The workshop on "PK/PD Modeling Methods and Clinical Applications" will have the following faculty and program:

Faculty:

Roger Jelliffe, MD
Irina Bondareva, Ph.D
George Drusano MD
Ruediger Port MD
Alexander Vinks Ph.D

Target Participants:
This workshop, using minimal math, starts at a beginning level and progresses to an advanced level over 2 intensive days. It is intended for physicians, pharmacists, clinical chemists and biomedical scientists who have an interest in clinical therapeutic drug monitoring and optimal individualization of drug therapy for patient care and in population pharmacokinetic and pharmacodynamic research modeling techniques. Participants will be introduced to the USC*PACK software which can be used both for therapeutic drug monitoring as well as for parametric and nonparametric population PK/PD and physiological modeling.

Objectives and Expectations:

After this workshop, the participant should:

1. Be able to describe basic pharmacokinetic behavior of drugs in patients.
2. Be able to design optimal initial individualized dosage regimens of drugs to hit selected target goals most precisely.
3. Be able to enter and store patient data of doses, TDM serum concentrations, etc., and to make an individualized model of drug behavior in that patient.
4. Be able to develop an adjusted dosage regimen based on the patients individualized model.
5. Understand how to apply these techniques to therapy with Vancomycin, Digoxin, anticonvulsants, and drugs for AIDS, cancer, and transplants.
6. Understand the basic ideas (not the math) behind parametric and nonparametric population PK/PD modeling.
7. Know how to determine the error polynomial for a drug assay, to fit each data point by an optimal measure of its credibility.
8. Understand Monte-Carlo simulation and its applications to clinical situations.
9. Understand the basic concepts of multiple model dosage design.

Preliminary Program:

Tuesday September 7, 2004

8:30 - Beginning Clinical PK 1

The basic PK model - Dr. Jelliffe
Its parameters: Ka, Kel, Vol, Clearance, Kcp, Kpc, T1/2
Dose Individualization using Target Concentration Strategy
An example for discussion: tracking drug behavior in unstable patients, with changing doses, changing renal function, and ad-lib serum samples.
Basic PK building blocks
Evaluating renal function, especially in unstable patients
Evaluating lab assay errors, and then acting on them!
Evaluating other environmental errors

9:30 - Beginning Clinical PK 2
Ways of fitting data - Dr. Jelliffe
Linear regression on logs of data
Weighted nonlinear least squares
Maximum Aposteriori Probability (MAP) Bayesian fitting
The Basic MAP Bayesian scenario
When to get data best Dr. Vinks

10:30 - Coffee

11:00 Beginning Population Modeling
Parametric, iterative 2 stage Bayesian (IT2B) population modeling - Dr. Jelliffe
Strengths and weaknesses of parametric models.

11:45 - Nonparametric Population Modeling - Dr. Jelliffe
Its strengths and weaknesses
Unified approaches to population modeling

12:30 - Multiple Model Dosage Design - Dr. Jelliffe

13:00 - Lunch

14:30 - Intermediate PK
Modeling diffusion in endocardial vegetations - Dr. Jelliffe
Modeling bacterial growth and kill, and post-antibiotic effect
15:30 - How to Describe and Build PD relationships for Anti-infective Drugs - Dr. George Drusano
16:00 Erythropoetin Therapy in Childhood Renal Anemia Dr. Ruediger Port

16:30 End

Wednesday September 8, 2004

8:30 - Advanced PK 3
Modeling linear and nonlinear antiepileptic drug models - Dr. Irina Bondareva
9:00 - Outcome and Costs of a Goal- Oriented, Model-Based, Active TDM Service Dr.Vinks

9:45 Combination Chemotherapy - Monte-Carlo Simulation: from PK/PD
Relationships to Clinical Applications Dr. Drusano

10:30 - Coffee

11:00 Applied Clinical PK 4
Getting Nonparametric Bayesian Posteriors - Dr. Jelliffe
Multiple Model versions
Interacting Multiple Model versions for very unstable patients
The structure of MM Bayesian Dosage Individualization and adjustment

12:00 Aminoglycoside ototoxicity Dr. Jelliffe

12:30 Introduction to Clinical Cases Dr. Jelliffe
Planning Initial MM Aminoglycoside therapy
Normal and reduced renal function

13:00 Lunch

14:30 Advanced Clinical PK 5
More Clinical case histories - Dr. Jelliffe
Planning Initial Vancomycin therapy
Planning Initial Digoxin therapy
A Gentamicin patient with changing renal function
A Tobramycin patient with changing renal function and changing clinical status
Digoxin and Atrial fibrillation.
Why the literature says it is no good for conversion
Why the literature is probably wrong
Four interesting digoxin cases
16:30 End