Day 1

8:15-8:30  Registration and Continental Breakfast (provided)

8:30-8:45  Introduction of the 2nd Annual Canadian Conducting Clinical Trials Conference

Helen Darwin, BSc, CCRP, President, Darwin Site Management
Jackie Busheikin, RN, CCRP, President, JANA Research

8:45-9:15  The value of Clinical Research in Canada

Stephen Garland, BA, AIM Health Group
Mr. Garland will discuss the current state of clinical research in Canada, the value of the industry sector, current initiatives within the environment, and its impact on our communities. The presentation will focus on sharing anecdotal and empirical information regarding the industry from a business perspective. Mr. Garland will discuss activities underway by various industry stakeholders aimed at creating a more favourable environment in Canada to attract additional clinical research opportunities.

9:15-10:15  Division 5 Regulations

Janet Gallant, BScN, RN, CCRP, Program Manager, Research Education, Capital District Health Authority
For several years, Health Canada has required researchers and other research team members to be trained on ICH-GCP. There is now an additional expectation that individuals who are working on clinical trials involving drugs be trained on applicable regulations (Division 5). This session will provide an overview of these regulations as well as highlights of ICH-GCP.

10:15-10:30  Break and Opportunity for Discussion

10:30-11:15  Navigating Canadian Regulations for Medical Device Clinical Studies

Kathryn Ronalds, MA, RAC, Associate Director, Medical Devices, OptumInsight
Device trials present some different regulatory requirements than drug trials. This session will discuss some of the key differences and how to conduct medical device clinical studies in Canada.

11:15-12:15  “Lost in translation”: Conducting transnational research in Canada and the United States

Martin Letendre, BA (Phil.), LLB, LLM (Bioethics), Managing Director, Veritas IRB Inc.
Although Canada has a long history of research collaboration with the United States, there is growing concern about divergent regulatory approaches. Such divergent approaches can have a direct impact on the interpretation of concepts commonly used on each side of the 49th parallel. The proposed talk will explore and navigate these divergent regulatory approaches through the review of expressions that carry different meanings in Canada and the United States including: placebo-controlled, investigator, safety reporting, and compliance.

12:15-1:15  Lunch (provided)

1:15-2:00  Network of Networks, an innovative approach to streamlining

Karen Arts, BSN, RN, CCRP, Director of Business Development, Ontario Institute for Cancer Research
The Network of Networks (N2) is an alliance of Canadian research networks and organizations working to enhance national clinical research capability and capacity. N2 provides a common platform for sharing best practices, resources and research-related content to ensure efficient and high-quality research, integrity of clinical practices and accountability. The presentation will provide an overview.

2:00-2:45  Applicability of U.S. Regulations to Canadian Research

Mary Kate Needler, MSc, Program Manager, Research Quality, Capital District Health Authority
An overview of U.S. regulations pertaining to drug trials, medical device trials and research funded with U.S. public money. Find out which requirements are mandatory, which are optional, and how to talk to your sponsors about the difference.

2:45-3:00  Break and Opportunity for Discussion

3:00-4:00  ICH / GCP

Jackie Busheikin, RN, CCRP, President, JANA Research
An Interactive presentation on core principles of ICH/GCP.

4:00-4:45  Panel Discussion / Question and Answer Session
Day 2

8:15-8:30  
Continental Breakfast (provided)

8:30-9:30  
Clinical Trial Agreements: What You Need to Know When Negotiating a Clinical Trial Agreement on Behalf of a Canadian Site.  
Marlon Rajakaruna, BA, LLB, MBA, Partner, National Co-Leader of Life Sciences Practice, Dentons Canada LLP  
This session will address key elements to consider when reviewing and negotiating a clinical trial agreement on behalf of a Canadian site. Among the items covered by the presentation are:  
- Ensuring you have properly bound all applicable parties  
- How do the CMPA's policies affect what you can and can not agree to in the CTA  
- Why you need to know your local laws

9:30-10:30  
The Initiative to Streamline Clinical Trials  
Karen Arts, BSN, RN, CCRP, Director of Business Development, Ontario Institute for Cancer Research  
Academic trials are an important and independent tool in developing and understanding the true clinical benefit of new therapies in all disease areas and provide critical validation (or in some instances has called into question the results) of research conducted by a for-profit entity. The primary objective of the ISCT was to develop specific, pragmatic and practical interpretations of current regulations, laws and guidelines, in order to facilitate, rather than limit, Canadian clinical trials, expanding on recommendations such as the CCRA and OECD recommendations, by identifying areas ‘feasible’ to implement by interpretation, and ‘recommend’ where ISCT believe changes to regulations or laws may be required. The process and final report will be discussed.

10:30-10:45  
Break and Opportunity for Discussion

10:45-11:30  
Preparing for a Health Canada Inspection  
Helen Darwin, BSc, CCRP, President, Darwin Site Management  
This presentation will focus on the documents, policies and procedures open to inspection. The speaker will discuss the mechanism of an inspection as well as the potential outcomes of an inspection.

11:30-12:30  
FDA Inspection of Clinical Investigators  
Mike Rashti, BS, President, BIMO Auditor and Trainer, LLC.  
FDA readiness for clinical investigators and sponsors; How to be prepared for an FDA audit.

12:30-1:30  
Lunch (Provided)

1:30-2:30  
GCP Compliance in Canada: Division 5 and Other Requirements  
Richard Kirchner, GCP Supervisor Ontario, Health Canada

2:30-2:45  
Break and Opportunity for Discussion

2:45-3:45  
Corrective Action Plans- CAPAs, When and How to Use in Clinical Research Practice?  
Sandhya Patel, BScN, Director, Research Quality Assurance, Centre for Addiction & Mental Health  
Lisa Johnston, BScN, RN, CCRP, Research Training Coordinator, Centre for Addiction & Mental Health  
Gregory Staios, MSc, Research Study Monitor, Centre for Addiction & Mental Health  
Managing compliance is critical to successful clinical trials. CAPA is a quality tool to identify compliance issues and put in place a means to address the deficiencies that may occur during the conduct of a research study. Effective CAPAs can lead to improved research participant protections and confidence in the integrity of the data. Lack of effective corrective action planning can lead to repeated non-compliance, compromised research participant safety, poor data quality and integrity, and/or unacceptable audit/inspection findings that may have negative impact on the final outcome of the study.  
Session will look at using CAPA as a means to identify non-compliance issues/discrepancies, note the root cause of the identified problem, identify the corrective action taken to prevent recurrence of the problem, and document that the corrective action has resolved the problem.

3:45-4:15  
Panel Discussion / Question and Answer Session