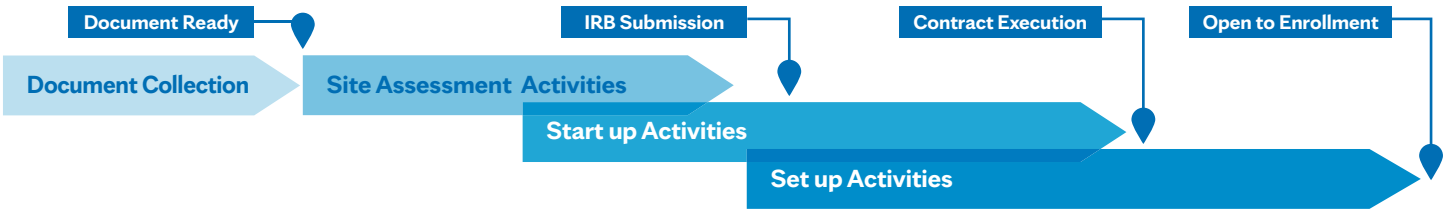
Information for Sponsors/CROs

Regarding Mayo Clinic's Clinical Trial Activation Process

Mayo Clinic works directly with Sponsors/CROs to expedite study activation for clinical trials. We will work closely with you to achieve study activation in an efficient manner while maintaining the highest level of accuracy.

At Mayo Clinic, four phases of activities are completed to prepare a new industry-sponsored study through activation to open to enrollment. The Sponsor Document Collection and Study Assessment phases must be completed in their entirety before initiating the next phase. Once those are completed, Study Start-Up and Set-Up will occur in parallel. Prior to entering the process, all new clinical trials will be allocated to one of the 16/22/30 week lanes for facilitation by Office of Clinical Trials (OCT). Lane selection is dependent on many factors, including, but not limited to study complexity, upcoming amendments, Sponsor and Departmental commitment to negotiation timelines, and institutional resource availability. The OCT-Associate Project Manager (APM) will liaise with the industry sponsor to ensure alignment with the proposed lane. Your timely attention to submitting documents is critical to ensure the success of the activation process.



SPONSOR DOCUMENT COLLECTION

Timeline Goal: Dependent upon availability of Sponsor documents

The first step is to collect critical information required to initiate the Study Assessment and Start-Up processes.

Specifically, if applicable to your trial, the documents required are:

- Final protocol
- Informed Consent (unlocked draft)
- Budget template (unlocked draft)
- Clinical Trial Agreement (unlocked draft)
- Investigator Brochure
- Device Manual
- Lab Manual
- Recombinant DNA Advisory Committee Letter
- Pathology Manual
- Pharmacy Manual
- Imaging Manual
- FDA letter (IND/IDE designation) or justification
- Participant contact materials
- Advertising materials
- DSMB/DMC Charter (or justification, if not provided)
- Completed Company Information Sheet (provided by Mayo)
- Feasibility Committee approval for Mayo Clinic Comprehensive Cancer Center (MCCCC) protocols

The information in these documents is **required** to start the study assessment process at Mayo Clinic. Study teams are instructed to await the receipt of all applicable documents prior to initiating study assessment activities (internal or departmental approvals, budget requests, scientific review, etc.).

STUDY ASSESSMENT

Timeline Goal contingent upon final lane assignment: 6 weeks (16 Week Lane), 8 weeks (22 Week Lane) or 12 weeks (30 Week Lane)

The study assessment process begins after receipt of all required documents and typically requires six to twelve weeks to complete. Once all documents are received, the study is assigned to a study team in the investigator's department. Timelines **may** be affected by committee review schedules and Sponsor review and approval responsiveness. Please note, some committees do not meet as frequently. Required assessment activities may include but are not limited to:

- Disease Group approval (Depending on the department; may occur earlier in some departments)
- Scientific or Departmental Committee Reviews (Some departments may require a separate prioritization assessment)
- Accrual feasibility assessment
- Gathering necessary budget elements including personnel efforts, apheresis, pharmacy, radiology, laboratory, and any other required service costs
- Converting the informed consent document to the Mayo template and obtaining your initial approval
- Completion of IRBe Financial Disclosures for study
- Preparation of the IRB application
- Third Party Risk Management (TPRM), if applicable
- Assessment of equipment needs
- Any ancillary committee approvals that may be required prior to the study start-up submission (IBC, Pediatrics, OB/GYN, etc.)
- The Office of Clinical Trials will contact you during Study Assessment to schedule a teleconference and discuss the Study Start-Up process and timeline

STUDY START-UP

Timeline Goal contingent upon final lane assignment: 10 weeks (16 Week Lane), 12 weeks (22 Week Lane) or 15 weeks (30 Week Lane)

At Mayo Clinic, study start-up refers to activities outlined below that are completed in parallel. As a reminder, the Study Assessment phase must be completed in its entirety to submit the study to the institutional shared services for the study start-up process.

- Contract negotiations
- Budget negotiations
- Code & Coverage Analysis
- ICF Review
- Ancillary Committee Reviews
- IRB Submission/Review
- Purchase Agreement, if needed

STUDY SET-UP ACTIVITIES

Timeline Goal contingent upon final lane assignment: 10 weeks (16 Week Lane), 12 weeks (22 Week Lane) or 14 weeks (30 Week Lane)

Study set-up activities listed below will be completed in parallel with study start-up to further streamline the activation process. Upon completion, the study will be opened to enrollment.

- Lab/Pharmacy/Service Area Set-up
- Regulatory files
- Study staff training and delegation
- Equipment/device procurement, if applicable
- EHR (Epic) builds, if applicable
- Site Initiation Visit
- Site Activation by Sponsor

MORE INFORMATION

If you have any questions regarding the process to develop and activate a study at Mayo Clinic, please contact the Office of Clinical Trials at ClinicalTrialsOffice@mayo.edu.

We look forward to working with you!

MC0248-104rev0625