CDISC Certification Launch

Marine Laurent, COO, CDISC
Amy Palmer, Head of Standards Development, CDISC

Monday, 16 NOV 2020
11:00AM – 12:00PM EDT
Today’s Agenda

1. Housekeeping
2. Presenter Introductions
3. Feature Presentations
4. Question & Answer Session
5. Upcoming Learning Opportunities + Resources
Housekeeping
Housekeeping

• You will remain on **mute** for the entirety of the webinar
• There will be a Q&A after all of the presentations are finished
• Audio issues? Shut down and restart the GoToWebinar app
• The slides from the presentation and a recording of this webinar will be available in the Members Only section of the CDISC website
  • To access – make sure that you create a login for the CDISC website if you haven’t already
  • If you are employed by a CDISC member organization, please ensure you use your employer-issued email address with your employer’s domain name, so we can verify membership for the purpose of applying discounts to purchasing event tickets, online courses, and more!
Submitting Questions

• To send a question, use the “QUESTIONS” function on your GoToWebinar app. (See red arrow)

• You can submit questions at any time during the presentation, we’ll answer them during the Q&A.

• If you have a question for a specific presenter, please indicate the presenter’s name at the beginning of the question
  • Examples:
    • John: ‘Question’
    • Alana: ‘Question’
Content Disclaimer

• The purpose of this webinar is to provide examples of implementation and should not be considered official recommendations by CDISC unless otherwise stated in the presentation.

• This webinar is not an authorized CDISC course, is not developed or delivered under CDISC Operating Procedures, and should not replace a published standard. Please refer to the latest published standards for the most authoritative implementation information.
Our Presenters

• Marine Laurent, COO, CDISC
• Amy Palmer, Head of Standards Development, CDISC
CDISC Certification Launch

Presented by Amy Palmer, CDISC Head of Standards and Marine Laurent, CDISC COO
16 November 2020
Agenda

1. Background and Test Development
2. Exam Scope
3. Exam Logistics
4. Q&A
Background and Test Development
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 Requirements

• Passing the CDISC Tabulate Certification Exam demonstrates that you have attained knowledge and the competency necessary to utilize the SDTM and the SDTMIG.

• To obtain the CDISC Tabulate Certification you must meet the following requirements:
  • Register for the certification and pay the corresponding fee
  • Demonstrate three years of experience with the CDISC standards by uploading your CV after registration
  • Pass the CDISC Tabulate Certification Exam
Test Development Timeline

- Nov 2019: Test Definition
- Job Analysis
- Job Analysis Survey
- Apr 2020: Test Blueprint
- Item Writing
- Dec 2020: Beta Testing
Test 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
Exam Scope
Exam Scope

• 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

- 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
Test Structure and Format

- Two pilot (beta) tests developed using SDTM v1.7 and SDTMIG v3.3
- 188 questions
  - The CDISC Tabulate Certification Pilot Exam consists of 125 scored items and 53 unscored questions.
- Multiple-choice (single answer) questions
- The exam duration is expected to last 4.5 hours (5 hours total sitting time).
- Pilot test used to determine the passing score for the exam
- Final tests expected to be 125-150 multiple-choice questions
Exam Logistics
Welcome to the CDISC Learning System

Welcome to the CDISC Learning System where you can access your training modules and view your learning records.

My Current Courses

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<th>Course Title</th>
<th>Progress</th>
<th>Course Enrol Date</th>
<th>Course Start Date</th>
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All Courses

Filter by Tags

+ Subject
- Certification coming soon
  - CDISC Tabulate
+ Course Type

Clear filters

Courses per page: 10

(Abbreviated Version) SDTM Theory and Application for Medical Devices Used ...
On Demand

Upcoming Virtual Training Schedule: 2 Nov, 1-4:30pm ET (each day)
Course Description
Study Data + Learn More

Add to Cart

ADAM001: Introduction to ADaM
On Demand

$700.00
$525.00

$150.00
All Courses

Filter by Tags

- Subject
- Certification coming soon
- CDISC Tabulate
- Course Type

Clear filters

CDISC Tabulate Certification
On Demand

Welcome to CDISC Tabulate Certification, based on knowledge of SDTM and + Learn More

$300.00

Add to Cart
Welcome to the CDISC Learning System

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Step 1: Upload your CV or Resume

To be certified, you must upload your CV that documents a minimum of three years implementing CDISC Standards.

- Files uploaded may be up to size: 1MB
- Accepted file types: image/PNG, image/JPEG, document/Word Doc, PDF

Click on the link below to upload your CV or resume.
Exam Scheduling
Exam Scheduling

• Exam scheduling and attendance is managed by our certification partner, Prometric

• 2 settings: at a testing center (onsite), or from your home or office (remote proctored)

• You can select any convenient timeslot during the 2-months testing window
Sitting for the exam

• Plan ample time prior to the exam

• No documentation is allowed

• A 15 min break is built in the 4.5h exam duration

• Familiarize yourself with the specific requirements of your exam location
Exam results

- Pilot session: pass / fail result available up to 6 weeks after the end of the sessions
- Regular session: results available immediately

- If successful - single “Pass” grade

- If unsuccessful – domain specific feedback will be provided
Maintenance

- Annual maintenance fee
- Every 3 years: exam re-take to ensure currency of knowledge
Pilot session specificities

- Reduced price
- Slightly longer exam
- Results not immediate – same validity as “regular” session
- Limited seats – first 150 registrants.
Any Questions?
Thank You!
CDISC Certification Launch

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Amy Palmer, Head of Standards Development, CDISC

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Audience Questions

Can we take the exam from our office space or home once it gets available, especially during this pandemic?
Audience Questions

Does "CDISC Certification exam on SDTM-based datasets & SDTMIG" covers "SEND-based datasets & SENDIG" as it derived from SDTM?
Audience Questions

Is there more than one opportunity to pass the test with the single payment?
When would the actual test be done for the cert? For my budget planning I need to know this in order to participate.
Audience Questions

Why do you think a certification is necessary for programmers?
Is there any Certification training program which covers all modules under CDISC?
Audience Questions

As part of your experience, do you have to have submitted SDTM tabulation data files or just know the process?
Audience Questions

How many hours to take the test?
Does it all have to be done in one session?
Audience Questions

Is a Data Manager eligible to apply for CDISC exam?
Audience Questions

Why do you need to have 3 years of CDISC exposure/experience to even be eligible to take the exam?
Does 3 years experience require full CDISC standards experience or can it be combined experience with other roles e.g. Clinical Programmer with CDISC experience, Data Manager with CDISC experience?
Will the application fee be reimbursed in case the candidate doesn't meet the exam criteria after CV verification?
Audience Questions

What should we do if our state has closed testing centers for the next few weeks as part of a COVID-19 lockdown- can we still register and receive a discount as part of the first 150 people even though we are not able to actually take the test at the moment?
Audience Questions

Amy: Does the certificate have an expiry date?
Audience Questions

Marine: How often can the test be repeated when not passed the first time (without registering and paying the fee again)?
For second test, is it a free attempt or does it require paying an additional fee
Audience Questions

Marine: How much will the maintenance fee be?
Audience Questions

Does SEND count for the 3 year experience?
Upcoming Learning Opportunities
New Virtual Training Methods

• CDISC Provides Many Ways to Begin or Continue Growing Your Standards Knowledge.
  • Popular self-paced training plus new Blended Learning and Virtual Classroom settings.
Thank You!

Questions, comments, concerns? Email bklinke@cdisc.org

Don’t forget to fill out the feedback survey!