WORKING TOGETHER TO CREATE FLEXIBLE SOLUTIONS: EMERGING BIOTECH CASE STUDY

A small biotech company, in collaboration with a mid-size pharmaceutical company, needed help conducting its Phase III trial for a hepatocellular carcinoma drug in Europe, the Americas and Australia.

Understanding the Challenge

- Gaining consensus among stakeholders
- Timely site activation and first patient enrolled
- Patient safety issues
- Site reapproval and motivation following protocol changes

Teamwork Enables Study Progression

To facilitate smooth communication among the parties from the outset of the project, a project team – with members from both sponsors and Covance – was established and weekly calls were instituted. During these calls, operational issues related to site identification, selection and activation were discussed to help achieve timely site activation and on-time delivery of the first patient enrolled. These calls were also a forum for discussing unexpected issues, such as the high incidence of neutropenia seen in study patients early in the study. Subsequently, it was determined that a lower dose of investigational product was necessary to address the potential safety issue and enrollment for the study was placed on hold.

After the protocol was amended, we leveraged the expertise of our Global Regulatory Services and Global Site Services teams to navigate the regulatory and ethics landscape across the study countries so that approvals could be achieved in an efficient and timely manner. This helped sites resume patient recruitment sooner. To help motivate sites and to regain their trust after the amendment of the protocol, we implemented programs such as Physician Investigator webinars hosted by the sponsor scientists and a regional investigator meeting in Europe. These, along with face-to-face interactions at scientific conferences and site motivational visits, were designed to answer questions and concerns related to the new dose, specifically its safety and efficacy profile. In addition, CRAs were deployed to retrain the sites on the new protocol and procedures.

In the end, by communicating clearly and championing innovative, creative ideas, the study team worked through the clinical strategy and found compromises and designed an effective study plan that resulted in on-target enrollment.

Your journey through the intricacies of drug development is never easy or straightforward. Together, we can navigate this journey to get results.

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