“Not everything that can be counted counts, and not everything that counts can be counted.”

- Albert Einstein

Data; we like data. Data is what makes the scientific enterprise work. Without clear, trustworthy and reproducible data, the scientific experiments we call clinical trials would not have much value.

But what is occasionally lost in the data is the human interaction. The communication between a patient and a clinician, a patient and the research team, and a patient and their family. All of these are different in their purpose but share many traits that deserve discussion.

First, they are trusted interactions. Inherent in volunteering for a clinical trial is the trust placed in the scientific team (from local research coordinator to the trial principal investigator). This extends to the trust we are collecting accurate data, and the trust we are avoiding duplication of information available on one or the other side of the clinical/research divide.

Second, the interaction between people is core to the scientific process as it involves the transmission of information. Sometimes this is the transmission of a diagnosis or lab value, and for researchers, transmission of instructions on, for example, how to take the experimental medication. For a patient it can be the transmission of an event – hospitalization, adverse event or recent change in a concomitant medication.

How does this all relate back to high quality and timely data? Trials are more often looking towards interacting with data differently by linking to administrative data for follow-up, electronic health records as source documents and both for clinical events. These linkages will become more and more critical as the research endeavor advances. These need to remain vital, trusted and high quality interactions between data ‘sources’ whether it be patient, EHR, mobile health data or an old-school paper chart.

Behind all this data is a research team, a patient and their family. None of the data is possible without the human interaction, often overlooked as we try to get at the data. I’d like to take this opportunity to remind us all on the importance of talking to patients, and remind ourselves and patients as to why we are collecting so much data. Lets not forget that behind that data point, there is a person.

Justin Ezekowitz
CVC Co-Director
EXSCEL

Thank you to all Study Coordinators for your continued efforts towards cleaning your data. A large number of ‘critical variable’ queries were released over the last few months and these data points are vital to the interpretation of safety and efficacy information. Cleanliness of these items is essential for the upcoming spring DSMB meeting and we appreciate your perseverance as we approach the latter stages of the trial.

If you are able to have a re-challenge discussion with a patient off study drug, please try to do so sooner rather than later. Even if the patient has been off for quite some time and restarts for only a short while, additional exposure can make a significant difference - not only for the patient’s outcomes but for the study results as well.

Thank you for your hard work in moving your patients through the TrialNetworks tool. The tool has provided substantial and meaningful information regarding LT FU patients off study medication. Retention specialists are reviewing all cases now and we look forward to receiving further information from the Sponsors to reach a final determination on a compensation payment. As a reminder, please update the tool with as much detail as possible. This will ensure we do not contact you unnecessarily for information about patients off study drug or lost to follow up.

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

GALILEO

It was a pleasure to meet face-to-face with each of the attendees from Canada at the North American investigator meeting that took place on January 19, 2016 in Fort Lauderdale.

It was nice to reunite with those we have worked with before, as well as to meet new PIs and SCs - all of whom we at CVC are excited to be working with on this new study which aims to compare a Rivaroxaban-based antithrombotic strategy to an antiplatelet-based strategy after a successful transcatheter aortic valve replacement (TAVR).

The study is in the very active phase of start-up, with 10 sites participating in Canada. GALILEO’s first patient was enrolled in the US in December. Enrollment is planned to be completed at the end of 2016 with over 1500 patients randomized into the trial.

In Canada, all sites have submitted to Ethics, and the collecting and reviewing of the regulatory documents required for start-up is well underway. We are looking to have our first site activated in April, with Canada’s first patient randomized soon thereafter! The goal will be to have all CVC sites activated and screening/enrolling patients this spring.

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.

GUIDE-IT

Thank you to the Investigators and Coordinators who attended the February Investigator Meeting in Fort Lauderdale, FL where the focus was on enrollment and protocol adherence. This was a great opportunity to review adherence including several case studies and we encourage you to contact your Project Lead and/or Dr. Ezekowitz with any adherence questions.

Lastly, CVC would like to extend our gratitude for overall great performance in data timeliness and cleanliness. As a reminder, visits are to be entered and queries are to be addressed within 5 business days.

Please continue to prioritize CEC queries and ensure documents are submitted for CEC adjudication in a timely manner.

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

The enrolment rate has increased recently, and the study is now expected to meet its enrollment target later this summer. Currently over 526 patients have been randomized at 60+ sites across Canada and the US.

The Canadian contribution to this trial has been outstanding. All 10 sites have enrolled at least 4 patients. In total, 87 patients have been randomized in Canada (as of April 4, 2016). Keep up the great work.

Congratulations to Dr. Kalavrouziotis and Dr. Bozinovski and their respective teams for consistently being the top two in Canada, and the top four and reviewing of the regulatory documents required for start-up is well underway. We are looking to have our first site activated in April, with Canada’s first patient randomized soon thereafter! The goal will be to have all CVC sites activated and screening/enrolling patients this spring.

Thank you for your hard work in moving your patients through the TrialNetworks tool. The tool has provided substantial and meaningful information regarding LT FU patients off study. The first 400 patients will be reviewed. Thanks to all the sites for their hard work throughout March to enter all data through the 30-day Study Completion Visit and answering all open queries for this important upcoming meeting.

The updated Investigator Brochure was sent to sites on March 8, 2016. There were no changes to the ICF. Sites are to submit the IB to their REB, and send CVC copies of the REB correspondence (submission and acknowledgement).

As a reminder, please continue to ensure CK, CKMB, Troponin and ECGs are collected at all protocol required time-points.

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.

GUIDE-IT has over 800 subjects randomized and as of late March, 120 of these are from Canada. Congratulations to Dr. Ezekowitz and Quentin Kushnerik who enrolled 3 patients in January. We are currently on target to meet our goal of 1,100 patients but cannot afford any lulls in recruitment so keep up the good work on screening and randomizing!

Enrollment in the ECHO Sub-study is going well and we are pleased to announce that Dr. Virani’s site at Vancouver General Hospital has been activated to participate and already enrolled 2 patients. Two hundred and fifteen patients have been enrolled so far and it is anticipated we will reach our goal of 300.

Thank you to all Study Coordinators for your continued efforts towards cleaning your data. A large number of ‘critical variable’ queries were released over the last few months and these data points are vital to the interpretation of safety and efficacy information. Cleanliness of these items is essential for the upcoming spring DSMB meeting and we appreciate your perseverance as we approach the latter stages of the trial.

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AEGIS-I

The last patient Visit 8 was conducted in early March which was the trigger for sites to begin conducting final Visit 11 MACE follow-up calls with all patients. There was a tight timeline to conclude these calls and have all of the Inform data entered and clean. Thank you to each of our sites for completing these final visits and the corresponding data entry so quickly. Great work!

We appreciate your continued dedication to AEGIS as the final periodic monitoring visits are scheduled throughout March and April. Your blinded monitor will be completing final source data verification and query resolution to meet these last monthly data cleaning targets and to ensure the data is 100% clean in preparation for database lock.

As we move towards the significant milestone of database lock and study close out, we ask our sites to be diligent in quickly answering any enquiries that may come up from the medical team, as well as provide all outstanding regulatory items to CVC.

For further information, please contact Clinical Trial Project Lead, Amanda Carapellucci at 1-800-707-9098, ext 2 or via email at amanda.carapellucci@ualberta.ca.

SODIUM-HF

The SODIUM-HF trial currently has 395+ subjects randomized (31-March-2016) at 16 active sites in Canada, Mexico and Chile. We look forward to activating additional sites in Canada and Argentina as we head into spring.

Thank you to all site personnel who joined the recent Steering Committee and Dietitian Working Group Teleconferences in February, 2016. If you were not able to join, please review the February 2016 newsletter for trial updates (DWG minutes on the last page) or contact CVC for minutes from the Steering Committee meeting.

A reminder that an Investigator’s Meeting is planned for June 4, 2016 in Montreal, QC in conjunction with the HF Update meeting (https://www.hfupdate.ca/en). This meeting will be an important opportunity to meet face-to-face and discuss some of the challenges and opportunities in the SODIUM-HF trial– we hope to see all sites represented. Details will follow; however, we encourage you to save the date for the time being!

Over the next few weeks please ensure your site’s data is updated in REDCap by 31-March-2016 and study close out, we ask our sites to be diligent in quickly answering any enquiries that may come up from the medical team, as well as provide all outstanding regulatory items to CVC.

For further information, please contact Clinical Trial Project Lead, Amanda Carapellucci at 1-800-707-9098, ext 2 or via email at amanda.carapellucci@ualberta.ca.

ODYSSEY

Thank you to all of our sites for our significant successes that were put forth prior to our first interim analysis. The data cut was a success and Canada was able to meet its data cleaning goals thanks to your hard work and persistence. Data continues to be a top priority for the ODYSSEY Outcomes trial as we move towards the next interim analysis.

We ask that you continue to stick to the data entry guidelines of entering visits within 5 days and resolving queries within 3 days. Please be aware that these timelines will be reduced as the next data cut approaches.

Patient retention is another top priority for us, as we want to ensure that our patients remain committed and engaged with the trial. You have all now received the “Site Retention Guide – Best practices to engage and retain participants”.

Please take some time to review this important tool as it offers excellent retention strategies, summarizes potential warning signs that indicate a patient may be wavering and it contains numerous template letters, forms and logs that can be customized and used. Special attention must also be given to patients who have come off study drug.

The tool just mentioned contains a great flow chart that outlines how to follow up with patients whether they are on or off study drug. Remember that all patients who have temporarily discontinued study drug should continue with their study visits, and a study drug re-start should continue to be offered, as applicable.

The majority of our sites have now been approved under Amendment 08. If you have not already done so, please make sure that your regulatory documents, training and REB approvals are submitted to CVC. All patients must be re-consented with your updated ICF once CVC has given you the green light to implement the amendment at your site. Please make sure that you have a process in place for re-consenting patients who are no longer attending clinic visits, and that you are aware of (and following!) your REB’s requirements for this patient group as well.

We look forward to meeting with many of you at the upcoming Study Update Meeting for ODYSSEY Outcomes Study Coordinators in Chicago! We are certain that this meeting will provide us with renewed enthusiasm as we move towards the final phases of this important trial.

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: NCT01663402

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: NCT02108262

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
Enrollment is now closed in the BLAST-AHF trial as the target sample size (n=600+) was reached at the end of February, 2016.

BLAST-AHF
CVC News

Sponsored by Trevena Inc., BLAST-AHF is a Randomized, Double-Blind, Placebo-Controlled, Dose Ranging Study to Explore the Efficacy of TIR627 in Patients Hospitalized for Acute Decompensated Heart Failure.

ClinicalTrials.gov identifier: NCT01966601

Upcoming Trials

VICTORIA - VericiguT: gObl study in patients with heart failure and Reduced ejection fraction (gACTION)

After many months of planning we are excited to move forward and aim to reach out to our investigative sites in the late spring regarding a phase 3 study in heart failure patients with reduced ejection fraction. Sponsored by Merck and Bayer,

this study is a unique ARO collaboration with DCRJ and CVC. We have excellent representation from Canada on this study with Dr. Paul Armstrong as the Study Chair and Dr. Justin Ezekwokis on the Executive Committee and they have been active in developing the study plan along with key ancillary studies. More information will be forthcoming in the coming weeks but please stay tuned to get this on your radar now.

Eva Roua joins CVC as a monitor for our Western Canadian ODYSSEY sites and brings an extensive background in both research and patient care. In her spare time she enjoys bicycling, running and swimming.

Lisa Soulard joins the CVC as Dr. Armstrong’s new Executive Assistant. In this role she will also be supporting CVC activities related to initiatives led by Drs. Ezekwokis and Westerhout. Lisa is not new to the University, she has worked for the last four years in the Faculty of Medicine & Dentistry’s Dean’s office. In her spare time she enjoys running, art and expanding her knowledge base in areas ranging from web design to organizational development.

Carla Price has recently returned from a maternity leave to the position of Acting Assistant Director, Operations in the CVC business office, alongside colleagues Ellen Pyear and Oksana Grant. Carla is the point of contact for various business functions such as contracts and agreements, invoicing and payments and other operational activities in support of the CVC’s staff and projects. Carla first began working for the CVC in 2004 and is excited to rejoin the team and interact with our many local, national and international collaborators.

The emphasis is now on data cleaning, database lock and close out, which we anticipate will occur quickly and efficiently. We look forward to sharing the results of this exciting Phase 2b trial later in the year. Thank you to all sites for your participation.

If you are interested in further information about BLAST, please contact Clinical Trial Project Lead Melisa Spaling at 780-492-8476 or via email at mspaling@ualberta.ca

O'Connor CM. Torsemide Versus Furosemide in Patients With Acute Heart Failure. JACC Heart Fail. 2015 Fall 25 Nov 20  http://www.ncbi.nlm.nih.gov/pubmed/26653359


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Fang ZA, Van Diepen S; Royal Alexandra Hospital and University of Alberta Hospital Cardiac Arrest Teams. Successful inter-hospital transfer for extra-corporeal membrane oxygenation after an amniotic fluid embolism induced cardiac arrest. 2016 Jan 29 http://www.ncbi.nlm.nih.gov/pubmed/26825107

