NICHD Extramural Clinical Trials Monitoring and Oversight

All NICHD new and competing renewal awards—grants, cooperative agreements, and contracts—that involve clinical trials are subject to monitoring and oversight procedures. Effective oversight ensures quality of the clinical trial, safety of research participants, reliability of data, and appropriate stewardship of funds.

As part of this process, NICHD applications to be funded or awards with one or more clinical trials must establish milestones and provide post-award updates on the milestones for each trial. See Milestone Plans in NOT-HD-18-020, NICHD Policy on Monitoring and Oversight of Clinical Trials.

Expectations for Milestone Planning and Updates for Grants and Cooperative Agreements

For applications under funding consideration or already awarded, NICHD program staff contacts the principal investigator (PI) and authorized organizational representative (AOR) or signing official (SO) to develop milestones. Timing of this request may vary and is not a guarantee of funding.

Note: The milestone process for contracts may differ and is addressed by the NICHD contracting officer and contracting officer's representative. Please consult the contracting officer if you have questions.

When notified to establish milestones, use the NIH eRA Commons to access the Human Subjects System (HSS) and perform the following steps:

- Select the appropriate study record for the application. If the application involves more than one study record that is considered a clinical trial, repeat this action for each applicable record.
- Update recruitment plans and inclusion enrollment information as needed
- Complete Section 6: Clinical Trial Milestone Plan
- Add FOA-required and/or custom milestones by updating the Study Timeline document in HSS
- Perform other updates to HSS fields and data elements if needed based on milestone discussions with your program officer, which are strongly encouraged
- (AOR or SO only) Submit applications, information requested just-in-time, mandatory reports, and other grant materials to NIH. In HSS, PI entries are routed to the AOR or SO for submission.

Frequency of Milestone Updates

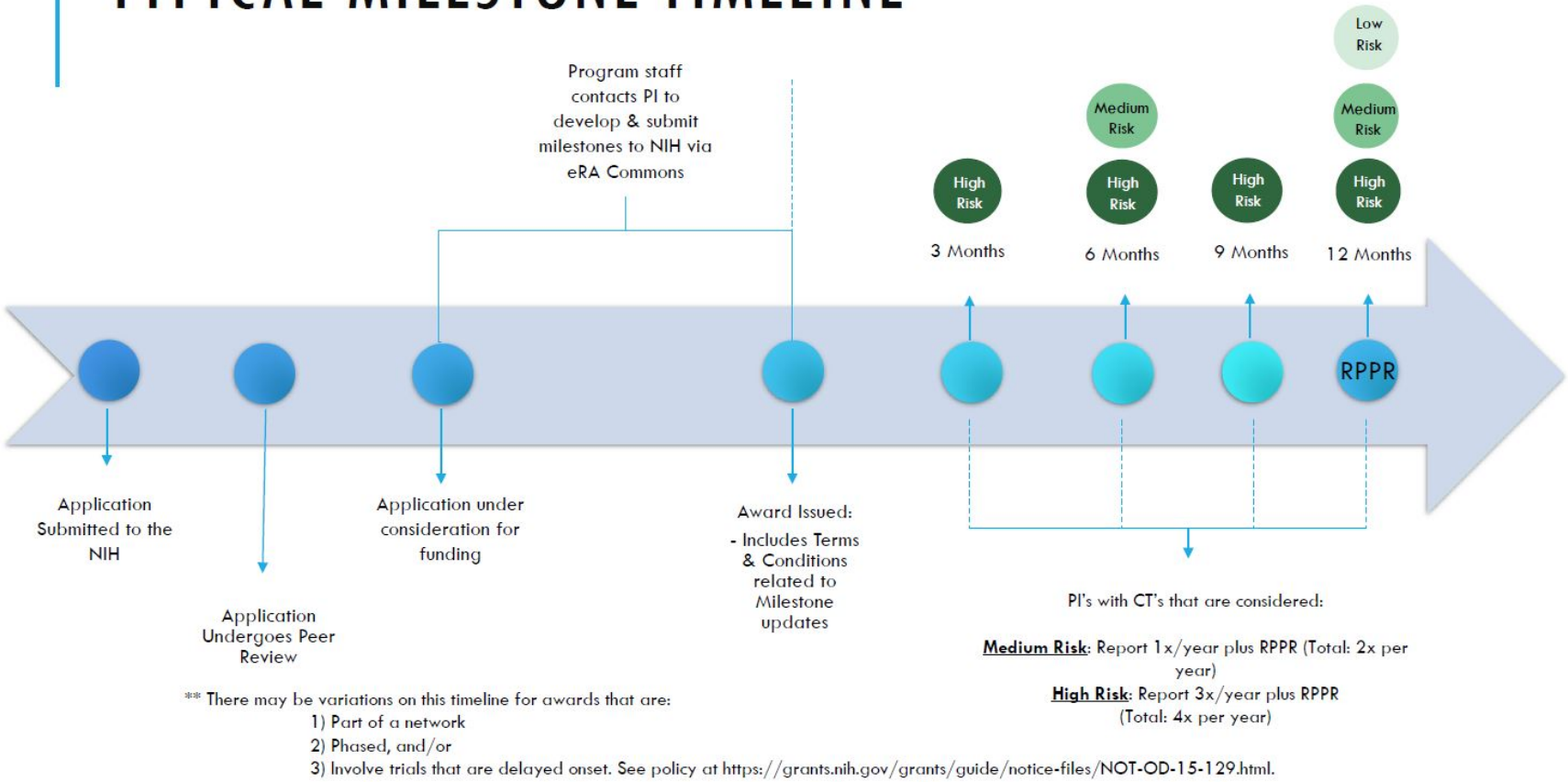
After peer review, NICHD staff assesses risks associated with proposed clinical trials and assigns a risk rating to each clinical trial. For additional information, see Risk Analysis in NOT-HD-18-020, NICHD Policy on Monitoring and Oversight of Clinical Trials.

As the following table illustrates, the NICHD risk rating determines the frequency of milestone monitoring. Due dates are typically based on an award's budget start date.

Risk rating	**Reporting frequency**
Low	Annually, with the Research Performance Progress Report (RPPR)
Medium	Twice yearly, 6 months after budget start date and with RPPR
High	Four times yearly, every 3 months after budget start date and with RPPR

The following "Typical Milestone Timeline"provides a visualization of the milestone update process.

TYPICAL MILESTONE TIMELINE



Timeline for a typical milestone plan based on the assessed risk rating of the clinical trial. Includes Step 1: Application submitted to NIH. Step 2: Application undergoes peer review. Step 3: Application under consideration for funding. Step 4: Program staff contacts PI to develop and submit milestones to NIH via eRA Commons. Step 5: Award issued, includes terms and conditions related to milestone updates. Notes that there may be variations on this timeline for awards that are: 1. Part of a network; 2. Phased; and/or 3. Involve trials that are delayed onset. See policy at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-129.html.

Also includes timing of milestone reporting for low-, medium-, and high-risk clinical trials. Low-risk trials require an RPPR once every 12 months. Medium-risk trials require reporting twice a year: once at 6 months and then the RPPR at 12 months. High-risk trials require reporting four times per year: once every 3 months and the RPPR at 12 months.

Access the Human Subjects System

Log in to the eRA Commons.

For detailed instructions, consult the HSS User Guide for External Users or view NIH's Accessing Human Subjects System for SOs and PIs video.

Completing Milestones

Work with the assigned NICHD program officer as you develop milestones and follow the steps outlined in this section.

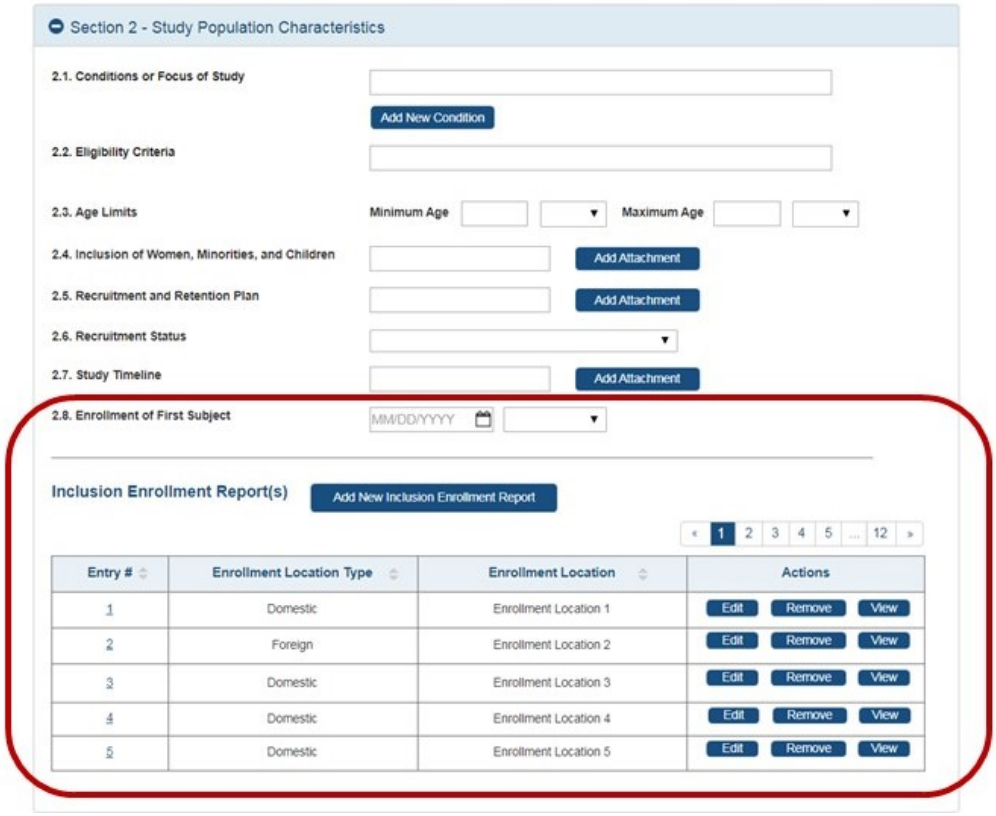
After your organization submits milestones to NICHD through HSS, the program officer reviews them and notifies the PI and AOR or SO if additional revisions are needed.

Update Recruitment Plans and Inclusion Enrollment Data (as needed)

Each study record supports data collection on study participants for up to 20 Inclusion Enrollment Reports (IER) in Section 2 – Study Population Characteristics.

Update planned or cumulative (actual) participant counts and other fields as needed. Consult New 2-Step Submission Process for RPPRs with Inclusion Enrollment Data for guidance on reporting inclusion data in a Research Performance Progress Report (RPPR).

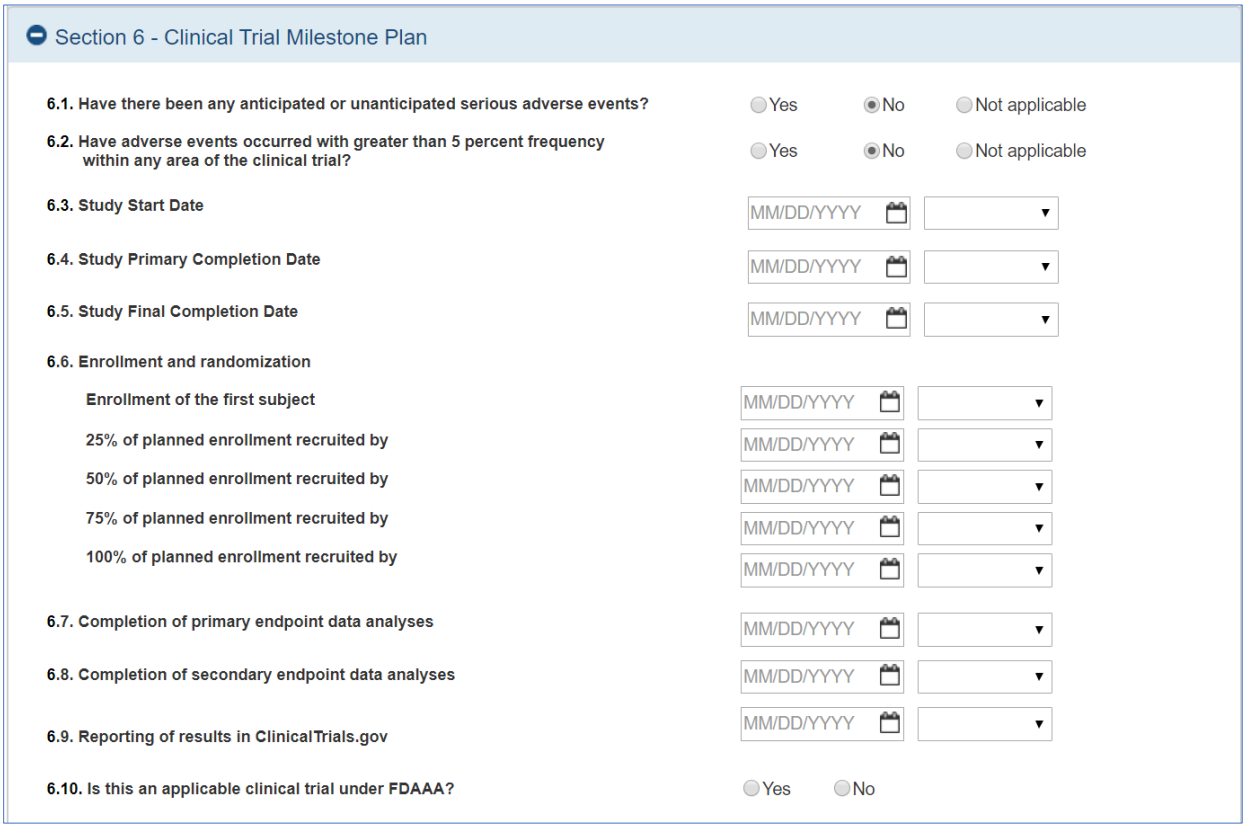
1. Access the bottom portion of the Inclusion Enrollment Report, which contains separate tables for planned and cumulative data.



2. To update the planned counts, enter numbers in the online report.
3. Follow instructions in HSS Online Help for saving and submitting the updates.

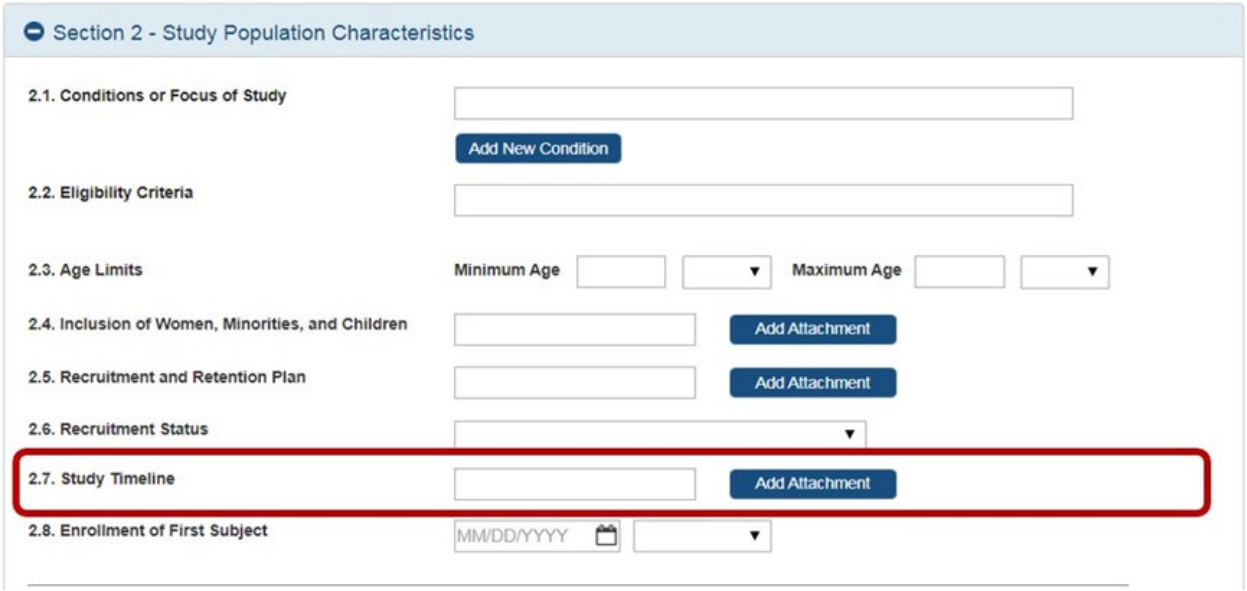
Complete Section 6

In HSS use Section 6, Milestone Plan, to define and update critical clinical trial activities.



Update the Study Timeline

In Section 2, Study Population Characteristics, attach a revised timeline document as needed to add milestones identified in the funding opportunity announcement or by NICHD program staff.



Make Other Requested Revisions or Updates

NICHD staff may also request changes to other fields or attachments in HSS, such as data and safety monitoring plans.

What Happens After Milestones Are Established

Once milestones have been finalized, NICHD incorporates the risk level and corresponding frequency for milestone updates into the terms and conditions of award.

Investigators must provide milestone updates to NICHD through the eRA Commons directly to HSS or, when appropriate, through the RPPR.

Questions or Concerns?

You are encouraged to contact your NICHD program officer. If you do not know who that is, email NICHDTrials@mail.nih.gov.