

A Message From The SATURN Study Team:

Happy Spring!

We wanted to thank everyone for their participation in the Investigator Meeting. Despite the unconventional circumstances, we had a successful turnout and an even better time during presentations. We could not have done it without all of the efforts of the PIs, coordinators, and regulatory staff.

Sincerely,
The SATURN Team



Recruitment Tips

- **Involve the clinical team** in the initial discussion
 - A clinician on the team should lead the discussion
- **Approach** the patient & family **early**
- **Engage** the patient & family
 - Establish **rappor**t & gain their **trust**
 - Educate them before asking for consent
 - **Highlight the controversy**; we don't know if ischemic stroke/MI is better/worse than a recurrent ICH
 - Emphasize other lipid-lowering agents (i.e. fibrates/ezetimibe) can be used if needed (remember, **no PCSK9 inhibitors! i.e. alirocumab, evolocumab**)
 - Take time to answer questions and make yourself accessible for potential follow up questions
 - **Give them time** to think about it, then follow up
- **Communicate directly** with the statin prescribers.
 - A physician-to-physician conversation is preferable.
 - Educate, provide estimates and don't be intimidated or give up from the get go
 - Highlight the **simplicity** of the protocol and follow up

Inside this issue:

- Introduction
- Enrollment Update
- Coordinator Spotlight
- Sample Collection Tips
- Reminders

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

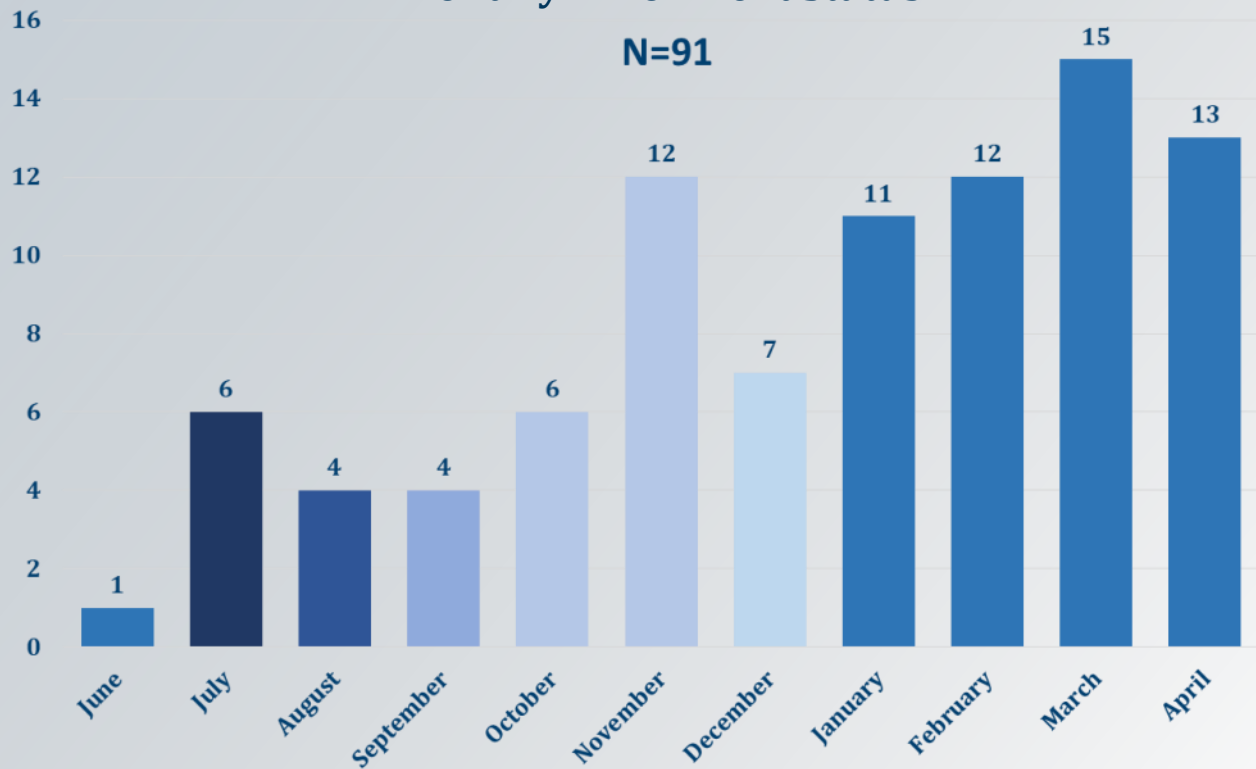
Enrollment Updates

Newest Enrollers



Congratulations to these sites on their first enrollments!

Monthly Enrollment Status



SATURN Coordinator Spotlight: Top Enrolling Coordinators



Tammy Davis

Tammy Davis is an enrolling coordinator at the Comprehensive Neurovascular and Stroke Center at The University of Alabama at Birmingham. As coordinator, Tammy has helped enroll 4 subjects at her site. She has worked in Clinical Research for over twelve years. The thing she loves most is seeing patients improve from study interventions and being able to offer a treatment or a service that a patient would otherwise be unable to afford or be eligible for.



Valentina Mursyla

Valentina is an enrolling coordinator at Kaiser Permanente. As the newest member of the ICH clinical trials team, she assisted in pre screening all ICH patients, helping enroll 4 subjects at her site. She credits her mentor, Neurosurgery PA, Tina Chin for her support and expertise. Valentina's favorite part of working in clinical research has been patient interactions and being allowed to participate in their care.



Yaneysy Penate

Yaneysy Penate is an enrolling coordinator for Mount Sinai Hospital in New York. As coordinator she has helped enroll over 5 subjects at her site. She loves working in research because she loves working with patients that want to advance science. Her favorite thing about clinical research is working with and respecting and honoring those who want to discover better treatments to better our health system. Her slogan is "We are what we repeatedly do. Excellence, then, is not an act, but a habit." – Aristotle

SATURN Coordinator Spotlight: SATURN Awards



Highest Enrolling Sites

Mount Sinai Hospital

Kaiser Permanente

University of Alabama Hospital

Super Helpful Coordinators

Kinga Aitken, University of Utah

Jason Weimer, UPMC Presbyterian Hospital

Emilia Jobe, Baylor College of Medicine

Timely Data Entry and CRF Completion

William To, Toronto Western Hospital

Heena Olalde, University of Iowa Hospital

Barbie Stahlman, Wellspan York Hospital



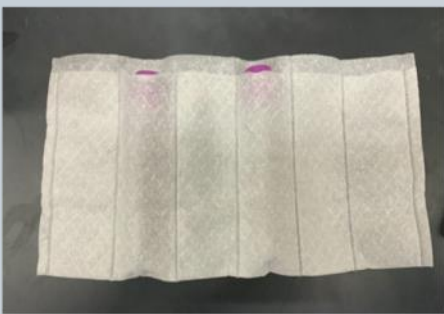
Sample Collection Tips

Blood Sample Shipping

What to do if blood collection happens after FedEx pick up time:

- Monday-Wednesday: draw blood as planned.
Ideally, ship sample same day.
Sample can be left **upright at room temperature overnight** & shipped the next day **with the room temp kit**.
 - Thursday: Store sample at **-80 (or -20 if not available)**.
Ship on Monday with **the wet/dry ice kit using dry ice**
 - Friday: Store sample **upright in the fridge** over the weekend.
Ship on Monday with the **wet/dry ice kit using frozen ice packs**.
- *Note: samples can sit overnight at **room temperature only** if being shipped the next day.

Room temperature lab kit



Tube sleeve



Biohazard bag, plastic shuttle



Small cardboard box (Room Temp mailer/kit)

Required stickers for shipping



Wet or Dry Ice lab kit



Styrofoam tube holder



Biohazard bag w/ absorbent material



Ice packs, styrofoam box insert (Wet/Dry Ice kit/Mailer)



Sample Collection Tips

3 Important WebDCU Shipping Procedures

1) Lab Kit Site Receiving



Used when you **receive a new lab kit or replacement blood tubes**. Always log the receipt of those items **ASAP**.

2) Lab Kit Site Removing

Used when you **receive replacement blood tubes**. Discard the old ones and always retire/remove the discarded tubes in WebDCU ASAP.

3) Specimen Shipping to Central Lab

Used after you **collected a blood sample**. Always enter shipping information into this form **BEFORE shipping out** the sample. This will alert MGH that a blood sample is coming.

No.	Item Description	Data Value
1	Site ID	1497
2	Site Name	Beth Israel Deaconess Medical Center, Boston, MA
3	Lab kit code	67422
4	Lab kit expire date	30-Apr-2021
5	Subject ID	1033
6	CRF ID	1208
7	Specimen collection date	08-Dec-2020
8	Specimen shipping confirm	<input type="radio"/> No <input checked="" type="radio"/> Yes
9	Specimen shipping date	09-Dec-2020
10	Specimen shipment tracking number	777940390314
11	Specimen shipping notes	
12	Specimen shipped by	Sarah MARCHINA
12	Specimen packing slip	 
13	Specimen shipping dated on	09-Dec-2020 09:22
14	Specimen lost in shipping	<input type="radio"/> No <input type="radio"/> Yes
15	Specimen central lab received on	
16	Specimen in good condition	<input type="radio"/> No <input type="radio"/> Yes

Reminders

General Data Entry Reminders:

- Please complete CRFs within 5 days of the visit
- SAEs **must** be reported **within 72 hours** of site knowledge
- All DCR responses must be submitted within 5 days of query
- If a DCR is associated with an SAE, it must be responded to within 24 hours of query
- Every **deceased** subject must be moved to the End of Study visit

Screen Failure Entry:

- Should be submitted within 5 days of screening
- Complete for all **lobar** ICH patients who **do not** meet the inclusion or exclusion criteria
- Since this form is only collecting those with lobar ICHs, Q02 should always be yes. If this is no, this patient should not be entered

Form 288 Statin Medication Log:

- Only list the statins taken since randomization
- Start date should be on or after randomization date
- If subject is assigned to 'discontinuation of statin', Q05 should be left blank
- After discharge, only central assessors will be editing this form

Form 106 Medical History:

- Use the date and time of ICH onset in Q01-Q02. If the date/time of onset is unknown, use the date and time last seen normal



Reminders

REDCap Entry Reminders

Please confirm that the primary and alternate contacts on a subject’s REDCap survey are not the same phone number.

You can return to edit a subject’s REDCap profile by using the original REDCap link and the return code. If you lost this code, you can email mminyett@bidmc.harvard.edu

ALTERNATIVE CONTACTS FOR SUBJECT

<p>Alternative Contact 1 Name <small>* must provide value</small></p>	<input style="width: 90%;" type="text"/> <small>This should be the subject's LAR, if applicable.</small>
<p>Alternative Contact 1 Relationship to Subject <small>* must provide value</small></p>	<input style="width: 90%;" type="text"/> <small>This should be the subject's LAR, if applicable.</small>
<p>Alternative Contact 1 Phone Number <small>* must provide value</small></p>	<input style="width: 90%;" type="text"/> <small>This should be the subject's LAR, if applicable.</small>

Subject Contact Info

To continue the survey, please enter the RETURN CODE that was auto-generated for you when you left the survey. Please note that the return code is **not** case sensitive.

Monthly Webinar

Join us for our next SATURN PI/coordinator webinar on **Thursday, May 27th, 2021 @12:30pm.**

<https://harvard.zoom.us/j/95759302168?pwd=SDNnaDIUTU81TXR4RzlhU3pZTHdoUT09>