CDISC Aligned NCI Standard Case Report Forms

In 2006, members of the National Cancer Institute's Center for Biomedical Informatics and Information Technology (NCI CBIIT) in conjunction with the cancer Data Standards Registry and Repository (caDSR) user community initiated a Case Report Form (CRF) harmonization activity. CRFs submitted from the community were reviewed and inventoried. The Harmonization group then reviewed all questions on the CRF and partitioned them into categories:

- Mandatory – A data collection variable that must be on the CRF (e.g., a regulatory requirement (if applicable)).
- Conditional – A data collection variable that must be collected on the CRF for specific cases that may be dictated by local or sponsor defined business rules.
- Optional – A data collection variable that is available for use if needed. There is no regulatory or business requirement for inclusion of this element on the CRF; if the design and scientific questions posed in the study dictate the need to collect this type of data; this is the element to include on the CRF.

A template form with modules that contain questions representing data to be collected and a companion electronic CRF instruction manual was developed. These CRF modules were vetted and adopted by the caDSR stakeholder community as metadata standards.

Since the original CRFs and manuals were adopted, the Food & Drug Administration (FDA) published guidelines for submission of clinical trial study data using the Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM) for Investigational New Drug (IND) trials starting after December 2017. In response, NCI CBIIT has aligned the NCI Standard CRF modules with the CDISC data collection standard, Clinical Data Acquisition Standards Harmonization (CDASH) where data is expected to be submitted to FDA in SDTM format.

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The NCI Standard CRFs were not edited, changed, or updated during the CDISC alignment process. The alignment consisted of mapping the CDEs within a CRF to CDASH or SDTM standard domains and variables and creating new CDEs when needed. The mapping and CDE curation were performed using the CDASHv2.0 model, CDASHIGv2.0 metadata table, SDTMv1.7 model and SDTMIGv3.3 metadata table. Later versions of the CDISC standards were used for mapping and curation when appropriate. Permissible values and value meanings for the NCI Standards were retained unless the CDISC CT value set matched exactly.

NCI CBIIT will compile requests for new CT concepts and submit them to EVS for review and inclusion in the NCIt. When new concepts are approved and added to CT value sets, Value Domains will be updated and any CDEs with Released Workflow Status will be versioned.

The NCI Standard CRFs may include CDEs which are used to collect data which is considered administrative or operational and not intended for FDA data submission. The original, harmonized NCI Standard CRF CDEs were not replaced for this type of data.

The mapping of caDSR CDEs to CDISC standards does not ensure complete conformance to the CDISC standards but is intended to make it easier for the caDSR user community to find and reuse CDEs that were created based on CDISC domain variables or supplemental variables in their data collection systems. caDSR users should work with their own CDISC subject matter expert(s) and/or FDA reviewer(s) to validate dataset submissions are conformant with the CDISC SDTM standard format.

CRF Downloads

The CDISC Aligned NCI Standard Template Forms/CRF modules are intended to be used to guide the development of protocol CRFs for data collection. Based on the CDASH standard, the CDEs allow for consistent and traceable data collection formats and structures to facilitate the creation of submission datasets using the SDTM.

A link is provided for each CRF in Microsoft Excel format. The data elements and most of the form information (such as headers, footers, instructions, and grouping of questions into modules) are included as part of the download.

Click on the CRF Downloads link above to access the page.

Instruction Manuals

The instruction manual is a set of directions to guide data collection in each module template. Specific implementation instructions are not present; various groups may wish to implement the contents of a module in a variety of software applications.

The instructions include mapping guidance for CDASH and SDTM domains, the field name, description or definition of each field, CDISC mapping instructions, and any special formatting notes that apply to entries such as the inclusion of full dates, use of values from a choice list only, etc. Each question is noted as Mandatory (m), Conditional (c), or Optional (o) and the CDE Public ID and short name is provided.

An annotated CRF is also provided to show the CDISC mappings. This does not include guidance for the layout of the CRFs which are organized according to the partition categories listed above.

Click on the Instruction Manuals link above to access the page.

Frequently Asked Questions

Questions and responses are provided for some of the most common questions received from the caDSR user community. These questions were received through time as caDSR users worked to implement the CDISC standards in oncology clinical trial data collection. As new questions are received we will add them to this page.

Click on the Frequently Asked Questions link above to access the page.