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Back to School: But the Learning Never Stops

The return to school is typically marked by the end of summer and the beginning of autumn. However, in the world of clinical cardiovascular-related research, the associated cycle of investigation, new learnings, and medical education is a continuous one.

Together with my Canadian VIGOUR Centre (CVC) colleagues, we have recently returned home from an exciting European Society of Cardiology annual scientific congress that revealed new strategies and treatments, several of them practice-changing. Further, the CVC strengthened, and made plans to extend, our national and international collaborations with both old and new friends.

"There's been a lot of research lately on your condition. Now I'm sorry I didn't read any of it."

As the cartoon suggests, we as healthcare providers are immersed in a constant battle to keep "up to date" in order to best serve our patients. However, it's not enough to simply read the new medical literature; we need to also critically appraise what we've heard and seen, determine whether it applies to our patients and healthcare settings, and then practically implement what we've learned.

To assist with this daunting task of knowledge translation, the CVC's Founding Director Dr. Paul Armstrong established a seminal satellite symposium as part of the Canadian Cardiovascular Society's (CCS) annual scientific Congress (CCC) in 1994.

Over the past 24 years, the "**Beyond 2000**" (B2K) symposium has been among the best-attended sessions during the CCC and has drawn rave reviews from participants for its cutting-edge delivery of "what you need to know" about cardiovascular disease (CVD) by national and international experts. Perhaps the most popular parts of the symposium have been the case presentations by front-line cardiologists, the lively faculty panel discussions, and the question and answer (Q&A) opportunities provided as part of this highly interactive learning experience.

Dr. Armstrong has handed over the reigns to Dr. Justin Ezekowitz and me over the past couple of years, and we have extended our partnership with the CCS to make B2K not only a "stand alone" satellite symposium, but an integral part of the Congress itself. Further, B2K has now become a formal part of the CVC's mandate, consistent with our vision to not only generate, but also translate and disseminate, knowledge on novel diagnostics and therapeutic strategies in CV medicine acquired through collaborative research. To that end, additional "Beyond 2000" information can be found on the **CVC B2K website**.

Further, following our 2018 symposium, we embarked upon a new, CCS-accredited webinar series: "**B2K18 – Bridging Knowledge to Patient Care**". Five topics (lipid-modifying therapy post-acute coronary syndrome [ACS]; oral anticoagulation in patients with coronary artery disease; oral antiplatelet therapy post-ACS; the heart failure-diabetes-renal axis; and diabetes and CVD) were covered in 2018-19 as we revisited some of the key presentations made during

B2K18, provided some relevant trial updates in the context of case presentations, and offered an interactive Q&A opportunity. These webinars are available on the CVC website **B2K Webinar Series**.

Together with our Planning Committee colleagues (Drs. Heather Ross, Robert Welsh, and David Bewick), Dr. Ezekowitz and I have been busy organizing B2K19: New Concepts in ACS, Atrial Fibrillation, Heart Failure, and Diabetes which will take place during the CCS Congress. We are excited to have an outstanding faculty and, in recognition of this quarter-of-a-century B2K session, we have a new logo (Please see insert).

In honour of this milestone and to acknowledge Dr. Armstrong's outstanding leadership in research and education, Dr. Warren Cantor - co-chair of the CCS Guidelines on acute management of ST-segment elevation myocardial infarction - will kick off the symposium with the **Paul W. Armstrong B2K Keynote Presentation**.

Hoping to see you in Montreal on Saturday, October 26th!

Shaun Goodman
CVC Co-Director

HEART-FID

We have recently reached two major milestones – global enrollment has reached 1000 subjects and Canada has enrolled 100 subjects! Your dedication to the trial is not going unnoticed. We appreciate the effort each site is putting forward in order to ensure trial success. Keep up your efforts!

Congratulations to our top three Canadian sites!

- **Dr. Shekhar Pandey, Stephanie Buck, and Patrick Toth** – Cambridge Cardiac Care Centre (Cambridge, ON)
- **Dr. Amit Khosla and Tracy Cleveland** – Surrey Memorial Hospital – Cardiology Clinical Trials (Surrey, BC)
- **Dr. Elizabeth Swiggum and Sarah Nelson** – Victoria Heart Institute (Victoria, BC)

Trial Reminders:

6 Minute Walk Test

A new 6MWT form was recently released. Please review the document with your team. Important reminders about the 6MWT:

- the course should remain consistent throughout the trial in location and length
- the test should only be conducted by blinded staff
- it is acceptable if the test is completed outside of the visit window

Data Entry

All sites are excellent at keeping their data up to date. Thank you! We would like to encourage you to continue regularly logging into RAVE to ensure there are no new open queries. We will continue working closely with each site to ensure Canada's data is as clean as possible.

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, 1-800-707-9098, ext 8 or via email at **kedawson@ualberta.ca**.

Sponsored by American Regent, 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

AEGIS-II

The enrollment phase of AEGIS-II is very much in full swing! In Canada, we have all 30 of our active sites enrolling patients, which is a very exciting milestone. Enrollment numbers have been exceeding projections not only in Canada, but globally as well.

We are encouraged by our sites' consistent enthusiasm and dedication to continually screen and work hard to find the right patients to enroll. As patients are enrolled, we will be sending out reminders to enter the Screening/Visit 1 data within 48 hours.

Congratulations to the top three enrolling sites in Canada!

- **Dr. Kevin Bainey and Norma Hogg** - University of Alberta Hospital/Mazankowski Heart Institute (Edmonton, AB)
- **Dr. Josep Rodes-Cabau and Karine Maheux** - IUCPQ (Quebec City, QC)
- **Dr. Warren Cantor and Kim Robbins** - York PCI Group Inc. (Southlake, ON)

The local and central labwork requirements for infusion eligibility must be adhered to at all times. If these labs are not done or the values do not meet eligibility parameters prior to randomization and/or infusion, this is a major protocol deviation. It also very important that there is documented PI assessment of these labs PRIOR to an infusion occurring. Please carefully review the Protocol, and the Infusion Dosing Eligibility Cards for guidance. Your CVC team is always available for questions or clarifications as well.

The required time window for eCRF data entry is within 2 days of each visit, or within 24 hours for all endpoints and serious adverse events. Please be mindful that if an endpoint also qualifies as an SAE, it must be reported as **both** within the appropriate sections of the eCRF. Please ensure that you continue to enter data and answer open queries in a timely manner. Thank you to all of the sites that have worked hard to keep their data consistently clean!

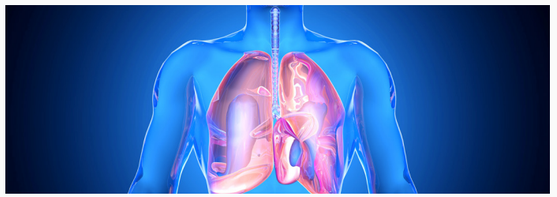
We encourage all site staff to be diligent with completing any new training modules in a timely manner, and it is particularly important that training be current prior to each onsite monitoring visit.

If you are interested in further information regarding this trial, please contact Clinical Trial Project Lead, Lyndsey Garritty at 1-800-707-9098, ext 4 or via email at **lyndsey.garritty@ualberta.ca,** or Senior Regulatory Specialist Kalli Renner, 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

MAP-AHF



The MRI Assessment of Pulmonary Edema in Acute Heart Failure study is a single-centre project taking place at the University of Alberta Hospital/Mazankowski Alberta Heart Institute in collaboration with the Peter S. Allen MR Research Centre.

The MAP-AHF study will determine the changes in *Lung Water Density* (i.e., quantification of pulmonary edema on MRI) over the course of hospitalization and treatment of Acute Heart Failure, as well as explore whether *Lung Water Density* is predictive of long term outcomes in the Acute HF population. Currently, this study is in its startup phase and we anticipate Dr. Richard Thompson and his team will enroll their first patient soon.

If you are interested in further information about the MAP-AHF study, please contact the Clinical Trial Project Lead, Karin Kushniruk, at 1-800-707- 9098, ext. 7 or **karin.kushniruk@ualberta.ca**.

Sponsored by: Canadian Institutes of Health Research MAP-AHF will examine the changes in lung water density over the course of treatment in patients hospitalized for acute heart failure, and will explore whether changes in lung water levels can predict long term outcomes.

ClinicalTrials.gov Identifier: NCT03999138

SODIUM-HF

The SODIUM-HF Operations Team is pleased to share that the study is nearing the 75% enrollment milestone! We encourage all sites to continue to enroll at least one patient/month in the home stretch!

If you have any suggestions, concerns or questions regarding increasing enrolment at your site, please reach out to Melisa Spaling (contact info below).

Regional Enrollment Summary:

- **Canada**: 470+ patients
- **Latin America**: 160+ patients
- **Australia & New Zealand**: ~90 patients

A special thank you to our Core Lab Personnel and all site personnel for responding to queries in a timely manner over the past weeks; this enabled the data to be as clean and up-to-date as possible for the upcoming data review. We appreciate your hard work and continued dedication to the SODIUM-HF trial!

Reminder - Dietitians:

Please remember to clarify as many details as possible with your study participants when reviewing their Food Records. Common Food Record queries include:

- the amount of any fluids consumed per day (including water)
- if any table salt was used and, if yes, the amount added
- cooking methods/preparation (e.g., boiled, fried, roasted, etc.)

Please continue to submit source documents and Food Records (or Food Recalls, where applicable) to **sodcore@ualberta.ca** as soon as possible after the visit. This enables timely analysis by the Core Lab and blinded event adjudication by the CEC. The date Food Records are sent to CVC should be entered into REDCap for internal verification purposes. For general study updates and news, follow us on Twitter **@sodiumhf**.

If you are interested in receiving more information about the SODIUM-HF trial, please contact the Clinical Trials 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 1-800-707-9098, 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 **S**tudy **O**f **DI**etary Intervention **U**nder 100 **M**MOL in **H**eart **F**ailure.

ClinicalTrials.gov Identifier: NCT02012179

FEAST-HF

Recruitment into the FEAST-HF pilot is nearly complete here at the University of Alberta. 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: NCT03409926

STREAM-2

A special acknowledgement to our local Canadian site who continues to lead the way as the highest enrolling site in this trial! Congratulations on this impressive achievement. Sites continue to enroll globally with July 2019 being the highest enrolling month so far. We encourage our Canadian site to keep up their search for potential subjects.

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.**

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

News

We are pleased to announce that **Dr. Padma Kaul** has taken on a new role as a **CVC Co-Director.**

We are introducing a new leadership model that will involve a partnership between the two current Co-Directors, Dr. Justin Ezekowitz (leading CVC's relationships with the Faculty of Medicine & Dentistry and the University at large, the Mazankowski Alberta Heart Institute and Alberta Health Services) and Dr. Shaun Goodman (leading the CVC in managing external academic research organizations and University of Toronto partnerships and continuing medical education) with a third Co-Director, Dr. Padma Kaul (leading data science, including machine learning, artificial intelligence, population health, and real world evidence research at the CVC). The three Co-Directors will continue to work closely with the Founding Director, Dr. Paul Armstrong, to fulfil the shared responsibilities of leading the CVC.

Congratulations to CVC Co-Director **Dr. Justin Ezekowitz** on his new appointment as the **Faculty of Medicine & Dentistry's Director of Cardiovascular Research** for a two year term, which commenced on August 15, 2019.

Along with his role as Co-Director of the CVC, Dr. Ezekowitz is a professor of medicine in the Division of Cardiology and a cardiologist at the University of Alberta Hospital and Mazankowski Alberta Heart Institute. He focuses his research and clinical work on heart failure. Dr. Ezekowitz is involved in numerous clinical trials in heart failure as the principal investigator, and is part of the steering committees for multicentre international trials. Other initiatives of Dr. Ezekowitz involve work with population health, registry-data and advanced data analytics around health system change and disease risk. In the position of Director, Cardiovascular Research, in partnership with Alberta Health Services, Dr. Ezekowitz will lead work to increase integration and collaboration in cardiovascular research in Edmonton and Northern Alberta.

New Staff

Dan Wales, CRA

Dan S Wales will be contracting with the CVC as a Senior Clinical Research Associate. He has been involved in clinical research since 1996 and has worked on many indications and all phases (I-IV) of clinical trial development. His experience encompasses a wide variety of knowledge and techniques. He is well versed in electronic eCRFs and has worked in many different systems. Mainly working as a field monitor, he has completed hundreds of site evaluations, initiations, and closeout visits as well as close to 4000 on site and remote monitoring visits. Dan can be contacted at 647-993-6194 or via email at **dwales@ualberta.ca.**

New Office Location

Publications

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Address for Inquiries:
4-120 Katz Group Centre for Pharmacy and Health Research, University of Alberta
Edmonton, AB, Canada, T6G 2E1
Phone: 1-800-707-9098 Fax: 780-492-0613

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