FOCUS-EU

HEALTH

April 2025

Overview of EU and global policy developments

Guideline on RWD in NIS for real-world evidence

The European Medicines Agency (EMA) has adopted a reflection paper on the design and conduct of non-interventional ((NI) studies that generate real-world data (RWD) for regulatory purposes. These studies can be used to characterise a disease's epidemiology, describe care standards, conduct post-marketing monitoring, and investigate safety issues. The paper discusses the legal obligations and regulatory requirements governing NI studies, design, bias and confounding, governance and transparency, data quality, and model specifications in the statistical analysis.
NI study is defined as a clinical study that does not fulfil the criteria that characterise a clinical trial (e.g. randomization, blinding, controlled environments) as primary methods for assessing a drug's safety and efficacy. In contrast, NI studies use RWD gathered from routine medical practice, where patients are treated with marketed drugs and are not assigned to specific interventions.
The EMA aims to tap to the potential of the electronic healthcare data and data from registries to generate RWE that reflects clinical practice and complement and support data from RCTs by filling gaps in knowledge and reducing uncertainties about a product's safety and effectiveness.

Quality of the data is a key in assessing the appropriateness of RWD for regulatory use and includes reliability and relevance of the data, as well as how accurately the data represent standard clinical practice based on the research question.

The use and adaptation of the Data Quality Framework for EU medicines regulation is recommended to fit the specific data source, and it is important to develop expertise to implement at least one data quality framework in the guidance.

Sources:
EMA reflection paper RWD NIS
RAPS EMA RWE

European Commission

Egypt joined Horizon Europe

The European Commission and the Arab Republic of Egypt have successfully concluded negotiations on Egypt's association to Horizon Europe. The Agreement is expected to be signed by November 2025, with its entry coming into force subject to final validations by both parties. Transitional arrangements will apply in the meantime to allow Egyptian entities to apply for and be treated as "eligible entities" established in an associated country in Horizon Europe for calls implementing budget from 2025 onwards. Once signed, the agreement will enable Egyptian researchers and organisations to participate on equivalent terms as entities established in EU Member States. Egypt will be the second African country fully associated to Horizon Europe after Tunisia.

Source: Egypt joins Horizon Europe

EU-Switzerland EU Programmes Agreement

Switzerland's Federal Council has signed off the EU Programmes Agreement, that will allow the country to join Horizon Europe, the Euratom atomic research programme and the Digital Europe Programme. Switzerland's Association to EU4Health will become applicable after the Health Agreement is signed. The agreement still needs to go through various stages of ratification in Switzerland and in the EU before it can take effect. Swiss researchers have been allowed to apply for most Horizon Europe

calls since the beginning of the year under a transitional agreement.

Source: https://www.eeas.europa.eu/delegations/switzerland/eu_

HealthData@EU Central Platform

The European Commission has released the open-source HealthData@EU Central Platform, a significant advancement in establishing the European Health Data Space (EHDS). This platform facilitates secure, interoperable, and multilingual access to health datasets across EU Member States, promoting research, innovation, and informed policymaking. Built using open-source tools and standards like HealthDCAT-AP, it enables seamless integration with national health infrastructures.

Source https://ec.europa.eu/newsroom/sante/newsletter

Unitary patent

The first edition of the Unitary Patent Guidelines (UPG) have entered into force on 1 April 2025. The UPG provides guidance on the practice and procedure for unitary patent protection, in accordance with the applicable EU Regulations, the Rules relating to Unitary Patent Protection and the Rules relating to Fees for Unitary Patent Protection. The UPG are structured into seven parts and feature an alphabetical keyword index. All parts and indexes can be accessed via the Unitary Patent Guidelines web page. Any infringements and validity of both Unitary Patents and classic European Patents are dealt by at the Unified Patent Court (UPC) comprising of judges from participating Member States of the EU. The UPC is a Court common to currently eighteen EU Member States for which the Agreement on a Unified Patent Court (UPCA) has entered into force in 2023. The UPG are revised annually through an annual public user consultation. All comments are discussed with the SACEPO Working Party on Guidelines. Reports of the meetings are published under Updates on the Guidelines revision cycle web page.

Feedback on the first edition of the UP

Each spring, users are invited to provide feedback on the most recent version of the UP Guidelines. Suggestions for additions or improvements can also be sent at any time of the year to Guidelines@epo.org.

Source: https://www.epo.org/en/legal/guidelines-up

MSCA awards €608.6 million for doctoral programmes

The European Commission awarded €608.6 million through the Marie Skłodowska-Curie Actions (MSCA) to fund 126 doctoral programmes. These programmes will support over 2,500 researchers across Europe, fostering interdisciplinary and international collaboration. The grants aim to enhance research training, employability, and innovation in various fields, including science, technology, and humanities. The MSCA initiative strengthens Europe's research landscape by promoting excellence, mobility, and career development for early-stage researchers.

Source https://marie-sklodowska-curie-actions.ec.europa.eu/news

EU offering new opportunities for US researchers

The allowance offered by European Research Council (ERC) to researchers relocating from a third country to the EU is doubled from €1 million to €2 million and covers eligible start-up costs in their new European host institution. It is reported that the change comes at the request of Ekaterina Zaharieva, the European commissioner responsible for research and innovation. A number of other actions at EU level open up additional opportunities:

- In 2025, the Marie Sklodowska Curie Actions (MSCA) will include the Choose Europe initiative as a pilot providing early-career researchers with a pathway to permanent positions by linking MSCA grants to long-term career opportunities in European universities and research institutions
- In 2027, the Commission will expand the budget of the European Research Area Chairs programme, which aims to attract high-level researchers to universities and research centres in the Widening countries, by €170 million. This financial boost should create around 80 permanent positions.

Other local, regional and national governments, are mobilising funding to attract US researchers.

Source: https://www.politico.eu/article/europe

European Parliament

European University Alliances

A report calls for the need to strengthen existing European Universities alliances before expanding the initiative any further. The alliances were set up under the Erasmus+ programme as transnational networks of higher education institutions with the

aim of promoting collaboration, shared programmes and academic mobility. The document considers that these alliances as an important tool for EU competitiveness and it calls for a comprehensive funding strategy to support them that draws not only on Erasmus+, but also on other EU programmes.

The concept of the European University Alliances stems from a long-standing tradition of cooperation and exchanges between European universities that dates to the middle ages, with examples such as the travels of Desiderius Erasmus to academic cities, or the Grand Tour, a traditional educational trip through Europe, for young men from the 17th to the 19th century. It was first mentioned in the 2017 Sorbonne speech by Emmanuel Macron, President of the French Republic. The initiative was launched in 2019 and it was implemented as part of the 2021-2027 Erasmus+ programme. The European University Alliance Initiative, in its current form, was designed as a network of universities that promotes student mobility between campuses, and to advance pedagogical innovation. While the original idea was to launch just 20 alliances, 65 alliances exist today, bringing together more than 570 universities, representing more than half of the student population of the European Union.

Source: https://www.europarl.europa.eu/doceo/document/

European Medicines Agency

International Council for Harmonisation on MIDD

The International Council for Harmonisation (ICH) M15 guideline on Model informed Drug development (MIDD) Guideline has been published drawing comments from the pharmaceutical industry regarding lack of clarity on the use of MIDD in specific therapeutic contexts, such as paediatrics or new indications based on similarities; the need for more information on how to validate modelling software; and the need to be more comprehensive, particularly for therapeutic proteins and antibody-drug conjugates (ADCs). The industry calls for the provision of examples to illustrate how different modelling approaches can be applied in drug development, particularly for more complex models. Above all stakeholders highlight the need for a shared language to address interdisciplinary gaps and to bridge disciplines like biology, data science, and process engineering. High-quality models depend on a common language and mutual understanding of interdisciplinary topics, and different interpretations of terms and conceptualisations of tasks between disciplines can hinder model development.

Sources:

https://www.ema.europa.eu/en/ich-m15

https://www.raps.org/news-and-articles/news-articles/2025/4/

ACT EU workshop on ICH E6 R3 (principles & Annex 1)

The video recordings and presentations from the two-day workshop on the ICH E6 R3 guideline on good clinical practice (GCP) are now available here. Stakeholders are invited to engage with the revised guideline, which becomes effective in the EU on 23 July 2025.

Across the World

FDA seeks input on using HL7 FHIR standard for collecting RWD

The US Food and Drug Administration (FDA) seeks to standardise clinical study data collected from real-world data sources for regulatory submissions and has issued a notice seeking feedback from industry and other stakeholders on using Health Level Seven's (HL7) Fast Healthcare Interoperable Resources (FHIR) standard for leveraging real-world data into regulatory submissions.
Information is wanted in a number of topics such as:

- challenges with the current submission of clinical study data from RWD sources;
- Perceived opportunities and challenges using HL7 FHIR when considering aspects such as business processes and technical considerations.

Deadline: 60 days from 16.04.2025

Sources:

https://public-inspection.federalregister.gov/2025-06967.pdf

https://www.raps.org/FDA-input HL7-FHIR-standard

Other

DEP work programme 2025-2027

Access the work programme for Digital Europe with details on objectives, scope, outcomes, deliverables, and budget allocations for each topic. Click on title for all relevant documents & updates.

Horizon Europe strategic plan for 2025-2027

Access the Horizon Europe strategic plan for 2025-2027 which sets out the strategic orientations for the final years of Horizon Europe. Click on title to access the full document.

Software as medical device: Applicable requirements for market entry in the EU and US

A RAPS article by Vornicu R and Ronchi S, describing and comparing the requirements for market entry of medical device software in the EU and US, based on the different applications and intended use that software can have in healthcare. The article examines the EU Medical Devices Regulation (EU MDR; 2017/745), the European regulation applicable to medical devices, the Medical Device Coordination Group (MDCG) guidelines for medical device software in the EU and the Federal Food, Drug, and Cosmetic Act (FD&C Act), the US Code, Title 21, and the FDA guidelines applicable to medical device software.

Source; https://www.raps.org/Software-as-medical-device

Establishing and maintaining the right level of clinical evidence under the EU IVDR

A RASP article by Bogaert P, regarding the steps needed to demonstrate safety and effectiveness in the EU before in vitro diagnostic medical devices can be made available on the regional market; how to conclude that a device has a favourable benefit-risk ratio throughout the product lifecycle and how this conclusion should be continuously re-evaluated. Risk management, documentation of the state of the art, performance evaluation, and post-market performance follow-up are continuous processes that manufacturers must carry out until product obsolescence.
Source: https://www.raps.org/Establishing-right-level-of-cl#citation

New Widening tools to target research collaboration and management

A Science|Business article by Juliette Portala on Draft plans on new actions for Widening participation in Horizon Europe, including a pilot research management facility.

Source: https://sciencebusiness.net/-widening-tools-target

Consultations, Calls & Events

Reflection paper on a tailored clinical approach in biosimilar development

The EMA has opened to a public consultation a new reflection paper on biosimilars. The approach proposed aims to reduce the amount of clinical data required for the development and approval of biosimilars. Deadline: 30.09.2025.

EUDAMED WORKSHOP

This workshop will guide stakeholders on mandatory usage, timelines, and processes for EUDAMED, the EU's centralised database for medical devices.
Place & date: STUTTGART: 21/05/2025 online or in person

Registration by 5 May (physical participation, Stuttgart) or 12 May (online).

Webinar on conditions & requirements of Digital Europe "DIGITAL-2025-AI-08-COMPLIANCE" call "Digital solutions for regulatory compliance through data"

Date (online): 05.05.2025

Ask the Expert: Open Online Q&A Session on Legal & Financial Aspects of Horizon Europe

Register by clicking at title or Insert your questions in advance here

Date (online): 05.05.2025

Projects with Seal of Excellence under MSCA

This call is specific to support projects that have been awarded the Seal of Excellence under the Marie Skłodowska-Curie Actions (MSCA) postdoctoral fellowships calls but they failed to receive funding due to budget constraints. This call is carried out within the framework of the "RESTART 2016-2020" funding scheme, co-financed by Cyprus and the European Regional Development Fund. The call budget is €1 million and the funding per project can reach up to €170.000.

Deadline: 09.05.2025

Digital Europe Programme Kick-Off Webinar

Information session on the DEP work programme 2025-2027 with a focus on Swiss participation possibilities. Click on title to register.

Date (online): 29.04.2025

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

FOCUS - EU Health | Dime Limited
74 Oxford Road, OXFORD OX4 4PE, UK | info@dimeltd.com

Assisting our clients in their communications