Clinical development expertise and software

Biostatistics, regulatory services and software for pharmaceutical R&D teams



Consulting expertise

Study design, analysis and regulatory support

Software tools

Practical tools for pharmaceutical R&D teams

Biostatistics consulting for clinical trial teams

Study design

Align endpoints and study assumptions with the development decision.

Statistical planning

Examine sample size and power, then define the efficacy and safety analyses.

Interpretation

Explain treatment effects, uncertainty and the sensitivity of conclusions.



Statistical support for regulatory submissions

Consistent documentation

Connect protocol objectives, analysis methods and the evidence narrative.

FDA and EMA submissions

Support the statistical contribution to submission materials and review questions.

Specialized development needs

Discuss disease prevalence estimates and evidence for orphan drug applications.



Software for study design and program planning

PowerYourStudy

Explore sample size and power across assumptions for binary, continuous and survival endpoints.

StudyDesignChatbot

Develop a protocol starting point for scientific and statistical review.

Portfolio Decision-making

Explore historical program transition probabilities by therapeutic area and milestone.



Historical benchmarks describe programs, not individual trial outcomes.

Software for response analysis and orphan drug planning

TumorResponseMarkovChain

Explore response-state transitions and average time spent in each response state.

Orphan Drug Status

Estimate U.S. disease prevalence to inform orphan drug application planning.



Interpret software estimates with qualified scientific and statistical review.

A conversation about your next development decision

Consulting discussion

Bring the study objective, indication, development phase and next milestone.

Software demonstration

Explore the tools that fit your planning or analysis question.



Request a Demo

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