TriNet Pharma
ADVANCING SCIENCE ONE PERSON AT A TIME

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TriNet Pharma understands science and the science of success. We are one of healthcare's largest and most respected agencies for providing permanent and contract Medical Science Liaisons (MSLs), Medical Directors, and other Medical Affairs professionals to Life Sciences organizations in the United States and abroad.

CASE STUDY

TRIAL ENROLLMENT

A build-out of a contract Medical Affairs team / Clinical Trial Liaison team boosts Oncology Clinical Trial Enrollment

Situation

A small US pharmaceutical company embarking upon a 1000-patient registration study for the approval of their first drug, engaged TriNet Pharma to search and place a Medical Science Liaison (MSL) team to support timely clinical trial enrollment, raise awareness of the company and the disease state, and develop Key Opinion Leader (KOL) relationships in preparation for the product launch.

The Chief Medical Officer (CMO) was the only medical employee of the company. There was one Clinical Operations employee, and a small Clinical Research Organization (CRO) was engaged to manage study execution. The MSL team was to become the "feet on the street" for this emerging pharmaceutical company.

Vision

After a needs review with the CMO, it was determined that the most pressing objective of the client was to enroll a very large prospective, randomized, Phase III registration study within a 12-month period. The team considered this to be highly aggressive. It was recommended that the number of clinical trial sites be increased and/or that three additional months be added to the timeline. After much discussion, the decision was to hire a highly experienced contract MSL Director and five contract MSLs across the United States to focus their efforts on clinical trial sites.

Target

- Enroll a very large prospective, randomized Phase III registration study within a 12-month period.
- Hire one contract MSL Director and five contract MSLs across the United States.

Solution

TriNet Pharma developed an employee profile, that was a cross between an MSL and a Clinical Trial Liaison (CTL), to meet the client's objectives. The profile emphasized identifying and hiring individuals with hands-on clinical trial research experience. Other MSL characteristics TriNet Pharma identified as critical for success were:

- comprehensive knowledge of clinical trial processes from study start-up through database close-out
- therapeutic area experience with sound scientific knowledge
- field-based experience as an MSL, CTL, or Nurse Educator
- prior relationship between the MSL and the majority of the clinical trial sites
- ability to effectively communicate with multiple types of health care providers (physicians, nurses, clinical research coordinators, CRAs, pharmacists, CRO employees, client)
- inherent flexibility, and the ability to handle change and ambiguity with finesse

TriNet Pharma managed the recruiting process and first identified and interviewed MSL Director candidates for vetting by the client.

NOTE: TriNet contractors are company employees, and our experienced operations team, who have all held MSL Director positions in the industry, oversee compliance for all contracted employees throughout the employees' engagement.

Once a contract MSL Director was identified, the TriNet Pharma team, CMO, and MSL Director interviewed and selected five MSLs in geographies identified by the MSL Director, based on clinical trial site locations and KOL mapping. The MSL Director built the MSL organization for the company from the ground up, including strategy, budgets, training, KOL identification and mapping, SOPs, CRM, and more.

NOTE: Seven months into the contract, TriNet Pharma's contract MSL Director was hired by the client to serve as VP of Medical Operations (Medical Affairs and Clinical Operations). The VP proceeded to further build-out both departments in coordination with the CMO.

MSL Team Primary Goals

The MSL team would:

01 Provide leadership in managing customer-focused relationships at the client's clinical trial sites.

02 Operationalize a plan for each clinical site for the appropriate identification of eligible patients.

03 Motivate sites to complete timely, quality, data entry.

04 Educate clinical trial sites on the drug's administration and known side effect profile.

05 Be a clinical resource for questions surrounding the therapeutic area, protocol, and product.

06 Act as a conduit of information between the clinical sites the sponsor and the CRO.

07 Provide meaningful scientific exchange within the defined geographies.

RESULTS

- Trial enrollment was underway in 15 months (the original 12 months planned plus the 3 additional months discussed with the client during initial meetings).
- During each clinical site visit the MSL team members educated one or more health care providers about the therapeutic area, the product, and the protocol.
- Clinical trial patient workflows were documented for each clinical site leading to earlier identification of eligible patients at the bulk of the clinical trial sites.
- The MSLs served as a communication bridge between the practices, the CRO, and the client leading to an enhanced protocol, more acceptable CRO processes for data entry at the clinical sites, and an increased level of respect for our client secondary to the support provided to them by our client.
- The MSLs motivated the clinical sites to enter data into the database in a timely fashion, leading to an unprecedented closure of the study database 5 days after the last patient came off-study.
- The client extended and retained the team beyond the end of the contract period. One MSL chose to stay on as a full-time employee following the completion of the study.
- The FDA approved the company's NDA and the drug alluded to in this case study was approved for marketing in the United States.