

Migrating a PRO Instrument

Presented by:

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Presenter Biographies

Serge Bodart is currently based in Montreal, Canada. He has been involved in the ePRO business since 2000. Serge was a co-founder of SYMFO, a European-based ePRO provider. Prior to this, he served as an officer and helicopter pilot in the Belgian Army for 20 years. He now acts as the subject matter expert for eCOA Services at Biomedical Systems.

Serge has over 30 years of experience in project management. He holds a Master of Science in Telecommunications from the Polytechnic Division of the Royal Military Academy in Brussels, Belgium.

Alisandra (Sandy) Johnson has been an ePRO Project Manager with Bracket for the past 3 years. Sandy has been involved in the clinical trial and pharmaceutical industry for almost 15 years working with Express Scripts, NIH and Parexel before coming to Bracket. At Bracket, Sandy serves as a representative to C-Path's ePRO Consortium, and as a Bracket subject matter expert in the field of ePRO and RTSM™ study implementation.

Sandy holds a Bachelor of Science in Public Health and Healthcare Management from Temple University.

Webinar Questions via Chat Box

The image shows a screenshot of the Cisco Webex Event Center Desktop interface. At the top, there is a toolbar with icons for 'Pause', 'Share', 'Assign', 'Teleconf...', 'Participants', 'Chat', 'Recorder', and 'Annotate'. A green notification bar below the toolbar says 'You are sharing your desktop'. A red box labeled 'Chat Box Opens' points to the 'Chat' icon in the toolbar. Below the toolbar, five numbered instructions are provided in red-bordered boxes, with red arrows pointing to the corresponding UI elements in the chat box window:

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2. Click Chat icon to open chat box
3. Click drop down to select All Panelists as recipients
4. Write your brief question in this box
5. Press Send button to send your question

The chat box window is titled 'Chat' and contains a text input field with the placeholder text 'write brief question here' and a 'Send' button. A dropdown menu is open, showing 'All Panelists' as the selected recipient.

Cisco Webex Event Center Desktop

ePRO Consortium



The Electronic Patient-Reported Outcome (ePRO) Consortium was established by the Critical Path Institute (C-Path) on April 1st, 2011.

Mission: To advance the quality, practicality, and acceptability of electronic data capture (EDC) methods used in clinical trials for PRO endpoint assessment.

ePRO Consortium Members



Webinar Objectives

- Define the concept of faithful migration and describe the process.
- Describe types of modifications:
 - Paper to IVR
 - Paper to Device
 - Paper to Web

ISPOR Recommendations and FDA PRO Guidance



Recommendations on Evidence Needed to Support Measurement Equivalence between Electronic and Paper-Based Patient-Reported Outcome (PRO) Measures: ISPOR ePRO Good Research Practices Task Force Report p. 422-24 (*)

FDA's 2009 PRO Guidance p. 20: *“When a PRO instrument is modified, sponsors generally should provide evidence to confirm the new instrument’s adequacy.”*

* Coons SJ, Gwaltney CJ, Hays RD, Lundy JJ, Sloan JA, Revicki DA, Lenderking WR, Cella D, Basch E, on behalf of the ISPOR ePRO Task Force. Recommendations on Evidence Needed to Support Measurement Equivalence between Electronic and Paper-Based Patient-Reported Outcome (PRO) Measures: ISPOR ePRO Good Research Practices Task Force Report. Value Health. 2009 Jun;12(4):419-29.

Evidence Needed to Support Measurement Equivalence

- Comparison of comparability of the data obtained via the original and adapted administration mode.
- The extent of additional validation recommended depends on the type of modification made.
- ISPOR Task Force identifies three modification levels:
 - Minor
 - Moderate
 - Substantial

Evidence Needed to Support Measurement Equivalence

Level of modification	Example	Level of evidence
MINOR	Non-substantive changes in instructions ('tap the screen') Minor changes in format (one item per screen)	Cognitive interview and usability testing \$, short timelines
MODERATE	Changes in presentation or wording that can alter the interpretation	Equivalence testing and usability testing \$\$, medium timelines
SUBSTANTIAL	Substantial changes in item response options or in item wording	Full psychometric testing and usability testing \$\$\$, long timelines

Faithful Migration

- A faithful migration is the implementation of the instrument on alternative modes of data collection that do not bias responses.
- Migration process must ensure that there no change in content and that subjects will interpret and respond the same way regardless of the mode.

Steps to Conduct a Faithful Migration

- Contact author, check for permission and instructions
- Review original mode (generally paper)
- Establish requirement specs
- Generate screenshots/scripts
- Perform Cognitive Interviewing and Usability Testing
- Perform Qualitative Analysis of the interviews
- Provide recommendations
- Present results to author

Steps to Conduct a Faithful Migration – EQ-5D-5L

Contact author, check for permission and instructions, if any:

- EQ-5D-5L is a standardized instrument for use as a measure of health status. Applicable to a wide range of health conditions and treatments, it provides a simple descriptive profile and a single index value for health status.
- Author is EuroQol Group
- Design specification developed by EuroQoL Group
- EQ-5D-5L, EQ-5D-3L, EQ-5D-Y

Steps to Conduct a Faithful Migration – EQ-5D-5L

Review original mode:

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

MOBILITY

- 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
- I am unable to walk about

ANXIETY / DEPRESSION

- 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

SAMPLE

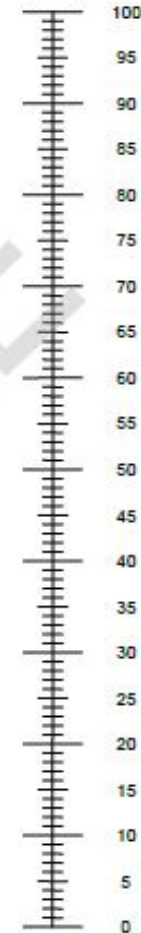
Steps to Conduct a Faithful Migration – EQ-5D-5L

Review original mode:

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine. 0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =

The best health
you can imagine



The worst health
you can imagine

SAMPLE

Steps to Conduct a Faithful Migration – EQ-5D-5L

- Spec for tablet and spec for smartphone
- Display Size (diagonal 2.8” (7.1 cm))
- User should be permitted to revisit items and change responses
- No scrolling
- Introduction screen contains version, language and copyright
- Instructions (please tap the statement...) on a screen PRIOR to the dimensions
- Indicator of current dimension
- No default response
- EQ VAS can be on a separate screen
- EQ VAS vertical and EQ VAS anchors

Steps to Conduct a Faithful Migration – EQ-5D-5L

Establish Requirement Specs:

- Limit to MINOR modifications
- One item per screen
- Non substantive changes to the wording
- EQ VAS

Steps to Conduct a Faithful Migration – EQ-5D-5L

Generate Screenshots

EQ-5D-5L Health Questionnaire
Display 1 of 9

Health Questionnaire

English version for the UK

EQ-5D™ is a trade mark of the EuroQol Research Foundation
© EuroQol Research Foundation

← Previous Next →

EQ-5D-5L Health Questionnaire
Display 2 of 9

Please tap the statement that best describes your health TODAY.

MOBILITY

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

I am unable to walk about

← Previous Next →

EQ-5D-5L Health Questionnaire
Display 3 of 9

Please tap the statement that best describes your health TODAY.

SELF-CARE

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

← Previous Next →

Steps to Conduct a Faithful Migration – EQ-5D-5L

EQ-5D-5L
Display 7 of 9

We would like to know how good or bad your health is TODAY.

On the next screen you will see a scale numbered 0 to 100.

100 means the best health you can imagine.

0 means the worst health you can imagine.

← Previous

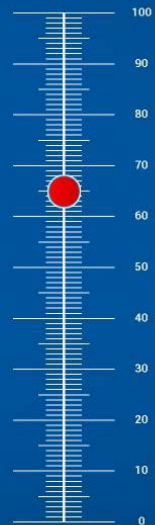
Next →

EQ-5D-5L Health Questionnaire
Display 8 of 9

Please tap on the scale to indicate how your health is TODAY.

65
YOUR HEALTH TODAY

The best health you can imagine



The worst health you can imagine

← Previous

Next →

EQ-5D-5L Health Questionnaire
Display 9 of 9

Thank you for completing this Health questionnaire. You must press 'NEXT' in order to save your data.

← Previous

Next →

Steps to Conduct a Faithful Migration – EQ-5D-5L

Perform Cognitive Interviewing and Usability Testing:

- **Cognitive Interviewing:** A qualitative research tool used to determine whether concepts and items are understood by patients in the same way regardless of mode.
- Cognitive interviews involve incorporating follow-up questions in a field test interview to gain a better understanding of how patients interpret questions asked of them. In this method, respondents are often asked to *think aloud* and describe their thought processes as they answer the instrument questions.
- **Usability Testing:** A formal evaluation with documentation of respondents' abilities to use the instrument, as well as comprehend, retain, and accurately follow instructions.

Steps to Conduct a Faithful Migration – EQ-5D-5L

Other Types of Modification Testing:

- **Feasibility Testing:** The evaluation of a system within a specific study design. It assesses whether the data collection mode will work in the context of a specific study design or a specific instrument.
- **User Acceptance Testing:** One aspect of an extensive system software validation process.

Steps to Conduct a Faithful Migration – EQ-5D-5L

Example: Cognitive Interviewing and Usability Testing

- 10 UK participants 20-73 years of age, no specific health condition
- Interviews were conducted by an experienced interviewer and were structured by an interview guide.
- Patients were asked to complete both paper and electronic (Smartphone and Tablet)
- Informed Consent
- Order of completion:
 - Tablet, Paper, Smartphone (5)
 - Smartphone, Paper, Tablet (5)
- Questions to elucidate whether change in layout affected interpretation and response
- Questions on ease of navigating, answering questions

Steps to Conduct a Faithful Migration – EQ-5D-5L

Cognitive Interviewing

- Examples of questions asked:
 - Did you understand the instructions provided?
 - Can you explain what you would be required to do in your own words?
 - How would you compare the instructions of the paper diary and the electronic diary?
 - How would you compare the overall appearance of the paper diary and the electronic diary?
 - Do you feel that any of your answers were different due to the layout of the diaries, from paper to electronic version?

Steps to Conduct a Faithful Migration – EQ-5D-5L

Usability Testing

- Example of questions asked:
 - Could you see all the text and images clearly on the screen?
 - How easy/difficult was it to navigate through the questionnaire on the device? What made it easy or difficult?
 - If you had to complete the questionnaire on the device without any help from me, do you think you would have been able to figure out how it works?

Steps to Conduct a Faithful Migration – EQ-5D-5L

- Qualitative Analysis
 - Compare results to Paper responses
- Recommendations
 - Potential changes in future study use
- Present results to authors
 - Document findings in Case Study Report

Migrating Paper to IVR



Consider Questionnaire Characteristics

- Questionnaire length, time required, frequency and duration must be considered together to evaluate patient burden and mode appropriateness.

Patient population/ therapeutic area

- Functional conditions of target population – ensure patients would be able to respond over IVR – hearing, being able to enter responses on phone.
- Ensure mode's ease of use for target population
- Cognitive burden

Preparing for IVR Migration

- Instructions must contain wording that makes sense for context of IVR mode
- Items must be self-contained
- Response options would need to be scripted out and associated with numbers on the phone.
- Instructions, items and response options need to be scripted out for auditory presentation on IVR.

Example: Minor Modifications Required for Migration to IVR



Instructions: Original Paper

Circle the response that best describes your pain symptoms over the past 4 weeks.



Instructions: Modified for IVR

“Select the response that best describes your pain symptoms over the past 4 weeks.”

Item/Responses: Original Paper

1. During the past 4 weeks, how much has your pain interfered with vigorous activities such as running or heavy lifting?

- Not at all
- Somewhat
- Moderately
- Extremely



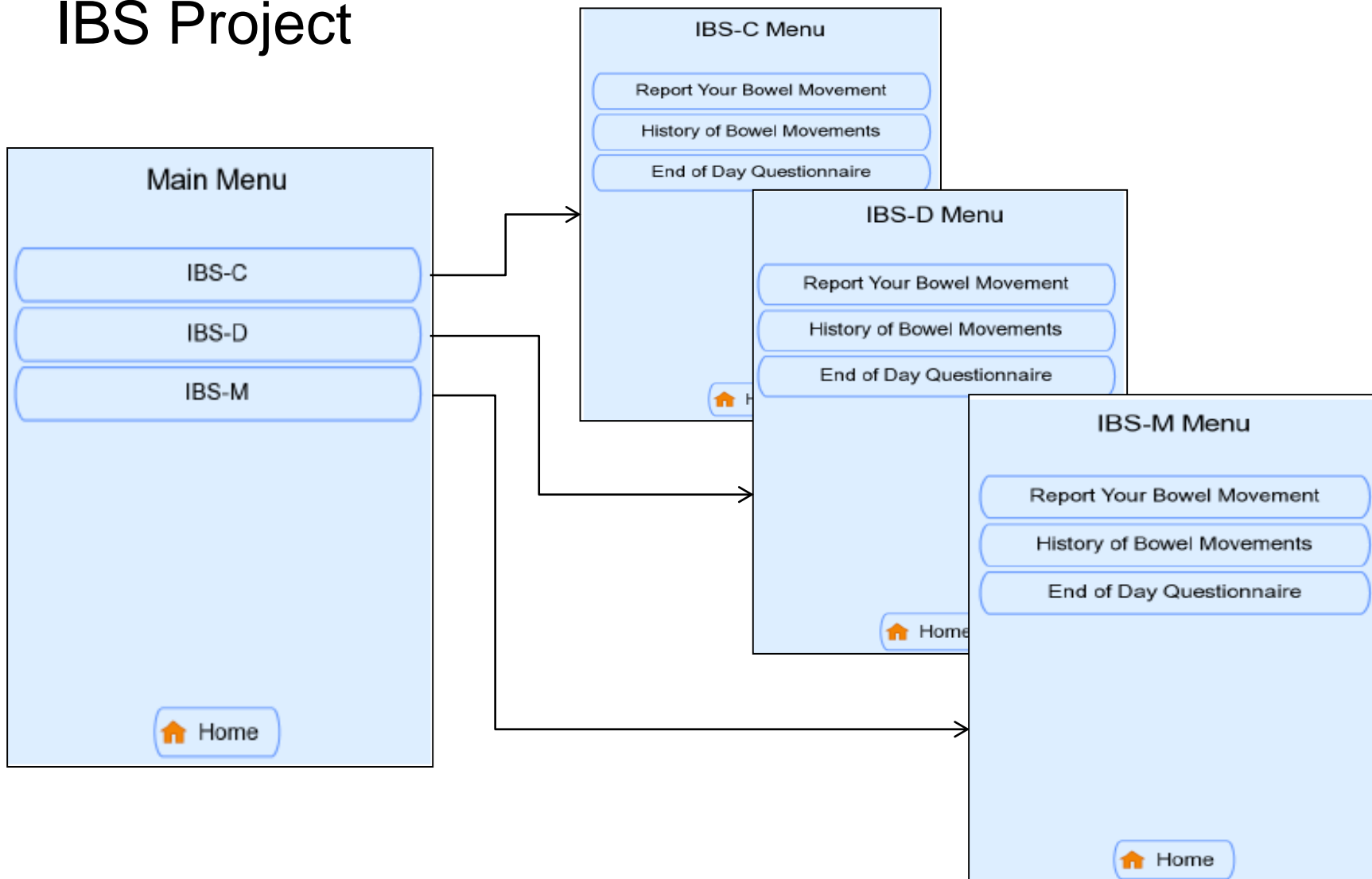
Item/Responses: Modified for IVR

1. *“During the past 4 weeks, how much has your pain interfered with vigorous activities such as running or heavy lifting?”*

*“For ‘Not at all’, select 1,
For ‘Somewhat’, select 2,
For ‘Moderately’, select 3,
For ‘Extremely’ select 4.”*

Migrating Paper to Device (Phone)

IBS Project



Migrating Paper to Device

- Different format of selectors based on paper source
- Allow User to select entire line in scale rather than number or picture ends

How would you rate your worst abdominal pain in the past 24 hours?

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

▲ No abdominal pain Worst possible abdominal pain ▲

◀ Back ✕ Exit Next ▶

How would you describe the consistency of your stool?

Very hard

Hard

Neither too hard nor too soft

Loose but not watery

Very loose and watery

◀ Back ✕ Exit Next ▶


Migrating Paper to Device

- Study on device allows on demand use (after event)
- Study on device also allows end of day review with entry of additional events and to make changes to entered events

You reported the following bowel movements since your last scheduled EOD Questionnaire :

Tue, 2-Jun-2013, 10:00PM
Tue, 2-Jun-2013, 12:30PM
Mon,1-Jun-2013, 7:30PM

Do you have any other bowel movements to report?

 Please confirm or change the date and time of your bowel movement.

Migrating Paper to Tablet

- Portrait or Landscape
 - Specified by developer?
- Screen size and resolution
- Patient population
- Site-based or Field-based questionnaires

Migrating Paper to Web

- Questions on paper are horizontal
- Questions on Web vertical
- Single question per screen

	Not at all	A little bit	Somewhat	Quite a bit	Very much
Runny or dripping nose	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Congested or stuffy nose	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Changed To

Patient Management : Patient Diary

[Main Menu](#)

[Patient Diary](#)

Note: An asterisk (*) indicates a required field.

Patient Diary Visit

Please rate the extent to which you had the following symptom during the past 24 hours.

Runny or dripping nose: *

Not at All
 A Little Bit
 Somewhat
 Quite a Bit
 Very Much

Additional Consideration

- Linguistic Validation
 - Paper version previously translated
 - Translations need to be modified for devices
 - Impact of translations and cultural issues
 - Examples – Linguistic Validation process
 - The impact of translations should also be reviewed

Summary of Faithful Migrations



- Types of migrations
- Process of migration
- Developer approval
- Translations
- Cognitive interviews
- Response analysis

Questions?

Webinar Questions via Chat Box

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Cisco Webex Event Center Desktop

ePRO Consortium Webinar Series

Webinar 1 – Intro to ePRO (Part I)

Webinar 2- Intro to ePRO (Part II)

Available for replay at c-path.org

Video and audio of this Webinar will be available within two weeks at c-path.org.

Thank you for attending ePRO Consortium Webinar 3: Migrating a PRO Instrument

You will have the opportunity to complete a short survey after the webinar closes. The ePRO Consortium would appreciate your feedback.