STANDARD Table

T-DS01: Accountability by Investigator

VERSION 2.0

|  |  | TABLE 14.1\_\_x.x  **PP**  **FAS**  **ITT**  Accountability by Investigator  **R**  (All Subjects) | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | |  |  |  |  |  |  |  |  |  |
| Current Investigator (Site Number)  Treatment | | | **R**  Screened  n | Screen  Failed  n | Randomized  n | Treated  n | Completed  n | Discontinued  Study Treatment  n | Intent  To  Treat  n | Full  Analysis  Set  n | Per  Protocol  n |
|  | | |  |  |  |  |  |  |  |  |  |
| All sites | | | x | x | x | x | x | x | x | x | x |
| Test Treatment Arm 1 | | |  |  | x | x | x | x | x | x | x |
| Test Treatment Arm 2 | | |  |  | x | x | x | x | x | x | x |
| Test Treatment Arm ... | | |  |  | x | x | x | x | x | x | x |
|  | | |  |  |  |  |  |  |  |  |  |
| Investigator name 1 (site number 1) | | | x | x | x | x | x | x | x | x | x |
| Test Treatment Arm 1 | | |  |  | x | x | x | x | x | x | x |
| Test Treatment Arm 2 | | |  |  | x | x | x | x | x | x | x |
| Test Treatment Arm ... | | |  |  | x | x | x | x | x | x | x |
|  | | |  |  |  |  |  |  |  |  |  |
| Investigator name 2 (site number 2) | | | x | x | x | x | x | x | x | x | x |
| Test Treatment Arm 1 | | |  |  | x | x | x | x | x | x | x |
| Test Treatment Arm 2 | | |  |  | x | x | x | x | x | x | x |
| Test Treatment Arm ... | | |  |  | x | x | x | x | x | x | x |
|  | | |  |  |  |  |  |  |  |  |  |
| Investigator name ... (site number ...) | | | x | x | x | x | x | x | x | x | x |
| Test Treatment Arm 1 | | |  |  | x | x | x | x | x | x | x |
| Test Treatment Arm 2 | | |  |  | x | x | x | x | x | x | x |
| Test Treatment Arm ... | | |  |  | x | x | x | x | x | x | x |
|  | | |  |  |  |  |  |  |  |  |  |

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

Treatment Groups

Test Treatment Arm 1

Test Treatment Arm 2

Test Treatment Arm …

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

Investigator name (site number): Obtain from data

# Optional Columns and Rows

Randomized (R) (only applicable for randomized studies)

Intent-to-Treat (ITT)

Full Analysis Set (FAS)

Per Protocol (PP)

# Special Programming Instructions (Optional)

When this document is used in a study, this section contains any special programming instructions specific to this table/study.

# 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 Discontinued Study Drug to Discontinued Study Treatment as referenced in eCRF standard  Updated the table population to be “All Subjects” instead of having option by Analysis Population  Updated by adding two columns of “Screened” and “Screen Failed” |  |