Society for Clinical Data Management
DATA DRIVEN

Data Basics

To advance excellence in the management of clinical data

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Letter from the Chair

Ralph J. Russo

Dear Member,

I'd like to wish you a Happy New Year!

I would also like to thank Linda Talley, 2009 Board Chair, for her leadership and dedication to the Society and to the data management profession. Linda contributed greatly to laying the foundation for much of the work you'll see from the Board of Trustees in 2010.

I am looking forward to leading the new Board and our many volunteers in furthering our strategic vision during my tenure as Chair. I am privileged and proud to be able to serve our membership in this role.

2009 was a good year for SCDM in many ways. We continue to become a more international organization, as witnessed by the growth in membership outside of North America. Our webinars continue to provide valuable educational opportunities to data managers across the globe. In addition, the GCDMP continues to serve as the one source for best practices across our industry.

The SCDM Leadership Forum and Annual Conference continue to set the standard for data management conferences. Each of these meetings offers a unique opportunity to understand industry trends, best practices and novel solutions to data management challenges. Attendance and sponsorship at the 2009 Annual Conference in Seattle exceeded our goals. A special thank you goes out to our Annual Conference sponsors for their very generous support of SCDM in 2009.

In addition to those successes, our Subject Matter Expert volunteers and SCDM staff were very busy in helping SCDM meet our annual goals. Here are some highlights:

- Our first online course, on Data Management Plans, was launched in June. We offered four online courses this year
- We formalized a partnership with the Japan Pharmaceutical Manufacturing Association to have our GCDMP translated into Japanese. A similar partnership with a Korean organization is in development
- We released four revised chapters and three new chapters to the GCDMP
- We've expanded our formal partnerships to nine data management and education-related institutions
- Our new Career Center was launched, and has become one of the most popular areas of our Web site
- Linked-In, Twitter and Facebook members continue to grow
- Our membership continues to grow. At the end of the year, we had 2,585 members
- We are nearing 500 CCDMs. Kudos to those who have achieved this designation!

In 2010, the Board will work to expand our strategic relationships with other clinical research organizations. We plan to explore ways to increase our presence internationally, serving the needs of CDMs across geographies.

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Letter from the Chair

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With the help of SCDM staff and our many volunteers, we'll expand our educational opportunities to help CDMs stay current in our fast-changing industry.

I encourage you to visit our Web site www.scdm.org and browse our education portal. Join the DataMatters listserv and participate in discussions with CDMs from various organizations. If you have not already joined our social networking groups, check us out on Facebook, Twitter and LinkedIn.

Thank you again for your support in 2009! Now let's get started on making 2010 a banner year for SCDM!

Sincerely,

Ralph J. Russo
2010 Chair
SCDM Board of Trustees

Finding and Communicating Data Trends Effectively Throughout a Clinical Trial

By Shelina Thomas, PharmaNet, LLC

Whether you work in Pharma or at a CRO, one of the key responsibilities as a data manager working on clinical trials is to ensure high data quality. As stated in *Good Clinical Data Management Practices*, "Data collected during a clinical trial must have as few errors as possible to be able to support the findings or conclusions drawn from that trial." One way data managers can work to ensure data quality is by identifying and communicating data trends. As such, data managers are challenged with identifying data trends and providing the project team with effective feedback throughout a trial.

While most data managers are familiar with reviewing data listings and validation output, they may not realize that these same review methods provide valuable information in identifying data trends. Here are a few examples to illustrate this:

- Reviewing a concomitant medication listing will let the data manager know that the site properly recorded Tylenol for an adverse event. However, the same listing may also draw attention to the fact that a site consistently recorded Benadryl as a pre-medication for every subject.
- Reviewing a lab listing for out of range results is a common item for data review. The lab listing may also identify that some sites are consistently recording commas (,) in place of decimals (.), which are causing many lab results to fall out of range.
- Reviewing data listings can also detect potential fraud, such as noticing that many subjects at a site experienced the same adverse event on the same day, or that many subjects appear to share the exact same weight and height measurements.

Validation output, or reviewing discrepancies, identifies where data discrepancies are located. However, reviewing a validation "trigger count" report provides a complete look of all programmed edit specifications and is a quick way to pinpoint data trends. The "trigger count" includes the name of the edit check, how many times the edit check fired, and the number of times the discrepancy was issued as a data query to the site. It provides a wealth of information to the data manager and the project team, and may help in understanding which data field/CRF caused the most data

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Finding and Communicating Data Trends Effectively Throughout a Clinical Trial

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queries, or by indicating where an edit specification may not be working properly.

For data managers working on a global trial, it is recommended that trends pertaining to a specific region or country be identified. For example, if it appears that an issue of repeating medications is frequently appearing for sites in India or Germany, that is constructive information that needs to be communicated to the team. This information will allow the team to understand where their attention should be focused, and enables them to drill down to the specific root of a problem.

Data trends should be shared with the project team as early as possible. Identifying these trends early, can indicate the need for additional CRA and/or site training, possible database and/or edit specification changes, or show the need for additional data cleaning. These can all have a financial impact on the trial regarding the amount of time spent performing data review, as well additional time spent by the CRA working with the site to correct CRF entries on site. Identified data trends may also show the need to update the CRF Completion Guidelines, which is often the best tool in helping the internal and external team understand how to record trial data within the CRF.

There are several ways to communicate data trends to a project team, and the data manager needs to consider the best method for communicating any data trends to his/her specific team. Holding a round table group discussion during a CRA/DM meeting is one way to accomplish this. However, for a global trial it is recommended to hold small group sessions with regional CRAs, which focuses on specific issues with their sites.

Providing specific information to the appropriate CRAs and choosing the best method of communication can be very productive for resolving data issues. Often times, data management will hold a general teleconference with all study CRAs to discuss data issues. If this type of meeting is not planned properly, it will not be productive. Sharing a lot of information at one time will often cause those invited to tune out and miss important information. Inviting a smaller group of CRAs to discuss issues that affect their specific sites will result in a more engaged audience and yield better results. Tailoring these meetings to address specific needs will also help the project financially in reducing the number of additional re-trainings that are required.

Other ways to communicate data trends include providing handouts or delivering Power Point presentations that summarize overall trends across the study. Whichever method is chosen, the data manager should ensure that his/her chosen method of communication is clear and concise, and that it provides suggestions and/or examples on how to eliminate these data trends. The data manager should also solicit comments from the CRAs on the CRF Completion Guidelines and/or edit specifications. As the CRAs have first-hand knowledge of working with the sites, they are able to provide beneficial feedback on what updates may be needed to these documents in order to improve the data trends.

Identifying and communicating data trends is an essential component of data management processes for all clinical trials and it plays an integral part in ensuring overall data quality. Review trends periodically to determine whether a reduction in frequency of identified issues has been noted. This will highlight whether the efforts made by the team have yielded the desired results. Team members and sites should be re-educated as needed, and CRF Completion Guidelines should be revised as necessary to include decisions made throughout the trial that affect CRF completion. ■

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2010 SCDM Board of Trustees

Is 100% EDC Realistic?

By Dr. Emma Banks, COO at Datatrial

This article is a continuation of the session Dr. Emma Banks lead at the SCDM Annual Conference.

An ongoing study measuring electronic data capture usage in clinical trials has reported that EDC is currently being used in 58% of clinical trials – a substantial increase from the 13% reported in the same survey conducted in 2001. Furthermore, 27% of survey respondents indicated that EDC is being used in all of their current studies, versus less than 1% in 2001. With these numbers in mind, we look ahead to if, and when, 100% EDC usage will be realistic – and how we can get there.

Barriers to 100% EDC adoption: Real and perceived

Let's begin by discussing the barriers that prevent the clinical trial community from using EDC for all of their clinical programs. Despite the fact that EDC has come a long way in the last decade, the perception still exists that EDC is expensive, time intensive to implement, and unreliable. This has been a real barrier to mass adoption across industry. The variety of technology choices – all slightly different – does not aid in evaluating vendors consistently across the board. Each EDC provider has their own way of pricing studies, building studies and working with sponsors. Therefore, it is important to find the company that shares similar values with your organization and takes the time to consider your trials.

Site perception of EDC has also played an instrumental role in why it has not been used in more trials. The viewpoint with most sites is that paper is easy, and they question the need to change. In addition, the shift in the skills needed to manage an EDC study contributes to site resistance. EDC vendors that understand exactly what site support is needed will help alleviate site resistance to this change. Demonstrating an appreciation for and an understanding of how the ultimate end user will interact with the system is critical in designing a system that sites will choose to adopt. Reliability of the technology and availability of "help desk" support is also a key factor in site acceptance.

Across industry we are seeing that roughly 58% of trials are now using EDC. This demonstrates that overall resistance to using EDC is changing. But are there situations when EDC is not a good fit for a trial?

Paper, EDC or both: Reporting needs, study size can impact solution decision

Smaller organizations focused on a single compound or a single study may not have the infrastructure, capital, skills or motivation to fully reap the rewards of EDC. For a single study or early phase studies (such as healthy volunteer studies), the benefits of instant validation and the higher accuracy that EDC provides may not be fully apparent to the organization, due to the costs surrounding installation and integration with existing business processes.

The definition of EDC has evolved to include many things, including IVR systems, electronic diaries, patient reported outcomes and other functionalities. As a result, some organizations and study teams may decide that they have no need for this level of functionality and will choose not to adopt an EDC solution. Since cost is rarely the sole deciding factor for sponsors, many organizations will choose to retain the flexibility to run paper trials, in addition to using an EDC solution.

Overcoming EDC-related financial concerns faced by smaller organizations

For smaller organizations, breaking cost-savings down on a per-trial basis can be misleading, because the initial installation costs often overshadows the down-the-road savings to the organization. When performing due diligence on the feasibility of shifting to EDC, companies of all sizes should factor in the overall efficiencies for training, vendor management, printing, process improvements, resource allocation and other areas to get an accurate picture of potential EDC savings. While the financial impact is a concern, to dismiss EDC solely based on these factors undermines the core real benefits – data availability, data integrity, safety and the ability to make early assessments on the viability of a treatment. Getting it right the first time will save time and money.

What needs to change to make EDC a viable 100% option?

In a survey conducted as part of the research for this session, the respondents cited cost and technology as the top two areas that would need to change in order for their organizations to consider using EDC for all studies. Given the number of vendors in the EDC space, it should come as no surprise that sponsors struggle to understand the wide variety in EDC systems and their associated costs and benefits. Because there is such a variance in providers, the value lies in finding a partner that understands your goals and needs, is as invested as you are in the work being done and can function as an extension of your clinical team.

Is 100% EDC Realistic?

While issues surrounding standardization, electronic patient medical records, the proliferation of vendors with little differentiation, and data storage & integration with other data streams have yet to be fully resolved, EDC is emerging as a viable 100% solution for forward-thinking organizations willing to confront and overcome all the risks, real and perceived. ■

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Four Steps to Bridge the Specifications Gap: How Technical and Clinical Staff Can Find a Common Language

By Jeff Sonas, BS, Owner, Sonas Consulting

It is widely accepted that high-quality software cannot be produced without systematic and comprehensive specifications, and EDC/eClinical study implementations are hardly exempt from this. In fact, the FDA is quite emphatic that you must have solid specifications in order to have a validated system:

> ***General Principles of Software Validation; Final Guidance for Industry and FDA Staff (2002)***
>
> *"It is not possible to validate software without predetermined and documented software requirements"*
>
> *"The software validation process cannot be completed without an established software requirements specification"*

Moreover, EDC/eClinical software has its own particular challenges, bringing together a diverse range of technical and clinical personnel who have very different needs and different priorities, and who perceive the software specifications quite differently. I believe there to be a significant disconnect between the clinical and technical perspectives, that can easily create misunderstandings resulting in costly errors and delays, and ultimately threatening the integrity of the study data. This article will provide practical, from-the-trenches advice on avoiding confusion between technical and clinical staff, facilitating a faster/cleaner database build and speeding up the go-live process significantly.

In any study that uses EDC/eClinical technology, the specification of study requirements will play a vital role. Each study implementation is unique, having its own combination of eCRFs, edit checks, visits, randomization, drug supply, etc. It follows that each study will require its own cycle of requirements specification, study building and testing before going into production. Everything derives from those initial study requirements.

What exactly do I mean by "study requirements?" Most mature technology providers in the industry will specify two completely different types of requirements: one set of requirements for each release of their "core software", and a separate type of requirements (defined for each study) to define how the software should be configured for specific studies. Now the core software requirements are certainly quite important, but typically not a significant factor during the push to go live for a particular study. Instead, I would like to focus on the study-specific requirements.

I have worked in this area for a dozen years and participated in the requirements process from many different angles. Over that time, I have become aware of an extremely challenging difference in perspectives, and in priorities, between those who write study-specific requirements and those who must approve them. I call this the "Specifications Gap" between technical and clinical staff.

The specifications gap

In an EDC/eClinical study implementation, the technical team (whether in-house or outsourced) needs the specifications to be unambiguous and comprehensive. Clear specifications allow the team to configure the software properly, validate the software systematically, and minimize errors and misunderstandings. Programmers prefer requirements that are detailed and complete, to make it crystal-clear how their software should behave.

Further, as vendor technology becomes more refined, many vendors have designed their software to support the direct import of specification documents in order to automatically generate the study build. These vendors prefer highly-structured specification formats such as XML files or spreadsheets, and often use Javascript or pseudo-code as a shortcut in their specifications to describe complex logic.

But the problem with a highly detailed technical specification document is that the sponsor must understand the document before approving it! Some clinical data managers are technically strong and fluent in "pseudo-code"; many talented and experienced CDMs are not. The rest of the clinical/operational team is even less likely to understand Javascript or XML, yet still needs to understand their own parts of the system. Often the CDM is forced to translate key portions of the specifications into plain English for the rest of the team, or the team has to wait for User Acceptance Testing (UAT) of the working system before really understanding what they will get. Both approaches are quite risky and would not be necessary if the specifications had been understandable in the first place. How can we develop universally clear specifications?

Step 1: Work together

It is not good enough to have a specifications document that is easily digested by technical personnel, but incomprehensible to someone unfamiliar with the finer details of the EDC/eClinical system. The document needs to stand alone and be approvable by the sponsor with minimal need for external clarification, because that document (minus the clarification) represents the agreement of what exactly will be built. So you need to consider at all times whether what you are writing is universally clear.

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Conversely, it is not good enough to have a specifications document that states all of the client's requests without due consideration for which requests are easily satisfied and which would require custom development (requiring extra time to specify, build, and test). If personnel unfamiliar with the EDC/eClinical system are controlling the documentation, they may not even realize the available options within the system, or how to decide which option is most appropriate. It is far better to have active involvement from the technical team in the specification process, to improve efficiency among other factors. In addition, the technical team will know better than anyone else exactly what content needs to go into the specifications to avoid ambiguity, and to fully satisfy the needs of both the study build team and the testing team.

Ultimately there is no substitute for collaboration. It is essential to close the gap between the clinical and technical teams. Sponsor personnel have specific business needs, but they may not be familiar with the technical details required to meet those needs. The technical team, on the other hand, knows the technical software details, but they may not be able to communicate these successfully with the outside world. Often neither the technical team nor the sponsor have the bandwidth to give this problem the attention it deserves, and in these scenarios it can work very well to bring in a skilled consultant who can focus on creating a strong, clear specification document that forms a bridge between the clinical and technical perspectives.

Step 2: Technical team must control the specifications

Of course the study-specific requirements ultimately come from the sponsor's needs and from the protocol. It is fine during initial requirements discovery for the sponsor to provide paper forms and other (potentially) ambiguous descriptions of their software needs. However, these initial requirements must be translated into unambiguous, feasible specifications by the technical team, and these specifications must be approved by the sponsor in order to become the new standard.

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If you allow ambiguous or contradictory specifications to constitute the approved standard that your study build must meet, you are courting disaster. Any language in the specifications that requires subjective interpretation leads to the real possibility that different people will interpret the language differently, and thus the software won't necessarily meet expectations. In the best case (when you catch this during testing) these inconsistencies can postpone the go-live date, and in the worst case (when you don't catch this before go-live) the integrity of your data is threatened.

So the technical team (i.e., either the in-house development team at a sponsor/CRO, or the EDC/eClinical vendor itself) must take responsibility for the specifications being unambiguous. However, not every vendor tackles this problem the same way. Some major EDC vendors don't write the study-specific requirements at all; they insist upon being handed fully approved and fully feasible specifications, and won't start the study build until the specifications are acceptable. Certainly this does allow the technical team to "control" the specifications, but I'm sure it also leads to long delays during the back-and-forth to resolve this. It must be preferable to have the implementation team more directly involved in writing the study-specific specifications and imposing more of a standardized format.

I have also seen other technology vendors trying to straddle both sides of the fence, controlling the specifications themselves when possible but also supporting sponsors that insist on providing approved specifications themselves in their own format and terminology. I don't prefer this approach and would definitely suggest the teams work more closely together. I think it really restricts the efficiency of the technical team (both in the study build and the development of test cases) if they have to work from new and unfamiliar specification formats. Admittedly, I have seen some very successful long-term sponsor/vendor relationships, where the sponsor and vendor work together to develop and agree a new specifications format that works for both sides. It would be even better to work together to fill out the specifications in the vendor's standard format, since that is what they are best equipped to work from.

Step 3: Develop visual eCRF specifications first

It can be tempting to try to develop all of the study specifications at once, but it typically works better to concentrate initially on the data being captured. Once you have finalized your eCRFs, including field identifiers, then you can begin referencing those fields (using their field identifiers) in other parts of the specifications, such as edit checks or skip logic. Otherwise change control on your documentation can become extremely painful.

It is important to acknowledge that most clinical personnel would much rather see an annotated CRF in PDF format, than a field listing in Excel or XML. A listing of fields is not always useful for review because it doesn't look like a CRF and therefore makes it harder for a reviewer to visualize what they will be getting from the EDC system. Many sponsor personnel are accustomed to paper CRFs and will feel more comfortable with specifications that look like annotated paper forms:

Race *(check one)*

- ☐ White RACE
- ☐ Black or African-American
- ☐ Asian
- ☐ American Indian or Alaska Native
- ☐ Native Hawaiian or other Pacific Islander
- ☐ Other, *specify:* _____RACEOTH_____

However, most EDC vendors need something less ambiguous and more structured. For instance, when we provide that race question (see above) as part of an electronic CRF, are those boxes for race supposed to be a mutually exclusive group of radio buttons, or a drop-down pick list, or even a group of checkboxes that support multiple selections? Is that "Other, specify" text field only supposed to appear once you mark the box next to it, or is it always visible but you can only click into it once you have marked the "Other" box? The specification must be crystal-clear on this type of question. If the vendor could completely control the EDC specifications, they would prefer something very structured, or (even better) a format that can be automatically imported into test cases and/or into the study configuration itself. So an ideal format from the vendor's standpoint would be something tabular:

PANEL	ID	TYPE	FORMAT	SIZE	CODELIST
DM	RACE	Picklist	n/a	n/a	1=White, 2=Black or African-American, 3=Asian, 4=American Indian or Alaska Native, 5=Native Hawaiian or other Pacific Islander, 6=Other
DM	RACEOTH	Textbox	text	50	n/a

Instead, the ideal compromise format would be a visual representation of the eCRF (easily reviewable by non-technical reviewers) that still contains all the detail required by the technical team for building and testing the fully functional eCRF. Over time, I have evolved a good compromise for both sides in what I call a "wireframe" specification format, striking a

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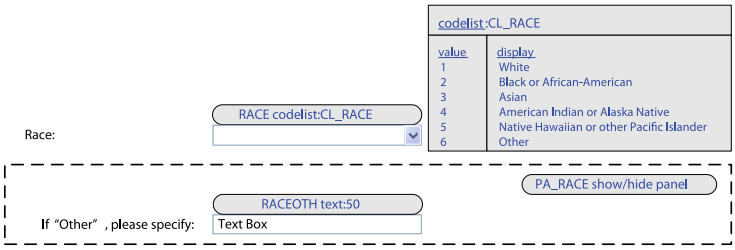
careful balance between sponsors' needs for visual simplicity and vendors' needs for accuracy and completeness:



Note the dashed box that defines the graphical region that will be dynamically shown/hidden based on skip logic. You can easily generate a non-annotated version of these wireframes for reviewers who just want to see what the eCRF will look like visually, without the annotation clutter with fieldnames and other technical details. And always remember, if you spend a lot of time up front finalizing the details with this "wireframe" format, it allows you to establish the names of all the various elements of the eCRF (even codelists and show/hide panels) so that you can refer to them in later parts of the specifications.

Step 4: Avoid pseudo-code. Use plain English

At all times, authors must remember their whole audience (technical and non-technical) and what they will easily comprehend. It is almost never a good idea to include pseudo-code in a specifications document that requires sponsor approval. Of course it is just as bad to have oversimplified language that leaves key questions unanswered. There is no substitute for carefully worded English:

Logic Definition (Too Simple)	Logic Definition (Too Complex)	Logic Definition (Just Right)
Calculates the patient age	if (month(DOB) < month(ICDATE)) return year(ICDATE)-year(DOB); elseif (month(DOB) > month(ICDATE)) return year(ICDATE)-year(DOB)-1; elseif (day(DOB) > day(ICDATE)) return year(ICDATE)-year(DOB)-1; else return year(ICDATE)-year(DOB);	Age at screening, calculated using the DEMOG. DOB and SCRN. ICDATE fields (assuming both fields are valid dates)

As I said earlier, vendors love it when they can include pseudo-code in their specifications because it makes the logic very easy to program. But many reviewers' eyes will just glaze over when they encounter something as technical as pseudo-code, in which case approval of the specifications is more indicative of the approver's confidence in the person who authored the section, rather than actually approving the content of it. When providing edit check specifications for review, it is certainly important to include the full logic, because many reviewers are quite technical and need to get into the details, but it is also important to provide the error messages because some people will only care about the messages shown to the end users.

Conclusion

It can be a very daunting task to provide a study specification that works well for both clinical and technical audiences. It is typically not practical to author two complete documents, one that is client-facing and one that is completely internal. That approach is quite costly and quite prone to inconsistencies. On the other hand, I strongly recommend the approach of specifying study details in one place, which then feeds into both a client-facing requirements document and also a more internal-facing technical specification. It could even feed into the automatic generation of test cases for validation of a study. I believe this to be the ideal approach, but I have not yet seen any vendors approach the ideal very closely.

This leaves us with the traditional choice to manually write one document, the study-specific specification, which is still the most frequently adopted approach. Whatever the format of your study-specific specifications, I hope I have given you good suggestions for improving the content and format of your study specifications, in a way that will reduce confusion, speed up the study build, and ultimately protect the integrity of your data. ■

Jeff Sonas is owner of Sonas Consulting, providing sponsors, vendors, and CROs with comprehensive EDC & eClinical services including study design, requirements/specification design, vendor auditing/evaluation, database validation/testing, and risk mitigation. He was founder and Chief Architect of Ninaza (an EDC vendor) for ten years until founding Sonas Consulting in 2006.

Is 100% EDC Realistic?

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Emma Banks joined Datatrial in 2002 with an impressive background in technical service environments in the clinical trials industry. She has been instrumental in developing and leading teams servicing data management, programming and statistical needs at Datatrial and for previous organizations in the clinical trials discipline. She specializes in developing strong customer/vendor relationships that provide excellent project delivery and flourish into long-term, mutually beneficial partnerships.

Vision 2: Boosting Data Quality Control by Using Metadata

By Dimitri Kutsenko, MSc, MA

Abstract

This article introduces a new methodology of data quality control (QC) in mapping projects. Following a data mapping process, we will first look at the points in the process where the QC can be generally applied. With a metadata based vision in mind we will analyze different means of improving the QC by extended usage of metadata templates and task automation. We will demonstrate how this critical activity can be made efficient and flexible, can eliminate many time consuming, manual tasks and reduce later costs of errors by shifting significant parts of the QC work to an earlier stage in the process. The particular examples taken from the CDISC SDTM world are used only for comprehension reasons – the principles are generic and model independent in their nature. The discussion will be conducted at an abstract level, allowing the transfer of the concepts to other processes and target models.

Since touching on the general requirements for efficient metadata management in the Summer issue of *Data Basics*, a visionary, metadata driven mapping process for data conversion to arbitrary models including SDTM has been explored. One aspect of the mapping process is especially critical and shall be considered here separately – quality control (QC). Due to the fact that data quality control can be understood very broadly (in the area of data management, for example), the scope of this article is narrowed solely to the QC activities during conversion of data to SDTM, a management perspective shall be presented without going into technical details.

What should the data QC function look like to offer maximum efficiency combined with process flexibility and to reduce tedious manual tasks to a necessary minimum? Answering this question is the objective of this article.

CDISC SDTM is an open data model, which allows company specific extensions as long as certain rules are adhered to. A recommended approach of creating company-wide standard models (so called SDTM+) would also offer significant advantages regard to data quality control. The process of negotiating the standards within an organization is beyond the scope of this brief article.

Let us move to the very beginning of the generic mapping process and extend it by the definition of organization specific, standard SDTM domains.

Domain structure descriptions (domain metadata) themselves can and should be subject to comprehensive quality control. This sounds trivial and obvious, but has wide-reaching consequences, especially given the number of mapping-related work results, where the target domain definitions are used. Mapping-related work results start from the target-annotated CRF and mapping specifications, through the mapping programs to transformed datasets and finally define.xml (or define.pdf).

A simple example illustrates a potential source of errors. After an organization has defined a set of global standards, it might need to be adjusted at the study level for specific project needs. A frequent occurrence (while mapping legacy studies, for example) is that the attributes expected or even required later in submissions are not available or are difficult to derive from older data. The least labor-intensive way would be to purge the ambiguities from the study-level target domain definitions. Consequently, the attributes will not be implemented in mapping programs and will not be available later in target datasets. At the latest during the SDTM content checks, the problems will be uncovered and sent for resolution back into the workflow, meaning project delays at the end and involvement of additional, unplanned resources with every new iteration.

Even before mapping specifications are created and mapping programs are developed, later errors can be eliminated by comparing study-level domain definitions with the global domain definitions. If deviations are detected, they must become subject to review. However, manual comparison of the attribute definitions is laborious, especially considering their significant number in a submission. An automated report of deviations is required at this step, which would allow comparison of selected domain definitions and detection of differences in them. Such a report could also be a sound discussion basis for the following reviews. In order to make this reporting requirement feasible, metadata should be stored in a structured format supporting automated evaluation (e.g., in datasets or repository).

Every error in the target domain definition will result in multiple added costs if passed down the workflow. For this reason, an organization must make every effort to discover such errors as early in the process as possible and

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Vision 2: Boosting Data Quality Control by Using Metadata

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make control of domain metadata an integral part of quality control.

Moving further in the mapping process toward actual data conversion, we stop and glance at the mapping specification. Similar to the domain definition problems, errors in a mapping specification are critical if propagated down the process. A mapping program which often includes many transformation steps built upon each other would be developed on the wrong specification and will need to be corrected later on.

One of the most consistent ways to counter this problem is to use an innovative single-source strategy. The key idea is to merge two classically separate steps, creation of the mapping specification and development of mappings programs. The unified mapping definition carries all the necessary information to generate both products from one source – feasible, if supported by adequate tools. For simplification reasons, we will deliberately ignore the fact that the process of creating a complete mapping definition might require several iterations to clarify open issues and involvement of different organization roles; metadata-based control of workflows will not be considered here.

Ideally, it should be possible to fully reuse the same domain metadata – be it study or global level – in mapping definitions making the whole step more consistent and less error prone, which can be considered as an indirect QC measure.

Are the target-converted datasets conformant to the target domain definitions? If the used domain metadata have passed QC at the beginning and the raw datasets have passed source-side checks, you need only controlled assignment of conversion algorithms to guarantee this.

One way would be to introduce graphical user interface to support standard and widely used conversion functions in your organization. In this case, the mapping specialist can depict the transformation logic by configuring available algorithms to be automatically translated into program code later on. This would minimize QC measures at this step to the validation of specific conversion algorithms, assuming that the transformation logic is correct.

Once the raw datasets have been converted to the target structure, the next reasonable question arises. Is their content compliant to the model (SDTM rules, in our case)? Usually, the content validation is done at the end of the mapping process. Following the same paradigm as discussed at the beginning, it would save a lot of time and effort later on if the content checks could be carried out earlier in the process, ideally shortly after the runs of mapping programs and without additional effort, such as manual uploading of datasets to a check portal every time. For this purpose, an executable program covering the standard checks would be a better solution.

In the best case, integration of additional formal checks and further user-defined content checks into the automated workflow should be also supported. This would guarantee that the formal aspects and requirements defined by an organization are validated, leading to improved data quality. Furthermore, the metadata-based approach offers substantial help in task automation, a description of which will not be expanded upon here.

Finally, it would be smart to use the same target domain metadata to create define.xml. Enhanced with controlled definition of relations between required metadata types, including derived metadata, an automatic, metadata-based define.xml generator would help avoid typical problems of define.xml. This would make obsolete the checks of define.xml, which are necessary in a technology-averse, where define.xml is programmed based on target datasets. This would guarantee the conformity of define.xml with the mapping specifications and converted datasets as well as consistent links.

To sum up, locating data quality control activities very early in the mapping process combined with the integration of reusable metadata definitions and metadata-based tools significantly shortens the process duration, supports more efficient data QC and consequently reduces the costs of errors and projects in total.

Already, the clinical world provides powerful examples of metadata based process implementations with off-the-shelf tools like Entimo® Integrated Clinical Environment (entimeICE) tool suite. Boost your processes with metadata based data quality control and enjoy the benefits of being quick off the mark. ■

Dimitri Kutsenko has worked in various industries including pharmaceutical, airline and telecommunication dealing with data analysis, data warehousing as well as product management in software development. He holds a MS degree from the Free University of Berlin (Germany) and an MA degree from the Minsk State Linguistic University (Belarus).

The Rising Importance of Data

By Andrew MacGarvey, president, Quanticate Inc.

I have always had a great interest in data and how they are collected and handled; my career has included roles in statistical programming, database design, systems implementation and EDC. Anyone who works in the biometrics field knows that as technology has advanced, more and more data has become available from increasingly diverse sources. The technical component of the role of a clinical data manager has increased greatly over the last 10 years and will continue to do so. For complex studies, the planning required to bring the data together in a reportable state is a big job, but in assessing the risks of the overall study, teams spend much less time examining this area than say, for example, patient recruitment rates. That may be absolutely correct in the current development model; after all, in terms of budget overrun, the biggest risk might well be slow recruitment, and so much effort is devoted to protecting against it. The biometrics portion of the project is relegated down the agenda, and there may be some talk of discussing the *back end* services further down the line.

Well here is the good news; that is going to change.

I was very lucky to see Steven Burrill present his view on the life sciences sector earlier this year. For those of you not familiar with Burrill, he is the CEO of Burrill and Company.[1] His company is heavily involved in the funding of life science companies and corporate activities in the sector such as mergers and acquisitions; they also publish a great deal of research on the life sciences sector. This background lends great credibility to Burrill and his vision for R&D, a vision which describes a significant change in how things will be done

His vision inspired me to do some further research on what is happening in the sector at a macroeconomic level. What are governments looking to achieve? Where is money being spent in health care? How will the market collapse of 2008 affect the industry? Burrill outlined his vision of the R&D environment over a 10-year horizon. His view: the development time for new drugs will drop from a norm of around 10 years to a norm of around two years. Most of the audience probably felt such a change was impossible until he went on to outline his thinking. I hope to share some of that thinking with you, supplemented by some of my findings in asking the questions above.

All change needs a driver, the "burning platform."[2] In the case of the current healthcare model, this driver is an economic imperative. The world cannot afford to treat everyone; the current system does not function now, and yet the number of new drugs approved is slowing down year after year while the population is growing. Even if it was felt that things were OK now, the model is not scalable in its current form. This problem is illustrated very well by the healthcare system in the United States, and not surprisingly, reform is very high on President Obama's agenda. Influential stakeholders are also crucial to successful change. Obama is certainly influential and has the energy that comes with a new appointment to drive transformation. He addresses the problem at a very good time. The 2008/2009 economic 'correction' has dramatically affected pharma/biotech companies and changed the way this business is viewed. With diminishing pipelines and increasing R&D costs, pharma had considered partnering with or acquiring biotechs as a way to boost product pipelines, and in fact, examples of this are seen more frequently, including some high profile acquisitions this year.

The problem going forward is that with a tightening credit market, a very high proportion of biotechs will fail over the coming months. This is bound to have some effect on the pipeline and will undoubtedly affect the rate of joint ventures and acquisitions over at least the next 12 months. As pharma companies (and the large biotechs) seek to improve margins, the next option is cost reduction. One way this can be achieved is through mergers (another way of boosting individual portfolios, but of course not increasing the overall pipeline). The current activity in terms of mergers will continue. The problem is that much work has already been done in terms of cost reduction; a lot of efficiency gains have already been taken. Current activities will not get the sector to where it needs to be.

So, there is political will in a major market (other nations are facing the same problem, such as the United Kingdom) and economic conditions are having a real effect on the sector and the model for R&D. These pressures on their own might be enough to force change, but probably not a reduction from 10 years to two years for approvals. Burrill thinks he can see a third strand, and I think this might be the most important factor. His belief is that there will be a shift away from "sickness management" to "wellness management", and it is this that will reshape R&D.

What Burrill is saying is that the paradigm will move from doctors reacting to illness and fixing the problem to you spending more money on preventing illness and maintaining your health (for all but the obvious acute and chronic illnesses). In this new world, you go to the supermarket to do weekly shopping and have several diagnostic checks run as you enter the store. While you are shopping, the results will be produced along with any necessary prescriptions. As you complete your shopping, you pick up your medication (for both prevention and cure), and your electronic health record is updated. You may or may not be referred for secondary care. The point is that blood pressure, cholesterol, insulin and others can be tested and

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managed in this way, and as more sophisticated diagnostics become available, increasingly complex testing and treatment regimes can be deployed.

This future state is actually not very hard to imagine; we are seeing in-store treatment rooms appearing already and not just in traditional pharmacies and healthcare stores. If you think the leap to seeing this in supermarkets is far-fetched, then take a look at Walmart to see some of the conditions they can deal with. Walmart is also investing significantly in the electronic health records market working with Dell to provide a cost-effective solution. In other words, the shift has started. The industry is taking notice too; J&J was very close to establishing a wellness and disease-prevention business unit, but have now announced it will be folded into their consumer business. Anticipated revenues? Twenty billion dollars per year. This whole approach requires patient centric systems and thinking. This means a cultural shift, known to be one of the most difficult transformations to affect. Again, much work has already been done, and the emergence of social networking sites has played a significant role. The age of privacy may well be past. Social networking sites have encouraged people from all over the world, from every demographic, to disclose all types of information (in many cases to anyone that cares to read it). There is some way to go, but the evidence is that a shift from withholding personal information to publicizing it is well under way with the associated 'comfort level' growing all the time. In researching this article, I looked at Google Health for the first time. If you want to see one way to manage wellness (and indeed sickness), visit www.google.com/health.

This online resource allowed me to log details related to my demographics, medical history and so on. I could also import my electronic health records, prescription records and lab tests from participating sites. If I had had paper records, the site would have linked me to service companies that can convert them to electronic records. I found the terms and conditions very interesting, particularly the clause:

> *"I hereby authorize Google to share the health information contained in my Google Health profile(s) in its entirety, to only those entities and individuals I designate, for the purpose of providing me with medical care and for the purpose of sharing my information with others that I choose."*

Google will be using my information to provide me with medical care!

So, while our corporations are working away to make this new paradigm a reality; there are many other large retailers and internet companies aiming for market share. All of this should be good for us, the patients. A wellness management approach detects conditions early, and hence the level of reversibility is high; the current, reactive model has lower reversibility. It seems like everyone wins. Burrill notes that if you wonder if populations will be willing to pay for more expensive diagnostics and for managing their wellness, you only have to look at what they will pay for nutraceuticals. A recent report in Nutraceuticals World quoted Global Industry Analysts whose projections suggest that sales in the global nutraceutical industry will reach $187 billion by 2010. I think this is a valid indicator. After all, the money spent here is spent to maintain or improve well-being.

So how does this all lead to an increasing focus on data? The answer is in what becomes of "sickness management" in the new paradigm, once you are all dealing with your own "wellness management."

With the onset of an environment of prediction, pre-emption and personalization the clinical study process is set to fundamentally change. With drugs being targeted to specific populations, the importance of complex computer modelling will increase and become more widely accepted. Programs will then run more quickly, and the Food and Drug Administration and other regulators will approve drugs much earlier once a response in the target population has been proven. It is because of this that Burrill sees the clinical phase reducing in time. Given the economics, it is clear that this will be very acceptable to healthcare providers, as the cost of development will be dramatically reduced, allowing for cheaper drugs. The win for pharma/biotech (and he sees most of these treatments being from biotech) is one of improved cash flow with revenues coming on stream far earlier than they do now. If patent protection rulings are static, then the negative effect on those revenues by generics or biosimilars is reduced by virtue of prolonged exclusivity. It is fairly easy to see how all of the stakeholders could be satisfied by this model. However, the key to all of this working is the design of the shorter clinical development program; that is where the skill sets of biometricians come to the fore.

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In the new model, the importance of intelligent design, conduct, and reporting of studies will be crucial. The regulators will require increasing amounts of data, which in turn will be more complex and come from more sources. How biometricians collect and use these data will be vital to a successful outcome, and expertise in the biometrics arena will become a focal point. Attention will shift from patient recruitment issues to data issues. It is in biometrics (and pharmacovigilance) that the risks will be weighed.

Is it realistic to bring down the time to market of new drugs even allowing for targeted therapies? I wonder if a parallel can be drawn with off-label use of drugs. With sophisticated computer modelling providing credible information with respect to how the drug might act, and intelligently designed trials gathering extended volumes of useful data, the regulators may well be comfortable approving drugs into targeted populations. In 2008, a report in *Nature Biotechnology* estimated that "off-label use of cancer drugs run from 50%-70% of total usage, and perhaps higher."[3] In critical care, there is always additional pressure to get new treatments to the patient. When sickness management is addressed in 10 years, if the technology in diagnostics has advanced sufficiently and more is known about how the drug will affect its population, the pressure to get new treatment to the patient will only increase. With the economic and demographic challenges ahead, the industry may have to rely on the benefit from a new approach. They can focus on accelerating the delivery of targeted therapies to specific populations. The main concern surrounding targeted medicine has been the cost; can a return on investment be made when the market is limited? Under a model where sales begin at the two- or three-year point and where pre-clinical work has also been accelerated, it may be possible.

This article has touched on a few different areas, and each area does rely on certain critical success factors. I hope that what it offers is some view of the potential for change in how we approach the development program when viewed against the challenges our industry is facing at the time of writing. The data has always been important; my view is that more attention will placed on mitigating the risk of bad data in our studies going forward, and this can only be a good thing, not just for the biometrics profession, but for development programs as a whole. ■

1. *www.burrillandco*
2. *Leading Change – John P Kotter 1996*
3. *Off-label or off-limits – Mark Ratner, Trisha Gura Nature Biotechnology 26, 867-875 (31 July 2008)*

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Awakening a Sleeping Giant – Thoughts for EDC Vendors to Support Medical Device Trials

By Christopher McEleney

After years of expectation, electronic data capture (EDC) finally seems to be fulfilling its potential across the pharmaceutical industry with a number of companies now making use of this technology. It is estimated that half of all pharmaceutical clinical trials set-up in 2007 were using some form EDC technology[1]. While this increased usage seems to be evident in the pharmaceutical industry, it does not seem to be the case currently within medical device trials, best demonstrated by the fact that it seems impossible to get figures of EDC use within this sector. From personal experience it seems that often medical device trials may be using some form of EDC technologies for large scale observational studies, or registries. However, most regulatory studies or post-market approval studies tend to follow the traditional paper methods.

Listed below are several well-known benefits of EDC. There is no question that these are realized in medical device trials and in their pharmaceutical trial counterparts equally:
Reduce paper administration of CRF pages and queries

- Allow cleaner data to be captured directly at the site through online edit checks
- Provide reduction in the number of queries
- Allow real-time access to data – helping maintain subject safety
- Require less storage space required at study sites that already have little room
- Reduce sponsor resource requirements in terms of data entry and data cleaning

A review of the literature published by all EDC vendor shows that nearly all cost-saving references and figures are from pharmaceutical companies alone. While there are a number of similarities, medical device trials are in many ways different from pharmaceutical trials, and these benefits and cost savings are not always a direct comparison – a distinction that is often not understood by some EDC vendors and is leading to the medical device sector lagging behind their pharmaceutical counterparts in the utilization of EDC. This is leading to a potentially large untapped market or something of a sleeping giant within the medical device trial community for an EDC vendor who fully understands the needs of the medical device trial market.

EDC vendors coming to present their software to our medical device company often quote one large benefit of their system: reduction of cycle time by reducing time between Last Patient Visit (LPV) and database lock. However this benefit is not as applicable for smaller scale medical device trials. There is little doubt that this is certainly an advantage in trials where you have thousands of patients, however, the majority of regulatory or post market medical device trials we work on are much smaller (often less than a few hundred patients). In these cases database lock is often dependent on the LPV of only one or two patients, which can have their CRFs faxed into the sponsor, and queries turned around on the same day.

This means the database can be locked very shortly after the LPV (often on the same day) and so there really is little benefit of EDC in reducing cycle time in this environment. EDC vendors sometimes try and break into medical device companies based on this benefit, without understanding that it is not universally applicable. In our environment, they should be focusing on the other benefits EDC can bring in order to have some resonance with management.

The cost structures of many EDC software systems are normally prohibitive for medical device companies. Most medical device companies operate on a fraction of the budget that major pharmaceutical companies wield and so cannot commit to the large cost of running a number of EDC systems.

There are also technical issues, which have a larger impact on smaller medical device companies compared to larger pharmaceutical companies. It is still the case that some EDC software requires software downloads onto local site computers (although this is largely being phased out). In the past this may have been easier to manage, but currently, it appears hospital IT groups are more technologically advanced than in the past and in some cases will not allow non-standard software to be installed on their computers. Pharmaceutical companies can get around this by offering the sites their own laptop PCs, however, this would be an increased cost issue for medical device companies with already limited resources and budgets

The next issue is training. EDC often requires site staff training and ongoing training for new staff; this requires additional sponsor resources. In a recent survey this was seen as the least-favored aspect of adopting EDC[2]. For paper studies the "training" for how to complete a CRF can be done in an hour or two during the site initiation visit by a CRA. Contrast this with EDC that often has large-scale, expensive, user training required before site staff can use the system. We need to keep in perspective that site staff (certainly in Western Europe and the United States) are often familiar with using the internet for banking or shopping which they did not require large scale training to use and so EDC systems need to be simple enough that these staff can use the systems with minimal training. The purpose of EDC is to make the process simpler, not more complicated and so begs the question why do we now require more training than the system used previously? The ongoing requirement of training can be a huge drain on already limited

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budgets. This is a universal issue that also impacts pharmaceutical trials, however, it has an arguably larger impact on EDC adoption within the medical device industry due to the restrained budgets.

EDC often brings a number of user questions that are normally resolved through the use of helpdesks. These are an expensive option that offers services that can often be automated. A large number of helpdesk calls received pertain to password administration issues. Again, all online banking and shopping sites have an option to retrieve or reset account details, so surely this must be a reasonably simple solution for our EDC systems.

In summary, it seems clear that there are a number of potential actions EDC vendors can take to help increase the use of EDC by medical device companies. The EDC system pricing structure for smaller scale, less complex medical device trials needs to be addressed in order to make the systems a more viable option. The technology needs to be assessed to be made as user-friendly as possible so that EDC companies can look at reducing the need for and complexity of training in their systems. We must be looking to roll out EDC systems to sites with minimal training, however remain confident that they will use the software correctly. Also in order to reduce costs to make EDC systems more attractive to medical device (and other small trial) companies, alternative methods to an expensive helpdesk option should also be explored, with suitable online methods to reset user accounts and passwords.

In order for EDC to really take off within the medical device sector, EDC companies must gain an understanding of these trials. It does appear that the market leaders are listening and some are making great strides towards this. But at present, some vendors treat medical device trials similarly to pharmaceutical trials. While there are clear similarities, the differences are causing problems and are delaying the adoption of this technology. They are keeping the sleeping giant dozing. ■

1 *EDC adoption in clinical trials: A 2008 analysis" Centrewatch, February 2008*

2 *"What monitors think of EDC – results of a survey of US monitors" Rod M. Saponjic, Scott Freedman, and Ali Sadighian, Applied Clinical Trials (actmagazine.com) May 2003, pp 50-54*

Culture vs. Capture: Creating a World-Class Data Management Department

By Gill Hallett

While the bottom line takes precedence in any and all ventures, it is also imperative that you spend time thinking about the culture and work environment of your organization. When implemented correctly and fostered over time, corporate culture helps to align the mission, values and vision of the organization with its management styles and work environment. You can mirror many concepts of corporate culture in your departmental culture to develop the trust necessary to build a world-class data management team. By creating the right work environment, you can focus your team on the attributes that make a data management department successful – attention to detail, accuracy, accountability and timeliness.

Too often, leaders of organizations are practicing "capture" techniques instead of "culture" techniques. Rather than growing the people and the environment they want, some companies only focus on capturing what they need from the employees. By paying attention to the 10 variables below, you can not only help create a successful corporate culture, but boost morale along the way.

Corporate and departmental culture work hand in hand

On a departmental level, culture is often built through perceiving a tangible connection to the work that is being done. If employees within a department feel as if the work they are pursuing is meaningful, it helps them to define their roles within the company. And seeing themselves in the context of contributing to the larger role of the company itself can assist in transitioning department-specific culture into the greater, company-wide culture.

Identifying the most important individual attributes

Establishing core competencies can go a long way toward breeding corporate culture. Achieving the balance between targeting the individual attributes that best fit a departmental team with the ones that best match the overall organization can be a challenge. However, once expectations surrounding preferred attributes are created and accepted among all hiring managers, the process of bringing in the appropriate talent is made easier, with the result being the advancement of the desired corporate culture.

Setting the right example at the top

Corporate culture is often a trickle-down function of leadership. When employees see organizational values personified by executives, it can often serve as a motivational tool, inspiring employees to also "live" the culture. The sense that the leaders are also capable of rolling up their sleeves and working alongside everyone else to accomplish vital goals or meet crucial timelines is another factor in building morale and culture. However, there also needs to be recognition that the leadership understands the need to allow teams to grow and flourish in the absence of micro-management.

Inspiration through validation

Some organizations talk about emphasizing corporate culture, but don't back it up with actions or follow through with tangible measurements. In order for culture to truly take root within an organization, it is imperative that accomplishments, awards and rewards are all shared in the spirit of positive feedback. Seeing the fruits of culture in the form of sales made and business won can affirm and validate that the approach is working – and further bolster buy-in to the overall corporate culture.

Happy people lead to loyalty, productivity

A byproduct of creating the right work environment is an elevation of overall morale within the organization. Armed with a sense that the company is serious about the cultural element of employment, people enjoy a more loyal outlook to working for the organization. That loyalty can manifest itself in feeling invested in the company's success, which provides extra motivation to go the extra mile and improve productivity for the common good.

The right customers help create the right culture

In following the old saying, "show me who you're with and I'll tell you who you are," it is important for organizations to ensure that they are establishing relationships with partners and customers that share their values. Not only does a mutual vision help to get business relationships off on the right foot, but it also serves to assist in creating the common ground

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that can lead to long-term partnerships. That's why choosing the right partners and customers has crucial ramifications on corporate culture.

Relating measurement and metrics to performance

By ensuring that job-related goals and parameters are in place and agreed upon early in the process, corporate culture can be more easily tied into performance. Measuring employee progress toward accepted expectations provides an easily understandable review process, and allows for training opportunities that can help speed and inform career development. When there is no ambiguity about the standards that employees will be held to, it can have the overall effect of boosting morale and helping corporate culture to flourish.

Promoting from within sends a powerful message

One of the benefits to carefully constructing a cohesive data management team is that it facilitates the process of growing individual members into leadership roles. That process allows employees to become viable candidates to be promoted to more and more important positions within the organization. By identifying and hiring to the proper attributes, not only does it become easier to build a team, but it naturally leads to the emergence of individuals who are well suited to become pillars of the company as a whole. Also, seeing coworkers elevated sends the message to fellow employees that there is a real career path if they excel in handling their own responsibilities.

Integrating culture makes it last

Getting to the point where culture is an ingrained aspect of the entire company and the way it operates is the ultimate goal of any serious pursuit of establishing a concrete corporate culture. Once it becomes less a message and more an accepted aspect of how the organization functions, it sustains itself and becomes very difficult to uproot. For teams that work hand-in-hand on an international level, the process of establishing culture for the long term is a welcome challenge that can actually foster the building of a truly global team. In a clinical environment, using a broader view can often play a large role in ensuring that culture and morale remain healthy. Taking time out to remember the stories and faces that are behind the study work that is being undertaken can go a long way toward fortifying corporate culture.

Differentiate yourself through culture

By promoting the positive corporate culture, it is possible to build a brand that allows you to win more business and to differentiate yourself from the competition. Touting a responsive, communicative and cohesive team to potential customers can send the message that your employees are eager to mesh with their existing team by serving as a virtual extension of their company. Also, because it often takes a mix of backgrounds, personalities and experiences to foster a sustainable corporate culture, prospective customers should be made aware that you have constructed not only a team of experts, but a well-rounded team that can handle a host of needs and responsibilities.

By overcoming the inherent tendency in most organizations to rely on capture techniques that focus on what they can get out of employees, companies that implement culture techniques can take advantage of what happy employees can *give* them. In this way, hiring and developing the right individual can, in turn, facilitate the creation of a sound team – which can lead to a productive, culture-driven organization. ■

Gill Hallett, director of global operations, joined Datatrial in 2003 and has served in a progression of roles at the company and now oversees the operational infrastructure and delivery of global clinical programs. His consultative approach to study delivery provides guidance and assurance to our customers and ensures the successful delivery of our studies.

Certification Corner

Chandra Wooten, CCDM, and Leader of the Certification Taskforce answers questions about SCDM's Certified Clinical Data Manager program.

Question: I have been working in the CDM industry for almost two and half years and I am planning to take the certification exam in October. Can you provide information about your experience taking the exam? What are the questions like? How can I prepare?

Chandra: I think you are very ambitious (and brave) to take the CCDM after such a short time in the field, but I wish you all the best of luck.

While I cannot divulge specific questions, I can tell you that they are complex and that there are very few "throw-away" answers; you really have to read through each question and each answer carefully. The answer choices are realistic reactions to a situation, but the correct answer is the *best practice*, given the specific situation described in the question.

The test is computerized and it is no longer divided into sections, which allows you to spend time on the questions you need to. However, it also means the clock never stops ticking so you have to be quick if you take a break! I suggest flagging any questions you can't answer quickly so you can come back to them later. My strategy was to get through them all as quickly as possible and then go back to the ones requiring extra thought. With one seven-minute break, I had just enough time to do that, with less than two minutes left at the end!

To prepare, I read the GCDMP from cover to cover, including the glossary and the regulations in 21CRF part 11 and a small section of the ICH reference guide. But I have the advantage of 10+ years experience in the business to call on, as well.

You might think 130 questions is not that many, but after two and a half hours it gets harder to think clearly – even if you are well-rested and pumped up with a long-acting caffeine drink like I was. Taking the exam is a pretty intense experience.

At the testing center you'll be assigned a locker to store your belongings. You can't bring anything into the exam room, even water or lip balm – you will be asked to turn your pockets inside out to show that they are empty, and there will be cameras as well as proctors monitoring you and your behavior during the exam. I recommend packing a protein snack, a water bottle and energy drink. I highly recommend using the provided earplugs or noise-reducing headphones, so that you aren't distracted by other test-takers in the room. Do take at least one break, but be quick about it and know that you will have to sign in and out – allow time for that.

Your total score is calculated before you leave the screen, so you get instant pass/fail results. A week or two afterwards you will receive a breakdown of your score in each area. If you didn't pass, this information will let you know what areas you need to focus on for the next time.

Again, good luck! I hope this information will help you as you prepare.

Have a question about certification? Submit it to info@scdm.org and a CCDM may answer it in this column.

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Metrics in Clinical Trials – A Snapshot

By Dr. Purushottam Surti, SIRO Clinpharm Pvt. Ltd.

Metrics refers to measurements in clinical trials. They measure whether the product being measured has or will have an expected quality. Metrics can qualitatively and quantitatively assess whether or not a process is efficient or effective.

At broader level, metrics align overall organizational strategic and tactical objectives to project individual performance. Metrics measure quantity, cost, quality and time in isolation or in combination. A good metric should be relevant, enduring, robust, valid, specific, actionable, and practical.

Examples of Metrics

Quantity: # of queries per patient, # of errors per # of data entered fields

Cost: % of FTE hours assigned vs. % actually used

Time: Time between pre-defined study timelines

Quality: Internal/external satisfaction, types of queries being generated (valid or in error)

The effort needed to collect and report metrics should be offset by the benefit of the metric. Metrics should encompass at least two of the four core metric categories, and those chosen must be able to answer the questions that have been pre-defined to measure the success or failure of the project. Metrics that don't answer the question are useless.

Project or performance goals must be considered while selecting metrics – the same metrics cannot be used across projects.

Efforts are underway for standardizing definition of metrics. Standardized metrics will allow comparison across projects or organizations and ensure everyone understands what the metric means. For example, database 'lock' can mean different things for different groups if a study uses various lock, freeze and break-blind functionalities.

Strive to use existing primary data (e.g., audit trails, tracking systems) to collect metrics. Document the process for collecting, reporting, and communicating study-specific metrics via the data management plan. And document corrective action to be taken if metrics demonstrate that goals and objectives are not being achieved.

Each metric should be categorized according to its attribute. An attribute could be study program, indication or data collection mode (EDC, paper). It helps stakeholders to know underlying causes of performance variances.

Availability of metrics in real time and on an ongoing basis can maximize the benefits and can offer project managers/ leads opportunity to take corrective action sooner rather than later.

Metrics should allow for tracking and comparisons across projects regardless of the process or technology used in the trial. Metrics goals for EDC are often more aggressive than for paper-based studies and may include some unique parameters such as 'the current status and history of SDV' or 'cycle-time from subject visit to in-house accessibility of data'.

Metrics should be shared across all relevant shareholders participating in clinical trial at predefined time-points. This will enable other all partners to take corrective action if needed. Useful reports for the analysis of the metrics include trend analyses, statistical techniques, flagging of outliers, identifying unanticipated trends in the data. ■

Data Basics

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