

Clinical and Laboratory Genomic and Genetic Standards

December 13-14, 2007 | Hyatt Regency Bethesda, Bethesda, MD, USA

PROGRAM CHAIRS

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PROGRAM COMMITTEE

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Chief Scientific Officer, GenArraytion

Co-sponsors



OVERVIEW

The second workshop on Clinical and Laboratory Genomic and Genetic Standards will review progress since the 2004 Paris meeting in the development of standard controls, best practices and qualifying algorithms for microarray-based assays in clinical applications as well as consider what additional guidelines and materials could help accelerate drug and diagnostic development.

This meeting is intended to serve as a forum for discussion of reference standards and guidelines as used in microarray-based assays to manage quality control, analytical reproducibility, algorithm qualification and failure analysis among stakeholders engaged in the drug and diagnostic pipeline including development, regulatory, and laboratory implementation.

Speakers from both public and private sectors will provide examples of the use of standard control materials from the development, regulatory, and clinical end-user perspective. An important aspect of the meeting will be identification of additional consensus standards that may be useful versus pipeline issues outside of the realm addressable by standards.

KEY TOPICS

- Collaborations for the development of standard controls and protocols for microarray assays
- The advantage and utility of standard reference materials and guidelines in submissions of microarray data to regulatory agencies
- Translating microarray data into clinical applications. What standards are being used? Would additional standards make the process more efficient, cost effective, higher quality?
- What standards do clinical end users want and how can Rx and Dx developers address that need?
- A regulatory perspective on the incorporation of standards during test development
- Standards in algorithm development and validation: Clinical decision-making algorithms
- Implementation of SRMs and guidelines to achieve a single clinical endpoint using multiplex diagnostic assays
- Standardization of electronic medical records: Current practice, standards initiatives, and the future

TARGET AUDIENCE

This program will benefit these individuals:

- ▶ Research scientists
- ▶ Industry representatives
- ▶ Regulatory agency representatives

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December 10-12, 2007

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Learning Objectives:

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

- ▶ Discuss how the FDA and international regulatory agencies work with submission of genomic data
- ▶ Identify the role of regulatory agencies in helping bring clinical tests to the market
- ▶ Illustrate algorithm development and validation to translate microarray data into clinical applications
- ▶ Discuss how the FDA and international regulatory agencies use standard reference material (SRM) information in the review of submitted genomic data
- ▶ Share examples of how standards have been implemented in microarray-based diagnostic test and drug development efforts, including how they can be used in qualifying algorithms for clinical tests
- ▶ Identify areas where additional SRMs could be useful to clinical end-users, developers and regulatory bodies as well as areas where existing tools are adequate

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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WEDNESDAY • DECEMBER 12

4:00-6:00 PM REGISTRATION

THURSDAY • DECEMBER 13

7:15-8:15 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:15-8:30 AM WELCOME AND OPENING REMARKS
Federico Goodsaid, PhD
 Genomics Group, Office of Clinical Pharmacology, Office of Translational Science, CDER, FDA
Janet A. Warrington, PhD
 Vice President, Standards and Government Policy Affymetrix Inc.

8:30-10:00 AM SESSION I
COLLABORATIONS FOR THE DEVELOPMENT OF STANDARD CONTROLS AND PROTOCOLS FOR MICROARRAY ASSAYS
 SESSION CHAIRPERSON
Janet A. Warrington, PhD
 Vice President, Standards and Government, Policy Affymetrix Inc.

Session one will focus on newly developed and developing standard controls and guidelines for use with genomic technologies including microarray assays. An overview will be presented including a description of guidelines developed by the Clinical and Laboratory Standards Institute (CLSI), a reference material to support expression assays

under development at the National Institute of Standards and Technology (NIST) based on the work of the External RNA Controls Consortium, the American Type Culture Collection Standards Development Organization (ATCC) mission and role in standards development.

NIST AND THE EXTERNAL RNA CONTROL CONSORTIUM
Marc Salit, PhD
 Team Leader, Metrology for Gene Expression
 National Institute of Standards and Technology (NIST)

CLSI DOCUMENTS FOR MICROARRAY ANALYSES
Roberta M. Madej, CLS, MS, MBA
 Director, Global Standardization
 Roche Molecular Systems, Inc.

THE ATCC SDO MISSION AND ROLE IN STANDARDS DEVELOPMENT
Joseph B. Perrone, ScD
 Vice President Standards and Certification
 American Type Culture Collection (ATCC)

10:00-10:30 AM REFRESHMENT BREAK

10:30-12:00 PM SESSION 2
THE ADVANTAGE AND UTILITY OF STANDARD REFERENCE MATERIALS AND GUIDELINES IN SUBMISSIONS OF MICROARRAY DATA TO REGULATORY AGENCIES
 SESSION CHAIRPERSON
Felix Frueh, PhD
 Associate Director for Genomics, Office of Clinical Pharmacology CDER, FDA

Speakers representing a variety of perspectives and areas of expertise will present thoughts on the utility of standard reference materi-

als and guidelines in submissions of microarray data to regulatory agencies. The session will include a summary of the recent efforts of the Microarray Quality Control Consortium to identify sources of variability in microarray data and to develop biological standards for microarray assays as well as a perspective on reference RNA materials for the quality control of microarray gene expression analysis.

REFERENCE RNA MATERIALS FOR THE QUALITY CONTROL OF MICROARRAY GENE EXPRESSION ANALYSIS
FDA Speaker Invited

THE COMPANION GUIDANCE TO THE PHARMACOGENOMICS GUIDANCE
Federico Goodsaid, PhD
Genomics Group, Office of Clinical Pharmacology, Office of Translational Science, CDER, FDA

Additional Presentation by FDA Speaker Invited

12:00-1:00 PM LUNCHEON

1:00-3:00 PM SESSION 3

TRANSLATING MICROARRAY DATA INTO CLINICAL APPLICATIONS

SESSION CHAIRPERSON

Arlene R. Hughes, PhD
Director, Pharmacogenetics, GlaxoSmithKline

How do we convert what may be huge volumes of microarray data [whether it be single nucleotide polymorphisms (SNPs), gene expression profiles or other marker sets] into a finite set of exploratory markers that can be replicated and validated in clinical drug studies? How do we design robust registration studies to demonstrate clinical utility? How does one convert biomarker assays developed on research platforms into validated research assays or in vitro diagnostic tests?

STANDARDS AND REFERENCE MATERIALS USED DURING BIOMARKER ASSAY DEVELOPMENT AND ANALYTICAL VALIDATION

Laura Reid, PhD
Senior Director of Scientific Affairs, Expression Analysis

CONTROLS AND STANDARDS AND THEIR USE IN CLINICAL RESEARCH STUDIES

P. Mickey Williams, PhD
Department of Pharmacogenetics
Roche Molecular Systems

PROSPECTIVE VALIDATION OF HLA-B*5701 SCREENING TO REDUCE THE INCIDENCE OF ABACAVIR HYPERSENSITIVITY IN A CONTROLLED CLINICAL STUDY

Arlene R Hughes, PhD
Director, Pharmacogenetics, GlaxoSmithKline

FACTORS AFFECTING TEST ADOPTION AND ORDERING PATTERNS FOR A PHARMACOGENETIC DIAGNOSTIC FOR HLA B*5701

David Johnston, PhD
Vice President and Chief Scientific Officer, Laboratory Corporation of America Holdings

3:00-3:30 PM REFRESHMENT BREAK

3:30-5:00 PM SESSION 4

WHAT DO LABORATORIES NEED TO ACHIEVE CLINICALLY MEANINGFUL RESULTS THAT TEST DEVELOPERS CAN PROVIDE?

SESSION CHAIRPERSONS

Ira M. Lubin, PhD, FACMG
Geneticist, Centers for Disease Control and Prevention
Daniel H. Farkas, PhD, HCLD
Executive Director, Center for Molecular Medicine

Array technologies, as well as other technologies, offer the capability of performing very high levels of assay multiplexing. The challenges in developing and manufacturing highly multiplexed assays that can meet the high regulatory standards of GMP manufacture and clinical laboratory verification and validation are many. Implementing these tests in clinical settings requires the use of appropriate quality control measures and reference materials to assure that clinically meaningful results are achieved. The respective roles, challenges, and needs of the test developer and laboratory will be considered by speakers representing each of these perspectives. Particular attention will be placed upon current practices, guidance documents, availability of reference materials, and what the community at large can do to advance the state of the art.

THE NEED AND USE OF GUIDANCE DOCUMENTS AND REFERENCE MATERIALS IN HIGHLY MULTIPLEXED ASSAY DEVELOPMENT AND MANUFACTURING

Michael A. Zoccoli, PhD
Vice President of Development, Instrument Systems and Software, Celera

INTEGRATING MICROARRAY TECHNOLOGY IN THE CLINICAL LABORATORY

Andrea Ferreira-Gonzalez, PhD, HCLD
Professor of Pathology and Director Molecular Diagnostics Laboratory, Virginia Commonwealth University

5:30-6:30 PM NETWORKING RECEPTION

FRIDAY • DECEMBER 14

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

8:30-10:00 AM SESSION 5

EHR STANDARDS AND GENOMIC INFORMATION: CURRENT PRACTICES, INITIATIVES, AND UNMET NEEDS

SESSION CHAIRPERSON

JUSTIN STARREN, MD, PhD, FACMI
Director, Biomedical Informatics Research Center
Marshfield Clinic Research Foundation

Electronic Health Records (EHRs) are rapidly becoming the dominant way that clinicians create, view and manage clinical data. The current state of EHRs represents several decades of standards development. For

genetic and genomic information to be efficiently incorporated into clinical practice, the devices producing that information will need to generate data in a form that is compatible with EHR practices and standards, either current standards or ones to be developed. This session will provide an overview of current EHR standards, as well as ongoing efforts to integrate genetic and genomic information into existing EHRs. The session will also present some of the lessons learned during the development of current national EHR standards that will be valuable for those considering developing new national standards.

DEVELOPMENT OF HL7 STANDARDS FOR THE EHR

Charles Jaffe, MD, PhD, FACMI
CEO, HL7

RELEVANCE OF CURRENT LABORATORY CODING STANDARDS FOR GENETIC AND GENOMIC DATA

Clement J. McDonald, MD
Director of Lister Hill National Center for Biomedical Communications, National Library of Medicine

CURRENT ACTIVITIES AT PARTNERS HEALTHCARE AND WORK WITH AHIC'S PERSONALIZED HEALTHCARE WORKGROUP

Mollie Ullman-Cullere, MS, MSE
Senior Information Architect/Project Manager, Harvard Medical School – Partners Healthcare Center for Genetics and Genomics

10:00-10:30 AM REFRESHMENT BREAK

10:30-12:00 PM SESSION 6

A REGULATORY PERSPECTIVE ON THE INCORPORATION OF STANDARDS DURING TEST DEVELOPMENT

SESSION CHAIRPERSON

FDA Representative Invited

This session will include speakers from two different centers in US FDA and one speaker from EuroGentest. The session will provide an overview of FDA's perspectives in the incorporation of standards for regulatory review of Genomics submissions. This session will also provide an update on EuroGentest's work on reference materials and on the regulation of genetic testing.

FDA PERSPECTIVE IN THE INCORPORATION OF STANDARDS FOR MULTIPLEX DIAGNOSTIC ASSAYS

FDA Speaker Invited

ANALYSIS OF THE REGULATORY ENVIRONMENT FOR GENETIC TESTING IN EUROPE

David Barton, PhD
Chief Scientist & Hon. Lecturer, National Centre for Medical Genetics

HOW CBER INCORPORATES STANDARDS IN REGULATORY REVIEW

FDA Speaker Invited

12:00-1:30 PM LUNCHEON

1:30-3:00 PM SESSION 7

STANDARDS IN ALGORITHM DEVELOPMENT AND VALIDATION: CLINICAL DECISION-MAKING ALGORITHMS

SESSION CHAIRPERSONS

Richard Deane Hockett, MD, PhD
Director, Genomic Medicine, Eli Lilly and Company
Sunil Kadam, PhD
Research Advisor, Genomic Medicine, Eli Lilly and Company

This session will focus on the development of decision algorithms beginning with an overview of an experimental design to evaluate several emerging technology platforms for clinical application. The rationale for validation of an array platform in the clinical context will be presented along with guidelines for data analysis. A companion presentation will address the evolution of immunohistochemical assays for phosphorylated protein markers and provide guidance for sample preservation, assay validation and data interpretation.

OVERVIEW OF CLINICAL VALIDATION: SIMILARITIES AND DIFFERENCES FROM BIOLOGIC VALIDATION

Richard Deane Hockett, MD, PhD
Director, Genomic Medicine, Eli Lilly and Company

Additional Presentations by Invited Speakers

3:00-3:30 PM CLOSING REMARKS AND SUMMATION

Federico Goodsaid, PhD
Janet A. Warrington, PhD

3:30 PM CONFERENCE ADJOURNED

TRAVEL AND HOTEL The most convenient airports are BWI Airport or Dulles Airport and attendees should make airline reservations as early as possible to ensure availability. The Hyatt Regency Bethesda is holding a block of rooms at the reduced rate below until November 16, 2007, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single \$209 / Double \$234

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EVENT INFORMATION

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4th Workshop in a Series on Pharmacogenomics

Biomarkers and Pharmacogenomics in Drug Development and Regulatory Decision Making

DECEMBER 10-12, 2007 Hyatt Regency Bethesda, Bethesda, MD, USA (#07041)

STEERING COMMITTEE CHAIR

FELIX FRUEH, PhD

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

ORGANIZING COMMITTEE CHAIRS

FELIX FRUEH, PhD

CDER, FDA

RICHARD DEANE HOCKETT, MD, PhD

Director, Genomic Medicine, Eli Lilly and Company

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BIO

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PhRMA

Pharmaceutical Research and Manufacturers of America

PWG

Pharmacogenetics Working Group

TARGET AUDIENCE

Scientists and clinicians working in industry, academia, clinical practice or government and engaged in drug development, regulatory assessment or clinical practice including those with an interest in the role of pharmacogenetics and pharmacogenomics in small molecule and/or biological drug development, and in the co-development of small molecule and/or biological products along with molecular diagnostic tests that are necessary for their use.

Those who should attend this workshop include:

- Physicians
- Regulatory affairs personnel
- Statisticians
- Nurses
- Clinical pharmacologists
- Clinicians
- Biologists
- Healthcare providers
- Molecular biologists
- Reimbursement specialists
- Clinical scientists
- Legal community
- Human geneticists

This fourth major workshop in the series of Pharmacogenomics Workshops that started in 2002, will focus on the implementation and integration of biomarkers and pharmacogenomics from the early to late stage clinical phases of the development of new drugs, biologics and associated devices. An important focus of the workshop will be on ways to facilitate the translation of biomarkers and pharmacogenomics into medical product development and clinical practice.

Recent activities and initiatives, such as the formation of a variety of biomarker-focused consortia, several new regulatory guidance documents, the introduction of legislative bills, and high-profile safety concerns continue to illustrate the prominent role biomarkers and pharmacogenomics play, or will play in moving drug development and therapy from a population-based to an individualized paradigm.

KEY TOPICS

Topics for this 4th workshop in the series will include but are not limited to:

- Challenges and solutions to the use of pharmacogenomics and biomarkers in drug development and clinical use including where progress has been made in safety biomarkers
- How much evidence is needed for safety and efficacy decisions based on novel biomarkers
- Strength of data needed to get a claim using a genetic test
- Co-development
- Postmarketing considerations
- Perspective of third party payors

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

- ▶ Recognize the innovative roles and uses of biomarkers and pharmacogenomics for safety and efficacy assessment in drug development and therapy
- ▶ Discuss analysis methods and database structures used to create information from biomarker-driven studies
- ▶ Describe challenges and strategies to bridge biomarker and pharmacogenomics information from drug development research to adoption into clinical practice to improve drug benefit/risk
- ▶ Discuss the progress made through voluntary genomic submissions and the lessons learned from meetings with health authorities and industry
- ▶ Explain the goals, current efforts, and deliverables of current biomarker and genomic consortia in drug development (e.g., Predictive Safety Testing Consortia, and other biomarker consortia)
- ▶ Identify strategic approaches to Drug-Test Co-Development and Clinical Pharmacogenomics
- ▶ Describe clinical and pre-clinical study designs that incorporate biomarker strategies for optimal dosing and benefit/risk
- ▶ Recognize international approaches and harmonization efforts to use biomarkers and pharmacogenomics for regulatory decision making
- ▶ Identify pertinent issues that need to be addressed by stakeholders (regulators, industry, public) to more effectively integrate biomarkers and pharmacogenomics in drug development and regulatory decision-making
- ▶ Walk away with a "to do" list of actionable conclusions

Clinical and Laboratory Genomic and Genetic Standards

Event ID #07042

Hyatt Regency Bethesda, Bethesda, MD, USA
DECEMBER 13-14, 2007

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CONTACT INFORMATION

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Register for this workshop (#07042) and the 4th Workshop in a Series on Pharmacogenomics: Biomarkers and Pharmacogenomics in Drug Development and Regulatory Decision Making (#07041, December 10-12)

SAVE AN ADDITIONAL \$175!

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On or before DECEMBER 3, 2007

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