COMPANY OVERVIEW

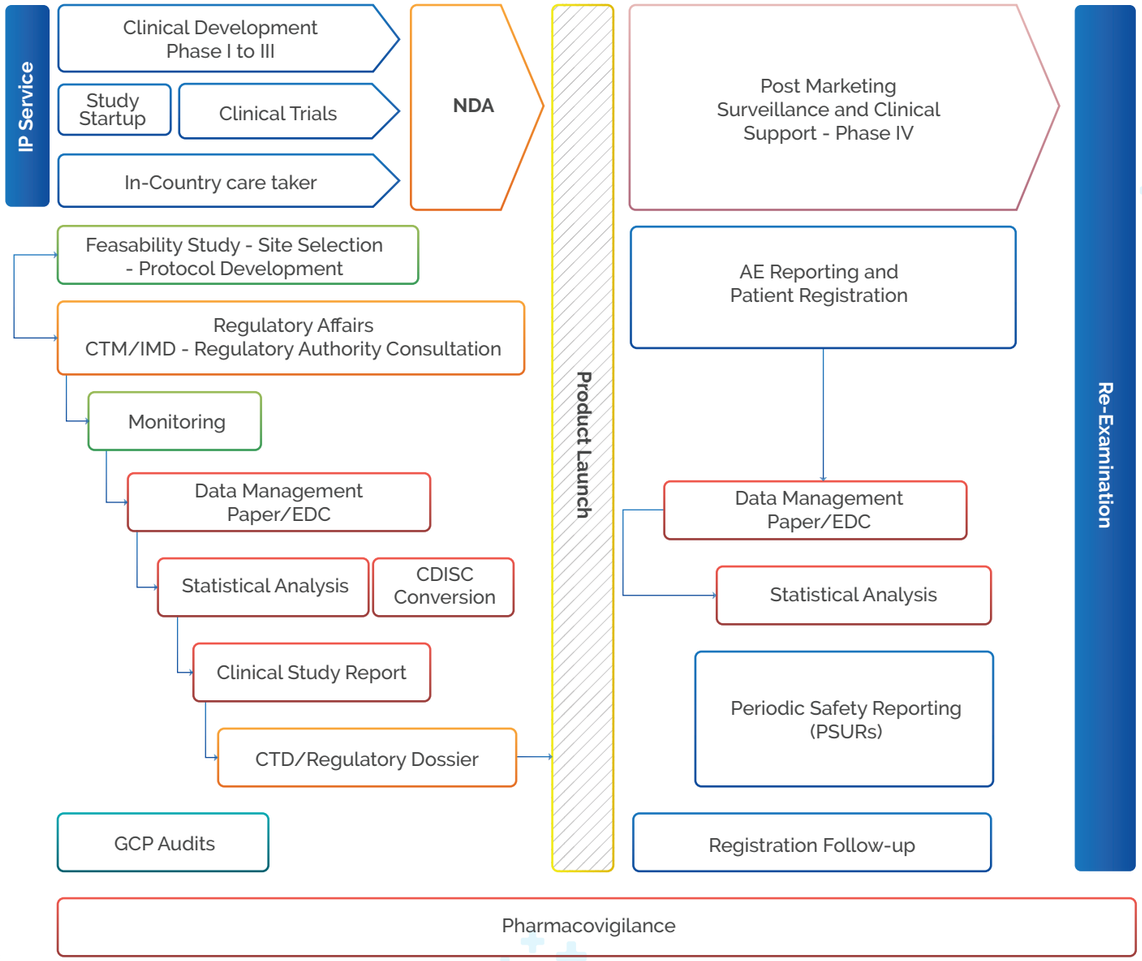
AKT Health is a Healthcare & Life Science Strategy Consulting firm. We partner with life science companies and health systems to develop a market-leading strategy for long-term top performance, engagement, growth, and sustainability.

Our consultants evaluate data, apply analytical models, study systems, and dissect workflows to unlock opportunities to improve performance through technology enablement and engagement planning.

Applied Knowledge & Technology in Healthcare – a philosophy on which AKT Health stands is reflected in our Clinical, Medical, Commercial and Technology services. Each is focused to address the needs of Pharmaceutical, Medical Device and Biotechnology firms.

AKT Health is also the sole distributor and promoter of Certara's industry-standard software in India and Japan.

CONSULTING SERVICES



CLINICAL SERVICES

STUDY SET-UP			STUDY EXECUTION		STUDY CLOSURE	
Design	EDC	Regulatory	Support	Recruitment	Database Closure and Study Conclusion	
Study Design	Portal Development	Protocol Evaluation	CRA Training	Project Management	Statistical Analysis and Report	Market Authorization
Study Protocol	eCRF Programming	Site and Investigator Agreements	Investigator Training	Data Management	Final Report (CSR)	
Statistical Analysis Plan	Forms Validation	Submission Package : Documents, Forms and Translations	Laboratory Preparation	Monitoring	Results Presentation and Visualization	
Feasibility	Online Reports Programming	Regulatory Submissions	Preparation for Starting Study Site	Reporting	Publication	
Monitoring Plan	Interactive Website Response System (IWRS)		Documentation	Safety Management		
Data Management Plan	EDC App is Connected with mHealth Devices		Site and Investigator Payment	Quality Control		
Project Plan			Patient Travel Cost and Reimbursement	Preparation of Study Center for Inspection and Audit		
Budget						

REGULATORY SERVICES

Pre-Clinical	Clinical	Approval	Post Approval
Regulatory Consulting ■ Development Plan ■ Data Gap Analysis	**PMDA Consultation** ■ Document Preparation ■ Correspondence With Regulatory Authority	**J-NDA Support** ■ CTD Preparation ■ Correspondence With Regulatory Authority ■ Marketing Authorization Holder (MAH) ■ Price (NHI) Consulting ■ GxP Compliance Inspection	**Post-Marketing Surveillance**
CTN Support ■ Document Preparation ■ Correspondence With Regulatory Authority	**Clinical Trial** ■ Monitoring ■ Data Management ■ Statistical Analysis ■ Pharmacovigilance ■ Project Management ■ Investigational Product Management ■ Quality Assurance ■ CSR Creation		**Pharmacovigilance**
	Cartagena Application ■ Document Preparation ■ Correspondence With Regulatory Authority		**Medical Affairs, Sales and Marketing (CSO)**
	Clinical Site Support (SMO)		**Clinical Site Support (SMO)**
	Patient Recruitment		**Call Center**
			Patient Communication and Support

Non-Clinical Safety Test
- Toxicity/Efficacy Evaluation Study
- Toxicity/Tumorigenicity Test Using Immunodeficient Mouse
- Cell Proliferation Analysis
- Soft Agar Colony Formation Test

Quality Assurance Test (GMP)
- Sterility
- Endotoxin Test
- Mycoplasma Test
- Residual Test for Antibiotics
- In-Process Control Test
- Release Testing

UNITED STATES

19266 Coastal Highway
Rehoboth Beach, DE 19971

INDIA

Vipra Elite, Patrikanagar,
Street No: 1, Madhapur,
Hyderabad

JAPAN

1-16-8, Higashi, Shibuya-ku,
Tokyo 150-0011

AKT Health Established

2017

Operations in 9 Countries and more than 24 Projects Delivered

45 Employees

45

- India
- Japan
- USA

AKT Health

9+

Expansion

Functional Experts and Developers

4

Offices

For more information

www.akthealth.com info@akthealth.com

AKT Health

Medical | Clinical | Commercial | Technology

REGULATORY AND CLINICAL SERVICES

Applied Knowledge and Technology in Healthcare