Clarity and Openness in Reporting: E3-based

News Summary

February 2026

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CORE Reference 10th birthday celebrations at EMWA Spring Conference

If you are attending the EMWA Spring 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 (12.35-13.25 CET). These lunchtime sessions are free for EMWA members who register for the conference.

Wednesday: Celebrating a Decade of CORE Reference: Still Powering Quality CSRs Today. Guest Speaker: Philip Burridge for Morula Health "Practical implementation of the CORE Reference User Manual for Delivering High Quality CSRs"

Friday: How CORE Reference Advances Global Consistency in the Next Era of CSR Writing: Regulatory Transparency in Asia and Intelligent AI Integration. Guest Speaker: Rona Vasey for Trilogy Writing "AI in CSR Writing: Why CORE Reference Still Matters."

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

Our CORE Reference LInkedIn page details learning content being presented during both lunchtime sessions; the full EMWA Spring conference programme can be accessed here.

MEDICINES AND VACCINES

ICH

1. New ICH E6 training on informed consent (Modules 4.1 and 4.2) is available from the EMA's ACT EU initiative. As well as an overview on the process, tools and stakeholders, there are some good reminders of what parts of ICF require regional and local considerations. Part of the Good Clinical Practice Modernisation work, this covers the ICF process with practical clarity. Link here.

2. ICH announced the adoption of its M15 guideline, which aims to harmonise general principles and best practices for utilising model-informed drug development (MIDD) to aid in drug development. The Guideline covers general principles and good practices for the use of MIDD and harmonises expectations regarding documentation standards, model development, data used in the analysis, and model assessment and its applications.

3. A post titled 'ICH M11 and USDM: Mind the Gap' about ICH M11 (note the post is not by ICH) provides context on how ICH M11 and USDM align, including areas where there is still some work to do. Writers and template owners should appreciate that with an ICH M11 compliant template, digital data flow still needs work.

CTR and CTIS

1. For information: As part of the ongoing work to modernise CTIS, the following improvements are currently under development: emails for notices and alerts with opt-in from users and display of information on the language of CTIS documents published on the CTIS public portal. Subject to successful testing, these improvements are expected to be implemented by the end of March 2026 along with a CTIS sponsor handbook Q&A. Watch this space.

2. Upcoming DIA-sponsored training: CTIS sponsor end user training programme; 9-12 March 2026, 08:00 - 12:30 Greenwich Mean Time (GMT).

3. Clinical Trials Information System (CTIS): Walk-in clinic 18 February 2026 event broadcast is now available to view here.

4. In all, 15 expressions of interest were received during the March submission slot for FAST-EU, a pilot initiative by the Heads of Medicines Agencies which offers shorter evaluation timelines for selected multinational trials in CTIS. Sponsors can express their interest to participate during dedicated windows each month. See the CTCG website for more information.

5. The Clinical Trials Coordination Group (CTCG) has published its workplan for 2026-2027.

6. CTIS modernisation will be featured in the upcoming system demo on 26 March 2026 , 08:00 - 11:45 Greenwich Mean Time (GMT). A system demo is an event held at the end of a planning interval (a three-month period of work) to demonstrate the developments achieved in that period and to collect stakeholder feedback. Each demo has a dedicated timeslot on the agenda, full details here.

7. The latest issue of Clinical Trials Highlights issue 30 - February 2026 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

1. The Good Lay Summary Practice group, co-led by EFGCP and EFPIA, has released the Good Lay Protocol Synopsis Practice for public consultation. The consultation period runs from 3 February 2026 to 3 March 2026 and comments can be submitted here.

2. Find a Treatment is a European clinical trials search platform designed to help patients, caregivers, and healthcare professionals find up-to-date information about clinical trials across Europe. You can search clinical trials by disease, by treatment or by location. The site is not affiliated with the EMA, the European Commission, or CTIS.

UK and MHRA News

The MHRA, in partnership with the HRA, will be holding a webinar titled "Clinical Trials Regulations: Countdown to Implementation" on 12 March 2026, from 2:00 to 4:00 pm GMT. The webinar will cover the key changes in the updated UK clinical trial regulations, the guidance that has been published to support sponsors through the transition, and a panel of HRA and MHRA experts will be on hand to answer questions. Early registration is encouraged.

FDA Guidance and News

1. The latest release notes for ClinicalTrials.gov and Modernised PRS have been posted (28 January 2026) with continued improvements made to the Results Section and other pages in response to user feedback.

2. FDA has published an article entitled "One Pivotal Trial, the New Default Option for FDA Approval — Ending the Two-Trial Dogma" in NEJM (authors Vinay Prasad and Martin A. Makary). RAPS regulatory focus article reports on how experts have reacted to FDA's announcement of single pivotal trials for most drugs.

EMA Guidance and News

1.The EMA has issued an updated Questions and Answers on Implementing Regulation (EU) 2025/1466: Amendment of Regulation (EU) No 520/2012 and Conclusion of the Signal Detection in EudraVigilance Pilot by MAHs (dated 28 Jan 2026).

2. Report from AESGP, EFPIA and Medicines for Europe provides a comprehensive overview of the electronic Product Information pilot in Europe and can be accessed here.

3. EMA published "Review of the stepwise paediatric investigation plan (sPIP) pilot: Outcomes and future perspectives" dated 27 Jan 2026. According to the report "The pilot demonstrated feasibility and value supporting timely paediatric development while ensuring scientific rigour and flexibility for future integration into routine regulatory practice." Access the report here.

Health Canada Guidance and News

1. On 05 May 2026 at the Canadian IAPP conference Khaled El Emam will moderate an IAPP regulator panel focusing on de-identification titled 'De-identification: Cross-Canada Regulatory Perspectives'. Regulators from Ontario, Quebec, and federally will be present. The topic will be the regulation of de-identification (anonymization) and de-identified data. Registration and agenda here.

2. Health Canada released Draft guidance (4 Feb 2026) on proposed new Clinical Trials Regulations. Comments received during the public consultation following publication of the proposed regulations in the Canada Gazette, Part 1, may inform the final version of this guidance document. Draft guidance can be accessed here. Details of the consultation process here. Process open until 20 March 2026.

3. New Clinical Trial Regulation upcoming in Canada, effective 26 April 2026 details Here. Article here.

Real World Data

1. Clinical Trials With Pragmatic Elements: A Review of Use Cases and Real-World Data Utilization. This is a literature review of pragmatic RCTs - useful if considering implementing either pragmatic trials or extension studies using RWD. Aug 2025.

2. "Real-World Data and Real-World Evidence in Regulatory Decision Making: Report Summary From the Council for International Organizations of Medical Sciences (CIOMS) Working Group XIII" can be accessed here. The publication is a high level summary of a recent report by the CIOMS working group. doi: 10.1002/pds.70117

Transparency and Disclosure Resources and News

1. Let's Talk Privacy podcast by Aakash Suri featuring Shaun Hastings entitled "Hidden Healthcare Privacy Risks: How Clinical Trials Really Protect and Expose Patient Data." This 50 minute episode is a conversation on privacy, trust, and the future of clinical research.

2. Help pilot-test a new proposed CONSORT reporting checklist for plain-language trial results. EMWA is supporting a pilot-testing opportunity led by the University of Oxford. Sanjana Choudhury is developing a new proposed CONSORT checklist to support clearer sharing of randomised trial results with patients and the public. Medical writers, trial professionals, and patient/public contributors are invited to help pilot-test the checklist and provide feedback on usability and feasibility. Contact: sanjana.choudhury@wolfson.ox.ac.uk if you are interested.

3. BMJ Research Article 18 Feb 2026: Analysis of non-prospective trial registration in clinical trials submitted to The BMJ: observational study.

GDPR and Data transfer Ex-EU

In a joint opinion, the EDPB (European Data Protection Board)- combining all independent data protection authorities - and the European Data Protection Supervisor (EDPS) expressed serious concerns about key elements of the proposed GDPR and ePrivacy changes. Read about the concerns here. Specifically, the authorities strongly oppose the proposed narrowing of the definition of personal data. The opinion also questions the need for various key proposals, such as the legal basis for AI training and restrictions on the right of access. Many other provisions are seen as not clear enough.

Development Strategy News

1. A recently published open access article from RAPs entitled "Enhancing representation in clinical trials: From principle to practice" by Wang et al., 2026 can be accessed here.

2. US FDA, UK's MHRA and Health Canada will host a joint symposium: "Regulatory Perspectives in Good Clinical Practice, Bioequivalence and Good Pharmacovigilance Practice" June 2-4, 2026. This hybrid event will take place in Ottawa with options for virtual attendance. Registration details here.

3. Jan 2026 edition of WHO Global Clinical Trials Forum (GCTF) Newsletter can be accessed here.

4. Webinar 3 in the PHUSE series entitled "Implementing Estimands & Target Trial Emulation (TTE) in Real-World Evidence: Case Studies & Perspectives" was held on 24 February at 11:00-12:00 (EST) / 16:00-17:00 (GMT) / 17:00-18:00 (CET). Content accessed here.

5. CIOMS Cumulative Glossary, with a focus on Pharmacovigilance (Version 2.4, dated 2026) is available from here.

6. BMJ News article 1 Feb 26: GP patient records to be shared to boost health research.

7. ACRP Clinical Researcher article entitled "Informed Consent Form Development: Making the Most of Your Resources" (dated 17 Feb 2026) can be downloaded from here.

8. The EMWA Spring Conference (5-8 May 2026) will focus on three core themes, clinical trial protocols, patient voice and how to use it effectively, and AI. The full EMWA Spring conference programme can be accessed here.

Artificial Intellligence/Machine Learning

1. 11 Jan 2026 article in the guardian "Dangerous and alarming': Google removes some of its AI summaries after users' health put at risk"

2. The Australian regulator (TGA) has confirmed when and how they regulate medical devices that are or use artificial intelligence technology. Examples of medical devices that use AI include apps that help diagnose melanoma from photos taken on a mobile phone; cloud-based analytics that predict patient deterioration; chatbots suggest, deliver or monitor treatment to consumers or health professionals; clinical decision support tools that use generative AI to provide diagnostic or treatment recommendation; seye disease screening apps for conditions such as diabetic retinopathy, glaucoma and macular degeneration; radiology image analysis to aid in diagnosing pneumothorax, pneumonia and tumours.

3. On 28 January 2026, the Office of the Information and Privacy Commissioner of Ontario hosted a series of conversations exploring how AI is being deployed in Ontario's health sector. Entitled "Trustworthy AI in Health: The Promise, Perils and Protections" the full recording of the meeting can be accessed here.

4. Registration is open for the first CIOMS webinar on the recently published CIOMS consensus report on Artificial Intelligence in Pharmacovigilance (scheduled for 2 pm – 3.30 pm CET / 5 am - 6.30 am PDT / 8 am - 9.30 am EDT on the 6 March 2026). Full webinar details here. Places are limited and prior registration is necessary.

News from US: Possible Impact on Clinical Trial Ecosystem

1. BMJ News article 02 Feb 2026: Trump to withhold Gavi funding until all vaccines with mercury removed.

2. On 10 Feb 2026, Moderna announced that the FDA had refused to file its application for a new influenza vaccine. This was reportedly at the behest of biologics head Vinay Prasad. Moderna requested a Type A meeting with CBER to understand the basis for the RTF letter. In the interest of transparency, the Company has posted the full RTF letter on its website. mRNA-1010 has been submitted and accepted for review in the EU, Canada and Australia. As of 18 Feb 2026 this initial decision has been reversed as outlined in Moderna press release here. Supplementary news updates:

- BMJ News article 12 Feb 2026: US and Moderna: FDA refuses approval process for new mRNA flu vaccine.
- BMJ 19 Feb 2026: FDA reverses stance on Moderna vaccine.

4. BMJ Feature Article 14 Feb 2026: Why clinical trials are leaving the US—and Asia and Australia are welcoming them.

5. RAPS news article discussing the FDA's increased reliance on expert panels, rather than advisory committees for external expert advice and whether this may violate the Federal Advisory Committee Act (FACA). Experts first reported this argument in a JAMA viewpoint article entitled Law, Politics, and Expert Panels at the US Food and Drug Administration.

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. On 16 March 2026, (09:00 - 17:00, CET) the European Commission will hold a conference in Brussels entitled “Medical Devices: Innovation and Patient Safety.” The conference will also be web-streamed live. The event page can be accessed here.

2. New publication of harmonised standards under the medical devices regulations (Jan 2026) can be accessed here.

EU Transparency

EUDAMED News

The MHRA has released updated guidance on how medical devices are regulated in Northern Ireland, including adding a section on European database on medical devices (EUDAMED). See MHRA section below for further details.

US FDA

1. FDA’s Clinical Decision Support (CDS) Software Guidance issued 29 January 2026 has superseded the 6 January 6 2026 version. This updated guidance clarifies the scope of FDA’s oversight of clinical decision support software intended for health care professionals (HCPs) as devices. In order for a software function to be excluded from the device definition by this provision, it must meet all four criteria outlined in the guidance.

2. On 18 February 2026, the FDA hosted a town hall on its new Real-World Evidence guidance for medical devices - to follow updated guidance released in December 2025 that removes some major barriers.The big change is that FDA will now accept de-identified RWE without always requiring individual patient-level data. This impacts those working with large registries or multi-site databases. Event details are here (expect the recording or summary to be posted here in due course). Refer also to How to Study and Market Your Device - (Updated module 12/19/25) 510k, De Novo, IDE, PMA, HUD/HDE, Q-Submissions, Standards, Classification

3. FDA issued updated Computer Software Assurance guidance (Feb 3, 2026) for production and QMS software, aligned with the amended Part 820 QMSR (ISO 13485:2016). This guidance supersedes “Computer Software Assurance for Production and Quality System Software,” issued September 24, 2025.

4. CDER Guidance Agenda New and Revised Draft Guidances Planned for Publication in Calendar Year 2026 has been released and can be accessed here. Pierre Mermet-Bouvier identifies his own top 10 guidances from this list in a LinkedIn post.

UK MHRA

1. On 16 Feb 2026, MHRA launched a consultation on proposals for the indefinite recognition of CE-marked medical devices in Great Britain. Around 90% of devices used in GB are CE marked. Current recognition arrangements are time-limited, and the proposals for indefinite recognition are intended to protect supply and reduce duplication. MHRA are seeking views on:

- Extending current transitional arrangements for devices certified under the EU Medical Device Directive (MDD), aligning GB timelines with the EU’s transition to the EU Medical Device Regulation (EU MDR).
- Indefinite recognition of EU MDR and IVDR-compliant devices.

- Introducing an international reliance route for a small proportion of CE-marked devices that would fall into a higher risk class under GB rules.

The proposals aim to protect patient access, support industry certainty and maintain appropriate oversight. The consultation will run until 10 April 2026. Share your views at the above link.

2. The MHRA has released updated guidance on how medical devices are regulated in Northern Ireland, including the legislation that applies to manufacturers and suppliers. Updated 12 February 2026 to add section on European database on medical devices (EUDAMED).