Handling non-standardized questionnaires

Anne-Sophie Bekx, Business & Decision Life Sciences, Brussels, Belgium
Éanna Kiely, Business & Decision Life Sciences, Brussels, Belgium

ABSTRACT

The CDISC QS sub-team is currently creating questionnaire (QS) supplements to the SDTM implementation guide (SDTMIG) and appropriate controlled terminology, to facilitate their usage and to ensure consistency between different SDTM submissions. However, this can only be done for questionnaires which are in the public domain or for which permission to publish controlled terminology was granted to CDISC. Nonetheless, the unavailability of a QS supplement to the SDTMIG for a particular questionnaire should not be an obstacle to creating a QS domain according to the SDTM philosophy. Applying the same simple and straightforward rules that are used to create QS supplements to the SDTMIG will ensure that the resulting QS domain:

- is of high quality
- is consistent with SDTM
- will be consistent with the supplements to the SDTMIG if/when they are created

INTRODUCTION

Over the past year, various initiatives, including C-FAST, CDISC SHARE, and the FDA TA Initiative, have induced an acceleration in the production of therapeutic area data standards. In conjunction with the development of these therapeutic area standards, there has also been an increase in the production of CDISC standardized questionnaires and their controlled terminology by the CDISC QS sub-team, in a bid to facilitate their usage and ensure consistency between different CDISC SDTM submissions.

The implementation of the CDISC standard by the CDISC QS sub-team is however, limited to public domain questionnaires and copyright questionnaires for which owner permission to implement has been granted to CDISC. This implies that, for various commonly used questionnaires, like the SF-36 Health Survey, there may never be a CDISC standardized version and its corresponding controlled terminology.

Nonetheless, this should not prevent us from creating a QS domain according to the CDISC SDTM philosophy and generating CDISC SDTM compliant QS data as will be demonstrated in this paper.

QUESTIONNAIRES

On the 23rd of April 2013 CDISC released the "CDISC Terminology Questionnaire Naming Rules", a simple 1-page document detailing conventions for the naming of QSCAT, QSTESTCD, and QSTEST. This document is followed by the QS sub-team to create the CDISC Questionnaire Standards and should be used by any person creating SDTM compliant QS datasets when the CDISC standardized version and its corresponding controlled terminology is not available. Its content is further detailed in the section below.

QSCAT

Naming conventions exist for the QSCAT submission value, synonym, and definition.

The submission value is a name that uniquely identifies the questionnaire and should be the most common name that the questionnaire is known by. This value will be used to populate the QS.QSCAT variable in SDTM-compliant datasets. It is therefore always in uppercase.

The QSCAT synonym is a short code name for the questionnaire, not included in SDTM-compliant datasets, but used as a basis for the QSTESTCD and QSTEST. It should be no more than 6 characters and include the version number as "0x", but can be shortened to accommodate for the 8-characters rule of QSTESTCD. Note that all questionnaires should have a version number even if only one version exists.

The QSCAT definition is the full name of the questionnaire including the version if available, followed by the questionnaire acronym in parenthesis, and the citation or copyright details in parentheses.

QSTESTCD

The QSTESTCD should be limited to 8 characters and start with the QSCAT synonym followed immediately by the item number. In the event that item numbers are included in the original questionnaire, the QSTESTCD should faithfully represent this numbering with alpha-numeric characters as provided. In the absence of item numbers on the original questionnaire, sequential numbering is used beginning with "01".

QSTEST

The QSTEST should contain a brief description of each questionnaire item's intent. It will begin with the QSCAT synonym, followed by a hyphen, excluding spaces, and the item text. The latter may be shortened to respect the 40 character limitation of TEST variables.
Rules have been defined for the casing of the QSTEST to facilitate consistency:
- Title case text format to be used after the hyphen
- Capitalize the first and last words in titles except as part of a name
- Capitalize all other major words (nouns, pronouns, verbs, adverbs, and **some** conjunctions
- Lowercase prepositions of 3 characters or less except when they are used adverbially or adjectivally, for example, the "on" in "The On Button".

AN EXAMPLE

The following example provides an overview of the above-mentioned standardization rules and how to implement them.

Questionnaire SF-36 has not yet been standardized by CDISC but is widely used in clinical trials.
The images below shows an application of the general rules above to a sample page of questionnaire SF-36 version 2.0.

The QSCAT would be defined in the following way:

SF-36 v2.0 – Health Survey	QSCAT Submission value: SF-36V2 HEALTH SURVEY Synonym: SF3602 Definition: Short Form (36) Health Survey version 2.0 (SF36) (© The Medical Outcomes Trust (MOT), Health Assessment Lab (HAL) and QualityMetric Incorporated)

Image 1: Defining the QSCAT

The submission value is the most commonly used name for this questionnaire which has been shortened to create the synonym. The definition contains the full name of the questionnaire including the acronym and copyright information.

As the QSCAT synonym is used to create the QSTESTCD, thorough investigation of its maximal length should be done to ensure the QSTESTCD is never longer than 8 characters.

The QSTESTCD and QSTEST would be defined in the following way:

1. In general, would you say your health is :
   - Excellent
   - Very good
   - Good
   - Fair
   - Poor

   QSTESTCD: SF360201
   QSTEST: SF3602-General Health

2. Compared to one year ago, how would you rate your health in general now?
   - Much better now than one year ago
   - Somewhat better now than one year ago
   - About the same as one year ago
   - Somewhat worse now than one year ago
   - Much worse now than one year ago

   QSTESTCD: SF360202
   QSTEST: SF3602-Gen Health Compared to 1 Year Ago

The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

3. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports
   - Yes, limited a lot
   - Yes, limited a little
   - No, not limited at all

   QSTESTCD: SF360203
   QSTEST: SF3602-Vigorous Activities

4. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf
   - Yes, limited a lot
   - Yes, limited a little
   - No, not limited at all

   QSTESTCD: SF360204
   QSTEST: SF3602-Moderate Activities

5. Lifting or carrying groceries
   - Yes, limited a lot
   - Yes, limited a little
   - No, not limited at all

   QSTESTCD: SF360205
   QSTEST: SF3602-Lifting or Carrying Groceries

6. Climbing several flights of stairs
   - Yes, limited a lot
   - Yes, limited a little
   - No, not limited at all

   QSTESTCD: SF360206
   QSTEST: SF3602-Climbing Flights of Stairs

7. Bending, kneeling, or stooping
   - Yes, limited a lot
   - Yes, limited a little
   - No, not limited at all

   QSTESTCD: SF360207
   QSTEST: SF3602-Bending, Kneeling, or Stooping

8. Walking more than a mile
   - Yes, limited a lot
   - Yes, limited a little
   - No, not limited at all

   QSTESTCD: SF360208
   QSTEST: SF3602-Walking More Than a Mile

9. Walking several hundred yards
   - Yes, limited a lot
   - Yes, limited a little
   - No, not limited at all

   QSTESTCD: SF360209
   QSTEST: SF3602-Walking Several Hundred Yards

10. Walking one hundred yards
    - Yes, limited a lot
    - Yes, limited a little
    - No, not limited at all

    QSTESTCD: SF360210
    QSTEST: SF3602-Walking One Hundred Yards

11. Bathing or dressing yourself
    - Yes, limited a lot
    - Yes, limited a little
    - No, not limited at all

    QSTESTCD: SF360211
    QSTEST: SF3602-Bathing or Dressing Yourself

Image 2: Defining the QSTESTCD/QSTEST

As per the naming rules define above, QSTESTCD is completed with the QSCAT synonym "SF3602" and the item number, "0n" included in the questionnaire. The limitations of 8 characters for TESTCD variables is hereby respected.

QSTEST contains the QSCAT synonym, "SF3602" followed by a hyphen and brief description of the questionnaire item "SF3602-xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx". To respect the 40 character limitation of TEST variables, the item texts were shortened while keeping the intent of the question.

CONCLUSION

The unavailability of a QS supplement to the SDTMIG for a particular questionnaire is a complication in the standardization of questionnaire data. However, with the availability of the "CDISC Terminology Questionnaire Naming Rules" it is possible to create a QS domain according to the SDTM philosophy.

Of course, the rules cannot ensure that different people standardizing the same questionnaire will not produce different questionnaire datasets but it does ensure any variations would be minor.

Applying the simple rules described throughout this paper will ensure that questionnaire data is CDISC SDTM-compliant, of high quality, and as consistent as possible with any future releases of CDISC standardized questionnaires and their controlled terminology by the CDISC QS sub-team.

CONTACT INFORMATION
Your comments and questions are valued and encouraged. Contact the author at:
> Anne-Sophie Bekx
> Business & Decision Life Sciences
> 141, Rue Saint-Lambert
> 1200, Bruxelles
> Belgium
> Work: 0032 2 774 1100
> Fax: 0032 2 774 1199
> Email: anne-sophie.bekx@businessdecision.com

Brand and product names are trademarks of their respective companies.