

# STARRT-AKI

Newsletter Issue 5: April 2017

## Standard versus Accelerated Initiation of Renal Replacement Therapy in Acute Kidney Injury

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### Follow STARRT-AKI on Twitter!

STARRT-AKI is on Twitter! Follow us on Twitter [@Aki-Starrt](#) to receive updates on new site activations and enrolment status.



### Visit Our Website

Visit our website [here](#) for the latest updates on the study and for access to study documents.



## A message from Sean and Ron/Un message de Sean et Ron

Dear STARRT-AKI Team Members,

Welcome to the spring 2017 edition of the STARRT-AKI newsletter. We hope you enjoy reading it! There is a lot of exciting news to share. With the activation of many new centres around the world, enrollment has steadily climbed. We want to extend a particular thanks to Didier Dreyfuss, Stephane Gaudry, Isabelle Hoffman, Aline Dechanet and the entire STARRT-AKI France Team. The addition of 26 STARRT-AKI sites in France has truly energized recruitment. At the same time we appreciate the continued dedication of all our active sites worldwide and eagerly await the addition of sites in the UK, Belgium, Austria, Australia and China in the coming months.

We appreciate your feedback on the case report forms and the supporting documentation. Thanks to the tireless work of Erika Dempsey at the George Institute in Sydney and Magda Zaprowska and Nikita Chavda at the Applied Health Research Centre in Toronto, we will soon be releasing an updated Operations Manual that contains a detailed data dictionary. We hope that this new user-friendly document will greatly facilitate the smooth completion of the case report forms on Medidata RAVE.

As always, we look forward to hearing from you if you have any questions or if you have advice to offer about how we can further improve any aspect of the trial. Feel free to email, text or call anytime. We wish you and your families the very best for a happy Easter and Passover.

With warmest regards,

Sean and Ron

Chers membres de l'équipe STARRT-AKI,

Bienvenue à l'édition du printemps 2017 du bulletin STARRT-AKI. Nous espérons que vous apprécierez de le lire! Il y a beaucoup de nouvelles à partager. Avec l'activation de nombreux nouveaux centres à travers le monde, nous faisons des progrès solides avec le recrutement. Nous souhaitons remercier particulièrement Didier Dreyfuss, Stephane Gaudry, Isabelle Hoffman, Aline Dechanet et toute l'équipe STARRT-AKI France. L'activation de 26 sites STARRT-AKI en France a stimulé le rythme des inclusions. Dans le même temps, nous apprécions le dévouement continu de tous nos sites actifs dans le monde entier et attendons avec impatience l'ajout de sites au Royaume-Uni, en Belgique, en Autriche, en Australie et en Chine dans les prochains mois.

Nous apprécions vos commentaires sur les formulaires de rapport et les documents à l'appui. Grâce au travail infatigable d'Erika Dempsey au *George Institute* à Sydney et de Magda Zaprowska et Nikita Chavda au *Applied Health Research Centre* à Toronto, nous allons publier une version mise à jour du manuel contenant un dictionnaire de données détaillé. Nous espérons que ce document facilitera le remplissage des formulaires sur Medidata RAVE.

Comme toujours, n'hésitez pas à nous contacter si vous avez des questions ou si vous avez des conseils à proposer pour améliorer l'étude. Envoyez un courriel ou un texte ou appelez-nous à tout moment.

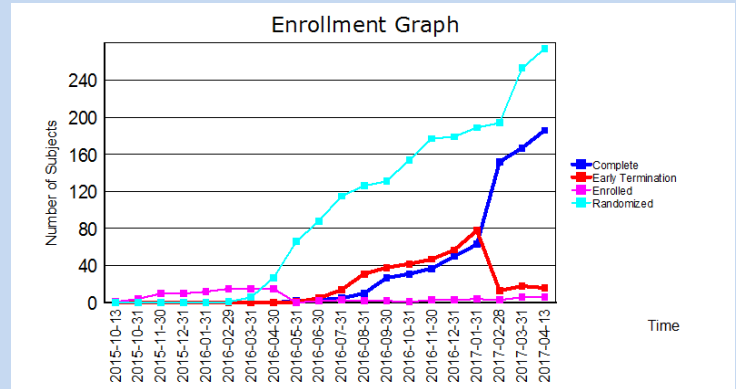
Nous souhaitons à vous et à vos familles les meilleurs vœux pour les Pâques et la Pâque.

Amicalement,

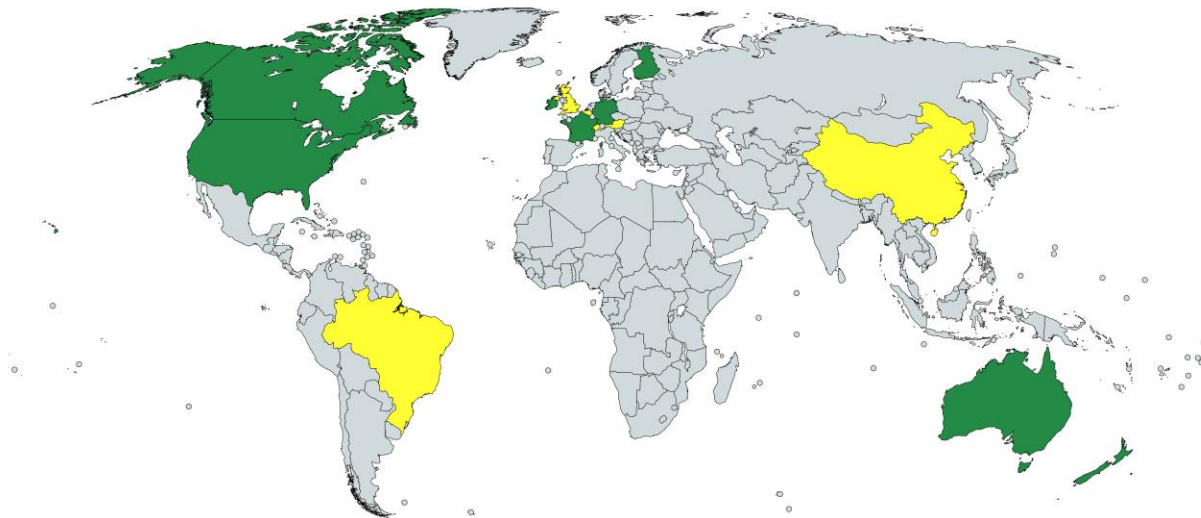
Sean et Ron

## Study Overview

- As of April 13, 2017, there are 474 patients in total enrolled in STARRT-AKI
- There are currently 74 active sites in Canada, Australia, New Zealand, Finland, Ireland, US, Germany, and France
- Recent site activations:**
  - France: 26 sites in total have been activated in France so far
  - Germany: University Hospital Munster
  - Finland: Turku University Hospital
  - Canada: Centre Integre Universitaire de Sante et de Services Sociaux de la Mauricie-et-du-Centre-du-Quebec, Centre Hospitalier Universitaire de Quebec – Universite Laval, Memorial University of Newfoundland, Red Deer Regional Hospital, and Mazankowski Alberta Heart Institute
- Upcoming site activations:**
  - We look forward to having few additional sites from France on board towards the end of April
  - London Health Science Centre, ON, Canada
  - University of Alabama at Birmingham, US



## STARRT-AKI across the World



**Active STARRT-AKI sites**

- Canada: 35 active sites
- France: 26 active sites
- Australia: 7 active sites
- US: 1 active site
- Germany: 1 active site
- New Zealand: 1 active site
- Ireland: 1 active site
- Finland: 2 active sites

**Upcoming STARRT-AKI sites**

- Brazil
- Switzerland
- China
- United Kingdom
- Belgium
- Scotland
- Austria

## Updates from the Upcoming STARRT-AKI Sites

Our site members from Austria, US, UK, Belgium, Brazil, Scotland, and Switzerland are working hard to get through the regulatory hurdles for site activation. Below is a summary of current status of the trial in each country:

- **UK (Dr. Marlies Ostermann):** Contract has been finalized, REB application will be submitted once the contract has been fully signed and executed.
- **Austria (Dr. Michael Joannidis):** Ethics approval has been obtained, and efforts are underway to finalize the contract.
- **Belgium (Dr. Eric Hoste):** Ethics approval has been obtained, and efforts are underway to finalize the contract.
- **Brazil (Dr. Fernando Thome):** Ethics and contracts process have been initiated, and efforts are underway to recruit more sites from Brazil on board.
- **Scotland (Dr. Malcolm Sim):** Ethics and contracts process have been initiated
- **Switzerland (Dr. Antoine Schneider):** Contracts process has been initiated.
- **China (Prof. Bin Du and Prof. Haibo Qui):** Efforts are underway to bring China sites on board; ethics and contract process have been initiated by The George Institute in Australia.

## Announcements

### New Documents Released

**Screening Log V 2.0 [28-Feb-2017]:** We have released a new version of the STARRT-AKI screening log effective March 01, 2017. We advise sites to start using the new version of the screening log effective March 01, 2017 and onwards. As you may have already noticed, the revised screening log captures two additional variables: *Date of Provisional Eligibility* and *Time of Provisional Eligibility*. If you haven't received the new version of the screening log or if you would like to obtain additional information on this new version, please contact the Coordinating Centre (please refer to Contact Us section on Page 5).

### Upcoming Document Updates

We are currently working towards updating the Manual of Operations and we hope to release V3.0 of this document soon. In the upcoming version of the Manual of Operations, we aim to address all the questions and concerns that we have received from the Study Coordinators. Stay tuned for the updates!

## STARRT-AKI kickoff at the Australia New Zealand Intensive Care Society Meetings in Noosa, March 2017



Pictured from Left to Right: Dr. Rinaldo Bellomo (Principal Investigator, Austin Hospital), Sean Bagshaw (Co-Sponsor) and Glenn Eastwood (CRC, Austin Hospital)

## Site Profile: Juravinski Hospital

Juravinski Hospital is located in Hamilton, Ontario-about 45 minutes Southwest of Toronto and is affiliated with McMaster University. The hospital is a Mixed Medical Surgical Oncology Centre with 228 beds and a 19 bed ICU. Juravinski team has been a part of STARRT AKI trial since April 2016 and they have recruited 40 patients so far.



*Pictured from left to right: Dr. Bram Rochweg (Co-Investigator), Tina Millen (Clinical Research Coordinator), and Dr. Timothy Karachi (Co-Investigator)*

## STARRT-AKI in France

### Lead Site: Assistance publique – Hôpitaux de Paris

Assistance publique – Hôpitaux de Paris (APHP) is located in Paris, France and is the National Coordinating Centre for France sites participating in the STARRT-AKI trial. They have helped us activate 26 sites in France to date. We would like to thank the team at APHP for their hard-work and dedication toward STARRT-AKI!



*Pictured from left to right: Dr Stéphane Gaudry, Aline Dechanet, Pr Didier Dreyfuss and Isabelle Hoffmann*

## Frequently Asked Questions (FAQs)

- **If a patient was initially on heparin circuit and then changed to citrate on the same day, how do we enter the anticoagulation strategy data on RAVE?** If a patient’s anticoagulation strategy changes on the same day, the first anticoagulant strategy used for that day should be chosen for data entry (in this case it would be heparin circuit).
- **If we have a patient who meets all of the eligibility criteria for the trial but the chart does not have an exact value for Baseline serum creatinine, how should we proceed with enrolling the patient into the trial?** Please treat this scenario as if you simply lacked a true baseline outpatient serum creatinine. In other words, you would ignore exclusion 7 and assume that the patient does NOT have an eGFR of <20mL/min/1.73m<sup>2</sup>.
- **If a patient passes away before they reach Day 90 follow-up period, would this patient be considered to have fully completed the study?** Yes, since Death is a primary endpoint for this trial, experiencing this event would not qualify for an early discontinuation. As such, if a patient experiences death prior to day 90, they would still be considered to have fully completed the study.
- **If a session of intermittent RRT (either IHD or SLED) is started on a given ICU day and ended on another, how would this affect the RRT Vascular Access form data entry for daily data collection?** In this setting, we recommend attributing the RRT session and all associated data (duration prescribed, anticoagulation and ultrafiltration achieved) to the study day on which RRT was initiated. For example, consider an ICU where the ICU day runs from 8:00 am to 7:59 am. If a patient commences SLED at 4 am on Day 2 and the session concludes at 12 noon (which is by definition on Day 3), the data on that RRT session should be attributed to Day 2 and NOT to Day 3.

## Site Reminders

### Screening Logs and Form 3

For sites which are actively screening, please remember to submit your screening logs to the Coordinating Centre on a monthly basis. Form 3 should be submitted on a quarterly basis.

### Database Queries

A gentle reminder to all the sites to ensure that data is entered and queries are answered in a timely manner. For any database related questions, please contact Nikita Chavda ([ChavdaN@smh.ca](mailto:ChavdaN@smh.ca)) or Magdalena Zaporowska ([ZaporowskaM@smh.ca](mailto:ZaporowskaM@smh.ca)).

## Study Contacts

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