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# EU Innovation Network Workplan 2026

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See websites for contact details

Heads of Medicines Agencies [www.hma.eu](http://www.hma.eu)  
European Medicines Agency [www.ema.europa.eu](http://www.ema.europa.eu)

# 1. Introduction

This 2026 EU-Innovation Network Workplan lays out strategic goals and deliverables within the mandate of the EU-Innovation Network (EU-IN) that are intended to deliver on the European Medicines Agencies Network Strategy to 2028. The workplan also considers relevant actions described in the multi-annual work plans associated with these strategies.

The EU-IN has a joint mandate from EMA and HMA and is formed by members from both EMA and NCAs who are working together on the goals and deliverables outlined in this workplan.

Other relevant initiatives such as Accelerating Clinical Trials in the EU (ACT EU), the Network Data Steering Group (NDSG), the joint action on capacity building within the EU medicines regulatory network (IncreaseNET) and the implementation of the revised general EU pharmaceutical legislation are also considered with a view to supporting these initiatives and avoiding duplication.

## EU-IN priorities and objectives:

- Enable early-stage research in medicines and MedTech development in Europe and promote its efficient translation into authorised medicines and ultimately into clinical practice.
- Operate a regulatory intelligence function to capture emerging science and technology trends and developments.
- Support the development of capability and expertise within the network to address and engage with emerging innovation.
- Facilitate the delivery of strategic priorities for the EMRN as outlined in the European Medicines Agencies Network Strategy (EMANS) and associated workplans.
- Contribute to the competitiveness of the European Innovation ecosystem by promoting mutual exchange and interactions between medicine regulators and stakeholders.

# 2. EU Innovation and Competitiveness

## Objectives:

- Enable and accelerate innovative pharmaceutical developments to contribute to EU competitiveness.
- Increase impact of innovative developments by integration of scientific and technological advancements in the development of medicines.
- Support the development and implementation of the new EU pharmaceutical legislation and related acts e.g. Critical Medicines Act, Biotech Act, Life-Science Strategy, MDR/IVDR that are related to innovation and EU competitiveness.

## Deliverables/Actions:

- Share experience on innovative product developments and best practices in relation to innovation support and its coordination across EMA, the network and other competent authorities.
- Reach out to TTOs, biotech HUBs, investors and funding organisations to raise awareness of support to innovation and EU competitiveness in the pharmaceutical field.
- Organise a joint workshop promoting EU Innovation framework and competitiveness.

- Identify innovation-relevant provisions in new EU legislation and strategies, and coordinate EMRN feedback and practical implementation activities with relevant network groups and innovators across the EU.

**Sponsors:** EMA, FR, ES

### **3. Regulatory science and research**

**Objectives:**

- Facilitate progress in regulatory science by supporting network-led partnerships with key stakeholders (e.g. academia, research institutes, industry and funding bodies).
- Increase the impact of externally funded research projects by involvement of EMRN experts and strengthen collaboration among regulators.

**Deliverables/Actions:**

- Raise awareness of relevant research funding, in particular national funding calls and nationally funded projects, for awareness and potential involvement and leverage across NCAs at EU level and seek to influence future funding calls to address regulatory science research needs.
- Coordinate and discuss with NCA experts involved in research projects as relevant; share best practices, review experience and identify opportunities for further collaboration between NCAs experts.
- Promote the European Platform for Regulatory Science and the delivery of Regulatory Science Research Needs in conjunction with relevant national funders and academic researchers, and develop best practices.

**Sponsors:** NL, EMA

### **4. Horizon Scanning**

**Objectives:**

- Future proof and support decision making of the European Medicines Regulatory Network (EMRN) by conducting Horizon Scanning activities.
- Increase impact of Horizon Scanning activities by disseminating and contributing to the implementation of identified Horizon Scanning recommendations preparing the EMRN for opportunities and challenges identified.
- Further develop a sustainable model for efficient and coordinated EU horizon scanning to inform the development of regulatory tools and approaches and identify challenges and opportunities.

**Deliverables/Actions:**

- Identify, share and prioritise trends in medicine research and development and upcoming medicine technologies, intervention modalities, methodologies and methods.
- Publish and disseminate (workshops/webinars/online communication) horizon scanning reports on identified and prioritised trends.
- Progress on the implementation of recommendations identified in Horizon Scanning reports.

- Further develop and optimise horizon scanning methodology involving relevant stakeholders (e.g. HTA, JRC, WHO, IncreaseNET).

**Sponsors:** IE, EMA

## 5. Regulatory support tools

### Objectives:

- Increase EU attractiveness to conduct research, development and manufacturing of pharmaceuticals by providing optimised regulatory and scientific support for the development of innovative medicines.
- Increase impact of regulatory support by optimising dialogue between sponsors/applicants and assessors, with the aim of addressing scientific and regulatory issues.

### Deliverables/Actions:

- Support the review of advice offerings within the EMRN.
- Engage with stakeholders to explore the suitability of available regulatory supports from their perspective and how these could be further optimised for different scenarios, (e.g. repurposing).
- Continue to facilitate member state cooperation on national scientific advice.

**Sponsors:** IT, NL, DE (BfArM), DE (PEI), BE, ES, FR, EMA

## 6. Training, Education and Communication

### Objectives:

- Increase efficiency of the EU Innovation Ecosystem by promoting the use of support tools via outreach and engagement.
- Increase regulatory knowledge and awareness of researchers and developers from academia, research institutions and hospitals and small and medium-sized enterprises (SMEs) to facilitate the translation of research into innovative medicines.
- Promote Network training supporting capacity and capabilities related to innovative products and technologies.

### Deliverables/Actions:

- Finalise and disseminate EU-IN guidance (TEC guidance) on available regulatory support tools for researchers and developers.
- Develop an EU-NTC innovation curriculum for use within the EMRN including training on non-clinical, clinical and manufacturing innovation (3Rs/NAMs, modelling/simulation, innovative trial designs, novel manufacturing and analytics).
- Support follow-up actions to EMA roundtable with stakeholders on the 20th anniversary of the SME Regulation on training & education of SMEs and collaborations with agencies such as the European Innovation Council and SMEs executive agency.

**Sponsors:** BE, IT, ES, DE-BfArM, EMA

## 7. Borderline Classification

### Objectives:

- Reduce uncertainties on the classification of innovative borderline product.
- Promote harmonization for product classification across the EMRN by supporting a clear and harmonized EU framework.
- Increase impact by collaboration with bodies relevant to product classification, e.g. medical device partners and the SoHO network.

### Deliverables/Actions:

- Provide a discussion platform for competent authorities and representatives from other networks in relation to the classification of innovative borderline products.
- Support the implementation of classification related provisions in the new EU pharmaceutical and related legislation as requested.
- Continue to monitor and discuss actual legal cases on product classification.

**Sponsors:** AT, BE, EMA

## 8. Collaboration and Integration

### Objectives:

- Enable best use of resources and efficiency of the EU Innovation Ecosystem by promoting collaboration and cooperation with other initiatives of the European Regulatory Network.
- Contribute to the competitiveness of the European Innovation ecosystem by supporting initiatives enabling and fostering the EU as an attractive region to do research, development and manufacturing of medicines.

### Deliverables/Actions:

- Support the delivery of the objectives of the IncreaseNET joint action, particularly WP8 focussed on innovation and consider the role of the EU-IN in sustaining the outputs.
- Promote collaboration with other European Network Groups, e.g. QIG, NDSG and relevant initiatives e.g. ACT-EU, ICMRA Innovation Network, EU4Health joint action on supports for non-commercial clinical trial sponsors etc.
- Explore how EU-IN can collaborate with EC financed projects on medicine repurposing and facilitate the interactions and/or joint discussion between not-for-profit organisations, SMEs, MAH and regulators working on a repurposing of a medicine.

**Sponsors:** FR, IT, ES, EMA