SMART DATA
ANALYSIS AND STATISTICS

Clinical Trial Predictive Modeling and Simulation Case Study

One Phase 1 Trial. Many Markets.
Embracing Advanced Clinical Trial Statistical Power

A mid sized global biopharmaceutical company ("Sponsor") wanted to more strategically design its Phase 1 biosmilars program in order to broaden the asset's market potential. Sponsor found that with a more strategic design, specifically, simulation studies for sample size estimation, the Phase 1 program could meet all market requirements in a single trial and be in a much stronger position to gain many market approvals. To do so, highly advanced clinical trial modeling and simulation was required. Sponsor looked for possible existing solutions but, despite a thorough review, the available tools were too simplistic, and and could not accommodate the program's needs.. The team considered its options:

DRUG SPONSOR PREDICTIVE MODELING OPTIONS

Use Internal Resources	All existing resources otherwise occupied, skills not as readily available, possibly not available internally
Hire FTE/s	The business unit's operating model was to rely 60-70% on outsourcing, so adding FTE for a single, 1.5 year part time project not an efficient option. Also, additional challenges- administrative burden of managing, hr burden of finding talent, training, etc.
Use one of the two full service CROs already engaged	Either CRO would have required more team members, each with only part of the skills required. Also would have required project management resources, an additional layer that is not needed with SDAS. "There is a correlation between size, agility, speed and cost"
Selected:	**"The Best in the field of simulation studies for clinical trials, Thomas DeBray, SDAS"** Drug -Sponsor Director of Biostatistics

"Traditional Statistical Power meant more patients, a lengthier, more expensive trial, and possibly less and delayed revenue potential

We knew existing tools were too simple. We knew the complexity we wanted. SDAS got us there."

"Our Head of R&D , Heads of Clinical Development and Operations are very proud of what we accomplished with SDAS.

Such an elegant solution. Even though on the surface it looks simple."

"SDAS designed it to be extremely user friendly. It can be used on other trials, and also by non-statisticians.

In the simpler, traditional trial design scenario, it's super easy to do- just plug and play some parameters in many software programs and it pops out a number; the sample size. However, without the expertise and possibility to add more layers of complexity, one has to rely on strong assumptions. But nobody really wants to work under strong assumptions in drug development. And nor should that be necessary in modern days drug development, due to the application of advanced clinical trial methodology.

Explore the Advanced Statistical Power in Clinical Trials. Talk to Thomas Debray now!

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