Regulatory Public Disclosure

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SECTION EDITOR

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Editorial

The Riga conference was fun! Besides the learning, as usual, we all enjoyed getting together and chatting between sessions. These for me were the moments that it became more apparent than ever that regulatory medical writing is undergoing mass workforce change. Certainly, there are still plenty of highly experienced medical writers producing rigorous study level documents fit for public disclosure – as we see from the now abundant clinical trial application documents published by the Clinical Trials Information System (CTIS). However, as less experienced, entry level colleagues join our profession at a time when artificial intelligence (AI) tools are really beginning to take hold, it is important to remember that there is simply no substitute for the deep foundational knowledge that underpins clinical document content. **There is no short cut, even with AI**. As newer writers join our ranks, and as we integrate AI tools into our workforce and workflows, we must not lose sight that the deeply knowledgeable medical writer remains the back stop – the expert – who provides the sanity check, scrutiny, and balance for outputs, whether they are created using AI support or not.

How can less experienced regulatory medical writers attain a deep level of knowledge and understanding, given such a complex writing environment? A reasonable place to start is to tune into the content requirements of the seminal study level document, the clinical study report (CSR). The free-to-download best practice guidance interpretation document, the CORE Reference manual (doi:10.56012/copjhc4062) written by a team of EMWA experts and published in May 2016, provides a detailed and granular "how to" guide for CSR authoring for newer medical writers – as well as being a constant reference companion for more experienced professionals. So, now you have your flying start, but you must also consider how to keep up with the ever-evolving clinical documents and public disclosure ecosystems. That means staying on top of all that is relevant as it is published. Without the requisite experience, it can be difficult to pick out which piece of information is important and which is interesting, but perhaps less important in terms of actual document preparation, and then contextualise that to reporting and public disclosure.

These days, LinkedIn postings and the deluge of information hitting our phones and laptops daily can almost drown us. So, besides using an AI Agent (yes, they are coming!) to sift material, how do you capture the relevant guidance, best practice, and news for reporting clinical trials and addressing public disclosure of clinical documents? You (or your Agent) don't have to do that and then wonder what you may have missed – because the EMWA CORE Reference Project Team is doing just that already. We also contextualise the information so that you understand why it is relevant and how to use it in your writing. We make what we find freely available in a downloadable News Summary that includes comprehensive links to all the cited sources (https://www.linkedin.com/company/the-core-reference-project). **So, our News Summaries only contain the relevant clinical trial-related and transparency and disclosure-related news and information that you can trust.** Sam

Spotlight on CORE Reference News Summaries

The topics that are covered in our monthly News Summaries typically include:

Medicines and Vaccines
ICH; CTR and CTIS; EU Regulatory; UK and MHRA guidance and news; FDA guidance and news; EMA guidance and news; real world data and evidence; transparency and disclosure resources and news; development strategy news; AI/machine learning; news from Asia regulators; news from US that may impact the clinical trial ecosystem.

Medical Devices
General updates and news; EU transparency; EUDAMED news; EU COMBINE initiative; UK MHRA.

For many of us working in drug development and medical writing, the inclusion of the "Medicines and Vaccines" section with its well-considered sub-topic areas seems logical to support drugs, biologics and vaccines reporting. It may not be quite so apparent why we also cover specific topics within a "Medical Devices" section. To clarify, the "Medical Devices" section is intended to cover 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. This is a hot topic as we heard in the "Combination Products Symposium Day" in Riga, which delved into regulatory, scientific, and communication aspects of this evolving field.

If you have suggestions for other relevant subsections for the News Summary to fit with the scope of the CORE Reference Project remit, please do get in touch. **New from May 2025: Updates from the 2025 US Administration (links to initiatives that may impact the clinical trial ecosystem).**

Abbreviations: CTIS, Clinical Trials Information System; CTR, Clinical Trials Regulation; EUDAMED, European Database on Medical Devices; ICH, International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use; MHRA, Medicines and Healthcare products Regulatory Agency

Meeting you in Riga: Learning and Sharing with EMWA Regulatory Medical Writers

Thanks to EMWA conference delegates who attended the CORE Reference Project "Learn and Share" at the EMWA Spring Conference in Riga, Latvia, on May 8, 2025.

At the May 2025 EMWA Riga conference, the CORE Reference Team held a "Learn and Share" lunch session, explaining the new ways in which we now connect with you. We also spoke of our plans for a new website. We took your suggestions for new topic areas for the monthly News Summary, so watch LinkedIn to see new topics appearing. The session ended with an open discussion on the Policy 0070 relaunch (Step 2) where we shared best practice and tips for addressing potential challenges of the expanded scope of Policy 0070. Finally, we reminded everyone that May 2026 will mark the tenth anniversary of the publication of the original CORE Reference resources – and we look forward to marking that milestone in Barcelona at the 60th EMWA conference. We were happy to announce our next external presenter, Obaraboye Olude, of Privacy Analytics (an IQVIA company) would present the June 11, 2025 webinar "Statistical anonymisation software for utility-preserving privacy protection in clinical documents for public disclosure".

As ever, Vivien Fagan and I were delighted to teach our Foundation Workshop on CORE Reference (DDF38). In this we demonstrate the granularity of the main clarity and transparency points integrated into the May 2016 publishedbest practice manual, CORE Reference (https://doi.org/10.56012/copjhc4062) and explain its value to medical writers for clinical study reporting. Remember to sign up for our next Workshop if you missed us in May 2025.

The CORE Reference Project on LinkedIn

We are enjoying our 2025 revamp and especially our LinkedIn page to communicate with followers. This is easier than before when we did everything by email, and hopefully we can increase our reach. Please follow us on https://www.linkedin.com/company/the-core-reference-project to receive our monthly News Summaries, and other materials to support your continuing professional development (CPD). Share our page information widely – it's free for everyone. Also check out our informational graphic at the end of this section for QR codes and dois for our main resources, and watch our YouTube video for a reminder of project aims: https://youtu.be/1UAHdKCKN3w.

A distillation of the most relevant information in the world of clinical study reporting and public disclosure in the last few months is in Table 1. Enjoy! To see the full News Summaries – you now know where to look!

Follow us on LinkedIn (https://www.linkedin.com/company/the-core-reference-project) to receive monthly News Summaries, with current information on regulatory reporting and public disclosure which support the continuing professional development (CPD) needs of medical and regulatory writers. The topics covered include FDA and EMA guidance and news, real-world data, transparency and disclosure resources and news, development strategy news, AI in the regulatory arena, the intersection of drugs and devices including in vitro diagnostics (IVDs), transparency in relation to medical devices, news from Asia regulators, and regulatory guidance open for public consultation. Archived News Summaries to December 2024 are here: https://www.core-reference.org/news-summaries/. News Summaries from January 2025 are all available at our LinkedIn page.

Table 1 provides a selection of key information shared by the CORE Reference Project Team between March and May 2025.

Table 1. A selection of key information shared by the CORE Reference Project Team between March – May, 2025

Disseminated information	Brief description	Link
March 2025 highlights		
ICH M11 guideline, clinical study protocol template and technical specifications – Scientific guideline – are updated	The updated template (Step 2 draft dated March 13, 2025) is provided as reference only for the second round of public consultation of the M11 Technical Specification (document dated Feb 3, 2025). The technical specifications consultation period closed on 22 April 2025	Guideline, protocol template, technical specifications:https://www.ema.europa.eu/en/ich-m11-guideline-clinical-study-protocol-template-technical-specifications-scientific-guideline
An integrated map of clinical trials in the EU and published within the CTIS public portal is active	The map provides real-time information about clinical trials by geographic area. A public webinar with a demo of the map's features was held on March 7, 2025	Meeting recording: https://www.slopeclinical.com/l/webinar-the-impact-of-ich-e6-r3-on-biospecimen-management
Regulation (EU) 2025/327 of the European Parliament and of the Council of February 11, 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847 was published on March – May, 2025.	The aim of this regulation is to "establish the European Health Data Space (EHDS) in order to improve natural persons' access to and control over their personal electronic health data in the context of healthcare." The EFPIA Press Release titled "A Call for Effective Stakeholder Engagement and Capacity Building during the Implementation of the EHDS" calls on policymakers to guarantee an actionable process for involvement in this new health data ecosystem. EFPIA have published a position paper on the regulation on the European Health Data Space (EHDS) and an FAQs document on the European Health Data Space has also been updated	Regulation: https://eur-lex.europa.eu/eli/reg/2025/327/oj/eng FPIA press release: https://www.efpia.eu/news-events/the-efpia-view/statements-press-releases/a-call-for-effective-stakeholder-engagement-and-capacity-building-during-the-implementation-of-the-european-health-data-space/ EFPIA position paper: https://www.efpia.eu/media/2t2dem05/efpia-position-on-ehds.pdf FAQs: https://health.ec.europa.eu/latest-updates/frequently-asked-questions-european-health-data-space-2025-03-05_en
The FDA publication "Artificial Intelligence & Medical Products: How CBER, CDER, CDRH, and OCP are Working Together" (first published in March 2024) was revised in February 2025	The paper aims to provide greater transparency around how FDA's medical product centres are collaborating to safeguard public health whilst fostering responsible and ethical innovation. Four areas are focussed on regarding development and use of AI across the medical product lifecycle	https://www.fda.gov/media/177030/download?attachment
EMA and other European National Health Agencies have published 'Clinical Evidence 2030'	By 2030, clinical evidence generation is expected to be "further guided by the patient voice [...]; study design will be driven by research questions [...]; clinical trials will be more efficient and impactful; real-world evidence (RWE) will be enabled and its value fully established; and trust will be built through transparency. This document outlines the 6 guiding principles for generating clinical evidence. Although all principles are important, at a time where diversity is being rolled back, Principle 1 is particularly significant as it reinforces the need for patient representation at every step of evidence generation.	https://ascpt.onlinelibrary.wiley.com/doi/10.1002/cpt.3596?af=R

Disseminated information	Brief description	Link
EU lawmakers question the viability of the transatlantic data transfer pact between the US and Europe.	This is significant because: • The DPRC is charged with protecting Europeans' privacy from US government surveillance by hearing privacy complaints from EU citizens. • The DPRC was created by Executive Order to ensure that the US complies with privacy rights obligations under the EU-US Data Privacy Framework. Its existence allows data transfers between the US and Europe to continue happening for now. • Privacy and Civil Liberties Oversight Board (PCLOB) members have resigned and been fired. This Board oversees the DPRC and acts as a critical safeguard against US surveillance overreach. • EU lawmakers are pressing the EC to consider suspending the DPF, as they no longer believe that the PCLOB can operate independently.	https://www.mlex.com/mlex/data-privacy-security/articles/2299678
Califf et al. published "The importance of ClinicalTrials.gov in informing trial design, conduct, and results"	Commentary is provided on the progress of clinicaltrials.gov in clinical trial design transparency, as well as reporting.	https://resolve.cambridge.org/core/journals/journal-of-clinical-and-translational-science/article/importance-of-clinicaltrialsgov-in-informing-trial-design-conduct-and-results/125B3C69C8923DC03550090EBB7E7A12
EMA has qualified the first AI tool, called AIM-NASH	The tool helps pathologists analyse liver biopsy scans to identify the severity of an inflammatory liver disease (MASH) in clinical trials. It is expected to help researchers obtain clearer evidence on the benefits of new treatments. This qualification marks a significant step towards integrating AI in medicine development. The tool is trained on more than 100,000 annotations from 59 pathologists who assessed over 5,000 liver biopsies across nine large clinical trials.	Press release: https://www.ema.europa.eu/en/news/ema-qualifies-first-artificial-intelligence-tool-diagnose-inflammatory-liver-disease-mash-biopsy-samples
The European Organization for Research and Treatment of Cancer (EORTC) published "Navigating EU Clinical Trials: Adapting to a New Era of Regulations"	The document outlines challenges between the EU's separate regulations. For example, drug-device protocols that have an IMP and medical device require submission under EU-CTR and MDR/IVDR – one (EU-CTR) requiring a centralised submission and the other requiring separate Member State submissions. This process is further complicated if an AI component is involved.	https://pubmed.ncbi.nlm.nih.gov/39961402/

Disseminated information	Brief description	Link
April 2025 highlights		
Transcelerate has developed an ICH E6 Asset Library	The tools are designed to help with the adoption of the latest good clinical practice (GCP) guidance, focusing on key areas of change including data governance, risk-based quality management, stakeholder collaboration, and risk proportionality.	https://www.transceleratebiopharmainc.com/assets/ich-e6-asset-library/?utm_source=hs_email&utm_medium=email&_hsenc=p2ANqtz-9cJB_7DEffbEw2z_rtUmUHS_3JFqtSNwsuXdmhv17W0KRSfhUMzVmrTMN5E2WDEt3_j0Ip#TrialDesign
EMA released the latest version (7.1) of the Clinical Trials Regulation (EU) No. 536/2014 Q&A document in March 2025	This version includes updates to Annex II: Language requirements for part I documents.	https://health.ec.europa.eu/document/download/bd165522-8acf-433a-9ab1-d7dceae58112_en?filename=regulation5362014_qa_en.pdf
The Clinical Trials Information System (CTIS) officially joined the Primary Registry Network of International Clinical Trials Registry Platform (ICTRP)	According to the WHO "Primary Registries in the WHO Registry Network meet specific criteria for content, quality and validity, accessibility, unique identification, technical capacity and administration. Primary Registries meet the requirements of the ICMJE."	https://www.who.int/tools/clinical-trials-registry-platform/network/primary-registries
EMA Clinical Data Publication Policy to cover all new marketing authorisation applications, line extensions and major clinical type II variations starting Q2 2025	From April 2025 onwards, Policy 0070 will cover all clinical data submitted under new marketing authorisation applications (MAAs) for medicinal products as well as any applications for line extensions or new indications, or where the MAA results in a negative opinion or is otherwise withdrawn.	https://www.insideeulifesciences.com/2024/11/27/ema-clinical-data-publication-policy-to-cover-all-new-marketing-authorization-applications-line-extensions-and-major-clinical-type-ii-variations-starting-q2-2025/
The new European Health Data Space regulation was enforced from March 26, 2025	The new regulation aims to facilitate access to and reuse of electronic health data across the EU. There will be a four-year transition period to establish the necessary electronic health data exchange infrastructures. This is significant and aims to revolutionise healthcare data management across the EU by enhancing accessibility, interoperability, and patient control over personal health data.	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32025R0327
New regulations for running clinical trials in the UK have been signed into law	A 12-month roll-out begins April 11, 2025, and will take full effect from April 10, 2026. Of note is that "... for the first time [the regulations will] legally require trial registration on a WHO-recognised public register and the publication of results summaries".	https://www.gov.uk/government/news/clinical-trials-regulations-signed-into-law
EMA has published a reflection paper on non-interventional studies that use real-world data (RWD) to generate real-world evidence for regulatory purposes	This reflection paper covers the aspects of design, conduct, and analysis of non-interventional studies, and focuses on methodological principles that are considered important for the conduct and assessment of non-interventional studies using RWD and used for regulatory decision-making throughout a medicine's lifecycle.	https://www.ema.europa.eu/en/documents/other/reflection-paper-use-real-world-data-non-interventional-studies-generate-real-world-evidence-regulatory-purposes_en.pdf

Disseminated information	Brief description	Link
European commissioner discusses EU-US Data Privacy Framework (DPF), potential GDPR reform. Comments on the emerging questions around EU-US DPF	The EU-US DPF is a set of rules designed to protect personal data transferred between the EU and the US. The EU is exploring a softened approach to digital regulation that aligns with US calls for deregulation to support digital innovation.	https://iapp.org/news/a/european-commissioner-discusses-eu-us-data-privacy-framework-potential-gdpr-reform https://iapp.org/news/a/schrems-addresses-emerging-questions-around-eu-us-data-privacy-framework
The European Association of Medical Devices Notified Bodies (Team-NB) has released v3 of their position paper on Best Practice Guidance for Technical Documentation under EU MDR	The Technical Documentation is the dossier submitted to NBs for conformity assessment of medical devices (MDs), equivalent to the CTD for medicinal product.	https://www.team-nb.org/wp-content/uploads/2025/04/Team-NB-PositionPaper-BPG-TechnicalDocEU-MDR-2017-745-V3-20250409.pdf
Team-NB also released v2 of the position paper on European Artificial Intelligence Regulation (AI ACT)	Provides an overview of the Team-NB perspective on the challenges of the AI Act with particular attention to its implementation.	https://www.team-nb.org/team-nb-position-paper-on-european-artificial-intelligence-regulation-v2/
The MHRA has published a guidance on how to apply for an Exceptional Use Authorisation (EUA) for MDs	EUA is a provision that allows non-UKCA/CE marked MDs to be placed on the UK market in exceptional circumstances, where this is necessary to protect public health.	https://www.gov.uk/guidance/exceptional-use-authorisation
May 2025 highlights		
EMA CTIS Simplification Task Force Topics for analysis was released last month	The Task force recommends a revised roles matrix for CTIS that reduces complexity and also the creation of a new safety module, with the aim to simplify the overall business rules for the Annual Safety Report.	https://www.ema.europa.eu/en/documents/other/ctis-simplification-task-force-topics-analysis_en.pdf
CTIS newsflash – 16 May 2025	EMA is redesigning the CTIS training materials for sponsor users, based on stakeholder feedback. The launch dates will be announced in upcoming issues of newsflash.	https://www.ema.europa.eu/en/documents/newsletter/ctis-newsflash-16-may-2025_en.pdf
FDA announced completion of first AI-assisted scientific review pilot and an aggressive agency-wide AI rollout timeline	The generative AI tools enable FDA scientists and subject-matter experts to minimise time spent on monotonous, repetitive tasks that typically hinder the review process.	https://www.fda.gov/news-events/press-announcements/fda-announces-completion-first-ai-assisted-scientific-review-pilot-and-aggressive-agency-wide-ai

Disseminated information	Brief description	Link
FDA released draft guidance "Accelerated Approval and Considerations for Determining Whether a Confirmatory Trial is Underway" in January 2025.	For drugs granted accelerated approval, sponsors have been required to conduct confirmatory studies post-approval to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. This guidance is developed following an amendment in the FD&C Act to help ensure timely completion of such trials. Allowing late comments.	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/accelerated-approval-and-considerations-determining-whether-confirmatory-trial-underway Comments: https://www.regulations.gov/docket/FDA-2024-D-3334/document
On May 14, 2025, EMA released the revised external guidance on the implementation of the EMA policy on the publication of clinical data for medicinal products for human use – Version 1.5 – along with the summary of changes document	Policy 0070 updates include: Clarification on the current scope of the policy and adding reference to Regulation 123/2022 on public health emergencies requirements for transparency; Clarifications aimed on the publication scope of individual patient data listings contained within the body of the Clinical Study Report and on the possibility for applicants/MAHs to propose additional redactions to protect from study unblind; Including the relevant and updated references to the current EU data protection legislation as well as additional relevant pieces of guidance issued by data protection authorities and professional organisations active within the data protection space.	https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/external-guidance-implementation-european-medicines-agency-policy-publication-clinical-data-medicinal-products-human-use-version-15_en.pdf https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/summary-changes-external-guidance-implementation-european-medicines-agency-policy-publication-clinical-data-medicinal-products-human-use-version-15_en.pdf
Canada's Drug Agency published their 2025 Watch List	This year's list focused on the use of AI technologies in health care in Canada.	https://www.cda-amc.ca/2025-watch-list#Issue3
New topic for May 2025: Possible Impact on Clinical Trial Ecosystem	Impact of a diversity, equity, and inclusion ban on the clinical research ecosystem. A Reuters news report of Robert F. Kennedy Jr., Health and Human Services Secretary, Congressional interview on May 14 2025	https://www.appliedclinicaltrialsonline.com/view/the-impact-of-dei-ban-on-clinical-research-ecosystem https://www.reuters.com/business/healthcare-pharmaceuticals/us-health-chief-kennedy-face-lawmakers-questions-mass-firings-measles-2025-05-14/

Abbreviations – AI: Artificial Intelligence; AI Act: Artificial Intelligence Act; AIM-NASH: Artificial Intelligence-based Measurement of Non-alcoholic Steatohepatitis Histology; CBER: Center for Biologics Evaluation and Research; CDER: Center for Drug Evaluation and Research; CDRH: Center for Devices and Radiological Health; CMS: Centers for Medicare & Medicaid Services; CTD: Common Technical Document; CTIS: Clinical Trials Information System; CTR: Clinical Trial Regulation; DPF: Data Privacy Framework; DPRC: Data Protection Review Court; EFPIA: European Federation of Pharmaceutical Industries and Associations; EHDS: European Health Data Space; EMA: European Medicines Agency; EORTC: European Organization for Research and Treatment of Cancer; EU: European Union; EUA: Exceptional Use Authorisation; FDA: Food and Drug Administration; GCP: Good Clinical Practice; GDPR: General Data Protection Regulation; HHS: Department of Health and Human Services; ICH: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; ICMJE: International Committee of Medical Journal Editors; I CTRP: International Clinical Trials Registry Platform; IMP: Investigational Medicinal Product; IVDR: In Vitro Diagnostic Regulation; MAA marketing authorisation application; MAH: Marketing Authorisation Holder; MASH: Metabolic dysfunction-associated steatohepatitis; MD: Medical Device; MDR: Medical Device Regulation; MHRA: Medicines and Healthcare products Regulatory Agency; NIH: National Institutes of Health; OCP: Office of Combination Products; PCLOB: Privacy and Civil Liberties Oversight Board; RWD: Real-World Data; RWE: Real-World Evidence; Team-NB: European Association of Medical Devices Notified Bodies; UKCA/CE: UK Conformity Assessed/Conformité Européenne; US: United States; WHO: World Health Organisation.