

Newsletter

February 2022 · Issue 9

A Message From The SATURN Study Team:

Happy New Year!



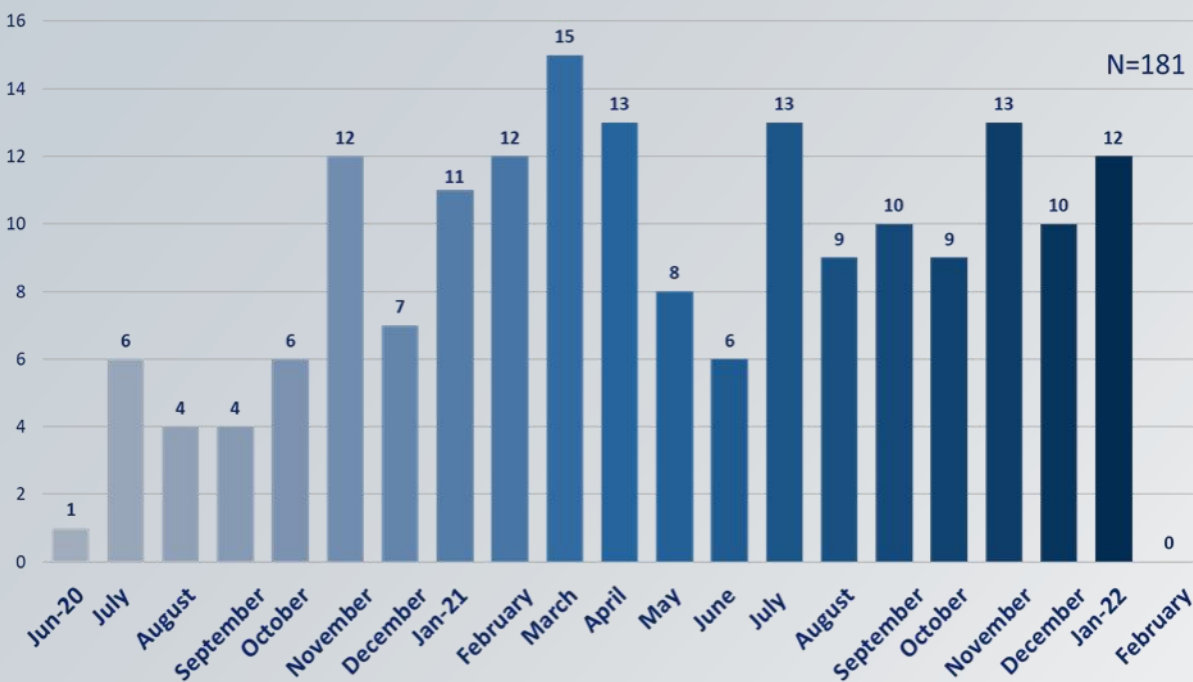
Thank you for all of your hard work! 2021 was a challenging year for SATURN, but you managed to randomize 169 subjects by the end of the year. 2022 is off to a good start. So far, we have randomized 12 subjects (for a total of 181 subjects!) and we are on our way to meet our next milestone of 200 subjects. You have also enrolled the first subjects into SATURN MRI.

We wish you all a safe and productive 2022!

Sincerely,
The SATURN Team



Monthly Enrollment Status



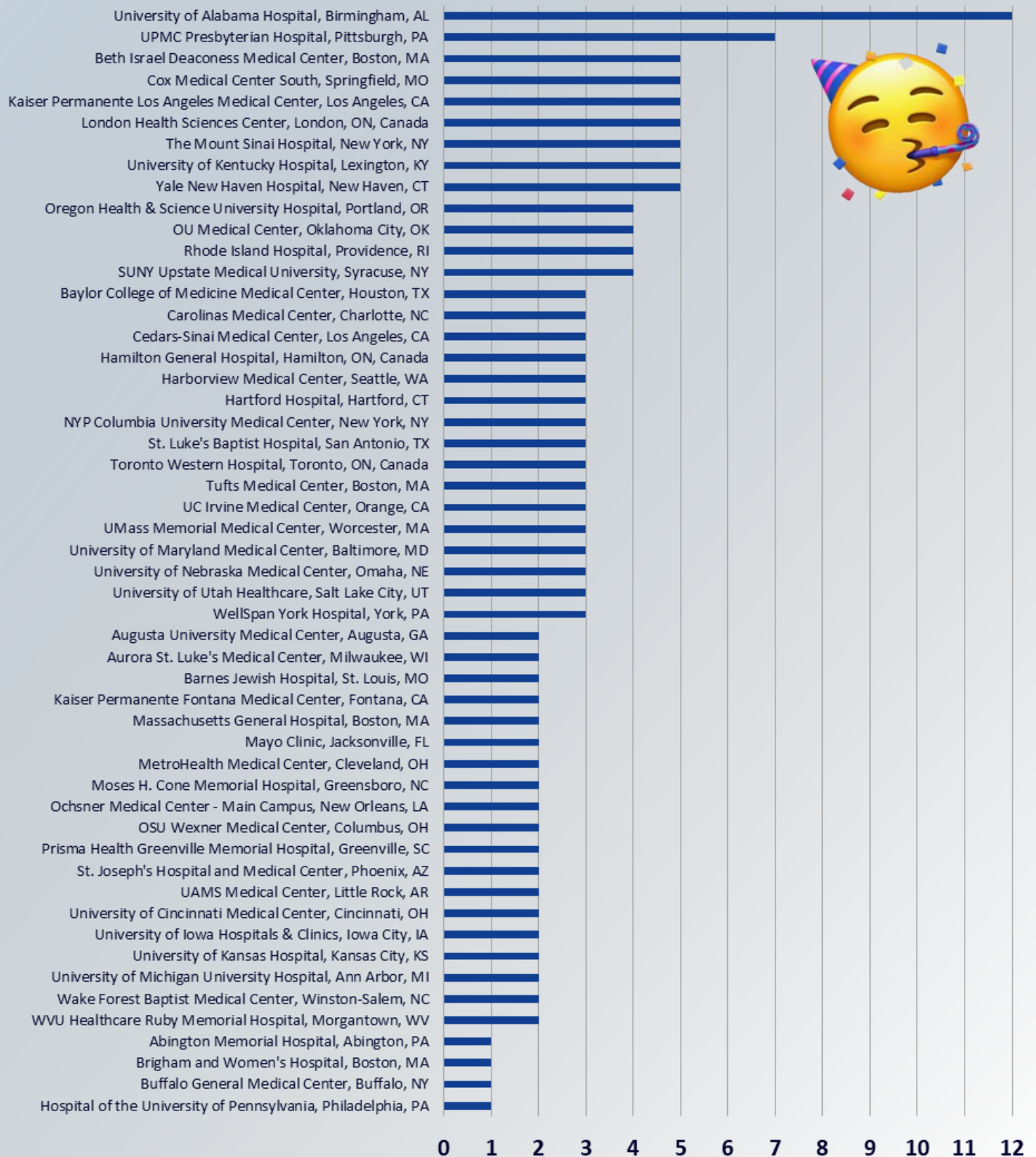
Inside this issue:

- Introduction
- Enrollment Updates
- SATURN MRI
- Updates and Reminders
- Crossword Fun:)

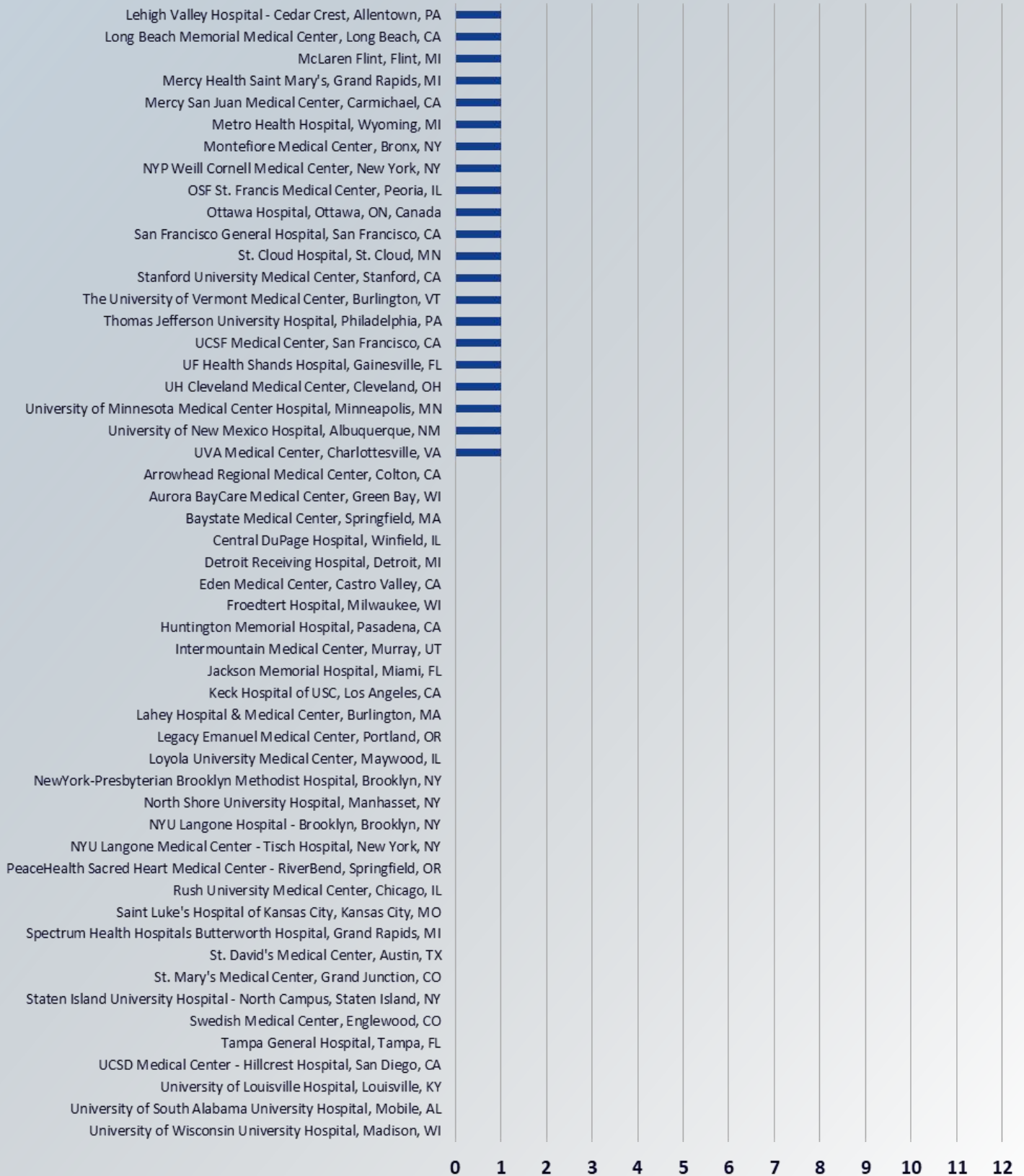
Got Questions?

- 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

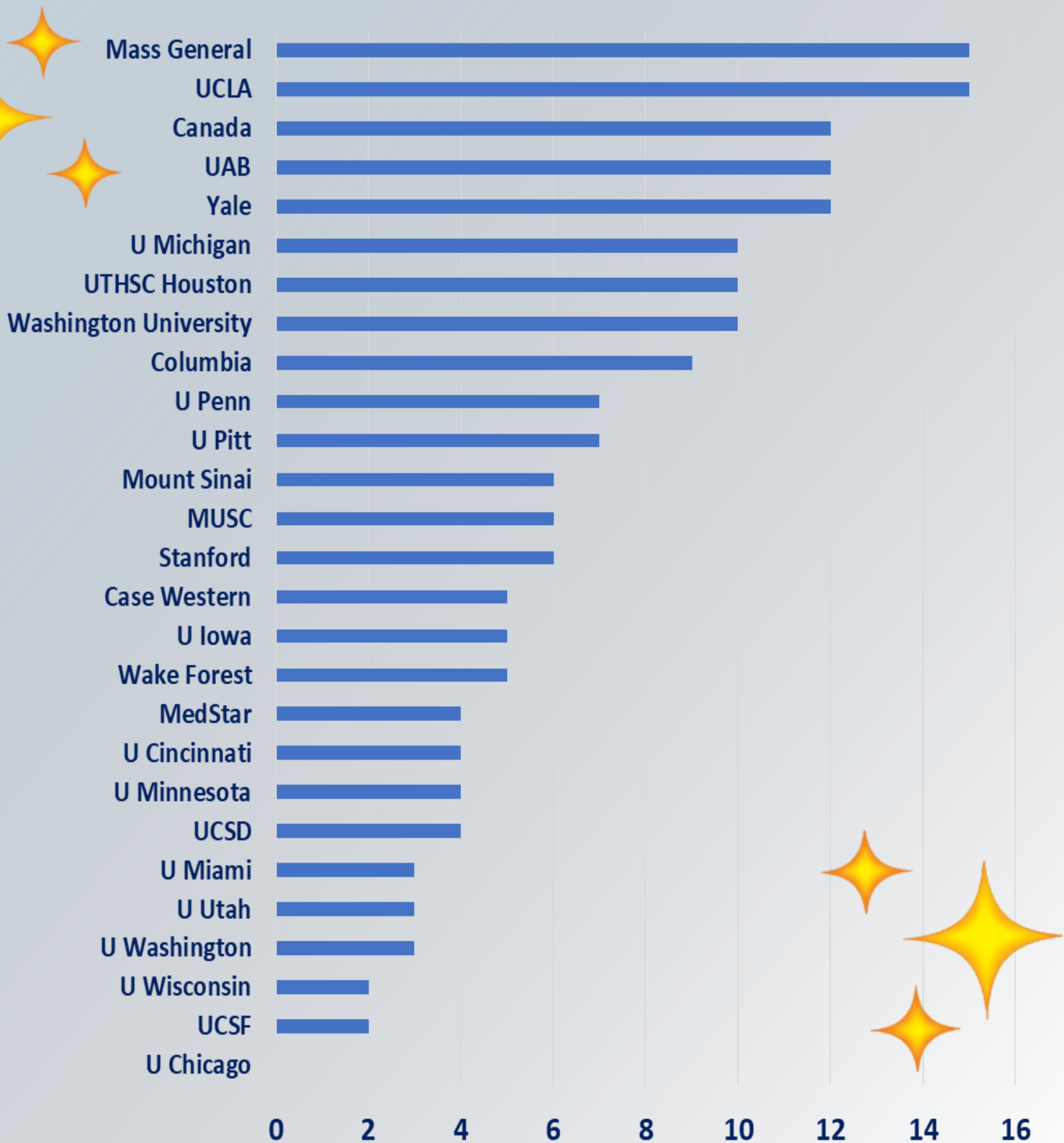
Total Enrollment by Site



Total Enrollment by Site



Total Enrollment by RCC



Congratulations!



The University of Alabama at Birmingham Medical Center continues to be our top-enrolling site, with 12 subjects!

Way to go!

Sites that randomized their first subject since the last newsletter:

NYP Columbia University Medical Center, New York, NY (3 subjects!)

UAMS Medical Center, Little Rock, AR (2 subjects!)

Ottawa Hospital, Ottawa, ON, Canada

Stanford University Medical Center, Stanford, CA

The University of Vermont Medical Center, Burlington, VT

UCSF Medical Center, San Francisco, CA

NYP Weill Cornell Medical Center, New York, NY

Lehigh Valley Hospital-Cedar Crest, Allentown, PA

Mercy Health Saint Mary's, Grand Rapids, MI



Here is the Mercy Health Saint Mary's Team! From L to R: Julie Bishop, RN (PSC); Dr. Muhammad Farooq (PI); Brad Haveman-Gould, PA-c; Amy Groenhout, RN. Well done everyone!

SATURN MRI: Introduction

Study Purpose

This ancillary study is looking to determine the effects of continuation versus discontinuation of statin therapy on the incidence of new cerebral small vessel disease markers that are detected through the MRI scanning technique.

MRI scans

- 1. At time of enrollment.** If an MRI was obtained for clinical purposes after the qualifying brain hemorrhage presentation, this may be used as the first scan (provided that it complies with study imaging protocol). If not, the subject can undergo the MRI within ± 7 days of randomization.
- 2. At the end of participation.** Once the subject has reached the end of their study participation, they will return to the enrolling institution for the final scan. This MRI can be done within 30 days of the 2 year end-study visit and subjects will be reimbursed for transportation and/or parking expenses.

Consent Process

Consent for SATURN MRI is included as an optional section in the newest version of the SATURN Informed Consent Form (version 6). Subjects can choose to opt-in to participate in SATURN MRI when consenting for SATURN.

Please initial about the separate SATURN MRI study:

<input type="checkbox"/>	I agree to participate in the SATURN MRI study
<input type="checkbox"/>	I do not want to participate in the SATURN MRI study.

The non-participating sites have a statement that notes “The SATURN MRI study is not offered at this site’

The SATURN MRI study is not offered at this site.

SATURN MRI: How to recruit subjects

Eligibility

Participants in SATURN MRI must meet all SATURN eligibility criteria, in addition to:

1. Subject or surrogate provides signed informed consent and opt to participate in the MRI study.
2. Subject has no known contraindications to MRI such as claustrophobia, metal implants, or pacemaker.

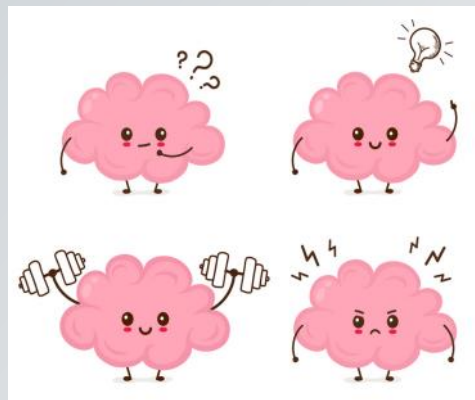
Retroactively screening already enrolled SATURN patients

Sites which participate in SATURN MRI and received their cIRB approved ICF version 6 should contact all of their subjects to inform them about the ancillary study and re-consent with new ICF in case patient is willing to be enrolled

If the enrolled subject had a MRI at the time of the qualifying ICH, but the site did not upload it to WebDCU, you can send us the MRI now & try to enroll the subject in SATURN MRI.

Enrolling new SATURN patients

Sites which participate in SATURN MRI and received their cIRB approved ICF version 6 should include information about the MRI study in their SATURN enrollment conversation and have the patient opt-in or opt-out before signing the consent form.



Updates and Reminders

Lab Kit Receiving and Blood Shipping

Please log the receipt of the tubes/lab kits within 5 days of receiving them.

Once you are ready to ship the blood sample, remember to fill out the Shipping Specimen to Central Lab form.

REDCap Subject Contact Information Updates

Please review all of your active subjects, and confirm that ALL information is correct and complete on REDCap. Make sure date of birth, pronouns, complete mailing addresses and alternative contacts are listed. This information is essential to the central assessors when completing follow-up visits.

Delegation of Authorities (DOA)

Remember to keep your DOA up to date by adding new members, deleting inactive ones, and updating responsibilities. Also, please edit any additional information such as emails, phone numbers and addresses if they change.

Neuroimaging File Collection

A *maximum* of 3 scans should be uploaded on WebDCU at the 'Baseline' visit:

1. The first CT scan acquired after hemorrhage
2. MRI/MRA if one is acquired
3. CTA if acquired

The date on the scans should match the date entered on the CRF.

Updates and Reminders

International Stroke Conference

We encourage you to attend these following ICH and statin-related events at the upcoming International Stroke Conference February 9–11, 2022!

Center for Brain Health for ICH

2/9: 3:54pm to 4:06pm (Central)

Statin usage Increases White Matter Hyperintensities: a Post-hoc Analysis of SPRINT-MIND

2/9: 12:30pm to 1:15pm (Central)

ICH Management: Now and Into the Next Decade

2/10: 9am to 10:30am (Central)

Clinical Quandaries in ICH: Includes “To Statin or Not: Lobar ICH”, “To Anticoagulate or Not: Afib and ICH”, and “To Treat BP or Not: Acute ICH”

2/10: 2pm to 3pm (Central)

Recent Innovations in Intracerebral Hemorrhage

2/10: 5pm to 6pm (Central)

What’s in the Pipeline? Hot Topics for the Future of Translational ICH Research

2/10: 5:30pm to 5:45pm (Central)

Happy Lunar New Year!

We would like to wish everyone a Lunar New Year with lots of happiness and prosperity!

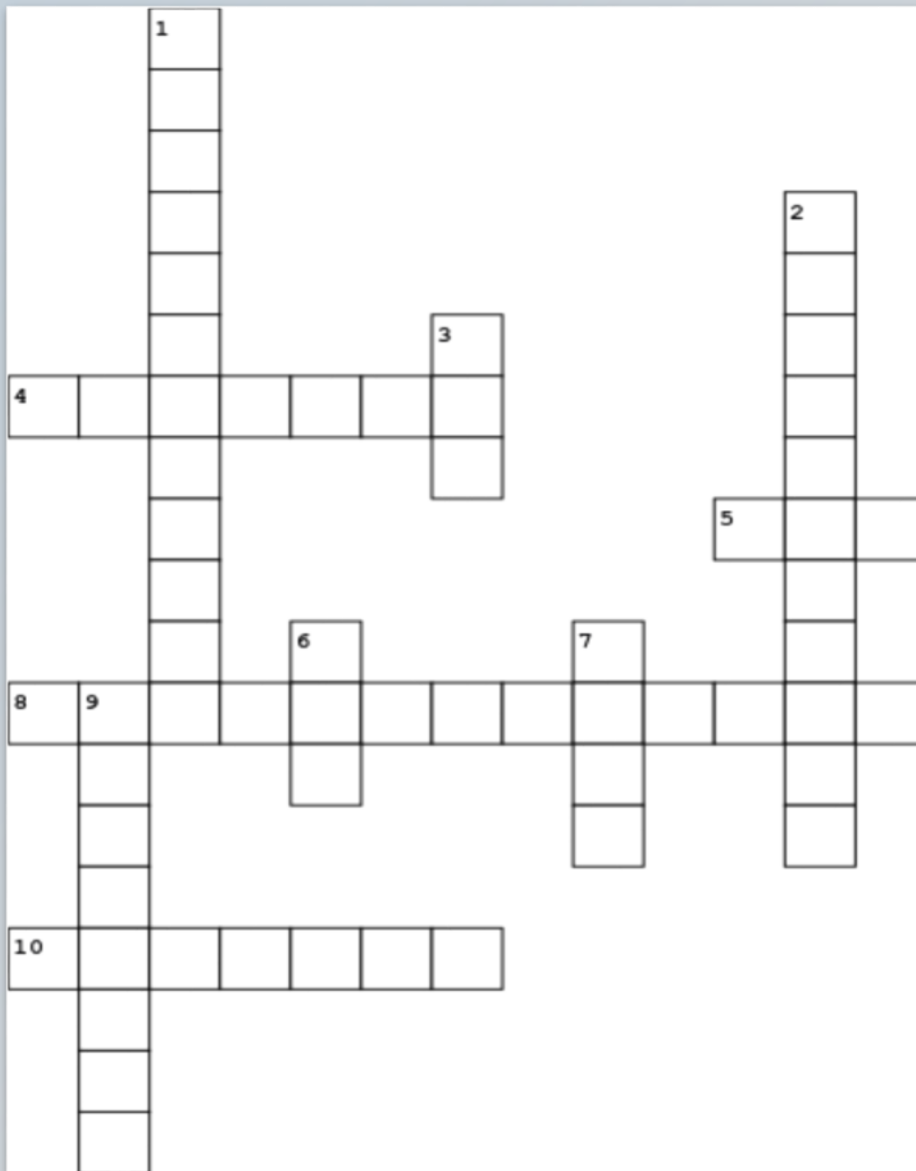
According to professor of Asian and Asian American religions and folklore studies at San Francisco State University, Jonathan H.X. Lee, the Year of the Tiger represents hope amongst evil. This cycle happens every 12 years and has previously happened in 2010, 1998 and 1986. Let us take this as a sign that after a difficult two years, times will start to get better!



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(Source: [NBC News](#))

SATURN Crossword Puzzle: MOP Edition



Prize alert: The first three people to send Elizabeth (eheistan@bidmc.harvard.edu) a completed and correct crossword puzzle, will receive a special Valentine's Day prize! Please email a screenshot of your submission to Elizabeth with the subject line "SATURN Newsletter Crossword".

Across

Down

- 4. Where blood samples are stored if collected on the last business day before a long weekend
- 5. A __ signs the consent form if a patient is cognitively incapable of doing so
- 8. A patient is a __ if they have a lobar hemorrhage but are otherwise ineligible
- 10. A __ signs the consent form if a patient is physically incapable of doing so

- 1. Where blood samples are stored if collected on a Friday
- 2. Lobar hemorrhages must be situated at least one cm from the body of the __ lateral ventricle
- 3. Blood collected before a long weekend should be shipped on __ ice the next business day
- 6. Blood collected on a Friday should be shipped on __ ice on Monday
- 7. When an SAE is flagged on WebDCU, the __ completes F104
- 9. (617)667-7000 is the number for the SATURN __ hotline