

**TITLE: Flexibility in Clinical Trial Design using Software in combination with R Code: Incorporating Bayesian Treatment Resistance Assumptions**

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**ABSTRACT:**

One of the crucial success factors in study design simulation is accurate representation of treatment response assumptions. While simplified or naïve assumptions about treatment effect are often used in the initial phases of trial design simulation, it is crucial to refine these inputs and employ reliable assumptions to achieve accurate results. Bayesian approaches to response generation are often a great fit. In the biostatistician's toolbox we will commonly find commercial statistical software, custom made for clinical trial design, R-code and other coding languages, as well as computational power to run simulations for design. On the one hand, commercial software allows for confident and quick design through validated workflows and precoded and verified design types, but with this speed and confidence there is also a degree of inflexibility in terms of the methods imbedded into the software. Coding in R allows for almost limitless flexibility in terms of methods, but is dependent on the user's coding ability, requires time for writing and validation, and demands additional resources for communicating results and design selection. In this case study, we propose leveraging the power and confidence of commercial software, in conjunction with the flexibility of R Code, to examine nuanced definitions of treatment effect. Specifically, we will implement varying assumptions of treatment resistance in a specific patient population and apply prior probabilities for a custom analysis showcasing how the two statistical tools can be used effectively together.

**Relevant topics:** Causal Inference; Complex Innovative Designs; Adaptive Designs

**PRESENTING AUTHOR'S BIO:**

Boaz Adler is Director of Global Product Engagement at Cytel. He has served as a Solutions Consultant and Analyst for Life Sciences companies and Health-Tech organizations for over a decade. Boaz's interests are focused on tech and novel services innovations that contribute to more coherent and robust evidence generation across the drug development cycle. At Cytel, Boaz enhances the connection between Cytel's software development team and its clients and supports clients in clinical trial optimization projects using Cytel's cutting-edge technology