NIH StrokeNet Study Coordinator Survey

1

Intro – Suggestions to Date

- **Career pathways**
  - StrokeNet might help provide framework
  - Explore hybrid clinical-coordinator roles for clinical staff such as bedside RNs
- **Funding**
  - Improve per patient payments;
  - Consider maintenance or other standing payments to create a stable income source, especially at satellites;
  - Perhaps reward high recruitment with infrastructure support consider paying from future with greater patient reimbursement (MOST, ASPIRE); RCC expanded trials but reduced infrastructure support;
  - Consider a separately funded regulatory role;
  - Ensure payment to coordinators for training time in trial startup budgets
- **Staffing shortage** (unstable funding, remote work, COVID-specific hiring freezes and reduced labor pool)
  - Remember non-RN backgrounds for certain roles to allow larger eligible pool and potential for lower salaries;
  - Consider premed pool, credit to undergrads;
  - Consider StrokeNet "fellowship" for coordinators, and incorporating under-represented populations of coordinators;
  - Need backup and acute call considerations
- **Coordinator empowerment**, including publication opportunities and conference attendance
- **Simplify trials** when feasible

2

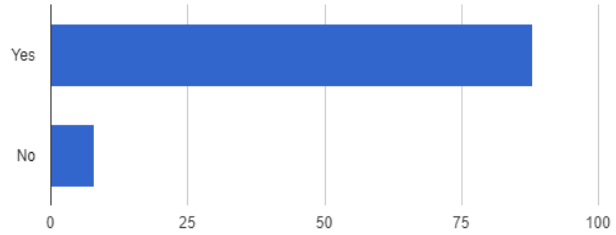
Survey

3

If not the primary/lead manager/coordinator for your RCC, are you a primary study coordinator for any trials?

Total Count (N)	Missing*	Unique
96	95 (49.7%)	2

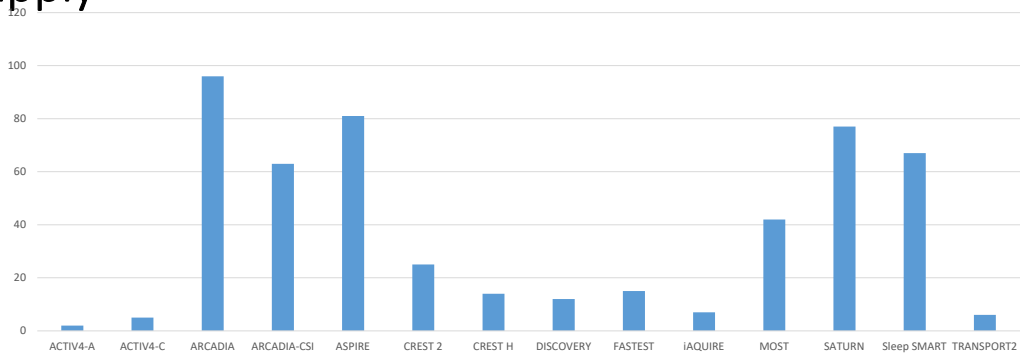
Counts/frequency: Yes (88, 91.7%), No (8, 8.3%)



- **88 respondents identified themselves as primary study coordinators**

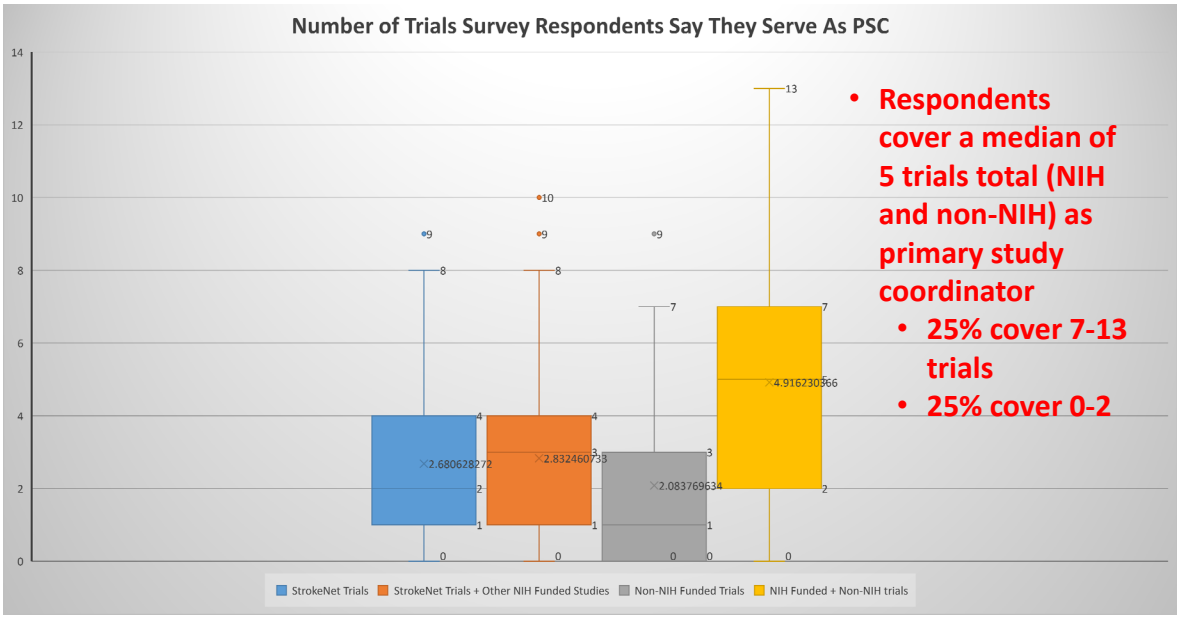
4

Please select the trials you are covering at this time as the primary study coordinator? Check all that apply



- **ARCADIA, CSI, ASPIRE, MOST, SATURN, SLEEP-SMART, and TRANSPORT2 site coordinators are well-represented**

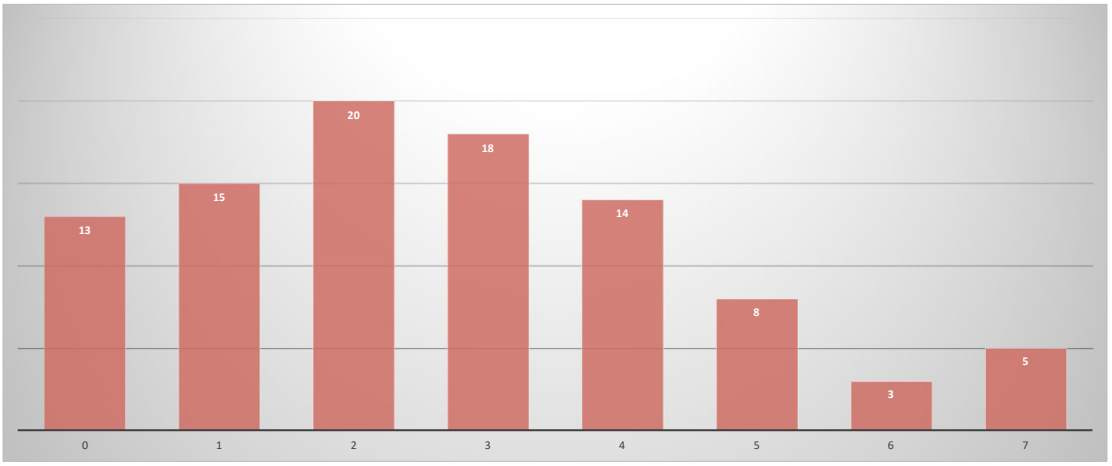
5



- **Respondents cover a median of 5 trials total (NIH and non-NIH) as primary study coordinator**
  - **25% cover 7-13 trials**
  - **25% cover 0-2**

6

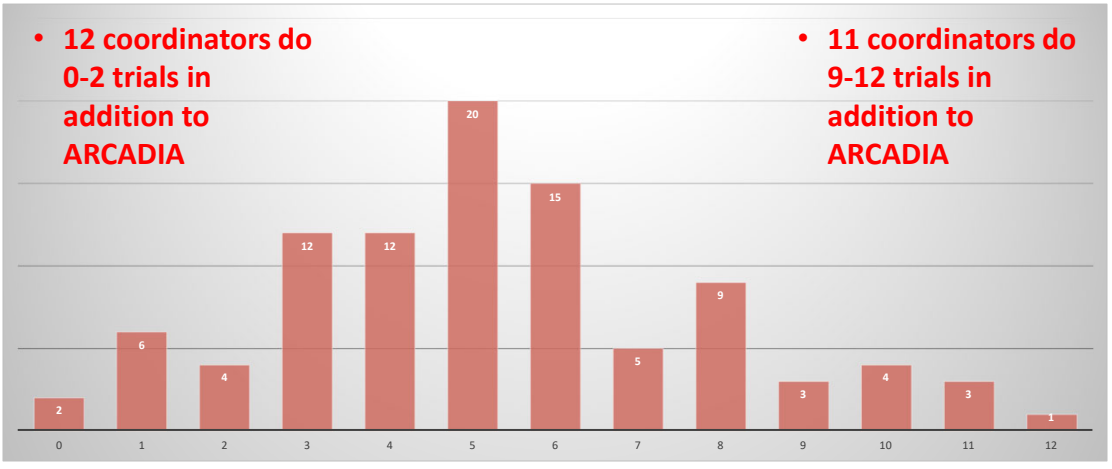
Surveyed ARCADIA PSCs Serving as PSC on Other StrokeNet Trials



7

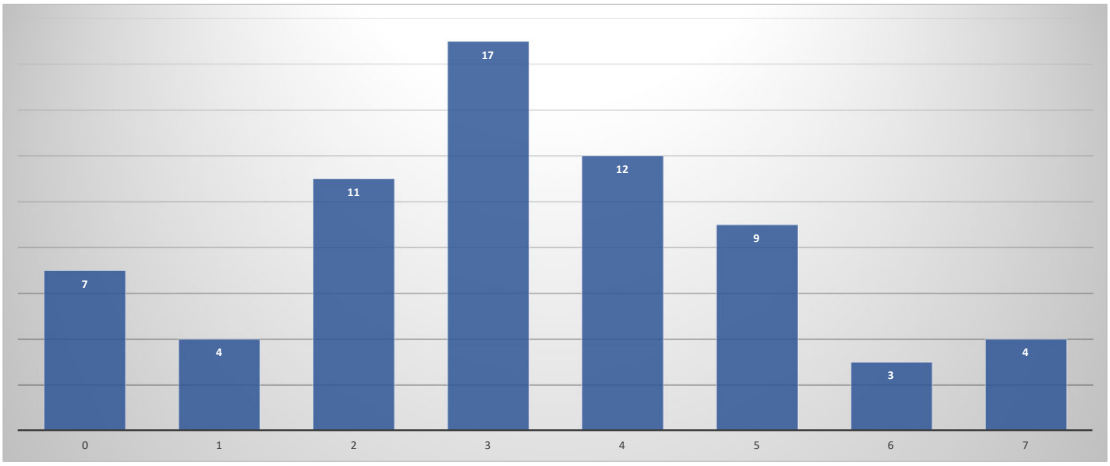
Surveyed ARCADIA PSCs Serving as PSC on Other NIH and Non-NIH Funded Trials

- **12 coordinators do 0-2 trials in addition to ARCADIA**
- **11 coordinators do 9-12 trials in addition to ARCADIA**



8

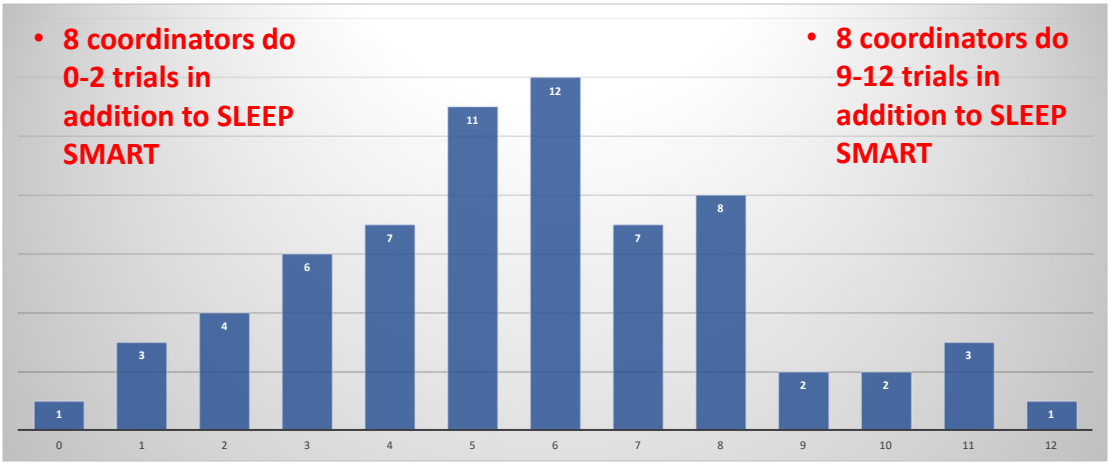
Surveyed Sleep SMART PSCs Serving as PSC on Other StrokeNet Trials



9

Surveyed Sleep SMART PSCs Serving as PSC on Other NIH and Non-NIH Funded Trials

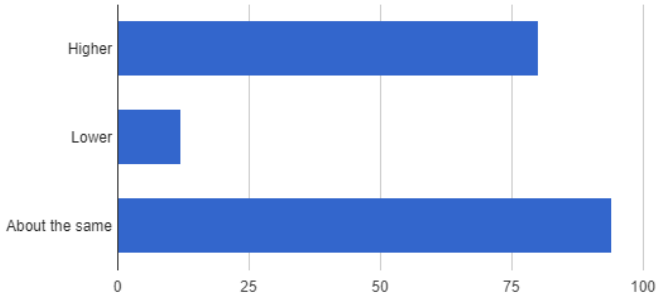
- **8 coordinators do 0-2 trials in addition to SLEEP SMART**
- **8 coordinators do 9-12 trials in addition to SLEEP SMART**



10

Is the number of trials that you cover higher/lower/same than prior to the COVID pandemic start?

Total Count (N)	Missing*	Unique
186	5 (2.6%)	3



Counts/frequency: Higher (80, 43.0%), Lower (12, 6.5%), About the same (94, 50.5%)

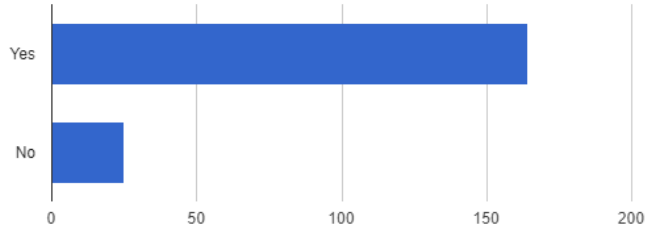
- **43% doing more trials with COVID pandemic**

11

Do you do the start up activities for trials?

Total Count (N)	Missing*	Unique
189	2 (1.0%)	2

Counts/frequency: Yes (164, 86.8%), No (25, 13.2%)

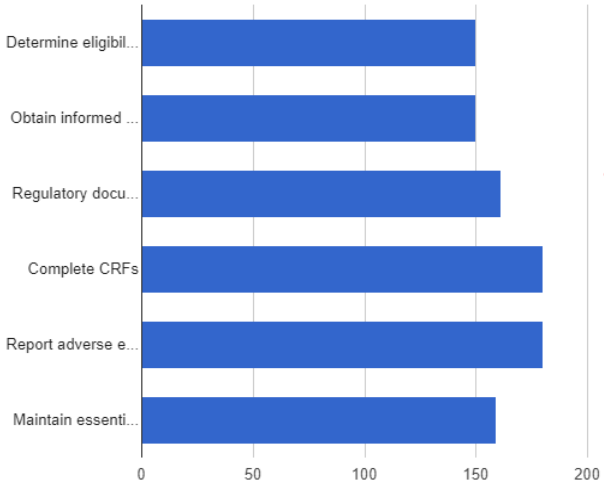


- **Almost 90% of study coordinators do their own start up activities**

12

Excluding startup activities, do you perform any of the responsibilities listed for trials? Choose all that apply.

Total Count (N)	Missing*	Unique
187	4 (2.1%)	6



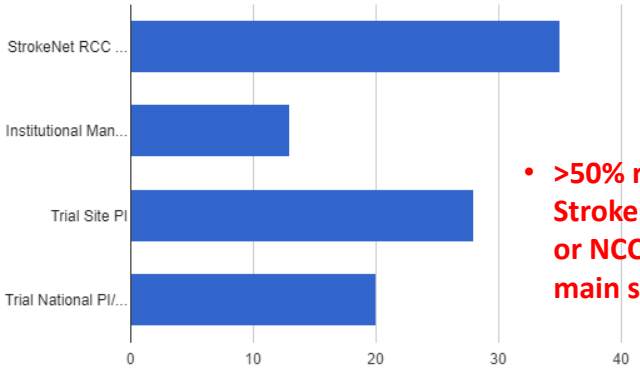
- **Majority (>80%) do all stages of activities**

Counts/frequency: Determine eligibility (150, 80.2%), Obtain informed consent (150, 80.2%), Regulatory document coordination (161, 86.1%), Complete CRFs (180, 96.3%), Report adverse events (180, 96.3%), Maintain essential regulatory documents (159, 85.0%)

13

Who is your main source of support when solving a StrokeNet trial challenging issue?

Total Count (N)	Missing*	Unique
96	95 (49.7%)	4



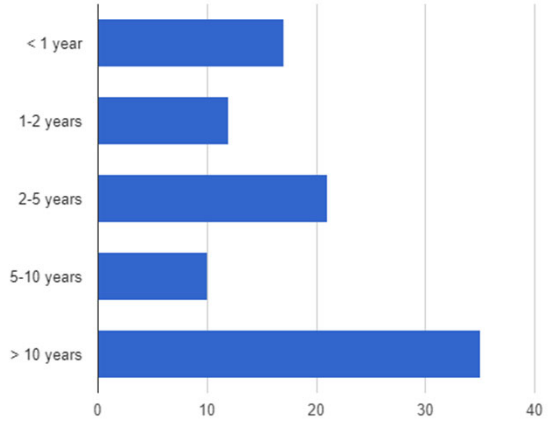
- **>50% rely on StrokeNet RCC PM or NCC Team for main support**

Counts/frequency: StrokeNet RCC Manager (35, 36.5%), Institutional Manager (13, 13.5%), Trial Site PI (28, 29.2%), Trial National PI/Team (20, 20.8%)

14

How many years have you worked as a research coordinator?

Total Count (N)	Missing*	Unique
95	96 (50.3%)	5



Counts/frequency: < 1 year (17, 17.9%), 1-2 years (12, 12.6%), 2-5 years (21, 22.1%), 5-10 years (10, 10.5%), > 10 years (35, 36.8%)

- **Over 1/3 have been coordinators for over 10 years experience**

15

Comments—Over-extended

- I do feel generally over-extended, making me not execute any trial to the fullest potential.
- I am the only full time study coordinator responsible for StrokeNet trials at my institution.
- I am the manager of all stroke studies in the department in addition to being the RCC manager for stroke net
- It can be tough to balance all activities needed of an RCC manager.
- We are greatly understaffed and enrollment suffers as coordinators are bogged down in regulatory, start up, and follow up visits.
- Follow up visits should be considered as they are time consuming and goes beyond completing CRFs. The level of work needed to access potential participants and their families has become more difficult for coordinators since COVID and so has the efforts needed for retention. People are overwhelmed and so coordinators need time to provide the level of handholding required by participants.
- We lost a highly experienced coordinator, and it required the rest of us to pick up her trials.
- We are overwhelmed with responsibilities of managing multiple studies.

16

Comments—Underfunded

- Sites complain about restricted StrokeNet reimbursement for study activities.
- The lack of funding is an issue and the industry trials are necessary to keep the Department financially stable. Without Industry trials, we would not be able to participate in many StrokeNet trials.
- The amount awarded for the current RCC performance cycle was reduced despite higher workload.
- Awarded funds are very limited to cover the effort invested by: RCC PI(s), Project Management Lead Coordinator, and StrokeNet Trainee protected research time
- We are consistent in our enrollment as top 1/3 enrollers or top 5 and the per patient reimbursements are not covering salaries of our coordinators.
- We need better per patient budgets and/or more RCC administrative funding to cover the coordinators. This isn't sustainable in the current model.
- What we get paid for NIH studies does not equal to the amount of work we put in.

17

Comments—Getting Better

- My workload was much, much higher up to about 2 months ago, then we were able to hire some new coordinators.
- Addition of staff within the past few weeks will help to get us back on track with respect to StrokeNet trials.

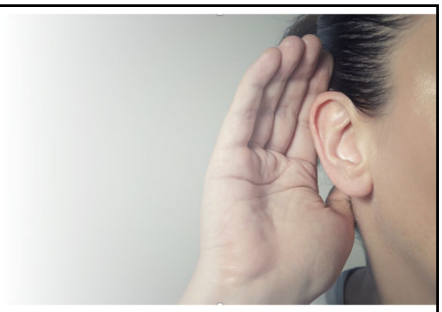
18

General Notes—Other

- The NIH stroke net trials should have a dedicated coordinator, if we did, enrollment from our site would increase dramatically.
- We also utilize the regulatory group through our University CTSI group work with Budget and contracts and regulatory in the start activities.
- None of our coordinators have been here since before covid.
- It is our pride to be part of the StrokeNet network.
- Most of the trials I work on are investigator initiated, and do not always have external funding.
- For the trials that I am listed as primary coordinator, I do have a team of back up coordinators who do help with recruitment/retention efforts.

19

Additional Comments or Suggestions?



- **Career pathways**
  - StrokeNet might help provide framework
  - Explore hybrid clinical-coordinator roles for clinical staff such as bedside RNs
- **Funding**
  - Improve per patient payments;
  - Consider maintenance or other standing payments to create a stable income source, especially at satellites;
  - Perhaps reward high recruitment with infrastructure support consider paying from future with greater patient reimbursement (MOST, ASPIRE); RCC expanded trials but reduced infrastructure support;
  - Consider a separately funded regulatory role;
  - Ensure payment to coordinators for training time in trial startup budgets
- **Staffing shortage** (unstable funding, remote work, COVID-specific hiring freezes and reduced labor pool)
  - Remember non-RN backgrounds for certain roles to allow larger eligible pool and potential for lower salaries;
  - Consider premed pool, credit to undergrads;
  - Consider StrokeNet "fellowship" for coordinators, and incorporating under-represented populations of coordinators;
  - Need backup and acute call considerations
- **Coordinator empowerment**, including publication opportunities and conference attendance
- **Simplify trials** when feasible

20