PRODUCT DEVELOPMENT AND MARKET ACCESS CONSULTING (PD&MA)

Achieving sponsor goals with efficient end-to-end solutions

Helping deliver regulatory success in faster, more efficient ways

Through a comprehensive range of solutions, efficient end-to-end services and connections with international regulatory agencies, we help build your program with a sound regulatory strategy, optimal trial design and compliance with global submission requirements. We support agency meetings and interactions, offering detailed scientific reviews, development of agency questions and meeting packages, logistics planning and follow-up minutes and actions, helping to achieve critical milestones throughout the development process, from discovery through registration and post-approval.

A more efficient, strategy-driven development process from discovery through market access

At Fortrea, we strive to be more than just a single partner. We offer comprehensive, integrated development planning at every stage of the development process and help uncover full process efficiencies, cost reductions, portfolio enhancements and continuity through programmatic outsourcing.

Starting with the end in mind, our team utilizes end-to-end solutions to add value to your program. Focusing on regulatory support for overall product development, providing strategic advice and implementation of advice on registration and market access, we support a product's full life cycle across the enterprise with expertise that can be trusted.

Fortrea is committed to supporting your product at all development stages from discovery through commercialization with a team of experts that provides a breadth of services that also includes content development, market access assessment and dossier assembly, publishing and submission.

Solutions designed to help you reach your long-term market access assessment

Discovery	Pre-Development	Pre-IND/CTA	Phase I/II	Phase II/III	Registration	Launch	Post-Approval
Biomarker strategy Nonclinical strategy Scientific review and gap analysis	Target product profile Clinical development plan Problem solving development issues	Differentiation strategy POM/POC design Endpoint selection	Study design and protocol development Pricing strategy Medical writing and content development HTA planning and submission support	Regulatory review and registration path Regulatory authorities interactions Dossier assembly, publishing and submission Global labeling	Differentiation studies Label/indication expansion Combination strategy Market access launch strategy		

Fortrea

Accurate data and strategic advice in pursuit of a more efficient process leading to registration and market access

Our science and data are always inspired by patients. The Fortrea team is comprised of recognized leaders across complementary disciplines who conduct a full review of evidence and existing data before conducting gap analysis.

Further expertise in gathering and reviewing stakeholder insights and analytics supports the collaborative development of an accurate product profile that is focused on patients, physicians and payers.

This profile delivers specific, quantifiable and actionable insights that show what success may look like while targeting the *future* market based on factors such as current and unmet medical needs, competitive intelligence and market research.

Reduce insufficiencies and find the fastest path to product review

At Fortrea, we are driven to deliver with urgency. Working with an experienced team that is aligned with your resources provides you with optimal support in traversing the intricate, iterative development process and helps set you on the fastest path toward product review.

We'll work with you to develop an efficient way to achieve your goals through the discovery organization, the development organization and commercial planning. These methods also support accelerating quality data generation, reducing insufficiencies at multiple stages and minimizing regulatory compliance risks.

Our goal is to partner with you in the planning of the best path forward for your product that supports your commercial objectives.

Over 80 years of experience

Market-leading regulatory consultancy

Product development and market access consulting highlights:

330+
Peer-reviewed publications

400+
Abstracts and posters

40+
Agency meetings and interactions completed each year

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