

# The Future of Health is Digital

## A Policy Roadmap

Countries and private companies are investing in digital health and promoting innovation to improve the quality of care, expand access, bring innovation into practice, and reduce costs through greater efficiencies, working alongside policymakers. Innovative companies have an opportunity to provide thought leadership to shape the discussion and policy development and the future of international digital health policy.

This Policy Roadmap is a snapshot of ten of the most important policy issues facing governments as they look to the role of digital technology in health care.

### Privacy & Data Use

**Balancing novel uses of data with protection of patients' privacy** – More health data is being collected, shared, and combined with other data than ever before to promote research, health care delivery, and innovation. Companies must develop practices that balance individuals' privacy with the value of data to transform population health. Regulators and companies are grappling with appropriate uses of both identifiable and de-identified data and many countries are developing new data privacy laws. Technical capabilities and utility of de-identified data are important considerations.

### Patient Access to Health Care

**Leveraging technology to improve access to health care** – Digital health tools provide opportunities to reach patients where they are, including in remote locations, and provide cost effective ways to provide needed health care services. As more countries seek solutions to providing access to care, digital health technologies are providing solutions, including telehealth, remote patient monitoring, digital therapeutics, and clinical decision support to rural health care workers. Governments and policymakers are looking at how to evaluate and make these tools available.

## Research & Real World Evidence

**Enabling the next frontier of cutting-edge research** – Scientific researchers are using real world data to support clinical trials and observational studies, enabling greater understanding of new treatment approaches. Technology is also enabling clinical trials over a broader set of individuals by enabling the enrollment and collection of data remotely. Also, data analytics and machine learning are helping researchers make new discoveries about treatments. Finally, regulations around data acquisition and use, human subjects research, and digital clinical trials are changing to address the changing technology and drive toward precision medicine.

## Variability & Convergence of Global Policies

**Harmonizing data policies to enable sharing of data across borders** – Jurisdictions around the world are developing new data protection policies, but variation may create a web of different regimes to navigate and may inhibit the flow of data across borders. As data becomes more liquid and as innovations are not limited to political boundaries, it is necessary to develop approaches to harmonize data policies across the globe.

## Cybersecurity

**Limiting cybersecurity vulnerabilities** – Entities that hold valuable health data are regularly considering new technical and administrative mechanisms to prevent unauthorized access to data at rest and in motion. Policymakers are considering new and creative approaches to encourage strong cybersecurity practices, breach notification requirements, and enforcement and modifying policies to protect information that is critical to their citizens.

## Data Access & Availability

**Opening up possibilities through increased data access and availability** – Data that is maintained in silos is not available for effective treatment, research, and innovation. Regulators are modernizing policies to encourage greater interoperability and appropriate access to health data by individuals, health care providers, researchers, public health authorities, and innovators that can build tools that improve health care. Governments are also releasing more data that can enable digital health innovation.

## Quality & Integrity

**Ensuring data quality and integrity** – Researchers and health care providers increasingly rely on data from various sources to power data analytics. Inaccurate, biased, or unreliable data has more impact on patient care than ever before. Companies should engage with policymakers to support patient matching, de-duplication of records, ensure lack of bias in artificial intelligence and machine learning, and identify appropriate mechanisms to correct information.

## Safety & Oversight

**Building a new regulatory paradigm for digital innovation** – Regulators are rethinking safety issues to keep up with rapidly developing digital health tools and digital therapeutics. Artificial intelligence and machine learning are addressing health care complexities and reducing burden on health care providers, and are already supporting clinical decision making and individualized treatment. Existing safety regulations need modernization and policy makers need to consider new oversight frameworks to ensure safety and effectiveness of these new types of devices, decision support, and digital therapeutics while allowing for innovation.

## Patient Rights & Consumer Protection

**Treating patients as partners to build trust in health care** – For too long, patients have been treated as “subjects” in the development of breakthrough treatments and cures. Today’s technologies, including patient access to electronic medical records, mobile-enabled clinical trials, and wearable remote monitoring devices, are democratizing the invention of new innovations and their integration into the practice of care. Patients and governments are focused on consumer protection, strengthening individual rights to data access, and greater transparency into how their data is used. Investments in patient advisory panels and funding of bioethics efforts will differentiate the truly patient-centric market leaders from the rest.

## Public-Private Partnerships

**Harness the efforts of the public and private sectors** – Policies should be designed to support the innovative partnerships and financial arrangements that bring digital technologies to patients at home and at the point of care. Funding and support from government and the private sector can enable new research and implementation and broader access to new digital therapeutics and digital health tools. Collaborative messaging from public and private sectors can lead to greater advancement of digital health tools to improve access to and quality of care and chronic care management.

## About Our Digital Health Practice

Crowell & Moring’s digital health practice works with global clients who are revolutionizing health care by offering a combination of legal, regulatory, and policy direction and strategic counseling on a wide range of issues affecting health technology. Our team serves as trusted advisors and counsel to technology companies, health care providers, health care plans, and industry groups, helping them convert complex health care policy into practical business strategies. We understand the goals of digital health regulation—reduced costs, improved population health, and higher quality of care across the continuum—and work with companies to develop, implement, and manage initiatives that create value; leverage technology; ensure compliance with health information privacy and data security requirements; build coalitions and drive policy on challenging issues; and align the goals and interests of product design, manufacturing, marketing, and leadership teams.

## About Crowell & Moring International LLC

Crowell & Moring International LLC is a global government affairs and public policy firm that helps clients shape the international regulatory landscape to support innovation, sustainable growth, and commercial competitiveness in foreign markets. The team of public policy experts, former trade negotiators, economists, and bio-medical scientists works with clients to resolve commercial and trade challenges, clear political hurdles, and shape policies and regulations in key international markets. Our team includes professionals who have served in senior roles on Capitol Hill and at key governmental agencies. Our clients range from startups to Fortune 100 enterprises and include many of the world's leading companies in health and life sciences, chemicals, technology, communications, food and agriculture, as well as the innovators pushing the boundaries of emerging industries such as digital health, blockchain, and global data management. We also work with the trade associations that represent these global companies, along with the international organizations that are shaping the global policy and regulatory environment.

## About Crowell & Moring LLP

Crowell & Moring LLP is an international law firm with more than 500 lawyers representing clients in litigation and arbitration, regulatory, and transactional matters. The firm is internationally recognized for its representation of Fortune 500 companies in high-stakes litigation, as well as its ongoing commitment to pro bono service and diversity. The firm has offices in Washington, D.C., New York, Los Angeles, San Francisco, Orange County, London, and Brussels.

## Contact Us



### Jodi Daniel

*Partner, Crowell & Moring LLP  
Director, C&M International LLC*  
Washington, D.C.  
+1.202.624.2908  
jdaniel@crowell.com



### Patricia Wu

*Managing Director,  
C&M International LLC*  
Washington, D.C.  
+1.202.624.2963  
pwu@crowell.com



### Robert Holleyman

*Partner, Crowell & Moring LLP  
President and CEO,  
C&M International LLC*  
Washington, D.C.  
+1.202.624.2505  
rholleyman@crowell.com



### Clark Jennings

*Director, C&M International LLC*  
Washington, D.C.  
+1.202.624.2652  
cjennings@crowell.com



### Maya Uppaluru

*Associate, Crowell & Moring LLP*  
Washington, D.C.  
+1.202.624.2518  
muppaluru@crowell.com