Clarity and Openness in Reporting: E3-based

News Summary

January 2026

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Webinar Presentation

Thank you to those attendees who joined our webinar by external speaker Mirjana Miric on 16 Jan 2026. If you missed it, the webinar recording and the slide deck are now available, please feel free to share these materials with peers and colleagues.

- Recording: https://lnkd.in/dNxWhup6
- Slide deck: https://lnkd.in/d2pbxyBf.

10th birthday celebrations for CORE Reference

If you are attending the EMWA Spring 2026 Conference (5-8 May 2026), we warmly invite you to join the 10th-anniversary celebrations for CORE Reference. We will be hosting educational sessions on both Wednesday and Friday in Barcelona. These sessions are free for EMWA members who register for the conference. Further details, including our programme plans and our generous celebration supporters, will follow soon.

MEDICINES AND VACCINES

ICH

1. The M11 Guideline on Clinical Electronic Structured Harmonized Protocol (CeSHarP), M11 Clinical Implementation Template, and M11 Technical Specification reached Step 4 of the ICH process on 19 Nov 2025, and have now entered the implementation phase. The M11 guideline describes general protocol design principles; the template presents the format and structure of the protocol; and the technical specification presents the data elements and technical attributes (e.g., definition, conformance, cardinality) that enable the interoperable electronic exchange of protocol

content. Further reading on M11 is available in Jonathan Mackinnon's latest December newsletter, see Development Strategy News section below.

2. In January 2026, ICH made training materials available for ICH E6(R3) Module 4 Informed Consent. Visit the ICH Training Library and scroll to the 'E' section and then E6(R3) to access the materials.

CTR and CTIS

1. The European Medicines Agency (EMA) is conducting a follow-up survey on Change Management Activities for CTIS to gather feedback from stakeholders. The short and anonymous survey can be found on the EU Survey platform. Insights from this survey will help EMA enhance future guidance and resources.

2. EMA is holding a CTIS Walk-in clinic on 18 February 2026, 15:00-16:00 GMT giving Sponsors an opportunity to receive practical information about CTIS. A video recording will be made available after the event.

3. The latest issue of Clinical Trial Highlights (Issue 29) is now available and provides the latest news on clinical trials from the European Medicines Regulatory Network (EMRN), including news on the joint Accelerating Clinical Trials in the EU (ACT EU) initiative and on CTIS.

EU Regulatory

European Health Data Space (EHDS) News

EFPIA have published "Safeguarding intellectual property and trade secrets in the European Health Data Space." The 15 Jan 2026 announcement and paper can be downloaded from here.

UK and MHRA News

1. Changes to MHRA Guidance that are related to substantial modification include the following:

Clinical trials for medicines: modifying a clinical trial approval.

2. MHRA has 'added some guidance about Good Clinical Practice (GCP)' to their Clinical Trials hub (CT hub). This draft guidance should be used to support sponsors in preparing for the implementation of the new regulations for clinical trials which come into force on 28 April 2026, namely Declaration of Helsinki and Clinical Trials Regulations alignment, archiving and retention of clinical trial records, and Clinical Trials Regulations enforcement provisions. Further guidance will follow.

3. The Clinical Trials (CTs) with in vitro Diagnostic (IVD) devices webinar will be held on Tuesday 3 February 2026 from 14:00 to 15:00 GMT, providing guidance and advice to sponsors who are submitting clinical trials with IVD devices. Click here to register.

4. The UK MHRA has published guidance entitled "UK-Specific annotations to ICH E6(R3)." The annotations reference UK specific guidance associated with the Clinical Trials Regulations and can be found here.

5. The MHRA has published draft guidance outlining "Clinical Trials Regulations enforcement provisions". Feedback deadline is 8 Feb 2026 via Clinical Trials Regulations enforcement provisions guidance survey.

6. Some of the definitions and terminology used for clinical trials of investigational medicinal products (CTIMPs) in the UK are changing when the amended regulations come into effect on 28 April 2026. These include:

- ‘amendments’ to become ‘modifications’
- new modification categories
- an update to the definition of a health care professional.

The following blog highlights all the changes and explains why they’re being introduced and what they will mean for sponsors and researchers: Blog: clinical trials regulations – changes to definitions and terminology.

7. HRA is joining a panel of speakers at a webinar about the upcoming changes to research transparency requirements as part of the amended clinical trials regulations. The webinar will take place on Wednesday 25 February from 3pm to 4pm UK time. Registration is free.

FDA Guidance and News

1. In Dec 2025, FDA released the final guidance “Enhancing Participation in Clinical Trials — Eligibility Criteria, Enrollment Practices, and Trial Designs”. This guidance advises clinical trial sponsors on strategies to enroll a diverse and representative population, considering both demographic factors (such as sex, race, age, and location) and non-demographic factors (such as comorbidities, organ dysfunction, and rare conditions). This helps to ensure the study reflects real-world patients and allows evaluation of how these factors influence the drug’s safety and effectiveness.

2. The latest release notes for ClinicalTrials.gov and Modernised PRS have been posted (7 January 2026). With this release, notices and selections have been added to guide users who are deciding whether or not to post information for ACTs studying devices that have not been approved or cleared by the FDA. In addition, this release includes enhancements to the Record List page and to the Protocol Section.

3. The FDA issued draft guidance to assist sponsors in using Bayesian methods to support the safety and effectiveness of new drugs in clinical trials. Read the announcement here. Read the draft guidance here.

4. FDA released the Guidance Agenda with the list of guidance documents that CBER is Planning to publish during 2026.

5. This 2024 paper titled ‘Collaborative Real-World Evidence Among Regulators: Lessons and Perspectives’ on international collaboration among regulatory reviewers details experience and learnings from international regulatory collaboration on observational studies on medicines and vaccines. This work led to the establishment of a working group for international regulatory cooperation on real world evidence of the International Coalition of Medicines Regulatory Authorities.

6. FDA has issued a list of guidance topics the Center for Biologics Evaluation and Research (CBER) is considering for development during 2026. The list includes topics that currently have no guidance associated with them, topics where updated guidance may be helpful, and topics for which CBER has already issued Level 1 draft guidances that may be finalized following review of public comments. The list can be found here.

EMA Guidance and News

1. From 22 December 2025, EMA has allowed optional submission of new Marketing Authorisation Applications (MAAs) for Centrally Authorised Products using eCTD v4.0, while eCTD v3.2.2 remains accepted during the transition. Applicants must contact EMA before submitting in v4.0 and ensure compliance with EU technical requirements; this update introduces improved metadata, lifecycle management, and global interoperability, marking a major step toward a more efficient electronic submission system.
For the new EU eCTD v4.0, an additional practical guidance has been published. The guidance

provides step-by-step instructions for submitting Centralised Procedure MAAs in eCTD v4.0, including recommended folder and file structures, naming conventions, and checksum file requirements to complement the ICH eCTD Implementation Guide. It details EU-specific requirements such as controlled vocabularies and keywords for context-of-use metadata, XML structure and lifecycle management aligned with HL7 RPS, and mandates submission units and contextual elements to reflect regulatory activities including consolidations.

2. EMA press briefing on human medicines in 2025 was held on 15 Jan 2026, and a video recording made available after the briefing in LinkedIN.

3. On 15 Dec 2025 EMA published ICH M11 guideline, clinical study protocol template and technical specifications - Scientific guideline. The purpose of this new harmonised guideline "is to introduce the clinical protocol template and the technical specification to ensure that protocols are prepared in a consistent fashion and provided in a harmonised data exchange format acceptable to the regulatory authorities."

4. Webinar for stakeholder engagement on the new draft guideline on general considerations for patient preference studies (ICH E22) will be held on 8 Feb 2026. Agenda and registration details here.

Health Canada Guidance and News

1. Health Canada is seeking feedback on the proposed Clinical Trials Regulations for drugs (pharmaceuticals, biologics and radiopharmaceuticals) and on multiple guidance documents related to the proposal. The proposed framework would replace the clinical trial regulatory schemes for drugs in the following sections of the regulations:

- Part C, Division 5 of the Food and Drug Regulations **and**
- Part 2 of the Clinical Trials for Medical Devices and Drugs Relating to COVID-19 Regulations.

Consultation ends on 20 Mar 2026. Read more and on how to participate here.

2. Health Canada has issued a draft guidance document on decentralised clinical trials which is now open for consultation. Consultation will close to new input on 21 February 2026. Access the draft guidance Imaging Data Anonymization Guideline and information around the consultation process here.

Australia TGA

As reported last month, TGA has adopted the ICH E6(R3) Guideline for Good Clinical Practice: Principles and Annex 1, which will come into effect on 13 January 2026. More information is available from here.

Real World Data

On 18 Dec 2025, the UK's MHRA put out a call for those working in healthcare, research, regulation, or medical innovation to help shape how AI is developed, regulated and used safely across the NHS and wider healthcare systems. The MHRA's Call for Evidence is a key opportunity to influence the National Commission's recommendations on AI regulation in healthcare. Share your views by 2 February 2026. Press Release here.

Transparency and Disclosure Resources and News

1. The PHUSE Data Transparency Working Group has published a draft white paper entitled "Imaging Data Anonymization Guideline". The paper (v1.1 05 Dec 2025) is open for review. Download the paper directly from here. Feedback should be sent to workinggroups@phuse.global by 03 February 2026.

Full project information is available from here. The aim of the guideline "is to ensure that all shared clinical trial imaging data complies with privacy regulations and ethical standards, thereby protecting the identities of clinical trial participants."

2. Open access article entitled "Publicly Available Clinical Trial Safety Data: Review and a Call for Standardization and Improved Reporting Practices" can be accessed here.

Development Strategy News

1. Jonathan Mackinnon's Protocol Development #82 issue includes more info on ICH M11 guideline, including a brief description of the guidance, what to focus on to understand the technical specifications, and the key changes in the M11 template vs TransCelerate's Common Protocol Template (CPT) standard.

2. Coming soon: The European Biotech Act - Fact Sheet and FAQs.

3. FAST-EU Facilitating and Accelerating Strategic Clinical Trials in the EU/EEA: Information was released on 21 Jan 2026 by HMA. Download the 14-page guide here.

4. FDA/MHRA/Health Canada Symposium: Regulatory perspectives in good clinical practice, bioequivalence and good pharmacovigilance practice; 2 to 4 June 2026 (8:30 a.m. - 5:15 p.m. ET). Registration details here. Bringing together regulators, investigators, clinical researchers, clinical trial staff, sponsors, research organisations, service providers, pharmaceutical and biotechnology companies, academics and patient advocacy groups. The symposium will highlight current and emerging topics of interest to the industry related to good clinical practice, bioequivalence and good pharmacovigilance practice.

Artificial Intellligence/Machine Learning

1. On 14 Jan 2026, FDA and EMA released guiding principles for good artificial intelligence practice in drug development. A common set of 10 guiding principles will inform, enhance, and promote the use of AI for generating evidence across all phases of the drug product life cycle. Download here.

2. BMJ opinion article entitled "Patients are disclosing sensitive information to AI tools—clinicians must adapt" written by Charlotte Blease can be accessed here.

3. FDA published draft guidance entitled "Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products." The guidance discusses the use of AI models in the drug product life cycle, where the specific use of the AI model is to produce information or data to support regulatory decision-making regarding safety, effectiveness, or quality for drugs.

4. A Viewpoint on AI in Medicine has been published in JAMA by Palmieri et al, 2025 (doi:10.1001/jama.2025.23059). Access the article entitled "New Guidance on Responsible Use of AI" here.

5. In a two part series of articles, Kimberley Chew et al, January 2026 explore firstly the legal and regulatory implications of the FDA's adoption of AI tools including Elsa (AI At The FDA: Legal Implications And Strategic Considerations For Drug Developers) and secondly they offer practical strategies and actionable guidance for sponsors navigating AI-enabled regulatory review (Navigating FDA's New AI Systems: Practical Tips For Regulatory Success). Part two includes seven main topics: Clarity and completeness in AI-era submissions; Writing for both human and AI reviewers; Proactive engagement with the FDA; Trade secret and data protection in practice; Meticulous recordkeeping and traceability; Identifying and addressing AI limitations; and Building internal AI literacy. The authors are

hoping to help Sponsors "maximize the benefits of AI-enabled review while protecting proprietary interests and ensuring regulatory compliance."

News from Asia Regulators

In January 2026, Taiwan FDA released the first draft guiding principles for manufacturing and research of gene editing technology for human gene therapy (page in Mandarin). Despite investment in gene therapy development in the country, no regulatory framework was in place. The draft guidance took reference from the US FDA's 2024 Human Gene Therapy Products Incorporating Human Genome Editing Guidance for Industry and other relevant international guidelines.

News from US: Possible Impact on Clinical Trial Ecosystem

1. BMJ published an Opinion (06 Jan 2026) entitled " Trump and RFK Jr are dismantling public health—aided and abetted by powerful doctors."

2. FDA Increases Flexibility on Requirements for Cell and Gene Therapies to Advance Innovation.

3. Reuters article published 22 Jan 2026 entitled "Focus: Vaccine makers feel a chill as US Health Secretary Kennedy's rhetoric becomes reality" written by Bhanvi Satija reports on the effect of vaccine policy changes in the US.

4. The United States left the World Health Organization on Thursday 22 Jan 2026.

5. Nature News article 22 Jan 26: Key NIH review panels are due to lose all members by the end of 2026. The law requires these panels to review applications for all but the smallest grants before funding can be awarded.

6. BMJ News article 28 Jan 26: FDA is now "open to bayesian statistics": transformational change or new Pandora's box?

7. BMJ News article 27 Jan 26: US measles outbreak gives "real world" data on the unvaccinated, CDC vaccine chair says, as he questions polio jab.

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.

General Updates and News

1. A summary report (from the recent 2026 Combinations Product in the EU meeting) by Regulatory Focus summarises the view of experts from the European Commission on the proposed MDR, IVDR revisions. Read the Regulatory Focus report here.

2. Webinar entitled "Smarter CER Maintenance: Achieving Efficiency, Consistency, and ROI with AI" will be held on 26 Feb 2026, registration and further details here.

EU Transparency

The MDCG issued 2 guidances in December 2025 that impact regulatory documentations for MDs and IVDs:

- MDCG 2025-9 Guidance on breakthrough devices (BtX) under Regulations 2017/745 & 2017/746. Documents impacted: CEP, CER, CIP, CIR, PMCF plans and report.
- MDCG 2025-10 Guidance on post-market surveillance of medical devices and in vitro diagnostic medical devices. Documents impacted: PMS Plan, PMCF plans and report.

RAPs article on EU officials' discussion about the revisions here.

EUDAMED News

A free on-demand webinar examining the first 4 EUDAMED modules presented by Jay Cowley can be accessed here.

EU Combine Initiative

The European Commission's Medical Device Working Group has issued guidance outlining the criteria for a device to qualify as a breakthrough device under the EU MDR and IVDR. The guidance establishes an official EU framework for breakthrough devices in accordance with both directives. This RAPS article is a good explainer.

US FDA

1. The U.S. FDA has published final guidance entitled "Clinical Decision Support Software — Guidance for Industry and FDA Staff", issued 6 January 2026. This document updates and supersedes prior CDS guidance, and clarifies how the agency interprets the statutory criteria that determine whether CDS software is regulated as a medical device under the Federal Food, Drug, and Cosmetic Act. The document provides numerous examples showing how different software functions are categorised, including what is considered non-device versus device CDS. Access US FDA guidance document here.

2. FDA published guidance to clarify FDA's interpretation of the compliance policy for low risk products that promote a healthy lifestyle (general wellness products) entitled: "General Wellness: Policy for Low Risk Devices."

3. An article in MedtechDive written by Elise Reuter discussing the above two new guidance documents can be accessed here.

UK MHRA

1. MHRA issued updated guidance on conformity assessment routes and the UKCA marking process to make it clearer and easier to follow for medical device manufacturers and UK Responsible Persons (published 31 Dec 2025). View updated guidance and flowcharts here.

2. Changes to MHRA Guidance that are related to combined trials of IMP and devices include the following:

- Clinical trials for medicines: apply for approval in the UK
- Clinical trials that include an in vitro diagnostic device.

3. MHRA webinar 3 Feb 2026 2-3pm GMT, "Clinical Trials (CTs) with in vitro Diagnostic (IVD) devices webinar". Registration details here. During this webinar the MHRA will present guidance and advice to sponsors who are submitting clinical trials with IVD devices.

China

1. The Center for Medical Device Evaluation (CMDE) of China's NMPA regularly releases multiple guidelines for registration review of medical devices and IVDs. Guidance released in Q4 2025 are as follows (source pages in Mandarin):

- Issuance #20 on 10 Sep 2025: 19 guidelines, 6 of which for IVDs, covering surgical and endoscopic tools, electronic stethoscopes, diagnostic analyzers, home-use ventilators, and laboratory reagents .
- Issuance #21 on 10 Sep 2025: Guidelines for the registration review of intracranial coils
- Issuance #22 on 30 Sep 2025: Guidelines for the registration review of X-ray beam scanning measurement equipment
- Issuance #23 on 11 Oct 2025: Guidelines for the registration review of single-use anesthetic needles
- Issuance #25 on 03 Nov 2025: Guidelines for registration review of intracranial thrombectomy stents
- Issuance #27 on 01 Dec 2025: 39 guidelines, covering cardiovascular, clinical chemistry and toxicology IVDs, obstetrics and gynecology, physical medicine and orthopedic, personal use, plastic surgery/gastroenterology, dental, and ophthalmic devices. Additional third-party reading on these guidelines here.
- Issuance #28 and #29 on 15 Dec 2025: 3 guidelines, covering plastic surgery, gastroenterology and urology, and ophthalmic devices; 4 guidelines, covering gene methylation/detection and PD-L1 antibody reagents.
- Issuance #32 on 30 Dec 2025: Guidelines for registration review of in vitro diagnostic reagent, Guidelines for registration review of tumor companion diagnosis-related gene mutation detection reagents (Real-time Fluorescent Polymerase Chain Reaction Method) (2025 Revised Edition).

2. Starting 01 Jan 2026, NMPA further expands its pre-submission technical consultation program for medical device registration. Read this third-party overview.