

San Diego CDISC Users Network



News/Updates

CDISC and Submission News/Updates

- COVID Resources
- SDTM v1.7/SDTM IG v3.3
- Define-XML 2.1
- SDTM Metadata Submission Guidelines v2.0
- Technical Rejection Criteria
- CDISC Library

COVID Resources

- FDA (<https://www.fda.gov/>)
 - COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders
- CDISC (<https://www.cdisc.org/standards/therapeutic-areas/covid-19>)
 - Interim User Guide - COVID-19
 - Guidance for Ongoing Studies Disrupted by the COVID-19 Pandemic
 - Resources for Public Health Researchers

SDTM Metadata Submission Guidelines v2.0

The screenshot shows the CDISC website interface. At the top right, there are links for "Log in", "Create Account", and a "Search" button. The CDISC logo is on the left, and a navigation menu includes "New to CDISC", "Standards", "Education", "Resources", "Events", and "Membership". The breadcrumb trail is "Home / Standards / Foundational / SDTM / SDTM Metadata Submission Guidelines v2.0". The main heading is "SDTM Metadata Submission Guidelines v2.0". A "Release Information" button is visible, and a grey box at the bottom contains the text "Preparing for Public Review."

Log in Create Account Search

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New to CDISC Standards Education Resources Events Membership

Home / Standards / Foundational / SDTM / SDTM Metadata Submission Guidelines v2.0

SDTM Metadata Submission Guidelines v2.0

Release Information

Preparing for Public Review.

Technical Rejection Criteria

- FDA has added technical rejection criteria to the existing eCTD validation criteria.
- Affects clinical and non-clinical
- The FDA will give the industry 90 days' notice on the eCTD web page prior to the new criteria becoming effective

CDISC Library

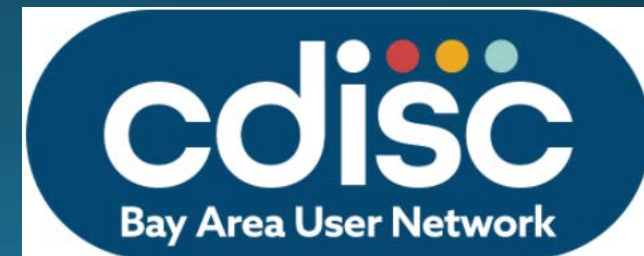
- Launched the CDISC Library Data Standards Browser at the US Interchange in San Diego in 2019.
- Change in authentication method
- CDISC and Microsoft workshop: Next Generation of Clinical Innovation in Standardized Data

Upcoming (*Virtual*) Events

- September 21-23 PhUSE CSS
- September 29 PhUSE SDE
- October 5-7 CDISC US Interchange
- Q4 2020 Bay Area CDISC Users Network Meeting

Connect: jbrega@pharmastat.com, BACDISC Wiki

- 2021 SDCUN



Thank you



<https://www.linkedin.com/groups/4055118/>
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