METRONOMIA

MULTIPLE ENROLLMENTS / SCREENINGS IN SDTM AND ADAM

Judith Köppert

TOPICS

- **What's the problem with multiple enrollments / screenings ?**

- **How to implement rescreening information in SDTM ?**

- **How to implement rescreening information in ADaM ?**

WHAT'S THE PROBLEM WITH MULTIPLE ENROLLMENTS / SCREENINGS?

- **For one subject multiple baseline information is present**
  - informed consent date
  - age, height, weight and so on at screening

- **Conflict**
  - two different SUBJIDs for the same person
  - only one USUBJID per person allowed
  - only one entry in DM domain and ADSL dataset allowed by CDISC standards

- **Points to consider:**
  - Clarify with the Sponsor how multiple enrollments should be included in the CDISC standard
  - Describe how multiple enrollments have been handled in the reviewers guide for SDTM and ADaM

HOW TO IMPLEMENT RESCREENING INFORMATION IN SDTM?

- **Presentation from Eanna Kiely (CDISC Italian User Network):**
  Updates on Handling Multiple Enrollments and Screenings Subjects in SDTM - ClinBuild - Eanna Kiely - V1.0.pdf

- **Create DM domain and DC domain (DC = Demographics as Collected)**

- **DC domain has a similar structure and content as DM domain**

- **DC domain contains all records from DM domain, even if no rescreening occurred (but could have happened)**

- **Primary enrollment should be submitted in DM domain (FDA statement)**

HOW TO IMPLEMENT RESCREENING INFORMATION IN SDTM?

- **SUBJID should be included in other domains besides DM domain to correctly link the records to the different enrollments/ screenings**

- **xxSEQ will be created for one USUBJID (not SUBJID)**

- **xxDY will be calculated based on DM.RFSTDTC for each USUBJID**

HOW TO IMPLEMENT RESCREENING INFORMATION IN SDTM?

- **Examples**
  - DM domain

DOMAIN	USUBJID	SUBJID	RFSTDTC	RFENDTC	RFICDTC	RFPENDTC
DM	ABC-102007	102007	2021-01-14T13:32	2021-12-15	2020-12-17	2021-12-15

AGE	AGEU	SEX	ARMCD	ARM	ARMNRS	ACTARMUD
29	YEARS	F	A-B	Treat A-Treat B		

  - DC domain

DOMAIN	DCSEQ	USUBJID	SUBJID	RFSTDTC	RFENDTC	RFICDTC	RFPENDTC
DC	1	ABC-102007	102005			2020-10-20	2020-11-03
DC	2	ABC-102007	102007	2021-01-14T13:32	2021-12-15	2020-12-17	2021-12-15

AGE	AGEU	SEX	ARMCD	ARM	ARMNRS	ACTARMUD
29	YEARS	F			SCREEN FAILURE	
29	YEARS	F	A-B	Treat A-Treat B		

HOW TO IMPLEMENT RESCREENING INFORMATION IN SDTM?

- **Examples**
  - LB domain

USUBJID	SUBJID	LBSEQ	LBTESTCD	VISIT	EPOCH	LBDTC	LBDY
ABC-301010	301003	1	ALB	Screening Visit	SCREENING	2020-12-21T14:25	-44
ABC-301010	301010	49	ALB	Screening Visit	SCREENING	2021-01-07T09:05	-27
ABC-301010	301010	50	ALB	Visit 1 - Week 0 (Baseline)	SCREENING	2021-02-03T13:10	1
ABC-301010	301010	51	ALB	Visit 3 - Week 12	TREATMENT 1	2021-04-28T14:50	85
ABC-301010	301010	52	ALB	Visit 5 - Week 28	TREATMENT 1	2021-08-19T12:33	198
ABC-301010	301010	53	ALB	Visit 7 - Week 52 /Early Termination	TREATMENT 2	2022-02-03T10:43	366

  - AE domain

USUBJID	SUBJID	AESEQ	AETERM	AESTDY	AEENDY	AETRTEM
ABC-102007	102007	1	Seborrheic dermatitis	84	97	Y
ABC-401012	401003	1	Acute upper respiratory tract infection	-35	-31	N

HOW TO IMPLEMENT RESCREENING INFORMATION IN ADAM?

- **Suggestion to use a similar approach as in SDTM programming for ADaM programming**

- **Create ADDC in addition to ADSL**
  - ADDC will include one record per subject per enrollment/ screening

- **Use ADDC as the basis for all other ADaM datasets, instead of ADSL**

HOW TO IMPLEMENT RESCREENING INFORMATION IN ADAM?

- **How to fill population flags in ADDC?**
  - Use record-level population flags (xxRFL) instead of subject-level population flags (xxFL)

ADSL variables	ADDC variables
SAFFL (Safety Population Flag)	SAFRFL (Safety Analysis Record-Level Flag)
FASFL (Full Analysis Set Population Flag)	FASRFL (Full Analysis Set Record-Level Flag)
ITTFL (Intent-To-Treat Population Flag)	ITTRFL (Intent-To-Treat Record-Level Flag)
PPROTFL (Per-Protocol Population Flag)	PPROTRFL (Per-Protocol Record-Level Flag)

HOW TO IMPLEMENT RESCREENING INFORMATION IN ADAM?

- **Examples:**
  - ADSL

USUBJID	SUBJID	PSUBJID	SAFFL	FASFL	TRT01A	TRT02A	TR01SDT	TR02SDT
ABC-102007	102007	102005	Y	Y	Treat A	Treat B	14JAN2021	26JUL2021
ABC-301010	301010	301003	Y	Y	Treat A	Treat B	03FEB2021	19AUG2021

  - ADDC

USUBJID	SUBJID	PSUBJID	SAFRFL	FASRFL	TRT01A	TRT02A	TR01SDT	TR02SDT
ABC-102007	102005							
ABC-102007	102007	102005	Y	Y	Treat A	Treat B	14JAN2021	26JUL2021
ABC-301010	301003							
ABC-301010	301010	301003	Y	Y	Treat A	Treat B	03FEB2021	19AUG2021

HOW TO IMPLEMENT RESCREENING INFORMATION IN ADAM?

- **Examples:** ADLB

USUBJID	SUBJID	SAFRFL	TRT01A	TRT02A	PARAMCD	AVISIT	ADT	ADY
ABC-301010	301003				ALB	Screening	21DEC2020	-44
ABC-301010	301010	Y	Treat A	Treat B	ALB	Screening	07JAN2021	-27
ABC-301010	301010	Y	Treat A	Treat B	ALB	Baseline V1 / Week 0	03FEB2021	1
ABC-301010	301010	Y	Treat A	Treat B	ALB	V3 / Week 12	28APR2021	85
ABC-301010	301010	Y	Treat A	Treat B	ALB	V5 / Week 28	19AUG2021	198
ABC-301010	301010	Y	Treat A	Treat B	ALB	V5 / Week 28	19AUG2021	198
ABC-301010	301010	Y	Treat A	Treat B	ALB	V7 / Week 52	03FEB2022	366

- It should be defined in the project team how variables in ADaM should be created/ derived
  - For example ADY: copy from SDTM xxDY (based on DM.RFSTDTC) or based on TR01SDT for each SUBJID ?

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