EDC versus Paper - A Head to Head Comparison

HealthPoint Case Study

The pharmaceutical, biotechnology, and medical device industries are constantly optimizing how they collect, process, and manage clinical data in an effort to streamline the clinical trial process. Specifically, collecting data electronically has served as an effective method over traditional paper collection for over 20 years. It is estimated, in 2012, 70% of clinical studies will be conducted using electronic data capture (EDC) instead of paper[i]. Nonetheless, there is little documented evidence comparing the two approaches, head-to-head.

This case study compares two sets of comparative studies conducted by HealthPoint, a biopharmaceutical company that develops novel, cost-effective solutions for dermal repair and regeneration. As outlined in Table 1 below, each set is composed of two studies, one using paper and the other using uEDC, *DATATRAK*'s EDC solution. Protocol A and Protocol B were conducted at the same site, with the same study personnel, over roughly the same timeframe, to offer a true head-to-head comparison.

Table 1

Protocol A	Protocol B
Study 1 – Paper Forms	Study 3 - Paper Forms
Study 2 - *DATATRAK*'s uEDC	Study 4 - *DATATRAK*'s uEDC

Examining each approach to data collection, several significant differences emerged during the following processes:

- *Using case report forms*
- *Entering study data*
- *Monitoring strategies*
- *Managing queries*

Using Case Report Forms

Both the paper and EDC methods required case report forms (CRFs) to be created, reviewed, and approved. However, paper CRFs incurred significant printing costs and shipping expenses to distribute, and, then ship the CRFs back to the data entry vendor. Additional shipping charges were incurred during the data cleaning process, as the sites had to send CRFs to the clinical data management group as well as ship data clarification forms back and forth to clarify any information. There were also considerable costs associated with the storage of paper eCRFs at the sites as well as storage of all paper study-related documents within the trial master file.

With uEDC, there are only disk space storage costs; no need for physical space to store the data collected nor printing or shipping expenses, eliminating substantial costs.

Entering Study Data

Using uEDC, site personnel were able to enter study data right after the patient visit. Entering patient data sooner and at the site reduces the potential for errors. In addition, should questions arise during EDC entry, patient charts are immediately available to use as a reference.

> ***"Multiple people handling paper is eliminated with uEDC."***

Conversely, with paper, each time another set of hands "touched" the data, there was potential for pages to be misfiled or lost in shipment. Moreover, data entry using paper is a multiple-step process with site personnel completing the CRFs, retaining the physical copies to the site files, and shipping the CRFs to the data entry vendor. The CRFs then undergo double-data entry at the data entry vendor's sites with the originals stored in the trial master files. This labor-intensive process fosters failure at each step. For example when the files

are received, they are checked, counted, and verified against the transfer manifest, and then processed by two independent data entry staff members. A minimum of three different people will handle these pages and, although there are safeguards in place, mistakes occur. Multiple people handling paper is eliminated with uEDC.

Monitoring Strategies

100% source data verification was carried out on all studies. Monitors previewed and performed preliminary reviews of the data using uEDC before visiting the sites, reducing a considerable amount of time. By contrast, with the paper-based approach, time at the site was extended to perform the same activities since the monitors could not analyze the study data prior to traveling to the sites.

Managing Queries

Datatrak's uEDC alerts the person performing data entry that the data entered did not conform to what is required on the CRF, allowing for immediate correction. As a result, the study team was able to address queries at the time of data entry, reducing the number of queries addressed by the site. The team only had to send queries that required a manual entry of a question back to the site, representing less than 15% of the overall number of queries generated by uEDC.

Since the initial data were entered in a "cleaner" state i.e. meeting the requirements of the eCRF using uEDC, fewer queries were generated and more eCRF pages were completed without queries, expediting the study conduct timeline. Consequently, the data entered, and subsequently reviewed, was higher quality than the data collected using paper. With paper, the ratio of CRFs completed to queries generated was much greater, thus draining time and money.

> ***"On average, it took half the time to resolve queries using uEDC (4 days) as it did using paper (8.3 days)."***

Just as significant, between the two approaches, was the final resolution of the queries. On average, it took half the time to resolve queries using uEDC (4 days) as it did using paper (8.3 days). Overall, the study team was able to curb their time generating and resolving queries by 90% using uEDC.

Results

HealthPoint was able to analyze study results earlier, evaluate and ensure patient safety instantly with real-time access to safety data, and provide the study data more quickly to the client. As a result, HealthPoint delivered study data sooner to regulatory agencies so that they could evaluate the studies as the drug development lifecycle progressed with the goal for an earlier approval of the study drug.

Table 2 provides a breakdown of the different approaches for each activity.

Table 2

Activity/Task	Paper	EDC
Case Report Forms	Printed (typically 3-part NCR)	Electronic
Case Report Form Tracking	Data entered manually and Tracking Program	Automated Tracking
Data Entry	Double-data entry	Single entry
Edit Check Programming	Separate programming effort	Part of EDC application
Edit Check Execution	After data entry; away from site	At time of entry, at site
Monitoring	Performed at individual sites	Performed at sites and remotely
Query Generation	On forms, majority after data entry	Electronically/majority at entry
Query Review	Completed at sites	Completed remotely or at sites
Query Resolution	Completed at sites	Completed remotely or at sites
Data Management - QC	Carried out after data entry, after final site visit	Prior to site visit at site

Summary of Findings

The comparison between paper-based and electronic data capture approaches illustrates the distinct advantages to EDC:

- *Lower costs*
- *Reduction in the potential to lose or misfile paper*
- *Quicker availability of cleaner data earlier in the drug development timeline*
- *Increased confidence in the quality of the data for decision-making*

This evaluation allowed HealthPoint to determine EDC is the best option for their clinical data collection and management.

[i]Handelsman, David, Electronic Data Capture: When Will It Replace Paper?, SAS Institute, Inc. Retreived 2010-09-03