# FOCUS-EU

HEALTH

February-March 2025

Overview of EU and global policy developments



### Critical Medicines Act

The Critical Medicines Act (CMA) is a new regulation ensuring availability of critical medicines within the EU through supply chain diversification and strategic projects to establish, expand, or modernise production capacities for essential medicines and their components within the EU. The CMA establishes the Union list of critical medicines; offers expedited administrative support and easier access to funding; provides guidelines for state aid; and highlights collaborative public procurement among member states to address disparities and access to medicines in EU.

Source: Critical Medicines Act

### AI gigafactories for medicine and science

During the launch of InvestAI, the European Commission announced €20bn for developing "AI gigafactories" as one of the pilot cases for strategic technologies announced in the Competitiveness Compass. The large AI clusters are the largest public-private partnership in the world, funded with a mix of grants and equity; and specialised in training the most complex next-generation AI models for medicine or science. They are selected by the EuroHPC JU, a joint initiative developing a World Class Supercomputing Ecosystem in Europe. Hosted at leading European research and technology hubs, they will provide access to supercomputers to start-ups and industry alike.

*Invest AI is an initiative with €200 billion for investment in AI coming from existing EU funding programmes with a digital component, e.g. Digital Europe Programme, Horizon Europe, and InvestEU. It includes a layered fund, with shares of different risk/return profiles with the EU budget de-risking the investment of other partners. Member States can also commit funds from their Cohesion envelopes.*

Locations of EUROHPC AI factories ecosystem and more info

Source: InvestAI

## European Commission

### Guidelines on the AI system definition

The first rules under the Artificial Intelligence Act (AI Act) have started to apply. These include the AI system definition, AI literacy, and a very limited number of prohibited AI use cases that pose unacceptable risks in the EU, as outlined in the AI Act.

Source: Guidelines on AI system definition

### European model for AI with humanity at its heart

A focus paper on a European Model for Artificial Intelligence (AI) published by ESIR members reports on key aspects of creating a unique European approach to AI. Increased investment, policy alignment and skill development are identified as crucial in leveraging the potential of AI in science, government, and industry, and the need to develop and support a strategic, trans-border and cooperative approach to AI development in Europe.

*The Expert group on the Economic and Societal Impact of Research and Innovation (ESIR) is a high-level expert group that advises the Commission on the development of a forward-looking and transformative research and innovation policy throughout the social, green and digital transitions.*

Source: European Model for AI

### ERA Policy Agenda 2025-2027

The European Commission proposed the European Research Area (ERA) Policy Agenda for 2025-2027, a three-year roadmap that includes open science principles and research assessment reforms. It comprises three components: a policy narrative outlining goals and achievements; structural policies addressing areas like AI in science and research security; and work plans for each proposed policy and action. The Council is to adopt this agenda in May 2025, coinciding with the ERA's 25th anniversary.

Source: European Research Area Policy Agenda 2025-2027

### Booster

The European Commission has launched an updated **Horizon Results Booster** – known as the **Booster –** to help beneficiaries of Horizon Europe, bring their research or innovations to concrete use and to maximise their impact. The Booster services will run until 2028 and are free for beneficiaries with results at all levels of technology readiness, in any scientific or technological field. The Booster provides targeted coaching, assisting participants in developing strategies, business plans, risk assessments, and more. Depending on the types of results, the coaching provided can help launch an innovation on the market, disseminate relevant findings to policy makers, or identify opportunities for further applied research. Working with the Booster also provides an opportunity for Horizon Europe beneficiaries to enhance the visibility of their findings, ensuring that impactful results are easier to discover for all potential users.

Source: Booster Services

### European Research Council Work Programme 2025

The 2025 Work Programme of the European Research Council has been adopted by the European Commission. More than 2.7 billion euro will be available for research grants in 2025. This includes contributions from the countries associated to Horizon Europe. In addition, EU countries can allocate resources from the European Regional Development Fund (ERDF) to help the ERC fund proposals rated as excellent, but which cannot be funded due to budget constraints. These grants must remain hosted at an institution in the country which contributes their ERDF funds.

Source: European Research Council Work Programme 2025

## European Parliament

### Standalone FP10

The European Parliament has adopted a report that calls for a standalone research Framework Programme in the next long-term EU budget with significantly larger budget and reduced administrative burdens for participants compared to the current programme, Horizon Europe. This comes in conflict with the European Commission's intentions to place the programme within a broader EU Competitiveness Fund.

Source: EP on 10th Research Framework Programme

### New MEP Interest Group on health inequalities, prevention, and risk factors

A new MEP on Health Inequalities, Prevention and Risk Factors is launched in close collaboration with Member States, the Presidencies of the Council of the EU, the European Commission, other MEP intergroup and interest groups, the WHO, the Joint Action Prevent NCDs, civil society organisations, and other key stakeholders.
The group calls for, among others, the following:

- Continued funding for health and especially for prevention and risk factors, in the next Multi-annual Financial Framework (MFF) and ongoing funding for NGOs working on public health issues.
- Health in all policy areas, such as agriculture and food policy, education, workforce resilience, and security.
- Better conflict-of-interest monitoring to stop the undue influence on health policies.

Source: MEP Group Health inequalities, prevention & risk factors

### SANT committee upgrade

SANT, the committee on Public Health of the European Parliament, is now an independent, full-standing committee with a strengthened mandate. The committee was established in 2023, as a public health subcommittee. It was made up of 30 full members and 30 substitute members and it dealt with the pharmaceutical and cosmetic products, the health aspects of bioterrorism, the European Medicines Agency, and the European Centre for Disease Prevention and Control. SANT plays a crucial role in shaping EU health policy, overseeing public health programmes, regulating pharmaceuticals and addressing major health challenges.

Source: SANT Committee; SANT_2023

## European Council

### European Health Data Space regulation

The Council of the EU has adopted a new regulation to facilitate exchange and access health data at EU level. The European Health Data Space (EHDS) Regulation enters into force on 26

March 2025. The EHDS Regulation aims to establish a common framework for the use and exchange of electronic health data across the EU and applicable in different phases according to data types and use cases. Data exchanges for the first group of priority categories (including patient summaries) under primary use will go live in March 2029 with the rules on secondary use applicable to most data categories. On 26 March 2031, the EHDS will expand to additional data categories. It is expected to enhance healthcare quality, efficiency, and sustainability with cross-border access to medical records across the EU and re-use of anonymised or pseudonymised health data for research, innovation, public health, and policymaking, in compliance to GDPR. The current focus is on developing and adopting more than twenty Implementing Acts, as well as establishing the EHDS governance bodies in close collaboration between the European Commission, Member States, healthcare providers, researchers, and industry.

Sources: EHDS; EHDS Overview & Timeline

# European Medicines Agency

### European Shortages Monitoring Platform

The European Shortages Monitoring Platform (ESMP) is now live enabling marketing authorisation holders and national competent authorities to directly report information on supply, demand and availability of nationally and centrally authorised medicines during crises and preparedness actions led by EMA's Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG).

Source: European Shortages Monitoring Platform

### New Clinical Trial map

A new clinical trial map has been published as part of the work of ACT EU, to give patients and healthcare professionals easy access to comprehensive, real-time information about clinical trials in their area. Users can look for ongoing trials by geographic area and medical condition. Initially the map will be available in English with other EU languages added later. The map will be automatically updated on a weekly basis every Sunday.

Source: CT map

Demonstration of the map's features  Access the map here

### Infographic on orphan medicines

The EMA has published an updated infographic on orphan medicines and a revamped webpage with key highlights and figures.

Access the infographic here

### Warning about unregulated ATMPs

The EMA and national medicine agencies are warning the public about the dangers of unregulated advanced therapy medicinal products (ATMPs). ATMPs are therapies based on genes, cells or tissues. When regulated and authorised, they can bring important benefits for patients, but there are currently unregulated products being advertised to patients, sometimes online or on social media. Any suspicious cases should be reported to the national competent authorities.

Source: EMA_Warning_ATMPs

# Across the World

### Study: FDA offers flexibility, expedited review to first-in-class drugs more often than EMA

A RASP article by Jeff Craven on the differences in regulatory flexibility between the FDA and the EMA.

### Study: Nearly one-third of device adverse event reports were late or missing data

A RASP article by Mary Ellen Schneider on late, missing or invalid date data in medical device adverse event reports to FDA.

# Other

### JARDIN: €18 million Joint Action for rare diseases

The Joint Action on Integration of ERNs into National Health Systems (JARDIN) has been launched aiming to enhance diagnosis, treatment, and care for rare disease patients across the EU. This initiative involves all EU Member States, Norway, and Ukraine and focuses on integrating European Reference Networks (ERNs)—virtual collaborations of specialised healthcare providers—into national healthcare systems. Funded with €15 million from the EU4Health programme and €3.75 million from participating countries, JARDIN seeks to bring specialised expertise closer to patients, enabling knowledge sharing across the EU.

*Since 2017, the European Reference Networks (ERNs), operate as cross-border networks bringing together patient representatives and 1,600*

*European centres of expertise and hospitals to improve diagnosis and treatment of rare, low prevalence and complex diseases and conditions. The ERNs maintain disease registries and develop harmonised patient pathways and guidelines virtually through the Clinical Patient Management System (CPMS).*

Sources: JARDIN An overview of the ERN work to today

### Vision and Driving

The ERN-EYE has released a video with updates on current recommendations to help physicians advise patients with visual impairments on driving fitness.

Source: Vision and Driving - ERN-EYE

Key Figures on Europe 2024

The latest edition of *Key figures on Europe* with intuitive visualisations, innovative data presentations and concise text.

**A note to our readers**
**Click on Call, Consultation, Event title for details on conditions, documents, registration & submission**

# Calls

### IHI JU Call 9 (HORIZON-JU-IHI-2025-09-single-stage)*

Call topics:

Boosting innovation for understanding health determinants;

Boosting innovation for better assessment of the added value of innovative integrated healthcare solutions;

Boosting innovation for peopled centred integrated healthcare solutions.
**Deadline: 29 April 2025**

### Open call HORIZON-JU-IHI-2025-10-01-two-stage*

- Topic 1: Digital label: one source of comprehensive information for medical technology products
- Topic 2: Enabling and safeguarding innovation in secondary use of health data in the European Health Data Space (EHDS)
- Topic 3: Per- and Poly-fluoroalkyl substance (PFAS) exposure, emissions, and end of life management in the healthcare sector

**Deadline: Short proposal 23 April 2025**
**Full proposal 14 October 2025**

* The *IHI Calls 9 & 10*, are under the Innovative Health Initiative (IHI), a multi-sector public-private partnership launching funding calls since 2021 and is a successor to the IMI, the Innovative Medicines Initiative, launched in 2008.

### Call for collaborations in rare diseases

A list of collaboration opportunities (academia & industry) on RARB Natural History Study; Association of ABCA4 macular dystrophy and NF1 – disease burden; and CNV in BEST disease in paediatric population.

# Events

### Booster Info Session

An overview of Booster's free-of-charge services to support EU-funded projects in dissemination and exploitation of results.
This event requires Registration

**Date: April 1st 2025**

### Innovative Health Initiative (IHI) Online Q&A Session for Calls 9 and 10

This event requires registration.

**Date: 9 April 2025**

### Horizon Europe - Marie Skłodowska-Curie Actions (MSCA) Doctoral Networks 2025 - Call info day

**Date: 28 May 2025**



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