Clinical Trials

- Nonclinical Planned Studies
- Relevant Model Selection
- Safety Margins & Signals
- ClinicalDosing Strategy
- Dosing Strategy
- Protocol Development & Study Design
- Clinical Trial Operations
- Data Management
- Statistical Plan & Analysis
- Investigator/Site Selection
- Site management
- Study Monitoring
- Integration with Regulatory & Health Economics
- Reimbursed Clinical Trials

Regulatory & Quality

- Regulatory Strategy
- GAP Assessment
- Auditing – GMP, GLP, GCP
- Preparing & Submitting: IND, IDE, 505(b)(2), 510(k), PMA, , 5139g), BLA and NDA
- Prepare for panel Meetings
- CE Makc & ISO 13845
- Prepare SOP's and forms for QMS
- Complete the Essential Requirements
- Train Staff on QMS

Market Access

- Reimbursement Landscapes
- Strategic Roadmaps
- Health Economic Strategy
- Health Economic Outcomes Research
- Payer Engagement
- New Code Applications
- Physician Society Relations
- Policy Intervention
- Dossiers
- Value Analysis
- Claims Data Analysis

Prior Authorization & Call Center

- Sales Team and Customer Hotline
- Perform prior authorizatio n
- Salesforce & Office Training
- Reimbursem ent Guides & Website Content
- Benefit Verification
- Appeals/De nials
- Documentat ion Of Medical Necessity
- Peer To Peer Guidance