Case Study

INVENTIVE OPERATIONAL STRATEGY FOR A CARDIOLOGY RESCUE STUDY

Investigational Product: Targeted Lipid-Lowering Agent
Therapeutic Area: Cardiology
Indication: Patients with high risk of occurrence of major cardiovascular events
Study Phase: III
Sponsor: Global top 10 pharmaceutical company
Study design: International, multi-center, double-blind, randomized, placebo-controlled, parallel group evaluation of the efficacy, safety, and tolerability
Total number of patients: 310 managed by Accell

Operational challenge: Prior to Accell's involvement, 31 sites have already been recruiting for 12 months in Russia by another CRO vendor, but recruitment was projected to fall behind the scheduled timelines.

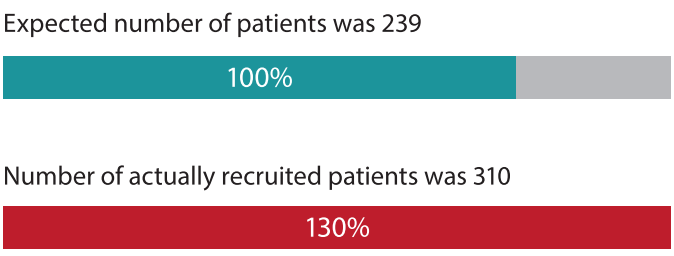
Sponsor's goals: Failing to meet patient recruitment timelines was not an option. The goal was to find more well-performing sites and patients in an already saturated and competitive cardiology landscape.

Our solution: Our operational goal was to discover and implement a strategy that would allow us to improve patient recruitment and retention rates in Russia overall. One of the challenges that presented itself was competitive environment between two operating CROs in one country. We needed to develop a smart way to build a collaborative environment, and to find additional high-recruiting sites in the face of stiff competition in cardiology clinical trials in Russia.

Our physician-led clinical team approached this task by prioritizing the review of "lessons learned" from the apparent problems with recruitment in the study, and factors influencing study recruitment most. Accell's in-house physicians were tasked with identification of risks and creating an operational strategy, which would allow us to foresee and circumvent patient enrolment challenges.

We identified the lack of provision of sites with supportive care as one of the major factors negatively influencing current recruitment, and our close collaboration with Key Opinion Leaders at the site selection stage suggested that provision of supportive care to sites could boost patient recruitment as well as site interest to participate by about 30%. In a country where 31 sites have already been recruiting for 12 months, finding additional interested sites and motivating them to perform was certainly a challenge, so our strategic approach focused on **solving site and patient problems** in order to drive up the recruitment rates. The cost of implementing this strategy has proven to be lower than the cost of potential recruitment delay, so Accell's team proceeded with implementation.

In only 4 months we have thoroughly interviewed 78 cardiology investigators and during the course of 41 site selection visit, selected top 28 strongest sites. Our site evaluation criteria included the requirement for sites to be large, federally funded institutions with a wide geographic outreach, to maximize their offering of this clinical study to patients.



On the clinical operations side, a correctly structured site and investigator budget and timely investigator reimbursement, along with patient pre-screening requirements and weekly communication of our physician-CRAs with site study team allowed us to motivate the sites, build investigator relationships, and deliver above expectations. **Our sites recruited 130% of promised patients, before the deadline for patient recruitment.**