



ASPIRE Monthly Webinar - Sept 28 3-4 pm ET



TOPIC: State of the Trial

Zoom: 951 0504 2660 Passcode: aspire

Recruitment Update *since last Newsletter (8/23)*

12 Randomizing Sites

Barnes Jewish Hospital*	1
Hospital of the University of Pennsylvania	1
Maimonides Medical Center*	1
Massachusetts General Hospital	1
Oregon Health & Science University Hospital	1
PIH Health Hospital - Whittier*	1
University of Alabama Hospital	1
University of Iowa Hospitals & Clinics	1
University of North Carolina Medical Center	1
University of South Alabama University Hospital*	1
Wake Forest Baptist Medical Center	1
Yale New Haven Hospital	2

New
Participants

13

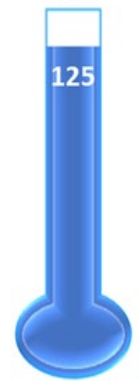
TOTAL

125

2022 Goal

140

125



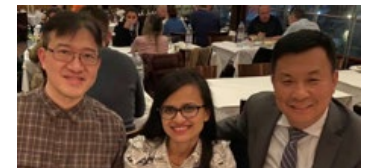
*Congratulations to 4 Sites for Enrolling their 1st ASPIRE Subject!



Yan Wang (PI), Lindsay Tessmer (SC),
Cyndi Midkiff (PSC), Jenny Babka (SC)



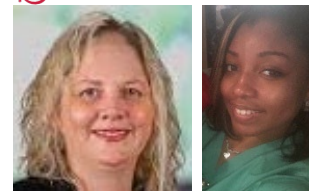
Amy Ng, Natasha Kovalchuk, Maryna
Mootoo (PSC), Galina Lenyk-Kolotsi
(SSC), Viktoriya Laznik



Weijun Jin (stroke attending),
Sanskriti Mishra (PI),
Qingliang T. Wang (SubI)



Gautam Ganguly (PI), Kristine Bradbury (PSC)



Rebecca Sugg (PI), Tamekia Grissett (PSC)



Change in ASPIRE Prohibited Medications

On September 19th the cIRB approved a revision to prohibited medications for ASPIRE. Medications that are **combined P-gp and strong CYP3A34 inhibitors or inducers** are now classified as prohibited (*instead of discouraged*) for ASPIRE participants. This change means that patients who are unable to stop such medications cannot be enrolled in ASPIRE and subjects in the trial must temporarily hold the study drugs while taking them.

Please refer to **Prohibited and Discouraged Medication List v4** posted in WebDCU ASPIRE Toolbox for list of medications involved.

- **Combined P-gp and strong CYP3A34 inducers** include several antiseizure medications.
- **Combined P-gp and strong CYP3A34 inhibitors** include several antiviral and antifungal medications.

One prohibited medication is ritonavir, a component of Paxlovid. Subjects who are prescribed Paxlovid should be advised to stop taking their ASPIRE study medication (*both bottles*) at the start of their course of treatment and should resume taking them 4 days after the last dose of Paxlovid. During the time off study medications, you may instruct your subjects to take aspirin 81 mg daily.

To alert ASPIRE participants of the need to hold study drug if they are prescribed a course of treatment, the **Paxlovid Letter to Participants** (*posted in Toolbox*) should be provided to and reviewed with each subject at their next scheduled study contact. Additional information for patients and caregivers can be found at the FDA website at: <https://bit.ly/3agHqSt>.

As before, please remind ASPIRE subjects to contact you if they are prescribed *any* new medication.

Revisions to the **Concomitant Medications CRF** are in progress that will capture *all* prohibited medications. If a subject contact occurs before the new CRF is available and a new prohibited medication is being used, please make a note in the General Comments section of the CRF and follow the MOP for prohibited medications.

Revised Guidance for Partnering with Rehabilitation and SN Facilities

- Updated guidance posted in Toolbox
- Reviewed and approved by ASPIRE cIRB

NEED MORE SUPPLIES?

Email ASPIRE@Yale.edu if you need additional supplies.

- Patient Brochures (English or Spanish)
- Inclusion/Exclusion Pocket Cards

ASPIRE CONTACT INFORMATION ASPIRE@YALE.EDU 24/7 Hotline: (800) 618-0643

Principal Investigators
Program Managers

Kevin Sheth (443) 615-4729 Hooman Kamel
Cristina Francois [NCC] (513) 558-3960
Catherine Viscoli [Yale] (203) 927-0443

Randomizations by RCC/Site and Year

RCC	SITE	2022	2021	2020
Case Western	Cleveland Clinic		1	
	MetroHealth Medical Center		1	
	UH Cleveland Medical Center	3		
	WVU Healthcare Ruby Memorial Hospital	1		
Columbia	Kings County Hospital Center	1		
	NYP Columbia University Medical Center	1		
MUSC	Augusta University Medical Center	1	1	
	Medical University of South Carolina University Hospital		2	
	Moses H. Cone Memorial Hospital	1		
	Prisma Health Greenville Memorial Hospital	1	2	
Mass General	Baystate Medical Center	1		
	Beth Israel Deaconess Medical Center	1		
	Massachusetts General Hospital	2		
	The University of Vermont Medical Center	3		
MedStar	MedStar Georgetown University Hospital	1	1	
	UVA Medical Center	1	1	
Mount Sinai	Maimonides Medical Center	1		
	NYU Langone Hospital - Brooklyn	2	2	
Non Network	Morton Plant Hospital	1		
	University of North Carolina Medical Center	2		
	Vassar Brothers Medical Center	1		
Stanford	Oregon Health & Science University Hospital	3	1	1
	Providence St. Vincent Medical Center	1		
	Stanford University Medical Center		1	
U Chicago	Central DuPage Hospital		1	
	Rush University Medical Center	2		
	University of Chicago Medical Center	2		
U Cincinnati	OSU Wexner Medical Center		1	
	University of Cincinnati Medical Center	1	2	
U Iowa	University of Iowa Hospitals & Clinics	2	1	3
	University of Nebraska Medical Center	2		
U Miami	Jackson Memorial Hospital		1	
	Mayo Clinic			1
	Tampa General Hospital		1	
U Michigan	McLaren Flint	1		
	McLaren Macomb	1		
U Penn	Hospital of the University of Pennsylvania	2	1	
	Temple University Hospital	1		
U Pitt	UPMC Presbyterian Hospital	1	2	1
U Utah	University of Utah Healthcare			1
U Washington	Harborview Medical Center	1		1
UAB	University of Alabama Hospital	1	2	
	University of South Alabama University Hospital	1		
UCLA	Cedars-Sinai Medical Center		1	
	Kaiser Permanente Los Angeles Medical Center		2	
	PIH Health Hospital - Whittier	1		
	UC Davis Medical Center	1		
	UC Irvine Medical Center	2	3	
University of New Mexico Hospital	1	3		
UCSD	Ochsner Medical Center - Main Campus		1	
UCSF	Kaiser Permanente Sacramento Medical Center		1	
	The Queen's Medical Center	1		
UTHSC Houston	Memorial Hermann Texas Medical Center	1		
	OU Medical Center	1	1	
	St. John Medical Center	2		
	University of Texas Health Science Center San Antonio		1	
Wake Forest	Wake Forest Baptist Medical Center	3	2	1
Washington University	Barnes Jewish Hospital	1		
	OSF St. Francis Medical Center	1		1
Yale	North Shore University Hospital		1	
	Rhode Island Hospital	2		
	Yale New Haven Hospital	6	3	1