



DS19: How unique is the subject identifier in a study having multiple screenings and enrollments?

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Agenda

Multiple Screenings / Enrollments - TCG

Benefits of Implementing Guidelines

Implementation challenges

Overcome Challenges

Mapping SUBJID – before TCG

Mapping SUBJID – after TCG

Mapping SUBJID in Findings domain

Mapping SUBJID in Disposition

Addressing P21 Issues

Summary



Multiple Screenings / Enrollments - TCG

FDA Study Data Technical Conformance Guide (TCG) V4.2 - First described in [October 2018](#)

Key Points 	Description
Unique Subject Identifier (SUBJID)	Each subject must have a unique SUBJID for every screening to prevent confusion and maintain data integrity.
Primary Screening (Demographics)	Collect demographic data (DM) during the initial screening to establish baseline characteristics.
Additional Screenings (Custom Domain DC)	Record data from subsequent screenings in a custom domain (DC) to distinguish them from initial data.
Inclusion in SDTM Domains	Include SUBJID in all SDTM domains to ensure consistent tracking across datasets.
Handling P21 Issues	Address P21 issues regarding data discrepancies in the Study Data Reviewer's Guide (cSDRG).



Benefits of Implementing Guidelines

✓ **Enhanced Accuracy:** Ensures thorough evaluation of subjects. Increases likelihood of enrolling only eligible participants.

🔍 **Improved Data Reliability:** Facilitates accurate data collection. Tracks each screening attempt with unique identifiers.

🔄 **Flexibility in Recruitment:** Retains potential participants needing additional screenings. Improves overall recruitment efforts.

💰 **Cost Efficiency:** Reduces recruitment costs. Maximizes use of individuals needing multiple attempts to meet criteria.

📈 **Documenting Eligibility Changes:** Documents changes in a subject's eligibility status over time. Supports understanding of participant dynamics.

📋 **Regulatory Transparency:** Promotes compliance with regulatory standards. Ensures precise record-keeping and subject tracking.



Implementation challenges

Category

Challenge



Data Management

Distinct SUBJID Assignments
Maintaining a Unique USUBJID
Data Duplication
Inconsistent Data Collection
Subject Withdrawal and Re-enrollment



Data Integrity

Impact on Data Integrity
Complicated Adverse Event Reporting



Regulatory and Compliance

Regulatory Compliance



Operational Challenges

Increased Administrative Burden
Statistical Analysis Complexity
Subject Retention Issues



Overcome challenges

 **Train Personnel:** Train staff to enter data accurately to avoid redundancy.

 **Design Data Entry Guidelines:** Create and implement guidelines for data collected via Case Report Forms (CRFs).

 **Assign Visits Accurately:** Ensure visits are assigned correctly. Maintain consistency in collecting information to link data appropriately for each subject.

 **Adhere to Regulations:** Follow regulatory rules and compliance standards diligently.

 **Standardized Data Mapping:** Map data in a standardized format with careful planning and execution.

 **Maintain Data Integrity:** Focus on preserving data integrity and reliability throughout the trial.



Mapping SUBJID - before TCG

Prior to the implementation of the FDA TCG, the randomization number (**RANDNUM**) can be mapped to **SUBJID** variable from Source.DM to SDTM.DM domain

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Subject Assignment	
4. Did Subject Meet All Eligibility Criteria?	☐ No ☐ Yes [NOT SUBMITTED]
5. Was Treatment/Randomization Number Given?	☐ No ☐ Yes [NOT SUBMITTED] If Yes, Please Enter Randomization Number: [NOT SUBMITTED]
6. Treatment/Randomization Number	SUBJID ←

Source.DM

STUDYID	FORMNM	USUBJID	RANDNUM	RFICDTC
1234-001	DM	1234-001_000100001	100001	2024-01-29
1234-001	DM	1234-001_000100002	100601	2024-02-20

SDTM.DM

STUDYID	DOMAIN	USUBJID	SUBJID	RFICDTC
1234-001	DM	1234-001_000100001	100001	2024-01-29
1234-001	DM	1234-001_000100002	100601	2024-02-20



Mapping SUBJID – after TCG

PNA (Participation Number Assignment) **form** is added to CRF where the participation number is collected field to identify each subject uniquely.

Blank CRF

Participation Number Assignment		
1.	Participation Number	←

Source.PNA_DC

STUDYID	FORMNM	USUBJID	DCPATNUM	RFICDTC	DCDTC	VISIT	VISITNUM
1234-001	PNA	1234-001_000100001	000100001A	2024-01-29	2024-01-29	Screening	10100
1234-001	PNA	1234-001_000100001	000100001B	2024-01-29	2024-03-05	Re-Screening	10200
1234-001	PNA	1234-001_000100002	000100002A	2024-02-20	2024-02-20	Screening	10100



Mapping SUBJID – after TCG contd.

PNA form maps **SUBJID** (Participation number) variable in **DM** and **DC** domains

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Participation Number Assignment		
1. Participation Number		SUBJID ←

SDTM.DC

STUDYID	DOMAIN	USUBJID	SUBJID	RFICDTC	DCDTC	VISIT	VISITNUM
1234-001	DC	1234-001_000100001	000100001A	2024-01-29	2024-01-29	Screening	10100
1234-001	DC	1234-001_000100001	000100001B	2024-01-29	2024-03-05	Re-Screening	10200
1234-001	DC	1234-001_000100002	000100002A	2024-02-20	2024-02-20	Screening	10100

Unique SUBJID for
each screening
visit

SDTM.DM

STUDYID	DOMAIN	USUBJID	SUBJID	RFICDTC
1234-001	DM	1234-001_000100001	000100001B	2024-01-29
1234-001	DM	1234-001_000100002	000100002A	2024-02-20



Mapping SUBJID – after TCG contd.

Mapping **RANDNUM** (Randomization number) to **SUPPDM**

aCRF

Subject Assignment	
5. Was Treatment/Randomization Number Given?	☐ No ☐ Yes [NOT SUBMITTED] If Yes, Please Enter Randomization Number: [NOT SUBMITTED]
6. Treatment/Randomization Number	QVAL when QNAM = 'RANDNUM' in SUPPDM

Source.DM

STUDYID	FORMNM	USUBJID	RANDNUM	RFICDTC
1234-001	DM	1234-001_000100001	100001	2024-01-29
1234-001	DM	1234-001_000100002	100601	2024-02-20

SDTM.SUPPDM

STUDYID	RDOMAIN	USUBJID	QNAM	QLABEL	QVAL
1234-001	DM	1234-001_000100001	RANDNUM	Randomization number	100001
1234-001	DM	1234-001_000100002	RANDNUM	Randomization number	100601



Mapping SUBJID in Findings domain

SUBJID with participation number values, is appended to SDTM.VS domain based on the **VISIT/VISITNUM** (from PNA and VS01 forms)

Source.VS01_VS

STUDYID	FORMNM	USUBJID	VSTESTCD	VSTEST	VSORRES	VSORRESU	VISIT	VISITNUM	VSDTC
1234-001	VS01	1234-001_000100001	TEMP	Temperature	36.5	C	Screening	10100	2024-01-29
1234-001	VS01	1234-001_000100001	TEMP	Temperature	36.8	C	Re-Screening	10200	2024-03-05
1234-001	VS01	1234-001_000100002	TEMP	Temperature	37	C	Screening	10100	2024-02-20

SDTM.VS

STUDYID	DOMAIN	USUBJID	VSTESTCD	VSTEST	VSORRES	VSORRESU	VISIT	VISITNUM	VSDTC	SUBJID
1234-001	VS	1234-001_000100001	TEMP	Temperature	36.5	C	Screening	10100	2024-01-29	000100001A
1234-001	VS	1234-001_000100001	TEMP	Temperature	36.8	C	Re-Screening	10200	2024-03-05	000100001B
1234-001	VS	1234-001_000100002	TEMP	Temperature	37	C	Screening	10100	2024-02-20	000100002A



Mapping SUBJID in Disposition

Multiple Source Data

STUDYID	FORMNM	USUBJID	DSTERM	DSDECOD	DSCAT	DSSCAT	DSSTDTC
1234-001	DM	1234-001_040100003	FULL STUDY INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE		7/24/2024
1234-001	FBRC	1234-001_040100003	GENETIC AND BIOMEDICAL CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE		7/24/2024
1234-001	PNA	1234-001_040100003	SCREEN FAILURE	SCREEN FAILURE	DISPOSITION EVENT	DISCONTINUED	8/19/2024
1234-001	DS01	1234-001_040100003	SCREEN FAILURE	SCREEN FAILURE	DISPOSITION EVENT	DISCONTINUED	8/19/2024

SDTM.DS

STUDYID	DOMAIN	USUBJID	DSGRPID	DSTERM	DSDECOD	DSCAT	DSSCAT	DSSTDTC	SUBJID
1234-001	DS	1234-001_040100003	DM	FULL STUDY INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE		2024-07-24	040100003A
1234-001	DS	1234-001_040100003	FBRC	GENETIC AND BIOMEDICAL CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE		2024-07-24	040100003A
1234-001	DS	1234-001_040100003	PNA	SCREEN FAILURE	SCREEN FAILURE	DISPOSITION EVENT	STUDY PARTICIPATION	2024-08-19	040100003A
1234-001	DS	1234-001_040100003	DS01	SCREEN FAILURE	SCREEN FAILURE	DISPOSITION EVENT	STUDY PARTICIPATION	2024-08-19	040100003A



Addressing P21 Issues

Rule ID	Message	Rationale
SD9999	Dataset DC class not recognized	False positive result within the P21 tool. P21 has limited support of Demographics as Collected (DC) domain and does not validate this domain.
SD1367	Multiple disposition events for the same DSSCAT and EPOCH	DSDECOD= 'SCREEN FAILURE' is collected from two CRF pages (DS01 and PNA forms)
SD0058	Variable appears in dataset, but is not in SDTM model	The variables listed below are required for analysis and hence are retained in the standard dataset. - SUBJID



Summary

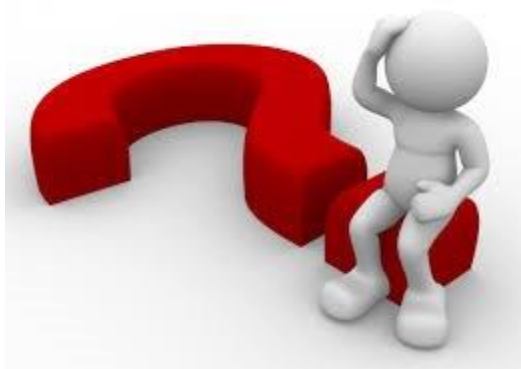
- ❖ **Better Subject Tracking:** Unique participation numbers enhance tracking of subjects in multiple screenings.
- ❖ **Comprehensive Data Collection:** New CRF field captures detailed information on re-screening for improved data analysis.
- ❖ **Mapping Re-Screened Data:** The DC domain allows for separate tracking of screenings, simplifying mapping to SDTM domains.
- ❖ **Regulatory Compliance:** Structured handling of re-screening data ensures adherence to TCG conformance and record-keeping requirements.
- ❖ **Minimized Confusion:** Separating SUBJID from the randomization number clarifies tracking across trial visits.



References

- **FDA Study Data Technical Conformance Guide Version 4.2**
U.S. Food and Drug Administration (FDA).
Available at: [StudyDataTechnicalConformanceGuide-v4-2-FINAL.pdf](#)
- **CDISC SDTM Implementation Guide**
Clinical Data Interchange Standards Consortium (CDISC).
Available at: [CDISC SDTM Implementation Guide](#)
- **FDA Guidance for Industry: Providing Regulatory Submissions in Electronic Format — Standardized Study Data**
U.S. Food and Drug Administration (FDA).
Available at: [FDA Guidance for Standardized Study Data](#)
- **FDA's Guidance on Electronic Submissions**
U.S. Food and Drug Administration (FDA).
Available at: [FDA Electronic Submissions Guidance](#)

Questions



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