Clarity and Openness in Reporting: E3-based

News Summary

July 2026

Follow The CORE Reference Project on LinkedIn

Our new dedicated information page is being finalised and will be fully available very soon. To keep up to date and find out more about CORE Reference continue to visit our EMWA Special Projects page. Here you can access links to CORE Reference guidance and relevant resources.

Useful links on the page include

- A short video outlining the CORE Reference project
- CORE Reference manual
- Mapping Tool which maps CORE Reference sectional content to ICH E3
- Launch paper

MEDICINES AND VACCINES

CTR and CTIS

1. A new version of the EU CTIS Sponsor Handbook (v6.3) is available. Changes include new information introduced by CTR Q&A v7.2 along with information on automated reminders in CTIS ahead of results submission deadlines, regular communications through established channels,, and detailed guidance on submitting results (see Chapter 5 of the handbook: End the clinical trial and submit results).

2. EMA Step-by-Step Guide: Support with Workload Management in the

Authority Workspace - CTIS Training Programme - Module 04 has been revised: Version 1.1, June 2026, as has the FAQ - Support with Workload Management by Workspace: Version 1.4, June 2026.

3. EMA's June 2026 edition of Big Data Highlights was released 30 June 2026 and includes the following featured topics: use of real-world evidence in regulatory decisions; AI activities of the European Medicines Regulatory Network: three years on; New Q&A on real-world data guidance.

4. EMA has published recommendations from the CTIS Simplification Task Force. Topics analysed include the CTIS role matrix and Clinical Trial Application (CTA) Workflow.

5. The new CTIS training environment access approach is effective now. The new approach makes it easier for all users to gain hands-on experience in CTIS before working in the production environment. Be familiar with the new CTIS safety module in view of the upcoming changes for the annual safety report (ASR) submissions via CTIS. To request access to the CTIS training environment, follow the instructions in Section 6.2.3 of Version 6.4 (07 July 26) of the Sponsor Handbook.

EU Regulatory

European Health Data Space (EHDS) News

1. Webinar titled "Understanding the European Health Data Space (EHDS) and the Secondary Use of Data (SUD): Requirements, Challenges, and the Path Forward" will be held on 19 Aug 2026 14.00 (UK time). Registration details here.

UK and MHRA News

1. On 02 July 2026, the UK government published guidance setting out expectations for how major holders of human genomic data can enable research while maintaining appropriate security safeguards through Secure Data Environments, controls on international access to genomic data, and the Five Safes approach. The Health Research Authority (HRA) full response is available here.

2. On 01 July 2026, the Health Research Authority (HRA) published the July edition of its bulletin, Building better research services. This issue includes an update on the timelines for development of the new digital service, and how to plan and manage health and care research.

3. The most recent 'HRA Latest' includes new guidance on safeguarding UK human genomic data as well as changes to Research Ethics Committee standard operating procedures.

4 A recent blog article summarising the UK Clinical Trials Regulations can be accessed here.

5. The blog by MHRA inspectorate entitled "Use of AI for GxP inspection responses: setting standards without stifling innovation" reports on submissions to Compliance Teams inspections. Although supportive of AI, the team report that they have "...encountered responses containing references to MHRA guidance that doesn't exist, citations of inappropriate regulatory frameworks, and responses to serious deficiencies that appear designed to mislead rather than address underlying problems...." Specific examples of thee issues are provided in their blog.

6. MHRA published updated guidance on patient information leaflets (new version dated 1 Jul 2026).

FDA Guidance and News

1. In June 2026, FDA published the revised draft guidance Master Protocols for Drug and Biological Product Development. Submit comments by 24 Aug 26. Check out the accompanying guidance snapshot and podcast.

2. A recording of the FDA webinar held on 23 June 2026 entitled "Office of New Drugs Standard Safety Tables and Figures for New Drug and Biologic Applications" can be accessed here.

3. Wartenberger, M., (2026) published an opinion piece entitled "Are You Ready for Elsa? What the FDA's Generative AI Inspection Tool Means for Clinical Data Teams" (doi: https://doi.org/10.47912/jscdm.503) the published opinion piece can be accessed here.

4. On 27 Aug 2026, FDA will hold a free virtual workshop to discuss statistical considerations for digitally-derived endpoints in drug and biological product clinical trials. Registration and details of the workshop (FDA Virtual Workshop on Digital Health Technologies and Statistical Considerations for Digitally-Derived Endpoints in Clinical Trials) can be accessed here.

5. In July 2026, FDA's Oncology Center of Excellence announced three final guidance documents for clinical investigators that are intended to increase

patient participation in clinical trials of oncology drugs. The guidance documents all concern trial eligibility and are open for comment:

- Cancer Clinical Trial Eligibility Criteria: Laboratory Values
- Cancer Clinical Trial Eligibility Criteria: Performance Status
- Cancer Clinical Trial Eligibility Criteria: Washout Periods and Concomitant Medications

EMA Guidance and News

1. On 13 July 2026, EMA published European Medicines Agency post-authorisation procedural advice for users of the centralised procedure. This is Revision 118 of the document and includes a revised Q&A to provide clear guidance on processes involved in post-authorisation submissions. For convenience, a tracked change version of the guidance is also available here.

2. The July 2026 edition of Clinical Trial Highlights - issue 35, is available with 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 the Clinical Trials Information System (CTIS).

Health Canada News

1. Health Canada has launched the Clinical Trials Search Portal, which provides up-to-date information on approved clinical trials for prescription drugs in Canada. The Canadian Clinical Trial Search Portal replaces the 2013 Clinical Trials Database. The portal has information on clinical trials that Health Canada has approved involving human pharmaceutical, biologic and radiopharmaceutical drugs.

2. Health Canada has published a new guidance document (effective 29 July 2026) on clinical trial transparency for sponsors of human clinical trials. The guidance outlines policy expectations, including registering clinical trials and reporting results in an international registry that meets WHO requirements. Full details and requirements can be accessed here.

Real-World Data

1. Registration for the PHUSE Real World Evidence Working Group's Autumn event 30 Sept–1 Oct 2026: 9:00-11:30 (EDT) / 14:00-16:30 (BST) / 15:00-17:30 (CEST) is now open. Details here and registration here.

2. Following the pilot in 2025, the MHRA is continuing with RWE Scientific Dialogue through ongoing workshops. Details on how to apply are here. Note: applications will not be accepted after 11.59pm BST 17 August 2026.

1. Don't forget: Registration is now open for the Data Transparency Autumn Event 2026 (15 Sep – 17 Sep 2026; 10:00-12:30 (EDT) / 15:00-17:30 (BST) / 16:00-18:30 (CEST)). The free event features expert-led sessions on topics including data privacy, regulatory compliance, patient-centred transparency, and AI innovation. Register in advance here and full details and agenda are here.

2. TranspariMED have published the EMA response to concerns around clinical trial transparency. EMA were asked to take urgent action because half of all drug trial results in Europe were not being made public as required by law. Copies of the original letter to EMA and EMA's response can be accessed here. According to TranspariMED "....They have already started contacting sponsors over unreported trials, and are providing national regulators with the data they need to hold pharma companies, universities and hospitals to account."

3. Recently published article titled "Marketing authorization and strategic patenting: Evidence from pharmaceuticals" reports how marketing authorisation "impacts follow-on patenting in the pharmaceutical industry, for both originators and other firms." The full article can be accessed here. The authors outline the role regulatory transparency plays in shaping innovation strategies.

4. The European Commission published guidelines on transparency obligations for providers and deployers of certain AI systems. Press Release 20 July 2026 here.

5. EMA/HMA has reported that they will monitor the timely submission and publication of trial results across Member States and take additional measures to improve compliance. In the coming months, quarterly reports on the performance of the EU clinical trials environment will include the number of trials with available summaries of results. ACT EU will also launch a targeted communication campaign for sponsors.

GDPR and Data Transfer Ex-EU

1. RD Privacy Watch article 03 July 2026 'US ruling may affect transfers to the United States'. The Swedish Authority for Privacy Protection (IMY) has commented on a recent US Supreme Court decision, issued in early July 2026, which may impact data transfers to the United States. Advice is no change for now but to stay informed and be prepared for potential changes, such as the revocation of the adequacy decision. The CORE Reference Project will keep an eye on this and provide updates as they become available.

Development Strategy News

1. If you enjoyed the CORE Reference Webinar on 17 June 26 on ICH M11 template, and want to know more about technical solutions, an attendee recommended this Webinar from April 2026 where companies like Oracle and Nurocor presented solutions. Recording here. Thanks to colleague, Hugo Hartmans, for the tip.

2. A recording of a webinar held on 30 June 2026 entitled " Medical Writing in the E6(R3) and M11 Era: Are We Ready?" is available here.

3. On 30 June 26, ACRO issued this document: 'ACRO Comment on Auchincloss Next-Generation U.S. Clinical Development to Accelerate Cures Discussion Draft' in support of the steps taken in the legislative summary to move toward clinical trial modernisation and improved access to new therapies. In their letter, ACRO encourages policymakers to leverage the organisations already driving clinical research: CROs and clinical technology companies.

4. EMA's PRIME (PRIority MEdicines) scheme helps medicine developers generate robust evidence and navigate the regulatory pathway with early scientific support. Hear directly from Kevin Cunningham, PRIME Scientific Coordinator at EMA, and Outi Maki-Ikola, Finnish member of the Committee for Medicinal Products for Human Use (CHMP), about how PRIME works and why it matters: Video here.

5. TransCelerate has collaborated with CDISC and other stakeholders to develop a standard data model for specifying protocol information, as well as a demonstrated way to connect systems that produce, exchange, or consume this information via the Digital Data Flow initiative. Follow the Digital Data Flow LinkedIn page to keep up with developments.

6. Steve Ruberg has a blog series on estimands. Some posts may be heavily statistical, but the 24 July 2026 post is relevant for MWs and fine for non-statisticians: Blog 27 – Estimands Part 3B – What Is the ITT Estimand Anyway? Visit the blog home page and bookmark the blog if you want to follow it.

Artificial Intelligence/Machine Learning

1. The HMA 2025 AI Observatory report (dated 12 May 2026) provides an overview of guidance and policy, applications of AI, ongoing collaborations and engagement activities with stakeholders and partners, as well as a high-level overview of progress in EU-funded initiatives and regulatory science research. The report is also discussed in the Regulatory Rapporteur article by James Smith here.

2 Slides and a summary report of the joint U.S. FDA, and Clinical Trials Transformation Initiative (CTTI) annual public workshop on Artificial Intelligence in Drug and Biological Product Development (held Dec 2025) are now available and can be accessed here.

3. RAPS article reports the findings from a 2025 benchmarking survey on the adoption of regulatory artificial intelligence (regulatory AI) across pharmaceutical and life sciences industries. Access the article here. The article was adapted from a presentation by the authors at the 2025 RAPS Convergence in Pittsburgh from 7-9 October.

4. On 20 July 2026, the European Commission published guidelines on transparency obligations under AI Act. The AI Act entered into force on 2 Aug 2024, and the transparency provisions take effect on 2 August 2026. According to the EC "Transparency obligations will help people recognise when they are interacting with AI or when content has been generated or altered by AI, reducing the risk of deception and manipulation. The guidelines published today clarify which providers and deployers must comply with the transparency obligations for interactive AI systems and the marking and labelling of AI-generated content." Download the guidance here. Download the announcement here. Although the guidance is not specific to healthcare, companies including AI components may be subject to transparency rules.

5. EU icons for labelling AI-generated content can be accessed here. Deployers of generative AI systems can use the EU set of icons to label certain AI-generated content, in accordance with the AI Act transparency rules.

6. The Code of Practice on transparency of AI-generated content can be accessed here.

7. Answers to frequently asked questions related to concepts and obligations in the Commission Guidelines on Article 50 of the AI Act can be accessed here. Includes the answer to the question "What constitutes the human review oreditorial control/responsibility required to qualify for an exemption from the labelling obligation?"

8. Opinion piece entitled "How well are AI-discovered drugs faring in the clinic?" by Kelly Bilodeau published online in PharmaVoice.

News from US: Possible Impact on Clinical Trial Ecosystem

1. Reuters article entitled " Inside RFK Jr.'s push to dismantle decades of U.S.

vaccine policy" by Yasmeen Abutaleb, Dan Levine and Bo Erickson can be accessed here.

2. Acting FDA Commissioner Kyle Diamantas has clarified that certain policies disseminated in medical journals by his predecessor Marty Makary are not official agency policy or guidance. In a letter to Rep. Diana DeGette (D-CO), he assured the ranking member of the House Energy and Commerce health subcommittee that some of the agency's major policy announcements from the past year that circumvented the agency's good guidance practices are not to be treated as guidance or policy. Further details can be found in the RAPS report here.

3. Nature news 24 Jul 2026: White House rolls out AI funding — and signals a new era for US science.

4. K Bilodeau has published an online article via MEDTECHDIVE entitled "The FDA was all in on AI. Will that change?"

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. An open access article published in the Journal of Regulatory Affairs, addresses best practices for development of companion diagnostics (CDx). The article, entitled "Companion diagnostics: Best practices for effective collaboration" can be downloaded from here.

The MHRA has published guidance clarifying how UK medical device law applies to AI scribes (ambient voice technology products). 29 July 2026 press release here; guidance here.