



Ensuring Excellence

Strategies for Rigorous Testing of Healthcare AI Systems

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Resources

For more information

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Responsible AI Testing in Healthcare

From treating patients to developing novel pharmaceuticals, organizations today are seeking to leverage emerging technology as part of their innovative approach to healthcare and the medical sector. Technology, and in particular artificial intelligence (AI), offers the promise of new solutions to the medical world.

But, without suitable safety measures, AI also brings with it several challenges. Algorithmic bias and the potential for algorithms to produce unfair or inaccurate outcomes in medical and clinical contexts (including those relating to race, gender, and socioeconomic grouping) are perhaps the most significant concerns, with the potential to negatively impact the quality of patient care, perpetuate health disparities, and erode trust in medical technologies. Such biases and inaccuracies can hinder the development and adoption of novel tools vital to the advancement of medical science.

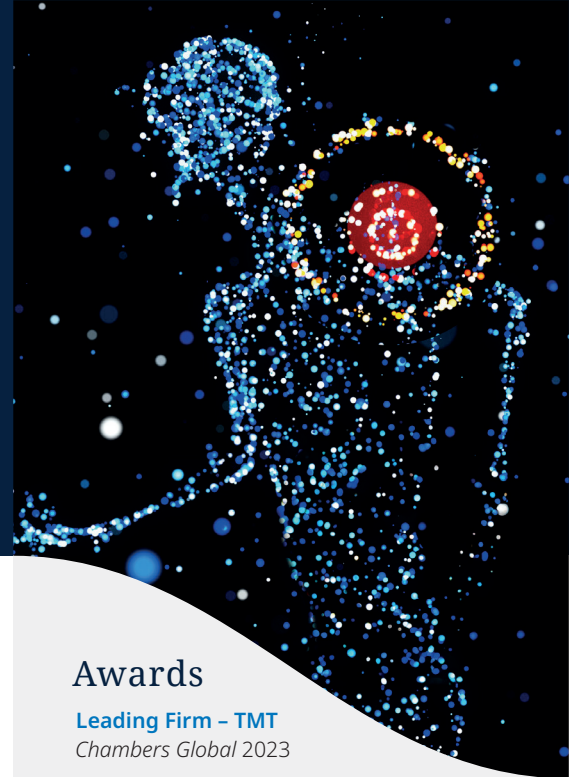
Many in the healthcare sector are coming to understand that, while they are eager to adopt AI into their organizations, they are not yet adequately addressing such concerns and are even falling behind strategically. Notably, Bain's survey of health system executives reveals that 75 percent believe generative AI has reached a turning point in its ability to reshape the industry, yet only six percent have an established generative AI strategy.

Meanwhile, regulators are growing increasingly concerned about the accuracy,

trustworthiness, and fairness of AI and algorithmic systems. The [White House Executive Order on Safe, Secure, and Trustworthy Artificial Intelligence](#) emphasizes the need for ongoing monitoring and testing of models to ensure their safe and secure deployment and performance. In 2022, the California Attorney General sent letters to 30 hospital CEOs on racial bias in healthcare AI as step one of a California Department of Justice inquiry. In 2023, a joint statement by 23 US State Attorneys General identified "health care delivery options" as the exemplar of higher-risk AI warranting their attention. And in some key jurisdictions, regulators are moving towards implementing guidance and legislation targeted at mitigating potential AI harms.

In the European Union, regulators have begun the process of augmenting existing regulations of medical technology through the AI Act, the world's first comprehensive AI regulatory framework. The AI Act impacts the use of AI in healthcare in several ways, including the categorization of algorithms used to detect diseases as "High-Risk," which requires that several additional obligations be followed. Failure to comply with the additional obligations may result in fines of up to seven percent of total global revenue or €40 million, whichever is higher.

Similar regulatory interventions are also developing in the United States. For example, the Food and Drug Administration has issued



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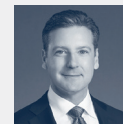
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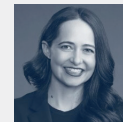
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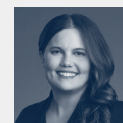
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final guidance on clinical decision support (CDS) software, indicating that non-device CDS software must be transparently labeled with adequate, plain-language background information on software inputs, algorithm logic or methods, training datasets, and validation. Furthermore, the Health and Human Services Office of the National Coordinator for Health Information Technology (HHS-ONC) issued a final rule in December 2023 requiring developers of certified health IT using predictive Decision Support Interventions (DSI) to make certain

disclosures, implement AI governance controls, and perform risk assessments of validity, reliability, robustness, fairness, intelligibility, safety, security, and privacy. Additionally, there is a pending 2022 HHS proposed rule that seeks to explicitly prohibit covered entities from discriminating through the use of clinical algorithms in their decision-making, noting “[w]hile covered entities are not liable for clinical algorithms that they did not develop, they may be held liable under this provision for their decisions made in reliance on clinical algorithms.”

DLA PIPER'S RESPONSIBLE AI TESTING WORK

DLA Piper is counsel to numerous leading health systems, pharmaceutical, and device companies. We conducted the first legal and compliance red teaming of a major medical generative AI product, as well as Trust & Safety analyses for a top large language model (LLM) provider. DLA Piper is a co-founder of the [Health AI Partnership](#) (HAIP) and advised the American Medical Association (AMA) on its AI policy. The HAIP Leadership Council consists of clinicians, engineers, lawyers, and social scientists from DLA Piper, Duke Health, Mayo Clinic, and UC Berkeley. AMA is a HAIP participant, and HHS-ONC and Centers for Medicare and Medicaid Services (HHS-CMS) have become official federal observers.

As legislative and regulatory bodies increasingly demand that healthcare AI meet new standards, DLA Piper's team of healthcare, computational, legal, and regulatory experts is uniquely positioned to provide the necessary expertise

and guidance. DLA Piper's responsible AI testing, done under the protection of privilege, is of great importance to healthcare and life sciences clients striving to build AI systems that are fair, accurate, and unbiased. Our Responsible AI Testing integrated team includes both lawyers and data scientists, and the firm has academic collaboration with leading institutions like Duke Institute for Health Innovation (DIHI) and Stanford Law to stay on the cutting edge of bias testing in healthcare AI.

DLA Piper advises several major healthcare systems, pharmaceutical, life science, and device companies on these critical issues, as lead counsel. With our combination of academic experience through our collaboration with DIHI and our deep knowledge of the legal and data science landscapes, DLA Piper is a resource for any organization dedicated to building unbiased and non-discriminatory healthcare AI.

OUR WORK WITH DUKE INSTITUTE FOR HEALTH INNOVATION (DIHI)

Our team includes sector-focused lawyers and data scientists with extensive experience in highly regulated industries such as life sciences and healthcare. In collaboration with DIHI, we can conduct statistical, clinical, and economic evaluation and validation of machine learning (ML) and AI solutions, including retrospective analyses, prospective analyses, simulations, design research, and user testing.

DIHI is the coordinating center for HAIP. This effort builds on ten years of experience in translating ideas into sustainable health innovations, not least the sourcing, design, development, and implementation of dozens of ML and AI based solutions. Our service offerings encompass the entire AI/ML product lifecycle, from design to deployment.

ML and AI testing activities

We perform ML and AI research activities that span the entire product lifecycle, including:

- Problem assessment
- Internal and external scan of solutions
- Clinical workflow development
- Model evaluation and audit
- Health equity impact assessment
- Model infrastructure assessment
- Training and communication materials

Shaping the future of AI law

We are working with leading research institutions to set the standards for AI quality and compliance that ultimately inform public policy. Our team's experience includes:

- Founding Member of NIST AI Safety Institute Consortium
- Founding Director of the US Senate Artificial Intelligence Caucus
- Principal author of the \$2.2 billion Artificial Intelligence Initiative Act (AI-IA)
- CEO of the National Cyber-Forensics and Training Alliance
- Chair of the House of Lords Select Committee on AI
- Chair of the Executive Committee of the UN's AI for Good law track
- Advisor to the American Medical Association on its AI liability policy
- Advisors to the UK, OECD, NIST, EU on AI regulation
- Special Assistant Attorney General of California
- Authors of *Fortune* 50 and 100 companies' global Responsible AI, Generative AI, and AI Procurement policies
- Co-authors with Stanford Law School CodeX on the future of legal AI impact assessments
- Founder of the Health AI Partnership with Duke Health, the Mayo Clinic, UC Berkeley, and others

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