Clarity and Openness in Reporting: E3-based

News Summary

October 2026

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NEW SEARCHABLE CORE REFERENCE WEBSITE

Our News Summaries are now posted on our new CORE Reference website as well as on our LinkedIn page. As a valuable new feature, there is also the ability to **search** our monthly News Summaries - **those issued from January 2025 onwards can be searched using key words or phrases**.

How to find and use the NEW search function: On the main page of the CORE Reference website, use the 'Navigate CORE Reference' pane on the right-hand side of the landing page. Click on 'News Summaries' where you will find the NEW search function. Search monthly summaries from January 2025 onwards using one of the listed search terms or phrases to identify relevant news summaries.

By accessing the News Summaries on the website and searching by topic, you will be able to more efficiently target specific CPD needs. An archive of pre-2025 News Summaries can be accessed on the same page.

Highlighting new resources on our website: Over the next few News Summaries we will highlight new resources on our website. This month, we focus on our recent slide deck and recording of a presentation to the AMWA community: 'CORE-Value for the Global Regulatory MW Community: An Evergreen User Manual & CPD for Self-led Learning.' To access this new learning resource: from the 'Navigate CORE Reference' pane on the right-hand side of the landing page, click on 'Publications', scroll down to find 'Live Meetings and Webinars.'

A huge thanks to EMWA for supporting the creation of this new site.

MEDICINES AND VACCINES

ICH

ICH have published new training materials covering 11 harmonised guidelines (access this link for embedded links to all bulleted trainings) in recent months:

- ICH E6(R3) – Good Clinical Practice (GCP) - new modules on data governance and essential records
- ICH E14/S7B Q&As (R1) – Clinical and Nonclinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential - Step 4 Presentation just published
- ICH M11 – Clinical electronic Structured harmonised Protocol (CeSHarP) – TEN new training modules developed by the ICH M11 Expert Working Group
- ICH M13B – Bioequivalence for Immediate-release Solid Oral Dosage Forms - Step 4 Presentation published in July
- ICH M15 – General Principles for Model-Informed Drug Development – Example of Assessment Table
- ICH Quality Guidelines 8 to 12 - the first four of eight planned modules on the principles and concepts governing this subset of the Q guidelines

CTR and CTIS

1. The next 'CTIS Bitesize Talk' on 18 Nov 2026, will focus on the Role Management functionality in CTIS, the new Safety user roles introduced with the CTIS Safety Module, and the new access process for the CTIS Training Environment. Full details here.
2. The October 2026 Clinical Trial Highlights can be found here and includes the latest on the new safety module in CTIS, the clinical trial applications advice pilot as well as ACT EU news and CTIS news.
3. The list of public holidays for 2027, as recorded in CTIS for each EU Member State, is now available on the EMA website.
4. EU CTR / CTIS Digest: August-September 2026 highlights published 01 Oct:
   - Proposed changes could affect ~70% of current CTIS functionality, including faster assessments, more flexible major modifications, risk-based procedures, common medicinal product dossiers and combined studies.
   - First CTR changes could apply as early as 2028. The current CTIS requires immediate investment; development of the modernised platform is planned for early 2027.
   - A more detailed roadmap is expected at the December 2026 EMA Management Board.
   - The Biotech Act proposal is under discussion in the EC so timelines may change.
5. A recording of 7 October 2026 CTIS Walk-in clinic is available to download from here.
6. A new version (7.4) of the Clinical Trials Regulation (EU) No 536/2014 Questions & Answers was published this month and includes a revised Chapter 6 on the submission of the summary of results and layperson summary of results.

UK and MHRA News

1. On 30 September 2026, the UK's HRA released a Blog - Make it Public: what we've learned and what comes next. The overall message from the Make it Public strategy launched in 2020 is that clinical trial registration has improved significantly, but reporting results and sharing findings with participants remain major challenges.
2. On 23 October 2026, the UK's HRA released a Blog - Our response to the ICO anonymisation and pseudonymisation consultation. The HRA response calls for clearer guidance on anonymisation, data identifiability and organisational responsibilities in health and social care research, particularly in secure research environments. It also stresses alignment between data protection, confidentiality and wider research governance.

FDA Guidance and News

1. The FDA is holding a webinar on the Modernised PRS on 5 November 2026 at 13:00 EST where CT.gov staff will discuss newly available features, the phased retirement of the classic system, and address questions from attendees. Register early and submit your questions in advance. The webinar will be recorded for those who can't make the live event.
2. FDA Voices 02 Oct 26: Transparency Makes Modern Regulatory Science Stronger - FDA's Transparency Roadmap. Takeaways:
    - FDA wants sponsors to make the existence of their Investigational new Drug Applications public upon filing
    - FDA intends to increase post-approval scientific data disclosures (with redactions) similar to how EMA now releases data
    - FDA wants more public data about the successful and unsuccessful uses of animal models in applications
    - FDA intends to be proactive about releasing inspection reports
    - FDA is working to finalise a rule on Patient Medication Information, and is also working on rules and guidances on advertising and promotion of medical products.
3. On 14 October 2026, FDA announced the Rare Disease Framework Initiative for the development of drugs and biologics for rare diseases. The initiative will develop a fit-for-purpose framework that considers the nuances of each rare disease, patient needs, product type, and the evidence that can be realistically generated in small patient populations. More details are discussed in this white paper.
4. FDA has released a final guidance on submitting clinical trial data to assess the ability to operate a motor vehicle. The document outlines the technical specifications for submitting data from a clinical trial designed to evaluate how a drug or biological product may affect driving ability, which is necessary to support a marketing application.
5. NIH has launched its new website experience with the beta version of NIH.gov and the new thematic hubs. Read all about it here, including the latest update around AI.

EMA Guidance and News

1. The ACT EU Workshop on Multiplicity in Confirmatory Clinical Trials: From Two-Arm to Platform Trials will bring regulators, industry, and academics together to discuss multiplicity in clinical trial design, multiple testing strategies, and platform trials. The workshop, planned for 27 November 2026, 09:00-15:00 CET, aims to inform future regulatory guidance and support evidence-based decision-making.
2. A table listing centrally authorised medicines that contain pharmacogenomic information in their summaries of product characteristics (SmPC) is now available on the EMA website: Pharmacogenomic information for centrally authorised medicines. The table is intended to help users identify whether a medicine contains pharmacogenomic information and, if so, where that information is located within the SmPC.
3. EMA's technical and regulatory support for preparing clinical trial applications will continue from January 2027. This represents the permanency of the Accelerating Clinical Trials in the EU (ACT EU) advice pilot, which helps sponsors prepare CTAs. Details at this EMA page: Clinical trial applications advice pilot becomes permanent, published 08 Oct 26.
4. On 05 October 2026, EMA updated the guidance document on post-authorisation procedural advice for the users of the centralised procedure. Some Q&A were revised around the protection periods for orphan medicinal products and period of marketing protection for any new therapeutic indication. Track change and clean version are provided.
5. A new paper, drawing on insights from the ACT EU multi-stakeholder workshop on clinical trials analytics, in The Lancet Digital Health highlights how clinical trial registry data can better support research and decision making. Improving clinical research through better use of clinical trial registry data identifies stakeholders' needs and use cases grouped according to 3 themes: optimising trial design, strengthening evidence evaluation and enhancing patient centricity.
6. EMA has updated "Notice to sponsors on validation and qualification of computerised systems used in clinical trials." The guidance, (first published 7 Apr 2020), has been updated to refer to currently applicable Regulation (EU) No 536/2014 and to the revised ICH E6 (R3) Guideline for Good Clinical Practice. References to Q&As published on the EMA website have been replaced with reference to Guideline on computerised systems and electronic data in clinical trials. These changes are administrative in nature and do not alter requirements.

Health Canada Guidance and News

Health Canada has announced a new pilot for Academic-led Pediatric Clinical Trials. The aim of the pilot is to reduce regulatory barriers for academic-led pediatric research while maintaining participant safeguards; it will test a lighter regulatory pathway for certain low-risk, academic pediatric trials of established standard-of-care medicines, with the goal of making pediatric evidence generation easier while retaining ethics, GCP, safety and transparency requirements.

Real-World Data

1. Recordings of the PHUSE Real World Data Autumn event (Days 1-2) are now online and can be accessed here.

2. PHUSE has published a white paper entitled 'Real-World Data Reliability and Integrity: Ensuring Real-World Data is Fit for Use for Regulatory Submissions' available to download from here.

Transparency and Disclosure Resources and News

1. Italy's Data Protection Authority has fined IQVIA Solutions Italy €7 million over its Longitudinal Patient Database, which contains health information on around 1 million patients collected from ~800 GPs. A central issue was whether the data could truly be considered anonymous. IQVIA argued that patients were pseudonymised before data transfer and that it could not access the re-identification key. The Garante concluded instead that the longitudinal and highly detailed nature of the data made re-identification reasonably possible.

   The Authority therefore considered IQVIA a data controller and identified several GDPR shortcomings, including lack of an appropriate legal basis for processing health data, insufficient transparency, unclear retention periods, absence of a DPIA, and inadequate security measures.

   This is an important case for real-world health data in Europe. For Italian readers, here is the article in Pharmacy Scanner, 05 Oct 2026. Article in English on BioScience Blog 06 Oct.
2. Smith et al Dec 2026. In J Med Informatics: FAIR data sharing, but what about the RREST? Towards the FAIRRREST Principles in health data sharing.
3. Recordings of the PHUSE Data Transparency Autumn event (Days 1-3) are now online and can be accessed here.
4. PHUSE has published a white paper entitled 'Protecting Commercially Confidential Information (CCI) While Complying with the European Union Clinical Trials Regulation (EU) 536/2014' available to download from here.
5. PHUSE Data Transparency Working Group has submitted a response to the NIH draft policy (NOT-OD-26-113) on sharing study results. Access their official response letter here.
6. BMC Medicine article published 22 Oct 2026: Clinical trial data transparency should match data access to scientific purpose: a tiered framework for reproducibility and reuse.

European Health Data Space (EHDS)

EHDS Implementation regulation and templates for secondary use of health data in the EU. Have your say - public consultation open 16 October to 13 November 2026. Feedback mechanism is open on three common templates for secondary use procedures:

- Health data access application (Article 67)
- Data permit (Article 68)
- Health data request application (Article 69)

Development Strategy News

1. Kahan et al's publication on What Makes an Estimand Useful? Guidance on the Choice of Intercurrent Event Strategies focuses on scientific utility as opposed to operational efficiency for ICE selection.
2. A new publication entitled "Improving clinical research through better use of clinical trial registry data" explores how clinical trial registry data can support research and decision making. Based on an ACT EU multi-stakeholder workshop on clinical trials analytics, the authors identify stakeholders' needs and use cases grouped according to 3 themes: optimising trial design, strengthening evidence evaluation and enhancing patient centricity.
3. A new publication by Machado et al; entitled "Clinical trials on medicinal products in the EU/EEA, 2013–2025: a cross-sectional analysis of CTIS and EudraCT data" describes trends in clinical trials on medicinal products in the EU/EEA from 2013 to 2025.

Artificial Intelligence/Machine Learning

1. EviData held a discussion on 02 Oct 2026 related to the reuse of data in the context of corporate AI initiatives, how that fits in with current legislative efforts and regulations in Canada and internationally, managing privacy risks when training and using AI models as a service, and how to enable the data-driven decision-making in the current environment. Speakers: Jan Kestle and Khaled El Emam. This is the page to reserve a place - post-session resources may be uploaded here.
2. The European Medicines Regulatory Network is advancing data and artificial intelligence (AI) to drive innovation, improve efficiency, and strengthen health decisions. The following workshop, scheduled for 12-13 November 2026, brings regulators and stakeholders together to share insights and shape future AI and data use in medicines. Watch live or catch the recording here: HMA / EMA multistakeholder AI and Data forum: Build trustworthy AI on strong data foundations.
3. Regulatory Focus 06 Oct 26 article: MHRA adopts AI framework proposed by UK docs.
4. RAPS AI in Regulatory Conference registration - Barcelona 5-6 Nov 2026.
5. Following Bioscript Group's State of AI in Regulatory Writing 2026 survey, there is a live panel discussion exploring what the findings mean in practice and what they mean for the future of regulatory writing. Wednesday 11 November 2026, 14:00-14:45 GMT (09:00 ET). Register here.

News from US: Possible Impact on Clinical Trial Ecosystem

BMJ News article 13 Oct 26: RFK Jr opens NIH clinic to investigate vaccine injuries, announces reporting reforms.

MEDICAL DEVICES

This subsection 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.

UK MHRA

1. More than 1,000 patients, healthcare organisations, industry representatives and others responded to MHRA's consultation on indefinite recognition of CE marked medical devices. Outcome: Government confirms indefinite recognition of CE marked medical devices.
2. MHRA is launching a new initiative to support developers of software and AI medical devices to better understand and meet regulatory requirements. The new Community of Practice will bring together developers, regulators and other stakeholders to share learning, explore common challenges and help strengthen regulatory compliance across the sector. Initially focusing on digital mental health technologies, MHRA are inviting organisations to complete a short survey to help shape the programme. The survey is also the first step in registering your interest in joining the Community of Practice. Read more and register your interest here.
3. Summary article on MHRA developments in AI for medical devices, 21 Oct 2026: UK Medical Device Update: Developments in AI, Proposed GB Licensing Framework and Indefinite CE Mark Recognition.

Taiwan

1. In August 2026, Taiwan FDA announced the implementation of 2 major digital transition measures for medical device applications (original source in Mandarin) starting 01 October 1 2026 to improve administrative efficiency and promote carbon reduction.
    - Applications submitted through the electronic system will undergo "online review," where applicants can simply upload scanned PDF files and retain the original paper documents for their own records without mailing them.
    - The TFDA will completely cancel the issuance of physical, paper-based approval documents for medical device labels, instructions, and packaging; instead, these will be replaced by electronically signed versions available for download directly from the TFDA's online system.
2. On 2 October 2026, Taiwan FDA mandates that, effective from 1 October 2026, trial sponsors must register all relevant clinical trial data for medical devices through a newly designated, digitized entry portal (original source in Mandarin).