Tool Summary Sheet

|  |  |
| --- | --- |
| Tool: | Closed Session Independent Monitoring Meeting Report Form |
| Purpose: | MS Word template to be used as a starting point for preparing a DSMB report for closed session |
| Audience/User: | Unblinded Statisticians responsible for preparation of DSMB reports |
| Details: | This template includes a proposed structure for a DSMB closed session report  |
| Best Practice Recommendations: | * Review this template several months prior to the date of the first DSMB meeting, and customize to the specific needs and requirements of the study.
* In the template, the instructions and explanatory text are indicated by {blue italics} Instructional text will also be enclosed in braces to signify this text for screen-readers used by the visually impaired.
* Text enclosed with <> is a placeholder for a specific detail (e.g., <protocol title>); replace as appropriate.
* Delete template-specific instructional text as well as this Tool Summary Sheet during the report development process.
* Leave the template version information in the lower left hand corner of the document.
* It is easiest and cleanest to use the styles that are embedded in the document, rather than to create your own. (In MS Word 2007: From the Home menu, select the bottom right arrow key to bring up the styles box, select “Options”, under “Select Styles to Show” select “in current document”.)
* Ensure that all placeholder and example text is replaced with the study specific information.
 |

**Tool Revision History:**

|  |  |  |
| --- | --- | --- |
| **Version Number** | **Version Date** | **Summary of Revisions Made:** |
| 1.0 |  | First approved version |

## DATA AND SAFETY MONITORING BOARD MEETING REPORT CLOSED SESSION ONLY

|  |  |
| --- | --- |
| Protocol Title: | <Insert title of the protocol> |
| Protocol Number: | <Insert protocol number> |
| Protocol Version: | <Insert version number and date of current protocol> |
| Principal Investigator: | <Name of PIPI’s TitleInstitutionAddress> |
| meeting date: | <Insert date of the scheduled meeting> |
| Date REport Issued: | <Insert date that the report is being issued> |
| Data Cutoff Date: | <Insert the date of the data snapshot for the analyses in this report> |
| Date of last data review: | <Insert date of last DSMB meeting>  |
| prepared by: | <Name of person who prepared the reportPerson’s TitlePlace of employmentAddress> |

Table of Contents

{This table uses the Table of Contents function in Microsoft Word that will automatically update headings and page numbers used in the body of the report. In the body of the report, add, delete, or modify headings as needed in order to best reflect your study.}

[Tool Summary Sheet 1](#_Toc25315518)

[DATA AND SAFETY MONITORING BOARD MEETING REPORT CLOSED SESSION ONLY 2](#_Toc25315519)

[Executive Summary 4](#_Toc25315520)

[1.0 Enrollment Status 6](#_Toc25315521)

[2.0 Subject Status 7](#_Toc25315522)

[3.0 Demographics (and Baseline Characteristics if Appropriate) 8](#_Toc25315523)

[4.0 Protocol Implementation 12](#_Toc25315524)

[4.1 Intervention Adherence 12](#_Toc25315525)

[5.0 Safety 13](#_Toc25315526)

[5.1 Serious Adverse Events 13](#_Toc25315527)

[5.2 Deaths 14](#_Toc25315528)

[5.3 Unanticipated Problems 15](#_Toc25315529)

[5.4 Other Clinical Assessments 15](#_Toc25315530)

[6.0 Quality Management 16](#_Toc25315531)

[7.0 Outcomes Data 16](#_Toc25315532)

Executive Summary

{Add, delete, or modify summary topics as needed.}

|  |  |
| --- | --- |
| **Report Overview** | {Example text:} This closed session report reviews enrollment and safety data available in the study database as of [Month Date, Year], by study intervention. Summary tables are provided in the body of the report. Additional tables and figures referenced in the report are provided in the Appendices.  |
| **Enrollment Status** | {Example text:} * XX subjects have been screened and enrolled for this study.
* XX subjects have been randomized to Intervention Group A; and YY subjects have been randomized to Intervention Group B.
 |
| **Subject Status** | {Example text:} * XX subjects have completed Intervention Session 1. YY of them are in Intervention Group A, and ZZ of them are in Intervention Group B.
* XX subjects have completed the protocol. YY of them are in Intervention Group A, and ZZ of them are in Intervention Group B.
* No treated subjects have been discontinued (withdrawn) from the study.
 |
| **Safety Summary** | {Example text:} * XX serious adverse events have occurred in XX subjects. YY of them are in Intervention Group A, and ZZ of them are in Intervention Group B.
* Of the XX serious adverse events, YY were considered related to study intervention.
 |
| **Protocol Deviations** | {Example text:} * XX protocol deviations associated with XX subjects have been reported.
* None of the deviations has impacted subject safety.
* XX deviations have impacted scientific integrity
 |
| **Quality Management**  | {Example text:}Quality management reviews are performed quarterly and were last completed on [Month Date, Year] and [Month Date, Year].  |

{Add, delete, or modify headings as needed in order to best reflect your study. Place summary tables, listings, and figures within the body of the report; however, if the tables, listings, or figures are long, place them in the Appendices. For small numbers of subjects, listings may be more appropriate than summary tables.}

# Enrollment Status

{This section corresponds to Section 4.0 in the Open Session Report. Describe enrollment and provide a summary table (see example below). Provide enrollment statistics by site if the study involves multiple sites. If the study is enrolling, provide the subject accrual target and estimated time to completion of enrollment. A figure showing expected/planned versus actual enrollment is helpful (see example on next page). For group randomized trial, include group/clinic enrollment status.

Sample Table:}

**Table #. Subject Enrollment Status for All Subjects**

| **Type – N (%)** | **Site A** | **Site B** | **Site C** | **Total** |
| --- | --- | --- | --- | --- |
| Pre-Screened |  |  |  |  |
| Consented and Screened |  |  |  |  |
| Eligible |  |  |  |  |
| **Randomized** |  |  |  |  |
|  **To Intervention Group A** |  |  |  |  |
|  **To Intervention Group B** |  |  |  |  |

{Sample Table for Group Randomized Trial:}

**Table #. Clinic Enrollment Status**

| **Type – Number of Clinics (%)** | **Site A** | **Site B** | **Site C** | **Total** |
| --- | --- | --- | --- | --- |
| Pre-Screened |  |  |  |  |
| Consented and Screened |  |  |  |  |
| Eligible |  |  |  |  |
| **Randomized** |  |  |  |  |
|  **To Intervention Group A** |  |  |  |  |
|  **To Intervention Group B** |  |  |  |  |

# Subject Status

{This section corresponds to Section 5.0 in the Open Session Report. Describe where patients are in the study in relation to major milestones, such as the number of subjects who have completed the baseline visit, the dosing visit, year 1 follow-up, and the final study visit. A summary table providing the study milestones and the number of subjects who have completed those milestones is recommended (see example on the next page). Present results by intervention group, both by site and aggregated.

Also, provide the number of subjects who were terminated and the reason for their termination, such as voluntary withdrawal, death, lost to follow-up, adverse event, or completed the protocol. A summary table of subject disposition is also recommended. For some protocols, it is important to distinguish between subjects who withdrew early from the study and those who discontinued intervention but may or may not still be followed.}

{Sample Tables:}

**Table #. Status of Randomized Subjects, by Intervention Group**

| **Type – N (%)** | **Intervention Group A** | **Intervention Group B** | **Total** |
| --- | --- | --- | --- |
| On Study  Number of Doses or Intervention Sessions |  |  |  |
|  1 |  |  |  |
|  2 |  |  |  |
|  3 |  |  |  |
| Completed the Intervention |  |  |  |
| Completed the Follow-up Visits |  |  |  |
| Prematurely Discontinued |  |  |  |

**Table #. Status of Randomized Subjects, by Intervention Group and Site**

| **Type – N (%)** | **Intervention Group A** | **Intervention Group B** | **Total** |
| --- | --- | --- | --- |
| **Site A** |
| On Study  Number of Doses or Intervention Sessions |  |  |  |
|  1 |  |  |  |
|  2 |  |  |  |
|  3 |  |  |  |
| Completed the Intervention |  |  |  |
| Completed the Follow-up Visits |  |  |  |
| Prematurely Discontinued |  |  |  |
| **Site B** |
| On Study  Number of Doses or Intervention Sessions |  |  |  |
|  1 |  |  |  |
|  2 |  |  |  |
|  3 |  |  |  |
| Completed the Intervention |  |  |  |
| Completed the Follow-up Visits |  |  |  |
| Prematurely Discontinued |  |  |  |

# Demographics (and Baseline Characteristics if Appropriate)

{This section corresponds to Section 6.0 in the Open Session Report. Describe the demographic characteristics (age, race, and ethnicity) and key baseline characteristics of enrolled subjects (if appropriate). Provide summary tables by intervention, both by site and aggregated. Include key clinic characteristics for group randomized trial.

{Sample Tables:}

**Table #. Baseline Patient Characteristics, by Intervention Group**

| **Patient Characteristics**  | **Intervention Group A** | **Intervention Group B** | **Total** |
| --- | --- | --- | --- |
|  Age, mean (SD) |  |  |  |
|  Gender – Female, N (%) |  |  |  |
|  Race, N (%) |  |  |  |
|  Ethnicity, N(%) |  |  |  |
|  Baseline health conditions, including measures of pain and/or function |  |  |  |
|  Baseline comorbid conditions, including substance use  |  |  |  |

{Sample Table for Group Randomized Study Only:}

**Table #. Baseline Patient and Clinic Characteristics, by Intervention Group**

| **Patient Characteristics**  | **Intervention Group A** | **Intervention Group B** | **Total** |
| --- | --- | --- | --- |
|  Age, mean (SD) |  |  |  |
|  Gender – Female, N (%) |  |  |  |
|  Race, N (%) |  |  |  |
|  Ethnicity, N(%) |  |  |  |
|  Baseline health conditions, including measures of pain and/or function |  |  |  |
|  Baseline comorbid conditions, including substance use |  |  |  |
| **Clinic Characteristics** |  |  |  |
|  Number of participating primary care providers at clinic, mean (SD) |  |  |  |
|  Clinic location/type |  |  |  |

{A CONSORT flow diagram for individual randomized trials1 or for group randomized trials2 can also be included to summarize enrollment and patient participation progress.}

1. Moher D, Schulz KF, Altman D. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomized trials. JAMA 2001;285:1987-91.
2. Campbell MK, Piaggio G, Elbourne DR, Altman DG; for the CONSORT Group. Consort 2010 statement: extension to cluster randomised trials. BMJ. 2012 Sep 4;345:e5661. [PMID: 22951546](http://www.ncbi.nlm.nih.gov/pubmed?term=22951546)

{Sample Diagram for individual randomized trials:}

**Enrollment**

Allocated to intervention (n= )

 Received allocated intervention (n= )

 Did not receive allocated intervention (give reasons) (n= )

Allocated to intervention (n= )

 Received allocated intervention (n= )

 Did not receive allocated intervention (give reasons) (n= )

Analysed (n= )
 Excluded from analysis (give reasons) (n= )

Analysed (n= )
 Excluded from analysis (give reasons) (n= )

Analysis

Lost to follow-up (give reasons) (n= )

Discontinued intervention (give reasons) (n= )

Lost to follow-up (give reasons) (n= )

Discontinued intervention (give reasons) (n= )

Allocation

Follow-Up

Randomized (n= )

Excluded (n= )

  Not meeting inclusion criteria (n= )

  Declined to participate (n= )

  Other reasons (n= )

Assessed for eligibility (n= )

{Sample Diagram for group randomized trials:}

Analysis

Allocated to intervention (n= No. of clusters)

 Received allocated intervention

* n= No. of clusters
* Average cluster size, variance of cluster sizes
* Total No. of patients screened, eligible, and enrolled

 Did not receive allocated intervention (give reasons) (n= No. of clusters )

Lost to follow-up (give reasons) (n= No. of clusters, average cluster size, variance of cluster sizes )

Discontinued intervention (give reasons) (n= No. of clusters, average cluster size, variance of cluster sizes )

Analysed (n= No. of clusters, average cluster size, variance of cluster sizes )
 Excluded from analysis (give reasons) (n= No. of clusters, average cluster size, variance of cluster sizes )

Allocated to intervention (n= No. of clusters)

 Received allocated intervention

* n= No. of clusters
* Average cluster size, variance of cluster sizes
* Total No. of patients screened, eligible, and enrolled

 Did not receive allocated intervention (give reasons) (n= No. of clusters )

Lost to follow-up (give reasons) (n= No. of clusters, average cluster size, variance of cluster sizes )

Discontinued intervention (give reasons) (n= No. of clusters, average cluster size, variance of cluster sizes )

Analysed (n= No. of clusters, average cluster size, variance of cluster sizes )
 Excluded from analysis (give reasons) (n= No. of clusters, average cluster size, variance of cluster sizes )

Follow-Up

Randomized (n= No. of clusters )

Assessed for eligibility (n= No. of clusters )

**Enrollment**

Allocation

Excluded (n= No. of clusters )

  Not meeting inclusion criteria (n= No. of clusters )

  Declined to participate (n= No. of clusters )

  Other reasons (n= No. of clusters)

# Protocol Implementation

## Intervention Adherence

*{ This section corresponds to Section 7.1 in the Open Session Report.Summarize intervention adherence, including number of doses/intervention sessions completed and missed. Separte reports by intervention groups. Active Intervention and Control Groups may have different measures of intervention (see sample tables on the next page). Group randomized studies may report adherence measures by clinic.*

Sample Tables:}

**Table #. Intervention Adherence, Active Intervention Group**

| **Adherence Assessment – N (%)** | **Site A** | **Site B** | **Site C** | **Total** |
| --- | --- | --- | --- | --- |
|  Attended XX or more sessions |  |  |  |  |
|  Attended less than XX sessions |  |  |  |  |
|  Loss to follow up |  |  |  |  |
| Overall adherence  |  |  |  |  |
| Reasons for non-adherence |  |  |  |  |

**Table #. Intervention Adherence, Control Group**

| **Adherence Assessment – N (%)** | **Site A** | **Site B** | **Site C** | **Total** |
| --- | --- | --- | --- | --- |
|  Service referal |  |  |  |  |
|  Service completion |  |  |  |  |
|  Loss to follow up |  |  |  |  |
| Overall adherence  |  |  |  |  |
| Reasons for non-adherence |  |  |  |  |

{Sample Tables for Group Randomized Trial:}

**Table #. Intervention Adherence, Active Intervention Group**

| **Adherence Assessment – N (%)** | **Clinic 1** | **Clinic 2** | **Clinic 3** | **Total** |
| --- | --- | --- | --- | --- |
|  Attended XX or more sessions |  |  |  |  |
|  Attended less than XX sessions |  |  |  |  |
|  Loss to follow up |  |  |  |  |
| Overall adherence  |  |  |  |  |
| Reasons for non-adherence |  |  |  |  |

**Table #. Intervention Adherence, Control Group**

| **Adherence Assessment – N (%)** | **Clinic 1** | **Clinic 2** | **Clinic 3** | **Total** |
| --- | --- | --- | --- | --- |
|  Service referal |  |  |  |  |
|  Service completion |  |  |  |  |
|  Loss to follow up |  |  |  |  |
| Overall adherence  |  |  |  |  |
| Reasons for non-adherence |  |  |  |  |

# Safety

## Serious Adverse Events

{ This section corresponds to Section 8.2 in the Open Session Report. Summarize all serious adverse events (SAEs) that have occurred since the previous DSMB report and over the course of the trial. Provide information by intervention group, on relatedness to treatment and study procedures (see an example of a summary table below). Provide information on expedited reports, and include MedWatch forms in the Appendix if applicable. In addition, a summary table of subjects experiencing adverse events by treatment group, system organ class, and preferred term should be considered. Extensive listings may be placed in the Appendix

Sample Tables:}

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

| **Topics -- N (%)** | **Intervention Group A** | **Intervention Group B** | **Total** |
| --- | --- | --- | --- |
| **Number of SAEs reported** |  |  |  |
| **Number of Subjects with SAEs [1]** |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Number of SAEs by Relatedness to Intervention\*** | **Intervention Group A** | **Intervention Group B** | **Total** |
|  Not Related |  |  |  |
|  Related |  |  |  |
| Possible |  |  |  |
| Probable |  |  |  |
| Definite |  |  |  |
| **Subjects with SAEs by Relatedness to Intervention [2]\*\*** | **Intervention Group A** | **Intervention Group B** | **Total** |
|  Not Related |  |  |  |
|  Related |  |  |  |
| Possible |  |  |  |
| Probable |  |  |  |
| Definite |  |  |  |

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

**[2] Subjects are counted only once within a particular severity grade or relatedness category.**

**\* Percentages are based on number of SAEs reported for each intervention group.**

**\*\* Percentages are based on N for each intervention group.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Number of SAEs by System Organ Class (SOC) and Preferred Term** | **Intervention Group A** | **Intervention Group B** | **Total** |
|  SOC 1 |  |  |  |
|  Preferred Term 1 |  |  |  |
|  Preferred Term 2 |  |  |  |
|  SOC 2 |  |  |  |
|  Preferred Term 1 |  |  |  |
|  Preferred Term 2 |  |  |  |
|  ……… |  |  |  |

## Deaths

{ This section corresponds to Section 8.3 in the Open Session Report. Summarize any deaths that have occurred since the previous DSMB report and over the course of the study, by intervention group.

Sample Table:}

**Table #. Summary of Deaths, by Intervention Group**

| **Death**  | **Intervention Group A** | **Intervention Group B** | **Total** |
| --- | --- | --- | --- |
|  N (%) |  |  |  |
|  Age, mean (SD) |  |  |  |
|  Gender – Female, N (%) |  |  |  |
|  Race, N (%) |  |  |  |
|  Ethnicity, N(%) |  |  |  |
|  Relatedness to Intervention – Yes, N(%) |  |  |  |

## Unanticipated Problems

{ This section corresponds to Section 8.4 in the Open Session Report. Summarize or list unanticipated problems, by intervention group. The Office for Human Research Protections (OHRP) considers unanticipated problems, in general, to include any incident, experience, or outcome that meets all of the following criteria:

1. Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB approved research protocol and informed consent document, and (b) the characteristics of the subject population being studied;

2. Related or possibly related to participation in the research (in this guidance document, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

3. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

OHRP notes that an incident, experience, or outcome that meets the three criteria above generally will warrant consideration of substantive changes in the research protocol or informed consent process/document or other corrective actions in order to protect the safety, welfare, or rights of subjects or others.}

## Other Clinical Assessments

{You may list types of tests, such as laboratory findings, imaging or physical examinations, as separate headings, by intervention group.

Summarize any other clinical assessments that are being monitored for subject safety. Results may be presented as summary tables, listings by subject, or plots. Depending on the study, identify by subject any significant changes from baseline, results that are clinically significant, or results that are considered adverse events.}

# Quality Management

*{Provide details regarding quality management activities completed since the last DSMB review, including frequency.  Summarize or list findings and identify measures or corrective actions taken to address the findings or issues, by intervention group.}*

# Outcomes Data

{As a general rule, interim results should not be performed or presented unless interim analyses are described in the protocol or the DSMB has requested an interim analysis to assess a safety concern or study futility. The decision whether or not to present interim or final results in this report, or to present results in an open or closed session, should be discussed with the DSMB and the study sponsor.}