Clarity and Openness in Reporting: E3-based

News Summary

December 2025

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CORE Reference Project Webinar January 2026

Our **next webinar** is scheduled for **Friday 16 January 2026 (12.30-13.30 CET/11.30-12.30 UK time).** External speaker Mirjana Miric from Worldwide Clinical Trials will present a webinar on the topic "**CTIS and Clinical Trial Transparency: Strategies, Challenges, and CRO Insights**." The webinar will cover the protection of personal data and commercially confidential information in clinical trial information submitted to Clinical Trials Information System. Click here to register directly for our upcoming webinar.

MEDICINES AND VACCINES

ICH

1. An updated glossary of ICH terms and definitions (V9, dated 9 Dec 2025) has been published. The glossary was compiled by CIOMS from the publicly available guidelines found on the ICH website. Download the free pdf from here.

2. On 16 Dec 25, the Australian regulator, the Therapeutic Goods Administration (TGA), adopted ICH E6(R3) Guideline for Good Clinical Practice: Principles and Annex 1, which will come into effect on 13 Jan 2026. A 12-month transition period from 13 Jan 2026 to 13 Jan 2027 will allow sponsors, trial sites and other stakeholders time to update processes, documentation, and training to meet the updated requirements. During this transition period, clinical trials of medicines and biologicals regulated under the CTN and CTA schemes must comply with either ICH E6(R2) or ICH E6(R3). Learn more here.

CTR and CTIS

1. CTIS Winter clock-stop: 22 Dec 2025 at 23:59:59 CET until 8 Jan 2026 at 00:00:01 CET.

2. The latest issue of Clinical Trial Highlights (Issue 28) is now available and includes news on the Facilitating and Accelerating Strategic Trials (FAST)-EU initiative launched by HMA and on the Clinical

Trials Information System. In addition, the ACT EU Trial Map has been enhanced with improved search capabilities in national EU/EEA languages, making it faster and easier for healthcare professionals and patients to access the information.

3. Module 06 of the CTIS Training Programme, How to evaluate an Initial CTA - RMS selection, has been updated: Version 1.2 - Nov 2025.

4. The EMA is conducting a survey of CTIS users to help improve communication, engagement and training activities and better support the implementation of the Clinical Trials Regulation. The deadline for feedback has been extended to 16 Jan 2026 details here.

5. Updated CTIS cover letter templates for initial applications and substantial modifications now include mandatory annexes and tick boxes for expedited resubmissions. The updated templates are available on the CTCG website, under 'Key documents list'. Details here.

6. The EMA offers a virtual CTIS sponsor end user training programme which is planned for 9-12 Mar 2026, 08:00-12:30 GMT. This training programme is open to sponsor users of CTIS: commercial and non-commercial sponsors as well as CROs.

7. The EUCTR/CTIS Network (EU clinical trials) user community on LinkedIn may interest some readers. Read the group 'Description'. The CORE Reference Project has no connection with nor does it endorse this group - however as it should include discussions about topics relevant to our readers, we are bringing this group to the attention of the community in case of interest.

UK and MHRA News

1. A reminder that it is less than 5 months until the amended clinical trials regulations come into force. HRA is encouraging all researchers and sponsors to start preparing for these changes and to update their policies, processes and procedures as soon as possible.

As a reminder:

- HRA final guidance 'The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025'.
- MHRA separate guidance 'Clinical trials for medicines: apply for authorisation in the UK'.

2. The HRA and MHRA have published an article titled "Addressing Inequity: Embedding Inclusion and Diversity in UK Clinical Trials", which explores current initiatives to improve representation and inclusion in clinical trials across the UK.

3. On 4 Dec 2025, Krystelis hosted a webinar titled "Clinical Trial Transparency in the UK: What is Changing and Why it Matters". You can view a recording on youtube here.

4. NIHR offers free Good Clinical Practice (GCP) training courses for people supporting clinical research delivery in the UK. New regulations for running clinical trials in the UK will start on 28 Apr 2026. NIHR are working with MHRA and HRA to update training packages to support the implementation of the changes.

5. MHRA have developed a new vaccine factsheet to help patients understand more about vaccines. Access the factsheet here.

6. On 12 Dec 2025, MHRA updated the GCP for clinical trials Inspection Dossier Template (Version 7.0) to include formal documentation requirements for artificial intelligence and machine learning systems used in the clinical trial lifecycle (Section 13. Artificial Intelligence and Machine Learning). Access the full version of Good clinical practice for clinical trials document here. Implications of this requirement are discussed in an article by Amer Alghabban which can be accessed here.

7. HRA Chief Executive, Matt Westmore, has written a blog reflecting on 2025 achievements and looking ahead to 2026. Read Matt's blog.

FDA Guidance and News

1. The latest release notes for ClinicalTrials.gov and Modernised PRS have been posted (3 Dec 2025). With this release, the Record Summary page has been redesigned to prioritize important information and improve usability. In addition, improvements were made to field-level validation and the Results Submission process.

2. 01 Dec 2025: Press Release: FDA have launched a new AI tool for FDA staff: Agentic AI. According to the press release, Agentic AI refers to advanced artificial intelligence systems designed to achieve specific goals by planning, reasoning, and executing multi-step actions. These systems incorporate built-in guidelines — including human oversight —to ensure reliable outcomes. The tool is entirely optional for FDA staff and is used voluntarily.

3. In an interview with STAT news (behind a paywall) FDA Commissioner Marty Makary announced the agency will shift its evidence standards for drugs to require a single pivotal trial – rather than two studies – for drugs by default. FDA has traditionally required two well-controlled clinical trials to meet the "substantial evidence" requirement for approval for most drugs – though the agency often requires only a single pivotal trial, along with other confirmatory evidence, for rare or serious diseases.

4. On 15 Dec 2025, the FDA published 2 final guidances outlining responsibilities one for Investigators and the other for Sponsors: "Investigator Responsibilities – Safety Reporting for Investigational Drugs and Devices (Guidance for Investigators, Industry, and Institutional Review Boards)" and "Sponsor Responsibilities - Safety Reporting Requirements and Safety Assessment for IND and Bioavailability/Bioequivalence Studies"

EMA Guidance and News

1. Europe's HMA released its latest newsletter with the most up-to-date news along with upcoming events and opportunities, including the launch of the Facilitating and Accelerating Strategic Trials (FAST)-EU initiative, a coordinated fast-track evaluation approach for multinational clinical trials, which will start in January 2026.

2. EMA and HMA held a multi-stakeholder workshop on AI last month (20-21 Nov 2025). This featured key notes on AI advancements, provided updates on the regulatory network's activities in AI, and discussed the Data and AI workplan and AI use cases in the medicines lifecycle. A video recording of the event can be accessed here.

3. EMA held a Quarterly System Demo - Q4 2025 on 16 Dec 2025. This included a topic on the new CTIS safety module, and provided a progress update. A video recording, and a Q&A document made available after the event can be accessed here.

4. EMA published a draft version of "ICH E22 Guideline on general considerations for patient preference studies Step 2b" on 11 Dec 2025 which is open for public consultation until 12 Apr 2025. Comments via template. The harmonised guideline outlines general considerations about the use, design, conduct, analysis, and submission of patient preference studies aimed at informing drug development, regulatory submission and evaluation, drug approvals and maintenance of such approvals.

5. The Heads of Medicines Agencies and the EMA set up a joint Network Data Steering Group to enhance data use in medicine regulation, supporting innovation and public health in the EU. They

released Big Data Highlights this month providing a recent update on the clinical study data pilot.

Health Canada Guidance and News

A blog on the EMA – Health Canada joint review process is available from here.

Transparency and Disclosure Resources and News

1. The IPC's updated de-identification guidelines provide practical answers on how organisations can unlock the huge potential of data while protecting privacy. Building on the globally recognized 2016 guidance, the new version reflects today's technologies, risks, and opportunities, offering clear tools to help organisations safeguard privacy while maximising the value of data. Review the guidance here.

2. TranspariMED summary article 28 Nov 2025: New study finds strong investments into improving clinical trial reporting by US universities, which talks about this 13 Oct 2025 paper: Evaluating the current landscape of clinical trials registration and results reporting policies, procedures and staffing at US-based academic centers: Survey revisited.

3. On 19 Dec 25, the EC renewed the two 2021 adequacy decisions for the free flow of personal data with the UK. The decisions ensure that personal data can continue flowing freely and safely between the European Economic Area (EEA) and the UK, as the UK legal framework contains data protection safeguards that are essentially equivalent to those provided by the EU.

GDPR and Data transfer Ex-EU

1. Politico article: EU justice chief draws red line on privacy reforms. Europe is entering 'a time of significant change after a period of stability' for data privacy, after the EU executive last week proposed plans to overhaul its flagship General Data Protection Regulation (GDPR). Read more in the article.

2. In a blog post the author Max Schrems explores EU-US data transfer and potential problems that may be encountered: "EU-US Data Transfers: Time to prepare for more trouble to come"

3. The first GDPR reform package was published in the Official Journal of the EU. This reflects the ongoing development of EU data protection rules and the start of the next phase in the GDPR framework. Regulation (EU) 2025/2518 of the European Parliament and of the Council of 26 November 2025 laying down additional procedural rules on the enforcement of Regulation (EU) 2016/679 (Text with EEA relevance); Document 32025R2518

4. The European Commission has renewed decisions to allow for the free and safe flow of personal data with the UK. The new decisions are subject to a sunset clause of 6 years, running until 27 Dec 2031, with the possibility to be renewed. Read the press release here. Access "Renewal of the EU adequacy decision for the UK under the GDPR" here.

Development Strategy News

1. Article published by MMS: '4 Key Takeaways from the EMA – Health Canada Joint Review Process and Evaluation of Its Efficiency'. There are four main takeaways and a discussion on how efficient the combined pathway really is for global sponsors. Takeaway 3 includes advice on shifts in anonymisation practice.

2. 04 Dec 25 publication: Aggregating and analysing clinical trials data from multiple public registers using R package ctrdata. Includes a tool for CTIS and three more registers. Various examples can help researchers, developers, patients and their organisations, health professionals and policy makers. Included are an overview of trial registers and the R code to get started.

3. On 16 Dec 25, the EC published a Press Release titled 'New measures to make EU health sector more innovative, competitive and resilient'. The package includes a Biotech Act, revised rules for medical devices, and a Safe Hearts Plan. Together, these initiatives will contribute to a more modern, efficient, and resilient health ecosystem for all EU citizens, while incentivising growth and innovation in this strategic sector. This factsheet titled 'Revolutionising Clinical Trials' covers the key changes.

Artificial Intellligence/Machine Learning

1. A regulatory focus report from the Food and Drug Law Institute (FDLI) Enforcement, Litigation, and Compliance Conference on 4 December can be accessed here. Experts at the conference asked that the US FDA provide more clarity on how it intends to regulate the use of AI and LLM when they are used in the development or manufacture of a product but are not part of the product itself. AI tools are employed to assist with aspects of clinical trials, such as selecting patients for trials, or for predicting outcomes, performing confounding adjustment, conducting pharmacometrics modeling, creating digital twins, and monitoring post-market safety.

2. CIOMS has published a report entitled "Artificial Intelligence in Pharmacovigilance." The free pdf can be downloaded from here.

3. EFPIA have published (9 Dec 2025) "AI Across the Medicines Lifecycle: Insights from Preliminary Case Studies and Considerations for Policy." It is a cross-industry perspective on how AI governance can be integrated effectively into medicinal product research and development and post authorisation settings. Download the full report from here.

4. The MHRA has launched a call for evidence on how AI in healthcare should be regulated. The call for evidence is from 18 Dec 2025 to 12pm on 02 Feb 2026. Details here.

News from Asia Regulators

1. Taiwan FDA announced the implementation of the "Simplified Measures for Reviewing Clinical Trial Protocols of Medicines" (page in Mandarin) starting 01 Sep 2025, which consolidates two previous review measures to enhance efficiency. The new measures introduce two 30-day fast-track mechanisms: (1) for trial protocols approved by US FDA and only conducted domestically (excluding regenerative medicine); (2) for certain multi-national, non-first-in-human, or academic research regenerative medicine trials. Additionally, the measures establish a stratified management system for protocol amendments based on risk level.

2. Taiwan FDA announced the revision and consolidation of three existing procedures into the "Simplified Review Procedure for Multi-Regional Multi-Center Clinical Trial Protocols" (page in Mandarin), implemented starting 01 Sep 2025, to align with modern clinical trial trends and boost domestic new drug development.

News from US: Possible Impact on Clinical Trial Ecosystem

1. The impact of US policy on literature research is discussed in the joint article from IQWiG, G-BA and Cochrane Germany. The article provides considerations for key healthcare providers in Europe on how they could respond to a potential outage of PubMed and ClinicalTrials.gov and includes alternatives to PubMed (MEDLINE). Access the full article here.

2. Similarly, according to reports from Swiss researchers, since 1 Oct 2025 there have been problems with new registrations and updates to existing registrations of clinical trials on clinicaltrials.gov. Instead of clinicaltrials.gov, other WHO-approved primary registries can be used for registration in accordance with Art. 64 para 4 of the Clinical Trials Ordinance (ClinO). Details can be found here.

3. FDA News Release 19 Dec 25: FDA Explores New Contracting Approach to Advance Public Health Innovation. This FDA Request for Information (RFI) seeks input from venture capital firms on

developing a new contracting approach to strengthen collaboration between the agency and America's most innovative companies. Responses to the RFI are due by 18 Jan 2026.

MEDICAL DEVICES

This section 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.

EU

1. On 16 Dec 25, the EC adopted a proposal to simplify the MDR and IVDR. The key elements of the revision are summarised in a factsheet, and in a questions and answers document.

2. On 12 Dec 2025, the EC published a draft implementing regulation outlining the need to set specific quotation and timeline requirements that notified bodies must meet to ensure greater regulatory consistency and predictability. The proposed initiative would lay down rules for applying the requirements to be met by 'notified bodies' – the independent bodies tasked with assessing and certifying medical devices and in vitro diagnostics. These bodies are designated and regularly monitored by the relevant national authorities. Feedback period 12 Dec 2025 - 23 Jan 2026.

FDA

1. FDA has published an updated list of medical devices that incorporate digital health technologies. This update includes a revised list of AI-enabled medical devices authorized for marketing in the US, along with two new lists: one for devices that utilize Augmented or Virtual Reality and another for sensor-based technologies. This demonstrates the expanding range of digital health technologies entering the regulatory landscape. Access the lists through the following links: Artificial intelligence; Augmented reality and virtual reality; Sensor-based digital health technology.

2. FDA News Release 15 Dec 25: FDA Eliminates Major Barrier to Using Real-World Evidence in Drug and Device Application Reviews. In new guidance for certain types of medical device submissions, the agency states it will accept RWE without requiring that identifiable individual patient data collected from real-world data sources always be submitted in a marketing submission. Link to guidance document here.

3. FDA issued an updated version of "Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices" on 18 Dec 2025. It supersedes "Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices," issued on 31 Aug 2017. FDA announcement here.

Health Canada

Health Canada IMDRF table of contents for medical device applications guidance. The International Medical Device Regulators Forum (IMDRF) is a voluntary group of regulators committed to the acceleration of medical device regulatory harmonization and convergence. The Table of Contents (ToC) format was developed by the IMDRF to provide a globally harmonized structure and has been adopted by Health Canada for medical device regulatory activities. It is expected that use of the ToC will reduce time and costs for both industry and the regulator, and result in timely access to medical devices for Canadians.

Asia Regulators

1. Ministry of Health Malaysia, Medical Device Authority (MDA) has published a draft guidance document “Definitions of Medical Devices” for public comment. This document defines accessories, components, and spare parts of medical devices, and provides examples to enhance clarity. The public comment period was from 4-18 Dec 2025, details here.

2. Central Drugs Standard Control Organization (CDSCO) of India has announced in a circular on 4 Dec 2025 a new, mandatory Risk Classification Module of medical devices. This online module is aimed to simplify the regulatory approval procedures and ease the process of risk classification of medical devices (except IVD). For medical devices not currently listed in the CDSCO’s published classification database (typically novel devices), applicants must submit their request for risk classification through this new online module on the CDSCO portal (cdscomdonline.gov.in).