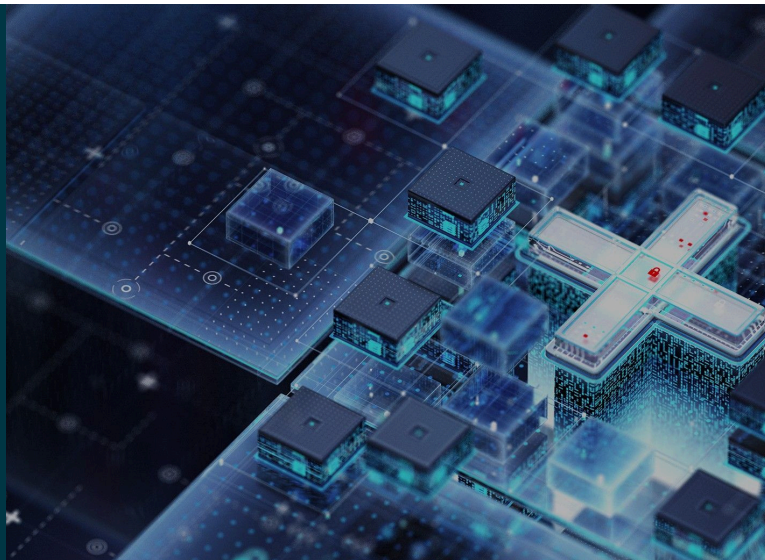


AI in Healthcare



HIGHLIGHTS

■ Advising Leading Healthcare Companies on AI

Because Wilson Sonsini represents the full range of participants in the healthcare AI ecosystem, the firm has a holistic view of the current business and regulatory realities of this sector, as well as the distinct ability to foresee the concerns and requests that potential clients and partners may present to companies and investors.

■ A Team Anchored by Regulatory Agency Experience

Wilson Sonsini's AI healthcare team includes a former HHS and ONC executive who helped draft and implement foundational healthcare data privacy and interoperability rules, including the HIPAA Privacy Rules that are a key consideration in every AI-related healthcare decision. This unique experience informs our approach to regulatory issues we routinely handle for our clients.

OVERVIEW

A Market Leader in Healthcare AI

Wilson Sonsini defined the internet era with its representation of Silicon Valley's digital giants since their earliest start-up days—and this legacy continues today with the firm as a pioneer in the healthcare artificial intelligence (AI) sector.

Just as the firm has been an integral part of the tech scene for decades, its commitment to client service has grown through its representation of the most impactful AI companies, including a third of the *Forbes 2025 AI 50*. Wilson Sonsini advises clients—including healthcare clients—on some of the biggest deals in AI, which totaled over \$50 billion in 2024, and takes on precedent-setting cases in AI-related law.

At the same time, the firm has built a highly experienced Digital Health practice, with a sharp focus on AI, representing clients ranging from cutting-edge healthcare technology start-ups to hospital systems. The firm's cross-disciplinary team blends its market-leading representation of the world's most influential technology companies with deep digital healthcare regulatory experience. Due to this unique combination, hundreds of healthcare innovators consider Wilson Sonsini to be their go-to strategic advisor when it comes to harnessing AI innovation in their business.

Wilson Sonsini's Healthcare AI Clients

Wilson Sonsini's clients include healthcare companies and investors that use AI to fundamentally reshape care delivery, clinical decision-making, and the use of healthcare data. The firm counsels on business strategy, helps its clients understand the law and its gaps, and predicts where future legal developments are likely to create significant risks or opportunities. Because Wilson Sonsini represents the full range of participants in the healthcare AI ecosystem, it has a holistic view of the current business and regulatory realities of this sector, as well as the distinct ability to foresee the concerns and requests that potential clients and partners may present to companies and investors. The firm's central position in the tech and healthcare industries helps facilitate significant and beneficial relationships that drive innovation and growth, and smooth the way to the adoption of AI in healthcare.

Wilson Sonsini advises healthcare AI companies on the full legal and regulatory landscape governing the development, training, deployment, and commercialization of AI in healthcare. This includes compliance with emerging state healthcare AI laws across all U.S. jurisdictions; HIPAA compliance and patient data protections; managing risks related to patient care and the influence of clinical outcomes; and FDA regulatory oversight. In addition to our firm's advisory services, we represent clients in regulatory inquiries and investigations related to healthcare AI.

Data Privacy, Security, Access, and Use

Data is the key to the development and deployment of innovative AI-enabled technologies in healthcare, but its use, security, and sharing present unique challenges in the healthcare context. Wilson Sonsini advises on issues related to the access, exchange, and use of health data for AI development and deployment. Our firm provides AI-related advice in contract negotiations and transactions, as well as during disputes and investigations. In addition, we help clients shape this rapidly developing area of the law through robust and effective advocacy.

Wilson Sonsini's AI healthcare team includes a former HHS and ONC executive who helped draft and implement foundational healthcare data privacy and interoperability rules, including the HIPAA Privacy Rules that are a key consideration in every AI-related healthcare decision. This unique experience informs our approach to regulatory issues we routinely handle for our clients, including issues related to health information exchange, interoperability, TEFCA, information blocking, and data rights. We also counsel health AI innovators on health data protections, including state and federal privacy and security requirements such as HIPAA, FTCA, and state laws. In addition, we provide strategic advice on business arrangements that implicate data access, as well as the right to use and exchange health information and other data.

AI Healthcare-Centered Deals

Wilson Sonsini is consistently ranked by *Bloomberg*, *Thomson Reuters*, and *Capital IQ* as a leading deal advisor to companies and underwriters in the tech space. The firm is also consistently ranked No. 1 by *LSEG* for the number of company-side venture capital deals it handles each year, including AI healthcare deals. Together with the firm's corporate attorneys, the team represents AI healthcare clients in a wide range of deals, including venture financings, private equity capital raises, M&A, strategic ventures, and IPOs.

In addition, Wilson Sonsini understands that intellectual property (IP) is an innovative company's most valuable asset, driving its valuation and ability to raise capital and enter into strategic partnerships. At the same time, protection of AI-related innovation poses new and unique challenges. Our AI healthcare team routinely collaborates with the firm's IP professionals to define the scope of available protection and help clients obtain patents, trademarks, and copyrights where appropriate, as well as provide practical advice on trade secret protections.

AI in Healthcare Regulatory Compliance

Wilson Sonsini helps healthcare AI companies innovate in one of the most highly regulated industries in the United States. The use of AI in healthcare raises novel legal and regulatory questions about clinical decision-making and patient-specific recommendations, which require guidance on structuring AI tools and workflows to distinguish between clinical care and wellness guidance, and to address the implications of AI on compliance with the corporate practice of medicine (CPOM) and associated requirements for a management services organization (MSO) and professional corporation (PC) structure. The legal and regulatory framework for the application of AI in healthcare is fluid and fragmented, with a patchwork of state and federal laws and regulations that demand careful synthesis. The firm's AI healthcare team counsels clients on both state-specific healthcare AI laws and broader healthcare and technology laws that do not explicitly address AI, but nonetheless govern healthcare AI businesses.

The AI healthcare team also helps clients manage liability risk in an evolving regulatory environment where the laws and legal standards are changing rapidly and still developing. Further, it advises on complex healthcare regulatory frameworks implicated by AI-enabled healthcare, including fee-splitting, the Anti-Kickback Statute, the Stark Law, CPOM, reimbursement, value-based care, licensing, and professional responsibility.

FDA Regulatory Strategy

Wilson Sonsini advises healthcare AI companies on how the U.S. Food and Drug Administration (FDA) regulates AI/ML-enabled products and platforms and strategic regulatory considerations for commercializing those technologies, including risk mitigation strategies, negotiations with FDA-regulated partners such as biopharmaceutical or medical device companies, quality agreements with suppliers, and post-market regulatory compliance. Our team helps clients analyze their product development and the use of AI in the context of their business model to determine potential go-to-market strategies, including pathways outside of FDA regulation or subject to FDA enforcement discretion, as well as FDA regulatory requirements pre- and post-market for FDA-regulated products, software functions, and/or SaaS platforms, including those that interface or connect with other medical devices, including wearables and remote monitoring products.

AI Policy and Engagement

Wilson Sonsini is actively engaged with federal agencies and policymakers on AI policy and its applicability to health care. The AI healthcare team partners with clients to advise them on shaping policy and advancing business goals related to healthcare AI. The

team's senior federal agency experience and Washington, D.C., presence contribute to its unique judgment and understanding of policy development, enabling our attorneys to provide exceptional advice and direction to clients seeking to track and understand policy development and engage with policymakers on rapidly developing AI policy and advancements in technology. We work with leaders at HHS, including ONC, CMS, OCR, and FDA, as well as the FTC.

Healthcare AI Insights

To stay up to date on the rapidly changing requirements for healthcare AI businesses, subscribe [here](#).

REPRESENTATIVE MATTERS

- SpectraWAVE on acquisition by Philips, December 15, 2025
- Radical Health on \$5 million Pre-Seed, December 4, 2025
- House Rx on \$55 million Series B, November 19, 2025
- Insilico on research and licensing collaboration with Lilly, November 13, 2025
- Iambic on oversubscribed \$100 million financing, November 10, 2025
- Pear Suite on \$7.6 million Series A, November 3, 2025
- Phare Health on acquisition by R1, October 22, 2025
- Sage Care on \$20 million funding, October 17, 2025
- Assort Health on \$76 million Series B, September 30, 2025
- Scientist.com on acquisition by GHO Capital, September 30, 2025
- Manas AI on \$26 million Seed Extension, September 24, 2025
- Lila Biologics on IP matters related to Eli Lilly collaboration, September 9, 2025
- Eight Sleep on IP matters related to \$100 million financing, August 21, 2025
- Iambic Therapeutics on technology and research collaboration with Revolution Medicines, July 10, 2025
- Juvena on \$650 million research collaboration with Eli Lilly, July 2, 2025
- Portal Biotech on IP matters related to \$35 million Series A, June 30, 2025
- ArrePath on IP matters related to financing round, June 27, 2025
- Weave Communications on its acquisition of TrueLark, May 6, 2025
- J.P. Morgan Growth Equity Partners on Nourish's \$70 million Series B, April 25, 2025
- Assort Health on \$22 Million Series A, April 16, 2025
- Isomorphic Labs on \$600 million external funding round, April 7, 2025
- RayThera on \$110 million Series A, April 7, 2025
- Junevity on \$10 million Seed funding, February 13, 2025
- Manas AI on \$24.6 million fundraiser, January 29, 2025
- Qventus on \$105 Million Series D, January 14, 2025
- Insilico on patent matters related to exclusive global license agreement with Menarini Group, January 13, 2025
- Prudentia Sciences on \$7 million funding, January 10, 2025
- Transcarent on acquisition of Accolade and preferred stock financing, January 8, 2025
- Fable Therapeutics on financings totaling \$53.5 million, October 24, 2024
- Neo Medical SA on Series B and \$68 million equity investment, September 18, 2024
- Cellino receives \$25 million ARPA-H Award, September 12, 2024
- Regard on \$61 million Series B, July 16, 2024
- a16z Investment in Talkiatry's \$130 million Series C, June 20, 2024
- Iambic Therapeutics on \$50 million Series B Extension, June 18, 2024
- Anterior on \$20 million Series A, June 13, 2024
- Ochre Bio on \$37.5 million license agreement with GSK, June 12, 2024
- Atropos Health on \$33 million Series B, May 30, 2024
- Plenful on \$17 million Series A, May 30, 2024
- Karius on IP matters related to \$100 million Series C, May 6, 2024
- Transcarent on \$126 million Series D, May 6, 2024
- Milu Health on \$4.8 million Seed round, March 13, 2024
- ArteraAI on \$20 million funding, February 5, 2024
- Insilico Medicine on license agreement with Menarini Group, January 5, 2024
- Transcarent in proposed acquisition of 98point6, March 7, 2023
- House Rx on \$30 million financing, March 18, 2022
- Verana Health on \$150 million Series E, January 18, 2022
- Innovaccer on \$150 million Series E, December 14, 2021
- Transcarent on partnership with Walmart, October 15, 2021
- Transcarent on \$58 Million Series B, June 14, 2021
- Verana Health acquisition and \$100 million financing round, February 6, 2020

RESOURCES

Alerts, Advisories, and Bylined Articles

- [ASTP/ONC Issues an RFI Seeking Input on How HHS Can Accelerate Adoption and Use of AI in Clinical Care](#), December 19, 2025
- [Navigating CMS's ACCESS Model and FDA's TEMPO Pilot: Opportunities for Digital Health Companies](#), December 19, 2025
- [Trump Administration Issues Executive Order on National AI Policy and Deregulation](#), December 16, 2025
- [California MSO Transaction Notification Requirements Begin January 1, 2026](#), November 19, 2025
- [Senator Cassidy Introduces Sweeping Health Privacy Bill](#), November 13, 2025
- [Legal Framework for AI in Mental Healthcare](#), October 9, 2025
- [HHS Announces Increased Resources to Enforce Information Blocking Prohibition](#), September 8, 2025
- [CMS Announces Creation of Health Tech Ecosystem for Improving Access to Patient Data](#), August 1, 2025
- [Nevada Passes Law Limiting AI Use for Mental and Behavioral Healthcare](#), June 25, 2025
- [Oregon Enacts Nation's Most Restrictive CPOM Law](#), June 13, 2025
- [Health Care Artificial Intelligence Code of Conduct](#), May 2025
- [Utah Enacts Mental Health Chatbot Law](#), April 15, 2025
- [FDA Issues Draft Guidance on Predetermined Change Control Plans for Medical Devices](#), September 3, 2024
- [FDA Publishes Machine Learning Transparency Guiding Principles for Medical Devices](#), July 9, 2024
- [An Artificial Intelligence Code of Conduct for Health and Medicine: Essential Guidance for Aligned Action](#), National Academy of Medicine, June 12, 2024

Speaking Engagements and Media

- [Keynote | Health Policy and AI](#), Society for Academic Urology Conference, May 14, 2026
- [Post-Event Report | Next-Level Health Systems Summit: Leading with AI](#), April 16, 2026
- [Panel | Representing the Founders, Investors, and Inventors of Health Care AI: Venture Capital and Emerging Companies](#), American Health Law Association's Winter Institute, February 12, 2026
- [In the News | Andrea Linna Quoted by *Inside Health Policy* on State Laws Regulating AI in Mental Health Care in 2026](#), January 6, 2026
- [In the News | Andrea Linna Quoted by *WSJ* on AI in Healthcare](#), December 8, 2025
- [Webinar | The Insider's Guide to Health Care AI Policy](#), Alliance for Health Policy, December 4, 2025
- [Panel | Responsible AI in Healthcare: From Guidance to Action](#), ADAPT Conference, November 11, 2025
- [Workshop | Advancing Responsible AI](#), Duke University, September 30, 2025
- [Panel | How Should Liability be Distributed in the AI Value Chain?](#) IAPP AI Governance Global North America Conference, September 18, 2025
- [Panel | An Artificial Intelligence Code of Conduct for Health and Medicine: Essential Guidance for Aligned Action](#), National Academy of Medicine, June 12, 2025
- [Panel | Navigating Legal Complexities of AI-Driven SaMD in Health Care](#), American Health Law Association, February 4, 2025
- [Panel | Venture Capital in Digital Health: Representing Healthcare Startups and Emerging Companies](#), Illinois Association of Healthcare Attorneys, November 9, 2024
- [Panel | Balanced Innovation: Regulatory Landscape of AI and Digital Health](#), American Bar Association Healthcare Delivery & Innovation Conference, September 26, 2024
- [Panel | The Good, Bad and Unknown: Navigating Artificial Intelligence in Healthcare](#), State Bar of Michigan Health Care Law Section 2024 Annual Meeting, September 19, 2024
- [Panel | AI in Digital Health](#), Techstars Healthcare, May 2, 2024
- [Webinar | AI in the Digital Health Industry](#), Wilson Sonsini, February 1, 2024