



Society for Clinical Data Management CERTIFICATION HANDBOOK



Introduction

Thank you for your interest in the Society for Clinical Data Management's (SCDM) Certified Clinical Data Manager (CCDM[®]) examination and for choosing SCDM as your certifying organization.

About SCDM

The Society for Clinical Data Management (SCDM) is a nonprofit professional society founded to advance the discipline of Clinical Data Management. The binding interest of all members is quality clinical data management practices.

SCDM was founded in 1994 and has grown to be a premier data management organization which embodies upwards of 2,500 domestic and international members who represent the biotechnology, medical device and pharmaceutical industries; as well as members of the academic, regulatory and scientific research communities. Third party organizations that support these groups include: Contract Research Organizations, consultants, hardware and software vendors and placement firms and represent an important portion of the Society's membership.

SCDM Core Values

Knowledge and Experience of our Members

The intellectual capital and collective experience of our members are our greatest assets. SCDM relies on and embraces the participation and contributions of our members and volunteers.

Scholarship

SCDM encourages and promotes rigor and discipline in the research of topics affecting our industry. Our positions, publications and programs are the result of scholarly investigation.

Quality and Continuous Improvement

SCDM is committed to the development and enhancement of products, services and relationships of the highest quality.

Open Communication

SCDM encourages open communication and information sharing. We provide our members with insight to the organization's initiatives and activities.

Integrity

SCDM exemplifies and expects honesty and integrity.

SCDM Certification Philosophy

The Society for Clinical Data Management established the certification program for clinical data managers to institute a standard of knowledge, education and experience by which clinical data managers would be professionally recognized by the medicinal, biological development and medical device therapies community. Through a rigorous application and examination process certified clinical data management professionals are able to demonstrate a high level of competence and expertise in their field.

The SCDM certification program was designed to meet the following goals:

- Establish and promote professional practice standards throughout clinical data management
- Identify qualified professionals within the profession



- Ensure recognition of expertise
- Enhance the credibility and image of the profession

About the CCDM® Exam

The CCDM® exam, revised and released in September 2008, contains 130 multiple choice questions. Candidates are allotted 3.5 hours for this exam.

Application Process

Certification application is available online at <https://www.scdm.org/certification/application/Default.aspx>. An application is also included in the back of this handbook and marked as **Appendix 1**.

Please send all certification applications to your relevant office:

American Office	Global Headquarters	India Office
Society for Clinical Data Management, Inc 7918 Jones Branch Drive Suite 300 McLean VA, 22102 USA Tel: +1-703-651.8188 Fax: +1-703- 506.3266 info-am@scdm.org	Society for Clinical Data Management, Inc 280 Boulevard du Souverain B-1160 Brussels Belgium Tel: +32 2 320 25 29 Fax: +32 2 320 25 29 info@scdm.org	Society for Clinical Data Management, Inc 203, Wing B, Citipoint (Near Hotel Kohinoor Continental) J. B. Nagar, Andheri-Kurla Road Andheri (East). Mumbai – 400059 India Tel: +91 22 61432600 Fax: +91 22 67101187 info-in@scdm.org

What are the Costs?

The cost to sit for the SCDM CCDM® exam is \$250 (US). The Society for Clinical Data Management will accept check, money order or credit card.

***Note: if we are unable to process your application, a portion of the application fee less administrative costs, will be returned to you. However, once your application is accepted, the fee is nonrefundable.*

Certification Application Status

Once your application has been processed, approximately 14 days after it is submitted, you will receive a letter of acceptance, denial, or a request for further information. The letter of acceptance will include an eligibility ID required to schedule your exam. You will have **90** days from the date of your acceptance letter to take your exam. The “90 days” is referred to as your eligibility period. We recommend that you schedule your exam immediately upon receipt of your acceptance letter.



Rejection of Certification Application

Applicants must meet at least one of the eligibility requirements listed on the [Eligibility Requirements Document](#) marked as **Appendix 2**. If an applicant does not meet the requirements, they will be entitled to a full refund.

Proctoring Agency: PSI

PSI has over 70 years of experience providing worldwide testing solutions to corporations, federal and state government agencies, professional associations, certifying bodies and leading academic institutions. PSI offers a comprehensive solutions approach from test development to delivery to results processing, including pre-hire employment selection, managerial assessments, licensing and certification tests, distance learning testing, license management services and professional services.

RPNOW a product of PSI Education (formerly Software Secure)

Take your exam anytime, anywhere.

RPNOW allows students to take their exam anytime, anywhere without the hassle of travel or scheduling an appointment. The platform provides this flexibility by proctoring your exam with a recording of the visual, audio, and desktop aspects of your exam and exam environment. Your exam is then reviewed by our certified proctors and the results are presented to your instructor.

How to prepare?

- Confirm your testing computer has a webcam, microphone, and a high-speed internet connection. System requirements can be found here: <http://clientportal.softwaresecure.com/support/index.php?Knowledgebase/Article/View/252/0/system-requirements-remote-proctor-now>
- Watch the exam taker video and read through the step-by-step guide at www.softwaresecure.com/rpnowuniversity/student
- Take a practice exam (scdm.remoteproctor.com)
- Ensure you are not in a public setting, you have a photo ID, and your exam space is cleared of all unauthorized materials



Where to take your exam?

- Start your exam at scdm.remoteproctor.com

Cancelation/changes

The Exam Cancellation/Change Deadline for any exam that has been scheduled is as follows:

- United States and Canada – two business days notice prior to exam before noon EST
- Outside the US and Canada – five business days notice prior to exam before noon

Cancellations/changes must be made and confirmed by contacting the SCDM HQ office at info@scdm.org.

Candidates will be charged the entire certification exam fee in the event that they negligently exceeded their eligibility period (90days from the approval date). SCDM realizes that there are extreme cases, i.e., sudden illness, death of an immediate family member or an accident on the way to the exam that prohibits you to sit for the exam. Candidate will be expected to present a physician's note, death certificate/obituary, police/accident report, or other valid documentation to reschedule. Candidate will be assessed a fee to reschedule the exam. This fee covers SCDM costs for adjusting eligibility and registration records.

What to expect when you take your exam

Identification and Check-in taking the test

There is ample time (3.5 hours) allocated to take the test. During the exam, you are permitted to take unscheduled breaks, however please note, the clock will not stop. You should plan to bring a snack or beverage with you since these provisions may not be available at all test centers.

Refunds

Once you schedule your test date it will be important that you take the test on your scheduled date. A fee will be assessed if you miss your scheduled test date without following the rescheduling procedures listed on SCDM website.

Preparing for the Exam

SCDM offers a webinar series at least four times per year on topics related to the exam as well as for professional development. SCDM also offers face-to-face workshops twice per year in collaboration with Duke University's Clinical Research Institute. The Annual Conference sessions are also a significant source of information and are archived on our website. Finally, *Good Clinical Data Management Practices* (GCDMP) is a foundational resource that will also help with exam preparation and is available in print form and as podcasts.



The SCDM Education Web Portal (<http://portal.scdm.org>) is an excellent source for additional resources to help candidates prepare to sit for the exam. This portal includes a self-assessment tool to help identify areas needing further study and direct users to helpful resources. These resources will include online short courses, reference materials and the DataMatters listserv to help answer questions and coach candidates as they study for the exam.

After the Exam

Notification of Results

Upon completion of the exam your results will appear on your screen. You will receive a print out of your results at the test site.

If you pass the exam

After completing the examination, candidates will receive, via mail, a CCDM[®] certificate, CCDM[®] pin and test results. Those who successfully complete the examination are asked to fill out a survey which will be incorporated into SCDM publications. Candidates who pass may use the appropriate credential immediately.

If you do not pass the exam

The applicant may retake the exam within one (1) calendar year of the formal notification letter date of your original exam results. After that, a full application must be submitted and the full fee structure applies.

The fee to retake the CCDM[®] exam is \$225 (US).

A [retake exam application](#) is available online and can be found at the back of this handbook, it is marked **Appendix 3**.



CCDM[®] Renewal

SCDM Certified Clinical Data Management professionals (CCDMs) are required to renew their certification every three years from the time of their original certification. By renewing, CCDMs demonstrate their willingness to continue to advance within the field and commitment to continued growth in both knowledge and competency in clinical data management.

The CCDM[®] [renewal application](#) must be submitted along with:

- Renewal or exam fee
- [CEU submission form](#), **Appendix 4** (required for non-SCDM CEU courses only)
- CEU certificates from all educational events (Non-SCDM)

The renewal application can be found at the back of this handbook; it is marked **Appendix 5**.

To renew certification, candidates must acquire a minimum of 1.8 CEUs within 3 years. This time frame begins from the date of certification until the date the CCDM[®] eligibility expires.

Obtaining CEUs through Educational Training and Conferences

SCDM requires that at least 60% of CEUs come from clinical data management (CDM) specific training.

SCDM allows up to 40% of CEUs to come from non-CDM specific training such as Society volunteer activities. SCDM recommends that CEU applicants consider the [CCDM[®] Core Competencies](#) when choosing any non-CDM specific training. For further explanation, view the CEU percentage breakdown [chart](#) (**Appendix 6**)

SCDM **will** accept CEU certificates for training completed within organizations that offer IACET CEUs. CEU certificates must be provided for each training course completed. Certificates for CEUs from public/nonprofit organizations (SoCRA, DIA, ACRP, Universities) as well as private organizations (Barnett, EDC and Beyond, etc), will be considered equally; however, *internal company training is not applicable*.

CEU certificates for training completed by organizations that do NOT offer IACET CEUs *are accepted only* when the applicant has submitted the [Non-IACET CEU Affidavit Form](#) to the SCDM Administrative Office and said provider is approved by SCDM. The affidavit can be found in the back of this handbook, marked **Appendix 7**.



* CEU Certificates **must** include the following:

- *Workshop title*
- *Date of offering*
- *Name of sponsoring organization*
- *Specific number of CEUs issued*
- *Signature and date of representative from sponsoring organization*



Appendix 1

Application for Certified Clinical Data Manager (CCDM®) Examination

Please type or print all information within this application, indicate responses where required, sign in the appropriate spaces, and return with a check, money order or credit card information for a non-refundable application fee of \$250 (US) and required enclosures to:

American Office	Global Headquarters	India Office
Society for Clinical Data Management, Inc 1444 I Street, NW, Suite 700 Washington DC, 20005, USA Tel: +1-202-712.9023 Fax: +1-202- 216.9646 info-am@scdm.org	Society for Clinical Data Management, Inc 280 Boulevard du Souverain B-1160 Brussels, Belgium Tel: +32 2 740 22 37 Fax: +32 2 743 15 50 info@scdm.org	Society for Clinical Data Management, Inc 410, Madhava, Behind Family Court Bandra Kurla Complex, Bandra (East) 400051 Mumbai, India Tel: +91 22 61432600 Fax: +91 22 67101187 Info-in@scdm.org

In the event that your application is rejected, a portion of your application fee, less administrative and handling costs, may be returned to you. Once the application is accepted, no refund will be granted.

Please allow 14 days for processing of your application. Upon confirmation of your qualifications, you will receive an e-mail with identification number and access link to the Exam portal.



**Required field*

Last Name* _____ First Name* _____ MI* _____
(Enter name exactly as it appears on your passport or photo identification ~ PLEASE PRINT OR TYPE)

Current Employer: _____

Title: _____ Department: _____

*Mailing Address: _____

*City _____ State/Province _____ Zip/Postal Code _____

*Daytime Phone: _____ Evening Phone: _____

*Fax: _____ *E-mail: _____

Section 1

Have you taken this examination previously?

- No
- Yes Date _____

EDUCATION

(Please indicate highest degree earned)

- No Degree
- BS or BA
- MS or MA
- PhD
- Other _____

NOTE: Enter degrees obtained in the table below. If you satisfy the maximum experience requirements of four years or more, then the following degree information is not required.



EDUCATION RECORD

Educational Institution Attended	Year Degree Obtained	Degree Obtained



Appendix 1

Section 2

WORK EXPERIENCE

(List any relevant positions held and indicate the CDM tasks performed during the time you held those positions. Reference the CDM task list on the following page.)

NOTE: You must include an updated copy of your resume or CV.

Company Name, Address and Phone	Supervisor's or Manager's Name	Employment Dates	Position Title	CDM Tasks <i>(Please use the list on the following page as a guide)</i>	FTE/PTE

Appendix 1

* Please use the appropriate “task letter from the CDM Task List” when completing the Work Experience section on page 3.

Task Letter	“CDM TASK LIST”
A	Protocol review
B	CRF Design
C	Data Management Plan development (includes database specifications, electronic edit checks, data review guidelines, annotated CRF)
D	CRF tracking and inventory
E	CRF data verification (data entry discrepancy resolution)
F	CRF data validation (i.e. scrubbing , cleaning, query generation, applying data handling conventions)
G	Manual CRF review
H	Query resolution (i.e. correspondence with investigator sites to obtain resolution to queries)
I	Query tracking
J	Communication of data trends
K	Database updates
L	Safety review
M	Coding adverse events/signs and symptoms
N	Coding medications
O	SAE reconciliation
P	Processing local laboratory data (collected via CRF)
Q	Processing (loading/merging) central laboratory data
R	Maintenance of laboratory normal range information
S	Application of randomization schemes to study databases (i.e. breaking the blind)
T	Database lock procedures
U	Database quality control audits
V	Review of final data listings
W	Review of final data tables or graphs
X	Review of final reports
Y	Archiving database and associated documentation
Z	CRO management
AA	Relational Databases – The data management software and data structures which allows the user to store and manipulate data from specific studies including capabilities to import and export specific data from compatible software.
BB	Time Management – Utilizing techniques to effectively organize and use own time for the accomplishment of project and organizational goals.
CC	Project Management – Utilizing techniques to effectively organize and manage multi-disciplinary resources to deliver projects or programs to customer expectations.



Appendix I

Section 3

ELIGIBILITY CERTIFICATION

I have read and understand the information in attached Eligibility Requirements Document. I hereby represent and warrant that I am eligible to apply to take the CCDM® Examination because I meet the eligibility requirements in the following manner (indicate eligibility category and complete blank if applicable.)

- Bachelor's degree or higher plus two or more years full time experience as a CDM
- Associate's degree (two years) plus three or more years full time experience as a CDM
- No degree plus four or more years full time experience as a CDM

AUTHORIZATION

I hereby authorize the Society for Clinical Data Management (SCDM) to make whatever inquiries it deems necessary and appropriate to confirm the accuracy of the contents of my application. I agree to provide any additional authorizations necessary to that process. I hereby authorize SCDM to use the information contained in my application and examination for purposes of statistical analysis, provided that my personal identifying information has first been deleted.

APPLICATION INFORMATION

I hereby certify that I have reviewed the information contained in this application and that it is complete and truthful. I understand that my presenting false or incomplete information may be cause for loss of eligibility to take the CCDM® examination, for denial of my application for certification or for revocation of any certification granted.

EXAMINATION

I understand that I may be disqualified from taking or completing the CCDM® examination or from receiving examination scores if SCDM determines through proctor observation or otherwise that I engaged in inappropriate behavior during the examination.

CLINICAL DATA MANAGEMENT ACTIVITY

I hereby represent and warrant that I have at all times acted in compliance with the SCDM Code of Ethics and with those laws and regulations applicable to clinical research, including without limitation, the Declaration of Helsinki and applicable U.S. Food and Drug Administration regulations. I understand that conduct at all times in violation of the spirit of the Code of Ethics or applicable laws makes me ineligible to take the certification examination and can be cause for permanent revocation of my certification status.

TERMS AND CONDITIONS OF USE OF THE CCDM® CERTIFICATION MARK

I hereby agree that, should I become a certified professional, I will abide and be governed by the Terms and Conditions of Use of CCDM® Certification Mark, a copy of which has been provided to me.

Candidate's Signature: _____

Date: _____



Appendix 1

Section 4

CONFIDENTIALITY AGREEMENT

In consideration of your participation in the examination process that forms the basis for SCDM's Certified Clinical Data Manager Certification Program ("the Program"), and to set forth a clear understanding of your obligations relating to the Program, you agree as follows:

(1) To preserve the integrity of the Program, you will maintain test questions and your knowledge of the contents of and the subject matter addressed in those questions ("the Test Questions"), in confidence and will refrain from disclosing or using them.

(2) Your obligation of nondisclosure does not apply to substantive information that was in your possession prior to this agreement or which became public through no fault or omission on your part, provided, however, that you may not disclose to others whether such substantive information is or is not a part of the Program's certification examination.

Your obligation of nondisclosure shall also not apply if you are required to disclose Test Questions in connection with a legal or administrative proceeding, provided, however, that you agree to give the SCDM Certification Committee chair prompt written notice of such a request.

(3) All intellectual property rights, including without limitation all copyright, are the sole and exclusive property of SCDM. SCDM shall have the right to obtain and hold in its name rights of copyright, copyright registrations and any similar protection.

(4) All nondisclosure obligations imposed by this agreement shall terminate ten (10) years from the date of this agreement.

(5) You represent and warrant that you are empowered to enter into this agreement and to grant and assign the rights granted and assigned herein to SCDM. You further represent and warrant that you have not previously granted or assigned, in whole or in part, to any other person or entity, including without limitation your employer, any of the rights granted or assigned herein to SCDM.

(6) This agreement shall be construed in accordance with the laws of the State of Wisconsin.

AGREED:

Signature

Print Name

Date



Appendix 1

Section 5

PAYMENT INFORMATION

Please include a check, money order or credit card number and expiration date for a NON-REFUNDABLE* application fee \$250. This fee must be paid in U.S. Dollars.

*In the event that your application is rejected, a portion of your application fee, less administrative and handling costs, may be returned to you. Once the application is accepted, no refund will be granted.

Method of Payment:

VISA MasterCard AMEX Check

Credit Card Number: _____ Expiration Date: ____/____

Name on Card: _____

Signature: _____

NOTE: Please contact the SCDM Administrative Office at info@scdm.org if you would like to submit your exam fee via a wire transfer.



Appendix 2

Eligibility Requirements for the Certified Clinical Data Manager Examination

You do not need to be a member of the Society for Clinical Data Management (SCDM) to apply for or take the examination to become a Certified Clinical Data Manager (CCDM[®]).

You do not need to be currently employed as a Clinical Data Manager (CDM) in order to apply for or take the examination.

You do not have to have a college degree to be eligible to take the examination; however, you must meet one of the following criteria:

- Bachelor's degree or higher plus two or more years full time CDM experience
- Associate's degree (two years) plus three or more years full time CDM experience
- No degree plus four or more years full time CDM experience
- Part-time work experience will be translated into full time work experience

Anyone who has had his/her CDM certification currently suspended is not eligible to take the certification examination until his or her suspension is completed.

Anyone whose name is on the FDA debarment list or has had his or her certification permanently revoked is not eligible to take the certification examination.



Appendix 3

Application for Certified Clinical Data Manager (CCDM®) Examination Retake

You may retake the exam within one (1) calendar year of the formal notification letter date of your original exam results. After that, a full application must be submitted and the full fee structure applies.

The fee to retake CCDM® exam is \$225.

Candidate Name: _____

Candidate ID: _____

Candidate Home Address:* _____

Candidate Daytime Phone:* _____

Candidate E-mail: _____

**Mandatory item your application will not be processed without this information.*

Retake Fee: \$225

Method of payment: *(Make checks payable to: Society for Clinical Data Management)*

Visa MasterCard American Express Check enclosed

Note: Credit Card information is kept secure.

Credit Card Number: _____

Expiration Date: (month/year): _____ / _____

Name on Card (please print): _____

Signature: _____ Date: _____

NOTE: Please contact the SCDM Administrative Office at info@scdm.org if you would like to submit the fee via a wire transfer.



Appendix 4

Submission Form

Use this form for professional development activities:

- IACET CEUs
- Webinars, conferences, forums, tutorials
- Listing of other SCDM involvement (committees, published articles, presentations)
- Non-SCDM educational activity

Title of Activity	Completion Date	Sponsoring Organization	Number of Contact Hours	Evidence of Attendance	Office Use Only

Name: _____ SCDM ID# _____

Date: _____ E-mail: _____

Contact Hours are actual time spent in the educational activity minus breaks
Evidence of Attendance can be a copy of a certificate or letter of completion/attendance.
1 contact hour = .1 CEU



Appendix 5

Certification Renewal Application

Please type or print all information below, indicate responses where required, sign in the appropriate space and return with the required enclosures to:

Table with 3 columns: American Office, Global Headquarters, India Office. Each column contains contact information for the respective office.

Section 1

First Name* _____ Last Name* _____ MI* _____
(*Enter name as it should appear on the certificate)

Company Name _____

Title _____ Department _____

Mailing Address _____

City _____ State/Province _____

Zip/Postal Code _____ Country _____

Work Phone _____

Fax _____

E-mail _____



Please include a current copy of your resume or CV, which should include updated education and work experience since your last application.

CCDM[®]s certified after 2004, will need to accumulate 1.8 CEUs for CCDM[®] renewal or you may choose to take the current CCDM[®] examination.

- I have acquired CEU's– **Please submit the attached form listing accumulated CEUs.**
If non-IACET CEUs were obtained, please complete the Non-IACET Affidavit Form
- I will take the CCDM[®] exam.

Section 2

Fee:

Renewal Application Fee: \$95

CCDM[®] Exam \$250

Method of payment: Visa Mastercard American Express Check Enclosed

Credit Card Number: _____

Expiration Date: _____

Name on Card: _____

Signature: _____

** The renewal fee is NON-REFUNDABLE. In the event that your application is rejected, a portion of your application fee, less administrative and handling costs, may be returned to you. Once the application is accepted, however, no refund will be granted.*



Appendix 5

SECTION 3

AUTHORIZATION

I hereby authorize the Society for Clinical Data Management (SCDM) to make whatever inquiries it deems necessary and appropriate to confirm the accuracy of the contents of my application. I agree to provide any additional authorizations necessary to that process. I hereby authorize SCDM to use the information contained in my application and/or examination for purposes of statistical analysis, provided that my personal identifying information has first been deleted.

APPLICATION INFORMATION

I hereby certify that I have reviewed the information contained in this application and that it is complete and truthful. I understand that my presenting false or incomplete information may be cause for loss of eligibility to take the CCDM[®] examination, for denial of my application for re-certification or for revocation of any certification granted.

EXAMINATION

I understand that I may be disqualified from taking or completing the CCDM[®] examination or from receiving examination scores if SCDM determines through proctor observation or otherwise that I engaged in inappropriate behavior during the examination.

CLINICAL DATA MANAGEMENT ACTIVITY

I hereby represent and warrant that I have at all times acted in compliance with the SCDM Code of Ethics and with those laws and regulations applicable to clinical research, including without limitation, the Declaration of Helsinki and applicable U.S. Food and Drug Administration regulations. I understand that conduct at all times in violation of the spirit of the Code of Ethics or applicable laws makes me ineligible to take the certification examination and can be cause for permanent revocation of my certification status.

TERMS AND CONDITIONS OF USE OF THE CCDM CERTIFICATION MARK

I hereby agree that, should I become a re-certified professional, I will abide and be governed by the Terms and Conditions of Use of CCDM[®] Certification Mark, a copy of which has been provided to me.

Candidate's Signature _____

Date _____



Appendix

Competency Domains Addressed in CCDM® Exam

Section 1

Project Management – Scope, Definition and Management
Project Management – Process Design, Management and Documentation
Project Management – Project Communications
EDC
Overall Clinical Trials Process, Roles & Responsibilities
Protocol Review
Data Management Plans
Clinical Database Design/Relational Databases
CRF Design

Section 2

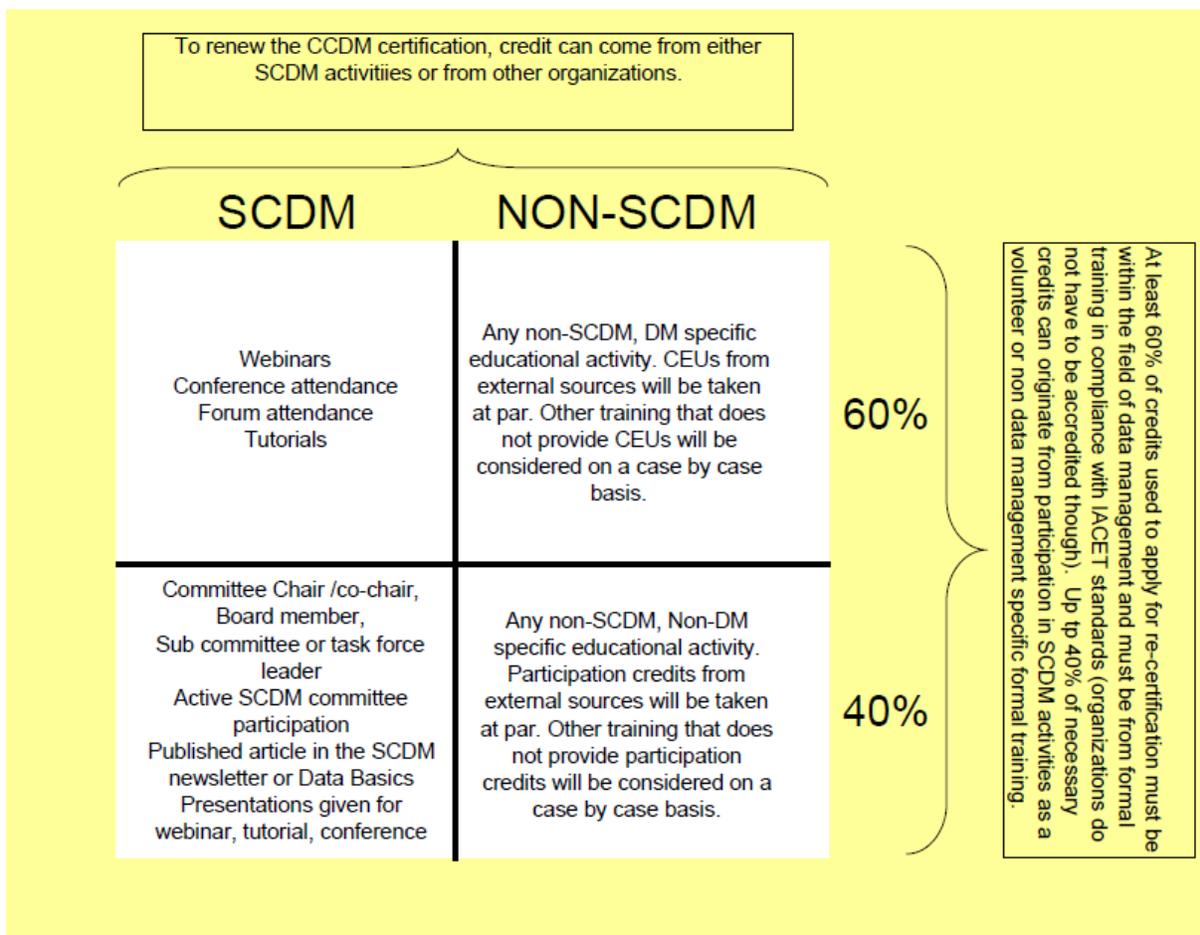
Processing Lab Data
Maintenance of Lab Normal Range Information
CRF Tracking
Communication of Data Trends
Query Resolution
Query Tracking
CRF Data Entry Process – Discrepancy Resolution
CRF Data Validation (e.g. data review, cleaning, query generation, applying data handling conventions)
Database Updates

Section 3

SAE Reconciliation/Safety Review
Coding (AEs; Signs and Symptoms)
Coding Medication
Database Quality Control Audits
Database Lock Procedures
Application of Randomization Schemes (Breaking the Blind)

Appendix 7

CEU & Participation Credit Percentage Chart





Appendix 8

Non-IACET CEU Affidavit Form

For non-SCDM educational offerings, applicant must sign affidavit below and include all course materials, brochure and/or advertisement of course as well as a corroborating reference signature.

Affidavit Requirement

I _____ verify under penalty of revocation, that I successfully completed the course titled _____

offered by (Institution) _____

on the dates of _____

Duration of course* _____

Participant Signature _____ Date _____

Reference Signature _____ Date _____

* excludes break and meal times

Attachments required for approval

1. Printed description and details provided by the educator
2. Speaker information (Bio/Curriculum Vitae)
3. Attendance Verification (A *Certificate of Completion* is the only verification acceptable)