# Bringing expertise to clinical trials

Veristat simplifies and increases efficiency through Zelta

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 is a scientific-minded clinical research organization (CRO) that relies on its solid record of running thorough, efficient and well-planned studies to make it stand out among the competition.

Ryad Ramda, Associate Director of Data Management at Veristat, describes the company's approach: "We really help guide our clients, working with them to understand their most difficult 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 electronic data capture (EDC) solution that it knew could support a wide variety of studies and study parameters.

Study efficiency

**increased**

products to market

Clinical study control

**enhanced**

from inception through completion

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**Ryad Ramda**
Associate Director of Data Management
Veristat

# Furthering expertise with technology

Veristat relies on the Zelta™ clinical trials platform by Merative platform for many of its clinical studies. Ramda explains why the organization selected the Zelta platform. “It’s a relatively easy drag-and-drop system that lets us develop our own databases quickly, while still having enough functionality to allow flexibility for the most complex protocols and studies that our clients are running.”

Veristat’s Data Management group has grown quite a bit over the past several years, and the Company has made sure that every designer on the team is certified as an Zelta designer. “We’ve been able to train our teams quickly,” Ramda says. “You don’t need to know computer science or programming languages to learn it.” Having designers with a strong Data Management study conduct experience and skills has set Veristat Data Management apart from the pack, many of which have programming skills but minimum data management insights.

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 Ramda, 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, he explains, that uncertainty is gone. “We take great comfort in knowing that the Zelta randomization module is solid. That trust has allowed us to make it more our standard, and we’ve been able to develop a proven process around doing randomization in Zelta.”

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 Ramda.

Another Zelta module that Ramda and the 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 Ramda, "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 Ramda. 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 Ramda.

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 Ramda. "Now, we can do an element of reconciliation just by looking at a page."

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# 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 Ramda, "The more quickly we can help our sponsors get new therapies developed and into clinical trials, the more quickly we can improve or save the lives of patients."

However, he explains, it's not all about speed to market. "It's important to us that we don't just deliver on time or early, but that we do it right." For Veristat, that means offering more hands-on project oversight and strategic consulting, which ultimately strenthens 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. Ryad elaborates: "We can control how quickly we build a database and what elements we 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 Zelta 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."

## About Veristat

Veristat is a scientific-minded CRO that helps pharmaceutical and biotechnology development firms solve the unique and complex challenges associated with accelerating therapies through clinical development to regulatory approval. With more than 26 years' experience in clinical trial planning and execution, Veristat is equipped to support any development program 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.

## About Merative

Merative is a data, analytics and technology partner for the health industry, including providers, payers, life sciences companies and governments. With trusted technology and human expertise, Merative works with clients to drive real progress. Merative helps clients reassemble information and insights around the people they serve to improve healthcare delivery, decision-making and performance. Merative, formerly IBM Watson Health, became a new standalone company as part of Francisco Partners in 2022. Learn more at www.merative.com.



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