DSMB Report Template
-Open Session-

For Multi-Site Studies

Title Page

(Title of the Study, PI)

Table of Contents

*** The final format of the reports, tables, and listings are to be determined by the Data and Safety Monitoring Board.**

Report Summary

Protocol Synopsis

Project Organizational Chart, Personnel

Brief Statement of Purpose of Trial

Projected Timetable and Schedule

List of Participating Clinics, Data Centers, Resource Centers

Narrative/Trial Summary

Study Status

Summary of Past DSMB Meetings

Action Items

Resolution of Action Items

Summary of Protocol Changes

Study Administration

Recruitment and Participant Status:

Figures and Tables

Study Name:

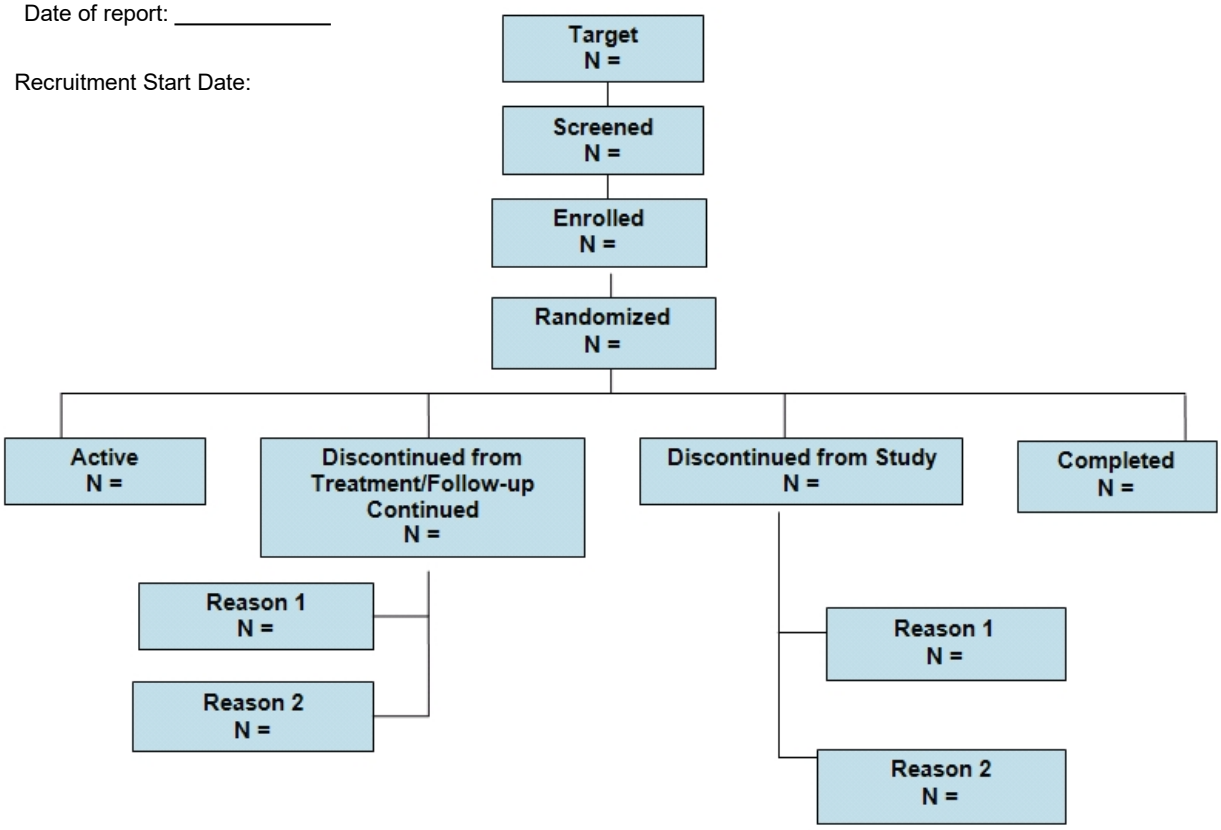
Principal Investigator:

Figure 1: Overall Study Status

Data as of: _____

Date of report: _____

Recruitment Start Date:



Study Name:

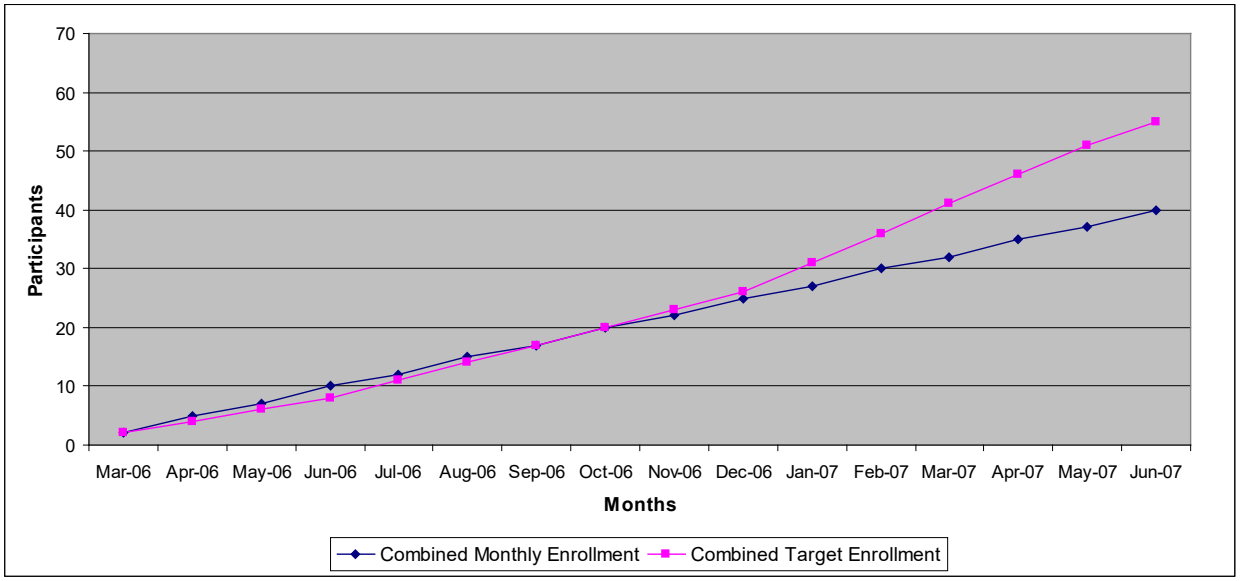
Principal Investigator:

Figure 2: Enrollment: Actual vs. Expected

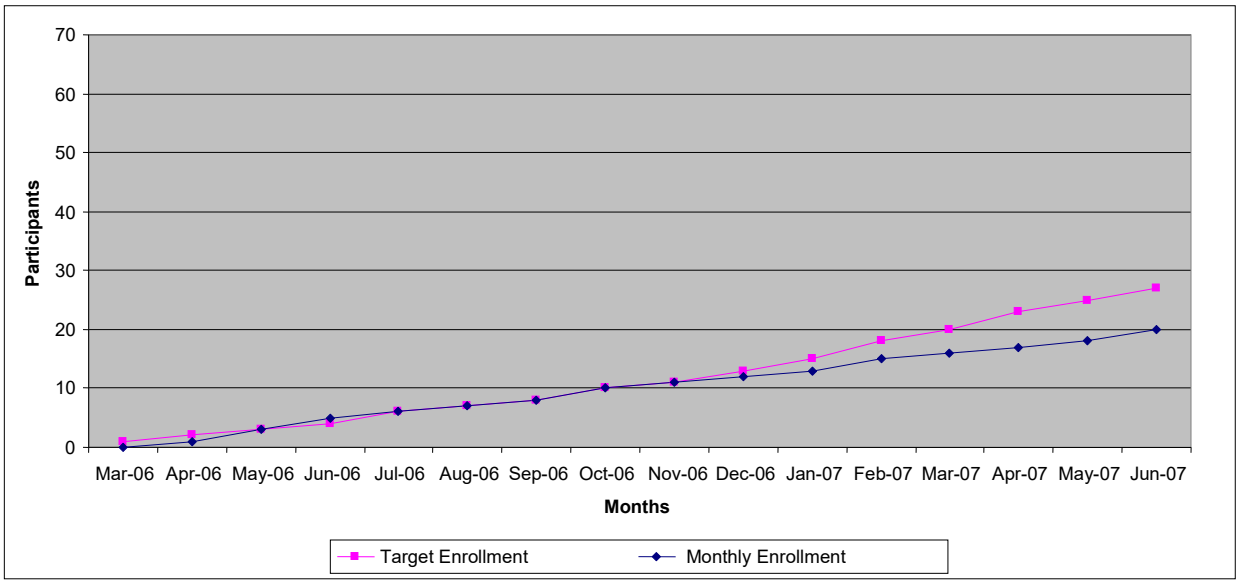
All Sites

Data as of:_____

Date of report:_____



Site 1*



** Add a graph for each participating site.*

Study Name:

Principal Investigator:

Table 1: Site Enrollment by Period

Data as of:_____

Date of report:_____

Period*	Site Number 1	Site Number 2	Site Number *i***	Total
Date First Participant Enrolled				
Date Last Participant Enrolled				
2004				
2005				
2006				
2007				
2008				
Total (%)				

* *Depending on the length of study and design, period in each row can be equal to days, weeks, months, quarters or years*

** *There should be one column for each site.*

Final format will be determined by the DSMB.

Study Name:

Principal Investigator:

Table 2: Participant Enrollment Status

Data as of:_____

Date of report:_____

	N	%
Enrolled		100
Active		
Completed		
Discontinued Treatment/Follow-up Continued		100
Personal Reason *		
Serious Adverse Event/ AE *		
Discontinued from Study		100
Lost to follow- up		
SAE/AE		
Withdrew Consent		

* *These are examples. Use categories relevant to protocol.*

Study Name:

Principal Investigator:

Table 2a – 2*i*: Participant Enrollment Status by Site

Data as of:_____

Date of report:_____

Site:_____

	N	%
Enrolled		100
Active		
Completed		
Discontinued Treatment/Follow-up Continued		100
Personal Reason*		
Serious Adverse Event/ AE*		
Discontinued from Study		100
Lost to follow- up		
SAE/AE		
Withdrew Consent		

* *These are examples. Use categories relevant to protocol.*

One table for each site.

Study Name:

Principal Investigator:

Table 3: Reasons for Screen Failures

Data as of:_____

Date of report:_____

Reason	N	%*
Total Screened		
Total Screen Failures		

** - % of the total number screened*

Study Name:

Principal Investigator:

Table 3a – 3*i*: Reasons for Screen Failures by Site

Data as of:_____

Date of report:_____

Reason	Site 1 N	Site 1 %*
Total Screened		
Total Screen Failures		

** - % of the total number screened*

One table for each site.

Study Name:

Principal Investigator:

Table 4: Protocol Deviations

Data as of:_____

Date of report:_____

	Protocol Deviation*	Total	*Since Last DSMB Report*
1			
2			
3			
4			
5			
6			
	Total # of Deviations		
	Participants Enrolled		
	Deviations per Participant		

**Possible deviations may include:*

- *Did not meet inclusion/exclusion criteria*
- *Visit noncompliance/incomplete visit*
- *Participant taking concomitant drugs which are not allowed*
- *Assessments outside protocol window*
- *Failure to obtain informed consent*

Study Name:

Principal Investigator:

Table 4a – 4*i*: Protocol Deviations by Site

Data as of:_____

Date of report:_____

Site:_____

	Protocol Deviation*	Total	*Since Last DSMB Report*
1			
2			
3			
4			
5			
6			
	Total # of Deviations		
	Participants Enrolled		
	Deviations per Participant		

- *One table for each site.*

**Possible deviations may include:*

- *Did not meet inclusion/exclusion criteria*
- *Visit noncompliance/incomplete visit*
- *Participant taking concomitant drugs which are not allowed*
- *Assessments outside protocol window*
- *Failure to obtain informed consent*

Study Name:

Principal Investigator:

Table 5: Demographic and Key Baseline Characteristics

Data as of:_____

Date of report:_____

Characteristics		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 6: Treatment Duration for All Participants

Data as of:_____

Date of report:_____

Time in Study* Total N=	n	%
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.

Study Administration

Data Quality Tables

Study Name:

Principal Investigator:

Table 7: Summary of Missed Visits by Site

Data as of:_____

Date of report:_____

Sites	Number of Participants Missing Visits	Number of Missed Visits
Site 1		
n		
Site 2		
n		
Site 3		
n		
Site N		
n		
Total N		

Study Name:

Principal Investigator:

Table 8: Summary of Forms Submitted

Data as of:_____

Date of report:_____

Forms	# Forms Expected	# Forms Submitted	% of Delinquent Forms
Demographics			
Medical History			
etc.			
Total			

Study Name:

Principal Investigator:

Table 9: Missing Outcome Measures

Data as of:_____

Date of report:_____

		Outcome 1	Outcome 2*
Site 1	Total		
	Since Last DSMB Report		
Site 2	Total		
	Since Last DSMB Report		
Site *i*	Total		
	Since Last DSMB Report		
TOTAL	Total N		
	Since Last DSMB Report		

** Additional outcomes can be added if necessary.*

Safety Assessments for All Participants:

Tables and Listings

Study Name:

Principal Investigator:

Table 10: Incidence of Adverse Events by Body System and Preferred Term

Data as of:_____

Date of report:_____

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

* *Number of participants experiencing an AE (participant is to be counted only once for each adverse event)*

** *% of total number of participants in the study*

*** *Number of events for Body System and Preferred Term*

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.

Study Name:

Principal Investigator:

Table 11: Severity of Adverse Events by Preferred Term

Data as of:_____

Date of report:_____

Preferred Term*	Total N=Mild n** (%)***	Total N=Moderate n (%)	Total 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 each participant is counted only once at highest level of severity.*

*** *% of participants experiencing a certain severity of an adverse event*

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 Site

Data as of:_____

Date of report:_____

Site	Participant ID	Onset Date	Stop Date	Expected (Y/N)	Relationship to Intervention*	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 Site

Data as of:_____

Date of report:_____

Site	Participant ID	Date of Death	Cause of Death	Relationship to Intervention*

** Definite, Possible, Not Related*

Study Name:

Principal Investigator:

Listing 3: Adverse Events by Site*

Data as of:_____

Date of report:_____

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

* *This listing can be sorted by Preferred Term or by Participant ID.*

** *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
Participant died

Study Name:

Principal Investigator:

Table 12: Laboratory Test Results Summary*

Data as of:_____

Date of report:_____

								----------Change from Baseline----------					
Laboratory Test	**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:

Table 12a- 12*i*: Laboratory Test Results Summary by Site*

Data as of:_____

Date of report:_____

								----------Change from Baseline----------					
Laboratory Test	**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.*

** *One table for each site.*

Final format is determined by the DSMB.

Study Name:

Principal Investigator:

Listing 4: Clinically Significant Abnormal Lab Values by Site

Data as of:_____

Date of report:_____

Site	Participant ID	Visit	Age	Gender	Lab Panel	Lab Test	Result