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

# -Open Session-

January 2022

## DSM Report Template:

## Instruction Sheet

The following report template is intended to provide guidance and serve as a reference document for investigators, study team members, data managers, study statisticians and others involved in creating and submitting periodic reports to a Monitoring Body (e.g., Data and Safety Monitoring Board, Safety Officer). The proposed structure should be customized based on study design and the type of data collected. 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 fit the data being collected and reported in accordance with the study 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.

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 textand this Instruction Sheet during the report development process.
 |

# Report Cover Page

|  |  |
| --- | --- |
| **Protocol Title/number:** | <Insert title of the protocol> |
| **NIH Grant Number:** | <Insert grant number> |
| **Principal Investigator (PI):** | <Name of PIPI’s TitleInstitutionAddress> |
| **Meeting date:** | <Insert date of the scheduled meeting, if applicable> |
| **Is this a masked study?** | <Yes or No> |
| **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 reportPerson’s TitlePlace of employmentAddress> |

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#

## Milestone Timeline

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

**Study Type**

* Interventional, specify type of Intervention (check more than one if applicable):
* Drug
* Device
* Biological/Vaccine
* Procedural/Surgery
* Radiation
* Behavioral
* Genetic
* Dietary Supplement
* Combination Product
* Diagnostic Test
* Other, *specify*:
* Non-interventional

### NIAMS Data and Safety Monitoring (DSM) Report Milestone Timeline

**Comments**

(If any of the information has changed since the time of the last report, please explain. For any milestone dates that have changed, specifically related to enrollment targets, please note the previous date and the reason for change. Recruitment target milestone changes must be discussed with the NIAMS and Monitoring Body)

|  |  |  |
| --- | --- | --- |
| 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> |  |  |
| **Trial Registered on ClinicalTrials.gov**<Insert date (i.e., mm/yyyy) the trial was registered on the ClinicalTrials.gov website. Date should be no later than 21 calendar days after enrolling the first participant> |  |  |
| Initial IRB Approval Date<Insert the date the study received IRB approval> |  |  |
| Regulatory Clearances Date<Insert the date the study received FDA clearance e.g. IDE/IND, if applicable>  |  |  |
| NIAMS Study Commencement Date<Insert date NIAMS granted approval for enrollment to begin> |  |  |
| Study Opened to Enrollment<Insert the date when the study was opened to recruitment> |  |  |
| 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****[[1]](#footnote-2)**<Insert date the first participant was enrolled> |  |  |
| **Target 25% Enrolled Date and Number**<Insert planned date (i.e., mm/yyyy) for when 25% of the participants will be enrolled><Insert the number of participants needed to achieve 25% of the overall enrollment goal> |  |  |
| **Actual 25% Enrolled Date\***<Insert the actual date (i.e., mm/yyyy) when 25% of the participants were enrolled> |  |  |
| **Target 50% Enrolled Date and Number**<Insert planned date (i.e., mm/yyyy) for when 50% of the participants will be enrolled><Insert the number of participants needed to achieve 50% of the overall enrollment goal> |  |  |
| **Actual 50% Enrolled Date\***<Insert the actual date (i.e., mm/yyyy) when 50% of the participants were enrolled> |  |  |
| **Target 75% Enrolled Date and Number**<Insert planned date (i.e., mm/yyyy) for when 75% of the participants will be enrolled><Insert the number of participants needed to achieve 75% of the overall enrollment goal> |  |  |
| **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> |  |  |
| **Target Last Visit Date** <Insert planned date for the last participant visit  (i.e., mm/yyyy); last patient out> |  |  |
| **Actual Last Visit Date\***<Insert date for the last participant visit> |  |  |
| **On-protocol Duration (per participant) – e.g., 24 months**<Insert the planned length of time each participant will be on protocol, starting with enrollment and ending with the last follow-up visit> |  |  |
| **Intervention Duration[[2]](#footnote-3)\*\*(per participant) – e.g., 6 weeks**<Insert the planned length of time the intervention will be administered to each participant per the protocol> |  |  |
| **Interim Analysis Planned**<Insert planned date (i.e., mm/yyyy) for the interim analysis> |  |  |
| **Interim Analysis Completed** <Insert date (i.e., mm/yyyy) when the interim analysis was completed> |  |  |
| **Interim Analysis Reviewed by Data and Safety Monitoring Board**<Insert date (i.e., mm/yyyy) when the interim analysis was reviewed by the safety monitoring board> |  |  |
| **Target Database Lock**<Insert planned date (i.e., mm/yyyy) for the database lock once all data queries have been completed> |  |  |
| **Actual Database Lock\***<Insert date the database was locked> |  |  |
| **Target Primary Analysis Complete**<Insert planned date (i.e., mm/yyyy) for the analysis of the primary outcome measure(s) to be completed> |  |  |
| **Actual Primary Analysis Complete\***<Insert date the analysis of the primary outcome measure(s) was completed> |  |  |
| **Target Secondary Analysis Complete** <Insert planned date (i.e., mm/yyyy) for the analysis of the secondary outcome measure(s) to be completed> |  |  |
| **Actual Secondary Analysis Complete\***<Insert date the analysis of the secondary outcome measure(s) was completed> |  |  |
| **Trial results Posted on ClinicalTrials.gov**<Insert date the results were posted on the ClinicalTrials.gov website no later than 1 year after the “primary completion date” of the trial. Date of final data collection for the primary outcome measure> |  |  |
| **Target Final Study Report Completed Date**<Insert planned date (i.e., mm/yyyy) when the final (or draft) report/manuscript that describes the study and its findings is expected to be available> |  |  |
| **Actual Final Study Report Completed Date\***<Insert date (i.e., mm/yyyy) the final (or draft) report/manuscript that describes the study and its finding was completed> |  |  |
| **Data Sharing – Submission to Repository** <Insert date (i.e., mm/yyyy) when data were submitted and specify location submitted, if applicable> |  |  |

## 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** | 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.  |
| **Overall Study Status** | {Example information:} * Provide status of study 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** {Use terminology that matches the protocol throughout this report} | *Provide information on whether any participants have met stopping rules since the previous Monitoring Body review.* |
| **Safety Summary** | 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. {Example text:} * 10 adverse events have occurred in 7 participants
* 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** | 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. {Example text:}* 10 protocol deviations associated with 5 participants have been reported
* None of the deviations have impacted participant safety
* The protocol deviations did not meet the IRB’s reporting requirements
* Any major protocol deviations leading to participant’s data being excluded from analysis
 |
| **Summary of Protocol Changes and New Requests for Protocol Changes** | 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. Any new protocol change requests for consideration by the Monitoring Body/NIAMS should also be summarized.{Example text:} * One protocol amendment was submitted allowing the upper age of participants to be extended to 65. This change was approved by the Monitoring Body on (date) and the IRB on (date). The protocol, MOP, and informed consent forms have been revised and submitted to the NIAMS through NCR.
 |

## Study AdministrationRecruitment and Participant Status: Figures and Tables

### Figure 1: Enrollment: Overall Study Status

Data as of:

Date of report:

Active

n = 20

Randomized

n = 45

Enrolled

n = 45

Overall Target Enrollment

n = 200

Screened

n = 50

Excluded (n) = 5

Reason 1 (n) = 3

Reason 2 (n) = 2

**Screened**

 = Enrolled + Excluded

**Randomized** = Active +

Discontinued Tx/Follow-up Ongoing + Discontinued Tx/Follow-up Completed + Discontinued from study follow-up not ongoing + Completed

To be randomized

n = 0

Completed Protocol

n = 15

Discontinued from Treatment/Follow-up Ongoing

n = 5

Discontinued from

Study/ follow-up not ongoing

n = 5

Reason 1

n = 3

Reason 2

n = 2

Reason 1

n = 4

Reason 2

n = 1

Reason 1 + Reason 2 = **Discontinued from Study**

Reason 1 + Reason 2 =

**Discontinued from Treatment /Follow-up Ongoing and /Follow-up Completed**

Discontinued from treatment/Follow-up completed

n = 0

{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 randomized trials. [Ann Int Med 2010;152](http://www.consort-statement.org/index.aspx?o=3444" \o "CONSORT 2010 Statement (Ann Int Med)).

### Figure 2: Enrollment: Actual vs. Planned

Aggregate

Data as of: Dec.20, 2016

Date of report: Jan. 31, 2017

0

10

20

30

40

50

60

70

Mar-16

Apr-16

May-16

Jun-16

Jul-16

Aug-16

Sep-16

Oct-16

Nov-16

Dec-16

Jan-17

Feb-17

Mar-17

Apr-17

May-17

Jun-17

**Months**

Combined Monthly Enrollment

Combined Target Enrollment

**Participants**

| **Time Period** | **Planned Number of Enrolled Participants (cumulative)** | **Actual Number of Enrolled Participants (cumulative)** | **% Target Enrolled** |
| --- | --- | --- | --- |
| Mar 16 | 5 | 2 |  |
| Apr 16 | 10 | 5 |  |
| May 16 | 15 | 7 |  |
| Jun 16 | **20** | 9 | 25% |
| Jul 16 | 25 | 11 |  |
| Aug16 | 30 | 11 |  |
| Sep 16 | 35 | 16 |  |
| Oct 16 | **40** | 18 | 50% |
| Nov 16 | 45 | 19 |  |
| Dec 16 | 50 | 22 |  |
| Jan 17 | 55 |  |  |
| Feb 17 | **60** |  | 75% |
| Mar 17 | 65 |  |  |
| Apr 17 | 70 |  |  |
| May 17 | 75 |  |  |
| Jun 17 | **80** |  | 100% |
| **Totals** | **80** | **22** |  |

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

*{Provide the planned 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** | **%[[3]](#footnote-4)** |
| Enrolled |  100 | 100 |
| Active  |  50 |  50 |
| Completed Protocol |  25 |  25 |
|   | **n** | **%[[4]](#footnote-5)\*\*** |
| Discontinued Treatment/Follow-up Ongoing |  10 | 100 |
| Reason 1[[5]](#footnote-6)\*\*\* |  5 |  50 |
| Reason 2 |  5 |  50 |
|   | **n** | **%[[6]](#footnote-7)\*\*\*\*** |
| 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 |   |   |

### Table 2: Screen Failures

Data as of:

Date of report:

| **Reasons[[7]](#footnote-8)** | **Total** |
| --- | --- |
| **n** | **%[[8]](#footnote-9)\*\*** |
| Reason 1 |  |  |
| Reason 2 |  |  |
| **Total Screened** |  |  |
| **Total Screen Failures** |  |  |

### Table 3: Demographics

Data as of:

Date of report:

| **Characteristics[[9]](#footnote-10)** | **Total Screened*****n (%[[10]](#footnote-11)\*\*)*** | **Total Excluded*****n (%[[11]](#footnote-12)\*\*\*)*** | **Total** **Enrolled** ***n (%[[12]](#footnote-13)\*\*\*\*)***  |
| --- | --- | --- | --- |
| **Total Enrolled n:** |
| **Age** | Mean |  |  |  |
| Standard Deviation  |  |  |  |
| Median  |  |  |  |
| Minimum  |  |  |  |
| Maximum |  |  |  |
| **Sex** | Male |  |  |  |
| Female |  |  |  |
| Unknown |  |  |  |
| Undifferentiated |  |  |  |
| **Ethnicity** | Hispanic or Latino |  |  |  |
| Not Hispanic or Latino |  |  |  |
| Unknown/Not Reported |  |  |  |
| **Race** | American Indian/Alaska Native |  |  |  |
| Asian |  |  |  |
| Black or African American |  |  |  |
| Native Hawaiian or Other Pacific Islander |  |  |  |
| White |  |  |  |
| More than one race |  |  |  |
| Unknown/Not Reported |  |  |  |
| **Education** | Grade School |  |  |  |
| High School or equivalent |  |  |  |
| Some college, no degree |  |  |  |
| College degree |  |  |  |
| Graduate degree |  |  |  |
| Doctoral |  |  |  |

### Table 3a: Inclusion Enrollment by Demographics: Actual vs Planned

Data as of: \_\_\_\_\_\_\_\_\_

Date of report: \_\_\_\_\_\_\_\_\_

| **Characteristics** | **Target Planned*****n[[13]](#footnote-14)\**** | **Target Planned****%[[14]](#footnote-15)\*\*** | **Actual Enrolled*****n*** | **Actual Enrolled** **%[[15]](#footnote-16)\*\*** |
| --- | --- | --- | --- | --- |
| **TARGET PLANNED ENROLLMENT n:****ACTUAL ENROLLMENT n:** |
| **Sex** |  Male |  |  |  |  |
|  Female |  |  |  |  |
|  Unknown/Not Reported |  |  |  |  |
|  Undifferentiated |  |  |  |  |
| **Ethnicity** |  Hispanic or Latino |  |  |  |  |
|  Not Hispanic or Latino |  |  |  |  |
|  Unknown/Not Reported |  |  |  |  |
| **Race** |  American Indian/Alaska Native |  |  |  |  |
|  Asian |  |  |  |  |
|  Black or African American |  |  |  |  |
|  Native Hawaiian or  Other Pacific Islander |  |  |  |  |
|  White |  |  |  |  |
|  More than one race |  |  |  |  |
|  Unknown/Not Reported |  |  |  |  |

### Table 4: Key Baseline Characteristics

Data as of:

Date of report:

| **Characteristics[[16]](#footnote-17)** |  |
| --- | --- |
| **Total** |
| **n (%)** |
| **Body Mass Index** | Below 18.5 |  |
| 18.5 – 24.9 |  |
| 25.0 – 29.9 |  |
| 30.0 and Above |  |
|  | **n** |
| **Western Ontario and McMaster Universities Arthritis Index (WOMAC) Total Score** | Mean |  |
| Standard Deviation  |  |
| Median  |  |
| Minimum |  |
| Maximum |  |

## Study AdministrationData Quality Tables

### Table 5: Summary of Missed Visits

Data as of:

Date of report:

| **Missed Visits** | **Total** |
| --- | --- |
| **n (%)** |
| Active Participants |  |
| Number of Active Participants |  |
| Number of Participants Missing Visits |  |
| Number of Missed Visits |  |
| Average Number of Missed Visits for Active Participants |  |
| Completed Participants  |  |
| Number of Completed Participants |  |
| Number of Participants Missing Visits |  |
| Average Number of Missed Visits for Completed Participants |  |
| Total number of missed visits |  |

*{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 6: Summary of Case Report Forms (CRFs) Completed

Data as of:

Date of report:

| **CRFs[[17]](#footnote-18)**  | **Total** |
| --- | --- |
| **Number of CRFs Expected** | **Number of CRFs Completed** | **% of Missing CRFs** |
| Demographics |  |  |  |
| Medical History |  |  |  |
| Vital Signs |  |  |  |
| **etc.** |  |  |  |
| All (total) |  |  |  |

# Safety Assessments for All Participants:Tables and Listings

### Table 7: Incidence of Adverse Events by Body System and Preferred Term

Data as of:

Date of report:

| **Body System and Preferred Term[[18]](#footnote-19)** | **Total n=** |
| --- | --- |
| **ni[[19]](#footnote-20)\*\*** | **(%)[[20]](#footnote-21)\*\*\*** | **Events[[21]](#footnote-22)\*\*\*\*** |
| **Overall**  |  |  |  |
| **Body System 1[[22]](#footnote-23)\*\*\*\*\*** |  |   |   |
| 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).*

### Table 8: Severity of Adverse Events by Preferred Term

Data as of:

Date of report:

| **Preferred Term[[23]](#footnote-24)** | **Severity[[24]](#footnote-25)\*\*****Total n=** |
| --- | --- |
| **Mild** | **Moderate** | **Severe** |
| **n[[25]](#footnote-26)\*\*\* (%)[[26]](#footnote-27)\*\*\*\*** | **n (%)** | **n (%)** |
| Preferred Term 1 |  |  |  |
| Preferred Term 2 |  |  |  |

### Listing 1: Adverse Events

Data as of:

Date of report:

| **Participant ID** | **Age** | **Sex** | **Event Term** | **AE Onset Date** | **AE Stop Date** | **Study Intervention Onset Date** | **Study Intervention Stop Date** | **Relationship[[27]](#footnote-28)** | **Participant discontinued from intervention?** | **Expected (Y/N)** | **Severity[[28]](#footnote-29)\*\*** | **Outcome[[29]](#footnote-30)\*\*\*** | **Serious (Y/N)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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### Listing 2: Serious Adverse Events[[30]](#footnote-31)

Data as of:

Date of report:

| **Participant ID** | **Age** | **Sex** | **Event Term** | **Study****Intervention Duration[[31]](#footnote-32)\*\*** | **Study****Intervention Start Date** | **Study****Intervention Stop Date** | **SAE Onset Date** | **SAE Stop Date or Ongoing** | **Relationship to Study[[32]](#footnote-33)\*\*\*** | **Expected? (Yes/No)** | **Outcome****[[33]](#footnote-34)\*\*\*\*** | **Unanticipated Problem?[[34]](#footnote-35)\*\*\*\*\* (y/n)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |

*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[[35]](#footnote-36)** | **Sex** | **Age** | **Date Enrolled** | **Date of Death** | **Study****Intervention Start Date** | **Study****Intervention Stop Date** | **Cause of Death** | **Relationship[[36]](#footnote-37)\*\*** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|   |   |   |   |   |   |   |   |   |
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### Listing 4: Unanticipated Problems

Data as of:

Date of report:

| **Site** | **Date UP Identified** | **Date of UP incident** | **UP Description[[37]](#footnote-38)** | **Participant ID (or describe group affected)[[38]](#footnote-39)\*\*** | **Action taken[[39]](#footnote-40)\*\*\*****(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)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |  |
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*{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 participants or others at a greater risk of harm than was previously known or recognized}*

### Listing 5: Protocol Deviations

Data as of:

Date of report:

| **Participant ID** | **Deviation Date** | **Deviation Description[[40]](#footnote-41)** | **Deviation Category[[41]](#footnote-42)\*\*** |
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### Table 9: Laboratory Test Results Summary\*

Data as of:

Date of report:

| **Laboratory Test (unit)[[42]](#footnote-43)** | **Study Visits** | **Observed** | **Change from Baseline** |
| --- | --- | --- | --- |
| **n** | **Mean** | **SD** | **Median** | **Min** | **Max** | **n** | **Mean** | **SD** | **Median** | **Min** | **Max** |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| **Test 1** | Screening |   |   |   |   |   |   |   |   |   |   |   |   |
|   | Visit 1 |   |   |   |   |   |   |   |   |   |   |   |   |
|   | Visit 2 |   |   |   |   |   |   |   |   |   |   |   |   |
|   | Visit 3 |   |   |   |   |   |   |   |   |   |   |   |   |
|   | Visit 4 |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| **Test 2** | Screening |   |   |   |   |   |   |   |   |   |   |   |   |
|   | Visit 1 |   |   |   |   |   |   |   |   |   |   |   |   |
|   | Visit 2 |   |   |   |   |   |   |   |   |   |   |   |   |
|   | Visit 3 |   |   |   |   |   |   |   |   |   |   |   |   |
|   | Visit 4 |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| **etc…** | Screening |   |   |   |   |   |   |   |   |   |   |   |   |
|   | Visit 1 |   |   |   |   |   |   |   |   |   |   |   |   |
|   | Visit 2 |   |   |   |   |   |   |   |   |   |   |   |   |
|   | Visit 3 |   |   |   |   |   |   |   |   |   |   |   |   |
|   | Visit 4 |   |   |   |   |   |   |   |   |   |   |   |   |

### Listing 6: Clinically Significant Abnormal Lab Values

Data as of:

Date of report:

| **Participant ID** | **Study Visit** | **Lab Test** | **Baseline Result** | **Current Result** | **% Change from Baseline** | **Normal Range** |
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*{Lab tests that are deemed clinically significant as specified in the study protocol should be listed along with baseline result and normal range as stated by the study lab.}*

1. Insert ‘not applicable’ until milestone is reached. [↑](#footnote-ref-2)
2. \*\* Insert ‘not applicable’ for studies without an intervention duration (i.e., surgical or observational studies) [↑](#footnote-ref-3)
3. % of participants who are enrolled. [↑](#footnote-ref-4)
4. \*\* % 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. [↑](#footnote-ref-5)
5. \*\*\* Reasons should be customized with items relevant to the study protocol. [↑](#footnote-ref-6)
6. \*\*\*\* % of participants who have discontinued the study and are no longer being followed. [↑](#footnote-ref-7)
7. Reasons should be customized with items relevant to the study protocol. [↑](#footnote-ref-8)
8. \*\* % 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. [↑](#footnote-ref-9)
9. Characteristics should be customized with items relevant to the study protocol; the items listed are only examples. [↑](#footnote-ref-10)
10. \*\* The denominator for the percentage should be the total number of participants screened overall. [↑](#footnote-ref-11)
11. \*\*\* The denominator for the percentage should be the total number of participants excluded overall. [↑](#footnote-ref-12)
12. \*\*\*\* The denominator for the percentage should be the total number of participants enrolled overall. [↑](#footnote-ref-13)
13. \* Insert numbers from target/planned enrollment table submitted with grant application (and entered annually into Human Subjects System (HSS) in eRA Commons). [↑](#footnote-ref-14)
14. \*\* The denominator for the percentage should be the total target number of participants planned to be enrolled. [↑](#footnote-ref-15)
15. [↑](#footnote-ref-16)
16. Characteristics should be customized with items relevant to the study protocol (e.g., stratification variables); the items listed are only examples. [↑](#footnote-ref-17)
17. The CRFs listed should be customized with items relevant to the study protocol; the CRFs listed are examples but are not required. [↑](#footnote-ref-18)
18. 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. [↑](#footnote-ref-19)
19. \*\* Number of participants experiencing an AE (participant is to be counted only once for each adverse event). [↑](#footnote-ref-20)
20. \*\*\* % of total number of participants in the study. [↑](#footnote-ref-21)
21. \*\*\*\* Number of events for Body System and Preferred Term. [↑](#footnote-ref-22)
22. \*\*\*\*\* 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. [↑](#footnote-ref-23)
23. For each preferred term, sort by most common event in descending order of incidence. [↑](#footnote-ref-24)
24. \*\* Severity categories should be consistent with those listed within the study protocol. [↑](#footnote-ref-25)
25. \*\*\* Number of participants experiencing a certain severity of an adverse event where each participant is counted only once at highest level of severity. [↑](#footnote-ref-26)
26. \*\*\*\* % of participants experiencing a certain severity of an adverse event. [↑](#footnote-ref-27)
27. 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. [↑](#footnote-ref-28)
28. \*\* The following are commonly used categories: Mild, Moderate, Severe. However, severity should be consistent with the definition of severity as listed within the study protocol. [↑](#footnote-ref-29)
29. \*\*\* *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* [↑](#footnote-ref-30)
30. This listing can be sorted by SAE Description or by Participant ID. [↑](#footnote-ref-31)
31. \*\* The number of days on study treatment at the onset of the SAE. [↑](#footnote-ref-32)
32. \*\*\* 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. [↑](#footnote-ref-33)
33. \*\*\*\* *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 [↑](#footnote-ref-34)
34. \*\*\*\*\* 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 participants or others at a greater risk of harm than was previously known or recognized [↑](#footnote-ref-35)
35. 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. [↑](#footnote-ref-36)
36. \*\* The following are commonly used categories for relationship: Definitely, Probably/Possibly, Not Related. [↑](#footnote-ref-37)
37. Describe harm or potential harm that occurred to participant(s), whether the incident is resolved, and whether the participant(s) remains in the study. If the Unanticipated Problem is a serious adverse event, submit this form and complete the Serious Adverse Event form. [↑](#footnote-ref-38)
38. \*\* If the Unanticipated Problem affects a particular group in the study, please identify that group, i.e., participants in Treatment Group A, participants 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. [↑](#footnote-ref-39)
39. \*\*\* Action taken with the study as a result of the Unanticipated Problem? (include all that apply)

No action

Revise protocol to eliminate apparent immediate hazards to participants

Modification of inclusion or exclusion criteria to mitigate newly identified risks

Implementation of additional procedures for monitoring participants

Suspension of enrollment of new participants

Notify currently enrolled participants

Suspension of research procedures in currently enrolled participants

Modification of consent documents to include a description of newly recognized risks (site and/or study wide)

Provision of additional information about newly recognized risks to previously enrolled participants

Other, specify [↑](#footnote-ref-40)
40. 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 was called to return the drug and was issued unexpired medication. [↑](#footnote-ref-41)
41. \*\* 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. [↑](#footnote-ref-42)
42. Table may include lab test results that are clinically significant, as defined by the protocol, or ALL lab test results. [↑](#footnote-ref-43)