Topics

1. Template Content

DISCLAIMER REGARDING THE CSR

This document is a guide related to the use of the Common Clinical Study Report template. The template contains sections marked as common text or text that may be used across CSRs with little to no editing if the user chooses to do so. The use of the template is at the discretion of the user.

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Common Clinical Study Report (CSR) Frequently Asked Questions

1 Template Content

1.1. Q: Is the Common CSR template aligned with ICH E3 and CORE?
   A: The Common CSR template was built in adherence with ICH E3 and CORE guidance. Some sections were rearranged for clarity and/or to prepare for upcoming technical advances, but all topics recommended by these guidances are included in the Common CSR template.

1.2. Q: Why are the first 5 headings unnumbered? Is this in line with ICH E3 and CORE?
   A: The first 5 sections are unnumbered as the numbering is no longer needed for navigation with electronic viewing using bookmarking and cross linking. In addition, the numbering will be disrupted when some sections are deleted from the full CSR template to create abbreviated or synoptic CSRs in future releases. Both ICH E3 and CORE provide guidance on CSR structure/content, but in fact, provide alternate guidance on section numbering (e.g., ICH E3 numbers the title page as Section 1, however, CORE states that the title page does not need to be numbered Section 1). In addition, a poll of some TransCelerate member companies involved in the development process indicated that multiple Sponsors have removed numbering for the initial sections of the CSR with no negative impact on regulatory review or feedback.

1.3. Q: Does the Common CSR template provide guidance on appendix and/or Tables/Listings/Figures numbering?
   A: No, the Common CSR template provides structure and proposed common content for the body of the CSR. Numbering/nomenclature of appendices and tables/listings/figures should be done per company standards, based on guidance from ICH E3 and CORE.

1.4. Q: Does a study have to have estimands to use the Common CSR template?
   A: No. Estimands are being introduced in the Common Protocol Template (CPT), Common SAP, and Common CSR templates in 2018 in accordance with ICH E9 (R1) guidance. For many studies initiated prior to the guidance; however, estimands will not have been implemented. The templates allow use of endpoints if estimands are not available.

1.5. Q: What is the purpose of the Objectives, Estimands/Endpoints, Statistical Methods and Results table in the CSR synopsis?
   A: Estimands are being introduced into CPT in 2018 in accordance with ICH E9 (R1) guidance. The CSR template has been aligned with the CPT, but Sponsors may use endpoints if applicable. Also, endpoints are included as part of the estimands.

In the synopsis, the Objectives, Estimands/Endpoints, Statistical Methods and Results table provides high-level, end-to-end visibility of the study near the top of the CSR.
that describes the planned study objectives and estimands (or endpoints), then the statistical methods applied, and finally the results of the study (e.g., were the objectives/estimands/endpoints achieved).

1.6. Q: If the Objectives, Estimands/Endpoints, Statistical Methods and Results table is implemented in the synopsis, how much detail is needed in the subsequent “Summary of Results and Conclusions” Section of the synopsis?

A: If the Objectives, Estimands/Endpoints, Statistical Methods and Results table is provided in the synopsis, only sparse content is needed in the “Summary of Results and Conclusions” Section to briefly describe important study results not provided above or to provide further detail or clarification of data presented in the table.

1.7. Q: Do abbreviations need to be defined on first use in the Common CSR?

A: No, to improve efficiency of authoring and reduce potential QC findings, abbreviations need only be defined in the List of Abbreviations and Definitions of Terms and not in the text upon first use.

1.8. Q: Why do many of the Common CSR sections not include content from the protocol and/or SAP and only reference these documents in the appendices?

A: To reduce redundancy and streamline the CSR, content previously in the protocol or SAP (e.g., study assessments, planned statistical analyses) is referenced rather than repeated in the CSR body. Reviewers can follow the cross link and view the content in the appended documents if needed.

1.9. Q: In the “Investigators and Study Administrative Structure” Section, the template recommends including Sponsor and CRO information in an appendix. To which appendix should this be added and why?

A: To avoid providing personal protected information (PPI) or commercially confidential information (CCI; e.g., which vendors were used for a specific patented measurement), it is recommended that this information is added to an appendix. For example, this information could be added in a subsection to the appendix that lists Investigators and other important study personnel.

1.10. Q: If a study protocol included predefined quality tolerance limits (QTLs) and any deviations were identified, where does that information belong in the CSR? And how should they be handled if some of the QTL deviations also qualified as protocol deviations?

A: Deviations to predefined QTLs should be reported in Section 3.5 “Data Quality Assurance”; any that also qualify as protocol deviations should also be discussed in Section 4.2 “Protocol Deviations”.

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1.11. Q: Why was post-intervention therapy added to the “Prior and Concomitant Therapy” Section?
   A: Optional post-intervention therapy was added to this section to accommodate participants who have completed the intervention period, but continue into long term follow up.

1.12. Q: Why were the major results sections “Efficacy Evaluation and Safety Evaluation” renamed/reorganized as “Evaluation of Response to Study Intervention”?
   A: To enable greater flexibility and use of the Common CSR template across study types and phases, level 2 sections were created for all assessment types including efficacy and safety as well as others such as PK and PD. Sections that are not relevant to a study may be deleted if not applicable to the study.

1.13. Q: Where should narratives be placed in the CSR?
   A: To support a lean CSR, full narratives are to be provided in an appendix and the use of in-text narratives is discouraged. Although discouraged, if in-text narratives are deemed critical for data interpretation, they may be added to the appropriate Safety subsection (e.g., Deaths, Serious Adverse Events).

1.14. Q: Can the Common CSR template be used for device studies?
   A: Yes. Safety findings can be described in Section 5.2.3.4 “Safety Observations Related to [Medical Device OR Combination Product]” and device findings not related to safety can be reported in Section 5.9 “Other”. The header for Section 5.9 can be edited to allow insertion of a relevant section title.

1.15. Q: Why is there no “Discussion” Section in the Common CSR template?
   A: The CSR is to be used as a mechanism to report the outcomes of the study. Discussions such as benefit/risk interpretations are better suited for summary documents where they may include data from across a range of studies. To support a lean, streamlined CSR, the “Conclusions and Discussion” Section was reduced to cover conclusions only. Sponsors may include discussions in this section if warranted.