The Use of Electronic Informed Consent (eConsent) in a Blood Collection Study

The Challenge: Complex Paper-based Patient Consent

The patient enrollment process in clinical trials can be tedious and quite cumbersome - overwhelming patients with pages of documents outlining potential risks, benefits, and consequences of their proposed medical treatments, and troubling them with long, complex, and difficult to understand forms. Patients often miss the opportunity for a dialogue around education and understanding with their clinical site staff, which can lead to poor engagement and ultimately, increased dropout rates. A recent CISCRP survey found 35% of patients who decided not to participate in a study reported that they felt the consent document was too difficult to understand[1].

Sites and sponsors are also plagued by the mounds of paperwork accompanying the informed consent process. The administrative workload for sites, who are responsible for consenting patients, involves initialing each page of the paperwork and managing the consent tracking, among other tireless efforts, which exposes the process to quality risks. Sponsors also incur travel expenses by relying on physical monitoring visits, and visibility into patient consent tracking and reporting remains limited.

With growing support from international regulatory agencies, recent FDA guidance documents, industry groups like Transcelerate Biopharma, and large central Institutional Review Board (IRBs), clinical research and bio banking industries are rapidly adopting eConsent as an alternative to paper.

A specialty division of a top ten pharma was preparing for an upcoming blood collection study, looking to recruit 6,000 patients spanning ten sites. As an alternative to their paper process, the company selected **Medidata eConsent** to modernize the clinical trial consenting process for patients, sites, and sponsors.

"We involved our sites early on in the decision-making process, which helped them understand the benefits of Medidata eConsent. While implementing a new technology always poses challenges, our sites ultimately loved Rave eConsent and were able to adapt and realize the benefits quickly."

Principal Clinical Research Associate

1.2013 CISCRP Report on Ineligible Participants and Those Who Terminate Participation Early

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The Solution: Medidata eConsent

Medidata eConsent provided the sponsor an innovative, patient-friendly solution for informed consent and enrollment across their ten sites. The study's 2,726 patients were presented an iPad for data collection during the consenting process. The data was subsequently collected in a hosted database, where clinical site staff were able to remotely access it online, allowing the sponsor the ability to conduct 100% remote monitoring.

Being a new process for both the sponsor and their sites, having support at the site level was critical for success. Because they hold the responsibility for consenting patients, sites were heavily engaged with the decision to implement eConsent. Their staff were trained to utilize Medidata eConsent technology so they could shift their focus back to the patient, and provide feedback throughout the study for future improvements and success.

The Results: Superior Patient Comprehension and Reduced Site Workload

Medidata eConsent provided an immediate benefit to sites -- a key factor for the speciality division, as they reuse sites when possible, and thus make site satisfaction a top priority. Over 70% of sites involved with the study strongly agreed eConsent reduced their paperwork and quality risks by eliminating physical paper from the consenting process. Implementing the technology also decreased the burden and administrative efforts for site staff, replacing complex and time-consuming study explanation tools with a clean, paperless system that provided automated reminders for consent amendments, study management tracking. Their sites can now focus on higher value activities, including addressing specific study participant questions and concerns.

Patients experienced superior comprehension throughout their consenting process by using Medidata eConsent, with 94% of site staff reporting that eConsent improved assessing the participant's understanding of the study. Because the patients were more engaged with and attracted to familiar technology, they asked more educated questions about the trial and its expectations - gaining insights they might have missed while reading a 40-page paper document.

With Medidata eConsent, the sponsor was able to understand the real value of automated reporting, and gained immediate ownership of the information in the cloud in real-time. The data and quality risks by collecting information manually were eliminated with this digital strategy, and they enjoyed greater visibility and immediate access into the enrollment process, as well as the ability to monitor the sites remotely, reduce monitoring and travel expenses, and ultimately, reduce cost.

About Medidata

Medidata is leading the digital transformation of life sciences, creating hope for millions of patients. Medidata helps generate the evidence and insights to help pharmaceutical, biotech, medical device and diagnostics companies, and academic researchers accelerate value, minimize risk, and optimize outcomes. More than one million registered users across 1,700 customers and partners access the world's most-used platform for clinical development, commercial, and real-world data.

Medidata, a Dassault Systèmes company (Euronext Paris: #13065, DSY.PA), is headquartered in New York City and has offices around the world to meet the needs of its customers.

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