

Best practice recommendations and considerations for designing and electronically implementing event-driven diaries in clinical trials

Florence Mowlem

The Gap

- Lack of consensus about how to define this type of data capture
- Inconsistent terminology
- Limited best practice guidance for design and implementation in clinical trials

Consensus based....



medrio

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NOVARTIS

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Lilly

CLARIO

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IQVIA

SIGNANT HEALTH

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Published in partnership with Seoul National University Bundang Hospital



<https://doi.org/10.1038/s41746-025-02165-1>

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 Check for updates

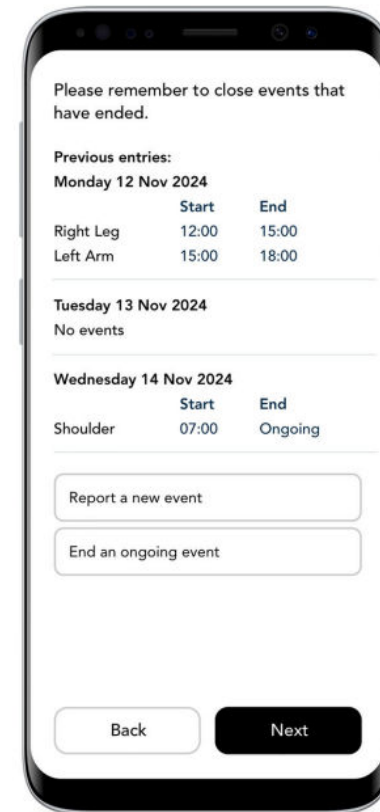
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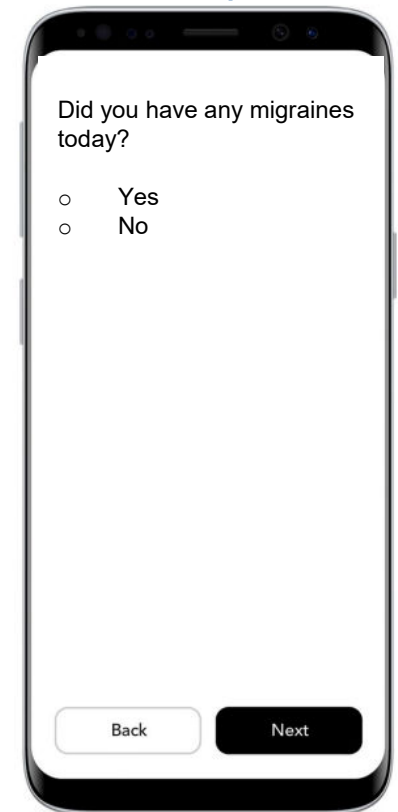
What is an Event-Driven eDiary?

An EDeD is defined here as an electronic data collection tool used to capture the occurrence of a pre-defined event of interest and any data associated with that specific event, as close as possible to the time the event occurs. This approach contrasts with scheduled assessments that are made at fixed frequencies (e.g., once daily, once weekly).

EDeD



(vs. scheduled
diary)



How they differ from other approaches

EDeD

- Data capture triggered by an event occurrence
- Capture data immediately after the event
- Granular, per-event detail
- Examples: bowel movement, seizure, bleeding episode

Scheduled Diary

- Fixed frequency (daily, weekly)
- Relies on recall over a given time-period
- Examples: daily pain rating

EMA / Ambulatory Assessment

- Repeated sampling over time
- Assesses experiences/behaviours generally
- NOT tied to a specific event occurrence
- Overlapping but conceptually distinct from EDeD

When is an EDeD the right choice?

When, what, who



High-Frequency Events

When events may occur multiple times per day and detailed per-occurrence information is needed, retrospective recall becomes cognitively burdensome and/or unreliable. An EDeD is strongly preferred.

✓ EDeD recommended



Low-Frequency Events

If events are uncommon and easily aggregated within a recall period (e.g., number of headaches), or only the most severe instance matters (e.g., worst pain), a scheduled diary may suffice.

Consider scheduled diary



Duration & Resolution

When measuring event duration or time-to-resolution is crucial to endpoint definition (e.g., bleeding in haemophilia, sickle cell crisis), real-time EDeD capture can support greater precision.

✓ EDeD recommended



Reporter Characteristics

Participant self-report is always preferred. Observer-reported data must only capture observable events. Device access and feasibility of contemporaneous reporting must be evaluated.

Case-by-case evaluation

Key Design Considerations

Balancing data quality and participant burden

Best Practices

Define what data to capture

Align with protocol

Specify the reporters

Prioritize self-report, consider implications of multiple reporters

Define how the event will be captured

Self, observer, or sensor triggered. Multiple events in parallel?

Display summary of prior entries on diary opening

Mitigate against duplicate entry. Only display required information

Schedule a reminder to report events

Confirms the absence of events

Determine data entry time window

Define time allowed between event occurrence and reporting

Practical application (DEE)



Seizure occurrence, type of seizure, rescue medication, duration

Consider bulk entry, nicknaming conventions

Caregiver

Ensure clear attribution in cases of multiple reporters, and training

Observer report

Sensors offer future possibility

List of individual events or number of each type of seizure

Time can help differentiate events

Daily

Ensures all events captured (or absence confirmed), reminds Reporters

Up to 7 days after event

Ensure date capture is part of design

Non-TA specific Best Practices

- Plan your device strategy
 - BYOD App
 - Offline capability
- Adhere to electronic implementation best practices



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Patient-Reported Outcomes

Best Practices for the Electronic Implementation and Migration of Patient-Reported Outcome Measures

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- Ensure usability
- Implement compliance monitoring
 - Use scheduled reminder system
 - Define threshold of missing data for alerting and follow-up

The future

- More publicly available information to assess the adoption of an event-driven data capture in clinical trials
 - Information on design and implementation methods adopted across TAs
- Further research on potential of sensors to capture events
- Expectations around what evidence is required to show an EDeD is fit-for-purpose

Q&A



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