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## Re-thinking Parkinson's Disease Patients Diary in the Digital Era: Signant Health's Electronic Hauser Diary



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Movement Disorders is a broad group of neurological disorders that cause abnormal movements such as increased / decreased or slow movements but can also cause involuntary movements. Movement disorders often pose challenges to diagnose and to treat. To raise awareness about this group of diseases, the "World Movement Disorders Day" is recognized annually on November 29th.

Parkinson's disease (PD) is a movement disorder where clinical trials and scientific research have made significant progress and contribution to the lives of those who live with this disease. The current treatment options available may have an impact on how the symptoms of patients with PD fluctuate throughout the day.

At the Movement Disorder Society International Congress 2024 in Philadelphia, Signant presented our latest research on an electronic Diary for Parkinson's disease used to assess the functional status of Parkinson's disease patients. [DOWNLOAD THE POSTER](#)

### Capturing Symptom frequency and severity with patient diaries

The most used common method used to track fluctuations in motor symptoms is the use of a patient diary. With the diary, patients can monitor daily symptoms and track their frequency and severity in specific time intervals, helping study teams to understand when the patient is in the "ON" state (defined as a "good" mobility due to the medication) or "OFF" state ("poor" mobility due to the lack of / poor response to medication).

Typically, diaries are provided in 'pen-and-paper' format. Paper diary completion poses questions of data integrity and quality as timely completion cannot be assured, recall over time may be inaccurate, and the fine motor skills required in its completion may be challenging at times.



The motor symptom diary in most common use was developed in a pen-and-paper format by Dr. Robert Hauser<sup>1</sup> and has been shown to be a valid and reliable instrument in the assessment of Parkinson's disease motor fluctuations<sup>2</sup>. It requires intensive use, with patients recording their motor status for each and every 30-min segment of the waking day when medication is thought to be providing motor fluctuation benefits, when such effects have worn off, and when dyskinesias are experienced. The diary is recommended for self-completion at home over 2–4-day intervals, periodically over a clinical trial treatment period.

Research has shown that true compliance in 'pen-and-paper' diaries is much lower than the diary entries themselves suggest, and that a "parking lot effect" is often observed - the behavior of completing missing entries in a paper diary just prior to a clinic visit (often in the parking lot)<sup>3</sup>. The 2009 FDA guidance<sup>4</sup> on patient-reported outcomes expresses the importance of ensuring the timeliness of patient diary entries on data integrity and states, "If a patient diary or some other form of unsupervised data entry is used, we plan to review the clinical trial protocol to determine what steps are taken to ensure that patients make entries according to the clinical trial design and not, for example, just before a clinic visit when their reports will be collected, or at other times – such as just prior to a clinic appointment."

The need for a more simple and more accurate way of capturing motor symptoms raises an opportunity to rethink the patient's diary and to redesign them it as a digital tools.

### **The case for electronic diaries**

Byrom and Muehlhausen<sup>5</sup> provide a comprehensive appraisal of the benefits of electronic formats to collect patient-reported outcome measures (PROMs). In relation to the collection of motor symptoms in Parkinson's disease studies, electronic screen-based formats deployed on smartphone or tablet computers offer the following advantages:

- **Demonstration of data timeliness and integrity.** All entries are time-stamped and dated, providing an audit trail which enables demonstration that entries are made within a suitable recall period. In addition, completion windows can prohibit entries being made beyond an agreed recall period.
- **Completion reminders.** Reminders and alarms can be used to ensure that patients remember to complete the diary in time during the intensive completion phases. Features such as suspending alarms during nap periods improve usability while maintaining the ability to remind patients for key time periods.



- **Improved data quality.** Paper diaries can be associated with ambiguous or unclear entries, conflicting data and the recording of extraneous data. In-built logic and error checking in electronic diaries eliminate these issues with paper diary data collection. activities, increasing their efficiency while at the investigator site.

## Introducing Signant Health's electronic version of the Hauser Diary

Signant Health developed an electronic version (tablet/smartphone) of the Hauser motor symptom diary, in collaboration with the diary's author Dr. Robert Hauser, focusing on ease of use for PD patients.

Qualitative interviews in 10 PD patients aged 60 and over were conducted to understand the usability of the solution and guide iterative design decisions.

Patient interviews helped to establish eDiary design principles:

ITEM	FINDINGS
Stylus vs. finger	Easy to navigate the device with fingertips or knuckles. The <b>stylus</b> proved to be extremely unpopular. Subjects reported that tapping the screen using a knuckle as opposed to a fingertip was helpful when experiencing tremor.
Alarm Sounds	Subjects liked the concept of being able to select their <b>own alarm sound</b> from options available. The sound of "Birds" chirping was the most popular option.
Layout and Navigation	General layout of the e-Diary, size and spacing of buttons, and the font sizes received extremely positive feedback; subjects found it <b>easy to navigate</b> the device after some training.
Paper vs. electronic	The use of an electronic device for PROs was the preferred choice not only for the <b>subjects</b> but also their <b>caregivers</b> .
Security	Subjects liked that they had the option of a personal <b>PIN code</b> which only they had access to.
General usability	The subjects indicated that they were more likely to want to use a <b>mobile device</b> compared to paper if they were taking part in a clinical trial. Most subjects reported no concerns about having to fill in the eDiary every 30 minutes for up to three days before a clinic visit.
Recall period	Subjects generally agreed that, if they had a mobile device with regular alarms to record their data, they were <b>more likely to accurately record their ON/OFF period</b> and other symptoms. With a paper questionnaire, they would be tempted to fill it in once a day.



## Patients with tremor and small joint issues indicated preference for:

- Knuckle for touchscreen actions instead of fingertip or stylus
- e-Diary “touch areas”: need for reliably accept feedback from the knuckles
- e-Diary components: large and separated sufficiently

## Design principles established:

- Landscape format to optimize layout
- Scrollable daily record format
- Single 30-min interval per screen

## Electronic Hauser Diary – new version 2.0:

More recently, Signant Health have reviewed the design of version 1.0 of the Hauser diary with an aim to providing an enhanced user interface and better user experience. This has included the adoption of a different color scheme, more modern stylized objects, and a simplified interface such that ON/OFF options only appear once the time period has been selected.



## Patient feedback:

Patient feedback on the eDiary design was overall positive. One patient concluded: “An eDiary would be my preferred method to use. The layout is nice and I like the bird alarm [completion reminder]. I might get a man bag to carry it”. Another patient stated: “The eDiary is definitely better than scribbling on a piece of paper. I can see myself using it”.

## Conclusions

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- Collecting patient-reported outcomes (PRO) data electronically is valuable in addressing the known limitations of paper collection.
- Good usability of electronic solutions is vital to ensure ongoing completion.



- There is sufficient evidence to support the measurement equivalence of instruments migrated to electronic screen-based formats from paper, when ePRO design best practice has been followed.
- The Signant Health Electronic Hauser diary has been developed by application of documented industry ePRO design best practice principles, in addition to additional learnings from qualitative research conducted by Signant Health in this patient population.
- Demonstration of usability and application of design best practice principles may be sufficient to support the acceptability of this implementation in regulatory submission studies.

The Signant Health Electronic Hauser diary version 2.0 provides additional user interface enhancements and is in line with our earlier usability testing findings and industry design best practice.

**Explore how our solutions and experience can enhance signal detection for your Parkinson's disease clinical trials. [LEARN MORE](#)**

## References

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