

Presented by Insight Information

4th Annual

# CLINICAL TRIALS IN CANADA

Regulatory Compliance | Maximizing ROI | Limiting Risk  
In Today's Highly-Competitive Global Market



April 28 – 29, 2008  
TELUS Convention Centre  
Calgary

Last year, our annual Clinical Trials in Canada conference in Toronto was a huge success and, after many requests, we're now bringing this conference to Western Canada! Conference highlights include:

- The impact of globalization on clinical trials: emerging trends and opportunities
- The 5 year review of Canada's clinical trial regulations
- A SWOT analysis of clinical trials in Canada
- How key stakeholders can grow the business in Canada
- Strategies for ensuring patient privacy/confidentiality
- Health Canada and FDA inspections/audits
- Retention strategies with good site and patient recruitment
- How technology is revolutionizing the clinical trial process
- The changing role of today's Research Ethics Boards (REBs) and public vs. private REBs panel

and much more...

## PROGRAM CHAIR

Brett Wilson  
*Associate Director  
Clinical Site Monitoring  
Saskatoon, Saskatchewan  
Bristol-Myers Squibb*

## FEATURED KEYNOTE:

Ghislain Boudreau, Ph.D.  
*Director, Medical Affairs and  
Clinical Research, Medical Division  
Pfizer Canada Inc.*

## Copper Sponsor



## Marketing Partners



## Sponsors



NewScientist Jobs

**ENROLL TODAY!** Call 1 888 777-1707 or fax 1 866 777-1292  
or register online at [www.insightinfo.com](http://www.insightinfo.com)



## Sponsorship Opportunities

If you are interested in displaying your company's products or services to high level key decision makers within your target audience, please contact:

Amy Leung

1 866 456-2020 ext. 6128

aleung@insightinfo.com

### Need additional information?

Subscribe to **inCONFERENCE™**.

Gain online access to valuable conference papers and reports from any Insight conferences – whether it's energy, environment, finance, legal, or any of the other sectors covered at Insight 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'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>

## HEAR TOP INDUSTRY EXPERTS FROM:

Bristol-Myers Squibb Canada

Canadian Association of Research Ethics Boards (CAREB)

Clinical Research Association of Canada (CRAC)

Canadian Treatment Action Council (CTAC)

Eli Lilly Canada Inc.

Health Canada

IRB Services

Ontario Institute for Cancer Research

Pfizer Canada Inc.

Sanofi Pasteur

Scimega Research Inc.

St. Michael's Hospital

University of Alberta

Wyatt Health Management

Dear Colleague,

The clinical trials industry continues to face new and unprecedented challenges. Trust in the clinical trials enterprise has suffered from media coverage of unanticipated safety findings, an apparent lack of transparency and a drug development environment rife with multiple conflicts of interest. Faced with low research productivity and decreasing revenues due to expiring patents, industry's deployment of studies to lower cost regions threatens Canada's historical high level of participation in multicenter trials.

Pharmaceutical, biotechnology and medical device companies, CROs, clinical trial researchers, ethics boards, regulatory and government agencies in Canada must react with cutting edge strategies to regain public trust and offer value-added benefits to trial conduct in Canada.

This **4th Annual CLINICAL TRIALS IN CANADA** conference, hosted by **Insight Information**, addresses today's challenges in clinical trials. You'll hear how colleagues are tackling these challenges and have the opportunity to meet and engage experts in current areas of change.

I look forward to seeing you in Calgary on April 28-29, 2008.



Brett Wilson

Associate Director, Clinical Site Monitoring

Saskatoon, Saskatchewan

Bristol-Myers Squibb

## WHO SHOULD ATTEND

Industry representatives, academics, scientists, clinicians and provincial regulatory agencies from Pharma, Biotechnology and Medical Devices including:

- Chief Medical Officers and Medical Directors
- Heads of Medical Affairs and Clinical Research
- Heads of Clinical Operations, Directors and Managers
- Heads of Clinical Research, Directors and Managers
- Directors or VPs, Scientific Affairs/Government Relations
- Research Ethics Board Members and Researchers
- Clinical Project Leaders and Research Associates
- Clinical/Site Monitors and Auditors
- Regulatory Managers and Clinical Investigators
- Heads of Quality Control/Assurance/Compliance/Ethics
- Clinical Statisticians and Study Coordinators
- Clinical Data Managers/Co-ordinators
- Health Canada, Senior Advisors, Researchers and Policy Developers
- Health, Pharma, Medical Device and Biotech Lawyers
- Health, Pharma, Medical Device and Biotech Trade Association Representatives
- Clinical Trial Consultants and Service Providers
- Agencies that fund research, including governments, research charities, and medical research councils

## MONDAY | APRIL 28, 2008

8:00 | 9:00

### Conference Registration and Continental Breakfast

9:00 | 9:10

### Welcome and Opening Remarks from Chair

**Brett Wilson**

*Associate Director, Clinical Site Monitoring  
Saskatoon, Saskatchewan  
Bristol-Myers Squibb*

9:10 | 10:00

KEYNOTE ADDRESS

### The Impact of Globalization on Clinical Trials

**Ghislain Boudreau, Ph.D.**

*Director, Medical Affairs and  
Clinical Research, Medical Division  
Pfizer Canada Inc.*

10:00 | 11:00

### Clinical Trials in Canada SWOT Analysis

**Dr. Ron Heslegrave**

*Chair, Research Ethics Board  
Ontario Institute for Cancer Research*

**Ronald Fehst**

*(Past) Senior Regional Research Manager  
Eli Lilly Canada Inc.*

An in-depth discussion concerning Canada's Strengths, Weaknesses, Opportunities and Threats in a highly-competitive global market.

11:00 | 11:15

### Networking Coffee Break

11:15 | 12:15

### Five Year Review of Canada's New Clinical Trial Regulations – What Works? What Needs to be Fixed?

**Jack Corman**

*President  
IRB Services*

**Adam Gibson**

*Associate Director, Office of Clinical Trials  
Therapeutic Products Directorate  
HPFB, Health Canada*

After a five year review of Canada's new Clinical Trials regulations, important lessons have emerged. The focus of this session will look at problems which have been addressed and as well as discussion surrounding what remains to be done. Don't miss this timely analysis.

12:15 | 1:30

### Networking Luncheon

1:30 | 2:15

CASE STUDIES

### Health Canada and FDA Audits – What Experience Has Taught Us?

**Kim McDonald-Taylor**

*President, Clinical Research Association  
of Canada (CRAC)  
Director of Clinical Services  
Wyatt Health Management*

- Understand the Health Canada Inspectorate's audit system and how it differs from our American counterparts
- Tracking of safety outcomes leads to better audit results – you must know your product – suggestions on how to do this better
- Training guidelines for both site staff and internal team – this is a key element of audits. Learn how to document properly
- Be prepared for audits with an internal QA process – case study of processes that worked

2:15 | 2:30

### Networking Refreshment Break

2:30 | 3:15

### Clinical Trial Registries: Challenges and Opportunities

**Pierre Geoffroy M.D., C.M., M.Sc., F.C.F.P.**

*Senior Director, Clinical Department  
Sanofi Pasteur*

US federal regulations require posting clinical trial protocols on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) and, since Dec. 2007, more information is mandated. Noncompliance with regulations will interfere with New Drug Applications. In addition to requirements to post data retrospectively for clinical trials ongoing December 26, 2007, new legislation also requires that study results be posted. Finally, individual states, such as Maine, are also enacting legislation for posting information which will impact already licensed medicines in that state. The numerous changes to Clinical Trial registries will be described and measures to manage them explored.

3:15 | 4:00

### Investigator-Initiated Trials

**Ronald Fehst**

*(Past) Senior Regional Research Manager  
Eli Lilly Canada Inc.*

- Advantages and disadvantages

- Logistical considerations; safety (DSMBs, AE Reporting), drug supply, data reporting
- Risk, liability and insurance issues
- Intellectual Property (IP) rights

4:00 | 4:45

## Health Canada's Food and Drug Regulations Clinical Trial Inspection Program

**Ms. Asma Syed**

*Acting Coordinator, Good Clinical Practices Unit  
Inspectorate  
HPFB, Health Canada*

This session will provide an in depth look into the Clinical Trials Inspection Program. It will focus on the role and responsibilities the Inspectorate plays in clinical trials and the observations made over the past six years. Current initiatives that the Inspectorate is working on to improve the clinical trial inspection process will be discussed briefly.

4:45

## Conference Adjourns for the Day

# TUESDAY | APRIL 29, 2008

8:00 | 9:00

## Continental Breakfast

9:00 | 9:15

## Chair's Recap of Day 1 and Introduction to Day 2

9:15 | 10:15

## How Can We (Canadian Sponsors, Institutions, Investigators, Government and CROs) Grow the Business in Our Country

**Brett Wilson**

*Associate Director, Clinical Site Monitoring  
Saskatoon, Saskatchewan  
Bristol-Myers Squibb*

**Pierre Geoffroy M.D., C.M., M.Sc., F.C.F.P.**

*Senior Director, Clinical Department  
Sanofi Pasteur*

This interactive session will discuss how key stakeholders can help grow the business in Canada. Delegate input is encouraged.

10:15 | 10:30

## Networking Coffee Break

10:30 | 11:15

## Cost-Effective Site Monitoring and Data Management Through New Web-Enabled Technologies

**Jason Ridderikhoff, B.Sc.N.**

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

This session will explore the benefits and challenges of site monitoring and data management using web-based technologies such as EDC and web portals. Additional points to be discussed include:

- Can monitoring occur remotely?
- Will web-based solutions save money?
- The evolving role of the "monitor"
- What do investigative sites have to say about web-based technologies?

11:15 | 12:00

## Overcoming Contracting Challenges: Efforts to Find a More Stream-Lined Approach

**Michelle Moldofsky, LL.B., LL.M.**

*Policy & Legal Advisor  
Office of Research Administration  
St. Michael's Hospital*

- The impact of multicenter clinical trials and globalization on contracts/CTAs
- Federal and provincial laws and regulations' impact on clinical trials agreements
- MAGI – Model Agreement Group Initiative
- What master agreements can and cannot do
- Negotiating and reviewing contracts from the institutional and REB "insiders perspective"

12:00 | 1:15

## Networking Luncheon

1:15 | 1:45

## The Current and Anticipated Landscape for Canadian Research Ethics Boards (REBs)

**Dr. Ron Heslegrave**

*Chair, Research Ethics Board  
Ontario Institute for Cancer Research*

- Several private REBs act on a multi-province basis. Does this work?
- Where do we go next?
- Can Canada-wide REBs, based on specific areas of research, be a next step?
- Advantages and disadvantages

1:45 | 2:45

PANEL DISCUSSION

## Public vs. Private REBs

**Moderator: Dr. Ron Heslegrave**

*Chair, Research Ethics Board*

*Ontario Institute for Cancer Research*

**Panelists:**

**Ghislain Boudreau, Ph.D.**

*Director, Medical Affairs and Clinical*

*Research, Medical Division*

*Pfizer Canada Inc.*

**Ron Fehst**

*(Past) Senior Regional Research Manager*

*Eli Lilly Canada Inc.*

**Shane Kimber MD FRCPC FACC**

*Associate Professor of Medicine*

*Chair, Human Research Ethics Board (Biomedical)*

*University of Alberta*

There are different jurisdictions with different approaches as to what's acceptable for their Research Ethics Boards. In some provinces only public boards are acceptable, in others, private are acceptable. What are the pros and cons of each?

concerted effort on the part of industry to broaden its reach through the globalization of clinical programs. To assure Canada's position in the global arena, we must select high performance sites to maximize patient recruitment performance while preserving quality.

We will discuss:

- How to qualify high performance sites
- Case study success stories from our personal experience with oncology studies
- How to keep the investigative team committed to the protocol

3:45 | 4:15

CASE STUDY

## Putting the Research Participant First

**Louise Binder**

*Chair*

*Canadian Treatment Action Council (CTAC)*

This case study will highlight the barriers to free and informed consent and provide recommendations to solve the gap between the theory and practice of informed consent.

2:45 | 3:00

## Networking Refreshment Break

3:00 | 3:45

## Good Site Recruitment = Good Patient Recruitment: Strategies for Success

**François Le Barbenchon**

*Director of Operations*

*Scimega Research Inc.*

*Canada's Premier Oncology CRO*

Difficulty in recruiting patients has been recognized as the bio-pharmaceutical industry's number one roadblock to the successful, timely completion of clinical trials. Consequently there has been a

4:15

## Conference Concludes

## Here is what past delegates to the Clinical Trials conference in Toronto had to say:

"Appreciated diversity and qualified presenters, audience participation was encouraged at all presentations. Many topics and information will be brought back internally for sharing with colleagues. Thanks for this great conference! Hope to be here again next year."

## UPCOMING CONFERENCES

### E-CLINICAL TRIALS IN CANADA

March 31 – April 1, 2008 | Montréal

### Latest Initiatives in LABORATORY SERVICES

April 7 – 8, 2008 | Toronto

6th Annual

### HEALTH INNOVATION AND POLICY SUMMIT

April 30 – May 1, 2008 | Toronto

### 7th Annual EMERGENCY CARE

June 19 – 20, 2008 | Toronto

## 4th Annual

# CLINICAL TRIALS IN CANADA

Regulatory Compliance | Maximizing ROI | Limiting Risk  
In Today's Highly-Competitive Global Market

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

April 28 – 29, 2008 | TELUS Convention Centre | Calgary

Conference Code: PHC08241

### HOTEL RESERVATIONS:

The TELUS Convention Centre is conveniently located at 120-9th Avenue S.E., Calgary, AB. Tel: (403) 261-8500. For overnight accommodation please contact the Marriott Hotel at (403) 266-7331, or fax (403) 231-4523. Please note, a block of rooms has not been held for this event. Delegates are advised to contact the hotel directly to secure overnight accommodation..

### CANCELLATION AND REFUND POLICY:

Refunds will be given for cancellations received in writing by April 7, 2008 subject to an administration fee of \$200.00 plus \$10.00 GST for a total of \$210.00. If your fees have not been paid and you are cancelling, you are still liable for the cancellation fees of \$200.00 plus \$10.00 GST for a total of \$210.00. Please note that if you register for the conference and do not attend, you are liable for the full registration fee unless you cancel within the period stated above. If you register after April 7, 2008, your order is firm. A refund will not be given; however a delegate substitution 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. To take advantage of this special offer, payment for all delegates must be made with one cheque or credit card charge.

**INSIGHT REWARD PROGRAM:** Attend multiple Insight conferences in 2008 and/or register during 2008 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:** You may receive by mail, telephone, facsimile or e-mail information regarding 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@insightinfo.com](mailto:privacy@insightinfo.com) or by telephone at 1 888 777-1707.

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

PRIORITY CODE: 8241-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 *in*CONFERENCE™, fully searchable online access to this conference's papers\*)

Please check your choice:

Regular Conference Price: \$1,695.00 + GST (\$84.75) = \$1,779.75

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 4-6 weeks after conference for activation of login and password.

**PLEASE NOTE:** Full payment is required in advance of conference dates. Please make all cheques payable to **Insight Information**. If payment is made by credit card, your credit card statement will quote "**ALM Events Canada, Inc.**" as the vendor.

**INSIGHT** reserves the right to change program date, meeting place or content without further notice and assumes no liability for these changes. ©2008 Insight Information