

# Migration Principles for Existing Clinical Outcome Assessment (COA) Instruments

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## Scope

This document is intended to provide considerations that would allow for existing clinical outcome assessment (COA) tools to be migrated to any available data collection mode (e.g., IVR, tablet, web, handheld, etc.). This document is intended to apply to the various types of COAs, namely observer-reported outcomes (ObsRO), clinician-reported outcomes (ClinRO), and patient-reported outcomes (PRO).

The assumptions and nomenclature related to the application of this document to the migration of an existing instrument are listed below.

## Assumptions

1. This document is intended for use by those embarking on migrating an existing instrument to a new mode of data collection from its original mode
2. The considerations below are independent of the mode used for data-collection
3. This document does not replace or supersede guidance for the development of COAs for use as endpoints in clinical trials or the translation and linguistic validation of COAs
  - a. References for Content Validity:
    - FDA PRO Guidance
    - ISPOR Task Force Report - Content Validity Part I
    - ISPOR Task Force Report - Content Validity Part II
  - b. References for Cultural and Linguistic Translation:
    - ISPOR Task Force Report – Translation and Cultural Adaptation
    - Brislin RW. The wording and translation of research instruments. In: Lonner WJ, Berry JW, eds. Field methods in cross-cultural research. Beverly Hills: Sage, 1986:137-164.

## Nomenclature

Throughout this document certain terms will be used synonymously. For example, when referring to a COA, the terms *instrument*, *tool*, *questionnaire*, and *scale* may be used interchangeably to refer to the COA.

The use of the words ‘mode’, and ‘method’ in this document departs from that used in the FDA’s PRO Guidance. The PRO Guidance defines *modes of administration* as self-administration, interview, or a combination of both. Further, *data collection methods* are defined to include paper-based, computer-assisted, and telephone-based assessments. However, an informal review of the articles included in a meta-analysis conducted by Gwaltney et al (2008) suggests a different use of this terminology in the ePRO literature. For the purposes of this document, the term *data collection mode* refers to various platforms available for instrument administration (i.e., paper and electronic platforms).

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## General Considerations

### Context of Use:

- Consider characteristics of the relevant patient population and therapeutic area (i.e., context of use) for which the instrument is intended for use.
  - Consider functional abilities or limitations associated with the target population (e.g., diabetes-related vision problems, Ménière's disease-related hearing loss, Parkinson's disease-related tremors, stroke-related physical or cognitive impairment)
- Trial planning should consider infrastructure for collection of data electronically (e.g., internet connectivity variation).

### Instrument Characteristics:

- Consider the setting (e.g. respondent's home, site) of where the instrument will be completed.
  - What are the restrictions/considerations for each setting
- Consider if multiple modalities of the instrument will be used together (i.e., mixed modes within a study).
- Consider patient burden and the length of the instrument, as well as the overall length of the battery of instruments being deployed.
  - Consider the patient burden of completing the questionnaires (e.g., the amount of time to complete the questionnaire, cognitive burden)
- Consider the characteristics of the instrument and the appropriateness of migration to each respective platform.
  - Length: number of items
  - Length of item text: words per item
  - Length and structure of responses
  - Complex (15 responses to evaluate change)
  - Moderate (verbal ratings)
  - Simple (yes/no)
  - VAS
  - NRS
  - Visual elements
- Consult the instrument developer about the available modes of administration

### Language Considerations:

- Consider regions of the world where the instrument will be utilized.
- Assume that translated text will take more space than US English.
- There are direct implications wording/phrasing changes for how the existing instrument is formatted in a new mode
- Certain formatting does not translate well (e.g., fonts, capitalization, and underlining)

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## Electronic Considerations:

- Electronic technology provides many potential data collection benefits that do not exist at all on paper, such as seamless skip logic, real-time edit checks, calculations, alarms, etc. The impact, and benefits, of these should be considered and evaluated as part of the migration and not focused solely on what exists if the original version of the COA is paper.
  - Consider the tradeoff between the incremental utility of using electronic data capture and the consequences to the instrument's integrity. Does the content of the existing instrument change? How much new technology can be introduced to target modality, what are the risks?
  - Depending on the level of change, additional testing may be required (refer to the Coons et al paper regarding measurement equivalence studies)

## Instructions

- Modification may be necessary for the instructions to make sense in the context of the target modality.
- Use platform-neutral language in instructions where possible.
- Instructions should be clear and succinct.
- Instructions need to be appropriate to the actions of the target modality. For example 'circle the one answer...' may become 'choose the one answer...'. Phrases such as 'mark the one answer...', may become an issue for the electronic implementation.

## Items

- Item stems are generally incomplete statements or direct questions. If the same incomplete statement is used for multiple items, each item should be self-contained (i.e., include the full stem and response options, avoid split-stems).
- Example of split stem (to be avoided)
  - During the past 4 weeks, how much has your pain interfered with:
    1. Vigorous activities such as running or heavy lifting?
    2. Moderate activities such as climbing a flight of stairs?
- Example of complete items
  1. During the past 4 weeks, how much has your pain interfered with vigorous activities such as running or heavy lifting?
  2. During the past 4 weeks, how much has your pain interfered with moderate activities such as climbing a flight of stairs?
- Instructional language should be left out of item stems where possible and appropriate.
  - If there is a time frame for recall, be sure that is presented with every item for which it is relevant, not just once in the instructions, or at the beginning of a series of items.

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- If instructional language is included in the item, then platform-neutral language should be used where possible.
- When migrating to an electronic platform that requires visual processing of the questions, full question text and all response options should be visible on the screen at all times.
  - If the full question and responses cannot be displayed on the screen, possible workarounds include toggling, scrolling, hover notes, and split screens.
  - [pending detail about IVR migration]

### Response Sets

- Consider the nature of each response set in the instrument to evaluate the appropriateness for migration to the target modality.
- The instrument should require the subject to enter an active response to each item, as it is imperative to avoid a passive (i.e., default) response. For example, if a respondent does not complete an item, the data should be recorded as missing, or no response.
- Length of response options and number of response options may have an impact on appropriateness for migrating to other modalities.
- It is important to consider how edit checks (e.g., the respondent is alerted to re-enter their response if an out range value, or missing value, is entered) would be implemented for alternative modalities. If possible, it is advisable to keep the edit checks consistent across modalities.
- Item branching logic based on the response chosen is an important factor to consider for the migration to electronic modalities.
- Anchors for visual analog scales (VASs) or numeric rating scales (NRSs) may be difficult to place far toward edges of screen; not as clean as paper. Consider using an upright mark to link the extreme value with the anchor text as shown below:

1. How much pain have you had when walking on a flat surface?

0 1 2 3 4 5 6 7 8 9 10

↑ No Pain ↑ Extreme Pain

◀ Back Next ▶

The image shows a digital interface for a pain assessment question. The question is "1. How much pain have you had when walking on a flat surface?". Below the question is a horizontal row of 11 boxes, each containing a number from 0 to 10. Below the numbers are two anchors: "No Pain" with an upward-pointing arrow under the number 0, and "Extreme Pain" with an upward-pointing arrow under the number 10. At the bottom of the interface are two buttons: "Back" with a left-pointing arrow and "Next" with a right-pointing arrow.

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Select the number that best describes your **worst** neuropathic pain during the **past 24 hours**.

0 1 2 3 4 5 6 7 8 9 10

No Pain Worst Possible Pain

◀ Back Next ▶