



Evidence of Budget Accuracy & Reliability

STUDY BUILD ASSESSMENT
ORIGINAL VS. **REVISED** ASSUMPTIONS

MID-COMPLEXITY, PHASE 1 ONCOLOGY STUDY
MID-SIZED WEST COAST BIOTECH

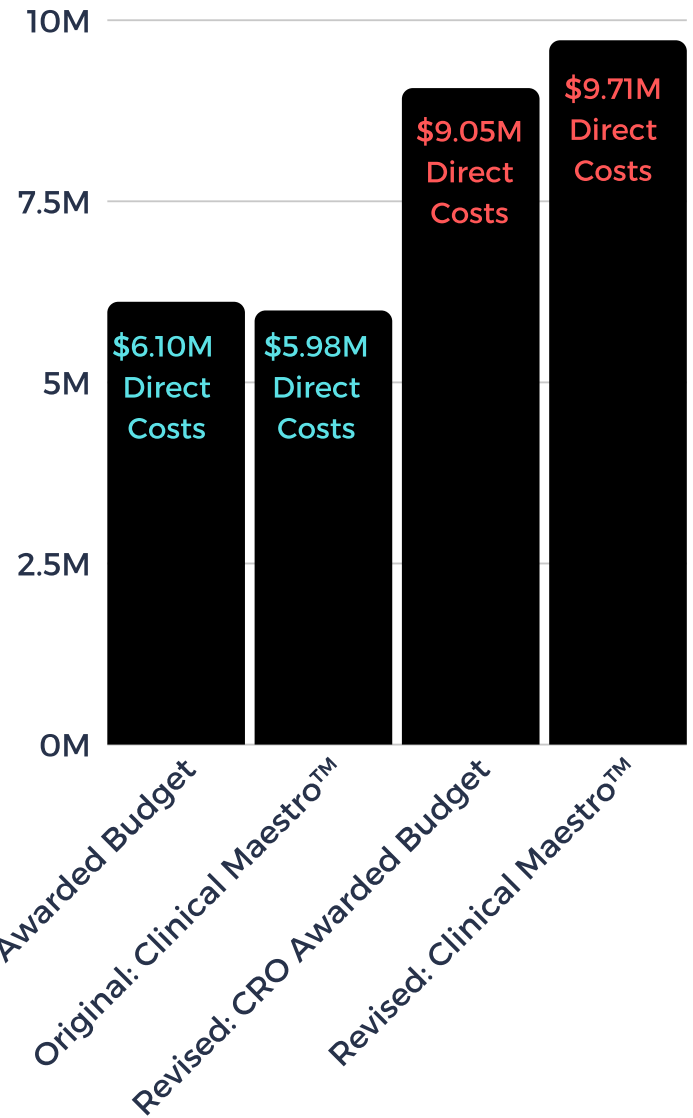
In an email table, the Sponsor provided key assumptions from a 2017 study for both the original scenario and a revised scenario. No protocol or study design was provided. The study was modeled as medium complexity using Clinical Maestro™'s PORTFOLIO application for planning and budgeting. The results of the exercise were then presented to the Sponsor and the awarded CRO budget was revealed and compared.

STUDY DESCRIPTION

- Phase 1
- Therapy Area: Oncology
- Indication: Biliary and Gallbladder Cancers
- USA, Thailand, S. Korea

Original & **[Revised]** Assumptions

- 41 **[56]** Sites
- 234 **[297]** Patients Screened
- 70 **[89]** Patients Enrolled
- 70 **[89]** Patients Completed
- 4 **[1]** Cohorts
- 266 **[553]** Total IMVs
- 14,000 **[17,800]** total eCRF pages



3

Hours of Effort

to create the study budget and scenarios in Clinical Maestro™

4

Scenarios Built

Two (Original+Revised) reverse-engineering the provided assumptions, and two (Original+Revised) using the Clinical Maestro™ calculated assumptions.

-1.9%

Variance

between Awarded CRO budget and Clinical Maestro™ calculated budget in Original scenario.

+6.6%

Variance

between Awarded CRO budget and Clinical Maestro™ calculated budget in **Revised** scenario.

RESULTS

With limited context provided by the Sponsor (no protocol, bid grid, tasks and responsibilities), the study budget built for the Original scenario using Clinical Maestro™ was calculated to be **\$5,984,246** in direct fees. This presents a **-1.9%** variance from the awarded CRO budget (\$6.1M).

The study budget built for the **Revised** scenario using Clinical Maestro™ was calculated to be **\$9,709,488** in direct fees. This presents a **+6.6%** variance from the awarded CRO budget (\$9.05M).

Variances are due to multiple factors including actual services outsourced, protocol-related assumptions, CRO expertise and operating model versus Clinical Maestro™ “market” assumptions.

CONCLUSIONS

Clinical Maestro™'s PORTFOLIO budget simulation tool predicted the study cost with near 99% accuracy in the Original study scenario and near 94% accuracy in the Revised study scenario.

Clinical Maestro™ is an effective means to reliably predict study cost and evaluate the impact various operational scenarios may have on timelines and budget. Most importantly, it can be used during bid negotiations with Providers to uncover assumptions and guide questioning, helping Sponsors to better understand what they are paying for: rates, effort and services.

ClinicalMaestro™ standardizes cost drivers and bid grids across the industry to simplify apple-to-apple comparisons on assumptions and task effort, strengthening Sponsor confidence on the fair market value for outsourced services.





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