



LAT Research

Your needs, our challenge

CONTRACT RESEARCH ORGANIZATION



LAT Research is a privately-owned full-service Contract Research Organization (CRO) company which operates in Latin American countries with staff dedicated to all aspects of Regulatory Affairs, Strategic Planning, Clinical Research, Medical Writing, Biostatistics and Pharmacovigilance.

LAT was created in 2010 to conduct the first full-scale clinical trial in the setting of Chagas Disease in pediatric population. Since then, our staff have been involved in 50 different studies, 26 of them fully conducted by **LAT** enrolling more than 9,000 patients in different therapeutic areas. Particularly, in neglected diseases, **LAT** is the more experienced organization in conducting clinical trials in LATAM.

Our longstanding relationship with local and global networking of research sites and our scientific leadership are the key for success for helping companies to reach the goals for priority review vouchers in neglected or tropical diseases, rare disease or pediatric indications based on qualified staff and access to target population.

STRENGTHS - KEY POINTS

- Non-bureaucratic structure
- Networking of consultants – KOLs & Investigators
- Open communication
- Local team based near the sites
- Formalized SOP's and "fast track" processes
- Strong experience with pediatric studies and orphan drugs
- Legal entity in most of Latin America countries
- Experience in Phase I, II, III & IV studies (devices, drugs, vaccines)
- Led by Health Professionals with previous experience in the pharmaceutical companies
- Competitive costs

LAT Team

The team at LAT Research is comprised of over 20 talented individuals with decades of experience in the pharmaceutical industry in Latam region.

LEYLÉN COLMEGNA

MD, CEO

She is the **CEO and founder** of the Company. She is a physician specialized in Pharmaceutical Medicine with more than 19 years of experience in Clinical Research. She worked at an Investigative Site and has held several leading positions in Regional and Global studies at the CROs and Pharmaceutical Industry.

She is responsible for the leadership of local management teams across all operational units.

PABLO DI BLASI

CPA, CFO

CFO and founder of the Company. Finance professional with more than 20 years of experience working in administration field. He has demonstrated ability to streamline business operations to drive growth, increase efficiency and bottom-line profit. He is responsible for the core business and acts as liaison between partners and clients.

Core Skills: Strategic financial Planning, Business Strategy, Scorecards, Strong multidisciplinary teams, Budgeting, Forecasting & Ad-hoc Analysis, Talent Selection, Development and retention.

Our responsive, non-bureaucratic structure has proven to be fundamental to simulate the close relationship we share with all our Clients.

At **LAT Research** our Client's needs become embedded through-out our organization.

Our staff embraces our client's challenges and will be committed in the project as if it were their own. When you engage LAT Research as your Partner your needs will be completely understood by the staff involved in the project.

SERVICES

CONSULTING IN RESEARCH

- Feasibility analysis
- Country & Site Selection
- Technical support to independent researchers

EARLY PHASES

- Protocol writing
- PK, PD, DDI, Drug-Food interaction monitoring, Single and Multi-dose
- Clinical Monitoring & Site management

CLINICAL MONITORING

- Investigator & Sites selection
- In Field Monitoring
- Site management

QUALITY ASSURANCE

- Prepare sites for FDA, EMA or any other Regulatory Agency inspection
- Prepare sites for Audits
- Conduct GCP Audits at Investigative sites

DATA MANAGEMENT & BIOSTATISTICS

- EDC set up
- eCRF or paper CRF design
- Results analysis
- Clinical Study Report

PHARMACOLOGY

- Protocol writing
- Epidemiological & post Marketing studies
- Scientific Publications
- Medical Literature search

MEDICAL WRITING

- Represent clients at Local Regulatory Agency
- Preparation regulatory package to fulfill all local requirements
- Ethic Committees and Competent Authorities follow up until approval

REGULATORY SERVICES

- General oversight of project
- Investigator Meeting
- Patient recruitment
- Coordination of logistics and administrative support

PROJECT MANAGEMENT

- 24/7 medical consultancy
- AEs/SAEs/CIOM reporting
- Post Marketing surveillance

PHARMACOVIGILANCE



PLACEBO

Why LATAM countries?

Latin American Clinical Research market is still growing. The development of this region in Clinical Research involves multiple factors, such as:



- More than 625 million inhabitants, with a high number of treatment native patients
- Population consolidated in few metropolitan areas allows to have:
 - Access to large population in concentrated geographic areas:
 - Multiple hospitals in small areas
 - Diverse hospital types (public vs. private)
 - Consistent standards of care
- Ethnic-genetic diversity
- Patients for all therapeutic areas, in special "neglected or tropical diseases"
- Reverse seasons with respect to Northern hemisphere allowing the region to act as "rescue plan" for protocols in seasonal conditions
- Tradition of Western Medicine education for investigators
- Reliable, well trained in ICH-GCP standards, and eager to participate investigators
- Quality of data ensured through strong adherence to ICH-GCP norms
- Adequate technology available at most investigative sites
- Strong patient-doctor relationship, leading to excellent patient retention and compliance rates

LAT enables companies to reach the goals for priority review vouchers in neglected or tropical diseases, rare disease or pediatric indications as those are our areas of expertise

MOST REMARKABLE AND CHALLENGED EXPERIENCES

1

Tropical Disease

10 different clinical trials have been executed in Chagas Disease for 4 different clients. 2 products obtained priority review vouchers from FDA.

2

Studies in microbiome

LAT was selected as partner of choice by a leading French biotech in probiotics. Because of a successful synergy, 3 studies have been executed so far in pediatric and adult population.

3

Epidemiological Studies

LAT was selected as CRO for a large study in RA conducted in LATAM countries. We were able to enroll 2231 subjects at 39 investigative sites in less than a year because of the close relationship with investigators population.

4

From pre clinical to the Market

LAT was contracted to perform all the clinical development for a new spray for alopecia. Based on the results and the methodology of the clinical studies, the client was able to register their product in many countries, including European Community's countries.

Broad Range of Experience

Infectology:

- Chagas Disease
- Acute diarrhea
- Hepatitis C
- Vaccines

Rare Diseases:

- Gaucher Disease
- Fabry Disease
- Duchenne Disease
- Mastocytosis
- Hereditary Angioedema

Respiratory:

- Bronchiectasis (NFCB)
- Idiopathic Pulmonary Fibrosis

Gastroenterology:

- Irritable Bowel Syndrome
- Reflux GERD
- Constipation
- Celiac Disease
- Acute diarrhea in children

Neurology:

- ALS

Dermatology

- Alopecia
- Atopic Dermatitis

Rheumatology

- Rheumatoid Arthritis

Oncology

- Solid tumors
- NHL

RESEARCH

Innovation

Science



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