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Electronic Diaries

Applications and What Works in the Field

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A literature review reveals that better subject compliance and more accurate field data can result from providing subjects with electronic rather than paper diaries.

Electronic diaries, or EDs, are beginning to replace paper diaries as the method of choice for collecting self-report data from subjects in the field. Clinical researchers have used paper diaries for that purpose since the 1940s,¹ but in an attempt to overcome subject noncompliance and data-quality problems associated with paper diaries,² they now often use EDs. The application of EDs to clinical research is flourishing thanks to improvements in the reliability of ED hardware and software, the documented success of ED applications, and the release of regulatory guidance for the use of EDs in clinical research.

When subjects are the end users of electronic devices in clinical research, however, important issues arise about subject acceptance and compliance, and the regulatory integrity of these systems.³ This review examines the empirical, peer-reviewed literature on EDs to help the

reader better understand the various applications of EDs to clinical research and the factors associated with the success and failure of ED use in the field.

Rationale for developing EDs

The application of EDs to the collection of subject self-report data in clinical research has its roots in three persistent problems associated with paper diaries:

- poor data quality
- long delays to data lock
- poor subject compliance.

Data quality. Paper diaries often produce data of poor quality. Specifically, paper diary data are often hard to read and contain missing or out-of-range data.^{2, 4} Furthermore, subjects often enter extraneous information that must then be transcribed, coded, and entered into a database. Because of these problems, paper diary data can generate an extraordinary number of queries. The extensive

data cleaning required to use paper diary data creates a significant burden in time and money. This results in paper diary data that is difficult to use and has impeded the use of diary methods in clinical research.³⁷

Data lock. The large number of queries and generally poor data quality result in long delays between last subject out and data lock. Studies that have examined the difference between locking paper and electronic data typically report that the EDs reduced time to data lock by approximately 80%.^{4,5} The significant differences in time to data lock have helped to show that robust, field-tested EDs can not only be a scientific success, but also can produce meaningful cost savings for the sponsor of a clinical trial.

Subject compliance. Subjects are frequently noncompliant with paper diaries. Investigators and clinical research assistants involved in conducting paper-diary trials find that many subjects exhibit “parking lot compliance”—hoarding diary cards and completing them in batches. A study by Litt and colleagues, for example, revealed that fully 70% of subjects falsified at least some of their diary entries every day by writing the time they

were prompted but then completing the entry at their convenience.⁶ This is more than a methodological curiosity, because faked diary entries rely on the very retrospective memory processes that motivated the use of diaries in the first place. It is also likely that back-filled entries do not represent the natural ebb and flow of subject experience.⁷

In sum, the empirical literature supports the observation of many clinical researchers who have been skeptical of the veracity of paper diary data.⁸ As a result of these historic misgivings about paper diary data, combined with the need for many trials to use diary data as primary and secondary endpoints, researchers began to incorporate handheld technology to the collection of diary data in clinical trials more than 10 years ago.

Literature review

This literature review of EDs in clinical research is based on a search of the Medicine's PubMed (Medline) databases (www.ncbi.nlm.nih.gov/pubmed) and the American Psychological Association's PsychINFO database (member's only, but abstracts can be viewed at www.apa.org/psycinfo/). The search terms used for this review were *computer diary* and *computer diaries*, *computerized diary* and *computerized diaries*, *electronic diary* and *electronic diaries*, and *ecological momentary assessment*. The search was limited to publications in English and the review is limited to peer-reviewed journal articles.

In addition, other articles were located by manual searches of bibliographies from existing ED studies. This literature search generated a total of 92 studies. For the purpose of this review, we examined only empirical studies published in the peer-reviewed literature, which reduced the number to 76 studies (Table 1). We also identified 16 published papers discussing methodological issues in ED research or other non-empirical discussions of EDs, which were not included in this review.

One important observation from the empirical literature is how rarely researchers report important details about the implementation of EDs. For example, one in four studies identified for this review did not mention the manufacturer, type, or size of the ED. More impor-

Table 1 Published studies of electronic patient diary use^a

Year	Authors	Research area	N	Assessm'ts per day ^b
1990	Barr-Taylor et al.	CNS (Panic disorder)	20	17
1991	Rivellese et al.	Food consumption	21	—
1992	Haythornthwaite et al.	Respiratory	18	24
1992	Totterdell & Folkard	Sleep	48	9
1993	Hyland et al.	Respiratory	24	—
1993	Rabin et al.	Urinary incontinence	50	—
1993	Rosenflack & Bendtson	Endocrinology	9	—
1993	Smith & Safer	Pain (Chronic)	31	—
1993	Waldman et al.	Location tracking	6	—
1993	Zogg et al.	CNS (Depression)	9	—
1994	Battig et al.	CNS (Addiction)	82	6
1994	Cox et al.	Endocrinology	41	—
1994	Hofer & Battig	CNS (Addiction)	120	6
1994	Jacober et al.	CNS (Addiction)	48	6
1994	Lewis et al.	Pain (Arthritis)	36	4
1994	Nived et al.	Pain (Arthritis)	307	1
1994	Penner et al.	CNS (Mood)	54	—
1994	Shiffman et al.	CNS (Addiction)	57	5
1994	Stone et al.	CNS (Chronic Fatigue Syndrome)	29	5
1994	Totterdell et al.	Sleep	30	9
1995	Clarke et al.	Endocrinology	78	—
1995	Drummond et al.	Gastrointestinal	46	1
1995	Lewis et al.	Pain (Arthritis)	36	4
1995	Parkinson et al.	CNS (Mood)	30	8
1995	Shiffman et al.	CNS (Addiction)	51	5
1995	Totterdell et al. (a)	Menstruation	24	—
1995	Totterdell et al. (b)	Sleep	61	10
1996	Affleck	Pain (Fibromyalgia)	50	4
1996	Donovan et al.	Pain (Arthritis)	19	1
1996	Kos & Battig	Food consumption	82	—
1996	Rabin et al. (a)	Urinary incontinence	50	—
1996	Rabin et al. (b)	Urinary incontinence	72	—
1996	Redelmeier & Kahneman	Pain (Surgery)	287	—
1996	Shiffman et al. (a)	CNS (Addiction)	151	5
1996	Shiffman et al. (b)	CNS (Addiction)	133	5
1996	Shiffman et al. (c)	CNS (Addiction)	108	5
1996	VanGerven et al.	Pain (Migraine)	159	—
1997	Apter et al.	Respiratory	21	3
1997	King et al.	Food consumption/ exercise	8	15

tantly, half of the studies failed to report compliance rates, and a similar proportion provided no description of subject training procedures. As others have noted, it is important that ED researchers adopt more thorough reporting standards.⁹

EDs in clinical research

The collection of studies in Table 1 reflects a broad array of applications. In terms of the range of ED applications, these studies range in duration from one

day to one year, with a mean length of ED monitoring of 34.8 (SD = 65.9) days. The mean age of subjects is 40.4, with a standard deviation of 8.5 in the 66 (87%) studies that report subjects' ages.

The average ED study assesses subjects' experiences 7.2 (SD = 6.9) times per day in the 56 (74%) studies that provide details of their sampling. Once-daily assessments, common for many paper diary protocols, account for only 8% of published ED studies. This is important

Table 1 continued (for table references, see actmagazine.com).

Year	Authors	Research area	N	Assessm'ts per day ^b
1997	Kos et al.	CNS (Addiction)	65	6
1997	Shiffman et al. (a)	CNS (Addiction)	214	6
1997	Shiffman et al. (b)	CNS (Addiction)	140	6
1997	Shiffman et al. (c)	CNS (Addiction)	105	5
1997	Shiffman et al. (d)	CNS (Addiction)	127	5
1997	Tiplady et al.	Respiratory	59	2
1998	Affleck et al.	Pain (Fibromyalgia)	50	4
1998	Carney et al.	CNS (Addiction)	48	—
1998	Collins et al.	CNS (Addiction)	37	7
1998	Finkelstein et al.	Respiratory	17	2
1998	Kamarck et al.	Cardiovascular	120	21
1998	O'Connell et al.	CNS (Addiction)	36	5
1998	Stone et al.	CNS (Coping)	100	24
1999	Faaij et al.	Gastrointestinal	94	—
1999	Honkoop et al.	Pain (Migraine)	56	6
1999	Kinne et al.	Cardiovascular	30	5
1999	Marco et al.	CNS (Coping)	100	24
1999	Milgrom et al.	Respiratory	283	2
1999	Schwartz et al.	CNS (Coping)	96	7
1999	Stephan et al.	CNS (Depression)	129	1
2000	Affleck et al.	Pain (Fibromyalgia)	89	4
2000	Catley et al.	CNS (Addiction)	41	—
2000	Finkelstein et al.	Respiratory	31	2
2000	Greeno et al.	CNS (Binge eating)	79	6
2000	Johannes et al. (a)	Menstruation	23	1
2000	Johannes et al. (b)	Menstruation	25	—
2000	O'Connell et al.	CNS (Addiction)	36	5
2000	Peters et al.	Pain (Back)	80	6
2000	Porter et al.	CNS (Coping)	95	24
2000	Salmun et al.	Allergy	60	4
2000	Shiffman et al.	CNS (Addiction)	244	11
2000	Swendsen et al.	CNS (Addiction)	100	3
2000	Tiplady et al.	Respiratory	118	2
2001	Cox et al.	Endocrinology	73	2
2001	Jamison et al.	Pain (Back)	20	1
2001	Whalen et al.	CNS (Addiction)	153	30
in press	Hufford et al.	CNS (Addiction)	33	7

^aNote that some of these studies represent multiple publications from the same dataset. A complete list of these references is provided in the Appendix.

^bThe number of assessments completed per day was not reported in some studies. These values represent averages across subjects, and had to be estimated from summary data in the Methods sections of some of these publications.

because it reflects the tendency of ED research to sample subjects' experiences several times per day. Unlike paper diaries, which are often completed right before a site visit, EDs can be used to ensure timely completion of diary entries. Not all ED studies are equivalent in this regard. As outlined below, rates of subject compliance differ across studies.

Our survey of the ED literature touches on a number of topics, including the increased use of EDs in clinical research,

the wide range of therapeutic areas that have published ED studies to date, and subject preference for EDs.

Increasing use of EDs in clinical research.

As shown in Figure 1, the empirical literature reflects a clear increase over time in the application of EDs to clinical research. These empirical studies inevitably underestimate the true prevalence of EDs because many studies conducted in the pharmaceutical industry may not be published yet or may be currently underway.

In addition, the lag time associated with publication of papers also serves to delay the appearance of ED studies in the peer-reviewed literature. That EDs are being used more begs the question of what factors are facilitating their acceptance by researchers. Several factors are responsible for the increase in ED use over time.

Hardware reliability. The hardware to support EDs in clinical research has become reliable, commercially available, and increasingly affordable. Many early studies relied on custom hardware for the ED.¹⁰ This was necessary at the time because few handheld computers were commercially available, and those on the market were not always highly reliable. Over time, researchers have adopted standard handheld platforms for use as EDs. In the early 1990s it was common for researchers to develop their own hardware for use as EDs in the field. In the past few years, this practice has become far less common. The increasing commercial availability of robust handheld computers (for example, Palm and Windows CE devices) is allowing broader applicability of EDs in clinical research.

Software support. The software required to support field use of EDs in subjects' real-world environments has become increasingly stable. This is not just an inevitable consequence of conducting an ED study. The literature contains many examples of EDs whose software failed to perform as required (for example, uploading data regularly) or that allowed subjects to enter data retrospectively, negating the advantages of diary data in the first place.⁵ Not surprisingly, researchers who have published the most studies—reflecting an increased maturity in the ED software—tend to have the highest rates of subject compliance. In short, experience counts in terms of the development of robust software for use in the field.

Regulatory guidance. Regulatory initiatives by the FDA, most notably the 1997 publication of 21 CFR 11 in addition to the creation of guidelines for electronic data collection systems, provided a framework to ensure that all electronic data can be collected to meet FDA data-integrity standards (defined by the principles that the data must be accurate, contemporaneous, attributable, and legible). As has been outlined elsewhere, an ED system must be

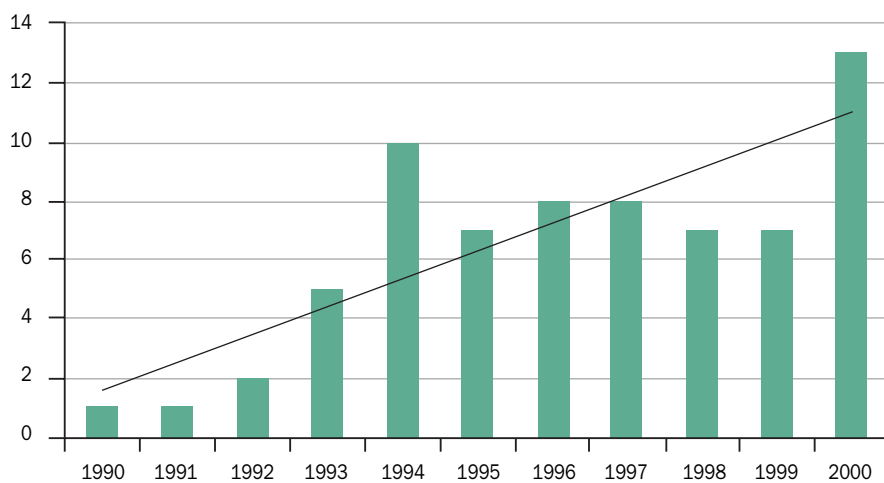


Figure 1. Graph of electronic diary publications by year (1990-2000).

developed and validated to FDA regulations (for example, 21 CFR 11) and also to general industry standards so clinical trial data can be submitted to the FDA.³ These regulations have offered important guidance and direction in the application of EDs to clinical trials.

Subject compliance. As outlined in detail below, the empirical data supports the assertion that EDs enhanced with livability and compliance features can succeed in driving high rates of subject compliance to diary protocols. Subject compliance is the key “vital sign” for how well an ED system is performing. If the user interface, hardware, software, or another issue is causing problems for subjects, the result will inevitably be a decrease in subject compliance.¹¹

Application across therapeutic categories.

EDs have been used across a variety of subject groups representing a broad range of therapeutic categories. Table 2 presents a breakdown of these studies by category. The most active researchers confound the number of studies per category (Shiffman and colleagues, for example, account for 27% of the published ED studies listed in Table 1.)

In addition, EDs have been subject to many primarily methodological inquiries to establish their validity. Of the 76 studies reviewed, 30% fall into this category. For example, several studies have examined reactivity to ED assessment. A reactive effect is the degree to which the intensity, frequency, and/or quality of a target variable changes when being observed, monitored, or assessed.¹² Four studies have examined whether real-time assessments engender significant reactivity among subjects. None of the four studies found reactivity effects.¹³⁻¹⁶

Other methodological studies have examined burden of use¹⁷ and direct performance comparison of EDs to paper diaries.¹⁸ These studies found that EDs produce higher quality, more reliable data than their paper diary counterparts. Also, ED data has been compared to data collected at site visits to examine bias, inaccuracy, and decreased sensitivity to medication effects of the retrospectively collected data.¹⁹⁻²² For example, Nived and colleagues showed that ED data could detect in four weeks a medication effect that took 24 weeks to emerge using data

collected episodically at site visits.¹⁹

Subject preference for EDs. One question that often arises regarding the application of EDs to clinical research is whether subjects prefer the more traditional paper diaries to EDs. Several studies examined subject preference for EDs and universally found that subjects readily accept and even prefer these devices to paper diaries. Drummond and colleagues reported that 57% of their subjects with gastrointestinal disorders preferred the electronic assessment, and only 13% preferred the paper versions; 30% expressed no preference.¹⁸ Furthermore, no association with assessment preference was found based on age, sex, or comfort with technology and computer use. Tiplady and colleagues compared EDs and paper diaries in 22 respiratory clinic outpatients who self-monitored with both methods for four weeks; 59% expressed preference for the ED over the paper diary, 18% preferred paper, and 23% expressed no preference.⁴ Again, a subject’s age, sex, and comfort or familiarity with technology were not associated with their diary preference. Rabin and colleagues also explored subject preference for EDs relative to paper diaries after allowing subjects in a urinary incontinence study to self-monitor with each method for one week.²³⁻²⁴ Over 98% of their subjects and over 80% of their control group expressed an explicit preference for the ED over the paper diary. Furthermore, both groups evaluated the ED more positively than the paper diary on a variety of attributes (for example, fun, easy to use, and feel involved). Finally, Johannes and colleagues found that approximately 70% of their all-female sample (n=23) preferred an ED versus a paper menstrual diary.⁵

Another study investigated whether previous computer experience was a necessary prerequisite to participate and be compliant with EDs. Finkelstein and colleagues²⁵ examined a sample of asthma subjects from a low socioeconomic urban community *without* previous computer experience (n=17). Over three weeks, the subjects were required to interact with the ED at least twice daily. Results were that the vast majority (82%) found the procedures “not difficult at all.” This suggests that previous computer experience is not necessary for subject compliance. In sum, the empirical literature reflects a clear

Table 2 ED studies^a

Research area	Number of studies
CNS (Addiction)	22
Pain	13
CNS (Misc.)	11
Respiratory	8
Endocrinology	4
Food consumption	3
Menstruation	3
Sleep	3
Urinary incontinence	3
Cardiovascular	2
Gastrointestinal	2
Allergy	1
Location tracking	1

^aNumber of studies by research area.

subject preference for EDs relative to paper diaries.

Evaluating ED success

ED success can be evaluated in two primary ways. We use the term *technical success* to refer to whether the ED functioned as required in the field. More broadly, *subject compliance* reflects not only technical success (the ED must be functioning properly for data to be entered) but also whether the subject understood the ED training, how to use the ED, and when to provide data. In other words, technical success is a necessary but not sufficient prerequisite to subject compliance,

who have developed a new ED solution for their research.

In terms of subject compliance, many researchers have noted that compliance data, despite its importance, is seldom reported in clinical trials—and often handled inappropriately.²⁷ Standards do exist for the reporting of compliance in clinical trials, which consist of dividing the number of completed assessments by the number of scheduled assessments and multiplying by 100.²⁸ When researchers do not follow these guidelines, the result can be an exaggeration of compliance rates with EDs. When evaluating compliance rates, it is important to avoid arti-

cles, adequate subject training can certainly not be taken for granted. Finkelstein and colleagues asked their subjects if they felt they received all the necessary information about self-monitoring during the training session.^{17,25} Although most subjects reported receiving all the information necessary to complete the protocol, a significant minority of both samples (26% and 24%) indicated that they did not. The actual length of training was reported in only 9 of the 76 studies, and length of training ranged from less than one hour to three hours. No clear relationship emerged between subject compliance and the length of training.

Somewhat surprisingly, the number of assessments per day appears to be unrelated to subject compliance, even after controlling for the length of the monitoring protocol. For example, Kamarck and colleagues had 99% compliance with a protocol requiring 12 or more assessments each day.³⁰ Their study used EDs with a number of compliance features and a short protocol to help balance out the intense subject burden during the monitoring period. Importantly, studies that sample subjects many times per day and have high rates of compliance demonstrate that researchers can use sophisticated EDs to do more than collect single assessments from subjects each day.^{30,32} More dynamic sampling protocols can be used to oversample critical periods, providing a sensitive test of medication effects as well as specific details of those effects, such as time-to-relief or onset-of-action hypotheses.

Some ED investigators have designed protocol components aimed specifically at increasing compliance, using them successfully in several ways and at varying levels of sophistication. For example, some researchers describe real-time feedback on the ED or regularly scheduled meetings throughout the course of protocols as excellent opportunities to provide subjects with detailed compliance reviews and feedback^{15,21,32–33} and to create a sense of accountability for the data they are providing.¹¹

The future of electronic diaries

The future of EDs in clinical research surely holds many promises and challenges. In terms of the promise of EDs, studies published to date clearly show that

The empirical literature reflects a clear subject preference for electronic diaries relative to paper diaries.

because subject compliance is also influenced by other important factors. For these reasons, subject compliance can be thought of as the best “vital sign” that researchers have to understand the success or failure of ED solutions.

One way to track technical success in ED studies is to evaluate the rate of technical problems in the field. Technical problems can be a source of missing data in ED studies.¹⁵ This is akin to missing data with paper diaries except that EDs can often track the date, time, and sometimes even the reason for the missing data. For example, Tiplady and colleagues concluded that technical problems associated with their ED system accounted for 45% of all missing data points in their data set.⁴ Whereas some studies report only episodic technical problems in the field,²⁶ other studies report significant and sustained problems regarding hardware and software. For example, despite planning to have regular uploads from the subject's home, some studies have had to use fallback data collection at research site visits to collect the data.⁵ The occurrence of technical problems is an inevitable consequence of using any technical device. Experience appears to be the key to minimizing the occurrence of these problems, because most significant technical problems seem to occur among researchers

especially inflating reported rates of compliance by collapsing completion rates across multiple scheduled assessments per day (for example, asking for hourly diary entries and then defining a day as 100% compliant if a single assessment is completed, as in Raymond and Ross⁸). Examining compliance rates for the 44% of studies in Table 1 that report compliance reveals wide variance in subject compliance—from less than 50%²⁹ to 99%.³⁰

Examining the facets of ED studies that relate to high rates of subject compliance reveals several features.

- High rates of subject compliance appear to be associated with experience. For example, Shiffman and colleagues' work that encompasses 27% of the studies in Table 1 averages a high compliance rate across studies, in excess of 90%.
- EDs that include a variety of “livability” features tend to achieve higher rates of compliance. That is, these EDs have functions that allow subjects to more easily incorporate them into their daily lives.³¹
- Researchers that explicitly discuss subject training tend to achieve higher rates of compliance.

Although it is difficult to tease out the type of training that occurred from the Methods sections of many of these stud-

subjects prefer EDs to paper diaries.²³ Moreover, when EDs are constructed with the features outlined above, subjects can be highly compliant with ED protocols.³²

Less than 10% of the ED studies reviewed collected data from subjects once daily, a practice that may be appro-

Robust hardware is a necessary, but not sufficient, precondition to a successful electronic diary.

appropriate given the indication or objective of the trial. Often, the questions presented during an end-of-day assessment ask subjects to reflect, aggregate, and then report some summary of their experiences throughout the day—"What was your average pain today?" for example, or, "How many micturitions did you have today?" In effect, the EDs in these instances become electronic case-report forms that the patient fills out each night before bedtime. However, because of the biases inherent in even brief periods of recall,³⁴⁻³⁵ end-of-day estimates may be biased and inaccurate.⁷

The literature clearly shows that EDs can be used as more than "digital paper" diaries. They can be used to actively engage subjects in the protocol. By sampling subjects' experiences at specific times, studies can be designed to provide more sensitive tests of medication effects, while collecting more ecologically valid data than is possible using paper diaries. The term for these methods, *ecological momentary assessment* (EMA)^{36, 38} has been widely applied in academic research and more recently used in pharmaceutical clinical trials.³²

Certainly, ED technology will continue to evolve at a rapid pace, offering improvements in computational power, screen resolution, on-board communication, and built-in features—and producing a wide array of impressive handheld hardware from which to choose. Another exciting area of innovation is the integration of ambulatory monitoring with EDs.³⁰ But this review of EDs in clinical research clearly suggests that fancy hardware alone is not enough to ensure success in the field. Robust hardware is a necessary, but not sufficient, precondition to a suc-

cessful ED. In other words, subject compliance with EDs shows that technology alone is insufficient to ensure successful data capture in the field. Researchers need to differentiate between technological novelty and true innovations that allow better data to be collected from subjects in a clinical trial. In short, the technology

must be used in the service of helping subjects provide the required data.

The principal challenges facing researchers who use EDs are not technological. Fundamentally, mundane issues will continue to be of primary concern. For example, a truly friendly user-interface is critical to ED success, yet the technological requirements for such an interface have been in place for more than 10 years. The logistical demands of ED research involving computer system validation, deployment, and proven subject and staff training will continue to dramatically affect the real-world success of EDs in clinical research.

Considering the evidence

A growing body of empirical evidence regarding the subject compliance and data quality problems associated with paper diaries is one powerful force encouraging the application of EDs to clinical research. When subjects save up their diaries and fill them out in batches after the fact, the scientific rationale for running a diary study is undermined, as the data are now subject to the very recall biases that researchers were trying to avoid.¹¹ In addition, the poor data quality that results from paper diaries creates additional economic burdens in terms of both data management and time-to-data lock. Understandably, researchers have turned toward EDs as one way to begin to address these problems.

Clinical researchers are showing increased interest in adopting EDs thanks to the documented value reflected in the peer-reviewed literature. Our survey found that the development of EDs over the past decade has resulted in improved hardware and software reliability, data

that shows subjects' preference for EDs, and empirical data that verifies high rates of subject compliance in many ED protocols. The peer-reviewed literature also shows that EDs are being used to sample subjects' experiences many times per day, providing researchers with new insights into the effects of experimental medications.³²

Clearly, not all ED studies are a success in the field. The variation in terms of both technical success and subject compliance appears to be a function of the maturity of the ED system, the robustness of the subject training, and incorporation of scientifically based compliance features that encourage subjects to use the devices in their daily lives.

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