Enabling the Digital Health Revolution

Background

Digital health has the potential to make transformative progress in achieving more accessible, efficient, and personalized health care. Remote tracking apps and devices empower individuals to monitor their health in real-time, fostering preventive care and enabling early intervention. Artificial Intelligence (AI)—particularly through new generative AI platforms—is not only increasingly being used to power these and other clinical care tools but also, is being adopted to improve health care operations and reduce workforce burdens and costs across the entire health care ecosystem, from research and care management and public health threat detection and response.

Duke-Margolis is undertaking a range of policy initiatives to help fulfill the potential of the digital health revolution to improve health, particularly in the health AI and mHealth (remote monitoring) space. **The goal of the Duke-Margolis digital health portfolio is to develop and support the implementation of practical and inclusive digital health and AI policies that increase evidence-based innovation and improve health outcomes, equity, and affordability while protecting patients**. We prioritize projects that:

- **Create innovative solutions** to the unique development, regulatory, and reimbursement challenges inherent in these products, while prioritizing safety, access, and effectiveness and value
- **Emphasize the importance of representation and inclusion** in the development and deployment of digital health technologies, to foster equitable health outcomes
- **Advance high-performing digital capabilities** through effective practices for sharing quality data and conducting timely, feasible evaluations to provide reliable evidence that these products are working as expected
- **Promote transparency** regarding the development, intended use, and performance of digital health technologies

Why this Work Matters

Digital health tools come both with new challenges and new twists on old challenges. Reliable data is critical to both building, using, and evaluating these technologies, and obtaining it may require updating how health data is collected, protected, and used. Fairness and equity need to be prioritized, as emerging tools may not work well across different communities or geographies. Many traditional governance and regulatory methods will not be sufficient for the pace of digital health technical breakthroughs, product development, and product updates. New generative AI platforms have opened unprecedented possibilities to reduce health care workforce burden and operational costs, and potentially to improve health-related decisions for individual patients. But these new opportunities have raised concerns, without as clear mechanisms for assuring reliability as other digital health technologies. To realize the opportunities that AI presents, policies are needed to provide incentives, support better evidence, and identify and avoid important risks so that the best tool is chosen for each

task, and that these technologies are built in ethical ways and validated across populations and geographies. And, finally, paths for payment for digital health need to be clear and based on the value of the new technologies to patient outcomes.

Finding Solutions

Duke-Margolis is working to expanding our digital health focus in important areas.

- **With the U.S. Food and Drug Administration**, and other public and private collaborators, we are exploring how the agency should consider and regulate the use of AI and other digital health tools in drug development.
- **With the Duke-Margolis Value in Medical Products Consortium**, we are exploring payment for innovative digital health products, including for digital therapeutics, a space that has the potential to substantially expand access to mental health treatment and other therapies. In this work, we are focused on payments that reflect patient outcomes and encourage supporting evidence and further innovation.
- **With The Gordan and Betty Moore Foundation and the University of California-San Francisco Diagnostic Excellence Center**, we will serve as a bidirectional policy translation arm for multiple demonstration projects related to the safe, reliable, equitable, effective, and efficient use of clinical AI in health care. Through this work, Duke-Margolis will help shape answers to key digital health policy questions.
- **With Duke AI Health**, we are highlighting early examples of health system governance for testing, deployment, and monitoring of AI tools, and creating a harmonized framework to help other health systems develop their own governance policies. Together with the Duke AI Health and the Coalition for Health AI, we seek to develop standards and support for validation and verification of AI tools as well as better incentives and more efficient ways to measure the impact of AI tools on clinical outcomes as well as administrative and operational burden.
- To advance policy development at the **Centers for Medicare & Medicaid Services**, and effective coverage and payment policies among private insurers, we are developing supporting work to encourage AI applications that reduce health care administrative and operational burdens.
- In response to the **Presidential executive order** for a national system to assure the safety and appropriate use of AI applications in health care, we are exploring how to link our work on creating assurance mechanisms for AI tools across a range of health care organizations.

Advance Our Work

Duke-Margolis has identified its Digital Health portfolio as one of its focus areas for 2024-2027 and we are seeking funding to support new student initiatives and scholarships focused on digital health, expanding Duke's community of health policy researchers and faculty who will shape responsible and inclusive digital health and AI policies, and establishing a Duke Health Policy Action Fund which will provide start-up funds to support innovative health policy scholarship & solutions for the most pressing digital health challenges.

For more information on this work, please contact Christina Silcox, Digital Health Research Director, christina.silcox@duke.edu. For ways to support Duke-Margolis and the Digital Health portfolio contact Morgan Pope, Director of Interdisciplinary Development, Duke University, morgan.pope@duke.edu.