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QRS (Questionnaires, Ratings and Scales) Domain Mappings and Updates

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QRS (Questionnaires, Ratings and Scales) Domains

- The Questionnaires, Ratings and Scales (QRS) domains are
  - Questionnaires (QS)
  - Functional Tests (FT)
  - Disease Response and Clin Classification (RS)
- We expect these to be published as a group in SDTMIG 3.3
- These domains are already available in the CDISC CT (Controlled Terminology)
  - The QRS sub-team advises users of SDTMIG 3.2 to create custom domains based on the planned use of FT and RS when new instruments are encountered.

FTs (Functional Tests)

- Named

- Stand-alone task-based evaluations

- Designed to provide an assessment of
  - mobility,
  - dexterity,
  - and/or cognitive ability.

- FTs are not a subjective assessment of how the subject generally performs a task. Rather it is an objective measurement of the performance of the task by the subject in a specific instance.

https://www.cdisc.org/foundational/qrs

FTs (Functional Tests) contd.

- Functional tests have documented methods for administration and analysis and require a subject to perform specific activities that are evaluated and recorded.

- Most often, functional tests are direct quantitative measurements.

Mobility	Dexterity	Cognitive Ability
6 Minute Walk Test	Nine-Hole Peg Test (NHPT)	Brief Assessment of Cognition in Schizophrenia (BACS)
Hauser Ambulation Index		Paced Auditory Serial Addition Test (PASAT)
Timed Up and Go (TUG)		Rey Auditory Verbal Learning Test (AVLT-REY)

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FT Mobility: 6 Minute Walk Test

FT=Functional Tests

FTCAT=SIX MINUTE WALK

Date: *FTDTC* _____

Subject: _____

Assisted Device: *QVAL when QNAM=FTASSTDV* _____

6 Minute Walk Test

FTORRES

	Cumulative Distance
Distance at 1 minute *FTTESTCD=SIXMW101*	
Distance at 2 minutes *FTTESTCD=SIXMW102*	
Distance at 3 minutes *FTTESTCD=SIXMW103*	
Distance at 4 minutes *FTTESTCD=SIXMW104*	
Distance at 5 minutes *FTTESTCD=SIXMW105*	
Distance at 6 minutes *FTTESTCD=SIXMW106*	

FTTESTCD	FTTEST	FTCAT	FTORRES	FTORRESU
SIXMW101	SIXMW1-Distance at 1 Minute	SIX MINUTE WALK	101	m
SIXMW102	SIXMW1-Distance at 2 Minutes	SIX MINUTE WALK	201	m
SIXMW103	SIXMW1-Distance at 3 Minutes	SIX MINUTE WALK	299	m
SIXMW104	SIXMW1-Distance at 4 Minutes	SIX MINUTE WALK	396	m
SIXMW105	SIXMW1-Distance at 5 Minutes	SIX MINUTE WALK	493	m
SIXMW106	SIXMW1-Distance at 6 Minutes	SIX MINUTE WALK	597	m

FT Dexterity: Nine-Hole Peg Test (NHPT)

FT Cognitive Ability: Rey Auditory Verbal Learning Test (AVLT-REY)

List A	1	2	3	4	5	AFTER B-RECALL 6	List B	List B Recall
Drum	AVL0201	AVL0201	AVL0201	AVL0201	AVL0201	AVL0201	Desk	AVL0218
Curtain	FTORRES =RECALLED/NOT RECALLED when FTTESTCD =						Ranger	
Bell							Bird	
Coffee							Shoe	
School							Stove	
Parent							Mountain	
Moon							Glasses	
Garden	...	...	...	...	...	...	Towel	...
Hat							Cloud	
Farmer							Boat	
Nose							Lamb	
Turkey							Gun	
Color							Pencil	
House							Church	
River	AVL0215	AVL0215	AVL0215	AVL0215	AVL0215	AVL0215	ish	AVL0232
Totals	AVL0216	AVL0216	AVL0216	AVL0216	AVL0216	AVL0216		AVL0233
Intrusions	AVL0217	AVL0217	AVL0217	AVL0217	AVL0217	AVL0217		AVL0234

FTTESTCD	FTTEST	FTCAT	FTSCAT	FTORRES
AVL0201	AVL02-List A Word 1	AVLT-REY	FORM 1	RECALLED
...	...	...	...	...
AVL0215	AVL02-List A Word 15	AVLT-REY	FORM 1	NOT RECALLED
AVL0216	AVL02-List A Total	AVLT-REY	FORM 1	13
AVL0217	AVL02-List A Intrusions	AVLT-REY	FORM 1	2
AVL0201	AVL02-List A Word 1	AVLT-REY	FORM 1	RECALLED
...	...	...	...	...
AVL0215	AVL02-List A Word 15	AVLT-REY	FORM 1	NOT RECALLED
AVL0216	AVL02-List A Total	AVLT-REY	FORM 1	13

What are QS (Questionnaires) again?

- Named

- Stand-alone measures designed to provide an assessment of a concept

- Have a defined standard structure, format, and content

- Consist of conceptually related items that are typically scored

- Have documented methods for administration and analysis

- Consist of defined questions with a defined set of potential answers

- Most often, questionnaires have as their primary purpose the generation of a quantitative statistic to assess a qualitative concept

Airway Questionnaire (AQ20)

Named

AQ20 RESPIRATORY QUESTIONNAIRE

QSCAT=AQ20

Please tick one box per question - If it does not apply to you please tick N/A (not applicable).

Scoring the AQ20

- Scores range from 0 - 20.
- 'Yes' responses are scored 1 'No' and 'Not applicable' score 0.

QSSTRESC/QSSTRESN

Scored

Answered by the patient

Patient-Reported Outcome (PRO)

	Yes	No	N/A
QSORRES when QSTESTCD=AQ0101			
	O	O	O

Defined set of potential answers

1. Do you cough often during the day?

QSORRES when QSTESTCD=AQ0102

2. Does your chest trouble often make you feel restless?   O   O   O

QSORRES when QSTESTCD=AQ0103

3. Does gardening make you breathless?   O   O   O

QSTESTCD	QSTEST	QSCAT	QSORRES	QSSTRESC
AQ0101	AQ01-Cough Often During Day	AQ20	Yes	1
AQ0102	AQ01-Feel Restless Due to Chest Trouble	AQ20	No	0
AQ0103	AQ01-Gardening Make You Breathless	AQ20	N/A	0

Extended Glasgow Outcome Scale (GOSE)

Glasgow Outcome Scale - Extended

Patient's name: _____   Date of interview: _____ `QSDTC`

Date of Birth: _____   Date of injury _____   Gender: M / F

Age at injury: _____   Interval post-injury: _____   `QNAM=PRIMSRC`

Respondent: Patient alone ___   Relative/ friend/ carer alone ___   Patient + relative/ friend/ carer ___

Interviewer: _____   `QSEVAL`   `QSEVALID`

QSTESTCD	QSTEST	QSCAT	QSORRES
GOSE101	GOSE1-Obey Simple Commands or Say Words	GOSE	Yes
GOSE102A	GOSE1-Daily Assistance at Home Essential	GOSE	Yes
GOSE102B	GOSE1-Need Frequent Help at Home	GOSE	Yes (Lower SD)
GOSE102C	GOSE1-Assistance at Home Before Injury	GOSE	No

Completed by patient or relative/carer

CONSCIOUSNESS `QSSCAT`   `QSORRES`

1. Is the head injured person able to obey simple commands, or say any words? `QSTESTCD=GOSE101`   ☐   1 = No (VS)   2 = Yes

Anyone who shows ability to obey even simple commands, or utter any word or communicate specifically in any other way is no longer considered to be in the vegetative state. Eye movements are not reliable evidence of meaningful responsiveness. Corroborate with nursing staff. Confirmation of VS requires full assessment as in the Royal College of Physician Guidelines.
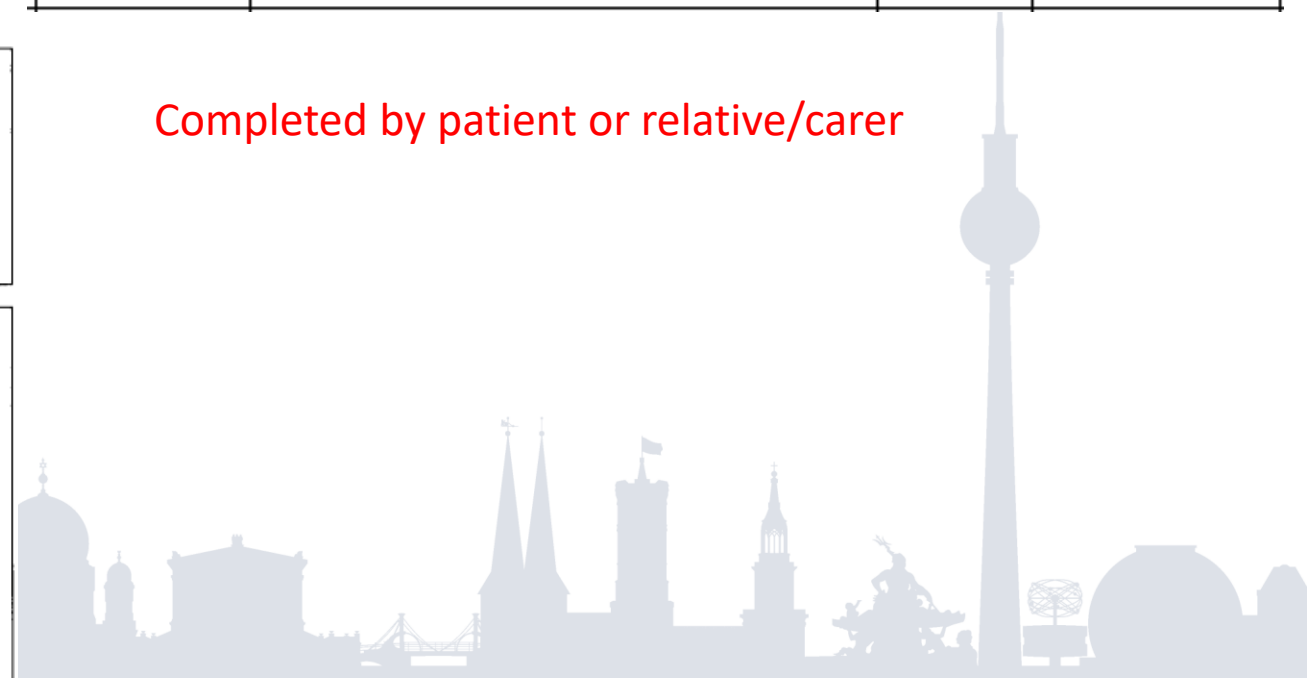
INDEPENDENCE IN THE HOME `QSSCAT`

2a   Is the assistance of another person at home essential every day for some activities of daily living? `QSTESTCD=GOSE102A`   ☐   1 = No   2 = Yes

For a 'No' answer they should be able to look after themselves at home for 24 hours if necessary, though they need not actually look after themselves. Independence includes the ability to plan for and carry out the following activities: getting washed, putting on clean clothes without prompting, preparing food for themselves, dealing with callers, and handling minor domestic crises. The person should be able to carry out activities without needing prompting or reminding, and should be capable of being left alone overnight.

2b   Do they need frequent help or someone to be around at home most of the time? `QSTESTCD=GOSE102B`   ☐   1 = No (Upper SD)   2 = Yes (Lower SD)

For a 'No' answer they should be able to look after themselves at home for up to 8 hours during the day if necessary, though they need not actually look after themselves. `QSTESTCD=GOSE102C`

Alzheimer's Disease Assessment Scale - Cognitive (ADAS-Cog)

ALZHEIMER'S DISEASE ASSESSMENT SCALE ADAS - COG (Modified) (85 point): (Page 1 of 9)

1. WORD RECALL TASK

Word Recalled?		Trial 1 Yes (1) No (2)	Word Recalled?		Trial 2 Yes (1) No (2)	Word Recalled?		Trial 3 Yes (1) No (2)
Butter	(Word 1)	ADCRLW01	Pole	(Word 11)	ADCRLW01	Shore	(Word 21)	ADCRLW01
Arm	(Word 2)	ADCRLW02	Letter	(Word 12)	ADCRLW02	Letter	(Word 22)	ADCRLW02
Shore	(Word 3)	ADCRLW03	Butter	(Word 13)	ADCRLW03	Arm	(Word 23)	ADCRLW03
Letter	(Word 4)	ADCRLW04	Queen	(Word 14)	ADCRLW04	Cabin	(Word 24)	ADCRLW04
Queen	(Word 5)	ADCRLW05	Arm	(Word 15)	ADCRLW05	Pole	(Word 25)	ADCRLW05
Cabin	(Word 6)	ADCRLW06	Shore	(Word 16)	ADCRLW06	Ticket	(Word 26)	ADCRLW06
Pole	(Word 7)	ADCRLW07	Grass	(Word 17)	ADCRLW07	Engine	(Word 27)	ADCRLW07
Ticket	(Word 8)	ADCRLW08	Cabin	(Word 18)	ADCRLW08	Grass	(Word 28)	ADCRLW08
Grass	(Word 9)	ADCRLW09	Ticket	(Word 19)	ADCRLW09	Butter	(Word 29)	ADCRLW09
Engine	(Word 10)	ADCRLW10	Engine	(Word 20)	ADCRLW10	Queen	(Word 30)	ADCRLW10

B. The subject is asked to name the fingers of his/her **dominant** hand.

Response correct?

ADCOFF01	**Thumb**	☐ (1) Yes	☐ (2) No
ADCOFF02	**Index**/forefinger/pointer	☐ (1) Yes	☐ (2) No
ADCOFF03	**Middle**	☐ (1) Yes	☐ (2) No
ADCOFF04	**Ring**	☐ (1) Yes	☐ (2) No
ADCOFF05	**Pinky or little finger**	☐ (1) Yes	☐ (2) No

If any task not administered or not completed, check one:

☐ (1) Participant refused
☐ (2) Participant unable for physical reasons
☐ (3) Participant unable for cognitive reasons
☐ (4) Not done for reasons other than physical/cognitive

RS (Disease Response and Clin Classification)

- Measures are named measures whose output is an ordinal or categorical score that serves as a surrogate for, or ranking of, disease status or other physiological or biological status.

- These measures are based on a trained health-care professional's observation of a subject's health condition or status with input from associated clinical records review.

- Clinical Classifications may be based solely on objective data from clinical records, or they may involve a clinical judgment or interpretation of the directly observable signs, behaviors, or other physical manifestations related to a condition or subject status.

- These physical manifestations may be findings that are typically represented in other SDTM domains such as labs, vital signs, or clinical events.

- Therefore, clinical classifications are often composite scores based on diverse inputs.

- This assessment method differs from a more traditional question-and-answer interview commonly seen in other Questionnaires, Ratings and Scales (QRS).

Body-Mass Index, Airflow Obstruction, Dyspnea and Exercise Capacity Index (BODE INDEX)

Variable	Points on BODE Index			
	0	1	2	3

RSTESTCD = BODE0102

FEV1PP/Percent Predicted FEV1 → FEV_1 (% of predicted)†

	0	1	2	3
FEV_1 (% of predicted)†	≥65	50–64	36–49	≤35
Distance walked in 6 min (m)	≥350	250–349	150–249	≤149
MMRC dyspnea scale‡	0–1	2	3	4
Body-mass index¶	>21	≤21		

SIXMW106/SIXMW1-Distance at 6 Minutes → Distance walked in 6 min (m)

MMRC01-Description of Breathlessness → MMRC dyspnea scale‡

BMI/Body Mass Index → Body-mass index¶

	RSLNKID	RSTESTCD	RSTEST	RSCAT	RSORRES	RSORRESU
VS	BD1	BODE0101	BODE01-Body-mass Index	BODE INDEX	>21	kg/m2
RE	BD2	BODE0102	BODE01-FEV1 % Predicted	BODE INDEX	50-64	%
QS/RS	BD3	BODE0103	BODE01-MMRC Dyspnea Scale	BODE INDEX	3	
FT	BD4	BODE0104	BODE01-Distance Walked in 6 Minutes	BODE INDEX	<=149	m
	BD5	BODE0105	BODE01-BODE Score	BODE INDEX	6	

Based on multiple body systems

Links multiple SDTM domains together

BODE INDEX – Linked SDTM Domains

relrec.xpt

DOMAIN	...	IDVAR	...	RELID
RS		RSLNKID		1
VS		VSLNKID		1
RS		RSLNKID		2
RE		RELNKID		2
RS		RSLNKID		3
QS		QSLNKID		3
RS		RSLNKID		4
FT		FTLNKID		4

VSLNKID	VSTESTCD	VSTEST	VSORRES	VSORRESU
BD1	BMI	Body Mass Index	32	kg/m2

RELNKID	RETESTCD	RETEST	REORRES	REORRESU
BD2	FEV1PP	Percent Predicted FEV1	55	%

QSLNKID	QSTESTCD	QSTEST	QSCAT	QSORRES
BD3	MMRC0101	MMRC01-Description of Breathlessness	MMRC	Stops for breath after walking about 100 yards or after a few minutes on the level

FTLNKID	FTTESTCD	FTTEST	FTCAT	FTORRES
	SIXMW101	SIXMW1-Distance at 1 Minute	SIX MINUTE WALK	57
	SIXMW102	SIXMW1-Distance at 2 Minutes	SIX MINUTE WALK	70
	SIXMW103	SIXMW1-Distance at 3 Minutes	SIX MINUTE WALK	92
	SIXMW104	SIXMW1-Distance at 4 Minutes	SIX MINUTE WALK	126
	SIXMW105	SIXMW1-Distance at 5 Minutes	SIX MINUTE WALK	137
BD4	SIXMW106	SIXMW1-Distance at 6 Minutes	SIX MINUTE WALK	149

Brooke Upper Extremity Rating Scale

## Brooke Upper Extremity Rating Scale

RSTESTCD=BUERS101

RSCAT=BUERS

Grade	RSORRES Description	RSSTRESC/ RSSTRESN
1	Starting with arms at the sides, the patient can abduct the arms in a full circle until they touch above the head. *	
2	Can raise arms above head only by flexing the elbow (shortening the circumference of the movement) or using accessory muscles.*	
3	Cannot raise hands above head, but can raise an 8-oz glass of water to the mouth.	
4	Can raise hands to the mouth, but cannot raise an 8-oz glass of water to the mouth.	
5	Cannot raise hands to the mouth, but can use hands to hold a pen or pick up pennies from the table.	
6	Cannot raise hands to the mouth and has no useful function of hands.	

Classification based on investigator assessment

Providing an overall rating
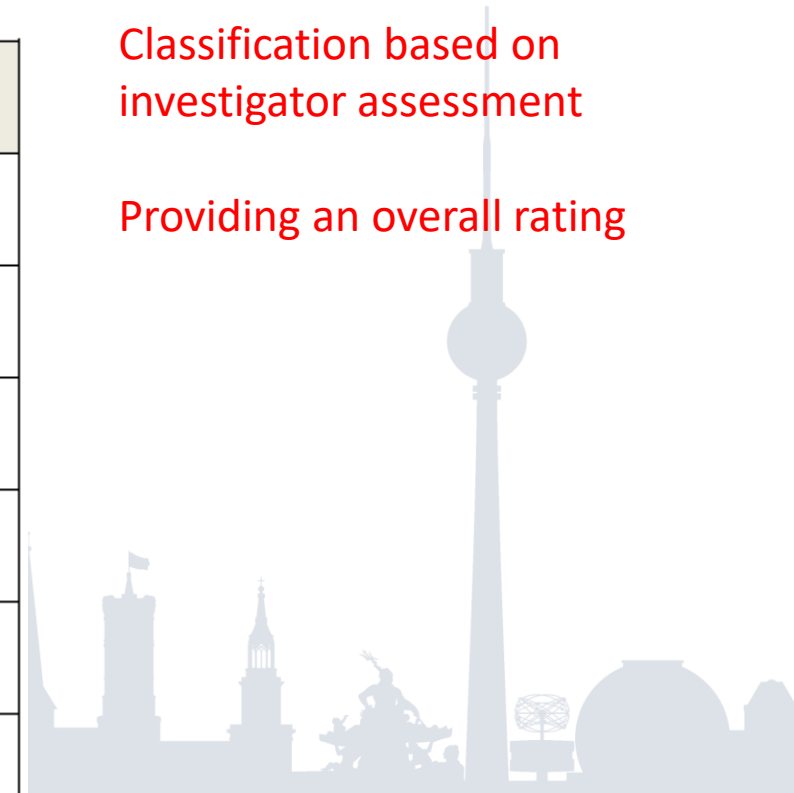
New QRS Instrument Flowchart
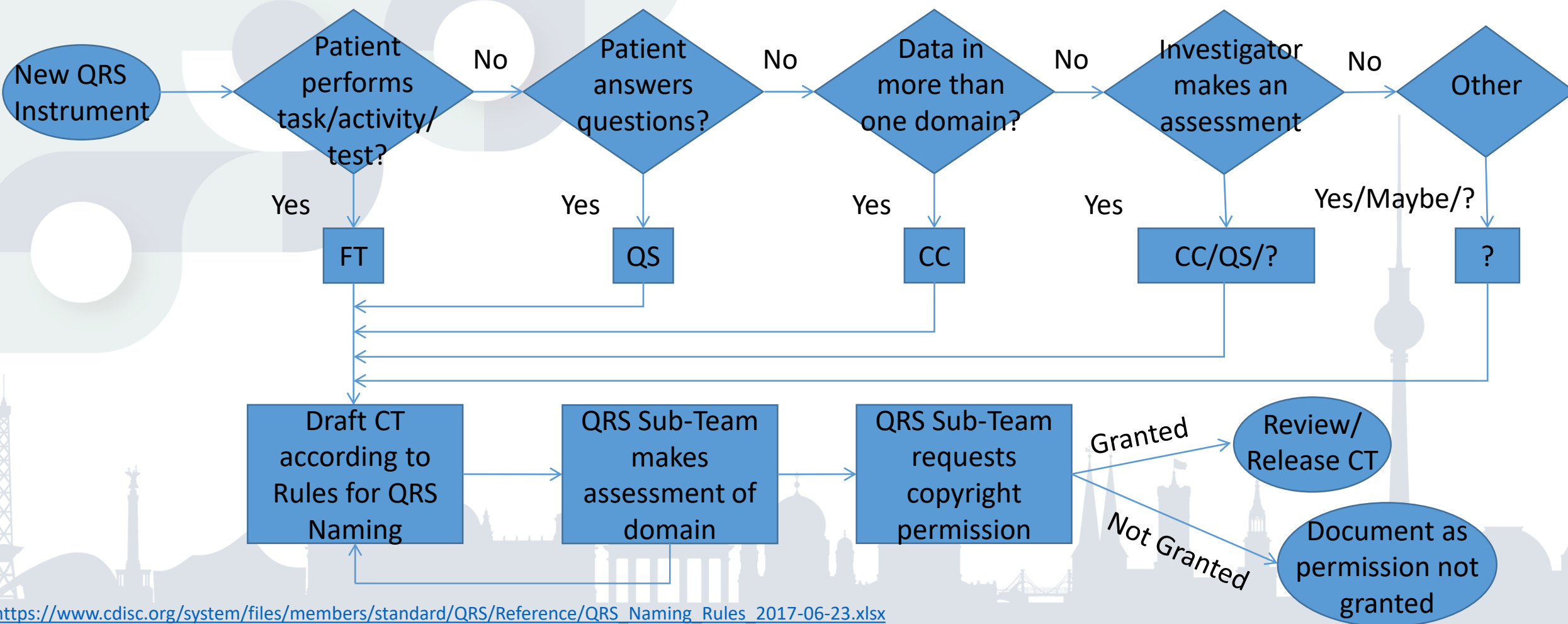
Bonus Slides

CC vs Single Body System(Physiology/Morphology) Domain – Forthcoming Public Review

- **Are their QRS-like instruments that are not stored in the FT, QS or RS domains?**

- Yes, certain clinical classifications may be stored in other domains. The rule for so storing clinical classifications is:

- If the instrument is a Grading Scale in which the intent of the instrument is to evaluate a single body system, then it would be stored in the morphology/physiology domain which represents that body system. All other Grading Scales related to multiple body systems and all Composite Score type instruments would be represented as a Clinical Classification in the RS domain.

CC vs Single Body System(Physiology/Morpology) Domain contd.

- Composite types of instruments provide an assessment based on multiple individual assessments that can be represented in other domains. For example, the APACHE II instrument has a CRF and is a composite instrument and would be stored as a Clinical Classification in the RS domain because it has a variety of labs, respiratory, and vital sign assessments in addition to the Glasgow Coma Score. This variety of data is scored separately in the APACHE II instrument. This composite scoring approach is currently represented as a Clinical Classification in the RS domain.

- Another type of Clinical Classification that is stored in the RS domain deals with the rating of symptoms or other medical conditions related to multiple body systems. These are not posed as a questionnaire with specific questions with specific answers but have CRFs with the symptoms or medical conditions listed with a specific rating scale that is evaluated by an examiner.

- Grading Scales are instruments which may or may not use observations from multiple body systems, but there is no CRF with a place for the individual assessments' values and thus no calculation of an overall score. For example, TIMI Grade is a grading system for coronary blood flow and has no case report form and is based on the CV body system. This is an example of a Grading Scale instrument that is related to a single body system and would be stored in the related morphology/physiology body system domain.

QRS CT Team & Sub-team

- Submit QRS instruments and volunteer!

- QRS sub-team
  - Steve Kopko skopko.external@cdisc.org
  - Dana Booth dbooth.external@cdisc.org
- QRS CT team.
  - Chris Gemma cgemma@cdisc.org
  - Dana Booth dbooth@cdisc.org
  - Roberta Rosenberg Roberta.E.Rosenberg@pfizer.com

Thank you!

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Back Up Slides

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APACHE II

VSLNKID	VSTESTCD	VSTEST
AP01	TEMP	Temperature
AP02	MAP	Mean Arterial Pressure
AP03	HR	Heart Rate
AP04	RESP	Respiratory Rate

RSLNKID	RSTESTCD	RSTEST	RSCAT
AP01	APCH101	APCH1-Temperature - Rectal	APACHE II
AP02	APCH102	APCH1-Mean Arterial Pressure	APACHE II
AP03	APCH103	APCH1-Heart Rate	APACHE II
AP04	APCH104	APCH1-Respiratory Rate	APACHE II
AP05	APCH105B	APCH1-Oxygenation: PaO2	APACHE II
AP06	APCH106A	APCH1-Arterial pH	APACHE II
AP07	APCH107	APCH1-Serum Sodium	APACHE II
AP08	APCH108	APCH1-Serum Potassium	APACHE II

LBLNKID	LBTESTCD	LBTEST
AP05	PO2	Partial Pressure Oxygen
AP06	PH	pH
AP07	SODIUM	Sodium
AP08	K	Potassium
AP09	CREAT	Creatinine
AP10	HCT	Hematocrit
AP11	WBC	Leukocytes

RSTESTCD	RSTEST	RSCAT	RSORRES
GCS0101	GCS01-Best Eye Response	GCS NINDS VERSION	Eyes open spontaneously
GCS0102	GCS01-Motor Response	GCS NINDS VERSION	Flexion withdrawal
GCS0103	GCS01-Verbal Response	GCS NINDS VERSION	Confused
GCS0104	GCS01-Total Score	GCS NINDS VERSION	12

Physiologic Variable *RSORRESU*		+4	
Temperature - rectal (°C) *RSTESTCD=APCH101*			39
Mean Arterial Pressure - mm Hg *RSTESTCD=APCH102*			
Heart Rate (ventricular response) *RSTESTCD=APCH103*		≥ 180	
Respiratory Rate (non-ventilated or ventilated) *RSTESTCD=APCH104*		≥ 50	
Oxygenation: A-aDO$_2$ or PaO$_2$ (mm Hg)			
a. FIO$_2 \geq 0.5$ record A-aDO$_2$ *RSTESTCD=APCH105A*			
b. FIO$_2 < 0.5$ record only PaO$_2$ *RSTESTCD=APCH105B*			
Arterial pH (preferred) *RSTESTCD=APCH106A*			
Serum HCO$_3$ (venous mMol/L) (Not preferred, use if no ABGs) *RSTESTCD=APCH106B*			
Serum Sodium (mMol/L) *RSTESTCD=APCH107*			
Serum Potassium (mMol/L) *RSTESTCD=APCH108*			
Serum Creatinine (mg/100 mL) (Double point score for acute renal failure) *RSTESTCD=APCH109*			
Hematocrit (%) *RSTESTCD=APCH110*		≥ 60	
White Blood Count (total/mm^3) (in 1,000s) *RSTESTCD=APCH111*		≥ 40	
Glasgow Coma Score (GCS): Score = 15 minus actual GCS		*RSORRES/RS*	
A. Total Acute Physiology Score (APS): Sum of the 12 individ			
B. Age Points (years): ≤44=0, 45–54=2, 55–64=3, 65–74			
C. Chronic Health Points (see below)			
Total APACHE II Score (Sum of A + B + C) *RSORRES/RS*			

PhUSE/CDISC Roundtable 2: Problem Statements

- Ambiguity exists regarding the tabulation of certain measurements as clinical classifications or physiological findings within a specific body system (e.g. cardiovascular, reproductive, etc.). The CDISC QRS team has developed a new rule clarifying the tabulation of these measurements. This new rule would require SDTM implementers to move/re-map the results for certain measurements (~12) from one domain to another.

  The QRS team would like to vet this new rule with the implementation community, and gather feedback on moving/re-mapping results for existing measurements.

PhUSE/CDISC Roundtable 2: Problem Statements

- 2. Standards developers and implementers use variable QSEVAL, Evaluator, to represent a variety of different concepts including instrument reporter, interviewer, health care professional, etc. As a result, data consumers struggle to understand the specific concept represented in QSEVAL for a given study. Further, these differences may impact pooled analyses. The QRS team proposes to remove QSEVAL/QSEVALID from SDTM and represent specific information about readers, responders, assessors, etc. as supplemental qualifiers.

  The QRS team would feedback on this proposal. Please note, this proposal does not impact the FT and RS domains.
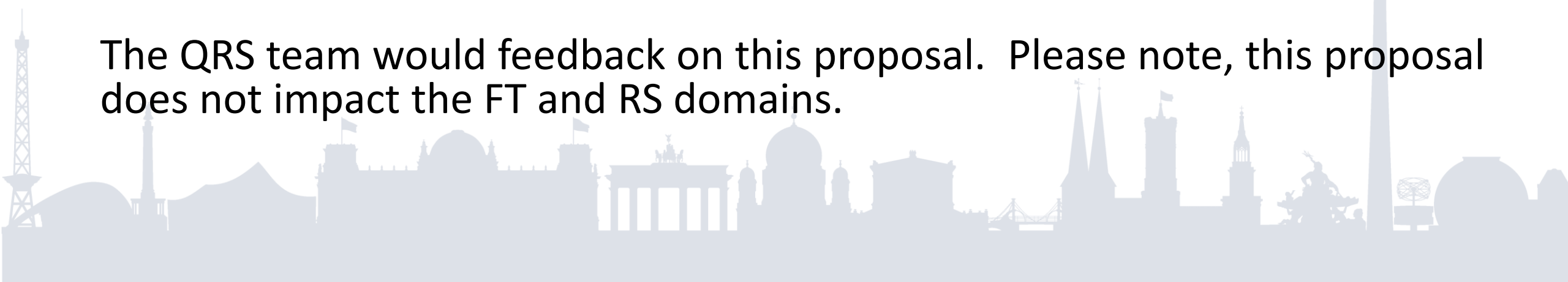
Logically Skipped Items

PhUSE/CDISC Roundtable 1: 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.

PhUSE/CDISC Roundtable 1: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.

Logically Skipped Items – FDA TCG v4.0

- FDA Study Data Technical Conformance Guide v4.0 section 4.1.1.3 SDTM Domain Specifications, QS Domain (Questionnaires)
  - Some items in an instrument may be logically skipped per the instrument's instructions. Responses for logically skipped items should be (1) recorded and/or scored according to the instructions provided in the instrument's user manual, scoring manual, or other documentation provided by the instrument developer and (2) included in the submission dataset.
  - If instructions on how to record and/or score responses to logically skipped items are available from the instrument developer, then records for logically skipped items should be included in the submission dataset with the following:
    - QSSTAT = "NOT DONE";
    - QSREASND = "LOGICALLY SKIPPED ITEM"; and
    - QSORRES, QSSTRESC, and QSSTRESN would be assigned according to the instrument's instructions.

Logically Skipped Items – FDA TCG v4.0

- FDA Study Data Technical Conformance Guide v4.0 section 4.1.1.3 SDTM Domain Specifications, QS Domain (Questionnaires), contd.
  - If instructions on how to record and/or score responses to logically skipped items are not available from the instrument developer, then records for logically skipped items should be included in the submission dataset with the following:
    - QSSTAT = "NOT DONE";
    - QSREASND = "LOGICALLY SKIPPED ITEM"; and
    - QSORRES, QSSTRESC, and QSSTRESN all set to null.

Logically Skipped Items 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

EXPANDED DRS-PI CAREGIVER VERSION

- Example from Expanded Disability Rating Scale – Postacute Interview Caregiver Version (EXPANDED DRS-PI CAREGIVER VERSION)
- The caregiver answered "2" (No, question 2.1 and possibly "1") questions 2.2 and 2.3 are answered

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 to2.2	Inconsistently 1 Go to 2.2	No 2 Go to 2.4

Representing Logically Skipped Items in SDTM

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
ED102_4	ED1-Few Words or Random Answers/Shouting	EXPANDED DRS-PI CAREGIVER VERSION	COMMUNICATION ABILITY
ED102_5	ED1-Moan/Groan/Sounds Not Understandable	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		
			NOT DONE	LOGICALLY SKIPPED ITEM
			NOT DONE	LOGICALLY SKIPPED ITEM

- 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"

Representing Logically Skipped Items in SDTM

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
ED102_4	ED1-Few Words or Random Answers/Shouting	EXPANDED DRS-PI CAREGIVER VERSION	COMMUNICATION ABILITY
ED102_5	ED1-Moan/Groan/Sounds Not Understandable	EXPANDED DRS-PI CAREGIVER VERSION	COMMUNICATION ABILITY

QSORRES	QSSTRESC	QSSTRESN	QSSTAT	QSREASND
Consistently	2	2		
			NOT DONE	LOGICALLY SKIPPED ITEM
			NOT DONE	LOGICALLY SKIPPED ITEM
No	0	0		
No	0	0		

- If this was scored by the instrument owner QSORRES, QSSTRESC, and QSSTRESN would be assigned according to the instrument's instructions.

Thank you!

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