MEDICAL DEVICE DEVELOPMENT

MEDICAL DEVICE TRIALS ARE UNIQUE - WE HAVE THE EXPERIENCE AND EXPERTISE TO SUPPORT YOU

A lot needs to happen to get a great idea to market. Devices need feasibility and pivotal studies, diagnostics require analytical and clinical validation. And, of course, you want it to happen as effectively, safely, economically and as urgently as possible. We are your source to help make this happen.

Medical device trials tend to be smaller than drug trials, but they are no less complex. Difficult to blind, randomize and control, they demand specialized

experience and the flexibility and expertise to understand how to leverage user feedback to optimize your product.

Our clinical, regulatory and marketing services focus on bringing medical devices to market and then supporting them throughout the life cycle. We dedicate resources to every project, working as an extension of your staff. Our full-service support coupled with our vast expertise across therapeutic areas maximize results.

MOVING THE FUTURE FORWARD

The MedTech industry is undergoing unprecedented change, driven by new regulations, M&A, value-based healthcare models, pricing and reimbursement pressures, new product introductions, and high-tech innovations.

Fervor MedTech helps you successfully navigate these evolving market dynamics. Our market leading, and specialized solutions and services enable you to boost commercial success, increase efficiency, ensure compliance and manage costs as you ideate, develop and bring new solutions to market advancing global healthcare.

SPECIFIC REGULATORY EXPERIENCE

Our extensive experience in all classes of medical devices and diagnostics and exacting regulation requirements can help you save time and money. Whether your medical device is targeted to domestic or global markets, we can help you overcome the challenges of an ever-evolving global regulatory environment. With offices in 46 countries, we have the global resources and local regulatory knowledge to facilitate effective strategies for approval.

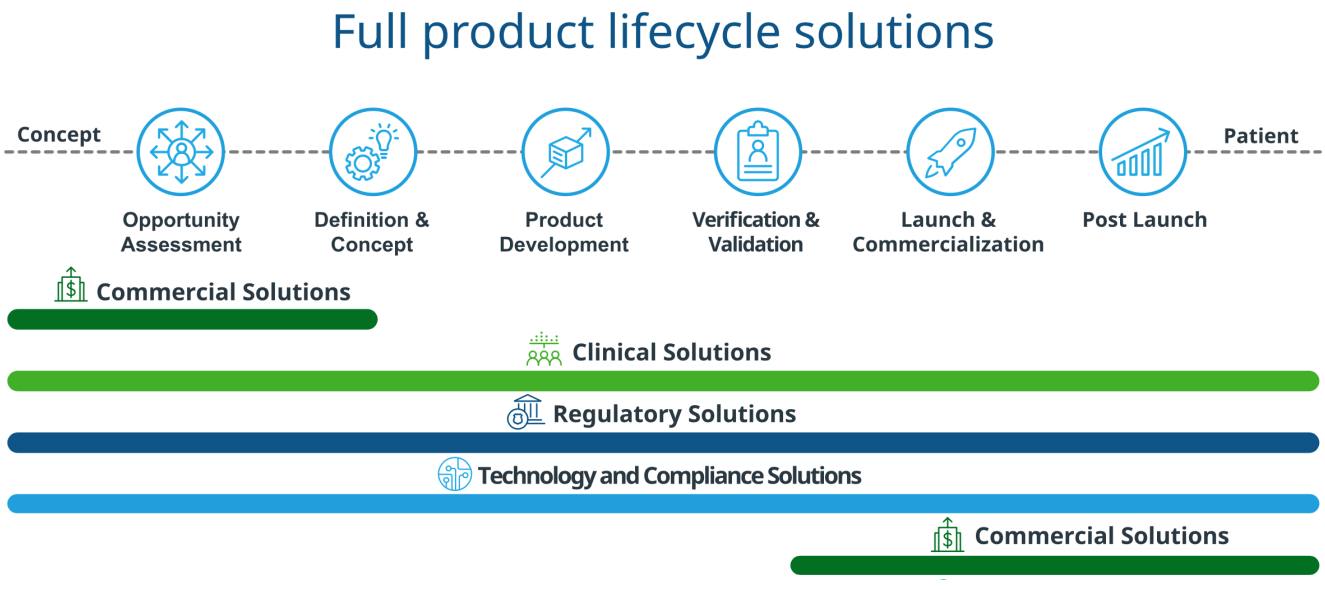
Working in partnership with a pre-eminent physician network and experienced consultants, we provide FDA regulatory compliance strategy for medical device development, including:

- Regulatory submissions
- Regulatory meeting preparation, attendance and follow-up
- Quality assurance auditing and compliance
- Quality system design and assessment
- Employee training and document control

MEDICAL DEVICE DIAGNOSTIC EXPERIENCE

Across the diagnostic device spectrum, Fervor's medical device team provides strategic and clinical trial support for new diagnostic devices and indications. Our experience includes simple normal and healthy sample collection and rigorous investigational device exemption (IDE) trials required by the Regulatory Agencies.

Fervor offers substantial experience in device and diagnostic study execution, strong leadership and significant regulatory experience with the Office of In Vitro Diagnostic Device (OIVD) Evaluation and Safety and the Center for Devices and Radiological Health (CDRH).



CLINICAL & MARKET APPROVAL

Trials for devices, in vitro diagnostics and combination products

Put your clinical strategy into action with support for pilot/feasibility, pivotal and post-market device trials. Your trial is seamlessly conducted - from study design consultation and protocol all the way through to the final analysis and summary report for regulatory submission.

Advance smartly with a dedicated clinical team that specializes in device trials. Your study is driven with strong science and deep care area experience to deliver a patient-centric trial. Plus, unique data sources are leveraged to inform and accelerate the recruitment of high-performing investigators and patient populations.

With innovative approaches from traditional to decentralized (virtual) trials, rest assured you will experience an expertly executed clinical study tailored to your specific clinical areas.

Contact

For further information or to discuss any aspect of Fervor's services in the field of regulatory submissions, please contact your Fervor Business Development Manager.

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