KRIEG DEVAULT

Digital Health Services

The health care landscape continues to experience rapid innovation in digital health technologies focused on improving patient outcomes and enhancing operational efficiencies. Krieg DeVault's attorneys regularly counsel clients in navigating the digital health landscape utilizing the firm's long-established experience in health care compliance and regulatory affairs, health care transactions, life sciences, and health information privacy and cybersecurity matters.

Our lawyers understand and resolve important and emerging issues impacting digital health services as the industry extends into mobile health platforms and internet applications, wearable devices, telehealth and telemedicine offerings, and personalized medicine. We also assist clients in negotiating contracts that provide clients with protection of their intellectual property and address applicable regulatory risks, as well as developing appropriate policies related to the delivery of digital health services.

The combination of expertise in the various aspects of digital health services uniquely positions Krieg DeVault to offer the best solutions for our clients in this evolving and expanding area of the health care industry.

Digital Health Services Resources

- AI/ML-Based SaMD Action Plan - January 2021
- AI/ML-Enabled Medical Device List
- CBER, CDER, CDRH Draft Guidance
- CDRH Proposed Guidances for Fiscal Year 2022
- Content of Premarket Submissions for Device Software Functions/ Draft Guidance for Industry and Food and Drug Administration Staff
- FDA Advances Data, IT Modernization Efforts with New Office of Digital Transformation
- FDA's Technology Modernization Action Plan
- FDA's Data Modernization Action Plan
- FDA's Pre-Cert Pilot Program
- Digital Health Center of Excellence (DHCoE)
- Good Machine Learning Practice for Medical Device Development: Guiding Principles

- International Medical Device Regulators Forum (IMDRF) AI Working Group Draft Guidance
- PDUFA VII Commitment Letter - August 2021
- PDURS Framework - November 2018
- Real-World Data: Assessing Electronic Health Records and Medical Claims Data To Support Regulatory Decision-Making for Drug and Biological Products - September 2021
- Real-World Data: Data Standards for Drug and Biological Product Submissions Containing - October 2021
- Real-World Data: Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products - November 2021
- Real-World Data: Considerations for the Use of Real-World Data and Real-World Evidence to Support Regulatory Decision-Making for Drug and Biological Products - December 2021