



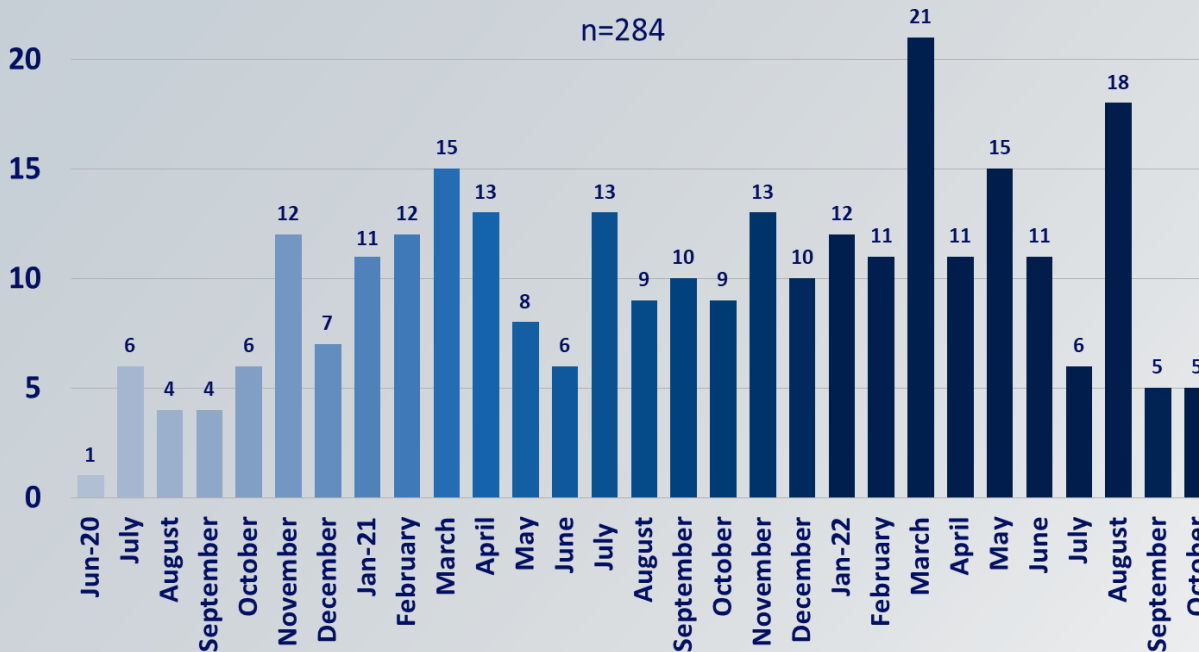
A Message From The SATURN Study Team:

We hope everyone has had a great start to the Autumn season! We are excited to have ended summer on such a great note, with August being our second highest enrolling month finishing at 18 subjects!! Now, we are focused on reaching our next target of 300 subjects. The SATURN team has been diligently reaching out to sites in order to discuss how to overcome barriers to enrolling subjects over the past few weeks. Please feel free to reach out if you need any refreshing on best strategies for approaching subjects, families or providers about the trial and alert the team if you have a possible eligible subject. We are looking forward to continuing our great streak from summer, and want to help support you all in achieving that goal. Good luck!



**Best,
The SATURN Team**

Monthly Enrollment Status



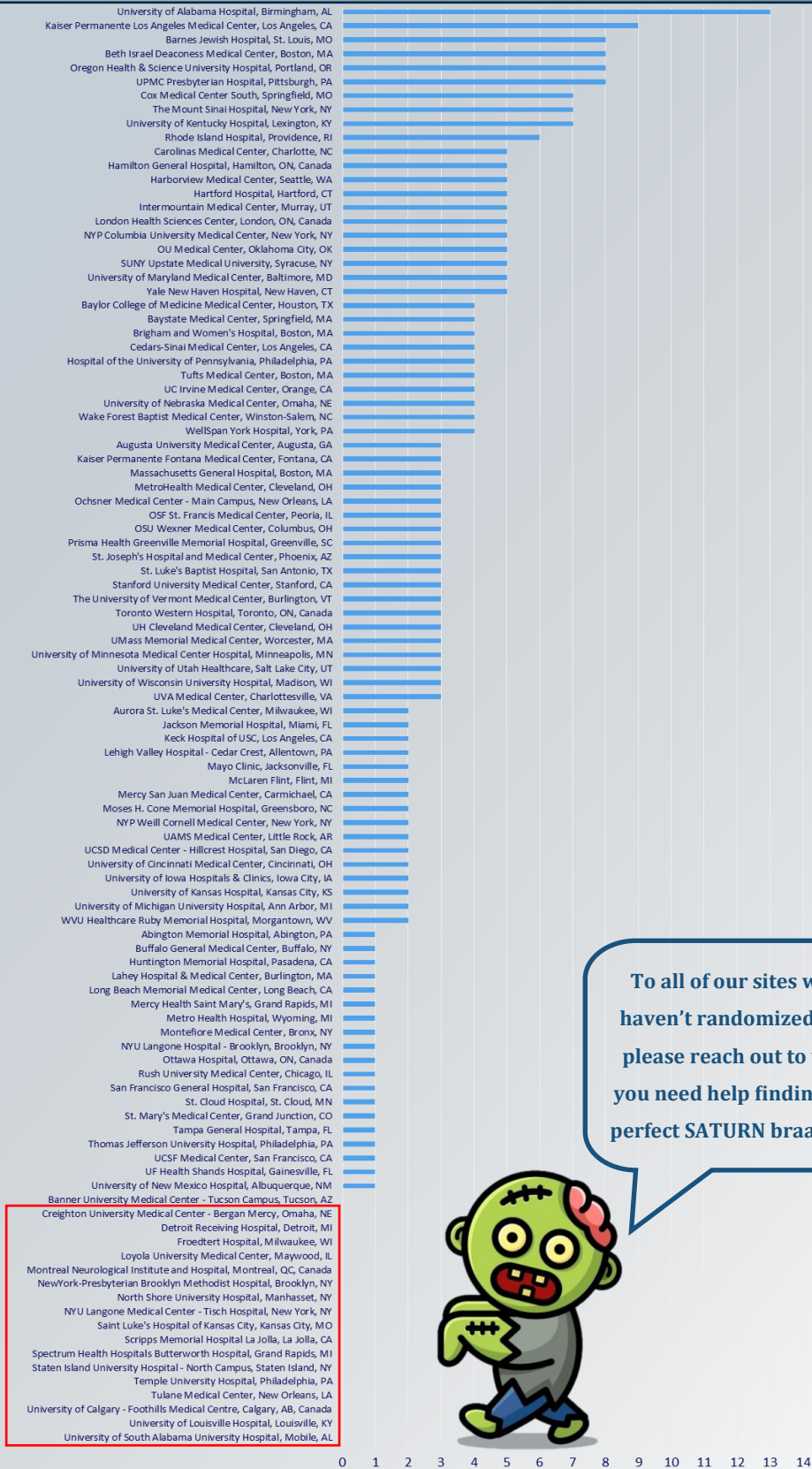
Inside this issue:

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

Got Questions?

- E-Mail us at: 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 by Site

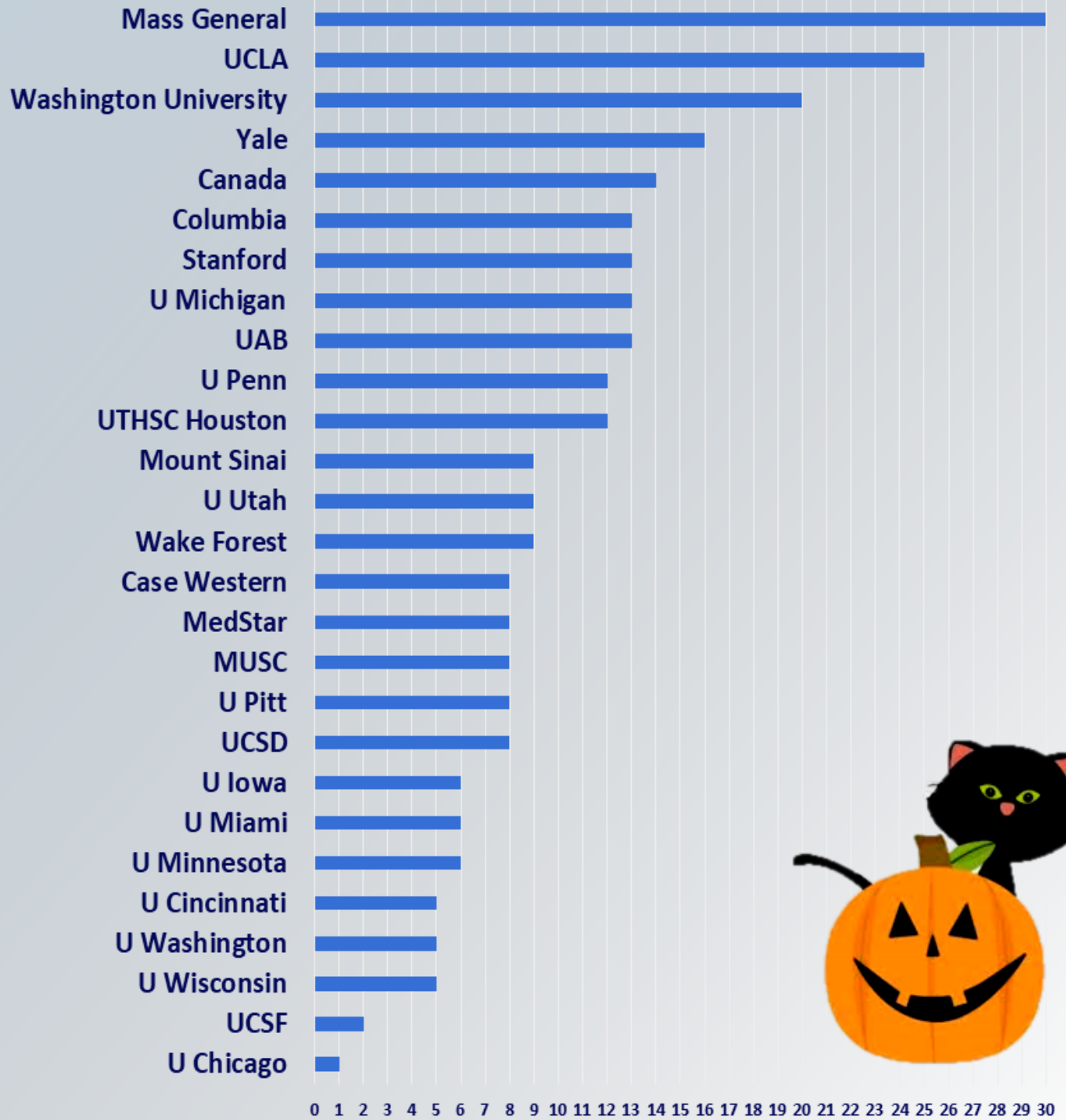


To all of our sites who haven't randomized yet, please reach out to us if you need help finding the perfect SATURN braaaain!



Enrollment Updates

Randomized by RCC



Webinar Highlights!



Thank you to everyone that attended our September webinar, and to those who participated in our Kahoot game! We hope you had fun with our SATURN trivia and we wanted to give a special shout-out to our three winners:

1) UPMC Presbyterian Hospital, Pittsburgh, PA

2) Creighton University Medical Center - Bergan Mercy, Omaha, NE

3) University of Maryland Medical Center, Baltimore, MD

The winning sites will receive a special Halloween treat in the mail in the coming weeks! Please join us for our next exciting monthly webinar on Thursday, October 27th, 2022!

Adverse Events Discovered by Assessors

FAQ for Adverse Events reporting:

During follow-up visits, central assessors may discover new adverse events have occurred, and they will report them under CRF 504. Adverse Events may include a new stroke, seizure, surgery, random hospital admission etc. When CRF 504 is submitted, the site will receive a WebDCU generated email alerting about a possible AE discovered. At this point, there are likely many questions and panic is setting in. However, no need to fret: here is a guide with frequently asked questions about site AE reporting.

Why does the F504 not provide a lot of information?

Central assessors can only report the information that was provided by the subject or proxy during follow-up. Most times, the individual reporting the event to the assessor does not have a perfectly complete account of the event including all clinical details. Assessors will try to gather maximum information to provide the site in order for the event to be found via medical records review.

How can the site learn more about the event?

The central assessors will reach out to the site with more information, if any is available. Since PHI cannot be shared on WebDCU, assessors will use identifying words such as “enrolling hospital”, if the event occurred at the enrolling site, or “local hospital” if at a smaller nearby institution. If more specific information is available, they will follow-up on the WebDCU generated email and also send you a brief file via secure file transfer so that no PHI is used in email or WebDCU.

WebDCU™ Email Notification

Possible SAE Noted by Central Assessor

A Central Assessor has noted a possible SAE for Subject 0001 at Boston Red Sox Fenway Hospital, Boston, MA
To review information entered by central assessor on Form 504, click on [Subject CRF List] and filter for CRF ID

This email was generated by Paul Revere.
For more information, log on to the WebDCU study website. Powered by the Data Coordination Unit at the Medical University of South Carolina, USA.

Adverse Events Discovered by Assessors

FAQ for Adverse Events reporting (continued):

How can the site complete an SAE report in 24 hours if information is requested from an outside hospital?

Stay up all night by the fax machine and hope the documents come in time— just kidding! Mark Q07 Outcome as “continuing review,” and submit the event with the information that the assessors provided. If the event being reported requires an event packet, and the records are pending, upload a document that says “Awaiting records from OSH before event packet can be completed. Will upload a proper redacted event packet once records are available.”

What if this subject no longer follows-up at the enrolling site?

The enrolling site is responsible for subjects from enrollment to end-of-study, even if the subject is no longer clinically affiliated with the site. This includes investigating and reporting all adverse events that may come to light via follow-up visits or site medical record review.



One of my subjects had a seizure, but was not admitted to a hospital; why do I have to report it as an SAE?

Good question! All seizures are considered reportable in SATURN, even if the subject did not have to be admitted for it. If the subject was discharged directly from the ED, or didn't even go to the ED, the seizure would *still* need to be reported as an SAE.

One of my subjects had a TIA; do I have to report it as an SAE?

It depends. It's especially Sometimes, a subject will claim they had a TIA even if they didn't really, so it's especially important for TIAs that the site PI evaluates them on a case-by-case basis to determine if the event really was a TIA or if the subject was being hyperbolic. If it was truly a TIA, then yes, you will need to report it as an SAE.

Updates and Reminders

SATURN Best Practices

- Screen daily and consider patients early in the hospitalization, as it can take the whole 7-day enrollment window to reach the patient's LAR, PCP or cardiologist in some cases.
- Work closely with the clinical team to introduce the trial and use the video link (<https://www.nihstrokenet.org/saturn-trial>) with the patient/LAR to introduce them to the trial.
- Consider using the provided script for explaining the study to collaborating cardiologists.
- Remember that remote electronic consent (i.e., weblink can be texted) is an option if the patient's LAR cannot come to the hospital.



SATURN Q3 Metrics

Reminding all sites that Q3 Metrics were recently sent to your site. Please review carefully and remember to complete all study visits for your subjects, check for open DCRs and reach out to the WebDCU team if you have any questions.

SATURN MRI

Remember to approach all of your active, eligible subjects for SATURN MRI participation. During follow-ups, central assessors will approach subjects about the trial if the site has not. If the subject is interested, the assessor will email you with information on how to best reach the subject or proxy for enrollment.

SATURN Word Search!

F V I C Q X Z B X Y N F C K P U W O L L O F K M R
 V Y Q Y R J M E V I H H C N B M D Z N K D K P Z O
 L H P H H Z I V U C H Q O N R J S F L C A X L U W
 Z Y M V S G E N O T Y P E L R Y D I Y V Z F Z O T
 M L D N H S C R E E N F A I L U R E D Z Q Y L C F
 I U I O M P D R G A J J L F Q K G R O E O V O N A
 C M O G T Y V D T H Q O X P T H K J M Q R M D S L
 R F L V Q E G A H R R O M E H O O R P C Z O K T R
 O I Y J X L T W C E E B Q S B O Z S D O U Q S B C
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 K U M R N G W T G N L U V L S V Y M I A U S N N H
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 Q Y O F I T R G M Z K C W N K K K T C S X S T U U
 C D A H I Y A U N B N B Y O E Y N N O A W F R T H
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AMYLOID
 FOLLOWUP
 HYPERTENSION
 NEUROIMAGING
 SATURNMRI
 STROKENET

CHOLESTEROL
 GENOTYPE
 LOBAR
 PITAVASTATIN
 SCREENFAILURE

FLUVASTATIN
 HEMORRHAGE
 MICROBLEED
 REDCAP
 SIDEROSIS

