What's New in Clinical Development Practices & Regulations Quarter 2 – 2026

PHARMACEUTICAL REGULATIONS

EU Pharmaceutical legislation

During the European Medicines Agency (EMA) Management Board meeting in June 2026, the Board noted that governance structures for implementing the new EU pharmaceutical legislation are largely in place, with the EMA, European Commission (EC) and national authorities preparing further guidance and implementation measures once the legislation is formally adopted. EMA Management Board: highlights of June 2026 meeting | European Medicines Agency (EMA)

Clinical Trial Transparency Requirements in the UK

The new Clinical Trial Regulation came into effect in the UK on 28 April 2026. New legal research transparency requirements have been introduced in the UK as part of the regulation.

Key requirements include:

- Trial registration: Sponsors must register clinical trials in a public registry before the first participant provides consent or within 90 days of trial approval, whichever occurs first.
- Results publication: A summary of trial results must be submitted to the registry (or registries) where the trial was registered within 12 months of the global end of the trial.
- Lay summaries: For trials subject to the new rules, sponsors must provide an accessible summary of results to participants (or the person who provided consent) within 12 months of trial completion.

A qualifying public registry must be a WHO-recognised registry. The Health Research Authority (HRA) recommends the ISRCTN registry. Registration in the Clinical Trials Information System (CTIS) alone does not satisfy UK requirements. Research transparency requirements for clinical trials - Health Research Authority

Transitional Arrangements:
The applicable requirements depend on a trial's status on 28 April 2026:

- Trials completed before 28 April 2026: Not subject to the new transparency requirements but must continue to meet existing ethics committee registration conditions.
- Ongoing trials on 28 April 2026: Must comply with registration and results publication requirements. Unregistered trials must be registered within 90 days of the Regulations coming into force. The lay summary requirement does not apply, although sponsors are encouraged to provide one.
- Trials submitted on or after 28 April 2026: Must comply with all new transparency requirements.

Additional transitional provisions apply to Phase 1 trials and trials with existing registration deferrals, including automatic extensions of certain deferral periods. Clinical trials for medicines: Clinical Trials Regulations transitional arrangements

MEDICAL DEVICE REGULATIONS

New EC Implementing Rules for Medical Devices

On 18 May 2026, the EC has introduced new implementing rules under the Medical Devices Regulation (MDR) to improve consistency, predictability and efficiency in notified body conformity assessments.

Implementing Regulation (EU) 2026/977 sets requirements for assessment timelines, permitted clock-stops, monitoring and reporting of assessment duration and costs, and clearer procedures for re-certification. The rules apply from 25 February 2027, with cost and timeline reporting requirements applying from 1 January 2028. SANTE - Medical Devices: New Implementing Regulation sets out uniform requirements for conformity assessment and notified bodies

European Database on Medical Devices (EUDAMED) Mandatory Modules

From 28 May 2026, four modules of EUDAMED became mandatory under the EU medical device framework: Actor Registration, Unique Device Identification/Devices Registration, Notified Bodies and Certificates, and Market Surveillance.

The remaining modules covering Post-Market Surveillance/Vigilance and Clinical Investigation/Performance Studies will become mandatory once available. Overview - Public Health - European Commission

ICH GUIDELINES

Updated and Expanded ICH Q9(R1) Quality Risk Management Briefing Pack

The ICH has released a revised and enhanced Q9(R1) Quality Risk Management Briefing Pack to facilitate the adoption of a structured and consistent quality risk management (QRM) approach across pharmaceutical development, manufacturing, and distribution. The updated briefing pack incorporates the latest QRM recommendations outlined in the revised ICH Q9(R1) Guideline, which was finalised in 2023. ICH Official web site

New ICH Training Module for M15 Guideline

On 9 April 2026, the International Council for Harmonisation (ICH) released a training module for the M15 Guideline on Model-Informed Drug Development (MIDD).

Developed by the M15 Expert Working Group, the module provides an overview of the guideline and its key principles, including the assessment of MIDD evidence, model evaluation, and reporting and submission requirements. The training supports implementation of the M15 Guideline, published in January 2026. ICH guidelines and training module

ICH Releases Overview of M11 Harmonised Protocol Guideline

On 12 May 2026, the ICH M11 Expert Working Group issued a final overview of the M11 Guideline on Clinical electronic Structured Harmonised Protocol (CeSHarP), which was adopted in November 2025.

The guideline provides a standardised approach for clinical trial protocols through a harmonised design framework, protocol template and technical specifications for electronic exchange. It aims to improve consistency, efficiency and interoperability in the creation, review and sharing of clinical trial protocols across all phases and therapeutic areas. ICH M11-expert-working-group-issues-final-overview-presentation

INDUSTRY INITIATIVES AND PROPOSALS

The MHRA and FDA strengthening collaboration on medical device regulation

On 2 April 2026, the MHRA announced enhanced regulatory cooperation with the FDA on medical devices to support patient access to safe, innovative technologies in the UK and US.

The initiative builds on the broader US–UK pharmaceutical partnership and aims to strengthen regulatory alignment while maintaining independent regulatory decision-making and high safety standards. The MHRA and FDA will explore measures to improve regulatory compatibility, including potential mutual recognition mechanisms for parts of device approval processes, reducing duplication

for manufacturers and streamlining market access for new medical technologies. UK and US deepen regulatory cooperation on medical devices

FDA Advances Real-Time Clinical Trials

On 28 April 2026, the US Food and Drug Administration (FDA) announced two major initiatives to advance the implementation of real-time clinical trials (RTCTs): the launch of two proof-of-concept RTCTs and a Request for Information (RFI) on a broader pilot programme. The FDA was inviting comments on the proposed pilot programme until 29 May 2026, with trial selection for the programme expected to be completed in August 2026. FDA Real-Time clinical trials.

EC Publishes Analysis Supporting Proposed Biotech Act

The EC has published its analysis supporting the proposed Biotech Act, which aims to strengthen the EU biotechnology and biomanufacturing sectors, particularly in healthcare.

The initiative seeks to accelerate biotechnology innovation, improve market access, simplify regulation, reduce administrative burden and enhance EU competitiveness while maintaining high standards of safety and public health protection. Commission publishes analysis underpinning the Biotech Act proposals

MHRA Consults on Updated Gene Therapy Definitions

On 11 May 2026, the Medicines and Healthcare product Regulatory Agency (MHRA), together with the Department of Health in Northern Ireland, launched a consultation on proposed changes to the UK legal definition of gene therapy medicinal products. The consultation was open until 22 June 2026.

The proposed update aims to ensure the regulatory framework reflects advances in gene therapy, gene editing and synthetic biology. Under the proposal, products would be classified as gene therapies based on their mechanism of action rather than existing definitions. The update is intended to provide greater regulatory clarity, support innovation, promote consistent oversight across gene therapy products, and maintain robust patient protections. Consultation on the regulation of Gene therapy medicinal products

Update on FAST-EU Approach for Multinational Trial Authorisations

The EU's FAST-EU (Facilitating and Accelerating Strategic Trials in the EU) initiative is testing a new approach to accelerate authorisation of multinational clinical trials. The Clinical Trials Coordination Group (CTCG) operating under the umbrella of the Heads of Medicines Agencies (HMA), and MedEthics EU under the auspices of the EC, on 26 May 2026 published the first interim results of the FAST-EU pilot initiative. The initiative supports faster access to innovative treatments, improved regulatory collaboration and enhanced Europe's competitiveness in clinical research. Heads of Medicines Agencies: Recently Published

FDA Initiative to Repurpose Approved Drugs

The FDA is seeking to expand the use of existing approved medicines to address unmet medical needs by identifying potential new indications or patient populations. Launched on 11 May 2026, the initiative invites input from stakeholders on priority areas and drug candidates where evidence may support new uses but commercial incentives are limited. It forms part of a wider effort to update drug labelling where supported by scientific evidence and improve clinical relevance for healthcare professionals and patients. FDA Advances Drug Repurposing to Address Unmet Medical Needs

HRA Plan for Safe Use of AI in UK Health Research

On 29 May 2026, the Health Research Authority (HRA) launched a 2-year plan (2026–2028) to support safe, trusted use of artificial intelligence (AI) in UK health and social care research.

The plan focuses on clarifying when AI activities are considered research, establishing appropriate use of health data for AI-enabled research recruitment, and ensuring AI research reviews are robust,

consistent and informed. The work will be delivered through seven workstreams across the UK. Plan to enable safe, AI-powered innovation in health and social care

GUIDANCE, ARTICLES AND PUBLICATIONS

UK

- The MHRA has updated guidance on the notification of serious breaches, to ensure that it is consistent with the new UK Clinical Trials Regulations that came into effect on 28 April 2026. The new Regulations do not change the requirements for, or the way in which, serious breaches of GCP or the trial protocol should be reported to the MHRA. However, MHRA have recommended to use the updated guidance regarding the practical arrangements for the notification of serious breaches, and also of what should and should not be classified as a 'serious breach', what must be reported, and what action the agency might take in response to the notification of a serious breach. Notification of Serious Breaches of GCP or the trial protocol
- Following the implementation of the new UK Clinical Trials Regulations on 28 April 2026, the MHRA published guidance clarifying investigator eligibility, delegation of trial activities and medical oversight requirements. The guidance confirms that a wider range of registered healthcare professionals, including nurses, pharmacists and allied health professionals, may now act as investigators or chief investigators where appropriately qualified and trained. Sponsors remain responsible for ensuring investigator suitability, while medically qualified professionals must continue to oversee participant medical care and safety reporting where required. Clinical trials for medicines: roles and responsibilities
- To support implementation of the new UK Clinical Trials Regulations, the HRA has introduced a new Modification Tool within the Integrated Research Application System. The tool is now required for all CTIMP modifications and reflects the new modification categories introduced by the Regulations. Clinical trials regulations: Modification Tool launched - Health Research Authority

  The HRA has also updated its CTIMP protocol guidance and template (Version 2.0) to align with the Regulations, the Data Protection Act 2018 and UK GDPR. Protocol - Health Research Authority

EU

- On 13 March 2026, the EMA opened a consultation on developing anti-cancer medicines for paediatric patients. The concept paper highlights the need for population-specific proof-of-concept data, supported by robust non-clinical evidence due to the limited availability of paediatric cancer trial participants. The consultation to submit comments closes on 30 June 2026. Submission of comments on 'Concept paper on the development of a reflection paper on proof-of-concept data to support the development of anti-cancer medicinal products in paediatric patients
- The EMA published new Clinical Trials Information System (CTIS) FAQs on 26 March 2026 to support clinical trial sponsors in using the CTIS more effectively. The FAQs address common sponsor queries and complement the updated CTIS Sponsor Handbook (Version 6.2). The document will be updated as further questions arise. CTIS: training and support
- The EMA is exploring an improved approach for biosimilar medicine development and evaluation. It has proposed reducing reliance on comparative efficacy studies where analytical, functional and PK comparability demonstrate similarity. The Reflection Paper was published in March 2026. Reflection paper on a tailored clinical approach in biosimilar development
- The EMA and HMA published the final Real-World Data Quality Framework (RW-DQF) on 27 March 2026. The guidance provides a framework for assessing the quality of real-world data

(RWD) used in medicines regulation, supporting more consistent use of RWD in regulatory decision-making. It covers key data quality considerations, methods for assessing data sources and processes, data quality metrics, and evaluation of data quality in relation to research objectives. Data Quality Framework for EU medicines regulation: application to Real-World Data

- In April 2026, the EMA introduced a voluntary support process allowing manufacturers and notified bodies developing orphan medical devices to seek advice from expert panels. The free service applies to all device classes and provides guidance on orphan device designation, clinical development strategies, clinical investigations and clinical evaluation requirements during conformity assessment. Expert panel support for orphan medical devices | European Medicines Agency (EMA)
- The Accelerating Clinical Trials in the EU (ACT EU) initiative has published its revised 2026–2027 workplan (published on 7 May 2026) to support faster, more efficient and patient-focused clinical trials across Europe. The initiative - Accelerating Clinical Trials in the EU - European Union

USA

- On 3 March 2026, the FDA issued draft guidance on new clinical investigation (3-year) exclusivity for drug products. The guidance provides Q&As on eligibility criteria and recommendations for submitting exclusivity requests with new drug applications (NDAs) or NDA supplements. Comments were open until 4 May 2026, with further updates planned as additional questions arise. *New Clinical Investigation Exclusivity (3-Year Exclusivity) for Drug Products: Questions and Answers Guidance for Industry*
- The FDA issued draft guidance on 9 March 2025 regarding its initiative to streamline the development of biosimilar medicines, proposing reduced clinical PK study requirements, including use of non-US comparator data in certain cases. FDA Takes Further Steps to Streamline Biosimilar Development and Make Medicines More Affordable
- On 11 March 2026, the FDA launched the Adverse Event Monitoring System (AEMS), a unified platform for analysing adverse event reports across drugs, biological products, vaccines and other regulated products. AEMS aims to improve safety monitoring, transparency and trend identification, with all FDA centres expected to use the system and historical data migrated by the end of May 2026. FDA Adverse Event Monitoring System (AEMS)
- In March 2026, the FDA has issued final M14 guidance on non-interventional studies (NIS) using real-world data (RWD), following adoption by the ICH in September 2025. The guidance outlines best practices for designing, analysing and reporting RWD-based safety studies, including research questions, data sources, bias management, analysis and regulatory submissions. M14 Guidance
- On 30 March 2026, the FDA has issued final guidance on incorporating voluntary patient preference information (PPI) throughout the medical device lifecycle. The guidance provides recommendations on when and how to collect and submit PPI to support regulatory decision-making. Incorporating Voluntary Patient Preference Information over the Total Product Life Cycle
- On 6 April 2026, the FDA confirmed new data standards for post-marketing individual case safety report (ICSR) submissions. From 1 October 2026, ICSRs for human drugs, biological products and related combination products must use the ICH E2B(R3) data standards. The FDA will no longer accept ICH E2B(R2) submissions after 30 September 2026, and organisations moving to E2B(R3) must use this format for all future ICSR submissions. Federal Register :: Electronic Submission of Postmarketing Individual Case Safety Reports to the FDA
- The FDA has issued draft guidance on responding to FDA Form 483 inspection observations following CGMP inspections. The guidance aims to help manufacturers provide clear, complete responses that support assessment of corrective actions and remediation. The guidance covers

investigation plans, CAPA development, effectiveness checks, management responsibilities and handling scientific disagreements. Comments on the draft guidance were open until 8 May 2026. Responding to FDA Form 483 Observations at the Conclusion of a Drug CGMP Inspection

- On 23 April 2026, the FDA announced the RAPID (Regulatory Alignment for Predictable and Immediate Device) coverage pathway to speed access to FDA-designated Breakthrough Devices for Medicare patients. The pathway enables earlier collaboration between the FDA and Centers for Medicare & Medicaid Services (CMS) so that evidence supporting FDA approval can also support coverage decisions, reducing delays between authorisation and Medicare coverage. A procedural notice will undergo public consultation before the pathway takes effect. CMS and FDA Announce RAPID Coverage Pathway to Accelerate Patient Access to Life-Changing Medical Devices
- On 8 May 2026, the FDA issued final guidance on post-approval pregnancy safety studies for drugs and biological products. The guidance outlines methods for collecting pregnancy safety data, including pregnancy registries, complementary studies and case reports, to support informed decision-making and updates to product labelling. Post approval Pregnancy Safety Studies
- On 28 May 2026, the FDA issued two final guidance documents on bioequivalence (BE) studies. The guidance on BE studies with pharmacokinetic endpoints provides recommendations for ANDA applicants on demonstrating BE across different dosage forms. The second guidance updates statistical approaches for analysing BE studies for INDs, NDAs and ANDAs, replacing the previous 2001 guidance. FDA publishes two final guidances for industry: "Bioequivalence Studies With Pharmacokinetic Endpoints for Drugs Submitted Under an ANDA" and "Statistical Approaches to Establishing Bioequivalence"

INTERNATIONAL

- On 7 April 2026, the International Medical Device Regulators Forum issued draft guidance on AI lifecycle management for medical devices. The proposed framework aims to harmonise best practices for managing risks associated with AI-enabled medical devices throughout their lifecycle. The public consultation on the draft document closes on 10 July 2026. Technical Framework for Artificial Intelligence Life Cycle Management | International Medical Device Regulators Forum

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

Prepared by:
Pegah Kiani, Director of QA and medical devices
S-cubed Ltd
Email: pegah.kiani@s-cubed.co.uk
Website: www.s-cubed-global.com