TACTICAL ADAPTATIONS IN ANTIBIOTIC DEVELOPMENT FOR VIRTUAL BIOTECHS

Case Study

A virtual biotech company chose Covance to conduct two Phase III clinical trials for a new antibiotic treating life-threatening skin infections, such as methicillin-resistant Staphylococcus aureus (MRSA). Covance was selected by the sponsor because of its expertise in managing antibacterial protocol clinical trials for infectious diseases. This case study explores the challenges faced and successes achieved as the Covance team advanced the sponsor's ultimate goal of submitting final study results to the US Food and Drug Administration (FDA) for accelerated approval.

Applying Data-Driven Solutions

- Provided flexibility, communication and collaboration with the sponsor during study development.
- Utilized proprietary data and technology to meet or exceed timelines and expectations.
- Delivered medical and operational expertise throughout the studies for a sponsor with limited infrastructure.

The Challenge: Delivering Expertise When and Where Needed

MRSA, a type of staph bacteria, is resistant to most treatments. People are mainly infected with MRSA in hospital settings, but can also contract it in the community. MRSA and other staph infections can cause a variety of issues such as skin infections, sepsis, pneumonia, bloodstream infections and ultimately, death. Due to the severity of MRSA infections, and lack of effective treatment, the sponsor wanted to submit study results for accelerated FDA approval. Advancing this goal required expediting timelines to meet the sponsor's desired start-up schedule.

Site selection was complicated as Covance needed to recruit 1,200 patients across 160 global sites, with each site located in regions with high MRSA-type infection rates. In addition, the Covance team needed to quickly choose, train and manage all staff to deliver the highest levels of scientific expertise across sites.

When Covance began working with the sponsor, the research strategies were still in development as the virtual biotech had limited infrastructure. In response, Covance created a core project team with a designated team leader, which helped identify the sponsor's scientific and operational needs and refine their research strategy. These circumstances also required financial flexibility in order to meet budgetary requirements.

RECRUITED
1,200 PATIENTS
ACROSS 160 GLOBAL SITES

PHASE III TRIAL COMPLETED
7 MONTHS
AHEAD OF SCHEDULE

COVANCE
SOLUTIONS MADE REAL®

The Action: Tapping Into Proprietary Solutions

To identify optimal sites and high-performing investigators quickly, Covance utilized its award-winning, proprietary trial design solution. LabCorp de-identified clinical laboratory data was analyzed to generate heat maps indicating regions with high MRSA incidence. The Covance team matched the highest-performing sites with patient densities.

To maintain an accelerated timeline, Covance continuously applied risk-based monitoring to its sites. Each site was reviewed for performance and operations while collecting data. Reports were regularly submitted to the sponsor to demonstrate progress and maintain clear communication. By consistently collecting both site and sponsor feedback, Covance was equipped to act in real time to keep the study on track.

The Result: Completion within Budget and Seven Months Ahead of Schedule

Despite the complexities of these studies, the first Phase III trial was completed an impressive seven months ahead of schedule while the second was completed on time. The sponsor has acknowledged that the Covance team's rapid selection and start-up of appropriate sites and accelerated rate of patient enrollment kept the trials on track and within budget.

The Lessons Learned: Flexibility, Communication, Collaboration Plus Proprietary Data Solutions are Key

Working with this sponsor required flexibility, communication and collaboration to support its research strategies and develop the protocol. This approach, combined with the utilization of Covance's proprietary trial design solution, enabled Covance to not only meet but exceed the sponsor's expectations and timeline for the study and its completion.

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REAL-WORLD **IMPACT.**

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