Country Selection for Your Clinical Study:
There is a Method to the Madness

By: Joan Meyer, PhD, Executive Director, Operational Strategy & Planning

Choosing where to conduct a global clinical trial is a critical strategic decision that can impact an entire drug development program, including patient recruitment and retention, the speed of execution and ultimately your marketing plan. Many factors must be taken into account when selecting countries, however, the relative importance of each factor will vary depending on clinical trial design, the therapeutic area being studied and your overall development strategy. For instance, while one study may rely on access to naïve patients or include a comparator arm, other conditions may require a more complex trial design and more robust clinical infrastructure, such as availability of specialized imaging capabilities.

Covance encourages our sponsors to challenge their perceptions of running trials in different countries, as optimal country selection will differ from study to study. It is critical to first obtain comprehensive data for the overall clinical trial program before making country selection decisions.

Many factors should be taken into account when selecting countries, including:

- epidemiology of the disease
- regulatory environment and timing
- speed of recruitment
- availability of experienced clinical trialists
- existence of placebos or comparator arms
- patient enrollment trends
- competitive information, such as competing trials and/or similar products on the market

Furthermore, the market strategy for the drug needs to be considered before choosing where it makes sense to conduct the trial. Is the country a significant player in the international economy, and does it have a market that can afford the medication after approval? What is the current pricing and reimbursement environment? Also worth noting is where the drug will first be launched, as investigators in countries that don't allow direct-to-consumer advertising often become the main advocates for the drug post-launch.

While data for many of these factors can be found in the public domain, Covance offers clients an added benefit in regards to country selection with access to proprietary information from our Xcellerate® Clinical Trial
Optimization knowledgebase. Xcellerate is a data-driven drug development approach that harnesses the power of the largest clinical trial knowledgebase in the industry, incorporating data from clinical trials including over 11,000 completed protocols, covering 600 indications and 175,000-plus unique investigators who have had over 10 million patient visits.

Covance leverages its 20-plus years of captured data in Xcellerate and our team’s clinical insight, to match studies with the right countries and sites for optimal performance. For instance, in regards to country selection, we use an evidenced-based approach, using data from the public domain coupled with the proprietary data in Xcellerate, enabling us to provide a more detailed and insightful epidemiological analysis and better predict which patients from a certain geographic region are likely to enroll in a study, e.g. cultural beliefs about specific diseases or illnesses can affect a potential patient’s willingness to participate. In addition, our analysis of the performance data of over 175,000 experienced clinical trialists helps us establish for our sponsors more accurate time frames for site activation and subsequent performance by geographic region and country.

Overall, country selection is inextricably linked to patient recruitment and retention, which is why effective country planning is such a critical component of the study start-up phase. Just because a particular country satisfied the needs for one trial, does not mean it will have the same impact for another. Covance’s goal is to make customized country recommendations for our sponsors based on the best countries for their particular study needs and business objectives. This includes taking all influencing factors into account and using our proprietary data to recommend an optimal country mix.

Joan Meyer, PhD, is the Operational Strategy & Planning Global Therapeutic Area Head for Inflammation, Infectious Diseases, and General Medicine at Covance. Dr. Meyer has more than 25 years of pharmaceutical and CRO experience, holding leadership positions in project management, strategic marketing, and study start-up. She has also served in leadership roles in the Ohio River Valley and National Arthritis Foundations. Dr. Meyer graduated from St. Mary’s University, Minnesota, with a BA in Biology and BA in Psychology. She received her Master of Science and PhD in Neuroscience from the University of Illinois at Urbana-Champaign, where she taught in the College of Medicine.

About Covance
Covance, with headquarters in Princeton, New Jersey, is one of the world’s largest and most comprehensive drug development services companies, with annual revenues greater than $2.2 billion and more than 11,000 employees in over 60 countries. Covance has the people, processes, client service, and global resource capabilities to respond to the toughest drug development challenges.

For more information about Covance, visit us online at www.covance.com.