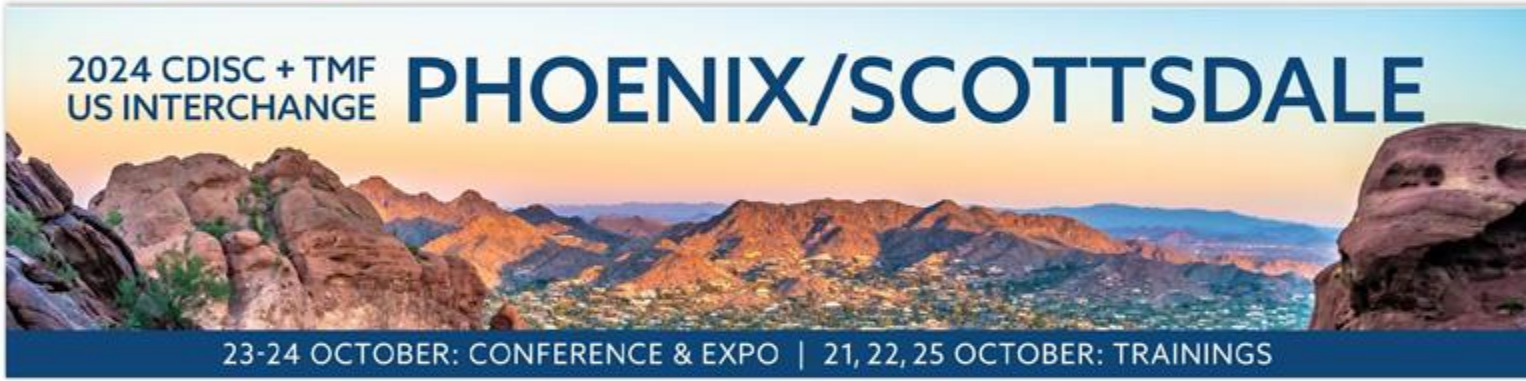


Status of CDISC Implementation and Outreach Activities in Japanese Academia

Presented by Toshiki Saito
Director, Department of Clinical Research Management,
NHO Headquarters & Nagoya Medical Center

Meet the Speaker

Toshiki Saito

Title: Director, Department of Clinical Research Management

Organization: NHO Headquarters & Nagoya Medical Center

1994 M.D., 2003 Ph.D., Molecular Immunology, University of Tokyo

2003-2008 Postdoctoral Fellow & Instructor, Harvard Medical School, Massachusetts General Hospital

2008-2010 Assistant Professor, Hematology & Oncology, University of Tokyo Hospital

2010-Present Director, Regenerative Medicine & Clinical Research Management, NHO Nagoya Medical Center

2018- Principal Researcher of AMED project "Study of CDISC standards implementation in academia"

2021 J3C, Vice Chair

2021-Present Director, Clinical Research Management, Clinical Research Center, NHO Headquarters

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 have no real or apparent conflicts of interest to report.*

Section 1: Introduction to the topic

Current Status of CDISC in Japan

1. Regulatory Context: PMDA Mandate
   - In 2020, the Pharmaceuticals and Medical Devices Agency (PMDA) mandated the use of CDISC standards for all drug approval applications.
   - The goal is to ensure consistency, quality, and efficiency in clinical data submissions.
2. Industry Adaptation: Pharmaceuticals and CROs
   - Pharmaceutical companies and Contract Research Organizations (CROs) have largely adapted to CDISC standards.
   - Efficient integration into regulatory submissions has been achieved, streamlining approval processes.
3. Challenges in Academia: Early Phases of Adoption
   - While CDISC adoption is well established among pharmaceutical companies and CROs, Japanese academia is still in the early stages of implementation.
   - Ongoing efforts are focused on promoting awareness and supporting the initial adoption phases.

Key Organizations Promoting CDISC (1/3)

Japan CDISC Coordinating Committee (J3C)

- Established in 2002 as the central body promoting CDISC adoption in Japan, providing feedback to the global CDISC organization.
- Main activities involve collaboration with CDISC Executive Operations, focusing on:
  - Expanding CDISC adoption and presence in Japan
  - Serving as a liaison between CDISC and other Japanese organizations, supporting partnerships and collaborations
  - Planning and organizing annual conferences and events related to CDISC within Japan

Key Organizations Promoting CDISC (2/3)

CDISC Japan User Group (CJUG)

- Established in 2002: The CDISC Japan User Group (CJUG) was formed to promote the use of CDISC standards in Japan.
- Collaboration Across Sectors: Brings together stakeholders from regulatory bodies, pharmaceutical companies, CROs, IT vendors, and academia.
- Educational and Support Activities:
  a. Organizes seminars, workshops, and hands-on training sessions.
  b. Conducts mock trials to help participants better understand CDISC implementation.
  c. Participates in the translation of CDISC guidelines to improve accessibility for Japanese users.
- Promotes Networking: Facilitates the exchange of knowledge and best practices among CDISC users in Japan, fostering a collaborative environment.

Key Organizations Promoting CDISC (3/3)

Japan Agency for Medical Research and Development (AMED)

- National organization supporting medical research and healthcare innovation in Japan.
- Operates with approximately 300 staff (1/60th the size of the U.S. NIH) and a budget of about 1 billion USD (1/47th of the NIH).
- Funds projects to promote CDISC adoption in academia, improving data standardization and facilitating collaboration in clinical research.

Section 2: Survey Findings on CDISC Implementation

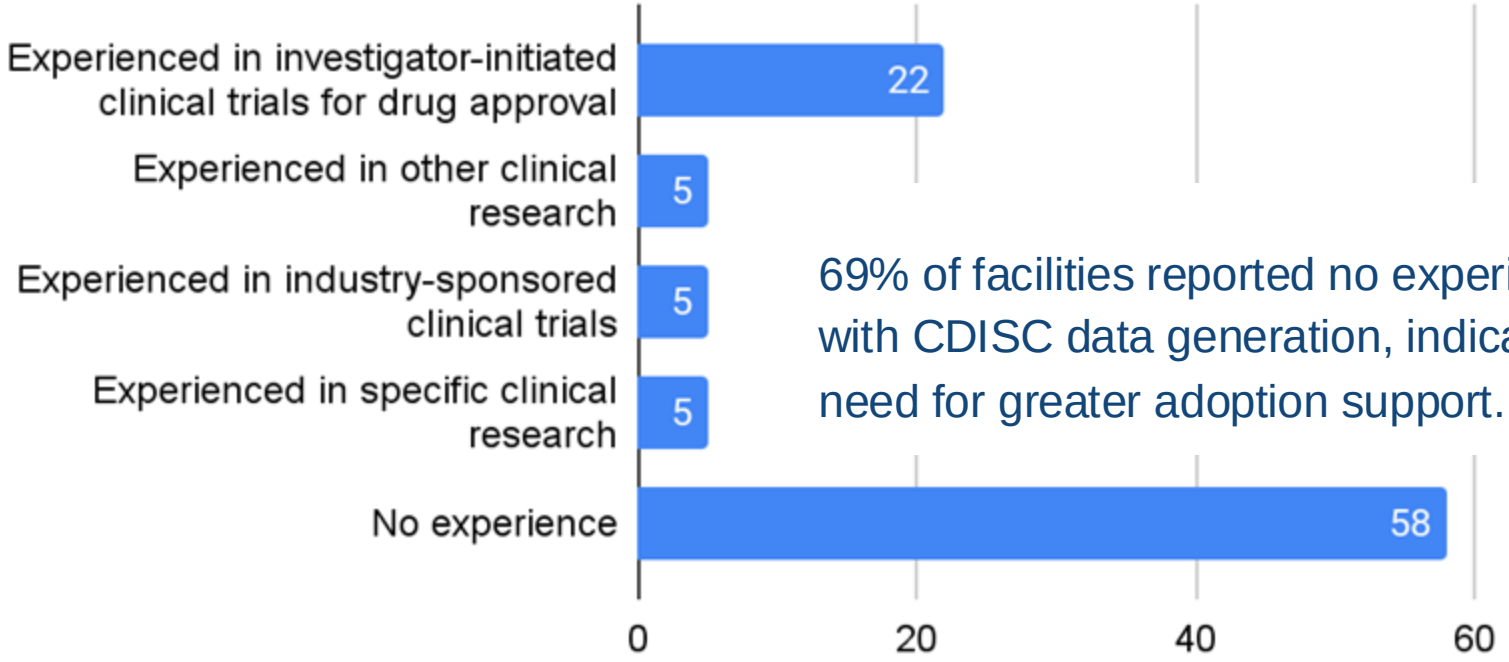
2024 Survey Overview - AMED project

- Purpose of the Survey
  - Assess the current state of CDISC adoption within Japanese academia.
  - Identify challenges and barriers to implementing CDISC standards.
  - Gather data to guide AMED's support and future initiatives for standardization.
- Scope
  - Focused on academic institutions legally defined to have clinical research as a core responsibility.
  - Included universities (national, public, private, government-affiliated, limited to universities with medical schools), National Centers (NCs), and the National Hospital Organization (NHO).
- Key Survey Questions
  - CDISC implementation status and challenges.
  - Awareness and use of AMED resources (SDTM-mapped CRFs, educational videos, data analysis tools).

2024 Survey Participants and Methodology

- Number of Institutions Surveyed: 91
- Responses Received: 84 (92% response rate)
- Breakdown of Responding Institutions
  - Universities: 76 out of 83
  - National Centers (NC): 7 out of 7 (formerly part of the national hospital system, now managed by 6 corporations overseeing 7 medical centers)
  - National Hospital Organization (NHO): 1 out of 1 (also formerly part of the national hospital system, currently a single corporation managing 140 hospitals)
- Survey Methodology
  - Questionnaires sent to stakeholders in clinical research management and data standardization.

Experience Levels in CDISC Data Generation



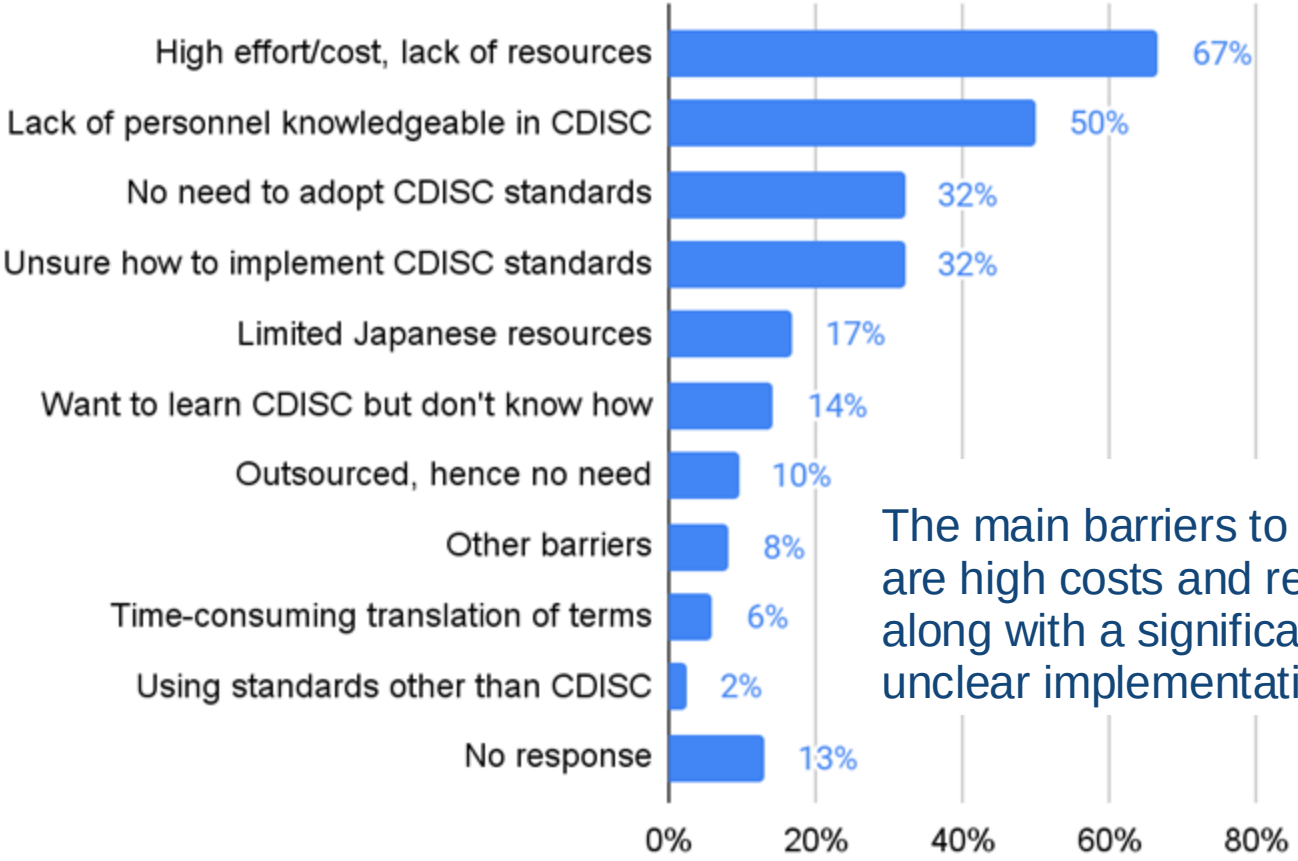
69% of facilities reported no experience with CDISC data generation, indicating a need for greater adoption support.

Current Implementation Status of CDISC Standards

CDISC Standard	Number of Responses	Percentage (%)
Not implemented	**64**	**76.2%**
CDASH, SDTM, ADaM	7	8.3%
SDTM, ADaM	4	4.8%
CDASH	4	4.8%
ADaM	3	3.6%
SDTM	1	1.2%
CDASH, SDTM, ADaM, ODM	1	1.2%
Total	84	–

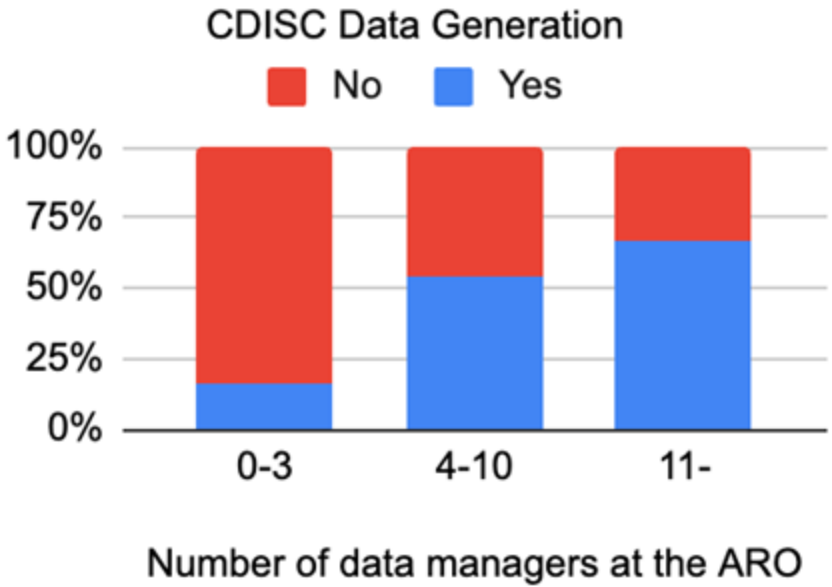
- 76% of facilities have not implemented any CDISC standards, with the few that have focusing primarily on CDASH, SDTM, and ADaM.
- Only 14% have integrated key standards - SDTM and ADaM, indicating limited comprehensive adoption.

Challenges in Implementing CDISC Standards



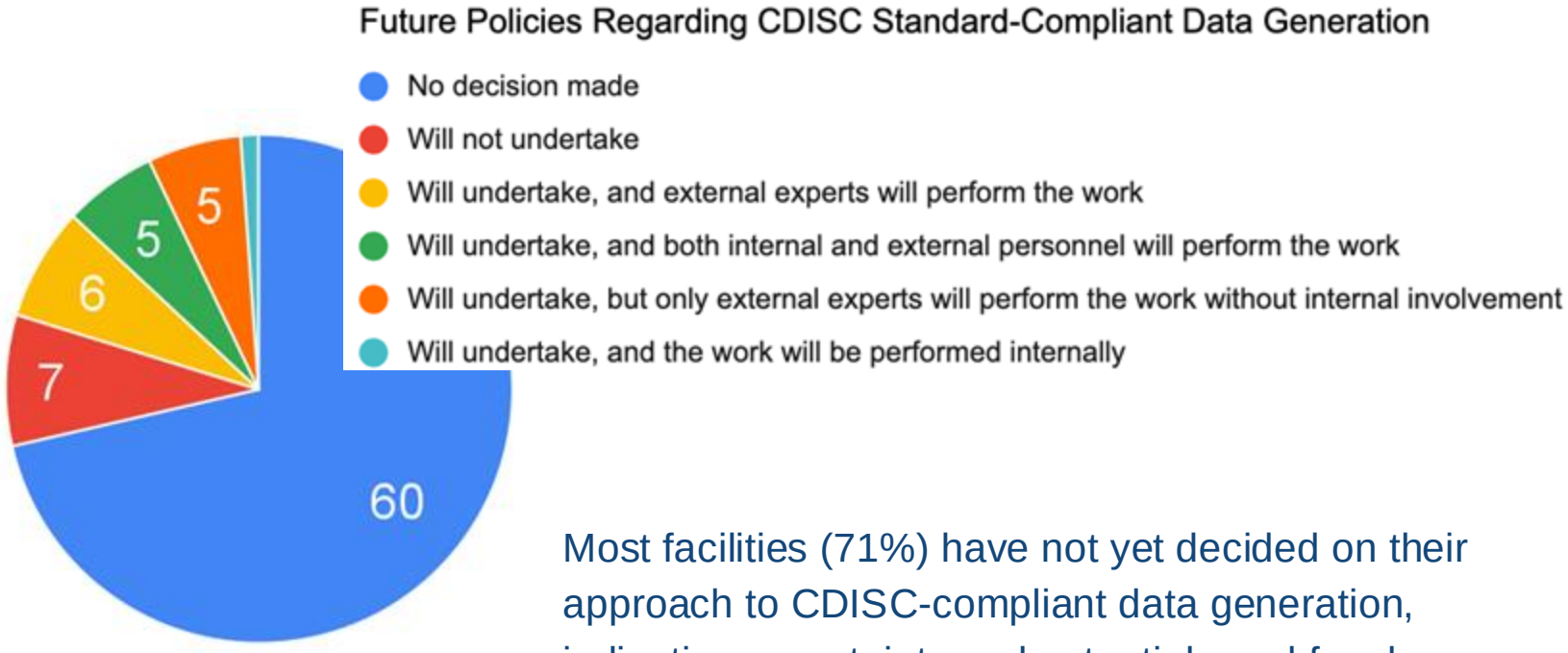
The main barriers to CDISC adoption are high costs and resource constraints, along with a significant skills gap and unclear implementation pathways.

Impact of Data Manager Availability on CDISC Data Generation



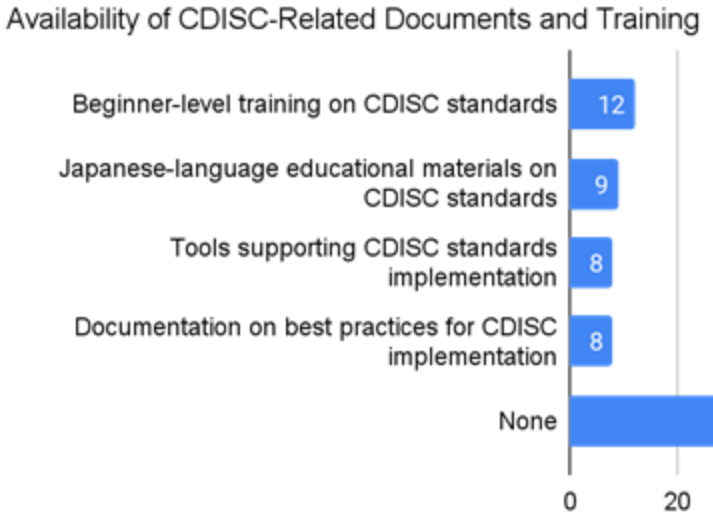
Facilities with more data managers are more likely to have experience in generating CDISC-compliant data, suggesting that resource availability plays a key role in successful implementation.

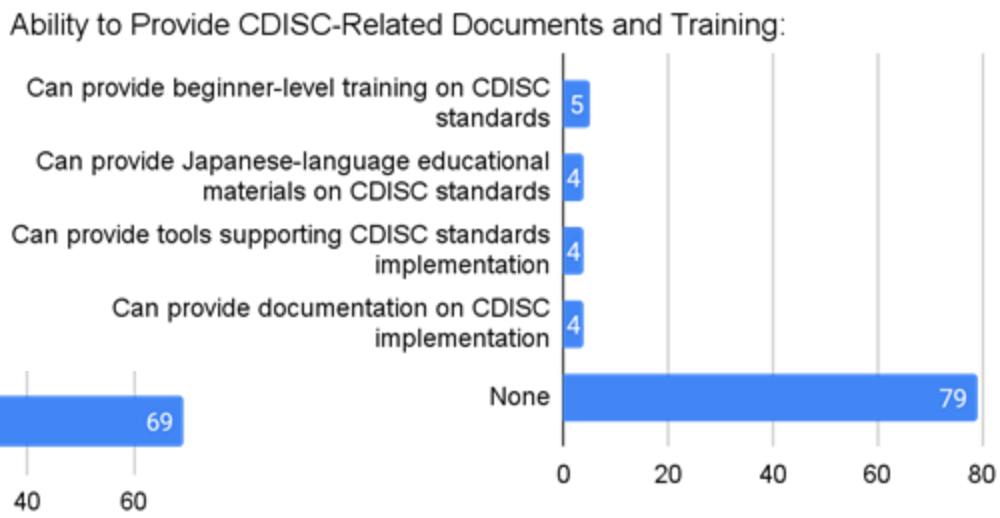
Future Policies Regarding CDISC Standard-Compliant Data Generation



Most facilities (71%) have not yet decided on their approach to CDISC-compliant data generation, indicating uncertainty and potential need for clearer guidance or support.

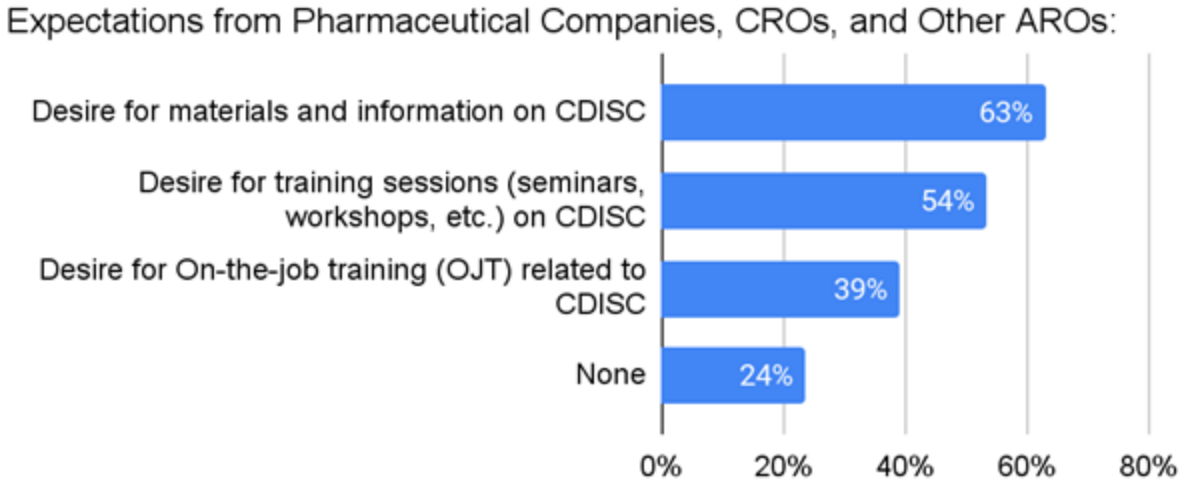
Training and Documentation Availability for CDISC





Most facilities lack access to CDISC-related documents and training, with 82% reporting no availability, and 94% indicating they cannot provide such resources, highlighting a significant gap in support and education.

Demand for CDISC Training and Resources from Academia



Most Japanese academic institutions expressed a need for CDISC materials, training sessions, and on-the-job training, highlighting the importance of hands-on support.

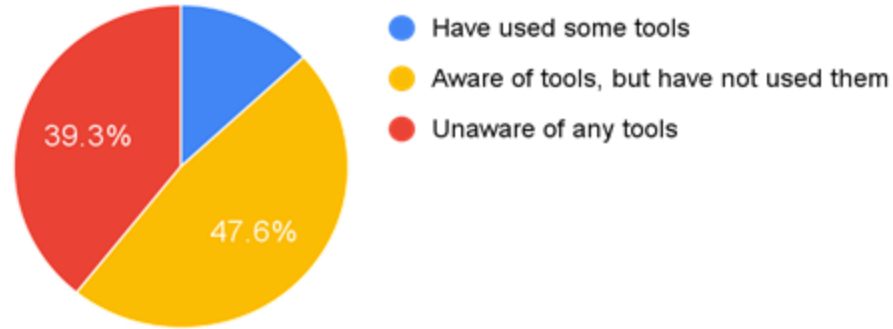
Utilization of SDTM-Mapped CRF on aCRF.jp

While only 12.4% of institutions have implemented SDTM, there is potential for greater engagement with SDTM-mapped CRFs on aCRF.jp, as 36% have explored the content, indicating growing awareness and interest in this resource.

Educational Resources: Videos and Data Tools Awareness

Awareness of Educational Videos

Knowledge and Use of CDISC Standard Data Tools



Nearly half of the institutions have watched educational videos on CDISC, indicating a positive trend in awareness, while 13% have actively used CDISC standard data tools, suggesting room for increased adoption and utilization.

Summary of 2024 Survey Findings - Key Insights (1/2)

- Current Adoption Status
  - 76% of institutions have not implemented any CDISC standards, with limited comprehensive adoption of CDASH, SDTM, and ADaM.
  - 69% reported no experience in generating CDISC-compliant data, indicating a need for further support.
- Challenges Identified
  - Main barriers include high costs, resource constraints, and a skills gap in CDISC implementation.
  - Uncertainty regarding the need and pathways for CDISC adoption remains prevalent.

Summary of 2024 Survey Findings - Key Insights (2/2)

- Resource Availability and Needs
  - Most institutions lack access to CDISC-related documents and training, with 82% reporting no availability of such resources.
  - 71% have yet to decide on their policy for generating CDISC-compliant data, reflecting a need for clearer guidance.
- Growing Awareness and Interest
  - While adoption is still limited, there is growing awareness of CDISC resources, including educational videos and tools, which shows potential for future engagement.
  - Increasing demand for training and hands-on support from academic institutions.

Section 3: Tools, Resources, and Future Directions

Overview of aCRF.jp - Academia CDISC Portal

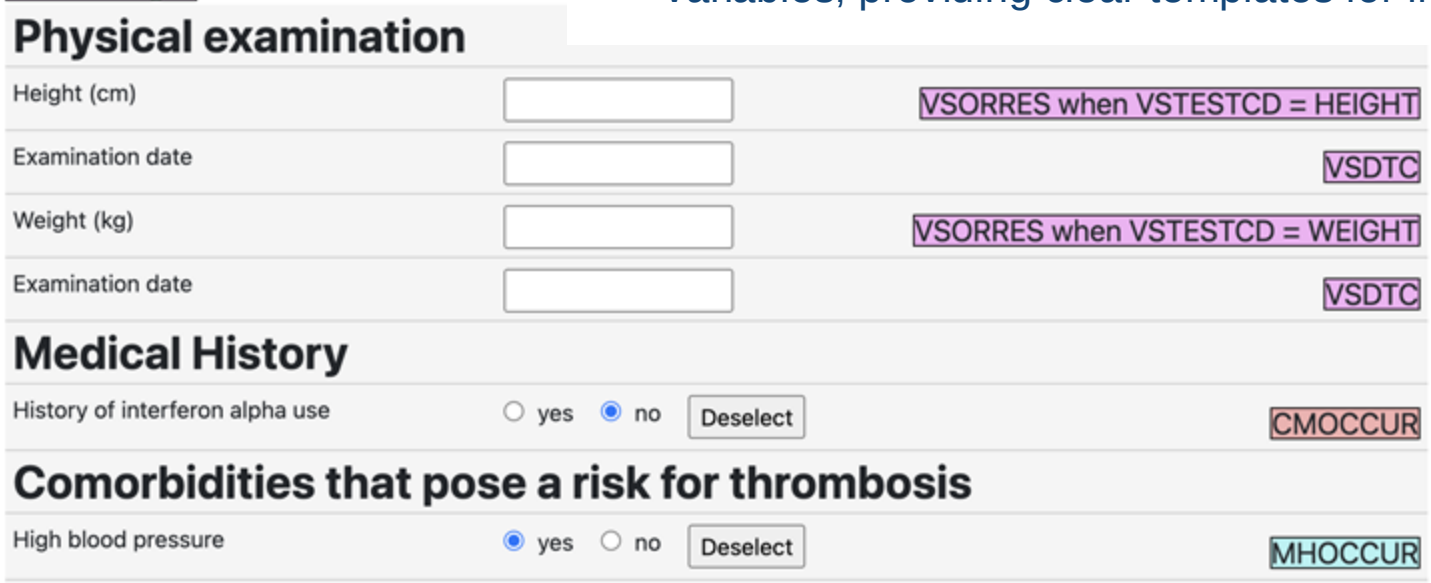
- Purpose
  - Established as part of AMED's research project
  - Facilitate the dissemination of CDISC standards across academic institutions.
- Key Features
  - SDTM-mapped, annotated Case Report Forms (aCRF) from Actual Clinical Studies
  - CDISC Tools and Programs
  - Curated Links to Educational Resources

Annotated CRFs(aCRFs) on aCRF.jp

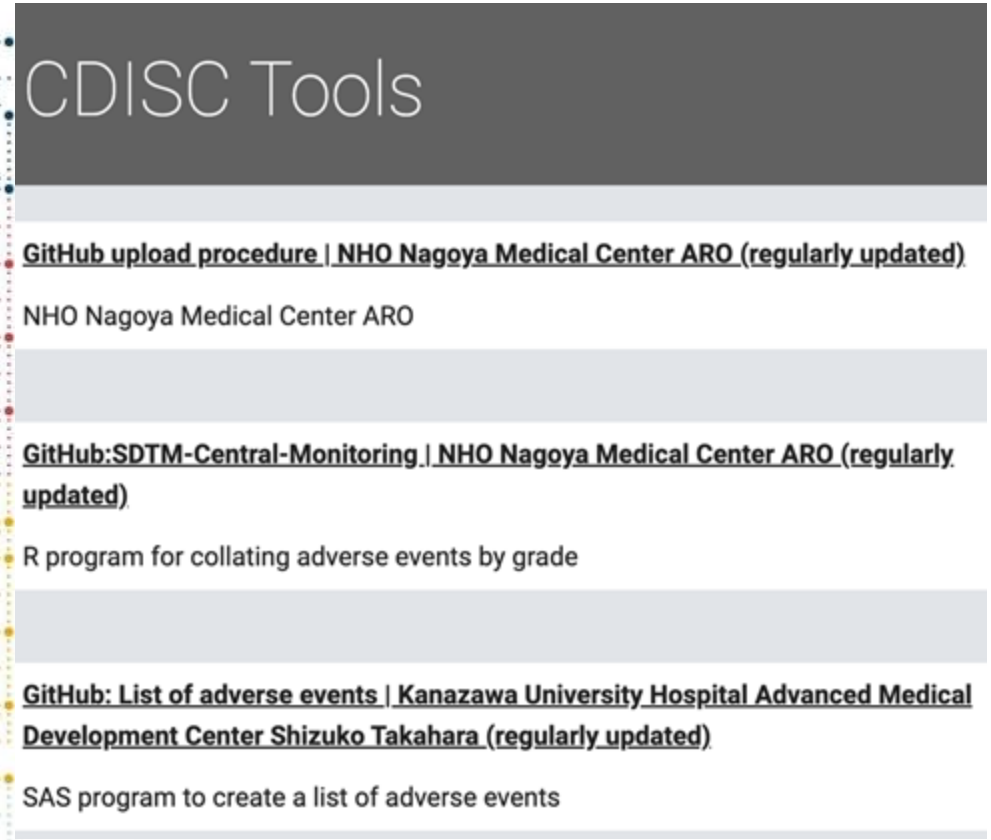
Patient background (baseline)

CM=Concomitant Medications
FA=Findings About Events or Interventions
LB=Laboratory Test Results
MH=Medical History
SU=Substance Use
VS=Vital Signs

- Annotated CRFs (aCRFs) from real clinical studies, including both interventional and observational research.
- These aCRFs show how to map clinical data to CDISC variables, providing clear templates for implementation.



Directly Applicable Analysis Tools for CDISC Data



R and SAS Programs

- Standardized datasets enable the use of shared tools, simplifying analysis and data review.
- These tools help academic users save time and streamline workflows by applying common programs.

Encouraging CDISC Standardization

- These tools aim to motivate academia to adopt CDISC standards, showing how standardization makes data handling more efficient and consistent.

Educational Video Resources on aCRF.jp

- Comprehensive Learning Materials
  - Links to 57 educational videos available on YouTube, designed to help users understand CDISC standards.
  - Videos cover basic concepts, practical applications, and step-by-step guides.
- Beginner-Friendly
  - Content tailored for those new to CDISC, offering clear explanations and examples.
  - Supports self-paced learning, accessible at any time.
- Easily Accessible
  - Videos are linked through aCRF.jp, providing a centralized resource for educational content.
  - Simplifies the process of finding relevant training materials.
  - *Note: Videos are currently available only in Japanese.*

Summary of Key Insights

- Section 1: Background
  - CDISC adoption in Japanese academia is still in early stages, with key support from J3C, CJUG, and AMED.
- Section 2: Survey Results
  - 76% of institutions have not yet adopted CDISC standards.
  - Main barriers: costs, resources, skills gaps.
  - Clear interest and demand for tools and educational support
- Section 3: aCRF.jp
  - Central platform offering aCRF, tools and educational resources to aid CDISC adoption.
  - Continues to expand resources and collaborations to promote broader use.

Thank You!