Clinical Trials in Canada has become an important industry event, bringing together key stakeholders to discuss strategic initiatives that will help us become more competitive, globally.

The focus of this year’s conference is to provide a forum at which stakeholders can lend their voice in generating constructive and proactive solutions to improve our competitive advantage on the world stage. **Highlights include:**

- The Impact of Globalization on Clinical Trials
- Clinical Research in Canada: Field of Dreams?
- Top 10 Do’s & Don’ts for Clinical Research Sites
- How Sponsors, Institutions and CROs Can Grow the Business in Canada
- Contract Negotiations: Canadian Challenges and Made-in-Canada Solutions
- Personalized Medicine: Right Drugs, Right Patients, Right Time
- Global Clinical Trial Registries and Research Ethics Standards in Canada: Update
- Health Canada: Progressive Licensing Framework and Bill C-51
- Effective Sponsor-Site Relationships in Canada, Europe and Asia Pacific
- Real World Drug Safety and Effectiveness: What You Need to Know
- Participant Protection Challenges: An International Perspective
- and much more…

**KEYNOTE PRESENTATION**

Clinical Trials Contribution to National R/D Strategies: Economic Drivers for Canada

Carl Viel, Chief Executive Office, Montreal InVivo

**PROGRAM CO-CHAIRS**

Janice E. Parente, Ph.D.
President/Managing Director
ethica Clinical Research Inc.

Brett Wilson, BSP
Associate Director
Clinical Site Monitoring
Regional Clinical Operations
Bristol-Myers Squibb Canada

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Dear Colleagues,
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 multicentre trials.

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

This 5th Edition 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 an opportunity to meet and engage experts in current areas of change.

This year Insight Information will launch its inaugural awards ceremony to recognize one outstanding Canadian’s contribution to Clinical Research in this country.

We look forward to seeing you in Toronto on October 20-21, 2008.

Janice E. Parente, Ph.D.
President/Managing Director
ethica Clinical Research Inc.

Brett Wilson, BSP
Associate Director, Clinical Site Monitoring
Regional Clinical Operations
Bristol-Myers Squibb Canada

Advisory Board Members include:
Ghislain Boudreau, Ph.d., Director, Medical Affairs and Clinical Research, Medical Division, Pfizer Canada Inc.
Ron Fehst, President, Ronald Fehst Research Consultants
Pierre Geoffroy MD, CM, MSc, F.C.F.P, Senior Director, Clinical Department, Sanofi Pasteur
Ron Heslegrave, Ph.D., Chair, Research Ethics Board, University Health Network Ontario Cancer Research Ethics Board
Kim McDonald-Taylor, President, Clinical Research Association of Canada (CRAC), Director of Clinical Services, Wyatt Health Management
Nestor Nituch, Unit Director, Regional Clinical Operations, Bristol-Myers Squibb Canada

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

SPECIAL OFFER
Delegates who register for this event will receive the Pharma & Bio Pharma Industry Guide courtesy of Contact Canada, a $249.95 value!
8:00 | 9:00
Conference Registration and Continental Breakfast

9:00 | 9:10
Welcome and Opening Remarks from Co-Chair
Brett Wilson, BSP
Associate Director, Clinical Site Monitoring
Regional Clinical Operations
Bristol-Myers Squibb Canada

9:10 | 10:00
KEYNOTE ADDRESS
Clinical Trials Contribution to National R&D Strategies: Economic Drivers for Canada
Carl Viel
Chief Executive Officer
Montreal InVivo

10:00 | 10:15
Networking Coffee Break

10:15 | 11:15
PANEL
The Impact of Globalization on Clinical Trials
Moderator:
Brett Wilson, BSP
Associate Director, Clinical Site Monitoring
Regional Clinical Operations
Bristol-Myers Squibb Canada

Pierre Gervais, B. Pharm., MSc
President and Research Director
Q&T Research

Maryse Simard
Associate Director, Site Start-up
Quintiles Canada Inc.

• Clinical research in Canada; barriers, challenges and solutions
• National or provincial strategies for overcoming barriers for research in Canada
• The impact of globalization of corporate structures on outsourcing clinical research
• The future of clinical research in Canada

11:15 | 12:30
Clinical Research in Canada: Field of Dreams?
Muhammad Mamdani, PharmD, MA, MPH
Director, Applied Health Research Centre (AHRC)
Li Ka Shing Knowledge Institute of St. Michael’s Hospital

Bob Phillips, Ph.D.
Deputy Director
Ontario Institute for Cancer Research (OICR)

Canada is home to some of the world’s best clinicians and research scientists with significant expertise in designing, managing, and coordinating large clinical trials. Although the desire and expertise exists within Canada to be an international leader in conducting clinical trials, significant efforts may need to be placed on fostering efficient, high quality, and cost-effective operational processes, coordination of leading scientific expertise, strategies to maximize patient enrolment, and building and maintaining relationships with public and private funders. These and related issues will be discussed during the presentation.

12:30 | 1:45
Networking Luncheon

1:45 | 2:30
PANEL
Top 10 Do’s & Don’ts for Clinical Research Sites
Moderator:
Ronald Fehst
President
Ronald Fehst Research Consultants

Sylvie Giroux
Director, Clinical & Regulatory Capabilities and Compliance
Novartis Pharmaceuticals Canada Inc.

Sonja Mitrovic, BSc., MD
Research & Development
Eli Lilly Canada Inc.

• How do institutions, sites and investigators get identified?
• How do they get on the short list?
• How do they get into the final group?

2:30 | 3:15
Personalized Medicine: Right Drugs, Right Patients, Right Time

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

In previous eras of medical research, a common approach focused on cure-all medicinal products, e.g. broadband antibiotics that cover nearly every bacterial infectious disease or analgesics suitable for every type of pain. Initially, the ‘one-fits’ all approach appeared to be a smart concept but it has also drawn attention to the fact that every individual may react differently to a medicinal product. While a specific medicinal product may offer the best possible efficacy and safety to an individual person, it may not have a sufficient effect on another person suffering from the same disease, or may even cause harm. This presentation will focus on the importance of personalized medicine in Clinical Trials.
3:15 | 3:30
Networking Refreshment Break

3:30 | 4:15
Health Canada: Progressive Licensing Framework and Bill C-51

Maurica Maher, MD, MSc
Senior Scientific Advisor
Progressive Licensing Project
Therapeutic Products Directorate
Health Products and Food Branch, Health Canada

- Why Health Canada is pursuing Bill C-51
- How we see it fitting into the cycle of a product from drug discovery to selling
- What actions the pharma industry will need to undertake, including post marketing research in the form of surveillance and registries, observational studies and other Phase IV initiatives

4:15 | 5:00
Real World Drug Safety and Effectiveness: What You Need to Know

Kim McDonald-Taylor
President, Clinical Research Association of Canada (CRAC)
Director of Clinical Services, Wyatt Health Management

With Bill C-51, this issue is going to become more and more critical. Basically, Bill C-51 is insisting that manufacturers continue with clinical research once the drug is on the market to ensure the drugs are safe and are effective in the “real world”, not just safe and efficacious in the clinical trial world. Internationally, Europe and the US have already started this process so it is here to stay. This session will look at the implications of these priorities in context with Bill C-51 on our business.

5:00 | 6:30
Wine and Cheese Reception and Award Ceremony

This award recognizes one outstanding Canadian’s contribution to Clinical Research in Canada

Recipient:
Wendy Porter
President
Endpoint Research

Sponsored by

TUESDAY | OCTOBER 21, 2008

8:00 | 9:00
Continental Breakfast

9:00 | 9:10
Co-Chair’s Recap of Day 1 and Introduction to Day 2

Janice E. Parente, Ph.D.
President/Managing Director
ethica Clinical Research Inc.

9:10 | 10:00
RESEARCH SURVEY
Effective Sponsor-Site Relationships in Canada, Europe and Asia Pacific: Results of CenterWatch Global Surveys

Mary Jo Lamberti, Ph.D.
Director, Market Research
CenterWatch

CenterWatch has been conducting global surveys for over 10 years examining the quality of relationships among sponsors and investigative sites. The CenterWatch surveys measure clinical investigators’ assessments of those attributes considered most essential in conducting trials across specific categories (including study conduct and initiation, project management, professionalism, and the grant payment process). The survey results provide insight into those factors that contribute to study delays, delays in patient recruitment and enrollment as well as the challenges that sites face in the conduct of clinical studies.

- Results from recent surveys conducted with investigators from the Asia-Pacific region; and also Europe and Canada. Selected results will be shared and those areas that investigators rate as most essential to an effective sponsor-site relationship will be highlighted
- Comparisons among the survey results globally; areas of strength and improvement areas will be identified in investigator-sponsor relationships
- Examination of those factors most often causing study delays and what can prevent future study delays will be shared

10:00 | 10:15
Networking Coffee Break

10:15 | 11:15
How Sponsors, Institutions and CROs Can Grow the Business in Canada

Moderator:
Ron Heslegrave, Ph.D.
Chair, Research Ethics Board
University Health Network
Ontario Cancer Research Ethics Board
Mary Bell, MD, MSc, F.R.C.P.C.
Head, Division of Rheumatology
Sunnybrook Health Sciences Centre
Pierre Geoffroy, MD, CM, MSc, F.C.F.P.  
Senior Director, Clinical Department  
Sanofi Pasteur

Murray Jensen, MSc  
Director of Clinical and Scientific Affairs  
ethica Clinical Research Inc.

Brett Wilson, BSP  
Associate Director, Clinical Site Monitoring  
Regional Clinical Operations  
Bristol-Myers Squibb Canada

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

11:15 | 12:15  
PANEL  
Contract Negotiations: Canadian Challenges and Made-in-Canada Solutions

Moderator: Martin Letendre, LLB, LLM  
Director of Ethics and Legal Affairs  
ethica Clinical Research Inc.

Sylvie Giroux  
Director, Clinical & Regulatory Capabilities and Compliance  
Novartis Pharmaceuticals Canada Inc.

Margaret H. Kerr, BA, LLB, MA, Ph.D.  
Barrister & Solicitor  
Office of Research Administration  
St. Michael’s Hospital

Michelle Moldofsky, LLB, LLM  
Policy & Legal Advisor  
Office of Research Administration  
St. Michael’s Hospital

• Canadian research environment from a contractual perspective  
• The impact of multi-center clinical trials and globalization on clinical trials agreements  
• Negotiating with sites located in clinics or SMOs  
• Top 5 issues that delay and derail contract negotiations  
• Solution-oriented initiatives and mechanisms towards standardization and harmonization

12:15 | 1:30  
Networking Luncheon

1:30 | 2:15  
Research Ethics Standards in Canada: An Update

Mathieu Gagné, LLM, LLD  
Partner  
Fasken Martineau

Ron Heslegrave, Ph.D.  
Chair, Research Ethics Board  
University Health Network  
Ontario Cancer Research Ethics Board

• Current initiatives for better standardization  
• Canadian standards for research ethics boards: where are we now?

3:00 | 3:15  
Networking Refreshment Break

3:30 | 4:15  
Global Clinical Trial Registries: An Update

Pierre Geoffroy, MD, CM, MSc, F.C.F.P.  
Senior Director, Clinical Department  
Sanofi Pasteur

Following cries for greater transparency in clinical research, governments worldwide have legislated Clinical Trial Registries into existence. The result is a complex array of various rules and regulations to be navigated by the pharmaceutical industry in order to ensure timely registration of products and avoidance of potentially hefty penalties. For better or for worse, since the creation of ClinicalTrials.gov, the clinical trial registry movement has gained momentum imposing tight timelines for the reporting of both protocol information and detailed trial results. In this lecture, the latest information regarding important trial registries will be presented and the impact discussed.

4:00 | 4:45  
INTERNATIONAL CASE STUDIES  
Participant Protection Challenges: An International Perspective

Miriam Shuchman, MD  
Associate Professor of Psychiatry  
University of Toronto and Women’s College Hospital  
Author of The Drug Trial

• How regulators have responded to these challenges globally  
• Where have we run into trouble? What do we need to do differently going forward?  
• How the role of CRO is impacting clinical trials participants today  
• A look at how we can achieve greater innovation without compromising participant protection

4:45  
Conference Concludes
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5th Annual

CLINICAL TRIALS IN CANADA
Creating Greater Competitive Advantage in Today’s Global Market

Presented by Insight Information

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Signature Date

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Refunds will be given for cancellations received in writing by September 29, 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 September 29, 2008, your order is firm. A refund will not be given; however a delegate substitution is welcome at any time.

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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.

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