

II. Topics for Discussion at the Public Workshop

At the public workshop, FDA plans to convene experts in AI to discuss topics, including but not limited to:

1. Optimizing model design through multidisciplinary expertise. Specifically, discussants will explore the importance of integrating experts from diverse fields, such as medicine, statistics, pharmacology, data science, and engineering to ensure the development of optimal AI models.
2. Exploring strategies for overcoming common data-related challenges, namely, the availability of fit-for-use data that can be used in drug development. Topics will include data availability and access via federated learning, data quality issues (*i.e.*, representativeness of data, bias, etc.), and the use of synthetic data.
3. Balancing model performance, explainability, and transparency of AI models. Additionally, discussants will share strategies for assessing the need to integrate humans into the decision-making process (human-in-the-loop and/or human-on-the-loop).
4. Identifying key gaps and challenges hindering the use of AI in drug and biological product development and exploring potential strategies, collaborations, and initiatives to address these challenges. Considering actionable next steps to advance the responsible use of AI in developing safe, effective, and quality drugs.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website: <https://duke.zoom.us/meeting/register/tjrcru-qrTmiHdayh1J3JhkCi6XkvmAIFey6>. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

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

If you need special accommodations due to a disability, please contact Kelly.Franzetti@duke.edu no later than July 30, 2024. Please note, closed captioning will be available automatically.

Dated: July 5, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business Metabolism.

Date: August 2, 2024.

Time: 12:00 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Dianne Hardy, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6175, MSC 7892, Bethesda, MD 20892, 301-435-1154, dianne.hardy@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics on HIV Comorbidities, Confections and Associated Cancers.

Date: August 5, 2024.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Raul Rojas, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6185, Bethesda, MD 20892, (301) 451-6319, rojasr@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Respiratory Sciences.

Date: August 6-7, 2024.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Michael L. Bloom, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6187, MSC 7804, Bethesda, MD 20892, 301-451-0132, bloomm2@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 5, 2024.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business Metabolism.

Date: July 26, 2024.

Time: 1:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Dianne Hardy, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6175, MSC 7892, Bethesda, MD 20892, 301-435-1154, dianne.hardy@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Hypersensitivity, Autoimmunity and Immune-mediated Diseases.

Date: August 2, 2024.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Alok Mulky, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4203, Bethesda, MD 20892, (301) 435-3566, mulky@mail.nih.gov.