June 2024

STEP by STEP

StrokeNet Thrombectomy Endovascular Platform Newsletter

In this issue:

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

-Vaclav Havel

Sir Austin Bradford Hill, an English epidemiologist and statistician, conducted the first randomized controlled trial in Medicine in 1948. The trial 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 a trial.

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".

3	Site Status	Preparing
4	Active team members	

To remove an existing team member from your site, enter the End Date into the record below.

5	Active Team Members																								
No.	Team Member	Start Date	End Date	PI	SubI	PSC	SSC	RDC	Adm	BA	MPI	A	B	C	D	E	F	G	K	L	AA	AB	AZ	SA
No Records Entered																									

Add new team members and make changes to existing team members. If making a change to an existing team member, their current record must be terminated from above by entering an End Date.

6	Team Member Request																							
No.	Team Member	Start Date	PI	SubI	PSC	SSC	RDC	Adm	BA	MPI	A	B	C	D	E	F	G	K	L	AA	AB	AZ	SA
No Records Entered																								

Study Roles
PI - Principal Investigator
SubI - Sub-Investigator
PSC - Primary Study Coordinator
SSC - Secondary Study Coordinator
RDC - Regulatory Document Coordinator
Adm - Administrator
BA - Blinded Assessor
MPI - Multiple Principal Investigator

DOA Responsibilities
A - Overall responsibility for the trial
B - Obtain informed consent
C - Determine eligibility
D - Perform randomization
E - Complete Case Report Forms
F - Assess Adverse Events
G - Maintain essential regulatory documents
K - Collect/transfer bio-specimens
L - Collect/transfer imaging files
AA - Administer NIH Stroke Scale
AB - Administer modified Rankin Scale
AZ - Administer Other study assessments
SA - Packing/shipping bio-specimens

7	DOA complete	
8	Site submission notes	
9	Review status	○ Rejected ○ Accepted
10	Reason not accepted	
11	DOA reviewed by	
12	DOA reviewed on	
13	Notes	

STEP Website

Find all things STEP at:

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

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.

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).

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 *initial* cIRB submission and cIRB modifications.
NCC Contract Specialist	Wren Hanson	hansonwm@ucmail.uc.edu	Questions regarding CTAs.
NCC Financial Specialist	Anne Murphy	strokenettrialpymts@ucmail.uc.edu	Per-subject payment questions.