

## Notice of Opportunity for Collaboration

### **TODAY (Treatment Options for Type 2 Diabetes in Adolescents and Youth) 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 medications and equipment/supplies required for the treatment of youth with type 2 diabetes.

**INTRODUCTION:** Type 2 diabetes has traditionally been viewed as a disease of adults; however, recent epidemiological data reveal an increasing number of cases of type 2 diabetes in the pediatric population, especially among adolescents and in certain minority populations. The increase of type 2 diabetes in youth is presumed to be a consequence of widespread obesity.

The drugs currently approved for use in adults with type 2 diabetes have not been systematically studied in children. Thus, treatment options for those children diagnosed with type 2 diabetes are restricted by the lack of data on the use of such pharmacological agents. In addition, the adolescent period presents special challenges to health care providers and families when attempting to promote behavior and life style changes, as well as medication adherence. Finally, treatment programs must also consider cultural differences among racial and ethnic groups that may influence acceptance of medical or lifestyle regimens. This is especially important for type 2 diabetes in children, which disproportionately affects minority groups.

**BACKGROUND:** The TODAY study is designed to determine the best approach(es) to treating children and adolescents with type 2 diabetes. The study, conducted at 15 clinical sites and a coordinating center, recruited 700 youth, ages 10-17 years, who were within two year of diabetes diagnosis. Youth were randomized to one of three arms: metformin, metformin plus rosiglitazone, and metformin plus an intensive lifestyle change program. TODAY is testing the hypothesis that initial aggressive therapy will provide better glycemic control than traditional, step-wise therapy. This could potentially have long-lasting benefits in adolescents who may be thrown into diabetes by pubertal insulin resistance.

The primary outcome is time to failure, defined as HgbA1c > 8% for 6 months. The intervention phase will end in February 2011.

**STUDY GOALS:** The NIDDK plans to maintain the TODAY cohort for at least two years once the intervention has ended, and possibly longer, to study the clinical course of type 2 diabetes in those who develop the disease at an early age, particularly with respect to 1) development of diabetes complications and risk factors for complications, and 2) evolution of beta cell function. To facilitate retention of the cohort and to enable the investigators to examine the long-term effects of original randomization arm, it is desirable to continue to provide diabetes treatment to the TODAY subjects, in as uniform a manner as possible.

**SUMMARY:** 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 TODAY study group by providing medications, equipment and supplies required to treat the TODAY subjects. This would include: 1) metformin; 2) insulin; 3) statin; 4) ACE inhibitor; 5) other anti-hypertensives, including thiazide diuretics and ARBs; 6) glucose meter and/or strips; 7) insulin syringes; 8) lancets; 9) urine ketone strips.

**SUPPLEMENTARY INFORMATION:** Collaborative arrangements may be either Clinical Trial Agreements or Cooperative Research and Developments Agreements (CRADAs) pursuant to the Federal Technology Transfer Act of 1986 (FTTA, 15 U.S.C. 3710; and Executive Order 12591 of April 10, 1987, as amended by the National Technology Transfer and Advancement Act of 1995), as appropriate. Clinical Trial Agreements and CRADAs are agreements designed to enable certain collaborations between Government laboratories and non-Government laboratories. They are not grants, and not contracts for the procurement of goods/services. The NIDDK is prohibited from transferring funds to a Clinical Trial or CRADA collaborator. Under a CRADA, NIDDK can contribute facilities, staff, materials, and expertise to the effort. The collaborator typically contributes facilities, staff, materials, expertise, and funding to the collaboration. The CRADA collaborator receives an exclusive option to negotiate an exclusive or non-exclusive license to Government intellectual property rights arising under the CRADA in a pre-determined field of use and make contributions that qualify one or more of its employees as a co-inventor(s) of new technology developed under the CRADA. Examples of the Clinical Trial Agreement and the CRADA can be found at <http://techdev.niddk.nih.gov/>.

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

1. The statement should provide specific details of the methods to be utilized in the investigation of therapeutic agents including drugs, biologics, and devices in patients with type 2 diabetes and clearly describe important issues surrounding the evaluation of disease management in these patients.
2. The statement should include a detailed plan demonstrating the ability to provide sufficient quantities of the medication, supplies and/or equipment in a timely manner for the duration of the study.
3. A description of the methods that would be used to assure privacy and maintain confidentiality of data.
4. The statement may include outcome measures of interest to the Collaborator. The specifics of the proposed outcome measures and the proposed support should include but not be limited to treatment and evaluation of type 2 diabetes, personnel, services, facilities, equipment, or other resources that would contribute to the conduct of the commercial development.
5. If appropriate, specific funding commitment to support the advancement of scientific research.
6. Must agree to have their preparation used in the above-mentioned TODAY study-developed protocols which will be conducted by the Network and will have data collection and analysis performed by the TODAY study's Data Coordinating Center.
7. Must provide IND sponsor of the studies with cross-reference access to a US FDA filing that contains the chemistry, manufacturing and controls information for the drug substance and drug product.
8. Adverse event profile from human studies must be provided.

9. Must agree to share (with NIDDK and potentially the TODAY study) all safety data from other studies involving their preparation as well as relevant efficacy data from other studies (, etc).

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

**SUBMISSION DATES:** Only written capability statements received by the NIDDK on or before October 1, 2010 will be considered.

**CONTACT INFORMATION:** Submit Capability Statements to:  
Patricia Lake  
Deputy Director, Office of Technology Transfer and Development  
National Institute of Diabetes and Digestive and Kidney Diseases  
6707 Democracy Blvd., Room 778  
Bethesda, MD 20892-5343  
Phone: (301) 594-6762  
Fax: (301) 480-7546  
e-mail: [lakep@mail.nih.gov](mailto:lakep@mail.nih.gov)

*For Scientific Inquiries contact:*  
Barbara Linder, M.D., Ph.D.  
Division of Diabetes, Endocrinology and Metabolic Diseases  
National Institute of Diabetes and Digestive and Kidney Diseases, NIH  
6707 Democracy Blvd., Room 699  
Bethesda, MD 20892-5460  
Phone: 301.594.0021  
Fax: 301.480.4803  
e-mail: [linderb@mail.nih.gov](mailto:linderb@mail.nih.gov)

A formatted version of the Notice of Opportunity will be posted at:  
<http://techdev.niddk.nih.gov/collabs.shtml>