

### 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





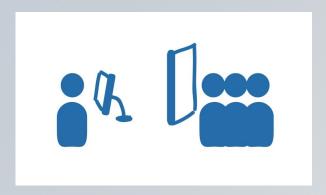
# Reminders

# **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/

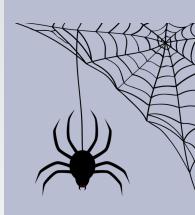


# Got Questions?



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	CTA	CIRB	CALL	REL	CTA execution / CIRB approval / Readiness CALL / Site RELeased to enroll	CAL
Mount Sinai					Thomas Jefferson University Hospital	
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	
UAMS Medical Center					Long Beach Memorial Medical Center	
Barnes Jewish Hospital					Cedars-Sinai Medical Center	
Cox Medical Center South					UC Irvine Medical Center	
Yale					Kaiser Permanente Fontana Medical Center	
Hartford Hospital					Arrowhead Regional Medical Center	
Rhode Island Hospital					UCSD	
Yale New Haven Hospital					St. Joseph's Hospital and Medical Center	
North Shore University Hospital					UCSD Medical Center - Hillcrest Hospital	
					Ochsner Medical Center - Main Campus	
					Scripps Memorial Hospital La Jolla	
					UCSF	
					San Francisco General Hospital	
					UCSF Medical Center	
					Eden Medical Center	
					Completed	