Digital health

2023

Hogan Lovells

Advancements in technology

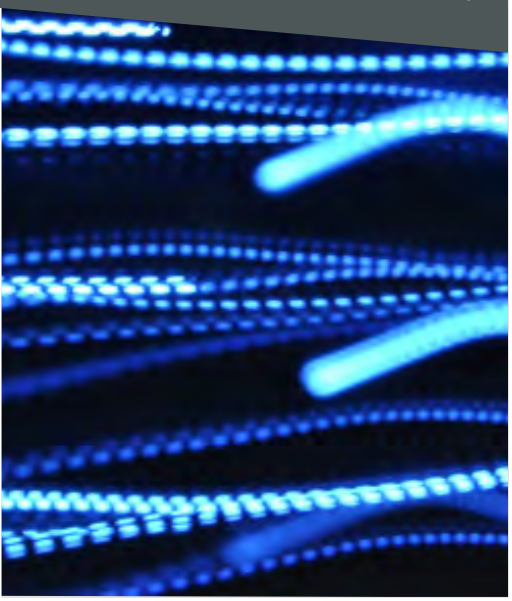
are revolutionizing the way in which the health care industry functions.

With the development of new products and services also comes a fluctuating regulatory environment. While innovation in the health care and life sciences industry leads to better lives and a wide range of opportunities, this also brings a new set of risks.

We advise at the cutting edge of technology with expertise in digital health areas – including 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.

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

Our team advises on the design, approval process, and regulation of digital health products. We regularly work with companies and health care providers on pricing and reimbursement frameworks. We advise on all aspects of health privacy and cybersecurity, including breach response, risk assessment, privacy policies, and transactions.



We help navigate collaborative arrangements such as commercial joint ventures and research studies and provide full commercial and corporate support for transactions.

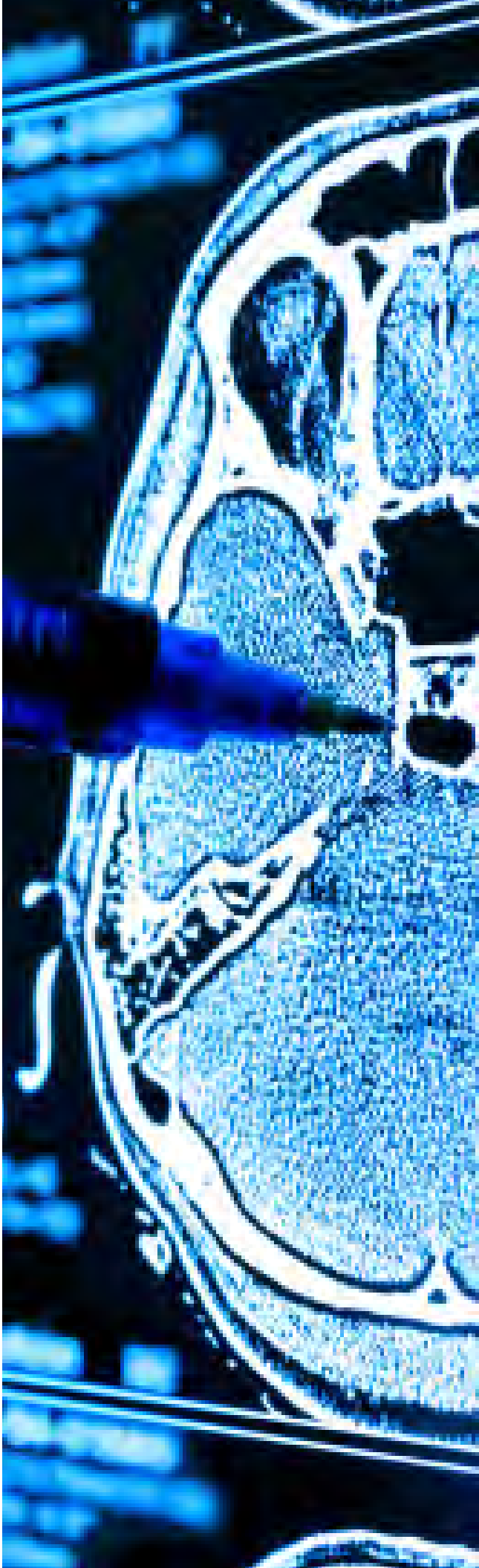
We advise across the full spectrum of deal aspects including intellectual property rights, licensing, data exploitation, and risk.

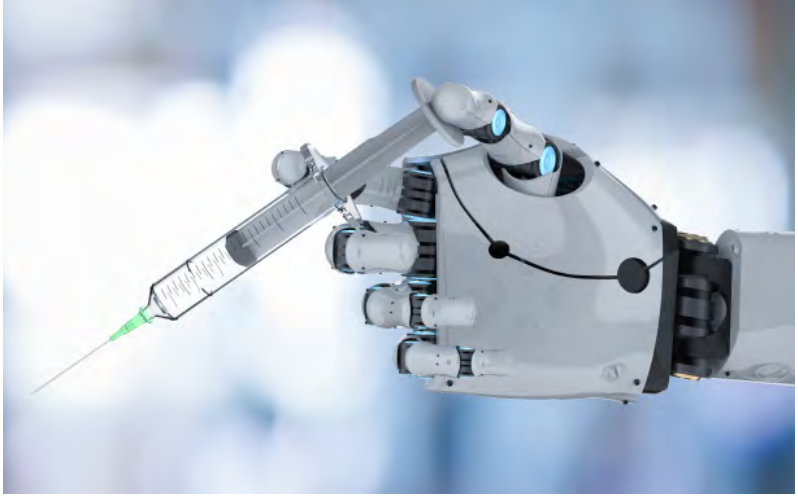
We also regularly counsel on risk mitigation strategies for liability, providing preventative strategies for product liability, professional liability, and negligence, and can help you step-by-step should new liability issues arise.

Artificial Intelligence

Companies pursuing AI technologies must realize that while the life sciences and health care industries are embracing this technology, the regulatory landscape is still finding its footing. That's where we can help.

In the life sciences, this year has seen AI achieve some impressive feats. For example, AI is being used to innovate compounds for medicinal use, and those compounds are in the process of being put forward for regulatory approval. However, questions are being raised by regulators worldwide as to the extent to which IP and regulatory protections can and/or should be available for innovations where AI has been involved. Regulators are in the process of considering any changes that might need to be made to the law. The answers to these questions could see monumental shifts in the way that R&D efforts are managed and/or compensated. Hogan Lovells has been advising clients on the present IP and regulatory landscape. Hogan Lovells has also been at the coalface of potential changes in the law, advising clients on what the future could hold, as well as how to be prepared. Our highly experienced cross-practice teams are able to advise on the regulatory landscape for operators in the life sciences industry.





Hogan Lovells has also been involved in a wide variety of transactions, helping clients to leverage developments in artificial intelligence and the life sciences. Whilst developments in AI are seeing novel and exciting collaborations between pharma and the computer sciences, we understand that such collaborations can require bespoke arrangements to deal with, among other things, the data being inputted into the AI and the allocation of rights produced by the AI.

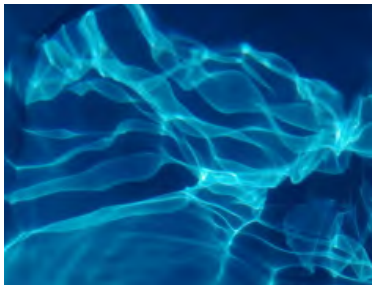
In addition, Hogan Lovells has been at the forefront of medical device artificial intelligence regulation. We have advised our clients on the clearance and approval of numerous medical devices that incorporate AI algorithms. These technologies have demonstrated enormous potential for health care, while at the same time raising unique regulatory questions due to their iterative and potentially self-updating nature, which is incongruent with historical regulatory approaches.

Our team has extensive experience counseling clients on the FDA and EU implications for new medical technologies, including AI technologies. We assist clients in determining whether AI products are regulated as medical devices. We understand the regulatory frameworks at issue, including FDA's new proposed framework for regulating AI devices. We have successfully advised our clients in navigating the unique regulatory issues involved in seeking FDA clearance, approval, or CE marking for AI-based devices and staying compliant in the postmarket phase. From inception and marketing authorization to debut and product maturity, our clients benefit from guidance that reflects their business strategies and legal needs.

We assist clients in developing and executing a reimbursement strategy based on our significant experience in reimbursement of health care AI. For example, we assisted our client in obtaining the first-ever national Medicare reimbursement for an AI system, and have advised on nearly every AI device reimbursed by the U.S.' largest federal payer to date. We have also helped clients obtain a series of landmark advancements in AI reimbursement, including the first-ever Category 1 Current Procedural Terminology (CPT®) code for an Autonomous AI device, first-ever inclusion of artificial intelligence in a Healthcare Effectiveness Data and Information Set (HEDIS) measure, first-ever Merit-Based Incentive Payment System (MIPS) quality measure.

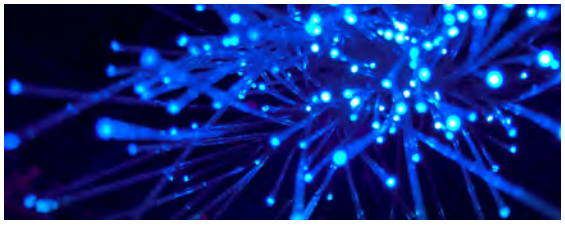
Representative experience:

Advising AI market-leaders on their IP and regulatory strategy for protecting medicinal products discovered using artificial intelligence.



Assisted numerous clients with novel medical devices featuring AI and machine learning algorithms in developing and gaining FDA alignment on creative regulatory strategies to bring these innovative products to market in the U.S. quickly and efficiently.

Helped Aidoc Medical, Ltd. to obtain 510(k) clearance for Briefcase—an AI based computer aided triage and notification software for analysis of non-enhanced head CT images.



Advising Novartis on IP aspects of its strategic artificial intelligence and data science collaboration with Microsoft as it founded the Novartis AI Innovation Lab.

Convened policymakers and stakeholders to discuss health care AI regulators and Medicare program representatives to discuss AI reimbursement and regulation.

Assisted CSD Labs in obtaining 510(k) clearance of eMurmur, an innovative, AI-based murmur detection software.

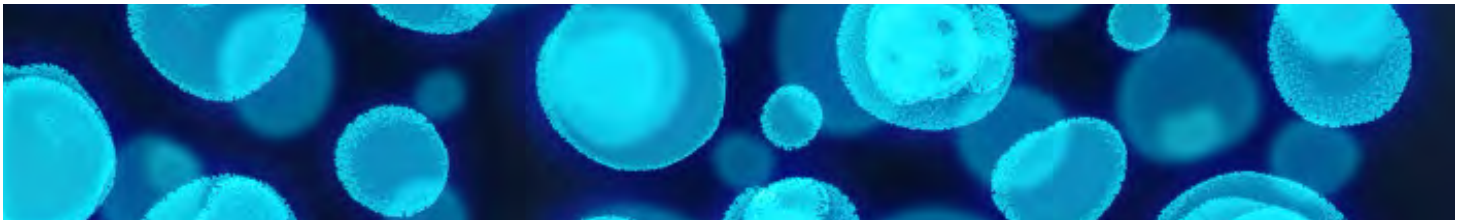
Counseled clients on advocacy and reimbursement strategy and interactions with reimbursement staff and leadership at the U.S. Department of Health & Human Services Centers for Medicare & Medicaid Services.

Assisted Digital Diagnostics to achieve De Novo reclassification from FDA for the groundbreaking AI-based device IDx-DR, the first device authorized for marketing that autonomously analyzes images of the retina for signs of diabetic retinopathy, detecting disease without the need for a clinician to also interpret the image or results.

Advised a leading Asia-Pacific headquartered technology company on the commercialization of its AI technologies through a collaboration with a robotics business.

Drafted formal comments and achieved regulatory wins related to healthcare AI in every major CMS payment rule, including the Medicare Physician Fee Schedule, the Inpatient Prospective Payment System, and the Outpatient Prospective Payment System.

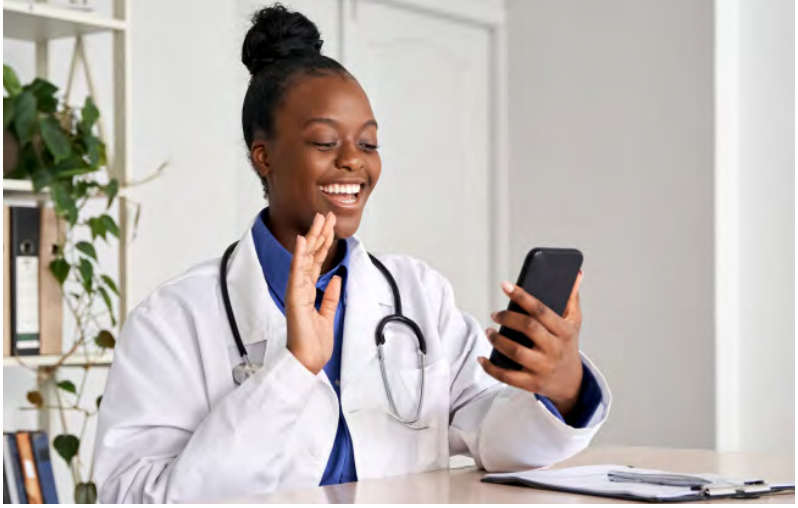
Developed an innovative strategy for interacting with FDA to allow our client Viz.ai to gain a quick De Novo clearance for a novel Computer-Aided Triage and Notification Platform to identify Large Vessel Occlusion (LVO) strokes in CTA imaging, meeting the company's tight deadlines.



Telehealth

Increasingly, health care services are conducted via telehealth technologies. Providers, third-party payers, and manufacturers of health technologies need to understand the complex legal issues that could arise when services are delivered through telehealth interactions, and how those services may be billed and paid for.

Hogan Lovells' comprehensive health regulatory practice advises health care providers, payers, manufacturers, and others in navigating the maze of legal schemes, and evolving coverage and reimbursement policies that may apply to telehealth devices and services. We advise clients on store-and-forward technologies, real-time telehealth interactions between patients and health care providers, and use of remote monitoring, each of which is subject to complex regulatory and reimbursement considerations. We counsel our clients in the U.S. and around the globe on the patchwork of national and state laws and regulatory schemes governing telehealth deployment, and telehealth reimbursement policies, as well as associated privacy and data use restrictions.



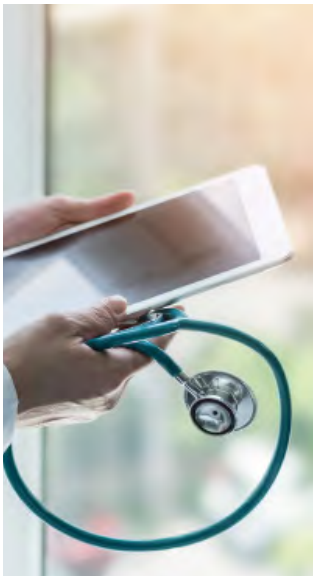
Additionally, we have experience incorporating these rules into agreements that may involve multiple jurisdictions and parties, and counseling clients on liability considerations. Many of our lawyers previously served as federal and state health care regulatory agency officials or as elected officials in Congress and legislatures. This means we intimately understand the policies and players involved in developing, implementing, and enforcing telehealth regulations, and can track and advocate for changes on your behalf.

Representative experience:

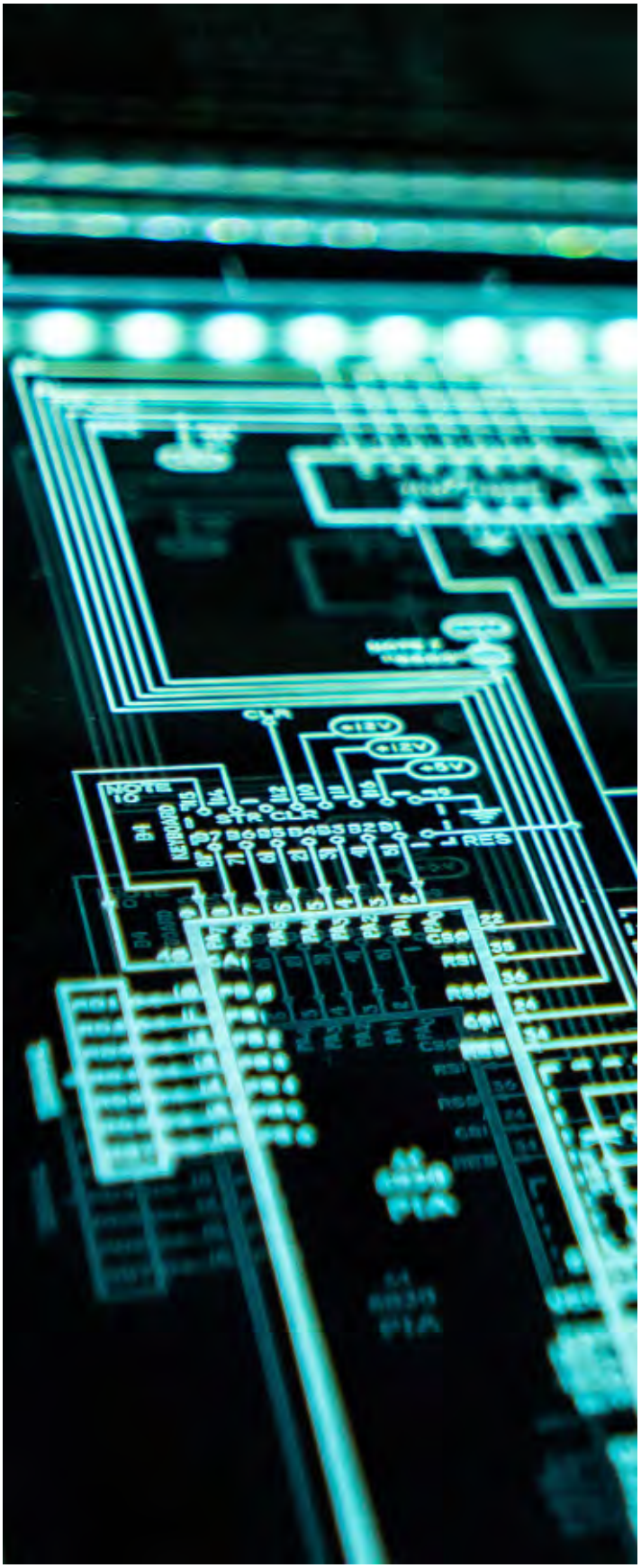
Advise on various regulatory aspects of international telemedicine, including cross-border health care, data privacy, and medical device questions.

Assist health systems, technology companies, and current telehealth providers with due diligence and review of regulatory compliance related to telehealth services provided by acquisition targets.

Counseled a large academic medical center regarding their telehealth platform expansion into new markets and advised on a partnership with a national telemedicine provider.



Advise on state laws and regulations, including COVID-related waivers governing licensure of telehealth practitioners, informed consent, privacy and IT, and fraud and abuse compliance and enforcement.



Advocated for statutory and regulatory modifications to allow more expansive coverage and reimbursement of telehealth services.

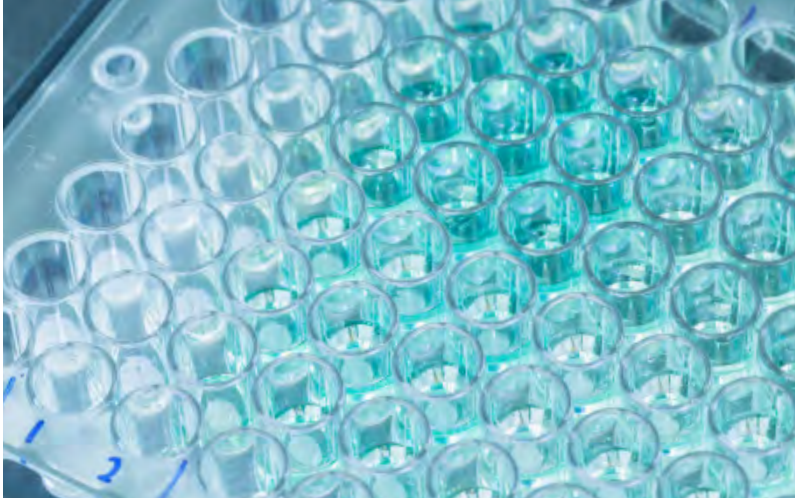
Track and interpret changes in state laws and Medicare and Medicaid coverage of telehealth services.

Helped a large technology company assess the legal issues associated with entering into a telehealth services venture and the options for structuring the business to reduce risks.

Product advisory and regulatory pathways

Innovating and bringing new digital health products and services to market requires addressing a host of issues: regulatory approval, patents, financing, manufacturing, distribution, and more. After your product debuts, the challenges continue throughout its lifecycle, from running compliance programs to responding to enforcement actions.

We routinely assist clients in getting their products tested and approved. Our firm stands out among major international law firms in combining its regulatory and commercial experience into one single, integrated team. We assist with clinical trial design and operations, early access programs, marketing approval, GMPs, importation, pharmacovigilance, and the many other regulatory issues that arise during product development. Integral to our regulatory practice is a deep understanding of all forms of regulatory exclusivity, as well as the intersection between regulatory exclusivity and patent protection.



We understand specialized strategies that can expedite the FDA approval and EU CE marking processes, streamline how much data is needed for approval to be granted, and successfully launch products to ensure continuing compliance. After approval, we work with you to commercialize products successfully, addressing issues related to: launch preparation, advertising and promotion, and compliance; managing regulatory inspections; coverage, reimbursement, and pricing; patient privacy; and careful use of intellectual property and regulatory exclusivities to manage product lifecycles.

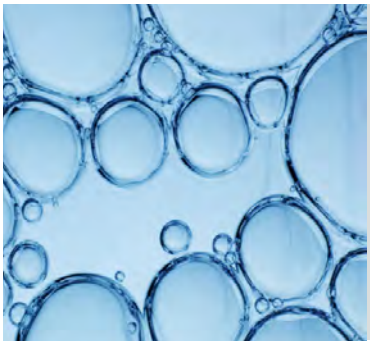
We also assist on postmarket issues relating to advertising and promotion, recalls, and adverse event reporting. This postmarket work extends to assisting companies that face FDA, DOJ, HHS, and state enforcement actions, which may include seizure, injunctions, civil penalties proceedings, and criminal prosecution. The firm's regulatory attorneys partner with our white collar and litigation teams to assist our clients in the most sensitive enforcement actions faced by the medical device industry.

Representative experience:

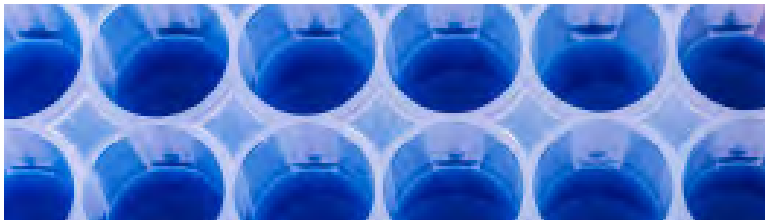
Advising a client on the development of a new digital health product consisting of a mobile app for the patient and web based apps for HCPs.

Counseling a major pharmaceutical company on the development and regulatory requirements for mobile applications and smart drug delivery tools to be used by patients.

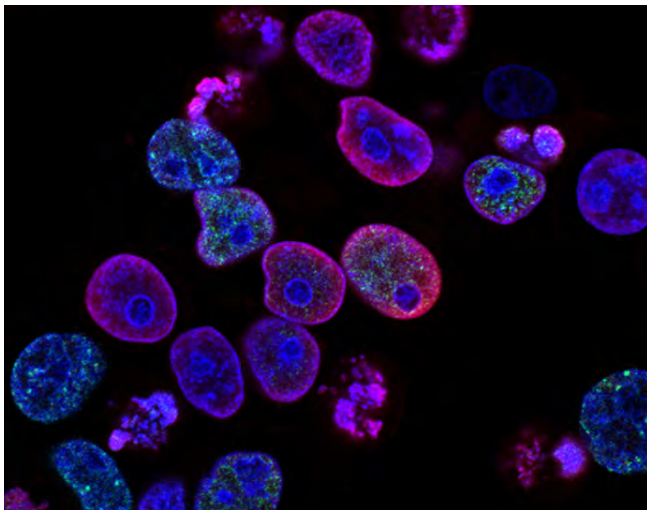
Advising Cisco Healthcare in rolling out its telemedicine products in China and related regulatory issues.



Obtained clearance for standalone software products in the imaging, anesthesia, and remote patient monitoring spaces.



Advised companies developing digital therapeutic tools on the regulatory pathway and associated clinical data needs.



Assisted a major Health IT company in conducting a complete regulatory assessment of all portfolio and pipeline products to determine which products may be subject to regulation and assisted with bringing products into compliance where needed.

Obtained clearance for a number of wearable sensors measuring various physiological signals.

Assisted a medical device manufacturer in the classification and CE marking of its new medical app and identifying a notified body for the conformity assessment procedure.

Data management and data protection

The massive amount of data collected by today's digital health products provides insight to the health care realities of the future. One of our clients' strengths is their ability to harness data in ways that provide meaningful value to patients. However, the collection and use of data triggers many legal risks.

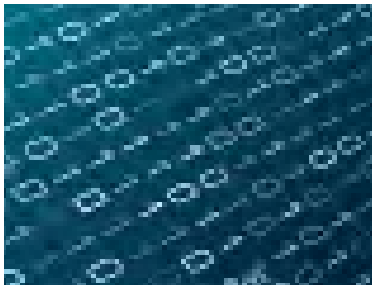
Our global health privacy and cybersecurity team advises health care organizations around the world on data protection and health privacy compliance issues. Whether it is responding to cyberattacks and data breaches; advising on transactional work; developing policies, procedures, and trainings; strengthening incident response protocols; or counseling on regulatory compliance, our team has a vast range of experience to share on health privacy and security issues.

We are a known “market-leading group of esteemed practitioners” with strong health privacy capabilities, including unparalleled knowledge of the Health Insurance Portability and Accountability Act (HIPAA) and EU General Data Protection Regulation (GDPR). We have a coordinated global approach that allows us to work seamlessly on major cross-border projects, even when local public health regulations create variations and specific issues.

We help to create solid and pragmatic global strategies. We are able to counsel our clients on industry practice and anticipated regulatory changes like no other firm due to our broad client base and deep involvement with policy makers in the development of new national and international legal standards for the protection of health privacy and cybersecurity. We have also managed the largest, most complex health care data breaches to-date and successfully represented clients in government investigations related to health care data breaches and compliance issues.

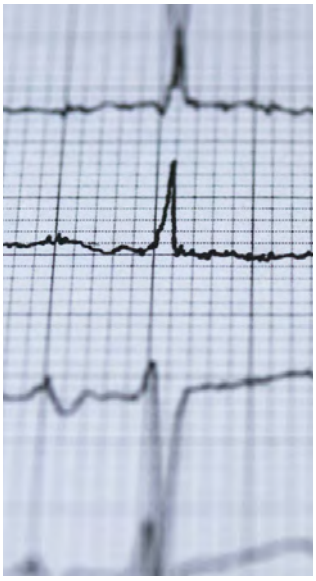
Representative experience:

Assist various clients with HIPAA, HITECH, and state privacy law compliance, including development of training and policies and procedures, as well business associate and HIPAA compliance structures.

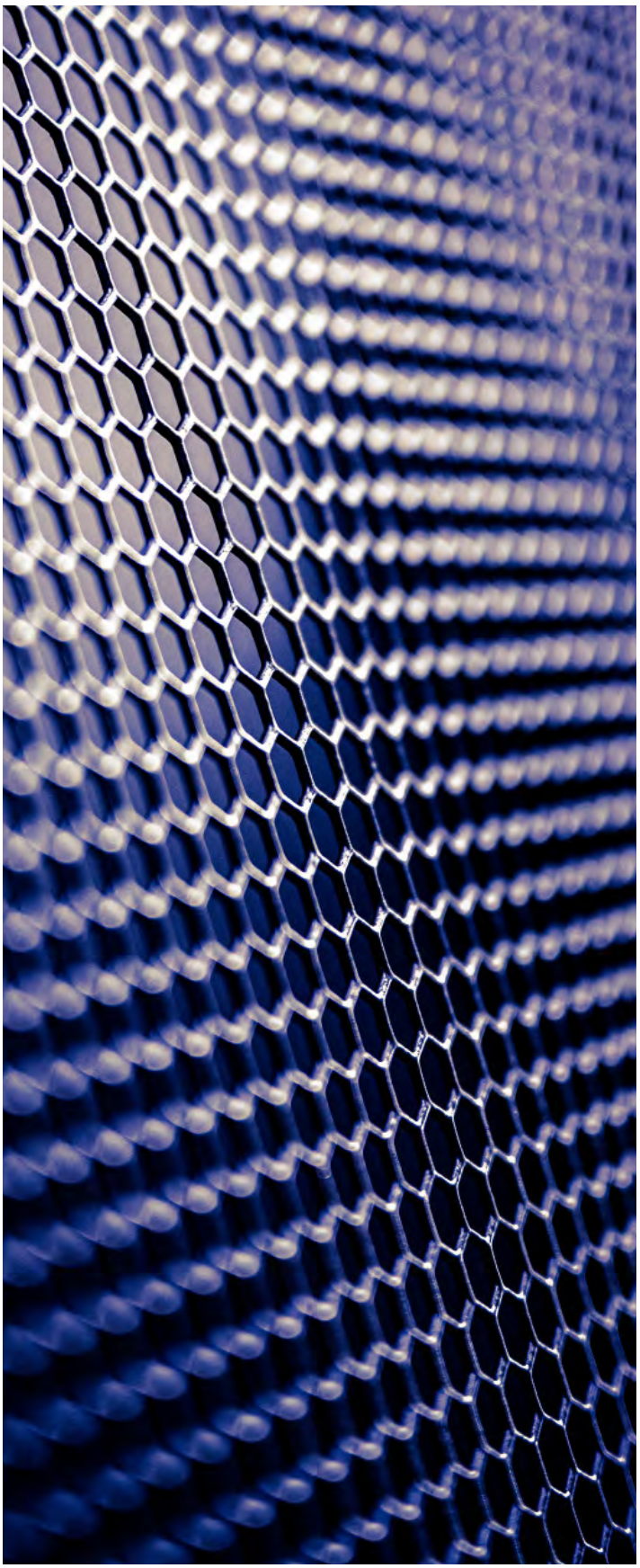


Advised Zimmer Biomet, a large medical device manufacturer, on connected health initiatives, GDPR readiness, HIPAA compliance, breach preparedness, incident response, investigations, and reporting.

Served as the outside privacy counsel to WebMD, the leading provider of personal health records and online health information, providing the full range of privacy counseling services, including compliance, investigations, and policies and procedures.



Providing privacy counseling services including, compliance, investigations, and policies and procedures to the leading provider of personal health records and online health information.



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

Advised a leading global technology company and a global health insurance provider on Asia-Pacific data protection and medical device regulation concerning their respective mobile apps.

Transactions

Health care transactions are complex in and of themselves, but especially challenging because they demand understanding of many regulatory issues and the economics of the changing health care marketplace. Our interdisciplinary team contains experts in each of these dimensions.

Our team has handled many of the most complex health system transactions, including those involving the most prestigious institutions. We have been at the forefront of dealmaking in the health care industry, negotiating mergers and acquisitions, joint operating agreements, leases, joint ventures, affiliations, restructurings, and health system reorganization and governance reforms.

When complex regulatory issues and challenges arise, we work with colleagues who are leaders in areas such as antitrust, anti-fraud and abuse compliance, reimbursement, tax, insurance regulation, labor/employment, and other issues. Our team takes an efficient, coordinated approach to help clients navigate through all these issues to complete strategically important deals.

Strategic alliances, licensing and collaborations

Our dedicated team of life sciences transactions lawyers understand the challenges and opportunities that strategic alliances and other partnering relationships present, and we work with you to structure collaborations that achieve your business goals.

We work extensively with pharmaceutical, bioscience, medical device, academic, and other research entities on licensing and collaboration transactions involving products at all stages of the product lifecycle. Our diversity of experience, deep industry knowledge, and understanding of the interplay of economic, governance, regulatory, and intellectual property issues give us unique perspective on each side of complex partnering transactions.

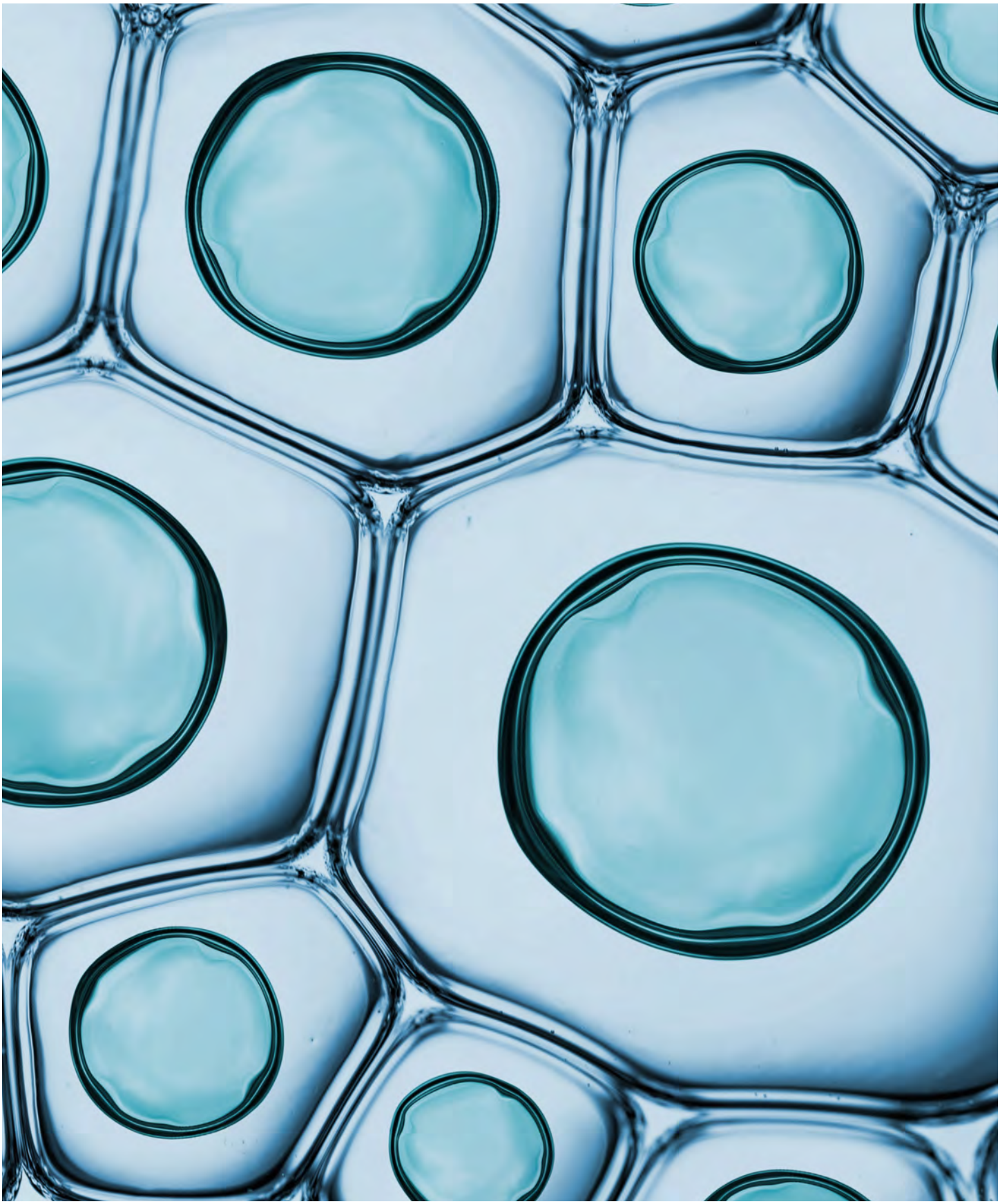
In a highly regulated industry such as life sciences, easy access to regulatory lawyers to advise on these arrangements is critical. We draw on the depth of our life sciences practice and work seamlessly with our regulatory experts to provide unparalleled transaction support.

Our lawyers recognize the central role that intellectual property plays in arrangements under which our clients join with others to develop and commercialize their inventions and discoveries, and we have significant experience protecting our clients' IP and handling the myriad ways in which IP assets can be allocated, licensed, and monetized to add value and reduce risk.

Representative experience:

Advised Novartis on multiple transactions, including its acquisition of Amblyotech, a U.S.-based software startup, pursuing the development of digital therapy for the treatment of amblyopia.

Advised Fresenius on its investment in AmbulNz, a national medical transportation company that uses digital technology to improve transportation times and quality care.



Commercialization

Some digital health technologies include software applications alone, while other interface with hardware or other systems. For this reason, commercialization for these technologies can encounter unique issues beyond the obvious challenge of driving market adoption.

For starters, Medicare has been slow to commit to modifications to the reimbursement infrastructure to allow for separate payment or other reimbursement adjustments that would encourage adoption of novel digital health products that the agency views as capital equipment. In fact, the agency has even been slow to implement adequate policies for digital therapeutics products that can fit nicely within existing payment schemes.

For example, there has long been a lack of clarity around whether and how software could be separately covered by Medicare.

Similarly, although payment policies have been implemented for certain digital health remote monitoring services, the agency has imposed significant restrictions that are likely to curtail widespread adoption.

Additionally, many of the digital health applications – especially digital therapeutics that have been approved by FDA as prescription products – require a health care provider to issue a prescription or order before a patient can access the product. Very often, companies will rely on partnerships with telehealth providers who can evaluate the patients, and if appropriate, issue a prescription for the product. The construct and the agreements between these parties requires careful consideration to avoid pitfalls with issues such as state regulation of telehealth, requirements for prescriptions provided via telehealth, the applicability of state pharmacy and medical device regulations, and the corporate practice of medicine.

Often, digital health technologies are incorporated into a prescription medical device, which are subject to complex and varied state licensing requirements that can attach to the activities of manufacturers and their distribution partners. Most state licensing paradigms were developed to handle prescription drugs and controlled substances and, consequently, are not always suitable for the distribution models used for prescription medical devices.

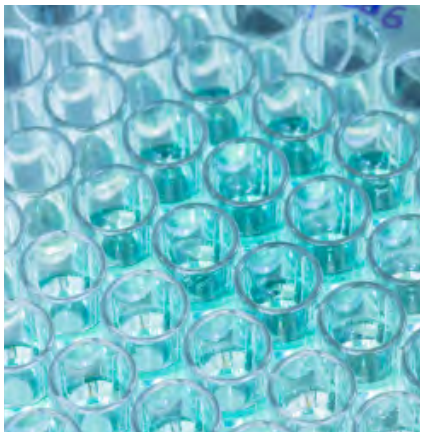
We regularly advise clients on navigating these complex challenges to bring their products to market.

Looking forward, changes to how manufacturers and distributors are licensed are coming that may affect medical devices as states revise their rules to meet the Drug Supply Chain Security Act (DSCSA) (Title II of the Drug Quality and Security Act), which was enacted to harmonize rules for drug distribution across the states by establishing standards. Because medical devices are largely regulated under states' drug licensing authorities, we expect the impacts of many of the drug distribution regulations to spill over to medical devices – including those incorporating digital health technologies — possibly resulting in higher standards or additional licensure requirements.

Because of the complexity of the licensing schemes, it is important for a digital health provider to be able to identify the right set of licensees that are required for the distribution model it has adopted for its products and also monitor the impact on medical devices. There may also be an opportunity as rules are reviewed to shape how the harmonized proposals are applied to digital health products. We understand these players and can advocate for you to ensure a smoother commercialization process.

Representative experience:

Assisted a digital therapeutic company with evaluation of the corporate ownership of a pharmacy to distribute a prescription digital therapeutic and also provided advice and guidance on the relationships with a third party telehealth provider to facilitate the issuance of some of the proscriptions for the product, including compliance in the areas of telehealth rules and fraud and abuse. Assisted the telehealth provider in identifying the necessary licensure for the current distribution model through an established mail order pharmacy as well as their future state distribution model through a wholly owned pharmacy.



Worked with the manufacturer of a Cognitive Behavioral Therapy Digital Therapeutic post FDA approval to assist them in developing their product launch strategy, secure state licensees, evaluate their telehealth provider relationship including state regulations related to whether they require synchronous telehealth interactions in order to prescribe, and assisted it in establishing their pharmacy provider relationship to dispense the digital therapeutic.

Clinical trials

Our leading specialists can advise on complying with applicable regulatory requirements and industry best practices across the board, from clinical contracting and Good Clinical Practice (GCP) to data protection compliance, and reimbursement advice. With our unmatched global resources and industry experience, we will assist you in designing protocols that reflect your marketing goals while adhering to industry and regulatory standards, developing practical strategies for execiution of the clinical trial, and negotiating the necessary agreements to enable you to quickly and smoothly initiate your clinical trials around the world. This includes negotiating clinical trial agreements, license agreements, and clinical research collaboration agreements with government bodies, industry partners, and academic institutions.

Our privacy and cybersecurity experts provide strategic advice on structuring clinical trials to comply with data protection requirements across the globe. We advise clinical trial sponsors, sites, and technology companies on privacy and security compliance, including development of mobile apps and other technologies for use in research studies, privacy policies, back-end security for app and research data bases, and incident preparedness and response. We also work with companies on data governance and uses of data in the research context and beyond.

Our FDA medical device and pharmaceutical experts leverage decades of institution knowledge to advise companies on how FDA regulations apply to their digital health solutions during clinical investigations and commercialization. Each intended use (e.g., stand-alone solution, companion tool, research only tool) comes with its own unique regulatory responsibilities and dictate how the digital product can be used during a clinical investigation and marketed. The FDA team uses their regulatory and scientific acumen to help companies position their digital health tools for effective integration into their business platform.

Our health care and reimbursement experts provide advice and assistance on structuring research budgets and interacting with physicians so that you can be confident in your compliance with U.S. Medicare fraud and abuse laws, equivalent requirements in EU Member States, international anti-corruption laws, and other applicable legal rules. In addition, our product liability practice provides practical advice in structuring clinical trials to avoid liability, including risk from clinical trial injury claims and litigation.

We are also here to support your business when difficult situations arise. Our global investigations practice and regulatory experts work closely with companies in urgent and high pressure situations. Drawing on our experience in a variety of complex investigations, we will guide you through internal investigations of all kinds, including those involving fraud, bribery, or corruption allegations that can arise from interacting with public officials in high-risk jurisdictions, as well as from potential data breaches or cyberattacks that may jeopardize clinical trial data and company assets.

Representative experience:

Work with numerous life sciences clients in preparation and negotiation of domestic and international multi-jurisdictional clinical trial agreements and other sponsored research agreements.

Regularly assist U.S. and foreign medical device companies with designing complex clinical studies, sequencing of clinical studies, negotiating protocol and statistical analysis plans with FDA, and persuasively presenting results to regulatory authorities.

Review informed consent forms for compliance with global data protection, human subjects rules, and broader regulatory requirements.

Advised multiple small medical device companies on the use of artificial intelligence in research studies.

Advised a major pharmaceutical company on use of digital tools for clinical trial recruitment and monitoring, including development of privacy policies, electronic consents, and data security.

“It is the best regulatory firm I have worked with and I would recommend them without hesitation.”

– Chambers Global

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