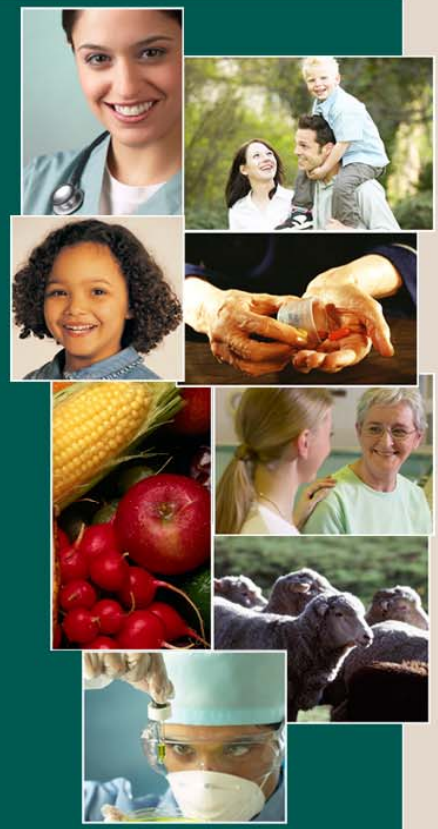
# Health Products and Food Branch

Your Health and Safety - Our Priority



# Registration and Disclosure of Clinical Trial Information

CAPRA Symposium

**November 27, 2007**

Health Canada Santé Canada

Canada

# Overview

- Background
  - Issue
  - International and Canadian Context
- Health Canada's Initiative:
  - Consultations
  - External Working Group
  - Internal Analysis
- Next Steps

# Background

Issue: Need for greater transparency in clinical trials

Registration of clinical trial information in a publicly accessible registry would:

- Mitigate selective reporting of trials
- Allow patients and health providers to make informed decisions
- Facilitate enrolment of prospective research participants
- Encourage good clinical practices
- Facilitate systematic reviews and meta-analysis
- Respond to ethical obligations to participants

# Background (cont'd)

- **International Context:**
  - International Committee of Journal Editors (ICMJE)
    - Effective July 2005, registration is a requirement for publication
  - World Health Organization (WHO)
    - Leading a global project to facilitate access to CT info – International Clinical Trial Registry Platform (ICTRP)
  - Worldwide proliferation of registries
    - Industry, disease/patient groups, *ClinicalTrials.gov*, etc.

# Background (cont'd)

- **Canadian Context:**
  - Standing Committee on Health Report (April 2004)
  - National Placebo Working Committee Report (July 2004)
  - CIHR policy decision: registration as a funding requirement (July 2004)
  - Leader's Forum for Health Research in Canada (Sept. 2004)

# Health Canada's Initiative

- Issue Identification: Spring 2005
  - Online questionnaire (sent to over 800 stakeholders)
  - 3 workshops (Ottawa, Halifax, Vancouver)

**Key Messages from 2005 Consultations:**

- Need a central Canadian approach
- Government should play a central role
- Need to be consistent with international standards

# Health Canada's Initiative (cont'd)

- Options Development: Spring – Fall 2006
  - External Working Group (EWG):
    - 1st meeting - April 2006
    - Mandate to develop and advise on options
    - 13 members, representing a range of stakeholders

# Health Canada's Initiative (cont'd)

- Options Development: Spring – Fall 2006 (cont'd)
  - Public Consultation on EWG's preliminary options (June 2006)
    - Online workbook format
    - Findings: generally high level of support for the group's early options, with a few exceptions
  - EWG: Final teleconferences (October 2006)
    - Considered results of public consultation
    - Final Report with recommendations submitted Jan/07 (available on HC website)

# External Working Group's Report: Key Messages

**Generally consistent with WHO standards, with a few exceptions…**

- **Use WHO data set items for registration, in addition to**:
  - *Informed consent form*
  - *Info about REB decisions*
  - *Adverse event info*
  - *Context/educational info*
- **Register all product types and all phases of trials**
  - *But allow for delayed disclosure of competitively sensitive info if "demonstrably justified" by sponsor*
- **HC should have a central role in registration**
- **Recommendations re: reporting on outcomes**
- **Link with www.*ClinicalTrials*.gov in U.S. with a Canadian "front-end"**

# Health Canada's Analysis

- Winter – Spring 2007
  - Considers:
    - Results of Health Canada's public consultations
    - External Working Group's Recommendations
    - Ongoing international and domestic initiatives
    - Ongoing Health Canada initiatives

# Current environment

- **Other Health Canada initiatives**
  - Progressive Licensing Framework
    - Part of HPFB's Blueprint for Renewal initiative
  - Review of Clinical Trial Regulations (Division 5)
    - Purpose: to determine whether 2001 regulatory framework met its objectives
    - Results of consultations with stakeholders will help inform short, medium and long term initiatives to strengthen and improve the current regulatory framework
  - Research Ethics Boards initiatives:
    - Sponsors' Table for Human Research Participant Protection in Canada
    - Development of Voluntary Standard for REBs

# Current environment (cont'd )

- **International Federation of Pharmaceutical Manufacturers and Associations (IFMPA)**
  - Launched Int'l clinical trials search portal: September 2005
- **WHO's Initiative**
  - Developed Registration Data Set
  - Issued Voluntary Policy: May 2006
  - Launched Clinical Trial Search Portal: May 2007
- **Int'l Committee of Medical Journal Editors (ICMJE)**
  - Issued Policy update: June 2007
- **Recent U.S. Legislation**
  - Individual states (Maine, California, Hawaii, Michigan, etc.)
  - FDA Amendments Act of 2007

# Health Canada's Approach

- Notice to Stakeholders – Fall 2007
  - HC is exploring development of regulatory requirement for registration and disclosure of results
  - Also examining creation of a bilingual Canadian search portal for clinical trials
  - HC encourages sponsors to register trials of therapeutic products while this work progresses
  - Trials should be registered within 21 days of a trial's onset on either:
    - www.*ClinicalTrials*.gov
    - www.controlled-trials.com/isrctn

# Next Steps

- Continue monitoring/analysis of international and domestic initiatives:
  - WHO, ICMJE, industry, other regulators, etc.
- Continue to examine development of regulatory requirement for clinical trial registration and disclosure of results
- Development of options for Canadian search portal for clinical trials
  - Consider including additional criteria?