

John Ezzell, Head of Education Amy Palmer, Head of Standards Development



TUE 7 SEP 11:00AM-12:00PM ET

Today's Agenda

- 1. Housekeeping
- 2. Feature Presentation + Q&A
- 3. Upcoming Learning Opportunities & Events





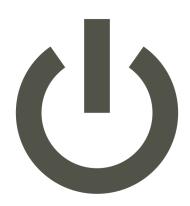
You will remain on mute





Submit questions at any time via the Questions tool on your GoToWebinar app





Audio issues?

Shut down & restart GoToWebinar app





A recording of this webinar and the slides will be available in the **Members Only** section of CDISC website





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TUE 7 SEP 11:00AM-12:30PM ET

CDISC Certification Public Webinar 7 SEP 2021 cdisc

Overview

- 1. Certification Exam Development Process
- 2. Certification Exam Scope
- 3. Certification Exam Registration Process
- 4. Certification Exam Delivery Process
- 5. Certification Maintenance Schedule
- 6. Accessing Certificates And Badges



Certification Exam Development Process

Blue Ribbon Commission

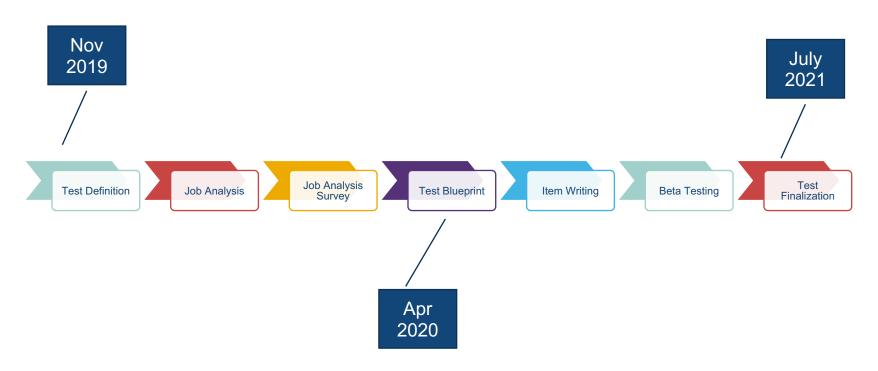
From the Commission Report:

Broad Theme #4: Build a strong standards ecosystem

"Establish a highly functional professional certification program that incorporates pragmatic implementation of the standards, not just learning theory and rules. Require regular knowledge updates to maintain certification credentials. Individual certification (1.) improves homogeneity of implementation; (2.) expands the pool of qualified job candidates available to the community; and (3.) may provide a substrate for company-level certification demonstrated by a critical mass of individual certifications"



Certification Exam Development Timeline





Certification Exam Development Process

- CDISC worked with Kryterion Global Testing Solutions
- SMEs developed Job Analysis, Test Definition, and Job Analysis Survey
- Survey administered received 331 responses
- Survey responses used to develop Test Blueprint
- Test Blueprint guide for item writing
- Items written, reviewed, and approved by SMEs





Test Definition

- 1st step in development of the certification exam
- Determines strategic direction of the certification program
- Determines exam purpose, who should take the test, what should the exam cover, credentials of candidates for the exam, exam stakeholders, description of a minimally qualified candidate





Job Analysis and Survey

- Creation of a list of tasks that may be performed as part of the certified job role (and assigned them to task domains or groupings)
- Creation of a list of knowledge and skills that may be needed to perform the job tasks of a person who is SDTM and SDTMIG certified





Test Blueprint

 Determines and outlines the total number of items required on a final test form to adequately assess a candidate on these knowledge and skills





Item Writing

- Over a period of 5 months, SMEs used Test Blueprint to develop test questions
- Individual SMEs assigned and developed test questions using SDTM and SDTMIG as reference
- Each question was reviewed, revised (if needed), approved/rejected by a group of SMEs
- Distribution of questions across exam domains and knowledge and skills adhered to Test Blue Print





Beta Testing

- Beta testers took the examination between December 8, 2020 and April 30, 2021
- Each beta test form contained 188 items to ensure that there would be a sufficient number of items with acceptable performance statistics (i.e., 125 items)
- SMEs reviewed and discussed the items with borderline or poor item statistics or candidate comments





Test Finalization

- SMEs reviewed items to determine if acceptable to use as is on the examination, or reworked for a future test or retired
- Two final test forms were created in alignment with Test Blueprint and are similar in difficulty level
- A standard setting (i.e., passing/cut score determination) process was conducted to determine the cut score for the Tabulate Certification examination forms



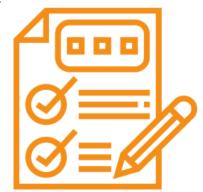




Certification Exam Scope

Exam Scope

- SDTM and SDTMIG Certification
- Exam Domains and Corresponding Weight
 - For example General Concepts, Terms and Assumptions, and Conformant Dataset Structure (30%)
- Knowledge and Skill Statements for each Exam Domain
- https://www.cdisc.org/education/cdisc-standards-certification





Exam Domains

General Concepts, Terms and Assumptions, and Conformant Dataset Structure **General Observation Classes** Domain-Specific Knowledge Findings About, Custom Domains, Associated Persons, and Study References **Special Purpose Domains** Controlled Terminology, Conformance, and Other References The Trial Design Model Relationships Among Datasets and Record



Examples of Knowledge and Skills Tested

General Concepts, Terms and Assumptions, and Conformant Dataset Structure

Skill to correctly apply formats for date/time variables, including the correct precision

Skill to correctly apply formats for duration and elapsed time variables

Knowledge of the algorithm for "study day" variables

Skill to appropriately use relative timing variables

Skill to appropriately use time point variables

Skill to appropriately use disease milestone timing variables

Skill to correctly represent original and standardized results

Skill to correctly represent options for indicating the fact that a test or set of tests was not done

Skill to correctly represent lengthy text strings







CDISC Tabulate Certification Exam Registration, Preparation, and Maintenance

CDISC Tabulate Certification Registration

Registration via CDISC Learning System

Requires CDISC.org account





Certification Exam Fees

\$500 exam fee

\$125 re-test fee (for failed exam)

Cancelation fees may apply

Passing exam grade establishes certification for 3 years

Recertification required after 3 years

Recertification exam fee: \$500

CDISC membership and group discounts available





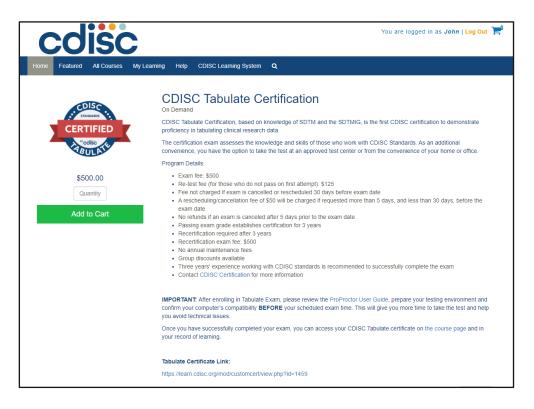
Certification Exam Registration Process

Log in to CDISC eCommerce Product Catalog Purchase CDISC Tabulate Program View Certification Details in CDISC Learning System Receive Eligibility ID within 5-7 business days Schedule Exam at Prometric site





Demo: Certification Exam Registration Process





Important Steps BEFORE the Exam

Review CDISC Certification Study Materials



Online: Check Computer Compatibility



Online: Prepare Room and Surroundings



In-Person & Online: Bring Government-issued I.D.





Certification Tabulate Exam Details

125 Exam Questions

Multiple-choice Format

Approximately 4 hours Long

2 Minutes Per Question

15-minute "Halftime" Break





Certification Maintenance

No maintenance fees

Every 3 years: Exam Retake

\$500 recertification exam fee



Certificates and Badges

Available Upon Successful Exam Completion

Accessible in CDISC Learning System Profile Page

Shareable via Learning System Public Pages







Certificates and Badges

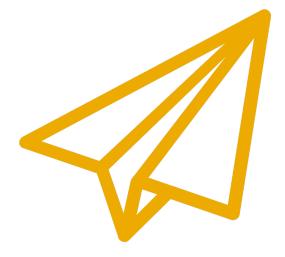
Demo:
CDISC
Tabulate
Certificate and
Badge





CDISC Certification Questions

Contact certification@cdisc.org



Thank You!





Questions & Answers



What score do you have to get to pass the exam?

Do you have to get a passing score in all domains, or just overall?



Could you tell us more about SEND tabulation and its alignment with SDTM?





Can I get CEUs for maintaining my professional certification taking this exam?







Do you plan to have any other certification exams for other standards in the future?





Upcoming Learning Opportunities

New Virtual Training Methods



- Information available at: <u>www.cdisc.org</u>
- Register at: https://learnstore.cdisc.org/
- Contact us at: training@cdisc.org

















2021 US INTERCHANGE

With Standards - Science Will Prevail!



Conference & Trade Show

Washington, DC or Virtually

20-21 October



2021 CHINA INTERCHANGE

With Standards - Science Will Prevail!



Conference | Trade Show

Beijing | 19-20 November



Upcoming Webinars

Pediatrics User Guide - Summary of Scoping

21 September 2021, 11am - 11:45pm EDT

REGISTER NOW!

CDISC, in collaboration with IMI's Connect4Children (c4c) Project, is developing a Pediatrics User Guide, which builds on existing CDISC standards, and will consist of data collection and data tabulation examples for use in pediatric clinical trials.

Join us as we share project progress and a summary of topics covered during the project's scoping period.

Panelist(s)

John Owen, Head of Partnerships & Development, CDISC Richard Marshall, Lead Developer, Accurate Systems

Language

English

2021 Hybrid US Interchange Sneak Peek

23 September 2021, 10 - 10:45am EDT

REGISTER NOW!

Join CDISC leaders for a preview of the upcoming hybrid US Interchange, which will take place 20 - 21 OCT in person in Washington, DC and online.

CDISC staff and community experts will introduce program highlights such as the CDISC Open Rules Engine (CORE) and the CDISC Open Source Alliance (COSA), regulatory topics, and more. Webinar attendees will get a look at the conference platform that will be available for both in-person and virtual attendees. We want all our attendees to experience the same great presentations, whether from seats in the conference rooms or from the comfort of their living rooms.

Panelist(s)

Sam Hume, Vice President, Data Science, CDISC
Bernard Klinke, Virtual Experience Manager, CDISC
Amy Palmer, Head of Standards Development, CDISC
Andrea Vadakin, Sr. Director, Membership and Events, CDISC

Language

English



Upcoming Webinars

Controlled Terminology Updates for Q3 2021

30 September 2021, 11am - 12:30pm EDT

REGISTER NOW!

This quarterly webinar series addresses the latest Controlled Terminology release package as well as content currently in Public Review. Controlled Terminology is the set of codelists and valid values used with data items within CDISC-defined datasets. Controlled Terminology provides the values required for submission to FDA and PMDA in CDISC-compliant datasets.

Panelist(s)

Dr. Erin Muhlbradt, Clinical/Biomedical Information Specialist, Enterprise Vocabulary Services, National Cancer Institute

Language

English

Controlled Terminology Updates for Q4 2021

21 December 2021, 11am - 12:30pm EST

REGISTER NOW!

This quarterly webinar series addresses the latest Controlled Terminology release package as well as content currently in Public Review. Controlled Terminology is the set of codelists and valid values used with data items within CDISC-defined datasets. Controlled Terminology provides the values required for submission to FDA and PMDA in CDISC-compliant datasets.

Panelist(s)

Dr. Erin Muhlbradt, Clinical/Biomedical Information Specialist, Enterprise Vocabulary Services, National Cancer Institute

Language

English



Thank you!



Contact the Events inbox: events@cdisc.org



Contact Certification inbox: certification@cdisc.org



Contact Bernard directly: bklinke@cdisc.org

