

Clinical Trial Center

Phase I-III services

0. Initiation Phase

- ◆ Request submission
- ◆ Idea consolidation
- ◆ Rapid feasibility assessment
- ◆ Preliminary resource estimation
- ◆ Contract and agreement
- ◆ Planning phase submission

1. Planning Phase

- ◆ Protocol development
- ◆ Essential documents development
- ◆ Project budgeting
- ◆ PI, Site, Lab, ... feasibility /selection
- ◆ Investigators/ Staff training plan
- ◆ IRB/REC preparation/submission
- ◆ Protocol registration (IRCT)
- ◆ Regulatory submission
- ◆ Trial management team (TMT) building
- ◆ Conduction Phase submission

2. Conducting Phase

- ◆ Site coordination
- ◆ Subject recruitment
- ◆ CRF handling/ EDC completion
- ◆ Data management
- ◆ Monitoring
- ◆ Internal audit
- ◆ Training / Retraining in field
- ◆ SAP implementation
- ◆ Drug accountability
- ◆ Lab sample management
- ◆ Safety info submission
- ◆ Study payment management

3. Close-out Phase

- ◆ TMF/ data archiving
- ◆ Queries answer
- ◆ Clinical supply recollection
- ◆ Site close-out report

4. KTE Phase

- ◆ CSR reporting
- ◆ Scientific paper writing
- ◆ Booklet, Brochure development
- ◆ Stakeholder communicating
- ◆ Web communicating
- ◆ Patients forum/ specialist networking
- ◆ Scientific meeting presentation

CTC units

- ◆ Marketing
- ◆ Project management
- ◆ Data management/Biostatistics
- ◆ Training management
- ◆ KTE management
- ◆ Regulatory affairs

CTC is not an option, it is a choice!