

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. Milestones may include, as applicable, but are not limited to:

- Finalization of the clinical study/trial protocol(s) and informed consent/assent forms (with NIDDK program official agreement, if applicable) and IRB approval
- Registration of the clinical trial(s) in ClinicalTrials.gov
- Completion of all required regulatory approvals (e.g., Investigational New Drug Application from the Food and Drug Administration)
- Contracts/third party agreements, including intervention product supply
- Good Clinical Practice (GCP) and other relevant technical training of study staff
- Anticipated date of enrollment of the first participant
- Recruitment and/or randomization of 25%, 50%, 75% and 100% of the target sample size
- Follow-up visit completion, if applicable, of 25%, 50%, 75% and 100% of the enrolled or randomized study population, including women, minorities and children
- Completion of data collection
- Completion of primary endpoint and secondary endpoint data analyses
- Completion of final study report and manuscript submission
- Closeout plans/communication of results to participants
- Reporting of results in ClinicalTrials.gov.

These milestones will be negotiated at the time of the award, as appropriate. Future year support is contingent on satisfactory achievement of performance milestones. 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.