cliantha research

20

YEARS OF EXCELLENCE
IN CLINICAL RESEARCH

Late Phase Capabilities

USA | CANADA | INDIA

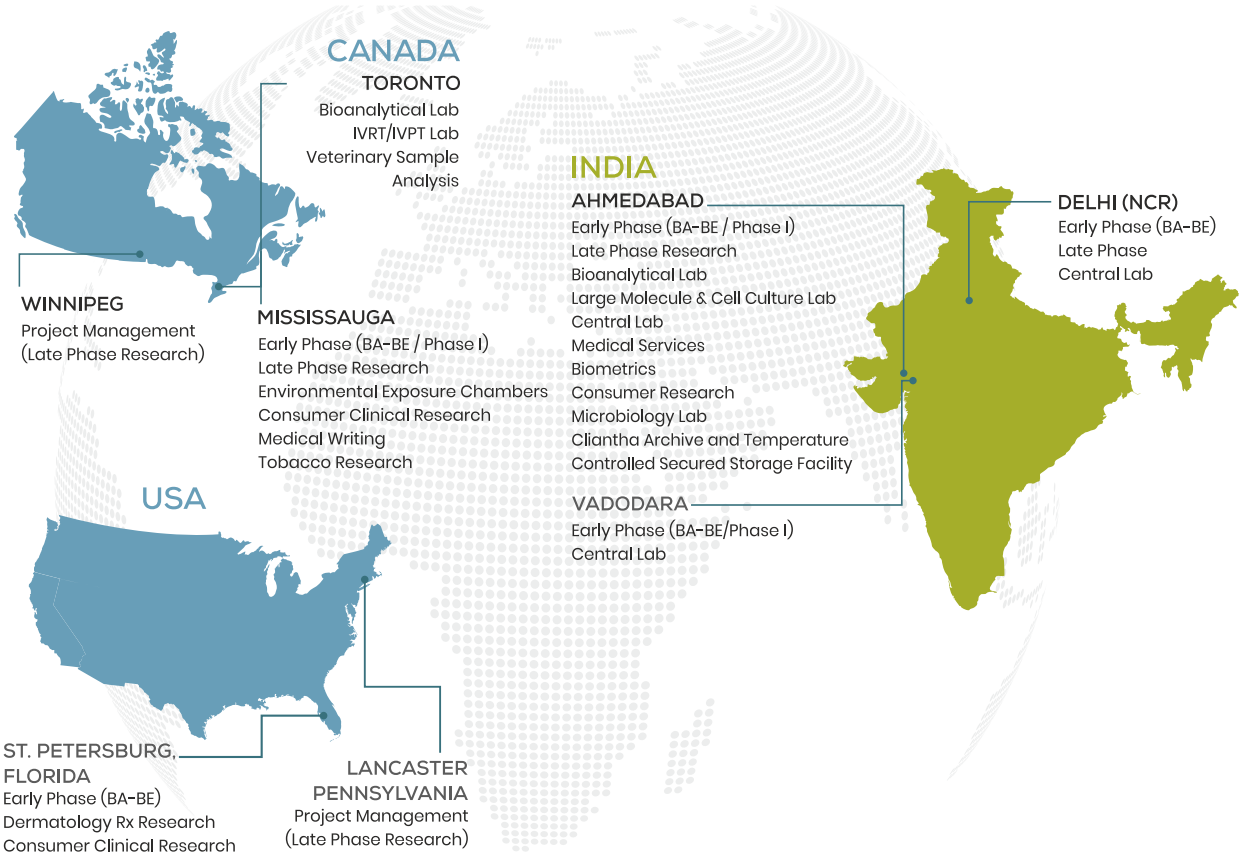
cliantha.com

ABOUT CLIANTHA

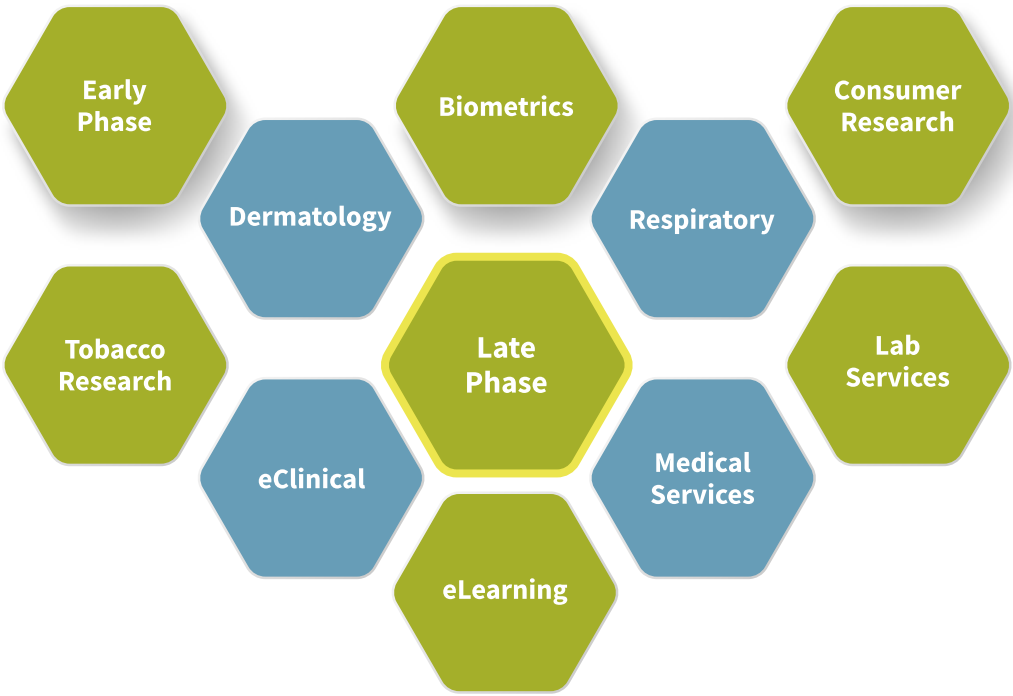
Cliantha Research, a full-service Clinical Research Organization (CRO), is a leading provider of Clinical research services, based in Ahmedabad, India. Cliantha's mission is Science with Integrity. Cliantha has eighteen years of impeccable regulatory history with Some of the key regulators, such as the USFDA, WHO, UK MHRA, GCC, EMA, AGES, ANSM, ANVISA, AMPS, MCC South Africa, Health Canada, DCGI, CAP, NABL, Turkey MOH, Thailand MoPH, Malaysia NPRA.

Cliantha Research is headquartered in Ahmedabad and has expanded its domestic reach with 3 regional offices & has presence in USA (Florida & Pennsylvania), Canada (Mississauga, Winnipeg & Scarborough).

In 20 years, Cliantha has accumulated expertise in Early Phase (BA/BE), First in Man, Late Phase (various therapeutic areas), Respiratory, Tobacco Research, Dermatology, Consumer Research, Bioanalytical Lab, Diagnostic Central Lab, IVRT, IVPT, Biometrics, Environmental Exposure Chambers and Medical Services.



CENTER OF EXCELLENCE



Global network of experienced sites, accelerated access to the patient pool and proactive risk management, are our pillars.

In an era of rising costs and increased pursuit over the development and manufacturing of therapies, generic drug trials hold the promise to deliver cost effective treatment options. In this pursuits, Sponsors look for a CRO partner with relevant experience, one that can contribute to the country specific protocol development process, conduct a detailed gap analysis of the necessary skill set to identify areas of risk, and can develop a robust clinical strategy.

At Cliantha, we have extensive experience navigating the complexities of conducting a complex generic product trial. We partner with your team to navigate and address complex regulations and compliance challenges; we ensure successful regulatory pathway; facilitate meetings with regulators early on to present the development strategy and seek their inputs on study design and comparability studies before we move forward. This enables our partner to optimize their program, streamline filings, and avoid surprises during the marketing application assessment process.

As your partner, we collaborate with you at every step to ensure success throughout the trial process and increase your chances of commercial success.

REGULATORY HISTORY

Ministry of Health Turkey

South Africa

Thailand

NABL

Standards Council of Canada
Conseil canadien des normes

Gulf Cooperation Council

Ministry of Healthcare of the Republic of Kazakhstan

REGULATORY HISTORY IMPECCABLE INSPECTION TRACK RECORD

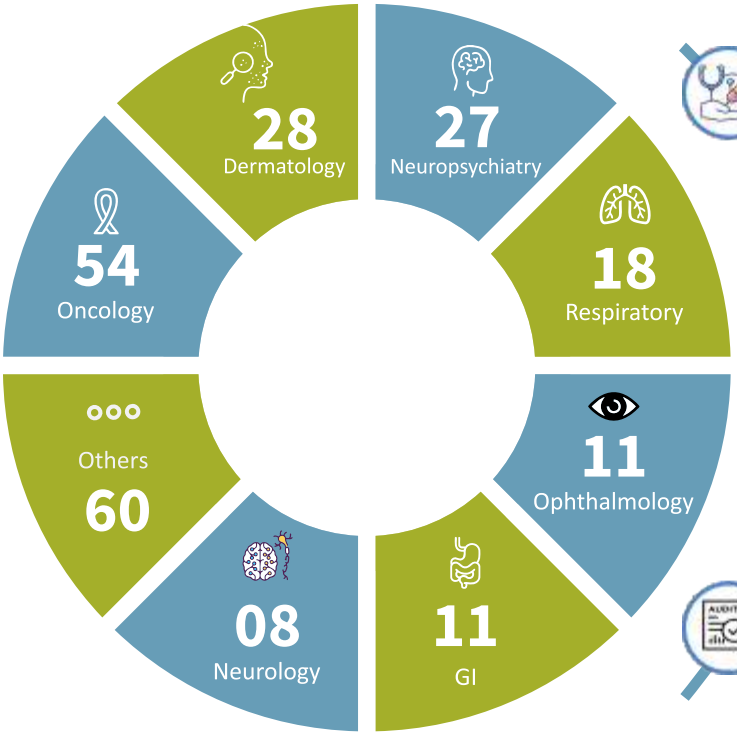
USFDA	101*
CDSCO	28
WHO	06
AEMPS	05
UK MHRA	03
AGES	02
ANVISA	02
ANSM	01
THAILAND MoPH	01
TURKEY MoH	01
MCC	01
Malaysia NPRA	01
GCC	01

USFDA	16
AEMPS	02
Health Canada	06

* Includes 74 multi-centric sites

TURNING ROADBLOCKS INTO CLEAR WAYS FORWARD

Therapeutic Experience and Global Reach



215+ Studies

20+ Therapeutic Categories

110+ Indications

2175+ Sites

35000+ Subjects

74 USFDA Audits

CLIENTELE

10%
ROW

19%
Asia

28%
Europe

43%
North America

CLINICAL TRIAL SERVICES

Medical Services

Regulatory Affairs

Clinical Trial Feasibility

Clinical Operations

Clinical Project Management

Biometrics

Biomarkers, Clinical & Bioanalytical Lab

Central Monitoring

eTMF Solutions

Clinical Trial Supply Management

PROJECT GOVERNANCE

Quality Standards

The blend of sites, central monitors and Cliantha's QMS replicates in the past regulatory inspection.

Budget Appropriateness

Project Management Leadership Team ensures that overall budget of project should not exceed to balance the project financial burden on sponsor.

Timeline Completion

Adherence to budget astutely thereby reducing the financial burden on sponsors

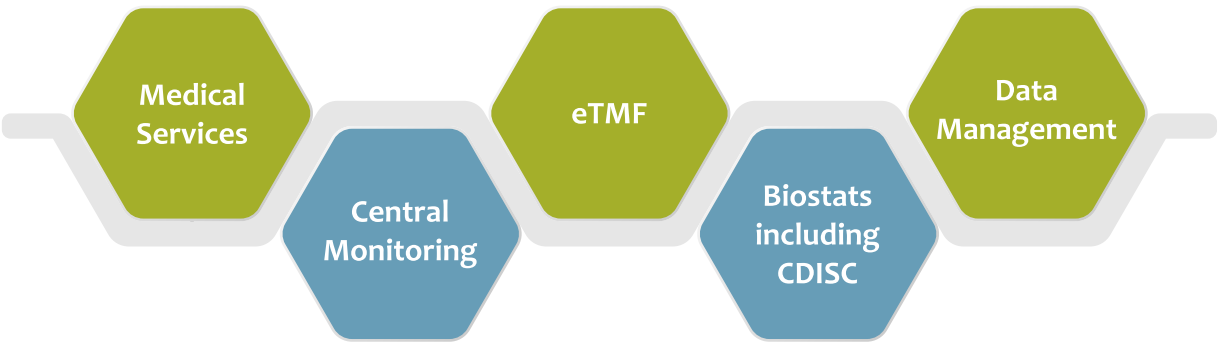
Patient Recruitment

With >92% success rate in timely completion of subject enrolment in studies.

Rescue CRO

Rescue your clinical studies with our expertise. Experience in handing >10 rescue clinical studies.

Our range of FSP models that help sponsors with customized solutions.

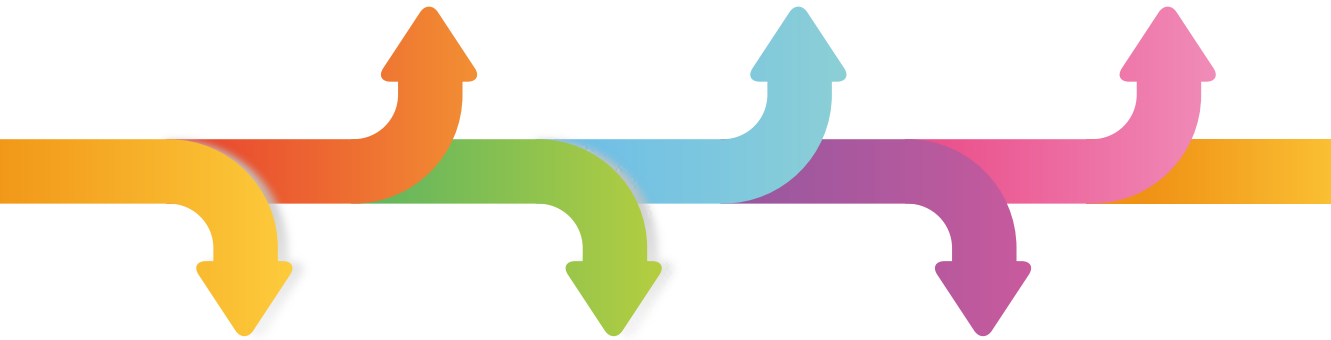


MEDICAL SERVICES

Medical Writing
Study Protocol
Amendments
Clinical Study Reports

Eligibility Verification
Patient Eligibility Guide
& Training Material

Regulatory Writing
Briefing documents
Regulatory Dossier
Response Risk Profiles



Other Medical Writing
Investigator Brochures
Patient Safety Narratives
Informed Consent

Safety data analysis
Periodic Efficacy and
Safety Data
Trend Analysis

Publication
Publications, Posters & Abstracts
Manuscript
Review Articles
Advisory Committee
Technical Support

CENTRAL MONITORING

Offers upto 25% reduction in overall monitoring cost

Code eTMF
Cliantha's Proprietary Tool

TMF management by dedicated team

Enhances visibility of study progress

Real time tracking of study documents

21 CFR part 11 compliant system

Secure eBack-up

Ensure readiness for surprise audits & inspections

Cost effective & Time saving

BIOMETRICS SERVICES

Cliantha Research also offers Biometric services. This division focuses on the management, analysis and reporting of data from clinical trials and post-marketing surveillance. As experts in clinical data, we provide competent outsourcing solutions for Clinical Data Management, Biostatistics, Statistical Programming.

Clinical Data Management Experience

- **110+** Indications
- **290+** Studies
- **70000+** Patients
- **200+** CodeAngelo Projects

Experience – By Study Phase

- BA/BE Studies **100+**
- Phase I **25+**
- Phase II **40+**
- Phase III **70+**
- Phase IV **50+**

CLINICAL DATA MANAGEMENT

Process

- Robust process for database set-up, conduct, and close-out
- 18 Global SOPs and standard templates
- Standardized CRF pages in compliant with CDASH standards
- Medical coding (MedDRA, WHO Drug

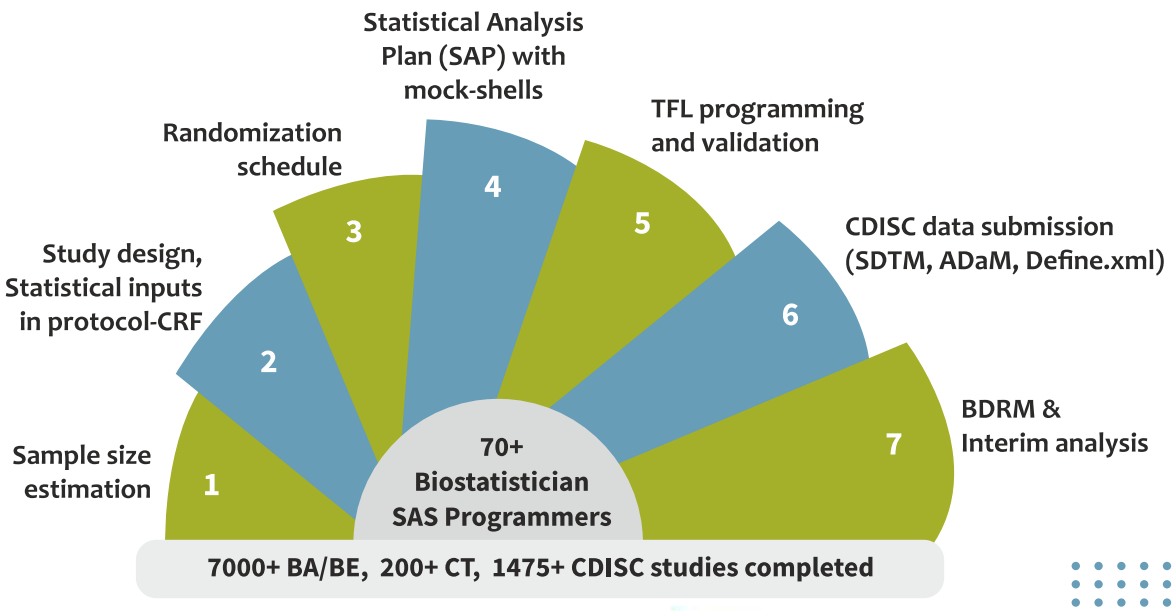
People

- Global team of 35+ data managers
- Multi-platform experience: Medrio, Inform, SAS Pheedit, Acceliant, Oracle Clinical (OC-RDC), Medidata Rave, Amedon
- Dedicated Data entry/Data Acquisition team

Technology

- CodeAngelo
- Proprietary EDC Tool
- 21 CFR compliant
- Web-based
- Experience with other EDC tools like Medrio, InForm, Oracle Clinical and sponsor - specific tools
- 24x5 helpdesk support

Biostatistics & Programming



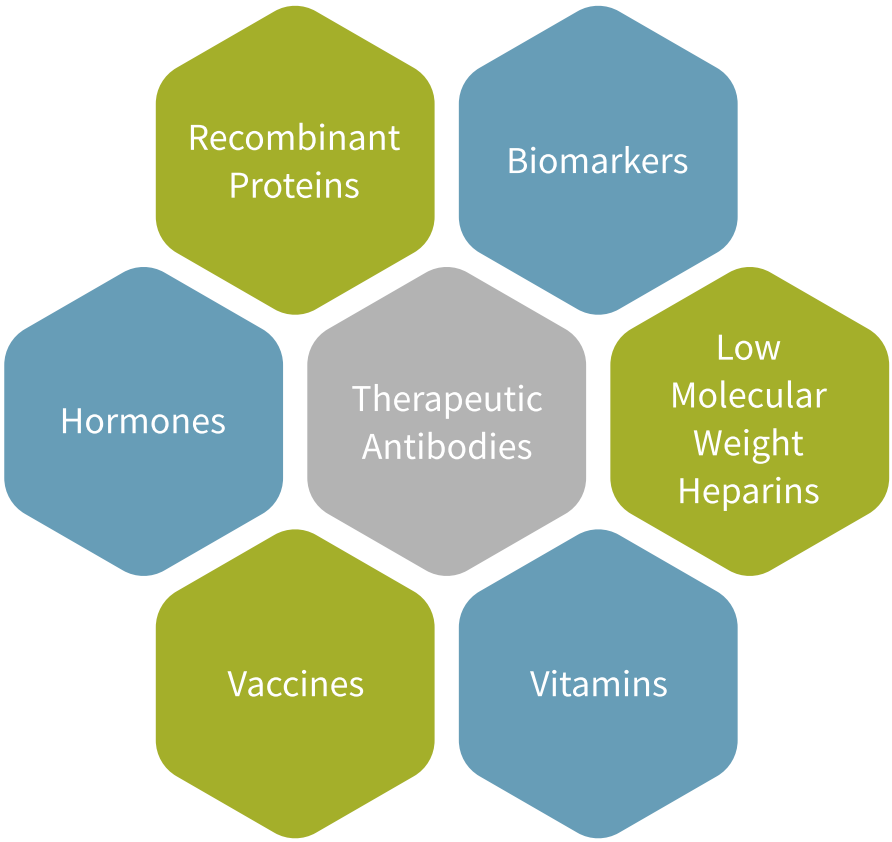
7000+ BA/BE, 200+ CT, 1475+ CDISC studies completed

Statistical Tools

REGULATED IMMUNOANALYTICS SERVICES

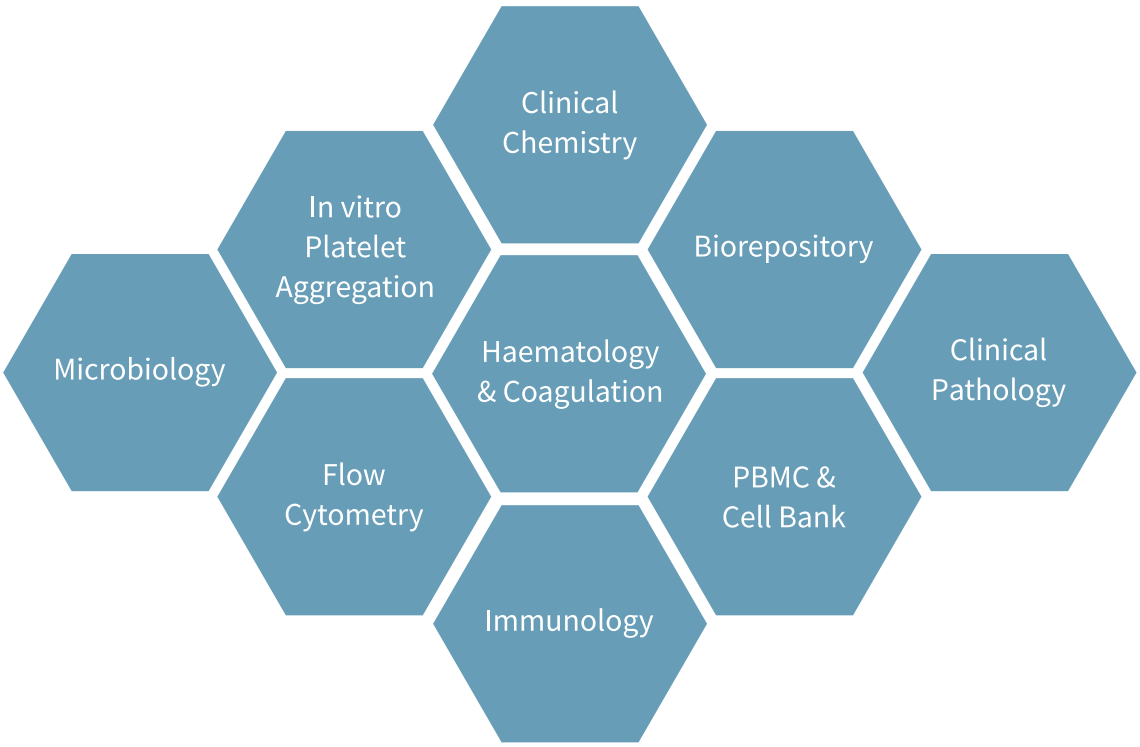
- Wide range of platforms including MSD-ECL, ELISA, Architect Alinity, STA compact, FACS
- MSD-ECL based Multiplex Platform
- BSL-II Cell Culture Lab
- Critical Reagent Lifecycle Management
- Immunogenicity Assessment (ADA & NAB)
- NABL accredited Vaccine Methods
- Ligand Binding & Cell Based in-Vitro Studies
- 100,000+ Samples Analysed
- 60+ Validated Methods

LARGE MOLECULE BIOANALYSIS

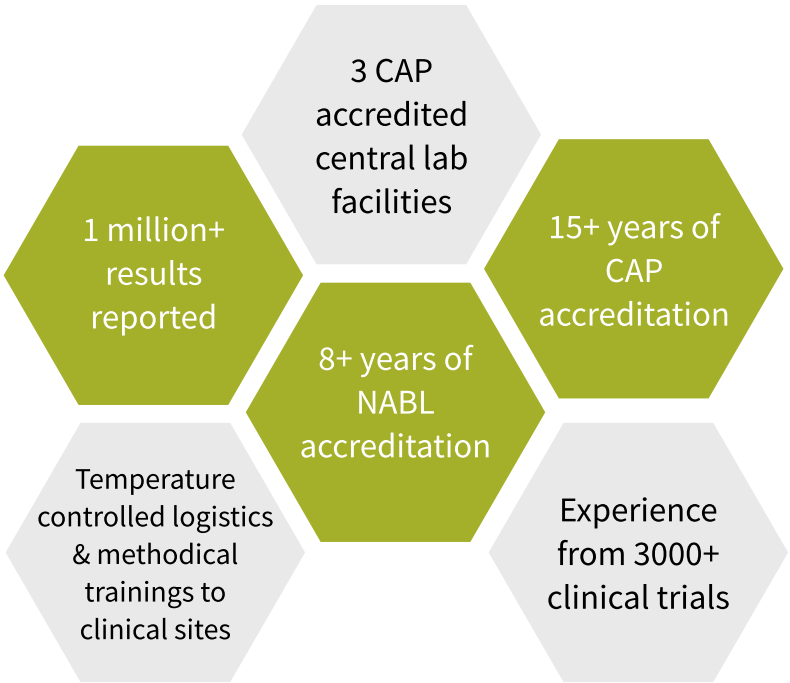


CENTRAL LAB

SERVICES



CAPABILITIES



OUR TEAM

Naveen Sharma
CEO
- 29+ years of experience
- 20+ years with Cliantha

Dr. Dharmesh Domadia
VP - Global Clinical Operations
- 20+ years of experience
- 7+ years with Cliantha

Devesh Verma
Project Director - Clinical Trials
- 18+ years of experience
- 8+ years with Cliantha

Hitesh Maheshwari
Project Director - Clinical Trials
- 16+ years of experience
- 7+ years with Cliantha

Dr. Ankesh Barnwal
Head - Medical Services
- 14+ years of experience
- 13+ years with Cliantha

Sumit Dodia
Manager - Regulatory, Study Start-up, eTMF, CRM
- 16+ years of experience
- 7+ years with Cliantha

Dhaval Patel
Head - Data Management
- 16+ years of experience
- 9+ years with Cliantha

Anshul Dogra
Head - Bioanalytical Lab
- 24+ years of experience
- 18+ years with Cliantha

Dr. Shaifali Gupta
Head – Clinical Lab
- 23+ years of experience
- 14+ years with Cliantha

Hitesh Chauhan
Head - Biometrics
- 24+ years of experience
- 19+ years with Cliantha

Arpana Prasad
Head - Global QA
- 27+ years of experience
- 20+ years with Cliantha

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