Clinical Research

NAMSA®

PEOPLE › SCIENCE › SOLUTIONS

Experience. We know what matters most.

And when it comes to clinical research, we know that you want the perfect combination of speed and expertise. So we deliver.

The clinical phase can be the most time consuming, least predictable, most expensive, and most important part of your development effort. So we work smart from the start, saving you time and preventing costly do-overs by optimizing strategies and tools to guide you through. Our clinical experience encompasses a broad range of technologies, therapies, and indications. With a tight focus on devices, IVDs, and biologics, we've designed and conducted trials to address many varied client objectives—from first-in-man through post-market—whether the intent is to obtain market approval, improve reimbursement, or generate publications.

We know that the best clinical data requires knowledgeable support staff and product-specific expertise. So we hire professionals with the right backgrounds and provide them with the best systems and tools available. We also create expert teams—clinical, regulatory, biostatistics, data management—and put them to work for you. The breadth and depth of their combined expertise brings efficiency to the process, helping you realize the full potential from your data.

Our clients return to us time and time again because they trust our integrity and judgment. By listening carefully, communicating clearly, and paying attention to the details, we deliver your clinical results with confidence. And our experience spans the globe: North America, Europe, Asia, South America, and Australia. Our systems and staff have been meeting needs and creating success for both start-up enterprises and Fortune 100 companies for decades with proven success.

STUDY DESIGN

Our clinical managers have both depth and breadth in multiple therapies and devices to assist you with:

- selecting the best endpoints to reach your goal
- writing the protocol
- managing FDA interactions effectively
- incorporating health outcomes measurements

STUDY MANAGEMENT

We are ISO 9001:2008 certified and consistently deliver results for all types and sizes of clinical trials through best practices such as:

- highly trained, device-focused staff who communicate with respect and warmth
- template documents, checklists, and forms
- meticulous planning to ensure clarity and efficiency
- GCP, ICH, and FDA standards for data integrity and patient protection

BIOSTATISTICS

From the most basic statistical analysis plans to clear, accurate data reports for regulatory submissions, we cover the full spectrum of statistical support. Common assignments include:

- FDA meetings and teleconferences focusing on statistical design
- audits of project conduct and data management practices
- support for FDA BIMO (bioresearch monitoring) inspections
- clinical data interpretations

DATA MANAGEMENT AND EDC

We offer both paper-based and electronic data capture (EDC) platforms for comprehensive data management support. Our customized EDC platform is the industry's best for functionality and ease of use. We offer:

- EDC core functionality
- EDC tools
- one of the most robust clinical trial management systems (CTMS) tools in the industry
- full-service data management support through in-house professional data managers
- a team approach to ensure integration with our clinical teams

DATA MONITORING AND CLINICAL EVENTS

Managing the administrative details and workload of clinical events committees (CECs) and data monitoring committees (DMCs/DSMBs) can be a huge burden. Our experts can lighten your load by establishing and managing these committees through a process for documenting and reporting adverse events (AEs) that ensures compliance. Common assignments include:

- developing committee charters and procedures
- negotiating remuneration with committee members
- document preparation, communication, scheduling, and facilitation

REPORT AND MANUSCRIPT WRITING

Our writers are postgraduate-level clinical and scientific experts who team with our statisticians and our clinical and regulatory colleagues for the clearest presentation of data. Common assignments include:

- interim and final clinical reports
- ghostwriting for academic journal manuscripts, advisory panel presentations, and expert opinion letters
- literature summaries
- regulatory submissions

CLINICAL EVIDENCE AND POST-APPROVAL

Regulatory approval is meaningless without clinical evidence to back product claims. We offer a broad array of support to help you justify and differentiate your product claims, including:

- literature-based meta-analysis
- post-market patient registries
- cost-effective support for FDA condition-of-approval (CoA) or post-market studies

CLINICAL AUDITING

We know what constitutes quality clinical data and data collection—from both regulatory and investor perspectives. Common assignments include:

- development and gap analysis of clinical SOPs
- pre-audit for bioresearch monitoring (BIMO) inspections
- preparation and support for FDA site inspections
- clinical audit assignments (M&A due diligence) for financial and strategic investors
- confirmation of data suitability for FDA submission
- expert opinion on statistical conclusions

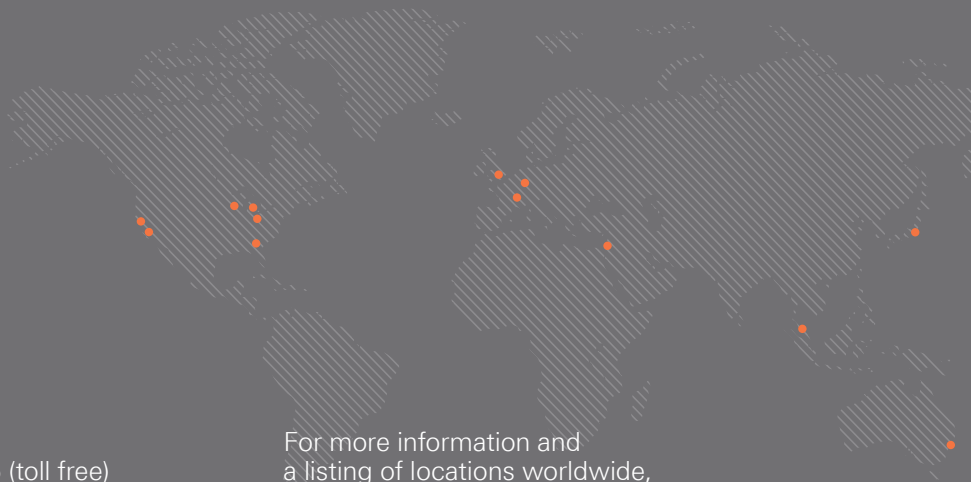
We've been the world's leading medical device research organization for over 40 years.

You want sound advice and action from a partner who can quickly move your product into a global market. So we've made a science out of service, identifying challenges and solving them with the right advice at exactly the right time. We can guide and support you through the most complex submissions and the most rigorous testing programs. We do the work that moves things forward quickly without ever compromising quality. And our passion for scientific integrity gives you the security that you're on the optimal path to market, anywhere in the world.

We've worked with thousands of companies to date—bringing safe, effective, and compliant medical products to market. We are passionate about our people, our scientific integrity, and the breadth of solutions we offer our clients globally. And we're ready. Ready to take you to market.

OUR SERVICES

Regulatory and Quality Systems Consulting
Research and Development Support
Non-Clinical Testing
Clinical Research
Post-Market Support



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