

CORE Reference

Clarity and Openness in Reporting: E3-based
3 years on - a resource for CPD

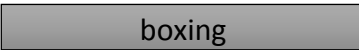

Dr Sam Hamilton – Chair
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RECAP: What Is CORE Reference?

1. CORE Reference (PDF)

- 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
 - Distinguished via shading and  boxing
 - Includes explanations  of CORE Reference clarifications

2. Mapping document (PDF)

- 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

3 Years On: Project Evolution

- www.core-reference.org **active** and **resource-rich** website:

ESTABLISHED RESOURCES

- Downloadable PDFs of CORE Reference + Mapping Tool (counters)
- Multiple publications with direct links

CONTINUING PROFESSIONAL DEVELOPMENT

- In 'real time' clinical trial disclosure-related news direct to your inbox
 - <https://www.core-reference.org/subscribe>
- Periodic 'News Summaries' dedicated page
- External links: Japanese language blog, TransCelerate CSR template
- Links to EMA, FDA, Health Canada disclosure regulations and portals



Finding CORE Reference

<http://www.equator-network.org/reporting-guidelines/core-reference/>

- PROBLEM: **NOT** easily findable through a 'guidelines search'
- SOLUTION: **EQUATOR** added 60+ keywords to our entry to aid search retrieval (March 19)



External Resource Development

- <http://www.transceleratebiopharmainc.com> - an alliance among “some of the world’s prominent biopharmaceutical organizations” ...“accelerating the development of new medicines”. TransCelerate provide solutions that “...are developed collaboratively and can be voluntarily adopted by stakeholders in the clinical research ecosystem”

TransCelerate CSR template developed November 2018

- TransCelerate CSR template is independent from CORE Reference
BUT... serves similar aims

TransCelerate CSR Template

- The CSR template and statistical analysis plan (SAP) templates – are under the “Common Protocol Template” resources at:
<http://www.transceleratebiopharmainc.com/assets/common-protocol-template/>
- ICH E3 and CORE Reference are confirmed as the two “well-known standards” used in development
http://www.transceleratebiopharmainc.com/wp-content/uploads/2018/11/CPT_ImpITK-How-was-Common-CSR-Developed_V001.pdf
- Budapest Working Group initial observations: Press Release Dec 18
<https://www.core-reference.org/news-summaries/core-reference-statement-on-transcelerate-csr-template/>

Reasonable Questions Arising...

- Was ICH, or a regional regulator, or the BWG involved in the development of the TransCelerate CSR template?
- Does the TransCelerate CSR template accurately reflect ICH E3 guidance and CORE Reference recommendations?
- Do the TransCelerate CSR template and CORE Reference complement each other as tools to facilitate compliance with ICH E3?
- Which resource(s) should MWs now use to write CSRs?
- What next for CORE Reference?

**THESE ARE ALL GOOD QUESTIONS THAT
NEED TO BE ADDRESSED...**

BWG's Detailed Review of TransCelerate CSR Template

- Reviewed Mar-Apr 2019 by BWG: SH, AG, TF, VF, AB, WS, GB
- Communication with global clinical research community
 - Target open-access journal : “Research Integrity and Peer Review”



- Manuscript contents:
 - Key findings and recommendations (Table 1)
 - Detailed line-by-line review of CSR template; consolidated comments (Appendix)
 - Version 2.0 of the CORE Reference Terminology (Table 2)

BWG's Well-Considered "Answers"

- Was ICH, or a regional regulator, or the BWG involved in the development of the TransCelerate CSR template? **We do not believe regulators were involved; BWG were not involved**
- Does the TransCelerate CSR template accurately reflect ICH E3 guidance and CORE Reference recommendations? **Additional instructional text would add value**
- Do the TransCelerate CSR template and CORE Reference complement each other as tools to facilitate compliance with ICH E3? **Yes; both offer different value**
- Which resource(s) should MWs now use to write CSRs? **All available**
- What next for CORE Reference? **Version 2.0 is no longer foreseen.**
www.core-reference.org is a resource for



Planned Publication



- **Review of the TransCelerate template for clinical study reports (CSRs) by the developers of CORE Reference (Clarity and Openness in Reporting: E3-based)**
- Hamilton S, Bernstein AB, Blakey G, Fagan F, Farrow T, Jordan D, Seiler W, Gertel A
 - Submitted 07 May 2019
- On publication, we will share the open-access link widely; please help us - **forward the link to your colleagues**

THANK YOU