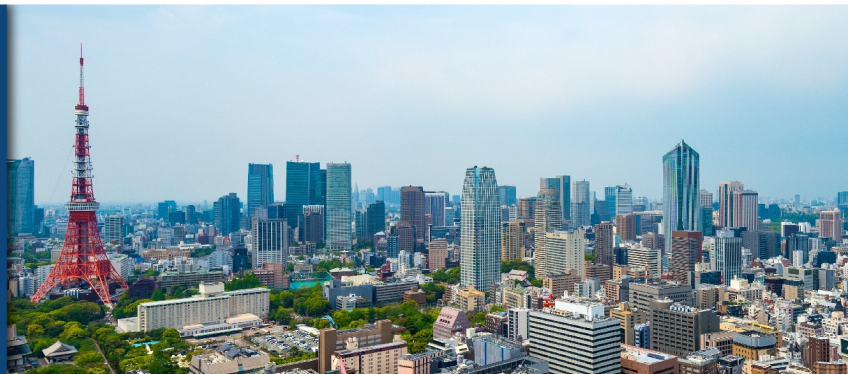




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JAPAN
INTERCHANGE
TOKYO | 10-11 JULY



Why is CDASH needed to map eCRF data to SDTM?

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Visiting Academic Staff, Faculty of Medicine, Osaka University
Visiting Researcher, Division of Health Sciences, Graduate School of Medicine, Osaka University



Meet the Speaker

Dr. Anna Tsutsui

Title: Assistant Professor

Organization: Department of Medical Statistics,
Faculty of Medicine, Toho University

Dr. Tsutsui has 10 years of experience working in Japanese information technology and global pharmaceutical companies. Following her retirement, she attended Osaka University Graduate School of Medicine for her doctoral studies and obtained a Doctor of Philosophy degree in Health Science. She assumed her current position after a one-year post-doctoral fellowship at Osaka University Hospital.

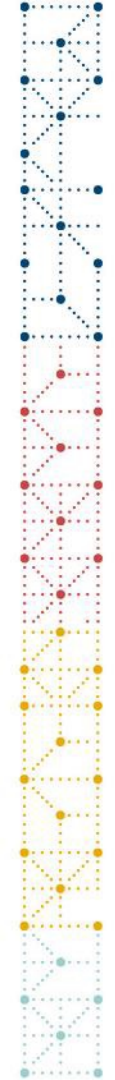
She has been a member of the SDTM team of the CDISC Japan User Group since 2013.



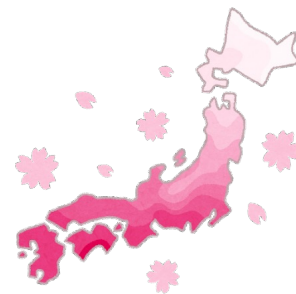


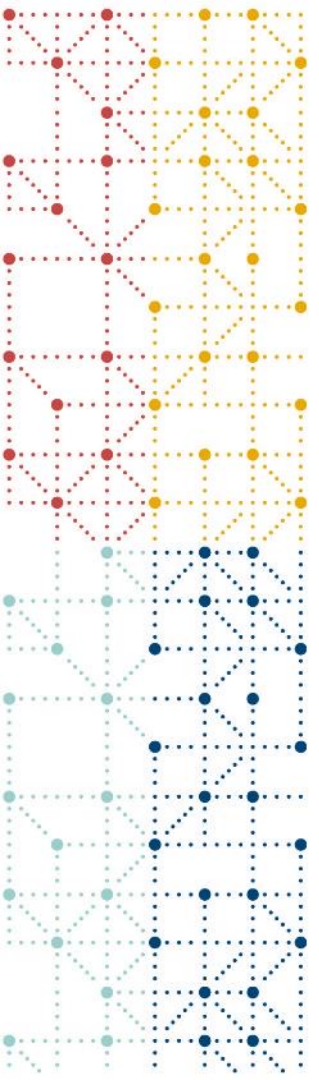
Disclaimer and Disclosures

- The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.
- The author(s) have no real or apparent conflicts of interest to report.



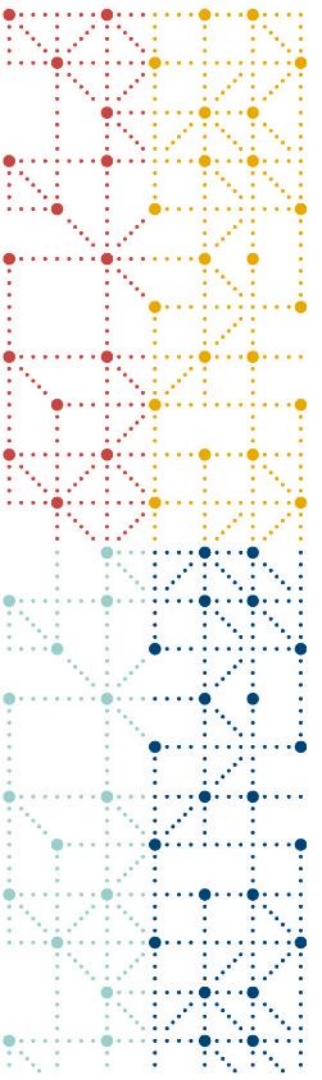
This presentation is based on deliverables from
the Regulatory sub-team, a sub-team in the SDTM team
at the CDISC Japan User Group.





Agenda

1. Introduction
2. Benefits of CDASH
3. CDISC eCRF Portal

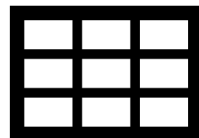


Introduction

Background (1)

CDASH, Clinical Data Acquisition Standards Harmonization

- Model for data collection

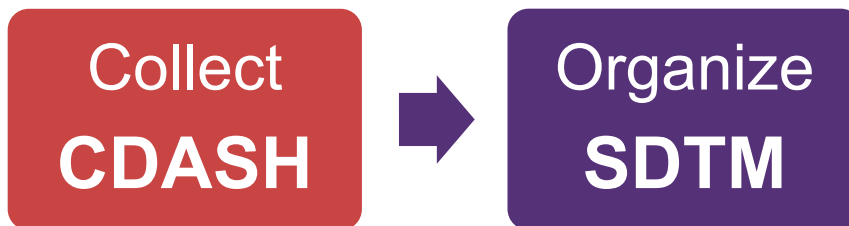


SDTM, Study Data Tabulation Model

- Model for tabulation of study data (submitted to regulatory authorities)



Case report forms
(CRF)

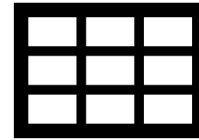


Based on CDISC: Standards, <https://www.cdisc.org/standards>

Background (2)

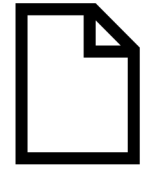
CDASH, Clinical Data Acquisition Standards Harmonization

- Model for data collection



SDTM, Study Data Tabulation Model

- Model for tabulation of study data (submitted to regulatory authorities)



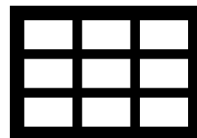
Case report forms
(CRF)

Non-CDASH-
based **CRF**

Background (3)

CDASH, Clinical Data Acquisition Standards Harmonization

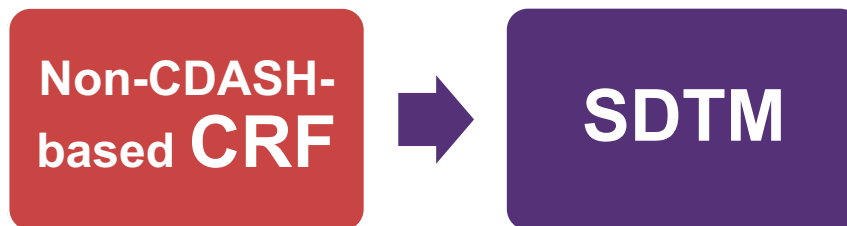
- Model for data collection



Case report forms
(CRF)

SDTM, Study Data Tabulation Model

- Model for tabulation of study data (submitted to regulatory authorities)



CDASH vs Corporate Standards?

The SDTM can be implemented from data that have any structure.
Therefore:

Will this study adopt CDASH?



CRO side



Sponsor side

No. Please follow our corporate standards.

CRO, Contract
Research Organization

Objective

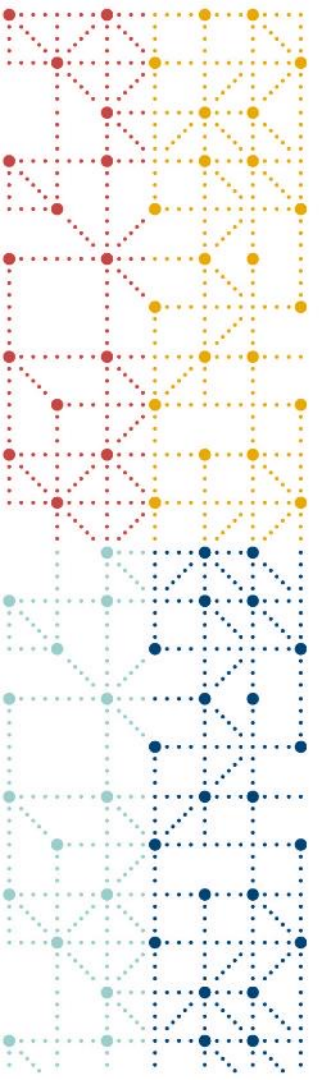
The SDTM is widely used for regulatory submissions.

The CDASH, however, is less widely used than the SDTM.

This presentation aims to:

- review the benefits of CDASH and
- introduce new free resources such as the “CDISC eCRF Portal” to encourage the adoption of CDASH-based CRF.





Benefits of CDASH

Differences in costs

Non-CDASH-based CRFs often need more complex mapping and, therefore, more resources for mapping specification and programming.

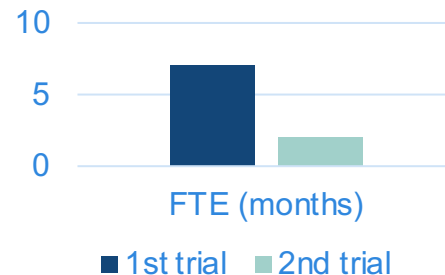
An ARO reported that it took about the following number of months* to convert data into SDTM:

- **Seven** months for the first trial with **non-CDASH**-based CRF data
- **Two** months for the second trial with **CDASH**-based CRF data

* Unit: full-time equivalent (FTE)

Jentoft et al. (2022)

ARO, Academic Research Organization



CDISC Website

“SDTM and CDASH: Why You Need Both”

(<https://www.cdisc.org/kb/articles/sdtm-and-cdash-why-you-need-both>)

The screenshot shows the CDISC website interface. At the top left is the CDISC logo. To the right are links for 'Sign in', a search bar, and a menu icon. Below the header is a breadcrumb trail: 'Home / Knowledge Base / Articles / SDTM and CDASH: Why You Need Both'. On the left side, there is a navigation menu with items: 'Dashboard', 'Articles', 'Examples Collection', 'Known Issues', and 'eCRF Portal'. The main content area features a search bar labeled 'Search Knowledge Base', two dropdown menus for 'Standard' and 'Proficiency', and an 'Apply' button. The article title 'SDTM and CDASH: Why You Need Both' is displayed in a large, bold font. Below the title, the text explains that CDASH and SDTM are optimized for different purposes, with CDASH being user-friendly and SDTM being a predictable format for data transmission and reuse. The text concludes that while both standards share data, they are designed for different purposes and thus have differences in philosophy and implementation.

cdisc

Sign in Search

Home / Knowledge Base / Articles / SDTM and CDASH: Why You Need Both

Dashboard

Articles

Examples Collection

Known Issues

eCRF Portal

Search Knowledge Base Standard Proficiency Apply

SDTM and CDASH: Why You Need Both

CDASH and **SDTM** are each optimized for different purposes, and the philosophy behind each drives the design. SDTM represents cleaned, final CRF data organized in a predictable format that facilitates data transmission, review and reuse. CDASH collects the data in a user-friendly, EDC/CRF-friendly way that maximizes data quality and flows smoothly into SDTM. While most of the data is the same in both standards, each standard is designed for different purposes; therefore, differences do exist, both in philosophy and implementation.

SDTM and CDASH: Why You Need Both (1)

Each standard is designed for different purposes; therefore, differences do exist, both in philosophy and implementation.

- Missing Data
- Non-Standard Variables
- Human vs Machine Readable Data
- Data Organization
- Horizontal vs. Vertical Data
- EDC CRF
- Metadata Content
- Unavailable Variables
- Benefits of Using Both CDASH and SDTM

CDISC: SDTM and CDASH: Why You Need Both

<https://www.cdisc.org/kb/articles/sdtm-and-cdash-why-you-need-both>

Example: Missing Data

SDTM assumes the data is clean.

- If a subject had no AEs, they will not be represented in the AE dataset.

CDASH assumes that the absence of evidence is not evidence of absence.

- It only means that no AE data was received, which must be verified.

SDTM's assumption only works if no record was checked in the data capture.

Form AE - Adverse Events

AE - Adverse Events

Were any adverse events experienced?

No Yes

* What is the adverse event term?

CDISC: SDTM and CDASH: Why You Need Both
<https://www.cdisc.org/kb/articles/sdtm-and-cdash-why-you-need-both>

SDTM and CDASH: Why You Need Both (2)

CDASH

Guides data collection so that data flow easily from the collection into SDTM, which **contributes to data traceability, integrity, and quality.**

Benefits of Using Both CDASH and SDTM

- Optimizes the site's data requirements and structure for transmission, analysis, review, and reuse
- Minimizes programming and validation resources and increases quality when transferring data from capture to tabulation

CDISC: SDTM and CDASH: Why You Need Both
<https://www.cdisc.org/kb/articles/sdtm-and-cdash-why-you-need-both>

Situations in Academia in Japan

Even among specific institutions, *

27 out of 41 institutions had not yet implemented the CDISC Standards.

Among other institutions,

CDASH was the most implemented standard.

*Implementation Status on
CDISC Standards*

Nagai et al. (2022)

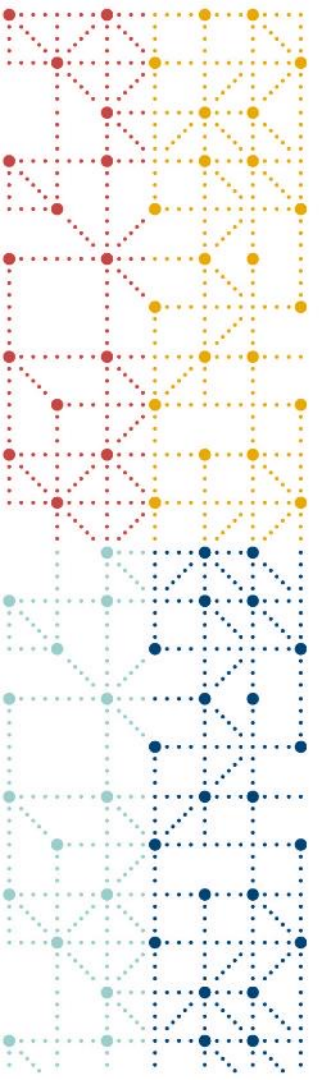
* Members of the CDISC expert liaison committee of the ARO council, TG3 (Topic Group 3) of the National University Hospital Clinical Research Promotion Initiative (NUH-CRPI), and Metropolitan Academic Research Consortium (MARC).

Category	N of sites (%)
Not implemented	27 (65.9%)
CDASH	6 (14.6%)
CDASH , SDTM	3 (7.3%)
SDTM	2 (4.9%)
SDTM, ADaM	2 (4.9%)
CDASH , SDTM, ADaM	1 (2.4%)

N, number

Why not adopt CDASH?





CDISC eCRF Portal

CDISC eCRF Portal (1)

Consists of ready-to-use, CDASH-compliant, annotated eCRFs to use as is or import to an EDC system for customization.

Available at <https://www.cdisc.org/kb/ecrf>

cdisc Sign in Search

Home / Knowledge Base / eCRF Portal

Dashboard

Articles

Examples Collection

Known Issues

eCRF Portal

Search eCRF Portal Apply

eCRF Portal

The eCRF Portal consists of ready-to-use, CDASH-compliant, annotated eCRFs, available in PDF, HTML and XML, to use as is or import to an EDC system for customization. The eCRFs are examples and are not meant to imply that any particular layout or collection plan is preferable over another.

The following information is applicable to the CDASHIG v2.1 eCRFs:

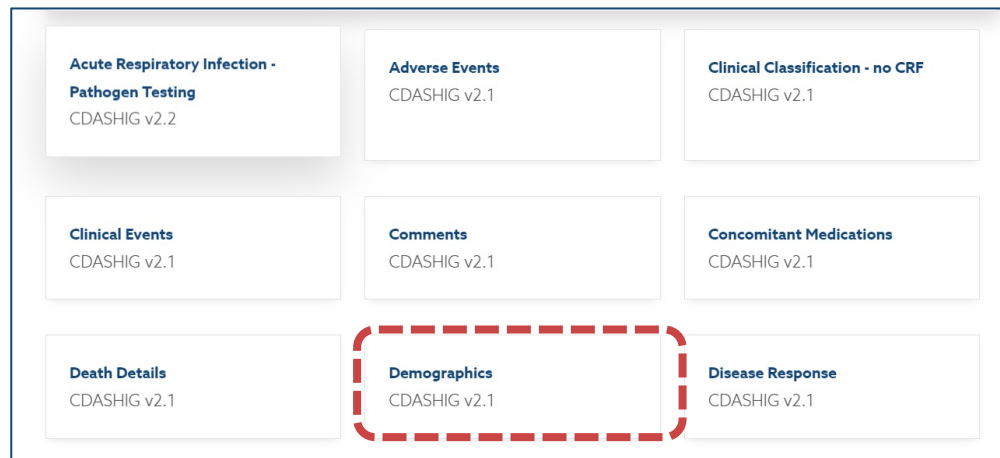
To facilitate broad use, these eCRFs were developed based upon data management best practices rather than features or limitations of any specific EDC system. The following guiding principles were followed:

- The Controlled Terminology publication from December 2019 was used.

CDISC: eCRF Portal, <https://www.cdisc.org/kb/ecrf>.

CDISC eCRF Portal (2)

- 66 of eCRFs available
(as of June 13, 2023)
- CDASHIG version 2.1
- Controlled Terminology:
December 2019




CDISC: eCRF Portal, <https://www.cdisc.org/kb/ecrf>

**Demographics
CDASHIG v2.1**

- Meets the basic needs of most users.
- Facilitates data reuse and reduces the time needed to develop eCRFs.
- Promote data quality by encouraging users to implement similar questions/answers as well as apply the same data assumptions.

Example: Demographics

Download (zip file)

 DM_eCRF_Package

Demographics **Preview**

Overview eCRF Considerations eCRF Preview **Download**

Form DM - Demographics

DM - Demographics

What is the subject's date of birth? 01 Jan 2000

What is the subject's age?

What is the age unit used? Years

What is the sex of the subject?


Do you consider yourself Hispanic/Latino or not Hispanic/Latino?


Which of the following five racial designations best describes you?
(More than one choice is acceptable.)


What was the other race?


* Mandatory field

xml (incl. xlsx),
html, and
pdf formats

 DM_Excel

 DM_HTML

 DM_PDF

 DM_XML

xlsx

1	Summary	
2	Property	Current value
3	Name	CDASH IG2.1 CRFs
4	Version	1
5	Asset Group	CDASH Library
6	Workflow State	Final
7	Therapeutic Area	None
8	Client	None
9	Program	None
10		
11		
12		

Summary Form Index DM Terminologies Units (+)

準備完了

xml

```
<ODM xmlns="http://www.cdisc.org/ns/odm/v1.3" FileOID="Demographics" FileType="Snapshot" SourceSystem="Data Acquisition Designer" SourceSystemVersion="4.8.0">  
  <Study OID="Demographics">  
    <GlobalVariables>  
      <StudyName>Demographics CRF</StudyName>  
      <StudyDescription>Demographics CRF</StudyDescription>  
      <ProtocolName>Demographics CRF</ProtocolName>  
    </GlobalVariables>  
    <BasicDefinitions>  
      <MeasurementUnit OID="mu.years" Name="YEARS">  
        <Symbol>  
          <TranslatedText>Years</TranslatedText>  
        </Symbol>  
      </MeasurementUnit>  
    </BasicDefinitions>  
  </Study>  
</ODM>
```


Collaboration with REDCap and OpenClinica

EDC, Electronic Data Capture

The eCRF data are integrated in the library in their EDC systems, which are widely used in academic institutions.

The details are reported in the following research articles:

- Cheng, A , et. al. Making Clinical Data Acquisition Standards Harmonization (CDASH) Electronic Case Report Forms Available on the **REDCap** Shared Data Instrument Library. **Journal of the SCDM**. 2022 12; 2(3).
- Tran, G & Collins, C. Dissemination of CDASH eCRFs via the CDISC Electronic Case Report Form (eCRF) Portal and the **OpenClinica** Electronic Data Capture system. **Journal of the SCDM**. 2023 6; 3(1)1.

(SCDM, Society for Clinical Data Management. <https://www.jscdm.org/>)

REDCap Shared Data Instrument Library

Users can import a CDASH-based eCRF into each project in a short time.

REDCap

Test project PID 1724

Project Home | Project Setup | Online Designer | Data Dictionary | Codebook

Create snapshot of instruments | VIDEO: How to use this page
Last snapshot: 2022/04/11 09:59

The Online Designer will allow you to make project modifications to fields and data collection instruments very easily using only your browser. NOTE: While in development status, all field changes will take effect immediately in real time.

Data Collection Instruments

Add new instrument:

- Create a new instrument from scratch
- Import** a new instrument from the official [REDCap Shared Library](#)
- Upload Instrument ZIP file from another project/user or [external libraries](#)

Survey options: Survey Queue | Survey Login | Survey Notifications

Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	Survey-re
Demographics	12			Choc	26 of 31 Survey

REDCap Shared Library

The REDCap Shared Library is a repository for REDCap data collection instruments and forms that can be downloaded and used by researchers at REDCap partner institutions. Curated instruments highlighted with a star ★ have been approved for inclusion by the REDCap Library Oversight Committee (REDLOC) after review for research relevance, accuracy in function and coding ([see guidelines](#)), and copyright issues. Other instruments and forms are shared by individuals or groups from consortium institutions on "as-is" basis.

You may search below for any available data collection instruments. If you got to this site directly, you will not be able to view the actual shared instruments themselves. This public view listing is for reference only and helps protect the authors' copyright. You will also not see instruments that have been shared locally by REDCap end users if they have not gone through the formal REDLOC curation process. If you arrived here from the REDCap application, you will have the options to view instruments as a webpage, view instruments as a PDF, and import the instruments directly into REDCap. If you wish, you may [download a list of all library instruments](#) in CSV format. To download and utilize an instrument from the REDCap Shared Library, please [cite the RSL manuscript](#). If you have questions or need assistance, please contact redcap@vumc.org.

[Return to REDCap](#)

Logged in as **Anna Tsutsui** (Osaka University)

Keyword search:

Search options:

Language: ▼

Type: ▼

Minimum downloads:

Recent additions: ▼

Curated by REDLOC?: ▼

Shared Library

Search

Library Metrics

My Activity

Institution Activity

Consortium Activity

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 >>

Found 3443 results matching your search Didn't find what you were looking for? [Suggest a validated instrument for library inclusion](#)

Title	Download
▶ ___ FOR TESTING AND DEMONSTRATION PURPOSES ONLY - Nacho Craving Index Survey ★	

Search for
"CDASH"

Test project

PID 1724

[Project Home](#)

[Project Setup](#)

[Online Designer](#)

[Data Dictionary](#)

[Codebook](#)

[Create snapshot of instruments](#)

[VIDEO: How to use this page](#)

Last snapshot: 2022/04/11 09:59

This page allows you to build and customize your data collection instruments one field at a time. You may add new fields or edit existing ones. New fields may be added by clicking the **Add Field** buttons. You can begin editing an existing field by clicking on the **Edit** icon. If you decide that you do not want to keep a field, you can simply delete it by clicking on the **Delete** icon. To reorder the fields, simply **drag and drop** a field to a different position within the form below. NOTE: While in development status, all field changes will take effect immediately in real time.

Learn how to use

[Smart Variables](#)

[Piping](#)

[Action Tags](#)

[Field Embedding](#)

[Special Functions](#)

[Return to list of instruments](#)

Current instrument: **CDISC | CDASHIG v2.1 | Demographics**

[Preview instrument](#)

[Add Field](#)

[Add Matrix of Fields](#)



Variable: dm_brthdat

Birth Date



Today

Y-M-D

Record the date of birth to the level of precision known (e.g., day/month/year, year, month/year, etc.).

[Add Field](#)

[Add Matrix of Fields](#)



Variable: dm_age

Age

Record age of the subject.

[Add Field](#)

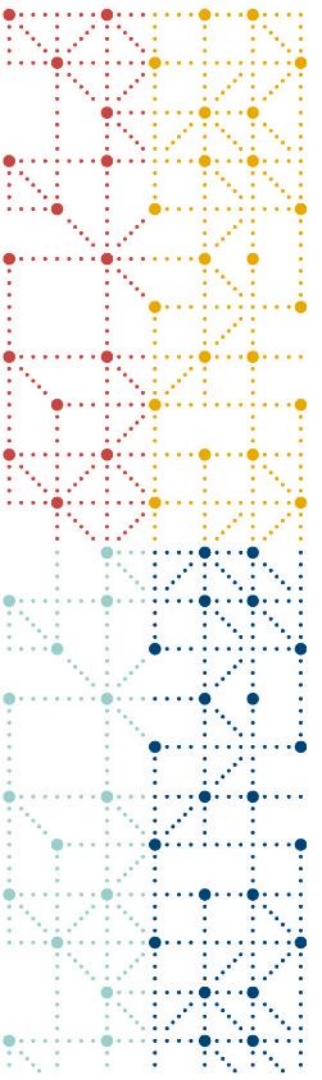
[Add Matrix of Fields](#)



Why not adopt CDASH?

Ready-to-use eCRF data
are now available!





Summary

Summary

CDASH guides data collection, which would promote cost reduction as well as data traceability, integrity, and quality.

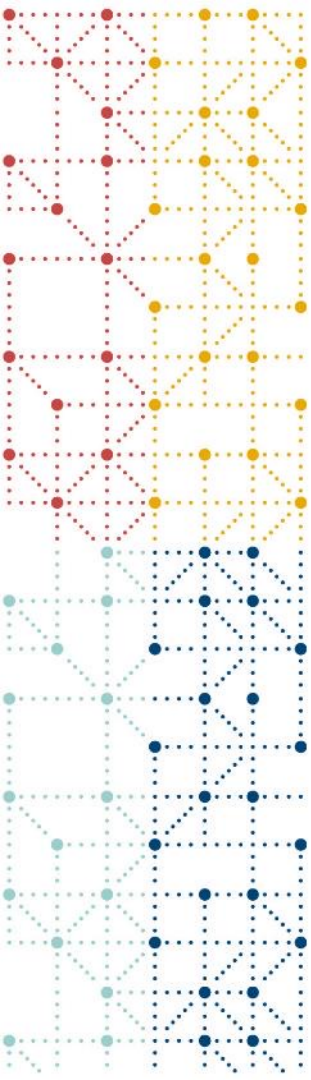
The ready-to-use CDASH-based eCRFs are available at the **CDISC eCRF Portal** and the shared library of **OpenClinica** and **REDCap**.



For academic institutions that have not yet adopted the CDISC standards, **CDASH**, rather than SDTM, can be the first step in adopting them.

References

- CDISC (n.d.). eCRF Portal. <https://www.cdisc.org/kb/ecrf> (Accessed June 16, 2023).
- CDISC (n.d.). SDTM and CDASH: Why You Need Both. <https://www.cdisc.org/kb/articles/sdtm-and-cdash-why-you-need-both> (Accessed June 16, 2023).
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Thank You!

cdisc



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