Custom Software Enhances Decision-Making

Cytel custom software boosts early phase decision-making at AstraZeneca

Background **Robust go/no-go decision-making is essential for effectively managing risk across a clinical portfolio. In early phase development, it is particularly important to have the correct tools in place to terminate ineffective compounds quickly, while accelerating promising ones through the process.**

The Challenge

AstraZeneca established a quantitative standard decision-making framework across its Early Clinical Development group. While the system was working successfully, AstraZeneca sought to further enhance the efficiency of the existing process by reducing the burden for statisticians, who were creating their own code to generate the required decision plots. The team required a software tool that could create standardized outputs to streamline communication, save time, and extend the framework with additional features. They needed a development partner with the unique statistical and software development expertise to ensure that:

- The software had the functionality and usability to accommodate the needs of the statistician users.
- The outputs were of presentation quality, making review and discussion among the other clinical stakeholders easier.

"The software collaboration with Cytel has added value to our decision-making approach. The creation of consistent, presentation quality decision plots eases communication between stakeholders. With this software tool in place decision information can now be generated in real-time. As well as saving time for the statisticians and the clinical project team, improving decision making will help us develop the right medicines, and get these medicines to patients faster."

-James Matcham, Head of Early Clinical Development Biometrics, AstraZeneca.

Software collaboration improves communication and increases efficiency

Response

Cytel Strategic Consulting assigned an expert team of statisticians and software developers to work closely with AstraZeneca counterparts.

Solution

The software is developed as a web-based platform using a Windows based server for statistical computations ensuring flexibility for AstraZeneca users who are able to access the tool via a standard internet browser.

Cytel statisticians worked in collaboration with AstraZeneca statisticians to accommodate a Bayesian as well as Frequentist approach within the software interface, extending the established framework.

The software supports various therapeutic areas with a diverse set of clinical endpoints (normal, binomial, survival), as well as different types of interim analyses.

Outcome

The introduction of validated software saves time for AstraZeneca statisticians and statistical programmers in creating and validating their own code.

The creation of consistent, presentation quality decision plots eases communication between stakeholders and ensures a standardized approach.

The user-friendly software interface has positively impacted the way the statistician and other clinical stakeholders work and the speed at which decisions can be made. For example, if, during a meeting, there is a question about the impact of a change in study parameters, it can be assessed with the software and discussed immediately during the meeting. This eliminates the need for the statistician to go back and program new criteria, create slides and arrange follow-up discussions.

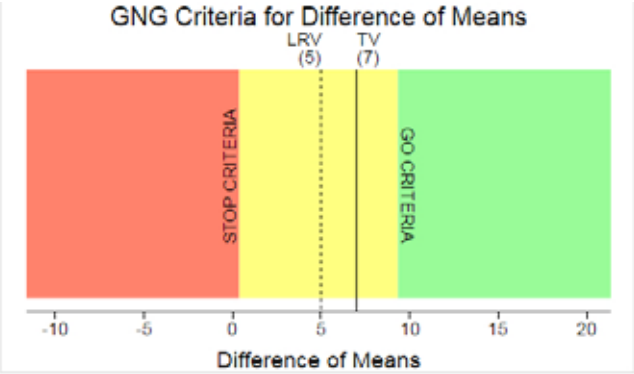
The Cytel Advantage

At Cytel we are committed to helping our pharmaceutical, biologic and medical device clients make better decisions, faster and improve clinical development success rates. Leading industry, academic and regulatory organizations around the world rely on our validated technology solutions, expert statistical consulting, and efficient clinical research services. Combining biostatistics expertise with programming talent, Cytel software collaborations deliver practical, user-friendly tools to power clinical trial innovation.

The Method

A quantitative go/ no-go decision-making framework allows studies to be designed from the outset with the program development decision in mind.

AstraZeneca's approach is based on a method proposed by Lalonde et al (1) and extended by Frewer et al (2). This 3 outcome framework is built on Go/ No- Go and Consider zones, and uses the input of various decision parameters to generate Go and Stop criteria. Based on these criteria standard decision plots are created (example below)



Probabilities	Go (9.35)	Consider	Stop (0.38)
Target Value (7)	32%	58%	10%
Lower Reference Value (5)	20%	61%	19%
User Interest Value (0)	4%	43%	53%

References

1) Lalonde, R., Kowalski, K., Hutmacher, M., Ewy, W., Nichols, D., Milligan, P., Corrigan, B., Lockwood, P., Marshall, S., Benincosa, L., Tensfeldt, T., Parivar, K., Amantea, M., Glue, P., Koide, H. and Miller, R. (2007) 'Model-based drug development', Clinical pharmacology and therapeutics., 82(1), pp. 21–32.
2) Frewer, P., Mitchell, P., Watkins, C. and Matcham, J. (2016) 'Decision-making in early clinical drug development', Pharmaceutical Statistics, 15(3), pp. 255–263. doi: 10.1002/pst.17