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# 2026 Europe Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION

MILAN, ITALY | MAIN CONFERENCE: 20-21 MAY | TRAININGS & WORKSHOPS: 18, 19, & 22 MAY

## Managing Multiple Screenings: How ADaM.ADPL Enhances Traceability and Analysis Integrity

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# Speakers

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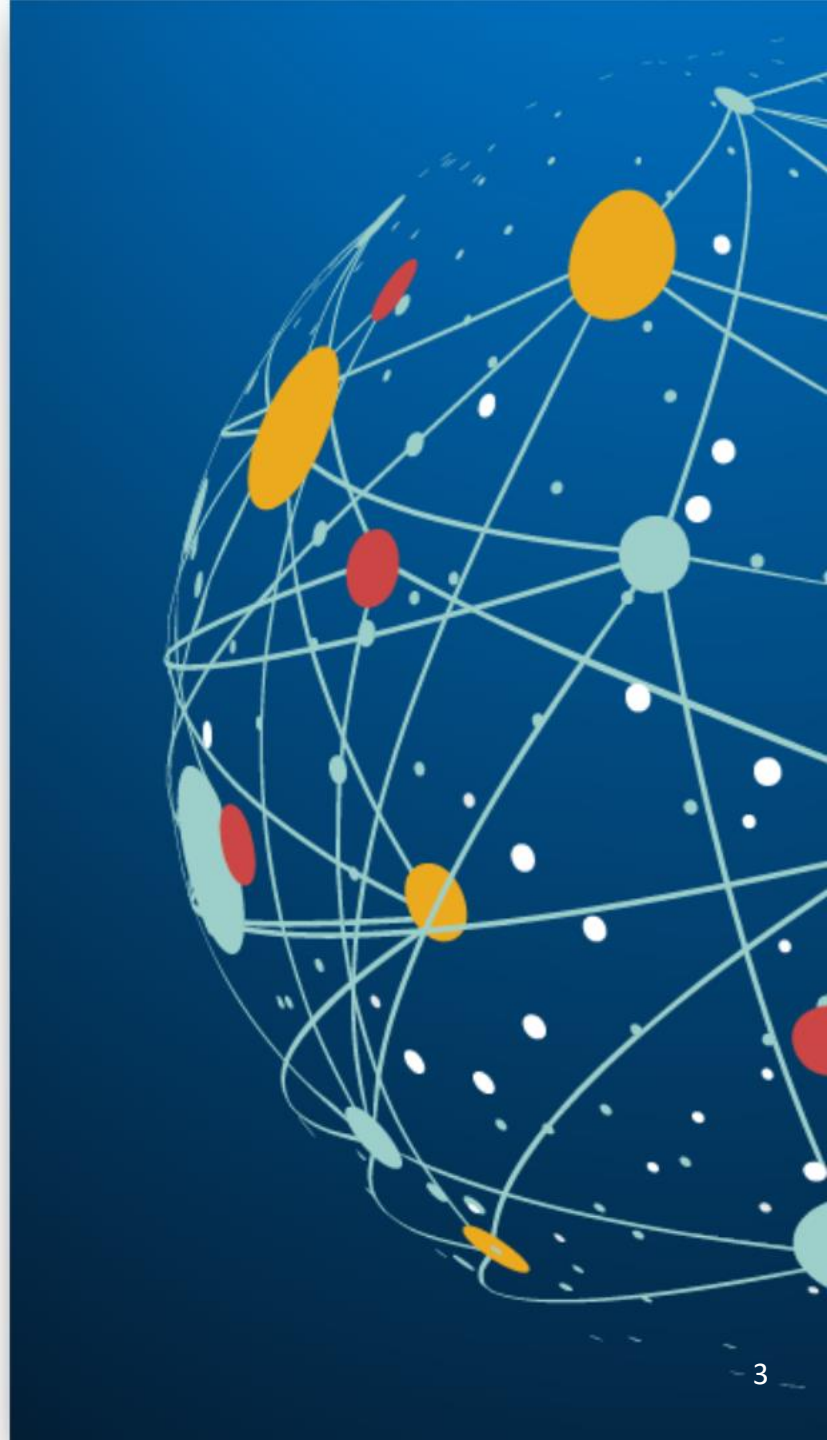
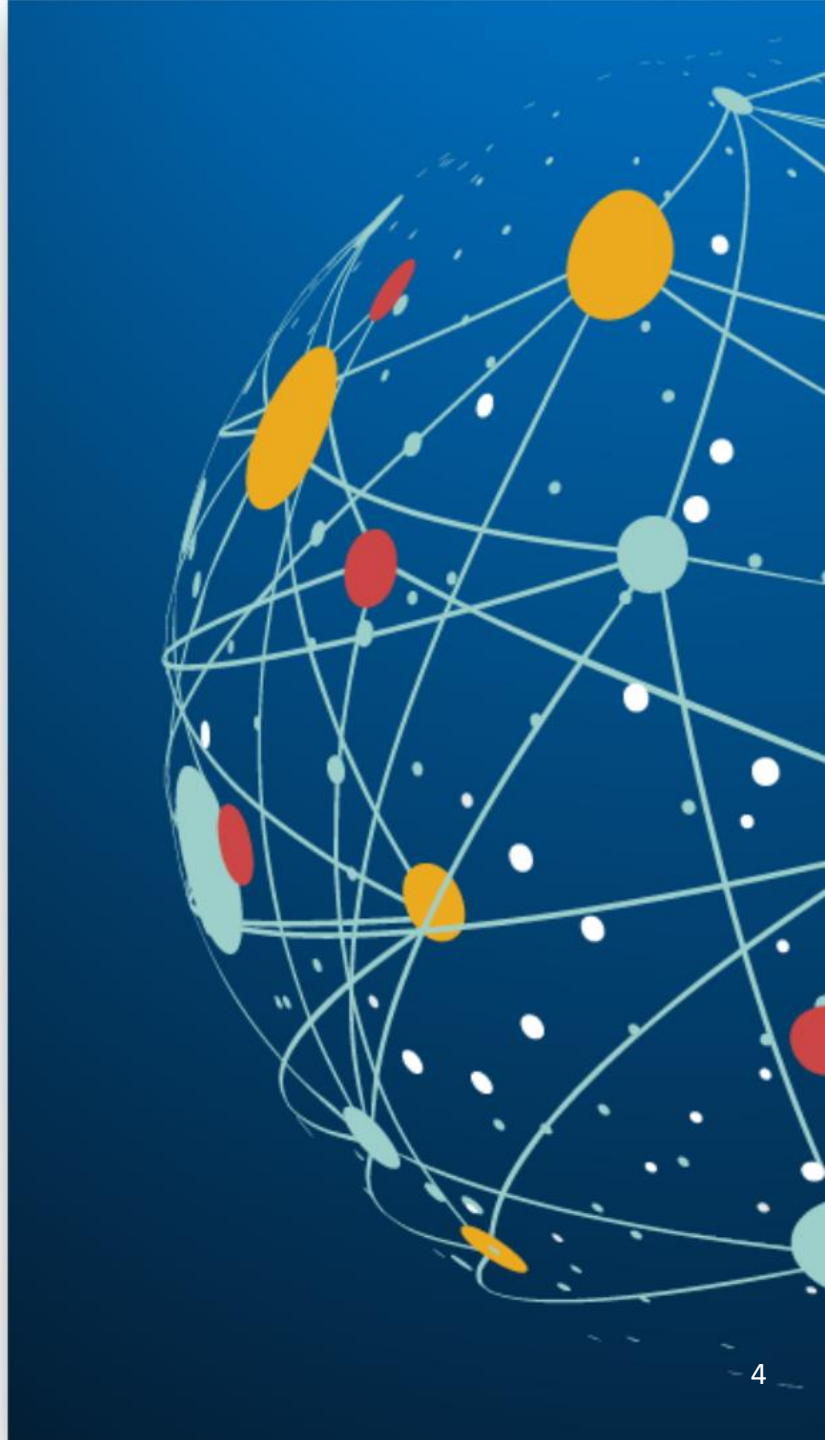
# Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of Chiesi and SGS.*
- *The authors have no real or apparent conflicts of interest to report.*



# Agenda

- Illustrating the issue
- Solution for SDTM
- Solution for ADaM
- Conclusion



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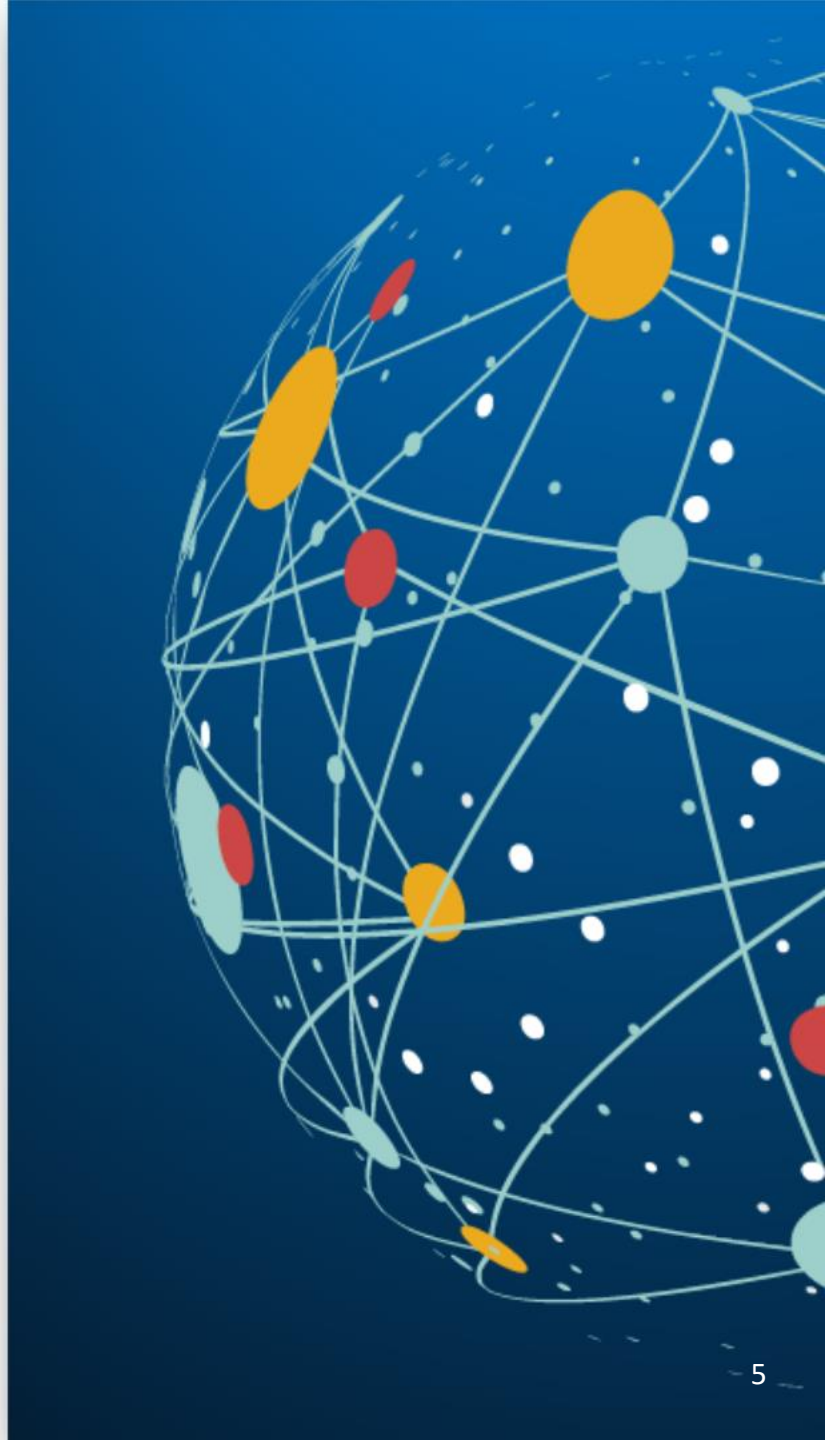
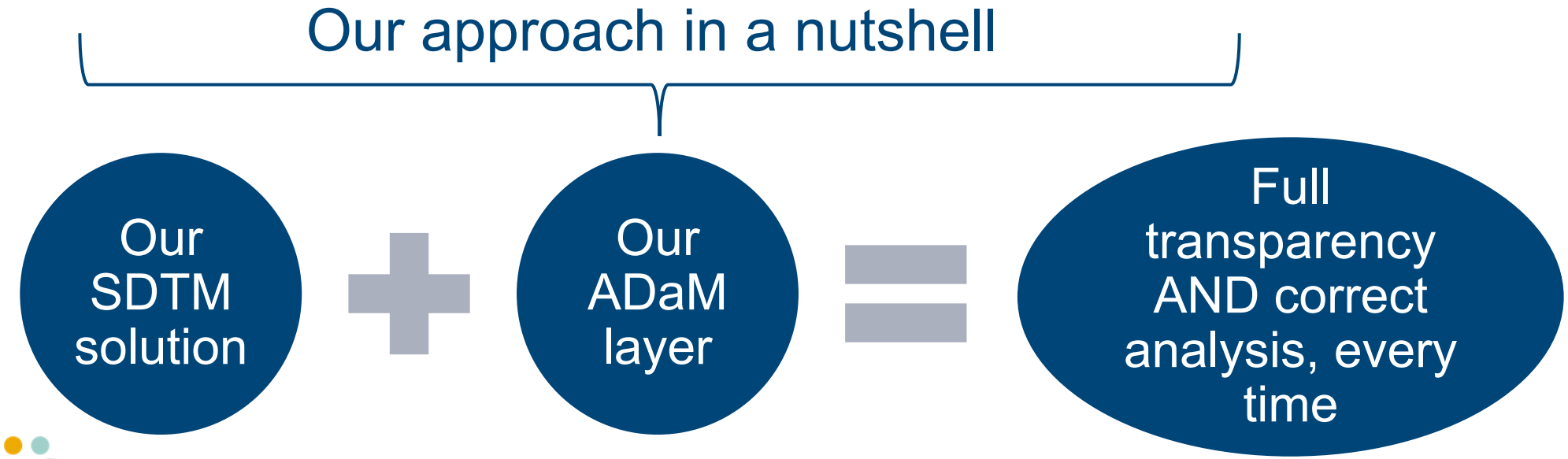


# Multiple screening: Illustrating the issue

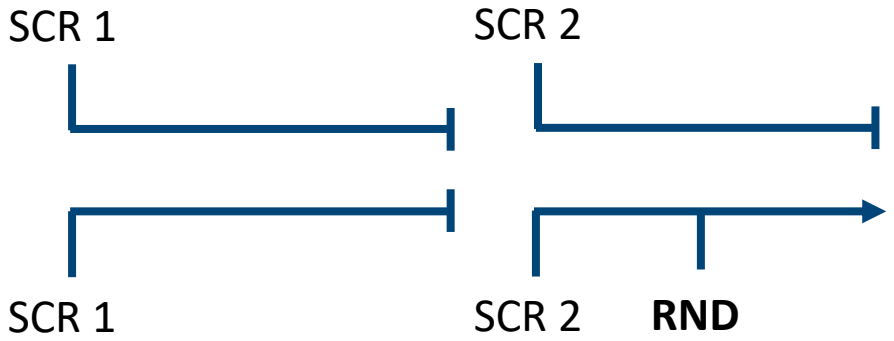
# Outline

- Subjects being screened more than once
- Capturing all information transparently

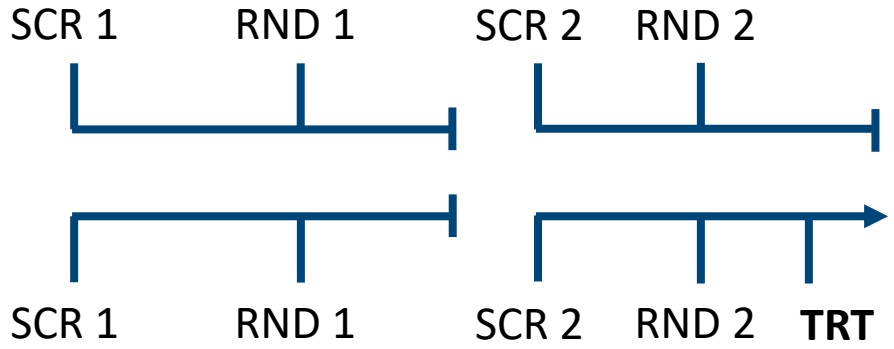


# Possible scenarios

- Multiple **screenings**
  - Case A: Without randomization
  - Case B: With randomization




- Multiple **randomizations**
  - Case C: Without treatment
  - Case D: With ≥1 treatment



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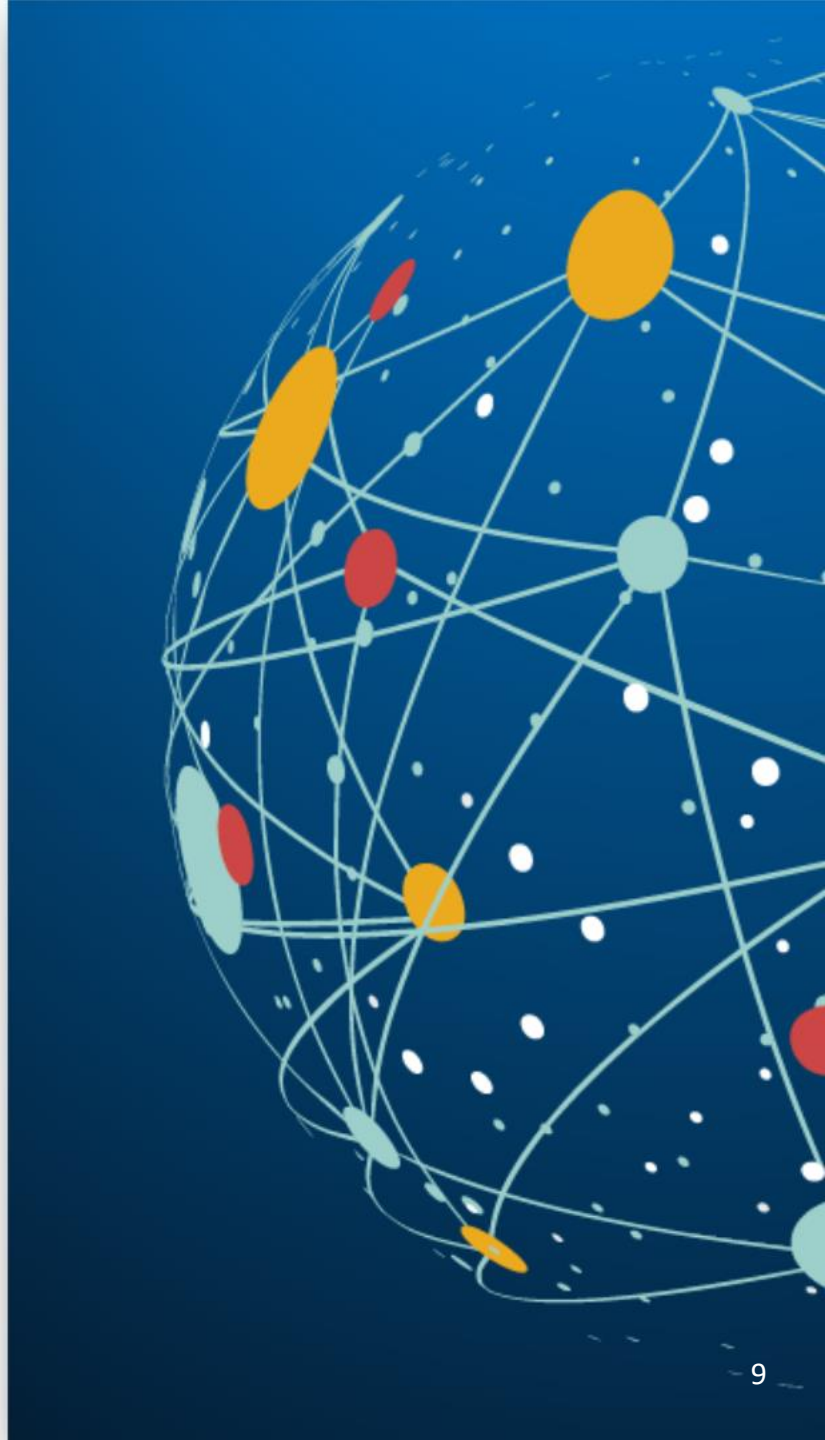


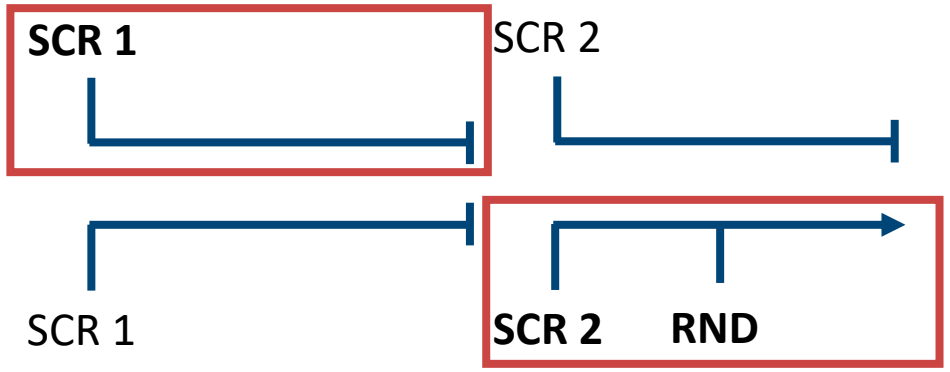
# Multiple screening: SDTM Solution

# SDTM Implementation

- **Select primary** screening/randomization:

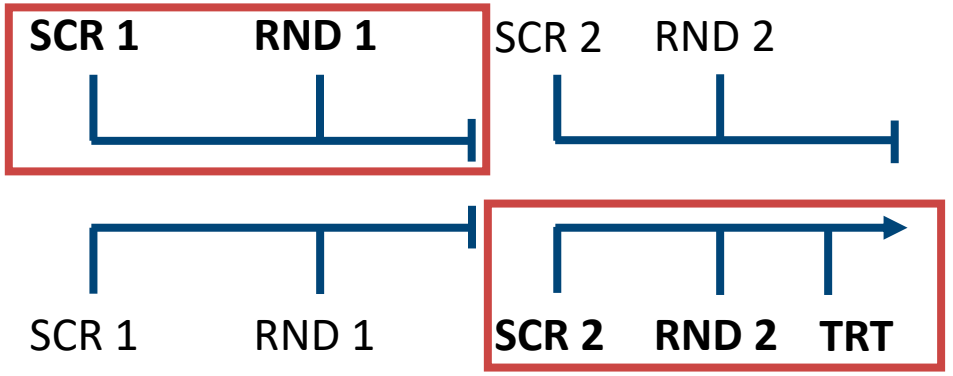
A. First screening

B. Screening with randomization



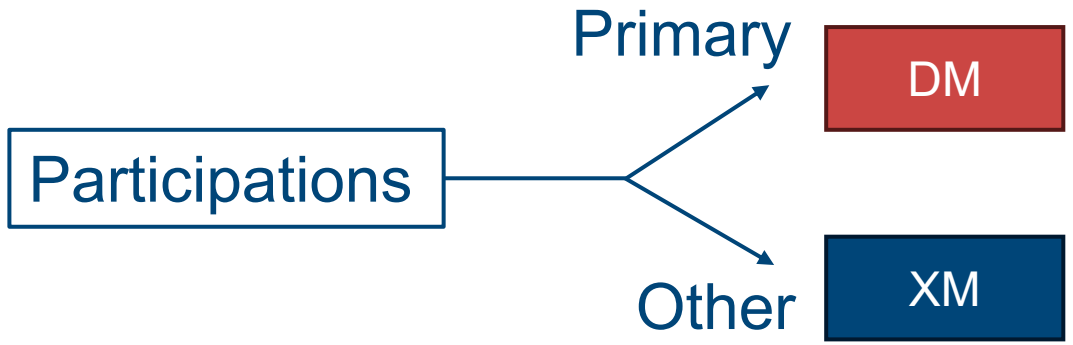

C. First randomization

D. Randomization with ≥1 treatment



# SDTM Implementation

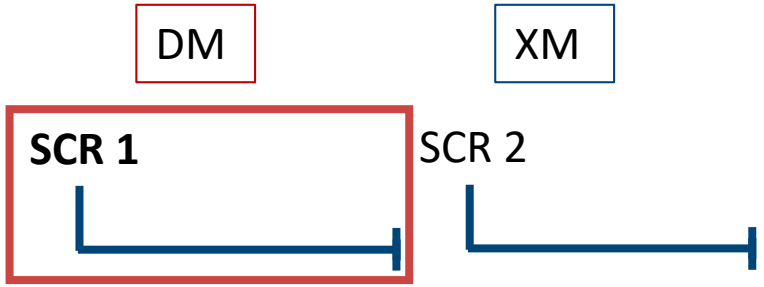
## How SDTM separates participations while keeping everything traceable




- Tracking in other datasets using subject identifier:
  - USUBJID: same across all records
  - SUBJID: unique per screening/randomization
    → added to all subject-level domains

# SDTM examples

- Case A (*multiple screenings, no randomization*):

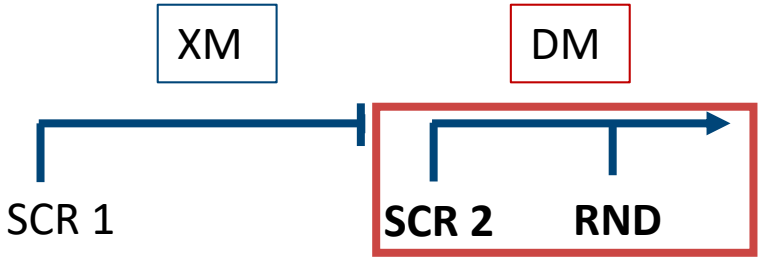



| DOMAIN | USUBJID | SUBJID | RFICDTC | RFSTDTC | RFPENDTC |
|---|---|---|---|---|---|
| DM | AA1_276101 | 276101 | 2022-01-12 | | 2022-01-17 |
| XM | AA1_276101 | 276103 | 2022-01-25 | | 2022-01-30 |

| DOMAIN | USUBJID | SUBJID | VISIT | VSDTC |
|---|---|---|---|---|
| VS | AA1_276101 | 276101 | SCREENING | 2022-01-13 |
| VS | AA1_276101 | 276103 | SCREENING | 2022-01-25 |

# SDTM examples

- Case B (*multiple screenings with randomization*):




| DOMAIN | USUBJID | SUBJID | RFICDTC | RFSTDTC | RFPENDTC |
|---|---|---|---|---|---|
| XM | AA1_276402 | 276401 | 2022-01-12 | | 2022-01-17 |
| DM | AA1_276402 | 276402 | 2022-01-25 | 2022-02-10 | |

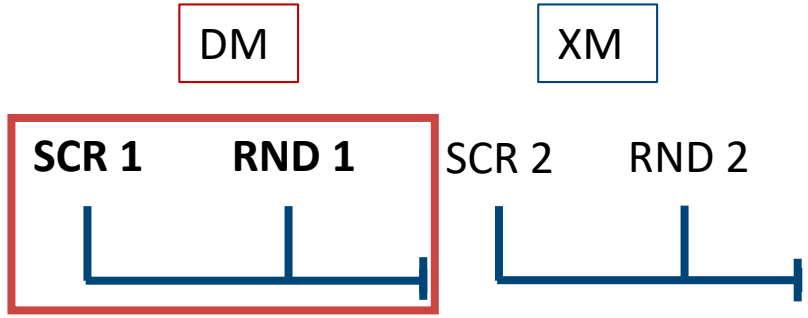
| DOMAIN | USUBJID | SUBJID | DSDECOD | DSSTDTC |
|---|---|---|---|---|
| DS | AA1_276402 | 276401 | SCREEN FAILURE | 2022-01-17 |
| DS | AA1_276402 | 276402 | RANDOMIZED | 2022-02-10 |

| DOMAIN | USUBJID | SUBJID | VISIT | VSDTC |
|---|---|---|---|---|
| VS | AA1_276402 | 276401 | SCREENING | 2022-01-12 |
| VS | AA1_276402 | 276402 | SCREENING | 2022-01-25 |

USUBJID uses the **Primary SUBJID**, not the first SUBJID by IC order.

# SDTM examples

- Case C (*multiple randomizations, no treatment*):



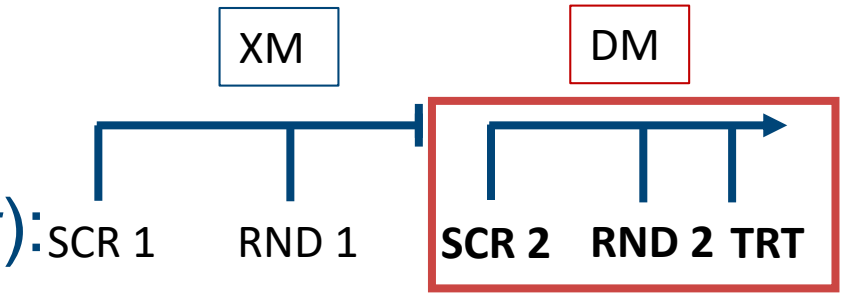

| DOMAIN | USUBJID | SUBJID | RFICDTC | RFSTDTC |
|---|---|---|---|---|
| DM | AA1_276305 | 276305 | 2022-01-25 | |
| XM | AA1_276305 | 276310 | 2022-02-09 | |

| DOMAIN | USUBJID | SUBJID | DSDECOD | DSSTDTC |
|---|---|---|---|---|
| DS | AA1_276305 | 276305 | RANDOMIZED | 2022-01-29 |
| DS | AA1_276305 | 276310 | RANDOMIZED | 2022-02-26 |

| DOMAIN | USUBJID | SUBJID | VISIT | VSDTC |
|---|---|---|---|---|
| VS | AA1_276305 | 276305 | SCREENING | 2022-01-25 |
| VS | AA1_276305 | 276310 | SCREENING | 2022-02-09 |

# SDTM examples

- Case D (*multiple randomizations with treatment*):



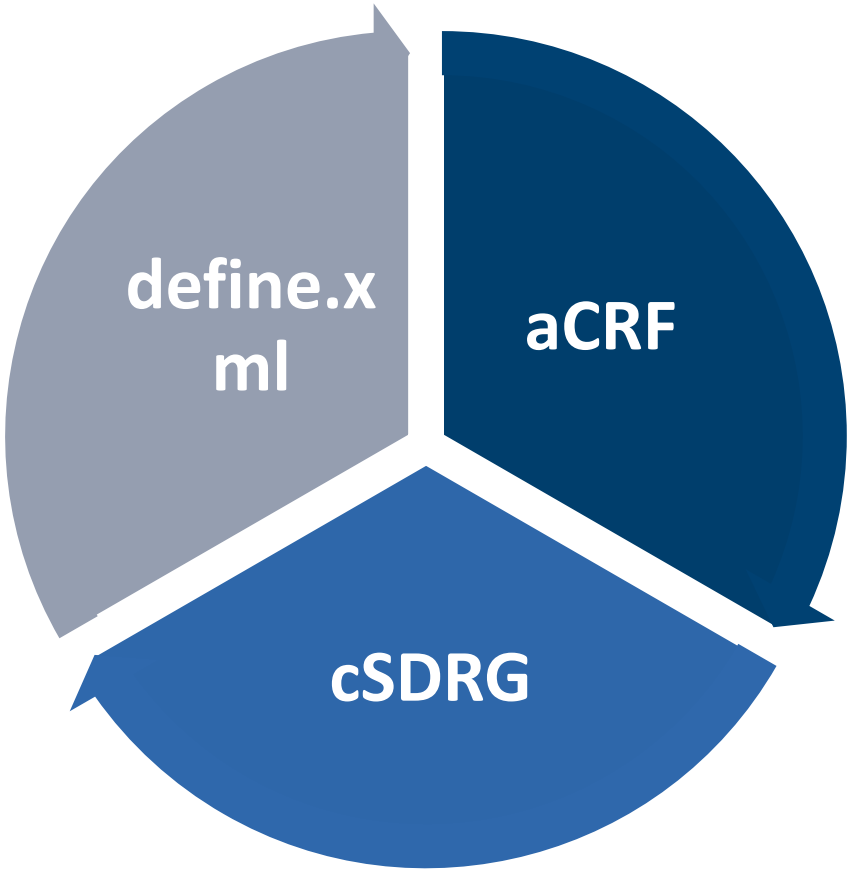

| DOMAIN | USUBJID | SUBJID | RFICDTC | RFSTDTC | RFPENDTC |
|---|---|---|---|---|---|
| XM | AA1_276807 | 276508 | 2022-02-09 | | 2022-02-27 |
| DM | AA1_276807 | 276807 | 2022-03-25 | 2022-04-01 | 2022-12-11 |

| DOMAIN | USUBJID | SUBJID | VISIT | VSDTC |
|---|---|---|---|---|
| VS | AA1_276807 | 276508 | SCREENING | 2022-02-09 |
| VS | AA1_276807 | 276807 | SCREENING | 2022-03-25 |

USUBJID uses the **Primary SUBJID**, not the first SUBJID by IC order.

# Impact on SDTM-related Documentation

Inclusion of **XM domain**




Clarification on **demography form**

**Section 3. Subject Data Description, 3.1. Overview.**
**Section 3.4 SDTM Subject domains.**

# Our Approach vs SDTM IG 4.0

| Chiesi/SGS approach (referring FDA TCG) | SDTMIG 4.0 approach |
|---|---|
| DM domain → only primary participation | DM domain → subject summary |
| XM domain → all other participations | DC domain → all participations |

- Separation
- Early disambiguation
- Reviewer-friendly

- Consolidation
- Late disambiguation (reviewer/SAP)
- More complete but more complex

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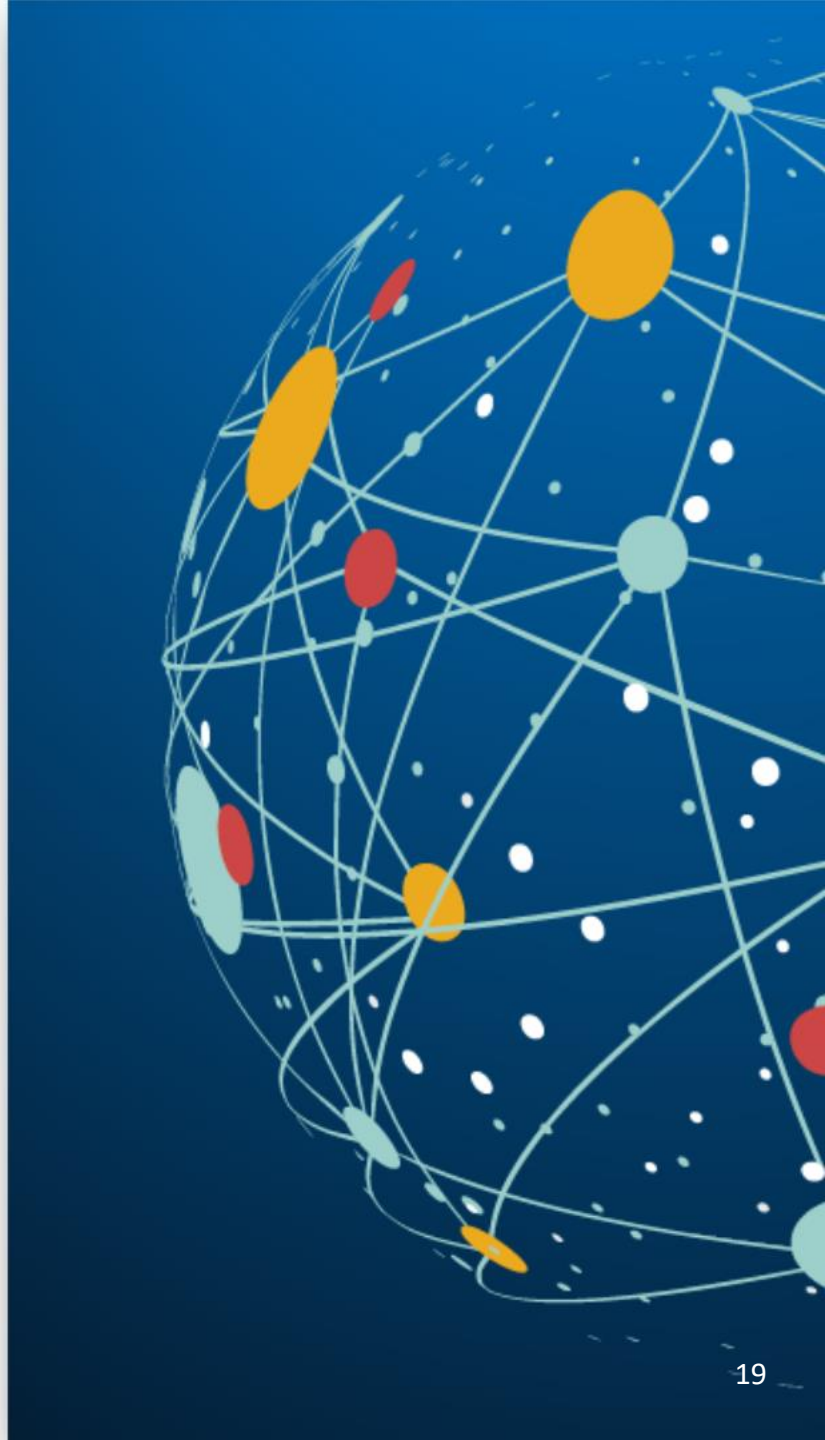


# Multiple screening: ADaM Solution

# ADaM implementation

- ADSL (Subject-Level Analysis Dataset)
  - Limited to one record per subject

- ADPL (Participation-Level Analysis Dataset)
  - 1 record **per participation** of the subject
  - ADSL-like structure, upstream of ADSL
  - ADSL = Sub-selection of ADPL

# ADPL structure

- Subset of ADSL variables + ADPL-specific variables
- Case A-D handling at SDTM level
- Copy selection using SRCDOM

| USUBJID | SUBJID | SRCDOM | RFICDTC | RFXSTDTC | ... |
|---|---|---|---|---|---|
| AA1_276807 | 276508 | XM | 2022-02-09 | | |
| AA1_276807 | 276807 | DM | 2022-03-25 | 2022-04-01 | |

| ... | PRANDFL | PRANDDT | PRANDNO | MRANDFL | PRTRTFL | SLINCLFL |
|---|---|---|---|---|---|---|
| | N | | | N | N | N |
| | Y | 2022-04-01 | 1001 | N | Y | Y |

# ADSL

- Selection on ADPL.SLINCLFL
- One record per subject

| USUBJID | SUBJID | RFICDTC | RFSTDTC | RFXSTDTC | TRTSDTM | RANDFL | RANDDT | RANDNO |
|---|---|---|---|---|---|---|---|---|
| AA1_276807 | 276807 | 2022-03-25 | 2022-04-01 | 2022-04-01 | 2022-04-01 | Y | 2022-04-01 | 1001 |

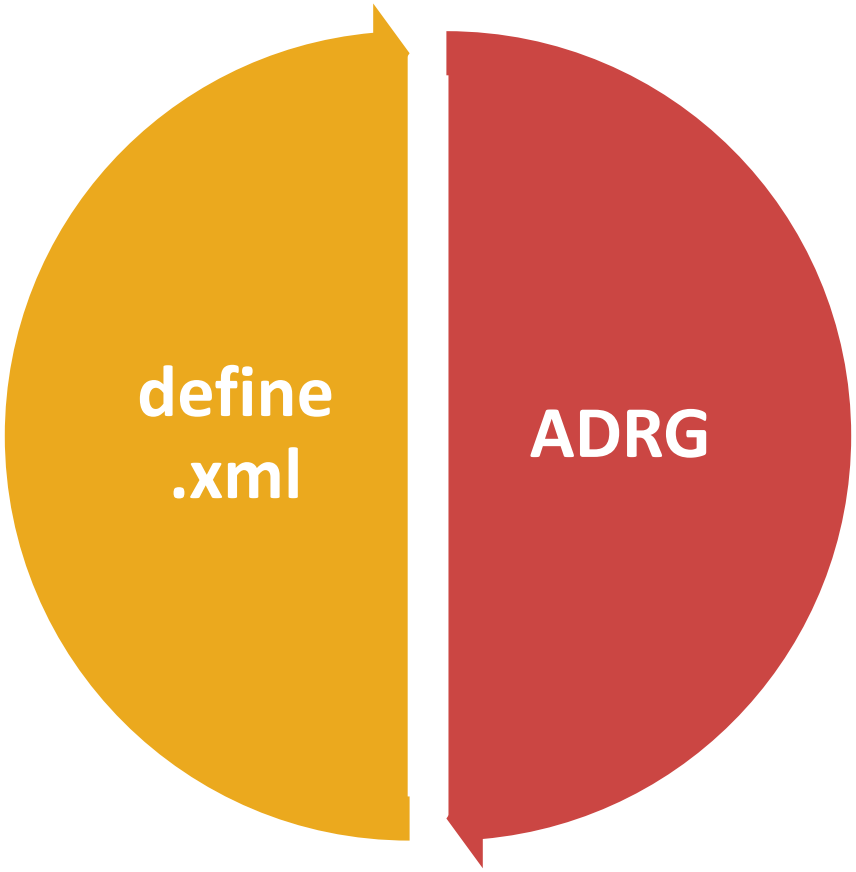
# Downstream of ADSL

- SUBJID tracks records at participation level
- Merging of datasets on USUBJID+SUBJID

| USUBJID | SUBJID | … |
|---|---|---|
| AA1_276807 | 276807 | |

# Impact on ADaM-related Documentation

- Include ADPL domain
- ADSL variables inheritance




**Section 3. Subject Issues that Require Special Analysis Rules**

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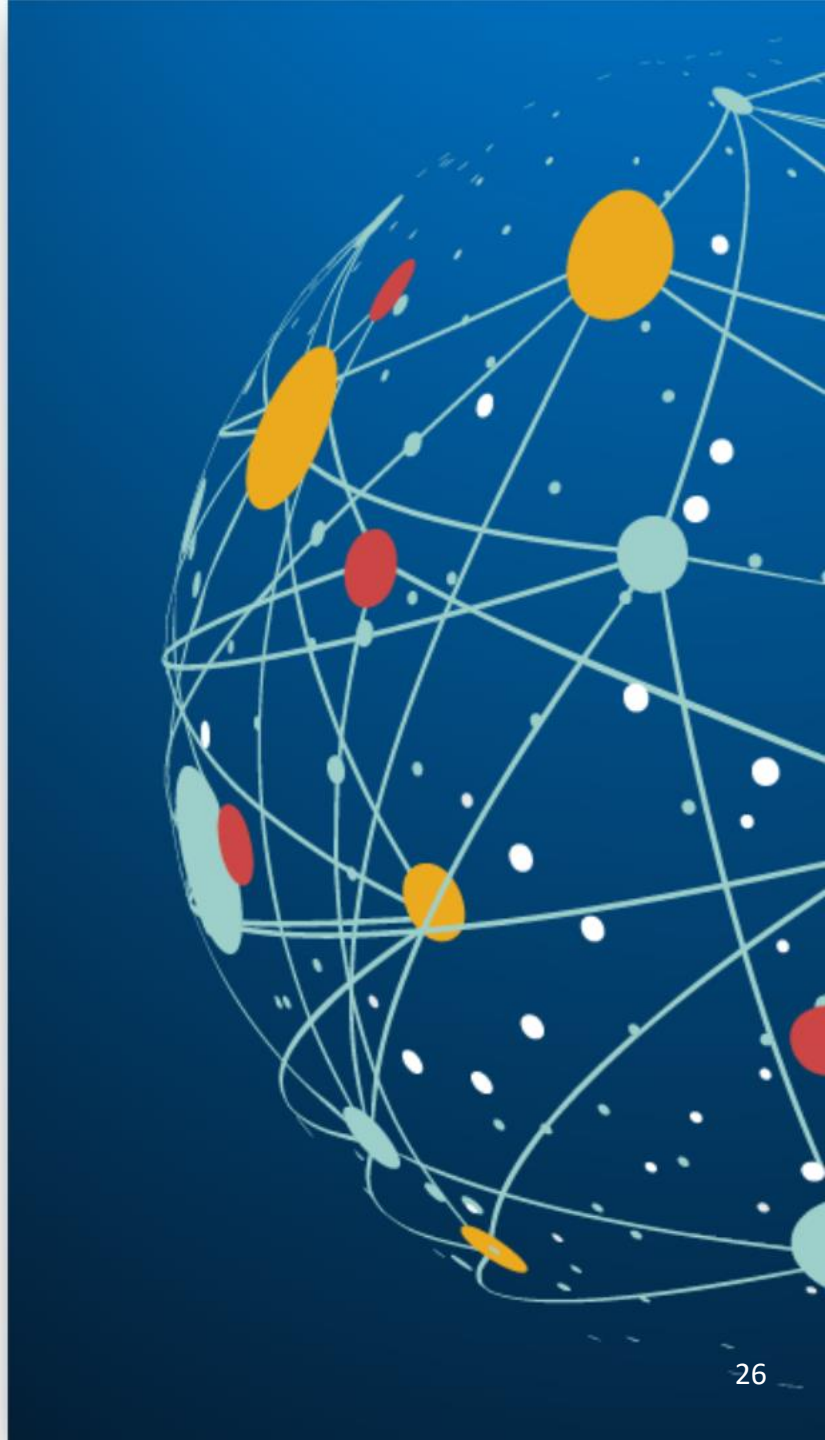

# Multiple screening: Conclusion

# Summary

- Problem: Capturing of multiple screening/randomization data

- Solution: SDTM + ADaM
  - **Clear selection rules**
  - Domains **XM** and **ADPL**
  - Full **modularity**
  - Transparency and **traceability**

- Collaboration:
  - Chiesi and SGS
  - DM and STAT departments


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Chiesi SGS

# References

- FDA TCG v5.6 (Dec 2023) section 4.1.1.2 and 4.1.1.3
- PHUSE - PharmaSUG 2023 - Paper SS-146 ADaM Datasets with Multiple Participations per Subject

# Thank You!


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