

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****National Cancer Institute: Development of a Method for High Speed Parallel Nucleic Acid Sequencing**

An opportunity for a Cooperative Research and Development Agreement (CRADA) is available for collaboration with the NCI Intramural Division of Basic Sciences to develop a new high speed method for DNA sequencing called Two Dye Sequencing (TDS). This new sequencing method employs the use of a fluoresced DNA polymerase to catalyze polymerization of likewise fluoresced oligonucleotides, with the entire construct working in the chamber of a microscope point of view which can detect individual molecules. Collaborator expertise in genetic engineering is essential to this project.

AGENCY: National Cancer Institute, National Institutes of Health, PHS, DHHS.

ACTION: Notice of opportunity for cooperative research and development agreement.

SUMMARY: Pursuant to the Federal Technology Transfer Act of 1986 (FTTA, 15 U.S.C. 3710; Executive Order 12591 of April 10, 1987 as amended by the National Technology Transfer and Advancement Act of 1995), the National Cancer Institute (NCI) of the National Institutes of Health (NIH) of the Public Health Service (PHS) of the Department of Health and Human Services (DHHS) seeks a Cooperative Research and Development Agreement (CRADA) with a pharmaceutical or biotechnology company. CRADA proposals should include development of a prototype. The CRADA would have an expected duration of one(1) to five(5) years. The goals of the CRADA will include the rapid publication of research results and timely commercialization of products, diagnostics and treatments that result from the research. The CRADA Collaborator will have an option to negotiate the terms of an exclusive or nonexclusive commercialization license to subject inventions arising under the CRADA.

ADDRESSES: Proposals and questions about this CRADA opportunity may be addressed to Mr. Kevin Brand, Technology Development & Commercialization Branch, National Cancer Institute—Frederick Cancer Research and Development Center, Fairview Center, 1003 West Seventh Street, Room 502, Frederick, MD 21701,

Telephone: (301) 846-5222; Facsimile: (301) 846-6820.

EFFECTIVE DATE: Organizations must submit a proposal summary of one page or less, to NCI on or before November 13, 2000. Guidelines for preparing full CRADA proposals will be communicated shortly thereafter to all respondents with whom initial discussions will have established sufficient mutual interest.

SUPPLEMENTARY INFORMATION:**Technology Available**

The National Cancer Institute (NCI) of the National Institutes of Health (NIH) has initiated the development of a new high speed DNA sequencing method designated as Two Dye Sequencing (TDS), and has a pending patent application embodying this technology. This method employs engineered DNA polymerases which are labeled with a fluorophore such as Green Fluorescent Protein (GFP) and are combined with an annealed oligonucleotide primer in a chamber of a microscope field of view capable of detecting individual molecules. Four nucleotide triphosphates, each labeled on the base with a different fluorescent dye are introduced to the reaction. Light of a specific wavelength is used to excite the fluorophore on the polymerase, which in turn excites the neighboring fluorophore on the nucleotide by Fluorescence Resonance Energy Transfer (FRET). As nucleotides are added to the primer, their spectral emissions provide sequence information of the DNA molecule. The NCI, in accordance with the regulations governing the transfer of agents which the Government has taken an active role in developing (37 CFR 404.8), is seeking a pharmaceutical or biotechnology company which can assist in the development of a working construct that embodies this technology for commercialization. Those potential collaborators interested in reviewing NCI's pending patent application on this technology should contact J.P. Kim at the National Institutes of Health, Office of Technology Transfer, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852, Telephone (301) 496-7056; Facsimile (301) 496-0220.

The role of the National Cancer Institute in this CRADA may include, but not be limited to:

1. Providing intellectual, scientific, and technical expertise and experience related to the development of this new method for sequencing DNA via the TDS technology.
2. Providing collaborator access to confidential information relating to the

pending patent application which embodies this technological improvement in DNA sequencing.

3. Planning research studies and interpreting research results.

4. Publishing research results.

The role of the CRADA Collaborator may include, but not be limited to:

1. Providing significant intellectual, scientific, and technical expertise or experience to the development of a prototype that employs this two-dye sequencing method. Although expertise in genetic engineering is essential, expertise in chemical synthesis, microscopy, laser optics, single molecule detection, imaging processing and computer algorithms or a willingness to enter these fields will be favored.

2. Providing technical and financial support to facilitate these scientific goals, as well as personnel and laboratory space.

3. Assuming responsibility for the commercialization, marketing and distribution of this sequencing method.

4. Planning research studies and interpreting research results.

5. Publishing research results.

Selection criteria for choosing the CRADA Collaborator may include, but not be limited to:

1. The ability to collaborate with NCI on the research and development of this technology. The ability to collaborate with NCI can be demonstrated through experience and expertise in this or related areas of technology indicating the ability to contribute intellectually to ongoing research and development.

2. The demonstration of adequate resources to perform the research and development of this technology (e.g. facilities, personnel and expertise) and accomplish objectives according to an appropriate timetable to be outlined in the CRADA Collaborator's proposal.

3. The willingness to commit best effort and demonstrated resources to the research and development of this technology, as outlined in the CRADA Collaborator's proposal.

4. The demonstration of expertise in the commercial development and production of products related to this area of technology.

5. The level of financial support the CRADA Collaborator will provide for CRADA-related Government activities.

6. The willingness to cooperate with the National Cancer Institute in the timely publication of research results.

7. The agreement to be bound by the appropriate DHHS regulations relating to human subjects, and all PHS policies relating to the use and care of laboratory animals.

8. The willingness to accept the legal provisions and language of the CRADA

with only minor modification, if any. These provisions govern the distribution of patent rights to CRADA inventions. Generally, the rights of ownership are retained by the organization that is the employer of the inventor, with (1) the grant of a license for research and other Government purposes to the Government when the CRADA Collaborator's employee is the sole inventor, or (2) the grant of an option to elect an exclusive or nonexclusive license to the CRADA Collaborator when the Government employee is the sole inventor.

Dated: September 3, 2000.

Kathleen Sybert,

Branch Chief, Technology Development & Commercialization Branch, National Cancer Institute, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute: Development of Molecular Computing Devices.

An opportunity is available for a Cooperative Research and Development Agreement (CRADA) for collaboration with the NCI Intramural Division of Basic Sciences for the development of a prototype molecular-based computer, whose mode of operation would be by the select binding of proteins along a construct. This computer could be capable of data storage, the transformation of binary information, and signal readout. This opportunity is open for a multi-party collaboration where one collaborator provides biological expertise, particularly in the field of genetic engineering, and the second provides silicon-based technological expertise, particularly expertise in silicon micromachining.

AGENCY: National Cancer Institute, National Institutes of Health, PHS, DHHS.

ACTION: Notice of Opportunity for a Cooperative Research and Development Agreement.

SUMMARY: Pursuant to the Federal Technology Transfer Act of 1986 (FTTA, 15 U.S.C. 3710; Executive Order 12591 of April 10, 1987 as amended by the National Technology Transfer and Advancement Act of 1995), the National Cancer Institute (NCI) of the National Institutes of Health (NIH) of the Public Health Service (PHS) of the Department of Health and Human Services (DHHS) seeks a Cooperative Research and

Development Agreement (CRADA with a biotechnology and/or silicon-based technology company. The CRADA would have an expected duration of one(1) to five(5) years. The goals of the CRADA will include the rapid publication of research results and timely commercialization of products, diagnostics and treatments that result from the research. The CRADA Collaborator(s) will have an option to negotiate the terms of an exclusive or nonexclusive commercialization license to subject inventions arising under the CRADA.

ADDRESSES: Proposals and questions about this CRADA opportunity may be addressed to Mr. Kevin Brand, Technology Development & Commercialization Branch, National Cancer Institute—Frederick Cancer Research and Development Center, Fairview Center, 1003 West Seventh Street, Room 502, Frederick, MD 21701, Telephone: (301) 846-5222; Facsimile: (301) 846-6820.

EFFECTIVE DATE: Organizations must submit a proposal summary, of one page or less, to NCI. Proposal review by NCI will begin on or before October 16, 2000. However, proposals will be accepted until appropriate collaborator(s) are found. Guidelines for preparing full CRADA proposals will be communicated to all respondents with whom initial discussions will have established sufficient mutual interest.

SUPPLEMENTARY INFORMATION:

Technology Available

The National Cancer Institute (NCI) of the National Institutes of Health (NIH) has a pending patent application relating to a molecular computing device. This device will act in a manner analogous to those of electronic-based computers, such as by way of flip-flops, AND gates, etc. Coupling of the gates allows for molecular computing. The method allows for data storage, the transformation of binary information, and signal readout. Possibilities include encoding "read only" memory for microscopic identifiers, digital control of gene expression, and quantification of analytes. The computing elements also provide means for complex regulation of gene expression. The NCI, in accordance with the regulations governing the transfer of agents which the Government has taken an active role in developing (37 CFR 404.8), is seeking a biotechnology and/or silicon-based technology company which can assist in the development of this prototype as described in the patent which is pending. Those potential collaborators interested in reviewing NCI's pending

patent application on this technology should contact J.P. Kim at the National Institutes of Health, Office of Technology Transfer, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852, Telephone (301) 496-7056; Facsimile (301) 496-0220.

The role of the National Cancer Institute in this CRADA may include, but not be limited to:

1. Providing intellectual, scientific, and technical expertise and experience related to the development of a prototype molecular computer.
2. Providing access to confidential information relating to the pending patent application.
3. Planning research studies and interpreting research results.
4. Publishing research results.

The role of the CRADA Collaborator may include, but not be limited to:

1. Providing significant intellectual, scientific, and technical expertise or experience to the development of a prototype molecular-based computing device, particularly in the area of genetic engineering and/or silicon micromachining.
2. Planning research studies and interpreting research results.
3. Publishing research results.

Selection criteria for choosing the CRADA Collaborator may include, but not be limited to:

1. The ability to collaborate with NCI can be demonstrated through experience and expertise in this or related areas of technology indicating the ability to contribute intellectually to ongoing research and development.
2. The demonstration of adequate resources to perform the research and development of this technology (*e.g.* facilities, personnel and expertise) and accomplish objectives according to an appropriate timetable to be outlined in the CRADA Collaborator's proposal.
3. The willingness to commit best effort and demonstrated resources to the research and development of this technology, as outlined in the CRADA Collaborator's proposal.
4. The demonstration of expertise in the commercial development and production of products related to this area of technology.
5. The level of financial support the CRADA Collaborator will provide for CRADA-related Government activities.
6. The willingness to cooperate with the National Cancer Institute in the timely publication of research results.
7. The agreement to be bound by the appropriate DHHS regulations relating to human subjects, and all PHS policies relating to the use and care of laboratory animals.
8. The willingness to accept the legal provisions and language of the CRADA