Consortium on Translational Research in Early Detection of Liver Cancer: Data Management and Coordinating Center (U24) Pre-Application Webinar for RFA-CA-22-032

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Purpose of this Funding Opportunity Announcement (FOA)

This FOA solicits applications for the NCI Translational Liver Cancer (TLC) Data Management and Coordinating Center (DMCC). This FOA is part of an initiative designed to establish a Liver Cancer Consortium to advance translational research focused on early detection of liver cancer.

The Consortium consists of the DMCC (to be supported by this U24 FOA) and several Translational Research Centers (TRCs, to be supported by the companion U01 FOA, RFA-CA-22-031).

Applicants must consult RFA-CA-22-032 for detailed information on the scope of this RFA, application procedures and requirements, and review criteria.

Scope: Areas of Responsibility

The DMCC will support the TRCs and coordinate trans-Consortium activities with the following specific responsibilities:

1. Consortium Coordination
2. Support Consortium Collaboration Research and Provide Statistical Support
3. Data Management

To achieve these goals, the DMCC is expected to provide multi-disciplinary expertise in liver cancer research, biomarkers for cancer detection, biostatistics, bioinformatics, and the information technology infrastructure to support data management for the Consortium.

1. Consortium Coordination

- Provide logistical and administrative assistance;
- Arrange Steering Committee meetings and conference calls for the Consortium;
- Develop and maintain all formal Network documents, including Manual of Operations and other procedure manuals; and
- Provide operational support for the Consortium

2. Support Collaboration Research and Statistical Support

- Participate in protocol development for biospecimen collection and collaborative biomarker research studies;
- Provide advice and consultation to Consortium investigators on study design and protocol development of Consortium-collaborative studies;
- Coordinate collaborative efforts for the establishment of a well-annotated repository of biospecimens (blood, other body fluids, and when feasible, liver tissue);
- Develop and implement standard uniform protocols for specimen and data collection (e.g., Common Data Elements, CDE), as well as, specimen tracking in individual and multi-center Consortium studies; and
- Provide statistical analysis of Consortium collaborative studies.

3. Data Management

- Develop and maintain an integrated research database and biospecimen database for all consortium studies; and
- Development/application of analytical tools for analyzing data (e.g. biomarker validation studies).

In this context, the proposed DMCC must have expertise and capabilities in liver cancer research as related to biorepositories, biostatistics, bioinformatics and information technology, study design, data management and analysis, protocol development, and logistical support.

The DMCC team should also have expertise in the phased approach to biomarker development and validation, and be able to provide the appropriate statistical and analytic support in developing these types of studies

Research Strategy

- Subsection A: Overview and Capabilities
    - Provide an overview of the proposed DMCC in the context of the DMCC's role in the Consortium
    - Highlight innovative ways of coordinating multi-institutional trans-disciplinary research.
    - Coordination/management/organizational support of collaborative research efforts/programs in translational cancer research with emphasis on the aspects of focus for this FOA
    - Various aspects of statistical expertise pertinent to early cancer detection and surveillance
    - Ability to handle large-scale bioinformatic data
    - Capability to design and analyze biomarker validation, preferably reflecting phase 2/3 studies according to the five-phase approach
- Subsection B: Plans and Approaches to Basic DMCC Functions
    - Describe a plan for the creation and maintenance of the DMCC that addresses all the aspects, attributes, and functions identified, ie. Network Coordination, Consortium Coordination, Support Consortium Collaboration Research and Provide Statistical Support, Data Management
- Subsection C: Trans-Consortium Collaborative Research
    - Describe plans for activities that lead and/or facilitate collaborations;
    - Describe plans facilitate and logistically support pilot projects utilizing the Restricted Network Collaborative Fund.

Award Information

The administrative and funding instrument used for this program will be the cooperative agreement:

- an "assistance" mechanism, not "acquisition"
- Substantial NIH programmatic involvement with the recipients is anticipated during the performance of the activities. Under the cooperative agreement
- NIH's purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role
- It is not to assume direction, prime responsibility, or a dominant role in the activities.

Project Period: 5 years

Award Budget: Direct Costs should not exceed $400,000

Letter of Intent Due: October 7, 2022

Application Due Date: November 7, 2022

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