Business challenge

To offer biopharmaceutical firms customized and flexible clinical development expertise, Veristat sought an intuitive clinical research platform with a wide range of capabilities.

Transformation

As a clinical research organization (CRO), Veristat works hard to build trust with its clients. The IBM® Clinical Development solution armed Veristat with a powerful clinical research platform that provides fully integrated advanced modules, such as medical coding and randomization, that help the organization continue to simplify clinical study processes and increase overall trial efficiency.

Kathleen Boruchowski
Director of Data Management
Veristat

Results

Increases study efficiency
to help bring products to market more quickly

Streamlines study start-up
creating more time for project oversight and strategic consulting

Enhances control and supports customization
of clinical studies from inception through completion

Veristat

Increasing efficiency and expertise with a powerful clinical research platform

Veristat is a full-service CRO that helps pharmaceutical and biotechnology development firms complete clinical trials and prepare regulatory submissions to the US Food and Drug Administration (FDA) and other regulatory agencies for approval. Veristat applies its 25 years of clinical and regulatory expertise across multiple medical disciplines, including oncology, infectious diseases, neurology, cardiology and respiratory, with considerable expertise in rare diseases. Veristat is headquartered in Southborough, Massachusetts and has offices in North America, Europe and Asia.

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—Kathleen Boruchowski, Director of Data Management, Veristat

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Bringing expertise to clinical trials

When emerging small and midsized biopharmaceutical firms are ready to take their therapies to the clinical study phase, the stakes are high. Will the therapy be safe and effective in a clinical setting, or will researchers have to go back to the lab for further development? Many of these emerging firms have spent years focusing exclusively on developing their therapies, so the clinical trial phase can seem daunting.

That's where companies like Veristat come in, offering clinical development services and expertise for this critical next step. Veristat relies on its solid record of running thorough, efficient and well-planned studies to make it stand out among the competition.

Kathleen Boruchowski, Director of Data Management at Veristat, describes the company's approach: "We really help guide our clients, working with them to understand their challenges and what they are trying to accomplish. Having done this many, many times before, we can use our knowledge and our best practices to design and execute the right path for them."

To strengthen best practices and offer its customers the best solutions possible, Veristat needed an EDC solution that it knew could support a wide variety of studies and study parameters.

Furthering expertise with technology

Veristat relies on the IBM Clinical Development platform for many of its clinical studies. Boruchowski explains why the organization selected the IBM solution: "It's a relatively easy drag-and-drop system that lets us develop our own databases quickly, while still having enough functionality to cater to the types of protocols and studies that our clients are running."

Veristat's Data Management group has grown quite a bit over the past several years, and Boruchowski has made sure that everyone on her team is certified as an IBM Clinical Development designer. "We've been able to train our teams quickly," she says. "You don't need to know computer science or programming languages to learn it." Having a full team of certified study designers has set Veristat Data Management apart from the pack, many of which have separate roles for database programmers and designers.

However, having a powerful, reliable and easy to use platform on which to build trials is just the beginning. Veristat further differentiates itself from the competition with its expertise in several of the solution's advanced modules, including the Randomization and Trial Supply Management (RTSM), Medical Coding and Lab Normal Ranges modules.

The RTSM module has simplified and standardized two previously complex processes: randomization and drug supply management. In the past, says Boruchowski, Veristat took a variety of approaches to ensuring trial randomization. "Sometimes, the randomization was done on paper, sometimes it was done through an external vendor, and sometimes it was done in the EDC system."

With the RTSM module, she explains, that uncertainty is gone. "We take great comfort in knowing that the IBM randomization module is solid. That trust has allowed us to make it more our standard, and we've been able to develop a process around doing randomization in IBM."

The supply management element of the RTSM module has also been a boon for Veristat. "It's not just about making sure the sites have enough clinical study supplies to meet their needs. It's also a proactive approach that allows us to inform sponsors of when they need to be producing more investigational product, especially for trials that are not randomized in a one-to-one schedule," explains Boruchowski.

Another IBM Clinical Development module that Boruchowski and her team have come to rely on is Medical Coding. Before Veristat deployed this module, it typically did the coding in a separate coding tool. That meant exporting data from the EDC system, applying the medical codes, and then merging the coded dictionary values back into the raw data. With the new module, the coded values are already a part of the raw data. Says Boruchowski, "It has streamlined a lot of our processes, especially downstream because we no longer need help from the programming group to get the coded terms back into our extracts manually."

Medical coding also makes study data more accessible while the trial is ongoing. "Our sponsors and other end users can pull reports in real time, without having to rely on data managers to supply them," says Boruchowski.

Similarly, the Lab Normal Ranges module simplifies study procedures. "We can enter lab normal ranges for the labs in our studies on the back end, which takes the burden off of the sites to enter the data themselves or for us to clean this data outside of EDC with the support of our programming team," says Boruchowski.

The Lab Normal Ranges module also gives Veristat and its customers a convenient, color-coded visualization that shows whether lab results are within normal ranges. "Historically, that was a really cumbersome process," explains Boruchowski. "Now, we can do an element of reconciliation just by looking at a page."

Increasing efficiency and enhancing quality

Streamlining randomization, supply management, medical coding and lab normal range processes has helped increase the efficiency of the studies Veristat oversees. In some cases, this helps bring therapies to market more quickly. Says Boruchowski, "The more quickly we can get new therapies developed and into clinical trials, the more quickly we can change the lives of patients who are suffering."

However, she explains, it's not all about speed to market. "It's really powerful and important to us that we don't just deliver on time or early, but that we do it in a quality way." For Veristat, that means offering more hands-on project oversight and strategic consulting, which ultimately enhances the partnership between Veristat and its customers.

Veristat also considers the control it retains over the EDC solution to be an important component of its success. Boruchowski elaborates:

"We can dictate how quickly to build a database and what elements we want to deploy on the first go-round. We can expedite a database go-live in whatever way makes the most sense for that trial."

Finally, the IBM Clinical Development platform helps Veristat bolster its reputation as a knowledgeable and capable CRO. "Adopting all of these modules as the ones we recommend has been really powerful for us because our sponsors don't always have any data management experience. It speaks volumes when we can say 'here's a process we recommend.' It makes us a more confident and valuable partner."

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Solution component

- IBM® Clinical Development

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