StrokeNet Thrombectomy Endovascular Platform Newsletter

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"It is not enough to stare up the steps, we must step up the stairs."

-Vaclav Havel



<u>Sir Austin Bradford Hill</u>, an English epidemiologist and statistician, conducted the first randomized controlled trial in Medicine in 1948. The <u>trial</u> was to treat the lung disease tuberculosis.

Bradford Hill decided whether a patient should be treated with the antibiotic streptomycin plus bed rest, or bed rest alone, by using a table of random numbers.

The investigators didn't know which patient got each treatment; details were in sealed envelopes. Patients were not told they were in

Central IRB (cIRB)/Regulatory/CTA Documents

All sites received Regulatory Documents and CTAs.

Sites are expected to have cIRB documents completed for submission to the UC IRB and CTAs executed by July 16th (StrokeNet goal of 4-6 weeks from receipt)

STEP Study Start-Up Timelines				
May 2024	UC StrokeNet NCC issued cIRB/Regulatory documents to sites			
June 2024	UC StrokeNet NCC issued CTA to sites			
July 2024	Sites to complete cIRB documents for submission and CTAs for execution			
August 2, 2024	Half-day Virtual Investigator Meeting			
Late Summer 2024	Site Readiness Calls			
Fall 2024	First Participant Enrolled			

Save the Date!

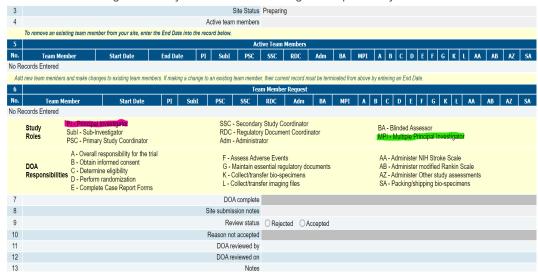


The STEP Virtual Investigator Meeting will be held on August 2, 2024 from 12- 4:30 EDT

Calendar invite forthcoming

Please complete your sites DOA with a minimum of the PI, MPI & PSC as soon as possible.

STEP is a little different than other StrokeNet trials since all STEP sites have 2 primary investigators, an endovascular and a non-endovascular. The **Principal Investigator (PI) role** should be assigned to the person you designated as the **Regulatory PI** on the Investigator Information Form. The other investigator (either the endovascular or non-endovascular physician listed on the CTA) should be listed as the **Multiple Principal Investigator (MPI)**. All other investigators should be listed as Sub-Investigators. Only the PI should be assigned responsibility "A".





Find all things STEP at:

https://nihstrokenet.org/trials/step-trial/home

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STEP Email Address

Please email non-urgent trial related questions to: STEP@uc.edu

WebDCU™

The STEP Regulatory Documents database is now available in WebDCU[™] under the STEP icon.



Please remember to upload all documents as a PDF.

The Regulatory Parameters Document is now available in the STEP Toolbox.

Congratulations to...





First sites to have a fully executed CTA!

- * UCSD- Drs Khalessi and Meyer; Karen Rapp, Teri McClain, and team
- * UCMC-Drs Demel and Shirani; Christina Mihova, and team

And

First sites to submit to the UC IRB!

- Barnes Jewish/Washington University-Drs Hooper and Chatterjee; Jenny Babka and team
- Kaiser Permanente LA-Drs Sangha and Feng; Ashima Sharma and team

AHA GWTG-Stroke/NVQI-QOD Agreements

AHA GWTG-Thank you to those sites that have already executed the AHA GWTG-Stroke agreement amendment. AHA resumed sending reminder emails regarding the GWTG-Stroke amendment this month to those sites that have not yet executed the amendment. All STEP sites are required to participate in the AHA GWTG-Stroke registry.

NVQI-QOD-STEP sent an email to sites regarding the NVQI-QOD agreement. Participation in the NVQI-QOD registry is not required, but is encouraged! NVQI-QOD has agreed to provide complimentary access for up to 38 participating STEP sites. If your site already participates in NVQI-QOD, the annual fee for the stroke module will be waived during participation in the STEP trial. If your site does not already participate, the NVQI-QOD will provide complimentary access to the registry, as long as your site is participating in at least one STEP domain.

Anne Murphy

NCC Financial Specialist

New STEP Proposals

NINDS has reported that the six preliminary applications submitted for consideration of new studies for the STEP platform are being reviewed by an external peer review committee on July 15, 2024. Proposals that are evaluated to be a high priority and approved by NINDS to proceed to Stage 2 will be sent to the STEP executive committee to begin protocol development. NINDS will continue to evaluate new proposals on a rolling basis.

The OTA for new proposals for STEP can be found at:

OTA-24-009 STEP Domain Clinical trials - Stage 1

Preliminary Application (nih.gov).

Per-subject payment questions.

one STEP domain.				
CONTACT LIST				
STEP Primary Study Contacts				
Title and Responsibility	Name	Contact Information	When to Contact	
Prime Project Manager	Harriet Howlett-Smith, RN	howletha@ucmail.uc.edu	Study related clinical or trial operations questions.	
NCC Project Manager	Melissa Hoffman	hoffm2ma@ucmail.uc.edu	Study or trial operations questions, regulatory and cIRB submissions, site payments.	
NDMC Data Manager	Faria Khattak, MPH	khattak@musc.edu	Study related data management questions.	
NDMC Site Monitoring Manager	Caitlin Schaffner, MPH	schaffne@musc.edu	Study related data management questions.	
UC StrokeNet NCC Contacts				
Title and Responsibility	Name	Contact Information	When to Contact	
NCC Regulatory Compliance Specialist	Jennifer Golan, MS	golanjl@ucmail.uc.edu	Questions about <i>initial</i> cIRB submission and cIRB modifications.	
NCC Contract Specialist	Wren Hanson	hansonwm@ucmail.uc.edu	Questions regarding CTAs.	

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