



ASA GEORGIA CHAPTER

## Winter Lecture Series

**4:00 PM, Thursday, December 14<sup>th</sup>, 2023**

Zoom Link: <https://zoom.us/j/99347646840>

**Vlad Dragalin**

Vice President, Scientific Fellow Janssen

### **SIMULATION GUIDED CLINICAL TRIAL DESIGN**

Simulation guided Clinical Trial Design is a framework for stimulating scientific dialogue between trial designer and clinical team with the final goal of developing the most appropriate design for the study. We create different “what-if” scenarios under different assumptions about the drug effect and simulate data from such scenarios and apply the design. We then see if under a scenario that drug doesn’t work, the design indeed says that the drug doesn’t work. Or, under a scenario that drug works, the design says that it works. We simulate under such scenarios thousands if not millions of times and check whether the design performs as required. This creates a new process of developing a study design and is a framework that allows fully vetting the design and challenging assumptions. This is especially important in Complex Innovative Designs. The operating characteristics of such designs can only be evaluated through intensive simulations to ultimately develop the optimal design that will answer more questions more efficiently and in less time. In this presentation, we will start with general principles and key steps for simulation guided clinical trial design. We will follow with a simulation case study that illustrates the principles, key steps of setting the scenarios, and the operating characteristics of different candidate designs that allow the selection of the most appropriate design for the objectives of the trial.

### **About the Speaker**

Dr. Vladimir Dragalin is a Vice President and Scientific Fellow at Janssen, Pharmaceutical Companies of Johnson and Johnson. He is adaptive designs expert with 25 years experience in developing the statistical methodology of adaptive designs, with over 12 years experience in pharmaceutical industry including positions at GlaxoSmithKline, Wyeth, Pfizer and at leading CROs Quintiles and Aptiv Solutions. Dr. Dragalin is a Fellow of the American Statistical Association and Member of the Drug Information Association, the Society for Clinical Trials, the International Society for CNS Clinical Trials and Methodology, and an Associate Editor of Journal of Biopharmaceutical Statistics. He is actively involved in the PhRMA Working Group on Adaptive Designs and the PhRMA Working Group on Adaptive Dose Ranging Studies (currently under DIA) and an elected member of the PhRMA Biostatistics and Data Management Technical Group.



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