

CDISC



CDISC is a global, open, multidisciplinary, non-profit organization that has established standards to support platform-independent data standards for the acquisition, exchange, submission and archive of clinical research data and metadata. FDA has announced that it will develop guidance that will require study data in conformance to CDISC standards.

CDISC has been engaged to help the TED Initiative and the greater TBI community to conform (**KEEP THIS LINK?**) TBI Common Data Elements [1] to CDISC standards for FDA regulatory submission.

CDISC standards are vendor-neutral, platform-independent and freely available via the **CDISC website** [2].

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Source URL: <https://tbiendpoints.ucsf.edu/cdisc>

Links

[1] http://www.commondataelements.ninds.nih.gov/tbi.aspx#tab=Data_Standards

[2] <http://www.cdisc.org/>