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DIA's 7TH 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 TUTORIALS November 2, 2009, 1:30-5:00 pm

Tutorial # 1 – Design and Analysis of Cluster Randomization Trials in Clinical Research

Tutorial # 2 – 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

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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!

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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.

- Tutorials are each 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)*[™]; 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)*[™]; 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. 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.

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.

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 Tutorials

Tutorial #1: Design and Analysis of Cluster Randomization Trials in Clinical Research

INSTRUCTORS

Allan Donner, PhD

Professor, University of Western Ontario, Schulich School of Medicine

Brian Feagan, MD

Director, Robarts Clinical Trials; Professor, University of Western Ontario

The purpose of this tutorial is to discuss issues related to the design and analysis of CRTs with emphasis on its role in clinical research. A key feature of CRT is the random allocation of intact clusters of individuals, ie, medical practices, clinics or hospitals, to different intervention groups. Recent reports recognize that the application of standard statistical procedures to the design and analysis of CRT can lead to serious problems of interpretation because these procedures as discussed in most clinical trial textbooks typically assume that the outcomes on individuals within the same cluster are statistically independent. This fails to hold in CRT since responses on individuals in the same cluster tend to be more similar than responses on individuals in different clusters. A consequence of this failure is CRTs are generally less efficient in a statistical sense than trials individually randomizing the same number of total subjects. Hence the decision to adopt a CRT must rest entirely on practical considerations, such as administrative convenience, desire to avoid experimental contamination, or to improve subject compliance.

This tutorial discusses a range of issues related to CRT, including the advantages and disadvantages of different study designs, methods of assuring adequate statistical power, choice of analytic approach, and reporting standards. Ethical issues arising from the potential need to obtain informed consent at both the cluster level and the individual level are also discussed. Common pitfalls such as cluster sub-sampling bias, failure to appropriately define the unit of inference and overuse of matching at the design stage will be illustrated with examples from the literature. The role of CRTs in post-marketing studies aimed at increasing the uptake of appropriate prescribing behavior or otherwise enhancing the level of physician knowledge will receive particular attention. Group interaction will be encouraged throughout.

Tutorial Learning Objectives

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

- Differentiate the consequences of cluster randomization on sample size estimation and data analysis
- Assess the advantages and disadvantages of different study designs
- Estimate the sample size requirements for the most frequently adopted cluster randomization designs
- Identify an appropriate method of statistical analysis based on (i) the experimental design, (ii) the selected unit of inference, and (iii) the primary study outcome
- Justify the unique ethical issues that arise in cluster randomization trials
- Discuss the role of cluster randomization trials in drug development

Tutorial Target Audience

This tutorial is designed for clinical researchers, study coordinators, project managers, and statisticians.

Tutorial #2: 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

Tuesday, November 3, 2009

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

8:30-10:00 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 Director, Pharmaceutical Services, British Columbia Ministry of Health Services

10:5-10:45 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?

- **NOTICE OF DECISION/SUMMARY OF BASIS OF DECISION**
Supriya Sharma, MD, MPH, FRCPC, Director General, Therapeutic Products Directorate, Health Canada
- **CLINICAL TRIAL TRANSPARENCY – INDUSTRY PERSPECTIVE**
Cecilia K. Potez, Director, EU and International Regulatory Policy and Intelligence, AstraZeneca
- **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
Marketed Pharmaceuticals and Medical Devices Bureau, 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.

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

SESSION 1 – TRACK 2

EVOLVING SAFETY SCIENCE**Session Chair****Kimby Barton, MSc**

Marketed Pharmaceuticals and Medical Devices Bureau, Health Canada

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

SESSION 1 – TRACK 3

DEVELOPMENTS IN BIOSIMILARS IN CANADA, US, EUROPE, ICH, AND WHO**Session Chair****Kwasi Nyarko, PhD**

Unit Manager, Special Projects, Policy and Promotional Division, BGTD, HPFB, 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, PhD**

Unit Manager, Special Projects, Policy and Promotional Division, 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 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

Vice President, Global Product Development Strategy, PAREXEL International

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 Health Canada, CDR/Provincial Formularies, Chronic Disease Management, PMPRB and last but not least, Patients.

PANEL DISCUSSION
Speakers
CHRONIC DISEASE MANAGEMENT
Speaker has been invited
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.

PATENTED MEDICINE PRICES REVIEW BOARD
Barbara Ouellet

Executive Director, Patented Medicine Prices Review Board

PATIENT PERSPECTIVE
Speaker has been invited

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

Marketed Pharmaceuticals and Medical Devices Bureau, 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

Ronald L. Wilder, MD, PhD

Therapeutic Area Head, Rheumatology and Immunology, PAREXEL Consulting

REGULATOR’S PERSPECTIVE

Speaker has been invited

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)

Melissa Robb, RN

Senior Policy Analyst, 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, THERAPEUTIC GUIDELINES AND THE PRODUCT MONOGRAPH?

Session Chair

Karen Feltmate

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

Health Canada and clinician debate panel. More and more often, the clinical use of a 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 (monograph)?

Panel members have been invited

3:00 PM

Canadian Annual Meeting Adjourned

**Register NOW for this
additional DIA Offering!**



Personalized Medicine Biomarkers and Diagnostics in Drug Development, Regulatory Approval, and Access to Patients

October 15-16, 2009 / The Sutton Place Hotel, Toronto, ON Canada

Today, 'Personalized Medicine' is one of the most used buzzwords in healthcare and seen as the next frontier. Each stakeholder has a different understanding of the term. This conference will explore the scope, science and medical elements of personalized medicine. Elements range from genetics (SNPs for example) to biomarkers. These can be used as indicators of disease diagnosis, progression, treatment and prognosis and would allow a better targeting of the right therapies to the right patients.

As the speed of biomedical research and diagnostics tools are increasing the need for ongoing education and alignment of all involved partners in personalized medicine, speakers from academia, pharmaceutical industry, regulators and patient representation will discuss the needs and opportunities from their specific points of view.

PROGRAM CO-CHAIRPERSONS

MARIA KLAPKA

Director, Regulatory Policy
& Intelligence
Pfizer, Canada

AGNES V. KLEIN, MD, DRPH

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

MICHAEL RIEDER, MD, PHD, FRCPC, FAAP, FRCP (GLASGOW)

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

WHO SHOULD ATTEND

This program will benefit individuals involved in

- **Academic Health Centers**
- **Biotechnology**
- **Clinical Safety/Pharmacoepidemiology/
Pharmacovigilance**
- **Clinical Research & Development**
- **Devices**
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Monitor DIA's website for further information.

Register ONLINE – www.diahome.org (keyword 09035)

DIA'S 7th CANADIAN ANNUAL MEETING

"Time to Act"

Westin Ottawa Hotel, Ottawa
Ontario, Canada

NOVEMBER 2-4, 2009

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 2 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

	On or before	After
	OCT. 15, 2009	OCT. 15, 2009
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

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	MEMBER	NONMEMBER*
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"/>

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TUTORIALS November 2, 1:30-5:00 pm

#1 Design and Analysis of Cluster Randomization Trials	US \$ 405 <input type="checkbox"/>
#2 Risk Communication	US \$ 405 <input type="checkbox"/>

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.

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

TWO TUTORIALS Monday, November 2, 1:30-5:00 PM

#1 Design and Analysis of Cluster Randomization Trials in Clinical Research

#2 Risk Communication

DRUG INFORMATION ASSOCIATION

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

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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 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.

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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.