U.S. Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Digital Health Advisory Committee (DHAC) Meeting

Meeting Topic: *"Total Product Lifecycle Considerations for Generative-AI Enabled Devices"*

AGENDA

November 20 and 21, 2024

Day 1 – November 20, 2024

9:00 AM **Digital Health Advisory Committee (DHAC) Call to Order**
Ami Bhatt, Chairperson, DHAC

Conflict of Interest Statement
James Swink, Designated Federal Official, CDRH, FDA

Welcome from FDA Commissioner
Robert M. Califf, M.D., Commissioner, FDA

Opening Remarks
Michelle Tarver, M.D., PhD, CDRH Director, FDA

FDA Perspective – Gen AI in Medical Devices
Troy Tazbaz, Office Director Digital Health Center of Excellence, CDRH, FDA

Sub-Topic: Premarket Performance Evaluation

9:35 AM **FDA Perspective – Regulatory Science Challenges for the Evaluation of Generative AI Applications in Medical Devices**
Aldo Badano, Director; Victor Garcia, Senior Staff Fellow, Division of Imaging, Diagnostics, and Software Reliability, Office of Science and Engineering Laboratories (OSEL), CDRH, FDA

Generative and Agentic AI for Pathology – Challenges with Evaluation
Faisal Mahmood, M.D., PhD, Associate Professor at Harvard University & Mass General Brigham

Stakeholder Perspective – The Considerations for Multimodal Foundational Models & Generative AI Frameworks in Healthcare
Parminder Bhatia, Chief AI Officer, GE Healthcare

Stakeholder Perspective – Measuring Performance of Generative AI – Methods and Lessons Learned
Pranav Rajpurkar, PhD, Assistant Professor at Harvard University

BREAK (~10 min)

Open Committee Discussion Q&A *(Clarification questions)*

12:00 PM **LUNCH**

1:00 PM **Open Public Hearing**

Open Committee Discussion Q&A *(Clarification questions)*

Committee Discussion of the FDA's Questions *(Deliberation and response to FDA)*

BREAK (~15 min)

Sub-Topic: Risk Management

3:00 PM **Stakeholder Perspective – Strategies and Controls to Mitigate Risks Associated with Gen AI Applications in Healthcare**
Michael J. Schlosser, MD, MBA, Senior Vice President, Care Transformation and Innovation, HCA Healthcare

Narrow VS Generative AI: Risk Determination > Controls => Safe Innovation
Keith J. Dreyer, DO, PhD, FACR, FSIIM, Chief Data Science Officer, Mass General Brigham, Chief Imaging Information Officer, Mass General Brigham, Associate Professor of Radiology, Harvard Medical School

Stakeholder Perspective – Safety from the Systems to Patient Levels: Risk Management for Large Language Models in Healthcare
Danielle Bitterman, MD, Assistant Professor at Harvard Medical School

BREAK (~10 min)

Stakeholder Perspective - Risk Management for Generative AI-Enabled Medical Devices
Gabriella Waters, AI Evaluation Research Associate at NIST, Director Cognitive and Neurodiversity AI Lab, Director of Operations - Center for Equitable AI & Machine Learning Systems, Morgan State University

Open Committee Discussion Q&A *(Clarification questions)*

Committee Discussion of the FDA's Questions *(Deliberation and response to FDA)*

Day 1 Closing Remarks
Ami Bhatt, Chairperson, DHAC

6:00 PM **Adjourn**

Day 2 – November 21, 2024

9:00 AM **Digital Health Advisory Committee (DHAC) Call to Order**
Ami Bhatt, Chairperson, DHAC

Conflict of Interest Statement
James Swink, Designated Federal Official, CDRH, FDA

Recap of Meeting Day 1
Aubrey Shick, Sr. Digital Health Advisor, Digital Health Center of Excellence, CDRH, FDA

9:15 AM **Open Public Hearing**

Open Committee Discussion Q&A *(Clarification questions)*

BREAK (~15 min)

Sub-Topic: Post Market Performance Monitoring

11:15 AM **FDA perspective – Approaches for managing changes for GenAI-enabled devices**
Jessica Paulsen, Associate Director for Digital Health, Office of Product Evaluation and Quality, CDRH, FDA

Stakeholder Perspective – Supporting Health AI for Impact
Christopher A. Longhurst, MD, MS, Clinical Professor of Pediatrics and Biomedical Informatics, Chief Clinical Innovation Officer and Associate Dean, UC San Diego School of Medicine

Stakeholder Perspective – Technological Innovation and Considerations for Post Market Performance Monitoring within Radiology
Nina Kottler, MD, MS, FSIIM, Associate Chief Medical Officer for Clinical Artificial Intelligence, Radiology Partners

Stakeholder Perspective – *In Real Life: The Patient Health Information Journey and Generative AI-Enabled Tech Impact*
Grace Cordovano, PhD, Board Certified Patient Advocate (BCPA), Founder of Enlightening Results and Co-Founder of Unblock Health

Stakeholder Perspective – Industry View on Effective Evaluation Methods and Post Market Performance for Health Generative AI Products
Dale Webster, Director of Health AI Research, Google

Open Committee Discussion Q&A *(Clarification questions)*

1:00 PM **LUNCH**

2:00 PM **Committee Discussion of the FDA's Questions** *(Deliberation and response to FDA)*

Day 2 Closing Remarks
Ami Bhatt, Chairperson, DHAC

Adjourn