ALBERTA CLINICAL RESEARCH CONSORTIUM
Managed by Alberta Innovates – Health Solutions

The Clinical Research Source

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Data Quality and the Elements of ALCOA

Attention to detail enables a clinical trial to provide solid evidence as to the risks and benefits of an intervention.

Good quality documentation of clinical trial data is essential in clinical research to permit reconstruction of the trial and results. C.05.012 of Division 5 of Canada's Food and Drug Regulations outlines the need for complete and accurate reporting of clinical trial data. Health Canada has adopted elements of ALCOA for the ICH Good Clinical practice document (Guidance For Industry, Good Clinical Practice: Consolidated Guideline, ICH Topic E6).

ALCOA principles

The ALCOA acronym arises from requirements in the FDA's Good Laboratory Practices and Good Clinical Practices, stating that **data should be:**

Attributable - Data should be linked to its source. It should be obvious where the data came from and who has observed and recorded the data. This is accomplished by dating and initialing case report forms (CRFs). In electronic systems, the system tracks who created the record and when it was changed. (4.9.3. ICH)

Legible - The documentation should be readable, in permanent medium, for example, pen and ink on paper. Changes must maintain legibility – e.g. crossing out an observation with a single line so as not to obscure the original. (4.9.3 ICH)

Contemporaneous- Data should be recorded as close as possible to the time of observation, so as not to call into question its accuracy. Date of data entry is required to be recorded, and there should be no back dating. In electronic systems, the time of entry is automatically recorded. (4.9.1 ICH)

Original- Original or source data, (e.g. laboratory results) rather than copies (although certified copies may be permissible) is considered of higher quality (4.9.2 ICH)

Accurate- The data should be free from error, with any corrections or changes documented (4.9.2 ICH). Auditing and automatic edit checks assist in this principle.

CITI-Canada GCP Refresher Course

An abbreviated course targeted to individuals who took the CITI-Canada GCP Course more than two years ago is available now to members of the ACRC. If 2 years has passed and you do not see the GCP refresher course available on your account, log into CITI and click "Add a course or update learner groups" from the Main menu page and add GCP. You will automatically be enrolled in the Refresher course because the Basic course was previously completed. Trainees can refresh their knowledge twice (every two years) before they will be directed to take the full course again.

Questions can be directed to acrc@albertainnovates.ca or for individuals at the University of Alberta, to QMCR.

New Version of N2 SOPs Released

N2 has released Version 6 of their Standard Operating Procedures, effective May 15, 2015, which cover clinical trial processes such as data management and study closeout. These SOPs are updated every two years. To support this roll-out, training materials are available and changes are highlighted in revision documents attached to each SOP. These revisions are compliant with Health Canada; USFDA regulations; ICH-GCP Guidelines and the revised Canadian TCPS on Research Involving Human Subjects. To get your copy, email acrc@albertainnovates.ca or at the University of Alberta, QMCR.

To support strengthening of clinical health research in Alberta, four times a year the ACRC will feature news relevant to you. Let us know if there are any ideas you have for an issue!

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

The ACRC is pleased to introduce the new ACRC Manager!

Trina Johnson, joins us from her position as the Associate Director of Experimental Therapeutics, at the Montreal Neurological Institute at McGill University, a clinical translational research program.
Trina has a PhD in Biochemistry and Molecular Biology from the University of Calgary.

We're Expanding!

The ACRC is interviewing for a Project officer to assist with the coordination and development of ACRC tools, templates and online platform.

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/

CANADIAN CLINICAL TRIALS ASSET MAP (CCTAM) LAUNCHES JUNE 4TH

The Canadian Clinical Trials Asset Map (CCTAM) is a free, searchable web-based database designed to showcase Canada's clinical research strengths to all stakeholders and position Canada as an attractive global destination for the conduct of clinical trials. It offers a list of investigators, clinical research sites, hospitals, institutions, research ethics boards and other clinical research resources available across the country.

Health Canada (HC) and FDA News

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

Acceptance of Medical Device Clinical Data from Studies Conducted Outside the U.S. (FDA): This draft guidance explains the FDAs existing policy on accepting scientifically valid clinical data from foreign clinical studies in support of premarket submissions for devices. It has become more common for investigators to rely on OUS data when applying for Investigational Drug Exemptions. This document explains some of the common issues in using this data, including regional differences in clinical conditions, study populations, and regulatory requirements, and provides recommendations to assist sponsors in developing data that are adequate under applicable FDA standards to support approval or clearance of the device in the United States.

Adaptive Design for Medical Device Clinical Studies*: Adaptive clinical trial designs allow prospectively planned modifications to the trial based on accumulating data, without compromising integrity and validity, when used appropriately. Advantages of adaptive designs include improved efficiency of resource use, quicker decision making, and optimizing the treatment of subjects enrolled in the study. This draft guidance has been released to clarify and encourage the use of adaptive designs in medical device studies.

Wanted:

ACRC Glossary Revisions: A reminder that the ACRC Glossary and Common Terminology is revised annually and a new release is upcoming. If you have suggestions for new terms, acronyms, or revised wording, please send to acrc@albertainnovates.ca.

Recruiting Working Group Members for the One-Stop-Shop: Provide input into the design, development and beta-testing of the One Stop Shop; a new website intended to be a clearinghouse of information for clinical health research in the province. It will include a provincial roadmap for research outlining each step required to get from study start to close, as well available tools, templates and guidance documents from across organizations. The resources available will assist researchers to develop and conduct their study**.** If you're interested in contributing to the on-stop-shop, contact acrc@albertainnovates.ca.

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 – Pregnancy/Perinatal Health

Each issue will highlight a research area that has been recently published by Alberta researchers.

Visit the ACRC website under Clinical Research Source for the full listing.

This month we're featuring articles in the field of pregnancy/perinatal health.

- Enhancing focused antenatal care in Ghana: an exploration into the perceptions of practicing midwives.
- Use of the Robson classification to assess caesarean section trends in 21 countries: a secondary analysis of two WHO multicountry surveys.
- Risk factors of transient and persistent anxiety during pregnancy.
- Stochastic process for white matter injury detection in preterm neonates.
- Development and function of the endocrine cells in the placenta.
- Sexually dimorphic adaptations in basal maternal stress physiology during pregnancy and implications for fetal development.