

CDISC Pain Therapeutic Area User Guide Now Available

CDISC, together with the Analgesic Clinical Trial Translations Innovations, Opportunities, and Networks (ACTTION) (<http://www.action.org>) group, is releasing v1.0 of the Pain Therapeutic Area Supplement to the Study Data Tabulation Model User Guide. This supplement, when used with the SDTMIG, is intended to guide the organization, structure, and format of standard pain clinical trial tabulation datasets submitted to a regulatory authority such as the US Food and Drug Administration (FDA).

The CDISC Pain Data Standards v1.0 package is being released for provisional use, since it depends on the approval of terminology submitted to the Controlled Terminology team and represents significant changes from the draft version posted for comment earlier this year. The package consists of a User Guide, 19 Questionnaire Supplements and 13 SDTM annotated CRFs. (CRFs are not included for 3 CRFs due to lack of permission from authors and 3 CRFs in the public domain.) The User Guide provides the background on the standards along with the specific Pain implementations of the Medical History domain, Questionnaire domain and Findings About domain. The Pain v1.0 Questionnaire folder in the ZIP file contains all 19 questionnaires as sub-folders that include the QS Supplement and the appropriate annotated CRF. This can be used to download all Pain questionnaires together.

Additionally, the package contains two documents that were generated as a result of the public comment period. The first is a README file that contains release announcement along with a high level summary of the major differences between the draft user guide and the final user guide. The second is a spreadsheet that contains all of the comments that were submitted during the review period with responses from the PAIN data modeling team. (PAIN Public Review February 2012 Consolidated Comments Responses Final.XLS) Controlled terminology relevant to this PAIN User Guide is being prepared through the CDISC Terminology Team and will be released as part of terminology package 12.

Standards implementers should be familiar with the CDISC Study Data Tabulation Model Implementation Guide for Human Clinical Trials. They should next read the User Guide and then refer to the individual questionnaires and related annotated CRFs to implement the Pain Standards in their environment. Below is a summary of the differences in the documents made since the public review period.

Summary of Differences between Draft and Provisional Version v1.0

1. General Pain Concepts: Pain Intensity, Pain Relief and General Clinical Global Impressions
 - a. Physiology – Nervous System domain was used in the public review and the final decision was made to use the Questionnaire domain (QS) for v1.0
 - b. __RESCAT was removed based on the need to create separate QSTESTCD's for AVERAGE, LEAST, WORST, MINIMUM and MAXIMUM Pain intensity and Pain Relief
 - c. The Frequency common data element description was updated for clarity with an example.

2. QSSTRNC, QSSTRNLO and QSSTRNHI were replaced by using SUPPQS to store a range of text and numeric values that are indicated in the SUPPQS domain as follows:

Visual analog or numeric rating scales used within a questionnaire with a range of text and numeric values that are indicated in the SUPPQS domain with:

QNAM=RNGTXTLO QNAM=RNGTXTHI
QNAM=RNGVALLO QNAM=RNGVALHI

By storing this information in SUPPQS, it is available for interpretation purposes. The SDS QS Team is researching alternative methods to handle this data, but until a new method is identified, this will be the agreed approach.

3. QSEVLINT or QNAM=EVLINTTX (evaluation interval text) is used whenever an evaluation interval can be determined from the CRF.
4. QSEVAL is used in all QS standards as an expected field.
5. When diagrams are included on the CRF for reference to a location and are not included in the QS domain, an explanation for why this was not included in the standard is provided:

Question # XX on the CRF requests the subject to shade in the areas where you feel pain on a diagram of the body and put an X on the area that hurts the most. The diagram was not considered a data field by the CDISC Terminology Team based on the need to identify a CDISC controlled terminology anatomical location term. The CRF does not provide the facility to record this on the CRF. The best approach for this is if the diagram locations could be transformed into anatomical location terminology, so it could be controlled and consistent for analysis of this questionnaire. Some organizations do not database this question. There is no consistent method to convert to an anatomical location and this question was considered out of scope until this concept can be researched further.

6. Terminology bullets are included in all QS assumptions stating the following:
 - A. Controlled terminology is still under development for the Pain data standards, thus some values in the examples are not CDISC controlled terms. Verify demonstrated terminology against current standards before adopting it.
 - B. The specific mapping strategy for “XXX Questionnaire” using standard QS fields is described in Section 4: Mapping Strategy for the following required fields.
 - Section 4 provides guidance on how the result and category variables in the QS domain need to be populated for a questionnaire. (ex. QSORRES, QSORRESU, QSSTRESC, QSSTRESN, QSSTRESU, QSCAT and QSMETHOD) If a result variable is not included in the table for a questionnaire, it should not be populated.
7. Mapping Strategy section had the following definition added:

This section is used for reference with the annotated CRF for further details on the CRF data capture and to understand the alignment of the questionnaire to the SDTM QS domain. It also provides guidance on how the result variables (QSORRES, QSORRESU, QSSTRESC, QSSTRESN, and QSSTRESU) should be populated for each questionnaire. If a result variable is not included in the table for a questionnaire, it should not be populated.

8. Hyperlink references were added to all QS Supplements and the Pain User Guide.