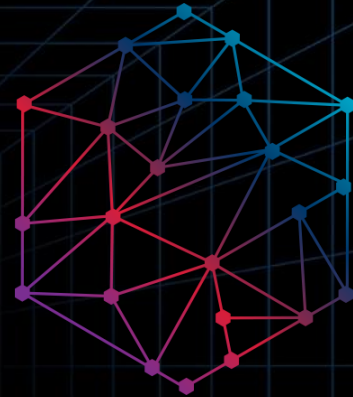


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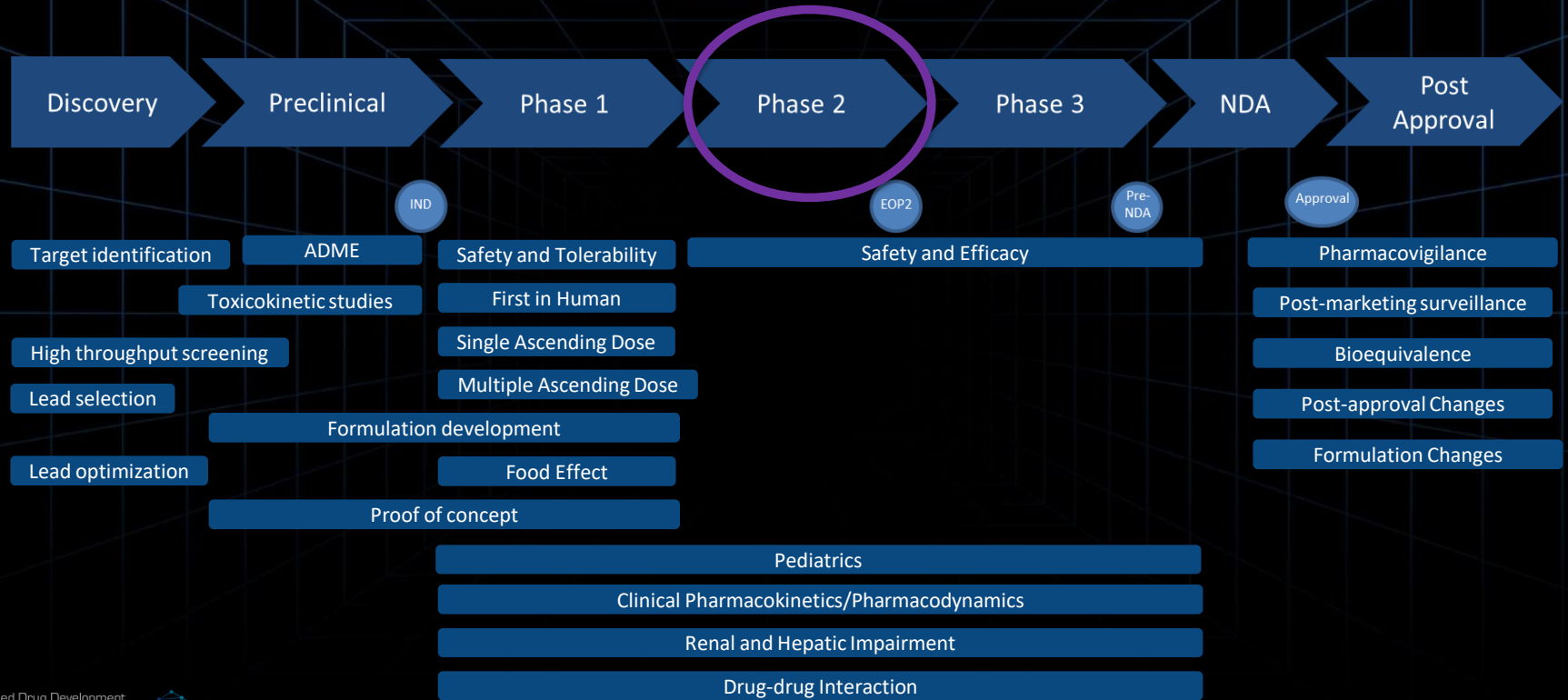


Introduction to Phase II Track

Joel S. Owen, Ph.D.

Vice President, Pharmacometric Services

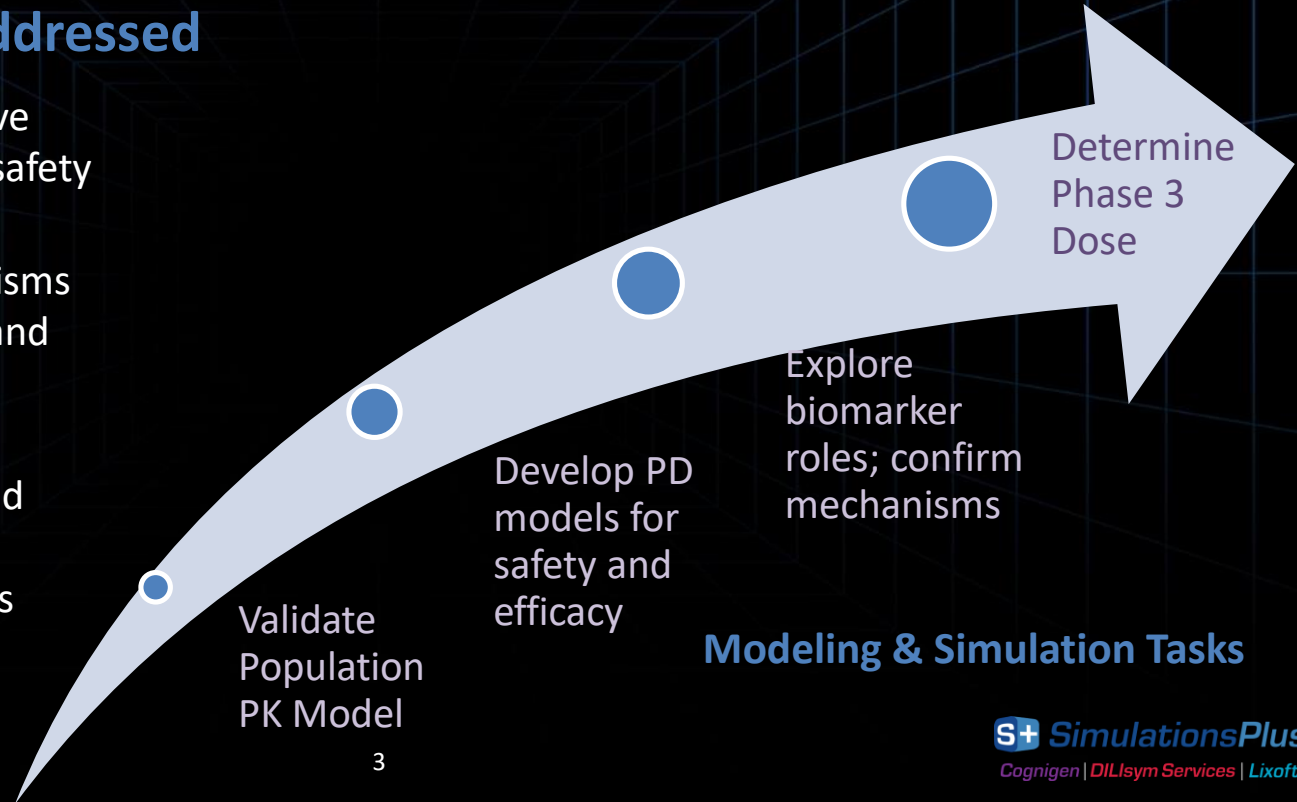
Drug Development Phases



Application of Modeling & Simulation in Phase 2

Questions to be Addressed

- Can we develop predictive quantitative models for safety and efficacy endpoints
- Can we confirm mechanisms of action; clinical utility and validation potential of biomarkers
- What is the best dose and study design for the subsequent Phase 3 trials



Phase 2 Panelists



Claude Magnard, PhD
Application Manager
Simulations Plus, Inc.

Investigation of the power of a phase III trial for different sample sizes via clinical trial simulations using a phase II population PD model

Sebastien Bihorel, PharmD, PhD

Director, Pharmacometrics and Workflow Automation
Simulations Plus, Inc.

Pharmacometrics in Phase 2 - PoC and Dose Selection for Phase 3/Marketing

Yaning Wang, PhD

Director, Division of Pharmacometrics, Office of Clinical Pharmacology
U.S. Food and Drug Administration

The impact of MIDD during phase 2 of new drug development - a Regulatory Perspective



Zack Kenz, PhD
Scientist II
Simulations Plus, Inc.

Mathematical Modeling with NAFLDsym[®] Supports the Role of Adiponectin in the Reduction of Steatosis by the Anti FGFR1/KLB Bispecific Antibody



Phase 3 Poster Presenters



David Jaworowicz, PhD
Senior Director, Pharmacometrics
Simulations Plus, Inc.

Semi-mechanistic PK/PD Model of the Effect of Odanacatib, a Cathepsin K Inhibitor, on Bone Turnover to Characterize Lumbar Spine Bone Mineral Density in Two Phase II Studies of Postmenopausal Women



Julie Passarell, MA
Assistant Vice President, Statistics
Simulations Plus, Inc.

Exposure-Response Modeling from the CLARITY Trial of Pimavanserin for Adjunctive Treatment of Major Depressive Disorder



Q & A

Questions & Answers

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