Clarity and Openness in Reporting: E3-based

News Summary

March 2026

Follow The CORE Reference Project on LinkedIn

Please join us at the EMWA Spring Conference in Barcelona (5-8 May 2026), as we celebrate the 10th birthday of CORE Reference. We will be hosting educational lunchtime sessions on both Wednesday and Friday in Barcelona. These sessions are free for EMWA members who register for the conference. The full #EMWA61 conference programme can be accessed here.

** The Wednesday CORE lunchtime session will mark 10 years of CORE Reference.

Alongside Guest Speaker Philip Burridge from Morula Health, a Celebration Supporter for the CORE Reference 10-year anniversary, team member Vivien Fagan will be joined by fellow CORE Reference author, Debbie Jordan. Guest talk: '**Practical implementation of the CORE Reference User Manual for Delivering High Quality CSRs**'.

** The Friday lunchtime learning session is titled '**How CORE Reference Advances Global Consistency in the Next Era of CSR Writing**'

Learning agenda:

§§ 'Clinical trial disclosure in Asia' by Zuo Yen LEE, PhD

§§ 'Learning Resilience in an AI-augmented environment' by Alison McIntosh

§§ '**AI in CSR Writing: Why CORE Reference Still Matters**' by Rona Vasey from Trilogy Writing & Consulting, An Indegene Company, Celebration Supporter for the CORE Reference 10-year anniversary.

Sign up for the free lunchtime learning sessions when you register for the conference.

Sam Hamilton & Vivien Fagan will also present the EMWA Foundation Workshop on CORE Reference (Wednesday 06 May: DDF38 13.30-17.00 CET).

MEDICINES AND VACCINES

CTR and CTIS

1. Upcoming DIA-sponsored training: EMA Clinical Trials Information System - Sponsor user training programme; 8-11 June 2026, 14:00 - 18:30 Central Europe Standard Time.

2. EMA has published the Joint Controllership Arrangement, dated 12 March 2026, with regard to CTIS and the processing of personal data captured in CTIS. The arrangement sets out the allocation of respective roles, responsibilities and practical arrangements between the parties, namely the EC, EMA, Member States, Sponsors and Marketing Authorisation Applicants/Holders.

Version 1.1 of the Q&A on the Joint Controllership Arrangement and data protection matters related to the use of CTIS has also been published, dated 12 March 2026.

3. Quarterly System Demo - Q1 2026 held on 26 March 2026 included a progress update on the submission of Annual Safety Reports in the safety module which is currently under development for CTIS. The recording and Q&A document are available here.

4. The CTIS Sponsor Frequently Asked Questions (FAQ) is based on questions frequently raised by sponsors during CTIS events such as walk-in clinics, bitesize talks, and through the EMA CTIS Service Desk. It was updated and published online 26 March 2026. It serves as a complementary document to the Sponsor Handbook, which is the main operational guidance for sponsors when using CTIS.

5. The CTIS sponsor handbook is the reference document that clinical trial sponsors should use when applying for a clinical trial authorisation through CTIS. The handbook was updated 26 Mar 2026 (v6.2).

6. The next CTIS walk-in clinic is on 16 April 2026. CTIS users can submit questions in advance via Slido by 8 April 2026 at 12:00, with the code #clinic254.

EU Regulatory

On 27 March 2026, the EU Commission released v7.2 of the EU CTR Q&A: The rules governing medicinal products in the European Union VOLUME 10 – Guidance document applying to clinical trials.
Includes :

- New Q&A 6.7 on Submission of Interim Results and Summary of Results in CTIS.
- New: Q&A 11.3 on Submission of notification of Serious Breaches in CTIS.
- New: Q&A 11.4 on Submission of third country Inspection Reports in CTIS.

The document can be downloaded from here.

European Health Data Space (EHDS) News

1. Cervera et al. published "The European Health Data Space: an opportunity to strengthen citizen rights and engage citizens in health data governance" in Front Med (Lausanne). 2026 Jan 20;12:1699941. doi: 10.3389/fmed.2025.1699941. PMID: 41641260; PMCID: PMC12864452.

2. An update to the "Frequently Asked Questions on the European Health Data Space" was released on 26 Mar 2026. Changes made include fixing typos and cross-references throughout. Expanding questions 22, 55, and 56. Adding questions 24, 40, 48, 66, and 67. Download the updated document from here.

UK and MHRA News

1. On 09 March 2026, MHRA released an annotation to the Guideline for General Considerations For Clinical Studies (ICH E8) to clarify the UK expectations - arranged helpfully in a comparative table.

2. MHRA Press Release 13 January 2026: Patients to benefit sooner as UK boosts clinical trials attractiveness with faster assessments and agile regulation.

3. Reminder that the amended clinical trials regulations go live across the UK on 28 April 2026. The HRA guidance sets out what will change in terms of processes, legal requirements, and expectations

for clinical trials of investigational products (CTIMPs). HRA has also published guidance for the changes to non-CTIMP studies to align with the clinical trial regulations.

- The CTIMP protocol template, designed to support sponsors and researchers when developing a research protocol, has been updated to reflect the amended clinical trial regulations and will be available on the HRA website at the end of March.
- MHRA guidance is also available and can be found on their clinical trials hub.
- Webinar recordings providing information about plans for implementing the new clinical trial regulations have been published.

4. MHRA have published a new webpage to keep you updated on their Improving Patient Information project. The project reflects a fully inclusive, collaborative approach across healthcare, industry and patient groups, and explores future models including digital delivery of product information. If you have any questions on the project, you can contact IPI@mhra.gov.uk.

5. The UK HRA have published the latest Clinical Trials update (19 March 2026) highlighting key updates ahead of the implementation of the amended clinical trials regulations.

FDA Guidance and News

1. FDA new draft guidance, "New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 4)" facilitates the development of proposed biosimilars and proposed interchangeable biosimilars. It revises and replaces the draft guidance for industry entitled "New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 3)" issued 17 Sep 2021, and includes revisions to certain Q&As that appeared in a previous version of the final guidance entitled "Questions and Answers on Biosimilar Development and the BPCI Act.

2. On 11 Mar 2026, FDA launched a new unified platform for analysing adverse event reports. The FDA Adverse Event Monitoring System (AEMS) aims to modernise and provide transparency into the safety of regulated products.

3. Last month, the US FDA CDER released its "CDER Guidance Agenda: New and Revised Draft Guidances Planned for Publication in Calendar Year 2026", including a total of 81 guidances planned.

4. CT.gov latest updates and release notes (18 March 2026) are available here and include upcoming Results Database Train-the-Trainer Workshops.

5. FDA has published a draft guidance for industry entitled "General Considerations for the Use of New Approach Methodologies in Drug Development." The purpose of this draft guidance is to provide drug developers with a validation framework and general recommendations for using new approach methodologies in drug development which furthers an important Center for Drug Evaluation and Research priority to move away from reliance on animal testing.

6. CDER's Center for Clinical Trial Innovation (C3TI) will celebrate a two-year anniversary by co-hosting (with Duke-Margolis Institute for Health Policy) the workshop: "Scaling Innovative Clinical Trial Approaches: Challenges, Progress, and Opportunities." This hybrid event is to be held 14 April 2026 — 9:00AM–4:30PM (ET). In person and virtual attendance registration details here.

EMA Guidance and News

1. EMA has published a draft guidance detailing how clinical trials should be designed and conducted when public health emergencies arise. The guidance is intended for sponsors and all parties involved in the design and conduct of clinical trials in the EU. A public consultation is open until 30 April 2026. Share your views here.

2. The EMA has released Questions & Answers on the Implementation of Three-dimensional printing (3DP) Technology (Additive Manufacturing Technology) for Solid Oral Dosage Forms. The aim of this

document is to provide guidance on Quality and Good Manufacturing Practice (GMP) requirements to support the use of 3DP technology in pharmaceutical manufacturing of solid oral dosage forms. This document focuses on some specific Quality and GMP requirements but should be read in conjunction with all other relevant EU guidelines. Q&A document available here. For background information: recent examples in Europe showing the use of 3D printed tablets in hospital pharmacy settings, are reported in an article published on 25 December 2025, in the International Journal of Pharmaceutics.

3. EMA has released an interim report from the ACT EU consolidated advice pilots. The pilots remain open for applications in 2026 and developers of medicines are encouraged to apply. Download the report from here.

4. The summary of the meeting of ACT EU regulatory partners in October 2025 is now available. It captures the key discussions on strengthening Europe's clinical trials environment, including progress on ACT EU priorities, emerging policy developments and the new targets for clinical trials by 2030.

5. The March 2026 edition of the EMA's Clinical Trials Highlights is available to download here.

Health Canada Guidance and News

Health Canada is extending the public consultation period for the proposed Clinical Trials Regulations and related guidance from 20 March to 19 April 2026. You can provide your comments here.

Real World Data

1. Marie Bradley, senior advisor for RWE in the Office of Medical Policy at the CDER has outlined what FDA looks for in evaluating RWD/RWE submissions in a presentation at the 2026 RAPS Global Regulatory Strategy (GRS) Conference. Read the RAPS report by JS Eglovitch here.

2. A field in its early stages is transportability methods in RWE. Read this 2024 review paper to kick-start your understanding of how they matter to regulatory and HTA decisions: Use of transportability methods for real-world evidence generation: a review of current applications.

3. Advance notice of the RWD Working Group's autumn event on 30 September – 1 October 2026, 09:00-11:30 (EDT) | 14:00–16:30 (BST) | 15:00-17:30 (CEST). The event will explore real world data. The call for speakers is open and 150 word abstracts should be submitted for consideration by 8 May 2026. Full details here.

4. On 27 March 2026 EMA released final recommendations on using the European Medicines Regulatory Network (EMRN) Data Quality Framework (DQF) when submitting premarket applications that include real-world data, entitled: "Data Quality Framework for EU medicines regulation: application to Real-World Data."

Transparency and Disclosure Resources and News

1. The European Data Protection Board (EDPB) and the EDPS - European Data Protection Supervisor have adopted a Joint Opinion on the European Commission's Proposal for a European Biotech Act. The proposal aims to strengthen Europe's biotech sector in healthcare simplifying the regulatory framework and updating clinical trial rules. Read more in this 12 March 2026 article 'EDPB and EDPS support harmonisation of clinical trials under European Biotech Act, but call for specific safeguards for sensitive health data'.

2. Advance notice of the PHUSE Data Transparency Autumn event 15–17 September 2026, 10:00–12:30 (EDT) | 15:00–17:30 (BST) | 16:00–18:30 (CEST). The Call for Speakers is open and 150 word abstracts should be submitted for consideration by 8 May 2026. Full details here.

3. Blog posting by Nirpal Virdee entitled "Confidential Information (CI): A Board-Level Risk Hiding in Plain Sight."

4. The Information and Privacy Commissioner of Ontario (IPC) has updated and expanded its de-identification guidelines for structured data. This update of the IPC's globally recognised guidelines, originally released in 2016, provides practical steps to help organizations maximize the benefits of data while protecting privacy

Development Strategy News

Transcelerate Common Protocol Template

The Transcelerate Common Protocol Template (CPT) V11 is now available, along with the supporting overview and reference materials. The Transcelerate CPT Basic Word edition is aligned with the finalized ICH M11 Protocol Template and Technical Specifications, as well as to the Unified Study Definitions Model (USDM) developed by CDISC and the digital data flow initiative. Download from here.

Other News

1. On 05 March 2026, the FDA Patient-Focused Drug Development Glossary web page was updated to define terms for Patient-Focused Drug Development (PFDD). PFDD is a systematic approach to help ensure that patients' experiences, perspectives, needs, and priorities are captured and meaningfully incorporated into drug development and evaluation.

2. EMA's 'Good pharmacogenomic practice - Scientific guideline' is open for consultation until 31 March 2026. This document describes requirements related to the choice of appropriate genomic methodologies during the development and the life-cycle of a drug.

3. This Applied Clinical Trials video of 03 March 2026 discusses how Bayesian methods are transforming clinical trial planning. The FDA's recent openness to Bayesian approaches is driving a strategic shift from traditional frequentist methods toward more flexible, probability-based trial designs that reduce regulatory uncertainty.

4. Reminder regarding the FDA/MHRA/Health Canada Joint Symposium on GCP, BE and GVP. Register now to secure your spot on 2-4 June, 2026. Visit FDA/MHRA/Health Canada Symposium: Regulatory perspectives in good clinical practice, bioequivalence and good pharmacovigilance practice for more information.

5. Springer book 'Estimands in Clinical Trials'. Selected chapters here for free:

- FDA Guidelines and Their Relationship to the Estimand Framework
- Leveraging the Estimand Framework Across Trial Designs
- Applying the Estimand Framework: Case Studies in Cardiovascular, Respiratory, and Infectious Diseases and Vaccines

6. Nature Health 04 March 2026: A large-scale database for clinical trial outcomes and features.

7. Clinical Leader guest column 04 March 2026: FDA's Draft Guidance On Bayesian Methods: Strategic Implications For Small Biotechs is an explainer for the FDA Jan 2026 Draft Guidance on the Use of Bayesian Methodology in Clinical Trials of Drug and Biological Products.

8. Several academic groups have published feedback on the draft FDA guidance on the use of Bayesian Methods in Clinical Trials in JAMA 23 March 2026. Access the 3 published articles: Evans et al, Gelman et al, Lee et al,

9. On 18 March 2026, EMA launched three major new tools of PRIME, the Agency's scheme to enhance support for the development of medicines targeting an unmet medical need. After a two-year pilot, they integrated these additional tools to help continue scientific dialogue, giving medicine developers faster answers and better supporting preparation for the submission of a marketing authorisation application. News announcement here.

10. FDA News Release 19 March 2026: FDA Releases Draft Guidance on Alternatives to Animal Testing in Drug Development. Draft guidance March 2026 'General Considerations for the Use of New Approach Methodologies in Drug Development'.

11. The outcome report from the multi stakeholder workshop on Bayesian statistics in clinical development (held 17 June 2026) is now available.

Artificial Intellligence/Machine Learning

The EC has published the second draft of Code of Practice on Marking and Labelling of AI-generated content. According to the EC "This second version, is drafted by independent experts, integrates written feedback from hundreds of participants and observers, including industry, academia, civil society and other stakeholders." See press release here and access the 2nd draft here.

Next steps: The Commission will collect feedback on the second draft from participants and observers to the code of Practice until 30 March EOB. The code is expected to be finalised by beginning of June this year. The rules covering the transparency of AI-generated content will become applicable on 2 August 2026.

News from Asia Regulators

1. In January 2026, NMPA China issued the implementation guidance on the Guiding Principles for the Application of Bayesian External Information Borrowing Methods in Drug Clinical Trials (page in Mandarin). This promotes the regulated use of existing external information to optimize trial design.

2. To align with international standards, NMPA China announced in December 2025 that ICH E6(R3) will be adopted for all clinical trials conducted from 31 March 2026 (page in Mandarin).

3. To align with international standards, NMPA China announced on 27 January 2026 that M14 General Principles for the Planning, Design, Analysis and Reporting of Non-Interventional Studies for the Safety Assessment of Pharmaceuticals Using Real-World Evidence (page in Mandarin) will be adopted for all relevant clinical trials starting from the date of the announcement.

4. In its January 2026 updates, PMDA Japan announced that Phase 1 studies in Japanese adults are no longer strictly essential prior to Japanese children participating in global pediatric trials planned in Europe and the US, provided safety data is robust and early consultation occurs. This marks a shift to improve early access to innovative medicines for children.

News from US: Possible Impact on Clinical Trial Ecosystem

1. BMJ News article 02 March 2026: US doctors withdraw from CDC vaccine committee, as RFK Jr appoints Bhattacharya as acting director.

2. Nature News article 17 March 2026: NIH pivots away from agency-directed science.

3. Reuters article by Julie Steenhuysen reports that a federal court injunction has put halted Health Secretary Robert F. Kennedy Jr.'s changes to U.S. vaccine recommendations." Read the full article here.

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 proposed document by the International Medical Device Regulators Forum (IMDRF) Clinical Evidence for In Vitro Diagnostic Medical Devices Working Group is open for public comment: "Clinical Evidence for IVD Medical Devices – Definitions and Principles of Performance Evaluation". Comment period: start date Wednesday, 4 March 2026 closing date Tuesday, 5 May 2026.

2. Medical devices: Simplifying the rules briefing document on EU Legislation in Progress published Mar 2026. Included in this is a proposed single conformity pathway for high-risk medical AI. The AI Act obligations will be assessed inside the existing MDR route.

3. RAPS open access article entitled "Engineering safety and effectiveness: A first-principles approach to drug-device combination products" is available to download from here. The article introduces a framework for assuring safety and effectiveness in drug-device combination products.

4. The University of Galway - Institute for Clinical Trials is holding a Clinical Research Innovation Day on 14 May 2026, together with the Health Products Regulatory Authority (HPRA), National Office for Research Ethics Committees, the Data Protection Commission Ireland, and the Health Research Consent Declaration Committee (HRCDC). The event will be supported by Medtronic and will share tips on how to prepare an application for review by the National Research Ethics Committee for Medical Devices as well as explain how the review process works and answer questions.

5. EU regulatory authorities, medical industry representatives, notified body representatives, and others met on 16 March for a high-level conference on medical devices hosted by the European Commission. Discussions around how the recent proposals to update the MDR/IVDR were progressing and when amendments might take effect. The video recording of the meeting can be accessed here.

US FDA

1. On 18 Feb 2026, FDA released a video and slides from their recent meeting on real-world evidence in medical devices.

2. The US FDA has published final guidance (dated 27 Mar 2026) on patient preference information (PPI) to enhance its evaluation of medical devices. This guidance explains the principal concepts that sponsors and other interested parties should consider when choosing to collect and submit PPI to aid in FDA-decision making across the total product life cycle.