

CERTARA INTERMEDIATE WORKSHOP ON PK/PD DATA ANALYSIS

Location: city, state

Dates: date

day date - Introduction

8:15am		Registration
8:30am		Welcome <ul style="list-style-type: none">◆ Aim of the Workshop
8:45am	1	Introduction/Overview
9:15am	2	Introduction to nonlinear regression <ul style="list-style-type: none">◆ Understanding the basic model◆ Historical methods◆ Maximum likelihood estimation◆ Trouble-shooting your model and fit
10:15am		Coffee/tea
10:30am	3	Introduction to WinNonlin – Overview & Demo <ul style="list-style-type: none">◆ Analysis of IV bolus data – library models◆ Going from data to insight (PK 1)
11:30am	4	Hands-on Examples (PK1, PK52, PK18) <ul style="list-style-type: none">◆ Data - Models - Results◆ What to Look at◆ IV Bolus Data (PK1)
12.00pm		Lunch
1:00pm	4	Hands-on Examples (continued) <ul style="list-style-type: none">◆ Impact of disease state on PK (PK52)◆ Nonlinear Kinetic Model – (PK18)
2:30pm		Break
2:45pm	4	Hands-on Examples (continued)
4:00 - 4:30 pm		Wrap-up of lectures and hands-on sessions

day date - Assessment of Goodness of Fit

8:30am	5	Residual Error Models <ul style="list-style-type: none">* Why specify a residual error model?* Objective Functions* Impact of residual error models on Parameters
9:45am		Coffee/tea
10:00am	6	Properties of Parameter Estimates <ul style="list-style-type: none">* Estimates* Standard Errors* Confidence Intervals* Bounds on Parameter Space
11:15am	7	Comparing Models & Assessment of Goodness of Fit <ul style="list-style-type: none">* Correlation of observed and Predicted Values* Residual Plots
12:00pm		Lunch
1:00pm	8	Hands-on 2 (PK14, PK15, PK10) <ul style="list-style-type: none">* Oral 2-compartment: Impact of residual error models* Assessment of Goodness-of-fit
2:30pm		Break
2:45pm	8	Hands-on 2 (continued) <ul style="list-style-type: none">* IV Bolus Example: Which Model Fits Best?* Multiple subjects* Plasma + Urine Data* Demo of model building
4:30 – 4:45pm		Wrap-up of lectures and hands-on sessions

day date - Pharmacodynamic Issues

8:30am	9	Introduction to Pharmacodynamic Models <ul style="list-style-type: none">* Steady-State Dynamics* Effect Compartment Models + Demo of Link Library
9:30am	10	Hands-on 3 (PD30, PD22) <ul style="list-style-type: none">* Steady-State Dynamics* Incomplete Concentration-Response Data* Effect-Compartment Models
10:00am		Coffee/tea
10:20am	10	Hands-on 3 (continued)
12:00pm		Lunch
1:00pm	11	Introduction to Turnover Models <ul style="list-style-type: none">* Turnover Models I (Indirect Response)
2:00pm	12	Analysis of Binary Data
2:45pm		Break
3:00pm	10	Hands-on 3 (continued) (PD4) <ul style="list-style-type: none">* Indirect Response Models
4:45pm		Wrap-up of lectures and hands-on sessions

day date - Design of Experiments and Comparisons of Models

8:30am	13	Experimental Design Issues <ul style="list-style-type: none">* Theoretical versus Practical Concerns* VIF (PK and PD Data)* Partial Derivatives (PK and PD Data)* Difference Functions
10.00am		Coffee/tea
10:20am	14	Combining Several Sources of Data <ul style="list-style-type: none">* Combining data of several sources such as plasma+urine, drug+metabolite, oral+iv etc. Also discussed during the hands-on session* Combining results from several subjects
11:15am	15	Hands-on 4 <ul style="list-style-type: none">* Combining Several Sources of Data* SAD study of a large molecule* Remifentanil
12:00am		Lunch
1.00pm	15	Hands-on 4 (continued)
2:30pm		Wrap-up and end of workshop