Letter from the Editors

Non-traditional EDC/Data Capture is the focus for this issue of Data Basics. By perusing the articles, you can find the answers to the following questions and much more.

What are the types of fraud and how is fraud detected in the EDC world? Can EDC be utilized for applications other than data collection and, if so, what opportunities are available? What is the status of CDISC submission standards today? How can you manage your career when external factors are redefining the role of data management? What tools are available to identify unsatisfactory site performance and what solutions are available for data management? What future webinar topics are SCDM members interested in? Chandra, the rest of the Publications Committee and I hope you find the articles useful, informative and fun to read.

The Winter Data Basics topic will be Vendor Interaction. If this is something that interests you or if you have a viewpoint you’d like to express on working with vendors, we’d love to hear from you. If you have read a good article in another publication let us know, we might be able to republish it with permission.

Lynda Hunter and Chandra Wooten

Utilizing EDC Functionality Beyond Patient Data Collection

By: Rob Case, Global EDC Group Manager, Procter & Gamble Pharmaceuticals

Electronic Data Capture (EDC) systems are most commonly used as stand-alone applications with limited interfaces to other necessary trial management systems. Additionally, EDC systems are most notably used to collect patient-related case report form (CRF) data. During the conduct of a clinical trial, however, CRF data is a small subset of information needed by the clinical project team to execute the trial successfully and in a timely fashion. EDC systems have been inherently designed to cater to the clinical data manager, whose job it is to clean the CRF data and deliver a high-quality dataset to the statistical analyst. EDC vendors steer their products toward the Clinical Data Management function; however, there is much opportunity available within the currently existing EDC systems to manage non-CRF data unrelated to this patient-related dataset, yet pertinent to the successful completion of the trial.

During the study initiation phase, several activities are taking place to ensure successful recruitment of the target population. Long before the first patient is dosed with a study drug, clinical site initiation activities are taking place. These activities include gathering site staff contact information, tracking regulatory document collection for the clinical compliance package (e.g. 1572s, Financial Disclosure Forms, CVs, etc.) and Institutional Review Board (IRB) progress, to name just a few. Throughout this phase of the trial, clinical monitoring visits are occurring at the investigative sites and monitors are identifying issues that need to be resolved in order for the investigator to begin patient recruitment.

Although this information is commonly collected in a Clinical Trial Management System (CTMS), an EDC database could be utilized as an alternative. Advantages to the latter as with any EDC application include: real time global access to the information being collected, a standardized format of collection (particularly for reporting efficiency), and any creative use of query management that

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Submission Requirements

Submission Deadlines (Articles and Advertising Art Work)
Themes for the 2007 issues of Data Basics include:

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<td>Spring 2007</td>
<td>Understanding CDISC</td>
<td>1/8/2007</td>
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Publication Policy
We welcome submission of materials for publication in Data Basics. Materials should preferably be submitted in electronic form (MS Word). Acceptance of materials for publication will be at the sole discretion of the Editorial Board. The decision will be based primarily upon professional merit and suitability. Publication may be edited at the discretion of the Editorial Board.

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Dear SCDM Colleagues,
Having just returned from the Board of Trustees meeting held in conjunction with the 2006 Fall Conference in Orlando, I am more energized and excited then ever about the many things currently happening in our Society as well as the opportunities ahead. In this letter, I will share just a few of them with you.

First, this year’s Fall Conference was excellent, as I am sure those who attended will agree. Judging from the attendance, exhibitors and sponsors (all record numbers for this year) the SCDM Fall Conference has clearly become a conference of choice. Special thanks goes to the Co-Chairs, Planning Committee and EDI who all did a great job in putting together an excellent program and to the Session Chairs and Speakers for their diverse, interesting and thought-provoking topics presented and discussed. Work has already begun on the 2007 Fall Conference to be held in Chicago, September 16th to 19th. You won’t want to miss it, so mark your calendars now!

Momentum is building around our Certification Program. We are getting more and more applications for certification as well as interest in the best way to study, available training classes and ideas for additional exam training. In addition to Certification being a focus during the Fall Conference Certification Dinner, it was also one of the most talked about hallway topics between sessions. It is great to hear that so many people are planning on joining the ranks of the CCDM. Don’t wait; sign up now to take the exam.

Another exciting focus area has centered on electronic data capture (EDC), a topic shaping the future of CDM and this issue of Data Basics as well. The first Task Force under the umbrella of our newly chartered Research Initiative Steering Group is working on creating a new GCDMP Chapter on EDC. The work of this Task Force was also the basis for a Fall Conference session and the highly successful EDC Webinar. Be on the look-out for the new GCDMP Chapter to be released in 2007.

Finally I would like to take this opportunity to…

• Thank the retiring Board of Trustees: Jane Hiatt, Lisa Freeman CCDM and Audra McRae for their three years of service to the Society. You will be missed!
• Welcome the new Board of Trustees: Paul Clarkson CCDM, Karen Hicks and Linda Talley. They will each be serving a 3-year term on the Board.
• Solicit volunteers for the many Committees and activities of the Society. Members are our greatest asset and to ensure SCDM continues to produce valuable products and services for the benefit of our membership and profession we need you! Consider volunteering today.

As we wind up 2006 and begin planning for 2007, I want to wish everyone a very happy holiday season!
Warm regards,
Jill
Continued from cover

Utilizing EDC Functionality Beyond Patient Data Collection

might apply. For example, an EDC database that includes information as described above might be constructed to have a query fire when the monitor identifies an issue at the site. This allows for resolution of that issue to be tracked (open vs. closed query status) and follows the history of action taken to achieve resolution via the audit trail. Automated email notices could also be sent to various sponsor personnel based upon entry of specific data fields in this database (e.g. email to Clinical Operations when IRB approval is documented).

The issues with the collection, collation, and summarization of these data are magnified when we think of managing this volume of information for larger Phase IIB/Phase III trials. In situations when multiple CROs/vendors are contracted to execute the in-life portion of the trial, the amount of data can be overwhelming. Centralized EDC databases allow for all users to globally access the information in a common format. This becomes particularly important because historically, CROs used their own reports to feed information back to the sponsor for tracking site initiation progress. The current path is to enter this information into an EDC database so that all organizations are using the same forms to complete the assessments. The efficiencies gained in reporting have allowed for the trials to progress at a much quicker pace due to the ability to identify sites who are ready to begin recruitment sooner.

Use of EDC systems for the collection of non-CRF data not only benefits the clinical operations team, but can also increase efficiencies for other functions as well. Forms can be designed to collect information related to immediately reportable, serious adverse events that arise and can expedite the adjudication process. Again, this information is not part of the statistical dataset, but can easily be captured within an EDC database. This allows for specific users of the application to access this information, complete the appropriate data fields, and track the adjudication process, with the ultimate goal of reducing the time to database lock. The dissemination of this information via a 7-day or 15-day letter can be accelerated as well by using the tools that are provided within an EDC application.

The clinical site audit is another opportunity to increase efficiency in the overall clinical trial timeline. Traditionally, audit reports are completed on paper, reviewed by the Sponsor and then approved by the Sponsor. As with pre-recruitment data, an EDC database allows for the collection of audit report information in a standardized format with predefined fields to ensure consistent reporting. Electronic signatures, inherent functionality in most (if not all) EDC applications, may also be employed in order to circumvent the former paper approval process. These “e-Audit Reports” can also be saved onto media that allows for its electronic transmission and archival (e.g. CD or DVD).

Given the progress that has been made in the industry to move towards EDC and away from paper CRFs, the same progress needs to be made in other facets of clinical trial management to allow for efficiencies similar to those for collecting CRF data. Existing EDC applications allow for this to happen, but both vendors and sponsors need to be creative in how they deploy them. Although other niche systems exist in the clinical trial business and are more specific to the processes outlined above, EDC applications could certainly provide an alternative method for capturing this information and maximizing further efficiencies yet to be attained in the clinical trial process.

Rob Case is the Global EDC Group Manager and has been responsible for establishing the EDC environment internally at Procter and Gamble Pharmaceuticals, including the creation of eSOPs, standard work processes, EDC training support, helpdesk services, and eCRF database development.

SCDM would like to welcome the following Board of Trustees members:

Paul Clarkson, CCDM  Trustee
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On the way up

At Kendle, a Clinical Data Manager (CDM) can have a truly exciting, fulfilling and dynamic career. That’s something to which Stacey Adams, a CDM based in the United States, can testify.

“Kendle will support me in whichever direction I choose to take.”

Stacey came to Kendle in 2003, and knew from day one she had made the right choice. “I knew right from the start that Kendle was a great place for me to develop my career,” she says.

It’s not just the atmosphere at Kendle that Stacey enjoys—it’s also the opportunity. Since joining Kendle, she has already been promoted twice into more senior roles, an example of the opportunities available. The company has grown rapidly into the world’s fourth-largest Phase II-IV CRO, with approximately 3,000 associates globally, and a reputation for successful project delivery.

Kendle has conducted trials and provided regulatory and pharmacovigilance services in more than 80 countries. The company offers unparalleled opportunities to work on a range of challenging projects across many therapeutic areas, for customers ranging from small biotech to large global pharma companies. Stacey is currently assisting one of the world’s largest global pharmaceutical companies on clinical studies across its portfolio. In addition, her passion for highly detailed data management is being fulfilled through her work for another global player in a different therapeutic area.

The expanded role of a CDM within a Kendle project team is especially rewarding. Stacey acts as a consultant to the clinical team and advises them on a variety of study needs, including the utilization of electronic data capture (EDC) to aid decision support and ultimately facilitate project delivery.

Personal achievement

Stacey’s work also is helping her to define her other personal goals. She believes that her role as a CDM has enabled her to develop a successful career and at the same time help patients. The challenge of coordinating the efforts of her department with the sponsor is another great part of her job, she says. “I answer questions from CDAs, upper management, trial monitors, project leaders, study sites and others,” she says. “I’m helping to resolve important issues all day long.”

Advance through training

Kendle places a high value on career development and meeting the desire of its associates to learn new skills. Kendle College, an in-house educational resource accessible to all associates from the moment they join the company, is just one example. There’s also support for external courses and on-the-job training, so whenever Stacey needs support or answers, her colleagues are always willing to help. “My managers have really helped me to identify my goals and enabled me to grow by being supportive and offering opportunities to advance,” she says.

Work-life balance

Kendle understands that to achieve career ambitions, people need a true work-life balance. So it harnesses the latest remote working practices and technologies to create a supportive, flexible and open work environment that few companies can match. “This style of working allows me to enjoy a great life outside of work too,” Stacey explains. “Kendle has exceeded my expectations.”

Being part of a successful and dynamic organization is important, and Kendle’s success means that Stacey is continuing to develop and fulfill her ambitions. “I really enjoy working at Kendle,” she says. “I know that whichever direction I choose to take in my career, they will support me. Now I’m achieving everything I set out to achieve.”

Join us

Kendle offers exciting data management, programming and statistics opportunities at all levels, as well as openings for Clinical Research Associates and Project Leaders. So if you’re looking to advance your career, apply online at www.kendle.com/careers or call the Kendle careers team at +1 513 381 5550 or toll-free at 1 800 733 1572.

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In March 2005, the U.S. Food and Drug Administration (FDA) released version 1.1 of its Study Data Specification for submitting study data in support of market approval applications, such as New Drug Applications (NDAs). The specification recommends the use of the Clinical Data Interchange Standards Consortium's (CDISC) Submission Data Tabulation Model (SDTM) and of CDISC's Case Report Tabulation Data Definition Specification (CRT-DDS), also known as define.xml.

CDISC submission data standards reveal the similarities in seemingly dissimilar clinical trial data. Consider this: Every clinical trial collects data about interventions. Interventions include concomitant medications and several other types of intervention data. A second case is that every clinical trial collects data about unscheduled events which take place before or during the clinical trial. A subject's pre-study medical history is essentially a collection of unscheduled medical events. A third case is that every clinical study collects data about planned evaluations and findings, such as physical examination findings.

The practices, procedures, and realities of day-to-day operations at individual companies have made intervention data, for instance, from different companies look different, even though just under the surface the same exact information is collected for all concomitant medications. Government regulations and expectations dictate the information collected on concomitant medication usage during a clinical study. The superficial dissimilarities in concomitant medication data from company to company that obscure the similarities result from the demands of legacy practices or computer systems or sometimes-just whim.

For instance, with concomitant medication data, the name of the concomitant medication and the submission-wide identifier of the subject are always collected. But, if the concomitant medication dataset itself is sometimes called CM or CONCOMITANT MEDICATION or CMED and then the field for the name of the medication in this concomitant medication dataset may sometimes be called CONCOMITANT MEDICATION or TRT and so on, thus, the simple act of combining concomitant medication data from two studies becomes complicated. All of the potential inconsistencies have to be identified and then resolved. The exceptions in the data and mistakes in programming have to be found and fixed. Repeat this for a dozen or more different domains of clinical data in a study and repeat it for several studies and a simple job becomes exponentially complicated.

Suppose that your job is to understand the clinical studies data of many different companies. Day in and day out you see the same concomitant medication information obscured by the arbitrary naming of datasets and fields in datasets. To do your job, you have to become familiar with each company’s idiosyncrasies. You have to ask yourself, everyday, if not more than once per day, why doesn’t everyone just agree on one way to name concomitant medication data and adverse event data and all the other domains that every product sponsor submits? The lives of the sponsor and reviewer would be easier and happier.

Imagine if every sponsor submitted standardized concomitant medication data, adverse event data, vital signs data, and standardized versions of the other domains. The FDA could create universal software tools and train reviewers to use them to understand the information, rather than having to decipher each individual study’s data in a submission.

This story explains the interest of the FDA, in the development of industry-wide standards for clinical study data and in CDISC. From the FDA’s perspective, recognizing and emphasizing the similarities in clinical study data by standardizing submission data makes it possible to create standard processes and tools for working with submitted data. The same logic applies to industry.

CDISC’s SDTM standard describes “classes” of study data, such as events, interventions, findings, trial design, and “roles” for fields, that is, variables, in each class. The roles include identifiers, timing fields, qualifiers, and the topic field.

For SDTM, CDISC publishes an implementation guide for human clinical data that describes standard sets of fields for some 13 or 14 specific domains of data typically found in human clinical trials. In a parallel implementation guide for pre-clinical safety studies, CDISC describes standard domains for pre-clinical studies.

The FDA's 1999 eNDA guidance as well as the FDA's Study Data Specification recommend the creation of data definition documents, such as the familiar define.pdf, that list the individual datasets submitted along with descriptions of each dataset and, for each dataset, list each field (referred to as variable in the guidance) with a brief description, code and decode, if any codes were used for the field, comments and derivation details, if any, and some other field-level information. This collection of dataset-level information and field-level information make up the data definitions. Data definitions are not clinical data. Data definitions are information about the way the clinical data is organized and stored. In CDISC documentation, particularly the documentation for define.xml, data definitions are called “metadata.” Metadata, in this context, is simply another word for data definitions.

CDISC’s implementation guides, such as the implementation guide for human clinical trials, precisely enumerate the metadata for CDISC’s standard data domains. This metadata is just the data definitions that go into the define.pdf documents submitted to the FDA with all clinical data submission. CDISC’s define.xml standard describes an XML replacement for define.pdf. Define.xml contains data definitions, “metadata,” in an XML format.

Today, SDTM and its companion standard for study metadata, define.xml are the industry consensus on organizing clinical study data domains, both for submissions and for other business needs. ■

Michael Palmer has co-authored or contributed to key CDISC submission standards including define.xml and the Submission Data Tabulation Model. He’s been a paid consultant to CDISC and has served on CDISC’s Operational Data Model team since 2000. CDISC itself has tapped Michael’s expertise in some two dozen training workshops and seminars held since 2003. Michael is the president of Zurich Biostatistics, Inc. in Morristown, New Jersey.
Introduction

The preamble to FDA’s regulation on electronic records (21 CFR Part 11) shows that the authors of that regulation had been concerned that the integrity of electronic records was vulnerable in ways that the more familiar paper records were not. Monitors wondered how to perform source data verification on electronic source (6). Regulators and clinical trial managers knew that eRecords weren’t heavy; and that if access could be gained, the entire content of a system could be copied, shredded or taken quickly—a theft that would otherwise require at least a truck for paper records. While there had been instances of research misconduct during the long age of paper records (3), clinical teams wondered whether electronic methods would make fraud easier and more widespread. What would experience with eClinical trials teach us about how to detect and prevent fraud? This article comments on fraud from the viewpoint of a technology provider. PHT provides an eSource data capture system that is used to obtain data directly from patients, usually in the form of electronic diaries (eDiaries).

After hundreds of trials, experience with eSource records has been reassuring. It looks like the prescription of the FDA (Part 11) has been effective. The positive expectation that electronic records would be of better quality than paper ones has been born out for eDiary data in clinical trials. The data is attributable, legible, contemporaneous, original and accurate. It is protected against premature loss and destruction. More of the data fields are completed, and thus there are generally more useful data to analyze than with paper. These better data can reasonably be expected to lead to more conclusive results (5). But what about the negative concerns? This article considers some instances of fraudulent data, and suggests the possibility that the role of data management will be of increasing importance in detecting fraud of eRecords. Since Part 11 emphasized that the threshold for acceptability was that electronic records and signatures be at least as trustworthy as paper records and signatures, this article discusses relative vulnerability to fraud in comparison to paper.

What is fraud?

Fraud involves the intent to deceive. The issue is research misconduct that actively betrays the truth, not the honest errors and failures that compromise the truth. I am convinced almost all clinical researchers aim to discover or confirm the conditions in which a treatment is effective and safe. They want evidence they can trust so that they can help develop good therapies that will improve clinical practice. I think the reason that instances of fraud get so much attention from press and media may be that the fraud is surprising. It violates our expectation that people who devote their lives to research are deeply motivated to avoid error and deception.

Detecting Fraud

In principle, fraud can be committed at any level of clinical research, by sponsors, subjects or sites. Let’s consider each level in sequence.

DETECTING FRAUD COMMITTED BY SPONSORS

If one judged on the basis of popular perception and the conviction of the FDA that the independent investigator is the cornerstone of research integrity, one would expect a good deal of intentional misconduct at the corporate level. A major thrust of arguments against centralization of eSource data had been distrust of sponsors, who would seem to have the most to gain financially from distorting research data under their control to make a bad drug look good or a dangerous drug seem safe (4).

Contrasting this perception, however, is the fact that there are relatively few incidents of fraud being committed at the sponsor level.

• Incidence of Sponsor Fraud

Our corporate experience in conducting more than 235 trials for sponsors ranging from major pharma to small biotechs is that we have never been asked by sponsors to change data so as to bias a result. Dr. Steve Wilson, of the FDA, has pointed out how sponsors conducting the analysis of a completed study might retrospectively disqualify sites or undertake patient disqualification in order to bias statistical analyses by excluding subjects who cause the analysis to be unfavorable (personal communications, 2004, 2005), but in discussing early withdrawals with sponsors at PHT during trials, we have invariably encountered data managers intent on adhering to practices (e.g. intent to treat) to avoid such bias. The stakes are too high and research that is conclusive and accurate is too necessary. Sponsors depend on their trials to understand whether or not they have a significant therapy. Our experience with sponsored research has left us with a favorable impression concerning fraudulent data. Rather than commit fraud with eDiary data, data managers and clinical teams at sponsors have made efforts to detect it. These efforts seem to represent examples of sponsors’ interest and diligence in meeting their responsibility for the integrity of trial findings. Monitors and data managers have reported suspicions several times to PHT, and we have worked with them to investigate. Others who have investigated research fraud in trials that used paper records in the past, have also found that it is the intent and practice of sponsors to root out fraud and prevent it (9, 7, 3).

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SCDM Professional Certification

The Society for Clinical Data Management (SCDM) would like to congratulate the following individuals for receiving their Certified Clinical Data Manager designation!!

Mir Imran Ali, CCDM Tina Lewis, CCDM Michael Goedde, CCDM

CERTIFIED CLINICAL DATA MANAGER

To advance excellence in the management of clinical data
• Detecting Sponsor Fraud, Paper Records
In the paper process, data is transcribed from paper source documents to CRF pages, which are then keyed into a database. An expensive process is in place to control for manual errors made in transcribing the data. The controls include sending monitors to sites to perform source document verification, which often includes manual examination of each field of data in the sponsor’s copy of the CRF or in the sponsor’s database to ensure it matches the value of the corresponding field on source documents (6). This manual check would thus reveal any fraudulent changes sponsors might have made in their database of clinical data. Guidance on GCP instructs monitors to look for errors in records, and they are also guided to be sure the investigator is enrolling only eligible subjects. They are not specifically guided to look for investigator fraud (ICH E6 section 5.18). The sponsor’s primary research activities that can control for data integrity are monitoring and data management of study data. As we will see, analysis of data can be used to reveal patterns that are suspicious (1). Ultimately proving fraud may be difficult. Disqualifying a site with lots of missing data (drop-outs, incomplete records) has elements of genuine diligence and may not necessarily hint of fraudulent intent.

• Detecting Sponsor Fraud, eSource
Computer systems for capturing and reviewing eSource data in clinical trials are subject to Part 11 controls. Sponsors establish the privileges and authorization for those who will act on electronic records for a trial. These specifications explicitly require that sponsor staff NOT have access to enter or alter data, and the validation of the system controls is evidence that sponsor personnel cannot access the central system used to store and manage the eSource on behalf of investigators. With eDiary data, which streams into the system as the trial progresses, some analysis for detection of anomalies can be performed during a trial. After a trial concludes, a comparison between the data in a report or in the sponsor’s clinical database can be run electronically, not by manual verification as with paper source, to detect any disparities between the data maintained by the sponsor and the eSource data prepared and entered by the investigator, including eDiary data entered directly by subjects. This routine task is easier when the original records and the trial records are both electronic.

DETECTING FRAUD COMMITTED BY SUBJECTS
There is a compelling literature of studies showing that subjects in clinical trials fake data and that they enter data before or after the time windows specified to them for such entry. Yet the level of stridency by both press and regulatory agencies does not seem to be very high given that this is a major source of technically fraudulent data pertaining to clinical research. In our interviews with clinical researchers and subjects we have heard that the subjects themselves do not view their misbehavior as fraud, but as shortcuts for fulfilling the request that data be provided. They do not seem to have a malicious intent to deceive. Nonetheless, readings of instruments are not done, medication consumption is not documented, and reports are not done when they are purported to be. The eDiary helps subjects by preventing the opportunities subjects otherwise have on paper diaries to enter fraudulent data. It also opens an opportunity to counsel subjects on how to be good self-observers and honest reporters.

• Incidence of Subject Fraud
The studies in Table 1 assessed the honesty of subjects in making and reporting measurements, usually of peak expiratory flow or medication dosing using a metered inhaler. The methods differed in detail, but involved having an automated counter or meter that kept a clandestine objective record of the number of measurements actually made by the subjects using the meters (Measures Counted). Subjects were usually unaware that the measuring devices had counters, and were instructed as usual to enter in paper diaries the readings from the measurements they made (Measures Reported). The measures reported were then counted and the number was compared to the counts of the number of uses of the measuring devices. The studies universally found that subjects reported more measurements than there were uses of their measuring device. In one study where subjects knew that medication levels would be checked, 30 of 101 subjects actuated their inhalers more than 100 times in a 3 hour span (medication dumping), usually right before a clinic visit (Simmons, 2000; row 4 in Table 1). As a rough gauge of the incidence, the weighted average for the number of faked measures as a percentage of measurements that subjects reported but didn’t actually do (Faked data) was about 24% for the studies in Table 1.

Table 1. Incidence of Reports of Faked Measurements by Subjects in Clinical Trials.

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</table>

Continued on page 9
The other class of fraudulent data that is commonly perpetrated by subjects concerns the authenticity of the time of completion of diaries and the time that data is entered. Protocols often require completion of a diary report within a particular span of time each day. Other trials will want assessments at particular intervals after an event (headache, time of treatment, etc.) Trial subjects will represent that they have completed their diaries each day even though they complete them all at once just prior to submitting them for a visit. With paper diaries, misrepresenting time of completion is hard to observe without laying a trap. When completing paper diaries are timed objectively, it has been proven that subjects claim to have entered data at the required time when they haven’t (8).

• Detecting Subject Fraud, Paper Methods
Paper technology does not lend itself to controls to prevent subjects from recording in their paper diary cards the guessed values for measurements they pretend to make or from recording as taken medication they did not take. Similarly, paper diaries implemented as cards or booklets usually have not had controls to limit the opportunity for data entry to the prescribed times. The EMEA and FDA have expressed disappointment with such “non-compliance”, and FDA investigators who audit clinical sites have historically detected the problem from clues they find in the appearance of the original diary records, e.g. all the diaries for a week done in the same ink. Since the time of completion is often not itself a data point on diary cards, the analysis of time-of-completion data to look for fraud is not common. The ultimate effect of these difficulties in preventing and detecting subject fraud has been that information directly entered by subjects has been distrusted.

• Detecting Subject Fraud, eSource
Faking of measurements can be prevented by building the capture devices so that the measuring device must be used in order for a value to be entered into the eDiary. It is likewise possible to use medication dispensers that record a timestamp upon withdrawal of medications from a blister pack or when a metered inhaler or a syringe ejects drug. Considering the centrality of documenting the use of the therapy under test and the importance of timely measurements of any effects, it is somewhat surprising that these technical capabilities are still so rarely used in conjunction with eDiaries to prevent fraudulent records. It is also relatively rare for measurement data to be analyzed for patterns and regularities that would arouse suspicion that subjects are faking the entries. With eDiaries such data streams are available for fraud analysis during the trial, and there is good information on some of the typical patterns such as “no outliers” or “highly repetitive values” that should arouse suspicion. (1, 3). Much more commonly, the capability of eDiaries to force subjects to conform to diary completion schedules is now routine in clinical trials (by making the eDiaries available for completion only during scheduled time windows), and this capability appears to have eliminated a significant source of fraudulent data.

DETECTING FRAUD COMMITTED BY INVESTIGATIVE SITE
The combination of incentive in the form of payments per enrolled subject, remoteness from oversight, capability to enter and alter data, and a prevailing attitude of trust by visitors and monitors marks cases where fraudulent data have been provided by sites. Most clinical research scientists are familiar with stories of invention of fake subjects, recruitment bias, and distortion of laboratory data and medical records of subjects in clinical trials by the physicians and scientists at sites.

• Incidence of Site Fraud
According to Dr. Frank Wells, an investigative expert for MedicoLegal Investigations Ltd., who has made a career out of detecting and preventing research malfeasance, has written, “Commonest type of case: Forged consent forms and diary cards”. He estimates that more than 1% of investigators in the UK (and elsewhere) engage in fraud. Between 1991 and 1996, 21 investigators in the UK were referred by the pharmaceutical industry to the General Medical Council and 20 were found guilty of “serious professional misconduct”. (9) Dr. Adil E. Shamoo, a research scientist who has studied and promoted responsible conduct of research, has said that these “few bad eggs” may amount to 2% and that as many as 10-15% are simply “sloppy”. (7). A census is obviously difficult, so Drs. Wells and Shamoo offer us their personal estimates, based on experience with paper records. In our experience with eDiary data, we have seen only 2 instances of suspected fraud by site investigators.
• Detecting Site Fraud, Paper Methods

Regulatory inspectors are taught to look for clues when they visit sites. They examine the penmanship, coffee stains, as well as wear-and-tear on paper records. Data managers look for data that is “too perfect” as well as data that is “too imperfect,” unusual incidence at a site of subject withdrawals or of adverse experience reports at a particular site, trending, etc. It is certainly apparent to those of us who have ever prepared data for demonstration that the data that actually reflects natural phenomena and genuine human health status has distinctly different statistics (distribution, incidence of same or similar values, etc.) than the values that are made up. Data managers have a skill set that can be used to detect concocted data (1).

But these manual controls on paper records have vulnerabilities. There is the disturbing case of Dr. Robert Fiddes of the Southern California Research Institute, whose research site recruited and medically oversaw subjects for 170 trials, and fabricated data on a massive scale. The trials were done for major drug companies and were monitored by reputable CROs. In the refrigerator were canisters of body fluids matching key ranges of lab values “ready to be substituted for the urine or blood of patients who did not qualify for studies.” When outside radiologists’ reports of X-rays of the knee kept disqualifying patients from a study of an arthritis treatment, Fiddes told the CRO and received authorization as a physician to interpret the X-rays himself, and became a star enroller. The many seasoned monitors who visited the site over the years found that the paper source record matched the data, and had been scrupulously transcribed to the CRFs and matched clinical data of the sponsors. The site, with the knowing collaboration of study coordinators, also passed inspections of the medical records of enrolled subjects since, though false, they agreed with the clinical data. The monitor of the arthritis study wrote, “I performed 100 percent source document verification and found no outstanding issues.” At least one suspicious monitor, tipped off by members of the site staff in 1995 reported the likelihood of fraud to her CRO. But the CRO responded to Fiddes request to replace the monitor, whom he had accused of injuring his reputation, by appointing a new monitor as per their process of dealing with instances of “personal conflict”. Ultimately after mass resignations of site staff and repeated calls by a disgruntled employee of body fluids matching key ranges of lab values “ready to be substituted for the urine or blood of patients who did not qualify for studies,” the investigative site has pretended to give diaries to subjects, but instead kept the diaries in a row, and a member of the site staff is completing 7 reports each morning as if each diary were being done by a subject. Data of the sort that such an example of fraud might yield has been prepared, based on an actual case, to show how such data fits with the fraudulent manner of its capture. Values for selected fields for 2 days of diaries from the site are presented in Table 2.

Table 2. Data Fields Useful in Detecting Fraudulent eDiary Data

<table>
<thead>
<tr>
<th>Subject</th>
<th>eDiary Report Date</th>
<th>Entry start timestamp</th>
<th>Submit timestamp</th>
<th>Send start date &amp; timestamp</th>
<th>Sleep Delay (min)</th>
<th>Current pain VAS score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1007</td>
<td>9-Nov-06 10:33:09</td>
<td>10:34:10</td>
<td></td>
<td>12 Nov 06 10:47:54</td>
<td>190</td>
<td>65</td>
</tr>
<tr>
<td>1001</td>
<td>10-Nov-06 10:01:09</td>
<td>10:02:00</td>
<td></td>
<td>12 Nov 06 10:45:49</td>
<td>100</td>
<td>45</td>
</tr>
<tr>
<td>1003</td>
<td>10-Nov-06 10:02:08</td>
<td>10:03:03</td>
<td></td>
<td>12 Nov 06 10:47:03</td>
<td>100</td>
<td>42</td>
</tr>
<tr>
<td>1010</td>
<td>10-Nov-06 10:05:26</td>
<td>10:06:28</td>
<td></td>
<td>12 Nov 06 10:51:12</td>
<td>101</td>
<td>46</td>
</tr>
<tr>
<td>1009</td>
<td>10-Nov-06 10:06:34</td>
<td>10:07:37</td>
<td></td>
<td>12 Nov 06 10:52:34</td>
<td>102</td>
<td>49</td>
</tr>
<tr>
<td>1002</td>
<td>10-Nov-06 10:07:43</td>
<td>10:08:44</td>
<td></td>
<td>12 Nov 06 10:54:08</td>
<td>97</td>
<td>43</td>
</tr>
</tbody>
</table>

In this example, we imagine that a data manager (DM) has run queries looking for suspicious instances where diary reports by several subjects at a site are all done at about the same time. DM has displayed each diary report in the table as a row and has ordered

Continued on page 11
the rows in temporal sequence of completion (submit timestamp in column 4). A number of suspicious features of the data appear.

1. On each day subjects complete their diaries in the same sequence, subject 1001 first and 1002 last.
2. The diary of one subject is always completed 6-9 seconds before the diary of the next subject is started (Entry start timestamp). See table 3. The DM learns that it takes about 7 seconds to authenticate a subject by entering an access code prior to starting a diary.
3. The time interval between starting a diary report and submitting that report (difference between column 4 and column 3 in Table 2) is consistently about a minute, except for the diary of subject 1010 on 8 Nov, which takes 11 minutes.
4. Completion of the diary for subject 1009, which consistently is the next subject after 1010 to do a diary, is also started 11 minutes after 1010 was started. DM thinks this would be expected if the person completing all the diaries at the site were to have had a 10 minute interruption while completing the eDiary for subject 1010.
5. The DM notes that the values for pain level and time taken to fall asleep show clustering according to the day done across all 7 subjects. The distribution of these values on analysis is later shown to be uncharacteristic of distributions for the same variables across other sites in the same study.
6. This 2 day representation was found to be repeated on successive days (… in Table 2)
7. The times of sending the accumulated diaries on 12 Nov (Send start date and time stamp in Table 2) showed that all the diaries captured on each device had been stored for the same interval and sent on the same day in the same sequence of sending as followed for report entry.
8. The handwritten signatures attached to all the diaries looked the same (not shown).

In the actual case that the above fictitious example represents, the site was approached by the sponsor and conceded that they had lined up the devices and entered reports in order because that was the only efficient way to do it. In contrast to fabricating paper diaries, the fabricators had to do each diary on the appointed day, and they had to submit on a regular basis. This would seem to be harder than completing batches of paper diaries at one time.

We are early in the age of eSource where we can capture reliable information in real time directly from subjects. At this point it appears that fraudulently completing such diaries would take more work and leaves more clues than the simple ones of pen color, penmanship and the wear and tear on paper diaries. Furthermore, auditing and analyzing for the clues to fraud with eSource can use electronic tools, can be accomplished remotely, and can be done before the trial is completed so as to address the matter with the sites while the suspected fraud is possibly still being committed. Data managers can also rely on or develop more sophisticated tools to look for unnatural patterns in the data itself. Not all such patterns confirm malfeasance. In another case where eDiaries at a site were completed at about the same time, it was learned that several of the subjects worked at the same company, and that they would get together and complete their eDiaries during a morning break. While such behavior may have its own problems, it was not an instance of site fraud.

Continued on page 12
Protection and Controls
The architecture of clinical research for therapies under development by sponsors is structured to prevent sponsor fraud by having the investigator prepare and maintain case histories at the site that can be audited against the final reports and market submissions. Sponsors and sites know that the accuracy and practices of transferring data from the repository at the site to the clinical team at the sponsor will be subject to monitoring, which probably discourages fraud. Monitors can learn to look for data that is too good, investigators who are greedy, needy or stressed, and site staff who have whistles to blow. Their formal obligations under GCP however, emphasize error detection to forestall any differences between the sponsor dataset and the true facts of the case at the site.

With eSource, electronic constraints apply. For eDiaries, these constraints make it hard to establish apparent authenticity of data fraudulently. Fraud has been seen in some sites, but instances have been so obvious they were hard to miss. Part 11 requires a number of general controls that are intended to ensure that investigators (and others acting on eRecords) cannot easily “repudiate” eSource data as not genuine, including diary data entered directly by subjects. Technology providers have a wide latitude to design and implement such controls. For example, the eSource XML may be especially protected as an electronic ASCII record in parallel with the database containing the same records. Logfiles of all telecommunications, and special programs on eDiary devices to record attempts at transmission, telephone numbers, IP addresses and the like can make it extremely difficult to alter a record stored in a central system by misusing database administration privileges. There are so many layers that must remain congruent in order for a record to maintain unimpeachable integrity that no one person can alter all of them. So, we can reasonably expect any such alteration to be detectable.

Experts assert that data audits prevent fraud, particularly if an investigator prepares and maintains case histories at the site that can be audited against the final reports and market submissions. Sponsors and sites know that the accuracy and practices of transferring data from the repository at the site to the clinical team at the sponsor will be subject to monitoring, which probably discourages fraud. Monitors can learn to look for data that is too good, investigators who are greedy, needy or stressed, and site staff who have whistles to blow. Their formal obligations under GCP however, emphasize error detection to forestall any differences between the sponsor dataset and the true facts of the case at the site.

Conclusions
Detection: In the age of electronic records, fraudulent clinical trial data production will undoubtedly occur. Not surprisingly, some of the methods for detecting and preventing fraud that were worked out in the age of paper records no longer apply. However, new and practical methods that can be applied at the level of the trial database (transferred data to be analyzed by the sponsor or CRO) or on the eSource data store have developed. Clues can be picked up from data that were not associated with paper records such as timestamps, telephone and device numbers. The future will yield more instances and methods, but it appears that database auditors and analysts will have an increasingly important role to play in detecting “eFraud”.

Prevention: Devices and electronic systems have built-in and validated constraints that make it harder to commit fraud. For eDiary data, common misrepresentations by trial subjects of measured values and time of completion can be successfully prevented. Given such constraints, sites may also find it easier simply to let qualified subjects enter the data directly rather than attempt to enter false data on their behalf.

Recommendation: FDA pins credibility of trials on the purportedly disinterested investigator and focuses suspicion on the pharmaceutical and device companies who have huge financial stakes in the outcome. From the perspective of fraud at the level of study conduct and committed with intent to deceive, I believe that the suspicion should be publicly withdrawn to a degree from sponsors and directed a bit more at investigators. We all benefit by knowing precisely what therapies do to the people who take them, and the drumbeat of suspicion directed at pharmaceutical “giants” is counterproductive if they are not a major source of fraudulent data. A cloud of inappropriate and unnecessary suspicion will make patients reluctant to become trial subjects and clinicians skeptical of trial results.

References

Stephen A. Raymond, PhD, is affiliated with PHT Corporation, a company that supplies eSource data capture products for clinical trials, particularly where data is captured directly from trial subjects. Some of the methods for detecting and preventing fraud that were worked out in the age of paper records no longer apply. However, new and practical methods that can be applied at the level of the trial database (transferred data to be analyzed by the sponsor or CRO) or on the eSource data store have developed. Clues can be picked up from data that were not associated with paper records such as timestamps, telephone and device numbers. The future will yield more instances and methods, but it appears that database auditors and analysts will have an increasingly important role to play in detecting “eFraud”.

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Time is Money
Participant recruitment and enrollment is critical to the success of a clinical trial. The importance of meeting deadlines in this first stage of trial implementation cannot be underestimated. Missed deadlines can quickly become costly as the overall length of a trial is extended. Trial recruitment is a great testing ground for potentially saving time and money of non-traditional electronic data capture (EDC) methods and eSource data. We developed an EDC system for study recruitment staff to enter data and dynamically determine eligibility as they conduct phone interviews with potential participants.

Planning Is Key
To accommodate the development of the electronic phone screen system (eScreen), the study start-up process was slightly longer than in similar studies. This allowed for finalization of all eligibility criteria critical to the screening process. An extensive process for gathering requirements analyzed the standard paper-based phone screen used by the organization as well as study-specific protocol requirements and process flow. Documentation of every data point included rules about data integrity constraints. Staff interviews were conducted with recruitment staff, project managers, and data managers to ensure that the eScreen would meet the expectations of all stakeholders.

User-Friendly Interfaces Make a Big Difference
Once requirements for each data point were documented, the questions for the eScreen were developed. These questions were tested on study staff to ensure a logical and understandable flow from the viewpoint of the caller. After the questions were finalized, the layout and usability of the eScreen was addressed. A key requirement of the eScreen was that it would capture enough specific medical information to reduce the number of participant screening visits at the study site. Because of this, the number of questions was extensive and an early challenge was to develop a layout that study staff found easy to navigate. The final design included a form header with multiple pages indicated with tabs. Recruitment staff progressed through the interview by reading the script from the form and typing or selecting the appropriate response. As they completed a page of the screen, validation checks were triggered and staff made the necessary data changes before continuing. At the end of the screening interview, the eScreen calculated whether the potential participant qualified to continue in the screening process using over 35 eligibility criteria.

Increased Data Quality
There have been many benefits from using this electronic phone screen system. First, data quality has been increased. Incomplete and invalid data are reduced because every data point has integrity constraints built-in. The referential nature of questions, such as gender-specific questions, is strictly enforced as well. In addition, errors in transcription are reduced because the data is not being transcribed from a paper copy to an electronic version; it exists solely in the database.

More Efficient Process
Next, the process flow of gathering recruitment data has been streamlined. In the paper screening process, data is recorded on paper forms, reviewed for completeness, data entered, and double entered or reviewed for accuracy of data entry. This process is simplified by the direct entry of data and the automatic validation and eligibility calculation done by the system. Staff time, specifically data management time, involved in the screening process is also reduced due to the lack of data entry and review, resolution of errors, and in the organization of thousands of multi-page paper phone screen forms.

Improved Communication
Further, the availability of the eScreen data has improved project management communication and coordination between members of the study staff. Recruitment is monitored daily and reports compare current progress with the goals set forth at the start of the study. Other critical features of recruitment, such as female and minority recruitment, are also closely monitored. Recruitment tactics can be adjusted quickly based on these demographic findings and data gathered about where potential participants heard about the study. Another key improvement in the recruitment process is the ability to report quickly and accurately the percentage of eScreens that resulted in randomization into the trial. This provides accurate data on the amount of screens needed to meet recruitment goals in the study timeframe.

Less Redundant
Finally, we used the eScreen to reduce redundant data collection. Data from the screen is used to pre-populate fields on individualized CRFs. Participants simply verify that the information provided for contact and other basic information is correct instead of completing additional forms.

Many Benefits
In conclusion, we successfully implemented a non-traditional EDC electronic phone screen for participant recruitment into a clinical trial. This success of the eScreen is highlighted by staff response to the new process and by efficient, on-target, on-time participant recruitment and randomization into the study. The next steps for this eScreen include standardization to allow it to be used across multiple studies and additional integration of the eScreen database within the core participant recruiting database. These modifications will increase the ability of recruitment staff to track participants throughout multiple studies, integrate information from previously conducted screens and improve targeted marketing of studies to potential participants.

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BRIDGING TALENT & OPPORTUNITY
A variety of external factors are redefining the traditional role of data management – some have even suggested that data management is doomed as an occupation. To that I say, “Hold on a second.”

A thousand articles have been written about managing change in one’s career, but let’s narrow the focus to the specific issues and options faced by today’s data managers.

The major factors causing this shift are off-shoring or remote data management, eClinical technologies, and cost and time pressures (the weight of each varies by organization.) As a result, the new skills required to succeed in this environment are solid communication (particularly electronic), people management, teambuilding and project management. More and more frequently, trials are conducted with partners and service providers that are off-site, even halfway around the world. While some of the old skills may disappear altogether, data managers need to adopt their existing skill set to eliminate that perilous “sole reason for my existence” notion.

Let’s start with an easy hypothesis. Success is a function of planning. You wouldn’t suggest that good trials are run ad hoc. Take the same approach for your career. A couple of fundamentals to ignite thinking:

- Join professional or trade associations (like SCDM)
- Subscribe to trade/industry publications (and read them!)
- Develop mentor relationships
- Continue to learn

So what’s at stake here? If you’re an SCDM member, probably a lot. And it’s difficult to be successful if you feel threatened, or are unclear on what you’re supposed to be doing. Now is the time to re-establish the value proposition for data management within your organization. You can choose to take an active role, or to let it happen to you. I suggest actively clarifying your goals (either way) to reduce stress, focus energies, simplify decisions and prepare for success.

The next steps require an even more proactive approach. I’m partial to “managing one’s career with style and grace.” This phrase is borrowed from Dr. Barbara Moses, author of *What Next? The Complete Guide to Taking Control of Your Working Life*. In her book, she offers strategies for assessing one’s strengths, needs and values to make the right choices at the right time, and figuring out what to focus on and what to give up (for good reasons). These strategies are:

1. Know yourself
2. Make appropriate decisions for your age and career stage
3. Recognize crossroads

**Know yourself**

We each bring a unique combination of personality, preferences, talents, values and needs to the job. Be honest - what is most important to you? What do you like or dislike about your work?

If disorganization is the bane of your existence, consider bulking up on project management (reading, training, opportunities for growth). Many companies are moving toward a virtual world of Functional Service Providers (FSPs). These are specialized partners that are plugged into projects as required, according to the phase of the project and necessary expertise. Data managers can leverage their intimate understanding of the clinical trial process and attention to detail to become outstanding project managers.

If you’d rather look at a CRF than deal with people, master the technology for future opportunity – system validation, study builds, edit check specs and audit skills will grow as eClinical expands—and many of these tasks are difficult to do remotely. Adoption of new technology has the potential to change all aspects of clinical data management and how it is accomplished in clinical research. These technologies offer new ways of organizing, new processes and more holistic ways of getting clinical data ready for analysis. Getting to database lock faster means learning to utilize new tools.

**Make appropriate decisions for your age and career stage**

Moving forward successfully means acknowledging the special challenges of each stage and the time required to execute your plan. If you’re in your 20s, formal education is a great investment, but may not be if you only plan to work for another 10 years. Take the time to focus on internal considerations, on what you *really* want. That can often supply the drive necessary to do the hard stuff. Make sure that you’ve chosen an appropriate mentor if you’re redirecting completely, make allowances if you decide to refocus on emerging skills or mine dormant ones in your repertoire.

**Recognize crossroads**

Are you bored? Happy? Scared? Dissatisfied? If you love what you do, make sure to practice the fine art of “managing up.” Make sure that what you do is recognized and appreciated. And don’t forget the unique qualifications of the incumbent (you).

Conversely, does your work have a foreboding predictability to it? If so, it may be time for a change. The next question is, which way will you choose to manage it.

To make the best possible choices, understand as much as you can about your organization’s plans and the industry. Train constantly – not all training needs to be formal, but all training should not be OTJ (on the job). Chance favors the prepared. Participate. The saying, “chance favors the prepared” is greatly enhanced if you see the opportunity first! With planning and purpose, it will be easy to overhaul obsolete goals and get past inevitable reversals.

Forward-thinking data managers will continue to be invaluable contributors in the growth and success of clinical research. Be one of them!
The Society for Clinical Data Management would like to express our sincere appreciation to our 2006 “Most Valuable Participants”

This year, these people have gone above and beyond the call of duty for their respective committees noted below. Thank you for all of your hard work and dedication…..

Certification Committee
Kathy Haag
Associate Clinical Data Management Consultant
Eli Lilly and Company

EDC Task Force
Debra Jendrasek
Manager, US EDC Solutions
Chiltern International

External Relations Committee
Hugh Donovan
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Linda Mathias
Sr. Clinical Data Scientist
GlaxoSmithKline

GCDMP Committee
John Estrada, CCDM
Product Development Manager
Nextri, Inc.

2006 Fall Conference Committee
Vesna Zovkic
Manager, Clinical Data Management
DePuy Orthopaedics, a Johnson & Johnson Company
The SCDM Membership Committee conducted a survey between May 10 and 26, 2006 to solicit member input regarding membership services and support. The survey results are summarized below.

Out of the 1,989 contacts, 358 (18%) completed the survey. Seventy-five percent of the respondents reported less than 5 years SCDM membership tenure. Respondents described their job function as Clinical Data Manager/Specialist/Coordinator (40%); Manager/Supervisor, Data Management (26%); and Vice President/Director (9%). The majority of the respondents were employed by Pharmaceutical/Biopharmaceutical companies (51%), Contract Research Organizations (22%), and Medical Device Companies (10%). The main reasons for joining SCDM were professional development (87%), networking (47%), and business opportunities (22%).

Meeting/event conflicts (46%) and financial reasons (33%) were the top two reasons preventing respondents from participating in SCDM programs or educational opportunities within the last 12 months. Respondents suggested a wide range of additional programs/educational opportunities that they would like SCDM to provide. Frequently suggested on the list were CCDM certification training support, electronic data capture and medical coding topics. Stronger support for advanced/senior CDM professionals was also requested.

Regarding future program and educational opportunities, the majority of the respondents preferred face-to-face meetings in a central location (48%), online independent study (23%), and webinars (20%). The majority of the respondents often read or always read the two major SCDM publications, Data Basics (68%) and Data Connections (63%).

The Good Clinical Data Management Practices (GCDMP) document was the most utilized service (71%) reported during the last 12 months. Sixty-five percent of the respondents used GCDMP. Forty-nine percent reported their companies used the GCDMP for general reference (80%), internal process development (52%), and training (39%).

Of the 180 GCDMP webinar participants in 2005 who responded to the survey, 64% indicated they are interested in attending additional GCDMP webinars. They were interested in hearing more about Electronic Data Capture Principles (65%); Metrics for Clinical Trials (65%); Database Validation, Programming Standards (62%); Measuring Data Quality (58%); Assuring Data Quality (53%); and Laboratory and Other External data (53%).

Twenty-two percent of the respondents participated in the Discussion Forum. Among them, 82% found the forum useful. Thirty-five percent of the respondents were planning to take the SCDM certification exam within the next year (40%) or within the next 2 years (40%). For the 59% not planning to take the exam, 41% believe that the certification exam had no benefit to their career and 19% were concerned that they would not pass due to limited preparation time. Among the latter group, 76% would be interested in a study group or study courses to help them pass.

The survey results clearly indicate a strong interest in utilizing SCDM services and training/educational support in general. These results were shared with other committees and the board of trustees to determine the next steps to better serve our members.

Thanks to all who supported us by responding to the survey. Your constructive feedback is highly valuable and critical to SCDM’s future.
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