2023

CCDM
Certification Handbook

Society for Clinical Data Management
DATA DRIVEN

CONTENTS

ABBREVIATIONS

ACRP	Association of Clinical Research Professionals
ADA	Americans with Disabilities Act
CCDM	Certified Clinical Data Management
CDM	Clinical Data Management
CEU	Continuing Education Unit
CRO	Contract Research Organization
DIA	Drug Information Association
IACET	International Association for Continuing Education and Training
SCDM	Society for Clinical Data Management
SoCRA	The Society of Clinical Research Associates

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

SCDM was founded in 1994 and has grown to be a premier data management organization that comprises upwards of 2,500 members in over 40 countries across the globe 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 are also members and 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 into 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, medical device therapies, and clinical research community at large. Through a rigorous eligibility assessment and examination process, certified clinical data management professionals can demonstrate a high level of competence and expertise in their field.

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.

The CCDM® exam, originally released in September 2005 and subsequently revised in 2008, 2010, and 2019, contains 130 multiple choice questions. Candidates are allotted 3.5 hours to complete the exam. All examinations are administered in English.

The exam and all test-related materials (i) are and will always remain the property of SCDM; (ii) are confidential; and (iii) are not available for review by any person or governmental agency, unless requested by a valid legal request (e.g., subpoena or court order).

Application Process

1. ····· Go to SCDM Exam Platform

2. ····· **«Create an account»**

3. ····· Complete the account setup process in the email sent from support@prolydian.com

4. ····· Log in at https://app.prolydian.com

5. ····· Go to **«Your applications»**

6. ····· Click on the **«SCDM» organization page button**

7. ····· Select **«Applications»**

8. ····· Click **«Apply now»**

9. ····· Complete the application

10. ····· **«Submit»**

What are the Costs?

Recognizing the important economic disparities in the global economy, the cost to sit for SCDM CCDM® exam is priced based on the three income levels as defined by the World bank. Please visit https://scdm.org/get-certified/ to know the CCDM® exam application price in your region.

Application Approval

Once an application has been processed, approximately 14 working days after it is received by SCDM, the applicant will receive an e-mail of acceptance/denial. The e-mail of acceptance will include instructions on how to access the platform and schedule your exam date. The accepted applicant will have 90 days from the date of the acceptance e-mail to take the exam. It is recommended that an accepted applicant schedule an exam immediately upon receipt of the acceptance e-mail to secure an exam date within the eligibility period. Except as set forth in this Handbook, the eligibility period will not be extended. The eligibility ID is not transferable.

Applicants must meet at least one of the eligibility requirements listed below. If an applicant does not meet the requirements, the application will be denied and the applicant will be refunded their application fee and $25 of administration costs will be charged on this refund.

Applicants for the Certified Clinical Data Manager (CCDM®) program must meet one of the following criteria:

› Bachelor's degree or higher and minimum two years full-time CDM experience
› Associate's degree and minimum three years full-time CDM experience
› Four or more years full-time CDM experience
› Part-time work experience equal to or surpassing full-time equivalent in criteria above

Scheduling the Exam

Scheduling the exam is done directly from Prolydian account. Log into the system and then go to the «Your exams» area. Click the Schedule button and follow the steps. Click here to learn how to schedule your exam.

Note:
Candidates can reschedule up to 24 hours before their scheduled appointment time via their Prolydian account.

What to expect when taking an exam

There are 3.5 hours allocated to take the test of 130 multiple choice questions. During the exam, unscheduled breaks are permitted, but the clock will not stop during those breaks.

When you're ready to start your exam you'll be connected with an Examity proctor, who will verify your identity and check your surroundings. Make sure the room is free of people, pets, and clutter. You'll complete a 360 degree sweep the room with camera to make sure it's free of anything that might get in the way of your testing experience and then the test will begin. You have to stay on screen for the duration of the exam otherwise the proctor may have to pause or stop the session.

The exam will be proctored live by our partner Prolydian, the CCDM® exam platform provider in partnership with Examity, the online proctoring company.

Before the Exam

›   *Preparation:*

Good Clinical Data Management Practices (GCDMP) is a foundational resource that will also help with exam preparation and is available here.

Furthermore, SCDM offers a webinar series on topics related to the exam as well as for professional development, and SCDM Annual Conference sessions are also valuable source of information.

›   *Registration:*

Prior to beginning your exam, you must complete your Examity profile setup, including the upload of a government issued Photo ID. You MUST complete the profile setup and computer requirements check prior to beginning your exam.

Follow the steps below to complete your profile setup:
›   Log into your Prolydian account.
›   Click the «Access my examity account» button from your Prolydian exams dashboard.
›   Click the «My profile» button.
›   Click the «Edit» button in the Account Information section, add your phone number, and then,
›   Click «Upload a photo of your government issued ID in the examiSHOW» section and then upload
›   Click the «Edit» button in the examiKNOW» section. Select your security questions, provide your responses, and then click Save

› Click the «Edit» button in the examiKEY» section. Provide the required typed input and then click Save.

› Check your computer readiness by clicking on "computer requirements check" or by clicking on the following link when you are on the computer you will be testing with.

› Please ensure that the computer you will be using can download Zoom and GoToMeeting. We encourage you to download them on your computer prior to your exam.

› ***Technical Requirements:***

› Browser: Google Chrome or Mozilla Firefox with popup blocker disabled. Other browsers are not supported and may not work as expected.

› A working built-in or external webcam and microphone.

› Desktop computer or laptop (tablets, Chromebook and cell phones do not meet the proctoring requirements).

› macOS X 10.5 or higher, Windows Vista or higher. Examity does not support Linux or Chrome OS

› Internet speed must be at least 2 Mbps download and 2 Mbps upload. Hot spot are not recommended.

If you experience any issues that require technical assistance, please contact Prolydian support at support+scdm@prolydian.com. All other inquiries should be directed to SCDM at latrese.wallace@scdm.org

› ***Online Testing Resources:***

We encourage you to review these helpful resources to ensure a successful testing experience:

› Online Test Taker FAQ
› 5 Tips to Boost Test Taker Success
› Online Proctoring Troubleshooting Guide
› Examity Check-In Process

After the Exam

All exams are subject to live remote proctoring and exam results become available after proctoring review; this process takes 48 hours. Any exams flagged for review will require manual adjudication to confirm the test results. Common reasons for manual adjudication include poor quality provision of photo ID, poor compliance with remote setup instructions (e.g., scan of room), and prohibited behavior. In these instances, a result will be provided to the applicant as soon as the review is complete.

After the examination, candidates will receive an e-mail indicating the results. Upon passing, a CCDM® certificate will be sent via postal mail service. A CCDM® certified individual may refer to the CCDM® certification if their certification is active. A CCDM® certified individual may use the CCDM® designation in block letters after his or her name on business cards, personal letterhead, resumes, websites, and in the person's email signature. The CCDM® designation may be used only in accordance with the Terms and Conditions of use in Section 4 of SCDM Policy & Procedure Manual.

SCDM maintains an online list of CCDM® certification holders. A certification holder may opt out of inclusion in the registry by contacting latrese.wallace@scdm.org.

Those who successfully complete the examination are asked to complete and return a survey, the results of which will be incorporated into SCDM publications.

Not passing the exam

The applicant may retake the exam one time for a reduced fee within one calendar year of the date of the formal notification letter date of the exam results. After expiration of that period, a full application must be submitted, and the full fee paid. Please refer to fee schedule and the retake application form on https://scdm.org/get-certified/

Routine Review of Test Results

SCDM reserves the right to undertake routine reviews of all test results, including using third-party forensic analysis. In the event this review raises concerns regarding the validity of any test results, SCDM has the right to invalidate the test results and to provide the candidate the opportunity to retake the exam, free of charge. In such an event, the candidate may not use the CCDM® credential until a passing grade on a subsequent exam is obtained.

CCDM® Renewal

Certification is valid for a three-year period from the date of original certification. SCDM Certified Clinical Data Management professionals (CCDMs) may renew their certification upon submission of a completed and valid renewal application.

By renewing, CCDMs demonstrate their intention 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 the following additional documentation for applications including Continuing Education Units (CEUs) earned from non SCDM educational opportunities:

› Continuing Education Unit ("CEU") Submission Form, (required for non-SCDM CEU courses only).
› Non-IACET CEU Affidavit form including course description, presenter biography, and certificate of successful completion (where applicable).
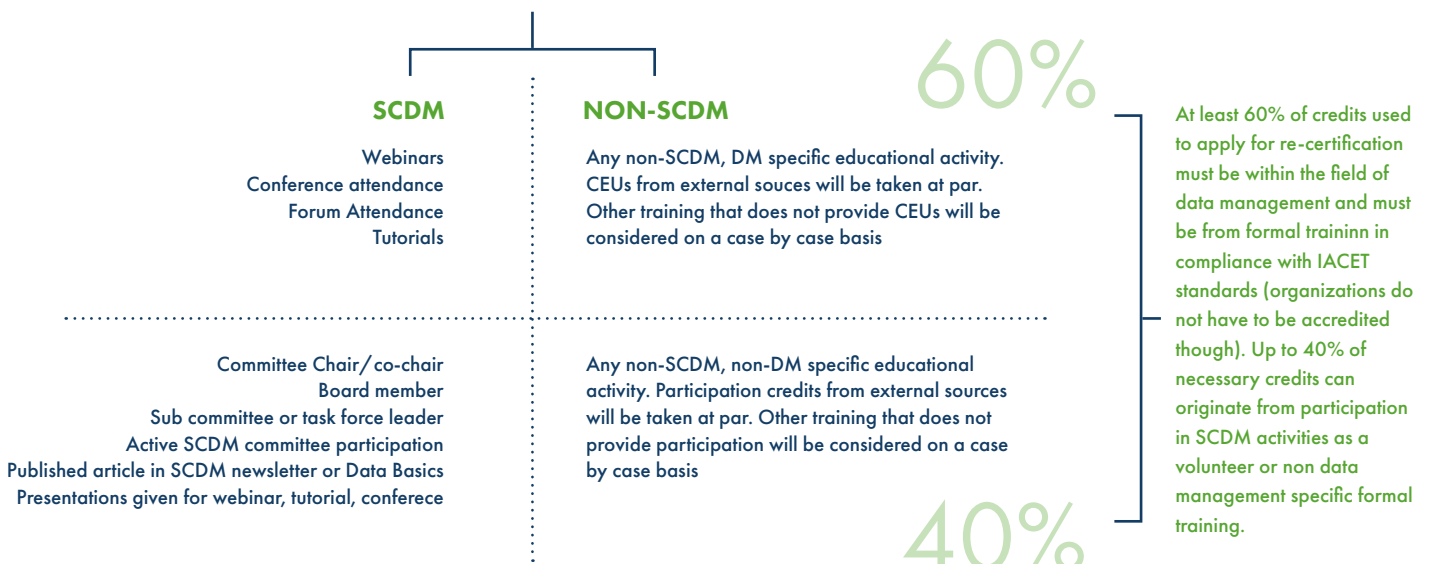› CEU certificates from all educational events (Non-SCDM)

To renew certification, candidates must acquire a minimum of 1.8 CEUs within three years of the date of the candidates CCDM® Certificate. This time frame begins from the date of most recent certification.

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 SCDM 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 Credit Breakdown Chart below.

To renew the CCDM certification, credit can come from either SCDM activities or from other organizations

SCDM
Webinars
Conference attendance
Forum Attendance
Tutorials

NON-SCDM
Any non-SCDM, DM specific educational activity. CEUs from external souces will be taken at par. Other training that does not provide CEUs will be considered on a case by case basis

60%
At least 60% of credits used to apply for re-certification must be within the field of data management and must be from formal traininn in compliance with IACET standards (organizations do not have to be accredited though). Up to 40% of necessary credits can originate from participation in SCDM activities as a volunteer or non data management specific formal training.

Committee Chair/co-chair
Board member
Sub committee or task force leader
Active SCDM committee participation
Published article in SCDM newsletter or Data Basics
Presentations given for webinar, tutorial, conferece

Any non-SCDM, non-DM specific educational activity. Participation credits from external sources will be taken at par. Other training that does not provide participation will be considered on a case by case basis

40%

SCDM will accept CEU certificates for training completed within organizations that offer IACET CEUs. CEU certificates must be provided with the description or sylabus for each trainining course completed. These may be submitted on an ongoing basis prior to renewal to establish their applicability for renewal purposes. 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 specific training is not acceptable for purposes of CCDM® renewal.

CEU certificates for training offered by organizations that do NOT offer IACET CEUs are accepted only when the applicant has submitted the Non-IACET CEU Affidavit Form to SCDM Administrative Office. The training is reviewed and approved by SCDM in it's sole discretion. It is recommended to confirm with SCDM by contacting us at latrese.wallace@scdm.org) whether such training will be accepted as part of a CCDM® renewal application prior to submitting said application.

* CEU Certificates must include the following:

› Workshop title
› Date of offering.
› Name of sponsoring organization
› Specific number of CEUs issued (when issued, or contact hours when no CEUs have been issued)
› Signature and date of representative from sponsoring organization (or other form of formal authentication)

Tracking of CEUs:

SCDM Members and Non-Members can track their CEUs on SCDM Community platform profile:

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