Leading biotech company reduces time, cost, and risk with Medidata's Site Cloud

About the Customer

A leading biotech company with a strong commitment to developing and delivering innovative therapies for patients.

The Challenge

The biotech company invests heavily in research and development, conducting dozens of studies and clinical trials over the past decade. The company relied on Medidata Rave EDC as its electronic data capture solution of choice. However, the company struggled to find a better way of sharing data once each clinical trial was completed.

The company followed the traditional method of sharing End of Study (EOS) documents with each site. It burned secure DVDs filled with PDF documents and then mailed copies of the DVD to each site. Processing all of these DVDs took a lot of time and money, and the company didn't always receive the regulatory required confirmation from the sites that DVDs were received.

Working with DVDs can also be challenging for sites. Sites are required to maintain study data for up to 15 years, so site administrators need ways to file and store the DVDs and manage passwords. More problematic, many current laptops and mobile devices are built without DVD drives, so sites would need to hunt down a DVD drive just to view data.

"We want to be the sponsor of choice for our sites, so we focus a great deal on the site experience," says the Director of eClinical Operations. "Sites were frequently asking for another method of sharing data, but thumb drives and cloud services didn't have the level of security that we wanted or was required. We needed to find a new solution."

The Solution

Medidata invited the company to be one of the first users of Site Cloud: End of Study (EOS), Medidata's end-to-end solution to streamline and simplify the EOS media process. Rather than burning data onto physical DVDs, EOS allows

100%

sites receiving their data with automated tracking

The Value of Site Cloud: End of Study

- Eliminates time and cost of burning and shipping physical media

- Sites receive automatic updates when media is available

- Eliminates risk of physical media getting lost

the company to seamlessly generate, distribute, and manage EOS data through a more secure digital platform. It is simple to use, both for the company and its sites. EOS operates as a stand-alone application but also works like an add-on to the Rave EDC solution.

Once EOS media is generated from Rave EDC, it is uploaded to Medidata's highly secure content management platform and shared directly with the sites in PDF format. Sites receive a message through their Rave portal that the study data is available, and they provide an e-Signature acknowledging that they have received the files.

"We always had great success with Rave EDC, so the introduction of Site Cloud: End of Study has been ideal for us," says the Director of eClinical Operations. "We've had overwhelmingly positive feedback from sites, who praise how easy it's been to get data through the familiar Medidata platform."

The Results

Site satisfaction surveys indicated very high satisfaction with EOS, with sites preferring this process over the old one and indicating that EOS was easy to use.

These results were not surprising since users don't need additional passwords; they simply use the same login that they use to access Rave EDC. Sites also no longer need to worry about losing DVDs, as data is always accessible digitally.

The biotech company also reduced the time it takes to distribute EOS data from months to days. While small clinical trials might have a relatively small number of sites, major trials work with hundreds. Since each site needs its own copy of the data, simply burning the DVDs could take weeks of work. e EOS eliminates that time and the need to purchase and mail physical media.

The time needed to update data was also reduced from days to hours. Before, when the company needed to append data with last-minute results or corrections, it would need to start from the beginning by burning new data to discs all over again. Now, the company can easily update the digital data, with all sites receiving notification to download new data.

Working with Site Cloud: EOS, the biotech reduced regulatory compliance risks with the ability to track 100% of sites receiving data. This is compared to the previous workflow where approximately 30% to 40% of sites that would neglect to notify the company that they had received the media. With EOS, the company now receives updates from all sites through automated audit trails that indicate when sites receive data.

"Medidata has been a fruitful partnership for us in driving greatly enhanced engagement with our sites and patients," says the Director of eClinical Operations.

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Director of eClinical Operations, Biotech Company

About Medidata

Medidata is the operating system for life sciences and precision medicine. Medidata helps pharmaceutical, biotech, medical device and diagnostics companies, and academic researchers accelerate value, minimize risk, and optimize outcomes. 185,000 certified users across 1,400 customers and partners access Medidata's intelligent platform for clinical, commercial, and real-world data insights to create hope for millions of patients. Headquartered in New York City, Medidata has 16 offices around the world and is part of **Dassault Systèmes** (Euronext Paris: #13065, DSY.PA). Discover more at **www.medidata.com**, and follow us **@Medidata**.

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