STANDARD Table

T-CM01: Number of Prior Medications per Subject

VERSION 2.0

**NM**

| TABLE 14.1\_\_x.x  Number of Prior Medications per Subject  **T1**  **T2**  (Analysis Population) | | | | | |
| --- | --- | --- | --- | --- | --- |
|  | | ---------------- Test Treatment ----------------- | | |  |
| Number of Prior Medications@ | Control  (N=x)  n (%) | Arm 1  (N=x)  n (%) | Arm 2  (N=x)  n (%) | Total  (N=x)  n (%) | Total  (N=x)  n (%) |
|  |  |  |  |  |  |
| 0 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| 1 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| 2 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| ... | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| >=x | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
|  |  |  |  |  |  |
| At least one medication | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
|  |  |  |  |  |  |
| Note: All medications with a start date prior to the first study treatment dose are included. @ Based on the WHO Q1\_yyyy generic name. | | | | | |

# 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 … \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

WHO Drug Dictionary Version: Obtain from data. Change value of year only, as AbbVie gets one update annually, in Q1. If a different schedule is followed, change Q1 to the appropriate quarter number.

# Optional Columns and Rows

Total (T1)

Active Total (T2)

Number of Prior Medications (NM)

1

2

…

>= x

# Version History

|  |  |  |
| --- | --- | --- |
| **Version** | **Description** | **Effective Date** |
| 1.0 | Initial version describing how to add functionality to standard TLF shells |  |
| 2.0 | Updated Analysis Population options for consistency across all tables  Updated Test Drug to Test Treatment and study drug to study treatment as referenced in eCRF standard |  |