StrokeNet Enrollment Update

ARCADIA	504/1100	CREST 2	1715/2480
Sleep SMART	314/3062	CREST H	157/500
TRANSPORT2	15/129	MOST	78/1200
I-ACQUIRE	27/240	ARCADIA-CSI	76/500
ASPIRE	1/700	SATURN	15/1456

StrokeNet Trial Updates

TRANSPORT2

Our next PI and Coordinator call will be on **Monday, 9/28/2020 at 11am ET**. If anyone has topics they would like to discuss during the call, please send them to Kristina Balderson (Kristina.balderson@duke.edu) or Julia Gonzalez, (Julia.jackson@duke.edu).

As sites are working to reopen to enrollment, please take inventory of your supplies and contact either Julia Gonzalez or Kristina Balderson for restock. When reaching out, please indicate the number of supplies needed, contact, and shipping location with confirmation that someone will be able to receive these shipments. Home addresses are approved for receiving shipments during this time of remote working or limited time at the site. For other questions or concerns, please contact Julia or Kristina.

Please make sure you have completed your BlueCloud recertification training by logging into the website: http://duke-transport2.trainingcampus.net. Individuals who have expired or about to expire training have been sent reminder emails. **Note this is for the scoring of the Fugl Meyer, not the video training.** Annual renewal is now being tracked in WebDCU™, which will notify coordinators directly when any of their staff have outdated training.

Seven sites have reopened to enrollment! Congratulations to Baystate, Duke, Medstar, Kentucky, UAB, USC, and Moss for being re-open to enrollment amidst the COVID-19 restrictions. Cleveland VA is under IRB review and UPMC is finalizing study start-up activities. We are hopeful that our remaining sites will be reopened to enrollment soon!! There are 15 subjects randomized in the trial, and seven have completed the study.

Thank you for your continued effort and flexibility during this time!

Thank you for your participation in Sleep SMART. We truly appreciate all your hard work, especially during this difficult time.

As of September 24, 2020, 934 subjects have been enrolled and 312 subjects have been randomized.

Congratulations to Kwan Ng, MD, Amy Hyatt, and the entire UC Davis Sleep SMART team for randomizing their first subject in September!

Two key reminders:
1. Please complete all 3-month assessments within window. These can be done by phone, if needed. The 3-month mRS is a primary outcome for Sleep SMART!
2. Please complete a "warm transition" for intervention subjects some time prior to discharge. This contact between intervention subjects and the FusionHealth Care Team helps facilitate CPAP adherence post-discharge.

CONTINUING REVIEW: The annual continuing review (CR) forms were distributed to sites by email on August 13th and were expected to be returned to sicklejb@ucmail.uc.edu by September 4th. If you have not returned your forms, please take time to carefully read the email instructions and return the forms immediately.

INFORMED CONSENT IMPLEMENTATION FORM: **All sites, even if you do not plan to use remote consent, will need to complete an Implementation form.** Please return forms to sicklejb@ucmail.uc.edu.

RE-OPENING: In WebDCU™, please update the COVID Impact Assessment survey to reflect the current status of research at your institution and, if you are ready to re-start enrollments, to indicate confirmation (in 'general comments') of the statements in the memo dated May 15, 2020. Email Kayla or Joelle to let them know when your site is ready to be re-released to enroll. Pending NDMC queries may delay our ability to release you, so please catch up on these. **You will not be released to enroll until you receive official notice from WebDCU™.** Since our re-opening, 62 sites have been released to enroll and conduct in-person activities and 58 subjects have been randomized. If your site is not ready to enroll, but is able to complete in-person 3- and 6- month assessments, please contact Kayla or Joelle to seek permission for these limited in-person activities.

<u>Sites not previously released to enroll</u>:

If your site was not previously released to enroll, please continue to work toward site activation:

- CIRB submission
- Finalize the Clinical Trial Agreement and FusionHealth DUA and Consignment agreement
- Upload site and people documents to WebDCU™
- Complete online trainings (https://webdcu.musc.edu/campus/)
- Complete readiness call (must have all contracts completed before this can be done)
- Please review the site to-do checklist found in the WebDCU™ toolbox

Save the date-FusionHealth Virtual Hands-On Workshop will be Wednesday, October 21, 2020 from 11-4 EST. A Zoom link invite will be sent the week prior to the workshop. All are welcome!

Congratulations!

New Haven enrolled participant 3 on 9/21/2020.

Total study enrolled as of 9/24/2020 = **27**

Save the dates: Upcoming PI/Co-I/Coordinator Webinar:

- ❖ Thursday 08 October (12-1pm ET)
- ❖ Thursday 12 November (12-1pm ET)
- ❖ Thursday 17 December (12-1pm ET)

Note: Max Mays will be contacting Study Coordinators to gather documentation for the 2020 I-ACQUIRE Continuing Review.

MOST Enrollment Update:
Total randomizations: **78**
Randomizations between 09Sep2020 and 23Sep2020: **4**
Sites released to enroll with at least one patient consented: **28**
There are now **70** sites that have been released to enroll, **57** of which are actively recruiting!

- Congratulations to the following sites that have randomized a subject in the past two weeks!
    - o McLaren Flint – Dr. Majjhoo and Marci Roberts **(4 total subjects!)**
    - o M Health Fairview Southdale Hospital – Dr. Bentho and Megan Tessmer **(9 total subjects!)**
    - o St. Louis University Hospital – Dr. Linares and Andre Guthrie **(1st subject!)**
    - o University of Chicago Medical Center – Dr. Kramer and Vikrant Chauhan **(3 total subjects!)**

- Congratulations to Santa Barbara Cottage Hospital who has been released to enroll!

The Most Investigator Call occurred on 21Sep2020. Topics discussed included current enrollment status and challenges, pharmacy process review and best practices. Thank you to everyone that attended the call and for keeping the MOST Trial a priority! A recording of the webinar can be found at http://nihstrokenet.org/most/webinars.

Please remember to update your **Delegation of Authority logs** to reflect current and active team members. The email distribution list for study-wide correspondence is generated through site DOA lists.

The **PI Hotline** is available 24/7 for any questions: **1-833-229-MOST**.

ARCADIA hits 500 patients! And keeps going!

Our month by month randomization numbers have been increasing. We have randomized 503 participants, an increase of 9 in less than two weeks. A special thanks to the nine teams that provided the last two weeks' randomizations: UVA Medical Center, Charlottesville, VA; Methodist University Hospital, Memphis, TN; St. Louis University Hospital, St. Louis, MO; Memorial Hermann Texas Medical Center, Houston, TX; Harborview Medical Center, Seattle, WA; UPMC Presbyterian Hospital, Pittsburgh, PA; Tampa General Hospital, Tampa, FL; NYP Columbia University Medical Center, New York, NY and University of Utah Healthcare, Salt Lake City, UT. This is definitely a team effort!

We are currently at 1895 subjects enrolled/consented, an increase of 28 in the last two weeks, thanks to 25 sites, with many sites enrolling more than once during this period – thank you to the site teams making this possible! A special thanks to Vanderbilt, TN and Memorial Hermann, TX who enrolled twice during this period!

We currently have 115 sites that completed their re-start or started new since the COVID pause. We also have another 18 sites working towards being released to enroll for the 1st time. Let us know if you know of a good site who would like to participate in ARCADIA.

Overall, 138 of the 150 sites ever released to enroll have consented at least one subject and 105 sites have randomized at least 1 participant. The ARCADIA teams have shown commitment and perseverance despite the many challenges that have come our way – thank you all!

We would also like to welcome the West Los Angeles VA Medical Center team in California as they have just been released to enroll this past week!

We hope to continue to re-start sites as per the ARCADIA re-start plan for the 20 sites still pending re-release to enroll. We understand many of your sites cannot yet re-start, but those that can re-start enrollment, even if only remotely, please reach out to Rebeca (ra2356@cumc.columbia.edu) to review any pending items needed for your re-release. PLEASE do not start enrolling new subjects until your site has been re-released to enroll.

We understand that the enrollment challenges will change from site to site during this pandemic, but this is also a good time to assess performance from initial startup and see if there is anything that can be done to improve the enrollment at sites that have not been able to consent or randomize for a while prior to COVID. We will be reaching out to you and the RCCs about this in the coming weeks.

PLEASE do not change the CALM lab address on your sample shipments as the lab has not yet finalized their move so that sample is not missed (use address on Lab MOP p. 11). We will send out an email when the move has been completed.

As discussed in this month's webinar, send us the stories of the challenges you and your team members have overcome enrolling in ARCADIA.

We thank you for your continued support and effort during these challenging times, but together we can move forward in ARCADIA.

Webinar: Our next PI and coordinator webinar will be October 27nd at 2 PM Eastern--save the date! We're asking that at least 1 person from each site attend the monthly webinar and pass the information along to their team. Also, please send suggestions for topics you'd like discussed.

If you miss out on a webinar, you will soon be able to find the slides on the StrokeNet website https://www.nihstrokenet.org/intranet/minutes/trial-webinars

Thank you to all the sites for your hard work in enrolling subjects into ARCADIA-CSI! We are now approved for eConsent. Please let us know if your site would like to use eConsent.

The study team would like to welcome **Emory University and UPMC Presbyterian Hospital to ARCADIA-CSI!**

Our top 3 enrolling sites are:
8 PATIENTS ENROLLED
UNIVERSITY OF IOWA
ENRIQUE LEIRA & HEENA OLALDE

7 PATIENTS ENROLLLED
UNIVERSITY OF CINCINNATI
POOJA KHATRI & JENNIFER POWERS

6 PATIENTS ENROLLED
GREENVILLE HOSPITAL
PAULO ZORTEA & VICTORIA HOLT

We need your help enrolling patients into the ARCADIA-CSI substudy! We have created Form 515 to make screening a breeze. When a patient is randomized in ARCADIA, Form 515 is posted in the patient's ARCADIA binder in WebDCU™. This form serves as the ARCADIA-CSI screening form and as a reminder to reach out to the patient to ask if (s)he would like to join ARCADIA-CSI.

Please complete the Covid19 Impact Assessment in WebDCU™ as soon as possible.

Contact Tashia Harris, herndotl@ucmail.uc.edu or Stephanie Kemp, skemp@standford.edu with any questions.

SATURN has 67 sites open for enrollment and has randomized 15 patients!

SATURN held the monthly PI/Coordinator Webinar 9/24/2020, if you were unable to attend please find the recording here: https://www.nihstrokenet.org/saturn-trial/home There were reviews on lab shipping, reporting screen failures and also consent procedures.

Please continue to update the COVID Impact Assessment with information on anticipated timelines for resuming research activities. Please reach out to the study team when your site is able to resume research activities. We will assist you with opening for enrollment when local restrictions allow.

Please upload all outstanding documents to WebDCU™ and address any expired documents.

The SATURN CR was approved at the board meeting on 9/23/2020. Once documents are available they will be distributed to each site.

Sites that have not yet been released to enroll should complete the COVID Impact Assessment once they have been activated.

MGH is shipping lab kits out to sites who have completed a readiness call. Please remember to confirm receipt of the lab kits in WebDCU™ upon receipt.

SATURN is actively looking to add sites; please reach out for further details.

If you have any questions regarding SATURN and reopening enrollment at your site please contact:
Kimberlee Bernstein NCC Project Manager gammk@ucmail.uc.edu
Sarah Marchina Prime Project Manager (BIDMC) smarchin@bidmc.harvard.edu

- Randomization into the ASPIRE study were paused on July 8 due to an issue with study drug stability. We expect sites will start to receive new drug ASAP. We are encouraging sites to continue screening and consenting patients. Sites who have consented patients will be restocked first.
- Documents for the ASPIRE Continuing Review were sent to sites this week. Site must return the Continuing Review form, Financial Conflict of Interest form(s), and (if applicable) redacted informed consent documents to ASPIRE@yale.edu by October 1, 2020.
- All sites must complete a Remote and Electronic Informed Consent Implementation form to be submitted to the cIRB via the ASPIRE NCC Project Manager. This form is posted in WebDCU™ > ASPIRE Toolbox.
- Please remember to update the COVID-19 Impact Assessment v2 in WebDCU™ to alert us to any changes in local restrictions on screening or enrollment.
- For sites still pending activation, please:
  o Upload/waive pending regulatory documents.
  o Enter addresses for study drug and lab kit shipments.
  o If CTA and cIRB approval in place, schedule readiness call.
- The ASPIRE/SATURN Investigator Meeting in New York has been postponed indefinitely. In lieu of the meeting, protocol training is posted on the WebDCU™ Training Campus https://webdcu.musc.edu/campus/
- ASPIRE next Webinar is October 28, 2020 3:00p-4:00p EDT https://nihstrokenet.adobeconnect.com/trials/ To take part in the conversation dial 1 (877) 621-0220 Pass Code: 745694
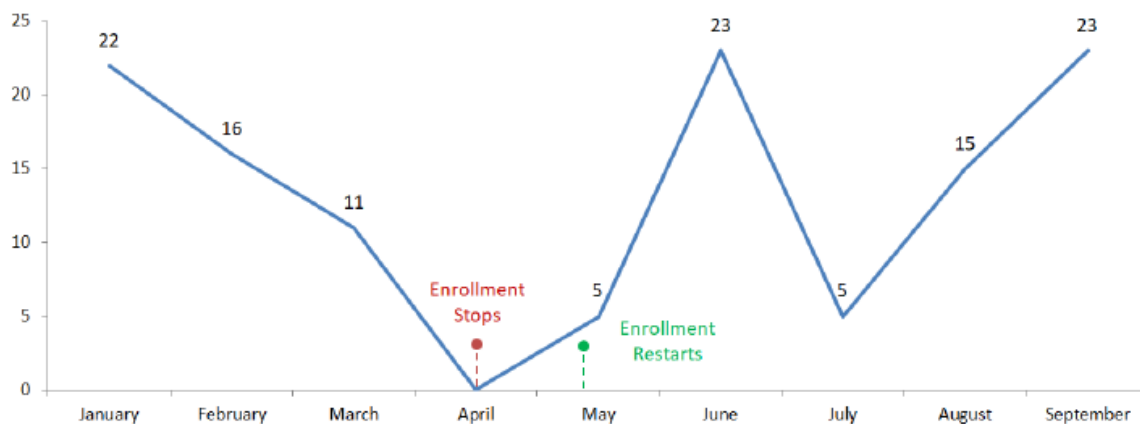

Site Startup and Enrollment Updates: sites: 55; enrollments: 157/350

Enrollment has picked up again with a total to 153, **45%** of our target. We are looking forward to reopening of the remaining CREST-H sites and the inclusion of **8** additional sites in the onboarding pipeline. CREST-2 has <800 patients left to recruit. We need 193 them for CREST-H. Let's continue the pace to meet our target. Keep an eye out for asymptomatic carotid patients and let's keep the enrollment going!

In the setting of COVID, minimizing exposure of patients is critical. We currently recommend that CREST-H be discussed in the context of consenting for CREST-2, at the time other imaging is being mentioned. In order to save the patient an extra trip to your medical center, you can have the patient verbally agree to the perfusion scanning, and then have them sign the CREST-H consent when they arrive at the scanner. Remember, consent signing must occur AT THE SAME TIME OR AFTER randomization into CREST-2.

Interested in becoming a CREST- site? Contact Randy Marshall rsm2@columbia.edu, Ron Lazar rlazar@uabmc.edu, Jaya Vijayan vijayan.jaya@mayo.edu, or Kevin Slane KJS4@columbia.edu with any questions.

From the CREST-2 Clinical Coordinating Center:

We've met our monthly goal for August & September! Keep in mind that **15** is the goal until the end of October, where we will then jump to 25. We will need to keep up a momentum through the end of 2020 to ensure our success. Congratulations to all the StrokeNet sites that have randomized this month thus far!

Novant Health ● Kaiser Permanente Los Angeles ● Wake Forest ● SUNY Buffalo ● Hartford Hospital ● Henry Ford Hospital ● Cornell

We now have **100** sites re-initiated to resume enrollment, including 46 StrokeNet sites. If your site is ready to re-open for enrollment, please notify your site manager (if you have not done so already), so that we can make note of your site's status in CREST-2.

Opportunity for Trainees

2020 NIH Virtual Seminar on Grants Administration and Program Funding

The National Institutes of Health invites you to take part in a unique (and *FREE*) opportunity to learn more about working with the NIH grants process, programs, policies, and staff at the 2020 NIH Virtual Seminar on Grants Administration and Program Funding.

Additional presenters and session information will be announced in the coming weeks. Registration is now open at https://nihvirtualseminar2020.vfairs.com/en/registration.

Questions regarding this event may be addressed to NIHRegionalSeminars@nih.gov.

FREE NIH Educational Opportunities

Ethical and Regulatory Aspects of Clinical Research - 7 Week Course

Register for the course Ethical and Regulatory Aspects of Clinical Research. This 7-week course covers essential topics in the ethics of clinical research and is designed for researchers and research teams, clinical staff, IRB members, and others interested in the ethics of clinical research. Presentations are given by experts from both within and outside the NIH.

The course runs from September 23, 2020 - November 4, 2020 and will be broadcast live. The course meets Wednesday mornings from 8:30 -11:30 am Eastern. This year, the course will be delivered on-line. In addition to lectures, we will host conversations with experts and engage in case discussions.

Information about the course and how to register as well as the schedule and syllabus are available at https://bioethics.nih.gov/courses/ethical-regulatory-aspects.shtml For Nursing CEU* or Core Curriculum (for NIH employees only) credits you must be registered for the course and complete course requirements.

This course is available to anyone via live video-cast live at http://videocast.nih.gov. **There is no charge.** If you want access to additional course materials and receive a Certificate of Completion for the course you must register. We will be using CANVAS to coordinate course activities. Once you register you will receive an invitation to join the course site.
For best performance, CANVAS should be used on the current or first previous major release of Chrome, Firefox, Edge, or Safari. Because it's built using web standards, Canvas runs on Windows, Mac, Linux, iOS, Android, or any other device with a modern web browser.

If your institution or group has participated from a satellite location in the past we are not organizing proctored groups. Each individual from your institution will register directly. For more information click https://bioethics.nih.gov/courses/ethical-regulatory-aspects.shtml.

The course textbook is "Ethical and Regulatory Aspects of Clinical Research: Readings and Commentaries (JHU Press, ISBN 9780801878138)." You can order the book on-line from the FAES Bookstore @ NIH https://faes.org/content/faes-bookstore-nih or other on-line purveyor of books. Additional readings will be recommended.

Individuals with disabilities who need sign language interpreters and/or reasonable accommodation should contact 301-496-2429 or bioethics-inquiries@mail.nih.gov. Federal TTY Relay number is 1-800/877-8339. Requests should be made at least 5 days in advance of the event.

-Nurses will receive 22 contact hours of CEU credits. Credits are provided through the Maryland Nurses Association, an accredited approver of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

Successful completion of this course is required for the Clinical Research Curriculum Certificate. For more information, see http://intranet.cc.nih.gov/clinicalresearchtraining/curriculumcert.

2020-2021 NIH Introduction to the Principles and Practice

of Clinical Research (IPPCR) course

Interested in expanding your clinical research knowledge base? Registration for the 2020-2021 NIH Introduction to the Principles and Practice of Clinical Research (IPPCR) course is now open.

This *free*, self-paced, online course runs from September 1, 2020 to August 1, 2021. Graduate students, post-doctoral scholars, medical, dental, and pharmacy students, scientists, nurses, and other health professionals are encouraged to enroll now.

The IPPCR course is a lecture series from thought-leaders around the world covering: study designs; measurement and statistics; ethical, legal, monitoring, and regulatory considerations; preparing and implementing clinical studies; communicating research findings and other topics.

To register, please visit the IPPCR website at https://ocr.od.nih.gov/courses/ippcr.html. If you have any questions, please contact the course coordinator at ippcr2@mail.nih.gov.

2020-2021 NIH Principles of Clinical Pharmacology (PCP) Course

Registration is now open for the 2020-2021 NIH Principles of Clinical Pharmacology (PCP) Course.

The PCP course is a *free* online lecture series covering the fundamentals of clinical pharmacology as a translational scientific discipline focused on rational drug development and utilization in therapeutics. Topics covered in the course include pharmacokinetics, drug therapy in special populations, drug discovery and development, and pharmacogenomics.

The course is free, self-paced, and entirely online through the PCP website: https://ocr.od.nih.gov/courses/principles-clinical-pharmacology.html.

Registration is now open and course materials are available through August 1, 2021. A certificate of completion is awarded to participants who achieve a passing score on the final exam.

The course will be of interest to graduate students, post-doctoral scholars, medical and pharmacy students, scientists, and health professionals interested in expanding their pharmacology knowledge base. For additional information on the course, please visit the website above or contact the course coordinator at odpcp@mail.nih.gov. Please feel free to share the course information with any internal or external colleagues that you feel may benefit from the course.

Coordinator Webinar

Coordinator Webinars are a requirement for the NIH StrokeNet RCC Coordinators/Managers however, all are welcome to attend

Wednesday, 28-October, 1:30pm ET

Topic: TBD
Moderator: Dave Haney, Case Western Reserve University

To join the meeting: https://nihstrokenet.adobeconnect.com/coordinator/
To take part in the conversation you MUST dial in. 1 (877) 621-0220 Passcode: 434578

Steering Committee Call

Steering Committee Calls are a requirement for all NIH StrokeNet RCCs; Please invite satellite sites to attend

The next Steering Committee call is the Fall Network Webinar, scheduled for **Wednesday, 14-October, 2020, 12pm – 3pm ET.** Calendar invitations have been sent.

To join the meeting please log in to the webinar and also dial in in order to speak:

https://nihstrokenet.adobeconnect.com/network/

1-877-621-0220 – Passcode 631088 - Please enter as a guest and then your first and last name. *Please note, this is a different passcode than the monthly Steering Committee calls.

Grand Rounds

Grand Rounds are a requirement for the NIH StrokeNet Trainees, however all are welcome to participate.

Thursday, October 29, 2020
4:00 pm ET

Topic: Patterns of White Matter Hyperintensities Define Underlying Causes of CSVD: An Unbiased Big Data Imaging Analytic Approach

Presenter: **Chia-Ling Phuah, MD, MMSc,** Washington University, St. Louis

Moderator: David Liebeskind, MD, UCLA

To join the meeting: *https://nihstrokenet.adobeconnect.com/grandrounds/*. Please enter as a guest, then your email address or your first and last name.

To take part in the conversation you MUST dial-in. (877) 621-0220 Passcode: 190825

Professional Development Webinar

Professional Development Webinars are a requirement for the NIH StrokeNet Trainees
Tuesday, September 29, 2020
12:00 pm ET

Presenter: **Dan Woo, MD,** University of Cincinnati

Presentation: Grant Writing

Moderator: Randy Marshall, MD, Columbia University

To join the meeting: *https://nihstrokenet.adobeconnect.com/pdw/*. Please enter as a guest, then your email address or your first and last name.

To take part in the conversation you MUST dial-in. (877) 621-0220 Passcode: 190825

NIH StrokeNet Employment Opportunities

For more information about StrokeNet employment opportunities, please visit
http://nihstrokenet.org/education/employment-opportunities

Please share your satellites and study teams!
Contact: Jamey Frasure, PhD, RN, Administrative Director · frasurjs@ucmail.uc.edu https://www.nihstrokenet.org