National Cancer Institute

Molecular and Cellular Characterization of Screen-Detected Lesions - Coordinating Center and Data Management Group (U01)

RFA-CA-14-011

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Scope

To establish a Coordination and Data Management Group (CDMG) for providing (1) coordination of consortium-wide meetings and conferences, and collaborative activities; (2) statistical support and computational analysis; and 3) data management and protocol development for the biorepository

Objectives

The CDMG will work with MCL teams to ensure that future data are collected according to established protocols and Standard Operating Procedures (SOPs), Common Data Elements (CDEs), etc.

The CDMG will function to provide:

(1) Logistical support and coordination of Consortium-wide meetings and conferences;

(2) Statistical support and computational analysis; and

3) Data management and protocol development.

Examples That Would Help Meet This Objective

Network Coordination

- Provide logistical and administrative assistance in arranging meetings of the SC, and the Executive Committee and provide logistical and administrative assistance in arranging workshops as needed;
- Provide other operational support for the Consortium (e.g., communications, subcommittee meetings, telephone conference calls);
- Produce and maintain all documents, including Manual of Operations and procedures manuals;
- Develop and maintain an interactive web page;
- Develop and maintain a "listserv" interactive email system for communication within the Consortium, and:
- Work with the NCI Program Coordinators on the review of applications/proposals submitted to the Steering Committee.

Statistical Support and Computational Analysis

Through the use of statistical Support and computational analysis the CDMG will:

- Develop and implement standard procedures for data collection by the Consortium MCLs;
- Develop instruction manuals for data collection from discovery work and interact with the participating institutions to resolve data errors;
- Develop programs to assist with or provide the following: screening of prognostic factors, survival analysis and curve graphing, covariate modeling of survival, descriptive statistics, least-squares regression analysis, power and sample size calculations, table making, data sub-setting, two variable scatter plots and analysis of time dependent covariates;
- Design interfacing modules with commercially available software necessary to support discovery related research activities. Preprocessing of high dimensional data derived from proteomic-, genomic-, epigenomic-, and metabolomic-based assays;
- Development/application of analytical tools for analyzing expression data (from DNA, RNA, or protein array expression) with respect to clinical endpoints;
- Development/application of analytical software to extract novel information from in silico data, relevant for sub-classification of screen-detected or symptom-detected cancers into indolent versus aggressive/progressive lesions.

Data Management and Protocol Development

- Support the development, coordination, implementation, and conduct of Consortium collaborative research protocols;
- Provide statistical analysis of Consortium collaborative studies;
- Assist in preparing data analysis for manuscripts on Consortium collaborative studies;
- Develop worksheets and information management systems for collection of data and specimen tracking in individual and multi-center Consortium studies, and verify all generated data deposited at the CDMG;
- Monitor Consortium protocol adherence, monitor data collection and submission, and report violations to the Steering Committee;
- Assist in the collection of epidemiologic information, data analysis, study designs, quality assurance for a central database, statistical analyses of pooled data, and distribution of specimens stored at sites participating in the Consortium;
- Support the formation and distribution of Consortium biospecimen sets and analyze data that results from the use of these specimens.

Requirements

Experience in:

- Managing multi-disciplinary projects and investigators
- Coordinating disparate group of investigators for meetings, conference calls, minutes, and other virtual meetings
- Experience and knowledge in managing protocols for data collection, storage, dissemination and managing multi-center studies
- Experience in methodology research and statistical approaches to complex data analysis
- Experience with managing clinical trials

Frequently Asked Questions

Q1. Will a new central database be created through this effort or is the intent there to leverage an existing database from another NCI program?

A1. *A big database is not expected. However, leveraging from existing resources to facilitate multi-center study is.*

Q2. Manuals and protocols are referenced in the RFA - do these refer to data preparation protocols or pathology protocols. We assume that the sites will have pathology protocols that they have already developed.

A2. *Manual refers to both organizational and procedural aspects. For every collaborative study (individual team study is excluded) that is identified and approved there will be a manual with roles and responsibilities of participating teams, data collection details, study design, etc.*

Q3. Will imaging data be part of this activity? If so, what types will be submitted by the sites?

A3. *Not known at this time.*

FAQ, continued

Q4. Can you provide an estimate of the amount of data that will be submitted by each site and also the frequency of data submissions?

A4. *We do not expect a lot. Will become clearer after the consortium is established and collaborative projects identified.*

Q5.Will the CDMG develop a web portal for data access as well as the batch data download mechanisms to support varied needs of the cancer research community?

A5. *A simple Web portal is expected and will evolve in collaboration with the NCI CBIT.*

Q6. In silico data are mentioned in the RFA. Do they refer to computational models or other information?

A6. *In silico data refers to publically-available genomic and proteomic data. We do not expect extensive modeling in this FOA.*

Q7. Will NCI provide web meeting software and conference call facilities as they have done in other projects or will the CDMG need to budget for them?

A7. *The CDMG is expected to provide these resources. Of course, NCI will work with the CDMG to find a cost-effective way to identify resources elsewhere, including NCI.*

FAQ

The RFA describes the expectation for a bioinformatics core, a biorepository, a biostatistics core, etc. It is hard to understand how the mechanism will support all of these things and still allow for the development and/or validation of a molecular signature for the differentiation of the cancers proposed.

- The CDMG will provide these expertise and resources. We plan to work with the NCI CBIT to provide additional resources for a bioinformatic core. We do not expect a large biorepository.