How Health Care Data can be Used to Expand the Evidence Base and Promote Cost-effective Health Outcomes

This is the age of opportunity for health care! There is now so much health care data available that when it is aggregated, analyzed, mined and visualized it can provide the information needed to enable evidence-based, cost-effective, better health care. Biomedical Informatics is the scientific discipline that optimizes the access to and use of biomedical and health care information for the benefit of public health. This conference is about Biomedical Informatics. It sets out to identify the critical questions of public health policy, drug discovery and development, health care delivery, and begins to address how biomedical informatics is fundamental to advances in these areas.

CRITICAL QUESTIONS INCLUDE:

1. How do we encourage participation in the clinical research enterprise? Is integrative biomedical informatics the key to maximizing the value of what is learned from clinical trials?

2. How do drugs in the same therapeutic class compare in terms of safety and effectiveness? What do we know about differences in comparative safety and effectiveness by patient subpopulations?

3. How much do we know about drug safety and effectiveness at the time of drug approval? How can analytics maximize continued learning post approval?

4. How quickly and accurately can we detect and understand new safety signals? What are the practical challenges of obtaining, integrating, and analyzing the necessary data?

5. What Risk Evaluation and Mitigation Strategies (REMS) would ensure that drug benefits outweigh risks while minimizing added health care costs and maintaining patient access?

6. Do key health care stakeholders have access to the right information, of the right quality, at the right time, to make the best-informed decisions?

FEATURED TOPICS

THEME A – Application of Biomedical Informatics to Health Care and Pharma

• Semantic Web
• Clinical and Health Care Data Quality and Integrity
• Predictive Analytics
• Data Repository

THEME B – Policy of Biomedical Informatics in Health Care and Pharma

• FDAAA and Comparative Effectiveness Research
• Technology & Data Standards in Public Health
• Meaningful Use of Electronic Health Care Records
• FDAAA: Sentinel Initiative
Investing in Biomedical Informatics for Drug Development and Health Care

October 13-14, 2010
Gaylord National Hotel & Convention Center
National Harbor, MD USA

HIGHLIGHTS

**Keynote Presentation - Integrative Informatics in R&D**
Presented by Dr. John Reynders, Head of Integrative Neuroscience and Head Informatics Center of Excellence, Janssen Pharmaceutical Companies of Johnson and Johnson

**Regulatory / Pharma / Health Care Interactive Panel**
Featuring Dr. Janet Woodcock, Director, Center for Drug Evaluation and Research, FDA

**Keynote Presentation – Health Informatics**
By Mark B. McClellan, MD, PhD, Director, Engelberg Center for Health Care Reform, Senior Fellow, Economic Studies, and Leonard D. Schaeffer Chair in Health Policy Studies, The Brookings Institution

WHO SHOULD ATTEND

- Informaticians in health care and pharma
- Physicians in health care and pharma
- Safety/Pharmacovigilance professionals
- Data management professionals
- Health policy analysts
- Clinical pharmacologists
- Regulatory personnel
- Government organizations
- Epidemiologists
- Biostatisticians
- Contract research organization professionals
- Information technology professionals

**PRE-CONFERENCE TUTORIALS**

*See next page for details.*

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Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of Postgraduate Institute for Medicine (PIM) and the Drug Information Association. PIM is accredited by the ACCME to provide continuing medical education for physicians.

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Disclosure of Conflicts of Interest
The Postgraduate Institute for Medicine (PIM) and DIA require instructors, planners, managers and other individuals who are in a position to control the content of this activity to disclose any real or apparent conflict of interest that may have as related to the content of this activity. All identified conflicts of interest are thoroughly vetted by PIM for fair balance, scientific objectivity of studies mentioned in the materials or used as the basis for content, and appropriateness of patient care recommendations.

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

- Describe usage of solutions, such as the semantic web, for the aggregation of disparate research, clinical and health care data.
- Describe methods for evaluating effectiveness of REMs.
- Identify the standards of interoperability across health care, pharma and basic research, e.g., HL7, CDISC and GO.
- Compare the effectiveness of clinical trial repositories, longitudinal studies, electronic patient records, and payor databases for biomarker identification.
- Identify how data repositories can be utilized for analytics.
- Describe Health & Life Science opportunities enabled by analytics and public domain databases, such as DrugBank and ClinicalTrials.gov.
- Describe how the Sentinel Initiative will facilitate quality-based safety signal detection.
- Describe the “meaningful use” of Electronic Health Records as authorized by the American Recovery and Reinvestment Act of 2009.
- Identify predictive analytics tools that can be used to determine likely disease progression, e.g. supervised and unsupervised data mining approaches, modeling and simulation.
- Describe how comparative effectiveness and outcomes research contributes to evidence-based medicine.

DAY 1 | TUESDAY, OCTOBER 12

10:00 AM-6:00 PM REGISTRATION

1:30-5:00 PM TUTORIALS

Tutorial #1 – Strategies on Developing and Deploying Semantic Linked Data to Biomedical Applications

Tutorial Instructor
Eric Neumann, PhD
Clinical Semantics
W3C Consortium

This workshop will describe the fundamentals of Semantic Linked Data and how it can be applied to several biomedical information applications. Methodologies presented will serve as an outline for augmenting existing information systems as well as designing whole new semantic frameworks. Participants will have access to hands on demonstrations including data aggregation, SPARQL queries, and faceted browsing of SDTM data.

LEARNING OBJECTIVES:

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

- Describe the fundamentals of Semantic Linked Data
- Explain how Semantic Linked data can be applied to biomedical information applications
- Describe methodologies that will help to supplement existing information systems
- Discuss methodologies that will support the design of new semantic frameworks

Tutorial #2 – Biomedical Informatics Tools for Preparing Observational Data for Active Surveillance and Outcomes Research

Tutorial Instructors
Patrick Ryan
Manager, Drug Development Sciences, Statistical and Quantitative Sciences
GlaxoSmithKline Research & Development

Christian Reich
Project Manager IT
Foundation for National Institutes of Health

The Observational Medical Outcomes Partnership (OMOP; http://omop.fnih.org) is a public-private partnership conducting methodological research to inform the appropriate use of observational healthcare databases (administered claims and electronic health records) for identifying and evaluating drug safety issues and benefits. To enable its research, OMOP has developed a series of tools and capabilities for transforming, characterizing and analyzing observational data that are applicable to the broader research community interested in using data for drug safety and outcomes research. This tutorial will teach you how to transform your data into a common data model, integrate standardized vocabularies, apply systematic processes for characterizing the data and assessing data quality, and conduct consistent and reproducible analyses across your data resources.

LEARNING OBJECTIVES:

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

- Discuss opportunities for leveraging observational data to support active medical product safety surveillance and comparative effectiveness
- Recognize the concepts, tools, and strategies for data quality assessment and how to apply them to observational data
- Apply data characterization tools and standardized vocabularies to observational data to enable drug outcome analyses
DAY 2 | WEDNESDAY, OCTOBER 13

8:00-9:00 AM REGISTRATION AND CONTINENTAL BREAKFAST

9:00-9:15 AM WELCOME AND INTRODUCTION

Program Co-chairpersons
Theresa Mullin, PhD
Associate Director, Planning and Informatics
CDER, FDA
Ron Fitzmartin, PhD, MBA
Senior Principal Consultant
Decision Analytics, LLC

9:15-10:00 AM SESSION 1

Plenary Keynote – Integrative Informatics in R&D
John Reynders, PhD
Head of Integrative Neuroscience and Head Informatics Center of Excellence
Janssen Pharmaceutical Companies of Johnson and Johnson

10:00-10:30 AM REFRESHMENT BREAK

PARALLEL BREAKOUT SESSIONS

10:30 AM-12:00 PM SESSION 2

THEME A - APPLICATION OF BIOMEDICAL INFORMATICS TO HEALTH CARE AND PHARMA

Semantic Web in Health Care and Pharma

Session Chairperson
Susie Stephens, PhD
Director In Silico Immunology
Johnson & Johnson Pharmaceutical Research & Development, LLC

The omnipresent challenge for information utilization in the health care and life science domains is the aggregation of different data types from different data sources stored in different formats. This session will illustrate how the next generation of web technologies – often known as the Semantic Web – are very well suited to meeting this challenge. The concepts that are key to understanding this new paradigm are those of “Linked Data” and “Ontology”; these will be described and explained. The session will close with an overview of the set of technologies that can be deployed to deliver the promise of the Semantic Web.

Using Semantic Technologies to Develop Platforms for Public-Private Secondary Use of Health Care Data
Joris Van Dam, PhD
IT Director Health Information Technology
Johnson & Johnson Pharmaceutical Research & Development, Belgium

Barriers and Solutions to Clinical Practice and the Development of Personalized Medicine: InterLinking Data from Bedside to Bench
Christopher A. Domarew, MBChB, PharmD, RPh
Physician
The Royal Liverpool and Broadgreen University Hospital NHS Trust, UK

Applications of Semantic Web Technologies in Research Informatics Infrastructure
Chimezie Ogbuji
Software Architect
Cleveland Clinic

THEME B - POLICY OF BIOMEDICAL INFORMATICS IN HEALTH CARE AND PHARMA

Comparative Effectiveness Research

Session Chairperson
John K. Cuddeback, MD, PhD
Chief Medical Informatics Officer
Anceta • AMGA’s Collaborative Data Warehouse

Comparative Effectiveness Research compares the benefits and harms of different interventions and strategies to prevent, diagnose, treat and monitor health conditions in “real world” settings. CER uses data that are becoming available as a result of the widespread use of EHRs and e-prescribing to “expand the evidence base,” complementing but not replacing traditional randomized controlled trials and providing guidance to clinicians and patients in practical decision-making. This session will explore the history of CER, the challenges of using real-world data, and recent developments in statistical methods for observational studies. CER asks not just whether a treatment works on average, but in which subgroups of patients and in which settings it leads to better outcomes or lower costs than alternative therapies. Thus CER moves us a step closer to personalized medicine and to balancing the quality/cost equation. CER also introduces important policy issues that will become increasingly relevant.

History, Current State, and Future of CER
Anne Trontell, MD, MPH
Program Director, Centers for Education and Research in Therapeutics (CERTs)
Center for Outcomes and Effectiveness Research, AHRQ

Data Resources and Methods for Observational Studies
Speaker Invited

Policy Issues: Optimizing Health Outcomes and Cost-Effectiveness
Speaker Invited
### 1:30-3:00 PM  
**SESSION 3**

**THEME A - APPLICATION OF BIOMEDICAL INFORMATICS TO HEALTH CARE AND PHARMA**

**Clinical Research and Health Care Data Quality and Integrity**

**SESSION CHAIRPERSON**  
**Catherine Celingant**  
Senior Director  
Medical Systems Innovative Technologies  
Millennium Takeda

Without a clear understanding of the business processes that drive information flow, any informatics strategy must be flawed. This session will tackle the fundamental yet non-trivial challenge of constructing the process architecture with the underpinning information flows and realizing the opportunity for optimization using computer-based technologies. With this foundation in place, domain experts will consider the clinical data base and the electronic patient record from a perspective of standards and from the potential for data aggregation and information extraction.

- **Functional Requirements of Clinical Metadata Repositories**  
  **David A. Evans, MS**  
  Chief Information Officer  
  Octagon Research Solutions

- **Getting the Right Data to Provide Biomarkers for Clinical Research**  
  **David Aronow, MD, MPH**  
  Director, Clinical Informatics  
  Humedica

- **Using Data Standards to Improve Product Review in CDER**  
  **Charles Cooper, MD**  
  Medical Officer, Office of Translational Sciences  
  Computational Science Center  
  CDER, FDA

### 3:00-3:30 PM  
**REFRESHMENT BREAK**

### 3:30-5:00 PM  
**SESSION 4**

**THEME A - APPLICATION OF BIOMEDICAL INFORMATICS TO HEALTH CARE AND PHARMA**

**Predictive Analytics in Health Care and Pharma**

**SESSION CHAIRPERSON**  
**David Isom**  
Senior Director, R&D Business Technology  
Pfizer R&D Business Technology

Predictive Analytics can be defined as the use of computer-based tools to predict high-level events of interest from a plethora of data usually originating from many different sources. This session will draw on the experiences of three industry experts to illustrate three fundamental points: (1) the importance of regulatory-compliant repositories capable of delivering data-on-demand, (2) how increasing volumes of clinical trial and health care data available in public domain allows increasingly informed decisions to be made about drug development strategy, (3) modeling & simulation platforms delivering predictive analytics to optimize critical clinical trial parameters.

- **Data Repositories: The Foundation for Analytics**  
  **George O. Strawn, PhD**  
  Director, National Coordination Office for Networking and Information Technology Research and Development  
  Executive Office of the President - National Science and Technology Council

- **Life Science Opportunities Enabled by Analytics & ClinicalTrials.gov**  
  **Eric Neumann, PhD**  
  Director  
  Clinical Semantics Group

- **Optimizing Clinical Trials with Modeling & Simulation**  
  **Bernd Doetzkies, MA**  
  Director Informatics  
  Daiichi Sankyo Pharma Development

### 3:30-5:00 PM  
**SESSION 4**

**THEME B - POLICY OF BIOMEDICAL INFORMATICS IN HEALTH CARE AND PHARMA**

**Informatics and The New Generation of Clinical Research and Care**

**SESSION CHAIRPERSON**  
**John Speakman**  
Associate Director  
Center for Biomedical Informatics  
NCI

This session will focus on the wide variety of IT and informatics capabilities that are available or in development for conducting 21st century biomedical research and clinical care. In particular, the session will focus on cancer as a testbed for new approaches in which standards-based data interoperability is enabling:

- Establishment of online standing populations of clinical trial participants
- Use of EHRs and PHRs to populate online patient data outcomes resources
- Use of genomics-informed clinical trials to test sub-populations for targeted therapeutic development
- New IT-facilitated collaboration models to accelerate translation of discoveries to the bedside
- Pathways to Comparative Effectiveness Research and the Rapid Learning Healthcare System

**Speakers Invited**

### 3:30-5:00 PM  
**SESSION 4**

**THEME B - POLICY OF BIOMEDICAL INFORMATICS IN HEALTH CARE AND PHARMA**

**Meaningful Use of Electronic Health Care Records**

**SESSION CHAIRPERSON**  
**Mitra Rocca**  
Senior Medical Informatician  
Office of Medical Policy, CDER, FDA

Achieving meaningful use will be critical for health care organizations to obtain Medicare incentives included in the American Recovery and Reinvestment Act (ARRA). This session will take a real-world look at best practices and lessons learned focusing on EHR adoption, usability and value assessment from a wide-range of perspectives - from health care providers, patients views to biopharmaceuticals executives. In addition, an in-depth focus will explore the impact of standards, policy and meaningful use criteria for EHRs.

- **Meaningful Use – An Industry Perspective**  
  **Michael Cantor, MD**  
  Director, R&D Business Intelligence  
  Pfizer, Inc.

- **Meaningful Use and HIT Architectures for Health Care Innovation and Transformation**  
  **Kenneth D. Mandl, MD, MPH**  
  Associate Professor  
  Children’s Hospital Boston  
  Harvard Medical School  
  Harvard-MIT Health Sciences and Technology

- **Charles Friedman, PhD**  
  Special Assistant to the National Coordinator, Scientific Director  
  Office of the National Coordinator for Health IT  
  Department of Health and Human Services
### DAY 3 | THURSDAY, OCTOBER 14

8:00-9:00 AM  REGISTRATION AND CONTINENTAL BREAKFAST

9:00-9:15 AM  WELCOME & INTRODUCTION

9:15-10:00 AM  SESSION 5

**Keynote – Health Informatics**  
**Mark B. McClellan, MD, PhD**  
Director, Engelberg Center for Health Care Reform, Senior Fellow, Economic Studies, and Leonard D. Schaeffer Chair in Health Policy Studies, The Brookings Institution

10:00-10:30 AM  REFRESHMENT BREAK

### PARALLEL BREAKOUT SESSIONS

**THEME A - APPLICATION OF BIOMEDICAL INFORMATICS TO HEALTH CARE AND PHARMA**

#### Predictive Analytics in Health Care and Pharma

**SESSION CHAIRPERSON**  
**Paul Bleicher, MD, PhD**  
Chief Medical Officer  
Humedica

Advances in information technology have made possible the collection and analysis of an enormous amount of data from and about patients in health care and life sciences research. Traditional data analysis techniques are insufficient in classification, prediction, and trend identification using this data. This session will examine the evolving role of data visualization, supervised and unsupervised machine learning, and predictive analytics and simulation modeling in the analysis of health care data and the application of such technologies to clinical research. The session will examine some of the techniques being used for visualizing and analyzing large health care datasets, and will provide real-world examples of the use of these analyses and predictive techniques in the improvement of patient care and the development of new therapies.

- **Outcomes Research Validity Using an EMR Database**  
  **Richard L. Tannen, MD**  
  Professor of Medicine  
  University of Pennsylvania School of Medicine

- **Look Before You Leap: Visual Exploration of Health Care Data for Hypothesis Framing**  
  **Sigfried Gold, MFA, MA**  
  Medical Informaticist  
  Lincoln Safety Group, Phase Forward, Inc.

- **Leveraging Simulation in Clinical Trial Design**  
  **Marc-David Cohen, PhD**  
  Chief Science Officer  
  Archimedes Inc.

**THEME B - POLICY OF BIOMEDICAL INFORMATICS IN HEALTH CARE AND PHARMA**

#### FDAAA: Sentinel Initiative

**SESSION CHAIRPERSON**  
**Richard Platt, MD, MSc**  
Professor and Chair  
Department of Population Medicine  
Harvard Medical School and Harvard Pilgrim Health Care Institute

The Food and Drug Administration Amendments Act of 2007 required that within 2 years the FDA develop methods to obtain access to disparate data sources and develop validated methods for the establishment of a post-market risk identification and analysis system. In particular the FDA must have access to the records of at least 25,000,000 patients by July 1, 2010; and at least 100,000,000 patients by July 1, 2012. In May 2008, FDA launched the Sentinel Initiative, the FDA's long-term effort to create a national electronic system for monitoring product safety. This session will describe the progress the Sentinel Initiative has made towards meeting this ambitious mandate.

- **Sean Hennessy, PharmD, PhD**  
  Associate Professor of Epidemiology and of Pharmacology  
  University of Pennsylvania School of Medicine

- **Judith A. Racoosin, MD, MPH**  
  Sentinel Initiative Scientific Lead  
  Office of Medical Policy, CDER, FDA

- **Mark Weiner, MD**  
  Associate Professor of Medicine  
  Division of General Internal Medicine  
  University of Pennsylvania School of Medicine

12:00-1:00 PM  LUNCHEON

5:00 PM  END OF DAY 1

5:00-6:00 PM  NETWORKING RECEPTION
1:00-3:00 PM   SESSION 7
Regulatory / Pharma / Health Care Interactive Panel Discussion

MODERATORS
Theresa Mullin, PhD
Associate Director, Planning and Informatics
CDER, FDA

Ron Fitzmartin, PhD, MBA
Senior Principal Consultant
Decision Analytics, LLC

This interactive panel session will focus on the transformational capability of bio-medical informatics to change the way we do clinical R&D and deliver health care. It has the promise to move us from our current slow and costly methods to a future of cost-effective, timely and targeted approaches. The panel includes opinion leaders from the FDA, biopharmaceutical industry, health care and technology providers. The session chairs, following opening remarks by each panelist, will lead the panel and audience through a discussion on biomedical informatics. This will embrace the challenges and opportunities of leveraging predictive analytics and data standards in designing more modern clinical trials and effecting the data aggregation, analysis, mining and visualization that can provide the information needed to enable evidence-based, cost-effective, better health care.

PANELISTS
Janet Woodcock, MD
Director, Center for Drug Evaluation and Research
FDA

Mark B. McClellan, MD, PhD
The Brookings Institution

John Reyenders, PhD
Head of Integrative Neuroscience and Head Informatics Center of Excellence
Janssen Pharmaceutical Companies of Johnson and Johnson

Richard Platt, MD, MSc
Professor and Chair
Department of Population Medicine
Harvard Medical School and Harvard Pilgrim Health Care Institute

John Speakman
Associate Director
Center for Biomedical Informatics
NCI

Paul Bleicher, MD, PhD
Chief Medical Officer
Humedica

Speaker from the Office of the National Coordinator for Health Information Technology Invited

3:00-3:30 PM   SUMMARY AND CLOSE OF MEETING
Theresa Mullin, PhD
Associate Director, Planning and Informatics
CDER, FDA

Ron Fitzmartin, PhD, MBA
Senior Principal Consultant
Decision Analytics, LLC

3:30 PM   END OF DAY 2

3:30 PM   MEETING ADJOURNED

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.

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Investing in Biomedical Informatics for Drug Development and Health Care

Event #10030 • October 13-14, 2010
Gaylord National Hotel & Convention Center, National Harbor, MD, USA

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<th>On or before SEP. 22, 2010</th>
<th>After SEP. 22, 2010</th>
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<td>Member Fee</td>
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TUTORIALS
#1 Strategies on Developing and Deploying Semantic Linked Data to Biomedical Applications US $405
#2 Biomedical Informatics Tools for Preparing Observational Data for Active Surveillance and Outcomes Research US $405

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The most convenient airports are Reagan National Airport, Dulles International Airport, and Baltimore Washington International Airport and attendees should make airline reservations as early as possible. The Gaylord National Hotel & Convention Center is holding a block of rooms at the reduced rate below until September 21, 2010, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single $217 Double $217
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Member or Nonmember = $200
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