



NAFLDsym[®]

Introductory Course

September 30, 2021



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

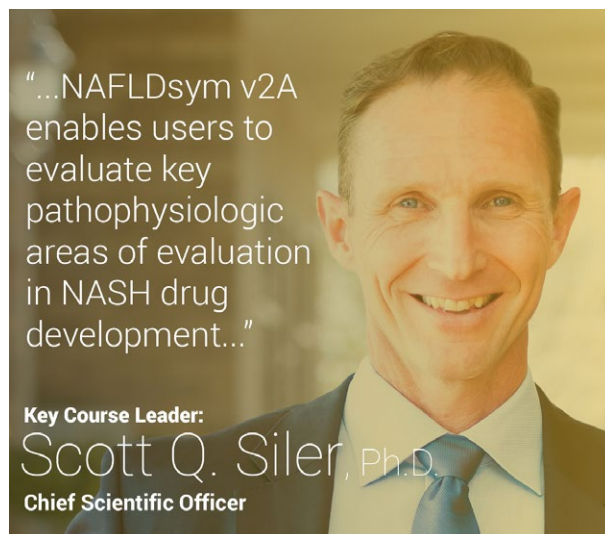
You will gain basic experience with:

- 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. 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.

Agenda by Topic – '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

DILsym Services

SP+ A SIMULATIONS PLUS COMPANY

REGISTRATION FORM

Attendance is limited • Please register by September 20, 2021

Please fill in this form and return to Brett Howell (bhowell@DILsym.com);

To register by phone, please call Brett at +1-704-202-1455

The NAFLDsym Introductory Course

September 30, 2021

NAFLDsym license holder from industry

Academic or government

Non-license holders from industry

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

First name:

Last name:

Company:

Position:

Department:

Address:

Telephone:

Email:

Purchase Order No. (if applicable):

FREE - NAFLDsym license holder from industry

FREE - Academic or government

\$300 - Non-license holders from industry

Cost for the workshop includes all workshop materials.

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 www.simulations-plus.com/workshops)

Terms and Conditions

Cancellation Policy: Cancellations made prior to September 20, 2021, 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.