



VERISTAT  
VERISTAT INC.

**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, Veristat has defined itself from the outset as a company of experienced professionals providing innovative solutions for complex problems. Offering a range of strategic consulting services to the pharmaceutical, biotechnology and medical device industries, this contract research organization (CRO) has carefully managed its growth in order to continue to deliver the highest level of service their customers have come to expect.

Veristat's success has created an exciting challenge for co-founders, Drs. John and Barbara Balsler: maintaining Veristat's quality of products and services while leveraging their professional staff for the growing base of repeat customers who are also a frequent referral source. Add to that challenge Veristat's commitment to service innovation and customization. Management decided that a new business model was needed that would allow Veristat to scale more easily while remaining true to what they do best. Their solution: partner with a complementary technology leader who values innovation and customer service in much the same way.

### Enter Phase Forward

Veristat began the process of selecting a technology partner by reaffirming, internally, its core competencies: process optimization, data management, biostatistics, reporting and overall strategic consulting. Not to be underestimated is Veristat's ability to fundamentally understand what it calls "client endpoints" and to work with "the end in mind" in designing a process that will achieve the sought-after results. This process includes developing protocols, structuring the study and analyses so that project objectives are achieved, designing data collection forms, data validation activities, analysis and reporting, and interacting with the FDA as required. Veristat does not view itself as a technology developer, but rather a savvy user who understands the advantage technology can bestow. The company's acumen is in knowing what types of tools are needed to bring new efficiencies to the process, and then working with a technology vendor to create and deploy those tools.

Enter Phase Forward. It is 2002, and Veristat has decided that it specifically needs an EDC (electronic data capture) vendor as a technology partner, and they begin a disciplined process of evaluation. Veristat values EDC because it allows them to leverage technology in order to expand their offering to very large clinical trials that would otherwise be a challenge to manage using a paper-based system. Having data entry performed by staff at the investigator site allows Veristat to focus on data management activities rather than data entry. By having edit checks programmed into the EDC system, data is entered cleaner since a query will automatically be generated if the data being entered is not within pre-specified parameters. Veristat also values the real-time data access provided by EDC which is viewed as enabling clients to dynamically modify their trials and facilitate faster reporting.

**In the time since Veristat implemented Phase Forward's InForm™ solution, nine trials have been jointly conducted at over 200 sites with 10,000 subjects. The trials have involved Phase I, Phase II and Phase III.**

Veristat applied the following criteria to select their EDC partner:

- **Product's ease of use and intuitive design**
- **Ability to address protocol amendments during study conduct**
- **Financial stability and market longevity of partner company**
- **Reliability and stability of system**
- **Responsiveness of services organization**
- **Scalability for larger and later phase global trials**

In May 2003, after systematically reviewing EDC vendors, Phase Forward's InForm™ solution was chosen because, as Irving Dark, Vice President, Business Development and Operations, comments, "Phase Forward was clearly the industry leader in its field. We felt they would be around for the long run. Their system was user-friendly, and their service organization seemed strong."

### **The Partnership Experience**

The partnership experience has exceeded the high expectations set by Veristat. To date, nine trials have been jointly conducted at over 200 sites with 10,000 subjects. The trials have involved Phase I, Phase II and Phase III. The leverage Veristat sought to enable its staff to service larger trials and additional clients has been achieved through the efficiencies of EDC. Shortly after Phase Forward was selected, Veristat began a study that was deployed at over 100 sites with 5,000 subjects – a study volume which would have been extremely challenging to manage using a paper-based system. Yet with EDC, the implementation was manageable. For Phase Forward the partnership has expanded their base of InForm customers and reinforced InForm's standing as the EDC gold standard. For customers, the partnership has provided a one-stop solution for technology and strategic consulting services that extend all the way to FDA submission and support.

A good example of how this partnership works on a tactical level can be seen in a large Phase III oncology study that was recently conducted. Having been involved with earlier phase trials for this client using a paper-based system, Veristat realized that implementing an EDC solution would greatly increase efficiency in data collection and cleaning. A collaborative approach was utilized in designing the data collection forms. This included active participation from the sponsor's medical representative, the Phase Forward design team, Veristat, and input from the principal investigator. The result of this collaborative approach was a well designed electronic case report form that leveraged the power of EDC by utilizing "dynamic forms." These dynamic forms pop up only after certain trigger questions are answered, thus reducing the possibility of data being recorded on the wrong form. This approach reduced input errors and accelerated data entry. The resulting engagement has proceeded on schedule with an energized implementation team comprised of Veristat, Phase Forward and client personnel.

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Irving Dark,  
Vice President,  
Business Development  
and Operations,  
Veristat

## The Customer's Viewpoint

"We recently partnered with Veristat in implementing Phase Forward's InForm software along with SAS technology to create a web-based electronic data capture Phase III trial program," states Dr. Christopher Nicodemus, Senior Vice President of Clinical Research and Development, Unither Pharmaceuticals, Inc. "This powerful solution was made available on an ongoing basis to the monitors and project team to assure the highest quality of study performance. Based on my experience, I can attest to the positive results of working with Veristat and Phase Forward to tackle complex challenges in a multi-center clinical trial environment."

## 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. Veristat sees a steady progression from being a pure ASP client where Phase Forward designs and hosts the trials, to the next stage where Veristat will take a more active roll in design and Quality Assurance.

For Phase Forward, the partnership will continue to accelerate adoption of their InForm solution as well as spur new innovations that will benefit individual clients and the market at large. As Bob Weiler, President and CEO, Phase Forward, concludes, "For a number of Phase Forward customers, CROs have become critical and strategic partners, 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 pre-sales 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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Bob Weiler,  
President and CEO,  
Phase Forward

**Phase Forward** is a leading provider of integrated data management solutions for clinical trials and drug safety. The company offers proven solutions for electronic data capture (InForm™), clinical data management (Clintrial™), clinical trials signal detection (CTSD™), strategic pharmacovigilance (WebVDME™ and Signal Management), adverse event reporting (Clintrace™) and applied data standards (WebSDM).

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