# 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, and installation instructions will be shared shortly before the course. More information on these opensource 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.

During the course, attendees will learn to identify some typical and less common pharmacokinetic (PK) profiles of medicines for linear and some nonlinear PK models. Attendees will explore examples of linking PK to PD. During this workshop, we will provide an overview of the most common of PK/PD models will be discussed with direct and indirect effects. This training will give you the keys to knowing when to use direct compared to indirect effects.

# CVs:

Anne Keunecke is a Consultant Pharmacometrician with LAP&P Consultants BV. (https://lapp.nl/). 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. At Pfizer, Bill designed clinical development plans, designed and ran clinical studies, quantified clinical and nonclinical study results, and trained colleagues on clinical development and modeling. In this position, he developed MBMA tools and models to enhance transparency and understanding of internal development compounds, marketed therapies, and competitive research. He led the team that developed a tool to efficiently review ongoing clinical study datasets for trend reviews of both safety and efficacy. He pioneered new methods for understanding precision of clinical trials and optimization of new trial design based on prior studies.

Prior to Pfizer, Bill worked at Merck in the Clinical Pharmacokinetics and Pharmacodynamics department. In that position, he provided insight to development teams on the translation of nonclinical drug metabolism and pharmacology into clinical study requirements and strategy. He also developed models that enabled inexpensive nonclinical studies to focus and eliminate clinical studies for both cost and time savings.

Throughout his time in the pharmaceutical industry, Bill has called on his decade of computer science and information technology experience to build quality and efficiency into his analyses and designs.

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