The Canadian Cardiac Chronicle

Volume 22, Issue No. 3

"**In God we trust; all others must bring data.**"
- W. Edwards Deming

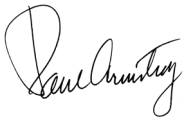
The familiar adage is attributed to W. Edwards Deming an American statistician considered the father of modern quality management. He advocated that data measurement and analysis were fundamental to attaining superior performance.

Yet in 2018 we are living in a new world where the search for truth is sometimes derailed by opinions and "alternative facts". The convincing and consistent metrics from multiple and credible sources supporting climate change are disputed and largely ignored in some prominent quarters. Denial of the facts raising false fears about vaccinations causing autism has led to unnecessary measles outbreaks. Public health now and in the future is at risk. In part this relates to the deluge of electronic information rapidly disseminated from non-credible sources making facts and opinions difficult to separate. Junk science abounds, arising from obscure websites or journals without critical standards. Health misinformation is especially problematic and has recently been defined (Chou et al JAMA 2018) as "*a health related claim of fact that is currently false due to a lack of scientific evidence. This misinformation may be abundant on social media and some evidence has linked the sharing of misinformation with health-related knowledge, attitudes, and beliefs.*" Such misinformation finds willing receptors among advocacy groups doubtful of scientific advances that contravene well established prior cultural beliefs. They especially resonate within information silos where these beliefs are reinforced and unchallenged by a more balanced and objective context.

As an academic research organization (ARO) we strive for high quality, best performance and work hard to measure indices that accurately reflect this aspiration. The data acquired by our collaborating investigators and research sites are subject to careful auditing and oversight by our sponsors, regulatory bodies, and ourselves. Site visits, timely submission and careful data entry coupled with quality checks happen at every step leading to the final results. These are replicated and independently confirmed so there is absolute accountability for all subjects and their outcomes. At the end of this fastidious process we are confident the results are correct, reliable and trustworthy. This is what science is meant to achieve.

Working in a university environment - which in large part is publically funded in Canada - we have a special responsibility to earn and maintain public trust. In presenting our work and ideas we must avoid hyperbole and find a balance between hopefulness and reality while striking a responsible tone. We also need to rout out scientific fraud and acknowledge that this does occur in exceptional circumstances: I believe these are ultimately detected and corrected in the best scientific traditions. Enhancing scientific literacy is part of our core responsibility. We need to externally validate social media sources of information and resist the temptation to further disseminate "shaky "claims. One of the most gratifying presentations I gave in 2018 was to high school students where I explained why we need the next generation to join in the search for new knowledge through scientific inquiry that contributes to human health. There is more for all of us to do here and this will be part of my New Year's resolutions.

At this special time of year and on behalf of our splendid team at CVC, we send you our very best wishes for a Happy Christmas, Hanukah or other celebrations. Take time to enjoy the comfort, joy and restorative power afforded by your family and friends. We look forward to collaborating with you on illuminating the path of discovery that will lead to better cardiovascular health in 2019.



Paul W. Armstrong
CVC Founding Director

SODIUM-HF

Congratulations to all participating sites in achieving a significant trial milestone - 600 patients randomized as of 31-Oct-2018. Importantly, **SODIUM-HF is the largest trial of its kind** – many interventions of this type are difficult to design and deliver, and have patients agree to participate. We have a real opportunity to move the needle in the care of our patients with this trial. Thank you to all sites for your pivotal role in identifying, enrolling, and retaining study patients!

A special **thank you** to the following sites for their outstanding performance:

- **Dr. Ross, Enza de Luca** and **Margaret Brum** (Toronto General Hospital) 130+ patients enrolled
- **Dr. Escobedo, Grecia Mendoza** and **Lubia Velazquez** (IMSS, Mexico City) 100 patients enrolled
- **Dr. Ezekowitz, Quentin Kushnerik, Liz Woo** and **Claire Kee** (University of Alberta Hospital) 75+ patients enrolled
- **Dr. Zieroth, Wendy Janz, Charissa Cepidoza** and **Jennifer Daniel** (St. Boniface Hospital) Randomized 3 patients in the month of November

New Site Activation

Welcome Site 126, **Dr. Saldarriaga, Elsa Gonzalez, Adriana Agudelo, Adriana Ortiz, Paola Tobon, Jorge Orrego** and **Paula Gomez**, Clinica Cardio VID, Colombia. We look forward to seeing your first patient enrolled!

Frequently Asked Questions

Question: Regarding Inclusion Criteria #3 NYHA Class II-III, if a subject is screened as a qualifying class (II or III) but at baseline the PI judges the subject to be an excluded class (I or IV), is the patient to be withdrawn from the study?
Answer: No, the patient may stay in the trial and be randomized. The class at screening is what should be entered into REDCap.

Question: My patient is withdrawing from the in-person study visits as he can no longer travel to clinic. How do I enter this in REDCap?
Answer: Please contact the Project Lead for detailed instructions.

Next Data Cut for Site Payment: December 31, 2018

Please remember to log in to 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 December 31, 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.

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 or ext 8.

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

Enrollment in Canada is building some momentum with 7 patients enrolled to date. We anticipate a steady increase in enrollment due to the recent protocol amendment which now also includes patients between 60 and 69 years old. **Congratulations to the Edmonton team** for your continued success!

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

Canada is continuing to do an excellent job with enrollment and data entry, and we wish to thank everyone for their efforts thus far in the trial!

As our final enrollment goal is approaching, please make every effort to enter your patients into the database as soon as they are identified. We will soon provide information regarding Close Out procedures and other end of study details, so please stay tuned for these important communications.

We wish to recognize the following sites for meeting their 50 patient enrollment milestone:

- **Dr. Christian Constance, Marie-France Gauthier** and **Nathalie Leblanc** (Montreal, QC)
- **Dr. Dante Manyari, Tracy Cleveland** and **Alicia Ibbitson** (Surrey, BC)
- **Dr. Michael Chan, Samantha McLean** and **Nicole Ell** (Edmonton, AB)

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 karin.kushniruk@ualberta.ca or the Regulatory Specialist, Kate Dawson, at kedawson@ualberta.ca or ext 8.

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

It's been just over a year since Canada's first patient was enrolled into the HEART-FID study. Thanks to all our sites for your continued dedication to this important IV iron heart failure trial. Your hard work pre-screening continues to pay off and move Canada towards our enrollment goal. Globally there are almost 700 patients enrolled with over 60 of those from Canada.

Trial Reminders

Data Entry
Data is typically entered very quickly in this trial so a big high five to all of the study coordinators! Just a reminder to routinely check back after your data is entered to see if any new queries have been posted. If you have any questions about how to enter an SAE or endpoint, please refer to the eCRF guidelines or give us a call to review the process.

6 Month+ Visits
Every 6 months your patient will have 3 visits – a lab draw, 1st dosing visit and 2nd dosing visit. Please plan your lab draw visit as early as possible within the allotted window so there is enough time for Covance to receive your blood sample, process it and upload the results into ALMAC. It is best to plan the lab visit at least a week prior to your 1st dosing visit in case there are problems with the lab sample, shipping or the upload to ALMAC.

Holiday Break

As the festive season is upon us, please remember to plan your follow-up visits keeping in mind your patients' holiday schedule. Please remember to review your lab kits to ensure you have enough kits over the break and that none of the kits have expired. Please order any required kits and supplies well before the holiday break as there may be delays with shipping. It is also a good idea to review your local courier's holiday schedule to confirm their pickup and delivery times and plan your visits around those times. Happy Holidays!

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 or ext 8.

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

A huge **THANK YOU** goes out to all the Canadian sites (especially the study coordinators!) for meeting the tight timelines during this Close-Out phase of the trial. All End of Treatment visits in Canada were completed for every patient - there were no LTFU patients! Close-Out Visits were conducted at all CVC sites in less than a month and throughout this busy time, data was entered in a timely manner, with queries being answered quickly and efficiently. In fact, on November 7, 2018, CVC reached a milestone of 0 open queries in Canada! Thank you also for all of your hard work and prompt attention to the final queries from Medical Review and Data Management that continued to trickle in during the remainder of November. It is because of your hard work that we are on schedule for database lock.

CVC continues to **follow up on the outstanding action items** mentioned in the Provisional COV follow-up letters in preparation for final close-out. We thank you for your attention to these items as well.

CVC will notify your site as to when the PI can begin **signing the CRFs**. This will be after the study team has confirmed that your site's data is completely clean. When the time comes, the PI (or a sub-investigator to whom the PI delegated this task per your site's Delegation Log) will be asked to sign the CRF pages in preparation for database lock. Please let CVC know if there are any issues accessing the CRF or signing the forms.

After database lock, CVC will let you know when your site can **close the study with ethics and finalize the delegation log.** At that time, final invoices will be requested. These will be the last steps before officially closing your site. You will be sent a final Close-Out letter to document that all activities have been completed.

General Reminders

- 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.

It has been a pleasure working with all of you on GALILEO and we look forward to working with you on future trials!

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 pilot is now well underway and we wish to **congratulate Dr. Ezekowitz and his team** on a successful trial start-up.

This 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.

We look forward to learning more about the potential health benefits of dietary fiber supplementation as well as new avenues for treatment and future research for patients with Heart Failure.

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 **karin.kushniruk@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 start-up phase for AEGIS-II is coming to a head and we are now engrossed in what is starting to look like a very successful enrollment phase in Canada!

There are now 24 sites activated in Canada, with a plan to have a total of 30 sites activated by January 2019. Thank you to all of our hardworking sites for meeting this initial milestone!

If your site is not yet activated, we would ask that you make it a priority to follow up with the different departments/groups at your institution in the days ahead to achieve an activated status in the coming weeks. Our team at CVC as well as the sponsor are happy to support you and will make every effort to respond quickly to contract, budget, regulatory and ethics questions. If you have not already established a date for your **Site Initiation Visit (SIV)** with your CRA, please look at potential dates through Dec/Jan; we appreciate how fast these fill up on everyone's calendars. Your CRA or our in house team will be in touch soon to confirm a date with you.

Canada is exceeding our enrollment projections so far with 31 patients randomized. Congratulations to the 11 sites that have enrolled one or more patients, and we look forward to the remaining sites contributing a patient very soon. As a reminder, the expectation is that sites enroll at least one patient every two months, however, based on our early start we expect our Canadian sites will continue to exceed our expectations.

Congratulations to the following sites for achieving these very important Canadian milestones!

First site activated: **Dr. Sohrab Lutchmedial & Gail O'Blenis**: New Brunswick Heart Centre Research Initiative, St. John's, NB - 2 patients

First patient enrolled: **Dr. Christopher Fordyce & Shirley Lim** - Vancouver General Hospital, Vancouver, BC - 2 patients

Congratulations to our Top Enrollers!

- **Dr. Joseph Rodes-Cabau & Karine Maheux**: IUCPQ, Quebec, QC - 7 patients
- **Dr. Warren Cantor & Kim Robbins**: Southlake Regional Hospital/York PCI Group, Newmarket, ON - 5 patients
- **Dr. Richard Gallo & Josee Morrissette:** Montreal Heart Institute, Montreal, QC - 3 patients
- **Dr. Samer Mansour & Caroline Vallieres**: Centre Hospitalier de l'Universite de Montreal, QC – 3 patients

It was a great opportunity to connect with many of our Canadian sites via webex in November where we shared an overall trial status update, reviewed some key points around inclusion/exclusion and general reminders about the study. We had some excellent questions and want to remind our sites that in addition to our in house operations team, **Dr. Shaun Goodman** a member of the AEGIS-II Executive Committee, along with **Dr. Kevin Bainey** who is our Canadian National Leader are available and happy to connect with you if you have any questions about the trial or protocol. At this early stage in the trial, and as you recruit your first patients we expect you will have many questions. To that end we want to encourage you to reach out. We look forward to hosting our next webex in the New Year.

As you prepare for the upcoming holidays, please ensure that your patients are scheduled within the protocol required time windows and that you have coverage in place for team members who will be away. If you have urgent patient/recruitment related questions during this time, remember to utilize the study helpline. We appreciate your hard work this past year and wish you a relaxing time with your family and friends. With your help we look forward to the New Year being a prosperous time for AEGIS-II recruitment.

If you are interested in further information regarding this trial, 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, 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

ACC ROCKIES

You won't want to miss the **ACC Rockies** (Canada's Premier Cardiovascular CME) being held in Banff, Alberta from March 10 - 13, 2019!

Continuing the traditional offering of highly clinically relevant presentations by national and international leaders in research and clinical care blended with case-based discussions and interactive knowledge translation workshops, we're confident that you'll find this meeting a valuable experience to facilitate applying the latest evidence to your clinical practice.

The preliminary program is available and early bird registration rates are in effect!

Visit www.accrockies.com for registration details and more information.

B2K Webinar Series

The **Canadian VIGOUR Centre (CVC) and the Beyond 2018 (B2K18) educational program** is pleased to host a **Canadian Cardiovascular Society-accredited webinar series initiative** that is being provided as an extension to the B2K18 symposium (held annually during the Canadian Cardiovascular Congress).

We will be covering a range of important cardiovascular-related research and clinical practice topics in 2019, including antiplatelet and anticoagulant therapy in coronary artery disease and atrial fibrillation (AF), heart failure (HF), and diabetes.

Topic dates and details will be available soon on the CVC website CVC Conferences and Events.

We will send you a personal email invitation in advance of each of these webinars.

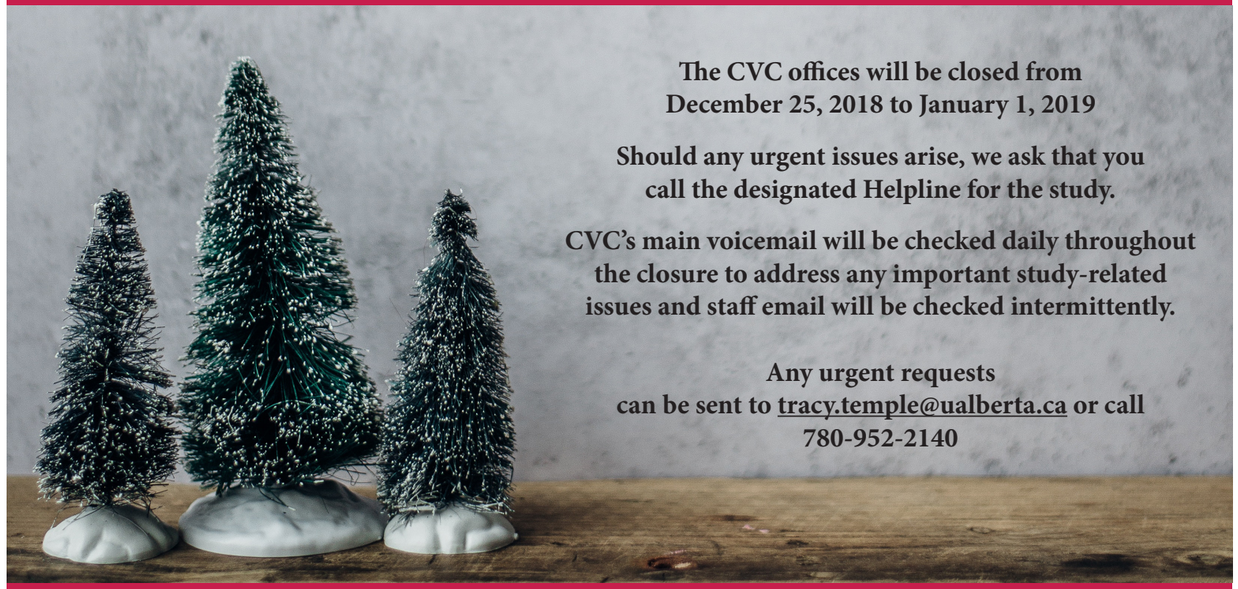
2019 CVC Clinical Trials Colloquium

The Canadian VIGOUR Centre is now planning the 6th Annual **CVC Clinical Trials Colloquium.**

The Colloquium is held yearly in Banff, Alberta in conjunction with the ACC Rockies Meeting.

The aim of the colloquium is to bring together investigative sites, sponsors, operational experts, and invited speakers to collectively discuss optimizing clinical research in Canada.We will be reaching out to select sites to join us in Banff on March 10, 2019.

CVC Holiday Closure



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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.

CVC gratefully acknowledges our sponsors and the funding support provided by:

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