CDISC Operational Procedure 017
CDISC SDTMIG Questionnaire Supplements

Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Version</th>
<th>Description</th>
<th>Author</th>
</tr>
</thead>
<tbody>
<tr>
<td>30-Apr-2013</td>
<td>0.1</td>
<td>Draft version</td>
<td>Steve Kopko</td>
</tr>
<tr>
<td>30-May-2013</td>
<td>0.2</td>
<td>Draft version</td>
<td>Steve Kopko</td>
</tr>
<tr>
<td>30-June-2013</td>
<td>1.0</td>
<td>Final</td>
<td>Steve Kopko</td>
</tr>
</tbody>
</table>
CDISC Operational Procedure 017
CDISC SDTMIG Questionnaire Supplements

1 Purpose
This document describes the policies and processes related to the implementation and maintenance for CDISC SDTMIG Questionnaire Supplements. This process is coordinated with the CDISC SDTM QS Sub-Team as a governing body for all questionnaire supplements implemented as a CDISC QS domain standard. The implementation involves drafting the controlled terminology and defining questionnaire-specific standardized values for qualifier, timing and result variables to populate the SDTM QS Domain, along with providing examples of use.

2 Definitions

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Controlled Terminology Team</td>
<td>The CDISC Terminology Team supports the terminology needs of all CDISC standards (for example: SDTM, CDASH, ADaM, SEND) and all disease/therapeutic area standards.</td>
</tr>
<tr>
<td>Controlled Terminology QS Sub-Team</td>
<td>The CDISC Controlled Terminology QS Sub-Team supports the terminology needs for questionnaires in biomedical and therapeutic area research.</td>
</tr>
<tr>
<td>CRF</td>
<td>Case Report Form</td>
</tr>
<tr>
<td>QS Implementer</td>
<td>Person (either a CDISC volunteer or sponsor-provided resource) assigned to implement a Standard CDISC SDTMIG Questionnaire Supplement</td>
</tr>
<tr>
<td>SDSLT</td>
<td>Submission Data Standards Leadership Team – reviews/approves all SDTM foundational standards</td>
</tr>
<tr>
<td>SDS Team</td>
<td>Submission Data Standards Team manages the development of Foundational SDTM Standards for human clinical trials – composed of Domain Area Leads and volunteers</td>
</tr>
<tr>
<td>SDTM</td>
<td>Study Data Tabulation Model</td>
</tr>
<tr>
<td>SDTMIG</td>
<td>Study Data Tabulation Model Implementation Guide: Human Clinical Trials</td>
</tr>
<tr>
<td>SDTM Area Leader</td>
<td><strong>SDTM Area Leaders</strong> represent their SDTM Area in all forums where Projects, Domains, and Variable Standards are evaluated, managed, or proactively planned. They are appointed by the SDSLT to serve as a liaison between their SDTM Area (and all sub-teams within), Subject Matter Experts (internal or external to the SDS Team), other SDTM Areas and the SDS Leadership Team.</td>
</tr>
<tr>
<td>SDS QS Sub-Team</td>
<td>Questionnaire Sub-Team within the Submission Data Standards Team that manages the development of the QS standards and implementation of all standard questionnaire supplements. The SDTM Area Leader for QS chairs this Sub-Team.</td>
</tr>
<tr>
<td>SME</td>
<td>Subject Matter Expert</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Therapeutic Area Standard (TA)</td>
<td>CDISC is actively collaborating with a variety of partners, including the National Cancer Institute, Critical Path Institute, FDA, other National Institutes of Health and TransCelerate Biopharma Inc. on the development of Therapeutic Area Data Standards.</td>
</tr>
</tbody>
</table>

### 2.1 References and Related Documents

The following documents are available for reference and use when implementing a CDISC SDTMIG Questionnaire Supplement. They are accessed in a public directory on the CDISC Home portal under **Documents/Questionnaire Documentation/1 – QS Implementation Files**.

1. QS Standard Request Form
2. QS Public Domain_Copyright Verification Document
3. CDISC Copyright Letter
4. QS Public Domain_Copyright Verification Document
5. QS Supplement Example
6. QS Terminology Spreadsheet Example
7. QS Terminology Naming Rules
8. QS Supplement QC_Checklist v1

### 3 Identifying Candidate Questionnaires

Questionnaire candidates for standardization may be identified from multiple sources, including those listed below. Requests to standardize a questionnaire are made via the **QS Standard Request Form**. The SDS QS Sub-Team reviews the request for implementation of a CDISC SDTMIG Questionnaire Supplement. Once approved the implementation effort is coordinated with the SDS QS Sub-Team Leader that is identified on the QS Standard Request Form.

1. Therapeutic Area (TA) Standard
   a. In scoping the effort for a TA Standard, various questionnaires relevant for the TA may be identified.
   b. The TA Project Lead sends the QS Standard Request Form to the SDS QS Sub-Team Leader after scoping the project and coordinates the implementation of the questionnaire between members of the TA Standards Team and the SDS QS Sub-Team.

2. Sponsor Clinical Development Plans
   a. Sponsors may request creation of a new questionnaire supplement for use in clinical studies as part of their clinical development plan via the QS Standard Request Form that is sent to the QS Sub-Team Leader.
   b. The sponsor coordinates identifying a sponsor-provided QS Implementer for the implementation of the questionnaire with the SDS QS Sub-Team.

### 4 CDISC SDS QS Sub-Team Review Process

Each new or updated **QS Standard Request Form** is required to be sent to the SDS QS Sub-Team Leader, who will review and approve before proceeding with the implementation and ensure the completed product is added to the inventory of CDISC standard questionnaire supplements. The following steps are completed for every questionnaire that is reviewed with the SDS QS Sub-Team:
1. QS Implementer obtains the questionnaire reference information either from the requester or via an internet search.

2. The **QS Public Domain_Copyright Verification Document** is revised with the specific questionnaire information, along with how and where it was obtained. This document provides the background on the questionnaire for review with the QS Sub-Team.

3. The QS Implementer updates the QS Public Domain_Copyright Verification Document with the QS Sub-Team implementation decision and notifies the sponsor and/or CDISC TA Standard Team that the implementation was granted or denied.
   a. The QS Public Domain_Copyright Verification Document is sent to the QS Sub-Team Leader to store on the CDISC Portal: Teams Projects/Questionnaires section.

4. **QS Owner Permission Approval Process**
   The following types of Questionnaires are considered for implementation as a CDISC questionnaire standard. The QS Implementer follows these steps.
   
   a. **Public Domain Questionnaire** – The **QS Public Domain_Copyright Verification Document** is updated to confirm the questionnaire is in the public domain and no further permissions are required.
   
   b. **Copyright Questionnaire** – requires copyright owner permission to implement in the CDISC QS standard:
      i. Send the CDISC copyright letter to copyright owner of the questionnaire. The copyright letter outlines the options for granting permission in detail and requests a response within 2 weeks. It is mandatory to obtain written permission prior to implementing the questionnaire as a CDISC SDTMIG Questionnaire Supplement in order to avoid copyright issues. No work on the QS supplement is started before permission is received.
         1. If Permission is granted, follow these steps.
            a. Update the QS Public Domain_Copyright Verification Document with the copyright owner documented permission.
            b. Notify the QS-Sub-Team Leader, sponsor and/or CDISC TA Standard Team that permission was granted. Provide the signed copyright letter to the QS Sub-Team Leader to store on the restricted CDISC Portal: Teams Projects/Questionnaires/Approved Documents/"Questionnaire Folder". The QS Sub-Team Leader is identified on the QS Standard Request Form.
            c. Proceed with the QS implementation.
         2. If No response from the Copyright owner within 2 weeks, follow these steps:
            a. Send the original dated copyright letter as a follow-up reminder, again requesting a response within an additional 2-week notice.
            b. If no reply, send a 3rd letter requesting a teleconference in order to talk directly to the copyright owner to address all questions on implementation as a QS data standard.
            c. In addition, if a phone number is available, call the copyright owner directly to discuss the data standard.
               i. If successful, proceed with permission granted process above.
ii. If unsuccessful in these attempts, proceed with the permission denied process below.

3. If Permission is denied, follow these steps.
   a. Send the dated follow-up copyright letter to the copyright owner informing the owner that the questionnaire will not be developed as part of the CDISC QS data standard.
   b. Update the QS Public Domain_Copyright Verification Document with a description of the permission process and the copyright owner's documented refusal or lack of response. This is sent to the QS Sub-Team Leader to store on the restricted CDISC Portal: Teams Projects/Questionnaires/Approved Documents/"Questionnaire Folder". The QS Sub-Team Chair is identified on the QS Standard Request Form.
   c. Notify the SDS QS Sub-Team Leader, sponsor and/or CDISC TA Standard Team of the issue and resolution. Provide the 3rd copyright letter to the QS Sub-Team Leader to store as documentation that the questionnaire is not being implemented on the CDISC Portal: Teams Projects/Questionnaires/Approved Documents/ "Questionnaire Folder".

5 QS Implementation Process

1. Obtain the Questionnaire CRF from the questionnaire owner and review with the TA Standards Team and/or the QS Sub-Team as necessary, being consistent with permissions and copyright law.

2. QS Terminology
   a. Draft QS CRF controlled terminology using the existing QS Terminology Naming Rules spreadsheet.
      i. Questionnaire Terminology Naming Rules for QSCAT, QSTEST, and QSTESTCD needs to be followed (.ex XX01001 – XX01030).
      ii. Draft QS Terminology is reviewed with the QS-Sub-Team as necessary.
      iii. The QS Terminology request is made via the CT Request process on the CDISC CT web page that links to the NCI EVS request system. The QS Controlled Terminology Sub-Team reviews, revises and approves the QS Terminology.
   b. Propose additional standardization for all necessary QS domain variable values, such as Qualifier, Timing, Results and Units (.ex QSSID, QSGRPID, QSRFID, QSEVAL, QSTPT, QSTPTNUM, QSEVLINT, QSORRES, QSORRESU, QSTRES, QSTRESU, etc.)
      i. These standardized values are QS CRF specific and only documented in the QS Supplement document, Section 4 - Mapping Strategy.
      ii. These standardized values do not get stored in NCI EVS.
      iii. Review as necessary with the QS Sub-Team and any additional SME's.

3. Annotate QS CRF with SDTM variables
   a. Apply SDTM field annotations to the QS CRF as described in the Study Data Tabulation Model Metadata Submission Guidelines (SDTM-MSG) v1. The final Annotated CRF is stored in PDF format.
   b. Review/approval is conducted with the SDS QS Sub-Team. Only one review is needed, since controlled terminology and specific CRF standardized field values are approved at this point.

4. Create an SDTMIG QS Supplement for end user documentation based on the QS Supplement Example listed in section 2.1 above.
a. Reference the SDTMIG QS section for QS table definition.
b. Add specific QS SDTM assumptions and rules.
c. Add a QS data example for at least one subject with one visit that lists all QSTESTCDs and QSTESTs from the CRF.
   i. Include a SUPPQS data example as necessary.
d. Section 4 – Mapping Strategy
   i. Add all specific QS SDTM qualifier, timing and results standardized values in separate tables. The use of QS CRF specific standardized values is detailed in this section, to ensure the data can be integrated for analysis.
e. Section 5 – Include Supplemental Qualifier Name Codes as needed.
f. The QS Sub-Team Leader identifies a member to perform a QC review of the QS Supplement.
g. The QS Implementer completes the QS Supplement QC_Checklist and then presents the QS Supplement to the SDS QS Sub-Team for approval.

5. Production Release of QS Supplement and Annotated CRF
a. NCI EVS includes the QS terminology according to the periodic update schedule. All QS terminology will be on the schedule as soon as it is approved to implement. The QS Supplement implementation can start after the QS terminology is approved. The completion of a QS Supplement could precede the NCI EVS terminology periodic update and public review process. If this happens, the approved terminology is included in the QS Supplement and the NCI EVS Terminology repository will catch up in the next terminology update. This ensures that users following the QS Supplement will be in compliance with the approved QS Terminology.
b. The final QS Supplement and Annotated CRF are stored on the CDISC portal. This step is coordinated with the QS Sub-Team Leader to ensure approved access to the CDISC portal.
   i. The QS Implementer sends the final QS Supplement and Annotated CRF PDF documents to the QS Sub-Team Leader to store on the CDISC Home Portal/Questionnaire Documentation. The QS Sub-Team Chair is identified on the QS Standard Request Form.
   ii. The QS Implementer sends the final source QS Supplement (.ex WORD) and CRF documents to the QS Sub-Team Leader to store on the restricted CDISC Portal: Teams Projects/Questionnaires/Approved Documents folder. The QS Sub-Team Leader is identified on the QS Standard Request Form.
c. The QS Sub-Team Leader updates the CDISC QS Documentation Table on the CDISC STANDARDS & INNOVATIONS/Implementations/Questionnaires web site with the CDISC Communication Team.
Authorization
This document has been approved and is in effect on this date by:

<table>
<thead>
<tr>
<th>Name: Rebecca Kush</th>
<th>President and CEO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date: 2 July 2013</td>
<td>[Signature]</td>
</tr>
</tbody>
</table>