Contract Research Organization (CRO) & Consulting Company for Global Biotech's, Pharmaceutical & Medical Device Companies Covering U.S. North America & Latin America

EM-No. V. 01 / 2014

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About the ESTERN Medical CRO Group

Who we are?

The ESTERN Medical CRO Corporation is one of the world's leading global full Contract Research Organizations (CRO), conducting clinical trials in the U.S. North America & the Emerging Latin American Geographic Markets.

We operate in two continents, in U.S. North America and Latin America. Our corporate office is located in Boston/Cambridge, USA and our own international subsidiary regional offices are spread across the following countries "Mexico, Colombia, Chile, Argentina & Brazil".

As an independent, privately owned corporation, since its foundation in 2002 we are passionate about being the preferred full service Contract Research Organization (CRO) partner worldwide, thus contributing to people's health and quality of life.

This leadership is built on our internal skills and competencies, and is complemented by collaboration with external partners and clients that include Global Pharmaceutical, Biotechnology, Medical Device, CROs & Academic – Government & Private Institutions.

ESTERN Medical CRO applies innovative dynamic Clinical Trial, Operational & Regulatory Development and a broad track record of diverse therapeutic expertise to our clients. We emphasize our commitment to quality to help our sponsors and partners maximize returns on their R&D investments by accelerating the delivery of safe and effective novel trial therapeutics to patients globally.

ESTERN Medical provides outsourced clinical trial services across all trial phases I, II, III & IV, through its years of experience, ESTERN Medical has developed the operational and therapeutic expertise to provide high quality, global service while maintaining our differentiating personal interaction element of commitment to excellence to our sponsor.

Our Full Range of Clinical Trials Development Services

Clinical Research

- Phase I, II, III & IV
- Biotech, Pharma & Medical Devices Trial Execution U.S. & Latin America
- Project Management Site Management, Regulatory EC/IRB & MoH Submissions, Monitoring
- Patient & Investigator Recruitment
- EDC-Data Management

Biostatistics

- Bioanalysis
- Medical Services

Process Expertise

Perceptive Informatics

- Medical Imaging (MRI, CT, Angio & Nuclear Medicine)
- IWRS (Interactive Web Response)
- EDC (Electronic Data Capture)
- Integration Services
- CTMS
- ePro (Electronic Patient Diaries)

Technology Expertise

Consulting

- Clinical Product/ Research Development & Regulatory Affairs
- Strategic Compliance & Risk Management
- Clinical & Manufacturing
- Quality Process
- Clinical Trials Development Consulting
- Pharma & Medical Device Country Registration & Market Positioning Services in the U.S. & LATAM.

Product Development Expertise

Why Go to U.S. North America & Latin America

Why U.S. or Latin America?
Our CRO Business Model Presence

- Strong government, academic & private clinical trials capabilities that generate strong enrollment rates, with superb patient compliance and retention to availability of treatment-naive patients.
- Top rated clinical research medical Governmental & Private Institutions.
- Physicians, Scientists and Key opinion leaders (Kols) with a broad range of expertise in clinical research trials with a track record in the field Biotech, Pharmaceutical and Medical Devices research.
- Broad geographic patient population across 21 countries with access to 597.5 million population in Latin America and in the U.S. 317 million.
- The top 20th Worlds largest and most populated metropolitan areas, provide us a broad patient concentrations in large public hospitals across the U.S. (New York, Los Angeles, Chicago, Houston etc.), Mexico City – Mexico; Buenos Aires – Argentina; Sao Paulo – Brazil; Bogota – Colombia; Lima – Peru; Rio de Janeiro – Brazil; Santiago – Chile, as some of the most populated cities in the World yielding enrollment efficiencies
- Limited cultural & language barrier differences compared to other countries as well as ethnic diversity covering most of the World's population, Large U.S. Hispanic populations as well as other European, Asian, and African populations
- Some Latin American countries provide a Fast Track regulatory form: Ministers of Health (MOH), IRB (Institutional Review Board) & Ethical Comities, FDA & EMEA quality assurance through strong adherence to GCP – ICH norms
- Competitive economic cost in clinical trials execution compared to US & Western Europe & other emerging countries

Our Global Presence & Partnership Alliances

Latin America Overview
Demographic & Economic trends support continued growth & new key opportunities in the Biopharma & Medical Device Market

DEMOGRAPHIC TRENDS

- ✔ **661 Millions** People in Latin America by 2025. Increase **14%** from **597** Millions currently
- ✔ **69%** of the region will be **MIDDLE CLASS** in 2025. Currently makes up 30%
- ✔ **71 Millions** in the over 60 segment in 2020. **Purchasing Power** expected to **increase 55%** in 2020
- ✔ **47%** of the Latin American Working Population will be **WOMEN** by 2025

ECONOMIC TRENDS

- ✔ **$15 T** Latin America's GDP in 2025; 3 Times 2012 GDP
- ✔ **7%** Healthcare spending expected annual growth through 2017
- ✔ **3.5%** regional **Economic Growth** rates into 2014.
- ✔ ↑ Focus on Domestic R&D/Production in pharmaceutical and biotechnology sector in LATAM

*Source: World Bank July 2013, Frost & Sullivan

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

	USA	Latin America	China	India	Eastern Europe
Population	317 Million	597.5 Million	1.353 Million	1.210 Million	190.2 Million
GDP (Nominal)	USD 16.724 Trillion	USD 5.16 Trillion	USD 8.939 Trillion	USD 1.758 Trillion	USD 2.385 Trillion
Language	• English	• Spanish (88%) • Portuguese (12%)	Mandarin and 10 other languages	Hindi, English and 8 other languages	14 languages

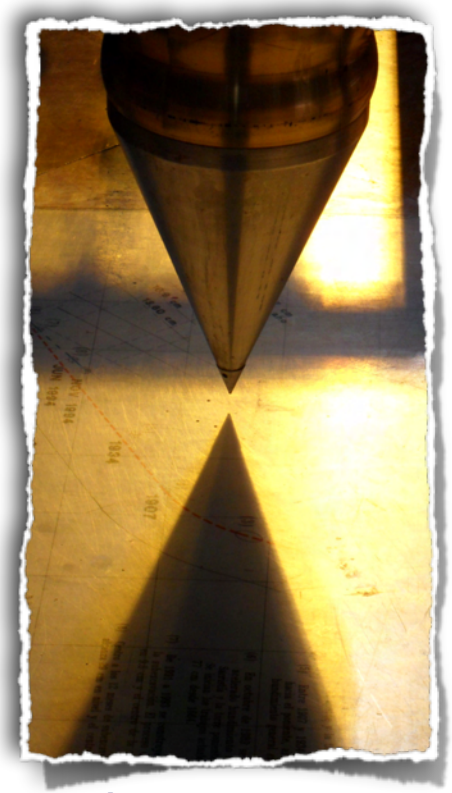
Source: Wikipedia Organization

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

	USA	Latin America	China	India	Eastern Europe
Education Standards of Physicians	Higher Educational Standards. On the vanguard clinical, scientific, ethical practices regulated by the AMA	Equals West European and North American educational standards	Educational standards do not correspond to West European and North American standards	Equals West European and North American educational standards	Educational standards do not correspond to West European and North American standards
FDA Compliance	• FDA full compliance • Adherence to the principles of good clinical practices (GCPs), including adequate human subject protection (HSP) is universally recognized as a critical requirement to the conduct of research involving human subjects.	• FDA has independent & regional based people • **FDA Regional Local Offices across Latin America** • 63% FDA GCP/GMP inspections passed with no actions required • Complies with GCPS, ICH Guidelines	• China does not comply with the FDA inspections • 29% failure to report adverse events • 21% inadequate clinical trial records	• India is FDA "approved" • No acquired comparable data	• 47% to adhere to clinical protocol • standards.

*Source: FDA. GOV & Wikipedia Org.

Fast & Efficient Execution of Clinical Trials in the U.S. & Latin America



Patient Recruitment for all Diseases in Latin America	
Effectiveness (patients / sites)	ESTERN experience: 6-25 patients per site
Regulatory Approval Times	Some Latin America countries have fast track regulatory regime

*Source: ESTERN Medical CRO Group Latin American Operations, 2014

Current Listed Clinical Trial Across USA & Latin America	
USA	73.693
Brazil	3.652
Mexico	2.005
Argentina	1.662
Chile	893
Colombia	715
Peru	687
Grand Total in US & Latin America	83.307

*Source: Clinicaltrials.gov, January / 2014

Capacity
Operating in Emerging Markets across Latin America can substantially increase your capacity re-balancing with U.S. & EU sites.

Productivity
Number of patients per site is usually higher than in USA and Western Europe, and LATAM leverages the overall trial performance

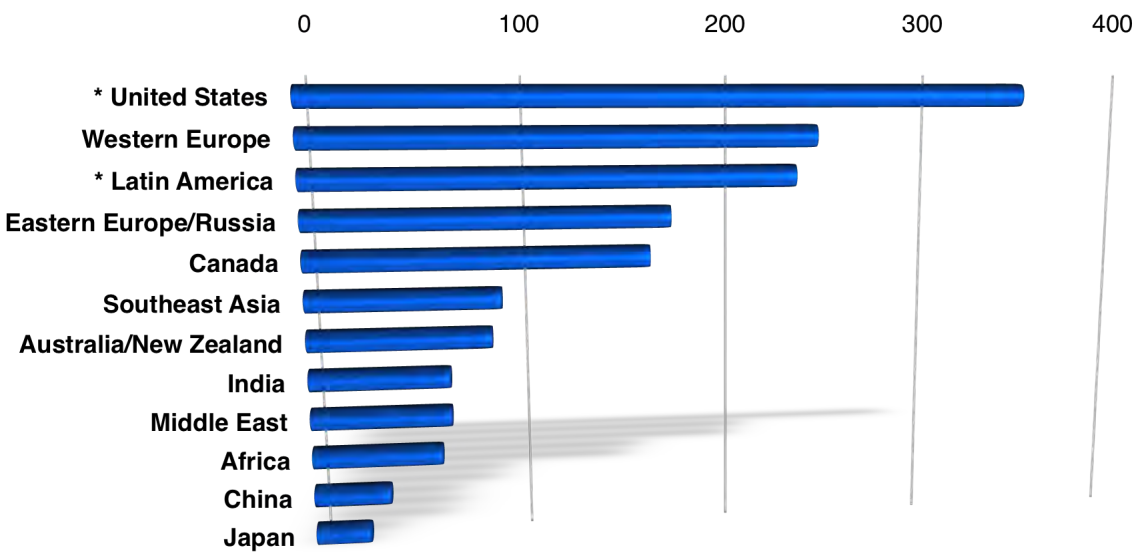
Quality
Quality of data is in LATAM comparable or equal / superior to USA & Western Europe.

U.S. & Latin America has more than 16,000 FDA Regulated Investigators & LATAM increasing rapidly

	1996	Percent of Total	2006	Percent of Total	Annualized 10-year Growth Rate
US North America	12,174	83.65%	14,555	63.18%	1.8%
Western Europe	1,899	13.05%	3,923	17.03%	7.52%
Central and Eastern Europe	56	0.38%	1,793	7.78%	41.4%
Latin America	**98**	**0.67%**	**1,095**	**4.75%**	**27.3%**
Asia	108	0.74%	1,054	4.58%	25.6%
Rest of the World	218	1.5%	617	2.68%	11%
TOTAL	14,574		23,089		

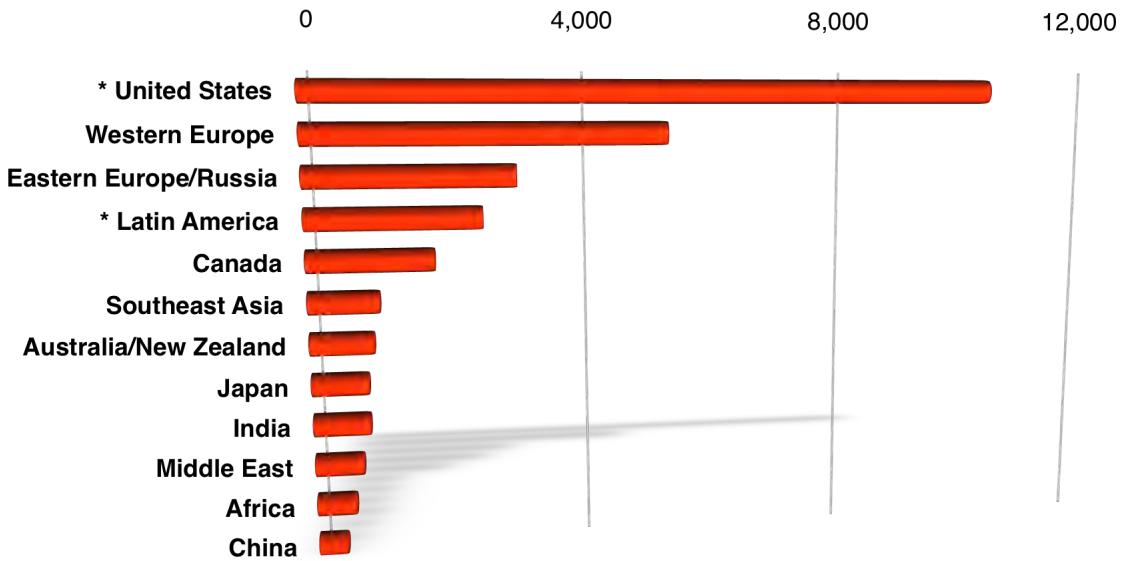
*Source: Tufts University Center for the Study of Drug Development

Open Phase III Clinical Trials Sponsored by the 20 Largest U.S.-Based Pharmaceutical & Medical Device Companies as of 2009
U.S. Ranks "1st" & Latin America "3rd" place



Global Number of Clinical Trials

Includes any trial conducted in a country that has at least one site
United States ranks in 1st place
*** Latin America ranks in 3rd place)**



Global Number of Clinical Trial Sites

Includes each location where a study is recruiting
United States ranks in 1st place
***(Latin America ranks in 4th place)**

*Source: New England Journal Medicine

LATAM Vs US Vs European "Review Process": Regulatory Key Limiting Steps

- In the "**USA**", each protocol (except for Phase 1 only requires submission to the FDA and in **parallel** an IRB review and approval.
  - Prior review by FDA is not required except for Phase 1.
  - The rate limiting step is **mainly the IRB submissions and approvals process**.
  - The IRB review is 45-60+/- days within the USA

- In "**Latin America**" the review process is sequential: first EC/IRB and then MoH.
  - MoH review time varies from country to country
  - Local Insurance covering patients can be rate limiting as many EC/IRB require
  - Many EC/IRB submissions and some regulatory authorities require a signed contract
  - The EC/IRB with MoH review is approximately 90 days in countries within LATAM

- In "**EU**", there is a **parallel** review process, and so submissions to EC's and Competent Authority (MoH) can be performed simultaneously.
  - The EC/IRB – MoH review is 60 days for countries within the EU.

*Source: ESTERN Medical Latin American Operations 2014

U.S. Vs LATAM Regulatory Timelines & Patient Recruitment Rates

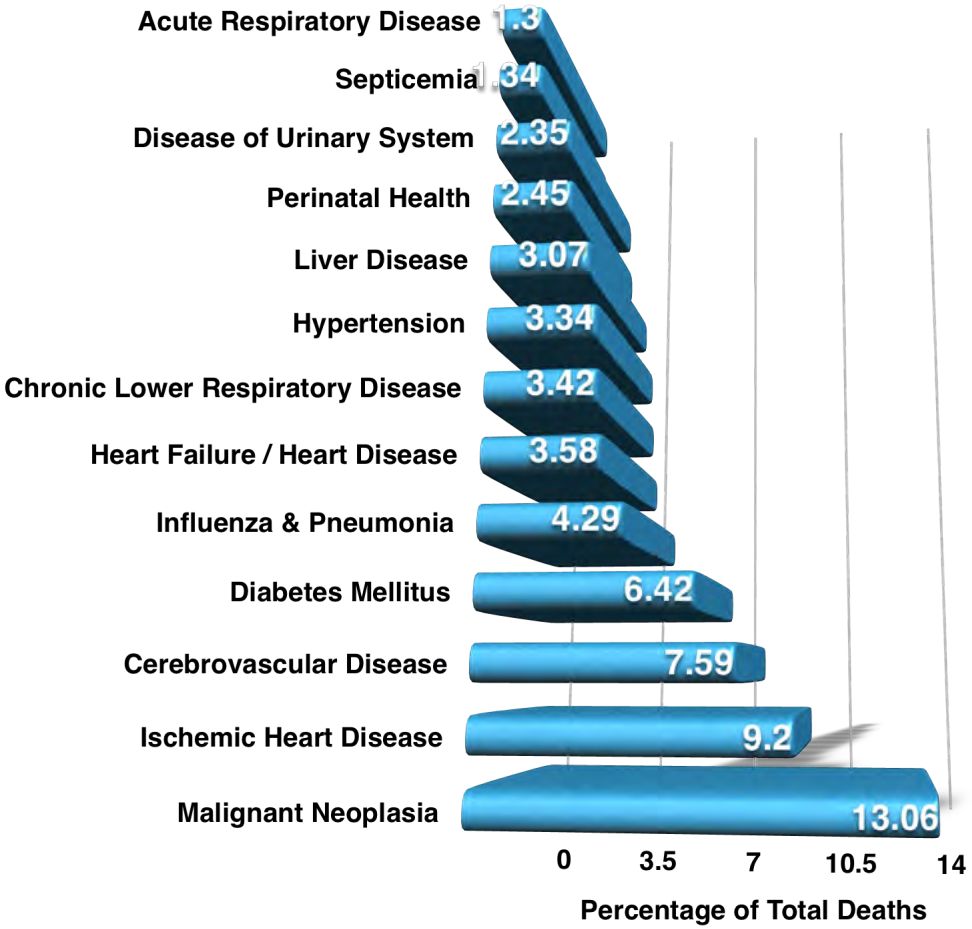
Our Most Common Regulatory Start-Up Times in the U.S. & Latin America			
Country	**Regulatory Startup rank**	**Population (2013)**	**Start-Up Time (Months)**
U.S.A.	1st Tier	317.1 Million	2
Mexico	1st Tier	118.4 Million	4
Colombia	1st Tier	47.1 Million	4
Argentina	2nd Tier	41.6 Million	4 – 5
Chile	1st Tier	17.4 Million	4 – 5
Brazil	3rd Tier	201.0 Million	10 – 15
*Source: ESTERN Medical Latin American Operations 2014			

Variation in Global Patient Recruitment Rates	
Region	**Average Number of Patients Enrolled Per Site**
Asia – Pacific	5.78
Latin America	4.56
Central & Eastern Europe	6.27
Western Europe	3.08
U.S.	1.92
*Sources: Lehman Brothers, Biopharmaceuticals R&D Statistical Sourcebook 2009 & **LATAM Clinical Trial Authorizations: Overview and update; Regulatory Focus, June 2009*	

- Latin American recruitment is well known to be of greater efficiency than other traditional regions

As clinical trial sponsors increasingly shift their radars towards the emerging economies of Latin America, ESTERN Medical, garners local knowledge from key industry figures in the region, uncovering some countries initiatives aimed at bringing their regulatory processes in line with traditional markets in the west.

Principal % Causes of Mortality in Latin America 2007 – 2010



*Source: Pan America Health Organization (Part of the WHO) 2013

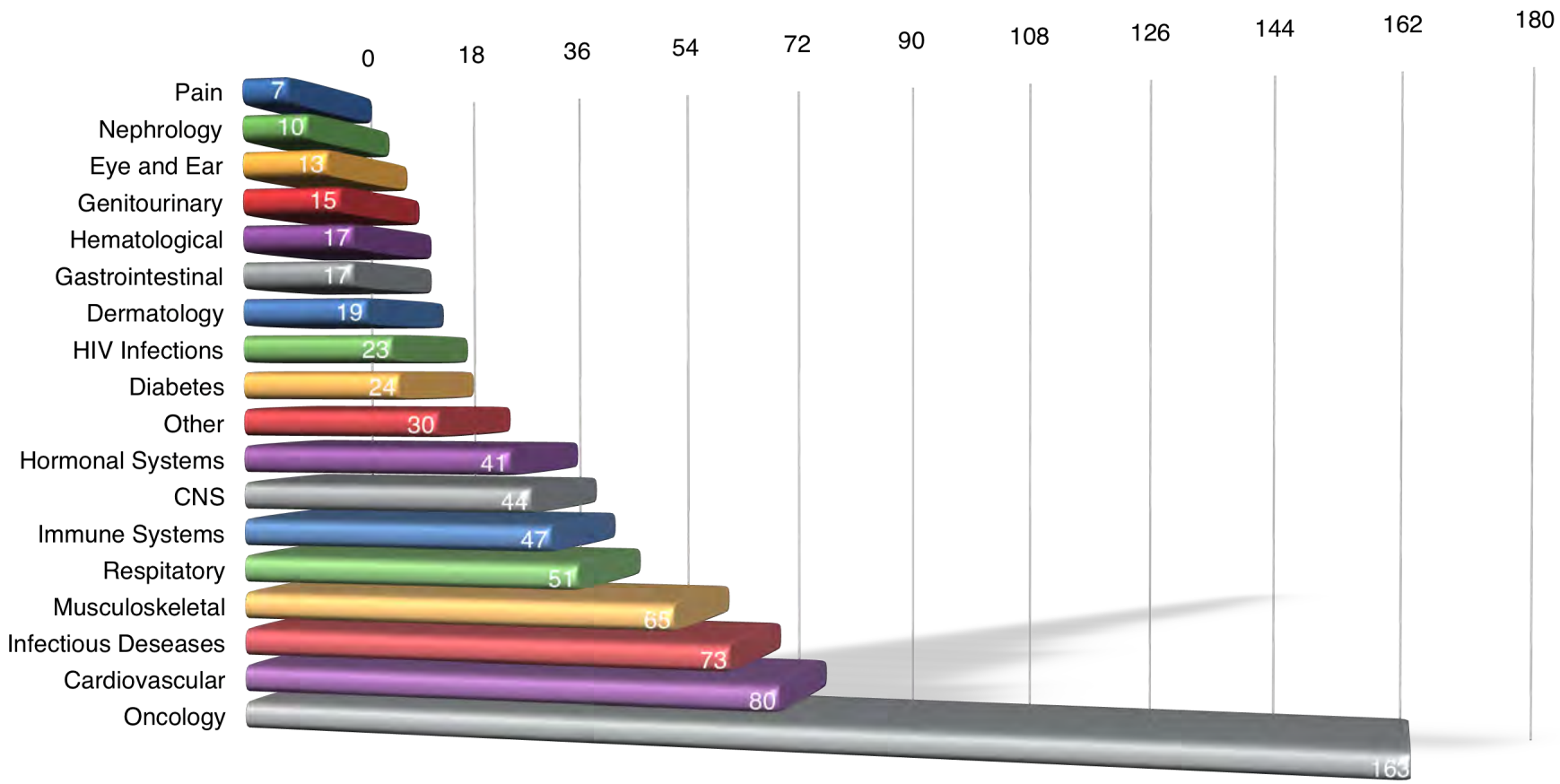
Progression of Socioeconomic Factors Drive Epidemiology in Latin America

Changes in lifestyle such as urban diets, smoking, & less exercise has contribute to the progression of chronic & other key diseases profiles in Latin America , driving the demand in for newer treatments

- The largest Cause of Deaths in LATAM are Cardiovascular Diseases followed by Oncological and Circulatory Diseases are 3 times more likely to be Cause of Death.
- Growing prevalence of Obesity (~24%)(*1) in Latin America correlates to increased risk of Diabetes & Cardiovascular disease.
- Since 2000, Obesity in adults in Mexico has risen 8% with now 32% of adults reported Obese in Mexico. (*2)
- Prevalence of tobacco use in Latin America (31% men & 17% women smoke)(*3) contributes to the progression of cancer, heart disease & certain respiratory disease.

*Source: (*1) WHO 2013
(*2) OECO Health Data 2013
(*3) John Hopkins University

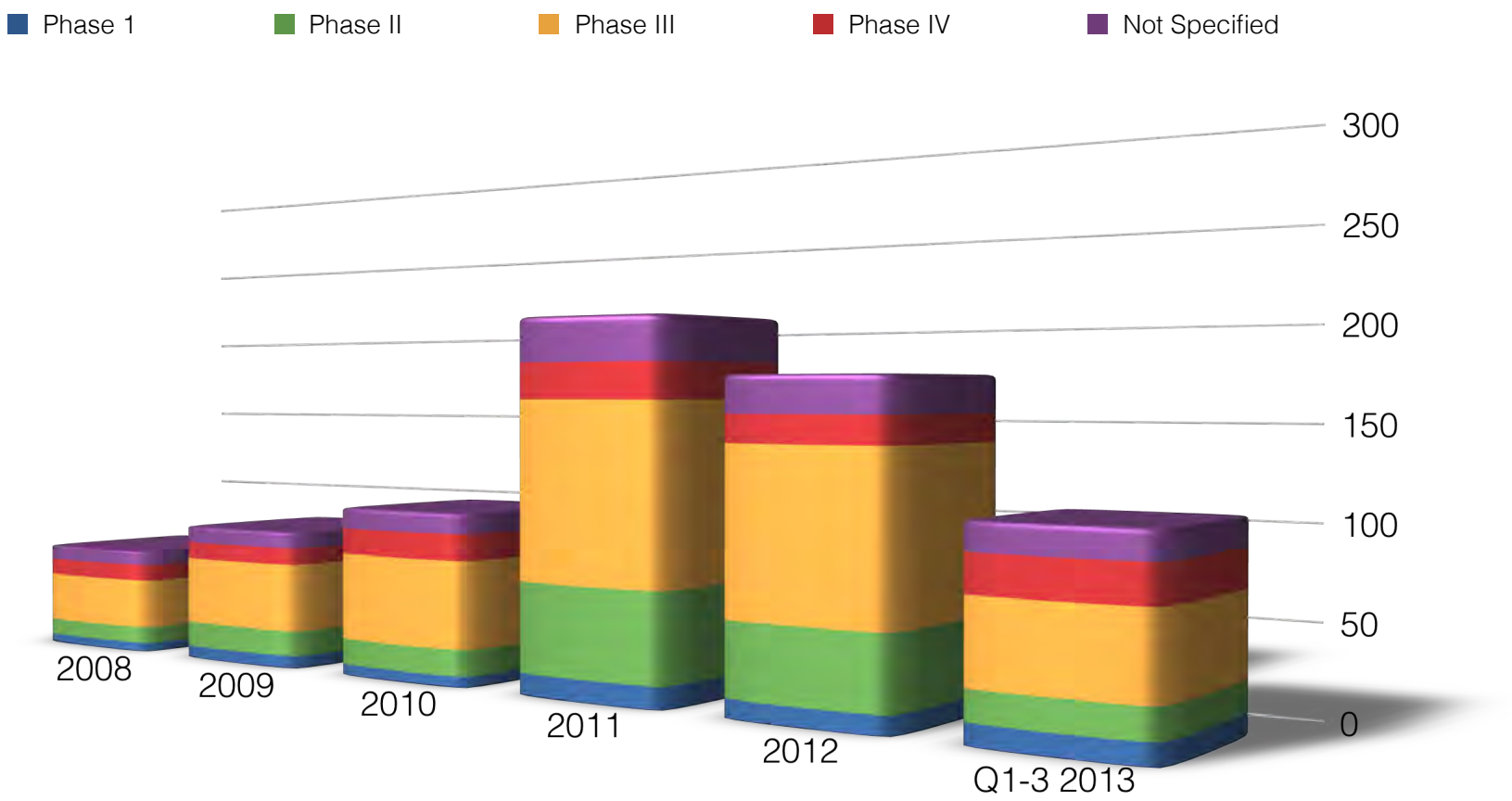
Oncology, Cardiovascular, Infectious Diseases and Musculoskeletal comprise 52% of all active Trials started since 2008 - 2013



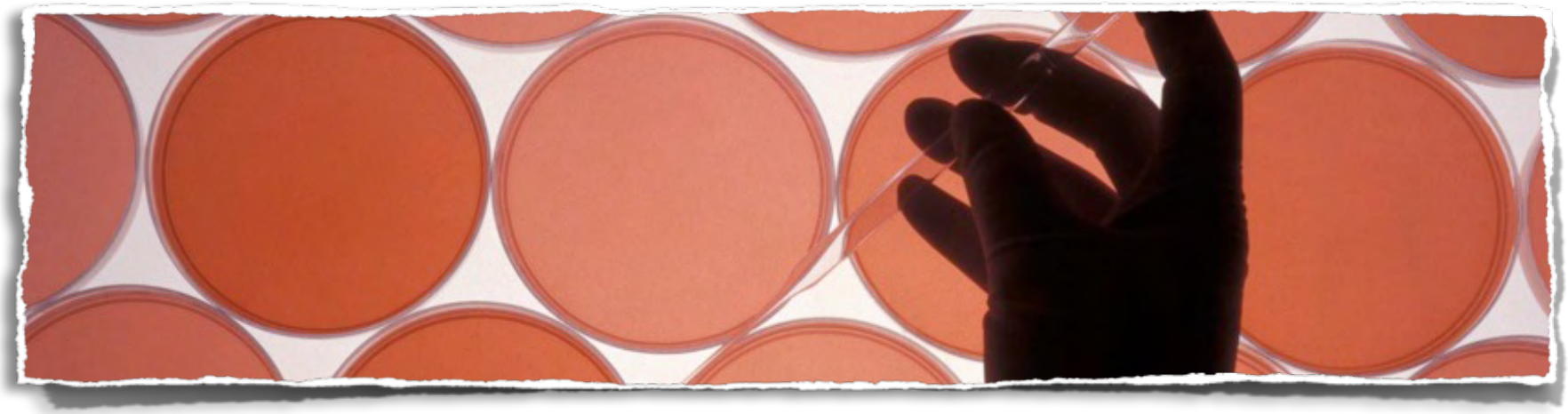
*Source: BioPharm Clinical – Data from 2008 – 2013

Clinical Trial Market Overview in Latin America by Trial Phases

*Source: BioPharm Clinical



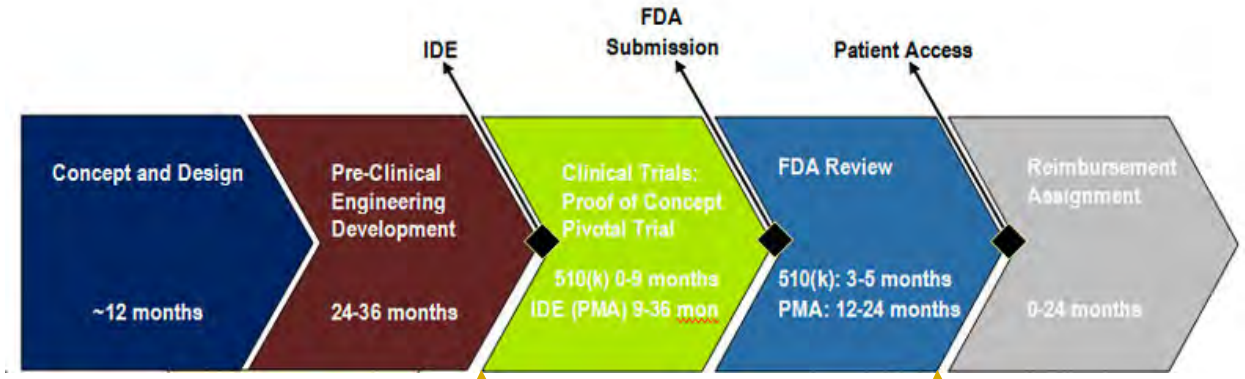
Phase III Trials make up 62% of all active trials in Latin America since 2008. The number of Trials has grown at a Compounded Annual Growth Rate (CAGR) of 32% in the past 5 years.



Our Areas of Expertise & Solutions in Clinical Site Selection

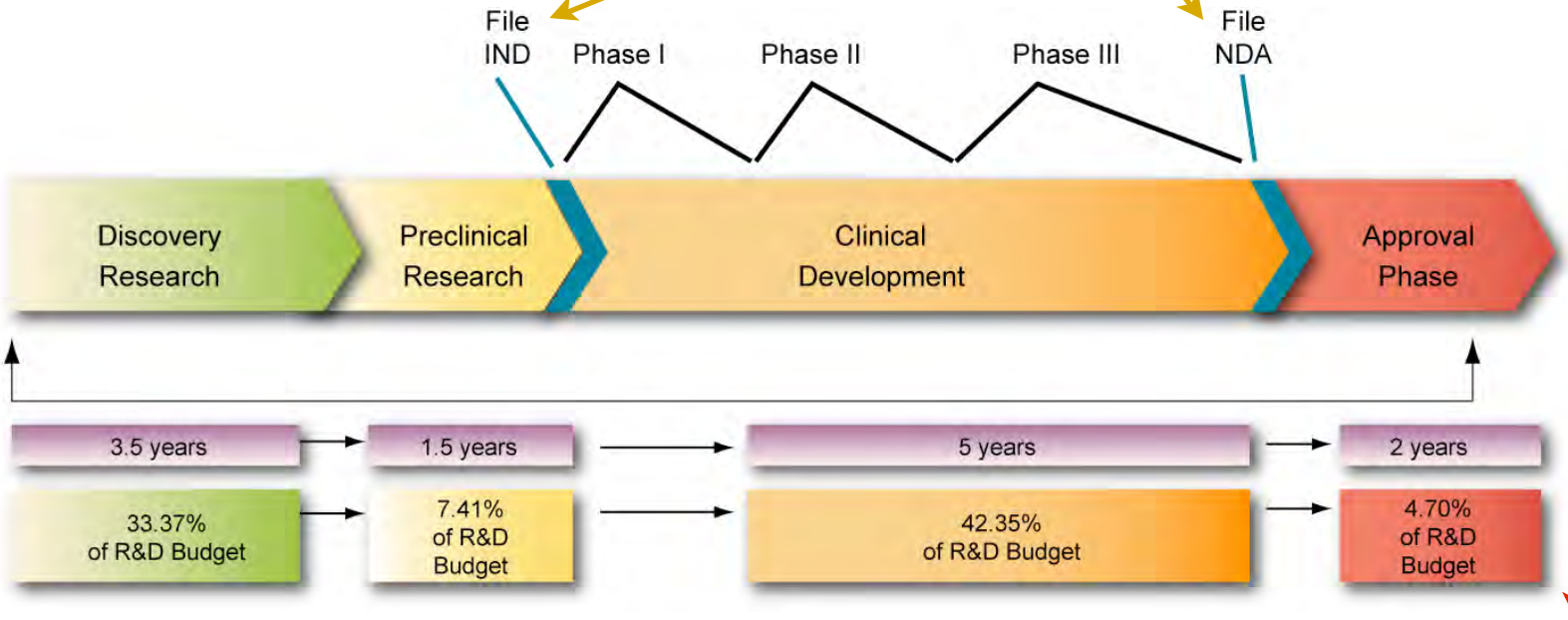
Our Areas focused Expertise in "Pharmaceutical & Medical Devices" Clinical Trials in the U.S. & Latin America

Medical Device Approval Process



ESTERN Medical Areas of Expertise

Pharmaceutical Drug Approval Process



We offer Tailored Solutions to our Sponsors across the U.S. & Latin America

Our Premium Quality Overall Services

- Clinical Development and Design of Clinical Studies across the U.S. & Latin America
- Expertise in Biotech, Pharmaceutical & Medical Device Clinical Trials
- Efficient Patient Recruitment in the U.S. & Latin America in highly qualified sites.
- Regulatory Strategies Dossiers Submissions (IRB/EC, MOH) in the U.S. & 21 Latin American countries.
- *Monitoring, *Project Management, *Biostatistics, *Medical Writing, *Translations, *Streamlined Site Selection & Recruitment Process, *Logistics, *EDC-Data Management, *Audits

Our Regulatory Services

- Thorough knowledge of regulatory environment in U.S. & Latin American countries.
- Regulatory approval process (Ethics Committees & MOH) more streamlined & predictable in the U.S. and LATAM.
- Customized Regulatory Strategy per country to expedite approval timelines.

Our Database Process of Clinical Site Selection in the U.S. & Latin America

ESTERN Medical Employs its Proprietary Database of High Profile Clinical Sites across U.S. & Latin America

Step 1: ESTERN Medical creates database considering Clinical Trial Specific Criteria

ESTERN Medical proprietary database includes, hospitals, patient population, diseases specific, Key Opinion Leaders, country in the U.S. & LATAM specific Ministry of Health regulations, etc.

ESTERN Medical Preliminary assessment

Step 2: ESTERN Medical filters into long list of candidates

Based on top-level information. Criteria can include:
U.S. & Latin America geographic location;
Clinical Trial region capabilities.

ESTERN Medical Detailed assessment

The criteria used in detailed assessments and proposal stages are based on:

Step 3: ESTERN Medical filters into short list of candidates

Request proposals

Final Selection Steps

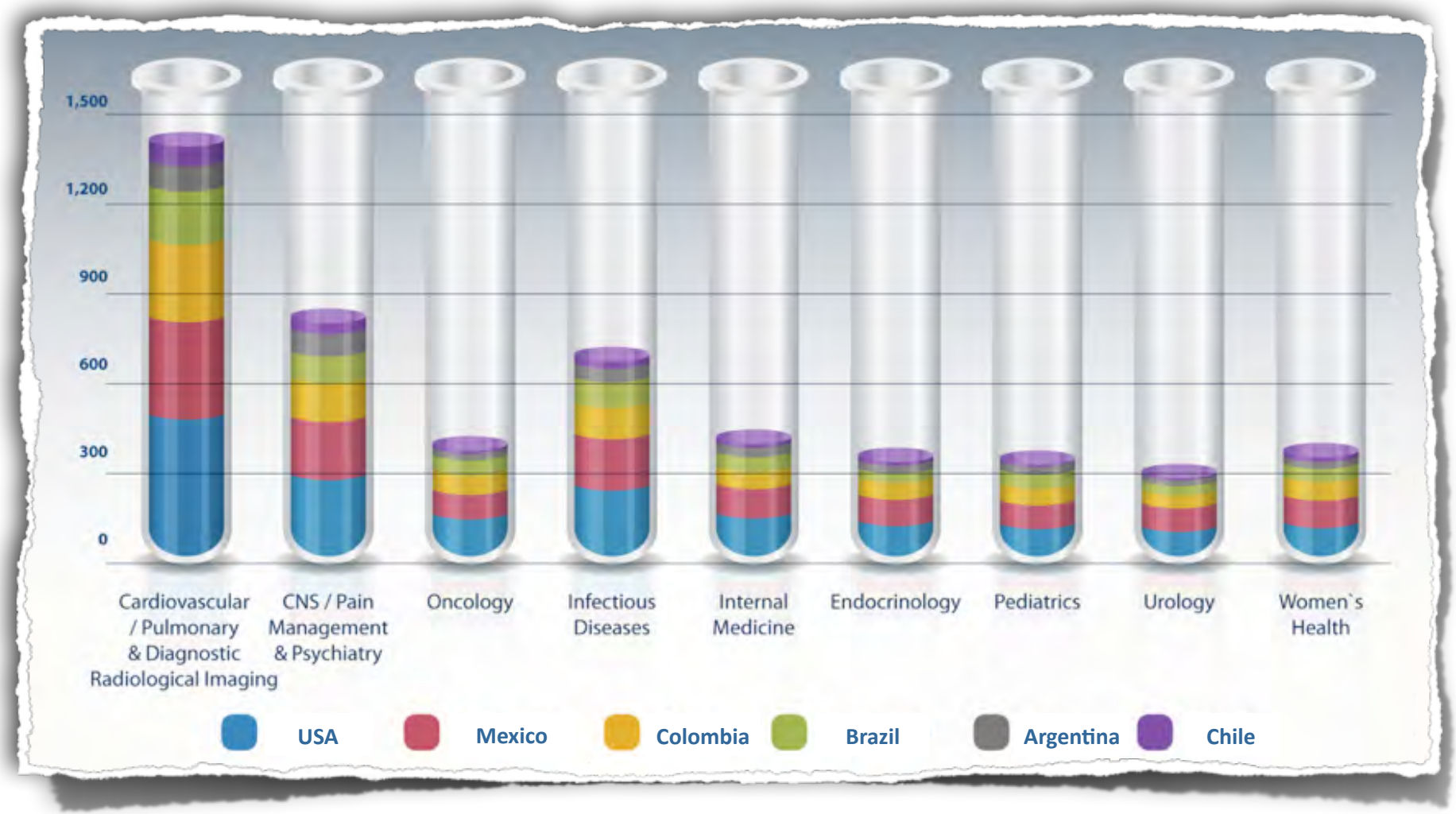
Tangible factors:
Financial stability
- Type of vendor
- Capacity
- Location
- Timescale
- Cost

Intangible factors:
- Reliability
- Reputation
- Experience
- Cultural fit
- Commitment to project
- Management strategy
- Patient population
- Disease Specific

Our U.S. & Latin America Therapeutic Expertise / Track Record of Executed Clinical Trials
&
Our Proprietary Clinical Sites Database U.S. & LATAM

Our Clinical Sites Database Across U.S & Latin America

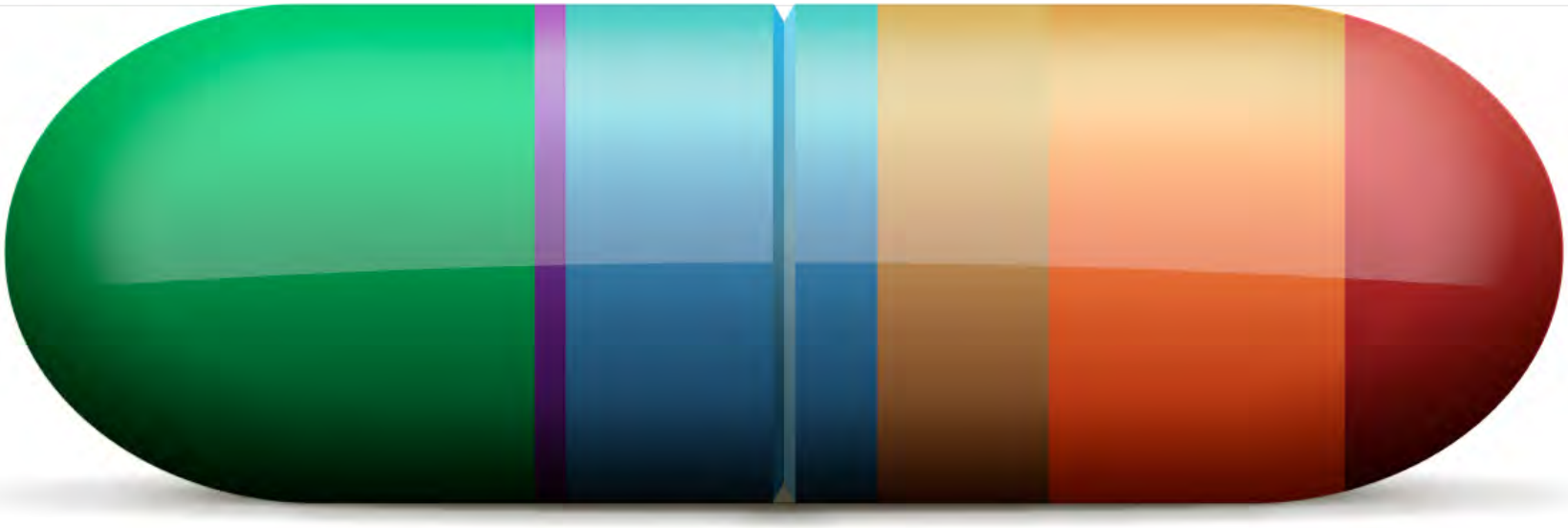
ESTERN Medical CRO Proprietary Database of Clinical Sites Network across U.S. North America & Latin America by Country and Therapeutic Area



*Source: ESTERN Medical CRO

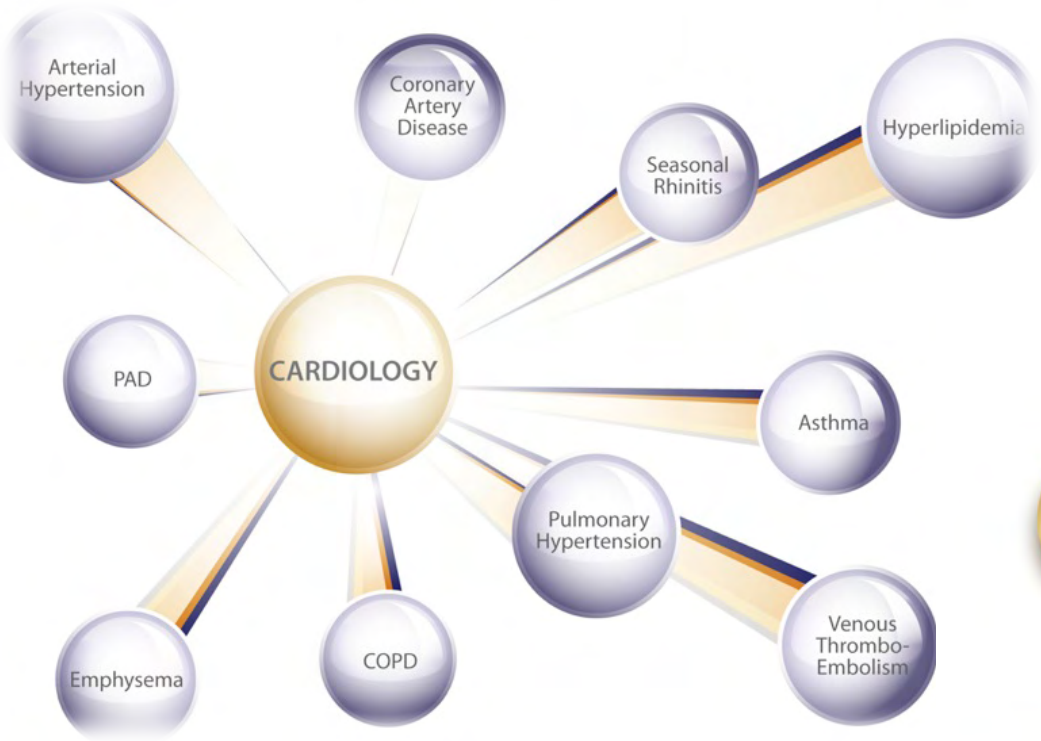
Our Track Record of Executed Pharmaceutical & Medical Device Clinical Trials Phases I, II, III through IV Across USA & Latin America

*Source: ESTERN Medical CRO

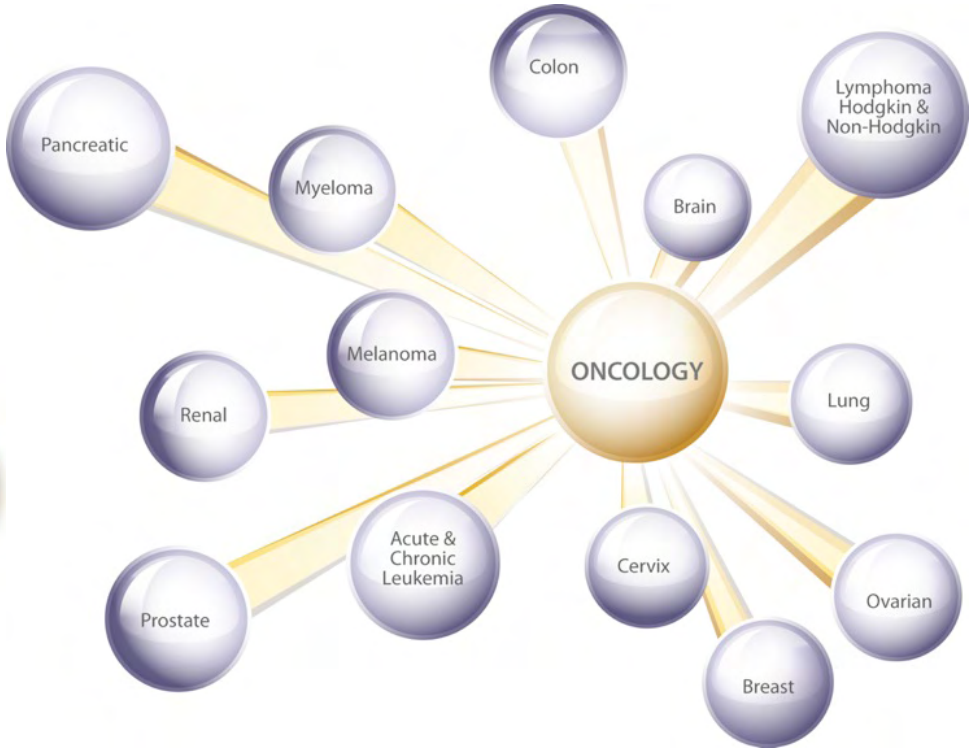


- 34% CNS / Pain Management & Psychiatry
- 20% Cardiology / Pulmonary
- 19% Infectious Diseases
- 2% Women's Health
- 11% Oncology
- 14% Diagnostic Radiological Imaging (MRI / MRA / CT & Angio)

Our Therapeutic Expertise: Cardiology & Infectious Diseases



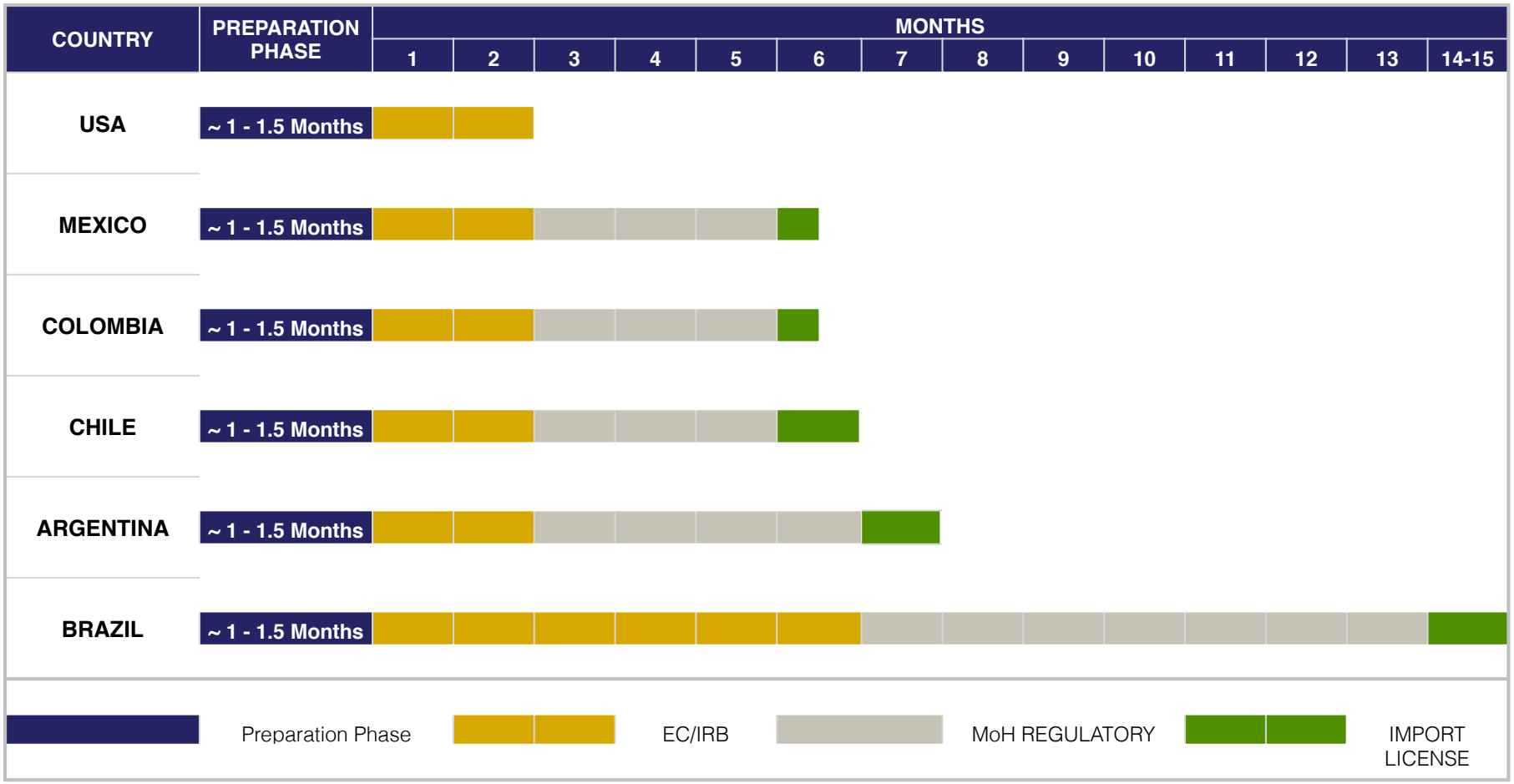
Our Therapeutic Expertise:
Oncology & CNS / Pain Management & Psychiatry



Our U.S. & Latin American Integration of Regulatory Activities & Cost Analysis

Our Overall Regulatory Timelines Across USA & Latin America

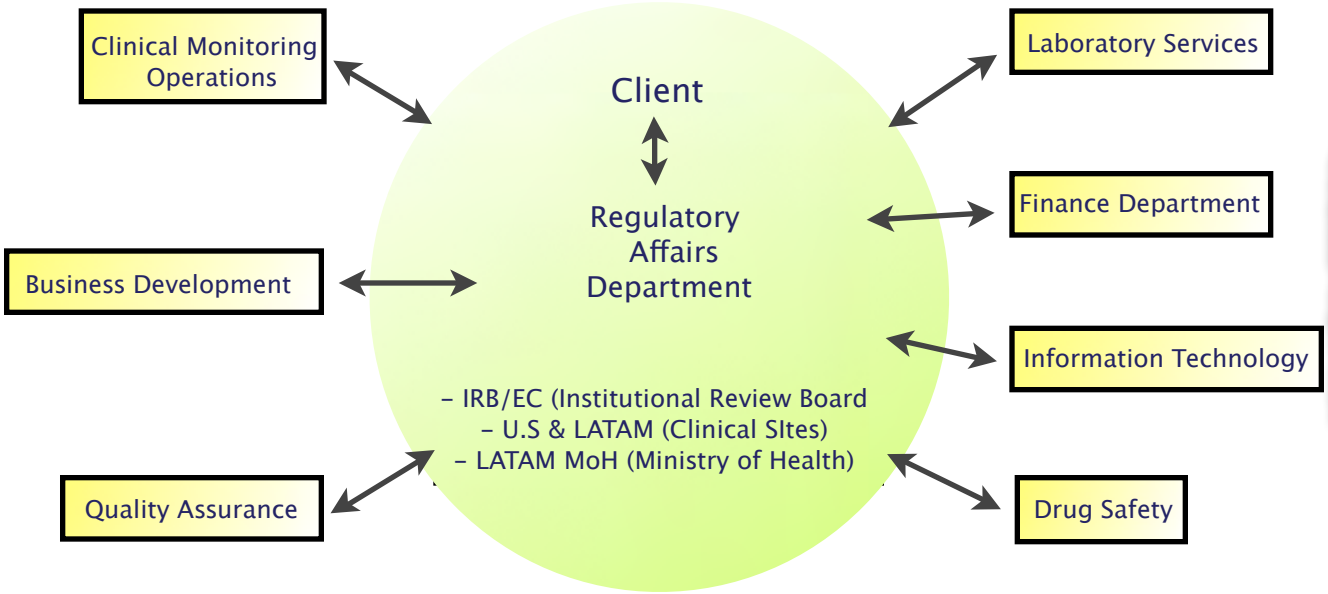
*Source: ESTERN Medical CRO



Our Key Responsibilities

- External and Internal Customer Advice, Guidance & Support
- Feasibility, Proposals, Budgets
- Regulatory Risk Analysis and Strategies
- Regulatory Requirements Compliance for U.S. & LATAM
- Regulatory Start-up – Documents Compilation and Review
- Independent Ethics Committee (EC/IRBs) and LATAM MoH Submissions
- Follow-up and Reports
- Import/Export processes U.S. & LATAM
- CTM Delivery, Logistic, Storage and Destruction

Our Regulatory Department- Interactions



Our Leverage Cost Savings from Executing Trials in U.S. & Latin American Countries

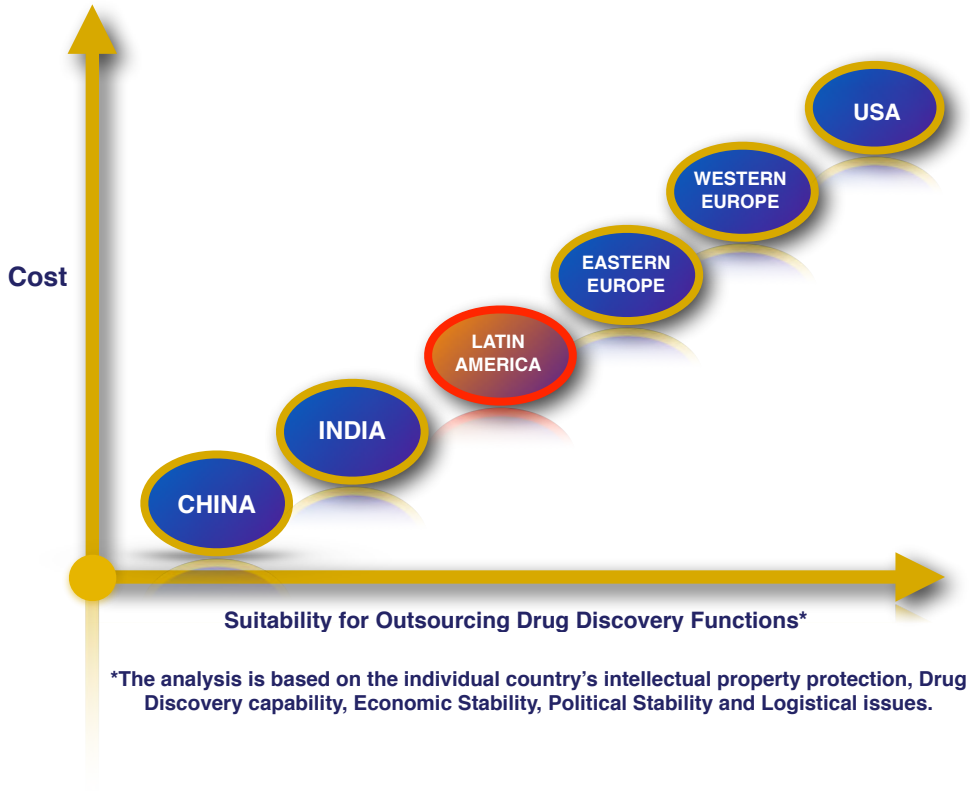
- **Patient recruiting is up to ten times more efficient**
  Patient concentration e.g. in Mexico, Colombia, Chile, Brazil and
  Argentina.

- **Treatment costs ~ "30%" less than in the US/Europe**
  Lower costs for medication, investigations and hospitalization

- **Cost reduction due to domestic travel in Latin American Countries.**
  Urban concentration of sites Regional & Local Representative in each regional Office

- **Support Services – Less Expensive**
  Printing, translation, local courier,
  Data Management

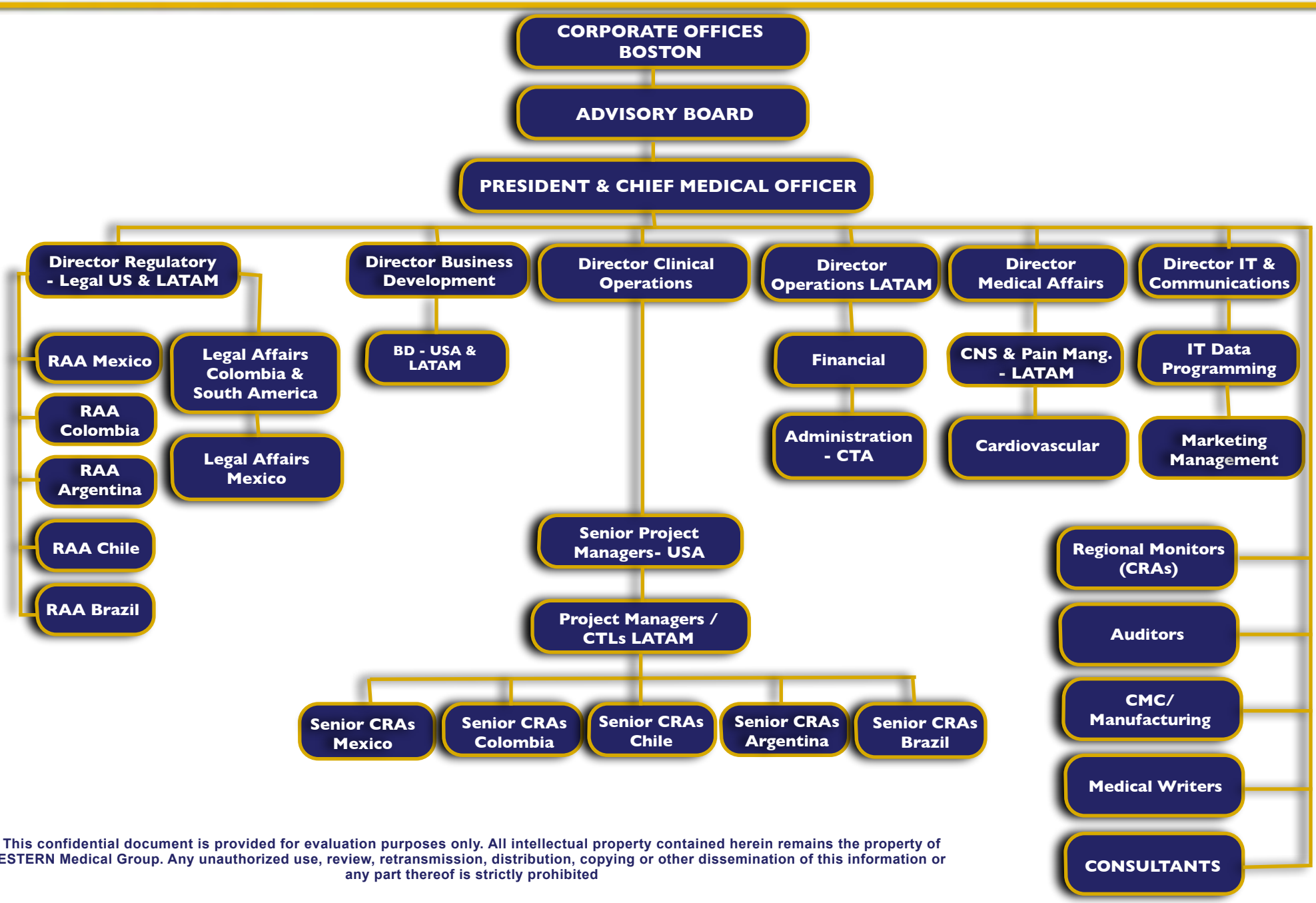
- **Regulatory – Less Expensive**
  Lower costs and fees in Latin America vs. US and Europe regulatory agencies



- ESTERN Medical takes advantage of the higher recruitment rates expected in LATAM & higher advantage with combine U.S. or EU trials:
  - Compensates for delayed start-up due to the regulatory process
  - Allows to gain efficiencies by concentrating a higher number of patients in a reduced number of sites:
    - Lower overall study costs for sponsors
    - May enable to complete rapid recruitment ahead of plan.

Our Company Organizational Structure & Senior Executive Management Team

ESTERN Medical CRO Operational Organizational Flowchart U.S. & LATAM



Dr. Jorge L. Estrella, M.D.

President & Chief Medical Officer

Dr. Estrella brings broad experience in the field of clinical Research development of cardiovascular and interventional medical devices, working previously as the Senior Physician Director-Clinical Trials Coordination at The Guidant Corporation - (ACS) Advanced Cardiovascular Systems in Santa Clara, California, Peripheral and Stent Division, having culminating with Guidant Corporation, with the "RX - HERCULINK®, 1st Renal and Peripheral Stent system platforms. Dr. Estrella also acquired extensive knowledge working in the clinical development of the CNS with RISPERDAL® (risperidone) indicated for treatment Schizophrenia as a Senior Director Clinical Research at "Janssen Pharmaceuticals".

Dr. Estrella is internationally recognized for his broad expertise in clinical trials & research development in the pharmaceutical and medical device scientific community in some of the most prestigious medical institutions, pharmaceutical and medical device companies. He has extensive expertise in the fields of cardiovascular, peripheral vascular diseases, interventional cardiology, CNS, infectious diseases and Diagnostic Imaging, bringing those clinical development products to future global market approvals.

Education

1994-1996	Internal Medicine and Infectious Diseases - Molecular Biology Research & Clinical Training at The National Institute of Nutrition, (INNSZ), Mexico City.
1993-1994	Medical Internship at The Institute of Medical Security and Services of the State Employees (ISSSTE), Mexico City.
1989-1992	Medical Doctor. Autonomous University of Guadalajara (UAG), Guadalajara, Mexico

Track Record

Dr. Estrella is the Founder of ESTERN Medical Clinical Research Organization & Consulting Group and current President & Chief Medical Officer.

He is responsible for overall corporate management and evaluating new clinical trials pipelines as well as sponsors relationships with Pharmaceutical, Biotech & Medical Device Companies.

Dr. Estrella brings to ESTERN Medical extensive experience in the Cardiovascular, CNS, Infectious Diseases and MRI Diagnostic Radiological Imaging therapeutic areas from EPIX Pharmaceutical Inc., in Cambridge, MA USA as the Director Clinical Development, his Clinical R&D culminated with "Vasovist" (gadofosveset trisodium) "First Imaging Agent Approved For Magnetic Resonance Angiography (MRA) In The US-FDA & EU-EMEA" a novel blood pool magnetic resonance angiography (MRA & MRI) agent, Vasovist®. Dr. Estrella brings a unique combination of entrepreneurial, scientific and business expertise, encompassing both pharmaceutical and medical device clinical trials development.

Professional Experience

2002-Present	ESTERN Medical CRO Global Group, LLC. Boston - Cambridge, Massachusetts, USA President & Chief Medical Officer.
2002 -2005	EPIX Pharmaceuticals, Inc & Schering AG Pharma - "now known as Bayer Schering Pharma AG" Cambridge, Massachusetts, USA Director Clinical Development
1999-2002	GUIDANT Corporation / ACS Advanced Cardiovascular System -" Known as Boston Scientific Inc & Abbott Vascular". Santa Clara, California, USA Senior Director Clinical Trials Coordinator Physician.
1998-1999	Janssen Pharmaceuticals North Carolina., USA Sr. Director of Clinical Research

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

Head of Scientific Regulatory Legal Affairs & Quality

He drafted proposed FDA legislation Reform, including the drafting as well a members of the US-Congress. Mr. Morgan has held diverse executive positions in some of the top and most prestigious Medical Research & Clinical Regulatory Global Companies with Ziopharm Oncology, Inc, EPIX Pharmaceuticals, Inc, DuPont Pharma Company, Genzyme Corp., PAREXEL International Corp. & Theseus Imaging Corp. before joining ESTERN Medical CRO Group.

Mr. Morgan is a Adjunct Faculty Member of The Healthcare Drug Development for the Graduate School of Engineering at Northeastern University in Boston.

Education

1992-1995	Massachusetts School of Law.
1980-1982	University of Kansas, Masters in Radiation Biophysics.
1973-1978	University of Massachusetts BS, in Zoology.

Track Record

Mr. Robert Morgan, is the Head of Scientific Regulatory Legal Affairs & Quality at ESTERN Medical CRO Global Group. He is also one of the key senior executive members of ESTERN'S Corporate Scientific Advisory Board since April 2009.

During his career he has submitted and maintained multiple IND, NDA and International regulatory filings. He also filed the first electronic IND application accepted by the FDA in the new international standard Common Technical Document format.

Mr. Morgan, has over 25 years experience in all areas of drug development, in the United States, Canada, Europe, India, Pacific Rim and Latin America. Author of numerous successful IND, NDA and Orphan Drug submissions, specializing in innovative treatments across multiple therapeutic areas, particularly Oncology, Interventional/Peripheral Cardiology and Diagnostic Radiological Imaging.

His effectiveness, hands-on direction: design early phase clinical studies, draft regulatory submissions, including US and European Orphan Drug applications, draft abstracts and manuscripts for publication in professional journals.

Professional Experience

2009-Present	ESTERN Medical CRO Global Group, LLC. Boston - Cambridge, Massachusetts, USA Head of Scientific Regulatory Legal Affairs & Quality
2006-2013	Ziopharm Oncology, Inc. Boston, MA USA. Senior Vice President, Regulatory Affairs - Quality Pharmaceutical Development & Drug Safety.
2003 -2006	EPIX Pharmaceuticals, Inc & Schering AG Pharma - now known as Bayer Schering Pharma AG Cambridge, Massachusetts, USA Executive Director Regulatory Affairs & Quality.
2001-2003	Theseus Imaging Corp. Subsidiary North America Scientific, Inc. Boston, MA USA. Vice President, Regulatory Affairs
1994-2001	Dupont Pharmaceuticals Company Boston, MA USA Senior Director Regulatory Affairs

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

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

Prior to joining BSP -Medrad Inc., she was a senior MRI manager clinician specialist for Siemens Healthcare in South America with diverse responsibilities from clinical physician training through operational commercialization support. Previous to her experience in the pharmaceutical & medical device industry she endure her clinical experience as the chief clinical MRI technologist at San Jose university hospital in Bogota, Colombia . Ms. Hernandez started her career as clinical physical therapist for more than 10 years.

Ms. Hernandez is internationally well recognized for her broad expertise as a clinician and scientific researcher in some of the most prestigious clinical institutions in the fields of cardiovascular, peripheral vascular diseases, interventional cardiology and diagnostic CT, MRI radiological imaging

Education

1993 – 1994 Masters Clinical Radiology at the (UDES) Universidad Santander, Bogota, Colombia

1985 – 1988 B.S., Clinical Physical Therapy at the Universidad del Rosario, Bogota, Colombia

Track Record

Ms. Hernandez, joined ESTERN Medical in April 2008 with an extensive clinical research and clinical technology support training in the fields of cardiology & interventional diagnostic radiology imaging. Ms. Hernandez brings a wide knowledge of scientific and business expertise with entrepreneurial hands on knowledge and expertise to the ESTERN Medical CRO Group.

Ms. Hernandez was previously the Head Senior Manager Clinical Research & Support Clinical Specialist for Latin American & Caribbean for Medrad Inc. a subsidiary of Bayer-Schering Pharma AG, where she initiated a business strategy that helped transform Medrad Inc. in Latin America from a distribution platform company to a fully independent clinical and training research network structure in South America.

Ms. Hernandez spent 10 years with BSP - Medrad Inc. culminating in her role with two of the most important company pipeline platforms, the Avanta cardiovascular interventional radiology MRI/CT diagnostic imaging injectors and most important the Stellant Dual Injector System for Multi-slice CT as a clinical research support training specialist for the Latin American region.

Professional Experience

2008 to Present	ESTERN Medical CRO, Global Group, LLC. Boston – Cambridge, Massachusetts, USA Director Clinical Operations U.S. & Latin America
1999 – 2008	Head Senior Manager Clinical Research & Support Clinical Specialist for Latin American & Caribbean Medrad Inc, a subsidiary of Bayer Schering Pharma, AG. Bogota, Colombia
1996 – 1999	Senior Manager Clinical MRI Specialist for Siemens Healthcare, for South America. – Bogota, Colombia.
1995 – 1999	Chief Clinical MRI Imaging technologist at the University Hospital San Jose Bogota, Colombia
1989 – 1995	Independent Physical Clinical Therapist, (RPT). Bogota, Colombia

Dr. John Jairo Hernandez, M.D.

Director CNS & Pain Management

Education

1995	Neuro-Imaging Clinical Training Biomagnetic Institute for Magnetic Resonance Imaging Caracas (Venezuela)
1987	Neurosurgery Spine & Pain Training Centre Hospitalier Universitaire "La Timone", Marseille (France)
1983-1988	Neurosurgery Residency Training. Colegio Mayor de Nuestra Señora del Rosario St. Jose Hospital, Bogota (Colombia)
1982	Medical Degree University of Rosario, School of Medicine Bogota (Colombia)

Dr. Hernandez obtained his medical degree from the Universidad del Rosario in Bogota, Colombia. He completed his internship and residency training in Neurosurgery at the Colegio Mayor de Nuestra Señora del Rosario, Bogota, Colombia, and continued his postgraduate studies in vertebral column and spinal medulla pain management in France at La Timone in Marseille.

His third postgraduate training was performed in Neuro-Imaging MRI at the Instituto de Resonancia Magnética Biomagnética in Caracas, Venezuela

Track Record

Dr. Hernandez joined ESTERN Medical in 2007 with extensive expertise in the clinical field, academia and clinical trials research as one of the top international Kols with broad expertise in Neurosurgery, Neuro-Imaging and Pain Management.

Dr. Hernandez is involved in the clinical and research as one of the top key opinion leader and medical speaker for ESTERN Medical in his field of expertise in academia in the pharmaceutical and medical device industry.

Professional Experience

Dr. Hernandez serves also as a professor at the School of Medicine & the Director Medicine Pain Management and clinical research at the Universidad del Rosario / Mederi Hospital in Bogota, Colombia, with more than 20 years of experience in this field.

He is one of the top senior clinical advisors & Key Opinion Leaders (KOL) for major global Pharmaceutical & Medical Device companies across the U.S, EU & Latin America such as Grunenthal Laboratories, Pfizer, Novartis, Medtronic, Janssen Cilag, Wyeth, Eli Lilly , Sanofi- Aventis in the fields of clinical research pharmacology and medical device pain management, neurology & neurosurgery.

He is also one of the first physician and (PIs) that implanted the first patient neurostimulators across Latin America and the first one in Colombia as well as broad experience in pharmaceutical delivery-pumps in Pain-Management

His strengths & knowledge are backed by more than 30 years of experience, with a broad academic trajectory background as a clinician & university professor. Dr. Hernandez has published more than 100 international clinical journal articles & books in the CNS & pain management field.

Dr. Hernandez is also active Member, "Founder and Former President of the Colombian Association for the Study of Pain" (ACED) and active member of the International Association for the Study of Pain (IASP).

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

Director Operations South America

Education

1978-1982 Surgeon in Dentistry
UNICOC - Universitaria Colegios de Colombia, School of Dentistry (Colegio Odontológico Colombiano)
Bogota, Colombia

Track Record & Professional Experience

Dr. Hernandez joined ESTERN Medical in June 2006 and serves as our Director of Operations for South America.

Before joining ESTERN Medical he worked in the Private & Health Government agencies across South America. He has a vast experience the EU, Spanish healthcare R&D industry as an executive & clinician, where he did acquired his clinical, regulatory and operational expertise on a global basis for major pharmaceutical, medical device companies & CROs in Seville, Spain.

Dr. Hernandez brings abroad experience in the clinical operations for pharmaceutical & medical device healthcare industry across South America including a vast strategic operational finance/accounting & legal business development planning expertise from his broad knowledge & experience working as a senior executive member at AFIDRO (Association of Pharmaceutical Research & Development) in Colombia.

Dr. Hernandez strengths are backed more than 20 years of experience an academic background as university clinician school of dentistry professor.

Dr. Jorge E. Estrella Sr., M.D.

Director Medical Affairs

Education

Dr. Estrella obtained his Medical Degree from the Universidad Autónoma de México, UNAM, in Mexico City.

He completed his internship and residency training in Internal Medicine Geriatrics at the National Institute of Gerontology and Geriatrics, Bucharest, Romania, with international renowned Professor, Dr. Ana Aslan, M.D.

Track Record

Dr. Estrella is one of the Co-Founders of the ESTERN Medical Group and was appointed Director of Medical Affairs for ESTERN CRO in 2002.

Dr. Estrella has over 40 years of experience as a clinician and academic university professor of internal medicine & geriatrics at the University of Mexico. As a clinical researcher and he is a key asset member at ESTERN Medical with broad knowledge in the fields internal medicine, geriatrics and cell therapy pharmaceuticals. Dr. Estrella brings a wealth of business development in the Latin American and European pharmaceutical markets.

Professional Experience

Dr. Estrella is a Clinician and Researcher with a broad knowledge gerontology and geriatrics were he has worked on cellular enzymatic therapy antibodies and protein therapeutics always the vanguard of novel medicine treatments.

Dr. Estrella brings a track record of experiences bringing the first novel wave of early geriatrics and gerontology clinical trials treatments to Latin America from Europe to present novel new indications.

Dr. Estrella was previously the Chief Medical Director & Co-founder of Distribuidora Imperial de Mexico previously part of a major European distribution company in Mexico Pharmaceutical field for more than 20 years. Dr. Estrella is key opinion leader for new novel emerging global pharmaceutical companies in the field geriatric compounds.

Antonio Ley Estrella, J.D.

Director Legal & Finance

Education

*Masters Degree in Legal Finance
Universidad Autónoma de Mexico (UNAM)

*Law Degree, Universidad Autónoma de Mexico (UNAM)

Track Record

Mr. Ley-E. is a Co-Founder at ESTERN Medical Mexico S.A. and join the company in 2002 as the Director Legal & Finance.

Mr. Ley is responsible for maintaining in accordance all legal & finance Business Legal Development with sponsors either Pharmaceutical & Medical Device companies and CRO partners across Latin America.

30 years of experience as an attorney in the legal and finance business development as the previous the President at the legal firm L.E. Associates, in Mexico.

Mr Ley strengths are also supported by more than 35 years of experience an academic background as university professor school of Law & Finance at the Universidad Autónoma de Mexico (UNAM) & (UABC).

Some of his past legal & finance clients are Merck & Pfizer Pharmaceuticals, Aeroméxico Airlines, Coca Cola of Mexico, MoH/Cofepris of Mexico bringing that bast experience of knowledge to ESTERN Medical CRO under his belt of expertise and knowledge in the legal and finance area.

Professional Experience

2002-Present ESTERN Medical - Director Legal & Finance

1978 - 2008 President & L.E. Associates Legal Firm - Mexico

Our Corporate & Scientific Advisory Board

Michael Webb, M.B.A.

Head Of Corporate Advisory Board

Mr. Michael D. Webb was appointed Head of Corporate Advisory Board since March 2009.

He is currently the President & CEO at Allegro Diagnostics Corp. in Boston, Massachusetts.

Mr. Webb has more than 25 years of experience in healthcare and life science. Recently, he was the founder and CEO of Anchor Therapeutics, a venture-backed company focusing on developing pepducins, a new biology platform for drug discovery. Prior to founding Anchor, he was the CEO of EPIX Pharmaceuticals, Inc. from 1994 through 2005. During this period, EPIX grew from a venture-backed startup to the world leader in discovery and development of pharmaceuticals for diagnostic imaging with MRI, achieving worldwide approval for its lead product Vasovist® and completing numerous financings and corporate partnerships including an IPO on NASDAQ. Mr. Webb joined EPIX from CIBA, where he was most recently Senior Vice President, Worldwide Marketing and Strategic Planning of CIBA Diagnostics, responsible for global marketing, program management, corporate planning, business development and licensing. Prior to CIBA, Mr. Webb was a senior consultant at Booz, Allen & Hamilton, specializing in healthcare and life sciences.

Mr. Webb holds Bachelors degrees in Biochemistry and Economics from the University of Kansas, Summa Cum Laude and an MA in International Relations from Sussex University in the UK, completing his thesis on "Pharmaceuticals Policy and the World Health Organization." In addition, Mr. Webb holds an MBA degree with honors from the Kellogg Graduate School of Management at Northwestern University.

He was the past chairman board of the Massachusetts Biotechnology Council and served on the boards of Anchor Therapeutics, Solmap Pharmaceuticals (Acquired by Forma Therapeutics)

Currently serves as Virtify, Executive Chairman of the Board. He also serves on the advisory boards of Deuteria Pharmaceuticals, ESTERN Medical CRO, Wolfe Laboratories, the Kellogg Center for Biotechnology at Northwestern, the Institute for Advancing Medical Innovation at the University of Kansas and is a Senior Advisor to Johnston Blakely, a life sciences investment banking firm.

Dr. Charles Schmidt, MD.

Senior Scientific Clinical Medical Advisor

Education

*Medical Doctor & Pediatrician – Faculdade de Ciências Médicas da Santa Casa de São Paulo – Brazil

*Masters & Doctorate Degree in Pediatrics Infectious Disease – UNIFESP – Brazil

*Post Graduated in Management NGOs – Faculdade de Saúde Pública da USP – Brazil

Track Record

Dr. Charles Schmidt, M.D., joined the ESTERN Medical Scientific Board in July 2013. Dr. Schmidt is a prominent clinician, professor & scientist who has spent more than 20 years working in the field of clinical trials, including as an executive director clinical director of some of the prestigious global pharmaceutical companies & global Clinical Research Organizations (CROs)

He is currently a professor & coordinator of the post-graduate program in clinical research at the University – Facultad De Ciencias Medicas da Santa Casa in Sao Paulo, Brazil

Prior to joining the ESTERN Medical Group, from 1992 to 2013, he was head of Quintiles Brazil, PRA Latin America, Medpace Latin America, Eurotrials Brazil for R&D clinical trials worldwide core research functions.

Previously, he held a series of scientific management positions at Abbott Laboratories and Biociência Lavoisier. Dr. Schmidt has been a member & ex-president and founder of the Brazilian Association of CROs (ABRACRO). Member of the board and Director of the Brazilian Association of Pharmaceutical Physicians (SBMF) and member of the steering committee of DIA Latin America on the discovery, development, evaluation and utilization of medicines and related health care technologies

Dr. Schmidt received his Medical degree from the University Faculdade de Ciências Médicas da Santa Casa in Sao Paulo, Brazil. School of Medicine and did further medical and research training in Pediatrics & Infectious Diseases at the Universidad Federal de Sao Paulo in Brazil (UNIFESP). Addition to his clinical background he received degree in Post-graduate Management at the Faculdade de Saúde Pública da USP Brazil.

Professional Experience

2013-Present	ESTERN Medical CRO Global Group Boston – Cambridge, Massachusetts, USA Senior Scientific Clinical Medical Advisor
2010 -2013	Eurotrials Brazil VP sales-marketing & clinical operations
2009-2010	Medpace – Latin America General Manager Latin America
2003-2009	PRA International – Latin America Director of Operations
1997-2002	QUINTILES Brazil General Manager
1994 -1999	Bio-Ciencia Lavosier Member of the Board – Research & development
1992 -1994	Abbott Laboratorios Do Brazil Scientific Manager – Pharmaceuticals Division

Dr. John Amedio, PhD.

Senior Corp. R&D Scientific Advisory Board

Dr. John Amedio was appointed Member of the Corporate Advisory Board since July 2009.

Dr. John Amedio is the Head at Amedio CMC Consulting firm in Boston.

Most recently he served as the Vice President, Manufacturing & Process Development at Seaside Therapeutics LLC. Dr. Amedio has more than twenty years of experience in major and start-up pharmaceutical companies. He has extensive experience in all aspects of Chemistry, Manufacturing and Controls (CMC), including regulatory agency document preparation, quality assurance, active pharmaceutical ingredient synthesis, drug product pre-formulation and formulation, analytical methods development and the preparation of clinical trial material for the appropriate developmental stage worldwide. Dr. Amedio has delivered numerous profitable and patented manufacturing processes (API and finished drug product, injectable and oral dosage forms).

Most recently Dr. Amedio was Vice President, Manufacturing & Process Development, ZIOPHARM Oncology, Inc., Executive Director, Analytical and Chemical R&D, EPIX Pharmaceuticals Inc., and Unit Leader, Chemical Research and Development Department, Sandoz Research Institute (currently Novartis Pharmaceuticals)

Dr. Amedio holds a Post-Doctoral, in Natural Product Synthesis/ Organic Chemistry from the State University of Oregon and completed his Ph.D., in Organic Chemistry (Synthesis, Isolation of Natural Products, Transition Metals) from the University of Delaware and B.S, Chemistry from the Manhattan College in New York.

Dr. Juan Gutiérrez, M.D.

Senior Corp. Diagnostic Radiological Imaging
Scientific Advisory Board

Dr. Juan E. Gutierrez, MD Joined on March, 2011 Diagnostic Radiological Imaging Corporate Scientific Advisory Leadership Team at ESTERN Medical CRO.

Therapeutic and Operational Clinical Trials Expert Strengthens Diagnostic Radiological Imaging Capabilities

Dr. Gutierrez has more than 20 years experience in clinical drug development in the fields of radiology and oncology. Previously at Bayer Health Care Pharmaceuticals (Former Berlex Laboratories) as the Director Medical Development Diagnostic Imaging, Dr. Gutierrez held increasing responsibilities for the operations, strategic planning and corporate development of a growing portfolio of radiopharmaceutical business. His key early phase experience includes multiple variations of early-phase Cardiology, CNS and Oncology trial designs including traditional dose-escalating maximum tolerated dose design as well as various optimal dose designs for targeted diagnostic radiological imaging agents.

Dr. Gutierrez later phase oncology, cardiology & CNS experience includes extensive pivotal trial experience in the United States, Western and Eastern Europe, Latin America, and Asia-Pacific. With such clinical trials projects under his belt of clinical design and global implementation with Bayer Health Care (e.g. Vasovist, Magnevist, Gadovist, Ultravist and Iopamiron and Also with Guerbet Pharma Group with Dotarem).

As a clinician, scientist and investigator, Dr Gutierrez focus his knowledge with the clinical community with a bast track record of scientific clinical journals and book publications.

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

Dr. Gutierrez is currently an Vice-Chair Clinical Operations & Assistant Professor of Radiology Division of Neuroradiology & Director of Clinical Trials Division at The University of Texas Health Science Center in San Antonio, Texas, USA.

Dr. Alfonso Lozada, M.D.

Senior Corp. Diagnostic Radiopharmaceuticals
Scientific Advisory Board

Dr. Alfonso Lozada was appointed Member of the Corporate Advisory Board since July 2009.

Dr. Lozada has over twenty years of experience in the clinical pharmaceutical industry. He formerly served as the Executive Medical Director & Clinical Development at Bayer-Schering Pharma AG. , where he directed development and clinical launch of diverse pharmaceutical products such as Magnevist, Iopamiron, Gadovist, Levovist some of the world's top radiopharmaceuticals.

Dr. Lozada, is a clinical radiologist and a director & professor of molecular radiology imaging at his alma matter at the National University of Colombia in Bogota.

Dr. Lozada has track record of numerous international clinical book publications in radiopharmaceuticals. His expertise has made him one of the top key opinion international leaders in the medical community.

Dr. Lozada received his medical degree and residency training in Diagnostic Radiology from the National University of Colombia in Bogota, (UNAL). With a subsequent fellowships at the Jackson Memorial Medical Center, Radiology Department in Miami, Florida, USA and at the Centro de Treinamento em Ultra-sonografia, Ribeirão Preto, São Paulo, Brazil.

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Our Company International Reach

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