REVIEW. REVISE. RESULTS. GLOBAL REGULATORY AFFAIRS CASE STUDY

A small biopharmaceutical company with limited late-stage expertise was getting ready to enter Phase III with a high-profile diabetes drug candidate. Before moving forward; however, the company asked Covance to evaluate their draft late-stage clinical development plan from a global regulatory strategy perspective.

Understanding the Challenge

- Determining how to decrease the trial's size and scope
- Maximizing global business objectives

Insights Reveal Opportunities

To maximize resources behind our client's request, Covance put together a team from our Global Regulatory Affairs and Molecule Development groups. Partnering with our client, we optimized country and site selection by reviewing patient exposure in each country and ensuring registration requirements would be met. We also reviewed the overall protocol design and based on our operational expertise recommended changes, including reducing the number of studies necessary to deliver the required label claims and addressing target product profile needs.

Next, leveraging insight gained through years of working with regulatory authorities around the world, we identified gaps and potential red-flag issues with different global health authorities. As a result, we recommended obtaining feedback from selected health agencies prior to entering Phase III, including those in the Asia Pacific region. Addressing potential opportunities, we counseled our client on key issues that required feedback and proactively helped organize and send both questions and background information to the various agencies. We also advised who should attend the agency meetings and practiced fielding questions. Personally invested in our client's success, we accompanied our client to the meetings and participated in the regulatory discussions.

Following the discussions, revisions were made to the clinical trial protocols, resulting in a more strategic Phase III development plan. Furthermore, because of our team's evaluation and recommendations, our client was able to course correct its late-stage plan before spending significant time and money. Finally, the client's improved global development program made the drug candidate more attractive to potential partners, maximizing its global business objectives.

Optimizing your global development plan before proceeding to Phase III is critical for all companies, especially biotechs whose resources are limited. Make sure you partner with someone who can guide you through the regulatory and operational hurdles of a complex late-stage program with insight, experience and the ability to deliver Solutions Made Real™.

Learn more about our drug development solutions at www.covance.com

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