“Life is like riding a bicycle. To keep your balance, you must keep moving.”
— Albert Einstein

Autumn means that we have moved forward, nearly completing another year. As a clinical and research community, it means 2 important gatherings are upon us — the American Heart Association and the Canadian Cardiovascular Congress. These meetings have long served as important educational and scientific milestones for our national and international collaborations. This year, we are looking forward to seeing our trainees and colleagues present their work at both of these conferences: those details are noted elsewhere in the Chronicle. Many of these posters or oral presentations would not have been possible without the collaborative efforts by each site, diligently collecting and entering data in each research project. Our patient partners in this effort rarely get to see this impact that stems from their volunteer spirit. This volunteerism provides extensive data ranging from vital signs, blood for biomarkers and imaging data, along with quality of life and health economic data. To this data, add a dose of mentorship and equal parts biostatistical support and co-investigator insight, and after appropriate shaking and stirring a trainee can be energized and a new line of investigation emerges or an expanded understanding of the ‘primary’ manuscript unfold. It is by these collective efforts that we train and expand our pool of clinician scientists in Canada, necessary for maintaining and advancing our research excellence. Yet exposure to this process for those that choose clinical practice is also key to being able to critically appraise the literature and engage in future collaborative research.

Education and training comes in many forms and we encourage our investigators, research personnel, and trainees to learn from each other. This interaction helps simplify some trials (e.g. shortening case report forms) and increase complexity inherent with other lines of inquiry (e.g. collecting serial blood tests in short periods of time). Additionally, trials that seek to be explanatory (e.g. does this intervention cause a specific benefit in highly controlled environments; e.g. AEGIS, BLAST-AHF) require different design and focus that those that seek to be pragmatic (e.g. does this intervention work in usual conditions; e.g. SODIUM-HF, PROACT-4). The design of the research question and subsequent trials takes collective effort to ensure we can deliver meaningful results. No idea, thought, practical consideration, concern, or local insight should be ignored in this scientific process.

We encourage our sites to join us in Toronto as we host a CVC Reception on Sunday, October 25, 2015 at 6:00pm (details enclosed) and attend one of the many scientific sessions that your work helped to bring to fruition. We also provide our traditional educational offerings at CCC that cover the spectrum of disease states, under the Beyond2000 umbrella http://beyond2000.org. We have a panel of national and international experts in a dynamic program on Sunday morning (Acute Coronary Syndromes, Rm 718AB, 0700-0900) and Monday morning (Heart Failure and Atrial Fibrillation, Rm 718AB, 0700-0900).

With autumn comes an expectation of winter, and as a reminder to all of us for when the temperature has dropped, spring will cycle through: much like the cycle of clinical research and new information.

Justin Ezekowitz
There was a terrific turnout from CVC sites and it was wonderful to meet so many of you at the Investigator’s Meeting that was held in Edmonton on June 2-3, 2015, where training on the protocol and the eCRF took place. (For the few sites who did not attend, protocol and eCRF training will occur during your SIV!) The take-home message from the investigator meeting was to emphasize just how important the CKMBS and ECGs are to the success of the trial, and that these tests need to be collected for every patient in the trial at all protocol-required timepoints.

As of September 1, 2015, over 165 patients (at more than 40 sites) have been randomized into this study that aims to evaluate the efficacy and safety of Levosimendan compared with placebo in reducing the composite of all-cause death or use of mechanical assist; OR the composite of all-cause death, perioperative MI, need for dialysis, or use of mechanical assist, in subjects with reduced LVEF undergoing cardiac surgery on CPB.

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.

GUIDE-IT

The GUIDE-IT trial currently has 660 subjects randomized (Canada: 94) as of 3-Sept-2015. We have exceeded our enrollment target of 620 subjects randomized by the end of August 2015. Thank you to all Investigators and Coordinators for contributing to this success – August was another solid month of enrollment for Canada with 5 subjects randomized.

Congratulations to Dr. Toma and Cynthia Van Hoof in Vancouver on randomizing 3 subjects in August!

We hope to see strong enrollment trends continue in September as our goal is to have 100 subjects randomized by the Investigators Meeting (September 29, 2015). The upcoming IM will be held in Washington, DC and will focus on the critical issue of adherence in subjects randomized to the biomarker-guided arm. At least 1 person from each Canadian site has registered to attend; any late registration requests should be directed to Melisa.

Thank you to all Study Coordinators for resolving queries and ensuring your data is up-to-date for the DSMB meeting. We receive consistent feedback that Canada is doing well with query resolution and data entry. We encourage sites to enter visit data within 5 days of the visit. The monitors suggest setting aside time on Fridays (for example) to review Inform for queries (especially CEC queries) and stay on top of data entry.

Welcome to Susan Bonar, CRA, who will be monitoring the GUIDE-IT sites in Western Canada over the coming months. Halina Nawrocki, Lead CRA, will continue to monitor sites in the Edmonton region local initiative sponsored by the University Hospital Foundation and the Mazankowski Alberta Heart Institute. Additional support for point of care meters provided by Alere Inc.

ClinicalTrials.gov Identifier: NCT01663442

ODYSSEY OUTCOMES

The ODYSSEY Outcomes trial is quickly approaching the recruitment finish line! Thanks to a fantastic job from all 38 of our active sites, Canada has now contributed over 300 patients globally we have over 16,000 patients randomized, and as last communicated, we anticipate that we will hit the 18,000 patient mark sometime in November. We thank you all for your continued support of this important trial! We would like to recognize Canada’s top recruiting sites [based on randomizations]:

PI Manohara Senaratne – SC Himani Ferdinandas – 23 Randomized
PI James Stone – SC Meagan Heard – 21 Randomized
PI Stephen Pearce – SC Lynn Breakwell – 17 Randomized
PI Danielle Dion – SC Andrée Morissette – 17 Randomized
PI Gilbert Gosselin – SC Margaux David – 15 Randomized

As you have all seen over the summer months, communications regarding site visits seem to be going out every single day via e-blasts and global newsletters. Please continue to pay special attention to these communications so that you are well informed of the most up-to-date timelines. A reminder that as we near the end of recruitment, we need all of our sites to continue to update Almac IVRS within 24 hours of a decision to screen fail a patient. Also, please remember to schedule randomization visits for patients who do qualify for the study, as soon as possible.

A new Investigator Brochure – edition 8 Amendment 1 – was recently posted to the MedPoint portal. Please be sure to review the e-mail communication sent out to all sites regarding the updated IRB and required actions on your part. We look forward to the coming Amendment and updated informed consent forms in the very near future.

Canada has done an excellent job to date on data cleaning – thank you for all of your hard work! Please ensure that you continue to keep on top of your data queries, making sure that they are responded to within 5 days. We would also like to encourage you to pay special attention to the “data cleaning” emails that we send out, as these also list all of the missing pages that need to be completed for your site. Special attention also needs to be given to any patients that are part of the ‘cleaning cohorts’. These cohort patients need to be 100% clear of queries and missing pages, and this status needs to be maintained as new visits are completed.

We look forward to speaking with all of you on our next Canadian Update WebEx call on October 1st! Please be sure to let us know if you have any questions or topics you would like discussed on the next call.

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.

ClinicalTrials.gov Identifier: NCT01663442

PROACT

EXCITING NEWS!! The PROACT Study has been selected as a Late Breaking Clinical Trial to be presented at the American Heart Association meetings in Orlando, Florida on Tuesday, November 10th from 10:45 to 12:10 in Hall D. We hope to see you there. This is a great accomplishment and it could not have happened without the collaborative effort of Edmonton Emergency Services and the Emergency Department Staff at the 5 major hospitals in Edmonton.

This very important milestone has been reached through the support of University Hospital Foundation, Alberta Health Services, Heart and Stroke Foundation and Alere Inc.

3. Dr. Kalavrouziotis & Hugo Tremblay (Hospital Laval, IUCPQ, Quebec)
4. Dr. Whitlock & Thais Creary (Hamilton Health Sciences, Hamilton)

Dr. Mazer’s site was the first to be activated in Canada in late July, and the team randomized their first patient less than a week later in early August (making them the first site to enroll a patient in Canada). They started so quickly that they set a new record for the fastest randomization following site activation for the trial. Dr. Mazer’s team has set the bar high for this study in Canada and the US!

We look forward to seeing the other activated sites randomize their first patients soon, and meet or exceed the enrollment target of 1 patient per month. Meanwhile, we continue to work through start-up with the six remaining CVC sites, with the goal to have them activated and ready to screen/enroll patients by the end of September.

Stay tuned to see if Dr. Mazer’s site continues their reign as the “fastest site to randomize a patient”, or whether another Canadian site earns that title!

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.

ClinicalTrials.gov Identifier: NCT02025621

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.

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Welcome to Susan Bonar, CRA, who will be monitoring the GUIDE-IT sites in Western Canada over the coming months. Halina Nawrocki, Lead CRA, will continue to monitor sites in Ontario and provide additional monitoring assistance as needed.

For further information, please contact Clinical Trial Project Lead Melissa Spaling at msparing@ualberta.ca or direct: 1-780-492-8476.

In collaboration with DCRI (Duke Clinical Research Institute) and Roche, GUIDE-IT is a prospective, randomized 1:1, multi-centre clinical trial evaluating Evidence Based Therapy Using Biomarker-Intensified Treatment in Heart Failure.

ClinicalTrials.gov Identifier: NCT01663442
TECOS is moving swiftly towards final close-out as we continue to receive REB close out letters and the final documents from sites. The primary results were presented at the American Diabetes Association 75th Scientific Sessions in Boston this June and were promising, concluding that among patients with type 2 diabetes and established cardiovascular disease, adding sitagliptin to usual care did not appear to increase the risk of major adverse cardiovascular events, hospitalization for heart failure, or other adverse events.

The SODIUM-HF trial currently has 122 subjects enrolled (3-Sept-2015) at 15 active sites. The summer was a relatively strong period of enrollment, with 16 subjects randomized in Sept-2015) at 15 active sites. The SODIUM-HF study began in November, 2014 – a new trial record! We look forward to seeing similar strong period of enrollment, with 16 subjects randomized in September, October and November!

Sponsored by Merck & Co. Inc., TECOS is a Randomized, Placebo Controlled Clinical Trial to Evaluate Cardiovascular Outcomes after Treatment with Sitagliptin in Patients with Type 2 Diabetes Mellitus and Inadequate Glycemic Control.

ClinicalTrials.gov Identifier: NCT00790205

CVC is looking forward to welcoming our Canadian sites to a special dinner meeting during the Canadian Cardiovascular Congress this October in Toronto, where the primary results as well as some additional TECOS data presented at the European Society of Cardiology this September will be discussed.

For further information, please contact Clinical Trial Project Lead, Lyndsey Garrity at 1-800-707-9098, ext. 8 or by email at lyndsey.garrity@ualberta.ca.

Sponsored by AstraZeneca, this trial is a pragmatic, long term, placebo-controlled, double-blind 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

If you are interested in further information about TECOS-HF, please contact Clinical Trial Project Lead, Melisa Spaling at 1-800-707-9098, ext. 1 or by email at kushniru@ualberta.ca.

CVC would like to extend our appreciation to each of our Canadian sites for their continued efforts with enrollment. With only one lost to follow up patient to date in Canada we are very pleased with the efforts from our sites.

As a reminder, we want to really focus and encourage all sites to work at keeping patients on study drug for the remainder of the study. To assist in this effort a new ‘TrialNetworks’ tool will soon be launched to help sites track patients who have discontinued study medication. The tool will also provide some points and educational materials to assist with bringing patients, who have discontinued study medication, back on (where appropriate). In the meantime, it is vital you continue to contact the Hotline physician regarding any patients who are considering or have discontinued study drug so that we may explore all options for keeping them on their medication.

The next DSMB meeting has been scheduled for November 2015. This means that we need to have all data entered and clean by September 30th, 2015. Please prioritize your CEC queries and late visits but aim to clean up all outstanding items as soon as possible. We are always eager to assist you with any questions or issues you may have so please don’t hesitate to contact your Project Lead for help.

The 2015 EXSCEL North America Rejuvenation Meeting is scheduled for October 15th -16th in Alexandria, VA. Invitations have gone out and we look forward to seeing you there! Please stay tuned for the forthcoming agenda.

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

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Global enrollment has been on the fast track the last few months and Main Study enrollment is now over 900 patients! The recruitment phase of the study will end at 1200 patients. Recruitment is competitive and with this target number getting closer we are very focused on increasing our Canadian enrollment numbers to ensure that our sites have every opportunity to contribute to this important study. We know that everyone is hard at work screening so we are optimistic that with your dedication Canada can increase their overall recruitment over the next couple months!

Congratulations to all of our enrolling sites!

Dr. Bruce Sussen & Jill Cole – St. John’s, NFLD – 4 patients
Dr. Samer Mansour & Catherine Bouchard-Pilote – CHUM, Montreal, QC – 2 patients
Dr. David Cleveland & Susan Valley – Pentiction Regional Hospital, Penticon, BC – 1 patient
Dr. Park Cheung & Linda Kivil – Royal Alexandra Hospital, Edmonton, AB – 1 patient
Dr. Minh Vo & Camille Meub – St. Boniface, Winnipeg, MB – 1 patient

AEGIS-I

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Congratulations to all of our enrolling sites!

Dr. Robert Welsh & Norma Hogg – University of Alberta Hospital, Edmonton, AB – 1 patient

A few reminders:

Data entry is required within 2 business days of each visit and queries are expected to be reviewed and answered quickly. Thank you to our sites for continuing to enter data in a timely and efficient manner.

Please ensure that all regulatory documents and REB submissions and approvals pertaining to Protocol Amendment #3 have been sent to CVC.

For further information, please contact Blinded Clinical Trial Project Lead, Lyndsey Garrity at 1-800-707-9098, ext 8 or via email at lyndsey.garrity@ualberta.ca or Unblinded Clinical Trial Project Lead Tracy Temple @ 1-800-707-9098 ext 5 or via email at tracy.temple@ualberta.ca.

Sponsored by CSL Behring LLC, this study is a Phase 2b, multicenter, 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

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BLAST-AHF

Congratulations to Dr. Haddad, Ann Baker and Laura Menchini and their team in Ottawa, ON on randomizing Canada’s first subject in the BLAST-AHF trial! We look forward to additional enrollments at their site as well as our other participating Canadian sites.

There are over 370 subjects enrolled in the trial with over 60 active sites – well on the way to achieving the enrollment target of 620 subjects! With the push to complete enrollment near the end of this year we encourage our sites to keep actively screening. CVC will continue to keep you up-to-date on study timelines.

Thank you to all study sites for your efficient return of expired study drug; all sites have been re-supplied with new study drug supplies (expiry date is either January 2016 or March 2016). As a reminder, study drug is auto resupplied via IVRS based on rate of enrollment at your site.

Reminders:
- Please remember to enter the study data within 5 days of the
  study visit. The monitor will be on site within 1 week of the
  Day 5 study visit.
- Lab kits and supplies are not auto-resupplied. Please be
  sure to check the expiry dates as the various kits expire at
different times. Log in to PPD INSITE to re-order any supplies
  you may need (note: please allow 2 weeks for delivery).
- As applicable, please check the expiry dates on your BNP
  kits and ensure adequate supplies are re-ordered well in
  advance.

If you have any questions about BLAST-HF, please contact Clinical Trial Project Lead, Melissa Spaling at 780-492-8476 or via email at mspling@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.

ClinicalTrials.gov Identifier: NCT01666601

GALILEO

GALILEO is a Phase III study that will enroll approximately 1500 patients and will look at the long-term benefit/risk profile of rivaroxaban, an oral Factor Xa inhibitor for the prevention of ischemic and thromboembolic events in patients post successful transcatheter aortic valve implantation (TAVI).

The Canadian VIGOUR Centre is pleased to be collaborating closely with the team from Icahn School of Medicine at Mount Sinai, New York, Bayer Healthcare AG and Cardialysis (Europe) on this exciting project. We are pleased to have CVC Faculty member, Dr. Robert Welsh with the University of Alberta Sinai, New York, Bayer HealthCare AG and Cardialysis (Europe) closely with the team from Icahn School of Medicine at Mount Sinai, New York, Bayer Healthcare AG and Cardialysis (Europe) representing Canada on the Executive Committee and

removing one subject.

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Sinai, New York, Bayer HealthCare AG and Cardialysis (Europe) representing Canada on the Executive Committee and

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and Prof. Dr. Stephan Windecker (Inselspital, University Hospital Bern, Switzerland).

Initial invitations have now been sent out and feasibility has started both in Canada and rest of world.

If you are a high volume TAVI site, with a research team in place and would be interested in hearing more about this study please contact Jodi Parrotta at jodi.parrotta@ualberta.ca or 1-800-707-9098 ext. 3.

Sponsored by Bayer Healthcare AG, GALILEO is a Global multi-center, open-label, randomized, event-driven, active-controlled study comparing a rivaroxaban-based anti-

thrombotic strategy to an antipLate-

let-based strategy after transcatheter aortic valve replacement (TAVR) to Optimize clinical outcomes.

ClinicalTrials.gov Identifier: NCT02556203

Upcoming Trials

The Canadian VIGOUR Centre is partnering with the Duke Clinical Research Institute (DCRI), Stanford Center for Clinical Research and a global pharmaceutical company on an exciting Phase III study in patients with chronic heart failure. Importantly, this program is expected to enroll a broad range of patients with both reduced and preserved ejection fraction and hence be very inclusive.

Please stay tuned for more information coming your way this fall.

CVC News

Wendimagegn Ghidey Alemayehu (PhD) joined the CVC as a biostatistician as of July 20, 2015. He recently hails from the Erasmus Medical Center Cancer Institute in Rotterdam, the Netherlands and was granted a PhD in Biostatistics from the Katholieke Universiteit in Leuven, Belgium.

Kris Reyz joined CVC as an Administrative Assistant in August 2015. She brings varied administrative experience from her work in the private and public sector. In her free time, Kris is an active community volunteer and enjoys spending time with her three children.

Monitoring Tips

Does a deviation/violation from protocol matter? – The answer is YES.

A deviation/violation is a departure from the protocol/amend-

ments and study requirements that has been approved by the

REB. Upon discovering a protocol deviation/violation, the

Principal Investigator is responsible for reporting this to the REB as per their reporting requirements and timelines. Documenting of the protocol deviation/violation is crucial as well as document-

ing a corrective action plan to ensure that the deviation/violation does not occur again. Examples of protocol deviations/violations:

- The subject did not sign an REB approved consent prior to any study related procedures.
- The site has not documented the consent process when recruiting a subject.

- Inclusion/exclusion criteria was not met.
- Prohibited medications were used.
- Protocol required tests were not performed.
- AE/SAE’s are unreported.
- The subject missed study visits or the visits out of window.
- Study medication was not taken as per protocol.

For monitoring related questions please contact Halina Nawrocki at halina.nawrocki@rogers.com or Tracy Temple at temple@ualberta.ca.

Abualigna S, Poddar M, Hernandez AF, McMurray JI, Starling RC, O’Connor CM, Califf RM, Armstrong PW, Ezekowitz JA. Acute Heart Failure and Atrial Fibrillation: Insights From the Acute Study of Clinical Effectiveness of Ne-
silide in Decompensated Heart Failure (ASCEND-HF) Trial. J Am Heart As-


Publication

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Publications Continued


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

Alere Inc.
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CIHR
CSL Behring LLC
Heart & Stroke Foundation Canada
Merck & Co., Inc.
Bayer Health Care AG

National Institutes of Health/NHLBI
Roche Diagnostics Operations Inc.
Sanofi-Aventis Recherche & Développement
Tenax Therapeutics, Inc.
Trevena Inc.
Mazankowski Alberta Heart Institute
University Hospital Foundation

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.

The VIGOUR (Virtual Coordinating Centre for Global Collaborative Cardiovascular Research) group is an international academic group committed to advancing cardiovascular medicine and enhancing patient care worldwide. Its membership includes: the Canadian VIGOUR Centre (CVC), University of Alberta, Edmonton, Alberta, Canada; Green Lane Coordinating Centre, Auckland, New Zealand; National Health & Medical Research Council – Clinical Trials Centre, Sydney, Australia; Flinders Medical Centre, Bedford Park, Australia; Duke Clinical Research Institute (DCRI), Duke University, Durham, NC, USA; Leuven Coordinating Centre, University Hospital Gasthuisberg, Leuven, Belgium; ECLA, Rosario, Argentina, South America; TANGO, Buenos Aires, Argentina, South America; Uppsala Clinical Research Centre, Uppsala, Sweden

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