Paper SI06

Electronic Clinical Outcome Assessment (eCOA) in SDTM: Challenges and Solution

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ABSTRACT

Electronic Clinical Outcome Assessment (eCOA) is a method of capturing outcomes data electronically in clinical trials. eCOA employs technologies such as handheld devices, tablets, or the web to allow trial participants, physicians, and caregivers to directly report information related to healthcare outcomes. Data can be submitted by participants from home and integrated with the trial's electronic data capture (EDC) system to reduce the burden on clinical site coordinators to manually input patient information.

Because of the different sources, volume, and complexity of eCOA data, it creates a challenge for Study Data Tabulation Model (SDTM), team to map it into standard domain without losing any information from raw data. In this paper, we will discuss the aftermath of receiving eCOA data, challenges for SDTM team to map this data and the solution. This presentation will also emphasize analysis of raw data along with pre planning to achieve streamlined and efficient SDTM output.

INTRODUCTION

Electronic Clinical Outcome Assessment (eCOA) tools have revolutionized data collection in clinical trials, enhancing the accuracy and efficiency of patient reported data. To facilitate regulatory submissions and data analysis, it is crucial to map eCOA data to the SDTM, which is a standardized format for organizing and submitting clinical trial data. However, this process is not without challenges. This paper aims to explore these challenges and offer solutions for effective eCOA data mapping to SDTM.

CHALLENGES AND SOLUTIONS IN MAPPING ECOA DATA TO SDTM:

DATA VARIABILITY

eCOA data often exhibit variability in terms of data types, formats, and structures. This variability can make it challenging to create a consistent mapping to SDTM domains and variables.

The very first step to map eCOA into SDTM efficiently is based on coordination of sponsor with vendor to finalize study specific Data Transfer Specification to receive raw data as close as possible to SDTM conventions. The vendor eCOA form should be reviewed by all stakeholders including Data Management, SDTM, Analysis Data Model (ADaM) and Stats to decide on TESTCD, TEST, Category (CAT), Subcategory (SCAT) and coded/decoded results in compliance with Clinical Data Interchange Standards Consortium (CDISC) standard. Once this is achieved, we can easily map vendor data to SDTM domains which results in standardized data available to all downstream teams.

Below is vendor data sample where QSTEST is not compliant with CDISC Code list. With extensive review of every test and related fields in Data Transfer Specification document, remapping of data in SDTM can be largely reduced. It will also support efficiency to the downstream team.

Vendor eCOA sample data:

	QSTESTCD	QSTEST	QSCAT	QSSCAT
1	SF36401	SF364-In General Your Health Is	SF36 V2.0 ACUTE	

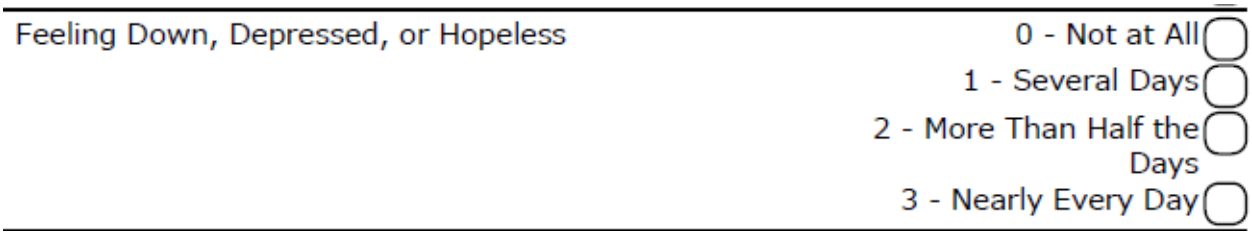
SDTM data with QSTEST formatted as per CDISC CT and QSSCAT:

	QSTESTCD	QSTEST	QSCAT	QSSCAT
1	SF36401	SF364-In General You Say Your Health Is	SF36 V2.0 ACUTE	GENERAL HEALTH PERCEPTIONS

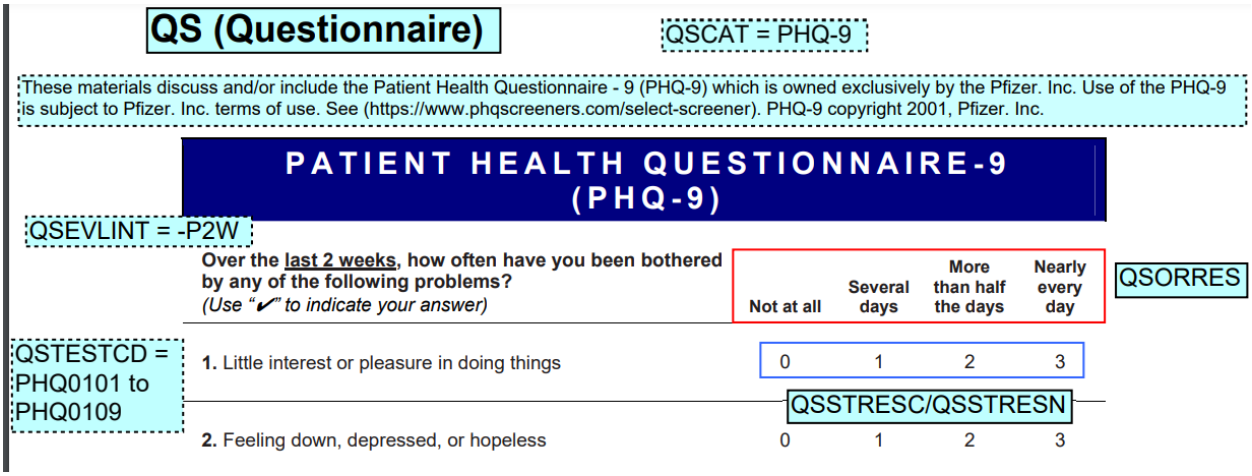
HANDLING DECODED RESULT VALUES

eCOA data often have numeric decoded values for test results and it is critical information for analysis team and stats. If eCOA data is coming from external vendor and eDC both, we need to make sure that decoded values are also same for a particular test in a form. Any mismatch between decoded values between two different sources can produce erroneous STRESC/STRESN in SDTM. Below is one example of Patient Health Questionnaire (PHQ-9) form:

QSSTRESC/QSSTRES	QSORRES
0	Not at all
1	Several days
2	More than half the days
3	Nearly every day



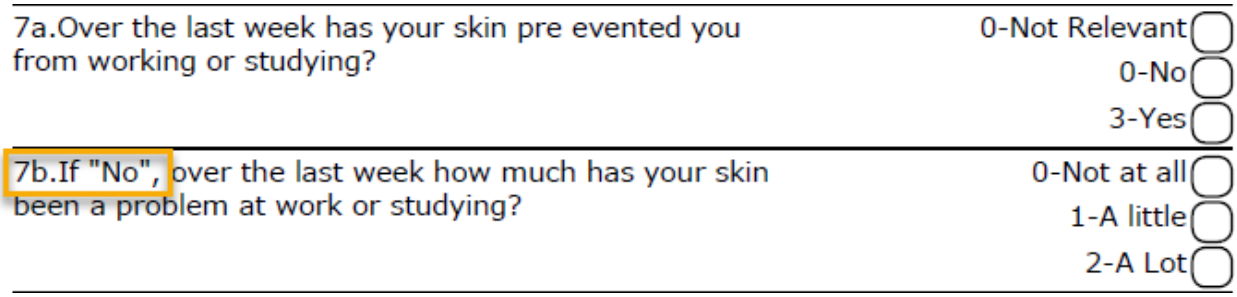
CDISC Questionnaires, Ratings and Scales (QRS) Standard should be the ultimate source for such decoded values:



MAPPING MISSING DATA VALUES AND LOGICALLY SKIPPED ITEMS

Questionnaire forms have series of questions and many times, as per design, questions can be interdependent and extension question might need no result based on a particular response from parent question. In below example, Question 7b response is expected to be missing if 7a result is not "No"

In cases where 7a result is not "No", we receive 7b as missing result in raw data. This is neither "Missing Result" nor "Not Done" record. We can map it with ORRES as missing while STAT as "NOT DONE" and REASND as "LOGICALLY SKIPPED ITEM" to reflect accurate value.



MAPPING EVALUATION INTERVAL DATA

Evaluation Interval tagged along with Questionnaire is sometimes tricky to find and map it in SDTM. As shown in the example below, we need to read through every question to know if it indicates any Evaluation Interval. In some cases, it's printed at the very start of form before questions but not applicable to all subsequent questions. Incorrect "Evaluation Interval" can lead to issue with analysis results.

Evaluation Interval Text	QSEVINTX	LIFETIME

4. During the past week, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

4a. Cut down on the amount of time you spent on your work or other activities QSEVLINT= -P1W	1 - All of the time ☐ 2 - Most of the time ☐ 3 - Some of the time ☐ 4 - A little of the time ☐ 5 - None of the time ☐

HANDLING NOT PERFORMED RECORDS

We have seen the cases with vendor data where "Not Done" record is collected on subject-visit level without relating it to eCOA forms where assessment was not done. Below is a sample row for such data.

Raw Data:

SUBJID	VISIT	QSTESTCD	QSCAT	QSSTAT	QSDTC
9999	Screening			NOT DONE	2/22/2023

SDTM:

In case we directly map above raw data in SDTM, it will not provide the detail of eCOA forms where assessment was not performed a particular visit.

USUBJID	VISIT	QSTESTCD	QSCAT	QSSTAT	QSDTC
Study/9999	SCREENING	QSALL		NOT DONE	2/22/2023

To get all eCOA forms, where assessment was not done at a visit, team needs to refer Protocol to populate QSCAT as shown in below example. However, the SDTM team ends up manufacturing records in this case.

USUBJID	VISIT	QSTESTCD	QSCAT	QSSTAT	QSDTC
Study/9999	SCREENING	QSALL	PHQ-9	NOT DONE	2/22/2023
Study/9999	SCREENING	QSALL	C-SSRS BASELINE/SCREENING VERSION	NOT DONE	2/22/2023
Study/9999	SCREENING	QSALL	EQ-5D-3L	NOT DONE	2/22/2023

The best solution is to collaborate with eCOA vendor to point out such cases and request to provide forms name as well in raw data even for "Not Done" records. It streamlines the process and provides full clarity of data to the downstream team.

In this paper, we pointed out specific cases to help SDTM teams to better understand eCOA data and proactively save time, deliver quality and to build efficiency in SDTM mapping. Above solutions can be generalized and summarized as below:

STANDARDIZATION
Implementing a standardized approach to eCOA data collection and mapping is essential. This includes defining standardized data types and formats for eCOA instruments.

METADATA MANAGEMENT
Maintaining comprehensive metadata for eCOA instruments, including controlled terminology and metadata standards, can facilitate mapping and ensure data quality.

CROSS-FUNCTIONAL COLLABORATION
Collaboration between clinical, data management, and regulatory affairs teams is essential. Regular communication and cross-functional review can help address mapping challenges effectively.

VALIDATION AND QUALITY CONTROL
Implementing rigorous validation and quality control processes for the mapped eCOA data can identify and rectify mapping errors, ensuring data accuracy.

REGULATORY ALIGNMENT
Stay up to date with regulatory guidance related to eCOA data mapping to SDTM. Compliance with evolving regulations is crucial for successful submissions.

CONCLUSION
Mapping eCOA data to SDTM is a complex process with inherent challenges, but it is crucial for standardized data submission and regulatory compliance. By adopting standardized approaches, leveraging technology, and fostering cross-functional collaboration, these challenges can be effectively addressed. Moreover, maintaining data quality and regulatory alignment are fundamental to ensuring the success of eCOA data mapping to SDTM, ultimately contributing to the advancement of clinical research and drug development.

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