Clarity and Openness in Reporting: E3-based

News Summary

April 2026

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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).

Next CORE Reference webinar- SAVE THE DATE

Wednesday 17 June 2026, 13.00-13.50 CET.

Our next CORE Reference webinar will be presented by Marcie Roche (Argenx) who will share her insights in ICH M11. More details to follow. Register in advance for this webinar: Register here.

MEDICINES AND VACCINES

CTR and CTIS

1. The latest issues of Clinical Trial Highlights providing the latest news on clinical trials from the European Medicines Regulatory Network, including news on the joint Accelerating Clinical Trials in the EU (ACT EU) initiative and on CTIS, can be found at the following links:

- March 2026
- April 2026.

2. EMA has updated Notices and alerts per role - CTIS Training Programme - Module 07. Notices and alerts are system-generated messages that help users track events throughout the lifecycle of clinical trial application and clinical trial (including notifications, corrective measures, ad hoc assessment, etc.).

UK and MHRA News

1. The amended clinical trials regulations went live across the UK on 28 April 2026. The HRA guidance sets out what has changed in terms of processes, legal requirements, and expectations for clinical trials of investigational products (CTIMPs).

2. HRA has published an updated version of the protocol guidance and template for use in a CTIMP. The guidance and template reflects the changes to the amended clinical trials regulations. Updates have also been made to align with the Data Protection Act 2018 and the UK General Data Protection Regulation (UK GDPR). The updated version (2.0) should be used from 28 April 2026.

3. HRA Head of Policy and Engagement, Clive Collett, has written a blog outlining the new research transparency requirements as a result of the amended clinical trials regulations. Read Clive's blog for a nice summary of the requirements.

4. MHRA has responded to the British Pharmacological Society position statement on medication use in pregnancy and breastfeeding. The statement draws attention to significant evidence gaps, inconsistent advice for patients, and the longstanding exclusion of pregnant and breastfeeding women from clinical trials. The MHRA welcomed the position statement and their response can be found here.

5. The HRA published the March edition of its monthly bulletin, HRA Latest, on 31 March 2026, outlining key regulatory, operational, and strategic developments across the UK health and social care research landscape.

6. Update from GOV.uk: Guidance, Declaration of Helsinki and Clinical Trial Regulations alignment updated 14 April 2026. Updated in response to stakeholder feedback to remove reference to specific versions of Declaration of Helsinki in section 'Use of placebo or no intervention'.

7. HRA has launched a Modification Tool on 09 April 2026. to help sponsors and researchers prepare for updated clinical trials regulations which come into force on 28 April 2026. The Modification Tool is

an updated version of the Amendment Tool and is now available on the Integrated Research Application System (IRAS). Read the announcement here.

8. Guidance entitled "Clinical trials for medicines: roles and responsibilities" was published 16 April 2026 and can be accessed here.

9. HRA published its latest research transparency report on 21 April 2026, covering the compliance of sponsors with regard to registration of clinical trials, publishing results on a registry and sharing a summary of results with participants. The data covers the registration status of clinical trials in the UK from 2024, and for the first time, data on whether trials that closed in 2023 have published a summary of results on a public registry within 12 months of the trial ending and shared a lay summary of results with their participants.

FDA Guidance and News

1. US FDA has announced that from 1 October 2026, manufacturers must submit adverse event individual case safety reports (ICSRs) for drugs, biologics, and combination products using the data standards specified in the International Council for Harmonisation's (ICH) E2B(R3) guideline.

2. The US FDA has reminded more than 2,200 medical product manufacturers and researchers of their legal requirement to disclose clinical trial results. According to an internal analysis, 29.6% of studies that are highly likely to fall under mandatory reporting requirements have no results information submitted to ClinicalTrials.gov. Read the FDA press announcement here.

3. The FDA Office of the Chief Medical Officer (OCMO) has released planned Guidances to be published or developed 2026-2028.

4. The 2026 ClinicalTrials.gov Results Database Train-the-Trainer Workshops will provide training to key personnel involved in submitting study results to ClinicalTrials.gov for their organizations. These workshops will take place in-person on 9+10 September or 16+17 September 2026 on the main NIH campus in Bethesda, MD. Attendees will only participate in one session, which will be free to attend.

5. Press Release 28 Apr 2026: FDA Announces Major Steps to Implement Real-Time Clinical Trials in which the 'Agency unveils real-time trial proofs-of-concept and upcoming pilot program'.

6. The FDA has issued a request for information to solicit input on a proposed pilot program to assess how artificial intelligence (AI)-enabled technologies can improve efficiency, speed, and quality of decision-making in early phase clinical trials. Details of the request here.

EMA Guidance and News

1. On 02 April 2026, EMA in collaboration with Health Canada established a Clinical Data Publication (CDP) Q&As document to promote transparency and efficiency in the review and publication of clinical data. This Q&A document provides guidance to applicants regarding the work-share process, eligibility criteria and applicants' responsibilities. The document will be revised regularly.

2. Multi-stakeholder European network of paediatric research at the EMA (EnprEMA) and Accelerating Clinical Trials in the EU (ACT EU) workshop focused on paediatric clinical trials to be held 12 May 2026, 10:00 - 17:00 Amsterdam time (CEST). Registration details here.

Real World Data

The FDA has published a new set of 73 examples of marketing authorisations using RWE from financial years 2020-2025. Further details are presented under heading Medical Devices (US FDA) below and the full press release can be accessed here.

Transparency and Disclosure Resources and News

1. The PHUSE 'EU CTR Implementation' project (part of the Data Transparency Working Group) is calling for feedback on their latest white paper entitled 'Protecting Commercially Confidential Information (CCI) While Complying with the European Union Clinical Trials Regulation 536/2014'. The white paper is designed to provide practical guidance to support clinical trial sponsors in navigating the EU Clinical Trials Regulation, while ensuring that CCI is appropriately safeguarded. Provide feedback to workinggroups@phuse.global by 6 May 2026. Further PHUSE Project information from here.

2. Free webinar "Addressing Anonymization Requirements Under Quebec Regulations and the GDPR" on Wednesday, 20 May 2026; 4 PM - 5 PM GMT+1. Registration details here.

GDPR and Data transfer Ex-EU

1. The Belgian Data Protection Authority has published a brochure titled "The Impact of Artificial Intelligence (AI) on Privacy", the first publication in its "AI & Data Protection" initiative. This information brochure has been prepared to help individuals understand how AI systems may affect their privacy and the protection of their personal data. It also provides practical recommendations to help individuals keep control over their data in an increasingly AI-driven environment. Access from here.

2. Comments on the European Data Protection Board Guidelines 1/2026 covering processing of personal data for scientific research purposes should be received by 25 June 2026 using the provided form. Details here. Additional background information can be accessed here.

European Health Data Space (EHDS)

Springer Nature paper 20 March 2026 on patients' views on health data sharing in the context of the EHDS: 'What patients value in data reuse for oncology research: a multi-stakeholder qualitative study to inform the European Health Data Space implementation in Belgium and beyond'.

Development Strategy News

1. WHO have published free online courses to help participants gain in-depth practical knowledge of how to effectively administer a Research Ethics Committee (REC).

- Ethics and Review of Interventional Clinical Research Part 1 (divided into 3 modules)
- Ethics and Review of Interventional Clinical Research Part 2 (divided into 3 modules)

2. PHUSE have released the results of their "Participant Data Return Survey." The survey asked study respondents to share their organisations' practices and perspectives on returning data to clinical trial participants. A blog post by Dan Boisvert summarising the results and next steps can be accessed here.

3. The PHUSE Blog entitled "Why the Pharma Industry Needs the Imaging Data Anonymization Guideline – and What You Can Do Now" can be accessed here. In the post the need to have robust anonymisation rules to ensure data privacy and compliance is explained. A collaborative Imaging Data Anonymization Guideline is now being endorsed by PHUSE to establish practical, minimum requirements for anonymising DICOM metadata, pixel data, and workflows.

4. PHUSE has a YouTube channel which covers event vlogs, educational resources, and presentations. You can review material and subscribe to the channel here.

5. WHO is launching a free, online, self-paced course on Good Practices for Clinical Trial Design and Implementation, aimed at supporting researchers and professionals involved in clinical research. The course launches on 4 May 2026 with an online event from 13:00 to 14:00 CET. Registration details for both events can be accessed here.

6. Free webinar by TransPerfect entitled "EU Clinical Trial Regulation: Latest Developments and Upcoming Opportunities" 28 May 28 2026; 10am EDT (NA) / 3pm BST (UK) / 4pm CEST (EU-Central). Registration details here.

7. The recording of the Bioforum's webinar "Per-Protocol Treatment Effects in the Estimand Era: Time for a Rethink?", held on 26 February 2026, is available. (Note: registration is required to watch the recording).

8. PSI webinar "Enhancing Clinical Study Reporting with the Estimand Framework" and a 2025 paper in Springer Nature highlights that if estimands are not carried through into reporting, much of their value is lost.

9. The latest Protocol Development newsletter (#86) from Jonathan Mackinnon reviews master protocols and adaptive design - barriers, facilitators, recommendations, case studies, and what lies in the future for these designs. Read it here.

Artificial Intellligence/Machine Learning

1. News feature from Nature 01 April 2026 entitled "Hallucinated citations are polluting the scientific literature. What can be done?" by Miryam Naddaf & Elizabeth Quill can be accessed here.

2. See information on RAPS article entitled "Navigating convergence and divergence between the EU MDR and EU AI Act" by Chakraborty & Setty in section on Medical Devices below.

News from Asia Regulators

1. China's Personal Information Protection Law (PIPL) introduces new requirements that directly affect how data is shared, accessed, and governed. Vivli will host a webinar which will provide a practical overview of the PIPL and its implications for organizations involved in clinical research data sharing: 04 May 2026, 9-10am EST/ 3-4pm CET. Register here.

2. On 08 April 2026, China's NMPA issued the "Technical Guiding Principles for Clinical Review of Investigational New Drug (IND) Applications" (Announcement No. 27 of 2026) (page in Mandarin) to improve the scientific design and overall efficiency of drug clinical trials, effective immediately. The guidance applies to chemical drugs and biologics. The scope of evaluation includes rationale of studies, preclinical data, scientific relevance and feasibility, study design, risk assessment, and safety reporting.

3. On 08 April 2026, China's NMPA issued the "Technical Guiding Principles for Clinical Review of Marketing Applications" (Announcement No. 26 of 2026) (page in Mandarin) to guide reviewers in performing scientific and efficient evaluations of the clinical efficacy, safety, and benefit-risk profiles of drug marketing applications, and to help applicants understand the key considerations of clinical reviews.

News from US: Possible Impact on Clinical Trial Ecosystem

1. BMJ News 10 April 26: Trump's war with Iran is threatening medical supply chains, experts warn.

2. Drug pricing body, Institute for Clinical and Economic Review (ICER) has stated that the US FDA should be more transparent when granting accelerated approval for certain drugs. The ICER report recommends several policies including strengthening the selection of surrogate endpoints, requiring

advisory committees for accelerated approval reviews and improving transparency in decision-making. Access the Reuters article here.

3. Nature News 26 Apr 26: Entire NSF science advisory board fired by Trump administration.

4. Nature News Feature 28 Apr 26: Key US science panels are being axed — and others are becoming less open. A Nature analysis shows that the Trump administration has terminated more than 100 advisory committees to science agencies — and reduced the transparency and independence of those that remain.

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. The International Medical Device Regulators Forum (IMDRF) has published a draft technical document entitled "Technical Framework for Artificial Intelligence Life Cycle Management." According to the document "This work contributes to the establishment of globally harmonised considerations that, when applied across a device's total product life cycle, can foster innovation while protecting public health." The document is open for consultation until 10 July 2026 and can be accessed here. A Regulatory Focus article by JS Eglovitch can be accessed here.

2. Public Health eNews from European Commission: Pilot programme to be launched to support breakthrough medical devices and in vitro diagnostics.

3. The European Commission issued proposed amendments to streamline its medical device and in vitro diagnostic regulations, MDR and IVDR. A news article discussing this topic can be accessed here.

4. RAPS article entitled "Navigating convergence and divergence between the EU MDR and EU AI Act" by Chakraborty & Setty compares the regulatory nuances between the EU MDR and the AI Act. Their article "highlighting points of convergence and divergence" can be accessed here.

EU Transparency

The European Commission published the updated EU harmonised standards for medical devices under the Medical Devices Regulations to support compliance with EU regulations. Harmonised standards in the field of medical devices and in vitro diagnostic medical devices are prepared by the European standardisation bodies CEN and CENELEC on the basis of a standardisation request issued by the Commission in line with the framework set out in Regulation (EU) No 1025/2012.

EUDAMED News

EUDAMED is ahead of the date of mandatory use - in respect of the first four modules. These will deploy on 28 May 2026.

To support this, new training activities are available in April and May 2026 as all-day events, web-streamed:

- Actor module – 28 April 2026 – 9:00-18:00 CEST
- UDI/Devices module – 5 May 2026 – 9:00-18:00 CEST
- Notified Bodies & Certificates module – 7 May 2026 – 9:00-18:00 CEST

See here for training sessions.

US FDA

1. The FDA has published a new set of 73 examples of marketing authorisations using RWE from financial years 2020-2025, building on the foundational work presented in the 2021 publication "Examples of Real-World Evidence (RWE) Used in Medical Device Regulatory Decisions. Read further details and the press release here. The new examples highlight the growing use of RWD to validate device software functions, including artificial intelligence (AI) and machine learning (ML)-enabled technologies.

2. A commentary titled “The Impact of FDA's Workforce Reduction on Regulatory Timelines for Medical Device Companies” can be accessed here.

3. FDA Voices article 02 Apr 26: Real-World Evidence: Advancing Regulatory Decision-Making for Medical Devices. This article includes links to Examples of Real-World Evidence (RWE) Used in Medical Device Regulatory Decisions.

UK MHRA

1. The UK MHRA and the US FDA announced they are strengthening cooperation on medical device regulation. The press release confirming this can be accessed here.

2. MHRA has secured further funding to expand the AI Airlock programme (the UK’s first regulatory sandbox for Artificial Intelligence as a Medical Device [AIaMD]) over the next three years. Press release details here.

CHINA

NMPA Center for Medical Device Evaluation (CMDE) implemented the “Pre-Review of Clinical Trial Protocols for Innovative Medical Devices” and released 2 checklists and requirements on 13 March 2026 for the pre-review of clinical trial protocols for 1) innovative medical devices, and 2) in vitro diagnostic reagents (page in Mandarin). Also read this third-party summary.