Exploratory Analysis of Electronic Seizure Diaries: Implications for Diary Design Best Practices

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Introduction and Objectives

Electronic diaries (eDiaries) that collect seizure events in clinical studies provide insight into the lived experiences of participants with epilepsy. eDiaries are a relevant tool for providing:

- Real-time information
- Improved participant compliance by allowing programming of reminders and notifications
- Standardised approach to seizure data collection to ensure data accuracy and completeness

We explored electronic seizure diaries to describe eDiary design, content of eDiaries, and participant compliance to identify elements that can influence data integrity and to help inform diary design best practices for collection of seizure data.

Methods

Five studies across different phases and various indications, such as epilepsy and genetic disorders, were analysed for content and participant compliance with seizure eDiaries using Clario's application.

Results

Study Characteristics: Five studies with seizure eDiaries were identified in Clario's metadata, out of which there were 3 Phase II and 2 Phase III studies (Table 1).

Study Population: All five studies included adult participants, and four studies included paediatric population from birth and up. Where the age range of the study population included paediatric population, eDiaries included the functionality for caregiver to complete the eDiary on behalf of the participants (n=4 studies).

Indication	Study Phase
Epilepsy	Phase II
Seizures	Phase II
Seizures	Phase II
Lennox-Gastaut	Phase III
Dravet Syndrome	Phase III

Table 1: Study Characteristics

eDiary Features and Content:

- All eDiaries were programmed to be episodic. The diaries were available all day for the participant or the caregiver to report a seizure after it occurs.
- Studies also included 'reminder or daily diaries' where the participant or caregiver would be reminded to report seizures for that day or if they had no seizures that day i.e., a seizure-free day. The reminder diaries were available from either 15:00 or from 18:00 pm until 23:59 for completion.
- Participants or caregivers could report previous seizures. The recall period for reporting previous seizures ranged from 2 to 7 days across the studies.
- All five studies included reminders to participants and caregivers, and email notifications to sites for missed diaries. Studies also included an on-demand participant compliance report for the sites.
- For each seizure, the eDiaries collected seizure type, date, and timing of occurrence of the seizures.
- One diary asked whether the occurred seizure was a single seizure or whether the participant had cluster seizures.
- All the studies utilised Clario's Seizure Module (Figure 1). The Seizure Module includes a site-facing interface where sites enter seizure types in the participant's own words. To report a seizure, the participant then selects a seizure from their personalized list of seizure descriptions in their eDiary. Participant-provided seizure descriptions focused on the characteristics of the seizures instead of the technical terminology (Figure 2).
- Two studies included the option to report 'New Suspected Seizure Type', where participants and caregivers could report an additional seizure type not already on their personalized list of seizure types.

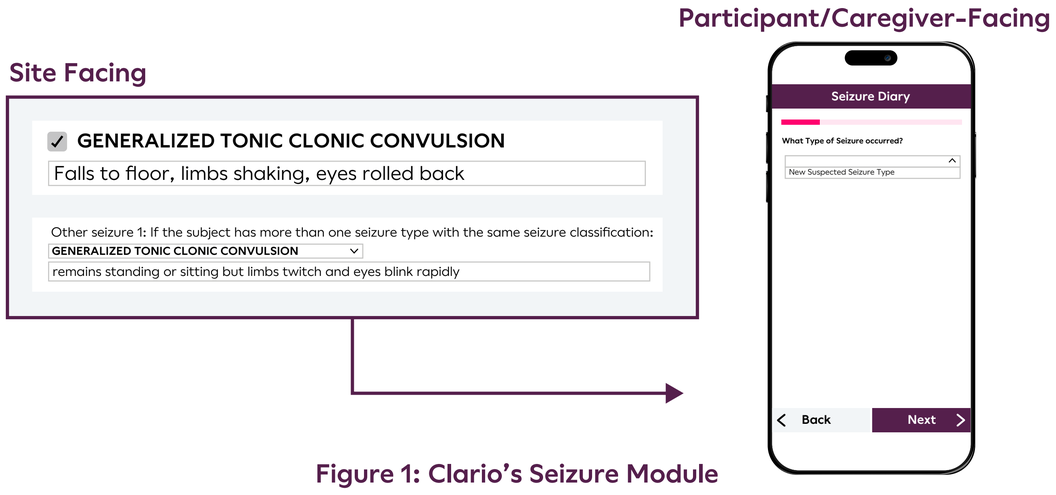

Figure 1: Clario's Seizure Module

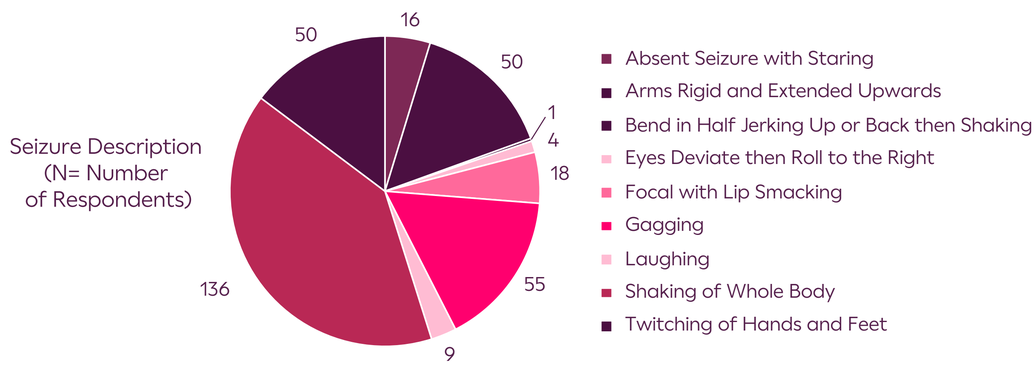

Figure 2. Example participant/caregiver-provided seizure descriptions

eDiary Compliance:
54,023 eDiary entries were analysed across five studies to measure eDiary compliance. Compliance for the diaries was high, with an average of 86% completion rate (n=5 studies), ranging from 82% to 90% (Figure 3).

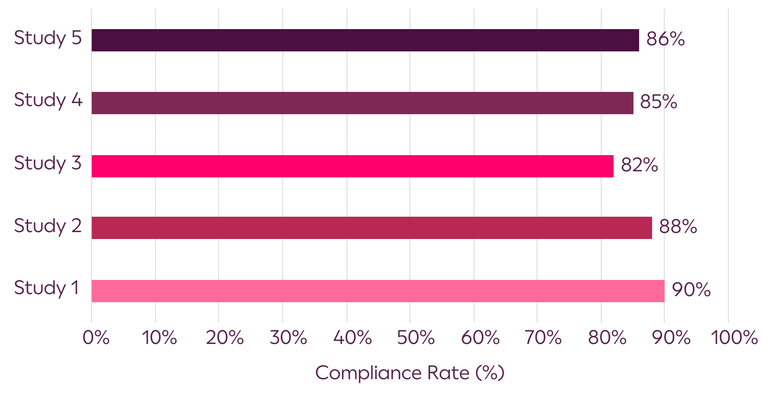

Figure 3: Average compliance for seizure eDiaries

Conclusions

- Key diary design best practices and features incorporated in all studies included: always-available episodic diary for real-time seizure reporting, daily reminder diaries available every evening, seizure types displayed in the diary using the participants' personalized descriptions, reminder alarms, and site notifications for missed diaries.
  - Allowing participants to report seizures in their own words may provide easier and more accurate reporting.
- As demonstrated by high compliance, this exploratory analysis suggests that eDiaries for recording seizures are feasible for participants/caregivers to accurately provide information about their seizures in clinical trials.
  - This is further supported by previous literature showing that app-based seizure diaries demonstrated higher precision (85.7%) in seizure reporting compared to paper diaries, which had a precision of 66.9% (Zabler et al. 2024, Sci Rep 14;15823.)

For questions, please scan the QR code for the author's email