

# QRS Office Hours

Steve Kopko, CDISC SME, External Consultant CDISC

Dana Booth, CDISC Standards Project Manager, CDISC

Jordan Li, Clinical/Biomedical Information Specialist, Enterprise Vocabulary Services,  
National Cancer Institute [C]

Barbara Lentz, Associate Director, Medical Standards, Bayer U.S. LLC



TUE 16 MAR  
11:00AM-12:30PM ET



## Today's Agenda

1. Housekeeping
2. Presenter Introductions
3. Feature Presentations
4. Question & Answer Session
5. Upcoming Learning Opportunities + Resources



# Housekeeping

# Housekeeping



You will remain on **mute**

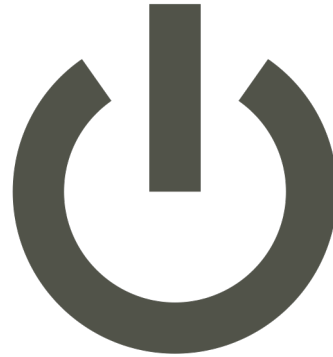


## Housekeeping



There will be a **Q&A**  
Submit questions at any time

# Housekeeping



**Audio issues?**

Shut down & restart GoToWebinar

# Housekeeping



Webinar slides & recording available  
for **CDISC Members**



# Our Presenters

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16 March 2021



# Agenda

1. QRS/ADQRS Publication updates: [New QRS Supplements](#)
  - 1<sup>st</sup> ADaM Supplement published January 29
    - Geriatric Depression Scale Short Form (GDS SHORT FORM)
  - January CDISC Internal Review - QRS 3 supplements completed February 11
    - COWAT, HCS, SES-CD V1
  - February Public Review - QRS 8 supplements completed March 5
    - AIMS, ADSD V1.0, ANSD V1.0, DRS, ECOG, KPS SCALE, KFSS, IBDQ
  - March Public Review - QRS 7 supplements to complete by April 9
    - COVI, DRRI-2, DISEASE STEPS, FAQ, GMSS VERSION TYPE 1 DIABETES, KDIGO AKI, PDDS
  - March CDISC Internal Review - QRS 3 supplements to be scheduled
    - CDAI V1, IPAQ-LF SELF-ADMINISTERED VERSION, FACT-C
  - Publication QRS supplement Requests in process
    - FDA Internal Review - 10-METER WALK/RUN
    - FDA Internal Review - NSCLC-SAQ V1.0 & SMDDS V1.0
      - FDA Qualified Clinical Outcomes Assessment (COA) instruments: [FDA COA Qualification website](#)
    - CDISC Copyediting Request in Process - FDA Internal Review - BPRS 1988 VERSION, HAMD 17, EDSS





# Agenda

## 2. QRS CT Package P45 Scheduled for 1Q21 release

- Approved by QRS CT team on February 4 and 11 2021
- New Terms
  - EXACT – to existing codelists
  - QRS METHOD –for public review
- Changes to existing terms
  - FAQ-NACC UDS V2.0
  - UPDRS 04Feb2021
  - SF36 V1.0 and 1.2 Public CT change control
  - SF8 additional 8 instruments Published QSCAT CT change control
  - SF8 1.0 Acute and Standard
  - SF10 V1.0 CHILDREN Acute and Standard
  - SF12 V1.0 Acute and Standard
  - SF12 V2.0 Acute and Standard
- QualityMetric - Short Form Health Survey instruments: CDISC is collaborating with QualityMetric, Inc. in the development of their Short Form Health Survey instruments




# Agenda

3. CDISC proposals in process:
  - QRS Logically Skipped Items and QRS Missing Data representation in review with FDA
  - Draft QRS Instrument TAUG/COA cross-reference table under development
  - Draft Functional Assessment of Chronic Illness Therapy (FACIT) Library in QRS CT development
    - FACT allows sponsors to select from the item bank to create their own instruments
    - CDISC to create QRS CT for each FACIT item in the library to ensure consistency within and across sponsors for each item
    - FACIT continues to develop specific individual instruments using the items from the item bank for additional therapeutic areas/disease indications
4. [CDISC QRS Supplement Request Form](#)
5. [CDISC COP 001 Standards Development](#)
  - Provides the capability for sponsors to develop QRS Instrument Supplements under QRS Subteam guidance
6. QRS Questions sent in ahead of time and Open Q&A Session



**Questions sent in ahead of time...**



## How should sponsors represent sponsor-developed instruments that include items from instruments that have CDISC standards?

The sponsor should:

- Use custom –CAT synonyms when controlled terminology (CT) is not available and/or when the sponsor CRF has somewhat different wording from the CDISC annotated CRF.
- Use the same test name as CDISC when CDISC CT exists.
- Keep in mind items numbered like 1A, 1B, etc. The test code needs to be no more than 8 characters.
- See the new naming rules to be posted in the next week or 2.

# Example of Sponsor-defined Test Codes

QSTESTCD	QSTEST
FAX10001	FAX1- Food Tastes Unpleasant to Me
FAX10002	FAX1-Interest in Food Drops Try to Eat
FAX10003	FAX1-Difficulty Eating Rich/Heavy Food
FAX10004	FAX1-Bothered by Change in Food Tastes
FAX11005	FAX1-I Can Digest My Food Well
FAX11006	FAX1-Difficulty Swallowing Solid Foods

In this example, the sponsor used a subset of items from the FACT Searchable Library.

- The synonyms are sponsor-created,
- The test names include the sponsor-created synonyms with CDISC Test Names.



**Some of the links to QRS Supplements and Terminology are not working. Please provide the correct links.**


- **Some examples would be great – please add into the chat or e-mail [qrsstandardrequest@cdisc.org](mailto:qrsstandardrequest@cdisc.org). On CDISC QRS webpage? or within supplements?**
- **If they are older, the links within supplements will be incorrect, but should redirect to the correct links.**
- **QRS Supplements are found on the 2<sup>nd</sup> tab (“QRS Supplements”, here:  
<https://www.cdisc.org/standards/foundational/qrs>**



**Some of the links to QRS Supplements and Terminology are not working. Please provide the correct links. (cont.)**

- **If the question is referring to instrument names in black typeface on the CDISC QRS webpage, those are instruments for which no supplement was created due to the reason in the “Permission” column.**





Very interesting about logically skipped items. Do you always need to fill out, for all fields and questionnaires, and so on.

- **We are working out the final details, but there should be one record for every item on the instrument.**
- **We are discussing with the FDA what they would like if a subject misses a visit, but we believe it will still be one record for every item on the instrument with --STAT = “NOT DONE”.**
- **If the item was logically skipped, then --STAT = “NOT DONE” and “REASND” = “LOGICALLY SKIPPED ITEM”.**

# Example of logically skipped items – FACT-C

Q2	Do you have an ostomy appliance? (Mark one box)	<input type="checkbox"/> No	or	<input type="checkbox"/> Yes			
	If yes, please answer the next two items:	<b>When QSTESTCD=FAC00835, QSORRES = No/Yes and QSSTRESC = N/Y</b>					
C8	I am embarrassed by my ostomy appliance ...	<b>FAC00836</b>	0	1	2	3	4
C9	Caring for my ostomy appliance is difficult ..	<b>FAC00837</b>	0	1	2	3	4

FAC00835 leads to two possibly skipped items:

- FAC00836 and
- FAC00837

# Representing logically skipped items – FACT-C

*qs.xpt\** - with no ostomy appliance

Row	USUBJID	QSTESTCD	QSORRES	QSSTRESC	QSSTRESN
1	P0001	FAC00835	No	N	
2	P0001	FAC00836			
3	P0001	FAC00837			

*qs.xpt (cont.)*

Row	QSSTAT	QSREASND
1 (cont.)		
2 (cont.)	NOT DONE	LOGICALLY SKIPPED ITEM
3 (cont.)	NOT DONE	LOGICALLY SKIPPED ITEM

\*Note:

- Due to space constraints, some variables are not shown in the *qs.xpt* table.
- Logically skipped items are not scored for the FACT-C. If standardized values for logically skipped items had been provided, then QSSTRESC and QSSTRESN would have been populated with those values in Rows 2 and 3.

# Representing logically skipped items – FACT-C (cont.)

*qs.xpt\** - with an ostomy appliance, answering all questions

Row	USUBJID	QSTESTCD	QSORRES	QSSTRESC	QSSTRESN	QSSTAT
1	P0001	FAC00835	Yes	Y		
2	P0001	FAC00836	Somewhat	2	2	
3	P0001	FAC00837	Quite a bit	3	3	

\*Note: Due to space constraints, some variables are not shown in the *qs.xpt* table.

# Representing logically skipped items – FACT-C (cont.)

*qs.xpt\** - with an ostomy appliance, but missing a response

Row	USUBJID	QSTESTCD	QSORRES	QSSTRESC	QSSTRESN	QSSTAT
1	P0001	FAC00835	Yes	Y		
2	P0001	FAC00836				NOT DONE
3	P0001	FAC00837	Quite a bit	3	3	

\*Note: Due to space constraints, some variables are not shown in the *qs.xpt* table. QSREASND is not included as the reason there was no response is not known.

# Representing logically skipped items – FACT-C (cont.)

*qs.xpt\** - missing all responses at the end of the FACT-C

Row	USUBJID	QSTESTCD	QSORRES	QSSTRESC	QSSTRESN	QSSTAT
1	P0001	FAC00835				NOT DONE
2	P0001	FAC00836				NOT DONE
3	P0001	FAC00837				NOT DONE

\*Note: Due to space constraints, some variables are not shown in the *qs.xpt* table. QSREASND is not included as the reason there was no response is not known.



Do you have any recommendations on how/where to map the SOFA questionnaire? some parameters are lab results?

- **fyi for other attendees – SOFA is Sequential Organ Failure Assesment. (<https://www.mdcalc.com/sequential-organ-failure-assessment-sofa-score>)**
- **As a Clinical Classification, this would be represented in the RS domain.**
- **I would recommend using the (Acute Physiology and Chronic Health Evaluation II) APACHE 2 as an example.**
- **Actual lab data is represented in *lb.xpt* as per usual.**
- **Use *relrec.xpt* to show the relationship between records.**





**Thank You!**





# Questions & Answers

# Audience Questions

SDTM3.3IG suggested to split QS based on instruments e.g, Clinical Global Impression (QSCG). Any guidance on DOMAIN/Dataset naming?



# Audience Questions



When is it appropriate to use the record qualifier QSLOC?

# Audience Questions

How can I volunteer with the QRS team?





# Audience Questions



I like this approach with `--STAT=NOT DONE` and `REASND=LOGICALLY SKIPPED ITEM`

# Audience Questions

Do you consider the questionnaire as custom if additional questions are added in form? Like Total score or else?





# Audience Questions



I have a question about the UPDRS questionnaire. Standard questionnaire, but we have an additional variable that was collected that shows the subject's state: ON or OFF. Control terminology for that questionnaire is not extensible. QRS the guide does not say anything about this, although the form (ON or OFF) is present in the example crf. What to do with this additional info?

# Audience Questions

logically items management falls into DM aspects. This logi could be extended to other domains but it would look like the cleaning database



# Audience Questions



If there is a case where "LOGICALLY SKIPPED" has to be mapped to SDTM can we add this exact value to the result codelist (a sponsor specific update to published questionnaire not sure if can do it!) for the ease of SDTM mapping/better understanding?

# Audience Questions

Could you please advise on the purpose to collect the status of 'Not Done' when the whole questionnaire is missed, such as a visit is missed?



# Audience Questions

In the QS document SDTM QS -BPI Short Form v1.1 Approved.pdf, Section 3.1.1 has the following:

Visual analog or numeric rating scales used within a questionnaire with a range of text and numeric values 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 in the future, but until a new method is identified, this will be the recommended approach. When a Low or High anchor value is collected in the data, QSORRES is populated with the text value, but for all other results, the number values is populated. This is consistent with feedback received from FDA (Amy Malla).

Is this still the recommended approach for handling low and high ranges for any QRS?





# Audience Questions



There were multiple Wiki documents and webpages that have been mentioned in this presentation, will you please post their names and status on a slide, so people who may not be as familiar with this work can have this point of reference? Thank you!

# Audience Questions



When the sponsor selects items from the FACIT item bank to create the sponsor specific instrument, shall the sponsor go through certain validation process to ensure the instrument validity?



# Audience Questions

For RS instrument which refers to lab, vital sign or other data which already collected on other eCRF form, is it allowed to do not prepare the RS instrument eCRF, but only do the scoring at ADaM level per the RS scoring rules?





# Upcoming Learning Opportunities

# New Virtual Training Methods

## Blended Learning from CDISC

Online Resources  
+ In-Person Instruction  
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- Register at: <https://learnstore.cdisc.org/>
- Contact us at: [training@cdisc.org](mailto:training@cdisc.org)

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Conference | Trade Show



# 2021 CHINA INTERCHANGE

With Standards – Science Will Prevail!



Beijing | 6-7 August

Conference | Trade Show



# 2021 US INTERCHANGE

With Standards – Science Will Prevail!



Washington, DC | 18-22 October

Conference | Trade Show



# 2021 Webinars

Date	Webinar Title
24 MAR	Sneak Peek at the 2021 Europe Virtual Interchange
25 MAR	Public Review Webinar: Pancreatic Cancer Therapeutic Area User Guide
30 MAR	Meet our New President and CEO: Hear CDISC's 2021 Vision and Direction
1 APR	Controlled Terminology Updates for Q1 2021
8 APR	CDISC Library: Ideas for Using the CDISC Library and a Look at What's Coming Next
1 JUL	Controlled Terminology Updates for Q2 2021
Coming Soon	CDASH "Office Hours"; ADaM "Office Hours"; More Public Reviews – stay tuned!

Visit <https://www.cdisc.org/education/webinars> for information on additional Public Training events.

# Questions



Use CDISC contact form:  
<https://www.cdisc.org/contact>



Contact general EDU inbox:  
[training@cdisc.org](mailto:training@cdisc.org)



Contact Bernard directly: [bklinke@cdisc.org](mailto:bklinke@cdisc.org)





# Thank You!

Questions, comments, concerns? Email [bklinke@cdisc.org](mailto:bklinke@cdisc.org)

Don't forget to fill out the feedback survey!

