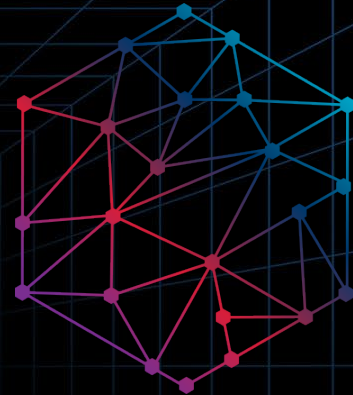


Model-Informed Drug Development

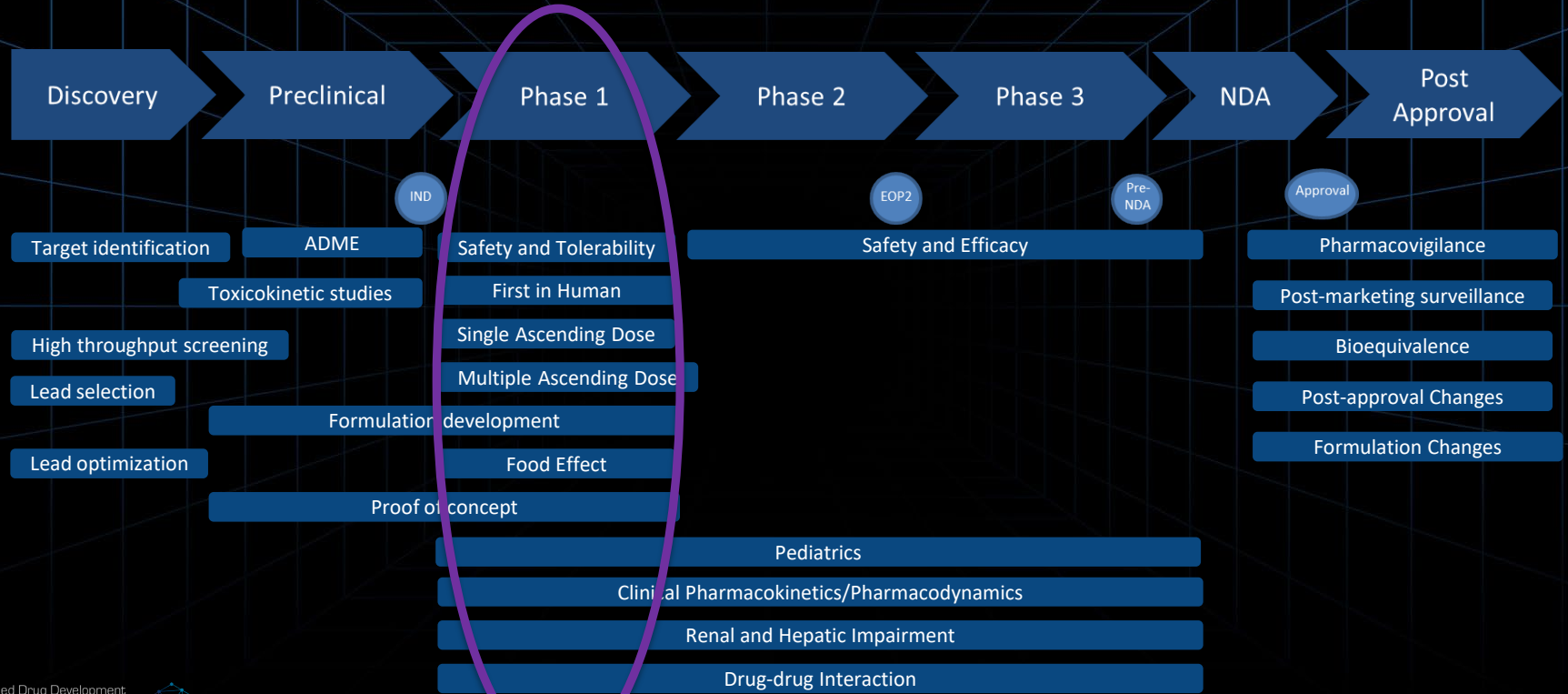
# MIDD+

2021 Virtual Conference



**Introduction to FIH/Phase 1 Track**  
Kevin Dykstra, PhD FCP  
Vice President, Consulting Services

# Drug Development Phases



# Application of Modeling & Simulation in Phase 1

## Questions to be Addressed

### First in Human Studies

- How much can we give safely?
- What is the human exposure?
- Does the drug engage with its target?

### Later ...

- What affects exposure?
  - Other drugs? Food? Physiological impairment?
- How do we administer the drug?
  - Exposure with new formulations
  - Bridging among study populations

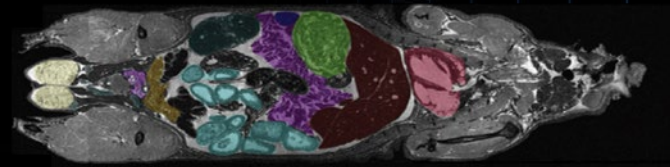


Image from Badea & Johnson. Analytical Cellular Pathology, 35(4):205-227 (2011).



Image from True Phantom Solutions.



# Phase 1 Speakers



Monika Twarogowska, PhD  
Applications Manager  
Simulations Plus, Inc.

Using a population PK/PD model developed on Phase I to select the dose for Phase II: an example with an IgG1 mAb



Yogesh Patel, PhD  
Associate Director, Quantitative Clinical Pharmacology  
Simulations Plus, Inc.

Pharmacometrics in Phase 1: First in Human and Dose Selection for Phase 2

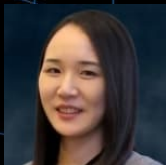


Michael Bolger, PhD  
Founding Scientist, Research & Development  
Simulations Plus, Inc.

GastroPlus® DDI Standards Update



# Phase 1 Poster Presenters



KyungHee Yang, PhD  
Senior Scientist  
Simulations Plus, Inc.

Assessment of the Mechanism for Remdesivir-Associated Clinical ALT Elevations Using DILIsym Quantitative Systems Toxicology Modeling



Vinal Lakhani  
Scientist 1  
Simulations Plus, Inc.

Quantitative Systems Toxicology Identifies the Mechanism and Data Gaps for Evaluating the Hepatotoxicity of Compound V



Bill van Osdol, PhD  
Principal Application Specialist  
Simulations Plus, Inc.

Computational Simulation of Dermal Absorption from Complex Topical Formulations



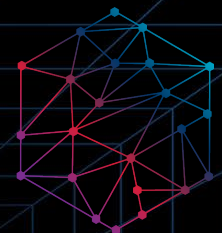
# Q & A

Questions & Answers

Model-Informed Drug Development

# MIDD+

2021 Virtual Conference



 **Learn More!** [www.simulations-plus.com](http://www.simulations-plus.com)

**S+** *SimulationsPlus*  
Cognigen | DILIsym Services | Lixoft