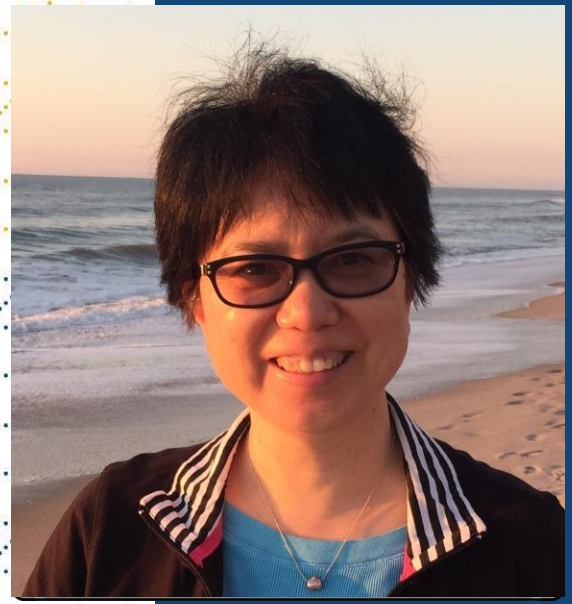
cdisc

2023
KOREA
INTERCHANGE
SEOUL | 11-14 DECEMBER

Standard is a Global Trend
Welcome from the CDISC Board of Directors

Wenjun Bao, Ph.D.
Chief Scientist and Director of Advanced Analytics R&D, JMP/SAS
Board of Director, CDISC
Dec 13, 2023



Meet the Speaker

Wenjun Bao

Title: Chief Scientist and Director of Advanced Analytics R&D

Organization: JMP Statistical Discovery, SAS Institute Inc.

Dr. Wenjun Bao is a Chief Scientist and Director of Advanced Analytics for JMP statistical Discovery, SAS Institute Inc. Before joining SAS, she was an Intramural Research Training Award (IRTA) Fellow at NIH (National Institutes of Health), a professor at Duke University, and a scientist at the US EPA (Environmental Protection Agency). She has rich experiences in clinical, bioinformatics, biochemistry, and molecular biology research. She has expertise in variety data analysis including clinical trial and genomics data analysis; AI/ML models in and text mining with multiple publications in peer-reviewed journals. Dr. Bao has been a research grant review committee member for NIH since 2005 and a research adviser for scientists at universities and government agencies. Dr. Bao is a Board of Director for CDISC and an adjunct professor at Fudan University.

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- *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.*

- *{Please disclose any financial relationship or conflict of interest relevant to this presentation here OR}*
- *The author(s) have no real or apparent conflicts of interest to report.*

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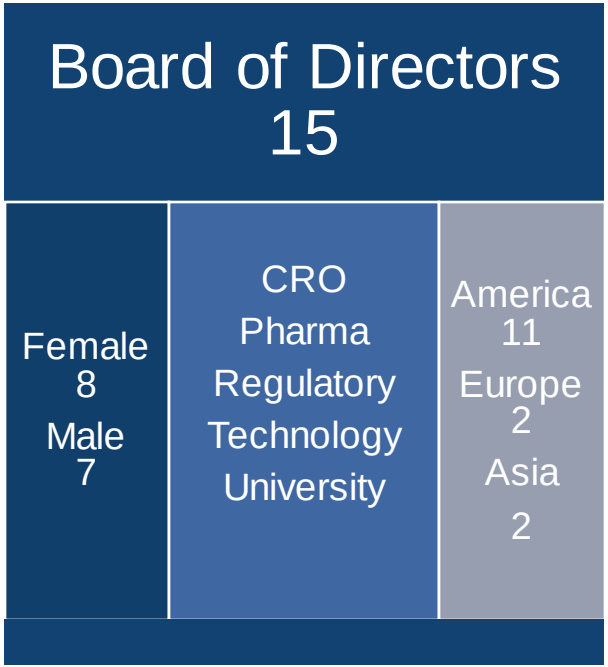
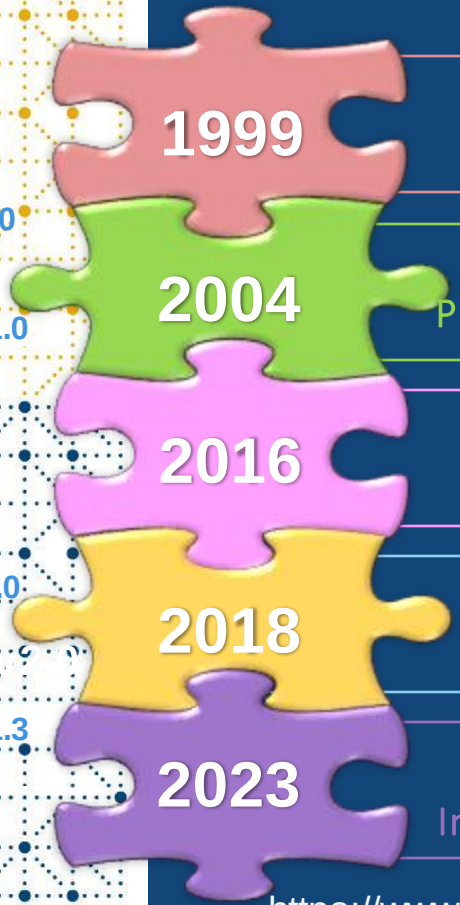


Milestones for Clinical Trial Data Standardization



1999
FDA Encouraged Electronic Submission
CDISC-FDA Collaboration, FDA Support for SAS XPT

SDTM v1.0
2004
ADaMIG v1.0
2009

2004
FDA Support for CDISC Submissions
Predictability, Traceability, Replication, Aggregation, Tools, Interchange

2016
FDA, PMDA Require CDISC Format Data for Submission
EMA, NMPA Recommend CDISC Format Data for Submission

SDTMIG v2.0
2021

2018
FDA Requires Reviewers to have Standards
Training for Career Advancement

ADaMIG v1.3
2021

2023
Record High Companies as CDISC Members and Volunteers
Innovations: CORE, 360°, JSON, eCRFs Portal/DHT, Library, RWD/RWE etc

https://www.cdisc.org/standards/foundation https://www.fda.gov/media/91152/download

Standard is a Global Trend in Health Fields

Standard in Clinical Trial Data: CDISC

FDA Standards Trainings for Reviewers' Career Advancement

CENTER FOR DRUG EVALUATION AND RESEARCH MAPP 4655.3 Rev 3

POLICY AND PROCEDURES

OFFICE OF MANAGEMENT

Procedures for CDER Medical Officer Conversion to Career-Conditional

https://www.fda.gov/media/80047/download
4/25/2018

6-9 Months

…s (classroom or online)

	CDER Review of Clinical Trials	OND: Office of New Drugs
	OND Ready, Set, Review	OTS: Office of Translational Sciences
	OND 2017 Clinical Review Template Introduction	OCS: Office of Computational Science
	OND The Road to Assessing Benefit and Risk	
	CDER MaPP 6010.3 Clinical Review Template Attachment B (Safety Review, p. 36 – print resource) http://inside.fda.gov:9003/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/manualofpoliciesprocedures/ucm080121.pdf	
	CDER Learn the Safety Dance	
	OTS MedDRA Training – I & II	Standard Terminology
	OCS Data standards training	Standard Data (CDISC)
	OCS JMP and JMP Clinical Training (multiple modules)	Standard Analysis Procedures
	FDA Library Electronic Resources	

Required Trainings

Japan Pharmaceuticals and Medical Devices Agency

Dr. Yuki Ando (PMDA)

Expected analyses in review teams

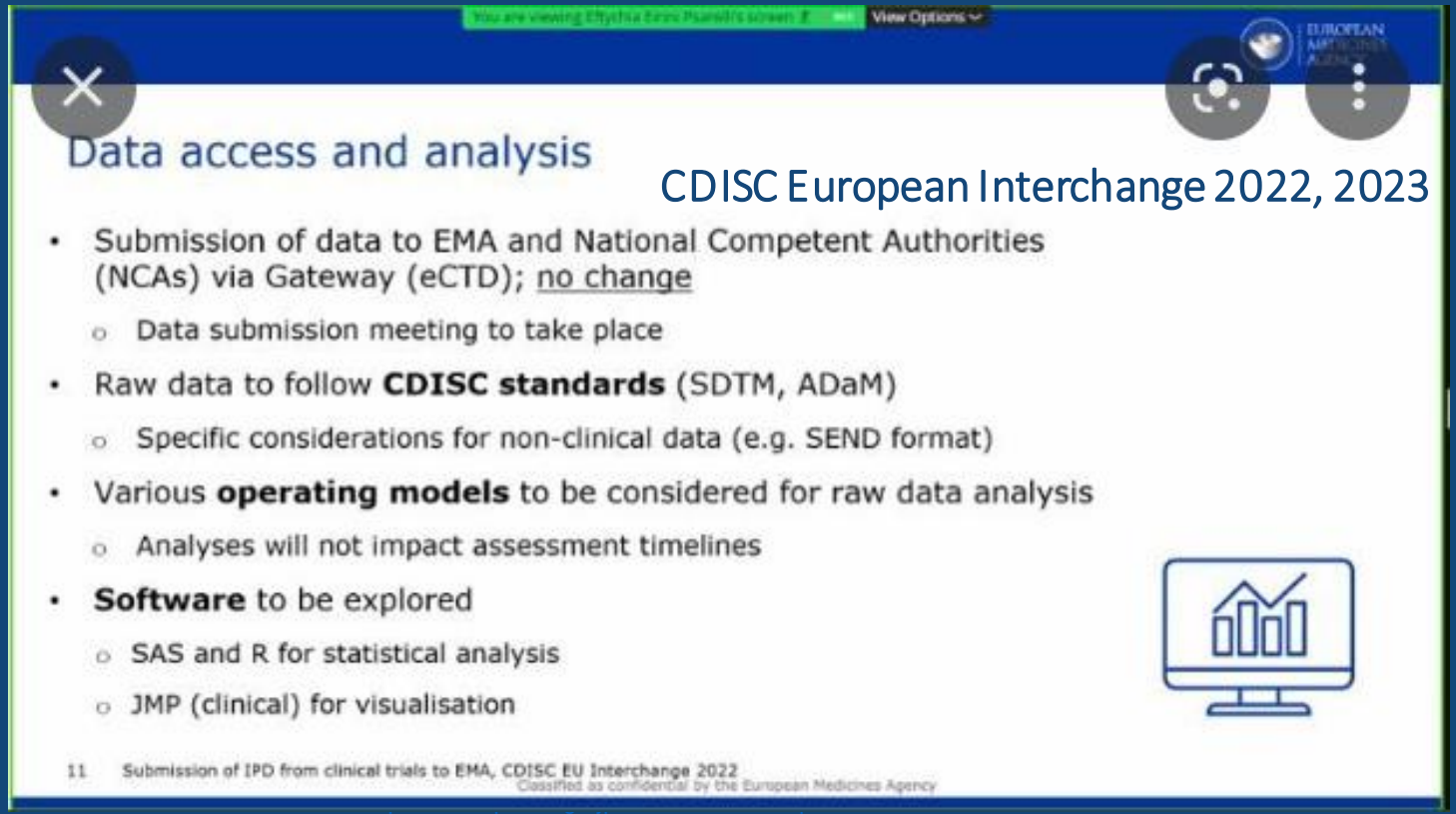
CDISC US Interchange, Nov. 2015

Common analyses to many clinical trials	• Distribution of patient demographics • Changes in laboratory data • Adverse events rates	STAT MEDICAL OTHERS Software: JMP Clinical, etc. Datasets: SDTM
General analyses for efficacy and safety data	• Simple analyses depending on the characteristics of evaluation variables – continuous/categorical/time-to-event)	STAT MEDICAL OTHERS Software: JMP, etc. Datasets: ADaM
Relatively complicated analyses	• Analyses with programing (innovative/complicated analyses) • Simulations	STAT MEDICAL OTHERS Software: SAS, etc. Datasets: SDTM, ADaM

https://www.pmda.go.jp/files/000208574.pdf

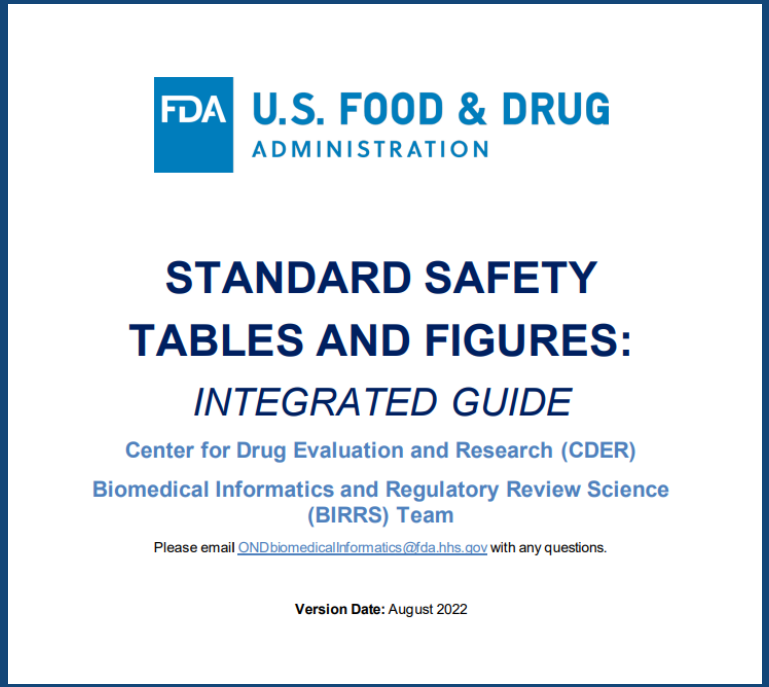
European Medicines Agency

Dr. Eftychia Eirini Psarelli (EMA)



Standard in Clinical Trial Data Analysis Presentation

Standard Figures and Tables



U.S. FOOD & DRUG ADMINISTRATION

STANDARD SAFETY TABLES AND FIGURES:

INTEGRATED GUIDE

Center for Drug Evaluation and Research (CDER)

Biomedical Informatics and Regulatory Review Science (BIRRS) Team

Please email ONDbiomedicalInformatics@fda.hhs.gov with any questions.

Version Date: August 2022

https://www.regulations.gov/document/FDA-2022-N-1961-0046

FDA Standard Safety Tables and Figures

Table 14. Patients With Adverse Events[1] by System Organ Class and FDA Medical Query, Safety Population, Pooled Analyses[2]

	Narrow FMQs				Broad FMQs			
System Organ Class[4] FMQ	Drug Name N = XXX n (%)	Active Control N = XXX n (%)	Placebo N = XXX n (%)	Risk Difference (%) (95% CI)[3]	Drug Name N = XXX n (%)	Active Control N = XXX n (%)	Placebo N = XXX n (%)	Risk Difference (%) (95% CI)[3]
SOC1								
FMQ1	n (%)	n (%)	n (%)	X (Y, Z)	n (%)	n (%)	n (%)	X (Y, Z)
FMQ2	n (%)	n (%)	n (%)	X (Y, Z)	n (%)	n (%)	n (%)	X (Y, Z)
FMQ3	n (%)	n (%)	n (%)	X (Y, Z)	n (%)	n (%)	n (%)	X (Y, Z)

Figure 5. Patients With Adverse Events[1] ≥X% in Any Treatment Arm by FDA Medical Query (Narrow), Safety Population, Trial X

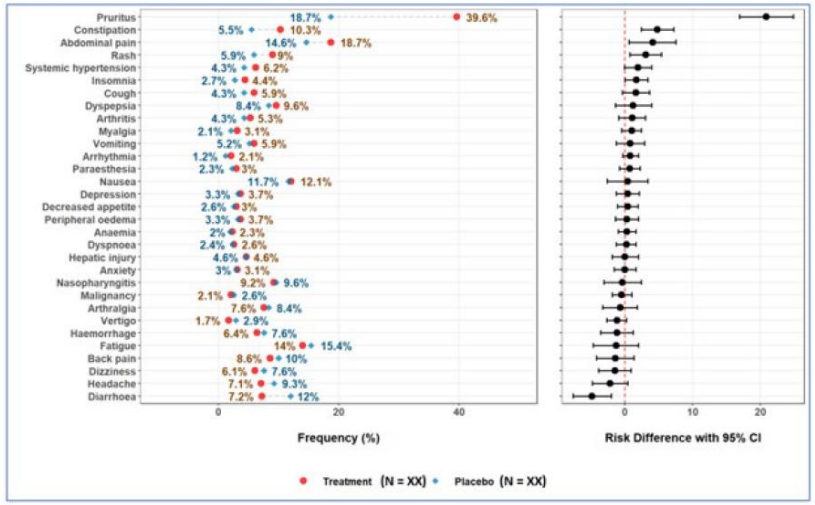
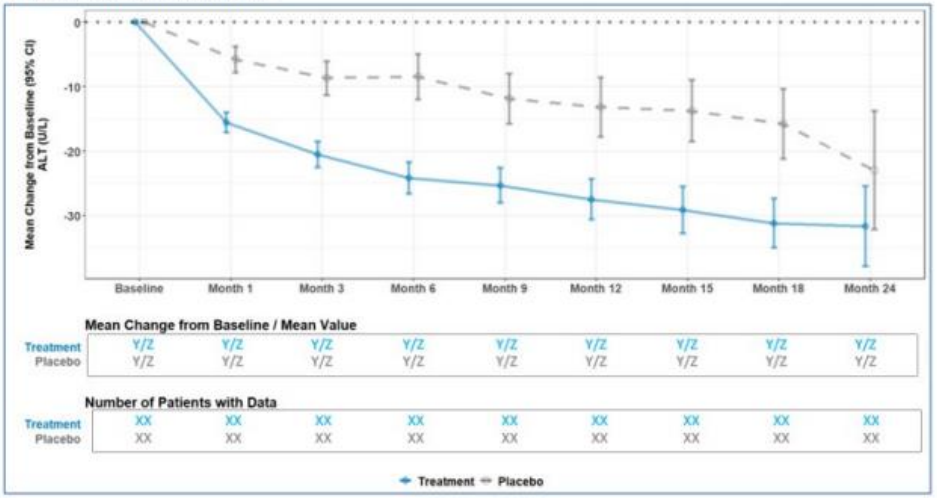


Figure 8. Mean Laboratory (Liver Biochemistry) Data Change From Baseline Over Time, Safety Population, Pooled Analyses



Standard in Multi-Omics: NIH FDA Initiatives

Omics Technologies: From Breakthroughs to Applications
October 10 to 11, 2023

October 10th Agenda

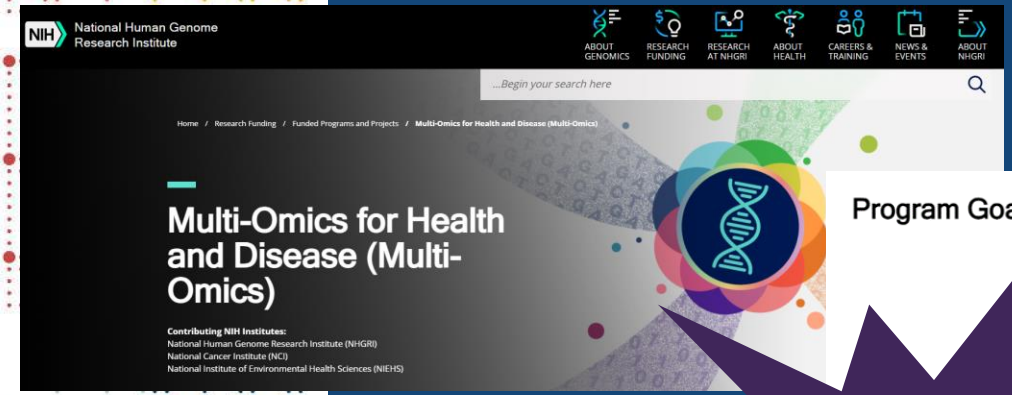
Time	Topics
9:00 am - 9:05 am	**Welcome** Omics Days Co-Chair Hermes Reyes Caballero, Ph.D., FDA/CTP
9:00 am - 9:25 am	**Opening Remarks** FDA Commissioner Robert M. Califf, M.D.
9:30 am - 10:20 am	**Keynote** Temesgen D. Fufa, Ph.D., NIH/NHGRI
10:20 am - 10:30 am	**Break**
10:30 am - 12:00 pm	**Breakout Session *"One Health"*** Lucas Harrison, Ph.D., FDA/CVM Padmini Ramachandran, M.S., FDA/CFSAN Hediye Nese Cinar, Ph.D., FDA/CFSAN Anwar Husain, Ph.D., FDA/CTP Q/A Panel Moderator: Carlo Mercado, Ph.D., FDA/CVM
12:00 pm - 1:00 pm	**Lunch**
1:00 pm - 1:45 pm	**Poster Session**
1:45 pm - 2:00 pm	**Break**
2:00 pm - 3:30 pm	**Breakout Session *"Genomics, Transcriptomics, Metagenomics"*** Sandip De, Ph.D., FDA/CBER Javier Revollo, Ph.D., FDA/NCTR Leming Shi, Ph.D., Fudan University Eliah Overbey, Ph.D., Weill Cornell Medicine Q/A Panel Moderator: Cinque Soto, Ph.D., FDA/CBER
3:30 pm - 3:45 pm	**Break**
3:45 pm - 4:45 am	**Keynote** Ryan Wick, Ph.D., University of Melbourne
4:45 pm	**Closing Remarks** Omics WG Member Matthew Hartog, Ph.D., FDA/CTP

October 11th Agenda

Time	Topics
9:00 am - 9:05 am	**Welcome** Omics Days Co-Chair Isha Patel, M.S., FDA/CFSAN
9:05 am - 9:25 am	**Opening Remarks** FDA Chief Scientist Namandjé N. Bumpus, Ph.D.
9:30 am - 10:20 am	**Keynote** Sudeepa Bhattacharyya, Ph.D., Arkansas State University
10:20 am - 10:30 am	**Break**
10:30 am - 12:00 pm	**Breakout Session *"Proteomics and Metabolomics"*** Ann Knolhoff, Ph.D., FDA/CFSAN Richard Beger, Ph.D., FDA/NCTR Paula Hyland, Ph.D., FDA/CDER Michael Brad Strader, Ph.D., FDA/CBER Q/A Panel Moderator: Heather Painter, Ph.D., FDA/CBER
12:00 pm - 1:00 pm	**Lunch**
1:00 pm - 1:45 pm	**Poster Session**
1:45 pm - 2:45 pm	**Keynote** Wendell Jones, Ph.D., Q2 Solutions Genomics
2:45 pm - 3:00 pm	**Break**
3:00 pm - 4:30 pm	**Breakout Session *"Data Integration and Data Management"*** Sudhir Varma, Ph.D., NIH/NCI Wenjun Bao, Ph.D., SAS Institute Inc. Luis Santana-Quintero, Ph.D., FDA/CBER Vikrant Vijay, Ph.D., FDA/NCTR Samir Lababidi, Ph.D., FDA/OC Q/A Panel Session Moderator: Samir Lababidi, Ph.D., FDA/OC
4:30 pm	**Closing Remarks** Omics Working Group Co-Chair Alexis Norris, Ph.D., FDA/CVM

FDA Omics Day

Time	Topics
9:00 am - 9:05 am	**Welcome** Omics Days Co-Chair Hermes Reyes Caballero, Ph.D., FDA/CTP
9:00 am - 9:25 am	**Opening Remarks** FDA Commissioner Robert M. Califf, M.D.
9:30 am - 10:20 am	**Keynote** Temesgen D. Fufa, Ph.D., NIH/NHGRI



Program Goals

The Multi-Omics for Health and Disease Consortium is a collaborative initiative that will advance the application of multi-omic technologies to study health and disease in ancestrally diverse populations. By leveraging disease contexts where multi-omic approaches are expected to be most impactful, the proposed consortium will

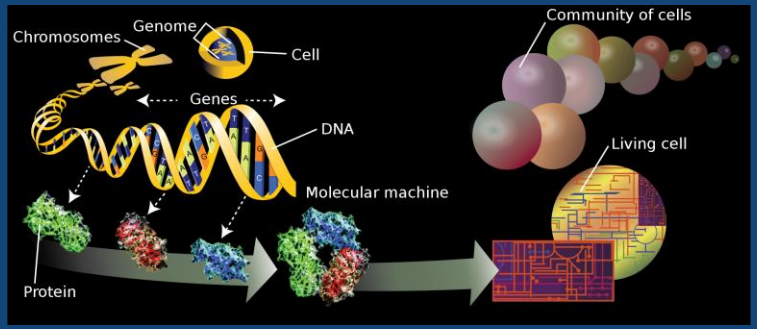
1. Examine the use of multiple 'omics data, combined with phenotypic and environmental exposure data, including social determinants of health (SDOH), to detect and assess molecular "profiles" associated with healthy and diseased states as well as transitions from health to disease or vice versa.
2. Leverage this collaborative analysis to develop generalizable data harmonization, integration, and analysis methods, as well as best practices and standards for the optimal application of multi-omics technologies across clinical conditions.
3. Create a standardized and harmonized multi-dimensional data set that is widely available to the broader research community, is interoperable with existing resources, and upholds data sharing and privacy principles. This rich data set will include 1) persons from ancestrally diverse populations; 2) persons with and without specific diseases; 3) harmonized and standardized phenotypic and environmental exposure data; 4) harmonized and standardized data for all or most 'omes for each biosample; 5) data from multiple time points; and 6) associated meta-data to facilitate links across data types.

Standardization is planned. CDISC can help

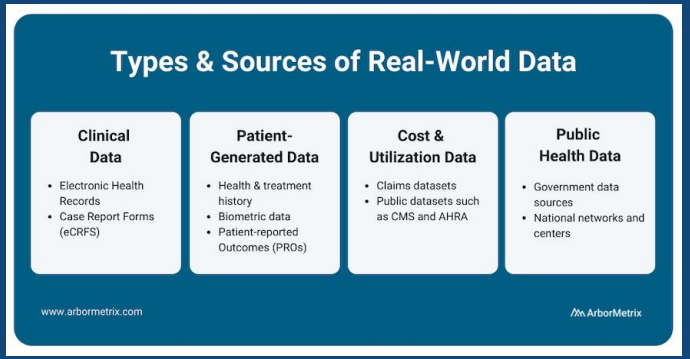
Multi-Omics for Health and Disease (Multi-Omics) (genome.gov)

NIH awards $50.3 million for "multi-omics" research on human health and disease | National Institutes of Health (NIH)

CDISC in Good Position to help Standardization



https://en.wikipedia.org/wiki/Omics



https://www.arbormetrix.com/blog/9-ways-real-world-evidence-is-changing-healthcare/

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Speedy Clinical Trial Goals Achieved by Standards

Quality, Efficiency, Reproducibility and Reusability

Evaluating Safety, Quality and Traceability of Regulatory Submission Data
Session 7 12/14/23

MedDRA SMQ

FDA FMQ

Standard Terminology

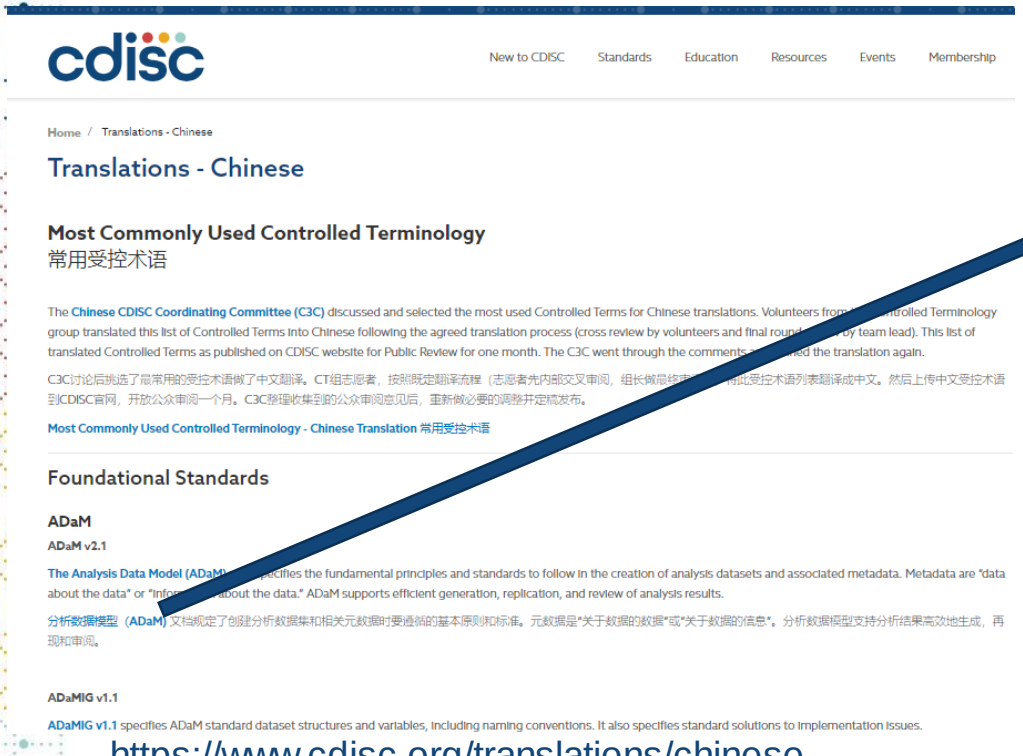
Standard Data

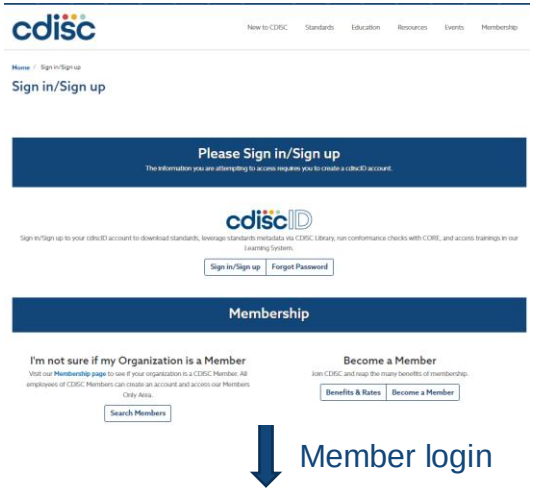
cdisc

Standard Presentation

CDISC Memberships

Member Benefits: Access translated Files





Member login

	A	B	C	D	E	F	G	H	I	J
1	Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist name	代码表名称	CDISC Submission Value	CDISC提交值	CDISC Synonym(s)	CDISC 同义词	CDISC Definition
20	C29848	C66781		Age Unit	年龄单位	YEARS	岁	Year	年	The period of time that it take make a complete revolution a approximately 365 days; a sp period. (NCI)
21	C74558		No	Category for Disposition Event	受试者分布事件类别	DSCAT	DSCAT	Category for Disposition Event	受试者分布事件类别	Classifications that describe pertinent events that occur th conduct of a clinical trial.
22	C74590	C74558		Category for Disposition Event	受试者分布事件类别	DISPOSITION EVENT	受试者分布事件	Disposition Event	受试者分布事件	The group of incidents that oc clinical trial and describe whe completed the study epoch o this event did not occur. The disposition is often described of the study.
23	C150824	C74558		Category for Disposition Event	受试者分布事件类别	OTHER EVENT	其他事件	Other Event	其他事件	Other important events that o trial but are not driven by prot requirements.

https://www.cdisc.org/translations/chinese

Membership Benefits

Become a Member

Be a Good Member
Involve Actively
Renew Membership on time

Thank You!

Wenjun.bao@jmp.com