

DATA BASICS

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



From the Editors

By the time this issue arrives, we hope that you have your summer plans well in place personally and professionally. With the incredible pace at which we live, it seems that summer is Nature's way of saying "slow down, not so fast, got to make the morning last". Please take some time from your busy schedules to enjoy the delights of the season and this issue of *Data Basics*. You will find it jam-packed with articles to spark interest and enthusiasm.

We are very happy to share with you the success of the 1999 Spring Forum (our 5th Annual). All the teamwork (Facilitators, Consultant, Program Chair, PMA, Hotel Staff, Attendees, etc.) really paid off!!

Note that the calendar of SCDM events has now been expanded through the year 2002. And don't forget to mark your calendars and plan to attend the next major SCDM event, the 1999 Fall Conference.

*Happy Summer!
Lana and Frannie*

One Recipe for Success! 1999 SCDM Spring Forum a la Coronado



A view from the Loews Coronado Bay Resort overlooking the "neighborhood" and the hills of Mexico!

Ingredients:

- 1 "Hot Topic"
- 4 Talented Facilitators
- 1 Excellent Meetings Coordinator
- 1 Gifted Consultant
- 1 Committed Program Chair

Directions:

Select all of the above with care and combine well. Place at a world class resort preferably on a beautiful island in

gorgeous Southern California. Now, add 60 committed, enthusiastic, talented CDM managers. Allow ingredients to rest and blend well for 2-3 days while surrounded by sparkling blue water, palm trees. Splash with endless sunshine. The result...the wonderfully successful 1999 Spring Forum in Coronado on March 21-23!

The meeting began with a leisurely, although cool, dinner cruise around San Diego harbor on a lovely starlit night. The evening provided a relaxing opportunity to greet old friends and meet some new! As the lights of San Diego drifted by, the attendees and their guests enjoyed the view and each other.

Monday dawned bright and beautiful — and what a day it was. The participants rotated through four sessions — each focused on a key aspect of the overall theme — "The Softer Side of CDM – Human Resources". By evening it was generally agreed that having all four sessions on one day is indeed challenging and exhausting. Congratulations to the Facilitators and the attendees for their endurance!!!

Following a free evening, the Forum gathered for a morning with Matt Mirisola. Matt, an HR consultant,

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One Recipe for Success!

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Matt Mirisola, HR Consultant, conducted the training session — "Employee Development: How Can the Manager Help?"

spent nearly four hours leading a training workshop entitled "How Can the Manager Help" (to develop employees). Matt's enthusiasm and knowledge of the topic re-energized the group! The interactive session provided new insights as well as challenges on

both the personal and professional level. The only regret was that there was not more time. The Forum then gathered for a wrap-up session over lunch. Each Facilitator provided a summary of the sessions. This gave the attendees a broad overview of the discussions that had occurred throughout the previous day on each topic. The 1999 Forum was then brought to a close by the Program Chair. You are invited to enjoy reading the session summaries written by the Facilitators that follow.

I would like to take this opportunity to once again congratulate and thank all those who participated — Susan Bornstein, Catherine Celingant, Brenda Hoepfer, Karen Klingler and Matt Mirisola. Special thanks to April Pennacchio, our Meetings Coordinator, who lead us to Coronado!

I want to wish Kristin O'Connor and the 2000 Forum at Wild Dunes every success! See you in South Carolina — fore!

Frannie Rink, Program Chair



Left to Right: Brenda Hoepfer, Karen Klingler, Catherine Celingant, April Pennacchio, Susan Bornstein, and Frannie Rink with San Diego harbor in the background



Recruiting

Facilitator: Catherine Celingant (Genetics Institute, Inc.)

OBJECTIVE: Share and discuss strategies to identify and attract talented data managers with the right skill set for the changing CDM environment.

INTRODUCTION

In this breakout session, the discussion was structured around the typical process hiring managers go through when recruiting. The typical process includes: establishing the profile for the position, getting leads, assembling the interview team, conducting the interview, and making the final decision.

ESTABLISHING THE PROFILE

In most organizations, the hiring manager takes the lead in establishing the profile of the ideal candidate for the position to be filled, sometimes with input from the team. A four-year degree is typically required for Data Management positions, whereas many participants reported not having that requirement for data entry positions. The most common background for CDM professionals seems to be life sciences.

Companies vary widely in their philosophy about the level of experience they require. Some larger companies, with established training programs, choose to hire recent graduates and invest in their training, while smaller organizations tend to hire experienced Data Managers to minimize basic training needs. These philosophies are also clearly impacted by current market conditions which make it increasingly difficult to attract experienced CDM professionals.

Throughout the industry a trend is emerging whereby companies are emphasizing the softer skills over technical skills in the hiring process. Softer skills include communication, ability to work in a team environment, flexibility, and ability to take risk.

The perennial debate about hiring permanent employees vs. contractors once again generated some very interesting discussions. Participants were very aware of and concerned about the potential legal exposure when employing contractors. However, a

majority of organizations seem to employ contractors in various capacities. With this approach, companies gain staffing flexibility and lower costs, while contractors typically enjoy a higher salary and the opportunity to acquire skills faster from working in a variety of environments. The downside for the company may be a lesser level of commitment on the part of contract employees. The contractors usually have to settle for a less attractive benefit package.

GETTING LEADS

Participants shared their experience on an amazing variety of approaches to identifying potential candidates. Besides the conventional approaches, i.e. recruiting agencies, advertising, and employee referrals, organizations are also experimenting with the various Internet bulletin boards, job fairs, college recruiting events, and work-study/internship programs.

When working with recruiting agencies, it is important to select a small number of them as either formal or informal preferred providers and to check their qualifications and track records in our specific field, as it is so specialized.

THE INTERVIEW TEAM

Organizations seem to vary widely in their practices when the time comes to assemble the interview team. Several practices were described. A majority continue to limit the interview to the hiring manager and/or a Human Resources representative. They feel that it brings focus and efficiency to the interview process.

Companies preferring a team approach believe that it makes the team feel more empowered and leads to a more thorough interview. In addition, it provides the candidate with the opportunity to meet future co-workers. Those interview teams may include the hiring manager, the hiring manager's supervisor, data managers, data entry assistants, SAS programmers,

members of the Clinical staff, a Biostatistician, and an HR representative. Human Resources representatives are very often available to coach the interview team on interview techniques and unlawful questions.

THE INTERVIEW

Many companies have experience with varying degrees of success with targeted interview techniques (i.e. specific questions designed to specific skills). Software packages and consultants can help with this process.

A few companies administer tests to their prospective hires, including inexperienced ones, to test their ability to think logically and detect data inconsistencies. A few participants reported practicing non-specific interviewing. In this case, the interviewer keeps an open mind about the position that would be the best fit for the candidate. On occasion, positions may be created for candidates who possess exceptional skills or show great potential.

When the team interview approach is used, a team-debriefing meeting often takes place to gather feedback before making the final decision. The general feeling, confirmed by the recruiters who were present, is that

the best decision is a consensus decision in which all members of a team are involved.

CURRENT MARKET CONDITIONS

There does not seem to be a shortage of entry-level candidates with the appropriate background. However, qualified candidates with experience are scarce! It may take as long as nine months to fill a senior level position.

Most participants reported dealing with equity issues with their long-time staff, as they must offer increasing salaries to attract new employees. This often leads to salary adjustments for existing employees.

Industry surveys are helpful in keeping track of market trends and justify requests for adjustments. However, when using salary surveys, one must realize that job description for the same title can vary greatly from company to company. It is sometimes necessary to take into account more than one job description to obtain accurate data.

IN CONCLUSION....

Recruiting remains a major challenge in the long-term maintenance of a capable and productive organization. The dynamic growth in the role played by CDM is reflected in the differing and changing approaches in the recruiting process. Regardless, the need to find, attract and hire the best possible staff is perhaps the most critical responsibility that an organization faces!



Calendar of Events

September 26-29, 1999

Fall Conference
The Fairmont Hotel
Chicago, IL

*Optimizing Clinical
Data Management
through People, Processes,
and Standards*

March 19-21, 2000

Spring Forum
Wild Dunes Resort
Isle of Palms, SC

October 15-18, 2000

Fall Conference
Crystal Gateway Marriott
Arlington, VA

March 18-20, 2001

Spring Forum
The Tremont House Hotel
Galveston, TX

September 23-26, 2001

Fall Conference
The Westin Seattle
Seattle, WA

March 10-12, 2002

Spring Forum
Radisson Bahia Mar Beach
Resort
Fort Lauderdale, FL

October 6-9, 2002

Fall Conference
Grand Hyatt Atlanta
Atlanta, GA



CDM Roles, Responsibilities and Relationships

Facilitator: Brenda Hoepfer (Kendle)

OBJECTIVE: Identify and explore CDM roles and responsibilities and the diverse relationships CDM experiences with other organizations involved in drug development.

INTRODUCTION

This session's goal was an ambitious one! The topics discussed were reporting

relationships of the CDM organizations, how CDM departments are organized, parameters affecting the organization of CDM, and the role and many responsibilities of CDM.

CDM ORGANIZATION

Session participants discovered there are many ways to successfully organize a CDM department. CDM is often still a part of statistics and/or reporting to the same individual responsible for the biometrics organization. This was the most commonly shared trait identified. As expected, there were CDM organizations that were described as flat, some very hierarchical and the newest term being used to describe some was matrix.

CDM organizations differ greatly. Organization may be based upon project teams, therapeutic expertise, the technology being used, the phase of clinical development, or function (e.g. data entry, CRF design, database set-up, data review). Several CDM organizations feel they have the most success by using a combination of the above structures.

The organizational structure of a CDM department is dependent on several parameters. These parameters became very apparent when discussing what needs to be considered when building or restructuring a CDM organization. Some of the more common parameters influencing CDM organizational structure are listed below.

- Type of company
- Goals
- Company size/department size
- Predicted project workload
- Globalization expectations
- Skill set of current resources
- Growth expectations
- Availability of qualified resources
- Mergers/acquisitions/downsizing

- Retaining qualified resources
- Philosophy of upper management
- Infrastructure
- Technology available/in use
- Costs
- Role/responsibilities
- Outsourcing policy/practice
- Structures of other clinical development organizations

TECHNOLOGY SEEN AS MAJOR FACTOR IN ORGANIZATIONAL CHANGE

The parameter having the largest impact on CDM organizational development is technology due to the changes it often brings to the roles and responsibilities, resources, globalization and the ability to meet infrastructure needs. It was agreed that growing or restructuring CDM is not a task to be taken lightly. It requires a great deal of thought, planning and support. It was also agreed that CDM organizations need to remain open to the idea of change and restructuring to keep ensuring the needs of the business and employees are being met. Most session participants felt their organizations needed some changes in order to better meet business needs and ensure retention of personnel.

CONSIDERING ORGANIZATIONAL CHANGE?

Two major issues CDM organizations are presented with when considering organizational change or growth are being able to provide an infrastructure that supports the change or growth and deciding whether the organization should pursue a generalized or a specialized structure. The generalized approach can be defined, as an organization in which each individual is educated in and performs the many tasks required of that particular CDM organization. The specialized structure is an organization in which individuals are assigned to one functional area within the CDM organization (e.g. CRF development, CRF review, database set-up, edit programming, etc.) and develop extensive expertise in only that area. There were many positives and negatives identified



for both structures. Being generalized provides more opportunities for individuals to develop an understanding of the big picture or whole process. Specialization allows for many tasks to be performed in parallel and thus decreases the time it takes to complete some tasks. However, there was a great deal of concern expressed that because CDM has so many responsibilities that if the specialized structure is adopted, career development may suffer and eventually senior CDM personnel will not have the big picture. Thus there is no way to ensure a solid infrastructure for continued growth and quality work. It was determined that neither of these structures provide the perfect solution and no resolution was reached during any of the sessions as to how avoid the issues associated with each. CDM organizations will continue to struggle with this issue.

ROLE OF CDM

Diversity and change were evident here! Over the past several years CDM has evolved from a data entry support function into a very diverse organization that has responsibility for a set of activities. Historically, the single role or mission statement for CDM organizations was widely accepted as being "to provide clean data in a useable format in a timely manner". With the ongoing controversy revolving around "what is clean?" and the need to speed up processing data, this definition or mission statement has been modified by some CDM organizations to read "provide a database fit for use". Still other CDM organizations take offense at such general statements as these.

Many CDM organizations have assumed responsibility for ensuring the data are clean and the database is ready to lock. In order to meet this goal CDM not only manages the entry of CRF data and merging of non-CRF data, but in many instances has developed very sophisticated systems and processes designed to flag inconsistent or erroneous data, generate and track CRFs and queries, determine protocol violators, etc. In addition, some CDM organizations are also now providing personnel that interact with investigative site personnel to resolve data issues. It is the opinion of some CDM organizations that CDM should decrease the roll it takes in *cleaning* data and focus on *managing* clinical data. Taking on all of these additional responsibilities, because of the attitude "we have the data, we'll do it" has caused some CDM organizations to, at times, be the rate-limiting area in finalizing databases. It has also driven up the costs of doing CDM. In addition, some of the tasks being performed by CDM overlap with tasks being

performed by other clinical development organizations. The metrics needed to provide information regarding added value of duplicative tasks are not available in most organizations to justify these efforts. Some organizations feel the technology available today provides for efficient methods for allowing site personnel and clinical monitors to record and resolve data issues in the field. Any further review and cleaning of data by CDM once the data is in-house is essentially performing duplicate work and these resources could be better used to manage the systems used to collect these data, the timely collection of these data and merging of non-CRF data.

This type of debate and difference in philosophy will ensure that CDM remains a very diverse functional area in clinical development for a long time!

RELATIONSHIPS

The majority of session participants indicated that their CDM organizations are strong and enjoy effective and productive relationships with other functional areas in clinical development. CDM is consistently being recognized as a primary part of the clinical development team and in some instances leads this team! Discussion of these relationships in a supplier/customer context was met with resistance. There is still a tendency for other functional areas to make decisions affecting CDM resources and costs without consulting with CDM. However, it appears this type of activity is due to a lack of knowledge regarding what types of decisions effect CDM and not done intentionally. CDM organizations believe that continuous education regarding CDM is very effective in limiting the occurrence of this independent decision making.

One way some CDM organizations are facilitating productive relationships with other organizations in clinical development is through the development and use of internal project contracts. These contracts are developed at the start of a project, agreed to by the whole project team, and maintained for the duration of a project. They outline project expectations. Identification of project parameters helps CDM to estimate the resources required to execute and maintain projects and also communicate more clearly to the project team what tasks CDM is responsible for and how changes to key parameters may impact CDM.

In addition to providing a communication tool, an added benefit to implementing the use of a project contract is the enhanced ability to manage resources and costs. Many CDM organizations have become more budget conscious and as a result are very

sensitive to program/project changes that result in unexpected added costs. Preparing a project contract provides a way to proactively manage these types of changes. Examples of parameters that may be included are listed below.

- Number of investigative sites
- Date first CRFs expected in-house
- Number of patients (enrolled/screened/dropouts/completers)
- Date last CRF expected in-house
- Duration of patient enrollment period
- Date of database lock
- Duration of project
- Number of AEs/patient
- Number of CRFs/patient
- Number of medications/patient
- Number of unique CRF pages/modules/screens

It was stressed these project contracts were to be used to help make individuals in other organizations aware of the impact of changes to projects on resource planning and budgets. Identifying the impact of a proposed change on a project budget often helps organizations decide if the costs of the proposed change is justified.

IN CONCLUSION....

Diversity rules! CDM organizations are still very diverse in regards to operational and management structures and, by all indications, will continue to be diverse.

CDM organizations are not static, they are continuing to change. Organizations are pursuing changes due to a variety of reasons. New technologies, growth predictions, globalization and the need for a supporting infrastructure are the primary forces driving the changes that are occurring.

The role of CDM in the overall drug development organization is continuing to evolve and this is also a major factor driving changes in CDM organizations. There are very different views regarding how the role of CDM should evolve. Should CDM continue to expand its responsibilities/tasks or should CDM, now that it has developed its own identity, become more focused in the services it provides?

Relationships with other organizations are continuing to be defined and developed. CDM is a very visible and strong organization now. It is considered an integral, respected, highly valued member of the clinical development team in most companies.



Training

Facilitator: Karen Klingler (Wyeth-Ayerst Research)

OBJECTIVE: How to assure that the training framework for CDM professionals is flexible enough to fulfill current and expanded roles in the face of technology advancement and process re-engineering.

INTRODUCTION

This session offered an opportunity for participants to evaluate and discuss the unique requirements and issues surrounding training CDM professionals in a rapidly changing environment. Participants were eager to exchange information on a variety of topics ranging from performing a needs analysis, designing a training program, performing advanced training to using interesting and fun tools to reinforce the training.

TRAINING NEEDS

The roles and responsibilities of CDM professionals have expanded over the years to now require vastly different and more diverse training. In addition to the routine training topics like technology, CDM processes, developing CRFs, etc., more of the softer skills are being trained. CDM professionals are now coordinating workload for a project and performing as members of clinical project teams. Today's CDM professional requires skills including project management, communications, teaming and leadership, negotiating and facilitating. In addition a good understanding of regulatory requirements, budgeting and quality assessment among others are now essential for success.

RESOURCES

It was recognized that these training needs require inventive use of a training curriculum compiled from a variety of sources — Human Resources, outside vendors, industry training seminars — to enhance the routine training provided within the CDM organization. A variety of approaches were discussed based on the fact that CDM does not typically include professional trainers and must rely on subject matter experts to train staff. It was suggested that in order to meet the need for professionals with more diverse skills, while balancing the training development costs, it may be beneficial to hire employees who already demonstrate capabilities that are more difficult to train, and train the skills for which you have the training capability. Employees can also be encouraged to advance their skills through training outside the organization by making use of tuition reimbursement programs.

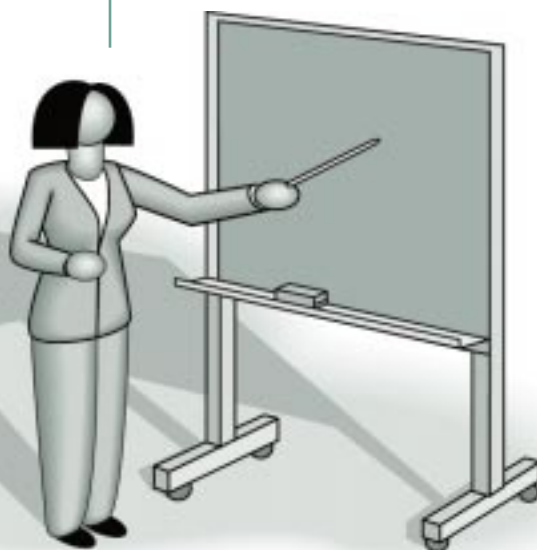
For those groups just building a training program, suggestions include:

- First get a dedicated resource to drive the training development
- Perform a needs analysis (e.g. gather lists of training topics, who needs training in what, etc.)
- Prioritize needs
- Coordinate with hiring practices and training resource/capabilities
- Modularize the curriculum — break it up into manageable, logical units

Training modules can be scheduled easily, trainers can become expert in them and the trainees are not overwhelmed by too much information at a time. The modules can be managed easily through change as well. Training modules can be version controlled over time.

GLOBAL ISSUES

Globalizing training programs in organizations where work is shared and practices are common, was a general interest. This can be satisfied with versions of training modules that maintain local flavor. This



is most easily accomplished where standard practices are already harmonized among sites. Having a core training plan with local trainers to champion the training is one way of assuring local flavor as well as commitment to the core training messages and methods.

TRAINING “OTHERS”

A common challenge faced is the tendency for CDM to not only train its own staff to perform, but to train the *larger organization* in the CDM profession. This, along with the routine training needs, tends to burden CDM training resources. On the positive side, it also creates visibility and appreciation for the CDM profession as well as the training capabilities that the CDM organizations value. Several ideas were shared on how to make this type of cross-functional training interesting and productive.

A simulation of a day in the life of a project is used by one company. In this training environment mocked-up CRFs, database and source documents are utilized. Site monitors, CDM, programmers, statisticians and medical monitors gather in one room to perform their usual study responsibilities. Interaction between the different players results in an improved understanding of roles and how the processes and technology fit together. Switching roles for a day by taking a site monitor into CDM or a data manager out to a site visit has also proved to be a valuable learning and teaming tool.

FUN AND GAMES

Other people shared some of the tools used to cross train and/or assure that the training material has been assimilated. These included games based upon the training topics. One group created their own Query Pursuit game, another a Jeopardy game using CDM and clinical trial training material. The *Pharm Game*, which is publicly available, is used to train the drug development process and is available through *The Learning Key* of New Hope, PA (phone: 215-862-9425). A web site where one can browse information on anatomy has been found useful (www.innerbody.com). In one company, the medical monitors perform “Grand Rounds” thus making themselves available to an audience to discuss the science behind the drug under study. Brown bag lunches are used to gather people for in-service training or to discuss issues in a free format.

SOME IDEAS ON “HOW TO...”

Adult learning theory — recognizing that adults learn better by doing than by lecture — is applied by

some participants in developing training programs. Designing training modules to have short information sessions interspersed with many exercises or hands-on activities has proven effective. One company calls it “tell me, show me, let me try it, give me feedback”.

Use of mixed media is also helpful — video, graphics, sound, computer-based training, games, etc. People have different learning styles and mixed delivery methods help to assure that information will be received. Delivering training “just-in-time” is desirable so information learned is immediately applied and reinforced, and re-training is kept to a minimum. Independent study follow-ups and homework are also often-used methods of reinforcing training.

DO-IT YOURSELF

Offering self-help training tools is a way of empowering employees to manage part of their own development. Computer-based and other independent learning materials can be made available to employees. Valuable tools include web-based information, frequently asked questions (FAQs), newsletters, tips and techniques, strong HELP systems and knowledge databases.

RECOMMENDED READING

Recommended reading material to assist people through change was the book *Who Moved My Cheese? An Amazing Way to Deal With Change in Your Work and in Your Life* by Spencer Johnson and Kenneth Blanchard.

TRAINING RESULTS

One of the challenges of working in this highly regulated environment is the need to assure that the trained staff is competent and the training is documented and tracked. Most companies have designed or purchased training tracking databases. There were mixed opinions as to the ability to prove that learning has occurred. Measurement or certification of staff is difficult. Some testing is used to accomplish certification. In addition, verbal review of material, mock exercises and games can be used to demonstrate competency. In most cases it still comes down to the judgment of the trainer. Mentors have been used successfully to assist and coach the trainee through the transition to the work environment. This strategy also serves to assure that competency is demonstrated through a mentor’s review until a satisfactory level of performance is achieved. Refresher training courses, delivered at scheduled time points (such as yearly refreshers on

SOPs) are helpful to assure competency over time and to achieve greater assimilation of information.

ALLOCATING RESOURCES

Another challenge to training in CDM is the ability to get resources to build and deliver training programs. Most groups use CDM experts to do this job and therefore must accommodate the production workloads that reallocating these resources causes. They often rotate the trainers in and out of the production environment so they keep their skills current and retain interest in their data management careers.

JUSTIFYING TRAINING RESOURCES

In order to build training groups, organizations have justified the cost versus benefit in different ways. Some groups hide the trainers in routine headcount and cover their workload. Others attempt to use metrics including:

- Turnover vs. speed of new staff effectiveness — the faster new employees are productive, the better
- Measuring the cost of mistakes — calculating person-hours utilized to fix mistakes; time lost in the market place because of mistakes
- Quantifying the cost of losing good people
- Measuring quality
- Tracking turnover rates

Less quantifiable information used to justify training includes relating training costs to retention of good employees. There is a strong desire for training and growth to be a part of career development. Feedback in exit interviews and turnover rates can help identify problems. Good training programs are recognized as a competitive advantage in an environment where there is a limited pool of qualified employees. Regulatory requirements around training and employee competency help to justify costs.

IN CONCLUSION...

As always when CDM professionals gather to discuss training, there were many challenges shared and many ideas and solutions offered. The interaction and coordination between job requirements, hiring practices, career development and training is constant and essential. Attaining the right balance requires time and vigilance. When done well the results are enormous in terms of quality, productivity and employee retention.



Employee Recognition and Retention

Facilitator: Susan Bornstein (MTRA, Inc.)

OBJECTIVE: Share information on how different companies recognize and retain their employees.

INTRODUCTION

This session began with each participant drawing and sharing a picture (work, family, hobbies, etc.) about him/herself. From these drawings, it was concluded that data managers make great stick figure artists. This session's topics included what motivates employees, monetary vs. non-monetary recognition, what employees value most, compensation

packages, and reasons for turnover. Below is a summary of the information shared from this breakout session.

MOTIVATION — WHY DON'T PEOPLE DO THEIR BEST?

- Bored
- Poor communication
- Not happy
- Lack of recognition
- Conflicting direction
- Lack of role models
- Lack of training
- Not involved in decision-making process
- OK to do OK
- Lack of management
- Lack of vision
- Personal
- Micro-management
- Lack of equipment, respect, commitment
- Expectations are unclear
- Apathy
- Office space inadequate
- Do not feel work is important
- Overworked
- Do not have the appropriate tools
- Bad fit
- Don't see opportunities
- Lazy and distracted
- Stress from change
- Don't take pride in what they do
- Told they're not doing their best
- Perceived favoritism
- Position is a stepping stone
- Not doing what they want
- Bad morale
- Culture
- Not interested

MOTIVATION — WHY DO PEOPLE DO THEIR BEST?

- Great manager
- Integral team member
- Sense of ownership
- Feel appreciated
- Defined objectives
- Make difference
- Trusted
- Shared common goal
- Intelligence
- Like what they do
- Timely feedback
- Sense of responsibility
- Self-motivated
- Participate in decisions
- Teamwork
- Proactive
- Rewards/compensation
- Job matches skill
- Enthusiastic
- Important/valued
- Thank yous
- Not afraid of change
- Respect
- Like what they do
- Promotional opportunities
- Challenged
- Obtainable goals
- Participatory environment
- Intrinsic motivation
- Over-achievers
- Participatory encouragement
- Title advancement

AWARD SYSTEMS

Both monetary and non-monetary rewards are important in recognizing employees. Below is a list of awards. You may want to implement some of these within your organization.

- Department shirts
- Announce promotions
- Celebrate with balloons — surprise a project team and decorate their office space
- Profit sharing plan
- Drug name competition
- Business casual dress
- Salary adjustments
- Merit increases
- Being project lead

SCDM

“Web Site” Committee Update

This group has met and the web site efforts are moving ahead. Additional participation is welcome. If interested, please contact SCDM Trustee, Doug Schantz (e-mail: douglas.schantz@wl.com; phone: 734-622-1310).



AWARD SYSTEMS (continued)

- On the spot awards, team awards, Leadership Excellence Awards, Excellent Performance Awards, Above and Beyond Award for Proactivity, Flexibility, Teamwork, or Customer Focus, Letter Carrier Award (Persevered all kinds of weather to make the deadline), or Battlefield Awards. These awards are peer, team or manager nominated. The team or individual receives a gift certificate (American Express \$25 – \$100), dinner, or a pen/pencil box engraved with name and lunch with the team.
- Birthday Breakfast Club monthly
- Breakfast or lunch with staff or team and welcome new staff or recognize individuals publicly for achievements
- Provide training and attend industry conferences
- “Stars” Award program — employees are awarded stars which can be redeemed for merchandise. The reasons for awards are aligned with corporate values.
- Assigned special projects such as heading up a technology initiative or a team to select a new CRF design software package
- More responsibility
- Bonus based on sales/performance
- Promotion
- Annual stock options
- Increased vacation time
- Discretionary bonus
- Holiday bonus
- Opportunity to discuss each staff member’s “Joys and Concerns” at the staff meeting — opportunity to voice the positive and negative
- Project completion parties
- Product launch party
- Suggestion award program for employee suggestions which are implemented
- Logo competition
- At-a-Boy/Girl gifts (pens, mugs, gift certificates)
- Thank you notes via e-mail, phone, note card, or formal stationary “people valuing people”. “Thank yous” are very much appreciated by staff and is a non-monetary award that works.
- Social team building events: Riverboat cruise, lunch, dinner, afternoon at the movies or bowling, ice cream sundae party, picnic, BBQ, Halloween costume contest
- Comp time
- Team meetings with treats or lunch
- One on one lunches
- Off-site staff meetings
- Planters for desks (permanent rather than flowers)
- Motivation Survey — managers act on results
- Each project team presents accomplishments each quarter at divisional meeting
- Praise for a job well done
- Laptops
- Treat implementation of a new technology like the birth of a baby — for example, announce “test was positive” (pregnant validation verified). “Delivery of the baby” is actually successfully getting data in and out of the new system — then send “birth announcements” to let everyone the “baby” (the new technology) has arrived!
- Compensation for increased 10% overtime in a given month
- Summer hours
- Alternate work schedule (4 ten hour days)
- Job sharing
- Flex time
- Work from home
- Bravo Award, Walking on Water Award, Special Recognition Award, Presidential Awards, Premier Circle Awards, Excellence Awards
- Movie passes
- Short term assignments in another office location — Formal Transfer Policy
- Senior directors bonuses depend on how well they recognize/reward/retain their employees
- Years of service recognition dinner
- Recognition with newsletter
- On-site child care facilities
- Share wedding videos/albums over lunch
- Letters from clients framed and displayed
- Employee of the year
- Courses and tuition reimbursement
- Offer scholarships, e.g. SAS certification
- Over the Bridge Awards for career development
- Close office Christmas to New Years
- No meeting policy on Fridays
- Have staff submit a profile on how they would like to be rewarded since different people are motivated by different rewards

REASONS FOR TURNOVER

- No growth opportunity
- Not challenged
- Personality conflict
- Increased salary
- Went to CRO start up
- Balance family
- Back to school
- Location
- Down sizing
- Stress/burnout
- Changed internally to CRA or IT
- Fear of change
- Wants full time
- Bad fit
- Better offer benefits and/or dollars
- Wants part time

Annual SCDM Business Meeting at Fall Conference Call for Agenda Items

The Annual General Meeting of SCDM will be held during the 1999 Fall Conference in September. Please submit topics for discussion for the business component of this general meeting to April Pennacchio, PMA (e-mail: april@profmgmt.com).



continued on next page

REASONS FOR TURNOVER (continued)

Many of these reasons for turnover can be decreased or avoided all together. Encourage cross training of staff and site visits and listen to staff needs. Develop an employee development plan for each of your staff with clear agreed upon goals.

USE OF CONTRACTORS

Contractors average 10% of Data Management Staff. The percent of contractors at companies represented at the Spring Forum ranged from 0 – 40%. The contractors at most companies were treated differently than the full time staff.

WHAT DO EMPLOYEES VALUE MOST?

- Feeling appreciated
- Good relationship with managers
- Empowerment
- Recognized for doing their best
- Professional growth opportunities
- Time with family
- Flexibility
- Role and task clarity
- Respect
- Friendly environment
- Clear career path
- Challenge
- Physical surroundings (on-site daycare/fitness center)
- Money — fairly compensated
- Acknowledgment

All employees are balancing their personal lives with their careers and flexibility is very important to them. Other concepts to consider: Individual vs. Team Recognition — which types of awards are appropriate when; Many Levels vs. Same Titles for all (flat organization). Keeping people feeling positive about their environment is crucial. Remember what motivates some will not motivate others.

JOB SATISFACTION

Managers and Directors who attended the conference were asked why they are satisfied with their positions and why they stay. Their reasons are below:

- Opportunity to implement new ideas and processes
- Feeling of accomplishment/ make a difference
- Initiative involvement such as technology, globalization, or process improvement
- Strategic thinking
- Sense of self
- Diversity
- Humanitarian/science-based aspect
- Recognition
- Flexible hours
- Challenge
- Location — short commute
- Fair compensation
- Autonomy

WHAT'S NEW WITH COMPENSATION PACKAGES?

- Sign on bonuses such as: 5-10% salary, or 3 – 5 K with length of service required to keep bonus ranging from none to 1 year
- Stock Options
- Tuition reimbursement although qualification requirements varied such as: grade requirements, cap per year, length of service required
- Concierge (need to pay) to run personal errands
- Relocation Package length of service required to keep compensation amount from package none to 1 year
- Adoption/new baby time off
- Sabbatical program
- Free coffee, tea, espresso
- Require spouse acceptance trip. Career counseling for spouse.
- Company store
- Dry cleaning
- Summer hours — leave 12 – 1 on Friday
- Business casual dress policy
- Offer Cafeteria style benefits — get to pick and choose benefits
- Discount movie tickets
- On-site Dentist 1 time per week
- Vacation time averaged 3 weeks plus sick days unlimited
- On-site massages 1 time per week, \$1.00/minute (can give gift certificates)
- Short and long term disability
- B.J.'s Wholesale Club Memberships
- 401 K with matching by company
- Stress relief area

REWARDS VS. JOB REQUIREMENTS

How do you separate rewards from job requirements? Where do you stop the rewards because “this is part of your job”? Rewards need to be rewards and not become expected to be appreciated.

SOME TIPS

- Do not tell people what you want them to *do*, tell them what you want them to *accomplish*.
- Set goals together. Self-set goals promote a high level of achievement. Imposed goals promote resistance.
- Empowerment equals high involvement.
- Every idea is an opportunity to coach, mentor, and redirect.
- Set SMART goals:

- S** Specific
- M** Metrics
- A** Attainable
- R** Relevant/Reachable
- T** Time-based

- Suggested Reading: *1001 Ways to Reward Employees* by Bob Nelson

IN CONCLUSION....

It is hoped that you can implement some of the suggestions in this article and succeed in motivating your employees. Thanks to all who contributed their ideas to this valuable discussion.



1999 SCDM Spring Forum

Evaluation Survey Results

Number of
Responses = 39
(unless noted
otherwise)

	EXCELLENT	GOOD	FAIR	POOR	NO RESPONSE
SESSION I: Recruiting					
Facilitator	20%	72%	3%	0%	5%
Session Content	28%	61%	5%	0%	5%
SESSION II: CDM Roles, Responsibilities and Relationships					
Facilitator	49%	41%	0%	0%	10%
Session Content	44%	41%	7.5%	0%	7.5%
SESSION III: Training					
Facilitator	69%	21%	0%	0%	10%
Session Content	51%	33%	5%	0%	11%
SESSION IV: Employee Recognition and Retention					
Facilitator	54%	26%	15%	0%	5%
Session Content	51%	33%	10%	0%	6%
WORKSHOP: Employee Development: How Can the Manager Help?					
<i>Speaker:</i>					
Was well prepared	92%	3%	0%	0%	5%
Was knowledgeable of subject matter	90%	5%	0%	0%	5%
Helped me relate concepts to my job	90%	5%	0%	0%	5%
<i>Content of Program:</i>					
74%	Helped me learn new skills				
87%	Helped me strengthen existing skills				
87%	Was of value to me				
82%	Will help me improve my performance on the job				
SESSION WRAP-UP LUNCHEON (16 RESPONSES)					
Session Content	56%	31%	13%	0%	0%
Panel of Facilitators	63%	31%	6%	0%	0%
SAN DIEGO HARBOR DINNER CRUISE (24 RESPONSES)					
Networking Opportunity	42%	54%	4%	0%	0%
Food	21%	42%	33%	4%	0%
Service	54%	42%	4%	0%	0%
LOEWS CORONADO BAY RESORT					
Accommodations	54%	15%	0%	0%	31%
Food	28%	38%	3%	0%	31%
Service	46%	26%	3%	0%	25%
OVERALL EVALUATION OF SPRING FORUM					
Promotional Materials	46%	31%	0%	0%	23%
Meeting Organization	54%	26%	0%	0%	20%
Meeting Materials	33%	44%	0%	0%	23%
Meeting Execution	49%	25%	0%	0%	25%

Additional Feedback on the **1999 SCDM Spring Forum**

FUTURE TOPICS OF INTEREST

The following ideas/suggestions on topics the participants would like to see addressed at a future SCDM Forum or Conference were collected via the Forum Evaluation Survey completed by the participants.

- It would be great if you had a yearly forum like this focused on management issues.
- Revisit training in CDM and how it has evolved.
- More about leadership development/employee development.
- Budgeting, the units to basic budgeting and how to track.
- Management of CROs.
- Workshops such as how to be a good trainer and how to conduct a quality interview.
- How to keep your staff challenged.
- The discipline needs to establish best practices. General open discussion is okay at these forums, but we need to gravitate to what works, what doesn't and what is truly value added in the CDM discipline.

Please provide additional topics of interest to any of the following Board of Trustee officers. Also indicate whether you would be interested in volunteering for future SCDM activities.

Ken Buchholz, *Chair*
(e-mail: drken@earthlink.net)

Pat Teden, *Vice Chair*
(e-mail: pteden@itsnpt.com)

Frannie Rink, *Secretary*
(e-mail: rinkf@labs.wyeth.com)

Spring Forum 2000

The next Spring Forum will be held on March 19 – 21, 2000 at the Isle of Palms, SC.

The proposed overall theme is “quality” covering key topics such as

How do you build quality into the process from the management perspective?

How do you balance quality vs. timelines?

Setting DM standards — what do we standardize, why and how?

How does one lead an organization towards quality?

What are the elements of a quality system (e.g. SOPs, guidelines, standards, QC, QA, etc.)?

How do we enable quality when working across multiple sites?

How do we harmonize across sites (both US and international)?

Some individuals interested in participating have already been identified from the 1999 Spring Forum Evaluation Survey Results. Additional volunteers are encouraged to contact Kristin O'Connor, *Program Chair* (e-mail: ko'connor@bi-pharm.com; phone: 203-798-4244).

Membership Survey: The Results are In!

As you may recall, the Membership Committee sent a survey questionnaire last summer to all current and past SCDM members. As SCDM is entering a very exciting growth phase and launching new initiatives, we wanted to understand better the needs and concerns of our members. We were encouraged by your positive responses to the existing SCDM programs and are already working to incorporate your suggestions into our new programs. We would like to thank those of you who took the time to complete and return your questionnaires and share with you what we learned from your responses.

DEMOGRAPHICS

Seventy-seven (77) people completed and returned the survey. The majority of survey respondents (75%) were from the bio-pharmaceutical, device, or manufacturing industries; the remaining (25%) worked for CROs.

While over half of the respondents (60%) worked for large companies (> 1,000 employees), a significant proportion (26%) were employed by small and mid-sized companies with less than 300 employees.

We saw a good distribution in the size of the CDM departments represented: >100 employees: 43%, 51-100 employees: 15%, 10-50 employees: 25%, and <10 employees: 18%.

Finally, 61% of the respondents were individual contributors, while 39% held management positions.

HOW IS SCDM DOING?

Generally, respondents indicated in their comments that they were happy to have found in SCDM a professional organization "solely devoted to Data Management" and working on "raising the level of awareness in the clinical community about the DM function".

The Fall conference and the Spring Forum were cited by more than half of the respondents (59%) as the programs they valued most, followed by *Data Basics* (20%), and the courses (8%).

Suggestions for improvements included primarily requests for increased logistical organization, e.g. to get the conference material out earlier, notify speakers that their abstract was accepted, or do more mass mailings. Your points are well taken and we're working on this together with PMA, our administrative organization.

ISSUES OF INTEREST/NEEDS

Training clearly emerged as a significant issue for the respondents. Sixty-three percent (63%) indicated that they were not or only somewhat satisfied with their current training services. Among the issues that Data Managers struggle with, training was the single most frequently cited (54%), well ahead of timelines (19%) and regulations (15%). Education-related services (i.e. courses, certification programs, audio and video-conferences, etc.) were also the most frequently requested (51%) as new services for SCDM to offer.

An overwhelming majority (93%) of the respondents felt that a certification program in CDM would be definitely or possibly valuable. We are happy to report that this is a priority initiative for the Board of Trustees and a new committee will be created shortly to work on a professional certification program.

The survey also revealed significant interest in the creation of an SCDM web site (16% of the suggestions) — watch for it later this year!

If you have any comments related to the results of this survey or would like a copy of the detailed survey results, please contact Catherine Celingant at ccelinga@genetics.com.

THE SCDM MEMBERSHIP COMMITTEE

Catherine Celingant, Genetics Institute, Inc. (Chair)

Pam Adkins, Clinical Trials Support Services

Bonnie Featherstone, Winnertech Corp.

Sharon Marmaros, Boehringer Ingelheim

Carol Nelson, Merck & Company, Inc.

Marianne Plaunt, STATPROBE, Inc.

Lynn Searles, Pharmacia & Upjohn, Inc.

Pat Teden, Independent
(liaison to Board
of Trustees)

SCDM

*"Standards of
Good CDM Practices"*
Committee

UPDATE

The following are members of this committee:

Debra Corak
Pharmacia & Upjohn, Inc.

Wendy Cuthbert
MDS Labs

Jennifer Manski
Abbott Laboratories

Merideth Nahm
Duke Clinical Research Institute

Susan Bornstein
MTRA, Inc.
(liaison to Board of Trustees)

Committee objectives are to monitor and report on current guidelines related to good CDM practices and to develop and publish GCDMP guidelines. If you would like to participate in this exciting and valuable committee and help achieve these goals, please contact Susan Bornstein (e-mail: sbornste@mtra.com; phone: 508-903-1153).



MARK YOUR CALENDARS FOR:

1999 SCDM FIFTH ANNUAL FALL CONFERENCE

Optimizing Clinical Data Management Through People, Processes and Standards

September 26-29, 1999

The Fairmont Hotel, Chicago, Illinois

Sessions are planned in the following areas:

- The Diversity of Roles in Clinical Data Management
- The Organizational Impact of New Technologies and Processes
- Clinical Data Management in the Product Development Teams: Challenges and Opportunities
- Effectively Partnering with CROs
- Clinical Data Management Quality Control Processes: Design, Maintenance, and Evaluation
- Standards Management in Clinical Data Management
- Experiences with Implementing MedDRA and other New Standards
- Developing a Global Database: People, Process and Standards

Conference will include a keynote speaker, panel discussions, vendor exhibits and excellent networking opportunities.

Keep an eye on your in-box for conference registration materials.

SCDM *Salary Survey*

SCDM conducted a salary survey during the 1999 Spring Forum. The results were found to be inconclusive and possibly misinterpretable due to some problems with the survey, e.g. insufficient responses, definitions of tasks by job title/position not considered.

At the next Board meeting, the SCDM Trustees will consider an alternative way to define jobs/responsibilities of CDM and what fair compensation is with the objective of distributing the resulting information to the SCDM membership as quickly as possible.

Looking forward to seeing you there!!



SOCIETY FOR CLINICAL DATA MANAGEMENT, INC.

DATA BASICS

Call for Articles

The search continues...!



Please submit any articles, ideas, etc. for publication to the Editorial Board.

EDITORIAL BOARD

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Frannie Rink, Co-editor

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E-mail: rinkf@labs.wyeth.com

Do you like to write?...edit? If so, we could use your help. We are looking for volunteers to join us as Editorial Board members to support the newsletter — *Data Basics*. Attention to detail and timelines is critical. Editorial experience would be helpful, but not necessary. Opportunities include:

- Reviewing and editing submitted materials, e.g. articles, etc.
- Assisting with new venues like advertising, future improvements/directions
- Identifying and implementing new opportunities for articles, materials to publish

Please let us know of any interest in joining the Editorial Board.

PUBLICATION SCHEDULE

Our quarterly publication schedule for 1999 requires the following input deadlines:

Issue #3 (Fall) July 30, 1999

Issue #4 (Winter) October 26, 1999

PUBLICATION POLICY

We welcome submission of previously unpublished materials for publication in *Data Basics*. Materials should preferably be submitted in electronic form (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.

Web Sites to Check Out

FDA guidance

<http://www.fda.gov/cder/guidance>

ICH guidance

<http://www.ifpma.org/ich1.html>

Please let the Editorial Board know about any other “hot” web sites that you feel would be of interest to the SCDM membership.

EVI SUGGESTED CLINICAL DATA MANAGEMENT READING LIST

*Read any good CDM articles
or books lately?*

You may want to check out
*Clinical Trials Dictionary:
Terminology and Usage Recommendations*
authored by Curtis L. Meinert and
published in 1996.

Please submit suggested reading to
the Editorial Board.



Professional Management Associates (PMA) provides professional management support to the SCDM organization in the following areas: administrative tasks, communications, financial, mailings, meeting arrangements (including registration), membership database, newsletter, printing and tracking.

Please contact SCDM @ PMA if you have questions about registration for upcoming meetings or if you need to provide updated mailing/contact information.

PMA has recently moved into new office space. Their *new* address is given below.

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c/o Professional Management Associates, LLC
203 Towne Centre Drive
Hillsborough, NJ 08876
Phone: 908-359-0623
Fax: 908-359-7619
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