

Revealing Opportunities to Deliver Exceptional Results in Bulgaria: Emerging Markets Case Study

A large multinational pharmaceutical company engaged Covance to conduct a Phase III study for a drug targeting schizophrenia. The study was an open label extension of two previous studies and involved more than 1,100 randomized patients across roughly 220 sites and 30 countries.

Understanding the Challenge

- ▶ Local regulatory and ethics committee reservations around psychiatric trials
- ▶ Identifying high-quality, capable Bulgarian sites
- ▶ Demanding level of data sweeps and monitoring co-visits

Dedicated Teamwork Transforms Results

At the outset of the trial, Covance medical experts collaborated closely with our client to demonstrate that the study delivered high-quality patient care and did not increase risk to patients. No psychiatric trials had been approved in Bulgaria for several years so together, Covance and our client had to convince both regulators and the ethics committee that the study would deliver high-quality patient care and not add risk for any patients in the study. Once we had their support, we needed to then focus on identifying sites with a documented history of delivering high-volume, high-quality patient enrollment. Our deep local knowledge and site network in combination with our proprietary clinical knowledgebase, Xcellerate®, enabled us to identify more than five times the originally expected number of qualified investigator sites, resulting in the randomization of more than 120 patients. Our site start-up team then provided fast, flexible and proactive management of all regulatory, ethics and legal requirements to complete all site contracting on time and in compliance with both local and global standards.

Anticipating future needs, we designed and implemented a monitoring plan specifically structured around the data sweep project milestones. This included on-site scheduling of visits in advance and identifying any need for operational back up to facilitate continuous coverage and timely data collection. We also proactively conducted site training to help secure protocol compliance, investigator motivation and quality data.

Finally, to help deliver Solutions Made Real™, we fostered a team environment built around frequent communication, clear roles and well-defined responsibilities. Quality was consistently tracked with a focus on best practices through a coordinated cascade of monthly teleconferences, regional quality forums and FAQs. The weekly forums were held to discuss and resolve ongoing issues, escalate

concerns where needed and share lessons learned across the region. To inspire accountability, roles and responsibilities were directly tied with specific tasks and top-priority activities were assigned to owners. Team members were given time allocations and were directed to preemptively query study performance to catch and resolve any emerging issues before they impacted study timelines.

In the end, Bulgaria – an emerging market – was the second-highest enrolling country in the entire study, contributing more than 10 percent of trial patients. In addition to the exceptional volume of patients, quality was documented to be exceptional with a screen failure rate of zero and a dropout rate of less than five percent. Looking to set our client up for success, our team helped ensure that each of the half dozen data sweeps was completed on time with not a single visit missed and 100% of the clinical trial data entered in a timely manner. Finally, all Bulgarian sites closed on schedule, database lock was achieved on time and our client filed their NDA with a robust volume of high-quality data.

In today's competitive global drug development market, identifying high-quality patients in emerging markets may give you an edge. Let Covance match your study with the right countries, sites and patients for optimal performance.

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

Covance is an independently held company
with headquarters in Princeton, New Jersey, USA.
Covance is the marketing name for Covance Inc. and its
subsidiaries around the world.

The Americas + 1.888.COVANCE + 1.609.452.4440
Europe / Africa + 00.800.2682.2682
Asia Pacific + 800.6568.3000

© Copyright 2014 Covance Inc.
CSCDS047-1114

COVANCE[®]
SOLUTIONS MADE REAL[™]