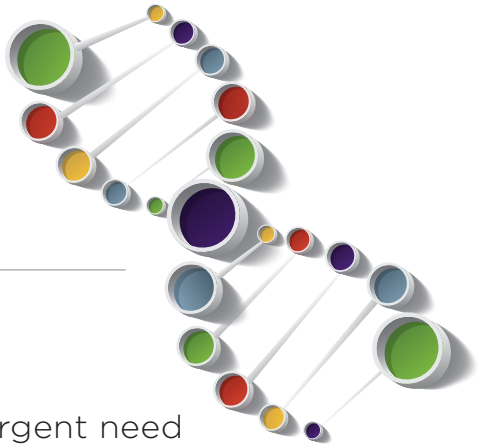
CASE STUDY

Faster NDA Submission for MS Program

Close Partnering Reduced Phase II/III Timelines for a Biotech Client



BACKGROUND

A biotech company originally engaged us for consultation on development of its multiple sclerosis (MS) program, with an urgent need to speed NDA submission. Impressed with PPD as an industry leader in multiple sclerosis, the biotech moved the Phase II and Phase III trials from another CRO to PPD. Our customized approach to partnering and close communication led to an NDA submission months ahead of schedule.

OBJECTIVE

Facing tough competition from rival agents, this biotech client needed an operational strategy that would deliver NDA submission as soon as possible.

CHALLENGES

The MS development landscape is very competitive. Finding and enrolling patients quickly is critical. At times, complex operational modifications were required, including scaling up the study with an additional 50 sites across seven countries. Our project team had to work closely with this client to address frequent adaptations, while keeping enrollment on track.

The complex global program also presented significant regulatory challenges. Regulatory applications for the Phase II and Phase III studies were originally submitted under a single protocol. A number of regulatory authorities took issue with the combined approach and required separate protocols, which delayed study timelines.

Additionally, this client's stakeholders and investors demanded frequent financial updates, beyond what we typically see with our clients.

STRATEGY

PPD Biotech built a close working partnership with the biotech company, forging an integrated operational platform that applied both executive oversight and strong project leadership to boost efficiencies.

Biotech with new MS therapy needed

early MARKET ACCESS

2,750+ PATIENTS

across all regions in a competitive landscape

FLEXIBLE TEAM AND EXECUTIVE ENGAGEMENT ENSURED EARLY DELIVERY

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Partnering Platform

The PPD Biotech team—including senior management, researchers and operations staff—met with the biotech team to define goals, expectations and areas of concern. Building from this blueprint, we established an integrated working structure that provided direct access to PPD executive leadership management, including an executive steering committee, which helped provide the internal prioritization this program required to meet tight timelines.

Flexibility and Ownership

We pride ourselves on our ability to partner effectively with biotechs of all sizes. In creating a customized solution that was right for this client and a global program of this size, we assigned regional project managers to establish clear communication of expectations.

We strategically selected leaders who were the right fit for this program. It was important that they approached the need for adaptation with a sense of ownership, rapidly navigating our organization to implement changes or resolve any issues. Their cross-functional leadership also helped the client overcome delays resulting from updated protocol submissions with regulatory authorities.

Finally, we customized our standard process to meet the biotech's need for rapid financial data updates for its stakeholders, delivering even faster data turnaround than the company requested.

> Our MS experts and study teams operated as an extension of the biotech's project team. Continuous sharing of ideas, strategy and experience drove record timelines.

THE RESULTS

Thanks to the efficient adaptable approach of the of the PPD Biotech team, we enrolled the last subject for the initial Phase III trial two months sooner than expected in a very competitive MS field.

Based on our performance on the initial Phase II and Phase III studies, the biotech awarded us a second Phase III study for this asset, which completed enrollment six months ahead of schedule, allowing our biotech partner to file the NDA one quarter sooner than expected.

Phase III completed enrollment

six MONTHS EARLY

NDA Submission Filed

one QUARTER EARLY

PPD® Biotech Partnering to Drive Innovation

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