Medidata Patient Cloud®
For Medical Device and Diagnostics

With study sponsors, regulators and payers focusing more on the value of disease treatments than ever before, patient outcomes have taken on a new priority.

An extension of Medidata Rave®—our electronic data capture (EDC) and management system—and the Medidata Clinical Cloud® platform, Patient Cloud is the electronic patient-reported outcome (ePRO) app that makes it easy to meet this demand by seamlessly capturing questionnaire and diary assessments. Simply downloaded to any app-ready iOS or Android device such as smartphones and tablets, Patient Cloud can be used in-clinic or as part of patients' daily lives: at home, at work and at play.

Unlike mobile web options, native apps like Patient Cloud offer a superior user experience while also operating off-line when wireless access is unavailable. Patient Cloud captures outcome data in a variety of formats, including visual analogue and numeric rating scales, while offering a satisfying tactile experience.

With Patient Cloud, sponsors can eliminate paper PROs once and for all.

Unified ePRO/EDC Solution

Because Patient Cloud is an extension of Rave and the Medidata Clinical Cloud, there is one database, one build and one vendor relationship rather than the two required of traditional standalone solutions.

Outcomes captured via Patient Cloud are stored directly in the Medidata platform, immediately becoming part of the clinical record—no integration, no reconciliation and instant visibility to patient data. Reviewing this data, reporting on it, coding it, analyzing it and exporting it are all available as part of the unified platform. Study teams access patient-reported outcomes using the single, unified solution, just like any other patient data.

New Model for ePRO

By challenging and overcoming long-standing limitations, Patient Cloud introduces a new model for ePRO that drives significant increases in efficiency and effectiveness. Rather than the expensive and time-consuming services/customization associated with traditional ePRO solutions, Patient Cloud offers a repeatable, easy-to-implement approach that reduces setup times, dramatically reduces overall costs and mitigates study risk while ensuring regulatory compliance.

New Model Components:

• Unification with EDC
• Configuration-only setup
• Instrument library
• Scalable cost structure

Pages of Assessments	Patient Cloud	Traditional ePRO
100	✓	No
1,000	✓	No
5,000	✓	No
10,000	✓	No
50,000+	✓	✓

Simple to Deploy, Simple to Use & Cost-Effective

The setup of Patient Cloud is part of the EDC study configuration with Medidata's Study Builder tool, which eliminates the need for programming. One-click form deployment means there's no need for a separate team to deploy ePRO—simply check a box to publish a form directly to the Patient Cloud app.

For patients, the in-app experience has a familiar look and feel similar to most consumer apps. Patients easily navigate Patient Cloud and are gently reminded to complete assessments with notifications similar to those received from other lifestyle apps.

While traditional ePRO solutions require significant investment for deployment, Patient Cloud offers a new model that dramatically reduces costs by scaling with the number of assessments. To illustrate, traditional ePRO solutions become cost-effective as a replacement for paper at 50,000 pages of assessments per study[**], while Patient Cloud does so at only 100 pages.

Patient Cloud Reduces Study Risk

Representing a new, simplified model, Patient Cloud significantly reduces overall study risk. Whether eliminating the problems with paper or supporting primary endpoints, Patient Cloud drives regulatory compliance by following ISPOR's ePRO Good Research Practices.

- Reduce **regulatory** risk with high-quality, eSource data
- Increase **patient compliance** by becoming part of their daily lives
- Increase **patient visibility** with centralized & real-time patient data

The Medidata Advantage

With over 400 clients across all segments, study types, disease areas and sites in 120 countries, Medidata offers unparalleled service to study sponsors and CROs:

- Multilingual and multicultural support
- Extensive network of accredited partners
- Dedicated regulatory compliance organization with comprehensive SOPs
- Medidata Professional Services dedicated to customer success
- Comprehensive training and development from Medidata Academy
- 24x7x365 native-language support

The Clinical Cloud encompasses eight billion clinical records from more than two million patients across more than 9,000 studies. And more than one-half million data points are added daily. Sponsors and CROs around the world rely on Medidata for their clinical development needs.

** Applied Clinical Trials, June 2010, "ePRO vs. Paper"

Medidata Clinical Cloud™

Cloud-based clinical research solutions | Innovative technology | Data-driven analytics
Reduced costs | Improved time to market | Faster decisions | Minimized risk

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.

info@mdsol.com | mdsol.com
+1 866 515 6044