1. **Promotion / Solicitation**

Solicitation, development and submission of clinical trials will be actively pursued through various appropriate mechanisms, including some or all of the following:

1. Frequent communication with StrokeNet Investigators and NINDS Program Directors who can refer investigators to StrokeNet as they are approached with appropriate projects
2. A Funding Opportunity Announcement (FOA) or Notice in the NIH Guide.
3. Encouraging StrokeNet investigators to engage their collaborators in academia or industry or other StrokeNet investigators to identify promising projects
4. Promotion of StrokeNet in appropriate journals including *Stroke*, *Neurology* and *Annals of Neurology*, as well as at appropriate scientific meetings such as International Stroke Conference( ISC), Society for Neuroscience (SFN), American Academy of Neurology (AAN), etc.
5. Frequent communication with industry, biotechnology and patient group representatives about goals and availability of StrokeNet.
6. Information about important, unanswered clinical questions and potential clinical trials on the StrokeNet website ([www.NIHStrokeNet.org](http://www.NIHStrokeNet.org)).
7. **Concept Approval and Scientific Review**

The initial determination of project suitability for StrokeNet will be made by NINDS. Projects to be considered for funding and conduct within StrokeNet must follow the process defined below.

1. Concept approval by NINDS
   * 1. Once the prospective applicant (i.e., Protocol Principal Investigator or PPI) is ready to proceed with a potential grant submission of a project to be conducted within the network, he/she should contact NINDS at ([StrokeNetInquiry@mail.nih.gov](mailto:StrokeNetInquiry@mail.nih.gov)). The PPI will be invited to complete and submit the StrokeNet Clinical Study Concept Synopsis Form to the NINDS.
     2. NINDS program staff will determine the completeness of the information provided and whether or not the proposed study is appropriate for the network. A telephone conference including NINDS program staff and the PPI may be scheduled to gather missing information.
     3. Projects deemed to be appropriate and complete will be presented to the NINDS Extramural Science Committee (ESC) for evaluation of the proposal’s alignment with the overall mission and priorities of NINDS. If approved by ESC, the PPI may proceed with the development of the project and a grant application.
2. Assessment of Feasibility and Development of the Grant Application
   1. Proposed studies that are approved by the NINDS for further development and grant submission are referred to the StrokeNet Executive Committee (StrokeNet EC), which in turn will refer the projects to the appropriate StrokeNet Working Committee to assess feasibility and provide information relevant for developing a final budget for the grant application.

Feasibility assessment will include:

* + - * 1. Confirmation of availability of patient population at StrokeNet sites.
        2. Determination of the number of StrokeNet sites needed and whether an adequate number of sites are willing to participate in the study.
        3. Determination of the ability of the StrokeNet sites to conduct the specific study including available technology, resources, personnel, etc.
        4. Assessment of regulatory requirements.
        5. Confirmation of availability of drug/placebo/devices for the proposed study, if applicable.
  1. Proposed studies deemed to be infeasible by the Working Committee are referred to the StrokeNet EC and NINDS for resolution.
  2. The PPI is responsible for writing and submitting the grant application to NIH but may work with the StrokeNet Investigators who may provide input into the proposal to ensure that is optimized to be conducted within the StrokeNet;
  3. The StrokeNet EC and the National StrokeNet Clinical and Data Coordinating Centers will provide any relevant information that may be needed in order to allow the PPI to comply with the NINDS regulatory submission policy (<http://grants.nih.gov/grants/guide/notice-files/NOT-NS-11-018.html>) ensuring the protocol is either under an open IND/IDE at the time of submission or has received an exemption from the FDA.
  4. The StrokeNet NCC PI and NDMC PI will provide letters of support for the grant application.

1. Grant Submission, Scientific Review and Project Initiation
2. Grant applications will be submitted to the NIH at the application cycle deadlines provided in the StrokeNet-specific FOAs:

* **NIH StrokeNet Clinical Trials and Biomarker Studies (UO1)** (PAR- 14-NNN)1
* **NIH StrokeNet Infrastructure Resource Access (X01)** (PAR-14-ZZZ)1
* **NIH StrokeNet Small Business Innovation (U44)** (PAR-14-XXX)1

1. Submitted applications will be reviewed by an NINDS StrokeNet Special Emphasis Panel followed by NINDS Council review.
2. Projects approved for funding by NINDS will be prioritized for implementation in the StrokeNet as follows:
   1. Competition with ongoing projects will be determined by the NCC/StrokeNet EC and the NINDS to determine when the project should begin.
   2. Projects that are not prioritized for immediate implementation will be put in a project queue and their initiation and funding will be deferred until approved to begin by the NCC/StrokeNet EC and the NINDS.
   3. Once a project is cleared to start, NINDS will award the approved funds and the project will be assigned to the appropriate StrokeNet working group to develop a final operational study protocol.

1 *The NIH FOAs are pending publication in the NIH Guide; however interested investigators may initiate the concept approval step in the interim.*