STANDARD Table

T-DM01: Demographic Characteristics

VERSION 2.0

| TABLE 14.1\_\_x.x  Demographic Characteristics  (Analysis Population) | | | | | |
| --- | --- | --- | --- | --- | --- |
|  | | ----------------- Test Treatment ----------------- | | |  |
|  | Control  (N=x) | Arm 1  (N=x) | Arm 2  (N=x) | Total  (N=x) | Total  (N=x) |
|  |  |  |  |  |  |
| Sex – n (%) |  |  |  |  |  |
| FEMALE | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| MALE | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Missing | x | x | x | x | x |
|  |  |  |  |  |  |
| Sex Reported at Birth – n (%) |  |  |  |  |  |
| FEMALE | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| MALE | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| UNDIFFERENTIATED | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Missing | x | x | x | x | x |
|  |  |  |  |  |  |
| Gender Identity – n (%) | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| CISGENDER | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| TRANSGENDER FEMALE | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| TRANSGENDER MALE | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| GENDER FLUID | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| OTHER | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Missing | x | x | x | x | x |
| Ethnicity – n (%) |  |  |  |  |  |
| HISPANIC OR LATINO | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| NOT HISPANIC OR LATINO | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Missing | x | x | x | x | x |
|  |  |  |  |  |  |
| Race – n (%) |  |  |  |  |  |
| AMERICAN INDIAN/ALASKA NATIVE | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| ASIAN | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| BLACK OR AFRICAN AMERICAN | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| WHITE | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| OTHER | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| MULTIPLE | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Missing | x | x | x | x | x |
|  |  |  |  |  |  |

Note: Percentages calculated on non-missing values. Weight by sex percentages based on the number of female or male subjects.

Nicotine/Alcohol percentages calculated on non-unknown values, a subject may be a current user of one type of tobacco, a former

user of another type of tobacco and never used another type of tobacco, a subject will be counted in the category closest to

user.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| TABLE 14.1\_\_x.x  Demographic Characteristics  (Analysis Population) | | | | | | | |
|  | | | ----------------- Test Treatment ----------------- | | | |  |
|  | Control  (N=x) | | Arm 1  (N=x) | Arm 2  (N=x) | Total  (N=x) | | Total  (N=x) |
|  |  | |  |  |  | |  |
| Age (year) | |  |  |  |  |  | |
| n | | x | x | x | x | x | |
| Mean (SD) | | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | |
| Median | | x.x | x.x | x.x | x.x | x.x | |
| Min, Max | | x, x | x, x | x, x | x, x) | x, x | |
|  |  | |  |  |  | |  |
| Age (year) – n (%) |  | |  |  |  | |  |
| <40 | x (x.x) | | x (x.x) | x (x.x) | x (x.x) | | x (x.x) |
| 40 – 64 | x (x.x) | | x (x.x) | x (x.x) | x (x.x) | | x (x.x) |
| >=65 | x (x.x) | | x (x.x) | x (x.x) | x (x.x) | | x (x.x) |
| Missing | x | | x | x | x | | x |
|  |  | |  |  |  | |  |
| Weight (kg) |  | |  |  |  | |  |
| n | | x | x | x | x | | x |
| Mean (SD) | | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | | x.x (x.xx) |
| Median | | x.x | x.x | x.x | x.x | | x.x |
| Min, Max | | x, x | x, x | x, x | x, x) | | x, x |
|  | |  |  |  |  | |  |
| Weight (kg) – n (%) |  | |  |  |  | |  |
| <60 | x (x.x) | | x (x.x) | x (x.x) | x (x.x) | | x (x.x) |
| >=60 | x (x.x) | | x (x.x) | x (x.x) | x (x.x) | | x (x.x) |
| Missing | x | | x | x | x | | X |
|  | | | | | | | |

Note: Percentages calculated on non-missing values. Weight by sex percentages based on the number of female or male subjects.

Nicotine/Alcohol percentages calculated on non-unknown values, a subject may be a current user of one type of tobacco, a former

user of another type of tobacco and never used another type of tobacco, a subject will be counted in the category closest to

user.

|  | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | |
| TABLE 14.1\_\_x.x  Demographic Characteristics  (Analysis Population) | | | | | | |
|  | | | ---------------- Test Treatment ---------------- | | |  |
|  | Control  (N=x) | | Arm 1  (N=x) | Arm 2  (N=x) | Total  (N=x) | Total  (N=x) |
|  | |  |  |  |  |  |
| Weight (kg) by Sex |  | |  |  |  |  |
| Female |  | |  |  |  |  |
| n | | x | x | x | x | x |
| Mean (SD) | | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) |
| Median | | x.x | x.x | x.x | x.x | x.x |
| Min, Max | | x, x | x, x | x, x | x, x) | x, x |
|  | |  |  |  |  |  |
| Female - n (%) |  | |  |  |  |  |
| <60 | x (x.x) | | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| >=60 | x (x.x) | | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Missing | x | | x | x | x | x |
|  | |  |  |  |  |  |
| Male |  | |  |  |  |  |
| n | | x | x | x | x | x |
| Mean (SD) | | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) |
| Median | | x.x | x.x | x.x | x.x | x.x |
| Min, Max | | x, x | x, x | x, x | x, x) | x, x |
|  |  | |  |  |  |  |
| Male – n (%) |  | |  |  |  |  |
| <60 | x (x.x) | | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| >=60 | x (x.x) | | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Missing | x | | x | x | x | x |
|  | |  |  |  |  |  |
| Height (cm) |  | |  |  |  |  |
| n | | x | x | x | x | x |
| Mean (SD) | | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) |
| Median | | x.x | x.x | x.x | x.x | x.x |
| Min, Max | | x, x | x, x | x, x | x, x) | x, x |
|  | | | | | | |
| Note: Percentages calculated on non-missing values. Weight by sex percentages based on the number of female or male subjects.  Nicotine/Alcohol percentages calculated on non-unknown values, a subject may be a current user of one type of tobacco, a former  user of another type of tobacco and never used another type of tobacco, a subject will be counted in the category closest to  user. | | | | | | |

| TABLE 14.1\_\_x.x  Demographic Characteristics  (Analysis Population) | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
|  | | | ---------------- Test Treatment ---------------- | | |  |
|  | Control  (N=x) | | Arm 1  (N=x) | Arm 2  (N=x) | Total  (N=x) | Total  (N=x) |
|  | |  |  |  |  |  |
| Body Mass Index (kg/M^2) |  | |  |  |  |  |
| n | | x | x | x | x | x |
| Mean (SD) | | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) |
| Median | | x.x | x.x | x.x | x.x | x.x |
| Min, Max | | x, x | x, x | x, x | x, x) | x, x |
|  |  | |  |  |  |  |
| Body Mass Index (kg/M^2) – n (%) |  | |  |  |  |  |
| <25 | x (x.x) | | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| >=25 | x (x.x) | | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Missing | x | | x | x | x | x |
|  | |  |  |  |  |  |
| Region - n (%) | |  |  |  |  |  |
| Europe | | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| North America | | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Rest of world | | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Missing | | x | x | x | x | x |
|  | |  |  |  |  |  |
| Nicotine - n (%) | |  |  |  |  |  |
| Current | x (x.x) | | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Former | x (x.x) | | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Never | x (x.x) | | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Unknown | x (x.x) | | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Missing | | x | x | x | x | x |
|  |  | |  |  |  |  |
| Alcohol - n (%) |  | |  |  |  |  |
| Current | x (x.x) | | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Former | x (x.x) | | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Never | x (x.x) | | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Unknown | x (x.x) | | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Missing | x | | x | x | x | x |
|  | |  |  |  |  |  |
| Note: Percentages calculated on non-missing values. Weight by sex percentages based on the number of female or male subjects.  Nicotine/Alcohol percentages calculated on non-unknown values, a subject may be a current user of one type of tobacco, a former  user of another type of tobacco and never used another type of tobacco, a subject will be counted in the category closest to  user. | | | | | | |

# Study-Specific Text (to be supplied by Statistician unless otherwise noted)

Analysis Population:

Full Analysis Set

Intent to Treat Population

Safety Analysis Set

Safety Population

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Treatment Groups

Control \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Control … \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Test Treatment Arm 1 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Test Treatment Arm 2 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Test Treatment Arm … \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# Optional Columns and Rows

Total (T1)

Active Total (T2)

Sex Reported at Birth (SRBRTH) \*Must populate if data is collected

Gender Identity (GENID) \*Must populate if data is collected

Age categories (AGECAT)

<40

40-64

>= 65

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Weight (WT) \*Must populate if data is collected

Weight categories (WTCAT)

<60

>= 60

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Weight (kg) by Sex (WTSEX)

Female - n (%)

< 60

>= 60

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Male - n (%)

< 60

>= 60

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Height (HT) \*Must populate if data is collected

Body Mass Index (kg/M^2) (BMI)

Body Mass Index (kg/M^2) – n (%) (BMICAT)

< 25

>= 25

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Region (REGION)

Europe

North America

Rest of world

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Nicotine (NICOTINE)

Alcohol (ALCOHOL)

# Version History

|  |  |  |
| --- | --- | --- |
| **Version** | **Description** | **Effective Date** |
| 1.0 | Initial version describing how to add functionality to standard TLF shells |  |
| 2.0 | * Updated to make Height/Weight as optional as per the Foundational eCRF * Updated Analysis Population options for consistency across all tables * Added the options (T1 T2) in the Optional row and column section * Added Sex reported by birth and Gender Identity based on eCRF standard for Inclusion and Diversity specifics * Changed the order of RACE as per the CRF standard * Changed Test Drug to Test Treatment to align with eCRF standard |  |