

A Message From The SATURN Study Team

On behalf of the entire SATURN Team, we hope that you are all staying safe and well during these difficult times.

Best wishes and be well,
Team SATURN



COVID-19 Impact and Updates

For Currently Activated Sites

- In order to ensure the safety and welfare of human subject participants and research staff during the COVID-19 public health emergency, the SATURN and StrokeNet NCC leadership decided to suspend enrollment into the SATURN trial on March 26th and until further notice. A letter from the cIRB acknowledging the hold on enrollment at this time is available in the toolbox on WebDCU.
- Please remember to complete the COVID-19 Impact Assessment in WebDCU, if you have not done so already. This can be found under the project management tab on SATURN’s WebDCU page.
- **We are exploring options and procedures that may allow sites to restart enrollment for SATURN while safeguarding the health of study teams and participants. Please watch your E-Mail for a SATURN Specific Site Status Questionnaire and complete it ASAP to guide our decision and let us know if your IRB allows recruitment into non-COVID related trials at this time. We are happy to work with you to see if SATURN enrollment can be re-opened at your site.**

For Sites Pending Activation

- We are working with sites that have yet to be activated to get everything completed to be released to enroll.
- Please upload or waive pending regulatory documents.
- Enter addresses for study materials and lab kit shipments into WebDCU
- Once you have CTA and cIRB approval in place your site will be sent a doodle poll with available dates. Please fill it out at your earliest convenience so we can schedule your readiness call. Choose only one date per site and use the SITE NAME to respond with your choice.
- **If your site is yet to complete CTA and/or cIRB submission, please use this time to complete the start-up activities. We may have to drop sites that fail to show significant progress.**

Inside this issue

- Message from Team SATURN
- COVID-19 Updates
- WebDCU Reminders
- FAQs
- Upcoming Events
- Trial Number Updates

Notable News

- Signature updates



**Helpful Tips:
Regarding Signatures**

Did you Know?

All regulatory documents can be e-signed. We can accept e-signature on all the documents under the following guidelines.

- iPad signature
- DocuSign signature
- Adobe signature

What we cannot accept

Signatures that appear to have been edited into a document.



WebDCU Reminders

Enter your site's address into WebDCU for supplies.

- Click on Site management
- Click on Clinical Site
- Click on your site to edit and enter address

Complete and submit site DOA in WebDCU

- Found under the user management tab

DOA Submission

Upload Regulatory documents in WebDCU

- Found under regulatory document tab
- Uploaded to site reg doc status

Site Reg Doc Status

Frequently Asked Questions

Q. The follow-up assessments include inquiry about blood pressure (BP) readings. Will participants be provided with BP cuffs to check BP at home?

We encourage subjects to check their BP at home as part of good practice to closely monitor their BP and to reduce risk of ICH recurrence. However, we do not provide subjects with BP machines. We will provide the subjects with BP diary to record their BP readings whenever they have their BP checked whether at home, in the doctor's office, or at a retail pharmacy.

Q. Can a subject who does not have a primary care physician be enrolled in the trial?

It is expected that most candidates will have a prescribing provider since the trial only targets patients already taking a statin. Not having a Primary Care Physician upon enrollment does not by itself exclude a subject from participation in the trial. However, it is necessary to identify/assign a provider for such participants prior to discharge to facilitate adequate follow-up and to ensure safety of the trial participants .

Q. My Sub-investigators do not have access to WebDCU. Why?

Until your site is released to enroll subjects for the SATURN study, only team members responsible for submitting regulatory documents will have WebDCU access. After your site has been released to enroll, all other members of your study team will be given WebDCU access .

Upcoming Events: *Mark your calendar!*

ASPIRE/SATURN Investigator Meeting

- Due to the COVID-19 emergency, the investigator meeting has been canceled. RSVPs/lodging arrangements/transportation arrangements for May's meeting have been canceled. A new invitation will be sent in August 2020.
- The SATURN/ASPIRE investigator meeting is now tentatively rescheduled for November 4-5, 2020.



Upcoming Webinar

We are tentatively planning a series of webinars for sometime in May. Please watch your E-Mails closely!



Got Questions?



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

| SATURN Site Progress List | | | | | | | | |
|--|-----|------|------|-----|---|------|------|-----|
| 4/27/2020 | | | | | CTA execution/CIRB approval/ Readiness CALL /Site RELEASEd to enroll | | | |
| | CTA | CIRB | CALL | REL | CTA | CIRB | CALL | REL |
| Canadian Sites | | | | | Non Network | | | |
| Enfant-Jesus Hospital | | | | | Johns Hopkins Bayview Medical Center | | | |
| Charles LeMoyné Hospital | | | | | University of North Carolina Medical Center | | | |
| London Health Sciences Center | | | | | Stanford | | | |
| Ottawa Hospital | | | | | Stanford University Medical Center | | | |
| University of Alberta Hospital | | | | | Oregon Health & Science University Hospital | | | |
| University of Calgary - Foothills Campus | | | | | Mercy San Juan Medical Center | | | |
| Toronto Western Hospital | | | | | U Chicago | | | |
| Health Sciences Centre | | | | | Froedtert Hospital | | | |
| Royal University Hospital | | | | | Central DuPage Hospital | | | |
| Montreal Neurological Institute and Hospital | | | | | Loyola University Medical Center | | | |
| Centre de Sante et de Services Sociaux de Chicoutimi | | | | | Rush University Medical Center | | | |
| Thunder Bay Regional Health Sciences Centre | | | | | U Cincinnati | | | |
| Brandon Regional Health Center | | | | | University of Cincinnati Medical Center | | | |
| Hamilton General Hospital | | | | | University of Louisville Hospital | | | |
| NSHA Halifax Infirmery | | | | | Miami Valley Hospital | | | |
| CIUSSS Hopital Fleurimont | | | | | OSU Wexner Medical Center | | | |
| Royal Columbian Hospital | | | | | U Iowa | | | |
| Case Western | | | | | University of Iowa Hospitals & Clinics | | | |
| WVU Healthcare Ruby Memorial Hospital | | | | | Mary Greeley Medical Center | | | |
| MetroHealth Medical Center | | | | | University of Nebraska Medical Center | | | |
| Spectrum Health Hospitals Butterworth Hospital | | | | | Sanford Medical Center Fargo | | | |
| UH Cleveland Medical Center | | | | | U Miami | | | |
| Riverside Methodist Hospital | | | | | Tampa General Hospital | | | |
| Columbia | | | | | UF Health Shands Hospital | | | |
| NYP Columbia University Medical Center | | | | | Mayo Clinic - Jacksonville | | | |
| NYP Weill Cornell Medical Center | | | | | Jackson Memorial Hospital | | | |
| New York-Presbyterian Brooklyn Methodist Hospital | | | | | U Michigan | | | |
| Buffalo General Medical Center | | | | | University of Kentucky Hospital | | | |
| SUNY Upstate Medical University | | | | | Detroit Receiving Hospital | | | |
| St. Josephs Regional Medical Center | | | | | University of Michigan University Hospital | | | |
| Mass General | | | | | Mercy Health Saint Mary's | | | |
| Baystate Medical Center | | | | | McLaren Flint | | | |
| Tufts Medical Center | | | | | Metro Health Hospital | | | |
| Massachusetts General Hospital | | | | | Ascension St. Mary's Hospital | | | |
| UMass Memorial Medical Center | | | | | U Minnesota | | | |
| Brigham and Women's Hospital | | | | | Regions Hospital | | | |
| Beth Israel Deaconess Medical Center | | | | | University of Minnesota Medical Center Hospital | | | |
| Lahey Hospital & Medical Center | | | | | United Hospital | | | |
| Eastern Maine Medical Center | | | | | University of Kansas Hospital | | | |
| The University of Vermont Medical Center | | | | | St. Cloud Hospital | | | |

| CTA execution/CIRB approval/ Readiness CALL /Site RE leased to enroll | CTA | CIRB | CALL | REL | CTA execution/CIRB approval/ Readiness CALL /Site RE leased to enroll | CTA | CIRB | CALL | REL |
|--|-----|------|------|-----|--|-----|------|------|-----|
| | | | | | | | | | |
| MedStar | | | | | U Penn | | | | |
| University of Maryland Medical Center | █ | █ | █ | | Abington Memorial Hospital | █ | █ | █ | █ |
| George Washington University Hospital | █ | █ | █ | | Temple University Hospital | █ | █ | █ | █ |
| UVA Medical Center | █ | █ | █ | | Hospital of the University of Pennsylvania | █ | █ | █ | █ |
| Mount Sinai | | | | | U Pitt | | | | |
| The Mount Sinai Hospital | █ | █ | █ | | UPMC Presbyterian Hospital | █ | █ | █ | █ |
| NYU Langone Medical Center - Tisch Hospital | █ | █ | █ | | U Utah | | | | |
| Montefiore Medical Center | █ | █ | █ | | Swedish Medical Center | █ | █ | █ | █ |
| NYU Langone Hospital - Brooklyn | █ | █ | █ | | University of Utah Healthcare | █ | █ | █ | █ |
| MUSC | | | | | U Washington | | | | |
| Augusta University Medical Center | █ | █ | █ | | Legacy Emanuel Medical Center | █ | █ | █ | █ |
| Greenville Hospital System | █ | █ | █ | | PeaceHealth Sacred Heart Medical Center - RiverBend | █ | █ | █ | █ |
| Moses H. Cone Memorial Hospital | █ | █ | █ | | Harborview Medical Center | █ | █ | █ | █ |
| U Wisconsin | | | | | UCSF | | | | |
| Aurora St. Luke's Medical Center | █ | █ | █ | | Overlake Hospital Medical Center | █ | █ | █ | █ |
| University of Wisconsin University Hospital | █ | █ | █ | | EvergreenHealth Medical Center - Kirkland | █ | █ | █ | █ |
| Aurora BayCare Medical Center | █ | █ | █ | | UTHSC Houston | | | | |
| UAB | | | | | Wake Forest | | | | |
| University of Alabama Hospital | █ | █ | █ | | St. David's Medical Center | █ | █ | █ | █ |
| University of South Alabama University Hospital | █ | █ | █ | | Baylor College of Medicine Medical Center | █ | █ | █ | █ |
| UCLA | | | | | Washington University | | | | |
| Kaiser Permanente Los Angeles Medical Center | █ | █ | █ | | OU Medical Center | █ | █ | █ | █ |
| Ronald Reagan UCLA Medical Center | █ | █ | █ | | St. Luke's Baptist Hospital | █ | █ | █ | █ |
| University of New Mexico Hospital | █ | █ | █ | | University Medical Center of El Paso | █ | █ | █ | █ |
| Long Beach Memorial Medical Center | █ | █ | █ | | Wake Forest | | | | |
| Cedars-Sinai Medical Center | █ | █ | █ | | Wake Forest Baptist Medical Center | █ | █ | █ | █ |
| UC Irvine Medical Center | █ | █ | █ | | Forsyth Medical Center | █ | █ | █ | █ |
| Keck Hospital of USC | █ | █ | █ | | Washington University | | | | |
| Kaiser Permanente Fontana Medical Center | █ | █ | █ | | Saint Luke's Hospital of Kansas City | █ | █ | █ | █ |
| Arrowhead Regional Medical Center | █ | █ | █ | | OSF St. Francis Medical Center | █ | █ | █ | █ |
| UCSD | | | | | Yale | | | | |
| St. Joseph's Hospital and Medical Center | █ | █ | █ | | UAMS Medical Center | █ | █ | █ | █ |
| UCSD Medical Center - Hillcrest Hospital | █ | █ | █ | | Barnes Jewish Hospital | █ | █ | █ | █ |
| Ochsner Medical Center - Main Campus | █ | █ | █ | | Cox Medical Center South | █ | █ | █ | █ |
| Scripps Memorial Hospital La Jolla | █ | █ | █ | █ | Yale | | | | |
| | | | | | Hartford Hospital | █ | █ | █ | █ |
| | | | | | Rhode Island Hospital | █ | █ | █ | █ |
| | | | | | Yale New Haven Hospital | █ | █ | █ | █ |
| | | | | | North Shore University Hospital | █ | █ | █ | █ |
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Completed █

Scheduled █

Pending █