

## Study Assessment

- Confidentiality Agreement
- Review Protocol
- Site Qualification
- Accrual Feasibility
- Recruitment Plan
- Logistics
- Design of ICF
- Financial Disclosure /COI Review

## Study Start-Up

- Study Activation
  - ACT Process
  - Code and Coverage
  - Budget
  - IRB/Ancillary Committee Review
  - Contract Negotiation
  - ClinicalTrials.gov Registration
- Study Set-Up
  - Study Operations Planning
  - Data Collection Plan
  - Regulatory Files
  - Staff Training and Delegation
  - Lab
  - CRTU
  - Research Billing
  - Pharmacy
  - Velos
  - Site Initiation

## Study Conduct

- Participant Recruitment
  - Advertising
  - Recruitment
  - Screening
  - Consenting
- Participant Management
  - Velos
  - Ordering and Scheduling
  - Biospecimen Management
  - Participant Follow-Up
  - Remuneration/Reimbursement
  - Research Billing
  - Maintaining Participant Records
  - Data Collection
  - Safety Monitoring
  - Re-consenting
  - Monitoring Consent Status
- Study Oversight, Maintenance and Reporting
  - Regulatory File Maintenance
  - IRB Continuing Review
  - Amendments
  - Reportable Events
  - Regulatory Reporting
  - Data Management
  - Data Query Resolution
  - Study Monitoring/Audits
  - Budget Management

## Study Closure

- Study Close Out Visit
- IRB Closure
- Archiving Records
- ClinicalTrials.gov Closure
- Post-Award Closure