Medical Device Leader Uses Patient Cloud ePRO for Simpler, Easy-to-deploy Patient Input

Overview

A diversified medical device company conducting a trial with pain and quality of life endpoints adopted the Medidata Patient Cloud — a mobile app that is part of the Medidata Clinical Cloud — to overcome burdens associated with collecting patient-reported outcomes. Initial set-up, validation and patient training for the trial, which includes several hundred patients, has been as easy as a quick paper start-up. The collection, cleaning and reporting of the patient input is now automatically aligned with site-entered data for each patient, reducing time and costs significantly for the execution phase of the study as compared to paper or separate ePRO (electronic patient-reported outcome) systems.

Challenge

Interest in direct patient-reported outcomes in evaluations of drugs and devices has never been higher, with studies including more quality-of-life endpoints, comparator designs and reimbursement-related evidence. The existing methods of collecting patient input, both on paper and in electronic formats, can increase site burden, create uncertain data quality and validation issues, and add to costs and trial time.

This sponsor is a diversified medical device company specializing in development of innovative orthopedic and spine solutions. Its medical device products, approved under Premarket Approval or with Special Controls, have been sold globally. They have an active R&D pipeline, including partnerships with foundations and hospitals.

For a pivotal three-year trial to test expanding use of a marketed device, their medical team identified pain diminution as an important endpoint. They sought to prove their regenerative device could safely promote healing, speed pain reduction and mitigate other complications.

The trial was designed as a randomized, placebo-controlled trial to include several hundred subjects and up to 50 sites. The protocol specified use of three pain and quality of life questionnaires, including the SF-36®, each to be completed at numerous times over 12 months. In all, approximately 8,000-10,000 pages of patient assessments would be collected on site by study coordinators.

About Patient Cloud ePRO

Medidata Patient Cloud is the mobile app that takes ePRO to new places. Patients report information directly from their mobile devices directly into the Medidata Clinical Cloud.

The Medidata Patient Cloud:

- **Reduces study risk.** Capturing better and more current patient data on devices patients already use mitigates a broad range of study risks — including regulatory risk, patient compliance and adverse events.
- **Accelerates study timeline.** Patient Cloud speeds database lock by eliminating the time-consuming transcription of paper-based PROs.
- **Lowers development costs.** Patient Cloud eliminates the many costs incurred from paper-based PROs, and informs earlier go/no-go and adaptive trial decisions. And without custom programming or devices, Patient Cloud offers a more compelling return on investment than traditional ePRO.

This sponsor frequently includes patient assessments of pain and quality of life in their device trials as secondary endpoints, using paper collection formats, but as they considered using their standard paper collection methodology, they thought about the significant challenges in capturing patient input through paper, including:

- Burden on sites: Paper increases burdens on investigator sites, which, for many device companies, are already managing new treatment protocols and additional interventions. Paper PROs are a burden both during site visits, which are already demanding, and following visits when transcription and source document verification are performed and forms are bound and stored.
- Data quality issues: Paper questionnaires do not immediately flag incomplete or incorrect responses, requiring edits after the fact, often when patients have left the clinic.
- Sponsor cost: The inclusion of an additional data source — paper forms — that are then input to the clinical trial data system introduces additional steps for the sponsors' monitors of data verification. Monitoring is frequently the largest operational expense in a trial, after direct payment to sites for procedure reimbursements, and multiple-page assessments that need data verification for each patient can raise monitoring costs significantly.

Solution

The sponsor had recently adopted the Medidata Clinical Cloud as its standard for electronic data capture (EDC) and data management (Medidata Rave®), and randomization and trial supply management (Medidata Balance®). They had heard that Medidata offers a new type of ePRO solution, the Medidata Patient Cloud, and wondered if it would fit their needs.

Once they became familiar with Medidata Patient Cloud, they decided it would be a preferable way to collect patient input, bringing more data quality and operational ease to the trial while potentially saving money. They decided to deploy Patient Cloud for their pivotal study in which they were assessing whether their device could speed healing.

About Medidata Sponsor Enablement Services

The Medidata Sponsor Enablement Service is dedicated to helping clients get the most out of the Medidata Clinical Cloud™, reducing study costs, accelerating timelines and lowering risk.

The first phase of engagement is to help clients simplify, standardize and optimize their clinical trial processes, based on industry best practices. Medidata consultants work closely with client teams, providing training and mentoring on Medidata solutions so that the client develops the capability to autonomously create efficient, best-practice studies, without being dependent on CROs or Medidata. Simplification, standardization and self-sufficiency drive significant cost savings.

The emphasis of the enablement service then transitions to continuous process improvement, achieved both through progressive adoption of the Medidata Clinical Cloud and ongoing process refinement. As a result, clients experience a continuous acceleration of their studies.

Medidata also provides comprehensive program management throughout the engagement process, including project management, performance management and client advocacy, greatly reducing risks typically associated with systems and process enhancements.

With Patient Cloud, they found a system that was easy to set up and manage and that was already part of their cloud trial platform of choice:

- **Easy to deploy:** The Patient Cloud implementation is built directly in the Medidata Clinical Cloud using guided wizards. There are no additional integrations or steps for the clinical research team.

  In fact, a team of two sponsor employees completed the builds of Rave, Balance and Patient Cloud while continuing to perform their daily duties. The deployment process was similar to the paper process, and future deployments will require less, if any, support from Medidata.

  They relied on ICON plc, a Medidata partner and expert in PRO instruments, to ensure faithful migration of the required questionnaires to Patient Cloud.
- **Operational efficiencies:** Patient data captured through the Patient Cloud is automatically accessible within the Medidata EDC at the patient level. There is no downtime or additional batch loading steps during the trial.

  As opposed to paper forms, significant efficiencies are realized through eliminating:

  - Manual entry of patient questionnaires
  - Data entry errors and reconciliation
  - Storage, sourcing and validity issues with paper forms

  As opposed to other electronic PRO systems, significant efficiencies are realized through eliminating:

  - System integrations
  - Multiple study builds
  - Managing an additional vendor
  - Data reconciliation between systems, including resulting queries
- **Site efficiencies:** Sites are responsible for training and tracking patient input; since the Patient Cloud interface was designed as a mobile app using familiar interfaces, training for patients is easy and intuitive. Transcription of paper forms into EDC by study coordinators, source document verification by CRAs, printing, shipping, binding and storage are eliminated entirely.
- **Monitoring:** A significant reduction in monitoring costs is also linked to Patient Cloud. The trial data comes directly from the patient into the trial record as eSource, with no intervening re-recording or system integration. This eSource advantage fully eliminates a monitoring step for the pre-validated Patient Cloud.

This sponsor successfully deployed the Medidata Patient Cloud to capture patient assessments electronically for the first time. They have already begun the deployment of Patient Cloud for a second study, again as part of the Medidata Clinical Cloud.

About Medidata

Medidata 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