



## Clinical Research Services

**With over twenty years in the field ASI is a leader in Clinical Research Services**

ASI Provides Health Care Support Services for

- Regulatory Affairs
- Quality Assurance
- Monitoring
- Data Management

### Clientele

- Pharmaceutical Industry
- Medical Device Manufacturers
- National Institute of Health
- Department of Defense

### Information Systems Support

- Technical Documentation Support
- Training
- Helpdesk Support
- Requirements development
- Software evaluation

### Regulatory Affairs

- Regulatory submissions (Food and Drug Administration & Institutional Review Boards)
- Clinical trial registration/licensing
- Safety reporting

### Quality Assurance

- Investigative sites audit
- Study documentation audit
- Preparation for regulatory inspection

### Program Management

- Main Sponsor Contact
- Training
- Conduct Investigator Meeting
- Quality Control
- Decision Management
- Budget & Timeline Control
- General clinical trial support
- Develop Case Report Forms

### Monitoring

- Clinical and Medical Monitoring
- Preparation and submission of reports on Serious Adverse Events
- Protocol review/input
- Informed Consent Form design
- Study Manual development

### Data Management

- Case Report Form design and review/input
- Development of Case Report Form Completion Instructions/Guidelines
- Development of Validation Specifications and checks
- Medical review of data and data coding
- Data Analysis

