

StATins Use in intRacerebral hemorrhage patieNts

Newsletter

October 2020 - Issue 4

A Message From The SATURN Study Team

Happy Fall!

We want to thank all the sites for their work in getting SATURN off the ground and for all of the successful enrollments we've had.

Keep the enrollments and the good work coming!



SATURN Milestones

There have been 20 enrollments in SATURN to date. We would like to send our congratulations to:

- . Oregon Health & Science University Hospital, Portland, OR (2)
- Harborview Medical Center, Seattle, WA (2)
- UF Health Shands Hospital, Gainesville, FL
- . Beth Israel Deaconess Medical Center, Boston, MA
- . Greenville Hospital System, Greenville, SC
- . Metro Health Hospital, Wyoming, MI
- · Cedars-Sinai Medical Center, Los Angeles, CA
- · WellSpan York Hospital, York, PA
- Cox Medical Center South, Springfield, MO
- St. Joseph's Hospital and Medical Center, Phoenix, AZ
- · UPMC Presbyterian Hospital, Pittsburgh, PA
- . McLaren Flint, Flint, MI
- Baylor College of Medicine Medical Center, Houston, TX
- Hartford Hospital, Hartford, CT
- Tufts Medical Center, Boston, MA
- Washington University School of Medicine St. Louis, Belleville, IL
- · University of Alabama Hospital, Birmingham, AL
- · SUNY Upstate Medical University, Syracuse, NY

Inside this issue

- Acknowledgements
- FAQs
- Helpful Tips
- Reminders
- Status Update











Frequently Asked Questions: Shipping

Q: What needs to be done before shipping a sample?

- Fill out CRF 181.
 This is the biospecimen collection form located in the subject CRF binder
- 2. Fill out the Lab Kit Tracking form
 This form is located under the Project Management tab.
- 3. Print the Shipping Manifest by clicking the green arrow at the bottom of the lab kit tracking form
- 4. Put the shipping manifest into the lab kit box before shipping

After submission:, an automated e-mail will be sent to the MGH team who will confirm sample receipt upon delivery to the lab.

Frequently Asked Questions: SATURN Blood Tube Replacement Instructions

Q: How are blood tubes replaced?

- 1. Discard the expired tubes
- 2. Replace the expired tubes with pre-labeled tubes wrapped in bubble wrap
- 3. Adhere the spare ID sticker from the replacement kit to the Styrofoam tube holder/plastic shuttle, preferably near the old study ID sticker. (Do not remove the old sticker)



Frequently Asked Questions: Screen Failure Log

Q: What's the proper way to fill out Q04? I am not sure how to answer it.

| Q04 | Randomization can be carried out within 7 days of the onset of the qualifying ICH | ○No | ○Yes | OUnknown |
|-----|---|-----|------|----------|

For question Q04, this should only be answered **no**, **if and only if** a subject cannot be randomized within 7 days of the index event. Good reasons to enter no are:

- If a patient is on day 6 of their enrollment window and is being transferred from the site
- Enrollment is frozen at a site
- Patient can't be reached until they are near the end of their enrollment window

Frequently Asked Questions: Exclusion Criteria

Q: One of the exclusion criteria is Known diagnosis of severe dementia. What is considered severe dementia?

Severe dementia means stage 3 on the Clinical Dementia Rating Scale

- Severe memory problems (for example a patient cannot remember what they had for lunch or names of immediate family members),
- Disoriented with respect to time
- Cannot participate in any community activity,
- May not be able to communicate
- Requires help with all activities of daily living
- Incontinence



Helpful Tips: 5 Recruitment Strategies

- 1. Involve the clinical team
- 2. Approach the patient/family as early as possible.
- 3. Engage the patient & family with these steps:
 - Involve the clinical team
 - Approach the patient/family early (There is never a perfect time)
 - Engage the patient & family
 - Educate them before asking for consent
 - A clinician on the team should lead the discussion
 - Make them understand the problem
 - Highlight the controversy that we don't know if ischemic stroke/MI is better/worse than a recurrent ICH
 - Point out that they can use non-statin lipid lowering agents if needed
 - Take time to answer questions & make yourself available/accessible for follow-up questions
 - Give them time, then follow up
 - Work hard to establish rapport & to gain their trust.
- 4. Take the initiative and communicate with the subject's providers
- 5. Highlight the simplicity of the protocol and follow up





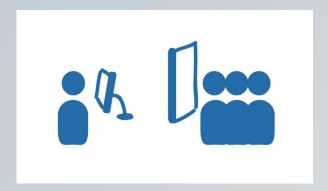
Reminders

Monthly Webinar

Please join us for our monthly SATURN PI/ coordinator webinar on the last Thursday of every month at 12:30 PM.

Next Webinar: November 19, 2020

https://nihstrokenet.adobeconnect.com/trials/

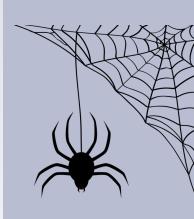


Got Questions?



E-Mail us at SATURN@bidmc.harvard.edu

24/7 Clinical Hotline
For urgent questions
Call +1-617-667-7000 & ask
to page beeper #3%36 re: the
SATURNTrial







SATURN Newsletter

| SATURN Site Progress as of 10/29/2020 | | | | | | | | | |
|--|---|------|---|----|--|-----|------|---|---|
| | Ω | CIRB | δ | 꼰 | CTA execution / CIRB approval / Readiness CALL / Site RELeased to enroll | Ω | CIRB | δ | 고 |
| | ⋝ | RB | F | Ε. | / Site Released to emon | СТА | RB | F | 7 |
| | | | | | | | | | |
| Canadian Sites | | | | | Stanford | | | | |
| Enfant-Jesus Hospital | | | | | Stanford University Medical Center | | | | |
| Charles LeMoyne Hospital | | | | | El Camino Hospital, Mountain View Campus | | | | |
| London Health Sciences Center | | | | | Oregon Health & Science University Hospital | | | | |
| Ottawa Hospital | | | | | Mercy San Juan Medical Center | | | | Ш |
| University of Alberta Hospital | | | | | U Chicago | | | | |
| University of Calgary - Foothills Campus | | | | | Froedtert Hospital | | | | |
| Toronto Western Hospital | | | | | Central DuPage Hospital | | | | |
| Health Sciences Centre | | | | | Loyola University Medical Center | | | | |
| Montreal Neurological Institute and Hospital | | | | | Rush University Medical Center | | | | |
| Hopital de Chicoutimi | | | | | U Cincinnati | | | | |
| Thunder Bay Regional Health Sciences Centre | | | | | University of Cincinnati Medical Center | | | | |
| Brandon Regional Health Center | | | | | University of Louisville Hospital | | | | |
| Hamilton General Hospital | | | | | OSU Wexner Medical Center | | | | Ш |
| CIUSSS Hopital Fleurimont | | | | | U Iowa | | | | |
| Royal Columbian Hospital | | | | | University of Iowa Hospitals & Clinics | | | | |
| Case Western | | | | | University of Nebraska Medical Center | | | | |
| WVU Healthcare Ruby Memorial Hospital | | | | | Sanford Medical Center Fargo | | | | |
| MetroHealth Medical Center | | | | | U Miami | | | | |
| Spectrum Health Hospitals Butterworth Hospital | | | | | Tampa General Hospital | | | | |
| UH Cleveland Medical Center | | | | | UF Health Shands Hospital | | | | |
| Columbia | | | | | Mayo Clinic - Jacksonville | | | | |
| NYP Columbia University Medical Center | | | | | Jackson Memorial Hospital | | | | Ш |
| NYP Weill Cornell Medical Center | | | | | U Michigan | | | | |
| NYP Brooklyn Methodist Hospital | | | | | University of Kentucky Hospital | | | | |
| Buffalo General Medical Center | | | | | Detroit Receiving Hospital | | | | |
| SUNY Upstate Medical University | | | | | University of Michigan University Hospital | | | | |
| St. Josephs Regional Medical Center | | | | | Mercy Health Saint Mary's | | | | |
| Mass General | | | | | McLaren Flint | | | | |
| Baystate Medical Center | | | | | Metro Health Hospital | | | | Ш |
| Tufts Medical Center | | | | | U Minnesota | | | | |
| Massachusetts General Hospital | | | | | Regions Hospital | | | | |
| UMass Memorial Medical Center | | | | | University of Minnesota Medical Center Hospital | | | | |
| Brigham and Women's Hospital | | | | | United Hospital | | | | |
| Beth Israel Deaconess Medical Center | | | | | University of Kansas Hospital | | | | |
| Lahey Hospital & Medical Center | | | | | St. Cloud Hospital | | | | |
| Eastern Maine Medical Center | | | | | U Penn | | | | |
| The University of Vermont Medical Center | | | | | Abington Memorial Hospital | | | | |
| MedStar | | | | | Temple University Hospital | | | | |
| University of Maryland Medical Center | | | | | Hospital of the University of Pennsylvania | | | | |
| UVA Medical Center | | | | | WellSpan York Hospital | | | | |
| | | | | | | | | | |

Scheduled Pending

| CTA execution / CIRB approval / Readiness CALL / Site RELeased to enroll | СТА | CIRB | CALL | REL | CTA execution / CIRB approval / Readiness CALL / Site RELeased to enroll | CALL | 2 |
|--|-----|------|------|-----|--|------|----------|
| Mount Sinai | | | | | Thomas Jefferson University Hospital | | T |
| The Mount Sinai Hospital | | | | | Lehigh Valley Hospital | | |
| NYU Langone Medical Center - Tisch Hospital | | | | | U Pitt | | |
| Montefiore Medical Center | | | | | UPMC Presbyterian Hospital | | |
| NYU Langone Hospital - Brooklyn | | | | | U Utah | | |
| MUSC | | | | | Swedish Medical Center | | |
| Augusta University Medical Center | | | | | University of Utah Healthcare | | |
| Greenville Hospital System | | | | | Intermountain Medical Center | | |
| Moses H. Cone Memorial Hospital | | | | | St. Mary's Medical Center | | |
| Non Network | | | | | U Washington | | |
| Johns Hopkins Bayview Medical Center | | | | | Legacy Emanuel Medical Center | | |
| University of North Carolina Medical Center | | | | | PeaceHealth Sacred Heart Medical RiverBend | | |
| UTHSC Houston | | | | | Harborview Medical Center | | |
| St. David's Medical Center | | | | | Overlake Hospital Medical Center | | |
| Baylor College of Medicine Medical Center | | | | | U Wisconsin | | |
| OU Medical Center | | | | | Aurora St. Luke's Medical Center | | |
| St. Luke's Baptist Hospital | | | | | University of Wisconsin University Hospital | | |
| University Medical Center of El Paso | | | | | Aurora BayCare Medical Center | | |
| Wake Forest | | | | | UAB | | |
| Wake Forest Baptist Medical Center | | | | | University of Alabama Hospital | | |
| Forsyth Medical Center | | | | | University of South Alabama University Hospital | | |
| Washington University | | | | | UCLA | | |
| Saint Luke's Hospital of Kansas City | | _ | - | | Kaiser Permanente Los Angeles Medical Center | | |
| OSF St. Francis Medical Center | | + | | | University of New Mexico Hospital | | 4 |
| UAMS Medical Center | | _ | | | Long Beach Memorial Medical Center | | 4 |
| Barnes Jewish Hospital | | + | | | Cedars-Sinai Medical Center | | 4 |
| Cox Medical Center South | | | | | UC Irvine Medical Center | | |
| Yale | | | | | Kaiser Permanente Fontana Medical Center | | 4 |
| Hartford Hospital | | + | | | Arrowhead Regional Medical Center | | |
| Rhode Island Hospital | | - | | | UCSD | | |
| Yale New Haven Hospital North Shore University Hospital | | + | | | St. Joseph's Hospital and Medical Center | | \dashv |
| North Shore offiversity hospital | | | | | UCSD Medical Center - Hillcrest Hospital | | \dashv |
| | | | | | Ochsner Medical Center - Main Campus | | |
| | | | | | Scripps Memorial Hospital La Jolla | | |
| | | | | | UCSF San Francisco Conoral Hospital | | |
| | | | | | San Francisco General Hospital UCSF Medical Center | | |
| | | | | | Eden Medical Center | | |
| | | | | | Lucii Medicai Centel | | |
| | | | | | Comple | ted | |