Hogan Lovells

Digital Health

As the industry forges ahead to advance the digital health ecosystem, the companies in this space will navigate a complex set of business and legal issues that are often evolving in real time. That's where Hogan Lovells can help.

Our cross-jurisdictional team of more than 50 life sciences lawyers bring a real-world sensibility to your challenges and business opportunities. We take a technology-based approach to counseling on digital health products and services and provide strategic guidance on how to leverage opportunities for growth, minimize legal barriers, comply with rules, protect your data, and realize its value.

We advise at the cutting edge of technology with expertise in areas such as artificial intelligence, big data, blockchain, cybersecurity, use of consumer grade wearables, digital therapies, virtual clinical trials, and telehealth by bringing together our experience from many angles of our life sciences practice. Moreover, we pull experience from our colleagues specialized in other industries, such as software and technology licensing, automation, and non-medical machine learning.

Representative experience

Multiple clients on the use of telehealth and other digital health applications to monitor COVID-19 patients in their homes.

Multiple clients – including high-technology companies – in drafting and negotiating agreements to develop and

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Practices

Health Law

Medical Device and Technology Regulatory

Privacy and Cybersecurity

Industries

Life Sciences and Health Care

commercialize digital health products that depend on access to and exchange of data.

Multiple pharmaceutical companies on the use of software applications within a clinical trial setting.

A client on the development of a new digital health product consisting of a mobile app for the patient and web-based apps for HCPs.

A provider of advanced diagnostic imaging, outpatient, and cancer care on the generation of their digital architecture strategy through licensing, joint venture, and acquisition arrangements.

Two successful de novo applications to FDA for AI medical products. IDx's product for use in diabetic retinopathy screening and Viz.ai's product that analyzes CT angiographic images to support acute stroke care.

A leading consumer product company on the development and classification of a consumer-oriented wearable sensor and associated mobile application.

Various regulatory aspects of international telemedicine, including cross-border health care, data privacy, and medical device aspects.

Medical device manufacturers with structuring their connected medical device services to facilitate cross-border data transfers and streamline EU data protection constraints.

Multiple life sciences companies on the use of data (including patient data) from handheld devices, mobile apps, tracking, and other personal devices for various use scenarios.

Competition law aspects of blockchain technology, which is explored for use in pharmaceutical supply chain management and patient data handling.

Technology companies, as well as hospitals, health plans, and biotech companies, on issues related to the use of data in research contexts, health privacy and the cloud, and core HIPAA compliance.

Various regulatory aspects of international telemedicine, including cross-border health care, data privacy, and medical device aspects.

A global technology company in licensing its glucose monitoring "smart lens" technology, and its joint ventures to develop next-generation surgical robots and bioelectronic medicines.

An international IT company concerning the use of AI in support of medical practice, especially diagnosis of diseases, and the potential classification of related software as a medical device in the EU.

Cisco Healthcare in rolling out its telemedicine products in China and related regulatory issues.

A surgical robotic company on competition law aspects, in particular as regards market definition in fields of nascent technologies.

Latest thinking and events

News
FDA proposes clarification in long-running tussle over “intended use” rules for drugs and devices

News
The EFPIA’s response to the EMRN’s strategy to 2025 focuses on real world evidence

News
COVID-19 Report for Life Sciences and Health Care Companies (21 - 24 September 2020)

News
FDA Pre-Cert update: “more work needed” to refine Streamlined Review Framework

News
COVID-19 Report for Life Sciences and Health Care Companies (14 - 18 September 2020)

News
COVID-19 Report for Life Sciences and Health Care Companies (7 - 11 September 2020)