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Right *SiZ*® your Trials

Introducing Cytel's new software to design, simulate, and analyze fixed sample studies

Yannis Jemiai, Ph.D.
Associate Director of Biostatistics
SiZ® Development Manager

Introducing *SiZ*®

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SiZ™

What is *SiZ*®?

- *SiZ*® is user-friendly validated software to design, simulate and analyze fixed sample studies
- Quickly and easily generate multiple study designs
- Compare and contrast operating characteristics across designs
- Simulate designs to test deviations from model assumptions
- Import, manage, explore and analyze data
- Produce tables, charts, and summary statements
- Organize libraries of designs, simulations, and analyses
- Context-sensitive help; references to all methods
- Run R programs and SAS scripts

Example: COPD study

- Single-center, randomized, placebo-controlled, double-blind study to evaluate the efficacy and safety of an inhaled drug given twice daily via an inhaler in patients with chronic obstructive pulmonary disease (COPD)
- 2 x 2 Cross-over design with eligible patients randomized to receive either Drug (A) or matching Placebo (B) twice daily for 4 weeks. The patients were then switched over to receive the alternative treatment, also for 4 weeks
- Primary comparison of efficacy based on the mean morning expiratory flow rate (PEFR)
- Suppose we are interested in a difference of $\Delta = 10$ units and wish to compute the power provided by 54 subjects, given a 2-sided type-1 error of 0.05, and a 1:1 allocation ratio
- Assume within-patient variance of $\sigma^2 = 326$

Example taken from Jones B. and Kenward M. (2003). Design and Analysis of Cross-Over Trials. CRC Press.

Available procedures in *SiZ*®

- Continuous, discrete, binomial and time-to-event outcomes
- Superiority, non-inferiority and equivalence hypothesis tests
- Single-arm, parallel groups and 2 x 2 crossover study designs
- ANOVA and regression procedures
- Studies of inter-rater agreement

See the complete list of available procedures at
www.cytel.com/Software/SiZ.aspx

Summary

- Broad set of validated methods
- Quickly and easily generate and compare across multiple designs with tables and charts
- Concise summary statements for insertion into trial documentation
- Simulate deviations from original assumptions
- Analyze and visualize study data
- Help and references to all procedures

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Question & Answer Session

Please complete the short survey at the Q&A session's conclusion

Your feedback is very important to us.

Thank you!