STEP BY STEP



StrokeNet Thrombectomy Endovascular Platform Newsletter

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Message From the NIH and STEP MPIs...

Welcome to the first edition of the **STEP** newsletter! We are very excited to take this first "step" together with you on what will hopefully be one of the most important trials to come out of the NIH StrokeNet!

Clinical Trial Agreement (CTA)

We appreciate your patience while we finalize the CTA template.

Central Institutional Review Board (cIRB)

We now have the University of Cincinnati cIRB approval for the STEP trial!





We are hopeful that CTAs and cIRB/
Regulatory Documents can be sent in the near future!

Updated STEP Study Start-Up Timeline

IMMEDIATELY!



| Start-Up Timeline | | | |
|-------------------|---|--|--|
| February 2024 | Sites selected | | |
| May 2024 | UC StrokeNet NCC to issue CTA to sites | | |
| May 2024 | UC StrokeNet NCC to issue cIRB packet to sites (UC IRB) | | |
| Early Summer 2024 | Sites to complete CTA and cIRB packets within 4-6 weeks of receip | | |
| Summer 2024 | Half-day Virtual Investigator Meeting (mid-July) | | |
| Late Summer | Site Readiness Calls | | |
| Fall 2024 | First participant enrolled | | |

STEP will allow the addition of performance sites if ALL of the following conditions are met: 1. The performance site is covered under the same IRB approval as the selected site (one IRB submission with two enrolling locations listed on the consent). 2. The performance site will be covered under the same CTA (The annual Site PI and Coordinator payment will not be increased for adding an additional performance site is covered under the same GWTG agreement (i.e. has the same hospital ID). OR The performance site's data for STEP randomized participants will be directly entered into WebDCUTM. If you plan to add a performance site, please notify Harriet Howlett-Smith and Melissa Hoffman

Get With The Guidelines (GWTG) Agreements

Thank you to those sites that have already executed the GWTG amendment.

We recognize that some sites will not be able to execute the GWTG agreement until the CTA/cIRB approval for the site is in place. If you have not done so already, please let us know if that is the case at your site so we can let the AHA team know not to email you until your site's CTA/cIRB approval are in place.



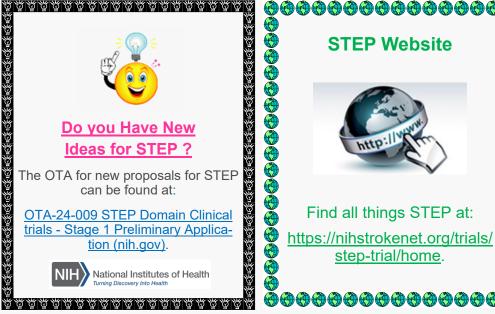


Investigator Meeting

STEP will have a half-day virtual Investigator Meeting in mid-July.

Calendar invite to follow.

Stay tuned for more information!





NIH StrokeNet Education

There is now an Education tab located on the NIH StrokeNet website. You will find educational resources for Fellows, Clinical Research Professionals, and Regional Coordinating Center Managers. These educational resources can be found at: https://www.nihstrokenet.org/strokenet-education.

| STEP Primary Study Contact List | | | | |
|---|-------------------------------|---------------------------------------|--|--|
| 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 Contact List | | | | |
| 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. | |
| NCC Financial Specialist | Anne Murphy | strokenettrialpymts@ucmail.u c.edu | Per-subject payment questions. | |