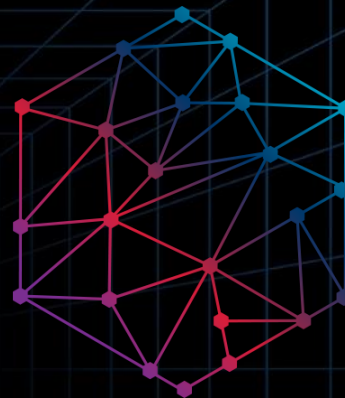


Model-Informed Drug Development

**MIDD+**

**2021 Virtual Conference**

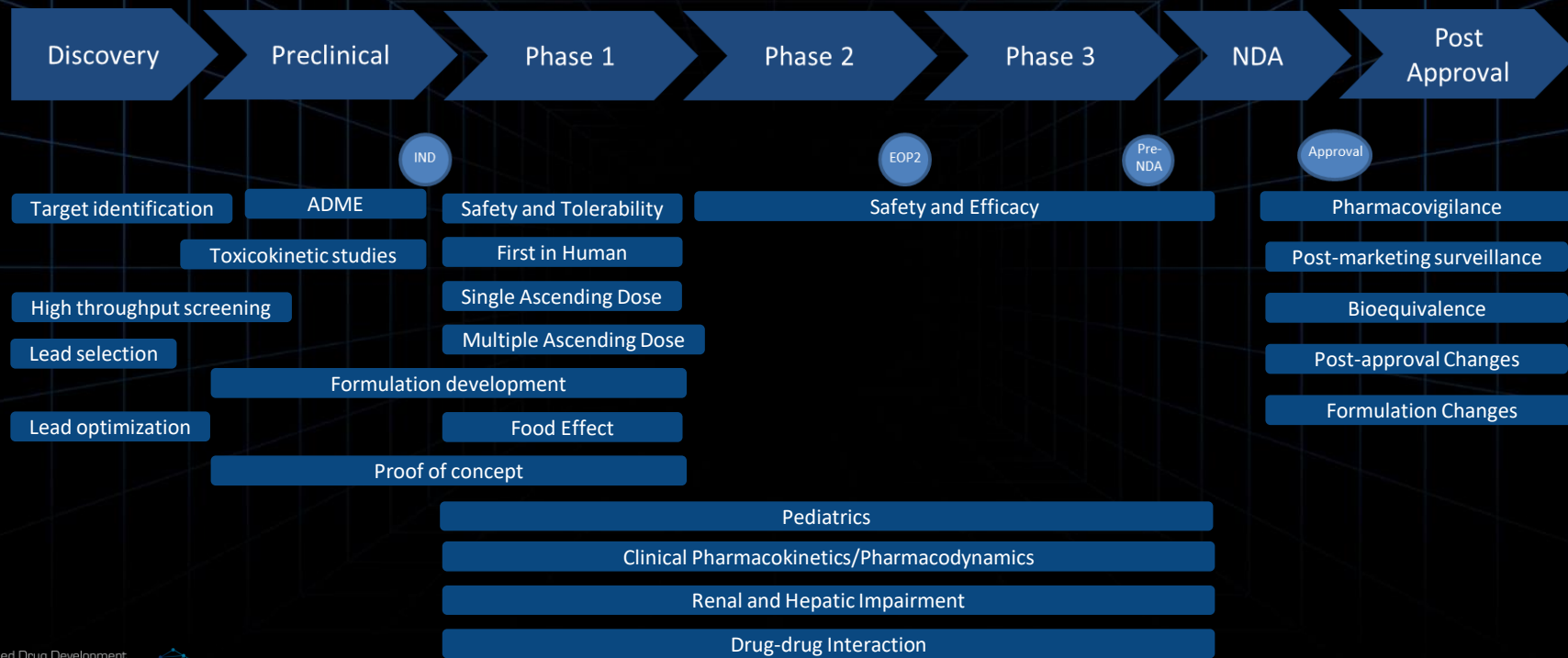


**Introduction to Phase III Track**

Elizabeth A. Ludwig

Associate Vice President, Quantitative Clinical Pharmacology

# Drug Development Phases

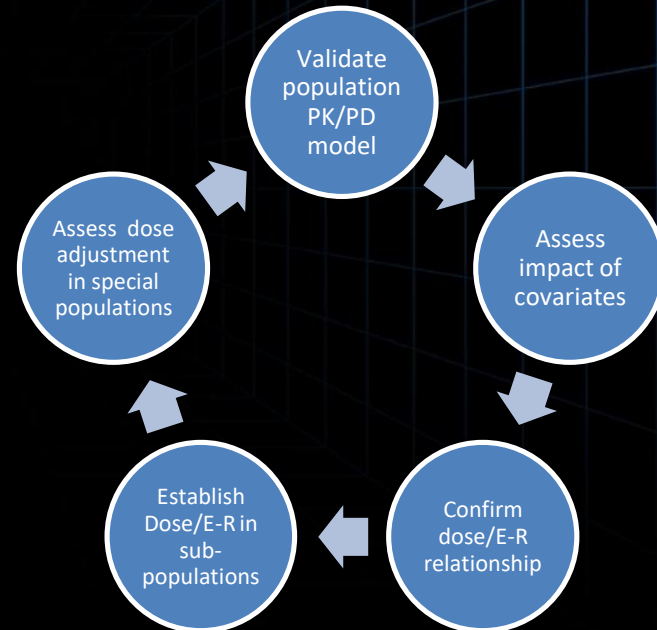


# Application of Modeling & Simulation in Phase 3

## Questions to be Addressed

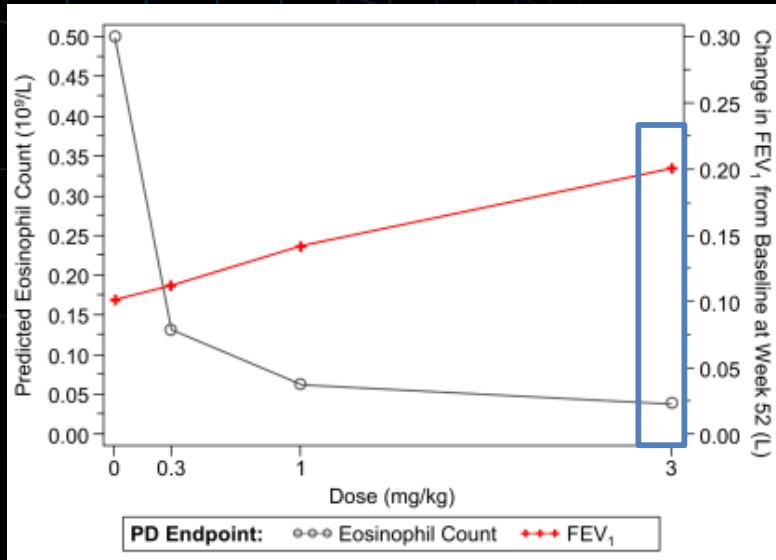
- Do the intended dose(s) demonstrate the desired safety and efficacy in the population?
- Is the dose likely to change in a given subpopulation or special population? If so, by how much?

## Modeling & Simulation Tasks

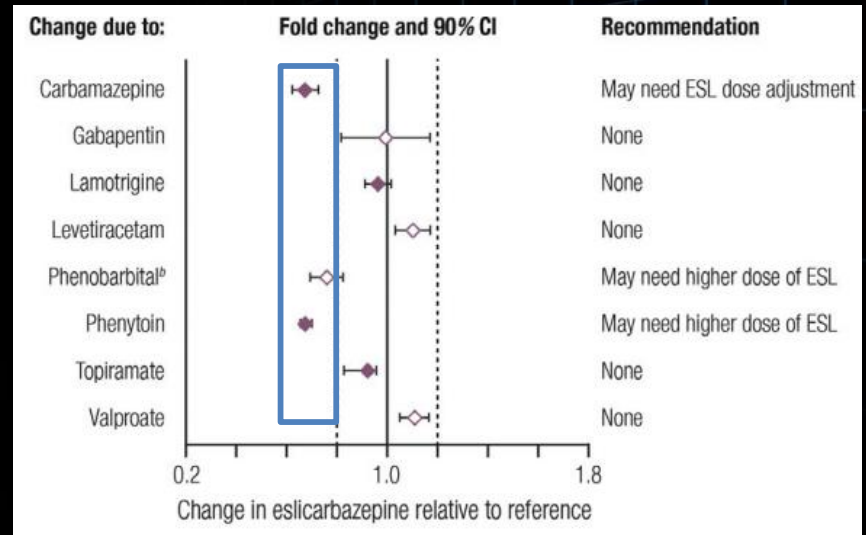


# Model-Informed Approaches to Characterize Exposure-Response and Potential for Drug-Drug Interactions

Exposure-response model predictions for eosinophil count and change in FEV<sub>1</sub> from baseline by reslizumab dose level supported dose selection in adults with asthma.



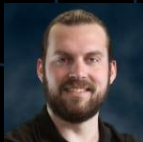
Population PK analysis included quantitative assessment of the effects of concomitant administration of other antiepileptic drugs on the PK of eslicarbazepine in adults with partial onset epilepsy; results were included in the product label.



# Phase 3 Panelists



Julie Passarell  
Assistant Vice President, Statistics  
Simulations Plus, Inc.  
Pharmacometrics in Phase 3 – Data Integration and Analysis to Support Dose and Labeling for the NDA



Maxime LeMerdy  
Senior Scientist  
Simulations Plus, Inc.  
Pregnancy PBPK Modeling, a Necessary Step Towards Safety and Efficacy



Paul Watkins, MD  
Howard Q Ferguson Distinguished Professor of Pharmacy  
University of North Carolina Institute for Drug Safety Sciences  
Quantitative Systems Toxicology Modeling Provides Novel Mechanistic Insights into Disease-related Tolvaptan Hepatotoxicity



James Beaudoin  
Scientist 1  
Simulations Plus, Inc.  
Quantitative Systems Toxicology Modeling Provides Novel Mechanistic Insights into Disease-related Tolvaptan Hepatotoxicity



Sarem Sarem  
Senior Biostatistician, Pharmacometrics  
Health Canada  
Regulatory Perspectives for Reliable Model Informed Drug Development



# Phase 3 Poster Presenters



Hannah Huang  
Assistant Director, Pharmacometrics  
Simulations Plus, Inc.  
Concentration-QTc Analysis of Quizartinib in Patients with Relapsed/Refractory Acute Myeloid Leukemia

Luann Phillips  
Distinguished Scientist, Pharmacometrics  
Simulations Plus, Inc.  
Population Pharmacokinetic Evaluation and Missed Dose Simulations for Eslicarbazapine Acetate Monotherapy in Patients with Partial-Onset Seizures

