

Managing the medical device lifecycle: The i3 difference

i3 can strengthen and accelerate the lifecycle of your medical device, from the strategic design and conduct of its clinical trials to the articulation of its value in the market, to help you gain greater competitive advantage. Here's how:

Operational expertise for deeper insight

We know that clinical trials for medical devices and technologies differ from pharmaceutical trials in significant ways:

- Randomized, double-blind studies are often not possible
- Regulatory pathways, including the opportunity for 510(k) approval, are more complex
- Key safety endpoints can be more challenging to establish

With the operational expertise to manage these nuances, i3 specialists apply an evidence-based approach to the design of cost-effective studies that can more precisely address your scientific, regulatory, and commercial needs.

i3 offers operations-enhancing capabilities in areas that include:

- Health economics
- Comparative effectiveness
- Safety/surveillance
- Technology

We can also provide clinical trial support for US Medicare reimbursement during an investigational device exemption (IDE), and offer a variety of post-market services in the areas of research, safety monitoring, and reporting. These reporting capabilities include coverage with evidence development, which provides limited Medicare coverage for sets of patients in exchange for contributing to a central data registry in support of post-market registry reporting requirements.

Therapeutic expertise for better patient care

i3's full-spectrum functional and therapeutic expertise—which includes the collective wisdom of 200 specialists with medical device experience in cardiovascular disease

alone—helps medical device companies gain the sharper insights that lead to better patient care.

Look to i3 for product development solutions that combine consulting-firm flexibility with the scientific depth of an integrated research organization, enhanced by deep expertise in therapeutic areas that include:

- Cardiology
- Central nervous system
- Oncology
- Respiratory & infectious disease
- Endocrinology & metabolic disease

i3 combines wide-ranging expertise with a deep understanding of your objectives

i3 appreciates the differences and similarities between clinical research for medical devices and technologies versus research for pharmaceuticals. Such considerations include:

- The importance of pre-trial integrity and post-trial positioning
- The intricacies of regulatory requirements from one country to the next
- The weight of doing things right through every complex step of a product's path to market

Our nuanced understanding of these and other key issues involved in bringing medical devices to market can make a critical difference in the real-world success of your product.

Regulatory expertise for smoother application processes

With the acquisition of CanReg, i3 has become one of the most comprehensive regulatory affairs consulting firms in the world. Combining our clinical trials capabilities with CanReg's drug- and device-specific experience in regulatory

approval processes enables us to provide sponsors with a definitive end-to-end solution for moving products through the development and commercialization lifecycle swiftly and efficiently, with less risk and expense.

Additionally, i3's market access and reimbursement expertise can help sponsors integrate regulatory and market access planning into lifecycle management. This can prove especially helpful in avoiding complications and their associated delays that sometimes result when reimbursement hurdles are not adequately integrated into a product's development.

Learn how i3 can apply its extensive knowledge of medical device and technology trials—coupled with innovative technologies, operational strategies, and regulatory expertise—to help you execute your research goals more effectively and maximize your return on investment.

Contact us

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