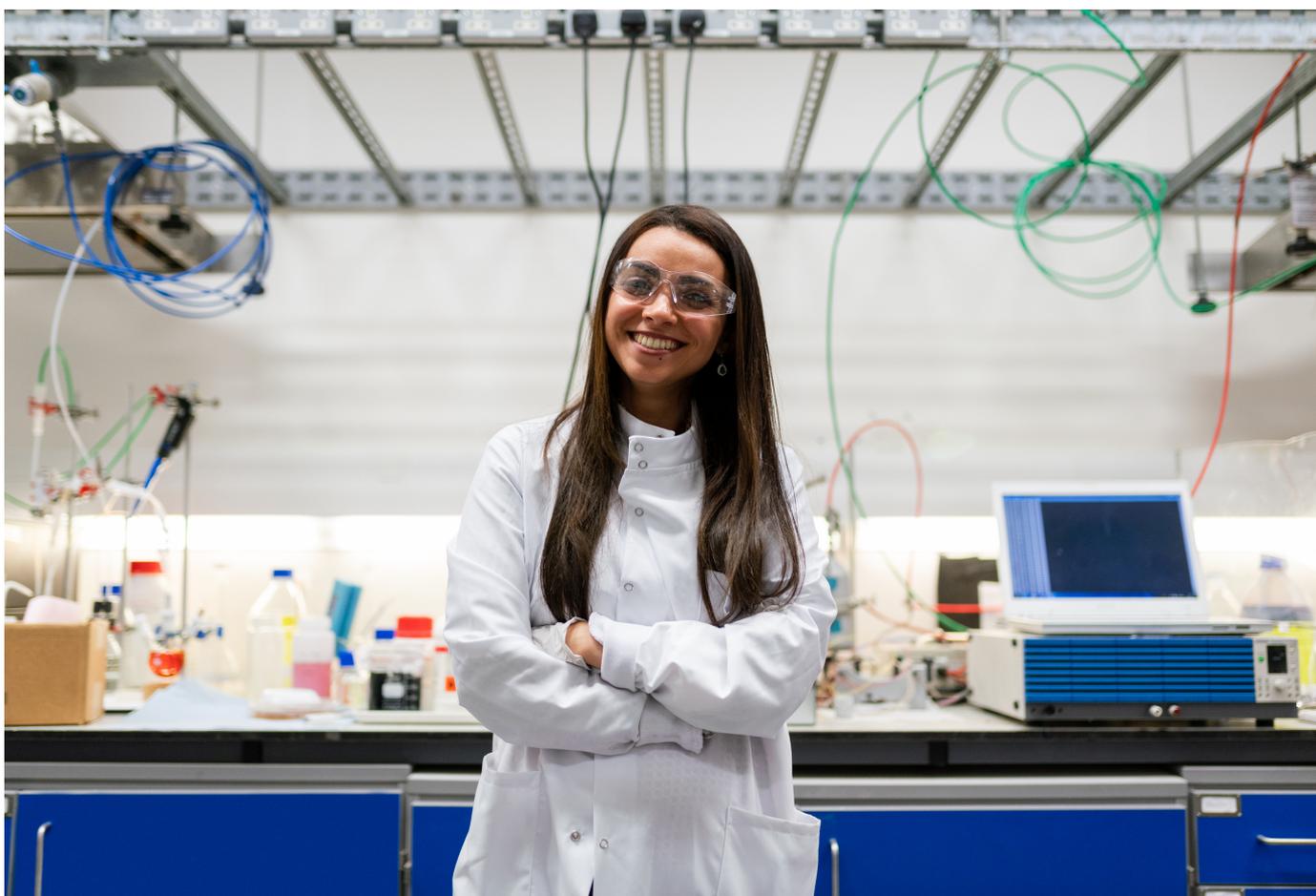


A report based on industry
analysis & trends

FAIR advantages of CDISC SEND

SEND not only makes your submissions
compliant, but also helps you make
the best use of your data



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ZIFO
RnD SOLUTIONS

CDISC SEND & FAIR

AN INTRODUCTION



Collectively called the Standard for Exchange of Nonclinical Data (SEND), the standards have been in development and recommended since early 2000s by Clinical Data Interchange Standards Consortium (CDISC) and the FDA.

They are now a requirement for preclinical studies started after December 2016 for New Drug Applications (NDA) and 2017 for Investigational New Drug (IND) submissions.

Implemented by the GO FAIR initiative, FAIR principles provide guidelines to improve the Findability, Accessibility, Interoperability, and Reuse of digital assets. Many organizations around the world, like Pistoia Alliance are championing FAIR.



**SEND AND FAIR
DATA PRINCIPLES
FORM A SYNERGY
THAT ENHANCES
THE VALUE OF
YOUR DATA ASSETS**

MAKING DATA FINDABLE & ACCESSIBLE (FAIR)

Practicing SEND in the non-clinical space affects the R&D space tremendously. In the R&D space, data is continuously evolving as innovation increases. Having standardized data helps in deriving meaningful insights on study conduct operations.

- Efficiency of operations can be evaluated by comparing parameters across multiple studies and timelines. Example: Comparing number of certain lab tests conducted (LBTEST), Data collected, Methods used (LBDTC, LBMETHOD[i]).
- The distribution of work and cost across departments and CROs can be evaluated and predicted.
- Numerous domains and variables in SEND eases determining patterns and correlations such as comparing animal species and study types.
- Comparing data across and within studies for various timepoints such as in-life and necropsy helps sponsors understand patterns.
- Insight into data allows labs to plan and predict future events, reduce failure rates, and improve safety outcomes, ultimately increasing ROI.

SEND datasets have defined variables and terms, each having a standard definition for an efficient and transparent way to form complete study datasets. Data is identified and easily searchable using controlled terminology, variables and metadata using define.xml.

- Study datasets can be stored long term with easy access.
- The dataset in XPT format is simple to view.
- XPT files are easily opened and read by humans due to the contextualization of associated metadata.

MAKING DATA INTEROPERABLE (FAIR)

Today, sponsors collaborate and use CROs extensively to carry out multiple studies. Representing data in SEND eases collaboration and communication between these groups, especially when parts of study data originate in different laboratories or even countries.

Sponsors can review interim data efficiently when CROs and collaborators share standardized SEND data.

MAKING DATA REUSABLE (FAIR)

Following SEND requirements removes the need to rework data for use in advanced analytics and predictive modeling.

- Sponsors can implement technology or statistical methods where terminology mapping is no longer required. With an automated process for analysis, the focus can be directed on developing and progressing the actual methods of analysis, prediction or AI models.
- The ability to evaluate issues in any study gives users the power to find anomaly, evaluate toxicologic or dose response for outliers.
- Furthermore, toxicologic decisions and predictions for new studies can be data-led and automated, with an ability to evaluate best course of action for each study or compound.

Having SEND data allows easy comparison of studies, compounds, targets, and sponsors can assess trends for future research.

CONSIDERATIONS & CHALLENGES

Producing, maintaining and utilizing SEND datasets requires Sponsors, CROs and other organizations to have capacity, funding and expertise to invest in databases or visualization tools.

Companies may require merging departments to streamline process. SEND standards are evolving. There is also a possibility that different organizations interpret the guidelines and definitions differently or map data to incorrect SEND terms. The lack of homogeneity for data capture could hinder collaborations and comparisons of multiple studies by different sponsors.

Although there are hurdles, SEND standardization is an exciting step towards advancement of digital science. It increases the value of data and enables systemic change in the industry to more openly and readily collaborate to bring treatments faster to market!

GLOSSARY OF TERMS

AI - Artificial Intelligence

CDISC - Clinical Data Interchange Standards Consortium - develops standards for medical research data

CRO - Contract Research Organization

Define-XML - Provides metadata to describe tabular dataset structure for human and animal model datasets

FAIR - Findable, Accessible, Interoperable and Reusable - guideline for data organization

FDA - Food and Drug Administration

IND - Investigational New Drug

ML - Machine Learning

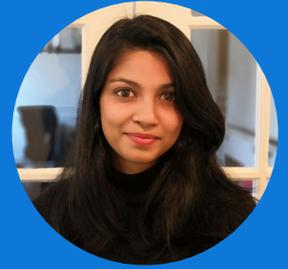
NDA - New Drug Approval

XPT - SAS Transport File Format

SEND - Standard for Exchange of Non-clinical Data

About the Authors

Aishwarya Balajee is a Scientific Informatics Consultant at Zifo RnD Solutions. With a background in Biomedical Engineering, her passion is to help accelerate Biopharma R&D with scientific and informatics expertise. She works in close coordination with scientists in designing, developing and implementing Informatics solutions and strategy that reflect the way scientists work. She leads the SEND initiative at Zifo and has been involved in shaping SEND strategy for many research-led organizations.



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About Zifo RnD Solutions

Zifo RnD Solutions is a global research informatics and digitalization solutions provider helping biopharma and biotech companies conduct efficient and faster research. Zifo's customers include 7 of the top 10 global biopharma companies and several innovative small biotech companies. Learn more about us at www.zifornd.com



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