

The Canadian Cardiac Chronicle



Volume 21, Issue No. 2

CANADA 150

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 (CEC) 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 IP.

The timelines for **data entry and query resolution** will tighten as we approach the end of the study. Please ensure your Principal Investigator, along with any back-up data-entry person (e.g., another study coordinator) or back-up CRF-signing person (e.g., a sub-investigator to whom this task has been delegated), has access to the study database. It will be a very busy and challenging period. Having properly delegated and trained "back-ups" in place will help immensely!

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 responsibilities as the primary Clinical Trial Project Lead as Jodi transitions off the project.

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



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 for 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. Macdonald, Kimberley, Carol, Carmen, and Hayley (Sydney, AUS)**
- **Dr. Bourke, Carla, and Romina (Osorno, CHL)**
- **Dr. Lanas and Ana (Temuco, CHL)**

- **Dr. Escobedo, Grecia, and Lubia (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 were 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) 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).

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 Study Of Dietary Intervention Under 100 MMOL in Heart Failure.

ClinicalTrials.gov Identifier: NCT02012179

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 Belseck, at 1-800-707-9098 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

EXSCEL

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 recommended that you do not archive your site’s documents until the green-light has been given by the sponsor.

REB Closure: Please ensure that you submit your site’s study termination report to your local/central REB, as applicable, following your closeout visit. Forward any relevant submission/approval documents to the Project Lead and file the final report in your ISF.

Record Retention: Investigators must retain all study records and source documents for the maximum period required by applicable regulations and guidelines. As per Health Canada regulations, investigators are responsible for maintaining all study-related records, including essential documents, for 25 years. The Investigator must contact the sponsor prior to destroying any records associated with the study. If the Investigator withdraws from the study for any reason (e.g., retirement, relocation), the records shall be transferred to a mutually agreed upon designee. Notice of such a transfer will be given in writing to the sponsor.

FDA/Health Canada Audit: 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.

Sponsored by AstraZeneca, this trial is a pragmatic, long term, placebo-controlled, double-blinded trial which seeks to characterize the effects of exenatide once weekly on cardiovascular (CV) - related outcomes in patients with type 2 diabetes when added to the current usual care for glycemic control in a standard care setting.

EXSCEL
Exenatide Study of Cardiovascular Event Lowering

ClinicalTrials.gov Identifier: NCT01144338

VICTORIA-HF Registry



The Canadian VIGOUR Centre is excited to collaborate with the Duke Clinical Research Institute on the VICTORIA Heart Failure (HF) Registry. This new registry complements the VICTORIA randomized clinical trial to further broaden our understanding of heart failure.

The VICTORIA-HF Registry aims to characterize the evolution of standard of care and patient flow throughout the duration of the VICTORIA randomized clinical trial.

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



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.

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

HILO-HF

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

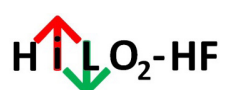
To date, the team has enrolled approximately 10 patients into the pilot study and 22 patients into the registry. This is great news, as they have reached the 20% enrollment mark for the pilot study!

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.

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

GALILEO

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 important.

In preparation for an upcoming DSMB meeting please ensure your data are 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.

- You can now delete a "Prior and Concomitant Medication" page in the eCRF, if required. You no longer have to send a data deletion request.
- Please continue to send your screening logs to us on a weekly basis.

If you are interested in further information regarding this trial, please contact the 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 the Regulatory Specialist, Devon Blanchette, at 780-492-1651, or via email at devon.blanchette@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

UPCOMING TRIALS

We are excited to be exploring some new trial opportunities in Acute Coronary Syndromes as well as Heart Failure, which we look forward to sharing with you in the months ahead. In addition to your email, keep an eye on our upcoming Chronicle issues for these new opportunities. If you have any questions about new trials and opportunities please contact Tracy Temple, Associate Director - Clinical Trials @ 1-800-707-9098 Option 5 or by email at tracy.temple@ualberta.ca.



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 System Security Certification Consortium (ISC²). 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 to be back. Devon can be reached at 780-492-1651 or by email at devon.blanchette@ualberta.ca.

CVC Annual Report 2016

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.



A PDF copy of the annual report can be found on our website at www.vigour.ualberta.ca

Publications

Alfredsson J, Neely B, Neely ML, Bhatt DL, Goodman SG, Tricoci P, Mahaffey KW, Cornel JH, White HD, Fox KA, Prabhakaran D, Winters KJ, Armstrong PW, Ohman EM, Roe MT; TRILOGY ACS Investigators. [Predicting the risk of bleeding during dual antiplatelet therapy after acute coronary syndromes](#). Heart. 2017 pii: heartjnl-2016-310090.

Armstrong PW, Van de Werf F. [STREAM characterisation correction](#). Lancet. 2017;389:2102.

Armstrong PW, Ezekowitz JA. [Navigating choices among a sea of comorbidities](#). J Am Coll Cardiol. 2017;69:2380-2382.

Armstrong PW, Westerhout CM. [Composite End Points in Clinical Research: A Time for Reappraisal](#). Circulation. 2017;135:2299-2307.

Bainey KR, Kaul P, Armstrong PW, Savu A, Westerhout CM, Norris CM, Brass N, Traboulsi D, O'Neill B, Nagendran J, Ali I, Knudtson M, Welsh RC. [Hospital variation in treatment and outcomes in acute coronary syndromes: Insights from the Alberta Contemporary Acute Coronary Syndrome Patients Invasive Treatment Strategies \(COAPT\) study](#). Int J Cardiol. 2017;241:70-74.

Benoit MA, Bagshaw SM, Norris CM, Zibdawi M, Chin WD, Ross DB, van Diepen S. [Postoperative complications and outcomes associated with a transition to 24/7 intensivists management of cardiac surgery patients](#). Crit Care Med. 2017;45:993-1000.

Bowker SL, Savu A, Yeung RO, Johnson JA, Ryan EA, Kaul P. [Patterns of glucose-lowering therapies and neonatal outcomes in the treatment of gestational diabetes in Canada, 2009-2014](#). Diabet Med. 2017 doi: 10.1111/dme.13394.

Brown PM, Ezekowitz JA. [Letter by Brown and Ezekowitz regarding article, "Development and evolution of a hierarchical clinical composite end point for the evaluation of drugs and devices for acute and chronic heart failure: A 20-year perspective"](#). Circulation. 2017;135:e889-e891.

Butalia S, Donovan L, Savu A, Johnson J, Edwards A, Kaul P. [Postpartum diabetes testing rates after gestational diabetes mellitus in Canadian women: A population-based study](#). Can J Diabetes. 2017 pii: S1499-2671(16)30261-1.

Chan M, Neely ML, Roe MT, Goodman SG, Erlinge D, Cornel JH, Winters KJ, Jakubowski JA, Zhou C, Fox KAA, Armstrong PW, White HD, Prabhakaran D, Ohman EM, Huber K; TRILOGY ACS Investigators. [Temporal biomarker profiling reveals longitudinal changes in risk of death or myocardial infarction in non-ST-segment elevation acute coronary syndrome](#). Clin Chem. 2017;63:265-272.

Dalby AJ, Gottlieb S, Cyr DD, Magnus Ohman E, McGuire DK, Ruzyllo W, Bhatt DL, Wiviott SD, Winters KJ, Fox KAA, Armstrong PW, White HD, Prabhakaran D, Roe MT; TRILOGY ACS Investigators. [Dual antiplatelet therapy in patients with diabetes and acute coronary syndromes managed without revascularization](#). Am Heart J. 2017;188:156-166.

Dhesi S, Savu A, Ezekowitz JA, Kaul P. [Association Between Diabetes During Pregnancy and Peripartum Cardiomyopathy: A Population-Level Analysis of 309,825 Women](#). Can J Cardiol. 2017 pii: S0828-282X(17)30073-9.

Donovan LE, Edwards AL, Savu A, Butalia S, Ryan EA, Johnson JA, Kaul P. [Population-Level Outcomes with a 2-Step Approach for Gestational Diabetes Screening and Diagnosis](#). Can J Diabetes. 2017;S1499-2671.

Gouda P, Gouda J, Butler C, Welsh RC. [Late presentation of an anomalous left coronary artery from the pulmonary artery treated with conservative surgical management with long-term cardiac magnetic resonance imaging follow-up](#). SAGE Open Med Case Rep. 2017;23:5.

Hess CN, Clare RM, Neely ML, Tricoci P, Mahaffey KW, James SK, Alexander JH, Held C, Lopes RD, Fox KAA, White HD, Wallentin L, Armstrong PW, Harrington RA, Ohman EM, Roe MT. [Differential occurrence, profile, and impact of first recurrent cardiovascular events after an acute coronary syndrome](#). Am Heart J. 2017;187:194-203.

Katz JN, Lishmanov A, van Diepen S, Yu D, Shen H, Pauley E, Bhatia J, Buntaine A, Das A, Dangerfield C, McLaughlin B, Stouffer GA, Kaul P. [Length of Stay, Mortality, Cost, and Perceptions of Care Associated With Transition From an Open to Closed Staffing Model in the Cardiac Intensive Care Unit](#). Crit Pathw Cardiol. 2017;16:62-70.

Publications Continued

Khan NA, McAlister FA, Pilote L, Palepu A, Quan H, Hill MD, Fang J, Kapral MK. [Temporal trends in stroke incidence in South Asian, Chinese and white patients: A population based analysis.](#) PLoS One. 2017;12:e0175556.

Lyons KJ, Ezekowitz JA, Liang L, Heidenreich PA, Yancy CW, DeVore AD, Hernandez AF, Fonarow GC. [Impact of current versus previous cardiac resynchronization therapy guidelines on the proportion of patients with heart failure eligible for therapy.](#) JACC Heart Fail. 2017;5:388-392.

Mackie AS, Tran DT, Marelli AJ, Kaul P. [Cost of congenital heart disease hospitalizations in Canada: A population-based study.](#) Can J Cardiol. 2017;33:792-798

McAlister FA, Youngson E, Kaul P. [Patients with heart failure readmitted to the original hospital have better outcomes than those readmitted elsewhere.](#) J Am Heart Assoc. 2017;6:e004892.

McAlister FA, Youngson E, Eurich DT. [Treatment Deintensification Is Uncommon in Adults With Type 2 Diabetes Mellitus: A Retrospective Cohort Study.](#) Circ Cardiovasc Qual Outcomes. 2017;10:e003514.

Mehta RH, Leimberger JD, van Diepen S, Meza J, Wang A, Jankowich R, Harrison RW, Hay D, Frenes S, Duncan A, Soltesz EG, Lubner J, Park S, Argenziano M, Murphy E, Marcel R, Kalavrouziotis D, Nagpal D, Bozinovski J, Toller W, Heringlake M, Goodman SG, Levy JH, Harrington RA, Anstrom KJ, Alexander JH; LEVO-CTS Investigators. [Levosimendan in patients with left ventricular dysfunction undergoing cardiac surgery.](#) N Engl J Med. 2017;376:2032-2042.

Ohman EM, Roe MT, Steg PG, James SK, Povsic TJ, White J, Rockhold F, Plotnikov A, Mundl H, Strony J, Sun X, Husted S, Tendera M, Montalescot G, Bahit MC, Ardissino D, Bueno H, Claeys MJ, Nicolau JC, Cornel JH, Goto S, Kiss RG, Güray Ü, Park DW, Bode C, Welsh RC, Gibson CM. [Clinically significant bleeding with low-dose rivaroxaban versus aspirin, in addition to P2Y12 inhibition, in acute coronary syndromes \(GEMINI-ACS-1\): a double-blind, multicentre, randomised trial](#) Lancet. 2017;386:1799-1808.

Pang PS, Butler J, Collins SP, Cotter G, Davison BA, Ezekowitz JA, Filippatos G, Levy PD, Metra M, Ponikowski P, Teerlink JR, Voors AA, Bharucha D, Goin K, Soergel DG, Felker GM. [Biased ligand of the angiotensin II type 1 receptor in patients with acute heart failure: a randomized, double-blind, placebo-controlled, phase IIB, dose ranging trial \(BLAST-AHF\).](#) Eur Heart J. 2017 ehx196. doi: 10.1093.

Raslan IR, Brown P, Westerhout CM, Ezekowitz JA, Hernandez AF, Starling RC, O'Connor C, McAlister FA, Rowe BH, Armstrong PW, van Diepen S. [Characterization of hemodynamically stable acute heart failure patients requiring a critical care unit admission: Derivation, validation, and refinement of a risk score.](#) Am Heart J. 2017;188:127-135.

Rodés-Cabau J, Masson JB, Welsh RC, Garcia Del Blanco B, Pelletier M, Webb JG, Al-Qoofi F, Généreux P, Maluenda G, Thoenes M, Paradis JM, Chamandi C, Serra V, Dumont E, Côté M. [Aspirin versus aspirin plus clopidogrel as antithrombotic treatment following transcatheter aortic valve replacement with a balloon-expandable valve: The ARTE \(Aspirin Versus Aspirin + Clopidogrel Following Transcatheter Aortic Valve Implantation\) randomized clinical trial.](#) JACC Cardiovasc Interv. 2017 pii: S1936-8798(17)30812-9.

Rosychuk RJ, Rowe BH, McAlister FA. [Geographic clustering of emergency department presentations for acute coronary syndromes and heart failure in Alberta: a population-based study.](#) CMAJ Open. 2017;5:e402-e410.

Rydén L, Van de Werf F, Armstrong PW, McGuire DK, Standl E, Peterson ED, Holman RR. [Corrections needed to 2016 ESC and AHA guidelines on heart failure.](#) Lancet Diabetes Endocrinol. 2017;5:325-326.

Tan NS, Sarak B, Fox KA, Brieger D, Steg PG, Gale CP, Bhatt DL, Spencer FA, Grondin FR, Goodman SG, Yan AT; Canadian GRACE/GRACE-2 and CANRACE Investigators. [Pulse pressure in acute coronary syndromes: Comparative prognostic significance with systolic blood pressure](#) Eur Heart J Acute Cardiovasc Care. 2017;1:2048872617700871.

Valgimigli M, Costa F, Lokhnygina Y, Clare RM, Wallentin L, Moliterno DJ, Armstrong PW, White HD, Held C, Aylward PE, Van de Werf F, Harrington RA, Mahaffey KW, Tricoci P. [Trade-off of myocardial infarction vs. bleeding types on mortality after acute coronary syndrome: lessons from the Thrombin Receptor Antagonist for Clinical Event Reduction in Acute Coronary Syndrome \(TRACER\) randomized trial.](#) Eur Heart J. 2017;38:804-810.


van Diepen S, Merrill PD, Carrier M, Tardif JC, Podgoreanu M, Alexander JH, Lopes RD. [Association between CK-MB Area Under the Curve and Tranexamic Acid Utilization in Patients Undergoing Coronary Artery Bypass Surgery.](#) J Thromb Thrombolysis. 2017;43:446-453.

Wang A, Kwee LC, Grass E, Neely ML, Gregory SG, Fox KAA, Armstrong PW, White HD, Ohman EM, Roe MT, Shah SH, Chan MY. [Whole blood sequencing reveals circulating microRNA associations with high-risk traits in non-ST-segment elevation acute coronary syndrome.](#) Atherosclerosis. 2017;261:19-25.



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

Address for Inquiries:
2-132 Li Ka Shing Centre for Health Research Innovation, University of Alberta
Edmonton, AB, Canada, T6G 2E1
Phone: 1-800-707-9098, Fax: (780) 492-0613
www.thecvc.ca

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

AstraZeneca	Heart & Stroke Foundation
Amylin Pharmaceuticals	Luitpold Pharmaceuticals Inc.
CIHR	Sanofi-Aventis Recherche & Développement
Bayer Health Care AG	

Chronicle Editorial Board		
Paul W. Armstrong	Shaun Goodman	Kris Reay
Jodi Parrotta	Julianna Wozniak	Melisa Spaling
Justin Ezekowitz	Corrina Boyd	Tracy Temple
Nubia Zepeda	Courtney Gubbels	Kate Dawson