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DATA BASICS

Volume 6
Number 3
Fall 2000

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

From the Editors

Fall is here! This is Lana's last issue as co-editor. She has brought this newsletter to a high quality publication that SCDM can be proud of. Special thanks to her for her dedication and effort. On a personal note, I would like to thank her for bringing me so graciously "into the fold". **Tam Blackstone** of MTRA/AAI will be joining me as new co-editor starting on the next issue.

This issue brings a re-print of an article that first appeared in the ACDM (our sister organization) newsletter of results from an SCDM/ACDM data collection survey. Preliminary results were first reported at the SCDM Fall Conference in 1997. The final analysis and results will be of interest to many. You will also find continuing articles: Part 2 in the series *"Other Data Management Organizations"* focuses on the Nordic Clinical Data Management (NCDM) society; and Part 3 in the series of articles on SCDM's continuing efforts by the Certification Committee highlights their work on drafting the core capabilities and competencies.

Don't miss the call for agenda items for our Annual SCDM Business Meeting to be held at the Fall Conference in October and the announcement that SCDM will soon have an on-line membership directory for use by its membership. There is also information pertaining to the 2001 Spring Forum.

We are looking forward to seeing you all at the Fall Conference in Arlington, Virginia! **Ken Carlson** and **Jean Mazalewski** have planned another exciting conference complete with entertainment!

Regards,
Cathie and Lana

Results of the SCDM/ACDM Clinical Data Collection Survey

John Shelton, Joann Masi, Robert Northington and Frances Rink*
Wyeth-Ayerst Research

INTRODUCTION

During early 1997, it was felt within Wyeth-Ayerst Research (W-AR) that more data were often being collected in clinical trials than was required by regulatory authorities, or even by the protocols themselves.

The justification that additional data was nice-to-have, or had been helpful in a previous trial situation, or might possibly be useful, was tenuous and the cost-benefit ratio likely to be unfavorable. Since all data collected on a case report form was usually entered, edited and reported regardless of its value with respect to any claims within a regulatory dossier, there was a significant resource impact across CR&D. Accordingly, a task force was charged with reducing the volume of data collection.

One approach to this problem was the idea of an industry survey to try to establish industry norms for the amount of data of particular types that was being routinely collected and processed in trials. A survey questionnaire was therefore designed and the concept was approved and supported by both the Boards of the US SCDM and the ACDM Committee in early 1997. The questionnaire was distributed to SCDM members in Q2/97 and to the ACDM membership in September 1997. A separate letter was also sent to group heads within the ACDM membership to give them the option of providing a single company response rather than multiple, potentially differing, responses from different individuals within the same company.

Since the data processing and analysis was to be undertaken by W-AR in the US rather than by an independent body, the ACDM Committee required that

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Calendar of Events

The State of Clinical Data Management as the Millennium Unfolds
October 15-18, 2000
Fall Conference
Crystal Gateway Marriott
Arlington, Virginia

March 18-20, 2001
Spring Forum
The Tremont House Hotel
Galveston, Texas

September 23-26, 2001
Fall Conference
The Westin Seattle
Seattle, Washington

March 10-12, 2002
Spring Forum
Radisson Bahia Mar Beach Resort
Fort Lauderdale, Florida

October 6-9, 2002
Fall Conference
Grand Hyatt Buckhead
Atlanta, Georgia

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

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

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

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

Results of the SCDM/ACDM Clinical Data Collection Survey

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the identities of the survey respondents should not be revealed to W-AR. The time taken to set up a process for maintaining respondent confidentiality meant that the ACDM questionnaires were distributed rather later than for the SCDM.

The US part of the survey moved quickly and an overview of the results was presented by Joann Masi at the SCDM Fall Conference in Arlington, Virginia from October 12-15, 1997. Progress then slowed down due to a global reorganization within W-AR and significant process re-engineering. The full analysis of the SCDM and ACDM data, separately and combined, was eventually completed in September 1998 and the summary tables were submitted to the ACDM Committee at that time. We apologize for the significant further delay to the appearance of this article but hope that the results will still be of value.

**Address for correspondence : Wyeth Research (UK) Ltd., Huntercombe Lane South, Taplow, Nr Maidenhead, Berkshire, UK, SL6 0PH*

RESULTS

The results are presented to match the questionnaire as far as possible and in question number order. No formal statistical analysis has been applied. The questionnaire included open-ended parts to question numbers 1, 4, 5, 6, 7, 9 and 10. No attempt has been made to summarize the large number of textual responses, but they have been tabulated and are available on request to the authors.

A total of 130 responses were received, 96 in the US and 34 in Europe. Because the SCDM survey was not blinded it was possible to categorize the US respondents according to the type of organization. The results follow.

Respondent Category :		
Pharmaceutical	**56**	**(61%)**
CRO	**15**	**(16%)**
Biotechnology	**12**	**(13%)**
Medical Products/Devices	**9**	**(10%)**
Anonymous	**4**	
Total	**96**	**(100%)**

No such analysis was possible for the ACDM survey as the responses were blinded prior to analysis. *In the SCDM survey the number of completed questionnaires ranged from one to three for nearly all the organizations that responded. Only three organizations returned more than three questionnaires with a maximum of six. Such an investigation for the ACDM was pre-empted by the blinding of the respondents. However, due to the extra emphasis by the ACDM on the option of a company response, the average number of respondents per company is also likely to be low in the ACDM survey. Thus no single organization dominated the results in either survey.*

Q.1 Does your Company attempt to control the amount of clinical data collected?

Table 1	US	EU	US+EU
Yes	81 (87%)	32 (97%)	113 (90%)
No	12 (13%)	1 (3%)	13 (10%)
Not stated	3	1	4
If YES, at what level?*			
Clinical Research Management	37 (46%)	21 (66%)	58 (51%)
Therapeutic Area	23 (28%)	15 (47%)	38 (34%)
Drug Project	25 (31%)	16 (50%)	41 (36%)
Protocol/Study	69 (85%)	26 (81%)	95 (84%)

*Answers not mutually exclusive. Percentages based on the number answering 'Yes'.

Overall around 90% of respondents attempted to control the amount of data collected, with the percentage being higher in EU than in the US. The most frequent level at which this control was exercised (75%) was at the protocol or study level and this was fairly consistent between the US and EU. However control at CR&D management, therapeutic area and drug project level occurred more frequently in the EU than in the US.

Q.2 What is your organization's standard approach in collecting and handling the following data?

A few respondents gave more than one answer to this question indicating the absence of a standard approach within their organizations.

TABLE 2A

Phase 1	Region	Not Recorded	Recorded, Not Brought in	Brought in, Not Entered	Entered, Not Validated	Entered and Validated	Not Stated	Total
Washout	US	20	7	2	1	33	33	96
	EU	10	0	0	0	10	14	34
	US+EU	30	7	2	1	43	47	130
Screening	US	1	9	3	3	53	28	97 *
	EU	2	3	0	0	16	13	34
	US+EU	3	12	3	3	69	41	131 *
Medical History	US	0	0	0	2	66	28	96
	EU	0	0	1	0	20	13	34
	US+EU	0	0	1	2	86	41	130
Prior Treatment	US	9	2	0	3	52	30	96
	EU	4	0	0	0	17	13	34
	US+EU	13	2	0	3	69	43	130
Inclusion/Exclusion Criteria Check List	US	2	5	6	2	53	28	96
	EU	0	2	4	0	15	13	34
	US+EU	2	7	10	2	68	41	130
Concomitant Medication - Name	US	1	0	0	3	64	28	96
	EU	1	0	0	0	20	13	34
	US+EU	2	0	0	3	84	41	130
Concomitant Medication - Total Daily Dose	US	13	1	1	5	46	30	96
	EU	8	0	0	0	12	14	34
	US+EU	21	1	1	5	58	44	130
Concomitant Medication - Dose and Frequency	US	12	1	1	5	46	31	96
	EU	6	0	0	0	15	13	34
	US+EU	18	1	1	5	61	44	130
Concomitant Medication - Route	US	8	1	2	5	50	30	96
	EU	6	0	0	1	14	13	34
	US+EU	14	1	2	6	64	43	130
Concomitant Medication - Reason for Use	US	7	0	1	4	55	29	96
	EU	2	0	0	0	18	14	34
	US+EU	9	0	1	4	73	43	130
Study Medication Compliance	US	4	2	3	1	55	32	97 *
	EU	2	0	1	1	17	13	34
	US+EU	6	2	4	2	72	45	131 *
Physical Examination	US	4	0	1	2	60	29	96
	EU	2	0	0	0	18	14	34
	US+EU	6	0	1	2	78	43	130
Textual Comments	US	5	0	8	18	39	28	98 *
	EU	1	0	0	5	15	13	34
	US+EU	6	0	8	23	54	41	132 *
Quality of Life	US	23	1	1	8	31	34	98 *
	EU	6	0	1	2	11	14	34
	US+EU	29	1	2	10	42	48	132 *
Economic Endpoints	US	31	2	0	6	20	37	96
	EU	10	0	0	0	8	16	34
	US+EU	41	2	0	6	28	53	130
Post Study	US	14	1	3	3	44	32	97 *
	EU	4	0	2	0	13	15	34
	US+EU	18	1	5	3	57	47	131 *

* Answers not mutually exclusive

TABLE 2B

Phases 2-3	Region	Not Recorded	Recorded, Not Brought in	Brought in, Not Entered	Entered, Not Validated	Entered and Validated	Not Stated	Total
Washout	US	24	7	1	1	46	17	96
	EU	6	0	0	0	21	7	34
	US+EU	30	7	1	1	67	24	130
Screening	US	2	6	9	5	70	6	98*
	EU	2	1	1	0	28	2	34
	US+EU	4	7	10	5	98	8	132*
Medical History	US	1	0	0	5	85	5	96
	EU	2	0	1	2	27	2	34
	US+EU	3	0	1	7	112	7	130
Prior Treatment	US	9	1	0	5	74	8	97*
	EU	2	0	0	1	29	2	34
	US+EU	11	1	0	6	103	10	131*
Inclusion/Exclusion Criteria Check List	US	3	8	9	1	70	5	96
	EU	0	3	5	0	24	2	34
	US+EU	3	11	14	1	94	7	130
Concomitant Medication - Name	US	0	0	0	6	85	5	96
	EU	0	0	0	2	30	2	34
	US+EU	0	0	0	8	115	7	130
Concomitant Medication - Total Daily Dose	US	24	1	0	9	55	9	98*
	EU	11	0	0	0	20	3	34
	US+EU	35	1	0	9	75	12	132*
Concomitant Medication - Dose and Frequency	US	24	1	2	8	53	10	98*
	EU	9	0	0	1	22	2	34
	US+EU	33	1	2	9	75	12	132*
Concomitant Medication - Route	US	20	1	1	8	59	8	97*
	EU	7	0	0	1	24	2	34
	US+EU	27	1	1	9	83	10	131*
Concomitant Medication - Reason for Use	US	12	0	0	6	71	8	97*
	EU	2	0	0	2	27	3	34
	US+EU	14	0	0	8	98	11	131*
Study Medication Compliance	US	5	3	2	3	75	10	98*
	EU	3	0	1	1	27	2	34
	US+EU	8	3	3	4	102	12	132*
Physical Examination	US	5	1	2	6	77	5	96
	EU	5	0	0	2	25	2	34
	US+EU	10	1	2	8	102	7	130
Textual Comments	US	5	1	13	22	52	5	98*
	EU	0	0	6	7	19	2	34
	US+EU	5	1	19	29	71	7	132*
Quality of Life	US	11	0	2	23	54	8	98*
	EU	3	0	1	8	21	2	35*
	US+EU	14	0	3	31	75	10	133*
Economic Endpoints	US	27	2	1	13	37	16	96
	EU	7	0	0	5	18	4	34
	US+EU	34	2	1	18	55	20	130
Post Study	US	14	2	3	4	61	13	97*
	EU	7	0	2	0	23	2	34
	US+EU	21	2	5	4	84	15	131*

* Answers not mutually exclusive

Results of the SCDM/ACDM Clinical Data Collection Survey *continued*

In Phase 1, as expected, several data types were frequently not recorded, e.g. washout, prior treatment, concomitant medication dose, route and frequency, quality-of-life, economic endpoints and post-study data. Data on washout, screening and inclusion/exclusion criteria checklist were sometimes recorded but not brought in-house. Inclusion/exclusion criteria checklist data and textual comments were sometimes brought in-house but not entered to the database. Textual comments and sometimes quality-of-life data were entered but not validated.

The results for Phases 2 and 3 were similar to Phase 1. Additional observations in Phases 2 and 3 were that sometime, screening data was brought in-house but not entered and economic endpoints were entered but not validated.

Q.3 Do you collect data electronically?

Almost 80% of respondents collected data electronically and this was consistent between the US and the EU. However in the EU, notably more respondents retrieved the hard copy than in the US. Where the hard copy was retrieved, 74% reconciled the hard copy with the electronic data and this was consistent between the two continents.

Q.4 Do you use hard copy diary cards in data collection?

Overall 74% of respondents used hard copy diary card in data collections but the proportion was notably higher in the EU than in the US. Where hard copy diary cards were utilized, the rate of transcription of summary data onto CRFs was consistent at 34%. However, the rate of data entry direct from diary cards was notably higher in the EU, while the rate of transcription of raw data to CRFs was higher in the US.

Q.5 Do you collect start/stop dates of Concomitant Medication?

Around 74% of respondents always collected start and stop dates of Concomitant Medication and this was fairly consistent between the US and the EU. The use of visit-specific format and running forms was consistent between the two continents, but running forms were notably more popular.

Q.6 Do you collect the same level of detail for ALL Concomitant Medications?

Overall 69% collected the same level of detail for all medications. The rate was slightly higher in the EU than in the US, which was consistent with a notably higher proportion in the US who did not collect some classes of medication.

Q.3 Do you collect data electronically?

Table 3	US	EU	US+EU
Yes	76 (80%)	26 (76%)	102 (79%)
No	19 (20%)	8 (24%)	27 (21%)
Not stated	1	0	1
If YES, do you also retrieve the hard copy of these data?*			
Yes	52 (70%)	20 (91%)	72 (75%)
No	22 (30%)	2 (9%)	24 (25%)
Not stated	2	4	6
If YES, do you reconcile the hard copy data with the electronic data?*			
Yes	36 (73%)	15 (75%)	51 (74%)
No	13 (27%)	5 (25%)	18 (26%)
Not stated	3	0	3

*Percentages based on the number providing a response among those answering 'Yes' in the previous part of the question.

Q.4 Do you use hard copy diary cards in data collection?

Table 4	US	EU	US+EU
Yes	64 (70%)	29 (85%)	93 (74%)
No	27 (30%)	5 (15%)	32 (26%)
Not stated	5	0	5
If YES, how are these data entered?*			
Directly from original diary card	35 (55%)	22 (76%)	57 (61%)
Transcription of raw data to CRFs	26 (41%)	8 (28%)	34 (37%)
Transcription of summary data to CRFs	22 (34%)	10 (34%)	32 (34%)
Other	6 (9%)	3 (10%)	9 (10%)

*Answers not mutually exclusive. Percentages based on the number answering 'Yes'.

Q.5 Do you collect start/stop dates of Concomitant Medication?

Table 5	US	EU	US+EU
Always	69 (72%)	27 (79%)	96 (74%)
Sometimes	26 (27%)	7 (21%)	33 (25%)
Never	1 (1%)	0 (0%)	1 (1%)
If you collect start/stop dates, please indicate the CRF format used.*			
Visit- specific format	48 (51%)	18 (53%)	66 (51%)
Continuous format ('running records')	80 (84%)	29 (85%)	109 (84%)

*Answers not mutually exclusive. Percentages based on the number answering 'Always' or 'Sometimes'.

Q.6 Do you collect the same level of detail for ALL Concomitant Medications?

Table 6	US	EU	US+EU
Yes	64 (67%)	25 (74%)	89 (69%)
No	31 (33%)	9 (26%)	40 (31%)
Not stated	1	0	1
Are there classes of Concomitant Medication that are not collected? (e.g. OTCs, vitamin supplements)			
No	72 (76%)	32 (94%)	104 (81%)
Yes	23 (24%)	2 (6%)	25 (19%)
Not stated	1	0	1

Q.7 Do you collect start/stop dates of Concomitant Non-Pharmacologic Treatment?

Start and stop dates of non-pharmacologic treatments were inconsistently collected on both continents. While 32% overall always collected them, 27% never collected them. As with concomitant medications, the running form format was more popular than visit-specific, particularly in the US.

Q.8 How many parameters are included in your laboratory safety data standard panels?

On average the number of laboratory parameters collected was consistent between Phases of study on both continents. However the US respondents collected 9 more parameters on average then the EU across the three categories.

Q.9 Do you collect start/stop dates of Adverse Events?

Start and stop dates of adverse events were almost always collected. Again the running form format was notably more popular than visit-specific, particularly in the EU.

Q.10 Do you collect patient compliance data?

More than 90% of respondents overall collected patient compliance data and the rates were similar in the US and the EU, though it was recorded in various ways. Percentage compliance was the most popular particularly in the US, though recording as periods of non-compliance and in other ways were also frequently used.

Has your e-mail address changed recently?

SCDM is utilizing e-mail to disseminate information of interest to the membership.

Don't miss out! Be sure SCDM@PMA (e-mail: info@scdm.org) has a current e-mail address where you prefer to receive SCDM information.

Q.7 Do you collect start/stop dates of Concomitant Non-Pharmacologic Treatment?

Table 7	US	EU	US+EU
Always	29 (32%)	10 (30%)	39 (32%)
Sometimes	39 (43%)	12 (36%)	51 (41%)
Never	22 (24%)	11 (33%)	33 (27%)
Not stated	6	1	7
If you collect start/stop dates, please indicate the CRF format used.*			
Visit-specific format	32 (47%)	14 (64%)	46 (51%)
Continuous format ('running records')	48 (71%)	17 (77%)	65 (72%)

*Answers not mutually exclusive. Percentages based on the number answering 'Always' or 'Sometimes'.

Q.8 How many parameters are included in your laboratory safety data standard panels?

Table 8		US Mean	EU Mean	US+EU Mean
Hematology	: Phase 1	12	9	11
	: Phases 2-3	11	9	11
Biochemistry	: Phase 1	17	13	16
	: Phases 2-3	16	12	15
Urinalysis	: Phase 1	8	6	7
	: Phases 2-3	8	5	8
n	: Phase 1	43	17	60
	: Phases 2-3	56	26	82

Q.9 Do you collect start/stop dates of Adverse Events?

Table 9	US	EU	US+EU
Always	91 (95%)	33 (97%)	124 (95%)
Sometimes	5 (5%)	0 (0%)	5 (4%)
Never	0 (0%)	1 (3%)	1 (1%)
If you collect start/stop dates, please indicate the CRF format used.*			
Visit-specific format	51 (53%)	16 (48%)	67 (52%)
Continuous format ('running records')	75 (78%)	29 (88%)	104 (81%)

*Answers not mutually exclusive. Percentages based on the number answering 'Always' or 'Sometimes'.

Q.10 Do you collect patient compliance data?

Table 10	US	EU	US+EU
Yes	84 (89%)	32 (94%)	116 (91%)
No	10 (11%)	2 (6%)	12 (9%)
Not stated	2	0	2
If yes, how is it recorded?*			
As a percentage (consumed/prescribed)	39 (46%)	15 (47%)	54 (47%)
As periods of non-compliance	33 (39%)	15 (47%)	48 (41%)
Other	28 (33%)	13 (41%)	41 (35%)
If yes, how is it collected?*			
CRF	74 (88%)	30 (94%)	104 (90%)
Diary Card	32 (38%)	17 (53%)	49 (42%)
Study Drug Dispensing/Returns Record	44 (52%)	19 (59%)	63 (54%)
Physical accounting of drug supplies	34 (40%)	17 (53%)	51 (44%)
Other	2 (2%)	4 (13%)	6 (5%)

*Answers not mutually exclusive. Percentages based on the number answering 'Yes' in the first part of the question.

Q.11 Do you collect Health Outcomes Assessment (HOA) data?

Overall, 80% of respondents collected health outcomes data and the rate was rather higher in the EU than in the US. When collected it was recorded in a different database 13% of the time. Overall 55% of respondents reconciled health outcomes data with clinical data, but mostly only for selected data. The rate and extent of reconciliation were greater in the EU than in the US.

Q.11 Do you collect Health Outcomes Assessment (HOA) data?

Table 11	US	EU	US+EU
Yes	73 (78%)	30 (88%)	103 (80%)
No	21 (22%)	4 (12%)	25 (20%)
Not stated	2	0	2
If yes, is it stored in the same database as efficacy and safety?*			
Yes	64 (88%)	26 (87%)	90 (87%)
No	9 (12%)	4 (13%)	13 (13%)
Do you reconcile HOA data with clinical data?*			
Yes	39 (53%)	19 (63%)	58 (55%)
No	34 (47%)	11 (37%)	45 (45%)
If yes, to what extent is this done?**			
All data	7 (18%)	9 (47%)	16 (28%)
Selected data	32 (82%)	10 (53%)	42 (72%)

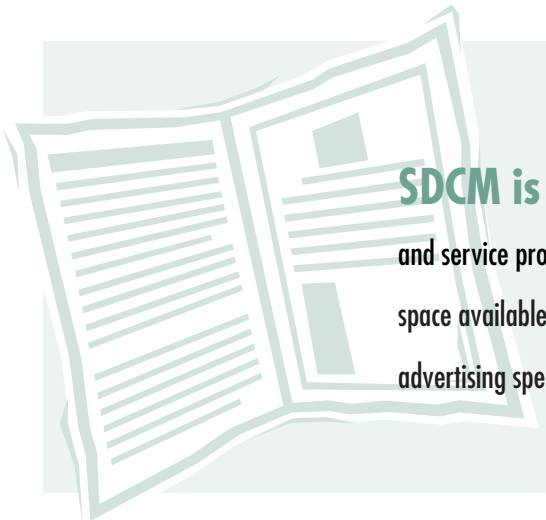
*Percentages based on the number answering 'Yes' in the first part of the question.
**Percentages based on the number answering 'Yes' in the third part of the question.

SUMMARY

- Around 90% of companies attempt to control the amount of data collected during clinical trials in the pharmaceutical industry and this is done in a variety of ways.
- The data most frequently not collected related to washout periods, prior treatment, the dose, route and frequency of concomitant medication, post-study data, quality-of-life and economic data although the latter two categories are probably being collected more frequently as health outcomes data takes on increasing significance.
- In general any data that is collected is entered into the database and validated, the notable exceptions being inclusion/exclusion criteria check list and textual comments.
- There is considerable variation in terms of how electronic data is handled and the extent of reconciliation with hard copies.
- There was considerable variation in the way hard copy diary card data were handled.
- Both 'running' and visit-specific forms were used regularly for collecting concomitant medications, non-pharmacological treatment and adverse events, but the running format was significantly more popular.
- ACDM respondents tended to collect nine fewer parameters in their laboratory data panels (biochemistry, hematology and urinalysis) than the SCDM respondents.
- A variety of methods are being used to collect data on patient compliance with test medication dosing schedules.
- Health outcomes data is frequently collected and stored on the same database as efficacy and safety data but there is considerable variation in the extent of reconciliation.

CONCLUSION

This survey has identified the frequency with which different types of data are collected, and the frequencies of different approaches to collection and processing. There is no clear regulatory advantage in any one approach. The choice is likely to depend primarily on company philosophy even though cost-benefit analysis would be a more rational approach to controlling data collection in clinical research and enhancing CDM productivity. The varying approaches identified in this survey imply varying underlying costs and hopefully provide some pointers to where companies can reduce their data collection and processing costs with marginal impact on database quality and the likelihood of regulatory success.



SDCM is pleased to announce that it will start accepting advertising (job ads and service provider ads) in the next issue of *Data Basics*. There will be quarter page to full page ad space available in either black and white or the *Data Basics* green. We have included the current advertising specifications under the Advertising Policy in this issue so you can plan your submission.

Other Data Management Organizations:

Nordic Clinical Data Management

In the second of a series of articles on international data management organizations, the third largest data management group is featured. Founded in 1994, the **Nordic Clinical Data Management** (**NCDM**) society has approximately 200 members from 20 companies in Sweden, Norway, Denmark and Finland, representing pharmaceutical, biotechnology and device companies, as well as CROs and academia.

Its objectives are:

1. to contribute to improved use of Data Management methods within medical areas
2. to provide a forum for discussions on aspects regarding applications mainly within the pharmaceutical industry
3. to enhance the exchange of professional experience between members

Its main event is the annual conference, held in conjunction with its annual meeting. The focus this year was on Data Quality in Clinical Trials. One of the speakers was Steve Wilson from the FDA, a strong supporter of the SCDM. Abstracts of the presentations are available on the NCDM's web site although you will need to find a translator for some of them!

Another key activity is training. Training courses are held regularly, often in conjunction with other organizations such as the ACDM and the Swedish Pharmaceutical Society. Again details can be found on the web site.

So if you need to find out more about doing clinical trials in the Nordic countries or just want to add to your sources of information on clinical data management, visit the NCDM at **www.ncdm.st.**

DATA BASICS

Call for Articles and Advertising

The search continues…!

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

(Articles and Advertising Art Work)

Our quarterly publication schedule for the next 3 issues requires the following input deadlines:

Volume 6, Issue #4 (Winter) October 26, 2000

Volume 7, Issue #1 (Spring) February 1, 2001

Volume 7, Issue #2 (Summer) April 27, 2001

Each issue is mailed to the membership approximately 6-7 weeks after the corresponding submission deadline.

Publication Policy

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.

Advertising Policy

AD RATES**

Size	Inches	Costs (USD)
Quarter Page	3 5/8 x 4 7/8	$240
Half Page-vertical	3 5/8 x 10	$400
Half Page-horizontal	7 1/2 x 4 7/8	$400
Full Page	7 1/2 x 10	$575

**Ads are net, non-commissionable

MECHANICAL REQUIREMENTS: Black and White scannable camera-ready art (no screens less than 72dpi). Digital art/electronic files may be Black and White or 2-color (PMS 556 and Black) and must be Mac format, supplied on floppy, Zip disk or 1 GB Jaz disk. Accepted software: QuarkXpress, Adobe Illustrator and Adobe Photoshop. Proof must be supplied with disk. All files and fonts must be supplied with disk.

Ads not conforming to size and mechanical requirements will be returned.

PAYMENT: Payment must be received with advertising. Space reservations cannot be made by telephone. There is NO Agency Discount; All ads must be paid in full.

CANCELLATIONS: Cancellations or changes in advertising requests by the advertiser or its agency 5 days or later after the submission deadline will not be accepted.

GENERAL INFORMATION: All ads must be pre-paid. Publisher is not liable for advertisement printed from faulty ad materials. Advertiser agrees to hold SCDM harmless from any and all claims or suits arising out of publication on any of his/her advertising. SCDM assumes no liability, including but not limited to compensatory or consequential damages, for any errors or omissions in connection with any ad. The SCDM does not guarantee placement in specific locations or in a given issue. SCDM reserves the right to refuse or pull ads for space or content.

Please submit all forms, artwork, and payments to:

Society For Clinical Data Management, Inc.
c/o Professional Management Associates, LLC
203 Towne Centre Drive
Hillsborough, NJ 08876
Phone: 908-359-0623
Fax: 908-359-7619
E-mail: info@scdm.org

On-line Membership Directory Approved

At its most recent meeting the Board of Trustees approved the development of an on-line membership directory. The development will commence in the near future, in association with our administrators at the PMA. The goal is to ensure rapid access to the most up-to-date membership information in a way that will allow the user to search the complete database in various ways. Also being considered is the ability for members to update their own information.

If you have any particular features you would like to see included in the on-line directory please contact Douglas Schantz at douglas.schantz@wl.com.

In conjunction with the directory, a 'members only' section will be developed. If you have would like to see other services included in this area again please contact Doug.

SUGGESTED CLINICAL DATA MANAGEMENT READING LIST

Read any good CDM articles or books lately?

Please submit suggested reading to the Editorial Board.

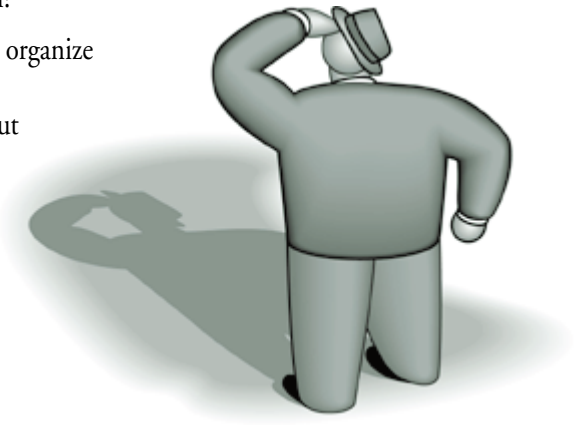
Calling All Clinical Data Managers Responsible for and/or Interested in the Professional Identity of Clinical Data Management

SPRING FORUM 2001

The next Spring Forum will be held on March 18-20, 2001 at The Tremont House Hotel in Galveston, Texas. The overall theme is *"Clinical Data Management as a Profession"*.

Key topics covered will include:

- What does it mean to be a "professional"?
- How will the SCDM-sponsored clinical data management professional certification program be structured?
- How will this program affect the professional lives of SCDM members?
- What is the link between certification and training?
- What challenges lie ahead for our profession?



As with other Spring Forums, the SCDM will organize a special event on Sunday evening. Check out **http://www.galvestonhistory.org** to learn about Galveston and get an idea of the types of events being considered.

Do not miss this! Mark these dates on your calendar and plan to attend. If you are interested in leading one of the discussion groups during the Spring Forum, contact **Pat Teden** at **pteden@itsnpt.com**.

Annual SCDM Business Meeting at Fall Conference — Call for Agenda Items

The Annual General Meeting of SCDM will be held during the 2000 Fall Conference in October. Please submit topics for discussion for the business component of this general meeting to April Pennacchio, PMA (e-mail: april@profmgmt.com).

From Competencies to Professional Certification

Part 3 in a Continuing Series

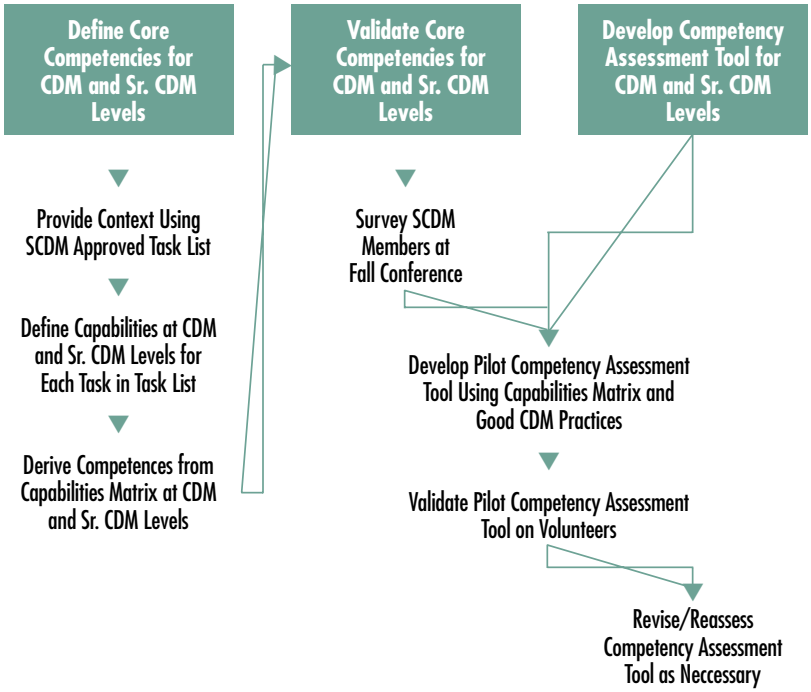
In our last *Data Basics* article, the Certification Committee published the highlights of its work. This included:

- A definition of certification
- The conditions for each of the two levels of certification: CDM and Senior CDM
- The professional eligibility requirements
- The industry need and benefits for certification
- The benefits to CDMs of being certified
- A description of the certification process
- How certified CDMs will be identified by prospective employers
- Contacts with ACDM on a global certification process
- Our committee's project plan

In this article, the Certification Committee is pleased to announce that it has recently completed a draft of core capabilities/competencies for CDMs that is based on the SCDM's published task list and the more recently issued draft Good CDM Practices document.

During this year's SCDM Fall Conference, we plan to collect your comments on the CDM capabilities document. The survey will also be available on the SCDM web site (if you don't get a chance to attend the Fall Conference). ***We NEED your feedback!!!*** This feedback is the first step in the development of a competencies assessment tool that is fair and realistic. Here's a high-level flow chart of the assessment tool development process:

Approach to Developing CDM Competencies Assessment Tool



Look for our booth and the chance to receive a valuable prize for returning the survey at the SCDM Fall Conference.

Watch Data Basics for updates as the Certification Committee's work progresses. *Please contact Armelde Pitre at Armelde_Pitre@Groton.Pfizer.com if you are interested in learning more about this committee.*

GOT A WEBSITE?

Want to support SCDM?

Please feel free to place a link on your web site to www.scdm.org!

Contact Doug Schantz (douglas.schantz@wl.com) if you need more information.

Web Sites to Check Out

ACDM	http://www.acdm.org.uk
CDISC	http://www.cdisc.org
FDA	http://www.fda.gov
ICH	http://www.ich.org

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

SCDM http://www.scdm.org

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

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.

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