

Evidence of Budget Accuracy & Reliability

STUDY BUILD ASSESSMENT

LARGE, HIGH-COMPLEXITY PHASE 2/3 ONCOLOGY STUDY LEADING JAPANESE PHARMA

The Sponsor provided key assumptions from a recently outsourced study in an excel file. No protocol or study design was provided. The study was modeled as high complexity using Clinical Maestro's PORTFOLIO application for planning and budgeting. A preferred discount rate of 10% was applied.



STUDY DESCRIPTION

- Phase 2/3
- Therapy Area: Oncology
- Indication: Relapsed and/or Refractory Multiple Myeloma (RRMM)
- 19 Countries (NA, EU, APAC, Japan)
- 113 Sites
- 600 Patients Screened
- 300 Patients Enrolled
- 240 Patients Completed

RESULTS

With limited context provided by the Sponsor (no protocol, bid grid, tasks or responsibilities), the study budget built using Clinical Maestro was calculated to be \$43,043,261 in direct fees. This presents a -12% variance from the awarded budget (Top Tier CRO).

CONCLUSIONS

Clinical Maestro is a reliable tool for modelling large, high complexity studies.

Study scenarios built in Clinical Maestro can be effectively leveraged during budgeting, long-range planning, and CRO bid negotiations to optimize direct costs, plan possible operations scenarios, and increase efficiency of the overall outsourcing process.

3

Hours of Effort

to create the study budget and scenarios in Clinical Maestro

4

Scenarios Built

Ranged from \$34.9M to \$43.1M depending on complexity and service assumptions

-12%

Variance

between Awarded CRO budget and Clinical Maestro calculated budget



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