**Tool Summary Sheet**

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| **Tool:** | DSMB Final Study Report Template |
| **Purpose:** | MS Word template to be used as a starting point for preparing the final DSMB report associate 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. * In the template, the 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. * 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:**

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| --- | --- | --- |
| **Version Number** | **Version 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. |

**Data AND Safety Monitoring Board**

**FINAL STUDY Report**

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| --- | --- |
| 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 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

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| --- | --- |
| Protocol Title | <Insert protocol title> |
| Principal Investigator | <Insert name of Principal Investigator> |
| Study Sites | <List name of each study site> |
| Study Activation Date | <Insert activation date of first 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

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| --- | --- |
| **Report Overview** | {Example text:}  This is to inform the DSMB of the final disposition of this <select one: completed or terminated> study. |
| **Study Site Status** | {Provide site-specific status information, including by-site information about sample processing and analysis, if applicable.  Example text:}  All sites completed subject recruitment and all study visits. Each site has processed all biospecimens and <shipped or stored> according to protocol. |
| **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).  Example text:}  500 participants, 400 cases and 100 controls, were enrolled. 488 subjects (393 cases and 95 controls) completed the final 6 month study visits.  Of those who did not complete the study, 3 subjects were lost to follow-up; 8 subjects withdrew consent; and 1 subject moved out of the area. |
| **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. |
| **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 subject 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, 2013 and October 7, 2013. |
| **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 IP or follow-up studies, etc. Delete this row if not applicable.} |