

Medical Devices and *In-Vitro* Diagnostics (IVDs)



The medical device market is going through a major transition, with more rigorous clinical trial requirements both pre- and post-approval. We know and understand this evolving landscape and offer guidance and project management for every aspect of the “go-to market” strategy including study design, clinical trial implementation, the regulatory submission process and product stewardship.

Dr. Alan Touch, Principal Strategist, Medical Devices and Diagnostics, INC Research



Preview INC Research’s capabilities

- We’ve conducted more than 330 medical device and IVD studies
- We’ve conducted more than 110 medical device regulatory consulting and management projects
- Our experience spans more than 100 countries
- We’ve worked on more than 60 different product types, from ablation to vestibular devices
- IVD/biomarker studies for diagnostic and predictive outcomes
 - Development and validation studies for laboratory-based, point-of-care or home-use products
 - Companion diagnostics
 - Specialized statistical models
- Pre-market studies
 - Medical devices and diagnostics with single or multiple endpoint models
 - Combination device-drug delivery products
- User acceptance/product satisfaction studies
 - Human factors impact (instructions for use)
- Post-approval studies
 - Voluntary post-marketing life-cycle surveillance
 - Agency-required safety surveillance studies
 - Claim-strengthening marketing studies
 - Registries
- Specialized statistical models
 - Adaptive design
 - Bayesian statistics
 - Sample collection models
 - Multiple end-point design

A unique approach in a growing market

Currently standing at \$300 billion, the medical devices market is growing. However, changing regulatory requirements and increased scrutiny from healthcare providers and the general public have resulted in the need for innovative trials that use the best statistical models to generate actionable and defensible data.

By utilizing our “whole lifecycle” experience (spanning from conception to commercialization and beyond), our team will help you develop “go-to-market” regulatory strategies and clinical trial plans that use local knowledge to ensure region-specific solutions. And because our cross-functional collaborative model combines global therapeutic, operational and regulatory expertise with medical device and diagnostics experience, we create fully integrated alliances that unite consulting with implementation to save time and money - a unique offering in the world of medical device service providers.

Medical device and IVD expertise and leadership



Therapeutic expertise and leadership



Trusted Process® quality delivery engine

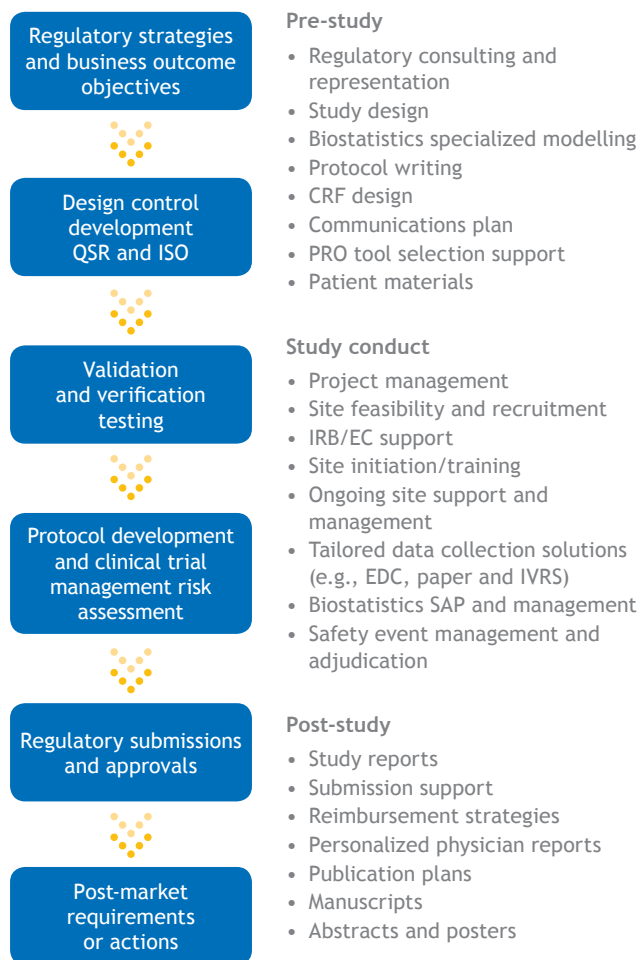


Study conduct success

An integrated alliance creates efficiencies by:

- Maximizing your return on investment
- Sharing the risks of product development
- Standardizing processes and resources across programs
- Leveraging clear communication protocols
- Eliminating the bidding process
- Avoiding project-based start-up costs
- Leveraging economies of scale
- Utilizing transparent and repeatable processes
- Developing performance-measured alliances based on payment milestones
- Ensuring quality with dedicated expert teams
- Utilizing proven project and alliance management tools

Our seamless full life-cycle approach



Long-standing therapeutic expertise

Solid therapeutic knowledge is essential to the efficient design and implementation of clinical development strategies. That's why we're particularly proud of the fact that our medical and operational expertise covers more than 90 percent of drugs in development today. This expertise means no matter the focus of your product, we have the patient insights and regulatory climate understanding needed to ensure your strategy is built on a solid foundation of knowledge, while adhering to the global medical device and IVDs regulatory guidelines.

Proven operational excellence

When it comes to implementation, INC Research has one advantage that's hard to beat - its global, full-service capabilities, ensuring we're well placed to turn your strategy from advice into action. And because our trials are conducted using our Trusted Process® methodology, we reduce risk, improve data reliability and reduce cycle times by standardizing the operational aspects of a trial.

Global regulatory expertise

Regulatory requirements change from region to region, making local knowledge invaluable. With experience spanning more than 100 countries, our experienced team can advise you on a plethora of issues, for example pre-IDE activities, safety/performance dossier preparation, the pre-IDE review process, 510(k) process, IDE/PMA approvals, CE mark registration, 2010 EU IVD Regulation application and international implementation of GHTF Device and Diagnostics Guidance.

For more information

about INC Research's medical devices and *in-vitro* diagnostics capabilities, please contact us at info@incresearch.com or at one of the numbers below:

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Therapeutic Foresight.
Trusted Results™