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

# -Closed 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. Outlined below are a few issues that should be considered as this document is tailored:

* It is recommended that data stratified by treatment group be masked (i.e., Treatment A versus Treatment B).
* For studies in which there are masked treatment groups, the Monitoring Body, at its discretion, may request to review unmasked data (e.g., Placebo versus Steroid) in the closed session materials. The decision to present results in an unmasked fashion should be discussed with the NIAMS and the Monitoring Body.
* 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> |
| **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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## Summary of Closed Session Report Contents

|  |  |
| --- | --- |
| **General summary of differences by masked group** |  |
| **Changes since the last DSMB meeting** | i.e., New tables, figures, etc.  |
| **Please note or highlight any information that is noteworthy for the DSMB’s review** |  |

## Study AdministrationRecruitment and Participant Status: Figures and Tables

##

### Table 1: Participant Enrollment Status by Site and Masked Treatment Group

Data as of:

Date of report:

|  | **Masked Treatment Group (n=)** | **Masked Treatment Group (n=)** |
| --- | --- | --- |
|  | **Site 1** | **Site 2** | **Site 3** | **Site 4** | **Site 5** | **Total** | **Site 1** | **Site 2** | **Site 3** | **Site 4** | **Site 5** | **Total** |
|  | **n** | **%****[[1]](#footnote-2)** | **n** | **%\*** | **n** | **%\*** | **n** | **%\*** | **n** | **%\*** | **n** | **%\*** | **n** | **%\*** | **n** | **%\*** | **n** | **%\*** | **n** | **%\*** | **n** | **%\*** | **n** | **%\*** |
| Enrolled |  | 100 |  | 100 |  | 100 |  | 100 |  | 100 |  | 100 |  | 100 |  | 100 |  | 100 |  | 100 |  | 100 |  | 100 |
| Active |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Completed Protocol |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | **n** | **%****[[2]](#footnote-3)\*\*** | **n** | **%**\*\* | **n** | **%\*\*** | **n** | **%\*\*** | **n** | **%\*\*** | **n** | **%**\*\* | **n** | **%**\*\* | **n** | **%**\*\* | **n** | **%\*\*** | **n** | **%\*\*** | **n** | **%\*\*** | **n** | **%**\*\* |
| Discontinued from Treatment/Follow-up Ongoing |  | 100 |  | 100 |  | 100 |  | 100 |  | 100 |  | 100 |  | 100 |  | 100 |  | 100 |  | 100 |  | 100 |  | 100 |
| Reason 1[[3]](#footnote-4)\*\*\* |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Reason 2 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | **n** | **%****[[4]](#footnote-5)\*\*\*\*** | **n** | **%**\*\*\*\* | **n** | **%****\*\*\*\*** | **n** | **%****\*\*\*\*** | **n** | **%****\*\*\*\*** | **n** | **%**\*\*\*\* | **n** | **%**\*\*\*\* | **n** | **%**\*\*\*\* | **n** | **%****\*\*\*\*** | **n** | **%****\*\*\*\*** | **n** | **%****\*\*\*\*** | **n** | **%**\*\*\*\* |
| Discontinued from Treatment/Follow-up Completed |  | 100 |  | 100 |  | 100 |  | 100 |  | 100 |  | 100 |  | 100 |  | 100 |  | 100 |  | 100 |  | 100 |  | 100 |
| Reason 1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Reason 2 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | **n** | **%**\*\*\*\* | **n** | **%**\*\*\*\* | **n** | **%**\*\*\*\* | **n** | **%**\*\*\*\* | **n** | **%**\*\*\*\* | **n** | **%**\*\*\*\* | **n** | **%**\*\*\*\* | **n** | **%**\*\*\*\* | **n** | **%**\*\*\*\* | **n** | **%**\*\*\*\* | **n** | **%**\*\*\*\* | **n** | **%**\*\*\*\* |
| Discontinued from Study/Follow-up Not Ongoing |  | 100 |  | 100 |  | 100 |  | 100 |  | 100 |  | 100 |  | 100 |  | 100 |  | 100 |  | 100 |  | 100 |  | 100 |
| Reason 1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Reason 2 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

*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.*

### Table 2: Demographics by Site and Masked Treatment Group

Data as of:

Date of report:

|  | **Masked Treatment Group (n= )** | **Masked Treatment Group (n= )** |
| --- | --- | --- |
| **Characteristics[[5]](#footnote-6)** | **Site 1** | **Site 2** | **Site 3****n (%\*\*)** | **Site 4****n (%\*\*)** | **Site 5****n (%\*\*)** | **Total****n (%[[6]](#footnote-7)\*\*\*)** | **Site 1** | **Site 2** | **Site 3****n (%\*\*)**  | **Site 4****n (%\*\*)**  | **Site 5****n (%\*\*)**  | **Total** **n (%\*\*\*)** |
| **n (%[[7]](#footnote-8)\*\*)** | **n (%\*\*)**  | **n (%\*\*)** | **n (%\*\*)** |
|  **Total Enrolled:**  |   |   |  |  |  |   |   |   |  |  |  |   |
| **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 3: Key Baseline Characteristics by Site and Masked Treatment Group

Data as of:

|  | **Masked Treatment Group (n= )** | **Masked Treatment Group (n= )** |
| --- | --- | --- |
| **Characteristics[[8]](#footnote-9)** | **Site 1** | **Site 2** | **Site 3** | **Site 4** | **Site 5** | **TOTAL** | **Site 1** | **Site 2** | **Site 3** | **Site 4** | **Site 5** | **TOTAL** |
| **n (%)** | **n (%)** | **n (%)** | **n (%)** | **n (%)** | **n (%)** | **n (%)** | **n (%)** | **n (%)** | **n (%)** | **n (%)** | **n (%)** |
| **Body Mass Index** | Below 18.5 |  |  |  |  |  |  |  |  |  |  |  |  |
| 18.5 – 24.9 |  |  |  |  |  |  |  |  |  |  |  |  |
| 25.0 – 29.9 |  |  |  |  |  |  |  |  |  |  |  |  |
| 30.0 and Above |  |  |  |  |  |  |  |  |  |  |  |  |
|  | **n** | **n** | **n** | **n** | **n** | **n** | **n** | **n** | **n** | **n** | **n** | **n** |
| **Western Ontario and McMaster Universities Arthritis Index (WOMAC) Total Score** | Mean |  |  |  |  |  |  |  |  |  |  |  |  |
| Standard Deviation |  |  |  |  |  |  |  |  |  |  |  |  |
| Median |  |  |  |  |  |  |  |  |  |  |  |  |
| Minimum |  |  |  |  |  |  |  |  |  |  |  |  |
| Maximum |  |  |  |  |  |  |  |  |  |  |  |  |

Date of report:

## Study AdministrationData Quality Table

### Table 4: Summary of Missed Visits by Site and Masked Treatment Group

Data as of:

Date of report:

|  | **Masked Treatment Group (n= )** | **Masked Treatment Group (n= )** |
| --- | --- | --- |
| **Missed Visits** | **Site 1** | **Site 2** | **Site 3** | **Site 4** | **Site 5** | **Total** | **Site 1** | **Site 2** | **Site 3** | **Site 4** | **Site 5** | **Total** |
| **n (%****[[9]](#footnote-10))** | **n (%\*)** | **n (%\*)** | **n (%\*)** | **n (%\*)** | **n (%****[[10]](#footnote-11)\*\*)** | **n (%\*)** | **n (%\*)** | **n (%\*)** | **n (%\*)** | **n (%\*)** | **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 |  |  |  |  |  |  |  |  |  |  |  |  |
| Number of Missed Visits |  |  |  |  |  |  |  |  |  |  |  |  |
| Average Number of Missed Visits for Completed 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.}*

## Safety Assessments for All Participants:Tables and Listings

### Table 5: Incidence of Adverse Events by Body System and Preferred Term and Masked Treatment Group

Data as of:

Date of report:

|  | **Masked Treatment Group (n= )** | **Masked Treatment Group (n= )** |
| --- | --- | --- |
| **Body System and Preferred Term[[11]](#footnote-12)** | **Total N=** | **Total N=** |
| **n****[[12]](#footnote-13)\*\*** | **(%)****[[13]](#footnote-14)\*\*\*** | **Events****[[14]](#footnote-15)\*\*\*\*** | **n**\*\* | **(%)**\*\*\* | **Events**\*\*\*\* |
| **Overall**  |  |  |  |  |  |  |
| **Body System 1[[15]](#footnote-16)\*\*\*\*\*** |  |  |  |  |  |  |
| 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 6: Severity of Adverse Events by Preferred Term and Masked Treatment Group

Data as of:

Date of report:

|  | **Severity[[16]](#footnote-17)** | **Severity\*** |
| --- | --- | --- |
| **Preferred Term[[17]](#footnote-18)\*\*** | **Masked Treatment Group Total n=**  | **Masked Treatment Group Total n=**  |
| **Mild** | **Moderate** | **Severe** | **Mild** | **Moderate** | **Severe** |
| **n****[[18]](#footnote-19)\*\*\* (%)****[[19]](#footnote-20)\*\*\*\*** | **n (%)** | **n (%)** | **n**\*\*\* **(%)**\*\*\*\* | **n (%)** | **n (%)** |
| Preferred Term 1 |  |  |  |  |  |  |
| Preferred Term 2 |  |  |  |  |  |  |

### Listing 1: Adverse Events by Site and Masked Treatment Group

Data as of:

Date of report:

| **Site** | **Participant ID** | **Masked****Treatment Group** | **Age** | **Sex** | **Event Term** | **AE Onset Date** | **AE Stop Date** | **Study Intervention Start Date** | **Study****Intervention Stop Date** | **Relationship[[20]](#footnote-21)** | **Participant discontinued from intervention?** | **Expected (Y/N)** | **Severity[[21]](#footnote-22)\*\*** | **Outcome[[22]](#footnote-23)\*\*\*** | **Serious (Y/N)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
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### Listing 2: Serious Adverse Events by Site and Masked Treatment Group[[23]](#footnote-24)

Data as of:

Date of report:

| **Site** | **Participant ID** | **Masked****Treatment Group** | **Age** | **Sex** | **Event Term** | **Study****Intervention Duration[[24]](#footnote-25)\*\*** | **Study****Intervention Start Date** | **Study****Intervention Stop Date** | **SAE Onset Date** | **SAE Stop Date or Ongoing** | **Relationship to Study[[25]](#footnote-26)\*\*\*** | **Expected? (Yes/No)** | **Outcome[[26]](#footnote-27)\*\*\*\*** | **Unanticipated Problem?[[27]](#footnote-28)\*\*\*\*\* (y/n)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
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*NOTE: All AEs in Listing 1 that have been designated as an SAE (“Y”) should be also listed on this Listing.*

###

### Listing 3: Deaths by Site and Masked Treatment Group

Data as of:

Date of report:

| **Site** | **Participant ID[[28]](#footnote-29)** | **Masked****Treatment Group** | **Sex** | **Age** | **Date Enrolled** | **Date of Death** | **Study****Intervention Start Date** | **Study Intervention Stop Date** | **Cause of Death** | **Relationship[[29]](#footnote-30)\*\*** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
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### Listing 4: Unanticipated Problems by Masked Treatment Group

Data as of:

Date of report:

| **Site** | **Date UP Identified** | **Date of UP incident** | **UP Description[[30]](#footnote-31)** | **Participant ID (or describe group affected)** | **Masked****Treatment Group (if applicable)[[31]](#footnote-32)\*\*** | **Action taken[[32]](#footnote-33)\*\*\*****(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 by Masked Treatment Group

Data as of:

Date of report:

| **Site** | **Participant ID** | **Masked Treatment Group** | **Deviation Date** | **Deviation Description[[33]](#footnote-34)** | **Deviation Category[[34]](#footnote-35)\*\*** |
| --- | --- | --- | --- | --- | --- |
|   |   |  |  |   |  |
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### Table 7: Laboratory Test Results Summary by Masked Treatment Group[[35]](#footnote-36)

Data as of:

Date of report:

| **Laboratory Test (unit)** | **Masked****Treatment Group** | **Study Visits** | **Observed** | **Change from baseline** |
| --- | --- | --- | --- | --- |
| **n** | **Mean** | **SD** | **Median** | **Min** | **Max** | **n** | **Mean** | **SD** | **Median** | **Min** | **Max** |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| **Test 1** |  **(n=)** | Screening |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   | Visit 1 |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   | Visit 2 |   |   |   |   |   |   |   |   |   |   |   |   |
|  |  **(n=)** | Screening |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   | Visit 1 |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   | Visit 2 |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| **Test 2** |  **(n=)** | Screening |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   | Visit 1 |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   | Visit 2 |   |   |   |   |   |   |   |   |   |   |   |   |
|  |  **(n=)** | Screening |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   | Visit 1 |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   | Visit 2 |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| **etc…** |  |   |   |   |   |   |   |   |   |   |   |   |   |   |

### Table 8a- 8*i*: Laboratory Test Results Summary by Site and by Masked Treatment Group[[36]](#footnote-37)

Data as of:

Date of report:

| **Laboratory Test Unit[[37]](#footnote-38)\*\*** | **Normal Range** | **Masked****Treatment Group** | **Study Visits** | **Observed** | **Change from baseline** |
| --- | --- | --- | --- | --- | --- |
| **n** | **Mean** | **SD** | **Median** | **Min** | **Max** | **n** | **Mean** | **SD** | **Median** | **Min** | **Max** |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| **Test 1** |  |  **(n=)** | Screening |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   | Visit 1 |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   | Visit 2 |   |   |   |   |   |   |   |   |   |   |   |   |
|  |  |  **(n=)** | Screening |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   | Visit 1 |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   | Visit 2 |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| **Test 2** |  |  **(n=)** | Screening |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   | Visit 1 |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   | Visit 2 |   |   |   |   |   |   |   |   |   |   |   |   |
|  |  |  **(n=)** | Screening |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   | Visit 1 |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   | Visit 2 |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| **etc…** |  |  |   |   |   |   |   |   |   |   |   |   |   |   |   |

###

### Listing 6: Clinically Significant Abnormal Lab Values by Site and Masked Treatment Group

Data as of:

Date of report:

| **Site** | **Participant ID** | **Masked****Treatment Group** | **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. % of participants who are enrolled. [↑](#footnote-ref-2)
2. \*\* % of participants who have discontinued treatment, but continued to be followed as part of the study. [↑](#footnote-ref-3)
3. \*\*\* Reasons should be customized with items relevant to the study protocol. [↑](#footnote-ref-4)
4. \*\*\*\* % of participants who have discontinued the study and are no longer being followed. [↑](#footnote-ref-5)
5. Categories should be customized with items relevant to the study protocol; the items listed are only examples. [↑](#footnote-ref-6)
6. [↑](#footnote-ref-7)
7. \*\* The denominator for the percentage should be the total number of participants enrolled by site.

\*\*\* The denominator for the percentage should be the total number of participants enrolled overall. [↑](#footnote-ref-8)
8. Characteristics should be customized with items relevant to the study protocol (e.g., stratification variables); the items listed are only examples. [↑](#footnote-ref-9)
9. Denominator should be the total number of participants enrolled by site. [↑](#footnote-ref-10)
10. \*\* Denominator should be the total number of participants enrolled overall. [↑](#footnote-ref-11)
11. 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-12)
12. \*\* Number of participants experiencing an AE (participant is to be counted only once for each adverse event). [↑](#footnote-ref-13)
13. \*\*\* % of total number of participants in the study. [↑](#footnote-ref-14)
14. \*\*\*\* Number of events for Body System and Preferred Term. [↑](#footnote-ref-15)
15. \*\*\*\*\* 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-16)
16. Severity categories should be consistent with those listed within the study protocol. [↑](#footnote-ref-17)
17. \*\* For each preferred term, sort by most common event in descending order of incidence. [↑](#footnote-ref-18)
18. \*\*\* 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-19)
19. \*\*\*\* % of participants experiencing a certain severity of an adverse event. [↑](#footnote-ref-20)
20. 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-21)
21. \*\* 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-22)
22. \*\*\* 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-23)
23. This listing can be sorted by SAE Description or by Participant ID. [↑](#footnote-ref-24)
24. \*\* The number of days on study treatment at the onset of the SAE. [↑](#footnote-ref-25)
25. \*\*\* 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-26)
26. \*\*\*\* 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-27)
27. \*\*\*\*\* 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-28)
28. 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 by Site. [↑](#footnote-ref-29)
29. \*\* The following are commonly used categories for relationship: Definitely, Probably/Possibly, Not Related. [↑](#footnote-ref-30)
30. 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-31)
31. \*\* 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-32)
32. \*\*\* 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-33)
33. 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-34)
34. \*\* 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-35)
35. Table may include lab test results that are clinically significant, as defined by the protocol, or ALL lab test results. [↑](#footnote-ref-36)
36. One table for each site. [↑](#footnote-ref-37)
37. \*\* Table may include lab test results that are clinically significant, as defined by the protocol, or ALL lab test results. [↑](#footnote-ref-38)