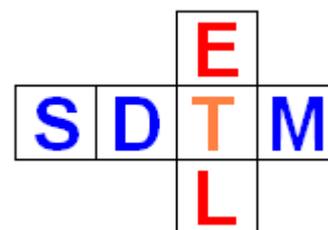


SDTM-ETL 5.0 User Manual and Tutorial

Creating Records for QS "Logically Skipped Items"



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Table of contents:

Introduction.....	1
Implementation in SDTM-ETL	2
Extension FDA Technical Conformance Guide March 2025	8
Further materials	11

Introduction

In some cases, the FDA publishes rules for SDTM that override existing SDTM rules (although also the FDA can comment during public review periods) and sometimes even conflicts with them.

A recent example of this is the rule that for QS (Questionnaires) datasets, also data of logically skipped questions must be submitted. See the latest "[Technical Conformance Guide](#)":

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.

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.

Remark that the above is not very consequent and violates SDTM rules, for example that population of "--ORRES" and "--STAT" are mutually exclusive, i.e. only 1 of both is allowed to be populated.

This is unproblematic when such skipped items are collected and marked as such in the database,

e.g. using a code "999". In most cases however (we checked with EDC and ePRO vendors), skipped questions are not explicitly collected and stored in the study database, as there is no data from them (logical, isn't it?), and because one can always do a lookup in the "skip rules" in order to see why a data point is missing. Such [skip rules can easily be defined in the define.xml](#), but it looks as the FDA did not think about that.

So, this new rule forces SDTM generation tools to create records for non-collected data that usually are not in the database, and thus also not in the ODM export.
 If the database however also contains records for skipped questions (such as "999" records), there is no problem at all.

Implementation in SDTM-ETL

In case the EDC system, thus also the ODM export, does not have information about questionnaire data that was not captured (as it was skipped due to the questionnaire workflow), a post-processing step is necessary.

In SDTM-ETL, we have solved this in an intelligent way. For the case that a questionnaire has "skip rules", such as the "[Disability Rating Scale](#)" questionnaire, for which also an [annotated CRF](#) exists, one can add a file "QS_skip_questions.txt" to the directory "QS_Skip_Questions".

2.0 Instruction: I have a series of questions that range from simple functioning to employment that I would like to ask. The first set of questions that I am going to ask you deals with communication abilities. Communication can be through voice, writing, or other methods such as signs or gestures.

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		
QSSSTRESQ/QSSSTRESN QSORRES	Go to #4	Go to #4	Go to #4

This file in the "QS_Skip_Questions" folder then contains the information whether an item can be skipped, and will be used to generate "NOT DONE" records for the skipped questions when that information is not explicitly available in the source database and ODM.

The SDTM-ETL distribution already contains such an example file for the "Disability Rating Scale". The file is named "QS_skip_questions.txt". Here are some of the contents:

```
QS_skip_questions.txt
6 DRS:QSDRS|ED102_1|ED1-Able to Communicate Clearly|COMMUNICATION ABILITY|false
7 DRS:QSDRS|ED102_2|ED1-How They Communicate Primarily|COMMUNICATION ABILITY|true
8 DRS:QSDRS|ED102_3|ED1-Correct Date and Time|COMMUNICATION ABILITY|true
9 DRS:QSDRS|ED102_4|ED1-Few Words or Random Answers/Shouting|COMMUNICATION ABILITY|true
10 DRS:QSDRS|ED102_5|ED1-Moan/Groan/Sounds Not Understandable|COMMUNICATION ABILITY|true
11 DRS:QSDRS|ED104_1|ED1-Fed Independently Without Help|FEEDING|false
12 DRS:QSDRS|ED104_2|ED1-Understand Feeding Utensils|FEEDING|true
13 DRS:QSDRS|ED104_3|ED1-Know Meal Times|FEEDING|true
14 DRS:QSDRS|ED105_1|ED1-Use Toilet Independently|TOILETING|false
15 DRS:QSDRS|ED105_2|ED1-Manage Clothing When Toileting|TOILETING|true
16 DRS:QSDRS|ED105_3|ED1-Know When to Use Toilet|TOILETING|true
17 DRS:QSDRS|ED106_1|ED1-Can Dress/Groom Independently|GROOMING|false
18 DRS:QSDRS|ED106_2|ED1-Know How to Bathe/Wash|GROOMING|true
19 DRS:QSDRS|ED106_3|ED1-Understand How to Get Dressed|GROOMING|true
20 DRS:QSDRS|ED106_4|ED1-Start/Finish Grooming Activities|GROOMING|true
21 DRS:QSDRS|ED107_1|ED1-Function Completely Independently|LEVEL OF FUNCTIONING|false
22 DRS:QSDRS|ED107_2|ED1-Require Specific Aids/Equipment|LEVEL OF FUNCTIONING|false
23 DRS:QSDRS|ED107_3|ED1-Require Physical Assistance|LEVEL OF FUNCTIONING|false
24 DRS:QSDRS|ED107_4|ED1-Require Assistance Thinking Tasks|LEVEL OF FUNCTIONING|false
25 DRS:QSDRS|ED107_5|ED1-Require Assistance Managing Emotions|LEVEL OF FUNCTIONING|false
26 DRS:QSDRS|ED107_6A|ED1-Need a Helper Always Close By|LEVEL OF FUNCTIONING|false
27 DRS:QSDRS|ED107_6B|ED1-Need Help With All Major Activities|LEVEL OF FUNCTIONING|false
28 DRS:QSDRS|ED107_6C|ED1-Need 24-Hour Care|LEVEL OF FUNCTIONING|false
29 DRS:QSDRS|ED108_1|ED1-Independent Work/Social Situations|EMPLOYABILITY|false
30 DRS:QSDRS|ED108_2|ED1-Understand/Follow Directions|EMPLOYABILITY|false
31 DRS:QSDRS|ED108_3|ED1-Keep Track of Time/Schedules|EMPLOYABILITY|false
32 DRS:QSDRS|ED108_4|ED1-Perform Jobs, Manage Home/School|EMPLOYABILITY|false
33 DRS:QSDRS|ED108_5|ED1-Successful With Accommodations|EMPLOYABILITY|true
```

Fields in the file are separated by a vertical bar "|". The fields are:

- Field 1: The QS dataset identifier
- Field 2: The question identifier (OID of the ItemDef in the ODM file – for populating QSTESTCD)
- Field 3: The question label (for populating QSTEST)
- Field 4: The category (for filling QSCAT)
- Field 5: Boolean value whether the question can be skipped or not: when the value is "false", no "NOT DONE" record will ever be created for that item, as it could never be "logically skipped".

For example, the line:

```
13 DRS:QSDRS|ED104_3|ED1-Know Meal Times|FEEDING|true
```

indicates that for the dataset with identifier "DRS:QSDRS" (i.e. the QSDRS dataset in study "DRS") has an item "ED104_3" (the test code), with test name "ED1-Know Meal Times", with the category (QSCAT) "FEEDING" is an item that can be skipped under certain circumstances. If the software then detects that for a certain subject/visit combination, there is no data for item "ED104_3", it will generated a record with QSORRES empty, QSSTAT="NOT DONE" and QSREASND="LOGICALLY SKIPPED ITEM".

This file can contain information for more than one QS datasets. For example:

```

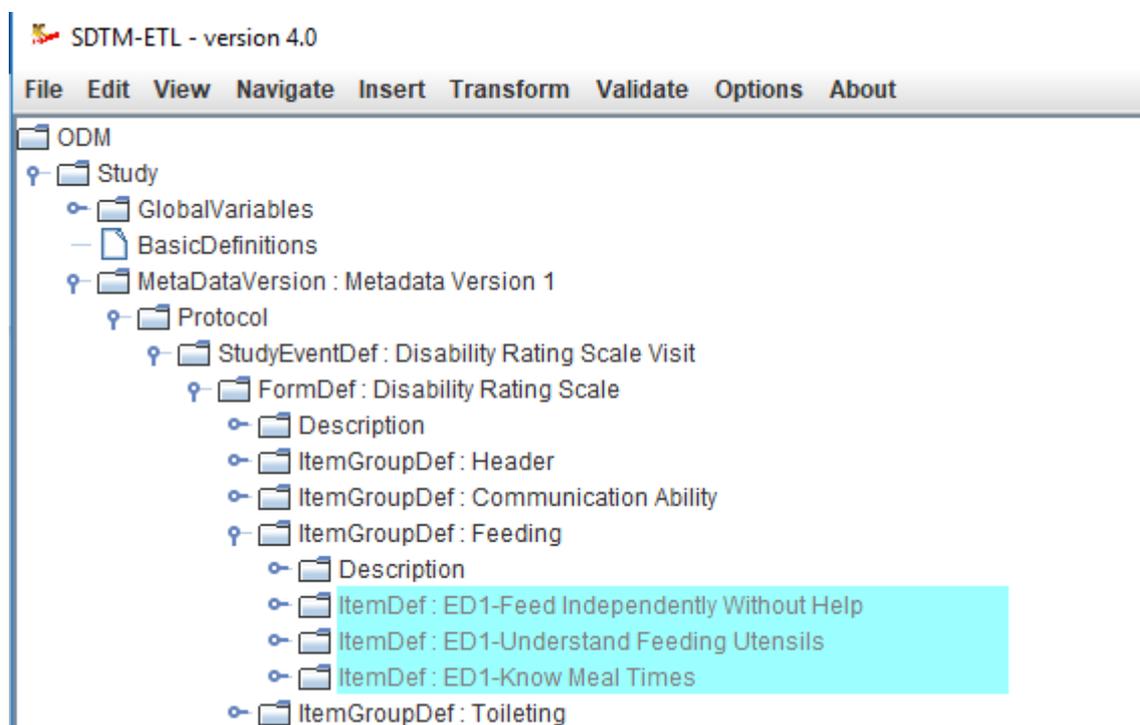
1 # mock questionnaire DDD
2 DRS:QSDDD|DDD_1|test question 1|NO CATEGORY|false
3 DRS:QSDDD|DDD_2|test question 2|NO CATEGORY|true
4 DRS:QSDDD|DDD_3|test question 2|NO CATEGORY|false
5 # Disability Rating Scale (DRS) questionnaire - see https://www.cdisc.org/foundational/qrs
6 DRS:QSDRS|ED102_1|ED1-Able to Communicate Clearly|COMMUNICATION ABILITY|false
7 DRS:QSDRS|ED102_2|ED1-How They Communicate Primarily|COMMUNICATION ABILITY|true

```

As one may have already guessed, lines starting with a "#" are comment files and will be ignored by the software.

If the software finds more than one file, or none at all, in the directory "QS_Skip_Questions", it will ask which one to use, and/or allow the user to select such a file.

In the SDTM-ETL, the ODM file with metadata for the "[Disability Rating Scale](#)" questionnaire, when loaded looks like¹:



The SDTM-ETL script for QSTESTCD looks like:

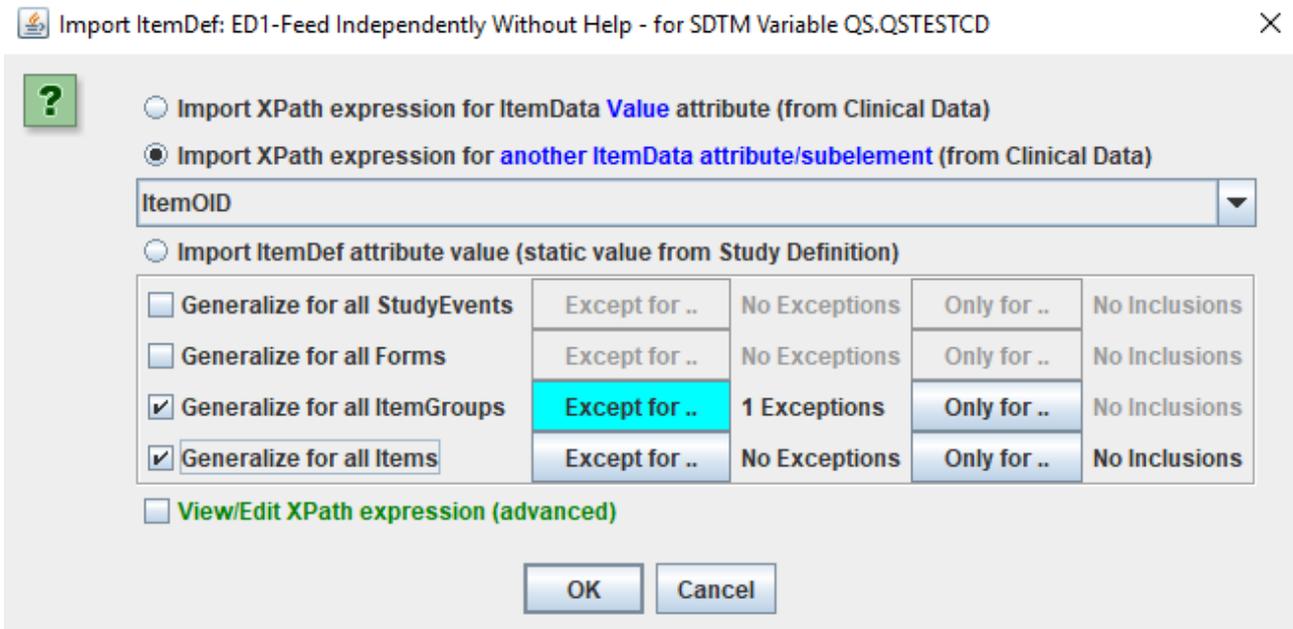
```

# Mapping using ODM element ItemData with ItemOID ED102_1 - value from attribute ItemOID
# Generalized for all ItemGroups within the Form
# Except for: IG.HEADER
# Generalized for all Items within the ItemGroup
$QS.QSTESTCD =
xpath(/StudyEventData[@StudyEventOID='SE.DRS']/FormData[@FormOID='FO.DRS']/ItemGroupData[not(@ItemGroupOID='IG.HEADER')]/ItemData/@ItemOID);

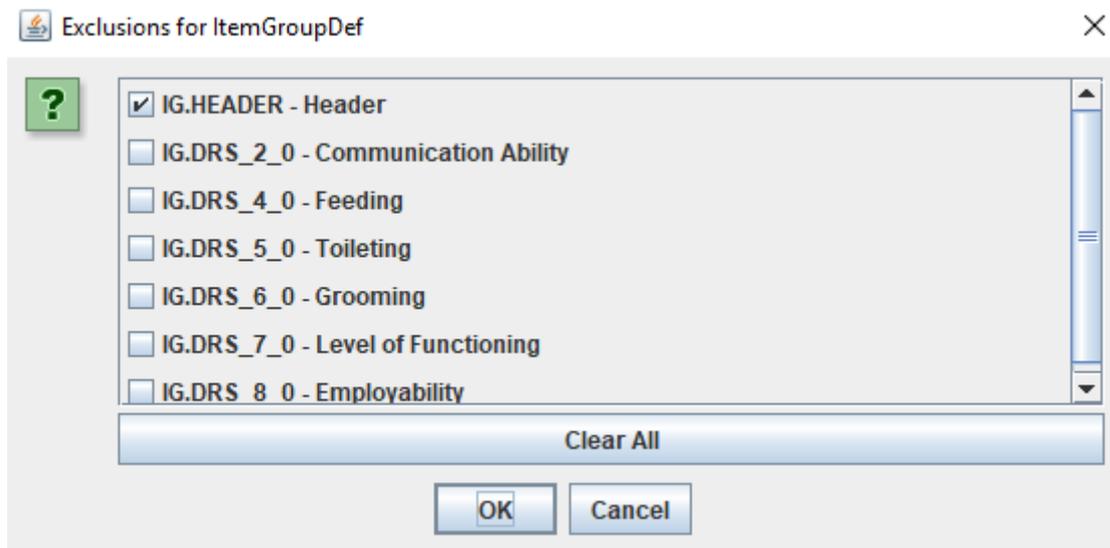
```

Stating an iteration over all items in the form, except for the items in the "header". It was automatically created after a simple drag and drop and using the wizard:

¹ A copy of the "Disability Rating Scale" ODM file and the corresponding SDTM-ETL define.xml file that were used for testing this new feature, can be found in the distribution. Look for file "DRS_QRS_Metadata_ClinicalData.xml" in the folder "TestFiles\ODM1-3" and the folder "TestFiles\Define_2_0_Mappings\QRS_skip_questions".



With the one exception generated by clicking "Except for ..." in "Generalize for all ItemGroups":



The script for "QSORRES" was generated in a very similar way and looks like:

?
External Document Link

Mapping Description and Link to external Document

SDTM-ETL mapping for QS.QSORRES

The Transformation Script

```

# Mapping using ODM element ItemData with ItemOID ED102_1
# Generalized for all ItemGroups within the Form
# Except for: IG.HEADER
# Generalized for all Items within the ItemGroup
# Generalized for all ItemGroups within the Form
# Except for: IG.HEADER
# Generalized for all Items within the ItemGroup
# Using decoded values from ODM CodeList CL.ED102_1
$CODEDVALUE = xpath(/StudyEventData[@StudyEventOID='SE.DRS']/FormData[@FormOID='FO.DRS']/ItemGroupData[not(@Item
if ($QS.QSTESTCD == 'ED102_1') {
    $TEMP = decode($CODEDVALUE,'CL.ED102_1','en');
} elseif ($QS.QSTESTCD == 'ED102_2') {
    $TEMP = decode($CODEDVALUE,'CL.ED102_2','en');
} elseif ($QS.QSTESTCD == 'ED102_3') {
    $TEMP = decode($CODEDVALUE,'CL.ED102_3','en');
} elseif ($QS.QSTESTCD == 'ED102_4' or $QS.QSTESTCD == 'ED102_5') {
    $TEMP = decode($CODEDVALUE,'CL.N_0_Y_1','en');
} elseif ($QS.QSTESTCD == 'ED104_2' or $QS.QSTESTCD == 'ED104_3') {
    $TEMP = decode($CODEDVALUE,'CL.ALWAYS_TO_NEVER','en');
        
```

It uses the "decode()" function as the answers in the database are stored as numeric values, like "0" for "Always", "1" for "Most of the time", "2" for "Some of the time" and "3" for "Never". Storing the answers in the database as numeric values makes sense, as these numbers represent a score, from which the total score is calculated.

This can be easily visualized using the menu "View – Item Associated CodeList":

Details for CodeList: Always to Never (OID: CL.ALWAYS_TO_NEVER) ✕

i

Coded Value	Language	Decoded Text
0	en	Always
1	en	Most of the time
2	en	Some of the time
3	en	Never

We also need take care that there is a "dummy" mapping specified in QSSTAT and QSREASND, as these will be automatically populated in a post-mapping run, i.e. this run will override the values in QSSTAT and QSREASND:

Mapping Description and Link to external

SDTM-ETL mapping for QS.QSSTAT

The Transformation Script

```
$QS.QSSTAT = '';
```

Mapping Description and Link to external

SDTM-ETL mapping for QS.QSREASND

The Transformation Script

```
$QS.QSREASND = '';
```

When we now run "Transform – Generate Transformation Code" followed by "Execute Transformation Code", the system detects that there is a study-specific QS dataset instance defined, and makes an additional checkbox "Generate 'NOT DONE' records for QS datasets" available:

Perform post-processing for assigning --LOBXFL
 Split records > 200 characters to SUPP-- records
 Move Relrec Variables to Related Records (RELREC) domain
 View Result SDTM tables
 Generate 'NOT DONE' records for QS datasets
 Save Result SDTM tables as SAS XPORT files
SAS XPORT files directory:

If we leave this checkbox unchecked, nothing special will happen, and our QSDRS dataset will look like:

SAS System Viewer - [QSDRS.xpt]

STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSORRES	QSSTRESC	QSSTRESN	QSSTAT	QSREASND	QSEVAL	VISITNUM	QSDTC
1	DRS	QS	P001	1	ED102_1	ED1-Able to Communicate Clearly	COMMUNICA	Consisten	0	0		CAREGIVER	1	2015-02-16
2	DRS	QS	P001	2	ED102_2	ED1-How They Communicate Primari	COMMUNICA	Speech	0	0		CAREGIVER	1	2015-02-16
3	DRS	QS	P001	3	ED102_3	ED1-Correct Date and Time	COMMUNICA	Sometimes	2	2		CAREGIVER	1	2015-02-16
4	DRS	QS	P001	4	ED104_1	ED1-Feed Independently Without H	FEEDING	Yes	Yes	.		CAREGIVER	1	2015-02-16
5	DRS	QS	P001	5	ED104_2	ED1-Understand Feeding Utensils	FEEDING	Always	0	0		CAREGIVER	1	2015-02-16
6	DRS	QS	P001	6	ED104_3	ED1-Know Meal Times	FEEDING	Always	0	0		CAREGIVER	1	2015-02-16
7	DRS	QS	P001	7	ED105_1	ED1-Use Toilet Independently	TOILETING	Yes	Yes	.		CAREGIVER	1	2015-02-16
8	DRS	QS	P001	8	ED105_2	ED1-Manage Clothing When Toileti	TOILETING	Always	0	0		CAREGIVER	1	2015-02-16
9	DRS	QS	P001	9	ED105_3	ED1-Know When to Use Toilet	TOILETING	Always	0	0		CAREGIVER	1	2015-02-16
10	DRS	QS	P001	10	ED106_1	ED1-Can Dress/Groom Independentl	GROOMING	No	No	.		CAREGIVER	1	2015-02-16
11	DRS	QS	P001	11	ED106_2	ED1-Know How to Bathe/Wash	GROOMING	Always	0	0		CAREGIVER	1	2015-02-16
12	DRS	QS	P001	12	ED106_3	ED1-Understand How to Get Dresse	GROOMING	Most of t	1	1		CAREGIVER	1	2015-02-16
13	DRS	QS	P001	13	ED106_4	ED1-Start/Finish Grooming Activi	GROOMING	Some of t	2	2		CAREGIVER	1	2015-02-16
14	DRS	QS	P001	14	ED107_1	ED1-Function Completely Independ	LEVEL OF	No	1	1		CAREGIVER	1	2015-02-16
15	DRS	QS	P001	15	ED107_2	ED1-Require Specific Aids/Equipm	LEVEL OF	No	0	0		CAREGIVER	1	2015-02-16
16	DRS	QS	P001	16	ED107_3	ED1-Require Physical Assistance	LEVEL OF	0	0	0		CAREGIVER	1	2015-02-16
17	DRS	QS	P001	17	ED107_4	ED1-Require Assistance Thinking	LEVEL OF	1	1	1		CAREGIVER	1	2015-02-16
18	DRS	QS	P001	18	ED107_5	ED1-Require Assistance Managng	LEVEL OF	0	0	0		CAREGIVER	1	2015-02-16
19	DRS	QS	P001	19	ED107_6A	ED1-Need a Helper Always Close B	LEVEL OF	No	0	0		CAREGIVER	1	2015-02-16
20	DRS	QS	P001	20	ED107_6B	ED1-Need Help With All Major Act	LEVEL OF	No	0	0		CAREGIVER	1	2015-02-16
21	DRS	QS	P001	21	ED107_6C	ED1-Need 24-Hour Care	LEVEL OF	No	0	0		CAREGIVER	1	2015-02-16
22	DRS	QS	P001	22	ED108_1	ED1-Independent Work/Social Situ	EMPLOYABI	Always	0	0		CAREGIVER	1	2015-02-16
23	DRS	QS	P001	23	ED108_2	ED1-Understand/Follow Directions	EMPLOYABI	Most of t	1	1		CAREGIVER	1	2015-02-16
24	DRS	QS	P001	24	ED108_3	ED1-Keep Track of Time/Schedules	EMPLOYABI	Most of t	1	1		CAREGIVER	1	2015-02-16
25	DRS	QS	P001	25	ED108_4	ED1-Perform Jobs, Manage Home/Sc	EMPLOYABI	Uncertain	1	1		CAREGIVER	1	2015-02-16
26	DRS	QS	P001	26	ED108_5	ED1-Successful With Accommodatio	EMPLOYABI	Certain o	0	0		CAREGIVER	1	2015-02-16
27	DRS	QS	J001	1	ED102_1	ED1-Able to Communicate Clearly	COMMUNICA	No	2	2		CAREGIVER	1	2019-03-07
28	DRS	QS	J001	2	ED102_4	ED1-Few Words or Random Answers/	COMMUNICA	Yes	1	1		CAREGIVER	1	2019-03-07
29	DRS	QS	J001	3	ED104_1	ED1-Feed Independently Without H	FEEDING	Yes	Yes	.		CAREGIVER	1	2019-03-07
30	DRS	QS	J001	4	ED104_2	ED1-Understand Feeding Utensils	FEEDING	Always	0	0		CAREGIVER	1	2019-03-07

QSSTRESN (and thus also QSSTRESC) contain the numeric (coded) values from the source database, whereas QSORRES contains the text value of the answer. This is also as described in the [CDISC document](#). Remark that "skipped questions" according to DRS rules are ... skipped, and do not appear in the dataset.

When however the checkbox "Generate 'NOT DONE' records for QS datasets" is checked:

View Result SDTM tables
 Generate 'NOT DONE' records for QS datasets
 Save Result SDTM tables as SAS XPORT files
SAS XPORT files directory:

The result is:

STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSORRES	QSSTRES	QSSTRESN	QSSTAT	QSREASND	QSEVAL	VISITNUM	QSD	
1	DRS	GS	P001	1	ED102_1	ED1-Able to Communicate Clearly	COMMUNICATION ABILITY	Consistently	0	0		CAREGIVER	1	2015-4	
2	DRS	GS	P001	2	ED102_2	ED1-How They Communicate Primarily	COMMUNICATION ABILITY	Speech	0	0		CAREGIVER	1	2015-4	
3	DRS	GS	P001	3	ED102_3	ED1-Correct Date and Time	COMMUNICATION ABILITY	Sometimes	2	2		CAREGIVER	1	2015-4	
4	DRS	GS	P001	4	ED102_4	ED1-Few Words or Random Answers/Shouting	COMMUNICATION ABILITY				NOT DONE	LOGICALLY SKIPPED ITEM	CAREGIVER	1	2015-4
5	DRS	GS	P001	5	ED102_5	ED1-Moan/Groan/Sounds Not Understandable	COMMUNICATION ABILITY				NOT DONE	LOGICALLY SKIPPED ITEM	CAREGIVER	1	2015-4
6	DRS	GS	P001	6	ED104_1	ED1-Feed Independently Without Help	FEEDING	Yes	Yes			CAREGIVER	1	2015-4	
7	DRS	GS	P001	7	ED104_2	ED1-Understand Feeding Utensils	FEEDING	Always	0	0		CAREGIVER	1	2015-4	
8	DRS	GS	P001	8	ED104_3	ED1-Know Meal Times	FEEDING	Always	0	0		CAREGIVER	1	2015-4	
9	DRS	GS	P001	9	ED105_1	ED1-Use Toilet Independently	TOILETING	Yes	Yes			CAREGIVER	1	2015-4	
10	DRS	GS	P001	10	ED105_2	ED1-Manage Clothing When Toileting	TOILETING	Always	0	0		CAREGIVER	1	2015-4	
11	DRS	GS	P001	11	ED105_3	ED1-Know When to Use Toilet	TOILETING	Always	0	0		CAREGIVER	1	2015-4	
12	DRS	GS	P001	12	ED106_1	ED1-Can Dress/Groom Independently	GROOMING	No	No			CAREGIVER	1	2015-4	
13	DRS	GS	P001	13	ED106_2	ED1-Know How to Bathe/Wash	GROOMING	Always	0	0		CAREGIVER	1	2015-4	
14	DRS	GS	P001	14	ED106_3	ED1-Understand How to Get Dressed	GROOMING	Most of the time	1	1		CAREGIVER	1	2015-4	
15	DRS	GS	P001	15	ED106_4	ED1-Start/Finish Grooming Activities	GROOMING	Some of the time	2	2		CAREGIVER	1	2015-4	
16	DRS	GS	P001	16	ED107_1	ED1-Function Completely Independently	LEVEL OF FUNCTIONING	No	1	1		CAREGIVER	1	2015-4	
17	DRS	GS	P001	17	ED107_2	ED1-Require Specific Aids/Equipment	LEVEL OF FUNCTIONING	No	0	0		CAREGIVER	1	2015-4	
18	DRS	GS	P001	18	ED107_3	ED1-Require Physical Assistance	LEVEL OF FUNCTIONING	Always	0	0		CAREGIVER	1	2015-4	
19	DRS	GS	P001	19	ED107_4	ED1-Require Assistance Thinking Tasks	LEVEL OF FUNCTIONING	Most of the time	1	1		CAREGIVER	1	2015-4	
20	DRS	GS	P001	20	ED107_5	ED1-Require Assistance Managing Emotions	LEVEL OF FUNCTIONING	Always	0	0		CAREGIVER	1	2015-4	
21	DRS	GS	P001	21	ED107_6A	ED1-Need a Helper Always Close By	LEVEL OF FUNCTIONING	No	0	0		CAREGIVER	1	2015-4	
22	DRS	GS	P001	22	ED107_6B	ED1-Need Help With All Major Activities	LEVEL OF FUNCTIONING	No	0	0		CAREGIVER	1	2015-4	
23	DRS	GS	P001	23	ED107_6C	ED1-Need 24-Hour Care	LEVEL OF FUNCTIONING	No	0	0		CAREGIVER	1	2015-4	
24	DRS	GS	P001	24	ED108_1	ED1-Independent Work/Social Situations	EMPLOYABILITY	Always	0	0		CAREGIVER	1	2015-4	
25	DRS	GS	P001	25	ED108_2	ED1-Understand/Follow Directions	EMPLOYABILITY	Most of the time	1	1		CAREGIVER	1	2015-4	
26	DRS	GS	P001	26	ED108_3	ED1-Keep Track of Time/Schedules	EMPLOYABILITY	Most of the time	1	1		CAREGIVER	1	2015-4	
27	DRS	GS	P001	27	ED108_4	ED1-Perform Jobs, Manage Home/School	EMPLOYABILITY	Uncertain	1	1		CAREGIVER	1	2015-4	
28	DRS	GS	P001	28	ED108_5	ED1-Successful With Accommodations	EMPLOYABILITY	Certain or very...	0	0		CAREGIVER	1	2015-4	
29	DRS	GS	P001	29	ED108_6	ED1-Successful With Limited Choices	EMPLOYABILITY				NOT DONE	LOGICALLY SKIPPED ITEM	CAREGIVER	1	2015-4
30	DRS	GS	P001	30	ED108_7	ED1-Work With Frequent Support	EMPLOYABILITY				NOT DONE	LOGICALLY SKIPPED ITEM	CAREGIVER	1	2015-4

We now see that there are "NOT DONE" records for ED102_4 and ED102_5 although the original ODM dataset does not contain any information about these "skipped questions". These records have been generated "post-mapping" from the information in the file "QS_skip_questions.txt".

Again, if your dataset also contains information about questions that were not asked or were skipped (e.g. as "999" records), all this is not necessary.

Extension FDA Technical Conformance Guide March 2025

In its "[Technical Conformance Guide March 2025](#)", the FDA has added yet-another-variable to be added in the case branching in the questionnaire has been defined:

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.

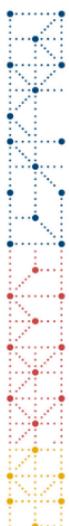
If instructions on how to record and/or score responses to items not done due to conditional branching are available from the instrument developer, then records for items with conditional branching should be included in the submission dataset with the following:

- QSCBRFL = "Y"
- QSORRES, QSSTRESC, and QSSTRESN would be assigned according to the instrument's instructions

If instructions on how to record and/or score responses to items not done due to conditional branching are not available from the instrument developer, then records for items with conditional branching should be included in the submission dataset with the following:

- QSSTAT = "NOT DONE",
- QSCBRFL = "Y" and,
- QSORRES, QSSTRESC, and QSSTRESN all set to null.
- QSREASND = missing or the sponsor-provided reason (e.g., "LOGICALLY SKIPPED ITEM")

but without any statement about what "QSCBRFL" means (label), or before/after which variable, or whether it should be added as a "Non-Standard Variable" (NSV). Adding it as a "standard variable" would violate the SDTM standard itself, as --CBRFL is not listed in the SDTM "Model". Fortunately, we could find some [background information in a presentation by CDISC](#) (from ... 2023 ...):



QRS Other Updates (Cont.)

- "Logically skipped item" update to "conditional branching" is under review with the representatives we work with at the FDA
- Meanwhile there's a new supplemental qualifier in use – --CBRFL (Conditional Branching Flag)
 - This will allow for indicating if an item was not done due to conditional branching
 - A new standard variable will be released in [SDTMIG v4.0](#) and the corresponding model SDTM v2.x/3.0.
 - Meanwhile, the CDISC SDS QRS Subteam will use QSCBRFL as a **non-standard variable**.

So, as we understand it, for FDA submissions, when there is branching, the QSCBRFL must be added as an NSV, with the label "*Conditional Branching Flag*", and thus appear in SUPPQS.

Adding the information into the NSV QSCBRFL will usually be very simple: just look for items like "go to" items in the questionnaire, and set QSCBRFL for these to "Y". For example for our "Disability Rating Scale" (not all questions shown here):

2.0 Instruction: I have a series of questions that range from simple functioning to employment that I would like to ask. The first set of questions that I am going to ask you deals with communication abilities. Communication can be through voice, writing, or other methods such as signs or gestures.

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
	Go to #4	Go to #4	Go to #4	Go to #4

Annotations in the table: **QSSSTRESC/QSSSTRESN** points to the '0' and '1' columns of row 2.3. **QSORRES** points to the 'Go to #4' cells of row 2.3.

One would need to set QSCBRFL=Y for QSTESTCD=ED102_1, and ED102_3, but not for QSTESTCD=ED102_2.

This can easily be accomplished by an if-elsif-else structure, e.g.

Mapping Description and Link to external Document

SDTM-ETL mapping for QS.QSCBRFL

Origin: No Origin has been added yet!

The Transformation Script

```

1 # Assignment of "Conditional Branching Flag" - QSCBRFL
2 if($QS.QSTESTCD = 'ED102_1' or $QS.QSTESTCD = 'ED102_3') {
3     $QS.QSCBRFL = 'Y';
4 } elsif(...) { # other variables from the "Disability Rating Scale"
5     ...
6 } else {
7     $QS.QSCBRFL = '';
8 }
9

```

In a next version of SDTM-ETL (once the new SDTMIG has been published) we will also add a feature that population of QSCBRFL can be steered directly from the file "QS_skip_questions.txt" contents (it will just be another boolean field in that file).

Further materials

Some interesting articles have been published about this new FDA rule and its implications and challenges for the generation of SDTM-QS datasets. Here is a short list (not claiming to be complete):

- [Challenges of Processing Questionnaire Data from Collection to SDTM to ADaM and Solutions using SAS®.](#)
- [CDISC Doesn't Tell You What to Collect, But Regulators Do!](#)
Phuse-US-2019 presentation Diane Wold, slides 22-25.
- [CDISC & PhUSE Roundtable: QRS \(Questionnaires, Ratings and Scales\) - Logically Skipped Questions in SDTM](#)
- [CDISC end-to-end: Logically Skipped Items in SDTM-QS](#)