I-CONECT DSMB Report

# Study Administration Recruitment and Participant Status

**Figure 2a-c: Overall Study Status**

**Figure 3a-c Enrollment: Actual vs. Expected**

**Table 1: Site Enrollment by Period**

**Table 2: Partcipant Enrollment Status**

|  |  |
| --- | --- |
| ps\_stt | n |
| Active | 14 |
| Discontinued | 1 |
| Enrolled | 10 |
| In Screening | 1 |

**Table 3a-b: Participant Enrollment Status by Site**

|  |  |
| --- | --- |
| ps\_stt | n |
| Active | 12 |
| Discontinued | 1 |
| Enrolled | 2 |

|  |  |
| --- | --- |
| ps\_stt | n |
| Active | 2 |
| Enrolled | 8 |
| In Screening | 1 |

**Table 4: Reasons for Screen Failures (Cumulative)**

**Table 5: Main Trial Protocol Deviations**

**Table 6: Main Trial Protocol Deviations by Classification**

**Table 7a-b: Main Trial Protocol Deviations by Site**

**Table 8: Main Trial Demographic and Key Baseline Characteristics**

|  |  |
| --- | --- |
| nac\_sex | n |
| Female | 5 |
| Male | 1 |

|  |  |
| --- | --- |
| nac\_hispanic | n |
| No | 6 |

|  |  |
| --- | --- |
| nac\_race | n |
| Black or African American | 2 |
| White | 4 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Age\_Mean | Age\_Median | Age\_SD | Age\_Min | Age\_Max |
| 80.13333 | 77 | 5.987543 | 75.3 | 89 |