2024 CDISC CHINA INTERCHANGE SHANGHAI

30-31 AUGUST: CONFERENCE & EXPO | 28-29 AUGUST: TRAININGS

Implementation and Harmonization end to end CDISC standard CDASH-SDTM-ADaM in a platform trial framework

Lei Zhang, Senior Clinical Data Engineer, Global Biostatistics & Data Sciences, Boehringer-Ingelheim

Meet the Speaker

Lei Zhang

Title: Senior Clinical Data Engineer

Organization: Boehringer-Ingelheim

Work as a clinical data manager more than 7 years

Focus on Immune Oncology therapy area projects/trials

Start in Pfizer from 2017 to 2021, join Boehringer Ingelheim Global Biostatistics & Data Sciences department from 2021 to present

Engage in the drug development of oncology rare target mutation such as KRAS, MDM2, and DLL3 as clinical data manager

Deep cooperation with biostatistician, statistical programmer during this period, accumulating abundant clinical data standard practical experience

Disclaimer and Disclosures

- *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.*

- *The author(s) have no real or apparent conflicts of interest to report.*
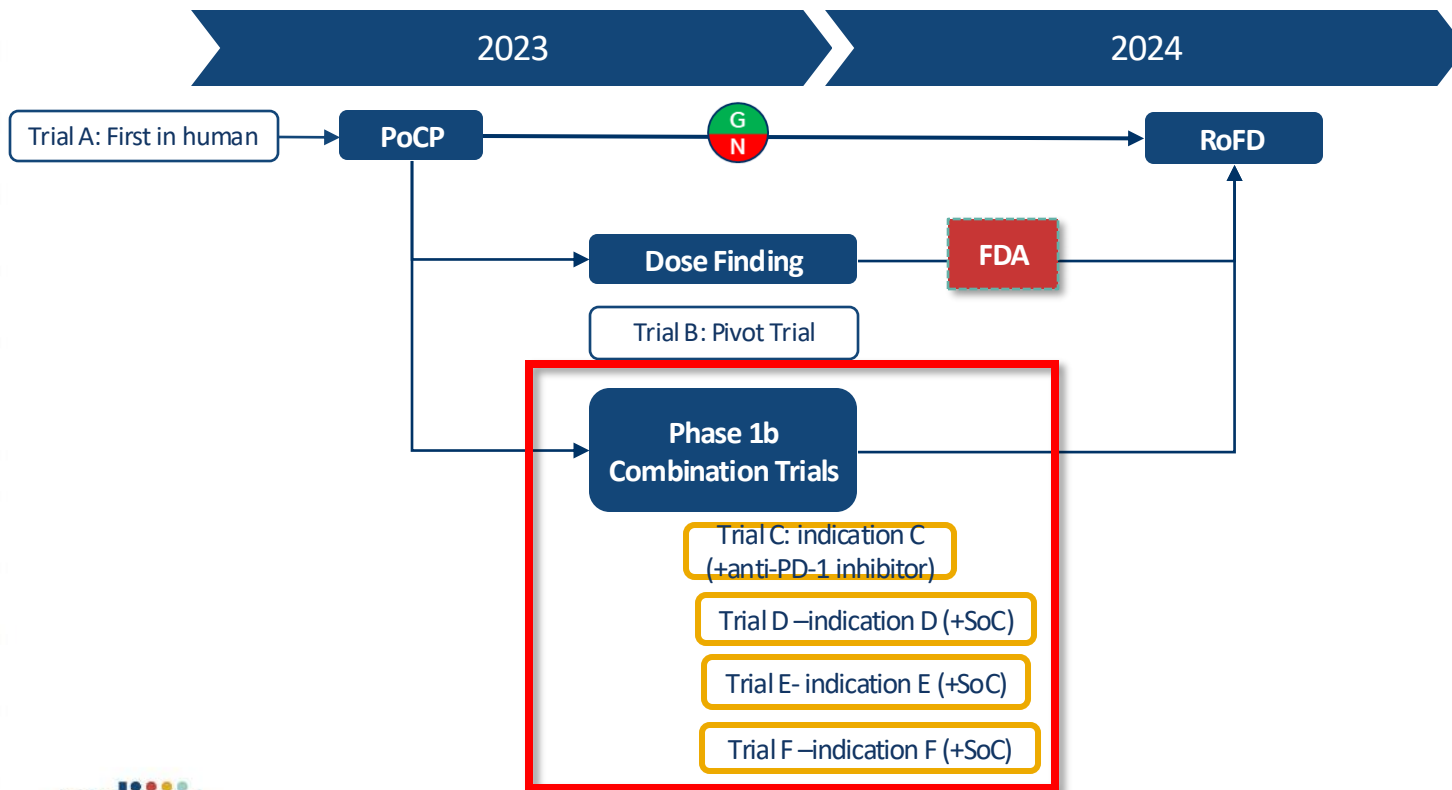
Agenda

1. What's the pain point?
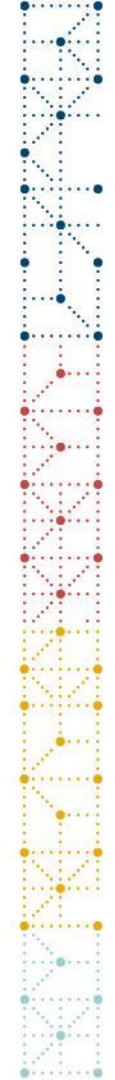2. Key Highlights in Implementation
3. Practice Makes Perfect

What's the pain point?

Picture of Development

2023	2024

Trial A: First in human → PoCP → (G/N) → RoFD

Dose Finding → FDA

Trial B: Pivot Trial

Phase 1b Combination Trials

Trial C: indication C (+anti-PD-1 inhibitor)

Trial D –indication D (+SoC)

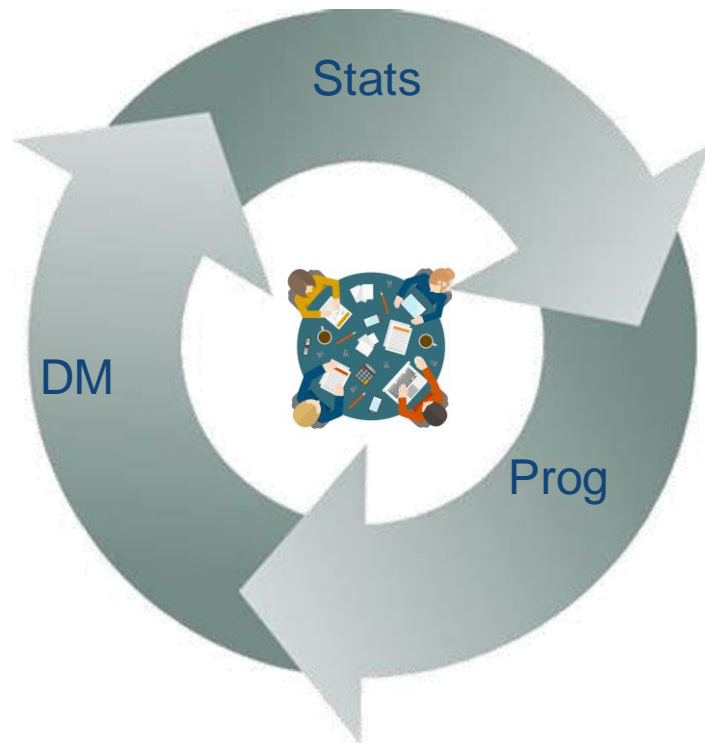Trial E- indication E (+SoC)

Trial F –indication F (+SoC)

Similarities

- Same candidate drug with different combinations
- Single master protocol
- Same MOA
- Across different tumor types
- Selected by single marker
- Similar trial design

Maybe now need a new way...

Stats

Prog

DM

Work independently

Stats

DM

Prog

Cooperate within same picture

Key Highlights in Implementation

Key Elements

Collection	Tabulation	Analysis
CDASH	SDTM	ADaM

Collection — CDASH
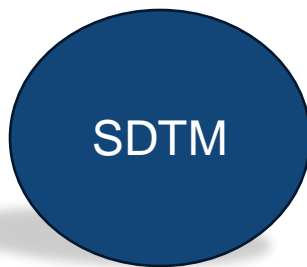DB design
(CRF+ Visit)
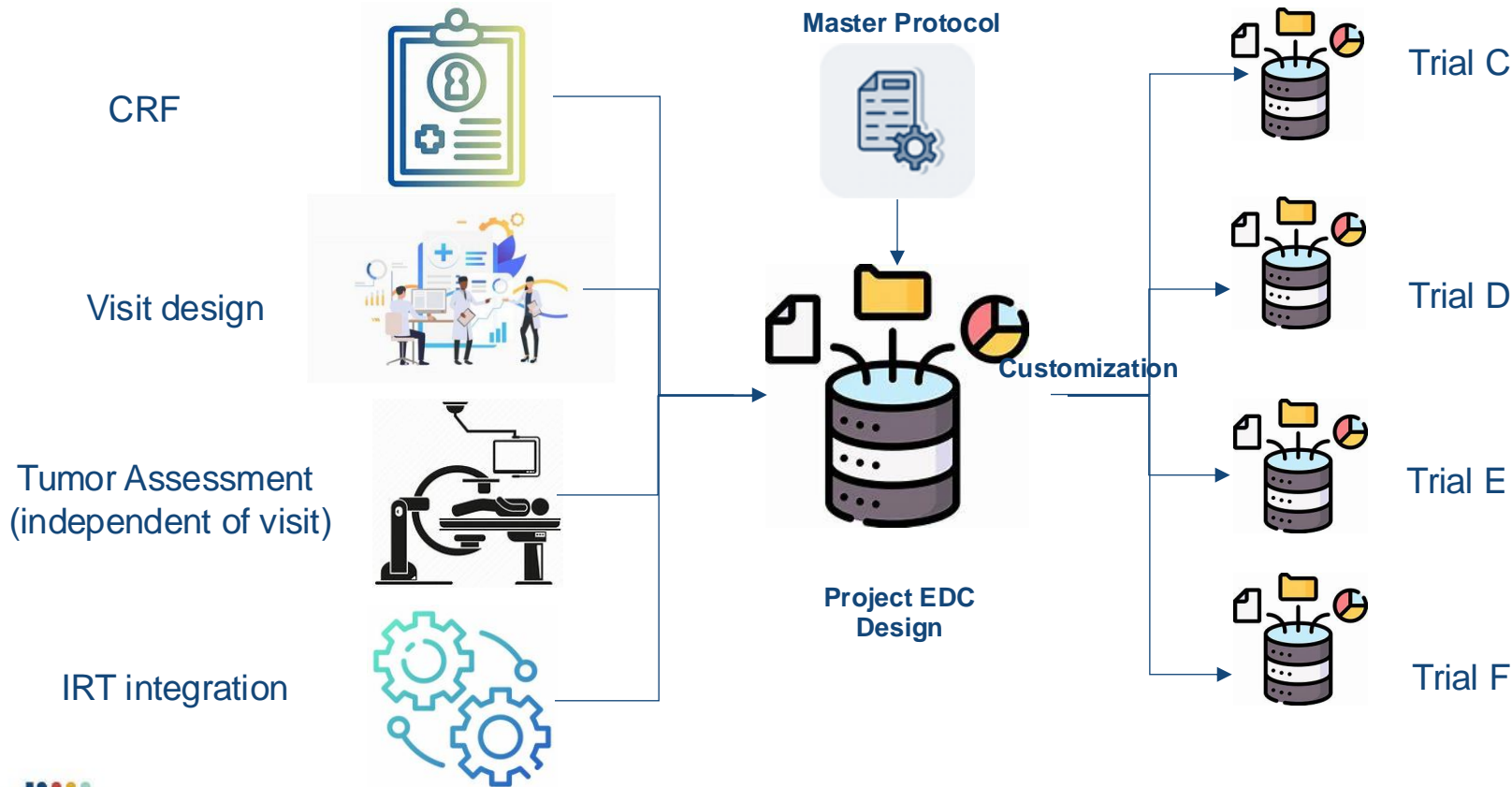Data cleaning

Tabulation — SDTM
Transformation
Dataset quality review
Project Database
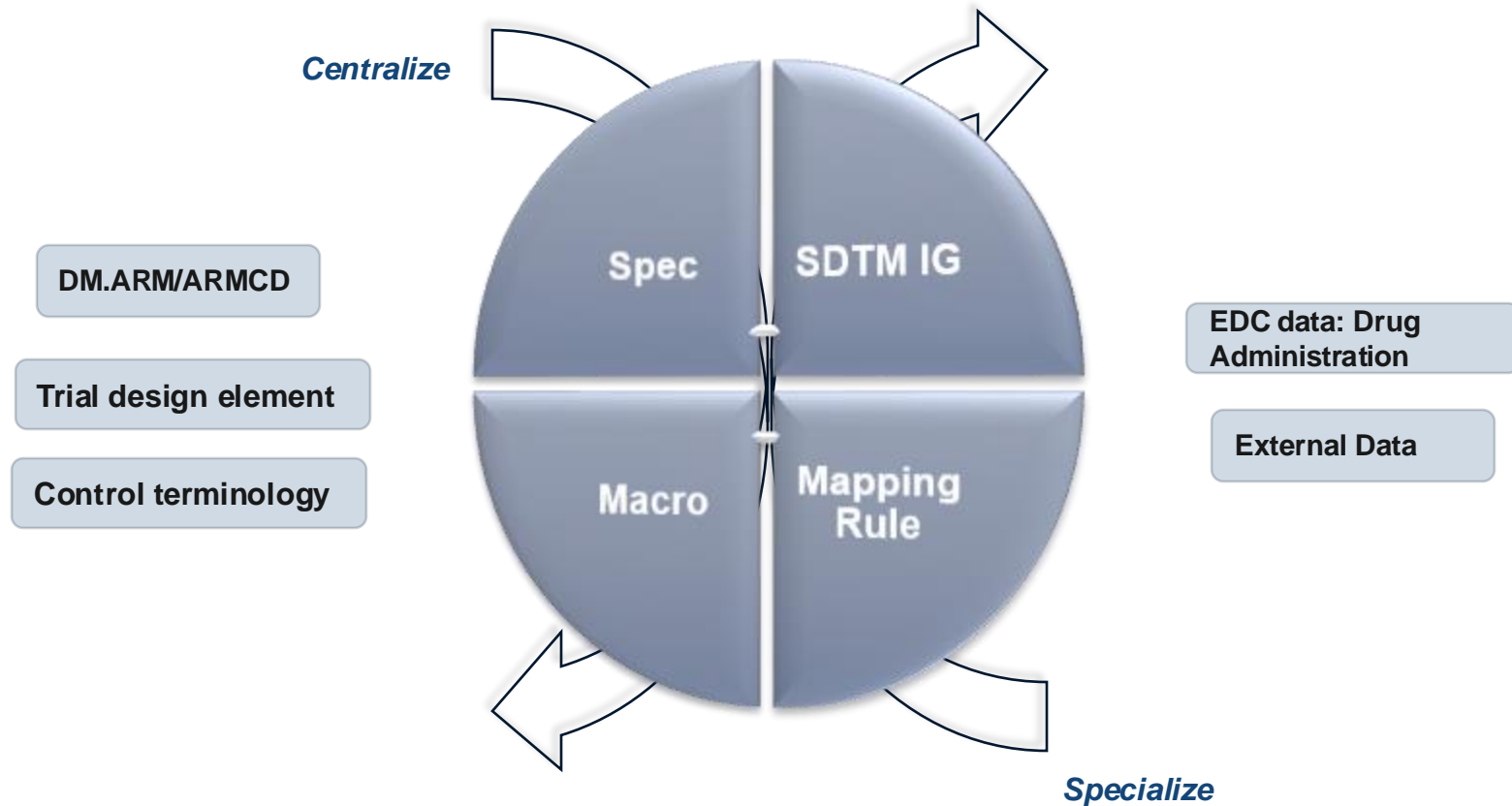Data Review/Clean Plan
Clinical Quality Review plan

Analysis — ADaM
PSAP
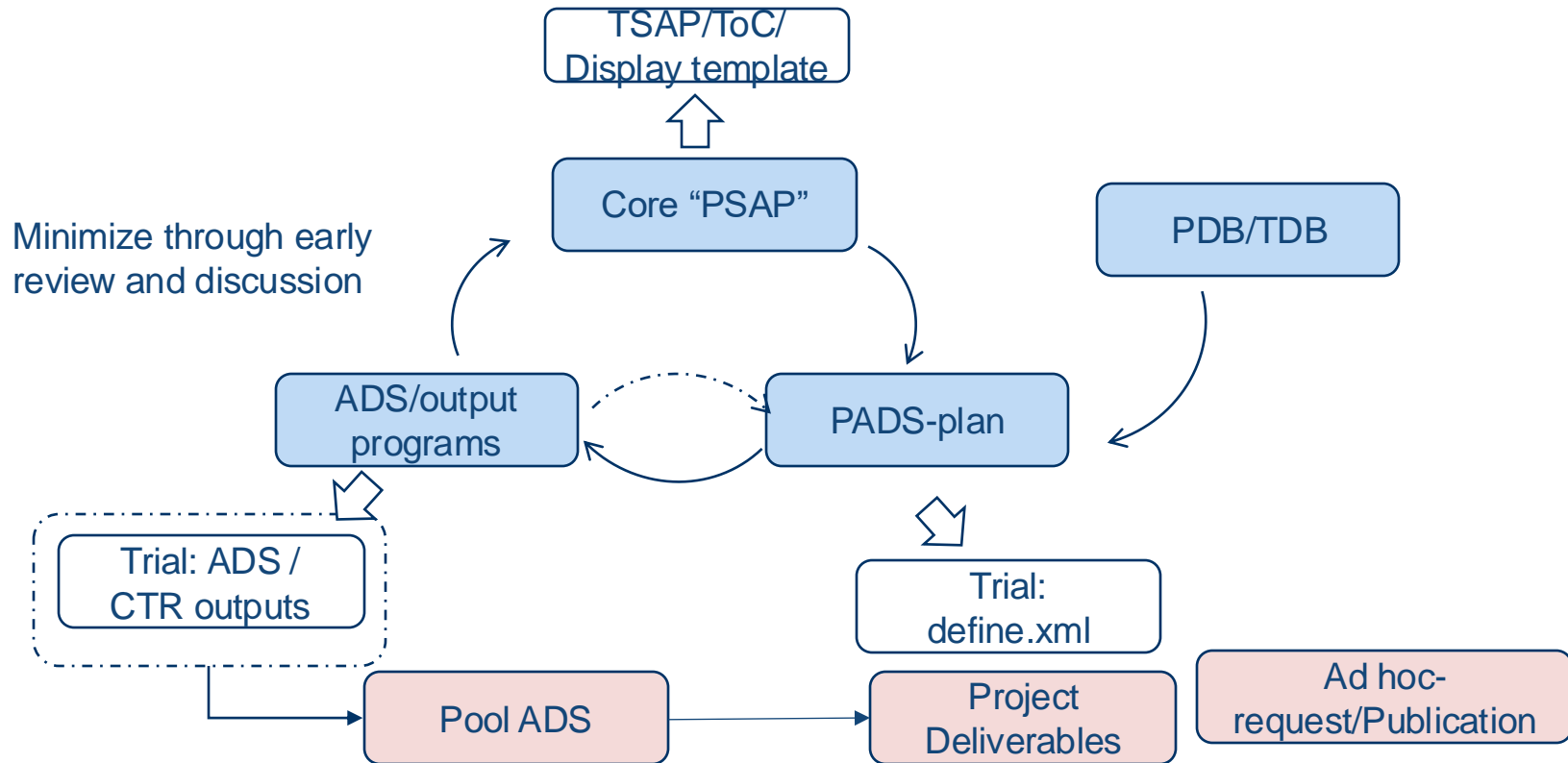PTOC
PDT
Layout of Outputs
PADS-plan
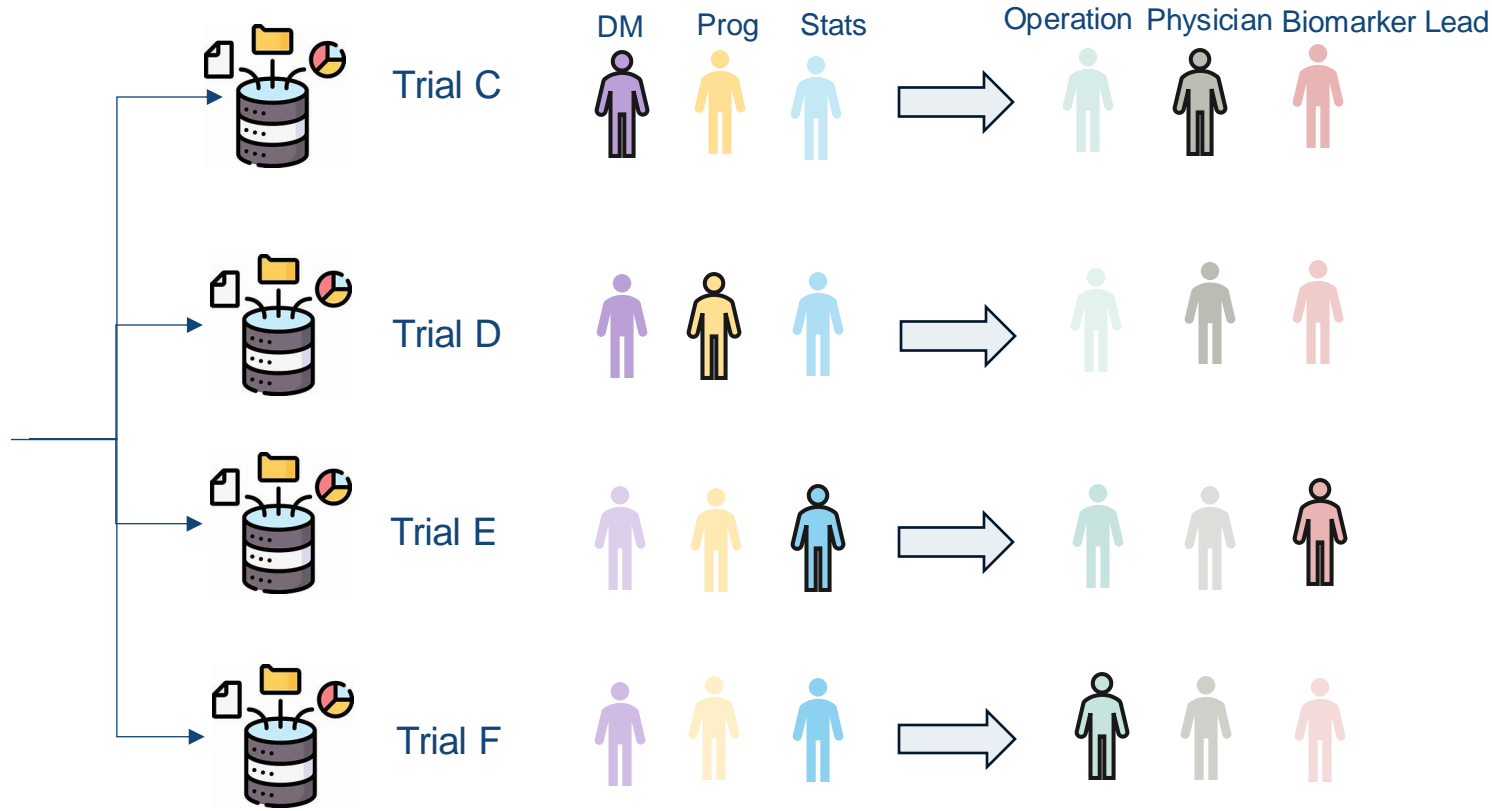ADS program
TFL program

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Data Collection

CRF

Visit design

Tumor Assessment
(independent of visit)

IRT integration

Master Protocol

Project EDC
Design

Customization

Trial C

Trial D

Trial E

Trial F

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Data Tabulation

Centralize

DM.ARM/ARMCD

Trial design element

Control terminology

Spec

SDTM IG

Macro

Mapping Rule

EDC data: Drug Administration

External Data

Specialize

Data Analysis

Practice Makes Perfect

Communication

Communication

Trial C

Trial D

Trial E

Trial F

DM

Prog

Stats

CD

TMCP

CO
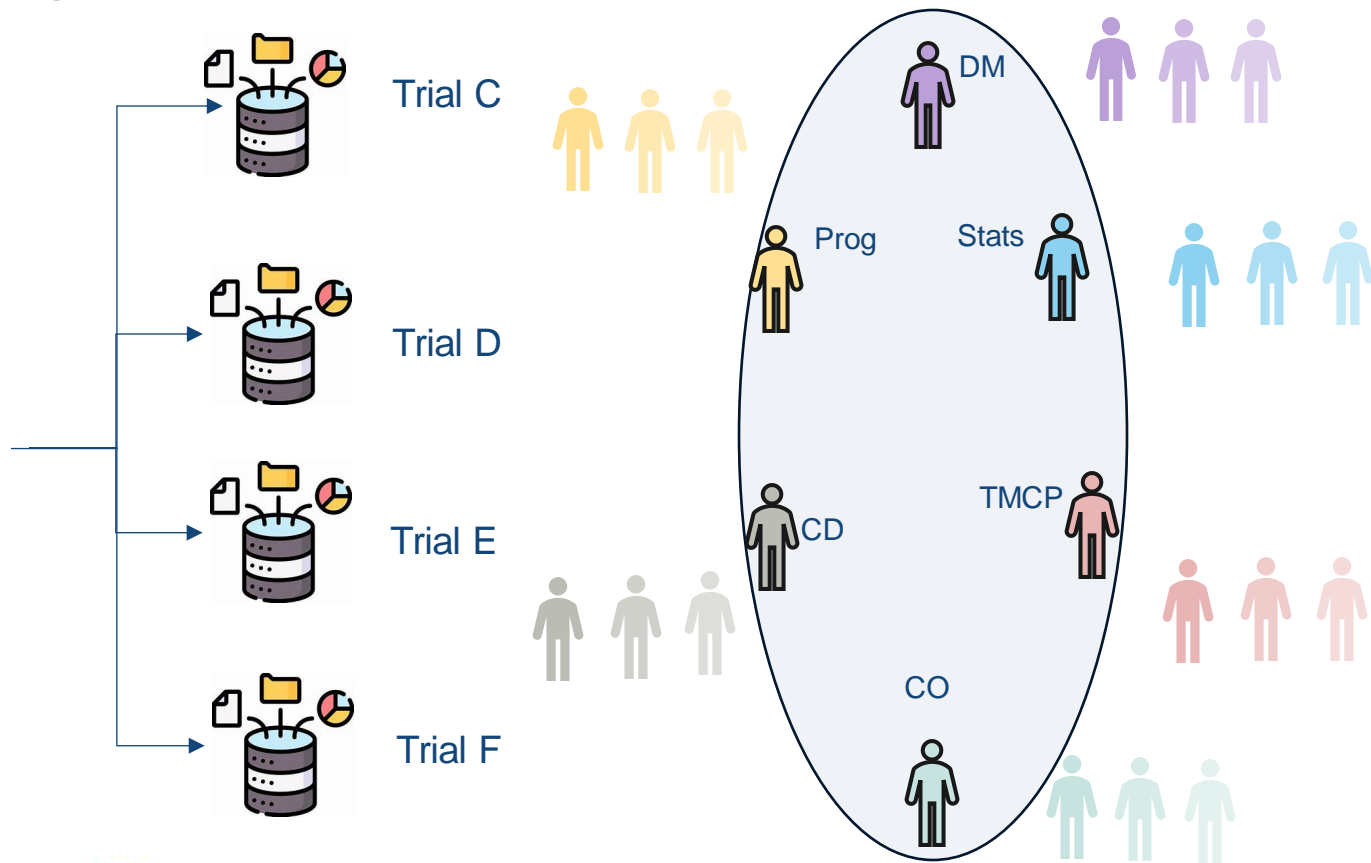
Delivery Process Optimization

- Dose Escalation Committee

Timeline (working days) When < 9 patients, outputs (only patient profiles and listings) from **source data**		Timeline (working days) When >= 9 patients, outputs from **SDTM**	
Data cut-off: last patient completes MTD evaluation period	**Day 0**	Data cut-off: last patient completes MTD evaluation period	**Day 0**
Data entry	**Day 2**	Data entry	**Day 2**
DDC outputs (only patient profiles and listings) from source data, when < 9 patients	**Day 3**	SDTM transformation	**Day 3**
		DDC outputs from SDTM, when >= 9 patients	**Day 7**

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Thank You!

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