

DS08 - A New Standard of Excellence: Introducing the Annotated Screen Report

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Agenda

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- 3 The Annotated Case Report Form
- 4 eCOA and The Annotated Screen Report
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CDISC – QRS Supplements

Clinical Data Interchange Standards Consortium

- Standardized questionnaire supplement.
- Terminology that aligns with SDTM.
- Clear instructions on how to implement certain questionnaires, ratings, and scales.
- Used in both Paper and eCOA.

QS=Questionnaires

QSCAT=EQ-5D-5L

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 ☐

The Annotated Case Report Form (aCRF): What is it?

- Annotated clinical questionnaire.
- Provides lineage from questions and answers to submission with mapping.
- Widely used and always in paper format.

Date: ____/____/____ Time: ____

Name: _____
Last First Middle Initial

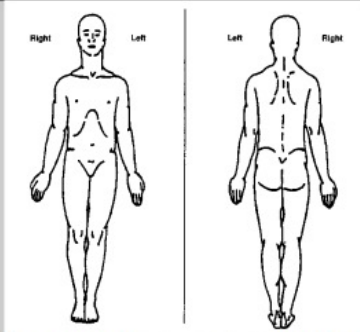
1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these every-day kinds of pain today?

1 Yes [QNAM=EVLINTTX] [QLABEL=Evaluation Interval Text] [QVAL=TODAY]
2 No

[QSORRES for QSTESTCD=BPI201]

2. On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.

Right Left Left Right



3. Please rate your pain by circling the one number that best describes your pain at its worst in the last 24 hours.

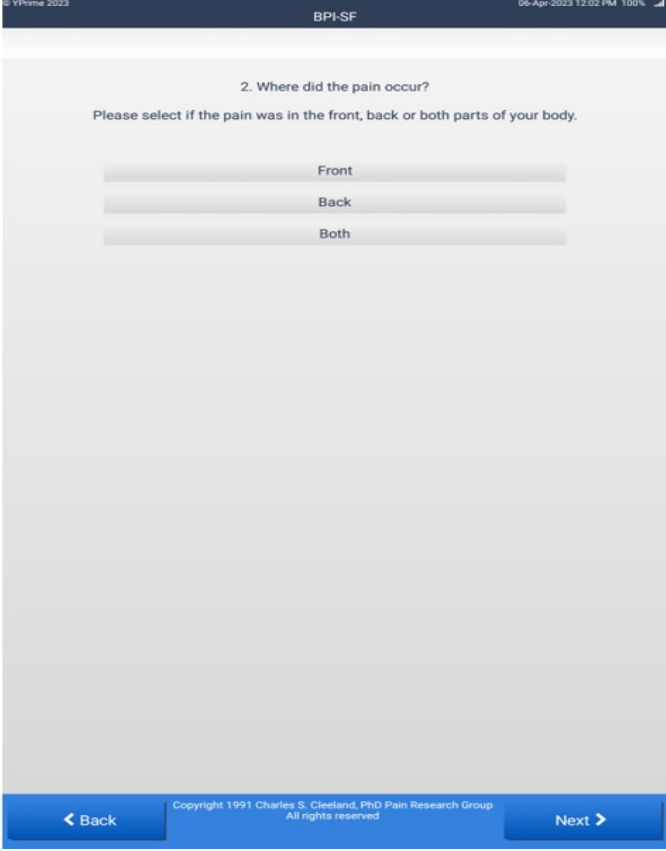
0 1 2 3 4 5 6 7 8 9 10
No Pain [QSORRES for QSTESTCD=BPI203] [QSINTEVL=-P24H] Pain as bad as you can imagine

4. Please rate your pain by circling the one number that best describes your pain at its least in the last 24 hours.

0 1 2 3 4 5 6 7 8 9 10
No [QSORRES for QSTESTCD=BPI204] [QSINTEVL=-P24H] Pain as bad as

What is eCOA and why use it?

- Widely used questionnaires that have been adopted into electronic format.
- Electronic Clinical Outcome Assessments have been found to improve compliance levels among patients.
- Simplified questionnaire process that is more engaging for patients.



BPI-SF

06-Apr-2023 12:02 PM 100%

2. Where did the pain occur?

Please select if the pain was in the front, back or both parts of your body.

Front

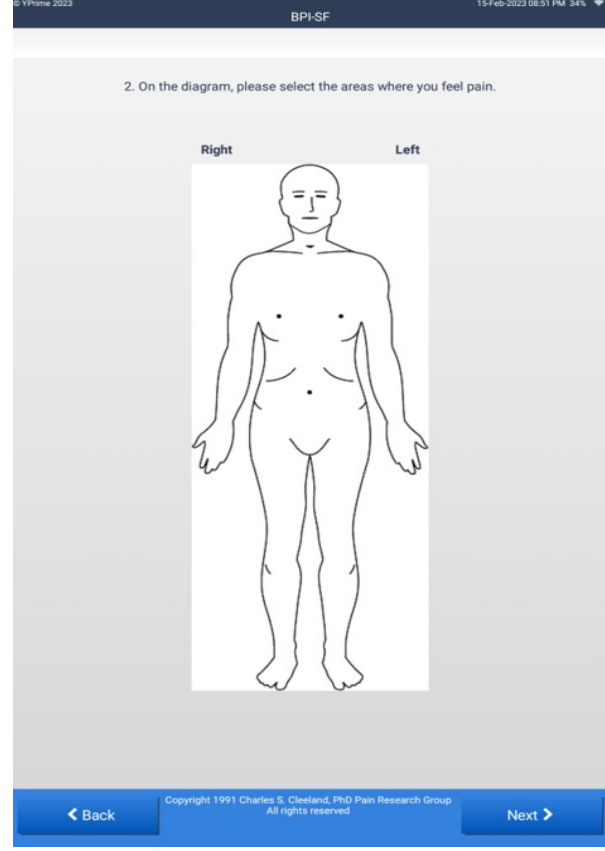
Back

Both

< Back

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Next >

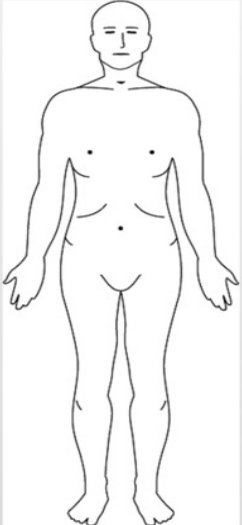


BPI-SF

15-Feb-2023 08:51 PM 34%

2. On the diagram, please select the areas where you feel pain.

Right Left



< Back

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Next >

The Annotated Screen Report (aSR): What is it?

- Electronic Format but same principles as aCRF.
- Provides lineage from database to submission with mapping.
- Being adopted more, work is being to standardize – QRS supplements (CDISC).

The screenshot displays the YPrime BPI-SF screen, titled "3. BPI Screen 3". The header includes the YPrime logo, the text "Regeneron R5678-ONC-1879 BPI-SF, English-US, Version 3.0", and several data fields: "QS=Questionnaires", "QSCAT=BPI SHORT FORM", "QSEVAL=SUBJECT", and "QSEVINTX=TODAY". The main content area shows a human figure diagram with the instruction "2. On the diagram, please select the areas where you feel pain." The diagram is labeled "Right" and "Left". Various body parts are annotated with "QSORRES" values: "QSORRES='Head'" for the head, "QSORRES='Front Right Arm'" for the right arm, "QSORRES='Front Left Arm'" for the left arm, "QSORRES='Trunk'" for the trunk, "QSORRES='Groin'" for the groin, "QSORRES='Head'" for the head, "QSORRES='Front Right Leg'" for the right leg, and "QSORRES='Front Left Leg'" for the left leg. The footer contains a copyright notice: "Copyright 1991 Charles S. Cleeland, PhD Pain Research Group All rights reserved", and navigation buttons for "Back" and "Next".

What's the Difference? aCRF vs aSR

- eCOA instruments need to be user-friendly and easy to navigate.
- Key stakeholders need to gather in order to make the eCOA instrument as similar as possible to the paper version.
- Font size, amount of questions per page and how many answers are selectable can differ but key principles of questionnaire remain the same.



Real-World Examples

- Some real-world examples of aSR in use.
- Early discussions are needed at the beginning of a study lifecycle to avoid common pitfalls.
- Key stakeholders need to be aligned.
- All programming is reproducible.



Conclusion

- This is not an overhaul of the system, this is guiding the system that already works into the new age.
- Same standards are applicable to both eCOA and aCRF.
- More work needs to be done on standardization but we are moving in the right direction, with a large library of standards already in use.





Closing and Questions

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