Letter from the Editors

If variety is the spice of life, then this issue should provide something of interest for everyone.

There are articles about computer and questionnaire validations, investigative data review, finding a great training class, going from data management to project management and much more.

Themes for Data Basics in 2007:
- Spring: Understanding CDISC
- Summer: Data Quality
- Fall: Regulations Impacting Clinical Data Management

Winter: Changing Roles of Clinical Data Management

What articles on these topics would be of special interest to you? Do you or someone you know have some expertise in one of these areas that your colleagues might benefit from? Our Article Submission Guidelines are posted in the Publications section of the SCDM website (www.scdm.org). Not a writer, but have some thoughts about what you'd like to see in Data Basics? Contact us at info@scdm.org to share your ideas for upcoming issues; we'd love to hear from you.

Lynda Hunter and Chandra Wooten

Developing Relationships with Third Party Team Members

By: Colleen M. Cox, Manager, Data Management, PROMETRIKA, LLC

Project teams are those that are dedicated to the successful completion of a clinical trial or series of trials. Team members can be located next door, a couple of floors away or a continent away. Participants can be from one company, two companies or however many companies are needed to see the project through to a successful completion.

While project teams can't control the outcome of the trial, it is possible for them to ensure that it is completed on time and on budget. The top priority for all team members is to work with others in executing the trial, no matter what aspect is their area of responsibility.

The main goal, the primary focus of the team, should be a successful project. Remember you were picked to be a part of the trial for a reason whether it be knowledge, experience or skills. The completion of your responsibilities to your high expectations should always be on the forefront of your mind.

Needs Assessment

During the proposal and/or planning stage, the project team should perform a needs assessment for the trial. What is the timeline? What would be the best workflow? Are there any idiosyncrasies that need to be addressed? All of those questions should be answered by representatives from each functional area and allow for as much pro activity as possible in the early stages of the trial.

Awareness of Changes

Depending on the configuration of the team, it is possible that you may be working with a monitoring group from one company, a data management group from a second and biostatistics from a third. What is the impact in this change? Is the monitoring group used to receiving specific reports from the DM group to facilitate monitoring? If so, what are they and how can the same information be provided on this trial?

Continued on page 4
Submission Requirements

Themes for the 2007 issues of Data Basics include:

<table>
<thead>
<tr>
<th>Issue</th>
<th>Theme</th>
<th>Input Deadline</th>
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<tbody>
<tr>
<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.

Neither SCDM nor the Data Basics Editorial Board endorse any commercial vendors or systems mentioned or discussed in any materials published in Data Basics.

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Web site: www.scdm.org
Dear Colleagues,

Happy New Year! Hope you all had a wonderful holiday season.

2006 was a great year for your Society! It was our first year of executing our new 2006-2009 Strategic Plan (Goals, Objectives and Tactics) and through the efforts of many of you, SCDM made significant progress on this Plan. Below are just a few of our many accomplishments:

- Our Society now has over 1800 members (a new record) and continues to be a financially healthy organization.

- SCDM has established two new Steering Groups to advance the mission of our Society:
  - The Research Initiative Steering Group has been charged with sponsoring Task Forces on specific topics of interest to our membership. Two Task Forces started in 2006. The first group has taken on the ominous task of updating the Electronic Data Capture (EDC), chapter of the GCDMP. This group is planning to release an updated chapter in the summer of 2007. The second group is concentrating Career Development in CDM evaluating training programs and trying to standardize job descriptions within the discipline. The fruits of their labor will be released early in 2008.
  - The Education Steering Group is the second Steering Group; their role is to function as an umbrella group to oversee the various educational activities of our Society (i.e., webinars, certification training, as well as the educational content of the Spring and Fall Conferences). Work is ongoing to establish an overall Educational Calendar for 2007.

- SCDM has established a Portfolio Management process as a way to evaluate potential new and assess existing products / services to ensure they continue to support the Society’s goals and meet the needs of our members.

- SCDM created a comprehensive Marketing Brochure detailing SCDM’s many products and services and a new logo with the associated tag line, ‘Data Driven’.

- Certification numbers jumped with 24 Clinical Data Managers added to our newly certified.

- SCDM developed a CEU policy and began offering CEU credits for appropriate programs and activities that will apply to CCDM recertification.

- In collaboration with DCRI SCDM offered five CDM training classes in 2006

- SCDM successfully conducted three GCDMP focused webinars (2006 marked the first full year of webinars).

- SCDM engaged in the new CDISC Initiative – Clinical Data Acquisition Standards Harmonization (CDASH) – whose focus is on developing data collection field standards.

- SCDM provided comments on both the FDA ePRO guidance document and the PhRMA eSOURCE position paper and was asked to contribute to other industry publications and conferences as well.

- SCDM planned and delivered an excellent and well attended Fall Conference in Lake Buena Vista, Florida last October.

As I end my year as Chair of SCDM I want to thank you, the members of our Society, as well as the staff at EDI for your ongoing commitment and contributions. It is only through you that our Society can reach its goals and continue to expand the opportunities and resources available to support all who are engaged in the management of clinical research data.

I wish everyone much success in 2007!

Jill
Developing Relationships with Third Party Team Members

Continued from cover

Remember, that almost every company has its own naming conventions, such as: DCFs, DRFs, DQFs, queries – all of which mean the same thing (or so you might think). It may sound silly, but making sure that the entire team understands the acronyms or nomenclature can save stress at crunch times.

**Kick-off Meeting**

This is the ideal place to address both the needs of the trials and the changes that will occur for each of the team members. A face to face meeting is preferred, but if this is not feasible, a conference call with all team members also works. There should be at least one representative from each functional area, who is empowered to make decisions and/or recommendations to the other team members. Meeting minutes should be kept and a list of action items should be generated and distributed to the entire team.

**Communication**

Here are the basics:

**WHO** - There should be a primary contact at the sponsor and each vendor should have a project manager or project lead. However, whenever necessary, the technical members should talk to their equals. If there is a data management question, then the two clinical data managers (CDMs) should discuss and identify a solution, rather than have the CDM discuss the issue with the project manager (PM). If the CDM speaks to the PM, rather than another CDM, then the PM will then talk to their contact, the PM at the other company. This PM will then explain the issue to their DM. It could be a lot of communication for a quick resolution.

**WHAT** – Study updates and relevant information includes, but is not limited to: protocol amendments, enrollment status and projections, changes in site personnel and site specific issues, such as unavailability of CRFs at the time that the first patient is screened.

**WHEN** – Communication should occur on both a regular and an irregular basis. Meetings should be held on a timetable (weekly, monthly) that best suits the needs of the trial at that point. They can be more frequent during set up and close down and less frequent during the maintenance phase.

Communication should also occur between meetings when an issue arises to allow for an immediate or timely resolution. This can be done either through email or phone calls. Email is generally preferred as a record is automatically created of both the issue and the resolution. Contact the appropriate person to resolve the issue and verify that all parties affected by the issue are notified as well.

**WHERE and HOW** – Communication can occur at team meetings, through phone calls or voice mails and through emails. **When in doubt, share it!**

**Meetings**

Agendas for team meetings should be distributed in advance, a minimum of 24 hours ahead of the meeting. This will allow the team members adequate time to prepare, research and be ready to discuss the topics. Keep the conversation focused. Tangents are easy to get lost in, but they can be detrimental as everyone’s time is extremely valuable. Ensure that the meeting minutes are distributed in a timely fashion and that they include a list of action items.

**Email**

Email is one of the best communication tools currently available. It is easy to share the same information with multiple team members at the same time as well as an effective tool for creating a record of what has transpired.

However, email can also be too easy. Be careful when forwarding or replying to emails, inappropriate comments or references may be sent to the wrong people. Always, double check the address section of the email before sending it.

**Document Review**

As a writer, this topic is near and dear to my heart. It is a good idea to clearly define what the expectation of the review is. If a CDM reviews a monitoring plan, are they looking for wording or grammar issues? Or are they looking to ensure that there are no conflicts between the monitoring guidelines and the other study documents? How will comments be returned to the author: one master document with compiled comments or separate documents for the author?
to compile? The most effective way to compile and finalize feedback is to hold a roundtable meeting with the appropriate team members allowing for consensus on decisions and changes.

**Metrics**
The type of metrics provided are defined in the either the contract/scope of work or the data management plan (DMP). This list should be reviewed and discussed at the Kick-Off Meeting to verify that all team members have the information that they need to perform their tasks. Again, nomenclature may need to be addressed.

Also, a discussion of how often the reports should be generated and the definition of the distribution list should occur. Lastly, it should be communicated or more accurately reflected on the report that metrics were generated at a particular date and time, therefore activity occurring at a later time will appear on the next report.

When the first shipment of metric reports is sent, they should be reviewed at the next team meeting to allow for questions or concerns to be addressed and resolved.

**Changes in Study Personnel**
This happens and it will happen in every trial. A transition plan presented to the team will allow concerns regarding project history, nuances will let project team members plan and/or modify plans to accommodate the new team member(s).

**Team Frustrations**
These happen and will happen in every trial. Frustrations that arise should always be addressed with the personnel in question, not the rest of the team. This can be done directly, person to person or the sponsor may ask to coordinate resolution of the issue.

Keep in mind that, what may seem like a major issue, could be really only be a minor bump in the road, so address the issue at the time that is best suited for it.

Part of the excitement in working as a data manager is the variety of both the trials that you get to work on and the people with whom you get to work with. By keeping your attention on the prize – a successful project, it is possible to juggle while walking on a tightrope!!

Colleen has over fifteen years experience in clinical data management including the achievement of certified status. She has worked in both pharmaceutical and device companies as well as having experience in the CRO environment. Colleen has experience in the day to day operations of data management; the development, validation, installation and maintenance of clinical data management systems and oversight of data management departments and personnel. She has been an active volunteer within the field of data management over the past years and has served on the Program Committee for the Drug Information Association 2005 and 2006 Annual Data Management Conference as well as previous participation as a speaker. She is also the Chair of the Certification Committee for the Society of Clinical Data Management assisting with the development of the Code of Ethics, the certification exam and the lifetime maintenance plan. Colleen has also played an active role in the development of the Good Clinical Data Management Practices (GCDMP) committee, particularly the review and update committee working on topics such as data privacy and data archiving. She also serves as an SCDM Board of Trustee.

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**Future SCDM Conference Dates and Locations**

**2007**
SDCM Annual Fall Conference
September 16th - 19th, 2007
Hyatt Regency Chicago on the Riverwalk
Chicago, Illinois

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**Web Sites to Check Out**

ACDM - www.acdm.org.uk
CDISC - www.cdisc.org
FDA - www.fda.gov
ICH - www.ich.org

There are more links to be found on our web site!

SCDM - www.scdm.org
Please email info@scdm.org about any other "hot" web sites that you feel would be of interest to the SCDM membership.
A New Platform in Computer Validation: Automated Testing Tools and Requirements Management

By: Karen Steenhoudt, Data Management Consultant, Valimation, Inc.

To ensure regulatory compliance, computerized systems for data management must maintain a validated state throughout the lifecycle of the applications employed. Maintaining validation is a challenge in rapidly changing IT environments, where approximately 25% of the source code for individual applications is rewritten each year. As a result, lifecycle documents associated with the system(s) must be continuously updated to reflect the changes made. Currently, system lifecycle documents are often unchanged after initial validation. Approved documents (e.g. test scripts, validation plans, etc.) are kept in binders after the initial testing is completed. As soon as validation binders are created, their content is typically outdated because computer systems are continuously evolving to meet business needs.

Which tests are affected by these changes? Are resources available to retest after source code changes have been made? Traditionally these questions have not had simple answers. Can technology be leveraged to reduce cost while increasing quality and compliance? One potential answer is the use of automated requirements management and automated testing tools. The purpose of this paper is to introduce the concepts of automated testing and requirements management.

**Principles of automated testing**

Table 1 provides definitions of four key terms required to understand automated testing: requirement, test, test case, and test script. An application is defined by a set of requirements specified by the user. To demonstrate that each requirement is met in the actual application a series of user-defined tests is performed to prove that the intended use is being met. During the execution of the validation test scripts, actual results are compared to expected results (which are based on specific requirements). When requirements have been met, the system is validated. Currently, this process is performed manually.

In automated testing, a test script (provided through source code generated by the testing tool) will contain the instructions required to execute the test case. Figure 1 shows a typical screen from an automated testing software tool. To create or run a test script, the user navigates through the application under test (e.g. enter data, click on fields, etc.). This is shown in the 'Active screen of the application'. These actions are recorded by the testing tool and are displayed in a graphical format in a ‘keyword view’ window. The testing tool uses keywords to describe the actions. The keyword (e.g. logon), together with the associated parameters (e.g. password and User ID) will identify the actions performed during recording. A series of actions will define a ‘keyword-driven’ test script. The recorded actions can subsequently be ‘run’ or ‘replayed’ in the same way that they were originally recorded. In the ‘data table’ (bottom left of Figure 1) the user can enter data values that will be used during subsequent runs of the testing.

For example, let’s assume we need to test the format validity of the data entered in the ‘Date of examination’ field in the application under test. An invalid and a valid date format can be entered in the data table. When the test script is run the first time the invalid date will be used in the test execution and a system error message is expected. After the first run is completed, the testing tool will automatically restart and use the next value entered in the data table. In this example the next value will be a valid date for ‘Date of Examination’. As a result, in this subsequent run, no system error message will be expected. During the analysis of the tests, actual results will be compared to the expected results and discrepancies will be highlighted.

**Testing Framework**

Implementation of automated testing requires proper planning and technical expertise. Two main factors are crucial to successful implementation: traceability and well-designed and maintained test-libraries.

- **Traceability:** In a well-designed framework, changes to an application must trigger prompts to adjust affected test cases. This can be accomplished by using computerized links between the requirements/change logs and the test cases.

- **Test library:** A test library must meet certain standards to assure its long-term utility. It is valuable to make the design of the test library part of the overall information management design plan. This will allow the standard naming conventions used in the application/studies to be tied in with the naming of the keywords and tests. The test library itself must contain modular tests with common functions and standard tests. The common functions can be used to build suites of tests. For example the ‘logon’ function can be called and used as part of a larger test script. As in any library, it is important to create templates for the test structures and naming conventions. This will assure that multiple users will produce consistent test scripts.

**Requirements Management Tools**

Traditionally lifecycle documents are Microsoft Word documents. To achieve automated traceability, it is a necessity to maintain and organize documents in a structured database. Several commercially available products offer the ability to organize documents in a structured manner. In this realm, each system requirement is an entity. These entities can be linked to entities in associated documents. This will allow users to establish links between requirements, design specifications, test scripts, test cases, and so forth. When computer systems are updated, the systems requirements often change. If the links between lifecycle documents are established, the potential impact of system changes on the validation documents can be assessed with ease and updates to lifecycle documents can be made quickly. This process is illustrated in Figure 2.

As lifecycle documents change, it is critical that proper audit trails track the history of the changes made. When requirements management tools are used, audit trails are automatically generated. Version control is automated. In addition to audit trails, custom reports and data views can be created. For example, traceability matrices that link user requirements to test cases can be generated automatically.

**Applicability beyond systems validation**

This paper has focused on the use of automated testing and
requirements management tools in the area systems validation. These tools can prove to be very useful within data management operational tasks. For example, standardized CRF fields with associated validation checks and test scripts can be the building blocks for CRF development. Each building block is a standardized template unit. When CRFs consist of these building blocks it will be easy and fast to implement new CRFs. This modularization can simplify downstream processes such as database design and validation check development and enable automated testing of the databases, screens, and validation checks.

SOP management is another area where these technologies are useful. SOPs are often linked to related documents. If these links are computerized, management of changes and updates to SOPs can be made efficient.

**Conclusion**

Automated testing and requirements management tools have great potential to improve the quality and efficiency of validation and document management processes. The most important benefits of automated testing tools are:

- Test script execution can be automated and the system can perform the tasks significantly faster than human testers.
- It is reliable because the same test script is repeated each time consistently.
- The tests can be reused on different versions of the application.
- The same test script can be repeated multiple times with different test data each time.
- The testing is fully audit trailed and documented.

The most important benefits of requirements management tools are:

- Rapid assessment of the potential impact of changes.
- Improved traceability through automated links.
- Consistent documentation,
- Automated audit trails and version control for all documents.

While requirements management and automated testing haven’t been used widely in computer systems validation or in data management, they can prove to be valuable. Information traceability will become increasingly important in different areas of clinical research. Improved information management and development of well-managed standards libraries (e.g. naming convention, CRF fields, tests, test scripts etc.) will become critical. New expertise will be required to fully realize the opportunity offered by this new platform for computer validation.

**Table 1: Terminology**

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tr>
<td>Requirement</td>
<td>A required feature or function of the application under test.</td>
</tr>
<tr>
<td>Test</td>
<td>Is the combination of a test case and test script.</td>
</tr>
<tr>
<td>Test Case</td>
<td>A set of inputs and expected application response that will confirm that a requirement has been met.</td>
</tr>
<tr>
<td>Test script</td>
<td>A series of commands or events stored in a script language file that execute a test case and report results.</td>
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**Figure 2: Illustration of computerized links between lifecycle documents**

**Acknowledgement:** Akaza Research for the use of OpenClinica. Mercury™ for the use of Mercury QuickTest Professional.

**References**


Ms. Karen Steenhoudt is working as a consultant in the areas of data management for clinical trials and computer systems validation. She works with Valimation, a full service consulting company that specializes in regulatory and compliance issues. Her activities include planning and implementing integrated data and information platforms, defining and implementing global data standards and libraries, system validation for clinical data management systems, and training.

She has previously worked as a manager in data management. She led operations for global and North American trials for top five pharmaceutical companies. Prior to this work, she developed statistically relevant models for budgeting costs for clinical trials.
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BRIDGING TALENT & OPPORTUNITY
Data management professionals are responsible for ensuring that a clinical trial dataset is an accurate representation of study observations that can be confidently used to support study analyses with high integrity. In other words, clinical data managers are ultimately responsible for the global consistency and quality of clinical trial data.

Achieving that goal must involve both data validation (generally initiated by edit checks for data completeness and reasonableness) and comprehensive data review (CDR). CDR involves looking at the overall trial data to identify such things as unusual data patterns at a particular site, duplicate data from subject to subject, and protocol violations.

In order to effectively perform CDR, clinical data managers must understand the study compound and review the data with the trial objectives, disease state, and subject safety in mind. Collaboration with the clinical research physician and project statistician may enhance understanding of these larger aspects of the trial. The examples below describe how clinical data managers identified issues in two clinical trials and subsequently drove the escalation and follow up of the issues to ensure the quality of the trial data.

During review of study drug diary dosing data collected in a clinical trial with as-needed dosing, the clinical data manager observed a definite pattern among the subjects’ diary entries at one study site. The dose data was transcribed from each subject’s diary onto the case report form (CRF) by site personnel. The initial finding indicated that 19 of 19 subjects from one site had recorded 36 doses of study drug. When the site was monitored, it was found that most of the diary source documents were missing, so the site was required to obtain the source documents from the subjects and verify the diary doses. “Corrected” diary data was subsequently received on the CRF for each subject; however, a definite pattern still remained in the number of doses, with 16 of 19 subjects taking 12 doses of study drug. The clinical data manager appropriately notified management of the findings and investigated additional data from this site and from other sites for comparison. In comparing handwriting samples on the CRF, it appeared that subject-completed questionnaires from the site were all completed by the same person, based on the appearance of “X’s” and numbers recorded on the CRF pages. Another unusual finding was that the site had only 2 of 19 subjects with pre-existing conditions, and no adverse events were reported during the trial. These additional findings provided further evidence of questionable data. The clinical data manager facilitated discussions and escalated these issues to the company’s medical quality group, resulting in a directed medical quality audit at the site, confirming site issues and ultimately leading to definitive corrective actions at the site.

In a second trial, the clinical data manager found that multiple subjects were randomized inappropriately while having exclusionary values on a primary study procedure. The study protocol required subjects to have baseline test values in a pre-established normal range in order to be randomized. The testing instrument software was designed to display a message to the test administrator at the site if the subject’s values fell outside of the normal range to aid the site in determining subject eligibility. The site printed out the test results from the instrument, transcribed the data to the paper CRF, and submitted the CRF for data entry and validation. The clinical data manager reviewed reports to ensure that all randomized subjects met the study entry criteria. During this report review, the clinical data manager observed that two study sites had an unusually high number of subjects who were screen failures and also had some subjects that had been randomized even though they had exclusionary test values. Upon follow-up by the study team, it was determined that two sites were not following the appropriate testing procedure as defined in the protocol and provided in training, resulting in values that were exclusionary per the protocol. It was also found that several other sites were not entering the correct visit number in the testing instrument which resulted in the out-of-range edit not being displayed. Early identification of these issues by clinical data management allowed the sites to be retrained on the proper technique and minimized the loss of study data. If this problem had gone undetected or was discovered much later in the trial, the loss of subject data and cost of adding additional subjects could have been substantial and may have required the study to be stopped and restarted.

As these examples illustrate, the clinical data manager plays an integral part in early issue identification through comprehensive data review of trends, outliers, and protocol violations in clinical trials. Other areas to consider when conducting CDR are: logical consistencies (e.g. height vs. weight; derived variables such as BMI), scientific integrity (e.g. inclusion/exclusion criteria, protocol compliance, event coding consistency, extreme values, and medically improbable measurements), and understanding for analysis (e.g. how missing data impacts analysis, logical data from multiple primary efficacy scales, and safety comparison of scale and event data).

There are no written rules to enable clinical data managers to conduct comprehensive data review, so thinking “outside the box” must be a mainstream activity for our profession. As clinical data management professionals, it is our responsibility to not only review data and identify issues, but also to initiate appropriate escalation and ensure actions are taken to deliver a quality database.

Marcia Brackman has a degree in Microbiology, and has worked in the pharmaceutical industry for 19 years, most of which was spent in research and development. She has been at Eli Lilly and Company for 6 years, with the past 4 years spent in clinical data management.
A STAFF THAT’S AS RIGOROUSLY SCREENED AS YOUR DRUGS.

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Validating Questionnaires

By: Kit Howard, Principal, Kestrel Consultants

As we all know from the political polls that abound every fall, the answer you get depends very much on the question you ask. In order for a questionnaire to be useful, the data it produces must be trustworthy, i.e., we must know that the results are meaningful and can be applied more generally than to just the sample tested. Proving that trustworthy for questionnaires involving subjective clinical endpoints is not trivial, and ensuring that the resulting data reflect the “truth” has spawned an entire field of study. This article will provide some insight into what that process entails and why it is important.

The term “validation” has a variety of meanings in clinical research, the first and most obvious being the assessment of computer systems to ensure they function as expected. “Validation” is also the process by which any data collection instrument, including questionnaires, is assessed for its dependability. Validating questionnaires is somewhat challenging as they usually evaluate subjective measures, meaning they can be influenced by a range of factors that are hard to control. In other words, a blood pressure machine can be assessed for accuracy and calibrated to ensure consistent readings. Obviously the SF-36 quality of life questionnaire cannot be similarly assessed.

That said, there are ways to evaluate the value of, or validate, a questionnaire. Validation involves establishing that the instrument produces reliable and true data. There are a number of ways to define this, some of which are outlined below:

Reliability: the degree to which a questionnaire will produce the same result if administered again, or the “test-retest” concept. It is also a measure of the degree to which a questionnaire can reflect a true change.

Validity: the degree to which a questionnaire reflects reality. There are a number of different facets to validity.

Internal validity: the degree to which questions within an instrument agree with each other, i.e., that a subject will respond to similar questions in a similar way. It also affects the likelihood of producing false positives and false negatives.

External validity: the ability to make generalizations about a population beyond that of the sample tested.

Sensitivity: the degree to which the instrument can identify a true positive, e.g., accurately identify a person who does have the condition.

Specificity: similar to sensitivity, this is the degree to which the instrument can identify a true negative, e.g., correctly identify the people who do not have the disease. Sensitivity and specificity are another side of the coin from internal validity.

Statistical validity: this is related to internal validity, and assesses whether the differences in the questionnaire results between patient groups can appropriately be subjected to statistical tests of significance.

“Validity” is not an absolute quality. It’s a continuum, with a questionnaire being valid to a certain degree in certain circumstances, and researchers must decide what degree of validity is considered sufficient, preferably before the validation study is run. The above categories also suggest that there are types of validity that relate to the internal validity of the questionnaire (are similar questions answered similarly), others that relate to the ability of the questionnaire to determine a given state in a patient (e.g., that it varies in alignment with the severity of the condition), and still others that involve the validity of comparing different groups on the basis of the questionnaire.

Each type of validity is distinct, meaning that a questionnaire can have one kind of validity but not another. Because of that, a questionnaire can never really be fully “validated.” It can only be validated for x patient population, under y conditions, and so forth.

This implies that it may not be appropriate, for example, to use a lymphoma quality of life questionnaire in a melanoma study if the questionnaire hasn’t been validated for that particular population, unless it has been shown to be applicable to cancer patients generally.

The validity of the results can be impacted by more than just the design of the questionnaire itself. Some questionnaires must be administered by individuals who have been trained in survey administration in general or that survey in particular. Others can be administered by any experienced clinician, or nurse, or indeed completed by the patient. If an otherwise valid questionnaire is administered by the wrong individual, the results are compromised. Similarly, some instruments must be used in their original published form, and changing the layout to create a CRF may compromise the results. Results can also be compromised if the questionnaire is not completed at the expected times (either time or day or relative to some other event) or in the right setting.

The process of validating an instrument varies depending upon what aspect(s) of validity are being assessed. Generally it involves running a study that is designed to determine a specific kind of validity, although it is sometimes possible to add a validation arm onto a trial with other primary objectives. One way to check the validity of a questionnaire is to compare its results with results from more objective measures. For example, a questionnaire assessing a patient’s perception of their chronic obstructive pulmonary disease (COPD) may be compared to measures of their lung function, and the results of each compared between groups of healthy subjects and ill patients. If the instrument has appropriate specificity, sensitivity and discriminant validity, one should see a good correlation between the lung functions of the more severely ill patients with “worse” scores on the questionnaire. The degree to which the differences in the scores vary in alignment with the lung function tests across the healthy and ill subjects is the measure of the validity of the instrument at identifying patients who have COPD.

If the same questionnaire was developed in the US in English, and researchers wanted to use it in Italy, it would need to be translated into Italian. The Italian version would then have to be tested to see

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Validating Questionnaires

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whether it varied with degree of illness in the way the English one did, or at least in a reliable and predictable fashion. Of course, there may be cultural differences that may require changing the content of the instrument. “Walking the length of a city block” is generally understood in the US, but the concept is meaningless in rural France.

Establishing longitudinal validation is particularly relevant to clinical trials, in that determining the degree to which the use of an instrument repeatedly in a study affects the instrument results. On the one hand, in order to be able to draw conclusions from the results, the same instrument should be used throughout the study. For that to work it must be longitudinally valid. There is a well documented test-retest effect; however, the first time a subject completes a given questionnaire the results are independent. After that, the subject is no longer naïve to the questions, and their answers in the second questionnaire may be influenced by their memory of their prior experience. Part of the process of validating instruments used over time is statistically evaluating that relationship.

There are many cases in clinical research where no validated instrument exists for a given disease or population. That doesn’t mean that the disease can’t be assessed, or that questionnaires cannot be used. The protocol authors must decide how important that objective is to the study, and whether it is acceptable to have less trustworthy results for that objective. It suggests that unvalidated instruments should probably not be used for key efficacy or critical safety assessments until appropriate validation studies have been conducted. Alternatively, the company can consult with the regulatory authorities to ensure their acceptance of the instrument prior to submission of the New Drug Application.

As with so much in clinical research, there are no black and white rules where it comes to assessing the reliability and validity of questionnaires. Each drug development team must determine their study objectives and the best way of achieving those objectives. If that includes the use of questionnaires, they will need to assess what type and level of validation is sufficient for their purposes. As data managers, we can play a role in ensuring that those discussions happen before the study starts and it’s too late to change.

References


Kit Howard is the owner of Kestrel Consultants, specializing in the design, development and implementation of cross-functional clinical data standards. She has been in the pharmaceutical industry for over 20 years, and has broad experience in many facets of clinical research.

Embrace the future ~ Join the Force

The EDC Task Force, which is part of the Research Initiatives Steering Group, has been tasked with updating the EDC chapter within the GCDMP. The task force is working to develop content for the chapter based on the task force chapter outline and the feedback received from attendees at the Fall Conference.

For more information on how to become involved in the EDC Task Force contact Jonathan Andrus at jandrus@pdsedc.com or the SCDM office at info@scdm.org.

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!!

Susan Krikorian, CCDM
Leigh Smith, CCDM
Jennifer Price, CCDM
Nancy Milliken, CCDM
Identification of Unsatisfactory Site Performance
By: Terri Blythe, Director; Shari Clark, Manager; Wanda Doles, CCDM, Manager; and Lynnea Wheeler, BSN, Manager; Clinical Data Management, PRA International

Poor site performance can be caused by a multitude of factors. It can be affected by something as simple as staff turnover or as complex as the motivations driving the investigator to conduct the trial. Data Management can mitigate many of the factors by identifying them proactively and developing processes for damage control.

The following is a Top 10 list of characteristics and opportunities for study success from the Data Management (DM) perspective.

10) Page flow — what and when are pages expected to be returned to the Data Management group?
CRF completion rate can be measured as the expected time from patient visit to harvesting of the CRF pages at the site. One indication of poor site management and performance is a site which falls behind in CRF completion or collects a bolus of pages just prior to the monitoring visit. The rate of CRF retrieval from data management pages received reports can be compared between sites to identify poor performance. The data management group can easily alert the monitoring team of any issues surrounding delay of page flow rates.

9) CRF Design
Design of the CRF can have an impact not only on the site, but on data management as well. Designing the CRF with the primary safety and efficacy endpoints in mind are the main goals of data collection. The CRF should allow for collection of data required for statistical analysis and report preparation. Below are some additional areas where CRF design can affect site performance:
• Group 'like data' together
• Avoid collecting duplicate data
• Keep data collection consistent between protocols for the same drug
• Too much “white space”, encouraging stray comments on CRF
• Too little “white space”, causing crowding and decreasing legibility
• Minimize use of comments
• Avoid capturing start and stop times for AEs and ConMeds when 90% of them are unknown and not necessary for analysis

8) External data issues - high instances of irreconcilable data
Poor record keeping and organizational skills can contribute to performance issues at the site. Lab data, images, randomizations, patient counts, ECG readings, etc. are examples of data collected at the site, but perhaps sent to a specialty vendor for analysis. Accurate identification of the samples and/or readouts, etc. need to be reconciled with CRF data. The data management group can identify data discrepancies, but it is the site which could have the most impact with good record keeping for the lab requisitions and legible information on the sample tubes, images, ECGs, etc. DM serves as the liaison for reconciliation of information between data from the vendors and the source of the data at the site by questioning discrepancies in the data to determine a resolution.

7) Prepare for the monitoring visits/On-Site DCF
High volumes of On-Site Data Clarification Forms, (OSDCFs), are often signs of concern. At times, this situation is a more direct indication of non-quality monitoring, but for the purposes of this article, the site is experiencing an influx of additional AE’s/ConMeds/SAE’s prepared after the monitor’s visit. It is time consuming and, therefore, costly for the data management group to process large amounts of new information received on the OSDCFs. The data management group should identify the sites to better address problem areas for post-collection CRF data changes to avoid these situations of costly data collection and processing.

6) Metrics for frequency of queries/types of queries
The DM group can set expectations for management of Data Collection Forms (DCFs) to aid site performance to achieve a clean database. Data management produces reports displaying numbers of queries outstanding for study progression. By reporting these metrics during study team meetings, the information is shared among all functions to show progression of the responses to the DCFs.

Other useful reports classify the most commonly occurring queries. By analyzing the root cause of these frequently occurring queries, the Data Manager can initiate education and updates to the sites to eliminate the root problem and minimize query output.

5) Manual listings/ aggregate data review/SAS listings
Manual listings for the review of aggregate data are key tools for DM in identifying poor site compliance with CRF collection. Comparison of ‘like data’ easily shows issues in the data. Aggregate data review is especially useful for numeric data. For instance, data collected for a lab result where some of the data is expressed as % and some of the data is expressed as a decimal could be such an inconsistency that could be easily corrected.

4) Training
Training makes a project run smoothly. Training for the sites usually starts with the investigator meeting(s) and may include some additional training by the CRA’s, other personnel or via some other media. Staff turnover at the site leads to poor site performance, especially if the new person at the site did not receive adequate training and/or if the CRF completion guidelines are not clear. It is important that CRA’s follow-up with sites that have had turnover to ensure that the CRFs are being completed according to the CRF guidelines and in a timely manner. DM can provide trends on problem areas with the sites to enable CRA’s to provide targeted retraining.

3) CRF Completion guidelines/ Frequently Asked Questions (FAQ)
It is assumed (for this paper) that the guidelines are well-written and approved by the DM group and the sponsor for the study. DM should keep the document up-to-date and reissue when changes occur to ensure the information is retained as a reference. FAQ is a nice tool for capturing changes during a study by logging problems along with the resolutions. Data management should be involved and ensure the documents are retained in the best and most current form for the sites CRF completion success.

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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.”

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.kundle.com/careers or call the Kendle careers team at +1 513 381 5550 or toll-free at 1 800 733 1572.

www.kundle.com
Two common coding dictionaries currently in use are the Medical Dictionary for Regulatory Activities (MedDRA) and the WHO Drug Dictionary (WHO-DD). Both of these dictionaries are used by pharmaceutical and biotechnology companies, device manufacturers, regulatory authorities, clinical research organizations, system developers and other support services organizations.

In the early 1990s, the International Conference on Harmonisation (ICH) developed MedDRA, which is owned by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) acting as a trustee for the ICH steering committee. As of September 2006, MedDRA 9.1 contains over 47,000 Lowest Level Terms (LLTs). MedDRA was designed specifically for use in sharing regulatory information for human medical products. MedDRA terminology applies to all phases of drug development, excluding animal toxicology. The Maintenance and Support Services Organization (MSSO) was created by the ICH to serve as the repository, maintainer and distributor of MedDRA. The MSSO is also responsible for ensuring the terminology is updated regularly and remains responsive to user needs. There is also a Japanese Maintenance Organization (JMO), a partner of the MSSO, providing MedDRA support for companies headquartered in Japan. The JMO responsibilities include maintaining and distributing MedDRA/J, the Japanese version of the dictionary.

The WHO-DD is an international classification of drugs providing proprietary and non-proprietary names of medicinal products used in 65 different countries, including their active ingredients and therapeutic use. The dictionary is used for coding and analyzing safety data. The current WHO-DD contains all the entries from the original dictionary (1968) with additional data provided by IMS Health integrated with the dictionary’s codes and IDs. By the end of June 2004, the dictionary contained 57,300 unique trade names in 70,000 different medicinal products. The database grows at the rate of about 10,000 medicinal products each year. Since 1978, the Uppsala Monitoring Centre (the UMC) has been the field name of the WHO Collaborating Centre for International Drug Monitoring. The UMC manages subscriptions to the dictionaries, conducts user group meetings and provides publications related to the dictionaries.

These dictionaries are considered intellectual properties by their owners. Those who use the dictionaries are expected to have subscriptions or licenses for the dictionaries. Subscribers are paying for the use of the dictionary, but, more importantly, are paying to support the maintenance of the dictionary. Historically, when maintenance of other dictionaries was sporadic and less well-managed, companies created internal versions of dictionaries. This led to significant dictionary maintenance within companies and a lack of a common dictionary for use by regulatory agencies, such as the FDA.

The MSSO clearly explains their point of view in the MedDRA Subscription Frequently Asked Questions (FAQs) area of their website: “It is the intent of the ICH, the creators of MedDRA, and the IFPMA, the holders of the property rights to MedDRA, that all pharmaceutical companies have a current MedDRA license in order to code, analyze, report, or hold MedDRA coded data. CROs who code, report, or hold MedDRA coded data must also have a current license to MedDRA. Otherwise the sharing of data violates the MedDRA licensing agreement created by the IFPMA regarding the distribution of MedDRA to another party.” The UMC WHO-DD expects before entering into collaboration with a CRO/Sponsor with the intention of using the WHO Drug Dictionary product family, the licensee shall verify the existence of such a license for the other party, before any dictionary related information is provided to the other part.

The following websites are available for additional information:

MedDRA  http://www.meddramsso.com/MSSOWeb/subscriptions/index.htm
For information on MedDRA subscriptions, including the MedDRA Licensing Statement, Terms and Conditions for Subscriptions to MedDRA Terminology and the Payment Policy.
There also is a demonstration version of MedDRA available.

WHO-DD  http://www.umc-products.com
The Uppsala Monitoring Centre provides licensing for the WHO-DD and contact information is on this website.

Identification of Unsatisfactory Site Performance
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2) Query responses
Data management sends queries to the sites based on client-approved Data Management Plans. At times, the frustration begins when sites return “smart remarks” as their responses resulting in requeries. Queries are sent to clarify the data collected by the site – the queries are sent to the source of the discrepancy for clarification; however, if the site has a particularly high query rate, the responses sometimes digress and can become, shall we say, “less than research quality”. The data management group can identify poor site performance by collecting examples of these non-quality responses to provide awareness of the importance of Good Clinical Practices in both study procedures and in the data collection processes.

1) Query rates
High query rates are directly proportional to dirty data. Data management can identify the sites with high query rates and use that information to determine the source of the problematic data. When several queries are generated on a particular site as compared to the others, it is a problem. DM can narrow this search down to module, page and even item. Perhaps the high query rates lead to a poor CRF instruction, question, etc. that should be corrected mid-study. Often, queries are similar in nature (for example, where dose administration or dose adjustment algorithms are complex) and the sites cannot determine if the data collected is the correct data.

With a little problem solving capabilities and some detective work, the root cause can be found and solutions applied to achieve site and data management bliss - a database fit for reporting within the timelines and budget of the study.
**Introduction:**
Recently, Pfizer has moved away from the traditional data manager role toward a data management project manager role. This new role, titled Clinical Data Coordinator (CDC), is just that, a coordinator of all data management activities. From CRF design to database lock, the CDC is responsible for overseeing all data management tasks, ensuring that milestones are met and that deliverables meet expected quality standards. The CDC does this by managing outsourced resources provided by preferred Functional Service Providers (FSP) and/or Pfizer's own offshore resources in Mumbai, India or Shanghai, China.

**Why a CDC Role is Needed:**
The goal of this model is to, through data standards and standard processes, decrease study startup timelines, increase productivity and, of course, with the use of FSPs, reduce overall data management costs.

Over the past decade Pfizer has gone through several mergers and acquisitions, more than doubling the size of the company. This left Pfizer with many development sites often performing redundant activities and with many different processes. In an effort to eliminate redundancies, standardize processes, increase productivity and reduce costs, Pfizer undertook several rounds of restructuring. In the area of data management, Pfizer centralized all data management oversight into one role, the Clinical Data Coordinator.

With the CDC role centralized, processes can be standardized and data standards can be created, implemented and enforced if necessary. Pfizer is also better positioned to take advantage of emerging technologies from implementation of Oracle Clinical-RDC, to capturing and loading new types of electronic data into Oracle Clinical (OC).

**Traditional Data Management Model:**
The traditional data manager is usually considered part of the clinical project team. The tasks that typically make up the traditional data management function include: case report form (CRF) design, database development, CRF imaging/data entry, discrepancy management, dictionary coding, serious adverse event (SAE) reconciliation and study close-out activities.

Depending on a company's model, data management may not have included all of these functions. Often, such specialized functions as CRF imaging, data entry, safety data management and dictionary coding are separated into their own groups. Sometimes, CRF design and database building are also separated into groups.

**CDC Model & Responsibilities:**
Under Pfizer's Clinical Data Coordinator model, the CDC is not part of the clinical project team. Instead the CDC works closely with a Study Manager (SM) who is part of the project team and is responsible for overseeing study start-up, study conduct and study close-out activities from the clinical side. The SM is the single point of contact for these activities for the project team. The CDC provides a data management project management service to the project team by overseeing all of the tasks of the traditional data manager. These tasks are performed by preferred FSPs or Pfizer's own off-shore resources in Mumbai, India and Shanghai, China. The CDC divides time between study start-up and study conduct activities and is the single point of contact for all data management activities for studies.

During study startup the CDC works directly with the CRF and database designer ensuring that proper data are collected per protocol. The CDC is responsible for oversight/creation of the Data Management Plan which consists of multiple documents that define how the data are to be captured, processed, cleaned and closed out. The CDC may kick off the creation and review of some of these documents while others may be completely developed by our FSPs. For example, the CDC completes the Study Design Specification (SDS) and Data Quality Specification (DQS). The SDS is a list of data modules that will be collected and the DQS details the edit checks to be programmed. The CDC works with the SM to finalize these documents which are then handed off to the FSP CRF or database designer for development. The CDC then works with the FSP to ensure that quality standards and timelines are met.

During study conduct, the CDC works directly with a Lead Data Manager (LDM) from the FSP to answer questions, resolve issues, and ensure quality and timeline goals are met. The LDM oversees...
data managers who are performing data cleanup activities for the study. The CDC also ensures that serious adverse event (SAE) reconciliations are performed regularly. The CDC, SM and the monitoring organization work together to resolve any issues that may arise; they also create timelines and implement the plans. The SM communicates study progress to the project team, raises issues and then communicates resolutions or project updates to the CDC and monitors.

Finally, the CDC performs and/or oversees the study close-out activities. Once all of the data have been received, cleaned and the final database audit performed, the CDC ensures that breakblind activities are performed, PK data are loaded and other electronic data that may un-blind the study are loaded. The CDC ensures that all documentation and signatures are in place, then locks and freezes the database.

**Challenges of the CDC Role:**

Pfizer is still working on moving to one central set of data standards. Even though this is getting better and better every day and with a core set of standards, the CDCs still have difficulty with some teams that still want to do things the ‘way they used to’ using the old standards. This resistance to change is in large part due to the restructurings. Although the CDCs sometimes have to work with the ‘we’ve always done it this way’ attitude, this will also get better with time as the new roles become embedded in the organization.

There are many very experienced people at Pfizer, but many need to be re-trained in order to perform the new tasks competently. There is also confusion over roles and responsibilities due to the restructurings. Many people used to do some of the tasks now under a different job function and some people may think that the task is still their responsibility. Pfizer has defined and documented roles and responsibilities on the Pfizer intranet which are available for review and also has instructor-led and on-line training available. Pfizer continuously re-visits these areas and updates as necessary.

Pfizer has sites in India and China and our FSPs have people working from Mexico, South Africa and Armenia. Time zones can be difficult with both Pfizer’s FSPs and Pfizer sites. It can sometimes take a day or more to have a request completed because of varying work hours. On the other hand, Pfizer often benefits by having 24-hour coverage. Achieving a balance between the two is the goal. Also, when making requests it is important to remember not to use slang and provide enough detail for people for whom English is not their first language. Language issues can result in incorrect interpretation of instructions. It is important that CDCs provide specific details when working with FSPs.

**Conclusions:**

The CDC role has challenges, but the benefits of this role will lead to many benefits for Pfizer. Centralizing the project management of all data management activities under the CDCs will lead to increased efficiency in the implementation of Pfizer’s goals. These goals include: global standards, faster setup, easier standard reporting, increased productivity and cost savings. The CDC will be able to leverage the company’s data management activities to better meet these goals.

Gary Caster has over twelve years of experience in the Pharmaceutical industry and is currently an Associate Director in the Clinical Data Coordinator (CDC) role. He is responsible for overseeing all data management activities for one of Pfizer’s high profile oncology projects. Gary began his career as a contract Data Manager at Pfizer, Inc. working on several anti-infective sNDAs. He later took a full-time position as a Clinical Data Coordinator for Bayer Corp. performing data management activities for an NDA bound Alzheimer compound. When an opportunity presented itself in Pfizer’s clinical database building group, Gary left Bayer. Until recently, Gary had remained in the technical areas of data management holding positions of increasing responsibility and has performed and managed such functions as application administration, Oracle Clinical business support, database development, patient randomization and procedure creation. He has experience working with the following data management systems: Oracle Clinical (more than 5 years), 3 different proprietary databases, a SAS-based data management system, ClinTrial and Access databases. Gary earned his B.S. from Eastern Connecticut State University in 1994 and obtained an MBA from the University of New Haven in 2002.
In 2004, SCDM released the beta version of Certified Clinical Data Manager (CCDM) examination. Many people took the exam, but only 33 were successful in obtaining the designation of CCDM. Since that time the number of CCDM’s has grown to 86.

In 2007, our first class of CCDMs is due to renew their CCDM status. All CCDMs including the beta testers must renew their certification every three years.

At the time the exam was created, the only renewal option was to retake this exam. Due to the well know “test anxiety” syndrome, the SCDM Certification Committee has come up with a less worrisome option. The new renewal option is Continuing Education Units (CEUs).

**SCDM Continuing Education Unit (CEU) Policy**

It is the policy of the Society for Clinical Data Management to grant credit as a means of quantifying and recognizing participation in educational programming determined by SCDM to be relevant to the professional development and education of individuals in or interested in the field of clinical data management.

- Such credit shall be known as SCDM Continuing Education Unit—SCDM-CEU
- Such credit shall be granted at the discretion and election of the SCDM Board of Trustees or its designated body
- Such credit shall be determined based on the SCDM-CEU Operational Guidelines. The guidelines are to be approved by the SCDM Board of Trustees. The Guidelines will be reviewed and approved by the Board of Trustees on a triennial basis or more often as deemed necessary by the SCDM Executive Committee.

**Equivalence**

One SCDM-CEU = ten contact hours of participation in (or the instruction of) an organized continuing education/training experience under responsible, qualified direction and instruction.

- Contact hour = one 60 minute clock hour of interaction between: learner and instructor OR learner and materials which have been prepared to cause learning.
  - Contact implies a connection between a learner and a learning source. For the purpose of the CEU, that connection is two-way. The instructor or learning source must monitor the learner’s progress and provide some form of feedback to the learner. This definition applies for face-to-face interaction as well distance learning programs.

For those candidates who took the beta CCDM, renewal options include:

- Retake the final version of the certification exam (this option applies to beta testers only)
- Complete a Recertification Portfolio to include .6 CEU (equivalent to 6 contact hours) of Professional Development
  - .4 CEUs (4 contact hours) out of the .6 CEUs must be in the form of SCDM or SCDM recognized Continuing Education Units (CEUs)

Candidates who took and passed the exam after February 2005 will have three years from the time of successful completion of the CCDM exam to renew their certification. Certification renewal for those who completed the exam after February 2005 require the attainment of 1.8 CEUs (18 contact hours within a three year period), 1.2 CEUs (12 contact hours) of which must be educationally related CEUs.

- Documented attendance* from any of the following SCDM or SCDM recognized educational opportunities beginning with all 2006 events
- SCDM Face-to-face meetings (Spring Forum or Fall Conference)
- Clinical Data Management Training Tutorials
  - Database Lock
  - Database Archiving
  - Relational Databases I - IV
  - CRF Design
  - CRF T & I
  - Laboratory Management
  - Data Management Plan
  - Coding
  - GCDMP webinar series (any one or all will count individually)**
- Other conference and educational opportunities as approved by SCDM

Acceptable Society involvement may include:

- Presentation during the 2006 or 2007 Fall Conference
- Presentation of a 2006 or 2007 GCDMP webinar
- Published article in the SCDM newsletter, Data Basics
- Active*** SCDM committee participation
- Board member
- Committee Chair
- Committee Co-chair
- Sub committee or task force leader
- Review of CDM tutorial materials
- Participation in Exam Development and Maintenance

Details regarding the point values of each acceptable society activity will be available soon.

*Documented Attendance is noted on program registrations under “CEUs”, through participant completion of a Zoomerang survey relevant to the program, or by confirmation of an SCDM representative. (i.e. committee chair)

** In order to obtain CEU credits for the SCDM webinars, the participant must fill out a Zoomerang survey. The link to the Zoomerang survey is listed on the webinar slides as well as the webinar login email. This is true for all people attending the webinar, including those registered as a “group.”

*** Active participation requires that all participants attend at least 10 of 12 annual meetings as well as maintains a level of participation in each meeting that is approved by the committee chair. Attendance is taken at each meeting and participation is at the discretion of the committee chair.

For more information on maintaining your CCDM designation through CEUs, please contact the SCDM Administrative Office at (414) 226-0362 or info@scdm.org.
Finding a Great Training Class
By: Michelle Zubatch, Director, Sales and Marketing, BioPharm Systems

Getting up to speed can require years of work experience, so why not save precious time by taking a great information technology (IT) training class.

How important is your career? For some of us newcomers, it’s the most important thing in life—trying to climb the corporate ladder as fast as possible. One of the quickest ways to climb is through politics and networking; however, to help you along the way you must learn some skills, through both experience and training.

After the corporate boom of educational services in the mid-1990’s, both the amount of training offered and costs have hit an all-time high. Now we see week-long courses costing thousands with travel expenses to boot. Making the right choice has never been more important for your career or your company's budget. Some of the more important facts to consider are the facilities of the hosted course, the instructor, the materials and lastly, the price.

There are three options in considering the location of the course: in-house, meaning at your work location; off-site, at the educational service location; or a Webinar.

Taking a course internally is a great way to save corporate expenses, provided you have enough attendees. However, organizing a course with fellow associates can be a challenge as it requires taking off from work at the same time, selecting a mutually beneficial location, and finally dividing up the costs between departments. All are challenges facing on-site training.

Off-site training is a great break for associates. This allows associates to network with employees from other organizations, and travel to new locations without the distraction of the daily grind, which tends to hinder the learning process. This situation is much more feasible for those taking courses unrelated to their current job or as part of a small group within an organization. A proper training facility will have a dedicated training room and computers, loaded databases and information for real-world scenarios.

A more innovative option is to take a Webinar. Webinars allow you to take courses online, through interactive internet presentations and conference calls, without ever leaving the office. For those one-off classes, saving time out of the office and expenses is often the only possible way to attend. However, with this choice there is no real interaction between students and no break from the office. Often times some preparation is required, such as pre-loading software and database information prior to class initiation. Obtaining references from other clients helps assure a quality training experience while satisfying curious managers.

The second item to research is the instructor. Personality, as well as experience, comes into play for a quality learning experience. Is the teacher patient? Is he/she willing and able to answer your complex questions? Does he/she have lessons learned to apply to the written materials? How many times has he/she taught the class? Again, references are helpful.

Now for the “take-home” giveaways—a quality training session will not only have interactive lectures and hands-on practice exercises, but also written materials that are useful after the class to reinforce and remind the student what they learned.

Last but not least is the price; a subjective matter at best. The actual cost will fluctuate depending on the complexity of the subject, location, number of days, and finally by the number of educational organizations offering the class. Price should correlate directly to a dollar amount of earned value obtained from increased work productivity and career advancement. Again, not set scale. Check to see which materials are at an additional cost and which are included in the stated price. Taking a course off-site will increase costs by the cost of your transport (plane/train/car), hotel, meals and other travel expenses.

Education is never a waste of money. Training courses, certifications and licenses are a part of any industry to ensure an updated level of competence for employers. In some cases, a lack of education can hold one back from moving up the chain of command. Most companies encourage employees to get training in some capacity. Many of these organizations have funding available and look kindly on associates that improve their skills to better both themselves and the organization. Do some research into your career position and see what training classes are offered to improve your skills or jump into a new position.

Michelle Zubatch started in technical as a teenager with her father’s Engineering firm creating documentation and programming with computers. After undergraduate school at Rider University with a double major in Computer Science and Accounting, she worked for McNeil Consumer Products, a division of Johnson and Johnson, continuing programming in computer and entering into Project Management arena. After a few years, Michelle had an opportunity to work for a large vendor, AT&T Global Information Solutions, as a Project Manager. There, she completed two Masters, one in Project Management and other in Business Administration along with a certification at the Project Management Institute (PMI). With a strong desire to return to the Pharmaceutical industry, Omnicare Clinical Research offered her a Management position within the Information Technology group. A few years past raising her kids and back into the industry once more to run the Business Development side of BioPharm Systems where she develops relationships with clients as well as spreads the word about their extensive, high-quality consulting Clinical IT services.

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WINTER 2006
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