

Authors' Presentation of BioMed Central Publication:

'Critical Review of the TransCelerate Template for Clinical Study Reports (CSRs) and Publication of Version 2 of the CORE Reference (Clarity and Openness in Reporting: E3-based) Terminology Table'.

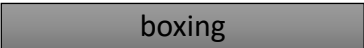

Dr Sam Hamilton – Chair
Dr Art Gertel – Strategist

Planned presentation 08 May 2020



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 
 - 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

4 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
- Links to EMA, FDA, Health Canada disclosure regulations and portals

GLOBAL VOICE: COMMENTARY IN WIDER RPD ARENA

- TransCelerate CSR Template
- Commenting on open FDA Docket

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 first released November 2018

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

Chronology

- NOV 2018: TransCelerate release CSR template
- AUG 2019: BWG publish paper detailing review findings:
 - <http://dx.doi.org/10.1186/s41073-019-0075-5>
- DEC 2019: TransCelerate update CSR & SAP templates; relocate resources:
 - <https://transceleratebiopharmainc.com/assets/clinical-content-reuse-assets/>

Research Integrity and Peer Review

[Home](#) [About](#) [Articles](#) [Submission Guidelines](#)

Review | [Open Access](#) | [Open Peer Review](#) | Published: 05 August 2019

Critical review of the TransCelerate Template for clinical study reports (CSRs) and publication of Version 2 of the CORE Reference (Clarity and Openness in Reporting: E3-based) Terminology Table

[Samina Hamilton](#) , [Aaron B. Bernstein](#), [Graham Blakey](#), [Vivien Fagan](#), [Tracy Farrow](#), [Debbie Jordan](#), [Walther Seiler](#), [Art Gertel](#) & on behalf of the Budapest Working Group [BWG]

Research Integrity and Peer Review 4, Article number: 16 (2019) | [Cite this article](#)

1666 Accesses | 9 Altmetric | [Metrics](#)

Abstract

Background

CORE (Clarity and Openness in Reporting: E3-based) Reference (released May 2016 by the European Medical Writers Association [EMWA] and the American Medical Writers Association [AMWA]) is a complete and authoritative open-access user's guide to support the authoring of clinical study reports (CSRs) for current industry-standard-design interventional studies. CORE Reference is a content guidance resource and is not a CSR Template.

TransCelerate Biopharma Inc., an alliance of biopharmaceutical companies, released a CSR Template in November 2018 and recognised CORE Reference as one of two principal sources used in its development.

BWG's 'Additional File'

- 44-page 'Additional file' published alongside BWG manuscript
- 69 detailed consolidated BWG comments on TransCelerate NOV 2018 CSR template
- Additional file served as reference used by TransCelerate to update their DEC 2019 CSR template release

Intended outcome achieved!

TransCelerate CSR Template Dec 2019

Tools & Resources

Click on the tabs below for Clinical Content & Reuse information and resources

Introductory and Implementation Materials	Clinical Template Suite (CTS); Template, Resources, and Use Guidance		
	CPT	SAP	CSR

Welcome!

- > [Introduction to TransCelerate](#)
- > [Implementation Toolkit Executive Summary](#)

Ready to take action? Let's get started:

- > [Objectives and Guiding Principles for the Implementation Leader](#)
- > [Approaches to Implementing in Your Organization](#)
- > [Text and Style Conventions](#)

CSR Template

Tools & Resources

Click on the tabs below for Clinical Content & Reuse information and resources

Introductory and Implementation Materials	Clinical Template Suite (CTS); Template, Resources, and Use Guidance			eTemplates (eCPT, eSAP, eCSR)
	CPT	SAP	CSR	

What is the CSR?

2019 CSR Updates

CSR Templates

CSR Foundation and Strategic Alignment

CSR Implementation Tools

2019 CSR Updates

TransCelerate is excited to release the second publicly-available version of the CSR template and the first version of the [eCSR!](#)

Since the November 2018 release, we have continued to collect feedback to further improve the content, utility, and sustainability of the CSR template. Complete details are in the [Summary of Changes in 2019 Release](#).

Highlights of this release include:

- > Alignment with this release of CPT
- > Updated instructional and suggested text
- > Alignment with CORE, in addition to alignment with ICH E3 (previous release).
- > eCSR functionality to create an abbreviated or synoptic-style report based on a user's needs.

Feedback on the CSR Template will be collected on an ongoing basis and used to inform future releases. Have feedback on the CSR Template? Click [here](#).

< Click to navigate between each section >

Summary of Changes

40 slide deck :

- Includes a rationale for each change. From Slide 25 or thereabouts, the rationale for change frequently includes 'Feedback from CORE review' or 'CORE feedback'.
- Other documents refer to 'public comment'

Quality Standard

- Does the TransCelerate CSR template DEC 2019 accurately reflect ICH E3 guidance and CORE Reference recommendations? **Unconfirmed**
- Do the TransCelerate CSR template DEC 2019 and CORE Reference complement each other as tools to facilitate compliance with ICH E3? **Yes - both offer different value; however they are symbiotic**
- What next for CORE Reference? **Version 2.0 is no longer foreseen.**
www.core-reference.org is a resource for 