**NIH StrokeNet Concept Synopsis**

**Date:**

|  |
| --- |
| **Title:** |
| **Study Acronym:** |
| **Principal Investigator(s):** | **Institution:** |
| 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. **Project Description:***Instructions: The entire synopsis should be no longer than* ***5 pages*** *(Excluding references – which can include up to 20 references on a separate page)* |
| **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** |
| **Provide a Lay person summary of the project (limit to 200 words):** |
| **Describe the scientific rationale/premise for the study (include biological premise and summary of any evidence supporting the need for the study; limit to 1 page):** |
| **What is the potential clinical, scientific and public health impact of doing this study (state impact in the event the trial is negative as well as positive)?** |
| **Intervention (drug/biologic/device/behavioral):** |
| **List participating pharmaceutical, biologic or device manufacturing companies (if any). Studies using patented drugs or devices should indicate the willingness of the company to provide resources to conduct the trial:** |
| **Primary Aim:**  |
| **Primary Outcome:** |
| **Secondary Aims/Outcomes:**  |
| **Provide brief description of the proposed design:** |
| **Patient selection criteria, including window of treatment:****Inclusion Criteria****Exclusion Criteria:** |
| **Diversity, equity, Inclusion and retention: Describe the demographics of the patient population under study (gender/sex, race, ethnicity of those with the disease/condition across the life span) and plans to ensure an adequate enrollment of populations that experience health disparities (e.g., study tools, training, outreach, community engagement, types of sites or specialties needed, etc).**  |
| **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. If a similar trial is currently being conducted, explain the scientific justification for starting the proposed trial before the other trial is completed and/or explain the potential impact that the potential results of that trial could have on the design or conduct of this proposed study.**  |
| **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 [ ]**  |

**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.

|  |
| --- |
| **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:** |
| **For exploratory phase 1 or phase 2 studies, what specific outcomes would make you determine that the investigational agent/biomarker warrants or does not warrant further study, e.g. a Phase III trial? What is the “go”, ‘no-go’ decision?**  |