

# Untitled Digital Article

*A new digital article*

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Digital Article System

Generated on October 17, 2025

## Abstract

This digital article presents a comprehensive computational analysis with data-driven insights and methodological approaches to address key research questions in the domain.

## Introduction

This investigation addresses important questions through computational analysis and data-driven methodologies, providing insights into complex patterns and relationships within the studied domain.

## 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

Comprehensive analysis of findings and conclusions from the digital article investigation.

## 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).

USU BJID	A G E	S E X	STUDYI D	TRT	TUMO RSTG	TUMOR GRD	ERS TAT	PRS TAT	HER2S TAT	RESPO NSE	FU PM
P01	45	F	TNBC-CO HORT	Neoadj uvant Chemo	IIIA	3	Negat ive	Negat ive	Negativ e	CR	6
P02	46	F	TNBC-CO HORT	Neoadj uvant Chemo	IIIA	3	Negat ive	Negat ive	Negativ e	CR	12
P03	47	F	TNBC-CO HORT	Neoadj uvant Chemo	IIIA	3	Negat ive	Negat ive	Negativ e	CR	18
P04	48	F	TNBC-CO HORT	Neoadj uvant Chemo	IIIA	3	Negat ive	Negat ive	Negativ e	CR	24
P05	49	F	TNBC-CO HORT	Neoadj uvant Chemo	IIIA	3	Negat ive	Negat ive	Negativ e	CR	6
P06	50	F	TNBC-CO HORT	Neoadj uvant Chemo	IIIA	3	Negat ive	Negat ive	Negativ e	CR	12
P07	51	F	TNBC-CO HORT	Neoadj uvant Chemo	IIIA	3	Negat ive	Negat ive	Negativ e	CR	18
P08	52	F	TNBC-CO HORT	Neoadj uvant Chemo	IIIA	3	Negat ive	Negat ive	Negativ e	CR	24
P09	53	F	TNBC-CO HORT	Neoadj uvant Chemo	IIIB	3	Negat ive	Negat ive	Negativ e	PR	6
P10	54	F	TNBC-CO HORT	Neoadj uvant Chemo	IIIB	3	Negat ive	Negat ive	Negativ e	PR	12
P11	55	F	TNBC-CO HORT	Surgery	IIIB	3	Negat ive	Negat ive	Negativ e	PR	18

USUBJID	AGE	SEX	STUDYID	TRT	TUMORSTG	TUMORGRD	ERSTAT	PRSTAT	HER2STAT	RESPONSE	FUPM
P12	56	F	TNBC-COHORT	Surgery	IIIB	3	Negative	Negative	Negative	PR	24

Note: Showing first 12 rows of 20 total observations.

Table 2. ae\_data (n = 40 observations).

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

Note: Showing first 12 rows of 40 total observations.

Table 3. lb\_data (n = 60 observations).

USUBJID	LBTEST	LBORRES	LBUNITS	LBSTAT	LBDMTC
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
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

USUBJID	LBTEST	LBORRES	LBUNITS	LBSTAT	LBDTC
P04	WBC	17.5	10 <sup>3</sup> /uL		2023-02-15
P04	WBC	18.0	10 <sup>3</sup> /uL		2023-03-15

*Note: Showing first 12 rows of 60 total observations.*

**Table 4.** dm\_data (n = 20 observations).

USUBJID	AGE	SEX	RACE	ETHNIC	BRTHTM	STUDYID
P01	45	F	White	Not Hispanic or Latino	2023-01-15	TNBC-COHORT
P02	46	F	White	Not Hispanic or Latino	2023-01-15	TNBC-COHORT
P03	47	F	White	Not Hispanic or Latino	2023-01-15	TNBC-COHORT
P04	48	F	White	Not Hispanic or Latino	2023-01-15	TNBC-COHORT
P05	49	F	White	Not Hispanic or Latino	2023-01-15	TNBC-COHORT
P06	50	F	White	Not Hispanic or Latino	2023-01-15	TNBC-COHORT
P07	51	F	White	Not Hispanic or Latino	2023-01-15	TNBC-COHORT
P08	52	F	White	Not Hispanic or Latino	2023-01-15	TNBC-COHORT
P09	53	F	White	Not Hispanic or Latino	2023-01-15	TNBC-COHORT
P10	54	F	White	Not Hispanic or Latino	2023-01-15	TNBC-COHORT
P11	55	F	White	Not Hispanic or Latino	2023-01-15	TNBC-COHORT
P12	56	F	White	Not Hispanic or Latino	2023-01-15	TNBC-COHORT

*Note: Showing first 12 rows of 20 total observations.*