2022 EMERGING TECHNOLOGY TRENDS

MARKET AND LEGAL INSIGHTS FOR INNOVATORS



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Because they have different purposes, healthtech and medtech involve different forms of enabling technology.

SECTOR OVERVIEW

What Is the Difference Between Healthtech and Medtech?

The term "healthtech" refers to technology-enabled healthcare, or healthcare administration. The product or service is typically delivered outside of a hospital or a doctor's office, but hospital and practice management software is considered an exception.

Whereas healthtech focuses on operational improvements, the term "medtech" refers to medical technology improvements. By enabling the development of the latest medical devices and techniques, medtech improves the diagnosis and treatment of medical conditions.

Associated Sectors

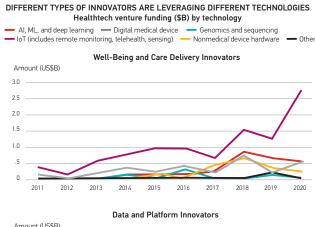
- Healthcare
- Telehealth
- Medical Device Manufacturing
- · Medical Research
- Pharmaceuticals
- Software Development

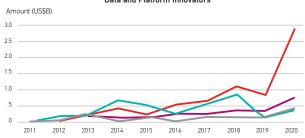
Technological improvements have implications for each vertical in the healthcare sector. Healthtech supports healthcare providers in running more efficient organizations and providing services in different ways. This has been especially important during the pandemic, as telehealth has become the preferred delivery option or, in some cases, the only option.

Medtech represents the cutting edge in medical research. As researchers and doctors find better ways to diagnose and treat medical conditions, their techniques are supported by specialized equipment.

Healthtech, Medtech Supported by Different Technologies

Because they have different purposes, healthtech and medtech involve different forms of enabling technology. As shown by the following charts, the Internet of Things (IoT) is the technology of choice for well-being and care delivery, whereas artificial intelligence (AI) and machine learning (ML) receive more investment from data and platform innovators. Investment in both subsectors rose substantially in 2020, reflecting the need for technology-enabled healthcare.





ENABLING SCIENCE AND TECHNOLOGY

Mobile and Digital Options Meet Increased Demand for Remote Care

Delivering healthcare through mobile and digital services offers several advantages—convenience, reduced costs, and, during the COVID-19 pandemic, personal safety. To meet increased demand, startups and incumbent providers and payers invested in their virtual health offerings. The Centers for Disease Control and Prevention (CDC) <u>identified</u> three different telehealth modalities: synchronous (or real-time) interaction, asynchronous interaction, and remote patient monitoring. Healthcare providers choose among a range of telehealth solutions, from specialized software to cloud

comfortable using at-home diagnostic tools, citing results from the Deloitte Center for Health Solutions' latest <u>consumer survey</u>. There are signs that deal activity is following this trend, as digital pathology and point-of-care testing companies received investor attention in the in-vitro diagnostics space in Q1 2021.

Another area to follow is Amazon's investment in at-home testing, as the company reportedly <u>plans</u> to launch a general diagnostics service. The move is part of a trend that began before the pandemic, namely when Apple Health and other companies <u>partnered</u> with direct-to-consumer health startups.

Paige announces Series C funding round of \$100M to accelerate transformation of digital pathology

JANUARY 14, 2001 | PAIGE

Ibex Medical Analytics Raises \$38M to accelerate adoption of Al-powered cancer diagnostics in pathology

MARCH 9, 2021 | IBEX

Truvian raises \$105M, plans to submit benchtop blood-testing tech to FDA

FEBRUARY 26, 2021 | TRUVIAN

Inflammatix nets \$102M to advance its immune system tests for infectious diseases

MARCH 16, 2021 | INFLAMMATIX

Source: State of Healthcare Q1'21 Report: Investment & Sector Trends to Watch (CB Insights)

solutions. Specialized solutions sometimes integrate several <u>functionalities</u>, such as video conferencing, store-and-forward data capabilities, and remote collecting/monitoring of patient medical data. Some clinics may also have a <u>patient portal</u>.

Diagnostics Improvements Achieved Through Digital Pathology and Point-of-Care Testing

Deloitte recently <u>predicted</u> that more diagnostic tools will be developed for home use, and that consumers will increasingly become accustomed to monitoring their health at home. They noted that between 30% and 50% of consumers are

The need for at-home testing and diagnostics plus consumers' willingness to use these services both increased during the pandemic. This led to growth in demand and investment, as observed above.

Care Coordination Software Helps Reduce Waste in US Healthcare System

As medical services are increasingly provided outside of the hospital setting, the number of physicians and care providers is on the rise, therefore increasing the need for coordination in the U.S. healthcare system. One <u>study</u> found that poor

ENABLING SCIENCE AND TECHNOLOGY (CONT'D)

communication among providers leads to \$78 billion in wasted healthcare spending annually. To solve this problem, the Centers for Medicare and Medicaid Services (CMS) enacted a Conditions of Participation rule that requires hospitals to inform primary care physicians and post-acute care providers when patients are admitted, discharged, or transferred from inpatient services or emergency rooms. To meet this need, a market has now emerged for care coordination software.

AI and ML Shorten the Research and Development Cycle for New Molecular Compounds

Al and ML are <u>leveraged</u> for medical research and development because of their powerful predictive and data analytics capabilities. The technology helps reduce the cost of launching new drugs by shortening the amount of time needed to develop new molecular compounds. It also helps determine a drug's side effects before the drug is released, reducing the

time needed for clinical trials. Carnegie Mellon University is improving R&D by integrating big data with an <u>ML algorithm</u> that can test and analyze various drugs. Partnerships are increasingly common between pharmaceutical companies and Al companies, as shown by recent deal activity.

3D Printing Technology Leveraged for Devices, Tissues

A growing number of medical devices and equipment components can be manufactured through additive technology. Examples <u>include</u> orthopedic and cranial implants, surgical instruments, dental restorations such as crowns, and external prosthetics. The technology can also be <u>used</u> to re-create tissues and organs, a process called "<u>bioprinting</u>." This is an area to follow for further research and investment, as well as government regulation.

Iktos announces collaboration with Pfizer in AI for drug design

MARCH 2, 2021 | IKTOS | PFIZER

Mila collaborates with Astrazeneca to maximize the potential of AI for drug discovery and development

FEBRUARY 26, 2021 | MILA | ASTRAZENECA

Cambridge Quantum to develop quantum algorithms with Roche for drug discovery and development

JANUARY 28, 2021 | CAMBRIDGE QUANTUM COMPUTING LIMITED | ROCHE

Valence Discovery announces multi-target AI-enabled drug design collaboration with Servier

MARCH 16, 2021 | VALENCE | DISCOVERY

Source: State of Healthcare Q1'21 Report: Investment & Sector Trends to Watch (CB Insights)

SECTOR AND INDUSTRY SIGNALS

Medtech Growth Prospects Are Closely Connected to Hospital Demand; Healthtech's Prospects Are More Diverse

The prospects of the medtech industry are directly tied to medical procedures—including <u>elective surgeries</u>. Accordingly, hospital demand is an important <u>indicator</u> within the industry.

Healthtech has a broader reach because it includes both technology-enabled healthcare and healthcare administration. Accordingly, this subsector encompasses more businesses' models. In fact, there are at least nine "value pools" within the healthcare industry that directly relate to healthtech or present further opportunities for innovation.

NINE HEALTHCARE VALUE POOLS ARE RIPE FOR TECHNOLOGICAL INNOVATION

Examples of innovations in nine value pools across five categories

RESEARCH AND DEVELOPMENT

Enhance drug R&D process

Artificial-intelligence and machinelearning drug discovery, siteless trials, protocol optimization, trial site operations, and patient engagement

SCREENING AND DIAGNOSIS

Intercept diseases through screening

Genomics and omics

3

FINANCE AND OPERATIONS

Optimize the financial model

Value-based care arrangements, population health management, benefits administration

5

PREVENTION

Improve wellness and prevent disease

Sleep-tracking, meditation and fitness, and disease-prevention tools

2

SCREENING AND DIAGNOSIS

Identify the right patient

Digital at-home diagnostics

Imaging diagnostics based on artificial intelligence and machine learning

FINANCE AND OPERATIONS

Increase operational efficiency

Back-office simplifiers (ePrescribe)

Nonclinical workflow support for providers

6

CARE DELIVERY

Provide more effective therapies

CDS, ¹1 adherence solutions, disease management, digital therapies,² EMR³ and claims data analysis, ePR0s⁴

7

CARE DELIVERY

Provide remote patient support

Telehealth, remote monitoring, digital information, digital communities, logistics and care navigation support

8

CARE DELIVERY

Supply therapies to patients

Rx onboarding, digital pharmacies, supply-chain solutions for medical supplies

9

Source: Rock Health; McKinsey analysis

¹ Clinical-decision support. ² For example, cognitive games and cognitive behavioral therapy. ³ Electronic medical records. ⁴ Electronic patient-reported outcomes.

SECTOR AND INDUSTRY SIGNALS (CONT'D)

This chart shows that digital technology can improve almost any aspect of the healthcare industry, from care delivery to finance and operations. Hence, demand indicators are much more varied than for medtech and medical equipment.

Direct Contracting Rules Could Accelerate the Adoption of Value-Based Care in US Market

CMS enacted direct contracting rules in 2021, incentivizing value-based care by linking earnings and losses to the quality of care and patient outcomes. Value-based care has implications for healthtech, because providers can leverage technology to rein in costs. With better data and predictive modeling, physicians can intervene proactively and improve patients' health, thereby keeping costs low and improving their practices' profitability under the new direct contracting rules. Some startups now specialize in developing infrastructure for value-based care and risk-based models, creating a growing area in venture capital (VC) as investors respond to a market opportunity created by the new regulatory environment. Patient engagement portals and dashboards, combined with remote patient monitoring, can also help physicians engage with patients at a lower cost.

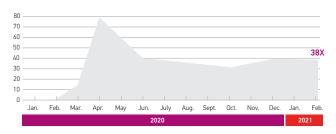
Government Makes Telehealth Billing Rules Permanent, as Utilization Stabilizes

In the first months of the pandemic, CMS enacted temporary rules on telehealth coverage. Some of the coverage provided by those rules was made <u>permanent</u> in January 2021, thus strengthening a new market opportunity even though the rules received pushback from medical groups due to lower reimbursement rates. Consumers view telehealth favorably, as utilization <u>stabilized</u> at 38 times the pre-pandemic levels.

Reflecting telehealth's popularity and a favorable regulatory environment, VC investment in the subsector increased threefold from 2017 levels and nearly doubled from 2019 to 2020.

GROWTH IN TELEHEALTH USAGE PEAKED DURING APRIL 2020 BUT HAS SINCE STABILIZED

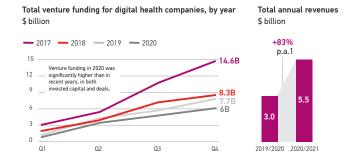
Telehealth Claims Volumes, Compared to Pre-COVID-19 (February 2020 = 1)1



1 Includes cardiology, dental/oral, dermatology, endocrinology, ENT medicine, gastroenterology, general medicine, general surgery, gynecology, hematology, infectious diseases, neonatal, nephrology, neurological medicine, neurosurgery, oncology, orthopedic surgery, poisoning/drug tox./comp. of TX, psychiatry, pulmonary medicine, rheumatology, substance use disorder treatment, urology. Also includes only evaluation and management visits; excludes emergency department, hospital inpatient, and physiatry inpatient claims; excludes certain low-volume specialties.

Source: Compile database; McKinsey analysis

INVESTMENT IN DIGITAL HEALTH AND THE REVENUES OF TELEHEALTH PLAYERS ALMOST DOUBLED COMPARED TO 2019



¹p.a., per annum

Source: Adriana Krasniansky et al. "H1 2021 Digital Health Funding: Another Blockbuster Year...In Six Months," Rock Health, July 2021, rockhealth.com; McKinsey virtual health vendor database

SECTOR AND INDUSTRY SIGNALS (CONT'D)

Industry Executives Point to Recovery in Equipment Spending

Medical equipment manufacturer Medtronic's CEO <u>explained</u>, during a February 2021 earnings call, that the company's earnings are directly tied to procedures. Thus, when elective procedures were down during the pandemic, demand for

medical equipment also dropped. With pandemic recovery underway, elective procedures are up again and Medtronic's CEO expressed optimism about demand in the coming months. The CEOs of Johnson & Johnson and Stryker have expressed similar confidence about upcoming demand for medical equipment.

INDUSTRY EXECS POINTED TO EARLY SIGNS OF RECOVERY

MEDTRONIC

equipment is tied directly to procedures. So, it's telling that hospitals are prioritizing spending on this type of equipment...It is, in our mind, a signal to a step back [up] in patient volumes that we expect over the coming months.

And that's consistent with conversations we've had with hospital CEOs [recently]."

GEOFF MARTHA, CEO

Earnings Call (2/23/2021)

JOHNSON & JOHNSON

We remain very confident in the longterm prospects around the medical device market. We would expect to see continued impact certainly in Q1'21, although [based on] the early signs, we're encouraged by what we're seeing...We would expect to see expansion over the course of 2021, and beyond that, see a return to a market... growing in the midsingle-digits."

ALEX GORSKY, CEO

Earnings Call (1/26/2021)

STRYKER

44 On the large capital front, we're actually very excited. From an order book standpoint, it's continuing to be very strong...

We have enough confidence now with the hospitals being ready to do these procedures as soon as the pandemic starts to subside...They will turn on [capital investment] pretty quickly, and they'll be pretty agile, and that's why we feel pretty confident of being able to give a healthy guide."

KEVIN LOBO, CEO

Earnings Call (1/28/2021)

Source: State of Healthcare Q1'21 Report: Investment & Sector Trends to Watch (CB Insights)

IMPACT

Economic

Some healthtechs specialize in helping healthcare providers and payers run leaner, more efficient organizations. Care coordination software, for example, ensures that physicians receive patient information when they need it. Likewise, data analytics help physicians identify and solve problems before they turn into chronic conditions. Finding efficiencies in healthcare systems represents a significant commercial opportunity and frees up public resources to improve the quality of care. Globally, there appears to be a gap between healthcare spending, at \$8 trillion, and the healthcare industry's market capitalization. This gap is expected to narrow, as investors increasingly want to participate in the health market and there are dozens of unicorns from which to choose.

Social

Technology can simplify healthcare administration and free up resources for frontline care. This is particularly important in the United States, which suffers from an ongoing <u>shortage</u> of nurses. Nurses' wages increased only <u>modestly</u> in 2020, and many nurses are thinking of leaving the occupation altogether.

Environmental

Medical waste continues to be a global problem, for many reasons. Some medical equipment is used only once and then discarded, even if it could potentially be <u>sterilized and reused</u>. In other situations, the equipment may not be recyclable or biodegradable. Even medications do not necessarily break down, representing a <u>challenge</u> for wastewater treatment facilities. Industry and nonprofit stakeholders are working toward more <u>sustainable solutions</u>, which include <u>recyclable and biodegradable</u> equipment. Around eight years ago, the International Joint Commission <u>found</u> that only half of drugs were removed by sewage treatment, and more efforts are still <u>needed</u> today to clean up public waterways.

Policy

Care coordination software and other health technologies support value-based care by improving the efficiency of the healthcare system and promoting the exchange of patient information. A more efficient system furthers the dual goals of improved patient care and reduced healthcare spending. Governments might therefore continue to enact rules that



AS MEDICAL SERVICES ARE INCREASINGLY PROVIDED OUTSIDE OF THE HOSPITAL SETTING, THE NUMBER OF PHYSICIANS AND CARE PROVIDERS IS ON THE RISE, THEREFORE INCREASING THE NEED FOR COORDINATION IN THE U.S. HEALTHCARE SYSTEM.

This is a global problem, as 90% of nursing associations recently <u>told</u> the International Council of Nurses they're concerned about heavy workloads, insufficient resources, and pandemic-related burnout. An improvement in employment conditions for nurses in the United States may help solve the retention issue and improve the quality of care.

favor value-based care; this is an area to follow in the U.S. market in particular.

LEGAL IMPLICATIONS

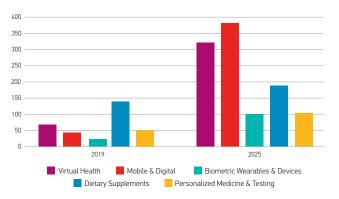
Healthtechs are receiving a growing share of VC investment, particularly if they specialize in virtual, mobile, or digital health. As technology becomes more powerful, questions are being raised related to Al's ability to provide medical "advice," and regulators are following the area closely. On a parallel track, companies are said to have an increasingly "collaborative" mindset, which spurs M&A and other forms of partnership but also raises potential antitrust implications.

OUTLOOK

Transactions and Financing | VC Investors Drawn to Healthtech

The investment outlook for the health and wellness technology market is strong, particularly in mobile and digital services, and virtual health.

RETAIL HEALTH & WELLNESS TECH MARKET SIZE ESTIMATE (\$B) BY SEGMENT



* As of March 31, 2021 Source: PitchBook, Geography Global

Overall, VC funding in healthtech almost <u>doubled</u> in 2020 compared to 2019. Companies focused on well-being and care delivery received around \$6.4 billion in funding, closely followed by data and platform innovation at \$6.1 billion. As the healthtech sector grows and receives more investment, IPOs and M&A become more likely.

M&A | Dealmaking Expected to Resume as Restrictions Lift

Globally, healthcare deal values <u>declined</u> 37% in 2020, to \$338.6 billion. Deal volume also dropped by 9% to 2,845 deals. There are some bright spots in the data, however. Biopharma was the most active sector, accounting for 67% of total deal value.

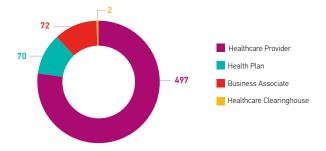
As for medtech companies, dealmaking slowed during the pandemic, partly due to restrictions on elective surgeries. Currently, restrictions are being lifted in many jurisdictions, which brightens the prospects—and M&A potential—of medtech companies. As mentioned above, industry executives have observed signs of recovery.

As for healthtech companies, they are said to be <u>shifting</u> from a competitive to a collaborative mindset. Companies can access complementary capabilities and realize efficiencies through joint ventures and other forms of partnership. This is a trend to watch for, potentially leading to more consolidation among healthtechs.

Litigation | Data Breaches Increasingly Target Healthcare Providers

Healthcare data breaches experienced a 25% year-over-year increase in the United States, based on government <u>data</u>. The data further shows that 2019 was itself a record-breaking year. This makes it more likely that class actions will be filed against healthcare providers, plans, and other stakeholders handling patient data. Healthcare providers are at greatest risk of being affected by data breaches.

2020 HEALTHCARE DATA BREACHES BY ENTITY TYPE



Source: HIPAA Journal, 2021

LEGAL IMPLICATIONS (CONT'D)

Due to the national public health emergency, however, the government has provided some relief from enforcement of the Health Insurance Portability and Accountability Act (HIPAA). In a March 2020 <u>notice</u>, the Office for Civil Rights (OCR) at the U.S. Department of Health and Human Services (HHS) said it would "exercise its enforcement discretion and will not impose penalties for noncompliance with the regulatory requirements under the HIPAA Rules against covered healthcare providers in connection with the good faith provision of telehealth during the COVID-19 nationwide public health emergency." Several other notifications of enforcement discretion were <u>issued</u> in later months

Data Privacy | HHS Enacts Healthcare Interoperability Rules

Two HHS rules recently took effect, clarifying which activities constitute information blocking and granting patients more access to their health data. Information blocking is any activity that interferes with the access to and exchange of electronic health information, whether by providers, health information technology developers, or health information networks. The information blocking rule aims to discourage the practice, while the patient access rule provides patients with unprecedented access to their medical information.

LITIGATION DEVELOPMENTS

Questions Raised About Algorithms' Ability to Provide Medical 'Advice'

Global reinsurer Swiss Re issued a <u>warning</u> on the litigation risk posed by health apps and wearables. The company notes that "faulty data or algorithm-bias can lead to inadequate health advice, resulting in bodily injury and single large-losses in casualty." If this happens, the fault or bias could affect multiple users, thus increasing morbidity or mortality and triggering liability coverage. Such an event would also pose reputational and investment risks for the companies involved, as well as their insurers.

Health Als Face Growing Regulatory Scrutiny

Two high-profile enforcement cases show that healthcare Als in the United States are coming under increased regulatory scrutiny. The first case involves "Project Nightingale," a partnership between Google and Ascension that provided Google with access to the medical records of 50 million patients. After the story broke through a whistleblower, HHS launched an investigation and prompted scrutiny from lawmakers. Some advocates also called for legislative reform.

Al and ML are increasingly leveraged for medical research and development because of their powerful predictive and data analytics capabilities.

The rule changes represent an <u>opportunity</u> for electronic health record (EHR) vendors, namely to provide mobile applications that facilitate the exchange of health information. The rules are also part of a broader international trend toward healthcare interoperability, a market that is expected to be worth around \$7.96 billion by 2024. Despite this opportunity, most providers and health plan executives are said to view the interoperability rules from a <u>compliance angle</u>, instead of a business opportunity angle.

In a separate proceeding, New York's Department of Financial Services and Department of Health are investigating whether Optum's ImpactPro algorithm discriminates against Black patients in violation of New York law. The investigation followed a <u>study</u> published in the journal *Science*, which suggested the algorithm prioritized care of white patients over Black patients through a "risk score" that was based on historical healthcare spending. Because Black patients often

LEGAL IMPLICATIONS (CONT'D)

spend less on healthcare, the algorithm concluded they were healthier than white patients with identical health conditions. Optum committed to correcting the software, but these events highlight the risks of incorporating bias into health Als.

Drug Payment Assistance Programs Before Federal Court

The U.S. Department of Justice (DOJ) alleges that Regeneron Pharmaceuticals used a patient assistance foundation to fund co-payments on its expensive macular degeneration drug Eylea. Drug companies are prohibited from subsidizing co-pays for Medicare patients. The proceeding is ongoing. Once resolved, it might have implications for the healthtech and medtech sectors, by clarifying or confirming the rules applicable to co-payments.

In the U.S. context, patent monopolies are at the center of an ongoing controversy, particularly in the pharmaceuticals industry where such monopolies typically <u>result</u> in higher drug prices. The U.S. government recently <u>supported</u> waiving IP rights on COVID-19 vaccines, in a move welcomed by developing countries that have struggled with vaccine access. President Biden also issued <u>remarks</u> at the signing of an executive order promoting competition in the U.S. economy through tougher enforcement of antitrust laws. This new stance could have implications for the enforcement of IP protections in the health sector.

PATENT TRENDS AND OUTLOOK

'Patent Monopolies' at Heart of US Drug-Pricing Debate

As <u>noted</u> by the World Intellectual Property Organization (WIPO), IP law incorporates a complex balance between global health, access to medical technologies, and a supportive environment for research and development.

A GROWING NUMBER OF MEDICAL DEVICES AND EQUIPMENT COMPONENTS CAN BE MANUFACTURED THROUGH ADDITIVE TECHNOLOGY.

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ABOUT US

Technology Transactions & Privacy | Healthtech & Medtech

Healthtech and medtech innovations are accelerating at a blistering pace. Our attorneys have significant experience structuring strategic alliances, collaborations, joint ventures, licenses, and research, development, manufacturing, and distribution relationships, often using novel approaches and pioneering methods that further the business objectives of healthcare and life sciences companies. We guide clients engaged in traditional and innovative healthcare businesses through complicated regulatory frameworks, including clinical research regulated by the Food and Drug Administration, Office for Human Research Protections, National Institutes of Health, and Office of Research Integrity, as well as clinical development, post-approval marketing compliance, telehealth/telemedicine and multistate provider licensing compliance, Stark Law and Anti-Kickback Statute compliance, Federal Trade Commission and Centers for Medicare & Medicaid Services regulations regarding clinical integration, and federal research grant management compliance.

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