

10th Edition

CLINICAL TRIALS IN CANADA

Highlights 2009 -2010, Latest Developments

June 3 - 4, 2010 | Four Seasons Hotel | Vancouver



This highly interactive event brings together key stakeholders with a common interest and vision in seeing Canada become a leader in clinical research. You will hear the latest on current issues and developments from industry leaders including:

- What B.C. is doing to advance its research capacity
- How *Research Ethics Boards* are responding to a rapidly changing environment
- What B.C. is doing to foster and build partnerships across the healthcare spectrum to drive innovation and growth
- An update on current regulatory issues critical to conducting successful research
- Changes in U.S. guidelines and regulations
- How contract negotiation can be successfully expedited for the benefit of all stakeholders
- How Canada rates as a destination for clinical trials

KEYNOTE ADDRESS

Dr. John Challis, DSc, FRCOG, FRSC, PhD
Michael Smith Foundation for Health Research

PROGRAM CO-CHAIRS

Dr. Pierre Geoffroy, MD, CM, MSc., F.C.F.P.
Biovail Contract Research

Ron Heslegrave MPh.D.
*Research Ethics Board
University Health Network
Ontario Cancer Research Ethics Board*

Benefit from the expertise of these Participating Organizations

ASKA Research

AstraZeneca Canada Inc.

Biovail Contract Research

Centre for Drug Research and Development

Consortium of Canadian Centres for Clinical
Cognitive Research (C5R)

Eli Lilly Canada Inc.

Genome BC

i3 CanReg

Institutional Review Board Services

Michael Smith Foundation for
Health Research

Northern Alberta Clinical Trials and
Research Centre

Ontario Cancer Research Ethics Board

Pfizer Canada Inc.

University of Ottawa

UBC BCCA Research Ethics Board

University of Saskatchewan

Attracting research activity to Canada is vital if Canada is to continue its quest to become a leading nation of innovators among increasingly savvy competitors. The impact on the economy of the departure of research activity and with it many of our brightest minds to countries offering a friendlier climate in which to conduct research would be significant, and represent a blow to national aspirations.

For clinical research 'friendlier climate' often includes a more streamlined process for the approval of clinical trial studies that keeps delays to a minimum and eliminates costly duplication and overlap of oversight activities. While there have been several initiatives underway in recent years to improve the process of initiating and running clinical trials, more needs to be done.

This **10th Edition** of **CLINICAL TRIALS**, produced by **Insight Information** has incorporated several of the most 'in-demand' topics from the past few conferences into a program that also includes the latest thoughts and opinions of leaders and experts in Western Canada on current initiatives and future directions.

This is an excellent opportunity to take part in an interactive discussion concerning the future of clinical trial activity and the spirit of discovery in Canada.

It's one you won't want to miss.

Sponsorship Opportunities



Gain additional presence and prestige in front of senior level decision makers through Insight Information's sponsorship opportunities. All of our exclusive sponsorship packages include a comprehensive suite of preferential benefits.

For further details, please contact Edward O'Hara at 416.642.6136 or ehara@alm.com

Who Should Attend

- Clinical Research Associates
- Study Coordinators
- Principal Investigators
- Research Administrators
- Research ethics board members
- Clinical research organizations
- Pharma, medical device and biotech study sponsors
- Clinical trial consultants and service providers

Need additional information? Subscribe to **inCONFERENCE™**.

Gain online access to valuable conference papers and reports from any **Insight Information** conferences - whether it's energy, environment, finance, legal, or any of the other sectors covered at **Insight Information** conferences by subscribing today to **inCONFERENCE™**. Delegates will receive a set of original materials as well as online access to fully searchable conference papers through **Insight Information's inCONFERENCE™** that will serve as an invaluable reference source. To find out more, or to receive a free trial subscription, please go to <http://inconference.insightinfo.com>

Thursday June 3, 2010

8:15

Registration and Coffee

9:00

Welcoming Remarks from Insight Information

9:05

Opening Remarks From the Co-Chair

Dr. Pierre Geoffroy, MD, CM, MSc., F.C.F.P.

Medical Director

Biovail Contract Research

9:15

OPENING KEYNOTE ADDRESSES

The Health Research Roadmap: Creating Innovative Research for Better Health and Healthcare in B.C.

Dr. John Challis, DSc,FRCOG, FRSC, PhD

President and CEO

Michael Smith Foundation for Health Research

10:00

CASE STUDY

Consortiums and their Impact on Research - The Role and Impact of C5R

Dr. B. Lynn Beattie

Secretary Treasurer

*Consortium of Canadian Centres for
Clinical Cognitive Research (C5R)*

C5R was born out of necessity, banding nascent cognitive clinical investigators to enable practical work with pharmaceutical companies for national and international multicentre clinical trials for sites in Canada. Over the years there has been an establishment of procedures to facilitate trials which includes protocol review and centralized negotiation of budgets for sites. Ongoing education of investigators and their coordinators is seen as a priority. Challenges come from changing economic pressures and of course the pipeline of the potential therapies available. Dealing with *Research Ethics Boards*, timely recruitment of subjects and new protocols where there is a higher risk benefit potential continue to be major issues that have to be tackled on an ongoing basis including the role of placebos.

10:45

Networking Coffee Break

11:00

PANEL PRESENTATIONS AND DISCUSSION

What's Working, What's Not in a Changing Environment for REBs

Ron Heslegrave Ph.D.

Chair, Research Ethics Board

University Health Network

Ontario Cancer Research Ethics Board

Dr. George Browman

Chair

UBC BCCA Research Ethics Board

- A National REB Review: National initiatives and innovation in REB review in Canada
- How emergence of new technologies, industry needs, changing ethics policies, and calls for collaborative review are affecting the work of REBs
- Finding a balance between innovation and participant protection

12:00

Networking Luncheon

1:30

Regulatory Updates and Issues

Anne Tomalin, BA, BSc, RAC

President

i3 CanReg

- Update on GCP and audits in Canada
- Regulatory competitiveness and transparency
- Clinical trials as required by post-marketing commitments
- Placebos in clinical trials
- Disease free survival as a registration endpoint in cancer studies

2:15

Changes in U.S. Guidelines and Regulations

Jack Corman

President

Institutional Review Board Services

- New investigator guidelines in the U.S.
- New legislation in the U.S. requiring ethics boards to be registered
- New FDA guidelines - continuing review, safety and unanticipated problems reporting
- Draft guidance on new elements of informed consent
- GAO/FDA new enforcement initiatives
- New draft human subject protection legislation (DeGette bill)

3:00

Networking Refreshment Break

3:15

Building Clinical Research Infrastructure and Harmonizing Practices in B.C.

Heather Harris-Harper

*British Columbia Clinical Research Infrastructure
Network Coordinator
Genome BC*

Structural changes taking place within the *BC Health Authorities* coupled with sustained research funding at federal and provincial levels are providing an ideal opportunity to integrate the outcomes of biomedical research at the heart of the healthcare delivery system in B.C. The main research-intensive health centres, the health authorities and UBC medical school have created the *BC Clinical Research Infrastructure Network (BCCRIN)*, an umbrella organization with a vision to integrate clinical research capabilities throughout B.C.

The BCCRIN will drive the development of a harmonized and coordinated network promoting clinical research and clinical trial activity that will transform the B.C. landscape in this regard. It is well established that patients treated in environments strong in clinical research have improved clinical outcomes and B.C. is poised to position itself as a vibrant centre for these activities over the next decade.

4:00

Creating and Sustaining Partnerships to Foster Collaboration, Innovation and Growth

Karimah Es Sabar

*Senior Vice President, Business and Strategic Affairs
Centre for Drug Research and Development*

- Building partnerships between healthcare organizations/hospitals, industry, the academic community and government
- Role and contribution of each sector
- Creating the right climate for research, innovation and commercialization
- Biotech and big pharma - strategic, innovative partnerships in R&D

4:45

Conference Adjourns for the Day

Friday June 4, 2010

8:15

Coffee

9:00

Opening Remarks from the Co-Chair

Ron Heslegrave Ph.D.

*Chair, Research Ethics Board
University Health Network
Ontario Cancer Research Ethics Board*

9:15

INTERACTIVE ROUNDTABLE DISCUSSION

How Sponsors, Institutions/PIs and CROs Can Smooth Out and Speed Up the Negotiation of Clinical Trial Contracts in Canada

Valerie Willetts

*President
ASKA Research*

Donna Mitchell

*Director, Saskatchewan Drug Research Institute
University of Saskatchewan*

At this roundtable discussion panelists will explore some of the practical tips and techniques they use to accelerate the contract process, and share their strategies for negotiating winning contracts.

- Key contract terms that adhere to specific policies of each party
- Negotiating challenges and delaying factors
- Template agreements and harmonization initiatives
- Tools and resources to help the process

10:15

Networking Coffee Break

10:30

Pharmacokinetic and First-in-Man Studies: Safety in Healthy Volunteers

Dr. Pierre Geoffroy, MD, CM, MSc., F.C.F.P.

*Medical Director and Principal Investigator
Biovail Contract Research*

Bioavailability/bioequivalence studies are designed to compare the pharmacokinetic profile of two or more compounds or compound formulations. These may be an essential part of an approval dossier for a generic drug, but rarely do they provide any therapeutic benefit for study participants. First-in-man studies are designed to test the safety of a new molecular entity for, as the name implies, the first time in man. These studies may be conducted in volunteers with the disease of concern, but more often will be conducted in healthy volunteers. At

best, drug testing in healthy volunteers presents a neutral benefit/risk ratio.

For this reason, and while volunteer safety should be a primary concern in all clinical studies, special emphasis must be placed on protecting the phase I study volunteer from harm. From study design to post-study follow-up, volunteer-centered safety checks best ensure the well-being of our study participants. In this session, the attendee will learn about volunteer-centered study safety through:

- Discussion of measures to best safeguard the health of study volunteers via careful screening of subjects, on-study monitoring, and post-study follow-up
- Examination of safety endpoints in protocol design
- Review of adverse event evaluation

11:15

Managing Privacy in Clinical Trials

Khaled El Emam Ph.D.

*Associate Professor
Canada Research Chair in Electronic Health Information
Faculty of Medicine and the School of Information
Technology and Engineering
University of Ottawa*

Through a series of case studies, this presentation will describe the technical and legal challenges and provide guidance on privacy issues that occur in clinical trials, especially in the context of using electronic data capture systems:

- The patient and physician privacy interests in prescription records
- Privacy considerations with using electronic data capture tools
- The collection of personal information for large pharmacogenomic trials, including consent, governance and data sharing issues
- Data mining EMRs and EHRs to identify subjects for recruitment

12:00

Networking Luncheon

1:30

Cost Effective Site Monitoring and Data Management for Greater Web-Enabled Collaboration

Jason Ridderikhoff, B.Sc.N.

*Regional Operations Manager, Clinical Research
Eli Lilly Canada Inc.*

The deployment of technology within clinical research has continued at a phenomenal rate. The ability to implement this in a collaborative manner between sponsors, vendors, and investigative sites has the potential to become a significant competitive advantage.

- An overview of available technology and its utilization in Canada

- Opportunities to leverage technology in order to reduce costs in monitoring for both sponsors and investigative sites
- Reducing work in process, improving safety surveillance
- Maintaining a competitive advantage in the face of increased competition from lower cost markets through the use of technology

2:15

Networking Refreshment Break

2:30

Clinical Trial Budgets: Sponsors and Sites Perspective

Cheryl Small

*Associate Director, Clinical Business Operations
Pfizer Canada Inc.*

Kate Bailey

*Regional Project Planner & Contracts Administrator
Northern Alberta Clinical Trials and Research Centre*

- How sites can best determine their costs, infrastructure, and methodology to consistently maximize revenue
- How budgets are constructed globally or by country
- Rationale for why some budget categories cannot be changed, while others can
- Biggest challenges/concerns going forward

3:30

PANEL PRESENTATIONS AND DISCUSSION

Clinical Research in Canada: How Competitive Are We? How Canada Rates as a Destination for Clinical Trials

Cheryl Small

*Associate Director, Clinical Business Operations
Pfizer Canada Inc.*

Dr. Catriona McMahon, BSc., MBChB, FRCA (UK), MFPM (UK)
*Vice President, Medical Affairs
AstraZeneca Canada Inc.*

- What we need to do to attract - and retain - clinical trials in Canada
- National and provincial strategies for overcoming barriers for our research
- The impact of globalization on clinical trials
- How the global picture affects our clinical trial agreements
- Global sponsors of Canadian trials - how a global study is different from a local study

4:30

Conference Concludes

10th Edition

CLINICAL TRIALS IN CANADA

Highlights 2009 -2010, Latest Developments

FIVE EASY WAYS TO REGISTER Call 1 888 777-1707 | Fax 1 866 777-1292 | Internet: www.insightinfo.com/clinicaltrialsvancover
Email: order@alm.com | Mail: Insight Information, 214 King Street West, Suite 300, Toronto, Ontario M5H 3S6

June 3 - 4, 2010 | Four Seasons Hotel | Vancouver

Yes! Please register the following delegate(s) (photocopy for additional delegates)

Priority Code: 10605_PDF

Mr. Ms. Name _____

Title: _____

Area of practice: _____

Company: _____

Business Address: _____

City: _____ Province: _____ Postal Code: _____

Telephone: [] _____ Fax: [] _____

E-mail: _____

Type of Business: _____ #of Employees: _____

Registrant's Signature Required:

Signature _____ Date _____

Registration Fee: (Includes meals, documentation and **inCONFERENCE™**, fully searchable online access to this conference's papers*)

Please check your choice:

Regular Conference Price: \$1,795.00 + GST (\$89.75) = \$1,884.75

Solution Provider / Vendor Pricing \$1,995.00 + GST (\$99.75) = \$2,094.75

I would like to order an extra copy of the conference binder (1 conference binder is included in the registration fee) \$100.00 + 5% GST

Payment enclosed. Payment to follow. (GST Reg. #856568779RT0001)

Charge to my VISA® AMEX® MasterCard®

Card Number: _____ Exp. Date: _____

Card Holder's Name: _____

Signature: _____ Date: _____

* Please allow 2 weeks after conference for activation of login and password.

Conference Code: PHC10605

HOTEL RESERVATIONS:

The Four Seasons Hotel is conveniently located at 791 West Georgia Street (the corner of Howe Street and West Georgia Street), Vancouver, B.C. For overnight accommodation please call the hotel at 604-689-9333 or by fax 604-684-4555.

CANCELLATION AND REFUND POLICY:

A refund (less an administration fee of \$200 plus GST) will be made if notice of cancellation is received in writing three weeks before the event. We regret that no refund will be given after this period. A substitute delegate is welcome at any time.

SPECIAL OFFER: Send 4 people for the price of 3!

Register 3 delegates for the main conference at regular price at the same time and you're entitled to register a fourth person from your organization at no charge. For other group discounts, please call 1-888-777-1707. All discounts must be redeemed when booking, discounts will not be valid or applied after this time.

Insight Information Reward Program:

Attend multiple **Insight Information** conferences in 2010 and/or register during 2010 and save! Attend and/or register for a 2nd conference in the calendar year (January to December) and receive a 25% discount and attend and/or register for a 3rd conference and receive a 50% discount. Buy more and save!

Privacy Policy:

By registering for this conference, **Insight Information** will send you further information relating to this event. In addition, you may receive by mail, telephone, facsimile or e-mail information regarding other relevant products and services from either **Insight Information** OR third parties with whom we partner.

If you do not wish to receive such information from either **Insight Information** or third parties, please inform us by email at privacy@alm.com or by telephone at 1 888 777-1707.

Please Note: Full payment is required in advance of conference dates. Please make all cheques payable to **Insight Information**.

Insight Information reserves the right to change program date, meeting place or content without further notice and assumes no liability for these changes.