Clarity and Openness in Reporting: E3-based

LEARN AND SHARE

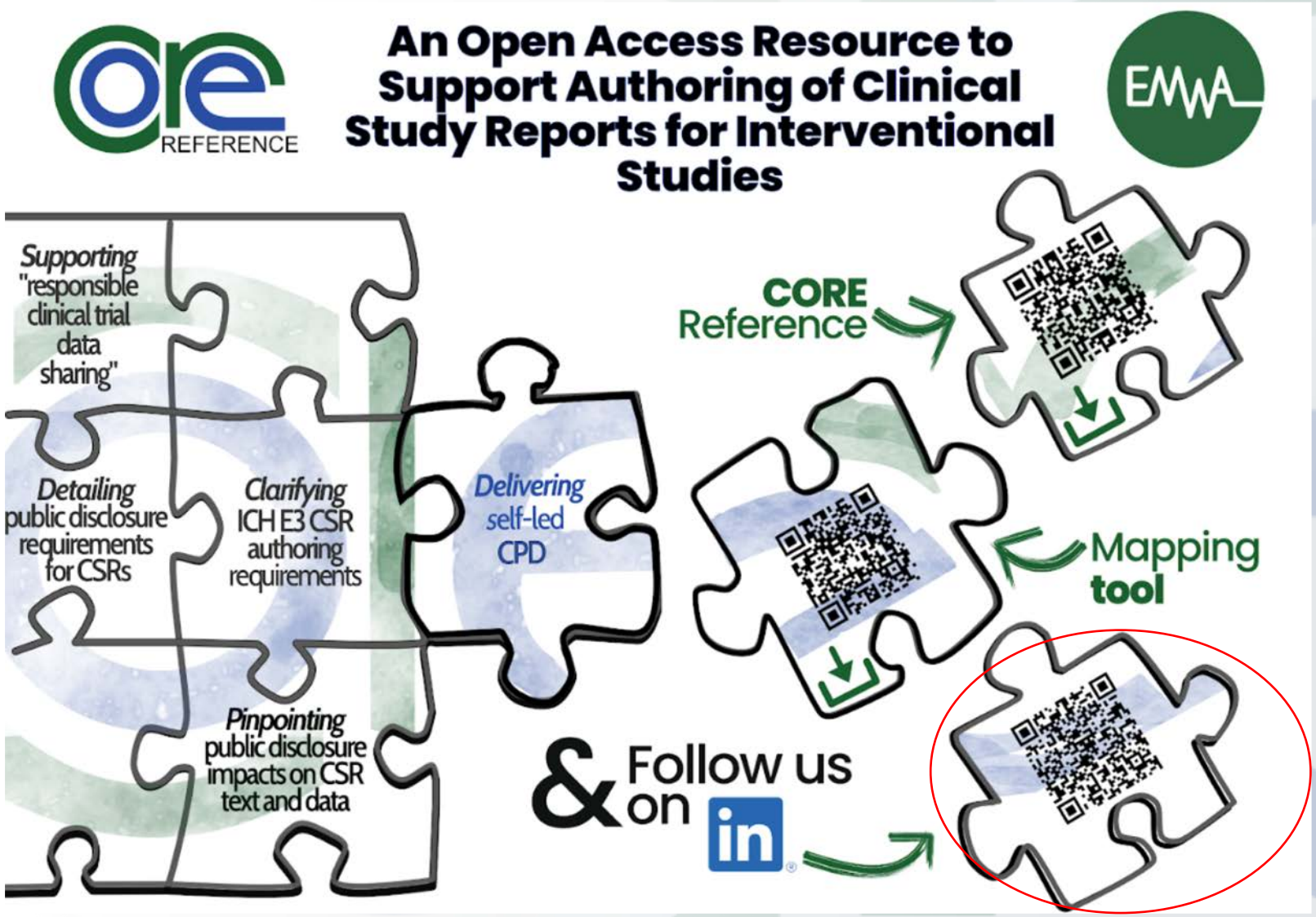
Sam Hamilton, Alison McIntosh, Vivien Fagan, Zuo Yen Lee

Thursday 8 May 2025: 12.30-13.15, RIGA

Agenda

- LinkedIn
- CORE Reference landing page on EMWA's new website
- CORE Reference new website update
- Engagement
- Webinar
  - External presenter, June 2025
- Discussion time
  - 10 min - open discussion Policy 0070 restart

LinkedIn


REFERENCE
An Open Access Resource to Support Authoring of Clinical Study Reports for Interventional Studies
EMWA
Supporting "responsible clinical trial data sharing"
Detailing public disclosure requirements for CSRs
Clarifying ICH E3 CSR authoring requirements
Delivering self-led CPD
Pinpointing public disclosure impacts on CSR text and data
CORE Reference
Mapping tool
& Follow us on in

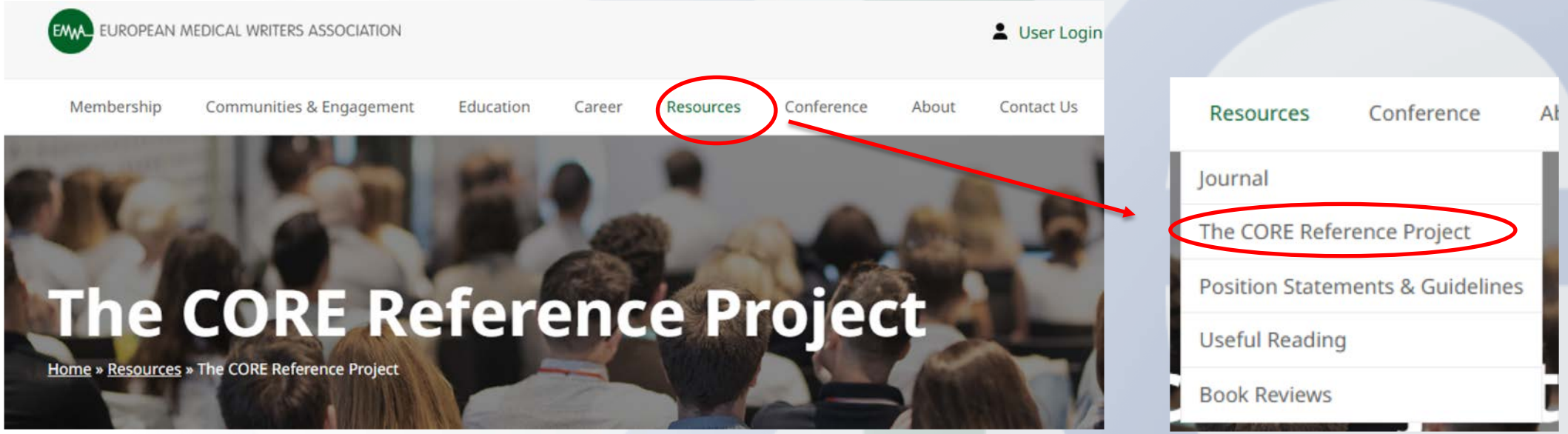
LinkedIn

https://www.linkedin.com/company/the-core-reference-project

Please share with your networks - forward, like, comment

EMWA site Landing page for CORE Reference (1)

https://emwa.org/resources/the-core-reference-project/ [landing page]



www.core-reference.org [direct link to existing site, also on landing page]

Landing page extract (2)

Why use CORE Reference?

- To support authoring of disclosure-ready CSRs
- Help MWs interpret ICH CSR authoring requirements
- Highlights privacy-related risks associated with published CSRs
  - Aids understanding of public disclosure requirements for CSRs
- Offers sectional content suggestions but does not mandate a particular CSR structure
- Shares regular updates on regulatory reporting and public disclosure; Pre-2025 archive

CORE Reference Outputs

- Downloadable open-access resource
- Mapping tool which maps CORE Reference sectional content to ICH E3
- Peer reviewed publication (2016)
- Self-led CPD archive
- LinkedIn updates on regulatory reporting and public disclosure

CORE Reference Keeps Medical Writers Informed

- Provides CPD for medical writers
  - Self-led CPD archive Pre-2025
  - LinkedIn updates on regulatory reporting and public disclosure 2025 onwards

New Website Update

- Existing website (www.core-reference.org) is not hosted by EMWA
- Aim is to incorporate our website under EMWA's new website build
  - Updates on progress will be in real time
- New website aims
  - Transfer of all resources on existing website (including News Summaries up to Dec 2024)
  - Upload Jan 2025 onwards News Summaries (shared via LinkedIn)
  - Introduce a search function for all News Summaries content so you can search by topic

LinkedIn publication of News Summaries will continue, regardless of website

Engagement (1)

- Webinar topics of interest to you?

Aim of the CORE Reference Project

To provide Continuous Professional Development (CPD) for the regulatory medical writing community through open access resources and intelligence dissemination on clinical study reporting and public disclosure of clinical-regulatory documents.

- Past webinars: https://www.core-reference.org/news-summaries/

Press Releases

- CORE Reference Webinar - Voydeya: A Real Life Example of EMA Policy 0070 in Rare Disease
- CORE Reference Seminar - EMWA Valencia May 2024 and Webinar 07 June 2024
- CORE Reference 2023 Utility Survey 25/10/23 - 05/12/23
- CORE Reference - Value for the Global Regulatory MW Community Webinar June 2023
- CORE Reference Project Team Compare TransCelerate CPT (v009) and Draft ICH M11 Step 2 Templates: A Comparison of Level 2 Headings

Engagement (2)

Any suggestions for new topic areas for News Summary?

Medicines & Vaccines

ICH; CTR & CTIS;

EU Regulatory; EHDS;

UK & MHRA News;

FDA guidance & news;

EMA guidance & news;

Transparency & disclosure resources and news;

EMA Policy 0070 in practice;

Development strategy news;

RWD; AI/ML;

News from Asia regulators

Medical Devices:

Transparency in relation to medical devices; emerging intersection of the regulatory MDs and the regulatory drugs spaces; MDs information or regulations that impact the reporting of device studies

General updates & news;

EU transparency;

EUDAMED news;

EU COMBINE initiative;

UK MHRA

[New subheadings when update is available…]

Next Webinar

External speaker: **Obaraboye Olude**, Privacy Analytics
“Statistical anonymization software for utility-preserving privacy protection in clinical documents for public disclosure”

11 June 2025, (13.30-14.15 CET) (12.30-13:15 UK time)

Webinar, with registration through info@emwa.org

Watch LinkedIn for details

Open Discussion Time

Clinical Data Publication (Policy 0070) relaunch (Step 2) from APRIL 2025

Policy 0070 relaunch now covers all clinical data submitted under new marketing authorization 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.

- Line extensions include changes to the product's active substance, strength, pharmaceutical form and/or route of administration etc
- Applications for major clinical Type II variations e.g. extension of indications

Challenges of EMA Expanded CDP Activity?

- Modules 2.5, 2.7 and 5.3 of the CTD dossier
  - Publication timelines: publication will occur within 120 days after the CHMP opinion
  - Proactive anonymisation?
  - When to prepare publication package documents?
- Alignment with CTIS publication timings
- EMA “publication upon request” policy for legacy clinical data (reactive publication)
- Collaboration with Health Canada
  - Align the processes, timings and scope of clinical data being published by each agency
  - Assess the potential for a single review procedure for certain applications