CRF Image Cover Page

CRF Attributes

Form RefName in CD library: **DM1001_LF2** **Library Identifier: Sharepoint** **Library Identifier:** **CRF_DM1001_LF2_CORE_v1.0**	Standard Class Ownership: ☒ CORE ☐ TA (Therapeutic Area) ☐ STUDY ☐ Compound Indication	CRF Reuse Level: ☒ CORE ☐ TA

Therapeutic Area (TA): Therapeutic Area of the drug compound, if applicable.

☐ AIIMIN	☐ DIAB	☐ HEMNEP	☐ NS	☐ N/A
☐ BI	☐ END	☐ IIR	☐ ONC	
☐ CV	☐ ENSTAR	☐ MUSC	☐ PAIN	
☐ CVVD	☐ GENIT	☐ ND	☐ PD	

Expectations for Use (General)

When this CRF should be used:
- Use this CRF for all phase 1-2 studies

CRF Title and Short Title conventions:
- Title should always start with: **Demographics**
  - Title can be customized as needed using format:
    - Demographics: <Additional Detail>
    - For example: Demographics: Male
    - Titles should be in title case, contain no special characters other than colons (:) and forward slashes (/).
    - Titles must be 63 characters or less including spaces.
- Short Title should always start with: **DM**
  - Short Title can be customized as needed using format:
    - DM_ <Additional Detail>
    - For example: DM_M
    - Short titles should be kept as short as possible, use ALL CAPS, contain no spaces, contain no special characters other than the underscore.

Allowable CRF modifications:
- BRTHYR – Birth Year
  - Date range should be defined on the DM1001 tab of the study specific Data Collection Specifications (DCS).
    - Beginning Year – typically:
      - Equals beginning year of on study date range minus 100 years

- Or, if upper age limit is defined in protocol: Equals beginning year of on study date range minus oldest age allowed to enroll + a few years if PI is allowed discretion on age of enrollment.
    - End Year – typically:
        - Equals ending year of on study year range minus youngest age allowed to enroll.
    - Do NOT define this range too tightly as changing it requires a post-production change to the CRFs. Other checks will be in place to ensure subjects are within allowed age range.
  - BRTHDAT – Full date of birth can replace BRTHYR when there is a study specific need allowed under Lilly's privacy rules – for example, pediatric trials.
- SEX – Sex
  - Can be removed and made a CRF label when all subject will be one sex.
- ETHNIC – Ethnicity
  - 'Not applicable' code choice should be removed if study will only be conducted at USA sites.
  - If study will only be conducted at sites outside of the USA, use library form DM1001_LF3
- RACE – Race
  - Race code choices should not be modified.

CRF placement in the study structure
- DM form is typically placed in the first visit prior to any status form.

Expectations for Use (Technical)

LS for CIS Mapping instructions
- Map all items to the DM1001 dataset.

Revision History for CRF Image

Ver sion	Effective Date (Publication ready date)	DED(s) and Version CRF is based upon	DED item group(s) and ig version(s) within DED CRF is based upon	CD CRF v#	Change history (Include request number and initials)
1.0	14-Aug-2014	F.DM1001 v6.0	IG.DM1001v6.0 IG.DM1001_Derived v1.0	V1.0	Initial release

: Demographics (DM) [DM1001_LF2]	
Demographics [igDM1001_F2_S1]	
1.* ✔	What is the subject's year of birth? [Birth Year]	**[BRTHYR_DM1001_F2]** Req ⌄ (1914-2006)
2.* ✔	What is the sex of the subject? [Sex]	**[SEX_DM1001_F2]** *[A:F]* ◯ Female *[A:M]* ◯ Male
3.* ✔	What is the ethnicity of the subject? [Ethnicity]	**[ETHNIC_DM1001_F2]** *[A:HISPANIC OR LATINO]* ◯ Hispanic or Latino *[A:NOT HISPANIC OR LATINO]* ◯ Not Hispanic or Latino *[A:NOT APPLICABLE]* ◯ Not Applicable
4.* ✔	What is the race of the subject? (Select all that apply) [Race]	**[RACE_CMPD_DM1001_F2]** **[RACE_84_DM1001_F2]** *[A:AMERICAN INDIAN OR ALASKA NATIVE]* ☐ American Indian or Alaska Native **[RACE_58_DM1001_F2]** *[A:ASIAN]* ☐ Asian **[RACE_2_DM1001_F2]** *[A:BLACK OR AFRICAN AMERICAN]* ☐ Black or African American **[RACE_79_DM1001_F2]** *[A:NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER]* ☐ Native Hawaiian or Other Pacific Islander **[RACE_1_DM1001_F2]** *[A:WHITE]* ☐ White
Key: [*] = Item is required [✔] = Source verification required	

Codelist Values and Tables: Demographics

Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
clSEX	String	Female	F	SEX_1	SEX_DM1001_F2
		Male	M	SEX_2	
clETHNIC	String	Hispanic or Latino	HISPANIC OR LATINO	ETHNIC_50	ETHNIC_DM1001_F2
		Not Hispanic or Latino	NOT HISPANIC OR LATINO	ETHNIC_56	
		Not Applicable	NOT APPLICABLE	ETHNIC_96	
clRACE_84	String	American Indian or Alaska Native	AMERICAN INDIAN OR ALASKA NATIVE	RACE_84	RACE_84_DM1001_F2
clRACE_58	String	Asian	ASIAN	RACE_58	RACE_58_DM1001_F2
clRACE_2	String	Black or African American	BLACK OR AFRICAN AMERICAN	RACE_2	RACE_2_DM1001_F2
clRACE_79	String	Native Hawaiian or Other Pacific Islander	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	RACE_79	RACE_79_DM1001_F2
clRACE_1	String	White	WHITE	RACE_1	RACE_1_DM1001_F2