premier research

Built for Biotech℠

Medical Device Development Services

Who is Premier?

premier research

Talent

Decades of R&D expertise, global compliance, and therapeutic experience

Culture

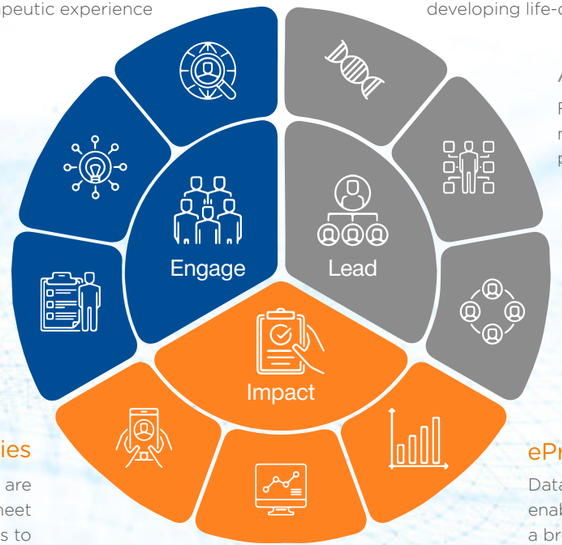
Passionate support for our sponsors to help answer the unmet needs of patients

Patient Focused

Dedicated patient access teams and advocacy initiatives to help support our patient-centered research

mHealth Strategies

Mobile strategies that are customized and designed to meet the demand for swifter access to critical patient data



Built for Biotech

Outcome-focused insight and commitment to developing life-changing therapies

Agility

Flexible services to meet the needs of our biotech, specialty pharma, and device customers

Consultants

Offering unique perspectives, intelligent study designs, and a relentless focus on product development

ePremier

Data integration hub that enables study teams access to a broad range of study data

Adaptive Trials

From innovative study designs to faster study timelines and improved risk management

Medical Device Experience

163 Projects in the Past Five Years

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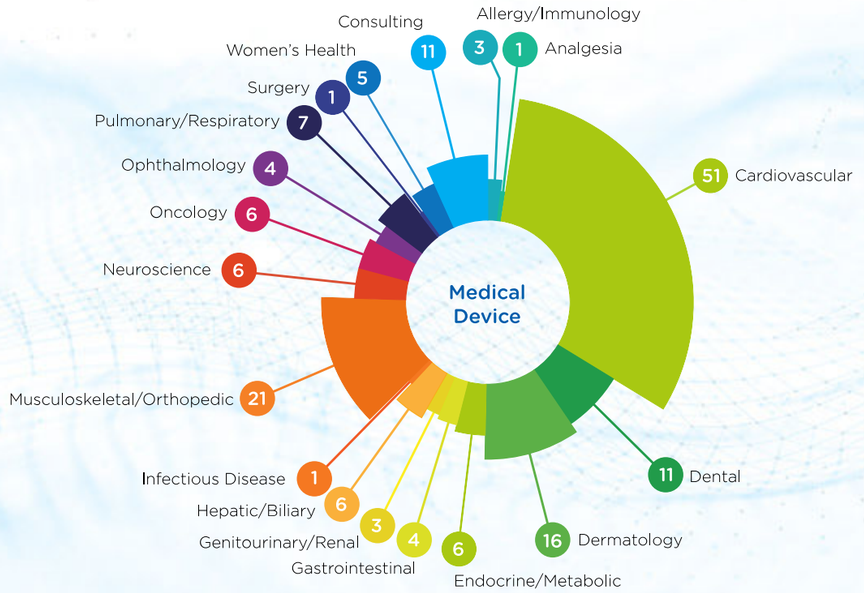
Clinical Development Expertise for Combination Studies

We supplement our device expertise with extensive clinical development experience across therapeutic areas.



Helping you Optimize Your Medical Device's Development Pathway

Whether you're conducting a 10-patient feasibility study or a 10,000-patient post-marketing surveillance study, we know all the steps — from scientific breakthrough to successful outcomes. Our experience spans just about every type of device, from transcatheter heart valves to dermatologic devices and everything in between.

Many members of our medical device team come from manufacturers, so they know which questions to ask: What endpoints will global regulatory bodies expect and approve? What indication provides the best return on investment? Which claims make sense? What about pricing, and ensuring that your device qualifies for separate reimbursement?

We understand the differences among categories of medical devices, and our regulatory team tracks the latest global policy shifts and regulatory requirements.

Innovating with our Sponsors

Nimble, Innovative, and Modular:

As devices rely more on technology and innovation; our teams are prepared to partner with you as innovators and provide our expertise in a ‘Fit for Service’ model that works best for your innovation.

Focused on Innovative Medical Device Development:

- Wearables
- FemTech
- Software as a Medical Device (SaMD)
- Biosensors
- AI and ML solutions
- Companion Diagnostics

Clinical Development Expertise For Combination Studies

When you're developing a combination product, therapeutic experience has no substitute. We supplement our device expertise with extensive clinical development experience across therapeutic areas.

Cardiovascular

- Transcatheter aortic valve implantation (TAVI)
- Heart valve replacement and repair (both aortic and mitral)
- Mechanical reperfusion device (bare metal and drug-eluting stents)
- Thoracic endoprosthesis and stent
- Drug-eluting balloon
- Catheter (laser and drug-eluting)
- Cardiac assist devices
- PFO closure devices
- EP – ablation systems
- CRT devices
- Baroreflex stimulator cardiac pressure monitoring devices

Clinical Development Expertise For Combination Studies (cont.)

Oncology

- IVD study for Polycythemia Vera
- Surefire® Infusion System – liver metastases

Dermatology

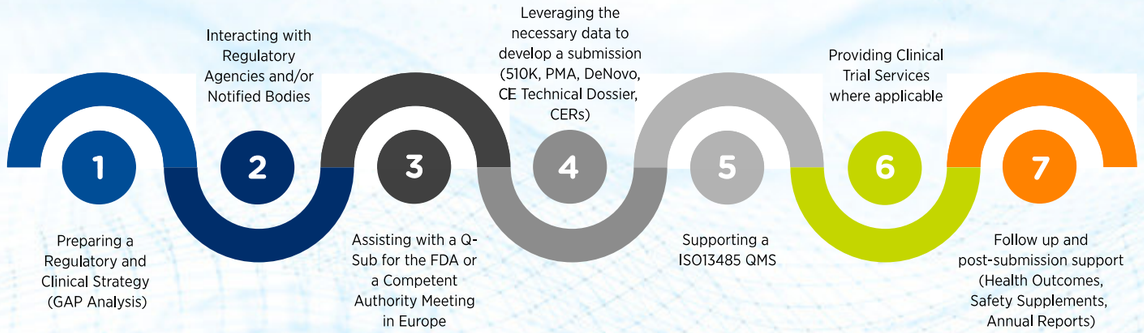
- Antimicrobial swabsticks
- Dermal filler
- Neuromuscular blocker, botulinum toxin (onabotulinumtoxinA)
- MT10109L (NivobotulinumtoxinA)
- In vitro diagnostic

Musculoskeletal/Orthopedic

- Autologous chrondrocyte implant system
- Injectable disc nucleus
- Interbody fusion
- Integrated knee system
- In vitro diagnostic – rheumatoid arthritis

Supporting the Device Journey

We understand the differences among categories of medical devices, and our regulatory team tracks the latest global policy shifts and regulatory requirements.



Helping You Optimize Your Medical Device's Development Pathway

Expertise:

Regulatory Affairs

- Regulatory submissions (510(k), De Novo, CE Marking, PMA)
- Agency meetings
- Regulatory writing
- Labeling support
- Project management
- Publishing services

Consulting

- Product development strategy
- Competitive intelligence
- Using regulatory, clinical, quality, and HECON to develop product development plans
- Product licensing and acquisition due diligence services

Quality Systems

- Quality management system strategy
- QMS set-up and compliance to ISO 13485
- Remediation programs
- Risk management
- SOP drafting and review

Getting Started is Easy

INITIAL CONSULTATION

SIMPLE TIME & MATERIAL CONTRACT

INITIAL DELIVERY OF A GAP ANALYSIS

- Sensitive to time and cost; our experts are keen to deliver a custom analysis of your requirements within an acceptable range.
- An average gap analysis project can be 2-4 weeks and costs range from $20-30K

Global Coverage and Office Locations

2000+ Employees
Managing Projects
in 75 Countries

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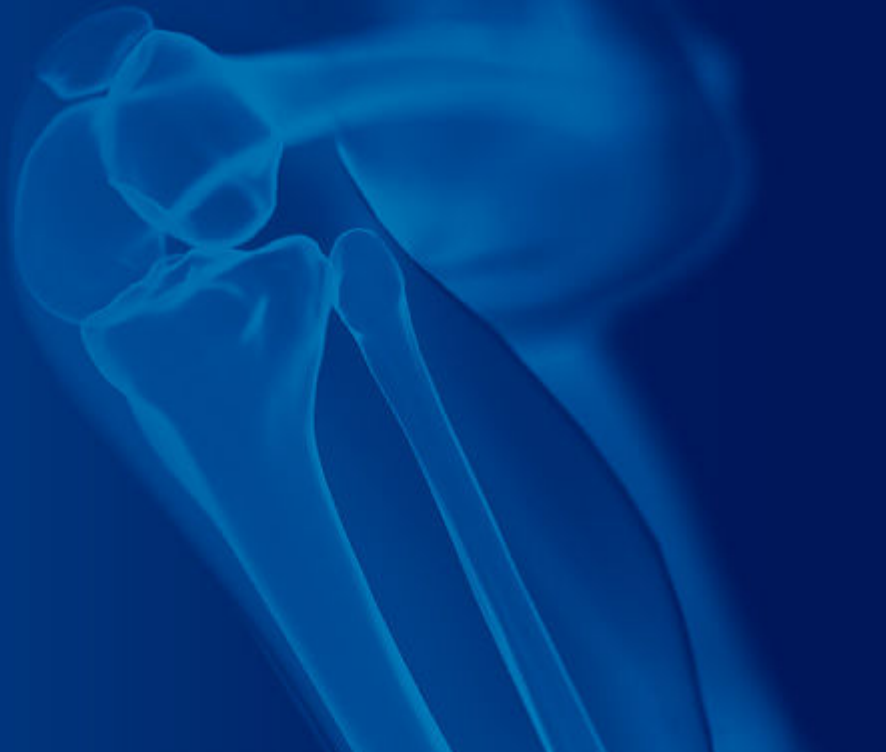

Need more information? **Contact us**

Email: info@premier-research.com

premier-research.com