



Navigating the CDISC Learning System and Our Many Training Offerings

John Ezzell, Head of Education Development

Bernard Klinke, Virtual Experience Manager

Andrea Rampone, Online Education Coordinator

Saad Yousef, Sr. Manager, Education Operations



TUE 2 FEB

11:00AM-12:30PM ET



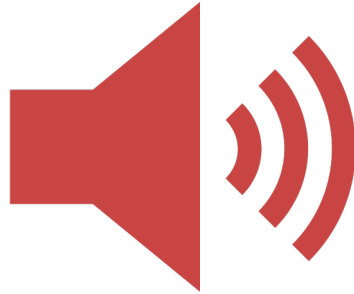
Today's Agenda

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



Housekeeping

Housekeeping



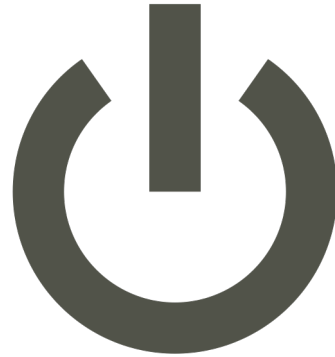
You will remain on **mute**

Housekeeping



There will be a **Q&A**

Housekeeping



Audio issues?

Shut down & restart GoToWebinar

Housekeeping



Webinar slides & recording available
for **CDISC Members**

Our Presenters



John Ezzell, Head of Education Development



Bernard Klinke, Virtual Experience Manager



Andrea Rampone, Education Coordinator for Course Development



Saad Yousef, Sr. Manager, Education Operations



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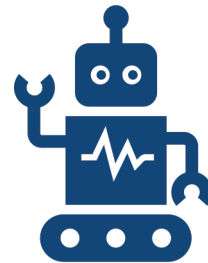


The CDISC Learning Management System (LMS)



What does 'LMS' stand for?

LMS is an acronym for
'Learning Management System'



What is an 'LMS'?

It manages and delivers education and training material, and learner-instructor interactions, online.





**There are many
LMS applications
available.**

CDISC uses Totara,



How-To

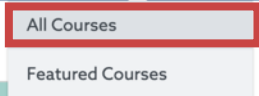
Creating and Accessing an Account in the CDISC Learning Management System (LMS)

CDISC Course Catalog & Store



Navigate to the CDISC Course Catalog

- Click on **‘Browse Our Course Catalog’** in the navigation bar and select **‘All Courses’**



NAVIGATION

- ▼ Home
 - ▶ CDISC Learning Management System (LMS)
- ▼ My courses
 - ▶ CDISC On Demand & Blended Learning
 - ▶ CDISC Instructor Training
 - ▶ CDISC Classroom & Virtual Training

Welcome to the CDISC Learning Management System (LMS)

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



CALENDAR

January 2021

Su	Mo	Tu	We	Th	Fr	Sa
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						

CDISC Training Product Catalog

- Filter by **Tags** (Subject, Certification, Course Type, or Course Region)
- Discounted training prices for members



You are logged in as **Andrea** | [Log Out](#) 

[Admin Panel](#)

All Courses

Filter by Tags

Subject


Module Bundles

ADaM

Chinese Translations

Certification

RRIDG

Courses per page: 



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

[View all 4 classes now](#)

\$700.00

[+ Learn More](#)



CDISC Training Discounts

- Discounted training prices for members



You are logged in as **Andrea** | [Log Out](#) 

[Admin Panel](#)

All Courses

Filter by Tags

Courses per page:

Subject

- Module Bundles
- ADaM
- Chinese Translations
- Certification
- BRIND



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

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[+ Learn More](#)

\$700.00





How to Navigate the LMS



How-to Access & Update Your Profile in the LMS

- Click on 'Profile'
- Click on 'Edit profile'
- Click on 'Update profile' to save your changes



Profile

Grades
Messages
Preferences

Log out

Record of Learning Reports Course Catalog Announcements Back to CDISC.org Help

Dashboard / My courses / CDISC Online Training / ADaM / ADAM001: Introduction to ADaM

NAVIGATION

- ▼ Dashboard
 - Home
 - ▶ CDISC Learning
- ▼ My courses
 - ▼ CDISC Online Training
 - ▼ ADaM



Announcements

Welcome

CDISC Educational Materials Intellectual Property Notice

- Sharing, copying, recording or reselling any CDISC educational material is strictly prohibited.
 - This includes classroom and eLearning audio, handouts, slides, quizzes, and all other materials provided as part of CDISC Educational offerings.
 - Scientific information and examples in this course provide context for the instructional

SEARCH FORUMS

Go

Advanced search

How-to Navigate to Your Enrolled Training

- Navigation column is on the left.



✉ 🔔 Andrea Rampone 

🏠 Access Learning Browse Our Course Catalog Certifications Programs Membership Benefits Visit CDISC.org Contact

NAVIGATION

▼ Home

▶ CDISC Learning Management System (LMS)

▼ My courses

▶ CDISC On Demand & Blended Learning

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How-to Navigate on Your Course Page

- Use the ‘**breadcrumbs**’ to navigate throughout course



[Home](#) [Access Learning](#) [Browse Our Course Catalog](#) [Certifications](#) [Programs](#) [Membership Benefits](#) [Visit CDISC.org](#) [Contact](#)

[Home](#) / [My courses](#) / [CDISC On Demand & Blended Learning](#) / [CDASH](#) / [CDASH001: Introduction to CDASH](#)

NAVIGATION

- ▼ Home
 - ▶ CDISC Learning Management System
- ▼ My courses
 - ▼ CDISC On Demand & Blended Learning



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SEARCH FORUMS

Go

Advanced search



Navigating Course Page

- Talk about the different components in a course
 - Videos
 - Activities (H5P preferable)
 - Assessment (show first page)
 - Certificates

How-to Access Your Record of Learning

- Navigate to the **Record of Learning**
- *Access Learning > Record of Learning*



✉ 🔔 Andrea Rampone 

🏠 Access Learning Browse Our Course Catalog Certifications Programs Membership Benefits Visit CDISC.org Contact

- Record of Learning
- Grades Overview
- My Certificates

NAV

- Home
 - CDISC Learning Management System (LMS)
 - My courses
 - CDISC On Demand & Blended Learning



Welcome to the CDISC Learning Management System (LMS)

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Record of Learning

The 'Record of Learning' displays:

- Enrolled Courses
- Course Type
- Course Progress
- Certifications

Record of Learning : All Courses

COURSES

OTHER EVIDENCE

32 records shown

▼ Search by

Course Title ⓘ

contains ▼

Search

Clear

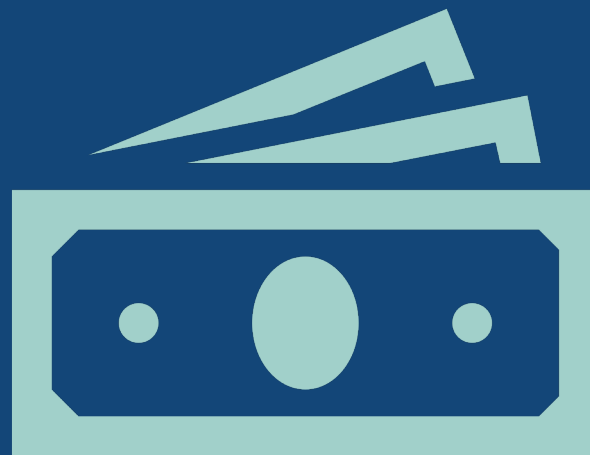
Show more...

Show/Hide Columns

Type	Course Title	Plan	Course due date
📄	CDASH Bundle		
📄	CDASH001: Introduction to CDASH		
📄	CDASH002: Header and Data Comments		

CDISC Member Discounts

Membership Credits



CDISC Member Education Benefits

CDISC Gold Members

\$1,000 online training credit

20% discount on CDISC Online Training

20% discount on CDISC Events

20% discount on ODM Certification

CDISC Platinum Members

\$2,500 online training credit*

40% discount on CDISC Online Training

40% discount on CDISC Events

40% discount on ODM Certification

***Complimentary ½ day** 'CDISC for Newcomers' virtual training

Member Online Training Credit

- To take advantage of this benefit, complete the 'Member Online Training Credit' form

Home / Member Online Training Credit

Member Online Training Credit

Each CDISC member organization receives credit annually to apply to our online training courses. Credit amount is based on membership level:

Gold Member:

Up to \$1,000 credit of [Online Courses](#)

Platinum Member:

Up to \$2,500 credit of [Online Courses](#)

To take advantage of this benefit, please complete the form for each employee that will enroll in the course using his/her organization email address. A CDISC Education representative will respond to your request with additional information within three to five days.

- If you do not use the entire credit amount, the remaining balance can be applied to another online training purchase during the year.
- If you exceed the annual credit amount, you will receive an invoice for the remaining balance with payment instructions.
- Enrollees will be contacted via email with course information once their registration is processed.
- Credits expire annually based on member membership renewal date.
- Credits must be used for individual enrollment in online training and are not to be shared among learners in an organization.
- Credits amounts are per member organization, not per employee.
- **Before requesting enrollment in CDISC online modules, please visit the guidelines for registering on our Learning Management System.**

For more information, please contact CDISC Education onlinetrainingsupport@cdisc.org.

First Name *

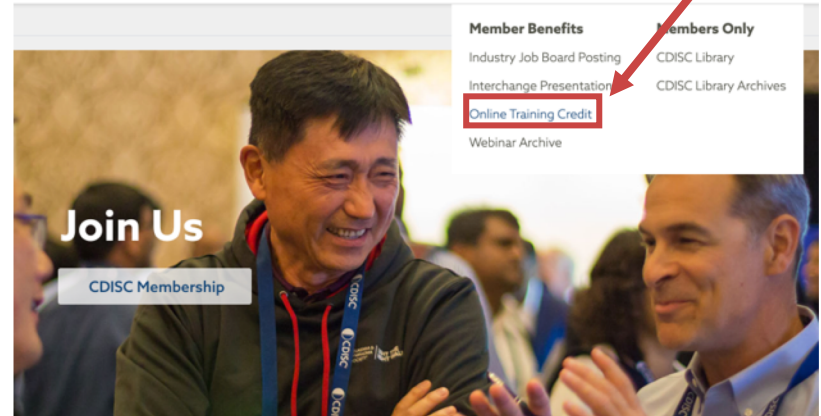
Last Name *

Email *

Work Phone



[New to CDISC](#) [Standards](#) [Education](#) [Resources](#) [Events](#) [Membership](#) [Members Only](#)



Member Online Training Credit

Enrollees will be contacted via email with course information once their registration is processed.



Training Credit Balance

For online training credit balance contact
onlinetrainingsupport@cdisc.org



Training Credit Distribution

Credit amounts are per member organization,
not per employee



Remaining Credit Balance

Remaining balance can be applied to another online training purchase during the year.



Invoice for Remaining Balance

If you exceed the annual credit amount, you will receive an invoice



Credit Expiration Date

Credits expire annually based on member membership renewal date.





CDISC Training Support



Online Training Support

Contact onlinetrainingsupport@cdisc.org





General Training Questions

Contact training@cdisc.org





Thank you!



Does my training expire?

- Your CDISC training does not expire.





CDISC Tabulate Certification



Origins of the CDISC Certification Program

2018-2019 Blue Ribbon Commission Report

- A Clinical Standards Certification:
 - builds strong standards ecosystem,
 - improves homogeneity of implementation, and
 - provides substrate for company-level certification

CDISC Certification Benefits

Validate Skills

Assess Potential Hires

Provide Clients With Proven Expertise



Tabulate Certification

Demonstrates knowledge and the competency necessary to utilize the SDTM and the SDTMIG.

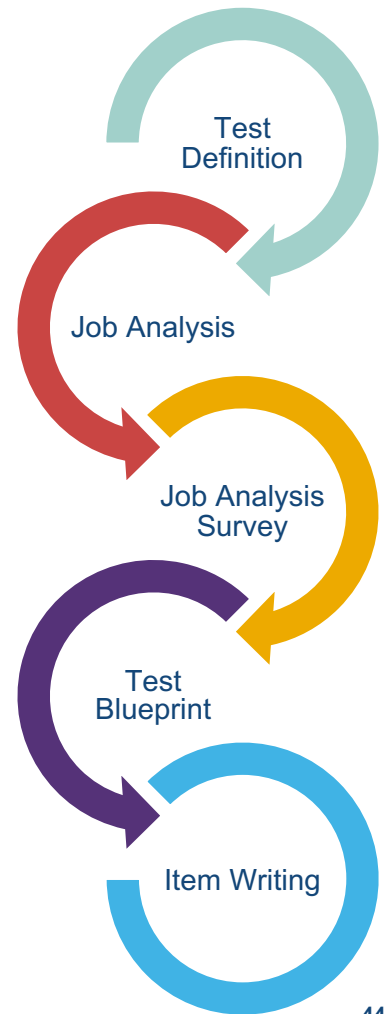
CDISC Tabulate Certification requirements:

- Three years of experience with the CDISC standards is recommended
- Register for the certification and pay the corresponding fee
- Pass the CDISC Tabulate Certification Exam



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



Exam Scope

- Exam Domains and Corresponding Weight
 - Example: General Concepts, Terms and Assumptions, and Conformant Dataset Structure (30%)
- Knowledge and Skill Statements for each Exam Domain:
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



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



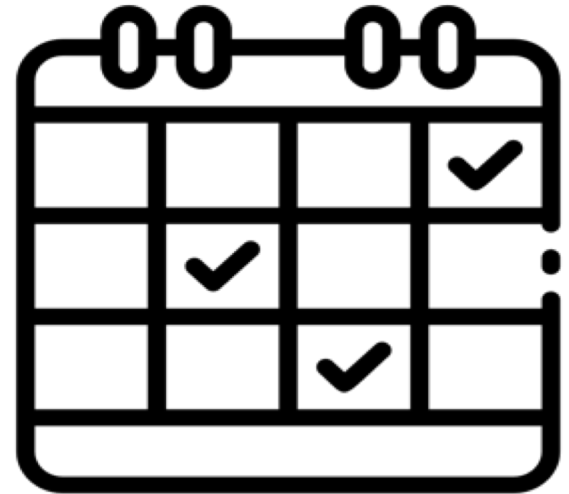
Certification Fees

- \$500 exam fee
- \$300 discounted pilot rate (through FEB 2021)
- No annual maintenance fees
- Recertification required every three years
- \$500 recertification exam fee



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
- Research specific requirements of your exam location

Exam results

Pilot session: pass/fail result available up to 6 weeks after session's end

Regular session: results available immediately

If successful: single "Pass" grade

If unsuccessful: domain-specific feedback will be provided



Certification Maintenance



No maintenance fees (New!)

Every 3 years: exam re-take to ensure currency of knowledge

\$500 recertification exam fee (New!)

Pilot session specificities

Reduced price

Slightly longer exam

Exam results not available immediately

Limited seats – first 150 registrants



Changes to Certification Processes

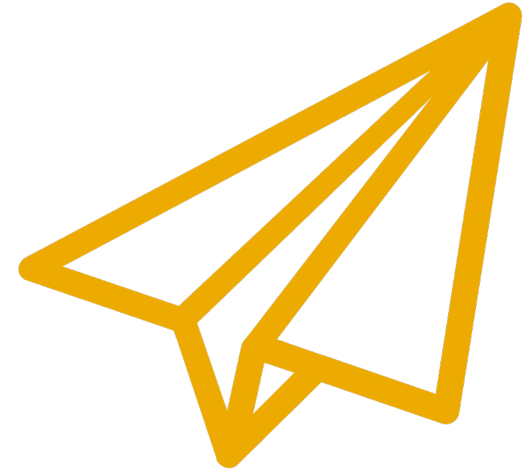
- Changes based on CDISC Community feedback:
 - No annual \$300 maintenance fee
 - \$500 flat recertification exam fee every 3 years
 - No work experience required
 - Pilot period extended to FEB 28 2021
 - Group Discounts (contact certification@cdisc.org for info)
- CDISC will continue to improve Certification program





CDISC Certification Questions

Contact certification@cdisc.org



Thank You!

Upcoming Training Opportunities



Blended Learning

Public Training

- Registration open to all
- **First 2021 event begins today! Contact syousef@cdisc.org to be enrolled.**
 - Next opportunity for SDTM, CDASH, and ADaM in May
- English and Japanese (separately)
- Full details here: <https://www.cdisc.org/education/online-training/blended-learning>

Private Training

- Exclusive to your organization
- Membership not required
- Available all year
- Submit request online: <https://www.cdisc.org/contact>

Virtual Classroom Training

Public Training

- Registration open to all
- Next opportunity in March: CDASH, SDTM, ADaM, XML, and more
- English language (Japanese and Mandarin sessions available later in year)
- Full details here: <https://www.cdisc.org/education/virtual-classroom-training>

Private Training

- Exclusive to your group
- Membership not required
- Available all year
- Submit request online: <https://www.cdisc.org/contact>



In-Person Training

*Public and private training on hold until
further notice*

Questions



Use CDISC contact form:
<https://www.cdisc.org/contact>



Contact general EDU inbox:
training@cdisc.org



Contact Saad directly: syousef@cdisc.org



2021 EUROPE INTERCHANGE

With Standards - Science Will Prevail!



Live Stream | 28-30 April

Conference | Trade Show | TechniCon

NEXT GENERATION TECHNOLOGY SOLUTIONS

TechniCon

30 APRIL 2021

A VIRTUAL CDISC EVENT

2021



2021 JAPAN INTERCHANGE

With Standards - Science Will Prevail!



Live Stream | 10-11 June

Conference | Trade Show



2021 CHINA INTERCHANGE

With Standards – Science Will Prevail!



Beijing | 6-7 August

Conference | Trade Show



2021 US INTERCHANGE

With Standards – Science Will Prevail!



Washington, DC | 18-22 October

Conference | Trade Show



2021 Webinars

Date	Webinar Title
4 FEB	Public Review Webinar: COVID-19 Therapeutic Area User Guide Update
23 FEB	What's Different about SDTM for Clinical and Non-Clinical Trials
2 MAR	Current and Forthcoming ADaM Publications
16 MAR	QRS "Office Hours"
25 MAR	Public Review Webinar: Pancreatic Cancer Therapeutic Area User Guide
1 APR	Controlled Terminology Updates for Q1 2021
1 JUL	Controlled Terminology Updates for Q2 2021
Coming Soon	CDASH "Office Hours"; ADaM "Office Hours"; CDISC Library Update

Visit <https://www.cdisc.org/education/webinars> for information on additional Public Training events.



Account/Login questions:
onlinetrainingsupport@cdisc.org

Certification questions:
certification@cdisc.org

General Training questions:
training@cdisc.org

Thank you!