**NIH StrokeNet Clinical Study Concept Synopsis**

***Date:***

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| **Title:** | |
| **Principal Investigator(s):** | **Institution (name and address):** |
| **Phone:** | **E-mail address:** |
| **Under which specific NIH funding mechanism do you intend to submit your application:**  **Funding Opportunity Announcement (FOA) number:** | |
| **Clinical Stroke or Related Project Description** | |
| **Aspect of cerebrovascular disease targeted: (Check all that apply)**  **Primary or secondary prevention**  **Emergent management or acute treatment**  **Recovery and rehabilitation**  **Biomarker-validation study** | |
| **Investigational product (drug/biologic/device):** | |
| **Primary aims of the trial:** | |
| **Secondary aims:** | |
| The primary goal of the **NIH StrokeNet** network is to maximize efficiencies to develop, promote and conduct a balanced portfolio of high-quality, multi-site exploratory phase 1, 2 and confirmatory phase 3 clinical trials in stroke prevention, treatment, and recovery. Such trials will be focused on key interventions, as well as on biomarker-validation studies that are immediately preparatory to trials. **In 150 words or less, please state the question that you wish to explore in this trial:** | |
| **Briefly describe the scientific rationale for the trial:** | |
| **If applicable, briefly describe relevant pre-clinical evidence used to support this trial-addressing the questions below (**[**http://grants.nih.gov/grants/guide/notice-files/NOT-NS-11-023.html**](http://grants.nih.gov/grants/guide/notice-files/NOT-NS-11-023.html) **):**   * **Which animal models were used for the preclinical evaluation?** * **Were control animals used during the preclinical evaluations?** * **Describe the steps taken to minimize bias during the conduct of the preclinical evaluations.** * **Have the preclinical results been independently replicated?** * **Is there evidence that the interventional agent reached and engaged the target?** * **Describe the route/timing of the intervention delivery/dosing.** | |
| **Briefly describe the proposed trial design:** | |
| **Patient selection criteria, including window of treatment:**  **Inclusion Criteria**  **Exclusion Criteria:** | |
| **List participating pharmaceutical, biologic or device manufacturing companies (if any):** | |
| **Is the investigational agent (drug/biologic/device) under an open IND/IDE? Yes  No**  **If yes, IND/IDE number:\_\_\_\_\_\_\_\_\_\_**  **If yes, is there written letter of approval authorizing the use of the IND/IDE for the IND/IDE holder: Yes  No**  **If no, will the proposed study be performed under an IND/IDE? Yes  No  Unknown**  **If yes, has this protocol been submitted to the FDA? Yes  No**  ***Please note our policy requiring documentation from the FDA regarding the status of the protocol you wish to implement:*** [***http://grants.nih.gov/grants/guide/notice-files/NOT-NS-11-018.html***](http://grants.nih.gov/grants/guide/notice-files/NOT-NS-11-018.html)  **If no, has the FDA provided a written exemption from the IND/IDE requirement? Yes  No** | |
| **Do you or any member of the study group have a financial conflict of interest or hold a patent with the use of the intervention? Yes  No** | |
| **For exploratory phase 1 or phase 2 studies what specific outcomes would make you determine that the investigational agent/biomarker warranted further study, e.g. a Phase III trial?:** | |
| **What specific outcomes would make you determine that the investigational agent/biomarker did not warrant further study, i.e what would cause a ‘no-go’ decision?:** | |
| **Have you (or one of the Co-investigators) received past NIH funding for the preliminary work leading to this proposed trial? If so, please list the grant numbers and titles.** | |
| **Is your institution a NIH StrokeNet Regional Coordinating Center or affiliated study site (not required)? Yes  No**  **If yes, have you discussed this proposal with the NIH StrokeNet PI at your institution?**  **Yes  No**  **Is your institution a CTSA site (not required)? Yes  No**  **If yes, have you discussed this proposal with your CTSA’s protocol development group and/or presented it at a CTSA Brainstorming Session / Studio / Mock Study Session? Yes  No**  **Are there “other resources” at your institution that you have used in developing this proposal? Yes  No**  **If yes, describe: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | |

**Statistical Considerations:**

All projects conducted in the network will utilize the StrokeNet National Data Management Center (NDMC) for all data management and study reporting activities. The Protocol Principal Investigator (PPI) is encouraged to include their own biostatistician to provide study-specific leadership in statistical design and analysis. If the PPI does not have access to a statistician, he/she may propose to make use of the statistical expertise at the StrokeNet NDMC. If the PPI proposes to use a biostatistician outside of the NIH StrokeNet NDMC, the NINDS expects that the scope of activities of the external Biostatistician will adhere to the following parameters.

The external Biostatistician:

* will collaborate with the StrokeNet NDMC in developing statistical aspects of the protocol, grant application, and statistical analysis plan;
* will be blinded to safety data and interim analysis results during the course of the trial;
* may only receive raw blinded data or datasets during the course of the trial if and when permitted or required by NINDS and the NDMC PI;
* may, for certain trials, be included as a blinded participant on the relevant NIH StrokeNet committees and may serve as a statistical advisor to these committees;
* will take a lead role in the final study analysis in collaboration with StrokeNet NDMC Biostatisticians.

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| **If you have a current statistician working with you on the project, please provide their name below:**  **Name:**  **Institution:** |
| **Please provide an estimate of your study sample size to assist with the feasibility assessment.**  **Proposed number of subjects to be enrolled: \_\_\_\_\_\_**  **Describe the statistical basis for the proposed sample size calculation:** |
| **List proposed statistical methods to be used to analyze the primary and secondary aims of the trial:** |
| **Additional information (optional):** |