

5th Workshop in a Series on Pharmacogenomics Generating and Weighing Evidence in Drug Development and Regulatory Decision Making

February 2-4, 2010

Marriott Bethesda North Hotel and Conference Center
Bethesda, MD, USA



STEERING COMMITTEE CHAIRS

Issam Zineh, PharmD, MPH

Associate Director for Genomics, Office of
Clinical Pharmacology
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Peter Shaw, PhD

Senior Director, Pharmacogenetics and
Molecular Profiling
Merck & Co., Inc.

**See page 2 and 3 for a complete list of
Steering Committee and Scientific Advisory
Group members.**

Who Should Attend

- Physicians
- Healthcare providers
- Legal community
- Molecular biologists
- Statisticians
- Reimbursement specialists
- Nurses
- Clinical scientists
- Pharmacologists
- Human geneticists
- Clinicians
- Regulatory affairs professionals
- Biologists
- Academic researchers

Worldwide Headquarters

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DRUG INFORMATION ASSOCIATION

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The field of genetics and its applications continue to evolve rapidly with the publication of multiple genome-wide association studies, the availability of new DNA sequencing technologies, and examples of biomarkers that are being used to help define patient response in myriad diseases (eg, oncology, HIV, autoimmune, cardiovascular). In addition, the increased pressure to demonstrate value of medicines is refocusing efforts and attention on how to effectively and practically define patients who are grouped by biomarkers during and following clinical development.

Between 2002 and 2007 the FDA, in collaboration with industry, has co-sponsored four major workshops on pharmacogenetics and pharmacogenomics (PGx) that have facilitated understanding of issues that surround implementation of PGx studies during clinical development and led to the development and drafting of several documents pertaining to the use of PGx in clinical development.¹ This workshop will develop and advance approaches and ideas to improve the value of PGx and other biomarker studies during clinical development and for regulatory decision making and provide

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STEERING COMMITTEE MEMBERS

Robert L. Becker, Jr, MD, PhD

Chief Medical Officer, Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Daniel K. Burns, PhD

Senior Director, Pharmacogenetics Consulting
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Global Head Biologics Oversight & Strategic Projects
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Vice President & Global Head of Molecular Medicine
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Director, Drug Discovery Global Regulatory Affairs
GlaxoSmithKline, UK

Sue-Jane Wang, PhD

Associate Director for Pharmacogenomics and Adaptive Design
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U.S. Food and Drug Administration

Amelia Wall Warner, PharmD, RPh

Chair, Industry Pharmacogenomics Working Group
Head, Clinical Pharmacogenomics
Associate Director
Early Clinical Research and Experimental Medicine
Schering-Plough Research Institute

continued from page 1

networking opportunities with colleagues from academia, regulatory authorities, industry, payors and providers who work on personalized medicines.

Featured Topics

- When PGx data will be required during clinical development
- Defining parameters that allow retrospective/prospective analyses to be conducted for regulatory approval of compounds in biomarker defined cohorts
- Case studies in efficacy, safety, and dosing which have integrated PGx
- Translation of genomic information to labels that are useful to prescribers and patients
- Challenges with sample collection for PGx in global development programs and ways to overcome them
- Critical analyses and recommendations for drug-diagnostic co-development paradigms which are feasible in the competing hurdles to develop new medicines
- Discussion panel of stakeholders including regulators, industry, third party payers, medical researchers and practitioners

¹ FDA "Guidance for Industry: Pharmacogenomic Data Submissions" (March 2005), "ICH E15 Definitions for genomic biomarkers, pharmacogenomics, pharmacogenetics, genomic data and sample coding categories" (April 2008), and "ICH E16 Genomic biomarkers related to drug response: context, structure and format of qualification submissions" (expected 1Q 2010).

SCIENTIFIC ADVISORY GROUP

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continued

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

- Discuss how the FDA and other international regulatory authorities view the use of retrospective analyses of PGx data in regulatory decision making
- Describe issues surrounding incorporation and use of PGx information in drug labels
- Explain barriers to sample acquisition in drug development programs in different geographic regions, and their potential implications
- Outline enabling factors for successful drug-diagnostic co-development (as well as development after drug approval) and examples in which this paradigm shift is most relevant

FEBRUARY 1, 2010

5:00-6:00 PM REGISTRATION

DAY 1 | FEBRUARY 2, 2010

7:00AM-8:00 AM REGISTRATION

8:00-8:30 AM WELCOME AND INTRODUCTION

Issam Zineh, PharmD, MPH

Associate Director for Genomics, Office of Clinical Pharmacology
CDER, FDA

Peter Shaw, PhD

Senior Director, Pharmacogenetics and Molecular Profiling
Merck & Co., Inc.

8:30-9:30 AM KEYNOTE 1

Targeted Therapy: The Brave New World

Janet Woodcock, MD

Director, CDER, FDA

9:30-10:30 AM TRACK 1

Learning from Labels and Label Changes: How to Build Pharmacogenomics into Drug Development Programs

CHAIRPERSONS:

Lawrence Lesko, PhD

Director, Office of Clinical Pharmacology, CDER, FDA

Nadine Cohen, PhD

Head of Pharmacogenomics
J&J Pharmaceutical Research and Development

Linda C Surh, MD, PhD, FRCP(C)

Director, Drug Discovery Global Regulatory Affairs
GlaxoSmithKline, UK

This workshop will provide an historic view of changes to labels that have occurred in current drugs, including the Vectibix, Plavix, Effient, and Coumadin labels as well as a discussion on what are the critical elements for developing pharmacogenetic data sets to make informative labeling recommendations in new products.

9:30-10:00 AM TRACK 1 - PLENARY 1

An Objective Analysis of Regulatory Decisions to Include Genetic Test Information in Drug Product Labels

Lawrence J. Lesko, PhD, FCP

10:00-10:30 AM TRACK 1 - PLENARY 2

KRAS as a Negative Selection Biomarker: The Path to Clinical Usefulness

Scott D. Patterson, PhD

Executive Director, Medical Sciences
Amgen Inc.

10:30-11:00 AM REFRESHMENT BREAK

11:00 AM-12:00 PM TRACK 2

Enabling Pharmacogenomic Clinical Trials Through Sampling

CHAIRPERSONS:

Amelia Wall Warner, PharmD, RPh

Chair, Industry Pharmacogenomics Working Group
Head, Clinical Pharmacogenomics
Associate Director, Early Clinical Research and Experimental
Medicine, Schering-Plough Research Institute

Allen Rudman, PhD

Associate Director, Office of Clinical Pharmacology and
Biopharmaceutics, CDER, FDA

Collection of quality samples is a cornerstone of pharmacogenomic research. However, this can be challenging because of heterogeneity in requirements and practices among institutional review boards, ethics committees, and global health authorities. This track will focus on current challenges with achieving high rates of sample collection on industry clinical trials and new strategies for implementing sample collection.

11:00-11:30 AM TRACK 2 - PLENARY 1

I-PWG Focus on Global Sampling Issues and Current Industry Practices

Amelia Wall Warner, PharmD, RPh

11:30 AM-12:00 PM TRACK 2 - PLENARY 2

Regulations and Policies Impacting Sample Collection

Allen Rudman, PhD

12:00-1:00 PM LUNCHEON

Unless otherwise disclosed, DIA acknowledges that the 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.

Recording of any DIA tutorial/workshop information in any type of media, is prohibited without prior written consent from DIA.

1:00-2:30 PM TRACK 1 – WORKSHOP SESSION 1**Safety Pharmacogenomic Models For Updating Drug Product Labels****CHAIRPERSONS:****Felix W. Frueh, PhD**

Vice President, R&D Personalized Medicine

Susanne B. Haga, PhDIGSP Scholar, Assistant Research Professor
Institute for Genome Sciences and Policy, Duke University

The session will focus on the situation where the development of a diagnostic test takes place independently from the development and registration of a drug which may be marketed by one or many sponsors. It will emphasize safety pharmacogenomics where relabeling of a previously approved drug with a diagnostic test occurs in order to improve the benefit-to-risk ratio of the drug. Questions to be addressed include: how the quality and quantity of evidence triggers a decision to add a diagnostic to the label, the rationale for label language and the placement of diagnostic test data in the label, the conflict between drug and device regulations which create challenges for relabeling and how healthcare providers react to and adopt label recommendations into their clinical practice and standards of care for treating individual patients.

1:00-2:30 PM TRACK 2 – WORKSHOP SESSION 1**Barriers/Issues to sample collection****CHAIRPERSONS:****Amelia Wall Warner, PharmD, RPh****Allen Rudman, PhD**

This session will place in context the current problems of sample collection with respect to pharmacogenomic clinical studies and examine the regulatory, clinical, ethical and societal issues. A case study will be introduced that frames the issues, identifies the causes of convenience sampling, and the consequences to clinical trial outcomes.

2:30-3:00 PM REFRESHMENT BREAK**3:00-4:30 PM TRACK 1 – WORKSHOP SESSION 2****Efficacy Pharmacogenomic Models for Labeling New Drug Products****CHAIRPERSONS:****Michael Mosteller, MS, PhD**

Statistical Geneticist, GlaxoSmithKline

Geoffrey S. Ginsburg, MD, PhDDirector, IGSP Center for Genomic Medicine
Duke Institute for Genome Sciences & Policy
Professor of Medicine and Pathology, Duke University Medical Center

In contrast to Workshop 1, this session will focus on the situation where both the diagnostic test and the drug product are co-developed (ie, companion diagnostics) by a single sponsor or several sponsors in collaboration with each other. It will emphasize efficacy pharmacogenomics where a diagnostic test is intended to optimize the benefit-to-risk ratio of the drug or differentiate it commercially in the marketplace. It will focus on cases outside the area of oncology. Questions to be addressed include: strategic approaches to generating the necessary evidence to satisfy regulatory expectations for both test and medicine, bridging the evidence gap between a research diagnostic and a market-ready diagnostic and challenges inherent in getting healthcare providers to adopt the new test-drug combination and insurers to reimburse for the value added.

3:00-4:30 PM TRACK 2 – WORKSHOP SESSION 2**Formulation of Best Practices for Sample Collection****CHAIRPERSONS:****Amelia Wall Warner, PharmD, RPh****Allen Rudman, PhD**

This session will discuss strategies for sample collection that will result in the development of industry best practices for optimal sample collection to improve pharmacogenomic data collection.

4:30-5:30 PM KEYNOTE 2**Evidence-based Medicine in the Era of Pharmacogenetics****Robert M. Califf, MD**

Vice Chancellor for Clinical Research

Duke University Medical Center

Director, Duke Translational Medicine Institute

5:45 -6:45 PM NETWORKING RECEPTION

DAY 2 | FEBRUARY 3, 2010

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

8:30-9:30 AM KEYNOTE 3

State of the Field: How Genetics Contributes to Drug Discovery and Treatment**Lon Cardon, PhD, FMedSci**Senior Vice President, Genetics and Quantitative Sciences
GlaxoSmithKline

9:30-10:30 AM TRACK 3

Designing Pharmacogenomics Studies to be Fit for Purpose

CHAIRPERSONS:

Aidan Power, MB, MSc, MRCPsychVice President and Global Head of Molecular Medicine
Pfizer Global Research and Development**Daniel K. Burns, PhD**Senior Director, Pharmacogenetics Consulting
Cabernet Pharmaceuticals**Sue-Jane Wang, PhD**Associate Director for Pharmacogenomics and Adaptive Design
Office of Biostatistics, Office of Translational Sciences, CDER, FDA**Scott D. Patterson, PhD**

Different kinds of study designs have been used for pharmacogenomic analyses from retrospective studies to meta-analyses to prospective patient selection for clinical trials. Different study designs will develop different degrees of confidence in evidence for different purposes. This track will examine two case studies and discussion will aim to synthesize different points of view to enable the development of a 'principles' document on fit for purpose study design.

9:30-10:00 AM TRACK 3 – PLENARY 1

Using All the Data in Pharmacogenomics Studies**Bruno Flamion, MD, PhD**

Professor in Molecular Physiology Research Unit, Laboratory of Physiology and Pharmacology at the University of Namur (FUNDP), Belgium, Chairman, EMEA Scientific Advice Working Party Federal Agency for Medicinal and Health Products, Belgium

12:00-1:00 PM LUNCHEON

1:00-2:30 PM TRACK 3 – WORKSHOP SESSION 1

Case Study K-Ras and Vectibix

CHAIRPERSON:

Aidan Power, MB, MSc, MRCPsych

This session will use levels of evidence developed in the exploration of K-Ras mutations and response to Vectibix as a springboard for a panel and audience discussion on the use of retrospective data during drug development, how it applies in a regulatory setting and translates into clinical practice.

PRESENTER:

Scott D. Patterson, PhD

10:00-10:30 AM TRACK 3 – PLENARY 2

Considerations for Inferring Pharmacogenomic-related Treatment Response: Some Recent Lessons Learned**Robert T. O'Neill, PhD**

Director, Office of Biostatistics, CDER, FDA

10:30-11:00 AM REFRESHMENT BREAK

11:00 AM-12:00 PM TRACK 4

Co-development of Drug and Diagnostics

CHAIRPERSONS:

Brian B. Spear, PhDDirector, Scientific Affairs
Global Pharmaceutical Research and Development, Abbott**Lois Hinman, PhD**Global Head Biologics Oversight & Strategic Projects
Drug Regulatory Affairs
Novartis Pharmaceuticals Corporation**Ronald A. Salerno, PhD**Senior Consultant
Biologics Consulting Group, Inc.**Robert L. Becker, Jr., MD, PhD**

Chief Medical Officer, Office of In Vitro Diagnostic Device Evaluation and Safety, Center for Devices and Radiological Health, FDA

This session will address the development of in vitro diagnostics during drug development and what issues arise in managing co-development paradigms prior and post approval of drugs.

11:00-11:30 AM TRACK 4 – PLENARY 1

Pharmacogenomic Discovery: In the Exercise of Virtue Is There an Economy of Truth?**Steven Gutman, MD**Technology Evaluation Center
Blue Cross, Blue Shield Association

11:30 AM-12:00 PM TRACK 4 – PLENARY 2

Reframing the Benefit-Risk Profile of a Medicinal Product through Use of a Genetic Predictive Safety Biomarker**Kevin M. Carl, PharmD**Director, Global Drug Regulatory Affairs
Novartis Pharmaceuticals Corporation

2:30-3:00 PM REFRESHMENT BREAK

1:00-2:30 PM TRACK 4 – WORKSHOP SESSION 1

Co-development of IVD in Early-stage Drug Development

CHAIRPERSONS:

Brian B. Spear, PhD**Lois Hinman, PhD**

A case study will be presented on developing a drug in phase 2 or phase 3 along with an IVD for patient selection. Some key questions that will be addressed include: retrospective data analysis; phase 3 enrichment trial; quality standards for tests at different drug phases; CLIA requirements; IVD bridging requirements; drug and IVD claims; IVD classification.

3:00-4:30 PM TRACK 3 – WORKSHOP SESSION 2

Case Study HLA-B*5701 and Abacavir Hypersensitivity

CHAIRPERSONS:

Daniel K. Burns, PhD**Sue-Jane Wang, PhD**

This session will examine study design considerations for evaluation of the clinical utility of HLA-B*5701 as a predictor of abacavir hypersensitivity within the context of rapidly emerging data, an uncertain regulatory environment and, finally, translation of the results into clinical practice.

PRESENTER:

Arlene R. Hughes, PhD

Genetics Therapy Area Head – Infectious Diseases
GlaxoSmithKline

3:00-4:30 PM TRACK 4 – WORKSHOP SESSION 2

Development of an IVD with Approved Drug(s)

CHAIRPERSONS:

Robert L. Becker, Jr., MD, PhD**Ronald A. Salerno, PhD**

A case study will be presented on developing a pharmacogenetic test using a biomarker for efficacy to aid physicians in selection a drug for treatment. Similar issues described in session 1 to be discussed include: 1) what data and study designs are appropriate for the use of retrospective data and when are prospective studies required; 2) What analytical performance data are needed from a laboratory test for bridging to a IVD for PMA; 3) How does population diversity, or its lack, affect IVD and/or drug labeling; 4) how are safety and efficacy findings reported 5) How will clinical trial data impact the benefit/risk for labeling of the test and the drug.

4:30-5:30 PM KEYNOTE 4

Title TBD

Sir Michael Rawlins

Chairman of the National Institute of Health & Clinical Excellence (NICE), UK

DAY 3 | FEBRUARY 4, 2010

7:00-8:00 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:00-9:00 AM KEYNOTE 5

What is Needed to Move PGx from Research to Reality?

Howard L. McLeod, PharmD

Fred N. Eshelman Distinguished Professor
Director, UNC Institute for Pharmacogenomics and Individualized Therapy
University of North Carolina, Chapel Hill

9:00-9:30AM TRACK 1 AND 2 OUTPUT

CHAIRPERSONS:

Issam Zineh, PharmD, MPH**Peter Shaw, PhD**

Presenters from Scientific Advisory Group/Steering committee will be selected during workshop

9:00-9:30 AM TRACK 3 AND 4 OUTPUT

CHAIRPERSONS:

Issam Zineh, PharmD, MPH**Peter Shaw, PhD**

Presenters from Scientific Advisory Group/Steering committee will be selected during workshop

10:00-10:30 AM REFRESHMENT BREAK

10:30 AM-12:00 PM

Stakeholder Panel Discussion on Output and Themes of Meeting

PANELISTS:

Felix Frueh, PhD**Lawrence Lesko, PhD****Amy Miller, PhD**

Public Policy Director, Personalized Medicine Coalition

Robert T. O'Neill, PhD**Marisa Papaluca-Amati, MD****Brian B. Spear, PhD****Scott D. Patterson, PhD****Yoshiaki Uyama, PhD****FDA Representatives Invited**

Additional subject matter experts from the drug regulatory divisions, payers, and others will be added to this panel.

12:00-12:30 PM CLOSING REMARKS AND NEXT STEPS

Issam Zineh, PharmD, MPH**Peter Shaw, PhD**

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Event #10005 • February 2-4, 2010

Marriott Bethesda North Hotel and Conference Center
Bethesda, MD, USA

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