Report for the Data and Safety Monitoring Board

NAME SHORT - NAME LONG

DATE

Report Number:

PROTOCOL TITLE	xxx
PROTOCOL NUMBER	xxx
PROTOCOL VERSION	xxx
COORDINATING PRINCIPAL INVESTIGATORS	xxx
MEETING DATE	xxx
DATE REPORT	xxx
DATA CUTOFF DATE	xxx
DATE OF LAST DATA REVIEW	xxx
PREPARED BY	xxx

Contents

1 Executive Summary

REPORT OVERVIEW	This report reviews enrolment and safety data available in the study database as of xxxx.Summary tables are provided in the body of the report.Additional tables and figures referenced in the report are provided in the Appendices.
STUDY SITE STATUS	Two of the 3 planned study sites have been activated.
ENROLLMENT STATUS	xxx subjects have been screened and xxx have been randomised.
SUBJECT STATUS	Of the xxx participants randomised, xx are no longer continuing. X withdrew, X died.
STOPPING RULES	No stopping rules have been met
SAFETY SUMMARY	No serious adverse events have occurred. xxx adverse events occurred.
PROTOCOL DEVIATIONS	xxx deviations have occurred. The reasons relate to...
QUALITY MANAGEMENT	Quality checks performed....

2 Protocol Synopsis

TITLE	xxx
BACKGROUND	xxx
PRIMARY OUTCOME	xxx
SECONDARY OUTCOMES	1. Outcome 1 2. Outcome 2
STUDY DESIGN	xxx
INTERVENTIONS	Domain A: 1. Control - 2. Intervention - Domain B: 1. Control - 2. Intervention -
STUDY DURATION	xxx
SAMPLE SIZE	xxx
INCLUSION CRITERIA	1. Criteria 1 2. Criteria 2
EXCLUSION CRITERIA	1. Criteria 1 2. Criteria 2
BLINDING	xxx
RANDOMISATION	xxx
ANALYSIS	xxx

3 Report Overview

The purpose of this report is to review cumulative enrolment, data quality, and safety data for the subjects enrolled in the ASCOT study. This report reflects data from the study database as of [DATE]. Within the body of the report are summary tables of enrolment, demographic characteristics, and adverse events. Additional tables, listings, and figures referenced in this report are provided in Appendices. There have been [Insert number of meetings] DSMB meetings for this study, and the last review was on [DATE].

Summarise what the recommendations regarding the trial were following the last DSMB meeting.

Readers of this report are asked to maintain the confidentiality of the information provided in this report.

4 Response to DSMB Recommendations

Identify DSMB recommendations/requests from the last meeting and clarify how those requests have been handled in the report and/or elsewhere. If this is the first DSMB meeting for this protocol or no previous recommendations/requests were made, indicate as such in this section. Doing so will provide a future reminder to the author who is likely to use the previous report as a starting point for the subsequent report.

5 Enrolment Status

Describe enrolment and provide a summary table (see example below). Provide enrolment 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 enrolment. A figure showing expected/planned versus actual enrolment may be helpful (see example on next page).

FLOWCHART

CUMULATIVE ENROLMENT OVER TIME

ENROLMENT BY STUDY SITE

6 Participant Status

Describe where patients are in the study in relation to major milestones, such as the number of subjects who have completed day 1, the number on treatment, completed day 28, and the final study visit. A summary table providing the study milestones and the number of subjects who have completed those milestones is recommended. 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.

It is important to distinguish between subjects who withdrew early from the study and those who discontinued treatment but may or may not still be followed-up.

7 Demographics

Describe the demographic characteristics (age, gender and ethnicity) and key baseline characteristics of enrolled subjects (if appropriate). Provide a summary table or a listing of the data. Listings are preferable over summary tables if only a few subjects have been enrolled. However, avoid listing any information that could potentially lead to the identification of a participant.

8 Safety

8.1 Adverse Events

Summarize or list the adverse events (AEs) that have occurred since the previous DSMB report and over the course of the trial. Provide information on severity and relatedness to treatment and study procedures (see an example of a summary table below). Please ensure that categories summarized match those in the protocol. For instance related/unrelated vs. the 5 category delineation.

If closed report, stratify by treatment group.

Table 5: Adverse events listing. AE's occurring since last DMSB report highlighted. SAE's italicised.

Participant ID	Diagnosis	Event	Date	Serious	Severity	Outcome	Relatedness
Sxxxxx				No	Mild	Unresolved	Unrelated
Sxxxxx				No	Moderate	Resolved	Possible
Sxxxxx				*Yes*	*Severe*	*Resolved*	*Definite*

8.2 Serious Adverse Events

Summarize or list all serious adverse events (SAEs) that have occurred since the previous DSMB report and over the course of the trial.

Participant ID	Diagnosis	Event	Date	Severity	Outcome	Relatedness
Sxxxxxx				Severe	Resolved	Definite

Table 4: Summary of adverse events (AEs).

	Treatment A	Treatment B	Total
Total	15	16	31
Number of AEs by severity			
Mild	10	10	20
Moderate	5	5	10
Severe	0	1	1
Number of AEs by relatedness			
Unrelated	10	10	20
Unlikely	5	5	10
Possible	0	0	0
Probable	0	0	0
Definite	0	1	1

9 Outcomes

9.1 Primary Outcome

9.2 Secondary Outcomes

9.3 Safety Outcomes

Appendix A: Additional Figures

Appendix B: Additional Documentation