



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



Transcontinental Clinical Trials: Redefining Medical
Research across U.S. North & Latin America



Revolutionize Clinical Trial Research with ESTERN Medical CRO Life Sciences

As a premier full-service Clinical Contract Research Organization (CRO), ESTERN Medical leads the charge in revolutionizing clinical trials.

Our comprehensive services span all phases of Pharmaceutical, Biotech & Medical Device Development, merging clinical R&D therapeutic and scientific operational expertise with localized insights. Tailoring our services to your specific clinical trial needs, ESTERN Medical leverages its extensive reach across the U.S. & Latin America, supported by an innovative approach and delivered by dedicated clinical research professionals adept at achieving your long-term R&D objectives.

With over 24,000 FDA-Regulated Investigators in the U.S. & Latin America, witnessing rapid expansion across LATAM, the region presents a vibrant research landscape. (*Source: Clinical Trials Gov)

Operating across more than 22 countries, ESTERN Medical conducts clinical trials across diverse therapeutic areas and provides comprehensive services throughout the U.S. & Latin America.

Since our establishment in 2002, we've accumulated expertise enabling us to engage with a spectrum of novel pharmaceutical compounds & medical devices, ranging from

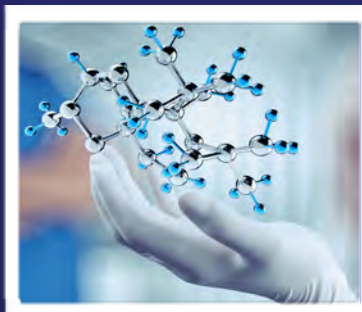
groundbreaking treatments to blockbuster drugs and biosimilars, including Class III medical devices.

ESTERN Medical's forward-thinking approach to clinical drug development & medical device programs, alongside our commitment to demonstrating the safety and efficacy of new drugs, medical devices, and patient outcomes, together with CRO services that transcend conventional methodologies, have left a tangible mark on global healthcare – a legacy that will shape 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.

With 22 years of experience, ESTERN Medical stands out as a CRO adept at conducting intricate, global clinical trials and introducing cutting-edge Pharmaceutical & Medical Devices to the market. Frequently entrusted to conduct research across multiple countries, integrate results into international databases, and prepare clinical trial submissions for various US & LATAM international regulatory authorities.

Leveraging our international presence, ESTERN Medical oversees clinical trial activities across numerous countries utilizing our clinical team members.





Experience that Inspires Confidence.

Your Study Our Focus

At ESTERN Medical, we're not just leading the pack in clinical trial development services. We're setting the bar higher, consistently surpassing industry benchmarks for service quality R&D.

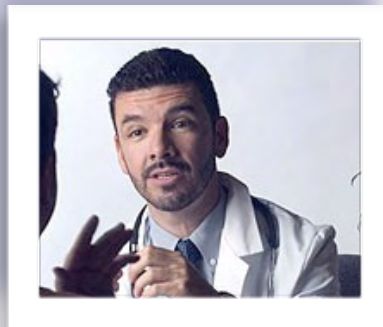
Whether it's managing small-scale projects or overseeing multinational endeavors, our extensive track record ensures outcomes that are not only dependable but also delivered promptly. With a steadfast commitment to excellence, we prioritize patient safety at every stage of the process.

Cost-Effective Solutions: Our collaborative approach means we work closely with Sponsors to align RFP projects with budget parameters while maintaining our signature commitment to personalized service.

What sets us apart?

We bring unmatched expertise across a broad spectrum of R&D trial types and therapeutic

categories, offering comprehensive support services and executing trials across the USA and Latin America. With access to some of the largest and most diverse study populations, both early and late-stage clinical development.



Our Global Reach: access to diverse populations!

ESTERN Medical conducts clinical trials sponsored by pharmaceutical and class III medical device companies in a variety of academic, private, and governmental institutions across the U.S. & LATAM.

Operating across North America and Latin America, our proprietary clinical database grants us access to

an extensive pool of participants. Whether it's first-in-human trials or overseeing Phases I, II, III & IV, our seasoned team is equipped to ensure the seamless execution of your pharmaceutical or medical device trials.

★ **Geographic diversity:** access to diverse patient populations across U.S. & LATAM.

★ **Specialized Demographics:** access Asian, African, Latin & European cohorts.

★ **Overcoming Recruitment Challenges:** access to hard-to-reach populations.

★ **Collaborative Engagement:** building partnerships with local physician, medical research communities, and Regulatory EC/IRB & MoH institutions.



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

CLINICAL RESEARCH



- Harnessing Phases I, II, III & IV
- Dynamic Execution of Biotech, Pharma & Medical Devices Trials across U.S. & Latin America.
- Comprehensive Clinical R&D Project Management, Site Oversight, Regulatory Compliance, Medical & Clinical Monitoring and Pharmacovigilance.
- Proactive Patient & Investigator Recruitment.
- Precision execution of INDs, NDAs, PMAs 510Ks.
- Innovative cutting-edge Pharma Bioanalysis & Medical Services

Exemplary Process Optimization Expertise and Innovation

TECH INNOVATION HUB



- Next-Gen Medical Imaging (MRI, CT, Angio & Nuclear Medicine)
- Dynamic Interactive Web Response Systems (IWRS).
- Revolutionary Electronic Data Capture (EDC)
- Streamlined Integration Services.
- Complete CTMS Solutions.
- Modern ePro (Electronic Patient Diaries) Platforms.

Technology Expertise

Innovative Consulting Expertise



- Leading Clinical Product/Research Development & Regulatory Affairs.
- Revolutionizing Strategic Clinical R&D Compliance & Risk Management.
- Enhancing Clinical & Manufacturing Quality Processes.
- Advancing Clinical Trials Development Consulting.
- Guiding Pharma & Medical Device Product Registration & Strategic Marketing Services in the U.S. & LATAM.

Unlocking Product Development Excellence

THE FACT SHEET

Empowering Clinical Development Across Phases I, II, III & IV

Seizing Opportunities in Latin America's Healthcare Landscape

In a world of constant change, accessing the right subjects swiftly is key. With a network of investigators across major Latin American countries, ESTERN Medical expedites your study timeline.

Latin America offers state-of-the-art hospitals and a pool of skilled physicians, PIs, and Kols, mirroring disease profiles seen in North America and Europe. On all ranges of therapeutic diseases. Overall, the patient population is enthusiastic about clinical trial participation.

Explore unique patient populations and year-round study options with ESTERN Medical's dynamic approach to clinical development in Latin America.

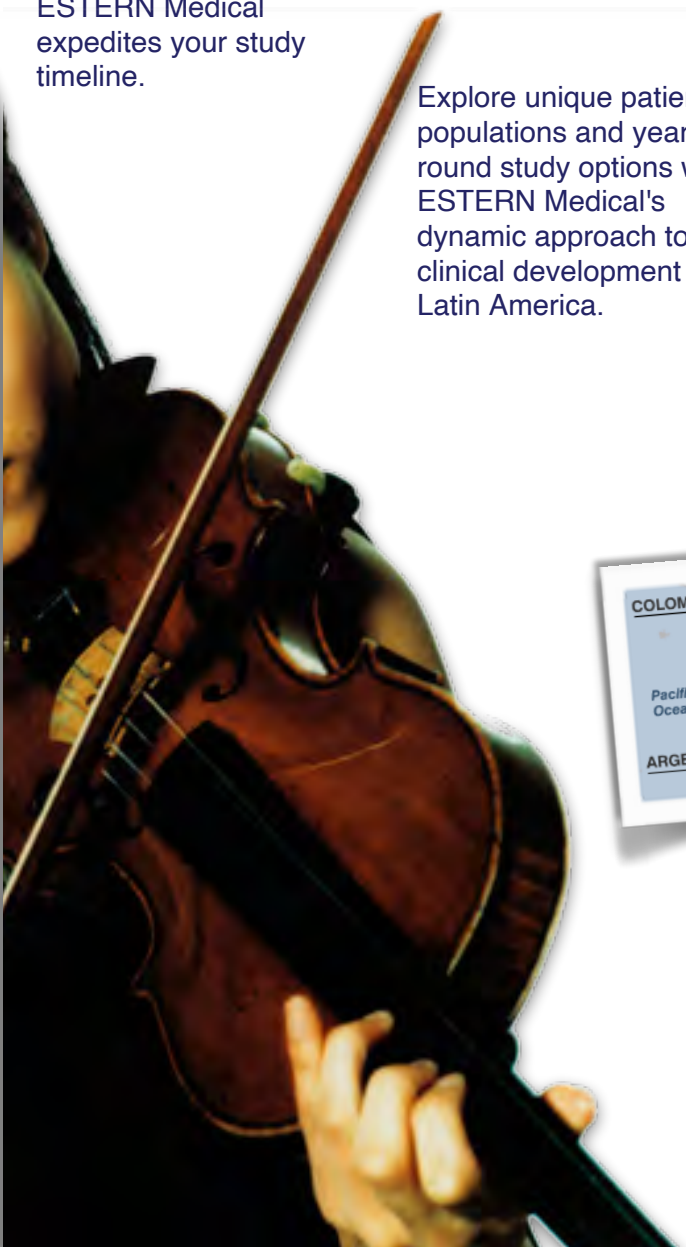
Prevalent Diseases	
★Oncology	★Rheumatoid Arthritis
★Diabetes	★COPD
★Infectious Diseases	★Osteoporosis
★Cardiovascular Diseases / Hypertension	★CNS / Alzheimer's Disease

Access Quality Data with Ease!

★ *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 US.*



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 Insights

★ Boasting a population of over 653 million across 21 countries.

★ Reflects a diverse demographic landscape on a global scale.

★ Abundant untreated patients present ample enrollment opportunities.

★ University hospitals uphold medical standards aligned with those in the U.S. Latin America

“LATAM Leads in Phase III Pharma & Medical Device Trials, with the U.S. ranking first”.

*Source: NEJM

ESTERN Medical CRO Life Sciences

★ Pioneering and setting the pace in the LATAM region since 2002, backed by extensive knowledge, expertise, and a proven track record in clinical trials, led by a seasoned management team acclaimed for their achievements in clinical trial development and management.

★ ESTERN Medical strategically positioned operational hubs across LATAM in Argentina, Brazil, Chile, Colombia, and Mexico.

Variation in Global Patient Recruitment Rates

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: Clinical Trials.Gov / US-FDA / EU-EMA / Q/1 2024

Current Listed Clinical Trial Across USA & Latin America

USA	171.238
Brazil	9.841
Mexico	4.939
Argentina	3.938
Chile	2.256
Colombia	1.899
Peru	1.244
Grand Total US & Latin America	195.355

*Source: Clinicaltrials.gov, April/ 2024

Patient Recruitment for all Diseases in Latin America

Effectiveness (patients / sites)	ESTERN experience: 20-60 patients per site
Regulatory Approval Times	Some Latin American countries have fast-track regulations regime

*Source: ESTERN Medical CRO Life Sciences Group Latin American Operations, 2024

Our Partners, Alliances & Sponsors



Our International Presence

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

Corporate Address

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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
of our management team will respond to you



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