



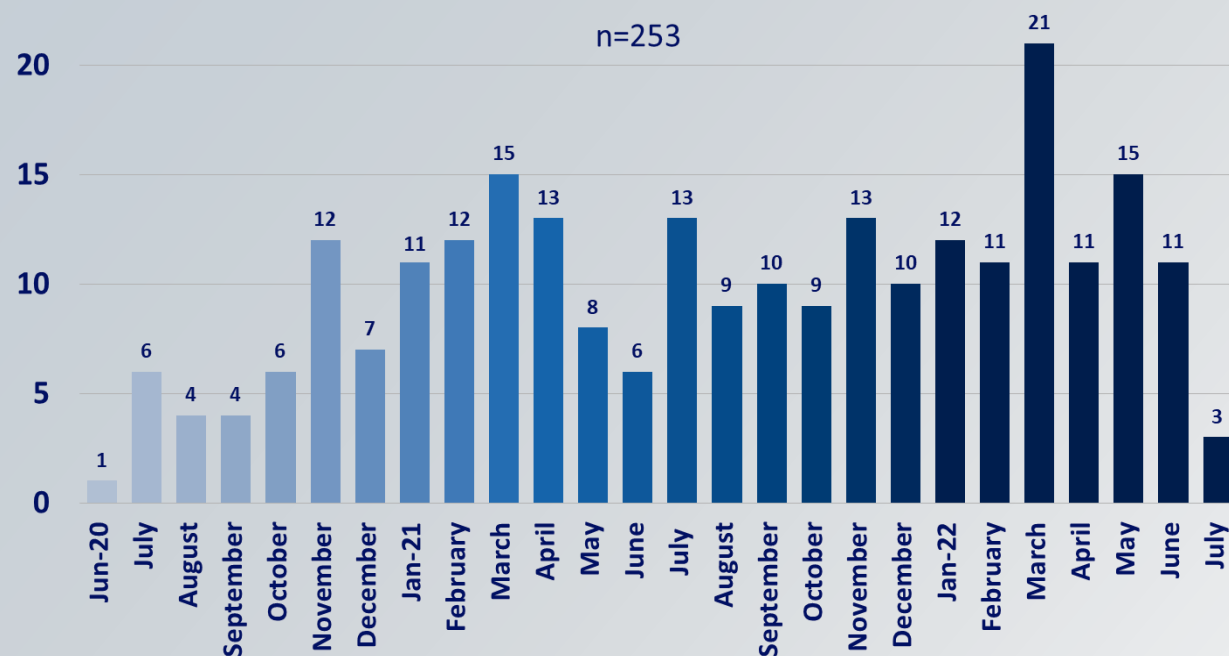
### A Message From The SATURN Study Team:

Happy Summer everyone! We are happy to start off the summer season with the major milestone of reaching 250 enrolled subjects. Thank you to all of our sites for their hard work that made this possible. We also want to welcome new study team members including new fellows who arrived earlier this month. Please see page 3 for a helpful SATURN enrollment guide that you can share with all the SATURN newbies at your site. We hope that you will all continue to enroll and reach out to us if you have any questions, especially as new personnel are introduced to the study.

**Stay cool,  
The SATURN Team**

### Monthly Enrollment Status

n=253



### Inside this issue:

- Introduction
- Enrollment Updates
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- Updates and Reminders
- SATURN Fun Corner

### Got Questions?

- E-Mail us at: [SATURN@bidmc.harvard.edu](mailto:SATURN@bidmc.harvard.edu)
- For 24/7 Clinical Hotline urgent questions call +1-617-667-7000 & ask to page beeper #39636 re: SATURN Trial

Enrollment Updates

First Time Enrolling Sites:

Keck Hospital  
of **USC**  
Keck Medicine of **USC**



Beth Israel Lahey Health   
Lahey Hospital & Medical Center

Top 3 Enrolling Sites:

Beth Israel Lahey Health   
Beth Israel Deaconess  
Medical Center

**UPMC**  
LIFE CHANGING MEDICINE

 **UAB**   
MEDICINE.

 **KAISER PERMANENTE**  
 **Los Angeles  
Medical Center**

 **COXHEALTH**

  
**OHSU**

  
**UK  
HealthCare**



## SATURN Enrollment 101



### 1. PATIENTS TO LOOK FOR

Patients aged  $\geq 50$  presenting within 7 days after the onset of a spontaneous lobar or superficial cerebellar ICH while taking a statin drug.

### 2. APPROACHING SUBJECT AND FAMILY

Approach the patient and family ASAP after admission in collaboration with the clinical team and link the purpose of the study to the clinical scenario and use the recruitment video (<https://www.nihstroke.net.org/saturn-trial/home>).



CONTINUE DISCONTINUE



### 3. STATIN PROVIDER APPROVAL

Get the outside statin prescriber's (Cardiologist or Internist) buy-in early in the consent process. Highlight that other lipid-lowering agents (Zetia, fish oil, and/or fenofibrate) can be used with the exception of statins (and PCSK9 inhibitors), if needed, to lower cholesterol levels. **You can always reach the SATURN 24/7 Hotline at 1-617-667-7000 and ask the operator to page beeper #39636 and state you have a "SATURN Question" or email SATURNebidmc.harvard.edu to have questions answered in real time.**

### 4. PLAN FOR SUCCESS

Consent is a process (start slow & provide incremental information over a couple of days to avoid overwhelming the family with complex information). Highlight the benefits of being in a research study (close follow-up, results will help us to know the best way to treat similar patients in the future), and the simplicity of SATURN's follow-up assessments.



### 5. POST-RANDOMIZATION

Ensure that the results of the treatment randomization & assigned treatment arm are communicated to the statin prescriber, to the clinical team caring for the patient in the hospital, and to the patient/family. If a subject is randomized to discontinue statin therapy, ensure that the clinical team adds a statement to the patient chart and discharge summary with instructions to indicate that the patient was enrolled into SATURN and randomized to discontinue statin therapy.



## SATURN Hospital Discharge Flowchart

**Where was the subject discharged?**

**Home**

- 1) Document all available subject and alternative contact information in REDCap survey.
- 2) Confirm that no two contact people have the same number and that a current address is listed for the subject.
- 3) Remind subject and proxy that assessors will be calling from 617 area code.
- 4) Fax PCP: provider letter, copy of subject ICF and reminder about study assignment.

**Short-term facility and then home**

- 1) Document all available subject and alternative contact information in REDCap survey. Include short-term facility information as an alternative contact in REDCap.
- 2) Confirm that no two contact people have the same number and that a current address is listed for the subject.
- 3) Remind facility Medical Records about study assignment and that central assessors will contact nursing for follow-ups. Fax Medical Records the provider letter and copy of subject ICF.
- 4) Fax PCP: provider letter, copy of subject ICF and reminder about study assignment.
- 5) Remind subject and/or proxy that assessors will be calling from 617 area code to complete follow-ups once subject is home.

**Long-term facility**

- 1) Document all available subject and alternative contact information in REDCap survey. Include facility information as an alternative contact in REDCap.
- 2) Remind facility Medical Records about study assignment and that central assessors will contact nursing for follow-ups every month for the first 3 months. Fax Medical Records the provider letter and copy of subject ICF.
- 3) Fax PCP: provider letter, copy of subject ICF and reminder about study assignment.
- 4) Remind proxy and/or subject that assessors can complete follow-ups either with facility or subject/proxy. They will be calling from 617 area code.

## Updates and Reminders

### WebDCU F254 Neuroimaging File Collection

All baseline images should be uploaded in zip file directly on F254 via Aspera. Baseline scans are those documenting the qualifying ICH and no more than 3 completed scans should be uploaded (max: 1 CT, 1 CTA, 1 MRI). The dates on the scan must match the dates entered on the CRF. If date of scan is anonymized at your site, use the date 01-Jan-1900 or remove date completely.

### DOA and Site Contact Information

Please remember to update your DOA and confirm your full site address(es) as well as the phone numbers and emails of your study team members. The site address(es) can be changed under the Site Management tab, while the DOA and study team member contact details can be updated under the User Management tab. If you have questions, please contact the WebDCU team.

### Q2 Performance Metrics

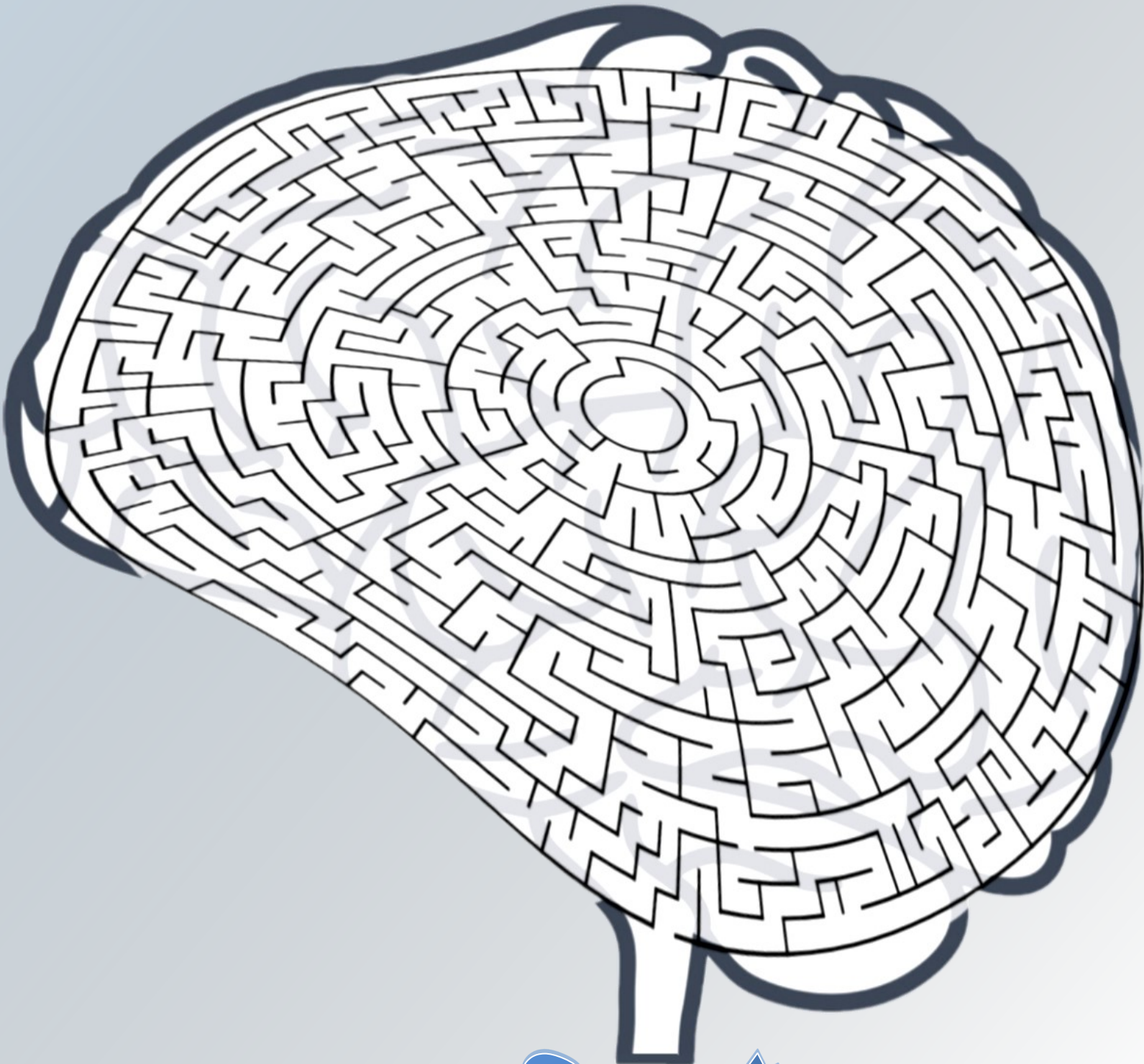
The Q2 Site Performance Metrics will be sent out soon. They go to the Site PI, Site PSC, RCC PI, RCC PSC, and trial leadership. Please feel free to share the metrics with other members of your study team. They are intended to give you a sense of how you are performing in the trial based on several measures that are benchmarked against overall trial averages as well as the Q1 Site Performance Metrics at your site. Please reach out to Aaron Perlmutter at [perlmutt@musc.edu](mailto:perlmutt@musc.edu) if you have any questions about your metrics, and we thank you for your commitment to SATURN.

### SATURN MRI

If your site is participating in SATURN MRI, please reach out to all qualifying subjects you had enrolled prior to the launch of the ancillary study to offer them the chance to participate. Once they have given you an answer, please update the SATURN MRI CRF in WebDCU accordingly (it's F311 in the baseline visit). There are still up to 60 participants who meet the eligibility criteria for SATURN MRI but have not been enrolled in the ancillary MRI study yet.



Brain Maze!



Start