Medidata eCOA: Unified Approach Streamlines Processes, Speeds Start Up and Improves Data Quality

50%
EFFICIENCY GAIN IN SYSTEM BUILD

100%
REDUCTION IN DCFS

One of the world's leading biopharmaceutical companies, an existing Medidata customer, sought to transform its clinical development process. In an initiative championed by the C-suite, a multi-disciplinary team undertook a bold, end-to-end overhaul of several work streams within clinical operations and data management, including electronic clinical outcomes assessment (eCOA). In seeking a seamless approach, standardization, efficiency, and a best-in-class solution, the team adopted Medidata eCOA as part of its clinical trial data platform.

The Challenge: Electronic and Paper Processes from Multiple Vendors

The sponsor company routinely gathered patient-reported outcomes (PROs) to measure secondary and exploratory endpoints in many of its studies, but did so in a mixed model that sometimes involved paper collection and at other times made use of electronic data capture (ePRO), albeit from a variety of vendors. The lack of consistency in the company's digital approach caused inefficiencies and frequent frustration within data management.

Having relied on point-solutions for eCOA, the sponsor experienced lengthy database and application build times (12-16 weeks), delays in accessing data (due to scheduled data transfers between eCOA applications and Rave EDC), and data discrepancies that resulted in lots of time and money spent on filling out Data Clarification Forms (DCFs). The sponsor wanted a technological solution that could be applied consistently across therapeutic areas to make the process more patient-centric, simpler, faster, and less expensive.

The Solution: A Seamless Solution with Full Service Support

The company elected to replace its legacy vendor and paper systems with Medidata eCOA for all of its new studies requiring the collection of patient-reported outcomes – with no paper backup. Medidata eCOA is built on the Medidata Clinical Cloud unified data platform, along with Medidata's powerful Rave EDC, thus the build is configured, rather than customized. The solution sits on top of a single database with the same audit trails and one common user experience with a single sign on.

While the sponsor continued to rely on its Contract Research Organization (CRO) partners to build the primary portion of the study in Rave EDC, it opted to leverage the expertise of Medidata's Patient Cloud Services team to support the deployment of Medidata eCOA. Medidata project managers and implementation consultants coordinated with the sponsor and its CROs to:

- Build all of the validated / copyrighted eCOA instruments and where necessary, migrate them from paper to digital
- Manage a library of instruments for reuse
- Manage the instrument translations
- Test / QC mobile applications
- Procure and distribute devices to sites and patients
- Conduct training
- Manage the help desk for sites and patients

The Benefits: Speed, Savings, and Scalability

By adopting Medidata eCOA, the sponsor now enjoys:

Efficiencies in data management. There are no integrations with separate start-up and close-out processes and no custom data transfers.

Real-time reporting and a single source of the truth. Data, which all reside in one place, is available for immediate extract.

50% reduction in build time. The build time was reduced to an average of six weeks, with the most significant cuts coming from instrument migration timelines (reduced by 4-6 weeks), the standardization of EDC and eCOA data during the build (saving 2-3 weeks), and User Acceptance Testing (UAT) that now takes hours, not weeks.

The complete elimination of DCFs and fewer inspection findings. The data clarification step has been eliminated since all data are captured in one system, and there are no discrepancies to explore. Companies can easily spend $80-$100k on the DCF process for each study with legacy vendors.

Speed to database lock. There are no discrepancies between systems, so the reconciliation step was eliminated.

Savings from re-using instruments and translations. Validated instruments are reused, as are their translations, saving considerable time and money.

Savings from re-usable site hardware. Hardware provisioned to sites can be reused, so investigators can access all studies for the sponsor on one familiar device.

The sponsor is using Medidata eCOA for 10 studies already and is well positioned for the future, as the platform is highly scalable and can support Medidata eConsent, Sensor Cloud and traditional, hybrid, or fully decentralized trials.