researcher, institutional review board, ethicist, professional society and other stakeholder input on the scientific and ethical issues that surround the inclusion of pregnant women in clinical trials for drug development.

DATES: The public meeting will be held on April 16, 2020, from 9 a.m. to 5 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration information.

ADDRESSES: The public meeting will be held at the National Press Club Main Ballroom, 529 14th St. NW, Washington, DC 20045.

FOR FURTHER INFORMATION CONTACT: Jasmine Smith, Office of New Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, at *ONDPublicMTGSupport@fda.hhs.gov* or 301–796–0621, or Catherine Sewell, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5360, Silver Spring, MD 20993–0002, Fax: 301–796–9897.

SUPPLEMENTARY INFORMATION:

I. Background

FDA endorses an informed and balanced approach to gathering data informing the safe and effective use of drugs and biological products in pregnancy through judicious inclusion of pregnant women in clinical trials and careful attention to potential fetal risk. Input from this meeting will help provide such information on the development of therapies for pregnancy-specific conditions and for general medical conditions that occur in women of childbearing age and require treatment during pregnancy. This meeting supports the objectives of The Task Force on Research Specific to Pregnant Women and Lactating Women (''Task Force'' or ''PRGLAC'') which was established by section 2041 of the 21st Century Cures Act, Public Law 114–255, to provide advice and guidance on activities related to identifying and addressing gaps in knowledge and research on safe and effective therapies for pregnant women and lactating women, including the development of such therapies and the collaboration on and coordination of such activities.[1] Input from this meeting may also help further inform FDA's work toward the finalization of the Agency's draft guidance: Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials (83 FR 15161, April 6, 2018).

[1] *https://www.nichd.nih.gov/sites/default/files/2018-09/PRGLAC_Report.pdf.*

II. Topics for Discussion at the Public Meeting

The meeting will allow participants (including industry, clinicians, patients, researchers, institutional review boards, ethicists, professional societies and other stakeholders) to provide input on key topics, including:

- Key areas of unmet needs for therapeutic development or clinical data in obstetrics
- The regulatory, scientific, and ethical considerations and challenges in the enrollment of pregnant women in clinical research

For more information on the meeting topics and discussion questions, visit *https://healthpolicy.duke.edu/events/scientific-and-ethical-considerations-inclusion-pregnant-women-clinical-trials.* FDA will publish a discussion guide outlining background information on the topic areas to this website approximately 2 weeks before the meeting date. FDA will also post the agenda and other meeting materials to this website approximately 5 business days before the meeting.

The format of the public meeting will consist of a series of presentations, panel discussions, and open discussion.

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website: *https://healthpolicy.duke.edu/events/scientific-and-ethical-considerations-inclusion-pregnant-women-clinical-trials.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting must register. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation once they have been accepted. If time and space permit, onsite registration on the day of the public meeting will be provided beginning at 8 a.m. We will let registrants know if registration closes before the day of the public meeting.

If you need special accommodations due to a disability, please contact Jasmine Smith, Office of New Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, at *ONDPublicMTGSupport@fda.hhs.gov* or 301–796–0621; or Catherine Sewell, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5360, Silver Spring, MD 20993–0002, Fax: 301–796–9897.

Persons attending FDA's meetings are advised that FDA is not responsible for providing access to electrical outlets.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast and archived video footage will be available at the event website. If you are unable to attend the meeting in person, you can register to view a live webcast of the meeting. Persons interested in viewing the live webcast are encouraged to register in advance. You will be asked to indicate in your registration if you plan to attend in person or via the webcast. Please register for the webcast by visiting *https://healthpolicy.duke.edu/events/scientific-and-ethical-considerations-inclusion-pregnant-women-clinical-trials.*

Registered webcast participants will be sent technical system requirements in advance of the event. It is recommended that you review these technical system requirements prior to joining the streaming webcast of the public meeting.

FDA has verified the website addresses in this document as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that transcripts of the public meeting will not be available.

Dated: March 6, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–04990 Filed 3–10–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Letters of Interest (LOI) for NCI-MATCH Laboratories

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute (NCI) through its National Clinical Trials Network (NCTN) is developing a successor precision medicine trial to 'NCI-Molecular Analysis for Therapy Choice (NCI-MATCH)' entitled 'NCI-ComboMATCH'. The principal of this intiative is to overcome drug resistance to single-agent therapy by developing genomically-directed targeted agent combinations. All combinations must be

supported by robust, preclinical *in vivo* evidence.

NCI-ComboMATCH trial leadership invites applications for Clinical Laboratory Improvements Program (CLIA) certified/accredited laboratories that test tumor specimens from patients utilizing Next-Generation Sequencing (NGS) assays to participate in the NCI-ComboMATCH trial. In order to support this trial, the designated laboratories participating in NCI-ComboMATCH will identify patients for the specific variants needed for trial eligibility. Laboratories will be required to contact any of the NCTN sites that have activated NCI-ComboMATCH if a specimen sent from one of these sites has a variant(s) that would potentially make the patient eligible for one of the treatment arms.

DATES: Letters Of Interest (LOIs) should be submitted to the National Cancer Institute (NCI), National Institutes of Health (NIH) on or before 5:00 p.m. EST on June 30, 2020.

ADDRESSES: Submit LOIs by email to *NCICOMBOMATCHLabApps@nih.gov*. 9609 Medical Center Drive, 3 West, Room 526, MSC 9728, Rockville, MD 20892.

FOR FURTHER INFORMATION CONTACT: Questions about this request for LOIs should be directed to *NCICOMBOMATCHLabApps@nih.gov*. James V. Tricoli *tricolij@mail.nih.gov* can also provide further information.

SUPPLEMENTARY INFORMATION: In accordance with 42 U.S.C. 285, of the Public Health Service Act, as amended. Similar to NCI-MATCH, NCI-ComboMATCH is conceived as a signal-seeking study. The NCI-ComboMATCH team will determine whether patients with tumor mutations, amplifications or translocations in the genetic pathway(s) of interest are likely to derive clinical benefit if treated with a combination of precision medicine agents targeting those specific pathway(s). This recruitment is for labs that can specifically screen 200 patients seen at NCTN sites per month.

Patients with histologically documented solid tumors and lymphomas whose disease has progressed following at least one line of standard systemic therapy or for whom no standard therapy exists are eligible if they meet the eligibility criteria for the trial.

The selected collaborating outside laboratories may only act (*i.e.,* refer patients) on any of the variant arms for which their assay reports actionable mutations of interest (aMOIs). The assay must also report all exclusionary variants for the arm unless these occur at a frequency of <1% in cancer patients.

Only CLIA accredited/certified laboratories located in the United States may be considered for addition to the laboratory network.

Letter of Interest (LOI) and Confidentiality Agreement

Candidate laboratories should submit a letter of interest to *NCICOMBOMATCHLabApps@nih.gov* stating:

- Statement of interest in the proposed activity
- Laboratory name
- Lead contact name, address, email address, and telephone number
- CLIA certification number
- Assay name
- Brief description of assay
  - Sensitivity and specificity for SNVs, indels, CNV, fusions
  - Method of analysis
  - Platform and variant calling
- Number of assays on patients per month
- Number assays on patients seen at NCTN study sites per month
- Provide a list of other CLIA approved/certified tests that have been validated in your laboratory
- Willingness to contact sites regarding results with a potentially eligible for NCI-ComboMATCH
- Willingness to sign a collaboration agreement with NCI (*https://ctep.cancer.gov/branches/rab/intellectual_property_option_to_collaborators.htm*) and to share data and publication rights

Following an acceptable eligibility review to the NCI-ComboMATCH screening committee, the laboratory would execute a confidentiality agreement with the NCI and will be provided with a detailed list of eligibility and exclusion variants for arms (approved at that time). The lab would then be required to submit an application within 6 weeks for review by the NCI-Combo MATCH review committee. Candidate laboratories will be required to meet the following general requirements:

- Testing must be performed in a CLIA-certified or -accredited laboratory located in the United States.
- Assays can be on tumor tissue (including lymphoma) or circulating tumor DNA (ctDNA).
- Laboratory NGS panels must be analytically and clinically validated on DNA from human tumor tissue, with performance characteristics as follows:
  - Specificity at least 99% for single nucleotide variants, indels
  - Sensitivity at least 95% for single nucleotide variants, indels
  - Sensitivity of 90% for copy number variants (state fold of copy number variants that can be detected with 90% sensitivity)
  - 99% reproducibility between sequencers (if more than one sequencer is used) and between operators
  - Lower limit of detection for SNV, indels, CNV must be stated.

Laboratories must supply the following information in their application:

- Lower limit of % tumor accepted, and whether (and which) enrichment procedures are employed
- Whether the lab archives images of slides from the tumor
- Whether the lab also runs germline as well as tumor with the assay (a simultaneous germline sequencing is not required by NCI-ComboMATCH)
- A detailed description of assay procedures, including starting material, extraction of nucleic acids, quality assurance, quality metrics, data analysis and filters must be supplied

- Laboratory NGS test panels must interrogate actionable mutations of interest (aMOIs) required for enrollment into the available variant arms.
- Academic laboratories must be located at a center that participates in NCI-Combo MATCH.
- The designated lab should be willing to provide residual nucleic acid from the sample they tested if the patient enrolls on NCI-ComboMATCH.
- Laboratories shall NOT advertise that they are screening laboratories for ComboMATCH eligibility without prior review by NCI and ECOG–ACRIN. Any press release or public disclosure requires clearance by NCI and the NCI-ComboMATCH team.
- Laboratories must agree to use the existing workflow established by the NCI NCI-ComboMATCH trial team to identify patients for the variant arms.
  - Laboratory results of NGS assays done for clinical care will be the subject of this initiative. There is no funding for ''screening'' a patient for NCI-ComboMATCH.
  - Laboratories must notify NCI-ComboMATCH sites that the laboratory results would potentially allow the patient to be eligible for NCI-ComboMATCH.
  - Laboratories must track how many assays per month detect variants that could make a patient eligible for NCI-ComboMATCH.
  - If the clinician presents the NCI-ComboMATCH study and the patient is eligible and desires to enter the study,

the laboratory must agree to enter the results into the informatics system that assigns treatment in NCI-ComboMATCH (MATCHbox).

○ Laboratories must have a way to answer questions from NCI-ComboMATCH sites about their assay and must have a contact person for optimal communication with the NCI-ComboMATCH team.

• Prior to participation, laboratories must enter into a collaboration agreement with NCI. A sample agreement is available upon request. As part of such a collaboration agreement, laboratories must agree to provide the licensing rights described in the CTEP IP Option to the Pharmaceutical Collaborators who provided agents for the NCI-ComboMATCH trial (*https://ctep.cancer.gov/branches/rab/intellectual_property_option_to_collaborators.htm*) as well as agree to the data sharing and publication rights consistent with those agreements.

• No reimbursement for these activities (testing or notification of sites of NCI-ComboMATCH eligibility) exists.

Qualified laboratories serving underserved populations are encouraged to participate. How to apply:

1. Submit letter of interest (LOI) as described above under ''Letter of Interest and Confidentiality Agreement'' to *NCICOMBOMATCHLabApps@nih.gov*.

2. LOIs will be accepted for 3 months from the date of this notice. LOIs will be reviewed immediately upon receipt.

3. Notification of acceptance, non-acceptance or questions from Steering Committee will be sent to the designated contact person as soon as the LOI has been reviewed. This notification will include further instructions if a full application is invited.

4. Applications that have not been submitted within 6 weeks of notification of acceptance of the LOI will be de-activated and not further considered.

5. DO NOT send a full application until you are invited to do so.

Review criteria for LOI:

Laboratory is a CLIA-certified laboratory within the United States.

Academic laboratories must have NCI-ComboMATCH open at their site.

Laboratory NGS assay has adequate sensitivity and specificity.

Laboratory tests tumor tissue for variants as described in NCI-ComboMATCH.

Laboratory agrees to provide needed information for evaluation of the analytical validity of the test.

Laboratory is likely to screen at least 200 patients at NCTN sites per month for NCI-ComboMATCH.

Laboratory agrees to contact sites regarding NCI-ComboMATCH eligibility.

Laboratory agrees to a collaboration with NCI as detailed above.

Review criteria for full application:

Laboratory supplies evidence that the assay meets analytical requirements as detailed above.

Laboratories are capable of contacting clinical sites, tracking activity, and screening at least 200 patients at NCTN sites per month to the study based on detection of potential variants.

Laboratories agree to execute a collaboration agreement with NCI, as well as to data sharing and sharing publication rights.

Laboratories agree to abide by the procedures in place for the NCI-ComboMATCH study and to collaborate fully with the NCI-ComboMATCH team.

For more information, contact *NCICOMBOMATCHLabApps@nih.gov.*

Dated: March 5, 2020.

James V. Tricoli,

Chief, Diagnostic Biomarkers and Technology Branch, Cancer Diagnosis Program, National Cancer Institute.

[FR Doc. 2020–04915 Filed 3–10–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, Member Conflict: Stroke, Traumatic Brain Injury and Sport-Related Concussions, March 25, 2020, 10:00 a.m. to 3:00 p.m., at the National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892, which was published in the **Federal Register** on March 04, 2020, 85 FR 12799.

The meeting will be held on March 26, 2020. The meeting time and location remain the same. The meeting is closed to the public.

Dated: March 5, 2020.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–04928 Filed 3–10–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, RFA–RM–19–008: NIH Director's Early Independence Award Review, March 18, 2020, 08:30 a.m. to March 19, 2020, 12:00 p.m. which was published in the **Federal Register** on February 20, 2020, 85 FR 9787.

The meeting location is being changed to National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, meeting start time is changing to 09:00 a.m. and meeting end time to 03:00 p.m. The meeting is closed to the public.

Dated: March 5, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–04929 Filed 3–10–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Letters of Interest (LOI) for Pediatric Focused NCI–MATCH Laboratories

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute (NCI) through its National Clinical Trials Network (NCTN) is developing a successor precision medicine trial to 'NCI-Molecular Analysis for Therapy Choice (NCI–MATCH)' entitled 'NCI-ComboMATCH'. The principal of this intiative is to overcome drug resistance to single-agent therapy by developing genomically-directed targeted agent combinations. All combinations must be supported by robust, preclinical *in vivo* evidence.

NCI-ComboMATCH trial leadership invites applications for Clinical Laboratory Improvements Program (CLIA) certified/accredited laboratories that test tumor specimens from pediatric patients utilizing Next-Generation Sequencing (NGS) assays to participate in the NCI-ComboMATCH trial. In order to support this trial, the designated laboratories participating in NCI-ComboMATCH will identify pediatric patients for the specific variants needed for trial eligibility. Laboratories will be