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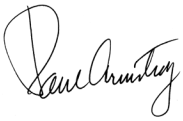
The leaves are off the trees, there is snow on the ground and Canadian Thanksgiving has receded into the distance in our rear view mirror. The winter solstice beckons and heralds both Christmas and the coming holiday season. Reflecting on this year that is passing and the new one looming ahead has always been a meaningful time for me. Counting my many blessings and appreciating the extraordinary privileges afforded to those of us engaged in the search for new and better solutions in health care is an integral part of that process. We must never take for granted the freedom to pursue our ideas that is only limited by our energy, talents and dedication.

For us at the Canadian VIGOUR Centre 2017 is a special year since it marks the 20th anniversary of the first **Canadian Cardiac Chronicle** that was distributed to our many colleagues and friends across Canada and around the world. In that original issue, we reported on the successful completion of GUSTO 3 (comparing reteplase to rTPA in STEMI) and PURSUIT (which evaluated eptifibatide in Non STE ACS). We also eagerly anticipated the arrival of ASSENT 2, SYMPHONY and GUSTO 4 as novel projects in development. In preparing to celebrate this 20th anniversary, I tracked down and spoke to one of our original project leads about the history of the CVC. She reported that in my original letter offering her a job I wrote, "Welcome aboard… It should be a great ride!" It has indeed been a great ride and the transformation in cardiovascular care over the past two decades has been truly remarkable.

The major improvement in outcomes of our patients with acute and chronic coronary disease as well as those with heart failure have been directly related to the fruits of research. It has been immensely gratifying to participate in this extraordinary and welcome shift in cardiovascular health. So too has been this journey decorated by several hard-won learnings and many wonderful collaborations that we have developed in every corner of the globe thereby enriching our professional lives.

Yet the unmet needs of our patients, their families and their family's families continue. New diseases and new insights into old diseases that we once mistakenly thought we understood keep us humble and catalyze us to do better. We have come to the stark realization that it is one thing to discover a new medicine or technique and quite another to ensure that it can be applied in an efficient and timely manner. Many of the major causes of CV morbidity and mortality remain unknown and we are grappling with an epidemic of obesity and diabetes. The costs of clinical trials has risen enormously and the administrative burden to undertake them has similarly grown. Our health care systems are groaning under burden of accelerating costs and we are being appropriately challenged to participate in finding value for investment. Fortunately a remarkable panoply of new tools ranging from stem cells, pharmacogenomics, precision medicine, big data and artificial intelligence have emerged that hold much promise in the search for new solutions. Recruiting the best and brightest young people to participate in this enterprise is the key to our future success.

On behalf of our great team at CVC let me send out very best wishes to all of you for a Happy Christmas, Hanukah or whatever you choose to celebrate in the days ahead. Take time to enjoy the warmth and company of your family and friends and recharge your batteries for the year ahead. We look forward to collaborating with you on the path to discovery and better cardiovascular health in 2018.



Paul W. Armstrong

HEART-FID

Congratulations to the following 3 Canadian sites that have enrolled their first participants!

- **Dr. Pandey, Jacqueline Lake,** Cambridge, ON
- **Dr. Ezekowitz, Quentin Kushnerik,** Edmonton, AB
- **Dr. Vizel, Bev Fox,** Cambridge, ON

We appreciate your hard work to get your site activated and enroll your first participant(s). Activated sites are now screening and we look forward to their first patient very soon. Please remember to continue to send in your pre-screening logs every Friday.

For all sites that are in start-up, please ensure you have discussed and appropriately documented the roles within your research team. Review the **Site Blinding Process Memo** and have a draft ready to review with your monitor when they are on site for your initiation visit which will facilitate activation of your site following the visit. For additional details regarding each role please contact us to discuss this further if needed.

If your site is not yet activated, we would appreciate anything you can do to finalize and submit all regulatory documents, continue to actively negotiate your budgets and site agreements and follow up with ethics regarding approvals on an ongoing basis. With your support, our goal is to have all sites in Canada active and recruiting early in the new year.

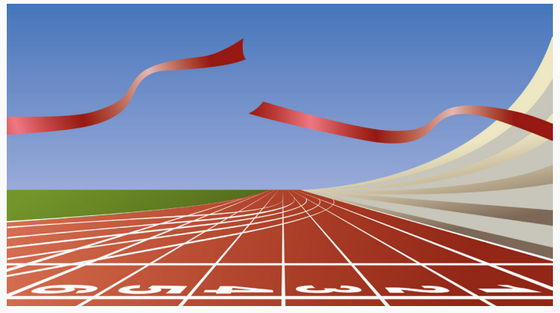
Happy holidays to you and your families! We look forward to continuing our work with you on this trial in the New Year.

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 Kalli Belseck, ext 6 or via email at **kalli@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

ODYSSEY OUTCOMES



We are in the final weeks of the Common Study End Date (CSED) and wish to extend our sincerest thanks for your hard work and dedication during this exciting and busy period.

Several significant study deadlines are quickly approaching, while others have successfully passed. We appreciate that sites have turned around large amounts of data in a short amount of time, and so we would like to recognize all of the study teams that are working diligently to enter data and resolve queries promptly.

As we prepare for the final monitoring visits we ask all sites to:

- Ensure all **regulatory requirements are complete;** including addressing all action items listed in the monitoring visit follow-up letters.
- If we are missing any **documents**, Paula will be in touch with your site to request them.
- Confirm that your site's PI can **access the study database RAVE** for casebook signing and let Paula Priest know if your site's PI has any issues accessing the database.

If the PI is planning time off/holidays, remember to prepare and have a back-up Sub-Investigator identified and trained to cover the investigator's responsibilities during that time.

For further information or questions regarding this trial, please contact Clinical Trial Project Lead Julianna Wozniak at 1-800-707-9098, Ext 1 or via email at **jwozniak@ualberta.ca.**

Sponsored by Sanofi-aventis Recherche & Développement this is a randomized, double-blind, placebo-controlled, parallel-group study to evaluate the effect of Alirocumab on the occurrence of cardiovascular events in patients who have recently experienced an Acute Coronary Syndrome.

ClinicalTrials.gov Identifier: NCT01663402

SODIUM-HF

Season's greetings everyone!

We are currently sitting at 459 patients and are inching closer and closer to the 500 patient mark. Let's keep up the screening and enrollment to hit that target by January next year! Dr. Ezekowitz recently challenged all SODIUM Principal Investigators and sites to a recruitment tournament with the first round ending December 31, 2017. We will announce the site "standings" early next year and let sites know who they will face during the next round. Good luck to all sites!

We would like to welcome **Haunnah Rheault's energetic team from Chemerside, Australia** and congratulate them on enrolling their first patient in November 2017. We would also like to welcome **Dr. Pandey's dynamic team from Cambridge, Ontario.** We eagerly await their first patient into SODIUM. We have three other sites from Canada, Australia and Colombia that we expect to activate early next year.

Please remember to frequently check your site's REDCap queries. Data queries are generated by our team and assigned to your site. However, you will not be prompted to log into REDCap if you have open queries, so it is important for you to check these queries frequently. For more information on viewing and responding to these queries, please refer to page 9 of the eCRF Data Entry Instructions. Reminders will be sent to sites that have not addressed all queries at the end of this quarter.

Also, the next data cut is **December 31, 2017.** Please ensure that all completed study visits and phone calls have been entered and saved as complete (i.e., green) in REDCap by the data cut. If you are sending 3-Day Food Records or source documents, please confirm that all documents have been received by the Core Lab before the upcoming deadline (**sodcore@ualberta.ca**).

We recently sent out the **SODIUM Visit Calculator** and the **Frequently Asked Questions Reference document.** The Visit Calculator is a tool to easily see when an enrolled patient's follow-up visits should be scheduled based on their baseline visit date. This is an optional tool that can be used on site as need. For the Frequently Asked Questions Reference Documents, we advise that sites carefully review this document and store with other important study manuals, as it will be useful during all study stages. This document contains FAQs regarding patient eligibility, screening, co-enrolment in other studies, study windows, the study protocol, the dietary intervention and REDCap.

If you are interested in receiving more information about the SODIUM-HF trial, please contact the Clinical Trial Project Lead, Nubia Zepeda, at 1-800-707-9098 ext 8, or via email at **nzepeda@ualberta.ca.** 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), 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

STREAM 2

The STREAM 2 study is examining the safety and efficacy of early fibrinolytic treatment of ST-elevation myocardial infarction patients compared to primary PCI. The study aims to enroll 600 patients in this multi-national multi-centre trial. This trial is currently enrolling patients in France with other sites around the globe planned to start recruiting shortly. We are looking forward to having our Canadian site active very soon.

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 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

GALILEO

Enrollment ended on a high note in Canada in early October. During the final 3 weeks of enrollment, 8 patients were randomized in Canada – 4 from Dr. Radhakrishnan's site alone! Bravo!

Congratulations on enrolling over 60 patients in Canada to GALILEO! Special congratulations go out to our top 3 enrolling sites:

- **Dr. Radhakrishnan and Camalene Chrysostoum,** Sunnybrook, ON
- **Dr. Della Siega and Elizabeth Pelzer,** Victoria, BC
- Dr. **Toleva, Kiran Atwal and James Ducas,** Winnipeg, MB

Now that we are in the Follow-up phase of the trial, patient retention and data cleaning are the focus.

Patient Retention

Please remember to review patient contact information **at every visit** to avoid any Lost-to-Follow-Up (LTFU) patients. We also want to avoid having any patients who completely withdraw from the study. There are many layers of withdrawal and it is our job to explain the options available to the patient. For instance, if the patient wishes to "stop the study", we need to find out what that means to the patient. Does the patient want to stop drug? (It could be temporary). Does the patient not want to come to clinic? Will the patient consider a phone visit or permit us to review their medical records to see how they are doing? Will the patient permit us to call them one final time at the end of the study?

These are the questions that need to be discussed with the patient (and documented in the patient's chart) to clarify what a patient means when they indicate that they don't want to participate any more. Safety follow-up with patients throughout the duration of the study is also an important aspect to discuss with patients who are considering withdrawal. At the very minimum, we (and the regulatory authorities like Health Canada and the US FDA) would like to know the patient's vital status at the end of the study (hence it is good to ask if the patient will permit one final phone call at the end of the study). And, if they agree to that, they are not considered to have completely withdrawn from the study. Thanks to the diligent work of our sites, this is a rare occurrence in Canada. Please contact CVC right away to discuss options if your GALILEO patient is thinking about "stopping the study".

Data Cleaning

Thanks to all of the study coordinators for your hard work in keeping the open queries to a minimum, and answering them within 5 business days. Thanks also for signing the Baseline and Screening Visits for your patients (once the data has been reviewed by the monitor, and is query-free). Per the e-CRF instructions (section 4.2), study coordinators can sign most CRF pages as they are completed and cleaned. At the end of the study, the PI will need to sign the Date of Last Visit form. CVC will continue to send sites their list of Visits that are ready to be signed.

Event Reporting

Per the recent communication from the sponsor, please be sure to report events even if they are only "suspected" events. The CEC will adjudicate these (and all) events, and decide if they are a study endpoint or not.

Key Reminders

- Ensure **copies of all study communications are on file at your site** (see the listing sent 30Oct2017), and let CVC know if you are missing any so it can be re-sent to you.
- Subsequent visits for EOT patients are called "**Scheduled visit (After EOT)" and must be manually added in Marvin.**
- Continue to send **invoices** to CVC for any outstanding items per your site's contract/budget.

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**.

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

VICTORIA-HF Registry

Thank you to all sites for completing part 1 and part 2 of the feasibility questionnaire over the last couple months! Using this information, we have invited select sites to participate in the Registry.

Our first round of site invitation letters and welcome packets have been sent to these select Canadian sites. Please remember to indicate your availability to participate in the site initiation visit calls using the link provided to you. We will begin to hold these visits throughout December.

We encourage all sites that will be participating in the registry to move forward with ethics submission and contracts negotiation as soon as possible. We expect that these processes should be fairly quick, and are excited to see rapid enrollment into the Registry once sites are up and running! A reminder to sites that the VICTORIA Registry is a stand alone study which does require a separate ethics submission and contract negotiation.

If you are interested in further information about the VICTORIA Heart Failure Registry, please contact the Clinical Trial Project Lead, Nubia Zepeda, at 780-492-0611 or via email at **nzepeda@ualberta.ca** or the Regulatory Specialist, Kalli Belseck via email at **kalli@ualberta.ca.**

VICTORIA-HF Registry

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

HILO-HF

Congratulations to **Dr. Ezekowitz, Nariman and Quentin** on their phenomenal rate of enrollment into the HILO Pilot Study and Registry!

The team passed the halfway milestone this fall, and have enrolled a total of 35 patients into the pilot study. That means they are only 15 patients away from reaching their goal of 50 patients. The team also continues to demonstrate strong enrollment of patients into the HILO-HF Registry, with 43 patients enrolled to date. Keep up the great work!

We also want to recognize Nariman's tireless efforts in recruiting and following up patients for HILO-HF. His steadfast determination to screen all possible patients and his enthusiasm for closely following-up patients is evidenced by the rapid movement of both studies thus far.

If you would like information on the HILO-HF study, please contact the Clinical Trial Project Lead, Nubia Zepeda, at 780-492-0611 or via email at **nzepeda@ualberta.ca.**

Funded by the Heart and Stroke Foundation and Alberta Innovates Health Solutions, HILO-HF is a study examining High versus Low SpO2 Oxygen Therapy in Patients with Acute Heart Failure.

ClinicalTrials.gov Identifier: NCT02518828

AEGIS-II

The Canadian VIGOUR Centre is pleased to be collaborating with Duke Clinical Research Institute and CSL Behring on AEGIS-II, a large, international, multicentre 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.

AEGIS-II is the successor to AEGIS-I, a phase IIb study that completed in 2016 and demonstrated the novel mechanism of action of CSL112 in an immediate increase of cholesterol efflux capacity, and demonstrated its safety and tolerability profile among patients following acute MI.

We are currently working through the site selection process, including the negotiation of confidential disclosure agreements and completion of feasibility surveys, with the sites initially approached.

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.**

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.

Monitoring Tips

Maintenance & Tracking of Investigational Product (IP)

In addition to maintaining accurate documentation of the IP, some of the most important site responsibilities while participating in a research trial include ensuring the correct **receipt, storage, security, dispensing, and return/destruction of the IP.**

When IP is first shipped from the Sponsor's depot, sites will be alerted that it is in-transit. This allows the site to watch for the IP and notify the designated person if it does not arrive. Upon arrival, there is usually a series of steps to acknowledge that the IP has arrived intact, undamaged, and without experiencing temperature excursions (if applicable). IP should immediately be **acknowledged as received** as soon as it arrives. If a temperature excursion has occurred during shipping, this should be reported without delay.

Once the IP is on site, it is the site's responsibility to ensure it is **maintained securely** and under the appropriate storage conditions. If temperature excursions occur, this should be reported immediately to avoid dispensation of potentially damaged IP to study participants. All IP that arrives on site must be carefully accounted for. To accomplish this, all trials will have some method of performing "**drug accountability**". Some trials have various paper logs to track the receipt, dispensing, and return/destruction of IP; others may use a "combo" log to capture everything on one form. More recently, some trials only utilize on-line systems. Whatever method is used to track IP, it is imperative that accountability is documented accurately and contemporaneously. Site staff must not only

be diligent to ensure that the IP dispensed is the same as what was assigned to the study participant, but also need to ensure that the dispensation is immediately captured on the accountability record.

IP should be noted as it is returned by the participants. If any IP is not accounted for (i.e., a participant lost a kit that they should have returned), this needs to be clearly documented in the source. Finally, the unused/used/expired IP will need to be returned for destruction or destroyed on site. A very careful accounting of the final dispensation of each kit is essential. Whoever is delegated to handle IP should regularly review accountability documentation to ensure that it is accurate and up-to-date at all times. If any component of the records is found to be incomplete, this should be rectified ASAP. For most trials, CRAs will be responsible for reviewing some or all aspects of IP accountability during monitoring visits.

If you have any questions regarding any aspect of **IP receipt/dispensation/destruction**, your CVC CRA would be pleased to answer them while on site. Your CVC Project Lead can also be contacted in between visits.

CVC News

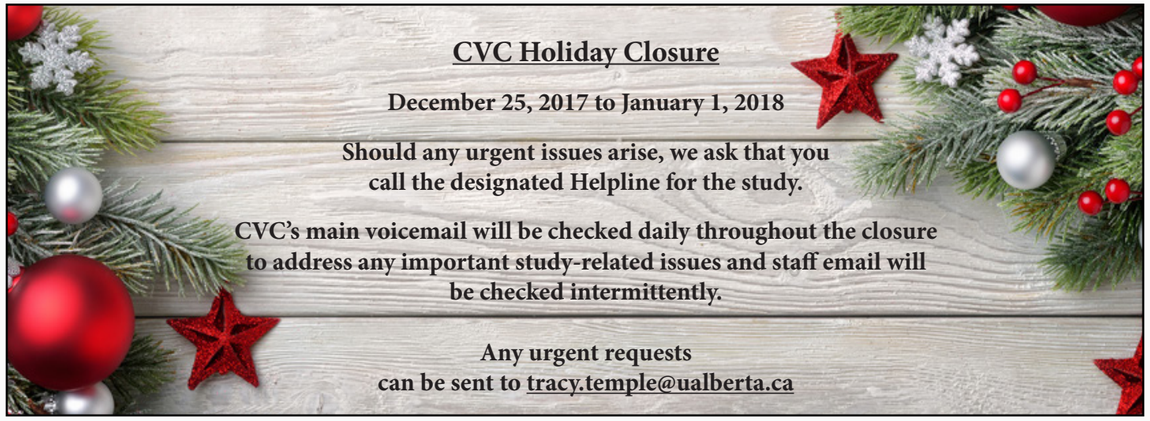
Karin Kushniruk has recently returned from a maternity leave and has resumed her position as a Clinical Trial Project Lead within the CVC Operations group. Karin will be assisting Julianna Wozniak on the EXSCEL Close Out and will transition onto other projects in the near future. Karin joined the CVC in 2015 and is excited to return to the team. Karin can be contacted at 780-492-8476 or **kushniru@ualberta.ca.**

Lyne Cantin joins CVC as a monitor for our Western Canadian HEART-FID sites. She started her career as a CCU nurse at the CHUL Hospital in Quebec and completed a baccalaureate in microbiology and a MBA in Pharmaceutical Management. Lyne has been managing as well as monitoring clinical research studies at different levels and stages with several organizations for 20 years. She is a problem solver, a great communicator and she thrives on helping sites achieve results. Lyne believes in simplicity and straight forward approaches.

Upcoming Events

- Early bird registration is now open for the **ACC Rockies** Canada's Premier Cardiovascular CME (February 25 – 28, 2018) in Banff, Alberta. More details can be found on the website www.accrockies.com.

- CVC is now planning the 5th Annual **CVC Clinical Trials Colloquium** and will be reaching out to select sites to join us in Banff on February 25, 2018.



Publications

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