



# Modeling and Simulation in Drug Development: Quantitative Approaches for Decision Making



October 28-29, 2009 | Marriott Bethesda Pooks Hill Hotel, Bethesda, MD, USA

## PROGRAM CO-CHAIRPERSONS

**RAJESH KRISHNA, PhD, FCP**  
Director, Clinical Pharmacology and Head  
Quantitative Clinical Pharmacology  
Merck and Company, Inc.

**JOSÉ PINHEIRO, PhD**  
Senior Biometrical Fellow, Biostatistics  
Novartis Pharmaceuticals Corporation

## PROGRAM COMMITTEE

**W. SCOTT CLARK, PhD**  
Director, Global Statistical Sciences  
Eli Lilly and Company

**PHILLIP DINH, PhD**  
Statistician, Division of Biometrics I  
Office of Biostatistics  
CDER, FDA

**FRANK J. HOKE, PhD**  
Vice President, Clinical Pharmacology Modeling  
and Simulation  
GlaxoSmithKline

**MATS KARLSSON, PhD, FCP**  
Professor of Pharmacometrics  
Department of Pharmaceutical Biosciences  
Uppsala University

**RAJNIKANTH MADABUSHI, PhD**  
Pharmacometrics Reviewer  
CDER, FDA

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**SURYA MOHANTY, PhD**  
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Johnson & Johnson Pharmaceutical Research and  
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**JERRY NEDELMAN, PhD**  
Global Head, M&S-Statistics  
Novartis Pharmaceuticals Corporation

**ROBERT O'NEILL, PhD**  
Director  
Office of Biostatistics  
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**ANTONIO PAREDES**  
Statistician, Safety Team  
Office of Biostatistics  
CDER, FDA

**SUE-JANE WANG, PhD**  
Associate Director for Adaptive Design and  
Pharmacogenomics, Office of Biostatistics  
Office of Translational Sciences, CDER, FDA

**YANING WANG, PhD**  
Team Leader, Pharmacometrics  
Office of Clinical Pharmacology  
Office of Translational Sciences, CDER, FDA

## Expand the Role of Modeling and Simulation in Clinical Drug Development.

### CONFERENCE OVERVIEW

The FDA Critical Path Initiative has stimulated interest in new tools and ways to improve the efficiency and success rates of drug development programs, including their planning and analysis. Among the opportunities being explored is the increased use of quantitative modeling and computer simulation (M&S) tools and approaches. Although mechanistic and stochastic modeling and/or computer simulation have long been used for the design and analysis of clinical trials by different stakeholders within drug development, such as statisticians and clinical pharmacologists, the recent trend is to expand the joint understanding of how M&S can be better integrated and utilized into the drug development process. This trend has been associated with some level of confusion in terminology and understanding of the role and scope of M&S. There is, however, broad consensus that M&S has an enormous potential, in many cases already realized, to greatly improve drug development through better clinical study and program design, more effective approaches to dose selection and regimen optimization, as well as better assessment of the risk/benefit of new and existing treatments.

This M&S conference will provide an opportunity for different stakeholders to learn, create greater awareness, share good and bad experiences, identify gaps and opportunities, and clarify terminology and understanding of M&S and its role in clinical drug development.

**WHO SHOULD ATTEND** This program will benefit individuals involved in

- ▶ **Statistics**
- ▶ **Clinical research**
- ▶ **Clinical pharmacology**
- ▶ **Pharmacometrics**
- ▶ **Epidemiology**
- ▶ **Health economics**
- ▶ **Regulatory affairs**
- ▶ **Pharmacokinetics**

**LEARNING OBJECTIVES** At the conclusion of this meeting, participants should be able to:

- ▶ Demonstrate a common understanding of what modeling and simulation is, and is not, and of the terminology used in the field;
- ▶ Apply, share and learn about both successful and unsuccessful case studies illustrating the benefits and pitfalls of the use of modeling and simulation in drug development and for regulatory applications;
- ▶ Discuss the role and scope of modeling and simulation in decision making at various stages of the drug development process, for example dose/regimen selection, patient population selection, clinical trial and program design choices, supporting information for regulatory application; and
- ▶ Recognize the value of collaborative multi-disciplinary interactions (across statistical, clinical, pharmacometrics, and clinical pharmacology areas) as a centerpiece to effectively realize the benefits of modeling and simulation.

### CONTACT INFORMATION

**Conference:** Ben Zaitz, Program Manager, Phone +1-215-293-5803  
email Benjamin.Zaitz@diahome.org

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### TUESDAY • OCTOBER 27

4:00-6:00 PM

#### CONFERENCE REGISTRATION

### WEDNESDAY • OCTOBER 28

7:30-8:15 AM

#### REGISTRATION AND CONTINENTAL BREAKFAST

8:15-8:30 AM

#### WELCOME/OPENING REMARKS

##### José Pinheiro, PhD

Senior Biometrical Fellow, Biostatistics  
Novartis Pharmaceuticals Corporation

#### KEYNOTE INTRODUCTION

##### Rajesh Krishna, PhD, FCP

Director, Clinical Pharmacology and Head,  
Quantitative Clinical Pharmacology  
Merck and Company, Inc.

8:30-9:15 AM

#### KEYNOTE ADDRESS

#### THE VISION OF MODELING AND SIMULATION FOR CLINICAL TRIALS: FDA AND INDUSTRY PERSPECTIVES

##### Robert O'Neill, PhD

Director, Office of Biostatistics, CDER, FDA

##### Donald R. Stanski, MD

Vice President and Global Head, PH, Modeling and Simulation  
Novartis Pharmaceuticals Corporation

9:15-9:30 AM

#### INTRODUCTORY LECTURE

#### TAXONOMY OF MODELING AND SIMULATION

##### Mats Karlsson, PhD, FCP

Professor of Pharmacometrics, Department of Pharmaceutical Biosciences, Uppsala University

This presentation will address differences and similarities in the view and terminology of modeling and simulation across disciplines involved in drug development.

9:30-10:30 AM

#### SESSION 1

#### MODELING AND SIMULATION IN EARLY DEVELOPMENT

SESSION CO-CHAIRPERSONS

##### Rajnikanth Madabushi, PhD

Pharmacometrics Reviewer  
CDER, FDA

##### Rajesh Krishna, PhD, FCP

Director, Clinical Pharmacology and Head  
Quantitative Clinical Pharmacology  
Merck and Company, Inc.

In this session, gaps and opportunities on the use of strategic modeling and simulation in the early clinical development space will be examined. Two specific areas of value include the use of modeling and simulation for utilizing adaptive designs in Phase I/II studies enabling dose selection and the use of the end of phase (EOP)2A mechanism to better leverage regulatory feedback on these early clinical opportunities for designing pivotal registration trials.

##### Nitin Patel, PhD

Chairman and Chief Technology Officer, CTO  
Cytel, Inc.

##### Pravin R. Jadhav, PhD

Pharmacometrician  
Clinical Pharmacologist  
Office of Clinical Pharmacology, CDER

10:30-11:00 AM

#### MORNING REFRESHMENT BREAK

11:00 AM-12:30 PM SESSION 2

#### MODELING AND SIMULATION TO INFORM DESIGN AND ANALYSIS OF CONFIRMATORY TRIALS

SESSION CO-CHAIRPERSONS

##### Dionne Price, PhD

Statistician  
Office of Biostatistics, CDER, FDA

##### José Pinheiro, PhD

Senior Biometrical Fellow, Biostatistics  
Novartis Pharmaceuticals Corporation

This session will discuss and illustrate the use of model-based methods and simulations to design and analyze clinical studies aimed at producing confirmatory evidence and labeling information. Case studies will be used to illustrate the benefits and challenges of this approach in clinical drug development.

##### Brenda L Gaydos, PhD

Senior Research Adviser, Center for Applied Statistical Expertise  
Eli Lilly and Company

##### H.M. James Hung, PhD

Director, Division of Biometrics I  
Office of Biostatistics  
CDER, FDA

**Jerold Schindler, PhD**  
*Vice President, Biostatistics & Research Decision Sciences*  
*Merck Research Laboratories*

**12:30-1:30 PM NETWORKING LUNCHEON**

**1:30-3:00 PM SESSION 3**

**FROM EARLY TO FULL DEVELOPMENT: STRATEGY AND EFFICIENCY**

SESSION CO-CHAIRPERSONS

**Yaning Wang, PhD**  
*Team Leader, Division of Pharmacometrics*  
*Office of Clinical Pharmacology, Office of Translational Sciences*  
*CDER, FDA*

**Jerry Nedelman, PhD**  
*Global Head, M&S-Statistics*  
*Novartis Pharmaceuticals Corporation*

This session will provide an overview of how modeling and simulation can bridge the gaps between early phase trials and late phase drug development. Challenges are often encountered in integrating all available information to support and guide further drug development after the proof-of-concept trials. Modeling and simulation can serve as a powerful tool to integrate information from many sources in an objective and quantitative way to justify key decisions. The speakers in this session will briefly present case studies to demonstrate successful

implementation of modeling and simulation for this purpose and also share examples where appropriate application of modeling and simulation could have shortened the drug development cycle and avoided unnecessary trials. An extended question-and-answer period and audience discussion will follow.

**Joseph Kahn, PhD**  
*Decision Analyst and Statistical Modeler*  
*Novartis Pharmaceuticals Corporation*

**Christoffer Tornoe, PhD**  
*Pharmacometrics Reviewer, Office of Clinical Pharmacology*  
*CDER, FDA*

**Yaning Wang, PhD**  
*Team Leader, Division Pharmacometrics*  
*Office of Clinical Pharmacology, Office of Translational Sciences*  
*CDER, FDA*

**3:00-3:30 PM AFTERNOON REFRESHMENT BREAK**

**3:30-5:00 PM BREAKOUT SESSIONS**

The focus of the Breakout Sessions will cover three selected topics listed below in an interactive and in-depth setting, where Session facilitators will provide additional insights into the topics and also invite active participation from the audience to allow for issues to be further discussed. These ideas will be shared in plenary session the next morning with the entire workshop audience.

**BREAKOUT SESSION 1: MISSING DATA**

SESSION CO-CHAIRPERSONS

**Philip Dinh, PhD**  
*Statistician, Division of Biometrics I*  
*Office of Biostatistics*  
*CDER, FDA*

**Peter Lane**  
*Director of Consultancy & Training*  
*Research Statistics Unit*  
*GlaxoSmithKline*

This session will focus on three aspects of missing data. The first is the level of model complexity that can reasonably be employed in the analysis of longitudinal trials. The second is the use of simulation to study missing value problems: of particular interest is the way missing data are simulated with specific characteristics relative to a given model (e.g. MCAR, MAR, MNAR). The third is the acceptability of the multiple-imputation approach, which simulates data and thereby adds an element of randomness into the analysis of trials.

**Ohidul I. Siddiqui, PhD**  
*Mathematical Statistician*  
*Division of Biometrics I, CDER, FDA*

*continued on page 4*

**BREAKOUT SESSION 2: MODELING AND SIMULATION IN THE LEARN-AND-CONFIRM PARADIGM**

SESSION CO-CHAIRPERSONS

**H.M. James Hung**  
*Director, Division of Biometrics I, Office of*  
*Biostatistics, CDER, FDA*

**Vladimir Dragalin, PhD**  
*Assistant Vice-President and Research Fellow*  
*Head of Statistical Research and Applications*  
*Wyeth Research*

The role and scope of modeling and simulation in the exploratory (“Learn”) and confirmatory (“Confirm”) phases of clinical drug development are quite different. This session will include two presentations emphasizing that learning and confirming require different model-based approaches to clinical trial and program design and analysis. The specifics of statistical simulations in trial planning and design operating characteristics evaluation will be discussed. Two panelists will provide regulatory and industry perspectives on the key issues, followed by a floor discussion.

**H.M. James Hung**  
*Director, Division of Biometrics I*  
*Office of Biostatistics, CDER, FDA*

*continued on page 4*

**BREAKOUT SESSION 3: MODEL DEVELOPMENT USING ACCUMULATING DATA, WHAT ABOUT MODEL VALIDATION?**

SESSION CO-CHAIRPERSONS

**Lei Nie, PhD**  
*Mathematical Statistician, Division of*  
*Biometrics, Office of Biostatistics*  
*Office of Translational Science, CDER, FDA*

**Sue-Jane Wang, PhD**  
*Associate Director for Adaptive Design and*  
*Pharmacogenomics, Office of Biostatistics,*  
*Office of Translational Science, CDER, FDA*

**Ted Grasela, PharmD, PhD**  
*President and CEO, Cognigen Corporation*

Model development is often data-driven and labor intensive. To meet project deadlines, it is sometimes desirable to start model development before database lock. Even if the modeler is allowed access to randomization codes, the data still accumulate and change as modeling proceeds. And sometimes even after database lock, data can change if late corrections are made. In addition, the validation of the developed model is of paramount importance for the model to be useful. In this session, participants will hear some case scenarios on strategies for proactive use of accumulating

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### BREAKOUT SESSION 1: MISSING DATA (CONTINUED)

**Peter Lane**  
 Director of Consultancy and Training  
 Research Statistics Unit  
 GlaxoSmithKline

**Panel Discussion**

### BREAKOUT SESSION 2: MODELING AND SIMULATION IN THE LEARN-AND-CONFIRM PARADIGM (CONTINUED)

**Vladimir Dragalin, PhD**  
 Assistant Vice-President and Research Fellow  
 Head of Statistical Research and Applications  
 Wyeth Research

**PANELISTS:**

**Norman Stockbridge, MD, PhD**  
 Director, Division of Cardiovascular and Renal  
 Products, Office of Drug Evaluation I  
 Office of New Drugs, CDER, FDA

**Frank Bretz, PhD**  
 Biometrical Fellow, Biostatistics  
 Novartis AG

### BREAKOUT SESSION 3: MODEL DEVELOPMENT USING ACCUMULATING DATA, WHAT ABOUT MODEL VALIDATION? (CONTINUED)

data, to be followed by discussion on validity with late changes in the data and proper model validation.

**Ted Grasela, PharmD, PhD**  
 President and CEO, Cognigen Corporation

**James Rogers, PhD**  
 Principal Scientist, Metrum Research Group

**Stephen Ruberg, PhD**  
 Senior Research Fellow, Global Statistical  
 Sciences and Clinical Data Management

**Eli Lilly and Company**  
**Sue-Jane Wang, PhD**  
 Associate Director for Adaptive Design and  
 Pharmacogenomics, Office of Biostatistics  
 Office of Translational Sciences, CDER, FDA

**5:00-6:00 PM NETWORKING RECEPTION**

## THURSDAY • OCTOBER 29

**7:30-8:30 AM CONFERENCE REGISTRATION AND CONTINENTAL BREAKFAST**

**8:30-9:00 AM FEEDBACK/RESPONSE FROM BREAKOUT SESSIONS**

SESSION CO-CHAIRPERSONS

**FDA Representative**

**Industry Representative**

**9:00-10:30 AM SESSION 5**

### MODELING AND PHARMACOGENOMICS

SESSION CO-CHAIRPERSONS

**Sue-Jane Wang, PhD**

Associate Director for Adaptive Design and Pharmacogenomics  
 Office of Biostatistics, Office of Translational Science  
 CDER, FDA

**W. Scott Clark, PhD**

Director, Global Statistical Sciences  
 Eli Lilly and Company

Early-phase drug development provides a learning space to explore whether treatment effects are potentially limited to patients possessing genomic characteristics or whether there is a favorable utility of the genomic profile adding to the existing clinical model. In early- to mid-phase clinical trials, both the genomic and clinical modeling could be explored via simulation studies to learn the variability of the treatment effects due to, e.g., genomic factors and/or joint clinical-genomic factors, and to address the clinical utility of the genomic biomarker. In contrast, when the genomic model outperforms clinical model or the joint clinical/genomic models provide favorable benefit/risk profile, confirmatory pharmacogenomics clinical trials can be designed to incorporate the model. Use of such model/simulations would allow prospective testing of

the treatment effect and demonstrate the clinical utility of the genomic associated model. This session will include three presentations. The utility of modeling and simulation in early- and late-phase clinical trials will be illustrated via some case examples.

**Samir Lababidi, PhD**

Statistician  
 CDRH, FDA

**Andrew Vickers, PhD**

Associate Attending Research Methodologist  
 Memorial Sloan-Kettering Cancer Center

**Patrick Kelly, PhD**

Senior Lecturer, Biostatistics  
 The University of Sydney

**10:30-11:00 AM MORNING REFRESHMENT BREAK**

**11:00-12:30 PM SESSION 6**

### PRODUCT DIFFERENTIATION

SESSION CHAIRPERSON

**Frank J. Hoke, PhD**

Vice President, Clinical Pharmacology Modeling & Simulation  
 GlaxoSmithKline

This session will provide an overview of the current landscape of the economics of drug discovery and development, a model of valuation of pharmacotherapies, and how product differentiation can play a key component in pricing and reimbursement. Various methodologies and tools that can be used in evaluating / predicting differentiation will be emphasized. Lastly, a discussion will be provided about the strategic thinking that one should consider when setting a development plan around product differentiation.

**Linda Harpole, MD**

Vice President, Global Health Outcomes  
 GlaxoSmithKline

**Kevin Dykstra, PhD**

Senior Vice President, Strategic Consulting  
Pharsight Corporation

**Norman Stockbridge, MD, PhD**

Director, Division of Cardiovascular and Renal Products  
Office of Drug Evaluation I, Office of New Drugs  
CDER, FDA

**12:30-1:30 PM NETWORKING LUNCHEON**

**1:30-3:00 PM SESSION 7**

**MODELING SAFETY AND EPIDEMIOLOGY**

SESSION CO-CHAIRPERSONS

**Raymond Miller, DSc**

Senior Director, Pharmacometrics  
Pfizer Global R&D

**Antonio Paredes**

Statistician, Safety Team, Office of Biostatistics  
CDER, FDA

To address the challenges arising from conducting a thorough evaluation of drug safety, different perspectives need to be integrated that could overcome the difficulties arising from this process. For this reason, safety tools have become increasingly integrated into the design and analysis of drug development strategies. For example, these tools could be useful in assessing a major safety concern associated with drugs under the same class. The session will feature how modeling and simulation can provide insights into the development of quantitative methodology associated with the assessment of drug safety, and open new directions into the assessment of safety via modeling and simulation.

**Daniele Ouellet, PhD, MSc**

Director, Clinical Pharmacology, Modeling & Simulation  
GlaxoSmithKline

**Bill Frame, BS, MS**

President and CEO  
Wolverine Pharmacometrics Corporation

**Lingling Li, PhD**

Assistant Professor and Biostatistician  
Department of Ambulatory Care and Prevention  
Harvard University

**3:00-3:15 PM AFTERNOON REFRESHMENT BREAK**

**TRAVEL AND HOTEL**

The most convenient airport is Reagan National Airport and attendees should make airline reservations as early as possible to ensure availability. The Marriott Bethesda, Pooks Hill is holding a block of rooms at the reduced rate below until October 6, 2009, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

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**3:15-4:15 PM SESSION 8**

**PATH FORWARD AND NEXT STEPS FOR MODELING AND SIMULATION**

SESSION CO-CHAIRPERSONS

**Sue-Jane Wang, PhD**

Associate Director for Adaptive Design and Pharmacogenomics  
Office of Biostatistics, Office of Translational Science  
CDER, FDA

**José Pinheiro, PhD**

Senior Biometrical Fellow, Biostatistics  
Novartis Pharmaceuticals Corporation

**Rajesh Krishna, PhD, FCP**

Director, Clinical Pharmacology and Head  
Quantitative Clinical Pharmacology  
Merck & Company Inc.

This panel discussion session will review the key issues discussed at the meeting and the path forward for better understanding the benefits and pitfalls of M&S, expanding its appropriate use in clinical drug development, and improving the dialogue and collaboration among key stakeholders involved. Different perspectives will be considered, including regulatory, industry, and academic points of view.

**Frank Bretz, PhD**

Biometrical Fellow, Biostatistics  
Novartis AG

**Oscar Della Pasqua, PhD**

Director, Clinical Pharmacology  
GlaxoSmithKline

**Richard L. Lalonde, PharmD**

Vice President and Global Head of Clinical Pharmacology  
Pfizer, Inc.

**Jogarao (Joga) V. Gobburu, PhD**

Pharmacometrics  
Office of Clinical Pharmacology  
CDER, FDA

**John K. Jenkins, MD**

Director, Office of New Drugs  
CDER, FDA

**Robert O'Neill, PhD**

Director, Office of Biostatistics  
CDER, FDA

**Robert Temple, MD**

Director of the Office of Medical Policy  
Associate Director for Medical Policy  
CDER, FDA

**4:15-4:30 PM CLOSING REMARKS AND CONFERENCE ADJOURNED**

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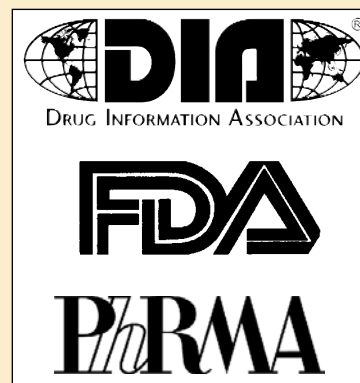
# Modeling and Simulation in Drug Development: Quantitative Approaches for Decision Making

Event ID #09024

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OCTOBER 28-29, 2009



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## CONTACT INFORMATION

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### Modeling and Simulation Drug Development: Quantitative Approaches and Decision Making

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