

# Level Up Your Clinical Data Skills with CDISC Education

16 July 2024

**Morgan Dancy**, Senior Manager of CDISC Education

**Nick De Donder**, Head of Data Standards, E3C Chair, Business & Decision Life Sciences

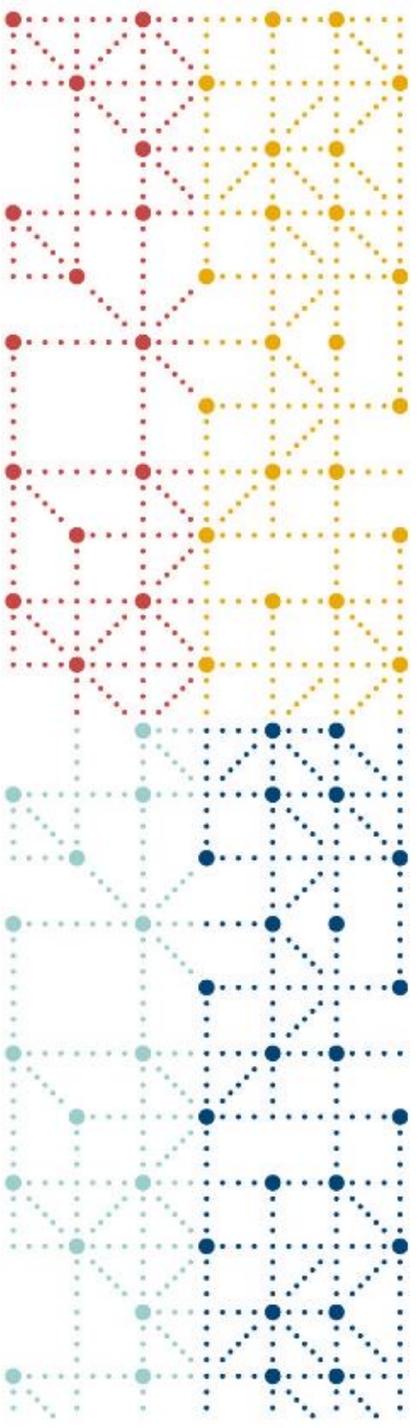
**John Ezzell**, Head of CDISC Education

**Lisa Mulcahy**, Owner of Mulcahy Consulting

**Dawn Niccum**, Executive Vice President, QA & Compliance, InSeption Group

**Mackenzie Voots**, Manager of CDISC Education





# Agenda

1. 2024 Education Update
2. New Training Updates
3. Upcoming Public Training Schedule
4. CDISC Learning Management System Demo
5. Private Training
6. SDTM Advanced Hands-On Implementation
7. Trial Master File Overview

# CDISC Education Team



**John Ezzell**  
Head of Education

- Oversees Education Departmental Operations
- Directs Curriculum and Instruction
- Manages and Develops Educational Partnerships



**Morgan Dancy**  
Senior Manager of Education

- Oversees Public Training Schedule
- Manages Training Development
- Coordinates Instructor Authorization



**Mackenzie Voots**  
Education Manager

- Oversees Private Training Schedule
- Manages Learning Management System (LMS)
- Leads Publication of Trainings

# CDISC Education Goals and Purpose

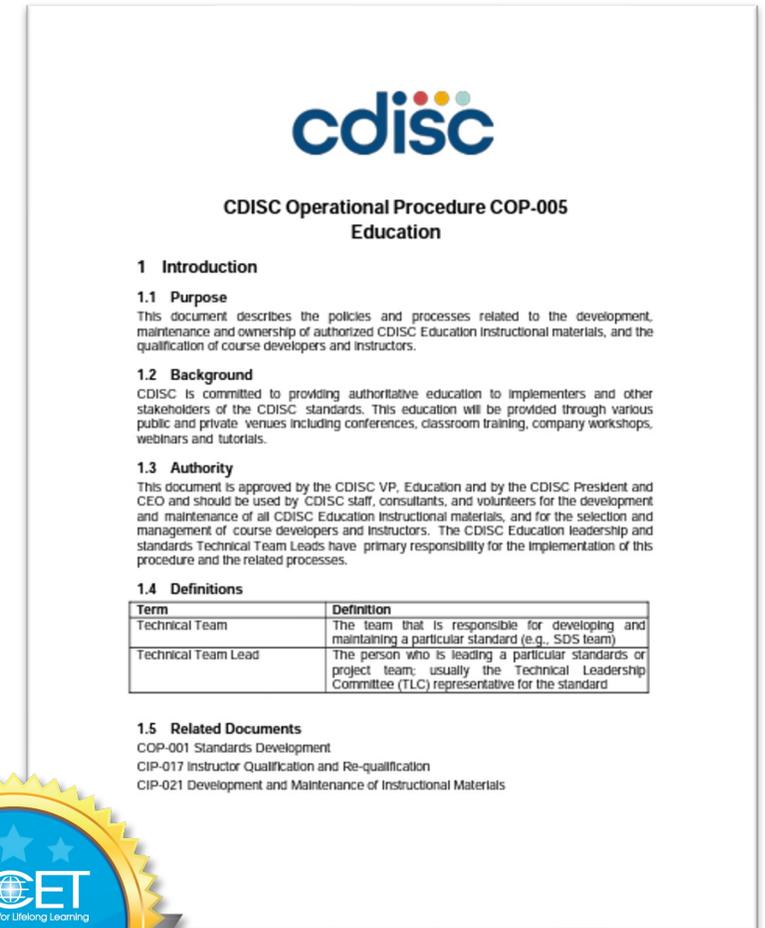
## Education in CDISC Charter

- *CDISC is committed to providing authoritative education to implementers and other stakeholders of the CDISC standards*

## IACET Certification

- Accredited in 2018
- Benchmark for Instruction and Training Development
- Allows CDISC to issue Continuing Education Units (CEUs) and certification
- Independent audit of program processes

## Vendor Neutral / Inclusive



# CDISC Education by the Numbers: 2012-2024



**75,000+ Training Module Enrollments**



**16,000+ Training Accounts Created**

# 2023 Instructor-Led CDISC Training Events



**1000+ Trainees**



**22 Training Clients**



**32 Live Training Events**

# CDISC Authorized Instructors



39 Instructors

The screenshot shows a list of authorized instructors with their names, photos, and contact information. Visible names include Josef Aerts, Yashika Arora, and Anne-Sophie Balle.



14 Countries

The photo shows a group of approximately 14 individuals, likely the authorized instructors, standing together in front of a backdrop that reads "CDISC Virtual Course" and "Developed under the authority of the CDISC Team." The backdrop also includes the CDISC logo and the year "©CDISC 2021".



CDISC  
Coordinating  
Committees  
Leaders

Most instructors  
have 20+ years  
clinical data  
experience



6 new instructors  
since 2022

# Trainings



Virtual Trainings



In-Person Trainings



On-Demand (self-paced modules)



Certifications

# CDISC Training Areas of Focus



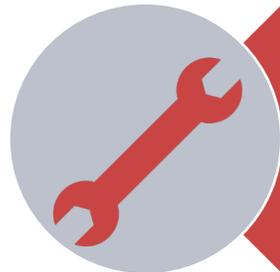
## CDISC Standards & Publications

- Foundational Standards
- Implementation Guides
- Therapeutic User Guides



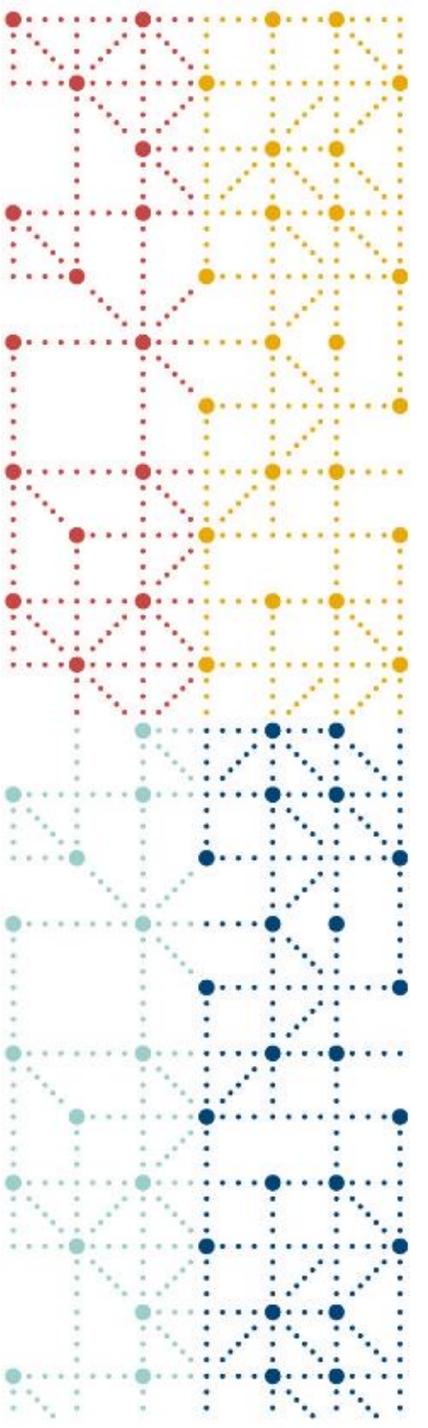
## Training by Audiences

- Experts and Newcomers
- Academics
- Reviewers



## Tools

- CDISC Library
- CORE



# CDISC Education Projects & Training Schedule

# NEW 2024 Trainings & Trainings In Progress

TMF Reference Model for Biometrics Professionals

SDTM On-Demand 2.0 Training

Learning Health Education Alliance (LHEA) On-Demand Training

Tobacco Implementation Guide (TIG) Training



Introduction to the TMF Module (English/日本語)



SDTM Theory and Application (日本語 Translation)



SDTM Theory and Application (中国人 Translation)

<https://learnstore.cdisc.org>

# NEW Hands-On Implementation Trainings In Progress

SDTM Advanced with Hands-On Implementation Component

ADaM Advanced with Hands-On Implementation Component

ARSD

CORE Hands-On Implementation Training

Dataset-JSON Hands-On Implementation Training

2024 CDISC + TMF  
US INTERCHANGE

**PHOENIX/SCOTTSDALE**

23-24 OCTOBER: CONFERENCE & EXPO | 21, 22, 25 OCTOBER: TRAININGS

<https://learnstore.cdisc.org>

# Hands-On Implementation Lesson Plan Template

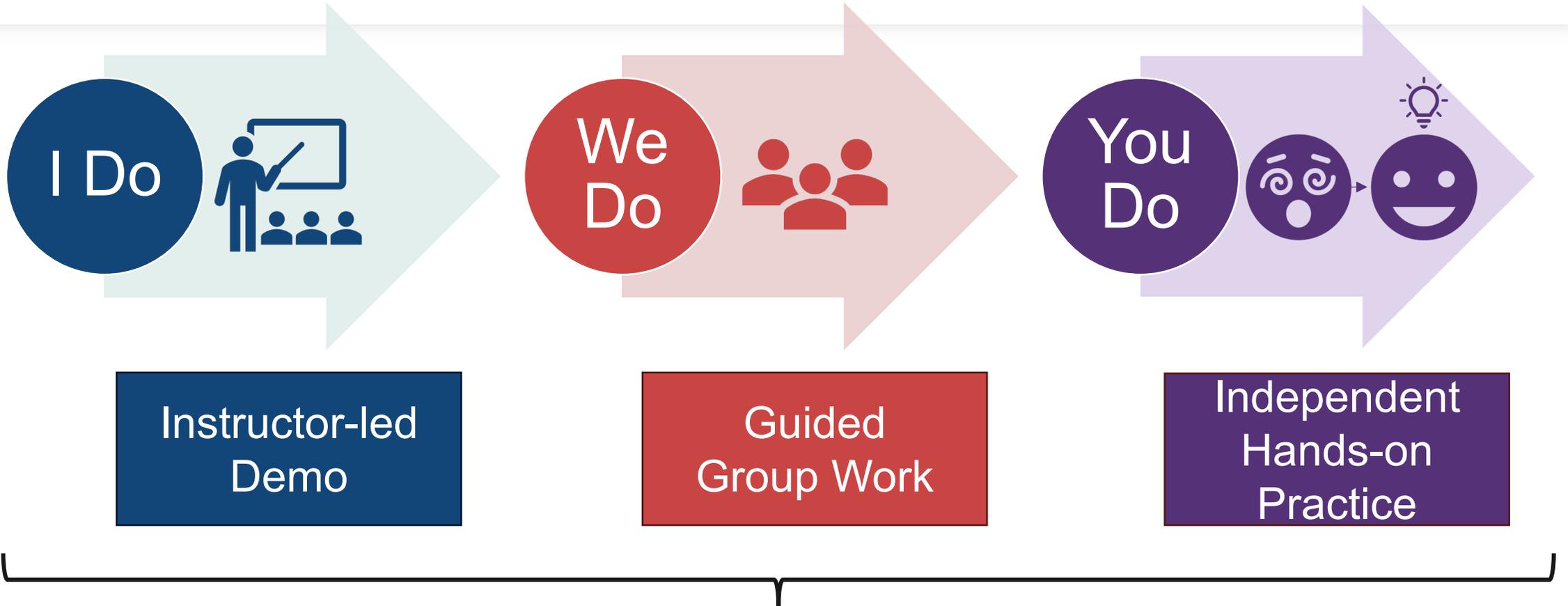
Lesson Plan Template for Instructors/Developers

"I Do, We Do, You Do" Instructional Model

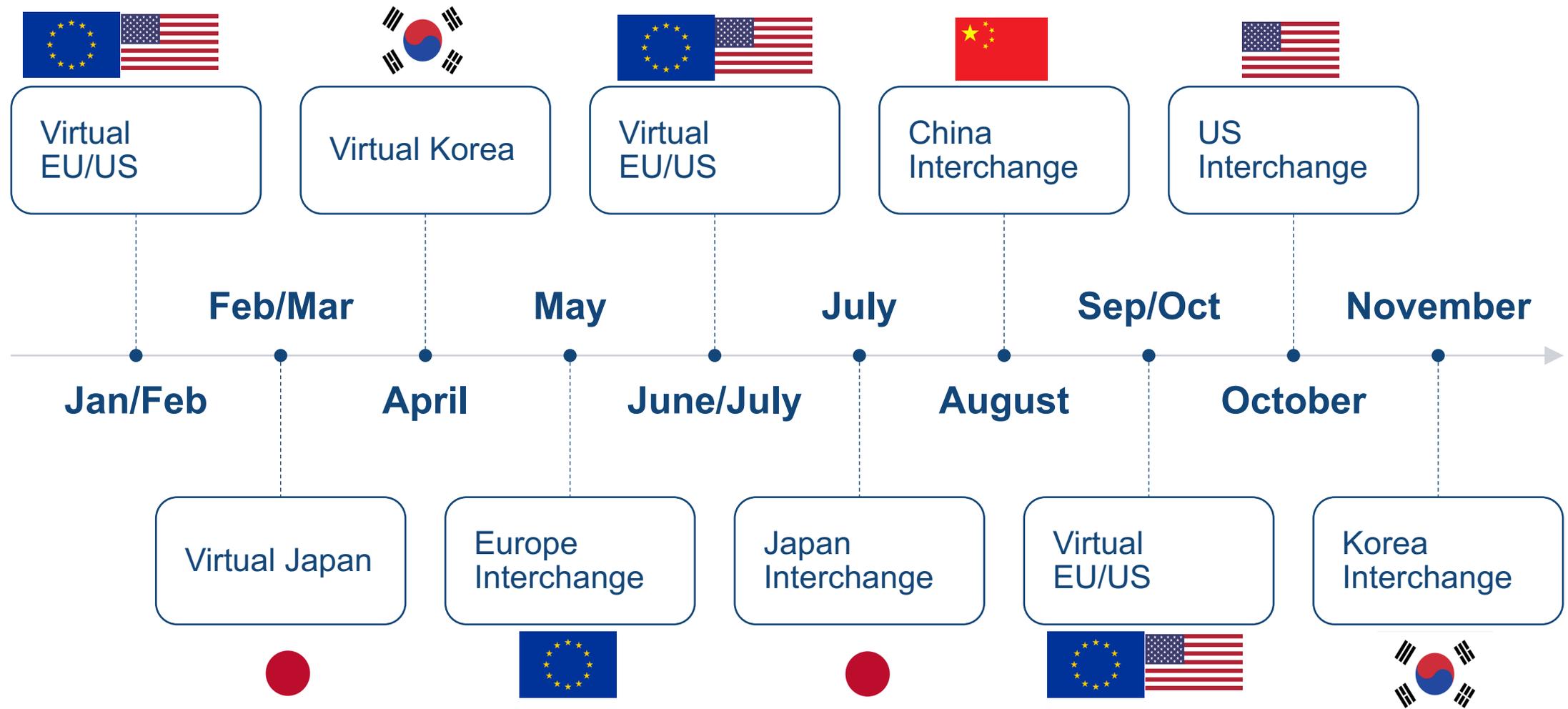
Template Includes Engagement Strategies

- Prior Knowledge Assessments
- Checks for Understanding
- Exit Slips

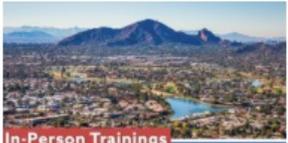
# "I Do, We Do, You Do" Instructional Model



# 2025 Public Training Schedule



# Upcoming Public Training Events

|  |  |   |   |
|--|--|---|---|
|  <p>In-Person Trainings</p> <p><b>SHANGHAI,<br/>CHINA</b></p> <p>28-29 August 2024</p> <p><b>Shanghai</b></p> |  <p>In-Person Trainings</p> <p><b>SCOTTSDALE,<br/>ARIZONA</b></p> <p>21-25 October 2024</p> <p><b>Scottsdale</b></p> |  <p>In-Person Trainings</p> <p><b>SEOUL,<br/>KOREA</b></p> <p>11,14,15 November 2024</p> <p><b>Seoul</b></p> | <p><b>SEPTEMBER</b></p> <p><b>EUROPE</b></p> <p>VIRTUAL TRAINING<br/>EVENT</p> <p><b>2024 Virtual<br/>Event</b></p> |
|--|--|---|---|

|  |  |  |   |
|--|--|--|---|
| <p><b>JANUARY-<br/>FEBRUARY</b></p> <p><b>EUROPE &amp; US</b></p> <p>VIRTUAL TRAINING<br/>EVENT</p> <p><b>2025 Virtual<br/>Event</b></p> | <p><b>FEBRUARY-<br/>MARCH</b></p> <p><b>JAPAN</b></p> <p>VIRTUAL TRAINING<br/>EVENT</p> <p><b>2025 Virtual<br/>Event</b></p> | <p><b>JUNE - JULY</b></p> <p><b>EUROPE &amp; US</b></p> <p>VIRTUAL TRAINING<br/>EVENT</p> <p><b>2025 Virtual<br/>Event</b></p> | <p><b>SEPTEMBER-<br/>OCTOBER</b></p> <p><b>EUROPE &amp; US</b></p> <p>VIRTUAL TRAINING<br/>EVENT</p> <p><b>2025 Virtual<br/>Event</b></p> |
|--|--|--|---|

<https://learnstore.cdisc.org>

# January Virtual Event



## Registration Opens Soon!

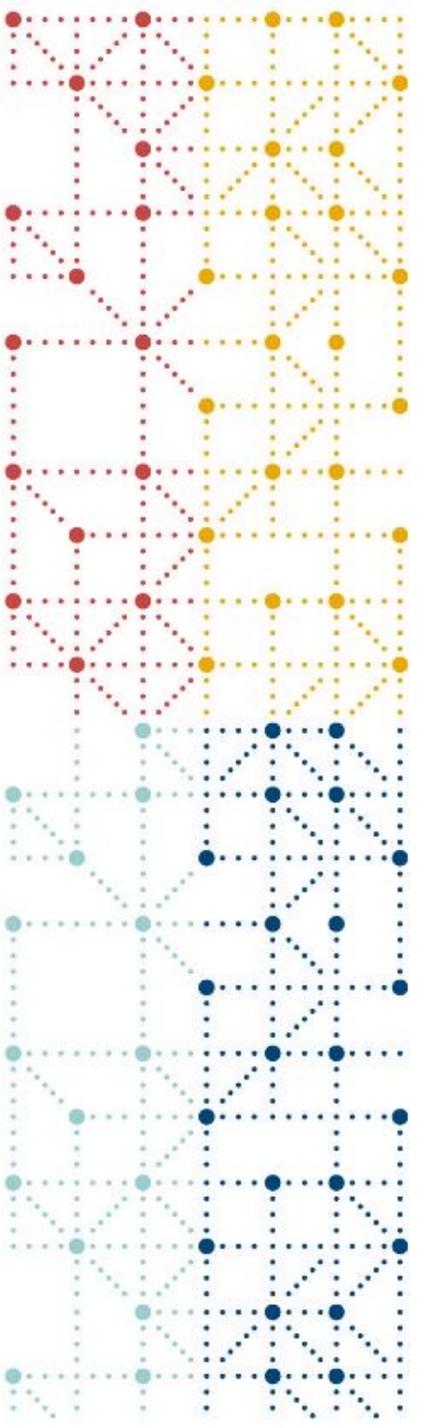
January/February 2025 Virtual Training Event (Zoom)

*All trainings begin at 9:00am US Eastern Time (15:00 Central European Time).*

*Trainings are open to the general public, regardless of region.*

Use [World Time Buddy](#) to convert to your time zone.

|   |                     |                                 |
|---|---------------------|---------------------------------|
| CDISC for Newcomers                                     | 6 January 2025      | 9:00 am - 12:00 pm Eastern Time |
| Controlled Terminology                                  | 7 January 2025      | 9:00 am - 100 pm Eastern Time   |
| CDASH Fundamentals                                      | 8-10 January 2025   | 9:00 am - 12:00 pm Eastern Time |
| SEND Implementation                                     | 13-17 January 2025  | 9:00 am - 12:00 pm Eastern Time |
| Fundamentals of the TMF Reference Model                 | 21-23 January 2025  | 9:00 am - 12:00 pm Eastern Time |
| Trial Master File for Biometrics Professionals          | 28 January 2025     | 9:00 am - 12:00 pm Eastern Time |
| SDTM Theory and Application<br>(SDTM v1.7, SDTMIG v3.3) | 27-31 January 2025  | 9:00 am - 12:30 pm Eastern Time |
| ADaM Core Theory & Application                          | 4-6 February 2025   | 9:00 am - 12:00 pm Eastern Time |
| Define-XML  | 11-13 February 2025 | 9:00 am - 12:00 pm Eastern Time |



# CDISC Learning Management System

# Activate Your CDISC Learning Account

1

Sign up for a cdiscID

2

Visit learn.cdisc.org

# CDISC Learning

## Learner Dashboard

## TRAININGS

### ▼ Dashboard

- Home
- ▼ My courses

#### ▼ CDISC Live Trainings

- ▶ CDISC for Newcomers
- ▶ Controlled Terminology

#### ▼ CDASH

- CDASH Fundamentals
- CDASH Advanced

- ▶ SDTM
- ▶ ADaM
- ▶ Define-XML
- ▶ ODM
- ▶ SEND
- ▶ TMF

#### ▼ CDISC On-Demand Trainings

- ▶ CDASH
- ▶ SDTM
- ▶ ADaM

## CURRENT LEARNING

|  |   |                                     |
|--|---|-------------------------------------|
|  | CT Module 2: Controlled Terminology Metadata and File Formats | <div style="width: 57%;"></div> 57% |
|  | Define-XML  | <div style="width: 50%;"></div> 50% |
|  | Define-XML Module 2: Submission Datasets and Variables        | <div style="width: 0%;"></div> 0%   |
|  | Fundamentals of the TMF Reference Model                       | <div style="width: 0%;"></div> 0%   |
|  | Define-XML Module 2: Submission Datasets and Variables        | <div style="width: 0%;"></div> 0%   |
|  | Fundamentals of the TMF Reference Model                       | <div style="width: 0%;"></div> 0%   |
|  | SDTM Changes & Updates (SDTM v1.7-2.0, SDTMIG v3.3-3.4)       | <div style="width: 0%;"></div> 0%   |
|  | SDTM for Medical Devices                                      | <div style="width: 0%;"></div> 0%   |
|  | SDTM Module 1: Introduction                                   | <div style="width: 0%;"></div> 0%   |
|  | SDTM Module 2: SDTM Basics                                    | <div style="width: 0%;"></div> 0%   |

Displaying 1 - 10 of 101 results



## Upcoming Events

## CALENDAR

July 2024

| 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 |    |    |    |

## ALERTS

- Training Booking Confirmation: SDTM Public Training, 9:00 AM-12:30 PM, 16 September 2024

- Home
- My courses
  - CDISC Live Trainings
    - CDISC for Newcomers
    - Controlled Terminology
    - CDASH
      - CDASH Fundamentals
      - CDASH Advanced
    - SDTM
    - ADaM
    - Define-XML
    - ODM
    - SEND
    - TMF
  - CDISC On-Demand Trainings
    - CDASH
    - SDTM
    - ADaM
    - Define-XML
    - Tobacco Implementation Guide (TIG)
- More...

|   |    |
|---|----|
| Fundamentals of the TMF Reference Model                 | 0% |
| Define-XML Module 2: Submission Datasets and Variables  | 0% |
| Fundamentals of the TMF Reference Model                 | 0% |
| SDTM Changes & Updates (SDTM v1.7-2.0, SDTMIG v3.3-3.4) | 0% |
| SDTM for Medical Devices                                | 0% |
| SDTM Module 1: Introduction                             | 0% |
| SDTM Module 2: SDTM Basics                              | 0% |

Displaying 1 - 10 of 101 results

« 1 2 3 4 5 6 7 8 9 10 11 »

### MODELS AND IGS

### CALENDAR

July 2024

| 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 |    |    |    |

### ALERTS

Training Booking Confirmation: SDTM Public Training, 9:00 AM-12:30 PM, 16 September 2024

### UPCOMING EVENTS

There are no upcoming events

Go to calendar...

New event...

### LAST COURSE ACCESSED

Define-XML

50%

### LATEST BADGES

CDISC Tabulate Certification



### PRIVATE FILES

Training

Manage private files...



## ▼ Dashboard

■ Home

## ▼ My courses

▶ CDISC for Newcomers

▶ Controlled Terminology

## ▼ CDASH

▼ **CDASH Fundamentals**

▶ Participants

🏆 Badges

📖 Grades

■ CDASH Advanced

▶ SDTM

▶ ADaM

▶ Define-XML

▶ ODM

▶ SEND

▶ TMF

▶ Controlled Terminology

▶ CDASH

▶ CDISC Live Trainings

▶ CDISC On-Demand Trainings

■ More...

# CDASH Fundamentals

🗨️ Announcements

## Public Training Schedule

**Please allow 24 hours after training registration for your automatic booking confirmation.***View-only recordings will be available for 2 weeks.*

👤 CDASH Public Training

| Event status             | Booked | Session times   | Rooms                         | Facilitators                            | Actions   |
|--------------------------|--------|---|-------------------------------|---|---|
| Upcoming<br>Booking open | 3 / 30 | September 13, 2024, 9:00 AM - 12:00 PM<br>Timezone: Europe/Copenhagen | Europe (Virtual)<br>Session 3 | Nick De Donder<br>Roger Gagali<br>Angoh | <a href="#">Go to event</a> <a href="#">...</a> |
|                          |        | September 12, 2024, 9:00 AM - 12:00 PM<br>Timezone: Europe/Copenhagen | Europe (Virtual)<br>Session 2 | Nick De Donder<br>Roger Gagali<br>Angoh |   |
|                          |        | September 11, 2024, 9:00 AM - 12:00 PM<br>Timezone: Europe/Copenhagen | Europe (Virtual)<br>Session 1 | Nick De Donder<br>Roger Gagali<br>Angoh |   |
| Upcoming<br>Booking open | 2 / 30 | October 22, 2024, 9:00 AM - 6:00 PM<br>Timezone: America/Phoenix      | US Interchange (In-Person)    | Jerry Salyers                           | <a href="#">Go to event</a> <a href="#">...</a> |

[View all events](#)

### Private Training Schedule

### Welcome

### CDASH Fundamentals Overview

### Training Material

### Activity 1-1

©CDISC 2024

### Activity 1-2

Your progress



### QUICK LINKS



Controlled Terminology  
 CDASH  
 SDTM  
 SDTMIG  
 ADaM  
 Define-XML  
 SEND  
 ODM  
 TAUGS

### GENERAL RESOURCES



#### CDISC Contacts and Links

- CDISC Education inquiries: [training@cdisc.org](mailto:training@cdisc.org)
- CDISC Membership inquiries: [membership@cdisc.org](mailto:membership@cdisc.org)
- CDISC general inquiries: [info@cdisc.org](mailto:info@cdisc.org)
- CDISC Website
- CDISC User Networks
- NCI EVS Controlled Terminology
- CDISC Glossary

#### Regulatory and Other Resources

*Monitor regulatory websites for updated versions*

- US FDA
  - CDER data issues: [cdcr-edata@fda.hhs.gov](mailto:cdcr-edata@fda.hhs.gov)
  - CDER submission issues: [cdcr-esub@fda.hhs.gov](mailto:cdcr-esub@fda.hhs.gov)

Activity 3A-2

Activity 3B-1

Activity 3B-2

Review the CRF then drag each variable to the correct place on the CRF.

### Case Report Form

|         |      |         |             |            |
|---------|------|---------|-------------|------------|
| ABC-654 | 53C  | 2301    | 25-Mar-2013 | WEEK THREE |
| STUDY   | SITE | SUBJECT | DATE        | VISIT      |

Were VITAL SIGNS collected?  Yes  No

|                  | TIME<br>(24-hr clock) | PULSE RATE<br>(beats/min)         | RESPIRATORY RATE<br>(breaths/min) | SYSTOLIC<br>BLOOD PRESSURE        | DIASTOLIC<br>BLOOD PRESSURE       | TEMPERATURE  |
|------------------|-----------------------|-----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|--|
| Pre-Dose         | 07:58                 | 76                                | 12                                | 120                               | 74                                | 37<br>C <input checked="" type="checkbox"/> F <input type="checkbox"/> |
|                  | H H : M M             | <input type="checkbox"/> NOT DONE | <input type="checkbox"/> NOT DONE | <input type="checkbox"/> NOT DONE | <input type="checkbox"/> NOT DONE | <input type="checkbox"/> NOT DONE                                      |
| 30 Min Post Dose | 08:30                 | 74                                | 11                                | 128                               | 90                                | 37<br>C <input checked="" type="checkbox"/> F <input type="checkbox"/> |
|                  | H H : M M             | <input type="checkbox"/> NOT DONE | <input type="checkbox"/> NOT DONE | <input type="checkbox"/> NOT DONE | <input type="checkbox"/> NOT DONE | <input type="checkbox"/> NOT DONE                                      |
| 90 Min Post Dose | 09:30                 | 73                                | 11                                | 118                               | 72                                | 37<br>C <input checked="" type="checkbox"/> F <input type="checkbox"/> |
|                  | H H : M M             | <input type="checkbox"/> NOT DONE | <input type="checkbox"/> NOT DONE | <input type="checkbox"/> NOT DONE | <input type="checkbox"/> NOT DONE | <input type="checkbox"/> NOT DONE                                      |
| 2 Hr Post Dose   | 10:05                 | 68                                | 11                                | 110                               | 70                                | 37<br>C <input type="checkbox"/> F <input type="checkbox"/>            |
|                  | H H : M M             | <input type="checkbox"/> NOT DONE | <input type="checkbox"/> NOT DONE | <input type="checkbox"/> NOT DONE | <input type="checkbox"/> NOT DONE | <input checked="" type="checkbox"/> NOT DONE                           |

cdisc

VSORRES

VSSTAT

STUDYID

VSTEST

VISDAT

SITEID

VSPERF

SUBJID

VISIT

VSORRESU

VSTIM

VSTPT

Check

Activity 3B-2

Activity 4

Activity 5

Activity 6

CDISC Contacts and Links

- CDISC Education inquiries: [training@cdisc.org](mailto:training@cdisc.org)
- CDISC Membership inquiries: [membership@cdisc.org](mailto:membership@cdisc.org)
- CDISC general inquiries: [info@cdisc.org](mailto:info@cdisc.org)
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  - CDER submission issues: [cdcr-esub@fda.hhs.gov](mailto:cdcr-esub@fda.hhs.gov)
  - Study Data Standards
  - CDRH standards page
- Japan PMDA
- China NMPA
- ICH
- LinkedIn CDISC Groups
  - Official CDISC LinkedIn Group
  - CDISC Standards Discussion Groups
    - Search for name of standard
- PhUSE

TIPS FOR VIEWING METADATA

Click  to view full screen.



Activity 3A-2

Activity 3B-1

Activity 3B-2

Review the CRF then drag each variable to the correct place on the CRF.

**Case Report Form**

STUDYID ✓ SITEID ✓ SUBJID ✓ VISIT ✗ VISDAT ✗

VSPERF ✓

|         |      |         |             |            |
|---------|------|---------|-------------|------------|
| ABC-654 | 53C  | 2301    | 25-Mar-2013 | WEEK THREE |
| STUDY   | SITE | SUBJECT | DATE        | VISIT      |

Were VITAL SIGNS collected?  Yes  No

VSTEST ✓ VSORRESU ✓

| VSTPT ✓          | VSTIM ✓ | TIME<br>4-hr clock | PULSERATE<br>(beats/min)          | RESPIRATORYRATE<br>(breaths/min)  | VSORRES ✓ | VSSTAT ✓ | SYSTOLIC<br>BLOOD PRESSURE        | DIASTOLIC<br>BLOOD PRESSURE       | TEMPERATURE  |
|------------------|---------|--------------------|-----------------------------------|-----------------------------------|-----------|----------|-----------------------------------|-----------------------------------|--|
| Pre-Dose         | 07:58   | 07:58              | 76                                | VSORRES                           |           |          | 120                               | 74                                | 37<br>C <input checked="" type="checkbox"/> F <input type="checkbox"/> |
|                  |         | HH:MM              | <input type="checkbox"/> NOT DONE | <input type="checkbox"/> NOT DONE |           |          | <input type="checkbox"/> NOT DONE | <input type="checkbox"/> NOT DONE | <input type="checkbox"/> NOT DONE                                      |
| 30 Min Post Dose | 08:30   | 08:30              | 74                                | VSSTAT                            |           |          | 128                               | 90                                | 37<br>C <input checked="" type="checkbox"/> F <input type="checkbox"/> |
|                  |         | HH:MM              | <input type="checkbox"/> NOT DONE | <input type="checkbox"/> NOT DONE |           |          | <input type="checkbox"/> NOT DONE | <input type="checkbox"/> NOT DONE | <input type="checkbox"/> NOT DONE                                      |
| 90 Min Post Dose | 09:30   | 09:30              | 73                                | 11                                |           |          | 118                               | 72                                | 37<br>C <input checked="" type="checkbox"/> F <input type="checkbox"/> |
|                  |         | HH:MM              | <input type="checkbox"/> NOT DONE | <input type="checkbox"/> NOT DONE |           |          | <input type="checkbox"/> NOT DONE | <input type="checkbox"/> NOT DONE | <input type="checkbox"/> NOT DONE                                      |
| 2 Hr Post Dose   | 10:05   | 10:05              | 68                                | 11                                |           |          | 110                               | 70                                | 37<br>C <input type="checkbox"/> F <input type="checkbox"/>            |
|                  |         | HH:MM              | <input type="checkbox"/> NOT DONE | <input type="checkbox"/> NOT DONE |           |          | <input type="checkbox"/> NOT DONE | <input type="checkbox"/> NOT DONE | <input checked="" type="checkbox"/> NOT DONE                           |

cdisc

10/12 Retry

Activity 3B-2

Activity 4

Activity 5

Activity 6

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    - Search for name of standard
- PhUSE

TIPS FOR VIEWING METADATA

Click  to view full screen.



## Activity 6

### Course Evaluation Survey

Please complete the survey to let us know what you thought of the class, the instruction, and the materials.

You must complete this survey to gain access to your Certificate of Attendance and the Final Assessment.

Course Evaluation Survey

Course Evaluation Survey

### Certificate of Attendance

### Final Assessment

This comprehensive exam covers material from the CDASH Fundamentals Virtual Training.

Final Assessment

CDASH Implementation Final Assessment

Not available unless: The activity **Course Evaluation Survey** is marked complete

### Certificate of Achievement

The Certificate of Achievement is available when you complete the Course Evaluation Survey and achieve a required score of 80% or higher on the Final Assessment.

Certificate of Achievement

Certificate of Achievement

Not available unless:

- The activity **Course Evaluation Survey** is marked complete
- The activity **CDASH Implementation Final Assessment** is complete and passed

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- LinkedIn CDISC Groups
  - Official CDISC LinkedIn Group
  - CDISC Standards Discussion Groups
    - Search for name of standard
- PhUSE

#### TIPS FOR VIEWING METADATA

Click  to view full screen.



# Certificate of Achievement and IACET CEUs



*To be granted IACET Accredited Provider designation, organizations apply demonstrating they are compliant with the ANSI/IACET 1-2018 Standard for Continuing Education and Training. The Accredited Provider (AP) application and review is a rigorous process that involves extensive hands-on evaluation.*

**Earn CEUs by completing a training and passing its final assessment.**

# Badges

Hands-On Implementation Trainings



Certification Programs



# Show Off Your Certificates and Badges!

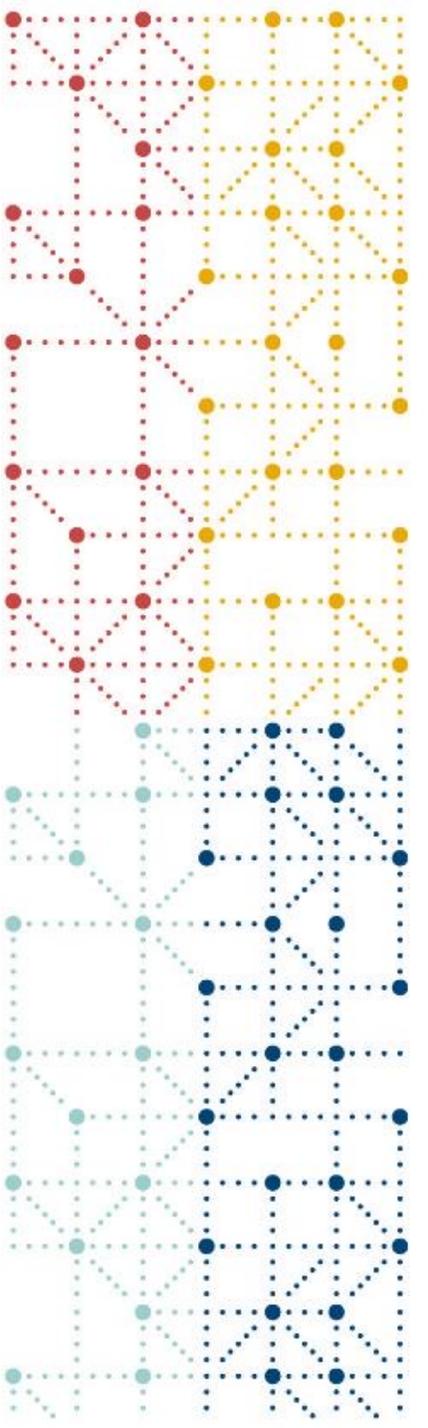


Add badges to your signature



Share on LinkedIn

The screenshot shows a web browser window displaying the CDISC Public Badge Verification Link page. The page features the CDISC logo at the top, followed by a navigation menu. The main heading is "Public Badge Verification Link" with a sub-note: "\*Badges are listed on your [profile page](#)". Below this, there is a circular badge icon with "CDISC CERTIFIED" text. The page is organized into sections: "Recipient details" (Name: Test CDISC ID), "Issuer details" (Issuer name: CDISC), "Badge details" (Name: CDISC Tabulate Certification, Description: The CDISC Tabulate Certification demonstrates that the recipient has attained knowledge and the competency necessary to utilize the SDTM and the SDTMIG. CDISC Tabulate Certification. Course: CDISC Tabulate Certification. Users are awarded this badge when they complete the following requirement: This badge has to be awarded by a user with the following role: Site Manager), and "Badge expiry" (Date issued: Tuesday, July 9, 2024, 6:58 PM; Expiry date: Friday, July 9, 2027, 6:58 PM).



# Private Trainings

# Private Trainings – Tailored to Your Team’s Needs

## Client Audience/Documentation Review

*Included*

- Learner preliminary survey
  - Audience roles, experience, topics of interest
- General review of sample documents if provided (CRFs, datasets...)

## Customization

*Additional Fee*

- Custom topics
- Significant focus on existing topics
- Additional hours of review and feedback on sample documents
- Custom activities created using sample documents, requested domains, specific tools, etc.
- Private learning environment (documents, Q&A forum with instructor...)

# Examples

Instructions: Map the data from the CRF below into the CDASH dataset underneath.

## Demographics

Race **RACE**

Asian **ASIAN\_CRACE**

Thai **THAI\_CRACE**

Cambodian **CAMBODIAN\_CRACE**

Indonesian **INDONESIAN\_CRACE**

Black **BLACK\_CRACE**

Botswanan **BOTSWANAN\_CRACE**

Namibian **NAMIBIAN\_CRACE**

Other, (please specify) \_\_\_\_\_

**CRACEO** **RACEOTH**

| Row | STUDYID | DOMAIN | SUBJID | ASIAN_CRACE | THAI_CRACE | CAMBODIAN_CRACE | INDONESIAN_CRACE | BLACK_CRACE | NAMIBIAN_CRACE | BOTSWANAN_CRACE | CRACEO | RACEOTH |
|-----|---------|--------|--------|-------------|------------|-----------------|------------------|-------------|----------------|-----------------|--------|---------|
| 1   | ABC     | DM     | 1      |             |            |                 |                  |             |                |                 |        |         |

## Case Report Form

|         |      |         |             |            |
|---------|------|---------|-------------|------------|
| ABC-654 | 53C  | 2301    | 25-Mar-2013 | WEEK THREE |
| STUDY   | SITE | SUBJECT | DATE        | VISIT      |

Were VITAL SIGNS collected?  Yes  No

|                  | TIME<br>(24-hr clock) | PULSERATE<br>(beats/min)          | RESPIRATORYRATE<br>(breaths/min)  | SYSTOLIC<br>BLOOD PRESSURE        | DIASTOLIC<br>BLOOD PRESSURE       | TEMPERATURE  |
|------------------|-----------------------|-----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|--|
| Pre-Dose         | 07:58                 | 76                                | 12                                | 120                               | 74                                | C <input checked="" type="checkbox"/> F <input type="checkbox"/> |
|                  | HH:MM                 | <input type="checkbox"/> NOT DONE | <input type="checkbox"/> NOT DONE | <input type="checkbox"/> NOT DONE | <input type="checkbox"/> NOT DONE | <input type="checkbox"/> NOT DONE                                |
| 30 Min Post Dose | 08:30                 | 74                                | 11                                | 128                               | 90                                | C <input checked="" type="checkbox"/> F <input type="checkbox"/> |
|                  | HH:MM                 | <input type="checkbox"/> NOT DONE | <input type="checkbox"/> NOT DONE | <input type="checkbox"/> NOT DONE | <input type="checkbox"/> NOT DONE | <input type="checkbox"/> NOT DONE                                |
| 90 Min Post Dose | 09:30                 | 73                                | 11                                | 118                               | 72                                | C <input checked="" type="checkbox"/> F <input type="checkbox"/> |
|                  | HH:MM                 | <input type="checkbox"/> NOT DONE | <input type="checkbox"/> NOT DONE | <input type="checkbox"/> NOT DONE | <input type="checkbox"/> NOT DONE | <input type="checkbox"/> NOT DONE                                |
| 2 Hr Post Dose   | 10:05                 | 68                                | 11                                | 110                               | 70                                | C <input type="checkbox"/> F <input type="checkbox"/>            |
|                  | HH:MM                 | <input type="checkbox"/> NOT DONE | <input type="checkbox"/> NOT DONE | <input type="checkbox"/> NOT DONE | <input type="checkbox"/> NOT DONE | <input checked="" type="checkbox"/> NOT DONE                     |

**VSORRES**

**VSTAT**

**STUDYID**

**VSTEST**

**VISDAT**

**SITEID**

**VSPERF**

**SUBJID**

**VISIT**

**VSORRESU**

**VSTIM**

**VSTPT**

**Re: Week 12 Topics/Questions**  
by [User] - Monday, September 25, 2023, 12:32 PM  
We want to capture information related to a patient entering a separate trial while enrolled in our natural history study. Which domain would that trial data fall under?  
[Permalink](#) | [Show parent](#) | [Edit](#) | [Split](#) | [Delete](#) | [Reply](#)

**Re: Week 12 Topics/Questions**  
by [User] - Wednesday, September 27, 2023, 6:33 AM  
Let's talk about this.  
  
I think one appropriate place to record this might be as a disposition record. There is no standard DSDECOD for this, so we can talk about creating one and submitting it to the Controlled Terminology team for addition (if this approach makes sense to you). I think this could be a record in DS where the DSCAT="OTHER EVENT". Right now the DSDECOD codelist for "Other Events" includes only "SITE TRANSFER", "TREATMENT UNBLINDED", and "WITHDRAWAL OF CONSENT FROM PROTOCOL-SPECIFIED ACTIVITY". I could see a value such as "SUBJECT ENTERED SEPARATE RESEARCH TRIAL" as a valid "OTHER EVENT".  
  
Alternatively, this could be a protocol deviation record, if the protocol prohibits concurrent enrollment in multiple studies.  
[Permalink](#) | [Show parent](#) | [Edit](#) | [Split](#) | [Delete](#) | [Reply](#)

**Re: Week 12 Topics/Questions**  
by [User] - Wednesday, September 27, 2023, 10:24 AM  
Thank you, this is very helpful. If we want to capture the name of the separate trial, would that be stored in supplemental qualifier SUPP DS?  
[Permalink](#) | [Show parent](#) | [Edit](#) | [Split](#) | [Delete](#) | [Reply](#)

**Re: Week 12 Topics/Questions**  
by [User] - Tuesday, September 26, 2023, 10:56 AM  
Is it typical to have two possible answers to a question mapped to the same SDTM variable? In the example below could we use MHORRES to map both "Refused" and "Don't Know" to "Unknown"?  
  
1. Have you had a surgery on your legs or feet in the past three months?  
o No o Yes o Refused o Don't know  
[Permalink](#) | [Show parent](#) | [Edit](#) | [Split](#) | [Delete](#) | [Reply](#)

**Re: Week 12 Topics/Questions**  
by [User] - Wednesday, September 27, 2023, 6:21 AM  
It depends on the question. In this case does the reply "Refused" mean that they refused to have surgery or that they refused to answer the question? If it's the later, then it could be justified that "Refused" (to answer) is the cause of the "Don't know" value. I also am assuming that the "Don't know" is the investigator/clinicians (and not the subject/patients) lack of knowledge.  
  
It would be good to get clarity about the meaning of "Refused" such as "Refused to answer" or "Refused surgery". If it means "Refused surgery" then that indicates that they needed or were recommended to have surgery, but did not have it as suggested, which is different question than did they have surgery. In that scenario, I would think that the "Refused surgery" should be in a different variable.  
[Permalink](#) | [Show parent](#) | [Edit](#) | [Split](#) | [Delete](#) | [Reply](#)

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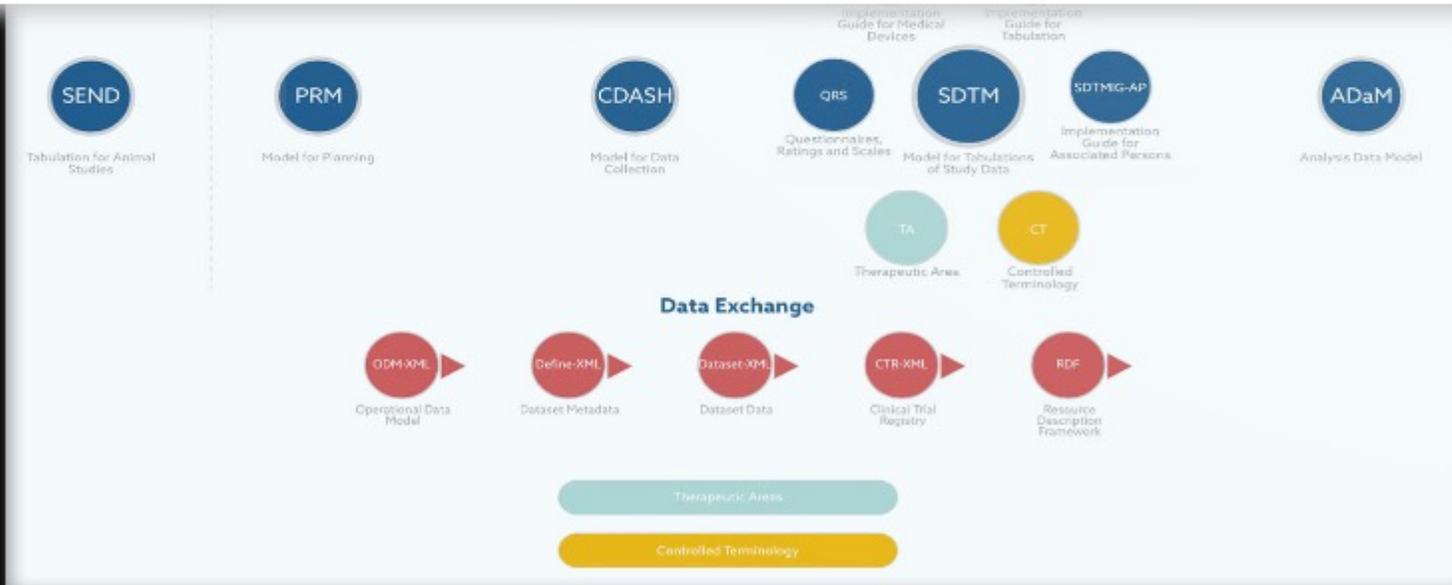
[Information for Learners](#)

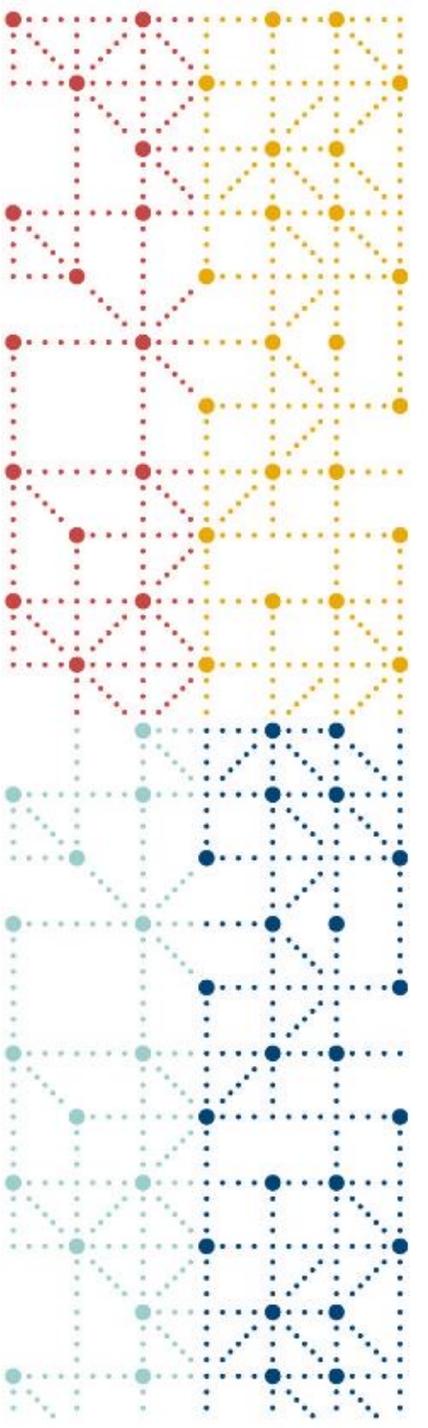
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# SDTM Advanced Hands-On Implementation

# Training overview

## ^ SDTM Advanced Hands-On Implementation Training Pilot

Overview

Objective and Learning Outcomes

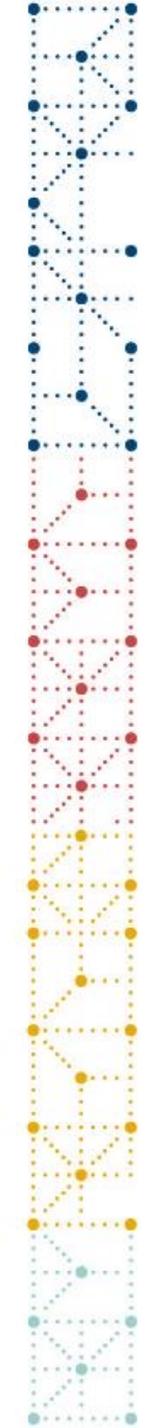
Learner Preparation

Materials

Activity 1: SDTM Annotation

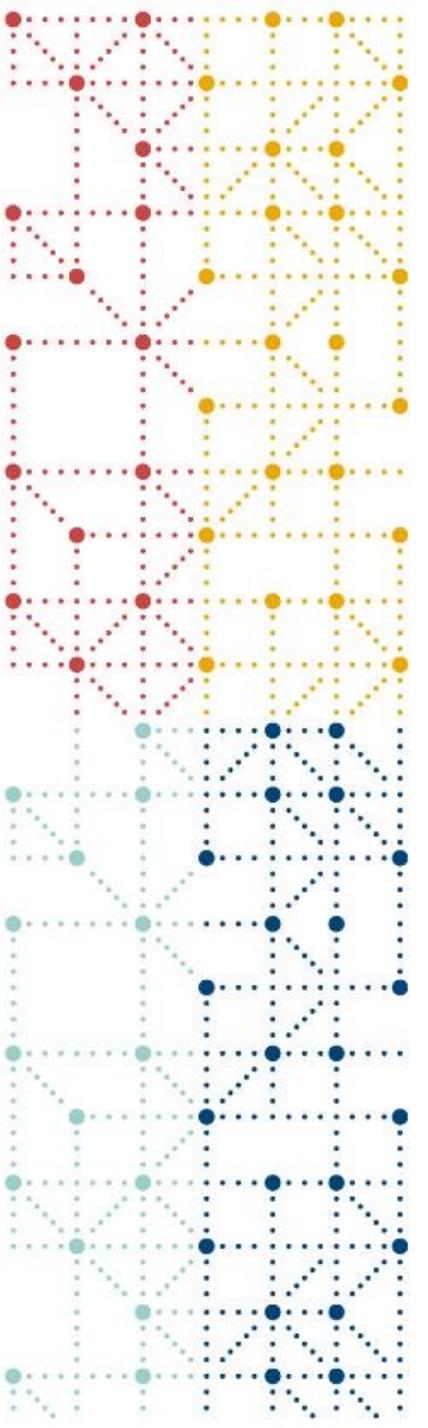
Activity 2: SDTM Quality Check

Activity 3: Upgrade from SDTMIG v3.3 to SDTMIG v3.4



# Training agenda

- Part I
  - Correctly annotate a CRF with the use of MSG
- Part II
  - CDASH data converted to SDTM data
  - QC of SDTM data
  - Use of CORE CLI
- Part III
  - Convert 3.3 to 3.4 with use of CDISC Library



# TMF RM Educational Offerings through CDISC

# CDISC TMF-related Educational Offerings

## Established Trainings:

### Introduction to the CDISC TMF RM

- English and Japanese language
- Free to members
- 10-minutes

#### **\*New Training\* TMF Reference Model for Biometrics Professionals**

Register for 25 October in-person training!

Virtual sessions scheduled in 2025



[View Course](#)

#### **\*New Training\* 日本語 TMF Module 1: TMF Reference Model の紹介 (FREE)**

Online (self-paced) On-Demand, Self-Paced Online



[View Course](#)

### Fundamentals of the TMF RM

- Offered both in person and virtual
- Next virtual course: 3,4,&5SEPT2024
- Offered in-person course: 22OCT2024 at the US CDISC Interchange Meeting in AZ

#### **Fundamentals of the TMF Reference Model (VIRTUAL Zoom)**

TMF-Zoom Virtual: 3 days; 3 hours per day



[View Course](#)

# CDISC TMF-related Educational Offerings

In development or coming soon:

## TMF RM for Biometric Professionals

- Pilot (virtual) planned to take place on 28 August 2024
- Offered in-person course: 25OCT2024 at the US CDISC Interchange Meeting in AZ

### **\*New Training\* TMF Reference Model for Biometrics Professionals**

Register for 25 October in-person training!

Virtual sessions scheduled in 2025



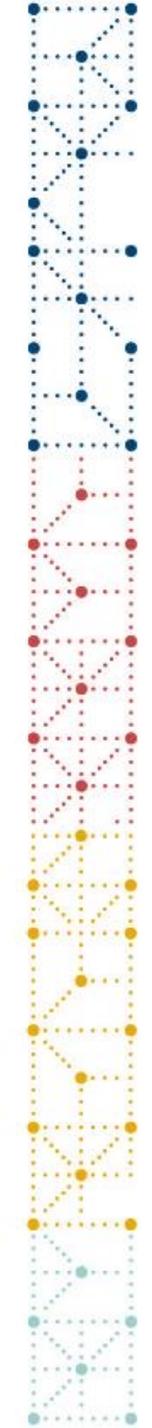
[View Course](#)

## Quality Check of TMF Records

- Explain the purpose and factors that contribute to the quality of the TMF.
- Apply principles of the CDISC TMF Reference Model, ALCOA++, and regulatory guidance towards the TMF Records check process.
- Influence how to take a risk-based approach to record quality checks.

## Risk-based Approach to TMF Management

- Based on the output of the CDISC TMF RM Risk Initiative



# More on the Fundamentals of the TMF RM

## Course-Level Learning Outcomes

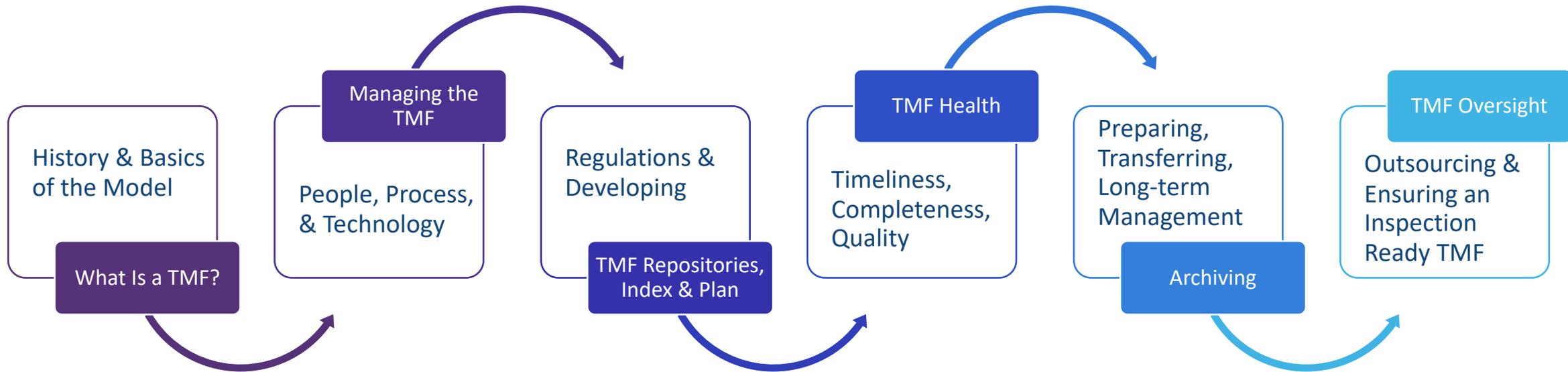
Apply current regulations and guidances to the management of the TMF.

Describe how the TMF Reference Model is integral to the comprehensive TMF management process.

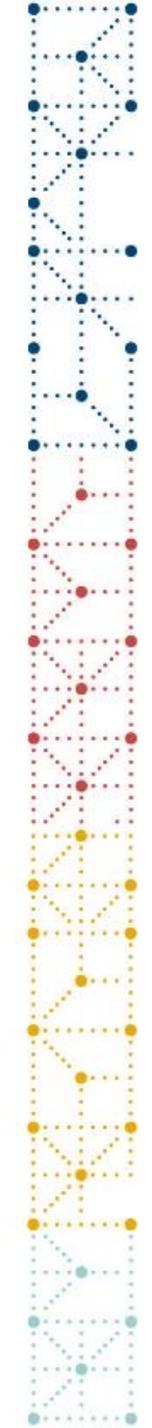
Apply required principles of the TMF Reference Model to understand where the records of the TMF are managed during and after the conduct of the study.

Design basic TMF management processes based on the TMF Reference Model, such as TMF Quality Control, TMF Index, TMF Plan, and TMF Oversight.

# Course Agenda



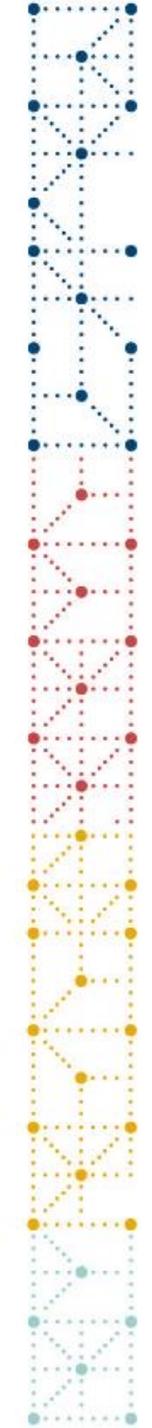
#tmf  
reference model learning  
engaging cdisc knowledge  
best  
interactive development  
networking practices



# More on the TMF RM for Biometric Professionals

## Course Description

Delve into more advanced TMF management with our specialized training spotlighting Zones 10 and 11 of the TMF Reference Model. This training is tailored for professionals overseeing records and data from Data Management, Biostatisticians, and Programmers. Gain expertise in defining and managing TMF records effectively, identifying functional application records, and assessing their completeness within the TMF Reference Model framework. Join us to enhance your TMF management skills and ensure robust regulatory compliance.



# More on the TMF RM for Biometric Professionals

## Course-Level Learning Outcomes

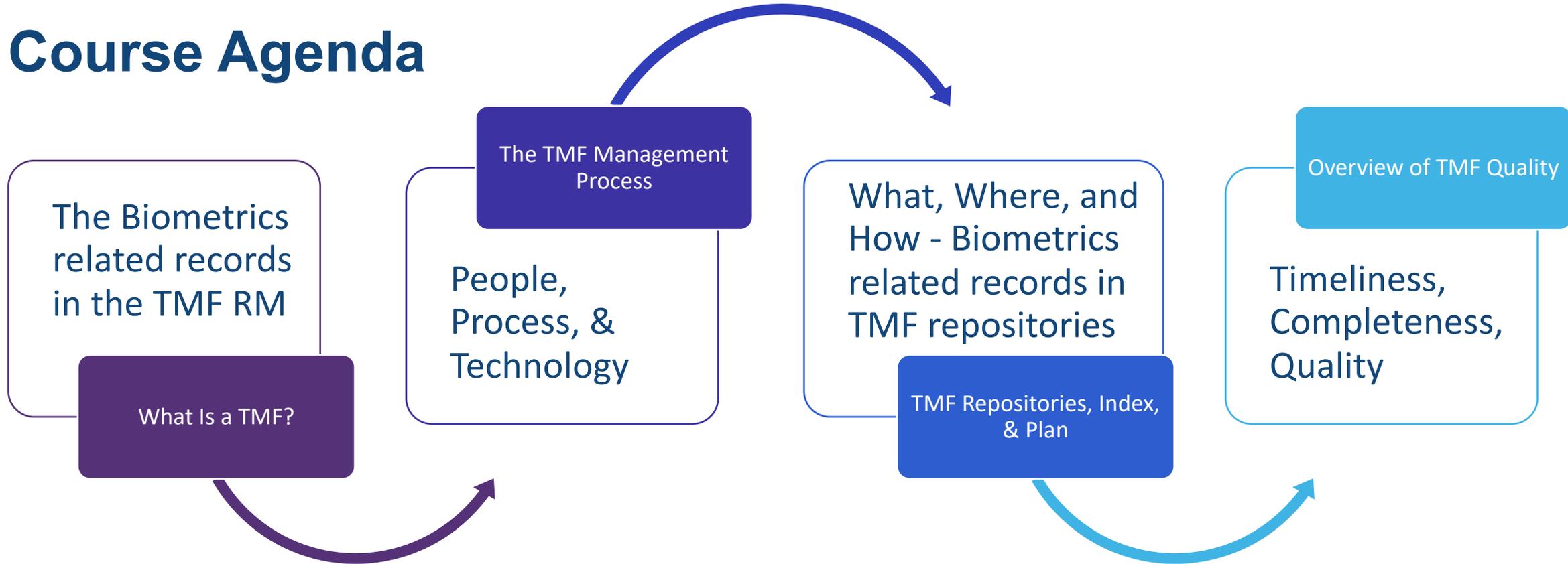
Describe and summarize the CDISC TMF RM and its purpose.

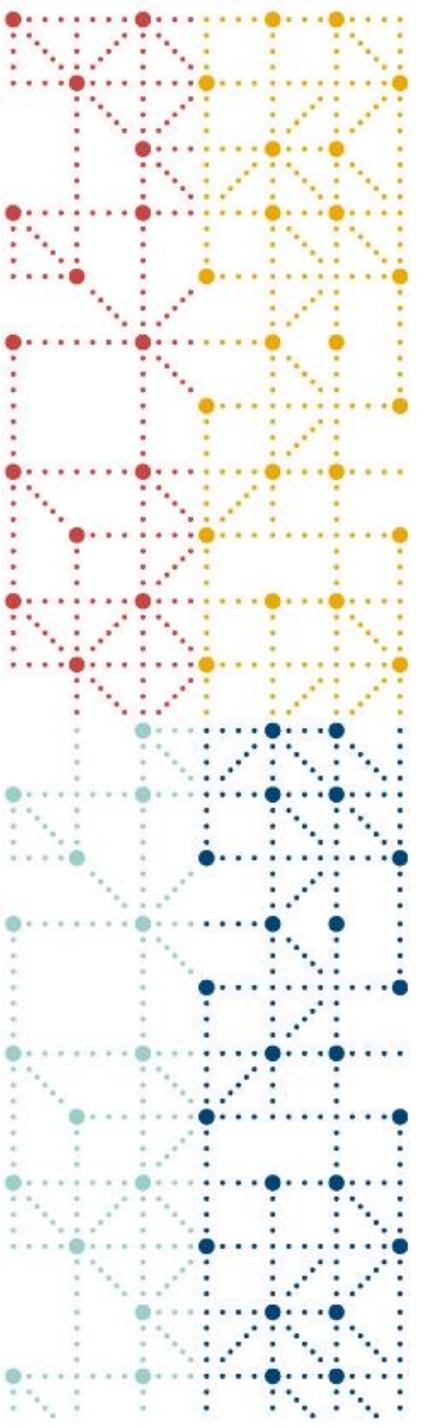
Describe biometrics-related TMF records and data (including the various file formats) indicated in the CDISC TMF RM.

Describe how management of biometrics-related TMF records and data in designated TMF repositories is documented in the study-specific TMF Index based on the CDISC TMF RM.

Develop the plan to evaluate biometrics records and data for completeness in the various TMF repositories utilizing the CDISC TMF RM

# Course Agenda





**Thank you!**