



AMERICAN CONFERENCE
ON PHARMACOMETRICS



OCTOBER 4-7, 2009
THE GRAND PEQUOT AT FOXWOODS RESORT
MASHANTUCKET, CT

Welcome to the 2009 American Conference on Pharmacometrics!

ACoP is a U.S. national meeting focusing on all aspects of modeling and simulation in pharmacology and therapeutics. The first ACoP meeting in Tucson last year proved to be the premiere U.S. event for excellence and knowledge sharing in pharmacometrics, with international participation from academia, industry, and government sectors.

While our first ACoP was a resounding success, we are excited by the tremendous growth we've experienced for the 2009 meeting:

	2008	2009
Participants	320	426
Organizations	108	125
Posters	100	164
Exhibitors	6	12
Students/Post-docs	29	70

We are especially pleased that, thanks to the generosity of our sponsors, we have been able to make the registration cost lower for students, allowing us to more than double their numbers from last year! In addition, we'll have some special student programming this year for the first time, which we hope to make a regular part of future ACoP meetings.

We look forward to sharing an exciting, educational, and entertaining 3 days with you!

The ACoP 2009 Organizing Committee:

Kyle Baron
Dick Brundage
David D'Argenio
Marc Gastonguay
Raymond Miller
Marc Pfister
Stacey Tannenbaum

Special Thanks to BMSR for their support of ACoP 2009!!



To ACoP Participants,

The Biomedical Simulations Resource in the Department of Biomedical Engineering at the University of Southern California is delighted to serve as a sponsor for ACoP 2009.

Since 1987, the BMSR has sponsored 12 workshops on Advanced Methods of PK/PD Systems Analysis as part of the service, dissemination and training activities of its NIH/NIBIB center grant. These meetings, held in Marina del Rey, California, brought together pharmaceutical scientists, clinical pharmacologists, clinical pharmacists, mathematicians, statisticians, engineers, chemists, physicists, biological scientists and others in a forum designed to facilitate the exchange of ideas between basic and clinical research scientists, experimentalists and modelers, for the purpose of advancing the study of pharmacokinetics and drug response.

The BMSR's continuing mission to promote the development and application of systems modeling in biomedicine is also shared by ACoP, and we look forward to working with its members to insure the success of this essential mission.

Best wishes for a stimulating meeting from the BMSR,

David Z. D'Argenio, PI
Vasilis Z. Marmarelis, Co-PI
Michael C.K. Khoo, Project Leader
Theodore W. Berger, Project Leader
Marcos Briano, Administrator

SUNDAY OCT 4

12:00 PM	5:00 PM	Registration
5:00 PM	9:00 PM	ACoP Opening Reception

MONDAY OCT 5

7:30 AM	8:30 AM	Breakfast/Registration
8:30 AM	8:45 AM	Opening remarks Stacey Tannenbaum
8:45 AM	10:15 AM	Applications of Modeling over the Development Life Cycle of Biologics Session Chairs: David D'Argenio and Don Mager Predicting human PK/PD of biologics from animal data Peiming Ma Modeling and simulations for assessment of PK and PD of a G-CSF biosimilar Wojciech Krzyzanski Population PK-PD Modeling of Biological Agents: When Modeling Meets Reality Diane Mould
10:15 AM	11:00 AM	Break/Poster set up/Software Demos
11:00 AM	12:30 PM	Model and Data Sharing Initiatives Session Chairs: Klaus Romero and Brian Corrigan TIPharma mechanism-based PKPD modeling platform Meindert Danhof The Coalition Against Major Diseases: Review of goals, accomplishments and future plans Klaus Romero OpenDiseaseModels.org: An Open Forum for Collaborative Model Building and Evaluation Bill Gillespie FDA Disease Models Christoffer Tornøe
12:30 PM	2:00 PM	Lunch
2:00 PM	3:30 PM	Dealing with Missing Data in Pharmacometrics Session Chairs: Marc Gastonguay and Jonathan French Introduction to Missing data and issues in pharmacometrics Jonathan French When Should We Be Concerned About Nonignorably Missing Data? Dan Heitjan The Impact of Missing Data on Model Evaluation Marc Gastonguay
3:30 PM	5:00 PM	Break/Posters/Software Demos
5:00 PM	6:00 PM	Lewis B. Sheiner Memorial Lecture: Connecting to the Other Side Mats Karlsson
6:00 PM	7:00 PM	Where will the pharmacometricians of the future come from? Session Chairs: Bernd Meibohm and Hartmut Derendorf Panel discussion Sandra Allerheiligen, David Cadieu, Amita Joshi, Richard Lalonde
7:00 PM	11:00 PM	ACoP Social Event

TUESDAY OCT 6

8:00 AM 9:00 AM Breakfast

9:00 AM 10:30 AM **Development and utilization of disease models**
Session Chairs: Mats Karlsson and Marc Pfister

A Mechanism-Based Disease Model for SGLT2 Inhibitors in Type 2 Diabetes (T2DM) Subjects	Chee Ng
Empirical Disease Progression Model for Ranibizumab in Age-Related Macular Degeneration	Satyendra Suryawanshi
The Antiviral Information Management System (AIMS): Leveraging prior knowledge to inform dose selection of new hepatitis C therapies	Lauren Neal
A Modeling Framework to Simulate Motesanib Efficacy in Thyroid Cancer	René Bruno

10:30 AM 11:00 AM Break

11:00 AM 12:30 PM **New Directions in Cardiovascular Modeling: From Biomarkers to Clinical Outcomes and Comparative Effectiveness**
Session Chairs: Christine Garnett and Richard Lalonde

The RAAS Hypertension PhysioLab platform: A Systems Modeling Approach to Hypertension	Ramprasad Ramakrishna
Conceptual Framework for Evaluating The CV Risk Manifested By Drug-Induced Elevations in Systolic Blood Pressure	Raj Madabushi
Quantitative Approaches for Comparative Effectiveness and Pharmacoeconomics	Jens Grueger

12:30 PM 2:00 PM **Student Session: Troubleshoot your project with M&S experts**
Diane Mould, David D'Argenio, Leonid Gibiansky, William Gillespie, Luann Phillips

12:30 PM 7:00 PM Afternoon off (on your own)

7:00 PM 8:30 PM **KEYNOTE PRESENTATION: Beautiful Evidence** **Edward Tufte**

8:30PM 10:00 PM Buffet dinner, posters, and exhibitors

WEDNESDAY OCT 7

7:00 AM 8:00 AM Breakfast

8:00 AM 9:30 AM **Communication Through Graphics: Looking at Data, Models, and Results**

Session Chair: Andreas Krause

Exploratory Data Visualisation: Taming the Technology	Richard Pugh
Visualizing PK/PD Models using Berkeley Madonna	Andreas Krause
Simulation Graphics to Enable Model-Based Decision Making	Kevin Dykstra

9:30 AM 11:00 AM Break/Posters/Software Demos

11:00 AM 1:00 PM **Event Driven/Non-continuous Data Models**

Session Chairs: Raymond Miller and Celine Dartois

Exposure-Response Analysis for Spontaneously Reported Dizziness in Pregabalin Treated Patients with Generalized Anxiety Disorder	Kaori Ito
Impact of Dosing Regimens on Dropout Across Pregabalin Trials in the Treatment of Generalized Anxiety Disorder	Bojan Lalovic
Apnea of prematurity: A mixed effects modeling approach to disease resolution and pharmacologic intervention modeling	Christopher J Godfrey
Estimation of Mixed Hidden Markov Models with SAEM. Application to daily seizures data	Marc Lavielle

1:00 PM 2:00 PM Lunch

2:00 PM 3:30 PM **Who Wants to Be the First to Dose this Drug in Children? Approaches to Use Knowledge to Inform Dosing Choices**

Session Chair: Steven Kern

The Design and Analysis of Informative Pediatric Clinical Pharmacology Trials Based on Integrating Modeling and Simulation With Available Prior Knowledge	Jeff Barrett
No Experience, No Problem: Using Bottom-up Approaches to Guide First-in-Children Dosing	Andrea Edginton
Evaluation of Performance of a Pediatric Pharmacokinetic Study Using a Simulation Based Design	Manisha Lamba

3:30 PM 4:30 PM Break/Posters/Software Demos

4:30 PM 5:45 PM **PhRMA working group updates**

Session Chairs: Julie Stone and Amit Roy

Adaptive Dose-Ranging Studies: An Update from the PhRMA Working Group	Jose Pinheiro
Optimizing TQT Studies through PK-PD: An OQT Working Group	Larisa Reyderman
Model-Based Drug Development PhRMA Initiative: Mapping the current status and future state for modeling and simulation in the pharmaceutical industry	Julie Stone

5:45 PM 6:00 PM **Closing remarks** **ACoP committee**

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