RESEARCHER TOOLBOX

This month we are adding the newly released Data Collection Package to the ACRC's toolbox. The package has several examples of **Case Report Forms (CRFs)**[1] that can be customized to collect study-specific participant information.

As the bridge between the protocol and data collection, CRFs—either in paper or electronic format (eCRFs)—are a crucial part of a study that must:

- accurately reflect the protocol;
- provide the data needed to meet the study needs without collecting extraneous information; and
- follow Good Clinical Practice for completion and storage[2].

Security considerations should be made for data storage and access including encryption and audit trails when using eCRFs. In addition, eCRFs are subject to additional regulatory requirements for electronic systems[3].

When developing case report forms for your study, it can be useful to develop standard forms that can be adapted to meet specific study needs. These templates provide customizable examples of common questions and sequences including:

- Common types of case report forms such as Concomitant Medications, Medical History, Physical Exam, Vital Signs, Baseline and Follow-up Study Visits, and Participant Study Completion.
- Customizable flowsheets may be helpful to study staff in following the sequence of study assessments and procedures through a particular study visit.

Alberta has many services available to researchers including assistance with developing CRFs or eCRFs. Find these and many other services, tools and resources listed in our Research Toolbox.

[1] Health Canada required documents
[2] *Guidance for Industry, GCP: Consolidated Guideline, ICH Topic E6, 4.9 and 8.2-8.3*
[3] In the United States, regulatory requirements of electronic systems are addressed in 21CFR, Part 11.

SoCRA CERTIFICATION COURSE OFFERINGS

The Society of Clinical Research Associates (SoCRA) has developed an International Certification Program. The purpose of this program is to evaluate a clinical research professional's knowledge, understanding, and application of the conduct of clinical investigations involving humans in accordance with ICH/GCP. CCRP certification is awarded after two criteria are met: 1) a successful written application and 2) a passing CCRP examination score. Upcoming certification courses and exams are available in Edmonton (hosted by NACTRC) and Calgary (hosted by the University of Calgary, CCCR), or go to the SOCRA website for more information.

AHS STREAMLINES PROVINCIAL RESEARCH ADMINISTRATION PROCESSES TO FACILITATE ACCESS IN THE CALGARY REGION

In collaboration with the University of Calgary, Alberta Health Services (AHS has implemented a streamlined approach to help researchers get the AHS resources they need to conduct clinical research studies approved by the Conjoint Health Research Ethics Board (CHREB) at the University of Calgary.

Effective February 1, 2016, the University of Calgary provides notification of CHREB approval and researcher's intent to use AHS resources to the AHS Provincial Research Administration team triggering the administrative processes to obtain AHS operational approval, IT system access, and HIA Research Agreements for studies requiring AHS data.

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!

Training Course on Health Research Impact Assessment

Are you asked questions about research impact? Do you want to learn about impact measurement and how to tell your impact story to diverse audiences?

Alberta Innovates – Health Solutions will be hosting the second provincial "hands-on" training course on how to put health research impact assessments into practice.

The course—which sold out last year—will take place in Banff from June 12-15, 2016. Sign up for more information or join our contact list; ihria@aihealthsolutions.ca .

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 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@aihealthsolutions.ca

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

Patient-Oriented Research Summer Institute

Join us for three days of engaging workshops, discussions, and networking at the Patient-Oriented Research Summer Institute, taking place May 2-4, 2016 in downtown Calgary.

Whether you are a researcher, patient, student, trainee, clinician, or policy maker, the institute is a key opportunity to learn more about the Alberta SPOR platforms and how you can access the valuable services they provide. It's also a great opportunity to connect with other Albertans interested in improving health outcomes through patient-oriented research.

Visit the **conference website** for more details on the Call for Abstracts and Accommodations.
More information on the program and registration will follow shortly.
Patient-Oriented Research Summer Institute Secretariat
c/o BUKSA Associates Inc.
Phone: 780-436-0983 ext. 0

> **Mark Your Calendars!**
> **May 2 – 4, 2016**
> **The Westin Calgary**

Health Canada (HC) and FDA News

Keeping you informed of changes in regulation

Publication of Good Clinical Practices Inspection Information (HC): UPDATE You can now access Information on all clinical trial inspections performed in Canada in the Health Canada's Drug and Health Product Inspections Database. This regularly updated database includes a list of all GCP inspections conducted since January 1, 2012, a preliminary overview of the inspection findings, and Inspection Report Cards, published within 30 days of the inspection.

Plain language labelling (HC): As of February 2, 2016, Notifiable Change and post-authorization Division 1 change submissions no longer require mock-ups of the Product Monograph, package insert, or inner and outer labels as part of their submission package. This applies to pharmaceutical drugs, biologic drugs, and radiopharmaceuticals that are available by prescription or administered/obtained through a health professional. All other Plain Language Labelling requirements continue to be applicable to all submissions. More information

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Clinical Research in Alberta

Alberta hosts 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

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

Visit our website for the full listing.

This month we are presenting publications in the field of **genetic conditions**.

- Autosomal-Recessive Intellectual Disability with Cerebellar Atrophy Syndrome Caused by Mutation of the Manganese and Zinc Transporter Gene SLC39A8.

- SLC39A8 Deficiency: A Disorder of Manganese Transport and Glycosylation.

- TAF1 Variants Are Associated with Dysmorphic Features, Intellectual Disability, and Neurological Manifestations.

- Granzyme B Deficiency Protects against Angiotensin II-Induced Cardiac Fibrosis.

- Kearns-Sayre Syndrome Is a Rare Cause of Diabetes.

- New methodologies for measuring Brugada ECG patterns cannot differentiate the ECG pattern of Brugada syndrome from Brugada phenocopy.

- Functional characterization of the novel DES mutation p.L136P associated with dilated cardiomyopathy reveals a dominant filament assembly defect.