Paper DS08

A new standard of excellence; introducing the annotated Screen Report

Frank Menius, YPrime, Raleigh, USA
Monali Khanna, YPrime, New Jersey, USA
Vincent Allibone, YPrime, Sandwich, UK

Abstract:

With the adoption of electronic Clinical Outcome Assessments (eCOA) and electronic Patient Reported Outcomes (ePRO) for collection of questionnaires and patient clinical data, there is a need for detailed data lineage from data collection to analysis and submission. This need can easily be met using the growing CDISC QRS supplements library and annotated eCOA/ePRO device screen reports. Like an annotated Case Report Form (aCRF), the annotated Screen Reports (aSR) document the location of collected data on a participant or clinician device to corresponding domains and variables included in the intermediate and the submitted datasets. When utilized, these annotated Screen Reports (aSR) can be a vital tool for anyone accessing these data including programmers, statisticians, and reviewers at regulatory agencies. This presentation will show how to adapt the QRS supplements and the principles of the annotated Case Report Form (aCRF) to electronically captured reports and why this practice should be the new standard of excellence for giving more transparency to the study data lifecycle. The presentation will also highlight the many benefits of annotated screen reports for eCOA/ePRO, guidelines for creating them, as well as provide examples and use cases.

Introduction:

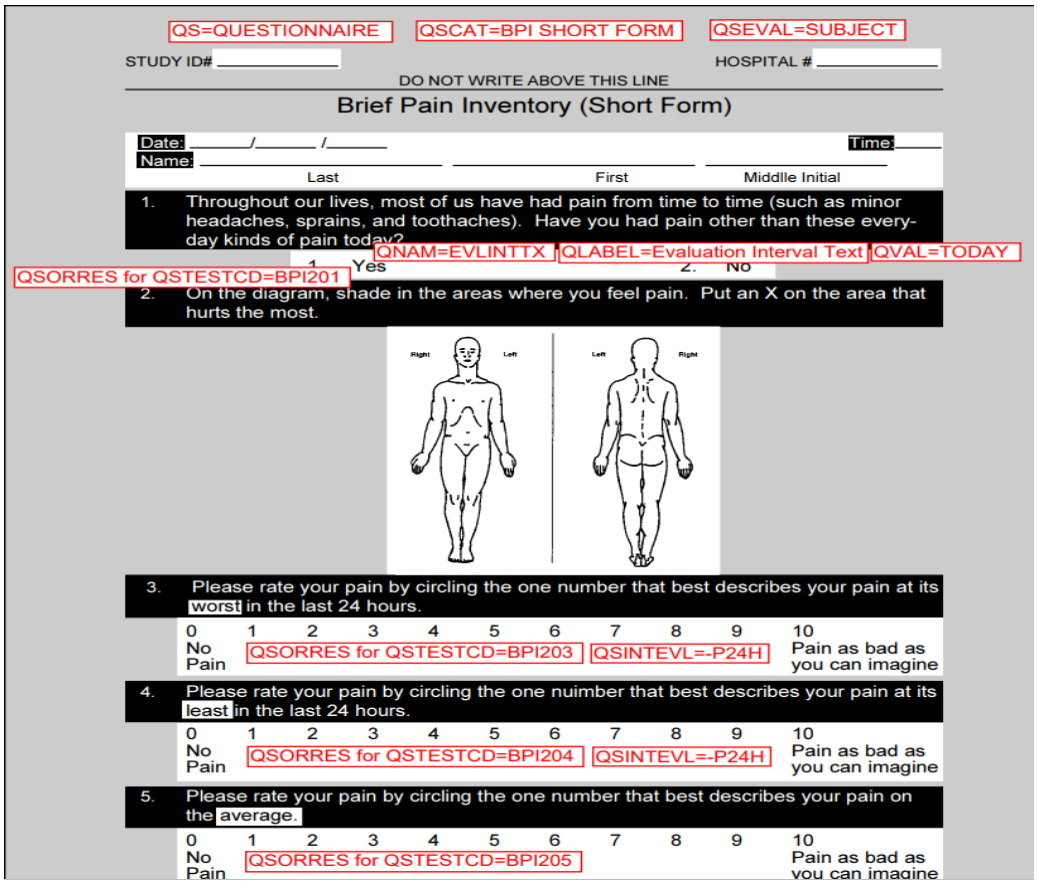
As the use of digital technologies picks up pace in Clinical Research, we have seen the emergence and, now, regular use of electronic Clinical Outcome Assessments (eCOA) and electronic Patient Reported Outcomes (ePRO). These packages have been transformative in the race to move away from paper collection, easing the burden on patients and clinicians alike whilst increasing subject compliance, retention and improving the quality of data. However, there seems to be a lack of a clear understanding of how these data move along through a study's lifecycle, which can cause problems further downstream. It is imperative that all stakeholders are able to benefit from understanding how the data was collected and how it evolves throughout a study. This is one of the many advantages of the annotated Screen Report (aSR). As we will explain in further detail, this document can provide lineage from collection and storage to how these data are mapped later downstream. This, in turn, allows for alignment on mapping of data and prevents problems, further down the line.

Origins:

The Annotated Screen Report is a tool utilized in clinical trials to provide lineage from database to data submission for all parties involved. It is a natural progression from Annotated Case Report Forms, which are captured on paper, to Annotated Screen Reports, which are fully electronic. Where a aCRF displays mapping at a question/answer level for questionnaires captured on paper, aSR provides similar outputs, with the difference being that aSRs are intended for the same questionnaires but answered via an electronic device. To fully understand the necessity for annotated Screen Reports, we need to look at the aCRF (annotated Case Report Form), a critical part of the study documentation. Questionnaire data – the main component of annotated Screen Reports – when captured on paper, is often included in the aCRF process, allowing for traceability from data collection and storage to the creation of Analysis and Tabulation datasets. This traceability enables all users to fully understand the data's origin and how they were collected. For the most part, we take our guidance for mapping these data from the vast amount of guidance documents created by the Clinical Data Interchange Standards Consortium (CDISC), known as their QRS supplements. These supplements provide the template for the use of questionnaires in clinical research and how they are included in datasets downstream of collection. Along with the supplements, CDISC also provide examples of aCRF documents for submission.

Figure 1 below is an example of an aCRF taken from the CDISC website for the Brief Pain Inventory short form – a standard questionnaire included in clinical trials. Here, we can see how the collected data (the questions, form name, evaluator, etc.) are linked to SDTM (Standardized Data Tabulation Model), standardized variables, and controlled terminology.

Figure 1 – BPI Short Form Page 1:



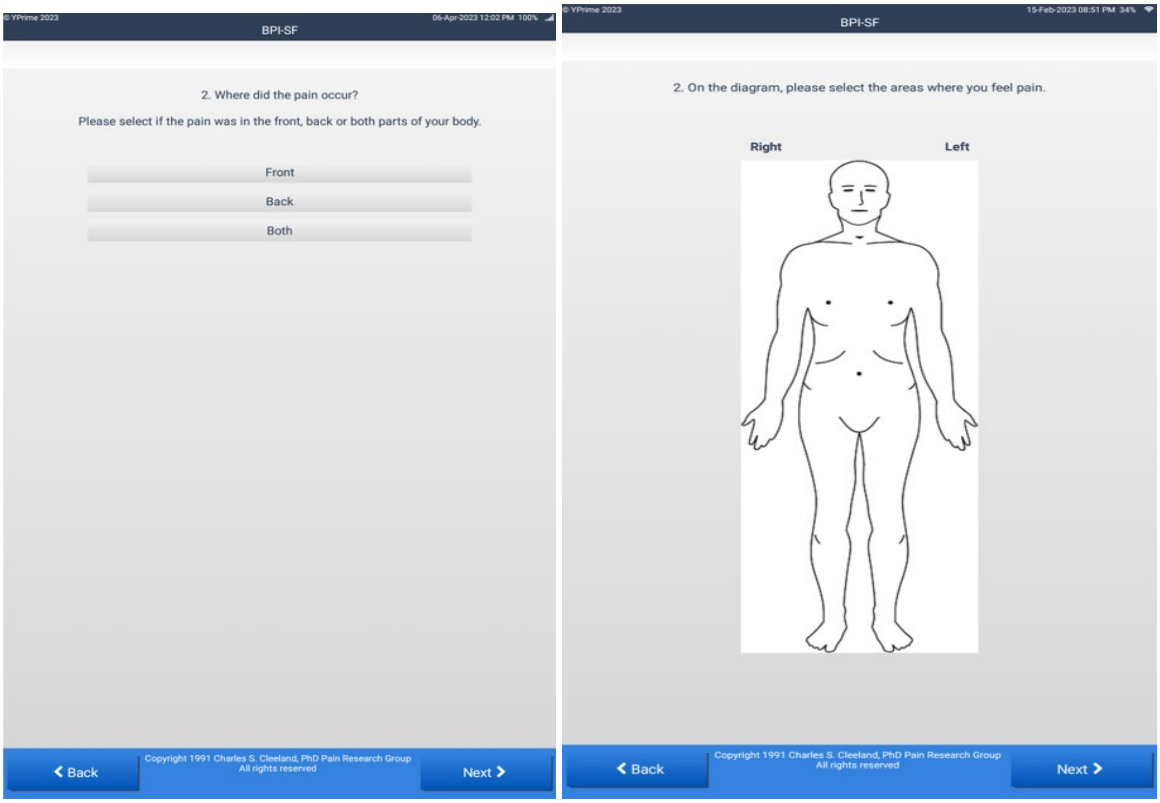
The New Standard:

Transitioning from paper to digitalized collection methods was always inevitable. From the ease of use for patients and clinicians alike to improving data quality, the benefits far outweigh the cons. However, it may be a challenging transition. For every instrument that gets converted from paper to digital, to make it happen, several key stakeholders need to come together to ensure that the digital build retains original data points. This can often be tricky to navigate because, although the digitalized version will often capture the same data, the presentation of the digitalized version will inevitably look different from the paper version. eCOA and ePRO instruments will usually need to be constructed in such a way that they are presentable on several different devices, meaning that there may be differences with the paper versions in terms of the number of questions that appear on screen, font size or differing instructions can be given.

Figures 2 and 3 below show the second and third pages from the eCOA Screen Report of the BPI Short Form. If we go back to Figure 1, we can see that this question, along with a few others are all captured on the same page; however, for eCOA screen report this question is actually extended and

given separate pages. Also, see how Figure 2 is a question that does not appear in the paper version – it is a pre-cursor to the subject identifying where on their body they feel pain. It works because if a subject selects 'Front' for the first question, they are presented with the image seen in Figure 3; however, if they select 'Back' they are shown the image of the back of a body. Now, the reasoning for this is solid; As the questionnaire has been constructed in such a way that only one questions is seen per screen, it eliminates the need for subjects to see information that is not relevant to them, potentially preventing confusion or, worse, bad data. If a subject has no pain in the back, they will not be presented with the 'Back' screen, the same applies to the front, saving the subject having to scroll through unnecessary screens and preventing erroneous entries.

Figure 2 – BPI Screen 2 and 3 not annotated



Same Principles, Different Format:

The need to provide the exact traceability from ePRO's and eCOA as with aCRF is evident. What is the point of moving to newer technolgy if it can't offer the same service as the previous one? Fortunately, the principles that these were built on are very similar, making life exceptionally easy in the case of some instruments, where the already existing QRS supplements applied to the paper versions can be applied directly to the digital format. See below Figures 4 and 5, the same pages from the BPI eCOA questionnaire as above, although these ones have annotations. These examples

give a small insight into how the same data can be collected, but with all the benefits of digital technology.

Figure 3 – BPI Screen 2 Annotated

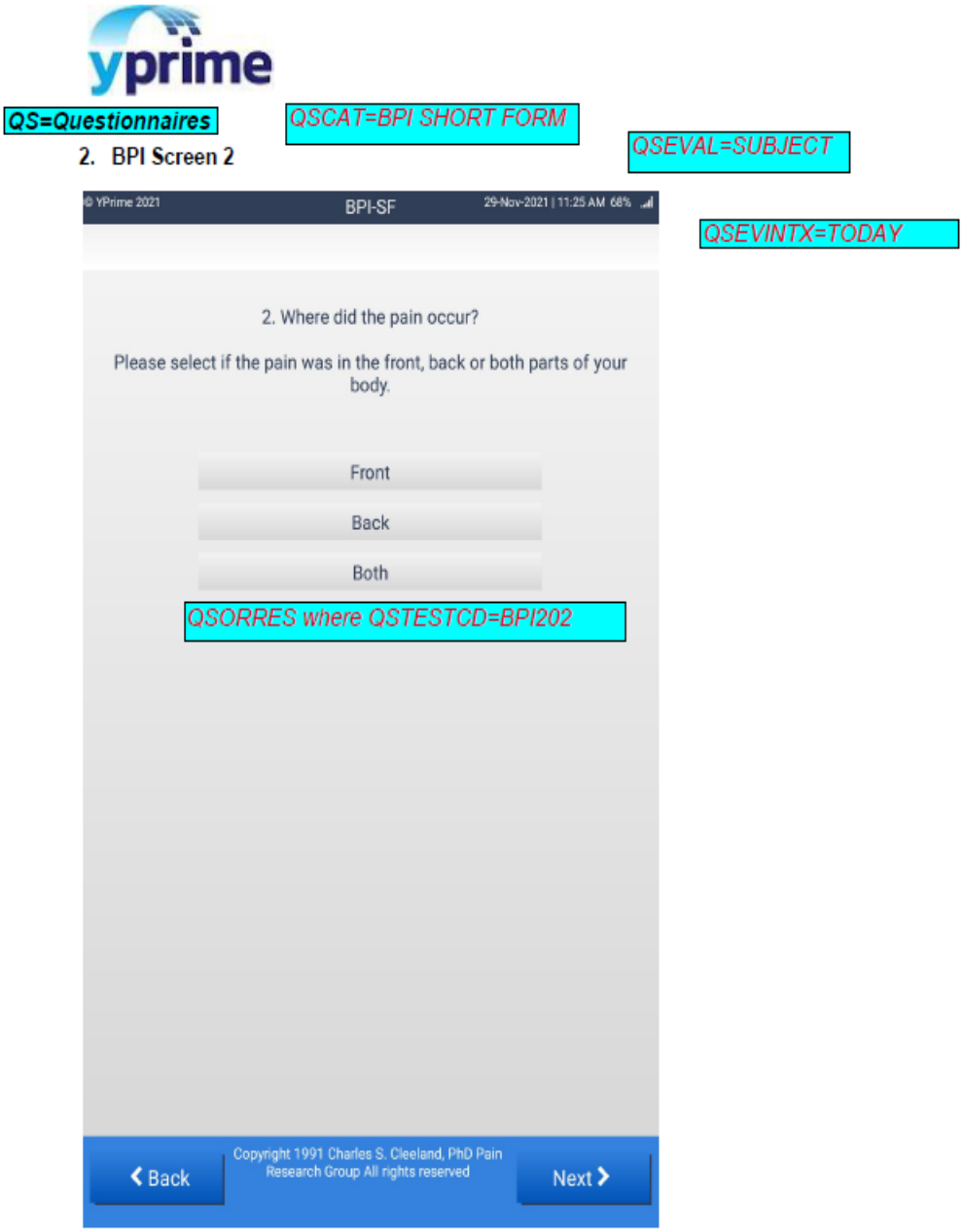
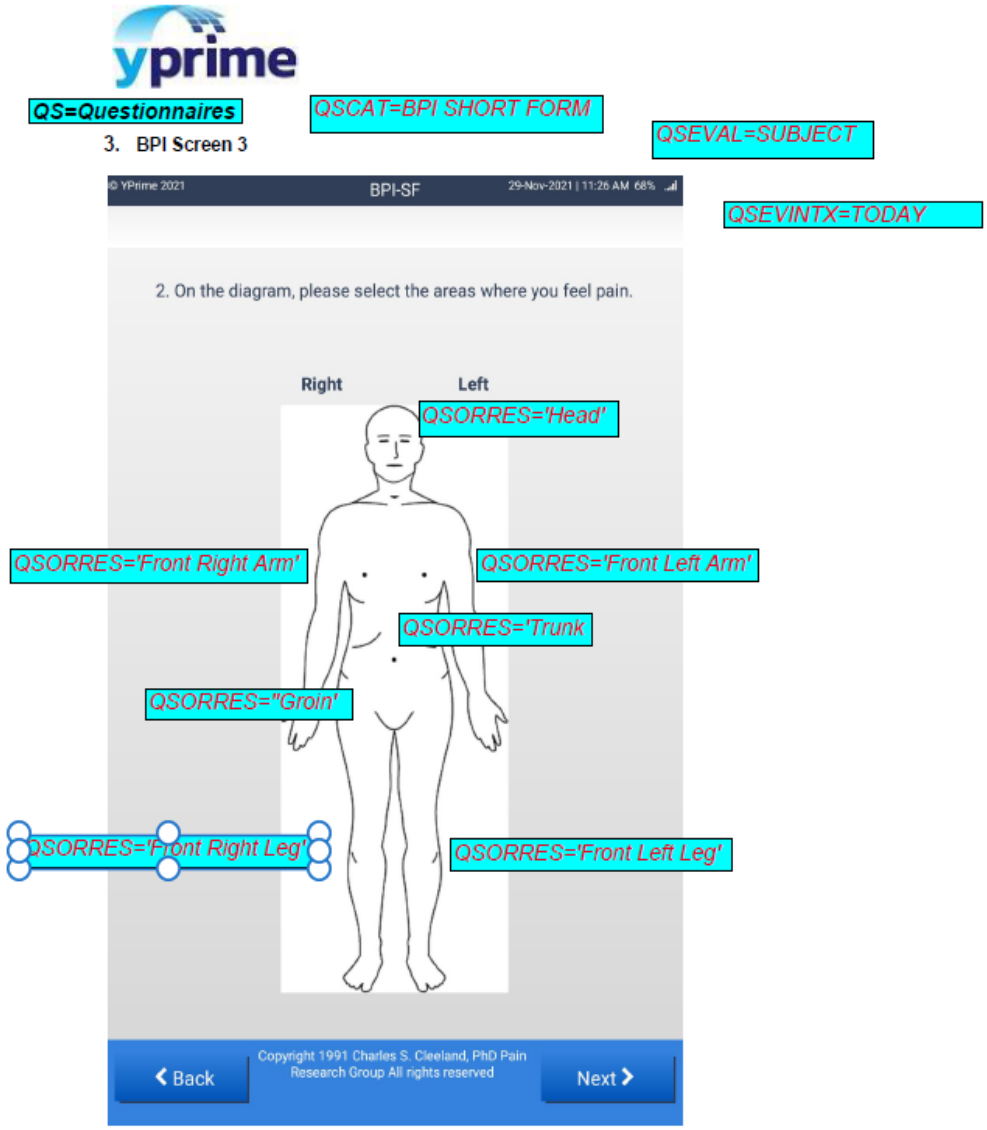


Figure 4 Annotated



Avoiding pitfalls with Early Discussions:

Adopting modern technologies is excellent and, as mentioned before, has many benefits; however, that does not mean that it does not come with its potential problems. However, these problems are easily navigated as long as discussions are had nearer the beginning of a study, as opposed to dealing with them as and when they come up. This is a real-life example of the type of problem that can occur and how it can be avoided, in future:

While working on a study where the BPI Short Form was being implemented, the sponsor got in touch to question some of the data that they had received. When reviewing these data, it was noted that the BPI only included certain body parts (head, trunk, right arm, right leg, left arm, left leg). The sponsor was surprised as they were used to receiving data with far more granularity, where the body parts were concerned, as in the paper format, the body part in question is just circled with a pen or pencil. If we applied the same logic to electronic formats, it would make it nearly impossible for a patient to answer the question, as the screen would be susceptible to several different parts of the body, making it very difficult to select the part that you intend. The sensible approach would have been to have these discussions early in the study's lifecycle. What body parts are important? Which ones are selected most often? Which ones can we fit in? With the aid of eCRF's, highlighting which data is collected and how that is going to be mapped and received further downstream is massively helpful to all stakeholders. Vendors know what they are sending, and sponsors know what they are receiving, with no surprises and, if that were the approach taken in the example above, there would have been no problems.

Conclusion:

To conclude, the process by which the most effective variable mapping for each individual questionnaire in a clinical trial is determined, has already been established and is one that works. However, as society progresses and developments occur, it is imperative that we move in parallel with this progression and Annotated Screen Reports give us the perfect basis to do this. We are not aiming to overhaul the whole system; essentially, we aim to gently guide the processes that we already use into the new age, with equipped tools. As more and more questionnaires are moved from paper to technology, Annotated Screen Reports allow us to keep the same outcome, with a slight tweak to how we got there.

CONTACT INFORMATION

Frank Menius
YPrime
3301 Benson Dr.
Raleigh, NC 27609
919-412-6537
fmenius@yprime.com
YPrime: https://www.yprime.com/
LinkedIn: https://www.linkedin.com/in/frank-menius/

Monali Khanna
YPrime
9 Great Valley Parkway, Malvern, PA 19355
Malvern, PA 19355
mkhanna@yprime.com
YPrime: https://www.yprime.com/
LinkedIn: https://www.linkedin.com/in/monali-k-a259a5178/

Vincent Allibone
YPrime
Sandwich Discovery Park
Sandwich, Kent
vallibone@yprime.com

YPrime: https://www.yprime.com