



Clinical Research Organization & Consulting
for Biotech, Pharmaceutical &
Medical Device Companies



Accelerating Clinical Trials Across the U.S North America
& Latin American Emerging Markets.
Your R&D Study Our Focus

Transform your Clinical Trial Research Development with ESTERN Medical CRO

As a leading full service Contract Research Organization (CRO), ESTERN Medical is at the forefront of transforming clinical trials.

We are transforming the clinical trial landscape across all phases of Pharmaceutical, Biotech & Medical Device Development, combining therapeutic and operational expertise with local knowledge. ESTERN Medical provides personalized service customized to your unique trial requirements. Our U.S. & Latin American International span and innovative approach is supported by our flexible and reliable service, delivered by dedicated employees skilled in ensuring that you achieve your long-term goals.

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

****Source Tufts University Study of Drug Development***

ESTERN Medical conducts clinical trials across all therapeutic areas in more than 22 countries and provides services in all phases of clinical development through our U.S. & Latin American offices.

Since our inception in 2002, ESTERN Medical has amassed a level of expertise that has enabled us to work on a variety of novel Pharmaceutical compounds & medical devices, ranging from

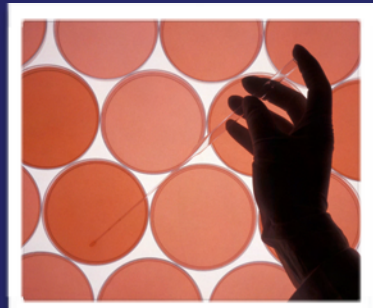
niche treatments to blockbuster drugs and biosimilars, as well as medical devices.

ESTERN Medical forward-thinking and innovative approach to drug development & medical devices programs, our commitment to demonstrating the safety and efficacy of new drugs, devices and patient outcomes and our CRO services that surpass the traditional methodology have made a clear difference to healthcare patients around the world – and will continue to do so in the future of Clinical Trials R&D.

Over the last 12 years, we have distinguished ourselves as a CRO adept at conducting complex, global clinical trials and bringing new Pharmaceutical & Medical Devices to market.

ESTERN Medical is often requested to conduct research in multiple countries, integrate research results in a global database and prepare clinical trial results for submission to multiple US & LATAM international regulatory authorities.

ESTERN Medical's international presence enables us to monitor clinical trial activities in numerous countries using our own clinical team members.





Experience That Inspires Confidence.

Your Study Our Focus

ESTERN Medical is of the leader in clinical trial development services, ranked first by sponsors across virtually all service quality attributes.

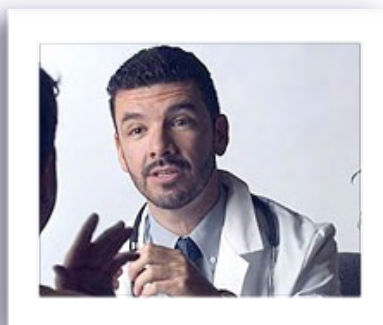
From small trials to multi-national mega-trials, we leverage our decades of experience to ensure you get results that are reliable and timely. We are committed to delivering quality results while ensuring patient safety at every step.

Competitive Costs work with our customers to find project within budget parameters to our sponsors while maintaining our differentiating personal interaction element of commitment of excellence

What Sets Us Apart?

We offer clients expertise in nearly every R&D trial study type

and therapeutics category, a comprehensive offering support services, clinical trial execution across the USA and Latin America, in some of the largest and most diverse study populations in early and late clinical development.



Our Scope Unmatched access to diverse populations

ESTERN Medical executes its Pharmaceutical & Medical Device sponsor clinical trials in university, private and government institutions in U.S.

Across U.S. North America & Latin America with access to a proprietary database of

participants. The team that you trust for fir-in-human or Phases I, II & III & IV will be there when your pharma-drug or medical device is ready for patient trial execution.

★ Geographic diversity in the patients populations across U.S. & LATAM

★ Access to special populations Asian, African, Latin & European.

★ Access to difficult to recruit populations.

★ Collaboration with local physician and medical research communities and EC/IRB & MoH institutions.



ESTERN Medical Unique Services & Capabilities Providing Integrated Solution Through Clinical Trial Development

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
- Medical Writing IND, NDAS, PMAs 510Ks, Biostatistics
- Pharma 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, Medical Writing, Biostats
- Pharma & Medical Device Country Product Registration & Strategic Marketing Services in the U.S. & LATAM.

Product Development Expertise

THE FACT SHEET

Phase I/III & IV Global Clinical Development

Highly Skilled Investigators, Broad Diverse Patient Population Across Latin America Land Opportunity

Reach Quality Patient Population Faster

To navigate the New Health with ease & success, you need simplified access to the right subjects at the right time. And with more than 2,000 investigators (adhering to FDA, EMEA and ICH-GCP standards) and professionals in offices across all nine major Latin American countries, ESTERN Medical is your key to expediting studies.

Latin America has large metropolitan hospitals the with latest

vanguard technology and more than 40,000 highly trained physicians. Much of this area has a disease profile similar to that of North America and Europe, including complex diseases such as oncology, cardiology, infectious diseases and HIV, as well as age-related chronic diseases. Plus, many previously untreated patients are highly motivated to enroll in Pharmaceutical or Medical Device clinical studies.

You also have rapid access to many special populations, including pediatric populations and patients with tropical and infectious diseases — and the flexibility for year-round seasonal studies via its southern hemisphere locations. With ESTERN Medical as your ally and partner in Latin America is now within reach.

Prevalent Diseases

- ★ Cancers
- ★ Diabetes
- ★ Infectious Diseases
- ★ Hypertension
- ★ Rheumatoid Arthritis
- ★ COPD
- ★ Osteoporosis
- ★ Alzheimer's Disease

Quality Data

★ *Data capture and management comply with FDA and EMEA guidelines*

★ *90% of the studies we have conducted supported submissions in the US and Europe*

★ *Consistent global data quality — we follow the same study protocols and deliver the same high-quality data as in Europe and the U.S.*



State-of-the-Art Technologies

★ 95% of our investigator sites have Internet access, which means we can undertake EDC clinical trials

★ 24/7 communications from anywhere in the world — study updates and patient recruitment data are uploaded real-time to a secure Project Communications Internet site giving you immediate access to data and reports anytime you need them

Key Regional Facts

★ A population of more than 597.5 million people across 21 countries

★ World representation from a wide range of demographics

★ Many previously untreated patients

★ Medical standards and procedures at university hospitals are identical to those in the U.S.

Latin America Ranks “3rd” place on Phase III Pharma & Medical Device Trials & U.S. Ranks “1st”.

*Source: NEJM

ESTERN Medical CRO

★ In the region since 2002

★ Five offices in all key major Latin American countries – Argentina, Brazil, Chile, Colombia, Mexico.

★ Central laboratory support in Latin America

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 & *LATAM Clinical Trial Authorizations: Overview and update; Regulatory Focus, June 2009

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 US & Latin America	83.307

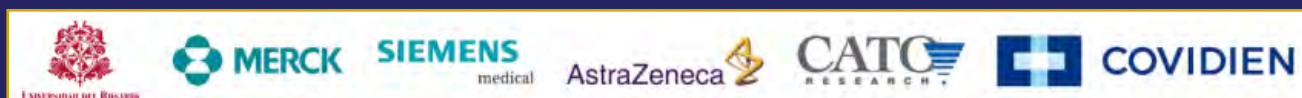
*Source: Clinicaltrials.gov, January/ 2014

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

Our Partners, Alliances & Sponsors



Our Company International Reach

- *Boston & Cambridge (USA)
- *Mexico City (Mexico) - *Bogota (Colombia) - *Santiago (Chile) -
- *Buenos Aires (Argentina) - *Sao Paulo (Brazil)

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For more information on our CRO Services, please Contact Us at one of our Country office locations or visit by Web: www.esternmedical.com
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