

Member Early-bird Rate — Register by October 15 and SAVE \$190

# DIA'S 7<sup>TH</sup> CANADIAN ANNUAL MEETING

## "Time to Act"



Pre-meeting Tutorials: November 2, 2009  
Meeting: November 3-4, 2009

The Westin Ottawa Hotel  
Ottawa, Ontario, Canada



#### PROGRAM CO-CHAIRS

##### DAVID KRAKOVSKY, BScPHM, PHARM D

Director, Medical Safety, Information and Governance, GlaxoSmithKline, Inc., Canada

##### AGNES V. KLEIN, MD, DrPH

Director, Center for Evaluation of Radiopharmaceuticals and Biotherapeutics, Biologics and Genetics Therapies Directorate, HPFB, Health Canada

### *Strategies to Overcome the Global Challenges Facing Government, Industry, and Health Care Professionals*

Three of the most important issues facing the biopharmaceutical community today are the need for increased transparency, the current global economy, and the changing methods used to develop drugs and to assess their efficacy and safety. This meeting will address all of these challenges and explain ways to overcome them through effective global collaboration:

- Find out the changes within the Canadian and global regulatory environments
- Describe the pharmacovigilance and risk assessment of therapeutics development
- Learn the latest domestic and international processes in conducting clinical trials
- Maximize the ongoing monitoring of therapeutics
- Learn the value of increased transparency

**PRE-MEETING TUTORIAL** November 2, 2009, 1:30-5:00 pm

#### Risk Communication

*Tutorial registration is separate; please indicate if you plan to attend a tutorial.*

**WHO SHOULD ATTEND** This program will benefit individuals involved in:

- Regulatory affairs
- Policy/pharmacoeconomics
- Clinical research
- Drug safety/pharmacovigilance
- Drug development
- Quality assurance
- Reimbursement
- Academia

#### CONTACT INFORMATION

**Meeting:** Joanne Wallace, Phone +1-215-442-6180 email Joanne.Wallace@diahome.org

**Exhibits:** Jeff Korn, Phone +1-215-442-6184 email Jeff.Korn@diahome.org

#### PROGRAM COMMITTEE

##### JUDITH ATKINS, PhD

Principal Consultant, PAREXEL Consulting, Canada

##### KIMBY BARTON, MSc

Interim Director in BCANs of TPD, Health Canada

##### DIANE COLIZZA, MBA

ICRO Group Head, General Medicines, Clinical Group, Novartis Pharmaceuticals, Canada, Inc.

##### KAREN FELTMATE

Vice President, Operations, Business Services, and Regulatory Affairs, AstraZeneca, Canada, Inc.

##### SARAH FRISE, PhD

Director, Patient Safety and Medical Information, AstraZeneca, Canada, Inc.

##### PARAMJIT KAUR, PHARM D, MSHA

Manager, Health Care Access Strategy, Ministry of Health and Long Term Care (Ontario), Canada

##### NIGEL RAWSON, PhD

Pharmacoepidemiologist, GlaxoSmithKline, Inc., Canada

##### MICHAEL RIEDER, MD, PhD, FRCPC, FAAP, FRCP (GLASCOW)

CIHR-GSK Chair in Paediatric Clinical Pharmacology, Schulich School of Medicine and Dentistry, University of Western Ontario, Canada

##### ANNE TOMALIN

President, CanReg, Inc., Canada

#### PROGRAM ADVISOR

##### JUDITH GLENNIE, PHARM D, MSc, FCSHP

Director, Submissions/Postmarketing Effectiveness Research (PMER) Planning Medical and Government Affairs Janssen-Ortho, Inc., Canada

#### VISIT WWW.DIAHOME.ORG FOR A COMPLETE SCHEDULE OF EVENTS!

DIA, 800 Enterprise Road, Suite 200, Horsham, PA 19044, USA tel: +1-215-442-6100 fax: +1-215-442-6199 email: dia@diahome.org

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# Continuing Education

## DIA's 7th Annual Canadian Meeting

### Accreditation and Credit Designation



The Drug Information Association is accredited by the Accreditation Council for Pharmacy Education as a Provider of continuing pharmacy education. This program is designated for 8.75 contact hours or .875 continuing education units (CEUs). 286-000-09-030-L04-P.



The Drug Information Association (DIA) has been approved as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 8405 Greensboro Drive, Suite 800, McLean, VA 22102. DIA is authorized by IACET to offer 0.9 CEUs for this program.

- Tutorial is approved for 0.3 IACET CEUs.
- The opening remarks will not offer credit.
- The opening plenary session will offer 1.25 pharmacy contact hours or .125 continuing education units (CEUs) and 0.1 IACET CEUs.

### The following tracks will offer these additional continuing education credits:

#### Tuesday, November 3, 1:30-3:00 PM

Session 1 – Track 1: 1.5 pharmacy contact hours or .15 continuing education units (CEUs) and 0.2 IACET CEUs

Session 1 – Track 2: 0.2 IACET CEUs

Session 1 – Track 3: 0.2 IACET CEUs

#### Tuesday, November 3, 3:30-5:00 PM

Session 2 – Track 1: 1.5 *AMA PRA Category 1 Credit(s)*<sup>™</sup>; 1.5 pharmacy contact hours or .15 continuing education units (CEUs); 0.2 IACET CEUs

Session 2 – Track 2: 1.5 pharmacy contact hours or .15 continuing education units (CEUs); 0.2 IACET CEUs

Session 2 – Track 3: 1.5 *AMA PRA Category 1 Credit(s)*<sup>™</sup>; 0.2 IACET CEUs

#### Wednesday, November 4, 8:30-10:00 AM

Session 3 – Track 1: 1.5 pharmacy contact hours or .15 continuing education units (CEUs) and 0.2 IACET CEUs

Session 3 – Track 2: 1.5 pharmacy contact hours or .15 continuing education units (CEUs) and 0.2 IACET CEUs

Session 3 – Track 3: 0.2 IACET CEUs

#### Wednesday, November 4, 10:30 AM-12:00 PM

Session 4 – Track 1: 0.2 IACET CEUs

Session 4 – Track 2: 1.5 pharmacy contact hours or .15 continuing education units (CEUs); 0.2 IACET CEUs

Session 4 – Track 3: 0.2 IACET CEUs

**To receive a statement of credit, complete the on-line credit request process through My Transcript at [www.diahome.org](http://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 Thursday, November 5, 2009.**

### Disclosure Policy

It is Drug Information Association policy that all faculty participating in continuing education activities must disclose to the program audience (1) any real or apparent conflict(s) of interest related to the content of their presentation and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Faculty disclosure will be included in the course materials.

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

- ▶ Recognize the changes that are occurring within the Canadian and global regulatory environments;
- ▶ Discuss new directions being taken to improve pharmacovigilance and risk assessment of pharmaceutical products;
- ▶ Describe the impact and implications of new domestic and international processes in conducting clinical trials;
- ▶ Identify the roles of multiple stakeholders (industry, regulators, health-care providers and patients) for effective medical product risk management and minimization;
- ▶ Discuss the value of increased transparency and the risks this could pose in the decision-making process;
- ▶ Compare the Canadian perspective to various international issues.

Monday, November 2, 2009 (Pre-meeting Event Only)

11:00 AM-1:30 PM **Tutorial Registration**

12:00-5:00 PM **Exhibitor Set-up and Registration**

1:30-5:00 PM **Tutorial**

#### Tutorial:

#### Risk Communication

##### INSTRUCTOR:

**Lisa Dolovich, BScPhm, PharmD, MSc**

Research Director and Associate Professor, Department of Family Medicine, McMaster University Scientist and Associate Director, Centre for Evaluation and Medicines

Ensuring the safe and effective use of medical products is becoming increasingly complex. Risk communication is an integral and vital element of any risk management strategy. Often this involves communicating emerging or identified safety risks related to pharmaceutical drug products to both providers and patients alike. Conveying complex information in a balanced, clear, quick and efficient manner is critical to effective communication. Challenges faced with this evolving discipline include gaining an understanding of the effectiveness of the communication when directed to providers and patients since the requirements are inherently different. How well does this communication work? What factors are the most important? Evaluating the effectiveness of risk communication is necessary to ensure the efficiency and quality of the communications.

#### Tutorial Learning Objectives

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

- Recognize the different factors which influence effective risk communications for providers and patients
- Identify best practices and factors which are important for effective risk communications directed to patients
- Recognize the shared responsibility of multiple stakeholders in effective risk communications (regulator, manufacturer, health care provider)

#### Tutorial Target Audience

This tutorial is designed for individuals involved in regulatory affairs, compliance and labeling, medical information, quality assurance/quality control, clinical research, risk management, drug safety/pharmacovigilance, academia.

4:00-6:00 PM **Meeting Registration**

#### TRAVEL AND HOTEL

The most convenient airport is Ottawa International Airport and attendees should make airline reservations as early as possible to ensure availability. The Westin Ottawa Hotel is holding a block of rooms at the reduced rate below until October 9, 2009, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

**Single \$219 CN      Double \$269 CN**

Please contact the Westin Ottawa Hotel by telephone at +1-800-WESTIN or 1-613-560-7000. The hotel is located at 11 Colonel By Drive, Ottawa, Ontario, Canada K1N 9H4.

**GROUP DISCOUNTS\*** Register 3 individuals from the same company and receive complimentary registration for a 4th! **All 4 individuals must register and prepay at the same time – no exceptions.** DIA will apply the value of the lowest applicable fee to this complimentary registration; it does NOT include fees for optional events or DIA membership. You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred. **Group registration is not available online and does not apply to the already-discounted fees for government or charitable nonprofit/academia.**

- ▶ **To take advantage of this offer, please make a copy of this registration form for EACH of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together to DIA.**

Tuesday, November 3, 2009

**7:30-8:30 AM Registration and Continental Breakfast**

**8:30-10:15 AM OPENING PLENARY SESSION**

**OPENING REMARKS – DIA**

**Judith Glennie, PharmD, MSc, FCSHP**, Director, Submissions/Postmarketing Effectiveness Research (PMER), Planning Medical and Government Affairs, Janssen-Ortho, Inc., Canada; DIA Board of Directors

**WELCOME**

**David Krakovsky, BScPhm, PharmD**, Director, Medical Safety, Information and Governance, GlaxoSmithKline, Inc., Canada

**Agnes V. Klein, MD, DrPH**, Director, Center for Evaluation of Radiopharmaceuticals and Biotherapeutics, BGTD, HPFB, Health Canada

**KEYNOTE ADDRESSES:**



**8:40-9:40 AM**  
**THE FUTURE OF HEALTH CARE AND PHARMACEUTICAL DEVELOPMENT**

**Paul Crotty**  
General Manager, IMS Canada



**9:45-10:15 AM**  
**THE NEED TO TAKE ON THE CHALLENGE OF ALIGNMENT OF PHARMA WITH PAYOR NEEDS**

**Bob Nakagawa**  
Assistant Deputy Minister, Pharmaceutical Services, British Columbia Ministry of Health Services

**10:15-10:45 AM Refreshment Break in the Exhibit Hall (Hall opens at 9:30 AM)**

**10:45 AM-12:15 PM OPENING PLENARY SESSION *continued***

**TRANSPARENCY – WHAT IS DESIRABLE? HOW FAR?**

- **TRANSPARENCY: CHALLENGES AND OPPORTUNITIES FOR THE CANADIAN REGULATOR**  
**Supriya Sharma, MD, MPH, FRCPC**, Director General, Therapeutic Products Directorate, Health Canada
- **CLINICAL TRIAL TRANSPARENCY – INDUSTRY PERSPECTIVE**  
**Cathie Schumaker**, Executive Director, FDA Liaison Office, Global Regulatory Policy, Intelligence and Labeling, AstraZeneca US
- **LEGAL IMPLICATIONS AND INCREASED RISK**  
**Jeffrey S. Graham**, Partner, Borden Ladner Gervais, LLP

**12:15-1:30 PM Luncheon in the Exhibit Hall**

**TRACK CHAIRS**

**Track 1: Clinical Development**

**Diane Colizza, BSc, MBA**  
ICRO Group Head, General Medicines, Clinical Group, Novartis Pharmaceuticals, Canada, Inc.

**Judith Atkins, PhD**  
Principal Consultant, PAREXEL Consulting, Canada

**Track 2: Safety/Pharmacovigilance**

**Sarah Frise, PhD**  
Director, Patient Safety and Medical Information, AstraZeneca, Canada, Inc.

**Kimby Barton, MSc**  
Interim Director in BCANs of TPD, Health Canada

**Nigel Rawson, PhD**  
Pharmacoepidemiologist, GlaxoSmithKline, Inc. Canada

**Track 3: Regulatory**

**Anne Tomalin**  
President, CanReg, Inc. Canada

**Karen Feltmate**  
Vice President, Operations Business Services and Regulatory Affairs, AstraZeneca, Canada, Inc.

**Agnes V. Klein, MD, DrPH**  
Director, Center for Evaluation of Radiopharmaceuticals and Biotherapeutics, BGTD, HPFB, Health Canada

**1:30-3:00 PM PARALLEL TRACKS – SESSION 1**

**SESSION 1 – TRACK 1**

**ROLE OF REBs IN THE PROTECTION OF HUMAN SUBJECTS: SPECIAL POPULATIONS**

*Session Chair*  
**Diane Colizza, BSc, MBA**  
 ICRO Group Head, General Medicines, Clinical Group, Novartis Pharmaceuticals, Canada, Inc.

**SESSION 1 – TRACK 2**

**EVOLVING SAFETY SCIENCE**

*Session Chair*  
**Kimby Barton, MSc**  
 Interim Director in BCANs of TPD Health Canada

**SESSION 1 – TRACK 3**

**DEVELOPMENTS IN BIOSIMILARS IN CANADA, US, EUROPE, ICH, AND WHO**

*Session Chair*  
**Kwasi Nyarko, MSc, PhD**  
 Unit Manager, Special Projects, Office of Policy and International Collaboration, Division, BGTD, HPFB, Health Canada

The safety and well-being of patients is the first consideration in clinical trials and the protection of human subjects is a responsibility shared by all stakeholders in clinical development. The Research Ethics Board review of the protocol, informed consent form, and investigator qualifications is a key step.

In this session, the role of the REBs in the protection of human subjects, particularly in special or vulnerable populations, will be explored.

**Speakers**

**AN UPDATE ON THE DEVELOPMENT OF VOLUNTARY CANADIAN REB STANDARDS**  
**Norman Viner, MD**  
 Manager, Clinical Trials Division, Health Canada

**ETHICAL AND REGULATORY CONSIDERATIONS IN REB REVIEW OF RESEARCH WITH SPECIAL AND VULNERABLE POPULATIONS**  
**Jack Corman**  
 President, IRB Services

**REB ACADEMIC STANDARDS**  
**Ronald Heslegrave, PhD**  
 Chair, Research Ethics Board, University Health Network

The science of safety is rapidly evolving. This science combines the growing understanding of disease origins, pharmacogenomics with new methods of detecting signals, mining and analyzing data. This evolving science is enabling researchers to develop and test hypotheses regarding the association between specific products and health outcomes. This session will discuss some of the traditional tools and newer tools used to detect signals and analyze benefit and risk.

**Speakers**

**OVERVIEW OF TRADITIONAL TOOLS AND TECHNIQUES USED IN SIGNAL DETECTION, RISK ASSESSMENT (PHARMACOVIGILANCE DATABASES, DATA MINING)**  
**Yola Moride, PhD, FISPE**  
 Associate Professor, Faculty of Pharmacy, University of Montreal

**DEVELOPING TRENDS IN THE APPLICATION OF MODELS TO BENEFIT-RISK ASSESSMENT**  
**Rick Hermann, MD, MPH**  
 Director, Clinical Research, Epidemiology, AstraZeneca Pharmaceuticals R&D

**TOOLS FOR RISK: BENEFIT QUANTIFICATION AND ASSESSMENT**  
**Lucye MJ Galand, DVM**  
 Manager, Scientific Section 1 Health Canada

This session will provide an update on developments related to subsequent entry biologics/ biosimilars in Canada, the United States, Europe, the ICH and WHO. In addition, a case study will be presented in terms of establishing similarity of structure between several biologic products, including associated preclinical/clinical similarities/differences.

**Speakers**

**DEVELOPMENTS IN BIOSIMILARS IN CANADA, US, EUROPE, ICH AND WHO**  
**Kwasi Nyarko, MSc, PhD**  
 Unit Manager, Special Projects, Office of Policy and International Collaboration, BGTD, HPFB, Health Canada

**SUBSEQUENT ENTRY BIOLOGICS IN CANADA: AN INNOVATIVE INDUSTRY PERSPECTIVE**  
**Karen Burke, PhD**  
 Director, Regulatory Affairs, Amgen Canada, Inc.

**THE INTERSECTION OF COMPLEX DRUGS AND BIOLOGICS: CHALLENGES IN CHARACTERIZATION OF SIMILARITY**  
**J. Michael Nicholas, PhD, Postdoctoral Fellow**  
 Senior Director, Strategic Regulatory Affairs and Postmarketing Labeling/Compliance, Teva Neuroscience

**3:00-3:30 PM Refreshment Break in the Exhibit Hall**

*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.*

**SESSION 2 – TRACK 1**
**PHARMACOGENOMICS**
*Session Chair*
**Agnes V. Klein, MD, DrPH**

Director, Center for Evaluation of Radiopharmaceuticals and Biotherapeutics, BGTD, HPFB, Health Canada

Pharmacogenomics is no longer a new brand to the art and science of drug development. Despite this, the uptake of pharmacogenomics is still evolving and its proper place is in the process of being better defined. Many of the issues that have given rise to concerns such as the use of biological materials stored for future research and the need to develop biomarkers in order to optimize the science are well on their way to being resolved, thanks to the impetus provided by Critical Path Initiative of the FDA.

It is clear that the initiatives that have spun off the Critical Path Initiative have increased the profile of research conducted to identify, qualify and validate analytically and clinically a number of biomarkers. Nonetheless, pharmacogenomics remains a new but rapidly evolving science with implications in a number of areas that range from discovery to clinical and regulatory. Pharmacogenomics holds the promise to improve both the efficacy and the safety of drug products. This session will provide three perspectives on what is needed to maintain and continue advancing the field.

*Speakers*
**REGULATORY PERSPECTIVE**
**Brian Foster, PhD**

Senior Science Advisor, Therapeutic Products Directorate, Health Canada

**RESEARCH PERSPECTIVE**
**Michael S. Phillips, PhD**

Canada Research Chair in Translational Pharmacogenomics, Director of Pharmacogenomics, Genome Quebec

**IMPACT OF PHARMACOGENOMICS ON CLINICAL TRIALS**
**Carolyn Finkle, MSc**

Senior Director, International Regulatory Affairs MedImmune

**SESSION 2 – TRACK 2**
**PHARMACOVIGILANCE OPERATIONS**
*Session Chair*
**Heather Sutcliffe**

Director, Marketed Health Products Safety and Effectiveness Information Bureau, Health Canada

With changes to the science of pharmacovigilance come necessary changes to associated operations. This session will provide information from Health Canada on the electronic submission of case reports, new processes regarding pharmacovigilance inspections and the latest guidance on responsibilities for ADR reporting.

*Speakers*
**ELECTRONIC REPORTING OF ADVERSE REACTION REPORTS TO CANADA VIGILANCE BY INDUSTRY**
**Michel Trottier, BScPhm, RPEBC, ACPR, RPh A**

Canada Vigilance Project Lead – Adverse Reactions Electronic Reporting, Health Canada

**POSTMARKET REPORTING COMPLIANCE INSPECTIONS**
**Sophie Lafrance**

HPFB Inspectorate, Health Canada

**GUIDANCE DOCUMENT FOR INDUSTRY -- REPORTING OF ADVERSE REACTIONS TO MARKETED HEALTH PRODUCTS**
**Jennifer Lo**

Head of Operations Unit – Case Report, Database and Terminology Section, Health Canada

**SESSION 2 – TRACK 3**
**PATIENT ACCESS: WHAT IS YOUR ROLE IN FACILITATING PATIENT ACCESS?**
*Session Chair*
**Karen Feltmate**

Vice President, Operations Business Services and Regulatory Affairs, AstraZeneca, Canada, Inc.

This session will feature five perspectives in delivering medicines to patients. Knowledgeable speakers representing the following organizations will introduce their role in this process and, through lively panel discussion, will respond to leading questions. The five perspectives are from Clinical Trials, Health Canada, CDR/Provincial Formularies, PMPRB and last but not least, Patients.

**PANEL DISCUSSION**
*Speakers*
**CLINICAL TRIALS**
**Karen Arts**

Director, Business Development, Ontario Institute for Cancer Research

**HEALTH CANADA**
**Brigitte Zirger, MSc**

Director, Bureau of Policy, Science and International Programs, Therapeutic Products Directorate, Health Canada

**CDR/PROVINCIAL FORMULARIES**
**George Wyatt**

Managing Director, Wyatt Health Management Consulting, Inc.

**CANADA'S PATENTED MEDICINE PRICES REVIEW BOARD - MOVING FORWARD WITH THE IMPLEMENTATION OF ITS NEW EXCESSIVE PRICE GUIDELINES**
**Barbara Ouellet**

Executive Director, Patented Medicine Prices Review Board

**PATIENT PERSPECTIVE**
**Kathy Kovacs Burns**

Best Medicines Coalition

**7:30-8:30 AM Registration and Continental Breakfast**

**8:30-10:00 AM PARALLEL TRACKS – SESSION 3**

SESSION 3 – TRACK 1

**SITE AUDITS AND SITE INSPECTIONS**

Session Chair

**Diane Colizza, BSc, MBA**

ICRO Group Head, General Medicines, Clinical Group, Novartis Pharmaceuticals, Canada, Inc.

Ideally investigator sites should always be 'audit-ready'. In reality, a wealth of activities and demands at the site, many with short deadlines, make it difficult to achieve documentation-readiness at all times. This session will explore recent trends in findings from site audits and inspections and approaches that can be taken by investigator sites to facilitate preparations and meet or surpass the requirements.

Speakers

**RECENT TRENDS AND FINDINGS**

**Ann-Merie O'Halloran, PhD**

Manager, Clinical Capabilities and Compliance Office, Novartis Pharmaceuticals, Canada, Inc.

**CLINICAL TRIAL INSPECTIONS: RECENT TRENDS AND FINDINGS**

**Stephanie Reid**

Manager, Good Clinical Practices Compliance Unit, Health Canada

**GET YOUR SITE TOGETHER**

**Deborah D'Urzo, MSc**

Research Director, Primary Care Lung Clinic, Canada

SESSION 3 – TRACK 2

**PATIENT RISK MANAGEMENT**

Session Chair

**Sarah Frise, PhD**

Director, Patient Safety and Medical Information, AstraZeneca, Canada, Inc.

Both Europe and the United States implemented Patient Risk Management Planning into their regulatory framework in 2005. As such, they have had a few years to work with these requirements. Health Canada is currently in the process of modernization of Canadian legislation and regulations with plans to formally require Risk Management plans for certain products. This session will provide an update from each regulator on their current status with respect to requirements for Risk Management Plans, some of their learnings and some idea of what the future might hold in this area.

Speakers

**EMEA PERSPECTIVE**

(VIA AUDIO COMMUNICATIONS)

**Stella Blackburn, MSc**

EMEA Risk Management Coordinator, Pharmacovigilance and Postauthorization Safety and Efficacy of Medicines Sector, European Medicines Agency, European Union

**FDA PERSPECTIVE**

**Barton Cobert, MD**

President, BLCMD Associates LLC

**HEALTH CANADA PERSPECTIVE**

**Kimby Barton, MSc**

Interim Director in BCANs of TPD Health Canada

SESSION 3 – TRACK 3

**ELECTRONIC INTERFACE WITH HEALTH CANADA 2009-2010**

Session Chair

**Vianney Caron**

Project Lead, Therapeutic Products Directorate eReview, Health Canada

Many industries have leveraged technology to revolutionize their business models and reshape their ability to interact with customers. With the advent of technologies like eCTD, XML labelling and new media, the life sciences industry is in the early stages of a major transformation. This transformation will have far reaching consequences and benefits, and will help reshape the way health care is managed.

Speakers

**THE OUTCOME OF THE HYBRID eCTD PROGRAM AND THE IMPACT IT WILL HAVE ON THE HPFB**

**Vianney Caron**

Project Lead, Therapeutic Products Directorate eReview, Health Canada

**ELECTRONIC LABELLING: A COMPARISON OF THE FDA, EMEA, AND HEALTH CANADA APPROACHES**

**Keith Thomas**

Product Strategist Infrastructures for Information, Inc. Canada

**THE POWER OF NEW MEDIA AND ITS USE IN HEALTH CARE**

**Joel Alleyne**

President, Alleyne, Inc.; Practitioner in Residence, Knowledge Media Design Institute, University of Toronto; Instructor, Faculty of Information and Faculty of Medicine, University of Toronto, Canada

**10:00-10:30 AM Refreshment Break in the Exhibit Hall**

## 10:30 AM-12:00 PM PARALLEL TRACKS – SESSION 4

### SESSION 4 – TRACK 1

#### ETHICAL ISSUES IN CLINICAL TRIALS

##### Session Chair

**Judith Atkins, PhD**

Principal Consultant, PAREXEL Consulting

Clinical trials involve a plethora of ethical issues. The issues vary based on the target population, location, indication and study design. This session explores various ethical issues in the conduct of clinical trials, not only in Canada, but also globally.

##### Speakers

#### ETHICS OF PLACEBO USE IN CLINICAL TRIALS

**Professor Kathleen Glass**

Clinical Trials Research, McGill University

#### PATIENT COMPENSATION

**Speaker has been invited**

#### REGULATORS PERSPECTIVE

**Agnes V. Klein, MD, DrPH**

Director, Center for Evaluation of Radiopharmaceuticals and Biotherapeutics, BGTD, HPFB, Health Canada

**Norman Viner, MD**

Manager, Clinical Trials Division, Health Canada

### SESSION 4 – TRACK 2

#### NEW DIRECTIONS IN SAFETY OUTCOME RESEARCH: DSEN, SENTINEL, ENCEPP

##### Session Chair

**Nigel Rawson, PhD**

Pharmacoepidemiologist, GlaxoSmithKline, Inc. Canada

The aim of this session is to compare and contrast three networks created for drug safety and effectiveness research. Speakers will be asked to address the purpose of each network, where they are today, and their future directions. Opportunities for international collaboration will also be addressed.

##### Speakers

#### DSEN (DRUG SAFETY EFFECTIVENESS NETWORK) CANADA

**Diane Forbes**

Associate Director for the Drug Safety and Effectiveness Network, Canadian Institutes of Health Research

#### SENTINEL INITIATIVE: USA

(VIA AUDIO COMMUNICATIONS)

**Judith Racossin, MD, MPH**

Sentinel Initiative Scientific Lead, Associate Director, Medical Product Safety Programs, Office of the Commissioner, FDA

#### ENCEPP – EUROPE (VIA AUDIO COMMUNICATIONS)

**Henry Fitt**

Specialized Group Leader ONC/CVS, European Medicines Agency, European Union

### SESSION 4 – TRACK 3

#### ORPHAN DRUGS

##### Session Chair

**Anne Tomalin**

President, CanReg, Inc. Canada

This session will explore how orphan drugs are developed, regulated, and accessed by patients in Canada, including a comparison to the US and Europe. The industry's perspective, the regulator's perspective and the patient's perspective will be considered.

##### Speakers

#### ISSUES IN DEVELOPING ORPHAN DRUGS FOR RARE DISEASES

**Dayton Reardan, PhD**

Vice President, Regulatory Affairs, Eleos Inc., USA

#### ORPHAN DRUG POLICY IN THE US AND EUROPE

**John J. McCormick, MD**

Independent Consultant, McCormick Consultation, LLC; Former Head of the Orphan Drug Division of FDA, USA

#### ACCESSING DRUGS FOR RARE DISEASES IN CANADA

**Elizabeth Fowler**

Partner, World Health Advocacy; Board Member, Canadian Organization for Rare Disorders

## 12:00-1:30 PM

## Luncheon in the Exhibit Hall (Hall closes at 1:30 PM)

## 1:30-3:00 PM

## CLOSING PLENARY SESSION

### IS THERE CONNECTIVITY BETWEEN DRUG DEVELOPMENT, CLINICAL THERAPEUTIC GUIDELINES AND THE PRODUCT MONOGRAPH? WHAT WEIGHT DO THE GUIDELINES CARRY WITH PHYSICIANS AND PAYORS?

#### Session Chair

**Karen Feltmate**, Vice President, Operations Business Services and Regulatory Affairs, AstraZeneca, Canada, Inc.

More and more often, the clinical use of product reflects the current published Therapeutic Guidelines and literature (ahead of a monograph revision). Clinical development is advanced using surrogate biomarkers which are not yet validated in regulatory approvals. How can we bring clinical practice closer together with the Regulatory Product Label (Product Monograph)? If and when this is accomplished, does it help, hinder or add any value to the payor review process?

#### ■ OVERVIEW OF CLINICAL GUIDELINE PREPARATION

**Antoine Abugaber**, President of ABUGABER CANADA Inc., Oncology Management Services

#### ■ INDUSTRY PERSPECTIVE ON THE VALUE/USE OF CLINICAL THERAPEUTIC GUIDELINES

**Gerry Jeffcott**, Health and Pharmaceutical Policy Consultant

#### ■ REGULATORY PERSPECTIVE ON USE AND CORPORATE GUIDELINES IN REGULATORY DECISIONS

**Agnes V. Klein, MD, DrPH**, Director, Center for Evaluation of Radiopharmaceuticals and Biotherapeutics, BGTD, HPFB, Health Canada

## 3:00 PM

## Canadian Annual Meeting Adjourned



# DIA'S 7th CANADIAN ANNUAL MEETING

## "Time to Act"

Westin Ottawa Hotel, Ottawa  
Ontario, Canada

NOVEMBER 2-4, 2009

### HEALTH CANADA PARTICIPANTS

KIMBY BARTON  
VIANNEY CARON  
BRIAN FOSTER  
AGNES V. KLEIN  
SOPHIE LaFRANCE  
KWASI NYARKO

STEPHANIE REID  
SUPRIYA SHARMA  
HEATHER SUTCLIFFE  
NORMAN VINER  
BRIGITTE ZIRGER

### FDA PARTICIPANTS

MELISSA ROBB  
JOHN J. McCORMICK (formerly FDA)

### EMEA PARTICIPANTS

STELLA BLACKBURN  
HENRY FITT

**TUTORIAL** Monday, November 2, 1:30-5:00 PM  
Risk Communication

### MEMBER EARLY BIRD

Register by OCTOBER 15, 2009 **SAVE \$190**

Register online or fax this page to +1-215-442-6199

#### CONTACT & EXHIBIT INFORMATION

Attendees may visit the exhibits during the meeting and during receptions (if applicable).

**Meeting information:** Contact Joanne Wallace at the DIA office by telephone +1-215-442-6180, fax +1-215-442-6103 or email Joanne.Wallace@diahome.org.

**Exhibit information:** Contact Jeff Korn, Exhibits Associate, at the DIA office by telephone +1-215-442-6184, fax +1-215-442-6199 or email Jeff.Korn@diahome.org. For exhibit space, please check the box below.

To receive an exhibit application, please check.

#### GROUP DISCOUNTS (not available online or on already discounted fees)

Register 3 individuals from the same company and receive complimentary registration for a 4th! All 4 individuals must register and prepay at the same time – no exceptions. See page 3 for complete details.

**Registration Fees** If DIA cannot verify your membership upon receipt of registration form, you will be charged the nonmember fee. Registration fee includes refreshment breaks, luncheons, and reception (if applicable), and will be accepted by mail, fax, or online.

#### MEMBER EARLY-BIRD OPPORTUNITY

Available on nondiscount member fee only

	<b>On or before</b>	<b>After</b>
	<b>OCT. 15, 2009</b>	<b>OCT. 15, 2009</b>
Member Fee	US \$1260 <input type="checkbox"/>	US \$1450 <input type="checkbox"/>

Join DIA now to qualify for the early-bird member fee! [www.diahome.org](http://www.diahome.org)

To qualify for the early-bird discount, registration form and accompanying payment must be received by the date above. Does not apply to government/academia/nonprofit members.

Nonmember Fee	US \$1590 <input type="checkbox"/>
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A one-year membership to DIA is available to those paying a NONMEMBER meeting registration fee. If paying a nonmember fee, please indicate if you do, or do not, want membership.

I want to be a DIA member  I do NOT want to be a DIA member

#### Discount Fees

	<b>MEMBER</b>	<b>NONMEMBER*</b>
Government (Full-time)	US \$ 365 <input type="checkbox"/>	US \$ 505 <input type="checkbox"/>
Charitable Nonprofit/Academia (Full-time)	US \$ 730 <input type="checkbox"/>	US \$ 870 <input type="checkbox"/>

\*If paying a nonmember fee, please check one box above, indicating whether you want membership.

#### TUTORIAL November 2, 1:30-5:00 pm

#1 Risk Communication	US \$ 405 <input type="checkbox"/>
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#### CANCELLATION POLICY: On or before OCTOBER 27, 2009

Administrative fee that will be withheld from refund amount:

Member or Nonmember = \$200

Government or Academia or Nonprofit (Member or Nonmember) = \$100

Tutorial = \$50

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.

DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.

#### DRUG INFORMATION ASSOCIATION

800 Enterprise Road, Suite 200  
Horsham, PA 19044-3595 USA

**REGISTRATION FORM** Do not remove mailing label. Please return this entire page. **09019**  
PLEASE CONSIDER THIS FORM AN INVOICE

#### Please check the applicable category:

Academia  Government  Industry  CSO  Student (Call for registration information)

Last Name  Check if part of group registration First Name M.I.

Degrees  Dr.  Mr.  Ms.

Job Title

Company

Address As required for postal delivery to your location Mail Stop

City State Zip/Postal Country

email Required for confirmation

Phone Number Fax Number Required for confirmation

Group Registrant #2 Last Name First Name Completed form required for each group registrant

Group Registrant #3 Last Name First Name Completed form required for each group registrant

Group Registrant #4 Last Name First Name Completed form required for each group registrant

#### PAYMENT REGISTER ONLINE AT [www.diahome.org](http://www.diahome.org) or please check payment method:

**CHECK** drawn on a US bank payable to and mailed along with this form to: Drug Information Association Inc, P.O. Box 95000-1240, Philadelphia, PA 19195-1240, USA. Please include a copy of this registration form to facilitate identification of attendee.

**CREDIT CARD** number may be faxed to: +1-215-442-6199. You may prefer to pay by check or bank transfer since non-U.S. credit card payment will be subject to the currency conversion rate at the time of the charge.

Visa  MC  AMEX Expiration Date \_\_\_\_\_

Card # \_\_\_\_\_

Signature \_\_\_\_\_

**BANK TRANSFER** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the Bank Transfer. Payment should be made in US dollars. Your name and company, as well as the Event I.D. # must be included on the transfer document to ensure payment to your account.