Do You Have Feedback on the Proposed TCPS2 Revisions?

The ACRC is collating your feedback to be part of a formal response from Alberta on the proposed revisions to TCPS2.


Please submit comments by December 31st to acrc@albertainnovates.ca.

New Health Canada Guidance: Clinical Trial Applications

Are you studying a new drug, conducting a comparative bioavailability study or trial that involves a marketed drug outside of the approved use (i.e. a different indication, target population, route of administration or dosage regimen)? If yes, your study may require a Clinical Trial Application (CTA).

The Guidance Document for Clinical Trial Sponsors: Clinical Trial Applications (May 29, 2013) is the definitive guide for sponsors (whether industry, academic, or contract research organization) who seek to sell or import a drug for a clinical trial in Canada.

The guidance document walks you through the process of a clinical trial application, including guidance on application requirements for comparative bioavailability trials, filing requirements for the importation of clinical trial supplies, clarifications to amendment and notification requirements, study termination and closure criteria, application and review processes, adverse drug reaction reporting criteria, and format requirements.

Check with your sponsor if a CTA is required and has been filed prior to starting the studying. Or if you are unsure whether a CTA is needed, contact either the acrc@albertainnovates.ca or your local research administrative office.

Health Canada launches new clinical trial database

Want to know about currently approved clinical trials in Canada?

The Health Canada Clinical Trials Database is a public listing of Phase I, II and III clinical trials for pharmaceutical and biological products that have had a Clinical Trial Application (CTA) approved. The database lists trials that were approved by Health Canada starting from April 1, 2013.

Patients/participants can determine if a clinical trial has met regulatory requirements, as well as find clinical trials relevant to specific medical conditions.

The database does not include clinical trials in healthy volunteers, or clinical trials involving natural health products or medical devices.

In accordance with TCPS2 (Article 11.3), clinical trials are to be registered in a registry that is compliant with the criteria set by the World Health Organization (WHO) or International Committee of Medical Journal Editors (ICMJE) as of Nov 2010. Researchers are to provide the REB with the number assigned to the trial. Check with your sponsor if the trial has been registered. Other clinical trial databases include: Clinicaltrials.gov.

To support strengthening of clinical research in Alberta, six times a year the ACRC will bring news relevant to you.

Let us know if this is helpful or if you have an idea for the next issue.

In this Issue:
- Proposed revisions to TCPS2
- HC - Clinical Trial Applications Guidance Document
- HC - Clinical trials database
- Health Canada and FDA news
- Newly opened trials in Alberta
- Alberta in Publication - Diabetes

The ACRC is collating your feedback to be part of a formal response from Alberta on the proposed revisions to TCPS2.


Please submit comments by December 31st to acrc@albertainnovates.ca.

Are you studying a new drug, conducting a comparative bioavailability study or trial that involves a marketed drug outside of the approved use (i.e. a different indication, target population, route of administration or dosage regimen)? If yes, your study may require a Clinical Trial Application (CTA).

The Guidance Document for Clinical Trial Sponsors: Clinical Trial Applications (May 29, 2013) is the definitive guide for sponsors (whether industry, academic, or contract research organization) who seek to sell or import a drug for a clinical trial in Canada.

The guidance document walks you through the process of a clinical trial application, including guidance on application requirements for comparative bioavailability trials, filing requirements for the importation of clinical trial supplies, clarifications to amendment and notification requirements, study termination and closure criteria, application and review processes, adverse drug reaction reporting criteria, and format requirements.

Check with your sponsor if a CTA is required and has been filed prior to starting the studying. Or if you are unsure whether a CTA is needed, contact either the acrc@albertainnovates.ca or your local research administrative office.

Want to know about currently approved clinical trials in Canada?

The Health Canada Clinical Trials Database is a public listing of Phase I, II and III clinical trials for pharmaceutical and biological products that have had a Clinical Trial Application (CTA) approved. The database lists trials that were approved by Health Canada starting from April 1, 2013.

Patients/participants can determine if a clinical trial has met regulatory requirements, as well as find clinical trials relevant to specific medical conditions.

The database does not include clinical trials in healthy volunteers, or clinical trials involving natural health products or medical devices.

In accordance with TCPS2 (Article 11.3), clinical trials are to be registered in a registry that is compliant with the criteria set by the World Health Organization (WHO) or International Committee of Medical Journal Editors (ICMJE) as of Nov 2010. Researchers are to provide the REB with the number assigned to the trial. Check with your sponsor if the trial has been registered. Other clinical trial databases include: Clinicaltrials.gov.

To support strengthening of clinical research in Alberta, six times a year the ACRC will bring news relevant to you.

Let us know if this is helpful or if you have an idea for the next issue.

In this Issue:
- Proposed revisions to TCPS2
- HC - Clinical Trial Applications Guidance Document
- HC - Clinical trials database
- Health Canada and FDA news
- Newly opened trials in Alberta
- Alberta in Publication - Diabetes

The ACRC is collaborating with researchers and administrators working together to achieve the vision of ‘high quality, integrated and efficient clinical research in Alberta.’

Partner organizations: Alberta Health Services, Alberta College of Physicians & Surgeons, Alberta Innovates - Health Solutions, CHRC (Covenant Health), NAC TRC (AHS/University of Alberta) and CCCR (University of Calgary).

Email: acrc@albertainnovates.ca
www.aihealthsolutions.ca/acrc
Newly opened trials in Alberta

Since June, the following clinical trials opened for recruitment. If you have a clinical trial that will be opening for recruitment in the upcoming month, let us know and we will include it in the next issue.

- **Minocycline in Acute Spinal Cord Injury (MASC)** Calgary (Foothills)
- **A Study of Subcutaneously Administered RoActemra/Acetemra (Tocilizumab) in Patients With Systemic Juvenile Idiopathic Arthritis** Calgary
- **Investigations of Mechanisms and Treatment in Post-traumatic Joint Contractures** Calgary (Peter Lougheed Centre)
- **Comparison of TAK-875 With Sitagliptin When Used in Combination With Metformin in Patients With Type 2 Diabetes** Red Deer
- **Efficacy and Safety of FIAsp Compared to Insulin Aspart Both in Combination With Insulin Detemir in Adults With Type 1 Diabetes** Edmonton
- **Feasibility of a Walking Program for Cancer Survivors Receiving Radiation Therapy** Edmonton (CCI)
- **Confirmation of Correct Tracheal Tube Placement in Newborn Infants - a Randomized Control Trial** Edmonton (RAH)
- **Randomised Controlled Trial to Investigate the Effect of Parental Presence at Intensive Care Unit to Ward Transfer Bedside Rounds on Parental Anxiety and Children's Safety** Edmonton (Stollery)

Alberta in Publication - Diabetes Research

- **Breaking Down Patient and Physician Barriers to Optimize Glycemic Control in Type 2 Diabetes**
- **Changes in Depressive Symptoms and Changes in Lifestyle-Related Indicators: A 1-Year Follow-Up Study Among Adults With Type 2 Diabetes in Quebec**
- **Concordance Between Self-Report and a Survey-Based Algorithm for Classification of Type 1 and Type 2 Diabetes Using the 2011 Population-Based Survey on Living With Chronic Diseases in Canada (SLCDC)-Diabetes Component**
- **Assessment of Serum Creatinine and Kidney Function among Incident Metformin Users**
- **Optimizing Diabetes Literacy: Lessons from African Canadians in Calgary about Type 2 Diabetes Diagnosis**
- **Glycated Hemoglobin and Risk of Death in Diabetic Patients Treated With Hemodialysis: A Meta-analysis**

*Dr. Stuart Ross is the Chair of the ACRC Strategic Priority 1 working group.*