Request for Project Concepts for Novel Biomarker Platforms in Understanding Tumor Heterogeneity

Cancer Steering Committee, High Content Data Integration Working Group

A. FNIH RFI NUMBER:  
B. DATE ISSUED: 

C. ISSUED BY:  
The Foundation for the NIH (FNIH)  
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Suite 600  
Bethesda, MD 20852  

D. ADDRESS RESPONSES TO  
(Electronic Submissions Only):  
Dana Connors, dconnors@fnih.org

E. FOR INFORMATION REGARDING THIS SOLICITATION CONTACT:  
E.1. NAME:  
Dana Connors  
E.2. EMAIL:  
dconnors@fnih.org

IMPORTANT:  
F. To be considered submissions must be received at the location specified in Block E.2. above by June 30, 2020 at 11:59 PM ET. Submission must be clearly identified with the solicitation number provided in Block A above.

The Biomarkers Consortium (BC), a division of the Foundation for the National Institutes of Health (FNIH), a non-profit, 501(c) (3) charitable organization that supports the NIH in its mission to improve health by forming and facilitating public-private partnerships for biomedical research, is issuing a Request For Proposals (RFP) for novel biomarker platforms to support the mission of the BC Cancer Steering Committee (CSC) High Content Data Integration Working Group (HCDI WG). The BC is a public-private partnership involving the National Cancer Institute (NCI), the U.S. Food and Drug Administration (FDA), multiple pharmaceutical, diagnostic and technology companies, non-profit and patient advocate organizations.

Purpose:

The mission of the HCDI WG is to develop and support pilot projects that use emerging technology platforms with the potential to overcome limitations of established methodologies in the application of multi-dimensional biomarkers. The working group is focused on technologies that have the potential to address recognized clinical challenges, such as for development of tailored signatures for patient stratification, alternatives to solid biopsies, and advanced imaging technologies. The working group provides project teams with development and implementation guidance to generate fundable projects that fit the intended use of a technology and potentially enable rational clinical decisions.

The HCDI WG invites investigators to submit brief project concept proposals for application of novel biomarker platforms to either of two clinical challenges. These proposals will be considered for funding under the BC precompetitive project model. The working group is currently focused on identifying
precompetitive, testable technical solutions with potential for commercialization that address the characterization of tumor heterogeneity:

1. Novel tissue imaging platforms to characterize tumor heterogeneity, tissue spatial connections/spatial heterogeneity. Particularly, given tumor heterogeneity, identify what is the minimal specimen required for assessment across multiple tumor types. This may involve the use of any of multiple imaging modalities (e.g., multiplex IHC, optical microscopy, image analysis, informatics and machine learning, spatial transcriptomics, and/or single cell sequencing) to characterize tissue.

2. A blood-based or remote sensing technology that can be used to replace solid tumor biopsies and to understand cancer of unknown origin or tumor heterogeneity to enable meaningful clinical intervention opportunities. For example, computational technologies or unique, novel blood-based technologies, e.g., methylation, single-cell profiling, deep sequencing, or nucleic acid fragmentation.

**Background:**

1. **Specific Objectives and Requirements:**

   This RFP solicits applications for proposals to develop novel biomarker platforms with the goal of advancing cancer treatment and research. The proposed projects must be designed such that the technology developed could ultimately be incorporated into the clinical setting. Thus, the investigators should indicate where the platform is on the developmental pipeline, and the applicants should discuss the intended use of proposed platforms relative to current technologies in use. In addition, standardization of the assay is critical, and responses to the RFP should seek to deploy assays which satisfy the definition of analytical validity as adopted by the Institute of Medicine (IOM) (Institute of Medicine 2012, *Evolution of Translational Omics: Lessons Learned and the Path Forward.* Washington, DC: The National Academies Press). Responses should outline the planned steps necessary to address analytical validity and clinical validity of an assay platform developed through an FNIH partnership.

**Project Contract Information:**

I. Consortium projects are awarded contracts administered by the FNIH. Once a project concept is reviewed and approved by the working group, the BC CSC, and the BC Executive Committee (EC), the principal investigator(s) will work with a project team comprised primarily of members of the HCDI WG to more fully develop the project plan for final EC approval for development. Once the project plan is complete, the FNIH will solicit funds from CSC industry partners (“funders”) to support the project. Once funded, the FNIH will oversee the project goals and progress, and the project team will be expanded to include two co-chairs (the principal investigator and usually either an NCI or industry member); select additional CSC and HCDI WG members (with a minimum of three funder organization representatives); government (FDA and NCI) representatives; and representatives from academic institutions, as appropriate. The FNIH will assist in establishment and development of the team. The principal investigators will report results to the project team minimally on a quarterly basis. Approval of project milestone achievements linked to funding decisions are the responsibility of the project team. Applicants must agree to work with the project team to refine the overall project and specific project goals to align with the FNIH mission and the goals of the funders.

II. **Funds Available and Anticipated Number of Projects**

The number of projects contracted and the amount per project is contingent upon (1) the number of projects approved by the FNIH committees responsible for review of the project proposals and (2)
industry funder support. These are dependent in part on the submission of meritorious applications and proper budget justification within the proposals. Selection of a proposal for consideration for development does not guarantee funding until the project is favorably reviewed by the FNIH CSC and Executive Committee (EC) and industry funding is secured.

III. Project Budget

Application budgets are typically $1 to 5 million over 3 – 5 years and must reflect the requirements of the project plan to develop the proposed biomarker/assay. Proper scientific and budget justification must be provided for evaluation. The committee reserves the right to award at a lower amount than requested.

IV. Contract Project Period

The scope of the proposed project should determine the award project period. The typical project period is 3 – 5 years with the potential for a no-cost extension to complete necessary analyses.

V. Eligibility Information

Organizations eligible to apply are:

- Private or public sector
- US-based or international
- All applicants will be expected to comply with the FNIH Policies and Guidelines that have already been established for the Biomarkers Consortium (https://fnih.org/what-we-do/biomarkers-consortium/about/policies).

VI. Application and Submission Instructions

Submission Deliverables

Complete applications will include:

- Application write-up, which should describe the information below. More details may be provided in the application response template (HCDI WG Project Concept Application Form, Appendix 1):
  - Summary of the project with the clinical challenge to be addressed, technological approach, specific aims, outcomes and deliverables.
  - The scientific strategy, overall experimental plan and the technology platform(s) to be tested as well as the definition of success given the stated aims, outcomes and deliverables.
  - Rationale for why this technology would benefit clinical oncology as described in the two clinical challenges outlined under Purpose.
  - Current status of the technology, background and supporting data (i.e., early stages, assay developed but needs analytical validation, analytical validation done but needs clinical validation, etc.).
  - High level project timeline and budget (accounting for project stages as appropriate, personnel, reagents and materials, equipment, sample acquisition, other requirements for work proposed as appropriate).

VII. Project Contract Reporting

As described under Project Information, principal investigators for awarded applications should expect to submit progress updates for the project at least quarterly to the Project Team. The format for progress reports will be agreed upon before launch and described in the award agreements.
VIII. Additional Information Required

Please provide any existing IP or patent information relevant to the technology platform that may affect its use in the partnership, or the banking of any resulting data funded by this effort in a public, but controlled-access resource.

IX. Submission Instructions

Send responses via e-mail to dconnors@fnih.org with a copy to skeating@ccsainc.com. You may email or call 301-435-2613 (DC) or 669-243-2126 (SK) with questions regarding the RFP or the submission process.

Key Dates

**Application Due Date:** June 30, 2020, 11:59 PM ET*

**Targeted Application Review Period:** July 1 - August 31, 2020

**Potential Oral Presentations from Finalists (if needed):**

Applicants will be informed by email after September 1, 2020, of the result of the initial review of proposals and whether they will be asked to provide an oral presentation to the HCDI WG by teleconference with the ability for Q&A. An invitation to present the proposal does not guarantee a selection for project development. Final selection of proposals to recommend for review by the CSC and EC will be made in the Fall of 2020. Pending a positive review by these committees, a project team will be formed as described above in *Project Contract Information*.

*If no adequate submissions are received in this timeline, the FNIH reserves the right to extend the target deadline.

About the Foundation for the NIH and the Biomarkers Consortium

*Established by the United States Congress to support the mission of the NIH – improving health through scientific discovery in the search for cure – the FNIH is a leader in identifying and addressing complex scientific and health issues. The Foundation is a non-profit, 501(c) (3) charitable organization that raises private-sector funds for and manages a broad portfolio of unique programs that complement and enhance NIH priorities and activities. For additional information about the FNIH, visit www.fnih.org. The BC is a public-private biomedical research partnership managed by the FNIH. The mission of the Biomarkers Consortium is to help create a new era of precision medicine, with more highly predictive markers that have an impact during a patient’s illness or lifespan. Its goal is to combine the forces of the public and private sectors to accelerate the development of biomarker-based technologies, medicines and therapies for prevention, early detection, diagnosis and treatment of disease. Visit https://fnih.org/what-we-do/biomarkers-consortium.*