Notice of Opportunity for Collaboration with the Glycemic Reduction Approaches in Diabetes: A Comparative Effectiveness (GRADE) study

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health (NIH) seeks collaborations with industry to provide therapeutic agents and supplies for a study of patients with type 2 diabetes with a known duration of less than 3 years.

The epidemic of type 2 diabetes that has affected the U.S. and other populations in the last half of the 20th and first part of the 21st centuries threatens to become the major public health problem of this century. The most recent estimates in the U.S. include a prevalence of approximately 24.5 million persons with type 2 diabetes, with an incidence of 1.8 million new cases per year. One of the major challenges for practitioners is to choose the best means for initially achieving and then maintaining an appropriate level of glycemic control over time. Unfortunately, there is a dearth of head-to-head comparator studies of different glucose-lowering medications, either alone or in combinations. Moreover, only a few studies have examined the durable effects of interventions on glycemic control. Given the importance of achieving and maintaining adequate glycemic control over time, it is critical to understand the relative effectiveness of the different medications and their combinations, and whether introducing them sequentially, the traditional treatment strategy, or initially in combination is most effective in maintaining glycemic goals over time.

This trial will compare:
1. The relative benefits of five anti-diabetic medications, with different glucose lowering mechanisms, when used in conjunction with metformin, and
2. Two treatment strategies: the introduction of combination therapy early in the course of diabetes care (early combination therapy) and sequential therapy to determine which strategy will provide improved glycemic control over time.

The trial will be conducted at clinical centers throughout the United States of America with expertise in the conduct of clinical trials in type 2 diabetes. These centers will enroll 7,500 patients with type 2 diabetes over approximately 3 years. The average duration of follow-up is expected to be approximately 4 years. The Study Chair for this clinical trial is David Nathan, MD from Massachusetts General Hospital, and the Coordinating Center will be the George Washington University Biostatistics Center.

In supporting this trial, the NIDDK wishes to provide important currently unavailable data on the comparative efficacy, safety, tolerability, and effects on other clinically relevant factors of currently available medications to treat diabetes that will help inform physicians when making treatment decisions. Additionally the results of this trial may inform organizations in the development of policy and treatment guidelines.

This notice is being provided to ensure that potential collaborators have sufficient time to respond to the opportunity.

Additional information about the study can be found at
http://www2.bsc.gwu.edu/bsc/grade.html

Details of the collaboration opportunity and Capability Statements are provided below.

Research Initiative Details

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health (NIH) is seeking proposals in the form of capability statements from companies that are interested in collaborating with The Glycemia Reduction Approaches in Diabetes: A Comparative Effectiveness (GRADE) Study group by providing selected currently approved therapeutic agents and diagnostic markers or devices or supplies. These could include the following:

-Metformin
-Sulfonylureas
-Thiazolidinediones
-Dipeptidyl peptidase-4 inhibitors
-Glucagon-like peptide-1 agonists
-Long- and intermediate-acting insulin
-Glucose meters and strips
-Any other equipment or testing supplies (e.g. syringes, lancets, etc) or agent that is consistent with the research objectives of the GRADE Study.

In NIDDK's selection of product to be used in the study, preference will be given to agents based on effectiveness in lowering glycemia, safety profile, tolerability and convenience of administration.

SUPPLEMENTARY INFORMATION: Collaborative arrangements may be made under a transactional agreement e.g. a Clinical Trial Agreement (CTA) or Clinical Material Supply Agreement (CMSA), as appropriate. These agreements are designed to enable certain collaborations between the federal Government and non-Government entities. They are not grants or contracts for the procurement of goods/services. Therefore, NIDDK is prohibited from transferring funds to a collaborator under these transactional agreements. However, NIDDK can contribute facilities, staff, materials, and expertise to the effort. The collaborator typically contributes materials and sometimes, in addition, facilities, staff, expertise, and/or funding to the collaboration. Please contact Anna Amar at the contact information given below for further details on mechanisms for collaboration.

CAPABILITY STATEMENTS: The NIDDK will utilize the information provided in the Collaborator Capability Statements received in response to this announcement to help in implementation of the GRADE Study. It is the intention of the NIDDK that all qualified Collaborators have the opportunity to provide information to be used for selection through their capability statements. The Capability Statement should not exceed 10 pages of narrative and should address the following selection criteria:

--The statement should include a detailed plan demonstrating the ability to provide, without charge, sufficient quantities of the material in a timely manner for the duration of the study which is anticipated to be 7 years. Approximately 7500 subjects will be treated with metformin, and approximately 1500 subjects will receive each of the other listed therapeutic agents.

--The statement may include outcome measures of interest to the Collaborator. The specifics of the proposed outcome measures should include, but not be limited to, treatment and evaluation of type 2 diabetes.

--The Collaborator's intention to provide support for the clinical research project to include, but not limited to, services, facilities, equiptment or the other resources as appropriate (i.e., pursuant to a Cooperative Research and Development Agreement authorized under 15 U.S.C. §3710a), such as funding to help support the cost of the project.

--The Collaborator must agree to have data collection and analysis performed by the Coordinating Center at the George Washington University Biostatistics Center (or other study-specified facility).

--A description of the methods that would be used to assure privacy and maintain confidentiality of data.

--The Collaborator must agree to share (with NIDDK and the GRADE Study Group) any new safety data from other studies involving any therapeutic agents or diagnostic device as well as relevant efficacy data from other studies (updated Investigator Brochure, or package insert).

--The statement must address willingness to promptly publish research results.

SUBMISSION DATES: Only written capability statements received by the NIDDK on or before June 30, 2011 will be considered. Applicants meeting the criteria as set forth in this announcement will be invited at the Applicant's own expense to discuss with the GRADE Study Steering Committee their plans, capabilities, and research findings pertinent to the study.

Note: No funding will be provided to Collaborators by NIDDK.

Inquiries

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A formatted version of the Notice of Opportunity will be posted at: http://TechDev.Niddk.nih.gov/