Qualitative Synthesis of Cognitive Debriefing and Usability Testing Studies to Inform Good Electronic Clinical Outcome Assessment Design

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CLARIO.

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Introduction

- Regulatory agencies placing increasing importance on the patient voice in clinical drug development
- FDA "Patient-Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome Assessments" guidance[1]:
  - Emphasizes the importance of high-quality measures
  - Recommends developers follow best practices to design clinical outcome assessments (COAs) to avoid common issues for respondent understanding as intended
- Gold standard to measure understanding: cognitive interview or cognitive debriefing (CD)
- Access to the findings of CDs across a diversity of therapeutic areas currently limited

Objective

Perform a qualitative synthesis of CD and usability testing (UT) studies of electronic COA (eCOA) across several therapeutic areas to:

- Ascertain common issues identified by patients/caregivers
- Help inform good eCOA design

Methods

- Retrospective analysis of 54 CD/UT studies conducted between 2013 and 2022 using Clario eCOA devices
- Key findings from CD/UT reports were analyzed and coded using ATLAS.ti for the following:
  - Interpretation and relevance issues
  - Usability issues
  - Recommendations
- For usability results:
  - Studies using a similar 1-5 scale for readability/font size and overall ease of use were pooled.
  - Anchor text varied slightly, with 1 being difficult, very difficult or very hard and 5 being easy or very easy for overall ease of use; and 1 being difficult, very difficult, poor, very poor or very bad and 5 being easy, very easy, very good or excellent for readability of font size.
  - The pooled findings were used to make recommendations on best practices for good eCOA design.

Results

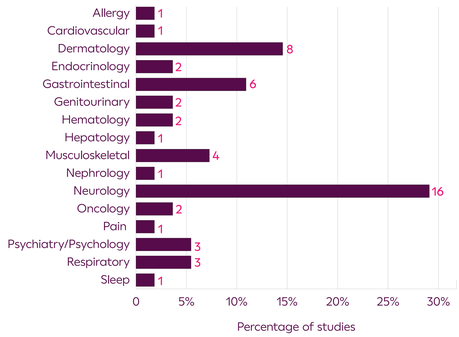
A summary of the 54 studies included in the analysis is provided in **Table 1.**

Table 1. Summary of study characteristics.

Total number of studies	**54**
Assessment	
CD/UT for interpretation, n (%)	35 (64.8)
CD/UT for P-to-E equivalence, n (%)	17 (31.5)
UT only, n (%)	2 (3.7)
Type of modality used	
Handhelds, n (%)	42 (77.8)
Tablets, n (%)	14 (25.9)
Web/computer, n (%)	1 (1.9)
Interactive voice response system (IVRS)	1 (1.9)
Total number of assessments	**131**
Total number of participants	**841**
Children/adolescents, n (%)	147 (17.5)
Caregivers, n (%)	139 (16.5)

A variety of therapeutic areas were included, with neurology (30%), dermatology (15%) and gastrointestinal (11%) representing the top 3 **(Figure 1).**

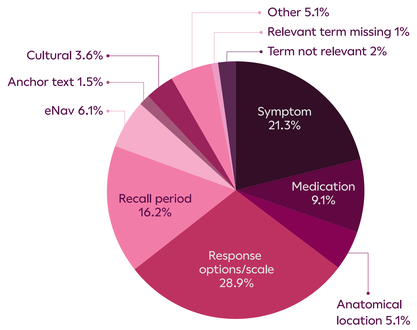
Figure 1. Therapeutic areas.



Interpretation issues included the following **(Figure 2)**:

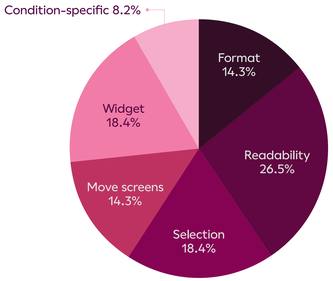
- Response options or scale (e.g., distinguishing mild and moderate or faces on a faces pain scale)
- Clinical terms such as signs/symptoms (e.g., aura)
- Recall period (e.g., time period of "yesterday")
- Medication (e.g., acetaminophen)
- Terms used for the electronic navigation (e.g., labels on buttons)
- Anatomical location (e.g., abdomen, nasal area)
- Cultural (e.g., using 24-hour clock in the United States)

Figure 2. Issues identified relating to interpretation/relevance.



In all studies, usability was rated well, and usability issues were rare. Of the few usability issues identified, the most frequent was with readability (26.5%); common feedback was a preference for a larger font **(Figure 3)**.

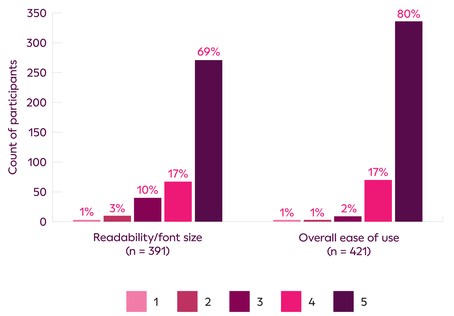
Figure 3. Issues identified relating to usability.



For the pooled studies regarding usability **(Figure 4)**:

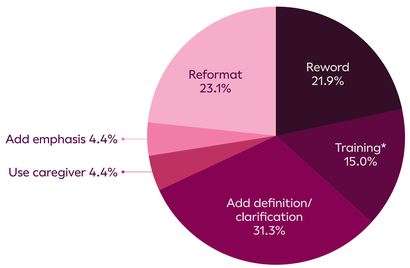
- 86.4% rated the readability/font size as good, very good, easy, very easy or excellent (4 or 5)
- 96.4% rated the overall ease of use as easy or very easy (4 or 5)

Figure 4. Usability testing results for Clario devices.



Recommendations to improve interpretation and usability from the studies are shown in **Figure 5**. While training was only 15% of all mentioned recommendations, it was recommended in 24 of the 54 studies (44%).

Figure 5. Recommendations for best practices.



*Training only coded once per study due to inconsistencies in reporting and that one training could cover all issues identified

Discussion/Conclusion

- **Suggested areas of focus for new COA design:**
  - Response options/scale were the most identified misinterpretation issue and should be a priority during COA design and testing given their significance to clinical trial outcomes.
  - Clinical terms or symptoms were also commonly misinterpreted by respondents, suggesting the importance of cognitively debriefing these terms with the population of interest.
  - Although usability issues were rare, the most common finding was readability issues, with preference for a larger font size, highlighting the FDA's recommendation for accessibility features.[1,2]
- Potential limitations of this synthesis include variations in different interview vendors and how they report the findings.
- Future studies could further examine therapeutic area-, age- or device-specific findings.

References

1. Food and Drug Administration. *Patient-Focused Drug Development: Selecting, Developing, or Modifying Fit-for Purpose Clinical Outcome Assessments, Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders*. June 2022. Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-focused-drug-development-selecting-developing-or-modifying-fit-purpose-clinical-outcome
2. Food and Drug Administration. *Digital Health Technologies for Remote Data Acquisition in Clinical Investigations. Guidance for Industry, Investigators, and Other Stakeholders*. December 2021. Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/digital-health-technologies-remote-data-acquisition-clinical-investigations