



Driving Innovation – Award-winning eSource Pilot Project

Case Study



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Introduction

With a traditional clinical trial which employs electronic data capture (EDC), source data (primary documentation or original record of a data element of a patient) are often captured both electronically and via paper, and then later entered into the EDC system. Electronic data could include medical devices, such as ambulatory blood pressure monitors. Paper capture of data could include the manual completion of patient notes, which are transcribed into the electronic case report form (eCRF). The transcription of data into the eCRF by the investigator (or more usually by a study nurse) often occurs sometime after the actual subject visit, resulting in a delay in the availability of the clinical data for review by the Sponsor (or CRO) staff. Validation checks in the EDC system can identify potential errors in the source data on its transcription. However in many cases, it is too late if the source data itself is inaccurate or incomplete. Also, the source data must be further checked against the clinical data to ensure no transcription errors have been introduced. This process is known as source data verification (SDV) and is usually performed by Sponsor or CRO Clinical Research Associates (CRAs). The SDV process requires CRAs to spend significant periods of time at the investigational site checking source data against eCRF data, often in less than ideal conditions for this task which needs care and concentration.

The concept of “eSource” refers to the capture of secure data in electronic format directly from the source, i.e. the patient, the medical device etc. The availability of eSource data for a clinical study introduces the possibility of avoiding the manual transfer of these data into the study specific eCRF. This could be accomplished by the site entering the source data into an Electronic Medical Record system

(EMR) and then having the data electronically transferred into the EDC/EDM system, or by first capturing the source data directly into an eCRF designed for source data, and then having the clinical trial data and full source data exported to the EDC/EDM or EMR respectively. This case study describes an approach whereby the latter was conducted in a pilot study.

The benefits of an eSource Project, compared to a traditional clinical trial, include:

- Real-time access to data as the data can be available in the EDC/EDM and data repository almost as soon as it first captured from the patient, thus allowing for more nimble trial execution and easier integration of adaptive trial designs
- Higher quality data, with fewer protocol deviations
- Improved patient safety oversight via data visualization tools
- Remove unnecessary duplication of data and unnecessary checking
- Significantly reduced monitoring costs

Ultimately, an eSource Project has the potential to reap significant cost savings and drastically reduce the overall duration of a clinical trial.

The FDA’s ‘Guidance for Industry: Electronic Source Documentation in Clinical Investigations’, published in December 2010 remains in draft form, but implies support of eSource Project methodology. Similar conclusions can be drawn about the EMEA position, as validated by their ‘Reflection paper on expectations for electronic source data and data transcribed to electronic data collection tools in clinical trials’, published in August 2012.

Pilot Project Summary

A major pharmaceutical company approached Cmed and Clinical Ink Inc. with a challenge of piloting their first, innovative eSource Project. Clinical Ink's SureSource™ solution "runs on tablets, allowing validated source data to be entered on protocol specific eSource documents that retain the look and feel of paper forms". Via the integration of SureSource™ with Cmed's innovative eClinical platform Timaeus™, the data would be streamed from SureSource™ directly into Timaeus™, where data management would be performed and data reported. Timaeus™ already had a direct, live, optimized data stream into the client's data repository, allowing for real time data review via the client's reporting tool.

Project Methodology

The parameters of the clinical trial included:

- One investigator site (USA)
- 20 patients enrolled
- 17 unique eCRF pages
- 187 eCRF pages per patient
- 3,179 eCRF pages in total

The pharmaceutical company was responsible for project services, such as Project Management and Clinical Monitoring. Clinical Ink was responsible for the eCRF design in SureSource™ and the provisioning of tablets to the site. Cmed were responsible for the integration and validation of the interface between SureSource™ and Timaeus™. Cmed also designed the Timaeus™ database, eCRFs and cross visit validation checks, laboratory data loads etc. and conducted the data management services.

Following the integration of SureSource™ with Timaeus™, data management processes, such as UAT, query handling, data loading etc. were defined using detailed process maps. Specific study edit checks for capturing source data and clinical data were programmed, using SureSource™ and Timaeus™ respectively.

Source data entered into SureSource™ was validated in real time with online checks to improve the accuracy of the data. Remote review of source documentation was performed and all data mapped to CRF data standards. There was an hourly data feed from SureSource™ into Timaeus™. Within Timaeus™ the following key processes were performed:

- Standard database UAT
- Data management validation and review
- Cross-subject edit checks and cleaning
- End to end query management
- Third party data integration
- Casebook signature
- Database lock
- SAS extracts and archiving
- Real-time feed to clinical data repository

Data was streamed live from Timaeus™ into the pharmaceutical company's data repository.

Project Results

Once the integration was complete, the total start-up period for the trial was nine weeks. The speed of data visualization (from first being entered to being able for review with the pharmaceutical company's repository) was 55 minutes (compared to many weeks for a standard clinical study).

Site user feedback (75 users) included:

- 89% found the system easy to use
- 85% said the system was as easy to use as the normal paper process
- 70% said the system caught errors that would have been missed on paper
- 74% would enjoy working on another eSource trial

If this project was conducted using traditional methodology, 105 hours would have been required for site monitoring activities. Applying the eSource Project methodology however resulted in this being reduced to 65 hours by eliminating the need for SDV. This represents a 38% reduction in monitoring time.

While real metrics and relevant data pertaining to project budget remain confidential, the potential cost savings of this approach are obvious!

Conclusions

This pilot project illustrated two benefits of the eSource Project methodology; the potential for cost savings and reduced project timelines.

Cost savings can potentially be achieved via:

- Shortening time to data availability to an hour, thus promoting rapid decision making and less waste
- Reducing the effort and expense of SDV
- Significant reduction of data queries
- Enabling remote monitoring of source documents (thus reducing further on-site time and decreasing site visits)

While the timelines of a clinical trial are predominantly driven off the length of patient recruitment, a reduction in data management workflow could shorten the gap between last patient last visit and database lock, streamlining one of the project's critical paths. This reduction is achieved via no delay in data entry (as the source data is transferred directly in to the clinical database), significantly reduced data query processing, and reduced CRA review time. Also if site workload can be reduced and their clinical trial experience improved, patient recruitment can only be helped!

Clinical Ink was presented with the SCDM Data Driven Innovation Award 2012 for this work with the Pharmaceutical company and Cmed named as Partners. While this project was a prototype, the companies continue to work on the integration of their technologies in order for eSource projects to be conducted on a wider scale.



About Cmed Clinical Services

Cmed Clinical Services is a long-established, flexible CRO with offices in the UK, US and Romania offering project management, clinical monitoring, data management, biostatistics, medical affairs, regulatory, consulting, and medical writing services. While Cmed's area of specialization is the design and delivery of both innovative and traditional phase I to IIb clinical trials, Cmed increasingly uses its experience and capabilities for existing clients phase III programs and for functional service provision of biometrics. Cmed Clinical Services is a privately held subsidiary of Cmed Group Ltd. To learn more, please visit www.cmedresearch.com.

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