

The Canadian Cardiac Chronicle

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Patient-Oriented Research: The Time is Now

Patient involvement in making medical decisions has been demonstrated to be an important contributor to treatment adherence, patient satisfaction, and health status. Thus, a large amount of literature exists which describes methods for improving health care provider-patient communication and shared decision-making. However, while clinicians rely on evidence-based randomized trials and clinical practice guidelines to inform their recommendations to patients, very little information is available on patients' preferences for how best to involve them in the development and execution of the studies we collectively work on.

The Canadian VIGOUR Centre (CVC) has been exploring how best to engage patients in clinical research, including as part of our developing national initiative - the **Canadian Cardiovascular Research Collaboratory (CCVRC)**. I recently met with Dr. Catharine Whiteside, Executive Director of Diabetes Action Canada, the **Strategy for Patient-Oriented Research (SPOR)** Network in Diabetes and Related Complications. Dr. Whiteside kindly shared the SPOR patient engagement framework they have developed, which advocates for "putting patients first". One of the key approaches identified by the SPOR group is patient involvement across the entire spectrum of research initiatives, including: engagement in the identification of important unanswered questions; collaboration in study development (including methodology); shared trial leadership and decision-making; and, communication related to study progress and results.

Similar patient engagement initiatives are underway in the United States. For example, the **Patient Focused Medicines Development (PFMD)** group notes that "simply enrolling and following patients as passive research subjects in a clinical trial does not rise to the level of patient engagement. Instead, patients should be treated as valued and valuable partners whose input, advice, and guidance is sought and implemented throughout these processes." Indeed, PFMD makes a key distinction between patients and partners: "A patient is a person who needs, awaits, and receives medical treatment and care. In contrast, a partner is a person who wants, co-designs, and co-delivers medical treatment and care. In order to commit to more meaningful partner engagement in medicines

development, we must invest more time to listen, involve them in finding solutions through co-creation, and engage in constant communication with them throughout the development lifecycle."

What are we at the CVC doing in light of this highly anticipated change? In collaboration with our academic research organization (ARO) partner, the **Duke Clinical Research Institute (DCRI)**, the CVC is coordinating the Canadian component of a randomized clinical trial where patient engagement is a key priority. The Apo A-I Event Reducing in Ischemic Syndrome (AEGIS-II) trial is a large, international, multicenter Phase 3 trial infusing intravenous apolipoprotein (Apo) A-I (CSL112) to reduce cardiovascular events in acute coronary syndrome (ACS) patients. In AEGIS-II, the CVC and DCRI are committed to ensuring a high-quality, efficient, patient-centered trial by: (1) developing a trial that is feasible and minimally burdensome for participants; (2) increasing enrolment rates by proactively addressing barriers to recruitment and improving study communications and materials; and, (3) driving higher rates of retention and protocol adherence through enhanced value and improved participant experience. Recognizing that patients are our partners in research, not our subjects, we are aiming to engage participants in the conduct, oversight, and dissemination activities of the trial. For example, there is a Canadian representative (enrolled in the phase 2 AEGIS-I trial) on the AEGIS-II Participant Advisory Group, who will help provide input on: the informed consent process, recruitment and retention strategies, tactics, and materials; anticipated participant experience (having themselves had a recent ACS and/or been part of AEGIS-I); and the conduct of the study related to optimizing participant comfort and convenience in the context of the protocol requirements. While this is simply a first step towards more optimal patient-oriented research, we hope that listening, co-creating, communicating, and collaborating with our partners will lead to better engagement and more impactful clinical trial results.



Shaun Goodman
CVC Co-director



SODIUM-HF



Well done SODIUM-HF team!

550 patients were enrolled by the end of July 2018. The project team wishes to thank all Investigators, Coordinators, and Dietitians for their hard work throughout the summer months. Now that enrollment is more than halfway done, plans are underway for the first DSMB meeting.

CVC will disseminate information regarding how sites can prepare for this first interim analyses over the coming months.

NEW SITE ACTIVATION

Welcome Dr. Alexander Zhai, Sarah (Study Coordinator) and Rochelle (Dietitian) from Royal University Hospital in Saskatoon, SK! We look forward to seeing your first patient randomized in the study.

REMINDERS!

Publication Dietary Materials Feedback

Trial Dietitian, Dr. Eloisa Colin, will be requesting further feedback on the publication of dietary materials. Don't miss out on your chance to provide your feedback and

comments on this important publication! If you have any questions, please contact Eloisa at eloisa_colin@yahoo.com.mx.

Data and Invoices

Please remember to log into REDCap and check your site's queries by clicking on the "Resolve Issues" link in the left hand column. The next quarterly data cut for site payments is **September 30, 2018**. As a reminder, a visit needs to be fully completed (saved as green / complete in REDCap, all queries resolved, and the Food Record [as applicable] submitted to the Core Lab sodcore@ualberta.ca) in order for payment to be triggered for that visit.

Project Lead Transition

We would like to welcome Melisa Spaling back to the SODIUM-HF trial as the CVC Project Lead starting August, 2018. Many of you have worked with her previously on SODIUM and other CVC trials. Thank you to Nubia Zepeda for her leadership and diligence in managing the trial for the past few years. The project team wishes her the best in her future endeavours!

If you are interested in receiving more information about the SODIUM-HF trial, please contact the Clinical Trial Project Lead, Melisa Spaling, via email at mspaling@ualberta.ca or 1-800-707-9098, ext 1. You may also contact the SODIUM-HF trial Regulatory Specialist, Kate Dawson, via email at kedawson@ualberta.ca.

SODIUM-HF

Funded by the Canadian Institute of Health Research (CIHR) and University Hospital Foundation, SODIUM-HF is a multicenter, randomized, open-label Study Of Dietary Intervention Under 100 MMOL in Heart Failure.

ClinicalTrials.gov Identifier: NCT02012179

STREAM 2

The study has reached 27 patients globally as of August 20, 2018 with a Canadian contribution of 4 patients. Congratulations to the Edmonton team for all their efforts enrolling their first patients. Conducting a study in a fast-paced emergency setting has its challenges.

A special thanks to the team for their diligence in working with all personnel and departments involved from first patient contact to study follow up. We are excited to see enrollment continue to increase over the upcoming months.

If you are interested in further information regarding this trial, please contact Clinical Trial Project Lead Courtney Gubbels at 1-800-707-9098 ext 2 or via email at courtney.gubbels@ualberta.ca or Senior Regulatory Specialist Kalli Belseck, ext 6 or via email at kalli@ualberta.ca.

Sponsored by Leuven Research & Development (LRD) at University of Leuven, Belgium, STREAM-2 is a Phase 4 trial on Strategic Reperfusion in elderly patients Early After Myocardial Infarction

ClinicalTrials.gov Identifier: NCT02777580

VICTORIA-HF Registry



Site start-up is drawing to a close and we wish to extend our gratitude to all of our sites for a successful and timely start! Canada is doing a terrific job with enrollment and we thank you for your efficient and accurate work.

We wish to recognize the following sites for their excellent enrollment efforts:

- Dr. Allen Schaffer and Wendy Janz/Charissa Cepidoza (Winnipeg, MB)
- Dr. Brian Clarke and Kim Ronak/Sneha Patel (Calgary, AB)
- Dr. Mustafa Toma and Carol Marchand (Vancouver, BC)
- Dr. Eva Lonn and Alison Magi/Linda Frenette (Hamilton, ON)

If you are interested in further information about the VICTORIA Heart Failure Registry, please contact the Clinical Trial Project Lead, Karin Kushniruk, at 1-800-707-9098, ext 7 or via email at kushniru@ualberta.ca or the Regulatory Specialist, Kate Dawson via email at kedawson@ualberta.ca.

VICTORIA-HF Registry

Sponsored by Merck and Bayer this registry will assess the risk/benefit profile of Vericiguat in those patients with chronic heart failure.



HEART-FID

The HEART-FID study is underway with 22 active Canadian sites and almost 50 randomized patients. The majority of sites have now screened at least one patient and over half have randomized! Canada started off the summer on a high note with June seeing the most patients enrolled per month so far. We are excited to see a continued increase in enrollment into the fall.

Important Trial Reminders:

Unblinded Lab Review

Please ensure your designated unblinded study team member reviews the unblinded labs well in advance of an upcoming 6 Month dosing visit. If the unblinded labs are unavailable in Almac, please inform CVC so that we may follow up to obtain these lab results in time for the scheduled visit. Your site process for unblinded lab review should be outlined in your site's blinding process memo. You can also find more information about who is able to review these unblinded labs in the Post Dosing Unblinding Labs Assessment flow chart.

Site Reference Guide

The new Site Reference Guide was sent to sites on June 26. This handy guide is your quick go-to document to reference when you have questions about the trial. The Site Reference Guide provides helpful information about contacts, study procedures, data entry, systems, and much more! If

you did not receive a copy of the guide, please contact us so we can send one to you.

Vacation Back Up

We know that many of you are taking well-deserved vacations this time of year. While summer will soon be drawing to a close please remember if you are going to be away, especially for any extended absences throughout the study, please drop us an email and remember to designate appropriate back up personnel to cover your responsibilities while you are away. Please be mindful of the availability of both blinded and unblinded staff for your team while scheduling study activities at your site.

If you are interested in further information regarding this trial, please contact Clinical Trial Project Lead Courtney Gubbels at 1-800-707-9098 ext 2 or via email at courtney.gubbels@ualberta.ca or Regulatory Specialist Kate Dawson, 780-492-3789 or via email at kedawson@ualberta.ca.

Sponsored by Luitpold Pharmaceuticals Inc., HEART-FID is a Randomized, Double-Blind, Placebo-Controlled Study to Investigate the Efficacy and Safety of Injectafer® (Ferric Carboxymaltose) as Treatment for Heart Failure With Iron Deficiency



ClinicalTrials.gov Identifier: NCT03037931

GALILEO



As the study now moves toward completion we ask that you please keep a close eye on your email regarding key updates, notifications and next steps.

Our study team and your CRA will be in contact with you over the next several weeks regarding final study visits and subsequently scheduling your COV in the months ahead.

Please ensure you have contacted your patients to set up End of Treatment or End of Study visits per the recent memo.

The planning of these visits will be tracked, and so we ask that sites provide CVC with the dates of all booked visits so we can ensure a timely and efficient end of the trial. Should a booked visit need to be re-scheduled, please be sure to notify CVC.

As a reminder all study visits including EOT, EOS and Post Treatment phone call should be entered in Marvin **within 48 hours** of the visit so that Data Management can review and clean the data in an efficient manner.

We want to thank you for your efforts to keep patients engaged in the study and appreciate your continued diligent follow up of them during this end of study phase.

General Reminders

- Please continue to report all events, even if they are just “suspected” events.
- Ensure copies of all study communications are on file at your site (per the listing that CVC sends out) and let CVC know if you are missing any.
- Send invoices to CVC for any outstanding items per your site’s contract/budget.
- Promptly notify CVC of any temperature excursions for Rivaroxaban.

If you have any questions about this trial, please contact the Clinical Trial Project Lead, Jodi Parrotta at 1-800-707-9098, ext. 3 or via email at Jodi.parrotta@ualberta.ca or Regulatory Specialist Paula Priest at paula.priest@ualberta.ca.

Sponsored by Bayer Healthcare AG, GALILEO is a Global multicenter, open-label, randomized, event-driven, active-controlled study comparing a rivaroxaban-based antithrombotic strategy to an antiplatelet-based strategy after transcatheter aortic valve replacement (TAVR) to Optimize clinical outcomes.



ClinicalTrials.gov Identifier: NCT02556203

FEAST-HF

The FEAST-HF trial will explore the potential beneficial effects of dietary fiber supplementation, compared with placebo, in patients with Heart Failure. Fermentable dietary fibers are emerging as therapeutic agents for improving health but also have systemic effects and thus the potential to improve symptoms of other diseases.

This trial has the potential to open up avenues leading to new treatments for patients with heart failure.

Currently this trial is in its pilot phase at the University of Alberta and we anticipate Dr. Ezekowitz and his team will enroll their first patient soon.

If you are interested in further information about the FEAST-HF trial, please contact the Clinical Trial Project Lead, Karin Kushniruk, at 1-800-707- 9098, ext. 7 or kushniru@ualberta.ca.

Sponsored by University Hospital Foundation, FEAST-HF trial will explore the potential beneficial effects of dietary fiber supplementation, compared with placebo, in patients with Heart Failure

ClinicalTrials.gov Identifier: NCT3409926

AEGIS-II



The summer months have brought some exciting milestones to fruition in Canada! The first three Canadian sites were activated:

- **Dr. Sohrab Lutchmedial & Gail O’Blenis** – New Brunswick Heart Centre (Saint John, NB)
- **Dr. Christopher Fordyce & Shirley Lim** – Vancouver General Hospital (Vancouver, BC)
- **Dr. Olga Toleva & Kiran Atwal/Dolores Friesen** – St. Boniface General Hospital (Winnipeg, MB)

A heartfelt congratulations to Dr. Fordyce and his team for enrolling the first Canadian patient on July 31!

We continue to work closely with our sites on ethics submissions and contract/budget negotiations and are on track to have the majority of our current sites activated for enrollment by October. We appreciate all the work that goes into study start up and thank all of our participating

sites for pushing through this over the next few week to help us meet this timeline.

The second Investigator Meeting took place in Chicago this July and was very well received. Thank you to our Canadian sites for taking the time to attend these very important meetings.

While many of the sites have now been selected in Canada we are still welcoming additional sites to participate.

As a reminder, AEGIS-II is a large, international, multi-centre Phase 3 trial of infusing an intravenous formulation of apolipoprotein A-I (CSL112) to reduce cardiovascular events in acute coronary syndrome patients. CSL112, an intravenous formulation of apoA-I, enhances cholesterol efflux capacity, and therefore has the potential to reduce plaque burden, stabilize plaque lesions at risk of rupture and decrease the high rate of early recurrent events.

If you treat this patient population and may be interested in participating or hearing more, please contact Clinical Trial Project Lead, Lyndsey Garritty at 1-800-707-9098, ext 8 or via email at lyndsey.garritty@ualberta.ca or Senior Regulatory Specialist Kalli Belseck at 1-800-707-9098, ext 6 or via email at kalli@ualberta.ca.

Sponsored by CSL Behring LLC, this is a Phase 3, Multicentre, Double-blind, Randomized, Placebo-controlled, Parallel-group Study to Investigate the Efficacy and Safety of CSL112 in Subjects with Acute Coronary Syndrome.



ClinicalTrials.gov Identifier: NCT03473223

QUALITY - ICH GCP E6

In case you are not already aware, **ICH GCP E6** was updated from R1 to R2 in November 2016. The reason for this update was to address the changes in the complexity of clinical trials and technology since 1996, when the guidelines were first released. To quote the ICH E6 (R2) Addendum per ICH’s “E6(R2) Step 4 Presentation” found on <http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html#6-2>:

ICH E6(R1) has been amended to encourage implementation of improved and more efficient approaches to clinical trial design, conduct, oversight, recording, and reporting while continuing to ensure human subject protection and reliability of trial results.

New terms such as “**Certified copy**,” “**Monitoring Plan**” and “**Validation of computerized systems**” have now been added to the guidelines. Additional recommenda-

tions pertain to **PI responsibilities** (Delegation of Duties and Maintenance of Records); **Sponsor responsibilities** (Quality Management and Risk-based Monitoring); and **Essential Documents**. Health Canada formally adopted ICH GCP E6(R2) on April 1, 2018, with the aim of implementing these new guidelines by April 1, 2019. As for training, there is a new 10-module ICH E6 R2 updated Good Clinical Practice (GCP) Basic Course now available through the Collaborative Institutional Training Initiative (CITI), to which many of our sites belong through their institution. The course includes the International Council for Harmonisation (ICH)-E6 (R2) guidelines, Health Canada-Division 5, and The Tri-Council Policy Statement 2.

We strongly encourage all sites to update their GCP training and send CVC a copy of updated training records for your study team.

CVC 2017 Annual Report

We are pleased to share with you our recently published **2017 Annual Report**.

As we celebrate our 20th anniversary at CVC, we reflect on our organization's development, evolution and direction. For this year's report we sought inspiration from Janus, the ancient Roman god of beginnings and transitions. Janus is often represented as a god with two faces - one which looks backwards and the other forwards. His spirit exactly captures what permeates our organization's lasting values and future orientation.

The timeless vision and mission, contained within our compass, is constantly energized by the unmet needs of cardiovascular disease and the remarkable array of new tools to address them. We remain resolute in our intent to continue bridging hearts and minds to enhance cardiovascular care.

A PDF copy of our annual report can be found on our website <http://thecvc.ca/>



CVC News



Linn Moore recently joined the CVC as a Research Associate working with Dr. Padma Kaul. Linn received her BSc from the University of Gothenburg, Sweden, and recently completed her PhD in clinical cardiopulmonary physiology at the University of Alberta. Throughout her PhD training, Linn has been teaching courses in anatomy and exercise physiology, has supervised numerous undergraduate research students, and has been involved with the activities of the office of the Respiratory Health Clinical Strategic Network within Alberta Health Services. Linn can be contacted at 780-492-1651 or by email at linn.moore@ualberta.ca.



Leiah Luoma recently joined the CVC as an Academic Research Administrator. She received her BSc in Molecular Genetics and a PhD in Medical Genetics, both from the University of Alberta. Her PhD focused on the gene regulatory processes involved in human neurodevelopment and cognition. After her PhD, Leiah held a Postdoctoral Fellowship in the Department of Surgery before joining the CVC in May 2018. Over the course of her training, her interests have turned from understanding genetic mechanisms and neurobiology to translation and synthesis of biomedical and health research information to realize health outcomes. Leiah can be reached at 780-492-7732 or by email at lluoma@ualberta.ca.



Sunjida Islam recently joined the CVC as a biostatistician. She received her MBBS (Bachelor in Medicine and Bachelor in Surgery) from Bangladesh, and MSc in Epidemiology from the University of Alberta. Following her MSc, Sunjida worked in the Pediatrics department for two years in different projects on congenital heart disease. She is excited to work with the CVC team and meet new people. Sunjida can be reached by email at sunjidat@ualberta.ca



Melisa Spaling has recently returned from maternity leave. She has resumed her position as Clinical Trials Project Lead at CVC and is working on the SODIUM-HF Trial and other projects. Melisa has worked at CVC since 2013 and is happy to return to the team! Melisa can be reached at 1-800-707-9098, ext 1 or mspaling@ualberta.ca.

Beyond 2000 - B2K18

Beyond 2000 is a symposium held each year in conjunction with the Canadian Cardiovascular Congress.

This year **B2K18** will be held at the Metro Toronto Convention Centre South Building (Exhibit Hall G) in Toronto, Ontario on October 22, 2018.

B2K18 will comprise of two sequential sessions - New Concepts in Acute Coronary Syndromes and New Concepts in Heart Failure and Atrial Fibrillation.

Please refer to the attached insert for more details.

Further information about B2K18 will be available soon on the CVC website <http://thecvc.ca/conferences-and-events/>.



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About the Chronicle

This newsletter is published periodically as a service to Canadian investigational sites. The purpose is to provide information of interest to individuals involved in cardiovascular clinical trials managed by the Canadian VIGOUR Centre, University of Alberta in Edmonton, Alberta, Canada.



Canadian VIGOUR Centre
Bridging Hearts and Minds

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