TraCS DSMB

Quarterly Enrollment Report

# REPORT DATE: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_

**Study IRB Number:**

**Study Title:**

Principal Investigator:

Name of Person Submitting Form:

Phone Number and Email Address:

Data reported as of \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_ (date)

1. Please describe the anticipated enrollment timeline and enrollment goals for this study.

2. Please describe the current enrollment situation and if enrollment goals are being met. If accrual or retention rates are insufficient to meet enrollment goals, what actions are in place to increase those rates?

*For the tables below, descriptive text or additional rows may be added describe enrollment trends. This may include defining ‘enrolled’ vs ‘randomized’ vs ‘screened’ based on the study.*

|  |  |
| --- | --- |
| Table 1a:  *Recruitment and Enrollment Summary* | |
|
|  | Study Numbers |
| Total **enrollment** # approved by IRB |  |
| Total # **screened** in the study to date |  |
| Total # **randomized/enrolled** in the study to date |  |
| Total # **screened** in the past year |  |
| Total # **randomized/enrolled** in past year |  |
| Projected # to be **randomized/enrolled** in coming year |  |
| Total # **discontinued** |  |
| Start date for enrollment |  |
| Anticipated stop date for enrollment |  |

*If DSMB review is* ***blinded****, enter numbers in the total column only. If DSMB review is* ***unblinded****, enter numbers under each arm as well as total. Additional columns may be added as needed.*

**Table 1b1: *Subject Disposition* – Since the last report**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Active  (Arm A)  N = # | Placebo  (Arm B)  N = # | Total  N = # |
| **Subject Disposition** |  |  |  |
| Screened (consented) |  |  | # |
| Randomized | # | # | # |
| Currently in trial | # (%) | # (%) | # (%) |
| Completed trial | # (%) | # (%) | # (%) |
| Discontinued trial | # (%) | # (%) | # (%) |

**Table 1b2: *Subject Disposition* – All subjects (to date)**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Active  (Arm A)  N = # | Placebo  (Arm B)  N = # | Total  N = # |
| **Subject Disposition** |  |  |  |
| Screened (consented) |  |  | # |
| Randomized | # | # | # |
| Currently in trial | # (%) | # (%) | # (%) |
| Completed trial | # (%) | # (%) | # (%) |
| Discontinued trial | # (%) | # (%) | # (%) |

Table 1c: *Subject Discontinuations*

|  |  |
| --- | --- |
| *Reasons for Subject Discontinuation* | |
|
|  | Study Numbers |
| Adverse Event(s) |  |
| Subject lost to follow-up |  |
| Subject Non-Compliance |  |
| Serious Adverse Event(s) |  |
| Death |  |
| Other Reasons |  |