Clinical Trials Capabilities

About us

Full Service CRO

1. Global CRO providing comprehensive & integrated offerings
2. 3 Continents, 4 Countries, 9 Offices
3. Steady core team backed by 1000+ dedicated full time experienced professionals across the group
4. Impeccable regulatory track record
5. Robust e - learning system

Global Footprints

CANADA
- Winnipeg
- Scarborough
- Mississauga

USA
- St. Petersburg
- New Jersey

EUROPE
- Portugal

INDIA
- Ahmedabad
- Delhi (NCR)
- Vadodara
- Mumbai
- Hyderabad

Milestones

…pathways to our growth

Established Clinical, Bioanalytical and Statistical services at **Ahmedabad**

Initiated **Clinical Trials**

Acquired **Hill Top Research,** North America

Acquired **Karmic Lifesciences**, India

Acquired **Inflamax Research,** North America

ARE NOW

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Centres of Excellence

- Early phase
- Late phase
- Biometrics
- Respiratory
- Pharmacovigilance & Medical Services
- Dermatology
- Lab Services
- Consumer Research
- Tobacco Trials
- eClinical

Location Specific Services

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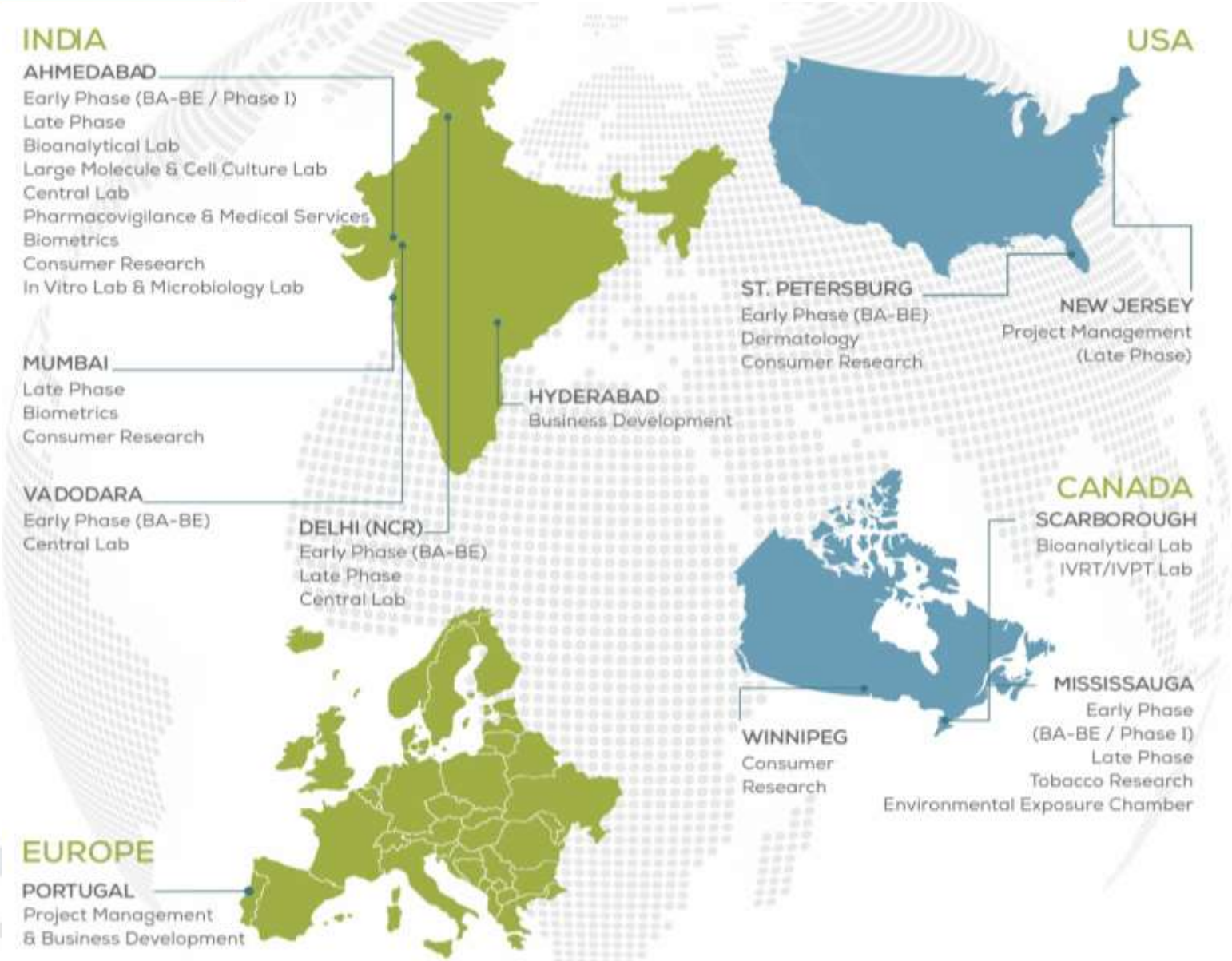

Global Regulatory Track Record

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U.S. FOOD & DRUG ADMINISTRATION 54*

World Health Organization 4

MHRA 2

AGES 2

ansm 1

agencia española de medicamentos y productos sanitarios 1

1

mcc 1

1

U.S. FOOD & DRUG ADMINISTRATION 17

Health Canada 7

agencia española de medicamentos y productos sanitarios 2

DEA 1

* Includes 34 Multicentric Sites (1: USA & 33: India)

Global Presence

US, Canada and India:

- Physical presence in form of offices
- Project Managers & CRAs are in US & Canada
- Capable to manage any Phase I - IV studies in the mentioned geographies
- Also pioneer in EEC studies for Allergic Rhinitis

Europe:

- Presence across Central and South Eastern Europe through a strategic partner
- Project Manager in Portugal

Russia:

- Presence in Russia through a strategic partner

Asia Pacific:

- Presence across South East Asia and Australia through a strategic partner

South Africa:

- Presence in South Africa and African continent through a strategic partner

Clinical Trial Services

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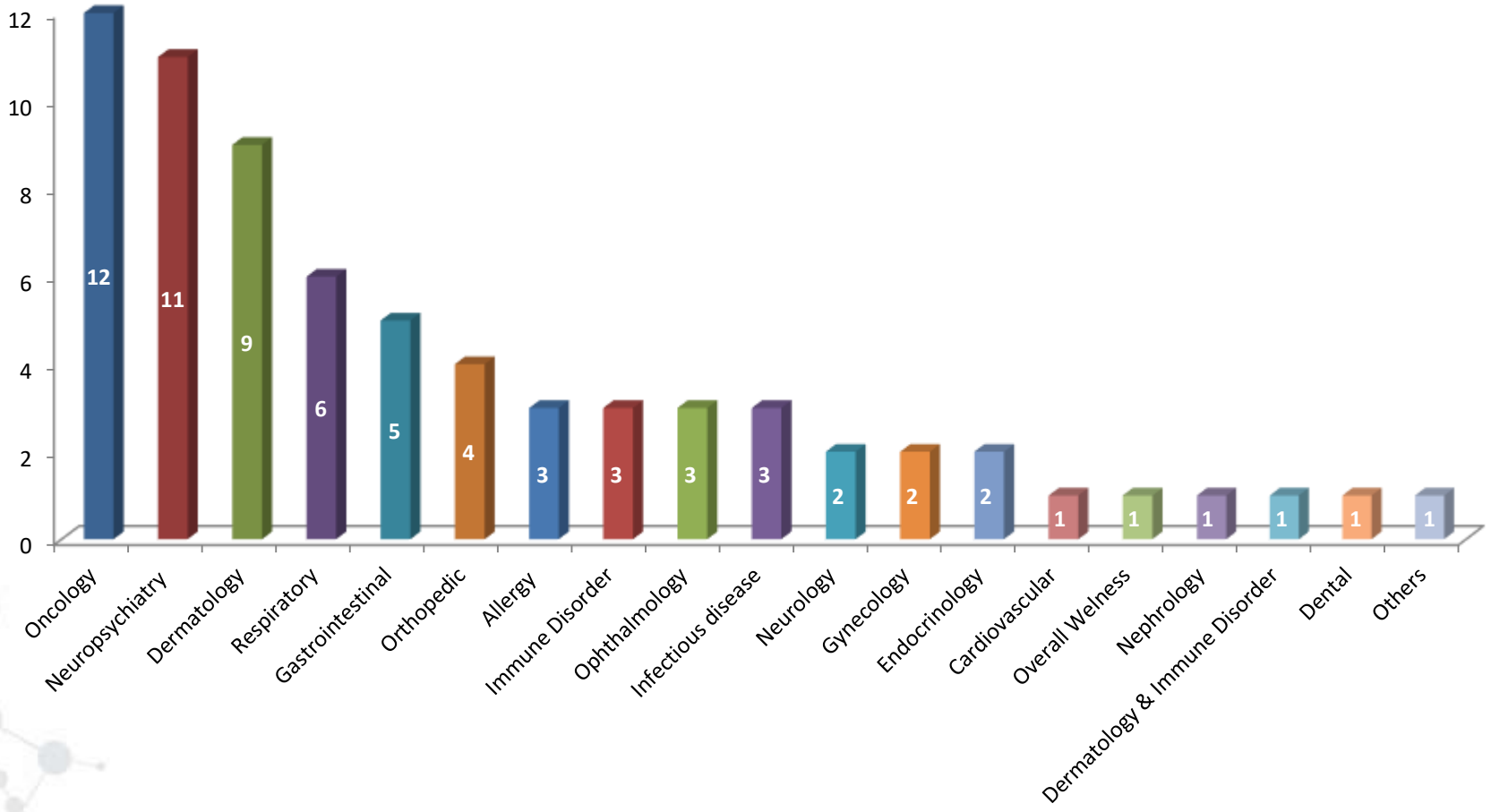
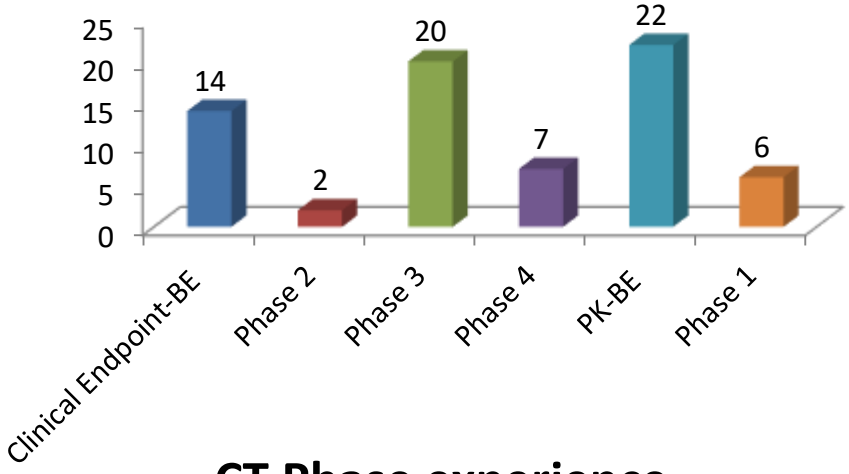
- Clinical Operations
- Supply Management
- Biostatistics
- Quality Assurance
- Training
- Project Management
- Medical Affairs and Writing
- Data Management
- Central Laboratory
- Regulatory
- Pre - Study Feasibility
- Pharmacovigilance

Late Phase – Experience

71	19	42	793	14456
Studies	Therapeutic Categories	Indications	Sites	Patients

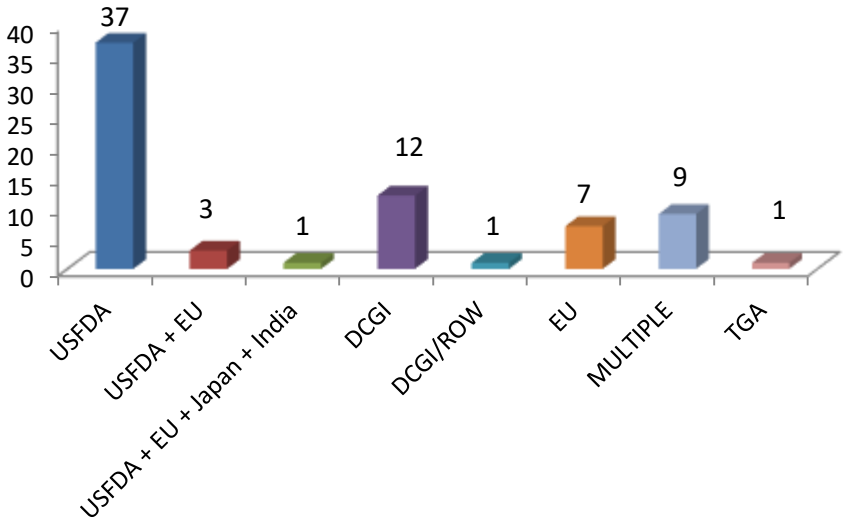


Late Phase – Phase - wise & Regulatory Exp.



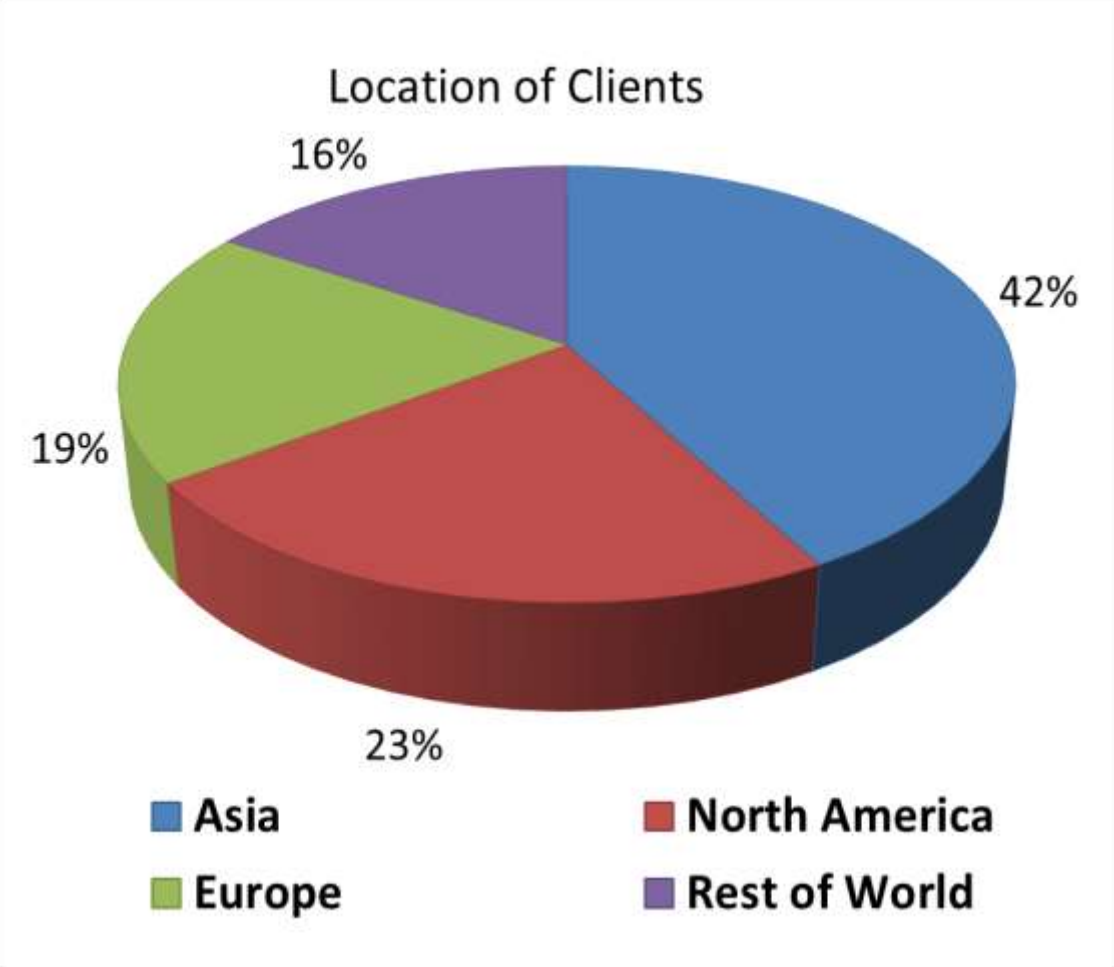
CT Phase experience

Regulatory submissions



*33- India & 1- USA

Client Locations



Clinical Data Management

- End to end services for complete data management
- Proprietary Clinical data management platform “Code Angelo” 21 CFR part 11 compliant system.
- Experience :
  - Phase I - IV including BA BE & personal health care trials
  - Patient population ranging from 20 - 25000
  - Study duration ranging from 1 month to 5 months
  - eCRF & paper CRF model
  - Different therapeutic area:
    - Oncology
    - Dermatology
    - Neurology
    - Diabetology
    - Ophthalmology
    - Respiratory
    - Medical device
    - Patch studies
    - Allergen studies
    - Vaccines
    - Hormones

Clinical Data Management –
North America Team Overview

- > 10 years average experience & over 7 years working together as a team
- All are CCDMs through SCDM
- ***> 400 EDC Databases built, released and closed out***
  - Single & multicenter trials, Phases I–IV & multiple therapeutic areas
  - 25+ sites: 1,200+ subjects: North America & Europe
  - 15+ First in Human trials
  - eClinical, TrialMaster, Medrio
  - CodeAngelo EDC proprietary tool

Biostatistics

- 40+ trained Biostatistician/SAS programmers
- Wide experience in various therapeutic categories

Deliverables

- Sample size calculation
- Protocol inputs
- Randomization
- Statistical analysis plan
- Preparation of table listing in figures
- Statistical analysis report (eCTD)

PHC Studies, Nutraceuticals & cosmetology

- DRC, VASO
- Adhesion, Irritation & Sensitization
- Claim Studies.

Software:

- Server SAS V9.4
- WinNonlin
- PASS 11
- nQUERY Advance

CDISC Services

- SDTM
- ADaM
- Define.xml

Pharmacovigilance Offerings

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Experienced MDs on board

Medical Information Management System

- Patient Support Call Center
- Medical Inquiry Handling
- Categorizing Inquiries & Responding
- Inquiry Close Out

Clinical Trial Safety Monitoring

- SAE Processing & Reporting
- Safety Listing Review
- Clinical Safety Meetings
- DSUR

Post Marketing Pharmacovigilance Services

- ICSR Processing
- Literature Monitoring
- Aggregate Reporting
- RMP, REMS
- PSMF, XEVMPD
- Product Label, CCDS

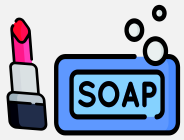
PV Support Services

- Auditing & Inspection Support
- E - Training System
- Quality Management System
- Document Support
- Consultation

Medicinal Products

Medical Devices

Human Vaccines



Cosmetovigilance

Herbal Products/ Nutraceuticals

Veterinary Vigilance

Central Laboratory

- CAP accredited lab located at
  - Ahmedabad
  - Vadodara
  - Noida
- NABL lab at Ahmedabad
- Wide range of tests
- Stringent quality control
- Automated system
  - LIMS
  - Bar coding
  - Bi - lateral interfacing of results
- Facilities adhere to the principles of GCLP.

- ✓ Equipped with State - of - the - art technology
- ✓ 24*7 assistance
- ✓ Highly trained & dedicated medical staff
- ✓ Stringent transportation of sample & logistic process

Clinical Trial Supply Management

Dedicated space

- ~1000 sq. feet

Temperature recording

- Monitoring systems
- Alarms

IP Storage

- Tablets, Capsules, Injectables, Medical devices
- Controlled temperatures
  - 2 - 8 degree Celsius
  - 15 - 25 degree Celsius

Flexible and Capable of expansion

Our Current Team

Clinical Operations

- Team of 65 in Clinical Trials Ops.
- Team of 20 in Medical Services & PV
- Team of 8 in QA for Clinical Trials
- Team of 6 in Support System

Data Managements/Statistics

- Team of 25 Full - time employees in Clinical Data Management
- Team of 23 Full - time employees on Statistics team
- Team of 22 in CDM / CDISC data entry
- Team of 8 QA team members for CDM and Statistics

Current Team 175+

Highly Flexible in Scope of work and Proactive communication

Why Cliantha?

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Experience Various Therapeutic Areas

- A team of veterans in most of the Therapeutic Area especially in Oncology/ Biologics

Training Consistent and Regular

- Robust ***e* - learning system**, only CRO with a dedicated and centralized training team

Global India, US and Partners in EU, Russia South Africa &APAC

- **International presence** with extensive operations in North America and India

Integrity Audited by International Regulatory Authorities

- Facilities and sites **successfully audited** and inspected by both national and international regulatory bodies including FDA

Thank You