

NIAMS Data and Safety Monitoring (DSM) Report Template for Single- Site Studies

-Open Session-

DSM Report Template: Instruction Sheet

The following report template is intended to act as guidance and a reference document for investigators, study staff, data managers, study statisticians and others involved in submitting periodic reports to a Monitoring Body (e.g., Data and Safety Monitoring Board, Safety Officer). The proposed structure should be customized according to the individual study needs. Additional or fewer reports may be appropriate, but the template serves as a starting point.

Prior to the first Monitoring Body report, study team members should review this template and customize it to the specific needs of the protocol. During the introductory call, the designated study team member who is responsible for preparing these reports (i.e., statistician, data manager) should present the customized table shells to the NIAMS and the Monitoring Body. The final format of the reports, tables, and listings will be approved by the Monitoring Body and the NIAMS. This process will ensure the appropriate study data are presented to the Monitoring Body and will promote efficiency in the creation of future safety reports.

The design, scope and nature of a study will impact how data are presented. Outlined below are a few issues that should be considered as this document is tailored:

- For studies in which there are masked treatment groups, the Monitoring Body, at its discretion, may request and review unmasked data in the closed session materials. The decision to present results in an unmasked fashion should be discussed with the NIAMS and the Monitoring Body.
- It is recommended that data stratified by treatment group be masked (i.e., Treatment A versus Treatment B).
- As a general rule, interim results should not be presented unless interim analyses are described in the protocol or the Monitoring Body has requested an interim analysis to assess a safety concern or study futility. The decision whether or not to present interim or final results in this report should be discussed with the Monitoring Body and the NIAMS.

Template
Recommendations:

- In the following templates, the instructions, explanatory text, and examples are indicated by **blue text**. Be sure to replace examples with protocol-specific details.
- Instructional text will also be enclosed in {braces} to signify this text for screen-readers used by the visually impaired.
- Delete template-specific instructional text and this Instruction Sheet during the report development process.

Report Cover Page

| | |
|-------------------------------------|--|
| Protocol Title/number: | <Insert title of the protocol> |
| Grant Number: | <Insert grant number> |
| Principal Investigator (PI): | <Name of PI PI's Title Institution Address> |
| Meeting date: | <Insert date of the scheduled meeting, if applicable> |
| Date of Report: | <Insert date that the report is being issued> |
| Data as of: | <Insert the date of the data snapshot for the analyses in this report> |
| Prepared by: | <Name of person who prepared the report Person's Title Place of employment Address> |

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Protocol Synopsis and Milestone Timeline

{Add, delete, or modify protocol headings as required. Enter appropriate information in second column; some guidance has been provided.}

Study Design Type

Intervention, specify type of Intervention (check more than one if applicable):

Drug Biologic Behavioral/Lifestyle Surgical

Non-interventional

| NIAMS Data and Safety Monitoring (DSM) Report Protocol Synopsis and Milestone Timeline | | Comments <i>If any of the information has changed since the time of the last report, please explain.</i> |
|---|--|--|
| Project Period <Insert the start and end dates of the study as stated on the Notice of Grant Award; indicate any no cost extensions/supplements if applicable> | | |
| NIAMS Study Commencement Date <Insert date NIAMS granted approval for enrollment to begin> | | |
| Planned Enrollment Number <Insert target number of participants to be enrolled. This is the number of participants required per protocol (this number will be compared to the "Actual Number Enrolled"). This number is expected to remain unchanged, unless a protocol amendment changes this required number and is approved by the NIAMS. A history of the changes should be noted in the comments section.> | | |

| | | |
|---|--|--|
| Enrollment Definition <Insert how enrollment is defined as stated in your study protocol (i.e., enrolled = consented and randomized)> | | |
| Target Enrollment Start Date <Insert planned date (i.e., mm/yyyy) for the first participant enrolled> | | |
| Actual Enrollment Start Date* <Insert date the first participant was enrolled> | | |
| Target 25% Enrolled Date <Insert planned date (i.e., mm/yyyy) for when 25% of the participants will be enrolled> | | |
| Actual 25% Enrolled Date* <Insert the actual date (i.e., mm/yyyy) when 25% of the participants were enrolled> | | |
| Target 50% Enrolled Date <Insert planned date (i.e., mm/yyyy) for when 50% of the participants will be enrolled> | | |
| Actual 50% Enrolled Date* <Insert the actual date (i.e., mm/yyyy) when 50% of the participants were enrolled> | | |
| Target 75% Enrolled Date <Insert planned date (i.e., mm/yyyy) for when 75% of the participants will be enrolled> | | |
| Actual 75% Enrolled Date* <Insert the actual date (i.e., mm/yyyy) when 75% of the participants were enrolled> | | |
| Target 100% Enrolled Date <Insert planned date (i.e., mm/yyyy) for the last patient enrolled> | | |
| Actual 100% Enrolled Date* <Insert date the last participant was enrolled> | | |

| | | |
|---|--|--|
| <p>Target Last Visit Date</p> <p><Insert planned date for the last participant visit (i.e., mm/yyyy); last patient out></p> | | |
| <p>Actual Last Visit Date*</p> <p><Insert date for the last participant visit></p> | | |
| <p>On-protocol Duration (per participant) – e.g., 24 months</p> <p><Insert the planned length of time each participant will be on protocol, starting with enrollment and ending with the last follow-up visit></p> | | |
| <p>Intervention Duration **(per participant) – e.g., 6 weeks</p> <p><Insert the planned length of time the intervention will be administered to each participant per the protocol></p> | | |
| <p>Target Database Lock</p> <p><Insert planned date (i.e., mm/yyyy) for the database lock once all data queries have been completed></p> | | |
| <p>Actual Database Lock*</p> <p><Insert date the database was locked></p> | | |
| <p>Target Primary Analysis Complete</p> <p><Insert planned date (i.e., mm/yyyy) for the analysis of the primary outcome measure(s) to be completed></p> | | |
| <p>Actual Primary Analysis Complete*</p> <p><Insert date the analysis of the primary outcome measure(s) was completed></p> | | |
| <p>Target Secondary Analysis Complete</p> <p><Insert planned date (i.e., mm/yyyy) for the analysis of the secondary outcome measure(s) to be completed></p> | | |

| | | |
|--|--|--|
| Actual Secondary Analysis Complete* <Insert date the analysis of the secondary outcome measure(s) was completed> | | |
| Target Final Study Report Completed Date | | |
| Actual Final Study Report Completed Date* | | |

*Insert 'not applicable' until milestone is reached.

** Insert 'not applicable' for studies without an intervention duration (i.e., surgical or observational studies)

Executive Summary

{Add, delete, or modify summary topics as needed. Executive summary information may also be presented in PowerPoint.}

| | |
|--|--|
| Study Overview Since the Last Monitoring Body Meeting | <i>Provide a summary of enrollment and important events since the last Monitoring Body meeting/report. The date through which the enrollment and safety data are provided should be indicated in this section.</i> |
| Overall Study Status | <p><i>{Example information:}</i></p> <ul style="list-style-type: none"> • Provide status of site (e.g., IRB approval, whether recruitment has begun, timeframe for IRB approval/enrollment start) • # of participants screened • # of participants enrolled • # of participants awaiting treatment • # of participants in follow up • # of participants completed the protocol • Discontinued from study/follow up not ongoing |
| Stopping Rules <i>{Use terminology that matches the protocol throughout this report}</i> | Provide information on whether any participants have met stopping rules since the previous Monitoring Body review. |
| Safety Summary | <p><i>Please summarize important safety events that have occurred in the study. Please also include details of any events that occurred since the last Monitoring Body meeting/report.</i></p> <p><i>{Example text:}</i></p> <ul style="list-style-type: none"> • 10 adverse events have occurred in 7 subjects • 5 new adverse events are being reported since the previous Monitoring Body report • There have been no additional serious adverse events since the last Monitoring Body meeting • Of the 10 adverse events, all were considered either mild or moderate • Only one adverse event was deemed related to the intervention |
| Protocol Deviations and Action Taken | <p><i>Please summarize protocol deviations that have occurred in the study. Please also include details of any events that occurred since the last Monitoring Body meeting/report.</i></p> <p><i>{Example text:}</i></p> <ul style="list-style-type: none"> • 10 protocol deviations associated with 5 subjects have been reported. • None of the deviations have impacted subject safety. |

| | |
|--|--|
| | <ul style="list-style-type: none"> The protocol deviations did not meet the IRB's reporting requirements |
| Summary of Protocol Changes and New Requests for Protocol Changes | <p><i>Please summarize any protocol changes that were implemented since the last Monitoring Body meeting/report. Please describe the change and status of IRB/Monitoring Body/NIAMS approval.</i></p> <p><i>Any new protocol change requests for consideration by the Monitoring Body/NIAMS should also be summarized.</i></p> <p><i>{Example text:}</i></p> <ul style="list-style-type: none"> One protocol amendment was submitted allowing the upper age of subjects to be extended to 65. This change was approved by the Monitoring Body on (date) and the IRB on (date). The protocol, MOOP, and informed consent forms have been revised and submitted to the NIAMS through KAI. |

Study Administration

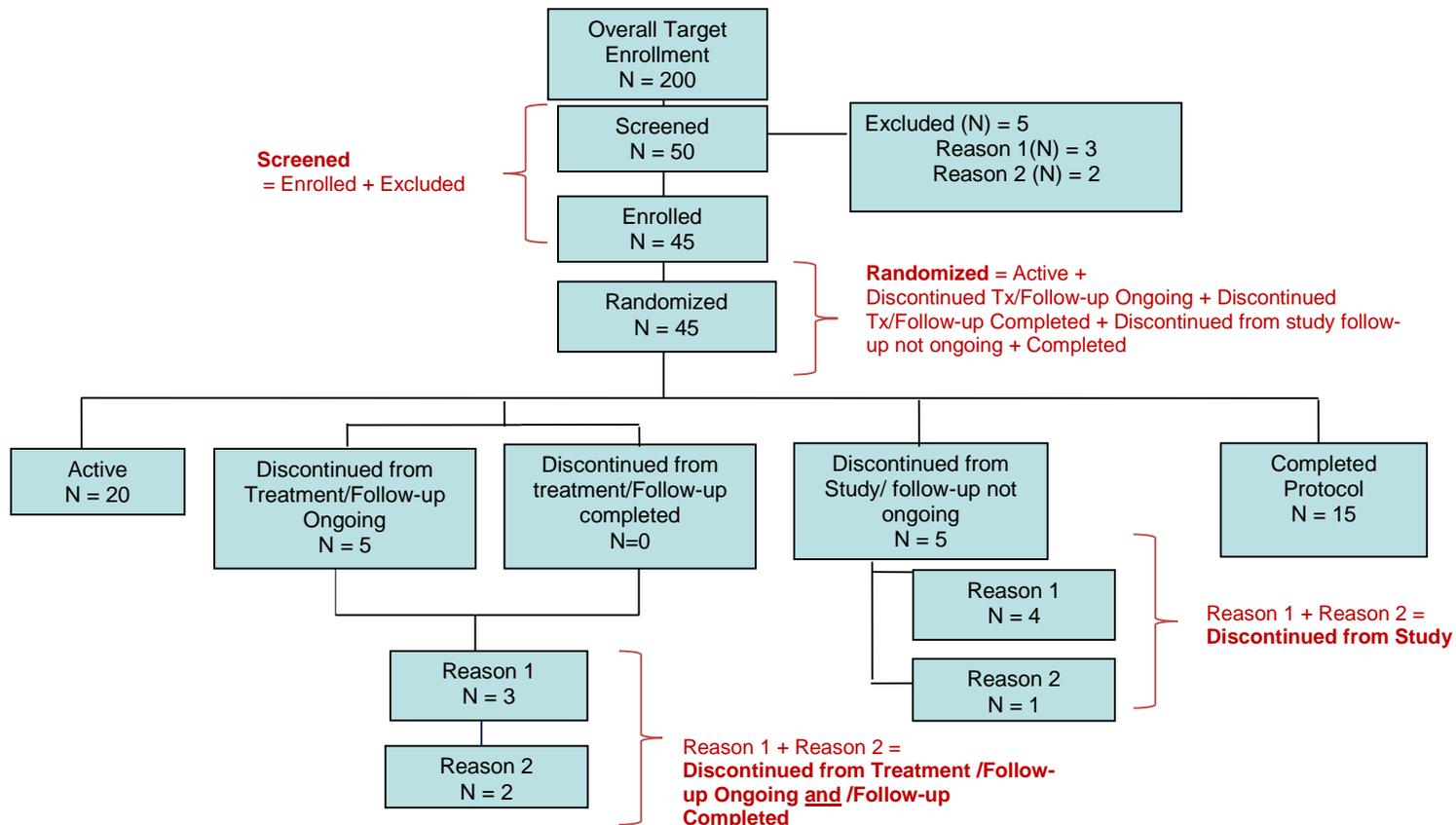
Recruitment and Participant Status:

Figures and Tables

Figure 1: Enrollment: Overall Study Status

Data as of: _____

Date of report: _____



{Describe where participants are in the study in relation to enrollment milestones, such as the number of participants screened, enrolled, and randomized. For some protocols, it is important to distinguish between participants who withdrew early from the study and those who discontinued treatment but may or may not still be followed.}

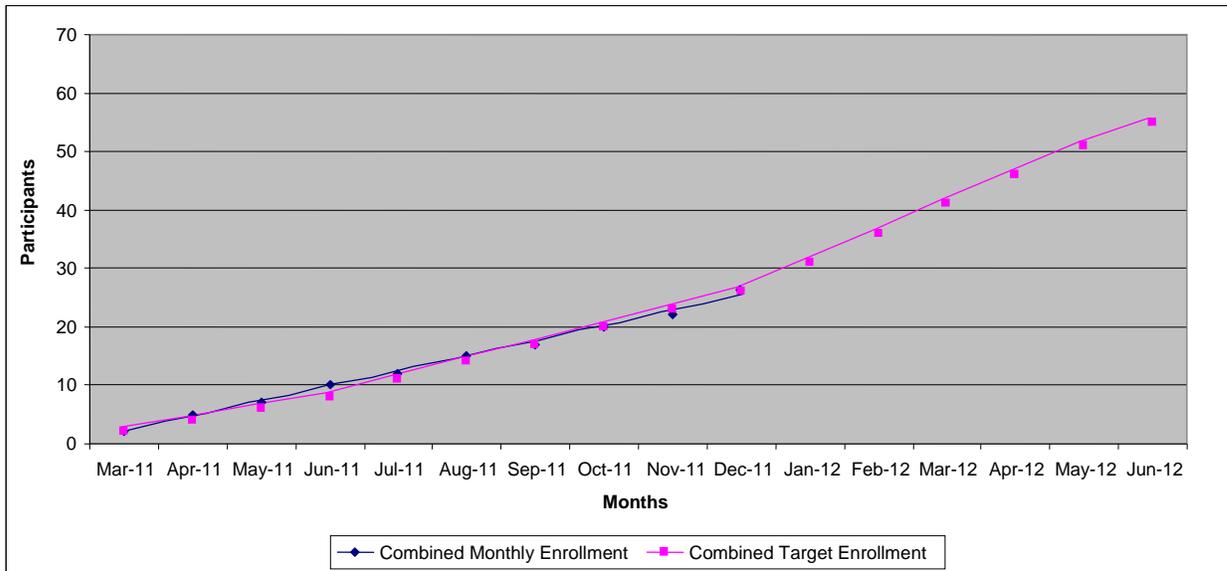
Reference: Schulz KF, Altman DG, Moher D, for the CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. [Ann Int Med](#) 2010;152.

Figure 2: Enrollment: Actual vs. Expected

Aggregate

Data as of: Dec.20, 2011

Date of report: Jan. 31, 2012



| Time Period | Expected Number of Enrolled Participants (cumulative) | Actual Number of Enrolled Participants (cumulative as of 12/20/2011) |
|---------------|---|--|
| Mar 11 | 2 | 2 |
| Apr 11 | 5 | 5 |
| May 11 | 7 | 7 |
| Jun11 | 10 | 9 |
| Jul 11 | 12 | 11 |
| Aug11 | 14 | 11 |
| Sep 11 | 16 | 16 |
| Oct 11 | 18 | 18 |
| Nov 11 | 20 | 19 |
| Dec 11 | 22 | 22 |
| Jan 12 | 30 | |
| Feb 12 | 35 | |
| Mar 12 | 40 | |
| Apr 12 | 42 | |
| May 12 | 50 | |
| Jun 12 | 55 | |
| Totals | 55 | 22 |

Numbers should be displayed **cumulatively**, adding the number of participants from the previous month(s) to each new row.

{Provide the expected number of cumulative participants by estimated enrollment time period through the end of the expected enrollment period. Provide the actual cumulative enrollment up until the Monitoring Body report closing date. As necessary, customize the X and Y axis categories per the protocol specifications. Depending on the length of study and design, the time points can be equal to days, weeks, months, quarters or years.}

Table 1: Participant Enrollment Status

Data as of: _____

Date of report: _____

| | Total | |
|---|-------|------|
| | N | %* |
| Enrolled | 100 | 100 |
| Active | 50 | 50 |
| Completed Protocol | 25 | 25 |
| | N | %** |
| Discontinued Treatment/Follow-up Ongoing | 10 | 100 |
| Reason 1 **** | 5 | 50 |
| Reason 2 | 5 | 50 |
| | N | %*** |
| Discontinued from Treatment/Follow-up Completed | 10 | 100 |
| Reason 1 | | |
| Reason 2 | | |
| | N | %*** |
| Discontinued from Study/Follow-up Not Ongoing | 5 | 100 |
| Reason 1 | | |
| Reason 2 | | |

* % of participants who are enrolled.

** % of participants who have discontinued treatment, but continued to be followed as part of the study. For some protocols, it is important to distinguish between participants who withdrew early from the study and those who discontinued treatment but may or may not still be followed.

*** % of participants who have discontinued the study and are no longer being followed.

**** Reasons should be customized with items relevant to the study protocol.

Table 2: Screen Failures

Data as of: _____

Date of report: _____

| Reasons* | Total | |
|------------------------------|-------|-----|
| | N | %** |
| Reason 1 | | |
| Reason 2 | | |
| Total Screened | | |
| Total Screen Failures | | |

**Reasons should be customized with items relevant to the study protocol.*

*** % of the total number screened; the number of screen failures should be equivalent to the total number of participants screened minus the total number of participants enrolled.*

Table 3: Demographics

Data as of: _____

Date of report: _____

| Characteristics* | | Total N (%) | Target N (%) <small>(from target enrollment table in grant)</small> |
|------------------------|---|----------------|---|
| Total Enrolled: | | | |
| Gender | Male | | |
| | Female | | |
| Ethnicity | Hispanic or Latino | | |
| | Not Hispanic or Latino | | |
| | Missing | | |
| Race | American Indian/Alaska Native | | |
| | Asian | | |
| | Black or African American | | |
| | Native Hawaiian or Other Pacific Islander | | |
| | White | | |
| | More than one race | | |
| | Missing | | |
| Education | Grade School | | |
| | High School or equivalent | | |
| | Some college, no degree | | |
| | College degree | | |
| | Graduate degree | | |
| | Doctoral | | |
| Age | Mean | | |
| | Standard Deviation | | |
| | Median | | |
| | Minimum | | |
| | Maximum | | |

** Characteristics should be customized with items relevant to the study protocol; the items listed are only examples.*

Table 4: Key Baseline Characteristics

Data as of: _____

Date of report: _____

| Characteristics* | | TOTAL N (%) |
|--|--------------------|----------------|
| Body Mass Index | Below 18.5 | |
| | 18.5 – 24.9 | |
| | 25.0 – 29.9 | |
| | 30.0 and Above | |
| Western Ontario and McMaster Universities Arthritis Index (WOMAC) Total Score | Mean | |
| | Standard Deviation | |
| | Median | |
| | Minimum | |
| | Maximum | |

** Characteristics should be customized with items relevant to the study protocol (e.g., stratification variables); the items listed are only examples.*

Table 5: Study Duration for All Participants

Data as of: _____

Date of report: _____

| Time in Study* | Expected** | Actual*** |
|-----------------------|-------------------|------------------|
| Total N= | N (%) | N (%) |
| Visit 1 | | |
| Visit 2 | | |
| Visit 3 | | |
| Visit 4 | | |
| Completed Study | | |

** Should be customized to visit schedule and can be shown by visits, days, weeks, months, or treatment periods.*

*** Number and percentage of participants expected to complete each study milestone.*

**** Number and percentage of participants who completed each study milestone.*

Study Administration

Data Quality Tables

Table 6: Summary of Missed Visits

Data as of: _____

Date of report: _____

| Missed Visits | Total N (%) |
|--|-------------|
| Completed Participants | |
| Number of Completed Participants | |
| Number of Participants Missing Visits | |
| Number of Missed Visits | |
| Average Number of Missed Visits for Completed Participants | |
| Active Participants | |
| Number of Active Participants | |
| Number of Participants Missing Visits | |
| Number of Missed Visits | |
| Average Number of Missed Visits for Active Participants | |

{This table should display the number of participants missing visits and the number of actual missed visits divided by those who are currently active on the protocol and those who completed.}

Table 7: Summary of Case Report Forms (CRFs) Completed

Data as of: _____

Date of report: _____

| CRFs* | Total | | |
|-----------------|-------------------------|--------------------------|-------------------|
| | Number of CRFs Expected | Number of CRFs Completed | % of Missing CRFs |
| Demographics | | | |
| Medical History | | | |
| Vital Signs | | | |
| etc. | | | |
| | | | |
| All (total) | | | |

** The CRFs listed should be customized with items relevant to the study protocol; the CRFs listed are examples but are not required.*

Safety Assessments for All Participants:

Tables and Listings

Table 8: Incidence of Adverse Events by Body System and Preferred Term

Data as of: _____

Date of report: _____

| Body System and Preferred Term* | Total N= | | |
|---------------------------------|----------|--------|------------|
| | n** | (%)*** | Events**** |
| Overall | | | |
| Body System 1***** | | | |
| Preferred Term 1 | | | |
| Preferred Term 2 | | | |
| etc. | | | |
| | | | |
| Body System 2 | | | |
| Preferred Term 1 | | | |
| Preferred Term 2 | | | |
| etc. | | | |
| | | | |
| Body System 3 | | | |
| etc. | | | |

{Standard medical terminology should be used when recording AEs. Furthermore, it is recommended that studies that plan to submit data to regulatory authorities should code their AE data using an electronic coding system such as the Medical Dictionary for Regulatory Activities (MedDRA) or the Common Terminology Criteria for Adverse Events (CTCAE).}

**The Preferred Term is a distinct descriptor (single medical concept) for a symptom, sign, disease, diagnosis, therapeutic indication, investigation, surgical, or medical procedure, and medical, social, or family history characteristics*

*** 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.*

****** Body Systems may include: Blood and lymphatic system disorders; Cardiac disorders; Congenital, familial and genetic disorders; Ear and labyrinth disorders; Endocrine disorders; Eye disorders; Gastrointestinal disorders; General disorders and administration site conditions; Hepatobiliary disorders; Immune system disorders; Infections and infestations; Injury, poisoning and procedural complications; Investigations; Metabolism and nutrition disorders; Musculoskeletal and connective tissue disorders; Neoplasms benign, malignant and unspecified (incl cysts and polyps); Nervous system disorders; Pregnancy, puerperium and perinatal conditions; Psychiatric disorders; Renal and urinary disorders; Reproductive system and breast disorders; Respiratory, thoracic and mediastinal disorders; Skin and subcutaneous tissue disorders; Social circumstances; Surgical and medical procedures; Vascular disorders.*

Table 9: Severity of Adverse Events by Preferred Term

Data as of: _____

Date of report: _____

| Preferred Term* | Total N= | | |
|------------------|------------|----------|--------|
| | Mild | Moderate | Severe |
| | n** (%)*** | n (%) | n (%) |
| Preferred Term 1 | | | |
| Preferred Term 2 | | | |

**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.*

Listing 1: Adverse Events

Data as of: _____

Date of report: _____

| Participant ID | Age | Gender | Event Term | AE Onset Date | AE Stop Date | Study Intervention Start Date | Study Intervention Stop Date | Relationship* | Participant discontinued from intervention? | Expected (Y/N) | Severity** | Outcome*** | Serious (Y/N) |
|----------------|-----|--------|------------|---------------|--------------|-------------------------------|------------------------------|---------------|---|----------------|------------|------------|---------------|
| | | | | | | | | | | | | | |
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* Relationship should be specifically defined for each study (i.e., Relationship to intervention, Relationship to study drug, etc.) The following are commonly used categories: Definitely, Probably/Possibly, Not Related

** The following are commonly used categories: Mild, Moderate, Severe.

*** 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

Listing 2: Serious Adverse Events*

Data as of: _____

Date of report: _____

| Participant ID | Age | Gender | Event Term | Study Intervention Duration** | Study Intervention Start Date | Study Intervention Stop Date | SAE Onset Date | SAE Stop Date or Ongoing | Relationship to Study*** | Expected ? (Yes/No) | Outcome **** | Unanticipated Problem?***** (y/n) |
|----------------|-----|--------|------------|-------------------------------|-------------------------------|------------------------------|----------------|--------------------------|--------------------------|---------------------|--------------|-----------------------------------|
| | | | | | | | | | | | | |
| | | | | | | | | | | | | |
| | | | | | | | | | | | | |

* This listing can be sorted by SAE Description or by Participant ID.

** The number of days on study treatment at the onset of the SAE.

*** Relationship should be specifically defined for each study (i.e., Relationship to intervention, Relationship to study drug, etc.) The following are commonly used categories: Definitely, Probably/Possibly, 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

*****The incident must meet the following criteria to qualify as an Unanticipated Problem:

- was unexpected in terms of nature, severity, or frequency
- is definitely or possibly related to participation in the research
- suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized

NOTE: All AEs in Listing 1 that have been designated as an SAE (“Y”) should be also listed on this Listing.

Listing 3: Deaths

Data as of: _____

Date of report: _____

| Participant ID* | Gender | Age | Date Enrolled | Date of Death | Study Intervention Start Date | Study Intervention Stop Date | Cause of Death | Relationship ** |
|-----------------|--------|-----|---------------|---------------|-------------------------------|------------------------------|----------------|-----------------|
| | | | | | | | | |
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* It is expected that individuals will be listed on Listing 1: Adverse Events, Listing 2: Serious Adverse Events and the more detailed Listing 3: Deaths.

** The following are commonly used categories for relationship: Definitely, Probably/Possibly, Not Related.

Table 10: Laboratory Test Results Summary*

Data as of: _____

Date of report: _____

| Laboratory Test | Normal Range | Study Visits | | | | | | -----Change from Baseline----- | | | | | | |
|-----------------|--------------|--------------|---|------|----|--------|-----|--------------------------------|---|------|----|--------|-----|-----|
| | | | N | Mean | SD | Median | Min | Max | N | Mean | SD | Median | Min | Max |
| Test 1 | | Screening | | | | | | | | | | | | |
| | | Visit 1 | | | | | | | | | | | | |
| | | Visit 2 | | | | | | | | | | | | |
| | | Visit 3 | | | | | | | | | | | | |
| | | | | | | | | | | | | | | |
| Test 2 | | Screening | | | | | | | | | | | | |
| | | Visit 1 | | | | | | | | | | | | |
| | | Visit 2 | | | | | | | | | | | | |
| | | Visit 3 | | | | | | | | | | | | |
| | | | | | | | | | | | | | | |
| etc... | | Screening | | | | | | | | | | | | |
| | | Visit 1 | | | | | | | | | | | | |
| | | Visit 2 | | | | | | | | | | | | |
| | | Visit 3 | | | | | | | | | | | | |

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

Listing 5: Unanticipated Problems

Data as of: _____

Date of report: _____

| Date UP Identified | Date of UP incident | UP Description* | Subject ID (or describe group affected**) | Action taken*** (1 -10, include all that apply) | Action taken, specify | SAE? (yes/no) | Reported to the IRB? (yes/no) | IRB action required? If yes, describe response from IRB (attach correspondence, if necessary) |
|--------------------|---------------------|-----------------|---|---|-----------------------|---------------|-------------------------------|---|
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |

{The incident must meet the following criteria to qualify as an Unanticipated Problem:

- was unexpected in terms of nature, severity, or frequency
- is definitely or possibly related to participation in the research
- suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized}

*Describe harm or potential harm that occurred to subject(s), whether the incident is resolved, and whether the subject(s) remains in the study. If the Unanticipated Problem is a serious adverse event, submit this form and complete the Serious Adverse Event form.

**If the Unanticipated Problem affects a particular group in the study, please identify that group, i.e., subjects in Treatment Group A, subjects enrolled before January 1, 2014, etc. If a group of individuals affected is across more than one treatment group, it may not be possible to complete this field.

***Action taken with the study as a result of the Unanticipated Problem? (include all that apply)

- 1- No action
- 2- Revise protocol to eliminate apparent immediate hazards to subjects
- 3 - Modification of inclusion or exclusion criteria to mitigate newly identified risks
- 4 - Implementation of additional procedures for monitoring subjects
- 5 - Suspension of enrollment of new subjects
- 6 - Notify currently enrolled subjects

- 7- Suspension of research procedures in currently enrolled subjects
- 8 - Modification of consent documents to include a description of newly recognized risks (site and/or study wide)
- 9 - Provision of additional information about newly recognized risks to previously enrolled subjects
- 10 – Other, specify

Listing 6: Protocol Deviations

Data as of: _____

Date of report: _____

| Participant ID | Deviation Date | Deviation Description* | Deviation Category** |
|----------------|----------------|------------------------|----------------------|
| | | | |
| | | | |
| | | | |
| | | | |
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| | | | |

**Deviation Description - record what occurred and why. For example, an expired drug was used by a new coordinator who did not check the expiration date. The description should also include remedies taken. In this case, the participant/subject was called to return the drug and was issued unexpired medication.*

***Deviation Category – provide a category of the protocol deviation description. Example deviation categories include: Randomization of ineligible participant; Failure to obtain consent; Participant seen outside window of follow-up; Not reporting serious adverse event.*