



DH05-Mapping missing QRS Responses in the SDTM

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Questionnaires Data:

- Questionnaire's data can be classified as both, quantitative and qualitative method depending on the nature of questions.
- Questionnaires can include the following types of questions
 - **Open question questionnaires:** Open questions differ from other types of questions used in questionnaires in a way that open questions may produce unexpected results, which can make the research more original and valuable.
 - **Multiple choice questions:** Respondents are offered a set of answers they must choose from.

Questionnaires Data:

- **Dichotomous Questions:** This type of questions gives two options to respondents – yes or no, to choose from. It is the easiest form of questionnaire for the respondent in terms of responding it.
- **Scaling Questions:** Also referred to as ranking questions, they present an option for respondents to rank the available answers to the questions on the scale of given range of values (for example from 1 to 10)

Mapping missing/logically skipped QRS Responses in the SDTM Questionnaires domain

- A Questionnaire may have some items that will be logically skipped per the instructions for the Questionnaire.
- Responses for logically skipped items (LSI) should as per the FDA Study Data Technical Conformance Guide be included in the submission dataset with QSSTAT = "NOT DONE", QSREASND = "LOGICALLY SKIPPED ITEM", and QSORRES, QSSTRESC, and QSSTRESN all set to null
- In FDA Study Data Technical Conformance Guide version 4.0 (October 2017), the concept of logically skipped items was introduced for the first time.

Mapping missing/logically skipped QRS Responses in the SDTM

- Below is one of the example where FDA would expect records for the logically skipped items

15. Are you currently driving, at least once in awhile?	Yes (skip to Q15c)	☐
QSORRES when QSTESTCD = VFQ215	No	☐
QSSTAT = NOT DONE / QSREASND = BLANK IN SOURCE	Blank in Source	☐
15a. IF NO: Have you never driven a car or have you given up driving?	Never drove (skip to Q17)	☐
QSORRES when QSTESTCD = VFQ215A	Gave up	☐
QSSTAT = NOT DONE / QSREASND = BLANK IN SOURCE	Blank in Source	☐
15b. IF GAVE UP DRIVING: Was that mainly because of your eyesight, mainly for some other reason, or because of both your eyesight and other reasons?	Mainly eyesight (skip to Q17)	☐
QSORRES when QSTESTCD = VFQ215B	Mainly other reasons (skip to Q17)	☐
	Both eyesight and other reasons (skip to Q17)	☐
QSSTAT = NOT DONE / QSREASND = BLANK IN SOURCE	Blank in Source	☐

Mapping missing/logically skipped QRS Responses in the SDTM

- Questions 15a and 15b are related to not driving and can be skipped if a subject answered YES to question 15 and can directly go to question 15C.

15c. IF CURRENTLY DRIVING: How much difficulty do you have driving during the daytime in familiar places
Would you say you have:

QSORRES when QSTESTCD = VFQ215C

QSSTAT = NOT DONE / QSREASND = BLANK IN SOURCE

No difficulty at all ☐

A little difficulty ☐

Moderate difficulty ☐

Extreme difficulty ☐

Blank in Source ☐

- Same would apply to question 15C where a subject can skip 15C when they answer “NO” for question 15 but then they need to answer 15a and 15b

Mapping missing/logically skipped QRS Responses in the SDTM

- Here is a follow-up example, where a subject can skip question 16 and 16a if they answer “NO” to question 15.

16. How much difficulty do you have driving at night?
Would you say you have:

QSORRES when QSTESTCD = VFQ216

No difficulty at all ☐
A little difficulty ☐
Moderate difficulty ☐
Extreme difficulty ☐
Stopped doing this because
of your eyesight ☐
Stopped doing this for
other reasons or not
interested in doing this ☐
Blank in Source ☐

QSSTAT = NOT DONE / QSREASND = BLANK IN SOURCE

16a. How much difficulty do you have driving in difficult
conditions, such as bad weather, during rush hour, on
the freeway, or in city traffic? Would you say you have:

QSORRES when QSTESTCD = VFQ216A

No difficulty at all ☐
A little difficulty ☐
Moderate difficulty ☐
Extreme difficulty ☐
Stopped doing this because
of your eyesight ☐

Mapping missing/logically skipped QRS Responses in the SDTM

- Data examples

QSTESTCD	QSTEST	QSCAT	QSORRES	QSSTRESC	QSSTRESN	QSSTAT	QSREASND
VFQ215	VFQ2-Are You Currently Driving	VFQ-25 SELF...	NO	2	2		
VFQ215	VFQ2-Are You Currently Driving	VFQ-25 SELF...	NO	2	2		
VFQ215A	VFQ2-Never Driven or Given Up Driving	VFQ-25 SELF...	GAVE UP	2	2		
VFQ215A	VFQ2-Never Driven or Given Up Driving	VFQ-25 SELF...	GAVE UP	2	2		
VFQ215B	VFQ2-Main Reason You Gave Up Driving	VFQ-25 SELF...	MAINLY EYESIGHT (SKIP TO Q17)	1	1		
VFQ215B	VFQ2-Main Reason You Gave Up Driving	VFQ-25 SELF...	MAINLY EYESIGHT (SKIP TO Q17)	1	1		
VFQ215C	VFQ2-Difficulty Driving During Daytime	VFQ-25 SELF...				NOT DONE	LOGICALLY SKIPPED ITEM
VFQ215C	VFQ2-Difficulty Driving During Daytime	VFQ-25 SELF...				NOT DONE	LOGICALLY SKIPPED ITEM
VFQ216	VFQ2-Difficulty Driving at Night	VFQ-25 SELF...				NOT DONE	LOGICALLY SKIPPED ITEM
VFQ216	VFQ2-Difficulty Driving at Night	VFQ-25 SELF...				NOT DONE	LOGICALLY SKIPPED ITEM
VFQ216A	VFQ2-Driving in Difficult Conditions	VFQ-25 SELF...				NOT DONE	LOGICALLY SKIPPED ITEM
VFQ216A	VFQ2-Driving in Difficult Conditions	VFQ-25 SELF...				NOT DONE	LOGICALLY SKIPPED ITEM

- As the subject's response to currently driving is "NO", questions related to driving were skipped and responded only to questions that were not related to "Why not driving"

Conclusion

- It is important and critical to decide which questions qualify for a logically skipped method.
- For example, questions like “If Yes, describe” (If answered No, should the Description field be considered in scope for LSI?)
- For traceability purposes it is important that we adopts methods like LSI suggested by FDA technical conference guide to capture the missing information to present them in a meaningful way.

References

- <https://www.lexjansen.com/phuse/2019/pp/PP04.pdf>
- <http://cdisc-end-to-end.blogspot.com/2019/03/logically-skipped-items-in-sdtm-qs.html>

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Thank you!!