

# Biomedical Innovation

## Emerging Initiative

### Enabling the Digital Health Revolution

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) has captured broad attention and inspired a range of notable commercial and policy-related activities across the health care industry. Generative AI is not only increasingly being used in health care to reduce administrative burdens and operational costs; it is also powering clinical care tools to speed triage, improve diagnosis, help create personalized treatment plans, and assist in providers working at the top of their license.

AI can also empower patients to better engage in their health care and shared decision-making. Finally, AI tools can potentially bring down costs and spread access to clinical research and evidence generation, by helping organizations and their interested patients become more “research ready” in terms of data quality, patient engagement, and support for high-quality research practices.

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## The Need

If care isn't taken, AI tools could exacerbate existing challenges in our health systems. AI can perpetuate and scale clinical and operational inequities in health care. It can be used to accelerate the “arms race” in coding and documentation to support coverage and payment. Without adequate human supervision and reasonable guardrails (e.g., governance and oversight processes within health care organizations), it could lead to inappropriate or biased clinical decisions.

The Duke-Margolis focus is to help to balance opportunities for rapid and valuable innovation with safety and avoiding bias, grounded in what is technically and practically possible for different stakeholders, and strengthening the ability of health care organizations, regulators, and payers to identify what works and to detect and address safety or bias issues.



**There needs to be near real-time translation between policy makers, developers, and users to ensure that policy is moving with practice.**

## Why This Work Matters

AI development and adoption is at a critical point, where innovation and use should be encouraged while maintaining guardrails for safety as we learn more about these tools and their implementation. Additionally, this is a growing field with many policy components, e.g., FDA regulation of AI-enabled “products” (over 700 approved so far), ONCHIT requirements for certified electronic health records (EHRs) to provide key data elements to help health care organizations assess AI capabilities added to EHRs, and many AI tools being developed within health care organizations or collaborating organizations.

Through the Duke-Margolis digital health portfolio, we are committed to developing and supporting 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

## Finding Solutions

Duke-Margolis has an opportunity to further engage stakeholders and build on our work to date to assess what is needed, what is possible, and what is practically feasible for different parts of the ecosystem. In a time where creativity and rigor are both needed, Duke-Margolis has become an active participant in a range of national and global initiatives and can serve as a convener to identify potential best practices and policy options. Through our work with regulators, payers, manufacturers, patients, and health care end-users, we can advance our work as a trusted voice in a complex and ever evolving field.

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, prioritizing 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

patients. Duke-Margolis’ researchers combine expertise in technology with knowledge of regulation, payment, and evidence development. We have conducted expensive research on evidence generation and assurance, market incentives, payment models, and coverage decisions and are well-positioned to be a leader in AI policy discussions and strategies.

Importantly, there needs to be near real-time translation between policy-makers, developers, and users to ensure that policy is moving with practice.

**Our work is focused on ensuring that health policy stays in step to ensure potentially life-changing treatments are informed by real-world evidence and are affordable and accessible for the patients that need them.**

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

- **With the Coalition for Health AI (CHAI), Duke AI Health,** Federal agencies, and other partners, we are working on establishing a step-wise path forward on AI policy that promotes innovation while providing guardrails for patients. One project, among several, will highlight early examples and potential best practices of AI governance in health care organizations for testing, deployment, and monitoring of AI tools, aiming to create a harmonized framework to help a broader range of health care organizations develop their own governance policies.
- **With the University of California, San Francisco Coordinating Center for Diagnostic Excellence (Co-DEx)** we will serve as a bidirectional policy translation arm for 10+ demonstration projects being explored across the nation 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 the Duke-Margolis Value for 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.