WORKSHOPS **PredIF**

November 9th



(Course in English) NO FEES

Mirjam N. Trame

The nlmixr team will be running a half-day hands-on workshop on simulation (RxODE) and parameter estimation using the free and open-source R-based nonlinear mixed effect modelling platform nlmixr on Friday, November 9th 2018 @ 1pm - 6pm. The course will consist of a mixture of lectures and hands-on exercises. nlmixr is an open source R package for population PK and PKPD modelling, and builds on the RxODE package for simulation of nonlinear mixed effect models using ordinary differential equations, by implementing parameter estimation algorithms like nlme and SAEM. nlmixr greatly expands the utility of existing packages (like nlme) by providing an efficient and versatile way to specify pharmacometric models and dosing scenarios, and allows for the estimation and simulation of nonlinear mixed effect models across multiple disease areas during drug development and clinical practice. nlmixr features a domain-specific modeling language unifying all the estimation engines and reducing the learning curve needed to become proficient. This session will further include discussion of "shinyMixR", a Shiny tool for nlmixr, which facilitates 1) dynamic and interactive model development, 2) quick and efficient communication of population PKPD models, 3) rapid demonstrations of simulation results from PK and PKPD modeling, and 4) report building. The ability to perform population modeling in R provides a single unified workflow for data management, data exploration, data analysis and report building. nlmixr is available on CRAN and GitHub (https://github.com/nlmixrdevelopment/nlmixr) with a dedicated nlmixr/shinyMixR bookdown (https://nlmixrdevelopment.github.io).

November 5/6th



(Course in Spanish) FEES ¹⁵⁰ USD Industry 50 USD accredited students 100 USD academic-NON PROFIT

Manuel Ibarra/Iñaki Trocóniz

This 2-day workshop will introduce the concepts, implementation, evaluation and application of population pharmacokinetic and pharmacodynamics models in NONMEM.

November 5/6th





Marc Lavielle

A 2 days workshop on the Monolix Suite will be given by Marc Lavielle on the 5th and 6th of November 2018. The course is designed for both beginners and advanced modellers. It will provide a complete presentation of the latest version of the Monolix suite and the R packages 'mlxR' and 'Rsmlx'. The course will present how to use the Monolix suite for PKPD modelling and population analysis. Advanced modelling features such as categorical and count data models, mixture models, time to events will be presented. The course will include training on Mlxtran, the simple and powerful declarative script language for continuous and discrete pharmacometric models. The course will also provide training on Rsmlx (R speaks Monolix), a new R package for model building (rsmlx.webpopix.org) and Simulx, a powerful clinical trial simulator for the simulation and visualization of longitudinal data and virtual patient populations. Simulx is part of mlxR, a R package developed by Inria for advanced clinical trial simulations with the full Monolix Suite. Students and academics have access to free, renewable licenses of the Monolix Suite.





MISSION

Our mission is to promote the advancement of pharmacometrics in Latin-America through its application in pharmacological research, enhancing drug development and introduction of therapeutic strategies, as well as in the clinical setting supporting dose optimization and rational use of medicines. Additionally, we aim to create a multidisciplinary framework for education and training of scientists getting into this discipline.

CUCE

VISION

To become a recognized Ibero-American network in the field of pharmacometrics by the promotion of education and training of personnel in this area and the encouragement of its application in the fields of development, registration and use of medicines, integrating academia, industry, regulatory and clinic sectors.

http://www.redifar.org/







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OBJECTIVES

Testosteron (TST)

AGN + BGN

1+ACN+RCN

1. To support the learning process about the development of mechanistic population pharmacokinetic/pharmacodynamic models in Latin America.

Total receptors

2. To promote and to spread the use of Pharmacometrics analysis tools in Latin America, and their application in monitorization, pharmacovigilance, as well as in the development of new active ingredients and pharmaceutical specialties from a multidisciplinary point of view.

3. To promote novel experimental design with improved safety and efficacy in the conduction of clinical trials.

4. To promote multicentric populationbased pharmacokinetic/pharmacodynamic and disease progression studies within Latin America.

5. To create an open access database about the Latin American population to help health science researchers in meta-analysis population studies.

6. To harmonize non-clinical and clinical practices based on GLP in order to facilitate exchange of information to fulfill registration requirements of new medications in Latin American countries.



November 7th 8th and 9th

Auditorium of Basic Sciences (Module Y).

Department of Pharmacobiology/Center of Exact Sciences an Engineering/University of Guadalajara

KEYNOTE LECTURES

40+10 minutes Q&A

Wednesday 7th

 Estimate
 CI

 1.50
 0.7-8.6

 0.59
 0.6-4.2

 0.25
 0.63

 0.12
 0.01-0.04

 0.099
 0.07-0.1
Estimate 0.46 0.59 0.49 0.22 0.29 0.0257 3.5 × 10⁻¹ 11.8 147 3.93 28

5.49 2.49 4.8-6.5 2.2-7.1 56-73

> Iñaki F. Trocóniz (University of Navarra, Spain): "Role of Quantitative Systems Pharmacology to understand and hit complex diseases"

> Professor of Pharmacy and Pharmaceutical Technology of the Nutrition and Pharmacy Faculty. University of Navarra.

Thursday 8th

Hartmut Derendorf (University of Florida, USA): "Pharmacometric modeling and simulation for dose optimization on earth and in space".

Distinguished Professor, V. Ravi Chandran Professor of Pharmaceutical Sciences and Chairman of the Department of Pharmaceutics at the University of Florida College of Pharmacy in Gainesville.

Friday 9th

Mats Karlsson (Uppsala University, Sweden): "Extensive model assessment through model-proxy analyses" Professor of Pharmacometrics at Uppsala University, Sweden. European Editor of Journal of Pharmacokinetics and Pharmacodynamics.



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SEMINARS

Senior presentations 30+10 minutes Q&A

- Therapeutic Drug Monitoring
- PK/PD Modeling
- Virtual Bioequivalence
- Translational PBPK/PD
- Drug-disease modeling

Registration fees:

- 25 USD Full time accredited students who do submit and present a poster or oral communication.
- 50 USD Full time accredited students.
- 100 USD Academics, non-profit participants, government employees.
- 200 USD Participants from industry and commercial enterprises. Accommodation:

https://www.opasesoresprofesionales.com/ More information related to this event: http://credif.cucei.udg.mx/en