What's New in Clinical Development Practices & Regulations Quarter 3 – 2025

REGULATIONS, GUIDELINES AND ICH

EU – FAQ Clinical Trial Regulation (EU) No 536/2014

The European Medicines Agency (EMA) and the Clinical Trials Coordination Group have jointly published a FAQ document for clinical trials submitted under (EU) No 536/2014. *CLINICAL TRIAL COORDINATION GROUP (CTCG)*

The EMA has issued updates to the 'Guide to Clinical Trials Information Systems (CTIS) Training Catalogue' *CTTM02_Guide to CTIS Training Catalogue* and the 'Sponsor Handbook' (version 6.0) *CTIS Sponsor Handbook*

EU – 'Pharma Package' New Regulation and Directive

In April 2023, the European Council (EC) published a proposal for a new Regulation and Directive aiming at making the EU's pharmaceutical sector fairer and more competitive. The EC is now ready to begin negotiations with the European Parliament. *'Pharma package': Council agrees its position on new rules for a fairer and more competitive EU pharmaceutical sector - Consilium*

EU – Revising Good Manufacturing Practice (GMP) Guidelines

On 7 July 2025, the EC launched a 3-month stakeholder consultation on revisions to the European GMP Guidelines. *Stakeholders' Consultation on EudraLex Volume 4 - Good Manufacturing Practice Guidelines: Chapter 4, Annex 11 and New Annex 22 - European Commission*

GB – Medical Device Regulations

On 16 June 2025, the Post-Marketing Surveillance (PMS) Regulation came into force in Great Britain and requires medical device manufacturers to proactively monitor the safety and performance of their products once on the market. *First major overhaul of medical device regulation comes into force across Great Britain - GOV.UK*

Before the end of 2025, the Medical Device Regulation 2002 for Great Briain will be amended to align with the EU by incorporating the EU Common Specifications for high risk *in vitro* diagnostics (IVD). *Government to align with European specifications on high risk in vitro diagnostic devices to reduce regulatory burden - GOV.UK*

UK – Implementation Period for New Regulations for Conducting Clinical Trials in the UK

The new Regulation comes into force on 28 April 2026. The implementation period has begun and the Medicines and Healthcare products Regulatory Agency (MHRA) has issued guidance on transitional agreements:

- The guidance explains whether specific regulatory activities relating to clinical trial approvals are subject to the old regulations from 2004 or to the new amended regulations of 2025. *Clinical trials regulations: transitional arrangements - GOV.UK*
- Specific guidance for reporting safety events. *Clinical trials for medicines: collection, verification, & reporting of safety events - GOV.UK*

ICH Guidance Documents

E6(R3) - The EMA shares comments on E6(R3) Annex 2 with the ICH Expert working group. *Overview of comments received on ICH E6 (R3) Guideline for good clinical practice – Annex 2*

E21 – ICH has issued a draft E21 Guideline 'Inclusion of Pregnant and Breastfeeding Individuals in Clinical Trials'. *New guideline on inclusion of pregnant and breastfeeding individuals in clinical trials | European Medicines Agency (EMA)*

E20 – ICH has issued a draft E20 Guideline 'Adaptive Designs for Clinical Trials'. *ICH Official web site : ICH*

INITIATIVES

EU

- The EC and EU Member States have launched a pilot project as part of the COMBINE programme. Combined studies may be included in this pilot in order to test a more efficient way approving these types of studies. *COMBINE Project 1 – pilot "all-in-one" coordinated assessment - European Commission*
    - Combined studies are studies involving both clinical trials of medicines and performance studies of medical devices.

UK

- On the 16 June 2025, the Government announced the UK 10 Year Health Plan. The Plan aims to encourage millions of people to take part in research and at the same time reduce the clinical trial set-up time. For further information, visit *Unprecedented boost for clinical trials under 10 Year Health Plan - GOV.UK* and *NHS App to be used for sign-up to clinical trials | UKAuthority* and *MHRA Performance Data - GOV.UK*
- The MHRA has been designated a World Health Organisation (WHO) Listed Authority *MHRA designated as WHO-Listed Authority: a milestone for UK life sciences and global health - GOV.UK*)
- On 23 July 2025, a new UK Regulations came into force *The Human Medicines (Amendment) (Modular Manufacture and Point of Care) Regulations 2025*. This allows certain personalised medicines to be manufactured at or near the point of care (including hospitals, clinics and mobile healthcare settings). *Cutting-edge personalised treatments, made while you wait, will deliver specialised care to patients more quickly - GOV.UK*.
- Route B Substantial Modification Pilot *The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025*.
    - Section 11B of the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 explicitly states the criteria for a route B substantial modification.

USA

- The Food and Drug Administration (FDA) aims to reduce review timelines by shifting focus and re-establishing its goals. They will use AI and big data and concentrate on neglected and rare diseases. The FDA's priorities are outlined in detail in a *JAMA Viewpoints* article, published 10 June 2025. *Priorities for a New FDA | Regulatory Agencies | JAMA | JAMA Network*
- On 17 June 2025, the FDA announced details of the Commissioner's National Priority Voucher (CNPV) programme. This is an incentive scheme for drug developers specifically supporting US interests. *FDA to Issue New Commissioner's National Priority Vouchers to Companies Supporting U.S. National Interests | FDA*

AI IN HEALTHCARE

AI in Pharmacovigilance (PV)

In 2022, the Council for International Organisations of Medical Science (CIOMS) established a working group on AI in PV in order to create and promote principles and guidance for the use of AI or intelligence augmentation in PV. Earlier this year, CIOMS issued a draft report to provide guidance to those working in PV and also to organisations developing AI solutions for the PV domain. *CIOMS-WG-XIV_Draft-report-for-Public-Consultation_1May2025-1.pdf*

The National Library of Medicine's article on AI in PV collates previously published research. *Artificial intelligence in pharmacovigilance: advancing drug safety monitoring and regulatory integration - PMC*

Workplan to Optimise Use of Data and AI

EMA and Heads of Medicines Agency have worked with the Network Steering Group to publish a joint workplan for 2025-2028. The workplan 'Data and AI in Medicines Regulation' consists of six workstreams and lays out a roadmap for managing, analysing and sharing data across the network, whilst adhering to high security and ethical standards. *NDSG workplan 2025-2028*

FDA Launches an Agency-Wide AI Tool (Elsa)

Elsa is a generative AI tool designed to help employees work more efficiently. It was launched following a successful pilot programme with FDA's scientific reviewers. Elsa uses a secure platform to access internal documents. Data submitted by the regulated industry is not included thus safeguarding sensitive research/data handled by the FDA. *FDA Launches Agency-Wide AI Tool to Optimize Performance for the American People | FDA*

UK and HealthAI Global Regulatory Network

The HealthAI Global Regulatory Network is an international platform focusing on the safe and effective use of AI in healthcare. It brings together regulators from ten different countries, including the UK, in order to strengthen AI oversight. *UK MHRA leads safe use of AI in healthcare as first country in new global network - GOV.UK*

CLINICAL TRIAL TRANSPARENCY

Improve Transparency in Trial Design & Reporting

SPIRIT 2025 and CONSORT 2025 have been published simultaneously in five leading medical journals and replace SPIRIT 2013 and CONSORT 2010.

Reliable clinical trial results can only be accomplished if trials are conducted properly and their methods reported fully. The SPIRIT and CONSORT checklists have been designed over several decades in order to improve clinical trial design, conduct and reporting. The recent updates reflect advances in clinical trial methodology and regulation.

- SPIRIT - Standard Protocol Items: Recommendations for Interventional Trials
- CONSORT - Consolidated Standards of Reporting Trials

Published statements | consort-spirit.org

EMA Policy 0070

The aim of EMA's policy on publication of clinical data for medicinal products for human use (referred to as Policy 0070) is to increase transparency in development and evaluation of medicines.

Policy 0070 came into force on 01 January 2015 and a year later, the EMA published external guidance on its implementation. This guidance is revised periodically and the current document is version 1.5, dated 14 May 2025. *External Guidance on the implementation of Policy 0070 (v1.5)*

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

Prepared by:

Christina Hägglund, QA Manager
S-cubed Ltd
Email: christina.hagglund@s-cubed.co.uk
Website: www.s-cubed-global.com