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SISTER

Volume 2, Issue 5

May 16, 2024



We have a Winner!

Yale New Haven Hospital

May 2, 2024 Randomized the 1st Subject
into the SISTER Trial!

Congratulations on a job well done!



2nd Subject Randomized

May 9, 2024

Congratulations! OSU Wexner

We're on a roll!



SISTER by the Numbers:

- **All of our 44** sites have executed their CDA

- **31** sites have executed their CTA
 - **29** sites received cIRB approval; 5 sites pending approval
 - **21** sites have completed their readiness calls
-

12 Sites Are Now Released To Enroll!



**Our Newest Sites
that have been
Released to Enroll**

Barnes Jewish Hospital

PI: Dr. Charles Kircher PSC: Matt Lewis

OSU Wexner Medical Center

PI: Dr. Jan Bittar PSC: Luke Herren

The Mount Sinai Hospital

PI: Dr. J. Mocco PSC: Cynthia Nguyen

M Health Fairview University of Minnesota Medical Center

PI: Dr. Muhammad Affan PSC: Jessica Staloch

M Health Fairview Ridges Hospital

PI: Dr. Muhammad Affan PSC: Jessica Staloch

M Health Fairview Southdale Hospital

PI: Dr. Muhammad Affan PSC: Jessica Staloch

Mount Sinai West

PI: Dr J. Mocco PSC: Cynthia Nguyen

Released Sites

Please make sure that you are entering your screen failures into the screen failure log in WebDCU within 5 days.

The SISTER study team is reviewing the screen failures weekly for any criteria that may be too restrictive.





June 6, 2024 4p-5p ET

Don't forget to attend our monthly webinar. We will focus on Pharmacy training, including compounding the study drug and administration. All are invited.

Email reminders will be sent.

[https://ucincinnati.zoom.us/j/94103284316?
pwd=aTFZb3diTEkvK09qaGFJWUJVBkIDZz09](https://ucincinnati.zoom.us/j/94103284316?pwd=aTFZb3diTEkvK09qaGFJWUJVBkIDZz09)

Meeting ID: 941 0328 4316 Passcode:201377

SISTER Site Shout Outs



**A special congrats to the following sites for completing their
site readiness calls:**

UVA

**Christiana Hospital
University of Utah Healthcare
University of Chicago Medical Center
Massachusetts General Hospital**



Congratulations to the following site for receiving cIRB approval:

**Jackson Memorial Hospital
M Fairview University of Minnesota Medical Ctr
M Health Ridges Hospital
M Health Southdale Hospital
NYU Langone Hospital, Brooklyn
Wake Forest Baptist Medical Center
University of Alabama Hospital, Birmingham
PRISMA Health Greenville Memorial Hospital**

Congratulations to the following sites for executing their CTA:

**University of Chicago Medical Center
Wake Forest Baptist Hospital**

SISTER Site Race to Activation

Race to Activation								
Site Name	CDA Executed	CTA Executed	CIRB Approval	Essential documents uploaded	Required Trainings	DOA Accepted	Site Readiness Call	Released to enroll
Ascension St. John								★
Banner Health/UofA							0.00	
Barnes Jewish Hospital								★ 8.00
Brigham and Women's Hospital								
Buffalo General								
Christiana Hospital								★
Duke University Hospital								
Grady Memorial Hospital								★
Harborview Medical Center								★
Houston Methodist Hospital								
Jackson Memorial Hospital								
JFK Neuroscience Institute								
Kaiser Permanente Los Angeles								★ 8
M Health Fairview Ridges Hospital								★ 8
M Health Fairview Southdale								★ 8
M Health Fairview Univ of MN								★ 8
Massachusetts General Hospital								★
Mayo Clinic Phoenix								
Memorial Hermann Texas								
Methodist University Hospital								
Mount Sinai Hospital								★ 8
Mount Sinai West								★ 8
MUSC								
North Shore University Hospital								
NYP Columbia								
NYU Langone Hospital Brooklyn								★
OSU Wexner Medical Center								★ 8
Prisma Health Greenville								★
Rhode Island Hospital								★
SUNY Upstate								
Sutter Medical Center				0.50				
Temple University Hospital								★
UCSD Health La Jolla								★
UCSD Hillcrest Hospital								★
UF Health Shands Hospitals								★
United Hospital								★ 8
University of Alabama Hospital								
University of Chicago								★
University of Cincinnati								★ 8
University of Iowa Hospital								★ 8
University of Utah								★
UVA Medical Center								★
Wake Forest Baptist								★
Yale New Haven Hospital								★ 8



Get your Gold Star!

SISTER Site Readiness Calls



We are scheduling readiness calls when you have an executed CTA, cIRB submission or approval, DoA entered and the majority of your documents uploaded into WebDCU

Central Pharmacy Reminders

- The pharmacy members listed on your DoA need to complete the pharmacy training for compounding the study drug and supplying the placebo.
- Please make sure to print the pharmacy documents from WebDCU and insert into your pharmacy binder to be available for all pharmacists to use. Examples of documents are below.
- After you have prepared the study drug, you will need to enter the vial numbers used into WebDCU. This is imperative to receive replacement vials. If it can't be done immediately then please save the vials for later input. It's suggested to take a picture of the vials with the numbers visible in case the empty vials are inadvertently discarded.
- Please remember that study teams are blinded except for pharmacy. Please communicate site pharmacy to central pharmacy if the topic for discussion is unblinded information.
- If you have any questions at all, please call the Central Pharmacy at (513) 884-3166

EXAMPLE SISTER Randomization Code List	
4-Letter Randomization Code	Treatment Arm
JDVS	PLACEBO
FDOG	PLACEBO
JAND	3.0 mg/kg (Max. 3 Vials)
OISD	3.0 mg/kg (Max. 3 Vials)
LKDG	5.0 mg/kg (Max. 5 Vials)
OURY	5.0 mg/kg (Max. 5 Vials)
NMSH	7.0 mg/kg (Max. 7 Vials)
ABCD	7.0 mg/kg (Max. 7 Vials)
NATS	10.0 mg/kg (Max. 10 Vials)
RQYW	10.0 mg/kg (10Vials)

Table 1: Dosing Based on Subject Weight (mg/kg)

Weight (kg)	TS23 dose (mg)				
	placebo 0 mg/kg	3 mg/kg	5 mg/kg	7 mg/kg	10 mg/kg
<60	0	180	300	420	600
60 to <70	0	210	350	490	700
70 to <80	0	240	400	560	800
80 to <90	0	270	450	630	900
>90	0	300	500	700	1000

**MAX DOSE
OF TS23=
1000 MG**

0.9% NaCl Volume to be Removed from 250 mL IV Bag (ml)					
Weight (kg)	placebo 0 mg/kg	3 mg/kg	5 mg/kg	7 mg/kg	10 mg/kg
<60	50	68	80	92	110
60 to <70	50	71	85	99	120
70 to <80	50	74	90	106	130
80 to <90	50	77	95	113	140
≥90	50	80	100	120	150

Weight (kg)	Placebo 0 mg/kg		3 mg/kg		5 mg/kg		7 mg/kg		10 mg/kg	
	TS23 (mL)	0.9% saline (mL)	TS23 (mL)	0.9% saline (mL)	TS23 (mL)	0.9% saline (mL)	TS23 (mL)	0.9% saline (mL)	TS23 (mL)	0.9% saline (mL)
<60	0	200	18	182	30	170	42	158	60	140
60 to <70	0	200	21	179	35	165	49	151	70	130
70 to <80	0	200	24	176	40	160	56	144	80	120
80 to <90	0	200	27	173	45	155	63	137	90	110
≥90	0	200	30	170	50	150	70	130	100	100

SISTER Updates, Reminders & Tips

Readiness Calls

1. Please be prepared for the readiness calls by having all documents uploaded & approved prior to the call.

2. If documents are in order, we will try to ship the IP & lab supplies prior to your call, otherwise we will need to wait until after your call has been completed.

Informed Consents

If a patient signs an informed consent and is not randomized into the study, **do not** discard this document. It must be maintained in your site regulatory binder as it's a legal document.

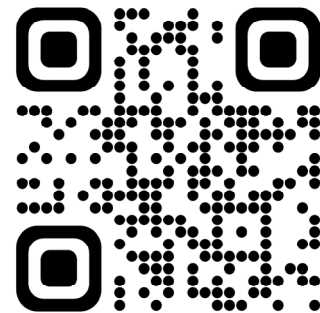
Certificates - mRS, NIHSS, Shipping

Do not let your certificates expire. If they do expire you will need to upload an updated certificate into WebDCU with a Note to File explaining why the certificate expired and if it affected a subject's assessment.

SISTER is on X

If you haven't already, **follow us on X**
@SISTERtrial

We are using the platform for announcements,
shout-outs, and a space to "gather" virtually.





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