**APPENDIX A**

**Safety Monitoring**

**Table 1. Enrollment by Month of Study**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Month | # Expected | # Screened | # Enrolled or Randomized | # Withdrawn | # Actual  (# Enrolled - # Withdrawn) | # Cumulative  (Sum of # Actual by Month) |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

\*Enrollment can also be displayed graphically in a Figure, with cumulative subject accrual plotted over time.

**Table 2. Demographics**

|  |  |  |
| --- | --- | --- |
| **Characteristics** | **N** | **N%** |
| Gender |  |  |
| Female |  |  |
| Male |  |  |
| Ethnicity |  |  |
| Hispanic or Latino |  |  |
| Not Hispanic or Latino |  |  |
| Unknown |  |  |
| Age |  |  |
| Mean (SE) |  |  |
| Median (min, max) |  |  |
| Race |  |  |
| AIAN |  |  |
| Asian |  |  |
| Nat Hawaiian/Other Pac Islander |  |  |
| Black or African American |  |  |
| White |  |  |
| Other |  |  |
| More than one race |  |  |
| Unknown |  |  |

**Table 3. Subject Status**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Pt Identifier | Date Enrolled | Date Completed Study | Study Status | Reason for Withdrawal | % Adherence to Intervention | Intervention Duration (Weeks) |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

Status:

A = Active

C = Completed

W = Withdrew

L = Lost to follow-up

**Table 4. Adverse Events**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Pt Identifier | AE Onset | AE End | AE Code (MedRA CTCAE) | Severity | SAE? (Y/N) | Related-ness | Action Taken | Outcome | Comments |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |

Severity of AE:                                            Relatedness to Intervention:

1 = Mild                                                       0 = Definitely unrelated

2 = Moderate                                              1 = Unlikely

3 = Severe                                                   2 = Possibly related

4 = Life threatening or disabling                3 = Probably related

4 = Definitely related

Action Taken:

0 = None                                                     Outcome:

1 = Dose modification                                1 = Resolved

2 = Medical intervention                            2 = Recovered with minor sequelae

(specify in comments)                         3 = Recovered with major sequelae

3 = Hospitalization                                      4 = Continuing treatment

4 = Intervention discontinued                    5 = Condition worsening

5 = Other                                                     6 = Patient death\*\*

\*\*Provide further details regarding all reported serious AEs and deaths in the SAE and Subject Deaths tables listed at the end of this section