May 2024

One STEP Ahead

StrokeNet Thrombectomy Endovascular Platform Newsletter

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"The most important step of all is the first step. Start something."

-Blake Mycoskie

May 20 was International Clinical Trials Day

In 1747, Dr. James Lind tested several scurvy treatments on crew members of the British naval ship Salisbury and discovered that lemons and oranges were the most effective in treating the condition. Lind is considered the first physician to have conducted a controlled clinical trial of the modern era.

May 20 is known as International Clinical Trials Day, because Lind's celebrated controlled trial began on that day in 1747.

Central IRB (cIRB)/Regulatory/CTA Documents

Initial STEP cIRB (UC IRB) and Regulatory documents were sent to sites the week of May 20th. Please contact Jennifer Golan (golanjl@ucmail.uc.edu) if you did not receive the STEP cIRB and Regulatory documents email.

CTAs will be sent from the UC Contracts office directly to your sites contract office no later than May 31st.

Sites are expected to have cIRB documents completed for submission to the UC IRB and CTAs executed within 4-6 weeks of receiving cIRB and CTA documents.

STEP Study Start-Up Timelines

May 2024	UC StrokeNet NCC issued cIRB/Regulatory documents to sites
May 2024	UC StrokeNet NCC to issue CTA to sites
June/July 2024	Sites to complete cIRB documents for submission and CTAs for execution within 4-6 weeks of receipt
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 EDT

Calendar invite forthcoming

AHA GWTG-Stroke/NVQI-QOD Agreements

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

STEP will soon be sending 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.

STEP Email Address

STEP now has an email address for non-urgent trial related questions. Please email your questions to:

STEP@uc.edu

STEP Website

Find all things STEP at:

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

WebDCU™

The STEP Regulatory Documents database will be available in WebDCU™ very soon.

New STEP Proposals

NINDS has reported to us that six preliminary STEP applications have been submitted for consideration of new studies to be added to STEP. These proposals are currently being evaluated and reviewed by NINDS, which will include an external peer review of the application. 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).

STEP Shoutout!

"A big shoutout to all the STEP team members who are tirelessly working on STEP startup. Our clinical and national coordinating center project managers, Harriet and Melissa; contracts managers, Wren and Sasha; and the IRB coordinator, Sue, are superstars. Our national data management center team members are absolutely amazing– Caitlin, Faria, Catherine, Jessica, Wenle, Keith, and Jonathan. Lastly, thank you to all the sites for working with us through this startup process and returning the AHA contracts when possible. We are looking forward to sending CTAs this week after sending the cIRB packets a few days ago." -Eva Mistry

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.