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CDISC & PhUSE Roundtable: QRS (Questionnaires, Ratings and Scales) - Logically Skipped Questions in SDTM

CDISC Round Table

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FDA and the QRS team

- The FDA has sent a number of resources to the CDISC Questionnaires, Ratings and Scales (QRS) Submission Data Standards (SDS) sub-team.
- They have worked on number of areas;
 - Patient Global Impression (PGI)
 - Clinical Global Impression (CGI)
 - Clarification of QRS-EVAL
 - Logically Skipped Questions

Logically Skipped Questions Example

- Example from Expanded Disability Rating Scale – Postacute Interview Caregiver Version (EXPANDED DRS-PI CAREGIVER VERSION)

2.0 Communication Ability		QSSCAT=COMMUNICATION ABILITY			
2.1 Is [name] able to communicate with you in a way that you and others clearly understand?	Consistently 0 Go to 2.2	Inconsistently 1 Go to 2.2	No 2 Go to 2.4		
QSTESTCD=ED102_1					
2.2 How do they communicate primarily?	0 Speech	1 Writing or spelling device	2 Gestures or signals		
QSTESTCD=ED102_2					
2.3 Is [name] able to give the correct date and time within a few seconds of being asked?	0 Yes	1 Yes but takes more than a few seconds	2 Sometimes	3 No	
QSTESTCD=ED102_3					
	Go to #4	Go to #4	Go to #4	Go to #4	
2.4 Does [name] have only a few words that [s/he] uses over and over or does [s/he] express him/herself <u>only</u> through random answers, shouting or swearing?	No 0 Go to 2.5	Yes 1 Go to #4			
QSTESTCD=ED102_4					
2.5 Does [name] only moan, groan or make other sounds that are not understandable?	No 0 Go to #4	Yes 1 Go to #4			
QSTESTCD=ED102_5					

QSSTRESC/QSSTRESN

QSORRES

QSTESTCD=ED102_4


Logically Skipped Questions Example

- The caregiver has two paths in question 2.1

2.0 Communication Ability	QSSCAT=COMMUNICATION ABILITY		
2.1 Is [name] able to communicate with you in a way that you and others clearly understand?	Consistently 0	Inconsistently 1	No 2
QSTESTCD=ED102_1	Go to 2.2	Go to 2.2	Go to 2.4

Logically Skipped Questions Example

- If the caregiver answers 0 (Consistently) or 1 (Inconsistently) questions 2.2 and 2.3 are answered

2.0 Communication Ability				
2.1 Is [name] able to communicate with you in a way that you and others clearly understand?	Consistently 0 Go to 2.2	Inconsistently 1 Go to 2.2		No 2 Go to 2.4
2.2 How do they communicate primarily? 	0 Speech	1 Writing or spelling device		2 Gestures or signals
2.3 Is [name] able to give the correct date and time within a few seconds of being asked?	0 Yes Go to #4	1 Yes but takes more than a few seconds Go to #4	2 Sometimes Go to #4	3 No Go to #4

Logically Skipped Questions Example

- If the caregiver answers 2 (No) questions 2.4 and possibly 2.5 are answered

2.0 Communication Ability <i>QSSCAT=COMMUNICATION ABILITY</i>			
2.1 Is [name] able to communicate with you in a way that you and others clearly understand? <i>QSTESTCD=ED102_1</i>	Consistently 0 Go to 2.2	Inconsistently 1 Go to 2.2	No 2 Go to 2.4

<i>QSTESTCD=ED102_4</i>	2.4 Does [name] have only a few words that [s/he] uses over and over or does [s/he] express him/herself <u>only</u> through random answers, shouting or swearing?	No 0 Go to 2.5	Yes 1 Go to #4
<i>QSTESTCD=ED102_5</i>	2.5 Does [name] only moan, groan or make other sounds that are not understandable?	No 0 Go to #4	Yes 1 Go to #4

Logically Skipped Questions Example

- Example from Expanded Disability Rating Scale – Postacute Interview Caregiver Version (EXPANDED DRS-PI CAREGIVER VERSION)

2.0 Communication Ability	QSSCAT=COMMUNICATION ABILITY		
2.1 Is [name] able to communicate with you in a way that you and others clearly understand? QSTESTCD=ED102_1	Consistently 0 Go to 2.2	Inconsistently 1 Go to 2.2	No 2 Go to 2.4
2.2 How do they communicate primarily? QSTESTCD=ED102_2	0 Speech	1 Writing or spelling device	2 Gestures or signals
2.3 Is [name] able to give the correct date and time within a few seconds of being asked? QSTESTCD=ED102_3	0 Yes	1 Yes but takes more than a few seconds	2 Sometimes
	3 No		
	QSORRES		
2.4 Does [name] have only a few words that [s/he] uses over and over or does [s/he] express him/herself <u>only</u> through random answers, shouting or swearing? QSTESTCD=ED102_4	No 0 Go to 2.5	Yes 1 Go to #4	
2.5 Does [name] only moan, groan or make other sounds that are not understandable? QSTESTCD=ED102_5	No 0 Go to #4	Yes 1 Go to #4	

Logically Skipped Questions Examples Links

- Expanded Disability Rating Sale – Postacute Interview Caregiver Version (EXPANDED DRS-PI CAREGIVER VERSION)
- <https://www.cdisc.org/standards/foundational/qrs/expanded-disability-rating-sale-%E2%80%93-postacute-interview-caregiver-version>
- Expanded Disability Rating Sale – Postacute Interview Survivor Version (EXPANDED DRS-PI SURVIVOR VERSION)
- <https://www.cdisc.org/standards/foundational/qrs/expanded-disability-rating-sale-%E2%80%93-postacute-interview-survivor-version>

Representing Logically Skipped Questions in SDTM

- The DRS supplement creates valid data points that were logically skipped with a QSSTAT of “Not Done” and QSREASND of “LOGICALLY SKIPPED QUESTION”
- Is this a prespecified question?

QSTESTCD	QSTEST	QSCAT	QSSCAT
ED102_1	ED1-Able to Communicate Clearly	EXPANDED DRS-PI CAREGIVER VERSION	COMMUNICATION ABILITY
ED102_2	ED1-How They Communicate Primarily	EXPANDED DRS-PI CAREGIVER VERSION	COMMUNICATION ABILITY
ED102_3	ED1-Correct Date and Time	EXPANDED DRS-PI CAREGIVER VERSION	COMMUNICATION ABILITY

QSORRES	QSSTRESC	QSSTRESN	QSSTAT	QSREASND
Consistently	0	0		
Writing or spelling device	1	1		
Yes but takes more than a few seconds	1	1		

- SDTMIG 3.2 section 4.1.5.1.2 Tests Not Done: *If the data on the CRF is missing and yes/no or done/not done was not explicitly captured a record should not be created to indicate that the data was not collected.*
 - Is the logically skipped question the equivalent to a “Yes/No” or “Done/Not Done”

CDISC & PhUSE Roundtable Format

- Two meetings were held on (recordings in the link)
 - Mon, 28AUG2017
 - <https://fccdl.in/24w0pUosM>
 - Mon, 11SEP2017
 - <http://fccdl.in/MZ2qQGvV5>
- Chaired by
 - Dana Booth, CDISC
 - Scott Bahlavooni, PhUSE
- Close to 100 attendees from CDISC, PhUSE, FDA and industry

Problem Statement

- Questionnaires, rating scales, and other instruments may contain items that may be logically skipped or left unanswered.
 - For example, an instrument may instruct the subject to skip to Question 5 when Question 1 is answered ?No?.
- Items that are logically skipped or left unanswered are typically *not* represented in SDTM. Regulatory agencies have been collaborating with CDISC to explore representing *all* items including those that have been logically skipped or left unanswered in SDTM. In order to maintain traceability, information about logically skipped items and/or items left unanswered would need to be collected in Electronic Data Capture (EDC) systems or Electronic Patient Reported Outcomes (ePRO) devices.

Request for Information Sharing

- CDISC asks members of the PhUSE community with experience implementing questionnaires or other instruments in EDC or ePRO for their perspective on the following:
 - Current industry practices configuring questionnaires or other instruments in EDC/ePRO systems.
 - Practicality of configuring EDC/ePRO systems to collect information about logically skipped and/or unanswered items.
 - Any changes to site data entry burden to collect information about logically skipped and/or unanswered items.
 - Any changes to data cleaning activities resulting from the collection of information about logically skipped and/or unanswered items.

Minutes Summary - 28AUG2017

- License:
 - Would submitting the questions invalidate a instrument owners license?
 - Possibly not since they are a part of the instrument.
 - Possibly not since the copyright agreement is related to how the instrument is shown to the subject
 - The instrument is still to be followed as described in the user manual
- Display
 - It was felt that any solution that is implemented would not require the investigator or site staff to enter data. It would be carried out in the background.
- FDA Usability
 - For item level analysis the correct denominator is needed and having these skipped items at subject level is useful.
 - Knowing if a subject skipped the questions v.s. if it was missed is important

Minutes Summary - 28AUG2017

- DCPs (Data Cleaning Prompts)
 - Most EDC system can handle missed data
 - How would it be implemented?
 - Would a checkbox be added in the background and completed if a question was logically skipped and removed if both a correct path and logically skipped were answered due to an incorrect interpretation of the instrument
 - ...
- Traceability
 - By adding the logically skipped questions we are creating records in SDTM without a source in the CRF
 - Could a record be created in ADaM instead?
- Missing Data in QRS
 - Handling missing data in QRS instruments is a separate discussion. E.g. if only half a instrument is complete or questions or missed or intentionally left blank
- Other Regulatory Authorities
 - Would this approach also be used for other regulatory authorities or just the FDA?

Minutes Summary – 11SEP2017

- Create an instrument level domain to capture information on the instrument including logically skipped questions similar to the TV and SV domains.
 - This was similar to a proposal that the QRS sub-team had investigated a number of years ago and could look into again.
 - It included storing the instrument owners codes.
- Data Quality Issues
 - If paper was used to record an instrument both the correct path and logically skipped questions could be answered
- Post-Processing Algorithm
 - It may be easier to add the logically skipped questions by an algorithm outside of the EDC system
- ADaM Traceability
 - Adding the records in ADaM is possible but could be problematic if data quality issues are present
 - FDA: it is best practice to have a reason why a record is missing in the SDTM domain

Minutes Summary - 28AUG2017

- Data Cleaning Prompt
 - Some sponsors add a default response of e.g. “99-Not Done” to all QRS instruments.
 - Is this still a best practice?
- Using the Data in Analysis
 - Having a further roundtable with statisticians to understand their use of the data could be useful.

Outcome of Roundtable

- Updates from the FDA could be mentioned in the forthcoming FDA webinar:
- Optimizing Your Study Data Submissions to FDA –Study Data Technical Conformance Guide October 2017 Version Update
 - Wed, 08NOV2017 14:00 to 15:30 EST (19:00 to 20:30 GMT)
- Clinical Outcome Assessments: QS Domain
 - 14:10 to 14:30 EST (19:10 to 19:30 GMT)
 - Sara Jimenez, Ph.D.
 - Staff Fellow
 - Office of Biostatistics | CDER
- <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm580656.htm>

Volunteer on the QRS Should be-Team

- If you would like to volunteering on the QRS sub-team contact
 - Gary Cunningham gcunningham@thegriessergroup.com
 - Steve Kopko skopko.external@cdisc.org
 - Dana Booth dbooth.external@cdisc.org

Thank You!

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