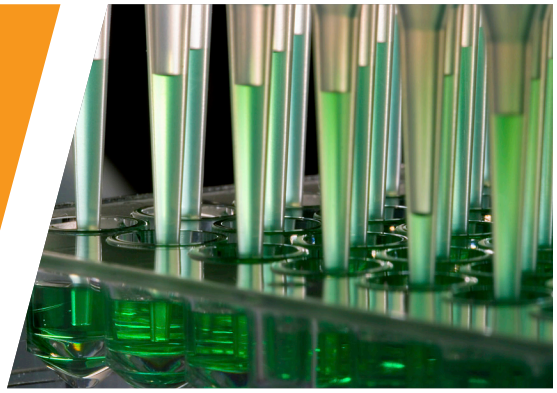
DIA Meeting on Personalized Medicines and Companion Diagnostics

November 6 | Alexandria, VA



PROGRAM CHAIR

Jennifer Paine
Worldwide Vice President
Regulatory Affairs
Ortho Clinical Diagnostic - Part of the
Johnson & Johnson Family of Companies

PROGRAM COMMITTEE:

Steven B. Binion, PhD, MBA
Director
Corporate Regulatory/Women's Health and Cancer
Becton Dickinson

Jennifer Dudinak, PharmD
Vice President
Regulatory Affairs, Oncology
Glaxosmithkline

Azin Shahzamani
Senior Director
Regulatory Affairs
Genentech, A Member of the Roche Group

Jeffrey N. Stuart, PhD, RAC
Director
Regulatory Affairs
Novartis Pharmaceuticals Corporation

Bradley Merrill Thompson, JD, MBA
Partner
Epstein, Becker and Green P.C.

John (Barr) Weiner, JD
Associate Director for Policy and
Product Classification Officer
OCP, FDA

Register at
diahome.org/PersonalizedMedicine

OVERVIEW:

Advances in scientific knowledge and technology are driving growth and innovation for combination products and companion diagnostics, thereby enabling personalized therapies that:

- target those patients most likely to benefit from treatment;
- exclude those patients most likely to suffer harm; and
- can be monitored during treatment for clinically significant changes.

This meeting will provide a practical approach to development processes and regulations in these evolving landscapes, and focus on personalized medicines and their companion diagnostics. .

Drug and device pairings allow treatment decisions to be tailored for each patient. However, development of companion diagnostics and targeted drug therapy still face challenges in clinical development as regulatory policy tries to keep up with and accommodate this growing field. One of the primary goals of the FDA Safety and Innovation Act (FDASIA) involves the advancement and modernization of regulatory science. Such enhancements have had direct impact on both biopharmaceutical and in vitro diagnostic manufacturers.

This day will focus on:

- Innovative Clinical Trial Designs for Drug-Diagnostic Co-registration
- Multimarker Diagnostics and Development Complexities
- New Developments in CDER/CDRH Working Framework
- Emerging Guidances for Companion Diagnostics and Co-development

LEARNING OBJECTIVES

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

- Discuss the US regulatory framework for drug/diagnostic development and registration
- Identify key challenges facing companion diagnostic manufacturers as well as potential options to address these challenges
- Discuss the current status and emerging issues in the EU

DIA is hosting a related one-day meeting on combination products, November 5: DIA Meeting on Combination Products.

Register for Both Meetings and Save!

DIA WORLDWIDE HEADQUARTERS
800 Enterprise Road, Suite 200
Horsham, PA 19044, USA

WORLDWIDE OFFICES
Basel, Switzerland I Beijing, China I Tokyo, Japan
Mumbai, India I Washington, DC, USA

FIFTY YEARS 1964-2014 DIA®
www.diahome.org

CONTINUING EDUCATION CREDITS

Drug Information Association has been accredited as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 1760 Old Meadow Road, Suite 500, McLean, VA 22102; (703) 506-3275. As an IACET Authorized Provider, Drug Information Association offers CEUs for its programs that qualify under the ANSI/IACET Standard. Drug Information Association is authorized by IACET to offer .7 CEUs for this program. Participants must attend the entire program in order to be able to receive an IACET statement of credit. No partial credit will be awarded.

Statement of Credit: All participants must sign-in to record attendance at the program to receive a statement of credit. If attendance is not recorded, a participant will not be eligible to receive credit. No partial credit will be awarded. To request credit, complete the on-line credit request process through My Transcript at www.diahome.org. Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests on Wednesday, November 20, 2013.

Disclosure Policy
It is Drug Information Association policy that anyone in a position to control the content of a continuing education activity must disclose to the program audience (1) any real or apparent conflict(s) of interest related to the content of their presentation and/or the educational activity, and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Faculty disclosures will be included in the course materials.

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, agenda, and CE information are subject to change without notice. Recording of any DIA educational material in any type of media, is prohibited without prior written consent from DIA.

View DIA's Grievance policy at **diahome.org/CE**

TO ACCESS PRESENTATIONS:

- Visit diahome.org
- Login at My DIA
- Enter your User ID and Password
- View 'My Presentation Downloads'

Please Note: DIA User ID and Password are needed to access presentations. If you have forgotten your DIA User ID and Password, or this is your first time logging into the DIA website, please use our Login Reminder

DIA'S CERTIFICATE PROGRAM

This program is part of DIA's Certificate Program and is awarded the following:

- Clinical Research Certificate Program: 4 Elective Units
- Regulatory Affairs Certificate Program: 4 Elective Units

For more information go to ***diahome.org/certificateprograms***

WEDNESDAY, NOVEMBER 6

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

8:30-8:40 AM WELCOME AND OPENING REMARKS

Jennifer Paine
Worldwide Vice President
Regulatory Affairs
Ortho Clinical Diagnostic

8:40-9:00 AM KEYNOTE ADDRESS

Reena Philip, PhD
Deputy Division Director
Division of Immunology and Hematology Devices
CDRH, FDA

9:00-11:00 AM SESSION 2

Innovative Clinical Trial Designs for Diagnostic Co-registration

Session Chair

Jeffrey N. Stuart, PhD, RAC
Director
Regulatory Affairs - Oncology
Novartis Pharmaceuticals Corporation

The registration study for a personalized biopharmaceutical therapy also serves as the registration study for the accompanying companion diagnostic, and it is often conducted in a small, molecularly-defined rare disease population. The frequent lack of available alternative treatment options in rare diseases makes it important for industry and FDA to reach a mutual understanding on the standards and evidentiary expectations needed for co-registration of novel personalized therapies in the rare disease setting with their companion diagnostics, so that safe and effective treatment options can be made available to patients as quickly as possible. In this session, a panel of experts from industry and government will discuss the latest innovations in registration study design for biomarker-defined rare diseases.

Speakers

Anne Pariser, MD
Associate Director
Rare Diseases
CDER, FDA

Michael A. Pacanowski, PharmD, MPH
Associate Director for Genomics and Targeted Therapy
Office of Clinical Pharmacology, Office of Translational Sciences
CDER, FDA

Axel Hoos, MD, PhD
Vice President
Oncology R&D
Glaxo Smith Kline

Richard Simon, DrSc, PhD
Chief
Biometric Research Branch
National Cancer Institute

Sue-Jane Wang, PhD
Associate Director, Adaptive Design and Pharmacogenomics
Biostatistics Leader, VXDS and CDER Biomarker Qualification Program
Office of Biostatistics, Office of Translational Sciences
CDER, FDA

11:00-11:30 AM REFRESHMENT BREAK

11:30-1:30 PM SESSION 3

Multimarker Diagnostics and Development Complexities

SESSION CHAIR

Jennifer Dudinak, PharmD
Vice President, Regulatory Affairs, Oncology
GlaxoSmithKline, Research and Development

Multiple marker diagnostics (multiplex) or next-generation sequencing (NGS) platforms offer the ability to test for a wide array of biomarkers and mutations at once. These platforms can be instrumental in fostering efficient healthcare utilization, maximizing sampling for tissue/specimen/biopsy and advancing innovations in molecularly-targeted therapeutic development and registration across a variety of therapy areas. There are several regulatory and development strategic considerations when employing a multiple marker diagnostic approach in a therapeutic development program. This session will explore challenges and opportunities of utilizing a multiple marker approach including test, bridging, analytical validation and labeling.

SPEAKERS

Anne-Marie Martin, PhD
Head, Precision Medicine & Diagnostics
Head, Molecular Medicine, Oncology R&D
GSK

Bill Pignato
Global Head
Regulatory Affairs
Novartis Molecular Diagnostics

Eunice Lee, PhD
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics and Radiological Health
CDRH, FDA

Panel Discussion
Reena Philip, PhD
Deputy Division Director
Division of Immunology and Hematology Devices
CDRH, FDA

1:30-2:30 PM LUNCHEON

2:30-4:00 PM SESSION 4

New Developments in CDER/CDRH Working Framework

Azin Shahzamani
Senior Director
Regulatory Affairs
Genentech

Over the last year, with the introduction of the breakthrough development path, the need for coordinated administrative processes and management commitment for development of co-diagnostics at FDA and in industry has been highlighted. In this session the panelists will provide their perspectives and experiences on CDER/CDRH working framework.

Jeff Allen
Executive Director
Friends of Cancer Research

Pamela Bradley
Staff Fellow
Office of In Vitro Diagnostics and Radiological Health
CDRH, FDA

Christopher Leptak
Medical Officer
Office of New Drugs
CDER, FDA

Mya Thomae, RAC, CQA
Founder and CEO
Myraqa

4:00-4:30 PM REFRESHMENT BREAK

4:30-5:30 PM SESSION 5

Emerging Guidances for Companion Diagnostics and Co-development

SESSION CHAIR

Jeffrey N. Stuart, PhD, RAC
Director
Regulatory Affairs - Oncology
Novartis Pharmaceuticals Corporation

Technologies supporting breakthrough therapies and their companion diagnostics are rapidly evolving, and global regulation is attempting to keep pace with fast-moving innovation in this field. This session will forecast how emerging global health authority regulations and guidance may evolve and what companies should be considering to prepare.

Mya Thomae, RAC, CQA
Founder and CEO
Myraqa

Erik Vollebregt
Lawyer
AXON

5:30 PM CLOSING REMARKS