The Canadian Cardiac Chronicle

Volume 20, No. 3 **Fall 2016**

Rome wasn't built in a day.

As the summer winds down and we prepare for the autumn equinox, many are returning from the European Society of Cardiology Congress in Rome, Italy. Rome, an ancient city with a long history of philosophical and scientific discourse, hosted this major event which explored new developments across the spectrum of cardiovascular disease.

The CVC, you as our investigative partners at our Canadian sites from coast-to-coast, and our scientific partners – Merck (Global and Canada), Bayer, DCRI and Stanford – are launching the VICTORIA trial. This trial, testing an oral soluble guanylate cyclase modulator, will enroll nearly 5000 of our volunteer patient partners that suffer from heart failure in a long term phase 3 trial. Canada is committed to playing a major role in the advancement of care and we value the time that each of you dedicate to participating in long-term trials such as this.

Key to launching a trial with all the complexity of electronic portals, regulatory documents, or ethics submissions is the training of study coordinators, principal investigators and all the personnel that make a trial of this magnitude possible. While much of the training occurs before a site is 'activated', there is a need to continually educate ourselves on new issues, solve problems and develop creative solutions to keep patients engaged in a longer trial. Many of you are experts at this and through sharing of best practices, others can gain from your wisdom.

Investigator meetings, often at the start of a trial or a rejuvenation meeting, serve as an opportunity to meet your colleagues, refine enrollment, share follow-up techniques and help clarify the 'how-to' of a trial aspect. This interaction with your colleagues should not be underestimated as these colleagues may provide a good sounding board for problems that can potentially arise during a multi-year project. As you are aware, we often ask experienced, high performing sites to actively participate and educate us all – including those deeply involved in the design or operations of a major trial. We can all learn something by interacting.

We encourage you to interact with us as we all arrive in Montreal in October. We have two additional educational offerings at the Canadian Cardiovascular Congress (CCC) that cover the spectrum of cardiovascular disease – atrial fibrillation, diabetes, coronary artery disease, and heart failure – under the Beyond2000 umbrella **http://beyond2000.org** (also see insert). We have a panel of national and international experts in a dynamic program on Monday morning (Acute Coronary Syndromes, and Heart Failure and Atrial Fibrillation, Room 517B) and encourage you to register and participate with us.

Justin Ezekowitz
CVC Co-director

In This Issue:

GALILEO

All 10 sites in Canada and nearly 125 sites globally have now been activated for enrollment in GALILEO. As of September 1, 2016, over 200 patients have been randomized into this study which aims to compare a Rivaroxaban-based antithrombotic strategy to an antiplatelet-based strategy after a successful transcatheter aortic valve replacement (TAVR).

Congratulations to our first 2 enrolling sites in Canada:

1. Dr. Welsh, Norma Hogg and Suzanne Welsh (University of Alberta, Edmonton)

2. Dr. Toleva, Dolores Friesen (St. Boniface Hospital, Winnipeg)

Dr Welsh is our National Lead (and Executive Committee member) for GALILEO, and was the first site in Canada to randomize a patient. Dr. Toleva followed that up with 2 randomizations within a couple of weeks this summer. We look forward to having all sites randomize their first patients soon.

We anticipate the upcoming protocol amendment will help to boost recruitment at our sites in Canada especially where patients are commonly discharged on the next day. With this amendment, ICFs will need to be revised. Stay tuned and watch your email in the coming weeks for the protocol and ICF. CVC will work with sites to obtain REB approval, so these changes can be implemented as soon as possible.

Sites were sent two Summary Reports of SUSARs for Rivaroxaban (3-month and 6-month). Please ensure both reports are reviewed by the PI and then submitted to your REB per their reporting requirements.

Please send CVC a copy of the REB correspondence (submission and/or acknowledgement). Don't forget to continue sending CVC a copy of your screening logs every Thursday.

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 Paula Priest, ext 9 or paula.priest@ualberta.ca.

Sponsored by Bayer Healthcare AG, GALILEO is a Global multi-center, 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

GUIDE-IT

Congratulations to all Canadian sites for an excellent contribution to the study enrollment.

We would like to extend our sincere appreciation for all your hard work in the trial and especially during this busy Close-Out period. Thank you to all sites for meeting the EOS visits deadline and for preparing your data for data base lock.

It has been a pleasure collaborating with all of you and we look forward to our continued work together during the remaining Close-Out period.

For further information regarding this trial, please contact Clinical Trial Project Lead Karin Kushniruk at 1-800-707-9098 ext 1 or via email at kushniru@ualberta.ca.

In collaboration with DCRI (Duke Clinical Research Institute) and Roche, GUIDE-IT is a prospective, randomized 1:1, multi-centre clinical trial **GUID**ing **E**vidence Based Therapy Using Biomarker **I**ntensified **T**reatment in Heart Failure.

ClinicalTrials.gov Identifier: NCT01685840

The Canadian Cardiac Chronicle - Volume 20

AEGIS-I

We are in the final stretch of the AEGIS-I trial! Now that all close out visits have been completed, please ensure that you keep an eye out for any emails from CVC requesting outstanding regulatory or final close out documents.

If you have not already done so please provide CVC with a copy of your submission to ethics notifying them of study closure as well as details regarding the location of where your study documents will be archived.

We look forward to sharing the results of this exciting trial with you at the American Heart Association Meetings where it will be presented in the late breaking clinical trials session LBCT.03 at 10:45 a.m. -12:00 p.m. on Tuesday, November 15, 2016.

Thank you for all of your hard work in support of the AEGIS-I trial!

For 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 Kalli Belseck at 780-492-4011 or kalli@ualberta.ca.

Sponsored by CSL Behring LLC, this study is a Phase 2b, multi-center, randomized,placebo-controlled, dose-ranging study to investigate the safety and tolerability of multiple dose administration of CSL112 in subjects with acute myocardial infarction.

ClinicalTrials.gov Identifier: NCT02108262

LEVO-CTS

Over 800 patients have now been randomized at approximately 60 sites. The Canadian contribution to this trial has been outstanding! We randomized our 150th patient in August.

Congratulations and many thanks to our top 5 enrolling sites:

1. Dr. Kalavrouziotis, Hugo Tremblay & Nathalie Gagne (Laval, QC): 29 patients

2. Dr. Nagpal & Stephanie Fox (London, ON): 29 patients

3. Dr. Bozinovski & Sheryll Sorensen (Victoria, BC): 22 patients

4. Dr. Teoh, Heather Hobson & Alexis Nikitopoulos (Southlake, ON): 18 patients

5. Dr. Mazer, Charmagne Crescini & Sanjay Yagnik (Toronto, ON): 16 patients

We are rapidly approaching the end of enrollment and with the relatively short follow-up, this study is expected to end within a few short months thereafter. With the end of the study just around the corner, we must focus on data cleanliness. Sites are reminded to enter data and respond to queries within 5 business days. To this end, CVC will continue to email sites their query listings each week.

We thank you for your prompt attention to these emails and we look forward to working with you on the last phase of this trial!

For further information regarding LEVO-CTS, please contact Clinical Trial Project Lead Jodi Parrotta at 1-800-707-9098 ext 3 or via email at jodi.parrotta@ualberta.ca or Kate Dawson at 780-492-3789 or kedawson@ualberta.ca.

Sponsored by Tenax Therapeutics, Inc., LEVO-CTS is a Double Blind, Randomized, Placebo-Controlled Study of Levosimendan in Patients with Left Ventricular Systolic Dysfunction Undergoing Cardiac Surgery Requiring Cardiopulmonary Bypass.

Clinical Trials.gov Identifier: NCT02025621

SODIUM-HF

The SODIUM-HF trial currently has more than 285 subjects randomized (20-Sep-2016) at 18 active sites in Canada, Chile, Mexico and New Zealand. Thank you to all the sites for your continual hard work and efforts in identifying, enrolling and retaining study patients. We look forward to activating sites in Chile, Argentina and Australia in the coming months.

Welcome and congratulations to the following teams on your recent activation and first patient enrollment:

- Dr. Troughton, Lorraine and Catherine from Christchurch, New Zealand

- Dr. Porepa, Jeanine and Amirhossein from Newmarket, ON

We would like to remind sites that the deadline for the next financial quarter is fast approaching (30-Sep-2016). Please ensure that all completed study visits and phone calls are up-to-date in REDCap. Once all the data is input, the form should be saved as “complete” (green) for each data entry with the exception of the Food Record, which can be saved as “unverified” once you have completed the site questions. The SODIUM Core Lab will complete these questions and update the status of the entry to “complete”. Please also ensure that source worksheets are complete, legible and received by the Core Lab by the 30-Sep-2016.

All Dietitians and Study Coordinators are invited to attend the Dietitian Working Group Teleconference on Thursday 13-Oct-2016. This is a great opportunity to ask questions and interact with other study coordinators and dietitians. Additional materials will be distributed before the meetings. If you have any questions or need assistance dialing in, please do not hesitate to contact the Clinical Trial Project Lead.

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

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.

SODIUM-HF 100

ClinicalTrials.gov Identifier: NCT02012179

VICTORIA

The Canadian VIGOUR Centre is pleased to share that we have received overwhelming interest from our sites regarding the VICTORIA trial!

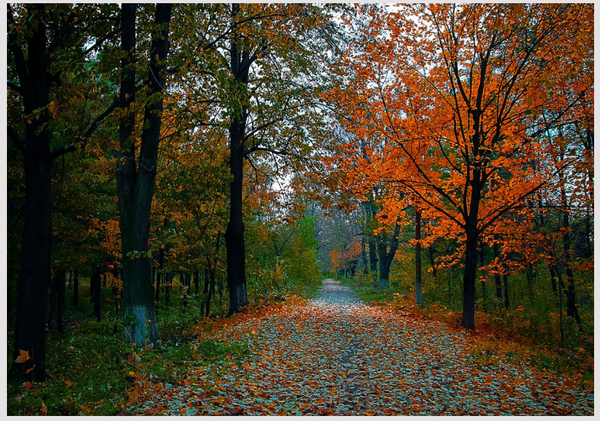
We are well on our way towards selecting 40-50 high quality heart failure sites in Canada. With Canada’s first SIV completed in August, 2016, we anxiously await the recruitment of the first patient in the coming weeks.

Thank you to the many sites who completed initial start-up activities quickly over the summer months! Please ensure you continue to work with CVC to complete the feasibility questionnaire and schedule validation visits in a timely manner. It is crucial that these steps are completed efficiently to avoid unnecessary delays with potential site selection.

In addition, completing initial study activities in a timely manner ensures selected sites receive sufficient notice for upcoming Investigator Meetings which are key to attend.

It was a pleasure to meet some of our sites at the first investigator meeting recently in Orlando. We look forward to meeting our other sites at the upcoming investigator meeting in Dallas.

Additional meetings or training opportunities may be scheduled for sites that are not available to attend the first two meetings or those who are selected to participate in the trial at a later date.



If you are interested in further information about VICTORIA, please contact Clinical Trial Project Lead Melisa Spaling at 1-800-707-9098 ext 4 or via email at mspaling@ualberta.ca or Kalli Belseck at 780-492-4011 or kalli@ualberta.ca.

Sponsored by Merck and Bayer, VICTORIA is a Randomized Parallel-Group, Placebo-Controlled, Double-Blind, Event-Driven, Multi-Centre Pivotal Phase III Clinical Outcome Trial of Efficacy and Safety of the Oral sGC Stimulator Vericiguat in Subjects With Heart Failure With Reduced Ejection Fraction (HFrEF) - VerICiguaT GlObal Study in Subjects With Heart Failure With Reduced EjectIon FrAction (VICTORIA)

ClinicalTrials.gov Identifier: NCTO2861534

ODYSSEY OUTCOMES

This past summer was a very busy one for our ODYSSEY Outcomes sites! Thank you for all of your hard work in completing all patient study visits within the required timeframe, as well as entering all your visit data in a timely fashion.

As we continue to reach the remainder of the second interim analysis targets and deadlines, your continued responsiveness will be greatly appreciated! As a reminder, Memo 31 and the Investigator Booklet clearly outline all upcoming goals.

This summer saw the release of a new protocol Amendment. Please ensure that all site staff that are actively working on the study have completed their training and that this training is sent to CVC. In addition, please submit the protocol related regulatory documents and your site specific ICF or addendum to consent to CVC for approval.

Remember that your REB approved ICFs should not be used until you are notified by CVC that you may implement the amendment at your site.

As you all know, we have had a very important modification to the eCRF Serious Adverse Events (SAE) reporting page. Each time an SAE is entered in the eCRF, a page will automatically appear within that event that the PI must complete. In order for the PI to log onto the eCRF, he must have completed his eCRF training. If this page is not completed by the PI, you will begin to receive automatic notifications from the eCRF indicating that PI review is required. With that in mind, please ensure that the PI has access to eCRF and has completed his/her training.If any assistance is required, please reach out to your CVC Project Lead.

We continue to keep a close eye on patient retention! Please use the resource provided to you earlier this year: the ‘site patient retention brochure’. It has excellent information to help you with any patients that may be more difficult to keep on study drug.

We appreciate all your efforts to keep patients on study drug, and to re-challenge them as their circumstances change. Once you receive REB approval, you may also distribute the ‘patient retention brochure’ to your patients to thank them for their continued participation in the trial, and to remind them of the importance of their commitment.

We look forward to the work ahead over the coming months!

For further information regarding this trial, please contact Clinical Trial Project Lead Jodi Parrotta at 1-800-707-9098 ext 3 or via email at jodi.parrotta@ualberta.ca or Paula Priest, ext 9 or paula.priest@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.

ODYSSEY OUTCOMES

ClinicalTrials.gov Identifier: NCT01663402

EXSCEL

Thank you to all sites who attended the EXSCEL Close-Out Meeting in Denver, CO this past June. This allowed us another great opportunity to connect with one another, receive important trial status updates and learn about key close-out timelines and objectives for the remainder of the trial.

We would like to extend our thanks for your continued success in keeping patients active in the trial! We are pleased with the low number of lost to follow up patients across all Canadian sites and that no Canadian patients have withdrawn their consent to participate to date.

As always, we would like to remind you that it is never too late to bring your patients back on study drug – every patient counts and every day on study drug counts towards helping us answer our important trial questions.

We look forward to working with you in this final phase of the trial. We are almost there, keep up the great work!

For further information regarding this trial, please contact Clinical Trial Project Lead Karin Kushniruk at 1-800-707-9098 ext 1 or via email at kushniru@ualberta.ca.

Exenatide **S**tudy of
Cardiovascular **E**vent **L**owering

EXSCEL
Exenatide Study of Cardiovascular Event Lowering

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.
ClinicalTrials.gov Identifier: NCT01144338

MONITORING TIPS

HELPFUL HINTS

Notes to file can be created to explain any inaccuracy that is noted and requires some form of study related explanation however it should not be used to explain CRF data.

To minimize queries, ensure that the data collected in the eCRF can be identified in the source document (i.e. medical record, clinic notes, laboratory reports or subject notes).

To maintain compliance at your site always ensure:

- consent is obtained/signed prior to any study related procedures being performed
- SAE's are reported to the sponsor within 24 hours of your sites' knowledge as well as reporting it as required to your REB
- protocol deviations are minimized
- data is always entered accurately
- study drug is only given to a study patient and that the correct study drug has been dispensed to the patient
- accurate study records are maintained

Why does a site receive a CAPA (Corrective and Preventative Action)?

A CAPA is a document put in place to correct a problem, show proof of immediate resolution and provide actions to prevent recurrence of these problems. You can prevent a CAPA if you follow the protocol, have no deviations, report SAE's within the specified time window, enter data/resolve queries in a timely manner and ensure continuous PI Oversight (see insert).

AEGIS-I Thank-You

The AEGIS-I monitoring team would like to thank all the blinded and unblinded study coordinators for accommodating us for all those study visits. We really enjoyed working with you.

Update your Contact List

The CVC monitoring team has new email addresses as noted below. We ask that you please change these in your contact list moving forward.

Halina Nawrocki – halina@ualberta.ca
Paula Tiller – ptiller@ualberta.ca
Francine Nole – nole@ualberta.ca
Linda Tardif – ltardif@ualberta.ca
Valerie Carr – vcarr@ualberta.ca
Sue Bonar – bonar@ualberta.ca
Eva Ruan – eruan@ualberta.ca

CVC NEWS

Kate Dawson

Kate Dawson joined the Clinical Operations team as a Regulatory Specialist in August. As a recent University of Alberta graduate, she is happy to be back on campus in a new role. Kate's research background is rooted in social and cultural psychology so she is very excited for this opportunity to learn more about cardiovascular research and clinical trials. Her administrative experience and passion for research will make her a great fit at the CVC.

Courtney Gubbels

Courtney Gubbels has recently returned from a maternity leave. She is currently the Project Lead for the GALILEO and AEGIS trials. She looks forward to working with the GALILEO sites as they continue enrollment into the trial. For the AEGIS sites, Courtney will be in touch with you if there are any remaining items following your recent site close out. She is excited to rejoin our CVC team.

Nubia Zepeda

As a graduate from the University of Alberta, **Nubia Zepeda** has obtained her Bachelor's degree in Science with Specialization in Pharmacology and her Master's degree in Science with Specialization in Experimental Oncology. After graduating, she interned at the Charité Hospital in Berlin, Germany in the Clinical Trials Unit. During the past two years, she has worked with the Department of Surgery at the University of Alberta and the Surgery Strategic Clinical Network with Alberta Health Services as a Research Coordinator and Project Manager, respectively. Nubia will be working closely with Dr. Justin Ezekowitz on the SODIUM-HF and HILO Projects.

Publications

van Diepen S, Alemayehu WG, Zheng Y, Theroux P, Newby LK, Mahaffey KW, Granger CB, Armstrong PW Temporal changes in biomarkers and their relationships to reperfusion and to clinical outcomes among patients with ST segment elevation myocardial infarction. 2016 Jun 20 http://www.ncbi.nlm.nih.gov/pubmed/27324144

Wallentin L, Held C, Armstrong PW, Cannon CP, Davies RY, Granger CB, Hagström E, Harrington RA, Hochman JS, Koenig W, Krug-Gourley S, Mohler ER 3rd, Siegbahn A, Tarka E, Steg PG, Stewart RA, Weiss R, Östlund O, White HD; STABILITY Investigators. Lipoprotein-Associated Phospholipase A2 Activity Is a Marker of Risk But Not a Useful Target for Treatment in Patients With Stable Coronary Heart Disease. 2016 Jun 2 http://www.ncbi.nlm.nih.gov/pubmed/27329448

McGuire DK, Van de Werf F, Armstrong PW, Standl E, Koglin J, Green JB, Bethel MA, Cornel JH, Lopes RD, Halvorsen S, Ambrosio G, Buse JB, Josse RG, Lachin JM, Pencina MJ, Garg J, Lokhnygina Y, Holman RR, Peterson ED; Trial Evaluating Cardiovascular Outcomes With Sitagliptin (TECOS) Study Group. Association Between Sitagliptin Use and Heart Failure Hospitalization and Related Outcomes in Type 2 Diabetes Mellitus: Secondary Analysis of a Randomized Clinical Trial. JAMA Cardiol. 2016 May 1 http://www.ncbi.nlm.nih.gov/pubmed/27437883

Hess PL, Wojdyla DM, Al-Khatib SM, Lokhnygina Y, Wallentin L, Armstrong PW, Roe MT, Ohman EM, Harrington RA, Alexander JH, White HD, Van de Werf F, Piccini JP, Held C, Aylward PE, Moliterno DJ, Mahaffey KW, Tricoci P. Sudden Cardiac Death After Non-ST-Segment Elevation Acute Coronary Syndrome. JAMA Cardiol. 2016 Apr 1 http://www.ncbi.nlm.nih.gov/pubmed/27437658

Jackson LR 2nd, Piccini JP, Cyr DD, Roe MT, Neely ML, Martinez F, Lüscher TF, Lopes RD, Winters KJ, White HD, Armstrong PW, Fox KA, Prabhakaran D, Bhatt DL, Magnus Ohman E, Corbalán R. Dual Antiplatelet Therapy and Outcomes in Patients With Atrial Fibrillation and Acute Coronary Syndromes Managed Medically Without Revascularization: Insights From the TRILOGY ACS Trial. Clin Cardiol. 2016 Jul 28 http://www.ncbi.nlm.nih.gov/pubmed/27468086

Armaganijan LV, Alexander KP, Huang Z, Tricoci P, Held C, Van de Werf F, Armstrong PW, Aylward PE, White HD, Moliterno DJ, Wallentin L, Chen E, Harrington RA, Strony J, Mahaffey KW, Lopes RD. Effect of age on efficacy and safety of vorapaxar in patients with non-ST-segment elevation acute coronary syndrome: Insights from the Thrombin Receptor Antagonist for Clinical Event Reduction in Acute Coronary Syndrome (TRACER) trial. Am Heart J. 2016 Aug http://www.ncbi.nlm.nih.gov/pubmed/27502866

Kaul P, Ohman EM, Knight JD, Anstrom KJ, Roe MT, Boden WE, Hochman JS, Gašparović V, Armstrong PW, McCollam P, Fakhouri W, Cowper P, Davidson-Ray L, Clapp-Channing N, White HD, Fox KA, Prabhakaran D, Mark DB; TRILOGY ACS Investigators. Health-related quality of life outcomes with prasugrel among medically managed non-ST-segment elevation acute coronary syndrome patients: Insights from the Targeted Platelet Inhibition to Clarify the Optimal Strategy to Medically Manage Acute Coronary Syndromes (TRILOGY ACS) trial. Am Heart J. 2016 Aug http://www.ncbi.nlm.nih.gov/pubmed/27502852

Åkerblom A, Clare RM, Lokhnygina Y, Wallentin L, Held C, Van de Werf F, Moliterno DJ, Patel UD, Leonardi S, Armstrong PW, Harrington RA, White HD, Aylward PE, Mahaffey KW, Tricoci P. Albuminuria and cardiovascular events in patients with acute coronary syndromes: Results from the TRACER trial. Am Heart J. 2016 Aug http://www.ncbi.nlm.nih.gov/pubmed/27502846

Povsic TJ, Lawrence MG, Lincoff AM, Mehran R, Rusconi CP, Zelenkofske SL, Huang Z, Sailstad J, Armstrong PW, Steg PG, Bode C, Becker RC, Alexander JH, Adkinson NF, Levinson AI; REGULATE-PCI Investigators. Pre-existing anti-PEG antibodies are associated with severe immediate allergic reactions to pegnivacogin, a PEGylated aptamer. J Allergy Clin Immunol. 2016 Jul 14 http://www.ncbi.nlm.nih.gov/pubmed/27522158

Publications Continued

Shavadia J, Welsh R, Gershlick A, Zheng Y, Huber K, Halvorsen S, Steg PG, Van de Werf F, Armstrong PW for the STREAM investigators. Relationship Between Arterial Access and Outcomes in ST-Elevation Myocardial Infarction with a Pharmacoinvasive versus Primary Percutaneous Coronary Intervention Strategy: Insights From the STrategic Reperfusion Early After Myocardial Infarction (STREAM) Study. J Am Heart Assoc. 2016; http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4937283

Patel M, Peterson ED, Armstrong PW, Stone G, Mehran R, Kirtane A, Solomon S, Sabatine M, Bhatt D, Mauri L, Harrington R, Mahaffey K, Perkovic V, Lincoff M, Fox K, Nicols S, Steg PG, Wallentin L, Gibson CM. Sharing Data from Cardiovascular Clinical Trials – A Proposal. Response to Institute of Medicine (IOM) and International Committee of Medical Journal Editors (ICMJE). N Engl J Med 2016; http://www.nejm.org/doi/pdf/10.1056/NEJMp1605260

Armstrong PW, McAlister FM. Editorial. Searching for Adherence: Can We Fulfil the Promise of Evidence Based Medicines? J Ame Coll Cardiol, 2016;68;789-801. http://www.ncbi.nlm.nih.gov/pubmed/27539171

McAlister FA, Ezekowitz JA. Letter by McAlister and Ezekowitz Regarding Article, "Temporal Trends and Variation in Early Scheduled Follow-Up After a Hospitalization for Heart Failure: Findings From Get With the Guidelines-Heart Failure". Circ Heart Fail. 2016 Jun 9 http://www.ncbi.nlm.nih.gov/pubmed/27296398

Thanh NX, Ezekowitz JA, Tran DT, Kaul P. Cost Effectiveness of Eplerenone for the Treatment of Systolic Heart Failure with Mild Symptoms in Alberta, Canada. Am J Cardiovasc Drugs. 2016 Jun 14 http://www.ncbi.nlm.nih.gov/pubmed/27300508

Alagiakrishnan K, Mah D, Ahmed A, Ezekowitz J. Cognitive decline in heart failure. Heart Fail Rev. 2016 Jun 14 http://www.ncbi.nlm.nih.gov/pubmed/27296398

Sepehrvand N, Ezekowitz JA. Oxygen Therapy in Patients With Acute Heart Failure: Friend or Foe? JACC Heart Fail. 2016 May 26 http://www.ncbi.nlm.nih.gov/pubmed/27289409

Alexander JH, Andersson U, Lopes RD, Hijazi Z, Hohnloser SH, Ezekowitz JA, Halvorsen S, Hanna M, Commerford P, Ruzyllo W, Huber K, Al-Khatib SM, Granger CB, Wallentin L; Apixaban for Reduction of Stroke and Other Thromboembolic Complications in Atrial Fibrillation (ARISTOTLE) Investigators. Apixaban 5 mg Twice Daily and Clinical Outcomes in Patients With Atrial Fibrillation and Advanced Age, Low Body Weight, or High Creatinine: A Secondary Analysis of a Randomized Clinical Trial. JAMA Cardiol. 2016 Jul 27 http://www.ncbi.nlm.nih.gov/pubmed/27463942

Brown PM, Anstrom KJ, Felker GM, Ezekowitz JA. Composite End Points in Acute Heart Failure Research: Data Simulations Illustrate the Limitations. Can J Cardiol. 2016 Mar 3 http://www.ncbi.nlm.nih.gov/pubmed/27499377

Ezekowitz JA, Lewis BS, Lopes RD, Wojdyla DM, McMurray JJ, Hanna M, Atar D, Cecilia Bahit M, Keltai M, Lopez-Sendon JL, Pais P, Ruzyllo W, Wallentin L, Granger CB, Alexander JH. Clinical outcomes of patients with diabetes and atrial fibrillation treated with apixaban: results from the ARISTOTLE trial. Eur Heart J Cardiovasc Pharmacother. 2015 Apr;1 http://www.ncbi.nlm.nih.gov/pubmed/27533976

Fitchett DH, Goodman SG, Leiter LA, Lin P, Welsh R, Stone J, Grégoire J, Mcfarlane P, Langer A. Secondary Prevention Beyond Hospital Discharge for Acute Coronary Syndrome: Evidence-Based Recommendations. Can J Cardiol 2016 Jul http://www.ncbi.nlm.nih.gov/pubmed/27342696

Bainey KR, Welsh RC, Toklu B, Bangalore S. Complete vs Culprit-Only Percutaneous Coronary Intervention in STEMI With Multivessel Disease: A Meta-analysis and Trial Sequential Analysis of Randomized Trials. Can J Cardiol. 2016 Mar 10 http://www.ncbi.nlm.nih.gov/pubmed/27378594

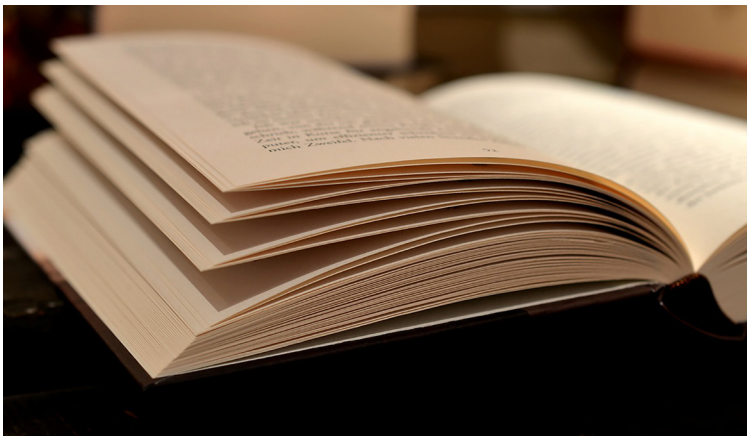
Katz JN, Minder M, Olenchock B, Price S, Goldfarb M, Washam JB, Barnett CF, Newby LK, van Diepen S The Genesis, Maturation, and Future of Critical Care Cardiology. J Am Coll Cardiol. 2016 Jul 5 http://www.ncbi.nlm.nih.gov/pubmed/27364053

Youngson E, Welsh RC, Kaul P, McAlister F, Quan H, Bakal J. Defining and validating comorbidities and procedures in ICD-10 health data in ST-elevation myocardial infarction patients. Medicine (Baltimore). 2016 Aug http://www.ncbi.nlm.nih.gov/pubmed/27512881

Chen G, Lix L, Tu K, Hemmelgarn BR, Campbell NR, McAlister FA, Quan H Hypertension Outcome and Surveillance Team Influence of Using Different Databases and 'Look Back' Intervals to Define Comorbidity Profiles for Patients with Newly Diagnosed Hypertension: Implications for Health Services Researchers. PLoS One. 2016 Sep 1 http://www.ncbi.nlm.nih.gov/pubmed/27583532

McAlister FA Overtreatment of Low-Risk Patients With Atrial Fibrillation-The Quality Coin Has 2 Sides. JAMA Cardiol. 2016 Aug 17 http://www.ncbi.nlm.nih.gov/pubmed/27541301

Luc JG, Shanks M, Tyrrell BD, Welsh RC, Butler CR, Meyer SR. Transcatheter Valve-in-Valve: A Cautionary Tale. Ann Thorac Surg. 2016 Sep http://www.ncbi.nlm.nih.gov/pubmed/27549545



Publication Information

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.

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.vigour.ualberta.ca

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

AstraZeneca
Amylin Pharmaceuticals
CIHR
CSL Behring LLC
Bayer Health Care AG
Bayer Health Care Pharmaceuticals Inc.
Merck & Co., Inc.
National Institutes of Health/NHLBI
Roche Diagnostics Operations Inc.
Sanofi-Aventis Recherche & Développement
Tenax Therapeutics, Inc.

MAZANKOWSKI ALBERTA HEART INSTITUTE

UNIVERSITY OF ALBERTA