PRESS RELEASE

CORE Reference Statement on the November 2018 Release of the TransCelerate Biopharma Clinical Study Report Template

Background

1. CORE Reference is a freely available (https://www.core-reference.org/core-reference/) resource for the reporting of human medicinal trials. Explore the website (www.core-reference.org), and key articles to understand how CORE Reference came about, and how it can facilitate reporting of modern clinical trials so as to retain the data utility needed to support regulatory decision-making, whilst safeguarding the privacy of participants:

- Non-technical article: 'Safeguarding the privacy of clinical trial patients': http://blogs.biomedcentral.com/on-medicine/2016/05/27/safeguarding-privacy-clinical-trial-patients/

- Technical publication: 'Developing the Clarity and Openness in Reporting: E3-based (CORE) Reference user manual for creation of clinical study reports in the era of clinical trial transparency': http://dx.doi.org/10.1186/s41073-016-0009-4

CORE Reference downloads exceed 15 000; see public declarations of support at: http://www.core-reference.org/adoption-and-use/

CORE Reference's primary goals are reducing the time and cost of getting medicines to patients in need. Resource development (2014 to 2016), and post-publication news (from May 2016) is publicised in real time, according to the important tenets of transparency and public disclosure (updates via: https://www.core-reference.org/subscribe).

CORE Reference, like the regulatory guidelines that it is based upon, is a practical tool and is not a CSR template.

2. TransCelerate Biopharma (http://www.transceleratebiopharmainc.com) - henceforth TransCelerate - is an alliance among "some of the world's prominent biopharmaceutical organizations" with the tagline "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".

3. Although independent, the CORE Reference project and TransCelerate serve similar aims.

TransCelerate Release a CSR Template

In November 2018, TransCelerate released a clinical study report (CSR) template.

The CSR template - and associated resources including a statistical analysis plan (SAP) template - are located on the TransCelerate website under the "Common Protocol Template" resources at:
http://www.transceleratebiopharmainc.com/assets/common-protocol-template/

CORE Reference's Initial Observations on the TransCelerate CSR Template

While the developers of CORE Reference were not involved in TransCelerate's CSR template development, we believe that TransCelerate's CSR template and CORE Reference serve distinct purposes, and offer the following observations:

- ICH E3 and CORE Reference are confirmed as the two "well-known standards" used in TransCelerate's CSR template development (http://www.transceleratebiopharmainc.com/wp-content/uploads/2018/11/CPT_ImplTK-How-was-Common-CSR-Developed_V001.pdf)
- TransCelerate's lean CSR template is 24 pages long (with instructional text hidden)
- CORE Reference is cited 4 times in the TransCelerate CSR template instructional text; reference is also made to the "Core Backbone" which is unconnected with CORE Reference
- "Core Backbone" Level 1 and Level 2 headings may not be rearranged or reordered according to the template instructional text
- In lieu of providing CSR appendices templates, TransCelerate points to ICH E3 and CORE Reference for guidance; ICH E3 and CORE Reference direct links are not included in the template
- For public disclosure guidance, TransCelerate reference the TransCelerate Implementation Toolkit.

CORE Reference Position Statement on TransCelerate's CSR Template

We created CORE Reference to save the industry time, effort, and expense. CORE Reference is a (regulatory guidance-underpinned) foundation stone that TransCelerate has used - alongside ICH E3 - to create a lean CSR template, which TransCelerate expect to continue to develop through user feedback. **We warmly welcome TransCelerate's work to date**.

We - as the developers of CORE Reference - welcome TransCelerate's recognition of CORE Reference as one of their two principal guidance resources. We acknowledge that some harmonies exist between TransCelerate's CSR template and CORE Reference.

We reiterate, that CORE Reference is a content guidance tool and not a template, and we suggest that a single CSR template cannot fit all study designs - without inherent structural flexibility (for example, where the primary study objective is safety- rather than efficacy-based). In the case of the TransCelerate CSR template, instructional text stipulates that Level 1 and Level 2 headings must not be rearranged. Further, and although not noted in the TransCelerate CSR template, CORE Reference remains the only CSR authoring tool that pinpoints each section in a CSR where disclosure considerations apply.

In future iterations of the TransCelerate CSR template, we would like to see the user experience enhanced by addition of these direct links in the template instructional text:

- www.core-reference.org (our website where CORE Reference may be downloaded from)
- https://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html (the ICH efficacy guidelines webpage where ICH E3 may be downloaded from)

since both resources are directly referenced for guidance on CSR appendices – but these are currently without clickable links.

The shared vision of both CORE Reference and TransCelerate for supporting rapid and efficient development of medicines is worthy. We encourage users of the TransCelerate CSR template to provide their feedback directly to TransCelerate via the link on their website (http://www.transceleratebiopharmainc.com/assets/common-protocol-template/feedback-form/). Please remember that TransCelerate and CORE Reference are wholly separate entities.

CORE Reference is a Resource for Your Continuing Professional Development

Informed authoring of CSRs for modern clinical trials requires understanding of mandatory, numerous, and ever-increasing global and regional regulatory guidances. To May 2016, all such guidances are incorporated in CORE Reference; newer guidances continue to be publicised via https://www.core-reference.org/subscribe.

CORE Reference is therefore a comprehensive educational tool - that supports your continuing professional development - as well as a writing resource. Sign up to receive CORE Reference emails at https://www.core-reference.org/subscribe to serve your up to date educational needs and enhance your learning.

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