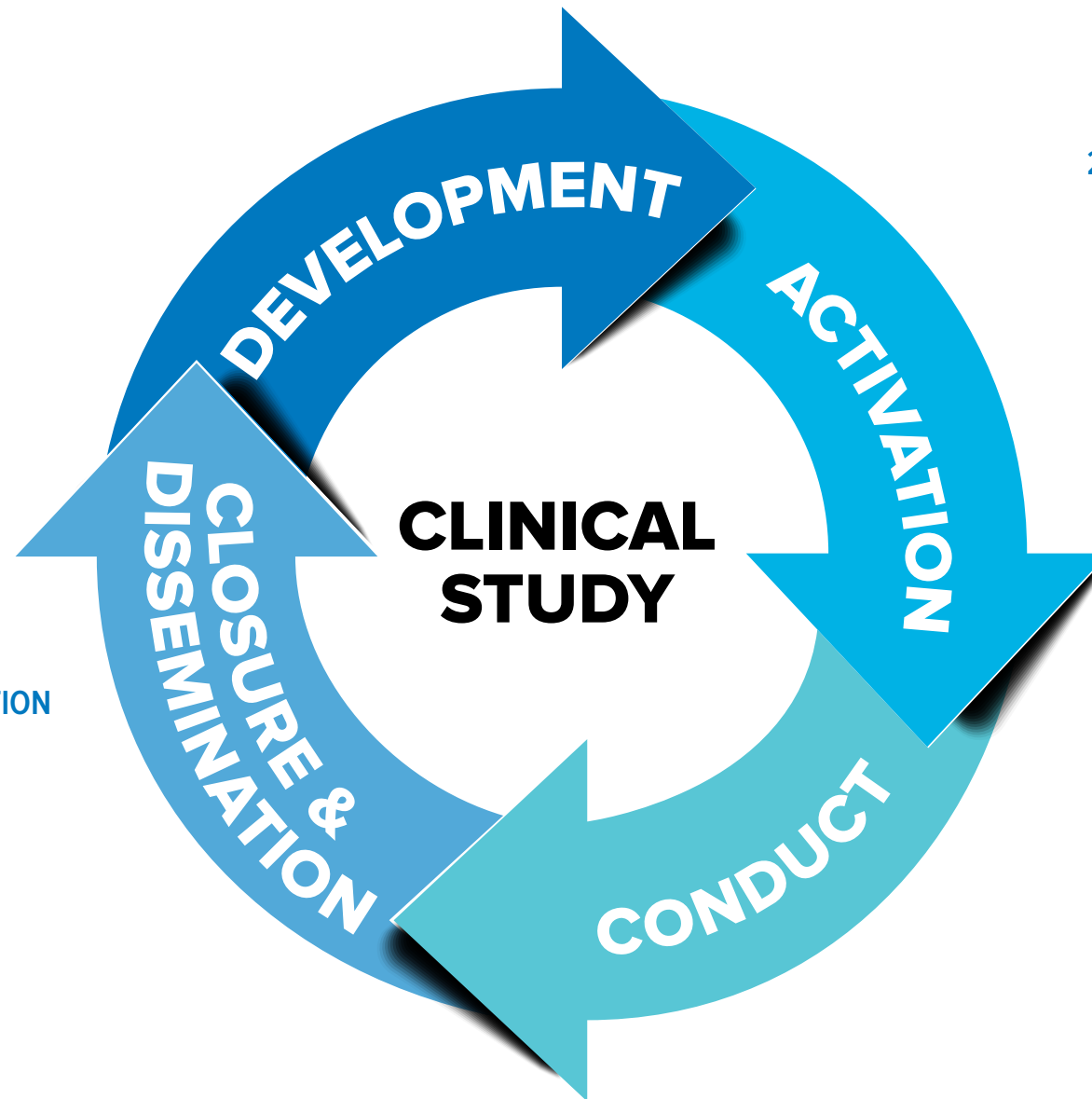


1. STUDY DEVELOPMENT

- Feasibility
- Study design
- Prepare grants
- Central study registration
- Staff training/education

2. STUDY ACTIVATION

- Develop data collection tools
- Create IRB submission/ consent
- IND/IDE support
- Contract review
- Budget development



CLINICAL STUDY

4. STUDY CLOSURE & DISSEMINATION

- Data analysis
- Publication, post results CT.gov, other dissemination
- Protocol closure
- Final accounting of drug/device
- Financial close-out
- External site closure
- Preparation for FDA audits

3. STUDY CONDUCT

- Recruit patients
- Support staff
- Billing review and invoicing of sponsors
- IRB, IND/IDE, and other annual reporting
- Research subjects payment
- Data management
- Site management/ data monitoring