



### Welcome to SATURN!

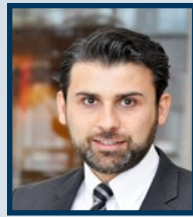
On behalf of the entire SATURN Team, it is our pleasure to welcome you to the first SATURN Trial Newsletter. This Newsletter will serve to keep investigators and study coordinators updated on all aspects of the trial including study status, updates, and clarifications. Important reminders, dates, and helpful tips will be sent directly to your email quarterly, and special bulletins will be sent as needed.

Thank you for all of your efforts toward getting your site up and running, and welcome to the SATURN family! We are counting on your dedication and enthusiastic participation in this important trial, *the first and largest NINDS-funded trial for ICH prevention*. We want you to know that we are here to help. If any questions arise at any point along the way, please don't hesitate to contact us (see *Study Leadership Team* on p.2). We look forward to working closely with you now, and throughout the coming years.

Best wishes,



**Magdy Selim**  
Lead PI



**Ashkan Shoamanesh**  
PI, Canada



**Sharon Yeatts**  
PI, Statistics



**Pooja Khatri**  
StrokeNet PI

### By the Numbers: Trial Start Up Status

- A total of **138 sites** (121 in USA and 17 in Canada) **are participating in SATURN.**
- A total of **119 Clinical Trial Agreements have been issued** as of January 17, 2020.
- **47 CTAs have been fully executed.**
- A total of **24 US sites have obtained cIRB approval; 31** are in process.
- A **No Objection Letter was issued by Health Canada** on December 23, 2019.
- **2 Canadian sites have already obtained local ethics approval.**

### Inside this issue

- Meet The Team
- Kudos!
- Start-up Tips
- Upcoming Events
  - Meet & Greet
  - Investigators' Meeting

### Notable News

- Regulatory Reminders



*Have you completed and returned Form 3B?*

- **If not**, please complete and return immediately to:

**Wren Hanson**

*NCC Contracts Specialist*

[hansonwm@ucmail.uc.edu](mailto:hansonwm@ucmail.uc.edu)

**Diane Sparks**

*NCC Contracts Manager/Legal Liaison*

[sparksdn@ucmail.uc.edu](mailto:sparksdn@ucmail.uc.edu)

- **If yes**, is your cIRB and CTA approval in place?
- **If not**, please let us know if you need our help!

**PLEASE NOTE:** We can't send out your CTA until we receive your completed Form 3B!

## Meet the SATURN Trial Team



**Kimberlee Bernstein**

*NCC SATURN Project Manager*

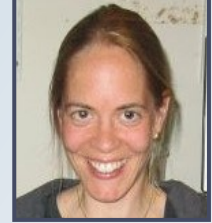
[gammk@ucmail.uc.edu](mailto:gammk@ucmail.uc.edu)



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**Aaron Perlmutter**

*NDMC Site Monitoring Manager*

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## Congratulations!

Special thanks & congratulations to the following sites for completing all regulatory and contracting paperwork. We will be scheduling "site readiness calls" soon. They will be the first SATURN sites released to enroll.

- \* UCSD Hillcrest Hospital - San Diego, CA
- \* Yale New Haven Hospital, New Haven, CT
- \* WVU Healthcare Ruby Memorial Hospital, Morgantown, WV
- \* North Shore University Hospital, Manhasset, NY
- \* Oregon Health & Science University Hospital, Portland, OR
- \* Tufts Medical Center, Boston, MA
- \* WellSpan York Hospital, York, PA
- \* UMASS Memorial Medical Center, Worcester, MA
- \* Beth Israel Deaconess Medical Center, Boston, MA
- \* Hartford Hospital, Hartford, CT

## Helpful Tips to *Expedite* Your Start-Up

- ✓ Complete and return Form 3B. We can't send out your CTA until Form 3B has been received by the NCC. For Canadian sites, Form W-8BEN will be requested, and sites' overseeing entity must be registered on SAM.gov to receive payment.
- ✓ Check the start-up e-mail from the NCC regulatory specialists for the documents that will be required for cIRB submission (for US sites) and CTA processing.
- ✓ Let your contract office know that the CTA is *non-negotiable*.
- ✓ For US sites, the study will **not** go through a full board review at your institution. Your institution has already signed a cIRB reliance agreement to cede to the cIRB as the IRB of record. Let us know if you are having any issues with local requirements. Regulatory Specialists at the NCC can help you. (Please include *Study Name* and *Site Name* in the subject heading of your e-mail).
- ✓ Upload Site and People documents and Delegation of Authority Log into WebDCU as soon as possible. You do not need to wait for CTA/cIRB approval to start this.

got questions?



email us!

SATURN@bidmc.harvard.edu

*We're here  
to HELP!*

### Upcoming Events: *Mark your calendar!*



## StrokeNet Meet & Greet Reception International Stroke Conference 2020

*Wednesday, February 19th 6:30 pm*

NIH StrokeNet will be hosting a **Meet & Greet Reception** during the International Stroke Conference at the JW Marriott Los Angeles on the evening of Wednesday, February 19th at 6:30pm. Come join us there and meet with fellow investigators to discuss this important trial!

*Hope to see you there!*



## Joint Investigator Meeting for the SATURN and ASPIRE Trials

**May 6-7, 2020  
TWA Hotel at JFK**

Stay tuned... Details to come!