# Figure 1: Enrollment: Overall Study Status

Data as of:

Date of report:

Randomized

n = 22

Enrolled

n = 22

Overall Target Enrollment

n = 80

Screened

n = 30

Excluded (n) = 8

Reason 1 (n) = 5

Reason 2 (n) = 3

**Screened**

= Enrolled + Excluded

**Randomized** = Active +

Discontinued Tx/Follow-up Ongoing + Discontinued Tx/Follow-up Completed + Discontinued from study follow-up not ongoing + Completed

To be randomized

n = 0

Active

n = 10

Completed Protocol

n = 2

Discontinued from Treatment/Follow-up Ongoing

n = 8

Discontinued from

Study/ follow-up not ongoing

n = 2

Reason 1

n = 5

Reason 2

n = 3

Reason 1

n = 1

Reason 2

n = 1

Reason 1 + Reason 2 = **Discontinued from Study**

Reason 1 + Reason 2 =

**Discontinued from Treatment /Follow-up Ongoing and /Follow-up Completed**

Discontinued from treatment/Follow-up completed

n = 0

{Describe where participants are in the study in relation to enrollment milestones, such as the number of participants screened, enrolled, and randomized. For some protocols, it is important to distinguish between participants who withdrew early from the study and those who discontinued treatment but may or may not still be followed.}

Reference: Schulz KF, Altman DG, Moher D, for the CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomized trials. [Ann Int Med 2010;152](http://www.consort-statement.org/index.aspx?o=3444).

# Figure 2: Enrollment: Actual vs. Planned

Aggregate

Data as of:

Date of report:

0

10

20

30

40

50

60

70

Mar-16

Apr-16

May-16

Jun-16

Jul-16

Aug-16

Sep-16

Oct-16

Nov-16

Dec-16

Jan-17

Feb-17

Mar-17

Apr-17

May-17

Jun-17

**Months**

Combined Monthly Enrollment

Combined Target Enrollment

**Participants**

| **Time Period** | **Planned Number of Enrolled Participants (cumulative)** | **Actual Number of Enrolled Participants (cumulative)** | **% Target Enrolled** |
| --- | --- | --- | --- |
| Mar 16 | 5 | 2 |  |
| Apr 16 | 10 | 5 |  |
| May 16 | 15 | 7 |  |
| Jun 16 | **20** | 9 | 25% |
| Jul 16 | 25 | 11 |  |
| Aug16 | 30 | 11 |  |
| Sep 16 | 35 | 16 |  |
| Oct 16 | **40** | 18 | 50% |
| Nov 16 | 45 | 19 |  |
| Dec 16 | 50 | 22 |  |
| Jan 17 | 55 |  |  |
| Feb 17 | **60** |  | 75% |
| Mar 17 | 65 |  |  |
| Apr 17 | 70 |  |  |
| May 17 | 75 |  |  |
| Jun 17 | **80** |  | 100% |
| **Totals** | **80** | **22** |  |

Numbers should be displayed **cumulatively**, adding the number of participants from the previous month(s) to each new row.

{Provide the planned number of cumulative participants by estimated enrollment time period through the end of the expected enrollment period. Provide the actual cumulative enrollment up until the Monitoring Body report closing date. As necessary, customize the X and Y axis categories per the protocol specifications. Depending on the length of study and design, the time points can be equal to days, weeks, months, quarters or years.}

# Table 1: Inclusion Enrollment by Demographics: Actual vs Planned

Data as of:

Date of report:

**TARGET PLANNED ENROLLMENT n:**

**ACTUAL ENROLLMENT n:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Characteristics** | **Target Planned *n[[1]](#footnote-1)\**** | **Target Planned  %****[[2]](#footnote-2)\*\*** | **Actual Enrolled n** | **Actual Enrolled %**\*\* |
| **Sex:** Male |  |  |  |  |
| **Sex:** Female |  |  |  |  |
| **Sex:** Unknown/Not Reported |  |  |  |  |
| **Sex:** Undifferentiated |  |  |  |  |
| **Ethnicity:** Hispanic or Latino |  |  |  |  |
| **Ethnicity:** Not Hispanic or Latino |  |  |  |  |
| **Ethnicity:** Unknown/Not Reported |  |  |  |  |
| **Race:** American Indian/Alaska Native |  |  |  |  |
| **Race:** Asian |  |  |  |  |
| **Race:** Black or African American |  |  |  |  |
| **Race:** Native Hawaiian or Other Pacific Islander |  |  |  |  |
| **Race:** White |  |  |  |  |
| **Race:** More than one race |  |  |  |  |
| **Race:** Unknown//Not Reported |  |  |  |  |

1. \* Insert numbers from target/planned enrollment table submitted with grant application (and entered annually into Human Subjects System (HSS) in eRA Commons). [↑](#footnote-ref-1)
2. \*\* The denominator for the percentage should be the total target number of participants planned to be enrolled. [↑](#footnote-ref-2)