NOTICE OF OPPORTUNITY FOR CLINICAL TRIAL COLLABORATION

A --- Utilization of Hemodialysis Devices in an NIH-Sponsored Multi-Center Clinical Trial of Frequent Dialysis for Patients with End-Stage Renal Disease (ESRD)

General Information

Document Type:	Special Notice
Solicitation Number:	Reference-Number-DK-04-0366
Posted Date:	August 30, 2004
Current Response Date:	October 12, 2004
Classification Code:	A -- Research & Development

Contracting Office Address

Department of Health and Human Services, National Institutes of Health, Nat'l Institute of Diabetes, Digestive, & Kidney Diseases, 2 Democracy Plaza, Suite 700W 6707 Democracy Blvd., MSC 5455, Bethesda, MD, 20892-5455

DESCRIPTION: The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health (NIH) and the Department of Health and Human Services (DHHS) seek collaboration with industry to provide dialysers and compatible tubing for hemodialysis for use in an NIH-sponsored multi-center clinical trial of frequent dialysis for patients with End-Stage Renal Disease (ESRD).

INTRODUCTION: The NIDDK is planning to test whether it is feasible to randomize a representative sample of patients with ESRD and requiring hemodialysis, into either (a) conventional thrice-weekly dialysis treatments, or (b) one of two forms of frequent dialysis. Two clinical centers have formed regional groups to randomize 300 subjects to either conventional 3 times per week in-center dialysis or 6 times per week in center dialysis. Another clinical center has formed a consortium to randomize 300 subjects to either conventional 3 times per week in-center hemodialysis or 6 times per week nocturnal hemodialysis at home. The overall study is named Frequent Hemodialysis Network (FHN). The following Clinical Centers will be recruiting patients: The Renal Research Institute (New York City); The University of California, San Francisco; and Wake Forest University. The NIDDK-funded Data and Analysis Coordinating Center will be the Cleveland Clinic Foundation.

STUDY GOALS: The overall goal of FHN is to evaluate more intensive hemodialysis in ESRD. The aim of this trial is to test whether it is feasible to randomize a representative sample of patients with ESRD and requiring hemodialysis, into either (a) conventional thrice-weekly dialysis treatments, or (b) one of two forms of frequent dialysis. The results of these trials will determine whether NIDDK should continue this research with a large-scale trial powered to measure the impact of more frequent dialysis on hard endpoints such as mortality and/or cardiovascular outcomes. The major outcomes will be hospitalization, quality of life and left ventricular mass. Other clinical

measurements will also be collected. The duration of treatment for each subject will be one year. The trials will also provide preliminary data on the impact of these modalities on patients.

SUPPLEMENTAL INFORMATION: It is anticipated that the protocol will be approved by an independent Data and Safety Monitoring Board established by the NIDDK. It is estimated that recruitment will begin January 2005. The Collaborator will be expected to provide hemodialysis equipment in the form of dialyzers and its compatible tubing without charge and in sufficient quantities for the expected duration and number of participants in the trial.

CAPABILITY STATEMENTS: A selection committee will utilize the information provided in the "Collaborator Capability Statements" received in response to this announcement to help in its deliberations. It is the intention of the NIDDK that all qualified Collaborators have the opportunity to provide information to the selection committee through their capability statements. The Capability Statement may not exceed 10 pages and should address the following selection criteria: the statement should provide specific details about the product to be supplied, particularly any validation of its use in a pediatric population, and in obese subjects, if relevant; and the statement should include a detailed plan demonstrating the ability to provide sufficient quantities of the product in a timely manner for the duration of the study. The statement may also include outcome measures of interest to the Collaborator.

TERMS: The Collaborator will be expected to execute a Clinical Trial Agreement, an example of which can be found at http://techdev.niddk.nih.gov/forms.htm. No funding from the government is available.

SUBMISSION DATES: A written statement of interest must be submitted by **September 27, 2004** and all Collaborator Capability Statements must be submitted by **October 12, 2004.**

Submit statements of interest and capability statements to:

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