The value proposition for clinical trial participation has changed not only for investigators and coordinators, but also for our patients. Particularly in an era of heightened awareness around privacy, associated limited access (and ability) to approach potential subjects, and the increasing demands and time required to participate in research, we all face the challenge of engaging patients in clinical trials. Indeed, our recent survey of 16 Canadian sites from 8 provinces identified that the time from site initiation to recruitment of the first patient in a new clinical study is often delayed, in part because eligible patients (and sometimes their families) are unwilling to make the necessary long-term commitment. Further, while Canadian sites continue to keep withdrawal of patient consent and lost to follow-up to a minimum amongst the vast majority of enrolled subjects, premature discontinuation of study treatment is an ever-increasing problem.

The first step towards meeting these challenges is recruitment of the “right” patient. It is critical to ensure the patient clearly understands the investigational treatment (e.g., study drug administration, potential side effects, potential comparison against a placebo), and the important commitment they need to make (e.g., study duration of several years, willingness to be followed even if they have to discontinue study treatment, making the study coordinator aware of changes in their health status and concomitant medications).

It is also important to consider “what’s in it for the patient?” when approaching potential study subjects. A review of the literature provides the following insights: (1) eligible patients who participate in clinical trials often experience better outcomes than those who chose not to participate, even if they are assigned a placebo (probably due, in part, to the evidence-based care and enhanced clinical surveillance they receive); (2) participation might not be limited to curiosity (an important pre-enrolment motivator for older adults) or altruistic considerations (e.g., “I’ll do it for the next generation”) since patients themselves may “realize” the benefits of study therapy in their own lifetime; and, (3) patients participating in a clinical trial suggested that they received personal benefits such as increased knowledge of their condition, treatment and information from specialists, “peace of mind”, and opportunities to interact with other patients.

Our surveyed sites indicated that several strategies could be employed to keep patients engaged, including: (1) an involved principal investigator who was accessible and participated (even briefly!) in face-to-face patient visits; (2) regular contact with the study coordinator; (3) providing reimbursement for out-of-pocket expenses (such as parking, gas, meals) incurred by patients for follow-up visits; and, (4) engagement of family members. Of note, our sites placed relatively lower importance on keeping patients updated on the trial status, retention items (e.g., heart healthy cookbooks), calendars for tracking appointments, and patient newsletters. However, patients participating in clinical trials have often highly ranked study progress updates through newsletters, provision of calendars, and the occasional opportunity to meet with the study staff and other trial participants in a group lunch setting as “incentives” to continued involvement. Thus, we should consider these strategies as an appropriate and ethical recompense for our clinical trial participants; think about a “lunch & learn” session not only at the beginning of the trial as a means to engage other physicians and allied health care personnel but also along the way to keep your patients engaged!

Shaun Goodman
CVC Co-director
While efforts throughout the open dialogue is a key element to any. Clearly as technology advances we will see its challenges. We were further reminded us how important it is to select the right trial for your investigator responsibilities, oversight, and presence throughout the course of the study.

Dr. David Mazer from St. Michael's Hospital in Toronto joined us wearing two hats, one as an experienced investigator and another as a hospital ethics chair. He was charged to provide us with a "Better Understanding of Ethics: Current and Future Issues for Research Ethics Boards (REBs) in Canada and recommended solutions." Reflecting on the Canadian landscape, Dr. Mazer shared recommendations from the Canadian Clinical Trials Coordinating Centre (CCTCC) which was created to implement an action plan to strengthen and improve clinical trials in Canada. One recommendation of this group was to improve efficiencies of ethics reviews. While efforts have been and are continuing to be initiated in many provinces across the country (including BC, AB, ON, QC, NS and Nfld) to harmonize ethics reviews, it is clear that this initiative is still a work in progress. Reflecting on some general observations from these initiatives to date it is clear that, (1) the lead investigator bears the most responsibility, (2) dealing with amendments, SAES, etc post initial review is “uncharted territory”, (3) contact reviews are an issue, and (4) while there is a reduction in redundant reviews the use of centralized/harmonized REBs does not necessarily speed up the process. Recognizing that change will take time we were encouraged to hear that there are ongoing efforts to address the need for shorter consents, SUSAR reporting, and access and utilization of electronic medical records (EMRs). We were further encouraged that, while the preparation of the ethics submissions ranged between 1-4 weeks, our survey suggested that most sites received ethics approval within 1-2 months of the submission. Lisa Berdan, Director of Global Mega Trials with the DCRI shared her experience and insights on feasibility and oversight. She reminded us how important it is to select the right trial for your site with trial statistics showing that the top 25% of performing sites enroll 63% of the patients in a study. She highlighted the guiding principles that the DCRI works to achieve with sites including; (1) have the right patients been enrolled according to the protocol, (2) did participants receive the right treatment and remain on treatment, (3) was the right data collected (i.e., complete ascertainment of primary and secondary safety and efficacy data), and (4) were there any major issues or GCP non-compliance. Sites were encouraged to think about what they need to put in place regarding investigator responsibilities, oversight, and presence throughout the course of the study.

The second related to budgets. With the surveys completed by all participating sites, this provided the basis for much of the discussion that ensued that day. Facilitated by the CVC Assistant Director of Clinical Trials, Tracy Temple, together with the CVC Co-directors Drs. Justin Ezekowitz and Shaun Goodman, the session commenced with opening remarks from the CVC’s Founding Director, Dr. Paul Armstrong. To set the stage for the day, he provided us with highlights from prior colloquia, talked about the pathway from discovery to application and reminded us not only of the challenges we encounter in clinical trials but also why we do clinical research.

Ty Rorick, Associate Director of Mega Trials at the DCRI shared his experience and insights on feasibility and oversight. He reminded us how important it is to select the right trial for your site with trial statistics showing that the top 25% of performing sites enroll 63% of the patients in a study. He highlighted the guiding principles that the DCRI works to achieve with sites including; (1) have the right patients been enrolled according to the protocol, (2) did participants receive the right treatment

CVC Clinical Trials Team

challenges of enrolling patients into clinical trials, those who are enrolled often do better, likely because they are being closely monitored and treated. As a reminder our survey highlighted the key things that have and continue to facilitate successful recruitment including (1) involved investigators, (2) having dedicated resources assigned to a project, (3) a protocol that is a good fit with standard practice, and (4) having a patient population that supports the protocol. While recruitment is the first hurdle we tackle in clinical trials, keeping patients engaged in long-term studies is critically important in maintaining the scientific integrity of the trial. Within Canada we have some excellent retention rates however as we strive to maintain that, it is important that we continue to enroll the “right” patients, that there is consistent focus on the commitment of patients, and that we remain proactive with preventing non-retention. Thanks to our Canadian sponsors Alere, Amgen, AstraZeneca, Bayer, Boehringer Ingelheim, Merck, Novartis, Pfizer, and Sanofi we were able to bring a representative sample of our Canadian sites together for this unique event. The Colloquium continues to give the CVC, our sites, and our sponsors an open forum for discussion while gaining a better understanding of how we can strive toward and implement more efficient clinical research in Canada. We look forward to continuing to share this year’s learnings with our broader community of sites and work toward the planning and implementation of future studies.

Lisa Berdan, Director of Global Mega Trials with the DCRI inspired us as she talked about dissecting budgets and running cost efficient clinical trials. Lisa nicely summarized that while the aim is to cover costs for site participation in clinical trials and meet a break-even point it is recognized that there are costs of participating in clinical trials which are not always covered and need to be considered by sites when determining if they will participate (i.e., amendments, re-consenting, dried, excessive safety reporting, time spent at investigator meetings, etc). While a required cost for most clinical researchers, but often not fully understood, through our survey we asked sites to share what overhead covers at their institutions. The top responses were legal review, financial management, physical office space, office equipment, departmental approvals and medical record access. Offering a sponsors perspective on budgets, Sonya Dubiner, Medical Science Liaison with AstraZeneca Canada, shared how study finances are calculated based on fair market value. One key point associated with budgets was surrounding costs associated with audits. It was helpful to have the sponsors clarify that while they recognize the significant time and effort that go into audit preparation and follow-up, most are unable to provide financial support to sites to cover any costs associated with them as this could be viewed as coercion and a conflict of interest. Throughout the open dialogue around budgets, many thoughts were shared from varying perspectives which we anticipate will inform future discussions and planning.

The day was further enhanced with a presentation from Dr. Eric Peterson, Executive Director of the DCRI who shared his insights on access to data. He challenged us to think about cost effective ways of doing clinical trials and collecting data. The electronic health record has opened many doors to insights on access to data vs implementation of policy. While the volume of data generated by electronic health records has increased, the electronic health record has also brought about many challenges including how we can strive toward and implement more efficient clinical research in Canada. We look forward to continuing to share this year’s learnings with our broader community of sites and work toward the planning and implementation of future studies.
GALILEO

 Globally, over 60 sites have been activated and nearly 50 patients have been randomized into this study which aims to compare a Rivaroxaban-based antithrombotic strategy to an antiplatelet-based strategy after a successful transcatheter aortic valve replacement (TAUR). There is projected to be approximately 135 sites activated, and 1500 patients randomized globally into the trial.

In Canada, as of June 1, 2016, five sites have been activated for enrollment:
1. Dr. Welsh, Norma Hogg and Suzanne Welsh (University of Alberta, Edmonton)
2. Dr. Toleва, Dolores Friesen (St. Boniface Hospital, Winnipeg)
3. Dr. Cantor, Kim Robbins (York PCI, Newmarket)
4. Dr. Aagar, Myriam Duhamel (Montreal Heart Institute)
5. Dr. Webb, Elizabeth Grieve (St. Paul’s Hospital, Vancouver)

Congratulations to Dr. Welsh for being the first site activated in Canada! We eagerly wait to see which site will be the first to enroll in Canada. We look forward to having all activated sites randomize their first patients soon. Meanwhile, we continue to work through start-up with the five remaining Canadian sites, with the goal to have them activated and ready to screen/enroll patients early this summer.

Activated sites were sent the current Summary Report of SUSARs for Rivaroxaban. Please ensure this is reviewed at your site and then submitted to your REB. Please send CVC a copy of the REB correspondence.

Don’t forget to send CVC a copy of your screening logs each week.

GUIDE-IT

GUIDE IT has nearly 900 subjects randomized and we would like to extend our appreciation for excellent enrollment at the Canadian sites.

Congratulations to Dr. Moe and Carlos Fernando for enrolling 4 patients in April! Enrollment in the ECHO Substudy is also proceeding well and we expect to reach our target of 300 patients later this year.

As a reminder, the DSMB will meet again in July and we want to thank you for your efforts towards tidying your data in preparation for the recent data cut.

We look forward to seeing you at the upcoming Investigator Meeting in Orlando, FL this September. If you have not received your invitation please contact your Project Lead. Please stay tuned for additional agenda details.

In collaboration with DCRI (Duke Clinical Research Institute) and Roche, GUIDE-IT is a prospective, randomized, 1:1, multi-centre clinical trial using biomarker identified Treatment in Heart Failure.

GUIDE-IT

ClinicalTrials.gov Identifier: NCT01685840

AEGIS-I

Our Canadian sites have been working very hard over the last few months to get all data entered and cleaned for the upcoming database lock. Your timeliness in responding to data requests has been greatly appreciated – Thank you!

As we move towards study close out, we will be completing regulatory file reviews/reconciliations. Please keep an eye out for any communications from CVC, as we will inform you of any documentation that is missing or may need updating.

Your blinded and unblinded monitors will be contacting you to schedule your monitoring close out visit over the coming month. Please remember that your monitoring close out visit is not an official close out of your site – your official close out will be communicated to you some time after your close out visit.

This means your ethics approvals must be maintained!

Please be sure to review your ethics expiry dates and submit your annual renewal, as required.

As the summer months are approaching, please be sure to communicate any anticipated office closures to CVC, as well as any extended periods of time where AEGIS study staff will not be available for the monitoring close out visit.

We wish you a warm and relaxing summer and look forward to working with you through this final phase of the AEGIS study.

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

ClinicalTrials.gov Identifier: NCT02108262

LEVO-CTS

Over 640 patients have been randomized at approximately 60 sites into the LEVO-CTS study. The Canadian contribution to this trial continues to be outstanding!

We randomized Canada’s 100th patient at Dr. Nagpal’s site in April, and as of June 1st, 117 patients have been randomized at 10 sites in Canada! Congratulations to our top 3 enrolling sites:

1. Dr. Kalavrouziotis, Hugo Tremblay & Nathalie Gagne (Laval, QC)
2. Dr. Nagpal & Stephanie Fox (London, ON)
3. Dr. Bozinovski & Sheryll Sorensen (Victoria, BC)

In April, the PK substudy met its enrollment target and was closed. Thanks to all the Canadian sites who participated in the substudy!

In May, updated FAQs were sent to all sites. As well, the DSMB’s decision was sent to sites on May 17, 2016. Please ensure your site has submitted this letter to your REB and send CVC a copy of your REB correspondence.

Enrollment is projected to end later this summer. As we approach the last few months of enrollment, sites are reminded to continue to collect all CK, CKMB, Troponin and ECGs at all protocol-required time-points so that the endpoint of MI can be properly adjudicated by the CEC. Additionally, sites need to stay on top of data entry, as well as ensure that queries are responded to in a timely manner.

Data cleanliness will be paramount once the study moves into the close-out phase later this fall.

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: NCT02253621

The Canadian Cardiac Chronicle - Volume 20
The results of the Phase 2b BLAST-AHF trial were recently presented at the ESC Heart Failure Congress in May 2016. In summary, the study did not achieve its primary or secondary endpoints and no potentially efficacious dose of TRV027 was identified. There were no significant safety concerns identified with the study drug and data analyses will continue.

Thank you again to our sites who participated in this study.

Sponsored by Trovirex 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

CVC would like to extend our appreciation for your continued hard work in cleaning your data, answering queries, and resolving CEC events in InForm. We are almost there!

As a reminder, it is never too late to bring patients back on drug – every patient counts and every day on study drug counts.

We know that patient circumstances can change so thank you for your continued efforts towards re-challenging your patients!

We look forward to seeing you at the upcoming EXSCEL meeting in Denver, CO later this month! Important closeout logistics and selection and study start-up through the summer.

The study is an exciting academic collaboration involving the Canadian VIGOUR Centre (CVC) and the National Lead on the Executive Committee. Paul Armstrong as the Study Chair and Dr. Justin Ezekowitz as the Oral sGC Stimulator Vericiguat in Subjects With Heart Failure With Reduced Ejection Fraction (VICTORIA) study of Efficacy and Safety of the Oral sGC Stimulator Vericiguat in Subjects With Heart Failure With Reduced Ejection Fraction (VICTORIA) 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) – every patient counts and every day on study drug counts.

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: Not Yet Available

The SOdium-Hf trial currently has 235+ subjects randomized (31-May-2016) at 16 active sites in Canada, Mexico and Chile. We are look forward to activating additional sites in Argentina, Canada, Chile, and New Zealand over the coming months.

Importantly, SOdium is now the largest trial of its type – many interventions of this type are difficult to design and deliver, and have patients agree to participate. Given we are succeeding at this; we have the opportunity to move the needle in the care of our patients with heart failure.

Thank you to all study teams for your pivotal role in identifying, enrolling, retaining and interacting with the study subjects and their families!

The SOdium-Hf Operations Team would also like to thank site personnel who attended the recent Investigator Meeting (IM) in Montreal. The IM was a great opportunity to meet study colleagues, network and discuss pertinent trial issues and solutions. Almost all sites were represented and we had a great turnout involving Principal Investigators, Dietitians and Study Coordinators. Special thanks to the following study personnel who were recognized at the IM for their hard work and contributions to the SOdium-HF trial:

- Steady Recruiter Award – Luba Velazquez, Mexico City, Mexico
- First to Double Digits – Enza De Luca, Toronto, ON
- Quality Food Record Award – Jennifer Mayor, Winnipeg, MB
- Clean House Award – Naomi Uchida, Vancouver, BC
- Follow Up Award – Lisa Stein, Thunder Bay, ON
- Patient Retention Award – Darlene Manning, Sheila Yarn, Halifax, NS
- Quality Food Record Award – Lauren Riegler, Red Deer, AB
- Ramping up Enrollment Award – Sinead Feeney, Vancouver, BC
- Stepping up to the Plate Award – Kwan Yu Li, Carlos Fernando, Toronto, ON

If you were not able to attend the IM, please be sure to review the presentation slides and materials which were recently distributed.

A reminder to please ensure your data is updated and clean in REDCap by 30-June-2016 as this is the cut off for the next financial quarter. Please ensure all completed visits are distributed.

A reminder to please refer to the most recent version of the REDCap Data Entry Guidelines or contact your Project Lead should you have any questions about your data or REDCap.
It was a pleasure to meet with many of our Canadian Study Coordinators at the Update Meeting held in Chicago last month! We were pleased to see so many of our Canadian sites represented - we hope the meeting was informative and helped to prepare you for the work ahead!

As the summer approaches, so does our 2nd interim analysis. With that in mind, it is critical that you communicate your timelines, while the appropriate study team members are available on-site!

You should have recently received numbered memo #31, along with an “Investigator Booklet” - both of these documents contain critical information pertaining to the upcoming analysis. You should have recently received numbered memo #31, along with an “Investigator Booklet” - both of these documents contain critical information pertaining to the upcoming analysis.

If you have not already done so, please ensure that you review with an “Investigator Booklet” - both of these documents contain critical information pertaining to the upcoming analysis.

ODYSSEY OUTCOMES

If you have not already done so, please ensure that you review with an “Investigator Booklet” - both of these documents contain critical information pertaining to the upcoming analysis.

- All patients must have at least one visit (clinic or phone) during the 3 month period prior to July 30th, 2016.
- All avenues must be explored in order to ensure that CV events and vital status are collected for all patients, including those who have prematurely stopped attending study visits.
- RAVE eCRF must be completed on an ongoing basis, within the following time frames: visit data completed within 5 working days, queries answered within 3 working days.
- Collection of source documents must begin as soon as you are notified of an event in order to prevent delays in adjudication.
- Patient Diaries – remind patients to keep their diaries up to date and that it is critical they return them to you at each on-site visit.
- IP and Lab Kits – please continue to monitor your inventory to ensure that you have sufficient supplies to complete your visits. Remember that only used lab kits are automatically re-supplied, therefore, if you have expiring lab kits you will need to re-order these yourself.

As we wrap up site approvals for Amendment 8, we are quickly moving on to Amendment 11. Once Health Canada approval has been received, you will receive the complete amendment package, including an updated Informed Consent Form.

Remember to submit your site-specific updated ICFs to CVC for approval prior to submission to your local REB.

We thank you for your continued support and wish you a wonderful summer season!

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

CVC CLINICAL TRIALS TEAM

Contact Information for Canadian VIGOUR Centre Clinical Trials Team

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MONITORING UPDATES

Effective immediately, we would like to make everyone aware that we are in the process of changing over our monitoring teams email accounts. Moving forward please be sure to use the following email addresses to reach out to your CVC Monitor:

<table>
<thead>
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<th>Name</th>
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INSPECTION TIPS

Results from our colloquium survey showed that over 85% of sites had undergone an audit. Some of the biggest takeaways they shared from those audits were:

1. Ensuring good documentation is maintained (including ICF process, equipment calibration, security of electronic files)
2. Recognizing the importance of PI oversight
3. Ensuring all training is documented
4. The importance of having Standard Operating Procedures (SOPs)
5. Having clear and concise corrective action plans for protocol deviations
6. Signing and dating documents
7. There is always room for improvement.

We encourage you to always be audit ready as it is not a matter of “if” but “when” your site will be chosen for an audit. The above points as well as planning ahead with your team and maintaining clean and accurate records will be key to your success in any audit.

Our team is very knowledgeable in audit readiness and many of the observations or follow up items from your monitoring visits not only stem from protocol and trial requirements but also what you will be asked to provide in a regulatory inspection.

If you have any questions related to monitoring please don’t hesitate to contact Halina Nawrocki, Lead CRA @ halina@ualberta.ca or Tracy Temple, Assistant Director, Clinical Trials @ tracy.temple@ualberta.ca or 1-800-707-9098, Option 5.
It is a pleasure to announce the 22nd edition of the Beyond 2000 (B2K) symposium to be held Monday morning October 24 in conjunction with the upcoming 2016 annual Canadian Cardiovascular Society meeting.

As is customary our goal is to present a stellar educational event, and we look forward to welcoming you back. This year we will build off of thebinocular approach introduced in 2015 in order to provide attendees with diverse content tailored to their individual interests. Specifically, the overall B2K symposium will be comprised of two sequential sessions as noted in this issue of the CVC chronicle. Responding to prior feedback we have incorporated brief Q&A opportunities after each presentation using electronic media. Each session will also be enhanced by challenging case presentations directed towards key learning points.

In the first session, we’ll explore the increasingly common and important subjects of atrial fibrillation (AFib) and heart failure (HF). Recognized thought leaders will speak on developing enhanced by challenging case presentations directed towards key learning points.

The second is aimed at our traditional target of acute coronary syndromes (ACS). You can expect to be informed by key thought leaders on new ACS clinical trials in progress, as well as integrating new lessons learned from recent clinical trials into practice. The remarkable advances in novel strategies for approaching diabetes and hypercholesterolemia will follow and we will conclude by exploring the lessons learned from large ACS population registry outcomes data and their relevance to clinical practice.

This year our symposium will be held in Montreal, one of Canada’s most engaging and cosmopolitan cities, beginning at 0700 on October 24th, 2016. We look forward to the opportunity engaging with our many friends, collaborators and colleagues in this exciting event.

Paul W. Armstrong
Publications Continued


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. CVC gratefully acknowledges our sponsors and the funding support provided by: AstraZeneca Amylin Pharmaceuticals CIHR CSL Behring LLC Bayer Health Care AG Bayer Health Care Pharmaceuticals Inc. Merck Sharp & Dohme Corp. National Institutes of Health/NHLBI Roche Diagnostics Operations Inc. Sanofi-Aventis Recherche & Développement Tenax Therapeutics, Inc. Trevena Inc.

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