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DATA BASICS

Volume 8
Number 1
Spring 2002

Promoting Clinical Data Management Excellence

A NEWSLETTER SUPPORTED BY AND FOR THE MEMBERS OF THE **SOCIETY FOR CLINICAL DATA MANAGEMENT, INC.**

From the Editors

Having just returned from the rescheduled 2001 Fall Conference held in Seattle, we'd like to take a moment to extend a very sincere "Thank you" to all the presenters, session chairs, vendors, organizers, and attendees who helped make it a success. The efforts of all demonstrated the amazing flexibility and ability to take initiative in the midst of difficult situations characterized by the professionals who comprise the field of data management. The rescheduled conference presented many logistical and personal challenges for everyone involved. The turnout was fantastic and attendees asked insightful and stimulating questions. The proceedings will be summarized in the next issue of *Data Basics*.

Welcome to the start of a new publishing year. This issue contains the results of the January Board of Trustees strategy meeting, an article discussing the benefits of tracking CRF print order processing electronically, a poem to the wonders of a data management training program, a discussion of the role of the board of trustees, an update on CDISC, an article from the Certification Committee, and a call for input to a new *Data Basics* feature "**Comments from the Membership**".

Regards,
Tam & Cathie

Call for Letters TO the Editors

Do you have an opinion or concern about some activity of one of SCDM's various committees?

Do you have a question you feel needs more discussion or a more in-depth answer?

Have you been wishing for a way to express yourself to both the society membership and those serving on a specific committee?

Well the wait is OVER! Your opportunity to express yourself is here.

Data Basics has created the "**Comments from the Membership**" column in order to give you that opportunity. We want to hear from you, the membership, on any data management or society related topic that interests you.

All letters should be submitted for publication to *Data Basics* co-editors Tam Blackstone (tblackstone@allos.com) or Cherie Stabell (stabell@gene.com). Materials are requested to be submitted in electronic form (MS Word) but may be submitted via e-mail, fax, or by mail. Acceptance for publication will be at the sole discretion of the Editorial Board. The decision to publish will be based primarily upon professional merit and suitability (i.e., topic, scope, and perceived interest to SCDM membership). Materials accepted for publication may be edited at the discretion of the Editorial Board (principally for formatting and grammar/spelling).

THIS ISSUE

Comments from the Membership

Welcome to a new section of *Data Basics.* This section will appear from time to time as comments are forwarded to *Data Basics.* A great deal of interest and discussion was generated by the session relating to DM Certification presented at the fall conference. The following items were sent to SCDM. "Thank You" to the first two volunteers for this feature!

Dear Editors,

With regard to the certification program, it seemed to me that those people in 'niche' DM positions should have the opportunity to be certified in the niches for which they have expertise. A certain amount of general DM knowledge would be required, and then they could take specialized tests to certify them in those 'niche' areas.

"It would be more work to devise such tests, of course. But would be more useful for the industry and for the individuals. The full certification, would of course, be most desirable, but one could take tests in additional areas as his/her knowledge base grows.

Just a thought.

Michelle Alton
Director, Data Management
Bio-Technology General Corp.

Dear Editors,

It has come to my attention that some people are confused about the SCDM Certification Program. I understand that SCDM's Certification will be given as a result of testing, but I have heard several people ask if that is the same as the Certification being granted after completing a specific training course being offered by several universities. I understand that these are two different things, but using same name for both is clearly confusing.

How about using two different names for these two different things? Colleges and universities consistently offer 'Certification Programs' in a variety of fields, where upon after completing the course a Certificate is given to the participant. This part is at least consistent with what is done in other fields. However there are a number of names used to describe what is earned by competing a professional examination in any given field. Accreditation is one that is often used and might better suit our needs in the field of Clinical Data Management. Perhaps the Certification Committee could research this a bit and get some feed back from the rest of the membership?

Sincerely,

Cherie Stabell
Genentech, Inc.

Notes from the Chair of the Society For Clinical Data Management

Hugh Donovan – *Aventis*

At the time of writing I have just returned from the excellent 2001 'Fall' Conference held in Seattle. While I was there several people asked me what does the Board of Trustees (BOT) do? I thought I would use the opportunity of my letter to the membership to let them and you know what it is we do, using the concrete example of our recent Board of Trustees two-day strategy meeting in Palm Springs.

"Why Palms Springs?" I hear you say. Not only it is it a nice place to spend two days of intensive discussions, it is also the location of the 2003 Spring Forum. So one of the purposes of the meeting was to check out the facility to see if there was any fine-tuning required. I am pleased to report that everything went very smoothly and I can thoroughly recommend attendance at the Spring Forum to be held there. The content, as always, will be of a high standard and the location will be excellent.

So what did we do at the 'strategy meeting'? As usual there were two main focuses, one looking at the mission and long term vision of the society, the other being the planning of the next year's activities, consistent with the mission and vision.

We are a volunteer organization with limited resources, therefore it is very important that we have a very clear mission and activities are consistent with that mission. I am pleased to write that the BOT does indeed have a very clear view of the role of the SCDM. It is best summed up in the words of one of the trustees, **Cherie Stabell,** namely "**Promoting Clinical Data Management Excellence**". This clearly differentiates us from other organizations in North America with involvement in clinical data management activities. Also it succinctly summarizes the five components of our mission detailed in our by-laws. Other than give us a nice slogan that we can use on our slides and in promotional material how does it help? As we evaluate how we can best use our scarce resources, it enables us to focus on improving the standards of data management and enabling individuals to achieve excellence within their jobs.

Two prime examples are the Good Clinical Data Management Practices (GCDMP) document and the Certification Program.

The GCDMP document is being recognized as defining excellence in data management with acknowledgement from the FDA, the DIA and other clinical data management organizations. As an example of how our new mission statement helps the BOT in its decision-making, a request came from the GCDMP committee to move the GCDMP document from the Members Only section to the open area. If our mission were to maximize membership or revenue then we would have left the document where it was, restricting it to our members' only section, requiring people to join the society to get the benefit. However as our mission is to get the message of Clinical Data Management excellence spread as broadly as possible, the decision is clear. The GCDMP document has been moved to the public section of our web site so it will be accessible for everyone. We have also made it available to the FDA and to other CDM organizations to share with their membership. Preliminary discussions have also taken place with the Drug Information Association to see how they can help us get the message out to a wider audience.

Similarly, consistent with our mission, Clinical Data Management Certification will be available to

Notes from the Chair

continued from previous page

members and non-members alike. At its strategy meeting, the BOT approved the budget for the development of the certification program, a major investment in the promotion clinical data management excellence.

Also at the strategy meeting, the BOT approved a new vision statement: "**To be the Organization of Choice for the Clinical Data Management Professional**". We believe that CDM professionals will recognize the value of the two activities highlighted above. However we recognize that other, more short-term, ongoing benefits are also needed in addition to these long-term, relatively fixed, deliverables. Therefore we have asked the Website Committee to develop discussion forums to enable members to share and learn. Also we have approved the Membership Committee's request to survey the members again to determine what will be required to make us the organization of choice for data management professionals.

A recent addition to our various communication vehicles has been the e-newsletter, introduced on a trial basis in 2001. At our strategy meeting we approved its continuation as a vehicle to provide regular informational updates out to our members. The BOT reiterated its support for *Data Basics,* which has a different focus from the e-newsletter, with its emphasis on longer articles on all aspects of CDM, from processes and technologies to human-interest stories. I encourage all members of consider contributing to *Data Basics.* Please send contributions to **Tam Blackstone** (tblackstone@allos.com).

So how do these clear mission and vision statements translate into activities for 2002? Each committee, through its BOT Liaison, presented its 2002 objectives and budget. You will see greater detail from each committee in this and future editions of *Data Basics* so I will not go into details here, but these discussions occupied a considerable amount of our time in Palm Springs.

We also discussed interactions with other organizations. Of particular note is the BOT's decision to pursue formal interactions with the FDA and the DIA. Although the organizations are very different, the purpose of both of these initiatives are the same, that is to promote CDM excellence by spreading the message of the GCDMP document and the Certification Program to a much broader audience.

The cornerstones of our society remain the two (well usually two, 2002 being an exception) annual meetings, the Spring Forum and the Fall Conference. The Board discussed the 2002 Fall Conference in detail, approving the theme of 'EDC: Making it Real'. The topic is a very important one for CDM and one that has major implications for all CDM Professionals. It gives us the opportunity to take on more strategic roles within the organization, centered on the integration of data and the provision of information. I believe it is critical that our society tackles this topic, in order to give unbiased, non-partisan information on a topic that has, in the majority of cases, been presented with a particular viewpoint and commercial objectives in mind. I therefore encourage all CDM professionals to actively participate in the meeting. Just to show you that we are not just focused on the short-term, you may be surprised to learn that the BOT also discussed potential meeting venues for 2008 and 2009, as most of the popular venues require at least five-year lead-times.

Promoting Clinical Data Management Excellence requires resources, both human and financial. We have been very fortunate with the extent of volunteering for committees but we can always do with more assistance; please visit our website and volunteer for whatever you are interested. As for financial resources, the BOT spent considerable time at our strategy meeting finalizing the 2002 budget. This year is particularly challenging for two reasons. First, the postponement of the 2001 Fall Conference has presented accounting challenges (for example our 2001 pre-paid Fall Conference registrations are shown as liabilities in the balance sheet and have not been considered revenue in 2001, leading to an apparent loss on the year even though we have received the payments up front). The postponement also presents a more significant challenge and that is the potential funding issue due to running two "Fall" Conferences in one year and the need to attract two full contingents of attendees and exhibitors. I am confident that the theme for Atlanta will enable us to meet the challenge but your help is needed to make it a success. The second financial challenge, made all the more difficult because of the uncertainty around revenue generation, is the major investment required to make the Certification Program a reality. I am pleased to report that, consistent with our mission, the BOT had the courage to commit the necessary funding for the development of the program. Please support this crucial initiative in whatever way you can.

I have tried to capture the highlights of our discussion (the complete list of 2002 objectives as agreed upon at the strategy meeting is shown in the accompanying table for those who would like to see more details). Hopefully you will now better understand what the role of your elected board is, and will recognize the individual effort and contribution required from each trustee.

Finally I hope that 2002 has got off to a good start for you; it certainly has for the SCDM, with our great 'Fall' Conference, thanks in large part to the organizers, **Jean Mazalewski** and **Karen Klingler,** and their teams of session chairs and speakers.

Please remember that the SCDM is your society and I ask you all to contribute to **Promoting Clinical Data Management Excellence.** As always, if you have any questions or comments, please contact me at hugh.donovan@aventis.com.

Objectives for the 2002 Society For Clinical Data Management

- Building on the GCDMP document
  - Globalization of the document
  - Additional Chapters
  - Incorporating FDA Input
- Implementing the beta-test of Certification program
- Defining and implementing a regulatory interaction strategy, to discuss issues related to CDM with focus on ICH-GCP, 21CRF11 and electronic submission.
- Defining and implementing interaction strategies with other associations that have a focus on CDM activities (e.g., DIA, ACRP in North America, ACDM in UK)
- Increasing communication
  - Continuing to grow *Data Basics*
  - Increasing the use of the Internet (Discussion forums, balloting, questionnaires)
  - Increasing the content of e-newsletter
  - Extending Advertising
  - Membership survey to determine value of current offerings and future needs
- Reviewing Long-term strategy
- Identifying new initiatives based on membership desires and long-term strategy where necessary.
- Achieving full attendance at Spring Forum
- Holding 2 "Fall" Conferences with over 400 attendees at each & exhibition space full.

Calendar of SCDM Events

March 10-12, 2002
Successful Data Management Implementations and How You Get There
Spring Forum
Radisson Bahia Mar Beach Resort
Fort Lauderdale, FL

October 6-9, 2002
EDC: Is it the Real Thing?
Fall Conference
Grand Hyatt Buckhead
Atlanta, GA

March 16-18, 2003
Spring Forum
Palm Springs Marquis Conference Resort
Palm Springs, CA

September 21-24, 2003
Fall Conference
Cheyenne Mountain Conference Resort
Colorado Springs, CO

March 21-23, 2004
SCDM Spring Forum
La Mansion del Rio Hotel
San Antonio, TX

October 10-13, 2004
SCDM Fall Conference
Royal York Hotel
Toronto, Canada

The Clinical Data Management Certificate Program: A Student's Viewpoint

Doris Kennedy

While one day reading the newspaper
An article I did find
About a Clinical Data Management Program
The very first of its kind.

I think I'll apply
What have I got to lose?
And if I am lucky
I'll be one that they choose.

So I went through the process
I gave it a shot
And as luck would have it
I was given a spot.

Clinical Data Management
What is that about?
Little did I know
I was about to find out!

So I and 14 others
Began on a track
To become CDM's
There was no turning back

We were ready for the challenges
That we would have to face
Like learning each Module's lessons
In a very short time space!

We began with Statistics
And SQL and SAS
And Microsoft Access
Only 3 weeks did pass!

We were set up in teams
There was not much dissention
A few disagreements
But too few to mention.

The pressures were many
The stress undeniable
The Data Management Plan alone
Seemed so undefineable.

We learned not only the lessons
But a new language too
Our vocabulary of acronyms
Just grew and grew!!

There were CRFs, DCRs,
Validations, SAEs,
Queries and tables,
NDAs, GCPs.

RDE, Audit trails,
Guidelines and lab ranges,
ICH, FDA,
And those document changes.

SOPs, CROs,
Clinical Trials, statisticians,
Edits and Protocols,
CRAs and clinicians.

We were taught, "It's the Process!"
We got lots of exposure
From database entry
To database closure.

We all worked quite hard
We would groan and lament
About how many times
That we had to present.

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Keeping Sight of the Goal: Professional Recognition for CDMs

By Karen Klingler – *Wyeth-Ayerst*

The Certification Committee formed in late 1999 and spent a bit of time trying to get their arms around what is a very large task – developing a professionally recognized certification for clinical data managers, and building a support and maintenance organization for it.

The Certification Committee consists of a solid core of diverse Clinical Data Managers (CDMs) who have committed their time and energy to creating a way of professionally recognizing CDMs. Although committee members have seen many personal and professional changes over the last 2 years, one thing remains consistent; they are all focused and committed to the goal of creating a professional certification for clinical data managers.

Led by Armelde Pitre, the committee defined their charter, developed a 5 year plan and was sanctioned by the SCDM Board of Trustees to proceed with the plan in 2000.

Today, after more than 2 years of research and work, the committee has a great deal to show for its efforts. With the current deliverables and the plans for this year, it is a very achievable goal to deliver a beta test of the certification at the 2002 Fall Conference in Atlanta.

There are several major activities under way in the committee. Colleen Cox and I have been working on the code of ethics – both writing the code itself and creating a set of rules around its application. Gathering input from SCDM Spring Forum 2001 attendees, Colleen drafted a fine code of ethics that exemplifies the CDM professional. It has been honed through reviews in the committee, by the Board of Trustees and by our legal colleagues, and it is now ready for the wider membership audience. The committee will work this year to define guidelines and an oversight body to act on complaints of misconduct. The Board of Trustees will serve as the ethics oversight board as we gain experience in this area.

Karen Fitzpatrick and Leigh Renee Smith head up the efforts to create a reference library of source materials, and publicly available training and educational opportunities that will assist the applicants in rounding out their knowledge prior to sitting for the certification exam. SCDM current policy and activities are not focused on developing and delivering training, but rather toward assisting members to find some of the many fine CDM training programs readily available in the marketplace. Stay tuned – this reference library will be available on the public portion of the SCDM web page.

Who Can Apply to Take the Certified CDM Test?

Balance of related work experience and educational background

- Experience qualifications
  - —2 years fulltime CDM work experience PLUS a BA (or higher)
  - —3 years of fulltime CDM work experience PLUS an associates degree
  - —4 years of fulltime CDM work experience (no educational requirement)
- No distinction made regarding the relevance of the educational studies
  - —"Relevant" degrees are difficult to catalog

    Agreement on life sciences, computer sciences and stats/math, but not other degrees

    No college degrees for CDM currently exist

    Questionable value of effort to "validate" a catalog of relevant degrees to CDM performance

More challenging and controversial, activities to define prerequisites for taking the CDM certification test and the requirements for the Senior CDM, have required extensive SCDM membership input. Sue Croft, Louise Deeming, Julie Grassell, Judy Pyke, and Pat Teden led the committee through efforts to gather and analyze this information. Surveys at the SCDM Spring Forum 2000, Fall Conference 2000, and discussion sessions at the Spring Forum 2001 were aimed at teasing out the membership ideas on the CDM professional capabilities list and the pre-requisites for sitting for the certification exam.

Comparative research with other professional certifications and communications with the ACDM on their certification activities rounded out the information. While it is difficult to satisfy all members, the team and the BOT feel they have set the pre-requisite guidelines appropriately —with respect to the ultimate goal: a professional level of recognition for the Clinical Data Manager consistent with other industry certifications. This includes a very exclusive Senior Clinical Data Manager level of recognition based on lifetime achievement and contribution to the profession.

Judy Pyke and Kathy Shields are working on the application process for the certification exam. They have designed a framework for this, working with information from other professional groups and with the proposed vendor for our test creation and delivery. This year they will create the formal application, document the process for applying, create an application review board, and publish the information for CDM Certification applicants and SCDM membership.

One of the more challenging parts of the certification program is to create the Senior CDM professional certification. This is meant to demonstrate lifetime industry contributions to the profession. Evaluating this level is considered not conducive to a test methodology. Pat Teden and Nanette Petko are going to develop a portfolio review process and content of contributions for these applicants. Also contributing to this effort are Louise Deeming and Julie Grassell who are doing research specifically on how industry contributions for the Sr. CDM professional will be evaluated.

Marissa Volpe, Pat Teden and Julie Grassell will also collaborate on a communication plan and set of communications deliverables to assure that there is a broad advertisement to CDM professionals about the professional Certification and the process for achieving it.

As you can see, there is a great deal more effort around developing a professional certification than just developing the test. Yet the test is what most of us think of first and get anxious over taking. The test is also the key to making this certification worthy of CDM professionals.

Armelde Pitre has worked tirelessly to identify and gather responses from vendors to our Request For Proposals for the test development and delivery. One vendor, Galton, with a great deal of experience in certification testing, is currently under a letter of intent with SCDM. We expect contracts to be signed very soon.

Test development has already begun. Many on the Certification Committee are volunteering to act as subject matter experts (SME) for writing test questions. The committee is gathering names of other SME volunteers to write test questions for various parts of the test. These SMEs will undergo a two day training workshop by Galton, to learn to write test questions properly. They will then be charged with writing up to 20 test questions in their area of expertise. The questions will undergo rigorous review by Galton, the Certification committee and other SMEs in order to assure the rigor, quality and content of the questions. This effort will take place over 2002 with the goal of being able to offer a beta certification exam at the Fall Conference in Atlanta.

The Committee has a list of SME volunteers and may need more in specific task areas — please watch the e-newsletter for any calls for more volunteers. For those SCDM members planning to come to the Fall Conference in Atlanta, you might want to think about being a beta test participant. Join about 100 of your professional colleagues in being the first to potentially become certified CDM professionals. This test will be offered at a reduced rate, but once the scoring and score cuts are defined, those who passed will be officially certified. More information on this will come via the e-Newsletter and member emails. The Certification Committee hopes to see you in Atlanta!

News from CDISC

In November, CDISC announced the release of Version 1.1 of the CDISC Operational Data Model (ODM). This new version of the model, which was developed by a cross-functional team representing pharmaceutical and biotechnology companies, technology providers, and contract research organizations, represents a substantial improvement over Version 1.0.

Among the improvements in ODM Version 1.1 are:

- increased support for incremental data transfers
- support for multiple studies
- reusable metadata, more complete archiving of clinical trials
- increased compatibility with the CDISC clinical laboratory data standards (LAB) and submission data standard (SDS) models
- vendor extensibility. ODM version 1.1 being was released with an extensive documentation set and a set of tools to encourage early adoption by the industry.

In July, in conjunction with the DIA annual meeting, a proof of concept "ConnectAThon" was held. During the ConnectAThon, more than 20 companies demonstrated the ability their products to work with the CDISC Version 1.0 Operational Data Model. The event, which drew a crowd estimated at nearly 1,000, was "… the highlight of the conference" according to Meredith Nahm, a SCDM Board of Trustees member, who currently serves as Director, Clinical Data Integration at Duke Clinical Research Institute.

Not to be outdone by the ODM team, the Submissions Data Standards team announced the publication of Version 2.0 of the CDISC Submission Standard Domain Models. The Submissions Data Standards team includes more than 20 active members from major pharmaceutical companies and contract research organizations.

Among the many improvements in the SDS Version 2.0 domains are revisions to the core and non-core variable contents, definitions and names, the addition of standard formats and decodes [including support for the Logical Observation Identifier Names and Codes (LOINC) database maintained by the Regenstrief Institute], compatibility with the ICH E2B standard for adverse event reporting, an improved presentation format, and expanded documentation. Version 2.0 also includes two new alternative vertical representations of Vital Signs and ECG data, in addition to the horizontal representations originally prepared for the Version 1.0 models.

Significant news in support of the CDISC efforts was made in December when the FDA announced the CDER Patient Profile pilot project in the Federal Register on 5 December 2001. This announcement acknowledges the planned use of the CDISC Submissions Standard Domain Models for a standard representation of CRT data sets and metadata in conjunction with a pilot to test a new standard patient profile application.

The CDISC LAB team has worked to develop a content model for lab data transfers. Specifically, they have defined content requirements consisting of a superset of data elements, including data type definitions, field length characteristics and a logical structure for representing the data. Also, by teaming pairs of sponsors and central labs, the team also tested the dataset to verify that requirements and definitions are comprehensive and work for handling real data (both 'sends' and 'receives'). The LAB team is currently looking for opportunities for further standardization by use of standardized code lists. They are also considering multiple implementation options, including the CDISC ODM model and the Health Level 7 Reference information Model (HL7 RIM).

The CDISC Analysis Dataset Modeling team (ADaM) has recently published a draft set of guidelines for the submission of analysis datasets. These include documentation and a strawman metadata model for percent change from baseline statistical analysis. These documents are posted on the CDISC website and currently undergoing review and testing by FDA statisticians.

Information about the CDISC ODM and SDS models is available on the CDISC Web Site. Information about the FDA Patient Profile pilot program is available at www.fda.gov/OHRMS/DOCKETS/98fr/12001a.htm.

CDISC is an open, non-profit organization committed to the development of worldwide industry standards to support the electronic acquisition, exchange, submission and archiving of clinical trials data and metadata for medical and biopharmaceutical product development. The CDISC mission is to lead the development of standard, vendor neutral, platform independent data models to improve data quality and accelerate product development in the biopharmaceutical industry. It is a CDISC principle to ensure that the data models support the scientific nature of clinical research while improving process efficiency. For more information visit the CDISC web site at www.cdisc.org or contact Shirley Williams, Director of Operations, CDISC at swilliams@cdisc.org or Rebecca Kush, Ph.D., President, rkush@cdisc.org.

A Student's Viewpoint

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At time I had doubts
Is this path right for me?
But our instructors assured us
"Just be patient and see".

I wasn't so sure
Perhaps they were right
When this course has ended
Would I see the light?

We were assigned mentors
Mine helped to show me the ropes
We talked of clinical trials and
tribulations,
And of dreams and of hopes.

When I visited my mentor
What a revelation I got
Only half way through the
program
I had learned quite a lot!

About CRFs, DCRs,
Validations, SAEs,
Queries and tables,
NDAs, GCPs.

RDE, Audit trails,
Guidelines and lab ranges,
ICH, FDA,
And those document changes.

SOPs, CROs,
Clinical Trials, statisticians,
Edits and Protocols,
CRAs and clinicians.

The program has ended
The first in the nation
And we all were quite proud
At the first graduation.

And we all have found
That the lessons we learned
Were well worth the time
For the rewards that we earned.

I am now using my knowledge
In a Data Management position
And thanks to the CDM program
It's been an easy transition.

So if you are thinking
About this course to attend
I can't think of any opportunity
I can more highly recommend.

Sign up for this program
Just give it a shot
And if you are lucky
You'll be given a spot.

And before you know it
In less than a year
The CDM Program will lead you
To a rewarding career!

Society of Clinical Data Management

Code of Ethics

The following Code of Ethics has been adopted by the board of trustees and will be expected to be upheld by professionals who have been awarded the status of Certified Clinical Data Manager or of Certified Senior Clinical Data Manager.

Clinical Data Management is a key component of the development of new medications, medical procedures and devices. Clinical Data Management professionals are:

- **COMMITTED** to following the laws and guidelines applicable to clinical research (including the Declaration of Helsinki), to participate in the protection of the safety, dignity and well being of patients and to maintain the confidentiality of medical records.
- **COMMITTED** to create, maintain and present quality clinical data, thus supporting accurate and timely statistical analysis, and to adhere to applicable standards of quality and truthfulness in scientific research.
- **COMMITTED** to facilitate communication between clinical data management professionals and all other clinical research professionals, to maintain competency in all areas of clinical data management, to keep current with technological advances, and to ensure the dissemination of information to members of the clinical research team.
- **COMMITTED** to work as an integral member of a clinical research team with honesty, integrity and respect. Striving to make and communicate accountability for clinical data management decisions and actions within the clinical trial process.
- **COMMITTED** to maintain and respect proprietary knowledge at all levels, to avoid the use of proprietary knowledge for personal gain, and to disclose any conflict of interest. Committed to avoid any conduct or behavior that is unlawful, unethical or that may otherwise reflect negatively on the profession of clinical data management.
- **COMMITTED** to advance the profession of clinical data management through the development, distribution and improvement of good clinical data management practices. Committed to aid the professional development and advancement of colleagues within the clinical trial industry.

Introducing Your 2002 SCDM Officers and Committee Chairs

Chair of the Society	**Hugh Donovan** Aventis (hugh.Donovan@aventis.com) / 908-231-3938
Vice-Chair of the Society	**Sally Cassells** Lexington Clinical Data Systems (sally44@rcn.com) / 781-863-9918
Treasurer of the Society	**Judy Kasperczyk** TAP Pharmaceuticals (judy.kasperczyk@tap.com) / 847-236-2474
Secretary of the Society	**Meridith Nahm** Duke University (nahm0001@onyx.dcri.duke.edu) / 919-668-8339
Effective Use of Technology	**Ken Carlson** Pfizer (carlsk@pfizer.com) / 212-573-2617
GCDMP Document	**Armelde Pitre** Pfizer (pitrea@groton.pfizer.com) / 860-732-5642
Membership	**Catherine Celigant** Genetics Institute/Wyeth-Ayerst Research (ccelinga@genetics.com) / 617-876-1170
CDM Certification	**Armelde Pitre** Pfizer (pitrea@groton.pfizer.com) / 860-732-5642
Worldwide WebSite	**Jeff Sadik** Immunex (sadikj@immunex.com) / 206-587-0430 ex. 3736
Data Basics	**Tam Blackstone** Allos Therapeutics, Inc.. (tblackstone@allos.com) / 720-540-5274 **Cherie Stabell** Genentech, Inc. (stabell@gene.com) / 650-225-7672

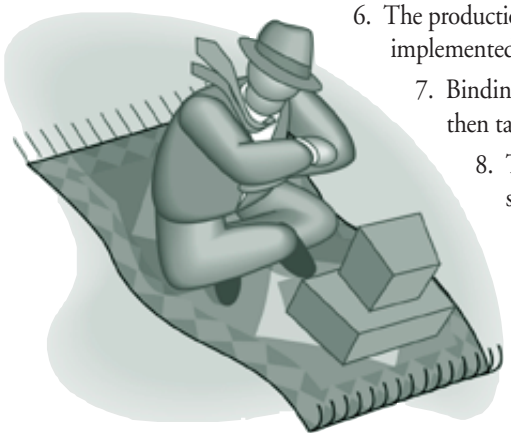
Using the Internet for Tracking Order Processing and Shipment of Paper Case Report Forms in the Global Pharmaceutical Clinical Trial Arena

Dave Mastro – *Strata Companies*

The tracking of Case Report Forms (CRFs) is the subject of this article. CRFs are one of the key documentation tools used during the clinical trial process. The purpose of this article is to describe an Internet based system that enhances the order processing, shipment and tracking of Case Reports Forms in the global arena

A successful Case Report Form (CRF) Production and Quality Assurance Program can be summarized into 10 key workflow steps. This article primarily addresses the last step in the process. However, all 10 steps are presented below for the reader's general information.

1. Case Report Form vendor receives electronic file from client.
2. The vendor creates a Job Specification Sheet. This identifies all aspects of the job needed to complete the CRF, including a Job Specification Sheet for each investigator site.
3. The file is then converted to processing format, and the output of this file is proofed, using a plain paper copy.
4. A set-up page layout is created, and each page is reviewed for correctness in format and image quality.
5. After all images are set-up, a proof document is processed. If any adjustments need to be made, they are corrected and resubmitted for an additional proof.
6. The production process, with ongoing proofing, is implemented.
7. Binding and finishing of the printed materials then takes place.
8. The finished product is boxed for shipment.
9. A final quality check to assure that packaging and labeling are in accordance with shipping instructions is undertaken.
10. Shipment to each site, including confirmation of receipt, is tracked.



While a pharmaceutical, biotechnology or other public or private organization may be the sponsor of the clinical study; the study itself typically takes place at multiple investigator sites. These sites can be widely dispersed geographically, and can be domestic as well as international.

Given all of the above, it is important in today's global clinical trial arena to be able to easily coordinate and track the entire Case Report Form ordering and shipping process with an Internet based system. It can be extremely costly, for example, if a monitor visits a new site and the Case Report Forms which were recently shipped cannot be located. In addition, being able to quickly identify when there is a delay in the process, such as a normally routine shipment being unexpectedly held up in customs is important. An Internet based tracking system is a tool, which can help minimize significant study downtime.

An Internet based system offers the potential for e-mail alerts when designated milestones such as order shipment and order receipt are completed. It also offers the potential for the electronic archiving of CRF order processing and shipping data on a dedicated web site. Being able to historically document the flow of these materials, from shipment through verification of receipt, is a valuable tool for all of the parties involved. Some examples of why these features are important are presented below.

- Before the clinical study begins, it is important to be able to document that the investigator and sponsor have received and reviewed the final CRF.
- During the clinical study, it is important to be able to document when amended versions of the CRF were shipped, how many copies were shipped, and to whom they were shipped.
- In same cases, it may also be important to document the number of CRFs shipped per investigator site relative to the number of patients studied at that site.

Examples of the type of data that could be included in this archival database are:

- Protocol number
- Site location
- Investigator name
- Content, number of boxes/CRFs
- Carrier and shipment ID Number
- Date shipped
- Arrival date
- Received by

A tracking system should include the following features:

- Internet based with a dedicated web site
- Tracking materials from shipment to delivery, with real-time e-mail alerts
- Locating any delays in delivery
- Providing fingertip access to the information about study materials and shipment details (both real time and historical data)
- Allowing for secure, global access to this information
- Providing automatic notification to the study coordinator, field management and others regarding order receipts, shipment releases, and shipment arrivals
- A permanent archival database
- Flexibility to adapt the system for your particular needs

Some of the key benefits of this type of system include:

- Since each order can be tracked in real time, any shipment that is delayed or fails to make its destination can be flagged at the earliest possible time, before it becomes a major problem.
- If a question arises from the field, the user can easily locate accurate and up-to-date on-line information instantly.
- The archival database is a vital component of this system, since it provides a permanent register of all of the shipment information collected on every trial. Authorized personnel should be able to review the complete history of the study, or to limit the search by site, investigator, time frame, etc.

In summary, the process described in this article is intended to help make the coordination of clinical trials smoother and easier. First, the order can be placed via e-mail or on a dedicated web site. Once the order is placed, a confirmation is sent to the originator confirming both the order and the scheduled release date of the shipment. Next, if a change occurs for any reason, a message reflecting this change would be sent to the originator. Upon completion and release to the carrier of the shipment, an e-mail notification is sent. Finally, the system should also include an e-mail notification confirming that the shipment has arrived at its final destination, along with a record of who signed for it. In addition, all of the above should be permanently archived in a dedicated web site.

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(Articles and Advertising Art Work)

Our quarterly publication schedule for the next 4 issues requires the following input deadlines:

Volume 8, #2 (Summer)	26 April 2002
Volume 8, #3 (Fall)	31 July 2002
Volume 8, #4 (Winter)	25 October 2002
Volume 9, #1 (Spring)	3 February 2003

Each issue is mailed to the membership approximately 6-7 weeks after the corresponding submission deadline and posted on the SCDM web page (www.SCDM.org).

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We welcome submission of previously unpublished 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 (i.e., topic, scope, and perceived interest to SCDM membership). Materials accepted for publication may be edited at the discretion of the Editorial Board.

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