SUPERB TIME MANAGEMENT + CONTINUOUS COMMUNICATION = EFFICIENT STUDY CONDUCT: EMERGING PHARMA CASE STUDY

A small emerging biotech company needed help conducting an open-label extension study for their molecule to gain confidence in its safety profile before filing for approval in the US. The study was to occur in 179 clinical investigator sites around the world with patients who participated in a prior pivotal Phase III clinical trial.

Understanding the Challenge

- Management of study start-up, maintenance and site closedown all at the same time
- Time sensitivity regarding patient rollover from the pivotal Phase III clinical trial to the open-label study
- Alignment of different corporate cultures

Meeting and Exceeding Expectations

We communicated daily with our client to develop custom timelines and action plans that addressed each site's varying lifecycle phase of the study. In addition, we tapped into our Global Regulatory Services and Global Site Services teams to help navigate the regulatory and ethics landscape in each country so that any site activation issues were addressed upfront. The team also used a just-in-time method for the regulatory and ethics committee approvals to ensure a site was approved for the open-label study only when the site's patients were nearing completion of the pivotal study. This approach helped to maximize time and cost efficiencies.

To create a positive working relationship, we adapted to our client's culture by demonstrating our flexibility and commitment to solving problems proactively and in real time. We were always transparent with our client, understanding their need for information and for wanting to be part of the solution. Accordingly, we quickly escalated issues and accommodated all requests with a recommended action plan. In the end, we completed database lock on time and enabled our client to remain on track for NDA submission.

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

The Americas + 1.888.COVANCE + 1.609.452.4440
Europe / Africa + 800.2682.2682 **Asia Pacific** + 800.6568.3000

COVANCE®
SOLUTIONS MADE REAL™