**NIH StrokeNet Concept Synopsis**

**Date:**

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| **Title:** | |
| **Principal Investigator(s):** | **Institution:** |
| **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**  **Ancillary study to ongoing NIH StrokeNet trial** | |
| 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 and ancillary studies to existing NIH StrokeNet trials.  **In one paragraph, please state the question that you wish to explore in this study:** | |
| **Intervention (drug/biologic/device/behavioral):** | |
| **Primary Aim:** | |
| **Primary Outcome:** | |
| **Secondary Aims/Outcomes:** | |
| **Briefly describe the scientific rationale/premise for the study:** | |
| **Describe the potential clinical, scientific and public health impact of this study:** | |
| ***Briefly describe relevant evidence (pre-clinical and/or clinical) used to support the proposed study-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) ***):***  ***Preclinical:***   * ***Describe any pre-clinical data that supports the proposed study, addressing rigor of those studies and relevance of the results (e.g., which models were used, were controls used, were data replicated, evidence the intervention reached its target, route and dosing of the intervention, etc.).***   ***Clinical:***   * ***Describe any prior clinical studies and/or trials that support the proposed study, addressing rigor of those studies and relevance of the results.*** | |
| **List any ongoing trials (in US or elsewhere) that are investigating a similar intervention/patient population or that otherwise may compete with the proposed study.** | |
| **Briefly describe the proposed design:** | |
| **Inclusion of women and minorities:**  **For clinical trials, describe available data regarding potential differences of clinical or public health importance in the intervention effect based on sex/gender, racial/ethnic, and relevant subpopulation comparisons and how such evidence will be accounted for in the study design (refer to** [**https://grants.nih.gov/grants/funding/women\_min/guidelines.htm**](https://grants.nih.gov/grants/funding/women_min/guidelines.htm) **for further information).** | |
| **Patient selection criteria, including window of treatment:**  **Inclusion Criteria**  **Exclusion Criteria:** | |
| **List participating pharmaceutical, biologic or device manufacturing companies (if any):** | |
| **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?** | |

**Statistical Considerations:**

All projects conducted in the network will utilize the NIH 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 NIH 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 NIH 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 NIH 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:** | | | |
| **Phase:** | **Max Sample Size:** | **Duration of Enrollment:** | **Length of Follow-Up:** |
| **Describe the assumptions made to derive the proposed sample size, including the clearly defined primary outcome and corresponding hypothesis, error probabilities, planned interim analysis, adjustments for noncompliance, etc:** | | | |
| **List proposed statistical methods to be used to analyze the primary aims of the trial, including methods to compare intervention effects among the sex/gender and racial/ethnic groups:** | | | |
| **Additional information (optional):** | | | |