NS NAFLDsym®

QSP Virtual Workshop

September 23, 2020

Who should attend?

This is a beginner's course for mechanistic modelers, pharmacologists, clinicians, pharmaceutical/biotechnology scientists, and engineers in the specific area of clinical and quantitative systems pharmacology (QSP) for **nonalcoholic fatty liver disease (NAFLD)** and **nonalcoholic steatohepatitis (NASH)**. Prior experience with NAFLDsym is not required. The course will focus on NAFLDsym v2A, but many of 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. Virtual networking among industry, government, and academic scientists is part of the experience!

What will you learn?

You will understand the following important aspects of NAFLD and NASH:
- key components of NASH pathophysiology, including steatosis, lipotoxicity, fibrosis, and inflammation
- examples of targets represented for *in silico* evaluation
- patient heterogeneity that makes these syndromes particularly challenging to develop effective treatments
- important biomarkers and bio-signatures used by developers and regulators to assess treatment efficacy and safety
- common mechanistic clinical study designs used for testing drug candidates
- disease progression
- influence of weight gain and weight loss on disease status

You will gain basic experience with:
- translating pre-clinical and clinical data into NAFLDsym parameter values, including the use of sensitivity analyses and optimization
- simulating expected treatment outcomes for simulated NAFLD/NASH patients at various stages of the disease
- validation and support for existing NAFLD/NASH simulated populations (SimPops) included in the software
- stratification of simulated populations to address a planned or possible clinical study

How will the workshop operate?

This workshop will be entirely virtual. Attendees will be responsible for acquiring/using their own computers to log on. Non-license holders will be provided limited access to the NAFLDsym software via an online portal. The workshop will start at 8:30 AM ET and conclude at 5 PM ET. Mid-morning and mid-afternoon breaks will be taken, and a break will be taken for lunch from Noon ET to 1 PM ET. All attendees will follow the same track. Log-in information will be sent out to all registered attendees in advance of the course, along with course materials.

Day 1 – "NAFLDsym Introduction and Applications,' including NAFLD/NASH overview, software overview, introduction to pathophysiologies included in NAFLDsym and associated SimPops validation, and included biomarkers. The general workflow for using the software from start to finish will be discussed, alongside an example compound simulation exercise.

"...NAFLDsym v2A enables users to evaluate key pathophysiologic areas of evaluation in NASH drug development..."

Key Course Leader:
Scott Q. Siler, Ph.D.
Chief Scientific Officer

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

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Please fill in this form and return to Patti Steele (psteele@dilisym.com);
To register by phone, please call Patti at +1-919-606-7270

The NAFLDsym QSP Virtual Workshop
September 23, 2020

NAFLDsym license holders
Non-license holders

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

First name:

Last name: **Company:**

Position: **Department:**

Address:

Telephone: **Email:**

Purchase Order No. (if applicable):

Current license holders of NAFLDsym (up to max of number of licenses held by organization): **FREE!**
Non-license holders of NAFLDsym or overage of individuals from organization compared to number of licenses held: **$300**.

Cost for the workshop includes all workshop materials. A training license will be granted to all paid attendees. A 30 day trial license will be made available to all attendees after the course upon request.

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 14, 2020, 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.