



Please join us for the ASPIRE Monthly Webinar

Wednesday October 27 3:00-4:00 pm ET

Dr. Rustam Al-Shahi Salman, the PI for **Start or Stop Anticoagulants Randomised Trial (SoSTART)**, will discuss the results of the study and implications for ASPIRE.

To join Zoom Meeting -- Meeting ID: 995 2558 8890 Passcode: 317043, or call in.
To find your local number, go to <https://ucincinnati.zoom.us/j/99525588890>

Recruitment Update

Since last newsletter...

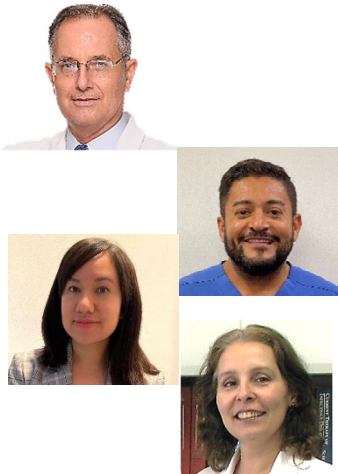
6 Randomizations

Jackson Memorial Hospital	1
MedStar Georgetown University Hospital	1
MetroHealth Medical Center	1
OSU Wexner Medical Center	1
University of Iowa Hospitals & Clinics	1
Yale New Haven Hospital	1

TOTAL PARTICIPANTS: 47

Enrolled from
31 Sites

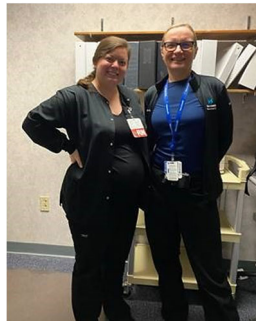
Congratulations to 4 Sites for their 1st Randomizations!



Sebastian Koch (PI)
German Orellana (PSC)
Andrea Escobar (SC)
Iszet Campo-Bustillo (RDC)



Douglas Mayson (PI)
Sarai Bartlett (PSC – not pictured)



Agnieszka Ardelt (PI)
Hailey Chesnick (PSC)



Yousef Hannawi (PI)
Weiping Ye, Luke Herren (PSC)



**ONE for ASPIRE Update - Since 9/20/21,
9 sites have met the goal
of consenting 1 patient before end of year!**

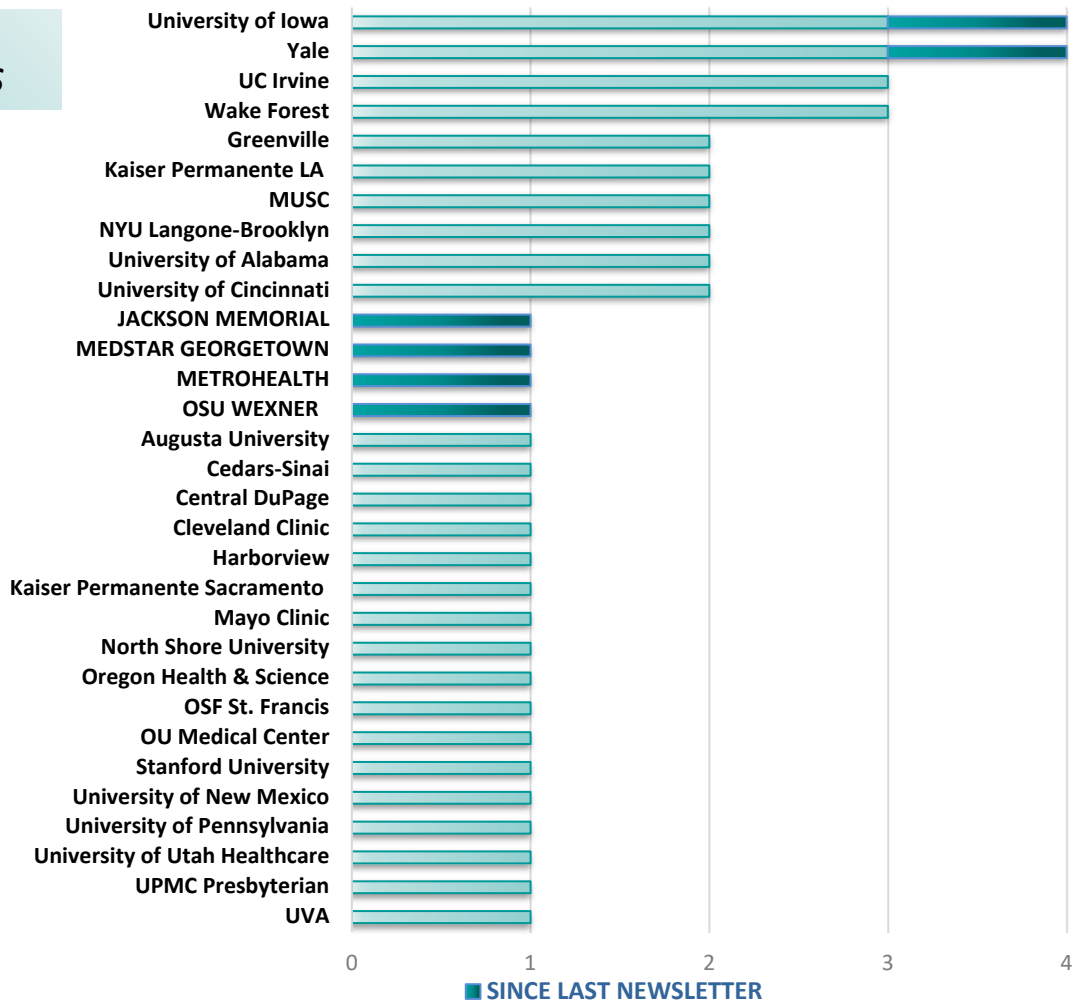
- ☑ Desert Regional Medical Center
- ☑ MedStar Georgetown University Hospital
- ☑ MetroHealth Medical Center
- ☑ Tampa General Hospital
- ☑ UPMC Presbyterian Hospital
- ☑ University of Chicago Medical Center
- ☑ University of Cincinnati Medical Center
- ☑ University of Iowa Hospitals & Clinics
- ☑ Yale New Haven Hospital



5 New Sites Have been Released to Enroll

Boston Medical Center, Boston, MA	Steven Feske (PI), Darya Musatova (PSC)
Javon Bea Hospital - Riverside, Rockford, IL	Vibhav Bansal (PI), Alexis Haynie (PSC)
Riverside Methodist Hospital, Columbus, OH	Vivek Rai (PI), Heather Bartelt (PSC)
Tufts Medical Center, Boston, MA	Emiliya Melkumova (PI), Leidy Guzman (PSC)
University of North Carolina, Chapel Hill, NC	David Huang (PI), Anne Beckwith (PSC)

**SITE
RANDOMIZATIONS**



Manual of Procedures (v5.0) Posted in WebDCU

MAJOR CHANGES:

❑ Procedures for facility unblinding (section 14.2.2)

Limited unblinding is now permitted if facility where a participant resides refuses to dispense the ASPIRE study drug without knowledge of the active medication.

- ASPIRE clinical team member without direct responsibility for participant follow-up can request treatment assignment and transmit this information to facility's treating clinician.
- Whenever possible, facility should dispense study drugs per protocol (i.e., using study provided bottles). Otherwise, prescription of open-label medication may be arranged with the facility by the unblinded ASPIRE clinical team member. Once participant leaves the facility, open label medication should be stopped, and blinded study drug resumed.

❑ Procedures for CRF submission for Screening Visit (section 8.3.2)

3 Screening Visit CRFs to be submitted after consented subject is enrolled in WebDCU: Eligibility, CHA₂DS₂-VASc, and Biosample Collection.

6 Screening Visit CRFs will now display in WebDCU *only* if subject is randomized:

Laboratory Tests; Short IQCODE; Concomitant Medications Checklist (for use within 7 days preceding index event); Alcohol/Tobacco Use (at index event); Imaging Collection; Imaging Read

NOTE: Although most screening data won't be entered in WebDCU until subject is randomized, all Screening Visit assessments should be completed as soon as possible after consenting to minimize the time needed for data collection at Baseline Visit.

❑ Baseline procedures for subjects residing in facility (section 10.1)

Added advice to follow for subjects who reside in rehab/other outside facility at time of enrollment.

❑ Procedures for remote consent/baseline/follow-up visits

Instructions from the standalone *ASPIRE Remote Study Visit Procedures* document have been incorporated throughout.

Data Collection Guidelines v5.0 Posted



Data collection schedule revised to reflect current protocol.

HCP Notification of Blood Pressure over Goal

Template letter posted in ASPIRE Toolbox.

ASPIRE CONTACT INFORMATION

24/7 Hotline: (800) 618-0643

ASPIRE@YALE.EDU

Principal Investigators Kevin Sheth (443) 615-4729 and Hooman Kamel

Project Managers NCC: Laura Benken (513) 558-3925

Yale: Catherine Viscoli (203) 927-0443