



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.

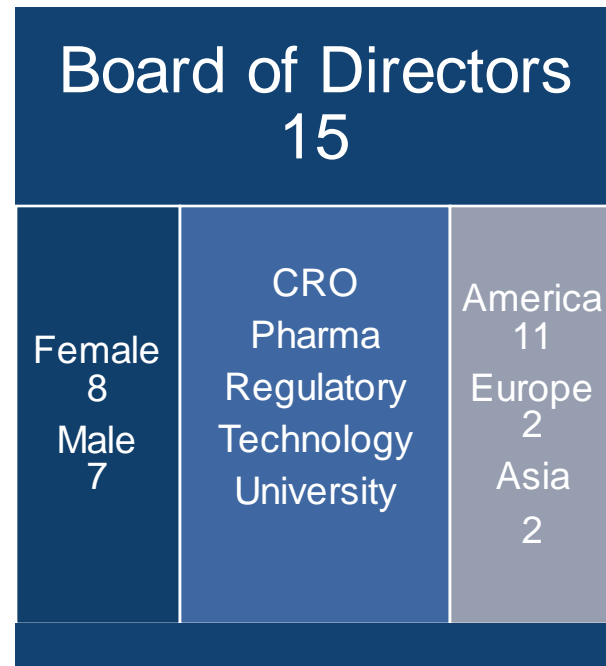


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- *{Please disclose any financial relationship or conflict of interest relevant to this presentation here OR}*
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Milestones for Clinical Trial Data Standardization

1999

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

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

2018

FDA Requires Reviewers to have Standards
Training for Career Advancement

2023

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

SDTM v1.0

2004

ADaMIG v1.0

2009

SDTMIG v2.0

2021

ADaMIG v1.3

2021



Standard is a Global Trend in Health Fields

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Standard in Clinical Trial Data: CDISC

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FDA Standards Trainings for Reviewers' Career Advancement

CENTER FOR DRUG EVALUATION AND RESEARCH

MAPP 4655.3 Rev 3

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

POLICY AND PROCEDURES

OFFICE OF MANAGEMENT

Procedures for CDER Medical Officer Conversion to Career-Conditional

6-9 Months

es (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

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 programming (innovative/complicated analyses)
- Simulations

STAT
MEDICAL
OTHERS

Software: SAS, etc.
Datasets: SDTM, ADaM

European Medicines Agency

Dr. Eftychia Eirini Psarelli (EMA)

Data access and analysis

CDISC European Interchange 2022, 2023

- Submission of data to EMA and National Competent Authorities (NCAs) via Gateway (eCTD); no change
 - Data submission meeting to take place
- Raw data to follow **CDISC standards** (SDTM, ADaM)
 - Specific considerations for non-clinical data (e.g. SEND format)
- Various **operating models** to be considered for raw data analysis
 - Analyses will not impact assessment timelines
- **Software** to be explored
 - SAS and R for statistical analysis
 - JMP (clinical) for visualisation





Standard in Clinical Trial Data Analysis Presentation

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Standard Figures and Tables



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.

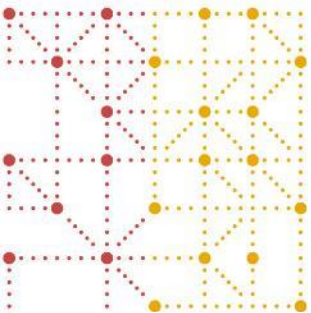
Version Date: August 2022

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

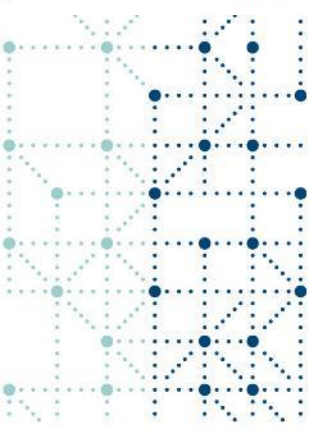


Standard in Multi-Omics: NIH FDA Initiatives

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



October 10th Agenda

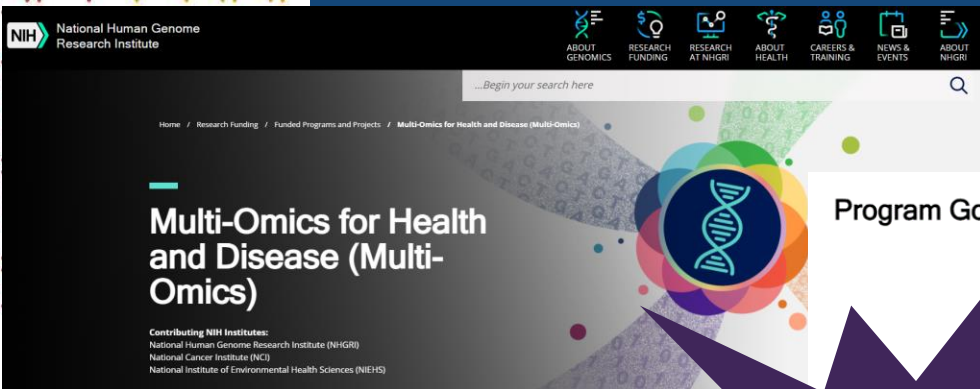
Time	Topics
9:00 am - 9:05 am	Welcome Omics Days Co-Chair Hermes Reyes Caballero, Ph.D., FDA/CTP
9:00 am - 9:25 am	Opening Remarks FDA Commissioner Robert M. Califf, M.D.
9:30 am - 10:20 am	Keynote Temesgen D. Fufa, Ph.D., NIH/NHGRI
10:20 am - 10:30 am	Break
10:30 am - 12:00 pm	Breakout Session "One 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 Elijah 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



NIH National Human Genome Research Institute

...Begin your search here

Home / Research Funding / Funded Programs and Projects / Multi-Omics for Health and Disease (Multi-Omics)

Multi-Omics for Health and Disease (Multi-Omics)

Contributing NIH Institutes:
National Human Genome Research Institute (NHGRI)
National Cancer Institute (NCI)
National Institute of Environmental Health Sciences (NIEHS)

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



Home » News & Events » News Releases

NEWS RELEASES

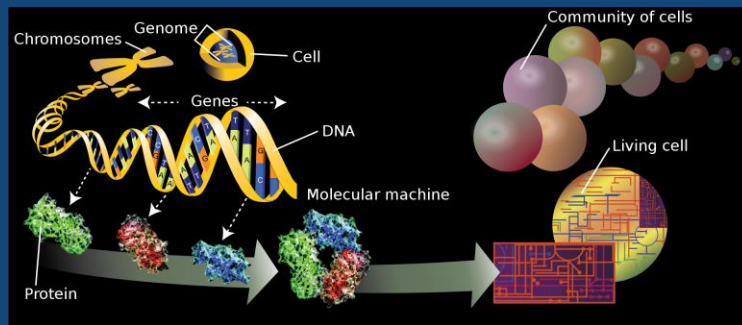
Tuesday, September 12, 2023

NIH awards \$50.3 million for “multi-omics” research on human health and disease

[Multi-Omics for Health and Disease \(Multi-Omics\) \(genome.gov\)](https://www.genome.gov/multi-omics)

[NIH awards \\$50.3 million for “multi-omics” research on human health and disease | National Institutes of Health \(NIH\)](https://www.nih.gov/news-events/press-releases/2023/09/12/niha-awards-503-million-for-multi-omics-research-on-human-health-and-disease)

CDISC in Good Position to help Standardization



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

Types & Sources of Real-World Data

Clinical Data

- Electronic Health Records
- Case Report Forms (eCRFs)

Patient-Generated Data

- Health & treatment history
- Biometric data
- Patient-reported Outcomes (PROs)

Cost & Utilization Data

- Claims datasets
- Public datasets such as CMS and AHRA

Public Health Data

- Government data sources
- National networks and centers

www.arbormetrix.com

ArborMetrix

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



The CDISC logo features the lowercase letters 'cdisc' in a dark blue font. Above the 'i' and 's' are four colored dots: red, yellow, green, and blue.

Speedy Clinical Trial Goals Achieved by Standards

Quality, Efficiency, Reproducibility and Reusability



MedDRA SMQ

FDA FMQ

Standard Terminology

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Standard Data

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



Standard Presentation



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Translations - Chinese

Most Commonly Used Controlled Terminology

常用受控术语

The **Chinese CDISC Coordinating Committee (C3C)** discussed and selected the most used Controlled Terms for Chinese translations. Volunteers from the Controlled Terminology group translated this list of Controlled Terms into Chinese following the agreed translation process (cross review by volunteers and final round by team lead). This list of translated Controlled Terms as published on CDISC website for Public Review for one month. The C3C went through the comments and finalized the translation again.

C3C讨论后挑选了最常用的受控术语做了中文翻译。CT组志愿者，按照既定翻译流程（志愿者先内部交叉审阅，组长做最终审定），将此受控术语列表翻译成中文。然后上传中文受控术语到CDISC官网，开放公众审阅一个月。C3C整理收集到的公众审阅意见后，重新做必要的调整并定稿发布。

Most Commonly Used Controlled Terminology - Chinese Translation 常用受控术语

Foundational Standards

ADaM

ADaM v2.1

The **Analysis Data Model (ADaM)** specifies the fundamental principles and standards to follow in the creation of analysis datasets and associated metadata. Metadata are "data about the data" or "information about the data." ADaM supports efficient generation, replication, and review of analysis results.

分析数据模型 (ADaM) 文档规定了创建分析数据集和相关元数据时要遵循的基本原则和标准。元数据是“关于数据的数据”或“关于数据的信息”。分析数据模型支持分析结果高效地生成、再现和审阅。

ADaMIG v1.1

ADaMIG v1.1 specifies ADaM standard dataset structures and variables, including naming conventions. It also specifies standard solutions to implementation issues.

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

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1	Code	Code	Code list (Yes/No)	Code list name	代码表名称	CDISC Submission Value	CDISC 提交值	CDISC Synonym(s)	CDISC 同义词	CDISC Definition
20	C29648	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 (INC)
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 i pertinent events that occur th conduct of a clinical trial. The group of incidents that oc clinical trial and describe wh completed the study epoch o this event did not occur. The i disposition is often described of the study
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	Other important events that o trial but are not driven by prob requirements
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	

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CRO - 34%



Nonprofit Organization - 3%



Biotechnology - 5%



Government - 2%



Pharmaceutical - 17%



Clinical Laboratory - 0.3%



Healthcare Provider - 2%



Technology Service Provider - 20%



Consulting - 6%



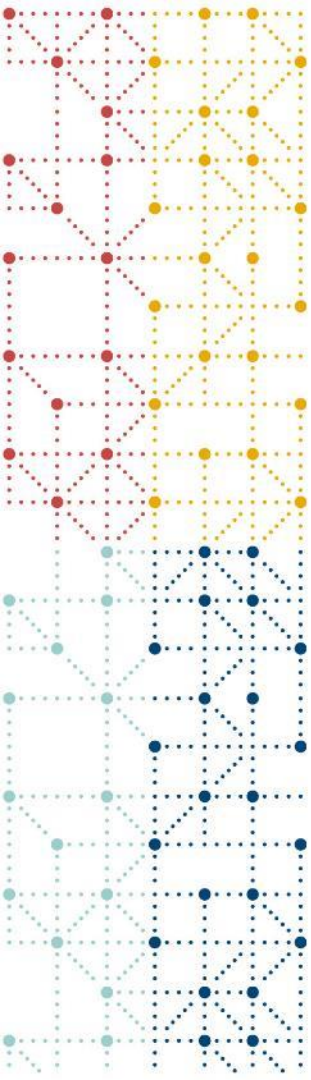
Medical Device - 0.7%



Other - 3%

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Thank You!

Wenjun.bao@jmp.com

