Standards for data exchange support sharing of structured metadata and data between parties and across different information systems. Standards referenced in this section support exchange of CDASH-compliant CRFs for data collection and exchange of tabulation and analysis datasets through provision of data-definition documents to describe datasets. Standards referenced in this section are supported by the CDISC Operational Data Model (ODM, available at https://www.cdisc.org/standards/data-exchange/odm). ODM is a vendor-neutral, platform-independent format for exchanging and archiving research data, along with their associated metadata, administrative data, reference data, and audit information.

Accessing CDASH-compliant CRFs

The CDISC eCRF Portal (https://www.cdisc.org/kb/ecrf) is a platform from which to download standard CRFs including metadata standardized per ODM. All example CRFs in Section 3.3, Product Impact on Individual Health, may be downloaded in ODM format and loaded into applicable EDC tools. Once loaded into an EDC tool, standard CRFs may then be used as-is or modified per the TIG and related CDISC standards to support needs.

CDISC Library

The CDISC Library (https://www.cdisc.org/cdisc-library) uses linked data and a REST API to deliver CDISC standards metadata to software applications that automate standards-based processes. The CDISC Library provides access to new relationships between standards as well as a substantially increased number of versioned CDISC standards and controlled terminology packages.

Creating Data Definition Documents to Support Data Submission

Version 2.1 of the CDISC Define-XML standard (available at https://www.cdisc.org/standards/data-exchange/define-xml/) supports creation of data-definition files which describe the structure and contents of tabulation and analysis datasets. Define-XML documents provide both a machine-readable format for use by various software applications and, through the provision of an XSL stylesheet, a browser-based rendition describing the metadata attributes of tabulation and analysis datasets. The Define-XML model is implemented using extensions to the ODM-XML schema.