



SYNTEREX

CASE STUDY:

Synterex Partners with Biotech on Clinical Intelligence for Rare Disease Lacking Comprehensive Standard of Care

Background & Introduction:

- A current biotech client reached out with a request for clinical intelligence coupled with organization of due diligence documents after acquiring a product in a rare disease area with a limited approved standard of care.
- We were tasked with providing support to the biotech's rare disease program through gathering clinical intelligence on ongoing clinical studies in the rare disease and reviewing and organizing legacy and due diligence documents.

Agile Approach Benefits:

- We identified over 40 different clinical trials at various stages of planning or completion for the rare disease in question using publicly available databases and supplied to the biotech a detailed summary of each trial (tested drugs and their mechanism of action, target, and therapeutic class; trial inclusion and exclusion criteria as well as primary and secondary endpoints; and patient population and region of the conducted trial, among other factors).
- We used clinical trial intelligence software to identify and incorporate additional data from studies more than 10 years old, observational/expanded access studies, and extension studies that were excluded from the publicly available databases.
- We compiled data spanning approach to trial endpoints and study populations, created a key opinion leader list (including appending of contact information), reviewed which studies were allowed to initially enroll pediatric populations and which ages were enrolled, and evaluated prior and concomitant medications received, including pre-/post-transplant medications.

Significant Achievements:

- Synterex demonstrated the ability to collect, analyze, and interpret a wealth of information on a niche topic.
- Synterex delivered a thorough clinical intelligence dataset to the biotech that promoted a successful rare disease program despite lack of a comprehensive standard of care for the disease.

Current Partnership & Outlook:

- Synterex has continued to work with the biotech client on gene therapy clinical and regulatory deliverables in other indications.
- Synterex uses its deep understanding in the rare disease space to guide strategic direction for documents.

This one-pager offers a concise summary of Synterex's pivotal role in conducting clinical intelligence to support acquisition of a product in a rare disease population, emphasizing its agile approach and broad-based research capabilities.