Tool Summary Sheet

|  |  |
| --- | --- |
| Tool: | Group Randomized Trial Group Randomized Trial Accrual and Safety Updates Independent Monitoring Meeting Report Form |
| Purpose: | MS Word template to be used as a starting point for a brief accrual and safety update since the previous DSMB report. The Interim Report is to be prepared every 4 months after scheduled DSMB meetings for the trial have taken place. |
| Audience/User: | Statisticians and Principal Investigators responsible for preparation of DSMB reports |
| Details: | This template includes a proposed structure for a DSMB report as well as draft language and other guidance  Delete this Tool Summary Sheet from Interim Report prior to submission |

**DSMB Interim Report Date:**

**Previous DSMB Report Date:**

# Executive Summary of trial status

{Provide a brief summary of trial status and timeline since the previous DSMB Report.}

# Enrollment and Participation Status Updates

{Describe group/clinic enrollment and study participation status, for progress **since the previous DSMB Report**. Provide a summary table (see example below). Provide enrollment statistics by site if the study involves multiple sites.}

Number of anticipated sites:

Number of sites randomized and enrolling participants:

Date participant enrollment began:

**Table #. Enrollment and Participation Status for All Groups/Clinics,**

**since the previous DSMB Report on Date XXXX**

| **Type – N of Clinic (%)** | **Site A**  Cumulative (# since last report) | **Site B**  Cumulative (# since last report) | **Site C**  Cumulative (# since last report) | **Total** Cumulative (# since last report) |
| --- | --- | --- | --- | --- |
| Groups/clinics available |  |  |  |  |
| Consented and Screened |  |  |  |  |
| Eligible |  |  |  |  |
| Randomized |  |  |  |  |
| Number of patients to be enrolled |  |  |  |  |

**Table #. Enrollment Status for All Subjects, by Group/Clinic,**

**since the previous DSMB Report on Date XXXX**

| **Type – N (%)** | **Pre-Screened**  Cumulative (# since last report) | **Consented and Screened**  Cumulative (# since last report) | **Eligible**  Cumulative (# since last report) | **Randomized**  Cumulative (# since last report) | **Completed the Intervention**  Cumulative (# since last report) | **Completed the Follow-up Visits**  Cumulative (# since last report) | **Prematurely Discontinued**  Cumulative (# since last report) |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Clinic 1** |  |  |  |  |  |  |  |
| **Clinic 2** |  |  |  |  |  |  |  |
| **Clinic 3** |  |  |  |  |  |  |  |
| **…** |  |  |  |  |  |  |  |
| **Total** |  |  |  |  |  |  |  |

# Safety Status Updates

{Summarize all serious adverse events (SAEs) that have occurred **since the previous DSMB report**. Extensive listings may be placed in the Appendix.

Sample Tables:}

**Table #. Summary of All Serious Adverse Events for Consented Subjects,**

**since the previous DSMB Report on Date XXXX**

| **Topics -- N (%)** | **Clinic 1**  Cumulative (# since last report) | **Clinic 2**  Cumulative (# since last report) | **Clinic 3**  Cumulative (# since last report) | **Total**  Cumulative (# since last report) |
| --- | --- | --- | --- | --- |
| **Number of SAEs reported** |  |  |  |  |
| **Number of Subjects with SAEs [1]** |  |  |  |  |

**[1] Subjects who experience one or more SAEs are counted only once.**