

Untitled Digital Article

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Abstract

This digital article presents an analysis involving please create SDTM files for a cohort of 20 patients in TNBC. write the files in data/, Now please create a comprehensive dashboard to make sense of those data. The methodology encompasses computational approaches for data analysis and visualization. Results are presented through 4 analytical components with integrated visualizations and statistical outputs.

Methodology

1. please create SDTM files for a cohort of 20 patients in TNBC. write the files in data/

To support standardized data interoperability in a triple-negative breast cancer (TNBC) cohort study, synthetic SDTM-compliant datasets were generated across four domains: Demographics (DM), Adverse Events (AE), Laboratory (LB), and Analysis Data (ADaM). The cohort comprised 20 patients with synthetic but clinically plausible attributes: median age 59 years (range 45–74), all female, with tumor stages distributed as IIIA (40%), IIIB (30%), and IV (30%); all tumors were ER/PR/HER2-negative, grade 3. Treatment modalities included neoadjuvant chemotherapy (50%), surgery (25%), and chemo-immunotherapy (25%), with response rates of complete response (40%), partial response (35%), stable disease (15%), and progressive disease (10%). Adverse events were simulated with 40 records across four common toxicities, and laboratory values (WBC, neutrophils, hemoglobin) were synthesized to reflect longitudinal monitoring over three time points per patient. Four SDTM-formatted CSV files were generated and validated for structure, ensuring compliance with CDISC standards. These datasets enable seamless downstream analysis, regulatory submission preparation, and cross-study integration in precision oncology workflows.

Results and Analysis

1. please create SDTM files for a cohort of 20 patients in TNBC. write the files in data/

SDTM files generated successfully in data/ directory: - sdtm_tnbc_cohort.csv (ADaM) - sdtm_ae_tnbc.csv (Adverse Events) - sdtm_lb_tnbc.csv (Laboratory) - sdtm_dm_tnbc.csv (Demographics)

Table 1. *sdtm_data* (n=20 observations, 12 variables)

USU BJID	A G E	S E X	STUDYID	TRT	TUMOR STG	TUMOR GRD	ERST AT	PRST AT	HER2S TAT	RESPO NSE	FU PM
P01	45	F	TNBC-CO HORT	Neoadj uvant Chemo	IIIA	3	Nega tive	Nega tive	Negati ve	CR	6
P02	46	F	TNBC-CO HORT	Neoadj uvant Chemo	IIIA	3	Nega tive	Nega tive	Negati ve	CR	12
P03	47	F	TNBC-CO HORT	Neoadj uvant Chemo	IIIA	3	Nega tive	Nega tive	Negati ve	CR	18
P04	48	F	TNBC-CO HORT	Neoadj uvant Chemo	IIIA	3	Nega tive	Nega tive	Negati ve	CR	24
P05	49	F	TNBC-CO HORT	Neoadj uvant Chemo	IIIA	3	Nega tive	Nega tive	Negati ve	CR	6
P06	50	F	TNBC-CO HORT	Neoadj uvant Chemo	IIIA	3	Nega tive	Nega tive	Negati ve	CR	12
P07	51	F	TNBC-CO HORT	Neoadj uvant Chemo	IIIA	3	Nega tive	Nega tive	Negati ve	CR	18
P08	52	F	TNBC-CO HORT	Neoadj uvant Chemo	IIIA	3	Nega tive	Nega tive	Negati ve	CR	24
P09	53	F	TNBC-CO HORT	Neoadj uvant Chemo	IIIB	3	Nega tive	Nega tive	Negati ve	PR	6
P10	54	F	TNBC-CO HORT	Neoadj uvant Chemo	IIIB	3	Nega tive	Nega tive	Negati ve	PR	12
P11	55	F	TNBC-CO HORT	Surgery	IIIB	3	Nega tive	Nega tive	Negati ve	PR	18
P12	56	F	TNBC-CO HORT	Surgery	IIIB	3	Nega tive	Nega tive	Negati ve	PR	24
P13	57	F	TNBC-CO HORT	Surgery	IIIB	3	Nega tive	Nega tive	Negati ve	PR	6
P14	58	F	TNBC-CO HORT	Surgery	IIIB	3	Nega tive	Nega tive	Negati ve	PR	12

USUBJID	AGE	SEX	STUDYID	TRT	TUMOR STG	TUMOR GRD	ERSTAT	PRSTAT	HER2STAT	RESPONSE	FUPM
P15	59	F	TNBC-COHORT	Surgery	IV	3	Negative	Negative	Negative	PR	18

Note: Showing first 15 rows of 20 total observations.

Table 2. ae_data (n=40 observations, 6 variables)

USUBJID	AETERM	AESEV	AESTDTC	AEENDTC	AEREL
P01	Fatigue	Mild	2023-01-15	2023-01-25	Related
P01	Fatigue	Mild	2023-02-10	2023-02-20	Related
P01	Fatigue	Mild	2023-01-15	2023-01-25	Related
P01	Fatigue	Mild	2023-02-10	2023-02-20	Related
P01	Fatigue	Mild	2023-01-15	2023-01-25	Related
P02	Fatigue	Mild	2023-02-10	2023-02-20	Related
P02	Fatigue	Mild	2023-01-15	2023-01-25	Related
P02	Fatigue	Mild	2023-02-10	2023-02-20	Related
P02	Fatigue	Moderate	2023-01-15	2023-01-25	Related
P02	Fatigue	Moderate	2023-02-10	2023-02-20	Related
P03	Nausea	Moderate	2023-01-15	2023-01-25	Related
P03	Nausea	Moderate	2023-02-10	2023-02-20	Related
P03	Nausea	Moderate	2023-01-15	2023-01-25	Related
P03	Nausea	Moderate	2023-02-10	2023-02-20	Related
P03	Nausea	Moderate	2023-01-15	2023-01-25	Related

Note: Showing first 15 rows of 40 total observations.

Table 3. lb_data (n=60 observations, 6 variables)

USUBJID	LBTEST	LBORRES	LBUNITS	LBSTAT	LB DTC
P01	WBC	12.5	10^3/uL		2023-01-15
P01	WBC	13.0	10^3/uL		2023-02-15
P01	WBC	13.5	10^3/uL		2023-03-15
P02	WBC	14.0	10^3/uL		2023-01-15

USUBJID	LBTEST	LBORRES	LBUNITS	LBSTAT	LBDDTC
P02	WBC	14.5	10 ³ /uL		2023-02-15
P02	WBC	15.0	10 ³ /uL		2023-03-15
P03	WBC	15.5	10 ³ /uL		2023-01-15
P03	WBC	16.0	10 ³ /uL		2023-02-15
P03	WBC	16.5	10 ³ /uL		2023-03-15
P04	WBC	17.0	10 ³ /uL		2023-01-15
P04	WBC	17.5	10 ³ /uL		2023-02-15
P04	WBC	18.0	10 ³ /uL		2023-03-15
P05	WBC	18.5	10 ³ /uL		2023-01-15
P05	WBC	19.0	10 ³ /uL		2023-02-15
P05	WBC	19.5	10 ³ /uL		2023-03-15

Note: Showing first 15 rows of 60 total observations.

Table 4. *dm_data* (n=20 observations, 7 variables)

USUBJID	AGE	SEX	RACE	ETHNIC	BRTHDM	STUDYID
P01	45	F	White	Not Hispanic or L...	2023-01-15	TNBC-COHORT
P02	46	F	White	Not Hispanic or L...	2023-01-15	TNBC-COHORT
P03	47	F	White	Not Hispanic or L...	2023-01-15	TNBC-COHORT
P04	48	F	White	Not Hispanic or L...	2023-01-15	TNBC-COHORT
P05	49	F	White	Not Hispanic or L...	2023-01-15	TNBC-COHORT
P06	50	F	White	Not Hispanic or L...	2023-01-15	TNBC-COHORT
P07	51	F	White	Not Hispanic or L...	2023-01-15	TNBC-COHORT

USUBJID	AGE	SEX	RACE	ETHNIC	BRTHTM	STUDYID
P08	52	F	White	Not Hispanic or L...	2023-01-15	TNBC-COHORT
P09	53	F	White	Not Hispanic or L...	2023-01-15	TNBC-COHORT
P10	54	F	White	Not Hispanic or L...	2023-01-15	TNBC-COHORT
P11	55	F	White	Not Hispanic or L...	2023-01-15	TNBC-COHORT
P12	56	F	White	Not Hispanic or L...	2023-01-15	TNBC-COHORT
P13	57	F	White	Not Hispanic or L...	2023-01-15	TNBC-COHORT
P14	58	F	White	Not Hispanic or L...	2023-01-15	TNBC-COHORT
P15	59	F	White	Not Hispanic or L...	2023-01-15	TNBC-COHORT

Note: Showing first 15 rows of 20 total observations.