Billing Code: 3510-13

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Notice of NIST's Consortium for the Advancement of Genome Editing

AGENCY: National Institute of Standards and Technology

ACTION: Notice of Research Consortium

SUMMARY: The National Institute of Standards and Technology (NIST), an agency of the United States Department of Commerce is establishing the Genome Editing Consortium with the goal of bringing together stakeholders across the genome editing community to identify and address measurement and standards needs to support this technical area. The Consortium intends to evaluate genome editing assay pipelines, develop benchmark materials, generate benchmark data, develop suggested minimal information reporting for public studies, and generate a common lexicon for genome editing studies, with the intent these resources can be used to increase confidence in evaluating genome editing and lower the risk to utilizing these technologies in research and commercial products. Participation fees will be at least $20,000 annually or in-kind contributions of equivalent value. Participants will be required to sign a Cooperative Research and Development Agreement (CRADA).

DATES: NIST will accept letters of interest containing required information for participation in this Consortium until January 1, 2020. Acceptance of participants into the Consortium after the Commencement Date will depend on eligibility as determined by NIST based upon the information provided in the letter of interest and upon the availability resources.

ADDRESSES: Information in response to this notice, including completed letters of interest or requests for additional information about the Consortium can be directed via mail to the

Consortium Manager, Dr. Samantha Maragh, Biosystems and Biomaterials Division of NIST's Material Measurement Laboratory, 100 Bureau Drive, Mail Stop 8312, Gaithersburg, Maryland 20899, or via electronic mail to samantha@nist.gov, or by telephone at (301) 975-4947.

FOR FURTHER INFORMATION CONTACT: For further information about participation opportunities to join the Genome Editing Consortium, please contact Jeffrey DiVietro, CRADA Officer, National Institute of Standards and Technology's Technology Partnerships Office, by mail to 100 Bureau Drive, Mail Stop 2200, Gaithersburg, Maryland 20899, by electronic mail to jeffrey.divietro@nist.gov, or by telephone at (301) 975-8779.

SUPPLEMENTARY INFORMATION: Targeted Genome Editing is a technology space where there is a great need for reliable measurement methods for assuring the results of editing. Modalities for targeted genome editing include but are not limited to Zinc Finger Proteins (ZFPs), Homing Endonucleases, Transcription Activator-Like Nucleases (TALENs) and Clustered, Regularly Interspaced Palindromic Repeats (CRISPR). These technologies are being actively pursued by industry, academic, government and non-profit sectors to advance medicine and bioscience in areas such as: regenerative medicine, synthetic biology, novel antimicrobials and antivirals, protein therapeutic biomanufacturing, agriculture and global food production. Utilizing these technologies for production and medicine will first require robust quantitative assays and measurements to enable high confidence characterization of DNA alterations resulting from genome editing.

NIST has reached out to companies to assess their measurement needs, and has co-led workshops that have brought together experts across the genome editing field including stakeholders in industry, academia and government. These discussions have identified common pre-competitive measurement needs that if resolved can push forward the field as it relates to

understanding the reliability of data from assays being used to measuring aspects of genome edited cells.

This Consortium's purpose is to develop measurement solutions and standards to advance confidence in measurements supporting the genome editing technology space.

The Consortium will have three working groups with the following responsibilities:

1) Specificity Measurements:
    a. Design, generate, and evaluate a set of purified DNA samples and mixtures that can be used to mimic both of on-target and off-target genome editing induced variants at known frequencies in a background of human genomic DNA which can be used to benchmark validation of sequencing pipelines intended to identify genome editing induced variants.
    b. Design and conduct controlled evaluations of assays intended to identify where genome editing enzymes have been active in a genome, with an experimental design that allows for enough power to assess the sources of variability, repeatability, and reproducibility within an assay.
2) Data and Meta Data:
    a. Identify community norms for data formats and tools for benchmarking data analysis including in silico data sets and an experimental data set.
    b. Determine the type of meta data that would be needed to be shared, housed, and interrogated from genome editing experiments.
3) Lexicon: Identify terms and related definitions to form a common genome editing community lexicon.

No proprietary information will be shared as part of the Consortium.

PROCESS: Interested parties with relevant genome editing associated capabilities (see below), products, and/or technical expertise to support this Consortium should contact NIST using the information provided in the ADDRESSES section of this notice. NIST will then provide each interested party with a letter of interest template, which the party must complete, and submit to NIST. NIST will contact interested parties if there are questions regarding the responsiveness of the letters. NIST will select participants who have submitted complete letters of interest based on the capabilities listed below. Eligibility will be determined solely by NIST based on information provided by interested organizations and upon the availability of necessary resources to NIST.

To participate, the eligible applicant will be required to sign a CRADA with NIST.

Requirements: Each letter of interest should provide the following information:

1) A description of the experience in genome editing or genome engineering, bioinformatics, next-generation sequencing, detection or quantitation of DNA variants or related expertise to contribute to the Consortium.
2) Subgroups or topic areas of interest for participation. There is no limit on the number of areas of participation.
3) List of interested party's anticipated participants.

Letters of interest may not include business proprietary information. NIST will not treat any information provided in response to this Notice as proprietary information. NIST will notify each organization of its eligibility. In order to participate in this Consortium, each eligible organization must sign a CRADA for this Consortium. All participants to this Consortium will

be bound by the same terms and conditions. Participants will be required to contribute financial or equivalent in-kind resources, as determined by NIST, of at least $20,000. NIST does not guarantee participation in the Consortium or in any other collaboration to any organization submitting a Letter of Interest.

Authority: 15 U. S. C. 3710a

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NIST Chief of Staff

[FR Doc. 2018-00315 Filed: 1/10/2018 8:45 am; Publication Date: 1/11/2018]