What's New in Clinical Development Practices & Regulations Quarter 1 – 2026

PHARMACEUTICAL REGULATIONS

EU 'Pharma Package' – New Regulation and New Directive

As detailed in S-cubed Newsletter Q3 2025, the 'pharma package' aims at making the EU pharmaceutical industry fairer and more competitive. *Reform of the EU pharmaceutical legislation | European Medicines Agency (EMA)*

On 11 December 2025, the European Medicines Agency (EMA) published details of co-legislators having reached an agreement on the new EU pharmaceutical legislation. *EMA welcomes political agreement on new EU pharmaceutical legislation | European Medicines Agency (EMA)*

UK Upcoming Clinical Trial Regulation

The new UK Clinical Trial Regulation comes into effect on 28-Apr-2026. As detailed in S-cubed Newsletter Q4 2025, the Medicines and Healthcare product Regulatory Agency (MHRA) published 10 guidance documents to support Sponsors to prepare for the new legislation. Four additional guidance documents have now been published: *Medicines: clinical trials hub - GOV.UK*

MHRA guidance on the alignment of the new Regulation and the Declaration of Helsinki. *Declaration of Helsinki and Clinical Trial Regulations alignment - GOV.UK*

MHRA blog article on Sponsor's and Site's responsibilities to ensure adequate insurance or indemnity to cover potential liabilities. *Insurance Review in Phase 1 Clinical Trials – MHRA Inspectorate*

ICH GUIDELINES

ICH Guidelines

During a biennial ICH meeting (in Singapore, 18-19 Nov-2025), the following guidelines were approved or endorsed: *ICH Official web site : ICH* and *ICH Official web site : ICH*

- Approval of concept papers: **E23** 'Considerations for the Use of Real-World Evidence (RWE) to Inform Regulatory Decision Making' and **M18** 'Framework for Determining the Utility of Comparative Effective Studies in Biosimilar Development Programs'.
- Final guidance adopted and enter implementation phase: **M11** 'Clinical electronic Structured Harmonised Protocol (CeSHarP)', **M14** 'Use of Real-Word Data for Safety Assessment of Medicines' and **E2D(R1)** 'Post-Approval Safety Data: Definitions and Standards for Management and Reporting of Individual Case Safety Reports'.
- Draft guidance has been endorsed: **E22** 'General Considerations for Patient Preference Studies' and **E20** 'Adaptive Designs for Clinical Trials'. The E22 Expert Working Group has issued training module and presentation. *ICH_E22 Training material.pdf* and *ICH_E22 Presentation_1211.pdf*)

On 15-Jan-2026, ICH announced that three Expert Working Groups have released update materials for **E2B(R3)** 'Individual Case Safety Report Specification', **M4Q(R2)** 'Common Technical Document' and E6(R2) Good Clinical Practice'. *ICH Official web site : ICH*.

The MHRA has published UK specific annotations to E6(R3). *UK-specific annotations ICH E6(R3)* and a NHS Health Research Authority (HRA) blog gives detail of the changes to definitions and terminology. *Blog: clinical trials regulations – changes to definitions and terminology - Health Research Authority*

INDUSTRY INITIATIVES

Measures to Improve the EU Health Sector

On 16-Dec-2025, the EC announced their plans to improve access and increase competitiveness. Included in these measures is a Biotech Act, revised rules for medical devices and a 'Safe Hearts Plan' to tackle cardiovascular diseases. *New measures to make EU health sector more innovative, competitive and resilient*

Pilot Initiative for Coordinated Assessment of Medical Devices in the EU

Sponsors wanting to participate, will submit a single application for coordinated assessment. This initiative will help competent authorities to build an EU coordinated assessment system. This will be mandatory when Article 78(14) MDR and Article 74(14) IVDR (modified by Regulation (EU) 2024/1860 Articles 1(3) and 2(2) respectively) become effective. *Pilot coordinated assessment for CI/PS - European Commission*

Regulation (EU) 2024/1860: *Regulation.*

EMA to Accelerate Development of Medicines for Emergencies

The EMA's Emergency Task Force (ETF) will offer a new scientific advice process for the most promising medicines and vaccines under development for public health threats. *Improved scientific advice for medicines for public health threats including antimicrobial resistance | European Medicines Agency (EMA)*

FAST-EU – Pilot to Accelerate Strategic Clinical Trials

On 21-Jan-2026, the Heads of Medicines Agencies (HMA) launched a voluntary pilot initiative (Facilitating and Accelerating Strategic Clinical Trials in the EU/European Economic Area 'FAST-EU'). FAST-EU offers Sponsors the opportunity to test (under the existing legal framework) shorter evaluation timelines for their multinational trials. *Heads of Medicines Agencies: Recently Published*

Electronic Product Information

The introduction of electronic product information (e-PI) is proposed as part of the European Pharmaceutical legislation review. Many European competent authorities have set up pilot projects to evaluate their readiness for phasing out paper based product information and introducing e-PI. *IATF-ePI-Pilots-Survey.pdf*

Rare Therapies and UK Regulatory Considerations

A patient-focused regulatory framework is required to address the unique challenges of rare diseases and support timely access to innovative therapies. *Rare therapies and UK regulatory considerations - GOV.UK*

GUIDANCE DOCUMENTS AND PUBLICATIONS

Europe and USA

- The use of Artificial Intelligence (AI) in drug development is expanding and evolving. On 14-Jan-2026, the EMA and the US Food and Drug Administration (FDA) jointly issued 10 principles for good AI practice in medicines lifecycle. *guiding-principles-good-ai-practice-drug-development_en.pdf*

EU

- New guidance on the conduct of clinical trials during public health emergencies in the EU. This guidance document is open for public consultation until 30-Apr-2026. *New guidance on the conduct of clinical trials during public health emergencies in the EU | European Medicines Agency (EMA)*
- The EMA has opened a consultation relating to updating Good Pharmacogenomic Guideline. The consultation will continue until 31-Mar-2026. Genomics has evolved over the years and the guideline requires revision to reflect this. *Concept paper on the guideline revision on good pharmacogenomic practice*
- The EMA has updated its Q&A document on the management of safety signals. *Q&A on signal management*
- The EMA has issued a new scientific guideline 'Guideline on non-inferiority and equivalence comparisons in clinical trials'. The guideline is open for public consultation until 31-May-2026. *Draft guideline on non-inferiority and equivalence comparisons in clinical trials*
- The EC has released new and updated guidance documents in Volume 10, which apply to clinical trials under the Clinical Trial Regulation ((EU) No. 536/2014). *New and updated documents - EudraLex Volume 10: Clinical trials guidelines - Public Health*
- Following a paediatric clinical trials workshop, held in July 2025, organised by the Clinical Trials Coordination Group (CTCG), EMA's Paediatric Committee (PDCO) and the Methodology Working Party, a meeting report and presentation slides have been published. *ACT EU meeting report - Workshop on paediatric clinical trials*

USA

- On 16-Dec-2025, the FDA issued two final guidance documents on clinical trial safety reporting:
  - 'Investigator Responsibilities – Safety Reporting for Investigational Drugs and Devices' *Investigator Responsibilities--* and
  - 'Sponsor Responsibilities – Safety Reporting Requirements and Safety Assessment for IND and Bioavailability/Bioequivalence Studies' *Sponsor Responsibilities—*
- On 19-Dec-2025, the FDA published final guidance entitled 'Processes and Practices Applicable to Bioresearch Monitoring [BIMO] Inspections'. *Guidance for Industry- Processes and Practices Applicable to Bioresearch Monitoring Inspections*
- In January 2026, the FDA published a draft guidance on modernising statistical methods for clinical trials, entitled 'Use of Bayesian Methodology in Clinical Trials of Drug and Biological Products'. *Draft Guidance for Industry Use of Bayesian Methodology in Clinical Trials of Drug and Biological Products*
- In January 2026, the FDA published a draft guidance 'M4Q(R2) The Common Technical Document for the Registration of Pharmaceuticals for Human Use' *M4Q(R2) The Common Technical Document for the Registration of Pharmaceuticals for Human Use: Quality | FDA*

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

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