

Case Study

Prologue Research

Prologue Research provides immediate feedback on clinical patient data with Cardiff TeleForm. TeleForm helps ensure high-quality clinical trials—increasing the chance of FDA approvals.

Do you know where your trial is today? That's the motto of Prologue Research International, Inc., a leading oncology contract research organization (CRO) based in Columbus, Ohio. As its tagline suggests, Prologue specializes in developing faster, more cost-effective oncology clinical research methods that enable pharmaceutical and biotech companies to maintain a high level of control over the patient data that is collected during a clinical trial, thus bringing quality products to market efficiently.

The Challenge

Bringing a new prescription medication to market is a formidable task, especially in the field of oncology, which often deals with very sick patients and potentially dangerous experimental drugs. Deviations from safety precautions and protocols approved by the Federal Drug Administration (FDA) may result in nonacceptance of the drug as well as life-threatening and unnecessary complications to participating patients.

Prologue Research sought to automate the collection of patient data in a way that would satisfy the industry's strict data entry accuracy requirements and to provide a feedback mechanism to its customers on how well the study is adhering to clinical protocols. The founders of the company, who had all worked with traditional, labor-intensive methods of gathering data from forms, also wanted to implement a system that would streamline processes and be less prone to error.

The Solution

Prologue Research turned to Cardiff and its interactive forms processing product, TeleForm, to solve the challenge of setting up an automated data collection system. With Cardiff and Nistar Data Systems, a



Cardiff vendor partner based in Cleveland, Prologue Research built a solution that would offer fast, accurate data collection and a way to provide immediate, continuous feedback relating to data anomalies that might jeopardize patient treatment or the results of a clinical trial.

"We have 50 clinical trials going on at any one time, with as many as 35 unique case report forms for each one," explained Dr. Richard Gams, CEO and president of Prologue Research. "We needed a solution that would let us design forms easily and quickly. We also wanted a system that would allow us to collect and process data as it was gathered on the patient, instead of waiting to enter the data for all patient visits at the end of the study, which is the way it's typically done."

According to Peter Goldstein, president of Nistar, "TeleForm was the obvious choice because of its ease-of-use, flexibility and open-systems approach. Though the clinical trials piece of the pharmaceutical industry is currently paper-based, in the future we'll be able to migrate the system to the Internet, giving Prologue's customers access to forms over the Web."

Today when a clinical trial begins, Prologue works with its clients to set up as many as 50 unique case report forms. The forms are created in TeleForm and handed off in PDF format to Prologue's print shop. Once printed, collated and put into binders, the case books are shipped to the research sites, with one case book assigned to each

Customer at a Glance

Prologue Research

Industry: Healthcare

Application: Case report forms

Challenge: Develop faster, more cost-effective clinical trials that monitor protocol compliance

Solution: CardiffTeleForm with AutoMerge Publisher (AMP), RightFax, In-house clinical data management and automated data cleaning system

Partner: Nistar DataSystems, Inc.

Results:

- Eliminated manual data entry
- Enhanced data quality
- Increased patient-level protocol compliance—from 60% to 97%
- Reduced number of clinical reviewers

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Amy Brozgold, VP and CFO of the WW Group

patient participating in the clinical trial.

As the study progresses, researchers complete the appropriate case books. As they are completed, the pages are immediately faxed to Prologue where the data is passed from RightFax servers to the TeleForm optical character recognition engine. Once the data is "read" off the form, it gets transferred to the TeleForm Verifier queue for an operator to review. "Because of strict regulatory requirements, every single data point is reviewed by a data entry operator," Gams said. "Once it is verified, it is exported to our clinical data management system. The data is checked again by our automated data cleaning system, using predefined rules set up at the beginning of the study."

Using the patient-specific information received into the system, protocol-specific advice for the patient is prepared and is sent to the AutoMerge Publisher module of TeleForm, which automatically faxes reports to the site where the form originated. Dr. Gams explained further, "This is an important step in the process—and one that sets us apart from other CROs. It allows us to remotely monitor the clinical study in a continuous, timely fashion and to send useful comments back to the site so they can correct the situation appropriately."

The Benefits of Cardiff

Dr. Gams cites continuous feedback and data quality as the most important benefits. "Since the data flow is timely, we can suggest to the research site what needs to be done to remain compliant with the study protocol. By providing continuous feedback of this nature we've been able to increase protocol compliance, in some cases, from 60 percent to as much as 97 percent."

And, with an automated data collection and data scrubbing system now in place, Prologue Research is able to do far more work with far fewer resources. "We are operating at a minimal level of manual data entry," said Gams. "Also we've been able to do our 'edit checks' on the data with one clinical reviewer for every two studies. This is almost unheard of in our industry. Most companies have teams of three to five people managing the data of one study. Bottom line: We've automated a paper-based system about as much as much as you can, and we've done it in a particularly data-intensive area of research."

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