Pillars of Service

Specific Services Offered:

- Training physician and medical staff on proper prep, set-up and use of novel medical devices
- Conducting in-depth hands-on training and proctoring innovative procedures
- Creation of study teams for the execution of clinical trial operations
- Performing project management activities including management of study start-up timelines, budgets and tracking regulatory submissions and approvals
- Managing support staff, contract personnel (CRAs) and core-lab personnel
- Creating and negotiating study and site budgets
- Conducting all aspects of clinical trial operations including: pre-qualification visits, site initiation visits, and interim/close-out monitoring visits
- Conducting data management function and data review
- Creating study protocol, informed consent template and CRFs including writing database completion guidelines
- Assisting with identification of project goals and determination of study objectives and clinical endpoints
- Implementing Quality System Program including creating and writing standard operating processes and procedures
- Assisting with study recruitment and developing strategies to achieve enrollment milestones
- Facilitating safety committee meetings including preparation of adverse event packets and documentation
- Ensuring and documenting on-going and productive communication between study site and sponsor personnel
- Assisting with site or sponsor inspections from regulatory agencies including the FDA
- Facilitating/conducting investigator meetings and

advisory board meetings