Premier Research Medical Device and Diagnostics

Complete life-cycle services for medical devices

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Who we are and what we stand for

+ We're a dedicated, experienced, well-informed Medical Device and Diagnostics team
+ We have two decades of experience across multiple therapeutic areas
+ Our experts provide full-service support across the medical device life cycle
+ We're expert project managers who put heavy emphasis on planning, strategy, and risk mitigation
+ We're a thoroughly modern company that is simplifying the complex work of drug development through innovative use of technology

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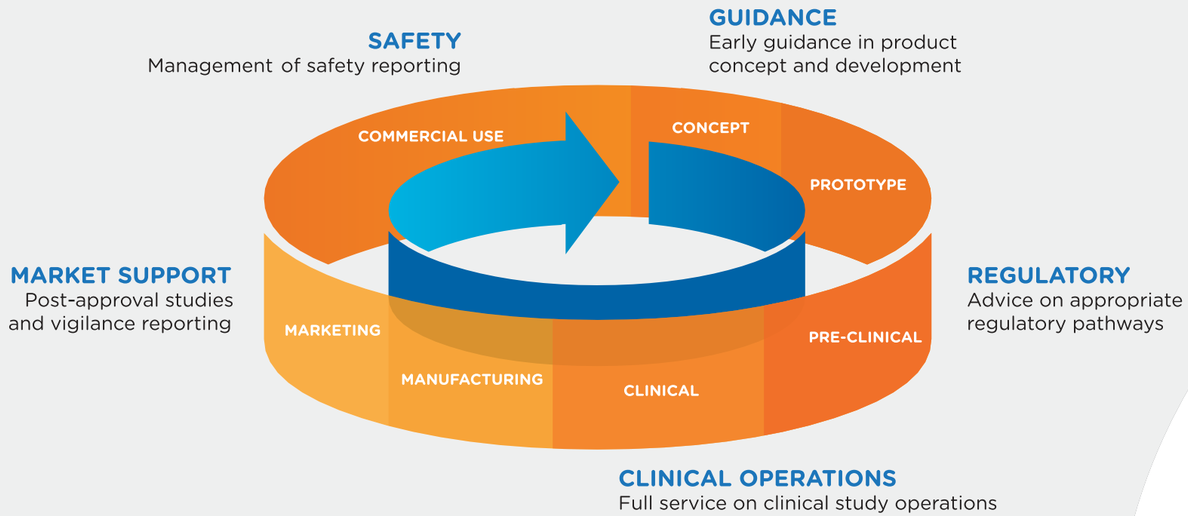
What we do

The device experts, from bench to bedside

A long road stretches between the birth of an idea and the launch of a new medical device. We've traveled that road extensively and know it well — every bend and every bump.

From early strategy development to regulatory approval, pricing, and reimbursement strategies, we know the challenges medical device companies face across every therapeutic area. We have more than 20 years of hands-on experience across key regulatory jurisdictions and patient populations worldwide, having completed more than 200 projects involving 34,000 patients in the past five years alone.

We know the nuances specific to each device category, whether you're working in cardiovascular, orthopedic and spine, oncology, gastrointestinal, infectious disease, combination products, or general surgery. You'll find us capable, reliable, and easy to work with. Whether you're doing a 10-patient feasibility study or a 10,000-patient post-marketing trial, we're ready to help you.



The best time to plan is ahead of time

Contact us today. We'll be happy to discuss any upcoming projects and offer ideas on the surest and most efficient ways to get where you want to go.

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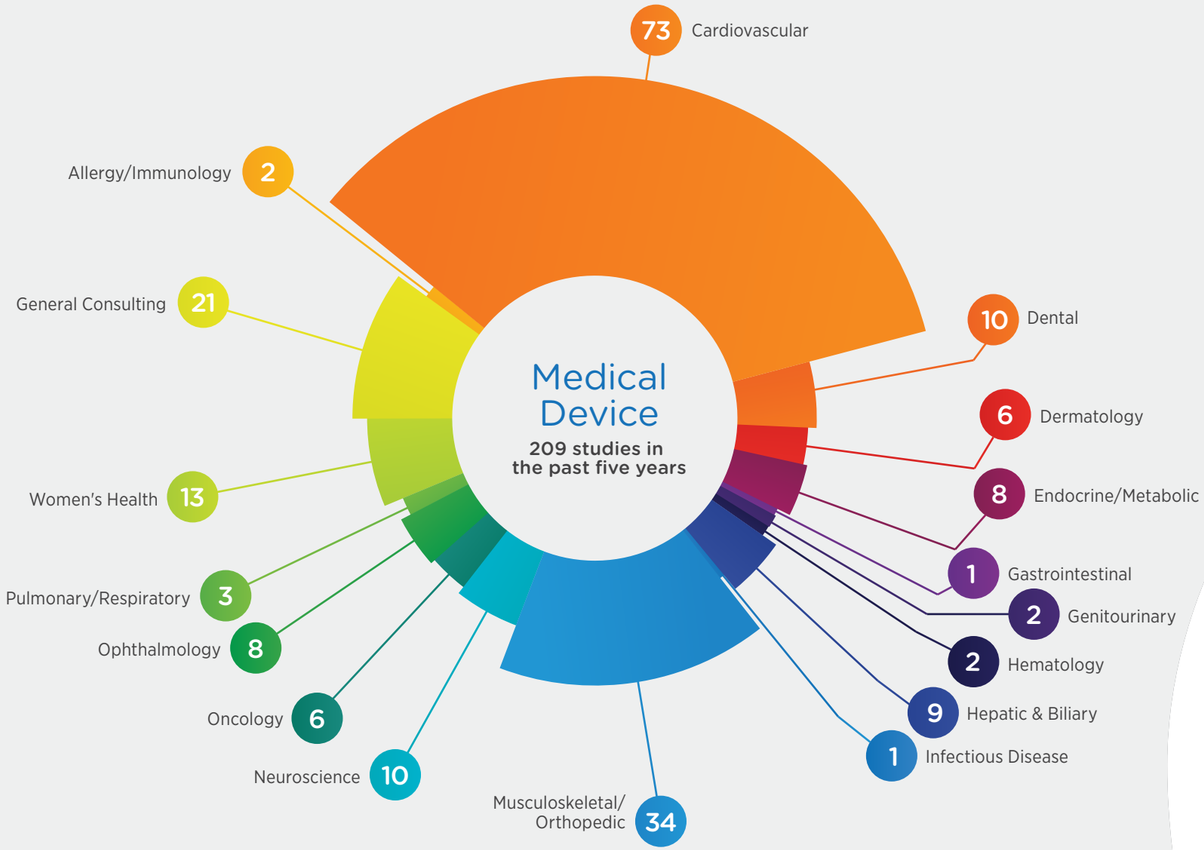
Experience across device types, therapeutic areas, and geographic regions

Medical device is a field of specialties, and we can staff your project with experts who have worked across multiple device areas, from transcatheter valves to device, biologic, or drug combinations. Our specialists:

+ Are locally based in key regions and fluent in the local languages, plus English. They know what needs doing and where to call for help.
+ Have established longstanding relationships with key opinion leaders globally.
+ Bring a lot of experience to the job. Our people are trained in the nuances unique to successful delivery of medical device trials. All have clinical or nursing backgrounds and can be trained to provide on-site technical support.



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Life-cycle services

We support our customers in managing the development process just as effectively as the global giants do. We don't do just what you ask, but think about everything you might need from the perspective of a team whose collective experience is almost certainly broader and more extensive than that of any single sponsor.

Regulatory expertise

Your development plan for attaining regulatory approval can make a huge difference in success and timing. Our experts within our Medical Device and Diagnostics team know how the regulatory maze works and how to find the best pathway for your product. In addition to unparalleled strategic and tactical input, we offer practical solutions on guiding regulatory submissions, attaining Medicare reimbursement, and ensuring compliance with newly revised FDA and EU regulations in areas such as 510(k) applications, CE marking, and post-market surveillance.

Our customers are big thinkers, pursuing the most challenging areas of study to advance the cause of life sciences. We've put everything in place to take you from proof of concept to regulatory approval and ensure that your clinical trial investment is spent wisely.

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Clinical operations

Knowing how to plan ahead

With 20 years of experience devoted to medical device development, the clinical experts at Premier Research know how to plan ahead, avoid issues, and resolve any that do arise before they cause major delays.

Our full-service support includes:

+ Strategic and tactical study design
+ Project management
+ Clinical monitoring
+ Medical affairs and strategic consulting
+ Interactive randomization technologies
+ Electronic data capture
+ Data management
+ Biostatistics
+ Medical writing
+ Quality assurance
+ Regulatory affairs
+ Technology that automates and simplifies the clinical development process and helps our customers, employees, and vendors focus more on innovation and less on administration

Post-marketing support

It isn't over until your new device is established as a valued, trusted brand. We can direct your efforts to most effectively build your brand's success by providing:

+ Health economics and reimbursement strategies
+ Post-marketing surveillance and registry services tailored to your internal capabilities and resources

Risk management

We hate unnecessary risk, so our global teams make a big point of predictive planning, with a strong emphasis on risk prevention. Rather than take a "find it and fix it" approach, we offer:

+ Up-to-date intelligence on changing FDA and EU regulations
+ Customized safety and vigilance management
+ Data and safety monitoring board and clinical events committee services
+ Risk-based monitoring

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Global reach

We're where our customers need us

Global doesn't always mean *big*. Here, it means we're strategically located where customers need us, providing rapid access to patients and improving efficiency.

Whether you need outpatient clinical sites or specialized surgical centers, we can engage the sites you need. And our regional office network provides biometrics, medical writing, safety, regulatory, and post-marketing services.

Quality compliance

Premier Research maintains a high level of standards and an effective Quality Management System. All medical device and diagnostics procedures, including SOPs, working guidelines, and workflow processes, are written to ensure compliance with ISO 14155: 2011, EU Clinical Trial Directives, and supporting documents — including local country requirements and all relevant FDA 21 CFRs.

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How can we help you?

Contact us today. We're ready to answer your questions and help you find the solutions that meet your needs.

+ Strategic and regulatory advisory services
+ Clinical trial set-up and operations
+ Post-marketing surveillance and registry support
+ Global safety services

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IT'S WHAT WE DO. BEST.™

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About Premier Research

Premier Research is a leading clinical development service provider that helps highly innovative biotech, medical device, and specialty pharma companies transform breakthrough ideas into reality. The company has a wealth of experience in the execution of global, regional, and local clinical development programs with a special focus on addressing unmet needs in areas such as analgesia, dermatology, medical devices, neuroscience, oncology, pediatrics, and rare disease. Premier Research operates in 84 countries and employs 1,000 professionals, including a strong international network of clinical monitors and project managers, regulatory, data management, statistical, scientific, and medical experts. They are focused on smart study design for advanced medicines that allow life-changing treatments.

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