



BA RESEARCH INDIA
2010 - 2011

About Us

BA Team has a passion for what they do that ignites inspiration every day. In this spirit, we constantly deliver flawless service to our clients. Our inspiration comes from our clients, auditors, as well as our critics. We are asking questions, listening closely and collaborating more effectively with our clients, regulatory institutions, advisory board members, and independent ethics committee to give our clients exceptional service.

Since five years of inception, we have remained focused on being the most dependable Life Science Company in India. We have been successfully audited by USFDA, AFSSAPS, MCC and International Companies. Our Central Pathology laboratory is accredited by College of American Pathologist (CAP).

I am grateful to our clients who have shown faith in us to launch their products in the International markets. I would like to invite you to audit our facilities and meet our astute team members. Thank you for your continued support.

– Vijay Patel, Executive Director



Company Overview

Contract Research Organization, specializing in conducting clinical phase I-IV phases in various therapeutic areas and analyzing biological samples supporting bioequivalence, bioavailability and clinical studies.

Audited by USFDA, AFSSAPS, MCC and International companies.

Central Reference lab is accredited by College of American Pathologists (CAP).

Successfully conducted over 1000 healthy human studies.

Temperature controlled and fire proof 3000 sq. ft. archive facility.

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

HISTORY:

- **2004:** BA Research India co-founded by Mr. Paul Likhari and led by Mr. Naveen Sharma. Opened with 122 beds and 4 LCMS and CAP certified Central Reference Lab.
- **2007:** Opened new facility at Baroda city (Two hour drive from Ahmedabad) with 200 beds with CAP certified Path Lab. Analytical lab upgraded to 13 LC/MS/MS. Introduction of transdermal clinical studies.
- **2009:** Opened new facility in Ahmedabad with 100 beds. Introduction of Data Management Services. Analytical lab upgraded to 16 LC/MS/MS.
- **2010:** Introduction of patient based Clinical trials (Phase I-IV)



Clinical

BA Research India provides Phase I-IV clinical services. The clinical team consists of well experienced doctors, pharmacologists, life science personnel having worked in different therapeutic areas. Our services include project management, site management, clinical monitoring, clinical trial supply management services and Medical Services including medical writing, monitoring and Safety reporting.

Healthy Human Studies

- Bioequivalence studies
- Phase I
- Drug Interaction studies
- Steady State
- Food effect
- Cardiac Monitoring studies
- Pulmonology
- Dose escalations/ranging studies

INFRASTRUCTURE:

- 150,000 sq.ft. facility with CCTV and nursing stations
- 9 clinical units, 400 beds & 11 ICU beds
- Clinical labs (CAP approved)
- Separate volunteer screening areas
- Separate sample processing and storage area for each unit
- Separate sample & ambulatory collection area for each clinical unit
- 3 walk-in freezers at -20°C, 8 freezers at -70°, and 11 freezers at -20°
- Temperature controlled Pharmacy with secured control access



Clinical trial

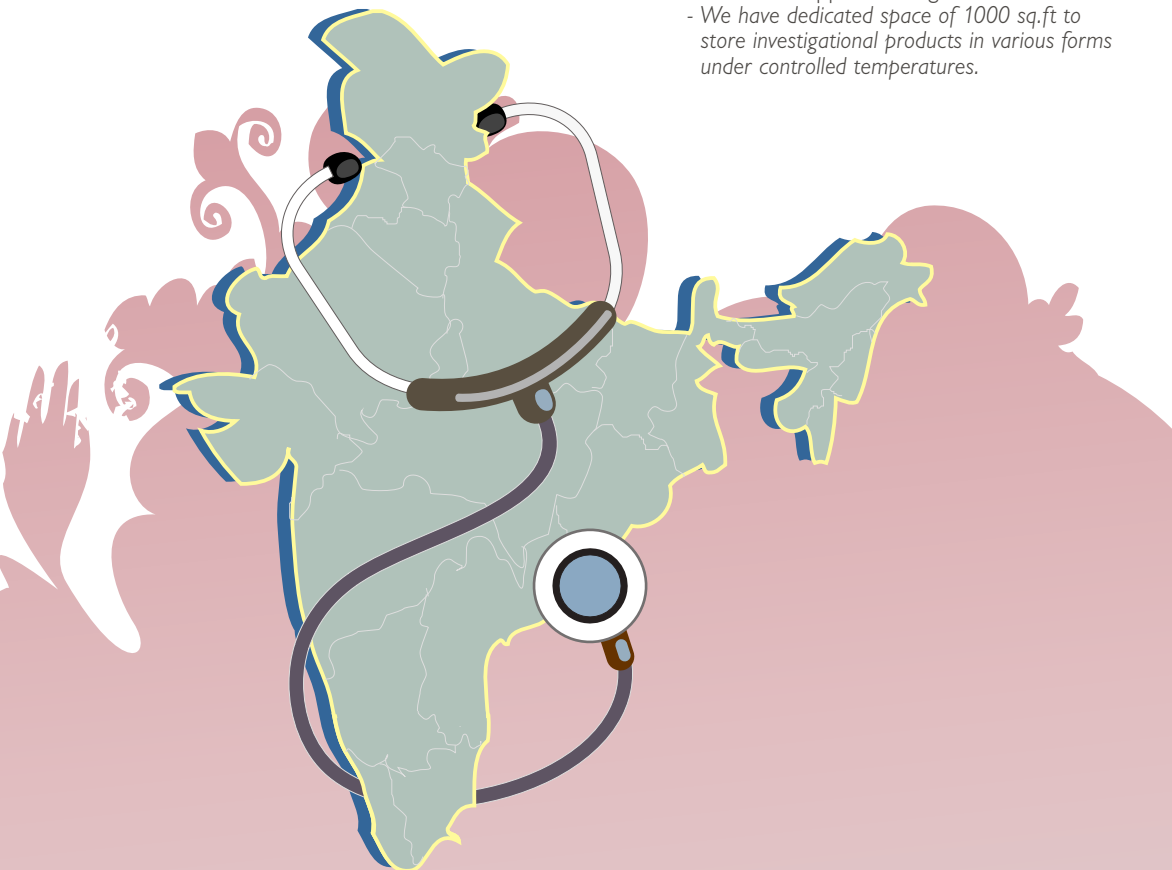
We provide comprehensive ranges of services in focused therapeutic areas of Oncology, Dermatology and Psychiatry. We have access to over 400 GCP trained Investigator sites across the India. Our team members selected for each project are driven by their expertise in that specific therapeutic area. The Team brings combined experience of over 40 years from leading CROs.

- Feasibility studies
- Investigator selection and recruitment
- Project Management
- Site Management and Risk based monitoring
- Medical Services with Safety monitoring
- Regulatory Affairs Support
- Data Management
- Biostatistics and SAS Programming

- Patient based Studies
 - PK end point studies
 - Clinical end point studies

- Late Phase
 - Phase II- Phase IV

- Clinical Trial Supplies Management
 - We have dedicated space of 1000 sq.ft to store investigational products in various forms under controlled temperatures.



Dermatology

BA Research is emerging to provide clinical trial services in Transdermal drug delivery systems and topicals. We have an exclusive setup and a dedicated team of investigators, scorers, patch applicators and removers. Team is undergoing a continuous, rigorous training and grind with a focused objective in mind i.e. to be able to deliver optimum results with ethical clinical research methodologies and applicable regulatory guidelines. We have experience on topical patches and transdermal drug delivery systems such as hormones, NSAIDS, short acting nitrates, anesthetics, antihypertensives etc. Our female volunteer pool provides us with ability to conduct studies on hormonal patches adhering to the timelines.

Transdermal and Topical Studies

- PK studies
- Bioequivalence
- Irritation, sensitization, and adhesion studies

INFRASTRUCTURE:

- Isolated Orientation, Application, Removal & Scoring areas with light arrangements for accuracy
- Consulting chambers
- Professionally designed studio in which scoring scales can be captured and viewed online

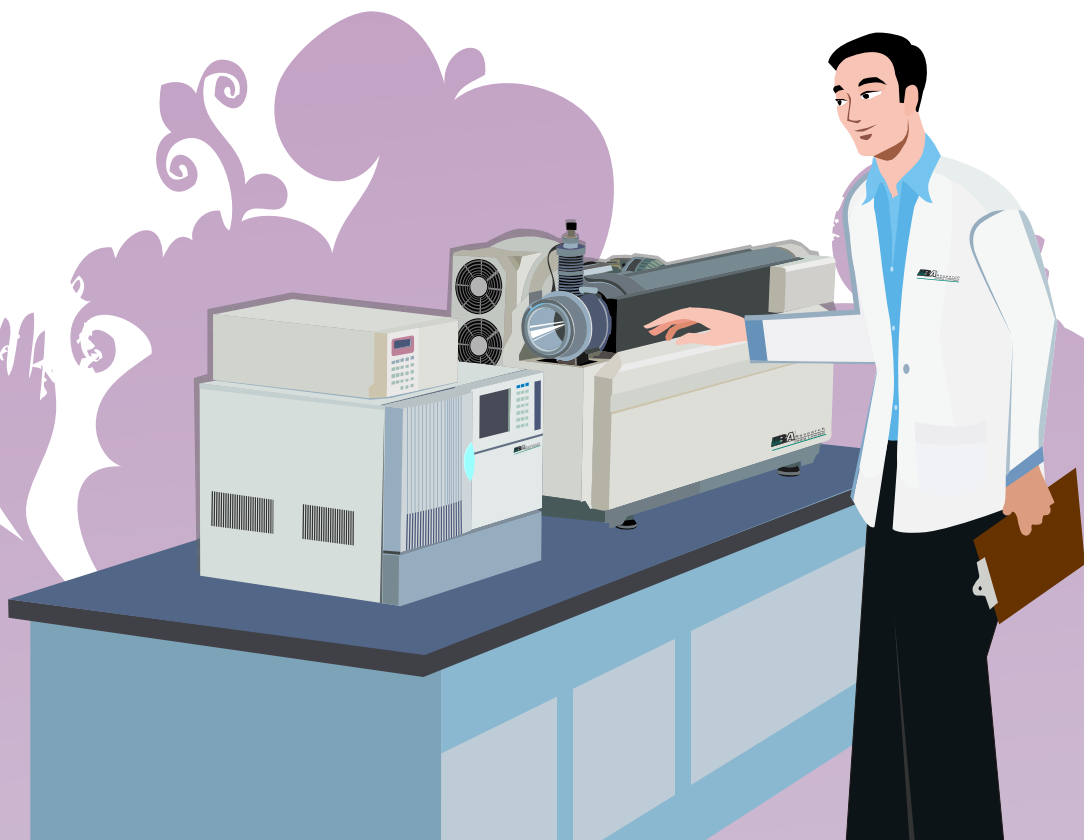


Bioanalytical

Our bio-analytical laboratory based in Ahmedabad is equipped with 16 LC/MS/MS. The laboratory is dedicated to method development, validation and subject sample analysis using validated analytical method. All operations performed in this department are based on the principles of Good Laboratory Practice (GLP) and appropriate regulatory guidelines. We are regularly updating our quality control systems to provide you with the most reliable results. Adhering to timelines and development of critical assays is our objectives.

INFRASTRUCTURE:

- Method Development
- Method Validation
- Sample Analysis
- 16 LC/MS/MS which consists of API 5500, API 4000, API 3000 connected with Shimadzu HPLC's as front end of LC/MS/MS
- 2 Walk-in freezer maintained at -20°C
- 2 Freezers maintained at -70°C
- Data acquisition with audit trail



Biometrics

1. Pharmacokinetics & Statistics

- Study design, pharmacokinetic and statistical inputs (SAP) in protocol preparation.
- Sample size determination in BA/BE & clinical trials.
- Pharmacokinetic, pharmacodynamic analysis and Statistical evaluation in BA/BE studies & Clinical trials using WinNonlin and SAS® software.
- Study reports as per regulatory requirement & in eCTD format.

2. Clinical Data Management

- CRF Designing, printing & distribution
- Database setup
- Data Processing/Delivery
- Coding
- External data Reconciliation
- Quality Reviews
- Trainings

Our Application: Clinical Data Management System (CDMS). SAS PheedIT, Any Sponsor specific application on ASP Model

Coding Dictionary: MedDRA, WHO DD, Any sponsor specific coding dictionary

CRF Designing: Adobe Frame Maker

INFRASTRUCTURE:

Pharmacokinetics / Statistics

- PK parameters calculated using WinNonlin
- Statistical analysis using SAS
- Reports as per FDA, ICH E3, TPD, TGA formats
- State of the art Archives

Clinical Data Management

- Redundant Power and internet facility
- Dedicated CDM Servers
- Scheduled Back up and disaster recovery
- Well equipped Physical and electronic access control measure to the server and archival facility.



Central Reference Lab

We have an in house Central Reference Lab to support our clinical Operations. The Central Reference Laboratory conforms to the highest Quality standards and is accredited by the College of American Pathologists (CAP).

The Lab is well equipped with High end instruments for immunology, Biochemistry, ELISA, Automated cell counter (5 part differential), Haematology testing and Urisys for urine testing.

The team is well experienced, led by Dr. Bhaskar Vyas. Stringent Internal Quality Control samples are tested with each run of samples. The Laboratory is enrolled with BioRad EQAS USA and CAP Surveys for proficiency testing Programs.



E-Learning

At BA Research training is an integral part of the Company. Our e-Learning initiative is headed by Dr. Gauri Patel, who previously was heading our Quality Assurance Department.

Our learning system is defined by different jobs and various competency levels. Our Learning Management System is a robust learning technology, custom designed for our life science needs. The content is deployed in short modules that have animations and videos with online assessments and need based reports.

The e-learning content is a list of all the available courses related to our SOPs, GCPs, GLPs, in-house Systems, operating procedures of bio-analytical, clinical, quality assurance, pharmacokinetics & biostatistics, clinical data management and clinical trials.

The training group ensures extensive assessments and re-training for all the BA team members. Training group also supports practical on-job orientation for various departments, as well as external trainings by experts, as and when required.



Regulatory Timeline

Regulatory body	Approval	Time
Drug Controller General of India (DCGI)	Bioequivalence No Objection Certificate (BENOC)	5-6 Weeks
	Test License to import investigational products (T License)	5-6 Weeks
	Regulatory approval for conducting clinical trials in India	8-10 Weeks
Drug Controller General of India (DCGI)	Sample Shipment No Objection Certificate (Export NOC)	2-3 Weeks
Ethics Committee	Approval (meets twice in a week)	1-2 Weeks

- * BENOC is required from DCGI for those products which fall under 'New Drug' category in India.
- * T License is required to import investigational products to India.
- * Export NOC is required to export biological samples outside India.
- * BENOC, T License and ethics committee approval are processed in parallel.



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The logo for cliantha group features the word "cliantha" in a lowercase, sans-serif font with a small leaf icon above the letter 'i'. The word "group" is in a similar lowercase, sans-serif font to the right of "cliantha".

Designed by: designtadka.com