

PP04 Novo Nordisk implementation of Logically Skipped Items for the QS=Questionnaires domain

Introduction

FDA Study Data 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 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.

CRF Example

QS = QUESTIONNAIRES

QSCAT=WPAI-SHP

QSSCAT= abbreviation for PROBLEM TA, when TA-specific

Work Productivity and Activity Impairment Questionnaire:
Specific Health Problem V2.0 (WPAI:SHP)

The following questions ask about the effect of your PROBLEM on your ability to work and perform regular activities. Please fill in the blanks or circle a number, as indicated.

1. Are you currently employed (working for pay)?
If NO, check "NO" and skip to question 6.

QSORRES for QSTESTCD=WPAI0101

___ NO ___ YES

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Challenges

Interpretation

- When to logically skip and when not to?
 - If Yes, describe
 - Suicidal Attempt=No, Total # of Attempts

Governance

- C-codes can be changed

Version

- Topic code vs C-code

MDR - Operational

- Structure, topic codes, categories

Language

- English – US/UK, e.g. EQ-5D-5L

Storage

- A huge number of "NOT DONE" records

Reflections

Why should one store data that is not captured, when the rules for not capturing are known anyway?

Alternatively describe "skip rules" in the define.xml

- Add the "skip rules" in a human-readable way to each variable definition in the "Derivation/Comment" field
- QSTESTCD EQ WPAI0102: Logically skipped for QSTESTCD=WPAI0101 with QSORRES=N

Glossary

LSI	Logically Skipped Item
Topic code	Identifies and classifies an observation with additional information linked to it ~ Biometrical concept

Solution & Examples

A Metadata Driven Solution

Define Questionnaires in scope for Logically Skipped Items

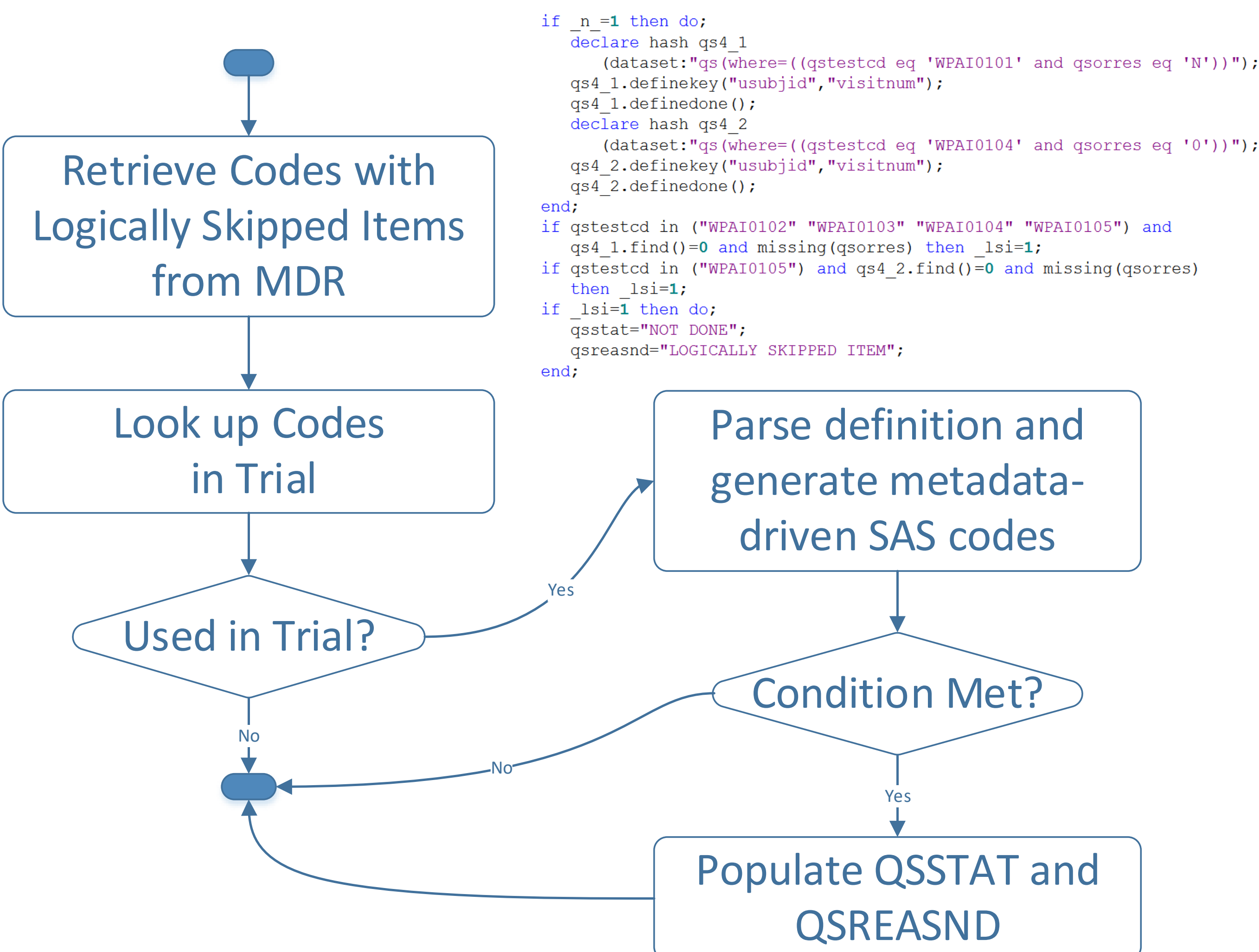
- User Defined Codelist for questionnaire category
- Define rule for when to apply 'logically skipped item' functionality
- 'Tag' specified in the code definition

[skip:(qstestcd eq 'WPAI0101' and qsorres eq 'N') | (qstestcd eq 'WPAI0104' and qsorres eq '0'))]

Standard Program

Will only apply 'logically skipped item' functionality if:

- Record exist
- No data for QSORRES already
- Rule fulfilled



SkipTag Syntax: LSI Condition

Example 1: Single LSI condition with multiple requirements

[skip:(qstestcd eq 'CSS0101' and qsorres eq 'N') and (qstestcd eq 'CSS0102' and qsorres eq 'N'))]

Example 2: Multiple LSI conditions

[skip:(qstestcd eq 'CSS0112' and qsorres ne 'Y') | (qstestcd eq 'CSS0121B' and qsorres ne '0'))]

Legend: Fixed text Required text Short Topic Code Collected Value Conditional

Data Examples

WPAI0102: [skip:(qstestcd eq 'WPAI0101' and qsorres eq 'N')]

WPAI0103: [skip:(qstestcd eq 'WPAI0101' and qsorres eq 'N')]

WPAI0105: [skip:(qstestcd eq 'WPAI0101' and qsorres eq 'N') | (qstestcd eq 'WPAI0104' and qsorres eq '0'))]

QSTESTCD	QSTEST	QSORRES	QSSTAT	QSREASND
WPAI0101	WPAI01-Currently Employed	N		
WPAI0102	WPAI01-Missed Work Hours Due to Problem		NOT DONE	LOGICALLY SKIPPED ITEM
WPAI0103	WPAI01-Missed Work Hours Due to Other		NOT DONE	LOGICALLY SKIPPED ITEM
WPAI0104	WPAI01-Hours Actually Worked		NOT DONE	LOGICALLY SKIPPED ITEM
WPAI0105	WPAI01-Problem Affect Productivity		NOT DONE	LOGICALLY SKIPPED ITEM
WPAI0106	WPAI01-Problem Affect Reg Daily Activity	0		

QSCAT=WPAI-SHP QSSCAT=OBESITY

QSTESTCD	QSTEST	QSORRES	QSORRESU	QSSTAT	QSREASND
WPAI0101	WPAI01-Currently Emp...	Y			
WPAI0102	WPAI01-Missed...Problem	0	HOURS		
WPAI0103	WPAI01-Missed...Other	20	HOURS		
WPAI0104	WPAI01-Hours...Worked	0	HOURS		
WPAI0105	WPAI01-Problem...Prod...			NOT DONE	LOGICALLY SKIPPED ITEM
WPAI0106	WPAI01-Problem...Activity	0			