# EDRN Data Management and Coordinating Center Pre-Application Webinar for RFA-CA-21-034

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**NIH NATIONAL CANCER INSTITUTE**

July 12, 2021
August 9, 2021

# Purpose of this Funding Opportunity Announcement (FOA)

This FOA solicits applications for the EDRN Data Management and Coordinating Center (DMCC) from investigators with expertise in data management, data science, protocol development, biostatistics, and information technology, and in coordinating and providing logistical support for meetings and conferences.

The DMCC is one of the three scientific units of the Early Detection Research Network (EDRN).

Applicants must consult RFA-CA-21-034 for detailed information on the scope of this RFA, application procedures and requirements, and review criteria.

# Scope: Areas of Responsibility

1. Network Coordination and Outreach

2. Data Science, Data Management and Study Protocol Development

3. Validation Infrastructure and Services

4. Management of EDRN Core Fund

# 1. Network Coordination and Outreach

- Provide logistical and administrative support for EDRN meetings, workshops, and conference calls.

- Produce and maintain documents, including Manual of Operations, and maintain the EDRN central filing system.

- Employ various electronic channels of communication to promote and disseminate information among EDRN investigators and the broader scientific community;
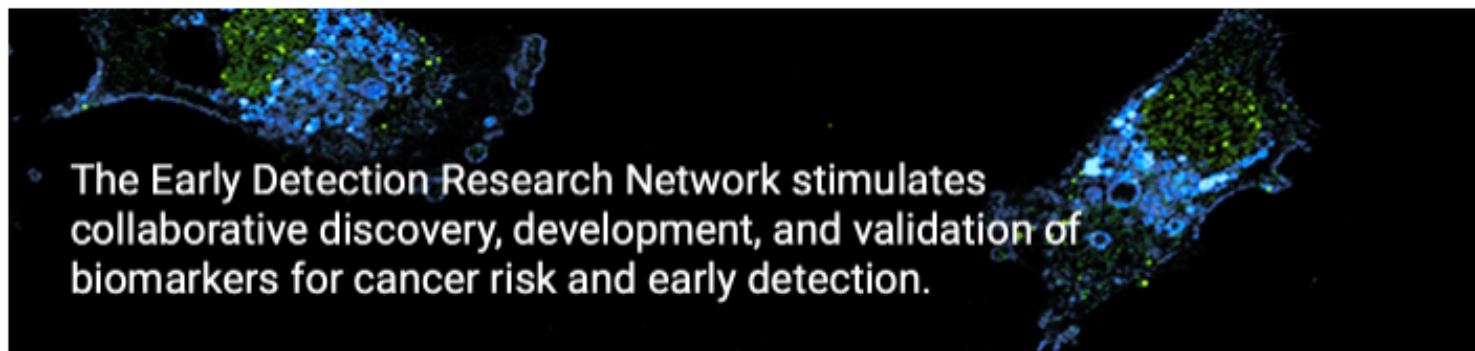
# Enhance and Maintain Public Portal

edrn.nci.nih.gov

# Enhance and Maintain Secure Website

## 2. Data Science, Data Management and Study Protocol Development

- Provide coordination and support for EDRN collaborative validation studies and other collaborative projects approved by the EDRN Steering Committee.

- Support the formation and distribution of EDRN biospecimen reference sets and analyze data that result from the use of these specimens.

- Develop uniform investigative protocols for data and specimen collection.

# Data Science and Data Management

- Possess expertise in data mining using AI and bioinformatic tools.

- Utilize data analytics (statistics, AI, MLL, Deep Learning, bioinformatics tools, etc.) to improve the understanding of the disease progression as well as new aspects of biomarker discover for early detection.

- Capture and deposit consequential data sets developed by the EDRN to Jet Propulsion Laboratory (JPL) as decided by the Steering Committee.

# Study Protocol Development

Deploy state-of-the-art system for management of data and protocol development, Laboratory Information Management System (LIMS)

- Study development
- Documentation of CDEs
- Development and distribution of biospecimens
- Data entry checks, study-specific reports
- Specimen tracking, monitoring and selection
- Eligibility programming
- Data harmonization

The LIMS must be flexible and adaptable using modern Cloud-based extensions to quickly support the various EDRN studies.

NCI anticipates that in any given year the DMCC will coordinate approximately six Network trials involving on average 10 study sites.

# 3. Validation Study Infrastructure and Services

The NCI has an Interagency Agreement with NASA's Jet Propulsion Laboratory (JPL) to support an Informatics Center (IC) to assist the EDRN in building information technology infrastructure of integrated databases, webpages and informatics tools.

The DMCC will take the lead in maintaining and developing resources for the EDRN Secure Website for data security, data warehouse with interfaces, and data analysis for Network supported validation studies.

The IC will take the lead in implementing the distributed Network-based data warehouse, tools and interfaces for publicly-accessible information.

# Manage EDRN Databases

All publicly accessible resources and tools developed by the DMCC and EDRN IC are integrated into the NCI-hosted EDRN public portal. Resources and tools include but are not limited to:

- Biomarker Database
- Specimen Reference Sets and Research Tools
- Informatics Tools
- EDRN Knowledge System
- Science Data Sets
- CDEs and CDE Mapping Tools
- Study Protocols
- Manual of Operations

DMCC will work closely with the EDRN IC in expanding and/or updating these resources to meet the growing needs of EDRN in the future.

# 4. Management of Core Fund

- The DMCC will administer the EDRN restricted Core Fund.

- The use of these funds will be restricted to support Network-wide collaborative studies and other resource-related activities, including patient accrual and collection of specimens.

- For activities reviewed and recommended by the EDRN Steering Committee and authorized by NCI, the DMCC will activate funds from the Core Fund by establishing appropriate sub-contractual arrangements with the institutions of the investigators involved.

# **Research Strategy** (up to 30 pages)

*Overview* - advantages of the proposed DMCC to serve as a scientific and organizational hub to the entire Network and explain the anticipated significance and innovation of the proposed strategies for early cancer detection, risk assessment, diagnosis, and prognosis.

*Experience and Accomplishments* - describe research accomplishments/preliminary studies relevant to biomarker development and the goals of the proposed DMCC.

- *Progress Report* (renewal application only). Include additional information in this section summarizing the current 5-year funding period.

*Plans for the Required Areas of Responsibility*

- o Network Coordination
- o Data Science, Data Management and Protocol Development
- o Validation Study Infrastructure and Services
- o EDRN Core Fund Management

# Budget

- Budget up to $6 million (direct costs) of which $4.2 million must be allocated to the restricted Network Core Fund in FY2022.

- For FY2023-2026, budget of up to $7.8 million per year (direct costs) of which $6 million per year must be allocated to the restricted Network Core Fund.

- 30% of the annual budget (excluding the Core Fund allocation) must be set-aside for Network collaborative studies. Release of these funds must be reviewed by the EDRN Steering Committee and authorized by NCI.

# **Budget (continued)**

Budget for travel and per diem expenses for the contact PD/PI together, at least one MPI or other senior investigator, and an early-stage/junior investigator to attend two Steering Committee meetings in the first year.

Budget $50,000 (direct cost only) each year for reserving a site for the Steering Committee and the Network Consulting Team meetings and other related expenses.

# Budget (Continued)
# EDRN Core Fund

- $4.2 million in FY2022 and $6.0 million in FYs 2023-2026 must be allocated to the restricted Network Core Fund, which will be used to support post-award Network-wide collaborative studies through sub-contractual arrangements.

- The exact dollar amount for Core Fund will be determined by the NCI at the time of award.

- Release of these funds must be reviewed by the EDRN Steering Committee and authorized by NCI.

# Summary

- Provide rigorous study design and development of study protocols.

- Describe your experience in management of large-scale collaborative research.

- Describe the organization of the proposed DMCC and the team's strengths in the various key components.

- Explain how the team will integrate and capitalize on the expertise of its members.

# Contact Information

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