CASE STUDY

A Top 10 Sponsor Improves Trial Data Quality through Bioclinica's EDC eSource Solution

Introduction

Despite the documented benefits of electronic source data collection methods (i.e., eSource) such as fewer data entry errors, real-time data visibility and improved data quality, the initial switch from traditional paper-based data collection methods to eSource can appear challenging and therefore not worth the risk.

Situation

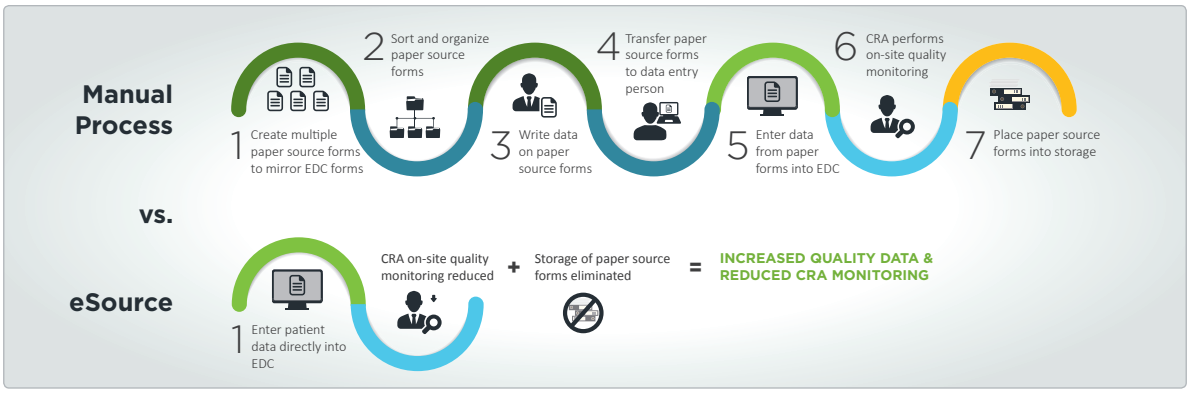
A medical device company has a long-standing relationship with Bioclinica (>10 years, 380+ studies total) and wanted to increase their data quality while decreasing the monitoring time required during their clinical trials. The sponsor is currently an avid user of the Bioclinica EDC and CTMS systems as well as Bioclinica Data Management services. However, they wanted to decrease the associated time and errors by directly populating the EDC with their assessment data rather than writing the source data on paper for later transcription into the EDC.

Solution

Bioclinica has a history of collaborating with their customers to develop solutions that meet the specific needs of the customer and protocol. To ensure consistent and complete data entry, the Bioclinica team partnered with the sponsor to approach the study build from a different perspective. The forms in EDC are presented to the clinician at each visit in the order of protocol steps for the visit. The flow and field locations on the form mimic the paper source forms and are designed to reflect how site users think while capturing subject information. For example, data for each eye is captured on the same form with one column for the right eye and another for the left eye. The subject's patient-reported outcomes (PRO) data is also entered directly into the system via a patient-accessed kiosk portal.

As assessment data are entered, the Bioclinica EDC system conducts real-time automatic data checks. The user is prompted in real-time to enter missing information or check the entered data. Completed assessment data from all sites are stored in real-time in the Bioclinica EDC, enabling real-time data access and monitoring through standardized and customized reporting capabilities.

Because of the long-standing relationship between Bioclinica and the sponsor, an extensive eSource library exists on which new studies can be built - to facilitate direct data entry. Additionally, the embedded Bioclinica



human resource on site facilitates an ongoing collaborative partnership. All of these factors result in quick builds of three weeks, which is important given the short overall study durations (e.g., 2 months); enabling lower upfront investment.

Impact

With the eSource system in place, this Bioclinica customer has realized their initial aims of increased data quality and decreased monitoring time, allowing them to bring their products to market faster. According to the Manager of Clinical Systems & Data "utilizing the eSource capability through Bioclinica's EDC allows us to differentiate among our competitors in the market."

Higher Quality Data

Inherently with eSource, there are fewer errors in data—by eliminating the need for the manual transcription of data from paper documents to an electronic database. In addition to the benefits of direct data entry by clinicians or the patients themselves, the automatic data checks in the current solution highlighted possible errors during the assessment that could be addressed in real-time. By presenting the assessment to the user in the order it should be completed and prompting the users to complete the required fields before moving on, this solution also reduced the amount of missing data.

Fewer errors mean fewer queries, reducing the time spent having to research and answer questions. Moreover, the centralized data storage facilitates remote monitoring and, further reducing the resources dedicated to this area.

Reduced Monitoring

From the start to the end of the trial, the need for monitoring decreased owing to:

- Inclusion of eSource in the data management plan, reducing the risk built into the protocol
- The reduced need for source data verification
- Fewer interim monitoring visits
- Identification of protocol deviations in real-time, alerting the monitors of quality issues that require tracking

33%
REDUCTION
in number of monitoring visits

With the centralization of and real-time access to study data, remote risk-based monitoring (RBM) can be continuously conducted, from study start-up to database lock. Sites that require additional oversight or training can be targeted easily.

Summary

This ongoing partnership enables streamlined, flexible solutions that truly meet the customer's needs. Because of this innovative use of eSource within their industry, they are viewed as an industry leader while at the same time benefiting from higher quality data and a need for fewer resources.