DSMB Report Template
-Open Session-

For Single-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

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Projected Timetable and Schedule

Narrative/Trial Summary

Study Status

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Study Administration

Recruitment and Participant Status:

Figures and Tables

Study Name:

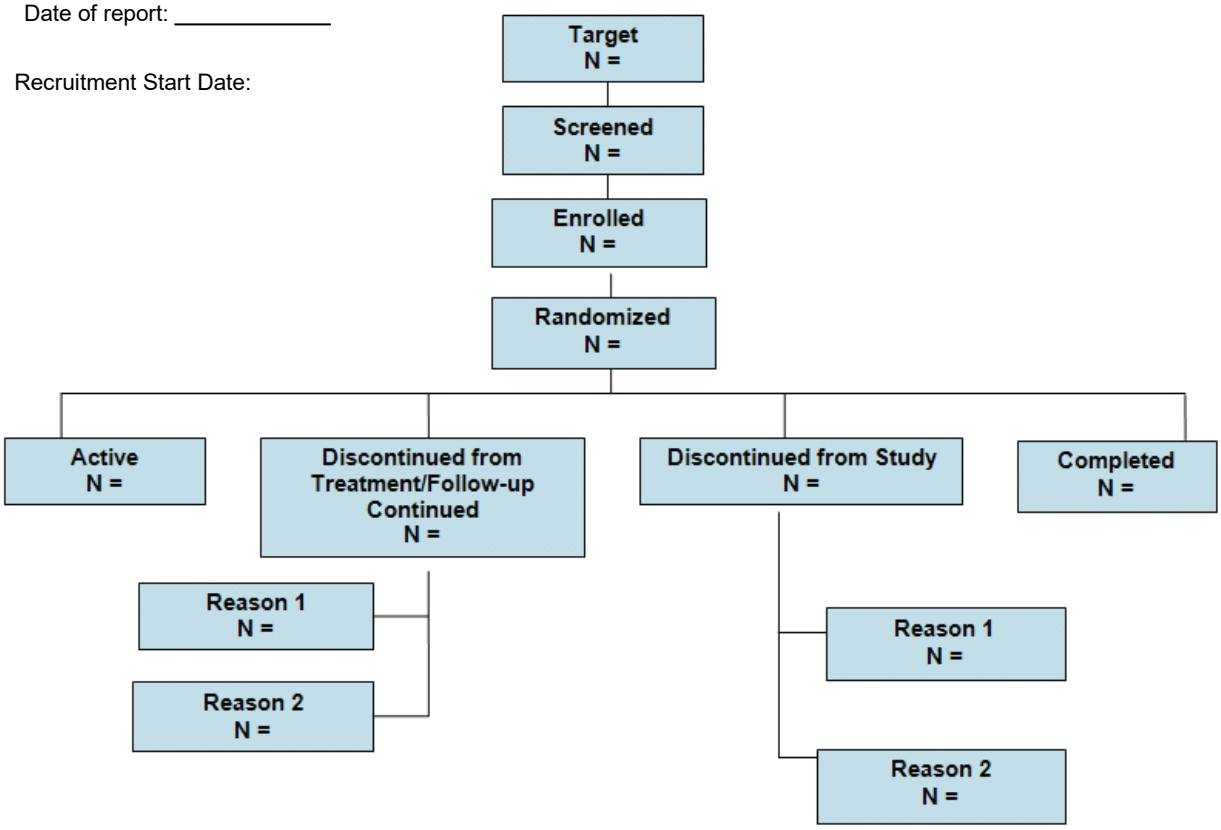
Principal Investigator:

Figure 1: Overall Study Status

Data as of: _____

Date of report: _____

Recruitment Start Date:



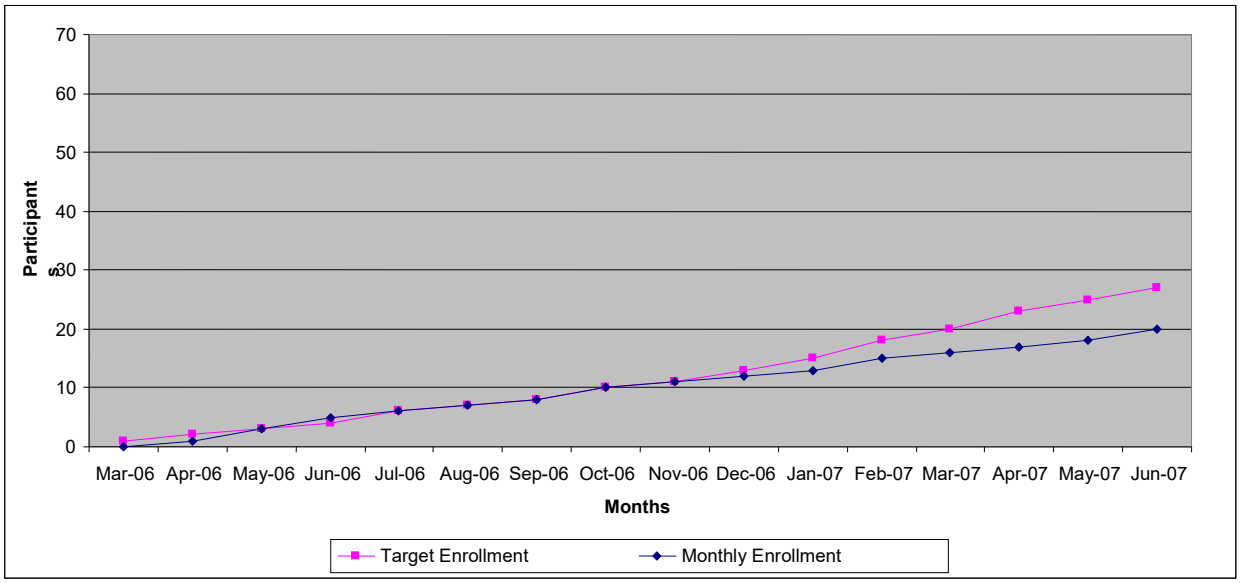
Study Name:

Principal Investigator:

Figure 2: Enrollment: Actual vs. Expected

Data as of:_____

Date of report:_____



Study Name:

Principal Investigator:

Table 1: 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 2: Reasons for Screen Failures

Data as of:_____

Date of report:_____

Reason	Total N	Total %*
Total Screened		
Total Screen Failures		

* - % of the total number screened

Study Name:

Principal Investigator:

Table 3: 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/met 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 4: 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 5: 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.*

Safety Assessments for All Participants:

Tables and Listing

Study Name:

Principal Investigator:

Table 6: 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 adverse event (participant is to be counted only once for each adverse event)*

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

*** *Number of events*

This table can present overall incidence of adverse events as shown above, adverse events related to the intervention as judged by the investigator, or treatment emergent events.

Study Name:

Principal Investigator:

Table 7: 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 the highest level of severity for the event*

*** *% 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, adverse events related to the intervention as judged by the investigator, or treatment emergent events.

Study Name:

Principal Investigator:

Listing 1: Serious Adverse Events

Data as of:_____

Date of report:_____

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

Data as of:_____

Date of report:_____

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

** Definite, Possible, Not Related*

Study Name:

Principal Investigator:

Listing 3: Adverse Events *

Data as of:_____

Date of report:_____

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

* *This listing could be provided in two ways – sorted by Preferred Term or sorted 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
Subject died

Study Name:

Principal Investigator:

Table 8: Laboratory Test Results Summary*

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:_____

Participant ID	Visit	Age	Gender	Lab Panel	Lab Test	Result