

Virtual Advanced Workshop: DMPK and Clinical Pharmacology

November 14th - 17th, 2022

# Workshop Overview

This advanced <u>GastroPlus®</u> workshop will provide a more in-depth exploration of PBPK theory, execution, and application of the software as compared to the introductory workshop.

#### To attend this workshop participants should be familiar with the following:

- Running basic GastroPlus simulations
- Database and support file structure
- · Primary inputs for physicochemical and pharmacokinetic parameters
- · Basic physiology options for human and animal simulations

The workshop will consist of a combination of live lectures and hands-on exercises within the software. The materials are selected to demonstrate both the theoretical and practical aspects of PBPK modeling.

#### The workshop benefits scientists working within:

- · Preclinical pharmacokinetics and pharmacodynamics
- · Clinical pharmacokinetics and pharmacodynamics
- · Interactive process of absorption (passive and carrier-mediated)
- Metabolism in the gut and other tissues
- · Whole-body distribution affecting PK and PD
- · This workshop will also include some examples of special populations

If you are new to GastroPlus we recommend attending one of our complimentary, monthly introductory training sessions or ideally one of our paid introductory workshops **prior** to attending this advanced workshop.

# **Learning Objectives**

## At workshop completion you will have an understanding of the following:

- Recognizing when to use PBPK vs. standard compartmental PK models
- Predicting first-in-human (FIH) doses with available preclinical and in vitro data (IVIVE)
- Tracking parent and metabolite concentrations through multiple pathways in plasma and tissues

The goal is to provide you with the necessary tools to communicate data needs to your operational groups producing preclinical and clinical data, and to clearly present your results to project leaders and management.







## **Course Instruction**

The workshop is taught by experienced PBPK modelers from SImulations Plus.

# Agenda (all times are Pacific Standard Time)

#### <u>Monday</u>

08:00 - 11:00	Course Introduction. First-in-Human (FIH) Predictions, Hepatic and Renal
	Clearance (includes a 30-minute break)
11:00 - 11:30	Lunch Break
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11:30 - 13:15 Transporter-based IVIVE

### <u>Tuesday</u>

08:00 - 11:30 Enterohepatic Circulation and Metabolite Tracking (includes a 30-minute break) 11:30 - 12:00 Lunch Break 12:00 - 13:15 PBPK-PD Modeling

### <u>Wednesday</u>

08:00 - 11:30 DDI Predictions (Dynamic and Steady State) with a focus on Auto-induction (includes a 30-minute break)

### <u>Thursday</u>

08:00 - 10:00 Pediatric Population Predictions 10:00 - 10:30 **Break (30 min)** 10:30 - 12:30 Disease State and Pregnancy

## **Virtual Platform**

Training sessions will consist of live instruction and guided, hands-on examples via Zoom Video Conference.

Participants will attend virtually using their own PCs. Use of cameras and microphones are optional but encouraged.

Participants will be provided with personal access to the Simulations Plus virtual learning environment. The learning environment will contain GastroPlus software and access to downloadable course materials and example files. The learning environment will remain open to participants for one week post workshop completion. Upon workshop completion, participants may request a complimentary trial GastroPlus license for further engagement and evaluation by reaching out to <u>https://www.simulations-plus.</u> com/software-evaluation-request-form/.

## Requirements

PCs equipped with internet access and Google Chrome with Flash 9+ plugins are required to participate.

Industry

# GastroPlus Virtual Advanced Workshop:

DMPK and Clinical Pharmacology

November 14th - 17th, 2022 - Register by November 7th

Title:	Professor	Dr.	Mr.	Mrs.	Miss	Ms.	Academia		
First name:									
Last nan	ne:				(	Company:			
Job Title	:				I	Department:			
Address	:								
Telepho	ne:				I	Email:			
Purchase Order No. (if applicable):									

Industry: \$2,000 Academia: \$1,000\*

\*You must register with a valid .edu email address

#### Method of payment (Please check one)

Payment by check (you will be invoiced upon receipt of your completed registration form)

Payment online (you will be redirected to the payment portal when registering online at simulations-plus.com/register-training-

workshop)

#### **Terms and Conditions**

**Registration:** The course is limited to 25 participants. An email confirming registration will be issued within 2 busines days upon receipt of registration.

**Cancellations:** Cancellations with a refund minus 4% credit card fees may be made two weeks before course date. No refunds will be given for cancellations received after this date. Substitutions may be made at any time.

**Payment Terms:** Following completion and return of the registration form, the total fee must be paid within 30 days of receipt of invoice. All fees must be paid in full prior to the start of the workshop.



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