

By: Janki Chokshi (Cognizant)/Sachin Yadav (Cognizant)

Janki Chokshi – 8+ years of experience in Biostatistics

Sachin Yadav – 9.6 years of experience in Statistical Programming, CDISC AdaM SME

Objectives

- Understand the ADaM BDS structure .
- Understand oncology analysis datasets – efficacy parameters .
- Understand how key primary endpoints, variables are incorporated in ADaM dataset .
- Examples

ADaM – Analysis Data Model

Basic ADaM definition and approach

ADaM dataset should be:

- Analysis Enabling
 - Report ready
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- Back Traceable
 - Able to add a row/column

BDS (Basic data structure)

- one or more records
per subject,

per analysis parameter,
per analysis time point

General BDS tip ☺

BDS allows you to add rows and columns as per rules defined in ADaM IG

- Most of the imputations/derivations, include as row in analysis dataset .
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- Populate column only for chg, pchg, flag variables .

Oncology Commonly Derived endpoints/variables

- ORR – Objective Response Rate
- DOR – Duration of response
- BOR – Best objective response
- PFS – Progression free Survival
- OS – Overall Survival
- RDI – Relative dose Intensity
- PID – Percentage intended dose

ADaM BDS and Oncology efficacy data

Most of oncology efficacy data fits into BDS structure.

- Non Time to Event
 - ADXXXX will be used for non time-to-event analysis data and endpoints.
e.g. ORR, BOR , RDI, PID
- Time to Event
 - ADTTE will be used for Time-to-event analysis data:
e.g. PFS, OS

Non Time to Event Data

ADEFON Metadata

Dataset Name	Dataset Description	Dataset Location	Dataset Structure	Key Variables of Dataset	Class of Dataset
ADEFON	Tumor response data for oncology	adefon.xpt	one record per subject per parameter per visit	USUBJID, PARAMCD, VISIT	BDS

ADEFON - Major part of the data divided into

- Visit level parameters
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- Subject level parameters

Key Endpoints/Variables which fit into ADEFON

- Visit level parameters
 - Sum of TL
- Previous Minimum Sum of Diameters
- % Change from Previous Minimum Sum of Diameters
- TL Visit Response, NTL Response, New Lesion
- Overall Visit Response

Key Endpoints/Variables which fit into ADEFON

- Subject level parameter
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- Best Objective Response

Sum of TL diameters

USUBJID	PARAM	PARAMCD	TRBASNUM	AVAL	AVALC	BASE	CHG	PCHG	AVISIT	AVISITN
ABCD1001	Sum of Diameters (mm)	TRSUMDIA	3	123	123	123			VISIT1	1
ABCD1001	Sum of Diameters (mm)	TRSUMDIA	3	96	96	123	-27	-21.95	VISIT2	2
ABCD1001	Sum of Diameters (mm)	TRSUMDIA	3	55	55	123	-68	-55.28	VISIT3	3
ABCD1001	Sum of Diameters (mm)	TRSUMDIA	3	49	49	123	-74	-60.16	VISIT4	4

