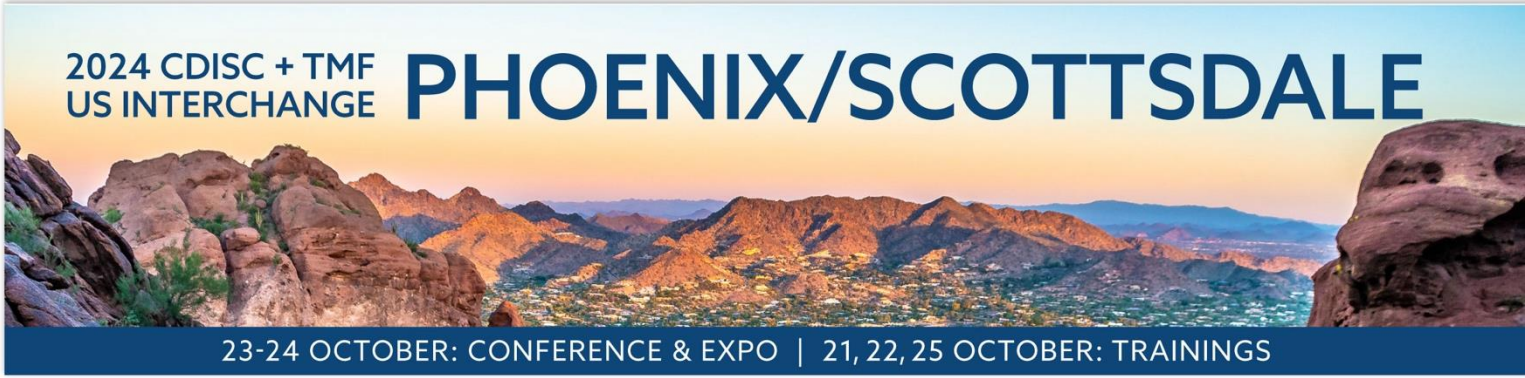
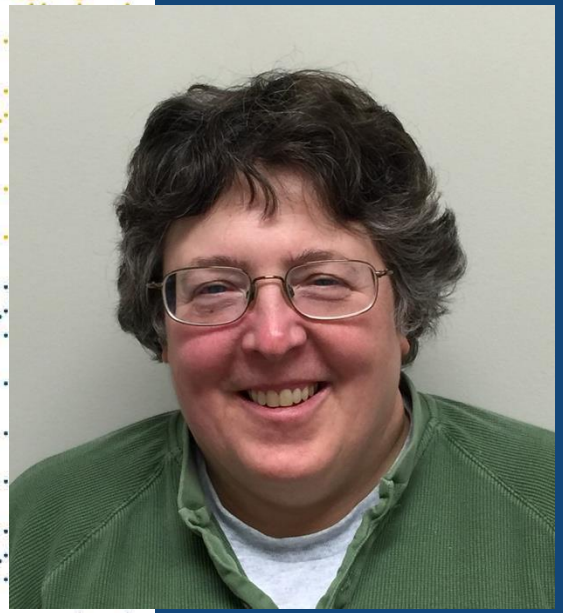


Name That ADaM Dataset Class

Presented by Nancy Brucken, Senior Standards Engineer, IQVIA



Meet the Speaker

Nancy Brucken

Title: Senior Standards Engineer

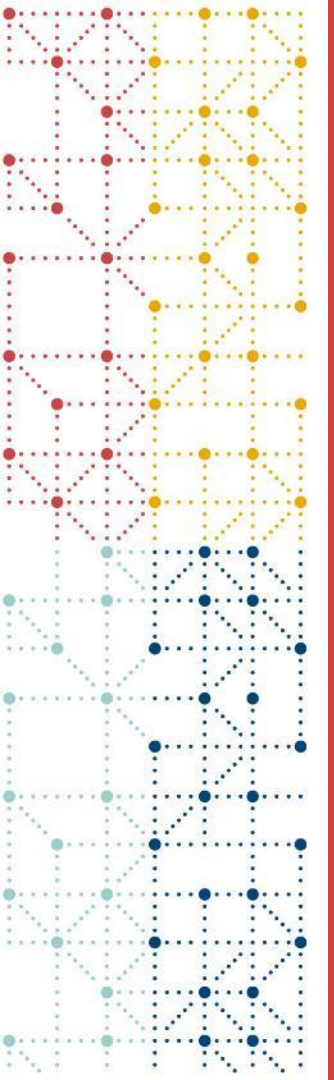
Organization: IQVIA

Nancy Brucken in a Senior Standards Engineer at IQVIA with over 30 years of statistical programming experience in the pharmaceutical industry. She is a CDISC-authorized ADaM instructor, a member of the ADaM 3.0 and regulatory document review sub-teams, and co-leads the ADaM ADQRS sub-team. A graduate of Marietta College, she is a devoted Ohio State fan despite living in that state up north.

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. ADaM Dataset Class/Subclass Overview
2. Name That ADaM Dataset Class (and Variables)
3. Summary

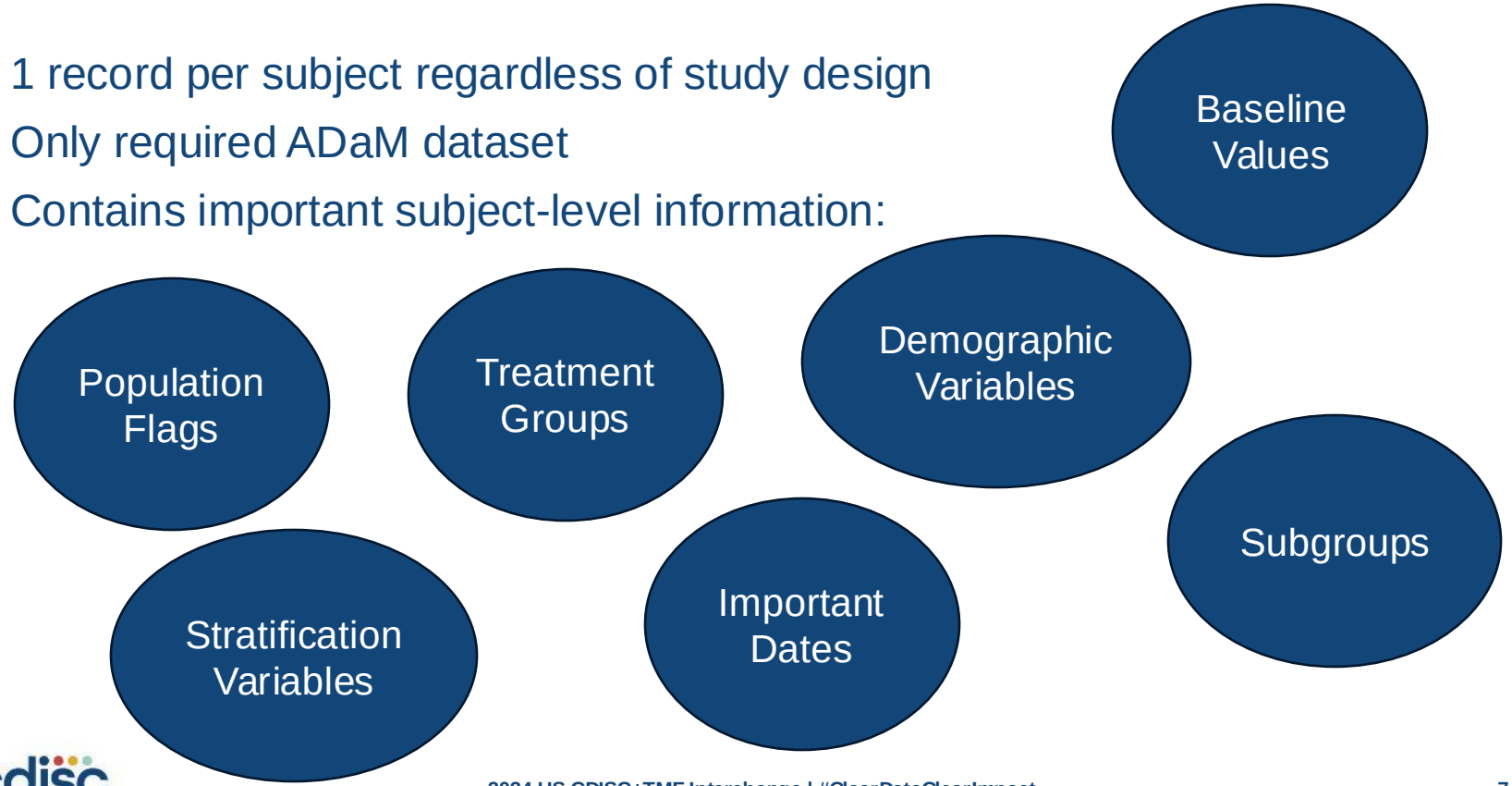
ADaM Dataset Class/Subclass Overview

ADaM Dataset Classes and Subclasses

- Subject-Level Analysis Dataset (ADSL)
- Basic Data Structure (BDS)
  - Time-to-Event (TTE)
  - Non-Compartmental Analysis (NCA)
  - Population PK (PPK)
- Occurrences Data Structure (OCCDS)
  - Adverse Events
- ADaM Other

Subject-Level Analysis Dataset (ADSL)

- 1 record per subject regardless of study design
- Only required ADaM dataset
- Contains important subject-level information:



Basic Data Structure (BDS)

- 1 record per subject, per parameter, per analysis timepoint (optional)
- “Vertical” instead of “horizontal”
- Most commonly used ADaM dataset class
- Supports a wide variety of analyses
  - Univariate summary statistics of values by timepoint
  - Repeated measures
  - Logistic regression
- Provides datapoint traceability

Time-to-Event Subclass (TTE)

- Specific version of a BDS
- 1 record per subject per parameter
  - Rarely by analysis timepoint
- Supports survival analysis
- Analysis value = time to event or time to censoring
- Includes censoring indicator and reason

Other BDS Subclasses

- Non-Compartmental Analysis (NCA)
  - Used as input to software packages performing non-compartmental PK analyses on drug concentration data
- Population PK
  - Used as input to software packages performing population PK analyses

Occurrences Data Structure (OCCDS)

- 1 record per subject per term
  - “Term” could be an event, a medication, or anything that is being counted
  - Often 1 record in ADaM for each record in source SDTM domain
- Supports analyses counting occurrences
- No need for an analysis value

Adverse Events Subclass

- Limited to adverse event records
- 1 record per subject per event

Name That ADaM Dataset Class!

Format

- TFL shell will be displayed on the screen
- You will need to provide
  1. Appropriate ADaM dataset class
  2. Variables needed to produce the TFL

First person to name the most appropriate ADaM dataset class wins a prize!

Table 1

14.1.2.1 Subject Demographics and Baseline Characteristics
Safety Population

	BP3304 (N =xx)	Placebo (N =xx)	Overall (N=xx)
Age (years)			
N	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Gender [n (%)][a]			
Male	xx (xx.x)	xx (xx.x)	xx (xx.x)
Female	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ethnicity [n (%)][a]			
Hispanic or Latino	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Hispanic or Latino	xx (xx.x)	xx (xx.x)	xx (xx.x)
Race [n (%)][a]			
White	xx (xx.x)	xx (xx.x)	xx (xx.x)
Black or African American	xx (xx.x)	xx (xx.x)	xx (xx.x)
Asian	xx (xx.x)	xx (xx.x)	xx (xx.x)
American Indian or Alaskan Native	xx (xx.x)	xx (xx.x)	xx (xx.x)
Native Hawaiian or Other Pacific Islander	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)

Reference: Listing 16.2.4.1

[a] Percentages are based on the number of subjects in the population.

Table 1

ADSL

SAFFL

TRT01P

AGE

SEX

ETHNIC

RACE

14.1.2.1 Subject Demographics and Baseline Characteristics
Safety Population

	BP3304 (N =xx)	Placebo (N =xx)	Overall (N=xx)
Age (years)			
N	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Gender [n (%)][a]			
Male	xx (xx.x)	xx (xx.x)	xx (xx.x)
Female	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ethnicity [n (%)][a]			
Hispanic or Latino	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Hispanic or Latino	xx (xx.x)	xx (xx.x)	xx (xx.x)
Race [n (%)][a]			
White	xx (xx.x)	xx (xx.x)	xx (xx.x)
Black or African American	xx (xx.x)	xx (xx.x)	xx (xx.x)
Asian	xx (xx.x)	xx (xx.x)	xx (xx.x)
American Indian or Alaskan Native	xx (xx.x)	xx (xx.x)	xx (xx.x)
Native Hawaiian or Other Pacific Islander	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)

Reference: Listing 16.2.4.1

[a] Percentages are based on the number of subjects in the population.

Table 2

TRT01P

14.1.2.1 Subject Demographics and Baseline Characteristics
Safety Population

	BP3304 (N =xx)	Placebo (N =xx)	Overall (N=xx)
Height (cm)			
N	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Weight (kg)			
N	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Body Mass Index (kg/m^2)			
N	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx

Reference: Listing 16.2.4.1
Note: SD = standard deviation, Min = Minimum, Max = Maximum.

Table 2

ADSL

SAFFL

TRT01P

HEIGHTBL

WEIGHTBL

BMIBL

TRTSDT

14.1.2.1 Subject Demographics and Baseline Characteristics
Safety Population

	BP3304 (N =xx)	Placebo (N =xx)	Overall (N=xx)
Height (cm)			
N	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Weight (kg)			
N	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx
Body Mass Index (kg/m^2)			
N	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx

Reference: Listing 16.2.4.1
Note: SD = standard deviation, Min = Minimum, Max = Maximum.

Table 3

[redacted]

14.3.1.1.2.1 Treatment-Emergent Adverse Events by System Organ Class
Safety Population

[redacted]

System Organ Class Preferred Term	[redacted]	BP3304 (N =xx) n (%)	Placebo (N =xx) n (%)	Overall (N =xx) n (%)
Any Treatment-Emergent Adverse Event	[redacted]	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class I		xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term I		xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term II	[redacted]	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class II		xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term I		xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term II	[redacted]	xx (xx.x)	xx (xx.x)	xx (xx.x)

[redacted]

Reference: Listing 16.2.7

Note: A treatment emergent adverse event (TEAE) will be any event that started on or after Day 1 up until the last dose date plus 14 days, inclusive. Subjects with more than one occurrence of a preferred term are counted only once.

Table 3

OCCDS – ADVERSE EVENTS

SAFFL

14.3.1.1.2.1 Treatment-Emergent Adverse Events by System Organ Class
Safety Population

System Organ Class Preferred Term	BP3304 (N =xx) n (%)	Placebo (N =xx) n (%)	Overall (N =xx) n (%)
Any Treatment-Emergent Adverse Event	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class I	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term I	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term II	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class II	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term I	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term II	xx (xx.x)	xx (xx.x)	xx (xx.x)

TRTA

TRTEMFL

AEBODSYS

AEDECOD

ASTDT

TRTSDT

TRTEDT

Reference: Listing 16.2.7

Note: A treatment emergent adverse event (TEAE) will be any event that started on or after Day 1 up until the last dose date plus 14 days, inclusive. Subjects with more than one occurrence of a preferred term are counted only once.

Table 3

OCCDS – ADVERSE EVENTS

14.3.1.1.2.1 Treatment-Emergent Adverse Events by System Organ Class
Safety Population

SAFFL

System Organ Class Preferred Term	TRTA BP3304 (N =xx) n (%)	Placebo (N =xx) n (%)	Overall (N =xx) n (%)
Any Treatment-Emergent Adverse Event (TRTEMFL)	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class I (AEBODSYS)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term I	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term II	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class II (AEBODSYS)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term I (AEDECOD)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term II (AEDECOD)	xx (xx.x)	xx (xx.x)	xx (xx.x)

ASTDT TRTSDT TRTEDT

Reference: Listing 16.2.7

Note: A treatment emergent adverse event (TEAE) will be any event that started on or after Day 1 up until the last dose date plus 14 days, inclusive. Subjects with more than one occurrence of a preferred term are counted only once.

Occurrence Flags??

Table 4

14.3.6.1 Vital Signs
Safety Population

TRTA

<Vital Signs Parameter (Units)>

Visit	BP33404 (N=xx) Actual	BP33404 (N=xx) Change From Baseline	Placebo (N=xx) Actual	Placebo (N=xx) Change From Baseline	Overall (N=xx) Actual	Overall (N=xx) Change From Baseline
Baseline						
N	xx		xx		xx	
Mean (SD)	xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)	
Median	xx.x		xx.x		xx.x	
Min, Max	xx, xx		xx, xx		xx, xx	
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

Reference: Listings 16.2.8.1.1-16.2.8.1.4
Note: SD = standard deviation, Min = Minimum, Max = Maximum. Baseline is defined as the last measurement before the first dose of study drug.

Programming note: The number of significant digits will vary by parameter.

Repeat for Week 8, 12, 16, 20 and 24 visits. Display for heart rate, weight and body mass index.

Table 4

BDS

PARAM

14.3.6.1 Vital Signs
Safety Population

TRTA

SAFFL

<Vital Signs Parameter (Units)>

AVISIT

AVISITN

Visit	BP33404 (N=xx) Actual	BP33404 (N=xx) Change From Baseline	Placebo (N=xx) Actual	Placebo (N=xx) Change From Baseline	Overall (N=xx) Actual	Overall (N=xx) Change From Baseline
Baseline						
N	xx		xx		xx	
Mean (SD)	xx.x (xx.xx)		xx.x (xx.xx)		xx.x (xx.xx)	
Median	xx.x		xx.x		xx.x	
Min, Max	xx, xx		xx, xx		xx, xx	
Week 4						
N	xx	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx

AVAL

CHG

PARAMN

PARAMCD

BASE

ABLFL

ANL01FL

Reference: Listings 16.2.8.1.1-16.2.8.1.4

Note: SD = standard deviation, Min = Minimum, Max = Maximum. Baseline is defined as the last measurement before the first dose of study drug.

Programming note: The number of significant digits will vary by parameter.

Repeat for Week 8, 12, 16, 20 and 24 visits. Display for heart rate, weight and body mass index.

ADT

TRTSDT

Table 6

14.3.7.3 Electrocardiogram Abnormalities
Safety Population

TRTA

ECG Abnormality	BP3304 (N =xx) n (%)	Placebo (N =xx) n (%)	Overall (N =xx) n (%)
Any Abnormality	xx (xx.x)	xx (xx.x)	xx (xx.x)
Abnormality I	xx (xx.x)	xx (xx.x)	xx (xx.x)
Abnormality II	xx (xx.x)	xx (xx.x)	xx (xx.x)
Abnormality III	xx (xx.x)	xx (xx.x)	xx (xx.x)

Reference: Listing 16.2.9.1
Note: Percentages are based on the number of subjects in each population. Subjects identified as having abnormalities more than once are only counted once for that abnormality. Only abnormalities reported after the start of study medication are displayed.

Table 6

OCCDS

TRTA

SAFFL

14.3.7.3 Electrocardiogram Abnormalities
Safety Population

ECG Abnormality	BP3304 (N =xx) n (%)	Placebo (N =xx) n (%)	Overall (N =xx) n (%)
Any Abnormality	xx (xx.x)	xx (xx.x)	xx (xx.x)
Abnormality I	xx (xx.x)	xx (xx.x)	xx (xx.x)
Abnormality II	xx (xx.x)	xx (xx.x)	xx (xx.x)
Abnormality III	xx (xx.x)	xx (xx.x)	xx (xx.x)

ATERM

Reference: Listing 16.2.9.1
Note: Percentages are based on the number of subjects in each population. Subjects identified as having abnormalities more than once are only counted once for that abnormality. Only abnormalities reported after the start of study medication are displayed.

ADT

TRTSDT

Summary

Conclusions

- Start with the TFL, and determine what dataset class can best produce the required analysis
- Identify variables displayed directly on the TFL
- Identify variables needed to derive those variables
- Identify variables helpful for providing traceability

Contact Information

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Thank You!