

Evaluating Patient Reporting Habits in Clinical Trials: A Comparison of Event-Driven vs. Prompted Evening eDiary Entries



Authors Sarah T. Gary, Ph.D., Kelly Dumais, Ph.D.

Affiliations: Clario, a part of Thermo Fisher Scientific, Philadelphia, PA, USA

Introduction

Electronic diaries (eDiaries) have become an important tool for collecting patient-reported data in clinical trials. eDiaries are often used to collect episodic events that contribute to important clinical trial endpoints such as migraines, seizures, and cataplexy events¹⁻³. The benefits of eDiaries include the ability to track the date/time of entries and events, which could be entered as they happen (event-driven), or through a once daily periodic diary (e.g. evening diary) that prompts the patient to complete through notifications (Figure 1). Often a combination of the two, an always available event-driven eDiary (EDeD) coupled with a periodic prompted evening “catch all” eDiary, is utilized. Events may be entered as they happen within the event-driven diary. The periodic diary provides a review of entered events or confirms no events occurred that day, and allows additional events to be entered either directly within the periodic diary or auto-launches the event-driven diary for entry.

Within a clinical trial setting, patient preference or habits for event-driven vs. prompted periodic evening diary entry remain unclear. Therefore, the objective of this research was to examine patient habits in reporting events in eDiaries to determine how often the entries are event-driven vs. reported through prompted evening diary to help inform good diary design.

Methods

eCOA data from clinical trials that included both event-driven and periodic evening eDiaries were identified and analyzed. Compliance was calculated based on number of evening diaries submitted vs. expected.

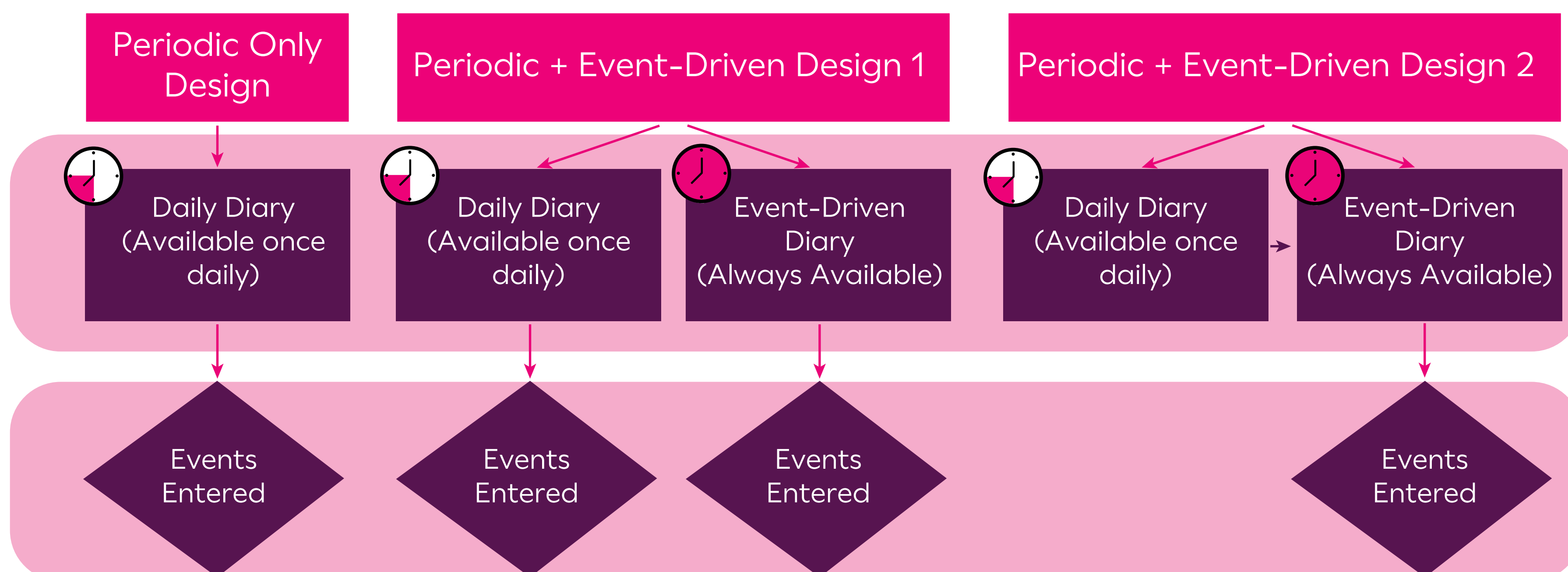


Figure 1: Overview of Electronic Diary Designs for Entering Episodic Events (e.g. Cataplexy, Seizures, Migraines)

Results

A total of 3,037 patients across 6 studies in narcolepsy, epilepsy, and migraine prevention that included both evening diaries (n=599,431) and event-driven diaries (n=379,517) were identified (Table 1). A total of 2,021 cataplexy events (narcolepsy), 174 seizures (epilepsy), and 269,369 migraines were reported. Average eDiary compliance with completing the daily evening diary was 86.3%.

In narcolepsy, cataplexy events were reported in 39.0% of evening diaries suggesting potential missed reporting within the event-driven diary at the time of event (Figure 2). Similarly, in epilepsy, seizures were reported in 11.1% of evening diaries. In migraine prevention therapy, 17.2% of evening diaries indicated that additional migraines needed to be reported. In migraine studies, migraine events originating from the evening diary were reported through auto-launch of the event-driven diary, making it difficult to determine the percent of events reported in the evening diary versus the event-driven diary. However, in Narcolepsy and Epilepsy studies, events could be entered in either the evening diary or the event-driven diary.

In Narcolepsy, cataplexy event reporting was almost evenly split between the evening diary (49.6%) and the event-driven diary (50.4%) (Figure 3). In Epilepsy, only 16.7% of seizures were reported in the evening diary, and 83.3% of seizures were reported in the event-driven diary (Figure 4), suggesting a preference for event-driven reporting.

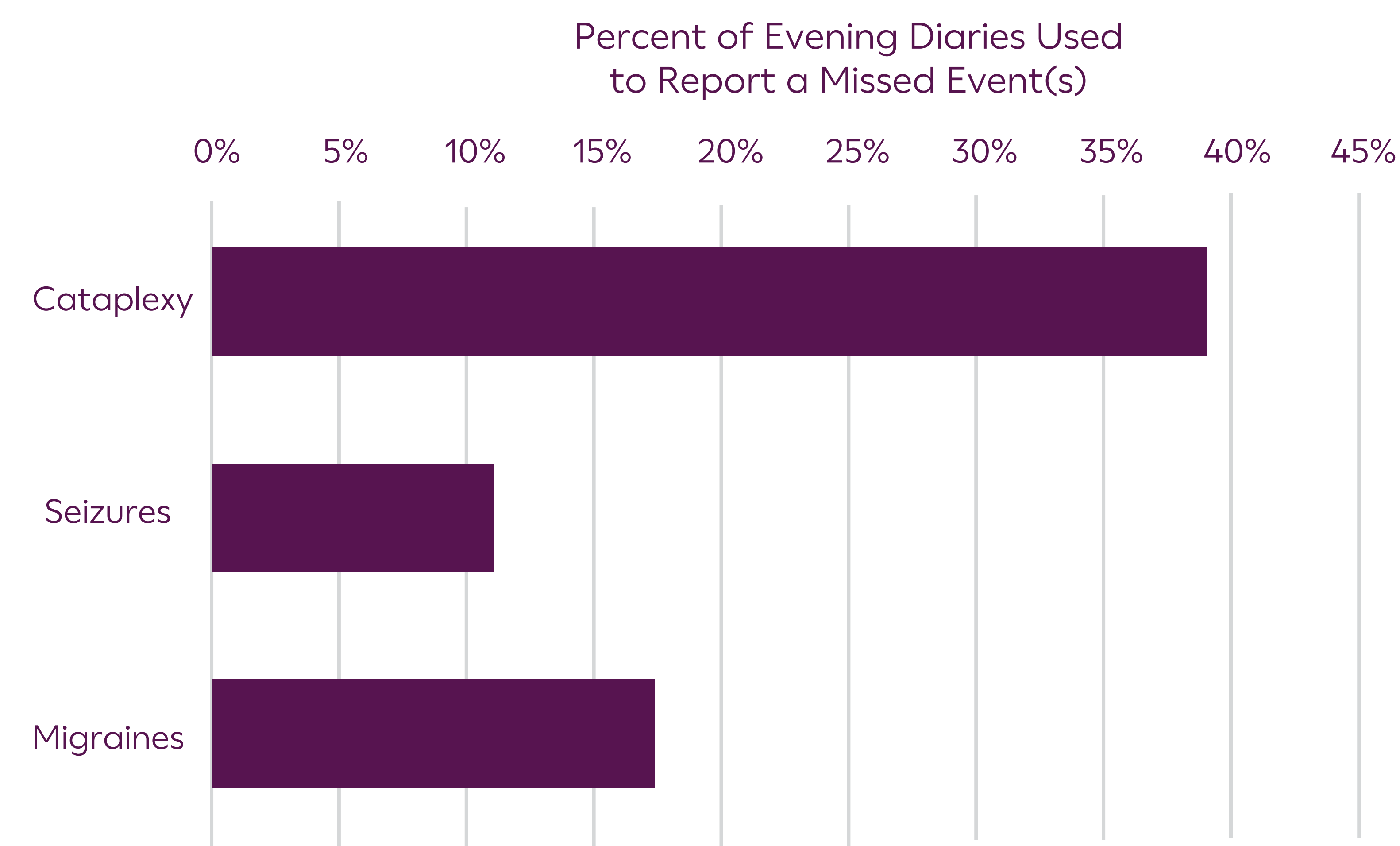


Figure 2: Evening Diaries Used to Report Missed Events (Cataplexy, Seizures, Migraines)

Table 1: Summary of Data

Total Studies	6
Total Patients	3,037
Total Evening Diaries	599,431
Total Event-Driven Diaries	379,517
Total Events	217,564
Cataplexy (Narcolepsy)	2,021
Seizures (Epilepsy)	174
Migraines	269,369
Average eDiary Compliance	86.3%

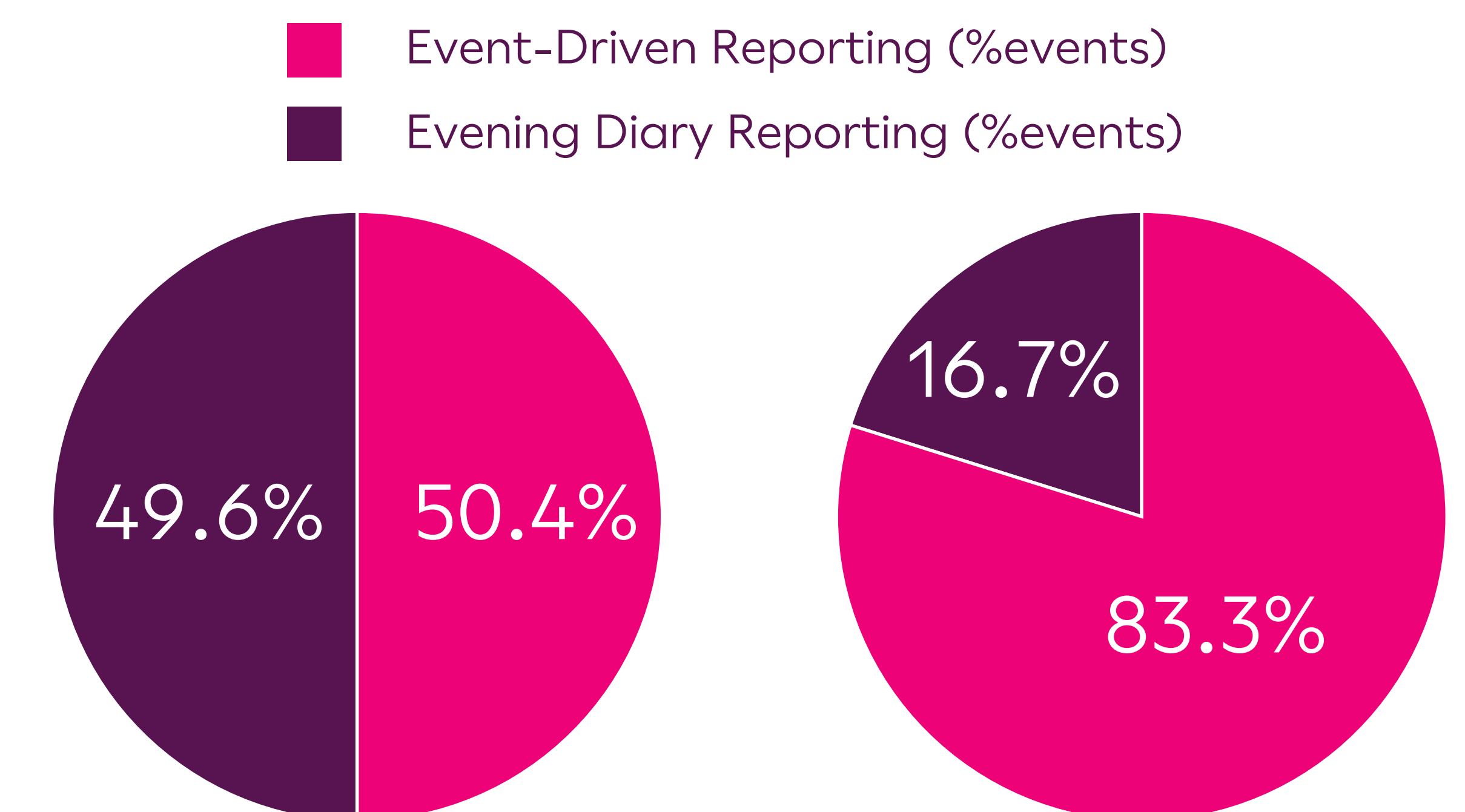


Figure 3: Cataplexy Events: Percent of Events Reported in the Evening Diary vs Event-Driven Diary

Figure 4: Seizure Events: Percent of Events Reported in the Evening Diary vs Event-Driven Diary

Conclusion

Prompted evening diaries are often used to report additional events showing the importance of their inclusion. However, a larger proportion of events were entered episodically, suggesting that including both a periodic evening diary and event-driven diary better matches patient’s habits and allows greater flexibility.

References

1. U. S. Food and Drug Administration. Patient-Focused Drug Development: Incorporating Clinical Outcome Assessments into Endpoints for Regulatory Decision-Making. (FDA, 2023).
2. Mowlem FD et al. Best practice recommendations and considerations for designing and electronically implementing event-driven diaries in clinical trials. NPJ Digit Med. 2025 Dec 15;8(1):745.
3. Gater A et al. Unique Challenges in Development, Psychometric Evaluation, and Interpretation of Daily and Event Diaries as Endpoints in Clinical Trials. Ther Innov Regul Sci. 2015 Nov;49(6):813-821.