FOR FURTHER INFORMATION CONTACT: Ethan Gabbour, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6306, Silver Spring, MD 20993, 301–796–8112, *Ethan.Gabbour@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Under the seventh iteration of the Prescription Drug User Fee Act, incorporated as part of the FDA User Fee Reauthorization Act of 2022, FDA committed to facilitate the advancement and use of systematic approaches to collect and utilize robust and meaningful patient and caregiver input that can more consistently inform drug development and, as appropriate, regulatory decision making. This included issuing a Request for Information (RFI) available at *https://www.federalregister.gov/documents/2023/05/02/2023-09265/methodological-challenges-related-to-patient-experience-data-request-for-information-and-comments* to elicit public input on methodologic challenges related to patient experience data, and other areas of greatest interest or concern to public stakeholders.[1] The RFI was published on May 2, 2023, and the public comment period was open until July 3, 2023. A summary of the comments was published on December 12, 2023, and is available at *https://www.regulations.gov* by entering the following docket number: FDA–2023–N–1506. The input received in response to the RFI helped inform the topics for this public workshop. This public workshop together with the input received in response to the RFI will also help inform a subsequent workshop focused on methodological challenges and will help FDA identify priorities for future work.

II. Topics for Discussion at the Public Workshop

The purpose of this virtual public workshop is to highlight and discuss methodological issues related to patient experience data, including the submission and evaluation of patient experience data in the context of the benefit-risk assessment and product labeling, as well as other areas of greatest interest or concern to stakeholders. This workshop will explore the different types of patient experience data and how FDA utilizes such data for regulatory decision-making, along with considerations for submitting patient experience data to FDA. In addition, this workshop will feature presentations and panel discussions with experts on selected methodologies and the challenges and opportunities they present.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website: *https://fda.zoomgov.com/webinar/register/WN_Jb5xMhbVS1-wYhLn6fwMng#/registration*. Please provide complete contact information for each attendee, including name, organization, email, and affiliation.

Registration is free and persons interested in attending this public workshop must register to receive a link to the meeting. Registrants will receive a confirmation email after they register.

If you need special accommodations due to a disability, please contact *Ethan.Gabbour@fda.hhs.gov* no later than December 6, 2024. Closed captioning will be available.

Dated: November 6, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–26399 Filed 11–13–24; 8:45 am]

BILLING CODE 4164–01–P

[1] The Federal Food, Drug, and Cosmetic Act, as amended by the 21st Century Cures Act (Pub. L. 114–255) and the FDA Reauthorization Act of 2017 (Pub. L. 115–52), defines patient experience data as data that are collected by any persons (including patients, family members and caregivers of patients, patient advocacy organizations, disease research foundations, researchers and drug manufacturers) and are intended to provide information about patients' experiences with a disease or condition, including the impact (including physical and psychosocial impacts) of such disease or condition or a related therapy or clinical investigation and patient preferences with respect to treatment of the disease or condition.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government Owned Inventions Available for Licensing or Collaboration: Single Source-Detector Separation Approach To Calculate Tissue Oxygen Saturation

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institute of Child Health and Human Development (NICHD), an institute of the National Institutes of Health (NIH), Department of Health and Human Services (HHS), is giving notice of the licensing or collaboration opportunities for the inventions listed below, which are owned by an agency of the U.S. Government and are available for licensing and collaboration to achieve expeditious commercialization of results of federally-funded research and development.

FOR FURTHER INFORMATION CONTACT: Inquiries related to these licensing or collaboration opportunities should be directed to: Zarpheen Jinnah, Ph.D., Technology Transfer Manager, NCI, Technology Transfer Center, Email: *zarpheen.jinnah@nih.gov* or Phone: 240–620–0586.

SUPPLEMENTARY INFORMATION: Tissue oxygen saturation (StO2) is an important parameter to assess oxygen delivery and uptake. Hypoxia, a term used to indicate inadequate StO2, is often seen in patients with cardiac problems, respiratory infections or pulmonary diseases. Prolonged hypoxia can damage vital organs such as the brain, lungs, and heart and can be fatal. Currently available tissue oximeters to monitor StO2 are expensive and cumbersome.

NICHD has developed a novel method, which uses a single source-detector separation to calculate StO2. With this technique, a simple tissue oximeter can be made with just a LED and a photodetector, which enables the development of a miniaturized device. As a result, it can be used independently or implemented on existing technologies to measure StO2 without any hardware modifications. It can be applied in wearable devices, implantable medicines or endoscopies to measure tissue oxygenation in different tissues such as muscle, brain, spinal cord, internal organs, fetus and placenta.

This Notice is in accordance with 35 U.S.C. 209 and 37 CFR part 404.

NIH Reference Number: E–037–2023–0.

Product Type: Device.

Therapeutic Area(s): Respiratory, Neurology or Cardiac.

Potential Commercial Applications:

- Miniaturized tissue oximeter for implantation or endoscopy.
- Measure tissue oxygen saturation.
- Multilayer tissue oximeter.

Competitive Advantages:

- Simpler and more compact as it only requires a single light source such as LED and a single photodetector such as a photodetector to build a tissue oximeter.
- Multilayer measurement.
- Implementation with existing technologies without any hardware modifications.

Publication: Nguyen, T., et al. Application of the Single Source—Detector Separation Algorithm in Wearable Neuroimaging Devices: A Step toward Miniaturized Biosensor for Hypoxia Detection. (*PMID 38671806*).

Patent Status: PCT Application PCT/US2023/085725 filed on December 22, 2023.

Development Stage: Clinical Phase I.

Dated: November 8, 2024.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2024–26451 Filed 11–13–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government Owned Inventions Available for Licensing or Collaboration: Methods of Detecting Loss of Heterozygosity and Damaging Mutations in Immune-Related Genes Using Liquid Biopsies

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute (NCI), an institute of the National Institutes of Health (NIH), Department of Health and Human Services (HHS), is giving notice of the licensing or collaboration opportunities for the inventions listed below, which are owned by an agency of the U.S. Government and are available for licensing or collaboration to achieve expeditious commercialization of results of federally funded research and development.

FOR FURTHER INFORMATION CONTACT: Inquiries related to these licensing and collaboration opportunities should be directed to: Suna Gulay French, Ph.D., Technology Transfer Manager, NCI, Technology Transfer Center, Email: *suna.gulay@nih.gov* or Phone: 240–276–7424.

SUPPLEMENTARY INFORMATION: The technology is a liquid biopsy diagnostic assay capable of detecting loss of heterozygosity (LOH) and somatic mutations in genes important for antigen processing and presentation and interferon-γ (IFN) response pathways. Immunotherapy is an effective cancer treatment utilizing T cells to recognize and eliminate cancer cells. Antigen processing and presentation machinery (APM) and IFN response pathways play an important role for T cells to target cancer cells. To evade immunotherapy, cancer cells can develop somatic mutations in genes important for APM and IFN.

Liquid biopsy is a non-invasive tool that can diagnose and monitor cancer by analyzing circulating tumor DNA. The ability to detect somatic mutations and predict response to immunotherapies using liquid biopsy would be critical to provide more personalized cancer treatment. However, currently marketed liquid biopsies cannot predict response to cellular immunotherapies. As a result, patients with relapsed or recurrent disease lose valuable time and resources on ineffective treatments.

The inventors at the NCI developed a novel method to detect somatic mutations from liquid biopsy samples. Combined with NCI's method to detect loss of heterozygosity in HLA genes—another mechanism for immunotherapy evasion—this invention allows for improved patient selection and non-invasive prediction of response. This novel precision medicine method will allow patient-tailored treatment by targeting treatment based on genetic mutations and prediction of immunotherapy response. This invention could potentially deliver better patient satisfaction, lower healthcare costs and better outcomes.

This invention will be used to select optimal patients and monitor efficacy of treatments—such as TCR–T cell therapy. There are no liquid biopsy assays on the market designed as companion diagnostics for cellular immunotherapy—such as TCR–T cell therapy. Therefore, this technology may be particularly appealing to co-development partners who are developing proprietary cellular immunotherapies.

This Notice is in accordance with 35 U.S.C. 209 and 37 CFR part 404.

NIH Reference Number: E–027–2024–0.

Related Technologies: E–045–2022–0.

Product Type: Diagnostic.

Therapeutic Area(s): Oncology or Immunology.

Potential Commercial Applications:

- Companion diagnostic for cellular immunotherapies.
- Companion diagnostic for monitoring the effectiveness of TCR-based immunotherapies.
- Companion diagnostic for T cell-based immunotherapies, including certain immune checkpoint inhibitors.
- Research use in labs studying and developing new pre-clinical therapeutic candidates.
- Research use in basic research labs studying immunotherapy resistance mechanisms, antigen processing and presentation, IFN response pathways, mutations in cancer cells, basic immunology and basic oncology.

Competitive Advantages

- First method to predict response to immunotherapies by detecting damaging mutations using liquid biopsy samples.
- Non-invasive test not requiring surgery.
- Easy to administer.
- Allows patient-tailored treatment and monitor the effectiveness of TCR-based immunotherapies in a simple and cost-effective manner.
- Potential improvement in patient survival.
- Potential time and money savings for patients, physicians and hospitals.

Patent Status: US Provisional Application 63/572,760 filed on April 4, 2024.

Development Stage: Prototype.

Dated: November 8, 2024.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2024–26446 Filed 11–13–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Integrative Health; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Advisory Council for Complementary and Integrative Health, January 24, 2025, 10:00 a.m. to January 24, 2025, 4:00 p.m., National Institutes of Health, DEM 2, 6707 Democracy Boulevard, Bethesda, MD, 20892 which was published in the **Federal Register** on September 25, 2024, 89 FR 78318.

The notice is being amended to change the start and end times of the open session portion of the meeting. The open session start time has changed from 12:30 p.m. to 1:00 p.m. and the end time has changed from 4:00 p.m. to 5:00 p.m. This meeting is partially closed to the public.

Dated: November 8, 2024.

David W Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–26527 Filed 11–13–24; 8:45 am]

BILLING CODE 4140–01–P