



National Institute of
Neurological Disorders
and Stroke



Competitive Renewal

*Coming together is a beginning.
Keeping together is progress.
Working together is success.*



~Henry Ford

<http://nihstrokenet.org/>

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Clinical Networks Evaluation Working Group

of the
National Advisory Neurological
Disorders and Stroke (NANDS) Council

- Presentation to the NANDS Council
- February 2, 2022

Working Group Charge

Assess processes and outcomes for two NINDS clinical research networks: **StrokeNet** and **NeuroNEXT**.

Identify areas for improvement in the design of the next iterations of these programs.

with consideration to:

- 1) The extent to which the programs are meeting their goals.
- 2) The programs' outcomes and impacts.
- 3) The extent to which the networks collaborate with and benefit the research community.
- 4) What improvements to program components and operations could allow the networks to better address current or new goals.

Strengths and Accomplishments

Continued support is justified for NeuroNEXT and StrokeNet

Both networks have developed the capacity to plan and efficiently execute clinical studies with significant impact on clinical practice and patient outcomes. Investigators and staff have built infrastructure from the ground up, often expanding to include additional, local practice communities in studies.

Outcomes and impacts (examples)

NeuroNEXT

- Observational study of infants with SMA informed clinical trials, contributing to approval of gene-targeted therapy (Nusinersen)
- Phase 2 trial of ibudilast provided evidence supporting effective therapy for progressive Multiple Sclerosis

StrokeNet

- DEFUSE 3 trial showed imaging can identify acute stroke patients who can benefit from endovascular thrombectomy beyond previously recognized time windows

Efficiency

- Once trials are activated, initiation and implementation are generally efficient
- Networks track data quality metrics and share with sites to encourage good performance and improvement
- Overall cost of trials appears reasonable
- Both networks have made significant improvements over time

Collaboration and benefits to the research community

- Convened expertise across relevant disciplines
- Engaged with broader academic research communities
- Funded proposals from investigators within and outside network sites
- Provided research training opportunities and partial support for new clinical investigators
- Recognized importance of patient perspective; collaborated with patients and patient advocacy groups (PAGs), particularly on recruitment and retention
- Engaged industry - two NeuroNEXT trials led or co-led by industry sponsors; companies have provided medications, placebos, devices, and financial support

Top-line Recommendations

Top 2 Recommendations



Proactively identify priorities



Monumentally improve pre-award/review efficiency



Strengthen internal and external community engagement



Set explicit goals to address equity, diversity, and inclusion and resource achieving them



Enhance clinical workforce development, readiness, and retention



Strengthen regular network evaluation and timely improvement

Workable solutions Bases on the NINDS Clinical Networks Evaluation Working Group



Proactively identify priorities

- Work with community (through workshops/conferences, strategic planning) to identify areas of high unmet need and scientific priority
- Strengthen generation of research ideas through existing network structures, (e.g. disease area interest groups)
- Require appropriate representation of diverse populations



Monumentally improve pre-award/review efficiency

- Innovate and accelerate Network award and review processes
- Streamline NINDS extramural pre-review processes
- Consider Administrative Core for non-academic coordination functions



Strengthen regular network evaluation and timely improvement

- Develop 5-year network evaluation plan
- Conduct Listening Sessions with investigators and community partners 2x/year for input on performance



Strengthen internal and external community engagement



Set explicit goals to address equity, diversity, and inclusion and resources for achieving them



Enhance clinical workforce development, readiness, and retention

RCC 2017 Renewal FOA

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

National Institutes of Health (NIH (<http://www.nih.gov>))

Components of Participating Organizations

National Institute of Neurological Disorders and Stroke (NINDS (<http://www.ninds.nih.gov>))

Funding Opportunity Title

NIH StrokeNet Regional Coordinating Stroke Centers (U24)

Activity Code

U24

ResearchProjects – Cooperative Agreements

Funding Opportunity Announcement (FOA) Number

PAR-17-276

<https://grants.nih.gov/grants/guide/pa-files/par-17-276.html>

Key Dates and Award Information

- One-time RFA (no re-submissions)
- R24s – renewal submissions accepted
- Anticipate submissions early 2023
- Review Summer/September Council
- Plan to approve up to 27 RCC awards
- Project period is 5 years
- Direct Costs increased to \$275,000/yr

Focused changes for the renewal

- Increase number of funded RCC's
- Increase in budget to accommodate additional coordinator support
- Coordinator training built into the training core – goal to enhance renewable workforce for the future. Commitment of RCC to mentoring coordinator training
- Plan for priority setting – including leading consensus workshops
- Renewed emphasis on including patient survivors, minority and diversity enrollment including community outreach, and pediatric populations.
- New strategies to enhance industry engagement

Remaining the same

- Commitment to single IRB and master trial agreement – with new language to focus on central vs. local IRB responsibilities
- Commitment to maintain a consortium of sites by the RCC with emphasis on more direct engagement of fewer sites
- RCC's that may be organized linked partners
- Diverse, multi-disciplinary expertise with commitment to NIH trials
- Educational commitment - \$50k to research fellow. Reworded to support 50% of effort

Research Strategy

Limit to 12 pages, divided into:

- A. Program Overview
- B. Research Program
- C. Leadership
- D. Training and Career Enhancement
- E. Administrative Core

Program Overview

- Experience in NIH/NINDS trials and observational studies over past 10 years (can be in a table)
- Can include involvement in COVID trials and also DISCOVERY/DIVERSE VCID observational studies
- Experience working as a group
- Description of catchment area
- Organizational structure with description how RCC manages their satellites

Accomplishments /Metrics

- Progress over past 5 years since last competitive review
- Table of metric performance focused on RCC's contribution (includes satellites) to SN trials/studies - include when joined the trial
 - Start-up
 - Notification to activation
 - Notification to first enrollment
 - Enrollments/randomizations
 - Avg monthly enrollment
 - Retention
 - % CRF's submitted on time
- Description how RCC was impacted and recovered by Pandemic
- Contribution to network activities
- Participation in educational activities

Metric table to be provided by NDMC to each RCC

RCC [Site Name]	Trial Name	Days to site activation	Days to first subject enrolled	Total enrolled (consented)	Total randomized	Average monthly enrollment rate	% Retention	% of CRFs submitted within window
	CREST2	-	-	-	N	-	-	-
	ARCADIA	80	179	70	18		77%	62%
	ARCADIA-CSI	113	156	7	7		100%	67%
	SleepSMART	261	85	85	17		85%	70%
	DEFUSE3						
	Telerehab							
	TRANSPORT2							
	I-ACQUIRE							
	MOST							
	SATURN							
	SATURN-MRI							
	ASPIRE							
	FASTEST							
	CAPTIVA							
	VERIFY							
	Summary							

Questions?

