Innovations Open New Avenues for Data Capture

Electronic and Traditional Systems Both Have Role to Play

Adam Cole, B.Math, I.S.P.
Manager, SPS Applications & Development, McKesson Canada

John McCormick, PhD
Associate, McKesson Phase 4 Solutions, McKesson Canada

Up until only a few years ago, clinical trials and studies were limited to paper diaries for data collection. Today, computers and electronic devices are opening new avenues for electronic data capture (EDC). Determining which data collection method is most appropriate for your study, however, is not always a simple task. Success relies upon understanding the pros and cons of both the traditional and electronic systems as well as the often unanticipated obstacles of EDC.

The first step in selecting a data collection method is to determine your trial's primary outcome. It is important to distinguish between clinical outcomes and patient reported outcomes (PROs). The latter are becoming more important, particularly in Phase IV trials. Patient quality of life, compliance and satisfaction with therapy assessments can assist long-term marketing and reimbursement strategies.

If PROs are important to the study, then the real-time aspects of an EDC format offer many advantages. On the other hand, if clinical outcomes are important, the convenience and instant data processing of the EDC systems must be weighed against the reliability and recognition of traditional paper-based case report forms.

One of the major advantages of switching from a paper-based system to EDC is the reliability of patient-recorded data and the potential savings generated through reduced data management and processing.

The use of eDiaries reduced data variability by 33% compared to paper-based data capture.

For example, a recent study reviewing the impact of electronic diaries (eDiaries) in a Phase III trial evaluating treatment of overactive bladder found that data variability was reduced by 33% compared to paper-based data capture.[1] The eDiaries offer higher levels of patient compliance in recording events as they occur, compared to paper diaries, where data may be recorded sporadically or falsified.[1,2] Thanks to reduced error variance, researchers estimate that future overactive bladder trials with eDiaries could be conducted with up to 50% fewer patients, achieving the same statistical power, but with a 45% reduction in trial costs.[1]

Table 1

Data capture options

Data capture format	Process	RTC*	RTP**	Pros/Cons
Paper case report forms	Data recorded by physicians; case report forms mailed to sponsor/CRO.†	Study dependent	No	Pros: Traditional method of assessment; physicians familiar and comfortable with process. Cons: Labour-intensive with double data entry and resolution of data queries; interpretation of written comments may be difficult; generates large amounts of paper and copies must be stored at site; delays between data capture and data analysis.
Paper case report forms sent to sponsor by fax, then automatically scanned	As above, but forms are electronically processed.	Study dependent	No	Pros: Sponsor/CRO can receive data quickly and data can be partially automatically entered into a database, reducing the data entry turnaround time. Cons: Scanning procedures must be coupled with human verification; handwritten text scans very poorly; copies of paper case report forms must be kept at sites.
Internet-based case report forms	Data still coming from physicians, not directly from patients.	Study dependent	Yes	Pros: Data captured in real time; properly designed electronic forms have a low error rate and reduce data queries; forms can have built-in logic and edit checks. Cons: Sites may have to train staff to use the system; all sites may not have access to the Internet; pharma company mindset and culture may not accept Internet-based trials.
Paper diaries	Common technique for PRO:†† Patients can record clinical outcomes, medical resource use, days lost from work and quality of life parameters through regular entries; completed diary sent to sponsor.	Study dependent	No	Pros: Easy process for subjects to follow with correct instructions; relatively inexpensive. Cons: Data has to be manually entered by sponsor with associated time-consuming data queries; patients may not be compliant with regular diary entries; patients may falsify data.
eDiaries	Ideal for PROs: Patients record outcomes in an eDiary; data can be automatically transferred to a central data server via a secure Internet transmission.	Yes	Yes	Pros: eDiary alarms and reminders promote high compliance rates; fewer data queries; data is entered into database and processed in real time. Cons: Can be expensive; eDiaries must be provided to each patient and subjects trained in their use.
Telephone surveys	Common method for assessing PROs: Patients are prompted to respond to specific questions, with their responses recorded electronically by a trained operator or automatically through touch-tone responses (Interactive Voice Response System).	Yes	Yes	Pros: Ideal for assessing medical resource use and patient quality of life; data recorded in real time. Cons: Potential problems connecting with patients, leading to delays and higher costs.
Mail surveys	Common method used for assessing PROs: Surveys are mailed to subjects for self-administration and mailed back to the sponsor.	No	No	Pros: Relatively inexpensive process; questions can be formatted to enhance accuracy. Cons: Usually poor response rate leading to follow-up calls; data has to be manually entered by sponsor with associated time-consuming data checks; poor response rates may impact scientific validity of study.

* RTC: Real-time capture—Does this format encourage recording of the event at the medical moment?
** RTP: Real-time processing—Does this format support data analysis, feedback, queries and reporting with negligible delays following the data being entered in the database?
† CRO: Clinical research organization
†† PRO: Patient reported outcome

In a Phase IV trial or PRO study, the setup and maintenance costs of managing an electronic system must be weighed against the relatively short duration and narrow scope of such studies. At Phase 4 Health, we often find that a hybrid system best addresses both the sponsor's objectives and the participants' needs. A current study managed by Phase 4 Health exemplifies this hybrid system. In this study, physicians complete paper case reports and submit them by fax. The forms are then scanned and the data is electronically entered into a database. Queries are automatically generated—based on pre-defined validation rules—and electronically faxed back to the investigator. At any point in time, the sponsor can view real-time reports on a secure Web site. This hybrid system, which combines traditional source data collection with electronic data processing, offers a winning solution for everyone involved.

A hybrid system can offer a winning solution for everyone involved.

Every trial and study is unique. To optimize your investment, it is important that you define and prioritize your objectives. There are a wealth of tools at your disposal (Table 1), each with advantages and disadvantages, and there is no need to feel constrained to traditional data-capture formats.

For more information about data collection and which format is right for your study, contact Adam Cole at 1-800-811-9880 ext. 191, acole@phase4health.com, *or John McCormick at ext. 461,* jmccormick@phase4health.com.

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