

# STARTRT-AKI

Newsletter Issue 10: October 2018

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

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## A Message from Sean Bagshaw and Ron Wald

Dear STARTRT-AKI Team Members,

The past few months have continued to be both exciting and rewarding for our trial. Despite well-deserved vacations over the summer months, we appreciate the steady pace of recruitment during this time. We have also been privileged to welcome new sites to the STARTRT-AKI family, most notably in Scotland and Switzerland. We continue to work through the regulatory documentation that will enable us to activate sites in Brazil and Kenya where we are fortunate to have enthusiastic STARTRT-AKI champions.

Our Data Safety Monitoring Board met on September 14 to review data on the first half of recruited patients. The Board recommended that the trial continue. You will soon be receiving an official letter for your Ethics Board.

By now, those of you outside of Australia, New Zealand and China, would have received an email about our plan for remote data monitoring. I am sure you can all appreciate the importance of being confident in the quality and consistency of data. We want to assure you that we have spent a great deal of time ensuring that the extra work associated with this process is modest by focusing on data elements that are truly the most critical. Please don't hesitate to reach out to us with any questions or concerns.

We have now surpassed the 75% mark for recruitment! Though we should all be proud of this accomplishment, we are not ready to "sit back and relax". There still are ~ 700 patients to recruit and we continue to urge every site to work hard on every recruitment opportunity. We sound like a broken record but will repeat the cliché that "every participant counts". Thank you for your ongoing support!

With warmest appreciation and best regards,

Sean and Ron

Chers membres de l'équipe STARTRT-AKI,

Les derniers mois ont continué d'être à la fois passionnants et enrichissants pour STARTRT-Aki. Malgré des vacances bien méritées pendant les mois d'été, nous apprécions le rythme soutenu du recrutement durant cette période. Nous avons également eu le privilège d'accueillir de nouveaux sites dans la famille STARTRT-AKI, notamment en Écosse et en Suisse. Nous continuons à travailler à travers la documentation réglementaire qui nous permettra d'activer des sites au Brésil et au Kenya où nous avons la chance d'avoir des champions STARTRT-AKI enthousiastes.

Notre DSMB s'est réuni le 14 septembre pour examiner les données relatives à la première moitié des patients recrutés. Le DSM a recommandé de continuer STARTRT-AKI. Vous allez bientôt recevoir une lettre officielle de votre comité d'éthique.

À l'heure actuelle, en dehors de l'Australie, de la Nouvelle-Zélande et de la Chine, vous auriez reçu un courriel concernant notre plan de surveillance des données. Je suis sûr que vous pouvez tous comprendre l'importance d'avoir confiance en la qualité et la cohérence des données. Nous voulons vous assurer que nous avons passé beaucoup de temps à vérifier que le travail supplémentaire associé à ce processus soit modeste en nous concentrant sur les éléments de données qui sont vraiment les plus critiques. N'hésitez pas à nous contacter pour toute question ou préoccupation.

Nous avons maintenant dépassé la barre des 75% pour le recrutement! Bien que nous devrions tous être fiers de cet accomplissement, nous ne sommes pas prêts d'être complaisant. Environ 700 patients doivent encore être recrutés et nous exhortons chaque site à travailler fort sur chaque opportunité de recrutement. Nous répétons le cliché selon lequel «chaque participant compte»!

Avec nos plus sincères remerciements et meilleures salutations,

Sean et Ron

Follow STARTRT-AKI on Twitter!



STARTRT-AKI is on Twitter!  
Follow us on Twitter @STARTRTAKI.

Visit Our Website!



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

QxCalculate

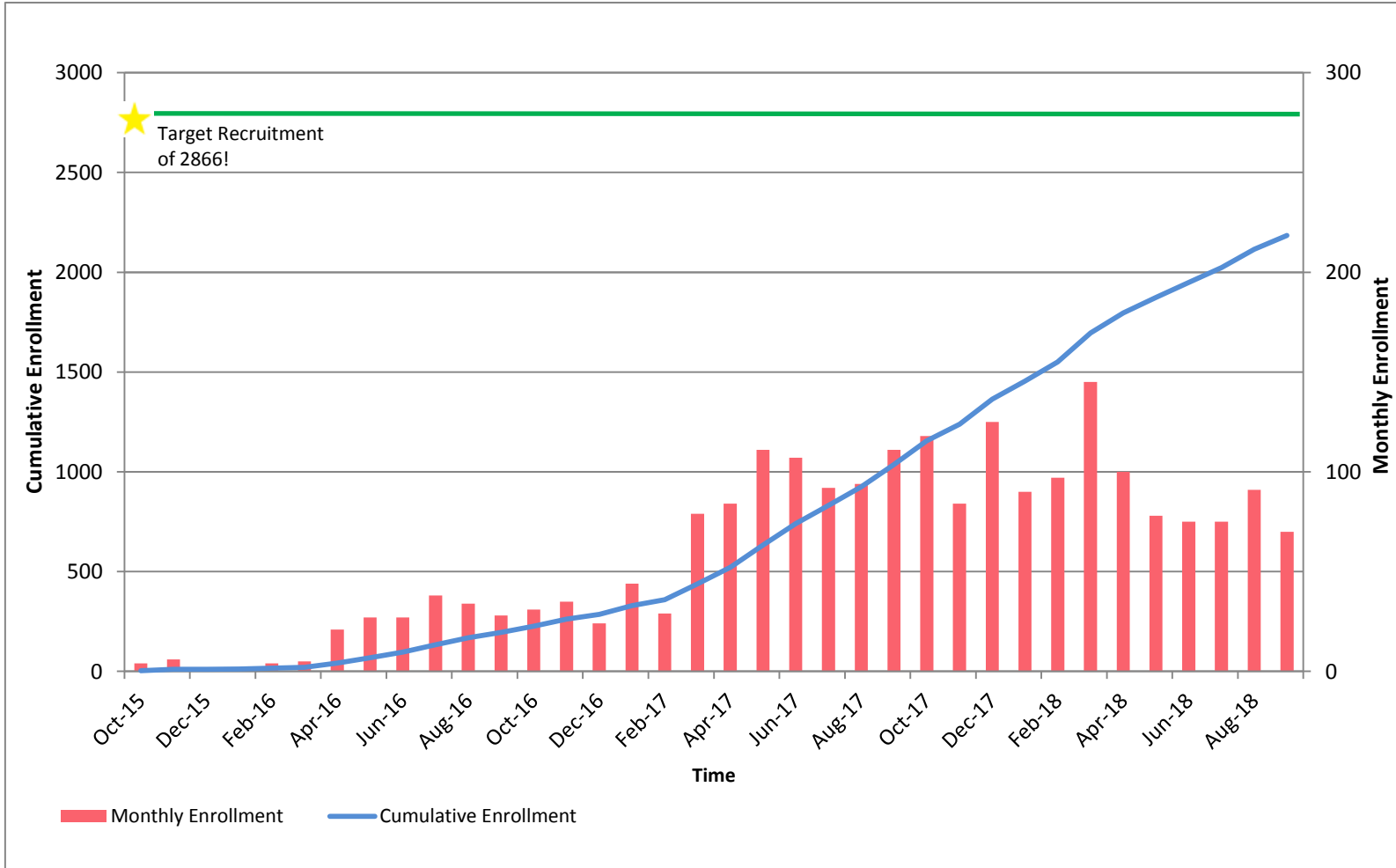


Investigators and coordinators are encouraged to download the FREE QxCalculate app (available on all smartphone operating systems) which includes interactive tools to aid in screening and randomizing patients for STARTRT-AKI.

## Cumulative & Monthly Enrollment Status

The average monthly enrollment for the STARRT-AKI study is currently approximately **60** participants per month.

In September 2018, a total of **70** patients were randomized.



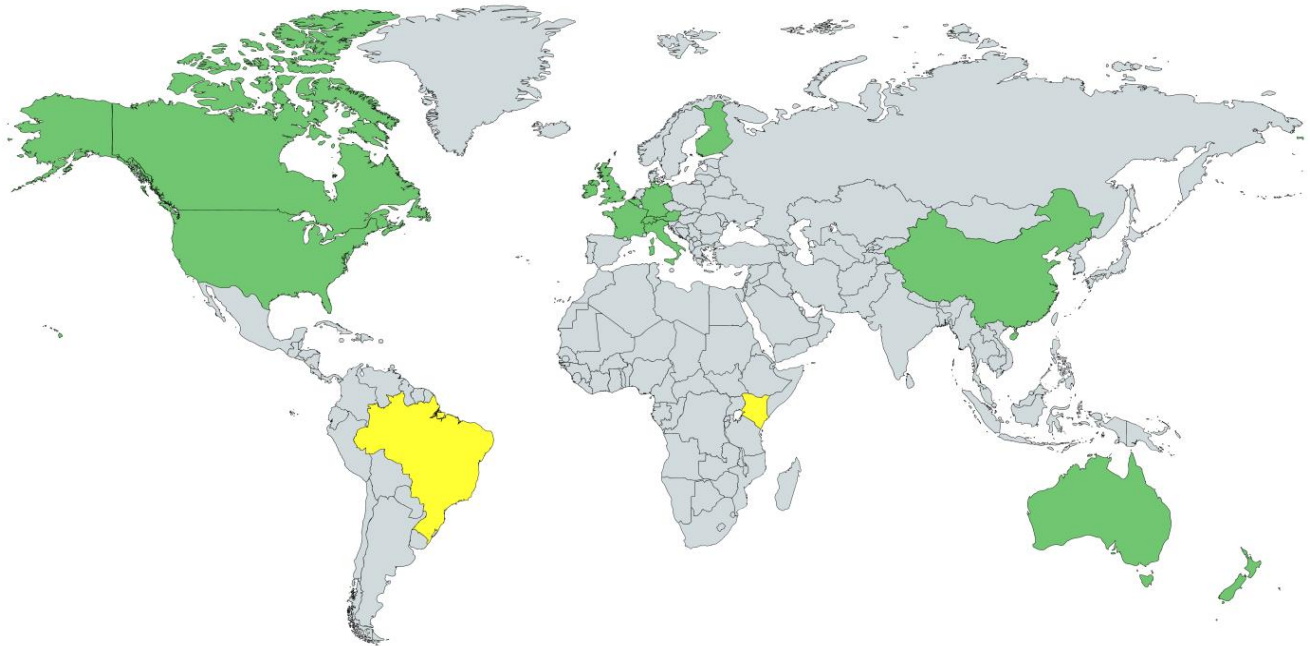
### Top Recruiters of the Summer 2018!

Our top recruiter during the summer months of June, July and August 2018, is **Zhongda Hospital Southeast University** in China. Congratulations for successfully randomizing an incredible 18 patients!

Congratulations to **Beijing Friendship Hospital, Capital Medical University** in China for randomizing 12 patients and to **Guy's and St. Thomas' Hospital** in the UK for randomizing 11 patients during the summer months!

Keep up the great work everyone!

## The World of STARRT-AKI

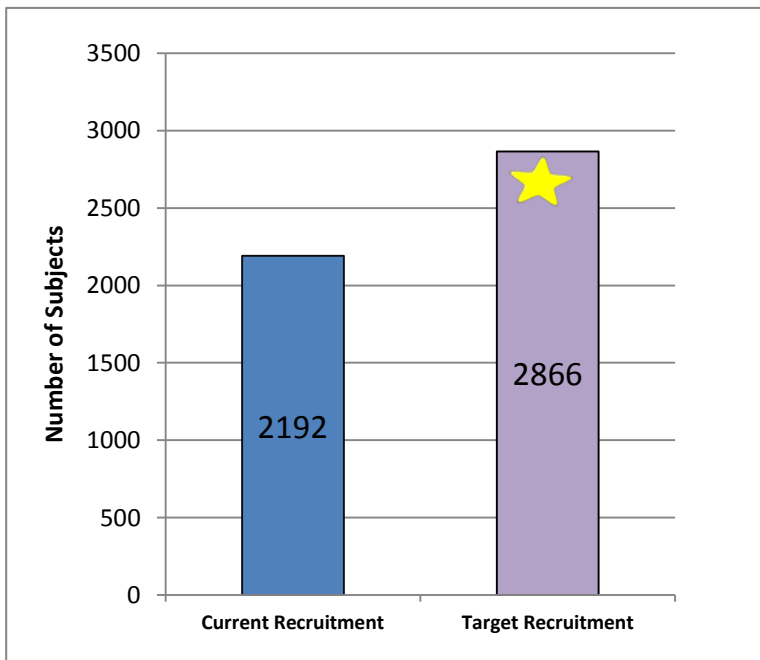


### Activated STARRT-AKI countries

- Canada: 42 activated sites; 681 subjects  
*(5 sites currently on hold)*
- Germany: 2 activated site; 17 subjects
- Australia: 15 activated sites; 291 subjects
- UK: 12 activated sites; 60 subjects
- Ireland: 1 activated site; 3 subjects
- Belgium: 1 activated site; 29 subjects
- Italy: 1 activated site; 0 subjects
- France: 29 activated sites; 762 subjects  
*(29 sites currently not recruiting)*
- US: 6 activated sites; 74 subjects
- New Zealand: 7 activated site; 116 subjects
- Austria: 3 sites; 27 subjects
- Finland: 3 activated sites; 44 subjects
- China: 12 activated sites; 80 subjects
- Switzerland 1 active site; 8 subjects

### Soon to Join STARRT-AKI

- Brazil
- Kenya



### Recruitment Status

As of October 5<sup>th</sup>, 2018, we have randomized **2,192** participants into the STARRT-AKI trial. We have now reached 75% of our targeted sample size!

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

## Study Overview and Updates

Welcome to **Taranaki Hospital** in New Zealand, which is our newest site activated in the month of September! As of October 5<sup>th</sup>, 2018, there are **135 activated sites** and **2,192 patients randomized**.

### Recent site activations:

- *China*: Peking Union Medical College Hospital, Wuxi People's Hospital
- *Switzerland*: Centre Hospitalier Universitaire Vaudois (CHUV)
- *UK (England)*: King's College Hospital, Liverpool University Hospital
- *UK (Scotland)*: Queen Elizabeth University Hospital, Aberdeen Royal Infirmary – NHS Grampian

### Upcoming site activations:

- *Australia*: Concord Hospital
- *Austria*: General Hospital Vienna, ICU
- *Brazil*: Hospital de Clínicas de Porto Alegre- Rio grande do Sul
- *Belgium*: CHU Brugmann University Hospital, ZNA Hospital Antwerp
- *Canada*: St. Joseph's Healthcare Toronto
- *China*: The First Affiliated Hospital of Xiamen University, Zhongnan Hospital of Wuhan University
- *Italy*: Ospedale San Carlo
- *Ireland*: Beaumont Hospital
- *Kenya*: Aga Khan University Hospital Nairobi
- *New Zealand*: Whangarei Hospital
- *Switzerland*: Bern Inselspital, Geneva University Hospital
- *UK (England)*: Princess Royal University Hospital, Brighton and Sussex County Hospital, Queen Elizabeth Hospital, 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, Bradford Teaching Hospitals NHS Foundation Trust, Tameside and Glossop Integrated Care NHS, Queen Alexandra Hospital – Portsmouth, Peterborough City Hospital - North West Anglia NHS Foundation Trust, Western Sussex Hospitals NHS Foundation Trust: St Richards Hospital, Western Sussex Hospitals NHS Foundation Trust: Worthing Hospital, Warwick Hospital - South Warwickshire
- *UK (Scotland)*: Golden Jubilee National Hospital, Hairmyres Hospital, Monklands District General Hospital, University Hospital Ayr (NHS Ayrshire and Arran)

## Announcements

### Third interim analysis

Early this month of September 2018 we reached 75% of our participant recruitment target, which means we are in the process of preparing for our third interim analysis! Details around data submission deadlines are forthcoming.

### Upcoming Investigator Meetings

We have two upcoming STARRT-AKI Investigator Meetings before the year is over! The first IM will take place at ASN Kidney Week 2018 on Friday, October 26 @ 6:30am (PDT) at the Manchester Grand Hyatt. The second IM will take place at Critical Care Canada Forum on Thursday, November 8<sup>th</sup> @ 7am (EDT) at the Sheraton Centre.





## Health Sciences North Site Profile

Located in Sudbury, Ontario, a 4-hour drive North of Toronto, this outstanding group has been active in STARRT-AKI since 2016. To date they have randomized 38 patients. The hospital has a 28-bed ICU with 12 intensivists and 4 nephrologists on staff. Sudbury is the largest city in Northern Ontario and is the home of many regional health programs for Northeastern Ontario.

*Pictured from left to right: Dr. J.P. Harmon (Co-Investigator), Nicole Haslam (Clinical Research Coordinator), Sarah Charette (Clinical Research Coordinator), Dr. Navdeep Mehta (Co-Investigator).*



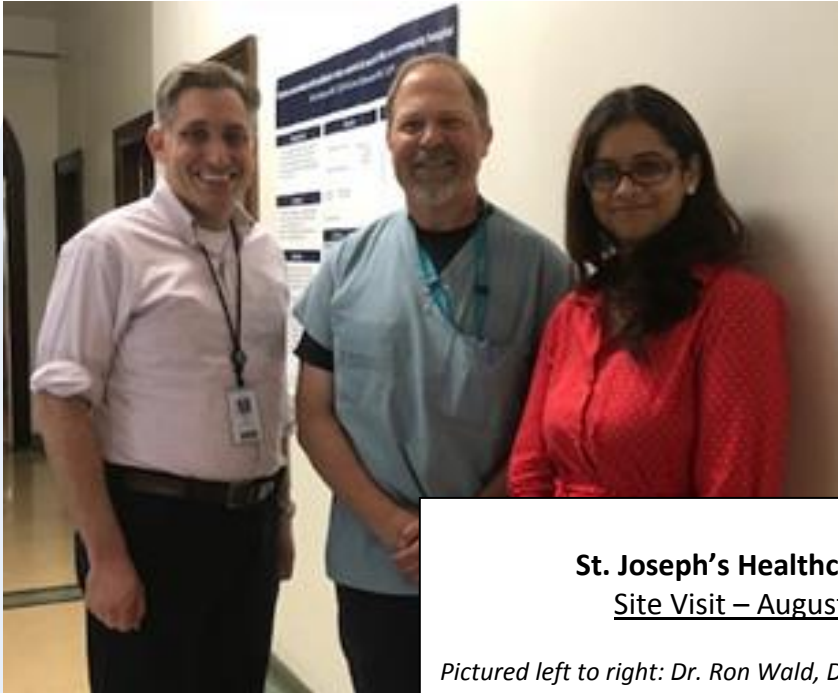
## Zhongda Hospital Southeast University Site Profile

Located in Nanjing, Jiangsu, the team at Zhongda Hospital has been recruiting for STARRT-AKI since April 2018. To date they have randomized 26 patients. The hospital has a 74-bed ICU with 20 intensivists on staff. Nanjing is the capital of Jiangsu Province.

*Pictured to the left: Zhongda Hospital Southeast University ICU staff*



## Meetings and Site Visits



**St. Joseph's Healthcare, Toronto**  
**Site Visit – August 15, 2018**

*Pictured left to right: Dr. Ron Wald, Dr. Robert Cirone (Site Investigator), Kanthi Kavikondala (Clinical Research Coordinator)*

**Harder Kulm, Interlaken, Switzerland**  
**Swiss Intensive Care Society Meeting –**  
**September 20, 2018**

*Pictured left to right: Dr. Sean Bagshaw, Dr. Antoine Schneider (Site Investigator, Lead for Switzerland)*



## Frequently Asked Questions (FAQs)

**Q. If a patient passes away before they reach Day 90 follow-up period, would this patient be considered to have fully completed the study?**

A. Yes, since death is a primary endpoint for this trial, experiencing this event would not qualify for an early discontinuation. As such, if a participant dies prior to day 90, he/she would still be considered to have fully completed the study.

**Q. For the Day 28 Resource Utilization Form, what is the time frame for data collection?**

A. Data collection for the day 28 resource utilization begins from randomization up to and including day 28. This will also include any re-admissions to the ICU/hospital that may have occurred between randomization and day 28.

**Q. Which patients should be included on the screening logs and Form 3?**

A. Screened patients who meet all the inclusion criteria should be entered in the screening log. If a patient does not meet ALL the inclusion criteria, he/she should not be entered in the screening log. Form 3 form is only completed for non-enrolled patients whose FINAL reason for non-participation was one of the following: (1) Exclusion 9 (clinician believes that immediate RRT is mandated); or (2) Exclusion 10 (clinician believes that deferral of RRT is mandated); or (3) Patient is fully eligible but consent could not be secured.

## 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

We kindly remind all 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			
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