



Clarity and Openness in Reporting: E3-based

News Summary

August 2026

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[New Joint Summary from The CORE Reference Project and Protocol Development by Jonathan Mackinnon.](#)

Keeping pace with evolving clinical trial regulations, guidance, and industry standards is an ongoing challenge for regulatory medical writers.

To help writers navigate today's landscape, The CORE Reference Project has collaborated with [Jonathan Mackinnon](#) (Protocol Development) on a practical 2026 Joint Summary that highlights:

- ✓ Key guidance every protocol and CSR writer should know, including ICH E6(R3), ICH E8(R1), and ICH E9(R1)
- ✓ The growing impact of ICH M11 on protocol development
- ✓ A practical overview of estimands and why they matter for both protocols and CSRs
- ✓ Tips for staying current with regulatory and industry developments.

Whether you are new to regulatory writing or an experienced professional looking to refresh your knowledge, this summary provides a concise overview of the topics shaping modern clinical trials and medical writing practice.

A [short introduction video](#) (~2 minutes) features Sam Hamilton and Jonathan Mackinnon explaining how this collaboration came about and why it's good for regulatory medical writers.

MEDICINES AND VACCINES

CTR and CTIS

1. EMA has published Sponsor Guidance on the new Safety Module for Annual Safety Reports (ASRs). The guidance is applicable to the New Safety Module on Annual Safety Report (ASR), which is now part of the Sponsor CTIS training environment and it is foreseen to be integrated in the CTIS Sponsor Workspace on 28 September 2026. Published on 31 July 2026 the guidance document can be accessed [here](#).
2. EMA will hold a CTIS: Walk-in clinic on 7 October 2026, 15:00 - 16:00 BST. The event summary and details on how to submit questions in advance can be accessed [here](#).
3. The Clinical Trials Coordination and Advisory Group have published V7.3 of the [EU Clinical Trials Regulation 536/2014 Q&A](#). Changes include:
 - Deletion of the Q&A 3.13 “Is the annual safety report considered a substantial modification?”
 - New Q&A 8.4 ‘Are there specific requirements for the labelling of cryopreserved medicinal products?’
 - New Q&A 10.1: inclusion of table reporting overview on notification requirements on status of clinical trials.
 - Revised Q&A 10.4 (new Q&A 10.5) “how is ‘temporary halt of a clinical trial’ defined?”
 - Revised old Q&A 10.7 (new Q&A 10.9) ‘Question: How should urgent safety measures (article 54) involving temporary halts (articles 38) be notified?’
 - Deletion old Q&A 10.8 ‘would a halt of recruitment be considered as a temporary halt of a clinical trial or of an end of recruitment?’
 - Simplified Annex II.

EU Regulatory

1. EMA announced the selection of TrialAssure anonymisation platform for clinical trial documents. The platform will be used to anonymise clinical dossiers submitted by marketing authorisation holders, to protect the identity of clinical trial participants before documents are made publicly available in line with EMA Policy 0043. An article by Abigail Beaney presents summary information about the announcement [here](#).
2. The European Medicines Regulatory Network (EMRN) established a data standards framework that supports the creation, updating, adoption, and application of data standards for both human and veterinary medicinal products. The [draft for the framework](#) was published on 17 August 2026 and is available for public consultation until 18 September 2026. Follow details [here](#) to submit comments.
3. On 18 August 2026, EMA updated the [guidance document](#) on pre-authorisation procedural advice for the centralised procedure. A [track-change version](#) is also available.

UK and MHRA News

The most recent '[HRA Latest](#)' includes information about informed consent for children as well as new guidance on setting up and managing studies involving NHS and health and social care staff.

FDA Guidance and News

1. Just a reminder that the National Library of Medicine (NLM) has completed modernization of the Protocol Registration and Results System (PRS) and the public website, [ClinicalTrials.gov](https://clinicaltrials.gov). The Modernized PRS is now the primary system for protocol registration and results submission. For more details on the phasing out of Classic PRS, see [here](#). [PRS guided tutorials](#) on the Modernised PRS are also available.
2. FDA will host a free, virtual webinar on how to communicate drug interaction and QTc information in the drug's prescribing information on 23 Sept 2026. Registration details [here](#).

Real-World Data

Reminder that the second PHUSE Real World Data Autumn Event, is taking place 30 September – 1 October, 2026. Registration details [here](#). Agenda [here](#).

Transparency and Disclosure Resources and News

1. PHUSE is looking for volunteers to join a new project within their Data Transparency Working Group: "Benchmarking ClinicalTrials.gov Usage and PRS Data Quality Review Findings: A Cross-Industry Survey and Remediation Framework". Full project description [here](#); if interested in volunteering contact workinggroups@phuse.global directly by 14 September 2026.
2. The Australian Government released the [August 2026 National Reforms to Clinical Trials Newsletter](#). It provides several updates relevant to clinical trial transparency, with a particular focus on the continued development of the National One Stop Shop (NOSS). NOSS is intended to provide a single national platform for health and medical research, including clinical trials and teletrials, while streamlining research approvals and related processes. Read the short summary [here](#).

Development Strategy News

1. The 7th Staburo Health Data Science Summit 'Advancing Precision Medicine - Biomarkers and Data Science' free Webinar takes place on 24 Sep 2026. Speakers from Sanofi, AstraZeneca, Bayer, Novartis, Boehringer Ingelheim, and Staburo GmbH will share expertise and insights. [Register here](#).
2. FDA white paper [Key Considerations for the Development and Use of Digitally](#)

[Derived Measures for Clinical Investigations](#) is covered in an FDA Voices article, 20 Aug 26: [FDA Weighs in on the Development and Use of Digitally Derived Measures for Clinical Investigations](#).

Artificial Intelligence/Machine Learning

1. Two day workshop coordinated by the Network Data Steering Group (NDSG) in collaboration with the CHMP Methodology Working Party and the ACT EU initiative entitled “HMA/EMA multistakeholder AI and Data forum: Build trustworthy AI on strong data foundations”. Thursday, 12 November - Friday, 13 November 2026. Agenda and registration details will be published in September/October 2026, further information [here](#).

2. WHO has published “[Artificial intelligence-related health research: ethics review and oversight](#)” (July 2026). The free to download report examines ethics review and oversight of: health-related data science using AI; research conducted with AI tools and technologies; and health-related research on AI tools and technologies. The guidance does not cover the use of AI across drug discovery and development, which is the subject of a separate WHO report (2024) entitled “[Benefits and risks of using artificial intelligence for pharmaceutical development and delivery](#).”

3. JAMA has issued updated author guidance for use of AI in medical publication. The guidance highlights to authors responsible use, what is permitted and not permitted and what needs to be disclosed. Read the JAMA editorial by Flanagin et al, [here](#).

4. Recently published open access article by van de Sande et al, entitled “Meaningful oversight of medical AI beyond human in the loop” can be accessed [here](#).

5. A european-wide survey was conducted and published by Pinheiro et al, 2026 in Clin Pharmacol Ther. The open access article, entitled “Regulatory Research Priorities for AI Use in the Medicine Lifecycle: A European Perspective with Global Relevance” can be accessed [here](#).

News from Asia Regulators

China NMPA released “[Technical Guidelines for the Management of Post-Approval Change Management Protocol \(PACMP\)](#)” on 17 July 2026 (page in Mandarin). This is a regulatory tool provided by ICH Q12, enhances the predictability and transparency of change management by proactively assessing the impact of proposed post-marketing pharmaceutical changes on the safety, efficacy, and quality control of a drug.

News from US: Possible Impact on Clinical Trial Ecosystem

1. [Moderna received U.S. FDA approval for Influenza Vaccine mFLUSIVA](#). The agency had originally refused to consider the application. For background to the story please

see CORE Reference [Feb 2026](#) and [May 2026](#) News Summaries (News from the US: Possible impact on clinical trial ecosystems).

2. President Donald Trump signed an [executive order on Monday 10 Aug 2026 calling for fewer childhood vaccinations](#). On 12 Aug 2026, the UK MHRA [reaffirmed the safety of childhood vaccination](#). BMJ Opinion piece 13 Aug 2026 titled: '[US policies are making a resurgence of vaccine preventable diseases inevitable](#).'

3. BMJ News 21 August 2026: [Why Trump's order to split MMR vaccine is costly and dangerous](#).

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.

General Updates and News

1. On 25 September 2026, FDA will hold an all day public meeting entitled "Regulatory Science Innovations Catalyzing Medical Device Development" to engage stakeholders in advancing regulatory science advancement. [Details here](#). Virtual audio attendance is possible.

2. The RAPS open access article (by Carnielli et al, 2026) entitled "[From IVDD to IVDR: The interplay between notified bodies and EU reference laboratories](#)" summarises changes brought about by the introduction of the EURL legal framework established under EU IVDR, Article 100.

3. Edition 4 2026 is released for '[ISO 10993-3:2026 Biological evaluation of medical devices Part 3: Evaluation of genotoxicity, carcinogenicity, reproductive toxicity, and developmental toxicity](#)'. As part of the globally recognized ISO 10993 series, this updated standard supports manufacturers in identifying and evaluating potential long-term biological risks associated with medical devices and their constituent materials. The publication replaces the previous ISO 10993-3:2014 version and reflects the latest scientific understanding and regulatory expectations regarding biological safety assessment. Note that a sample is available for free on the ISO website, but as always with ISO, the publication remains behind a paywall.

Artificial Intelligence/Machine Learning

FDA News Release 18 Aug 2026: [FDA Seeks Public Feedback to Inform Regulatory Approach for Generative AI-Enabled Medical Devices](#). FDA issued a [discussion paper](#) on considerations for the regulation of generative artificial intelligence (GenAI)-enabled medical devices, seeking feedback from interested parties on risk assessment, premarket evaluation, postmarket monitoring, and other topics relevant to the regulation of GenAI-enabled medical devices. Feedback from device manufacturers, clinicians, consumers, researchers, the public, and other interested parties, to be submitted under the [docket FDA-2026-N-7874](#) on Regulations.gov by 19 October 2026.

UK and MHRA

UK MHRA issued a warning about devices supplied without valid UKCA/CE conformity markings or certification. They should be removed from use and placed in quarantine (DSI/2026/007). View identified devices and read the MHRA announcement [here](#).

Asia

1. China's NMPA released a draft guideline "[Inspection under the Medical Device Good Manufacturing Practices](#)" on 9 June 2026 for public feedback (ended 24 June 2026) (page in Mandarin), which focuses towards risk-based, lifecycle-oriented regulation of medical device manufacturing in China. The guidance provides 39 critical check items that must be followed for compliance. Manufacturers should perform necessary gap analyses to check for the new requirements before the release of the final guideline. A third-party blog post is available [here](#).
2. Korea's MFDS issued new guidelines for [Approval of Large Language Model-based \(LLM-based\) digital medical devices](#) (page in Korean). Key focus includes examples of LLM-based devices, guidance on preparing license applications, and methods for verifying clinical and functional performance.