cdisc

2023
JAPAN
INTERCHANGE
TOKYO | 10-11 JULY

Why is CDASH needed to map eCRF data to SDTM?

Anna Tsutsui RN, PHN, PhD., Assistant Professor,
Department of Medical Statistics, Faculty of Medicine, Toho University

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.

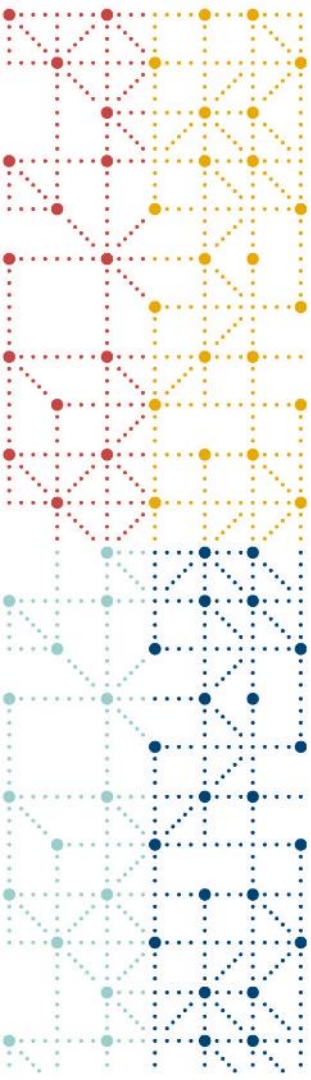
- The author(s) have no real or apparent conflicts of interest to report.

This presentation is based on deliverables from

the Regulatory sub-team, a sub-team in the SDTM team at the CDISC Japan User Group.

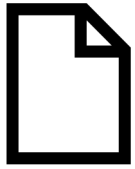
Agenda

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



Introduction

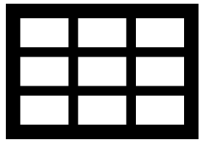
Background (1)



Case report forms (CRF)

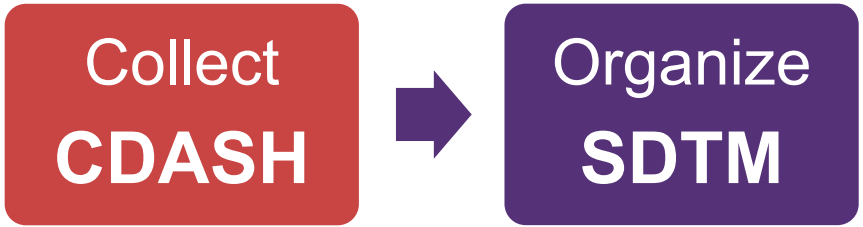
CDASH, Clinical Data Acquisition Standards Harmonization

- Model for data collection



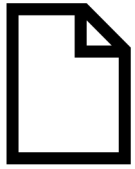
SDTM, Study Data Tabulation Model

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



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

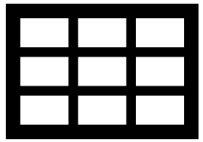
Background (2)



Case report forms (CRF)

CDASH, Clinical Data Acquisition Standards Harmonization

- Model for data collection

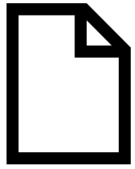


SDTM, Study Data Tabulation Model

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

Non-CDASH-based CRF

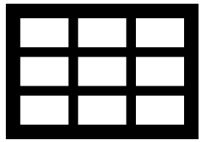
Background (3)



Case report forms (CRF)

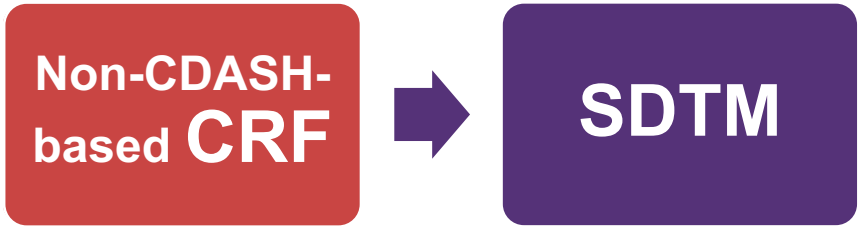
CDASH, Clinical Data Acquisition Standards Harmonization

- Model for data collection



SDTM, Study Data Tabulation Model

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



CDASH vs Corporate Standards?

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

Therefore:

CRO, Contract Research Organization

Objective

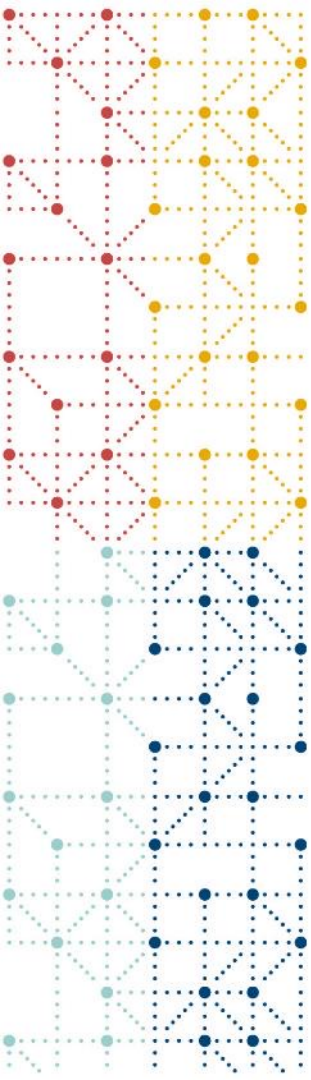
The SDTM is widely used for regulatory submissions.

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.

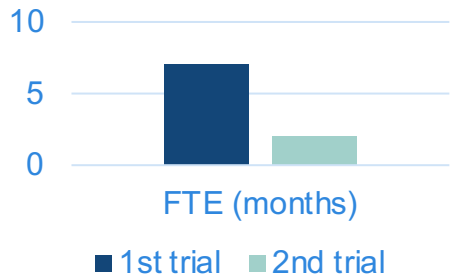
An ARO reported that
it took about the following number of months* to convert data into SDTM:

- 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)

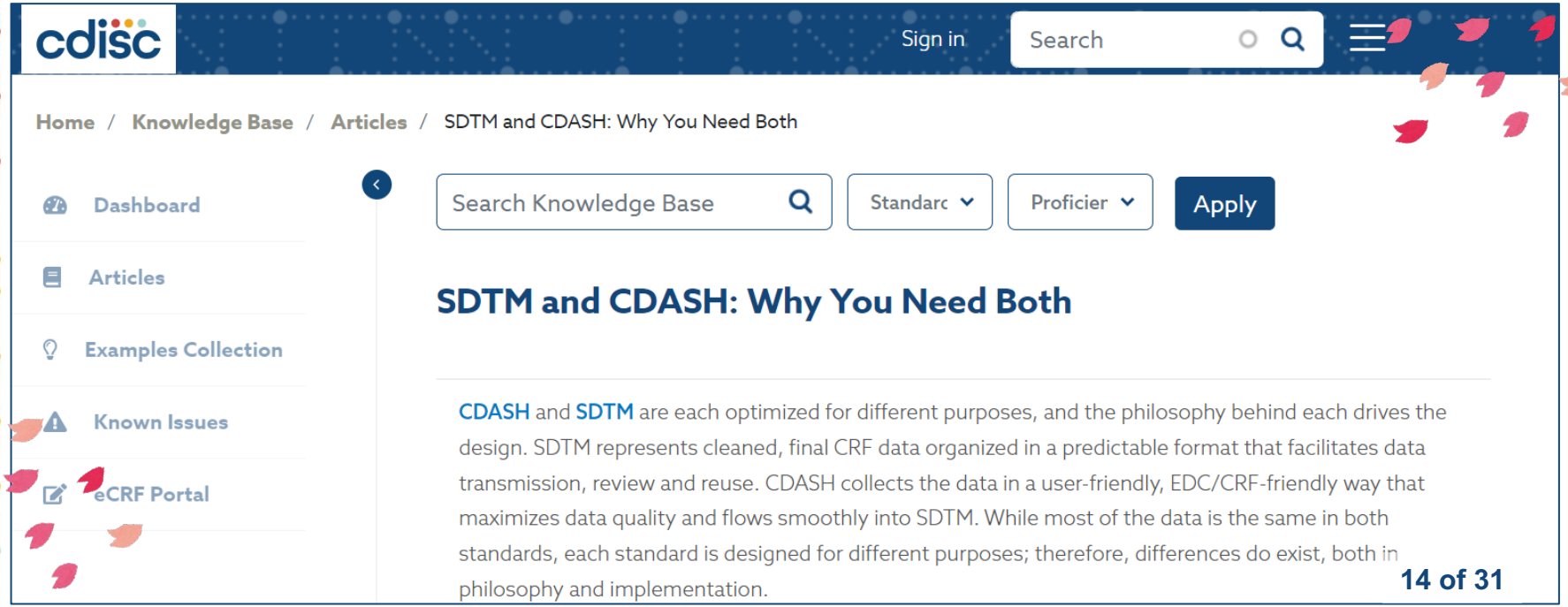
ARO, Academic Research Organization



CDISC Website

“SDTM and CDASH: Why You Need Both”

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



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

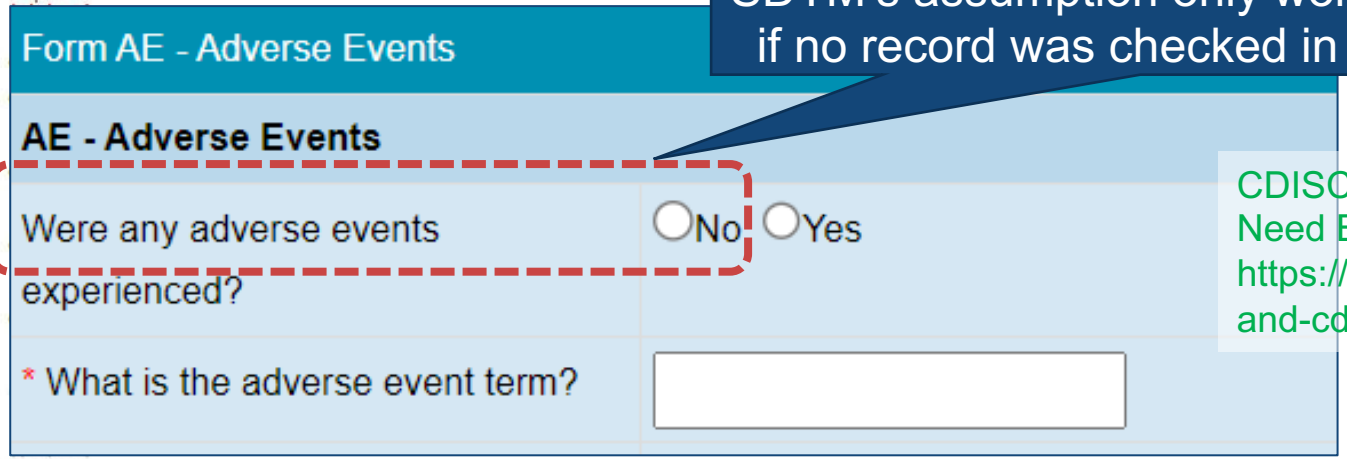
SDTM assumes the data is clean.

- 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.



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

* 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).

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.

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

Implementation Status on CDISC Standards
Nagai et al. (2022)

cdisc

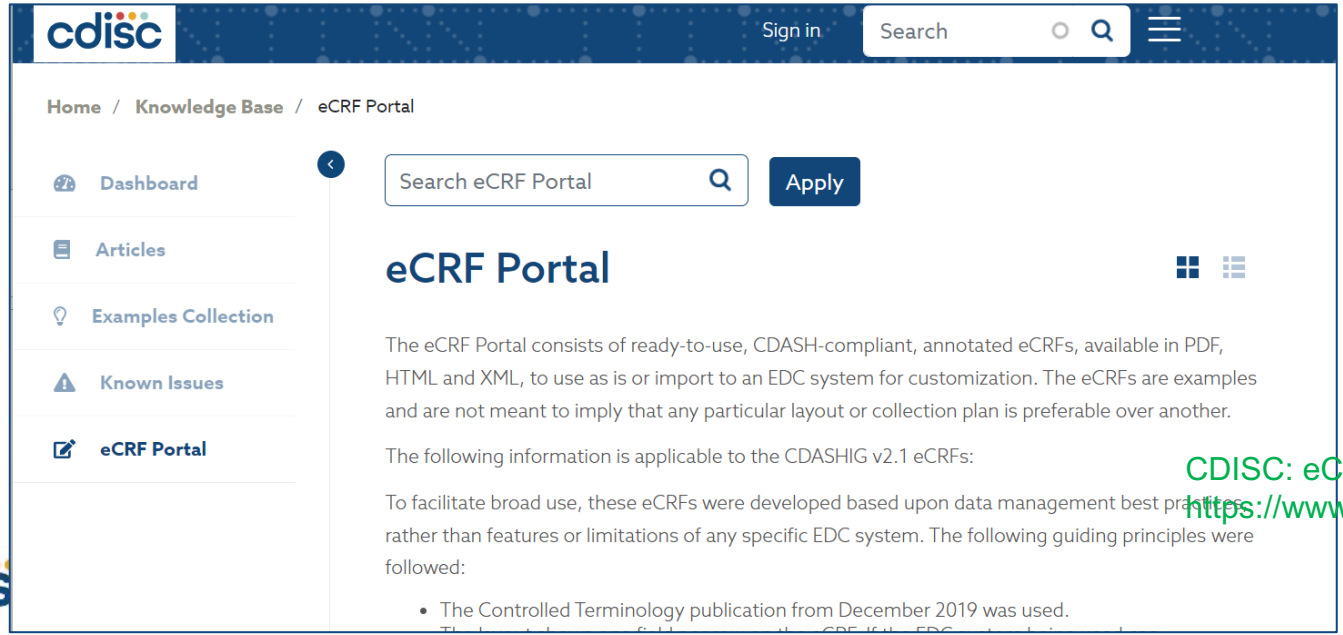
Why not adopt CDASH?

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



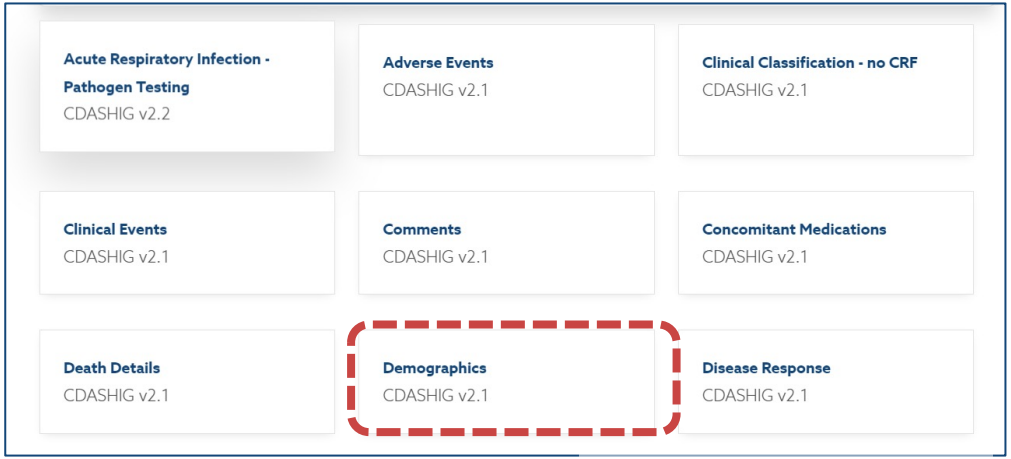
CDISC: eCRF Portal, https://www.cdisc.org/kb/ecrf.

CDISC eCRF Portal (2)

- 66 of eCRFs available

  (as of June 13, 2023)
- CDASHIG version 2.1
- Controlled Terminology:

  December 2019



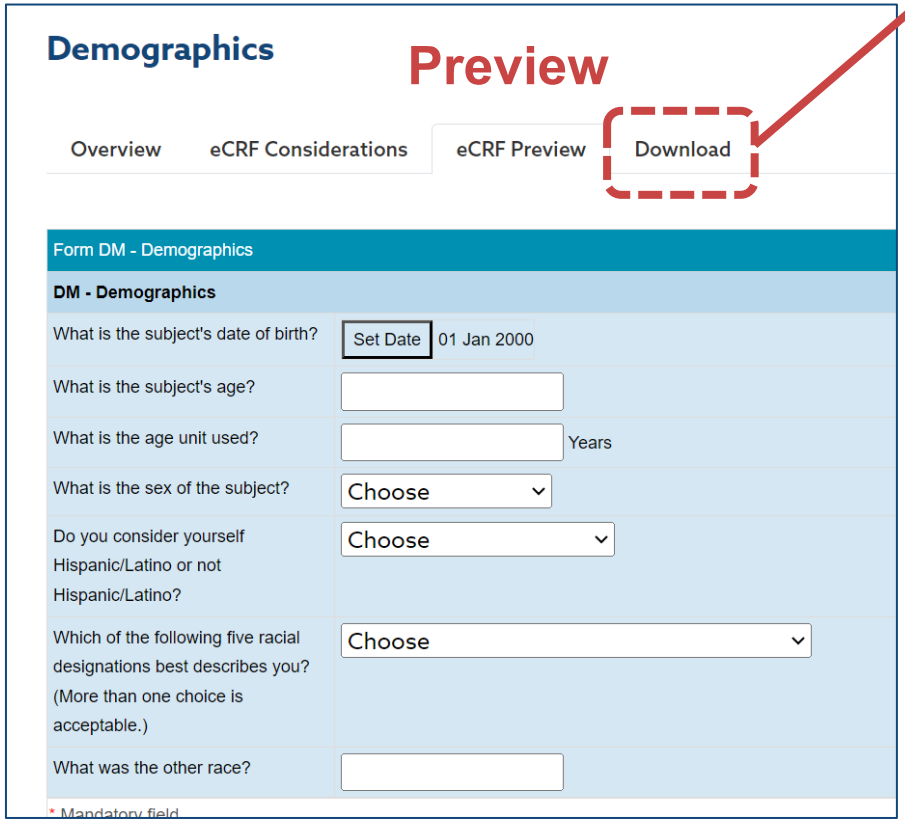
CDISC: eCRF Portal, https://www.cdisc.org/kb/ecrf

Demographics CDASHIG v2.1

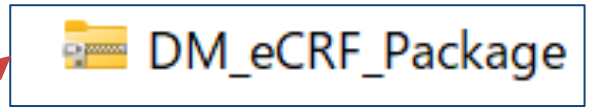
- Meets the basic needs of most users.
- Facilitates data reuse and reduces the time needed to develop eCRFs.
- Promote data quality by encouraging users to implement similar questions/answers as well as apply the same data assumptions.

CDISC: Introducing the eCRF Portal (newsletter) (2021).

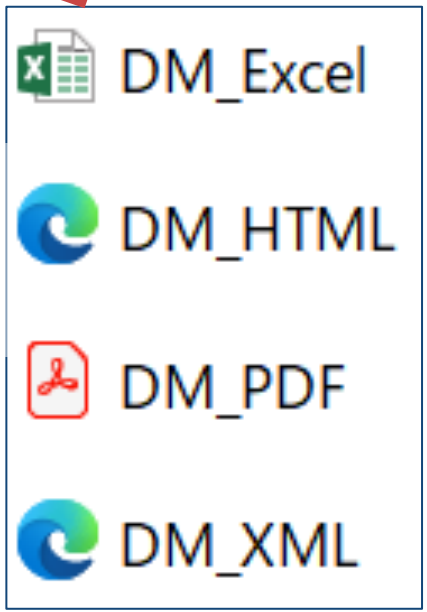
Example: Demographics



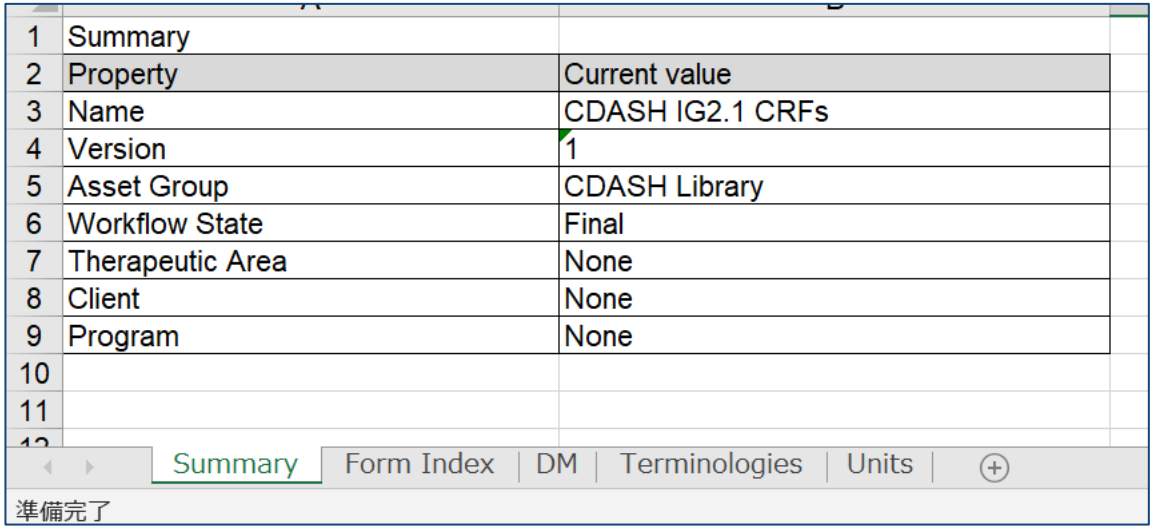
Download (zip file)



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



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		

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" C
 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>
```

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.

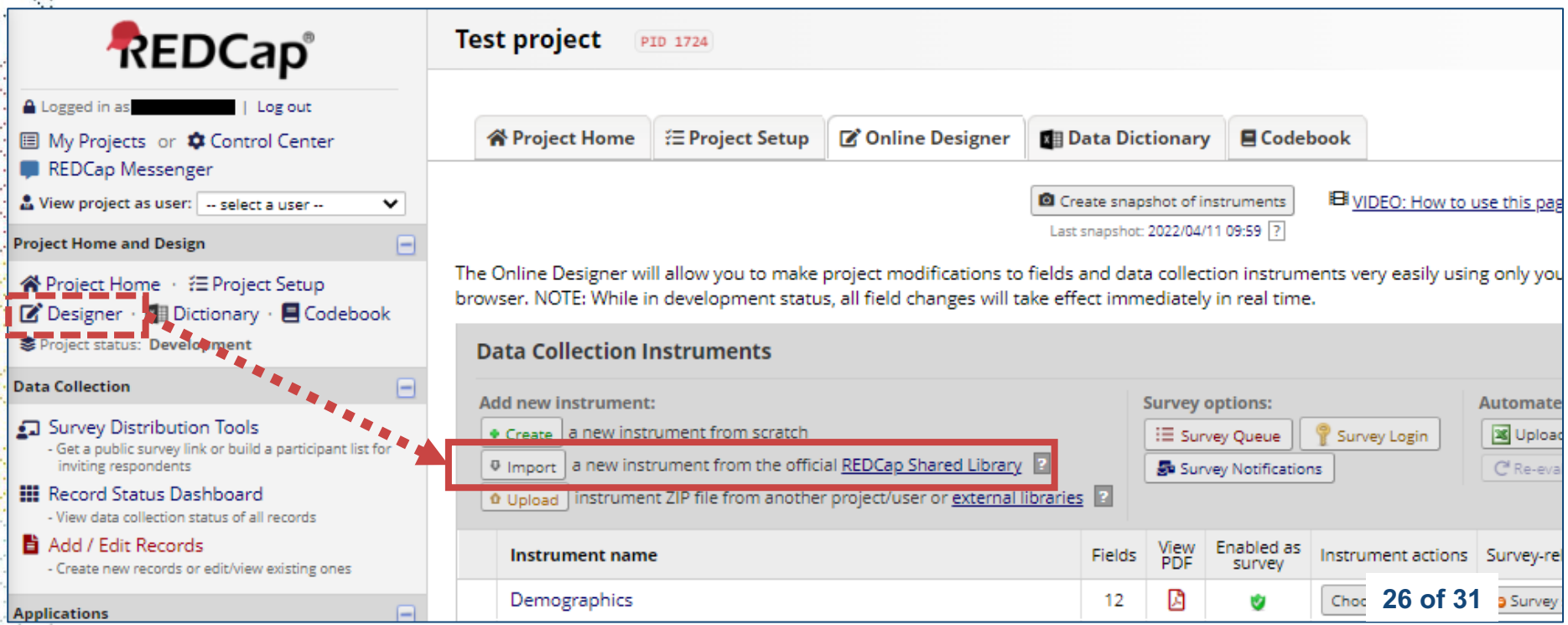
The details are reported in the following research articles:

- 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 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 i nload and utilize an instrument from the REDCap Shared Library, please cite the RSL manuscript. If you have questions o e contact redcap@vumc.org.

Search for "CDASH"

Return to REDCap

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

Keyword search:

Search the library

Search options:

Language: - All -

Type: show all

Minimum downloads: 0

Recent additions: show all

Curated by REDLOC? show all

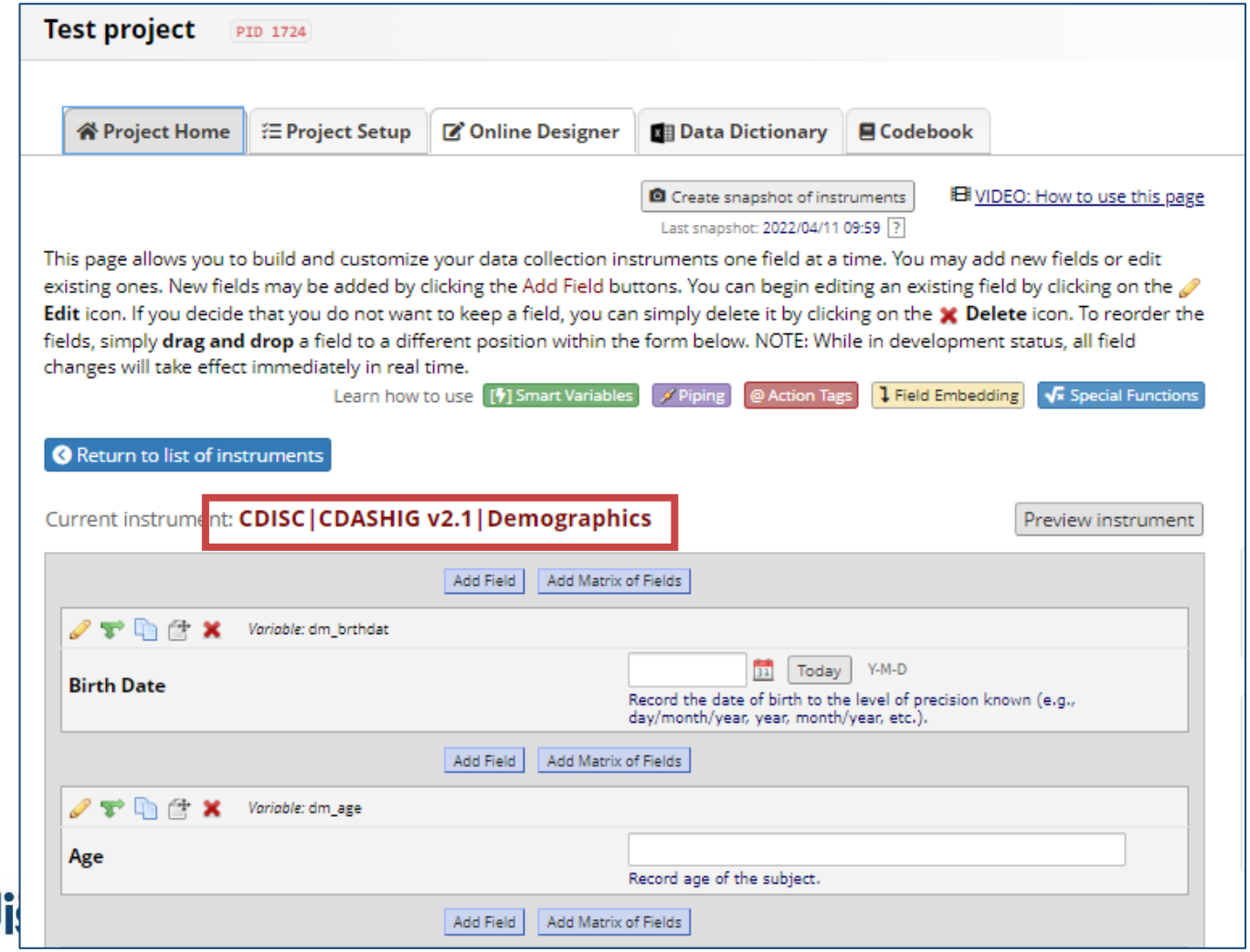
Shared Library
Search
Library Metrics
My Activity
Institution Activity
Consortium Activity

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

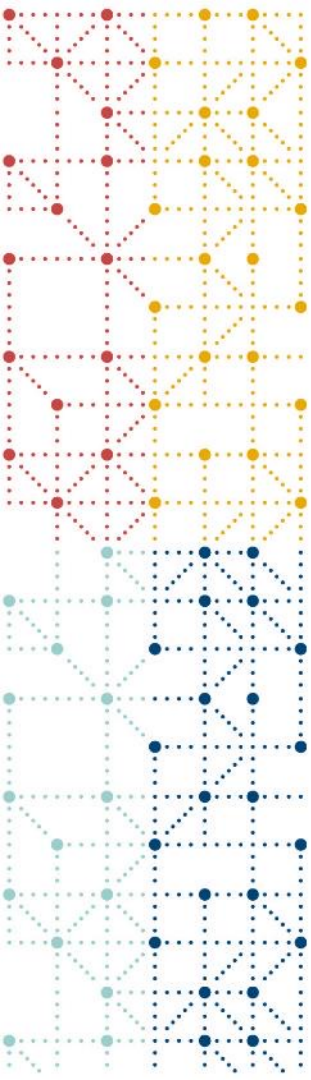
Didn't find what you were looking for? Suggest a validated instrument for library inclusion

Title	Do
➤ ___FOR TESTING AND DEMONSTRATION PURPOSES ONLY - Nacho Craving Index Survey ★	


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).
- CDISC (n.d.). Standards. https://www.cdisc.org/standards (Accessed June 16, 2023).
- CDISC (2021) Introducing the eCRF Portal. *CDISC Newsletter.* (Received February 25, 2021).
- Nagai K, Ikeda Y, et al. (2022). Current Status and Challenges of CDISC Standards Implementation among Academia in Japan. *Japanese Pharmacology & Therapeutics* 50, 51-61.
- Jentoft, K Tustison, E & Yu, H. (2023). CDISC Implementation in an Academic Research Organization. *Journal of the Society for Clinical Data Management* 2(3) doi: 10.47912/jscdm.164.

Thank You!

Feel free to contact me at
anna.tsutsui@med.toho-u.ac.jp