Comparative Analysis of Smartphone Application and Web-based Electronic Clinical Outcome Assessment (eCOA) Modalities

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Why did we perform this research?

• To allow patients to respond to eCOAs across a range of digital modalities, a data collection suite was developed that includes a unified smartphone app and a web-based solution compatible with smartphones, tablets, and computers.¹ • Providing multiple modalities for data collection in clinical trials may help to maximize inclusivity and compliance and enhance participant user experience, ultimately improving clinical trial delivery.² • ISPOR guidelines recommend establishing the usability of each modality and the measurement equivalence between different data collection modalities before use;^{3,4} therefore, the objective was to evaluate the usability of each modality and the equivalence of responses via the smartphone application and web-based data collection modalities. How did we perform this research? • The study was conducted in two phases, with participants using four modalities to answer questions on four different types of eCOA response scales (Figure 1) across both phases. Figure 1. Response modalities (A) and eCOA response scales (B) used in study phases 1 and 2 (A) Smartphone Tablet **(B)** Computer NRS Web Арр Web Web Sleep quality Phase 1: usability interviews • Qualitative interviews were conducted with adults in the USA (Figure 2). • Participants were observed for ease of use and other non-verbal behaviors while using each modality. Questions were asked to evaluate the participants' perceptions of the usability of modalities and response scales and their preferences. - Interviews were audio recorded and transcribed and qualitative data were thematically summarized. **Figure 2. Interview structure** ntroduction and Task observation + item and modality discussions device set-up Randomized order Web Web App Phase 2: equivalence analysis • A quantitative equivalence study was performed to assess the agreement of responses between modalities (Figure 3). • Participants recruited to phase 2 were divided into six groups, depending on the devices they owned, to answer eCOA questions on two modalities (the smartphone app and one web-based modality) spaced apart during a single day. Inter-modality equivalence was assessed by intraclass correlation coefficients (ICCs) between the app and the webbased modalities combined. - ICCs range from 0 to 1, with higher values indicating greater inter-modality equivalence. Figure 3. Quantitative equivalence study design Timepoint 1 Break First modality test 4 to 12 hour Six groups 6 3 washout 035 246 6 8 6 (n = 9-10 each)Numbers in circles represent the group numbers. Each participant remotely completed four single-item eCOAs with different response scales (Figure 1) on their two assigned modalities (smartphone) app and one web-based modality). The washout period was to eliminate carry-over effects from one modality to the next. Response scale and modality presentation was randomized

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VAS-H Daytime sleepiness









Scan the QR code to access the

What did we find?

Phase 1: usability interviews

Figure 4. Outcomes of usability interviews

Modality



– App	





Phase 2: equivalence analysis

- on the scale.⁶



Abbreviations

app, application; eCOA, electronic clinical outcome assessment; ICC, interclass correlation coefficient; NRS, numeric rating scale; VAS-H, visual analog scale-horizontal; VAS-V, visual analog scale-vertical; VRS, verbal rating scale.

• Phase 2 included 59 adults (aged 20–69 years) with various levels of education and employment, and some participants required eyesight correction (see **Supplementary Table 2** for participant characteristics).

• For all response scales, ICCs showed good to excellent agreement (0.77–0.93), exceeding the target threshold of ≥ 0.75⁵ (Figure 5). - As expected, the ICCs were lowest for the VAS response scales, which are generally considered difficult to score because of a lack of intermediate descriptors

Figure 5. Agreement between app and combined web-based modalities for the four eCOAs tested in the study





ICC (95% CI)

What are the key takeaway messages?

Overall, the app and the web-based modalities were considered to be simple, clear, and easy to use.



Findings demonstrated equivalence between the smartphone application and the web-based modalities for four common response scale types.

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0.77 (0.70–0.85)





This research shows that smartphone, tablet, and computer-based modalities in this data collection suite may be used interchangeably, providing reliable and equivalent data across devices.

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