



We enable you to bring drugs faster to the market



**BA Research India** is a **Contract Research Organization**, specializing in conducting clinical phase and analyzing samples for bioequivalence and bioavailability studies. Clinical facilities has total of **322 beds and 11 ICU beds**. Analytical and diagnostic laboratories are equipped with modern instruments. Our studies have been approved by **USFDA and AFFSAPPS**.

#### **Our Milestones**

- We have developed over **90+ analytical methods** in biological fluids
- Over **400,000** samples analyze, **10,000** subjects studied
- Over **15,000** proprietary people database
- **400** studies completed
- 13 studies approved by **USFDA** and 90+ pending approval
- 4 studies approved by **AFSSAPS**

#### **Our Services:**

Protocol writing and study design

Case Report Form design

Independent Review Committee submissions

Regulatory submissions (IND, CTA, NDA, NDS, ANDA, ANDS)

Recruiting of healthy subjects and special populations

Phase I bioequivalence clinical trials

QT/QTc Studies

In-house diagnostic laboratory

Adverse event coding and reporting

Data management

Drug and metabolite assay development

Drug analysis in biological matrices

Biostatistics, pharmacokinetic and pharmacodynamic modeling and reporting

Clinical trial reports

Electronic data submission and electronic reports

Quality assurance

## **Our Expertise:**

Bioavailability

Bioequivalence

Clinical services

Statistical and Report Services

Pharmacokinetics

Single and multiple dose escalation with on-line PK analysis

Special populations



## **Clinical Facilities:**

BA Research India currently has a total of 322 beds, with 11 ICU beds. Our clinical facilities have units dedicated to early clinical research. Each unit is strategically located for ease of subject recruitment and is well designed. Our facilities have electronic keycard access for entry and exit at all times. Our medication rooms, reference standard cabinets, and incubators are all monitored 24 hours. The recruitment, clinical and pharmacy software's are validated by independent companies.



## **Clinical Laboratory: Approved by College of American Pathologists (CAP)**

Clinical Laboratory can perform the tests required in all areas including Hematology, Chemistry, Coagulation, Urinalysis, Special Chemistry, Serology, Radiology and Viral Markers. BA Research India is licensed by the India Space Research Organization, Institute of Plasma Research and College of American Pathologists. We have full-time biochemist on site and doctors on staff, which helps us rapid turnaround of screening and admission laboratory results.



### **Analytical Laboratory:**

At BA Research India we have capabilities to work on high volume analysis of compounds in biological fluids at low level of sensitivity using 14 LC/MS/MS systems. We work on Method Development and Validation.

### **Our promise to Sponsors:**

The relationships we develop and maintain with our sponsors are an essential part of our philosophy. We ensure optimum communication and delivery deadline with our Sponsors.

At BA Research we work in conjunction with leaders in the field and global regulatory bodies, our Quality Assurance Group has developed strict quality assurance controls covering every step in the process.

All departments, including clinical, Quality Control/Assurance engineering, data processing and report writing, comply with the standards of Good Clinical Practices (GCPs) and Good Laboratory Practices (GLPs), in accordance with current Standard Operating Procedures (SOPs). Study data and reports are 100% audited before receiving our Quality Assurance seal.

We also call on an independent ethics committee to review study protocols and informed consent forms. This committee complies with current regulations and ensures a written response within 72 hours of the review. Weekly meetings allow greater flexibility in the review and approval of study documents.

### **Our team:**

Our team includes doctors, pharmacologists, statisticians, and individuals proficient in pharmacokinetics; each with 12+ years domain expertise

### **Contact:**

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