Cliantha Research India Ltd – Company OUTLINE

Thank you for giving us the opportunity to introduce ourselves.

Background

Cliantha (previously known as BA Research) is a Contract Research Organisation that specialises in Bioequivalence and Bioavailability studies, Clinical Trial Studies and Clinical Data Management. The company, based in Ahmedebad in the state of Gujarat in India, was founded in 2004 with a 100-bed unit to which we have since added several hundred more (currently 400 beds) and we have been audited by the US FDA, MHRA (UK), AFSSAPS (France), AGES-PharmMed (Austria), MCC (South Africa) and WHO for example and by several multinational companies

We offer:

- Phase I- IV clinical studies
- Bio-analytical Lab
- Pharmacokinetics/Statistics
- Clinical Data Management

and provide our clinical services to the generics industry, consumer health companies and to branded prescription manufacturers of all sizes. Since our foundation, we have completed over 800 studies of various types.

New American locations

Following the acquisition of Hill Top Research, Cliantha can now offer its clients clinical centres in Canada, the US (Miamiville, Ohio and St. Petersburg, Florida) and Mexico for studies that need to be conducted in the Americas.

Core Business

- **Early Phase**
  - Phase I/IIA (Bioequivalence, Drug Interaction studies, Steady State, Food effect, dose escalations/ranging studies)
- **Late Phase**
  - Phase II- Phase IV
- **Special Studies**
  - Transdermal Studies
  - Cardiac monitoring studies
  - Pulmonology
  - Clinical End point studies
  - PK studies in patients
  - Studies in special populations
  - Biosimilars

Scope

We specialise in trials in:

- Oncology/Hematology
- Dermatology
- Psychiatry
- Cardiology

- Diabetology

and have access to over 1500 GCP trained Quality Investigator sites. We are constantly adding more such sites to the database.

Facilities

- Clinical Trial Supply Management
- Pathology labs approved by College of American Pathologists (CAP)
- GLP compliant Bioanalytical labs where we have developed over 125 + analytical methods in biological fluids and analysed over 750,000 samples
- Pharmacokinetics & Statistics
- Clinical Data Management

Staff

Our team includes doctors, pharmacologists, statisticians, and individuals proficient in Clinical Trials and Pharmacokinetics; each with over 12 years' experience in their field. Total staff are over 400 of which: Clinical scientists: 127; Analytical scientists 90; PK and Data management 19
Brief biographies of staff members can be found at http://www.cliantha.in/team-cliantha.html

Quality

We have a Database of GCP trained investigators consisting of more than 1500 GCP trained Quality Investigator sites for studies not conducted in-house plus access to over 30,000 patients and are constantly adding more such sites to the database on an ongoing basis.

Timelines for Indian studies

- Drug Controller General of India (DCGI) = 45-60 days
- Ethics committee Approval = 45-60 days (conducted in parallel)
- **Total time** (parallel process) = 60-75 days for study start up after protocol finalisation

Pricing

Cliantha Research's pricing is very competitive due to the lower cost of operating clinical trials in India. Please contact us for an indicative quote for your next clinical project.

Access to Ahmedabad

Ahmedabad is located in the western part of India, and is around one hour flying time from Mumbai or two hours flight from New Delhi International Airport. It is also well connected by air to major international destinations such as Frankfurt, London, New York, Singapore and the Gulf States

Please do not hesitate to contact us if you have any questions about our services.

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