

Medidata Patient Cloud: 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)? ePRO 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 ePRO 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 ePRO option and, therefore, teams resort to the old standby—paper.

Medidata Patient Cloud™

Medidata set out to build a new model for patient-reported outcomes, one as simple to use and deploy as paper, one already unified with electronic data capture (EDC) and one with a compelling ROI, whether for a large number of assessments or small. The result is Medidata Patient Cloud, a mobile app that runs on smart devices (smartphone, tablet, etc.), delivers fully validated instruments to the patient and feeds completed assessments directly to EDC (Medidata Rave). There are no separate ePRO databases to integrate or reconcile.

Simple-to-Use Mobile App

Patient Cloud is a downloadable native app used by sites and patients. Sites use the app to register and train patients while patients use the app to complete assessments, whether on-site or remote. With a user-experience similar to other familiar, consumer apps, Patient Cloud is simple to use:



Furthermore, mobile apps have the potential to not only serve as a new interface for patient-reported outcomes, but also to serve as a new platform for patient participation in clinical research, incorporating the patient's voice in a way not previously possible. The following video provides some metrics that underscore the immediate and longer-term potential for the use of mobile apps in clinical development:

[Mobile Apps: The New Platform for Patient Engagement](#)

Simple to Deploy

Study teams configure Patient Cloud 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, Patient Cloud 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

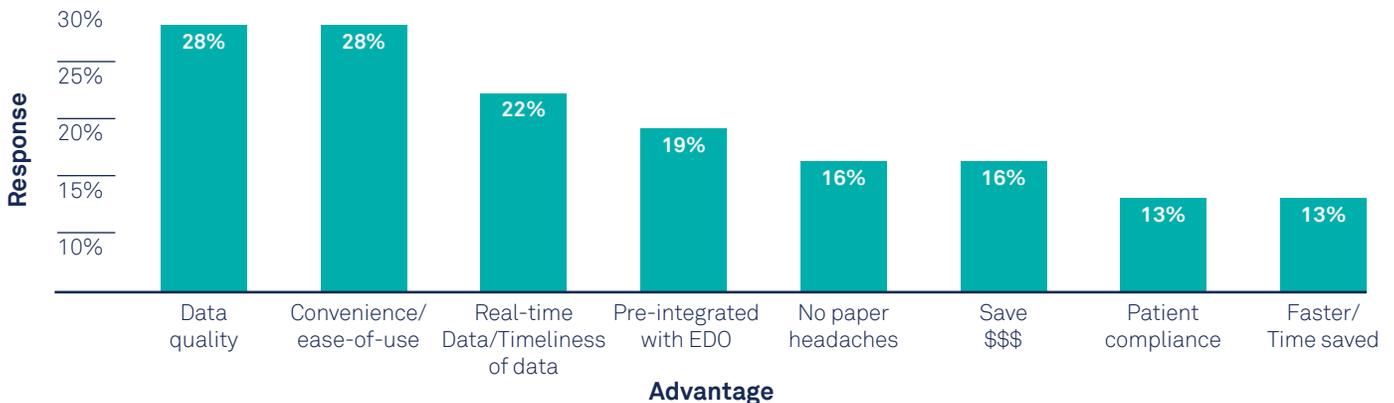
Asking patients to record their experiences using the Patient Cloud leaves two very different impressions from paper:

- “Wow, they built an app for this – it must be important”
- “They may know when I’m entering the data – I had better get it done now”

And mobile apps are not just for the millennial generation. A recent study by the Mayo Clinic using an app running on a tablet experienced a 98 percent self-assessment compliance rate. And although patients ranged in age from 52 to 85, the oldest patients were, on average, just as engaged as the youngest.¹

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 ePRO. 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 ePRO. While Data quality and Convenience were the top responses, the wide range of perceived advantages was surprising:



Some additional perspective on the advantage to this approach is provided by Chris Tyers, CDMS lead at ICON plc, in the following video:

[ICON talks about Medidata Patient Cloud](#)

Conclusion

“You never change things by fighting the existing reality. To change something, build a new model that makes the existing model obsolete.”

-Buckminster Fuller

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

About Medidata

Medidata Solutions is the leading global provider of cloud-based solutions for clinical research in life sciences, transforming clinical development through its advanced applications and intelligent data analytics. The Medidata Clinical Cloud™ brings new levels of productivity and quality to the clinical testing of promising medical treatments, from study design and planning through execution, management and reporting. We are committed to advancing the competitive and scientific goals of global customers, which include over 90% of the top 25 global pharmaceutical companies; innovative biotech, diagnostic and device firms; leading academic medical centers; and contract research organizations.

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1. MobileHealthNews, Dec. 10, 2013, [Mayo's iPad study had 98 percent engagement among seniors](#)

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