

**Industry Representative Pool for the Interests of the Medical Device Industry  
Digital Health Advisory Committee**

The FDA published a notice in the Federal Register (October 12, 2023, Vol. 88, No. 196, pp. 70675-70676) requesting that interested industry organizations select a pool of individuals, with varying areas of expertise, to represent industry interest for the Committee. The Commissioner or designee has the authority to select an individual from this pool to serve temporarily as a nonvoting member, depending on the meeting topic. In accordance with the process described in the notice, the following candidates were identified as participants in the pool, with terms continuing to **July 31, 2028**.

| <b>Industry Segment</b>  | <b>Primary</b>   | <b>Alternate</b>  |
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| <b>Hospital system integration of digital health technologies, especially those enabled by AI</b>                                    | <b>Joseph M. Smith, M.D., Ph.D.</b><br>President,<br>Joseph M. Smith LLC, Digital Transformation Consulting                        | <b>Eve Cunningham, M.D., M.B.A.</b><br>Chief of Virtual Care and Digital Health<br>Providence Virtual Care and Digital Health                   |
| <b>Post-market monitoring of AI-enabled medical devices</b>  | <b>Yarmela Pavlovic, J.D.</b><br>Chief Regulatory Officer<br>Medtronic, Inc.   | <b>Lee Shapiro, J.D.</b><br>Managing Partner<br>7wireVentures   |
| <b>Transparency and labeling considerations for AI-enabled medical device</b>  | <b>Diane Johnson, M.S.</b><br>Senior Director, North American Policy and Global Digital Health Policy Lead<br>Johnson & Johnson    | <b>Yarmela Pavlovic, J.D.</b><br>Chief Regulatory Officer<br>Medtronic, Inc.  |
| <b>Digital therapeutics</b>  | <b>Joseph M. Smith, M.D., Ph.D.</b><br>President,<br>Joseph M. Smith LLC, Digital Transformation Consulting                        | <b>Doug Lee, M.B.A.</b><br>Vice President, Global Head Digital & Data Science   Business Development & Licensing<br>Bayer Pharmaceuticals       |
| <b>Digital diagnostics</b>   | <b>Yarmela Pavlovic, J.D.</b><br>Chief Regulatory Officer<br>Medtronic, Inc.   | <b>Andrew Molnar, B.S.</b><br>Chief Executive Officer<br>Digital Therapeutics Alliance  |
| <b>Technologies to enable decentralized clinical trials &amp; other innovative trial designs &amp; implementations</b>               | <b>Sandra Nagale, Ph.D.</b><br>Director/ Senior Fellow, AI Partnerships and Portfolio Strategy<br>Boston Scientific Corporation    | <b>Andrew Molnar, B.S.</b><br>Chief Executive Officer<br>Digital Therapeutics Alliance  |
| <b>Patient-generated health data, wearables, IoT, remote patient monitoring, clinical integration of digital health technologies</b> | <b>Damien McPhillips, PMP, CSQE</b><br>Senior. Director, Quality Global Software & Digital Health<br>Boston Scientific Corporation | <b>Achintya K. (Achin) Bhowmik, Ph.D.</b><br>Chief Technology Officer & Executive Vice President of Engineering<br>Starkey Hearing Technologies |
| <b>Generative AI / Large Language Models</b>   | <b>Diana Miller, B.A.</b><br>Senior Director Data Science<br>Medtronic Diabetes  | <b>Richard Clarke, Ph.D.</b><br>Chief Analytics Officer<br>Highmark Health  |
| <b>Real-world data and real world evidence</b>   | <b>Diane Johnson, M.S.</b><br>Senior Director, North American Policy and Global Digital Health Policy Lead<br>Johnson & Johnson    | <b>Andrew Molnar, B.S.</b><br>Chief Executive Officer<br>Digital Therapeutics Alliance  |
| <b>Personalized medicine/genetics</b>  | <b>Diana Miller, B.A.</b><br>Senior Director Data Science<br>Medtronic Diabetes  | <b>Sabha Madhavan, Ph.D.</b><br>Vice President & Head of AI/ML, Quant. Sciences, Global Product Development, Pfizer                             |
| <b>Interoperability</b>  | <b>Doug Lautner, Ph.D., M.B.A.</b><br>Senior Director of Software & Neuroscience<br>Abbott Laboratories                            | <b>Richard Clarke, Ph.D.</b><br>Chief Analytics Officer<br>Highmark Health  |

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| <b>Software development for cloud-based software</b>                                  | <b>Nidhi Narang, B.E.</b><br>Senior Director, Software Engineering<br>Abbott Laboratories | <b>Daniel Cody, B.A., MIM</b><br>Managing Partner<br>Danko Enterprises                 |
| <b>Best practices for cybersecurity</b>   | <b>Ajay Gopinath, Ph.D.</b><br>Director, R&D Product Development<br>Abbott Laboratories   | <b>Keith Wiley, M.B.A.</b><br>President<br>Medical Aegis                               |
| <b>Augmented reality and virtual reality including technical and clinical aspects</b> | <b>Ajay Gopinath, Ph.D.</b><br>Director, R&D Product Development<br>Abbott Laboratories   | <b>Andrew Molnar, B.S.</b><br>Chief Executive Officer<br>Digital Therapeutics Alliance |