# 5 Models for Special-Purpose Domains

## Demographics (DM)

### DM – Description/Overview for the Demographics Domain Model

The Demographics domain includes a set of essential standard variables that describe each subject in a clinical study. It is the parent domain for all other observations for human clinical subjects.

### DM – Specification for the Demographics Domain Model

**dm.xpt, Demographics — Version 3.2. One record per subject, Tabulation**

| Variable Name | Variable Label | Type | Controlled Terms, Codelist or Format | Role | CDISC Notes | Core |
|---|---|---|---|---|---|---|
| STUDYID | Study Identifier | Char | | Identifier | Unique identifier for a study. | Req |
| DOMAIN | Domain Abbreviation | Char | DM | Identifier | Two-character abbreviation for the domain. | Req |
| USUBJID | Unique Subject Identifier | Char | | Identifier | Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product. This must be a unique number, and could be a compound identifier formed by concatenating STUDYID-SITEID-SUBJID. | Req |
| SUBJID | Subject Identifier for the Study | Char | | Topic | Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF. | Req |
| RFSTDTC | Subject Reference Start Date/Time | Char | ISO 8601 | Record Qualifier | Reference Start Date/time for the subject in ISO 8601 character format. Usually equivalent to date/time when subject was first exposed to study treatment. Required for all randomized subjects; will be null for all subjects who did not meet the milestone the date requires, such as screen failures or unassigned subjects. | Exp |
| RFENDTC | Subject Reference End Date/Time | Char | ISO 8601 | Record Qualifier | Reference End Date/time for the subject in ISO 8601 character format. Usually equivalent to the date/time when subject was determined to have ended the trial, and often equivalent to date/time of last exposure to study treatment. Required for all randomized subjects; null for screen failures or unassigned subjects. | Exp |
| RFXSTDTC | Date/Time of First Study Treatment | Char | ISO 8601 | Record Qualifier | First date of exposure to any protocol-specified treatment or therapy, equal to the earliest value of EXSTDTC. | Exp |
| RFXENDTC | Date/Time of Last Study Treatment | Char | ISO 8601 | Record Qualifier | Last date of exposure to any protocol-specified treatment or therapy, equal to the latest value of EXENDTC (or the latest value of EXSTDTC if EXENDTC was not collected or is missing). | Exp |

| Variable Name | Variable Label | Type | Controlled Terms, Codelist or Format | Role | CDISC Notes | Core |
|---|---|---|---|---|---|---|
| RFICDTC | Date/Time of Informed Consent | Char | ISO 8601 | Record Qualifier | Date/time of informed consent in ISO 8601 character format. This will be the same as the date of informed consent in the Disposition domain, if that protocol milestone is documented. Would be null only in studies not collecting the date of informed consent. | Exp |
| RFPENDTC | Date/Time of End of Participation | Char | ISO 8601 | Record Qualifier | Date/time when subject ended participation or follow-up in a trial, as defined in the protocol, in ISO 8601 character format. Should correspond to the last known date of contact. Examples include completion date, withdrawal date, last follow-up, date recorded for lost to follow up, or death date. | Exp |
| DTHDTC | Date/Time of Death | Char | ISO 8601 | Record Qualifier | Date/time of death for any subject who died, in ISO 8601 format. Should represent the date/time that is captured in the clinical-trial database. | Exp |
| DTHFL | Subject Death Flag | Char | (NY) | Record Qualifier | Indicates the subject died. Should be Y or null. Should be populated even when the death date is unknown. | Exp |
| SITEID | Study Site Identifier | Char | | Record Qualifier | Unique identifier for a site within a study. | Req |
| INVID | Investigator Identifier | Char | | Record Qualifier | An identifier to describe the Investigator for the study. May be used in addition to SITEID. Not needed if SITEID is equivalent to INVID. | Perm |
| INVNAM | Investigator Name | Char | | Synonym Qualifier | Name of the investigator for a site. | Perm |
| BRTHDTC | Date/Time of Birth | Char | ISO 8601 | Record Qualifier | Date/time of birth of the subject. | Perm |
| AGE | Age | Num | | Record Qualifier | Age expressed in AGEU. May be derived from RFSTDTC and BRTHDTC, but BRTHDTC may not be available in all cases (due to subject privacy concerns). | Exp |
| AGEU | Age Units | Char | (AGEU) | Variable Qualifier | Units associated with AGE. | Exp |
| SEX | Sex | Char | (SEX) | Record Qualifier | Sex of the subject. | Req |
| RACE | Race | Char | (RACE) | Record Qualifier | Race of the subject. Sponsors should refer to "Collection of Race and Ethnicity Data in Clinical Trials" (FDA, September 2005) for guidance regarding the collection of race (http://www.fda.gov/RegulatoryInformation/Guidances/ucm126340.htm) See Assumption below regarding RACE. | Exp |
| ETHNIC | Ethnicity | Char | ETHNIC) | Record Qualifier | The ethnicity of the subject. Sponsors should refer to "Collection of Race and Ethnicity Data in Clinical Trials" (FDA, September 2005) for guidance regarding the collection of ethnicity (http://www.fda.gov/RegulatoryInformation/Guidances/ucm126340.htm). | Perm |
| 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 |

| Variable Name | Variable Label | Type | Controlled Terms, Codelist or Format | Role | CDISC Notes | Core |
|---|---|---|---|---|---|---|
| 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.<br><br>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 |
| COUNTRY | Country | Char | (COUNTRY) ISO 3166 | Record Qualifier | Country of the investigational site in which the subject participated in the trial. | Req |
| DMDTC | Date/Time of Collection | Char | ISO 8601 | Timing | Date/time of demographic data collection. | Perm |
| DMDY | Study Day of Collection | Num | | Timing | Study day of collection measured as integer days. | Perm |

** Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)*

## DM – Assumptions for the Demographics Domain Model

1. Investigator and site identification: Companies use different methods to distinguish sites and investigators. CDISC assumes that SITEID will always be present, with INVID and INVNAM used as necessary. This should be done consistently and the meaning of the variable made clear in the define.xml.
2. Every subject in a study must have a subject identifier (SUBJID). In some cases a subject may participate in more than one study. To identify a subject uniquely across all studies for all applications or submissions involving the product, a unique identifier (USUBJID) must be included in all datasets. Subjects occasionally change sites during the course of a clinical trial. The sponsor must decide how to populate variables such as USUBJID, SUBJID and SITEID based on their operational and analysis needs, but only one DM record should be submitted for the subject. The Supplemental Qualifiers dataset may be used if appropriate to provide additional information.
3. Concerns for subject privacy suggest caution regarding the collection of variables like BRTHDTC. This variable is included in the Demographics model in the event that a sponsor intends to submit it; however, sponsors should follow regulatory guidelines and guidance as appropriate.
4. The values of ARM and ARMCD in DM must match entries in the Trial Arms (TA) dataset, except for subjects who were not fully assigned to an Arm. Subjects who did not receive the treatments to which they were assigned will still have the values of ARM and ARMCD to which they were assigned. SE/DM Examples 1 and 2 in ***Section 5 - SE Domain: SE - Examples for the SUBJECT ELEMENTS Domain Model*** show examples of subjects whose actual treatment did not match their planned treatment.

   Some subjects may leave the trial before they can be assigned to an Arm, or, in the case of trials where Arm is assigned by two or more successive allocation processes, may leave before the last of these processes. Such subjects will not be assigned to one of the planned Arms described in the Trial Arms dataset, and must have special values of ARM and ARMCD assigned.

   - Data for screen failure subjects, if submitted, should be included in the Demographics dataset, with ARMCD = “SCRNFAIL" and ARM = “Screen Failure”. Sponsors may include a record in the Disposition dataset indicating when the screen failure event occurred. DM/SE Example 6 shows an example of data submitted for a screen failure subject.
     - Some trial designs include Elements after screening but before Arm assignments are made, and so may have subjects who are not screen failures, but are not assigned to an Arm. Subjects withdrawn from a trial before assignment to an Arm, if they are not screen failures, should have ARMCD = "NOTASSGN" and ARM = "Not Assigned". Example Trial 1in ***Section 7.2 - Experimental Design: Example Trial 1, A Parallel Trial, TA – Examples For Trial Arms Dataset***, which includes a screening Epoch and a run-in Epoch before randomization, is an example of such a trial; data for a subject who passed screening but was not randomized in this trial are shown in DM/SE Example 6.
     - In trials where Arm assignment is done by means of two or more allocation processes at separate points in time, subjects who drop out after the first allocation process but before the last allocation process, should be assigned values of ARMCD that reflect only the allocation processes they underwent. Example Trial 3, ***Section 7.2 - Experimental Design: Example Trial 3, A Trial With Multiple Branch Points, TA - Examples for Trial Arms Dataset***, is such a trial. DM/SE Example 7 shows sample data for subjects in this trial.
5. When study population flags are included in SDTM, they are treated as Supplemental Qualifiers ***[see Section 8: 8.4, Relating Non-Standard Variables Values To A Parent Domain]*** to DM and placed in the SUPPDM dataset. Controlled terms for these subject-level population flags, (e.g., COMPLT, SAFETY, ITT and PPROT) are listed in ***Appendix C2 - Supplemental Qualifier Name Codes***. See ICH E9 for more information and definitions. Note that the ADaM subject-level analysis dataset (ADSL) includes population flags; consult the ADaM Implementation Guide for more information about these variables.

6. Submission of multiple race responses should be represented in the Demographics domain and Supplemental Qualifiers (SUPPDM) dataset as described in ***Section 4: 4.1.2.8.3, Multiple Values For A Non-Result Qualifier Variable***. If multiple races are collected then the value of RACE should be "MULTIPLE" and the additional information will be included in the Supplemental Qualifiers dataset. Controlled terminology for RACE should be used in both DM and SUPPDM so that consistent values are available for summaries regardless of whether the data are found in a column or row. If multiple races were collected and one was designated as primary, RACE in DM should be the primary race and additional races should be reported in SUPPDM. When additional free text information is reported about subject's RACE using "Other, Specify", Sponsors should refer to ***Section 4: 4.1.2.7.1, "Specify" Values For Non-Result Qualifier Variables***. If the race was collected via an "Other, Specify" field and the sponsor chooses not to map the value as described in the current FDA guidance (see CDISC Notes for RACE) then the value of RACE should be "OTHER". If a subject refuses to provide race information, the value of RACE could be "UNKNOWN". Examples are provided below in ***Section 5 - DM Domain: DM - Examples for the DEMOGRAPHICS Domain Model***.
7. RFSTDTC, RFENDTC, RFXSTDTC, RFXENDTC, RFICDTC, RFPENDTC and BRTHDTC represent date/time values, but they are considered to have a Record Qualifier role in DM. They are not considered to be Timing Variables because they are not intended for use in the general observation classes.
8. Additional Permissible Identifier, Qualifier and Timing Variables

   Only the following Timing variables are permissible and may be added as appropriate: VISITNUM, VISIT, VISITDY. The Record Qualifier DMXFN (External File Name) is the only additional qualifier variable that may be added, which is adopted from the Findings general observation class, may also be used to refer to an external file, such as a patient narrative.
9. The order of these new variables within the domain should follow the rules as described in ***Section 4: 4.1.1.4, Order Of The Variables*** and the order described in ***Section 4: 1.2, Organization Of This Document***.

10. As described in ***Section 4: 4.1.1.4, Order Of The Variables***, RFSTDTC is used to calculate study day variables. RFSTDTC is usually defined as the date/time when a subject was first exposed to study drug. This definition applies for most interventional studies, when the start of treatment is the natural and preferred starting point for study day variables and thus the logical value for RFSTDTC. In such studies, when data are submitted for subjects who are ineligible for treatment (e.g., screen failures with ARMCD=SCRNFAIL), subjects who were enrolled but not assigned to an arm (ARMCD=NOTASSGN), or subjects who were randomized but not treated (ACTARMCD=NOTTRT), RFSTDTC will be null. For studies with designs that include a substantial portion of subjects who are not expected to be treated, a different protocol milestone may be chosen as the starting point for study day variables. Some examples include non-interventional or observational studies, studies with a no-treatment arm, or studies where there is a delay between randomization and treatment.

11. RFXSTDTC may be the same as RFSTDTC, but it might be different for some studies. An example of the latter would be when RFSTDTC was defined as the date the informed consent was signed. RFXSTDTC should be the same as SESTDTC for the first treatment Element described in the SE dataset.

12. RFXENDTC may often be the same as the SEENDTC for the last treatment Element described in the SE dataset. RFXENDTC may or may not be the same as RFENDTC, the date defined as the reference end for a subject.

13. RFICDTC should correspond to the date of the informed consent protocol milestone in DS, if that protocol milestone is documented in DS. In the event that there are multiple informed consents, this will be the date of the first one.

14. RFPENDTC will be the last date of participation for a subject for data included in a submission. This should be the last date of any record for the subject in the database at the time it's locked for submission. As such, it may not be the last date of participation in the study if the submission includes interim data.

## DM – Examples for the Demographics Domain Model

Examples of using the DM domain for typical scenarios are provided below. Example 1 displays the all Required and Expected variables; in examples 2 - 6, certain Required or Expected variables have been omitted in consideration of space and clarity. Example 1 is a general Demographics example showing typical data recorded for a clinical trial. Examples 2 through 5 display various scenarios for representing race and ethnicity information. Example 6 shows the handling of ARMCD for Subjects Withdrawn before Assignment to an Arm, and Example 7 shows the handling ARMCD for Subjects Withdrawn when assignment to an Arm is Incomplete.

### *DM Example 1 – General Demographics*

dm.xpt

| Row | STUDYID | DOMAIN | USUBJID | SUBJID | RFSTDTC | RFENDTC | RFXSTDTC | RFXENDTC | RFICTTC | RFPENDTC |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | ABC123 | DM | ABC12301001 | 001 | 2006-01-12 | 2006-03-10 | 2006-01-12 | 2006-03-10 | 2006-01-03 | 2006-04-01 |
| 2 | ABC123 | DM | ABC12301002 | 002 | 2006-01-15 | 2006-02-28 | 2006-01-15 | 2006-02-28 | 2006-01-04 | 2006-03-26 |
| 3 | ABC123 | DM | ABC12301003 | 003 | 2006-01-16 | 2006-03-19 | 2006-01-16 | 2006-03-19 | 2006-01-02 | 2006-03-19 |
| 4 | ABC123 | DM | ABC12301004 | 004 | | | | | 2006-01-07 | 2006-01-08 |
| 5 | ABC123 | DM | ABC12302001 | 001 | 2006-02-02 | 2006-03-31 | 2006-02-02 | 2006-03-31 | 2006-01-15 | 2006-04-12 |
| 6 | ABC123 | DM | ABC12302002 | 002 | 2006-02-03 | 2006-04-05 | 2006-02-03 | 2006-04-05 | 2006-01-10 | 2006-04-25 |

| Row | SITEID | INVNAM | BRTHDTC | AGE | AGEU | SEX | RACE | ETHNIC |
|---|---|---|---|---|---|---|---|---|
| 1 (cont) | 01 | JOHNSON, M | 1948-12-13 | 57 | YEARS | M | WHITE | HISPANIC OR LATINO |
| 2 (cont) | 01 | JOHNSON, M | 1955-03-22 | 50 | YEARS | M | WHITE | NOT HISPANIC OR LATINO |
| 3 (cont) | 01 | JOHNSON, M | 1938-01-19 | 68 | YEARS | F | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO |
| 4 (cont) | 01 | JOHNSON, M | 1941-07-02 | | | M | ASIAN | NOT HISPANIC OR LATINO |
| 5 (cont) | 02 | GONZALEZ, E | 1950-06-23 | 55 | YEARS | F | AMERICAN INDIAN OR ALASKA NATIVE | NOT HISPANIC OR LATINO |
| 6 (cont) | 02 | GONZALEZ, E | 1956-05-05 | 49 | YEARS | F | NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDERS | NOT HISPANIC OR LATINO |

| Row | ARMCD | ARM | ACTARMCD | ACTARM | COUNTRY |
|---|---|---|---|---|---|
| 1 (cont) | A | Drug A | A | Drug A | USA |
| 2 (cont) | P | Placebo | P | Placebo | USA |
| 3 (cont) | P | Placebo | P | Placebo | USA |
| 4 (cont) | SCRNFAIL | Screen Failure | SCRNFAIL | Screen Failure | USA |
| 5 (cont) | P | Placebo | P | Placebo | USA |
| 6 (cont) | A | Drug A | A | Drug A | USA |

*DM Example 2 – Single Race/Single Ethnicity Choice*

**Sample CRF:**

| Ethnicity | Check one |
|---|---|
| Hispanic or Latino | ☐ |
| Not Hispanic or Latino | ☐ |

| Race | Check one |
|---|---|
| American Indian or Alaska Native | ☐ |
| Asian | ☐ |
| Black or African American | ☐ |
| Native Hawaiian or Other Pacific Islander | ☐ |
| White | ☐ |

**Row 1**: Subject 001 was Not-Hispanic and Asian.
**Row 2**: Subject 002 was Hispanic and White.

dm.xpt

| Row | STUDYID | DOMAIN | USUBJID | RACE | ETHNIC |
|---|---|---|---|---|---|
| 1 | ABC | DM | 001 | ASIAN | NOT HISPANIC OR LATINO |
| 2 | ABC | DM | 002 | WHITE | HISPANIC OR LATINO |

### *DM Example 3 - Multiple Race Choices*

In this example, the subject is permitted to check all applicable races.

**Sample CRF:**

| Race | Check all that apply |
|---|---|
| American Indian or Alaska Native | ☐ |
| Asian | ☐ |
| Black or African American | ☐ |
| Native Hawaiian or Other Pacific Islander | ☐ |
| White | ☐ |
| Other, Specify: _____ | ☐ |

**Row 1 (DM) and**
**Row 1 (SUPPDM):** Subject 001 checked "Other, Specify:" and entered "Brazilian" as race.
**Row 2 (DM) and**
**Rows 2, 3, 4, 5 (SUPPDM):** Subject 002 checked three races, including an "Other, Specify" value. The three values are reported in SUPPDM using QNAM values RACE1 - RACE3. The specified information describing other race for is submitted in the same manner as subject 001.
**Row 3 (DM):** Subject 003 refused to provide information on race.
**Row 4 (DM):** Subject 004 checked "Asian" as their only race.

**dm.xpt**

| Row | STUDYID | DOMAIN | USUBJID | RACE |
|---|---|---|---|---|
| 1 | ABC | DM | 001 | OTHER |
| 2 | ABC | DM | 002 | MULTIPLE |
| 3 | ABC | DM | 003 | |
| 4 | ABC | DM | 004 | ASIAN |

**suppdm.xpt**

| Row | STUDYID | RDOMAIN | USUBJID | IDVAR | IDVARVAL | QNAM | QLABEL | QVAL | QORIG | QEVAL |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | ABC | DM | 001 | | | RACEOTH | Race, Other | BRAZILIAN | CRF | |
| 2 | ABC | DM | 002 | | | RACE1 | Race 1 | BLACK OR AFRICAN AMERICAN | CRF | |
| 3 | ABC | DM | 002 | | | RACE2 | Race 2 | AMERICAN INDIAN OR ALASKA NATIVE | CRF | |
| 4 | ABC | DM | 002 | | | RACE3 | Race 3 | OTHER | CRF | |
| 5 | ABC | DM | 002 | | | RACEOTH | Race, Other | ABORIGINE | CRF | |

### *DM Example 4: Mapping Predefined Races*

In this example, the sponsor has chosen to map some of the predefined races to other races, specifically Japanese and Non-Japanese to Asian. Note: Sponsors may choose not to map race data, in which case the previous examples should be followed.

**Sample CRF**

| Race | Check One |
|---|---|
| American Indian or Alaska Native | ☐ |
| Asian | |
| Japanese | ☐ |
| Non-Japanese | ☐ |
| Black or African American | ☐ |
| Native Hawaiian or Other Pacific Islander | ☐ |
| White | ☐ |

**Row 1 (DM), Row 1 (SUPPDM):** Subject 001 checked "Non-Japanese" which was mapped by the sponsor to "Asian".
**Row 2 (DM), Row 2 (SUPPDM):** Subject 002 checked "Japanese" which was mapped by the sponsor to "Asian".

**dm.xpt**

| Row | STUDYID | DOMAIN | USUBJID | RACE |
|---|---|---|---|---|
| 1 | ABC | DM | 001 | ASIAN |
| 2 | ABC | DM | 002 | ASIAN |

**suppdm.xpt**

| Row | STUDYID | RDOMAIN | USUBJID | IDVAR | IDVARVAL | QNAM | QLABEL | QVAL | QORIG | QEVAL |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | ABC | DM | 001 | | | RACEOR | Original Race | NON-JAPANESE | CRF | |
| 2 | ABC | DM | 002 | | | RACEOR | Original Race | JAPANESE | CRF | |

### *DM Example 5: Mapping "Other, Specify" Races*

In this example, the sponsor has chosen to map the values entered into the "Other, Specify" field to one of the preprinted races.
Note: Sponsors may choose not to map race data, in which case the first two examples should be followed.

**Sample CRF and Data:**

| Race | Check One |
|---|---|
| American Indian or Alaska Native | ☐ |
| Asian | ☐ |
| Black or African American | ☐ |
| Native Hawaiian or Other Pacific Islander | ☐ |
| White | ☐ |
| Other, Specify: _____ | ☐ |

**Row 1 (DM), Row 1 (SUPPDM):** Subject 001 checked "Other, Specify" and entered "Japanese" which was mapped to "Asian" by the sponsor.
**Row 2 (DM), Row 2 (SUPPDM):** Subject 002 checked "Other, Specify" and entered "Swedish" which was mapped to "White" by the sponsor.

**dm.xpt**

| Row | STUDYID | DOMAIN | USUBJID | RACE |
|---|---|---|---|---|
| 1 | ABC | DM | 001 | ASIAN |
| 2 | ABC | DM | 002 | WHITE |

**suppdm.xpt**

| Row | STUDYID | RDOMAIN | USUBJID | IDVAR | IDVARVAL | QNAM | QLABEL | QVAL | QORIG | QEVAL |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | ABC | DM | 001 | | | RACEOR | Original Race | JAPANESE | CRF | |
| 2 | ABC | DM | 002 | | | RACEOR | Original Race | SWEDISH | CRF | |

### *DM/SE Example 6*

The following examples illustrate values of ARMCD for subjects in Example Trial 1, described in ***Section 7.2 - Experimental Design: Example Trial 1, A Parallel Trial, TA – Examples For Trial Arms Dataset***. The sponsor is submitting data on screen-failure subjects.

**Row 1:** Subject 001 was randomized to Arm A. Rows 1-3 of SE dataset show that the subject completed all the Elements for Arm A.

**Row 2:** Subject 002 was randomized to Arm B. Rows 4-6 of SE dataset show that the subject completed all the Elements for Arm B.

**Row 3:** Subject 003 was a screen failure. Row 7 of SE dataset shows that they passed through only the Screen Element.

**Row 4:** Subject 004 withdrew during the Run-in Element. They were not considered a screen failure, but they were not randomized, so they have been given the special ARMCD value NOTASSGN. Rows 8-9 of the SE dataset show the two Elements (Screen and Run-in) this subject passed through.

**dm.xpt**

| Row | STUDYID | DOMAIN | USUBJID | ARMCD |
|---|---|---|---|---|
| 1 | ABC | DM | 001 | A |
| 2 | ABC | DM | 002 | B |
| 3 | ABC | DM | 003 | SCRNFAIL |
| 4 | ABC | DM | 004 | NOTASSGN |

**se.xpt**

| Row | STUDYID | DOMAIN | USUBJID | SESEQ | ETCD | ELEMENT | SESTDTC | SEENDTC |
|---|---|---|---|---|---|---|---|---|
| 1 | ABC | SE | 001 | 1 | SCRN | Screen | 2006-06-01 | 2006-06-07 |
| 2 | ABC | SE | 001 | 2 | RI | Run-In | 2006-06-07 | 2006-06-21 |
| 3 | ABC | SE | 001 | 3 | A | Drug A | 2006-06-21 | 2006-07-05 |
| 4 | ABC | SE | 002 | 1 | SCRN | Screen | 2006-05-03 | 2006-05-10 |
| 5 | ABC | SE | 002 | 2 | RI | Run-In | 2006-05-10 | 2006-05-24 |
| 6 | ABC | SE | 002 | 3 | B | Drug B | 2006-05-24 | 2006-06-07 |
| 7 | ABC | SE | 003 | 1 | SCRN | Screen | 2006-06-27 | 2006-06-30 |
| 8 | ABC | SE | 004 | 1 | SCRN | Screen | 2006-05-14 | 2006-05-21 |
| 9 | ABC | SE | 004 | 2 | RI | Run-In | 2006-05-21 | 2006-05-26 |

***DM/SE Example 7:***

The following example illustrates values of ARMCD for subjects in Example Trial 3, described in ***Section 7.2 - Experimental Design: Example Trial 3, A Trial With Multiple Branch Points, TA - Examples for Trial Arms Dataset***

**Row 1:** Subject 001 was randomized to Drug A. At the end of the Double Blind Treatment Epoch, they were assigned to Open Label A. Thus their ARMCD is AA. Rows 1-3 of the SE dataset show that subject passed through all three Elements for the AA Arm.

**Row 2:** Subject 002 was randomized to Drug A. They were lost to follow-up during the Double Blind Epoch, so never reached the Open Label Epoch, when they would have been assigned to either the Open Drug A or the Rescue Element. Their ARMCD is A. Note that A is not one of the Arm code values in the Trial Arms dataset for this trial. See ***Section 7.2 - Experimental Design: Issue 2, Subjects Not Assigned To An Arm, TA – Issues In Trial Arms Dataset*** for more information on handling subjects who do not reach all branch points in the trial design. Rows 4-5 of the SE dataset show the two Elements (Screen and Treatment A) the subject passed through.

**dm.xpt**

| Row | STUDYID | DOMAIN | USUBJID | ARMCD | ARM |
|---|---|---|---|---|---|
| 1 | DEF | DM | 001 | AA | A-OPEN A |
| 2 | DEF | DM | 002 | A | A |

**se.xpt**

| Row | STUDYID | DOMAIN | USUBJID | SESEQ | ETCD | ELEMENT | SESTDTC | SEENDTC |
|---|---|---|---|---|---|---|---|---|
| 1 | DEF | SE | 001 | 1 | SCRN | Screen | 2006-01-07 | 2006-01-12 |
| 2 | DEF | SE | 001 | 2 | DBA | Treatment A | 2006-01-12 | 2006-04-10 |
| 3 | DEF | SE | 001 | 3 | OA | Open Drug A | 2006-04-10 | 2006-07-05 |
| 4 | DEF | SE | 002 | 1 | SCRN | Screen | 2006-02-03 | 2006-02-10 |
| 5 | DEF | SE | 002 | 2 | DBA | Treatment A | 2006-02-10 | 2006-03-24 |