EM - V.01 June / 2024

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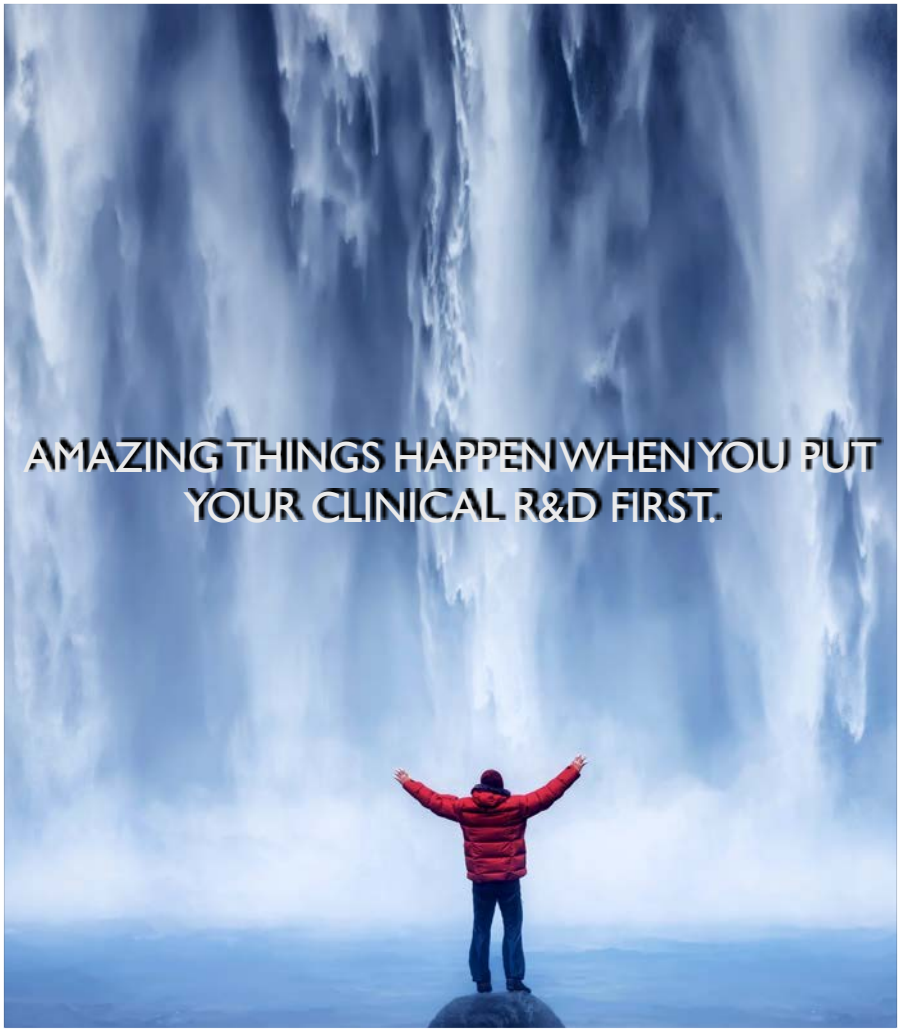
Exploring ESTERN Medical CRO Life Sciences Group

Discovering our identity: Who We Are



The ESTERN Medical CRO Life Sciences Corporation Group is recognized as one of the foremost international full-service Clinical Contract Research Organizations (CRO) in the Life Sciences sector, specializing in clinical trials across the US North America, and emerging markets in Latin America.

Operating across two continents, namely the U.S. North America and Latin America (LATAM), our corporate headquarters are strategically located in the New England Area, particularly in **Boston-Cambridge, USA**, renowned as the Genetown Hotbed Life Science community. Additionally, our regional presence extends across Latin America / South America with operational locations in Mexico, Colombia, Chile, Argentina, and Brazil.

Founded as an **independent and privately owned corporation** in 2002, we are deeply committed to serving as the preferred full-service partner in the global CRO Life Sciences industry. Our mission is to contribute to advancements in healthcare and the quality of life through Clinical Research Trial Development. Our leadership is derived from a blend of internal expertise and collaborations with esteemed partners and sponsors, including global pharmaceutical, biotechnology, and medical device companies, as well as CROs, academic institutions, government bodies, and private organizations.

At ESTERN Medical CRO Life Sciences, we employ innovative methodologies in **Clinical, Scientific, R&D, Operational, and Regulatory Development**, tapping into our vast therapeutic knowledge to deliver exceptional results for our sponsors. Our unwavering dedication to quality guarantees that we help sponsors and partners maximize their R&D investments and expedite the delivery of safe and effective treatments to patients globally.

With a comprehensive range of outsourced R&D clinical trial services spanning all phases, we have refined our capabilities over the years to provide international excellence while upholding a personalized approach that underscores our dedication to excellence.

Integrated Life Sciences & Clinical Trials Development: Phases I, II, III through IV

I. Clinical Research Trials & Development Services

- Comprehensive Clinical Trial Execution: Phases I, II, III, and IV, including IND, NDAs, PMAs, and 510Ks.
- Specialization in Biotech, Pharma, and Medical Devices: Class III Clinical Trials conducted across the USA and Latin America.
- Regulatory Support: Expertise in US/FDA and LATAM EC/IRB & MoH submissions, including INDs, NDAs, PMAs, and 510Ks, with integrated services.
- Medical Writing and Translation Services: Ensuring accurate and compliant documentation for regulatory submissions and clinical trial protocols.
- Project Trial Management: Experienced project management to oversee all aspects of clinical trials from initiation to completion.
- Site Management: Efficient management of trial sites to ensure adherence to protocol and regulatory requirements.
- Clinical Monitoring: Expert monitoring services to ensure data quality and protocol compliance throughout the trial.
- Patient Recruitment Strategies: Tailored strategies to maximize patient recruitment and retention throughout the trial duration.
- Biostatistics: Robust biostatistical analysis to ensure accurate interpretation of trial results.
- Bioanalysis: Precise analysis of biological samples to support clinical trial endpoints and assessments.
- Medical Services, MSLs & Pharmacovigilance: Provision of medical support, Medical Science Liaisons (MSLs), and pharmacovigilance services to ensure patient safety and regulatory compliance.
- Clinical Audits: Conduct audits to ensure adherence to Good Clinical Practice (GCP) standards and regulatory requirements.
- Salvage Projects: Expert support for salvaging and managing clinical trials that encounter challenges or setbacks.

Processes Optimization Expertise

II. Bio-Pharma/MedTechs/R&D Technology

- Medical Imaging: Utilizing advanced technologies such as MRI, CT, Angiography, and Nuclear Medicine for precise clinical assessments.
- IWRS (Interactive Web Response System): Implementing interactive systems to manage randomization and drug supply management in clinical trials.
- EDC (Electronic Data Capture): Employing electronic platforms to collect, manage, and analyze clinical trial data efficiently and securely.
- Integration Services: Providing seamless integration of various technology platforms and systems for streamlined clinical trial operations.
- CTMS (Clinical Trial Management System): Utilizing comprehensive platforms to plan, track, and manage all aspects of clinical trials.
- ePro (Electronic Patient Diaries): Implementing electronic diaries to capture patient-reported outcomes and streamline data collection.
- RWE & RWD: Leveraging Real-World Evidence (RWE) and Real-World Data (RWD) from the US and Latin America to inform decision-making and enhance clinical trial designs.
- ESTERN Medical CRO, Market Life Sciences Intelligence: Offering comprehensive intelligence on the Biotech, Pharma, Medical Device, and CROs Pipelines in the US and EU, covering R&D, Regulatory, Clinical, Profiling, and Partnerships.

Leading the Way in Life Sciences Technology

III. Consultancy Life Sciences R&D Services

- Clinical Product/Research Development & Regulatory Affairs: Offering expertise in developing and navigating regulatory pathways for clinical products, ensuring compliance with regulatory standards.

- Strategic Compliance & Risk Management: Providing strategic guidance and risk assessment to ensure compliance with regulatory requirements and mitigate potential risks.

- Clinical & Manufacturing Quality Process: Advising on quality processes and standards in clinical and manufacturing operations to maintain product quality and safety.

- Clinical Trials Development Consulting: Offering consultancy services in all aspects of clinical trial development, from protocol design to study execution and regulatory submissions.

- CMC & GMP Consulting: Providing expertise in Chemistry, Manufacturing, and Controls (CMC) and Good Manufacturing Practice (GMP) compliance to ensure product quality and regulatory compliance.

- International Pharma, Biotechs & Medical Devices Target Country Registration & Market Positioning Services in the U.S. & LATAM: Assisting pharmaceutical, biotech, and medical device companies in registering their products and strategically positioning them in the markets of the US and Latin America.

- Strategic Pharma & Medical Device Partnerships: Facilitating strategic partnerships and collaborations between pharmaceutical, biotech, and medical device companies to enhance product development and market access.

- Senior Advisory Board Support: Offering senior advisory board support and guidance to organizations, leveraging industry expertise and insights to drive strategic decision-making.

Strategic Guidance in Product R&D Consultancy

Exploring the Clinical Trials R&D Opportunities in U.S. North America & Latin America

Unlocking Opportunities: U.S. and Latin America Clinical Research Comparative Analysis

- At ESTERN Medical CRO Life Sciences, we recognize the importance of robust Life Sciences corridors supported by extensive infrastructure in government, academia, and renowned private research centers. These corridors play a vital role in achieving high enrollment success rates, enhanced by exceptional ICH/GCP patient compliance and retention, further facilitated by access to newer R&D treatment-naive patient indications.

- Our close collaboration with top-rated clinical research centers and institutions allows us to tap into their expertise in conducting global clinical trials across all phases, including Phase I, II, III, and IV, with extensive experience in handling INDs and NDAs.

- Within our extensive network, we have cultivated relationships with physicians, scientists, and key opinion leaders (KOLs) who bring diverse expertise in various fields of clinical research, spanning biotechnology, pharmaceuticals, and medical devices.

- With our presence across two continents and supporting 33 countries, our network grants access to a combined population of 662 million in Latin America and 333 million in the U.S. North America.

- We strategically target the top 20 largest and most populated metropolitan areas worldwide, ensuring access to a diverse patient population. These areas include major cities such as New York, Boston, Houston, Los Angeles, and Chicago in the U.S., and Mexico City, Bogota, Buenos Aires, and Sao Paulo in Latin America and South America.

- The cultural and linguistic diversity across the U.S. and Latin America poses fewer barriers compared to other regions of the world, allowing for seamless patient recruitment. Additionally, the ethnic diversity across both continents caters to a wide epidemiological demographic range, including large U.S. Hispanic populations, as well as European, Asian, and African communities.

- Certain Latin American countries offer an accelerated approval process regulatory framework, supported by efficient processes involving Ministries of Health (MOH), Institutional Review Boards (IRBs), and Ethical Committees (ECs). These countries adhere strictly to international GCP-ICH norms, ensuring quality assurance on par with US-FDA and EU-EMA standards.

- One of our key advantages over other CROs and clinical trial companies is our ability to leverage the combined strengths of the U.S. and Latin America/South America emerging countries, offering a competitive economic edge. This advantage allows us to execute trials efficiently without compromising quality and compliance.

Our CRO International Presence & Partnership Alliances

DEMOGRAPHIC TRENDS

USA

- ✓ Population: 370 million by 2035 (currently 333.3 million)
- ✓ Middle class: Expected to decrease to ~48% by 2030 (currently 50%).
- ✓ Female workforce: Projected to comprise ~48% by 2025.
- ✓ Focus: Increasing emphasis on domestic and international novel R&D pipeline production in the pharmaceutical, biotechnology, and medical device sectors in US North America for potential indications.

Latin America

- ✓ Population: 711 million by 2030 (currently 662 million)
- ✓ Middle class: Expected to increase to ~43% by 2030 (currently 30%)
- ✓ Female workforce: Projected to comprise 47% by 2025
- ✓ Focus: Increasing emphasis on domestic and international R&D/production in LATAM's pharmaceutical, biotechnology, and medical device sectors.

Source: World Bank, Frost & Sullivan, WHO

Why U.S. North America or Latin America Outperforms other Emerging Countries & Regions?

	USA	Latin America	China	India	Eastern Europe
Population	335.8 Million	669.04 Million	1.430 Million	1.440 Million	287 Million
GDP (Nominal)	USD 25.4 Trillion	USD 5.1 Trillion	USD 17.7 Trillion	USD 4.11 Trillion	USD 2.54 Billion
Language	• English	• Spanish (88%) • Portuguese (12%)	Mandarin and 10 other languages	Hindi, English and 8 other languages	14 languages

Source: World Bank Organization & World Health Organization (WHO)

Why U.S. North America or Latin America Outperforms other Emerging Countries & Regions?

	USA	Latin America	China	India	Eastern Europe
Education Standards of Physicians	Higher Educational Standards: At the forefront of clinical, scientific, and research and development (R&D) endeavors are ethical practices regulated by the American Medical Association (AMA).	Equals Western European and North American Educational Standards.	Educational standards do not align with those of Western Europe and North America.	Equals Western European and North American educational standards.	Educational standards in this region do not align with those of Western Europe and North America.
FDA Compliance	Full FDA Compliance: Adherence to the principles of Good Clinical Practices (GCPs), including ensuring adequate protection for human subjects, is universally recognized as a critical requirement for conducting research involving human subjects.	• The FDA has independent and regionally-based employees. • Additionally, FDA Regional Local Offices are established across Latin America. • A noteworthy accomplishment is that 63% of FDA GCP/GMP inspections have passed without required actions. • Furthermore, the organization complies with Good Clinical Practice (GCP) Standards and International Council for Harmonization (ICH)	• China does not comply with FDA inspections, with a reported ~30% failure to report adverse events and ~25% inadequate clinical trial records.	• India is FDA "approved," although comparable data has not been acquired.	• ~47% adherence to clinical protocol standards.

*Source: FDA. GOV & World Health Organization (WHO)

Accelerated and Efficient Execution of Clinical Trials in the U.S.A. & Latin America

Current Listed Clinical Trials Across the USA & Latin America	
USA	172.471
Brazil	9.916
Mexico	4.964
Argentina	3.968
Chile	2.284
Colombia	1.911
Peru	1.246
Grand Total in Latin America	24.289
Grand Total in USA.	172.471
Source: Clinicaltrials.gov, Q/2 / 2024	

Patient Recruitment for all Diseases in Latin America	
Effectiveness (patients / sites)	ESTERN Experience: 20-60 patients per site
Regulatory Approval Times	Certain countries in Latin America offer expedited regulatory pathways
Source: ESTERN Medical CRO Life Sciences Group Latin American Operations, 2024	

Capacity Enhancement:

Operating in Emerging Markets across Latin America can significantly augment your capacity, offering a balanced approach alongside U.S. & EU clinical research Hospital sites

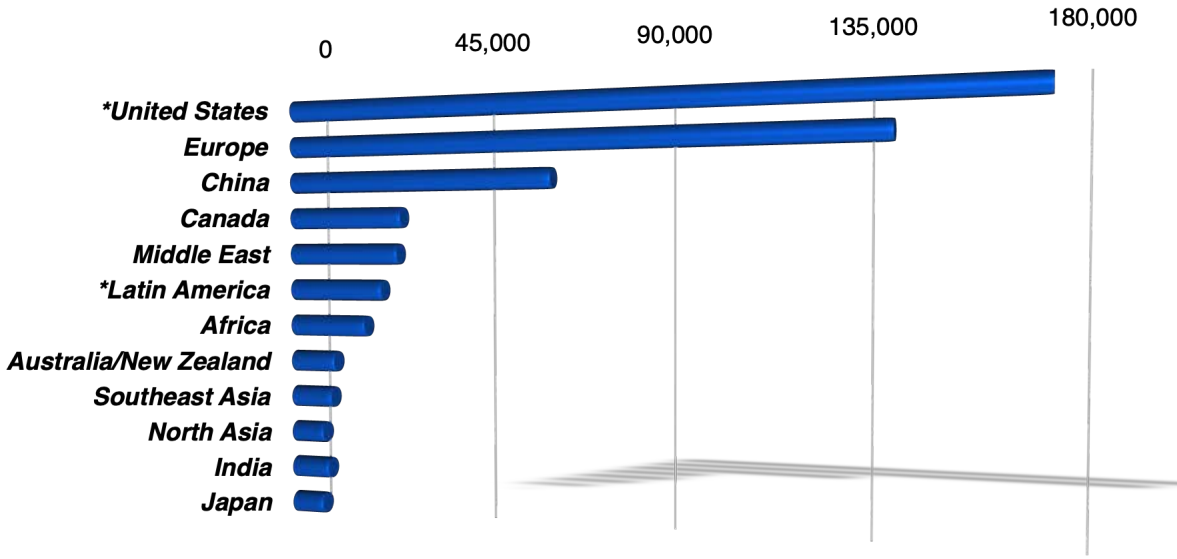
Productivity Enhancement:

The patient volume per site typically exceeds that of the USA and Western Europe, and LATAM maximizes overall trial performance.

Quality Assurance:

The data quality in LATAM is comparable to or superior to that of the USA & Western Europe.

Clinical Trials Around the World Executed by the fastest growing R&D Biotech's, Pharmaceutical, and Medical Device corporations. The United States is ranked 1st, with Latin America ranking 6th.

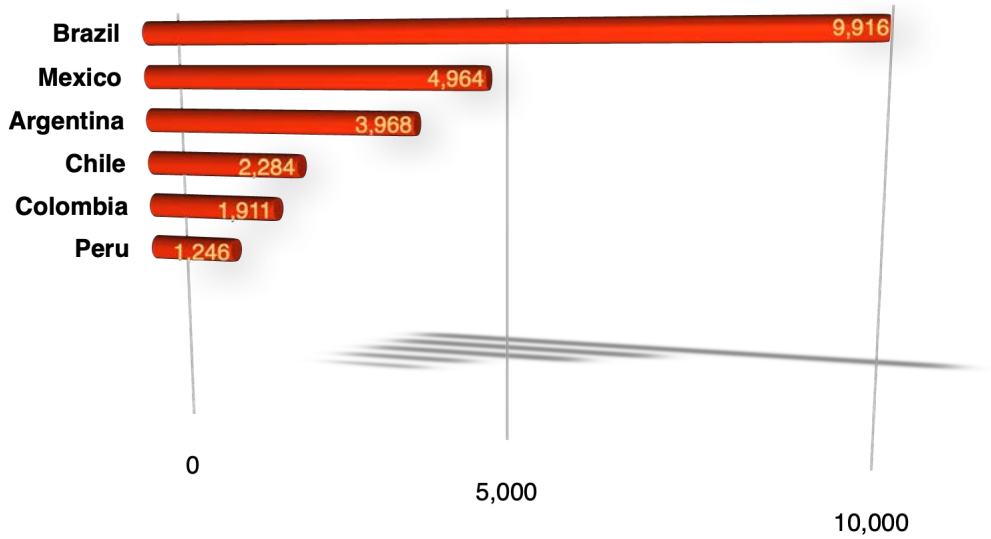


Global Number of Clinical Trials

Any clinical trial conducted in a country that has at least one site has been included.

United States ranks in 1st place

Latin America ranks in 6th place



Number of Registered Clinical Trials in LATAM in 2021

Includes each country location where a study is recruiting

Source: Clinicaltrials.gov, Q/2 / 2024

Regulatory Key Limiting Steps in LATAM, USA, and European Review Processes

- In the **USA**, each protocol (except for Phase 1) only requires submission to the FDA, with parallel EC/IRB review and approval. Prior review by the FDA is not required, except for Phase 1 trials. The rate-limiting step primarily lies in the EC/IRB submission and approval process, which typically takes ~45-60 days.

- In **Latin America**, the review process is sequential: first, EC/IRB approval, followed by the Ministry of Health (MoH) review. The MoH review time varies from country to country. Local insurance coverage for patients can also be a limiting factor, as many ECs/IRBs require it. Additionally, multiple ECs/IRB submissions and some regulatory authorities necessitate a signed contract. The combined EC/IRB with MoH review takes approximately ~90 days in countries within LATAM.

- **The European Union (EU)**, has a parallel review process, allowing submissions to EC/IRB and the Competent Authority (MoH) to co-occur. The review by the EC/IRB and the MoH typically takes ~60 days for countries within the EU.

**Source: US FDA, EU-EMA & ESTERN Medical CRO Life Sciences Group Latin American Operations, 2024*

Comparison of Regulatory Timelines and Patient Recruitment Rates between the USA and LATAM

Our Most Common Regulatory Start-Up Times in the U.S. & Latin America			
Country	**Regulatory Startup Rank Overview**	**Population**	**Start-Up Time (Months)**
U.S.A.	1st Tier	335.8 Million	~ 2
Colombia	1st Tier	51.8 Million	~ 4
Argentina	1st Tier	46.2 Million	~ 4
Chile	1st Tier	19.6 Million	~ 4
Mexico	2nd Tier	127.5 Million	~ 5
Brazil	3rd Tier	215.3 Million	~ 10

*Source: ESTERN Medical CRO Life Sciences Latin American Operations 2024, UK-BBC & WHO

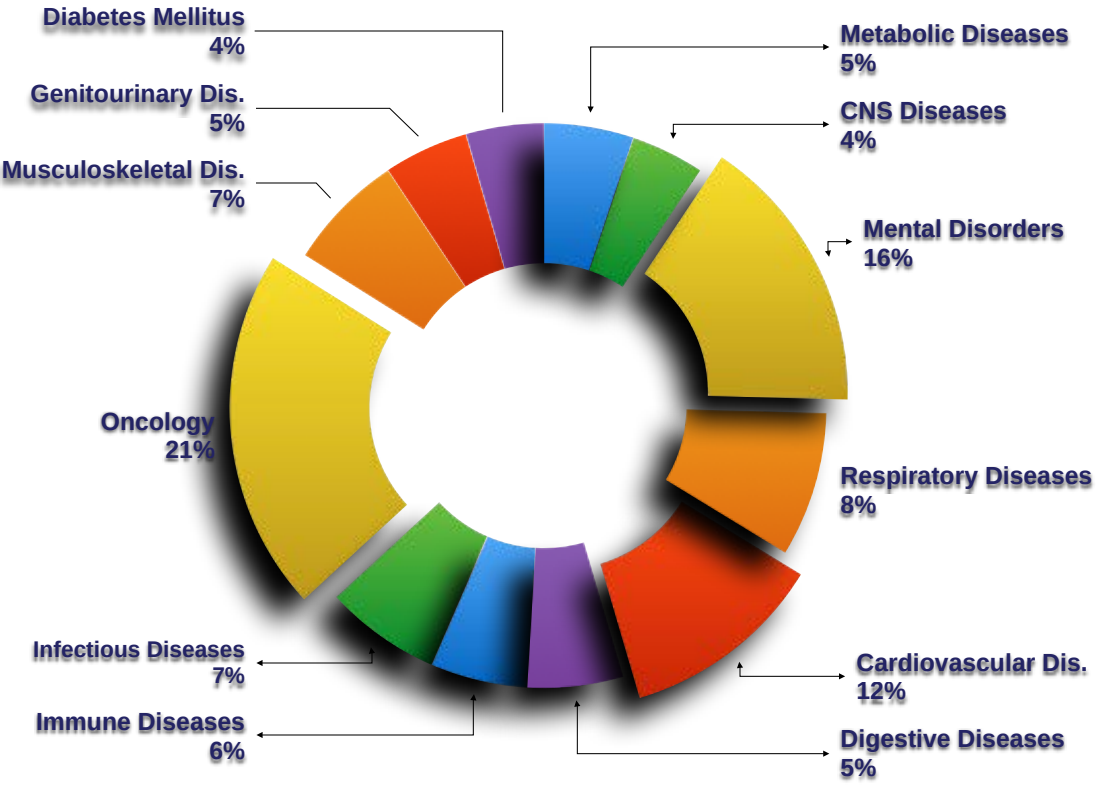
Variability in Patient Recruitment Rates Across Global Clinical Trials	
Region	**Average Number of Patients Enrolled Per Site**
Asia - Pacific	~30 - 60
Latin America	~20 - 40
Europe	~15 - 40
Africa	~10 - 30
U.S.	~20 - 50

*Sources: ClinicalTrials.Gov / US - FDA / EU - EMA / 2024

- Latin American recruitment is renowned for its greater efficiency compared to other traditional regions.

As clinical trial sponsors increasingly focus on the emerging economies of Latin America, ESTERN Medical leverages local expertise from key industry figures in the region. Through this collaboration, we uncover initiatives in certain countries aimed at aligning their regulatory processes with those of traditional Western markets.

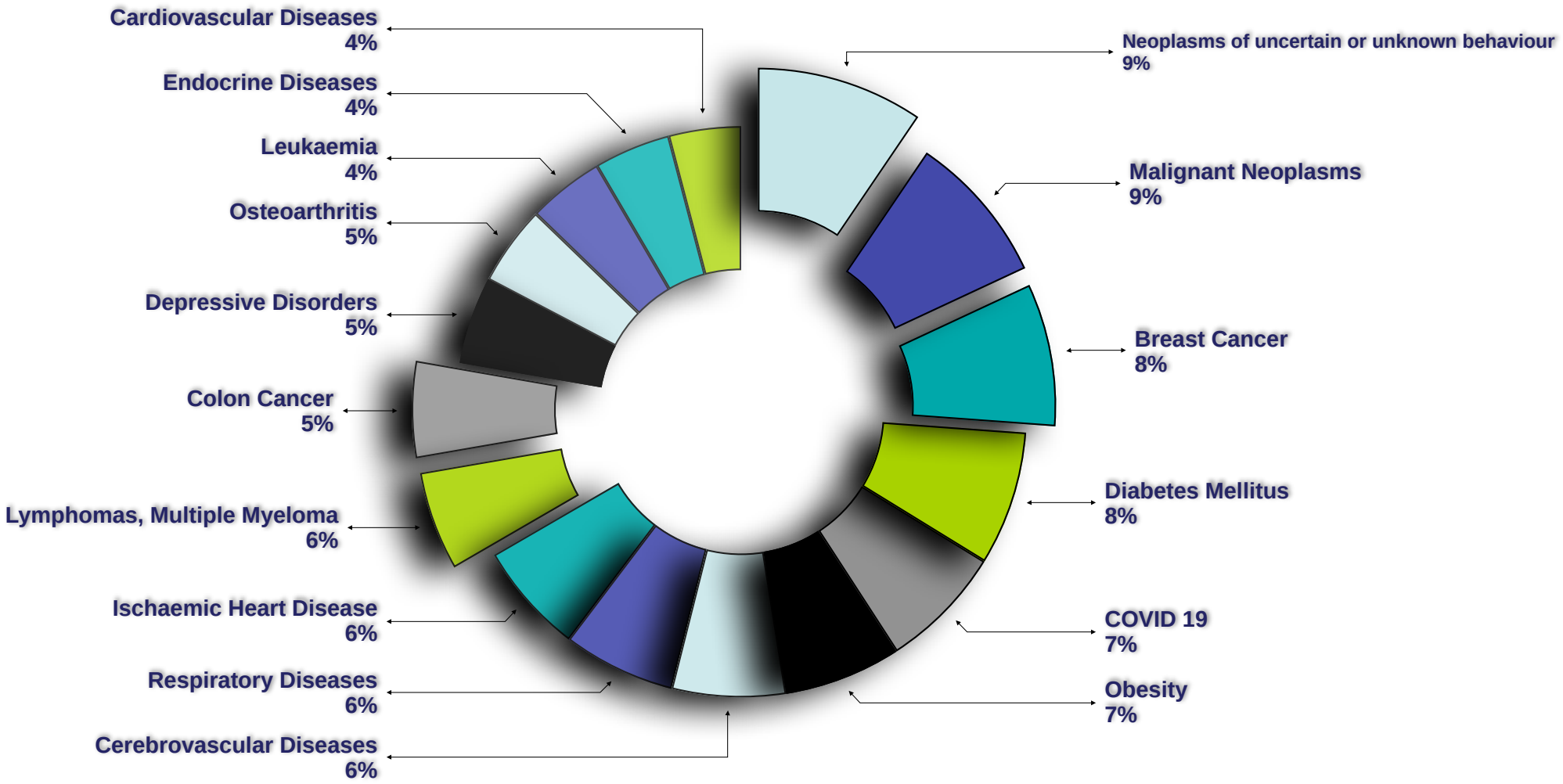
Global Landscape of Major Therapeutic Areas



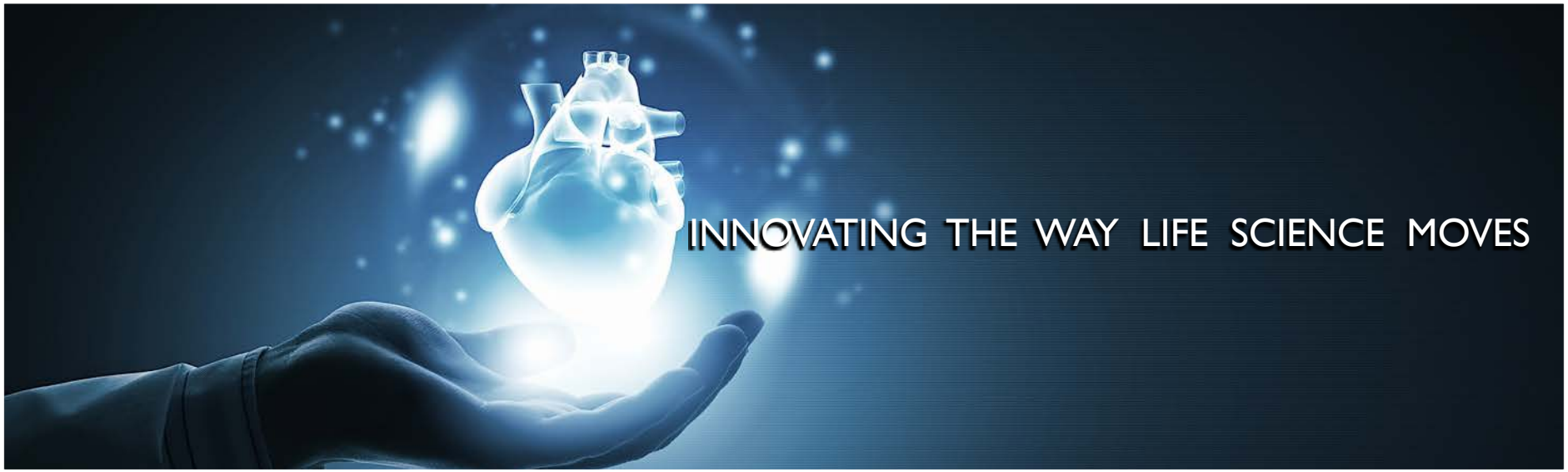
**Source: World Health Organization (WHO) Q2/2024*

- According to the World Health Organization and recent clinical sources, chronic diseases such as heart disease, stroke, cancer, respiratory diseases, and diabetes continue to be the leading causes of mortality globally, representing a significant portion of all deaths.
- Projections for 2030 suggest that chronic diseases will maintain their position as major contributors to mortality, with seven out of the top 10 causes of death expected to be related to these conditions.
- The incidence of new cancer cases worldwide has been steadily increasing, with estimates indicating a rise from approximately 12.7 million cases in 2008 to around 21 million cases by 2030.
- Rare diseases remain a significant health concern, affecting approximately 350 million to 400 million people worldwide. In the US, an estimated 25 million to 30 million individuals are impacted by rare diseases, while in Asia, over 45 million people may be living with rare conditions.
- In recent years, heart disease has continued to be a leading cause of death in the US & LATAM, accounting for a substantial percentage of all mortality. Despite advancements in treatment and prevention, there has been an increase in heart disease-related deaths, highlighting the ongoing challenges in managing this condition.
- COVID-19 has had a significant impact on mortality trends worldwide. While COVID-19 mortality rates have fluctuated over time, efforts to control the spread of the virus through vaccination and other measures have led to fluctuations in its ranking among leading causes of death.
- In Latin America, cardiovascular diseases remain the primary cause of mortality, followed by oncological conditions. Circulatory diseases continue to pose a significant risk, with a higher likelihood of resulting in fatalities compared to other health conditions.
- The prevalence of obesity in Latin America has been on the rise, contributing to an increased risk of developing diabetes and cardiovascular diseases among the population. This trend underscores the importance of addressing lifestyle factors to improve overall health outcomes.

Global Clinical Trials by Disease or Condition



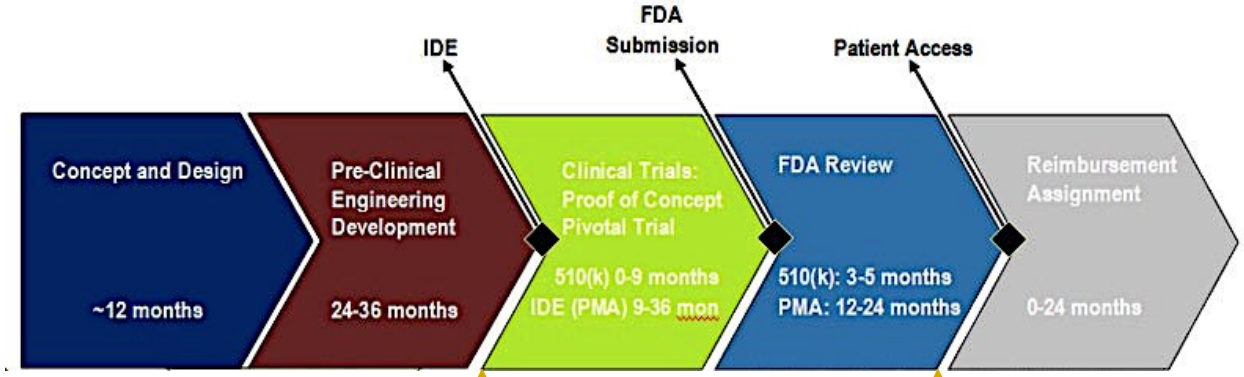
**Source: World Health Organization (WHO) Q2/2024*



Leading the way: Clinical Trial Solutions and Expertise

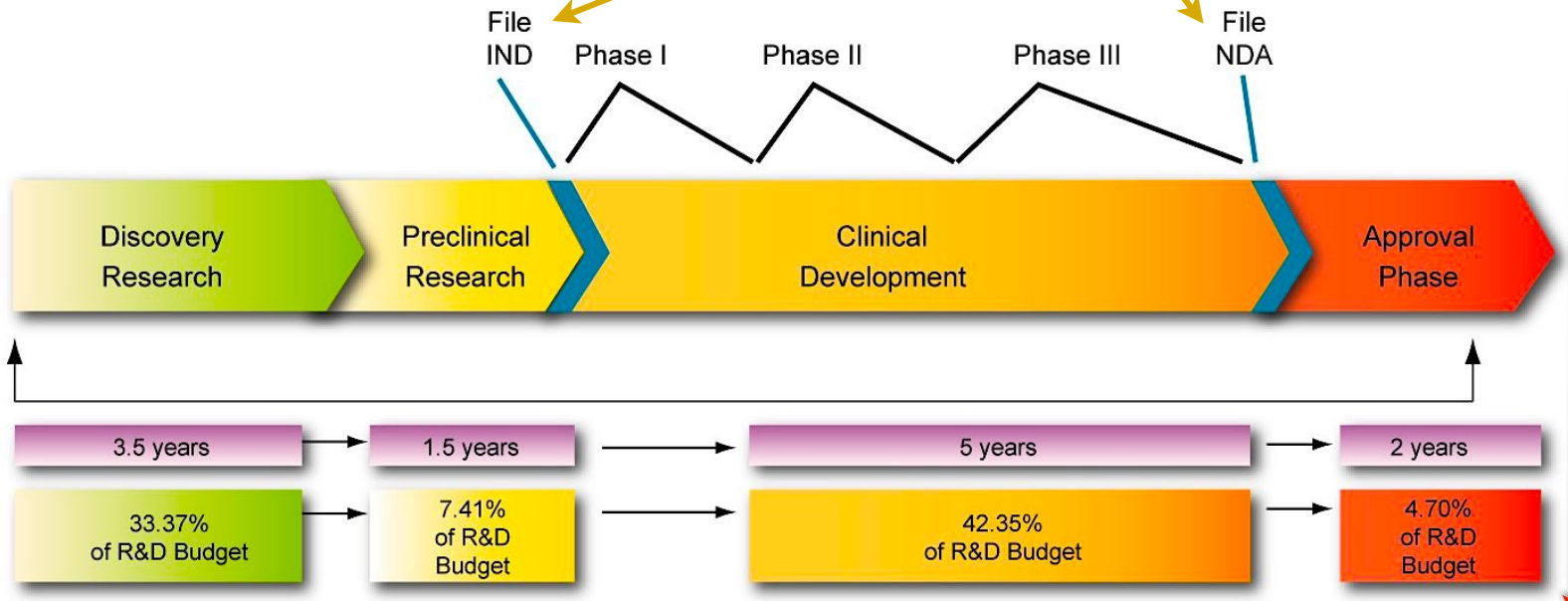
Strategic Focus: Clinical Trial Expertise in Pharmaceutical & Medical Device Sectors Across the Americas

Medical Device Approval Process



ESTERN Medical Areas of Expertise

Pharmaceutical Drug Approval Process



Our Premium Quality Comprehensive Clinical Trial Services

✓ Clinical Development and Design of Clinical Studies across the USA & Latin America, including INDs & NDAs, 510ks, PMAs.
✓ Expertise in developing and executing phase I, II, III, and IV clinical trials in the Biotech, Pharmaceutical & Medical Device R&D sectors.
✓ Efficient Patient Recruitment in the USA & Latin America at highly qualified sites.
✓ Regulatory Strategies Dossiers Submissions (IRB/EC, MOH) in the USA & Latin American countries.
✓ Clinical Monitoring, Project Management, Pharmacovigilance, Biostatistics, Medical Writing, Translations, Streamlined Site Selection & Recruitment Process, Logistics, EDC-Data Management, and Audits.

Our Regulatory Services:

✓Thorough understanding of the Pharma-Biotech & Medical Device regulatory environment in the U.S. & Latin American countries.
✓- The regulatory approval process (Ethics Committees & MOH) is more streamlined & predictable in the USA and LATAM.
✓- Customized Regulatory Strategy tailored per country to expedite approval timelines.

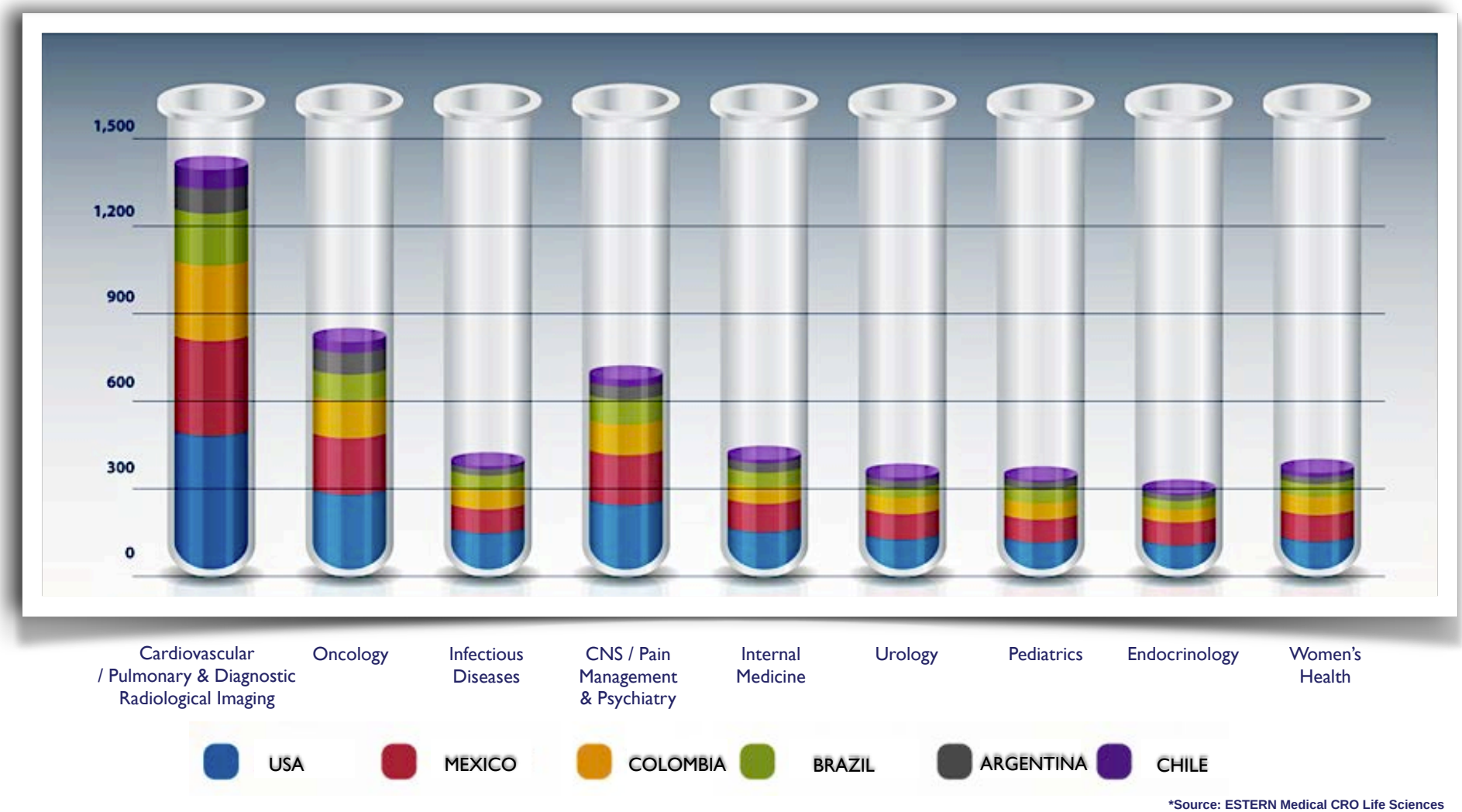
Our Life Sciences Go-to-Market Strategies

✓- Guiding your path toward seamless entry into international life sciences markets for Pharmaceuticals, Biotechs & Medical Devices Healthcare products.
✓- Bridging the gap to international markets, turning challenges into opportunities
✓- Comprehensive expertise enabling healthcare innovators to extend their reach with minimal investment and risk
✓- Ensuring advanced healthcare solutions are effectively delivered to patients globally
✓- Strategic foresight, operational excellence, and a commitment to making a global impact
✓- Assisting in creating and delivering sustainable long-term value

Clinical Trial Success: Our Therapeutic Expertise Across U.S. & LATAM

Advancing Solutions: Our Dynamic Clinical Life Sciences CRO Portfolio

ESTERN Medical CRO Life Sciences: Pioneering Clinical Site Solutions Across the Americas



*Source: ESTERN Medical CRO Life Sciences

34% Cardiology / Pulmonary / Diagnostic Radiological Imaging (MRI / MRA / CT & Angio

20% Oncology

19% Rare Diseases, Women's Health

2% Ophthalmology, Dermatology

11% CNS / Pain Management & Psychiatry

14% Infectious Diseases

*Source: ESTERN Medical CRO Life Sciences

Unlocking Solutions Across the Spectrum: ESTERN's Therapeutic Diversity Expertise

Cardiology
Arterial Hypertension
Angina Pectoris
Coronary Artery Disease
Cardiac Arrhythmias
Cardiovascular Outcome Studies
Deep Vein Thrombosis
Heart Failure
Hyperlipidemia / Dyslipidemia
Peripheral Arterial Disease (PAD)
Pulmonary Hypertension / COPD
Venous Ulceration

Infectious Diseases
COVID - 19
AIDS / HIV
Tuberculosis (TB)
Malaria
Hepatitis B
Hepatitis A
Influenza (Including H1N1)
Cholera
Meningitis
Respiratory Tract Infections
Ebola
SARS
Travel Diarrhea

Oncology
Pancreatic
Myeloma
Renal
Melanoma
Protate
Acute & Chronic Leukemia
Colon
Brain Tumor
Cervix
Hodgkin & Non-Hodgkin Lymphoma
Lung
Breast
Ovarian

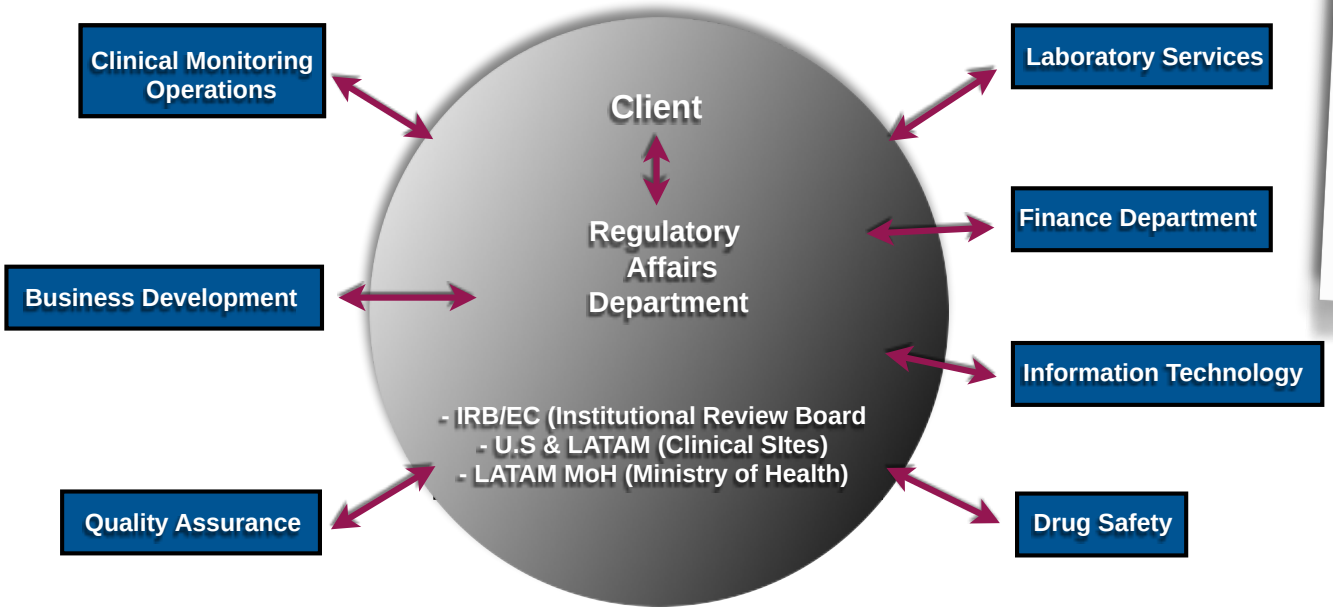
CNS / Psychiatry / Pain Management
Multiple Sclerosis
Bipolar Disorders
Pain Management
Parkinson's Disease
Stroke
Psychosis
Depression
Alzheimer's Disease
Epilepsy
Pulmonary Hypertension / COPD
Venous Ulceration

Our USA & Latin American Integration of Regulatory Activities & Cost Analysis

Our Key Responsibilities

- Providing External and Internal Sponsors with Clinical Development Advice, Guidance, and Support in all clinical trial Phases I, II, III and IV for Pharma / Biotechs & Medical Device Projects.
- Conducting Feasibility R&D Studies by country, Preparing Proposals, and Developing Financial Budgets.
- Analyzing Regulatory Risks and Developing Strategies to Address R&D Clinical Trials.
- Ensuring Compliance with Regulatory Requirements from all Agencies in the USA EC/IRB & (US-FDA) and Latin America / South America EC/IRB and Ministry of Health authorities (MoH)
- Compiling and Reviewing Regulatory Start-Up Documents
- Submitting Documents to Independent Ethics Committees in the USA/LATAM and Latin America (MoH)
- Clinical Monitoring and Reporting on Clinical Pharmacovigilance and Scientific Clinical Trial Progress.
- Managing Import/Export Processes for Investigational Products in the USA and Latin America / South America
- Overseeing the Delivery, Logistics, Storage, and Disposal of Clinical Trial Materials

Our Regulatory Department- Interactions



Cost Advantage: Trial Execution in U.S. vs Latin America

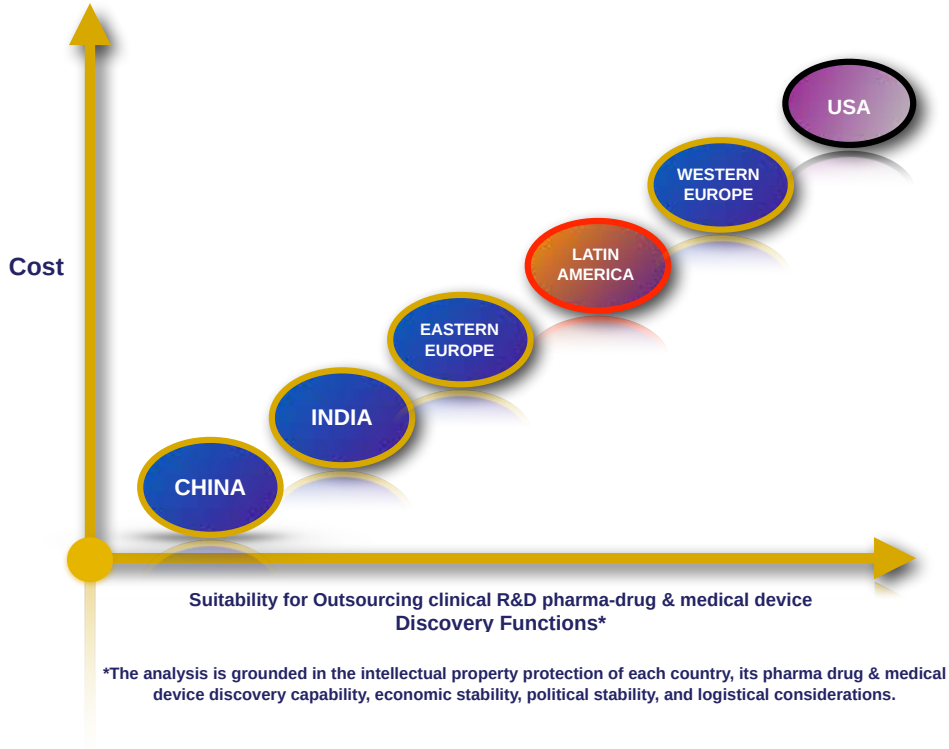
- **Patient recruiting is up to ten times more efficient** in Latin America compared to the US, attributed to higher patient concentration.

- **Treatment costs 30% less than in the US & Europe,** resulting from reduced expenses on medication, investigations, and hospitalization.

- **Cost reduction** is facilitated by domestic travel within Latin American / South American countries, alongside the urban concentration of clinical trial sites and the presence of ESTERN Medical's regional and local workforce in each office.

- **Services** are more cost-effective, including professional fees for pharmaceutical and medical device sponsors.

- **Regulatory** processes are less expensive in Latin America compared to the US and Europe, with lower costs and fees associated with regulatory agencies such as EC/IRBs or MoHs.



☑ ESTERN Medical capitalizes on the higher recruitment rates expected in LATAM and gains an advantage by combining US or EU trials targeting US/FDA or EU/EMA approvals.

☑ This approach compensates for sponsors' delayed start-up due to the regulatory process and allows for efficiency gains by concentrating a higher number of patients in a reduced number of countries and clinical trial sites.

☑ Overall, our sponsors benefit from lower study costs, and patient recruitment may be completed ahead of schedule for their clinical trial IND & NDA project phase finalization.

Our Company Organizational Structure & Senior Executive Management Team

Dr. Jorge L. Estrella, M.D.

President & Chief Medical Officer

Dr. Estrella is the esteemed Founding President and Chief Medical Officer at ESTERN Medical CRO Life Sciences International Group, a distinguished Clinical Contract Research Organization (CRO) specializing in the life sciences and clinical trials development for pharmaceutical and medical device R&D, serving both the US North America and Latin American regions.

Dr. Estrella assumes a pivotal role in the evaluation of Biotech's, Pharmaceutical, Medical Device / MedTech's, and CRO Companies, focusing on innovative R&D technologies, potential business partnerships, and strategic alliances. His responsibilities extend to scrutinizing company pipelines and clinical development operational priorities and influencing R&D organizational strategy for senior management across all business units.

With over 25 years of comprehensive experience in clinical research and development (R&D) across various international corporate pharmaceutical and medical device enterprises, Dr. Estrella possesses extensive expertise in all clinical trial phases, particularly in Cardiovascular, Central Nervous System (CNS), Infectious Diseases, and Diagnostic Radiological Imaging. His distinctive combination of entrepreneurial and scientific business acumen positions him as a key driver for ushering novel R&D products into global & international markets and securing approvals for clinical indications.

Throughout his illustrious career, Dr. Estrella has held distinguished senior executive positions in renowned Medical Research and Clinical Development International Companies, including EPIX Pharmaceuticals, Inc., located in Cambridge, Massachusetts, where he served as the Head Director of Clinical Development. Notably, during his tenure at EPIX, he spearheaded the development of groundbreaking clinical compounds, INDs, and NDAs, most notably Vasovist® (gadofosveset Trisodium), also recognized as ABLAVAR®. Vasovist® was the first Imaging Agent to receive approval for Magnetic Resonance Angiography (MRA/MRI) in the U.S., offering superior intravascular contrast imaging for the cardiovascular and peripheral artery system through magnetic resonance angiography imaging (MRA/MRI). This achievement was marked by global marketing approval in the United States, Europe, and 40 other countries. Additionally, Dr. Estrella oversaw the development of EP-2104R, a cutting-edge diagnostic radiological imaging pharmaceutical agent designed for the detection of blood clots using Magnetic Resonance Imaging.

Before his tenure at EPIX Pharmaceuticals, Dr. Estrella made significant contributions to the Cardiovascular Medical Device industry as the Senior Physician Director and Clinical Trials Coordinator at the Guidant Corporation Inc., now part of Boston Scientific Inc. & Abbott Vascular, focusing on the Advanced Cardiovascular Systems (ACS), Peripheral & Stent Division in Santa Clara, California. His journey culminated with Guidant's HERCULINK® Stent platforms.

Dr. Estrella further enriched his expertise and knowledge within the medical clinical research arena during his tenure at Janssen Pharmaceuticals, Inc., where he collaborated on the global clinical development of RISPERDAL® (Risperidone) and Antipsychotic drugs. These drugs were instrumental in treating symptoms associated with psychiatric disorders such as schizophrenia and bipolar disorder.

Internationally renowned for his profound expertise in global clinical research development within the biotech, pharmaceutical, and medical device sectors, Dr. Estrella is highly regarded by the medical and academic community.

Dr. Estrella earned his medical degree from the Autonomous University of Guadalajara in Mexico (UAG) and completed his residency training at the National Institute of Nutrition in Mexico City in the Department of Internal Medicine, where he honed his clinical and research medical skills.

Robert Morgan, J.D., M.S. & B.S.

Head of Scientific Regulatory Legal Affairs & Quality

Mr. Robert Morgan serves as the Head of Scientific Regulatory Legal Affairs and Quality at ESTERN Medical CRO Life Sciences Group. A pivotal member of ESTERN Corporate Scientific Advisory Board since April 2009, Mr. Morgan boasts a multifaceted, hands-on, senior-level career in Clinical and Regulatory affairs spanning over 30 years. His expertise encompasses all facets of drug and device development across the United States, Canada, Europe, Latin America, India, and the Pacific Rim.

Possessing an MS in Biophysics with practical clinical and research experience, coupled with a JD specializing in contract analysis and negotiation, Mr. Morgan has authored numerous successful INDs, CTAs, 510(k)s, NDAs, MAAs, SPAs, Orphan Drug, and Pediatric submissions. His focus on innovative treatments, particularly in Oncology, has solidified his reputation as a distinguished professional in the field.

Mr. Morgan achieved a significant milestone by filing the first electronic IND application accepted by the FDA in the new international standard Common Tech.nical Document format. His proactive approach and hands-on direction extend to designing early-phase clinical studies, drafting regulatory submissions, including US and European Orphan Drug applications, and composing abstracts and manuscripts for publication in professional journals. Additionally, he played a pivotal role in drafting proposed legislation on FDA Reform, providing background information to members of the US Congress.

Throughout his career, Mr. Morgan has held diverse senior executive positions with esteemed companies, including Samus Therapeutics, Medivector, ZIOPHARM Oncology, EPIX Pharmaceuticals, Inc., DuPont Pharmaceuticals Company, Genzyme Corp., Serono, PAREXEL International Corp., and Theseus Imaging Corp. Notably, he served as the Senior Vice President of Development Operations at Verastem Oncology and as the Head of Regulatory Affairs/Program Management for COVID-19 at Immunome, Inc.

In addition to his executive roles, Mr. Morgan contributes to academia as a professor in Regulatory, Quality, and Drug Development at Northeastern University in Boston, Massachusetts, and as a Faculty Member of the European Regulatory Professional Society, TOPRA. His educational background includes BS and MS Science degrees, complemented by a Law Degree, harmonizing his extensive expertise in legal contract analysis and negotiations.

A prolific author, Mr. Robert Morgan has an extensive publication track record and is an active member of various scientific organizations in the pharmaceutical industry. He is a distinguished member of the Massachusetts Bar Association, Food & Drug Law Institute, and DIA & Regulatory Affairs Professional Society

Claudia Hernandez-E., B.S., RPT., & MRI-Tech.

Director Clinical Operations U.S. North America & Latin America

Mrs. Hernandez became an integral part of the esteemed ESTERN Medical CRO Life Sciences Group in 2008, bringing with her an extensive background in clinical trials research and technical clinical & regulatory support, with a focus on the cardiology, pulmonary, and CNS fields. She boasts a diverse blend of R&D and scientific business expertise, drawing from over 25 years of comprehensive experience.

Before her tenure at ESTERN Medical CRO Life Sciences, Mrs. Hernandez held notable senior positions within some of the world's most prestigious International Pharmaceutical and Medical Device Companies, including Siemens AG, Schering AG Pharma, and Medrad, Inc.

At Schering Pharma AG and Medrad, Inc. (now part of Bayer Pharmaceuticals), she served as the Senior Executive Manager for Clinical R&D Education and Clinician Training Support. During her tenure, she spearheaded a transformative strategy that shifted US & Latin America from a sales and distribution model to a fully independent clinical development and training network. Her significant contributions spanned over a decade with Schering AG Pharma & Medrad Inc., during which she played pivotal roles in two vital company platforms: the Avanta MRI cardiovascular interventional injector and the groundbreaking Stellant Dual Injector System for Multi-slice CT clinical support training in the Latin American & US region.

Before her time at Schering Pharma AG and Medrad, Inc., Mrs. Hernandez held the role of Senior Manager of Clinician MRI Specialist at Siemens Medical AG & Latin America. Her responsibilities encompassed clinical R&D training through to commercialization. Preceding her involvement in the pharmaceutical and medical device industry, she accrued clinical experience as a Chief MRI Technologist in Bogotá, Colombia, and as a clinical physical therapist, where she dedicated over a decade to clinical practice.

Mrs. Hernandez enjoys international recognition for her extensive expertise in the field of clinical trials. She has made significant contributions to some of the most prestigious pharmaceutical and medical device companies, and medical institutions, particularly in the realms of cardiovascular health, peripheral vascular diseases, interventional cardiology, and diagnostic CT and MRI imaging clinical research development.

Mrs. Hernandez holds a Bachelor of Science degree in Clinical and Physical Therapy from the University of the Rosario in Bogotá, Colombia. She also holds a Master's degree in Technical Diagnostic Imaging from the University of Santander in Bogotá, Colombia.

Dr. Fabricio Tello, M.D.

Director of Medical Affairs and Pharmacovigilance

Dr. Fabricio Tello is a preeminent authority in pharmaceutical life sciences R&D and clinical development, contributing over three decades of invaluable experience and expertise to ESTERN Medical CRO Life Sciences.

As a highly accomplished and dynamic physician, Dr. Tello boasts an impressive track record of success within the life sciences and clinical trials pharmaceutical industry. His seasoned professionalism is evident in his extensive history of spearheading the implementation and advancement of pharmacovigilance, techno-surveillance, and life science training programs for globally recognized pharmaceutical companies.

In his previous diverse roles as Medical Director, Dr. Tello played a pivotal role in directing the implementation and development of pharmacovigilance, techno-surveillance, and life science training initiatives within the pharmaceutical industry. Serving as a medical scientific liaison and regional medical advisor, he demonstrated proficiency in guiding health professionals through clinical studies and adeptly managing security health crises arising from the use of pharmaceutical products.

Dr. Tello is distinguished by his ability to influence and persuade, coupled with meticulous attention to detail that ensures results meet the highest standards of quality and excellence. His strategic insight positions him as a key asset in driving success and innovation in the pharmaceutical life sciences sector.

His extensive professional journey includes serving as a medical scientific liaison for Novo Nordisk in Latin America, specializing in diabetes and obesity arena with key vanguard molecules such as insulin Degludec, and the incretins Liraglutide and Semaglutide. Dr. Tello also held the position of Head of Pharmacovigilance in Latin America for Bayer Pharmaceuticals, providing pharmaceutical pharmacovigilance drug safety for major R&D pipeline products. Furthermore, he served as the Medical Director for Radio Pharmaceutical Management in molecular imaging within the MRI and CT department for Bayer Pharmaceuticals, working with novel molecules for diverse clinical indications such as rivaroxaban, Eylia, Betaferon, Gadovist, Ultravist, Riociguat, Regorafenib, Kogenate, and Sorafenib.

Dr. Tello earned his Medical Doctor degree from Antioquia University in Medellín, Colombia, and pursued further specialization in Health Administration at Pontificia Universidad Javeriana – Bogotá, Colombia.

Additionally, Dr. Tello holds a degree in Molecular Biology, Physiology, and Biochemistry of Microorganisms, and Bacterial Molecular Genetics from the National University. His robust educational background, coupled with his wealth of practical experience, establishes Dr. Tello as a distinguished professional in the field of pharmaceutical life sciences and clinical development.

Dr. Hernan Dario Hernandez C., D.D.S

Director Operations South America

Dr. Hernandez, a seasoned professional with extensive experience in clinical operations and a robust background in the pharmaceutical healthcare industry across Latin America, became an integral part of ESTERN Medical's CRO Life Sciences in June 2006. He assumed the pivotal role of Director of South America Operations.

Boasting a diverse career that spans both governmental and pharmaceutical sectors, Dr. Hernandez excels in strategic operations planning and possesses a profound understanding of clinical trials within the Pharmaceutical and Medical Device CRO industry. His illustrious career path includes prestigious positions within government agencies in Colombia and Spain, where he contributed as a clinician. Moreover, his international exposure in Europe further honed his clinical and operational proficiency on a global scale. These experiences uniquely position him to meet the demands of major pharmaceutical sponsors and government health agencies internationally.

Dr. Hernandez's academic journey culminated in the attainment of a Dentistry Degree from the esteemed Colegio Odontológico Colombiano de Bogotá, underscoring his unwavering commitment to excellence in the healthcare field.

His extensive knowledge of life sciences and clinical trial operations, combined with his strategic acumen, renders him an invaluable asset to the ESTERN Medical team, driving success in the ever-evolving and dynamic CRO industry.

Rodolfo Diaz, B.S.

Director of Healthcare Life Sciences Business Development & Commercialization Strategy

Rodolfo Diaz has joined ESTERN Medical CRO Life Sciences as our Director of Healthcare Life Sciences Business Development & Commercialization Strategy. In his role, Mr. Diaz will be based across the US North America, and Latin America, leading and executing healthcare growth strategies, partnerships, and commercialization for Pharmaceutical, Biotechs, Medical Device / MedTech, and CRO initiatives within the clinical R&D corporate pipeline.

Mr. Diaz is a Biomedical Engineer with a Pre-Med degree from the Ibero-American University (UIA). With over 25 years of experience in life science healthcare, he has worked for global companies such as Siemens Healthineers, Bayer Pharmaceuticals, Schering Ag Pharma, and Medrad Inc. as a senior executive in the US and LATAM regions. Mr. Diaz has played a pivotal role in structuring the first Latin American Medrad, Inc. subsidiary, now known as Bayer Radiology Pharma Solutions, from proof of concept to product launches, and the strategic consolidation of business development and marketing teams in LATAM and the US.

Throughout his career, Mr. Diaz has developed strong business acumen and experience in clinical management, enabling him to establish effective work management for international teams focused on corporate profitability, product lifecycle management, and building strong relationships with business partners, clients, sponsors, and end-users for commercialization.

In his past and present professional responsibilities, Mr. Diaz has been involved in various medical modalities such as Cardiac Disease, Central Nervous System, Ophthalmology, Oncology, Liver and Kidney Disease, as well as Magnetic Resonance Imaging (MRI), Computed Tomography Imaging (CT), Cardiac and Peripheral Interventional Diagnostic and Therapeutic, Nuclear Medicine Imaging, and imaging management PACS (Picture Archiving & Communication Systems), and RIS Radiology information systems. He brings this broad international expertise and knowledge to ESTERN Medical CRO Life Sciences.

Mr. Diaz offers a balanced perspective from Pharmaceutical, Medical Device, CRO, Life Sciences, and Sponsor viewpoints, across the R&D clinical drug development spectrum, from early-phase to late-phase clinical trials.

Antonio Ley Estrella, J.D.

Director Legal & Finance

Mr. Antonio Ley-Estrella, a distinguished professional, became an integral part of ESTERN Medical in 2002, bringing with him a wealth of experience amassed over more than four decades as an attorney specializing in legal and financial business development. His extensive expertise has been instrumental in providing invaluable guidance to major international pharmaceutical companies in Latin America, including renowned names such as Upjohn & Pfizer Pharmaceuticals, Coca-Cola Corporation, and Aero-México Airlines.

At ESTERN Medical, Mr. Ley-Estrella assumes a leadership role in the company's legal and financial business development in Latin America, overseeing the establishment of strategic collaborations for ESTERN Medical CRO Medical Life Sciences programs and assets, while actively contributing to strategic planning activities. Under his stewardship, the company has successfully initiated and negotiated collaborations in the United States, the European Union, and various Latin American countries.

In addition to his role at ESTERN Medical, Mr. Ley-Estrella concurrently serves as the President of the esteemed legal firm of L.E. and Associates in Mexico. His academic journey includes graduating from the Universidad Autónoma de México (UNAM) School of Law, further bolstered by a master's degree in legal finance and law. His extensive legal acumen and financial prowess make him a key figure in driving the success and growth of ESTERN Medical.

Our Corporate & Scientific Advisory Board

Michael Webb, M.B.A.

Head Of Corporate Advisory Board

With over 30 years of distinguished experience in healthcare and life sciences, Mike Webb is a seasoned professional whose leadership has made a lasting impact on the industry. Recently, he held the positions of CEO and Board Member at Enveric Biosciences Inc., iQure Pharma Inc., GMDx, and CXL Ophthalmic, demonstrating his versatile expertise across diverse companies. Additionally, he served as a Board Member at DeuteRx.

Prior to joining the ESTERN Medical CRO Life Sciences Corporate & Scientific Advisory Board, Mike Webb made notable contributions to Ascent Therapeutics, a venture-backed company dedicated to developing pepducins, a groundbreaking platform for drug discovery. As the founder of Ascent, he played a pivotal role in shaping its trajectory. Before this venture, Mr. Webb served as the CEO of EPIX Pharmaceuticals, Inc. Under his leadership, EPIX evolved from a venture-backed startup to the global leader in pharmaceuticals for imaging with MRI & MRA. The company achieved worldwide approval for its lead product and successfully executed numerous public financings and corporate partnerships, including an IPO.

Before his tenure at EPIX, Mr. Webb held a senior position at CIBA, where he served as Senior Vice President, Worldwide Marketing and Strategic Planning of CIBA Diagnostics. In this role, he oversaw global marketing, program management, corporate planning, business development, and licensing. Prior to CIBA, he was a senior consultant at Booz, Allen & Hamilton, specializing in healthcare and life sciences.

Mike Webb's educational background is impressive, with Bachelors degrees in Biochemistry and Economics from the University of Kansas, Summa Cum Laude. He continued his academic pursuits with an MA in International Relations from Sussex University in the UK, completing his thesis on "Pharmaceuticals Policy and the World Health Organization." Additionally, he holds an MBA degree with honors from the Kellogg Graduate School of Management at Northwestern University.

Beyond his executive roles, Mr. Webb actively contributes to the industry as a board member of the Massachusetts Biotechnology Council, where he served as the past Chairman and the Kellogg Center for Biotechnology at Northwestern. He also serves as a Senior Advisor to Johnston and Blakely, a prominent life sciences investment banking firm. With a wealth of experience and a commitment to advancing the field, Mike Webb continues to be a respected figure in the healthcare and life sciences sector.

Daniel Vasquez

Head of Clinical Trials Regulatory Advisory Board

Daniel Vazquez is a highly accomplished professional with a wealth of experience spanning over 30 years. Prior to joining the ESTERN Medical CRO Life Sciences Corporate & Scientific Advisory Board, Mr. Vazquez held the esteemed position of Senior Head Director and Global Regulatory Affairs Executive at IQVIA (formerly Quintiles).

During his tenure at Quintiles/IQVIA, Daniel played a pivotal role in transforming the organization into a leading Clinical Research Organization (CRO) in the industry. His strategic vision focused on establishing a robust leadership team dedicated to specializing in Life Sciences and clinical trials for biotech, pharmaceutical, and medical device companies. This involved navigating the complexities of Investigational New Drugs (INDs), New Drug Applications (NDAs), and executing clinical trials across all phases.

Presently, Mr. Vazquez serves as the Head Manager of Regulatory Affairs for Latin America and Canada at Philip Morris International. Simultaneously, he holds the position of President at eHealth Solutions, a consortium dedicated to advancing clinical trials in Life Sciences development.

As a member of the advisory board, Mr. Vazquez significantly enhances the strength of ESTERN Medical's leadership team and regulatory and scientific advisory board. This aligns seamlessly with the company's strategic focus on global growth and international expansion.

With his extensive experience, Mr. Vazquez is poised to provide invaluable guidance for ESTERN's strategic clinical trial research and development initiatives. His expertise will be instrumental in supporting sponsors, including Biotech, Pharma, and Medical Device Life Sciences industry companies.

Mr. Vazquez earned his Pharmacist degree from the University of Buenos Aires in Argentina and is internationally acclaimed for his expertise and numerous scientific publications in global strategic regulatory clinical research development. He has made significant contributions to prestigious life sciences academic institutions and holds key memberships in various scientific organizations within the pharmaceutical and medical device industry. Notably, he is a member, honorary founder, and former president of the Association of CROs (CAOIC) and serves on the Clinical Trials Board of CAEME in Latin America.

Carmen Serfezi

Executive Advisory Board for Healthcare International Life Science Expansion

Carmen Serfezi, is a seasoned senior management executive with an entrepreneurial mindset, boasting over 35 years of expertise in steering healthcare sales, marketing, and operations across multiple EU nations and China. With an MBA Master's degree, she is recognized as an international visionary, strategist, and tactician, with a proven track record of spearheading pivotal corporate entrepreneurial initiatives to surmount intricate global business obstacles.

With extensive international leadership experience, Carmen has successfully recruited, guided, and nurtured senior executive business management and functional executive teams in The Netherlands, Germany, Italy, France, the United Kingdom, Scandinavia, China, the Russian Federation, Middle East, Southeast Asia, and Latin America. A proficient intercultural communicator, she excels in managing business relationships and fostering partnerships in key European and Middle Eastern countries, China, Japan, and the Russian Federation. Fluent in English, German, and Romanian.

Her core competencies as an executive include Visionary Leadership with Strategic & Tactical Planning, Business Entrepreneurship with Leadership & Mentorship, Business Development, Mergers & Acquisitions expertise, along with cultivating international business partnerships and healthcare global Distribution Network Development.

Some of her top professional highlights include:

- Membership in the Senior Executive Management Team at Medrad Inc., Pittsburgh, USA, for 25 years. Medrad was a global leader in designing, manufacturing, and commercializing radiology MRI/MRA, CT, and Angio medical devices and healthcare products. Medrad's business merged with Bayer Radiology & Interventional – Medical Care Division of Bayer AG.
- Founder and General Manager of S&C Enterprises Ltd., Cyprus. S&C Enterprises delivers healthcare product solutions to the economy and quality-minded healthcare service providers, aiming to consistently deliver superior value at moderate costs.
- Co-founder and Senior Partner of The Mikan Group LLC, Pittsburgh, U.S.A. The Mikan Group focuses on supporting emerging medical device companies and helping them bring novel technologies and solutions to the global market.

Dr. Charles Schmidt, M.D.

Head of Scientific Clinical Medical Advisory Board

Dr. Schmidt brings to the table over 30 years of extensive experience in the clinical, clinical trials, central lab, pharmaceutical, CRO, and medical device industry. Currently serving as the Latin America Regional Head and holding the position of Tigermed CRO, Dr. Schmidt also serves as the Coordinator and Professor of the post-graduation program in clinical research at the Faculdade de Ciencias Medicas da Santa Casa de SP in Brazil.

Prior to joining the ESTERN Medical CRO Life Sciences Corporate & Scientific Advisory Board, Dr. Schmidt held significant roles, including Head of Operations Latin America ACMA and Head of Outsourcing, at major US and European biopharmaceutical companies such as Abbott Labs, Quintiles, PRA International, Medpace, and Eurotrials. His experience spans both the pharma and medical device sectors, as well as international CROs. Dr. Schmidt has showcased his industry expertise in various senior management positions, covering clinical strategic project and operations management, clinical development, strategic business planning, and international clinical affairs.

As the distinguished founder and former president of the Brazilian Association of CROs (ABRACRO), Dr. Schmidt plays a pivotal role in shaping the industry. He also serves as a board member and Director of the Brazilian Association of Pharmaceutical Physicians (SBMF) and as a member of the steering committee of DIA Latin America, focusing on the discovery, development, evaluation, and utilization of medicines and related healthcare technologies.

His academic background is equally impressive. Dr. Schmidt obtained his Medical degree from the University Faculdade de Ciências Médicas da Santa Casa School of Medicine in Sao Paulo, Brazil. He pursued further medical and research training, earning Master's and Doctorate degrees in Pediatrics and Infectious Diseases at the Universidad Federal de Sao Paulo (UNIFESP). In addition to his clinical expertise, he holds a degree in Post-graduate Management from the Faculdade de Saúde Pública da USP Brazil.

Currently serving as a professor and coordinator of the post-graduate program in clinical research at the University – Faculdade de Ciencias Medicas da Santa Casa in Sao Paulo, Brazil, Dr. Schmidt's rich background, encompassing clinical practice, research, and leadership roles, positions him as a highly respected and accomplished professional in the healthcare and clinical research arena.

Dr. Juan E. Gutiérrez, M.D.

Senior Corp. Diagnostic Radiological Imaging Scientific Advisory Board

Dr. Juan E. Gutierrez brings over 30 years of extensive experience in clinical drug development, specializing in the fields of radiology, CNS, cardiology, and oncology, to significantly strengthen our company's scientific board.

Currently, Dr. Gutierrez serves as the Director of Medical and Scientific Affairs at RADMD. Prior to joining the ESTERN Medical CRO Life Sciences Corporate & Scientific Advisory Board, he held the position of Medical Director for Neurelis, Inc., a CNS pharmaceutical company.

Before Neurelis, Dr. Gutierrez served as the Vice-Chair of Clinical Operations and Associate Professor of Neuroradiology at The University of Texas Health Sciences in San Antonio, Texas. In a previous position, he was the Director of Medical Development Diagnostic Imaging at Bayer HealthCare. In this role, he held increasing responsibilities for the operations, strategic planning, and corporate development of a growing portfolio of radiopharmaceutical clinical R&D businesses. His key early-phase experience included serving as the Associate Director of Clinical Development Diagnostic Imaging for Schering AG (now known as Bayer Pharmaceutical). His broad experience covered multiple variations of early-phase cardiology, CNS, and oncology trial designs, including traditional dose-escalating maximum tolerated dose designs, as well as various optimal dose designs for targeted agents.

In later-phase oncology, cardiology, and CNS, Dr. Gutierrez has extensive pivotal trial experience in the United States, Western and Eastern Europe, Latin America, and Asia-Pacific. He successfully managed clinical trial projects with Bayer Health Care, involving Vasovist, Magnevist, Gadovist, Ultravist, and Iopamiron. Additionally, he collaborated with Guerbet Pharma Group on Dotarem.

As a clinician, scientist, and investigator, Dr. Gutierrez has focused his knowledge on the clinical community, showcasing a vast track record of scientific clinical journals and book publications.

Dr. Gutierrez holds a fellowship in Interventional Radiology from the Jacksonville Memorial Hospital in Miami, Florida, and a Neuroradiology Research Fellowship from Thomas Jefferson University in Philadelphia. He received his medical degree from CES University in Medellin, Colombia, and completed residency training in Clinical Radiology at Javeriana Pontificial University in Bogota, Colombia.

Dr. Gutierrez's multifaceted clinical and research background and expertise make him a valuable asset to the ESTERN Medical CRO Life Sciences advisory board.

Dr. John Amedio, PhD.

Senior Corp. R&D Scientific Advisory Board

Dr. John Amedio is a highly accomplished professional with an impressive 32-year track record in major and start-up pharmaceutical companies. Currently serving as the Principal Consultant at Amedio CMC Consulting, he plays a pivotal role in guiding emerging and established pharmaceutical and life science companies through the intricacies of technical and regulatory Chemistry, Manufacturing, and Controls (CMC) development for small molecules and peptides, ultimately steering them toward market success.

Prior to joining the ESTERN Medical CRO Life Sciences Corporate & Scientific Advisory Board, Dr. Amedio held various significant leadership positions, including Acting Chief Manufacturing Officer at Samus Therapeutics, Inc., Vice President of CMC & Commercial Manufacturing at Corbus Pharmaceuticals, Senior Vice President of Technical Operations at ArQule, and Vice President of Manufacturing & Process Development at ZIOPHARM Oncology, Inc. His earlier roles encompassed serving as the Executive Director of Analytical and Chemical R&D at EPIX Pharmaceuticals Inc. and as the Unit Leader in the Chemical Research and Development Department at Sandoz Research Institute (currently Novartis Pharmaceuticals).

Demonstrating a proven track record of delivering results on time, Dr. Amedio provides invaluable leadership and guidance in drug development, regulatory affairs, and quality programs. His expertise spans organic chemistry, process research and development, analytical method development, formulation development, and cGMP manufacturing for drug substances and drug products, including parenteral, lyophilized, and solid dosage forms. Dr. Amedio possesses extensive knowledge in primary/packaging, labeling, and supply chain/distribution activities, having successfully executed several technology transfers to and from Contract Manufacturing Organizations (CMOs).

Dr. Amedio's contributions extend to delivering numerous profitable and patented manufacturing processes for both drug substances and drug products. He actively participates in face-to-face FDA meetings, including pre-IND, end-of-phase 1, end-of-phase 2, and pre-NDA discussions. Additionally, he plays a key role in budget planning and forecasts, establishes hiring plans, and contributes to overall strategic planning. Dr. Amedio is a lead author or co-author of several peer-reviewed articles, publications, and patents and has been a featured speaker at numerous invited presentations.

On the academic front, Dr. Amedio holds a Post-Doctoral degree in Natural Product Synthesis/Organic Chemistry from the State University of Oregon. He completed his Ph.D. in Organic Chemistry, specializing in the synthesis and isolation of natural products and transition metals, at the University of Delaware. Dr. Amedio earned his B.S. in Chemistry from Manhattan College in New York.

Dr. John Amedio's comprehensive experience, strategic leadership, and commitment to advancing pharmaceutical manufacturing solidify his standing as a respected and influential figure in the field, making substantial contributions to the success and innovation of the companies he has served.

Global Alliances & Partnerships

Our Global Life Sciences Partners, Alliances & Sponsors

Our sponsors include Biotechs, Pharmaceutical, Medical Device, and Clinical Research Organization (CRO) Companies

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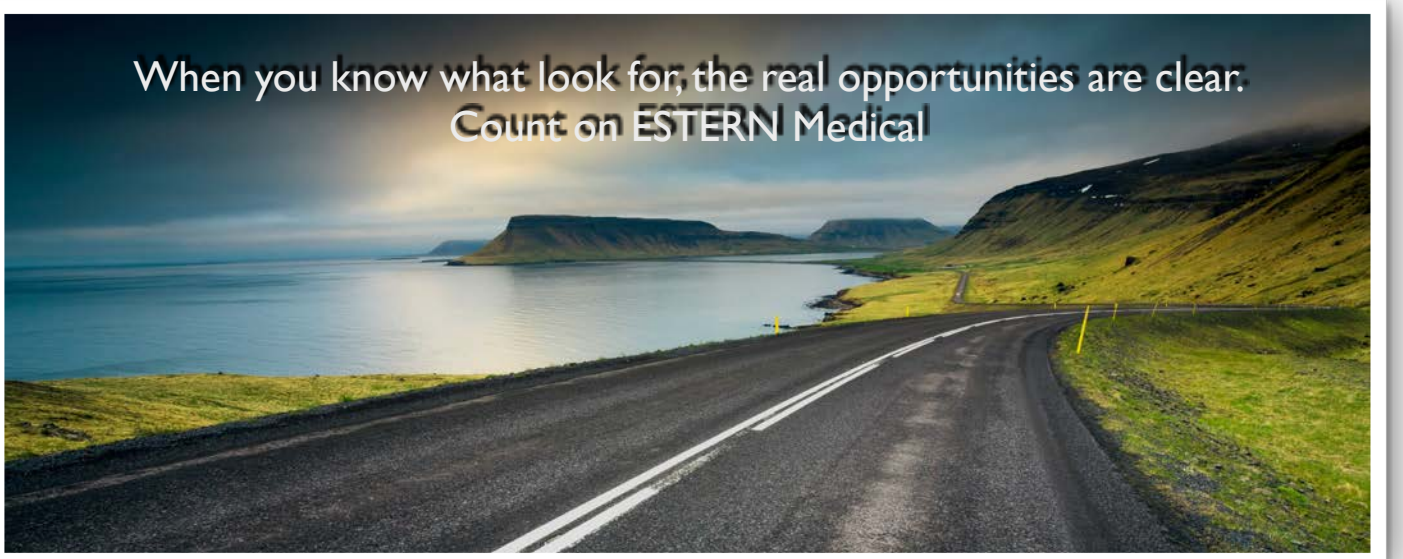

Our International Presence

Boston & Cambridge (USA)
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Buenos Aires (Argentina) | Sao Paulo (Brazil)

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To inquire about our CRO Services, please reach out via our company website: www.esternmedical.com or fill out our company's web "Contact Us Form", and a member or our management team will respond to you.

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