

# Early multicenter experience with standardized approaches to seizure outcome measurement in Pediatric epilepsy trials

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## INTRODUCTION

Accurate seizure outcome measurement remains a core challenge in pediatric epilepsy trials. Children with epileptic disorders frequently present with diverse seizure types, multiple comorbidities, and limited capacity to consistently communicate seizure occurrences due to cognitive or physical impairments. Consequently, caregiver reports serve as the primary data source; however, these are prone to under-detection of sporadic and nocturnal seizures and subject to variability across sites, especially when responsibilities are shared among multiple caregivers<sup>1</sup>. Enhancing the sensitivity and reproducibility of seizure endpoints is essential for progress in therapeutic development for rare and severe epileptic conditions.

## OBJECTIVE

To evaluate operational feasibility and caregiver compliance of standardized daily seizure eDiary reporting in multicenter pediatric epilepsy trials under real-world conditions.

## METHODS

Daily electronic diary (eDiary) entries were collected across three multicenter pediatric epilepsy trials (Studies A, B, C) using standardized digital platforms. Vendor-provided operational metrics included:

- Total caregiver-days of daily seizure reporting (Figure 1)
- Daily eDiary completion (adherence) rates (Figure 2)
- Time required to complete each daily diary entry, summarized as median and interquartile range (IQR) for a single study (Study B; Figure 3)

Participants encompassed a broad pediatric age range consistent with typical epilepsy trial populations. Only aggregated, study-independent data are presented to preserve participant confidentiality.

Additional components of the broader methodological framework (e.g. structured caregiver training workflows and data adjudication processes) were integral to the overall approach but were not quantitatively assessed due to limitations in accessible data.

## DISCUSSION

This multicenter operational evaluation demonstrates that daily seizure eDiary reporting using standardized approaches is feasible, scalable, and well-tolerated in pediatric epilepsy trials. High caregiver adherence and rapid completion times indicate that daily digital reporting can be reliably sustained, even across geographically diverse and operationally complex settings.

Although quantitative assessment of broader framework components (e.g., structured training or adjudication processes) was not feasible within the available dataset, the observed operational performance aligns with key objectives of standardized seizure outcome methodologies, including consistent reporting, improved data completeness, and enhanced readiness for harmonized endpoint implementation.

Together, these findings support standardized seizure eDiary reporting as a scalable operational backbone for pediatric epilepsy trials, robust to substantial clinical variability.

## CONCLUSION

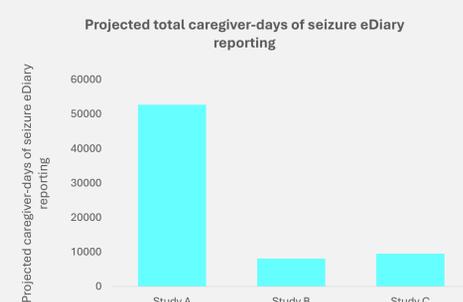
Seizure eDiaries provide a feasible, low-burden, and reliable approach for daily seizure documentation in pediatric epilepsy trials. High seizure eDiary completion compliance support their integration into harmonized seizure outcome strategies. Broader adoption of harmonized digital methodologies may further enhance data consistency, strengthen methodological rigor, and support the efficient development of therapies for pediatric epilepsy trials.

## REFERENCES

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2. Stone AA, Shiffman S, Schwartz JE, et al. Patient compliance with paper and electronic diaries. *Control Clin Trials*. 2003;24(2):182-99. doi:10.1016/s0197-2456(02)00320-3.
3. Stone AA, Broderick JE, Porter LS, et al. Patient non-compliance with paper diaries. *BMJ*. 2002; 324:1193-1194.

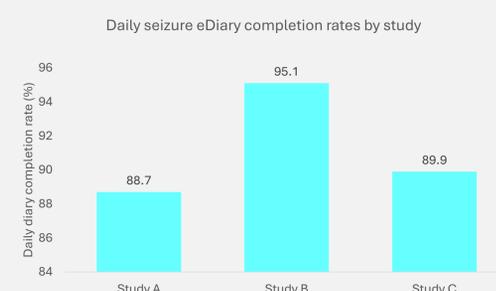
## RESULTS

FIGURE 1: LARGE DAILY REPORTING VOLUME DEMONSTRATES FEASIBILITY AT SCALE



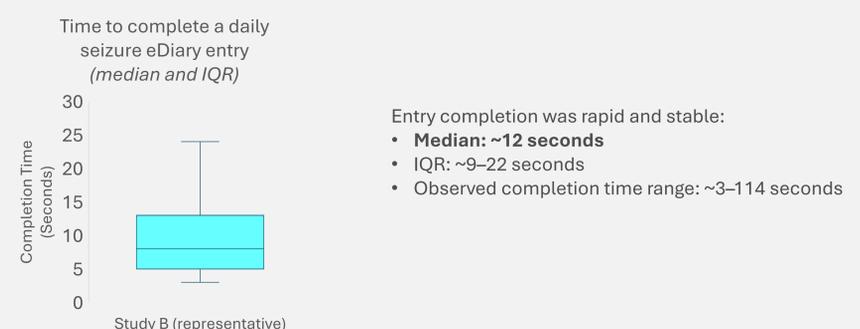
Across three multicenter pediatric epilepsy studies, more than **70,000 projected caregiver-days** of seizure eDiary reporting are expected, reflecting the operational scale and sustained caregiver engagement required over extended reporting intervals. Projected total caregiver-days of seizure eDiary reporting per study were calculated by multiplying the total number of calendar days on which caregivers are expected to complete a daily seizure eDiary with the number of participants in the study (based on planned study duration and enrollment assumptions, independent of seizure frequency per day).

FIGURE 2: COMPLIANCE (%) OF SEIZURE EDIARY REPORTING ACROSS THREE MULTICENTER PEDIATRIC STUDIES



High daily eDiary completion rates were consistently observed across all three pediatric epilepsy studies, despite differences in study design, duration, and geographic footprint. Daily completion was calculated at the study level as the proportion of expected caregiver diary days with a completed daily seizure entry, independent of the number of seizures reported per day. Completion rates for individual studies ranged from approximately 88% to 95%, with an **average compliance 92.3%**, substantially exceeding published real-world compliance estimates for paper-based diaries (as low as ~11%<sup>2,3</sup>). These findings demonstrate that seizure eDiaries can support sustained caregiver adherence in long-duration, multinational pediatric studies.

FIGURE 3: LOW CAREGIVER BURDEN: RAPID DAILY EDIARY ENTRY COMPLETION



Daily eDiary entry completion time was consistently short, indicating low caregiver burden for routine seizure reporting. The median completion time was approximately 12 seconds, with a narrow interquartile range (~9-22 seconds), reflecting efficient and repeatable caregiver workflows. Rapid entry completion time serves as a proxy for low caregiver burden in daily seizure reporting. Outliers (>1.5×IQR) were excluded from the boxplot visualization to improve interpretability but are included in the reported observed range. Data shown represent a single representative pediatric epilepsy study (Study B).

