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WHITE PAPER

Rave eCOA: A New Model for Patient-Reported Outcomes

Industry Challenge

Why in this day and age, with people connected 24x7 via smartphones and apps, do clinical trials still use paper to capture patient-reported outcomes (PROs)? eCOA solutions have been around for decades, but up to half of studies still use paper to capture patient assessments.

Despite the site burden & costs

Although a known entity, paper is not an easy medium to work with. Sites have to concern themselves with the logistics, transcription and archiving of the physical assets. Sponsors have to budget for these activities as well as having monitors perform source data verification (SDV).

Despite regulatory guidance

Janet Woodcock, director of the Center for Drug Evaluation & Research (CDER), stated recently that "Data quality in general needs industry's attention." The FDA, for example, "promotes capturing source data in electronic form."

Despite the "Parking Lot" effect

Perhaps the most damning aspect of paper is the Parking Lot effect. Asking a patient to report their experiences on a piece of paper in today's connected world leaves two impressions:

- "They obviously don't care all that much about the data"
- "This feels like homework. I'll do it later."

Even the best effort by patients to accurately recall their experience is subject to bias. And if they don't complete their diaries until their next office visit, the added time pressure may lead to fabricated results.

Traditional eCOA Solutions: Effective but Limited Applicability

Study teams typically evaluate the cost-effectiveness of using traditional solutions, as many are not well-suited for their specific trials. They were designed to meet the needs of the most challenging PRO studies, like the inclusion of unique instruments and/or exceptionally large volumes of assessments. Studies without these "industrial" requirements have been left without a real eCOA option and, therefore, teams resort to the old standby—paper.

Rave eCOA

A simple eCOA solution already unified with Rave EDC and has a compelling ROI, whether for a large number of assessments or small. Rave eCOA is a mobile app that runs on smart devices (smartphone, tablet, etc.), delivers fully validated instruments to the patient and feeds completed assessments directly to Rave EDC. There are no separate eCOA databases to integrate or reconcile.

Simple-to-Use Mobile App

Rave eCOA is a downloadable native app used by patients. Patients use the app to complete assessments, whether on-site or remote. With a user-experience similar to other familiar, consumer apps, Rave eCOA is simple to use:

Furthermore, mobile apps serve as a new platform for patient participation in clinical research, incorporating the patient's voice in a way not previously possible.

Simple to Deploy

Study teams configure Rave eCOA the same way they configure EDC, using the same interface and pushing the relevant forms directly to patients by checking a box. Step-for-step, Rave eCOA is as simple to deploy as paper; and best of all, these steps are already performed as part of the EDC deployment so there is **very little incremental effort.**

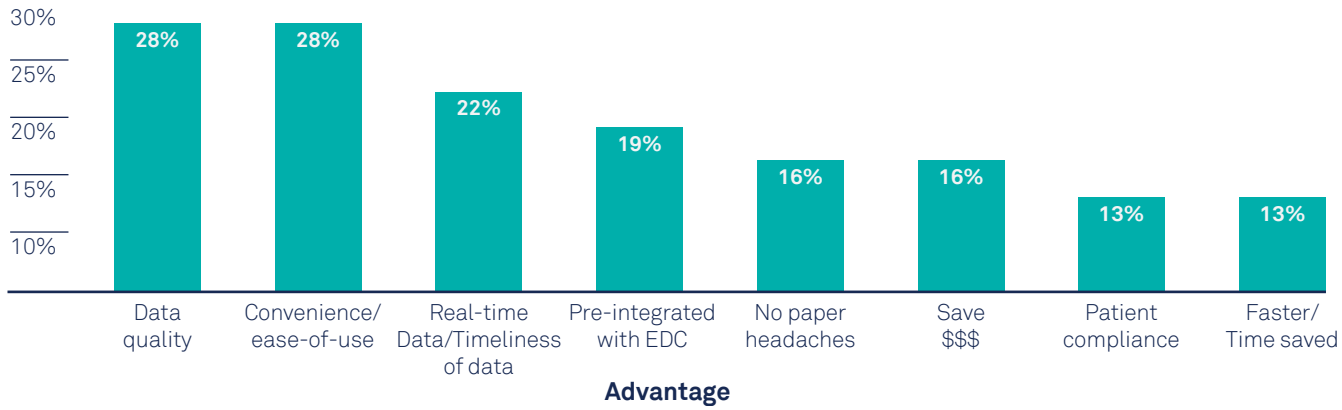
Impact on Patients

Rave eCOA can automatically provide a record of the date and time an entry is made and restrict to specific time windows. Rave eCOA prevents the ability to input out-of range, back-fill or forward fill diary entries, thus enhancing the data integrity and accuracy of data collected during the study.

Patients have an improved experience during the trial, with the ability to input their data in a user friendly, compliant manner through the use of technology they are already familiar with.

Impact on Data Managers

For data managers, data visibility is critical. The better and earlier the visibility, the greater the likelihood of a successful database lock. We recently conducted a series of workshops focused on this new approach to Rave eCOA. At the conclusion, we asked attendees (many of whom were data managers) for feedback. In a free-form question, we asked participants to share their views on the



advantages of this new model for Rave eCOA. While Data quality and Convenience were the top responses, the wide range of perceived advantages was surprising:

> "You never change things by fighting the existing reality. To change something, build a new model that makes the existing model obsolete."
>
> **-Buckminster Fuller**

Conclusion

Rave eCOA is the new model for patient-reported outcomes, intended to make older forms of reporting—beginning with paper but also including other eCOA modalities—obsolete. By leveraging new technologies in an innovative way, Rave eCOA elevates the entire patient-reporting experience.

Rave Data Capture and Management

It Starts with Data Capture

Rave Data Capture and Management is a product suite that powers clinical trials of the future including virtual, mobile, adaptive, and master protocols. It seamlessly captures and integrates all data streams and biomarker measurements that today's targeted therapies demand, going beyond clinic and lab data to also include data from sensors, apps, images, genomics and RWE (Real World Evidence)

By capturing and integrating such a wide array of study data, **Rave Data Capture and Management** also automates many of the most challenging data management workflows across randomization, supply, coding, and safety. It is now possible for a patient to be electronically consented, randomized, provided their first supply, and automatically be coded – all in their first visit.

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1. **Stephen Joel Coons, Jason Lundy, Paul O'Donohoe et al. *C*apturing Patient-Reported Outcome (PRO) Data Electronically: The Past, Present, and Promise of ePRO Measurement in Clinical Trials. Patient. 2015; 8(4): 301–309**