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Improving Drug Development Using Patient Adherence Data in Clinical Trials

May 6-7, 2008 | The University of California, Washington Center, Washington, DC, USA

PROGRAM CHAIR

CRAIG LIPSET

Director, Health Technologies
Pfizer, Inc.

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Professor of Medicine and Molecular Pharmacology
(Active Emeritus)
Stanford University School of Medicine

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THOMAS J. PODSADECKI, MD

Medical Director
Global Pharmaceutical Research and Development,
Antiviral Clinical Project Team, Abbott Laboratories

JOHN URQUHART, MD

Professor, Center for Drug Development Science,
University of California San Francisco
Chief Scientist, AARDEX Group

Keynote Address
**"Why Adherence Can Be
a Matter of Life
and Death"**

KEYNOTE SPEAKERS

PROFESSOR SIR ROY M. ANDERSON, FRS, FMedSci

Chair in Infectious Disease Epidemiology, Faculty of
Medicine, St. Mary's Campus, Imperial College,
London

CHARLES W. FLEXNER, MD

Professor of Medicine (Divisions of Clinical
Pharmacology and Infectious Diseases),
Pharmacology and Molecular Sciences and
International Health, Johns Hopkins University

Co-sponsored by:

Center for Drug Development Science
University of California, San Francisco



Facing the Critical Challenge of Patient Adherence to Long-term Therapeutic Regimens

Data from trials and practice show that ambulatory patients frequently underdose, either by: never starting dosing, omitting scheduled doses, or premature cessation of dosing. Routine methods fail to detect most of these errors. Yet variable dosing histories are a major source of variance in drug response, confounding the estimation and interpretation of all dose/time-dependent trial outcomes, eg, PK parameters, dose-dependent efficacy, regimen definition, dose-dependent toxicity. Fully analyzed dosing histories can substantially upgrade learning from all trials.

FEATURED TOPICS

- ▶ Documenting and managing adherence in clinical trials
- ▶ Methods of compiling and assessing drug dosing histories
- ▶ Adherence-informed pharmacometric analysis of effectiveness
- ▶ Safety
- ▶ Dosage-regimen optimization
- ▶ Regulatory issues
- ▶ Labeling
- ▶ Statistical considerations

WHO SHOULD ATTEND

- ▶ Pharmaceutical development scientists
- ▶ Regulatory scientists
- ▶ Academic clinical investigators

LEARNING OBJECTIVES

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

- ▶ Describe the current state of adherence (compliance) in clinical trials and implications of maladherence;
- ▶ Explain advantages and opportunities for use of new methods in the conduct and interpretation of clinical trials through the use of reliable patient adherence data; and
- ▶ Identify solutions for monitoring adherence.

CONTACT INFORMATION

Conference: Kathleen Donner, Phone +1-215-293-5810/email Kathleen.Donner@diahome.org

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Learning Objectives: *At the conclusion of this conference, participants should be able to:*

- ▶ Describe the current state of adherence (compliance) in clinical trials and implications of maladherence;
- ▶ Explain advantages and opportunities for use of new methods in the conduct and interpretation of clinical trials through the use of reliable patient adherence data; and
- ▶ Identify solutions for monitoring adherence.

Statements made by speakers are their own opinion and not necessarily that of the organization they represent, or that of the Drug Information Association.

Speakers and agenda are subject to change without notice.

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▶ MONDAY • MAY 5

4:00-6:00 PM

REGISTRATION

▶ TUESDAY • MAY 6

7:15-8:15 AM

REGISTRATION AND
CONTINENTAL BREAKFAST

8:15-8:30 AM

WELCOME AND OPENING REMARKS
CRAIG LIPSET
Director, Health Technologies
Pfizer, Inc.

8:30-10:00 AM

SESSION I – KEYNOTE

WHY ADHERENCE CAN BE A MATTER OF LIFE AND DEATH

ADHERENCE, CONVENIENCE, AND DOSING FREQUENCY AS DETERMINANTS OF OUTCOME IN ANTIRETROVIRAL THERAPY

Charles W. Flexner, MD

Professor of Medicine (Divisions of Clinical Pharmacology and Infectious Diseases), Pharmacology and Molecular Sciences and International Health, Johns Hopkins University

IMPACT OF ADHERENCE TO ANTIRETROVIRAL DRUG DOSING REGIMENS ON THE DYNAMICS OF HIV REPLICATION WITHIN THE HOST

Professor Sir Roy M. Anderson, FRS, FMedSci

Chair in Infectious Disease Epidemiology, Faculty of Medicine, St. Mary's Campus, Imperial College, London

10:00-10:30 AM

REFRESHMENT BREAK

10:30AM-12:00 PM

SESSION 2

PERSPECTIVES

CHAIRPERSONS

Terry Blaschke, MD

Professor of Medicine and of Molecular Pharmacology (Active Emeritus), Stanford University School of Medicine

Carl Peck, MD

Adjunct Professor

Center for Drug Development Science, School of Pharmacy, University of California San Francisco

Drug development has been characterized as a process for generating new knowledge about a compound which ultimately leads to a decision as to whether the compound is safe and effective for the indication for which it is being evaluated. Central to this process is the concept of “learning” in clinical trials. Imperfect adherence if unmeasured, represents a significant problem in the design and interpretation of clinical trial data. This session will discuss the dominance of variable adherence as a source of variability in drug response, the bias that it introduces in the analysis of pharmacokinetic and efficacy data, and the utility of incorporating adherence estimates in the design of clinical trials intended to learn about exposure-response relationships.

MAGNITUDE AND SOURCES OF INTER-INDIVIDUAL VARIABILITY IN DRUG RESPONSE

Carl Peck, MD

Adjunct Professor
Center for Drug Development Science, School of Pharmacy
University of California San Francisco

NON-COMPLIANCE WITH DRUG DOSING REGIMENS: AN UNDERESTIMATED BIAS IN DRUG TRIALS

Bernard Vrijens, PhD

Chief Scientist, Pharmionic Systems, AARDEX Group

INCORPORATING ADHERENCE INTO CLINICAL TRIAL PREDICTIONS

Bill Poland, PhD

Vice President and Lead Scientist, Strategic Consulting Services, Pharsight Corporation

12:00-1:30 PM

LUNCHEON

1:30-3:00 PM

SESSION 3

ADHERENCE ISSUES IN CLINICAL PHARMACOLOGY AND PHARMACOKINETICS

CHAIRPERSON

John Urquhart, MD

Professor, Center for Drug Development Science, University of California San Francisco
Chief Scientist, AARDEX Group

Variance in drug response is a major contributor to costs and time of clinical drug development. A leading but long-neglected source of this variance is unrecognized and unquantified variation in trial participants' dosing histories. Recent studies show: the patterns and consequences of variable dosing, and how dosing history data can simplify, strengthen, and probably shorten the learning phase of clinical drug development. This session will include a roundtable discussion: key lessons from knowing versus assuming drug dosing histories in the learning phase of clinical drug development.

MEASURED VS. ASSUMED DRUG DOSING HISTORIES IN PHASES I AND II STUDIES OF ANTIRETROVIRAL DRUGS IN HIV+ PATIENTS: DOSES, DRUG CONCENTRATIONS, VIRAL LOADS

Bernard Vrijens, PhD

Chief Scientist, Pharmionic Systems, AARDEX Group

MEASURED VS. ASSUMED DRUG DOSING HISTORIES IN THE MANAGEMENT OF ORAL ANTICOAGULATION: DOSES & INR LEVELS

Steven Kimmel, MD

Associate Professor, University of Pennsylvania

MEASURED VS. ASSUMED DRUG DOSING HISTORIES IN THE POLYPHARMACEUTICAL MANAGEMENT OF CONGESTIVE HEART FAILURE: WHICH DRUGS ARE MOST IMPORTANT? HOW STRONGLY CORRELATED ARE DOSING HISTORIES OF MULTIPLE MEDICATIONS?

Michael D. "Mick" Murray, PharmD, MPH

Mescal S. Ferguson Distinguished Professor

Division Chair, Division of Pharmaceutical Outcomes and Policy, University of North Carolina School of Pharmacy

MEASURED VS ASSUMED DRUG DOSING HISTORIES IN CLINICAL TRIALS OF EFFECTIVENESS: SAVING A TRIAL FROM FAILURE

Joyce A. Cramer

Associate Research Scientist, Yale University School of Medicine

3:00-3:30 PM

REFRESHMENT BREAK

3:30-5:00 PM

SESSION 4

PHARMACOMETRIC ASSESSMENT OF PATIENTS' ADHERENCE

CHAIRPERSONS

Simon Day, PhD

Statistical Expert, Roche Products Limited

Howard Lee, MD, PhD

Associate Adjunct Professor, Director, Center for Drug Development Science, Department of Biopharmaceutical Sciences
School of Pharmacy, University of California, San Francisco

Randomization (and the intention to treat principle), when performed in a perfect world, allows for valid inferences from clinical trials. Furthermore, incorporating the effects of covariates, if done appropriately, can also lead to valid inferences. However, these issues pertain to confirmatory trials; therefore, may not be relevant in the learning stage of drug development. Adherence data can be complex post-randomization covariates, akin more to observational or epidemiological data than data from a confirmatory randomized controlled trial. This unique nature of adherence data makes indispensable the use of model-based analyses. This session will illustrate how such data have been analyzed, discussing methodological approaches and more subtle issues of possible biases that may be introduced.

PATIENT ADHERENCE: A REGULATORY PERSPECTIVE

Leslie Kenna, PhD

Pharmacologist, Office of Clinical Pharmacology, CDER, FDA

NON-ADHERENCE ISSUES IN ORAL ANTI-CANCER TREATMENT: IN SILICO AND IN VIVO ESTIMATION

Pascal Girard, PhD

INSERM Researcher, University Claude Bernard Lyon 1

MODELING DRUG CHARACTERISTICS AND PATIENT BEHAVIOR TO PREDICT CLINICAL OUTCOME

Marc Pfister, MD, FCP

Executive Director, Discovery Medicine & Clinical Pharmacology Head of Strategic Modeling & Simulation Research & Development, Bristol-Myers Squibb Company

Liping Zhang, PhD

Associate Director, Discovery Medicine & Clinical Pharmacology Group Leader, Strategic Modeling & Simulation Research & Development, Bristol-Myers Squibb Company

DISCUSSANT

Donald Rubin, PhD

Jon L. Loeb Professor of Statistics, Harvard University

5:00-6:00 PM

NETWORKING RECEPTION

WEDNESDAY • MAY 7

7:30-8:30 AM

REGISTRATION AND CONTINENTAL BREAKFAST

8:30-10:00 AM

SESSION 5

MEDICAL AND SAFETY IMPLICATIONS OF VARIATIONS IN ADHERENCE

CHAIRPERSON

Terry Blaschke, MD

Professor of Medicine and of Molecular Pharmacology (Active Emeritus), Stanford University School of Medicine

Unstudied and often overlooked are the effects of varying periods of non-adherence on the efficacy and safety of drugs, especially those exhibiting tolerance or rebound effects. This session will provide an overview of the problem, define the concept of drug forgiveness, and provide examples of the impact of intermittent dosing on clinical outcomes.

NON-LINEAR PHARMACODYNAMICS AND DRUG TOLERANCE: IMPLICATIONS OF DRUG HOLIDAYS ON SAFETY AND EFFICACY
John Urquhart, MD

Professor, Center for Drug Development Science, University of California San Francisco
Chief Scientist, AARDEX Group

NON-ADHERENCE INCREASES HOSPITALIZATIONS AND EMERGENCY-ROOM VISITS

Michael D. "Mick" Murray, PharmD, MPH
Mescal S. Ferguson Distinguished Professor

Division Chair, Division of Pharmaceutical Outcomes and Policy, University of North Carolina School of Pharmacy

REBOUND EFFECTS AFTER EARLY DISCONTINUATION OF CLOPIDOGREL

John S. Rumsfeld, MD, PhD

Cardiology and Health Services Research, Denver VA Medical Center

10:00-10:30 AM

REFRESHMENT BREAK

10:30-12:00 PM

SESSION 6

MANAGING ADHERENCE IN CLINICAL TRIALS

CHAIRPERSONS

Craig Lipset

Director, Health Technologies
Pfizer, Inc.

Thomas J. Podsadecki, MD

Medical Director
Global Pharmaceutical Research and Development, Antiviral Clinical Project Team, Abbott Laboratories

Monitoring of subject adherence in clinical trials is essential to understanding product safety and efficacy. The goals for this session are 1) to review means to prospectively evaluate subject adherence prior to enrollment to maximize on-study adherence (mock adherence trials, study run-in periods, etc.), 2) to review methods

of adherence monitoring (patient acceptance, operational issues and subject management), 3) to utilize adherence information to provide real-time feedback to study subjects (managerial or behavioral methods for improving adherence) and 4) to discuss the added value of adherence data in evaluating clinical outcomes.

PROSPECTIVE EVALUATION OF ADHERENCE

Speaker Invited

METHODS TO IMPROVE ADHERENCE IN CLINICAL TRIALS

Speaker Invited

THE VALUE OF ADHERENCE DATA IN EVALUATING CLINICAL OUTCOMES

Richard Rode, PhD

Research Fellow, Abbott Laboratories

12:00-1:30 PM

LUNCHEON

1:30-3:00 PM

SESSION 7

REGULATORY PERSPECTIVES AND IMPLICATIONS

CHAIRPERSON

Carl Peck, MD

Adjunct Professor

Center for Drug Development Science, School of Pharmacy
University of California San Francisco

Traditionally, regulatory authorities have encouraged adherence observations during clinical trials for the purpose of monitoring integrity of trial execution, but have not embraced inclusion of adherence data in determination of effectiveness or safety, or in drug labels. In this session, thought leaders in international regulatory agencies will discuss implications of advances in adherence science (pharmionics) on regulatory guidance for phase 2 and 3 trial designs and statistical analyses, and how reliable adherence data may contribute to regulatory decisions.

ADHERENCE IN CLINICAL TRIALS: PERSPECTIVES OF THE UK
MHRA

Professor Sir Alasdair Breckenridge, MD, PhD

Medicines and Healthcare Products Regulatory Agency
(MHRA)

ADHERENCE IN CLINICAL TRIALS: PERSPECTIVES OF THE DUTCH
MEDICINES EVALUATION BOARD

Hubert G.M. Leufkens, PhD

Chairman, Netherlands Medicines Evaluation Board

ADHERENCE IN CLINICAL TRIALS: PERSPECTIVES OF THE SWEDISH
MEDICAL PRODUCTS AGENCY

Speaker Invited

ADHERENCE IN CLINICAL TRIALS: PERSPECTIVES OF THE FDA

FDA Speaker Invited

3:00-3:15 PM

CLOSING REMARKS

3:15 PM

WORKSHOP ADJOURNED

Upcoming DIA Conferences and Training Courses

CONFERENCES

MARCH 26, 2008

DIA Biotechnology Outsourcing Workshop
San Francisco, CA

APRIL 6-8, 2008

QT and Arrhythmia Issues in Drug Development
Bethesda, MD

APRIL 14-16, 2008

2nd Annual FDA/DIA Statistics Forum
Bethesda, MD

MAY 6-7, 2008

Improving Drug Development Using Patient Adherence Data in Clinical Trials
Washington, DC

MAY 13, 2008

Digital Signatures: Practical Strategies for Life Science Organizations
Arlington, VA

MAY 19, 2008

Celebrating 25 Years of the Orphan Drug Act: Retrospective and Future Views
Washington, DC

JUNE 22-26, 2008

44th DIA Annual Meeting
Boston, MA

TRAINING COURSES

MARCH 10-12, 2008

Regulatory Affairs – Part I: The IND Phase
Baltimore MD

MARCH 10-12, 2008

Introduction to Good Clinical Practices
Boston, MA

MARCH 10-12, 2008

Fundamentals of Clinical Research Monitoring
Baltimore, MD

MARCH 10-13, 2008

The Leadership Experience
Philadelphia PA

MARCH 12-13, 2008

Project Risk Management
Horsham, PA

MARCH 17, 2008

Overview of Drug Development
Horsham, PA

MARCH 27-28, 2008

New Drug Product Development and Lifecycle Management
Horsham, PA

MARCH 31-APRIL 2, 2008

Electronic Reporting of ICSRs & EudraVigilance
Horsham, PA

MARCH 31-APRIL 2, 2008

Clinical Project Management
Horsham, PA

APRIL 7-8, 2008

Clinical Statistics for Nonstatisticians
Philadelphia, PA

APRIL 7-9, 2008

Drug Safety Surveillance and Epidemiology
Philadelphia, PA

APRIL 7-10, 2008

**Regulatory Affairs – Part I: The IND Phase
Part II: The CTD/NDA Phase**
Itasca, IL

APRIL 14-16, 2008

Clinical Data Management
Horsham, PA

APRIL 14-16, 2008

Advanced Topics in Clinical Research/Drug Development
Washington, DC

APRIL 30-MAY 2, 2008

Essentials of Project Management
Washington, DC

MAY 5, 2008

Good Clinical Practices for the Clinical Research Professional
Horsham, PA

MAY 5-7, 2008

Regulatory Affairs – Part II: The CTD/NDA Phase
Baltimore, MD

MAY 5-8, 2008

The Leadership Experience
San Diego, CA

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 Courtyard by Marriott-Embassy Row is holding a block of rooms at the reduced rate below, until April 12, 2008, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single \$259 Double \$259

Please contact the Courtyard by Marriott-Embassy Row by telephone at +1-800-321-2211 and mention the DIA event. The hotel is located at 1600 Rhode Island Avenue, Washington, DC 20036, USA.

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Register by APRIL 15, 2008

SAVE \$180

Improving Drug Development Using Patient Adherence Data in Clinical Trials

Event ID #08017

The University of California, Washington
Center, Washington, DC, USA
MAY 6-7, 2008

Keynote Address

"Why Adherence Can Be a Matter of Life
and Death"

Keynote Speakers

PROFESSOR SIR ROY M. ANDERSON, FRs, FMEDSCI
Imperial College, London

CHARLES W. FLEXNER, MD
Johns Hopkins University

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CONTACT INFORMATION

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	On or before	After
	APRIL 15, 2008	APRIL 15, 2008
Member Fee	US \$1200 <input type="checkbox"/>	US \$1380 <input type="checkbox"/>

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US \$ 130

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Charitable Nonprofit/Academia (Full-time)	US \$ 695 <input type="checkbox"/>	US \$ 825 <input type="checkbox"/>

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CANCELLATION POLICY: On or before APRIL 30, 2008

Administrative fee that will be withheld from refund amount:

Member or Nonmember = \$200
Government or Academia or Nonprofit (Member or Nonmember) = \$100
Tutorial (if applicable) = \$50

Cancellations must be in writing and be received by the cancellation date above. Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations. You may transfer your registration to a colleague at any time but membership is not transferable. Please notify DIA of any such substitutions as soon as possible. Substitute registrants will be responsible for nonmember fee, if applicable.

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email Required for confirmation

Phone Number Fax Number Required for confirmation

Group Registrant #2 Last Name First Name Completed form required for each group registrant

Group Registrant #3 Last Name First Name Completed form required for each group registrant

Group Registrant #4 Last Name First Name Completed form required for each group registrant

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