Clarity and Openness in Reporting: E3-based

News Summary

September 2025

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MEDICINES AND VACCINES

ICH

On 4 September 2025, ICH announced the adoption of M14 guideline: "General Principles on Planning, Designing, Analysing, and Reporting of Non-interventional Studies That Utilise Real-World Data for Safety Assessment of Medicines." The guideline objective is to recommend international standards for, and promote harmonisation of, the general principles on planning, designing, analysing, and reporting of noninterventional studies that utilise fit-for-use (frequently referred to as fit-for-purpose) data for safety assessment of medicines (drugs, vaccines, and other biological products). A slide presentation covering the guidance is accessible here. See the 'Development Strategy News' subsection for a linked article.

CTR and CTIS

1. A recording of the CTIS 24 September 2025 walk-in clinic is available here.

2. The European Medicines Regulatory Network published a report in September analysing clinical trial data from 31 January 2022 to 30 January 2025. This period marks the three-year transition of the Clinical Trials Regulation (CTR). The report shows that since the use of the Clinical Trials Information System (CTIS) became mandatory, an average of 200 new clinicals trials were submitted every month. Of these, around 80 applications per month were for multinational clinical trials. The full report is available here.

2. On 24 September, EMA hosted a LinkedIn live session to discuss the new targets for clinical

research. A recording of the event is available here. An EMA news article can be accessed here. The presentation includes a discussion of CTR and CTIS.

3. A LinkedIn summary article titled 'Understanding the EU Clinical Trial Regulation (CTR): A New Era for European Research' dated 05 Sep 2025 is available.

EU Regulatory

The results of the electronic product information leaflet (e-PIL) pilot from Belgium and Luxembourg hospitals have been reported and a summary of results can be accessed here.

UK and MHRA News

1. MHRA and UK HRA authored paper 'The Evolution of Digital Transformation to Support the UK Clinical Trials Regulation' examines the critical steps the UK has taken to digitise its clinical trials regulation, from the inception of the MHRA to the latest legislative reforms in 2025. The authors highlight how digital systems have been leveraged to enhance efficiency, transparency, and public engagement, even in the face of challenges like Brexit and the global pandemic.

2. MHRA and UK HRA authored paper 'UK Clinical Research Regulation: A Collaborative Path to Modernization, Innovation, and Access' outlines the UK's strategic transformation of its clinical research regulatory environment following its exit from the EU. It highlights a collaborative, digitally enabled approach led by the MHRA and HRA to create a streamlined, patient-centered, and proportionate system that accelerates access to innovative treatments while maintaining high standards of safety.

3. The HRA is holding a free online event on Thursday 2 October 2025 from 2pm to 4pm GMT "to support researchers to provide good quality feedback to participants and give clarity on the new clinical trials regulations". Information and registration here: Research transparency webinar - sharing results with research participants.

4. The MHRA Inspectorate Blog post, "New regulations for clinical trials – Join our Route B substantial modifications pilot" provides information about the Route B substantial modifications and why you should sign up to take part in the pilot if you are eligible.

5. The UK is aiming to reduce trial startup times from 250 days to 150 days, a target that will require studies to enroll patients within 90 days of regulatory approval or site selection. A report (dated 22 September 2025) on increasing research activity in the NHS is available here.

Canada Guidance and News

It has been reported that Canada will endorse ICH E6(R3) on 1 April 2026. Further information will follow when it becomes available.

FDA Guidance and News

1. The FDA announced the availability of a final guidance for industry titled E6(R3) Good Clinical Practice. September 2025. Note that this only contains Annex 1; Annex 2 on other types of studies is still to come in 2026.

2. The News and Updates section of ClinicalTrials.gov has been updated with the latest information regarding the Modernised PRS, including new guided tutorials.

3. FDA Voices, published 26 Sep 2025: FDA Focuses on Closing the Clinical Trial Reporting Gap for Research Integrity.

4. On 26 Sep 2025, FDA updated its page on the use of real-world evidence in regulatory decision making.

5. On 29 Sep 2025, FDA released the ICH E20 Draft Guidance on Adaptive Designs for Clinical Trials. It is in Public Consultation in other countries for some time, with a deadline for comments from Sep to end Nov 2025 (Europe, UK, China, Saudi Arabia, Switzerland) per the ICH web page.

EMA Guidance and News

EMA has published a recording of the Accelerating Clinical Trials in the EU (ACT EU) workshop on ICH E6 R3 principles and Annex 1 that took place back in February 2025. The workshop report is available here.

Real-World Data

1. A July 2025 NEJM perspective by Abassi and colleagues calls for urgent action to unlock the potential of real-world data in clinical research. Despite widespread adoption of electronic health records - structural, technical, and regulatory barriers remain. The authors propose several priorities outlined in this 'The Evidence Base' 22 July 2025 post.

2. On 4 September 2025, ICH announced the adoption of M14 guideline: "General Principles on Planning, Designing, Analysing, and Reporting of Non-interventional Studies That Utilise Real-World Data for Safety Assessment of Medicines." See further information under the ICH subheading above.

Transparency and Disclosure Resources and News

1. On 4 Sep 25, FDA Announced Real-Time Release of Complete Response Letters (CRLs), and Posted a Previously Unpublished Batch of 89. "Going forward, the agency will promptly release newly issued CRLs, and when approving applications will release all CRLs associated with that application. The agency will also publish batches of previously issued CRLs associated with withdrawn or abandoned applications. All CRLs will be redacted to remove confidential commercial information, trade secrets, and personal private information, but will contain company names."

2. Recordings of the 12 presentations held over the 3 days of the PHUSE Data Transparency Autumn Event (16–18 September 2025) are available to access from here.

GDPR and Data Transfer ex-EU

1. In July 2025, European Federation of Pharmaceutical Industries and Associations (EFPIA) submitted its GDPR Code of Conduct for Clinical Research and PV to the Belgium Data Protection Authority. The code seeks to ensure a harmonised understanding of key GDPR requirements in the context of PV and clinical research. Its purpose is to strengthen legal clarity while easing the administrative workload across the EU

2. Press Release dated 03 Sep 25 from the European Data Protection Office (EDPO) details the General Court of the EU's landmark ruling upholding the EU-US Data Privacy Framework, dismissing a challenge brought by French MEP Philippe Latombe. The Court confirmed that, at the time of the European Commission's adequacy decision in July 2023, the US provided an adequate level of protection for personal data transferred from the EU. The EU-US Data Privacy Framework (DPF), which has been in force since July 2023, is at issue. The pact enables US companies to process Europeans' personal data more easily, based on the premise that data transferred to the US is protected in a manner equivalent to EU privacy standards. This Euractiv article explains the wider issues given the change in US Administration since July 2023, and the implications. Subscribe for the EDPO Newsletter.

Development Strategy News

1. Clinical Leader article by Mishra dated 13 Aug 25 titled 'FDA's Elsa May Prompt Pharma To Rethink Regulatory Filings' is a useful read in our opinion - even if ostensibly discussing filings to FDA rather than individual study level documents - it inevitably speaks to directional change that may eventually flow through to development programmes.

2. On Wed 22 Oct 2025, join the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center)'s **2025 Annual Symposium**, which unites **leaders across industry**, **academia**, **regulators**, **and patient advocacy groups** to tackle the **biggest challenges in global clinical trials**. **Register here**.

3. WHO launched the Arabic translation of the WHO Guidance for Best Practices for Clinical Trials. This milestone will support stronger governance, enhance the quality and integrity of clinical research, and promote greater participation in global scientific collaboration across the Eastern Mediterranean Region.

4. TransCelerate and the Tufts Center for the Study of Drug Development (Tufts CSDD), Tufts University School of Medicine are launching a collaborative study that reveals opportunities to reduce participant and site burden in clinical trials through smarter, more efficient data collection. The manuscript, titled "Insights Informing Strategies for Optimizing the Collection of Clinical Trial Data," has been submitted to DIA TIRS and is now publicly accessible via pre-print.

5. FDA Draft Guidance Approaches to Assessment of Overall Survival in Oncology Clinical Trials was released on 18 Aug 2025. Submit comments online by 20 Oct 2025.

6. A Q&A with Rob DiCicco, VP of portfolio management, TransCelerate BioPharma entitled "Are Pragmatic Trials The Patient Recruitment Solution We've Been Looking For?" can be accessed here.

7. WHO Guidance for Best Practices for Clinical Trials has now been published in Russian, marking the

completion of translations into Arabic, Chinese, English, French, Portuguese, Spanish, and Russian. Access all versions here.

8. Final ICH M14 guideline on non-interventional studies using real-world data for safety assessment of medicines was adopted on 17 Sep 2025. Read the News Article by European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCPP) here.

9. On 29 Sep 2025, EMA published a 25-page draft reflection paper on patient experience data for public consultation ending 31 Jan 2026. Download here. News article here.

News from Asia Regulators

The Chinese version of the WHO Guidance for Best Practices for Clinical Trials is now available. The WHO Guidance for Best Practices for Clinical Trials provides a practical framework to address barriers to clinical research, strengthen clinical trial ecosystems, and promote research that is ethical, inclusive, and trustworthy. By making the Guidance available in Chinese, WHO is reinforcing its commitment to equity and to ensuring that communities, researchers, and decision-makers across regions can use, adapt, and implement best practices in their own contexts. This is a step towards improving trust in science, accelerating innovation, and ensuring that people everywhere benefit from safe, effective, and accessible health interventions.

News from US: Possible Impact on Clinical Trial Ecosystem

1. BMJ News Article 01 Sep 2025: CDC director is forced out over vaccine policy, and four senior scientists resign.

2. Nature News article 12 Sep 2025: Childhood vaccines up for review in the US: what's at stake.

3. Nature News Article 17 Sep 2025: Three ways ex-CDC chief says that Trump team is sidelining science.

4. Reuters article for 18 Sept 2025 entitled "Kennedy is rewriting US vaccine policy-fast and on his terms" by Ahmed Aboulenein can be accessed here.

5. Nature News Article 20 Sep 25: 'Hotly anticipated US vaccine meeting ends with confusion — and a few decisions'.

MEDICAL DEVICES

This subsection covers transparency in relation to medical devices, and the emerging intersection of the regulatory medical devices and the regulatory drugs spaces. Devices information or regulations that impact the reporting of device studies are also covered. Combination products, including

pharmaceutical and medical device components, may need to be reported under pharmaceutical legislation, depending on what the product is, and how regulatory authorities in different global regions assess combination products. Contextualisation is provided, where possible, to help readers navigate the information.

General Updated and News

1. EMA published a manual on borderline and classification for medical devices under Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (Version 4 – September 2025)

2. The EC has published a call for evidence on the medical device and in vitro diagnostic regulations (MDR/IVDR). Feedback period 08 September 2025 to 06 October 2025 (midnight Brussels time). Submit and review feedback here.

3. MedTech Europe, Eurom, and EuromContact have published a position paper entitled "Electronic Instructions for use (eIFU) for certain medical devices intended for lay users". The paper can be accessed from here and the press release can be accessed here.

EU Transparency

EUDAMED News

The European Commission is organising two free hybrid workshops to support onboarding to EUDAMED. Each workshop provides an overview of the obligations under the Medical Devices Regulations (Regulation (EU) 2017/745 — MDR, and Regulation (EU) 2017/746 — IVDR). Registration and further details are available here.