A. Now Available in Your Toolbox

**Internal Costing Template**

Introducing the ACRC Internal Costing Template, a comprehensive budgeting tool that can help estimate the expense of conducting grant, industry, and PI sponsored clinical trials.

Common budget items are built into the template and can be customized to any research discipline. This helps you account for all administrative and procedural expenses, staff salaries, overhead rates, and funding sources.

We will be hosting a training webinar on December 17, 2014. Email acrc@albertainnovates.ca if you’re interested in attending.

**Regulatory Binder Tabs**

How do you organize your regulatory binder?

The ACRC has developed Regulatory Binder Tabs to help you organize a regulatory binder. Print off your own set on your next visit to the ACRC research toolbox.

A regulatory binder contains study specific information and regulatory documentation for a single trial and is recommended for all intervention studies. It helps to organize and provide easy access to essential study documents for study staff, monitors and auditors.

**Glossary & Common Terminology – Version 2.1**

Having a common language is key to avoid misunderstandings and is one way the ACRC is adding clarity to clinical research in the province. The Glossary & Common Terminology – Version 2.1 collates definitions of commonly used clinical research acronyms and terms from Health Canada, TCPS2, FDA and other sources. It also includes Alberta specific terminology.

The second version of the glossary incorporates almost 400 new terms primarily from:

- CDISC (Clinical Data Interchange Standards Consortium)
- Terms defined in the research ethics harmonization platform
- Recommendations from the community

B. ACRC Clinical Research Conference – October 15’14

The ACRC’s first Clinical Research Conference was held in Edmonton this year and attended by 125 individuals from across the province. Some of the highlights included:

- Rachel Hayward’s (OIPC) discussion of recent changes to reporting requirements and penalties in the event of a health information breach. Further guidance on interpretation of Bill 12 (Statutes Amendments Act) is expected in 2015.
- Increased awareness of the history of research ethics and considerations for participant recruitment and retention as presented by Dr. Stacey Page (UofC).
- The experience of a young mother with a baby enrolled in a clinical trial, reminding us all of the importance of clinical research and the impact study staff have on participants and their families.

We are already looking towards the next conference in Calgary 2015. If you have recommendations for session topics, we want to know. Contact us at acrc@albertainnovates.ca.

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

Borrowing someone else’s issue or want to be one of the first to know when it comes out? Subscribe to the ACRC for updates!

Let us know if you have an idea for the next issue.

**Test your Health Canada knowledge**

TRUE or FALSE

In Canada, it is the responsibility of the investigator conducting a clinical drug trial to notify the sponsor if Research Ethics Board (REB) approval is withdrawn.

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

ACRC Partner organizations:

- AHS Research, Innovation & Analytics,
- Alberta College of Physicians & Surgeons,
- Alberta Innovates - Health Solutions,
- Covenant Health - CHRC,
- AHS/University of Alberta - NACTRC
- University of Calgary - CCCR.

Email: acrc@albertainnovates.ca

http://www.aihealthsolutions.ca/initiatives-partnerships/acrc/
Health Canada (HC) and FDA News

Keeping you informed of changes in regulations - * Are open for comments

Investigational Device Exemption (IDE) Clinical Investigations (FDA): IDE approval permits patient enrollment in a medical device clinical trial of significant risk. In Aug '14 final guidance was released describing the FDA’s decision-making and communications regarding IDE applications. For additional information, view the webinar.

Revised Draft Guidance - Reconsideration of Decisions Issued for Human Drug Submission (HC): Revised to reflect a more transparent and impartial Reconsideration Process, the draft guidance describes appropriate mechanisms to address submission-related disputes for Clinical Trial, New Drug and Medical Device License Applications.

Standard for Exchange of Non-Clinical Data (SEND) (FDA): Validation rules for SEND are now available. Sponsors can refer to these rules to validate their study data before submitting to the Center for Drug Evaluation and Research. Find out more.

Revised Natural Health Products (NHP) POL-0044 (HC): POL-0044 describes the compliance and enforcement approach for NHPs under the Food and Drugs Act. The policy was revised to reflect a planned shift from a primarily reactive compliance model to a more balanced and proactive approach.

Inspectorate Program Annual Inspection Summary Report 2013-2014 (HC): The latest HC summary report was released in Aug '14 outlining common health product inspection findings for clinical trials, medical devices, good manufacturing practices and more. Be prepared for an inspection - know the common HC audit findings.

* Patient Participation in Medical Product Discussions (FDA): The FDA is asking stakeholders to recommend strategies for patient engagement in order to obtain their perspectives during the development of medical products and regulatory discussions.

* Drug Trials Snapshot - A Pilot Project (FDA): The FDA is piloting a website that provides information on the demographics of clinical trial participants of recently approved drugs. Comment on the content and usability of the website has been requested.*

Clinical Research in Alberta

Alberta is host to numerous clinical trials in a wide range of fields including oncology, psychology, metabolic disorders and more. Stay on top of the latest research in the province by viewing recently opened clinical trials.

If you have a clinical trial that will be opening for recruitment in the upcoming months, let us know and we will include it on our website.

Alberta in Publication - Systematic Review and Meta-analysis

This month we’re featuring articles that use meta-analysis to synthesize findings in such diverse research areas as endocrinology, health services, and gastroenterology.

- A systematic review and meta-analysis of exercise interventions in adults with type 1 diabetes.
- Quantification of subfield pathology in hippocampal sclerosis: a systematic review and meta-analysis.
- Comparative Effectiveness of Immunosuppressant and Biologics for Inducing and Maintaining Remission in Crohn’s Disease: A Network Meta-Analysis.
- Hospital to community transitional care by nurse practitioners: A systematic review of cost-effectiveness.
- Impact of primary palatoplasty on the maxillomandibular sagittal relationship in patients with unilateral cleft lip and palate: a systematic review and meta-analysis.
- Mortality risk among sulfonylureas: a systematic review and network meta-analysis.
- Evidence for efficacy of acute treatment of episodic tension-type headache: methodological critique of randomised trials for oral treatments.

Test your knowledge

Answer: TRUE, the investigator must notify the sponsor if IRB approval is withdrawn

Want to learn more?
Take the CITI-Canada GCP training course.