



DILIsym® 2-Day Workshop

September 11-12, 2019 in Research Triangle Park, NC

Who should attend?

This is a beginner's course for clinicians, pharmaceutical/biotechnology scientists, and engineers in the areas of toxicology, clinical pharmacology, pharmacovigilance, DMPK and ADME - prior experience with DILIsym is not required. The course will use DILIsym, but the guiding principles will be taught in a software-independent manner. Class size is limited to encourage interaction with the course instructors and among attendees. Networking among industry, government, and academic scientists is part of the experience!

What will you learn?

You will understand the following important aspects of liver safety investigation:

- concepts accepted by regulators related to DILI monitoring and detection
- primary mechanisms, (e.g., mitochondrial dysfunction, ROS, bile acids, and lipotox) often involved in DILI events
- *in vitro* assay design and execution for DILI-related mechanisms
- pharmacokinetics, including prediction of liver concentrations and how this impacts DILI predictions

You will gain basic experience with:

- translating *in vitro* data into DILIsym parameter values
- simulating expected DILI outcomes for humans, rats, mice, and dogs
- utilizing simulated populations (SimPops™) to predict infrequent events in a diverse patient population

How will the workshop operate?

On-site and remote attendance are both available and welcome. All attendees will be responsible for acquiring/using their own computers. Non-license holders will be required to access the software via an online portal.

Day 1 – 'DILIsym Introduction' and 'Advanced features in DILIsym' (SimPops, Optimization, Clinical Monitoring, Specified Data for PK)

- * Attendees may customize their schedule by participating in a mix of intro and advanced materials

Day 2 – Step by step compound representation in DILIsym

- * All attendees will follow the same track

Breakfast and lunch will be provided each day.

Where will this be held?

Marriott at Research Triangle Park

4700 Guardian Drive, Durham, NC 27703

Tel: +1-919-941-6200 | www.marriott.com

Access DILIsym Group Rate: www.simulations-plus.com/marriott



"DILIsym is helping to address major DILI events for drug developers & regulators. It has been recently licensed to the USFDA."

Lecture on assessing liver safety in clinical trials by:
Paul B. Watkins, M.D.
Director of UNC Institute for Drug Safety Sciences

DILIsym Services

S+ A SIMULATIONS PLUS COMPANY



Register online! www.simulations-plus.com/workshops

REGISTRATION FORM

Attendance is limited • Please register by September 4, 2019

Please fill in this form and return to Patti Steele (psteele@dilisyms.com); Fax: +1-919-226-3150
To register by phone, please call Patti at +1-919-558-1297

The DILIsym 2-Day Workshop

September 11-12, 2019 in Research Triangle Park, NC

DILI-sim members or DILIsym license holders
Non-members and non-license holders from industry
Non-members and non-license holders from academia
or government

Title: Professor Dr. Mr. Mrs. Miss Ms.

First name:

Last name:

Company:

Position:

Department:

Address:

Telephone:

Email:

Purchase Order No. (if applicable):

DILI-sim Initiative members and DILIsym license holders (both academic, government, and industry): **FREE!**

Non-members and non-license holders from industry: **\$600.**

Non-members and non-license holders from academia or government: **\$300.**

Cost for the workshop includes all workshop materials, continental breakfast, refreshment breaks, and lunch each day.

A training license will be granted to all paid attendees. The training license will begin on the last day of the workshop and expire 30 days later. Hotel accommodations are not included.

Method of payment (Please check one)

Credit card (a confirmation message will be sent to the email address provided)

Name on card:

Email:

Tel:

Card billing address:

Zip/Post Code:

Type of card: Visa MasterCard AMEX Card Number:

Expires:

Security code:

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

Payment by wire transfer (you will receive wire transfer information upon receipt of your completed registration form)

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

Terms and Conditions

Cancellation Policy: Cancellations made prior to September 4, 2019, will be eligible for an 80% refund. Refunds for cancellations will be honored up to 45 days after the date of payment for credit card transactions. Substitutions are allowed up to 10 days before the event.

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.