Clarity and Openness in Reporting: E3-based

News Summary

May 2026

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The next CORE Reference webinar will be presented by Dr Marcie Roche who will share her insights on ICH M11

When: Wednesday 17th June 2026, 13.00-13.50 CET
Title: ICH M11: an integrated and forward-looking CeSHarP perspective

Abstract: Viewed through a regulatory medical writing lens, ICH M11 (CeSHarP [Clinical Electronic Structured Harmonised Protocol]; adopted 19 November 2025) reframes clinical study protocols as structured, reviewable, and reusable source documents that preserve scientific intent and decision-making transparency. The harmonised template and technical specification reduce variability, support interoperable electronic exchange, and minimise unnecessary repetition through consistent content placement.

With the convergence of established industry approaches, TransCelerate's Common Protocol Template (V11, 2026) was realigned to ICH M11, reflecting a reconciliation of legacy authoring practices with emerging global standards that support operational efficiency and submission readiness.

While CPT V11 reflects the ICH M11 protocol template and associated technical specification, the level of detail and content implementation requires medical writing judgment beyond simple adherence to the template.

Within the clinical study documentation continuum, disciplined lean authoring, traceability, and the critical evaluation of content for use or AI-assisted text remain essential to ensure that protocol decisions remain aligned with downstream reporting (as reflected in the CORE Reference framework).

This webinar encourages medical writers and regulatory professionals to take a deliberate, forward-looking approach to their craft, recognising that precise structure and clear intent are essential to scientific integrity and effective communication.

Speaker Bio: Marcie A. Roche, PhD is a senior director of medical writing at argenx with over 20 years of pharmaceutical industry experience. She promotes the strategy and development of clinical and regulatory documents that support global health authority submissions and related agency interactions. Her work prioritises clear, consistent, guideline-aligned content that integrates complex

concepts into lean authoring narratives, valuing cross-functional leadership and mentoring medical writers.

Register in advance for this webinar:

https://us06web.zoom.us/meeting/register/4DsqsiD1TI25ZSre6hIEcw

After registering, you will receive a confirmation email containing information about joining the meeting.

To help shape webinar discussions, please share your questions or comments with us on LinkedIn around the following three aspects:

- Where are you encountering friction in applying ICH M11 principles?
- What aspects of structure or content placement remain unclear?
- How is this shifting your approach to protocol development or review?

EMWA Barcelona Lunchtime Learning Sessions:

The slide decks from our two lunchtime learning sessions at EMWA Barcelona held on Wednesday 6 May and Friday 8 May 2026 have now been posted on our LinkedIn page. We are grateful for the generosity of our supporters Morula Health, and Trilogy Writing & Consulting, An Indegene Company. Thank you for supporting the CORE Reference project and helping to make our 10th anniversary celebrations a great success!

MEDICINES AND VACCINES

ICH

The ICH M11 Expert Working Group has recently issued a final overview presentation (at Step 4 of the ICH harmonisation process) for ICH M11: The Clinical electronic Structured Harmonised Protocol (CeSHarP), a guideline adopted in November 2025.

CTR and CTIS

1. The EMA has published the video recording of the CTIS Walk-in clinic which took place on 16 April 2026. The recording can be found here.

2. EMA has published Version 2.2 of the Guidance document on how to approach the protection of personal data and commercially confidential information while using the Clinical Trials Information System (CTIS), dated 30 April 2026. This document provides guidance to users on the revised CTIS transparency rules and on the protection of personal data and commercially confidential information (CCI) submitted to CTIS.

3. EMA will be hosting a CTIS Information Day for all sponsor organisations on 17 June 2026, 12:30-17:30 CET. The event aims to strengthen understanding of the Clinical Trials Regulation (CTR), promote best practices, and gather stakeholder input to support effective implementation of the CTR and continuous system improvement. Participants are encouraged to submit their questions related to CTIS use, implementation, and sponsor preparedness by noon June 05, 2026, using Slido (code:#CTISInfoDay2026).

4. ACT EU has made available several tools to support non-commercial sponsors, including an interactive map of existing support initiatives at national level and a dedicated helpdesk to assist them in navigating the clinical trial landscape and using CTIS. details are available from the ACT EU website here.

5. CITIS release notes v1.0.61.0 were released May 2026. In this release, improvements have been made for: Application creation/preparation of documents and data; Authorisation and supervision of clinical trials; Communication between sponsors and Member States; Other issues indirectly fixed during the validation of this version. The updated pdf can be accessed here.

6. CTIS news: Ahead of the launch of the new safety module in CTIS later this year, users will be able to familiarise themselves with the new module via the training environment and training materials, to be available in Q3 2026. A bitesize talk will also be organised to support users. Details to follow when available.

7. EMA's quarterly system demo in June will include an update on CTIS modernisation. Thursday, 25 June 2026 , 08:00 - 11:15 British Summer Time (GMT+1). Agenda and registration details here.

8. EMA has released an updated version (Version 1.3, April 2026) of Module 16 - CTIS Training Programme "Supervise a CT - Inspection Records" which includes FAQs regarding general information of inspection records, creation and submission of inspection records, uploading of inspection outcomes and reports, search, update and cancellation of inspection records along with roles and permissions.

UK and MHRA News

1. Following the implementation of the new UK clinical trials regulations, the MHRA Clinical Trials Hub provides a variety of guidance including, but not limited to, applying for clinical trial approval, making changes to trials, ending a trial.

2. UK's NIHR Clinical Trials Toolkit has been updated to reflect the amended Clinical Trials Regulations, which took effect in the UK on 28 April 2026. Access the toolkit route map here.

FDA Guidance and News

1. On 11 May 2026, the US FDA issued a final guidance for industry "Postapproval Pregnancy Safety Studies", with recommendations on several methods that should be considered when collecting pregnancy safety data, pregnancy registries, and complementary studies that evaluate real-world data and descriptive studies that rely on reports from individual cases. Instruction to provide comments here.

2. FDA announced the launch of Elsa 4.0 on 6 May 2026, which it called a "significant upgrade to the agency's internal AI tool available to all FDA staff, from scientific reviewers to investigators." The agency also announced the consolidation of more than 40 disparate application and submission data sources, systems and portals across all FDA centers into a new platform called HALO (Harmonized AI & Lifecycle Operations for Data). According to the press announcement the agency began integrating HALO and Elsa so that FDA staff can query data and build workflows without having to manually upload documents within each chat. The HALO consolidation is expected to enable more penetrating deployment of AI capabilities within agency operations.

3. FDA 11 May 26: FDA Advances Drug Repurposing to Address Unmet Medical Needs. FDA is soliciting input (via an RFI in the Federal Register) on efforts with respect to drug repurposing to help address unmet medical needs across a range of diseases and conditions.

4. FDA posted a Notice in the Federal Register on 22 May 26 that the Guidance document dated May 26 'M11 Clinical Electronic Structured Harmonised Protocol' is available.

5. Following feedback from industry, FDA is extending the public comment period on their Request for Information: AI-Enabled Optimization of Early-Phase Clinical Trials Pilot Program until 29 June 2026. This initiative aims to harness AI-enabled technologies to enhance the efficiency, speed, and quality of decision-making in early-phase clinical trials.

6. FDA has published two final guidances intended to help applicants more effectively plan their bioequivalence (BE) studies and use equivalence criteria in analysing these studies: "Bioequivalence Studies With Pharmacokinetic Endpoints for Drugs Submitted Under an ANDA" and "Statistical Approaches to Establishing Bioequivalence."

Health Canada News

5th US-FDA / MHRA-UK / Health Canada Symposium: Regulatory Perspectives in Good Clinical Practice, Bioequivalence & Good Pharmacovigilance Practice (2-4 June 2026). Agenda and full details for free registration here.

Transparency and Disclosure Resources and News

1. On 16 June 2026, 12-1:30pm ET, the MRCT centre will host a conversation with panelists from two sponsor organizations and a patient partner on how the MRCT's CDISC global standard clinical research glossary is being adopted, implemented, and used in practice. Register here.

2. BMJ News Article 12 May 2026: GPs and hospitals to be forced to share patient data as Palantir is granted "unlimited access" to identifiable information.

3. NEW: Global privacy news, in one feed. You can subscribe for free to receive weekly news from 46 official Data Protection Authorities worldwide. The weekly digest page gives a summary. Note that this endeavour is not restricted to clinical data privacy, so there will be other privacy material to wade through!

4. The HTA CG (Member State Coordination Group on Health Technology Assessment) has released Guiding Principles on Data Transparency, which can be downloaded from here. The purpose of this document is to provide general principles to be used when assessing the requests for confidentiality from health technology developers in the context of joint clinical assessments. There is also a Q&A on general methodological and procedural issues for joint clinical assessments.

5. Webinar entitled "AI-Guided Anonymization" will be held on Tuesday 23 June 4 PM - 5 PM GMT+1. Registration details and agenda here.

Development Strategy News

1. Cubells et al. discussed the advantages and challenges of conducting decentralized clinical trials in the article "Decentralized Clinical Trials: Flexible or Challenging?" by using a real-life example of a paediatric study.

2. In April 2026, the MRCT Centre released the first three tools in the Pregnancy Privacy Protections for Participants (P4) Toolkit.

1. Local Context: Reproductive Health Information for the Research Team and the IRB
2. Recommended Language for Informed Consent Forms: Guidance for Researchers on Pregnancy Privacy Protections
3. Privacy Protections: Considerations for Pregnant Participants (for research staff to adapt and share with participants)

3. Topaz and co-authors (2026) have published a paper in Lancet entitled "Fabricated citations: an audit across 2·5 million biomedical papers." The authors "present findings from a reference-integrity audit of 2·5 million biomedical papers spanning 3 years, showing that fabricated references are embedded in the peer-reviewed literature at scale, and that the rate of fabrication is accelerating."

4. Article in Nature Reviews Drug Discovery, authored by Domergue et al., entitled "Better data for better medicines: a path to data-driven medicines regulation" explains how the EU medicines regulatory system is transitioning to a more data-driven ecosystem that can improve decision making and accelerate medicines development to the benefit of patients. The article is open access until 5 June 2026.

Artificial Intellligence/Machine Learning

1. Shleifer et al. wrote an article "Agentic AI in Regulatory Affairs: Rewiring the Global Regulatory Compliance Function" which discussed applying agentic AI in enabling regulatory intelligence, submissions, quality management systems (QMS), and pharmacovigilance (PV) workflows to operate as a single, orchestrated system.

2. BMJ News article 01 May 2026: US pushes real time clinical trials to eliminate "dead time" in approvals. Unlike standard trials—where data are compiled and sent to the FDA only after each phase ends—real time trials will use AI to send agreed safety and endpoint signals to FDA reviewers as the study is running, in theory cutting the months of administrative "dead time" between phases. Two "proof of concept" real time clinical trials are now under way, and the agency is planning a larger pilot programme this summer, it announced on 28 April. Also posted in 'News from US' section below.

3. FDA News Release 11 May 26: FDA Expands AI Capabilities and Completes Data Platform Consolidation. Elsa 4.0 launched. See also FDA news for further details.

4. FDA warning letter 02 April 2026 to Purolea Cosmetics Lab explicitly citing AI misuse in pharmaceutical manufacturing. Amongst other issues, FDA flagged that the company had used AI agents to generate drug product specifications, procedures, master production and control records - and had not reviewed the outputs for accuracy or compliance. The FDA's position is clear: "Any output or recommendations from an AI agent must be reviewed and cleared by an authorised human representative of your firm's quality unit." AI can assist in document creation. It cannot replace the human judgement, expertise, and accountability that underpins regulatory compliance.

5. At PHUSE US Connect 2026, 80+ professionals were asked where the industry stands on GenAI "AI Pulse: Taking the Industry's Temperature on GenAI in Statistical Programming" is the blog written by Bhavin Busa and reporting the findings from this survey and can be accessed here.

6. The European Commission has published Draft Commission guidelines on the classification of high-risk AI systems. These Guidelines aim to support providers and deployers of AI systems, as well as competent market surveillance authorities, in assessing whether an AI system should be classified as high-risk, thereby facilitating the uniform application and effective enforcement of Article 6 AI Act. The guideline can be accessed here.

News from US: Possible Impact on Clinical Trial Ecosystem

1. BMJ News article 01 May 2026: FDA blocks publication of studies showing covid and shingles vaccines to be safe.

2. BMJ News article 11 May 2026: Trump mental health: 30 senior US doctors declare president mentally unfit.

3. Science Insider article 20 May 26: U.S. researchers face new restrictions on publishing with foreign collaborators.

4. External experts on FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) will discuss recommending Moderna's MFLUSIVA (influenza vaccine) on 18 June, which had initially received a refuse to file (RTF) letter due to objections from Prasad, but was allowed to move forward after political and industry pushback. The vaccine is intended to prevent disease caused by the influenza virus subtypes A and B, as represented in the vaccine, for people 50 years and older.

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

Free webinar entitled "Regulatory Challenges at the Borderline of Device Regulation" 16 June 2026 15.00-16.00 BST. In the webinar presenters will use case studies of complex healthcare products, with particular focus on regulatory borderlines between drugs, devices, excipients, container closure systems, or software. They share challenges, solutions and recommendations on how to navigate authority interactions for similar products. Details and registration here.

EU Transparency

EUDAMED News

EUDAMED is composed of six modules related to: actor registration, unique device identification (UDI) and device registration, notified bodies and certificates, clinical investigations and performance studies, vigilance and post-market surveillance and market surveillance. From 28 May 2026, the use of the first four modules is mandatory:

- Actor registration,
- UDI/Devices registration,
- Notified bodies and certificates,
- Market Surveillance.

US FDA

On 28 May 2026 US FDA released final guidance (earlier draft issued 9 Dec 2022) on what human factors (HF) information sponsors should include in premarket submissions for medical devices. An important consideration for medical devices is the critical impact the device user interface design has on the safe and effective use of the device. The purpose of this guidance is to provide a risk-based framework to guide manufacturers and FDA staff on theHFs information that should be included in a marketing submission to CDRH to facilitate efficiency of the FDA review process. Guidance available from here.

UK MHRA

The MHRA has published draft pre-market regulatory requirements for medical devices and in vitro diagnostic (IVD) devices entering the GB market, set out in the Medical Devices (Amendment) Regulations 2026. The MHRA invites views on proposed changes to medical device regulation.

Respond to the survey by 11:59pm (UK time) on Friday 19 June 2026. Access the announcement here, and the survey here. Read a news article on the subject here.