# Title

An interactive train-the-trainer course on PKPD exploration and pharmacometric problem solving using open-source tools including nlmixr2, PKNCA and ShinyMixR

# Speakers

* Anne Keunecke; LAP&P consultants; Leiden, Netherlands
* Bill Denney; Human Predictions, LLC; Boston, MA, USA

# Cost

The course will be provided at no cost.

# For whom it is intended

This interactive train-the-trainer course is intended for researchers and professionals with knowledge of the basic PK/PD concepts and the population approach, preferably with basic modelling experience.

The total number of participants is set at 15.

Pre-requisites:

Attendees should have experience using R and some amount of experience using the nlmixr2 package for R (or experience with nlmixr, rxode2, or RxODE). Participants will be asked up front to provide some detail on their experience in the form of a questionnaire, to align expectations.

Hands-on activities will use R and nlmixr2 within a shinyMixR workflow [Fidler et al., 2019]. Installation of R is required before the course, and installation instructions for nlmixr2 and related packages will be shared shortly before the course. More information on these open-source packages please visit: https://nlmixr2.org/

# Learning objectives

In this two-day course we will specifically discuss the importance of understanding PK/PD data to make the right decisions in popPK/PD model development and application of popPK/PD approach to answer your research question or support dose/treatment decisions, etc.

If you want to learn more on:

* Identifying typical and less common pharmacokinetic (PK) profiles for linear and some nonlinear PK models.
* Understanding the interplay between PK and PD (e.g., direct and indirect effects),
* Scaling the model for first in human (FIH) approaches.
* Obtaining initial estimates to PK models, fitting, and modifying the PK models, and fitting PK/PD models.

After a short introduction, we will directly dive into a hands-on session, in which the participants work in small groups on data-exploration, the development of linear and some nonlinear PK models and the most common of PK/PD models addressing direct and indirect effects using nlmixr2, PKNCA and ShinyMixR.

CVs:

Anne Keunecke is a Consultant Pharmacometrician with LAP&P Consultants BV (<https://lapp.nl/>), where she works on a wide range of projects to support drug development with different modelling techniques. She obtained her PhD in Clinical Pharmacy and Pharmacometrics at the Rheinische Friedrich-Wilhems University in Bonn (Germany), where she focused on optimizing dosing regimen of metal complexes in cancer patients via PK/PD modeling, and was responsible for related bioanalytical assay development and validation functioning as a CRO for pharmaceutical companies. In 2008 she started as PostDoc at the University in Halle and later in Berlin at the departments of Clinical Pharmacy, where she developed PK models for monoclonal antibodies and was a member of the DDMoRe consortium. Her technical skills and experience with large molecules bring constructive input in drug development projects.

William Denney founded Human Predictions after 8 years working inside large pharmaceutical companies and has over 20 years of experience in mathematical modeling. Prior to starting Human Predictions, Bill was a Director of Clinical Pharmacology at Pfizer combining the science of drug development, the art of clinical trial execution, and the mathematics bringing those together efficiently. Prior to Pfizer, Bill worked at Merck in the Clinical Pharmacokinetics and Pharmacodynamics department. Bill has experience designing clinical development plans, designing and running clinical studies, quantifying clinical and nonclinical study results, and training colleagues on clinical development and modeling.

Bill received his PhD and Master’s degree from the University of Pennsylvania in Chemical and Biomolecular Engineering and his Bachelor’s of Science from the Georgia Institute of Technology.