**Table 1: DM Domain specifications**

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| **Dataset** | **Variable** | **Label** | **Man-datory** | **Assigned  Value** | **Codelist** | **Origin type** | **Origin path** | **Derivation/ Comment** |
| DM | STUDYID | Study Identifier | Yes |  |  | Protocol |  |  |
| DM | DOMAIN | Domain Abbreviation | Yes | DM |  | Assigned |  |  |
| DM | USUBJID | Unique Subject Identifier | Yes |  |  | Derived | STUDYID + SUBJID |  |
| DM | SUBJID | Subject Identifier for the study | Yes |  |  | Derived |  |  |
| DM | RFSTDTC | Subject reference start date/time | Yes |  |  | Derived |  | *Will be set equal to index date.* |
| DM | RFENDTC | Subject reference end date/time | Yes |  |  | Derived |  | *Will be last date of last visit within window of the study.* |
| DM | RFXSTDTC | Date/Time of First Study Treatment | Yes |  |  | Not applicable |  | Variable will be empty. No study treatment applicable for control arm. |
| DM | RFXENDTC | Date/Time of Last Study Treatment | Yes |  |  | Not applicable |  | Variable will be empty. No study treatment applicable for control arm. |
| DM | RFICDTC | Date/Time of Informed Consent | Yes |  |  | Not applicable |  | No IC applicable for this data source |
| DM | RFPENDTC | Date/Time of End of Participation | Yes |  |  | Collected |  | *Will be set to last date of encounters available from data source.* |
| DM | DTHDTC | Date/Time of Death | Yes |  |  | Collected |  |  |
| DM | DTHFL | Subject Death Flag | Yes |  |  | Derived |  | If dthdtc is available then DTHFL will be set to ‘Y’. |
| DM | SITEID | Study Site Identifier | Yes |  |  | Not available |  | Variable will be empty. For privacy reasons not available. |
| DM | BRTHDTC | Date/Time of Birth | No |  |  | Collected |  |  |
| DM | AGE | Age | Yes |  |  | Derived |  | *Will be derived by based on date of birth and the index date as ….* |
| DM | AGEU | Age Units | Yes | YEARS | C66781 Age Unit | Assigned |  | Ages are referred to in registry as years. |
| DM | SEX | Sex | Yes |  | C66731 Sex | Collected |  |  |
| DM | RACE | Race | Yes |  | C74457 | Derived |  | See RC\_ALIAS  Source to target mapping information will be provided. |
| DM | ETHNIC | Ethnicity | No |  | C66790 | Derived |  | See previous – race collected in source is mix of both SDTM ethnicity and race. |
| SUPPDM | RC\_ALIAS | Race Alias | No |  |  | Collected |  | Source race value1) |
| SUPPDM | ET\_ALIAS | Ethnicity Alias | No |  |  | Collected |  | Source ethnicity value1) |
| DM | ARMCD | Planned Arm Code | Yes | ECA |  | Assigned |  | External control arm |
| DM | ARM | Description of Planned Arm | Yes | External control |  | Assigned |  |  |
| DM | ACTARMCD | Actual Arm Code | Yes |  |  | Assigned |  | *Not available yet – eligibility not yet evaluated* |
| DM | ACTARM | Description of Actual Arm | Yes |  |  | Assigned |  | *Not available yet – eligibility not yet evaluated* |
| DM | ARMNRS | Reason Arm and/or Actual Arm is Null | Yes |  |  | Assigned |  | Will be filled with “Unmatched Control Patient” if not included in the external control arm. |
| DM | ACTARMUD | Description of Unplanned Actual Arm | Yes |  |  | Assigned |  | Will be filled with “eligible unmatched control patients” if not included in the external control arm. |
| DM | COUNTRY | Country | Yes |  |  | Not available |  | Set to USA |

1) Alias variables containing source data are recommended in the FDA guidance for Industry ‘Data Standards for Drug and Biological Product Submissions Containing Real-World Data’: “To achieve this objective, the *Alias* element in Define-XML file can be used to document the conversions to a single nomenclature while ensuring traceability.”