

**Clinical research milestones:** Prior to award, investigators conducting clinical studies or clinical trials will be required to provide detailed interim performance measures and timelines for completing key objectives and administrative functions for the proposed clinical study or trial, as applicable. Milestones should be easily measurable and realistic. Below is a list of potentially useful milestones; please tailor this list to each of your clinical study/trial aims and provide approximate dates or project year and quarters (e.g., Yr01/Q1, Yr01/Q2, Yr01/Q3, etc.) when each will be conducted/completed.

- Completion of all required regulatory approvals (e.g., IND/IDE from the FDA or agencies in other countries)
- Finalize contracts/third party agreements
- Finalize clinical protocol(s)
- Finalize consent forms
- Finalize recruitment materials, surveys and data collection tools
- DSMB approval
- IRB approval
- Finalize data entry forms/system
- Finalize training manuals and manuals of operations
- Good Clinical Practice (GCP) and other relevant technical training of study staff
- Training of staff on study protocol and procedures
- Registration of clinical trial in ClinicalTrials.gov
- Anticipated dates of:
  - Enrollment of the first participant
  - Enrollment of 25% of the target sample size
  - Enrollment of 50% of the target sample size
  - Enrollment of 75% of the target sample size
  - Enrollment of 100% of the target sample size
- Posting of consent forms on ClinicalTrials.gov
- Completion of intervention (i.e., date of last intervention visit)
- Completion of data collection (i.e., date of last study visit)
- Completion of primary endpoint and secondary endpoint data analyses
- Completion of primary outcome paper
- Closeout plans/communication of results to participants
- Reporting of results in ClinicalTrials.gov
- Sharing of study data per NIH policies

These milestones will be negotiated at the time of the award, as appropriate. Future year support is contingent on satisfactory achievement of performance milestones. Investigators should track and report milestone achievement in the annual progress report. If milestones are not achieved fully, NIDDK may request development of a remedial plan and more frequent monitoring of progress, or take other remedial actions.