QRS Updates: Logically Skipped Items, EVAL and More

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Tuesday, 2020-07-14
11:00 – 12:30 EDT

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** for the entirety of the call
- There will be a Q&A after all of the presentations are finished
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Content Disclaimer

- The purpose of this webinar is to provide examples of implementation and should not be considered official recommendations by CDISC unless otherwise stated in the presentation.
- This webinar is not an authorized CDISC course, is not developed or delivered under CDISC Operating Procedures, and should not replace a published standard. Please refer to the latest published standards for the most authoritative implementation information.

Our Presenters

- Dana Booth, SDS QRS Subteam Co-Lead, CDISC
- Steve Kopko, SDS QRS Subteam Co-Lead, CDISC

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Representation of Questionnaires, Ratings, and Scales (QRS) items in SDTM

07.14.2020

Definition

Logically skipped items (e.g., questions) on a QRS instrument are items which may be skipped due to a specific response to a previous item on the instrument or when the item does not apply to the subject.

Suggested representation of CDISC QRS logically skipped items

- CDISC QRS supplements will have a record in *qs.xpt* with
  - original and standardized results that are null (QSORRES/QSSTRESC/QSSTRESN are all missing).
  - a status of NOT DONE (QSSTAT="NOT DONE").
  - reason not done equal "LOGICALLY SKIPPED ITEM" (QSREASND="LOGICALLY SKIPPED ITEM").

FDA Technical Conformance Guide

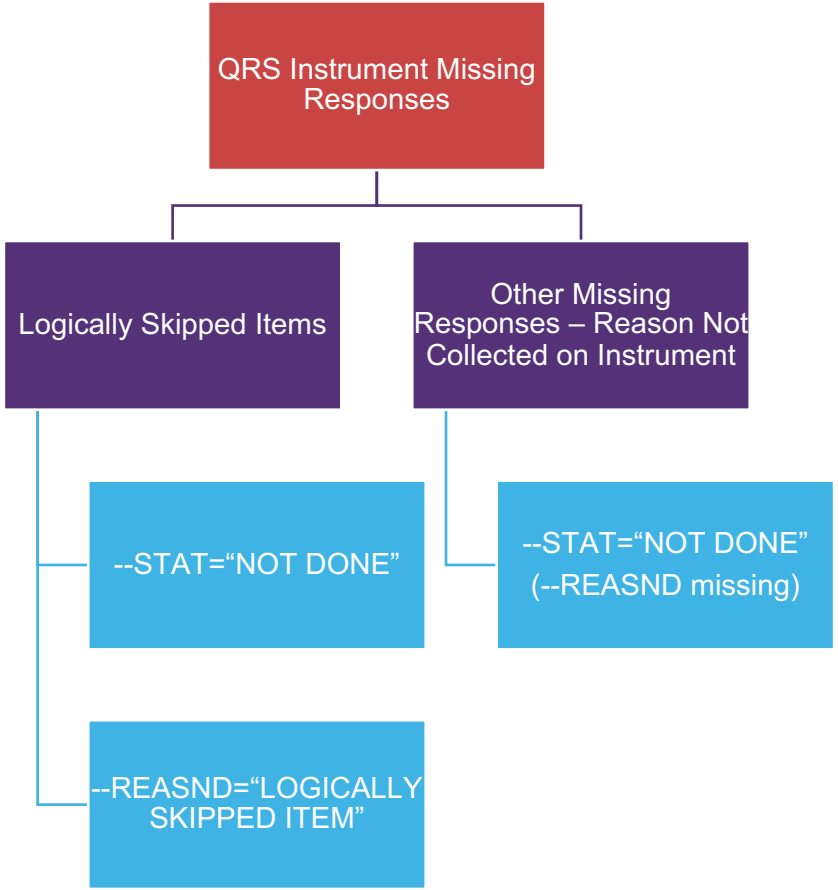
If instructions on how to record and/or score responses to logically skipped items are available from the instrument developer, then records for logically skipped items should be included in the submission dataset with the following:

- QSSTAT = “NOT DONE”;
- QSREASND = “LOGICALLY SKIPPED ITEM”; and
- QSORRES, QSSTRESC, and QSSTRESN would be assigned according to the instrument’s instructions.

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.

Tree Diagram for Determining --REASND



*Note: --ORRES, --STRESC, --STRESN are missing in all of these instances.

Example of logically skipped items – FACT-C

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

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.

Example of logically skipped items – Expanded DRS-PI Caregiver Version, Section 2

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
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
QSTESTCD=ED102_4	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 only through random answers, shouting or swearing?	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		

To examiner: There is no item #3. Go to #4.

When EDR102_1 is "Consistently" or "Inconsistently", then items ED102_4 and ED102_5 are skipped.

When EDR102_1 is "No", then items ED102_2 and ED102_3 are skipped.

When ED102_4 is "Yes", then item ED102_5 is skipped.

Representing logically skipped items – Expanded DRS-PI Caregiver Version, Section 2 (cont.)

qs.xpt (with ED102_1 = "Consistently")*

Row	USUBJID	QSTESTCD	QSORRES	QSSTRESC	QSSTRESN
1	P0001	ED102_1	Consistently	0	0
2	P0001	ED102_2	Speech	0	0
3	P0001	ED102_3	Yes, but takes more than a few seconds	1	1
4	P0001	ED102_4			
5	P0001	ED102_5			

qs.xpt (cont.)

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

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

Representing logically skipped items – Expanded DRS-PI Caregiver Version, Section 2 (cont.)

qs.xpt (with ED102_1 = "No")*

Row	USUBJID	QSTESTCD	QSORRES	QSSTRESC	QSSTRESN
1	P0001	ED102_1	No	2	2
2	P0001	ED102_2			
3	P0001	ED102_3			
4	P0001	ED102_4	Yes	1	1
5	P0001	ED102_5			

qs.xpt (cont.)

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

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

Example of logically skipped items – Expanded DRS-PI Caregiver Version, Section 8

How certain are you that [name] can:

	Certain or very certain s/he can	Uncertain	Certain or very certain s/he cannot
8.4 perform in a wide variety of jobs of [his/her] choosing or manage a home independently or participate in school full-time *QSTESTCD=ED108_4*	0	1	2
	END	Go to 8.5	
8.5 be successful at work, school or in home management with some reduction in the work load or with other accommodations due to disabilities *QSTESTCD=ED108_5*	0	1	2
	END	Go to 8.6	
8.6 be successful at work, school or in home management but with limited choices in jobs or school courses due to disabilities *QSTESTCD=ED108_6*	0	1	2
	END	Go to 8.7	
8.7 be able to work at home or in a special setting like a sheltered workshop in which the work is very routine and there is very frequent supervision and support *QSTESTCD=ED108_7*	0	1	2
	END	END	

ED108_4, ED108_5, and ED108_6 can each lead to items being skipped when the response is "Certain or very certain s/he can".

From the Expanded Disability Rating Scale –

Representing logically skipped items – Expanded DRS-PI Caregiver Version, Section 8

*qs.xpt**

Row	USUBJID	QSTESTCD	QSORRES	QSSTRESC	QSSTRESN
1	P0001	ED108_4	Uncertain	1	1
2	P0001	ED108_5	Certain or very certain s/he can	0	0
3	P0001	ED108_6			
4	P0001	ED108_7			

qs.xpt (cont.)

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

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

Example of logically skipped items – IDS-C

Complete either 11 or 12 (not both)

11. Appetite (Decreased): **RSTESTCD=IDSC111**

0	No change from usual appetite.
1	Eats somewhat less often and/or lesser amounts than usual.
2	Eats much less than usual and only with personal effort.
3	Eats rarely within a 24-hour period, and only with extreme personal effort or with persuasion by others.

12. Appetite (Increased): **RSTESTCD=IDSC112**

0	No change from usual appetite.
1	More frequently feels a need to eat than usual.
2	Regularly eats more often and/or greater amounts than usual.
3	Feels driven to overeat at and between meals.

- Data needs cleaning if IDSC111/IDSC112 conflict
- A record is created for both items.
- The item that does not apply is considered to be logically skipped.

Representing logically skipped items – IDS-C

rs.xpt

Row	USUBJID	RSTESTCD	RSORRES	RSSTRESC	RSSTRESN
11	P0001	IDSC111	No change from usual appetite.	0	0
12	P0001	IDSC112			

rs.xpt (cont.)

Row	RSSTAT	RSREASND
11 (cont.)		
12 (cont.)	NOT DONE	LOGICALLY SKIPPED ITEM

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

Example of logically skipped items– PHQ-15

		Not bothered at all (0)	Bothered a little (1)	Bothered a lot (2)
QSTESTCD =PHQ0204	d. Menstrual cramps or other problems with your periods WOMEN ONLY	☐	☐	☐

- Data needs cleaning if PHQ0204 is answered for “Male” subjects.
- If the item does not apply, it is considered to be logically skipped.

Representing logically skipped items – PHQ-15

qs.xpt (female respondent for which this applies)

Row	USUBJID	QSTESTCD	QSORRES	QSSTRESC	QSSTRESN	QSSTAT
1	P0001	PHQ0204	Not bothered at all	0	0	

qs.xpt (male respondent, menopausal woman, someone that does not use traditional gender identification, etc.)

Row	USUBJID	QSTESTCD	QSORRES	QSSTRESC	QSSTRESN
4	P0004	PHQ0204			

qs.xpt (cont.)

Row	QSSTAT	QSREASND
4 (cont.)	NOT DONE	LOGICALLY SKIPPED ITEM

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

Which kinds of QS items are NOT considered logically skipped items?

Another item does not instruct that the item be skipped

- Presence of data styles of items
  - “Other, Specify:” text responses
  - “Check all that apply” type questions

- Items that indicate a specific response when an item does not apply
- Items the subject skips for some unknown reason

How are other items represented in QS?

- A record is created in *qs.xpt* for all items.
- If an instrument is not done, then a record will be created for all items on the instrument.
- Items with responses are represented as per usual.
- For those in which the subject checks all that apply, if an item is not checked, there is still a response recorded of "NOT CHECKED" so QSSTAT is not used.
- For other missing data, including for items the subject skips (e.g., when the item does not apply or no response was provided), no assumption is made as to the reason (e.g., QSSTAT="NOT DONE" and QSREASND is not needed for that record).

How are other items represented in QS? (cont.)

- If an original result is indicated on a QRS instrument for an item that does not apply, then that item is not considered to be logically skipped (e.g., In the Expanded DRS-PI, Sections 4-6, it states to mark 0 if an item does not apply and move to the next item. The item marked 0 has an original result of QSORRES=0 and is not logically skipped.).

Example of presence of data with "other, specify" – HAQ-DI

HEALTH ASSESSMENT QUESTIONNAIRE - DISABILITY INDEX (HAQ-DI):

Please check any AIDS OR DEVICES that you usually use for any of these activities:

QSTESTCD= HAQ0210 ... QSTESTCD= HAQ0217

- ☐ Cane
- ☐ Walker
- ☐ Crutches
- ☐ Wheelchair
- ☐ Devices used for dressing (button hook, zipper pull, long-handled shoe horn, etc.)
- ☐ Built up or special utensils
- ☐ Special or built up chair
- ☐ Other, (specify): _____

(QSTESTCD=HAQ0218 and QSORRES=specified written text) when (QSTESTCD=HAQ0217 and QSORRES='CHECKED')

HAQ0218 (the specify part of the last checkbox above) is only responded to when HAQ0217 (the checkbox for "Other, (specify)") is "CHECKED"

- Data needs cleaning if HAQ0217/HAQ0218 conflict.
- Records are created for all checkboxes and HAQ0218.
- HAQ0218 is not considered to be logically skipped because the subject checks all that apply; it is a "presence of data" style of item.
- If HAQ0217 is not checked, then HAQ0218 has QSSTAT="NOT DONE"

Representing presence of data – HAQ-DI

qs.xpt

Row	USUBJID	QSTESTCD	QSORRES	QSSTRESC	QSSTAT
10	P0001	HAQ0210	CHECKED	CHECKED	
11	P0001	HAQ0211	NOT CHECKED	NOT CHECKED	
12	P0001	HAQ0212	NOT CHECKED	NOT CHECKED	
13	P0001	HAQ0213	NOT CHECKED	NOT CHECKED	
14	P0001	HAQ0214	NOT CHECKED	NOT CHECKED	
15	P0001	HAQ0215	NOT CHECKED	NOT CHECKED	
16	P0001	HAQ0216	NOT CHECKED	NOT CHECKED	
17	P0001	HAQ0217	NOT CHECKED	NOT CHECKED	
18	P0001	HAQ0218			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.

Representation of standardized results in CDISC standards

- Sometimes standardized results are known to exist for a QRS instrument, but not stated on the CRF. When this occurs, the standardized values will be represented in SDTM. As per CDISC QRS Best Practices: "...This is only done when the numeric standardized responses are documented in the QRS CRF instructions, a user manual, website specific to the QRS instrument, or other reference document that provides a clear explanation and rationale for providing them in the SDTMIG QRS dataset."

Representation of subtotal and total scores in CDISC standards

- Subtotal and total scores provided directly on the CRF will be represented in SDTM as captured data.
- Sometimes subtotal and total scores are indicated in a manual for a QRS instrument, but not shown on the CRF. Vendors and sponsors do sometimes submit these electronically to SDTM so these scores will be represented in SDTM as captured data.

Final notes regarding representing missing data in QS/RS/FT

- Providing records for items with no response will be unique to QRS domains (QS, RS, and FT).
- We are working to revise the SDTMIG to reflect the representation of missing data for QRS instruments.

Thank You!

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Audience Questions

The CDISC Summer Stay at Home Learning Guide email lists this webinar as "QRA Updates" - please clarify if QRS is being renamed?

Audience Questions

If we aren't able to differentiate between logically skipped questions and questions just not answered by the dr, how do we proceed?

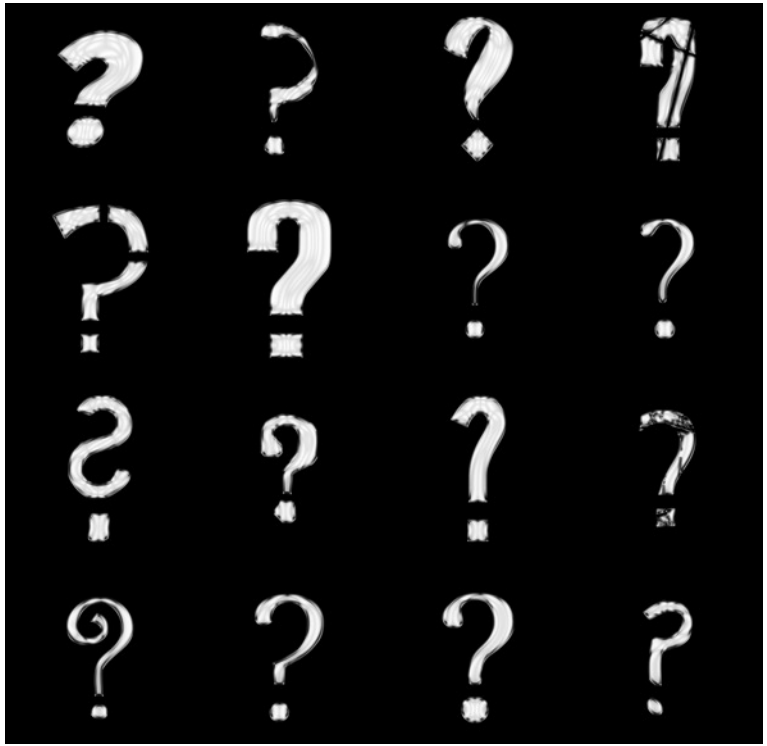
Audience Questions

Is QRS team revisiting published instruments to accommodate LOGSKIP? For example AUDIT self report is also part of LOGSKIP process, but we don't see those changes

Audience Questions

How will CDASH suggest to use these instruments at collection level - or is it only done at SDTM level? Can we have E2E process?

Audience Questions



Should "not done" or "logically skipped" items be taken into ADaM dataset?

Audience Questions

Does the new information "If an instrument is not done, then a record will be created for all items on the instrument" make the QSALL convention invalid? Or are these separate conventions and there would still be a use case for QSALL with QSSTAT=NOT DONE?

Audience Questions

Is there any expectation that the logically skipped item come from the collection instrument (EDC or loaded data)? Most EDC instruments can be designed to dynamically trigger questions for logically skipped items and therefore will not have data in the raw datasets from EDC. Are there best practices for implementation of this in SDTM - w.r.t to deriving these in SDTM?

Audience Questions

How do you recommend for sponsors to best accomplish the recommendation "that sponsors consult with SDS QRS Subteam to confirm that the supplemental qualifier is not in use elsewhere"?

Audience Questions

How we will distinguish between patient reported and clinician data?

Audience Questions

Why is CDISC increasing number of domains? We already have 150+ CDISC domains - why do we need to have one more QX domain?

Audience Questions

Are we considering sponsors feedback when we introduce new domains

Audience Questions

Are we going to keep single VLM data going forward for instruments - not based on evaluator?

Audience Questions

Will PGI and CGI have same VLM going forward?

Audience Questions

Steve: Once QX is officially approved, will someone go back through all of the published QRS instruments and create QX domains for them? That's obviously going to be a huge job.

Audience Questions

For Steve –
1) what is difference between "Mode of Administration" and "Collected Administration".
2) You should strongly consider adding some of these as permissible variables for QS in 3.4, instead of SUPP--
3) Why is it necessary to remove EVAL and EVALID from parent domain, is that absolutely necessary?!!

Audience Questions

Can I use same wiki username and password for JIRA?

Audience Questions

What is the value of separating out EVAL and EVALID into separate supp datasets? Instead of having all relevant information in one QRS dataset related to a interview administration, won't separating them out into separate datasets only create room for mistakes/errors?

Upcoming Learning Opportunities

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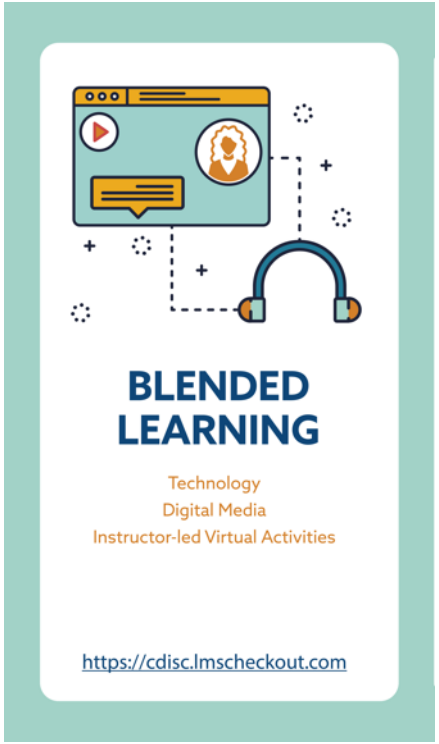

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China	3 – 29 SEP	Weekly	Mandarin

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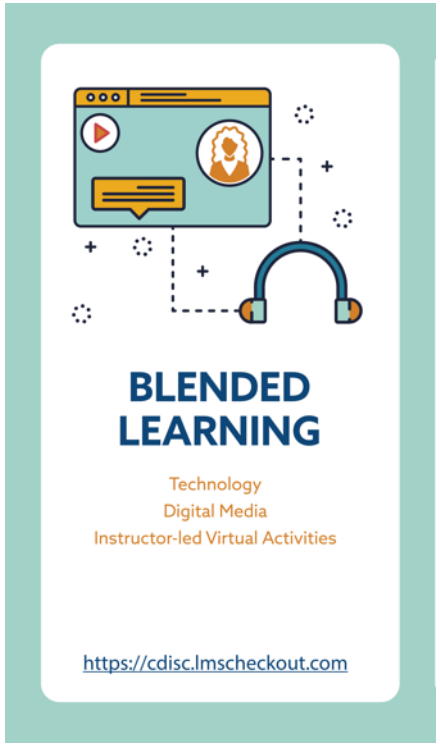
Japan	4 – 18 AUG	Weekly	Japanese
China	3 – 17 SEP	Weekly	Mandarin

**Includes eight modules & weekly Q&A sessions



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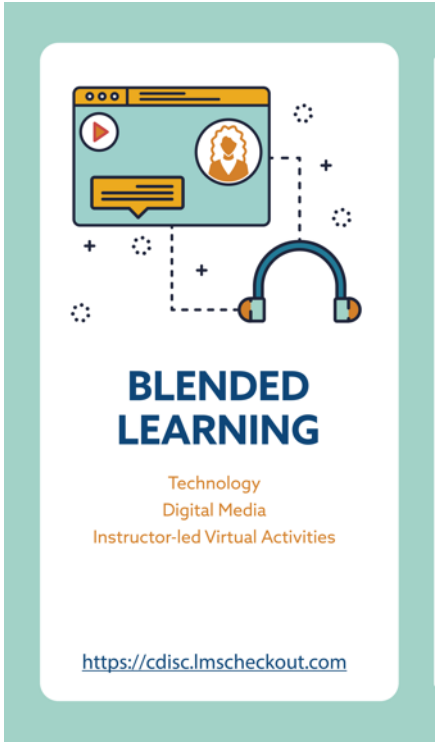

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2020 Webinars

Date	Webinar Title
21 JUL 2020	Introducing the CDASH eCRF Project + CDISC Standards for Animal Rule Studies
28 JUL	Leveraging Clinical Research Data Standards in Academia: What's in it for Me?
13 OCT 2020	Controlled Terminology Updates for Q4

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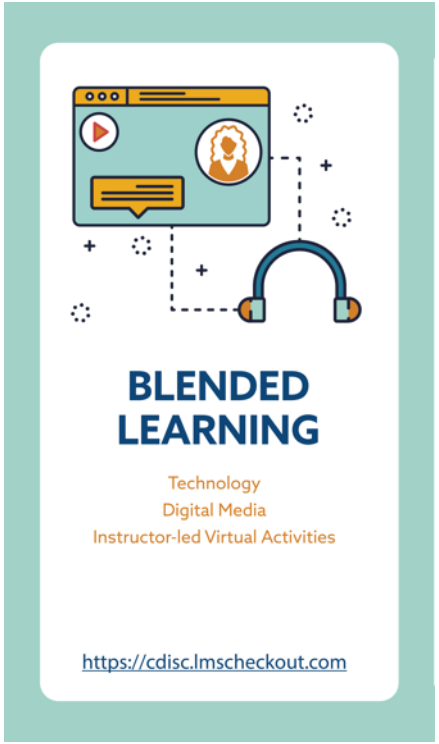
The workshop also identifies standards strategies that can make the clinical research process more efficient and offers a high-level introduction into the current regulatory requirements for submissions.

- **Agenda**:
- Topic 1: What is CDISC?
- Topic 2: Why Are Standards Needed?
- Topic 3: Overview of Regulatory Requirements
- Topic 4: Overview of CDISC Models
- Topic 5: CDISC Connects Research Globally
- Topic 6: Therapeutic Area User Guides
- Topic 7: Data Exchange Standards
- Topic 8: Implementing CDISC Standards
- Topic 9: CDISC Library
- Topic 10: How Does CDISC Work?

Date and Time:

29 JUL – Asia/Tokyo
5 AUG – Europe/Brussels



Thank You!

Questions, comments, concerns? Email bklinke@cdisc.org

Don’t forget to fill out the feedback survey!