ALBERTA CLINICAL RESEARCH CONSORTIUM
Managed by Alberta Innovates – Health Solutions

# The Clinical Research Source

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## MANAGING CLINICAL STUDIES IN EDGE

***Getting your clinical study up and running can be time consuming and complicated.***

**Effective clinical study management** requires knowledge of the entire research roadmap. You need to consider everything from study set-up to closure while following strict regulations. There can be reporting requirements on top of sponsor and department targets. ***The Alberta Clinical Research Consortium (ACRC) aims to help by providing access and co-developing tools to support you.***

As an ACRC partner, Alberta Innovates – Health Solutions (AIHS) has licensed the **web-based application, EDGE,** a clinical trial management system (CTMS) for researchers in Alberta. **You can watch a one minute video about EDGE here**. Currently, Alberta Health Services and Covenant Health have sub-licenses and are rolling out use to their clinical research administrative units in a phased approach. The ACRC is helping to train sites to customize and manage their own areas within the system.

***EDGE helps clinical research staff to manage the work that you already do, in the way you do it.*** With management support you can spend more time doing and less time reporting. Sites, departments and organizations can customize their own area of EDGE to track and report on financial activity, patient accruals, approvals and renewals, and the mountains of paper associated with each of these activities.

**Research administrators at AHS, Covenant Health and the Information Stewardship Office are using EDGE**. As of March 2016, these research administrators are using EDGE to review and issue HIA s.54 research agreements and operational approvals for clinical research studies. EDGE helps them track and report on projects that need review and approval as part of study set-up. Each study has a shared space where all individuals working on that study can share documents, approvals and record activities. Soon, the trial launch teams at the Tom Baker Cancer Centre and Cross Cancer Institute will track cancer clinical trials in EDGE (i.e. launch, accruals, finances, resources) enabling easier sharing of relevant information with Alberta Cancer Clinical Trials (ACCT).

**EDGE is for clinical research teams**. EDGE helps all study staff to manage many projects at the same time. EDGE was built by clinical researchers for clinical researchers. Hospitals and Universities who license the *web-based software* (yes, you can use it in Cuba!), can share it with unlimited numbers of users and studies within their organization. Each organization can then choose how they wish to use it and have the power to customize it themselves.

## RESEARCHER TOOLBOX

The latest addition to the *Research Toolbox* is the **Product Accountability Package**. Accurate and detailed record keeping of all investigational products must be kept in accordance with ICH GCP E6 (4.6). This process documents all aspects of the receipt, storage, use and disposal of an investigational product, which can be a drug, device or natural health product.

The package includes an **Investigational Product Log**, **Participant Drug Accountability Log**, **Device Accountability Log**, **investigational product labels** (drug, natural health product and device) and **Temperature Log**.

*To support strengthening of clinical health research in Alberta, four times a year the ACRC will feature news relevant to you. Let us know your ideas for future issues!*

*Email us at:*
*acrc@albertainnovates.ca*

*Borrowing someone else's issue? Want to be one of the first to know when it comes out? Subscribe to the ACRC for updates.*


***N2 will be hosting their 10th Annual Meeting***
***February 2nd and 3rd, 2017***

*The meeting will be once again held at the St. Andrews's Club and Conference Centre in Toronto. More information will be posted on the N2 website in the near future.*

N2 NETWORK OF NETWORKS RÉSEAU DES RÉSEAUX

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

Email: acrc@albertainnovates.ca

Find out more about the ACRC and how AIHS supports the initiative.

## New from N2

Are you looking for good resources to refer to potential participants about clinical trials, or to use when you talk to potential participants about clinical trials? As a member of N2, ACRC members have access to the ***It Starts with Me*** resources (website, video, PowerPoint, and brochure). All of these resources are available here - feel free to use them!

## The Association of Clinical Research Professionals (ACRP) announces free public access to the 'Introduction to Clinical Trials' training program

The ACRP is releasing the new educational training program, 'Introduction to Clinical Trials.' The one hour online course is available free of cost and is targeted towards novice investigators, coordinators and monitors to develop the foundation of knowledge that is essential to clinical research professionals.

The course provides an overview of the development of medicinal products, ethics principles, and the protection of clinical research participants.

In addition to educating new clinical research professionals, organizations can use this tool to raise public awareness and understanding of clinical trials. For more information, visit the ACRP website.

## Health Canada (HC) and FDA News

*Keeping you informed of changes in regulation*

**Regulatory Transparency and Openness Framework and Action Plan (RTOF) Annual Report (HC):** In June 2015, Health Canada's RTOF for 2015-2018 was launched. The RTOF will help Canadians make informed decisions about their health by providing access to timely, useful and relevant health and safety information in plain language.

**The impact of clinical holds on drug development programs (FDA):** If there is any question to the safety of a new drug, the FDA may place a clinical hold on the investigational new drug application (IND). This hold halts all testing pending further review. The Center for Drug Evaluation and Research conducted a study on the impact of clinical holds on new drug development. For results of this study and tips on how to decrease the chance of a hold being put on your IND, visit the FDA website.

## Research Impact Assessment (RIA) Alumni & Community Engagement Forum – Oct 6th

Alumni from Research Impact Assessment (RIA) training courses and the International School on Research Impact Assessment (ISRIA) are invited to join their colleagues at the inaugural RIA Training Alumni & Community Engagement Forum. You will hear about your peers' RIA experience, and have the opportunity to seek advice. There will also be opportunity to contribute to discussions about ways to address RIA challenges and advance the practice of RIA. The forum is an opportunity to share lessons from the RIA training and create connections among this community of practice.

**Register now** as **space is limited**. Registration is on a first-come, first-served basis.

## Clinical research in Alberta


Alberta hosts numerous clinical research studies in a wide range of fields including oncology, psychology, gastroenterology and more. Please visit our website for a comprehensive list of studies that have opened for participant recruitment. These studies have been collated from clinicaltrials.gov and through your submissions to the ACRC between February 2016 and September 2016.

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

**September is Prostate Cancer Awareness Month.**

Featured new Alberta study to recognize the work being done in this area:

**INT**ense **E**xercise fo**R** sur**V**iv**AL** Among Men With Metastatic Castrate-Resistant Prostate Cancer **(INTERVAL)**