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

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Register online at www.insightinfo.com/clinicaltrialsvancouver
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.

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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

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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

9:15  
OPENING KEYNOTE ADDRESSES

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9:15  
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President and CEO  
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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
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.

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