



Customer Success Story

Operational Services

ONE DAY TO RE-SCOPE A CLINICAL TRIAL INTERRUPTED BY COVID19

Bay-Area Biotech focused on Rare Disease

INTRODUCTION

Developing new medical treatments is a top priority for biotechnology and pharmaceutical organizations. When the pandemic interrupted a trial in progress the Biotech's Executive Team called an emergency meeting to assess the impact and review the alternatives and associated budgets. With only one day to generate these new scenarios, the clinical outsourcing team turned to Strategikon's Clinical Maestro Operational Services to help them respond quickly and confidently. Clinical Maestro digitizes business operations processes and simplifies decision-making, including clinical trial planning and budget simulation. It provides an alternative to Excel and aged point solutions to provide business users with rich, actionable insights - fast.

CHALLENGE

The Biotech had already used Clinical Maestro, however, not for this study. Because of the urgency triggered by the pandemic, their timeframe was extremely compressed and the team requested Strategikon's assistance to meet their deadline. Strategikon's highly experienced clinical business operations support team responded using Clinical Maestro technology to remodel the study and timeline.

RESULTS

- **80% reduction of time required to re-forecast the study.**
- **300% more detail to effectively negotiate services for the new plan.**
- **100% executive satisfaction with timeliness and level of detail provided for decision making.**

The problem that the Biotech was trying to solve was how their costs would shift/change due to a 3-month delay caused by the COVID-19 pandemic. Since the CRO budget was only in an Excel spreadsheet, it would be significantly time consuming to estimate this.

The other option was to rely on the CRO to inform them of the cost changes, which would leave no independent way of verifying the CRO's estimate for the timeline shift.

In order to simulate this, the first step was to get the Biotech's current costs into Clinical Maestro. This meant more than simply hitting the bottom line points in the process. It required creating the study in Clinical Maestro and aligning the subcategories that affected the duration and pricing with the start and stop dates so that the Biotech could explain both fixed and activity-based costs.

Quotes

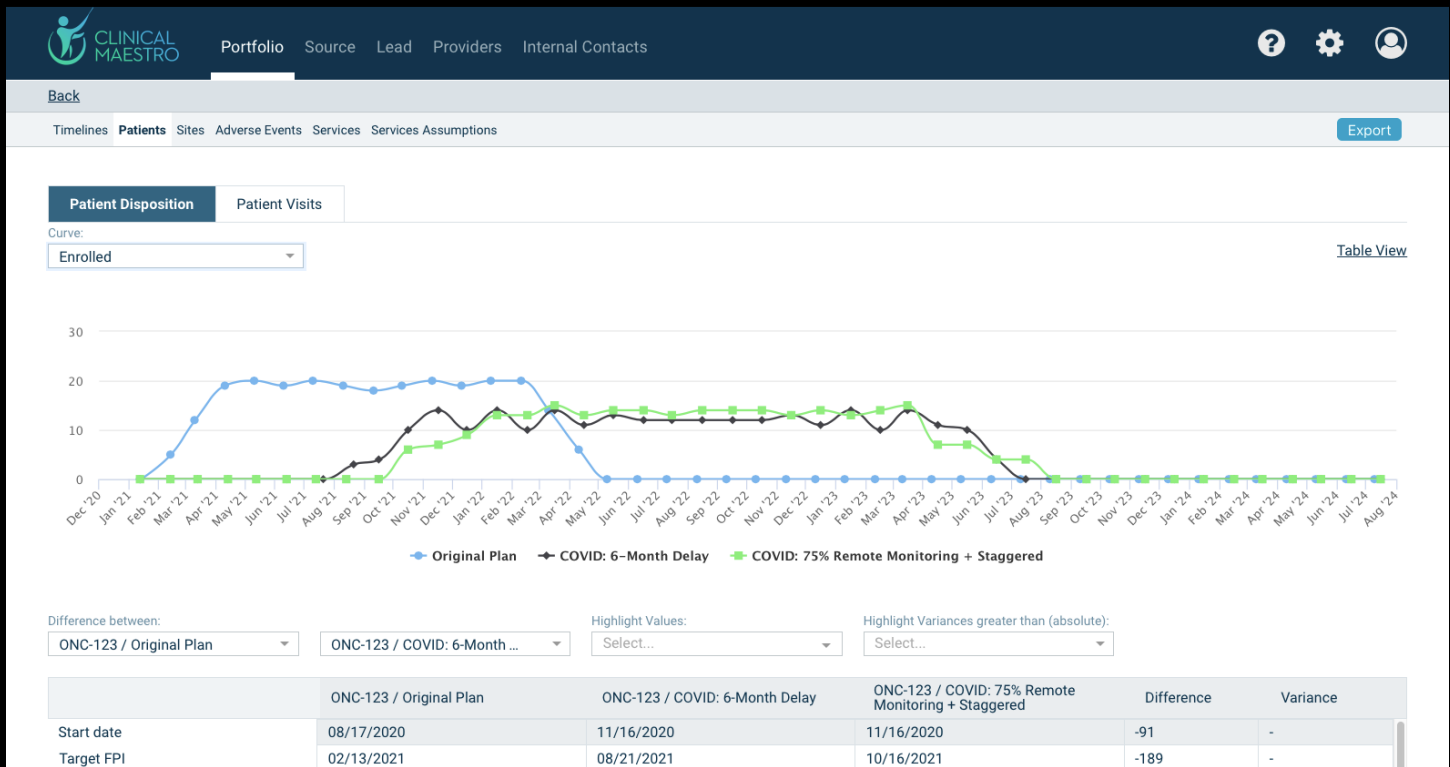
"This partnership has opened the door for our team to improve our success for both the management and communications of outsourcing processes."

- Sr. Manager, Clinical Finance

"You guys are amazing... thank you!"

- Sr. Clinical Outsourcing Manager

SCENARIO COMPARISON EXAMPLE - PATIENT ENROLLMENT



Once this was done, it was a simple matter to answer questions such as “what if the study shifted by 3 months” etc. It was also easy to compare the base plan to the what-if scenarios to see the differences across multiple categories including cost. In less than one day, the combined team generated the new scenarios requested with the backup information to enable the Executive Team make decisions. The Clinical Maestro 'Operational Services team also provided additional advanced training so the Biotech's internal team could address any new alternative scenarios that surfaced during the meeting.

CONCLUSIONS

Clinical Maestro is an efficient tool to reliably model complex study changes in a fraction of the time, enabling more confident decision making for clinical executives.

Strategikon's Clinical Maestro Services team bears deep expertise within clinical business operations from both the Sponsor and the Provider perspectives, driving valuable customer support through consultation on industry best practices and advanced system operation.

-80%

Less Time
required to reforecast the study.

+300%

Greater Detail
to effectively negotiate services
and timelines.

100%

Executive Satisfaction
on timeliness and visibility
provided for decision making.



New Ways to Solve Old Problems

For more information or to request a proposal, please contact us at info@strategikonpharma.com or visit our website at strategikonpharma.com