

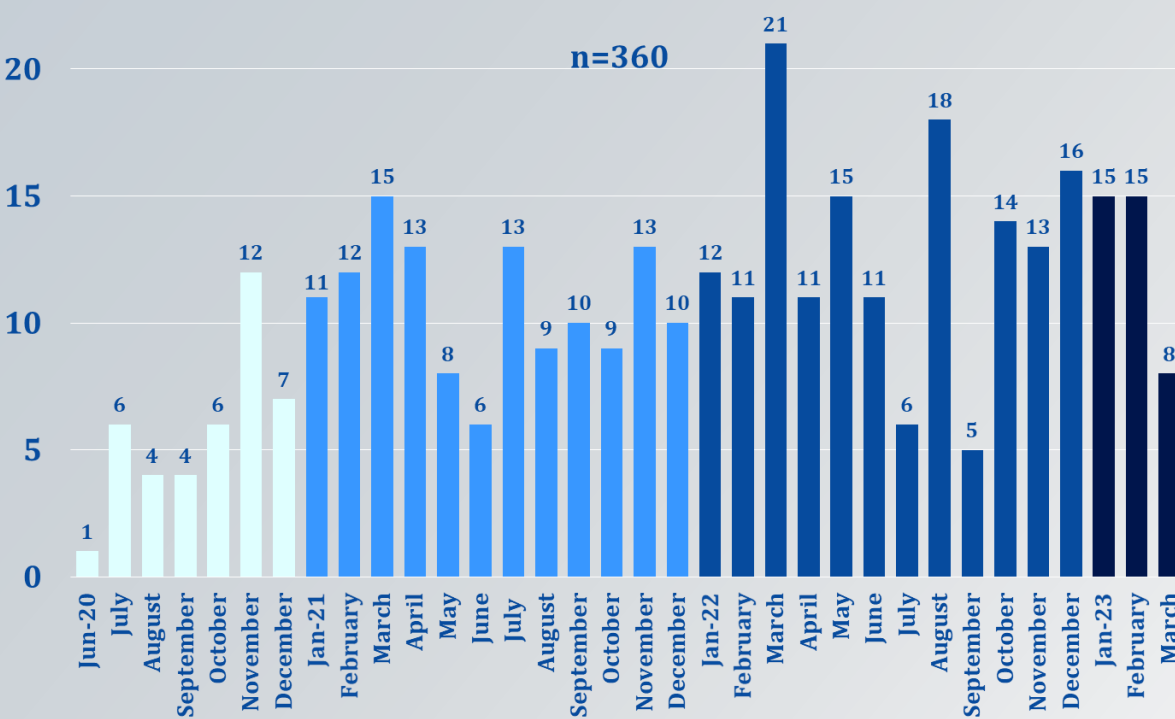
A Message From The SATURN Study Team:

Welcome to our first issue of our newsletter in 2023! After everyone’s incredibly hard work last year, we have started off 2023 with reaching our milestone of 350 randomized subjects! Now, we are well on our way to our next target, 400 subjects. We also hope to welcome a new addition to the SATURN family: SATURN Spain. More on that later, stay tuned! Thank you again for your efforts, we are confident that 2023 will be an even better year for SATURN than the last.

**Best,
The SATURN Team**



Enrollment Status



Inside this issue:

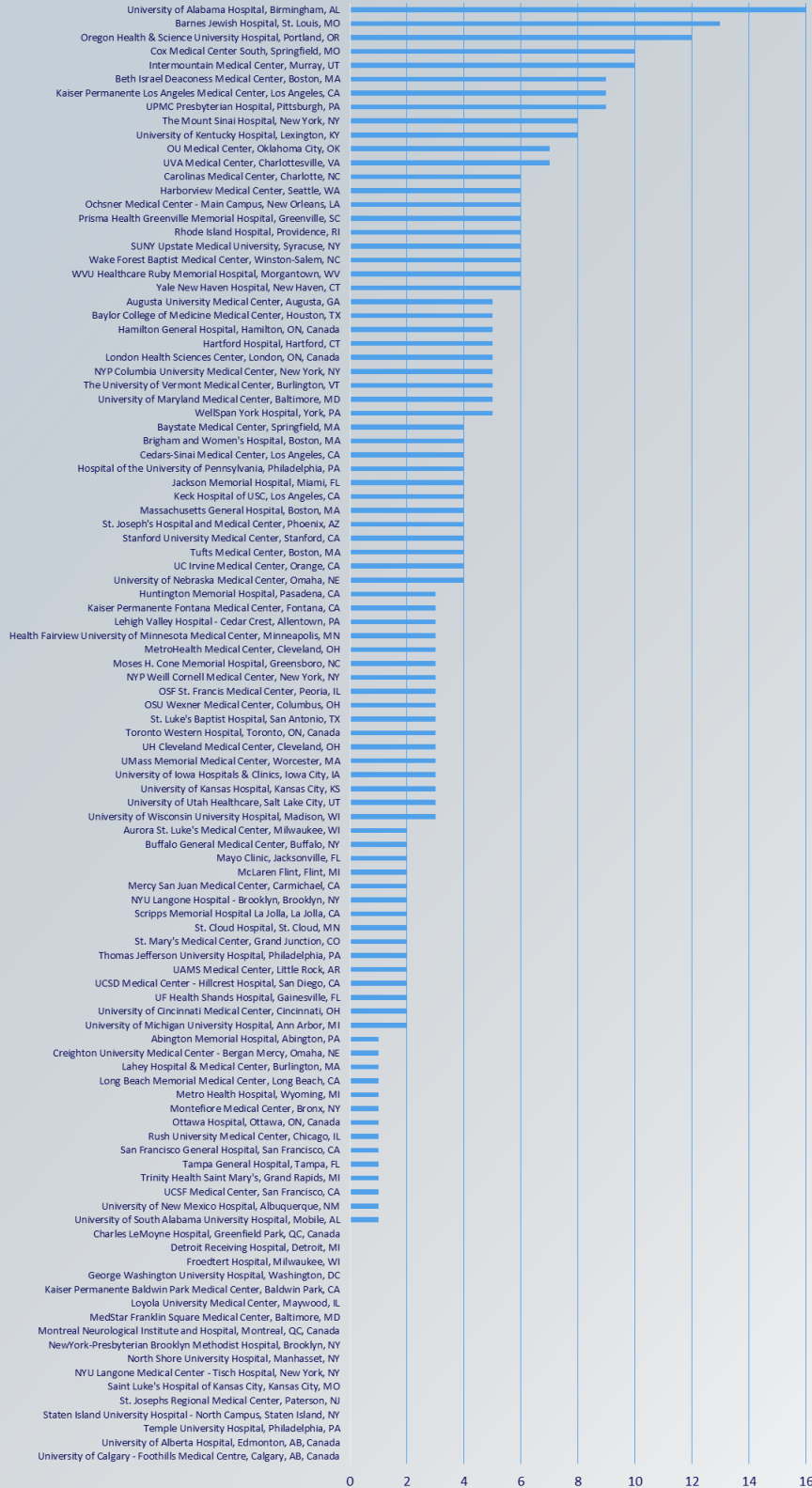
- Introduction
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- Continuing Review
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Got Questions?

- 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

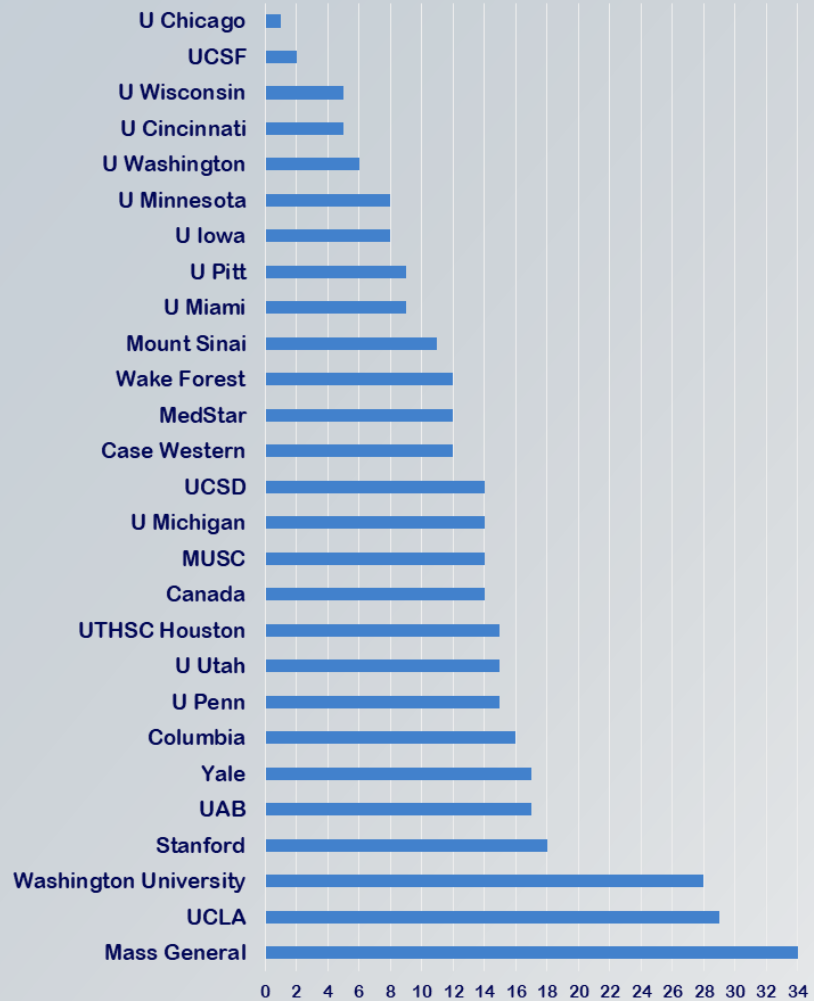
Enrollment Updates

Enrollment by North American Sites

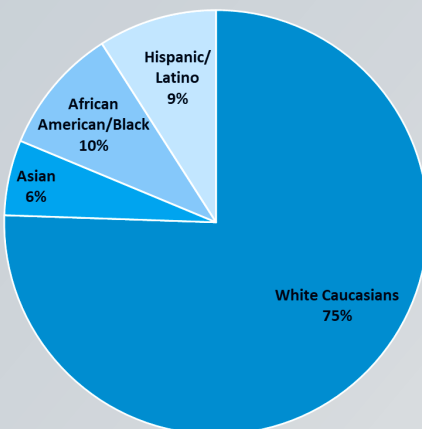


Enrollment Updates

Enrollment by RCC



Enrollment Breakdown by Race



As depicted in the graph to the left, 75.5% of currently enrolled subjects identify as White Caucasians. We encourage sites to increase their efforts to enroll subjects that reflect all racial and ethnic backgrounds. On a similar note, we hope to increase the number of participants with a secondary prevention indication for statins. While 75% of enrolled subjects were on a statin for primary prevention, only 25% used statin for secondary prevention indication. We hope to increase the proportion of patients with secondary prevention indication to increase the generalizability of our results.

Continuing Review

On March 17th 2023, NCC Project Manager Kim Bernstein sent out an email containing next steps for this year's continuing review:

All SATURN sites who have received cIRB approval by 6/1/2023 must complete and return the CR documents. Please complete ASAP, so as not to delay the continuation of study activities at your site! The cIRB will review SATURN at their meeting on June 28, 2023. Approval documents will automatically be distributed after the cIRB meeting and approval.

Instructions:

1) 2023 CR Form

- Please complete the form in its entirety and return by email to Kim by **Wednesday April 12th**
- Person completing the form signs and dates; PI signature is not necessary
- There is no screening, consenting, or randomization numbers to collect as well as AE or UAE information as Kim can obtain that from WebDCU in one study report.
- If you have had a subject withdraw and have not completed the information on the CRF to explain why they withdrew please add this information to a separate word document and include with forms to be returned.

2) Financial COI Form

- All Principal Investigators will need to complete a new form for CR submission. The form must be signed March 15, 2023 or later. The new PI fCOI will be uploaded to WebDCU once the CR is approved. The expiration date for the PI fCOI is the date of study expiration provided once the CR is approved.
- All site members will need to complete a financial COI per your organization's SOP and maintain records at your site in the regulatory binder. You do not need to upload the form into WebDCU.
- **If you do have a positive "yes" response and need to disclose a relationship, please email the completed "positive disclosure" COI form by Wednesday April 12th.**

Please return both completed forms as separate attachments to one email to both:

Kimberlee Bernstein gammk@ucmail.uc.edu and **Laura Benken** osinsklr@ucmail.uc.edu by **April 12th 2023.**

For any questions, feel free to email Kim Bernstein at gammk@ucmail.uc.edu. For questions regarding COI reporting requirements and site responsibility, you may also refer to the **SOP** and **Explanation of financial COI** documents Kim included in the March 17th email.

Specimen Shipping Reminders

Blood samples are required in SATURN. If a subject declines the blood draw, they are not to be consented into SATURN.

- If you are unable to collect a blood sample before the subject is discharged, make arrangements to have it collected as soon as possible (perhaps when they come back for clinic). If they have cut all clinical ties to your site, they would have to come in **specifically** for the blood draw.
- When collecting the sample, make sure **both** tubes are filled, and remember to **only fill them 3/4 full**.
- When are you drawing blood?
 - **Monday-Thursday:** Ship it same day to the central lab, at **room temperature**.
 - **Friday-Sunday:** **Refrigerate** the sample, then ship on Monday on **wet ice**.
 - **Before a long weekend:** **Freeze** the sample and then ship after the holiday on **dry ice**.
- **Under no circumstances are you to centrifuge or in any way “process” the blood sample before shipping.**

When you are ready to ship:

1. Go to WebDCU and click on SATURN.
2. Go to the subject’s CRF binder.
3. Complete and submit F181 Biospecimen Collection in the Baseline visit.
4. Print the completed form and include it in the mailer with the tubes.
5. Use the MOP** to finish packing everything appropriately.
6. Go back to WebDCU and click on SATURN.
7. Click on “Study Material Tracking”
8. Click on “Specimen Shipping.”
9. You will be prompted to fill out some info about the kit you used/the shipment.
10. Make sure the sample gets put in the mail.

**MOP= Manual of Procedures. You can find it by going to WebDCU>SATURN>Toolbox>Project Documents. It’s document #53, it’s called “Lab Manual.” The whole thing is dedicated solely to blood sample collection and shipping.

For any questions, please contact Sarah Marchina (smarchin@bidmc.harvard.edu) or Christina Kourkoulis (ckourkoulis@partners.org). They are very nice, and very knowledgeable!



SATURN Fun Corner

The first 3 sites to complete this fill-in-the-blank story will receive a special treat: Send your completed stories to ehistan@bidmc.harvard.edu for a chance to win!

Christopher Robin is a 65M who presented to Hundred Acre Hospital on Thursday morning with a spontaneous parietal IPH within 12 hours of symptom onset. He takes rosuvastatin 40 mg at home, and is fully independent at baseline, with no evidence of dementia. He does have a remote history of MI (8 years ago) but does not have _____.

Your PI, Dr. Owl, confirms that Mr. Robin is eligible and approaches the patient, who agrees to participate. Dr. Owl calls Mr. Robin’s cardiologist (who prescribes the statin) _____ the patient signs the ICF. The cardiologist agrees to support Mr. Robin’s enrollment.

Once enrolled, Mr. Robin also signs a medical records release form. You, the coordinator, enter Mr. Robin as a subject in WebDCU, and fill out the 3 Baseline CRFs required for randomization: _____, _____, and _____. Subject 1926 is randomized to discontinue statin.

You inform Subject 1926 of their randomization assignment and collect the subject’s contact information for the _____ survey.

Mr. Robin’s nurse, Winnie, draws the blood sample; as it is now Friday afternoon, you refrigerate the blood sample and will ship on Monday on _____ ice. You plan to fill out the “Specimen Shipping to Central lab” form under the _____ tab in WebDCU when the sample is shipped on Monday.

You fax the two _____ letter templates from the WebDCU toolbox to the cardiologist’s office. You plan to fill out REDCap and the rest of baseline CRFs on Monday.



Word bank (not all words will be used!):

**ABCD2
Afib
After
Aspirin
Before
Cardiologist
Congratulations
Diabetes**

**Dry
Eligibility
Endocarditis
GCS
ICH Score
NIHSS
Provider
Randomization**

**REDCap
Statin Dosing
Statin Medication Log
Stroke
Study Material Tracking
Study Progress
WebDCU
Wet**