DSMB Report Template
-Closed Session-

For Single-Site Studies

Title Page

(Title of Study, PI)

Table of Contents

*** Please note that the tables are numbered based on the corresponding Open session tables for consistency. Only tables that are applicable to Closed session need to be included here. The final format of the reports, tables, and listings are to be determined by the Data and Safety Monitoring Board.**

Closed Session Report Summary

Study Administration

Recruitment and Participant Status:

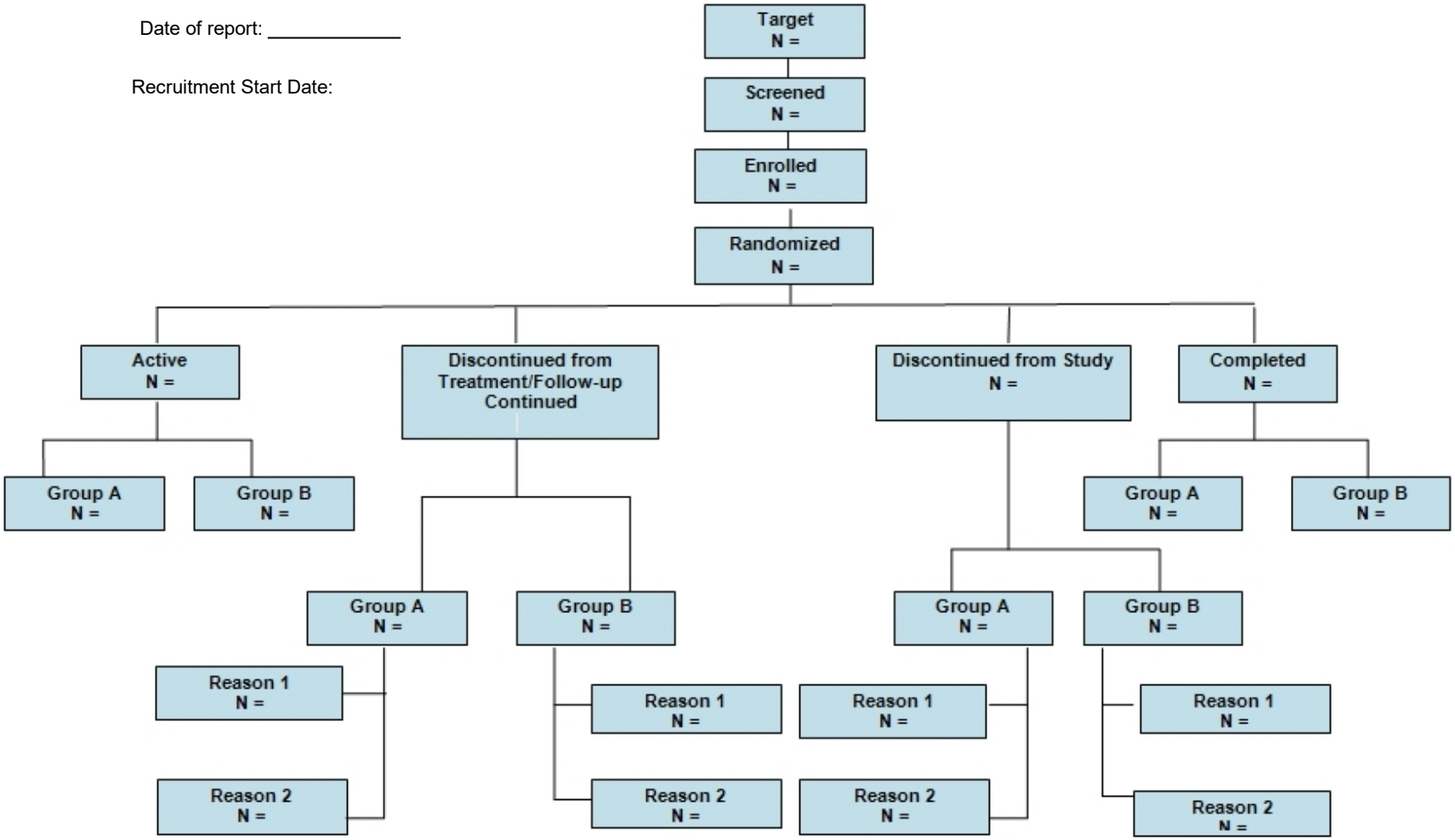
Figure and Tables

Figure 1: Overall Study Status by Treatment Group

Data as of: _____

Date of report: _____

Recruitment Start Date:



Study Name:

Principal Investigator:

Table 4: Demographic and Key Baseline Characteristics by Group

Data as of:_____

Date of report:_____

Characteristics		Group A n (%)	Group B n (%)	Total N
	Total Enrolled:			
Gender	Male			
	Female			
Ethnicity	Hispanic or Latino			
	Not Hispanic or Latino			
	Unknown or not reported			
Race	American Indian/Alaska Native			
	Asian			
	Black or African American			
	Native Hawaiian or Other Pacific Islander			
	White			
	More than one race			
	Unknown or not reported			
Clinical Features/ Stratification	BMI ≥ 30*			
Age	Mean			
	Median			
	Standard Deviation			
	Minimum			
	Maximum			

** This is an example, needs to be protocol specific.*

Study Name:

Principal Investigator:

Table 5: Treatment Duration for All Participants

Data as of:_____

Date of report:_____

Time in Study* Total N=	Group A n	Group A %	Group B n	Group B %	Total
Visit 1					
Visit 2					
Visit 3					
Visit 4					
Completed Study					

** Needs to be protocol specific and can be shown by visits, days, weeks, months, or treatment periods. Final format is determined by DSMB.*

Safety Assessments:

Tables and Listings

Study Name:

Principal Investigator:

Table 6: Incidence of Adverse Events by Body System, Preferred Term and Treatment Group

Data as of:_____
Date of report:_____

Body System and Preferred Term	Group A N=n*	Group A N=%**	Group A N=Events***	Group B N=n*	Group B N=%**	Group B N=Events***
Overall						
Cardiovascular						
Myocardial Infarction						
Increased Blood Pressure						
etc.						
Genitourinary						
Yeast Infection						
Vaginal Bleeding						
etc.						
Gastrointestinal						
etc….						

* *Number of participants experiencing an adverse event (participant is to be counted only once for each adverse event) in a treatment group*
** *% of total number of participants in the study*
*** *Number of events*
This table can present overall incidence of adverse events as shown above; or adverse events related to the intervention as judged by the investigator; or treatment emergent events.

Table 7: Severity of Adverse Events by Preferred Term and Treatment Group

Study Name:

Principal Investigator:

Data as of:_____

Date of report:_____

Preferred Term*	Group A N=Mild n** (%)***	Group A N=Moderate n (%)	Group A N=Severe n (%)	Group B N=Mild n** (%)***	Group B N=Moderate n (%)	Group B N=Severe n (%)
Headache						
Pain						
etc.						

* *For each preferred term, sort by most common event in descending order of incidence.*

** *Number of participants experiencing a certain severity of an adverse event where participant is counted only once at highest level of severity for the event.*

*** *% of participants experiencing a certain severity of an adverse event within Treatment Group.*

This table can present severity of all adverse events sorted by preferred term in descending order of incidence as shown above; or adverse events related to the intervention as judged by the investigator; or treatment emergent events.

Study Name:

Principal Investigator:

Listing 1: Serious Adverse Events by Treatment Group

Data as of:_____

Date of report:_____

Treatment Group	Participant ID	Onset Date	Stop Date	Expected (Y/N)	Relationship to Intervention* (Y/N)	Outcome**	Description of SAE

* *Definite, Possible, Not Related*

** *Outcome:*

Recovered, without treatment
Recovered, with treatment
Still Present, no treatment
Still Present, being treated
Residual effect(s) present – no treatment
Residual effect(s) present- being treated
Subject died

Study Name:

Principal Investigator:

Listing 2: Deaths by Treatment Group

Data as of:_____

Date of report:_____

Treatment Group	Participant ID	Date of Death	Cause of Death	Relationship to Intervention*

** Definite, Possible, Not Related*

Study Name:

Principal Investigator:

Listing 3: Adverse Events by Treatment Group*

Data as of:_____

Date of report:_____

Treatment Group	Participant ID	Days on Intervention	Preferred Term	Relationship to Intervention**	Severity	Serious (Y/N)	Outcome***

* *This listing can be sorted by Treatment Group or by Preferred Term.*
** *Definite, Possible, Not Related*
*** *Outcome:*
Recovered, without treatment
Recovered, with treatment
Still Present, no treatment
Still Present, being treated
Residual effect(s) present – no treatment
Residual effect(s) present- being treated
Subject died

Study Name:

Principal Investigator:

Table 8a: Laboratory Test Results Summary Treatment Group A*

Data as of:_____

Date of report:_____

								----------Change from Baseline----------					
Laboratory Test	**Sample Study Visits**	**N**	**Mean**	**SD**	**Min**	**Median**	**Max**	**N**	**Mean**	**SD**	**Min**	**Median**	**Max**
Test 1	Screening												
	6 Months												
	12 Months												
	24 Months												
	36 Months												
Test 2	Screening												
	6 Months												
	12 Months												
	24 Months												
	36 Months												
Etc…	Screening												
	6 Months												
	12 Months												
	24 Months												
	36 Months												

* *Table can include lab test results that are clinically significant, as defined by the protocol, or ALL lab test results. Final format is determined by the DSMB*

Study Name:

Principal Investigator:

Table 8b: Laboratory Test Results Summary Treatment Group B*

Data as of:_____

Date of report:_____

								----------Change from Baseline---------					
Laboratory Test	**Sample Study Visits**	**N**	**Mean**	**SD**	**Min**	**Median**	**Max**	**N**	**Mean**	**SD**	**Min**	**Median**	**Max**
Test 1	Screening												
	6 Months												
	12 Months												
	24 Months												
	36 Months												
Test 2	Screening												
	6 Months												
	12 Months												
	24 Months												
	36 Months												
Etc…	Screening												
	6 Months												
	12 Months												
	24 Months												
	36 Months												

* *Table may include lab test results that are clinically significant, as defined by the protocol, or ALL lab test results. Final format is determined by the DSMB*

Study Name:

Principal Investigator:

Listing 4: Clinically Significant Abnormal Lab Values

Data as of:_____

Date of report:_____

Treatment Group	Participant ID	Visit	Age	Gender	Lab Panel	Lab Test	Result