



CASE STUDY

Fledgling Biotech Speeds towards NDA Due to Intense Coordination Effort

PROJECT BACKGROUND

A privately held, startup biopharmaceutical company had acquired a key compound for treating cancer, one of a new class of anti-cancer agents. The company had launched a multi-national pivotal trial—its first drug development effort. Additional clinical trials were planned for other cancer indications.

As with most fledgling companies, the firm had very few employees—in this case, only seven full-time experienced staff. The company relied heavily on third-party consultants, as well as clinical research and manufacturing organizations (CROs and CMOs), to fill the gaps in expertise and infrastructure. Commercial success required intense collaboration among all of the parties on clinical, technical, and manufacturing development, as well as launch prep activities to achieve the aggressive approval timeline promised to investors.

Facing the complexity of managing numerous sub-projects across multiple third parties, time zones, and even countries; management employed Integrated Project

Management Company, Inc. (IPM) to lead the effort.

IPM'S SOLUTION

After a brief review of the background information, IPM helped to develop a robust, detailed project plan that incorporated the sub-projects' key activities, durations, critical milestones, and interdependencies. Then, IPM worked with the collective team to identify those activities that were truly on the critical path of the overall timeline.

Once the finalized project plan was in place, IPM worked with the team to create a risk assessment and mitigation plan that identified and outlined responses to major development risks, such as expanding the clinical study into new countries to facilitate patient accrual and identifying resource alternatives to address an underperforming third-party vendor.

IPM also formalized a communication plan that ensured all parties knew what they needed to know, and when. Transparency of information was essential, not only to coordinate activities among such a disparate group of players, but to help establish trust and team unity, as well.

Once plans were in place, IPM drove execution—notifying the company when critical path activities were slipping, facilitating course corrections, and reinforcing collaboration among the third parties. For example, IPM was able to identify discrepancies across patient databases maintained by two different CROs. By creating a tool to analyze 4,500 data records, IPM was able to identify the gaps, alert the CROs, and help them realign.

PROJECT RESULTS

IPM enabled a true partnership among a wide group of parties. Their carefully coordinated efforts are enabling the team to achieve submission of the client's first NDA.



200 South Frontage Road, Suite 220
Burr Ridge, IL 60527
T 630.789.8600
F 630.789.7945
www.ipmcinc.com