Announcement of Requirements and Registration for the National Heart, Lung, and Blood Institute (NHLBI) Big Data Analysis Challenge: Creating New Paradigms for Heart Failure Research

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

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DESCRIPTION

Subject of the Challenge

The National Heart, Lung, and Blood Institute (NHLBI), part of the National Institutes of Health (NIH), is inviting novel Solutions for the NHLBI Big Data Analysis Challenge: Creating New Paradigms for Heart Failure Research. The goal of the challenge is to foster innovation in computational analysis and machine learning approaches utilizing large-scale NHLBI-funded datasets to identify new paradigms in heart failure research. The challenge aims to address the need for new open source disease models that can define sub-categorizations of adult heart failure to serve as a springboard for new research hypotheses and tool development in areas of heart failure research from basic to clinical settings.

Adult heart failure is a chronic, progressive disorder in which the heart is unable to efficiently pump blood, and more than 6.5 million Americans suffer from this condition. It is currently often categorized by a single metric – left ventricular ejection fraction – but is known to be a multi-organ, systemic syndrome with many related but seemingly disparate phenotypes. Additionally,

social, behavioral, environmental, and genetic determinants often captured in study data have a considerable influence on outcome but are not well-understood. The field of heart failure research currently lacks a systematic framework that incorporates these many factors in a comprehensive disease model. An adult heart failure sub-phenotyping scheme incorporating many disease-associated factors would provide a new paradigm that will benefit investigations into the mechanism of disease, diagnosis, and, ultimately, prevention and treatment.

The NHLBI seeks to foster such paradigm shifts in heart failure research by awarding innovative Solutions that utilize existing large health datasets. NHLBI has a history of making considerable investments in the creation of deep data resources including: long-standing, deeply-phenotyped epidemiological cohorts, innovative clinical trials, and large-scale precision medicine efforts that have generated whole genome sequencing and "other omics" data for more than one-hundred thousand individuals. Many of these and other data are publicly accessible via the Database for Genotypes and Phenotypes (dbGaP) and the Biologic Specimen and Data Repository Information Coordinating Center (BioLINCC). The NHLBI Heart Failure Big Data Analysis Challenge webpage provides further details about available open- and controlled-access NHLBI-funded datasets and data access resources.

With these datasets in hand, the NHLBI is seeking to promote the application of computational analysis and machine learning approaches to create opportunities for hypothesis generation and research tool development for heart failure research. This challenge aims to reward innovative, computational Solutions utilizing large health datasets to develop a schema for the subphenotyping of adult heart failure that facilitates basic and/or clinical heart failure research objectives. A successful adult heart failure sub-phenotyping Solution will be a novel, pragmatic, accessible research tool for a spectrum of heart failure researchers. Successful Solutions will also be free and openly available to the research community. Participants are strongly encouraged to take advantage of NHLBI-funded datasets in the development of their Solution and are also welcome to bring other relevant data to their analyses.

Dates

Solution Packages must be submitted to nhlbi_nih.gov by NOON (12p.m.) EST on August 28, 2020.

• Challenge Launch: February 28, 2020

• Competition Period: February 28, 2020 – August 28, 2020

• Judging Period: September – October 2020

• Winner(s) Announced: November 2020

Statutory Authority to Conduct the Challenge

The general purpose of the NHLBI is the conduct and support of research, training, health information dissemination, and other programs with respect to heart, blood vessel, lung, and blood diseases and with respect to the use of blood and blood products and the management of blood resources (42 U.S.C. 285b). The mission of the NHLBI is to promote the prevention and treatment of heart, lung, and blood diseases and enhance the health of all individuals so that they can live longer and more fulfilling lives. In order to fulfill its mission, the NHLBI stimulates basic discoveries about the causes of disease, enables the translation of basic discoveries into clinical practice, fosters training and mentoring of emerging scientists and physicians, and communicates research advances to the public. The NHLBI Strategic Vision specifically encompasses an objective to leverage emerging opportunities in data science to open new frontiers in heart, lung, blood, and sleep research. The NHLBI is conducting this Challenge under the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science (COMPETES) Reauthorization Act of 2010, as amended [15 U.S.C. § 3719]. In line with these authorities, this Challenge will lead to innovation in disease research paradigms to revolutionize basic discovery, translational research, and/or clinical investigations in adult heart failure; the result will be generalizable models of adult heart failure that will be widely available to fill longstanding gaps in our understanding and treatment of this disease.

PRIZES

Amount of the Prize

NHLBI will award up to a total of \$250,000. Up to five (5) winners will be selected, with each winning up to \$50,000. NHLBI will advertise the results of the competition and publicly display the winning Solutions. Winning participants may be invited to present their Solutions at an NHLBI-hosted scientific symposium.

Award Approving Official

The Award Approving Official will be Gary H. Gibbons, M.D., Director of the National Heart, Lung, and Blood Institute (NHLBI).

Payment of the Prize

Prizes awarded under this Challenge will be paid by electronic funds transfer and may be subject to Federal income taxes. If the Participants submit as a team, the prize will be awarded in one payment to the designated team leader. HHS/NIH will comply with the Internal Revenue Service withholding and reporting requirements, where applicable.

NIH reserves the right, in its sole discretion, to (a) cancel, suspend, or modify the Challenge, or any part of it, for any reason, and/or (b) not award any prizes if no entries are deemed worthy.

RULES

Eligibility Rules for Participating in the Challenge:

- (1) To be eligible to win a prize under this Challenge, a Participant (whether an individual, group of individuals, or entity)
 - a. Shall have complied with all the requirements set forth in this announcement;
 - b. In the case of a private entity, shall be incorporated in the United States and also maintain a primary place of business in the United States. In the case of an individual, whether

participating singly or in a group, shall be a citizen or permanent resident of the United States. However, non-U.S. citizens and non-permanent residents can participate as members of a team that otherwise satisfies the eligibility criteria. Non-U.S. citizens and non-permanent residents are not eligible to win monetary prizes (in whole or in part). Their participation as part of a winning team, if applicable, may be recognized when the results are announced.

- c. Shall not be a federal entity or federal employee acting within the scope of their employment.
- d. Shall not be an employee of the Department of Health and Human Services (HHS), or any other component of HHS, acting in their personal capacity.
- e. Shall, if employed by a federal agency or entity other than HHS or any component of HHS, consult with an agency ethics official to determine whether the federal ethics rules will limit or prohibit the acceptance of a prize under this Challenge.
- f. Shall not be a judge of the Challenge, or any other party involved with the design, production, execution, or distribution of the Challenge, or the immediate family of such a party (i.e., spouse, parent, step-parent, child, or step-child).
- (2) Federal grantees may not use federal funds from a grant award to develop their Challenge Solutions or to fund efforts in support of their Challenge Solution.
- (3) Federal contractors may not use federal funds from a contract to develop their Challenge Solutions or to fund efforts in support of their Challenge Solution.
- (4) Federal awardees may not use federal funds from an Other Transaction (OT) award to develop their Challenge Solutions or to fund efforts in support of their Challenge Solution.
- (5) By participating in this Challenge, each Participant (whether an individual, group of individuals, or entity) agrees to assume any and all risks and waive claims against the federal government and its related entities, except in the case of willful misconduct, for any injury,

death, damage, or loss of property, revenue, or profits, whether direct, indirect, or consequential, arising from participation in this Challenge, whether the injury, death, damage, or loss arises through negligence or otherwise.

- (6) Based on the subject matter of the Challenge, the type of work that it will possibly require, as well as an analysis of the likelihood of any claims for death, bodily injury, property damage, or loss potentially resulting from Challenge participation, no Participant (whether an individual, group of individuals, or entity) participating in the Challenge is required to obtain liability insurance or demonstrate financial responsibility in order to participate in this Challenge.
- (7) By participating in this Challenge, each Participant (whether an individual, group of individuals, or entity) agrees to indemnify the federal government against third party claims for damages arising from or related to Challenge activities.
- (8) A Participant (whether an individual, group of individuals, or entity) shall not be deemed ineligible because the Participant used federal facilities or consulted with federal employees during the Challenge if the facilities and employees are made available to all Participants participating in the Challenge on an equitable basis.
- (9) By participating in this Challenge, each Participant (whether an individual, group of individuals, or entity) warrants that he, she, or it is the sole author or owner of, or has the right to use, any copyrightable works that the Solution comprises, that the works are wholly original with the Participant (or is an improved version of an existing work that the Participant has sufficient rights to use and improve), and that the Solution does not infringe any copyright or any other rights of any third party of which the Participant is aware.
- (10) By participating in this Challenge, each Participant (whether an individual, group of individuals, or entity) grants to the NIH an irrevocable, paid-up, royalty-free nonexclusive worldwide license to reproduce, publish, post, link to, share, and display publicly the contents of the Participant's Solution Package on the web or elsewhere, and a nonexclusive, nontransferable, irrevocable, paid-up license to practice, or have practiced for or on its behalf, the Solution throughout the world. Additionally, each Participant agrees to make freely and openly available

(via GitHub or other applicable open source development platforms) to the public any tools or other resources developed as part of the Solution. Each Participant will retain all other intellectual property rights in their Solutions, as applicable. To participate in the Challenge, each Participant must warrant that there are no legal obstacles to providing the above-referenced nonexclusive licenses of the Participant's rights to the federal government. Participants will *not* be required to transfer their intellectual property rights to NIH; however, by participating in this Challenge, Participants grant to the federal government the *nonexclusive licenses* recited herein.

- (11) Each Participant (whether an individual, group of individuals, or entity) agrees to follow all applicable federal, state, and local laws, regulations, and policies.
- (12) Each Participant (whether an individual, group of individuals, or entity) in this Challenge must comply with all terms and conditions of these rules, and participation in this Challenge constitutes each Participant's full and unconditional agreement to abide by these rules. Winning is contingent upon fulfilling all requirements herein.
- (13) By participating in this Challenge, each Participant (whether an individual, group of individuals, or entity) agrees to allow NHLBI to publicly display (e.g., on the web) the Participant's Solution(s).
- (14) By participating in this Challenge, each Participant (whether an individual, group of individuals, or entity) assures NHLBI that any data used for the purpose of developing a Solution for this Challenge were obtained legally through authorized access and data use procedures.
- (15) Each individual Participant in this Challenge must be at least 18 years old.

JUDGING CRITERIA

Basis Upon Which a Winner Will be Selected

Technical reviewers with expertise relevant to the Challenge will evaluate the Solutions based on their ability to achieve the criteria listed below. The Solutions and evaluation statements from the technical panel will then be reviewed by federal employees serving as judges, who will select up to five (5) Challenge winners, subject to a final decision by the Award Approving Official.

Basis Upon Which Solutions Will Be Evaluated

This challenge aims to encourage and reward innovative adult heart failure disease modeling. These computational models will help create heart failure research paradigms that drive discovery and new treatment approaches. Successful Solutions of sub-phenotyping schema will facilitate hypothesis development and study design in the basic and/or clinical research communities. For example, an adult heart failure sub-phenotyping scheme incorporating large genomic and imaging datasets could reveal new insights into the mechanism of disease. It could also refine adult heart failure diagnoses, and identify subgroups of adult heart failure patients for personalized treatment. The Solution should address the following judging criteria from the NHLBI. The points assigned to each set of evaluation criteria suggest which scientific milestones interest the Institute and warrant emphasis.

Evaluation Criterion 1: Impact and Innovation (15 points)

- To what extent has the Solution brought together NHLBI-funded (or other, if used) biomedical health datasets, using an approach that is novel and innovative to adult heart failure research?
- O How high is the likelihood that the Solution will have major impact in the field of adult heart failure research? How significantly might the Solution change the concepts, methods, and/or technologies that drive this field?
- Where applicable, to what extent do the datasets used to develop the Solution include data from **diverse participants** (including ethnicity, race, gender, and/or age)?
- To what extent have the Participants demonstrated why/how the Solution could provide new insights in the field of heart failure research compared to existing adult heart failure phenotyping models?

Evaluation Criterion 2: Functionality and Implementation (30 points)

- O How well documented is the approach for developing the Solution? To what extent will it be possible for other researchers to reproduce/validate the development of the sub-phenotyping scheme?
- To what extent are datasets that serve as the basis of the Solution rigorously generated and relevant to the field of heart failure research?
- To what degree of success has the utility of the sub-phenotyping scheme been validated in independent datasets?
- To what extent was the sub-phenotyping scheme developed with open-source codes/packages versus commercial software packages?
- o To what extent has the Solution utilized NHLBI-funded biomedical health datasets?
- O How well can the Solution identify phenotypic categories that may be associated with various adult heart failure events or outcomes and/or subsets of adult heart failure patients?
- O How well can the sub-phenotyping scheme clearly delineate among the identified adult heart failure phenotype classifications?
- o To what degree can the Solution provide **additional context for investigation** of basic and/or clinical heart failure research questions?
- O How well have the Participants demonstrated the ability of the proposed Solution to provide sufficient information necessary for the development of research approaches and/or research tools in basic and/or clinical research settings?
- To what degree have the Participants described a model for sub-phenotyping adult heart failure that is an easy-to-use, free, and publicly accessible tool for the basic and/or clinical heart failure research community?

Evaluation Criterion 3: Applied Expertise (5 points)

- o How well have the Participants demonstrated that appropriate expertise was utilized to develop the Solution?
- o To what extent have the Participants brought together cross-disciplinary expertise?
- O How well have the Participants integrated their relevant expertise in the development of the Solution?

HOW TO ENTER

Registration Process

Participants are invited to send an optional letter of intent to nhlbi.nih.gov
briefly describing the anticipated approach for developing the Solution. Letters of intent should include a tentative title and a one-paragraph summary of the planned approaches. If a letter of intent is being submitted on behalf of a team or entity, it should identify the team leader. Limit 1 page.

The optional letter of intent should be submitted to nhlbi.nih.gov by NOON (12 p.m.) EST, July 28, 2020.

Solution Requirements

Each Solution for this Challenge requires a complete "Solution Package." If Participants submit as a team or as an entity, they should identify a team leader who will serve as a point of contact and submit the Solution Package on behalf of the team. Only complete and correctly formatted Solution Packages will be reviewed. The Solution Package includes a cover page and a written description of the Solution, including approach and utility. Detailed instructions on the content of the Solution Package are listed below.

Submit the Solution Package <u>as a single PDF file</u> to <u>nhlbi_challenge@nhlbi.nih.gov</u> by NOON (12 p.m.) EST, August 28, 2020.

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1. The Solution writeup must consist of a single PDF file with at least 1-inch margins. Font

size must be no smaller than 11-point Arial. All Solutions must be in English.

2. On the Cover Page, include a project summary (abstract) that describes the Solution.

Explain how the heart failure research community can benefit from the Solution and why

the approach is innovative. Describe applicable expertise utilized in developing the

Solution. Limit 1 page.

3. Describe clearly your Solution to the Challenge, including a concise title. Explain the

methods used to meet the main requirements for the challenge. Cite appropriate

references to support the work. Include figures/illustrations where appropriate

(figures/illustrations will count towards the page limit). Limit 6 pages.

4. References will *not* count towards the page limit.

5. Participants cannot use the logo or official seal of the Department of Health and Human

Services (HHS); the National Institutes of Health (NIH); or the National Heart, Lung, and

Blood Institute (NHLBI). Participants cannot claim federal government endorsement of

their Solutions.

ADDITIONAL INFORMATION

Supplementary Information

Participants are encouraged to visit the **NHLBI Heart Failure Big Data Analysis Challenge**

webpage for helpful information, including: a sample list of available open- and controlled-

access NHLBI-funded datasets, data access resources including step-by-step instructions for

applying to use controlled-access datasets, streamlined data access request information for

participants developing Solutions for this Challenge, and NHLBI data access help desk

contact information.

For Further Information Contact: nhlbi challenge@nhlbi.nih.gov

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Gary H. Gibbons, M.D.

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Director, National Heart, Lung, and Blood Institute

02/11/2020

Date