The Canadian Cardiac Chronicle

Volume 20, No. 1 **Spring 2016**

"Not everything that can be counted counts, and not everything that counts can be counted."

- Albert Einstein

Data; we like data. Data is what makes the scientific enterprise work. Without clear, trustworthy and reproducible data, the scientific experiments we call clinical trials would not have much value.

But what is occasionally lost in the data is the human interaction. The communication between a patient and a clinician, a patient and the research team, and a patient and their family. All of these are different in their purpose but share many traits that deserve discussion.

First, they are trusted interactions. Inherent in volunteering for a clinical trial is the trust placed in the scientific team (from local research coordinator to the trial principal investigator). This extends to the trust we are collecting accurate data, and the trust we are avoiding duplication of information available on one or the other side of the clinical/research divide.

Second, the interaction between people is core to the scientific process as it involves the transmission of information. Sometimes this is the transmission of a diagnosis or lab value, and for researchers, transmission of instructions on, for example, how to take the experimental medication. For a patient it can be the transmission of an event – hospitalization, adverse event or recent change in a concomitant medication.

How does this all relate back to high quality and timely data? Trials are more often looking towards interacting with data differently by linking to administrative data for follow-up, electronic health records as source documents and both for clinical events. These linkages will become more and more critical as the research endeavor advances. These need to remain vital, trusted and high quality interactions between data 'sources' whether it be patient, EHR, mobile health data or an old-school paper chart.

In This Issue:

Letter - Justin Ezekowitz 1
Trial Updates 2-6
Upcoming Trials 6
CVC News 6
Publications 7-8

Behind all this data is a research team, a patient and their family. None of the data is possible without the human interaction, often overlooked as we try to get at the data. I'd like to take this opportunity to remind us all on the importance of talking to patients, and remind ourselves and patients as to why we are collecting so much data. Lets not forget that behind that data point, there is a person.

Justin Ezekowitz
CVC Co-Director

EXSCEL

Thank you to all Study Coordinators for your continued efforts towards cleaning your data. A large number of 'critical variable' queries were released over the last few months and these data points are vital to the interpretation of safety and efficacy information. Cleanliness of these items is essential for the upcoming spring DSMB meeting and we appreciate your perseverance as we approach the latter stages of the trial.

If you are able to have a re-challenge discussion with a patient off study drug, please try to do so sooner rather than later. Every single day the patient is on study drug really does count! Even if the patient has been off for quite some time and restarts for only a short while, additional exposure can make a significant difference - not only for the patient's outcomes but for the study results as well.

Thank you for your hard work in moving your patients through the TrialNetworks tool. The tool has provided substantial and meaningful information regarding LTFU patients off study medication. Retention specialists are reviewing all cases now and we look forward to receiving further information from the Sponsor as to which cases will earn a compensation payment. As a reminder, please update the tool with as much detail as possible. This will ensure we do not contact you unnecessarily for information about patients off study drug or lost to follow up.

For further information about this trial, please contact Clinical Trial Project Lead, Karin Kushniruk at 1-800-707-9098, ext. 1 or by 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

LEVO-CTS

The enrollment rate has increased recently, and the study is now expected to meet its enrollment target later this summer. Currently over 525 patients have been randomized at 60+ sites across Canada and the US.

The Canadian contribution to this trial has been outstanding. All 10 sites have enrolled at least 4 patients. In total, 87 patients have been randomized in Canada (as of April 4, 2016). Keep up the great work.

Congratulations to Dr. Kalavrouziotis and Dr. Bozinovski and their respective teams for consistently being the top two enrolling sites. They have set the bar high in Canada, and continue to excel. Special recognition goes to Dr. Nagpal's site where enrollment only began in January and 11 patients have already been randomized. At this rate, they could easily catch up to Dr. Bozinovski's site and possibly dethrone Dr. Kalavrouziotis' site this spring. We would also like to congratulate Dr. Nagpal's team for finishing in the final four of the March Madness charity contest.

The next DSMB meeting is planned for May 2016, when the data on the first 400 patients will be reviewed. Thanks to all the sites for their hard work throughout March to enter all data through the 30-day Study Completion Visit and answering all open queries for this important upcoming meeting.

The updated Investigator Brochure was sent to sites on March 8, 2016. There were no changes to the ICF. Sites are to submit the IB to their REB, and send CVC copies of the REB correspondence (submission and acknowledgement).

As a reminder, please continue to ensure CK, CKMB, Troponin and ECGs are collected at all protocol required time-points.

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.

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.

LEVO CTS
levosimendan in cardio thoracic surgery

ClinicalTrials.gov Identifier: NCT02025621

GALILEO

It was a pleasure to meet face-to-face with each of the attendees from Canada at the North American investigator meeting that took place on January 19, 2016 in Fort Lauderdale.

It was nice to reunite with those we have worked with before, as well as to meet new PIs and SCs - all of whom we at CVC are excited to be working with on this new study which aims to compare a Rivaroxaban-based antithrombotic strategy to an antiplatelet-based strategy after a successful transcatheter aortic valve replacement (TAVR).

The study is in the very active phase of start-up, with 10 sites participating in Canada. GALILEO's first patient was enrolled in the US in December. Enrollment is planned to be completed at the end of 2016 with over 1500 patients randomized into the trial.

In Canada, all sites have submitted to Ethics, and the collecting and reviewing of the regulatory documents required for start-up is well underway. We are looking to have our first site activated in April, with Canada's first patient randomized soon thereafter! The goal will be to have all CVC sites activated and screening/enrolling patients this spring.

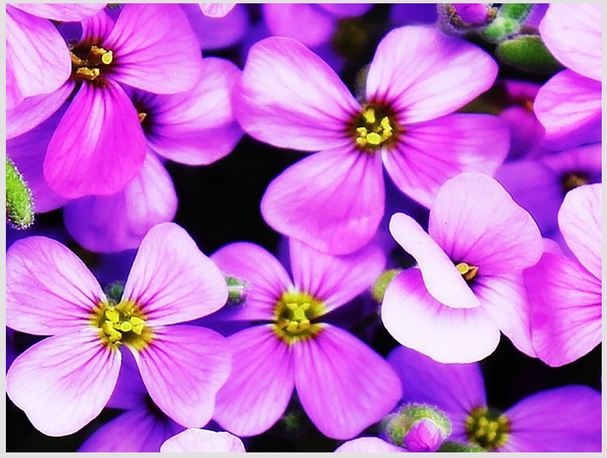
If you are interested in hearing more about this trial, please contact Clinical Trial Project Lead, Jodi Parrotta at 1-800-707-9098, ext. 3 or by email at jodi.parrotta@ualberta.ca.

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.

GALILEO

ClinicalTrials.gov Identifier: NCT02556203

GUIDE-IT



GUIDE-IT has over 800 subjects randomized and as of late March, 120 of these are from Canada. Congratulations to Dr. Ezekowitz and Quentin Kushnerik who enrolled 3 patients in January. We are currently on target to meet our goal of 1,100 patients but cannot afford any lulls in recruitment so keep up the good work on screening and randomizing!

Enrollment in the ECHO Sub-study is going well and we are pleased to announce that Dr. Virani's site at Vancouver General Hospital has been activated to participate and already enrolled 2 patients. Two hundred and fifteen patients have been enrolled so far and it is anticipated we will reach our goal of 300.

Thank you to the Investigators and Coordinators who attended the February Investigator Meeting in Fort Lauderdale, FL. where the focus was on enrollment and protocol adherence. This was a great opportunity to review adherence including several case studies and we encourage you to contact your Project Lead and/or Dr. Ezekowitz with any adherence questions.

Lastly, CVC would like to extend our gratitude for overall great performance in data timeliness and cleanliness. As a reminder, visits are to be entered and queries are to be addressed within 5 business days.

Please continue to prioritize CEC queries and ensure documents are submitted for CEC adjudication in a timely manner.

For further information about this trial, please contact Clinical Trial Project Lead, Karin Kushniruk at 1-800-707-9098, ext. 1 or by 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.

GUIDE-IT

ClinicalTrials.gov Identifier: NCT01685840

AEGIS-I

The last patient Visit 8 was conducted in early March which was the trigger for sites to begin conducting final Visit 11 MACE follow-up calls with all patients. There was a tight timeline to conclude these calls and have all of the Inform data entered and clean. Thank you to each of our sites for completing these final visits and the corresponding data entry so quickly. Great work!

We appreciate your continued dedication to AEGIS as the final periodic monitoring visits are scheduled throughout March and April. Your blinded monitor will be completing final source data verification and query resolution to meet these last monthly data cleaning targets and to ensure the data is 100% clean in preparation for database lock.

As we move towards the significant milestone of database lock and study close out, we ask our sites to be diligent in quickly answering any enquiries that may come up from the medical team, as well as provide all outstanding regulatory items to CVC.

For further information, please contact Clinical Trial Project Lead, Amanda Carapellucci at 1-800-707-9098, ext 2 or via email at amanda.carapellucci@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

AEGIS-I

SODIUM-HF

The SODIUM-HF trial currently has 195+ subjects randomized (31-March-2016) at 16 active sites in Canada, Mexico and Chile. We look forward to activating additional sites in Canada and Argentina as we head into spring.

Thank you to all site personnel who joined the recent Steering Committee and Dietitian Working Group Teleconferences in February, 2016. If you were not able to join, please review the February 2016 newsletter for trial updates (DWG minutes on the last page) or contact CVC for minutes from the Steering Committee meeting.

A reminder that an Investigator's Meeting is planned for June 4, 2016 in Montreal, QC in conjunction with the HF Update meeting (https://www.hfupdate.ca/en). This meeting will be an important opportunity to meet face-to-face and discuss some of the challenges and opportunities in the SODIUM-HF trial – we hope to see all sites represented. Details will follow; however, we encourage you to save the date for the time being!

Over the next few weeks please ensure your site's data is updated in REDCap by 31-March-2016 in line with the next financial quarter/invoicing period.

Please ensure the following areas are updated, retroactively as needed, for all subjects per recent changes to the eCRF.

• Baseline visit: Additional fields added to Heart Failure History

• All study visits: Use of Entresto added to Medications

• End of Study page: Date of Last Study Contact field added, as applicable

• Clinical Outcomes page: Unable to Contact Subject field added and to be completed as appropriate.

If you have any questions about your site's data please refer to the most recent version of the REDCap Data Entry Guidelines or contact Melisa (below).

Reminders:

• 3-day food records should be submitted within 3 business day of the study visit to sodium-corelab@ualberta.ca or via fax to 780-492-0613. Please ensure the subject's REDCap ID and study visit is clearly documented on each page.

• Please be sure to randomize subjects at Baseline – this eliminates problems that occur with REDCap when a subject consents and is randomized, but then does not show up for their Baseline visit.

If you are interested in further information about SODIUM-HF, please contact Clinical Trial Project Lead Melisa Spaling at 780-492-8476 or via email at mspaling@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

The Canadian Cardiac Chronicle - Volume 20

ODYSSEY

Thank you to all of our sites for the fantastic efforts that were put forth prior to our first interim analysis. The data cut was a success and Canada was able to meet its data cleaning goals thanks to your hard work and persistence. Data continues to be a top priority for the ODYSSEY Outcomes trial as we move towards the next interim analysis.

We ask that you continue to stick to the data entry guidelines of entering visits within 5 days and resolving queries within 3 days. Please be aware that these timelines will be reduced as the next data cut approaches.

Patient retention is another top priority for us, as we want to ensure that our patients remain committed and engaged with the trial. You have all now received the "Site Retention Guide – Best practices to engage and retain participants".

Please take some time to review this important tool as it offers excellent retention strategies, summarizes potential warning signs that indicate a patient may be wavering and it contains numerous template letters, forms and logs that can be customized and used. Special attention must also be given to patients who have come off study drug.

The tool just mentioned contains a great flow chart that outlines how to follow up with patients whether they are on or off study drug. Remember that all patients who have temporarily discontinued study drug should continue with their study visits, and a study drug re-start should continue to be offered, as applicable.

The majority of our sites have now been approved under Amendment 08. If you have not already done so, please make sure that your regulatory documents, training and REB approvals are submitted to CVC. All patients must be re-consented with your updated ICF once CVC has given you the green light to implement the amendment at your site. Please make sure that you have a process in place for re-consenting patients who are no longer attending clinic visits, and that you are aware of (and following!) your REB's requirements for this patient group as well.

We look forward to meeting with many of you at the upcoming Study Update Meeting for ODYSSEY Outcomes Study Coordinators in Chicago! We are certain that this meeting will provide us with renewed enthusiasm as we move towards the final phases of this important trial.

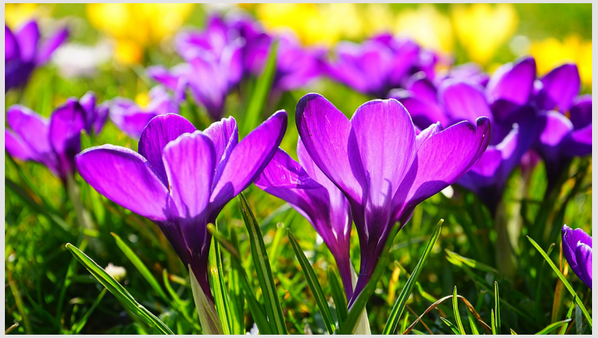
For further information regarding this trial, please contact Clinical Trials Project Lead Amanda Carapellucci at 1-800-707-9098, ext. 2 or by email at amanda.carapellucci@ualberta.ca or Paula Priest, ext. 9 or paula.priest@ualberta.ca.

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

BLAST-AHF



Enrollment is now closed in the BLAST-AHF trial as the target sample size (n=600+) was reached at the end of February, 2016.

The emphasis is now on data cleaning, database lock and close out, which we anticipate will occur quickly and efficiently. We look forward to sharing the results of this exciting Phase 2b trial later in the year. Thank you to all sites for your participation.

If you are interested in further information about BLAST, please contact Clinical Trial Project Lead Melisa Spaling at 780-492-8476 or via email at mspaling@ualberta.ca

Sponsored by Trevena Inc., BLAST-AHF is A Randomized, Double-Blind, Placebo-Controlled, Dose Ranging Study to Explore the Efficacy of TRV027 in Patients Hospitalized for Acute Decompensated Heart Failure.

BLAST-AHF

ClinicalTrials.gov Identifier: NCT01966601

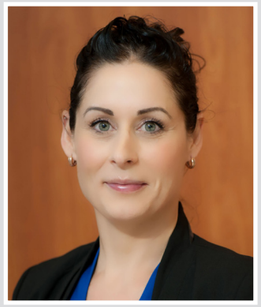
Upcoming Trials

VICTORIA - **V**er**I**Cigua**T**: gl**O**bal study in patients with heart failure and **R**educed eject**I**on fr**A**ction

After many months of planning we are excited to be moving forward and aim to reach out to our investigative sites in the late spring regarding a phase 3 study in heart failure patients with reduced ejection fraction. Sponsored by Merck and Bayer, this study is a unique ARO collaboration with DCRI and CVC. We have excellent representation from Canada on this study with Dr. Paul Armstrong as the Study Chair and Dr. Justin Ezekowitz on the Executive Committee and they have been active in developing the study plan along with some key ancillary studies. More information will be forthcoming in the coming weeks but we want to get this on your radar now.

CVC News

Eva Ruan joins CVC as a monitor for our Western Canadian ODYSSEY sites and brings an extensive research background. As a RN, she has over 6 years of relevant experience in national and global clinical trials in many different therapeutic areas. She is a very active person. In her spare time she enjoys bicycling, running and swimming.



Lisa Soulard joins the CVC as Dr. Armstrong's new Executive Assistant. In this role she will also be supporting CVC activities related to initiatives led by Drs. Ezekowitz and Westerhout. Lisa is not new to the University, she has worked for the last four years in the Faculty of Medicine & Dentistry's Dean's office. In her spare time she enjoys running, art and expanding her knowledge base in areas ranging from web design to organizational development.

Carla Price has recently returned from a maternity leave to the position of Acting Assistant Director, Operations in the CVC business office, alongside colleagues Ellen Pyear and Oksana Grant. Carla is the point of contact for various business functions such as contracts and agreements, invoicing and payments and other operational activities in support of the CVC's staff and projects. Carla first began working for the CVC in 2004 and is excited to rejoin the team and interact with our many local, national and international collaborators.

Publications

Ezekowitz JA, Welsh RC, Weiss D, Chan M, Keeble W, Khadour F, Sharma S, Tymchak W, Sookram S, Brass N, Knapp D, Koshy TL, Zheng Y, Armstrong PW Providing Rapid Out of Hospital Acute Cardiovascular Treatment 4 (PROACT-4). J Am Heart Assoc. 2015 Dec 1 **http://www.ncbi.nlm.nih.gov/pubmed/26627881**

Roe MT, Cyr DD, Eckart D, Schulte PJ, Morse MA, Blackwell KL, Ready NE, Zafar SY, Beaven AW, Strickler JH, Onken JE, Winters KJ, Houterloot L, Zamoryakhin D, Wiviott SD, White HD, Prabhakaran D, Fox KA, Armstrong PW, Ohman EM; TRILOGY ACS Investigators. Ascertainment, classification, and impact of neoplasm detection during prolonged treatment with dual antiplatelet therapy with prasugrel vs. clopidogrel following acute coronary syndrome. Eur Heart J. 2015 Dec 5 **http://www.ncbi.nlm.nih.gov/pubmed/26637834**

van Diepen S, Tricoci P, Podder M, Westerhout CM, Aylward PE, Held C, Van de Werf F, Strony J, Wallentin L, Moliterno DJ, White HD, Mahaffey KW, Harrington RA, Armstrong PW Efficacy and Safety of Vorapaxar in Non-ST-Segment Elevation Acute Coronary Syndrome Patients Undergoing Noncardiac Surgery. J Am Heart Assoc. 2015 Dec 15 **http://www.ncbi.nlm.nih.gov/pubmed/26672080**

Perez AL, Grodin JL, Wu Y, Hernandez AF, Butler J, Metra M, Felker GM, Voors AA, McMurray JJ, Armstrong PW, Starling RC, O'Connor CM, Tang WH Increased mortality with elevated plasma endothelin-1 in acute heart failure: an ASCEND-HF biomarker substudy. Eur J Heart Fail. 2015 Dec 14 **http://www.ncbi.nlm.nih.gov/pubmed/26663359**

Tang WH, Wu Y, Grodin JL, Hsu AP, Hernandez AF, Butler J, Metra M, Voors AA, Felker GM, Troughton RW, Mills RM, McMurray JJ, Armstrong PW, O'Connor CM, Starling RC. Prognostic Value of Baseline and Changes in Circulating Soluble ST2 Levels and the Effects of Nesiritide in Acute Decompensated Heart Failure JACC Heart Fail. 2015 Nov 25 **http://www.ncbi.nlm.nih.gov/pubmed/26656144**

Pokorney SD, Radder C, Schulte PJ, Al-Khatib SM, Tricocci P, Van de Werf F, James SK, Cannon CP, Armstrong PW, White HD, Califf RM, Gibson CM, Giugliano RP, Wallentin L, Mahaffey KW, Harrington RA, Newby LK, Piccini JP. High-degree atrioventricular block, asystole, and electro-mechanical dissociation complicating non-ST-segment elevation myocardial infarction. Am Heart J. 2016 Jan;171 **http://www.ncbi.nlm.nih.gov/pubmed/26699597**

Déry JP, Mahaffey KW, Tricoci P, White HD, Podder M, Westerhout CM, Moliterno DJ, Harrington RA, Chen E, Strony J, Van de Werf F, Ziada KM, Held C, Aylward PE, Armstrong PW, Rao SV.Catheter Arterial access site and outcomes in patients undergoing percutaneous coronary intervention with and without vorapaxar Catheter Cardiovasc Interv. 2015 Dec 23 **http://www.ncbi.nlm.nih.gov/pubmed/26698636**

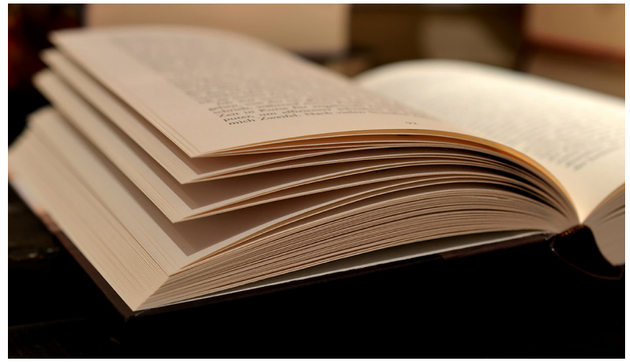
Shavadia J, Armstrong PW Risk stratification in non-ST elevation acute coronary syndromes: searching for the right formula. Eur Heart J. 2015 Dec 18. **http://www.ncbi.nlm.nih.gov/pubmed/26685972**

Samsky MD, Dunning A, DeVore AD, Schulte PJ, Starling RC, Wilson Tang WH, Armstrong PW, Ezekowitz JA, Butler J, McMurray JJ, Teerlink JR, Voors AA, Metra M, Mentz RJ, O'Connor CM, Patel CB, Hernandez AF. Liver function tests in patients with acute heart failure and associated outcomes: insights from ASCEND-HF Eur J Heart Fail. 2015 Dec 28 **http://www.ncbi.nlm.nih.gov/pubmed/26707029**

Mentz RJ, Hasselblad V, DeVore AD, Metra M, Voors AA, Armstrong PW, Ezekowitz JA, Tang WH, Schulte PJ, Anstrom KJ, Hernandez AF, Velazquez EJ, O'Connor CM. Torsemide Versus Furosemide in Patients With Acute Heart Failure (from the ASCEND-HF Trial). Am J Cardiol. 2015 Nov 18 **http://www.ncbi.nlm.nih.gov/pubmed/26704029**

Bainey KR, Armstrong PW Transatlantic Comparison of ST-Segment Elevation Myocardial Infarction Guidelines: Insights From the United States and Europe. J Am Coll Cardiol. 2015 Dec 18 **http://www.ncbi.nlm.nih.gov/pubmed/26724199**

Bainey KR, Fresco C, Zheng Y, Halvorsen S, Carvalho A, Ostojic M, Goldstein P, Gershlick AH, Westerhout CM, Van de Werf F, Armstrong PW; STREAM Investigators. Implications of ischaemic area at risk and mode of reperfusion in ST-elevation myocardial infarction. Heart. 2016 Jan 18 **http://www.ncbi.nlm.nih.gov/pubmed/26783237**



Wong YW, Mentz RJ, Felker GM, Zekowitz J, Pieper K, Heizer G, Hasselblad V, Metra M, O'Connor CM, Armstrong PW, Starling RC, Hernandez AF. Nesiritide in Patients Hospitalized for Acute Heart Failure - Does Timing Matter? Implication for Future Acute Heart Failure Trials Eur J. Heart Fail 2016 Jan 27. **http://www.ncbi.nlm.nih.gov/pubmed/26817735**

Kaul P, Welsh RC, Liu W, Savu A, Weiss DR, Armstrong PW Temporal and Provincial Variation in Ambulance Use Among Patients Who Present to Acute Care Hospitals With ST-Elevation Myocardial Infarction. Can J Cardiol. 2016 Feb 6 **http://www.ncbi.nlm.nih.gov/pubmed/26860779**

Sinnaeve PR, Danays T, Bogaerts K, Van de Werf F, Armstrong PW Drug Treatment of STEMI in the Elderly: Focus on Fibrinolytic Therapy and Insights from the STREAM Trial. Drugs Aging. 2016 Feb 5 **http://www.ncbi.nlm.nih.gov/pubmed/26849132**

Chin CT, Neely B, Magnus Ohman E, Armstrong PW, Corbalán R, White HD, Prabhakaran D, Winters KJ, Fox KA, Roe MT. Time-Varying Effects of Prasugrel Versus Clopidogrel on the Long-Term Risks of Stroke after Acute Coronary Syndromes: Results from the TRILOGY ACS Trial. Stroke. 2016 Feb 16 **http://www.ncbi.nlm.nih.gov/pubmed/26883498**

Harskamp RE, Clare RM, Ambrosio G, Held C, Lokhnygina Y, Moliterno DJ, White HD, Aylward PE, Armstrong PW, Mahaffey KW, Harrington RA, Van de Werf F, Wallentin L, Strony J, Tricoci P. Use of thienopyridine prior to presentation with non-ST-segment elevation acute coronary syndrome and association with safety and efficacy of vorapaxar: insights from the TRACER trial. Eur Heart J Acute Cardiovasc Care. 2016 Feb 19 **http://www.ncbi.nlm.nih.gov/pubmed/26895973**

Vavalle JP, van Diepen S, Clare RM, Hochman JS, Weaver WD, Mehta RH, Pieper KS, Patel MR, Patel UD, Armstrong PW, Granger CB, Lopes RD. Renal failure in patients with ST-segment elevation acute myocardial infarction treated with primary percutaneous coronary intervention: Predictors, clinical and angiographic features, and outcomes. Am Heart J. 2016 Mar **http://www.ncbi.nlm.nih.gov/pubmed/26920597**

Doll JA, Neely ML, Roe MT, Armstrong PW, White HD, Prabhakaran D, Winters KJ, Duvvuru S, Sundseth SS, Jakubowski JA, Gurbel PA, Bhatt DL, Ohman EM, Fox KA; TRILOGY ACS Investigators. Impact of CYP2C19 Metabolizer Status on Patients With ACS Treated With Prasugrel Versus Clopidogrel. J Am Coll Cardiol. 2016 Mar **http://www.ncbi.nlm.nih.gov/pubmed/26916483**

Kragholm K, Goldstein SA, Yang Q, Lopes RD, Schulte PJ, Bernacki GM, White HD, Mahaffey KW, Giugliano RP, Armstrong PW, Harrington RA, Tricoci P, Van de Werf F, Alexander JH, Alexander KP, Newby LK. Trends in Enrollment, Clinical Characteristics, Treatment, and Outcomes According to Age in Non-ST-Segment Elevation Acute Coronary Syndromes Clinical Trials. Circulation. 2016 Mar 8 **http://www.ncbi.nlm.nih.gov/pubmed/26957532**

Colin-Ramirez, Ezekowitz JA Salt in the diet in patients with heart failure: what to recommend. Curr Opin Cardiol. 2015 Nov 20. **http://www.ncbi.nlm.nih.gov/pubmed/26595701**

Whellan DJ, Stebbins A, Hernandez AF, Ezekowitz JA, McMurray JJ, Mather PJ, Hasselblad V, O'Connor CM. Dichotomous Relationship between Age and 30-Day Death or Rehospitalization in Heart Failure Patients Admitted with Acute Decompensated Heart Failure: Results From the ASCEND-HF Trial. J Card Fail 2016 Mar 4 **http://www.ncbi.nlm.nih.gov/pubmed/26952241**

Publications Continued

Savu A, Schopflocher D, Scholnick B, Kaul P. The intersection of health and wealth: association between personal bankruptcy and myocardial infarction rates in Canada. BMC Public Health. 2016 Jan 13 **http://www.ncbi.nlm.nih.gov/pubmed/26762139**

Mackie AS, Liu W, Savu A, Marelli AJ, Kaul P. Infective Endocarditis Hospitalizations Before and After the 2007 American Heart Association Prophylaxis Guidelines. Can J Cardiol. 2016 Feb 9 **http://www.ncbi.nlm.nih.gov/pubmed/26868840**

Bainey KR, Norris C, Shavadia J. Response to: Letter to the Editor regarding the manuscript "Symptomatic graft failure and impact on clinical outcome after coronary artery bypass grafting surgery: Results from the Alberta Provincial Project for Outcome Assessment in Coronary Heart Disease registry". Am Heart J. 2016 Jan;171 **http://www.ncbi.nlm.nih.gov/pubmed/26699607**

Norris CM, Bainey KR Does Ivabradine SIGNIFY Improvements in Quality of Life? Circ Cardiovasc Qual Outcomes. 2015 Dec 22 **http://www.ncbi.nlm.nih.gov/pubmed/26696612**

Padwal RS, Bienek A, McAlister FA, Campbell NR; Outcomes Research Task Force of the Canadian Hypertension Education Program. Epidemiology of Hypertension in Canada: An Update. Can J Cardiol. 2015 Aug 15 **http://www.ncbi.nlm.nih.gov/pubmed/26711315**

Lau D, Majumdar SR, McAlister FA Patient Isolation Precautions and 30-Day Risk of Readmission or Death after Hospital Discharge: A Prospective Cohort Study. Int J Infect Dis. 2016 Jan 2 **http://www.ncbi.nlm.nih.gov/pubmed/26751237**

Weir DL, McAlister FA, Majumdar SR, Eurich DT. The Interplay Between Continuity of Care, Multimorbidity, and Adverse Events in Patients With Diabetes. Med Care. 2016 Jan 22 **http://www.ncbi.nlm.nih.gov/pubmed/26807539**

Pederson JL, Majumdar SR, Forhan M, Johnson JA, McAlister FA; PROACTIVE Investigators. Current depressive symptoms but not history of depression predict hospital readmission or death after discharge from medical wards: a multisite prospective cohort study. Gen Hosp Psychiatry. 2015 Dec 18 **http://www.ncbi.nlm.nih.gov/pubmed/26804774**

Pederson JL, Warkentin LM, Majumdar SR, McAlister FA Depressive symptoms are associated with higher rates of readmission or mortality after medical hospitalization: A systematic review and meta-analysis. J Hosp Med. 2016 Jan 29 **http://www.ncbi.nlm.nih.gov/pubmed/26824220**

McAlister FA, Bakal JA, Rosychuk RJ, Rowe BH. Does reducing inpatient length of stay have upstream effects on the emergency room: exploring the impact of the general Internal Medicine care Transformation initiative. Acad Emerg Med. 2016 Feb 6 **http://www.ncbi.nlm.nih.gov/pubmed/26850577**

McAlister FA, Rowe BH. Variations in the emergency department management of atrial fibrillation: Lessons to be learned. Am Heart J. 2016 Mar **http://www.ncbi.nlm.nih.gov/pubmed/26920608**

Shiu JR, Fradette M, Padwal RS, Majumdar SR, Youngson E, Bakal JA, McAlister FA. Medication discrepancies associated with a medication reconciliation program and clinical outcomes after hospital discharge. 2016 Mar 6 Pharmacotherapy **http://www.ncbi.nlm.nih.gov/pubmed/26945706**

AlHabib KF, Sulaiman K, Al Suwaidi J, Almahmeed W, Alsheikh-Ali AA, Amin H, Al Jarallah M, Alfaleh HF, Panduranga P, Hersi A, Kashour T, Al Aseri Z, Ullah A, Altaradi HB, Nur Asfina K, Welsh RC, Yusuf S. Patient and System-Related Delays of Emergency Medical Services Use in Acute ST-Elevation Myocardial Infarction: Results from the Third Gulf Registry of Acute Coronary Events (Gulf RACE-3Ps). PLoS One. 2016 Jan 25 **http://www.ncbi.nlm.nih.gov/pubmed/26807577**

van Diepen S. Is Coronary Intensive Care Unit Volume a Quality Metric? J Am Heart Assoc. 2015 Jun 11 **http://www.ncbi.nlm.nih.gov/pubmed/26729769**

Sean van Diepen MD, MSc, Meng Lin MSc, Jeffrey A. Bakal PhD, Finlay A. McAlister MD, MSc, Padma Kaul PhD, Jason N. Katz MD, MHS, Christopher B. Fordyce MD, MSc, Danielle A. Southern MSc, Michelle M. Graham MD, Stephen B. Wilton MD, MSc, L. Kristin Newby MD, MHS, Christopher B. Granger MD, Justin A. Ezekowitz MBBCh, MSc Do Stable Non-ST Segment Elevation Acute Coronary Syndromes Require Admission to Coronary Care Units? **http://www.ahjonline.com/article/S0002-8703(16)00024-7/fulltext**

Fang ZA, Van Diepen S; Royal Alexandra Hospital and University of Alberta Hospital Cardiac Arrest Teams. Successful inter-hospital transfer for extra-corporeal membrane oxygenation after an amniotic fluid embolism induced cardiac arrest. 2016 Jan 29 **http://www.ncbi.nlm.nih.gov/pubmed/26830639**

Senaratne JM, Norris CM, Graham MM, Galbraith D, Nagendran J, Freed DH, Afilalo J, Van Diepen S; APPROACH Investigators. Clinical and angiographic outcomes associated with surgical revascularization of angiographically borderline 50-69% coronary artery stenoses†. Eur J Cardiothorac Surg. 2016 Jan 29 **http://www.ncbi.nlm.nih.gov/pubmed/26825107**

Chan WK, Goodman SG, Brieger D, Fox KA, Gale CP, Chew DP, Udell JA, Lopez-Sendon J, Huynh T, Yan RT, Singh SM, Yan AT; ACS I and GRACE Investigators. Clinical Characteristics, Management, and Outcomes of Acute Coronary Syndrome in Patients With Right Bundle Branch Block on Presentation. Am J Cardiol. 2015 Dec 12 **http://www.ncbi.nlm.nih.gov/pubmed/26762726**

Montalescot G, van 't Hof AW, Bolognese L, Cantor WJ, Cequier A, Chettibi M, Collet JP, Goodman SG, Hammett CJ, Huber K, Janzon M, Lapostolle F, Lassen JF, Licour M, Merkely B, Salhi N, Silvain J, Storey RF, Ten Berg JM, Tsatsaris A, Zeymer U, Vicaut E, Hamm CW; ATLANTIC Investigators. Effect of Pre-Hospital Ticagrelor During the First 24 Hours After Primary PCI in Patients With ST-Segment Elevation Myocardial Infarction: The ATLANTIC-H²⁴ Analysis. JACC Cardiovasc Interv. 2016 Mar 4 **http://www.ncbi.nlm.nih.gov/pubmed/26952907**

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
National Institutes of Health/NHLBI
Roche Diagnostics Operations Inc.
Sanofi-Aventis Recherche & Développement
Tenax Therapeutics, Inc.
Trevena Inc.