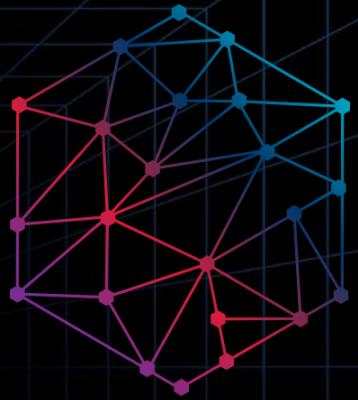
Model-Informed Drug Development

MIDD+

2021 Virtual Conference



Post-Approval/Generics

Moderator: Ryan M. Franke

SimulationsPlus

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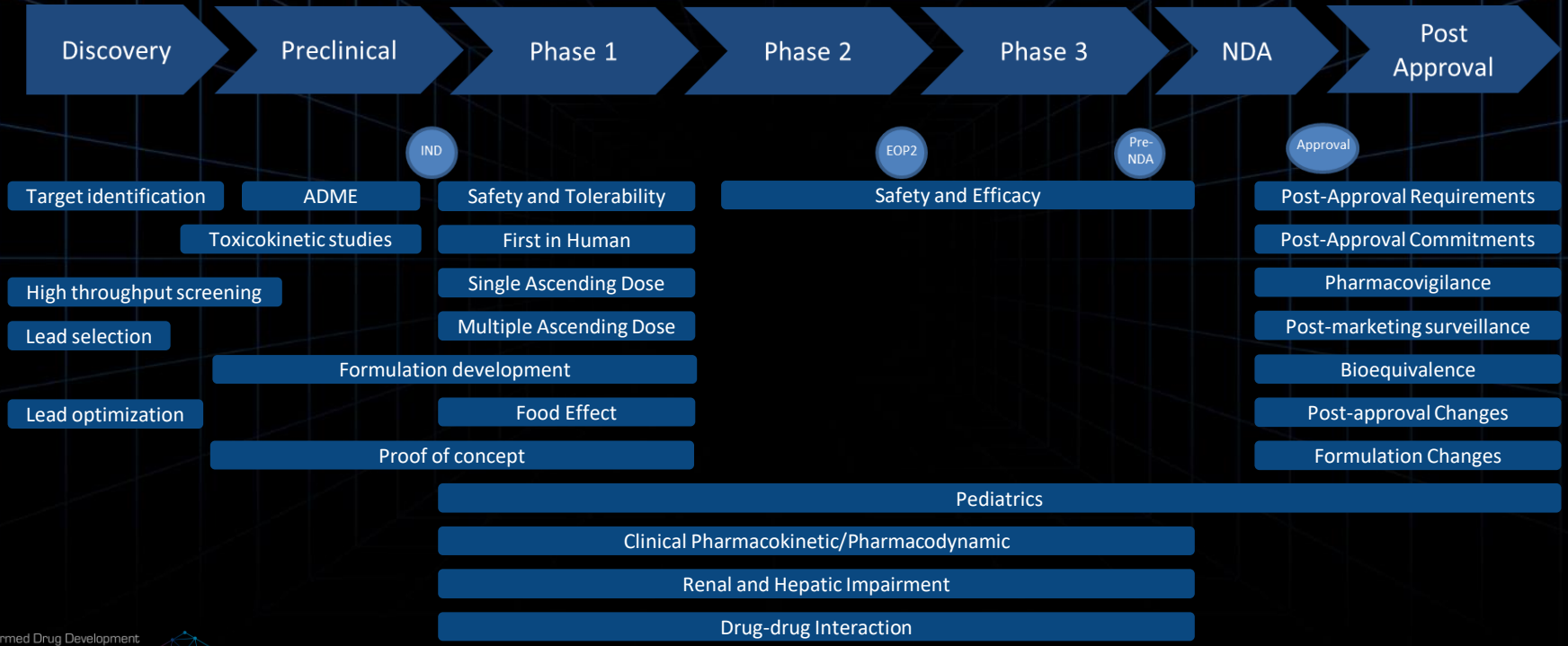
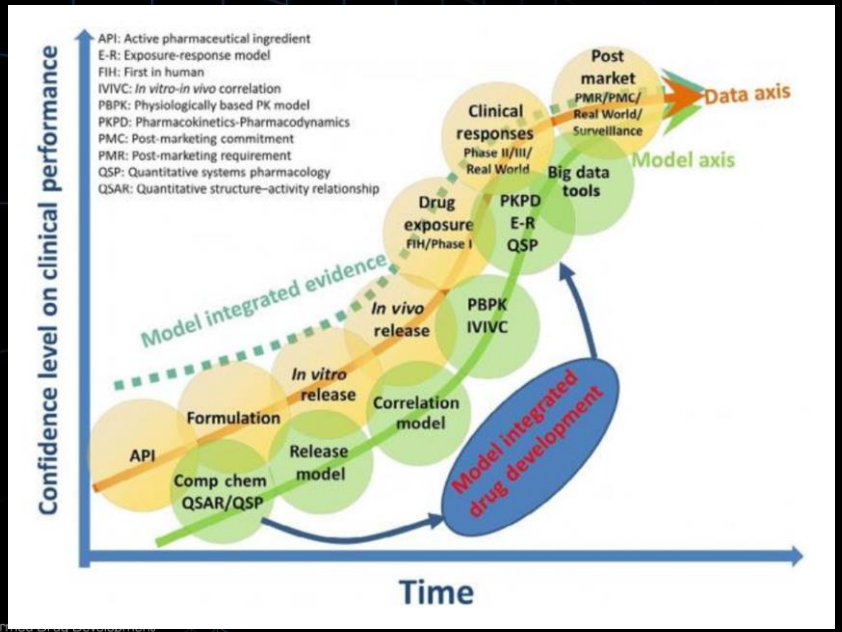
Drug Development Phases

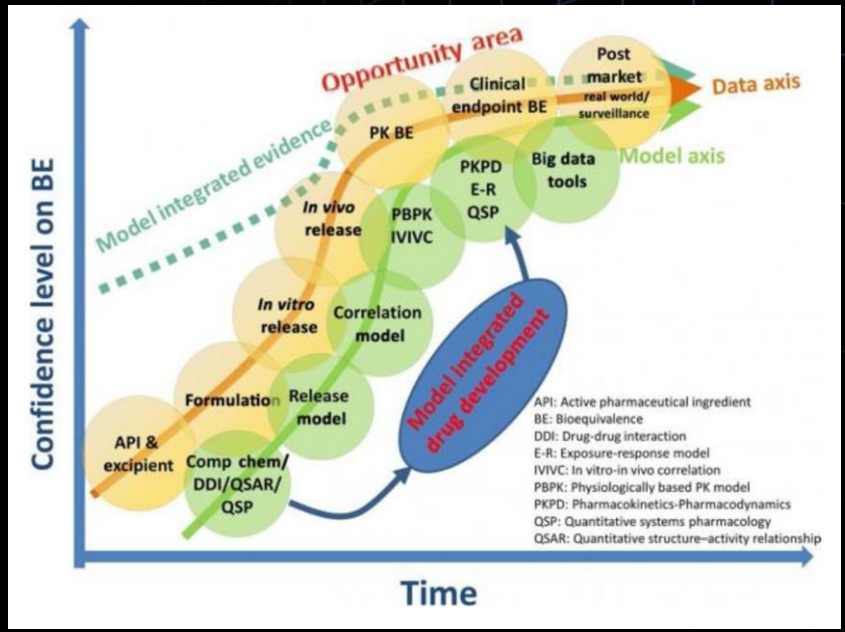


Value of Modeling & Simulation

Post-Approval of NDA/BLA



Development of Generic



Source: FDA; Impact Story: Modeling Tools Could Modernize Generic Drug Development, June 2020

Post-Approval/Generics Panelists

Aksana Jones
Associate Director, Pharmacometrics
Simulations Plus, Inc.
Pharmacometrics in Post Approval: Fulfillment of Requirements, Label Extension, and Life-Cycle Management

Banu Zolnik
Pharmacology, ONDP/FDA
U.S. Food and Drug Administration
FDA's Perspective on the Physiologically Based Pharmacokinetic (PBPK) Analyses for Biopharmaceutics Applications

Liang Zhao
Director of the Division of Quantitative Methods and Modeling, Office of Research and Standards, Office of Generic Drugs, CDER, FDA
U.S. Food and Drug Administration
Using Model Informed Drug Development and Model Integrated Evidence to Support Generic Drug Development and Assessment

Gustavo Mendes Lima Santos
General Manager, Medicines and Biological Products
ANVISA
The role of modeling and simulation in the approval of generic drug products

Brett Howell
Divisional President
Simulations Plus, Inc.
Application of the DILIsym® QST drug-induced liver injury model to evaluate the carcinogenic hazard potential of acetaminophen