

Clinical Research Data Sharing Alliance (CRDSA) Standards Development Process

Revision Log

Each release of this document supersedes all previously released versions. The change history log lists all significant changes made to the document since its initial release.

<u>Revision Date</u>	<u>Summary of Changes</u>
July 1, 2024	Version 1 Release

About this Document

This document is intended to provide information relating to the development and use of Industry Standards developed by the Clinical Research Data Sharing Alliance (hereinafter “Alliance”). Alliance Industry Standards are developed through a consensus-based standards developed process. This process brings together volunteers from industry, nonprofit organizations, foundations, and academic institutions representing varied viewpoints and interests to achieve consensus.

The Alliance establishes the rules to promote fairness in consensus development. IEEE-ISTO serves as a neutral facilitator to oversee the process's administration and adherence to the Alliance Bylaws and this document's Standards Development Process.

This Alliance does not independently test, evaluate, or validate the accuracy of any information contained in the Alliance Standards.

Standards Disclaimer

The CRDSA disclaims any liability for any damages of any nature whatsoever, whether special, direct or indirect, consequential or compensatory, directly or indirectly resulting from the use of, or reliance on these Alliance Standards. The Alliance also makes no guarantee or warranty as to the completeness or accuracy of any information published within the Standards.

In issuing Industry Standards, the Alliance is not undertaking to render professional or other services on behalf of any entity or person. Anyone using these documents should rely on his/her independent judgment or, as appropriate, seek the advice of competent professionals in determining the exercise of reasonable care in any given Standards implementation.

CRDSA Standards Development Process

1. The Alliance Standard Process begins with the approval of a new Standards project in the Alliance by the Alliance Steering Committee.
2. The Alliance Steering Committee approves a Work Group chartered to develop an Industry Standard with a specific scope. The Steering Committee approves the Charter for the Work Group (WG).
3. The Work Group formed has a WG lead who directs meetings in the WG's drafting of the Industry Standard.
4. Once the WG has completed an initial Draft Standard for Public Comment, the WG submits the Draft Standard to the Alliance Steering Committee and Board of Directors for review and comment.
5. Once the WG has addressed internal comments from Alliance member organizations, the Draft Standard is released for a public comment period of not less than 60 calendar days. The Draft Standard for Public Comment will be published on the Alliance's website and the public comment period will be announced through the Alliance's marketing and social media channels.
6. Once the WG has reconciled any public comments received, the WG votes to approve the Final Draft Standard for submission to the Alliance Steering Committee for approval. The WG vote will be in compliance with the Alliance Bylaws for voting approvals of Industry Standards. Once a WG vote to approve a Final Draft Standard passes, the WG Lead then submits the Final Draft Standard to the Alliance Steering Committee for approval, initiating a **Draft Standards Review period for two (2) weeks**.
7. The Alliance Steering Committee reviews the WG-approved Standard during the review period. Any edits to the Standards, cosmetic or substantial in nature, are codified in a red-lined document and submitted back to the WG for discussion and edits as required.
8. Once the Alliance Steering Committee completes the Review Period for the Draft Standard, it conducts a formal vote to approve the Draft Standard in compliance with the Alliance Bylaws.
9. Once the Steering Committee approves the Draft Standard, it is then submitted formally to the Alliance Governing Board for Board ratification. The Alliance Board has a seven (7) day review period. Any questions or comments by the Board on the Draft Standard are communicated to the Steering Committee by the Board.
10. The Alliance Board ratifies the Alliance Standard in a formal vote in compliance with the Alliance Bylaws. Once ratified, the Industry Standard is ready for public dissemination.

*Notes

- 1) WG membership is open to members of the Alliance who are in Good Standing.
- 2) Steering Committee membership is open to members of the Alliance in Good Standing, limited to no more than one representative per member organization.