The Canadian Cardiac Chronicle

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"If you want to go fast go alone. If you want to go far go together" African proverb.

We are blessed with great people at the Canadian VIGOUR Centre. Their multicultural diversity and varied talents constitute a metaphor that is truly representative of our many Canadian and international friends and colleagues around the world with whom we have been privileged to work over the past several years. Recent investigator meeting travels to the U.S., Europe and the Asian Pacific region have reinforced Tom Friedman's view that we live in a "small flat world". In cardiovascular medicine we have made great advances together; it is now gratifying to observe a new generation of energetic and talented clinician investigators and other health professionals emerge along with a cohort of enlightened and collaborative industry partners.

As the African proverb cited above implies, doing clinical research requires a long collaborative haul that is challenging, costly and time consuming. Being prepared for failure and strategizing to acquire meaningful learnings - irrespective of the primary trial result - is part of fulfilling the social contract with our patient volunteers.

It is sometimes difficult for relative newcomers to research to understand that changing clinical practice and health policy demands sustained effort and time. Recent modifications in the STEMI reperfusion guidelines prompted by results from the STREAM study are one such example of a sustained journey. Rob Welsh and I began the pre-hospital program in Edmonton over 15 years ago as part of our long standing collaboration with Frans Van de Werf at the University of Leuven. Using lessons learned from that exercise we crafted the WEST study (Which Early ST-elevation myocardial infarction Therapy) at CVC and executed this in Canada. That work found a welcome, fast- tracked home in the European Heart Journal and was accompanied by a complimentary editorial written by 2 French colleagues Gabriel Steg and Nicholas Danchin. With their help and others we proceeded to build on our strong collaboration with the University of Leuven to undertake the STREAM study which convincingly demonstrated a meaningful role for an integrated pharmaco-invasive strategy in the care of STEMI patients. This approach has now been applied in several countries around the world and contemporary parallel registry data are supportive of its favorable impact on patient care. We are proud of the significant impact on STEMI mortality and in particular data indicating our own region has the lowest mortality rates in the country. When I reflect on all of the pieces and players required to accomplish this, it stands as an impressive genuine team effort. It is important to recognize that paramedics, study nurses, research coordinators, biostatisticians, administrative staff, participating investigators came together to achieve an agreed upon goal. Along with colleagues in industry we collectively weaved the fabric of better patient care together.

In This Issue:

Now that both Canadian and American Thanksgiving are behind us, a new American president has just been elected and the American Heart Association meeting has concluded we look ahead to the beckoning of the holiday season and Christmas. The speed of time and events seems somehow to have accelerated with nearly brain numbing velocity. When faced with such an overwhelming buffet of activity it is always wise in my view to pause and take stock of why we are doing what we do, what we are about and why the privilege of residing and working in an academic environment should never be taken for granted. We at CVC are greatly appreciative of your friendship, collaboration and support that genuinely inspires us to push forward to achieve our mission of enhancing cardiovascular care. It is my genuine hope that the readers of the Chronicle take time to reflect on our many blessings and to enjoy the warm company of family and friends in the holiday season ahead.

Wishing you and yours' a Merry Christmas, blessed Holiday Season and happy New Year.

Paul W. Armstrong

GALILEO

With the study now actively recruiting around the world, we are looking forward to building some momentum with our 10 Canadian sites. We anticipate as our sites receive approval and are activated under Amendment 3 which will more closely reflect current practice, that enrollment will increase.

As enrollment is competitive, we encourage all of our Canadian sites to keep actively screening with an aim to recruit 1 to 2 patients a month.

Thank you for working hard to clean up all the data entered into the eCRF in time for the DSMB meeting this December. We appreciate your diligence with getting your data entered in a timely manner and answering queries as they arise.

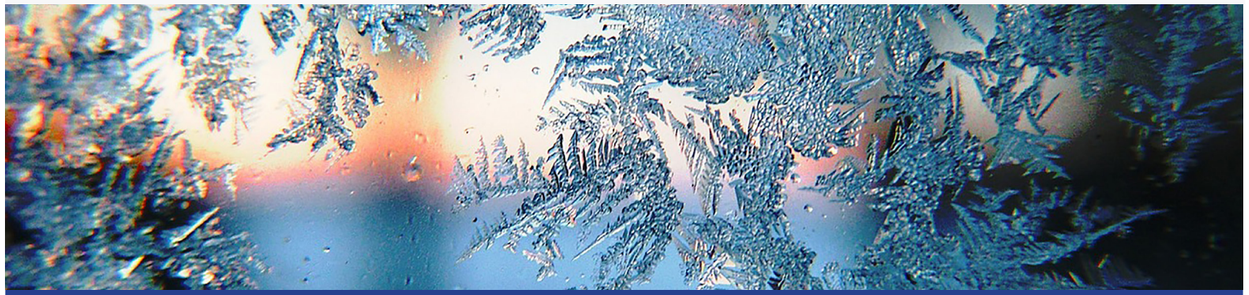
As always, please remember to send your screening logs each week to CVC.

We wish you a wonderful holiday season!

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 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



LEVO-CTS

The LEVO-CTS study recruited the last patient in November. Canada made a solid contribution to this trial with every Canadian site enrolling 6 or more patients. In total, CVC sites randomized over 160 patients. Bravo to all of our CVC LEVO-CTS sites!

With enrollment complete and the short follow-up required per protocol, sites are reminded to keep the data as complete and current as possible, with no queries. Please complete all follow up visits and enter the data as soon as possible. To help support you in this effort please keep an eye out for the emails coming your way each week on your sites data status. Your prompt attention to these emails is appreciated as we work to prepare for database lock in the new year.

As you know, the Principal Investigator at each site will need to sign the eCRFs for every patient randomized at their site. Sites are reminded to ensure that their PI can access the database now, so they are ready to begin signing the eCRFs when the time comes. The PI signature process is expected to begin in the very near future, so please let CVC know if your site's PI has any issues accessing the database.

As we prepare for close-out, CVC is also working closely with sites to ensure all regulatory requirements are complete, including addressing all action items listed in the monitoring visit follow-up letters.

We look forward to working with you on the final phase of this trial – close-out!

For further information regarding 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.

Clinical Trials.gov Identifier: NCT02025621

SODIUM-HF

The SODIUM-HF trial currently has more than 323 subjects randomized (30-Nov-2016) at 18 active sites in Canada, Chile, Mexico and New Zealand. We are working with sites in Argentina and Australia and hope to have them activated in the New Year.

We would like to welcome our newest site:

- Dr. Paz Bourke, Dr. Carla Tiznado and Romina Delgado from Osorno, Chile

We also would like to recognize the following sites on their outstanding contributions to SODIUM-HF:

- Dr. Escobedo and Lubia Valezquez from Mexico City, Mexico on their exceptional recruitment during the month of October 2016 (5 patients recruited).

- Dr. Ross, Lisa Garrard, Enza De Luca and Margaret Brum from Toronto, ON for their steady enrollment. They are recruiting an average of 2.8 patients / month!

- Dr. Porepa, Jeanine Harrison and Amirhossein Sharifzad from Newmarket, ON for their strong start. Since being activated in September 2016 they have recruited 6 patients!

A reminder that the next data cut is 31-Dec-2016:

- Please review all data queries and complete any outstanding information.

- Once all the data is entered, 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".

Thank you to all Study Coordinators and Dietitians who joined the Dietitian Working Group Teleconference in October 2016. If you were not able to join, please review the October newsletter for trial updates as well as the Dietician Working Group (DWG) minutes on the last page.

The Dietitian Training Video will be distributed to our Canadian and New Zealand sites. This video, featuring Elizabeth Woo, includes helpful tips and advice on how to teach patients to manage their sodium intake. It also outlines tools used by Elizabeth to teach patients about food portions and nutrition label reading. If you have any tips or tricks you use when providing dietary counselling for the SODIUM study that you would like to share with other sites, please send us an email and we can discuss in our next Dietitian Working Group.

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.

SODIUM-HF

Funded by the Canadian Institute of Health Research (CIHR), SODIUM-HF is a multicenter, randomized, open-label **S**tudy **O**f **DI**etary Intervention **U**nder 100 **M**MOL in **H**eart **F**ailure.

ClinicalTrials.gov Identifier: NCT02012179

GUIDE-IT

We are in the final phases of Close-Out and wish to extend our sincerest thanks for your hard work and dedication during this busy time. Congratulations to all Canadian sites for their excellent enrollment and data quality throughout the study! We were very pleased to finish the study with 138 patients recruited from our six participating sites in Canada.

Just a reminder to please keep a close eye on your email in the coming weeks for any final requests from the team at CVC. Your site monitors will be in contact with you if they have not already to book and complete your study closeout call. It will be important following that call to notify your ethics committee of the close of study and provide both the submission and closure notice from ethics to the CVC.

We appreciate your support as we work through the final details of Close-Out.

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 until December 23, 2016. After December 23, please contact Clinical Trial Project Lead Nubia Zepeda at 1-800-707-9098 ext 8 or via email at nzepeda@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

AEGIS-I

We are pleased to share that on Tuesday, November 15, 2016, the results of the AEGIS-I trial were presented by study Co-chair Dr. Michael Gibson, at the American Heart Association Congress in New Orleans, LA. The results were simultaneously published in Circulation. (Gibson CM, Korjian, S, Tricoci P, Daaboul Y, Yee M, Jain P, Alexander JH, Steg PG, Lincoff AM, Kastelein JJ, Mehran R, D'Andrea DM, Deckelbaum LI, Merkely B, Zarebinski M, Ophuis T, Harrington RA Safety and Tolerability of CSL112, a Reconstituted, Infusible, Plasma-Derived Apolipoprotein A-I, After Acute Myocardial Infarction: The AEGIS-I Trial (ApoA-I Event Reducing in Ischemic Syndromes I) http://www.ncbi.nlm.nih.gov/pubmed/27881559

The primary objective of this study was to assess the hepatic and renal safety of CSL112 compared with placebo in subjects post MI. Subjects received weekly infusions of CSL 112 (2g or 6g) or placebo for 4 weeks and all patients were stratified to normal or mild renal function based on eGFR. A total of 1258 patients were randomized from 188 sites in 16 participating countries. The study concluded that "CSL112 following MI and contrast was well tolerated and does not significantly alter liver or kidney function and that it elevates cholesterol efflux capacity in a dose dependent fashion." Based on these results we look forward to seeing more to come with CSL112 in an adequately powered phase 3 trial that would assess efficacy.

A special thank you to our 8 enrolling Canadian sites who participated in this study contributing 25 patients to the total global enrollment: O. Bertrand (Quebec, QC), P. Cheung (Edmonton, AB), D. Cleveland (Penticton, BC), A. Della Siega (Victoria, BC), S. Mansour (Montreal, QC), B. Sussex (St. John's, NFLD), M. Vo (Winnipeg, MB), R. Welsh (Edmonton, AB).

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

ClinicalTrials.gov Identifier: NCT02108262

VICTORIA

The Canadian VIGOUR Centre would like to extend our warm thanks to all sites in working through the initial site selection activities so quickly during the summer months. Site selection is now closed and we are pleased to be working with over 40 high quality sites in Canada on this important trial. Canada is off to a great start having been the second country to recruit in the study and 8 patients already randomized.

We would like to congratulate the following sites on achieving important trial milestones:

- Dr. Ezekowitz and Quentin Kushnerik, University of Alberta Hospital, AB: Congratulations on randomizing Canada's first subject in the VICTORIA trial! This is a fantastic achievement and put Canada on the map as this was the first patient randomized in the Americas.

- **Dr. Heffernan and Marie Lantz, Oakville Cardiologists, ON**: Congratulations on randomizing your site's first patient earlier in November!

- Dr. Constance and Marie-France Gauthier, Clinique Sante Cardio MS, QC: Congratulations on being the lead enrolling site in Canada with 5 subjects randomized in the month of November!

Study Reminders:

- Central labs should be drawn **pre-dose** at the randomization visit (V2). While this is not specified in the Protocol, the Lab Collection Flow Chart indicates the PK sample should be drawn pre-dose.

- Applicable sites in Canada will receive Central Lab Kits (Screening Kit A) to assist with cardiac biomarker screening.

- Please ensure your site is using the Site Source Documents (v1 dated 03-Oct-2016). These are 3 source worksheets for 1) Vital Signs, 2) Cardiovascular Procedures, and 3) Events of Clinical Interest. These will be included in your site's regulatory binder and have been distributed electronically by CVC.

- Note: Per Sponsor, if your site can not use the 3 required source data worksheet templates due to institutional requirements, you can utilize your own while ensuring the same content from the Sponsor provided source data worksheets is incorporated.

If you are interested in further information about VICTORIA, please contact Clinical Trial Project Lead Melisa Spaling at 780-492-8476 or toll free via 1-800-707-9098 ext 4 or via email at mspaling@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

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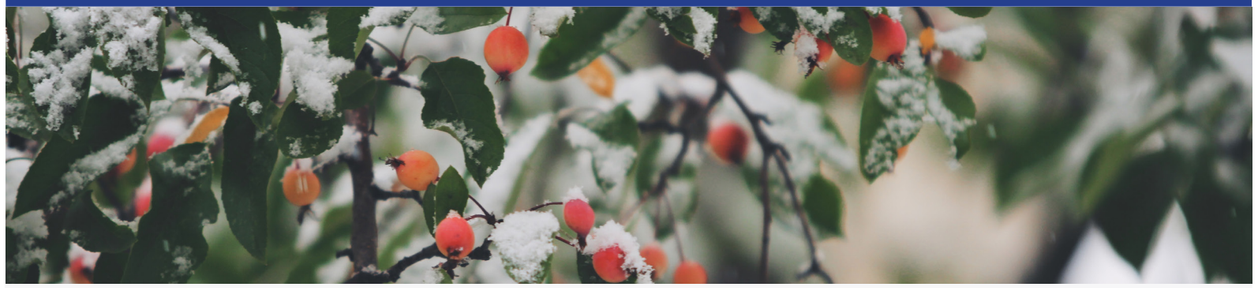
ODYSSEY OUTCOMES



We made it through the second interim analysis, thanks to everyone's hard work! In November, following the DSMB's review of the data they recommended that the study should continue as planned.

With any long-term study, retention is critical. CVC continues to follow up with sites who have patients that have temporarily or permanently stopped study drug. We appreciate all of your patient retention efforts to not only ensure that patients stay on study drug but continue to be followed throughout the duration of the study. Please make sure to update the contact information with your patients at each visit and ensure you have alternate contacts to reach them.

CVC continues to email all sites their data status on a weekly basis. Thank you for promptly addressing these open queries and/or missing pages. Sites will notice the new queries for PI signature of SAEs and AESIs. Please let CVC know if your site's PI is experiencing any issues either accessing the eCRF, or within the eCRF to sign these pages.

Data Clean-Up – Commendations to the following sites that have had 0 open queries and 0 missing data at least once in the past 8 weeks (Keep up the great work!):

- Dr. Bata & Heather Haldane (Halifax)

- Dr. Bourgeois & Glenda Shea Landry (Moncton)

- Dr. Cha & Judy Otis (Oshawa)

- Dr. Ducas & Dolores Friesen (Winnipeg)

- Dr. Dupuis, Francine Ouimet & Brigitte Roberge (Thetford Mines)

- Dr. Fadlallah & Nancy Harvey (Montreal)

- Dr. Hameed & Jody Gowling (St. Catharines)

- Dr. Lepage & Daniel Soucy (Sherbrooke)

- Dr. MacDonald & Joy Howard (Sydney)

- Dr. Michaud & Melissa Cote (Levis)

- Dr. Nigro, Cindy Cryderman Pushplata Bhada (Thunder Bay)

- Dr. Nogareda & Craig Hollingshead (Red Deer)

- Dr. Pandey & Jacqueline Lake (Cambridge)

- Dr. Robinson & Sarah Nelson (Victoria)

- Dr. Rodes & Micheline Charron Giguère (Quebec)

Nearly all sites have submitted the latest amendment to their REB. If you haven't already done so, please send CVC your site's ICF or Addendum to review prior to REB submission. And as a reminder, after you receive REB approval, you should not use your approved ICF or Addendum until you have been given the "green light" from CVC to implement the amendment at your site.

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 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

EXSCEL

We are excited to report that the final study visits have begun! We would like to extend our appreciation for your continued hard work as we move through the final visits and prepare for Close Out. This is a busy period for all and we sincerely appreciate your dedication during this time. Congratulations to our sites on their excellent data quality and patient retention!

As a reminder please enter data from your patient visits within 5 days of the visit. We will be sending out regular updates, newsletters and reminders so please keep a close eye on your email for these.

As we approach the end of the year this is a good time to see if you have any documents that are expiring such as ethics annual renewal, medical licenses, and lab certifications. As you work to update these don't forget to send us a copy at CVC for your study files.

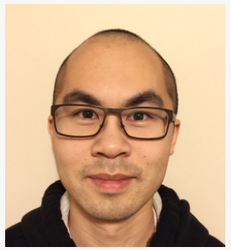
For further information regarding this trial, please contact new Clinical Trial Project Lead Julianna Wozniak at 1-800-707-9098 ext 1 or via email at jwoznikak@ualberta.ca.

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

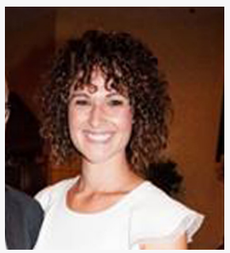
ClinicalTrials.gov Identifier: NCT01144338

CVC News



Eric Ly

Eric Ly recently joined the CVC as an ECG reader for the ECG Core Lab. He received his Bachelor of Human Kinetics degree from the University of Windsor and recently completed his education for cardiovascular technology at St Clair College where he received his certification as a rhythm analysis technician. He enjoys staying physically active and promotes eating a healthy diet.



Julianna Wozniak

Julianna Wozniak recently joined the CVC as a new Clinical Trials Project Lead. She will be taking over the EXSCEL trial from Karin Kushniruk who will be commencing a maternity leave in December 2016. Julianna obtained her Bachelor's degree in Biological Science from the University of Alberta and her Master's degree in Medical Science with Specialization in Psychosocial Palliative Oncology from the University of Calgary. After graduating, she moved to Vancouver and worked as the Research Associate for the Department of Surgery at St. Paul's Hospital. During the past 3 years, she had worked with the University of Alberta's Department of Ophthalmology & Visual Sciences as the Research & Development Coordinator. Julianna is excited to be joining the CVC team!

Upcoming Events - 2017

We are excited to announce that CVC will be launching a new website and logo early in 2017. Stay tuned for additional details in the next issue of the Chronicle!

Early bird registration is now open for the ACC Rockies (March 12-15, 2017) in Banff, Alberta. More details can be found on the website http://www.accrockies.com

CVC is now planning the 4th Annual CVC Clinical Trials Colloquium and will be reaching out to select sites to join us in Banff on March 12, 2017.

Monitoring Tips

Source Documentation

Are you confused about source document requirements in today's increasingly complex regulatory environment? If so, you are not alone.

Health Canada has a valuable resource available on their website entitled "Guidance for Records Related to Clinical Trials (GUIDE-0068)". http://www.hc-sc.gc.ca/dhp-mps/compli-conform/clini-pract-prat/docs/gui_68_tc-tm-eng.php

In this document, source documents are defined as "Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial)".

Given that many sites have now converted to electronic medical records, provisions need to be made for how CRAs/auditors will access these documents. It is always preferred that CRAs/auditors be able to view the actual electronic medical record at your site.

If this is not possible, printed copies of these records are acceptable, however the person that performs the task of transferring from the original to the secondary medium must attest (sign and date an attestation), that the secondary documents are true copies of their respective primary documents. This is why CRAs are always asking for you to "certify" any medical records printed from EMR that you use as source. If your site finds it convenient to print portions of the medical records for ease of monitoring, but the CRAs/auditors are also able to view the medical record upon request, those printed copies of records do not need to be certified.

Bear in mind, however, that if you are relying on direct viewing of your EMR as your source, the EMR will need to be available for the full 25 years after conclusion of the trial. It will be important to take all these points into consideration when your site decides how you will maintain/archive medical records for source documentation.

Your CRAs would be pleased to answer any questions you may have regarding source documentation during your site visits.

CVC Holiday Closure

December 25, 2016 to January 2, 2017

Should any urgent issues arise, we ask that you call the designated Helpline for the study.

CVC's main voicemail will be checked daily throughout the closure to address any important study-related issues and staff email will be checked intermittently.

Any urgent requests can be sent to

tracy.temple@ualberta.ca

Publications

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