

great flexibility. As a result, it has matured into an approach which is unusually broad in its cope, and its ability to create a fabric of information out of very disparate data types.

The described methods are the subject of a patent application, USPA SN 09/203,037 filed November 30, 1998 by the Government.

Under the present proposal, the goal of the CRADA will be to enhance the development in one or more of the following areas:

### 1. Client Software Development

The prototype client software, KBTool is written in Microsoft Visual Basic 6.0 running under Windows operating systems. Planned evolution includes steps such as the following:

- (a) flexible interfaces for information viewing and update via the WWW;
- (b) rewriting parts of the application in C++ and Java;
- (c) porting to other operating systems (or re-writing in portable code);
- (d) enhanced graphical interfaces to view and manipulate the thought objects in a graphical way; and
- (e) development of specific enhancement for use for specific tasks such as workflow management, document and library management, simulation of biological processes, expert systems.

### 2. Database Engine/Server Development

The prototype knowledge base is stored in a standard relational database manipulated primarily via SQL. In the long run, the application will likely benefit from using a database engine optimized for it. This would likely include speed improvements, and ability to handle validation and integrity issues at the level of the engine rather than the client software.

### 3. Content Development

The design of this system is well adapted to many different kinds of content. Such content can be added by a range of strategies: human input, automated transfer from existing information resources, and combinations thereof. NCI seeks collaborative partner for optimizing input in areas related to cancer which encompasses many aspects of biology. For example, NCI seeks sophisticated textual analysis tools to facilitate harvest information from existing sources such as MEDLINE.

#### Party Contributions

*The role of the NCI includes the following:*

- (1) Provide staff, expertise and materials for the further development of the KBTool system;

- (2) Evaluate the work product of the Collaborator to ensure progress toward meeting the CRADA goals;

- (3) Provide work space and equipment for production and testing of any components or improvements of the KBTool system.

*The role of the successful Collaborator will include the following:*

- (1) Provide funding, if and as necessary, in support of the development of the KBTool system;
- (2) Provide expertise and assistance in the extension of KBTool in areas outlined above and in the production and market of any products resulting from CRADA;
- (3) Provide expertise and materials to aid in the development of the KBTool system during this CRADA collaboration; and
- (4) Provide, assist, or advise the NCI in quality assurance testing, operator training, and user support for any products resulting from this CRADA.

#### Selection Criteria

Proposals submitted for consideration should fully address each of the qualifications shown below. The importance of individual criteria will differ between the three areas for a proposed CRADA: client software development, database engine/server development, and content development. Please address the criteria that relate to the area(s) in which your proposal will contribute.

- (1) Expertise:
  - A. Demonstrated expertise in the creation of important new approaches in software design, database design, data visualization, and data mining, or expert systems.
  - B. Demonstrated expertise in software engineering, data warehousing, data visualization, textual analysis;
  - C. Demonstrated ability to secure national and international marketing and distribution of software;
  - D. Demonstrated expertise in overseeing all aspects of product development;
  - E. Demonstrated expertise in serving and supporting a significant client base;
  - F. Familiarity with application of knowledgebase techniques to biomedical fields.
- (2) Demonstrated experience in the software industry with regards to:
  - A. Producing, marketing and supporting knowledgebase and related applications;
  - B. Indications of high levels of satisfaction by software experts and users of knowledgebase products; and
- (3) Physical Resources:

- A. An established headquarters with offices, space and equipment;

- B. Access to the organization during business hours by telephone, mail, email, the Internet, and other evolving technologies; and

- C. Sufficient financial and technological resources to support, at a minimum, the then current activities of the CRADA to meet the needs of the NCI.

- (4) Other:

- A. The willingness to accept the legal provisions and language of the CRADA with only minor modifications, 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.

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

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

- D. 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.

Dated: April 8, 1999.

#### Kathleen Sybert,

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

[FR Doc. 99-9757 Filed 4-16-99; 8:45 am]

BILLING CODE 4140-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute (NCI); Opportunity for a Cooperative Research Agreement (CRADA) for the Scientific and Commercial Development of an Improved Cytologic Sampler for the Early Detection of Esophageal Cancer

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice of a Cooperative Research and Development Agreement (CRADA) opportunity.

**SUMMARY:** The National Cancer Institute seeks a company to collaboratively pursue the preclinical and clinical development of an orally administered cytologic sampler for the early detection of esophageal cancer. The National Cancer Institute has preclinical data and evidence that currently available sampling devices need to be and can be improved. Thus, the overall goal of this research project is to develop an improved cytologic sampler for the early detection of esophageal cancer.

**ADDRESSES:** Inquiries and statements of interest regarding this opportunity should be addressed to Rita Khanna, Technology Development and Commercialization Branch, National Cancer Institute, Executive Plaza South, Suite 450, 6120 Executive Blvd., Rockville, MD 20852 (Tel. # 301-496-0477 Fax # 301-402-2117).

**DATE TO RESPOND:** In view of the important priority of developing an orally administered cytologic sampler for the early detection of esophageal cancer, interested parties should notify this office in writing no later than thirty (30) days from date of publication of this announcement.

**SUPPLEMENTARY INFORMATION:** Cooperative Research and Development Agreement or "CRADA" means the anticipated joint agreement to be entered into by NCI pursuant to the Federal Technology Transfer Act of 1986 and Executive Order 12591 of October 10, 1987 as amended by the National Technology Transfer Advancement Act of 1995. The goal of this CRADA will be to collaborate on the specific research project described below. Under the present proposal, the Government is seeking a collaborator, who can develop an improved cytologic sampler to a marketable status to meet the public need for the early detection of esophageal cancer. The expected duration of the CRADA will be four years.

Currently, the most widely used esophageal screening method is to obtain a cytologic sample of the esophageal mucosa using an inflatable balloon or an encapsulated sponge. Although cytologic screening of asymptomatic high-risk individuals remains a promising method for the early detection of curable squamous esophageal dysplasia and cancer, a recent study by the NCI Division of Cancer Prevention and Control showed that current cytologic samplers had a low sensitivity for identifying these lesions.

Under a CRADA, the NCI can offer the selected collaborator access to facilities, staff, materials, and expertise. The

collaborator may contribute facilities, staff, materials, expertise and funding to the collaboration. the NCI CANNOT CONTRIBUTE FUNDING. The CRADA collaborator may elect an option to an exclusive or non-exclusive license to Government intellectual property rights arising under the CRADA and may qualify as a co-inventor of new technology developed under the CRADA.

The role of the National Cancer Institute, the Division of Clinical Sciences under the CRADA will include the following:

1. Providing intellectual expertise in the form of cytologic and histologic evaluation of biological samples for preneoplastic and neoplastic lesions;
2. Making suggestions regarding sampler design based on its clinical experience with existing cytologic samplers;
3. Arranging field studies to test the efficacy of new samplers;
4. Evaluating each of the active studies as they progress to ensure that the appropriate questions are being addressed and to ensure that the studies are modified as required based on the developing data; and
5. Providing technological considerations for patient safety, position and comfort.

The role of the successful corporate partner under the CRADA will include the following:

1. Understanding the biological and physiological obstacles that need to be overcome and contributing its expertise in innovative engineering toward overcoming these obstacles;
2. Providing proven competence to carry out the work of developing an improved cytologic sampler;
3. Providing technical support including design concepts, engineering analysis, detailed design, fabrication management and contribution to experimental design;
4. Performing studies to assess the physical properties of new designs in an effort to improve patient tolerance and design efficacy; and
5. Commercializing the resulting device including providing the necessary resources.

Criteria for choosing the collaborating company will include the following:

1. Experience in aspects of innovative engineering necessary for the development of cytologic samplers;
2. Scientific expertise and demonstrated commitment to the development of cytologic samplers;
3. Willingness to cooperate with the NCI in the collection and evaluation of data;
4. Experience and track record of taking such products to market;

5. Nature of resources to be contributed to the collaboration;

6. Willingness to accept the legal provisions and language of the CRADA with only minor modifications, if any. These provisions govern the distribution of patent rights to CRADA inventions. Generally, the right 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 of inventor;

7. Willingness to cooperate with the National Cancer Institute in the timely publication of research results;

8. Level of financial support the CRADA Collaborator will provide for CRADA-related Government activities; and

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

Dated: April 9, 1999.

**Kathleen Sybert,**

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

[FR Doc. 99-9758 Filed 4-16-99; 8:45 am]

BILLING CODE 4140-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C., Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed the public in accordance with the provisions set forth in section 552b(c)(4) and 552b(c)(6), Title 5, U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the discloser of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Child Health and Human Development Initial