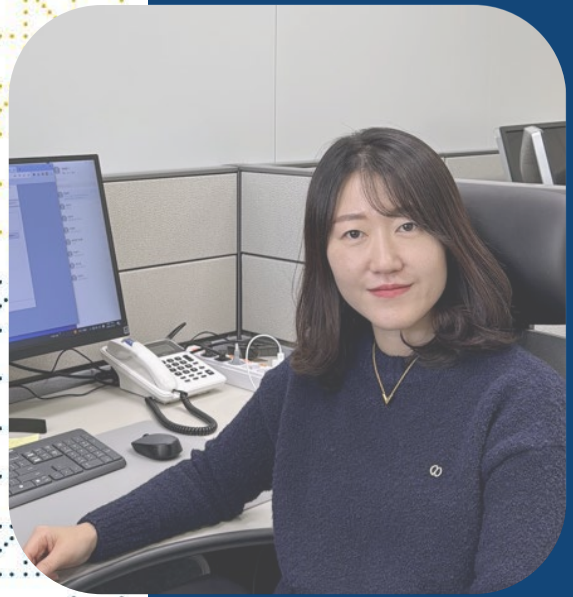
Shaping the Future of SEND Together: The Importance and Impact of User Group Activies

Presented by Yoongi Kim



Meet the Speaker

Yoongi Kim

Title: Study Data Standardization Manager, Senior Researcher

Organization: Korea Institute of Toxicology

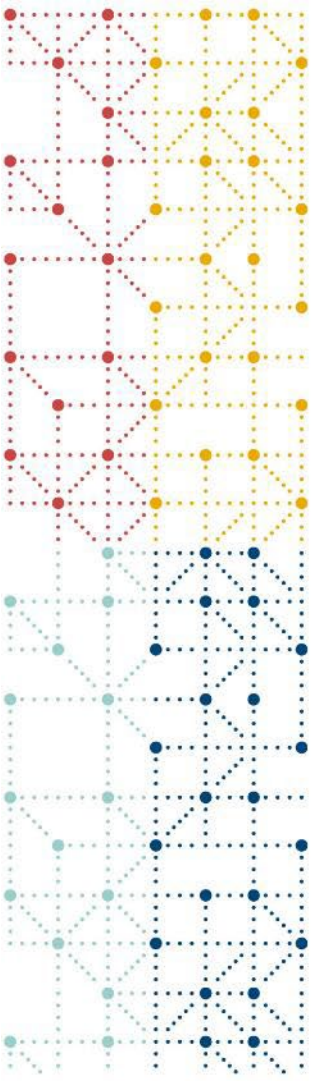
Yoon-gi Kim is a Senior Researcher at the Korea Institute of Toxicology and has actively worked as a GLP QA expert in both the United States and South Korea. Currently, as a Study Data Standardization Manager, Kim is engaged in conducting various research projects utilizing CDISC SEND. Kim is also a dedicated volunteer in the Phuse nonclinical working group, striving to establish a foundation for international collaboration through the use of standardized nonclinical data.

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.*
- *For some slides, you may need to get permission from the author to reproduce them due to copyright issues.*
- *The author(s) have no real or apparent conflicts of interest to report.*

Agenda

1. User Group Network
2. Current Status
3. Korea SEND User Group



User Group Networks

What is a User Network?

Enhancing Global Health through Collaboration

"CDISC" A pioneer in making clinical research data standards freely and openly available, and continues to be one of the leading organizations maintaining this open-access model

Improved worldwide health outcomes

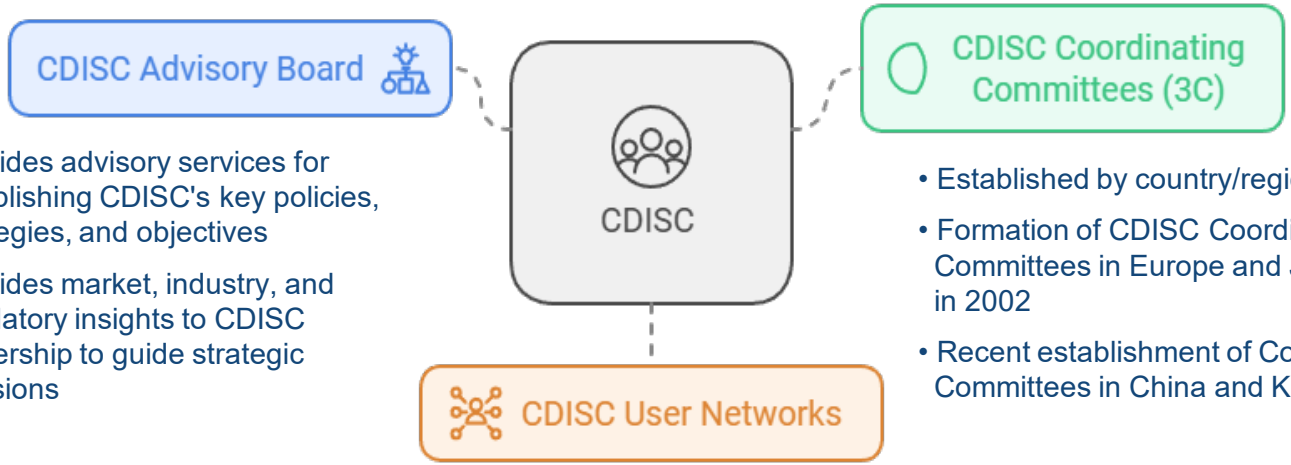
Advanced scientific studies

Diverse medical fields

Consistent data frameworks

Partnerships with global entities

Enhancing Global Health through Collaboration



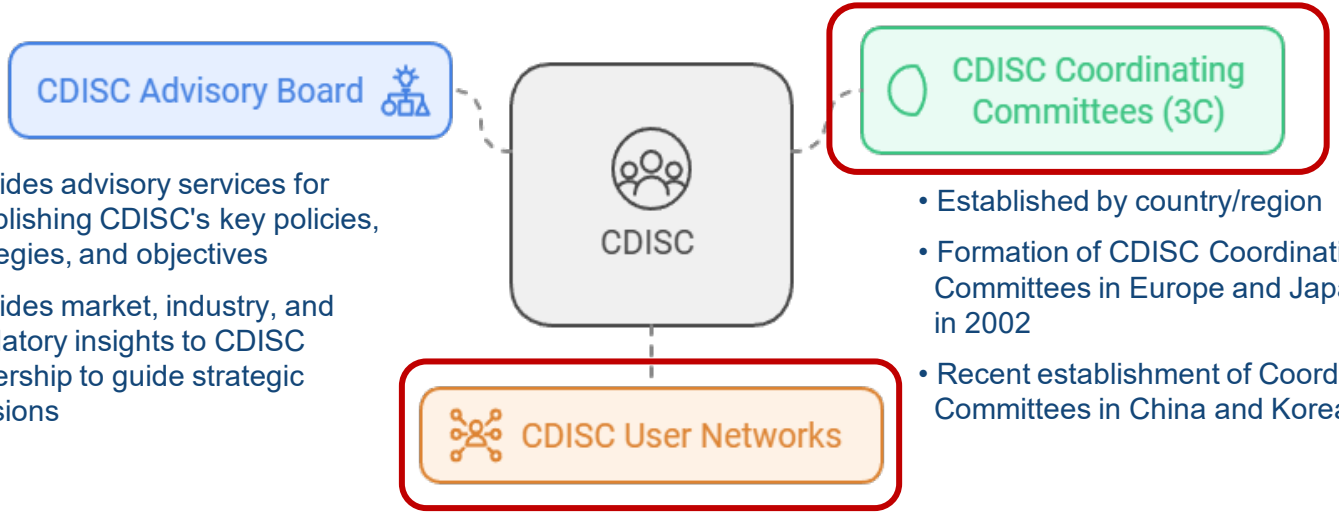
- Provides advisory services for establishing CDISC's key policies, strategies, and objectives
- Provides market, industry, and regulatory insights to CDISC leadership to guide strategic decisions

- Established by country/region
- Formation of CDISC Coordinating Committees in Europe and Japan in 2002
- Recent establishment of Coordinating Committees in China and Korea

Established and maintained by our community with support of CDISC based on the CDISC Operational Procedure.

Enhancing Global Health through Collaboration

Through its organizational framework, CDISC maintains active collaborations with multiple countries, facilitating the development and maintenance of international standards



- Provides advisory services for establishing CDISC's key policies, strategies, and objectives
- Provides market, industry, and regulatory insights to CDISC leadership to guide strategic decisions

- Established by country/region
- Formation of CDISC Coordinating Committees in Europe and Japan in 2002
- Recent establishment of Coordinating Committees in China and Korea

Established and maintained by our community with support of CDISC based on the CDISC Operational Procedure.

CDISC User Networks

Discuss standards updates and developments, share implementation and learning experiences, participate in public review, and circulate feedback and new ideas to CDISC.

“CDISC User Network Operational Procedure (COP-011)”

CDISC Operational Procedure CDISC-COP-011
CDISC User Networks

Purpose

Defines the appropriate roles and expectations between the User Networks and CDISC. This is important to define since CDISC is a non-profit organization with a product consisting of freely available, open CDISC standards, which are produced largely by volunteers through a consensus process.

CDISC User Networks

Self-formed User Networks developed in the United States to enable face-to-face interactions among CDISC users.

In Europe, E3C encouraged User Network formation centered around five language areas: French, German, Italian, Nordic and English.

There are now additional User Networks in Korea, Japan and China.

CDISC User Networks

CDISC User Networks

Joe Ben Clark님이 작성, 3월 13, 2024에 최종 변경

CDISC User Networks are established and maintained by our community with support of CDISC based on the CDISC Operational Procedure. Please Contact Us if would like to start one in your area

North America

- Tri-state
- San Diego
- Bay Area (San Francisco)
- Boston Area
- Austin, Texas
- Midwest (Chicago) (Contact us to start one)
- Delaware Valley (Philadelphia Area) (Contact us to start one)
- Heartland (Contact us to start one)
- RTP (Raleigh) (Contact us to start one)
- Seattle (Contact us to start one)
- Washington DC (Contact us to start one)

Europe

- English Language/UK Network
- French Language
- German Language
- Italian Language
- Nordic User Network (contact us to start one)
- Polish User Network (contact us to start one)
- Russia User Network

Other

- Pediatric User Network

Asia/Pacific

- Africa
  - South Africa (Contact us to start one)
- Asia
  - China
    - Beijing (Contact us to start one)
    - Shanghai (Contact us to start one)
    - Guangzhou (Contact us to start one)
  - India
  - Japan - CJUG
- South Pacific
  - Australian User Network

CDISC User Networks

- Purpose and Benefits of CDISC User Networks

Share Conference Learnings

Share insights and knowledge gained from conferences

Share Implementation Experiences

Exchange regional or language-specific CDISC experiences

Network Among Colleagues

Facilitate professional networking among peers

Discuss Draft Standards

Provide feedback on draft standards to CDISC

Channel New Ideas

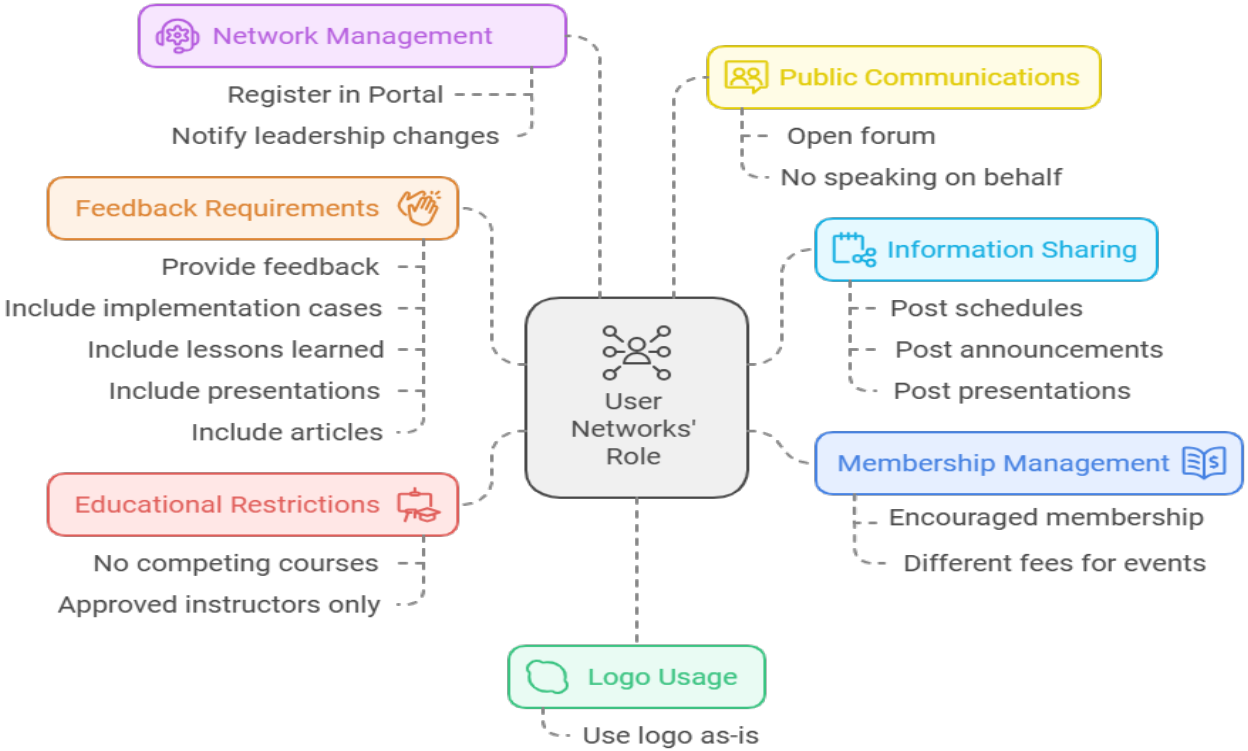
Introduce and develop new ideas for CDISC

Feedback on Mature Standards

Evaluate and provide feedback on established standards

CDISC User Networks

- User Networks' Role



CDISC User Networks

- CDISC Japan User Group (CJUG)

CDISC User Networks

- CDISC Japan User Group (CJUG)

ADaM

CJUG資料	説明　（日本語　&　英語）	作成時期	備考
ADaMとADaMに係る成果物のチェックリスト (Checklist for ADaM and ADaM related deliverables)	ADaMと、ADaM define.xml、ADRG、TFLsプログラム仕様を品質を確認するためのチェックリスト This checklist that is to confirm the quality of ADaM, ADaM define.xml, ADRG, and TFLs program specifications.	2018	Checklist.zip
はじめてのADaM version 1.1	ADaMとADaM IGの初心者向けの解説 This booklet titled “ADaM for Beginners in Japanese” (hereinafter called “this document”) is a hand book on ADaM (Analysis Dataset Model) by Japan User Group ADaM.	2013	ADaM handbook_v.1.1.pdf

CDISC User Networks

- CDISC Japan User Group (CJUG)

SEND

CJUG資料	説明　（日本語　&　英語）	作成時期	備考
SEND IG V3.0日本語訳(英語併記版）	SEND IG V3.0の日本語訳(英語併記版） Japanese translation of SEND IG V3.0(Japanese and English are described in parallel)	2013	SENDIG V3.0日本語訳(英語併記版）_Chapter 1-5.doc SENDIG V3.0日本語訳(英語併記版）_Chapter 6_1.doc SENDIG V3.0日本語訳(英語併記版）_Chapter 6_2.doc SENDIG V3.0日本語訳(英語併記版）_Chapter 7.doc
SEND IG V3.0日本語訳	SEND IG V3.0の日本語訳 Japanese translation of SEND IG V3.0	2013	SENDIG V3.0日本語訳_Chapter 1-5.docx SENDIG V3.0日本語訳_Chapter 6.docx SENDIG V3.0日本語訳_Chapter 7-8.docx

CDISC User Networks

- CDISC SDTM, SEND IG Korean version

CDISC

Study Data Tabulation model

Version 1.5

Prepared by the

CDISC Submission Data Standards Team (CDISC 제출 데이터 표준팀) 및

CDISC SDTM Governance Committee (CDISC SDTM 관리위원회)

참고 사항

본 문서는 Study Data Tabulation Model Document(SDTM)의 버전 1.5입니다. 본 문서에는 인간 임상 시험, 동물 시험, 의료 기기, 약물 유전체학/유전학과 관련된 변수의 추가와 본문에 대한 수정 및 명확화를 실시하였습니다. 이전 버전의 모든 변경 사항에 대한 자세한 설명은 7장에 나와 있습니다.

SDTM 관리위원회는 현재 SDTM에 대한 이슈사항들에 대해 관리하고 있습니다. 이러한 이슈에 대한 설명은 CDISC Wiki(http://wiki.cdisc.org/x/5cDdAQ)에서 확인할 수 있습니다.

Notice

1. 본 SDTM 한글판에서 원본 CDSIC 문서와 불일치가 발견될 경우, 원본 CDISC 문서가 우선해야 합니다.
2. 자세한 사항은 원본 문서를 사용하십시오.

개정 이력(Revision History)

날짜(Date)	버전(Version)
2016-06-27	1.5 최종(Final)
2015-07-13	1.5 초안(Draft)
2013-11-26	1.4 최종(Final)
2012-07-16	1.3 최종(Final)
2008-11-12	1.2 최종(Final)
2005-04-28	1.1 최종(Final)
2004-06-25	1.0 최종(Final)

진술 및 보증, 책임 제한 및 면책 사항에 대해서는 부록A를 참조하십시오.
See Appendix A for Representations and Warranties, Limitations of Liability, and Disclaimers.

목 차
CONTENTS

1 서론

Introduction

1.1 목적

Purpose

본 문서는 의약품 신청의 과정에서 미국 식품의약품청(FDA)과 같은 규제 기관에 제품허가신청을 위해 제출될 시험 데이터에 관해 표 형식의 표준 구조를 정의하는 SDTM(Study Data Tabulation Model)에 관한 것이다. 본 문서는 원래 CDISC (국제임상데이터표준컨소시엄, Clinical Data Interchange Standards Consortium)의 SDS (제출 데이터 표준, Submissions Data Standards) 팀이 작성한 자료를 기반으로 하지만 현재 CDISC의 SDTM 관리위원회(SGC, SDTM Governance Committee)에 의해 유지 관리된다. 모든 이전 버전을 대체하는 해당 문서는 이전 버전인 1.4버전의 많은 변경 사항이 포함되어 있으며, 변경 사항에 대해서는 7.1장에 설명되어 있다.

This document describes the Study Data Tabulation Model (SDTM), which defines a standard structure for study data tabulations that are to be submitted as part of a product application to a regulatory authority such as the United States Food and Drug Administration (FDA). This document is based on material originally prepared by the Submissions Data Standards (SDS) Team of the Clinical Data Interchange Standards Consortium (CDISC), but is now maintained by the SDTM Governance Committee (SGC) of CDISC. This document, which supersedes all prior versions, includes numerous changes from the prior version 1.4, which are described in Section 7.1.

표 형식 데이터 세트는 FDA에 제출되는 피험자의 Case Report Tabulation (CRT: 사례 보고서 표) 및 동등한 동물 데이터를 제시하기 위한 4가지 방법 중 하나이다. CRT는 또한 피험자 프로필, 데이터 리스트 및 분석 데이터 세트 형식으로도 제출된다. 표준 구조를 준수하는 표 형식 데이터 세트를 제출하는 것에 있어서 업계의 한 가지 이점은 동일한 형식의 데이터를 여러 형식으로 제출할 필요성을 최소화한다는 것이다.

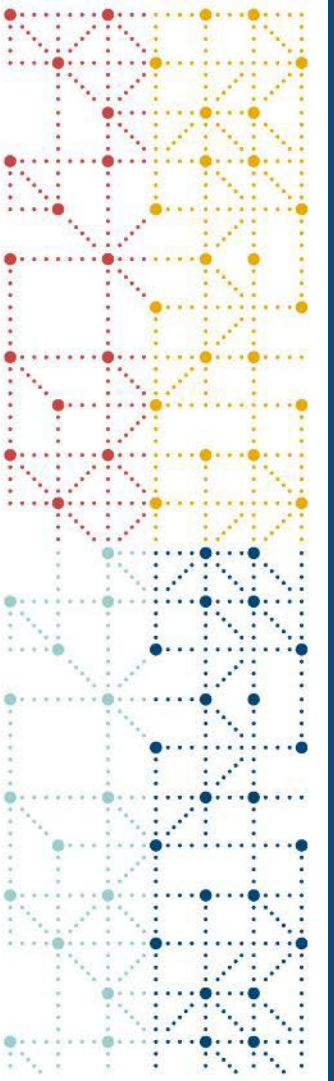
Data tabulation datasets are one of four ways to represent the human subject Case Report Tabulation (CRT) and equivalent animal data submitted to the FDA. CRTs are also submitted in the format of subject profiles, data listings, and analysis datasets. One benefit to industry of submitting data tabulation datasets that conform to the standard structure is that it minimizes the need to submit the same data in multiple formats.

표준화된 제출 데이터를 이용함으로써 규제기관의 심사담당자에게 많은 이점을 제공할 수 있다. 심사담당자는 이제 표준화된 데이터 세트 원칙과 표준 소프트웨어 툴의 사용법에 대해 교육을 받을 수 있으므로 보다 짧은 준비 시간에 보다 효율적으로 데이터를 처리할 수 있게 된다. 표준화된 데이터 세트의 또 다른 이점은 제출된 모든 시험에 대한 저장소와 시험 데이터에 접근하고 조작하고 보기 위한 일련의 표준화된 심사의 툴을 개발하려는 FDA의 노력에 도움을 줄 수 있다는 것이다.

The availability of standard submission data may provide many benefits to regulatory reviewers. Reviewers can now be trained in the principles of standardized datasets and the use of standard software tools, and thus be able to work with the data more effectively with less preparation time. Another benefit of the standardized datasets is that they can provide support for the FDA's efforts to develop a repository for all submitted studies and a suite of standard review tools to access, manipulate, and view the study data.

본 문서는 규제 당국에 제출되는 시험 데이터의 수집, 준비 및 해석과 관련된 기업 및 개인을 대상으로 한다. 본 모델의 적용에 대한 지침, 규격 및 규칙은 규제 당국이 별도로 제공한다. SDTM에 기초하여 규제기관에 신청을 준비하기 전에 이러한 문서를 참조할 것을 권장한다.

This document is intended for companies and individuals involved in the collection, preparation, and analysis of study data submitted to regulatory authorities. Guidance, specifications, and regulations for the application of this model will be provided separately by regulatory authorities. Audiences are advised to refer to these documents before preparing a regulatory submission based on the SDTM.



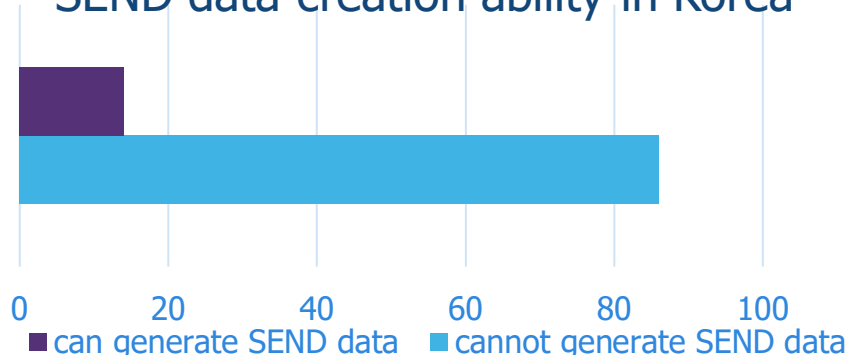
Current Status

Current Status

- Adoption Status of CDISC Standards by Country

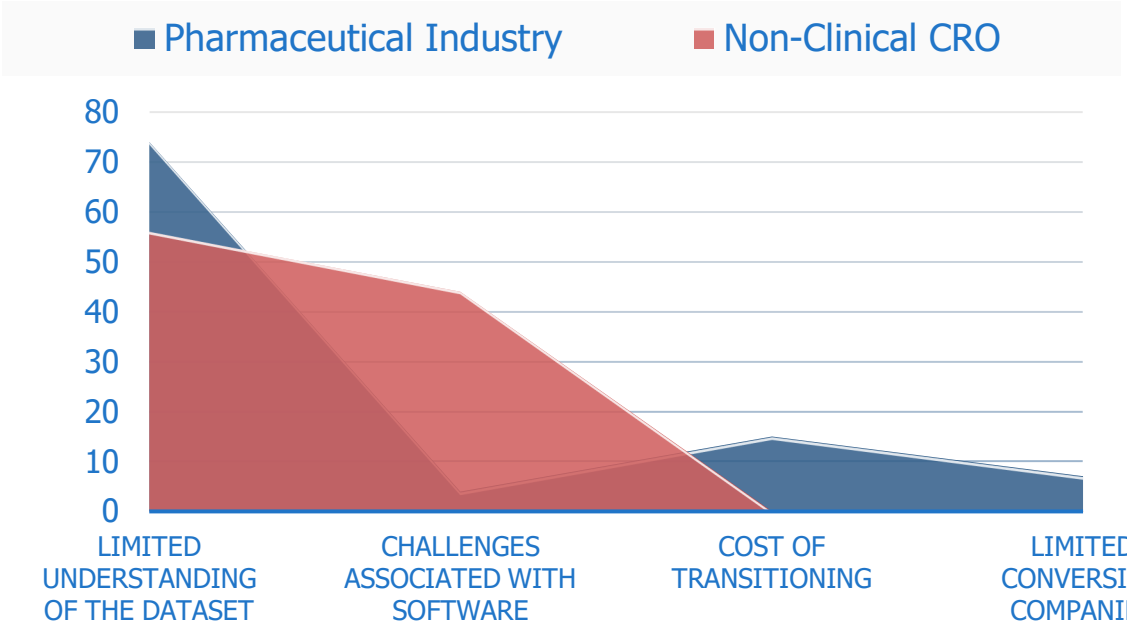
Country	CDISC Standard Adoption	Mandatory Implementation	SEND Application
United States	Adopted	Yes	Applied
Europe	Adopted	No	In progress
Japan	Adopted	Yes	In progress
China	Adopted	Yes	In progress
Korea	Adopted	No	In progress

- SEND data creation ability in Korea



Current Status

- Reasons for the difficulty in constructing the SEND datasets



Current Status

CDISC submission Pilot Project

민원사무목록

순번	업무분류	민원사무명
1	단순민원	CDISC 시범제출

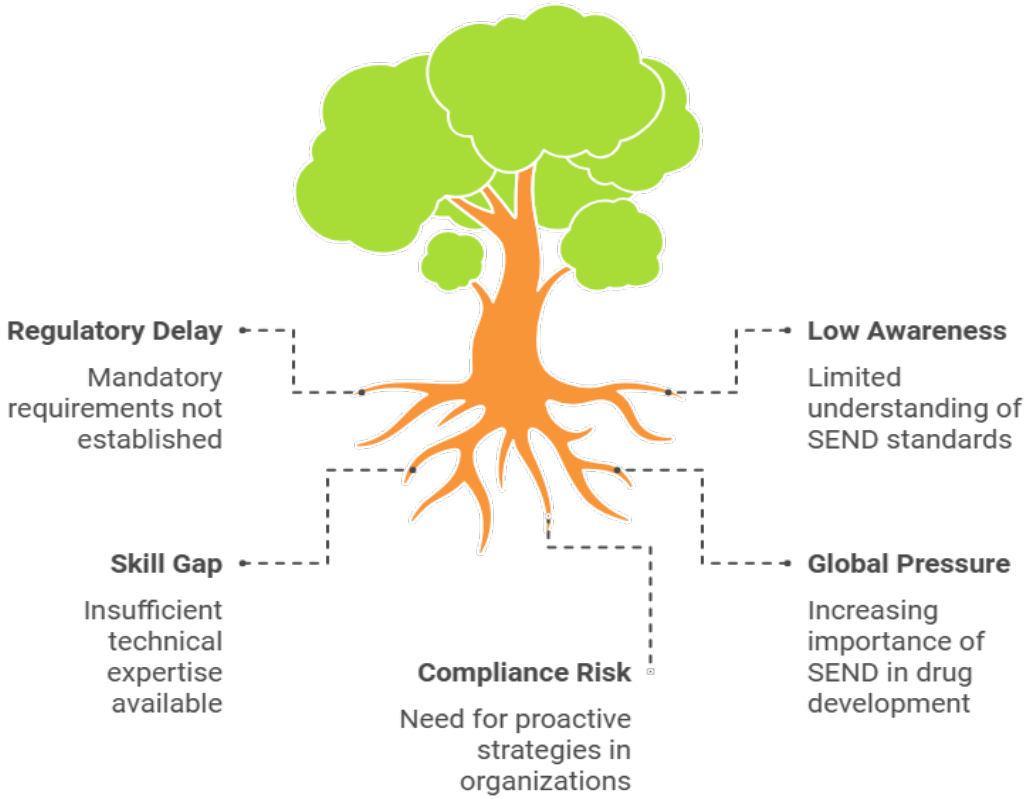
Standards in Development

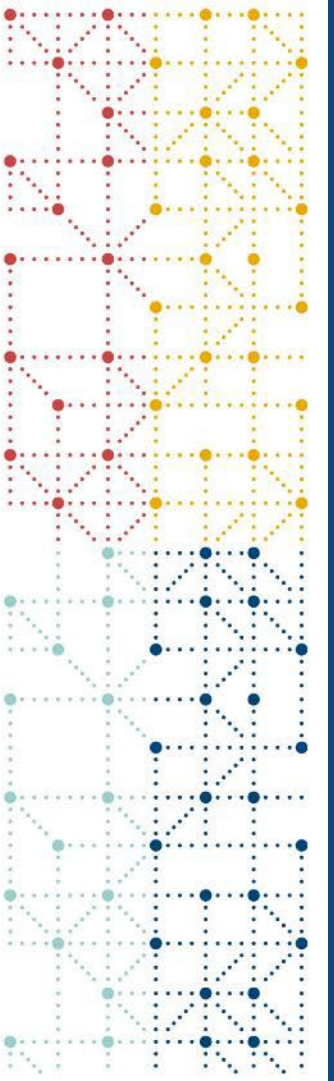
Standard	Release Notes	Projected Publication
ADaM and IG v3.0	In Development	2026
ADaM Oncology Examples v1.0	Resolving Public Review Comments	2024
CT Relationships for SDTM v1.7, SDTMIG v3.3, SDTMIG-MD v1.1	Resolving Public Review Comments	2024
SDTM v3.0	In Development	2025
SDTMIG v4.0	In Development	2025
SENDIG v4.0	In Development	2025

FDA Data Standards Catalog v10.4

Use	Standard	Exchange Format	SDO	Property	Related Properties	FDA Center(s)	Date Support Begins	Date Support Ends	Date Requirement Begins [10] [11]
Nonclinical study datasets	**SEND**	**XPT**	**CDISC**	**SDTMv1.5**		**CBER**	**03-15-2021**		**03-15-2023**
Nonclinical study datasets	SEND	XPT	CDISC	SENDIGv3.1		CDER	08-21-2017		03/15/2019 [1] 03/15/2020 [2]
Nonclinical study datasets	SEND	XPT	CDISC	SENDIGv3.1		CBER	07-14-2020		03-15-2023
Nonclinical study datasets	SEND	XPT	CDISC	[illegible]		CDER, CBER	02-15-2022		[illegible]
Nonclinical study datasets	SEND	XPT	CDISC	SENDIG-Genetoxv1.0		CDER, CBER	12/13/2023 [12]		03-15-2025
Nonclinical study datasets	**SEND**	**XPT**	**CDISC**	**SDTMv1.6**		**CDER**	**03-05-2021**		**03/15/2023 [1] 03/15/2024 [2]**
Nonclinical study datasets	SEND	XPT	CDISC	SENDIG-DARTv1.1		CDER	03-05-2021		03/15/2023 [1] 03/15/2024 [2]

Need to incorporate characteristics of local research environment





Korea SEND User Group

Korea CDISC(SEND) User Group(KSUG) formation

Initial Planning and Stakeholder Identification	Organizational Structure Development	Official Launch	CDISC Affiliation and Network Expansion	Regular Operations and Activities	Continuous Improvement and Global Integration
Identify domestic organizations and individuals interested in SEND	Establish the group's mission, vision, and objectives	Organize an official launch event	Apply for official CDISC affiliation	Conduct regular meetings and educational sessions	Regularly review and update group activities based on member feedback
Organize informal meetings to discuss the need for a user group	Define the organizational structure and roles	Invite key stakeholders from industry, academia, and regulatory bodies	Establish communication channels for members	Collaborate with CDISC and other international SEND user groups	Participate in global CDISC events and initiatives
Contact CDISC to discuss the formation of a Korea SEND User Group	Draft operational guidelines and membership criteria	Begin membership recruitment	Actively recruit new members from various sectors	Implement SEND-related projects and initiatives	Contribute to the advancement of SEND implementation in Korea and globally

Korea SEND User Group Activity

- Translate SEND implementation guides into Korean
- Create Korean language resources explaining SEND concepts and best practices

Enhancing Accessibility through Guideline Translation

- Focus on virtual control group research aligned with international efforts
- Identify Korea-specific challenges in SEND implementation for collaborative problem-solving

Collaborative Mission Discovery

- Annual event to showcase SEND advancements in Korea
- Provide a platform for Korean organizations to present their SEND implementation experiences

Organizing CDISC Day Korea

- Regular SEND training sessions for beginners and advanced users
- Hands-on workshops for practical SEND implementation

Educational Workshops and Seminars

- Develop templates and tools to assist in SEND dataset creation
- Establish a mentorship program pairing experienced SEND users with newcomers

Resource Development for SEND Understanding and Implementation

Japan SEND User Group Activity

J Toxicol Pathol 2015; 28: 57–64

Review

Responses to the Standard for Exchange of Nonclinical Data (SEND) in non-US countries

Takayuki Anzai[1]*, Masamichi Kaminishi[1], Keizo Sato[1], Laura Kaufman[2], Hijiri Iwata[3], and Dai Nakae[4]**

[1] Showa University School of Medicine, 1-5-8 Hatanodai, Shinagawa, Tokyo 142-0064, Japan
[2] PDS Life Sciences, 100 Valley Road, Suite 204, Mt. Arlington, NJ 07856, U.S.A.
[3] LunaPath LLC, Aoihigashi 3-5-1, Naka-ku, Hamamatsu-shi, Shizuoka 433-8114, Japan
[4] Department of Nutritional Science and Food Safety, Faculty of Applied Biosciences, Tokyo University of Agriculture, 1-1-1 Sakuraga-Oka, Setagaya, Tokyo 156-8502, Japan

Abstract: The Standard for the Exchange of Nonclinical Data (SEND), adopted by the US FDA, is part of a set of regulations and guidances requiring the submission of standardized electronic study data for nonclinical and clinical data submissions. SEND is the nonclinical implementation of SDTM (Study Data Tabulation Model), the standard electronic format for clinical regulatory submissions to FDA. SEND, SDTM, and the associated Controlled Terminology have been developed by CDISC (Clinical Data Interchange Standards Consortium). In order to successfully implement SEND, interdisciplinary contributions between sponsors and CROs, need a model for task allocation. This is being undertaken by the Pharmaceutical Users Software Exchange (PhUSE). Because SEND is currently the preferred submission format of the US FDA only and will become required by it starting in December 2016, only American academic societies and companies are actively involved. An exception to this is the INHAND initiative, which leads the way in standardizing terminology for toxicological pathology. On the other hand, international globalization of other clinical and nonclinical practices is not feasible because there are substantial differences between the US and non-US countries in CRO involvement in drug development. Thus, non-US countries must consider and develop approaches to SEND that meet their needs. This paper summarizes the activities of the major organizations involved in SEND development and implementation, discusses the effective use of SEND, and details a compliance scheme (research material of the Showa University School of Medicine) illustrating how pharmaceutical companies can complete a large amount of work up to an FDA application with the effective utilization of CROs and solution providers. (DOI: 10.1293/tox.2015-0007; J Toxicol Pathol 2015; 28: 57–64)

Key words : SEND, CDISC, FDA, INHAND, controlled terminology

Introduction

Globally, countries are actively computerizing medical product registration. In Japan, the Pharmaceuticals and Medical Devices Agency (PMDA), with the support of the Japan Pharmaceutical Manufacturers Association (JPMA), has started computerizing clinical study data and performed a pilot project[1] for computerizing application screens. It has also started to recruit personnel in anticipation of the future introduction of SEND and the SDTM. Obviously, the US FDA is staying ahead of other countries in clinical study and preclinical study data computerization and standardization. As a result, patients have greatly benefited from the speedier approval of new drugs, and the US pharmaceutical industry has been able to maintain its advantage over rivals in other countries. According to research conducted by a Yale University study group[2], among three administrative agencies, FDA, European Medicines Agency (EMA), and Health Canada, the period (median value) from application to completion of the first examination (2001–2010) was shortest for FDA. FDA is trying to further shorten the review period by standardizing the electronic formats for clinical and preclinical study submissions using the SDTM and SEND, developing electronic tools to analyze and visualize these submissions, and building data warehouses to rapidly query data across drugs, companies, and clinical and nonclinical disciplines. This infrastructure is already in place and being used by FDA.

Received: 26 January 2015, Accepted: 28 January 2015
Published online in J-STAGE: 1 April 2015
*Corresponding author: T Anzai (e-mail: takayuki.anzai@me.com)
**Co-corresponding author: D Nakae
(e-mail: agalemde.dai@nifty.com)

✓ Key Challenges for Non-US Countries

- Managing multiple CROs across different countries
- Ensuring SEND dataset reliability
- Dealing with varying CRO capabilities
- Meeting FDA accountability requirements

✓ Response Strategies

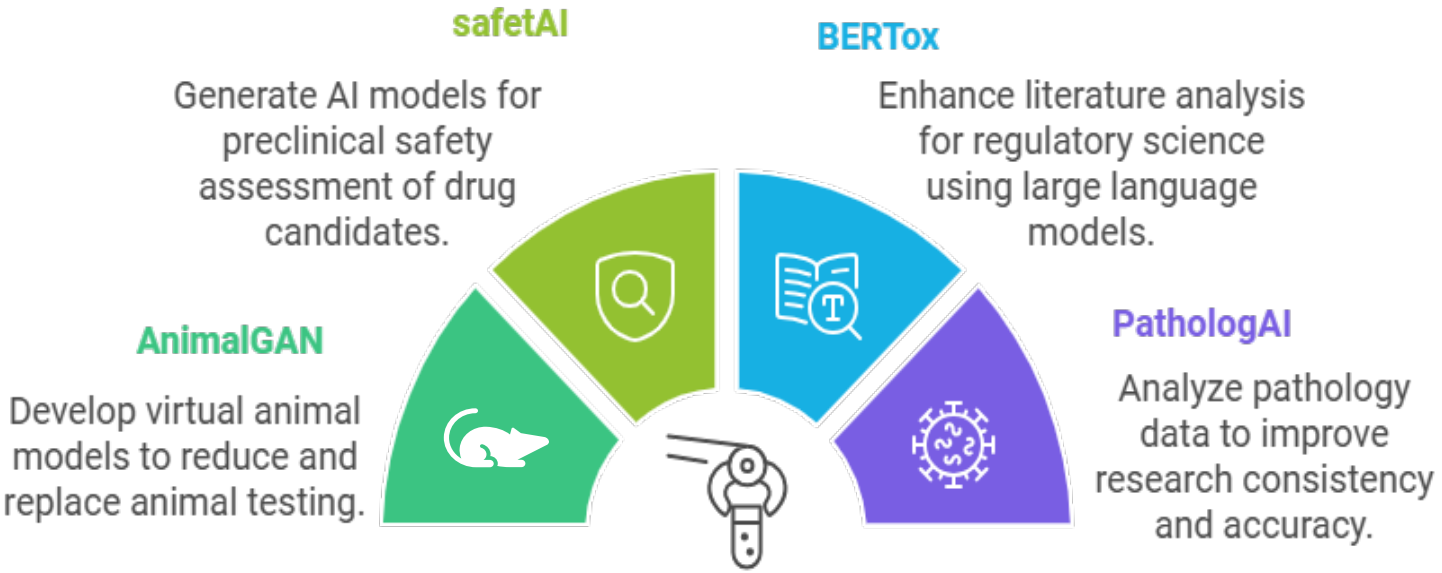
- Use Registered Solution Providers (RSPs) for expertise
- Follow three main phases:
  - Preparation: Plan and assess requirements
  - Dataset Creation: Convert and verify data
  - Final Check: Validate against FDA requirements
- Establish clear processes for CRO coordination

✓ Critical Points

- Avoid FDA submission rejection risks
- Define clear CRO responsibilities
- Ensure data integrity and quality
- Develop strategic long-term approach

FDA AI4TOX

FDA's Artificial Intelligence Program for Toxicology Research



FDA AI4TOX

FDA's Artificial Intelligence Program for Toxicology Research

AnimalGAN

Develop virtual animal models to reduce and replace animal testing.

Research on AI-based Generative Adversarial Network (GAN) Architecture Following the 3Rs Principles (Reduction, Refinement, and Replacement) of Animal Research

Chen, X. et al. A generative adversarial network model alternative to animal studies for clinical pathology assessment. Nat Commun 14, 7141 (2023)

The pilot study demonstrated that AnimalGAN's synthetic data for toxicogenomics, hematology, and clinical chemistry showed potential for use in toxicity assessment, mechanistic studies, and biomarker development, comparable to actual experimental data.

Using AnimalGAN, a virtual experiment with 100,000 mice determined the hepatotoxicity ranking of three structurally similar drugs, showing trends comparable to those observed in human populations.

Relentless Collaboration

Multi-institutional research on data standards becomes feasible

- Enables sharing of standardization status and standard policies among various institutions
- Enables joint resolution of standardization challenges within Korea

Establishment of a cooperation system with private institutions for data standardization

- The shortage of professional workforce specialized in non-clinical data standardization can be resolved through establishing domestic cooperation frameworks

Multi-Institutional Research

Sharing policies and resolving challenges collaboratively

Cooperation with Private Institutions

Establishing frameworks to address workforce shortages

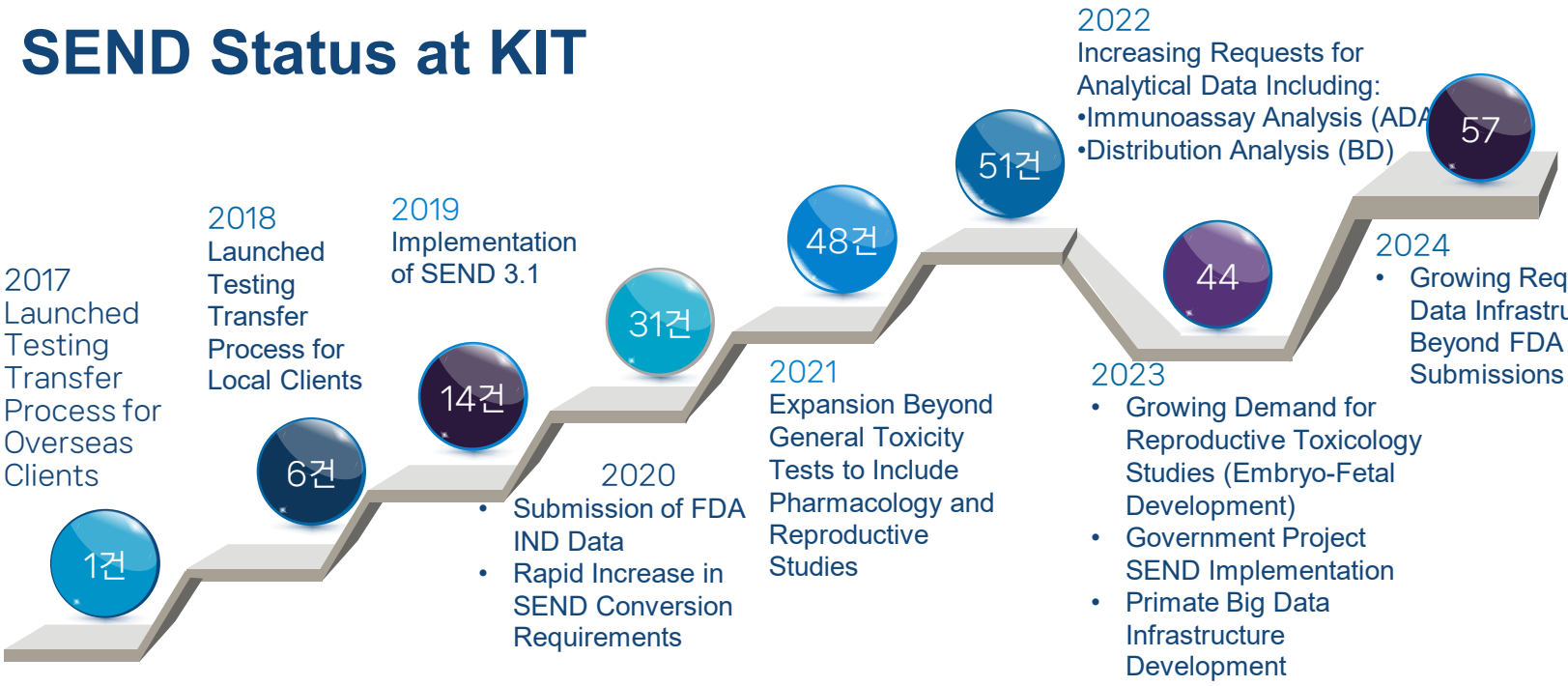
Regulatory Authority Impact

Positive environment for CDISC standards adoption

Impact of data standard implementation by domestic regulatory authorities

- High awareness and understanding of CDISC standards within the domestic community creates a positive environment for regulatory authorities to adopt and recommend CDISC standards
- Contributes to strengthening cooperative relationships between CDISC and domestic regulatory authorities

SEND Status at KIT



GLP	2017	2018	2019	2020	2021	2022	2023	2024	TOTAL
Y	1	5	9	25	40	45	44	52	247
N	0	1	5	6	8	6	0	5	

Thank You!