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FOUR WAYS TO STRENGTHEN PATIENT ENGAGEMENT AND IMPROVE DATA COLLECTION IN CNS TRIALS

EXECUTIVE BRIEF

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Central nervous system (CNS) trials present unique challenges in terms of patient engagement and data collection. Discover how combining behavioral science with innovative technology can reshape the success of a CNS study.

CNS trials cover a wide spectrum of participants and indications—from older adults with Alzheimer's disease to pediatric participants with autism spectrum disorder and people of all ages living with neuropathic pain, migraine headaches, anxiety, depression, schizophrenia, etc. Most of these trials have diverse measures with a range of reporters, including investigators, caregivers, and participants. Each subjective endpoint introduces a level of variability and potential bias into the data that need to be mitigated. In addition, CNS trials typically require a high level of involvement and support from caregivers. And, unlike participants in other types of trials, CNS trial participants may not always maintain a high level of awareness and motivation about joining a study.

Historically, CNS trials relied heavily on paper-based data collection. This approach has benefits in terms of "technical" simplicity and people's familiarity with using paper questionnaires. However, paper-based instruments also present real challenges to all stakeholders. For participants, it can be burdensome or impossible to recall and/or capture their responses using pen and paper (and for caregivers, that can translate into additional responsibility). Similarly, sites can be challenged to decipher handwritten data: *Was the questionnaire completed by the participant or by the caregiver? Are the data reliable? How can we validate the responses?*

Recent years have brought a shift toward more digitized and automated approaches to data collection. While these tools have improved data quality, they have often fallen short in keeping participants and caregivers engaged and effectively reducing the overall burden of participation. Given current advances in technology, there is no longer a compelling reason to settle for anything less than *both* better data *and* higher engagement.

CNS trials can achieve a higher level of performance by combining innovative, accessible technology with best practices from behavioral neuroscience and neuroeconomics research.

Here are four ways to start.

1. Find friction, and then eliminate it.

Take a hard look at sources of friction at every stage of your CNS trial. These may include:

- **Time lost** getting to and from study visits, sitting in waiting rooms, and completing lengthy instruments in clinic.
- **Money lost** paying for transportation and meals, as well as wages lost when a participant and/or caregiver misses work to attend an in-person visit.
- **Trust lost** when consent paperwork is confusing, appointments run late, and site personnel don't listen to participant or caregiver feedback.

Technology provides valuable ways to reduce these sources of friction. Conducting visits virtually and using eConsent are two ways of preventing lost time, money, and trust. Providing proactive reminders helps prevent lost time, while passive data collection (discussed further below) can prevent loss of time and trust.

2. Use defaults to improve performance.

Outside the realm of clinical trials, there is evidence that choice architecture can help shape better outcomes. For example, converting from an "opt in" to an "opt out" structure has helped improve uptake of organ donation consent in some European Union countries as well as participation in 401(k) or other retirement plans among employees at numerous organizations.

The same approach—making compliance a default rather than an option—can support the success of CNS trials. Consider how defaults for appointment times, rides, and logins can help. Rather than receiving a reminder to schedule a visit (opt in), the participant gets an email with a pre-scheduled date and time. The participant only needs to act if they need to reschedule (opt out).

3. Manage expectations and avoid losses.

Behavioral science research has demonstrated that people experience losses twice as intensely as they experience gains. Use this principle to guide how you set expectations. For example, if running behind schedule for a study visit, be intentional about how you set expectations with the participant. If you tell the participant/caregiver there will be a 15-minute wait, but it ends up taking 30 minutes, the participant/caregiver will experience that as a loss. But if you tell them there will be a 45-minute wait and it ends up taking 30 minutes, they will experience it as a gain. It's the same experience—the difference is simply how you framed what to expect.

Whether communicating with the participant, the caregiver, or both, set accurate expectations about how long required activities will take. Ensuring that everyone understands what is expected and how long activities will take can go a long way toward building trust, keeping participants engaged, and maintaining compliance and retention over the course of the CNS study.

4. Collect data passively.

One of the best ways to reduce participant burden—and improve data quality—is to use passive data collection methods when possible. Employing wearable sensors is especially valuable when studying CNS indications, where participants may also have other conditions and comorbidities with a heavy healthcare burden. Connected wearables help reduce friction by capturing accurate, reliable information without any effort by the participant. Data points collected could range from activity and heart rate to other quality-of-life measures that could be valuable exploratory endpoints.

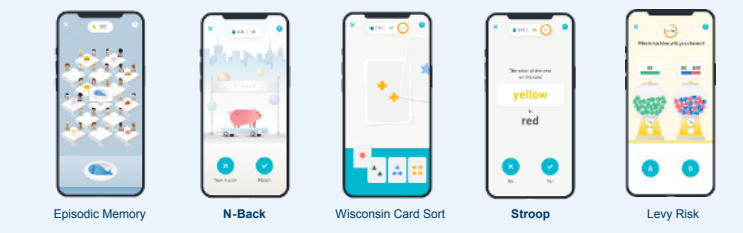
Geofencing is another tool for passive data collection. Not to be confused with geotracking (which involves using a mobile device to monitor a person's real-time location), geofencing makes it possible to be alerted only if a participants enters a medical clinic or hospital. Crossing one of these virtual "fences" could suggest a potential adverse event and would prompt a check-in by study staff to confirm whether or not the visit is related to the CNS trial.

MAXIMIZE BENEFIT. MINIMIZE BURDEN.

CNS trials present a distinct set of patient engagement and data collection challenges. Overcome them—and improve the success of your study—by taking advantage of innovative tools informed by behavioral neuroscience.

Bring it all together

For participants with CNS indications, completing a paper-based instrument might be difficult, even unpleasant. That can erode patient engagement. It can also produce unreliable or inaccurate data. Using "gamified" versions of common instruments—including Episodic Memory, N-Back, Wisconsin Card Sort, Stroop, and Levy Risk—solves both problems. It captures data you can trust while providing an engaging, even fun, experience for the patient.



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