

## **UNDERSTAND RISKS IN DRUG DEVELOPMENT THROUGH SIMULATION**

Fei Chen

Janssen Pharmaceutical Research & Development

Johnson & Johnson

902 Rt 202 S.

Raritan, NJ 08812

### **ABSTRACT**

Running a clinical trial program that leads to the approval of a new medical compound takes a tremendous amount of investment. The probability of success is low, and properly evaluating and understanding this risk is crucially important to drug companies with large portfolios. Simulation-based modeling plays an increasingly critical role in this endeavor. In this talk, I will discuss how simulation guided design can significantly reduce cost of a trial through assessing risk-benefit trade-offs from a drug safety perspective.