# Tool Summary Sheet: DSMB Final Study Report Template

Purpose: MS Word template to be used as a starting point for preparing the final Data and Safety Monitoring Board (DSMB) report associated with a completed or terminated study

## Audience/User

Statisticians and Principal Investigators responsible for preparation of final DSMB reports

## Details

This template includes a proposed structure for a DSMB final report as well as draft language and other guidance

## Best Practice Recommendations

* Customize this template to the specific needs and requirements of the study.
* This template does not include a Table of Contents. You may choose to add one if your report includes additional sections or appendices.

## Technical/Formatting Notes

* Instructions and explanatory text are indicated by *{blue italics}* (“CROMS\_Instruction” style). 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.
* Sample text is provided for reference only. Ensure that all placeholder and example text is replaced with the study-specific information.
* It is easiest and cleanest to use the styles that are embedded in the document. (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”.)
* Retain the template version information in the lower left hand corner of the document.

## Tool Revision History:

### Version

| **Number** | **Date** | **Summary of Revisions Made:** |
| --- | --- | --- |
| 1.0 | 31Jul2013 | First approved version. |
| 2.0 | 21Apr2014 | Added Protocol Version to cover page and QM Section to Executive Summary. |
| 3.0 | 30Aug2018 | Reformatted TSS; added fields to tables; updated instructional and sample text; revised subject to participant. |

# Data and Safety Monitoring Board Final Study Report

|  |  |
| --- | --- |
| Protocol Title: | <Insert title of the protocol> |
| Protocol Number: | <Insert protocol number> |
| Protocol Version: | <Insert version number and date of current protocol> |
| Grant number: | <Insert grant number> |
| Principal Investigator: | <Name of PI PI’s Title Institution Address> |
| 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 report Person’s Title Place of employment Address> |

# Protocol Synopsis

|  |  |
| --- | --- |
| Protocol Title | <Insert protocol title> |
| Principal Investigator | <Insert name of Principal Investigator> |
| Study Sites | <List name of each study site> |
| Planned Accrual | <Insert planned number of participants to be enrolled> |
| Planned Accrual Period | <Insert time (months, years, etc.)> |
| Planned Duration | <Insert time from first participant-first visit to last participant-last visit (months, years, etc.)> |
| Study Design | <Briefly describe study design> |
| Study Objectives | <Briefly describe study objectives> |
| Treatment Description | <Briefly describe study treatment(s)> |
| Inclusion Criteria | <List inclusion criteria> |
| Exclusion Criteria | <List exclusion criteria> |
| Study Outcomes | <Briefly describe study outcomes> |
| Study Stopping Rules <or Halting Rules or Suspension Guidelines> {Use terminology that matches the protocol} | <Clarify stopping rules or suspension guidelines> |

# Executive Summary: Final Study Disposition

|  |  |
| --- | --- |
| Report Overview | {Example text:}  This is to inform the DSMB of the final disposition of this <select one: completed or terminated> study. |
| Study Activation Date | <Insert activation date of first site> |
| Study Close-out Date | <Insert date of study close-out or note projected date> |
| Database Lock Date | <Insert date of database lock or note projected date> |
| Study Site Status | {Provide site-specific status information, including by-site information about sample processing and analysis, if applicable. Provide an update on notifications sent to Institutional Review Board (IRB) per institutional reporting policies.  Example text:}  All sites completed participant recruitment and all study visits. Each site has processed all biospecimens and <shipped or stored> according to protocol.  Study close-out activities have <begun or been completed>. Study files are completed and up-to-date, and maintained in the study binder per the records retention policy. A final report has been submitted to the IRB and the study status has been updated from Active to Completed. |
| Enrollment and Completion Status | {Provide detailed information about number enrolled and percent of target enrollment. If appropriate, include the same information for retention (e.g., clarify reasons for withdrawal/discontinuation). Specify study groups, if relevant, (e.g., case-control or adult-child). Provide details about whether a final letter will be sent to the participants with study findings.  Example text:}  500 participants, 400 cases and 100 controls, were enrolled. 488 participants (393 cases and 95 controls) completed the final 6 month study visits.  Of those who did not complete the study, 3 participants were lost to follow-up; 8 participants withdrew consent; and 1 participant moved out of the area.  All participants who completed the study will receive a letter summarizing initial study findings and results. |
| Stopping Rules  <or Halting Rules or Suspension Guidelines> {Use terminology that matches the protocol} | {Provide information about any stopping rules met or Alerts issued, or state that there were none.  Example text:}  No stopping rules were met during the course of the study.  Or  There were no ‘Alerts’ issued during the course of the study. |
| Safety Summary | {Example text:}  One serious adverse event occurred on the study: severe skin reaction to betadine used during a study visit that resulted in hospitalization. This allergy had not been previously diagnosed. This was also considered to be an unanticipated problem. This event was previously reported to the DSMB.  All adverse events (both serious and non-serious) have been recorded and followed up to resolution in accordance with procedures detailed in the protocol. All serious adverse events (SAEs) and unanticipated problems (UPs) have been reported to the DSMB, Medical Monitor, Institute, IRB, and other organizations, as specified in the protocol and Data and Safety Monitoring Plan (DSMP). |
| Protocol Deviations | {Summarize overall protocol deviations and those since the last DSMB meeting. Note any important events or trends that impact the interpretability of the study data.  Example text:}  A total of 15 protocol deviations occurred in this study, 3 since the last DSMB report. No deviations affected participant safety or the interpretability of the study data. |
| Quality Management | {Example text:}  Quality management reviews were performed quarterly and were last completed on July 8, 2017 and October 7, 2017. |
| Plans for Publication | {Briefly describe plans for publication of the trial results. Describe if any publications/manuscripts have been submitted and/or accepted.} |
| Final Comments | {Optional section for any final remarks or observations, including timelines to completion, disposition of any remaining safety issues, non-specific future plans for investigational product (IP) or follow-up studies, etc. Delete this row if not applicable.} |