



A Better Way: eCOA/ePRO Annotated Screen Reports (aSR) Provide Data Clarity from Data Collection to Submission

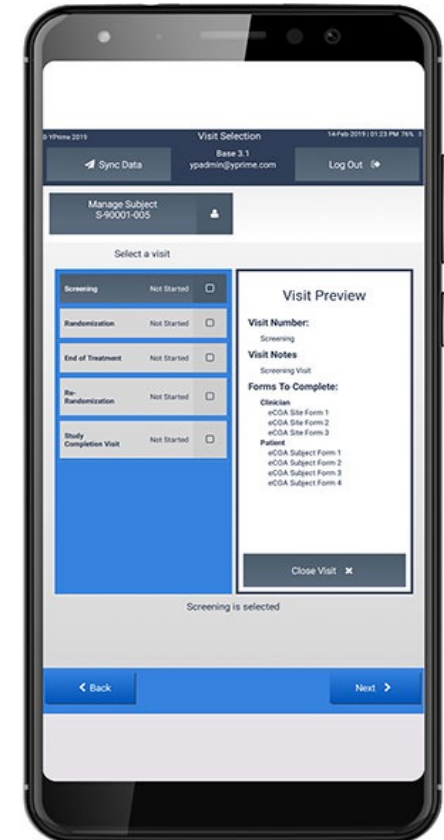


Agenda

1. Rise of electronic data collection, and need of efficiently mapping collected data
2. Established Use Of Annotated Case Report Form (aCRF)
3. Transition from paper to digital, and how we can apply the principles of the aCRF to the Screen Report
4. How traceability can be achieved from using annotated Screen Reports
5. Implementing the Annotated Screen Reports (ASR) today and tomorrow

Rise Of Electronic Data Collection

- In recent years, regulatory agencies such as the FDA and EMA have increasingly promoted the use of eCOA solutions to capture patient data in the development and approval of investigational products.
- This is because electronic devices can be used to motivate and engage patients and because ePROs simplifies the questionnaire process for patients.



Use Of Annotated Case Report Form

- aCRF is a critical part of study documentation that links data collection fields used to capture data to their corresponding values in SDTM
- Allows for traceability from collection to analysis
- Crucial link for all users and reviewers
- Figure 1 illustrates a page from the aCRF of the (EQ-5D-5L), linking the collected data to variables and controlled terminology

Figure 1: EQ-5D-5L v1.2 aCFR Page 2

QSEVINTX=TODAY

Under each heading, please check the ONE box that best describes your health TODAY

MOBILITY **QSORRES when QSTESTCD=EQ5D0201**

I have no problems walking ☐

I have slight problems walking ☐

I have moderate problems walking ☐

I have severe problems walking ☐

I am unable to walk ☐

SELF-CARE **QSORRES when QSTESTCD=EQ5D0202**

I have no problems washing or dressing myself ☐

I have slight problems washing or dressing myself ☐

I have moderate problems washing or dressing myself ☐

I have severe problems washing or dressing myself ☐

I am unable to wash or dress myself ☐

USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities) **QSORRES when QSTESTCD=EQ5D0203**

I have no problems doing my usual activities ☐

I have slight problems doing my usual activities ☐

I have moderate problems doing my usual activities ☐

I have severe problems doing my usual activities ☐

I am unable to do my usual activities ☐

PAIN / DISCOMFORT **QSORRES when QSTESTCD=EQ5D0204**

I have no pain or discomfort ☐

I have slight pain or discomfort ☐

I have moderate pain or discomfort ☐

I have severe pain or discomfort ☐

I have extreme pain or discomfort ☐

ANXIETY / DEPRESSION **QSORRES when QSTESTCD=EQ5D0205**

I am not anxious or depressed ☐

I am slightly anxious or depressed ☐

I am moderately anxious or depressed ☐

I am severely anxious or depressed ☐

I am extremely anxious or depressed ☐

Transition From Paper To Digital

- Questionnaire instruments have transitioned from paper to digital.
- There are a series steps that take place between the software/device provider, the study team, and the copyright holder for the instrument to ensure that nothing is lost or changed about the collected data.
- The electronic version of the instrument (eCOA/ePRO), while collecting the same data in an approved way, often has a different presentation of the instrument to the user that needs to be accounted for.

Figure 2. EQ-5D-5L Page 2 eCOA Screen Report

The screenshot shows a mobile application interface for the EQ-5D-5L questionnaire. At the top, a dark blue header bar displays "Subject: 769-11112" and "EQ-5D-5L". Below this, a light gray instruction box says "Please select the ONE box that best describes your health TODAY." The "MOBILITY" section lists five options with corresponding checkboxes: "I have no problems in walking about", "I have slight problems in walking about", "I have moderate problems in walking about", "I have severe problems in walking about", and "I am unable to walk about". At the bottom, a blue navigation bar contains a "Back" button, copyright information for the EuroQol Research Foundation, and a "Next" button. A progress bar at the very bottom shows "4/2" and "12%".

Following Principles of Annotated Case Report Form

- Fundamental principles that have been developed to annotate the CRF (Case Report Form) can readily be applied to the approved screen reports.
- For many instruments, the annotations and controlled terminology can be copied directly from the already existing CDISC QRS supplements.
- This example shows the SDTM domain as well as all variables collected from this page.

Figure 3. EQ-5D-5L Page 2 eCOA annotated Screen Report

The screenshot displays the EQ-5D-5L Page 2 eCOA screen report. At the top left is the yprime logo. To its right, a box contains 'QSEVINTX= TODAY'. Below the logo, a box contains 'QS=Questionnaires'. To the right of this, a box contains 'QSCAT=EQ-5D-5L'. In the top right corner, the text reads 'Sponsor ABC 999-ABC-1234', 'EQ-5D-5L, enGB,', and 'Version 1.0'. The main content area shows a progress bar at the top with '2.' and 'Subject: 789-11112'. Below this, a box contains 'QSTESTCD=EQ5D0201' and 'EQ-5D-5L'. The main question is 'Please select the ONE box that best describes your health TODAY.' under the heading 'MOBILITY'. There are five options with checkboxes: 'I have no problems in walking about', 'I have slight problems in walking about', 'I have moderate problems in walking about', 'I have severe problems in walking about', and 'I am unable to walk about'. Each option has a corresponding box containing 'QSSTRESC/' and 'QSSTRESN=' followed by a number (1, 2, 3, 4, 5). At the bottom, a box contains 'QSORRES where QSTESTCD=EQ5D0201'. The bottom navigation bar includes 'Back', 'Next', and a progress indicator showing '12%'.

Achieving Traceability

- Figure 4 illustrates the same aSR (from previous slide) from the 5Q-5D-5L with the addition of the unique vendor record identifiers (Yellow) and how these data may flow into a sponsor data warehouse (Gray).
- Improved granularity especially helpful to data management teams trying to reconcile databases.

Figure 4. EQ-5D-5L Page 2 aSR with data mapping

The screenshot displays the EQ-5D-5L Page 2 aSR form. The form includes a header with the yprime logo and a subject ID of 289-11112. The form is titled "EQ-5D-5L" and contains a section for "MOBILITY" with five radio button options. The form is annotated with various data mapping labels in yellow and gray boxes. The labels include:

- QSEVINTX=Today** (Gray)
- QSCAT=EQ-5D-5L** (Gray)
- QSTESTCD=EQ5D0201** (Gray)
- QSSSTRESN=1** (Gray)
- QSSSTRESN=2** (Gray)
- QSSSTRESN=3** (Gray)
- QSSSTRESN=4** (Gray)
- QSSSTRESN=5** (Gray)
- QSSORRES where QSTESTCD=EQ5D0201** (Gray)
- YPrime QuestionnaireID=BA24821A-245D-4742-13B4-08D879635FE4** (Yellow)
- YPrime QuestionID=E6C17F7C-C342-4D98-C378-08D87963DC4A** (Yellow)
- YPrime ChoiceID=A24D86D3-B010-4995-C682-08D87963DC56** (Yellow)
- YPrime ChoiceID=2216A0A8-C7FF-453A-C683-08D87963DC56** (Yellow)
- YPrime ChoiceID=8CCA74EA-EDCD-435D-C684-08D87963DC56** (Yellow)
- YPrime ChoiceID=F308CD81-0CB1-4C24-C685-08D87963DC56** (Yellow)
- YPrime ChoiceID=8936E692-A398-40EE-C686-08D87963DC56** (Yellow)

The form also includes a footer with the yprime logo and a copyright notice: "© EuroQol Research Foundation. EQ-5D™ is a trademark of the EuroQol Research Foundation. UK (English) v2.1".

Annotating The Screen Reports: **Today & Tomorrow**

- ① **Create** the aSR in much the same way as the aCRF
- ② **As Of Now Manual Process:** Data standards expert reviews the screen reports in addition to data for each questionnaire then manually adds standardized annotations to the .PDF file using a PDF writer.
This process is manual, requires expertise, and several hours to complete.
- ③ **The road to automating** the annotation of the screen reports is also being paved

Benefits of Annotated Screen Reports (aSR)

- Provide clear mapping of the collected eCOA data to the corresponding variables or discrete variable values.
- Facilitates clear and transparent review to help identify incorrect data mapping decisions that may delay the eventual analysis.
- Fills the need of data traceability not only for reviewers at regulatory agencies but also for any stakeholders working with the data from collection to submission and beyond.
- Easy to implement using existing standards and methods and has room for improvements with automation and the inclusion of additional metadata.
- Simplifies analysis but also has the potential to improve the study design.

If introduced early the aSR can ensure that data collected meets the needs and expectations of data analysis.

Closing and Questions



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