HORIZON EUROPE (2021-2027)
EU Research & Innovation Programme

Investing to shape our future

"Εθνική ημερίδα ενημέρωσης για τον Ορίζοντα Ευρώπη:
Cluster 1 Health & Cancer Mission“

17 February 2023

Christina Kyriakopoulou, PhD
Senior Policy officer, Health Research Programmes
Unit ‘Health Innovations & Ecosystems’
Directorate General for Research & Innovation
European Commission

European Commission

Structure of the presentation (1)

- The aims of Horizon Europe
- The structure of Horizon Europe
- Strategic Plan
- The Health Cluster
- The pathway to impact
- The Health cluster and its 6 Destinations

European Commission

Structure of the presentation (2)

- Funding Opportunities for Health research in 2023 & 2024
- Destination 1
- Destination 2
- Destination 3
- Destination 4
- Destination 5
- Destination 6
- Cross-cutting issues
- Clinical studies
- Social Sciences & Humanities (SSH)
- Gender aspects
- Who is eligible
- Key principles of the evaluation process
- Information sources and web-links

European Commission

Horizon Europe Budget: €95.5 billion (2021-2027)

The ambitious EU research and innovation framework programme

(including €5.4 billion from NGEU – Next Generation Europe – programme of EU for Recovery from COVID-19 crisis)

fuel EU's **scientific and technological excellence** and the strengthen the European Research Area (ERA)

Science & technology

tackle policy priorities, including **green and digital transitions** and Sustainable Development Goals

Society

boost Europe's **innovation uptake**, **competitiveness** and **jobs**

Economy

European Commission

The Commission ('college' of 27 Commissioners) **and its policy departments** (32 Directorates-General, 'DGs' or 'Commission services')

Political Guidelines 2019-2024

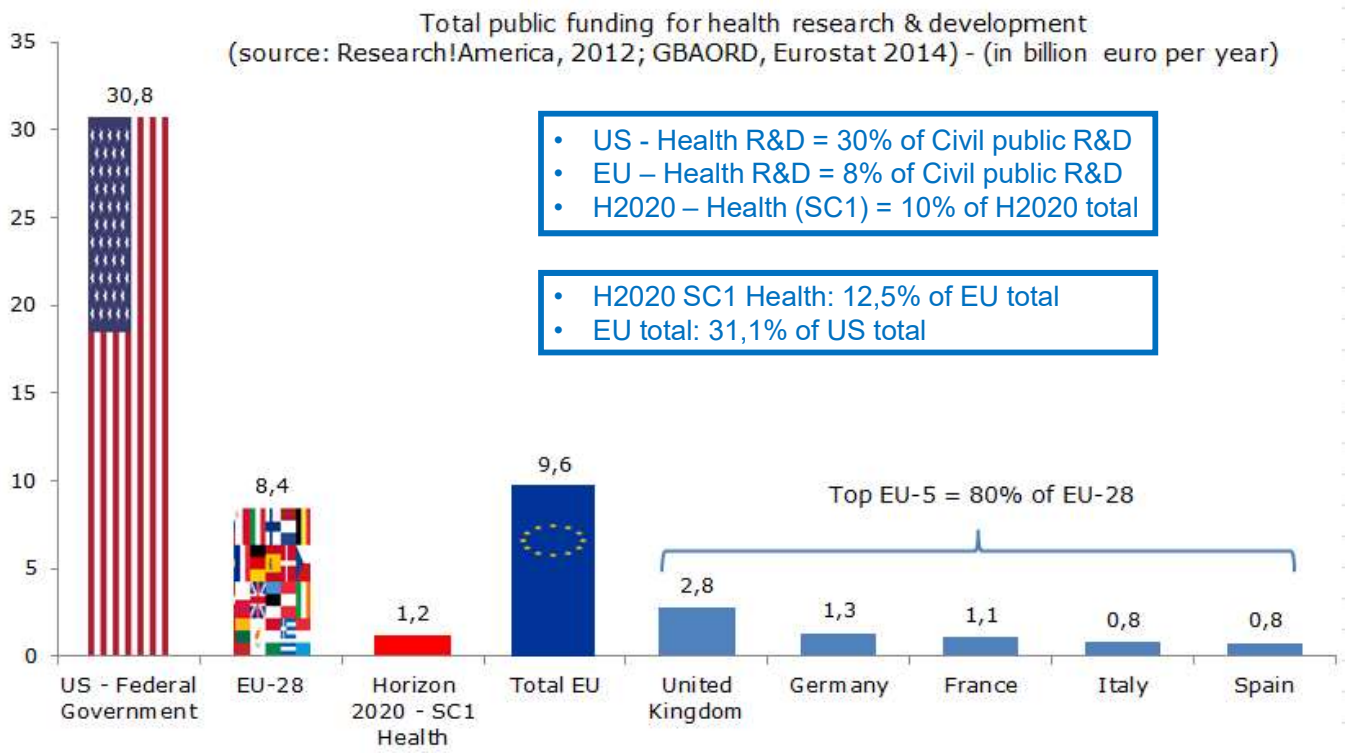
Ursula von der Leyen, Commission President-elect

- *A European **Green Deal***
- *A Europe for the **Digital Age***
- *An Economy that Works for **People***
- *Promote our **European Way of Life***
- *A Stronger **Europe in the World***
- *A New Push for **European Democracy***

DGs develop, implement and manage EU policy, law, and funding programmes (European agencies support and report to parent-DGs, incl. regulatory agencies like EMA, EFSA)

European Commission

Health R&D in Europe* and in US (NABS)



*Giorgio Clarotti, European Commission ©

Lessons Learned

from Horizon 2020 Interim Evaluation

Key Novelties

in Horizon Europe

Support breakthrough innovation	European Innovation Council
Create more impact through mission-orientation and citizens' involvement	EU Missions
Rationalise partnerships' landscape	New approach to partnerships
Reinforce openness	Open science policy
Strengthen international cooperation	Extended association possibilities
Encourage participation	Spreading Excellence

European Commission

HORIZON EUROPE

EURATOM

SPECIFIC PROGRAMME: EUROPEAN DEFENCE FUND

Exclusive focus on defence research & development

- Research actions
- Development actions

SPECIFIC PROGRAMME IMPLEMENTING HORIZON EUROPE & EIT*

Exclusive focus on civil applications

Pillar I
EXCELLENT SCIENCE

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

Pillar II - €53.5 billion
GLOBAL CHALLENGES & EUROPEAN INDUSTRIAL COMPETITIVENESS

Clusters

- **Health – €8.25 billion**
- Culture, Creativity & Inclusive Society
- Civil Security for Society
- Digital, Industry & Space
- Climate, Energy & Mobility
- Food, Bioeconomy, Natural Resources, Agriculture & Environment

Joint Research Centre

Pillar III
INNOVATIVE EUROPE

- European Innovation Council
- European Innovation Ecosystems
- European Institute of Innovation & Technology*

WIDENING PARTICIPATION AND STRENGTHENING THE EUROPEAN RESEARCH AREA

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

EURATOM

- Fusion
- Fission
- Joint Research Center (JRC)

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

European Commission

CLUSTER 1: Health

Sustainable Development Goals

European Commission

Pillar II

Budget for clusters & for JRC

in current prices

Cluster 1	**Health**	**€8.246 billion** (including €1.35 billion from NGEU)
Cluster 2	**Culture, Creativity & Inclusive Societies**	**€2.280 billion**
Cluster 3	**Civil Security for Society**	**€1.596 billion**
Cluster 4	**Digital, Industry & Space**	**€15.349 billion** (including €1.35 billion from NGEU)
Cluster 5	**Climate, Energy & Mobility**	**€15.123 billion** (including €1.35 billion from NGEU)
Cluster 6	**Food, Bioeconomy, Natural Resources, Agriculture & Environment**	**€8.952 billion**
	JRC (non-nuclear direct actions)	**€1.970 billion**

Clusters are including a budget for Partnerships and Missions
NGEU is Next Generation EU programme – Recovery Fund

European Commission

HORIZON EUROPE

Strategic Planning and programming

European Commission


2021
2022
2023
2024
2025
2026
2027
European Policy for Research & Innovation
Horizon Europe (2021-2027)
Strategic Planning (2021-2024)
Strategic Planning (2025-2027)?
Work Programme 2021-2022
Work Programme 2023-2024
Work Programme 2025-2027
European Commission

Strategic plan gives direction to the work programme

Main Features

Early involvement and extensive exchanges with Member States
Extensive exchanges with the European Parliament
Consultations with stakeholders and public at large

European Commission

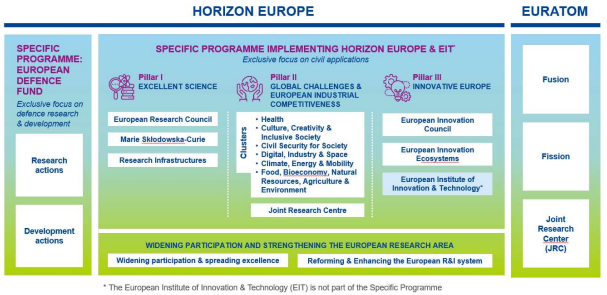
Horizon Europe – impact-oriented funding

2021-2027

Horizon Europe Legislation
EU legal base

Pillars Clusters Budget

Intervention Areas



2021-2024

Strategic Plan
Programme-level
(focus on Pillar II)

EU policy priorities

Key Strategic Orientations for R&I

Expected Impacts
in the cluster-specific annexes

2023-2024

Work Programmes
e.g. for Clusters 1-6

Destinations

Topics

Expected outcomes

European Commission

HORIZON EUROPE

Pillar II, Cluster 1 ‘Health’

Only the workprogramme text has legal value; the oral presentation is only advisory.

Disclaimer: information not legally binding

European Commission

Horizon Europe – Cluster 1 - Health

Aims:

- to contribute to the promotion of social cohesion and inclusiveness and the health and well-being of people.
- to help develop "*an economy that works for people*" by supporting research (and coordination) in order *to make innovative, high-quality health technologies and health care both available and affordable for citizens*;
- and *to make health care systems more accessible and sustainable*, including through the digital transformation of health and care.

Horizon Europe – Cluster 1 ‚Health‘

Strategic Plan 2021-24 (link) → **6 Expected Impacts**

↳ **Work Programme 2021-22** (link)

6 “Destinations” → Topics (Calls)

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

Focus on outcomes contributing to the impacts specified per Destination

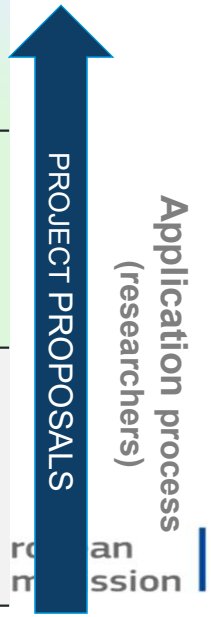
Project proposals should

- make a **clear case** (*value proposition*)
- supported by a **convincing trajectory** (*pathway to impact*) for the project proposal to deliver the **output**, promote the **outcome** described in the topic, and contribute to the **impact** expected under that destination.

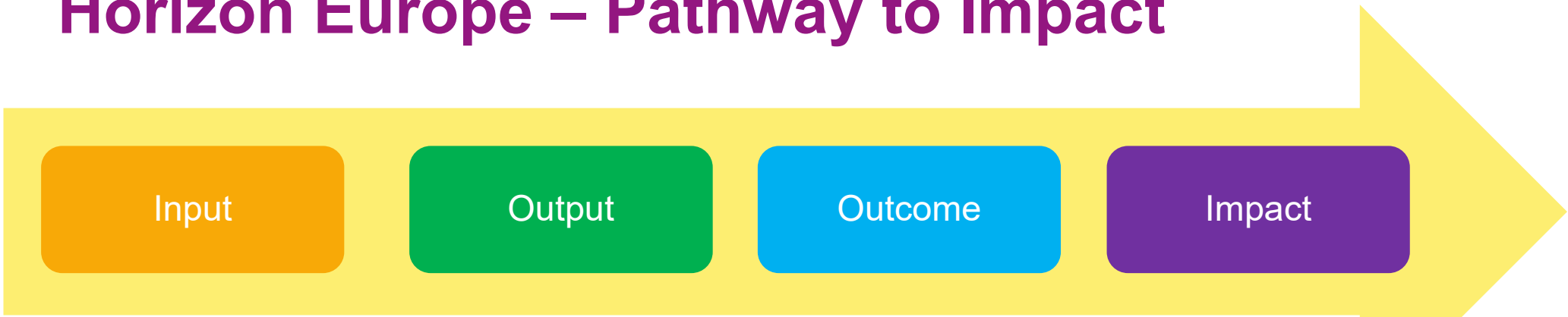
European Commission

Link between policy priorities and project results

EU POLICY PRIORITIES	Overall priorities of the European Union (Green Deal, Fit for the Digital Age,…)
KEY STRATEGIC ORIENTATIONS	Set of strategic objectives within the EC policy priorities where R&I investments are expected to make a difference
IMPACT AREAS	Group of expected impacts highlighting the most important transformation to be fostered through R&I
EXPECTED IMPACTS = DESTINATIONS	Wider long term effects on society (including the environment), the economy and science, enabled by the outcomes of R&I investments (long term). It refers to the specific contribution of the project to the work programme expected impacts described in the destination. Impacts generally occur some time after the end of the project.
EXPECTED OUTCOMES = TOPICS	The expected effects, over the medium term, of projects supported under a given topic. The results of a project should contribute to these outcomes, fostered in particular by the dissemination and exploitation measures. This may include the uptake, diffusion, deployment, and/or use of the project's results by direct target groups. Outcomes generally occur during or shortly after the end of the project.
PROJECT RESULTS	What is generated during the project implementation. This may include, for example, know-how, innovative solutions, algorithms, proof of feasibility, new business models, policy recommendations, guidelines, prototypes, demonstrators, databases and datasets, trained researchers, new infrastructures, networks, etc. Most project results (inventions, scientific works, etc.) are 'Intellectual Property', which may, if appropriate, be protected by formal 'Intellectual Property Rights'



Horizon Europe – Pathway to Impact



Resources
e.g. Human, Financial, Expertise, Know-how, Infrastructures, Networks

Results of R&I
e.g. Knowledge, Advice, Processes, Procedures, Technologies, Data, Methodologies, Standards

Immediate use or uptake of R&I results
e.g. result of **'Productive Interactions'** between 'producers' and 'users' of R&I
- short- to medium-term

Wider benefits for "society"
e.g. social, economic and environmental impact
- 5 Ps of SDGs: people, planet, prosperity, peace, partnerships
- medium- to long-term

Topics calling for R&I actions (RIA, CSA, partnership)

Expected Outcomes leading to impact per Destination (set by WP23-24)

Expected Impacts per Cluster (set by SP21-24)

European Commission

Horizon Europe – funding modalities

- *Grants to individual researchers/fellows, teams, infrastructures, innovators*
  under Pillar 1 (ERC, MSCA) and Pillar 3 (EIC)
  → bottom-up open competition
- ***Grants to collaborative R&I projects*** *(Pillar 2, incl. Cluster 1 'Health')*
  → top-down open competition by multi/international consortia proposing projects on specific topics in response to calls for proposals
- ***Grants to contracting authorities/entities*** *(Pillar 2, incl. Cluster 1 'Health')*
  → *for pre-commercial procurement of R&I services and procurement of innovative solutions*
- *Partnerships between R&I investors and funders (Pillar 2 and Pillar 3, incl. Cluster 1 'Health')*
- *Missions driven by inspirational goals for impact (Pillar 2, incl. mission on cancer)*
- *Synergies with EU4Health, Digital Europe Programme, InvestEU, other*

Horizon Europe – Cluster 1 ‚Health‘

Timelines for 2023 calls (WP 23-24, Topics/Calls in 23)

- *Launch of 2023 single-stage calls for proposals* — *12 Dec 2022*
- *Closing of calls (deadline)* — *13 Apr 2023*
- *Evaluation and selection*

  information on the outcome of the evaluation, around 5 months from the deadline

  indicative date for the signing of grant agreements: around 8 months from the deadline

European Commission

Horizon Europe – Cluster 1 ‚Health'

Timelines for 2024 calls (WP 23-24)

- *Launch of 2024 two-stage calls for proposals* — *12 December 2023*
- *Opening of calls* — *30 March 2023*
- *Closing of the calls (1st stage deadline)* — *19 September 2023*
- *Closing of the calls (2nd stage deadline)* — *11 April 2024*

information on the outcome of the evaluation, around 5 months from the deadline

indicative date for the signing of grant agreements: around 8 months from the deadline

European Commission

HORIZON EUROPE

Destination 1: Staying healthy in a rapidly changing society

Only the workprogramme text has legal value; the oral presentation is only advisory.

Disclaimer: information not legally binding

European Commission

Destination 1: Staying healthy in a rapidly changing society

Citizens of all ages stay healthy and independent in a rapidly changing society thanks to healthier lifestyles and behaviours, healthier diets, healthier environments, improved evidence-based health policies, and more effective solutions for health promotion and disease prevention.

- **Key Strategic Orientation**: 'Creating a more resilient, inclusive and democratic European society'

- **Impact areas**: (broad impact per destination)
  - Good health and high-quality accessible health care
  - High quality digital services for all
  - Sustainable food systems from farm to fork on land and sea
  - Climate change mitigation and adaptation

European Commission

Destination 1: 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.
- **Children and adolescents are empowered to better monitor and manage their physical, social and mental health with a view to lifelong healthy lifestyles**
- **Citizens´ trust in knowledge-based health interventions and in guidance from health authorities is strengthened**, including through improved health literacy, resulting in increased engagement in and adherence to effective strategies for health promotion, diseases prevention and treatment.
- **Health policies** and actions for **health promotion** and **disease prevention** are knowledge-based, **people-centred**, **personalised** and thus targeted and tailored to citizens' needs, and designed to **reduce health inequalities**.

European Commission

Destination 1: Staying healthy in a rapidly changing society

- In WP23-24, R&I will focus on major societal challenges: on holistic and integrated approaches to disease prevention and health promotion, notably healthy ageing, on a life course approach to physical and mental health starting in early childhood and on personalised approaches to prevention of diseases.

- R&I should provide new tools, digitally enabled solutions and evidence-based health and care services to prevent and delay progression of age-related diseases.

  R&I should provide tailor made strategies and solutions to support children and adolescents adopting and maintaining person-centred healthy lifestyles.

  call for proposals specifically aiming to develop integrated and holistic personalised disease prevention strategies, making use of multiple data sources, including real-world health data.

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

Destination 1: Topic in WP 2023

- HORIZON-HLTH-2023-STAYHLTH-01-01: **The Silver Deal - Person-centred health and care in European regions**

- Closure**: 13.04.2023**
- Instrument: RIA
- Total: €40M
- Project size: €15-20M

European Commission

The Silver Deal - Person-centred health and care in European regions

This topic aims to implement strategies and actions in line with the:

- Communication on enabling the Digital Transformation of Health and Care
- Green Paper on Ageing
- the EU Long-term care report
- the 'Healthier Together' – EU Non-Communicable Diseases Initiative'
- the EU Care Strategy
- the Council Recommendation on affordable high-quality long-term care

striving to address demographic change and enable better health and care for Europe's growing ageing societies, as well as to harness the potential of the Silver Economy.

European Commission

The Silver Deal - Person-centred health and care in European regions

Expected outcome (contributing to **all of the following** elements)

- **Citizens and patients will get effective, preventive, integrated, coordinated, evidence-based and people-centred high-quality health and care services** to identify and tackle or prevent multi-morbidities, frailty, biologically or mentally reduced capacities, (sensory) impairments, dementia and/or neurodegeneration, fostering mental and physical health, wellbeing and quality of life.
- **Primary and community based health and care services will be better equipped** to early identify people at risk of developing non-communicable diseases (NCDs) and multi-morbidities.
- **Older people will be empowered to take an active role in the management of their own physical and mental health**, as well as increase their social interactions and wellbeing.
- **Citizens, all relevant stakeholders, public authorities, cities and rural environments, as well as health care providers will be engaged** to ensure the introduction to and the integration of age-friendly, mental and physical health promoting innovative care pathways and digitally enabled solutions into the daily life and wellbeing of the ageing population.

European Commission

The Silver Deal - Person-centred health and care in European regions

Scope (address **all of the following** elements)

- **Consolidate high-quality effective, integrated, innovative and digitally enabled person-centred health and long-term care services and solutions**, both in primary care, hospital and home settings, around older people's needs for physical and mental health, care and wellbeing, strengthened disease prevention, rehabilitation and for staying active and healthy as they age.
- Such integrated and holistic solutions could include, but are not limited to, **integrated care solutions,** serious games, connected wearables, ambient sensors, social robots, assistive technologies, age-friendly environments, diagnostic screenings, self-monitoring devices, robotics and others, tackling age-related physical and mental diseases and co-morbidities
- Develop and **provide** evidenced-based new approaches, **coordinated care models and pathways, for delivering effective, person-centred health and long-term care solutions.**
- **Support adoption and market innovation of novel health and care solutions**, for older age related health conditions, through large-scale testing and deployment piloting, guidance on relevant HTA and CE procedures, demonstrating cost-effectiveness, as well as through stakeholder involvement and policy collaboration on European, local, regional, and international level.

Destination 1: Topics in WP 2024* (forthcoming)

- HORIZON-HLTH-2024-STAYHLTH-01-02-two-stage:**Towards a holistic support to children and adolescents' health and care provisions in an increasingly digital society**
- **Closure:** 19.09.2023 (1st stage) and 11.04.2024 (2nd stage)
- Instrument: RIA
- Total: €30M
- Project size: €8-10M

- HORIZON-HLTH-2024-STAYHLTH-01-05-two-stage: **Personalised prevention of non communicable diseases - addressing areas of unmet needs using multiple data sources**
- **Closure:** 19.09.2023 (1st stage) and
- 11.04.2024 (2nd stage)
- Instrument: RIA
- Total: €50M
- Project size: €8-12M

*** Not yet open for applications**

European Commission

HORIZON EUROPE

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

Only the work programme text has legal value; the oral presentation is only advisory.

Disclaimer: information not legally binding

European Commission

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

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

- Destination 2 → filling knowledge gaps in the understanding of the impacts on our health and well-being of those environmental, occupational and socio-economic risk factors that have the most significant or widespread societal impacts.

- Results will support the EU's environment and health policies and overarching policy frameworks such as the European Green Deal, the Chemical Strategy for Sustainability, the Zero Pollution Action Plan, the Climate Adaptation strategy, the EU Strategic Framework on Health and Safety at Work and the WHO European Environment and Health Process (EHP).

- International collaboration is welcomed, collaboration between projects under the same call is requested!

European Commission

Destination 2: Expected impacts

- **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;
- The upstream **determinants of disease are known**, **understood** and **reduced**;
- The **health threats and burden** resulting from hazardous chemicals and air, water and soil pollution and contamination is **substantially reduced**;
- **Living and working environments** in European cities and regions are **healthier**, more **inclusive, safer, resilient and sustainable**;
- The **adaptive capacity and resilience** of populations and health systems in the EU to climate and environmental change-related health risks is **strengthened**;
- **Citizens' health and well-being is protected and promoted**, and premature deaths, diseases and inequalities related to environmental pollution and degradation are prevented;
- Environmental, occupational, social, economic, fiscal and health **policies and practices** at the EU, national and regional level are **sustainable** and **based on solid scientific evidence**;

Destination 2: Topics in WP 2023

HORIZON-HLTH-2023ENVHLTH-02-01: **Planetary health: understanding the links between environmental degradation and health impacts**
Closure: 13.04.2023
Instrument: RIA
Total: €30M
Project size: €5-6M

HORIZON-HLTH-2023-ENVHLTH-02-02:**Evidence-based interventions for promotion of mental and physical health in changing working environments (post-pandemic workplaces)**

Closure: 13.04.2023
Instrument: RIA
Total: €30M
Project size: €5-6M

HORIZON-HLTH-2023-ENVHLTH-02-03: **Health impacts of endocrine-disrupting chemicals: bridging science-policy gaps by addressing persistent scientific uncertainties**

Closure: 13.04.2023
Instrument: RIA
Total: €40M
Project size: €6-7M

HORIZON-HLTH-2023-ENVHLTH-02-04: **Global coordination of exposome research**

Closure: 13.04.2023
Instrument: CSA
Total: €3M
Project size: €3M

European Commission

Planetary health: understanding the links between environmental degradation and health impacts

Expected outcome

- **Climate and environmental policies** are supported with **better knowledge** on the **Earth natural systems** and **human health interactions**;
- **Sustainable planetary health policies** which foster co-benefits to human health and the health of ecosystems are supported with **robust evidence**;
- **Cross sectorial** and **multidisciplinary scientific collaborations**, including expertise in **public health and One Health**, are established;
- **Public authorities** rely on **indicators** about the **impacts on human health** of **changes** or **degradation of natural systems** to support adaptation and mitigation strategies to natural hazards;
- **Policymakers** have **better tools** to improve the predictive capability and **preparedness** as well as to envision **prevention** strategies to deal with the impacts on human health of changes or degradation of ecosystems;
- **Citizens** are **engaged** and **informed** about the impact of natural systems' degradation on human health and **behaviours** aiming at the conservation of ecosystems are **promoted**.

European Commission

Planetary health: understanding the links between environmental degradation and health impacts

Scope (address several of the following elements)

- Providing evidence for **health and wellbeing impacts of planetary changes**, considering a systems thinking framework or a fragmentary approach (impacts of climate change and biodiversity loss on human health);
- Improving the understanding of **human–ecological systems interactions** and **ecosystem-mediated effects on human health and well-being**;
- Providing methodological approaches to **identify and prioritise threats for public health** caused by **environmental degradation**;
- Investigating how **infections agents** can **spread** via the **environment**, enhancing **monitoring strategies**;
- Lay the foundations for **integrated surveillance systems** considering established monitoring systems and using available and newly collected data;
- Explore **implications of planetary health** for **health systems** and **public health**;
- Advance knowledge and actions to **reduce the burden of non-communicable diseases** while **reducing the environmental pressure** in areas like **nutrition, physical activity, and mobility**;
- **Improved health impact assessment approaches** accounting for environmental externalities and estimating the cost and benefits of interventions versus no action.

Evidence-based interventions for promotion of mental and physical health in changing working environments (post-pandemic workplaces)

Expected outcome

- **Public authorities and regulators** are supported with **evidence-based guidance** to design occupational health policies;
- **Public authorities, employers, organisations and social partners** are better supported with **tools, evidence-based intervention options and guidelines** to promote mental and physical well-being and health in the workplace;
- **Public authorities and the scientific community** have access to **FAIR data and robust evidence** on direct links between **psychosocial and physical risk factors** at the workplace and specific **health outcomes**;
- **Public authorities, regulators and social partners** are informed by evidence on the **costs, benefits, sustainability** and expected **challenges** of available **solutions**;
- **Public authorities and employers** take advantage of the **best available knowledge** to **support interventions** and **solutions** on the design of the **built working environment**;
- **Public authorities and employers** develop adequate measures to **prevent and reduce** the **negative outcomes** of exposure to **psycho-social and physical risk factors** in the workplace and support recovery;
- **Workers** are more **protected** against **work-related hazards** and **informed** about effective **prevention approaches** based on specific and appropriate measures and health enhancing behaviours;
- **Workers** living with a chronic disease and/or recovering from a mental of physical health problem are **supported to continue/return to work**.

Evidence-based interventions for promotion of mental and physical health in changing working environments (post-pandemic workplaces)

Scope (address several of the following elements)

- Provide **adequate and robust data on the impact** that the **ongoing changes in the workplace** are having on the **mental and physical health** of different categories of workers and working sectors;
- Generate **evidence** on **mental health** and on **mental well-being** at the **workplace** and how changing work organisation due to the twin transitions and the pandemic affects workers' work-life balance and work ability;
- Generate **evidence** on the importance of **risk factors** in the development of **chronic and acute diseases**;
- Increase the **understanding** of the **links** between different **health-promoting factors** in the working-built environment and **physical and mental health outcomes**, and how these may be mutually reinforcing;
- Explore the **health impacts of changing working times**, including excessive and atypical working hours and work in different time zones that blur work from leisure time, limiting recovery;
- Provide **recommendations** for effective **interventions** to **prevent occupational risks** and **support** the **mental and physical health and well-being** at individual, organisation and policy levels, including an analysis on their cost-effectiveness, sustainability and barriers to implementation at national and/or EU level;
- Advance the development of a **scientific framework** addressing **occupational safety and health (OSH)** across policies and sectors and support new and sustainable (future-proof) tools, guidelines and policies concerning the evaluation and design of physical and psychosocial work environment;
- Provide **tools and approaches** to **anticipate new OSH risks**;

Health impacts of endocrine-disrupting chemicals: bridging science-policy gaps by addressing persistent scientific uncertainties

Expected outcome

- **Public authorities and regulators** are supported with **evidence** to implement the **EU Framework on Endocrine Disruptors** as well as the **Chemicals Strategy for Sustainability** and EU legislation on plant protection products;
- **Public authorities** improve risk assessment, management and communication via access to FAIR data and more robust evidence on causal links between EDC exposure and health outcomes;
- The **research community** has access to better data on the role of EDCs and other factors to better understand their **individual** or **combined** health impacts;
- **Public authorities and the scientific community** capitalise on the latest methodologies to advance the understanding of the health impacts of EDC exposures;
- **Public authorities, employers and citizens** rely on practical evidence-informed guidelines for exposure prevention and reduction;
- **Citizens** are **engaged** and **informed** about the health impact of exposures to EDCs and risk-preventing behaviours are promoted.

European Commission

Health impacts of endocrine-disrupting chemicals: bridging science-policy gaps by addressing persistent scientific uncertainties

Scope (address several of the following elements)

- Studying the **impact of EDCs** on **target organs**, in **multi-organ models**, on **physiological barriers** and on **interactions with microbiota**;
- Elucidating **health endpoints for which insufficient data exists**, like disturbances in the development and functioning of the nervous and CV systems, immune system, fertility, etc.;
- Providing **better biological and imaging biomarkers** to predict EDC-mediated health outcomes;
- Gaining better insights into the **developmental origins of health and disease**, and assessing the occurrence and relevance of **multi- and transgenerationally inherited effects**;
- Gaining better insights into the **most sensitive windows of susceptibility**, during which exposure is of particular importance for health effects;
- Gaining a better understanding of the effects of chemicals and mixtures on **underlying mechanistic crosstalk** between **endocrine axes**, **endocrine pathways and other key biological systems**;
- Improving the **understanding of chemical mixture effects**, including with other toxins and at low doses;
- Investigating **biological effects of realistic mixtures** for a more detailed understanding of the **endocrine effectome**;
- Exploiting **non-mammalians as test organisms** to predict effects or raise concern on potential effects in humans;
- Exploiting **systems biology** to understand **how exposure to an EDC results in an altered phenotype.**

Global coordination of exposome research

Expected outcome

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

Global coordination of exposome research

Scope (address most of the following elements)

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

European Commission

Destination 2: Topics in WP 2024* (forthcoming)

- HORIZON-HLTH-2024-ENVHLTH-02-06-two-stage: **The role of environmental pollution in non-communicable diseases: air, noise and light and hazardous waste pollution**

- Closure: 19.09.2023 (1st stage) and 11.04.2024 (2nd stage)
- Instrument: RIA
- Total: €60M
- Project size: €7-8M

*** Not yet open for applications**

European Commission

HORIZON EUROPE

Destination 3: Tackling diseases and reducing disease burden

Only the work programme text has legal value; the oral presentation is only advisory.

Disclaimer: information not legally binding

European Commission

Destination 3: Tackling diseases and reducing disease burden

Communicable and non-communicable diseases cause the greatest amounts of premature death and disability in the EU and worldwide.

Destination 3 → addressing an urgent need for research and innovation to develop new prevention measures, public health interventions, diagnostics, vaccines, therapies, antimicrobials and their alternatives, as well as to improve existing prevention strategies to create tangible impacts, taking into account sex/gender-related issues.

- Key Strategic Orientation: 'Creating a more resilient, inclusive and democratic European society'

- Impact areas:
  - **Good health and high-quality accessible health care**
  - A resilient EU prepared for emerging threats
  - Climate change mitigation and adaptation
  - High quality digital services for *all*

European Commission

Destination 3: Expected impacts

- **Health burden of diseases in the EU and worldwide is reduced** through effective disease management, including through the development and integration of innovative diagnostic and therapeutic approaches, personalised medicine approaches, digital and other people-centred solutions for health care.
- **Premature mortality from NCDs 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, human capacities and know-how for combatting communicable and non-communicable diseases**, including through international cooperation.
- Citizens benefit from **reduced (cross-border) health threat of epidemics and AMR pathogens, in the EU and worldwide**. In particular, the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases are contained and hepatitis, water-borne diseases and other communicable diseases are being combated.
- Patients and citizens are **knowledgeable of disease threats, involved and empowered to make and shape decisions for their health, and better adhere to knowledge-based disease management strategies and policies** (especially for controlling outbreaks and emergencies).

Destination 3: Topics in 2023

- HORIZON-HLTH-2023-DISEASE-03-01: **Novel approaches for palliative and end-of-life care for non-cancer patients**
- Closure: **13.04.2023**
- Instrument: RIA
- Indicative budget: €50M
- Project size: €6-7M

- HORIZON-HLTH-2023-DISEASE-03-03: **Interventions in city environments to reduce risk of non-communicable disease (Global Alliance for Chronic Diseases - GACD**)
- Closure: **13.04.2023**
- Instrument: RIA
- Indicative budget: €20M
- Project size: €3-4M

- HORIZON-HLTH-2023-DISEASE-03-07: **Relationship between infections and non-communicable diseases**
- Closure: **13.04.2023**
- Instrument: RIA
- Indicative budget: €30M
- Project size: €6-7M

- HORIZON-HLTH-2023-DISEASE-03-06 : **Towards structuring brain health research in Europe**
- Closure: **13.04.2023**
- Instrument: CSA
- Indicative budget: €1M
- Project size: €1M

European Commission

Destination 3: Topics in 2023

- HORIZON-HLTH-2023-DISEASE-03-04: **Broad spectrum anti-viral therapeutics for infectious diseases with epidemic potential**
  Closure: **13.04.2023**
- Instrument: RIA
- Indicative budget: €50M
- Project size: €7-8M

- HORIZON-HLTH-2023-DISEASE-03-05: **Pandemic preparedness and response: Sustaining established coordination mechanisms for European adaptive platform trials and/or for cohort networks**
  Closure: **13.04.2023**
- Instrument: CSA
- Indicative budget: €3M
- Project size: €1-2M

- HORIZON-HLTH-2023-DISEASE-03-17: **Understanding vaccine induced-immunity**
- Closure: **13.04.2023**
- Instrument: RIA
- Indicative budget: €20M
- Project size: €7-8M

- HORIZON-HLTH-2023-DISEASE-03-18: **Immunogenicity of viral proteins of viruses with epidemic and pandemic potential**
- Closure: **13.04.2023**
- Instrument: RIA
- Indicative budget: €50M
- Project size: €7-8M

European Commission

HORIZON-HLTH-2023-DISEASE-03-01: Novel approaches for palliative and end-of-life care for non-cancer patients

Expected outcome:

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

European Commission

HORIZON-HLTH-2023-DISEASE-03-01: Novel approaches for palliative and end-of-life care for non-cancer patients

Scope:

- … **the effectiveness and cost-effectiveness** of **pharmacological and/or non-pharmacological interventions** to improve well-being and quality of life of patients.
- **Randomised clinical trials and observational studies**, targeting different age groups, should be considered
- **The legal and ethical aspects** … should be considered and fully addressed.
- Prove **the feasibility** of integrating the proposed interventions in current **pain management, palliative and/or end-of-life care regimes and healthcare systems across Europe.**
- **The views and values of patients and their caregivers** should also be appropriately taken into account **in patient-centred care decisions.**
- Identify and analyse **relationships between sex, gender, age, disabilities, socio-economic factors in health and any other relevant factors** (e.g. ethical, familial, etc.).
- Analyse the barriers and opportunities to re-invigorating and enhancing **timely social inclusion and active engagement of patients in need of palliative and end-of-life care and their caregivers.**
- **… strategies and guidelines of patient-centred communication** for health and social care professionals as well as **standards for evidenced based communication trainings** for caregivers.
- Effective contribution of **social sciences and humanities disciplines** is required.

Research on cancer excluded - covered through WP 21-22

European Commission

HORIZON-HLTH-2023-DISEASE-03-03: Interventions in city environments to reduce risk of non-communicable disease (Global Alliance for Chronic Diseases - GACD)

Expected outcome:

- Health care practitioners and providers in LMICs and/or in HICs serving vulnerable populations have access to and use **specific guidelines to implement health interventions that decrease risk factors of non-communicable diseases (NCDs)** associated with city environments.
- Public health managers and authorities have access to improved insights and evidence on the **NCDs caused or impacted by city environments** and which factors influence the **implementation of preventive actions that address risk behaviours** in concerned city populations.
- Adopting an implementation science approach to studying interventions in different city contexts, researchers, clinicians and authorities have an improved understanding how **specific interventions can be better adapted to different city environments** and how the **interventions could be scaled within and across cities.**
- Public health managers and authorities use **evidence-based strategies and tools for promoting population health** in equitable and environmentally sustainable ways, enabling cities to better address the challenges of rapid urbanisation, growing social inequalities, and climate change.
- Communities, local stakeholders and authorities are fully engaged in implementing and taking up **individual and/or structural level interventions and thus contribute to deliver better health.**

HORIZON-HLTH-2023-DISEASE-03-03: Interventions in city environments to reduce risk of non-communicable disease (Global Alliance for Chronic Diseases - GACD)

Scope (1)

- … **implementation research** with the potential to **reduce the risks of NCDs in cities in LMICs and/or vulnerable populations in HICs**.
- Select **one or more city/ies** in which the research will be conducted.
- Select **one or more evidence-based interventions** known to reduce NCD risk factor(s) associated with city environments.
- **Adapt these intervention(s)** for selected **study population(s) based in one or more city/ies**, taking into account the unique **social, political, economic, and cultural context(s)**.
- Provide a **research plan** for investigating how to promote the **uptake and/or scale-up of the intervention(s) in the selected study population(s),** using validated implementation research frameworks.
- Have an appropriate **strategy for measuring both implementation research outcomes and real-world effectiveness outcomes and indicators** (related to NCD prevention and, if feasible, planetary health and/or non-health sectors).
- Demonstrate a **commitment to stakeholder engagement** … and … **to planetary health …**
- Provide a **sustainability plan or describe a pathway to sustain the proposed intervention**.

HORIZON-HLTH-2023-DISEASE-03-03: Interventions in city environments to reduce risk of non-communicable disease (Global Alliance for Chronic Diseases - GACD)

Scope (2)

- … should be **gender-responsive and consider socioeconomic, racial or other factors** …
- Effective contribution of **social sciences and humanities disciplines** is required.

Importantly, the proposed interventions of focus may fall under one or both of the following themes:

Theme 1 interventions: **Behavioural change interventions** comprised of innovative approaches to help people living in cities maintain good physical and mental health despite infrastructural, environmental, climate, and social challenges (e.g., programmes and policies that target alcohol and tobacco use, exercise promotion, etc.)

Theme 2 interventions: **Interventions that focus on modifying the built environment** to improve its health-promoting potential. Proposals should aim to inform urban design such that it reduces NCD risks (e.g., by improving a city's walk- or bike-ability, increasing green space to reduce the health impacts of air pollution or extreme heat, reducing environmental toxins, etc).

***Please note** that proposals are intended for research that helps guide the implementation and/or scale up of the proposed intervention. Therefore, the execution of infrastructural interventions (e.g., constructing bike lanes or housing, etc.) is not in the scope of this topic.*

MLJ(1 Greg -

MOLTO LOPEZ Julia (RTD); 19-12-22

HORIZON-HLTH-2023-DISEASE-03-07: Relationship between infections and non-communicable diseases

Expected outcome:

- All players along the health care value chain are provided with new knowledge for **a better understanding of the links (e.g. causalities) between infectious diseases (IDs) and NCDs and comorbidities,** including knowledge on host risk factors that impact the development of disease progression for NCDs and/or IDs.
- Researchers and clinicians are provided with a robust evidence base that will contribute to the development of **new or improved tools to diagnose and prevent the development and aggravation of NCDs** as well as **early treatment and management of patients suffering from co-morbidities following an ID.**
- Healthcare practitioners have access to knowledge to guide them **on preventive measures, on early identification of diseases onset and of those patients at risk of developing severe disease progression, and on the optimal treatment of patients.**

European Commission

HORIZON-HLTH-2023-DISEASE-03-07: Relationship between infections and non-communicable diseases

Scope:

- … elucidate and provide **a better understanding of causative links between infections and NCD onsets, and/or the impact of infections on the exacerbation of existing NCDs or vice versa,** in children and/or adults.
- **… analysis of genetics, immune status, immune or inflammatory responses, microbiome, lifestyle and/or other relevant** factors (e.g. differences in age, sex/gender, vaccination status, ethnicity) should be integrated to get information for **prevention, early diagnosis, risk factors,** and to better understand **causative links** as well as the **progression of those NCDs.**
- … address **any infection including those with pandemic potential** (viral, bacterial, or fungal) with NCDs of major importance (research on cancer is excluded).
- **Preclinical research, observational studies and/or clinical studies** can be considered for this topic.

Research on cancer excluded – will be covered by the Mission on Cancer

European Commission

HORIZON-HLTH-2023-DISEASE-03-06: Towards structuring brain health research in Europe

Expected outcome:

- Policymakers, funders and other relevant stakeholders identify and agree on the governance structure and implementation modalities, allowing for an **efficient establishment of a potential future partnership.**
- Policymakers, funders and other relevant stakeholders build on the **knowledge gathered in past studies performed at EU and national level.**
- Policymakers, funders and other relevant stakeholders identify and agree on **common research priorities and research needs,** also taking into consideration developments at the international level where relevant.
- Policymakers, funders and other relevant stakeholders develop and align **national and regional research strategy plans** with long-term sustainability in mind.
- Policymakers and funders commit to providing financial support that will allow for a **comprehensive, impact-driven structuring of the field of European brain health research.**

European Commission

HORIZON-HLTH-2023-DISEASE-03-06: Towards structuring brain health research in Europe

Scope:

- **… a structured system of exchange of information** between policymakers, funders, and other relevant bodies in order to establish synergies and avoid duplication of efforts … and **pave the way for a possible future partnership.**
- **… a strategic research and innovation agenda,** taking into account the efforts already undertaken by EU-supported actions.
- **… plans for a governance structure of a future partnership**, as well as **implementation modalities with long-term sustainability**
- **… a broad geographical representation of European countries** and plan for **inclusion of all main related research initiatives, as well as key organisations and associations.**
- **…engaging with global organisations,** as well as with **global initiatives and research organisations** in the field.
- Elaborate on **platforms and tools for use by the research community**, including on how they can best complement, integrate with each other.
- Effective contribution of **social sciences and humanities disciplines** is required.

European Commission

HORIZON-HLTH-2023-DISEASE-03-04: Pandemic preparedness and response: Broad spectrum anti-viral therapeutics for infectious diseases with epidemic potential

Expected outcome:

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

European Commission

HORIZON-HLTH-2023-DISEASE-03-04: Pandemic preparedness and response: Broad spectrum anti-viral therapeutics for infectious diseases with epidemic potential

Scope (1):

- … to develop and advance **broad-spectrum anti-viral compounds** and … **novel approaches to the development of such compounds,** which target viruses with high epidemic or pandemic potential for the EU.
- … cover **viruses for which there are no currently available effective therapeutics or for which the therapeutics available are sub-optimal,** and are expected to **incorporate state-of-the-art screening technology and innovative approaches to identify new targets for antiviral compound development.**
- Emphasis … on the **research and development of broad-spectrum antivirals, which may include repurposing of previously approved or in-pipeline drugs**.
- **Preclinical work and proof-of-concept/first-in-human studies and early safety and efficacy trials** for testing new or improved anti-viral therapeutics (Phase IIb/III phase trials will not be supported).
- **Innovative delivery systems and suitable safety profiles** for broad use should be considered when possible.

European Commission

HORIZON-HLTH-2023-DISEASE-03-04: Pandemic preparedness and response: Broad spectrum anti-viral therapeutics for infectious diseases with epidemic potential

Scope (2):

- … **novel approaches and widely applicable workflows** (e.g. artificial intelligence) for rapid and reliable identification of broad-spectrum anti-viral therapeutics.
- Attention should be paid to **critical social factors such as sex, gender, age, socio-economic factors, ethnicity/migration, and disability.**

On 22/23 November the Commission organised a multidisciplinary workshop on the development and availability of broad-spectrum antivirals as high priority medical countermeasures for better pandemic preparedness.

The report of this workshop is published and a link to it is provided under the Frequently Asked Questions (FAQs) of this topic in the F&T Portal.

European Commission

HORIZON-HLTH-2023-DISEASE-03-17: Pandemic preparedness and response: Understanding vaccine induced-immunity

Expected outcome:

- The scientific and clinical communities have an increased knowledge of **vaccine-induced immunity** and, in particular, a better understanding of **factors that affect the magnitude, breadth, nature and duration of immunity to vaccine antigens**.
- The scientific and clinical communities have an increased knowledge of the durability and breadth of vaccine-induced immunity in **vulnerable populations and older age groups**.
- The scientific and clinical communities have an increased knowledge of **correlates of protection for pathogens with epidemic potential** to allow the development of effective vaccines.
- The scientific and clinical communities have an increased knowledge of the **characteristics that influence vaccine effectiveness** to allow for novel approaches for the development of vaccines for emerging and re-emerging infections, including antigenic variants, in the context of epidemic and pandemic preparedness.

European Commission

HORIZON-HLTH-2023-DISEASE-03-17: Pandemic preparedness and response: Understanding vaccine induced-immunity

Scope:

- Understand the **factors that affect vaccine durability and strength** to improve the global vaccine research and development pipeline for emerging and re-emerging viral infections.
- Study the **magnitude and breadth of initial immune responses and the duration of immunity after vaccination** with different vaccine types (mRNA, vector, inactivated, subunit, attenuated,…).
- Assess **how different factors** (e.g. sex, age and/or life style, genetic and molecular factors, pre-existing conditions or chronic infections) **affect the immune response** in humans.
- Identify **correlates of protection** that can be used to develop vaccines against viruses with a high epidemic or pandemic potential.

European Commission

HORIZON-HLTH-2023-DISEASE-03-18: Pandemic preparedness and response: Immunogenicity of viral proteins of viruses with epidemic and pandemic potential

Expected outcome:

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

European Commission

HORIZON-HLTH-2023-DISEASE-03-18: Pandemic preparedness and response: Immunogenicity of viral proteins of viruses with epidemic and pandemic potential

Scope

- Identify **targets for optimal vaccine design** for those pathogens where **information on host-pathogen interaction and viral surface structures is already available**, with particular attention to:

  Hendra and Nipah Virus, Lassa virus, Crimean Congo haemorrhagic fever virus, Rift Valley fever virus, Ebola virus, Dengue virus, Yellow Fever virus, Zika virus, West Nile fever virus and Chikungunya virus.

- Identify **key antigenic targets** for the priority pathogens as mentioned above.
- Improve or, if necessary, establish **animal models** for the testing of vaccine candidates where alternative models are not available.
- Characterise the **immunogenicity of antigenic targets** in appropriate animal or alternative models and in pre-clinical tests.
- Include, if possible, **proof-of-concept studies in humans** of the vaccine candidate.

European Commission

HORIZON-HLTH-2023-DISEASE-03-05: Pandemic preparedness and response: Sustaining established coordination mechanisms for European adaptive platform trials and/or for cohort networks

Expected outcome:

- The research community sustains appropriate coordination mechanisms **1) among different EU-wide adaptive platform trials** and/or **2) among established cohorts** in Europe and beyond with a view for better pandemic preparedness and response.
- **The adaptive platform trial and/or the cohort networks** maximise coordination and harmonisation of their respective studies within their relevant network for **maximum research efficiency and optimal evidence generation.**
- **The European adaptive platform trial and/or the cohort networks** coordinate with the **European Pandemic Preparedness Partnership,** and are well connected to each other and to relevant other regional and global initiatives.

European Commission

HORIZON-HLTH-2023-DISEASE-03-05: Pandemic preparedness and response: Sustaining established coordination mechanisms for European adaptive platform trials and/or for cohort networks

Scope:

- … maintaining and strengthening existing strategic **coordination mechanisms across adaptive platform trials and across cohort studies in Europe and beyond** …
- … address proper **connections with relevant European initiatives and organisations** (e.g., the European Pandemic Preparedness Partnership, HERA, EMA, ECDC).
- … a **trusted and proactive environment …** that supports the timely exchange of research results, allows for discussion … and … ensure cooperation and synergy within each network.
- … a **common approach for the European clinical research** to enable pragmatic solutions to shared challenges across European clinical trials and/or cohorts …
- … an **optimal use of resources**, based on a sound scientific approach and maximising the value added for the generation of scientific evidence …
- Involving **relevant European stakeholders** … as well as relevant **non-European networks and stakeholders** (e.g., representatives from regulatory authorities, industry, policymakers, patient organisations, etc.).
- Promoting the **visibility and attractiveness of European adaptive platform trials and/or cohorts** for clinical investigators in Europe and beyond.

Destination 3: Call Partnerships- topics in 2023

- HORIZON-HLTH-2023-DISEASE-07-01
  European Partnership on Rare Diseases

- Closure: 19.09.2023
- Type of action: HORIZON-COFUND
  HORIZON Programme Cofund Actions
- Total: €50M

European Commission

Destination 3: Topics in 2024* (forthcoming)

- HORIZON-HLTH-2024-DISEASE-03-08-two-stage: **Comparative effectiveness research for healthcare interventions in areas of high public health need**
- **Closure:** 19.09.2023 (1st stage) and 11.04.2024 (2nd stage)
- Instrument: RIA
- Indicative budget: €45M
- Project size: €6-7M

- HORIZON-HLTH-2024-DISEASE-03-14-two-stage:**Tackling high-burden for patients, under-researched medical conditions**
- **Closure:** 19.09.2023 (1st stage) and 11.04.2024 (2nd stage)
- Instrument: RIA
- Indicative budget: €25M
- Project size: €6-7M

- HORIZON-HLTH-2024-DISEASE-03-13-two-stage**Validation of fluid-derived biomarkers for the prediction and prevention of brain disorders**
- **Closure:** 19.09.2023 (1st stage) and 11.04.2024 (2nd stage)
- Instrument: RIA
- Indicative budget: €25M
- Project size: €6-8M

- HORIZON-HLTH-2024-DISEASE-03-11-two-stage:**Adaptive platform trials for pandemic preparedness**
- **Closure:** 19.09.2023 (1st stage) and 11.04.2024 (2nd stage)
- Instrument: RIA
- Indicative budget: €30M
- Project size: €8-10M

*** Not yet open for applications**

European Commission

Destination 3: Topics in 2024* (forthcoming)

- HORIZON-HLTH-2024-DISEASE-08-12**:**
- **Maintaining the European partnership for pandemic preparedness**
- Closure: **11.04.2024**
- Instrument: CSA
- Indicative budget: €2M
- Project size: €2M

- HORIZON-HLTH-2024-DISEASE-08-20: **Pandemic preparedness and response: Host-pathogen interactions of infectious diseases with epidemic potential**
- Closure: **11.04.2024**
- Instrument: RIA
- Indicative budget: €50M
- Project size: €7-8M

*** Not yet open for applications**

European Commission

Destination 3: Call Partnerships- topics in 2024

- HORIZON-HLTH-2024-DISEASE-09-01:
  European Partnership: One Health AntiMicrobial Resistance

- Closure: 11.04.2024
- Type of action: HORIZON-COFUND HORIZON Programme Cofund Actions
- Total: €100M

European Commission

HORIZON EUROPE

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

Only the workprogramme text has legal value; the oral presentation is only advisory.

Disclaimer: information not legally binding

European Commission

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

Health care systems provide equal access to innovative, sustainable and high-quality health care thanks to the development and uptake of safe, cost-effective and people-centred solutions, with a focus on population health, health systems resilience as well as improved evidence-based health policies.

- Key Strategic Orientation: '*Creating a more resilient, inclusive and democratic European society*'.

❖ Impact areas:
  - ➢ *Good health and high-quality accessible health care;*
  - ➢ *A resilient EU prepared for emerging threats;*
  - ○ *Climate change mitigation and adaptation;*
  - ○ *High quality digital services for all;*
  - ○ *A competitive and secure data economy.*

European Commission

Destination 4: Expected impacts

- Health care systems provide **equal access** to **innovative, sustainable and high-quality health care** thanks to the **development and uptake of safe, cost-effective and people-centred solutions**, with a focus on **population health, health systems resilience** and **improved evidence-based health policies**;
- **Effective, efficient, accessible, resilient** and **sustainable health care services** and **-systems**, with emphasis on **health promotion** and **disease prevention** enable **shifting from hospital-centred to community-based, people-centred and integrated health care structures**;
- **Health care providers** are equipped with **skills and competences suited for future needs** and **health care systems** are **modernized, digitally transformed** and **equipped with innovative tools, technologies and digital solutions**;
- **Citizens** are **empowered in their own health management**, **informal carers are supported** and **specific needs of more vulnerable groups are addressed**;
- Health policy and systems adopt a holistic approach for the evaluation of health outcomes in the context of public health interventions.

European Commission

Destination 4: Topics in 2023

- HORIZON-HLTH-2023-CARE-04-01: **Maintaining access to regular health and care services in case of cross-border emergencies**
- Closure: **13.04.2023**
- Instrument: RIA
- Tot: 20M€
- Project size: 4-6M€

- HORIZON-HLTH-2023-CARE-04-02: **Resilience and mental wellbeing of the health and care workforce**
- Closure: **13.04.2023**
- Instrument: RIA
- Tot: 20M€
- Project size: 4-6M€

- HORIZON-HLTH-2023-CARE-04-03: **Environmentally sustainable and climate neutral health and care systems**
- Closure: **13.04.2023**
- Instrument: RIA
- Tot: 20M€
- Project size: 4-6M€

European Commission

Maintaining access to regular health and care services in case of cross-border emergencies

Expected outcome (contributing to **several of the following** elements)

- **Decision-makers** have access to **modelling tools** and **foresight studies** for anticipating regular and unplanned health and care demand during large-scale cross-border emergencies
- **Decision-makers** and **providers** can **better facilitate and manage access** to regular health and care delivery during cross-border emergencies; and **avail of management frameworks** including organisational models for handling both unplanned and regular health and care needs
- **Health and care professionals** have access to **training** on how to deliver regular health and care services during cross-border health emergencies
- **Health and care professionals, citizens and patients** access **advanced digital tools** enabling managed access to regular health and care services complemented by other modes of health and care delivery (e.g., telemedicine)
- **Patients** can be **involved in the design and production of health and care delivery models** during cross-border emergencies and can benefit from better access
- **Health and care providers** and **professionals** have access to **knowledge and data** on, and **innovative solutions to combat, decreasing demand** for regular health and care services resulting from an ongoing emergency.

Maintaining access to regular health and care services in case of cross-border emergencies

Scope (address **several of the following** elements)

- **Analysis, evaluation, cost studies** of different epidemics or other emergencies **response measures** in Member States and Associated Countries aimed at maintaining access to regular health and care services.

- **Development of innovative tools and models** for maintaining access to regular health and care services during cross-border emergencies.

- **Development and implementation of digital tools** and of effective communication strategies based on digital health literacy studies.

European Commission

Resilience and mental wellbeing of the health and care workforce

Expected outcome (contribute to **several of the following** elements)

- **Health and care workers** receive **support**, and access to **tools and guidance** that enhances their wellbeing and ability to adapt to changing working conditions
- **Decision- and policymakers, employers and social partners** in the health and care sectors have **knowledge of, and solutions to prevent and manage,** the specific risks for health and care professionals and informal carers
- **Funders of health and care provision** have access to e**vidence, novel approaches** and **cost-effective recommendations** for interventions supporting the mental health and well-being of health and care workers
- **Policymakers cooperate** with relevant **stakeholders.**

European Commission

Resilience and mental wellbeing of the health and care workforce

Scope (address **all of the following** elements)

- Collect and analyse **new evidence** and **data generation**
- Develop **action-oriented recommendations** to policymakers, employers, social partners and relevant civil society organisations at the appropriate levels (EU, national, regional, local) based on evidence generated by the proposed action
- Develop, or identify, **innovative solutions** (including digitally enabled ones), **organisational models** and **management approaches**
- Develop **financing and resource allocation models**
- Carry out **testing and validation activities** for new or improved solutions.

European Commission

Environmentally sustainable and climate neutral health and care systems

Expected outcome (contribute to **all of the following** elements)

- **Policy and decision makers, providers of health and care, health and care workers** and **citizens** have **increased knowledge** on how today's health and care systems are not environmentally sustainable
- **Policy and decision makers** and **providers of health and care** services have access to **innovative solutions**, **organisational models,** and **guidelines and recommendations**
- **Monitoring and reporting of carbon emissions and pollution** is **mainstreamed** through a life-cycle approach and with standard methods in the health and care systems.

European Commission

Environmentally sustainable and climate neutral health and care systems

Scope (address **several of the following** elements)

- **Research and innovative solutions** for **decarbonisation** of hospitals and other care providers.
- **Research and innovative solutions** for **increased circularity** of hospitals or other care providers that integrate the zero-pollution ambition.
- **Research and innovative solutions** for **decarbonisation** and greening of **supply chains** and material inflows.
- Development of a **framework** to measure and benchmark the **environmental footprint** of the health and care sectors or improving infrastructures for relevant collecting, sharing, accessing and processing of data.

European Commission

Destination 4: Call Partnerships- topics in 2023

- HORIZON-HLTH-2023-CARE-08-01::
  European Partnership on Personalised Medicine

- Closure: 13.04.2023
- Type of action: HORIZON-COFUND
  HORIZON Programme Cofund Actions
- Total: €100M

European Commission

Destination 4: Topics in 2024* (forthcoming)

- HORIZON-HLTH-2024-CARE-04-04-two-stage:
  Access to health and care services for people in vulnerable situations

- **Closure:** 19.09.2023 (1st stage) and 11.04.2024 (2nd stage)
- Instrument: RIA
- Indicative budget: €30M
- Project size: €4-6M

*** Not yet open for applications**

European Commission

HORIZON EUROPE

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

Only the workprogramme text has legal value; the oral presentation is only advisory.

Disclaimer: information not legally binding

European Commission

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

Technology is a key driver for innovation in the health care sector. It can provide better and more cost-efficient solutions with high societal impact, tailored to the specific health care needs of the individual.

- Key Strategic Orientation: '*Promoting an open strategic autonomy by leading the development of key digital, enabling and emerging technologies, sectors and value chains*'.

- Impact areas
  - *High quality digital services for all,*
  - *Health technologies, new tools and digital solutions are applied effectively thanks to their inclusive, secure and ethical development, delivery, integration and deployment in health policies and health and care systems,*
  - *A competitive and secure data-economy,*
  - *Industrial leadership in key and emerging technologies that work for people*
  - *Good health and high-quality accessible health care.*

European Commission

Destination 5: Expected impacts

- 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 care is world-class.
- Citizens benefit from targeted and faster research resulting in safer, more sustainable, efficient, cost-effective and affordable tools, technologies and digital solutions,
- The EU gains high visibility and leadership in terms of health technology development,
- The burden of diseases in the EU and worldwide is reduced through the development and integration people-centred solutions for health care,
- Both the productivity of health research and innovation, and the quality and outcome of health care is improved,
- Citizens trust and support to innovative technologies for health care.

European Commission

Destination 5: Topics in 2023 – Single stage

- HORIZON-HLTH-2023-TOOL-05-01: **Clinical trials of combined Advanced Therapy Medicinal Products (ATMPs)**
- Closure: 13.04.2023
- Instrument: RIA
- Tot: €50M
- Project size: €8-10M

- HORIZON-HLTH-2023-TOOL-05-03: **Integrated, multi-scale computational models of patient patho-physiology ('virtual twins') for personalised disease management**
- Closure: 13.04.2023
- Instrument: RIA
- Tot: €50M
- Project size: €8-10M

- HORIZON-HLTH-2023-TOOL-05-04: **Better integration and use of health-related real-world and research data, including genomics, for improved clinical outcomes**
- Closure: 13.04.2023
- Instrument: RIA
- Tot: €35M
- Project size: €8-10M

- HORIZON-HLTH-2023-TOOL-05-05: **Harnessing the potential of real-time data analysis and secure Point-of-Care computing for the benefit of person-centred health and care delivery**
- Closure: 13.04.2023
- Instrument: IA
- Tot: €35M
- Project size: €8-10M

European Commission

Destination 5: Topics in 2023 – Single stage

- HORIZON-HLTH-2023-TOOL-05-08: **Pandemic preparedness and response: In vitro diagnostic devices to tackle cross-border health threats**
- Closure: 13.04.2023
- Instrument: IA
- Tot: €40M
- Project size: €5-7M

- HORIZON-HLTH-2023-TOOL- 5.09: **Developing a Data Quality and Utility Label for the European Health Data Space**
- Closure: 13.04.2023
- Instrument: CSA
- Tot: €4M
- Project size: €4M

European Commission

Clinical trials of combined Advanced Therapy Medicinal Products (ATMPs)

Expected outcome (contributing to **all of the following** elements)

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

European Commission

Clinical trials of combined Advanced Therapy Medicinal Products (ATMPs)

Scope (address **all of the following** elements)

- **Phase 2 CTs of combined ATMP** with**:**
  - **Technologies ready to undergo interventional clinical trials** in patients/end users assessing the usability and clinical performance;
  - Technologies with **safety/performance** profiles that should undergo **clinical validation** in view of their **inclusion into** guidelines for specific clinical pathways;
- Delivery of **safe and clinically validated combined ATMPs** compliant with current EU regulatory requirements;
- **Consultation/interaction with competent regulatory agencies**, such as EMA, national regulatory agencies and HTA bodies.

European Commission

Integrated, multi-scale computational models of patient patho-physiology ('virtual twins') for personalised disease management

Expected outcomes (contributing to **all of the following** elements)

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

European Commission

Integrated, multi-scale computational models of patient patho-physiology ('virtual twins') for personalised disease management

Scope (address **all of the following** activities)

- Develop **multi-scale** and **multi-organ**, **dynamic**, interoperable, modular **computational models**, capable of accurately **simulating the individual patient patho-physiology**, spanning different anatomical scales from molecular to cell, tissue, organ and systems).
- Advance the state of the art in multi-scale modelling by employing **diverse modelling methodologies** as a means for **modelling the healthy state**, **disease onset, progression**, **treatment** and **recovery** with the necessary **diverse data types**.
- **Integrate** standardised **spatiotemporal multi-scale models** as a basis for developing personalised 'virtual twin' models reflecting patient's individual characteristics. This must be driven by **active involvement of end users, usability** must be demonstrated.
- **Validate** multi-scale patient-specific models, generate **evidence** on delivering clinically meaningful, real-world observations for diseases under study. **Utility vis-à-vis current practice** must be shown and an **exploitation strategy** elaborated.

Better integration and use of health-related real-world and research data, including genomics, for improved clinical outcomes

Expected outcome (contributing to **most of the following** elements)

- Better **linkage of health data from various sources**, based on **harmonised approaches** applicable **across certain disease areas** and national borders
- Access to advanced **digital tools** for **health data integration, management and analysis** in a secure, cost-effective and clinically meaningful way for **improved health outcomes**
- Advanced **understanding of the risk factors, causes, development and optimal treatment** in disease areas through **integration of genomics with other health data**
- **Data-driven solutions** and **better evidence base** for addressing healthcare challenges
- **Data-driven patient-focused health interventions** for improved disease prevention, diagnosis, treatment and monitoring towards better patient outcomes and well-being
- **Increased trust** in the re-use of health data for research and healthcare

Better integration and use of health-related real-world and research data, including genomics, for improved clinical outcomes

Scope (address **all of the following** elements)

- Identification of the **barriers to health data integration and access** and of specific **existing tools, technological solutions** and agreements addressing those barriers
- **New approaches** to assemble large, easily findable and lawfully accessible high-quality datasets **integrating multiple types of health data** leading to improved clinical outcomes
- **New techniques, support tools**, mechanisms and modalities to enable **GDPR compliant access to sensitive personal data**, including genomics, allowing for their **re-use across borders and integration** of different types of data relevant to human health
- **Data management** approaches for cross-border distributed **data storage and processing**, including joint data governance piloted among several clinical centres across Europe
- **Data analytics platform** applying **distributed learning and AI** to query and aggregate data securely from multiple sources and for multiple use cases

European Commission

Harnessing the potential of real-time data analysis and secure Point-of-Care computing for the benefit of person-centred health and care delivery

Expected outcome (contributing to **all of the following** elements)

- **Healthcare professionals** benefit from secure, highly performant Point-of-Care computing technologies and devices to enable **continuous monitoring and/or fast real-time health status checks** in clinical settings and workflows
- **Patients and clinicians** benefit from wider access to **real-time diagnosis, screening, monitoring and treatments**
- **Quicker reaction times and improved patient safety** in care settings
- **Researchers and healthcare professionals** have more opportunities to **use, extract value from and contribute to the uptake of real-time health data**
- **Health and care settings** benefit from **reduced energy consumption**

European Commission

Harnessing the potential of real-time data analysis and secure Point-of-Care computing for the benefit of person-centred health and care delivery

Scope (address **all of the following** elements)

- Develop and validate **compact, cost- and energy-efficient, extended reality-enabled and other Point-of-Care devices and systems**, to be integrated into clinical settings;
- Develop and validate **instruments, continuous monitoring systems and/or analysis algorithms for the analysis of biological samples**, enabling detection of biomarkers in body fluids and tissues in clinical settings;
- Develop and validate **imaging systems with a high spatial resolution down to the cellular level allowing for immediate clinical interventions**;
- Advance the use of **Point-of-Care computing, data modelling, extended reality and/or machine learning/AI technologies applied to diagnosis and risk assessment** in cases requiring very fast, near to real-time response times in clinical settings and workflows.

Pandemic preparedness and response: In vitro diagnostic devices to tackle cross-border health threats

Expected outcome (contributing to **all of the following** elements)

- The scientific and clinical communities, including health care providers and payers, as well as regulators, health systems and patients **benefit from innovative diagnostic solutions that are better suited to tackle cross-border health threats**.
- The scientific and clinical communities have access to **novel and improved methodologies for detection of pathogens with pandemic potential** in humans and for timely discovery of other health threats, such as chemical, radiological and nuclear threats, including considerations on detection in animals and environmental conditions (One Health approach).
- A **diverse and robust pipeline of in vitro diagnostics** is available, increasing options for clinical deployment in case of an epidemic or pandemic.

European Commission

Pandemic preparedness and response: In vitro diagnostic devices to tackle cross-border health threats

Scope (address **all of the following** elements)

- Develop and advance on **new in vitro diagnostics relevant for detecting and characterising cross-border health threats**, incl. pathogens with pandemic potential, chemical, radiological and nuclear threats;
- Develop **proof-of-concept/early studies** linked e.g. to performance evaluation of new diagnostics that facilitate screening, detection of the presence or exposure to a cross-border health threat or determination of infectious/disease status through human samples;
- Develop **data-driven diagnostic and prognostic platforms with AI and other advanced data analytics functionalities**, adaptable to respond to new and multiple pathogens/threats, e.g. covering prototype viruses;
- Develop **innovative systems** linked to high sensitivity/specificity profiles **adaptable for broader use**, e.g. portable, faster, more compact or accurate devices and technologies;
- Develop **innovative diagnostics sampling methods** or samples bringing a significant improvement, such as less invasive sampling methods.

Developing a Data Quality and Utility Label for the European Health Data Space

Expected outcome (contributing to **all of the following** elements)

- **Data Users** are able to identify the most relevant datasets that meet their specific needs through better defined datasets with **a label describing the quality and utility dimensions of the datasets**;
- **Data holders** have **clear specifications for dataset quality and utility labelling** to comply with the requirements proposed in the EHDS legal provisions;
- **Public funders** ensure that the datasets, for which they provided funding for the creation and curation of, are more widely available, **furthering their reuse**;
- **The European Commission** has access to a **set of specifications for the data quality and utility label** supporting the implementation of the EHDS legal provisions.

European Commission

Developing a Data Quality and Utility Label for the European Health Data Space

Scope (address **all of the following** elements)

- Develop a **data quality and utility framework** to articulate the characteristics and the potential usefulness of datasets;
- Support **data holders** in identifying and addressing areas of **improvement;**
- Take into account the **various needs of data users** whilst at the same time avoid becoming an excessive burden on data holders;
- Develop a **framework (set of technical specifications)** for the data quality and utility label that supports the implementation of the EHDS legal provisions;
- Develop **recommendations for the successful implementation and adoption** of the data quality and utility label and maturity model

European Commission

Destination 5: Topics in 2024 (forthcoming)

- HORIZON-HLTH-2024-TOOL-05-06-two-stage: **Innovative non-animal human-based tools and strategies for biomedical research**
- **Closure:** 19.09.2023 (1st stage) and 11.04.2024 (2nd stage)
- Instrument: RIA
- Indicative budget: €25M
- Project size: €4-8M

- HORIZON-HLTH-2024-TOOL-11-02: **Bio-printing of living cells for regenerative Medicine**
- Closure: 13 Apr 2023
- Instrument: RIA
- Tot: €25M
- Project size: €6-8M

*** Not yet open for applications**

European Commission

HORIZON EUROPE

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

Only the workprogramme text has legal value; the oral presentation is only advisory.

Disclaimer: information not legally binding

European Commission

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

The health industry is a key driver for growth and has the capacity to provide health technologies to the benefit of patients and providers of health care services.

- Key Strategic Orientation: '*Promoting an open strategic autonomy by leading the development of key digital, enabling and emerging technologies, sectors and value chains*'.

- Impact areas
  - *A competitive and secure data-economy,*
  - *Industrial leadership in key and emerging technologies that work for people,*
  - *High quality digital services for all,*
  - *Good health and high-quality accessible health care,*

European Commission

Destination 6: Expected impacts

- Health industry (including SMEs) is more competitive and sustainable, assuring EU leadership and strategic autonomy in medical supplies and digital technologies.
- Health industry is working more efficiently along the value chain.
- European standards ensuring safety and quality of healthcare, as well as effectiveness and interoperability of health innovations.
- Swift uptake of innovative health technologies and services.
- Reliable and timely access to key manufacturing capacity (e.g. vaccines and medical radioisotopes).

Destination 6: Topics in 2023 – Single stage

- HORIZON-HLTH-2023-IND-06-01: **Supporting the uptake of innovative Health Technology Assessment (HTA) methodology and advancing HTA expertise across EU**
- Closure: 13.04.2023
- Instrument: CSA
- Tot: €5M
- Project size: €5M

- HORIZON-HLTH-2023-IND-06-02: **Expanding the European Electronic Health Record exchange Format to improve interoperability within the European Health Data Space**
- Closure: 13.04.2023
- Instrument: RIA
- Tot: €8M
- Project size: €3-5M

- HORIZON-HLTH-2023-IND-06-04: **Modelling and simulation to address regulatory needs in the development of orphan and paediatric medicines**
- Closure: 13.04.2023
- Instrument: RIA
- Tot: €25M
- Project size: €4-6M

- HORIZON-HLTH-2023-IND-06-05: **Mapping the hurdles for the clinical applications of Advanced Therapy Medicinal Products (ATMPs)**
- Closure: 13.04.2023
- Instrument: CSA
- Tot: €5M
- Project size: €5M

European Commission

Destination 6: Topics in 2023 – Single stage

- HORIZON-HLTH-2023-IND-06-07: **Development and harmonisation of methodologies for assessing digital health technologies in Europe**
- Closure: 13.04.2023
- Instrument: RIA
- Tot: €15M
- Project size: €7-8M

European Commission

Supporting the uptake of innovative Health Technology Assessment (HTA) methodology and advancing HTA expertise across EU

Expected outcome (contributing to **all of the following** elements)

- **Identification** of the most innovative **HTA methods** developed by EU-funded projects, and **endorsement by HTA bodies** of such methods;
- **Dissemination** among EU HTA bodies of robust innovative HTA methods and tools;
- **Harmonisation of HTA expertise** across EU though the development of a **training programme** in accordance with **Regulation (EU) 2021/2282** and based on the methodological **guidelines of the Coordination Group on HTA**;
- Contribution to a successful **implementation of the HTA regulation** as well as to building an **EU methodological HTA framework.**

European Commission

Supporting the uptake of innovative Health Technology Assessment (HTA) methodology and advancing HTA expertise across EU

Scope

Two strands of activities should be tackled in the proposals**:**

- Implementation of innovative **HTA methods**;
- Advancing **HTA expertise** across the EU and Associated Countries.

(Applications should address **all of the following** elements):

- Identification of **innovative methods and tools**;
- Identification of **barriers to the uptake** of these methods;
- **Use cases to facilitate the endorsement** by HTA bodies of innovative methods;
- Development of an **implementation plan** including supporting tools and training modules;
- Recommendations for **broader dissemination**.

European Commission

Expanding the European Electronic Health Record exchange Format to improve interoperability within the European Health Data Space

Expected outcome (contributing to **all of the following** elements)

- European Health Record (EHR) **stakeholders** (e.g. **developers, suppliers, integrators, and operators**) have at their disposal and use fit-for-purpose **standards, guidelines, and toolsets for prioritised health information domains** to address interoperability of EHRs
- **Stakeholders** have at their disposal **better quality and better integrated health datasets** within the European Health Data Space, to foster innovations in the health sector and leverage the potential of new analytics solutions such as AI and big data, get new insights and detect trends from aggregated data, including for cross-border health threats
- **Citizens** are provided with an **expanded access to their health data**, also across borders, and **innovative digital services** for high-quality health and care across the EU

Expanding the European Electronic Health Record exchange Format to improve interoperability within the European Health Data Space

Scope (address **all of the following** elements)

- Research, develop and validate **harmonised interoperability formats** for sharing data in specific priority health information domains that should be selected with reference to the EU policies and priorities
- Leverage and scale up the potential of EHR through enhanced interoperability to **improve quality, safety, and efficiency of patient care**, enforce patients' right to **data portability**
- Address **semantic interoperability** for prioritised information domains so that the transmitted health record contains standardised coded data.
- **Maximise synergies with relevant initiatives**, activities and programmes, building upon previous and linking to on-going actions

European Commission

Modelling and simulation to address regulatory needs in the development of orphan and paediatric medicines

Expected outcome (contributing to **all of the following** elements)

- **Developers** and **regulators** have access to **robust modelling** and **simulation tools** to accelerate the effective development of **orphan** and/or **paediatric** medicinal products.
- **Clinical researchers**, **developers** and **regulators** use accurate computational models to improve the **statistical robustness in clinical trials** intended for **small populations** and guide cost-effective **clinical trial designs**.
- **Clinical researchers** and **regulators** have access to **accurate in-silico tools** for assessing the actionable use of **real-world data** and for successfully estimating the **risk-benefit** effects in **clinical trials for small populations**.
- **Regulators** develop **guidance** for the use of **validated computational models** to support a robust **extrapolation framework** and facilitate the **safety and efficacy assessment** in the process of **regulatory appraisal** of orphan and/or paediatric medicinal products.

European Commission

Modelling and simulation to address regulatory needs in the development of orphan and paediatric medicines

Scope (address **all of the following** elements)

- **Assess the utility of mature computational models**, to support the design of innovative clinical trials for small populations and regulatory decisions on the development of orphan and/or paediatric medicines;
- **Calibrate and optimise mature computational models** to enhance their clinical performance, by using relevant sources of patient data;
- **Assess** the validated in-silico models for their **capability to increase the statistical robustness, improve the risk/benefit assessment** in small population clinical trials, and for their **accuracy to predict and extrapolate the therapeutic effects**;
- **Benchmark diverse computational models** by showcasing their performance and credibility in use cases representing well-justified group(s) of **rare and/or paediatric diseases** with commonalities, **excluding rare cancers and rare infectious diseases.**
- **Set-up the criteria for the performance and credibility assessment** to progress on regulatory qualification and acceptability.
- **Develop and disseminate standards** for the design, performance assessment and reporting of modelling and simulation tools with an emphasis on those of high regulatory value.
- Demonstrate the **availability of the relevant data** to address the requirements of the topic.

Mapping the hurdles for the clinical applications of Advanced Therapy Medicinal Products (ATMPs)

Expected outcome (contributing to **all of the following** elements)

- Aspects of **regulation, policy, safety, efficacy, manufacturing, organisation, infrastructure, decision-making, and commercialisation** are identified
- **EU regulatory frameworks are adapted to novel scientific progress** (platform approaches, genome editing, interface with medical devices, AI)
- **Competent authorities in the MS can propose adapted pricing and reimbursement schemes** that allow European citizens to benefit from novel ATMPs
- Academic and SME developers and manufacturers of ATMPs have an **increased knowledge of the regulatory aspects**
- Decentralised **manufacturing** of ATMPs is **consistent across health care centres**

European Commission

Mapping the hurdles for the clinical applications of Advanced Therapy Medicinal Products (ATMPs)

Scope (address **all of the following** elements)

- **Map the** regulatory, safety and efficacy assessment, manufacturing, organisational and infrastructural **needs to improve translation of ATMPs**
- Address g**aps and uncertainties** in regulatory and policy aspects for complex ATMPs;
- Address p**redictivity of preclinical data** for safety and efficacy testing of ATMPs
- Tackle **Decision-making processes relating to ATMPs** (assessment of their values, long-term safety and effectiveness, new pricing and reimbursement, etc.);
- Improved **knowledge of regulatory processes** for academic developers;
- Involve **regulatory authorities, HTA bodies, clinicians, ethics committees** and **patients**

European Commission

Development and harmonisation of methodologies for assessing digital health technologies in Europe

Expected outcome (contributing to **all of the following** elements)

- **Policymakers** dispose of a **methodological framework** and **standardised approaches** for **assessing digital health technologies**, that helps making **evidence-based decisions** regarding the introduction of digital health technologies in health and care systems with added value for patients and society.
- **Regulators** have access to robust, scientifically underpinned **evaluation methodologies**.
- **EU citizens** gain **faster access** to safe and well-performing **person-centred digital technologies** and are **empowered** through these tools.
- **Health technology developers** are better informed and dispose of **more guidance** on the **evidence** needed to demonstrate the **added value of digital health technologies** and have **better insights** in market predictability.
- (Digital) **Health Industry**/digital health technology developers and **HTA bodies** can **contribute** to the development of **EU harmonised Health Technology Assessment (HTA) rules** based on **common principles**.
- Improved **cross-border use and interoperability** of **digital health tools and services** throughout the EU and Associated Countries.
- **Increased trust** in digital health technologies and **better integration** of **digital health tools and services** in health and care systems.

Development and harmonisation of methodologies for assessing digital health technologies in Europe

Scope (address **all of the following** elements)

- Develop and/or expand a **general methodological framework** and **standardised approaches** to assess digital health technologies with a particular **focus** on criteria such as **privacy**, **cybersecurity**, **data quality**, **data storage and handling**, **interoperability** etc.;
- **Test robustness** of developed methodologies on **min. 3** different digital health technology use cases;
- **Collect best practice** for common approaches in methodology for digital health technology assessment and develop an **open access European repository** for evaluation methods, studies, results and evidence of digital health technologies and services;
- **Pilot** the development of **common specifications** to the **harmonisation of assessment frameworks** (pre-market and post-market phases) throughout the EU and Associated Countries;
- **Include end-users** of digital health technologies (be it professionals, care users or citizens), developers of digital health technologies, producers of health services, regulators and governments;
- Contribute to a **framework to evaluate and monitor** whether the **uptake and use** of digital health services contribute to the overall goals of the health and care system;
- Comply with relevant requirements proposed in the **European Health Data Space** (EHDS) legal provisions;

Destination 6: Topics in 2024 (forthcoming)

- HORIZON-HLTH-2024-IND-06-08: **Developing EU methodological frameworks for clinical/ performance evaluation and post-market clinical/performance follow-up of medical devices and in vitro diagnostic medical devices (IVDs**)

- **Closure:** 11.04.2024
- Instrument: RIA
- Indicative budget: €10M
- Project size: €8-10M

- HORIZON-HLTH-2024-IND-06-09: **Gaining experience and confidence in New Approach Methodologies (NAM) for regulatory safety and efficacy testing – coordinated training and experience exchange for regulators**

- Closure: 11 Apr 2024
- Instrument: CSA
- Tot: €2M
- Project size: €2M

*** Not yet open for applications**

European Commission

Horizon Europe – Cluster 1 „Health“

Cross-cutting issues

- **Ethics and Integrity** remain absolute priorities;
- **Open Science** practices will continue to expand;
- **Social Sciences and Humanities** should continue to be taken into account;
- **International Cooperation** will remain a key feature and opportunity of the framework programme, that is of particularly important for health research.
- **Gender**

European Commission

Horizon Europe – Cluster 1 „Health“

Cross-cutting issues – Gender

- **integration of the gender dimension** into R&I content is further strengthened, it will become **mandatory** unless indicated as not relevant at topic level.
- **additional provisions** to foster gender equality in organisations;
- having a **gender equality plan** in place will become an eligibility criterion for public bodies, research organisations and higher education institutions.

Clinical study template

European Commission

Background and purpose of the ‘Clinical study template’

- Clinical **studies are** usually **complex** but the main types of **challenges** that can hinder their timely and efficient implementation **are well known**.
- With **appropriate planning**, securing the availability of the necessary **intelligence** and **resources**, applicant consortia can overcome the expected challenges.
- Two intertwined **objectives:**
    - Guide applicants in **designing** scientifically **sound** and operationally **feasible** clinical studies
    - Provide a structured overview for expert evaluators on the **robustness** of various aspects of the required **planning** of clinical studies

Definition of clinical study

For the purpose of the template, **clinical study means**

any systematic prospective or retrospective collection and analysis

of health data obtained from individual patients or healthy persons in order

to address scientific questions related to the understanding, prevention, diagnosis, monitoring or treatment of a disease, mental illness, or physical condition.

It **includes** but it is **not limited to**

clinical studies as defined by Regulation 536/2014 (on medicinal products),

clinical investigation and clinical evaluation as defined by Regulation 2017/745 (on medical devices),

performance study and performance evaluation as defined by Regulation 2017/746 (on in vitro diagnostic medical devices).

Social Sciences and Humanities (SSH)

European Commission

Social Sciences and Humanities (SSH)

Calls for proposals - Work programme

- Topics flagged as SSH
- Sentence included in SSH-flagged topics:

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

Proposals

- Special attention to SSH aspects in SSH-flagged topics.
- If applicants consider that **an SSH component** is **not relevant** for their proposal - **Need to justify why not**. Experts evaluators will assess the justification provided by the applicants.

Evaluation

- SSH is a requirement embedded in the award criteria that will be assessed.
- SSH experts evaluators will take care especially of the SSH part of the proposal, taking into account how applicants have integrated the SSH dimension in the proposal.

European Commission

HORIZON EUROPE AWARD CRITERIA

Integration of the gender dimension in R&I content

European Commission

Gender equality: a strengthened crosscutting priority in Horizon Europe

- **Article 7(6)** and **Recital 53** of Framework Regulation
- **Articles 2(2)(e)** and **6(3)(e)** of the Specific Programme

Gender Equality Plan (GEP): **Eligibility Criterion**

- Detailed **Horizon Europe Guidance on Gender Equality Plans** published 28/09/2021
- Dedicated webinar on 23/06/2022: **The Gender Equality Plan eligibility criterion in Horizon Europe: Who is concerned? How to comply with it?**

Integration of the gender dimension in R&I content: **Award Criteria**

Gender balance: **Ranking Criteria** – for *ex aequo* proposals

European Commission

Who is eligible for funding?

EU COUNTRIES

- Member States (MS) including their outermost regions
- The Overseas Countries and Territories (OCTs) linked to the MS.

NON-EU COUNTRIES

- Countries associated to Horizon Europe (AC)
- Low and middle income countries: See HE Programme Guide.
- Other countries when announced in the call or exceptionally if their participation is essential

SPECIFIC CASES

- Affiliated entities established in countries eligible for funding.
- EU bodies
- International organisations (IO):
  - International European research organisations are eligible for funding.
  - Other IO are not eligible (only exceptionally if participation is essential)
  - IO in a MS or AC are eligible for funding for Training and mobility actions and when announced in the call conditions

Associated Countries

For the purposes of the eligibility conditions, applicants established in Horizon 2020 Associated Countries or in other third countries negotiating association to Horizon Europe will be treated as entities established in an Associated Country, if the Horizon Europe association agreement with the third country concerned applies at the time of signature of the grant agreement.

Specific situation of UK

- The UK is expected to soon become an associated country to Horizon Europe. UK entities can take part in the first calls for proposals of Horizon Europe
- The UK is associating to the full Horizon Europe programme with the only exception of the EIC Fund (which is the loan/equity instrument of the EIC).

European Commission

HORIZON EUROPE

What is new in the evaluation process?

European Commission

Evaluation (award) criteria

Same criteria as in H2020

Same three award criteria: '**Excellence**', '**Impact**' and '**Quality and efficiency of the implementation**'. Excellence only for ERC.

Adapted following lessons learnt

- The number of '**aspects to be taken into account**' have been **reduced**, ensuring that the same aspect is not assessed twice
- **Open Science** practices assessed as part of the scientific methodology in the excellence criterion
- **New approach to impact**: Key Impacts Pathways (KIPs)
- The assessment of the **quality of applicants** is assessed under 'implementation', rather than as a separate binary assessment of operational capacity
- Assessment of **management structures** has been removed.

European Commission

Evaluation criteria (RIAs and IAs)

EXCELLENCE

- ✓ Clarity and pertinence of the **project's objectives**, and the extent to which the proposed work is ambitious, and goes beyond the state-of-the-art.
- ✓ Soundness of the proposed **methodology**, including the underlying concepts, models, assumptions, inter-disciplinary approaches, appropriate consideration of the **gender dimension** in research and innovation content, and the quality of **open science practices** including sharing and management of research outputs and engagement of citizens, civil society and end users where appropriate.

IMPACT

- ✓ Credibility of the **pathways** to achieve the expected **outcomes and impacts** specified in the work programme, and the likely scale and significance of the contributions due to the project.
- ✓ Suitability and quality of the **measures to maximize expected outcomes and impacts**, as set out in the dissemination and exploitation plan, including communication activities.

QUALITY AND EFFICIENCY OF THE IMPLEMENTATION

- ✓ Quality and effectiveness of the **work plan**, assessment of risks, and appropriateness of the effort assigned to work packages, and the resources overall.
- ✓ Capacity and role of each **participant**, and extent to which the **consortium** as a whole brings together the necessary expertise.

Proposals aspects are assessed to the extent that the proposed work is within the scope of the work programme topic

European Commission

HORIZON EUROPE

Points to consider when writing a proposal in HE

European Commission

Key principles

Updated slide (June 2021)

Your proposed work must be within the scope of a work programme topic

You need to demonstrate that your idea is ambitious and goes beyond the state of the art

Your scientific methodology must take into account interdisciplinary, gender dimension and open science practices.

You should show how your project could contribute to the outcomes and impacts described in the work programme (the pathway to impact)

You should describe the planned measures to maximise the impact of your project ('plan for the dissemination and exploitation including communication activities')

You should demonstrate the quality of your work plan, resources and participants

European Commission

Horizon Europe – Cluster 1 „Health“

Keep informed. Get involved.

- Register to receive the latest updates of developments.
- Reach out to National Contact Points.
- Become an independent evaluator for HE proposals

ALL this can be done via **EC portal for *Funding & Tenders Opportunities***.
https://ec.europa.eu/info/funding-tenders/opportunities/portal

General information on Horizon Europe: https://ec.europa.eu/info/horizon-europe

You can also follow us on Twitter @EUScienceInnov

HorizonEU

European Commission

Thank you!

#HorizonEU

http://ec.europa.eu/horizon-europe