

SCDM **CCDA**



**2024 CCDA**

# Certification Handbook

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## INTRODUCTION

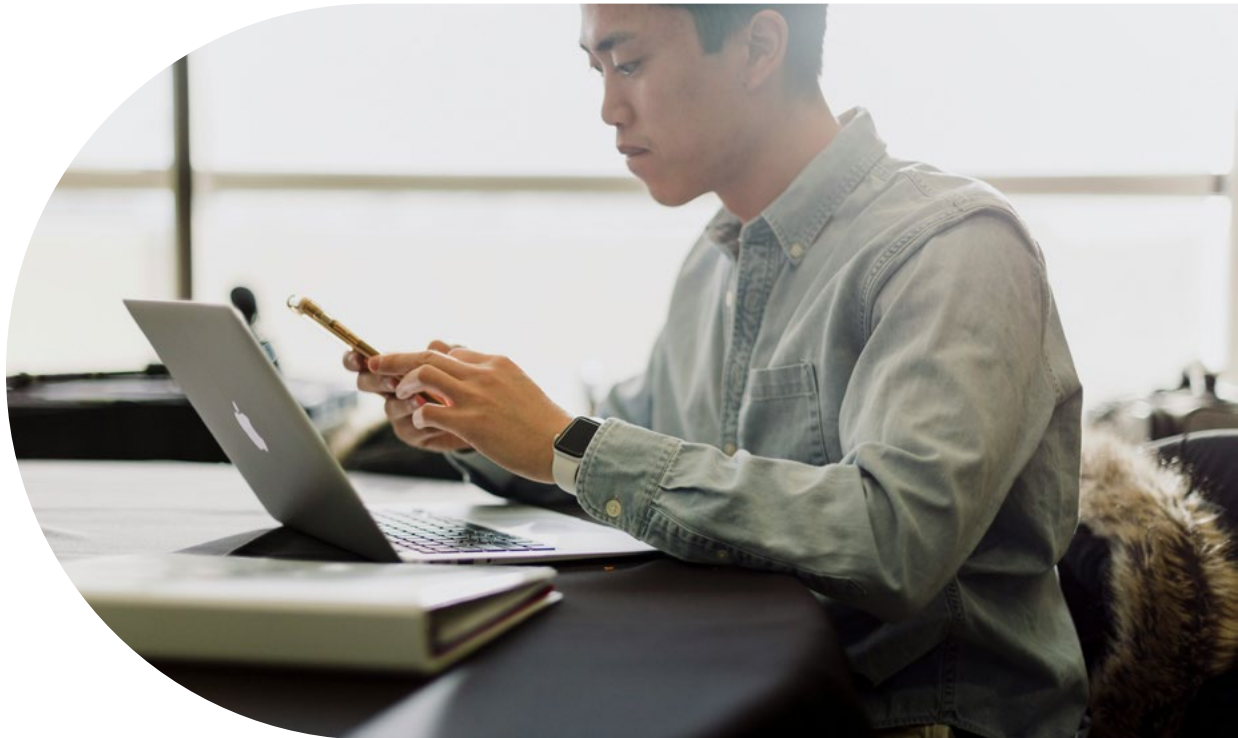
**Thank you for your interest in the Society for Clinical Data Management's (SCDM) Certified Clinical Data Associate (CCDA) examination and for choosing SCDM as your certifying organization.**

### 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 3,000 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.



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## INTRODUCTION

### 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 associates 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.

## ABOUT THE CCDA EXAM

The release date for the CCDA Exam is October 2024. The exam contains 80 multiple choice questions. Candidates are allotted 2.5 hours to complete the exam. All exams 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](mailto:support@prolydian.com)
- 4 Log in at <https://app.prolydian.com>
- 5 Go to **your applications**
- 6 Select my applications
- 7 Click apply now to start the process



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## ABOUT THE CCDA EXAM

### What are the Costs?

Recognizing the important economic disparities in the global economy, the cost to sit for SCDM CCDA exam is priced based on the three income levels as defined by the World bank. Please visit <https://scdm.org/ccda-certification> to know the CCDA 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.

**Applicants for the Certified Clinical Data Associate (CCDA) program must meet one of the following criteria:**

- > Bachelor's degree or Associate's degree or higher
- > 0-2 years full-time CDM experience

### 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.

## ABOUT THE CCDA EXAM

### What to expect when taking the Exam

There are 2.5 hours allocated to take the test of 80 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 CCDA exam platform provider in partnership with Examity, the online proctoring company.

### Before the Exam

> **Preparation:**

**Good Clinical Data Management Practices (GCDMP®), ICH GCP E6 (R2) and ICH GCP E6 (R3)** Guidelines are foundational resources that will help with exam preparation..

Furthermore, SCDM offers a free on-demand webinar titled **Clinical Data Associate 101**. This on-demand webinar provides an introduction to the role of Clinical Data Associate and the Society for Clinical Data Management. Additionally, SCDM provides a supplemental study aid - the **CCDA Study Guide**. This guide outlines the chapters in the Good Clinical Data Management Practices (GCDMP©) handbook that align with the core CCDA exam domains and associated tasks.

Finally, there will be questions to test the general knowledge needed in order to be a successful clinical data associate. These questions will be things picked up in your education and general knowledge of the positions and/or industry.

**The main domains covered in this exam include:**

- > Coordination and Management
- > Data Processing
- > Design
- > Program and Testing
- > Review
- > Training

> **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.

## ABOUT THE CCDA 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](mailto:support+scdm@prolydian.com)**. All other inquiries should be directed to SCDM at **[info@scdm.org](mailto:info@scdm.org)**



## ABOUT THE CCDA EXAM

### > **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](#)

## 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 CCDA electronic certificate will be accessible via the Prolydian platform. A CCDA certified individual may refer to the CCDA certification if their certification is active. A CCDA certified individual may use the CCDA designation in block letters after his or her name on business cards, personal letterhead, resumes, websites, and in the person's email signature. The CCDA 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 CCDA certification holders. A certification holder may opt out of inclusion in the registry by contacting [info@scdm.org](mailto:info@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

You may retake the examination any time after 90 days, but within one year of the date of the original examination. To register again and pay the \$95 retake fee, please visit the My Exams page in your Prolydian account and click the «Register Again» button. After registering you'll receive a confirmation email with instructions on how to schedule your retake exam.

## ABOUT THE CCDA EXAM

### 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 CCDA credential until a passing grade on a subsequent exam is obtained.



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## CONTACTS



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