

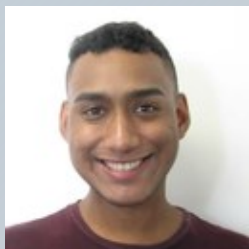
A Message From The SATURN Study Team:

Happy 2021!

We want to thank all the sites for their hard work in helping us get to our first 40 enrollments in 2020! Despite the circumstances we got SATURN started and hope to do even better in 2021.

SATURN Coordinator Spotlight: Meet The BIDMC Team

Michael



My role as a coordinator involves screening potential subjects, scheduling follow up calls, and maintaining regulatory documents for stroke trials across BIDMC. My interests include reading, traveling, and film. My favorite part of clinical research is working in a field that is cutting edge where we are learning and studying treatments that could positively impact the lives of millions of patients around the world.

Jorge



My role as a coordinator involves making sure patients have their follow up assessments scheduled within their assessment windows and ensuring they are not lost to follow up. Further, I am also involved in screening potential participants in real time to determine if they are eligible for any of the stroke net studies our site is participating in. I am interested in Neurology/neuroscience, clinical research, live music, movies, cycling, yoga. My favorite part of clinical research is getting to know participants and developing a relationship with them over the course of their participation. It is a privilege to see how they progress over time

Filipa



I am the newest research assistant at the site and am currently in the process of learning how to screen patients for participation in the trials that BIDMC is a part of, conduct subject assessments and schedule follow-up appointments. My interests include neuroscience research, playing the violin and baking. My favorite part of working in clinical research is learning how the research affects patients in direct ways. It is a great feeling to know that the work can positively impact patients' health and lives.



Inside this issue:

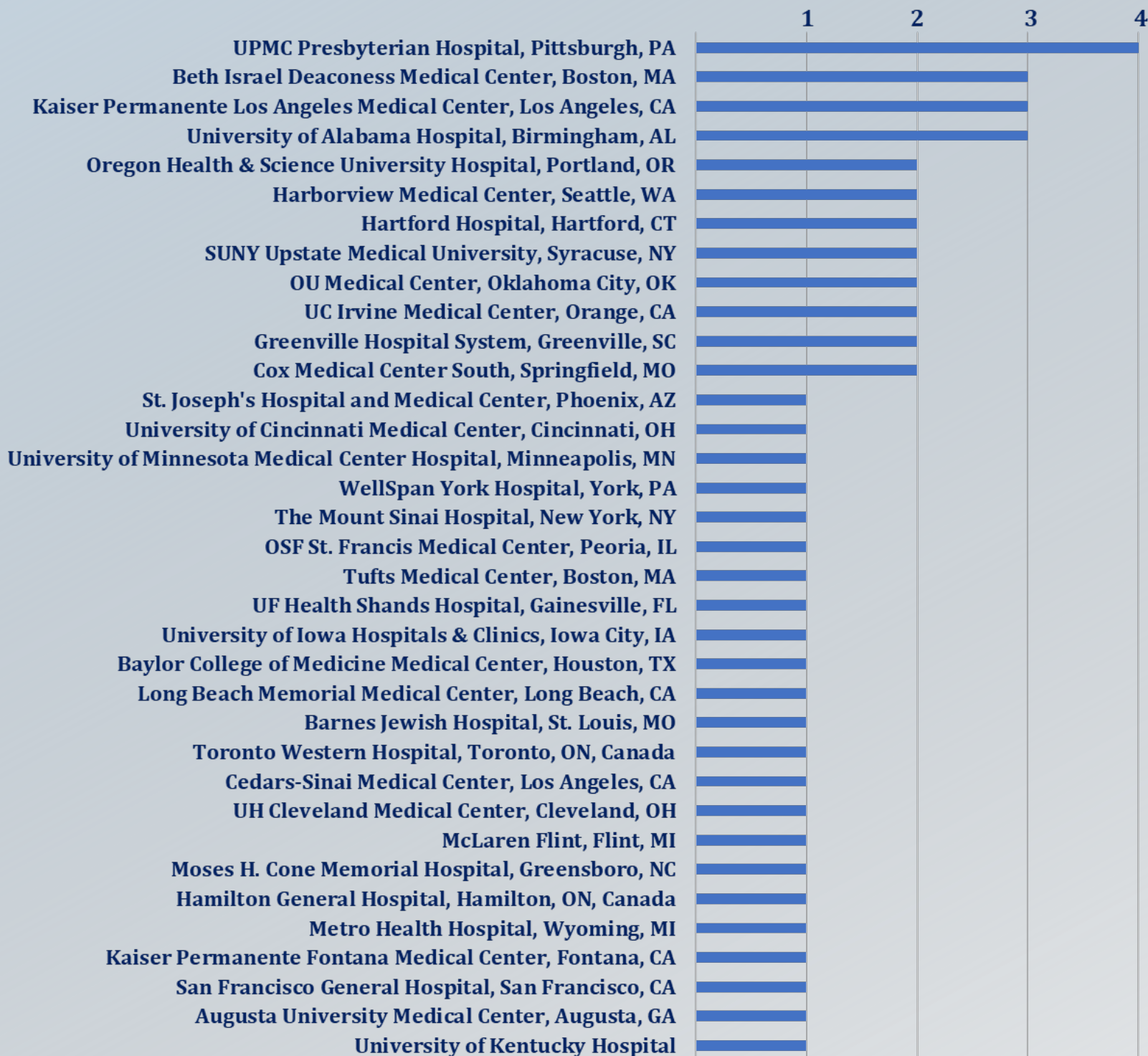
- Introduction
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- Enrollment Updates
- Tips and Tricks
- Release of Medical Records
- Screen Failure Update
- Reminders
- Status Update

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: the SATURN
Trial

Enrollment Updates

Enrollment Status by Site



Enrollment Updates

Congratulations!

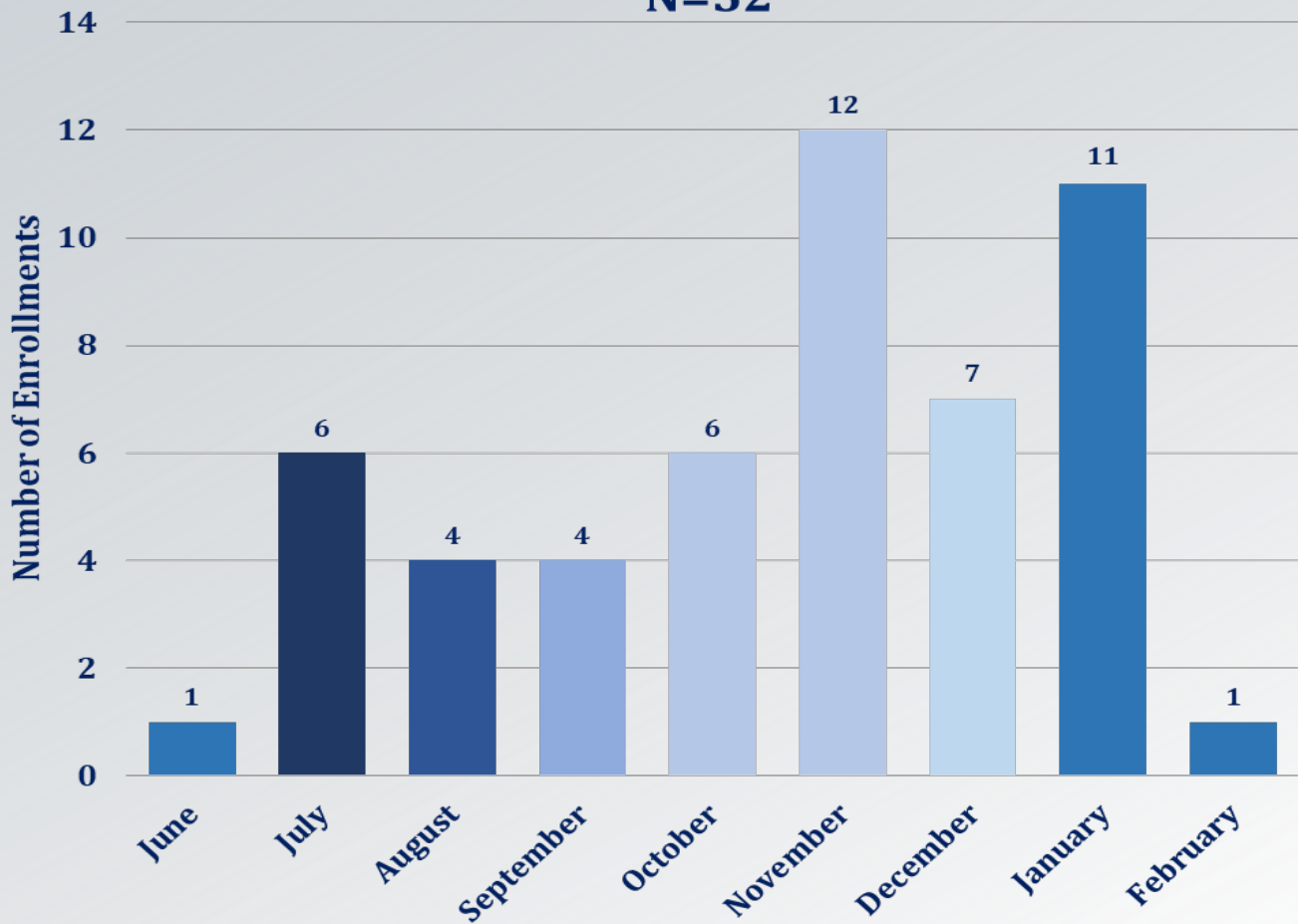
UPMC Presbyterian Hospital in Pittsburgh, PA

has the highest enrollment to date!

We thank you all for your hard work!

Monthly Enrollment Status

N=52



Tips and Tricks: *Ensuring Successful Enrollment and Randomization*

- Confirming whether a hemorrhage in proximity to the ventricles is lobar or non-lobar can sometimes be confusing. The key element is to determine whether the hemorrhage seems to originate from the thalamus, putamen, globus pallidus, caudate or internal capsule. If it does, then this is not a lobar ICH. If uncertain or in doubt about ICH proximity to the ventricle or its origin, please feel free to send us an anonymized image depicting the location of the hemorrhage (mseim@bidmc.harvard.edu), we will have the images reviewed by our Imaging Adjudicator and will let you know if this meets the eligibility criteria for enrollment.
- Please make sure that a member of the study team discusses the trial with the subject's provider(s) prescribing statin before enrollment. This provides an opportunity to educate providers about the purpose and nature of SATURN, and ensures that the provider agrees with the subject's randomization and the possibility that statin may be discontinued. This is important to minimize the chances of crossover because a providers feels strongly that his/her patient should continue statin. **Feel free to share this video link with the providers (<https://www.youtube.com/watch?v=5kHeBOfDpIA&feature=youtu.be>).**
- Remind the potential subjects/LARs and their physicians that while SATURN may prohibit the use of statin, the use of non-statin lipid-lowering agents such as ezetimibe and/or omega-3 fatty acids is permitted if felt necessary.
- It is important that the study team communicates the results of the randomization assignment (i.e. continue/restart vs. discontinue statin) to the treating team and to make sure that the medication orders reflect the actual randomization assignment. Please check the discharge summary and instructions to make sure that they accurately reflect the randomization assignment.
- Remember to send the follow-up letter to the subject's providers to let them know that the subject is enrolled in SATURN and to inform them of the randomization assignment.



Authorization for Release of Medical Records

Please make sure the subject or LAR signs the medical release at the time of consent. This is referenced in the consent form and **important in order to obtain needed medical records in case of adverse event or death.**

By signing this consent document, you are allowing the investigators at BIDMC to contact your doctors. In some cases, we may request medical information or records about you from your doctor(s) or hospital(s) in which you receive future treatment.

For this reason, we ask you to sign an authorization for release of medical record/information form (attached) to allow your doctors and medical facilities to release your records to the investigators at Beth Israel Deaconess Medical Center in Boston (if needed). Again, the investigators at Beth Israel Deaconess Medical Center are obliged to protect your privacy and confidentiality.

Screen Failure Log: *Updates*

Going Forward: Only **Lobar** ICH patients should be entered into the screen failure form. Questions Q02 and Q03 **MUST** be answered.

No.	Item Description	Data Value
Q02	Spontaneous lobar ICH confirmed by CT or MRI scan Q02 must be answered	<input type="radio"/> No <input type="radio"/> Yes
Q03	Taking a statin drug at the onset of the qualifying/index ICH Q03 must be answered	<input type="radio"/> No <input type="radio"/> Yes
<p><i>If Q02 and Q03 are both Yes, enter responses below for the reason(s) why the patient was not eligible for the study. It is not required or expected for a response to be entered for each item. At least one eligibility violation (whether inclusion or exclusion) should be marked to indicate why the patient was not enrolled/randomized. Please do not mark an item if the answer is unknown.</i></p>		

Reminders

Monthly Webinar

Please join us for our monthly SATURN PI/coordinator webinar on the last Thursday of every month at 12:30 PM EST. Next Webinar 2/25/21

Investigator Meeting

Please join us for our first ever Virtual investigator meeting on April 8, 2021 at 12:30-3:30 PM EST. More information including the meeting link will be provided as we approach the date of the meeting.

SATURN Recruitment Video

Our SATURN recruitment video is now live! Make sure to watch and share with any new patients as well as providers.

<https://www.youtube.com/watch?v=5kHeBOfDpIA&feature=youtu.be>

<https://www.nihstrokenet.org/saturn-trial>

SATURN Newsletter

SATURN Site Progress as of 1/29/21					CTA execution / CIRB approval / Readiness CALL / Site RELEASED to enroll				
	CTA	CIRB	CALL	REL		CTA	CIRB	CALL	REL
Canadian Sites					Stanford				
Enfant-Jesus Hospital					Stanford University Medical Center				
Charles LeMoyné Hospital					El Camino Hospital, Mountain View Campus				
London Health Sciences Center					Oregon Health & Science University Hospital				
Ottawa Hospital					Mercy San Juan Medical Center				
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				
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				
NYP Weill Cornell Medical Center					U Michigan				
New York-Presbyterian Brooklyn Methodist					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				
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				

SATURN Site Progress as of 1/29/21	CTA	CIRB	CALL	REL	CTA execution / CIRB approval / Readiness CALL / Site RELEASED to enroll	CTA	CIRB	CALL	REL
Mount Sinai					Thomas Jefferson University Hospital	Completed	Completed	Pending	Pending
The Mount Sinai Hospital	Completed	Completed	Completed	Completed	Lehigh Valley Hospital	Completed	Completed	Completed	Pending
NYU Langone Medical Center - Tisch Hospital	Completed	Completed	Completed	Completed	U Pitt				
Montefiore Medical Center	Completed	Completed	Completed	Completed	UPMC Presbyterian Hospital	Completed	Completed	Completed	Completed
NYU Langone Hospital - Brooklyn	Completed	Completed	Completed	Completed	U Utah				
MUSC					Swedish Medical Center	Completed	Completed	Completed	Completed
Augusta University Medical Center	Completed	Completed	Completed	Completed	University of Utah Healthcare	Completed	Completed	Completed	Completed
Greenville Hospital System	Completed	Completed	Completed	Completed	Intermountain Medical Center	Completed	Completed	Completed	Completed
Moses H. Cone Memorial Hospital	Completed	Completed	Completed	Completed	St. Mary's Medical Center	Completed	Completed	Completed	Completed
Non Network					Banner University Medical Center	Pending	Pending	Pending	Pending
Johns Hopkins Bayview Medical Center	Completed	Completed	Completed	Completed	UTHSC Houston				
University of North Carolina Medical Center	Completed	Pending	Pending	Pending	St. David's Medical Center	Completed	Completed	Completed	Completed
U Washington					Baylor College of Medicine Medical Center	Completed	Completed	Completed	Completed
Legacy Emanuel Medical Center	Completed	Completed	Completed	Completed	OU Medical Center	Completed	Completed	Completed	Completed
PeaceHealth Sacred Heart Medical Center	Completed	Completed	Completed	Completed	St. Luke's Baptist Hospital	Completed	Completed	Completed	Completed
Harborview Medical Center	Completed	Completed	Completed	Completed	University Medical Center of El Paso	Completed	Completed	Completed	Pending
Overlake Hospital Medical Center	Completed	Completed	Completed	Completed	Memorial Hermann Texas Medical Center	Pending	Pending	Pending	Pending
Virginia Mason Medical Center	Pending	Pending	Pending	Pending	University Health System University Hospital	Pending	Pending	Pending	Pending
U Wisconsin					Wake Forest				
Aurora St. Luke's Medical Center	Completed	Completed	Completed	Completed	Wake Forest Baptist Medical Center	Completed	Completed	Completed	Completed
University of Wisconsin University Hospital	Completed	Completed	Completed	Completed	Forsyth Medical Center	Completed	Pending	Pending	Pending
Aurora BayCare Medical Center	Completed	Completed	Completed	Completed	Carolinas Medical Center	Pending	Pending	Pending	Pending
UAB					Washington University				
University of Alabama Hospital	Completed	Completed	Completed	Completed	Saint Luke's Hospital of Kansas City	Completed	Completed	Completed	Completed
University of South Alabama University Hospital	Completed	Completed	Completed	Completed	OSF St. Francis Medical Center	Completed	Completed	Completed	Completed
UCLA					UAMS Medical Center	Completed	Completed	Completed	Completed
Kaiser Permanente Los Angeles Medical Center	Completed	Completed	Completed	Completed	Barnes Jewish Hospital	Completed	Completed	Completed	Completed
University of New Mexico Hospital	Completed	Completed	Completed	Completed	Cox Medical Center South	Completed	Completed	Completed	Completed
Long Beach Memorial Medical Center	Completed	Completed	Completed	Completed	Yale				
Cedars-Sinai Medical Center	Completed	Completed	Completed	Completed	Hartford Hospital	Completed	Completed	Completed	Completed
UC Irvine Medical Center	Completed	Completed	Completed	Completed	Rhode Island Hospital	Completed	Completed	Completed	Completed
Keck Hospital of USC	Pending	Pending	Pending	Pending	Yale New Haven Hospital	Completed	Completed	Completed	Completed
Kaiser Permanente Fontana Medical Center	Completed	Completed	Completed	Completed	North Shore University Hospital	Completed	Completed	Completed	Completed
Arrowhead Regional Medical Center	Completed	Completed	Completed	Completed	Staten Island University Hospital - North Campus	Pending	Pending	Pending	Pending
Baldwin Park Medical Center	Pending	Pending	Pending	Pending					
UCSD									
St. Joseph's Hospital and Medical Center	Completed	Completed	Completed	Completed					
UCSD Medical Center - Hillcrest Hospital	Completed	Completed	Completed	Completed					
Ochsner Medical Center - Main Campus	Completed	Completed	Completed	Completed					
Scripps Memorial Hospital La Jolla	Completed	Completed	Completed	Pending					
UCSF									
San Francisco General Hospital	Completed	Completed	Completed	Completed					
UCSF Medical Center	Completed	Completed	Completed	Completed					
Eden Medical Center	Completed	Completed	Completed	Pending					

■ Completed
■ Scheduled
■ Pending