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New DM Variables in SDTMIG 3.3

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New DM Variables in SDTMIG 3.3: what is new

- In SDTMIG v3.3 batch 3 there has been a first hint about two additional variables for the DM domain
- In the draft for SDTM 1.7 Model this has been confirmed

30	ARMNRS	Reason Arm and/or Actual Arm is Null	Char		Record Qualifier	NEW The reason why the actual arm variables are null or why both the planned and actual arm variables are null. Examples: SCREEN FAILURE, NOT ASSIGNED, NOT TREATED, UNPLANNED TREATMENT. It is assumed that if the arm and actual arm variables are null, the same reason applies to both.
31	ACTARMUD	Description of Unplanned Actual Arm	Char		Record Qualifier	NEW A description of actual treatment for a subject who did not receive treatment described in one of the planned trial arms.

New DM Variables in SDTMIG 3.3: what is it good for?

Why do we need two additional variables for the ARM section?

- The idea is to have only the planned ARM terms as defined in the TA domain in the old variables ARM, ARMCD, ACTARM and ACTARMCD
- Therefore those variables are no longer “REQUIRED”, they are “EXPECTED” in the future
- …and there are new variables to explain why a subject is not assigned to a planned ARM
  - The previous defined terms for “SCREEN FAILURE”, “NOT ASSIGNED”, “NOT TREATED” and “UNPLANNED TREATMENT” have to be listed in the new variable ARMNRS - “Reason Arm and/or Actual Arm is Null”

New DM Variables in SDTMIG 3.3: old definition of the metadata

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
ARMCD	Planned Arm Code	Char	*	Record Qualifier	ARMCD is limited to 20 characters and does not have special character restrictions. The maximum length of ARMCD is longer than for other "short" variables to accommodate the kind of values that are likely to be needed for crossover trials. For example, if ARMCD values for a seven-period crossover were constructed using two-character abbreviations for each treatment and separating hyphens, the length of ARMCD values would be 20.	Req
ARM	Description of Planned Arm	Char	*	Synonym Qualifier	Name of the Arm to which the subject was assigned.	Req
ACTARMCD	Actual Arm Code	Char	*	Record Qualifier	Code of actual Arm. When an Arm is not planned (not in Trial Arms), ACTARMCD will be UNPLAN. Randomized subjects who were not treated will be given a value of NOTTRT. Values should be "SCRNFAIL" for screen failures and "NOTASSGN" for subjects not assigned to treatment. Restricted to values in Trial Arms in all other cases. ACTARMCD is limited to 20 characters and does not have special character restrictions. The maximum length of ACTARMCD is longer than for other short variables to accommodate the kind of values that are likely to be needed for crossover trials.	Req
ACTARM	Description of Actua	Char	*	Synonym Qualifier	Description of actual Arm. When an Arm is not planned (not in Trial Arms), ACTARM will be "Unplanned Treatment". Randomized subjects who were not treated will be given a value of "Not Treated". Values should be "Screen Failure" for screen failures and "Not Assigned" for subjects not assigned to treatment. Restricted to values in Trial Arms in all other cases.	Req

New DM Variables in SDTMIG 3.3: new definition of the metadata

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format [1]	Role	CDISC Notes	Core
ARMCD	Planned Arm Code	Char	*	Record Qualifier	ARMCD is limited to 20 characters. It is not subject to the character restrictions that apply to TESTCD. The maximum length of ARMCD is longer than for other "short" variables to accommodate the kind of values that are likely to be needed for crossover trials. For example, if ARMCD values for a seven-period crossover were constructed using two-character abbreviations for each treatment and separating hyphens, the length of ARMCD values would be 20. If the subject was not assigned to an arm, ARMCD is null and ARMNRS is populated. With the exception of studies which use multi-stage arm assignments, must be a value of ARMCD in the Trial Arms Dataset. If the subject was not assigned to an arm, ARMCD is null and ARMNRS is populated.	Exp
ARM	Description of Planned Arm	Char	*	Synonym Qualifier	Name of the Arm to which the subject was assigned. If the subject was not assigned to an arm, ARM is null and ARMNRS is populated. With the exception of studies which use multi-stage arm assignments, must be a value of ARM in the Trial Arms Dataset. If the subject was not assigned to an arm, ARM is null and ARMNRS is populated.	Exp
ACTARMCD	Actual Arm Code	Char	*	Record Qualifier	Code of actual Arm. ACTARMCD is limited to 20 characters. It is not subject to the character restrictions that apply to TESTCD. The maximum length of ACTARMCD is longer than for other short variables to accommodate the kind of values that are likely to be needed for crossover trials. With the exception of studies which use multi-stage arm assignments, must be a value of ARMCD in the Trial Arms Dataset. If the subject was not assigned to an arm or followed a course not described by any planned arm, ACTARMCD is null and ARMNRS is populated.	Exp
ACTARM	Description of Actual Arm	Char	*	Synonym Qualifier	Description of actual Arm. With the exception of studies which use multi-stage arm assignments, must be a value of ARM in the Trial Arms Dataset. If the subject was not assigned to an arm or followed a course not described by any planned arm, ACTARM is null and ARMNRS is populated.	Exp
ARMNRS	Reason Arm and/or Actual Arm is Null	Char	*	Record Qualifier	A coded reason that arm variables (ARM and ARMCD) and/or actual arm variables (ACTARM and ACTARMCD) are null. Examples: "SCREEN FAILURE", "NOT ASSIGNED", "NOT TREATED", "UNPLANNED TREATMENT". It is assumed that if the arm and actual arm variables are null, the same reason applies to both arm and actual arm.	Exp
ACTARMUD	Description of Unplanned Actual Arm	Char		Record Qualifier	A description of actual treatment for a subject who did not receive treatment described in one of the planned trial arms.	Exp

New DM Variables in SDTMIG 3.3: example

- ARMCD and ACTARMCD will be populated if the subject was assigned to an arm and received treatment consistent with one of the arms in the TA dataset
- If ARMCD is null, then ARM must be null and ARMNRS must be populated with the reason ARMCD is null.
- If ARMNRS is populated with "UNPLANNED TREATMENT", ACTARMUD should be populated with a description of the unplanned treatment received.

Row	STUDYID	DOMAIN	USUBJID	ARMCD	ARM	ACTARMCD	ACTARM	ARMNRS	ACTARMUD
1	ABC	DM	001	A	Drug A	A	Drug A		
2	ABC	DM	002	B	Drug B	B	Drug B		
3	ABC	DM	003					SCREEN FAILURE	
4	ABC	DM	004					NOT ASSIGNED	
5	ABC	DM	005	A	Drug A			NOT TREATED	

New DM Variables in SDTMIG 3.3: what will change?

- Subjects which have not been treated are easier to identify
  - …but Pinnacle 21 checks have to be updated (will such version be available close to the SDTMIG 3.3 release?)
- It's easier to explain why a subject is not treated
  - There should be a (self-defined?) CT allocated to the field ARMNRS to harmonize the terms
  - …but who will provide the explanation for variable ACTARMUD?
- There won't be any impact to the ADSL as normally only treated subjects will be analyzed


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