The first sentence of every novel should be: Trust me, this will take time but there is order here, very faint, very human.

- In the Skin of a Lion, Michael Ondaatje

It comes as no surprise that this Chronicle arrives around the longest day of the year. The longest day, June 20th, will see nearly 18 hours of light in Edmonton – so, there is no limit to getting outside and enjoying the summer! Some of you are working equally long hours in your pursuit of clinical care or research activities and recognize that it can’t always be done in a day, or sometimes, even in a year.

The 150th year celebration for Canada, starting on July 1st, is an opportunity for us all to reflect on Canadian contributions to existing pivotal research, as well as those discoveries that are still to come. Similar to Canada’s history, research has to incorporate many changes over time, introduce adjustments where needed, and adapt to the environment while staying committed to the overarching goals we initially set out to test. Over the past 150 years, Canada has seen many challenges and we have recognized the importance of inclusivity, adapting to change, and ensuring that we remain committed to the goals set forth a long time ago. Importantly, Canada holds a unique place in the world and we value our friendships with our collaborators outside of Canada. Without our international friends and neighbours, we cannot achieve our collective goals.

Like the longest day of the year, the pathway from a research hypothesis regarding a molecule in a lab or a patient encounter resulting in an unanswered clinical question to the completion of a pivotal phase III clinical trial is similarly long (but measured in years). It often takes over 10 to 15 years to develop and refine a concept that we are all engaged in testing. Sometimes, this process can be much shorter; we look for these rapid, early wins when we are deciding what should be pursued and how it may impact human health. To that end, clinical research requires commitment over multiple years in order to continually train and re-educate teams with new techniques that advance how we all perform research. The commitment of patients participating in studies that can often run over multiple years also deserves consideration. It is this commitment (e.g., staying on therapy, coming back to the clinical research site, blood work, and repeat imaging) that I have to admire of our patient volunteers; we should make sure we express this when we see them each and every time.

The overall health of our research and clinical teams is often forgotten. I’d like to encourage you to make sure you are eating healthy, sticking to a minimum of 150 minutes per week of exercise, and maintaining your work/life balance. Get outside; you’ve earned it.

Justin Ezekowitz
CVC Co-director
**ODYSSEY OUTCOMES**

**Summer is here!**

Before the end of the year, sites are expected to begin conducting the final visits for all patients. Just a reminder when scheduling end of study visits to be sure you accommodate for any last-minute changes in the patients’ schedule, and to ensure there is sufficient time to obtain and submit the source documents for any reported Endpoints (CIC) or SAEs (Safety/PV).

As you know, **patient retention** is a key component to the outcome of any long-term clinical trial. In Canada, our performance regarding patient retention in ODYSSEY Outcomes is great. Keep up the great work by maintaining regular contact with your patients (for instance, by offering reduced follow-up methods such as medical records review or one final call at the end of the study) so that withdrawal of consent is prevented and no other patients become lost to follow-up.

Ideally, we want as many patients as possible to remain on study drug until the end of the study. Please let CVC know if your site is considering stopping study drug, either temporarily or permanently, for any patient. Dr. Goodman is available for consultation on any medical decisions with respect to holding or stopping study drug. For those patients who are currently off study drug temporarily, now is the time for the PI to decide whether the patient should resume study drug or permanently discontinue IPR.

The timelines for **data entry and query resolution** will tighten as we approach the end of the study. Please continue to be mindful of where you are sending source documents for SAEs and Endpoints, as Safety (PV) and the CEC are two distinct groups for the ODYSSEY Outcomes trial. The Safety emails that CVC sends out are for SAEs only. The CEC requires the documents listed on the CEC cover-sheet (depending on the Endpoint), or those that they request via queries in the database.

Please continue to complete your ICF logs as patients come in for their clinic visits this summer. If your site has any patients that are on reduced follow-up due to being off study drug, please follow your site’s SOP on the Consenting Process, or consult with your REB regarding the recommended process for these patients. Remember another option is that the patients sign during their CSED visit. Your monitor will check that this log is complete.

Throughout this summer, we will be reconciling the investigator site files at CVC. We thank you in advance for sending us copies of any requested documents which are required for the sponsor’s TMF. The more work that can be completed now, the smoother the close-out period will be.

If you have any questions about this trial, please contact Clinical Trial Project Lead, Jodi Parrotta, at 1-800-707-9098 ext. 3, or by email at jodi.parrotta@ualberta.ca. As of July 3, 2017 Julianna Wozniak will be assuming the role of Clinical Trial Project Lead.

**Congratulations to:**

- Dr. Macdonald, Kimberly, Carol, Carmen, and Hayley (Sydney, AUS)
- Dr. Bourke, Carla, and Romina (Osorno, CHL)
- Dr. Lasans and Ana (Temuco, CHL)

**SODIUM-HF**

As of June 22nd, the SODIUM-HF trial has 395 subjects randomized across 21 sites in Canada, Chile, Mexico, New Zealand, and Australia. We would like to welcome Dr. Macdonald and his team from Sydney, Australia to the study! Since being activated in March 2017, Dr. Macdonald’s site has enrolled six new patients into SODIUM-HF. We would also like to welcome Dr. Atherton’s team from Melbourne, Australia to the SODIUM-HF study. The site was recently activated and we look forward to the enrollment of their first patient! Additionally, numerous new Canadian and International sites have expressed an interest in joining this exciting study. We look forward to working with these sites to activate them over the coming months.

We would also like to announce the winners of the Winter/Spring Enrollment Challenge. Our INTERNATIONAL Team was able to boost enrollment from 0.79 patients/month to 0.86 patients/month! The team has since increased their enrollment number to 1.08 patients/month, as of June 1st, 2017.

**Congratulations to:**

- Dr. Escobedo, Grecia, and Lilia (Mexico City, MEX)
- Dr. Troughton, Lorraine, and Catherine (Christchurch, NZ)

Thank you to all site personnel who joined the recent Dietitian/Study Coordinator Working Group Teleconference on June 19th during which we covered trial updates, enrollment, REDCap reminders, study FAQs, adjudication, and study metrics. If you are unable to attend, keep your eyes out for the June Trial Newsletter where we will provide study updates and meeting minutes.

**General data queries and REDCap data queries** were recently sent to all sites. As a reminder, please respond to all queries by the upcoming data entry cut on June 30th, 2017. Please ensure that all completed study visits and phone calls have been entered and saved as complete (i.e., green) data. 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.

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 nzepeda@ualberta.ca. You may also contact the SODIUM-HF trial Regulatory Specialist, Kate Dawson, via email at kedawson@ualberta.ca.

**HEART-FID**

Start-up is picking up speed in Canada for the HEART-FID trial! We are working closely with sites to complete ethics submissions and other regulatory requirements in order to get sites activated as quickly as possible. We are aiming to have our first site activated in late July with Canada’s first patient to be enrolled shortly afterwards. We appreciate our sites’ continued interest and commitment to this exciting trial.

Stay tuned for more information on plans for an upcoming Investigator Meeting. Only sites with an executed contract will be able to attend. Therefore, we strongly encourage all sites to work towards achieving a finalized contract as quickly as possible so that your site can attend the meeting.

We are still searching for additional Canadian sites that would be interested in participating in this trial. If you would like more information about HEART-FID, please contact Clinical Trial Project Lead, Courtney Gubbels, at 1-800-707-9098 ext 2, or via email at courtney.gubbels@ualberta.ca. You may also reach Regulatory Specialist, Kalli Underwood, at 1-800-707-9098 ext 6, or via email at kalli@ualberta.ca.

Sponsored by Luitpold Pharmaceuticals Inc., HEART-FID is a multicentre, randomized, open-label study Of MOL in Heart Failure.

ClinicalTrials.gov Identifier: NCT02012179

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

ClinicalTrials.gov Identifier: NCT03077931
The last few months have been busy for the EXSCEL Trial! Casebook signing occurred at the beginning of May, database lock followed on May 11th, and close-out visits began shortly afterwards. Site close-out visits are currently well underway, with the last visit for Canadian sites scheduled in late June.

On May 23, 2017 AstraZeneca announced the topline results of the EXSCEL study:

“(1) Based on a composite measure of major adverse CV events (MACE), Bydureon did not increase cardiovascular (CV) risk and showed a consistent safety profile.

(2) Fewer CV events were observed in the Bydureon arm, however, the efficacy objective of reduction in CV risk did not reach statistical significance.”

A complete evaluation of the EXSCEL data is ongoing. The full trial results will be presented at the European Association for the Study of Diabetes (EASD) annual meeting on Thursday, September 14th, 2017 in Lisbon, Portugal.

**General End-of-Trial Reminders:**

**Invoicing:** Please send any remaining/outstanding study related invoices to Linda Wesson, linda.wesson@duke.edu, for processing ASAP.

**Study Archival:** A CD containing your patient data is expected to be sent to your site by August 2017. It is required that you make study records available if requested by Health Canada, the FDA, or other regulatory authority. If you are contacted by any of these regulatory authorities regarding this protocol, please notify the sponsor, your REB, and your CVC Project Lead as soon as possible to receive audit preparation assistance.

**Financial Disclosure:** Principal Investigators and Sub-Investigators are required to promptly provide any relevant updates to previously-submitted financial disclosure/certification forms for one year following the study end date. Kindly forward any updates for you and any additional investigators or sub-investigators listed on the 1572 to the Project Lead at CVC. If financial disclosure/certification status remains unchanged, no action is required.

**Regulatory Specialist:** Kate Dawson, is supporting the regulatory component of the trial’s closure and may be in touch if any corrections or clarifications are needed for any of your site’s essential documents. Kate can be reached by phone at 780-492-3789 or by email at kedawson@ualberta.ca.

Thank you all for your continued support, enthusiasm, and dedication to the EXSCEL trial in these final months! For further information 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.

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**ClinicalTrials.gov Identifier:** NCT01144338

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**EXSCEL**

The Canadian Cardiac Chronicle

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**VICTORIA-HF Registry**

We plan to enroll 2000 heart failure patients at approximately 40 sites across North America.

We look forward to starting feasibility in the coming weeks with select VICTORIA sites. We plan to move forward with ethics submission, regulatory, and contracts shortly thereafter.

If you are as site participating in the VICTORIA study and interested in further information about the VICTORIA Heart Failure Registry, please contact the Clinical Trial Project Lead, Nubia Zepeda, at 1-800-707-9098 ext 8, or via email at nzepeda@ualberta.ca. Regulatory Specialist, Kalli Belseck, may also be contacted via email at kalli@ualberta.ca.

**VICTORIA-HF Registry**

**Sponsored by Merck and Bayer**

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**STREAM-2**

In Canada, STREAM-2 is being conducted in Edmonton, Alberta. Construction of the foundation for this unique collaboration between pre-hospital Emergency Medical Professionals and PCI centres is well underway. Dr. Robert Welsh, the Principal Investigator in Edmonton, is working collaboratively with CVC towards study start up.

 Globally, 600 patients are expected to be enrolled in the trial, with the first patient enrollment to occur in the coming weeks. We look forward to Canada contributing to enrollment very soon.

If you would like 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. You may also contact Regulatory Specialist, Kalli Belseck, at 1-800-707-9098 ext 6, or via email at kalli@ualberta.ca.

**ClinicalTrials.gov Identifier:** NCT02777580

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**HILO-HF**

Congratulations to Dr. Ezekowitz, Nariman, and Quentin for their rapid enrollment of patients into the HILO-HF pilot study and registry!

To date, the team has enrolled approximately 10 patients into the pilot study and 22 patients into the registry. This is great news, as they have reached the 20% enrollment mark for the pilot study!

We would also like to remind investigators of the upcoming Steering Committee meeting on June 26th, 2017. We will provide trial updates, and discuss enrollment and study data at this meeting.

If you would like further information about the HILO-HF study, please contact the Clinical Trial Project Lead, Nubia Zepeda, at 1-800-707-9098 ext 8, or via email at nzepeda@ualberta.ca.

**ClinicalTrials.gov Identifier:** NCT02318828
Galileo is a Global multicenter, open-label, randomized, event-driven, accrual-controlled study comparing a rivaroxaban-based anticoagulant strategy to an antiplatelet-based strategy after transcatheter aortic valve replacement (TAVR) to optimize clinical outcomes.

GALILEO - sponsored by Bayer Healthcare AG

ClinicalTrials.gov Identifier: NCT02562603

With summer vacations fast approaching, we encourage sites to keep up patient screening throughout the summer, as every patient in Canada that is able to contribute to the enrollment target is up to date and all queries are answered in the weeks ahead.

Site Study Reminders

- As this is an event-driven trial, it is important to enter data on an ongoing basis. Please try to log in regularly to make sure that your site’s data are clean.
- Even though the protocol states that Visit 4 is a 180 day telephone assessment, all Canadian patients are required to have an on-site visit.
- Please remember to record all endpoints within 24 hours of awareness and upload any required source documents to Box.

We are pleased to share with you our recently published 2016 Annual Report. This year’s theme, Moving Forward Together, speaks to our organization’s commitment to finding a path forward that reflects the evolution of cardiovascular health care, as well as the research strategies needed to inform its future.

The theme for 2016 also touches on the importance of collaboration. The African proverb “If you want to go fast, go alone. If you want to go far, go together” perhaps best expresses the progress we have made as a Centre over the last two decades, and the strong relationships we have built with our many partners across Canada and around the world.

We hope you enjoy reading more about who we are and what we do.

CVC News

Karen Mellor has very recently joined the CVC as the Associate Director of Operations. Previously, Karen received her CPA, CMA designation in Alberta while working with BDO Dunwoody, a public accounting firm in Edmonton. She furthered her education by diversifying into systems work. Karen has successfully obtained the CISA, CISM, and CGEIT designations from the Information Systems Audit and Control Association (ISACA), as well as the CISSP designation from the International Information Systems Security Certification Consortium (ISSC). She has also worked with the University of Alberta in the Office of Advancement and is happy to be back on campus. Karen can be contacted at 780-492-6474 or by email at karen.mellor@ualberta.ca.

Devon Blanchette has recently returned from maternity leave and has resumed her position as a Regulatory Specialist within the CVC Clinical Operations team. Devon is currently supporting the GALILEO trial and will be transitioning onto new projects in the near future. Devon originally joined CVC in 2014 and is excited for the work. Devon can be reached at 780-492-1651 or by email at devon.blanchette@ualberta.ca.

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