health promotion and disease prevention, primary and secondary healthcare. Waste is reduced by targeting scarce resources in appropriate, cost-efficient ways, to areas of

[21] https://ec.europa.eu/health/non-communicable-diseases/overview_en

highest social return, contributing to an improvement and optimisation of health and well-being of EU citizens and reduction of health inequalities.

- Public health policies, programs and organizations have access and use new or improved ambitious policy and intervention options, with expected high population-wide impact, for effective health promotion and disease prevention.

Scope:

Non-communicable diseases (NCDs) are responsible for the majority of the disease burden in the EU and the leading causes of avoidable premature death. The human and financial costs of NCDs are high and expected to grow. Reducing the burden of NCDs requires a holistic approach and tackling health inequalities across the board. Preventing diseases from developing in the first place is at the core of successful public health programmes in the future.

Personalised approaches and the development of targeted interventions have led to an impressive progress in several fields of medicine and have been included in several treatments. However, the use of individualisation and stratification in guiding prevention strategies is still not widely in use even though examples of its potential are accumulating. Identifying people at risk of developing a particular disease before the disease starts to manifest itself with symptoms greatly improves treatment options. It is estimated that about two thirds of all chronic diseases are preventable, many affecting people who are unaware of their disease risks or do not have access to information pertaining to the management of the condition.

Personalised prevention is the assessment of health risks for individuals based on their specific background traits (genetic, biological, environmental, lifestyle, social, behavioural, etc.) to recommend tailored prevention and disease management schemes. This can include for example: medication, diet programmes, early diagnostics, monitoring, lifestyle advice and modification, specific training/exercise, meditation, or any other evidence based method. Personalised prevention strategies complement general public health prevention programmes without replacing them.

The approach lends itself to computational approaches, with design of algorithms, machine learning and artificial intelligence technology.

In analogy to the 'Healthier Together' – EU Non-Communicable Diseases Initiative[22], the funded projects will work towards reducing the burden of NCDs. The focus should be on specific diseases within key areas such as: cardiovascular diseases, diabetes, chronic respiratory diseases, mental health and neurological disorders, and health determinants. Other diseases of interest can also be addressed as well as co-morbidities.

[22] https://ec.europa.eu/health/non-communicable-diseases/overview_en

Accordingly, the proposed research is expected to deliver on several of the following:

- Through effective prevention, including a personalized dimension, a population is stratified into groups showing similar traits. Individuals can then be assigned to a particular group based on their characteristics, and receive advice adequate to that group.

- Understanding areas of unmet needs in non-communicable diseases prevention and management of disease progression and relapse. Providing new approaches for prevention, including the personalised dimension, that can be adopted and scaled up.

- New or improved ambitious policy and intervention options, with expected high population-wide impact, are devised, proposed and made available for effective health promotion and disease prevention.

- Develop and validate effective schemes/strategies/programmes to be proposed to policy makers to prevent NCDs and optimise health and well-being of the most vulnerable EU citizens. Propose mechanisms to policy makers to monitor their progress. Such schemes/strategies/programmes need to be aligned with relevant national and EU health laws and policies.

- Deliver scientific evidence on interactions between the genetic predisposition to multifactorial diseases and environmental factors or environmental triggers. Scientifically supported personalised prevention strategies that ensure how to modify the environmental drivers of behavioural risk factors.

- New computational tools developed to combine data from different sources, e.g. biomarkers, metagenomics, lifestyle, wearables, physical and social environment, to generate risk scores for several diseases.

- Develop deep machine learning techniques for application in artificial intelligence tools, aiding risk prediction and predisposition to diseases and identifying the optimal solution/intervention for different targeted groups.

- Analytical development of data with different dimensions to identify risk factors/modifiers. Creating procedures and algorithms to combine information from different sources (genomic/biomarkers/environment/diet/lifestyle/wearables (physical activity)/gender, age, profession, etc.) into health promotion recommendations for the individual as advised by healthcare professionals. The approach of the projects must be holistic and thus predicting risk and predisposition needs to be addressed together.

- Tools and techniques to increase the effectiveness and cost-efficiency of interventions, adjusting their scope, characteristics and resources so that they reach the (different) population groups.

- Tools and techniques to increase the effectiveness and cost-efficiency of healthcare infrastructure and how it promotes and delivers health promotion, disease prevention, and care effectively to the different population groups.
- Support better knowledge and data, screening and early detection, diagnosis and treatment management, and quality of life of patients.
- Tools to collect data, from omics-to-human sciences, to advance health promotion and disease prevention. Balancing the ecosystem associated with the economic, social, and health consequences of chronic diseases.
- Demonstrators/prototype projects on a given health challenge: from multimodal data collection to identification of an effective prevention strategy to be tested and validated for one or several NCDs.
- Ethical, legal and social aspects as well as health economics of personalised prevention tools and programmes. Legal aspects of balancing the right not to know and the obligation of helping people in danger.
- Integrated approach that includes genetic predispositions for NCDs, meta-genomics, metabolomics, microbiome, large cohorts, population wide longitudinal health screening using technologies for molecular profiling, effects of diets and nutrition, nutrition and health, impact of lack of physical activity, geographical variation in eating habits for designing customized dietary patterns to prevent NCDs, sleep disorders, the influence of choice environment on personal choices.
- How to optimize the benefits of physical activity, smart monitoring of physical activity with measurable data, addressing barriers to uptake and implementation of healthy lifestyles in daily life, understanding what promotion methods work and why, behavioural science to understand healthier choice environments for healthier lifestyles.
- Quantifiable and distinguishable indicators from wearables data, data mining of real world data.

The projects should contribute to and where relevant create synergies with ongoing national, European and international initiatives such as the European Partnership for Personalised Medicine; the ‘Healthier Together’ - EU Non-Communicable Diseases Initiative; Europe’s Beating Cancer Plan and the Mission on Cancer; WHO’s 9 targets for NCDs, etc.

Where relevant, activities should build on and expand results of past and ongoing research projects. Selected projects under this topic are expected to participate in joint activities as appropriate, possibly including also related projects from other call topics. This can take the form of project clustering, workshops, joint dissemination activities etc. Applicants should plan the necessary budget to cover this collaboration.

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

Topics 2023

HORIZON-HLTH-2023-ENVHLTH- 2.01: Planetary health: understanding the links between environmental degradation and health impacts

Single-stage

Action type: RIA

Expected outcome:

This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 2 'Living and working in a health-promoting environment'. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to most of the following expected outcomes:

- Climate and environmental policies are supported with better knowledge on the Earth natural systems and human health interactions;
- Sustainable planetary health policies which foster co-benefits to human health and the health of natural ecosystems are supported with robust evidence;
- Policy-makers have better tools to improve the predictive capability and preparedness to deal with the impacts on human health of changes in natural ecosystems';
- Cross sectorial scientific collaborations are established;
- Public authorities rely on indicators about the impacts on human of changes in natural systems to support mitigation strategies to natural hazards;
- Citizens are engaged and informed about the impact on human health impact of natural systems' degradation and conservation behaviours are promoted.

Scope:

Life quality and expectancy have increased to unprecedented levels over the last decades due to the significant public health, agricultural, industrial and technological achievements of the 20th century. On the other hand, the ongoing trend of environmental degradation and global

climate and environmental changes has introduced new pressures, which might put at risk the recent health gains.

Among others, climate change, biodiversity loss, environmental pollution, changes in land use and degradation, deforestation, thawing permafrost, overfishing and acidification of water bodies can result in reduced food and water availability and security and increased exposure to factors causing infectious and non-communicable diseases. Additionally, changes in weather and climate extremes have been observed across the globe, resulting in an increase of the frequency and intensity of extreme weather events such as heavy precipitation and floods, heat waves and hot extremes, droughts and tropical cyclones. Global surface temperature is predicted to continue to increase in the coming decades and global warming of 1.5°C and 2°C will likely be exceeded during the 21st century.

Planetary health is a new concept focused on the interdependencies between human health and the state of earth's complex natural systems. A key focus is on understanding how the current trend of human-related environmental degradation can affect the health and well-being of future generations. The Rockefeller Foundation-Lancet Commission on Planetary Health[23] published a report in 2015, laying the foundation for the development of this important new field of study[24]. In 2020 the Helsinki declaration[25] was published, resulting from a conference where participants discussed how to implement the planetary health approach in Europe in the context of the European Green Deal. This declaration highlights the human and planetary health connections and calls for collaborative action to prevent further environmental degradation. In support to the European Green Deal[26] the European Climate and Health Observatory[27], launched in 2021, allows policy- and decision-makers to visualize climate change-related health risks and it helps them to take action and respond to these risks. Additionally, the Zero Pollution Action Plan[28], also published in 2021, puts forward a zero

[23] https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(15)60901-1.pdf

[24] "*Our definition of planetary health is the achievement of the highest attainable standard of health, well-being, and equity worldwide through judicious attention to the human systems—political, economic, and social—that shape the future of humanity and the Earth's natural systems that define the safe environmental limits within which humanity can flourish. Put simply, planetary health is the health of human civilisation and the state of the natural systems on which it depends*"

[25] Halonen et al. A call for urgent action to safeguard our planet and our health in line with the Helsinki declaration

[26] https://ec.europa.eu/clima/eu-action/european-green-deal_en

[27] https://climate-adapt.eea.europa.eu/observatory

[28] https://ec.europa.eu/environment/strategy/zero-pollution-action-plan_en

pollution vision for 2050, aiming at reducing pollution to levels no longer considered harmful to health and natural ecosystems, that respect the boundaries with which our planet can cope. The Climate Adaptation mission[29] aims at increasing the preparedness and resilience of Europe to deal with climate related challenges supporting regions and communities to become more climate resilient by 2030.

There is increasing evidence showing that many of these environmental stressors and changes can cause profound short- and long-term negative impacts on human health and well-being, contributing to increased morbidity and mortality worldwide. Understanding and acting upon these challenges calls for a multidisciplinary, cross-sectorial and transborder approach ranging from the local to the global scale. The effects can be direct due to increases in floods, heatwaves, water shortages, landslides, exposure to ultraviolet radiation, exposure to pollutants, among others, or ecosystem-mediated (e.g. altered infectious disease risks, reduced food yields leading to undernutrition, depletion of natural medicines, mental health, effects of aesthetic or cultural impoverishment).

Applicants are invited to submit proposals providing actionable evidence for policy-makers to take preventive actions to protect the human health and wellbeing by exploring the links between human health and environmental degradation in an integrated and comprehensive manner. More fragmented contributions focused on less studied aspects such as the links between climate change and health and, between biodiversity and health, will also be considered.

To advance the knowledge on planetary health to support policy-making in this area, the applicants should address the following:

- Provide strengthened evidence for direct health and wellbeing impacts of planetary changes, considering a systems thinking framework or a fragmentary approach focused on the impacts on human health of climate change and biodiversity loss (for biodiversity loss, proposals should not focus on zoonotic diseases since this topic will be covered by CL6-2023-BIODIV: Prevention of zoonotic emerging diseases & biodiversity);

[29] https://climate-adapt.eea.europa.eu/eu-adaptation-policy/eu-mission-on-adaptation

- Provide improved understanding and modelling of human–ecological systems interactions and ecosystem-mediated effects on human health and well-being;
- Provide a methodology to identify and prioritise threats for public health caused by environmental degradation, with a view to improving preparedness of health systems to these threats;
- Lay the foundations for integrated surveillance systems that collect health, socioeconomic, and environmental data for defined populations over longer time periods to provide early detection of emerging disease outbreaks (e.g. zoonotic diseases) or changes in nutrition and non-communicable disease burden and to assess the integrated health, environmental, and socioeconomic effect of policies and technologies. Proposals should coordinate with the work being developed under EU4Health 2022 CP-g-22-04.01 Direct grants to Member States' authorities: setting up a coordinated surveillance system under the One Health approach for cross-border pathogens that threaten the Union;
- Explore strategies to reduce environmental damage and harmful emissions including assessment of health co-benefits through engagement with relevant HE partnerships and missions;
- Explore implications of planetary health for health systems and public health and identify opportunities to mitigate adverse health impacts of environmental degradation;
- Improve risk communication to policy makers, industry and the public and support policy makers to make evidence-informed decisions, including by increasing capacity to do systematic reviews and provide rigorous policy briefs;
- Improved impact assessment approaches accounting for environmental externalities and estimating the cost of no action.

All projects funded under this topic are strongly encouraged to participate in networking and joint activities, as appropriate. These networking and joint activities could, for example, involve the participation in joint workshops, the exchange of knowledge, the development and adoption of best practices, or joint communication and dissemination activities. This could also involve networking and joint activities with projects funded under other clusters and pillars of Horizon Europe, or other EU programmes, as appropriate. Therefore, proposals are expected to include a budget for the attendance to regular joint meetings and may consider to cover the costs of any other potential joint activities without the prerequisite to detail concrete joint activities at this stage. The details of these joint activities will be defined during the grant

agreement preparation phase. In this regard, the Commission may take on the role of facilitator for networking and exchanges, including with relevant stakeholders, if appropriate.

HORIZON-HLTH-2023-ENVHLTH- 2.02: Evidence-based interventions for promotion of mental and physical health in changing working environments (post-pandemic workplaces)

Single-stage

Action type: RIA

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 2 'Living and working in a health-promoting environment'. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to most of the following expected outcomes:

- Public authorities and regulators are supported with evidence-based guidance to implement occupational health policies;
- Public authorities, employers, organisations and social partners are better supported with tools, evidence-based intervention options and guidelines to promote mental and physical well-being and health in the workplace;
- Public authorities and the scientific community have access to FAIR data[30] and robust evidence on direct links between mental and physical risk factors at the workplace and specific health outcomes, including also age and gender differences;
- Public authorities and regulators are informed by evidence on the costs, benefits, sustainability and expected challenges of available solutions;
- Public authorities take advantage of the best available knowledge to support interventions on the design of the built working environment and promote healthier behaviours at the workplace;

[30] 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.

- Public authorities and employers develop adequate measures to prevent and reduce the negative outcomes of exposure to mental (psycho-social) and physical risk factors in the work place and support recovery;
- Workers are more protected against work-related hazards and informed about health enhancing behaviours and effective prevention approaches based on specific and appropriate measures;
- Workers living with a chronic disease and/or recovering from a mental of physical health problem are supported to continue/return to work.

Scope

The digital and green transitions (referred to as 'twin transition') and the demographic transformation have been changing the workplace with a rapid pace, leading to new forms of work (e.g. hybrid work, gig economy jobs) or changes in the forms of management and work organisation (e.g. through algorithmic decision-making and digital worker performance monitoring) for workers across the spectrum. These changes have varying impacts on the working conditions, income and health and occupational safety both for skilled and unskilled workers. Furthermore, they contribute to the high costs of work-related illnesses and accidents for employers and the European economy in general.

Mental health and ergonomic-related problems affect a significant number of EU workers. Musculoskeletal disorders (MSDs) are one of the most common work-related health problems in the EU and workers and managers commonly identify stress, depression and anxiety as serious psychosocial outcomes of workplace exposures. Changes in the organisation of work can bring flexibility that allows more people to enter the labour force, but may also lead to psychosocial problems (for example, insecurity, compromised privacy and rest time, inadequate OSH and social protections and stress due to excessive working hours).
Some workplaces have either become exclusively virtual or they have evolved into a 'hybrid' model, some work tasks and processes performed virtually and others having physical presence[31]. The emergence and persistence of the Covid-19 pandemic has accelerated the pace of change, causing, in some cases, additional challenges for the workers' mental health (differentially affecting certain segments of the working force) and intensifying already

[31] The future of working in a virtual environment and occupational safety and health, https://osha.europa.eu/en/publications/future-working-virtual-environment-and-occupational-safety-and-health

existing physical risk factors (e.g. ergonomic risks). For example, the increase in computer use, the change to non-traditional workstation settings (e.g. home office) and the reduction in physical activity of office workers often result in prolonged static positions and repetitive movements, which increase the probability of negative health outcomes. These trends may be associated with an increase in mental health and wellbeing disorders caused by stress, mental exhaustion and social isolation. The European Pillar of Social Rights Action Plan[32] aims to promote a healthy, safe and well-adapted work environment in the EU and relies on Horizon Europe for research and innovation supporting economic and social resilience and sustainability. The **EU strategic framework on health and safety at work 2021-2027[33]** recognises the needs, challenges and opportunities that technological innovation and the pandemic bring for the (remote) working population and calls for strengthening the evidence-base for policymaking and implementation. The Commission is also working on an initiative ('Healthier Together') to support EU countries to improve the health of citizens by reducing the burden of the main Non-Communicable Diseases (in coordination with the Europe's Beating Cancer Plan[34]).

Research actions under this topic should include part of the following activities:

- provide adequate and robust data on the impact that the ongoing changes in the workplace are having on the mental and physical health of different categories of workers affected (e.g. teleworkers, gig economy workers, vulnerable groups (such as women, migrants and young and older workers with increased demonstrated risk for MSDs));
- promote the collection and analysis of data not only on mental health, but also on mental well-being at the workplace and how changing work organisation due to the twin transitions and the pandemic affects workers' work-life balance and work ability;
- promote the collection of data on the importance of risk factors such as static postures and physical inactivity arising from the workplace design in the development of chronic and acute MSDs;

[32] https://op.europa.eu/webpub/empl/european-pillar-of-social-rights/en/
[33] https://osha.europa.eu/en/safety-and-health-legislation/eu-strategic-framework-health-and-safety-work-2021-2027
[34] https://ec.europa.eu/health/system/files/2021-02/eu_cancer-plan_en_0.pdf

- explore the varying (positive and negative) impacts the working environment changes bring upon the mental and physical health of the different categories of workers and working sectors;
- Increase the understanding of the links between different health-promoting factors in the working built environment and physical and mental health outcomes, and how these may be mutually reinforcing;
- Provide recommendations for effective interventions to prevent occupational risks and support the mental and physical health and well-being at individual (worker), organisation (employer) and policy (government) levels for different sectors/types of work, including an analysis on their cost-effectiveness, sustainability and barriers to implementation at national and/or EU level;
- Advance the development of a scientific framework addressing OSH across policies and sectors supporting new and sustainable (future-proof) tools, guidelines and policies concerning the evaluation and design of physical and psychosocial work environment;
- Provide tools and approaches to anticipate new OSH risks, also taking account of lessons learnt from the COVID-19 pandemic, for instance in relation to digital technologies and associated new ways of working.

All projects funded under this topic are strongly encouraged to participate in joint networking and capacity-building activities, as appropriate (such as joint workshops, development, exchange and adoption of best practices, or joint communication and dissemination activities). This could extend to joint activities with projects funded under other clusters and pillars of Horizon Europe, or other EU programmes, as appropriate. Therefore, proposals are expected to include a budget for the attendance to regular joint meetings and the costs of any other potential joint activities without the prerequisite to detail concrete joint activities at this stage. The details of these joint activities will be defined during the grant agreement preparation phase. In this regard, the Commission may take on the role of facilitator for networking and exchanges, including with relevant stakeholders, if appropriate.

HORIZON-HLTH-2023-ENVHLTH- 2.03: Research in support of identification and understanding of human health effects of endocrine disrupting chemicals

Single-stage

Action type: RIA

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 2 'Living and working in a health-promoting environment'. To that end, proposals under this topic should aim for delivering results that are directed towards and contributing to all of the following expected outcomes:

- Public authorities and regulators are supported with scientific evidence to implement the comprehensive European Union Framework on Endocrine Disruptors, Chemicals Strategy for Sustainability Towards a Toxic-Free Environment and EU legislation on plant protection products;
- Public authorities improve their risk assessment, management and communication through access to FAIR[35] data and more robust evidence on the causal links between exposure to endocrine disruptors and health outcomes for which insufficient data exist;
- Research community has better data on the role of endocrine disruptors and other co-factors (e.g., life-style, behavioural, socio-economic) to enable a better understanding of their individual or combined health impacts;
- Public authorities and the scientific community take advantage of latest methodologies for advancing the understanding of health impact of exposures;
- Public authorities, employers and citizens rely on practical evidence-informed guidelines for exposure prevention and reduction;
- Citizens are engaged and informed about the health impact of exposures to endocrine disruptors and risk-preventing behaviours are promoted.

Scope:
The function and regulation of the endocrine system in humans and other species is of high biological complexity. Endocrine disrupting chemicals (EDCs or endocrine disruptors) are chemical substances that alter the functioning of the endocrine system and negatively affect the health of humans and animals. They may either be of synthetic or natural origin. Exposure to endocrine disruptors can occur from different sources, such as residues of pesticides or consumer products used or being present in our daily life.

EDCs are of increasing importance in chemical regulations in the European Union, and criteria have been proposed to identify them for two pieces of EU legislation (biocides regulation, pesticides regulation[36]). According to the Comprehensive European Union

35 FAIR data are data, which meet principles of findability, accessibility, interoperability, and reusability
36 https://www.efsa.europa.eu/en/efsajournal/pub/5311

Framework on Endocrine Disruptors[37], adopted in 2018, the EU strategic approach on endocrine disruptors for the years to come should be based on the application of the precautionary principle aiming at, *inter alia*, minimising overall exposure of humans and the environment to endocrine disruptors, paying particular attention to exposures during important periods of development of an organism, such as foetal development and puberty, as well as accelerating the development of a thorough research basis for effective and forward-looking decision-making. This includes research for the further management of chemicals (including for chemical mixtures), the understanding of the mechanistic effects of endocrine disruptors (including at the molecular and cellular level through the use of new approach methodologies, such as 'omics', *in vitro* 2D and 3D models and computational approaches), and the collection, sharing, harmonization and combination of robust data sources.

Closing existing knowledge gaps in the understanding of EDC effects will support more effective and evidence-based regulations at the European level. The understanding of health impacts of endocrine disruptors is in particular hampered by the time lag between disease initiation and the diagnosis of effects ('early exposure-late effect'), the absence of methodologies for dealing with exposures to multiple chemicals during critical life stages, the poor understanding of the mechanistic effects of endocrine disruptors and the full spectrum of chemicals that might contribute to risks. There is also persistent paucity of knowledge on whether low-dose exposures are linked to adverse effects.

Bringing together, *inter alia*, (molecular) epidemiologists, exposure scientists, toxicologists, endocrinologists and risk assessors, research actions under this topic should focus on the understanding of the impact of exposures at critical life stages in diseases developing later in life, focusing on the several health endpoints for which there is currently less information available. Advantage should be taken of existing biobanks and disease registries and/or new cohorts, with carefully planned measurement strategies and clearly worked-out hypotheses. The issues of non-monotonic dose-response relationships and whether effects are threshold-dependent should be addressed in the study designs. Similarities between endocrine systems and certain health outcomes across species should be exploited to improve understanding of endocrine functioning. Finally, research should attempt at identifying predictive biomarkers that would allow the tracing of endocrine disrupter-mediated health effects in a shorter period of time than normally would be required for epidemiological studies.

Research actions under this topic should provide forward-looking mechanistic information on potential hazards and health risks of exposures to EDCs, through innovative molecular epidemiological, multifactorial models and systems biology approaches, exploiting the use of new approach non-animal methodologies when relevant, and should include most of the following activities:

- Studying the impact of EDCs on target organs and physiological barriers, such as the placenta, the blood-brain barrier, intestinal, pulmonary and immune cells as well as their interaction with microbiota;

[37] https://ec.europa.eu/info/policies/endocrine-disruptors_en

- Elucidating health endpoints for which insufficient data exist, such as disturbances in the development and functioning of the nervous and cardiovascular systems, the immune system, bone development and disease, obesity, diabetes, hormone-dependent cancers and fertility (e.g. minipuberty, prepuberty and puberty);
- Providing better biomarkers to predict EDC-mediated health outcomes;
- Gaining better insights into the developmental origins of health and disease, especially for those where less data are available. Assessing the occurrence and relevance of multi- and transgenerationally inherited effects, including molecular and epigenetic mechanisms that drive multigenerational effects;
- Gaining better insights into the most sensitive windows of susceptibility, during which exposure are of particular importance for health effects;
- Better understanding of the effects of chemicals and chemical mixtures on the underlying mechanistic crosstalk between endocrine axes, endocrine pathways and other key biological systems, including immune, neurological and metabolic functions;
- Improving the understanding of chemical mixture effects, including with other toxins and at low doses. Investigating biological effects of realistic mixtures to get a more detailed understanding of the endocrine effectome, taking advantage of computational toxicology and development of up-to-date models (including state of the art new approach non-animal models);
- Exploiting non-mammalian species as test organisms, e.g. non-mammalian vertebrates and invertebrates to predict effects or raise concern about potential effects in humans or vice versa and performing comparative analysis between species;
- Exploiting systems biology approaches in order to understand how exposure to an EDC results in an altered phenotype, a process that implies complex interactions across multiple levels of biological organization.

Aspects such as gender, regional variations, socio-economics and culture should be considered, where appropriate. Proposals should ensure that chemical monitoring data are shared in IPCHEM[38] through involvement with the European Commission's Joint Research Centre (JRC). Proposals should also consider involving JRC with respect to the value it could bring in providing an effective interface between the research activities and regulatory aspects and/or to translating the research results into validated test methods and strategies fit for regulatory purpose. In that respect, the JRC will collaborate with any successful proposal and this collaboration, when relevant, should be established after the proposal's approval.

Proposers should be acquainted with planned activities under the European partnership for the assessment of risks from chemicals PARC[39]. PARC will be informed about successful proposals. Successful proposals will be invited to establish synergies with PARC and take advantage of the partnership as a facilitator for open data and methodology sharing with risk assessors and their scientific networks.

[38] IPCheM Portal (europa.eu)

[39] https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-hlth-2021-envhlth-03-01

All projects funded under this topic are strongly encouraged to participate in networking and joint activities, as appropriate. These networking and joint activities could, for example, involve the participation in joint workshops, the exchange of knowledge, the development and adoption of best practices, or joint communication activities. This could also involve networking and joint activities with projects funded under other clusters and pillars of Horizon Europe, or other EU programmes, as appropriate. Therefore, proposals are expected to include a budget for the attendance to regular joint meetings and to cover the costs of any other potential joint activities without the prerequisite to detail concrete joint activities at this stage. The details of these joint activities will be defined during the grant agreement preparation phase. In this regard, the Commission may take on the role of facilitator for networking and exchanges, including with relevant stakeholders, if appropriate.

HORIZON-HLTH-2023-ENVHLTH- 2.04: Global coordination of exposome research

Single-stage

Action type: CSA

Expected outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 2 'Living and working in a health-promoting environment'. To that end, proposals under this topic should aim for delivering results that are tailored towards and contributing to all of the following expected outcomes:

- Environment and health research community, research-policy-making authorities, research funders and other relevant stakeholders work together at the European and international level towards establishing a medium-long-term Global Human Exposome Network;
- Environment and health research community, research-policy-making authorities and research funders provide options for functioning, financing and governance of a medium-long-term Global Human Exposome Network considering also the strengthening of the coordination of the European Human Exposome Network;
- Relevant stakeholders profit from a strengthened coordination and collaboration globally among different fields of research and innovation with relevance to deciphering the human exposome;
- A roadmap and a R&I agenda for international cooperation in specified areas of exposome research and innovation, including, among others, recommendations for exchange of knowledge and data, policy uptake, technological and conceptual approaches and promotion of global level coordinated initiatives on the exposome are made available to the relevant international stakeholders;
- The coordination of research initiatives, infrastructures, facilities and resources in the area of the Exposome in Europe is supported and reinforced;
- The interoperability and harmonisation between data and studies is increased facilitating the exchange and use of information across research disciplines and groups.

Scope:

The concept of the exposome refers to the totality of environmental exposures (diet, lifestyle, occupational and environmental factors) from conception onwards, including its external and internal components. Developing a comprehensive Human Exposome Project would present a fundamental shift in looking at health, by moving research away from 'one exposure, one disease' understanding to a more complex picture upon which to build solid, cost-effective preventive actions and policies. At its most complete, it could resemble the Human Genome Project.

The European Human Exposome Network (EHEN)[40], a cluster of 9 projects funded since 2020 for five years from Horizon 2020, is currently the world's largest network of projects studying the impact of environmental exposure on human health with an exposome angle. Together, the network of projects aims to study the combination of exposures to pollutants and other stressors via a number of exposure vehicles such as diet, consumption patterns, lifestyle and working and living environment, and their collective effect on human health. Examples of these exposures include diet, air pollution, noise, persistent organic pollutants, lack of green spaces, as well as interactions with an individual's health vulnerability across different life stages and socio-economic conditions.

During its first two years, the Network has laid the first foundations of building a conceptual and operational framework under which to advance the understanding of the human exposome. It has established a model of cooperation between the projects, which includes, e.g., the establishment of targeted working groups around themes of common interest such as data harmonisation and ethics. EHEN research will lead to better prediction of disease risk and an 'Exposome Toolbox', enabling the development of solid, cost-effective preventive actions and policies.

At the international level, some related activities are ongoing in, e.g., the US (National Institute for Environmental Health Sciences) and Japan. Currently, there is only sporadic cooperation between the ongoing research at the EU level and important research groups outside Europe. However, in order to fulfil the promise of deciphering the human exposome, a large-scale effort similar to the Human Genome Project could be envisaged, for which a preparatory coordination and support action would be highly useful to identify and discuss the research needs and specific areas of potential cooperation at the global level. Additionally, both at the European and International level better coordination is essential to foster new opportunities to collect, harmonise, combine and analyse large data sets emanating from new and evolving technologies. This offers also new possibilities to understand the pathways leading from a multitude of environmental exposures to the global health burden of common chronic diseases. Standardization and interoperability of data is also needed to assure access to quality data sources at the European and global level.

On the policy side, the outcomes of advancing the exposome research can touch upon and contribute to a better implementation of a wide range of policies and EU priorities such as the

[40] https://www.humanexposome.eu/

EU Chemicals Strategy[41], Zero Pollution Action Plan[42], the European Green Deal[43] and climate policies[44], among others. The benefits of cooperation would also extend to international initiatives such as activities of the World Health Organization related to environment and health[45] and the United Nations activities on climate[46] and environment[47].

Accordingly, proposals should cover, among others, the following activities:

- Proposal for a common agreed conceptual framework for the exposome;
- Proposal for options for a global governance structure for a Global Human Exposome Network taking advantage of and connecting to the existing research infrastructures and services in the area of the Exposome at the European level;
- Agreed technologies needed to decipher the external and internal exposome, support longitudinal studies and potential for international cooperation;
- Proposal for data mining, analysis, opportunities for harmonisation, interoperability, and standardisation in data collection, knowledge storage and transfer, and bioinformatics needs at the European and global level;
- Cooperation between population and patient cohorts, integrating a large number of variables and comprehensive environmental datasets, and biobanks;
- Facilitation of the regulatory uses of results including for regulatory science and risk assessment.

Proposals should interact with existing research infrastructures, services and research projects in the area of the exposome (namely the European Human Exposome Network) and build and integrate the work being developed in these initiatives.

Topics 2024

HORIZON-HLTH-2024-ENVHLTH- 2.05: Exposure to hazardous substances (including nanomaterials) or biological agents in occupational environments and adverse health outcomes

Single stage

Action type: RIA

[41] https://ec.europa.eu/environment/strategy/chemicals-strategy_en
[42] https://ec.europa.eu/environment/strategy/zero-pollution-action-plan_en
[43] https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en
[44] https://ec.europa.eu/clima/index_en
[45] https://www.who.int/health-topics/environmental-health; https://www.euro.who.int/en/health-topics/environment-and-health
[46] https://www.un.org/en/climatechange
[4747] https://www.unep.org/

Expected outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 2 'Living and working in a health-promoting environment'. To that end, proposals under this topic should aim at delivering results that are tailored towards and contributing to all of the following expected outcomes:

- Public authorities and regulatory entities are supported with robust scientific evidence to implement the new EU Strategic Framework on Health and Safety at Work[48] and other EU strategies[49];
- Public authorities and regulators are better informed about biological and chemical risk factors, the determinants of disease, assessment approaches and exposure levels at the workplace;
- Workers are more protected against work-related hazards and informed about effective risk prevention approaches and specific and appropriate measures;
- Public authorities and employers improve their risk assessment and management and cross-disciplinary collaboration through better access to robust evidence on exposures and their causal links to potential health effects and outcomes in an occupational context;
- The importance and effectiveness of mitigation measures in reducing work-related diseases is quantified and the results inform the adoption of best prevention practices in the working environment;
- The research community has better data on the causes of work-related diseases;
- Science-based guidelines are available and disseminated to employers on exposure assessment and risk prevention and management practices for handling of hazardous chemicals and biological agents.

Scope:

Occupational safety and health (OSH) is a multidisciplinary field covering the safety, health, and well-being of people at work. Nearly half of the world's population are active workers and, at the global level, exposure to risk factors at work results in almost 2 million premature deaths per year with 80% of these deaths being due to diseases.

The EU Strategic Framework on Health and Safety at Work 2021-2027 sets out a number of actions to improve health and safety at work over the coming years. This strategic framework promotes a vision zero approach to work-related deaths in the EU. In particular, it includes actions to prevent work-related diseases, such as the update of occupational exposure limits for certain hazardous substances and the EU rules on hazardous chemicals.

Given the amount of time spent at the workplace, frequently indoors, worker's exposure to risk factors in the occupational environment has potentially significant impact on their

[48] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12673-Health-&-Safety-at-Work-EU-Strategic-Framework-2021-2027-_en

[49] https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en

health and safety. However, the extent of workers' daily exposure to chemical and biological hazards is still poorly understood as well as the routes of exposure and the causal relations between exposure and health outcomes.

Workers are exposed to dangerous substances in many European workplaces. Such exposures, may occur in almost all workplaces. Overall, 36 % of European enterprises report potentially dangerous chemical or biological substances in their workplaces.[50] According to the European Survey on Working Conditions, the proportion of workers that report being exposed to chemicals for at least a quarter of their working time has not changed since 2000, remaining at around 17 %, and 13% of workers report to be exposed to infectious materials under these conditions.[51] In many workplaces, workers are likely to be exposed to both chemical and biological agents.

Chemical exposure is a leading cause of occupational disease, with important associated healthcare costs and a negative impact on enterprises through, for example, reduced worker productivity. Exposure to dangerous substances at work can lead to serious illnesses such as asthma, cancer, neurodegenerative diseases, and reproductive health issues. This includes substances that are generated by the work processes, such as welding fumes, diesel motor exhaust and organic dust. Among the identified chemicals of concern at the workplace, asbestos has been one of the substances in the spotlight due to its recognized carcinogenic effects and potential causal link to other health conditions, the wide variety of potential exposure environments and the expected time lag between exposure and noticeable health impacts. A recent resolution from the European Parliament[52] calls for more evidence on the causal link between exposure to asbestos and health outcomes and on the exposure pathways and recommended exposure threshold across occupational settings.

Regarding biological agents, a recent review on the exposure of workers and related health problems[53,54] concluded that there was a lack of awareness about the prevention of exposures and the European legal framework that protects workers. Prevention approaches identified in the review did not seem to cover the whole range of risks due to biological agents that were identified through literature review and expert interviews. Carrying out workplace risk assessments and setting out effective management approaches at the workplace are challenging due to the multiplicity of potential exposure sources, the lack of knowledge on exposures, the fact that biological agents are living organisms that may grow in workplace environments and the lack of measurement methods and occupational exposure limit values that would allow to benchmark exposures. Some biological agents may have a severe negative impact on workers´ health, as could be experienced in the Covid-19 pandemic. There are

[50] European Survey of Enterprises on New and Emerging Risks (ESENER) 2019, https://osha.europa.eu/en/facts-and-figures/esener

[51] European Working Conditions Survey, https://www.eurofound.europa.eu/surveys/european-working-conditions-surveys-ewcs

[52] https://www.europarl.europa.eu/doceo/document/TA-9-2021-0427_EN.pdf

[53] Biological agents and work-related diseases: results of a literature review, expert survey and analysis of monitoring systems, https://osha.europa.eu/en/publications/biological-agents-and-work-related-diseases-results-literature-review-expert-survey-and/view

[54] Biological agents and prevention of work-related diseases: a review, https://osha.europa.eu/en/publications/review-specific-work-related-diseases-due-biological-agents/view

many professional activities involving biological hazards in various fields (e.g. health care, agriculture, scientific research, waste and wastewater treatment and disposal) with different infectious agents and pathways of exposure involved. The spread of new pathogenic agents due to travelling and trade patterns and climate change is also an issue of concern.
Workers in a number of sectors, such as healthcare, waste management, agriculture, and many others are likely to be exposed to both chemicals and biological agents.
Guidance is needed on reliable and effective strategies to identify, evaluate, manage and prevent such complex scenarios in occupational settings with a particular attention to workers with specific needs and higher levels of risk. The risks might be greater because these workers are inexperienced, uninformed or physically more vulnerable, because they frequently change jobs or work in sectors where awareness of the issue is low, in low-wage and minority workers, who might be disproportionally affected by these exposures, or because of greater or different physiological sensitivity (e.g. in young apprentices, or because of gender differences)[55].

Research actions under this topic should provide forward-looking information on potential hazards and health risks of exposures to chemical and biological stressors at the workplace, through innovative approaches projecting current and future scenarios, multifactorial models and interventions and should include most of the following activities:

- Increase of the knowledge base for chemical, materials and biological hazards identification, exposure and risk assessment in the context of occupational safety and health;
- Understanding the interactions between chemicals and biological agents causing health problems in the context of occupational environments;
- Evaluation of the combined risks from co-exposure to multiple workplace risks, in particular combined biological, chemical, and both biological and chemical risks;
- Collection of FAIR[56] data on causal associations between occupational chemical and biological risk factors and health outcomes, taking also into account vulnerable workers groups;

- Support to evidence-based approaches to the reduction of exposure to chemicals of concern such as asbestos in the workplace;
- Understanding the impact of preventive measures on exposure reduction and the decrease of short-term and long-term health effects that may lead to work-related diseases for specific sectors, occupations or worker groups;
- Developing reliable and standardised measurement and exposure assessment methods for exposure to chemical and biological agents, incl. nanomaterials.
- Development of exposure assessment approaches, incl. modelling, that will contribute to the assessment of the contribution of occupational exposures in a regulatory context;

[55] EU-OSHA Healthy Workplaces campaign 2018-19 info sheet ”Vulnerable workers and dangerous substances”, available at https://osha.europa.eu/en/publications/info-sheet-vulnerable-workers-and-dangerous-substances.

[56] 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.

- Support to the derivation of exposure limit values for hazardous substances of concern and biological agents in working environments (covering different sectors and work tasks, frequency and level of exposure) and development of relevant indicators to support monitoring.
- Understanding the impact of preventive measures on exposure reduction and the decrease of short-term and long-term health effects that may lead to work-related diseases for specific sectors, occupations or worker groups;

Proposals should ensure that chemical monitoring data are shared in IPCHEM[57] through involvement with the European Commission's Joint Research Centre (JRC) after the proposal is approved.

Proposers should be acquainted with planned activities under PARC[58]. PARC will be informed about successful proposals. Successful proposals will be invited to establish synergies with PARC and use PARC as a facilitator for open data and methodology sharing with risk assessors and their scientific network.

All projects funded under this topic are strongly encouraged to participate in networking and joint activities. These networking and joint activities could, for example, involve the participation in joint workshops, the exchange of knowledge, harmonization of collected datasets, the development and adoption of best practices, or joint communication and dissemination activities. Therefore, proposals are expected to include a budget for the attendance to regular joint meetings and to cover the costs of any other potential joint activities without the prerequisite to detail concrete joint activities at this stage. The details of these joint activities will be defined during the grant agreement preparation phase. In this regard, the Commission may take on the role of facilitator for networking and exchanges, including with relevant stakeholders, if appropriate.

An approach that strongly promotes applied research linking research to practical workplace prevention is favoured.

HORIZON-HLTH-2024-ENVHLTH- 2.06: The role of environmental pollution in non-communicable diseases: air, noise and light and hazardous waste pollution

2-stage

Action type: RIA

Expected Outcome:

- National and EU authorities apply user-friendly tools to produce and use generated data on the impact of pollutants on health;

[57] IPCheM Portal (europa.eu)
[58] European partnership for the assessment of risks from chemicals (PARC),

- National and EU authorities benefit from access to robust and transparent indicators for health impact assessment to monitor efficacy of pollution-mitigating actions and policies;
- Policy-makers and other stakeholders, e.g. public authorities such as urban planners, health professionals, employers, civil society organisations and citizens, use developed guidelines to take action to prevent pollution-related illnesses and impairments, and choose healthier lifestyles and behaviours;
- EU, national and regional authorities receive guidance and recommendations for updates of (1) limit values for different classes of pollutants in the environment, (2) potential health effects and (3) advice on management and mitigation of related health risks; these recommendations should take into account vulnerable population groups and people with increased vulnerability because of pre-existing medical conditions;
- The Zero-Pollution Action Plan, Chemical Strategy for Sustainability and the EU noise and waste regulations are supported by a strong evidence-base;
- Relevant actors in our daily lives, e.g. medical personnel, building engineers, teachers, urban planners etc., have access to information such as training courses on pollution and health impacts.

Scope:

The European Green Deal set out by the European Commission recognises that man-made environmental pollution is an increasing threat for human health and wellbeing. Opinion polls[59] show that climate change, air pollution, and waste are the three most important environmental issues that European citizens are concerned about. Over three-quarters (78%) of respondents believe that environmental issues have a direct effect on their daily life and health.

Pollution affects a large number of people in Europe and beyond: Over 7 million people die of exposure to polluted air every year worldwide; 600 000 in Europe[60]. Today, more than 1 in 4 Europeans is exposed to traffic noise levels dangerous to their health in their homes, schools and workplaces[61]. Waste[62] continues to be a persistent environmental issue in Europe, and it is estimated that there are 2.5 million contaminated sites in Europe, with potentially significant adverse health effects[63].

The global burden from non-communicable diseases (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

[59] E.g. Eurobarometer 501 – 2020- https://ec.europa.eu/commission/presscorner/detail/en/ip_20_331
[60] Ref
[61] ref
[62] https://ec.europa.eu/environment/topics/waste-and-recycling_en
[63] Data presented at the Ministerial Meeting on Environment and Health, Ostrava, CZ (2017)

costs. Currently, around 50 million European citizens suffer from two or more chronic conditions and most of these people are over 65.[64] 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 WHO Europe region are attributable to environmental stressors. 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.[65] 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 environmental and lifestyle factors play a major role. 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 and computational technologies to elucidate biological pathways from exposure (including combined exposures) to disease. The work should build on data from sources such as pollution-related databases, disease registries, epidemiological studies and biobanks, environmental and human biomonitoring data, and could consider citizen science and other innovative approaches. All exposure routes should be considered where relevant (oral, inhalation, dermal).

The focus of this topic shall be on three areas where the understanding of and evidence on causality should be strengthened to overcome the current paucity of data and respond to calls from policy-makers. The applicants shall focus on one of the following three aspects:

i. Air pollution, especially in the urban environment, taking into account its various components and emerging pollutants, e.g. ultrafine particles and interactions with aeroallergens, black carbon, sand and dust storms and impact on human health;

ii. Noise pollution and light pollution impact on human health;

iii. Pollution from hazardous waste (e.g. pharmaceuticals, illicit drugs, e-waste, plastics) in heavily contaminated environments and adverse health outcomes.

The research design should where appropriate, take into account vulnerable groups and socio-economic factors. Most of the following activities shall be included:

i. Research activities to strengthen the evidence base for pollution-disease associations and underlying causality mechanisms and biological pathways, taking into account combined exposures;

[64] European Commission 2020 Report on the Impact of Demographic Change

[65] EEA 2020 report on Healthy environment, healthy lives: how the environment influences health and well-being in Europe

ii. Delivery of FAIR[66] data on causal associations between environmental risk factors and health outcomes, taking into account vulnerable population groups and specific exposure situations in a life-course approach;

iii. Development of user-friendly tools for systematic mining and assessment of the knowledge generated and translation into best practices;

iv. Proposals for environmental limit values for the studied pollutants and generation of health impact indicators, where relevant;

v. Development of guidelines for different actors including policy makers, health professionals and citizens to take action to prevent pollution-related illnesses and impairments, and to enable the choice of healthier lifestyles and behaviours;

vi. Identification of cross-sectoral interventions (case studies) with the potential for remediating pollution and risk of exposure and improving human health and well-being in the short/medium term;

vii. Development of training courses on pollution and health impacts to inform professionals impacting our daily lives e.g. medical personnel, engineers, teachers, urban planners etc;

viii. Design of best-practice evidence-based communication actions for fact-based risk and benefit communication and improving citizen awareness of pollution and preventive actions, offsetting dissemination of misinformation;

ix. Undertaking case studies to demonstrate the added societal value of tools, methodologies and guidelines developed and the implementation of resulting actions to decrease health impacts of exposures.

Aspects such as gender, regional variations, socio-economics and culture should be considered, where appropriate. Proposals should ensure that chemical monitoring data are shared in IPCHEM[67] through involvement with the European Commission's Joint Research Centre (JRC).

All projects funded under this topic are strongly encouraged to participate in networking and joint activities, as appropriate. These networking and joint activities could, for example, involve the participation in joint workshops, the exchange of knowledge, the development and adoption of best practices, or joint communication and dissemination activities. This could also involve networking and joint activities with projects funded under other clusters and pillars of Horizon Europe, or other EU programmes, as appropriate. Therefore, proposals are expected to include a budget for the attendance to regular joint meetings and may consider to cover the costs of any other potential joint activities without the prerequisite to detail concrete

[66] 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.

[67] IPCheM Portal (europa.eu)

joint activities at this stage. The details of these joint activities will be defined during the grant agreement preparation phase. In this regard, the Commission may take on the role of facilitator for networking and exchanges, including with relevant stakeholders, if appropriate.

Destination 3. Tackling diseases and reducing disease burden

Topics 2023

HORIZON-HLTH-2023-DISEASE- 3.01: Palliative and end-of-life care for non-cancer patients

Single-stage

Action type: RIA

Expected outcomes:

This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 3 "*Tackling diseases and reducing disease burden*". To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- 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.
- Patients have early and better access better access to palliative or end-of-life care services of higher quality and (cost)effectiveness.
- Patients and their professional and family caregivers use the improved evidence-based and information-driven palliative care decision-making process.
- Health care providers and health policy makers have access to and use the improved clinical guidelines and policy with respect to pain management, psychological and/or spiritual support, and palliative or end-of-life care for patients.
- Reduced societal, healthcare and economic burden associated with increasing demands of palliative or end-of-life care services that is beneficial for citizens and preserves sustainability of the health care systems.

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 also their treatments affect quality of life of patients and their families and pose an immense societal and economic burden. Palliative[68] 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 such as 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

[68] https://www.who.int/cancer/palliative/definition/en/

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 of all ages in the domains of palliative and end-of-life care.

Proposals should address all of the following activities:

- Demonstrate the effectiveness and cost-effectiveness of newly proposed or specifically adapted pharmacological and/or non-pharmacological interventions to improve well-being and quality of life of patients suffering from life-threatening and chronic diseases[69] (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. The legal and ethical aspects of the proposed interventions should be taken into consideration and be fully addressed.
- 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, cultural and ethical aspects that are necessarily managed by those care regimes and healthcare systems should be reflected from patients' as well as those of 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, disabilities 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[70] to the proposed interventions, including equitable access.
- 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 caregivers.
- Provide guidelines for patient-centred communication as well as standards for evidenced based communication trainings for caregivers, considering the potential of social innovation approaches or tools.
- When relevant, provide policy recommendations for pain management, psychological and/or spiritual support, and palliative or end-of-life care of patients.

Randomised clinical trials and observational studies, targeting different age groups, should be considered for this topic. Proposals should give a sound feasibility assessment, provide details of the methodology, including an appropriate patient selection and realistic recruitment plans, justified by available publications and/or preliminary results.

[69] Proposals focused on cancer-related research are not in the scope of this topic. The supportive, survivorship, palliation and end-of-life care of cancer patients was already covered by the specific topic in the Cluster Health Work Programme 2021-2022. Applicants are invited to check the Work Programme of the Mission on Cancer for further funding opportunities for this research areas.

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

This topic requires effective contributions from the social sciences and humanities (SSH) through the involvement of SSH experts and institutions as well as the inclusion of relevant SSH expertise, in order to produce meaningful and significant effects enhancing the societal impact of the related research activities. Proposals should consider a patient-centred approach that empowers patients, promotes a culture of dialogue and openness between health professionals, patients and their families, and unleashes the potential for social innovation.

All projects funded under this topic are strongly encouraged to participate in networking and joint activities, as appropriate. These networking and joint activities could, for example, involve the participation in joint workshops, the exchange of knowledge, the development and adoption of best practices, or joint communication activities. This could also involve networking and joint activities with projects funded under other clusters and pillars of Horizon Europe, or other EU programmes, as appropriate. Therefore, proposals are expected to include a budget for the attendance to regular joint meetings and may consider to cover the costs of any other potential joint activities without the prerequisite to detail concrete joint activities at this stage. The details of these joint activities will be defined during the grant agreement preparation phase. In this regard, the Commission may take on the role of facilitator for networking and exchanges, including with relevant stakeholders, if appropriate.

HORIZON-HLTH-2023-DISEASE- 3.03: Interventions in urban environments to reduce NCD risk (GACD)

Single-stage

Action type: RIA

The final text of this topic will be produced based on the topic description provided the GACD Programme Subcommittee (i.e. developed jointly by all Associate Members, including the Commission). The stable vision of the GACD topic draft is expected in June-July 2022.

Expected Outcomes:

This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 3 "Tackling diseases and reducing disease burden". To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to some of the following expected outcomes:

- Health care practitioners and providers in low- and middle-income countries (LMICs) and those in high-income countries (HICs) serving vulnerable populations have access to and use specific guidelines to implement health interventions that decrease risks of non-communicable diseases (NCDs) related to urban environment.

- Public health managers and authorities have access to improved insights and evidences on the NCDs caused or impacted by urban environment and which factors influence the implementation of preventive actions that address risk behaviours in concerned urban populations. They use this knowledge to design improved urban planning policies to diminish health associated risks.
- Adopting an implementation science approach to studying interventions in different urban contexts, researchers, clinicians and authorities have an improved understanding how specific interventions can be better adapted to different urban environments and how the interventions could be scaled within and across cities taking into account specific social, political, economic and cultural contexts.
- Communities and local stakeholders and authorities are fully engaged in implementing and taking up individual and/or structural level interventions and thus contribute to deliver better health.

Scope:

The European Commission is a member of the Global Alliance for Chronic Diseases (GACD), an alliance of international funding agencies representing over 80% of the world's public health research funding and the first collaboration of its kind to specifically address NCDs. The GACD supports implementation science to improve health outcomes. This topic is launched in concertation with the other GACD members funding agencies and aligned with the GACD call 2022.

The topic is focused on implementation research about common health prevention interventions that decrease risks NCDs related to urban environments in LMICs and vulnerable populations in HICs. Proposals should focus on implementation science around evidence-based interventions that promote healthy behaviours, and that have the potential to profoundly reduce the risk of chronic diseases and multimorbidity.

Over the past 40 years, practitioners and policymakers have observed a rise in the prevalence of many chronic conditions such as diabetes, heart disease, asthma, musculoskeletal conditions, certain cancers and mental health conditions, including a rise in prevalence of multi-morbidity, despite the best efforts focused on individual-level interventions to change behaviours. These persistent health trends have spurred a greater interest in exploring population-level strategies for chronic disease prevention and management. As more than half of the worlds' population currently lives in cities and this number is projected to rise to 68% by 2050, there is an urgent need to understand how we can maximize the health promoting potential of cities and minimize unhealthy environments and widening health inequities. Along with tremendous social, cultural and economic opportunity, cities also present unique challenges, for example most of the top ten global causes of death are directly or indirectly influenced by urban design and planning policies.

Evidence suggests that environments have the potential to become engines of good health by promoting physical activity, healthy eating, social connectivity, economic opportunity, and injury prevention, as well as access to health services, clean air, nutritious food, and green space. The key to unlocking this powerful potential is in understanding which interventions

would be most effective in achieving these outcomes and how can cities implement them in ways that will be impactful, sustainable and equitable considering their own local context. It is key that the study of proposed interventions consider the contexts and experience of different populations, including those who are marginalized, and is done in partnership with those communities that will be most impacted.

The proposed implementation research must be focus on behavioural change intervention programmes and policies that reduce NCD risk in the context of existing urban environments. Proposals should build on evidence-based interventions (including cost-effectiveness) under defined contextual circumstances and should aim to level health inequities in urban populations. Proposals that focus on extremely vulnerable populations, such as communities living in informal settlements, or urban post-disaster settings or in situations of homelessness, are encouraged but not required.

Behavioural change interventions should focus on innovative approaches to helping urban communities maintain good physical and mental health despite structural, environmental, and social challenges. Proposals should articulate the challenges to the urban environment that their interventions help overcome. Interventions might include programmes and policies that target alcohol and tobacco use, exercise promotion, and healthful nutrition. Interventions that help reduce exposure to common urban contaminants through behaviour change, such as school-based policies that reduce outdoor play activity during days with high air pollution, are also encouraged.

Targeted upstream interventions to address environmental factors that promote social inequality have been shown to reduce behaviour-related illnesses and risks. In this context, whenever relevant, poverty, racism, and other inequities that are often directly associated with deficits in urban infrastructure and reduced potential for health promotion should be also taken into account in the proposed research.

All projects should be gender-responsive and consider socioeconomic, racial or other factors that relate to equitable impacts of the intervention or barriers to equitable implementation. The aim should be to adapt and scale-up the implementation of these intervention(s) in accessible and equitable ways in order to prevent or delay the onset of chronic diseases in real-life settings.

Proposals should present a strategy to include the relevant policy makers, local authorities, as well as other stakeholders such as community groups, or other individuals or organizations involved in the implementation of the intervention, from the development to the implementation knowledge translation phase.

HORIZON-HLTH-2023-DISEASE- 3.04: Broad spectrum anti-viral therapeutics for infectious diseases with epidemic potential (Pandemic preparedness research)

Single-stage

Action type: RIA

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 3 "*Tackling diseases and reducing disease burden*". To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- The scientific and clinical communities have an increased knowledge on viruses with epidemic potential and in particular a better understanding of different potential mechanisms of action for the development of broad-spectrum anti-viral therapeutics for these viruses.
- The scientific and clinical communities have access to novel approaches for the development of anti-viral therapies for emerging and re-emerging infections in the context of epidemic and pandemic preparedness.
- The scientific and clinical communities have access to experimental broad-spectrum anti-viral candidates against emerging or re-emerging viral infections for further clinical investigation.
- A diverse and robust pipeline of broad-spectrum anti-viral drug candidates is available for emerging and re-emerging viral infections, increasing therapeutic options for clinical deployment in case of an epidemic or pandemic.

Scope: As shown by the COVID-19 pandemic, infectious diseases remain a major threat to health and health security in the EU and globally. Viral disease emergence is expected to accelerate due to among other, climate change, and thus a proactive approach to the development of anti-viral therapeutics in preparedness for future infectious disease outbreaks is needed. The availability of broad-spectrum anti-viral therapies would provide a critical preparedness measure against future health threats, due to infectious disease epidemics or pandemics.

Proposals should develop and advance broad-spectrum anti-viral compounds and develop novel approaches to the development of such compounds, which target viruses with high epidemic or pandemic potential for the EU, such as those included in the list of priority diseases of the World Health Organization (WHO)[71], with particular attention to those identified by the Health Emergency Preparedness and Response Authority (HERA).

Proposals should cover viruses that lack effective therapeutics or for which the therapeutics available are sub-optimal, and are expected to incorporate state-of-the-art screening

[71] https://www.who.int/activities/prioritizing-diseases-for-research-and-development-in-emergency-contexts

technology and innovative approaches to identify new targets for antiviral compound development. Emphasis should be put on the research and development of broad-spectrum antivirals, which may include repurposing of previously approved or in-pipeline drugs.

Proposals should aim to diversify and accelerate the global therapeutic research and development pipeline for emerging and re-emerging viral infections, and to strengthen the current leading role of the EU in therapeutic research and development.

Proposals should address several of the following areas:

- Proof-of-concept/first-in-human studies and early safety and efficacy trials for testing new or improved anti-viral therapeutic, with a clear regulatory and clinical pathway. Phase IIb/III phase trials will not be supported.
- Innovative delivery systems and suitable safety profiles for broad use should be considered when possible. Attention should be paid to critical social factors such as sex, gender, age, socio-economic factors, ethnicity/migration, and disability.
- Timely engagement with the relevant regulatory bodies is expected to ensure adequacy of the actions from a regulatory point of view.

HORIZON-HLTH-2023-DISEASE- 3.05: Sustaining European Clinical Trial networks for pandemic preparedness and response through well-established coordination mechanisms between EU adaptive platform trials (CSA for pandemic preparedness research)

Single-stage

Action type: CSA

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 3 “Tackling diseases and reducing disease burden”. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- The research community sustains appropriate coordination mechanisms between different EU adaptive platform trials for pandemic preparedness and response, as a foundation for the European clinical trial networks for pandemic preparedness and response.
- The European clinical trial networks enable common approaches across EU adaptive platform trials for maximum efficiency and optimal evidence generation.

- The European clinical trial networks are associated to the European Pandemic Preparedness Partnership, and are well connected to related regional and global initiatives.

Scope: The concept of the European clinical trial networks was developed in the context of the COVID-19 pandemic, and currently encompasses a network for COVID-19 therapeutic trials[72] and a network for COVID-19 vaccine trials[73]. The recently established Ecraid[74] is a European clinical research network that has been in development since before the COVID-19 pandemic.

This topic aims at maintaining and strengthening existing coordination mechanisms across adaptive platform trials for infectious diseases within the context of the European clinical trial networks for pandemic preparedness and response. Proposals should strengthen the leading role of the EU in clinical research preparedness for future epidemics and pandemics. In the longer-term perspective of preparedness for future infectious disease epidemics and pandemics, these networks should enable the conduct of perpetual platform trials, with the in-built agility to pivot when an epidemic strikes.

Proposals should consider the coordination of adaptive platform trials addressing diverse trial target populations (e.g. primary care or hospitalised patients) as well as different possible medical countermeasures (e.g. therapeutics, vaccines), within or across networks which could include performance study plans for diagnostics. Proposals should address proper connections with relevant initiatives or organisations such as the European Pandemic Preparedness Partnership, the European Health Preparedness and Emergency Response Authority (HERA), the Global Research Collaboration for Infectious Disease Preparedness (GloPID-R)[75], the Coalition for Epidemic Preparedness Innovations (CEPI), or the World Health Organization (WHO).

Proposals should address the following areas:

- Fostering a trusted environment that supports the timely exchange of trial plans, challenges encountered and relevant (early) findings, between adaptive platform trials;
- Developing a common framework for the European trial networks to enable pragmatic solutions to shared challenges across European adaptive platform trials for pandemic preparedness and response, guaranteeing the best interest of European trial patients or volunteers;
- Promoting an optimal use of resources, based on a sound scientific approach and maximising the value added for the generation of scientific evidence, through a common baseline approach towards protocol development, harmonised data collection and analysis;

[72] https://covid19trials.eu/en
[73] https://vaccelerate.eu/
[74] https://www.ecraid.eu/
[75] https://www.glopid-r.org/

- Involving relevant European stakeholders beyond the adaptive platform trial coordinators, such as representatives from regulatory authorities, industry, policy makers, patient organisations, etc., as well as relevant non-European trial coordinators and stakeholders.
- Promoting the visibility and attractiveness of the European trial networks for investigators and sponsors interested to test new or repurposed products, alone or in combination; as well as active communication with the science community, patient advocacy groups and other stakeholders, to develop trust and promote the innovative approach of adaptive platform trials.

HORIZON-HLTH-2023-DISEASE- 3.06: Towards a European partnership on brain health

Single-stage

Action type: CSA

This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 3 "Tackling diseases and reducing disease burden". To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to most of the following expected outcomes.

Expected outcomes:

- Stakeholders[76] identify and agree on the governance structure and implementation modalities, allowing for an efficient establishment of the future partnership.
- Stakeholders build on the knowledge gathered in past studies performed at EU and national level.
- Stakeholders identify and agree on common research priorities and research needs, also taking into consideration developments at the international level where relevant.
- Policy makers, funders and other relevant stakeholders develop and align national and regional research strategy plans with long-term sustainability in mind.
- Policy makers and funders commit to providing financial support that allows for the development of a strong and impact-driven partnership.

[76] Stakeholders include policy makers and funders in the health and research areas, researchers, health care providers and practitioners, patients, citizens, regulators and industry.

A European partnership on Brain Health[77] is expected in the second Strategic Plan of Horizon Europe.

Scope:

- To pave the way for the future partnership, this coordination action will develop a structured system of exchange of information between policy makers, funders, and other relevant bodies[78] in order to establish synergies and avoid duplication of efforts.
- It will further facilitate the development of a strategic research and innovation agenda, taking into account the efforts already undertaken by EU-supported actions[79]. The strategic research and innovation agenda will identify a number of measurable, scientific-technological priorities and socio-economic objectives, supported by an appropriate analysis.
- The coordination action should develop plans for a governance structure of the partnership, as well as implementation modalities with long-term sustainability in mind.
- It should ensure a broad geographical representation of European countries and plan for inclusion of all main related research initiatives, as well as key organisations and associations. In this way, the coordination action should reflect the 'umbrella' role of the future partnership.
- Consideration should be made for international initiatives by engaging with global organisations[80], as well as with global initiatives and research organisations[81] in the field.
- The action should elaborate on platforms and tools for use by the research community, including on how they best complement, integrate with each other. In this context, infrastructures already developed at the European[82] or national level that enable sharing of samples, quality data and advanced analytical tools should be included in the analysis. Reflections should also be made on how the future partnership can contribute to the development of the European Health Data Space.
- This coordination action implies the preparation and organisation of meetings, as well as support to information exchange with relevant stakeholder groups and with the public.

[77] In the context of the partnership, 'brain health' should be interpreted as a concept that encompasses neural development, neuroplasticity, brain functioning, and recovery across the life course, including mental health and wellbeing elements.

[78] Relevant bodies include EU-supported initiatives, scientific and clinical societies, patient organisations, regulators and the industry.

[79] This includes the common research agenda developed by the 'European Brain Research Area' (EBRA) project, as well as the strategic research agendas of the partnerships: 'EU Joint Programme – Neurodegenerative Disease Research' (JPND), 'Network of European Funding for Neuroscience Research' (NEURON), 'Human Brain Project' (HBP) and the 'Innovative Medicines Initiative' (IMI) and its successor the 'Innovative Health Initiative' (IHI).

[80] Global organisations include the World Health Organisation (WHO), the Organisation for Economic Co-operation and Development (OECD) and the Global Alliance for Chronic Diseases (GACD).

[81] Entities include the global brain initiatives, the International Initiative for Traumatic Brain Injury Research (InTBIR) and the International Brain Research Organisation (IBRO).

[82] EU-supported infrastructures include, for example, the BBMRI-ERIC infrastructure for biobanking, the EBRAINS research infrastructure, and various platforms developed by the Innovative Medicines Initiative (IMI) and its successor the Innovative Health Initiative (IHI).

HORIZON-HLTH-2023-DISEASE- 3.07: Relationship between infectious and non-communicable diseases (Comorbidities - relationship between infectious pathogens and non-communicable diseases and its relevance to comorbidities)

Single-stage

Action type: RIA

EXPECTED OUTCOMES:

This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 3 "Tackling diseases and reducing disease burden". To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to the following expected outcomes:

- All players along the health care value chain are provided with new knowledge for a better understanding of the links (e.g. causalities) between infectious diseases (IDs) and non-communicable diseases (NCDs) and comorbidities, including knowledge on host risk factors that impact the development of disease progression for NCDs and/or IDs.
- Researchers and clinicians are provided with a robust evidence base that will contribute to the development of new or improved tools to diagnose and prevent the development of non-communicable disease(s) as well as early treatment and management of patients suffering from co-morbidities following an infectious disease.
- Healthcare practitioners have access to knowledge to guide them on preventive measures for the early identification of diseases onset, particularly those at risk of developing severe disease progression, and on the optimal treatment of patients.
- When NCDs are related to infectious diseases with pandemic potential, healthcare practitioners will be provided with new evidence to help them in future informed decision on the management of the diseases. Public health authorities will be better prepared to issue targeted recommendations linked or not to the use of specific medical countermeasures in crisis times.

SCOPE:

Increasing evidence suggests that several infectious diseases might influence the development of many non-communicable diseases (e.g. multiple sclerosis, Alzheimer, post-covid-19

condition[83]), or that NCD can be strongly influenced by concurrent presence in the same individual of one (or more) infections. On the other hand, NCDs might represent risk factors for IDs.

The proposals are expected to elucidate and provide a better understanding of causative links between infectious and non-communicable diseases onsets, and/or the impact of infections on the exacerbation of existing NCDs. The analysis of genetics, microbiome, lifestyle and/or other relevant factors (e.g. differences in age, sex/gender, ethnicity) should be integrated to get information for early diagnosis and to better understand causative links as well as the progression of those non-communicable diseases.

In determining the connection between one or multiple concomitant infection(s) and the development of non-communicable disease(s), the proposals might address any infectious disease(s) including those with pandemic potential (viral, bacterial, fungal or parasitic) with non-communicable diseases of major importance, such as, but not limited to, rheumatic or cardiovascular diseases, neurodegenerative diseases or diabetes. Research on cancer is excluded as it will be covered by the Mission on Cancer.

Special attention should be given to vulnerable individuals, such as those with known existing preconditions.

Preclinical research, observational studies and/or clinical studies can be considered for this topic. Proposals could include patient follow-up to identify conditions that may appear only after one patient has recovered from the infectious disease. Those proposals including clinical evaluation should give a sound feasibility assessment, provide details of the methodology, including an appropriate patient selection and realistic recruitment plans, justified by available publications and/or preliminary results.

The applicants are encouraged to incorporate artificial intelligence (AI) tools that enable advanced quality data analysis and for assessing and predicting the risk of developing a disease and/or the risk of disease progression/severity where relevant.

Projects funded under this topic that focus on COVID-19 and post COVID-19 condition (also known as long-COVID) are strongly encouraged to collaborate and build links with (one of) the relevant EU-funded projects, such as ORCHESTRA[84]. They should also pay special attention and link to the newly established European COVID-19 data sharing platform[85].

Topics 2024

[83] https://www.who.int/publications/i/item/WHO-2019-nCoV-Post_COVID-19_condition-Clinical_case_definition-2021.1

[84] https://orchestra-cohort.eu/

[85] https://www.covid19dataportal.org/

HORIZON-HLTH-2024-DISEASE- 3.08: Comparative effectiveness research for healthcare interventions in areas of high public health need

2-stage

Action type: RIA

This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 3 "Tackling diseases and reducing disease burden". To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to most of the following expected outcomes.

Expected outcomes:

- Health policy makers are aware of the healthcare interventions (pharmacological, non-pharmacological or technological interventions; including preventive and rehabilitative actions) that are identified as working best for the specific population groups from the point of view of safety, efficacy, patient outcomes, adherence, quality of life, accessibility, and (cost-) effectiveness.
- Health professionals have access to and use the improved clinical guidelines on the optimal treatment of patients and prevention of diseases e.g. through vaccines. Considerations made in the guidelines include the harmonisation and standardisation of care for high burden diseases or conditions throughout Europe, as well as possible individualised needs of patients.
- The scientific and clinical communities make effective use of state-of-the-art information, data, technologies, tools and best practices to develop interventions that are sustainable.
- Citizens, patients, prescribers, and payers receive more accurate information on available healthcare interventions via ad hoc communication platforms.
- The scientific and clinical communities make wide use of the newly established open access databases and/or integrate them with existing open access infrastructures for storage and sharing of collected data according to FAIR principles.

Scope:

Effective, affordable and accessible healthcare for diverse population groups is challenging and complex. For example, specific needs underlie the delivery of effective preventive actions and therapeutic treatments to a rapidly growing elderly population, often presenting comorbidities and associated poly-pharmacy. The paediatric population has also its specific needs in specially adjusted therapeutics and early interventions to address emerging health and developmental problems. Similar to the elderly population, the paediatric population is often excluded from many clinical trials that generate the evidence base for healthcare

interventions. Other population groups with limited access to quality healthcare and/or under-representation in clinical studies include women, low-income groups, and refugees. Intersectionality within these groups also needs consideration.

Applicants should address most of the following:

- Compare the use of currently existing (pharmacological, non-pharmacological and technological) 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[86].
- Ensure acceptability and sustainability of the healthcare intervention through early involvement of 'end users' (e.g. patients, care providers) in the design of the study (integrating patient valued outcomes) and, where possible, in the research process including implementation. Additionally, proposals should take into account the diversity of health systems in different regions of Europe to allow large-scale uptake.
- Consider involving HTA bodies in order to create synergies and accelerate the practical implementation of the results. Where relevant, existing work of EU-funded projects such as EUnetHTA[87] should be also taken into account.
- Consider issues of particular relevance for the target populations, for example, multimorbidity, complex chronic conditions, poly-pharmacy, substance misuse, vaccine efficacy, compliance, age, gender specificities and diseases with high societal burden (including but not limited to e.g. musculoskeletal diseases and mental health disorders). Special consideration should be given to fulfilling all ethical requirements.
- For the chosen population, assess clinical and safety parameters, as well as health and socio-economic outcomes (e.g. quality of life, patient mortality, (co)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. Consider using new instruments and methods for determining the burden of disease and for evaluating the effects of the interventions. Low cost innovations should also be considered.
- Inclusion of patient organisations and associations of caregivers and other healthcare professionals is recommended.
- Clinical trials, including pragmatic clinical trials, observational studies, use of existing health data in different study designs, creation of large-scale databases and performing meta-analyses may be considered for this topic. Use of existing data should always be considered to add value, increase quality and increase implementation speed of the study. Regarding databases, sustainability after the proposed action's end also needs to be considered.
- The proposed research needs to take into account sex and gender aspects.

[86] 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.
[87] https://www.eunethta.eu/

This topic requires the effective contribution of social sciences and humanities (SSH) disciplines and the involvement of SSH experts, institutions as well as the inclusion of relevant SSH expertise, in order to produce meaningful and significant effects enhancing the societal impact of the related research activities.

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. 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.

HORIZON-HLTH-2024-DISEASE- 3.09: Contribution to the Global Research Collaboration for Infectious Disease Preparedness (GLOPID-R) coordinated funding initiative (co-programmed preparedness research at international level)

2-stage

Action type: RIA

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 3 "Tackling diseases and reducing disease burden". To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- EU funded research contributes to addressing research gaps in epidemic and pandemic preparedness for emerging infectious diseases on a global scale, as identified by the Global Research Collaboration for Infectious Disease Preparedness (GloPID-R), and addressed through the GloPID-R coordinated funding initiative.

- Research funders, policy-makers and the research community have access to improved insights and evidence on the public health and/or research preparedness and response to infectious diseases with epidemic or pandemic potential.

- International research funders can rely on a tested framework underpinning a rapid and effective coordinated funding initiative, and as such ensure stronger research coordination for preparedness and response for public health emergencies, including in cross-cutting areas such as data sharing, social sciences, clinical trial networks and others.

- The EU sustains a diverse and modernised pandemic preparedness research pipeline in light of future health threats.

Scope

The COVID-19 pandemic has been a confronting reality-check of the potential extent of threats posed by new or emerging infectious diseases, and illustrated the enormous challenges for a coordinated research response in the face of a large epidemic or pandemic.

The European Commission is a member of the Global Research Collaboration for Infectious Disease Preparedness (GloPID-R)[88], and has been funding the network's secretariat since it was established in 2013. GloPID-R has 32 members across the globe, all committed to facilitating an effective research response to new or re-emerging infectious diseases with epidemic and pandemic potential. GloPID-R is piloting a coordinated funding initiative in order to align and increase efficiency of funding for pandemic preparedness and response. As a strong partner of the network, the European Commission will make a contribution to this pilot initiative. This topic will be launched in concertation with the other GloPID-R members.

Topics to be defined by GloPID-R are expected to directly contribute to supporting global infectious disease research, to better tackle and improve preparedness for potential emerging epidemics or pandemics. The research stemming out of this topic is expected to continue to build on existing pandemic preparedness networks, and contribute to the objectives of the Health Emergency Preparedness and Response Authority (HERA).

The actual scope of the research topic will be defined by GloPID-R in the context of the piloting of the coordinated funding initiative. It is expected that proposals should:

- Respond to the scope and objectives of the topic as defined by GloPID-R, and as such enable the European Commission to take part in the piloting of a GloPID-R coordinated funding initiative;
- Contribute to research activities that address or support epidemic and pandemic preparedness for emerging infectious diseases on a global scale;
- Establish coordination and collaboration with relevant initiatives related to pandemic preparedness such as HERA;
- As relevant, apply a cross-cutting, interdisciplinary One Health approach.

HORIZON-HLTH-2024-DISEASE- 3.10: Integrated management of multimorbidity (GACD)

Single-stage

Action type: RIA

[88] https://www.glopid-r.org/

The final text of this topic will be produced based on the topic description provided the GACD Programme Subcommittee (i.e. developed jointly by all Associate Members, including the Commission). The stable vision of the GACD topic draft is expected in June-July 2023.

Expected Outcome:

This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 3 "Tackling diseases and reducing disease burden". To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to some of the following expected outcomes:

- Health care practitioners and providers in low- and middle-income countries (LMICs) and those in high-income countries (HICs) serving vulnerable populations have access to and use specific guidelines to implement effective evidence-based integrated care for patients with multimorbidity.
- Researchers, public health managers and authorities have access to improved insights and evidences on when, for whom, and under what circumstances, cost-effective, patient-centred models can reduce the fragmentation of care for patients with multimorbidity.
- Health care practitioners, public health managers, communities and local stakeholders and authorities are fully engaged in implementing and taking up evidence-based models of integrated care management for patients with multimorbidity, therefore promoting healthier, more equitable, and more prosperous societies globally.

Scope:

The European Commission is a member of the Global Alliance for Chronic Diseases (GACD), an alliance of international funding agencies representing over 80% of the world's public health research funding and the first collaboration of its kind to specifically address non-communicable diseases (NCDs). The GACD supports implementation science to improve health outcomes. This topic is launched in concertation with the other GACD members funding agencies and aligned with the GACD call 2023.

The overarching goal of this topic is to gather evidence about when, for whom, and under what circumstances, cost-effective, patient-centred models can reduce the fragmentation of care for patients with multimorbidity in LMICs, as well as for patients in vulnerable indigenous populations in HICs.

Multimorbidity is highly prevalent[89], and this prevalence is projected to rise with the ageing of the world population. Collaborative care models, in which physicians, nurses and other specialists work together to manage care for two or more chronic conditions in primary care settings, have taken hold in some LMICs. However, there is still limited evidence to guide

[89] Eyowas FA, Schneider M, Yirdaw BA, Getahun FA. Multimorbidity of chronic non-communicable diseases and its models of care in low- and middle-income countries: a scoping review protocol. BMJ open. 2019 Oct 16;9(10):e033320.

integrated care management for patients, as most clinical guidelines are limited to supporting the management of single diseases in isolation.

Multimorbidity has a profound impact on patients, and is associated with premature death, physical disability, substance abuse, poor quality of life, depression, financial difficulties from high costs of care. It also associated with difficulties in adherence to and high rates of adverse effects from treatment with multiple medications. In addition, due to poor health and the complexity of managing their conditions, patients with multimorbidity are high utilisers of health care. The growing burden of multimorbidity that has accompanied the rise in NCDs therefore adds immense stress to health systems, especially in LMICs, where health systems are still grappling with infectious disease, maternal and infant health, and nutritional problems.

Evidence for how to manage NCD multimorbidity is emerging, mostly from research in HICs. This evidence suggests that integrated and coordinated care, patient-centred interventions, and optimised medication therapy are key to improved management of NCD multimorbidity.

Implementation science proposals should explore evidence-based strategies or interventions around integrated management for multimorbidity and may focus on patient self-management or interventions that transform communities, clinical practice or health systems. Proposals may address any one, or a combination, of following:

- Strategies for improved multimorbidity identification, stratification/staging, management, and/or monitoring
- Strategies to streamline and improving quality of care in individuals with multimorbidity to reduce fragmentation of services, including task-sharing and/or the use of clinical decision-making tools
- Interventions that improve transitions through the health system, from primary to tertiary care and beyond, such as to home or hospice care
- Strategies that optimise appropriate medication and (non-pharmacological) therapeutic prescribing, adherence, and/or reduced drug interactions/ adverse effects
- Health behavioural change interventions that improve management across different risk factor clusters (e.g., exercise, tobacco, nutritional, substance abuse, or alcohol initiatives)

Applicants are encouraged to explore the integrated care management of multimorbidity for any combination of chronic diseases, including mental health disorders and substance abuse. It is not expected that all patients in the study will have the same combination of chronic diseases. Proposals must focus on NCD health outcomes but may include patients with one or more NCDs plus one or more infectious diseases, including, but not limited to, hepatitis, HIV, tuberculosis, and long COVID-19.

It is expected that projects will focus on management of patients with existing multimorbidity and will not focus on prevention of multimorbidity (though projects focusing on the secondary prevention of increased severity of existing NCDs through risk factor management are welcome).

Applicants may take a multi-sectoral, multidisciplinary approaches in their projects. The use of digital interventions, including those that incorporate artificial intelligence, is highly encouraged.

Projects will require a strategy to include policy makers, local authorities, as well as other relevant stakeholders such as community groups, or other individuals or organizations involved in the implementation of the intervention, from the conception and development of the project through to the implementation knowledge translation phase. Project partners should be engaged from the beginning to contribute to the sustainability of the intervention after the end of project.

Patients themselves can be powerful assets. Their contributions should be nurtured through meaningful engagement from the outset, not only as participants in the research undertaken.

In recognition of the relatively few evidence-based interventions for integrated care for NCD multimorbidity, especially in LMICs, applicants are permitted to embed a development or formative phase into their proposal.

Proposals should include implementation research outcomes (e.g. feasibility, fidelity and/or adaptation, spread and/or penetration, acceptability, sustainability, uptake, and cost effectiveness) and where relevant, include service outcomes (e.g. efficiency, safety, effectiveness, patient-centeredness, timeliness). The aim is to harmonise the research common goals and the outcomes assessment of GACD-funded projects in order to maximise the potential for learning across the network and the impact of the initiative as a whole. To this end, all funded teams are expected to use explicit indicators and measures of project context, reach, outcomes evaluation, and scale-up potential in their plans and protocols. In the context of the current call, use of the following measures are encouraged: i) proxy measures for NCD outcomes, which will vary depending on the disease clusters explored (e.g., pre- and post-intervention HbA1C levels, spirometry measures, PHQ-9 scores, etc.); ii) quality of life; iii) disability or pain, and iv) frequency of health service utilisation, including hospital admissions and doctors' visits.

In order to promote the adoption of equitable interventions, proposals must power their studies so that they can capture sex and/or gender differences in intervention acceptability and effectiveness and must present sex-stratified findings in any publications resulting from the work. If it is only feasible to conduct the project in one sex, justification for this must be given in the proposal. It is also required that applicants capture data about the age and socioeconomic status of their study sample and population and consider the generalisability of their findings in any resulting publications.

HORIZON-HLTH-2024-DISEASE- 3.11: Adaptive platform trials for pandemic preparedness (Pandemic preparedness research)

2-stage

Action type: RIA

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 3 "*Tackling diseases and reducing disease burden*". To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- A diverse and comprehensive EU landscape of multi-country adaptive platform trials (i.e. able to study multiple interventions in a disease or condition in a perpetual manner, thus allowing modification to the trial after its initiation without undermining its validity and integrity) that assess medical countermeasures[90] for infectious diseases, and have the capacity to pivot rapidly in the case of epidemic or pandemic health threats.
- Innovative and improved design of clinical studies, suited for pandemic preparedness, is available for the clinical research community, taking into account the high safety standards in the European regulatory environment.
- Trial sites across multiple countries have the capacity to deliver robust clinical evidence in a diverse European population, using harmonised research methods, data collection and analysis.

Scope: As shown by the COVID-19 pandemic, infectious diseases remain a major threat to health and health security in the EU and globally. Health threats are expected to arise due to among others, climate change, and thus a need for proactive approaches to ensure timely availability of medical countermeasures during disease outbreaks is anticipated. The conduct of perpetual adaptive platform trials, with the in-built agility to pivot when an epidemic strikes, is key to be prepared for infectious disease epidemics or pandemics.

This topic aims to provide funding to adaptive clinical platform trials that may be implemented routinely outside of an epidemic or pandemic context, but that are designed to be ready for the timely assessment of novel diagnostics, therapeutics or vaccines in the face of an epidemic or pandemic.

Proposals should develop the wide range of elements needed to sustain multi-country adaptive platform trials, including the trial implementation capacity, laboratory analysis capacity, and a harmonised approach to the collection, storage, sharing and analysis of data.

Proposals should consider the European regulatory environment and take full use of the European capacity to deliver quality trials, including the possibility for registration of new medical products. Proposals should strengthen the leading role of the EU in clinical research preparedness for future epidemics and pandemics.

The proposals should address the following areas:

[90] vaccines, companion diagnostics and therapeutics

- Development of robust clinical evidence that contributes to the knowledge base for the diagnosis, treatment and prevention of infectious diseases. Sex, gender, age, ethnicity and socio-economic factors should be taken into account.
- Known hurdles related to ethical, administrative, regulatory and logistical aspects should be anticipated and addressed to the extent possible, in order to avoid such barriers when the trial needs to pivot in response to an epidemic or pandemic.
- Engagement with clinical researchers and biostatisticians, to increase capacity for the design and implementation of adaptive platform trials across Europe.

Collaboration and coordination with existing adaptive platform trials in the EU is expected, where relevant.

HORIZON-HLTH-2024-DISEASE- 3.12: Maintaining the European partnership for pandemic preparedness (CSA for Pandemic preparedness research)

Single-stage

Action type: CSA

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 3 "Tackling diseases and reducing disease burden". To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- Research funders, policy-makers and the research community maintain a consolidated research and innovation framework for the European partnership for pandemic preparedness, including the Partnership's objectives, governance and ways of working/operationalisation;
- Research funders, policy-makers and the research community are aligned towards common objectives and have a common understanding of the long-term Strategic Research and Innovation Agenda for the Partnership;
- European research funders are supported by a dynamic and efficient secretariat in their coordination efforts for pandemic preparedness research;
- Healthcare providers, European and international stakeholders engage with the appropriate partners through the research and innovation framework for the partnership.

Scope: The COVID-19 pandemic illustrated how unilateral research initiatives may lead to a fragmented research landscape, with substantial room for efficiency gains in the development

of the highly needed evidence to guide policy actions when facing an emergency. The European partnership for pandemic preparedness is working to improve the EU's preparedness to predict and respond to emerging infectious health threats by better coordinating funding for research and innovation at EU, national (and regional) level towards common objectives and an agreed Strategic Research and Innovation Agenda. Such a partnership contributes to building a coherent European Research Area (ERA), enabling Member States, Associated Countries and the European Commission to rapidly and jointly support research and innovation in pandemic preparedness.

The Partnership is expected to continue to build on existing pandemic preparedness networks, and work in synergy with the Health Emergency Preparedness and Response Authority (HERA).

Proposals should foresee administrative and technical support through a secretariat to maintain and support the European partnership on pandemic preparedness.

Proposals should include all of the following activities:

- Provide an efficient secretariat for the European partnership for pandemic preparedness
- Provide administrative and organisational support to the Members in the European partnership for pandemic preparedness;
- Provide strong scientific support on topics requested by the GloPID-R Chairs, scientific advisors or (working) groups;
- Actively engage with relevant stakeholders and initiatives in the area of pandemic preparedness, ensuring collaboration and coordination, and avoiding duplication; e.g. GloPID-R, WHO R&D blueprint, ACT-Accelerator, etc.;
- Implement strong communication and dissemination activities at EU level and in Member States and Associated Countries, on the purpose, activities and outputs of the European partnership for pandemic preparedness, both outside and during epidemic/pandemic episodes;
- Establish coordination and collaboration with relevant initiatives related to pandemic preparedness such as HERA to ensure complementarity and avoid overlaps;
- As relevant, apply a cross-cutting, interdisciplinary One Health approach;

HORIZON-HLTH-2024-DISEASE- 3.13: Validation of fluid-derived biomarkers for the prediction and prevention of brain disorders

2-stage

Action type: RIA

This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 3 "Tackling diseases and reducing disease burden". To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to most of the following expected outcomes.

Expected outcomes:

- The scientific and clinical communities make effective use of state-of-the-art information, data, technologies, tools and best practices to underpin the development of the diagnostics, and as such can also facilitate the development of effective therapeutics and/or preventive strategies.
- The scientific and clinical communities advance the field through a better understanding of mechanisms underlying brain disorders at the molecular, cellular and systemic level.
- The scientific and clinical community make wide use of newly established and where relevant open access databases and/or integrate them with existing infrastructures for storage and sharing of collected data according to FAIR principles, thereby encouraging further use of the data.
- Policy makers, funders, scientific and clinical communities, patient organisations, regulators and other relevant bodies are informed of the research advances made, while health professional envisage use of the biomarker tests for early detection of the disorder and for guiding patients in the selection of personalised treatments.
- Patients and caregivers are sufficiently engaged with the research, which also caters for their needs.

Treatments for some high-burden brain disorders are potentially on the horizon[91]. Consequently, many patients and citizens will want to know if they are eligible for these treatments. For some disorders, a definitive diagnosis is difficult, expensive and time-consuming. Simple blood or other fluid-derived (e.g. saliva, urine, sweat) tests for markers that may indicate early signs of the disorder, and which can be deployed for widespread clinical use are needed.

The brain disorders within the scope of this topic fall under two categories, namely those listed under chapters six and eight of the International Classification of Diseases[92]. Funding will be available for at least one project in each category. Proposals in the area of psychiatric disorders are encouraged.

[91] For example, Aducanumab is the first FDA-approved therapy to address the underlying biology of Alzheimer's disease, while other products are upcoming.

[92] International Classification of Diseases 11th Revision (ICD-11), developed by the World Health Organisation (WHO); Chapter 6: 'Mental, behavioural or neurodevelopmental disorders'; Chapter 8: 'Diseases of the nervous system'.

Scope:

- Proposals should aim to validate biomarkers that can reliably confirm early stages of the human brain disorder and thereby guide treatment selection[93].
- Proposals should aim to provide evidence supporting the regulatory acceptance of the biomarkers[94].
- Exploitation of existing data, biobanks, registries and cohorts is expected, together with the generation of new key data.
- Inclusion of patients or patient organisations in the research is strongly encouraged, as to ensure that their views are considered.
- Sex and gender aspects, age, socio-economic, lifestyle and behavioural factors should be taken into consideration in the study.
- To enable sharing of samples, quality data and advanced analytical and digital tools, consideration should be made for using infrastructures already developed at the European[95] or national level.
- To enable the management of brain disorders, consideration should be made in demonstrating the gained cost efficiency.
- SME participation is encouraged.

HORIZON-HLTH-2024-DISEASE-3.14: Tackling under-researched high-burden medical conditions

2-stage

Action type: RIA

This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 3 "Tackling diseases and reducing disease burden". To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to most of the following expected outcomes.

Expected outcomes:

- The scientific and clinical communities make effective use of state-of-the-art information, data, technologies, tools and best practices to better understand the

[93] The biomarker should link to a clinical meaningful endpoint.
[94] The European Medicines Agency (EMA) offers scientific advice to support the qualification of innovative development methods for a specific intended use in the context of research and development into pharmaceuticals.
[95] EU-supported infrastructures include, for example, the BBMRI-ERIC infrastructure for biobanking, the EBRAINS research infrastructure, and various platforms developed by the Innovative Medicines Initiative (IMI) and its successor the Innovative Health Initiative (IHI).

condition, underpinning the development of diagnostics, therapeutics and/or preventive strategies.
- The scientific and clinical community exchange data, knowledge and best practices, thereby strengthening their collaboration and building a knowledge and care networks in Europe and beyond.
- The scientific and clinical community make wide use of newly established and where relevant open access databases and/or integrate them with existing infrastructures for storage and sharing of collected data according to FAIR principles, thereby encouraging further use of the data.
- Policy makers and funders are informed of the research advances made and consider further support in light of the sustainability of the studies.
- Patients and caregivers are constructively engaged with the research, which also caters for their needs.
- Health professionals have access to and use improved clinical guidelines on diagnosis and/or treatment of the condition.

A number of medical conditions fail to be recognised and/or be correctly diagnosed in a significant proportion of patients. As a consequence they are inadequately treated and often can become a chronic burden for the patient. These medical conditions may be insufficiently researched even though they manifest with high prevalence[96].

Note: the European Commission is commissioning an independent scoping study[97] to help identify under-researched high-burden medical conditions and define the type of research and/or research priorities to better address the different needs of patients with these conditions. This study will be used to adapt the scope of this topic, based on identified priorities.

Scope:

- Proposals should aim at identifying causative mechanisms (e.g. genetic, cellular, molecular, environmental) of the medical condition(s) through basic, pre-clinical and/or clinical research. These efforts should underpin the development of diagnostics, therapeutics, and/or preventive strategies for the condition.
- Where applicable, the development of biomarkers and other technologies for diagnosis, monitoring in patients, and stratification of patient groups.
- Where applicable, the development of clinically relevant, (non-)human model systems that can complement clinical investigations.
- Exploitation of existing data, biobanks, registries and cohorts is expected, together with the generation of new (e.g. genomics, proteomics) data.

[96] The medical conditions do not fall in the category of rare diseases.
[97] The scoping study is expected to be completed in Q3 (2022).

- To enable sharing of samples, quality data and advanced analytical tools, it is encouraged to make use of existing infrastructures developed at the European[98] or national level.
- Sex and gender aspects, age, ethnicity, socio-economic, lifestyle and behavioural factors should be taken into consideration.
- Inclusion of patients or patient organisations in the research is strongly encouraged, to ensure that their views are considered.
- SME participation is strongly encouraged.

[98] A variety of infrastructures have been developed at European level and include, for example, the BBMRI-ERIC research infrastructure for biobanking, while others are being developed like the 'Federated European infrastructure for genomics data'.

HORIZON-HLTH-2023-DISEASE- P5: European Partnership on Rare Diseases

1-stage

Action type: Co-funded Partnership

Budget topic: € 100 Million

Budget per project: € 100 million

HORIZON-HLTH-2024-DISEASE- P6: European Partnership: One Health Anti-Microbial Resistance

1-stage

Action type: Co-funded Partnership

Budget topic: € 100 Million

Budget per project: € 100 million

HERA-specific topics.

HORIZON-HLTH-2023-DISEASE-3.15: research and innovation medical devices and protective equipment for better preparedness for cross-border health threats

X-stage

Action type: RIA

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 3 "*Tackling diseases and reducing disease burden*". To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- The scientific and clinical communities, public health systems and the general public have an increased knowledge of ways to tackle cross-border health threats (including CBRN natural or deliberate release) and can benefit from increased research and innovative medical devices (excluding in vitro diagnostic devices)[99] and personal protective equipment[100] in this context.
- The scientific and clinical communities have access to novel and improved approaches for among others, the prevention, monitoring, prognosis, treatment or protection linked to cross-border health threats.
- Innovative health technologies developed and validated in clinical practice.
- Better surveillance, prevention, detection, treatment and crisis management of infectious disease threats.

Scope: As shown by the COVID-19 pandemic, infectious diseases remain a major threat to health and health security in the EU and globally, this is also the case for other health threats that can be linked for instance to terror attacks. New cross-border health threats are expected to emerge in the coming years and therefore it is essential to promote advanced research of medical countermeasures that can be used to detect, prevent and treat in case of a new health emergency. One of the most important aspects in crisis preparedness times is to ensure the availability of medical devices and personal protective equipment that can be ready for use and deployment in case of a future pandemic.

This call addresses consortia consisting of innovative medical technology providers, including SMEs, and/or organisations that can offer the range of activities required to address the objectives of the topic. The call includes advance research, early stages of product development, accelerator,

[99] According to Regulation 2017/745 EUR-Lex - 32017R0745 - EN - EUR-Lex (europa.eu)
[100] According to Regulation 2016/425 EUR-Lex - 32016R0425 - EN - EUR-Lex (europa.eu)

incubator and technical services and capabilities such as testing and experimentation facilities together with expertise, prototyping, design, engineering or pilot manufacturing services.

Proposals should develop and advance on new medical devices and personal protective equipment to, among others, prevent, monitor, treat or protect against cross border health threats and develop novel approaches to the development of such medical countermeasures to facilitate their use, which target threats identified by HERA[101] or by the WHO[102].

Proposals should aim to diversify and accelerate the global medical research and development of innovative solutions addressing cross-border health threats, and to strengthen the current leading role of the EU in research and development, and therefore contributing to the work of the Health Emergency Preparedness and Response Authority (HERA).

Proposals should address one or more of the following areas:

- Proof-of-concept/early studies of new medical devices and protective equipment for preparedness against cross-border health threats for which there is a lack of devices or PPE or other innovative medical technologies can bring an added value. These solutions should have a clear regulatory and clinical evaluation pathway when applicable. Targeted COVID-19 proposals are excluded from this call.

- New designs, prototypes, engineering and manufacturing concepts that can be readily modified to produce medical devices and/or PPE that can respond to new and multiple pathogens/threats;

- Fast, cost-effective and easily deployable monitoring, screening and prognostic systems that are targeted to individual health threats and can be easily adapted to a wider range;

- protection of healthcare practitioners and the general public with innovative solutions that protect against different cross-border health threats, using for example data-driven approaches, AI and sensors, to detect and warn of health threats at an early stage;

- New designs, prototypes, engineering and manufacturing concepts that allow for a more sustainable production and supply chain including supporting environmentally friendly disposal;

- Innovative devices, equipment or systems linked to better clinical outcomes or broader use should be considered, for instance, portable, faster, more compact or precise devices, tools and technologies.

- Attention should be paid to critical social factors such as sex, gender, age, socio-economic factors, ethnicity/migration, and disability.

- Repurposing of existing medical countermeasures should be considered, in particular in collaboration with low and middle-income countries.

[101] Reference to the HERA list when available
[102] https://www.who.int/activities/prioritizing-diseases-for-research-and-development-in-emergency-contexts

- Regulatory knowledge to ensure future compliance with the legal requirements will be necessary.

HORIZON-HLTH-2023-DISEASE-3.16: Pandemic Preparedness: in vitro diagnostic devices to tackle cross-border health threats

X-stage

Action type: RIA

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 3 "*Tackling diseases and reducing disease burden*". To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- The scientific and clinical communities, health systems and patients benefit from innovative diagnostic solutions that are better suited to tackle cross-border health threats.
- The scientific and clinical communities have access to novel and improved approaches for the detection of pathogens with pandemic potential or other health threats (e.g. CBRN) in the context of epidemic and pandemic preparedness.
- The scientific and clinical communities have access to new tools to detect emerging health threats for clinical investigations.
- A diverse and robust pipeline of in vitro diagnostics is available, increasing options for clinical deployment in case of an epidemic or pandemic.

Scope: As shown by the COVID-19 pandemic, infectious diseases remain a major threat to health and health security in the EU and globally, this is also the case for other health threats that can be linked for instance to terror attacks. New cross-border health threats are expected to emerge in the coming years and therefore it is essential to promote advanced research of medical countermeasures that can be used to detect, prevent and treat in case of a new health emergency. One of the most important aspects in crisis preparedness times is to ensure the availability of diagnostics that can detect health threats.

Proposals should develop and advance on new in vitro diagnostics relevant for detecting cross border health threats and develop novel approaches to the development of such medical countermeasures, which target threats identified by HERA[103] or by the WHO[104].

Proposals should cover pathogens and threats (such as CBRN) for which there are no existing diagnostics or where clinical practice could benefit from innovation. Emphasis should be put on the development of new diagnostics or in the improvement of existing health technologies advancing diagnostics.

[103] Reference to be included
[104] https://www.who.int/activities/prioritizing-diseases-for-research-and-development-in-emergency-contexts

Proposals should aim to diversify and accelerate the global diagnostic research and development pipeline to tackle cross-border health threats, and to strengthen the current leading role of the EU in research and development, and therefore contributing to the work of the Health Emergency Preparedness and Response Authority (HERA).

Proposals should address several of the following areas:

- Proof-of-concept/early studies including research linked e.g. to performance evaluation of new diagnostics that facilitate detection of cross-border health threats for which there is a lack of in vitro diagnostics or existing diagnostics have a sub-optimal performance. These solutions should have a clear regulatory and performance evaluation pathway.
- Data-driven diagnostic and prognostic platforms that can be readily modified to respond to new and multiple pathogens/threats.
- Innovative systems linked to high sensitivity/specificity profiles for broader use of existing in vitro diagnostics should be considered, for instance, portable, faster, more compact or accurate devices and technologies.
- Innovative diagnostics sampling methods or samples to be used that could be a significant improvement.
- When relevant, possibility to develop point of care or self-tests can be considered.
- Attention should be paid to critical social factors such as sex, gender, age, socio-economic factors, ethnicity/migration, and disability.
- Regulatory knowledge to ensure future compliance with the legal requirements will be necessary.

HORIZON-HLTH-2023-3.17 Pandemic Preparedness and Response: Understanding vaccine induced-immunity

X-stage

Action type: RIA

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 3 "*Tackling diseases and reducing disease burden*". To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- The scientific and clinical communities have an increased knowledge of vaccine-induced immunity and, in particular, a better understanding of factors that affect the magnitude and duration of immunity to vaccine antigens.
- The scientific and clinical communities have an increased knowledge of the durability of vaccine-induced immunity in vulnerable populations and older age groups.

- The scientific and clinical communities have an increased knowledge of correlates of protection for pathogens with epidemic potential to allow the development of effective vaccines.
- The scientific and clinical communities have an increased knowledge of the characteristics that influence vaccine effectiveness to allow for novel approaches for the development of vaccines for emerging and re-emerging infections in the context of epidemic and pandemic preparedness.

Scope: As shown by the COVID-19 pandemic, vaccines are a critical component needed to bring infectious disease pandemics under control. The availability of effective vaccines that are able to induce a strong and durable immune response are critical to respond to health threats caused by infectious disease epidemics or pandemics. A proactive approach to understanding the factors that affect vaccine durability and strength is necessary to ensure development of effective vaccines for future infectious disease outbreaks.

Proposals should study vaccine-induced immunity in the general population and vulnerable groups. Proposals should look both at the magnitude of initial immune responses and the duration of immunity after vaccination. Proposals should assess how sex (e.g. male vs female, pre- vs postmenopausal), age (childhood vs adolescent vs elderly) and life style (e.g. obesity, drug addiction, diet, sport) affect the immune response. Proposals should examine genetic factors that may influence immune response.

Proposals should identify correlates of protection that can be used to develop vaccines against viruses with a high epidemic or pandemic potential, such as those identified by HERA or included in the list of priority diseases of the World Health Organization (WHO)[105].

Proposals should aim to improve the global vaccine research and development pipeline for emerging and re-emerging viral infections, and to strengthen the current leading role of the EU in vaccine development, and therefore contributing to the work of the Health Emergency Preparedness and Response Authority (HERA).

HORIZON-HLTH-2023-DISEASE- 3.18: Immunogenicity of surface proteins of viruses with epidemic potential (Pandemic preparedness research)

X-stage

Action type: RIA

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 3 "*Tackling diseases and reducing disease burden*". To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

[105] https://www.who.int/activities/prioritizing-diseases-for-research-and-development-in-emergency-contexts

- The scientific and clinical communities have an increased knowledge on viruses with epidemic potential and in particular a better understanding of viral targets for vaccine development.
- The scientific and clinical communities have access to novel approaches for the prevention and treatment for emerging and re-emerging infections in the context of epidemic and pandemic preparedness.
- The scientific and clinical communities have access to experimental vaccine candidates against emerging or re-emerging viral infections for further clinical investigation.
- A diverse and robust pipeline of vaccine candidates is available for emerging and re-emerging viral infections, increasing therapeutic options for clinical deployment in case of an epidemic or pandemic.

Scope: As shown by the COVID-19 pandemic, infectious diseases remain a major threat to health and health security in the EU and globally. Viral disease emergence is expected to accelerate due to among other, climate change, and thus a proactive approach to the development of vaccines and inhibitors for the cellular uptake of viruses in preparedness for future infectious disease outbreaks is needed. The availability of vaccines would provide a critical preparedness measure against future health threats, due to infectious disease epidemics or pandemics.

Proposals should identify targets for optimal vaccine design for those pathogens where information on host-pathogen interaction and viral surface structures is already available. These surface structures may require further characterisation. It is necessary to determine the extent of genetic variation with a view to develop vaccines with variant efficacy. In addition, it is necessary to develop animal and alternative models for the testing of vaccine candidates and for the kinetics, strength and persistence of the immune response. Proposals should focus on viruses causing diseases that are in the list of priority diseases of the World Health Organization (WHO)[106], such as Hendra and Nipah Virus, Lassavirus, Rift Valey Fever virus, Crimean Congo hemorrhagic fever, Lassa fever, Rift Valley fever, Ebola, Dengue, Yellow Fever, Zika, West Nile fever and Chikunguya. In order to ensure complementarity to ongoing research and development projects, proposals addressing influenza and coronaviruses are discouraged as well as projects overlapping with vaccine development projects of CEPI.

Proposals should provide innovative approaches with the aim to diversify and accelerate the global pandemic preparedness research and development pipeline for emerging and re-emerging viral infections, and to strengthen the role of the EU in therapeutic research and development, and therefore contributing to the work of the Health Emergency Preparedness and Response Authority (HERA).

Proposals should address the following areas:

[106] https://www.who.int/activities/prioritizing-diseases-for-research-and-development-in-emergency-contexts

- Selection of prototype pathogens from virus families
- Identification of key antigenic targets for the prototype priority pathogen
- Establishment of animal models for the testing of vaccine candidates.
- Characterisation of the immunogenicity of targets in the animal models and in pre-clinical tests.

HORIZON-HLTH-202X-DISEASE-3.19: Host-pathogen interactions of infectious diseases with epidemic potential (Pandemic preparedness research)

X-stage

Action type: RIA

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 3 "*Tackling diseases and reducing disease burden*". To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- The scientific and clinical communities have an increased knowledge on viruses with epidemic potential and in particular a better understanding of pathogen–host interactions for the targeted development of vaccines and inhibitors for the prevention of viral infection and the viral transmission during pathogenesis.
- The scientific and clinical communities have access to novel approaches for the prevention and treatment for emerging and re-emerging infections in the context of epidemic and pandemic preparedness.
- The scientific and clinical communities have access to experimental vaccine candidates and candidates that inhibit cellular uptake of viruses against emerging or re-emerging viral infections for further clinical investigation.
- A diverse and robust pipeline of vaccine candidates and candidates that inhibit cellular uptake of viruses is available for emerging and re-emerging viral infections, increasing therapeutic options for clinical deployment in case of an epidemic or pandemic.

Scope: As shown by the COVID-19 pandemic, infectious diseases remain a major threat to health and health security in the EU and globally. Viral disease emergence is expected to accelerate due to among other, climate change, and thus a proactive approach to the development of vaccines and inhibitors for the cellular uptake of viruses in preparedness for future infectious disease outbreaks is needed. The availability of vaccines and candidates that inhibit cellular uptake of viruses would provide a critical preparedness measure against future health threats, due to infectious disease epidemics or pandemics.

Proposals should follow innovative approaches to characterize host-pathogen interactions with a view to inhibit viral replication, viral proteases, viral exist strategies and to develop

therapeutic antibodies and vaccines that target viruses with high epidemic or pandemic potential for the EU. Proposals should focus on viruses causing diseases that are in the list of priority diseases of the World Health Organization (WHO)[107], such as Hendra and Nipah Virus, Lassavirus, Rift Valey Fever virus, Crimean Congo hemorrhagic fever, Lassa fever, Rift Valley fever, Ebola, Dengue, Yellow Fever, Zika, West Nile fever and Chikunguya. In order to ensure complementarity to ongoing research, proposals addressing influenza and coronaviruses are discouraged.

Proposals should aim to diversify and accelerate the global therapeutic research and development pipeline for emerging and re-emerging viral infections, and to strengthen the current leading role of the EU in therapeutic research and development, and therefore contributing to the work of the Health Emergency Preparedness and Response Authority (HERA).

Proposals should address several of the following areas:

- Identification and characterisation of receptors on the host cell that enable the docking and internalisation of a virus with a particular emphasis on the diversity of cellular entry receptors and tissue specificity.
- Identification and characterisation of viral surface proteins that are capable of interacting with host target cells.
- Characterisation of the mechanism of viral uptake in the host cell with regard to the topology and the dynamics of the host receptor – virus ligand interaction.
- Identification of receptor and ligand (sub)units that could be targeted by preventive or therapeutic intervention.

[107] https://www.who.int/activities/prioritizing-diseases-for-research-and-development-in-emergency-contexts

Destination 4. Ensuring access to innovative, sustainable and high-quality health care

Topics 2023

HORIZON-HLTH-2023-CARE- 4.1: Maintaining access to regular care in case of cross-border health emergencies

Single-stage

Action type: RIA

Expected outcomes:

This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 4 "Ensuring access to innovative, sustainable and high-quality health care". To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to some of the following expected outcomes:

- Decision- and policy makers have access to modelling tools and foresight studies on health and care systems[108] to anticipate regular[109] and unplanned care demand during large-scale cross-border health emergencies.
- Decision- and policy makers and health and care providers can better manage access to regular care delivery during cross-border health emergencies.
- Decision- and policy makers and health and care providers avail of management frameworks including organizational models to handle unplanned care demand linked to cross-border health emergencies, while maintaining necessary regular care.
- Health and care professionals have access to training on how to deliver regular care (including by means such as telemedicine) during cross-border health emergencies.
- Health and care professionals, citizens and patients access advanced digital tools enabling managed access to regular care, complemented by other modes of care (e.g., telemedicine, self-care, prioritized care).
- Patients are co-designers of health and care delivery models during cross-border health emergencies and can benefit from a better access to regular care during such periods.
- Health and care providers and health and care professionals have access to knowledge and data on, as well as innovative solutions to counter, decreased demand for health and care despite a need for care, that takes place as a result of an ongoing health

[108] In the EC COM(2018)233 health and care systems is defined as follows: "The term "health and care systems" implies a broader notion than "health systems" or "healthcare systems" notably encompassing public health and social care.

[109] Regular care refers to the care that would be expected to be needed and delivered under normal circumstances. This includes all types of morbidities (chronic diseases, mental health disorders, traumatology etc.) and also all parts of the health and care systems (prevention, long-term care, primary care, both in- and out hospital care etc.), as well as related support services such as laboratories.

emergency (for example because patients are worried about infections at hospitals or do not want to add extra burden to the health and care systems).

Scope:

Since the outbreak of the Covid-19 pandemic European, as well as global, health and care systems have been facing unprecedented challenges. Many health and care delivery systems were overwhelmed and short on critical infrastructure, supplies, and staff. Beyond the initial challenges posed by the pandemic, its prolonged duration has strained health care facilities and providers and had a negative impact on regular care provision. Temporary disruptions in routine and non-emergency medical care access and delivery have been observed. It is hence timely to take stock and identify lessons for maintaining care delivery. The goal is to be better prepared for the multiple challenges faced by health and care systems in health emergencies, and to ensure that necessary access to regular care can be maintained.

Proposals for research and innovation actions are expected to address several of the following:

- Analysis and evaluation of the different epidemics response measures in Member States aimed at maintaining access to regular care, including training needs of the health and care workforce.
- Development of innovative tools and models – for example to develop modelling and foresight tools to assess and anticipate impact of cross-border health emergencies on the delivery of regular care; to develop novel technical solutions or organizational management models for regular care delivery in future cross-border health emergencies; to demonstrate applicability of novel modelling tools, management frameworks and organizational models in selected areas of regular care (e.g. chronic diseases, mental health disorders, traumatology).
- Development and implementation of digital tools – develop, implement and generate evidence of benefit of novel digital systems connecting health and care professionals, citizens and patients at-scale, helping maintain access to care during emergencies (including but not limited to appointment management, chronic disease self-management application, primary care and/or referral caseload prioritisation and management incl. triage, integrated telecare suites complemented by new computational methods such as AI/ML, etc.).

Interdisciplinary research is encouraged, including the involvement of social sciences considered essential for care delivery in different social contexts and for the evaluation of health economical aspects.

Synergies should be sought with potentially contributive research initiatives, data collectors and research infrastructures such as the European Observatory on Health Systems and Policies, the OECD, the Population Health Information Research Infrastructure, the future European co-funded partnership on Transforming Health and Care Systems (THCS).

Successful projects need to adequately link and integrate with relevant EU health policy efforts towards a European Health Data Space (EHDS) and the nascent Health Emergency Response Authority (HERA)[110].

HORIZON-HLTH-2023-CARE-4.2: A resilient health and care workforce for the future

Single-stage

Action type: RIA

Expected outcomes:

This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 4 "Ensuring access to innovative, sustainable and high-quality health care". To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to some of the following expected outcomes:

- Health and care workers receive support (including mental health support), access to tools and guidance in order to adapt to changing working conditions, as a result of new technologies, new work models or unexpected adverse events, including emergency situations.
- Decision- and policymakers, employers and social partners in the health and care sectors[111] have knowledge of the specific risks for the resilience and well-being of health and care professionals or informal workers, and access to solutions (regulatory, organisational, technological, educational, HR, health services) to prevent and manage them.
- Decision- and policymakers, providers, employers and social partners in the health and care sectors have knowledge of and benefit from new or existing good practices on how to ensure that working in the health and care sector remains attractive, workers are retained and new people are attracted to the sector and related education programmes.
- Funders of health and care provision have access to evidence, novel approaches and cost-effective recommendations for interventions supporting health and care workers at all levels.
- Policy makers cooperate with relevant stakeholders, including health and care professionals associations and social partners to foster specific solutions to improve resilience and well-being of health workers and carers including informal carers.

[110] COM(2021) 576 final

[111] In the EC COM(2018)233 health and care systems is defined as follows: "The term "health and care systems" implies a broader notion than "health systems" or "healthcare systems" notably encompassing public health and social care.

Scope:

Working in the health and care sectors is an important activity and essential for the sustainability of our societies. However, careers in the health and care sector can be physically and mentally taxing and constitute potential psychosocial risks (for example heavy workload, stressful working conditions, risk of exposure to infectious agents, precariousness etc.). This should be seen in the context of European health and care systems struggling with challenges related to attracting new people to their workforce, but also to maintain the ones already working there. The combination of factors such as changes in work organisation, budgetary and administrative pressures faced by health systems, systemic shortages of health professionals, precarious working conditions, structural inequalities and leaps in technological innovation may leave health workers with feelings of helplessness, physical or mental vulnerability or moral injury.

Digital and technological innovations provide opportunities for a more efficient provision of health and care services, and for lightening the workload of health and care workers. However, they also create new risks, potentially affecting the well-being of the workforce: acquisition of new skills, new organisational models, worker surveillance, lack of control or accountability in workplace decisions, are elements that can increase stress and hamper the ability of health and care workers to function in their jobs on a daily basis.

The COVID-19 pandemic has put a strain on health and care workers' resilience and exacerbated mental health issues that were already a problem pre-pandemic, ranging from anxiety due to increased workload to burnout and post-traumatic stress disorder. Informal carers suffer from similar stress, but the situation is different, e.g. as for them there is no employer to hold accountable. Lack of acknowledgement that one's mental health is deteriorating, barriers to seeking help or the stigma that still surrounds mental illness may impede people from addressing such problems early enough. Different socio-economic groups are affected to different extents: in emerging virus outbreaks prior to the COVID-19 pandemic lower educational level among other things was associated with higher risk for adverse psychological outcomes among health workers[112].

A resilient health and care workforce is of utmost importance for health and care systems to function properly, especially if under pressure by future pandemics or events of a similar impact. Synergies between health and care and research policies, management decisions, work organisation models and personalised approaches are necessary to mitigate the impact of psychosocial risks, support workers' resilience and adaptation to new working conditions and promote their well-being in the workplace, through novel and more holistic approaches.

With women making up over 70 % of EU health care professionals and employees in the care sector, an appropriate gender approach is essential in research and policy interventions, to prevent or mitigate workplace inequalities and imbalances. Researchers and policymakers should also take into account the inclusion dimension, as a significant share of health

[112] https://ec.europa.eu/health/system/files/2021-10/028_mental-health_workforce_en_0.pdf

professionals or care workers typically come from minority groups, whether through declared or undeclared work.

Successful applicants must address one or more/several of the following activities:

- Evidence and data generation, including cost-benefit studies – such as the building of evidence (data) on occupation-specific factors building the resilience and well-being of health and care workers, or informal carers. Where appropriate, evidence should be gathered and analysed on the interplay of such factors with non-occupation specific factors (e.g. genetic, social etc.). When relevant, such evidence should be target-group specific, considering variation of challenges for professionals working in various settings (primary care, hospitals, residential care institutions, disadvantaged geographic locations).
- Policy recommendations – development of action-oriented recommendations to policymakers, employers, social partners and civil society organisations at the appropriate levels (EU, national, regional, local) based on evidence generated by the proposed action. Such recommendations should suggest effective policy interventions or elements for further research regarding a future workplace in the health and care sector, which rewards professionals and promotes their resilience and well-being.
- Development of innovative solutions – develop innovative solutions (including digitally enabled ones), organisational models, management approaches and/or novel educational strategies, to support health policymakers, employers and formal or informal carers in promoting resilience and well-being in the workplace; develop financing and resource allocation models to ensure access to support and mental health services for health and care workers specifically; create trainings and protocols for health and care workers to accurately perform their job in crises situations while ensuring a good level of resilience and well-being.
- Implementation activities – For example support actions to implement or upscale specific solutions[113] improving conditions for health and care workers or informal carers according to specific factors influencing well-being (e.g. burnout, exposure to pandemic, moral injury, roles, factors intrinsic to the job, inter-personal); collect and disseminate good examples of policies and solutions to support resilience and improve well-being, including mental health, of formal and informal carers, with specific attention to more vulnerable groups (e.g. unsecure job contracts, working conditions, minority groups, lower educational level, higher stressed due to performed functions etc.). Activities could include twinning, piloting, capacity building, leadership trainings, etc.

Applicants can select one or more worker groups or informal carers as target of R&I activities, based on credible scientific criteria. For example, by taking into account the effects

[113] The European Commission supports Member States' health priorities via the implementation of good practices and implementable research results. See Steering Group (europa.eu) for information on how this process works.
Practices can also be shared via the Best Practice Portal (pb-portal (europa.eu). Examples of interventions that were initiated to tackle the mental health impact of the pandemic are also available on the pages of the dedicated web space on that topic on the Health Policy Platform https://webgate.ec.europa.eu/hpf/

and risks on health and care workers in different parts of the health and care systems, such as hospital settings, primary care settings, long-term or other community-based care settings.

Health and care professionals associations, informal carers associations, workers and SSH experts, should be consulted or involved in the design and implementation of the above-mentioned research projects.

Applicants should consider potential synergies and avoid overlaps with ongoing calls or actions funded under EU or national programmes (for example EU4Health, Digital Europe), particularly in the areas of (digital) skills and training of the medical workforce, for example the Joint Action on Health Workforce Forecasting and Planning (set up under the EU4Health programme), the future cofunded partnership on Transforming Health and Care Systems (THCS).

Proposals are encouraged to use, when relevant, the EU Strategic Framework on Health and Safety at Work (2021-2027) https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021DC0323&from=EN, the report on mental health https://ec.europa.eu/health/other-pages/basic-page/mental-health-and-pandemic-living-caring-acting_en.

When relevant, the recommendations and analysis presented in the Expert Panel on effective ways of investing in health (EXPH) opinion on supporting the mental health of the health workforce and of other essential workers[114] should be taken into account by the proposals in this topic.

HORIZON-HLTH-2023-CARE- 4.3: Environmentally sustainable and decarbonised health and care systems

Single-stage

Action type: RIA

Expected outcomes:

This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 4 "Ensuring access to innovative, sustainable and high-quality health care". To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to some of the following expected outcomes:

[114] hat the potential current mental health conditions do not become disabilities. Therefore, the Expert Panel on effective ways of investing in health (EXPH) was requested by the European Commission to provide an opinion on supporting the mental health of the health workforce and of other essential workers

- Policy and decision makers, providers of health and care, health and care workers and citizens have increased knowledge on how today's health and care systems[115] are not environmentally sustainable, what the costs of that are (today and future) and where improvements are possible with maintained or improved quality of care.
- Policy and decision makers and providers of health and care services have access to innovative solutions, organisational models (including financing models), and guidelines and recommendations that increase the environmental sustainability of health and care systems, so that health and care provision can become more sustainable and cost-effective while maintaining or improving quality of care thanks to the reduction of energy and materials use, decreased carbon emissions, reduced waste and discharges, and efficient resource management.
- Monitoring and reporting of carbon emissions and environmental performance is mainstreamed in the health and care systems.

Scope:

The health care sector is responsible for 4-5% of global total carbon emissions[116], and generates significant demands for energy and materials, as well as dangerous waste streams. At the same time, health and care provision generally experiences less pressure to decarbonise and improve its circularity than other sectors of the economy. With the European Green Deal, the EU commits to reducing net greenhouse gas emission by at least 55% by 2030, and no net emissions by 2050, and the health and care systems are not exempt. Research and innovation can help by ensuring a smooth transformation while maintaining or improving quality of health and care services.

In 2020 the UK's national health service announced its intention to achieve a carbon net zero goal by 2040 and 2045 (for its direct and extended carbon footprints, respectively)[117]. During COP26, 13 other countries (including Member States Belgium and Spain) have pledged to join the UK in cutting all carbon emissions from their health systems over the next 10 to 30 years.

In February 2022, the WHO published a report on the waste that had been generated as a result of the COVID-19 pandemic, even more emphasising the need to improve waste management systems of the health and care systems[118]. The report states that 30% of healthcare facilities word-wide, and 60% in the least developed countries, are not fit to handle the waste generated even when not taking the extra waste generated by the pandemic into account. Not only does this pose environmental risks such as water and air quality, but it also poses a risk to health workers' safety by increasing the risk of being exposed to stick injuries, burns and pathogenic microorganisms.

[115] In the EC COM(2018)233 health and care systems is defined as follows: "The term "health and care systems" implies a broader notion than "health systems" or "healthcare systems" notably encompassing public health and social care.

[116] https://www.thelancet.com/action/showPdf?pii=S2542-5196%2820%2930271-0

[117] https://www.england.nhs.uk/greenernhs/wp-content/uploads/sites/51/2020/10/delivering-a-net-zero-national-health-service.pdf

[118] https://www.who.int/news/item/01-02-2022-tonnes-of-covid-19-health-care-waste-expose-urgent-need-to-improve-waste-management-systems

Research and innovation activities under this topic should address one or more/several of the following:

- Research and innovative solutions for decarbonisation of hospitals and other care facilities: improvements in new and existing building stock, decarbonisation of energy supply to premises, reduction in energy demand of hospital sites (heating and cooling, hot water, laundry, cooking, transport systems). Piloting research results onsite in hospitals or other care settings while generating accessible knowledge could be included. Cost studies included when relevant.
- Research and innovative solutions for increased circularity of hospitals or other care facilities: improved waste disposal (with a possible focus on water effluents and AMR), sustainable use of linen. Piloting research results onsite in hospitals or other care settings while generating accessible knowledge could be included. Cost studies included when relevant.
- Research and innovative solutions for decarbonisation and greening of supply chains and material inflows: reduction of single-use plastics, substitution of anaesthetic gases and inhalers with high GWPs, substitution of conventional pharmaceuticals with green(er) alternatives, low-carbon supply chains of food, waste reduction. Piloting research results onsite in hospitals or other care settings while generating accessible knowledge could be included. Cost studies included when relevant.

Projects with interdisciplinary teams representing both the health and care sector, and the environmental sector or other relevant sectors are welcome.

Applicants are encouraged to consider how their proposals can contribute in the context of the European Green Deal, and to take into account the principles of the Circular Economy Action Plan as well as the Technical guidance on the climate proofing of infrastructure in the period 2021-2027.

Topics 2024

HORIZON-HLTH-2024-CARE-4.4: Access to health and care services for vulnerable groups

Single-stage

Action type: RIA

Expected outcomes:

This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 4 "Ensuring access to innovative, sustainable and high-quality health care". To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to some of the following expected outcomes:

- Decision- and policy makers, service providers, and health and care workers have better availability to and make use of knowledge on barriers to access to health and care services, experienced by groups that are vulnerable and at risk of stigma or discrimination (from now on referred to as vulnerable groups)[119].
- Decision- and policy makers, providers and health and care workers have access to innovative solutions to promote and improve access to health and care services for vulnerable groups.
- Health and care authorities and providers and decision-makers use innovative solutions to facilitate and encourage the access to health and care services for vulnerable groups.
- Decision- and policy makers and providers have access to reliable quantitative data on health inequalities in access to health and care services for vulnerable groups.
- Vulnerable groups are involved in the design and implementation of research and innovation activities concerning access to health and care services.

Scope:

Equal and needs-based access to health and care services are important values of the EU, as well as central principles within the Member States (for example Art. 3 TFU, 2006 Council Conclusions on Common values and principles in European Union Health Systems, European Pillar of social rights). At the same time, plenty of evidence indicates that there is unmet need for health and care services. Although financial barriers are an important part of the explanation[120], it is also evident that even in countries where co-payment is low or even zero,

[119] Groups of people and/or patients vulnerable from a social, financial, or health perspective, or at risk of discrimination, such as migrants, Roma people, trans and intersex people, specific age and gender groups (such as/elderly women), homeless people, people in poverty or at risk of poverty, people with disabilities or patients with complex conditions.

[120] See for example OECD Health at a glance 2021.

access to health and care services differs between groups. Certain groups are more at risk of not accessing all the health and care services they need, depending among other factors, on their socio-economic and legal status, age, sex and gender identity, (dis)ability, ethnicity and geographical location.

For example, the Roma people – the largest ethnic minority in the EU – on average live more than ten years less compared with the general population. This is because too many Roma live in poor socio-economic conditions and ethnically segregated enclaves where standard opportunities including infrastructure and services, are lacking. Due to these inequalities that are also rooted in antigypsysim[121], Roma are facing much greater difficulties accessing and receiving standard health and care services including prevention compared to other citizens. [122].

There are significant health inequalities between the LGBTIQ community and the population as a whole. One part of the explanation is reluctance to seek health and care services because they have experienced or fear hostile reactions. Trans- and intersex people still struggle to access quality and affordable medication and care, both related to general health services and specific health care relating to transition, such as a lack of relevant medication or surgical procedures[123].

Compared to men, older women have a higher poverty risk also due to lower pay and lower pensions. They face a higher risk to live longer in poorer health, so their overall need for health and especially care services is therefore higher[124]. Other persons living in difficult socio-economic situations, such as homeless people or people at the risk of poverty may experience similar issues. For migrants and refugees, uncertain legal status, fear of public authorities, or language difficulties may cause additional barriers to seeking adequate health and care services.

Whilst factors outside the health and care sector also have an impact on people's access to health and care services, health and care systems can influence and facilitate access through accessibility, costs, referrals and attitudes.

Another aspect concerns access to data regarding certain groups. Whereas data on access to health and care when it comes to factors related to socio-economic characteristics, geographical barriers, sex, age is more accessible, data on specific vulnerable groups (often due to the problem of sensitivity of data) is often less accessible, contributing to making the situation of these groups less visible.

[121] Antigypsyism (a form of racism against Roma) is a historically rooted structural phenomenon that appears at institutional, social and interpersonal levels.

[122] The EU Roma strategic framework for equality, inclusion and participation sets up the ambitious goal to lessen the life expectancy gap and ensure that by 2030 Roma women and men live 5 years longer . https://ec.europa.eu/info/sites/default/files/eu_roma_strategic_framework_for_equality_inclusion_and_participation_for_2020_-_2030_0.pdf

[123] stateofart_report_en.pdf (europa.eu) The Commission's Health4LGBTI project concluded that trans and intersex-focused research is needed that addresses health inequalities and healthcare.

[124] To be inserted

Activities under this call should focus on groups that are vulnerable from a social, financial or health perspective, or at risk of discrimination, such as migrants, Roma people, trans and intersex people, specific age and gender groups, such as elderly women, homeless people, people in poverty or at risk of poverty, people with disabilities or patients with complex conditions. Where relevant, activities should use intersectional approaches to consider, inter alia, socioeconomic factors, geography, citizenship, age, sex and gender identity, and ethnicity.

Next to the above-mentioned, research and innovation activities under this topic should address one or more of the following:

- Different types of barriers - different barriers to study could be financial, geographic, social, marginalization and discrimination. The selection of factors should be context specific as groups suffering from access barriers vary a lot across EU countries and at subnational level. The principle of needs-based health and care should be taken into account.
- Access to what? – for example: what part of the health and care system (from prevention, primary care and long-term care to tertiary care, any specific services, e.g. mental care) do different groups have access to? Is integrated care provided for these groups taking into account their particular needs? How much health and care services do different groups access?
- Solutions - What measures are needed to counter inequalities in health and care access and make sure that vulnerable groups access health and care services and that access is based on needs? Piloting of measures could be included. Community-based and/or co-created initiatives and peer-support approaches: what works and how can these be supported, sustained and/or integrated in the wider service landscape.
- Better data – improving access and quality of data will contribute to identify vulnerable groups' health needs and implement targeted measures corresponding to the challenges that each group experiences. The data could for example explore effectiveness of provided care (metrics helping to assess if provided care addresses the root causes of inequalities). Quantitative and qualitative data on inequalities in prevention, prevalence and treatment of different morbidities.
- Cost analyses - The cost of inequalities in access to health and care services: Quantitatively and/or qualitatively measure the negative impact on not taking measures for helping vulnerable groups have access to health and care services including prevention.

Proposals are expected to involve the vulnerable groups studied in the design and implementation of the research and innovation activities and where relevant service providers and other stakeholders.

When relevant, funded actions should build on the work done by the European Joint Action on Health Equity Europe (JAHEE) and the upcoming activities under the EU4Health Programme (Direct grants to international organisations (WHO): supporting Member States in improving access to healthcare and effectiveness of health coverage, taking into account vulnerabilities of specific groups and targeted intervention and access to mental health for vulnerable groups).

Also, when relevant, projects should build on, and are encouraged to consider how their proposals can contribute to, the Commission's LGBTIQ Equality Strategy 2020-2025, the EU Strategy for the rights of persons living with disabilities, EU strategy on the rights of the child the Child Guarantee, the Gender Equality Strategy, the EU Roma Strategic Framework and the EU Strategy for the Rights of Persons with Disabilities 2021-2030[125].

Projects are encouraged to coordinate their activities with the planned European Partnership on Transforming Health and Care Systems, the Cancer Inequalities Registry and the EU Non Communicable Diseases Initiative.

Projects may explore the Health Systems Performance Assessment (HSPA) Report on more effective ways of measuring access to healthcare, published in 2021. The report provides a collection of tools used on the ground to better understand needs of vulnerable groups and adapt the health coverage to ensure more effective care.

2021 Country Profiles published in the framework of the State of Health in the EU can be used as a source of basic comparable data on health inequalities.

HORIZON-HLTH-2024-CARE-4.5: Pre-commercial procurement for environmentally sustainable and low-carbon health and care systems

Single-stage

Action type: PCP

Expected Outcomes:

This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 4 "Ensuring access to innovative, sustainable and high-quality health care". To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to some of the following expected outcomes:

- Public and private procurers in the area of health and care systems[126] stimulate the competitive development of market-ready, environmentally sustainable innovative solutions (materials, technologies and systems/practices).

[125] (under the European Pillar of Social Rights) Delivering on the European Pillar of Social Rights - Employment, Social Affairs & Inclusion - European Commission (europa.eu) Union of equality: Strategy for the rights of persons with disabilities 2021-2030 - Employment, Social Affairs & Inclusion - European Commission (europa.eu) https://ec.europa.eu/social/BlobServlet?docId=23598&langId=en

[126] In the EC COM(2018)233 health and care systems is defined as follows: "The term "health and care systems" implies a broader notion than "health systems" or "healthcare systems" notably encompassing public health and social care.

- European health and technology industry actors (including start-ups/SMEs) bring to the market environmentally sustainable innovations that are secure, and when relevant 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 for patients as well as reduce pollution and expenses for health and care systems and patients.
- Procurers facilitate the commercialisation of environmentally sustainable innovative solutions at a large scale (EU/international) by their successful suppliers through providing them with first customer references for the validation and first pilot deployment in multiple countries and health and care settings.
- Policymakers, health care providers and professionals, patients and their carers – each in their respective areas – exchange and adopt good practices and the best solutions the market can deliver to improve the environmental sustainability of health and care systems.
- Health and care workers and patients have a higher awareness of environmentally sustainable innovations and practices

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 plastics 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. The health care sector is responsible for 4-5% of global total carbon emissions[127]. 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 Annexes X of Horizon Europe.

[127] https://www.thelancet.com/action/showPdf?pii=S2542-5196%2820%2930271-0

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

Successful applicants should focus on, but are not limited to:

- reducing health and care sectors' carbon footprint and environmental impact, through improving energy consumption and usage in heating, lighting, ventilation, air conditioning, electrical (including diagnostic) equipment, transport, supply chain, among others. Full design of new or improved care facilities could be included.
- adopting green health and care solutions (e.g. alternatives to plastics and single-use devices) and reducing production of waste and contamination of the environment attributable to the 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.
- Improving climate-neutrality of digital solutions in health and care systems.

Within this topic, it is possible to foresee the transfer and adaptation of solutions and/or interventions from other sectors to health and care systems, 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.

Applicants are encouraged to consider how their proposals can contribute in the context of the European Green Deal, and to take into account the principles of the Circular Economy Action Plan.

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-2023-CARE- P4: European Partnership on Personalised Medicine

Single-stage

Action type: Co-funded Partnership

Budget topic: € 100 Million

Budget per project: € 100 million

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

Topics 2023

HORIZON-HLTH-2023-TOOL- 5.01: Clinical trials of Combined ATMPs

Single-stage

Action type: RIA

Expected outcomes

This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 5 "Unlocking the full potential of new tools, technologies and digital solutions for a healthy society". To that end, proposals under this topic should aim for delivering results that are directed towards and contributing to several of the following Expected Outcomes:

- Healthcare providers get access to innovative treatment options with demonstrated health benefits for unmet medical needs
- Developers of Combined ATMPs obtain scientific certainty on proposed therapeutic approach
- Patients benefit from new advanced therapies delivered through the combined ATMPs
- EU companies get a better market position in the field of combined ATMPs

Scope:

Subject of this topic are Combined ATMPs according to the definition of the ATMP-regulation (EU 1394/2007, Article 2d). Such Combined ATMPs are composed of an ATMP and one or more Medical Devices and their cellular or tissue part must either contain viable cells or tissues, or non-viable cells or tissues liable for exerting the primary action on the human body.

Research should focus at advanced stages of clinical development with completed safety studies, i.e. phase 2 clinical trials and above on:

- technologies ready to undergo interventional clinical trials in patients/end users assessing the usability and clinical performance, and/or

- technologies that have demonstrable safety/performance profiles and should undergo clinical validation in view of their inclusion into guidelines for specific clinical pathways.

The combined ATMPs addressed should be more effective than current state-of-the-art solutions on the European market owing to improved features like personalization, accuracy, reliability and usability and contribute to long-term sustainability (faster and affordable) of European health systems.

Deliverables should consist of safe and clinically validated combined ATMPs that are compliant with current European regulatory requirements. The related regulatory work should be considered as an essential component and the proposed work should involve consultation/interaction with competent

regulatory agencies (EMA or national regulatory agency). Applicants are encouraged to seek regulatory and/or HTA advice as appropriate.

The topic invites proposals that include innovative treatments for any medical condition excluding rare diseases that are ready to be assessed for clinical efficacy (performance and clinical benefit) in a specific indication on a big number of patient cohorts; already existing market solutions are not in the scope of this topic.

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.

For all proposals including clinical studies, the use of the template "essential information on clinical studies" that can be found on the portal is mandatory (one template per study) and constitutes an eligibility criterion.

The Commission considers that proposals requesting a contribution from the EU of between EUR 8 and 10 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts

HORIZON-HLTH-2023-TOOL- 5.03: Integrated, multi-scale computational models of patient patho-physiology ('virtual twins') for personalised disease management

Single stage

Action type: RIA

Expected Outcomes

This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 5 "Unlocking the full potential of new tools, technologies and digital solutions for a healthy society". To that end, proposals under this topic should aim for delivering results that are directed towards and contributing to several of the following expected outcomes:

- Clinicians and other healthcare professionals have access to and/or use validated multi-scale models of individual patients for delivering optimised and cost-effective patient management strategies superior to the current standard of care.
- Healthcare professionals benefit from enhanced knowledge of complex disease onset and progression by recourse to validated, multi-scale, multi-organ models.
- Clinicians and patients benefit from new, improved diagnostics, medicinal products, devices, and therapeutic strategies tailored to the individual patient patho-physiology.
- Citizens and patients have access to novel 'virtual twin' models enabling longitudinal follow-up combining up to date citizen-generated data with medical and other clinical data, and benefit from early prognosis, detection of disease onset, simulation of disease progression and treatment options, and effective disease management.

Scope

This topic will contribute to the consolidation of existing virtual twin models and support research to move towards a human virtual twin. Virtual twin models hold the potential for accelerating translational research towards cost-effective development of new health technologies. Furthermore, virtual twin patient models could transform clinical processes and healthcare with longitudinal monitoring, making personalised medicine, disease prevention, and individualised patient management a reality.

Proposals shall address holistic, dynamic simulations and prediction of an individual person's patho-physiology, by integrating disease models with multiscale modelling across different anatomical scales (molecular, cell and tissue to organ and organism including healthy states), in the direction of developing an integrated 'virtual twin' of an individual patient.

Proposals are expected, as appropriate, to contribute to the virtual human twin roadmap and ecosystem supported under the Digital Europe programme.

The proposals should address all of the following activities:

- Develop multi-scale and/or multi-organ, dynamic, interoperable, modular computational models, including reference models, capable of accurately simulating the patho-physiology of complex communicable and non-communicable diseases, spanning different anatomical scales, from the molecular to cell, tissue, organ and systems level as necessary for addressing the respective clinical need(s) under study.
- Advance the state of the art in multi-scale model integration by employing diverse modelling methodologies, including but not limited to: mechanistic modelling, AI, machine learning, network physiology, disease pathways as a means for modelling disease onset, progression, reversal and recovery. Availability of diverse data types necessary (e.g. lab tests, medical imaging, wearables, sensors, periodic/scheduled medical check-ups, mHealth device data, longitudinal monitoring) should be demonstrated.

- Combine standardised, scalable multi-scale models as a basis for developing 'virtual twin' models addressing complex patient patho-physiology taking account of patients' individual characteristics. Proposals should ensure development is based on end users, citizens, healthcare professionals' needs and are thus expected to include measures for end user involvement in all project stages. Furthermore, applicants should utilise appropriate IT solutions for model visualisation and demonstrate their accessibility and usability for clinical uptake. Use of state-of-art computing architectures (e.g. edge, cloud, fog computing, High Performance Computing) is encouraged.

- Validate multi-scale patient-specific models and generate evidence that results can deliver clinically meaningful, real-world observations for the human disease(s) under study. Applicants should implement proof-of-concept, feasibility studies in relevant end user environments and/or real-world settings, and collect evidence of safety and efficacy vis-à-vis current practice (e.g. standard of care, clinical research, other). Dynamic models and simulations as clinical decision support tools will need be shown to improve prognosis, medical diagnosis, targeted treatments and health outcomes across the continuum of disease(s) evolution, including co-morbidities and long-term care as appropriate.

HORIZON-HLTH-2023-TOOL- 5.04: Better integration and use of health-related real-world and research data, including genomics, for improved clinical outcomes, research and innovation

Single-stage

Action type: RIA

Expected outcomes:

This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 5 "Unlocking the full potential of new tools, technologies and digital solutions for a healthy society". To that end, proposals under this topic should aim for delivering results that are directed towards and contributing to most of the following expected outcomes:

- Researchers and healthcare professionals benefit from better linkage of health data from various sources, including 'omics, based on harmonised approaches related to data structure, format and quality, applicable across certain disease areas and across national borders.
- Researchers and healthcare professionals have access to advanced digital tools for the integration, management and analysis of various health data re-use in a secure, cost-effective and clinically meaningful way.
- By using effectively more data and new methods and tools, researchers and healthcare professionals are able to advance our understanding of the risk factors, causes,

development and optimal treatment in disease areas where 'omic data offer additional information potential.
- Healthcare professionals and health policy-makers benefit from reinforced evidence base informing their respective decisions.
- Citizens can be offered data-driven patient-focused health interventions, resulting in improved disease prevention, diagnosis, treatment and monitoring towards better patient outcomes and well-being.
- Citizens' trust in the sharing and re-use of health data for research and healthcare increases due to the application of advanced technologies and data governance preserving data privacy and security.

Scope:

Health data bear vast information potential in many disease areas, to significantly improve the outcomes and efficiency of healthcare delivery, unlock new research and innovation avenues, and inform public health policy across Europe. There is a huge need of integration, use and deployment of health data from multiple sources for effectively addressing the challenges of medical research, e.g. extraction of multi-dimensional marker signatures for diagnostics or therapy guidance. Such integration requires linking data of different types, disease areas and provenance that are scatted in several repositories and databases across Europe.

This topic aims to support proposals focusing on the integration of health data from multiple sources (e.g. electronic health records, genomics, transcriptomics, medical imaging, laboratory and diagnostic results, public health registries and other clinical research data) by linking real-world and clinical research data. The data integration should be exemplified in several use-cases, i.e. well-justified groups of diseases, within and/or across medical domains (excluding cancer), and showcase the delivery of improved health outcomes. At least one of those use cases should focus on whole genomes.

The consortium should be representative geographically of the European landscape to capture the necessary diversity of health data sources.

The proposals are expected to align with and complement the relevant European initiatives, in particular the European Health Data Space, the 1+Million Genomes initiative (1+MG) and the European Open Science Cloud. They should also consider and address the research needs for FAIR, secure health data access and integration across borders, including interoperability requirements and applicable legal rules.

Proposers have to demonstrate that the necessary data sources are, or will be, effectively, timely and legally available for the proposed research activities.

The proposals should address all of the following activities:

- Identification of the barriers to health data integration and access for the selected use cases and of specific existing tools, technological solutions and coordination and standardization agreements to address them. Issues to be addressed include data ontologies, standards and formats, data quality, data storage, management and access

modalities, as well as enhanced findability of relevant datasets through improved metadata standards and data catalogues.

- New approaches to assemble large, easily findable and lawfully accessible datasets integrating multiple types of data (e.g. new care solutions, personalised disease management, advanced diagnostic tools) leading to improved clinical outcomes.
- New techniques, support tools, mechanisms and modalities to enable GDPR compliant access to sensitive personal data, including genomics, allowing for their re-use across borders and integration of different types of data relevant to human health. Legal and ethical frameworks need to be duly considered to cater for the heterogeneity in national and sectorial rules and procedures for data access and re-use.
- Data management approaches in line with cross-border distributed data storage and processing, enabling remote collaboration, electronic consent management and data provenance tracking tools, using technologies ensuring data privacy and security, ensuring scalability of data systems' resources, thus providing robust support to advanced, innovative clinical workflows. Data governance is expected to be piloted among several clinical centres across Europe.

Where relevant, coordination and integration solutions should build on existing, clearly stated and justified tools and harmonization efforts, such as widely used standards for encoding the different types of health data. Also the data collection, management and/or modelling should build on ongoing EU and international efforts to avoid possible duplication of efforts and fragmentation. In particular, projects are expected to take into account the forthcoming legislation on the EHDS so as to align, where possible, project activities with pertinent EHDS infrastructure efforts that provide for the secondary use of health data as regards e.g. cross-border access to data, cross-border infrastructures, data quality and utility labelling, etc.

The tools developed by the projects are expected to be widely accessible and amenable to appropriate updates after projects end. Moreover, newly generated genomic data and linked patient level data are expected to be made accessible through the 1+MG data infrastructure for secondary use after project end (the same applies to retrospective data, if reasonably feasible).

HORIZON-HLTH-2023-TOOL-5.05: Harnessing the potential of real-time data analysis and secure Point-of-Care computing for the benefit of person-centred health and care delivery

Single-stage

Action type: IA

Expected Outcome:

This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 5 "Unlocking the full potential of new tools, technologies and digital solutions for a healthy society". To that end, proposals under this topic should aim for

delivering results that are directed towards and contributing to several of the following expected outcomes:

- Healthcare professionals benefit from secure, highly performant edge computing technologies able to process and analyse vast amounts of real-time data at the point of care, combined with extended reality and visualisation techniques, to enable continuous monitoring and/or a fast real-time health status checks.
- ·Novel imaging and/or robotics systems and/or Point-of-Care devices are seamlessly integrated in care environments and workflows, allowing real-time diagnosis, screening, monitoring and treatment of a patient.
- Quicker reaction times and improved patient safety in care settings.
- Extended use and contribution to valorisation and uptake of real-time health data and/or Point-of-Care devices by researchers and healthcare professionals; existing technologies and methods are expected to progress from their current technology maturity levels (TRL), from TRL 3-4 to at least TRL 7.
- Reduced energy consumption of Point-of-Care tools, devices and systems, and/or data analysis.

Scope:

The proposals are expected to develop and test innovative tools, devices and systems for point-of-care applications, including but not limited to robotics, photonics, artificial intelligence, providing clinicians with real-time imaging, data analysis and interactive visual presentation for understanding and diagnosing diseases, facilitating risk-assessment, prevention, and carrying out medical interventions. Devices and systems should be designed, developed and tested vis-à-vis defined use cases, based on the appropriate involvement of clinicians and other stakeholders, ensuring they can be seamlessly integrated into existing digital infrastructures and clinical workflows. Data quality, integration and interoperability, as well as issues of cybersecurity and data protection have to be addressed. Design should take gender specificities into account. Clinical studies should be an integral part of the work proposed, with developmental iteration steps and consultation of regulators included as appropriate. Proposals must include an initial business plan.

The proposals should address all of the following activities:

- Development and clinical validation of compact, cost- and energy-efficient, extended reality-enabled and other Point-of-care devices, with fast/real-time response times as required, reliable and capable of integration into surgery workflows.
- Development of instruments and analysis algorithms, including artificial intelligence approaches, for the analysis of biological sample morphology and molecular composition, enabling detection of biomarkers in body fluids and tissues.

- Imaging systems with a high spatial resolution down to the cellular level allowing for immediate clinical interventions. Single imaging modalities or the combination of different imaging modalities should be compatible with other imaging tools and with state-of-the-art or novel medical devices, for example those used to remove tissue in precision surgery (e.g. robotic surgery).
- Advancements in the use of edge computing, data modelling, extended reality and machine learning/AI technologies applied to diagnosis and risk assessment in cases requiring very fast, near to real-time response times, for example during surgery. In addition, projects should showcase how distributed systems bringing computation and storage physically close to where data is generated and used can most effectively deliver actionable outputs for person-centred health care, from healthy living support to remote patient monitoring and acute care settings.

Topics 2024

HORIZON-HLTH-2024-TOOL-5.02: Bio-printing of living cells for regenerative medicine

Single-stage

Action type: RIA

Expected outcomes:

This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 5 “Unlocking the full potential of new tools, technologies and digital solutions for a healthy society”. To that end, proposals under this topic should aim for delivering results that are directed towards and contributing to several of the following expected Outcomes:

- Biomedical scientists will get access to entire bio-printing units for regenerating human tissue.
- Availability of larger-scale bio-printed tissues for biomedical research purposes to both industry and academia.
- Healthcare providers dispose of tools enabling them to treat conditions of unmet medical need.

- Individual patients will benefit from a personalised approach to their respective medical condition thanks to the bio-printed regenerative medicine solution.

Scope:

Regenerative medicine is a branch of translational research in tissue engineering and molecular biology which deals with the "process of replacing, engineering or regenerating human cells, tissues or organs to restore or establish normal function". 3D-printing in general is considered an advanced manufacturing technique and 3D-printing of non-viable biomaterials to serve e.g. as scaffold for cell growth or as structure for medical devices is already broadly used.

However, bio-printing technology involving living cells is still in early stages of development, but has huge potential for tissue engineering, drug testing and other biomedical applications.

It is currently not possible to obtain fully functional and complex synthetic tissues or organs at all scales with a single bio-printing technique. All bio-printing strategies, however, use cells that are collected from a subject and cultured in a cell culture system, followed by mixing with a suitable biomaterial thus giving the bio-ink, which is then fed into the bio-printing system. After the feeding, the bio-printing process starts employing CAD/CAM to produce the tissue according to the desired 3D-pattern.

Despite of increasing articles and patents of 3D bio-printing of living tissues or organs1, the technology still faces significant challenges like unstable cellular behaviour and more complexities

compared to non-biological printing processes. In order to address these challenges, researchers need to work in multidisciplinary teams with engineers, biomedical scientists, and medical doctors.2

Tissue-specific functional 3D bio-printing is a new approach for transplantation applications in regenerative medicine, relying on the fabrication of tissues and organs with respect to desired shape and function and their delivery and application in vivo. 3 Despite some success with thin tissue, thick tissue and complex organs remain a challenge because it is difficult to sufficiently mimic their properties to satisfy their metabolic needs. To reach such a level of growth it will be necessary to find ways of scaling up manufacturing and developing equipment able to print constructs with higher resolution in a smaller amount of time with a diverse selection of feedstock material. Next to these limitations, the lack of standardized manufacturing protocols and standardized bio-ink formulations with tuneable properties equally needs to be addressed. “In-situ bio-printing” known as printing cells and biomaterials directly onto or in a patient is a very recent development faced with multiple challenges.4

Therefore, proposals should address all steps of the bio-printing process from the collection, over GMP-conform manufacturing to delivery of tissue at the target site.

Proof of regulatory knowledge of the field is required in the proposal by documented contacts with relevant national or international European regulatory authorities.

The chosen medical area (tissue, organ, condition) should be duly justified, the targeting of common diseases (affecting more than 1/2000 people in the EU) is an asset.

Preclinical stage and early clinical development are eligible. In case of a clinical trial, the template sheet for clinical trial information should be completed. The involvement of SMEs is encouraged.

HORIZON-HLTH-2024-TOOL-5.06: Innovative non-animal human-based tools and strategies for biomedical research

2-stage

Action type: RIA

Expected Outcomes

This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 5 "Unlocking the full potential of new tools, technologies and digital solutions for a healthy society". To that end, proposals under this topic should aim for delivering results that are directed towards and contributing to several of the following Expected Outcomes:

- Researchers utilize tools and strategies that are more relevant to the human situation as compared to the currently used animal models.
- Less live animals are used in biomedical research.
- Health technology developers will get access to improved human-relevant tools or strategies allowing for a faster pace of innovation.
- Legislators and regulators will benefit from strengthened EU leadership in non-animal based biomedical research that is socially accepted and sustainable.
- Healthcare providers and patients will benefit from innovative tools or strategies opening up novel biomedical concepts enabling improved disease prediction, prevention and treatment.

Scope:

The proposal(s) should develop tools and strategies that address critical areas of biomedical research where animal-models are currently used but are of limited translational value for investigation and development of prevention and treatment. Such advanced tools and strategies should aim at a better understanding of the pathogenesis in disease areas that feature a high impact on public health and exhibit a high rate of animal use or severe animal

suffering, and enable to develop biomedical concepts with increased translational value, thereby ultimately leading to improved disease prediction, prevention and treatment.

These innovative tools and strategies can include a variety of technologies and methodological approaches such as –omics and other high-throughput procedures, human cell-based material, organoids, micro-physiological systems, and in-silico models. It should be clearly demonstrated how the newly proposed tools and strategies will advance the state-of-the-art in specific areas of biomedical research.

Prospects and avenues for dissemination, knowledge sharing, uptake or translation into health policies of the proposed tools and strategies within the EU should be provided. Aspects such as cost-benefit assessment with respect to current practices should also be considered. Criteria for model qualification should be developed in well-justified use-case contexts to demonstrate their translational values.

All projects funded under this topic are strongly encouraged to participate in networking and joint activities, as appropriate. These networking and joint activities could, for example, involve the

participation in joint workshops, the exchange of knowledge, the development and adoption of best practices, or joint communication activities. Therefore, proposals are expected to include a budget for the attendance to regular joint meetings and may consider to cover the costs of any other potential joint activities without the prerequisite to detail concrete joint activities at this stage. The details of these joint activities will be defined during the grant agreement preparation phase. In this regard, the Commission may take on the role of facilitator for networking and exchanges, including with relevant stakeholders, if appropriate

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

Topics 2023

HORIZON-HLTH-2023-IND-6.01: Supporting the uptake of innovative HTA methodology and advancing HTA expertise across EU

Single-stage

Action type: CSA

Expected outcomes

This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 6 "Maintaining an innovative, sustainable and globally competitive health industry". To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing all of the following expected outcomes:

- Testing and validation of innovative HTA methods developed by EU-funded projects into real-life settings, allowing for advancing HTA methodology and improve evidence-based decision making , and patient access to novel health technologies
- Dissemination among EU HTA bodies of robust innovative HTA methods and tools developed by EU-funded projects.
- Harmonisation of HTA expertise across EU though the development of a training programme developed in collaboration with academia.
- The CSA is expected to contribute to a successful implementation of the HTA Regulation as well as to building an EU methodological HTA framework fit for purpose and fit for the future.

Scope and activities

Challenges

- HTA bodies have the responsibility to assess the added value of new health technologies and advise on its reimbursement and use within a healthcare system. Due to the rapid pace at which technology advance and in order to support decision making in an appropriate manner, HTA experts have to adapt/revise regularly their methodology. Whilst EU-funded projects in the field of HTA have addressed some of the research needs of the HTA bodies (e.g. methods of analysis, use of real world data, use of patient reported outcomes), translation of their results/recommendations into HTA work remains limited.

- Advancing HTA methodology and expertise could benefit from a more systematic dialogue between HTA bodies and academia. Therefore this action could represent an excellent opportunity for both those generating and those using the evidence to come together and discuss the key HTA methodological issues.

Scope:

- Identification of innovative methods and tools, in particular those developed in EU-funded projects able to address HTA bodies needs (in different areas: relative effectiveness assessment, cost-effectiveness assessment, …)
- Identifications of barriers to the uptake of these methods (and potential associated tools, e.g. open source software to run cost-effectiveness analyses)
- Development of an implementation plan including supporting tools and training modules (by researchers to be delivered to HTA bodies/agencies)
- Use cases (based on the needs identified by HTA bodies)
- Recommendations for broader dissemination

The topic will be divided into 2 strands of activities:

- **Implementation of innovative HTA methods**: EU-funded research projects (among others) develop innovative methods aiming at addressing HTA bodies' needs. Testing of these methods in real-life settings is a first crucial step towards broader uptake and dissemination. Successful implementation of innovative methods in actual HTA practices will contribute to provide a timely response to HTA challenges (e.g. use of real-world data in HTA) also providing a sound scientific resource for updates of methodological guidelines for joint activities as requested by the HTA Regulation. HTA bodies/agencies participating in testing activities will gain expertise in those methods that could be later transferred to other bodies/agencies using the training framework developed in the second strand of work.
- **Advancing HTA expertise across Europe**: twinning programmes between HTA bodies/agencies to develop expertise and facilitate knowledge sharing among HTA bodies/agencies in the EU, supporting the implementation of high-quality and robust HTA methodology across EU, and also promoting the development of expertise in carrying out the joint HTA activities (e.g. joint clinical assessments, joint scientific consultations) laid down in the Regulation on HTA (to be adopted by end of 2021). This will done by implementing a well-defined framework/process to systematise the training activities. Such activities are expected to contribute to the harmonisation of HTA practices in the EU that will in turn contribute to a greater consistency of health technology assessments across EU countries. It will also contribute to the dissemination of the scientific methodology to be adopted by the newly established Member States HTA Coordination Group (based on the methodology developed and fine-tuned by EUnetHTA joint actions and EUnetHTA21 service contract) and thus facilitate an active participation of all HTA bodies/agencies in the joint work foreseen under the HTA Regulation.

HORIZON-HLTH-2023-IND- 6.02: Expanding the European Electronic Health Record exchange Format to improve interoperability within the European Health Data Space

Single-stage

Action type: RIA

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 6 "*Maintaining an innovative, sustainable and globally competitive health industry*". More specifically, this topic aims at supporting activities that are contributing to the following impact area: "*High quality digital services for all."* To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes, and provide appropriate qualitative and quantitative indicators to measure their progress and specific impact:

- European EHR stakeholders (e.g. developers, suppliers, integrators, and operators) dispose and use fit-for-purpose standards, guidelines, and toolsets for prioritised health information domains to address interoperability of EHRs in line with the principals set in the EEHRxF Recommendation[128].
- Stakeholders dispose better quality and better integrated health datasets within the European Health Data Space, to foster innovations in the health sector and leverage the potential of new analytics solutions such as AI and big data, and to get new insights and detect trends from aggregated data, including for cross-border health threats.
- Individuals are provided with an expanded access to their health data, and innovative digital services for high-quality health and care across the EU.
- European healthcare industry (including SMEs) is more competitive and sustainable, assuring EU leadership and strategic autonomy in digital technologies or can better target current and future needs for medical countermeasures.

Scope:

EHR interoperability has yet to become a reality in a number of use cases and health information domains. It is a complex, multi-dimensional challenge. EHRs across the Member States are diverse; so are languages, cultures, and practices in the health sector. They use different technical specifications, technologies and clinical terminologies. They involve the interplay of a range of stakeholders, within and across care settings.

Proposals are expected to address all of the followings:

- Research, develop and validate harmonised interoperability formats for sharing data in some priority health information domains. The latter should be selected with reference to the EU policies and priorities. The output formats should enable EHR interoperability across the Member States and address cross-border health data exchange by-design and in line with the principals set in the EEHRxF Recommendation.
- Leverage and scale up the potential of EHR through enhanced interoperability to improve the quality, safety, and efficiency of patient care, enforce patients right to data portability, enhance care coordination, guide crisis planning, reduce medical errors, and lower costs. For example, based on the lessons learnt from COVID-19, enable incorporating EHR data into the early stages of clinical crisis planning and

[128] Commission Recommendation on a European Electronic Health Record exchange Format (EEHRxF) (C(219)800)

leveraging it to identify potential cross-border health threats based on the analysis of patients' data trends.

- Address semantic interoperability for prioritised information domains so as the transmitted health record contains standardised coded data.
- Maximise synergies with relevant initiatives, activities and programmes, and build upon previous actions[129].
- Closely coordinate and collaborate with various stakeholders, from patients, and healthcare professionals to EHR providers, policy makers and legislators to progress towards a more comprehensive EHR interoperability.

HORIZON-HLTH-2023-IND- 6.04: Modelling and simulation to address regulatory needs in the development of orphan and paediatric medicines

Single-stage

Action type: RIA

Expected outcomes This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 6 "Maintaining an innovative, sustainable and globally competitive health industry". To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- Developers and regulators have access to robust modelling and simulation tools to accelerate the effective development of orphan and/or paediatric medicinal products.
- Developers and regulators use accurate simulation tools to improve the statistical robustness in clinical trials intended for small populations and guide cost-effective clinical trials designs.
- Regulators have access to accurate in-silico tools for assessing the actionable use of real world data (RWD) and patient reported outcomes for optimizing the clinical endpoints in clinical trials for small populations.
- Regulators develop guidance for the use of new modelling and simulations methods to support a robust extrapolation framework for the safety and efficacy prediction during the regulatory assessment of orphan and/or paediatric medicinal products.

Scope

[129] Such as "Support for European eHealth Interoperability roadmap for deployment TOPIC ID: SC1-HCC-07-2020"

https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/sc1-hcc-07-2020

In its "Regulatory Science Strategy to 2025", the European Medicines Agency included specific recommendations to optimise the capabilities of modelling and simulation in the medicines development process and in particular to benefit special populations and neglected patient populations.

Orphan drug development faces numerous challenges, including low disease prevalence, patient population heterogeneity and strong presence of paediatric patient populations. Consequently, clinical trials for orphan and/or paediatric medicines are often smaller than traditional large-scale randomised ones and they require the development of efficient trial designs relevant to small populations to gain the maximum useful information from the available data. Furthermore, the ability of conventional statistical methods to evaluate new therapeutic effects is limited due to the small number of patients concerned.

Model-based approaches are significantly advantageous in small populations, as extrapolation tools for rationalising and increasing the statistical robustness in clinical trials' design and pharmacometric studies. The rapid and widespread adoption of in-silico methods in the regulatory process could drastically reduce the cost of health innovations.

The topic intends to support research and innovation activities to boost regulatory science with regards to the use of diverse modelling and simulation tools for their ability to accurately predict/extrapolate the safety/efficacy effects during the regulatory assessment and before the marketing authorisation of new medicinal products. The topic is not intended to support new preclinical/clinical studies but to use the existing knowledge/data for assessing the performance of mature in-silico models for improving the clinical trials designs for small populations.

The proposals should address all of the following regulatory science gaps:

- Assess validated in-silico models for their capability to accurately extrapolate the interactions between mode of actions, therapeutic effects, patient characteristics, disease variables, patient-reported outcomes, surrogate endpoints for delivering robust evidence of safety and efficacy. The models should include a variety of modelling approaches and/or their combinations (e.g. systems pharmacology, disease pathways mechanistic models, physiology-based pharmacodynamic/pharmacokinetic models, Bayesian modelling etc.).

- Build a methodological framework of any novel modelling and simulation tools considered, to guide accurate extrapolation and prediction in the development of orphans and/or paediatric products. The proposals should put forward a methodological framework for the credibility assessment of any computational models considered, built upon using the mechanistic knowledge gained therein of physical, biological, physiological and chemical phenomena, including the selection of best practice randomisation and analysis for small population clinical trials.

- Exploit in-silico tools for improving the safety, efficacy, quality and design of clinical trials by integrating real world evidence from diverse sources, including from natural history studies and registries with the goal of demonstrating optimised clinical trial designs in small populations. Further develop, consolidate and disseminate standards for the design, conduct, analysis and reporting of modelling and simulation with a

particular emphasis on those of high regulatory impact for paediatric and rare diseases medicinal products.

- Benchmark of groups of in-silico tools by re-analysing clinical trials data, (including from failed ones) and by comparing the effectiveness of those models against current regulatory approval standards. This should lead to a conclusion on the credibility of a prediction for the specific use of the models considered for eventual regulatory purposes. Availability of clinical trials data and other relevant data should be demonstrated at the proposal submission. Benchmark studies of the in-silico tools should be performed on group(s) of rare and/or paediatric diseases with commonalities within the same and/or across different medical areas, excluding cancer and infectious diseases.

HORIZON-HLTH-2023-IND- 6.05: Mapping of regulatory requirements for the translation of Advanced Therapy Medicinal Products (ATMP)

Single-stage

Action type: CSA

Expected outcomes: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 6 "Maintaining an innovative, sustainable and globally competitive health industry". To that end, proposals under this topic should aim for delivering results that are directed towards and contributing to all of the following expected outcomes:

- A report is produced with regulatory, safety assessment, organisational, infrastructural and knowledge needs for speeding up the safe and efficacious clinical applications of ATMPs. This report should be sustainable and available to competent authorities of all Member States.

- Academic developers of ATMPs and those seeking to manufacture ATMPs at multiple sites have an increased knowledge of the regulatory aspects of ATMPs.

- The impact of public investment into ATMP development is enhanced.

- The decentralised manufacturing of ATMPs is consistent across care centres.

Scope:

The project should map the regulatory, safety assessment, organisational, infrastructural and knowledge needs to improve the translation of ATMPs from preclinical development to clinical use. The project should address the gaps and uncertainties in regulatory frameworks pertinent to complex innovative ATMPs and their decentralised manufacture. Predictivity of preclinical data for safety testing of ATMPs should also be assessed, and improved novel models could be proposed. Decision-making processes relating to ATMPs, such as for

instance the reimbursement of high cost ATMP products should be tackled. Opportunities for an improved knowledge of the regulatory processes among academic ATMP developers should be identified Regulatory authorities should be involved in order to ensure higher clinical use of ATMPs.

HORIZON-HLTH-2023-IND- 6.06: Innovation Partnership 2024 - Development procurement and responsible management of new antimicrobials

Single-stage

Action type: CSA

Preparatory CSA needed to establish an innovation partnership for AMR.

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 6 "*Maintaining an innovative, sustainable and globally competitive health industry*". To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- Health authorities and healthcare providers have identified the needs and potential procurers;
- Potential procurers are ready to establishing an innovation partnership for the development and the procurement of new antimicrobials;
- Potential procurers are able to engage and commit financially in view of the establishment of an innovation partnership.

Scope: The aim of this topic is to prepare for the establishment of a pull incentive for new antimicrobials where there is an unmet public health need and a market failure. In line with the Pharmaceutical Strategy for Europe that was published in November 2020[130] innovative approaches at EU level should be developed for supporting research, development and public procurement of antimicrobials to address the issue of antimicrobial resistance. These approaches could make use of European legislation, such as the possibility of an innovation partnership[131] that would allow for the combination of development of new antimicrobials and procurement elements and should be tailored to public health needs.

To that end, a preparatory phase is necessary. Proposers are expected to create the conditions for the establishment of a future innovation partnership. They should take advantage of the latest developments such as experiences gained within Europe on the advance purchase agreements for COVID-19 vaccines. With the help of experts, potential procurers of new antimicrobials in the Member States have to set out the requirements and conditions for the

[130] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0761&from=EN
[131] https://ec.europa.eu/growth/content/8699-innovation-partnerships-keep-public-services-date_en

final product(s) to be developed and purchased. This will needs to be guided by public health needs and should be based on priority pathogens such as those identified by WHO[132]. These requirements and conditions needed to guide development will have to be developed with input of scientific experts and in close collaboration with Commission services, and need to be agreed upon with a view of EU Member States' and Associated States commitments to purchase the new antimicrobials. Proposers should also develop a broad communication strategy towards stakeholders and other potential procurers.

Proposals are expected to address all of the following:

- Emerging health threats, particularly those resulting from antimicrobial resistance (AMR), and identification of relevant public health needs in the development of new antibiotics.
- Design of a feasible option for a pull incentive that combines EU support for late stage development of antimicrobials with procurement by Member States and Associated Countries (implementation of the pull incentive will be beyond the scope of this CSA).
- Readiness and interest of potential developers/suppliers of antimicrobials
- Market failures and the challenges of availability and accessibility of therapeutics.
- Conditions for development and purchase of new antimicrobials.
- Requirements for financing.
- Conditions for prudent use of new antimicrobials.

HORIZON-HLTH-2023-IND- 6.07: Development and harmonisation of methodologies for assessing digital health technologies in Europe

Single-stage

Action type: RIA

Expected outcomes:

- Policy-makers in the EU have at their disposal framework of methodologies for assessing digital health technologies, that help them make evidence-based decision regarding the introduction in their health and care systems with added value for patients and society
- Establish use cases and best practice examples for the assessment of relative safety and effectiveness of digital health technologies
- EU citizens have better access to person-centred digital technologies and are empowered through these tools

[132] https://www.who.int/medicines/areas/rational_use/prioritization-of-pathogens/en/

- Health technology developers are better informed on the evidence needed to demonstrate the added value of digital health technologies and have better insight on market predictability
- (Digital) Health Industry/digital health technology developers can benefit of EU harmonised assessment rules based on common principles
- improved cross-border use and interoperability of digital health tools throughout Europe
- Increased trust in digital tools and better integration of digital tools in health and care systems

Scope:

Challenges: Digital health technologies are expected to contribute to better people-centred health care systems. However assessing their added value of health benefits for patients and society pose a number of challenges in particular of methodological and technical nature. Best practice for common approaches in methodology for digital health are lacking, especially in the digital health tools that include artificial intelligence algorithms.

Objective: to develop and harmonise methodologies for assessing digital health technologies (including mhealth apps and telehealth, as well as Artificial Intelligence powered health technologies) in order to facilitate assessment of their added value at individual, health system and society levels and facilitate their free movement in the EU.

The selected projects are expected to build on the results of previous EU-funded projects, such as COMED, project that already identified HTA challenges of telehealth and mhealth, and mHealth hub[133]

ASSESSING THE IMPACT OF DIGITAL TRANSFORMATION OF HEALTH SERVICES, Report of the Expert Panel on effective ways of investing in Health (EXPH) - https://ec.europa.eu/health/system/files/2019-11/022_digitaltransformation_en_0.pdf

Topics 2024

HORIZON-HLTH-2024-IND- 6.03: Setting up a European wide collaborative mechanism to support the adoption of innovative health solutions across European regions

Single-stage

Action type: IA

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 6 "Maintaining an innovative, sustainable

[133] https://mhealth-hub.org/

and globally competitive health industry". To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

1. Strengthening the European Strategic Value Chain for Smart Health[134] , European Health-Tech industry and the Digital transformation of Health and Care[135]. 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.

2. 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).

3. New tools and technologies for prevention, diagnosis, treatment, monitoring and therapy of diseases are designed, developed, tested, validated, brought to market and adopted by their end-users quickly, for the benefit of patients and the health and care systems.

4. Increased uptake of digitally enabled health and care solutions, including for cross-border health threats, in clinical settings and by citizens and patients, also through quicker and more coordinated health information and secure use of health data.

5. New data-driven approaches, computer models and –simulations, epidemiological forecasts, predictions and other digital solutions are developed, translated and optimised for the prevention, health care and person-centred care, including smart data infrastructures and AI-based data analytics.

Scope:

The European Innovative Health Industry and ecosystem have been steadily growing. However, there is still a need to strengthening the European Strategic Value Chain for Smart Health, and support the European Health-Tech industry in line with the increasing digitalisation of Health and Care provision. The aim of the action is to create a wide collaborative mechanism across European regions to scale-up digitally enabled health and care solutions, ensuring streamline processes for innovators, health and care providers and policy makers to better adopt such technologies.

The proposed research and innovation should focus on all the following aspects:

1.) Consolidate an effective EU collaborative mechanism and ecosystem to accelerate the adoption of digitally enabled health promoting, person-centred innovative tools across

[134] https://ec.europa.eu/docsroom/documents/37824/attachments/2/translations/en/renditions/native

[135] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2018%3A233%3AFIN

European Regions, with a multi-policy approach. This ecosystem shall include the developers of these innovative solutions as well as users, payers, authorities and industry, in compliance with the relevant data protection legislation and ethical standards, needed for the development and uptake of innovative health and care products and applications, including digital therapeutics.

2) Support solutions that are close-to-market (TRL 6, 7 or higher) and are about to receive the CE marking to proceed to large scale testing, piloting and deployment operations in various healthcare areas (promoting healthy living and wellbeing, prevention of cross-border health threats, prevention, diagnosis and treatment of diseases, supporting management of long-term conditions, rehabilitation from treatments, etc, etc);

3.) Support market innovation (from lab-to-fab) for further developing and maturing innovative solutions (in healthcare areas mentioned above), that have already been validated in lab environments with the aim to help accelerate developments, including clinical investigations, and achieve conformity assessment (CE marking).

4.) The tools should be designed, developed and tested to ensure that they can be easily integrated into existing digital infrastructures and clinical workflows. The issues of data quality, data integration and interoperability, as well as issues of cybersecurity and data protection have to be addressed. These solutions can include a variety of technologies and approaches such as nano medicines, advanced therapies, IoT, MedIoT, assisted technologies, biomaterials, medical devices, hybrid technologies, digital solutions, Artificial Intelligence applications, robotics, -omics[1] and other data-driven interventions and procedures.

This topic addresses consortia consisting of innovative technology providers, including SMEs, and/or organisations that can offer the range of activities required to address the objectives of the topic; the latter could for example be based on Digital Innovation Hubs, digital health accelerators and knowledge hubs, Centres offering Pilot Lines or similar technology, business and/or knowledge transfer organisations. Participation of European/Regional/National networks is strongly encouraged, in order to ensure wide dissemination and higher impact across EU regions.

The innovative technology providers can be either members of the applicant consortia or selected through open calls organised by the consortium using financial support to third parties. The support offered could include access to product development, accelerator, incubator and technical services and capabilities such as testing and experimentation facilities together with expertise, prototyping, design, engineering or pilot manufacturing services as necessary, as well as providing support for the conduction and drawing up of the clinical evaluation and support for the conformity assessment.. Any use of third party grants must result in minimal administrative burden for participants, and allow the fastest possible launch of the projects.

In all instances, gender as well as demographic, geographic and socio-economic aspects should be duly taken into account. Proposals should be highly integrated, ambitious, go beyond simple networking and provide appropriate indicators to measure progress and

impact. Selected projects under this topic are strongly encouraged to participate in joint activities as appropriate. These joint activities could, for example, take the form of clustering of projects and involve joint coordination and dissemination activities such as the participation in joint workshops, the exchange of knowledge, the development and adoption of best practices and adoption strategies on regional, national and European level.

HORIZON-HLTH-2024-IND- 6.08: Developing an EU methodological framework for clinical/performance evaluation and post-market clinical/performance follow-up of medical devices and in vitro diagnostic medical devices (IVDs)

Single-stage

Action type: RIA

Expected outcomes: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 6 "Maintaining an innovative, sustainable and globally competitive health industry". To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- Patients gain faster access to innovative, safe and well-performing medical devices;
- Regulators have access to sound scientific resources for clinical/performance evaluation guidance and development of common specifications as foreseen in the Article 9 MDR;
- Notified bodies, by their direct participation to the production of such documents, will have a harmonised way of assessing the clinical evidence in the pre-market and post-market phases; furthermore their network[136], will be enhanced;
- Health technology developers gain insight on the evidence needed to demonstrate that their devices meet MDR clinical requirements throughout their lifetime. They will also have more guidance on the use of real-world data for their clinical development strategies.

Scope

Challenges:

The Medical Device Regulation (MDR) and *in vitro* diagnostic medical device Regulation (IVDR) provides a new regulatory framework where reinforcement of clinical/performance evaluation of medical devices and IVDs, and in particular high-risk medical devices, is a key element. The confirmation of conformity with the relevant general safety and performance requirements set out in the MDR and IVDR[137] is based on clinical data and its assessment (clinical/performance evaluation), including the evaluation of the acceptability of the benefit-risk- ratio. Within this new framework, the clinical/performance evaluation should follow a defined and methodologically sound procedure based on the critical evaluation of the relevant scientific literature, a critical evaluation of the results of all available clinical investigations/performance studies, as well as consideration of currently available alternative

[136] Article 49 – Coordination Group of notified bodies

[137] Annex I General safety and performance

treatment options for the device under evaluation. Clinical/performance evaluation has to be updated throughout the life cycle of the device. Hence, clinical/performance evaluation can draw on multiple types of data including data from initial clinical investigations/performance studies and data gathered by the manufacturer's post-market surveillance system. To operationalise this new requirement, research is needed to help regulators develop common methodological frameworks (including common specifications[138]) on the clinical evidence needed to demonstrate safety, performance and clinical benefit all along the life cycle of devices taking into account the type of device and clinical intended purpose.

Such methodological frameworks and standardised approaches are particularly needed for high-risk medical devices , e.g. implantable and class III medical devices, class C and D IVDs, medical device software (including AI enabled devices and next generation sequencing) and other highly innovative devices.

Activities

In order to address the differences between evidence generation for medical devices and IVDs, the project should be tackled taking into account those differences.

- Development of a framework for a life-cycle approach to evidence generation and evaluation of high-risk and innovative medical devices and IVDs. This framework will provide a description of the types of evidence i) that meet safety and performance for market access, and ii) that have to be generated to fulfil post-market responsibilities. When appropriate it would be beneficial to consider to what extent the framework could be relevant to demonstrate relative effectiveness as needed for Health Technology Assessment. As regards highly innovative devices, particular attention may be paid to defining acceptable levels of uncertainty in terms of benefit-risk ratio at market entry as well as the type of post-market follow-up to be implemented to generate additional clinical evidence able to reduce this uncertainty. This could be particularly relevant for devices e.g. having no or little similarities with existing devices in terms of intended purpose, mode of action, materials or, for IVDs, with no existing reference materials.;
- For medical devices, a pilot to support development of common specifications which would set the stage for a common specification ecosystem for medical devices in Europe[139], including the development of standardised/common endpoints and associated health outcomes measures by technology type and where relevant by clinical intended purpose;
- Development of a general methodological approach to define, determine and update the state of the art for different device technologies. The robustness of the developed approach should be evaluated on 3 different medical devices types and 3 different IVD types;
- Possible use of registries and other sources of real-world data for demonstration of regulatory compliance both pre- and post-market: minimum requirements for data quality, completeness and data reliability, statistical methods for data analysis, methods for limiting

[138] Mandatory applicable "technical standards" providing to the manufacturers means of proving conformity with the safety and performance legal requirements, issued by Commission as Implementing Acts.
[139] building on previous initiatives such as PARENT, CORE-MD, JAMS

biases, methods for data linkage, determination of what acceptable evidence can be drawn from registries;
- Methodology for bridging studies for devices and IVDs with iterative development: assessment of data coming from previous versions of the device and where relevant integration of that data into the device's clinical investigation/performance study and gap assessment between the different versions of the device. ,
- Identification of relevant quantitative and qualitative methodologies for integrating evidence derived from various data sources in the clinical evaluation/performance evaluation;
- Development of a dedicated framework for the clinical investigation and evaluation of AI-based medical devices [to be further developed with CNECT colleagues];

- Tools to identify trends, patterns and signals in Eudamed data, including for the use of the expert panel on medical devices. [to be confirmed with EUDAMED team]

Proposals should build on relevant completed and ongoing initiatives in the field, in particular (but not restricted to) EU-funded initiatives.[140] Proposals should involve researchers who are specialised in the clinical/performance evaluation of medical devices/IVDs and in the use of real-world data to evaluate medical products. Proposals should involve national competent authorities, notified bodies, IVD laboratories as well as Health Technology Assessment bodies and could involve patients' representatives where relevant.

[140] e.g. PARENT (PAtient REgistries iNiTiative) Joint Action, CORE-MD (Coordinating Research and Evidence for Medical Devices) H2020 research project, JAMS (Joint Action on Market Surveillance of Medical Devices) initiative

Main Other Actions for 2023 and 2024

1. Contribution to the Coalition for Epidemics Preparedness Initiative (CEPI)- vaccine development for priority disease (Ex-Topic HEALTH- 2023-DISEASE- 3.02)

Action type: Co-fund (Grant to identified beneficiary)

This is a topic for a grant awarded without a call for proposals (Article 195 (e) of the EU Financial Regulation). CEPI has been a key partner for implementing the common Union response to the COVID-19 epidemic. The funding rate will be 70%. With this funding, CEPI will be able to award grants to third parties through competitive calls for proposals. The focus will be on development of new medical countermeasures to prevent and contain infectious diseases that have epidemic potential, before these diseases become global health emergencies. The call(s) will be issued by the Norwegian beneficiary, to fund advanced pre-clinical as well as clinical research on new vaccines for the prevention of emerging and re-emerging infectious diseases, with a view to preventing future epidemics. It will be aligned with activities of HERA and a new Partnership for Pandemic Preparedness.

2. Mobilisation of research funds in case of Public Health Emergencies

Expected Impact. Proposals should set out a credible pathway to contributing to one or several expected impacts of destination: "Tackling diseases and reducing disease burden".

Expected Outcome. Project results are expected to contribute to the following expected outcome: Allow the Union to respond to Public Health Emergencies

Scope:

In case of a public health emergency[141] (such as a Public Health Emergency of International Concern (PHEIC) according to the World Health Organization, a public health emergency under Decision 1082
/2013/EU or under applicable national frameworks and regulations), funding will be mobilised for :

1. The award of grants without a call for proposals according to Article 195 (b) of the EU Financial Regulation[142] in exceptional and duly substantiated emergencies. At that time, the Funding & Tenders Portal will open a dedicated section where proposals can be submitted. This will be communicated to the National Contact Points. The invitation to apply for funding will be open to all eligible entities or be limited to targeted entities,

[141] Should there be no Public Health Emergency in 2023 or 2024, the indicative budget may be reallocated.

[142] Article 195 (b) of the Financial Regulation 2018/1046 "Grants may be awarded without a call for proposals only in the following cases: […] (b) in other exceptional and duly substantiated emergencies;".

taking into account the need to achieve the underlying objectives in a quick and efficient manner considering the exceptional circumstances; and/or

2. The award of additional funding for ongoing grant agreements to cover additional activities specifically linked to the public health emergency, in exceptional and duly substantiated emergencies. Providing such additional funding to ongoing grants that can support pertinent short- and mid-term research efforts to confront the public health emergency will save valuable time and allow addressing the situation with the appropriate urgency. Restricted calls for expression of interest or proposals will develop such additional activities or add additional partners to existing actions.

It is expected that quality-controlled data are shared in accordance with the FAIR[143] principles. The use of harmonised protocols in collaboration with other actors is recommended for this purpose.

The standard eligibility and admissibility criteria, evaluation criteria, thresholds, weighting for award criteria, maximum funding rate and conditions for providing financial support to third parties, are provided in the General Annexes.

The beneficiaries must comply with the public emergency related provisions listed in the General Annexes concerning the project implementation under - Intellectual Property Rights (IPR), background and results, access rights and rights of use (article 16 and Annex 5) for the duration of the Public Health Emergency; and under Communication, dissemination, open science and visibility (article 17 and Annex 5) during the entire duration of the action and for four years after the end of the action.

The following derogations to the evaluation procedure described in General Annexes D and F apply to open invitations to submit applications:

In order to ensure a balanced portfolio covering responses to different aspects of the public health emergency, grants will be awarded to applications not only in order of ranking, but also to those projects that enhance the quality of the project portfolio through synergies between projects and avoidance of overlaps, provided that the applications attain all thresholds.

The action may also include justified derogations from the standard limits to financial support to third parties. Where applicable, the relevant grant agreement options will be applied.

Form of Funding: Grants not subject to calls for proposals

Type of Action: Grant awarded without call for proposals according to Financial Regulation Article 195 (b)

The general conditions, including admissibility conditions, eligibility conditions, award criteria, evaluation and award procedure, legal and financial set-up for grants, financial and

[143] FAIR data are data, which meet principles of findability, accessibility, interoperability, and reusability. https://www.openaire.eu/how-to-make-your-data-fair

operational capacity and exclusion, and procedure are provided in parts A to G of the General Annexes.

Indicative timetable: Will depend on the Public Health Emergency