excelya

Case Study

Type:	**Geography:**	**Study Type:**	**Client:**
Rare disease, pediatric	Europe	Phase II	Biotech

PROJECT TITLE:

"A multicenter, open-label Phase II study with escalating doses of XXXXX on top of a stable dose of PPEs, to investigate the efficacy and safety of this combination for the compensation of severe exocrine pancreatic insufficiency in Cystic Fibrosis patients not fully compensated with only PPEs"

Study Challenges:

1) Study was conducted in the middle of the COVID-19 pandemic with 2 weeks of mandatory hospitalization for both patients and parents. This caused significant challenge of patient recruitment.

2) Multidisciplinary study: Required full interdepartmental collaboration of the pediatric, gastroenterology and chest departments.

Excelya Solutions:

1) Thanks to our **network of partner sites globally**, and our **positive working relationships with them**, we were able to successfully manage and motivate the PI to find appropriate patients, despite the complicated global scenario.

2) High staff competency and expertise resulted in high quality outcome and communication.

Key metrics

3 Countries

20 patients

12 Sites

Client Testimonial/Outcome:

"Excelya were actively involved in the review of the study protocol and all other relevant trial documents. They have been a **trustworthy point of contact** for investigators and site staff and were involved in effectively training the sites on the study procedures.

From a budget perspective they were **cost-effective,** and their **straight-forward structure** allowed us to be able to clearly estimate our project costs. They were **flexible** during the COVID-19 pandemic, covering only the necessary activities, and with them you get **a true partner.**"

- CEO, US Biotechnology company