

CASE STUDY: FUNCTIONAL STAFFING CRO

The CASE

- Project Cost: \$2,100,000 (2 years)
- 100% of the CRO team had advanced degrees & licensed professionals (full time team included at least 3 MDs, 2 PhDs as well as MS regulatory and engineer graduates)
- Cost Per CRO Team Member: Less than \$100/hour
- Project Duration: 2 years
- Project entirely conducted in the United States

The SITUATION

- **Cross- Functional Technical Team Required:** RxRS CRO was selected by the Client to assemble a team of engineering, regulatory affairs, scientists and medical contract workers who could work well together on the technical review, analysis and interpretation of safety information.
- **Technical Writing Required.** This team needed advanced scientific expertise to review the data and engineering-related device components / design, and needed linguistic and technical writing skills to appropriately narrate, scrutinize and breakdown the evaluation associated with the research study's ongoing developmental and safety investigation.
- **Quality Professionals with Compliance Audit Skills:** For this one study project, it was anticipated that at least 200 sites involving over 8,000 subjects had "unclean" data with inconsistencies and discrepancies as commonly associated with raw, un-validated and often times handwritten data.
- **Scientific Expertise:** Critical to providing engineering and technical analysis for this type of project, each contract worker had to understand the medical and scientific principles behind the research protocol so as to properly evaluate and assess the impact of the data and the its implications for the company's research, development and safety efforts. This team was also tasked with managing Client safety data requests, executing data queries, performing statistical analysis and adjudicating data claims on a routine basis.
- **Host Facility Operations Required:** The Client also needed a supplier who could personally manage and operate the team at the supplier's facility with supplier computer systems and equipment – outside of the Client's California headquarters.
- **Data Secure Systems:** Security systems (facility and computer), data protections and overall accountability had to be in place as the Client's confidential data required sophisticated protections.
- **Little or No Budget Planned:** And, the Client's budget was extremely limited as little funds had been budgeted for this unanticipated project's expense.

The CHALLENGES

- **Tight Timeline**
 - The entire "Team" needed to be identified, screened, psychologically profiled for team interpersonal workplace dynamics, and be ready to work in 90 days.

- If a proper team was not assembled immediately in the United States, the work was scheduled to be transferred to India.
- **Team Dynamic Required**
 - As the Client required that RxRS CRO package an entire high-performance team, RxRS CRO needed to utilize systems and profile based analysis to ensure the interpersonal workings of each of the team member complimented the other team member's skills, education, experience, work style, personal character, and ability to work and thrive as a whole interrelated operation.
 - Workers Needed with Advanced Degrees & Scientific Expertise. As RxRS CRO's affiliate entity, RxResearch Staffing, had placed staffing contractors with this Client before, the Client trusted RxRS CRO to find the right candidates with regulatory affairs, engineering, medical, and scientific expertise. Also, considering the advanced technical aspects of the project and its details. The Client requested that RxRS CRO use workers with advanced (MS, PhD, MD degrees) so as to ensure rapid technical start up and work productivity.
- **Separate Secure Facility Requested**
 - As the project involved federally protected and sensitive personal data, the Client required that its work be performed in a separate secure facility using state of the art computer systems and data security. RxRS CRO needed to secure the separate facility, equipment and systems in time to meet the Client's timeline.
- **Minimal Budget Planned**
 - Although the Client desired advanced degree / licensed technical and scientific trained workers for the skill levels appropriate for the project, the Client's budget did not anticipate the market rates for advanced professionals.
 - RxRS CRO's On-Site Management / Supervision of Team. The Client also needed a supplier who could provide day-to-day on-site supervision, coaching, mentoring, metrics tracking/reporting and management oversight.

The RxRS CRO SOLUTION

- **Team Staffed Ahead of Schedule**
 - The Client knew they could count on RxRS CRO and gave us total responsibility for staffing, advertising, screening, identification and selection of contract workers. RxRS CRO's Talent Managers worked closely with the Client to ensure the precise skill sets and scientific expertise were assembled so as to form a team that operated synergistically for the project's success and objectives.
 - 100% of contracted professionals had scientific backgrounds and experience working in or for regulated industry.
 - 100% of the team had advanced degrees and professional licenses (CRO employees included at least 3 MDs, 2 PhDs as well as engineer and regulatory MS degree graduates)
 - 100% of employees remained dedicated to the Client's study for the duration of the project
 - 100% of the federally-protected personal health data remained in the United States (and not sent to India as originally planned as the Client's offshore solution).
 - Project resulted in Jobs created and performed in America (Alhambra, CA and direct hires / employee conversions by the Client).

- **Separate Secure Facility Established**
 - At the Client's request, RxRS CRO established a separate secure facility for the contract workers and the project. Based on the Team psychological profile data, the office was configured in a manner to enhance operations and ensure cross-communication between team mates resulting in efficiencies and high levels of productivity.
 - RxRS CRO Compiled a Clock-Like Team. RxRS CRO looked for and compiled the right combination of staff who were capable of maintaining solid working relationships so as to work together effectively. Finding such technical staff, who also showed commitment, contribution, communication, coordination characteristics presented staffing challenges in such a short time frame. The success of the RxRS CRO team demonstrates how a careful staffing partner with expertise in work-style analysis / profiling can lead to project success.
- **Accountability & Transparency**
 - In order to ease Client involvement and interface with the Team, and minimizing the cost of expensive and time-consuming travel, RxRS CRO implemented a sophisticated Cloud-based file system so as to allow the Client 24/7 access to their data and the work product deliverables.
- **Cost Savings Achieved Through Creative Staff Sourcing**
 - The Client needed advanced degrees, but the budget could not afford such advanced degreed/licensed professionals as may have been in practice for a number of years. To achieve the Client's objective on such a minimal budget, RxRS CRO approached the Client about hiring new graduates with theoretical education, to be placed at "Fellowship" rates.
 - As RxRS CRO partners with many educational institutions on their STEM (aka science, technology engineering, math) career programs, we were able to pick the best and the brightest from Southern California's top universities and colleges.
- **Compliance & Substantive Training Program**
 - RxRS CRO further implemented substantive and hands-on technical training, practical coaching/feedback program with mentoring as part of RxRS CRO's overall management and retention services, resulting in highly degreed workers trained to the Client's SOPs and specifications.

The CUSTOMER ADVANTAGE

- The project was so successful that **Contracts were renewed / expanded to include 3 additional projects / studies** – a testament to RxRS CRO services to the Client.
- According to the Client, the **work product deliverables produced "the best, cleanest" data and technical writing** the Client had ever received from a third party service provider.
- One Client staff member commented that **RxRS CRO saved the Client at least \$900,000 in labor costs in 1 year** through its creative staffing.
- **No Overseas Travel Required:** The Client's employees were also extremely happy on a personal level as they did not have to extensively travel, train and invest their time and resources overseas in an India-based team – and the Client saved by not having to pay these travel expenses as well.