

# The Endometriosis Health Profile (EHP)

## A Case Study of Successful ePRO Collaboration

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## Introduction

The increasing use of electronic patient-reported outcome measures (ePRO measures) brings with it a need and an opportunity for those involved in their development, translation and use to work closely together to secure successful results. Here we present a case study where the collaborating parties have each contributed their expertise towards the successful migration of a patient-reported outcome (PRO) measure from its original paper-based format through to an electronic tablet-based format in over 25 language versions.

## Objectives

The study focussed on the Endometriosis Health Profile (EHP) – a widely-used measure for assessing health-related quality of life in women with endometriosis – with the aim of creating an electronic version, the ‘eEHP’, and corresponding translations.

*The work followed 3 main phases:*

- development and review of the source English eEHP
- testing of the ePRO version
- adaptation of new and existing EHP translations for the ePRO format.

*The collaborative parties were:*

- CRF Health – a global leader in eCOA solutions for the life sciences industry;
- Crispin Jenkinson – the developer of the original paper-based EHP;
- Isis Outcomes – the owners, managers, licensors and providers of support in the use of the EHP;
- Bayer Pharma AG – the study sponsors; and
- PharmaQuest – a specialist PRO translation company.

Our joint objective was to create an electronic version of the EHP that would be an accurate and equivalent representation of the source paper-based version, not only in its UK English implementation but also across the generated language translations.

## Methods

### Development and Review of the ePRO Measure

- CRF Health's Application Specialists used the company's TrialStudio® software to create an electronic representation of the EHP. This system was chosen as it allows the electronic version to be defined without the need for manual coding by using visual tools, which enables all stakeholders regardless of technical ability to take part in the design process. TrialStudio® uses a wizard-based Graphical User Interface (GUI) with drag and drop functionality.
- This allowed stakeholders to see how the eEHP worked at any time during the eCOA system development.
- The system allows for intuitive, easy to use interface design which is ideal for reducing patient burden and increasing patient retention.

This draft ePRO version was then reviewed by the questionnaire developer, the EHP licence holder, the ePRO project managers at PharmaQuest and the sponsors. Each party reviewed the migrated measure according to their own specialisms and requirements. The reviews covered:

- linguistic equivalence between the paper version and draft ePRO
- changes made to create the ePRO version
- layout of the ePRO
- clarity and suitability of instructions
- response input methods
- forced completion
- potential effects of the adaptations on upcoming translations.

Recommendations were discussed in a group forum and joint decisions made, taking into consideration the capabilities of the software and the requirements of the patient group.

### Testing of the ePRO Measure

The revised eEHP was loaded onto 10-inch tablet devices using the TrialMax Slate™ platform. PharmaQuest then used these to conduct pilot testing of the measure, as follows:

|                                        |                                                                                                                                                                                                                                                                                                                                            |
|----------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Administration of ePRO measure:</b> | <ul style="list-style-type: none"><li>- 10 women with endometriosis</li><li>- All native speakers of UK English</li><li>- Individual face-to-face interviews</li><li>- Each patient filled in the eEHP using a tablet device</li><li>- They explained their understanding of the instructions to the investigator as they did so</li></ul> |
| <b>Cognitive debriefing:</b>           | <ul style="list-style-type: none"><li>- Patients undertook cognitive debriefing</li><li>- Aim: to assess any difference in understanding between paper-based &amp; ePRO versions</li></ul>                                                                                                                                                 |
| <b>Usability testing:</b>              | <ul style="list-style-type: none"><li>- Patients were asked a series of questions to assess usability</li><li>- Questions were based on appearance &amp; layout, functionality, physical aspects of the device, and the requirements of the population</li></ul>                                                                           |
| <b>Feedback to the ePRO developer:</b> | <ul style="list-style-type: none"><li>- Full results and any recommendations for change were provided to the ePRO developer</li></ul>                                                                                                                                                                                                      |

### Adaptation of Translations to the ePRO Format

Over 25 language versions of the eEHP were required. PharmaQuest took existing and newly-developed translations of the paper-based EHP and updated the wording to correspond to the new ePRO version, taking into consideration the delivery format (tablet device) and the new layout.

CRF Health uploaded the updated translations into the eEHP layout in TrialStudio® and PharmaQuest conducted proofreading of the generated screenshots for accuracy.

Results

Development and Review of the ePRO Measure

Only fairly minimal changes were required at the initial review stage. For example, “If not relevant, please tick here” (which was consistent with the source paper version) was updated to “If not relevant, please tap here” to reflect the context of use.

Testing of the ePRO Measure

Feedback from patients indicated that some amendments to the formatting and ordering of instructions would be beneficial. For example, feedback from pilot testing revealed that the order of the final two instruction lines might lead to unintentional data submission.

Initially, the sentences read:  
*Please save your answers by pressing the “Save” button. Once you press “Save”, you will not be able to go back to review or change your answers.*

It was noted by the respondents that there was a possibility future respondents might press the “save” button after reading the first sentence, before reading the second and therefore not knowing they would not be able to make any changes after saving.

It was therefore agreed that the order of these sentences would be reversed to make these instructions clearer (Figure 1).

However, all respondents indicated that the eEHP was easy to use and preferable to a paper-based questionnaire (Table 1).

Adaptation of Translations to the ePRO Format

The ePRO format posed some difficulties for specific languages, which required an adjustment to the layout or wording structure.

For example, the source English uses the following introductory line for each question:

DURING THE LAST 4 WEEKS,  
HOW OFTEN, BECAUSE OF YOUR ENDOMETRIOSIS, HAVE YOU...

In the paper version, this line appears at the top of each page, which may contain up to 8 corresponding questions, whereas in the ePRO version, the text is broken down to one question per screen, and the introductory line is repeated above each question.

In French, ‘have you’ is expressed as either ‘avez-vous’ or ‘vous êtes-vous’ depending upon the verb that follows, and this had been addressed in the existing French (Canada) translation of the paper-based EHP by using both phrases in the introductory sentence, as follows:

AU COURS DES 4 DERNIÈRES SEMAINES,  
À QUELLE FRÉQUENCE,  
À CAUSE DE VOTRE ENDOMÉTRIOSE, AVEZ-VOUS  
(VOUS ÊTES-VOUS)...

This works well when used for multiple items, but when placed against a single item it is unnecessarily complicated and may cause confusion. However, as consideration had been given to translations at the review stage, adaptations for individual languages were easily accommodated. It was decided that the best solution would be to use a different opening sentence for each question, depending upon which version was needed (Figure 2). The TrialMax Slate™ system was able to adapt to cover this requirement, which meant that the changes applied to linguistically validated wording could be kept to a minimum. The change in format required for the French (Canada) translation highlights the importance of translation vendors being involved in the process to adapt translations for ePRO administration.

Figure 2: Screenshots of the French (Canada) eEHP showing specially adapted introductory sentences

Figure 1: Update to ePRO instructions made following usability testing

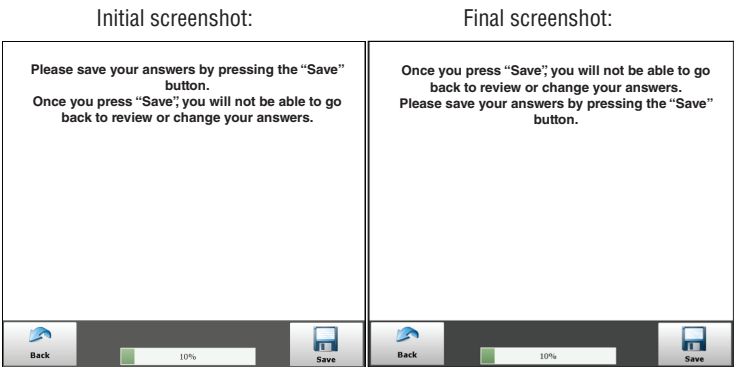
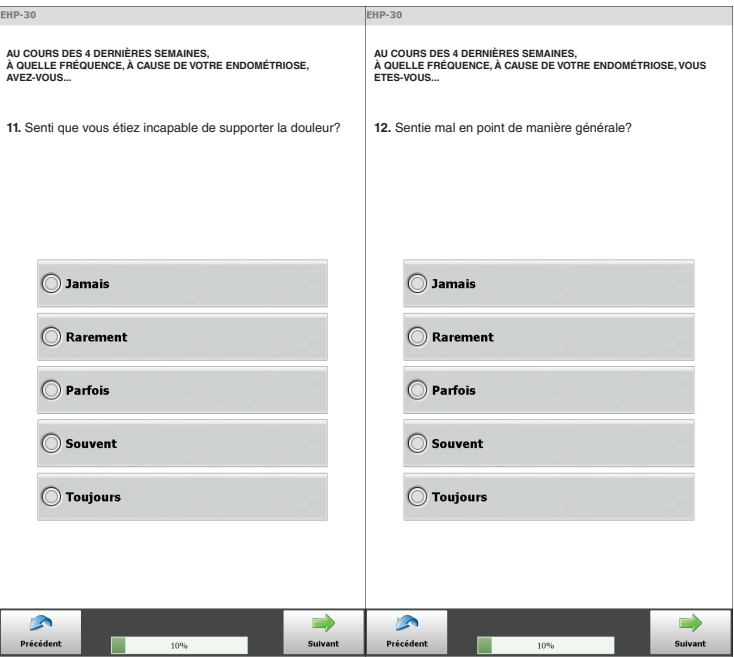


Table 1: Extract from eEHP Usability Testing Report

| Compared to a traditional paper and pencil questionnaire would you say the tablet device questionnaire is:                                                                         |                    |                            |                            |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|----------------------------|----------------------------|
| Response                                                                                                                                                                           | Easier to complete | About the same to complete | More difficult to complete |
| Number of respondents                                                                                                                                                              | 8                  | 2                          | 0                          |
| Respondent comments:<br>R1- It's also quicker.<br>R2- You don't need a pen and you don't need to post anything.<br>R5- This flows well and has a nice layout.<br>R6- It's quicker. |                    |                            |                            |



Conclusions

The results from the cognitive debriefing and usability testing confirmed that the eEHP is an accurate representation of the original paper-based version. This positive outcome was achieved through cooperative input at the initial review stage to ensure that all aspects were considered, and close collaboration throughout the project to find appropriate solutions to the challenges posed by the ePRO administration of the EHP across all its target languages.

