StaNdard TabLe

T-PRO02: FACIT-Fatigue Item-Level ResponseS by ViSIT

VERSION 1.0

| TABLE 14.2\_\_x.x  FACIT-Fatigue Item-Level Responses by Visit (Analysis Population) | | | | |
| --- | --- | --- | --- | --- |
|  |  | ----------------- Test Treatment ----------------- | | |
| Item  Time point&  Response@ | Control  (N = XXX)  n (%) | Arm 1  (N = XXX)  n (%) | Arm …  (N = XXX)  n (%) | Total  (N = XXX)  n (%) |
|  |  |  |  |  |
| I feel fatigued |  |  |  |  |
|  |  |  |  |  |
| Baseline | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 0 (Not at all) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 1 (A little bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 2 (Somewhat) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 3 (Quite a bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 4 (Very much) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Missing | XX | XX | XX | XX |
|  |  |  |  |  |
| Time point 1 | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 0 (Not at all) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 1 (A little bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 2 (Somewhat) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 3 (Quite a bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 4 (Very much) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Missing | XX | XX | XX | XX |
|  |  |  |  |  |
| Time point 2 | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 0 (Not at all) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 1 (A little bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 2 (Somewhat) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 3 (Quite a bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 4 (Very much) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Missing | XX | XX | XX | XX |
|  |  |  |  |  |
| & The numerator for each time point row is the total number of responses and the denominator is the Analysis Population.  @ The denominator for each response level is the number of non-missing responses at that time point. | | | | |

| TABLE 14.2\_\_x.x  FACIT-Fatigue Item-Level Responses by Visit (Analysis Population) | | | | |
| --- | --- | --- | --- | --- |
|  |  | ----------------- Test Treatment ----------------- | | |
| Item  Time point&  Response@ | Control  (N = XXX)  n (%) | Arm 1  (N = XXX)  n (%) | Arm …  (N = XXX)  n (%) | Total  (N = XXX)  n (%) |
|  |  |  |  |  |
| I feel weak all over |  |  |  |  |
|  |  |  |  |  |
| Baseline | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 0 (Not at all) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 1 (A little bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 2 (Somewhat) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 3 (Quite a bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 4 (Very much) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Missing | XX | XX | XX | XX |
|  |  |  |  |  |
| Time point 1 | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 0 (Not at all) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 1 (A little bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 2 (Somewhat) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 3 (Quite a bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 4 (Very much) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Missing | XX | XX | XX | XX |
|  |  |  |  |  |
| Time point 2 | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 0 (Not at all) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 1 (A little bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 2 (Somewhat) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 3 (Quite a bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 4 (Very much) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Missing | XX | XX | XX | XX |
|  |  |  |  |  |
| & The numerator for each time point row is the total number of responses and the denominator is the Analysis Population.  @ The denominator for each response level is the number of non-missing responses at that time point. | | | | |

| TABLE 14.2\_\_x.x  FACIT-Fatigue Item-Level Responses by Visit (Analysis Population) | | | | |
| --- | --- | --- | --- | --- |
| |  |  | ----------------- Test Treatment ----------------- | | --- | --- | --- | | | | | |
| Item  Time point&  Response@ | Control  (N = XXX)  n (%) | Arm 1  (N = XXX)  n (%) | Arm …  (N = XXX)  n (%) | Total  (N = XXX)  n (%) |
|  |  |  |  |  |
| I feel listless (“washed out”) |  |  |  |  |
|  |  |  |  |  |
| Baseline | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 0 (Not at all) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 1 (A little bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 2 (Somewhat) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 3 (Quite a bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 4 (Very much) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Missing | XX | XX | XX | XX |
|  |  |  |  |  |
| Time point 1 | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 0 (Not at all) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 1 (A little bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 2 (Somewhat) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 3 (Quite a bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 4 (Very much) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Missing | XX | XX | XX | XX |
|  |  |  |  |  |
| Time point 2 | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 0 (Not at all) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 1 (A little bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 2 (Somewhat) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 3 (Quite a bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 4 (Very much) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Missing | XX | XX | XX | XX |
|  |  |  |  |  |
| & The numerator for each time point row is the total number of responses and the denominator is the Analysis Population.  @ The denominator for each response level is the number of non-missing responses at that time point. | | | | |

| TABLE 14.2\_\_x.x  FACIT-Fatigue Item-Level Responses by Visit (Analysis Population) | | | | |
| --- | --- | --- | --- | --- |
|  |  | ----------------- Test Treatment ----------------- | | |
| Item  Time point&  Response@ | Control  (N = XXX)  n (%) | Arm 1  (N = XXX)  n (%) | Arm …  (N = XXX)  n (%) | Total  (N = XXX)  n (%) |
|  |  |  |  |  |
| I feel tired |  |  |  |  |
|  |  |  |  |  |
| Baseline | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 0 (Not at all) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 1 (A little bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 2 (Somewhat) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 3 (Quite a bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 4 (Very much) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Missing | XX | XX | XX | XX |
|  |  |  |  |  |
| Time point 1 | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 0 (Not at all) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 1 (A little bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 2 (Somewhat) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 3 (Quite a bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 4 (Very much) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Missing | XX | XX | XX | XX |
|  |  |  |  |  |
| Time point 2 | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 0 (Not at all) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 1 (A little bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 2 (Somewhat) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 3 (Quite a bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 4 (Very much) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Missing | XX | XX | XX | XX |
|  |  |  |  |  |
| & The numerator for each time point row is the total number of responses and the denominator is the Analysis Population.  @ The denominator for each response level is the number of non-missing responses at that time point. | | | | |

| TABLE 14.2\_\_x.x  FACIT-Fatigue Item-Level Responses by Visit (Analysis Population) | | | | |
| --- | --- | --- | --- | --- |
|  |  | ----------------- Test Treatment ----------------- | | |
| Item  Time point&  Response@ | Control  (N = XXX)  n (%) | Arm 1  (N = XXX)  n (%) | Arm …  (N = XXX)  n (%) | Total  (N = XXX)  n (%) |
|  |  |  |  |  |
| I have trouble starting things because I am tired |  |  |  |  |
|  |  |  |  |  |
| Baseline | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 0 (Not at all) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 1 (A little bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 2 (Somewhat) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 3 (Quite a bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 4 (Very much) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Missing | XX | XX | XX | XX |
|  |  |  |  |  |
| Time point 1 | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 0 (Not at all) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 1 (A little bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 2 (Somewhat) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 3 (Quite a bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 4 (Very much) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Missing | XX | XX | XX | XX |
|  |  |  |  |  |
| Time point 2 | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 0 (Not at all) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 1 (A little bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 2 (Somewhat) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 3 (Quite a bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 4 (Very much) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Missing | XX | XX | XX | XX |
|  |  |  |  |  |
| & The numerator for each time point row is the total number of responses and the denominator is the Analysis Population.  @ The denominator for each response level is the number of non-missing responses at that time point. | | | | |

| TABLE 14.2\_\_x.x  FACIT-Fatigue Item-Level Responses by Visit (Analysis Population) | | | | |
| --- | --- | --- | --- | --- |
|  |  | ----------------- Test Treatment ----------------- | | |
| Item  Time point&  Response@ | Control  (N = XXX)  n (%) | Arm 1  (N = XXX)  n (%) | Arm …  (N = XXX)  n (%) | Total  (N = XXX)  n (%) |
|  |  |  |  |  |
| I have trouble finishing things because I am tired |  |  |  |  |
|  |  |  |  |  |
| Baseline | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 0 (Not at all) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 1 (A little bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 2 (Somewhat) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 3 (Quite a bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 4 (Very much) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Missing | XX | XX | XX | XX |
|  |  |  |  |  |
| Time point 1 | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 0 (Not at all) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 1 (A little bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 2 (Somewhat) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 3 (Quite a bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 4 (Very much) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Missing | XX | XX | XX | XX |
|  |  |  |  |  |
| Time point 2 | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 0 (Not at all) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 1 (A little bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 2 (Somewhat) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 3 (Quite a bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 4 (Very much) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Missing | XX | XX | XX | XX |
|  |  |  |  |  |
| & The numerator for each time point row is the total number of responses and the denominator is the Analysis Population.  @ The denominator for each response level is the number of non-missing responses at that time point. | | | | |

| TABLE 14.2\_\_x.x  FACIT-Fatigue Item-Level Responses by Visit (Analysis Population) | | | | |
| --- | --- | --- | --- | --- |
|  |  | ----------------- Test Treatment ----------------- | | |
| Item  Time point&  Response@ | Control  (N = XXX)  n (%) | Arm 1  (N = XXX)  n (%) | Arm …  (N = XXX)  n (%) | Total  (N = XXX)  n (%) |
|  |  |  |  |  |
| I have energy |  |  |  |  |
|  |  |  |  |  |
| Baseline | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 0 (Not at all) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 1 (A little bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 2 (Somewhat) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 3 (Quite a bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 4 (Very much) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Missing | XX | XX | XX | XX |
|  |  |  |  |  |
| Time point 1 | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 0 (Not at all) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 1 (A little bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 2 (Somewhat) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 3 (Quite a bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 4 (Very much) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Missing | XX | XX | XX | XX |
|  |  |  |  |  |
| Time point 2 | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 0 (Not at all) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 1 (A little bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 2 (Somewhat) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 3 (Quite a bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 4 (Very much) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Missing | XX | XX | XX | XX |
|  |  |  |  |  |
| & The numerator for each time point row is the total number of responses and the denominator is the Analysis Population.  @ The denominator for each response level is the number of non-missing responses at that time point. | | | | |

| TABLE 14.2\_\_x.x  FACIT-Fatigue Item-Level Responses by Visit (Analysis Population) | | | | |
| --- | --- | --- | --- | --- |
|  |  | ----------------- Test Treatment ----------------- | | |
| Item  Time point&  Response@ | Control  (N = XXX)  n (%) | Arm 1  (N = XXX)  n (%) | Arm …  (N = XXX)  n (%) | Total  (N = XXX)  n (%) |
|  |  |  |  |  |
| I am able to do my usual activities |  |  |  |  |
|  |  |  |  |  |
| Baseline | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 0 (Not at all) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 1 (A little bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 2 (Somewhat) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 3 (Quite a bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 4 (Very much) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Missing | XX | XX | XX | XX |
|  |  |  |  |  |
| Time point 1 | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 0 (Not at all) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 1 (A little bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 2 (Somewhat) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 3 (Quite a bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 4 (Very much) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Missing | XX | XX | XX | XX |
|  |  |  |  |  |
| Time point 2 | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 0 (Not at all) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 1 (A little bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 2 (Somewhat) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 3 (Quite a bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 4 (Very much) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Missing | XX | XX | XX | XX |
|  |  |  |  |  |
| & The numerator for each time point row is the total number of responses and the denominator is the Analysis Population.  @ The denominator for each response level is the number of non-missing responses at that time point. | | | | |

| TABLE 14.2\_\_x.x  FACIT-Fatigue Item-Level Responses by Visit (Analysis Population) | | | | |
| --- | --- | --- | --- | --- |
|  |  | ----------------- Test Treatment ----------------- | | |
| Item  Time point&  Response@ | Control  (N = XXX)  n (%) | Arm 1  (N = XXX)  n (%) | Arm …  (N = XXX)  n (%) | Total  (N = XXX)  n (%) |
|  |  |  |  |  |
| I need to sleep during the day |  |  |  |  |
|  |  |  |  |  |
| Baseline | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 0 (Not at all) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 1 (A little bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 2 (Somewhat) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 3 (Quite a bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 4 (Very much) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Missing | XX | XX | XX | XX |
|  |  |  |  |  |
| Time point 1 | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 0 (Not at all) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 1 (A little bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 2 (Somewhat) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 3 (Quite a bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 4 (Very much) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Missing | XX | XX | XX | XX |
|  |  |  |  |  |
| Time point 2 | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 0 (Not at all) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 1 (A little bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 2 (Somewhat) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 3 (Quite a bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 4 (Very much) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Missing | XX | XX | XX | XX |
|  |  |  |  |  |
| & The numerator for each time point row is the total number of responses and the denominator is the Analysis Population.  @ The denominator for each response level is the number of non-missing responses at that time point. | | | | |

| TABLE 14.2\_\_x.x  FACIT-Fatigue Item-Level Responses by Visit (Analysis Population) | | | | |
| --- | --- | --- | --- | --- |
|  |  | ----------------- Test Treatment ----------------- | | |
| Item  Time point&  Response@ | Control  (N = XXX)  n (%) | Arm 1  (N = XXX)  n (%) | Arm …  (N = XXX)  n (%) | Total  (N = XXX)  n (%) |
|  |  |  |  |  |
| I am too tired to eat |  |  |  |  |
|  |  |  |  |  |
| Baseline | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 0 (Not at all) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 1 (A little bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 2 (Somewhat) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 3 (Quite a bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 4 (Very much) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Missing | XX | XX | XX | XX |
|  |  |  |  |  |
| Time point 1 | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 0 (Not at all) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 1 (A little bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 2 (Somewhat) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 3 (Quite a bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 4 (Very much) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Missing | XX | XX | XX | XX |
|  |  |  |  |  |
| Time point 2 | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 0 (Not at all) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 1 (A little bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 2 (Somewhat) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 3 (Quite a bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 4 (Very much) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Missing | XX | XX | XX | XX |
|  |  |  |  |  |
| & The numerator for each time point row is the total number of responses and the denominator is the Analysis Population.  @ The denominator for each response level is the number of non-missing responses at that time point. | | | | |

| TABLE 14.2\_\_x.x  FACIT-Fatigue Item-Level Responses by Visit (Analysis Population) | | | | |
| --- | --- | --- | --- | --- |
|  |  | ----------------- Test Treatment ----------------- | | |
| Item  Time point&  Response@ | Control  (N = XXX)  n (%) | Arm 1  (N = XXX)  n (%) | Arm …  (N = XXX)  n (%) | Total  (N = XXX)  n (%) |
|  |  |  |  |  |
| I need help doing my usual activities |  |  |  |  |
|  |  |  |  |  |
| Baseline | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 0 (Not at all) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 1 (A little bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 2 (Somewhat) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 3 (Quite a bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 4 (Very much) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Missing | XX | XX | XX | XX |
|  |  |  |  |  |
| Time point 1 | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 0 (Not at all) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 1 (A little bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 2 (Somewhat) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 3 (Quite a bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 4 (Very much) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Missing | XX | XX | XX | XX |
|  |  |  |  |  |
| Time point 2 | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 0 (Not at all) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 1 (A little bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 2 (Somewhat) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 3 (Quite a bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 4 (Very much) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Missing | XX | XX | XX | XX |
|  |  |  |  |  |
| & The numerator for each time point row is the total number of responses and the denominator is the Analysis Population.  @ The denominator for each response level is the number of non-missing responses at that time point. | | | | |

| TABLE 14.2\_\_x.x  FACIT-Fatigue Item-Level Responses by Visit (Analysis Population) | | | | |
| --- | --- | --- | --- | --- |
|  |  | ----------------- Test Treatment ----------------- | | |
| Item  Time point&  Response@ | Control  (N = XXX)  n (%) | Arm 1  (N = XXX)  n (%) | Arm …  (N = XXX)  n (%) | Total  (N = XXX)  n (%) |
|  |  |  |  |  |
| I am frustrated by being too tired to do the things I want to do |  |  |  |  |
|  |  |  |  |  |
| Baseline | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 0 (Not at all) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 1 (A little bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 2 (Somewhat) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 3 (Quite a bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 4 (Very much) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Missing | XX | XX | XX | XX |
|  |  |  |  |  |
| Time point 1 | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 0 (Not at all) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 1 (A little bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 2 (Somewhat) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 3 (Quite a bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 4 (Very much) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Missing | XX | XX | XX | XX |
|  |  |  |  |  |
| Time point 2 | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 0 (Not at all) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 1 (A little bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 2 (Somewhat) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 3 (Quite a bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 4 (Very much) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Missing | XX | XX | XX | XX |
|  |  |  |  |  |
| & The numerator for each time point row is the total number of responses and the denominator is the Analysis Population.  @ The denominator for each response level is the number of non-missing responses at that time point. | | | | |

| TABLE 14.2\_\_x.x  FACIT-Fatigue Item-Level Responses by Visit (Analysis Population) | | | | |
| --- | --- | --- | --- | --- |
|  |  | ----------------- Test Treatment ----------------- | | |
| Item  Time point&  Response@ | Control  (N = XXX)  n (%) | Arm 1  (N = XXX)  n (%) | Arm …  (N = XXX)  n (%) | Total  (N = XXX)  n (%) |
|  |  |  |  |  |
| I have to limit my social activity because I am tired |  |  |  |  |
|  |  |  |  |  |
| Baseline | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 0 (Not at all) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 1 (A little bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 2 (Somewhat) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 3 (Quite a bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 4 (Very much) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Missing | XX | XX | XX | XX |
|  |  |  |  |  |
| Time point 1 | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 0 (Not at all) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 1 (A little bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 2 (Somewhat) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 3 (Quite a bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 4 (Very much) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Missing | XX | XX | XX | XX |
|  |  |  |  |  |
| Time point 2 | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 0 (Not at all) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 1 (A little bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 2 (Somewhat) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 3 (Quite a bit) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| 4 (Very much) | XX (XX.X) | XX (XX.X) | XX (XX.X) | XX (XX.X) |
| Missing | XX | XX | XX | XX |
|  |  |  |  |  |
| & The numerator for each time point row is the total number of responses and the denominator is the Analysis Population.  @ The denominator for each response level is the number of non-missing responses at that time point. | | | | |

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

Analysis Population

Full Analysis Set

Intent to Treat Population

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

Treatment Groups

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

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

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

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

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

Time Points

Baseline \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

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

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

# Version History

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