

**VERISTAT**

Scientific integrity. Client focus.

**Partnering for Success:
How a CRO and EDC Provider
Join Forces to Deliver
High Value to Customers**

- Veristat and Phase Forward have partnered to strengthen their offering to customers. Veristat provides process optimization, data management, analysis and reporting while Phase Forward brings proven and innovative technologies to help customers gain new efficiencies. This partnership makes the customer the ultimate beneficiary.

CASE STUDY

Background

Founded in 1994 in Holliston, Massachusetts, contract research organization (CRO) Veristat has established a reputation as a dynamic company of experienced professionals that offers innovative solutions to complex problems. Veristat provides comprehensive clinical trial services to the pharmaceutical, biotechnology and medical device industries, while remaining committed to its original principle of delivering the highest level of service to its customers with a focus on quality and scientific integrity.

Veristat's client base has steadily grown, largely based on industry referrals and the company's commitment to client-focused services. Veristat's success has further been attributed to its ability to adapt to industry changes and embrace new technologies. True to its forward-looking business practices, in 2002, management resolved to partner with an electronic data capture (EDC) provider to allow Veristat to extend its capabilities while continuing to provide services customized to clients' needs.

Enter Phase Forward

EDC would allow Veristat to expand its offerings and provide a solution that streamlines the data entry and validation process and automates query resolution, resulting in a decrease in time from first patient in to database lock. The company began the process of selecting an EDC partner by first reaffirming its own core competencies—process optimization, data management, biostatistics, reporting and strategic consulting—and then sought an organization that would complement its strengths. Veristat's acumen is in knowing what types of tools are needed to bring new efficiencies to a process and then working with a technology provider to create and deploy those tools.

This ability to fundamentally understand what it calls "client endpoints" and to work with "the end product in mind" in designing a process that will achieve the sought-after results, led Veristat to Phase Forward in May of 2003. By bringing Phase Forward's InForm™ solution in-house, EDC would become a strategic resource for the company and not a disconnected series of one-off tactical solutions. Additionally, partnering with Phase Forward fit well with its business model, as it allowed Veristat to replace annual upfront license fees for EDC with a more flexible, cost-effective project-based model.

In the time since Veristat implemented Phase Forward's InForm™ solution, 30 trials have been jointly conducted at over 600 sites with 18,000 subjects. The trials have involved Phase I, Phase II and Phase III.

The Partnership Experience

The experience of partnering with Phase Forward has exceeded the high expectations set by Veristat. To date, over 30 trials have been jointly conducted at more than 600 sites with over 18,000 subjects. The trials have spanned all phases—from Phase I to Phase III registry trials. The leverage Veristat sought to enable its staff to service any phase clinical trial was achieved through the efficiencies of EDC. In fact, this partnership has been so successful that in December of 2006 Veristat strengthened its relationship with Phase Forward by moving from an ASP paradigm to a full enterprise adoption (EA) model. “Moving to a full EA model has allowed Veristat to take a customized and streamlined approach to database builds. By using our in-house experienced database developers and clinical data managers we can be flexible and precisely meet the needs of our clients, both from a design and budgetary perspective,” said Cindy Henderson, senior director of data technologies at Veristat.

This strategic relationship with Phase Forward has transformed Veristat into an experienced EDC service provider, and it can now offer contracts at the same cost as it once did for paper-based trials. While Veristat can still build paper-based trials, its internal competency with EDC has maximized the organization’s potential for conducting quality clinical trials and fully servicing sponsor needs. As an EA client, Phase Forward now also provides Veristat with appropriate sales and marketing support, further enabling Veristat to focus on managing trials and servicing customers.

For Phase Forward, the partnership has expanded its base of InForm customers and reinforced InForm’s gold standard. For customers, the partnership has provided a one-stop solution for technology and strategic consulting services.

Evolving the Relationship

In January 2009, Veristat and Phase Forward extended their strategic relationship when Veristat selected Phase Forward’s Web Submission Data Manager (WebSDM™) application to help its clients submit CDISC SDTM-compliant data to the U.S. Food and Drug Administration (FDA). Phase Forward developed the WebSDM application in cooperation with the FDA, where it has been in use since 2004. “We chose WebSDM knowing we will be working with an application that the FDA itself co-developed,” said John Balser, Ph.D., president and co-founder of Veristat. “As a standard aimed at expediting the integration and analysis of clinical trial data by the FDA, SDTM is of paramount importance. WebSDM gives us confidence that our clients’ submission files are compliant with SDTM.”

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As an experienced CDISC provider, Veristat maintains current and high-level knowledge of data standards, and utilizes the latest technology platforms to assist their clients in the challenges of adhering to these new standards. The WebSDM application allows users to load SDTM-format data, check for and correct errors and inconsistencies, and browse data in a variety of tabular and graphical formats. Users may browse studies one at a time or perform pooling of data across studies for combined analysis. Utilizing WebSDM along with Veristat's suite of additional validation checks for data consistency and CDISC compliance ensures submission files conform to the SDTM standard so that clients can present them to regulatory agencies with confidence.

"Phase Forward understands that CROs require innovative tools to help their clients optimize the process of submitting clinical trial data for regulatory review," said Dr. Mike Davies, vice president of global CRO partnerships at Phase Forward. "Ensuring compliance with standards is a key component of this process. Partners like Veristat tell us they are choosing WebSDM for its use as a strategic asset."

The Partnership Looks Ahead

How does the future look for Veristat and Phase Forward's partnership? Veristat, a company that leaves nothing to chance and is in the business of assisting clients to more efficiently navigate the clinical development process, has its own plan regarding how the companies will continue working together. With Veristat's recent expansion of its service offerings, Phase Forward will continue to support Veristat's needs for innovative solutions that meet the objectives of these new initiatives. Phase Forward has helped Veristat compete beyond its target market, opening up new opportunities in biotech and with pharmaceutical companies of all sizes.

For Phase Forward, the strategic relationship is expected to continue to accelerate adoption of its InForm and WebSDM solutions as well as spur new innovations that will benefit individual clients and the market at large. As Bob Weiler, chairman and CEO of Phase Forward, concludes, "CROs are critical and strategic partners to Phase Forward, and we have learned to successfully adapt our approach so that specific aspects of their business are met—whether it be technology or services-based. Key to a strong outcome is the collaborative process that Veristat and Phase Forward use to define deliverables early on in the presales phase, so that milestones are understood by the entire team." When all is said and done, it is a winning partnership for Veristat, Phase Forward and their clients.

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Phase Forward is a leading provider of integrated data management solutions for clinical trials and drug safety.

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