



Announcement for Solicitation of Satellite Sites

Background

The Cardiothoracic Surgical Trials Network (CTSN) was established in 2007 with support from the National Heart, Lung, and Blood Institute (NHLBI), the National Institute of Neurological Disorders and Stroke (NINDS) at the National Institutes of Health (NIH), and the Canadian Institutes of Health Research (CIHR).

The goal of the Cardiothoracic Surgery Network (CTSN) is to establish a cooperative network of cardiac surgery programs to promulgate the use of evidence-based medicine in surgical practice. The Network is intended to design, conduct, and analyze important, randomized clinical trials and observational studies, disseminate the results, and thereby translate the findings into clinical practice.

The Network currently consists of 8 Core Clinical Sites, 4 Affiliate Sites, 4 Ancillary Sites and 8 Satellite Sites in the USA and Canada. The CTSN Data Coordinating Center (DCC) is located at the International Center for Health Outcomes and Innovation Research (InCHOIR), The Mount Sinai School of Medicine, N.Y.

Solicitation Announcement

The Network is soliciting additional Satellite Sites (investigative sites outside the CTSN) to participate in the Network trial ***SURGICAL ABLATION VERSUS NO SURGICAL ABLATION FOR PATIENTS WITH PERSISTENT OR LONGSTANDING PERSISTENT ATRIAL FIBRILLATION UNDERGOING MITRAL VALVE SURGERY***. These Satellite Sites will enhance recruitment, provide additional clinical expertise, and participate in the intellectual output of the Network.

Purpose of the Study

The primary aim of this proof-of-concept trial is to determine if surgical ablation for persistent or longstanding persistent AF is more effective than mitral valve surgery (MVS) alone in reducing occurrence of post-MVS AF at 6 months and 1 year. Patients are randomized in a 1:1 fashion to surgical ablation and LAA closure versus LAA closure alone. Inclusion of 2 different lesion sets in the ablation group (pulmonary vein isolation only [PVI] and a biatrial Maze lesion set) will provide preliminary data to guide development of a follow-up study comparing effectiveness of these 2 lesion sets. In addition to 72-hour continuous rhythm assessment at 6 months and 1 year (Holter), patients perform transtelephonic monitoring to inform follow-up strategies for future trials of rhythm control in AF.

Applicant Requisites

The information required in response to this solicitation has been determined to be essential in the evaluation, review and sub-award contract process. The application document will demonstrate the Satellite Site's ability to participate in this clinical trial of the Network and adhere to the processes described in the research protocol and manual of operations.

The potential Satellite Site must have a large volume of cardiothoracic surgery with a substantial number of patients that meet enrollment criteria for the trial described above. In addition, the sites must have a

favorable history of collaboration in clinical research and successful enrollment in surgical trials, institutional support and established relationships between the Cardiothoracic Surgical program and the Interventional, Echocardiology and general Cardiology departments.

Application Process

Each potential Satellite Site will need to complete an application document. In this application document, the applicant will need to document:

- the Site's clinical trials experience and clinical and research infrastructure
- the Site's track record in recruiting patients for surgical clinical trials
- the Site's enrollment potential for the current Network trial
- Standard NIH Biosketches or CVs, licenses and human subject training certifications for the PI, and Co-I.

Selection Process

The potential Satellite Site will submit their application document (and supporting materials) to the CTSN Data Coordinating Center (DCC) for review of completeness. The DCC will distribute the materials to the CTSN Satellite Site Sub-Committee for evaluation and recommendation. Complete application documents will be reviewed for responsiveness to the requirements specified and willingness to participate in CTSN trial within the budget approved by NHLBI. Final approval of a satellite site application will occur upon majority vote from the CTSN Steering Committee. Satellite sites will be notified of final decisions by the DCC.

All materials must be received at the DCC by **April 21, 2011**. Satellite sites will be notified by **May 15th, 2011** of the decision of the CTSN Steering Committee. Applications and relevant documents may be obtained by visiting the CTSN website at:

www.ctsurgerynet.org

For any questions or to receive an application and supporting documents, please contact:

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Website: For more information on the CTSN, please visit our website: www.ctsurgerynet.org