NIH StrokeNet

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StrokeNet Meeting: 9-12-2017

Joe Broderick

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Vision

- To be the leading platform for stroke trials in the U.S. and globally

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Ongoing NIH StrokeNet Trials = 5

Current Trials	Domain	PI	Actively enrolling
CREST 2	Prevention	Tom Brott	Yes
MISTIE III	**Acute**	**Daniel Hanley**	**Recruitment Completed**
iDEF	Acute	Magdy Selim	Yes (275 of 294)
TeleRehab	Recovery & Rehabilitation	Steve Cramer	Yes (109 of 124)
DEFUSE III	**Acute**	**Greg Albers**	**Completed Early**
ARCADIA	Prevention	Mitch Elkind, Hooman Kamel, Dave Tirschwell, Will Longstreth	Not yet

Just Approved Trials 9/2017 Council

Current Trials	Domain	PI
SLEEP-SMART	Prevention/Recovery	Devon Brown (Contact PI) Ronald Chervin
MOST	Acute	Ope Adeoye (Contact PI) Andrew Barreto Jim Grotta Joe Broderick

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Trials Submitted for Peer Review

Trial	Domain	PI	Submitted
ARREST	Prevention	D. Hasan	February, 2016, July 2017
Transport2	Recovery	W. Feng, G. Schlaug	October, 2016, July 2017
IMPACT	Acute	A. Naidech	October 2015, July 2016, July 2017
I-ACQUIRE	Recovery	S. Ramey, W Lo	July, 2017
Veritas II	Prevention	S. Amin-Hamjani	July, 2017
ASPIRE	Prevention	K. Sheth H. Kamel	July, 2017

Trials To Be Submitted for Peer Review

Trial	Domain	PI	Submitted
ALISAH	Acute	J. Suarez	June, 2016, November 2017
SATURN	Prevention	M. Selim	October, 2016, November 2017
CAPTIVA	Prevention	B. Hoh	October, 2017
FURRTHER	Prevention	B. Boden-Albala	October, 2017
Pre-LIMBS	Acute	S. Koch	October, 2015 November, 2017
I-WITNESS	Acute	L. Schwamm	February, 2017, November, 2017?

Ancillary Studies

Trial	Domain	PI	Submitted
CREST H (x2)	Prevention (Ancillary)	R. Marshall, MD	Funded

Survey Results and Action Plans

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Survey of RCCs and Sites

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Question 1: Role in StrokeNet

Question 1: Role in StrokeNet (Total respondents = 163)

RCC PI or Co-PI	12.88%
RCC Coordinator/manager	28.83%
Site PI or Co-PI	17.79%
Site coordinator	32.52%
Other	7.98%

Question 2-4: Communication – how and how often information is communicated.

Out of 113 respondents, 81% agree or strongly agree that they are satisfied with information dissemination methods and 86% agree that they agree or strongly agree with frequency of meetings/calls. For the NCC, alternative approaches suggested were to improve the functionality of the nihstroket.org website, send email reminders for webinar conferences, streamline the quarterly activity reporting, include the RCCs on all communications to satellite sites and clinical performing sites, and ensure all sites/coordinators are getting the biweekly updates. People unaware that many pieces of information are posted on website on public side but also on backend when you have sign-on.

For the NDMC, it was noted that some feel that they receive too many unnecessary automated emails from WebDCU™ whereas others asked for more communication from the NDMC. A few noted in their comments that it is not clear who to contact at the NDMC when there are issues with WebDCU™. NDMC contact information is listed in WebDCU™, the Manual of Procedures for each trial, the StrokeNet WebDCU User Manual, and on the NIH StrokeNet website.

It was noted that there is not enough training available and that there needs to be more communication regarding WebDCU updates in real time. Some said that the system is difficult to navigate and is not user friendly. Some also found the DCR process and transfer of regulatory documents across studies both frustrating and confusing.

Question 2-4: Communication – how and how often information is communicated.

Action Plan:

1. Provide a Coordinator Webinar to review the nihstrokenet.org website and WebDCU™ resources and conduct ongoing training during the course of the network. (Done)

2. Schedule time with new RCC program managers to provide network orientation and overview.

3. Discussed with RCCs on steering committee call in 3/2017 about whether to have information flow from NCC directly to sites (example biweekly report) or to have it flow through RCC leadership/coordinator to the sites. The consensus was the latter. However, another option was providing site coordinating/investigators with access to the non-public part of website by providing ID and passwords so they can access RCC and NIH StrokeNet documents such as biweekly reports and work group minutes and SOPs. This we will also do.

4. The NDMC is considering alternatives to improve WebDCU™ information dissemination.

Question 5: Usefulness of Site Visit by NCC and NDMC

In the first three years of the award, all 25 RCC had a site visit from the NCC and NDMC leadership team. **Of the 107 respondents, 74% found the visit informative and helpful, 15 % neutral.** Of those who did not find it helpful (3%), some thought the visit was perfunctory or more for data gathering purposes.

Action Plan:

1. Dr. Broderick is having phone conferences with the 25 RCC PIs with plans to complete the calls before the competitive renewal applications are due in 2017 (completed). Will continue annually.

2. NCC directors will be also making individual phone calls to the 25 RCC program managers (started).

Questions 6: Availability of opportunities to express comments and concerns.

78% were satisfied with the opportunities. Suggestions for improvements were to define roles of those at the NCC, increase networking within the coordinator group, and have the steering committee meetings at ISC offered as a webinar.

Action Plan:

1. Continue to promote and support coordinator-networking activities.
2. Discuss the nihstrokenet.org website contact directory during the coordinator website refresher and make clear the contact numbers for different questions for NCC and NDMC.
3. Make better use of technology when possible.

Question 7: Feasibility surveys for the proposals are of reasonable lengths and contents.

74% agreed or strongly agreed. For those who didn't, specific comments included that questions were too specific, the surveys were too long, and that there is no standardized completion timeline. In the past year, the survey length has been decreased to 10-12 questions. Prior to this year, some surveys reached 30 questions which the NCC and NDMC felt was too much of a burden on the RCCs and sites. There has always been a standardized completion timeline of 10 business days, however, some sites would like extra time to complete when the questions are especially complex. Another comment pertained to the same questions being asked on multiple surveys. Another respondent suggestion was for enthusiasm to be assessed anonymously, as this may result in more honest answers.

Action Plan:

1. The network is completed a new site information form. This form will be completed annually by each site and will include basic information on each site that tends to show up on multiple feasibility surveys.

2. Consideration of additional survey time for more complex data, if submission timeline allows.

Question 8: Process for site selection is clear and equitable.

Of the 107 respondents, 56% agree that the process is transparent and equitable, 28% were neutral on this item. Comments included were that the process is not transparent enough, need clear dissemination of criteria for selection for a given study, and frustration not being approved by NINDS despite enthusiasm.

Action Plan:

1. Continue to mandate trial PIs to have clear selection criteria and to share site selection criteria as often as possible.

2. Work with trial PIs to adhere to the trial selection criteria for the duration of the trial.

NINDS does not choose sites.

Question 9: NCC provides adequate direction and support to my RCC/clinical site

83% agree that the NCC provides adequate direction and support to the RCCs. A few RCCs want more hands on assistance in terms of detailing their responsibilities and providing guidance with managing their network. More relationship building was also an identified theme.

Action Plan:

1. Continue to include the RCC PIs and program managers on all correspondence to their satellite sites and clinical performing sites and to trouble-shoot if this is not occurring.
2. Maintain a helpful and customer-friendly attitude in all StrokeNet correspondence.
3. During RCC and manager calls, ask for specific questions/issues with which we can help.
4. Ask RCCs for specific issues and have other RCCs present best practices

Question 10: My RCC provides adequate direction and support to my clinical site.

83% of satellite and performance sites personnel agreed. Suggestions included desire to have better instructions for the quarterly reports, the need for financial support, and more direction from the RCC.

Action Plan:

1. Review management SOP with program managers to see if plan is being implemented as written (ongoing).

2. Use the biweekly newsletter to highlight RCCs that are using innovative ideas to stay connected to their regional network (suggestions).

Question 11: NDMC provides adequate support and training to my RCC/clinical site on data-related issues.

75% agreed or strongly agreed. The respondents liked the Web-DCU but several comments indicated difficulty with navigation of the program and need for more training. Also question of who to call if problem. Finally, one comment suggested using regulatory documents such as training for one trial counting for another trial, if possible with central data platform. Also, comments about updated dashboards – difficult for trials that Web-DCU and NDMC don't manage (like CREST 2 and MISTIE 3).

Action Plan:

1) Webinar regarding Web-DCU as noted above to be scheduled (Done).

2) Training of new coordinators as noted above.

3) Try to maintain update from CREST 2 and MISTIE 3 as soon as possible.

Survey of PIs Regarding Survey Development Process (N = 22) Results and Action Plan

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Questions 1 and 2: Process for new trial development was communicated clearly to me.

Out of 22 respondents, 59% agree or strongly agree. Several comments that there was ambiguity regarding process at early time points of the network, e.g. whether PI should approach NINDS or the NCC, when PI was supposed to start working with the NCC/NDMC in regards to budgeting. Also several comments that the approach has been clarified and streamlined. One comment suggest a flowchart and a step-by-step checklist.

Action Plan:

1. Redistribute current flowchart of process to RCCs and through them to satellites (Done).
2. Distribute budget template (Done).
3. Trial checklist – use and expand on NIH guideline (Done).

Question 3: Input from the Working Group made my proposal stronger in the scientific premise and research aims.

77% agree or strongly agree. Comments included: recommendations didn't help the score, and were faulted in reviews; not enough transparency; limited comment; great experience – like mini-study section review.

Action Plan:

1. Share with working group chairs.
2. Sharing best practices between working groups ongoing.

Questions 4: Input from the statistical team at the NDMC made my proposal stronger in study design and methods

91% agreed.

Action Plan:

1. Continue with current process. Require PIs to have draft of grant to NDMC and NCC PIs (or designates) within 1 month of submission. Otherwise, goes to next submission cycle.

Question 7: Input from the NCC and the NDMC was helpful in the budget development process.

82% agreed or strongly agreed. Comments included: need for a better education process to assist those who have no experience in the submission of a clinical trial; suggest better budget justification prior to ESC submission.

Action Plan:

1. Seminar on putting together a budget has run twice and we will do this again. They are also available online at website. Hands on input from NCC/NDMC with PI, particularly those with less experience, will be continued. Since NCC and NDMC are not submitting final budget at PIs institution, suggest experienced person at PI institution being involved in last steps.

2. There has already been evolution of more detailed budget discussions prior to ESC (not done in earlier grant submissions) to address the above comment. This will be continued.

Question 8: Feasibility surveys and epidemiological input to assess feasibility were helpful.

94% of those who responded agreed. Comments included: I think this is so important and made me think about my inclusion and exclusion criteria. Certainly thinking about future grant submissions, I will more strongly consider how I select i/e criteria. It is a good exercise- just needs to be more clearly explained up front. This is essential.

Action Plan:

1. Work on making feasibility surveys as useful as possible to PIs for feasibility but also site selection.

Question 9: Satisfied with the support I received from NINDS program staff, such as grantee meetings, communications, etc.

73% agreed or strongly agreed. Comments included: there were often significant time lapses before emails received responses; communications are sparse; I did not receive specific, actionable feedback regarding my trial proposal's review in the NINDS Extramural Science Committee; NINDS personnel are wonderful.

Action Plan:

1. NINDS established a StrokeNet dedicated email box for combined management of requests. The email will be distributed to multiple members of the NINDS StrokeNet to ensure that we are able to more rapidly respond to all requests. The new email address is: (strokenetinquiry@mail.nih.gov.

Question 10: Feedback I received from the NINDS ESC was fair and helpful.

55% of those who responded agreed or strongly agreed. Comments included: 1) Need more transparency on ESC decision-making rationales. 2) The process seems to grind slowly, and the advice from the ESC was contradicted down the road.

Action Plan:

1. NINDS established a formal, internal process to respond to the NIH policy that requires applicants requesting research support of at least $500,000 (direct costs) in a single year to seek permission from an NIH Institute or Center in order to submit an application for peer review. NINDS established the Extramural Science Committee (ESC) to advise the NINDS Director, who makes the final decision. The committee is composed entirely of NINDS staff, including program directors and senior staff from all offices and divisions in the institute. ESC considers mission relevance, cost/benefit to mission, extent of current NINDS investment, appropriate mechanism of support and the rigorous nature of the scientific premise. NINDS staff try to provide useful guidance and feedback based on the committee discussions. Although there is no appeal process, applicants can resubmit if concerns identified by ESC are addressed.

Question 11: Satisfied with the current process for new trial development.

45% agreed or strongly agreed and 14% were neutral.

Comments:

1) whatever can be done to shorten the lead time from idea generation and approval to actual submission would be great. Since the feasibility and epi work dictates the cases per site per year, it is hard to do any budgeting or hospital site estimates until those are done. Having a navigator assigned to the proposal from NCC or NDMC would be a great help.

2) I think the development process is fine. The issue is with the review process. I understand that it's very difficult now to get reviewers that are not in conflict with most proposals but for these StrokeNet proposals there should be more input from investigators working in the field of acute neurology or neurocritical care.

3) I would recommend the NINDS work hard to assure the process does not come to be viewed as serving an unfair gatekeeper function or weakening peer review. The process must encourage the best science to come forward and must be viewed as fair and efficient. I think it is not quite there yet. I say this, however, with enormous regard and respect for the dedicated staff of scientists and administrators at the NINDS, truly a national treasure.

4) I am very grateful for the excellent help I have received from the Prevention Working Group.

5) The process need to be evaluated in part on how much it increases the funding rate for trial proposals. The people involved are very knowledgeable and kind, but the process is also very labor intensive.

6) The process is prolonged and inefficient. I'm not sure how to make things move more quickly but there is a bottleneck that adds to the time from idea to grant submission.

Question 11: Satisfied with the current process for new trial development.

Action Plan:

1) Assign working group chair and NCC director as grant navigators for each trial submission (Done).

2) Posting current step of concept proposal and submission and who is responsible for current step (Done, Project Development Progress in Web-DCU – Working Group Chairs have access).

3) Improve transparency and feedback from ESC review

4) NINDS working on review process (Discussions with Chair and Review Group).

5) Other action items as noted previously.

Upcoming Plans

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Princeton Conference – New Version

- Major input from preclinical researchers – ideally from StrokeNet sites
- More focused meeting – example – neurorecovery
- Different funding model
- Timing of meeting – possibly extra day adjacent to StrokeNet meeting (not at ISC).
- Comments

Brainstorming Sessions – Programmatic Needs

- Look at original results of strategic planning meeting sponsored by NINDS.
- Look at ongoing trials and proposed trials.
- Consider potential gaps and ideas.