SEND-based Data Analysis Platform

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Agenda

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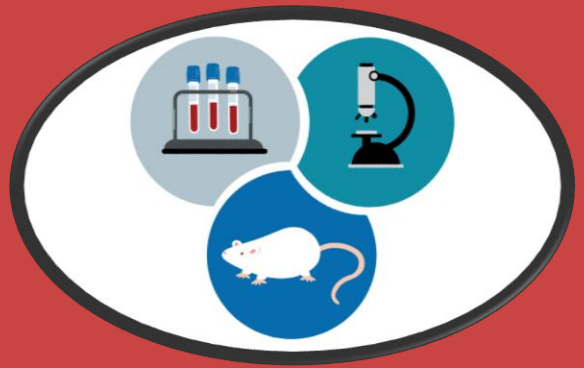
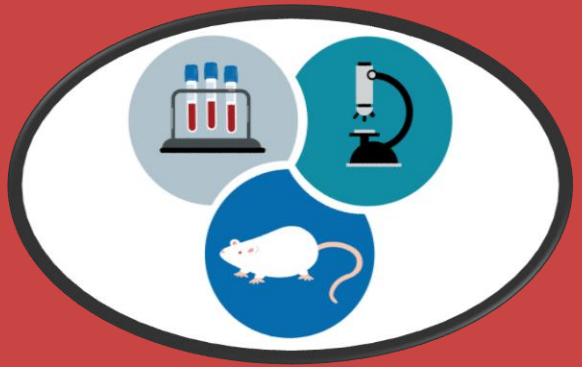
4. SEND data visualization platform introduction
5. Conclusion

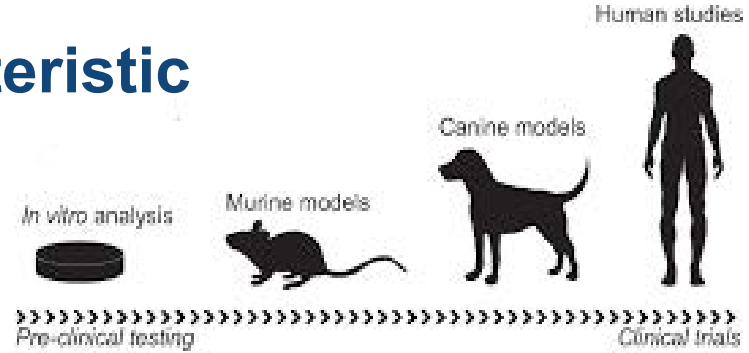


Pre-clinical Studies – Characteristic & Challenges



Pre-clinical Studies – Characteristic

- Assess compound safety and efficacy before human trials
- Provide foundational data for safe and effective clinical trial design
- Facilitate identification of optimal dosing regimens and combination therapies



Target selection → Lead Optimization/ candidate nomination → Preclinical Development → Clinical Development (Phases I, II and III) → Regulatory filing/approval

cdisc

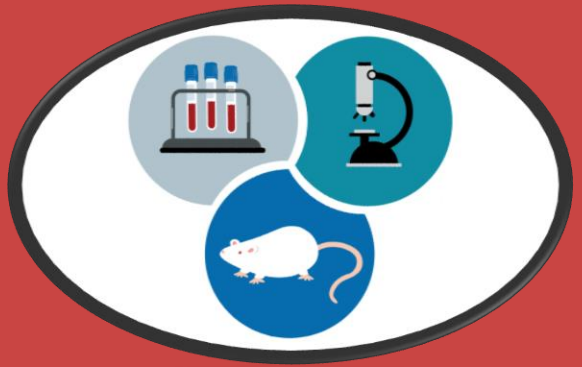
Pre-clinical Studies – Challenges

- **Large amount of data**
- **Lack of standard reference comparing to clinical data**
- **SEND not mandatory before for regulatory submission, leading to inconsistent datasets**

Impact:

- Low productivity: repetitive manual cleaning before analysis
- Inefficient visualization: broad demand for visualization but data structure hinders automation
- High error risk: manual curation introduces inconsistencies and mistakes
- Poor data reuse: valuable data stored but not easily searchable or comparable
- Difficulty in cross-study comparison: lack of standardized variables and coding

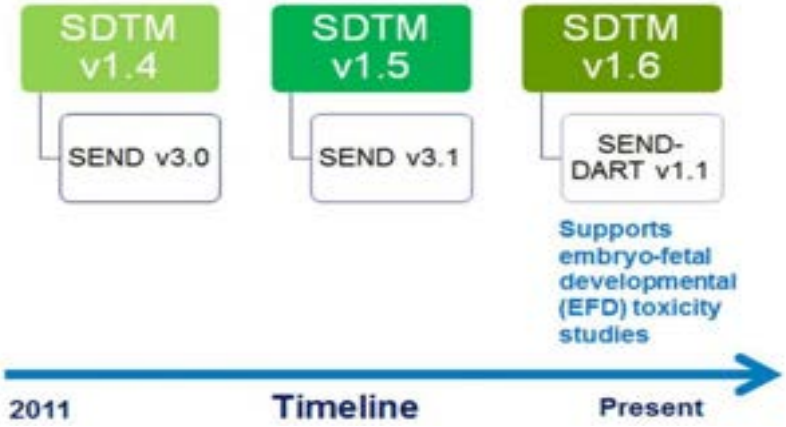
SEND – Brief Introduction



SEND Dataset - Brief Introduction

- **SEND (Standard for Exchange of Nonclinical Data) is an implementation of the SDTM (Study Data Tabulation Model)standard for nonclinical studies.** SEND specifies a way to collect and present nonclinical data in a consistent format.
- **SEND is one of the required standards for data submission to FDA.**

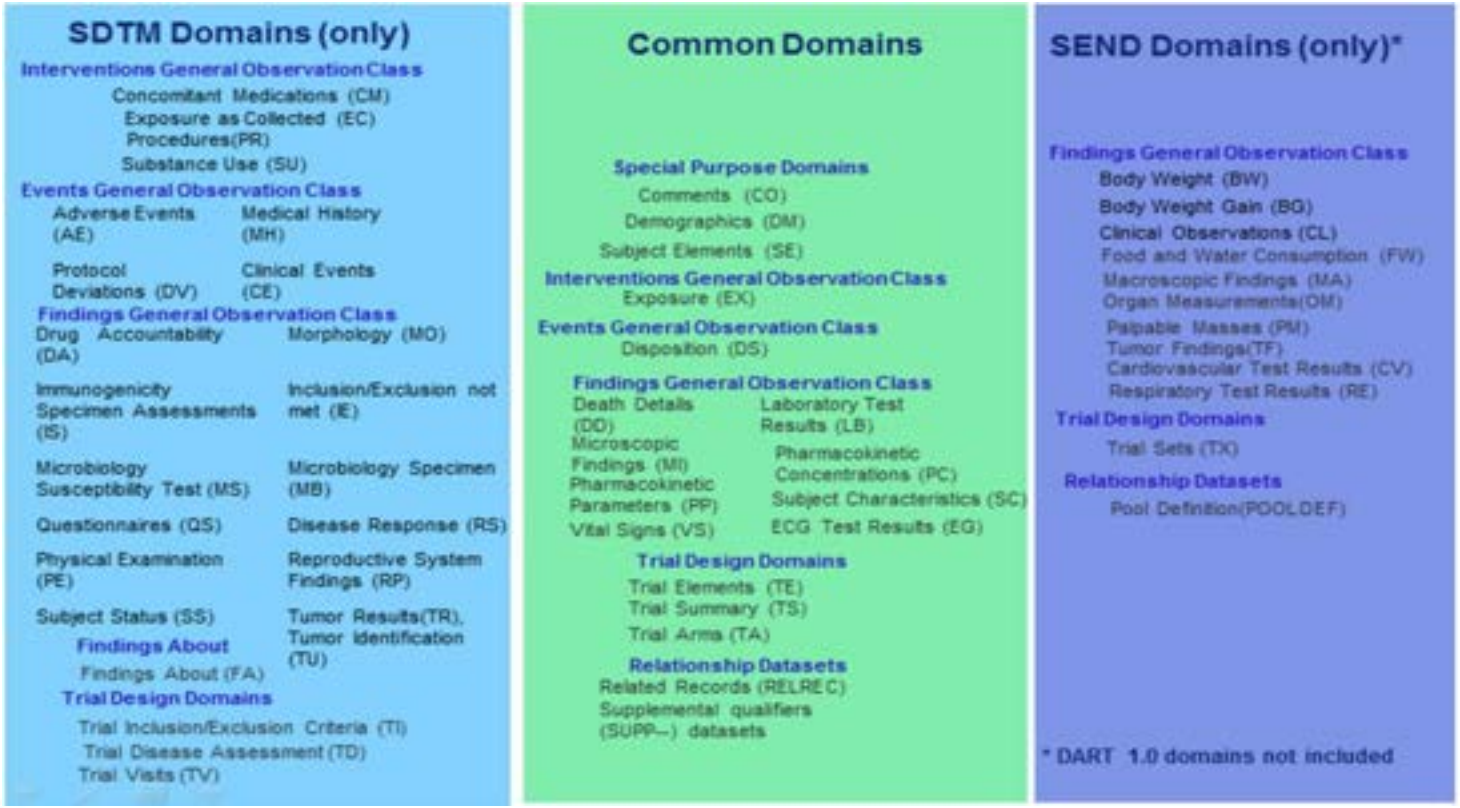
The SDTM supports multiple implementation guides (IG) such as SDTMIG and SENDIG. Currently, the implementation guides of SDTM and SEND are supported by different versions of the SDTM.
Ex:



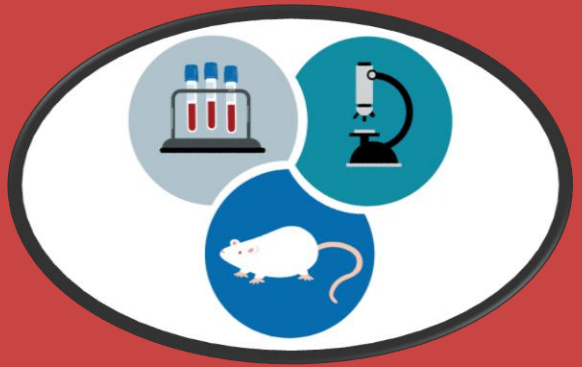
SEND 3.1 needed new variables, a new version of SDTM v1.5 was released

SEND Dataset - Brief Introduction

The below figure represents the comparison of the SDTM 3.2 domains with SEND 3.1 model:



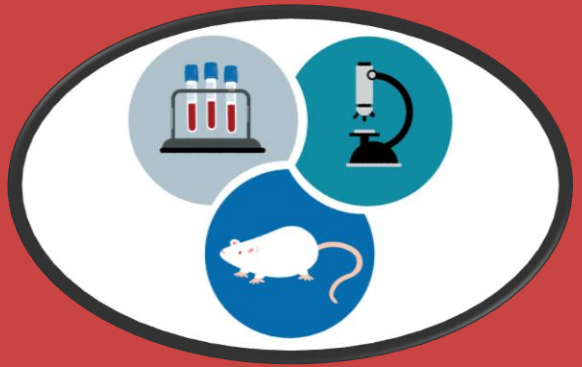
SEND – Benefits



SEND Dataset - Benefits

- Efficiency: faster turnaround from raw data → analysis → visualization
- Data Quality: reduced errors, standardized terminology
- Reusability: easier to reuse data across studies/projects
- Comparability: direct cross-study and cross-project analysis
- Visualization: standardized input enables automation of Shiny apps and dashboards
- Regulatory Readiness: smoother transition when SEND becomes mandatory
- Troubleshooting: faster identification of anomalies/outliers across datasets
- Collaboration: standardized format supports multi-team and cross-functional work

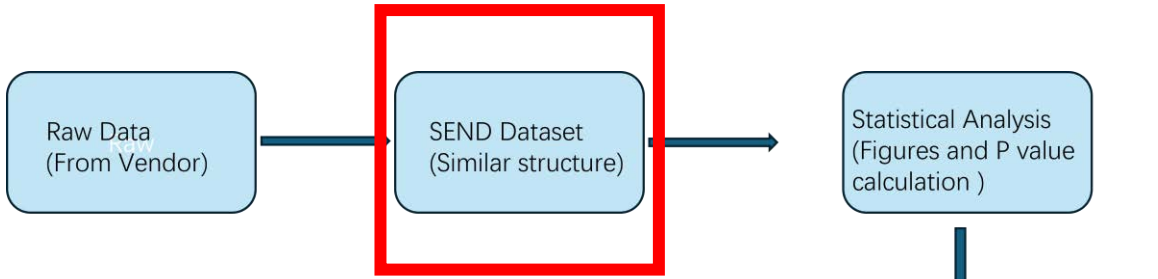
SEND data visualization platform introduction



Tox Data Visualization Platform

- Standardizes toxicological data using SEND format (CDISC standard)
- Focus on LB (laboratory test results) and BW (body weight) domains
- Automates dose-response modeling and outlier detection
- Provides interactive visualization of toxicity profiles across compounds and species by Plotly

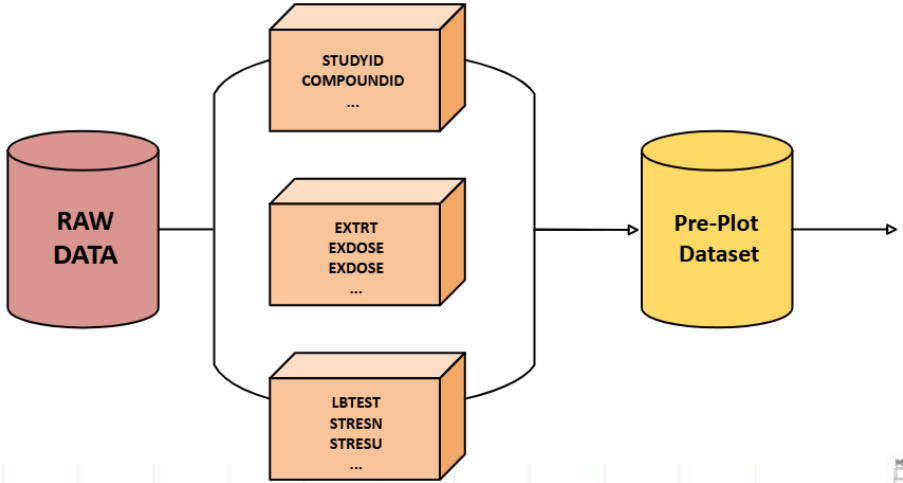
Developers:



Users:

Tox Data Visualization Platform

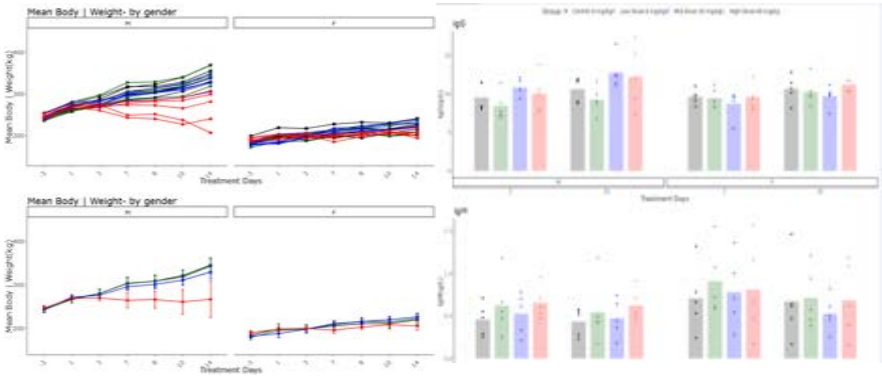
SEND Dataset
(Similar structure)



180-1237-TX_LB

Day 6

Subject Na	WBC	[HEI	RBC	[HEM	HGB	[HEM	HCT	[HEM	MCV	[HEI	MCH	[HEI	MCHC	[HI	RDW	[HEI	PLT	[HEM	MPV	[HEM
1001	6.56		6.2		12.6		39.9		64.4		20.4		31.6		12.7		1029		7.6	
1002	7.44		6.41		13.1		41.3		64.5		20.5		31.8		11.9		1086		7.4	
1003	5.83		6.26		13.1		41.3		66.1		20.9		31.6		12.3		1016		7.4	
1004	8		6.98		13.7		42.2		60.5		19.7		32.5		12.2		720		7.4	
1005	10.76		6.38		13		40.4		63.3		20.3		32.1		11.9		1140		7.3	
2001	9.68		8.26		15.6		48.2		58.3		18.9		32.4		12.4		1233		7.4	
2002	8.67		7.3		14.8		45.7		62.6		20.2		32.3		12.5		1313		7.7	
2003	8.14		7.84		15.4		46.8		59.8		19.6		32.9		11.9		1158		7.4	
3001	5.1		8.22		16.5		51.6		62.7		20.1		32.1		12.6		1139		7.7	
3003	3.61		7.87		15.3		47.4		60.3		19.4		32.2		12.8		1124		7.4	
1501	6.64		6.85		13.3		39.8		58.1		19.4		33.4		11		939		7.2	



Tox Data Visualization Platform

User define colors: Number of color choice is based on number of treatment group of each study

Day 6

Subject Na	WBC	[HEI	RBC	[HEN	HGB	[HEN	HCT	[HEN	MCV	[HEI	MCH	[HE	MCHC	[H	RD
1001	6.56		6.2		12.6		39.9		64.4		20.4		31.6		
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1005	10.76		6.38		13		40.4		63.3		20.3		32.1		
2001	9.68		8.26		15.6		48.2		58.3		18.9		32.4		
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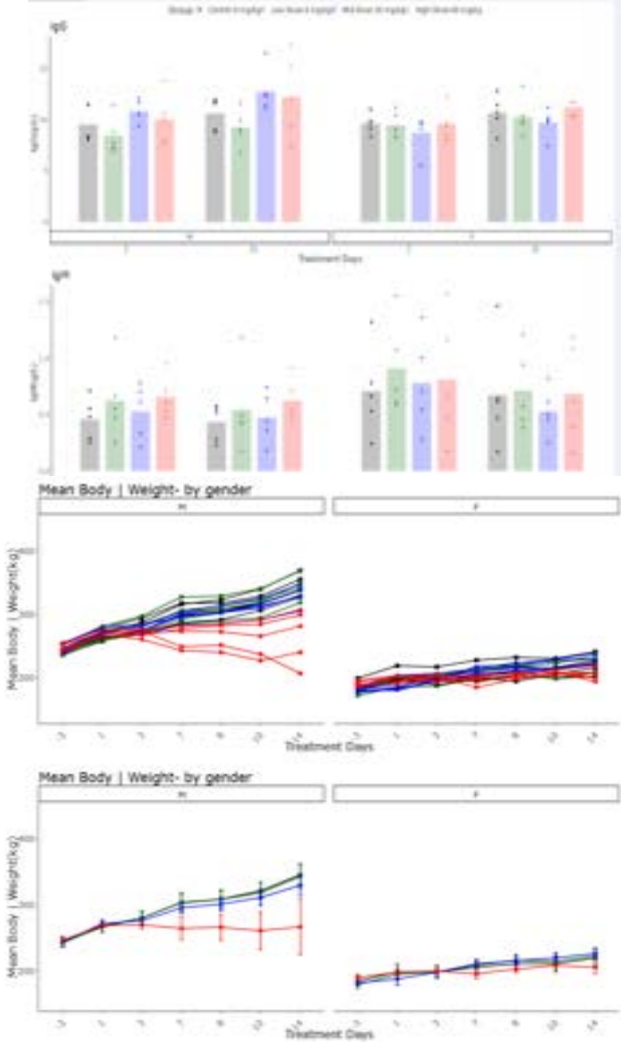


Conclusion

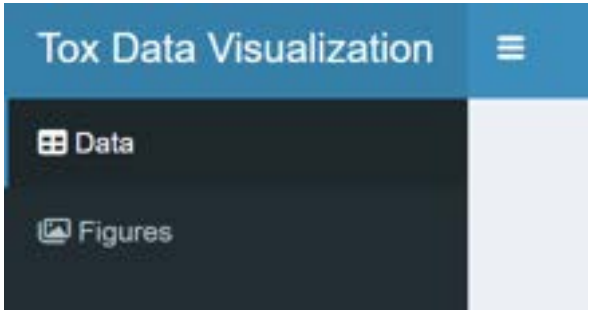
Conclusion:

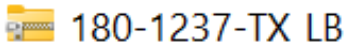
Pre-clinical data: **abundant**, remains **underutilized** due to lack of standardization.

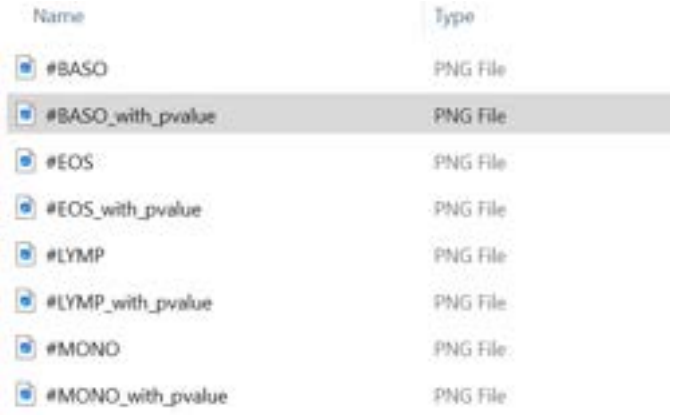
Pre-clinical data analysis: **Inefficiencies, errors, and missed opportunities for insight**.

SEND : the standard for nonclinical datasets, organizations can **improve efficiency, quality, comparability, and visualization power.**

Tox data visualization platform introduction: **Workflow from raw data to SEND dataset then do visualization.**







Q & A

Thank you!