# Digital Health: A Multidisciplinary Approach

At the forefront of the Digital Health Environment, Digital Health projects raise complex and multi-faceted legal and regulatory considerations.

Covington's market-leading global <u>Digital Health team</u> has unmatched breadth and depth of experience providing clients with solutions to navigate the legal, regulatory and policy issues that affect their digital health products and services.

### Overview

Our lawyers are at the leading edge of cross-sectional developments worldwide in regulation, data and information technology and have represented key players throughout the digital health ecosystem, including:

- pharmaceutical, medtech, and technology companies,
- emerging digital health companies,
- health data storage and analytics platforms,
- AI platform providers,
- investors, and
- trade associations.

### Capabilities

Our team helps pharma and device clients operating in highly regulated environments and tech clients operating in relatively less regulated environments understand each other to create balanced and workable deal structures.

With exceptional service including an integrated approach across practices, offices, and jurisdictions in the U.S., Europe, Asia, the Middle East and Africa, we are uniquely positioned to help clients respond to these challenges anywhere in the world at any given moment.



"Band 1" firm for Life Sciences across US, UK, Europe, China and Global surveys



"They are a highly skilled, integrated law firm that really is able to provide the full spectrum of services that we need both locally and globally."

- Covington client

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## Capabilities

#### Regulatory and Public Policy

- Development strategies, regulatory pathways, and codevelopment approaches
- Classification determinations for software medical devices
- Al in drug discovery, development and commercialization
- Decentralized clinical trials
- Real world data and evidence

#### Market Access and Reimbursement

- Market access contracting and legal strategies
- Coding, coverage and reimbursement strategy and support in negotiations

Government

Contracting

Contracting with national

Procurement law

health services

Value-based contracts

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#### Privacy and Data Security

- Evaluating impact and compliance with privacy laws, like EU GDPR, HIPAA and emerging U.S. state privacy laws
- Managing third-party risk, including contracts with vendors and evaluating analytics and ad tech partner arrangements
- Cybersecurity
- Data governance

#### M&A and Corporate

- M&A
- Investment rounds
- Due diligence
- Corporate joint ventures
- Strategic tax advice

#### Antitrust and Competition

- Data portability, exclusivity, device interoperability, and other "access" issues
- Approvals for M&A, JVs, collaborations and other agreements

#### Artificial Intelligence

- AI and data-driven drug discovery agreements
- Al and medical devices
- Ethics and governance



- Diversity, Equity, and Inclusion
- Product Responsibility and Consumer Protection
- Supply Chain Diligence
- Environmental Marketing Claims

### Commercial

- Collaborations
- Data licensing
- Technology: software agreements, cloud, AI, data analytics, professional services
- Regulatory infrastructure agreements
- Telehealth arrangements
- Terms of use and privacy policies

#### Liability Considerations

- Product liability laws
- Insurance claims
- Liability limitation structures and other planning
- Health Care Compliance
- Fraud and abuse and interactions with health care providers
- Telemedicine and practice of medicine
- Compliance program development and implementation

#### Intellectual Property

- Patent portfolio and trade secrets strategies
- Enforcement and defense of IP rights
- IP diligence for transactions

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## **Key Contacts**



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