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Development and Content Validation of a Seizure eDiary Optimized for Clinical Trials: A Partnership with Industry Epilepsy Experts

Methodological Question Being Asked

Can an innovative seizure electronic diary (eDiary) be developed to be fit for purpose across protocol and target population needs and user friendly for patients, caregivers and investigators?

Introduction (Aims)

Clinical trials in epilepsy typically evaluate seizure frequency and type (among other variables) to determine a treatment effect. Historically this information has been collected using a patient completed paper diary. It has been established that electronic data collection offers benefits over paper due to eliminating manual transcription of source data into the EDC database, availability of an audit trail, time stamped entries and ability to complete assessments on one's personal device [Bring Your Own Device (BYOD)]. To leverage the well-documented advantages of electronic data collection, industry scientific and technological experts worked with the Epilepsy Study Consortium, Inc. (ESCI) Working Group comprised of members of the ESCI, key opinion leaders in epilepsy clinical trials, and pharmaceutical company representatives to design a new seizure eDiary.

Figure 1: Diary Summary and Insight Pages

TYPE OF SEIZURES COLLECTED	SELECT FROM ILAE CLASSIFICATON LIBRARY
Clusters	Include: Yes or No
Count	Number of seizures
Duration	Length of seizure
Timeframe	Approximate time seizure occurred
Collection of rescue medication	Include: Yes or No

Table 1: General Diary Configuration Options

Methods

Input from the Working Group guided the creation of initial eDiary mockups, followed by iterative feedback cycles. Following the initial development, formal semi-structured qualitative interviews were conducted with a representative sample of ten individuals with epilepsy and ten individuals who are caregivers of patients with epilepsy (Table 2). Interviews involved two stages: (1) cognitive debriefing to ensure that the instructions and content of the eDiary are relevant and comprehensible and (2) usability testing to evaluate the ease of use of the eDiary (Figure 2). This is in line with regulatory agencies' emphasis on the importance of the patient voice and best practices in Patient-Reported Outcome (PRO) development.

PARTICIPANTS	NUMBER	YEARS WITH DIAGNOSIS *MEAN (SD)*	SEX N (%)	AGE IN YEARS *MEAN (SD)*	EDUCATION IN YEARS *MEAN (SD)*
Adults with epilepsy diagnosis	10	28 (9.7)	Female 5 (50%) Male 5 (50%)	44 (15.9)	14 (1.6)
Caregivers	10	20 (9.4)	Female 5 (50%) Male 5 (50%)	44 (15.7)	13 (4.3)

Table 2: Summary of Participant Characteristics

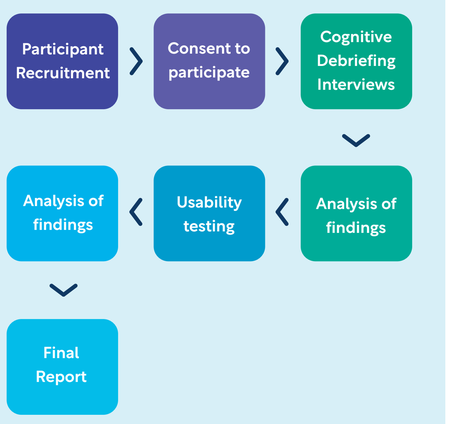


Figure 2: Cognitive Debriefing and Usability Testing Process

Results

Users reported no major issues regarding the relevance or appropriateness of the eDiary instructions or content. Twenty-one minor modifications were suggested during cognitive debriefing; eighteen were implemented, two will be addressed in training and one was preferential (Figure 3). Suggested changes include minor rewording (i.e., changing "Individual or Multiple Countable Seizure(s)" to "One or More Countable Seizures") and formatting (i.e., changed the use of symbols ">" and "<" to number ranges) (Figure 4). No significant usability problems were encountered during usability testing, and subjects reported liking some of the features (insights page). Usability testing results include six suggested minor modifications; three will be addressed in training and three are preferential (Figure 5). Suggested changes include additional text for clarity (e.g., add date to "My tasks" page) and formatting (e.g.., increase font size or change colors) (Figure 6).

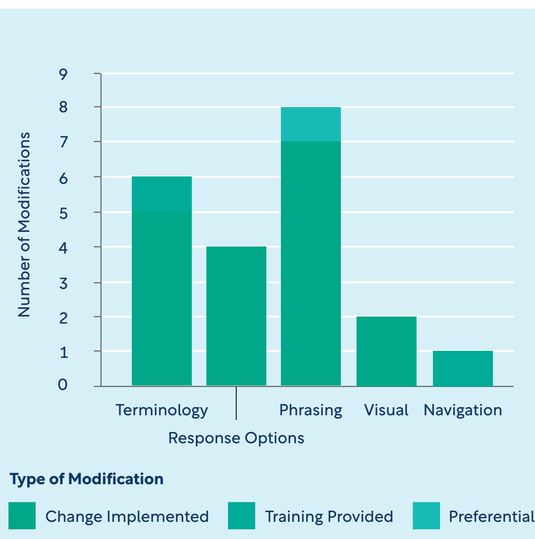


Figure 3: Cognitive Debriefing Outcome of Suggested Modifications

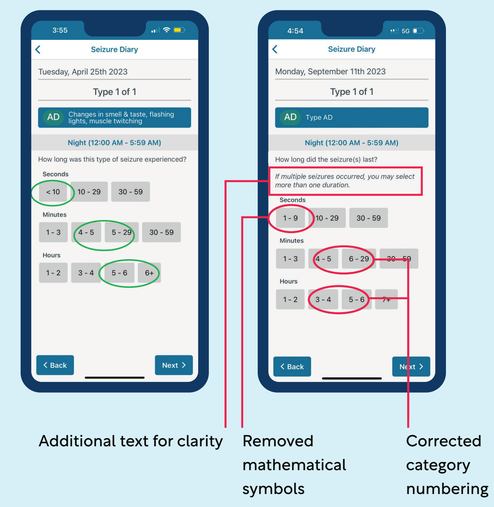


Figure 4: Cognitive Debriefing Suggested Change and Outcome

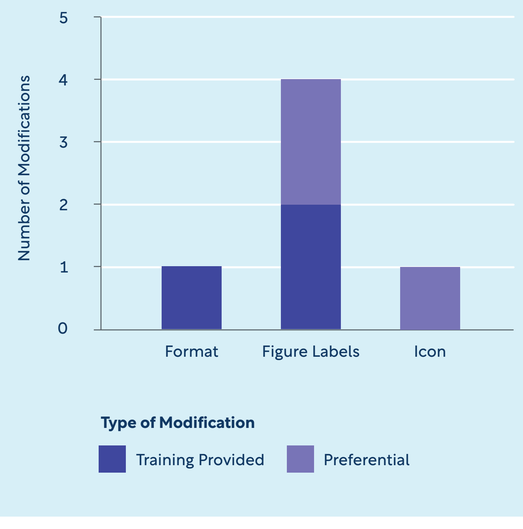
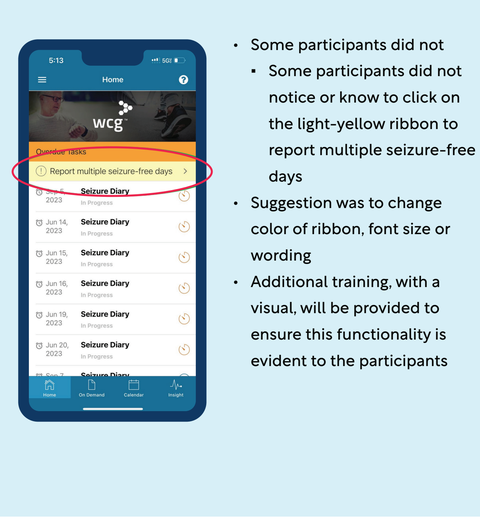


Figure 5: Cognitive Debriefing Outcome of Suggested Modifications



- Some participants did not
  - Some participants did not notice or know to click on the light-yellow ribbon to report multiple seizure-free days
- Suggestion was to change color of ribbon, font size or wording
- Additional training, with a visual, will be provided to ensure this functionality is evident to the participants

Figure 6: Usability Testing Suggested Change and Outcome

Conclusions

The qualitative research provided supportive evidence for the usability and content validity of the Seizure eDiary to capture information about subjects' seizure experiences to evaluate the efficacy of an investigational product in clinical trials. Minor changes may be considered over time to further improve data capture and ease of use. Confirmation of ease of use and improved data quality will be undertaken once the Seizure eDiary is implemented.

Disclosures

Chris Brady, Shelly Steele, Lindsey Christy, Mike Cioffi, Amee Patel, Dorothee Schoemaker, Lydia Hatfield are all full-time employees of WCG.

References

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