

## The Win Ratio: Sample Size Considerations using a Network Framework

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**Abstract:** The win ratio is an innovative statistical method for evaluating treatment efficacy in clinical trials. It involves pairwise comparisons of study participants with a hierarchical ordering of clinically meaningful outcomes. Despite the rising popularity of the win ratio, there has been little advancement in sample size calculations to support this analytic strategy. As successful study planning hinges on determining an adequate sample size, we developed a simulation-based sample size calculation, relying on the relationship between the win ratio and the rank distribution. Using properties of the hypergeometric and rank distributions, we proved that the simulation strategy samples from the distribution determined by the desired win ratio under the alternative hypothesis. While the proposed strategy offers a flexible approach for calculating sample size, it does rely on an important assumption of transitivity. Thus, to further explore the effects of incomplete data on the win ratio, we considered a network framework. Preliminary results suggest the proposed network simulation framework can incorporate bias in the win ratio due to incomplete data, allowing for scenarios when the transitivity assumption is likely to be violated.

**About the Speaker:** Dr. Balmert is an Assistant Professor of Preventive Medicine, in the Division of Biostatistics, at Northwestern University. Her affiliation with the Biostatistics Collaboration Center and the Northwestern University Data Analysis and Coordinating Center involves collaboration across a range of clinical fields including HIV maternal child health, pulmonary and critical care, and pediatric medicine. She is particularly interested in clinical trial design and analysis, leading the DCC efforts for a pharmacodynamic study in patients with critical Covid-19 pneumonia and a high-intensity walking trial to reduce frailty in older adults. Dr. Balmert is also the Data Management Core PI for the newly launched HeartShare network to define heart failure subtypes and treatment targets. Her methodological research has focused on nonparametric methods for time-to-event data analysis and sample size considerations for the win ratio.

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**Carmen Zoom**

