# NIAMS 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> |  |  |
| Anticipated Site Agreements Signature Date <Insert the planned date of the signature on the first site’s agreement and note the site to which the date corresponds> |  |  |
| Actual Site Agreements Signature Date <Insert the actual date of the signature on the first site’s agreement and note the site to which the date corresponds > |  |  |
| 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-1) <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\*[[2]](#footnote-2)\* <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[[3]](#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[[4]](#footnote-4)\* <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[[5]](#footnote-5)\* <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> |  |  |

## Enrollment: Actual vs. Expected

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** | **Expected 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 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.}

1. Insert ‘not applicable’ until milestone is reached. [↑](#footnote-ref-1)
2. \* Insert ‘not applicable’ until milestone is reached. [↑](#footnote-ref-2)
3. Insert ‘not applicable’ for studies without an intervention duration (i.e., surgical or observational studies) [↑](#footnote-ref-3)
4. \* Insert ‘not applicable’ until milestone is reached. [↑](#footnote-ref-4)
5. \* Insert ‘not applicable’ until milestone is reached. [↑](#footnote-ref-5)