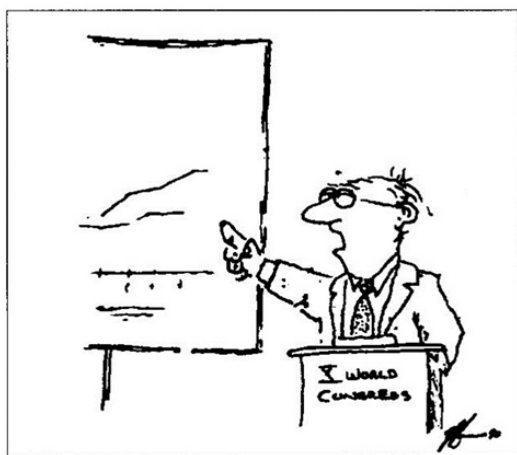


# The Canadian Cardiac Chronicle

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Summer 2015

## The Future of Cardiovascular Clinical Research: Challenges and Opportunities



*“This randomized, double-blind trial involving over 20,000 patients was conducted over a 10 year period. Unfortunately we’ve forgotten why.”*

As the cartoon suggests, it isn’t easy doing clinical trials. Many of us who have been involved in cardiovascular research over the past 20-plus years fondly recall the more simple days of the first GUSTO trial. GUSTO-I was a study designed and run by a confederation of global academic leaders—including the founders of the Canadian VIGOUR Centre [CVC] and the Duke Clinical Research Institute [DCRI]—which engaged a grassroots network of thousands of investigators and coordinators who enrolled almost 42,000 patients in just over 2 years, with the majority coming from North America. While hard to imagine in our current research environment, GUSTO-I was performed in an era when confidentiality disclosure agreements (CDAs) weren’t required before reviewing a copy of the study protocol, when informed consent forms (ICFs) and case report forms (CRFs) were no more than 3-4 pages each, when study drug was shipped without a contract, and when the 30-day follow-up was mainly undertaken through a postcard given to patients to mail to the coordinating center!

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What has changed? As highlighted in our recently published “white paper” (Roe et al Am Heart J 2015; see P.S. below), clinical trial research has become increasingly complex with declining morbidity and mortality in the context of improved evidence-based management (good news for the patients but resulting in large sample sizes and longer duration of follow-up for the trialists), higher costs, and a shrinking pharmaceutical pipeline. Indeed, a decreasing downstream return on the sale of cardiovascular drugs, with markets often populated with generic formulations, has led industrial sponsors to consolidate, cut back, and/or shift their investments to other areas of medicine. There are multiple challenges and impediments for conducting cardiovascular clinical research studies, particularly in North America. These include: increased site costs and complexities of trial participation, a limited pool of experienced investigators and study coordinators, increasing enrollment competition from developing countries, strong concerns about patient privacy issues, and increasing regulatory burden for sites. Further, the value proposition for clinical trial participation has changed not only for investigators and coordinators, but also for our patients particularly as study participation has become more demanding and time-consuming.

Despite these potential threats, we believe there are also opportunities to: expand clinical and site-based research training programs; build strong and durable site networks; support more academic recognition of site-based researchers; support sponsor and regulatory reforms (e.g., risk-based monitoring, focused adverse event reporting, streamlined data collection

## Co-Director's Letter Continued

and safety reporting requirements); access and leverage electronic health record information; simplify trial participation; advocate for new, simplified ethics processes and policies; and, appropriately acknowledge and compensate for the complex and expensive start-up process undertaken at each site by investigators and coordinators.

Given that many pharmaceutical companies have downsized their clinical research operations groups and are often outsourcing a growing amount of research activity to contract research organizations (CROs), the execution and conduct of clinical trials are increasingly being undertaken by companies that focus on providing data to sponsors for regulatory purposes rather than on integrating new knowledge into practice by disseminating and implementing the results across the clinical community. In contrast, the aspirational goals for AROs like the CVC are to address clinically relevant questions and improve clinical practice through scientifically robust, operationally innovative, and well-executed clinical research studies that specifically engage site investigators and research personnel. The recent experience in the Trial to Evaluate Cardiovascular Outcomes after Treatment with Sitagliptin (TECOS) in patients with Type 2 Diabetes Mellitus and suboptimal glycemic control is a good example of a very successful ARO-led collaboration (Oxford University and the DCRI) sponsored by an industrial partner (Merck). With CVC oversight, Canadian investigators and coordinators have done a tremendous job enrolling patients, keeping them on study drug, minimizing the number of patients withdrawing consent, and having no patients lost to follow up. The TECOS primary results will be presented at the 2015 American Diabetes Association 75th Scientific Sessions in

Boston, on June 8th—a preliminary press release was very encouraging; stay tuned for the final results!

Thus, together with our partners at the DCRI and Stanford, we are keen to continue to work with you and offer new, pragmatic research opportunities (more clinical studies coming soon!) and provide support (e.g., our annual CVC Colloquium held prior to the ACC Rockies meeting) and educational opportunities (e.g., the annual Beyond 2000 satellite symposium held during the Canadian Cardiovascular Congress—there will be 2 this October in Toronto - preliminary programs enclosed!) designed to translate new evidence into clinical practice. Together with you, we believe that our North American collaboration makes us uniquely positioned to further enhance grassroots collaborations across all types of practices, to delineate successful solutions to obstacles that limit clinical research initiatives, and help guide the future of cardiovascular research in the global research environment.

Have a great summer!



Shaun Goodman

P.S. Our North American ARO collaboration paper is now published (Am Heart J 2015;169:43-50) and a video interview with Drs. Matt Roe (DCRI) and Ken Mahaffey (Stanford) regarding this manuscript is now available to view on the American Heart Journal website: <https://vimeo.com/dcricreview/127952608/a0e43a2a66>

## LEVO-CTS



In the US, over 100 patients have been randomized so far. In Canada, we are in the early stages of start-up, working with 14 sites in this new study which 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.

We are pleased to see many of our Canadian sites working toward a rapid start up. Over half of our sites have submitted to ethics, and we are working at collecting and reviewing the regulatory documents required to complete their start-up.

Training on the protocol and the eCRF will take place at the Investigator's Meeting on June 2-3, 2015 in Chicago. Eleven sites have registered for this meeting. We look forward to meeting all of you! For those sites who cannot attend, protocol and eCRF training will occur during your on-site initiation visit. We are looking to have our first site activated before the end of June, with Canada's first patient randomized soon thereafter!

The goal will be to have all sites activated and screening/enrolling patients by the end of summer.

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](mailto: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**



## ODYSSEY OUTCOMES

2015 continues to be a fantastic year for Canada in the ODYSSEY Outcomes trial. The combined efforts of our 43 active sites have resulted in consecutive record-breaking screenings and randomizations each month for Canada! Worldwide nearly 13,000 patients have now been randomized into the trial with Canada contributing over 250. A special thank you goes out to our top recruiting sites (based on randomizations):

- PI Manohara Senaratne – SC Himani Ferdinandis – 21 Randomized
- PI James Stone – SC Meagan Heard – 18 Randomized
- PI Stephen Pearce (previously Jan Kornder) – SC Lynn Breakwell – 17 Randomized
- PI Gilbert Gosselin – SC Margaux David – 15 Randomized
- PI Danielle Dion – SC Andrée Morissette – 14 Randomized

As we continue to move closer and closer to our goal of 18,000 patients worldwide, please continue to be on the lookout for communications in the coming months which will provide details related to end of recruitment. Also, as mentioned on our May 2015 Canadian Update WebEx, please ensure that you are updating Almac IVRS within 24 hours of a decision to screen fail a patient, as this will allow for more accurate data on the number of patients eligible for randomization.

Summer 2015 will be a busy time for ODYSSEY Outcomes, as we anticipate the release of a Protocol Amendment in Canada by early July. We also have a new Investigator Brochure (Edition 8)

and the associated ICF changes that will come along with it.

Please work closely with your project lead to ensure a quick turn around on the completion and implementation of these important updates.

All sites have now received the updated drug accountability logs (CVC Version Date: 13May2015). As noted in the email communication you received, these should only be used for future shipments – shipments received before their release should be tracked on the previous version of the log that you were using (including the subject specific tracking log). If you have any questions regarding this transition, please contact your project lead.

We appreciate your continued attendance on our monthly Canadian Update WebEx calls! 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](mailto:amanda.carapellucci@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**

## PROACT

Enrollment in the PROACT study was completed in Feb 2015 with a total of 602 patients recruited. The follow up, data abstraction and the adjudication process are also now complete and the analysis is underway. The plan is to bring together the Steering Committee in the near future.

The cleanup process of any database can be very tedious and we appreciate the speedy and efficient help of Kim Simpson, Operations Supervisor EMS.

This study would not have been possible without the support of the EMS crews and the staff in the Emergency Departments at the major hospitals in Edmonton. We also appreciate the

support from the various Records management departments at the hospitals.

For further information please contact Paula Priest at 1-800-707-9098, ext. 9 or by email at [paula.priest@ualberta.ca](mailto:paula.priest@ualberta.ca).

Providing Rapid Out of Hospital Acute Cardiovascular Treatment

## PROACT

An 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: NCT01634425**

## EXSCEL

Retention Retention Retention! As you know, large numbers of patients off study drug or without outcome information decreases the statistical power of the study and reduces the ability to detect a significant result at the end of the trial. Canada has zero patients lost to follow up and zero patients who have withdrawn consent. That is fantastic! Please take some time during patient visits to remind your patients on and off study drug about the importance of their involvement in the study and remaining on study medication. Of course if the patient has a protocol specified reason to be off study drug we would not encourage them to restart the study drug. If you do have a patient that is permanently discontinuing study drug please call or email the trial hotline to discuss your plans with a trial medical physician.

Also please document the decision clearly in InForm.

For further information about this trial, please contact Clinical Trial Project Lead, Courtney Gubbels at 1-800-707-9098, ext. 1 or by email at [courtney.gubbels@ualberta.ca](mailto:courtney.gubbels@ualberta.ca).

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*

## AEGIS-I



Global enrollment is now over 300 patients in the Main Study and the PK/PD Sub-Study has recruited over half of the patients to date. With an enrollment target of 1,200 patients and most of the sites now activated around the world we are well on our way to achieving our enrollment goal! We are pleased to have 4 activated sites in Canada. Great job to Dr. Sussex and Jill Cole in St. John's, Newfoundland for enrolling Canada's first patient in the trial! We anticipate seeing enrollment take off in Canada as our remaining sites are activated. We look forward to seeing Dr. Welsh's and Dr. Cheung's (Edmonton, Alberta) and Dr. Lavi's (London, Ontario) sites who were recently activated recruit their first patient in the coming days.

Our goal is to have all Canadian sites active by the end of June

2015. For our remaining sites who are not yet activated we need your help to make this happen before the end of the month. Thank-you for all your hard work so far!

Currently our main focus has been on site activation and patient enrollment but another important aspect of the trial is data entry. Data is reviewed very quickly in this trial. Therefore all data needs to be entered within 72 hours of the visit occurring and queries need to be answered as quickly as possible. If you encounter any issues with data entry please contact CVC for assistance.

For further information about this trial, please contact Blinded Clinical Trial Project Lead, Courtney Gubbels at 1-800-707-9098, ext. 1 or by email at [courtney.gubbels@ualberta.ca](mailto:courtney.gubbels@ualberta.ca) or Unblinded Project Lead, Tracy Temple at [tracy.temple@ualberta.ca](mailto:tracy.temple@ualberta.ca) or ext. 5.

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*



## BLAST-AHF

All Canadian sites are now active under Amendment 4; we eagerly await Canada's first patient! Thank-you to all site Investigators and Coordinators in your efficient and hard work to be activated so quickly under the Amendment. Global enrollment is over 250 with 80 participating sites around the world. Reminders:

- Please remember to enter the study data within 5 days of the study visit. The monitor will try to 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 are interested in further information about BLAST-HF, please contact Clinical Trial Project Lead Melisa Spaling at 780-492-8476 or via email at [mbspaling@ualberta.ca](mailto:mbspaling@ualberta.ca).

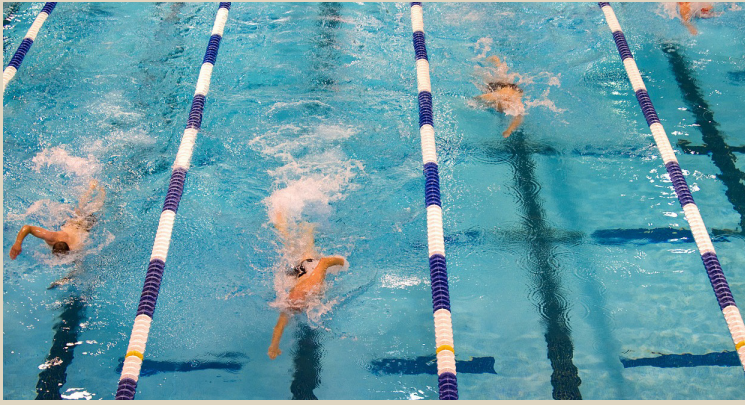
Sponsored by Trevena Inc., BLAST-AHF is A Randomized, Double-Blind, Placebo-Controlled, Dose Ranging Study to Explore the Efficacy of TRV027 in Patients Hospitalized for Acute Decompensated Heart Failure.

*ClinicalTrials.gov Identifier: NCT01966601*





## TECOS



The TECOS Executive Committee will be presenting the primary results at the 2015 American Diabetes Association 75th Scientific Sessions in Boston on June 8, 2015 at 4:30pm EST. A Live Broadcast will follow that evening at 7:30pm EST with an expert panel discussion on CV safety trials in Type II Diabetes and a review of the late-breaking data from TECOS and other recent CV safety trials. If you will not be attending the ADA but wish to view the broadcast remotely, please register by visiting [www.imedius.ca/ada2015](http://www.imedius.ca/ada2015).

Unblinding information is expected at some point following the presentation of results and will be sent to sites for communication to subjects as soon as it is available.

Database lock successfully occurred as planned in March 2015. Over the next few months we will continue to focus on reconciling any outstanding site regulatory documents in preparation for close out. As a reminder, please ensure that you do not submit a close-out notice to your REB until you have received a communication from CVC providing the go-ahead to do so. Thank you to our sites for responding to any regulatory requests in a timely manner over these next months as we get closer to the finish line.

A reminder that any outstanding site invoices for pass-through items within your contract should be sent to CVC as soon as possible for processing and payment.

For further information, please contact Clinical Trial Project Lead, Lyndsey Garritty at 1-800-707-9098, ext. 8 or by email at [lyndsey.garritty@ualberta.ca](mailto:lyndsey.garritty@ualberta.ca)

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**

## SODIUM-HF

The SODIUM-HF trial currently has 82 subjects enrolled (20-May-2015) – well on the way to meeting our enrollment target of 100 patients randomized by the end of June, 2015. The month of March, 2015 was a record-breaker with 15 subjects enrolled across many sites! We look forward to maintaining this enrollment trend and encourage each site to work towards a goal of 1 subject/month. As a reminder this is in line with our current enrollment challenge which is focusing on randomizing 1 subject/site/month in April, May and June.

The first site in Mexico was activated in May, 2015 and additional sites are expected to be activated over the summer months. We look forward to international collaboration on this exciting project!

- Welcome to Dr. Escobedo and Luvia Velazquez (Site 117) at Instituto Mexicano del Seguro Social (IMSS) in Mexico

Please note the next Dietitian Working Group Teleconference is scheduled for Thursday, June 4 at 1:00 PM / 3 PM Eastern.

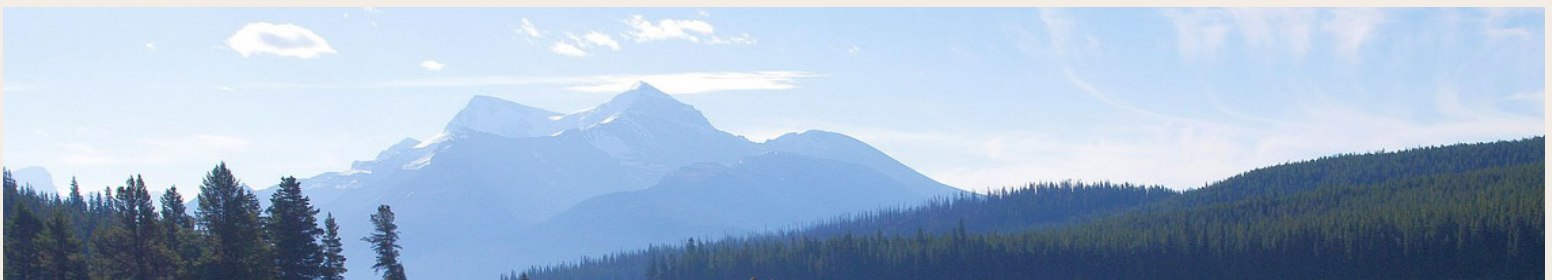
The focus of this call will be REDCap / eCRF. Please feel free to forward any questions or issues you have with REDCap to Melisa to ensure your concerns are addressed. As usual, there will also be time for discussion of site topics, particularly related to the dietary intervention. If you are unable to dial in, a trial newsletter will be distributed in the following week which will contain meetings minutes for your reference.

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 [mbspaling@ualberta.ca](mailto:mbspaling@ualberta.ca).

Funded by the Canadian Institute of Health Research (CIHR), SODIUM-HF is a multicenter, randomized, open-label Study Of Dietary Intervention Under 100 MMOL in Heart Failure.



**ClinicalTrials.gov Identifier: NCT02012179**



## GUIDE-IT



The GUIDE-IT trial currently has 594 subjects enrolled (Canada: 78). Canada's contributions to the trial remain strong. The month of April, 2015 was a record month for enrollment with a total of 9 subjects randomized. We are confident if recruitment remains strong the goal of 620 patients by the end of August will be accomplished.

Thank you to all sites for your diligence in recruitment/randomizing over the past few months. Special recognition goes to the following for their remarkable achievements:

1. Congratulations Dr. Virani and Naomi Uchida (Vancouver General Hospital) for setting a trial record and enrolling 4 subjects in 1 day!
2. Congratulations Dr. Grant, Kim Ronak, and Leslie Jackson-Carter (Foothills Medical, Calgary) for randomizing 4 subjects in the month of April! They are also one of the top ten enrolling sites in the trial – well done!

Central Lab Collection:

- After the 12 month visit is complete, a reminder that the only central lab sample to collect is NT-proBNP. This sample should

be collected for all patients, at all regular study visits (visits MON 15, 18, 21, 24). The LabCorp kits will not be adjusted; therefore, sites may discard all other collection tubes and cryovials. (Data entry reminder: Please record '0' on the Biobank page for the central lab samples that you did not collect).

- Lab sample reconciliation: Please ensure you carefully document (source worksheets and Inform) the number of cryovials for each sample that were collected and shipped to Lab Corp. Inform data entries are compared to the samples received at Lab Corp; sites will be queried if there are discrepancies.
- As a reminder, the DNA sample is only collected at Baseline. All subsequent visits should have '0' entered in Inform for the 'whole blood, EDTA' sample on the BIOBANK page.

For further information, please contact Clinical Trial Project Lead Melisa Spaling at [mspaling@ualberta.ca](mailto:mspaling@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 **GUIDing Evidence Based Therapy Using Biomarker Intensified Treatment in Heart Failure**.



**ClinicalTrials.gov Identifier: NCT01685840**

## Colloquium

As noted in the last issue of the chronicle there was a wealth of information gained from the Study Coordinator session during the Colloquium in March. Given we are unable to have all sites in attendance we want to continue sharing some of the key feedback as it relates to clinical trials and hope that you may be able to implement some of these recruitment strategies which have proven effective at other sites.

- Ensure your team is involved and engaged throughout the clinical trial and understand what the trial is working to achieve.
- The site Investigators involvement is key to the trial success. A very keen and involved PI equals a very keen study team where everyone will believe and buy in. This enthusiasm and interest will shine through in the discussions with potential patients.
- Consider hiring extra staff to help with screening i.e. summer students.
- Develop a screening tool which you can share with other study coordinators/members of your team with the aim to

screen for multiple trials at one time.

- Look at lists of patients that were screened for other trials to determine if they may be eligible for new trials. When a patient screen fails for one trial make a list and consider re-approaching them for future trials which they may be eligible for.
- Involve the patient's significant other or family in the consent process to ensure everyone is on board and understands what it will involve. If they understand what it is they are more likely to be supportive.
- Work toward simplifying the consent. The lengthy consent is not only challenging in ensuring a patient is fully informed, but may be a deterrent to participation.
- Work with your institution to ensure you have access to patient charts and databases to screen potential patients.

We appreciate the sites who have shared these ideas and encourage all of you to continue sharing your successes with us and other sites as we work to enhance clinical research in Canada. If you have any questions please contact Tracy Temple at 1-800-707-9098 ext. 5 or email [tracy.temple@ualberta.ca](mailto:tracy.temple@ualberta.ca).



## Monitoring Tips

### Why Informed Consent and the Informed Consent Process is Important

It is important to have a patient take the time to read the consent, ask questions and/or clarifications before they sign the consent. It is even better if the patient has a significant other present during this time so both can understand the consent and time commitment to the study.

Consequences of patients not understanding the consent, such as that they will be taking experimental drug, risks or limitations of the drug or that they may not be receiving drug, can be significant.

Such consequences lead to a patient not taking drug at all, not coming for scheduled visits, withdrawing consent or worse, being lost to follow up. This can have consequences to the sponsor for potential loss of data for regulatory submission.

So we encourage you to take the time with your patients to

ensure they understand the study, study timelines, and the study medication and/or placebo.

Document the consent process and make sure to document the patient's understanding and willingness to participate.

For monitoring related questions please contact Tracy Temple by email at [tracy.temple@ualberta.ca](mailto:tracy.temple@ualberta.ca) or by phone at 1-800-707-9098 ext. 5 or Halina Nawrocki at [halina.nawrocki@rogers.com](mailto:halina.nawrocki@rogers.com).



## Publications

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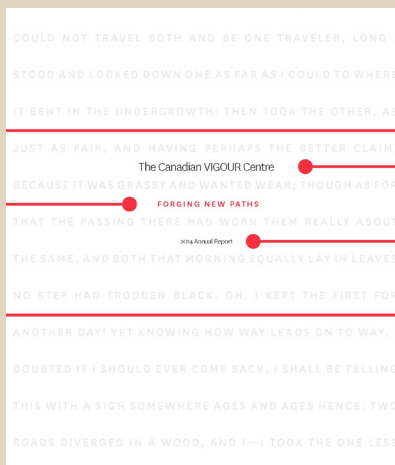
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## CVC News



We are pleased to share our 2014 Annual Report available online at [www.vigour.ualberta.ca](http://www.vigour.ualberta.ca). Here you will find an overview of our collaborative projects, faculty, trainees, national and international collaborations and partnerships. Our CVC support staff described herein, are key to the success of our efforts. Our research presentations, academic visits and publications signal the external CVC profile. We hope you enjoy this distillate about who we are and what we did, collectively, in the last year.



## In Remembrance: Jan Kornder, MD



In the course of clinical research in this country over the last 40 years I have encountered many colleagues. There are few as unforgettable as Jan Kornder. He was a big man in many respects. Big in stature, energy, enthusiasm, heart, generosity of spirit and ideas. He was a valued and respected clinician and leader in cardiology at the Surrey Memorial Hospital in Vancouver, British Columbia and the Director of Quality and Patient Safety at Fraser Health in British Columbia.

For all of us at CVC his untimely death represents the loss of a great friend and splendid clinical research collaborator who made many contributions to enhancing the care of patients with cardiovascular disease. Jan was always keen to participate in clinical research, as long as he was convinced it had the potential to benefit his patients. Once committed he was all in. What then followed during our many investigator meetings and medical educational events over the years, was penetrating questions, constructive critique, vigorous high quality recruitment and sage insights into the ultimate findings and their implications for patients. In the course of many such events I came to know him as a friend and to enjoy his irrepressible sense of humor, his obsession with NHL hockey and other sports and his love for his family.

On behalf of CVC, we send our sincere condolences to his wife Carolyn and his family on the passing of a special man. We are better because of his contributions and for having known him.

## Publication Information

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