Society for Clinical Data Management
DATA DRIVEN

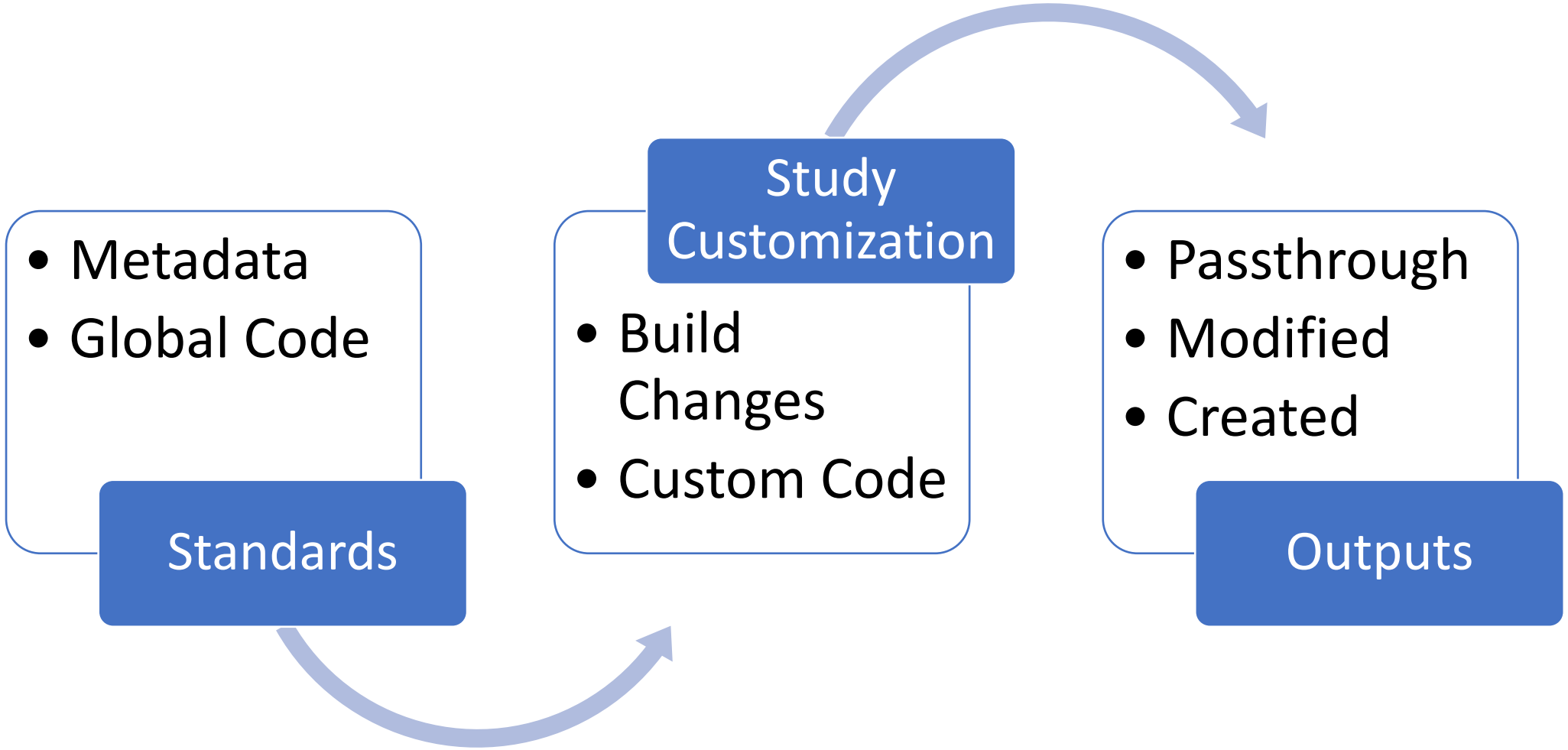
Theme:
Capabilities | Collaboration |
Change on the way to Clinical Data Science

SCDM Live

India conference

2nd - 3rd December 2022
Radisson Blu Hotel, Bengaluru

Standardization to Automation



Possibilities

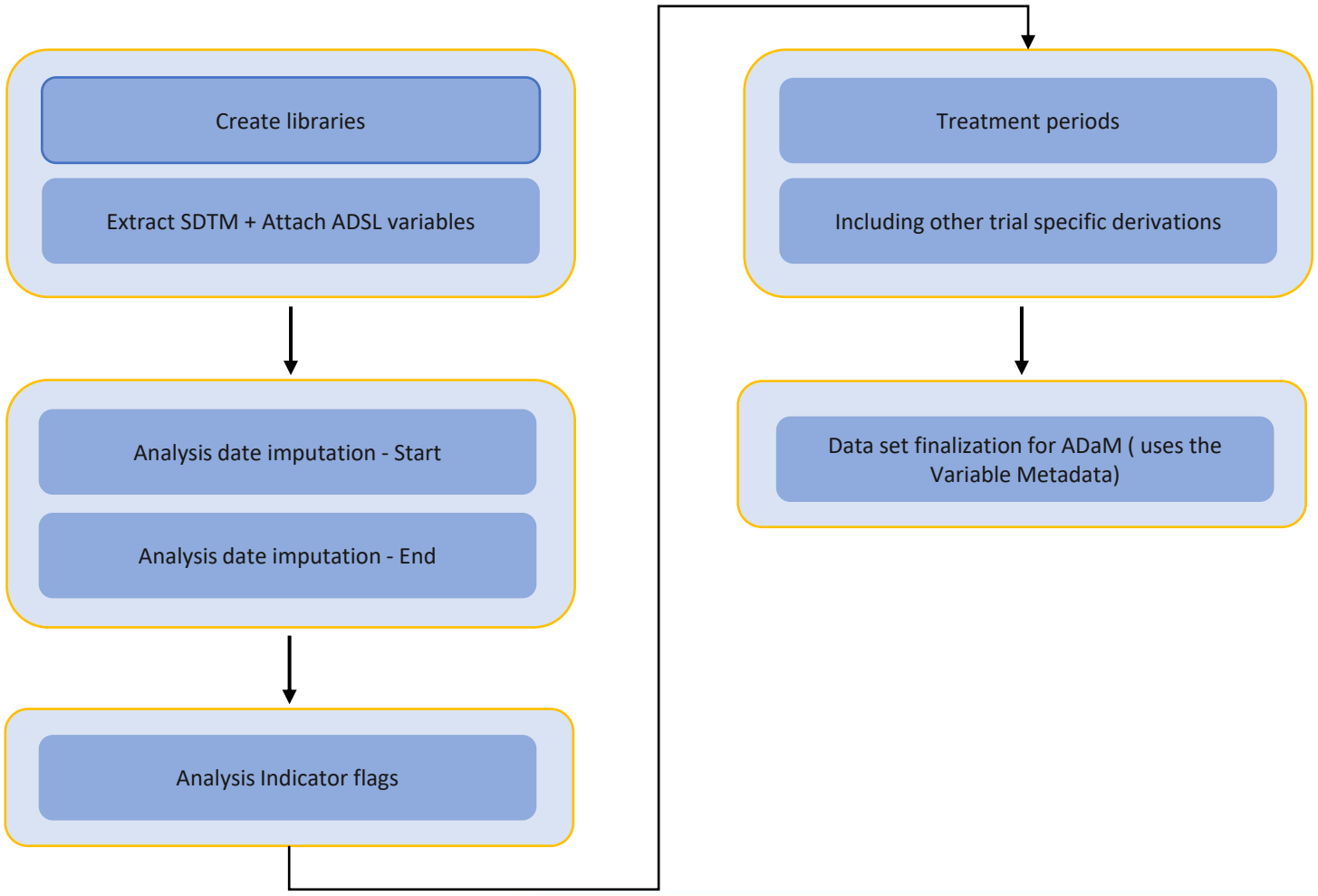
- MDR (Metadata Repository) – holds standards including:
  - EDC builds, SDTM, ADaM, and TLF mapping metadata
  - Custom study modifications
- Automatic annotated CRF
- Patient Narratives

Possibilities

- MMAPs (Modular Mapping Assisted Programs)
  - SDTM Mapping generation
  - ADaM Mapping generation

Possibilities

- MMAPs (Modular Mapping Assisted Programs) – Overview



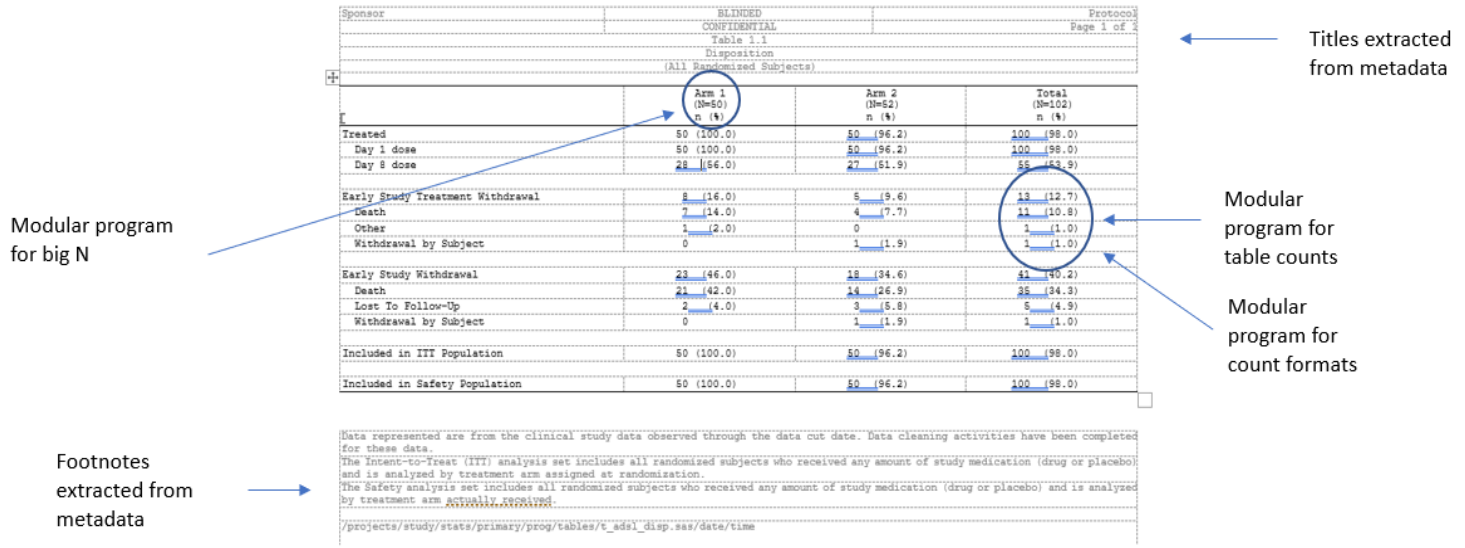
TLF Programming

- Modular automation – Building blocks towards displays.

```
%include config.sas

%let percent =()

%gmBigN() -> dataset
%gmCountCategorical() -> dataset
%gmGetPercent() -> dataset
```



Sponsor | BLINDED CONFIDENTIAL | Protocol | Page 1 of 2

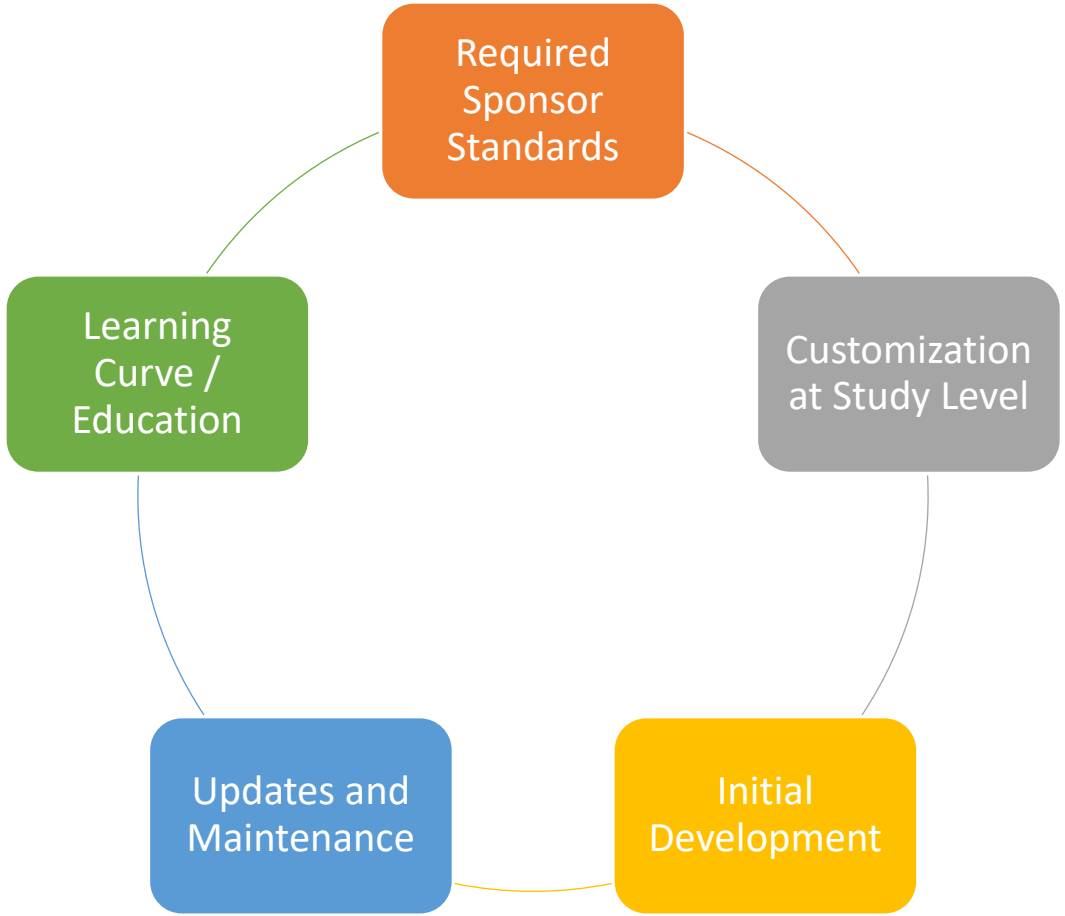
Table 1.1
Disposition
(All Randomized Subjects)

	Arm 1 (N=50) n (%)	Arm 2 (N=52) n (%)	Total (N=102) n (%)
Treated	50 (100.0)	50 (96.2)	100 (98.0)
Day 1 dose	50 (100.0)	50 (96.2)	100 (98.0)
Day 8 dose	28 (56.0)	27 (51.9)	55 (53.9)
Early Study Treatment Withdrawal	8 (16.0)	5 (9.6)	13 (12.7)
Death	7 (14.0)	4 (7.7)	11 (10.8)
Other	1 (2.0)	0	1 (1.0)
Withdrawal by Subject	0	1 (1.9)	1 (1.0)
Early Study Withdrawal	23 (46.0)	18 (34.6)	41 (40.2)
Death	21 (42.0)	14 (26.9)	35 (34.3)
Lost To Follow-Up	2 (4.0)	3 (5.8)	5 (4.9)
Withdrawal by Subject	0	1 (1.9)	1 (1.0)
Included in ITT Population	50 (100.0)	50 (96.2)	100 (98.0)
Included in Safety Population	50 (100.0)	50 (96.2)	100 (98.0)

Data represented are from the clinical study data observed through the data cut date. Data cleaning activities have been completed for these data.
The Intent-to-Treat (ITT) analysis set includes all randomized subjects who received any amount of study medication (drug or placebo) and is analyzed by treatment arm assigned at randomization.
The Safety analysis set includes all randomized subjects who received any amount of study medication (drug or placebo) and is analyzed by treatment arm actually received.

/projects/study/stats/primary/prog/tables/t_adsl_disp.sas/date/time

Risks


Required Sponsor Standards
Customization at Study Level
Initial Development
Updates and Maintenance
Learning Curve / Education