

AD03

Streamlining SEND Dataset Generation: Enhancing Efficiency and Quality with Shiny Dashboards

Conference: PHUSE APAC Connect 2026

Madhulika Mishra, PhD, Labcorp, Bangalore, India

Michael DeNieu, PhD, Labcorp, Madison, WI, USA



Agenda

- Introduction
- Challenges and opportunities
- In-house approach and examples
- Key Takeaways



Introduction

Introduction

Why SEND matters

- Standardized data format
- Accelerated regulatory review
- Improved data quality and automation
- Future scalability and integration



Challenges and opportunities

Challenges

Why data engineering is essential

- Manual step-outs are time consuming
- Operational bottlenecks
- Need for automation



Benefits of data engineering



Modular and Reusable Architecture

Flexible, reusable components



Enable advanced analytics

Supports dashboards and AI/ML models



Data Quality and Traceability

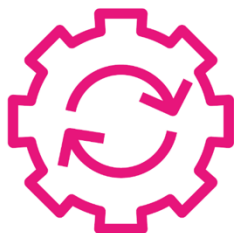
Validation checks and audit trails.

Benefits of data engineering approach in non-clinical data science



Complexity of data

Large heterogeneous data from multiple sources



Automation and Scalability

ETL automation for faster turnaround



Regulatory compliance

Automated SEND mapping and validation.



ETL process for nonclinical data

Data engineering approach

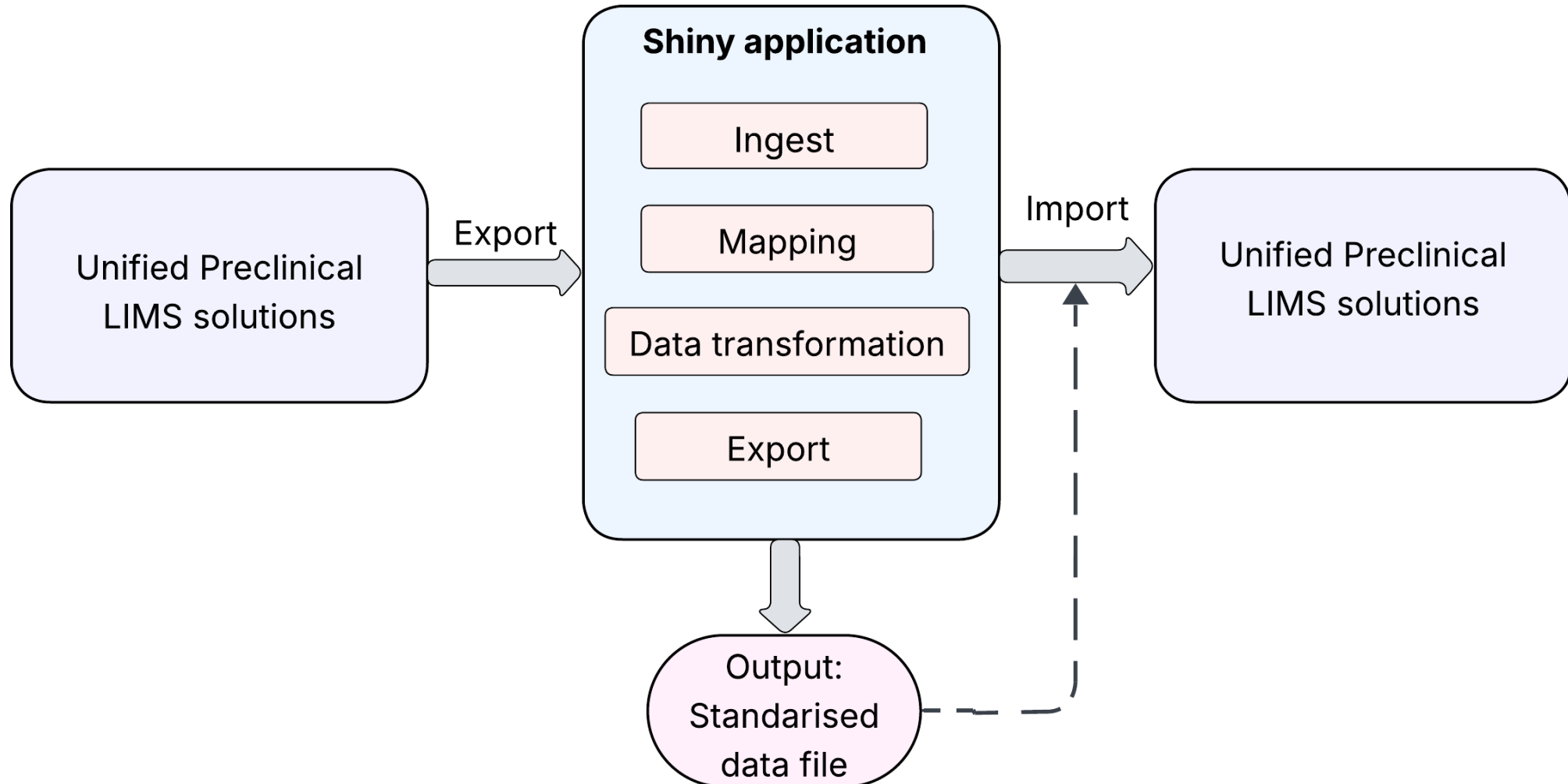
Extract	Transform	Load
Raw Data  Raw data from CRO outputs, LIMS, Excel	Standardize and validate  Apply SEND mapping rules, data cleaning, validation	SEND Data  Submission, analysis, and visualization



In-house approach

In-house approach

Data engineering approach (ETL Principle)



Examples

Suite of R shiny dashboards

- Domain mapping dashboard: SE generation
- Missing data handling dashboard: EDITCSV
- Automated creation of Nonclinical Study Data Reviewer's Guide (NSDRG) document

SE Generation Dashboard

Subject elements (SE) domain

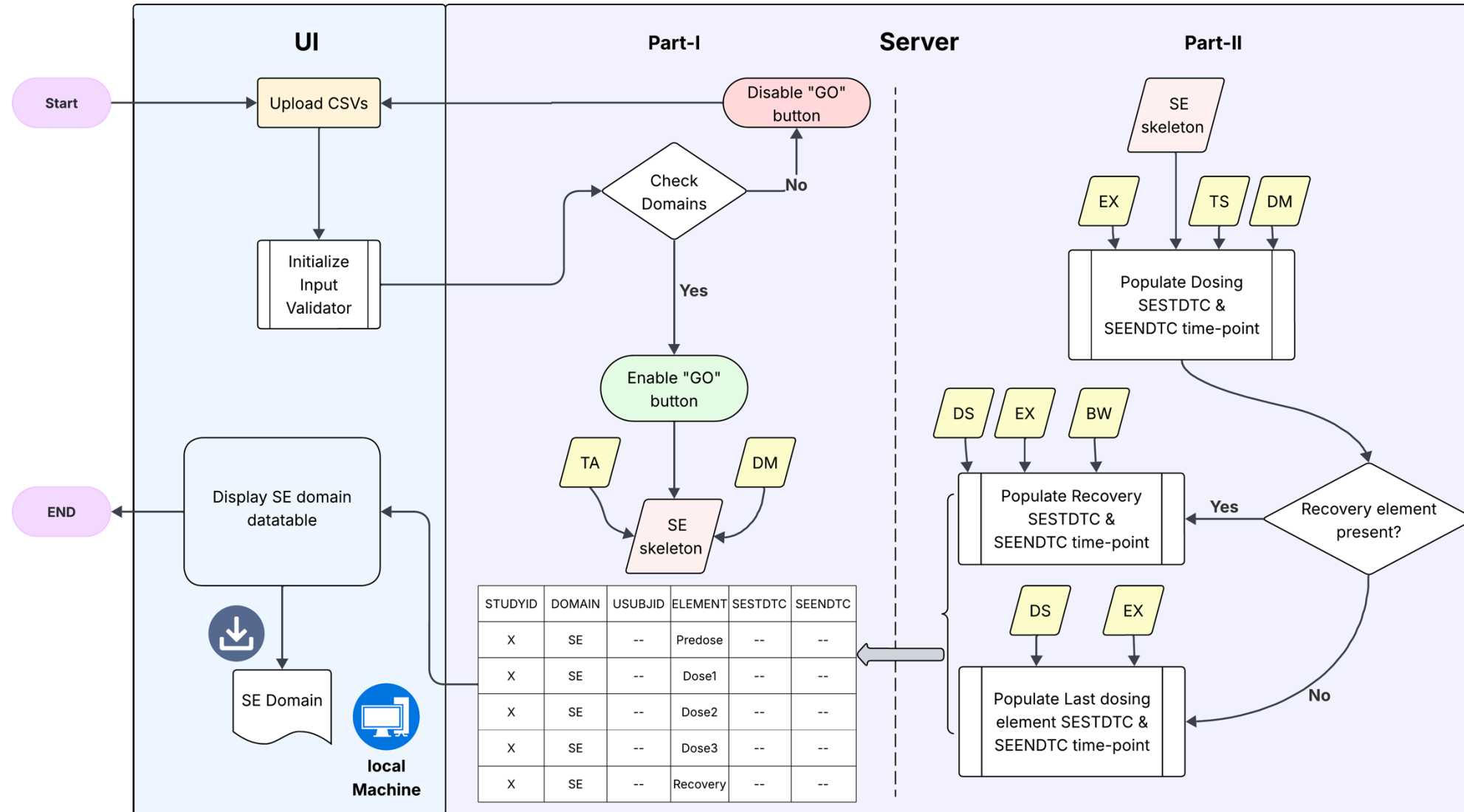
- Describes the **planned phases or segments of a study for each subject**. Example:
For a toxicology study, SE might show:
 - **Element 1:** Dosing for 28 days
 - **Element 2:** Recovery for 14 days
- This helps reviewers understand **what happened and when** for each subject



Subject elements (SE) domain

STUDYID ▴ ▾	DOMAIN ▴ ▾	USUBJID ▴ ▾	SESEQ ▴ ▾	ETCD ▴ ▾	ELEMENT ▴ ▾	SESTDTC ▴ ▾	SEENDTC ▴ ▾
ABCXXX	SE	ABCXXX-0001	1	PHPP	Predose	2013-04-23	2013-05-09
ABCXXX	SE	ABCXXX-0001	2	1DP	1DP - med1: 0 mg/kg/day	2013-05-09	2013-06-07T08:38:36
ABCXXX	SE	ABCXXX-0002	1	PHPP	Predose	2013-04-23	2013-05-09
ABCXXX	SE	ABCXXX-0002	2	1DP	1DP - med1: 0 mg/kg/day	2013-05-09	2013-06-07T08:38:02
ABCXXX	SE	ABCXXX-0003	1	PHPP	Predose	2013-04-23	2013-05-09
ABCXXX	SE	ABCXXX-0003	2	1DP	1DP - med1: 0 mg/kg/day	2013-05-09	2013-06-07T08:38:18

SE generation shiny application: Workflow



SE generation shiny application: UI



CSV files (Required domains: DM, BW, EX, TA, TS & DS)

Browse...

Required

Upload a CSV file to import data.

Attention!
Be aware, the application is designed to work with a standard study structure of predose, dosing elements, and recovery for parallel and Latin square studies. If you have dosing stops or other non-standard elements, the application is unlikely to function properly.



CSV files (Required domains: DM, BW, EX, TA, TS & DS)

Browse... 25 files

Upload complete

Upload a CSV file to import data.

Attention!
Be aware, the application is designed to work with a standard study structure of predose, dosing elements, and recovery for parallel and Latin square studies. If you have dosing stops or other non-standard elements, the application is unlikely to function properly.

SE generation shiny application: Output



CSV files (Required domains: DM, BW, EX, TA, TS & DS)

Browse...

25 files

Upload complete

Upload a CSV file to import data.

Attention!
Be aware, the application is designed to work with a standard study structure of predose, dosing elements, and recovery for parallel and Latin square studies. If you have dosing stops or other non-standard elements, the application is unlikely to function properly.

Go

Download SE

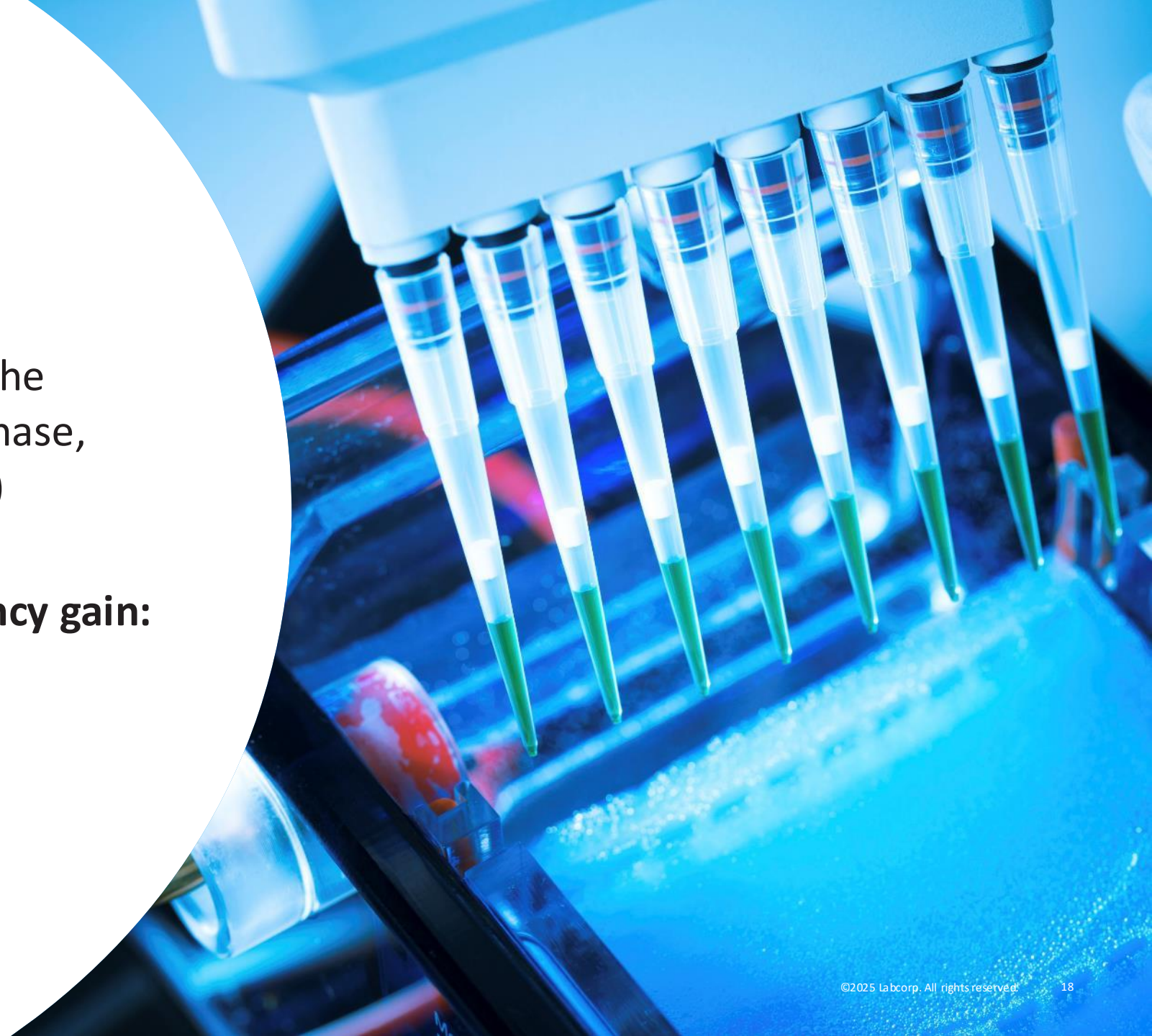
Search:

STUDYID	DOMAIN	USUBJID	SESEQ	ETCD	ELEMENT	SESTDTC	SEENDTC	USRRE
AAXXX	SE	AAXXX-P0001	1	PHPre	Predose	2025-06-30	2025-08-04	
AAXXX	SE	AAXXX-P0001	2	Dose1	Dose1- MT: 0 mg/kg/dose	2025-07-28	2025-08-04	
AAXXX	SE	AAXXX-P0002	1	PHPre	Predose	2025-06-30	2025-07-28	
AAXXX	SE	AAXXX-P0002	2	Dose1	Dose1- MT: 0 mg/kg/dose	2025-07-28	2025-08-04	
AAXXX	SE	AAXXX-P0003	1	PHPre	Predose	2025-06-30	2025-07-28	

Impact

SE Dashboard

- Makes life easy, especially for the complex study design (multi-phase, cross-over, large subject count)
- Complete task ~10sec (**Efficiency gain: ~98.3%**)



EDITCSV Dashboard

Comprehensive Data Transformation Engine for SEND Domains

EDITCSV Dashboard

This application streamlines SEND data preparation by performing **complex data transformations, validations, and automated data completion**, across multiple domains.

EDITCSV shiny application

Core capabilities

Multi-domain automation

- Realtime editing of time-point variables—`--TPT`, `--TPTNUM`, and `--ELTM`
- Derives and updates `--TPTREF` and `--RFTDTC`
- Populate the `--USCHFL` flag

Data completion

- Automatic completion of missing `--DTC` and `--DY` values

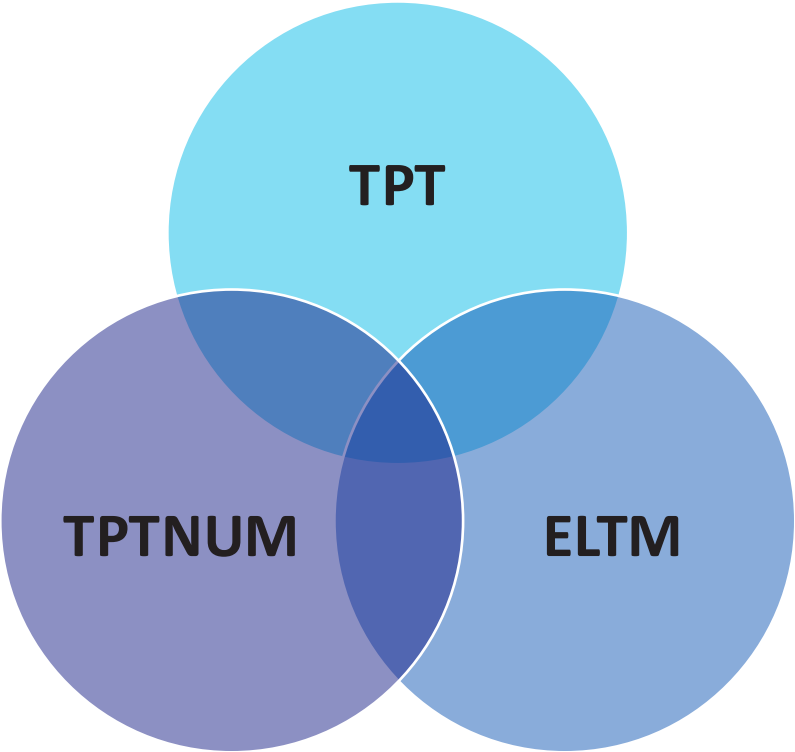
Validation and review

- Display read-only exception tables whenever `--STAT/--REASND` are incorrectly populated

Case study1: Real-time timepoint edit feature

Case study1: Real-time timepoint edit feature

TPT/TPTNUM/ELTM triplet = Foundation of time-point accuracy



TPT	TPTNUM	ELTM (ISO 8601)	Meaning
Pre-dose	1	-PT8H	8 hours before dosing
0 hour	2	PT0M	At dosing reference
6 hour	3	PT6H	6 hours after dosing
Week 4	4	PT672H	4 weeks post-dose (4×7×24=672 hr)

Case study1: Real-time timepoint edit feature (CL domain)

CSV Inputs

CSV files

Browse... 4 files

Upload complete

Who Are You??

mishra

Select EXTPT to Merge RFTDTCs On

Single dose per day

Choose start or end of dosing

EXSTDTC

☒ check



TPT/TPTNUM/ELTM error alert!

CL : TPT_table_error

EX Domain

CL Domain

EG Domain

LB Domain

CV Domain

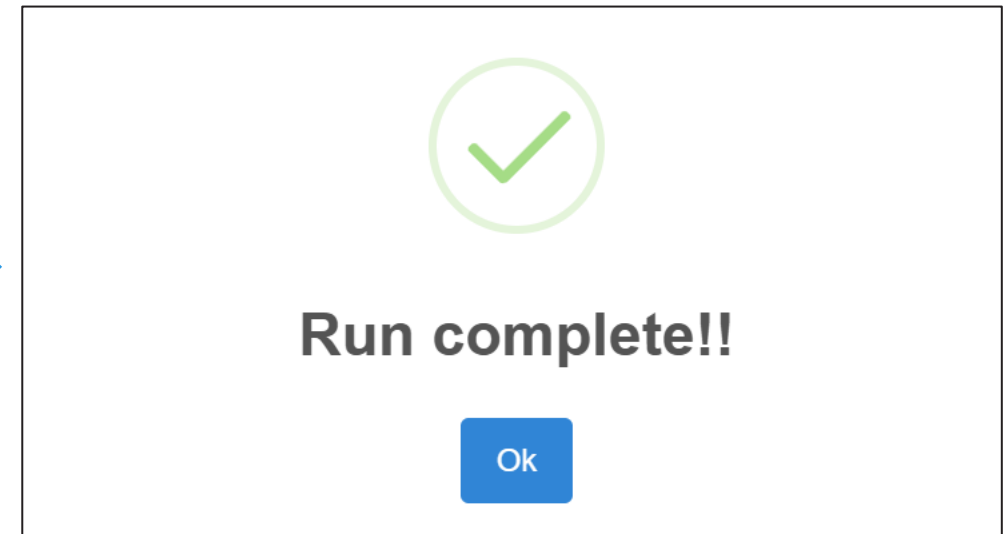
	CLTPT	CLTPTNUM	CLELTM	DELETE
1	Morning observation	1		☐
2	Evening observation	1		☐
3	Qualitative food consumption	1		☐
4	Physical observation	2		☐
5	1 hour postdose	2	PT1H	☐

Case study1: Real-time timepoint edit feature

EX Domain CL Domain EG Domain LB Domain CV Domain

	CLTPT	CLTPTNUM	CLELTM	DELETE
1	Morning observation	1		☒
2	Evening observation	1		☒
3	Qualitative food consumption	1		☒
4	Physical observation	2		☒
5	1 hour postdose	2	PT1H	☐

 CLEAN DATASET



Output
Edited domain file
log file

Case Study 2: Populating the Unscheduled Flag using EDITCSV

Examples of --USCHFL

Domain	NOMLBL	Description	--USCHFL
CL	Week 4	Observation per protocol	N
CL	Unscheduled	Extra observation due to abnormal event	Y
VS	Pre-dose	Measured at planned timepoint	N
VS	(blank)	Ad hoc measurement	Y

Case Study 2: Populating the Unscheduled Flag using EDITCSV

Before

USUBJID	CLTESTCD	CLNOMLBL	CLUSCHFL	SCHEDULE
SUBJ-001	HGB	Visit 2		S
SUBJ-001	HGB	Unscheduled		S
SUBJ-002	HGB	UNSCHEDULED		
SUBJ-003	WBC	Visit 5 (unsch)		NA



After

USUBJID	CLTESTCD	CLNOMLBL	CLUSCHFL	SCHEDULE
SUBJ-001	HGB	Visit 2		S
SUBJ-001	HGB	Unscheduled	Y	U
SUBJ-002	HGB	UNSCHEDULED	Y	U
SUBJ-003	WBC	Visit 5 (Unsch)	Y	U

Impact

EDITCSV Dashboard

- **Automate for speed and accuracy:**
From ~35-40 minutes to 10 seconds
with guaranteed SEND compliance



Key Takeaways

Key Takeaways



Transformative Leap: Modular R Shiny dashboards automate and modernize SEND dataset generation.



Efficiency Gains: Processing time drops from minutes to seconds for scalable performance.



Compliance & Traceability: Tools like SE Domain Generator and EDITCSV ensure CDISC SEND compliance with full audit trails.



Strategic Impact: Delivers a repeatable, auditable, rapid workflow that accelerates drug development.

Acknowledgments

A special thank you to...

Vanessa and Jack

Supervisor: Michael DeNieu

Q&A

Madhulika Mishra

email: madhulika.mishra@labcorp.com

Michael Denieu

email: michael.denieu@labcorp.com