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Visit Our Website!



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

QxCalculate



Investigators and coordinators are welcome to download the FREE QxCalculate app (available on all smartphone operating systems) which includes interactive tools to aid in screening and randomizing patients for STARRT-AKI.

#### A Message from Sean Bagshaw and Ron Wald

Dear STARRT-AKI Team Members,

The last few months have been very fulfilling for our study. Recruitment has continued at a good pace. We bade a warm farewell to our colleagues in France who withdrew from STARRT-AKI as they embark on another exciting trial on the topic of renal replacement therapy initiation in the setting of AKI. We would like to acknowledge the outstanding leadership of Didier Dreyfuss and Stephane Gaudry for the immense success of the trial in France which resulted in the recruitment of 762 participants at 29 sites. We wish them the best of luck with AKIKI-2. At the same time, we have been fortunate to welcome many new sites to STARRT-AKI and we are in the midst of ramping up activity in the United Kingdom, Belgium and China where recruitment has been off to a great start. Most recently, we had the pleasure of activating San Raffaele Hospital in Milan (our first site in Italy—welcome Giovanni Landoni and team!) and next week, we will officially activate the Centre Hospitalier Universitaire Vaudois in Lausanne (our first site in Switzerland—welcome Antoine Schneider and team). We are also looking forward to soon welcoming sites in Kenya and Brazil.

With summer vacations starting for many of us (at least in the Northern hemisphere), we kindly ask that you make a concerted effort to complete the relevant data forms for your participants and address all queries, as soon as possible. We (desperately) need these data to perform our second interim analysis that will be reviewed by our Data Safety and Monitoring Board at their upcoming meeting. Also, though we have made great strides with recruitment, we want to keep up the momentum, even during the summer. We need every site to contribute and remember, every participant counts towards reaching our goal of 2866. WE CAN DO THIS!

As always, we remain incredibly grateful for your support of STARRT-AKI. A special thanks is extended to colleagues who have hosted us in recent months and demonstrated such outstanding hospitality. Please don't hesitate to reach out to us anytime if you have any questions.

With warmest regards,  
Sean and Ron

Chers membres de l'équipe STARRT-AKI,

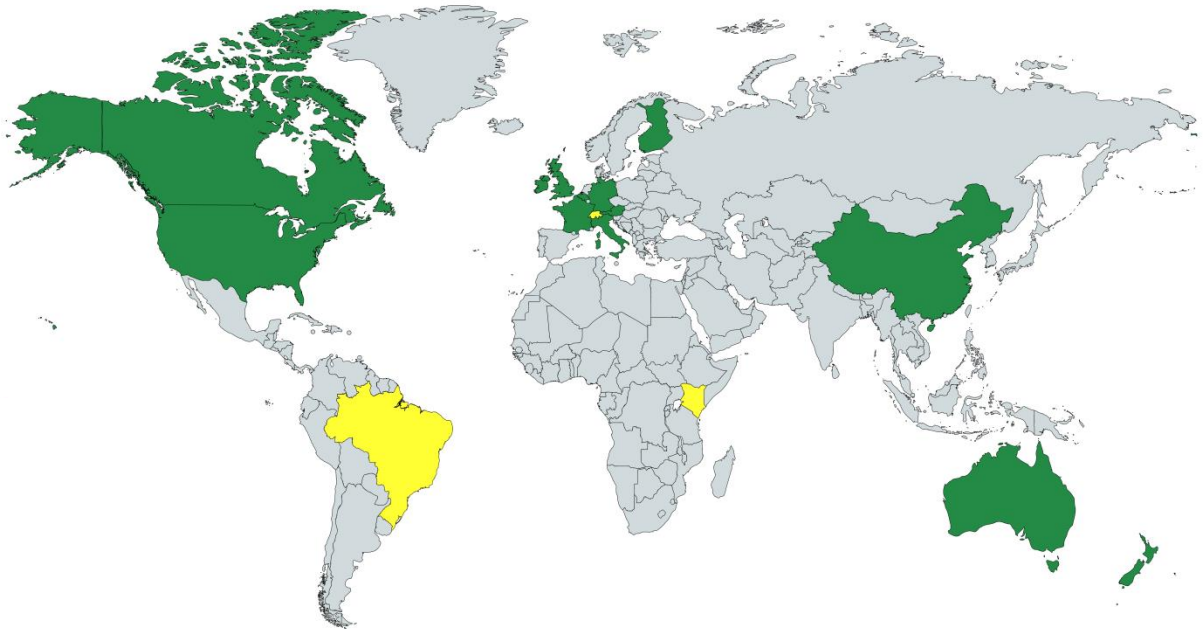
Les derniers mois ont été très satisfaisants pour notre étude. Le recrutement s'est poursuivi à un bon rythme. Nous avons fait nos adieux chaleureux à nos collègues en France qui se sont retirés de STARRT-AKI pour lancer un autre essai sur le thème de l'initiation de la thérapie de remplacement rénale. Nous tenons à remercier le leadership exceptionnel de Didier Dreyfuss et Stéphane Gaudry pour l'immense succès de STARRT-AKI en France où nous avons eu 762 participants recrutés sur 29 sites. Nous leur souhaitons bonne chance avec AKIKI-2! En même temps, nous avons eu la chance d'accueillir de nombreux nouveaux sites et nous sommes en pleine activité au Royaume-Uni, en Belgique et en Chine, où le recrutement a bien démarré. Plus récemment, nous avons eu le plaisir d'activer l'hôpital San Raffaele à Milan (notre premier site en Italie - bienvenue à Giovanni Landoni et l'équipe!) Et la semaine prochaine, nous allons activer officiellement le Centre Hospitalier Universitaire Vaudois à Lausanne (notre premier site en Suisse- bienvenue à Antoine Schneider et à l'équipe). Nous sommes également impatients d'accueillir bientôt des sites au Kenya et au Brésil.

Avec les vacances d'été qui commencent pour beaucoup d'entre nous (au moins dans l'hémisphère Nord), nous vous demandons de s'il vous plaît remplir les formulaires de données pour vos participants sur MedidataRAVE et répondre au "queries" dès que possible. Nous avons (désespérément) besoin de ces données pour effectuer notre deuxième analyse intermédiaire qui sera examinée par notre DSMB lors de leur prochaine réunion. De plus, même si nous avons fait de grands progrès en recrutement, nous voulons maintenir ce cadence, même pendant l'été. Nous avons besoin que chaque site contribue et on doit se souvenir que chaque participant compte pour atteindre notre objectif de 2866. NOUS POUVONS LE FAIRE!

Comme toujours, nous restons incroyablement reconnaissants pour votre soutien de STARRT-AKI. Un remerciement spécial est adressé aux collègues qui nous ont accueillis au cours des derniers mois et ont démontré une hospitalité exceptionnelle. N'hésitez pas à nous contacter à tout moment si vous avez des questions.

Avec nos salutations distinguées,  
Sean et Ron

## The World of STARRT-AKI



### Activated STARRT-AKI countries

- Canada: 42 activated sites; 618 subjects  
*(5 sites currently on hold)*
- Germany: 2 activated site; 14 subjects
- Australia: 15 activated sites; 254 subjects
- UK: 8 activated sites; 42 subjects
- Ireland: 1 activated site; 3 subjects
- Belgium: 1 activated site; 21 subjects
- France: 29 activated sites; 762 subjects  
*(29 sites currently not recruiting)*
- US: 6 activated sites; 53 subjects
- New Zealand: 6 activated site; 90 subjects
- Austria: 3 sites; 19 subjects
- Finland: 3 activated sites; 40 subjects
- China: 10 activated sites; 38 subjects

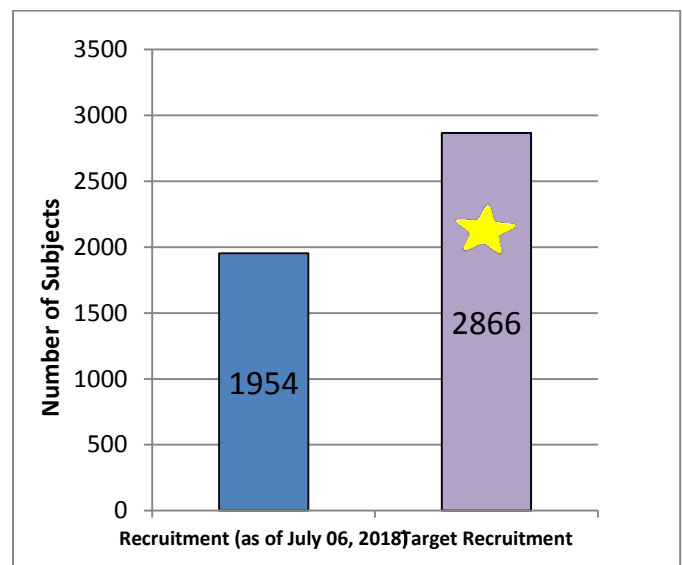
### Soon to Join STARRT-AKI

- Brazil
- Kenya
- Switzerland

## Recruitment Status

As of July 06, 2018, we have randomized **1954** participants into the STARRT-AKI trial. We are currently less than 1,000 participants away from reaching our target recruitment of 2,866!

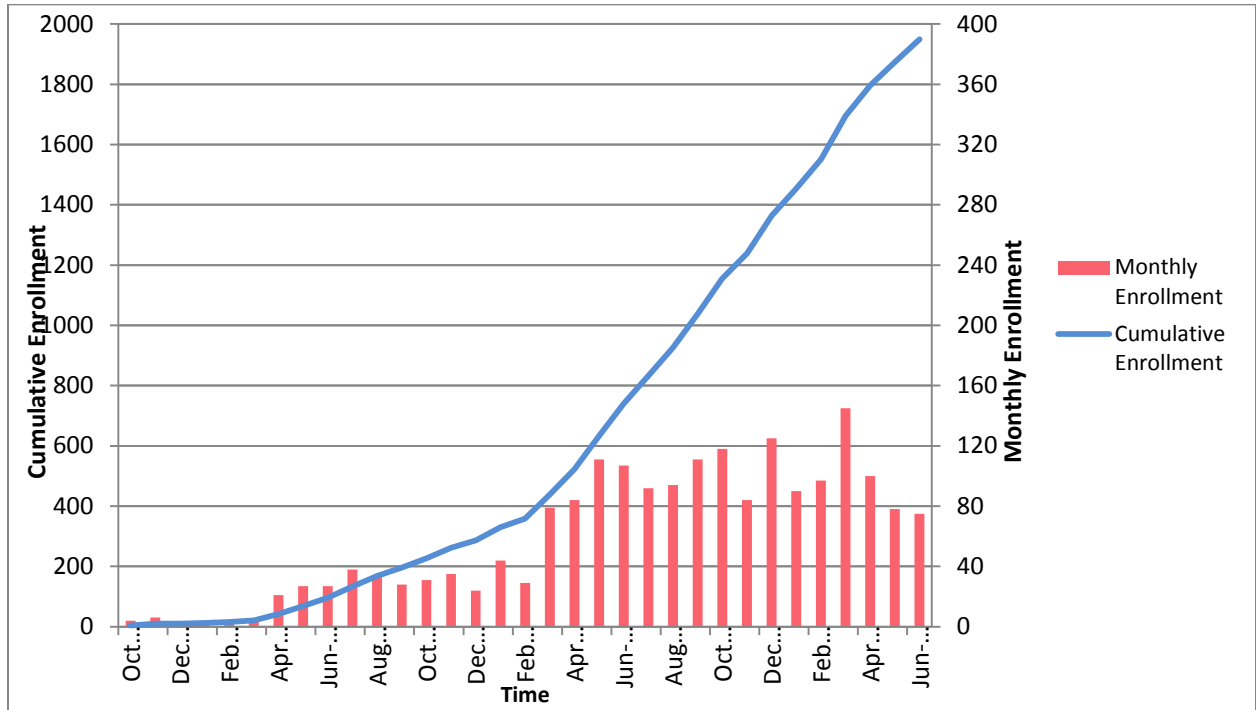
A big thank you to all the participating sites for your dedication and hard work in helping us get this far!



## Cumulative & Monthly Enrollment Status

The average monthly enrollment for the STARRT-AKI study is currently approximately 58 participants per month.

In June of 2018, a total of 75 patients were randomized.



## Study Overview and Updates

Welcome to **San Raffaele Hospital** in Italy, which is our newest site activated in the month of June! As of July 06, 2018, there are **127 activated sites** and **1954 patients randomized**.

### Recent site activations:

- *Australia*: The Northern Hospital (Melbourne)
- *China*: The First Hospital of Jilin University (Changchun), The First Affiliated Hospital of Bengbu Medical College
- *New Zealand*: Auckland Hospital DCCM
- *UK*: Wycombe Hospital (Buckinghamshire), Stoke Mandeville Hospital (Aylesbury), East Kent University Hospitals NHS Trust, Leeds Teaching Hospital (West Yorkshire), Nottingham University Hospital (Nottingham), Milton Keynes Hospital, University Hospital Lewisham
- *USA*: Rhode Island Hospital (Providence), The Miriam Hospital
- *Italy*: San Raffaele Hospital (Milan)

### Upcoming site activations:

- *Australia*: Concord Hospital (Sydney)
- *Brazil*: Hospital de Clínicas de Porto Alegre- Rio grande do Sul (Porto Alegre)
- *China*: Peking Union Medical College Hospital (Beijing), The First Affiliated Hospital of Xiamen University (Xiamen), Zhongnan Hospital of Wuhan University (Wuhan), Wuxi People's Hospital
- *Kenya*: Aga Khan University Hospital Nairobi (Nairobi)
- *Scotland*: Queen Elizabeth University Hospital (Glasgow), Ayr Hospital (Ayr), Golden Jubilee National Hospital (Clyebank), Aberdeen Royal Infirmary (Aberdeen), Hairmyres Hospital (East Kilbride), Monklands District General Hospital (Airdrie)
- *Switzerland*: Centre Hospitalier Universitaire Vaudois, CHUV (Lausanne)
- *UK*: King's College Hospital (London), Princess Royal University Hospital (London), Liverpool University Hospital (Liverpool), Lewisham and Greenwich NHS Trust - Queen Elizabeth Hospital, Royal Sussex County Hospital, Queen Elizabeth Hospital (Birmingham), St. Helens & Knowsley Teaching Hospital, Royal Surrey County Hospital NHS Foundation Trust, Frimley Health NHS Trust - Frimley Park Hospital, Frimley Health NHS Trust - Wexham Park Hospital, Western Sussex Hospitals NHS Foundation Trust: St Richards Hospital, Western Sussex Hospitals NHS Foundation Trust: Worthing Hospital, Bradford Teaching Hospitals NHS Foundation Trust

## Announcements

### France Sites

As of May 4, 2018, the France sites have halted recruitment for the STARRT-AKI study. They have randomized an outstanding total of 762 patients among 29 sites! We are grateful for their contribution to STARRT-AKI and thank them for their amazing work! We wish our French colleagues the best of luck as they embark on AKIKI-2!

### 2<sup>nd</sup> Interim Analysis

Our first interim analysis was reviewed at a DSMB meeting held in early January 2018 and it was a success! Since we crossed the 50% recruitment mark in January 2018, we are in the process of preparing for a second interim analysis. We would like to thank all the sites for their ongoing diligent data entry and hard work!

**Beijing Friendship Hospital**  
Beijing, China



*Pictured left to right: Dr. Sean Bagshaw  
and Prof. Meili Duan*

**Congratulations to Dr. Dean Fergusson of the  
STARRT-AKI DSMB for being chosen as the  
President-Elect of International Clinical Trials  
Society!**



“With the promise of innovative therapies coupled with innovative clinical trial designs, we have a tremendous opportunity to advance the science and practice of trials through mutual collaboration and learning”

**Dr. Dean Fergusson**

Senior scientist at The Ottawa Hospital,  
Professor at the University of Ottawa

**Health Sciences Centre**  
Winnipeg, Manitoba, Canada  
**April 23, 2018**



*Pictured left to right: Dr. Herman Lam (Nephrology, site Co-PI), Dr. Ron Wald, Dr. Claudio Rigatto (Nephrology, site PI), Dr. Bojan Paunovic (Critical Care, site Co-I), Dr. Owen Mooney (Critical Care, site Co-I), Anna Glybina (MD, study coordinator)*



## STARRT-AKI Site Profile

### Sunnybrook Health Sciences Centre (Toronto, Ontario, Canada)

Sunnybrook Health Sciences Centre is located in Toronto, Ontario, Canada. It is the largest trauma centre in Canada and is fully affiliated with the University of Toronto. We screen patients for STARRT-AKI in two level III ICUs, one with medical, surgical, and trauma patients, and the other with primarily cardiac and vascular surgical patients. Our team started recruiting for STARRT-AKI in September 2016. To date, 21 patients have been enrolled!



*Pictured from left to right: Neill Adhikari, Site Principal Investigator (Critical Care), Nicole Marinoff and Navjot Kaur, Critical Care Research Coordinators, and Alireza Zahirieh, Sub-Investigator (Nephrology). Not pictured: Adic Perez, Research Coordinator and Andre Amaral, Sub-Investigator (Critical Care).*

## STARRT-AKI Site Profile

### Beijing Friendship Hospital (Beijing, China)



*Pictured above: Beijing Friendship Hospital staff*

Beijing Friendship Hospital is affiliated with Capital University of Medical Sciences. The hospital is a tertiary hospital with 1,423 beds in total and 30 critical care beds with a strong clinical team. The Department of Critical Care Medicine in Beijing Friendship Hospital is the National Clinical Specialty Project Unit and Municipal Bureau of Health Quality Control Centre in Critical Care Medicine. The Friendship team recruited the first STARRT-AKI patient in China led by Professor Meili Duan. Beijing Friendship Hospital has recruited 13 patients since their activation in February.



*Pictured above: Prof. Meili Duan, Site Principal Investigator*

## Frequently Asked Questions (FAQs)

- Q. With regard to SOFA score, if a value to calculate a given component of the score is not available, is there an option to choose 'not available'?**
- A. If a value is not present, then choose “0” in the database.
- Q. If a patient is discharged from ICU before day 14 and experiences an AE/SAE after the ICU discharge (for example on day 8), does this need to be recorded in the database?**
- A. No, AE/SAEs are only collected from Randomization/Day 0 to Day 14 AND while the patient is in ICU (same days as Daily Data collection for the patient).
- Q. What data do you need from the patient at Day 90?**
- A. As a priority, collecting patient vital status is the most crucial. Additionally, key outcomes such as the ongoing need for RRT, serum creatinine and urine ACR should be collected and recorded within the database. Please also remember to complete the quality of life (EQ-5D-5L) and clinical frailty assessments at 90 days.

## 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

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

## Study Contacts

Coordinating Centre		Principal Investigators	
<p><b>Nikita Chavda,</b> Project Lead Email: <a href="mailto:ChavdaN@smh.ca">ChavdaN@smh.ca</a> Phone: 416-864-6060 ext. 7893</p>	<p><b>Jessica Marchese,</b> Project Assistant Email: <a href="mailto:MarcheseJ@smh.ca">MarcheseJ@smh.ca</a> Phone: 416-864-6060 ext. 7856</p>	<p><b>Ron Wald</b> Principal Investigator Email: <a href="mailto:WaldR@smh.ca">WaldR@smh.ca</a> Office: 416-867-3703 Cell: 416-258-6540</p>	<p><b>Sean Bagshaw</b> Principal Investigator Email: <a href="mailto:Bagshaw@ualberta.ca">Bagshaw@ualberta.ca</a> Office: 780-492-3817 Cell: 780-722-9756</p>