Reviewer’s report

Title: 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

Version: 0  Date: 07 Jun 2019

Reviewer: Mitzi Allred

Reviewer's report:

The TransCelerate CPT team welcomes the helpful feedback from the authors and will look to revising the existing assets and template to incorporate some of the suggestions. The template was based on the core principles in ICH E3 and direct experience by member company interactions with Regulatory Authorities as well as the CORE Reference by the Budapest Working Group. And as such the template represents a synthesis of the best practices. Updates are refreshed regularly. Further feedback is welcomed from all users of the CPT suite of templates and can be provided via the following link: https://www.transceleratebiopharmainc.com/assets/common-protocol-template/feedback-form.

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