SISTER

ISSUE NO 1 | January 23, 2025 | VOLUME 3

Sites in the News

M Health Fairview Southdale Team

Congratulations on your 2nd enrollment, #114, on 11/10/2024

Thanks for all of your efforts for the SISTER Study!

Pictured left to right: Dr. Affan (PI), Saketh Annam, Jessica Staloch (PSC), Abbey Staugaitis (SC), Jessica Gieseke (SC), Erica (med student), Ahmed Hasan (SC-Research Fellow), Garcia (med student)

JFK Team

Congratulations on your 1st enrollment, #121 on 1/15/2025

Persistence pays off!

Pictured left to right: Suanne Fleyzor APN, Dr. Nancy Gadallah (PI), Latoya Stewart RN, Surekha Patel, Jasmeen Johal MD, Sara Strauss DO, Alexandra Burbelo RN

Calendar of Events

SISTER Jan/Feb Webinar 1/30/2025
SISTER March Webinar 3/6/2025
SISTER Investigator Meeting 4/24-25/2025
SC Office Hour 2/11/2025
SISTER CR Meeting 3/12/202

Enrollment

20/300

6.6% of target enrollment

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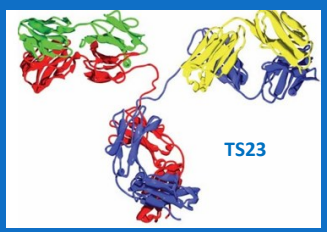
The next best treatment for stroke patients!



Biospecimen Shipments

- **Sites with July and August 2024 enrollments will be contacted by RCL the second week of February (not to interfere with the ISC meeting) to schedule return biospecimen shipments.**
- **Please make sure that your lab address and contact information in WebDCU is updated if things have changed.**

SISTER Investigator Meeting

Don't forget to keep your calendar open for our IM in Miami, Florida on April 24–25, 2025.

More information to come on booking flights and hotel.

- **We will fund PI & PSC (hotel for 1 night & flight reimbursement up to $500 each)**
- **Free shuttle to & from Miami International Airport every 15 minutes**
- **Meals Included - 4/24/2025 Group Dinner; 4/25/2025 Breakfast, morning snack, working lunch, afternoon snacks**

Reminders, Updates & Tips

- Protocol Deviations are occurring at a rate higher than expected. Please make sure to follow the protocol and windows for each and every visit. Please use the visit checklists uploaded into the toolbox.

  Most common PDs: timed labs out of window, visits out of window, mRS not being collected using RFA method, missing SOC labs and fibrinogen levels

- When dismissing rule violations, please be as specific as possible and do not put the response in the General comments field. You must put the reason for dismissal in the violation itself by clicking on the pencil icon.
- Data entry timeline reminders:

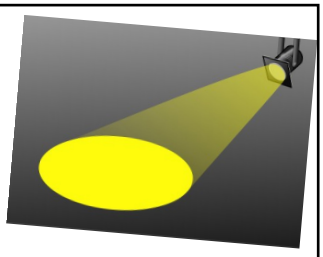
  1. CRFs and Screen Failure forms should be submitted within 5 days of collection. Two exceptions are F206 Study Drug Administration that should be submitted within 8 hours of study drug administration and SAEs should be submitted on F104 within 24 hours of knowledge of the event.
  2. Queries need to be responded to within 5 days of query generation. This excludes SAEs as those queries should be responded to within 24 hours.

- F1572 - If you make a DoA change that affects the investigators on your F1572, you must update the document and have it resigned and dated. Please upload the amended document for review.
- In the event that your site has a temperature excursion, please note that the communication needs to come from the site pharmacy to the central pharmacy. Do not include any other site or study team members as this may unblind the team.
- After consent, all assessments must be completed by a blinded, certified study team member. This includes mRS & NIHSS.
- Please keep your "people" regulatory documents up to date. If any of the certifications expire, you will need to upload a NTF with your updated certificate stating whether or not screening or enrollment was affected.
- NDMC would like you to complete a survey on your use of WebDCU & Training Topics to better understand the needs of their users. Visit the link below.

https://forms.office.com/Pages/ResponsePage.aspx?id=yVlKXGtt4E2IwFOs1Wa_g7t6_dPTvjNHvFA1Ca9yYkJUNk9QSzFaWjc1SVQ0OTgzS0g2OVNYRVY4Uy4u

Spotlight on Sites

Sites with Recent Randomizations



#116 UAB on 11/27/2024

#117 UC on 12/4/2024

#118 University of Chicago on 12/12/2024

#119 KP LA on 1/2/2025

#120 UCSD Health La Jolla

New Sites Released to Enroll

SUNY Upstate - Released to enroll 12/16/2024

Brigham and Women's Hospital - Released to enroll 1/16/2025

We are currently having issues with our Screen Failure Log

The WebDCU team is currently aware and working on the issue. If you continue to have issues adding patients to the log, please reach out to the study team.

A special thanks to UAB's PI, Dr. Felix Guerra for presenting their site's enrollment experiences. Enrolling back-to-back subject's is quite the accomplishment! Your dedication is greatly appreciated!

RAPID AI Completion of Installation

Please remember to continue to work through the RAPID AI process with the RAPID AI Team. This is mandatory for trial participation.

After you are released to enroll, you can continue to use your current software until the installation has been completed. The expectation is that you complete installation within 3 months of site release. Non-responsiveness to installation requests & progress will trigger a call with the National PIs.

Please work with your hospital IT departments to ensure a smooth & timely installation.

Please reach out to Natalie Zaba (zaba@rapidai.com) or Brandon Berger (berger@rapidai.com) for assistance.

Please reach out for any questions!

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Noor Sabagha Chris Unger	Central Pharmacists	Unblinded	sistertrialrx@ucmail.uc.edu	(513) 584-3166
Riley Luckmann	Data Manager	Blinded	Luckmann@musc.edu	(843) 792-2077
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SISTER is on X