STANDARD Table

T-PRO01: Analysis of PRO Change from Baseline BY VISIT

VERSION 1.0

|  | TABLE 14.2\_\_x.x  Analysis of PRO Change from Baseline by Visit - Method  (Analysis Population) | | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | |  | | | Within Group  Change from Baseline | | ------------------- Model-Based Results [N&=xx] $ ------------------ | | | | |
| Within Group  Change from Baseline | | Between Groups Difference  -------- Compared to Control -------- | | |
| Parameter  Time Point  Treatment | | N@ | Baseline  Mean (SD) | Visit Mean (SD) | Mean (SD) | P-value # | LS Mean (SE) | (95% CI) | LS Mean (SE) | (95% CI) | P-value |
|  | |  |  |  |  |  |  |  |  |  |  |
| Parameter Label 1 | |  |  |  |  |  |  |  |  |  |  |
| Baseline Visit | |  |  |  |  |  |  |  |  |  |  |
| Control | | x |  | x.x (x.x) |  |  |  |  |  |  |  |
| Arm 1 | | x |  | x.x (x.x) |  |  |  |  |  |  |  |
| Arm ... | | x |  | x.x (x.x) |  |  |  |  |  |  |  |
|  | |  |  |  |  |  |  |  |  |  |  |
| Time point 1 | |  |  |  |  |  | x.x (x.x) |  |  |  |  |
| Control | | x | x.x (x.x) | x.x (x.x) | x.x(x.x) |  | (x.xx, x.xx) |  |  |  |
| Arm 1 | | x | x.x (x.x) | x.x (x.x) | x.x(x.x) | x.xxxx | x.x (x.x) | (x.xx, x.xx) | x.x (x.x) | (x.xx, x.xx) | x.xxxx\* |
| Arm ... | | x | x.x (x.x) | x.x (x.x) | x.x(x.x) | x.xxxx | x.x (x.x) | (x.xx, x.xx) | x.x (x.x) | (x.xx, x.xx) | x.xxxx |
|  | |  |  |  |  |  |  |  |  |  |  |
| Time point 2 | |  |  |  |  |  |  |  |  |  |  |
| Control | | x | x.x (x.x) | x.x (x.x) | x.x(x.x) |  | x.x (x.x) | (x.xx, x.xx) |  |  |  |
| Arm 1 | | x | x.x (x.x) | x.x (x.x) | x.x(x.x) | x.xxxx\*\*\* | x.x (x.x) | (x.xx, x.xx) | x.x (x.x) | (x.xx, x.xx) | x.xxxx\*\* |
| Arm ... | | x | x.x (x.x) | x.x (x.x) | x.x(x.x) | x.xxxx | x.x (x.x) | (x.xx, x.xx) | x.x (x.x) | (x.xx, x.xx) | x.xxxx |
|  | |  |  |  |  |  |  |  |  |  |  |
| Parameter Label 2 | |  |  |  |  |  |  |  |  |  |  |
| Baseline Visit | |  |  |  |  |  |  |  |  |  |  |
| Control | | x |  | x.x (x.x) |  | **COMP2** |  |  |  | **COMP1** |  |
| Arm 1 | | x |  | x.x (x.x) |  |  |  |  |  |  |  |
| Arm ... | | x |  | x.x (x.x) |  |  |  |  |  |  |  |

**COMP2**

|  |
| --- |
| $ Mixed-Effect Model with Repeated Measures (MMRM) analysis includes treatment, visit, treatment-by-visit interaction, and XXX [stratification factor] as fixed factors and baseline value as covariate. XXXX [other covariates] are also included in the model. [Unstructured] covariance structure is used. Data [as observed at all visits] are included in the model.  @ Number of subjects with observed measurements at both baseline and the given visit.  & Number of unique subjects contributing to the model estimates, and it is not visit-specific.  # P-value is based on the paired t-test.  \* P-value <=0.05; \*\* P-value <=0.01; \*\*\* P-value <=0.001. |

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

PRO Variable:

SF-36v2

EQ-5D-3L

EQ-5D-5L

WPAI:SHP

FACIT-FATIGUE

PROMIS-FATIGUE

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

Analysis Population

Full Analysis Set

Intent to Treat Population

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

Methods/Model: examples of methods/model which can share this shell:

MMRM

ANCOVA

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

Comparator

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

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

Treatment Groups

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

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

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

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

Time Points

Baseline visit \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Time point 1 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Time point 2 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Time point 3 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Time point …\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Input methodology corresponding to the symbol $: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# Optional Columns and Rows

Comparison to the reference group (COMP1)

Comparison within group change from baseline (COMP2)

# Special Programming Instructions

Time point can be only one time point, such as analysis by ANCOVA, etc.

The table can have optional rows for postbaseline Time Period Across Time Point T1 to Time Point T2.

Parameters for each PRO that are to be displayed on the table in the order as listed below:

* SF-36v2

Physical Functioning

Role Physical

Bodily Pain

General Health

Vitality

Social Functioning

Role Emotional

Mental Health

Physical Component Summary

Mental Component Summary

EQ-5D-3L and EQ-5D-5L

Health Index Score

VAS Score

WPAI:SHP

Absenteeism

Presenteeism

Work Productivity Loss

Activity Impairment

FACIT-Fatigue

Total Score

PROMIS-Fatigue

Symptom Score

Impact Score

Total Score

*Note: The ordering of parameters is per scoring manuals referenced below and conventions agreed upon with DSS/HEOR Initiative Establishing Scientific Standards for COA Endpoints in AbbVie’s Clinical Trials Sub-Committee on Analysis and Reporting Standards for Commonly Used COA Endpoints.*

|  |  |
| --- | --- |
| Reference | Version Number |
| SF-36v2 User Guide | 3rd Edition |
| EQ-5D-3L User Guide | 6.0 |
| EQ-5D-5L User Guide | 3.0 |
| WPAI Scoring | 2.0 |
| FACIT-Fatigue Subscale Scoring Guidelines | 4.0 |
| PROMIS-Fatigue Scoring Manual | Version dated 28-June-2022 |

# Version History

|  |  |  |
| --- | --- | --- |
| **Version** | **Description** | **Effective Date** |
| 1.0 | Initial version |  |