Clarity and Openness in Reporting: E3-based **CORE** Reference

Value for the Global Regulatory MW Community

Webinar 21 June 2023

Add your questions into the ‘chat’ on:

- Website and resources
- Practical utility of CORE Reference
- Transparency and disclosure in Asia

These will be answered after the main presentation

What Is CORE Reference?

1. CORE Reference

- Preface (21 pages, references + assumptions)
- Main body text (103 pages)
  - ICH (E3 and 2012 Q&A) guidance text
  - EU and US regional guidances
  - CORE Reference text

2. Mapping document

- ICH E3 

CORE Reference sectional structure

3. Explanation and elaboration paper published in a peer-reviewed journal

Hamilton S, et al Research Integrity and Peer Review 2016

Ongoing Value of CORE Reference

- **EMWA ‘Special Project’ from 2022**
- Continuous Professional Development (CPD) for medical writers
- Surveillance of regulatory reporting and public disclosure landscapes
- Subscribe to receive regular CPD email updates
- Growing CPD reference library

Web-based User Manual

http://www.core-reference.org

CORE Reference

- Mapping tool
- Launch paper

Web & NewsSummary Tour

PDF: Open Book Demonstration

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

https://www.core-reference.org/media/1032/core-reference-v1_0.pdf

Current Clinical Trial Results Disclosure Landscape in Asia

Country	China	Japan	South Korea	Taiwan
National Clinical Trial Registry (Mandatory)	Drug Clinical Trial Registration and Information Disclosure Platform (www.ChinaDrugTrials.org.cn)	Japan Registry of Clinical Trials (jRCT) (https://jrct.niph.go.jp/)	Ministry of Food and Drug Safety (MFDS) Registry (https://nedrug.mfds.go.kr/searchClinic)	Taiwan Clinical Trial Registry (TCTR) (https://www1.cde.org.tw/ct_taiwan/)
Type of Trial	Interventional (including BE, PK, Phase 1-4) (Not required: Observational)	Interventional (Phase 1-4) Observational (Not required: BE)	Interventional (Phase 0-4) (Not required: Observational)	Interventional (Phase 1-4), Observational
Trial Registration Timeline	Before subject enrollment	Before subject enrollment	After the study obtains MFDS approval; Before subject enrollment	After the study obtains TFDA/CDE approval; Before subject enrollment
Results Posting Required	Yes	Yes	Yes	No
Results Posting Timeline	Within 12 months of study completion or before marketing authorization (for trials supporting NDA, whichever earlier)	Within 1 year of study completion	Within 1 year of last subject last visit	-
Public Accessibility to Posted Results	No	Yes	Yes	-
Format of Posted Results	Uploaded as a separate summary or overview document. Per CDE guidance: the results summary/overview should at least consist of the content of the CSR Synopsis as described in the ICH E3.	Posted within the registry as brief synoptic summary/ summary in text boxes, with limited trial results (mostly only include primary and key secondary endpoints). Links to publications.	Posted within the registry as brief synoptic summary/ summary in text boxes, with limited trial results (mostly only include primary and key secondary endpoints).	-
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Policy 0070 Relaunch

- 16 May 23 EMA Webinar
  - Agenda topics covered were
    - Scope and updates
    - Timelines
    - Guidance and new Q&A document
    - Anonymisation Report Template

https://www.ema.europa.eu/en/events/clinical-data-publication-policy-0070-re-launch-ema-webinar

Policy 0070 Relaunch: Key Messages

Policy 0070 aims are unchanged; some procedural updates will be implemented:

- Applies to new active substances from September 2023 Committee for Medicinal Products for Human Use (CHMP) assessments
  - Includes negative and withdrawn products
- At this time no plan to request clinical data for products authorised during suspension of Policy 0070 (This is step 1 of launch. Step 2 will look at the backlog of studies e.g. publication upon request)
- Detailed specific invitation letters will be sent to request packages
  - 1st batch of letters due end May/beginning June – for those expecting September 2023 CHMP
- Pre-submission meetings offered
- Some changes to improve efficiency and continue work with Health Canada
- Covid-19 and other public health emergency clinical data publication continues

Policy 0070 Relaunch: What is New?

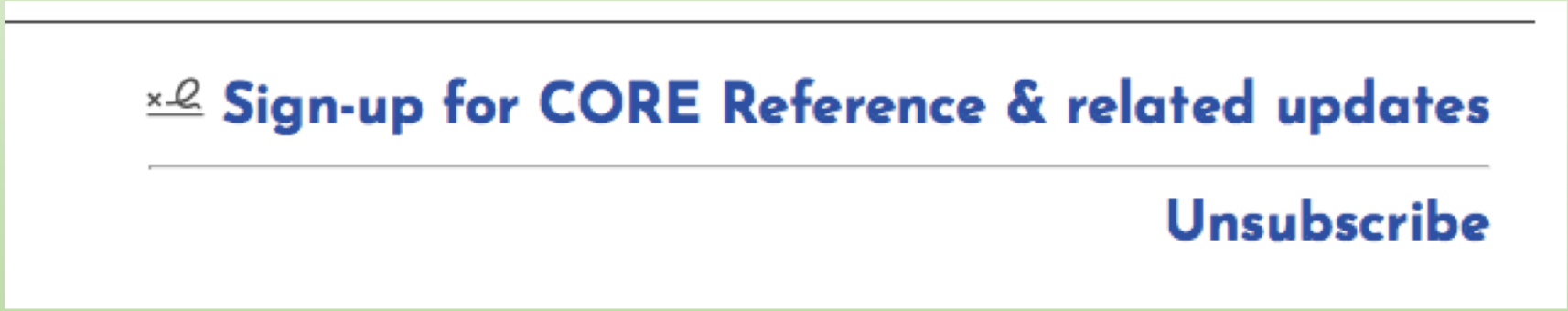
- Updated cover letter to include checklist to ensure validation success
- More guidance to be published: new Q&A document relevant to the 2023 relaunch of Policy 0070
- New anonymisation report template developed jointly with Health Canada: ready in “good time” for restart in Sep 2023

Q&A – your questions on:

- Website and resources
- Practical utility of CORE Reference
- Transparency and disclosure in Asia

Sign up for CORE Reference CPD emails

- Via the website:
  https://www.core-reference.org/subscribe



Thank you for attending

30th EMWA Anniversary 1992-2022

REFERENCE

Chair: Sam Hamilton

Committee members: Vivien Fagan, Zuo Yen Lee, Alison McIntosh

Advisor: Art Gertel

Supporting member: Raquel Billiones (MD-SIG)

THE CORE REFERENCE PROJECT

The **C**larity and **O**penness in **R**eporting: **E**3-based (CORE) Reference Project aims to provide continuous professional development for the regulatory medical writing community through open-access resources and intelligence disemmination on clinical study reporting and public disclosure of clinical-regulatory documents.

contact@core-reference.org