



CAREB – ACCER 2009 Network Forum:

New Developments in the Management of Adverse Events

***Fairmont Waterfront Hotel
900 Canada Place Way, Vancouver, B.C.***

Agenda

***Thursday, April 30th, 2009
4:00 pm – 6:30 pm***

4:00 – 4:10

Welcome and Introduction

*Dr. Ray Saginur
Chair, Human Research Ethics Board, Ottawa Hospital*

The current system and why it isn't working

4:10 – 4:20

New Developments in the EU and the U.S.

*Marianne Vanderwel, MEng, MSc
Director, HRPP, IRB Services*

- **FDA Guidance**
- **EU Directive**

*Dr. Vernon Stringer, MD, MSc,
Acting Director, Office of Clinical Trials
Therapeutic Products Directorate, Health Canada*

- **Draft (Step 2) ICH E2F**

4:20 – 4:50

Summary Reports in Canada – What some Canadian Companies are Doing

*Connie Dupuis
Country Study Manager, Roche Canada*

*Ruth Bell
Manager, Safety Drug Regulatory Affairs, Pfizer Canada Inc.*

4:50 – 5:10

Research Ethics Board Response / Perspective

*Dr. Ray Saginur
Ottawa Hospital*

*Dr. Joseph Connors
BC Cancer Research Ethics Board*

5:10 – 5:30

Health Canada's Perspective

*Dr. Vernon Stringer, MD, MSc
Acting Director, Office of Clinical Trials
Therapeutic Products Directorate, Health Canada*

5:30 – 5:50

The Potential Role for Data Safety Monitoring Boards or similar committees?

*Dr. Robert Peterson
Director, BC Child Health Network,
Former Director General, Therapeutic Products Directorate*

5:50 – 6:20

Moving Forward: Facilitated Minuted Discussion generating a report and Recommended move-forward action

*Laurel Evans
Associate Director, Research Ethics, UBC*

*Janet Manzo
Executive Director, Ontario Cancer Research Ethics Board*

6:20 – 6:30

Wrap Up and Thank You

*Dr. Ray Saginur
Ottawa Hospital*