

CDISC Certification Launch

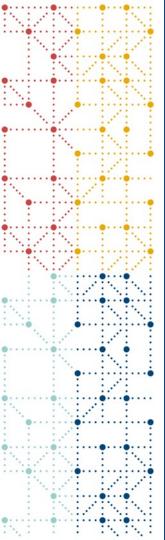
Marine Laurent, COO, CDISC Amy Palmer, Head of Standards Development, CDISC



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



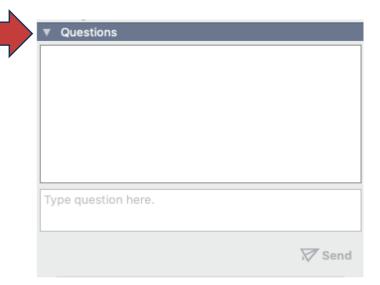
Housekeeping

- 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'

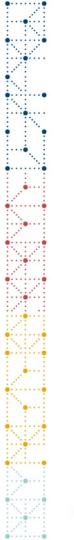




Content Disclaimer

- 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

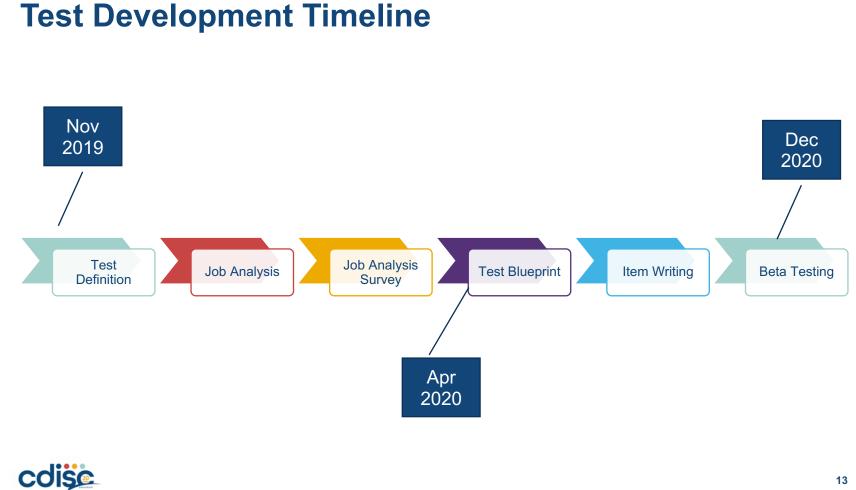
"Establish a highly functional professional certification program that incorporates pragmatic implementation of the standards, not just learning theory and rules. Require regular knowledge updates to maintain certification credentials. Individual certification (1.) improves homogeneity of implementation; (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

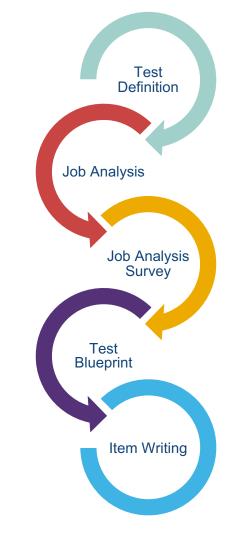




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Test Development Process

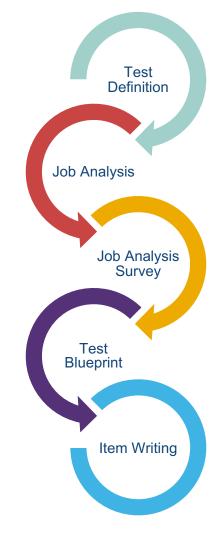
- CDISC worked with Kryterion
 Global Testing Solutions
- SMEs developed Job Analysis, Test Definition, and Job Analysis Survey
- Survey administered received 331 responses
- Survey responses used to develop
 Test Blueprint
- Test Blueprint guide for item writing
- Items written, reviewed, and approved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





Test Definition

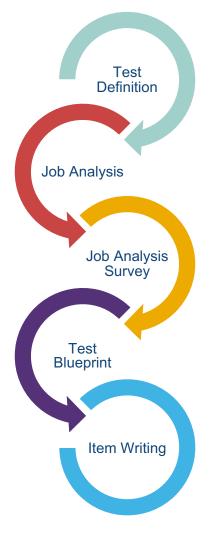
- 1st step in development of the certification exam
- Determines strategic direction of the certification program
- Determines exam purpose, who should take the test, what should the exam cover, credentials of candidates for the exam, exam stakeholders, description of a minimally qualified candidate

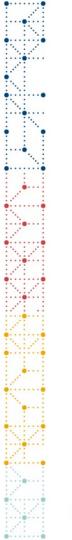




Job Analysis and Survey

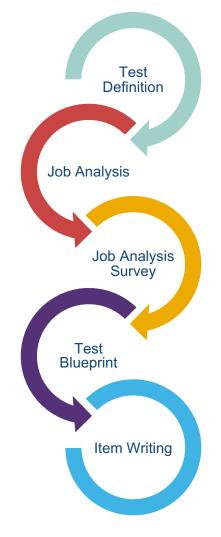
- Creation of a list of tasks that may be performed as part of the certified job role (and assigned them to task domains or groupings)
- Creation of a list of knowledge and skills that may be needed to perform the job tasks of a person who is SDTM and SDTMIG certified





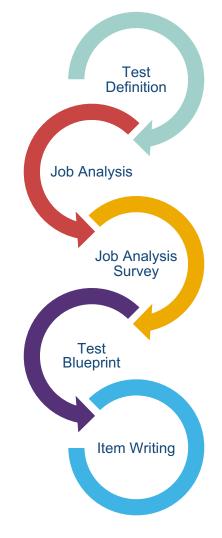
Test Blueprint

 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
- <u>https://www.cdisc.org/education/cdisc-standards-certification</u>





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

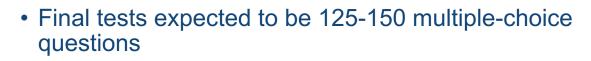
Skill to correctly represent lengthy text strings





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



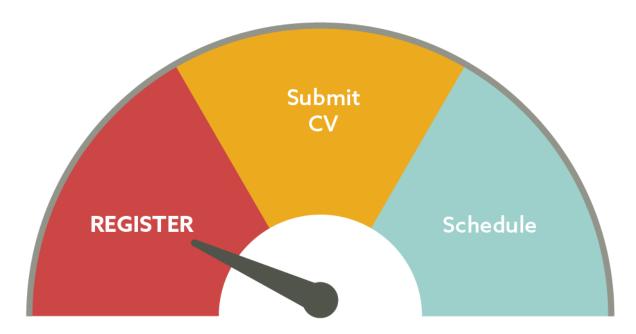




Exam Logistics



Registration





cdisc	New to CDISC	Standards Education	Resources Events Mer	nbership Members Only
	Featured Courses	Classroom Training	Online Training	Support
and the second second	ADaM Core Theory and Application	Virtual Classroom Training	My Learning	Calendar of Events
	CDASH Advanced Topics	On-Site Training	Course Catalog	Contact Us
	SDTM Advanced Topics	Public Training	Webinars	Information for Learners
Greater C	All Courses	Instructors	Blended Learning	Certification
CDISC Education		Workshops	ADaM Core Theory and Application	
SHARE BOOM IN		CDISC for Newcomers	CDASH Implementation	
		CDISC Library Workshop	SDTM Theory and Application	

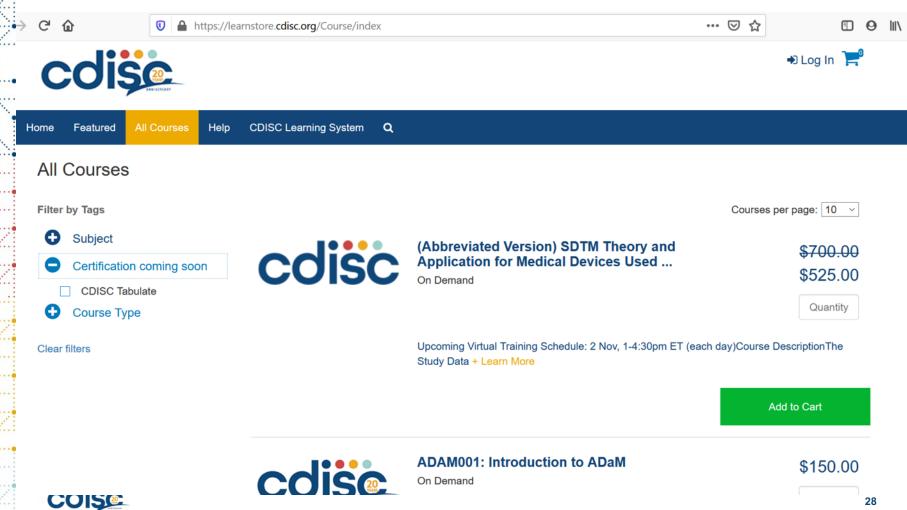


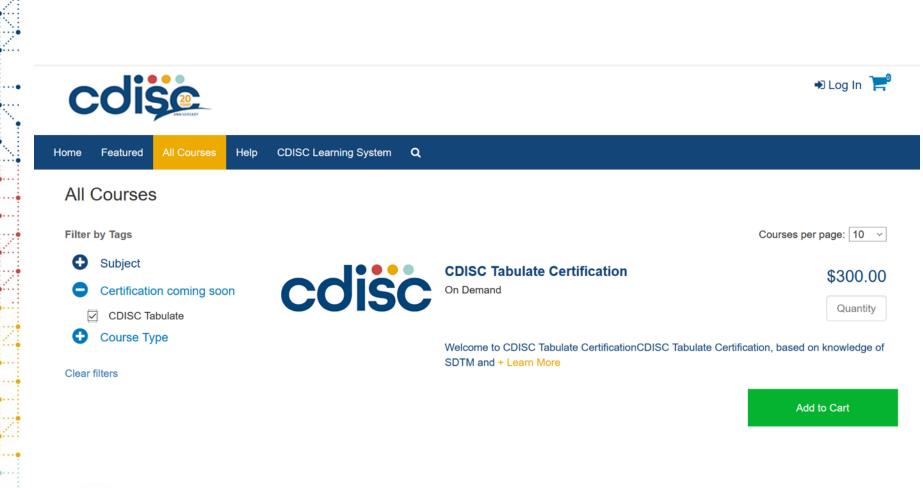


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Marine Laurent 🔹 🗸

Access	Learning	Browse Our Co	ourse Catalo	g Certifications	Membership Benefits	Visit	CDISC.org	Contact							
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		Featured Cour	ses												
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CV Submission







- Home

NAVIGATION

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- CDISC Learning System
- My courses
- ► CDISC On Demand & Blended Learning

- ▶ CDISC Classroom & Virtual Training
- CDISC Certification Program
- CDISC Tabulate
 Certification
- CDISC Internal Training
- CDISC Volunteer Training

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

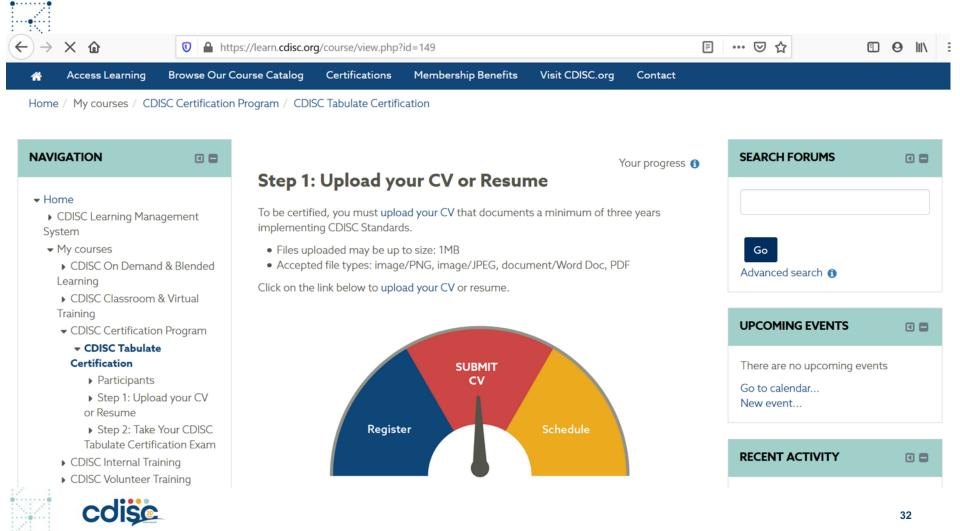


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Course Course Type Course Title * Progress Enrol Date Start Date ADaM Bundle No criteria 21 Feb 21 Dec 2020 2019 ADaM Primer 28 Mar 4 Nov 2018 0% 2019

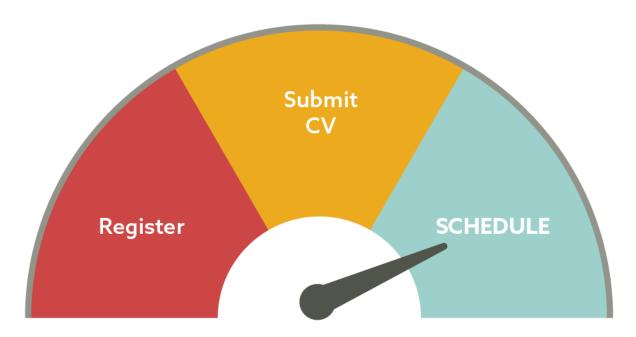








Exam Scheduling





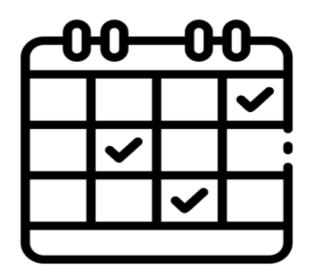


Exam Scheduling

• 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



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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.









Thank You!





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

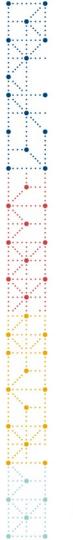






Does "CDISC Certification exam on SDTM-based datasets & SDTMIG" covers "SEND-based datasets & SENDIG" as it derived from SDTM?





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.





Why do you think a certification is necessary for programmers?









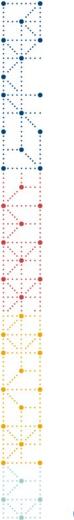
Is there any Certification training program which covers all modules under CDISC?



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



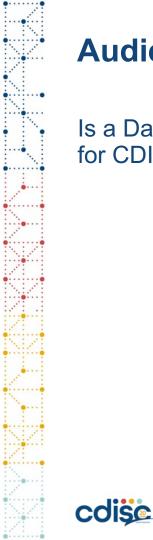






How many hours to take the test? Does it all have to be done in one session?

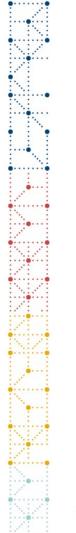




Is a Data Manager eligible to apply for CDISC exam?



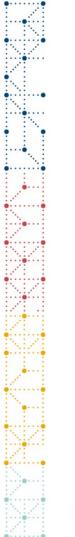






Why do you need to have 3 years of CDISC exposure/experience to even be eligible to take the exam?



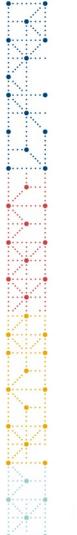


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Audience Questions

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?

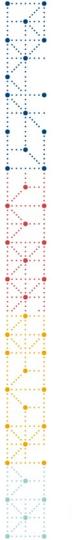




What should we do if our state has closed testing centers for the next few weeks as part of a COVID-19 lockdown- can we still register and receive a discount as part of the first 150 people even though we are not able to actually take the test at the moment?







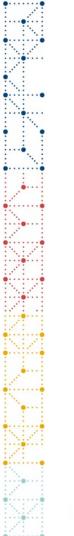
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Audience Questions



Amy: Does the certificate have an expiry date?





Marine: How often can the test be repeated when not passed the first time (without registering and paying the fee again)?







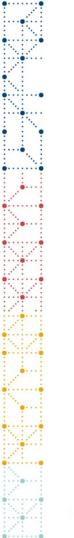
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Audience Questions



For second test, is it a free attempt or does it require paying an additional fee





Marine: How much will the maintenance fee be?







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Audience Questions



Does SEND count for the 3 year expereince?

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 <u>bklinke@cdisc.org</u>

Don't forget to fill out the feedback survey!

