What's New in Clinical Development Practices & Regulations Quarter 4 – 2025

PHARMACEUTICAL REGULATIONS

EU Clinical Trial Regulation (CTR) (EU No. 536/2014)

The European Commission (EC), the Heads of Medicines Agencies (HMA) and the European Medicines Agency (EMA) have issued a detailed report on clinical trial applications and the characteristics of clinical trials in the EU/European Economic Area during the 3-year CTR transition period, which ended 30-Jan-2025. *EU clinical trials during the 3-year CTR transition period*

A new clinical trial map is accessible via Clinical Trials Information System (CTIS) and gives comprehensive and current information on 10,000 EU clinical trials. *Clinical Trials Information System | European Medicines Agency (EMA)*

EU Pharmacovigilance Regulation

Pharmacovigilance (PV) in the EU is regulated by Regulation (EC) No. 726/2004 for EU-authorised medicinal products and by Directive 2001/83/EC for nationally authorised medicinal products.

The Implementing Regulation (EU) No. 520/2012, which outlines practical details for MAH, national CA and the EMA has been updated to "Implementing Regulation (EU) No. 2025/1466" and became effective 22-Jul-2025.

Implementing Regulation (EU) No. 2025/1466 aims to harmonise PV activities by Marketing Authorisation Holders, national Competent Authorities and the EMA. *Commission Implementing Regulation (EU) 2025/1466*

Health Technology Assessment (HTA) Regulation

On 05-Sep-2025, the EC issued a Frequently Asked Questions (FAQ) document to clarify HTA Regulation ((EU) 2021/2282). The FAQ will be maintained and updated on a regular basis. *b81a42c4-b2ba-47bc-b807-0c667c8de32e_en*

UK Upcoming Clinical Trial Regulation

The new Clinical Trial Regulation comes into effect in the UK on 28-Apr-2026 and is the most significant update to UK clinical trial regulations in two decades.

The Medicines and Healthcare products Regulatory Agency (MHRA) and the Health Research Authority (HRA) have developed regulations that are shaped by - and will benefit - patients, researchers, health professionals and industry.

The MHRA has published 10 guidance documents to support sponsors to prepare for the new legislation. *Medicines: clinical trials hub - GOV.UK* Additional training material is available on the MHRA inspectorate blog '6-month countdown'. *Clinical trials regulations: six-month countdown begins – MHRA Inspectorate*

Under the new Regulation, substantial modifications can be granted automatic approval through the Route B substantial modification process, provided certain eligibility criteria are met. On 01-Oct-2025, the MHRA launched a 6-month pilot scheme to help sponsors prepare for this. *New regulations for clinical trials – Join our Route B substantial modifications pilot – MHRA Inspectorate*

ICH GUIDELINES

ICH E6(R3) – Annex 1, Principles and Annex 2

- On 09-Sep-2025, the US Food and Drug Administration (FDA) published a final guidance for 'E6(R3) Good Clinical Practice'. *E6(R3) Good Clinical Practice (GCP) | FDA*
- In October 2025, ICH began publishing training material for E6(R3). Module 1, which is in three parts, is the first such training and is found under 'E6(R3) Training Materials'. *ICH Official web site : ICH*
- Accelerating Clinical Trials in the EU (ACT EU) has published a report following a workshop exploring the major changes of ICH E6(R3) Principles and Annex 1, in particular Sponsor (and Investigator) Oversight and Data Governance requirements. *ACT EU workshop report on ICH E6 R3*
- ICH E6(R3) Annex 2 will provide GCP considerations for non-traditional interventional clinical trials, including trials using Real World Data (RWD) and decentralised designs. There is a delay in the finalisation and adoption process and the guideline remains at step 3. *ICH Official web site : ICH*

ICH E20 Guideline

On 25-Jun-2025, ICH E20 Guideline 'Adaptive Designs for Clinical Trials' reached Step 2b and has been issued for public consultation in the ICH regions:
ICH_E20EWG_Step3_DraftGuideline_2025_0625_0.docx and in the US: *download*

ICH E14 Guideline

On 04-Sep-2025, ICH M14 Guideline 'General Principles on Planning, Designing, Analysing and Reporting of Non-interventional Studies that Utilise Real-World Data for Safety Assessment of Medicines' reached Step 4 and has entered the Step 5 implementation phase.
ICH_M14_Step4_Final_Guideline_2025_0905.pdf

ICH E2D(R1) Guideline

On 15-Sep-2025, ICH adopted E2D(R1) Guideline 'Post-Approval Safety Data: Definitions and Standards for Management and Reporting of Individual Case Safety Reports'.
ICH_E2D(R1)_Step4_FinalGuideline_2025_0819.pdf

ENHANCED ACCESS TO CLINICAL TRIALS & MEDICINE

World

On 01-Sep-2025, the EMA and World Health Organisation (WHO) published an overview of key initiatives and interactions following 10 years of collaboration in advancing global access to medicines. *EMA-WHO collaboration and partnership*

The Association of the British Pharmaceutical Industry (ABPI) and the Association of Medical Research Charities (AMRC) have met to discuss the challenges of ensuring diverse and under-represented populations are included in clinical research. This was a UK meeting, but their proposals apply globally. *abpi_amrc_airc_report_v06.pdf*

EU

To overcome geographical barriers, the EU-X-CT initiative looks at the challenges faced by sponsors, investigators and potential participants seeking to engage in EU cross-border clinical trials. The recommendations address many of the complex issues relating to accessing clinical trials in a country other than the participants' home country. *EU-X-CT - Recommendations - Version 1.0 - 17 June 2025.pdf*

UK

The UK's National Institute for Health and Care Research (NIHR) has signed a joint statement with more than 40 major UK research funders committing to encouraging inclusion of older adults in research. *Statement of intent: Integrating older age into health and care research | NIHR*

The MAPLE project aims to reduce the exclusion of clinical trial participants with a lower English language literacy. *MAPLE*

On 31-Jul-2025, the MHRA described how it will enable earlier access to innovative medical devices that address unmet clinical needs within the NHS and that show a clear benefit to patients. The policy will support investment in a new Early Access service, which will provide time-limited conditional access to promising technologies ahead of full regulatory approval. *MHRA outlines intent to speed up patient access to innovative medical devices - GOV.UK*

On 06-Aug-2025, the MHRA and the National Institute for Health and Care Excellence (NICE) described how their 10 Year Health Plan will lead to faster access to medicines. *Patients will receive medicines 3-6 months faster under 10-Year Health Plan, as regulators set out plans - GOV.UK*

PUBLICATIONS, ARTICLES AND GUIDANCE

WORLD

- On 07-Oct-2025, WHO launched the Global Clinical Trials Forum (GCTF). The GCTF supports the implementation of WHO's Guidance for Best Practices for Clinical Trials. *WHO launches the Global Clinical Trials Forum*
- The EMA is calling for increased global awareness of antimicrobial resistance: *Antimicrobial resistance | European Medicines Agency (EMA)*; *antimicrobial-resistance-act-now-protect-our-present-secure-our-future_en.pdf* and Podcast *Podcast: Inside EMA | European Medicines Agency (EMA)*

EU

- The EMA has published its third annual report on using Real World Evidence (RWE) framework to support the EU regulatory decision-making process. *Real-world evidence framework to support EU regulatory decision-making*
- The EMA has issued a draft reflection paper on Patient Experience Data (PED) and has opened a public consultation, ending 31-Jan-2026. *Patient experience data (PED) reflection paper | European Medicines Agency (EMA)*

USA

- In June 2025, the FDA issued final guidance entitled 'Conducting Remote Regulatory Assessments [RRAs] – Questions and Answers'. *Guidance for Industry: Conducting Remote Regulatory Assessments - Questions and Answers*
- On 16-Jul-2025, the FDA released new draft guidance entitled 'Development of Cancer Drugs for Use in Novel Combination – Determining the Contribution of the Individual Drugs' Effects'. *Development of Cancer Drugs for Use in Novel Combination - Determining the Contribution of the Individual Drugs' Effects | FDA*
- On 23-Jul-2025, the FDA's Center for Drug Evaluation and Research (CDER) released a White Paper encouraging the adoption of Selective Safety Data Collection (SSDC), referencing the International Council for Harmonisation E19 Guideline. *Selective Safety Data Collection (SSDC) Demonstration Project | FDA*
- On 19-Aug-2025, the FDA issued draft guidance 'Approaches to Assessment of Overall Survival [OS] in Oncology Clinical Trials'. *2025-15796.pdf*

- On 22-Aug-2025, the FDA began a daily publication of adverse event (AE) data from the FDA Adverse Event Reporting System (FAERS). This is part of FDA's commitment to modernising safety monitoring, transparency and real-time protection of public health. *FDA Begins Real-Time Reporting of Adverse Event Data | FDA*
- In September 2025, the FDA issued draft guidance entitled 'Safety Labeling Changes – Implementation of Section 505(o)(4) of the FD&C [Federal Food, Drug, and Cosmetic] Act'. *Safety Labeling Changes-Implementation of Section 505(o)(4) of the FD&C Act*
- On 11-Sep-2025, the FDA issued a draft guidance 'Development of Non-Opioid Analgesics for Chronic Pain'. *Development of Non-Opioid Analgesics for Chronic Pain | FDA*
- On 15-Sep-2025, the FDA published an article on the Development and Use of Office of New Drugs Custom Medical Queries for Safety Analyses of Clinical Trial Data. *The Development and Use of Office of New Drugs Custom Medical Queries for Safety Analyses of Clinical Trial Data - PubMed*

UK

- In September 2025, the HMRA published 'Standardised Format for Medical Devices Post-Market Surveillance Report'.
  Medical_devices_Standardised_format_for_the_post_market_surveillance_report.pdf

ARTIFICIAL INTELLIGENCE (AI) IN HEALTHCARE

AI in Scientific Research

On 08-Oct-2025, the EC's Joint Research Centre (JRC) published a report to provide a foundation for future European policy on AI in science. *JRC Publications Repository - The Role of Artificial Intelligence in Scientific Research*

UK Improve on Approval Times

New published data shows that the UK MHRA's risk-proportionate approach to authorising clinical trial applications is delivering many decisions ahead of the statutory timelines. Digital innovation, AI and risk-proportionate oversight mean that lower-risk studies can move ahead without unnecessary delay, while higher-risk trials still receive the detailed expert review they require. *UK clinical trial approval times twice as fast with AI and reforms - GOV.UK*

New UK Commission to Accelerate AI use in the NHS

A new rule book for AI in Healthcare, is due to be published in 2026. A new National Commission has been set up to provide AI advice for MHRA and aim for the NHS to gain quicker access to the latest AI tools. *New Commission to help accelerate NHS use of AI - GOV.UK*

Thank you for taking the time to read this Industry Update from S-cubed

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