CORE REFERENCE

EMWA EUROPEAN MEDICAL WRITERS ASSOCIATION

AMWA AMERICAN MEDICAL WRITERS ASSOCIATION
The Resource for Medical Communicators

Clarity and Openness in Reporting: E3-based

Value for the Global Regulatory MW Community:

An Evergreen User Manual & CPD for Self-led Learning

Webinar Presented by The CORE Reference Team
28 July 2026

Agenda

- Introduction – Dr Sam Hamilton
- Original manual open book demonstration – Vivien Fagan
- News Summaries, Webinars, LinkedIn tour – Dr Zuo Yen Lee
- Learning resilience in an AI-augmented environment - Dr Alison McIntosh
- Links to resources

Evergreen …

- EMWA and AMWA 2014-2016
- User Manual and original resources 2016
- No planned update of CORE Reference User Manual
- EMWA Special Project with expanded team 2022

… and expanding

- 2026 website relaunch – https://emwa.org/resources/the-core-reference-project/
- Monthly News Summaries https://www.linkedin.com/company/the-core-reference-project
- Additional learning resources
  - Regulatory Public Disclosure Section in EMWA's *Medical Writing Journal*
  - Biannual Webinars with external SMEs - open access
  - Ad hoc collaborations across the regulatory MW ecosystem

CORE Reference

- Original open-access best practice resources published in May 2016
  - **CORE Reference**
  - **Mapping Tool**
  - Launch paper in BMC

- emwa.org/resources/the-core-reference-project/

CPD Resources

- **Quarterly CPD through 2018**
  - 2017: Utility Survey
- **Ad hoc CPD Dec 2018 – Apr 2022**
  - Jul 2019: comments on FDA pilot program
  - 2019: peer-reviewed T/Cel CSR template critique & estimand worked example
- **Monthly CPD since May 2022**
  - Dec 2022: Comparison T/Cel CPT and ICH M11 Level 2 headings
  - June 2023 - June 2026: Webinars
  - Dec 2023: Utility Survey
  - July 2026: 'Protocol development' collaboration

AI in Medical Writing Processes

Changing role of medical writer:

- AI prompt engineer
- Critical review of AI outputs

DEEP FOUNDATIONAL KNOWLEDGE

MEDICINES DEVELOPMENT

Celebrating 10 years of the CORE Reference Project

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Abstract

CORE Reference is a user manual, developed by the Budapest Working Group over the period 2014 to 2016, to help medical writers navigate relevant guidelines as they create clinical study report content relevant for today's studies. CORE Reference (with its Preface) and the mapping tool constitute the user manual. In 2022, CORE Reference was designated an EMWA Special Project , and as such it has expanded to support the increased workload

Open access link:
https://www.linkedin.com/feed/update/urn:li:activity:7454670090568007680

PDF: Open Book Demonstration

Presenter: Vivien Fagan

- CORE Reference PDF User Manual
- Key Elements
- Live demo

CORE Reference Manual 2016

Monthly News Summaries
Biannual Webinars
The CORE Reference Project on LinkedIn

Presenter: Zuo Yen Lee

Monthly News Summaries

Medicines and Vaccines	Medical Devices
ICH	General Updates and News
CTR and CTIS; EMA Guidance and News	EU Combined Initiatives
EU Regulatory European Health Data Space (EHDS) News	EU Transparency Eudamed News
UK and MHRA News	UK MHRA
FDA Guidance and News	FDA
Heath Canada	Health Canada
Real World Data	Asia Regulators
Transparency and Disclosure Resources and News GDPR and Data transfer Ex-EU EMA Policy 0070 in Practice	
Developmental Strategy News	
Artificial Intelligence/Machine Learning	
News from Asia Regulators	
News from US: Possible Impact on Clinical Trial Ecosystem	

Biannual Webinars

Date	Webinar	Recordings and/or slide decks
17 Jun 2026	ICH M11: An Integrated and Forward Looking CeSHarP Perspective Presenter: Marcie Roche	https://emwa.org/resources/the-core-reference-project/publications/
16 Jan 2026	CTIS and Clinical Trial Transparency: Strategies, Challenges, and CRO Insights Presenter: Mirjana Miric	
11 Jun 2025	Statistical anonymization software for utility-preserving privacy protection in clinical documents for public disclosure Presenter: Obaraboye Olude	
04 Dec 2024	Voydeya: A real-life example of EMA Policy 0070 in rare disease Presenter: Raquel Billiones	
07 Jun 2024	CORE Reference: An Open Access Resource (Presentation from EMWA Conference Valencia 2024) Presenter: CORE Reference Committee	
21 Jun 2023	CORE Reference: Value for the Global Regulatory MW Community Presenter: CORE Reference Committee	

The CORE Reference Project on LinkedIn

A tour of:

The CORE Reference Project on LinkedIn

Find all CORE Reference *latest updates/posts* and the *Monthly News Summary* in our dedicated LinkedIn page!

Follow ✓ us on LinkedIn. **Like**  and **share**  our posts with your peers and colleagues!

Learning Resilience in an AI-augmented environment

Presenter: Alison McIntosh

Auto Generation of Trial Documents

- Use of generative models to create and draft Plain Language Protocol Synopses (PLPS) and Informed Consent Forms (ICFs) from clinical study protocol*
- AI-Generated Protocol Summaries: generative tool produces short, non-technical summary for patients and ethics boards from clinical study protocol*
- Generative AI for Clinical Study Reports: assists in compiling clinical study reports*
- Use of AI in the development of lay summaries (LS) of clinical trial results**
- Use of AI in development of Plain Language Summaries of Clinical Trial Results in the EU***

*GenAI Proof of Concept in Pharma: Accelerating Drug Discovery and Development: https://intuitionlabs.ai/articles/genai-proof-of-concept-in-pharma

**Considerations for the use of artificial intelligence in the creation of lay summaries of clinical trial results. Medical Writing. 2025;34(2):74–81. https://doi.org/10.56012/vmag9372

***Plain language summaries of clinical trial results: What is their role, and should patients and AI be involved? Medical Writing. 2024;33(3): 34-37. https://doi.org/10.56012/yayy4394

AI-generated Outputs Need Human Oversight

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 September 2024
EMA/CHMP/CVMP/83833/2023
Committee for Medicinal Products for Human Use (CHMP)
Committee for Medicinal Products for Veterinary Use (CVMP)

Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle

2.3.5. Product information

AI/ML applications used for drafting, compiling, editing, translating, tailoring, or reviewing medicinal product information documents should be used under close human supervision. Given that generative language models are prone to include plausible but erroneous or incomplete output, quality review mechanisms need to be in place to ensure that all model-generated text is both factually and syntactically correct before submission for regulatory review.

https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-use-artificial-intelligence-ai-medicinal-product-lifecycle_en.pdf

Cognitive off-loading*

- “Google Effect” - people expect information to be easily accessible online, and are less likely to remember it themselves
- Over-reliance on AI tools can act as a replacement to critical thinking and effective learning
  - Thinking develops for speed rather than comprehension

*Jose B et al., (2025) Outsourcing cognition: the psychological costs of AI-era convenience. Front. Psychol. 16:1645237. doi: 10.3389/fpsyg.2025.1645237

Potential to

- Reduce knowledge
- Impact engagement
- Impact critical thinking skills
- Reduce deep engagement with content
- Create the illusion of competence

Medical writers must guard against this outcome

Gerlich, M. AI Tools in Society: Impacts on Cognitive Offloading and the Future of Critical Thinking. *Societies* **2025**, *15*, 6. https://doi.org/10.3390/soc15010006

Medical Writers: Develop Learning Resilience

AI must complement, not replace, human expertise and review of complex clinical trial data

EMA guidance for use of AI "under close human supervision"

Requires active participation by the user (MW)

MWs need "learning resilience" in an AI-augmented environment

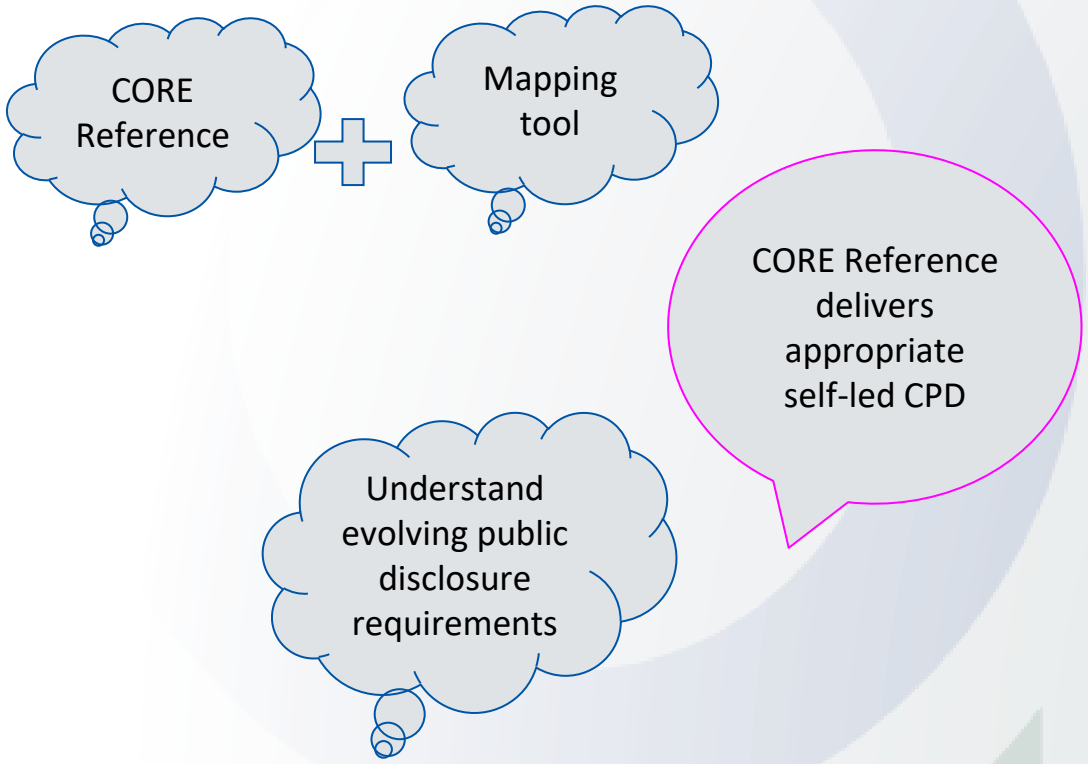
Access appropriate continuous professional development and training

Foster learning resilience, critical thinking, and in depth knowledge acquisition

MWs evolve deep understanding of document content

AI tools do not represent a stand-alone path to compliant clinical trial documents, including CSRs

AI depends on the expertise of MWs with a deep, up to date, foundational knowledge



EUROPEAN MEDICAL WRITERS ASSOCIATION

An Open Access Resource to Support Authoring of Clinical Study Reports for Interventional Studies