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

continued on page 2
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

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).

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American Enterprise Institute

Stephen Grant, MD
Clinical Team Leader, CDER
U.S. Food and Drug Administration

continued from page 1
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.

Physician Continuing Medical Education

Accreditation Statement

This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of Postgraduate Institute for Medicine (PIM) and Drug Information Association (DIA). PIM is accredited by the ACCME to provide continuing medical education for physicians.

Credit Designation

Postgraduate Institute for Medicine designates this educational activity for a maximum of 18.5 AMA PRA Category 1 Credit(s)™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

Pharmacist Continuing Education

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Credit Designation

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Type of Activity

Knowledge
FEBRUARY 1, 2010

5:00-6:00 PM REGISTRATION

DAY 1 | FEBRUARY 2, 2010

7:00 AM-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
Head of Pharmacogenomics
J&J Pharmaceutical Research and Development

Nadine Cohen, PhD
Director, CDER, FDA

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.

9:30-10:30 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:**

**Bryan Dechairo, PhD**  
Senior Director, Personalized Medicine, Medco Health Solutions  

**Susanne B. Haga, PhD**  
IGSP 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.

2:30-3:00 PM  REFRESHMENT BREAK

3:00-4:30 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.

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  

**Michael A. Pacanowski, PharmD, MPH**  
Office of Clinical Pharmacology  
Center for Drug Evaluation and Research  
U.S. Food and Drug Administration

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, MRCPsych
Vice 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

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, PhD
Director, 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

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

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.

2:30-3:00 PM Refreshment Break
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

4:30-5:30 PM KEYNOTE 4
Managing Health Care Costs in the Context of Pharmacogenomics

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

9:00-9:30 AM 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

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.

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.

10:00-10:30 AM REFRESHMENT BREAK

10:30 AM-12:00 PM 
Stakeholder Panel Discussion on Output and Themes of Meeting

Panelists:
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

12:30 PM WORKSHOP ADJOURNED
REGISTRATION FORM
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DIA is a financially independent nonprofit, global, multidisciplinary association that provides a neutral forum for sharing information that optimizes the development and lifecycle management of biopharmaceutical and related products.

5th Workshop in a Series on Pharmacogenomics:
Generating and Weighing Evidence in Drug Development and Regulatory Decision Making
Event #10005 • February 2-4, 2010
Marriott Bethesda North Hotel and Conference Center
Bethesda, MD, USA

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The most convenient airports are Ronald Reagan National or Dulles Airport and attendees should make airline reservations as early as possible to ensure availability. The Marriott Bethesda North Hotel and Conference Center is holding a block of rooms at the reduced rate below until January 11, 2010, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single $162 Double $162
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Administrative fee that will be withheld from refund amount:
Member or Nonmember = $200
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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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