



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

Meeting Topic: "Generative Artificial Intelligence-Enabled Digital Mental Health Medical Devices"

AGENDA

November 6, 2025

Virtual

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| 9:00 AM | Digital Health Advisory Committee (DHAC) Call to Order <i>Ami Bhatt, Chairperson, DHAC</i> |
| 9:10 AM | Conflict of Interest Statement <i>Letise Williams, Designated Federal Official, CDRH, FDA</i> |
| 9:20 AM | Opening Remarks <i>Michelle Tarver, M.D., Ph.D., CDRH Center Director, FDA</i> |
| 9:25 AM | FDA Perspective: Generative Artificial Intelligence (GenAI)-Enabled Digital Mental Health Medical Devices <i>Gioia Guerrieri, D.O., DFAPA, FASAM, Digital Behavioral Health Lead, Digital Health Center of Excellence, CDRH</i> |
| 9:35 AM | FDA Perspective: Regulatory Considerations for Digital Mental Health Diagnostics <i>Jay Gupta, Assistant Director, Neurodiagnostic Devices Team, Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices (DHT5A), Office of Neurological and Physical Medicine Devices (OHT5), Office of Product Evaluation and Quality (OPEQ), CDRH</i> |
| 9:45 AM | FDA Perspective: Regulatory Considerations for Digital Mental Health Therapeutics <i>Pamela D. Scott, Assistant Director, Neuromodulation Psychiatry Devices, OHT5, OPEQ, CDRH</i> |
| 9:55 AM | Speaker- Topic 1: Generative AI and Mental Health <i>Lieutenant Commander Anthony Becker, M.D., U.S. Navy</i> |
| 10:05 AM | Speaker- Topic 2: The Impact of GenAI on Digital Mental Health Medical Devices and Mental Health Technologies <i>Vaile Wright, Ph.D., Senior Director, Office of Health Care Innovation, American Psychological Association</i> |
| 10:15 AM | BREAK (15 minutes) |
| 10:30 AM | Open Public Hearing |



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| 12:30 PM | LUNCH (30 minutes) |
| 1:00 PM | Speaker- Topic 3: Academic Perspective on GenAI Digital Mental Health Medical Devices <i>Nicholas Jacobson, Ph.D., Associate Professor, Dartmouth Geisel School of Medicine</i> |
| 1:10 PM | Speaker- Topic 4: Clinical Trial Evaluation of GenAI Digital Mental Health Medical Devices <i>Patricia Arean, Ph.D., University of Washington CREATIV Lab; Former Division Director, National Institute of Mental Health Division of Services and Interventions Research</i> |
| 1:20 PM | Speaker- Topic 5: Best Practices and Lessons Learned from Other Fields of AI <i>Andrew Trister, M.D., Ph.D., Chief Medical and Scientific Officer, Verily</i> |
| 1:30 PM | Speaker- Topic 6: Patient-Provider Considerations in the Use of GenAI-enabled Digital Mental Health Medical Devices <i>Brooke Trainum, J.D., Senior Director, Practice Policy, American Psychiatric Association</i> |
| 1:40 PM | Speaker- Topic 7: Payer Perspectives on Digital Mental Health Technologies <i>Bradley Karlin, Ph.D., ABPP, M.S.C.P., M.B.A., Program Manager, Resilient Systems Office, Advanced Research Projects Agency for Health</i> |
| 1:50 PM | Speaker- Topic 8: Peterson Health Technology Institute Evaluations of Virtual Solutions for Depression and Anxiety and Opioid Use Disorder <i>Caroline Pearson, Executive Director, Peterson Health Technology Institute</i> |
| 2:00 PM | Open Committee Discussion Q&A (Clarification questions) |
| 2:45 PM | BREAK (10 minutes) |
| 2:55 PM | Question Grouping 1 Committee Discussion of the FDA Questions (deliberation and response to FDA) |
| 3:55 PM | BREAK (10 minutes) |
| 4:05 PM | Question Grouping 2 Committee Discussion of the FDA Questions (deliberation and response to FDA) |
| 5:00 PM | Question Grouping 3 Committee Discussion of the FDA Questions (deliberation and response to FDA) |
| 5:45 PM | Closing Remarks <i>Ami Bhatt, Chairperson, DHAC</i> |
| 6:00 PM | Adjourn |