



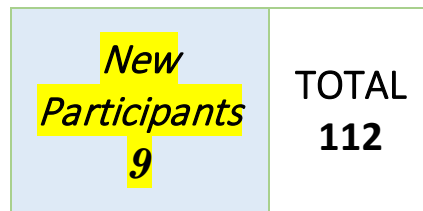
ASPIRE Monthly Webinar - August 24 3-4 pm ET

- o **Getting Your 1st ASPIRE Randomization**
- o Zoom: 951 0504 2660 Passcode: aspire

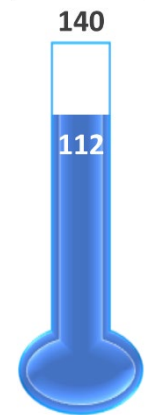
Recruitment Update *since last Newsletter (7/25)*

9 Randomizing Sites

- Augusta University Medical Center
- Massachusetts General Hospital*
- McLaren Macomb*
- Providence St. Vincent Medical Center*
- Rhode Island Hospital
- Temple University Hospital*
- University of New Mexico Hospital
- Vassar Brothers Medical Center*
- WVU Healthcare Ruby Memorial Hospital*



2022 Goal



**Congratulations to 6 Sites that Enrolled their 1st ASPIRE Subject!*



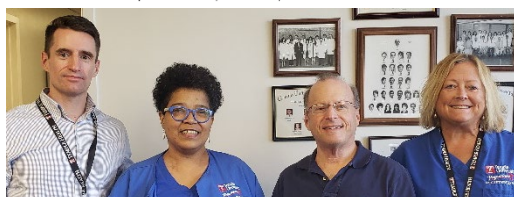
Beatrice Duvert (StrokeNet PM), Rhiana Carr (PSC), Devin Qualls (SSC), Mariel Kozberg (PI), Chris Espinoza (SSC)



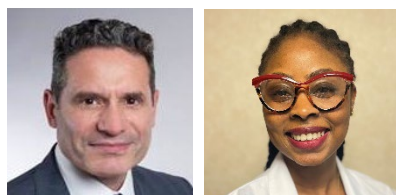
Mahmoud Rayes (SubI), Emily Paschall (SSC), Valentyna Onishchuk (PSC), Bharath Naravetla (PI)



John Zurasky (PI), Bo Banks (PSC), Alexis Young (SSC)



Michael Mullen (Sub-I), Sandra Combs (PSC), Paul Katz (PI), Kathleen Hatala (SSC)



Paul Wright (PI), Barakat Onabanjo (PSC)



Amelia Adcock (PI), Jay Sherman (PSC) [not pictured]

Updated ASPIRE Materials Posted in Toolbox



Clinical Performing Site Study Drug Procedures

MAJOR CHANGES

- Permitted range for temperature excursions for study drug changed from 20-25°C (68-77°F) to 15-30°C (59-86°F) to follow package insert.
 - Study Drug Temperature Excursion Report Form revised with new permitted range.
- New IP Drug Accountability Log to record both drug dispensing and destruction on a single form (replaces Patient Specific Drug Accountability Log and Study Drug Inventory and Dispensing Log).



Data Collection Guidelines

MULTIPLE UPDATES

- **Subject Enrollment:** How to obtain information on ethnicity and race.
- **Eligibility (F101):** Enter *after* **CHA₂DS₂-VASc (F304)**; investigator OKing checked against DOA.
- **Adverse Event (F104):** How to date outcome *Resolved with sequelae*; how to code study drug questions; narrative template for brain hemorrhage revised to include relation to trauma.
- **End of Study (F126):** When form is needed; how to date early termination; how to revise Eligibility Form if consent withdrawn before randomization.
- **Assessment instructions:** Revised to follow a consistent format throughout. In addition,
 - MoCA: Instructions added for scoring patients with visual or motor impairments.
 - PROMIS measures: Corrected to remove reference to baseline assessment.
 - CHA₂DS₂-VASc: Text added on derived age field.
- **Relevant History (F503):** How to code condition found after randomization; education levels defined.
- **Imaging Collection (F508):** Instructions made c/w form; how to select CT if multiple available.
- **Study Drug Kit Dispensing (F513):** Instructions clarified.
- **Troubleshooting Study Drug Forms:** New section to help if replacement or 2nd kit needed.



BIOBANK Procedures

MINOR EDITS

- Record receipt of Blood Draw kit in WebDCU>Study Materials Tracking>**Lab Kit Receiving**.
- Submit **Biosample Collection CRF** to link subject number to blood draw kit used.
- Overnight courier service used to ship kit to Biobank is not limited to FedEx.
 - Please use your site's preferred service.

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	2020	2021	2022
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		2	1
Mass General	Baystate Medical Center			1
	Beth Israel Deaconess Medical Center			1
	Massachusetts General Hospital			1
	The University of Vermont Medical Center			3
MedStar	MedStar Georgetown University Hospital		1	1
	UVA Medical Center		1	1
Mount Sinai	NYU Langone Hospital - Brooklyn		2	2
Non Network	Morton Plant Hospital			1
	University of North Carolina Medical Center			1
	Vassar Brothers Medical Center			1
Stanford	Oregon Health & Science University Hospital	1	1	2
	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		2	1
U Iowa	University of Iowa Hospitals & Clinics	3	1	1
	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		1	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		2	
UCLA	Cedars-Sinai Medical Center		1	
	Kaiser Permanente Los Angeles Medical Center		2	
	UC Davis Medical Center			1
	UC Irvine Medical Center		3	2
	University of New Mexico Hospital		3	1
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	1	2	2
Washington University	OSF St. Francis Medical Center	1		1
Yale	North Shore University Hospital		1	
	Rhode Island Hospital			2
	Yale New Haven Hospital	1	3	4
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