THE EU RESEARCH & INNOVATION PROGRAMME

2021 – 2027

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Research and Innovation

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KOREA-EU HORIZON EUROPE RESEARCHERS FORUM

EU policy related to the Health Cluster - Advanced Biotechnology

Presentation on Cluster 1 - Destination Disease & Tool

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Horizon Europe

The ambitious EU research and innovation framework programme (2021-2027)

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

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

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

Science & technology

Society

Economy

Horizon Europe is impact driven

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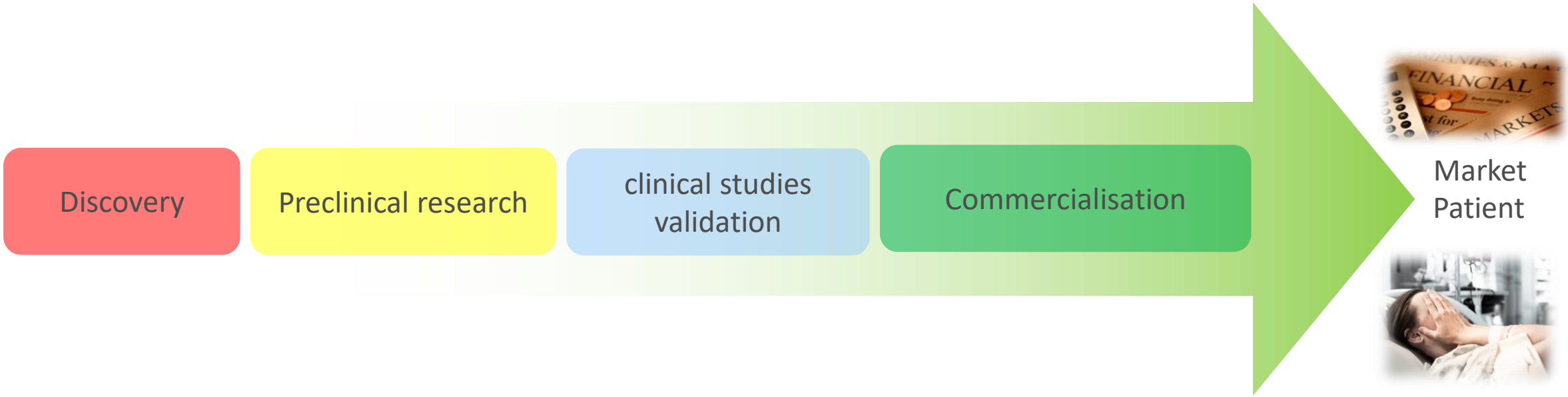
IMPACT

An example: medicine development

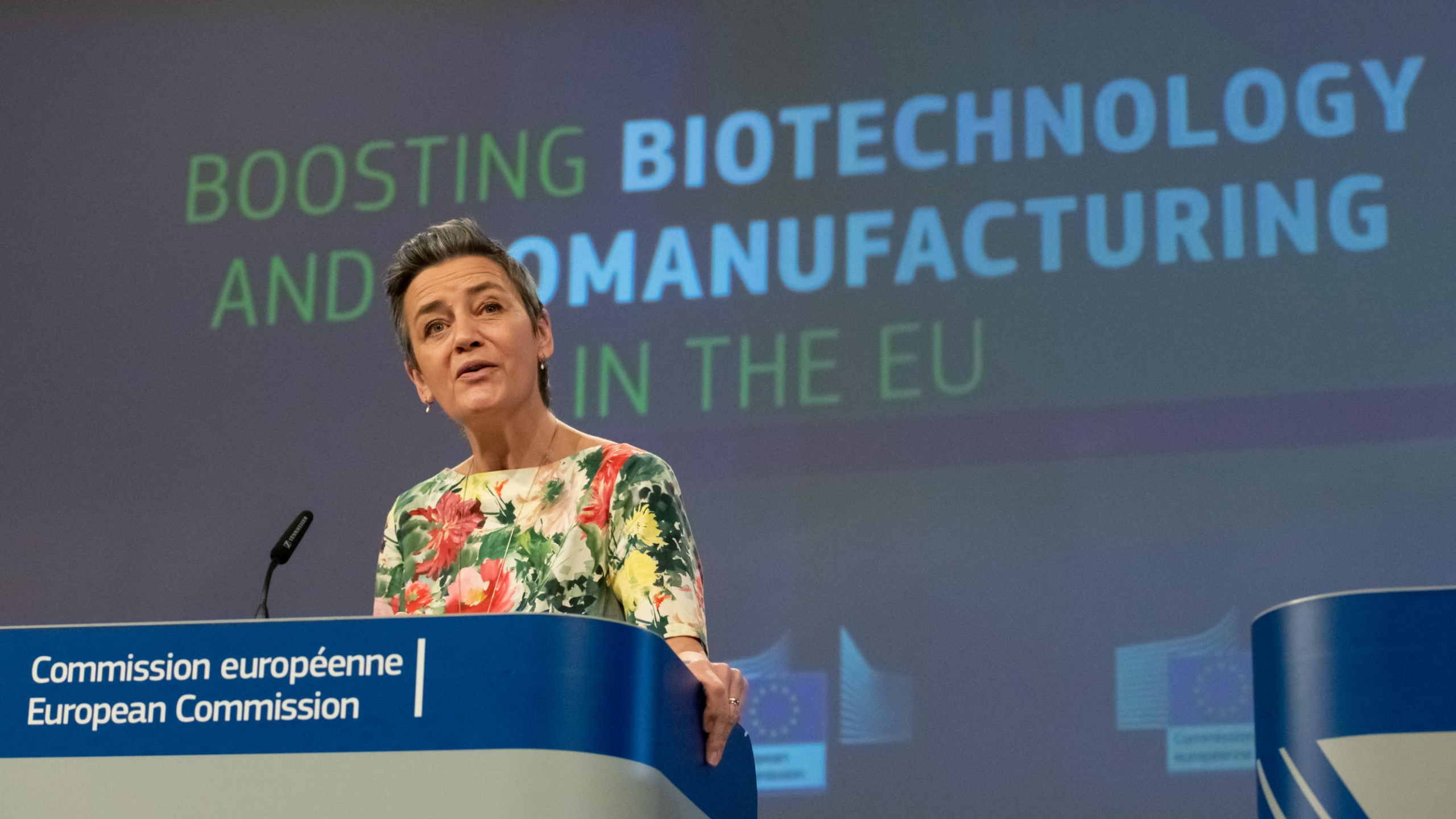


R&I support along the value chain

Support to EU policy priorities and legislation

- The European Green Deal
- Europe's Beating Cancer Plan
- The European One Health action plan against AMR
- The AI Continent Action Plan

- The European Health Data Space
- EU clinical trials regulation
- The pharmaceutical package (incl regulatory sandboxes)
- ……


BOOSTING BIOTECHNOLOGY
AND OMANUFACTURING
IN THE EU
Commission européenne
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The Biotech & Biomanufacturing Communication (March 2024)

- Summarises the current challenges and barriers for biotechnology and biomanufacturing.
- Proposes >20 actions to address these challenges in a timely manner.
- In line with the Communication on the Long-term competitiveness of the EU.
- Explores ways to foster engagement and collaboration, including through international dialogue and cooperation.

Main challenges for the biotech sector in the EU

- **Research and technology transfer to the market**
- **Regulatory complexity**
- Access to finance
- Skills
- Value chain obstacles
- Intellectual property
- **Public acceptance**
- **Economic security**

Research and innovation transfer to the market

To ensure that the EU benefits from high-quality R&D and innovation environment

- Identify how best to leverage existing assets and infrastructures for health biotechnology with the aim to boost biomanufacturing capacity within the EU
- Identify mechanisms to support responsibly the development of advanced (Generative) AI models for healthcare

Streamlining regulatory pathways for all biotech applications

To assess how EU legislation and its implementation could be further streamlined to reduce any fragmentation, explore simplification, and shorten the time to market.

- The Commission launched a study that will map key current industrial bio-based value chains, analyse the regulatory framework and the impact of relevant legislation, and thereby lay the foundations for a possible EU Biotech Act.

To respond to current needs and to help biotech companies bringing innovative products to the market.

- Established an EU Biotech Hub, an operational tool for biotech companies to navigate through the regulatory framework and identify support to scale up.

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 - €58.9 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

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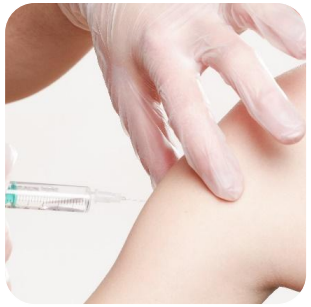
6 Expected Impacts = 6 Destinations

1. Staying healthy in a rapidly changing society



2. Living and working in a health-promoting environment

3. Tackling diseases & reducing disease burden

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

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

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

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DESTINATION 3

Tackling diseases and reducing disease burden

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Destination 3
Expected impacts include:

- Reduced health burden of diseases in the EU and worldwide
- Reduced premature mortality from NCDs
- Promoted mental health and well-being
- Strengthened research and innovation expertise, human capacities and know-how for combatting communicable and non-communicable diseases
- Reduced (cross-border) health threat of epidemics and AMR pathogens, in the EU and worldwide
- Better knowledge of disease threats that allows to be involved and empowered to make and shape decisions for health, and better adhere to knowledge-based disease management strategies and policies

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Destination 3:

6 RIAs

- HORIZON-HLTH-2025-01-DISEASE-01: **Testing safety and efficacy of phage therapy for the treatment of antibiotic-resistant bacterial infections** Total: 45 M€ Project size: 15 M€
- HORIZON-HLTH-2025-03-DISEASE-02-two-stage: **Advancing innovative interventions for mental, behavioural and neurodevelopmental disorders** Total: 50 M€ Project size: 6-8 M€
- HORIZON-HLTH-2025-01-DISEASE-03: **Development of antibodies and antibody-derived proteins for the prevention and treatment of infectious diseases with epidemic potential** Total: 50 M€ Project size: 10 M€
- HORIZON-HLTH-2025-01-DISEASE-04: **Leveraging artificial intelligence for pandemic preparedness and response** Total: 35 M€ Project size: 6-8 M€
- HORIZON-HLTH-2025-01-DISEASE-06: **Implementation research addressing strategies to strengthen health systems for equitable high-quality care and health outcomes in the context of non-communicable diseases (GACD)** Total: 20 M€ Project size: 3-4 M€
- HORIZON-HLTH-2025-01-DISEASE-07: **Tackling high-burden for patients and under-researched medical conditions** Total: 30 M€ Project size: 6 M€

- Closure: 16 September 2025

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HORIZON-HLTH-2025-01-DISEASE-01: **Testing safety and efficacy of phage therapy for the treatment of antibiotic-resistant bacterial infections**

- Closure: 16 September 2025
- Instrument: RIA
- Total: 45 M€
- Project size: 15 M€

Expected outcome

- the best use of the state-of-the-art knowledge and resources for **an effective development of new treatment options for patients suffering from difficult-to-treat infections**
- **the availability of clinically useful phage therapies**
- **quantifiable, verifiable and replicable data on safety and efficacy of phage therapy for human use** and move faster towards market approval of **novel phage-based therapies against antimicrobial resistant infections**
- **innovative phage-based treatments as alternative therapeutic options** complementary to antibiotics

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HORIZON-HLTH-2025-01-DISEASE-01: **Testing safety and efficacy of phage therapy for the treatment of antibiotic-resistant bacterial infections**

Scope

- **develop phage-based therapies to treat bacterial infections** that do not respond to conventional treatment options.
- carry out **multicenter, multinational randomised controlled clinical trial (RCT) to generate scientific evidence demonstrating safety and efficacy of phage-based therapy** as stand-alone or in combination with standard-of-care (such as antibiotic or other innovative non-antibiotic-based treatment) for the treatment of difficult-to-treat bacterial infections.
- **personalised phage preparations or ready-to-use phage cocktails** are in scope and the topic is open to **any pathogen causing difficult to treat infections mainly due to AMR or to biofilms**, for any clinical indication and applying phage treatment in any route of administration.
- the use of **computational modelling and/or artificial intelligence (AI) tools** is encouraged.
- applicants should describe how they take into account **scientific advice or protocol assistance from the European Medicines Agency (EMA).**
- **sex and gender-related differences should be addressed**, where relevant and **effective contribution of social sciences and humanities (SSH)** disciplines is required.

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HORIZON-HLTH-2025-03-DISEASE-02-two-stage: **Advancing innovative interventions for mental, behavioural and neurodevelopmental disorders**

Scope (The disorders under Chapter 6 of the ICD-11. Rare diseases are excluded)

- perform **rigorous clinical studies into the safety and efficacy of the innovative interventions and their mode of administration,** ensuring adequate cohorts/sample sizes with adequate representation of the patient population, including in terms of age, sex and ethnicity.
- gain further **insight into the mechanism(s) of action of the innovative therapies and complementary approaches.**
- use and/or develop **technologies, including digital ones (e.g., (generative) AI, wearable technologies).**
- exploit **existing data, biobanks, registries and/or cohorts, together with the generation of new data.**
- engage all relevant stakeholders **to design end-user optimised interventions** as well as with public health authorities and regulators **to ensure a robust development pathway and further uptake of the intervention**.
- leverage already existing and emerging **state-of-the-art research infrastructures**, as well as results stemming from EU-supported research projects, where applicable.
- **effective contribution of social sciences and humanities** disciplines is required.
- **networking and joint activities** between all funded project will be strongly encouraged.

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HORIZON-HLTH-2025-01-DISEASE-03: **Development of antibodies and antibody-derived proteins for the prevention and treatment of infectious diseases with epidemic potential**

Scope

- exclusively pursue **the development of existing antiviral and prophylactic and therapeutic candidates** that are based on antibody and/or antibody-derived proteins **targeting at least one of the priority viruses** (listed in the Work Programme).
- proposals may focus **either on antibody or on antibody-derived proteins, or both.**
- conduct **preclinical studies of antibodies and antibody-derived proteins**, **prepare GMP quality test batches and carry out first in human clinical safety studies.**
- **participation of third countries where viruses addressed in the proposal are endemic or where outbreaks have occurred or are ongoing** is encouraged.
- **engagement with regulatory bodies in a timely manner** to ensure adequacy of the actions from a regulatory point of view is expected.
- leverage already existing and emerging **state-of-the-art research infrastructures.**

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HORIZON-HLTH-2025-01-DISEASE-04: **Leveraging artificial intelligence for pandemic preparedness and response**

Scope

- generate **new, or improve existing AI-based tools, methods and technologies**, geared towards greater safety, efficiency and impact of medical, societal or logistical countermeasures aiming at **the prevention, containment or control of epidemics or improved response management of health system**.
- scout, assemble and prepare appropriate **datasets generated across the EU and Associated Countries for the development, training and testing of targeted AI-supported generative assessment and prediction tools** in support of evidence-based policy and decision making for pandemic preparedness and response.
- leverage the capacities of the existing and emerging **data research infrastructures and the future European Health Data Space and the European Open Science Cloud architectures and research environments.**
- identify and address the current **technical, operational, and social limitations related to the (cross-border) access to quality data and to the smooth implementation of AI-driven solutions.**
- **engage with relevant stakeholders in the development, improvement, testing and validation of trustworthy and ethical AI-based tools and technologies,**
- **networking and joint activities** between all funded project will be strongly encouraged
- effective contribution of **social sciences and humanities disciplines** is required.
- attention should be paid to **detecting and mitigating gender, ethnicity and other biases,** aiming to develop AI models that are fair, trustworthy, and beneficial for all.

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HORIZON-HLTH-2025-01-DISEASE-06: **Implementation research addressing strategies to strengthen health systems for equitable high-quality care and health outcomes in the context of non-communicable diseases (GACD)**

Scope

- implementation research focused on **strategies to support health system transformation and/or strengthening** using evidence-based interventions in the context of NCDs that can be adapted to and implemented in LMICs and/or disadvantaged populations in HICs
- one or more evidence-based interventions (or complex interventions) focused on **building equity-orientated health systems change to tackle the growing burden of chronic conditions, including NCDs.**
- **justify the choice of intervention(s)** and **provide evidence of the intervention's effectiveness, acceptability, feasibility, and potential for long-term health and other impacts**
- explore the implementation of proposed intervention(s) for **a selected study population(s) taking into account the unique social, political, economic, and cultural context(s)** in which the study will take place
- the study population may include the **general population, people with one or more existing NCDs, those currently without NCDs, or a combination of both.** The study population may also include **patients with NCDs and chronic infectious disease(s) (e.g., HIV or tuberculosis)**
- an appropriate strategy for measuring **implementation research outcomes and real-world effectiveness outcomes and indicators**

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HORIZON-HLTH-2025-01-DISEASE-07: **Tackling high-burden for patients and under- researched medical conditions**

Scope (rare diseases, including rare cancers, and under-research medical conditions already addressed by projects funded under topic HORIZON-HLTH-2024-DISEASE-03-14-two-stage are not in the scope of this topic)

- **the gaps in robust, scientific evidence for improved policies and practices** to tackle such medical condition, and aim at identifying the **pathophysiological mechanism(s) and potential risk factors** of the medical condition through basic, pre-clinical and/or clinical research
- **demonstrate that the medical condition under study is insufficiently understood, inaccurately diagnosed or inadequately treated** in a significant proportion of patients
- **Sex and gender aspects, age, ethnicity, socio-economic, lifestyle and behavioural** factors should be taken into consideration
- **the development of biomarkers and other technologies for diagnosis, monitoring in patients, and stratification of patient groups** should be considered
- **the development of clinically relevant, (non-)human model systems** that can complement clinical investigations should be considered
- **exploitation of existing data, biobanks, registries and cohorts** is expected
- to enable sharing of samples, quality data and advanced analytical tools, **consideration should be made for using existing infrastructures.**
- **inclusion of patients or patient organisations** in the research is strongly encouraged
- effective contribution of **social sciences and humanities** disciplines is required

DESTINATION 5

Developing and using new tools, technologies, and digital solutions for a healthy society

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Destination 5: Expected impacts

- Europe's scientific and technological expertise and capabilities for innovation in new tools, technologies and digital solutions, and its ability to integrate innovation in healthcare is world-class.
- Citizens benefit from innovations that improve disease prevention, diagnosis, treatment and monitoring for better patient outcome and wellbeing.
- 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 of innovative diagnostic and therapeutic approaches, personalised medicine approaches, digital and other people-centred solutions for healthcare.
- Both the productivity of health Research and Innovation, and the quality and outcome of healthcare is improved.
- Citizens trust and support the opportunities offered by innovative technologies for healthcare, based on expected health outcomes and potential risks involved.

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Destination 5: Topics in 2025 – Single stage

- HORIZON-HLTH-2025-01-TOOL-01: **Enhancing cell therapies with genomic techniques**
- Closure: 16 Sept 2025
- Instrument: RIA
- Tot: 50M€
- Project size: 8-10M€

- HORIZON-HLTH-2025-01-TOOL-02: **Advancing cell secretome-based therapies**
- Closure: 16 Sept 2025
- Instrument: RIA
- Tot: 40M€
- Project size: 9-13M€

- HORIZON-HLTH-2025-01-TOOL-03: **Leveraging multimodal data to advance Generative Artificial Intelligence applicability in biomedical research (GenAI4EU)**
- Closure: 16 Sept 2025
- Instrument: RIA
- Tot: 50M€
- Project size: 15-17M€

- HORIZON-HLTH-2025-01-TOOL-05: **Boosting the translation of biotech research into innovative health therapies**
- Closure: 16 Sept 2025
- Instrument: RIA
- Tot: 80M€
- Project size: 4-8M€

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Enhancing cell therapies with genomic techniques

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

- **Engineering of synthetic genetic circuits** that operate as switches to **modulate the desired function(s) and their integration in the chosen cells** (derived from human cells, allogeneic), with the help of **new genomic techniques** (e.g. on-off switches and control systems, acting like a "sense-and-respond" mechanism);
- Use of **state of the art tools including digital ones** for the efficient construction and acceleration of the design-build-test cycles of the engineered cells containing the programmed functionalities;
- Use of suitable in-vitro and ex-vivo systems for the **demonstration of function and performance** of the engineered cells as well as their testing in **appropriate pre-clinical models for one specific therapeutic area** (chosen from 11 therapeutic areas mentioned);
- **Show safety and efficacy** of the engineered cells in-vivo and engagement and interaction with **regulatory authorities** for qualification of the developed cell-based therapy in view of the conduct of clinical studies (translation in humans is an asset).

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Advancing cell secretome-based therapies

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

- Selection of **secretome therapy based on human cells that has already been characterized** (main MoA elucidated, and therapeutic activity demonstrated in pre-clinical models);
  • Optionally inclusion of an engineering step of the secretome, for increased safety and improved therapeutic effect (genetic modification of parent cells is excluded);
- **All activities needed for regulatory and ethical approvals enabling the conduct of the clinical study** (full characterisation, standardised analytical methods, further pre-clinical studies in relevant models and appropriate quality assurance assays);
- Establishment of **manufacturing protocol for the selected secretome or its components**, including all steps of the biogenesis, processing of the conditioned media, extraction of the secretome or its components and its/their delivery to target site in the human body;
- Definition of relevant quality criteria for and **establishment of a fully GMP-conform production process** and **all necessary regulatory activities**, allowing to perform clinical trials;
- **Conduct of an interventional randomised controlled clinical trial comprising phase 1 and phase 2** to generate scientific evidence demonstrating safety and efficacy of the proposed secretome-based therapy;

To be delivered: at month 12: SOP for the GMP production
at month 24: documentation needed for the conduct of the clinical trial.

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Leveraging multimodal data to advance Generative Artificial Intelligence applicability in biomedical research (GenAI4EU)

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

- Develop new or re-purpose existing **Generative AI models** for biomedical research **across** various **medical fields** and/or **therapeutic indications**. The models should be robust, based on the use of **large-scale**, **complex**, and **multimodal high-quality data**.
- Develop a proof of concept with at least two use cases relevant for **predictive** and **personalised medicine** in different medical fields to demonstrate the **scientific added value** compared to currently used methods and/or potential future **clinical utility** of the Generative AI models in biomedical research.
- Develop or revise existing methodologies to **assess alignment with human values** and the use cases of developed and/or repurposed Generative AI models, their **applicability**, **performance**, **limitations** and **added value** in biomedical research. These methodologies should demonstrate the **technical**, **scientific**, and potential future **clinical utility**, **robustness** and **trustworthiness** of the developed or repurposed Generative AI models.

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Boosting the translation of biotech research into innovative health therapies

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

- **Clinical study of the targeted biotech-derived therapeutic product with either phase I, II or I/II** depending on the appropriate stage of development.
- **Convincing demonstration of significant economic potential of the final product(s)** for the Single Market.
- **A clear exploitation plan**, with a detailed proposed route to commercialisation, description of the IP ownership and benefit for the SME(s) and including an anti-shelving strategy, commercial forecasts for the product sales & revenue, and strategies for follow-up financing as well as market authorisation.
- Justification of the **patient populations that will benefit directly** from the development of the therapies; clinical indications affecting large patient populations will be favoured.

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DESTINATION 6

Maintaining an innovative, sustainable and globally competitive health industry

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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 supported by cross-sectoral R&I in the context of convergence of health technologies along with strengthened market positions.
- Health industry is working more efficiently along the value chain.
- Swift uptake of innovative health technologies and services through the provision of evidence and guidelines for stakeholders, policymakers and regulators.
- **Reliable and timely access to key manufacturing capacity for essential medical supplies.**

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Optimizing the manufacturing of Advanced Therapy Medicinal Products (ATMPs)

Scope (addressing **all of the following activities**):

- Design an **improved manufacturing process for one specific category of ATMPs** by:
  - Exploring the potential of platform technologies in manufacturing, quality control, non-clinical or clinical testing;
  - Integrating either computational modelling, automation, robotics or digital/AI solutions with meaningful and measurable impact;
- **Verify the improved performance** of the developed process
- Demonstrate a **reduction in the timeframe and costs** of manufacturing
- Demonstrate the **translatability, scalability, and robustness** of the process suitable for flexible manufacturing and deployment
- Assess the process and methods developed for their **regulatory validity and utility**
- Promote **green and sustainable industrial production and minimise environmental impact.**

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Always carefully read the whole topic texts and their conditions

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Thank you!

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