

HORIZONTE EUROPA. PRINCIPALES NOVEDADES EN SALUD

Seminario online

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HORIZONTE EUROPA. PRINCIPALES NOVEDADES EN SALUD.

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European Research Area

Horizon Europe



* The European Institute of Innovation & Technology (EIT) is not part of the Specific Programme

“Evolution, not revolution”



Presupuestos en Horizonte Europa

Pillar 1
Excellent Science

- European Research Council
- Marie Skłodowska-Curie Actions
- Research Infrastructures

Pillar 3
Innovative Europe

- European Innovation Council
- European innovation ecosystems
- European Institute of Innovation and Technology

- Pillar I Excellent and Open science**
 - European Research Council (ERC)
 - Marie Skłodowska-Curie actions
 - Research infrastructures
- Pillar II 'Global Challenges and European Industrial Competitiveness'**
 - 1. Health
 - 2a. Inclusive and Creative Society
 - 2b. Secure Society
 - 3. Digital, Industry and Space
 - 4. Climate energy and mobility
 - 5. Food, Natural Resources and Agriculture
 - 6. Non-nuclear direct actions of the JRC

- Pillar III Innovative Europe**
 - European Innovation Council (EIC)
 - European Innovation Ecosystem
 - European Institute of Innovation & Technology (EIT)

- IV Strengthening the European research Area**
 - Spreading excellence and widening
 - Reforming and enhancing European (Union) R&I System
- TOTAL (IN MILLION EURO)**

25,011 M€
16,003
6,602
2,406
53,516 M€
8,246
2,280
1,596
15,349
15,123
8,952
1,970
13,598 M€
10,105
528
2,965
3,393 M€
2,955
438
95,519 M€

7.472 M€ en H2020

Pillar 2
Global Challenges and European Industrial Competitiveness

- Clusters
 - Health
 - Culture, Creativity and Inclusive Society
 - Civil Security for Society
 - Digital, Industry and Space
 - Climate, Energy and Mobility
 - Food, Bioeconomy, Natural Resources, Agriculture and Environment
- Joint Research Centre

- Widening participation and spreading excellence
- Reforming and Enhancing the European R&I system

Widening Participation and Strengthening the European Research Area

Del 1^{er} Plan Estratégico para Horizonte Europa

- Diseases and disabilities pose a major societal and economic burden on citizens and health systems of the EU and worldwide.
- Non-communicable diseases, including mental disorders and illnesses, are currently responsible for up to 80% of health care costs in the EU. This will further increase should the ageing society not adopt healthier lifestyles and more effective health care approaches.
- Likewise, infectious diseases, including antimicrobial resistant infections, represent a major health risk to people as well as a serious cross-border health security threat for countries in the EU and worldwide.
- These challenges call for more health promotion, better disease prevention and more effective solutions to manage diseases and reduce disease burden as well as for health care systems .

Clúster Salud – 6 “Destinations”



1. Staying healthy in a rapidly changing society.

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



3. Tackling diseases & reducing disease burden.

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



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

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



Nueva distribución en el texto de la convocatoria (a 22/02/21)

Distribución (en el borrador actual):

1. Destinations (en total 6 “Destinos”)

1.1. Impacto esperado según los KSOs fijados en el Plan Estratégico de Horizonte Europa 2021-2024

2. Convocatoria agrupada por año en cada “Destino”

2.1. Cuadro de presupuestos, nº de propuestas a financiar y condiciones (anexos relevantes)

2.2. Título del topic

2.3. Cuadro con condiciones específicas: Tipo de acción (RIA, CSA, PCP, PPI, etc.)

2.4. Topic

2.4.1. Expected outcomes

2.4.2. Scope

2.4.3. Pies de página



Novedades destacables frente a H2020 (I)

- Las misiones, con textos de convocatoria propios
- Los “Partenariados” (Asociaciones) tratan de racionalizar el número de iniciativas basadas en los art. 183 y 187 del TFUE (ERA-Nets, JPI, EJP, AAL, EDCTP, IMI...)
- Como regla general, los consorcios deberán contar siempre con **al menos un Estado Miembro**
- *Topics menos prescriptivos* dejando margen para una variedad más amplia de potenciales soluciones
- Piloto de **propuestas anónimas (*blind evaluation*)** en convocatorias de 2 stage y **right to react (rebuttal)** como fórmulas para mejorar la calidad de los ERS
- Posibilidad de **entrevistas (*hearings*)** en algunas convocatorias
- **Simplificación** de la Parte A (Administrativa) de la propuesta. La Parte B en **Fase única** : RIA/IA máximo 45 páginas. CSA 30 páginas, en convocatorias en **dos Fases**, Fase 1: 10 páginas; Fase 2: 45 páginas



Novedades destacables frente a H2020 (II)

- **Métodos simplificados de costes:** No se prevé la generalización del *lump-sum*, pero sí seguir ampliando los pilotos (pdt definir)
- **Planes de Igualdad como criterio de elegibilidad** (no para empresas pero sí para entidades públicas, centros de investigación, universidades, etc.)
- Simplificación de los **escrutinios éticos y de seguridad** dando más relevancia a las agencias nacionales
- **Criterios de Evaluación:** evaluación de la calidad de las entidades solicitantes entre los criterios de implementación y eliminación de la evaluación de las estructuras de gestión
- **Portfolio-based calls** (*Missions y EIC Pathfinder*): las evaluaciones se podrán reestructurar en función de su contribución a los objetivos estratégicos del portfolio siguiendo las indicaciones del Art. 26.2 RdP
- **Explotación de los resultados por terceras partes:** obligación de usar la *Horizon Results Platform* para dar visibilidad a los resultados explotables de sus proyectos en caso de no haber explotación un año tras la finalización del proyecto.

Avanzando hacia el primer texto de convocatorias del Clúster Salud (y **DISCLAIMER**)

- Toda la información a transmitir hoy en esta sesión está basada en el último borrador, puede sufrir modificaciones aún y es una síntesis de la información contenida de los topics.
- Se recomienda encarecidamente el análisis minucioso del topic completo de interés sobre el borrador y en el texto definitivo cuando se publique por la CE.
- Los presupuestos globales son: 948 Mio. € (conv. 2021) y 914,3 (conv.2022).
- Las cifras de presupuesto para los proyectos es siempre indicativa ('around').
- La fecha de apertura sería el 22 de abril de 2021 (conv. 2021) y cierre el 21 septiembre de 2021, en principio. Pero, **puede tener un retraso de una o dos semanas.**
- Los topics de la conv. 2021 serán de una sola etapa.
- La fecha de apertura de la convocatoria 2022 sería en octubre de 2021.
- Importancia en la colaboración con otros proyectos financiados en el mismo topic.
- Cáncer es elegible como área de I+D en algunos topics de 2021. ¡Comprobar en el texto!


Destination 1 – Staying healthy in a rapidly changing society

- To provide new evidences, methodologies and tools for understanding the transition from health to disease, preventing diseases and promoting health inclusive through social innovation approaches.
- Specific measures will be developed to educate and empower citizens of all ages and throughout their life.
- Key to achieving the expected impacts is the availability and accessibility of health data from multiple sources including real-world health data, requiring appropriate support by research and data infrastructures, AI-based solutions, and robust and transparent methodologies for analysis and reporting.

Expected impacts:

- Citizens adopt healthier lifestyles and behaviours, make healthier choices and maintain longer a healthy, independent and active life with a reduced disease burden, including at old ages or in other vulnerable stages of life.
- Citizens are able and empowered to manage better their own physical and mental health and well-being, monitor their health, and interact with their doctors and health care providers.
- Citizens' trust in knowledge-based health interventions and in guidance from health authorities is strengthened, including through improved health literacy (including at young ages).
- Health policies and actions for health promotion and disease prevention are knowledge-based, people-centred and thus targeted and tailored to citizens' needs, and designed to reduce health inequalities.

 Call Identifier: **HORIZON-HLTH-2021-STAYHLTH-01-02**

 Name: **Towards a molecular and neurobiological understanding of mental health and mental illness for the benefit of citizens and patients.**



Type of Action: Research and Innovation Action (RIA)



Call: Staying Healthy (2021)



Budget: ≈10 Mio. €/Project; Total: 60 Mio.€/topic

Expected outcomes (one or several):

1. Researchers, healthcare professionals and developers of medical interventions have a much better understanding of how genetic, epigenetic and environmental risk and resilience factors interact to drive or prevent the transition from mental health to mental illness throughout the life course.
2. Mental health professionals have access to different types of validated biomarkers for making more accurate diagnoses (beyond current symptom-based criteria) and for optimising and personalising preventive and therapeutic treatment decisions.
3. Citizens have the possibility to undergo laboratory testing for assessing their mental health and their predisposition to mental illnesses,
4. Public health authorities and policy makers have access to comprehensive clinical trial data on the effectiveness of different types of pharmacological and non-pharmacological strategies.

Scope: Proposed research is expected to deliver on **several** of the following (depending on the selected outcomes):

- Significantly advance the molecular and neurobiological understanding.
- Develop relevant predictive models.
- Identify, validate and document different types or combinations of (bio)markers for all of the described purposes.
- Discover new disease pathways and drug targets.
- Establish the molecular and neurobiological effects, as well as cognitive and psychological consequences of both pharmacological and non-pharmacological prevention strategies.



Call Identifier: HORIZON-HLTH-2021-STAYHLTH-01-03



Name: Healthy citizens - 2.0 Supporting digital empowerment and health literacy



Type of Action: Coordination and Support Action (CSA)



Call: Staying Healthy (2021)



Budget: ≈3 Mio. €/Project; Total: 3 Mio.€/topic

Expected Outcome (all):

1. European citizens are educated, motivated and empowered to use digital tools for monitoring and managing their own physical, mental and social health and well-being.
2. Member States actively contribute to health literacy efforts, monitor and evaluate them.
3. Healthcare and social services are better integrated, affordable, open to diversity and inclusion.
4. Health promotion and disease prevention are enhanced by the awareness of healthier lifestyle behaviours, and overall there are better health outcomes throughout the life-course.

Scope:

The proposed activities should address **all** of the following (**selection**):

- Map health literacy research in the EU (and beyond).
- Develop a comprehensive and inclusive European strategy in improving digital health literacy for the benefit of all citizens,
- Help patients navigate the health care systems, interact with their doctors and carers as well as better manage their own health at home, in the community and at work.
- Create a network of champions in digital health literacy champions across the EU (and beyond).
- Set concrete targets as well as areas for improvement on health literacy levels across Europe.
- Develop monitoring mechanisms and indicators to assess health literacy levels and their evolution across MS.
- Include stakeholders from all the relevant sectors (including but not limited to education, social innovation, health care, Medtech, medial and involve also citizens in the co-creation, design, planning, implementation and evaluation of the strategy.

Call Identifier: HORIZON-HLTH-2021-STAYHLTH-01-04

Name: A roadmap for personalised prevention.

Type of Action: Coordination and Support Action (CSA)

Call: Staying Healthy (2021)

Budget: ≈ 3 Mio. €/Project; Total: 3 Mio.€/topic

Contribute to **all** of the following expected outcomes:

- Researchers, research funders and policy-makers implement a Strategic Research and Innovation Agenda.
- Policy makers, public health services, industrial stakeholders and citizen associations across Europe work together with a coordinated, harmonised and comprehensive research approach towards personalised prevention for all.
- Public health services, health systems, and citizen associations are aware and adopt personalised prevention strategies for all.
- Insurers and public authorities take evidence-based policy decisions for implementing personalised prevention strategies for all.

Scope:

Applicants should propose activities that address **all** the following areas:

- Identification and networking of key stakeholders for the co-creation of strategies for personalised prevention.
- Literature mapping and research gap analysis, in Europe and beyond.
- Identification of the existing bottlenecks and analysis of evidences and examples of successful implementation of personalised prevention approaches and assessment of their transferability.
- Analysis of how personalised prevention can be delivered most effectively and efficiently and cost effective.
- Robust, professional communication strategy to maximise the impact of the findings and the uptake of personalised prevention strategies.
- A Strategic Research and Innovation Agenda on personalised prevention throughout the life course.

Call Identifier: HORIZON-HLTH-2021-STAYHLTH-01-05

Type of Action: Coordination and Support Action (CSA)

Name: Mobilising the network of National Contact Points in the Health Cluster.

Call: Staying Healthy (2021)

Budget: ≈3 Mio. €/Project; Total: 3 Mio.€/topic

Contribute to **all** of the following expected outcomes:

- An improved and professionalised NCP service across Europe,
- A more consistent level of NCP support services across Europe.
- The Network of National Focal Points (NFPs) supporting the implementation of the EU Health programmes will be closely collaborating based on identified synergies with the Research and Innovation Health NCPs.
- Proposals should include a work package to implement matchmaking activities to link up potential participants from widening countries with emerging consortia in the domain of the Health Cluster.
- NCPs representing third countries, in particular those neighbouring the European Research Area should benefit from dense collaboration with the NCP Health network.

Scope:

Proposals should describe a credible pathway from their project results and outcomes towards the following expected impacts:

- Staying healthy in a rapidly changing society;
- Living and working in a health-promoting environment;
- Tackling diseases and reducing disease burden;
- Ensuring access to innovative, sustainable and high-quality health care;
- Unlocking the full potential of new tools, technologies & digital solutions for a healthy society;
- Maintaining an innovative, sustainable and globally competitive health industry.

Call: Staying Healthy (**Two Stage** - 2022)

Opening: 06 October 2021

Deadline(s): 01 February 2022 (First Stage), 06 September 2022 (Second Stage)

HORIZON-HLTH-2022-STAYHLTH-01-01-two-stage: Boosting mental health in Europe in times of change (RIA).

HORIZON-HLTH-2022-STAYHLTH-01-04-two-stage: Trustworthy artificial intelligence (AI) tools to predict the risk of chronic non-communicable diseases and/or their progression (RIA).

HORIZON-HLTH-2022-STAYHLTH-01-05-two-stage: Prevention of obesity throughout the life course (RIA).

Call: Staying healthy (**Single stage** - 2022)

Opening: October 2021

Deadline : April 2022

HORIZON-HLTH-2022-STAYHLTH-02-01: Personalised blue print of chronic inflammation in Health-to-disease transition (RIA).



Call Identifier: **HORIZON-HLTH-2022-STAYHLTH-01-01-two-stage**



Type of Action: Research and Innovation Action (RIA)



Name: Boosting mental health in Europe in times of change



Call: Staying Healthy (2022)



Budget: ≈7 Mio. €/Project; Total: 50 Mio.€/topic

Expected Outcome (all):

- Health and care professionals, national/regional public authorities and other relevant actors in key settings (e.g. schools, workplaces, etc.):
 - Have access to and apply evidence-based, innovative, cost-effective/cost-neutral, large-scale, comprehensive strategies and interventions for mental health promotion and mental ill health prevention, targeting the most vulnerable populations, which they may choose to uptake;
 - Adopt clinical guidelines, best practices, implementation strategies and policy recommendations (as applicable to them) to mitigate the mental health burden and help cope with the (combined) effects of a transforming Europe (e.g. the socio-economic consequences of the COVID-19 pandemic, climate change, environmental degradation, energy transition, demographic and migration factors, digitalization, and exponential technological advancements);
- The scientific community together with the public authorities anticipate new and emerging risks to mental health associated with a transforming Europe, this transformation contributing to a better and inclusive public mental health preparedness.
- Citizens have access to and make use of new tools and services to take informed decisions about their wellbeing and mental health care needs (including for self-management and self-care).
- Citizens feel less stigmatised and marginalised due to their mental ill health.



Call Identifier: **HORIZON-HLTH-2022-STAYHLTH-01-01-two-stage**



Type of Action: Research and Innovation Action (RIA)



Name: **Boosting mental Health in Europe in times of change**



Call: Staying Healthy (2022)






Budget: ≈7 Mio. €/Project; Total: 50 Mio.€/topic


Scope:

The proposed research should aim to deliver in **all three dimensions** listed below, **focusing on one or several of the** (combined) effects of a transforming Europe highlighted in the **“Expected outcomes”** .

1. Provide a comprehensive knowledge base of how a transforming Europe can influence mental health in a fast-evolving society, especially in the most vulnerable populations,
2. Develop and implement (pilot and/or scale-up) interventions.... Outputs may include, but are not limited to:
 - o Evidence based guidelines for health care professionals.
 - o Evidenced based pedagogical practices for education professionals to foster mental health promotion in schools (including higher education) and/or via eLearning.
 - o Consultation during school time to educate students (e.g. on coping with change) and to detect early students at risk..
 - o Educational material and campaigns targeting the most vulnerable groups, (e.g. children and the elderly), disseminated via the most appropriate and effective media and communication channels,
 - o Studies on occupational mental health in the workplace, in particular in small and medium-sized enterprises.
3. Inform policy makers and regulators on:
 - i) the prevalence and burden of mental ill health related to a transforming European society (e.g. digital technologies, climate change, etc); and/or
 - ii) the effects of a transforming European society (e.g. digitalisation, climate change and transition to “green jobs”) on occupational mental health; and/or
 - iii) the (comparative) cost-effectiveness of public mental health interventions/policy choices.

 **Call Identifier:** **HORIZON-HLTH-2022-STAYHLTH-01-04-two-stage**

 **Type of Action:** Research and Innovation Action (RIA)
 **Call:** Staying Healthy (2022)
 **Budget:** ≈6 Mio. €/Project; Total: 60 Mio.€/topic

 **Name:** **Trustworthy artificial intelligence (AI) tools to predict the risk of chronic non-communicable diseases and/or their progression**

Expected Outcome:

Project results are expected to contribute to **all** of the following outcomes:

1. Clinicians, medical professionals and citizens have access to and use validated AI tools for disease risk assessment. Hence citizens are better informed for managing their own health.
2. Health care professionals can utilize robust, trustworthy and privacy-preserving AI tools that help them to assess and predict the risk for and/or progression of chronic non-communicable diseases.
3. Health care professionals can develop evidence-based recommendations and guidelines for the implementation of AI-based personalized prevention strategies. Hence, citizens can benefit from optimized health care measures superior to the standard-of-care.
4. Health care professionals can employ quantitative indicators in order to identify and follow-up on individuals with high risk for the development and/or risk for the progression of chronic non-communicable diseases.



Call Identifier: **HORIZON-HLTH-2022-STAYHLTH-01-04-two-stage**



Type of Action: Research and Innovation Action (RIA)



Call: Staying Healthy (2022)



Budget: ≈6 Mio. €/Project; Total: 60 Mio.€/topic




Name: AI tools to predict the risk of chronic non-communicable diseases and/or their progression

Scope:


The proposals should address **all** of the following areas:

- Leverage of existing high-quality health-relevant data from multiple sources (i.e. cohorts, electronic health records and registries, taking into account the individual's genotypic/phenotypic, medical, life-style, socio-economic, behavioural data etc.) and/or generation of new high-quality health data necessary for the rigorous development of the AI disease-risk tools.
- Develop the adequate performance metrics to assess the technical robustness of the developed AI tools for risk assessment of disease and/or disease progression and in particular their accuracy, reliability, reproducibility and generalizability. Proposals should assess the possible inherent bias introduced to the AI tools originating from the data quality used for their development
- Develop the criteria to assess the effectiveness of the AI tools for disease-risk assessment in terms of improving health outcomes and enabling personalized prevention strategies.
- Implement proof of concept and/or feasibility studies to validate the AI tools tools for risk assessment of disease and/or disease progression in a relevant end-users environment and/or real-world setting and assess their performance in comparison to the standard-of-care.

 Call Identifier: **HORIZON-HLTH-2022-STAYHLTH-01-05**

 **Type of Action:** Research and Innovation Action (RIA)

 **Name:** Prevention of obesity throughout the life course

 **Call:** Staying Healthy (2022)

 **Budget:** ≈10 Mio. €/Project; Total: 60 Mio.€/topic

Expected Outcome:

Results are expected to contribute to **some** of the following expected outcomes:

1. Researchers, developers of medical interventions, and health and care professionals have a much better understanding of basic biological pathways (genetic and epigenetic blueprints) conferring susceptibility to and protecting against overweight/obesity.
2. Health and care professionals, national/regional/local public authorities and other relevant actors (e.g. schools, canteens, hospitals, work places, shopping malls, sport centres)
 - o Have access to, adopt and implement evidence-based clinical guidelines, best practices, coordinated, pan-European, multidisciplinary preventive strategies, policy recommendations and/or new policies to fight overweight/obesity and their co-morbidities throughout the life course.
 - o Have access to and make use of a robust outcomes framework and tool-kit for standardised collection of economic and cost data related to the prevention and treatment of overweight/obesity and its co-morbidities at population level across European regions and countries.
 - o Adopt and implement tailor-made prevention campaigns to tackle overweight/obesity, including campaigns for improving integration of health education into academic learning and raising awareness of health care providers and citizens.
3. Citizens have access to and make use of new tools and services to make informed decisions about lifestyle choices that will prevent them to from becoming overweight/obese.

 Call Identifier: **HORIZON-HLTH-2022-STAYHLTH-01-05**

 Name: **Prevention of obesity through the life course**



Type of Action: Research and Innovation Action (RIA)



Call: Staying Healthy (2022)



Budget: ≈10 Mio. €/Project; Total: 60 Mio.€/topic

Scope:

The proposals should address **several** of the following research bottlenecks :

- A comprehensive understanding of biological pathways (genetic, epigenetic, molecular, microbiome, and/or neuroimmune) conferring susceptibility to and protecting against uncontrolled "weight gain".
- Identification of socio-economic and lifestyle factors influencing consumer behavior and their association to overweight/obesity prevention.
- Identification of pre-obesity biomarkers (genetic, laboratory, imaging, etc.) and their association to lifestyle and environmental interventions aiming at obesity prevention and tailored to specific target populations.
- Mapping existing implementation research activities to prevent overweight/obesity, outcome analyses and identification of best practices.
- Conducting a thorough meta-review of information from available scientific literature and identification of the relationship between the risk for overweight/obesity and the biology of obesity, lifestyle habits, exposures, susceptibility to co-morbidities and/or all of their combinations.
- Developing recommendations and guidelines for what constitutes an appropriate healthy diet for different age and health groups.

 Call Identifier: **HORIZON-HLTH-2022-STAYHLTH-01-05**

 Name: **Prevention of obesity through the life course**



Type of Action: Research and Innovation Action (RIA)



Call: Staying Healthy (2022)



Budget: ≈10 Mio. €/Project; Total: 60 Mio.€/topic

The proposals should address **several** of the following research bottlenecks (**cont.**):

- Understanding the links between overweight/obesity and sedentary behaviour, quality and quantity and types of food/drinks, physical activity and personality traits.
- Designing a creative and engaging programme to reach the optimal balance between diets and physical activity for the prevention of overweight/obesity.
- Analysing stress and work-life balance, mental health (including psychological problems), screen-time dependency, drugs and side effect of drugs, on overweight/obesity.
- Analysing obesity stigma, stress and work-life balance, circadian rhythm disruption, mental health (including psychological problems), screen-time dependency, drugs and side effect of drugs, for the prevention of overweight/obesity.
- Addressing inequality aspects of overweight/obesity at multiple levels, taking into account vulnerable groups, gender and socio-economic factors.
- Setting up pilots to assess the effectiveness of obesity management strategies, including cost-effectiveness, and analyse the impact of inactions, taking into account co-morbidities and value-based care system.
- Developing a system for monitoring population indicators relevant to overweight/obesity by extending European Core Health Indicators.



Call Identifier: HORIZON-HLTH-2022-STAYHLTH-02-01



Type of Action: Research and Innovation Action (RIA)



Name: : Personalised blueprint of chronic inflammation in health-to-disease transition



Call: Staying Healthy (2022)



Budget: ≈7 Mio. €/Project; Total: 50 Mio.€/topic

Expected Outcome:

Project results are expected to contribute to **several** of the following outcomes:

1. Researchers and medical professionals understand the chronic inflammation factors triggering the health-to-disease transition and subsequently provide optimal counselling to citizens for improving their health.
2. Health care professionals have access to and/or employ objective personalised health indicators linked to chronic inflammation with respect to monitoring of the health status, establishing personalised prevention measures and improving the health outcomes for citizens.
3. Health care professionals have the scientific evidence and understanding of health-to-disease transition to develop and/or use improved guidelines for personalised prevention strategies to tackle chronic diseases.
4. Citizens are better informed to actively manage their own health and have the tools to maintain their healthy status, improve their health and reduce their risk for developing chronic diseases.

 Call Identifier: **HORIZON-HLTH-2022-STAYHLTH-02-01**

 Name: **Personalised blue print of chronic inflammation in health-to-disease transition**



Type of Action: Research and Innovation Action (RIA)



Call: Staying Healthy (2022)



Budget: ≈7 Mio. €/Project; Total: 50 Mio.€/topic

Scope:

The proposals should address **several** of the following areas:

- Integrate the state-of-the-art knowledge and the data from suitable human studies (i.e. medical/clinical, well-being, life-style etc.) to identify actionable factors linking chronic systemic and/or local inflammation to the health-to-disease transition. Take stock of omics, of dynamic measurements of the health and well-being status and of data-driven analytical tools in order to identify biomarkers and other health indicators linked to the health-to-disease transition.
- Understand at the systems-level the human biology and physiology underlying chronic inflammation in connection to the tissues/organ dysregulation, organ cross-talk and homeostasis breakdown triggering the health-to-disease transition, taking into account the person's genotype, phenotype, medical history, nutritional and well-being status, life-style and/or occupational/environmental/life stressors.
- Develop and utilize robust sensors, devices and/or mobile apps and other innovative technologies to monitor dynamically the individual's health status and to identify objective indicators of chronic inflammation correlative to the health-to-disease transition
- Implement proof-of-concept human studies to assess the beneficial effect of diverse prevention and/or interventions strategies with the aim to demonstrate improved health outcomes.
- Test suitable interventions with the aim to demonstrate the reduction and/or reversion of the pre-disease state linked to chronic systemic and local inflammation.

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

The environment we live and work is a major determinant of our health and well-being, estimated to account for almost 20% of all deaths in Europe.

The impacting factors on both physical and mental health and well-being are not all identified nor their effects comprehensively understood.

Understanding of the environmental, occupational and socio-economic risk factors for health and well-being and improving economic assessments.

Expected impacts (one or several):

- Policy-makers and regulators are aware and well informed about environmental, socio-economic and occupational risk factors as well as health-promoting factors across society.
- Policy-makers and regulators are aware and well informed.
- The upstream determinants of disease - are known, understood and reduced.
- The health threats and burden is reduced.
- Living and working environments are healthier, more inclusive, safer, resilient and sustainable.
- The adaptive capacity and resilience of populations and health systems are strengthened;
- Citizens' health and well-being are protected and promoted, and premature deaths and diseases are prevented.
- Citizens understand better complex environment and health issues.

Call Identifier: HORIZON-HLTH-2021-ENVHLTH-02-01

Name: Exposure to electromagnetic fields (EMF) and health

Type of Action: Research and Innovation Action (RIA)

Call: Environment and health (2021)

Budget: ≈8 Mio. €/Project; Total: 30 Mio.€/topic

Expected Outcomes (all):

Scientific evidence to implement the Council Recommendation 1999/519/EC as well as Directive 2013/35/EU as well as the most recent ICNIRP guidelines for limiting exposure to electromagnetic fields.

Public authorities improve their risk assessment, management and communication on the exposure to EMF.

Public authorities and the scientific community take advantage from novel and robust methodologies, including models.

Stakeholders consistently use quality criteria and standards (CEN/ISO) for the analytical methodologies in the assessment of exposure to EMF, including 5G.

Public authorities, employers and citizens rely on practical guidelines for exposure prevention and reduction.

Citizens are effectively engaged and informed about the health impact of EMF exposures and risk-preventing behaviours.

Scope (all) (selection):

Scope (all)

- Monitoring of exposures of the general population and specific groups at risk.
- Establishment of potentially new exposure patterns and comparison with existing patterns.
- Investigating evidence of local and systemic biological effects and health impacts across the lifecycle.
- Proposing new quality criteria and standards (CEN/ISO) for the analytical methodologies.
- Delivering FAIR data on the causal links between level and duration of exposures and potential health (biological) effects, including potential mechanisms.
- Undertaking case studies on solutions for exposure reduction based on acquired evidence.
- Proposing and testing efficient communication methods and tools for engaging citizens in preventive actions

 **Call Identifier:** **HORIZON-HLTH-2021-ENVHLTH-02-02**

 **Name:** **Indoor air quality and health.**



Type of Action: Research and Innovation Action (RIA)



Call: Environment and health (2021)



Budget: ≈8 Mio. €/Project; Total: 40 Mio.€/topic

Expected Outcome (all):


- Access to FAIR data on air pollutants, including both chemical and microbiological determinants.
- Society has access to user-friendly solutions to monitor indoor air quality and knowledge on risk factors.
- Policy-makers are provided with proposals for revised indoor air quality standards for the main determinants identified.
- The Zero-Pollution Action Plan of the European Green Deal is supported by science-based evidence.


Scope (all):

- Identification and characterization of sources and routes of exposure and dispersion of chemical and biological indoor air pollution.
- Identification of differences and modes of interaction between indoor and outdoor air quality.
- Development and deployment of technologies for monitoring of indoor air quality, and effect-based test systems for the detection of synergistic effects of different biogenic particles and substances.
- Investigation of body burdens resulting from multipollutant (real life scenario) exposures and pathways indoors and associated health effects.
- Conducting dose-response studies to facilitate the setting of purposeful quality standards.
- Development of cost-effective, environment-friendly and scalable technologies to improve indoor air quality to reduce disease burdens.
- Preparation of guidelines.
- Delivery of FAIR data and databases.

 Call Identifier: **HORIZON-HLTH-2021-ENVHLTH-02-03**

 Name: **Health impacts of climate change, costs and benefits of action and inaction**

 Type of Action: Research and Innovation Action (RIA)

 Call: Environment and health (2021)

 Budget: ≈10 Mio. €/Project; Total: 60 Mio.€/topic

Expected Outcomes (all):

- Global and EU climate policies, the EU Observatory for Climate and Health, and the Green Deal activities are supported with up-to-date scientific evidence.
- Public authorities and surveillance organisations will have access to predictive and early warning systems.
- Public authorities, employers and risk managers draw benefit from user-friendly tools for integrated risk assessments and cost-benefit analysis.
- Public and private health authorities and care providers use guidelines and training materials produced to adapt and innovate health systems and practices.

Proposals must choose and address **one of the following areas of research:**

1. Research on relationships between changes in environmental pollution induced by climate change, and subsequent impacts on interrelated ecosystems and their influence on human health;
2. Climate induced emergence and transmission of pathogens and spread of zoonotic pathogens using Eco-health and One Health approaches;

(I)

 **Call Identifier:** HORIZON-HLTH-2021-ENVHLTH-02-03

 **Name:** Health impacts of climate change, costs and benefits of action and inaction



Type of Action: Research and Innovation Action (RIA)



Call: Environment and health (2021)



Budget: ≈10 Mio. €/Project; Total: 60 Mio.€/topic

Scope (all):

- Development of suitable indicators and backward-looking monitoring mechanisms
- Development of predictive models and early warning systems for health impacts
- Development of tools for health impact and cost-benefit assessment of climate-change adaptation and mitigation measures;
- Investigation of health co-benefits of adaptation and mitigation policy measures outside the health sector;
- Demonstration of the validity of tools and methods developed in the above-listed activities in policy-relevant case studies;
- Determination of the societal implications of climate change on health systems,
- Development of training materials and guidelines to educate relevant actors in citizen's daily life on climate change health impacts and to facilitate adaptation of health systems and practices;
- Delivery of FAIR data on positive and negative health impacts of climate change, including impact on groups at higher risk or vulnerability.

(II)

Call – Partnerships in health (2021)

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


Call - Environment and health (Single Stage - 2022)


Opening: 06 Oct 2021


Deadline(s): 21 Apr 2022

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

 **Call Identifier:** HORIZON-HLTH-2022-ENVHLTH-04-01:

 **Type of Action:** Research and Innovation Action (RIA)

 **Name:** Methods for assessing health-related costs to environmental stressors

 **Call:** Environment and health (2022)

 **Budget:** ≈4 Mio. €/Project; Total: 20 Mio.€/topic

Expected Outcome (all):

- EU and national public authorities regularly use economic and health modelling in policy impact assessments and policy evaluation, and promote the use of these to other stakeholders;
- Stakeholders agree on the most relevant population health and quality of life metrics, including DALYs (Disability Adjusted Life Years) or QALYs (Quality Adjusted Life Years) , and economic metrics;
- The stakeholder community follows common guidelines and methodologies for integrative socio-economic assessments and cost-benefit analysis of environmental pollution in Europe.

Scope (all):

- Systematic review and exploitation of latest evidence of exposure-response functions and causation resulting from published medical and scientific research accumulated data from the past 10-20 years,
- Identification of data gaps and health-related tangible and intangible costs and recommendations.
- Advancement of methodological rigor and consistency in accounting for morbidity and mortality.
- Application of experimental approaches addressing the potential link of quality of life and the burden of disease indicators with more integrative impact indicators.
- Enhancement of the understanding of the role of discounting and other methods for weighing costs and benefits.
- Development of innovative tools, methods and models, and associated guidelines for health impact assessments.
- Consultation of experts and stakeholders on tools, models, methods and.
- Development of case studies involving public authorities comparing the costs of action and non-action in at least three EU or associated countries

Destination 3 – Tackling diseases and reducing disease burden

- It will focus on major societal challenges linked to the Commission's political priorities such as the fight against **cancer** and other non-communicable diseases, better diagnosis and treatment of rare diseases, preparedness and response to and surveillance of health threats and epidemics, reduction of the number of antimicrobial-resistant infections, improving vaccination rates, demographic change, mental health and digital empowerment in health literacy.
- Some research and innovation actions should deliver relevant complementary inputs to the announced "Europe's Beating Cancer Plan" , contributing to actions covering the entire cancer care pathway, including prevention, early detection, diagnosis, treatment, cancer data monitoring, as well as quality of life of cancer patients and survivors.

Expected impacts (consider several):

- Health burden of diseases in the EU and worldwide is reduced through effective disease management.
- Premature mortality from non-communicable diseases is reduced by one third (by 2030), mental health and well-being is promoted, and the voluntary targets of the WHO Global Action Plan for the Prevention and Control of NCDs 2013-2020 are attained (by 2025), with an immediate impact on the related disease burden (DALYs).
- Health care systems benefit from strengthened research and innovation expertise.
- Citizens benefit from reduced (cross-border) health threat of epidemics and AMR pathogens.
- Patients + citizens knowledgeable of disease threats, involved empowered to make and shape decisions for their health.
- The EU benefits from high visibility, leadership and standing in international fora on global health and global health security, especially in partnership with Africa.

Call Identifier: HORIZON-HLTH-2021-DISEASE-04-01

Type of Action: Research and Innovation Action (RIA)

Name: Improved supportive, palliative, survivorship and end-of-life care of cancer patients.

Call: Tackling diseases (2021)

Budget: ≈6 Mio. €/Project; Total: 50 Mio.€/topic

Expected outcomes (all):

- Reduced health-related suffering and improved well-being and quality of life for cancer patients in need of supportive, palliative, survivorship or end-of-life care as well as for their professional and family caregivers.
- Cancer patients (independently of their age) have early and better access to supportive, palliative, survivorship or end-of-life care services of higher quality and (cost)effectiveness.
- Reduced societal, healthcare and economic burden associated with increasing demands of supportive, palliative, survivorship or end-of-life care services .
- Health care providers and health policy makers access to and use the improved clinical guidelines and policies with respect to pain management, psychological and/or spiritual support, supportive, palliative or end-of-life care for cancer patients.
- Cancer patients and their professional and family caregivers use the improved evidence-based and information-driven palliative care decision-making process.

Scope (all):

- Demonstrate the effectiveness and cost-effectiveness of newly proposed or specifically adapted pharmacological and/or non-pharmacological interventions.
- Prove the feasibility of integrating the proposed interventions in current pain management, palliative, supportive, survivorship and/or end-of-life care regimes and healthcare systems across Europe.
- Identify and analyse relationships between sex, gender, age, disabilities and socio-economic factors in health and any other relevant factors.
- Analyse the barriers and opportunities to re-invigorating and enhancing timely social inclusion and active engagement of cancer patients in need of supportive, palliative, survivorship and end-of-life care and their caregivers.
- Guidelines for patient-centred communication and standards for evidence-based communication trainings for caregivers.

Call Identifier: HORIZON-HLTH-2021-DISEASE-04-02

Name: Building a European innovation platform for the repurposing of medicinal products.

Type of Action: Research and Innovation Action (RIA)

Call: Tackling diseases (2021)

Budget: ≈25 Mio. €/Project; Total: 50 Mio.€/topic

Expected Outcomes (all):


- Researchers continue to use the platform as an effective and sustained approach to coordinate and manage their efforts on the repurposing of medicines
- Patients have new and effective therapeutic options addressing unmet medical needs,
- Health care systems and payers have available more cost-effective treatments.
- The public sector and the pharmaceutical industry can engage in new models of sustainable collaboration.
- Policy makers adjust the EU's regulatory landscape for pharmaceuticals towards further harmonization.


Scope (all):

- Set up a platform supporting an innovative repurposing model with a harmonized and sustainable dimension in the EU.
- Provide robust selection mechanisms for prioritising already approved medicinal products or investigational products for repurposing.
- Leverage and pool existing high quality data assets in the EU repurposing landscape by using pharmacogenomics, in silico, and artificial intelligence (AI) approaches.
- Resolve the fragmentation and lack of ownership of the repurposing approach.
- Devise and test a European innovation platform to enhance the collaboration among relevant European stakeholders.

 **Call Identifier:** **HORIZON-2021-HLTH-DISEASE-04-03**

 **Name:** **Innovative approaches to enhance poverty-related diseases research in sub-Saharan Africa**

 **Type of Action:** Research and Innovation Action (RIA)

 **Call:** Tackling diseases (2021)

 **Budget:** ≈8 Mio. €/Project; Total: 40 Mio.€/topic

Expected outcomes (all):

- Health care providers and professionals in sub-Saharan Africa have a better understanding of poverty related infectious diseases affecting these countries and use new evidences and advance innovative technologies or concepts.
- Health authorities and health care systems have access to health data and evidences to better develop and implement informed health policies and improved clinical guidelines in sub-Saharan Africa.
- Health care systems, clinicians and researchers have access to improved clinical research capacities and strengthened infrastructures for clinical research, development and implementation in sub-Saharan Africa.
- More researchers at early stages of their career able to develop their own scientific career in sub-Saharan Africa.
- More clinicians and researchers in sub-Saharan Africa have the capacity to develop and design large-scale studies.

Scope (all):

- Any or group of PRD diseases affecting sub-Saharan Africa (within the scope of EDCTP2 or the SRIA of EDCTP3).
- Combine health medical and pharmaceutical technologies with other scientific areas such as mHealth and eHealth and big data processing, and other emerging technologies.
- Implement one or more medium-scale clinical trials and/or clinical research studies that can deliver the proof-of-concept or validate smart, highly innovative health technologies or concepts to prevent, treat or diagnose PRDs in sub-Saharan Africa, drawing lessons from the COVID-19 experience.
- Increase collaboration with investors in development cooperation and international partnerships to create solutions for improved development or delivery of medical interventions for vulnerable populations in low resource settings.
- Proposals involving pharmaceutical companies and small- or medium-sized enterprises (SMEs) are encouraged.
- Develop solutions that are easily integrated or linked to existing electronic or digital systems that are used in the implementation of clinical research and health systems' patient management.
- Include activities that promote collaboration with ongoing and future EDCTP projects.



Call Identifier: HORIZON-HLTH-DISEASE-2021-04-04



Name: Clinical validation of artificial Intelligence (AI) for treatment and care



Type of Action: Research and Innovation Action (RIA)



Call: Tackling diseases (2021)



Budget: ≈6 Mio. €/Project; Total: 60 Mio.€/topic

Expected outcomes (all):

- Health care professionals employ safer and evidence-based clinical decision support systems for affordable treatment including home-based care.
- Health care professionals better predict patients' (long-term) response, including adverse side effects of a specific personalised specific treatment.
- Patients and carers will have access to disease-specific communication packages informing about a disease and the proposed treatment.
- Clinical guidelines are enhanced thanks to novel, clinically validated and (cost-) effective AI solutions.

Scope (all):

- Supporting the clinical development, testing and validation of AI-assisted treatment and care options.
- Timely end-user inclusion (e.g. patient, caregiver and health care professional) along the clinical development of AI-based solutions and the clinical validation process.
- Enhancing accurate prognosis for, and response to, a specific personalised treatment.
- Inclusion of sex and gender aspects, age, socio-economic, lifestyle and behavioural factors and other social determinants of health, considering also early stage/phases of development.
- Assessing potential manual or automated biases for large uptake.
- Integration of an extensive information and communication package about the disease, highlighting their relevance for the patients and carers.
- Measuring the (cost-)effectiveness of AI-assisted development of therapeutic strategies and its implementation in clinical practice.

Call Identifier: HORIZON-HLTH-2021-DISEASE-04-07

Type of Action: Research and Innovation Action (RIA)

Name: Personalised medicine and infectious diseases:
understanding the individual host response to viruses
(e.g., SARS-CoV-2)

Call: Tackling diseases (2021)

Budget: 7 Mio. €/Project; Total: 60 Mio.€/topic

Expected outcomes (some):

- Enhanced knowledge of risk factors, symptoms expression, disease progression and clinical outcomes in relation to host and viral characteristics, and host-pathogen interaction.
- Clinicians, regulators and other stakeholders have access to decision support based on characterized diversity of host response at the level of genetic patterns, molecular pathways and physiological mechanisms.
- Clinicians and researchers use information on the deep characterization of the dynamics of the immune responses to the chosen virus(es), identifying factors critical for viral control and immune protection.
- Clinicians can use biomarkers in the broad sense for personalised patient management.
- Clinicians and other stakeholders along the healthcare value chain have access to and use guidance on preventive measures and for the early identification of patients at risk of developing severe symptoms.

Scope (all):

- To characterize the host response and host-pathogen interaction to a virus (or viruses) at the level of genetic patterns, physiological mechanisms and molecular pathways involving different organs and systems.
- Include patient follow-up to identify conditions (including long-term ones) after the patient has recovered.
- Deep immunological phenotyping of the host response, including the use of animal models if relevant
- Effect of differences in age, sex, gender, ethnicity, chronic conditions, co-morbidities, treatments offered and other relevant characteristics. The sample should be geographically representative for Europe.
- Proposals on COVID-19 should build links with the project "ORCHESTRA" and the COVID-19 data-sharing platform and collaborate with the network of H2020 COVID-19 projects.

New Partnerships (One Stage - 2021)

Opening: April 2021

Deadline: September 2021

HORIZON-HLTH-2021-DISEASE-04-05: A roadmap towards the creation of the European One Health antimicrobial resistance partnership (OH AMR) ([CSA](#))

HORIZON-HLTH-2021-DISEASE-04-06: Building a European research and Innovation Partnership for Pandemic Preparedness ([CSA](#))

Call - Tackling diseases (Two Stage - 2022)

Opening: Oct 2021

Deadline(s): Feb 2022 (First Stage), Sep 2022 (Second Stage)

HORIZON-HLTH-2022-DISEASE-06-02-two-stage: Pre-clinical development of the next generation immunotherapies for diseases or disorders with unmet clinical need ([RIA](#))

HORIZON-HLTH-2022-DISEASE-06-03-two-stage: Vaccines 2.0 - developing the next generation of vaccines ([RIA](#))

HORIZON-HLTH-2022-DISEASE-2022-06-04-two stage: Development of new effective therapies for rare diseases ([RIA](#))

Call - Tackling diseases (One Stage - 2022)

Opening: Oct 2021

Deadline(s): Apr 2022

HORIZON-HLTH-2022-DISEASE-07-02: Pandemic Preparedness ([Placeholder](#))

HORIZON-HLTH-2022-DISEASE-07-03: Non-communicable diseases risk reduction in adolescence and youth ([RIA](#))


HORIZON-HLTH-DISEASE-2022-03-01: European Partnership Fostering an ERA for Health Research ([Placeholder](#))

HORIZON-HLTH-DISEASE-2022-07-01: GloPID-R secretariat ([Placeholder](#))

 Call Identifier: **HORIZON-HLTH-2022-DISEASE-06-02-two-stage**

 **Type of Action:** Research and Innovation Action (RIA)

 **Name:** **Pre-clinical development of the next generation of immunotherapies for diseases or disorders with unmet clinical needs**

 **Call:** Tackling diseases (2022)

 **Budget:** ≈6 Mio. €/Project; Total: 60 Mio.€/topic

Expected outcomes (some):

- The scientific and clinical communities make effective use of the pre-clinical validation of new immunotherapies for high burden diseases or disorders with unmet medical needs.
- The scientific and clinical communities have access to new knowledge allowing for a better understanding of the mode of action of the next generation of immunotherapies and/or combinatorial treatments.
- The scientific and clinical communities have access to and use new personalized models (in vitro and in vivo) for high burden diseases or disorders as well as protocols for the next generation of immunotherapies.
- Health care professionals have access to and use new evidence-based safety and efficacy guidelines for immunotherapies.

Scope (some):

- Preclinical development and study of new immunotherapeutic agents in vitro and in relevant animal model(s) of the disease(s). A robust regulatory and Health Technology Assessment (HTA) strategy should be in place at the start of the proposal.
- Off-the-shelf therapies, including the cell-based therapies, will be considered as assets during the evaluation.
- Proposals could include proof-of-concept (PoC)/first-in-human studies for testing the new therapies, with a clear regulatory and clinical pathway and should address as appropriate the therapy-related potential for adverse side effects.
- Development of a standardised framework for assays and data usage to assess safety and efficacy.
- In case treatments are already available for the proposed targeted disease(s), a justification of the need for development of a new immunotherapy treatment is requested.
- The proposed action should include a pathway of the necessary steps to ensure sustainable therapeutic agent production and uptake by health systems.
- **Preventive vaccines, immunotherapies for rare diseases, cancer and the repurposing of drugs are excluded. Therapeutic vaccines are included.**



Call Identifier: **HORIZON-HLTH-2022-DISEASE-06-03-**
two-stage



Name: **Vaccines 2.0 - developing the next generation**
of vaccines



Type of Action: Research and Innovation Action (RIA)



Call: Tackling diseases (2022)



Budget: ≈8 Mio. €/Project; Total: 40 Mio.€/topic

Expected outcomes (all):

- The scientific and clinical communities use the increased knowledge on pathogens and better understanding of the immune system's role in infectious diseases to develop vaccines with improved efficacy.
- Vaccine manufacturers use more innovative and sustainable manufacturing technologies and improved GMP manufacturing know-how for producing the next generation of vaccines.
- A diversified portfolio of vaccine candidates ready for testing in clinical trials help policy makers and funders to make informed decisions about support to vaccine development.
- New innovative and improved design of preclinical/clinical studies that match the features of the next generation of vaccines is available for clinical community and regulators, and will shorten vaccine development time.

Scope (several):

- Innovation and integration of expertise and capabilities, including alignment of preclinical and clinical models, biomarker studies and new vaccine approaches from discovery to late stage development, from bench-based research to clinical development of promising preventive candidates.
- Application of iterative processes (including cross-learning, back-translation steps, integrative analysis of data) to allow exploitation and integration of novel findings between clinical, preclinical and discovery research and development..
- Deciphering mechanisms of protection of candidates, new approaches to antigen discovery and immunogen engineering, reverse vaccinology, evaluation of vaccines in novel platforms and technologies, novel adjuvants, innovative vaccine manufacturing approaches, relevant animal models, evaluation of alternative vaccine delivery routes.
- Effective, evidence-based decision-making for progression of vaccine candidates in the pipeline based on transparent and objective portfolio management. Regulatory requirements be considered. Sex, gender, age and socio-economic factors should be taken into account.



Call Identifier: **HORIZON-HLTH-2022-DISEASE-2022-06-04-two stage**



Type of Action: Research and Innovation Action (RIA)



Name: **Development of new effective therapies for rare diseases**



Call: Tackling diseases (2022)



Budget: ≈8 Mio. €/Project; Total: 60 Mio.€/topic


Expected outcomes (some):

- Researchers and developers make the best use of the state-of-the-art knowledge and resources for a fast and effective development of new therapies for rare diseases.
- Researchers and developers increase the development success rate of therapies for rare diseases by employing robust preclinical models, methods, technologies, validated biomarkers, reliable patient reported outcomes and/or innovative clinical trials designs.
- Developers and regulators move faster towards market approval of new therapies for rare diseases (with currently no approved treatment option) due to an increased number of interventions successfully tested in late stages of clinical development.
- Healthcare professionals and people living with a rare disease get access to new therapeutic interventions and/or orphan medicinal products.

Scope (most):

- Establish multidisciplinary collaborations between all relevant stakeholders by integrating disciplines, technological developments and existing knowledge.
- Develop and utilise relevant preclinical models and/or innovative tools/technologies to: verify molecular/cellular pathways/genes that can be therapeutically targeted, increase the confidence in the targets selection and/or perform toxicity studies.
- Develop and/or execute innovative clinical trials designs for small populations and novel approaches to assess and monitor the safety and efficacy of the proposed interventions
- Carry out preclinical proof-of-concept (PoC) studies and/or multinational interventional clinical studies to demonstrate the safety and efficacy of the therapeutic interventions under study.

 Call Identifier: **HORIZON-HLTH-2022-DISEASE-07-03**

 Name: **Non-communicable diseases risk reduction in adolescence and youth**

 Type of Action: Research and Innovation Action (RIA)

 Call: Tackling diseases (2022)

 Budget: ≈3 Mio. €/Project; Total: 25 Mio.€/topic

Expected outcomes (some):

- 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 prevention interventions.
- Public health managers and authorities have access to improved insights and evidences on the NCDs related to behaviours and conditions in youth and adolescence. They establish improved health policies to diminish these risks.
- Researchers, clinicians and authorities have an improved understanding of the factors that influence the implementation of preventive actions that address risk behaviours in youth and adolescence.
- Communities and local stakeholders and authorities are fully engaged in implementing and taking up health interventions and thus contribute to deliver better health.

Scope (all):

- All proposals must make the case for why their selected life stage is a critical period for the reduction of NCD risk in the communities where the research will be undertaken.
- Proposals should be gender-responsive and consider socioeconomic, racial or other factors that relate to equitable impacts of the intervention or barriers to equitable implementation.
- Proposals should include implementation research outcomes and where relevant, include service outcomes.
- Proposals should include a strategy to include policy makers and local authorities, as well as other relevant stakeholders such as community groups.

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

Main foci:

1. Modernising health care systems in the EU, especially through a European public-public partnership on transforming health and care systems;
2. Improving the quality of health care along the entire health care continuum and being people-centred;
3. Supporting evidence-based health care decisions both for health care providers and policy-makers, fostering improved foresight and enabling sound planning of health care resources;
4. Development and uptake of innovative health care services and solutions, including environmentally sustainable ones that contribute to the European Green Deal.

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

Expected impacts (one or several):

- Health and social care services and systems have improved governance mechanisms and are more effective, efficient, accessible, resilient, trusted and sustainable, both fiscally and environmentally.
- Health care providers are trained and equipped with the skills and competences suited for the future needs of health care systems that are modernised, digitally transformed and equipped with innovative tools, technologies and digital solutions for health care.
- Citizens are supported to play a key role in managing their own health care, informal carers are fully supported and specific needs of more vulnerable groups are recognised and addressed.
- Health policy and systems adopt a holistic approach (individuals, communities, organisations, society) for the evaluation of health outcomes.
- The actions resulting from the calls under this destination will also create strong opportunities for synergies with the EU4Health.

 **Call Identifier:** **HORIZON-HLTH-2021-CARE-05-01**



Type of Action: Research and Innovation Action (RIA)

 **Name:** **Enhancing quality of care and patient safety**



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



Budget: ≈5 Mio. €/Project; Total: 25 Mio.€/topic

Expected outcomes (some):

1. Health policy-makers use context specific knowledge and evidence to develop inclusive, effective and affordable interventions ensuring patient safety;
2. Health care professionals know how to prevent, identify, evaluate and address risks for patient safety, and use harmonised or standardised patient-centred procedures and practice guidelines;
3. Health care providers integrate harmonised and standardised practices with personalised treatment schemes;
4. Health care providers use quality assured processes to bridge inter-sectorial gaps in the clinical pathways of patients to improve patient safety;
5. An increased number of health care professionals and patients/citizens accept and adhere to recommendations for improved patient safety.

Scope: (consider **already existing EU-funded initiatives** in this area, and **at least 3 of the following items, or others**)


- Fill knowledge and practice gaps in quality of care and patient safety.
- Development and piloting of harmonised evidence-based interventions in a uniform and structured way in health care institutions of different EU regions and countries.
- Research on translation of international standards and clinical guidelines into national practice for improved quality of care and patient safety.
- Provide context-specific evidence on facilitators + barriers for transferring good practices across regions and countries.
- Comprehensive comparison of practices related to clinical guidelines in European Union and Associated Countries.
- Development of innovative approaches for the integration of harmonised and standardised practices with personalised treatment plans.

Proposals should consider a patient-centred approach that empowers patients/citizens, promotes a culture of dialogue and openness between health professionals and citizens/ patients, and unleashes the potential for social innovation.

 **Call Identifier:** HORIZON-HLTH-2021-CARE-05-02



Type of Action: Research and Innovation Action (RIA)

 **Name:** Data-driven decision-support tools for better health care delivery and policy-making with a focus on cancer



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



Budget: ≈10 Mio. €/Project; Total: 40 Mio.€/topic

Expected outcomes (some):

1. Health care organisations and policymakers adopt robust and transparent modelling (including data collection, storage and analysis), planning algorithms and artificial intelligence (AI) solutions in support of health and care decision-making processes;
2. Healthcare providers, caregivers (formal and informal), citizens, and other relevant stakeholders take better informed decisions about their health or the health of persons they are responsible for and/or about the organisation of the health care service or system they are involved in or in charge of;
3. Policymakers get access to evidence-based decision support tools for public health policy-making and health care delivery;


Scope: (one or more)

- The development of data-driven, interactive policy and visualisation tools (i.e. through creation of digital twins /virtual models) bringing novel insights on populations, systems and services as a whole, to help policymakers make data-driven decisions.
- The development of data-driven solutions (i.e. scenario-building tools and models) helping health care organisations take evidence-informed decisions on cancer care delivery processes such as logistics planning and management, capacity, utilisation of health services and allocation of resources and infrastructures and availability of and access to health and care technologies and interventions;
- The development of data-driven solutions empowering citizens and cancer patients interaction with the health and care systems;
- The development of digital toolkits and indicators to improve the reporting and assessment of outputs from end-user involvements including of patient-reported outcomes measures (PROMs) and patient-reported experience measures (PREMs);

 Call Identifier: **HORIZON-HLTH-2021-CARE-05-02**



Type of Action: Research and Innovation Action (RIA)

 **Name:** Data-driven decision-support tools for better health and care delivery and policy-making with a focus on cancer



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



Budget: ≈10 Mio. €/Project; Total: 40 Mio.€/topic

Scope: (cont.)

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

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

Proposals should adopt a patient-centred approach that empowers patients, promotes a culture of dialogue and openness between citizens/patients, caregivers, health care providers and other relevant stakeholders, and unleashes the potential for social innovation.

Call Identifier: HORIZON-HLTH-2021-CARE-05-04

Type of Action: Coordination and Support (CSA)

Name: Health and Care procurement innovation network

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

Budget: 5 Mio. €/Project; Total: 5 Mio.€/topic

Expected Outcomes (all):

- Stakeholders involved in the demand side of health/care innovations reach a common understanding that reflects their key clinical, procurement/supply, organisational and coordination priorities.
- Public/private procurers and decision makers at a local, regional, national and EU level collectively develop and adopt optimal, cost-efficient and flexible innovation procurement strategies taking into account the ongoing changes in the organisational procedures of health care structures caused by the COVID-19 pandemic.
- Procurers and decision makers in procurement organisations mainstream health and care-related Innovation Procurement best practices in their respective policy and investment strategies.
- Health and care procurers from participating Member States and associated countries scale up cross-border collaborations in research and deployment of innovative solutions, thereby minimising investment risks.

Scope (all):

- Hold an open market consultation with the industry across Europe on the current state of the art;
- Develop cooperation models for implementing Pre-Commercial Procurement and Public Procurement of Innovative solutions;
- Conduct a market analysis and propose solutions to overcome potential;
- Consult with relevant stakeholders, end-users to prepare for a future market uptake of the solutions;
- Take measures ensuring the sustainability of outcomes beyond the lifespan of the proposed project and their integration into the procurement strategies of participating organisations;

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

Opening: 06 Oct 2021

Deadline(s): 21 Apr 2022


HORIZON-HLTH-2022-CARE-08-02: Pre-commercial research and innovation procurement (PCP) for building the resilience of health and care systems in the context of recovery ([PCP](#)).

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

HORIZON-HLTH-2022-CARE-08-04: Better economic foresight, financial planning and procurement/contractual strategies for health systems ([RIA](#)).

HORIZON-HLTH-2022-CARE-2022-10-01: European Partnership on Transforming Health and Care Systems ([Cofund Actions](#)).

 Call Identifier: **HORIZON-HLTH-2022-CARE-08-02**

 Name: **Pre-commercial research and innovation procurement (PCP) for building the resilience of health care systems in the context of recovery**



Type of Action: **PCP**



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



Budget: ≈ 5 Mio. €/Project; Total: 25 Mio.€/topic

Expected outcomes: (some)

- Public and private procurers in the area of health care procure the competitive development of market-ready, sustainable, innovative solutions (materials, technologies and systems/practices) which are made in Europe;
- European health and technology industry actors (including start-ups/SMEs) bring to the market secure, interoperable digital health care solutions;
- Procurers facilitate the commercialisation of innovative solutions at a large scale (EU/international) by their successful suppliers;
- 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;

Scope: (all)

- Proposals should be based on clearly identified user needs and well-structured work plans, explaining how the procured research and development will contribute to the expected outcomes.
- Proposals should clearly state the expected health benefits of the solutions that will be developed during the course of the action.
- Applicants should consider aspects of accessibility and affordability of the solution, efficiency of the technology when implemented in the relevant contexts and how it contributes to health systems resilience.
- Prioritised areas of health care to be considered: health promotion, preparedness, prevention, surveillance and rapid response to cross-border health threats, etc.



Call Identifier: **HORIZON-HLTH-2022-CARE-08-03**



Type of Action: **PPI**



Name: **Public procurement of innovative solutions (PPI) for building the resilience of health care systems in the context of recovery**



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



Budget: ≈ 5 Mio. €/Project; Total: 15 Mio.€/topic

Expected outcomes: (some)

- Public and private procurers in the area of health care deploy at a critical scale, innovative, market-ready solutions that are relevant to the preparedness and resilience of health care systems;
- European health and technology industry actors (including start-ups/SMEs) bring to the market secure, interoperable digital health care solutions;
- Procurers facilitate the commercialisation of innovative solutions at a large scale (EU/international) by their successful;
- 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 resilience of health care systems.

Scope: (all)

- Proposals should therefore be based on clearly identified user needs and well-structured work plans, explaining how the procurement of the innovative solutions will contribute to the expected outcomes.
- Proposals should clearly state the benefits of the solutions that will be developed during the course of the project.
- Applicants should consider aspects of accessibility and affordability of the solution, efficiency of the technology when implemented in the relevant contexts and how it contributes to health systems resilience.
- Prioritised areas of health care are health promotion, preparedness, prevention, surveillance, rapid response to cross-border health threats, etc.

 Call Identifier: **HORIZON-HLTH-2022-CARE-08-04**

 Name: **Better economic foresight, financial planning, and procurement/contractual strategies for health systems**



Type of Action: **Research and Innovation Action**



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



Budget: ≈5 Mio. €/Project; Total: 30 Mio.€/topic

Expected outcomes: (some)

- Decision and policymakers in the field of health care avail of new approaches to financial planning and financing mechanisms that provide flexibility to stretched health budgets.
- Decision and policymakers in the field of health care use cost-effective spending strategies based on the optimisation of benefits packages.
- Decision and policymakers in the field of health care access tools that enable them to better remunerate, contract and incentivise health care professionals and providers.
- Decision and policymakers in the field of health care take evidence-based and socially equitable health care financial decisions.

Scope: (one or more):

- Economic modelling and foresight of health system performance and sustainability .
- Financing of health care systems .
- Financing of preventive health care – novel models and appropriate structure of financial incentives for effective health promotion and disease prevention, financial incentives for stronger co-operation between primary, etc.
- Cost-effective health care delivery with focus on optimisation of benefits packages.
- New or improved cost-effective and transparent procurement methods .
- Innovative purchasing and contract methods .
- New and improved tools for better design of remuneration or non-financial incentives for health care.

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

Aim: to promote the development of tools, technologies and digital solutions for treatments, medicines, medical devices and improved health outcomes

Expected impacts (several):

- 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.
- Citizens benefit from targeted and faster research resulting in safer, more efficient, cost-effective and affordable tools, technologies and digital solutions.
- The EU gains high visibility and establishes leadership in terms of technology development.
- The burden of diseases in the EU and worldwide is reduced through the development and integration of innovative diagnostic and therapeutic approaches, personalised medicine approaches, digital, etc.
- Both the productivity of health research and innovation, and the quality and outcome of health care is improved thanks to the use of health data and innovative analytical tools, such as artificial intelligence (AI) supported decision-making.

Call Identifier: HORIZON-HLTH-2021-TOOL-06-01

Name: Smart medical devices and their surgical implantation for use in resource-constrained settings

Type of Action: (Research &) Innovation Action (IA)

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

Budget: 6 Mio. €/Project; Total: 25 Mio.€/topic

Expected Outcomes (all):

- Medical device developers provide sustainable and affordable smart active implants validated in the operational environment.
- Medical professionals in resource-constrained clinical settings have at their disposal sustainable and affordable surgical procedures for smart active implants.
- Patients have access to sustainable and affordable smart medical devices suitable for minimally invasive surgical implantation through further clinical studies.

Scope (all):

- The device targeted and its intended use is open for applicants to choose (e.g. orthopaedic, neural, cardiovascular, metabolic, etc.), but should at the start of the proposed work be at **TRL 4** (min.) and will necessitate appropriate tailored surgical procedures and interventions.
- R&I activities should comprise medical device design, regulatory work, clinical stages and developmental iterations, reaching a **TRL of at least 7**, and involve key medical specialists (e.g. surgeons) and/or other health care professionals, developers, patients and relevant regulatory bodies as appropriate.
- The work proposed should take into account the new EU legal framework on medical devices with the targeted implants meeting all the essential requirements as defined therein.

Call Identifier: HORIZON-HLTH-2021-TOOL-06-02

Type of Action: (Research &) Innovation Action (RIA)

Name: Next generation advanced therapies to treat prevalent and high burden diseases with unmet medical needs

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

Budget: 6 Mio. €/Project; Total: 60 Mio.€/topic

Expected outcomes (all):

- Competent authorities, researchers and developers have use assays for the valorisation and/or assessment of efficiency, delivery, safety, potency or mode of action of novel advanced therapeutic interventions based on either pluripotent stem cells, genome editing or RNA, that are aligned with regulatory standards.
- Clinicians, researchers and developers test several new advanced therapies based on pluripotent stem cells, gene editing or RNA ready through clinical trials meeting the regulatory requirements.


Scope (one or several):

- Method development for the production and differentiation of pluripotent stem cells. Complimentary activities to assess mode of action, safety, in vivo validation or upscaling procedures could be considered.
- Development and validation of biological assays and methods that can demonstrate efficacy, delivery, specificity, and safety (including off-target effects) of genome editing products in the targeted cells and tissues (e.g. base editing, prime editing, transcription activator-like effector nucleases, zinc-finger nucleases, clustered regularly interspaced short palindromic repeats). Complementary activities to assess in vivo validation or upscaling procedures could be considered.
- Development and validation of novel RNA-based therapeutics targeting non-communicable diseases. Complimentary activities to assess mode of action, delivery, safety in vivo validation or upscaling procedures could be considered.
- Study, analysis and tackling of different immune responses, taking into account factors like sex and age, generated by any of the above-mentioned advanced therapies in vivo, facilitating regulatory approval for next phase of research and development.

 Call Identifier: **HORIZON-2021-HLTH-TOOL-06-03**



Type of Action: Research and Innovation Action (RIA)

 **Name:** Innovative tools for use and re-use of health data (in particular of electronic health records and/or patient registries)



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



Budget: ≈8 Mio. €/Project; Total: 30 Mio.€/topic

Expected outcomes (all):

- Novel solutions improve quality, ensure interoperability and enable re-use of health data, data analytics and metadata from different repositories across countries.
- Health professionals, researchers and health authorities make effective use of tools enabling them to exploit unstructured and heterogeneous data from different sources to improve the delivery of care and advance health research.
- Increased use and valorisation of health data by patients, researchers and clinicians thanks to better data portability due to the standardization of meta knowledge and clinical data, especially health data coming from different clinical services and sites, and/or from multiple countries.
- Health care professionals use more efficient and cost-effective health care procedures and workflows

Scope (all):

- Developing robust novel solutions compliant with legal requirements that will improve the quality, interoperability, machine-readability and re-use of health data and metadata in compliance with FAIR data management principles, making these data more accessible to clinicians, researchers and citizens. The focus should be on data in electronic health records (EHRs) and/or patient registries, taking into account the Commission Recommendation on a European Electronic Health Record exchange format .
- Developing innovative natural language processing tools, including computational semantics, ontologies, text mining, associated machine learning and deep learning, to improve accessibility, interoperability, translation, transcription, and analysis of health data (e.g. to predict risks).
- Developing and piloting AI-powered virtual assistants that will utilize the tools and solutions developed (as mentioned above) in order to demonstrate improved usability of health data for end-users.

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

Opening: Oct 2021

Deadline(s): Apr 2022

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

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


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

Opening: Oct 2021

Deadline(s): Apr 2022

HORIZON-HLTH-2022-TOOL-12-01-two-stage: Computational models for new patient stratification strategies (RIA).

 **Call Identifier: HORIZON-HLTH-2022-TOOL-11-01**

 **Name: Optimising effectiveness in patients of existing prescription drugs for major diseases (except cancer) with the use of biomarkers**



Type of Action: Research and Innovation Action



Call: Tools and technologies for a healthy society (2022)



Budget: ≈10 Mio. €/Project; Total: 60 Mio.€/topic


Expected outcomes: (all)

- Diagnostics industries move towards market approval for companion diagnostics.
- Regulatory authorities approve companion diagnostics and make recommendations for the prescription of existing drugs.
- Health care providers use biomarkers with existing pharmaceuticals to treat more efficiently and cost-effectively patients, with less adverse effects.

Scope: (all)

- The applicants should perform the clinical validation of qualified biomarkers (not limited to molecular biomarkers) that will enable the identification of appropriate patients to ensure an effective and efficient use of existing pharmaceuticals in the treatment of major diseases and conditions.
- This topic excludes cancer and rare disease treatments.
- The applicants should consider existing guidelines, standards and regulations, as appropriate.
- Synergies with relevant European Research Infrastructures are encouraged.

 **Call Identifier:** HORIZON-HLTH-2022-TOOL-11-02

 **Name:** New methods for the effective use of real-world data and/or synthetic data in regulatory decision-making and/or in health technology assessment



Type of Action: Research and Innovation Action



Call: Tools and technologies for a healthy society (2022)



Budget: ≈ 7 Mio. €/Project; Total: 35 Mio.€/topic


Expected outcomes: (all)

- Health regulatory bodies and/or Health Technology Assessment (HTA) bodies adopt optimised data-driven methodologies for the effective use of real-world data (including omics data), and/or synthetic data derived from digital twins and advanced computational methods, for the assessment of medicinal products and/or digital health innovations.
- Health regulatory authorities and bodies use optimised guidelines for the development and assessment of medicinal products and/or medical devices including digital health innovations.
- Health regulatory authorities and bodies across Europe are trained in data-driven decision making using emerging data types.

Scope: (all)

- Develop a set of evidentiary standards to be pre-specified and used in the analysis of real-word evidence and/or synthetic data applied to different types of regulatory advice and/or health technology assessment and decisions on the safety and efficacy/effectiveness of medicines and digital health.
- Address aspects that would enable moving towards a standard data quality framework reproducible across different types of RWD and/or synthetic data sources for regulatory decision-making and/or health technology assessment.
- Enhance the performance and efficiency of large randomised clinical trials and new models of clinical trials by developing standardised processes and methods to access RWD and/or synthetic data (.).
- Define methodological standards for the regulatory acceptability of RWD, and/or synthetic data in the context of clinical trials augmented with RWD, and/or synthetic data, for regulatory decision making and/or health technology assessment.
- Test the ability of machine learning methods to help identify relevant RWD, and/or synthetic data to match with and to interpret clinical trials, for regulatory decision-making and/or health technology assessment.
- Assess and validate how machine learning methods can be systematically harnessed to screen a large amount of data, including unstructured data, in many electronic databases to identify factors affecting efficacy and safety of treatments and/or digital health innovations, for regulatory decision-making and/or health technology assessment. The cross-border interoperability dimension should be taken into account.

 **Call Identifier:** **HORIZON-HLTH-2022-TOOL-12-01-twc**
stage

 **Name:** **Computational models for new patient stratification strategies**



Type of Action: Research and Innovation Action

Call: Tools and technologies for a healthy society (2022)

Budget: ≈ 6 Mio. €/Project; Total: 60 Mio.€/topic

Expected outcomes: (some)

- Clinical researchers use effective health data integration solutions for the classification of the clinical phenotypes.
- Researchers and/or health care professionals use robust and validated data-driven computational tools to successfully stratify patients.
- Regulatory bodies approve computer-aided patient stratification strategies to enable personalised diagnosis and/or personalised therapy strategies.
- Health care professionals adopt evidence-based guidelines for stratification-based patient management superior to the standard-of-care.

Scope: (several)

- Establish interdisciplinary research by bridging disciplines and technologies (disease biology, clinical research, data science, -omics tools, computational and mathematical modelling of diseases, advanced statistical and/or AI/machine learning methods, Virtual Physiological Human and/or digital twin technologies).
- Develop new computational models for the integration of complex health data from multiples sources, including structured and unstructured data.
- Develop and optimise robust, transparent and accurate computational models to guide patient stratification strategies for improving clinical outcomes.
- Demonstrate, test and clinically validate such models with respect to their utility to realistically stratify patients with the aim of improving the standard-of-care.
- The development of new patient stratification strategies guided by computational models and the validation of the new concepts of stratification in pre-clinical and/or clinical studies.

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

- Production of pharmaceuticals in compliance with the objectives of the European Green Deal.
- Methodologies, guidelines and standards, assessment studies, and structuring activities adapted to digital solutions and interventions for GDPR compliant translation into health care practice, including inter-operability, cyber-security and data confidentiality.
- Public authorities supported with better methodologies and interdisciplinary approaches to assess and value new health technologies and interventions.
- Development of pharmaceutical products meeting unmet medical needs in the context of market failures.

Expected impacts (one or several):

1. Health industry in the EU is more competitive and sustainable and growing, it contributes to job creation and economic growth, in particular with SMEs.
2. Health industry is working more efficiently along the value chain from the identification of needs to the scale-up and take-up of solutions at national, regional or local level.
3. European standards, including for operations involving health data, ensure patient safety and quality of healthcare services as well as effectiveness and interoperability of health innovation and productivity of innovators.
4. Citizens, health care providers and health systems benefit from a swift uptake of innovative health technologies and services offering significant improvements in health outcomes.
5. Health security in the EU benefits from reliable access to key manufacturing capacity.

Call Identifier: HORIZON-HLTH-2020-IND-07-01

Name: Green pharmaceuticals

Type of Action: Research and Innovation Action (RIA)

Call: A competitive health-related industry (2021)

Budget: 8 Mio. €/Project; Total: 40 Mio.€/topic

Expected outcomes (some):

- Researchers and regulators understand the environmental impact of pharmaceuticals.
- Public authorities inform pharmaceutical strategies and policies based on scientific evidences.
- Researchers, innovators and pharmaceutical industries develop and produce greener pharmaceuticals that are either greener by design, intrinsically less harmful for the environment, and/or use greener and economically more sustainable manufacturing processes for the production of pharmaceuticals.

Scope (several):

- Research and innovation to support the development of “greener” pharmaceuticals that degrade more readily to harmless substances in waste water treatment plants and the environment;
- Research on the eco-toxicity and environmental fate of pharmaceuticals, in particular those that are not yet subject to environmental risk assessment.
- Propose innovative manufacturing technology that are greener, low in energy consumption and emissions, using less solvent or recycling solvents;
- Propose methods for eliminating carcinogenic impurities in pharmaceuticals (e.g. nitrosamines) process and medicinal products, in particular as complementary technologies to the manufacturing methods relying on recycled solvents;
- Explore innovative uses of digital transformation or robotic for competitive and scalable methods of production;

Call Identifier: HORIZON-HLTH-2021-IND-07-02

Type of Action: Research and Innovation Action (CSA)

Name: Development procurement and responsible management of new antimicrobials

Call: A competitive health-related industry (2021)

Budget: 2 Mio. €/Project; Total: 2 Mio.€/topic

Expected outcomes (all):

- 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 (all):

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.

- 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.

Call Identifier: HORIZON-HLTH-IND-2021-07-03

Type of Action: Coordination And Support Action (CSA)

Name: Promoting a trusted mHealth label in Europe: uptake of technical specifications for quality and reliability of health and wellness apps

Call: A competitive health-related industry (2021)

Budget: 2 Mio. €/Project; Total: 2 Mio.€/topic

Expected outcomes (all):

- European suppliers of health technology and services benefit from enhanced single market conditions for mHealth that facilitate economies of scale.
- Health care systems and authorities are able to integrate mHealth solutions more rapidly thanks to a European 'mHealth label'.
- Citizens, patients and health and care professionals make more use of trusted mHealth solutions for promoting their health and self-managing their health care needs.
- European mHealth stakeholders can build upon a digital ecosystem around a trusted mHealth label.
- Health systems and citizens benefit from the supply and use of health innovations facilitated by the promotion of common pan-European principles for validation and certification.

Scope (all):

- Set up a structured dialogue on the uptake of the technical specifications among all stakeholders.
- Co-create, develop and implement an action plan on the promotion of the mHealth label in the health and care system.
- Implement concrete actions on the integration and use of secure and qualitative health and wellness apps, using the new label, in specific health and care settings, covering the entire EU.
- Ensure that the promoted health and wellness apps are bias-free and adequately address the needs of different social groups, considering gender, age, ability and ethnicity, where relevant.
- Support and set-up an inclusive dissemination strategy to promote the use of the health app quality label taking into account the different levels of digital health literacy among the actors involved .

Call - A competitive health-related industry (2022)

Opening: Oct 2021

Deadline: Apr 2022

HORIZON-HLTH-2022-IND-13-01: Enhancing Cybersecurity of connected Medical Devices (RIA).


HORIZON-HLTH-2022-IND-13-02: Scaling up multi-party computation, data anonymization techniques and synthetic data generation (RIA).

HORIZON-HLTH-2022-IND-13-03: New payment models for cost-effective and affordable health innovations/new models of pricing (RIA).

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

HORIZON-HLTH-2022-IND-13-05: Setting up a European Electronic Health Record Exchange Format Ecosystem (CSA).

 **Call Identifier: HORIZON-HLTH-2022-IND-13-01**

 **Name: Enhancing cybersecurity of connected medical devices**



Type of Action: Research and Innovation Action



Call: A competitive health-related industry (2022)



Budget: ≈ 6 Mio. €/Project; Total: 20 Mio.€/topic

Expected outcomes: (some)

- Stakeholders (e.g. manufacturers, suppliers, health care providers, integrators, operators) apply measures to identify and address cybersecurity risks and gaps in connected medical devices.
- Stakeholders adopt and use newly developed risk benefit analysis schemes and capabilities for cybersecurity of connected medical devices.
- Stakeholders adopt and use newly developed methodologies and toolboxes for ensuring cybersecurity of connected medical devices by design.
- Stakeholders adopt and use fit for purpose guidance covering challenges posed by connected medical devices, including software.

Scope: (some or all)

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

 **Call Identifier:** HORIZON-HLTH-2022-IND-13-02

 **Name:** Scaling up multi-party computation, data anonymisation techniques, and synthetic data generation



Type of Action: Research and Innovation Action



Call: A competitive health-related industry (2022)



Budget: ≈ 7 Mio. €/Project; Total: 30 Mio.€/topic

Expected outcomes: (all)

- The EU contributes strongly to global standards for health data through enhancement of common European standards for health data (including medical imaging data) by researchers and innovators.
- Innovators have access to advanced secure data processing tools to test and develop robust data-driven digital solutions and services in response to the needs of researchers, clinicians and health systems at large.
- Cross-border health data hubs further facilitate the innovation process by providing secure, trustable testing environments for innovators.
- Clinicians, patients and individuals use a larger variety of high quality data tools and services for wellbeing, prevention, diagnosis, treatment and follow-up of care.
- Researchers and innovators have more opportunities for testing and developing GDPR compliant data driven solutions based on actual needs of the health care environments.

Scope: (all)

- Consolidate and scale up multi-party computation and data anonymisation techniques and synthetic data generation.
- Support the development of innovative unbiased AI based and distributed tools, technologies and digital solutions.
- Advance the state-of-the-art of de-identification techniques, to tackle the challenge of anonymised datasets that can be traced back to individuals.
- Develop innovative anonymisation techniques demonstrating that effective data quality and usefulness can be preserved without compromising privacy.
- Explore and develop further the techniques of creating synthetic data, also on demand for specific use cases.
- Widen the basis for GDPR-compliant research and innovation on health data.
- Ensure wide uptake and scalability of the methodologies and tools developed.

 **Call Identifier: HORIZON-HLTH-2022-IND-13-03**



Type of Action: Research and Innovation Action

 **Name: New pricing and payment models for cost-effective and affordable health innovations**



Call: A competitive health-related industry (2022)



Budget: ≈ 5 Mio. €/Project; Total: 15 Mio.€/topic

Expected outcomes: (all)

- Health authorities and insurers adopt new payment models for health technologies, including pharmaceuticals.
- Health industries anticipate better the marketing conditions for innovative health technologies. Patients and health care providers have faster access to innovative health technologies.
- Health authorities, insurers and health care providers have affordable innovative health technologies both on short and longer terms.

Scope: (all)

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

 Call Identifier: **HORIZON-HLTH-2022-IND-13-04**



Type of Action: Coordination and Support Action (CSA)

 **Name:** **Setting up a European Smart Health Innovation Hub**



Call: A competitive health-related industry (2022)



Budget: ≈2 Mio. €/Project; Total: 2 Mio.€/topic

Expected outcomes (all):

1. Empowered patients and citizens of all ages, gender, social and economic background adopt and use digital tools to monitor their health status independently.
2. A strong European ecosystem is created by innovators in the health domain involving end-users.
3. Public and private entities adopt the innovations of European digital health companies, especially SMEs and mid-caps, enhancing their sustainability and resilience.
4. Citizens, patients, health practitioners and facilities, public and private actors access and make use of sustainable EU-wide reference repository of digitally-enabled innovative solutions.

Scope (several):

- Promote transfer and exchange of knowledge and best practices (such as twinings) between different actors working on innovation of digital health solutions, including training to end-users.
- Promote scalability of digital innovation solutions by organising market places and pitching events to public health organisations and private entities and by involving industry and Member States.
- Integrating existing repositories into a sustainable European repository, serving as a reference.
- Reinforce the European Digital Health ecosystem by enhancing collaboration and networking between the different actors working on digital health innovation across Europe.
- The Digital Health solutions that would be part of the European Smart Health Innovation Hub should match the needs of all citizens and patients.

 Call Identifier: **HORIZON-HLTH-2022-IND-13-05**



Type of Action: **CSA**

 Name: **Setting up a European Electronic Health Record Exchange Format (EEHRxF) Ecosystem**



Call: A competitive health-related industry (2022)



Budget: ≈ 2 Mio. €/Project; Total: 2 Mio.€/topic

Expected outcomes: (all)

- Individuals, researchers, health services and the workforce across borders in the EU Digital Single Market use significantly improved and interoperable cross-border digital health.
- Individuals have an improved level of accessibility, control and portability of health data, including donation for research across Europe and jurisdictions.
- Policy makers and members of the eHealth Network are better informed and advised regarding potential evolutions of the EEHRxF and its extension to other uses cases.
- Different target populations such as designers, developers, health care professionals, and individuals have access to exploitation and capacity building support.

Scope: (all)

- Establishing and sustaining a scalable public infrastructure for digital health innovation based on the EEHRxF principles and the functional and technical specifications of its information domains (i.e. medical imaging, discharge letters, laboratory results, etc.).
- Demonstrating feasibility of real-life interoperable digital solutions for use by individuals, researchers, health services and the workforce across borders in the EU Digital Single Market by leveraging the above EEHRxF-based infrastructure.
- Establishing and sustaining a Pan-European ecosystem of digital health stakeholders by promoting and ensuring adoption of the EEHRxF-based infrastructure, involving both supply and demand sides, reinforcing collaboration and networking between the different actors working on digital health innovation across Europe around that infrastructure.
- Creating and validating a framework for enabling further exploitation of the public infrastructure for digital health innovation, including its terms of reference, governance and operations rules and procedures, as well as support for capacity building.

¡Muchas gracias por su atención!



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