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Getting More Efficiency from your Instruments Using CDISC

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ABSTRACT

It is common in clinical programming to reuse programs, macros, and snippets for efficiency in time and processes. Entire libraries of programs are stored to be taken "off the shelf" and plugged into new studies. In the emerging area of electronic Clinical Outcome Assessments (eCOA) and electronic Patient Reported Outcomes (ePRO), this translates into a library of standardized questionnaires that can be dropped into new studies for faster startup and quicker subject enrollment. This presentation will focus on expanding the efficiency of questionnaire libraries by applying CDISC standards to collected data. Utilizing the growing library of CDISC QRS supplements and existing questionnaire libraries, vendors can prepopulate SDTM variables with appropriate code lists and controlled terminology. Having these CDISC standards stored in their existing "Off the Shelf" questionnaires means that eCOA vendors can expedite startup, patient enrollment, analysis, and submission reducing the need for post-processing data downstream.

INTRODUCTION

As with any business, there is a push to make clinical trials faster, cheaper, and more efficient to get products into the hands of consumers as quickly and as affordably as possible. The clinical trial industry has pushed this trend beyond just pure economics which has improved patient outcomes. Every day that is removed from the timeline of compound and device development might mean extra or improved days in a patient's life. Every dollar that is saved from the cost of a single drug's development might go on to fund research in other life-saving compounds. Those of us in this industry have a duty to our patients to shorten the clinical trial life cycle so that life-saving treatments can be made available safely and quickly.

In the area of electronic Clinical Outcomes Assessments (eCOA) and electronic Patient Reported Outcomes (ePRO), gaining efficiency through digital record collection is already a primary goal by eliminating the need to transcribe paper entries into electronic formats. However, authors believe that eCOA, ePRO, and the industry could gain even more efficiency by utilizing a common programming tool: the program library. A program library, when combined with Clinical Data Interchange Standards Consortium (CDISC) standards, can be used to grow a collection of standard "off the shelf" instruments (questionnaires) that could then be dropped into new clinical trials with little to no customization. This could lead to faster study setup, faster enrollment, and savings in cost and effort.

HOW ARE ECOA AND EPRO DATA COLLECTED NOW?

Currently, eCOA and ePRO only go a little beyond the paper source of the instrument. There is a question on a form and the instrument collects the subject's answer and the date and time it was answered. Below is a screenshot of an electronic version of a standard instrument: EQ-5D-5L (figure 1) and the electronically collected values (figure 2).

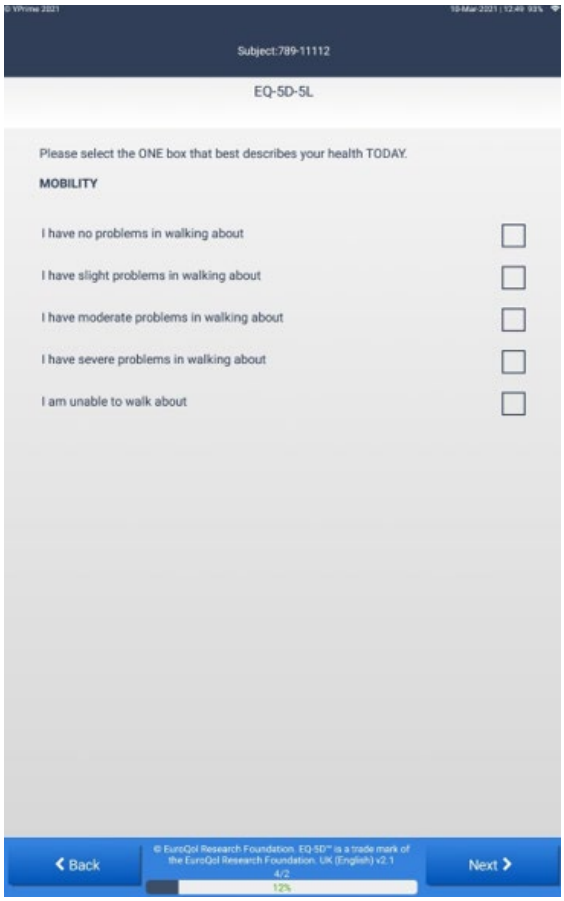

Figure 1

INSTRUMENT	ITEM	VALUE	DATE
EQ-5D-5L	Please tap the ONE box that best describes your health TODAY. MOBILITY	I have no problems walking	2023-09-19T15:32:33

Figure 2

It seems straightforward that this information is appropriate to collect and should be the only thing needed because if the subject were still filling this form out on paper, that is all that would be available, minus the timestamp. There is, however, more to consider: How are these data used downstream? How are they used in conjunction with other study data? How are they ingested into the overall data stream? How are they analyzed? How are they presented to regulatory authorities for submission? Most readers will realize that the answer to the above questions is that they are post-processed into industry-wide standardized data models established in partnership with CDISC and regulatory authorities. What does this mean in practice? It means that someone has to take the collected data and spend time, effort, and money processing them so that they fit these models. Compare Figure 2 above to Figure 3 below, which is the exact same answer to the exact same question processed to meet some of the CDISC Standard Data Tabulation Model (SDTM) standard. Why not just collect data in this format from the beginning?

DOMAIN	QSDTC	QSCAT	QSTESTCD	QSTEST	QSORRES	QSSTRESC	QSSTRESN	QSEVINTX	QSEVAL
QS	2023-09-19T15:32:33	EQ-5D-5L	EQ5D0201	EQ5D02-MOBILITY	I have no problems walking	1	1	TODAY	STUDY SUBJECT

Figure 3

USING CDISC STANDARDS TO GAIN EFFICIENCY

eCOA and ePRO vendors are already gaining efficiency by building programming libraries to create a group of off-the-shelf instruments for studies. It is time to combine those libraries with CDISC standards to gain further efficiencies by populating CDISC values simultaneous to entry on the device. This will eliminate much of the need to post-process collected eCOA and ePRO data after the vendor collects them. While this will mean the vendor may need to invest more upfront time in adding this information to existing library programs, much of the information needed to be included is already detailed clearly in the CDISC Questionnaires, Ratings, and Scales (QRS) Supplements web page. One part of the QRS supplement that is particularly useful is the Annotated Case Report Form (aCRF). Below in Figure 4 is the aCRF for the page of the EQ-5D-5L used in the previous examples, while Figure 5 shows that same information applied to the electronic device screen. This clearly shows how information from CDISC supplements can be directly applied to eCOA and ePRO devices to simplify data collection.

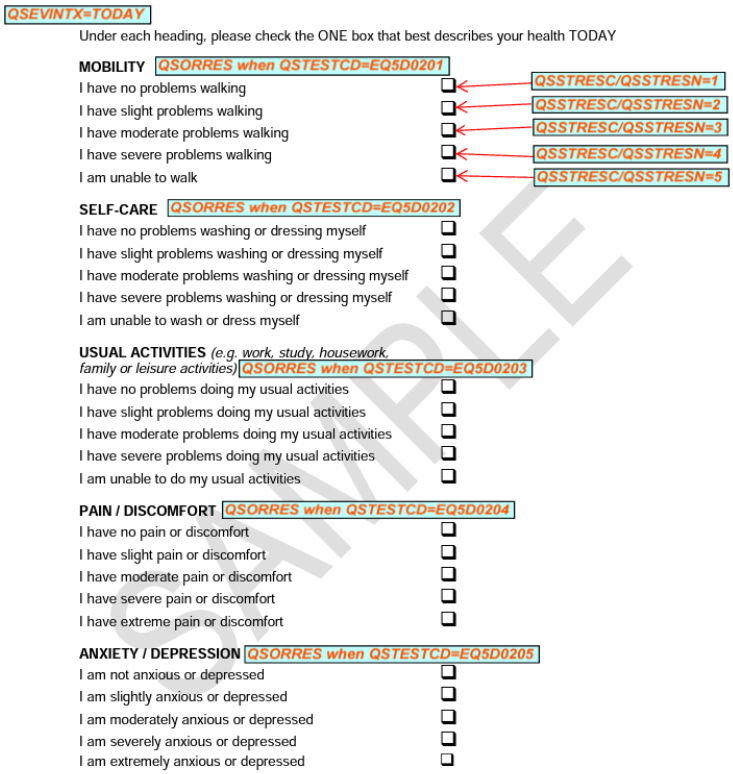

Figure 4

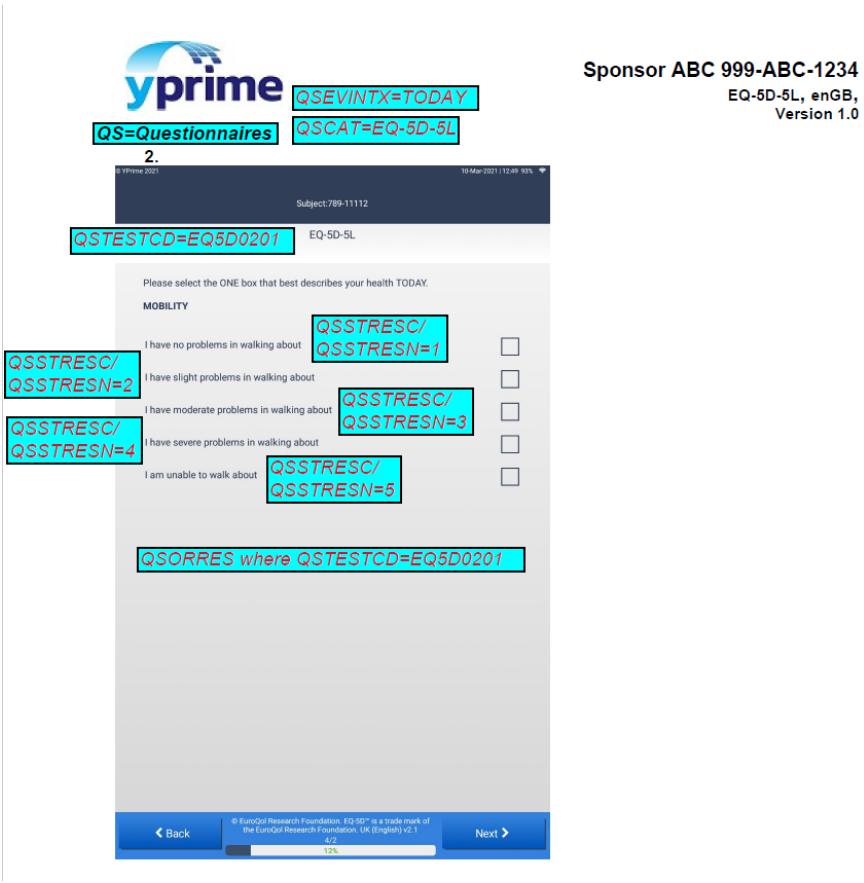

Figure 5

CHALLENGES TO IMPLEMENTATION

While moving to put CDISC standardization in vendor programming libraries will ultimately gain efficiencies for the overall clinical trial process, several challenges and barriers can impact or slow these gains.

- The Programming and development costs moves upstream to the vendor.
  - Mitigation: Each subsequent use of a programmed instrument increases overall efficiency
- Study-specific customization nullifies any efficiencies gained by the pre-programmed standard library.
  - Mitigation: Study teams may need to prioritize time and cost over customization.
- CDISC QRS supplement library is large and growing but not exhaustive.
  - Mitigation: Use of basic SDTM processes can be used to implement for instruments that do not exist in QRS supplements or have their own controlled terminology
  - Mitigation: Assist CDISC in developing QRS supplements or Controlled Terminology for the desired instrument.
- Lack of consistent standard adoption by sponsors. Many sponsors have in-house, custom, or no standards for eCOA and ePRO data.
  - Mitigation: Push sponsors to adopt CDISC standards and make SDTM the standard for the entire data life cycle.
  - Mitigation: The availability of faster and more cost-effective pre-programmed standardized instruments may encourage sponsors to adopt CDISC standards and gain overall efficiencies.

CONCLUSION

While there are some challenges to combining instrument programming libraries with CDISC standards, the benefits of collecting data in the manner in which it can easily be transferred, analyzed, and submitted have inherited benefits to the overall costs of time and effort. By implementing CDISC standards at data collection, eCOA and ePRO vendors can provide a product that not only reduces clinical trial costs but helps to get life saving treatments into the hands of caregivers faster. Additionally, embedding these standards in data collection may coax the industry to adopt an industry-wide standard from data collection to submission.

RECOMMENDED READING

CDISC QRS SUPPLEMENTS https://www.cdisc.org/standards/foundational/qrs

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