



A full-service CRO, SynteractHCR has a proven track record of success in all phases of clinical development.

Shared Work – Shared Vision: This is a promised standard, the way we do business. It conveys our collaborative, customized approach to conducting trials tailored to your needs, which meet or exceed your expectations.

Case Study: Cystic Fibrosis

Introduction

SynteractHCR is a privately held contract research organization (CRO) dedicated to meeting the needs of biotech, pharmaceutical and medical device companies. SynteractHCR provides high quality, full-service clinical research services to support its client's global drug and device development projects, and prides itself on working collaboratively as an extension of the client's team.

Mpex Pharmaceuticals, Inc., the Sponsor based in San Diego (and now a subsidiary of Aptalis), focuses on antibacterial drug development to treat Cystic Fibrosis (CF). Prior to working with SynteractHCR, the Sponsor had worked with another CRO on their research program but elected not to continue the collaboration. In 2008 SynteractHCR began working with the Sponsor on Study-204, a blinded, placebo-controlled Phase 2 study involving more than 150 patients at 51 clinical sites internationally. The study was designed to evaluate the efficacy, safety and tolerability of Aeroquin®, a new aerosolized form of Levofloxacin, to treat CF. Aeroquin was administered in three dosage regimens over 28 days compared to a placebo drug. The trials were conducted in the U.S., Germany and the Netherlands, to assess Aeroquin's effectiveness against *P. aeruginosa* (bacteria in the lungs that causes infection), as well as against other organisms that colonize the lungs of CF patients.

Challenges

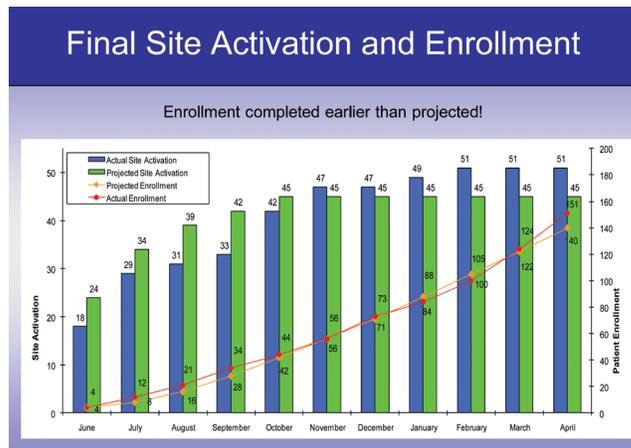
A major challenge for Study-204 was recruitment of patients. CF is a rare disease, and due to the relatively low number of CF patients who participate in clinical trials and the enrollment criteria, only about 12% of CF patients in the world were willing and eligible to participate in this clinical trial. In addition, there was a significant increase in competition for patients at the time the study was initiated, as multiple pharmaceutical companies were also pursuing drug development for CF. Due to a limited patient population and intense competition for study participants, CF trials in general have a history of not meeting their timeline for enrollment and study completion. A strong, targeted study plan was a necessity in order to identify good research sites, meet aggressive monthly and overall enrollment targets, and meet defined timelines cost-effectively.

Our Solutions

In order to meet the challenges of the study, SynteractHCR and the Sponsor worked together collaboratively to assess site and country viability, selecting the most appropriate sites to participate in the study, provide quality data, and meet enrollment goals. To differentiate from competing studies, the Sponsor and SynteractHCR focused on building close relationships with sites and investigators. Based on their longstanding experience with managing clinical trials for small to mid-size biopharmaceutical companies, SynteractHCR provided the Sponsor with critical insight on best approaches to working with research sites as an integrated team, collaborating together around the world to meet the study goals and timeline.

Successful Results

Study-204 was a success, clinically and logistically. The reduction of *P. aeruginosa* was statistically significant. Aeroquin® was well tolerated at all doses and there were strong efficacy results in the treated population. As depicted in the chart below, the study was completed earlier than anticipated, with the number of patients slightly exceeding the enrollment goal. Mpex was pleased with the conduct and quality of the study, noting that it was “a robust trial with very good study conduct.”



Following the completion of Phase 1 and Phase 2 (Study-204) trials, SynteractHCR and the Sponsor have continued their successful partnership, working together on additional non CF trials in another respiratory indication. All completed studies were finished on time, and on budget with high-quality data integrity and study conduct.

SynteractHCR and the Sponsor are now engaged in their largest collaborative effort to date, the conduct of two concurrent Phase 3 studies involving nine countries and hundreds of research centers. This cohesive team approach was successfully applied to navigate a complex global project that involved numerous regulatory authorities and regulations outside the U.S., while ensuring high data quality and adherence to timelines. In addition, as the Sponsor’s needs as a small biotech company evolved, SynteractHCR was able to increase its full-service support of the Aeroquin program to include specific targeted additional work such as detailed feasibility analysis for country selection, QA and regulatory consulting, biostatistical support and integration of Phase I, 2 and 3 data for an upcoming NDA.

Elizabeth Morgan, Vice President of Clinical Operations for the Sponsor says, “Working with the team at SynteractHCR was a great experience. As a very collaborative group, they really became an extension of our team, adding support and expertise just where we needed. It was a productive relationship, with good outcomes, and we have chosen to work with them several times as a result. They have even supported our research by sending a team to participate with us in the Cystic Fibrosis “Great Strides: Taking Steps to Cure Cystic Fibrosis” 3K walk. Overall, SynteractHCR was a great partner and supporter of our mission to develop treatments to extend and improve the lives of patients with CF.”