

Case Studies in Global Trials

Case Study #1

Scenario: Treatment-Naïve Subjects for Phase 1 Trial

The client, a small start-up virtual biotech company, was having a difficult time deciphering how to best recruit subjects that would show preliminary efficacious data in conjunction with the Phase I safety data needed to proceed. After realizing treatment-naïve, subjects would be required and that the US would be slow in finding and recruiting these subjects, and because all this would need to take place close to the holiday season, the client turned to Trial Runners because of our resources and reliability.

Results:

After quickly analyzing the situation and determining that Eastern Europe would be an ideal location to quickly find these subjects, Trial Runners contacted the appropriate staff to begin communicating with the investigators. Because of our emphasis on building relationships with clients, vendors and investigators, the sites quickly signed the CDA, read the protocol and agreed to meet with the client and Trial Runners.

Even though it was the holiday season, and many investigators were already out of the office, we managed, within a week, to fly with the client to Eastern Europe. We met several sites in a matter of a few days, with access to large treatment-naïve subjects. Tirelessly, Trial Runners worked to secure staff for the client to meet and ensure that the facilities exceeded the expectations of the biotech company.

In less than two weeks, Trial Runners was able to provide a preliminary country and risk management analysis, execute the initial paperwork to meet with sites, schedule conferences and visits, and inquire on regulatory requirements, and still be home in time for holiday dinner- all at a cost much less than larger CROs.

Case Study #2

Scenario: Global Analysis for Expedited Phase 1 Submission

The client, a small biopharma company, realized that due to an oversight in pre-clinical procedures certain countries were not willing to accept the data to proceed to a phase 1 trial. Initiating further toxicology studies would have been very expensive and the client needed to be resourceful in finding a pathway to develop their program.

Results:

After an initial meeting with Trial Runners, the predicament at hand was quickly understood. By that afternoon, Trial Runners had identified a few countries and was already in contact with alliances in those areas.

Dedicated to making our clients feel secure, we searched throughout Latin America and Asia Pacific for the appropriate countries. Several meetings were held with our strategic partners in those areas. Decisions of whether or not to submit the product as a biologic, timelines regarding all possible submissions and pathways, and a list of countries were provided to the client by the end of the week. All this was done at no cost to the client because we understood the predicament of this biotech company and the importance of executing the Phase 1.

Case Study #3

Scenario: Support of Clinical Program in India

The client had begun initial conversations with contacts in India to execute a trial. Without a full clinical department, the biopharma company did not have the resources to review and write portions of the protocol, develop a monitoring plan and submit relevant paperwork to health authorities.

Trial Runners played multifunctional roles until the client was able to hire the appropriate staff. Drawing from an experienced project management staff, Trial Runners worked around the clock to write and review portions of the protocol in time to meet the EC submission deadline, which was not determined until 12 hours before the submissions was due. With little information, Trial Runners put together a project management plan to conduct the trial in India, alongside a monitoring plan and timelines. We were able to fly to India several times to lay the groundwork to conduct this trial, including developing a questionnaire, plans, manual, and monitor the study to ensure GCP/ICH compliance and that safeguard were in place.

Communication with the client took place outside of the normal business hours to meet these timelines because Trial Runners understood that in this environment one could not have regular business hours in order to successfully and efficiently execute these pivotal trials. The client was able to successfully enroll and monitor the study.