“Winter always turns into Spring.”
- Buddha

It will come as no surprise to those in the eastern parts of Canada that 6 more weeks of winter were predicted on groundhog day, adding perhaps insult to injury to those who endured a colder and snowier winter than usual. Yes, this is Canada and we seem to forget this periodically.

However, as this communication arrives on your doorstep (which is hopefully clear of snow) you will recognize the importance of spring. Spring brings with it hope, renewal and new life, in nature and inevitably in how we think and act. As Shakespeare suggests in his sonnet, “April ... hath put a spirit of youth in everything”. This is evident in our co-workers, collaborators and our patients, all of whom have an extra kick in their step after the Spring equinox.

We had opportunity to observe the effects of an early spring in Banff, Alberta in early March. CVC hosted our 2nd annual Research Colloquium in conjunction with the ACC Rockies 2015 where investigative sites from across Canada, CVC, sponsors and project leaders explored clinical research on multiple levels. We covered topics from contracts through retention of subjects to issues on ethics review boards and others. It was a fruitful exchange of ideas and information with the often overlooked groups that are nestled between a good idea or hypothesis to be tested and the end results: clinical investigative sites. The dialogue included a discussion on contracts where we heard from a global contracts lead on the importance of experience coupled with communication: sometimes the most efficient way to negotiate a contract is through a phone call. The experienced sites also shared their best practices and mostly, their continued enthusiasm for participating in novel and innovative investigative projects that will change clinical practice and patient care.

Canada remains a core location in the global arena for conducting research due to the high quality in the conduct of a trial, and areas for improvement on many parts of a trial from data collection, SAE reporting and how to be audit-ready (and what to do if it happens!). Overall, this exchange embraced the best of spring: new ideas, areas for growth and renewed enthusiasm for playing a critical role in clinical research all of which are further detailed in this issue of the chronicle.

We look forward to seeing the end-result of this collaboration between the site, patients, partners and CVC with the upcoming TECOS trial to be presented in Boston in June. This is the culmination of the hard work, dedication and volunteer spirit in which Canadians have played a key role. Lets capitalize on this re-invigoration and continue our collaborative efforts.

Justin Ezekowitz
PROACT

We are excited to share with you that on Feb 13, 2015 the PROACT study completed enrollment with 602 patients randomized. With the data abstraction almost complete and the adjudication process ongoing we look forward to having the data clean and ready for analysis by mid-April. We will be sitting down with the PROACT Steering Committee in the near future to digest the data and explore next steps.

This has truly been a major collaborative effort involving Edmonton Emergency Services, the Emergency Departments at the 5 Edmonton Hospitals and the Canadian VIGOUR Centre.

The EMS crews who successfully enrolled patients in the ambulance deserve our utmost appreciation, as do the support crews that make a collaborative effort like this happen. We also appreciate the support to date from AHS, The University Hospital Foundation and that of our biomarker partner Alere Inc., as well as the peer-reviewed funding we received from the Heart and Stroke Foundation Canada.

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

EXSCEL

The EXSCEL trial completed enrollment on February 20, 2015. Thanks to our Canadian sites for all your hard work screening and enrolling patients! Global enrollment finished at 14,454 patients with 544 of those patients being enrolled in Canada. A special shout out to our highest enrolling site who recruited 66 patients, Dr. Dube and Marilene Bolduc. Thanks to you and the rest of your team for this substantial contribution to Canada’s enrollment!

As we move out of the enrollment phase of the trial our focus has turned to patient retention and data collection. We are impressed to see that Canada does not have any withdrawn or lost to follow-up patients and want to take this opportunity to acknowledge the effort our sites have put forth to ensure they are staying connected and keeping the patients engaged in the trial. Keep up the great work!

TECOS

The TECOS finish line is in sight! The final site monitoring visits have been completed and database lock is planned for the end of March 2015. Thank you to all of our sites for quickly and diligently cleaning data, answering queries, signing casebooks and providing requested source documentation over the last several months, and in particular the last few weeks, as we worked towards this very important milestone in TECOS.

With Database Lock complete, we will be focusing on reconciling any outstanding site regulatory documents in preparation for final site closure. 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.

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.

A very exciting and long-awaited moment for TECOS will be occurring later this Spring when the TECOS Executive Committee presents the primary results at the 2015 ADA 75th Scientific Sessions in Boston on June 8, 2015. We are eagerly anticipating these results, and our sites must be as well, after dedicating several years (6 years for many sites!) to this study. CVC would like to extend our gratitude and appreciation to each of our Canadian sites involved in TECOS for the hard work and commitment you have demonstrated throughout!

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.
A new patient material was presented at the meeting, which has now been sent out to all sites – the beautiful patient calendars. These should be used, along with the stickers provided, in order to help your patients keep track of their injection schedule. We are certain that this will help keep your patients compliant with respect to injection timelines. Note that this material must be REB approved prior to distributing it to your patients. If you have any questions, please reach out to your project lead.

We would like to remind all sites to keep a close eye on your inventory of lab kits. In order to avoid the frustrations of having to reschedule patient visits, please ensure you have the lab kits you need well in advance. On average, the kits are taking 10 business days to arrive at Canadian sites once an order is placed. Also, please remember that the central lab does not automatically resupply for expired kits, only used kits; so it is important to ensure you are aware of what is available and useable at your site!

As always, we look forward to speaking with you all on our monthly Canadian Update WebEx. Please be sure to send Amanda 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@uaberta.ca or Paula Priest, ext. 9 or paula.priest@uaberta.ca.

Sponsored by Sanofi-aventis Recherche & Développement this is a randomised, double-blind, placebo-controlled, parallel group study to evaluate the effect of SAR236553/REGN727 on the occurrence of cardiovascular events in patients who have recently experienced an Acute Coronary Syndrome.

ClinicalTrials.gov Identifier: NCT01663402

GUIDE-IT

GUIDE-IT currently has 518 subjects enrolled, 62 of which are enrolled in Canada from our 6 participating sites (current as of 13-March-2015). A special acknowledgement goes out to our sites whose recruitment is in the double digits:

- Calgary / Dr. Grant – 13 subjects
- Edmonton / Dr. Ezechowitz – 14 subjects
- Toronto / Dr. Moe – 11 subjects
- Vancouver / Dr. Toma – 10 subjects

Thank you to the GUIDE-IT Investigators and Coordinators who attended the recent Rejuvenation Meeting (February 17 & 18) in Florida! The presentation slides are available on the GUIDE-IT website for review at: https://www.guide-it.org/. The focus of the meeting was on strategies to increase enrollment – as addressed by the NH and DCR, it is imperative that enrollment increases at all sites. With the recent modifications to the per patient funding, we anticipate this will help to offset the costs associated with the 2 week follow-up visits and boost recruitment in Canada from the current average of 0.65 subjects / month. As a reminder please ensure the “GUIDE-IT Memo of Clarification: Biorepository Samples” is submitted to your REB, as appropriate. Please forward the REB approval / acknowledgement letter to CVC.

Thank you to all Coordinators for working hard to clean your site’s data for the recent data cut and DSMB meeting (scheduled to occur April 23, 2015)!

Canada’s data completion rates from Baseline to the 6 month visit are above the target of 90% - well done! A kind reminder to stay on top of your data entry for the 9, 12 and 15 month visits as our data completion rate is not as high on these visits. If the CEC requests that your site submit source documentation for an event, please ensure you forward (at a minimum) the anonymized hospital discharge summary containing a) date of admission, b) date of discharge and c) discharge diagnosis. If any of these 3 items are not included, CEC will not accept the document and will request that you re-send additional source.
Please note: As a back-up when you submit fax/source documents, please feel free to copy Melisa/CVC and if they are not received we can then work directly with the team at DCRI to get them through.

For further information, please contact Clinical Trial Project Lead Melisa Spaling at mspalingleauaberta.ca or direct: 1-800-707-9098 ext.4.

In collaboration with DCRI (Duke Clinical Research Institute) and Roche Diagnostics AEGIS-I is a prospective, randomized 1:1, multi-centre clinical trial guiding Evidence Based Therapy Using Biomarker Directed Therapy for Heart Failure.

ClinicalTrials.gov Identifier: NCT01685840

ODYSSEY OUTCOMES

Our Canadian team has started off 2015 with a bang! We have seen record numbers of both monthly screens and randomizations this year, and we look forward to the trend continuing as we push towards the recruitment finish line. Worldwide, the study has now screened nearly 23,000 patients. Canada’s 42 active sites have now contributed over 500 patients screened.
We would like to congratulate our top 5 randomizing sites – thank you for your continued dedication to the ODYSSEY Outcomes Trial! (data as of 17/Mar/2015)
• PI Manahora Senaratne – SC Himani Ferdinands – 18 Randomized
• PI James Stone – SC Megaan Heard – 16 Randomized
• PI Jan Kornder – SC Lynn Breakwell – 15 Randomized
• PI Gilbert Gosselin – SC Margaux David – 12 Randomized
• PI Danielle Dion – SC Andrée Morisette – 10 Randomized

We were very happy to have had the chance to meet with many of you at the ODYSSEY Outcomes Study Coordinator Update Meeting in San Diego this past January; we hope that if you were in attendance, you found this meeting beneficial, and that it has re-energized and re-invigorated us as we continue our ODYSSEY!

AEGIS-I

The AEGIS-I Main Study and PK/PD Sub-Study kicked off after the Investigator Meetings in January with over 65 sites now activated worldwide and global enrollment climbing steadily with over 100 patients recruited. The enrollment target is 1,200 patients so we are well on our way to our enrollment goal! We are eager to get our first site activated for enrollment in Canada by the end of March.

Thank-you to all of our sites who joined the meeting in Miami. Your participation and thoughtful discussion was appreciated. As we near activation for many of our sites, please work with your monitor Valerie Carr to secure a date for a Site Initiation Visit.

As a reminder, in order to activate a site we need an ethics approval, an executed contract and completed regulatory documents. If there have been any delays at your site we encourage you to work with your team so that the activation process can be finalized at your site as quickly as possible.

We are eager to have all our sites in Canada activated over the next couple months to ensure we can make a significant contribution. To that end we are happy to assist you in any way that we can. We look forward to a successful trial in Canada!

For further information about this trial, please contact Clinical Trial Project Lead, Courtney Gubbel at 1-800-707-9098, ext. 1 or by email at courtney.gubbel@uaberta.ca.

In collaboration with DCRI (Duke Clinical Research Institute) and Roche Diagnostics AEGIS-I 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.

BLAST-AHF

In January 2015, an Interim Analysis was held to explore the safety / efficacy of the three doses of study drug being used in the BLAST-AHF trial. The results of the analysis were recently distributed to sites via Amendment 4!
A big thank-you to all Study Coordinators for your impressive turnaround and quick submission of Amendment 4 – this is much appreciated! We hope to have all sites activated by early May (pending receipt of the Health Canada NOL). For this to occur, CVC will work closely with each site to ensure that site training, regulatory documents and REB queries and feedback on Amendment 4 are completed in a timely manner.
As a reminder, please ensure that you have adequate supplies for an anticipated activation date in May:

- Please check the expiry date on your lab kits. Lab kits can be re-ordered via PPD Inside
- If applicable, please check the expiry dates on your BNP kits

If you are interested in further information about BLAST-AHF, please contact Clinical Trial Project Lead Melisa Spaling at 1-800-707-9098 ext. 4 or via email at mspaling@uaberta.ca.

Sponsored by Trevirena 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

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LEVO-CTS

Preserving heart function during and immediately following cardiac surgery is a major goal of current perioperative therapies. Despite available therapies, low cardiac output syndrome (LCOS) remains a substantial risk.

Levosimendan is a promising new agent for the perioperative treatment of cardiac surgery patients. It is a calcium sensitizer which exerts a positive inotropic effect. It also has a vasodilatory effect, causing smooth muscle relaxation.

CVC is excited to share with you a new study (LEVO-CTS) that will evaluate the efficacy and safety of levosimendan compared with placebo in reducing the composite of all-cause death or LCOS in patients undergoing cardiac surgery on CPB.

Our first Steering Committee Teleconference will be held March 26 at 3 PM Mountain / 5 PM Eastern. We look forward to discussing trial updates and receiving input from the study investigators. The next Dietitian Working Group Teleconference will be announced – stay tuned for more details.

Congratulations to the following sites on randomizing your first subject:

- Dr. Rajda, Sheila Yarn and Darlene Manning, Halifax, NS
- Dr. Lai and Lisa Stein, Thunder Bay, ON
- Dr. Gupta, Yobiga Thevakumaran and Winnie Christopher, Brampton, ON
- Dr. Singh, Kelly Lehmann and Lauren Rieger, Red Deer, AB

The study has received approval (NOL) from Health Canada, and we have already started the regulatory and start up plan to have approximately 8-10 centres participating.

Canadian regulatory inspections are conducted by Health Canada Health Products and Food Branch Inspectorate in all provinces and territories across Canada. Inspections at the site are not only intended as a site inspection but also a sponsor inspection, therefore the involvement of your sponsor is important.

During an inspection any deviations from Division 5 will be noted by the inspector and classified as risk 1 (critical), risk 2 (major) and risk 3 (minor). At the conclusion of an inspection the inspector will conduct and exit interview with the site/sponsor where they will receive an overall rating provided as C (compliant) or NC (not compliant). A few weeks following the inspection the sponsor and site will receive an official document outlining the observations and will need to mutually work together to provide responses to the observations within the requested time frame.

Listed in the table below are a few common deviations that were cited from Health Canada inspections as noted in the “Summary Report of Inspections of Clinical Trials Conducted from April 2004 to March 2011”.

<table>
<thead>
<tr>
<th>Regulation</th>
<th>Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>C.05.012</td>
<td>Inadequate records – examples: validation that computer records are maintained for 25 years, incomplete subject files, inadequate records for drug shipment, receipt, dispensing, return and destruction</td>
</tr>
<tr>
<td>C.05.010(c)</td>
<td>Insufficient quality systems – examples: procedures for handling biological samples, training staff on the protocol</td>
</tr>
<tr>
<td>C.05.010(h)</td>
<td>Inadequate process for informing, obtaining and maintaining informed consents from subjects – examples: amended consent not obtained at next subject visit; consent process not documented</td>
</tr>
<tr>
<td>C.05.010(a) and C.05.010(b)</td>
<td>Deviations from the research protocol – examples: not taking or recording B/P the required number of times as per protocol; required labs not taken</td>
</tr>
</tbody>
</table>

Monitoring/Inspection Tips

As of the end of February the CVC monitors completed all the final onsite TECOS study monitoring visits. Our team would like to thank each and every site especially the study coordinators for accommodating us. We will miss seeing you.

For monitoring related issues, please contact Tracy Temple or Halina Nawrocki. Tracy can be reached at 1-800-707-9098 ext. 5 or email tracy.temple@ualberta.ca. Halina can be reached at 905-896-7292 or email halina.nawrocki@rogers.com.
On Sunday March 8, 2015 we held the 2nd Annual CVC Clinical Trials Colloquium in Banff, Alberta in collaboration with the ACC Rockies Meetings. Thanks to the support from our Canadian sponsors AstraZeneca, Amgen, Bayer, Eli Lilly, Novartis, Pfizer, and Sanofi we were able to host this unique event and bring together representative investigators and study coordinators from 16 sites across the country (BC, AB, MB, ON, QC, NS, NL). This year’s Colloquium was intended to build on last year with key objectives to include (i) gaining a better understanding of all aspects of clinical trial research and participation, (ii) develop strategies for choosing and executing a clinical trial successfully, (iii) gain a better understanding of legal requirements for negotiating Canadian clinical trial site agreements, (iv) discuss opportunities to enhance the overall clinical trial experience at a site level, (v) engage in open discussion with colleagues, sponsors and CVC as it relates to challenges in participation and execution of clinical trials. The Colloquium was expanded to not only include the main Colloquium session but also a Study Coordinator Workshop, and as part of the ACC Rockies Meeting a Canadian VIGOUR Centre Workshop, highlighting recent clinical trials results and opportunities.

Our morning agenda was ambitious but proved to be very informative, covering, the changing landscape in clinical trials, lessons learned, choosing trials wisely, costs, contract negotiations, investigator engagement, expectations and roles of the executive, steering committees and DSMB’s and finally why do clinical research. The discussion in the room generated some clear insights as it relates to each of these topics and recognizing we could not have our full network of sites in the room anticipate that this summary will be beneficial in helping to engage all of our sites across the country. The science and importance of pursuing the answer to the question being studied came across as a strong predictor of choosing to participate in clinical research studies, followed by a patient population to support the study and past performance in similar studies, and finally ensuring a “break even” point on the budget. As anticipated the cost of doing clinical research led to much discussion following presentations from our co-sponsor representatives Marc Zarenda with AstraZeneca and Jaqueline Atallah with Pfizer who shared the challenges they face in securing funding for Canada’s participation in clinical research. With Canada being considered one of the most expensive countries to do research in, the importance of ensuring the trial is the right fit for a site is critical. Discussions around the increasing costs of overhead and noticeable increases in harmonized ethics fees was highlighted and identified as needing attention and clarification at the local site level to better understand what these costs are covering and how we can work together to control these costs moving forward and ensure they don’t negatively impact the ability to participate in future research. Recognizing the Canadian contribution which brings good recruitment, high quality data that can be used and high patient retention are assets to the overall study and marketing of the drug, it will be key to continue addressing the increasing and arbitrary costs to ensure continued involvement in clinical research at all of our sites across the country.

At last year’s colloquium contracts were cited as one of the major contributors to delays in the start-up of a clinical trial. In an effort to address this we invited Marlon Rajakaruna, a lawyer/partner with Dentons Canada, who has extensive experience in negotiating clinical trial agreements with sites, sponsors, ARO/ Cro’s across Canada and around the world, to speak about the contentious issues in the contract and provide the best strategies for resolution. While this is not meant to provide you with legal advice, a few of the highlighted points of importance were (i) ensuring the right people are negotiating the contract and ensuring the parties at either end are directly connected, (ii) the importance of the investigator understanding if he/she is signing as a party to the agreement where he/she is assuming liability vs signing as “read and acknowledged” where he/she is not assuming legal liability, (iii) understanding that in order for the investigator to be covered by CMPA the jurisdiction must be in Canada. It was clear that these are not new issues however, they seem to resurface on each contract that is negotiated and to this end we need to be smarter about looking back at previously negotiated contracts or master contracts to utilize agreed upon language in order to facilitate quicker turnaround.

In the afternoon we reconvened with the study coordinators and engaged in open sharing and discussion on ethics, electronic migration, training, recruitment strategies, audits, understanding why all the data is collected on the CRF, trial fatigue, and withdrawals and lost to follow up. As always our study coordinators were a wealth of knowledge and this session enabled them to share best strategies with each other, which not only reinforced what they perhaps were already doing but also gave them some new strategies to take back to their site and work on implementing. Given the multitude of information gained from this session a few key highlights have been shared below and we will continue to provide tips from the study coordinator workshop in our upcoming chronicles.

(i) Ethics - once a decision is made to participate in the study, the preparation of the ICF for review by the sponsor is key
(ii) Training - utilize your administrative support staff to track training of your staff
(iii) Recruitment Strategy - work with your institution to implement a consent upon admission for review of charts for research purposes.
(iv) Audits - perfect is not attainable, but ensuring you have SOP’s, well documented training aligned with your delegation log and are audit ready at all times is important.
(v) Trial Fatigue – remember to thank your patients for participating.

While each of you know why you participate in clinical research, the colloquium reminded us that clinical research gives us the opportunity to be a leader and champion in enhancing clinical practice and being at the forefront of new technologies. Research not only offers us career satisfaction through intellectual curiosity but also provides opportunities for mentorship, collaboration, staff education and learning new skills. While it is clear that there are challenges that come with participating in clinical research, it was clear that the benefits far outweigh the risks.

While the Colloquium is expected to be an annual event we want to continue the momentum gained from the meeting throughout the year. We anticipate this will be accomplished through our many communications with you as we strategize the best approaches to streamline and make clinical trials more efficient at your sites. We are also working on a few networking strategies to help connect our sites and provide an ongoing opportunity for sharing useful strategies in running clinical trials. If you have any questions please don’t hesitate to contact Tracy Temple @ 1-800-707-9098 ext. 5 or tracy.temple@ualberta.ca.
CVC News

Oksana Grant joined the CVC Business Office in December 2014 as a Business Operations Assistant. She has recently returned to school and has completed a Diploma in Accounting and Payroll Administration. Oksana also completed her National Certification as a Payroll Compliance Practitioner. In her spare time, Oksana enjoys spending time with friends and family.

Sheila Li joined the CVC ECG Core Lab in March 2015 as a Jr. ECG Reader. Sheila completed medical school in China and in 2009 obtained a Master’s degree in Science in Human Nutrition from the University of Alberta. She comes to CVC from the Department of Paediatrics at the University of Alberta where she spent time as a clinical research assistant. Outside of work, Sheila enjoys swimming, jogging and playing tennis.

Prairie-born but now living on the west coast, Sue Bonar has worked in clinical research for over 15 years. She enjoys monitoring for the challenges it brings, and the new faces she meets every day. When she is not working, she enjoys anything outdoors, rain, snow or sun! With Sue’s background in nursing and extensive experience in research, we feel she will be a great asset to our monitoring team. Sue will initially be monitoring our EXSCHEL and GUIDE IT sites in the west.

Distinguished Visitors Series
Dr. Michael Pencina, PhD
Professor of Biostatistics and Bioinformatics at the School of Medicine at Duke University and Director of Biostatistics at Duke Clinical Research Institute, Dr. Pencina will be presenting on June 2-3, 2015 at the University of Alberta and the Mazankowski Heart Institute. More details will be provided on the CVC website in the near future.

Upcoming Events

Save the Date: A Celebration of the work of Dr. Paul Armstrong

Paul Armstrong Symposium

A celebration of the work and influence of Dr. Paul Armstrong. 35 years of exemplary care, discovery and mentorship as a cardiologist and the University of Alberta’s 2014 University Cup recipient. The all day symposium will feature four internationally renowned speakers.

Saturday, June 13, 2015 9:00 AM - 3:00 PM at the University of Alberta.

Publications


**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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