THE COMING AGE FOR DIGITAL HEALTH
IMPLICATIONS FOR THE LIFE SCIENCES INDUSTRY

By Maya Khurana and Filiz Yucebay

With increasing pressures to contain costs, expand access to care and improve patient experience, healthcare systems are adopting digital technology at an accelerated rate. This has been further accelerated by the COVID-19 pandemic.

The traditional model for healthcare delivery involves patients visiting a physical office or facility to meet face-to-face with their physician or provider. The last decade has seen these exchanges fail to live up to shifting consumer demands for increased access and convenience. Digital health has the potential to help healthcare providers realize a number of benefits, including:

- Reduced inefficiencies
- Improved access
- Reduced costs
- Increased quality
- Enhanced personalization for patients

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What is digital health?

Broadly speaking, digital health is defined as using technology to improve patients' health (directly or indirectly) by advancing systems and processes within which care is delivered.

There are two digital health solution archetypes:

- **Product-based solutions** enhance the efficacy of a drug to improve patient adherence.

- **Service-based solutions** help with overall patient and care management, usually requiring coordination between different stakeholders.

Health systems, payors and the pharmaceutical industry all want to control healthcare costs while simultaneously improving quality of care, but the current model is limited. At the same time, technology disrupters are fueling innovation and changing the game for providers by empowering patients to take control of their own healthcare.

Today, there are more than 300,000 healthcare-focused applications (with upward of 200 added every day) and 340 wearable devices on the market. Yet wide-scale adoption is still nascent. The top 41 apps (across all categories) each have over 10 million installs, while 85% of healthcare apps have acquired no more than 5,000 downloads. Experts estimate that the consistent use of these apps across just five therapeutic areas (diabetes prevention, diabetes, asthma, cardiac rehabilitation and pulmonary

rehabilitation) could save the United States $7 billion and the United Kingdom $227 million (170 million pounds) annually. Extrapolate that across all disease groups, and that number jumps to $46 billion in the U.S. or $2.67 billion (2 billion pounds) in the U.K.

300,000+

Number of healthcare applications currently on the market

85%
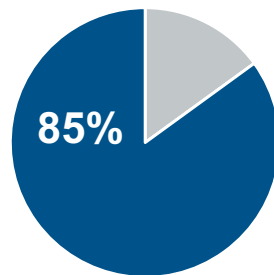
Percentage of healthcare apps that have fewer than 5,000 downloads

Consistent use of healthcare apps in just five patient populations could save
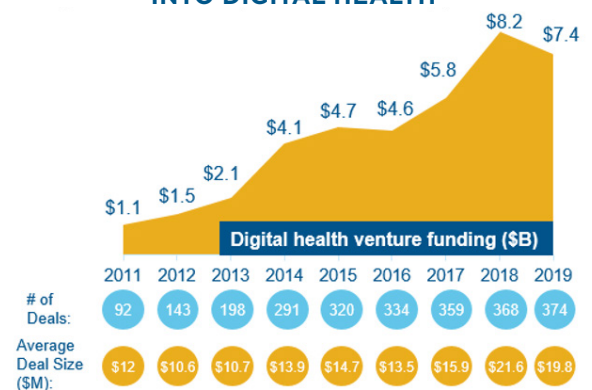
$7 BILLION (U.S.)

170 MILLION POUNDS (U.K.)

Other trends that have led to the prevalence of digital health solutions include the following.

- **Healthcare system stakeholder needs are shifting.** Providers and patients realize drug treatment is not enough. Patients also need personalized education, adherence and disease monitoring tools, lifestyle changes, financial

and emotional support, etc. At the same time, patients are taking more ownership of their health by taking advantage of increased access to information and new tools (e.g., apps, devices). Payors and healthcare systems are struggling to control rising costs as resources remain strained, resulting in a greater focus on outcomes-based care. These trends are accelerating the need to innovate delivery to keep patients out of the hospital by managing their care at home.

VENTURE CAPITAL INVESTMENT INTO DIGITAL HEALTH

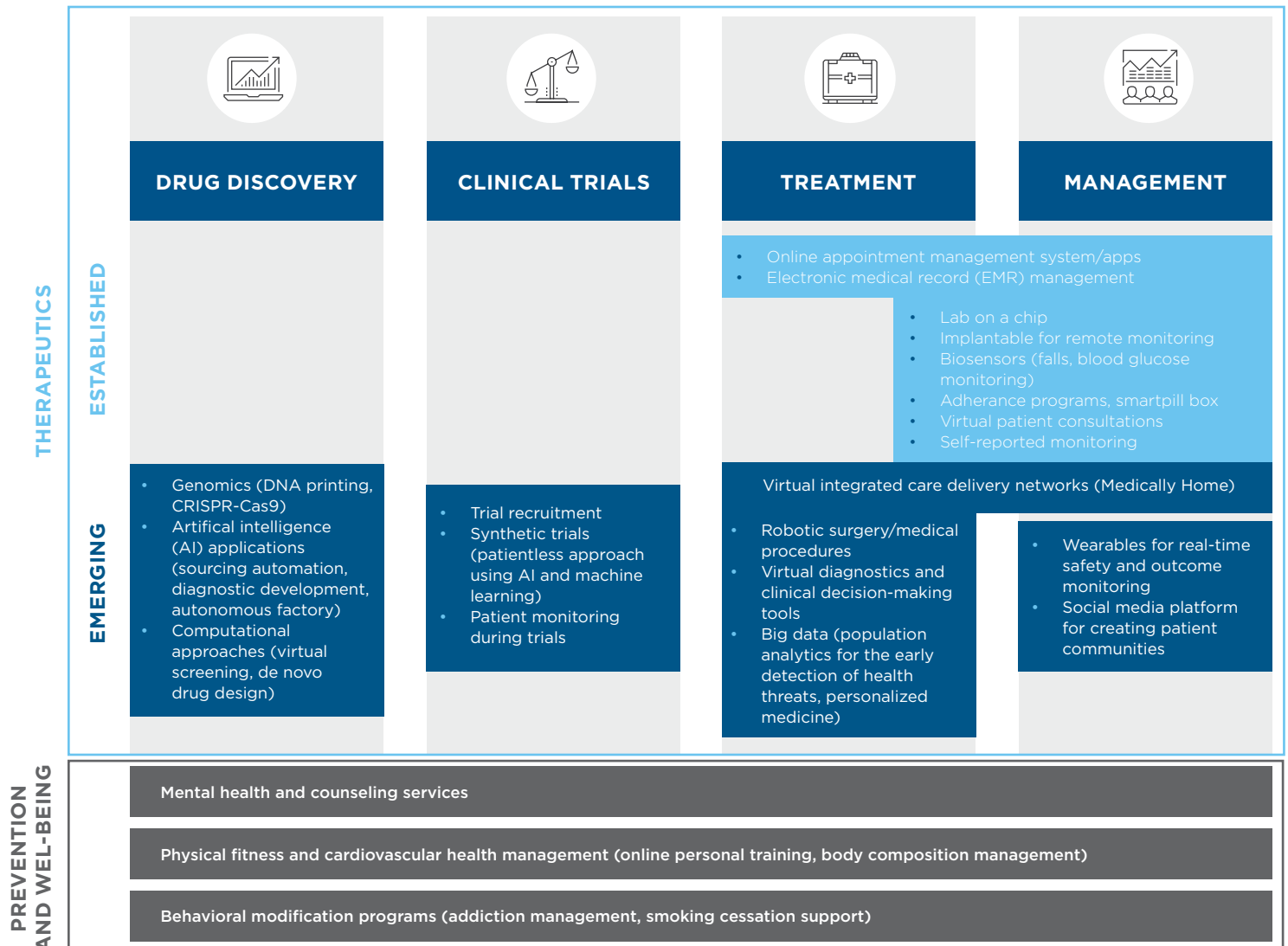|	2011	2012	2013	2014	2015	2016	2017	2018	2019
Digital health venture funding ($B)	$1.1	$1.5	$2.1	$4.1	$4.7	$4.6	$5.8	$8.2	$7.4
# of Deals:	92	143	198	291	320	334	359	368	374
Average Deal Size ($M):	$12	$10.6	$10.7	$13.9	$14.7	$13.5	$15.9	$21.6	$19.8

- **Regulators and payors are enabling faster adoption of digital health.** Key enablers include:

  - New regulatory structures.
  - The 21st Century Cures Act.
  - The Food and Drug Administration's (FDA's) software pre-certification process.
  - Three new Centers for Medicare & Medicaid Services (CMS) current procedural terminology (CPT) codes for remote patient monitoring.
  - Shifts toward outcomes-based pricing and pay for performance.
  - The United Kingdom's National Health Service inclusion of "digitally-enabled care" as one of the pillars of its long-term plan (2019).

- **Technology is being developed and adopted at an accelerated pace.** Startups are entering the market and disrupting the status quo via agile new solutions that provide enhanced

data tracking and user experience capabilities. To that end, there continues to be steady venture capital investment into digital health technology. In 2019, $7.4 billion was invested as funding followed a record-breaking year in 2018 at $8.2 billion.

Applications of Digital Health

There are many digital health applications along the value chain, with clinical trials, treatment delivery and patient management being three of the most critical to innovate and improve.

THERAPEUTICS

	DRUG DISCOVERY	**CLINICAL TRIALS**	**TREATMENT**	**MANAGEMENT**
ESTABLISHED			• Online appointment management system/apps • Electronic medical record (EMR) management • Lab on a chip • Implantable for remote monitoring • Biosensors (falls, blood glucose monitoring) • Adherance programs, smartpill box • Virtual patient consultations • Self-reported monitoring	
EMERGING	• Genomics (DNA printing, CRISPR-Cas9) • Artifical intelligence (AI) applications (sourcing automation, diagnostic development, autonomous factory) • Computational approaches (virtual screening, de novo drug design)	• Trial recruitment • Synthetic trials (patientless approach using AI and machine learning) • Patient monitoring during trials	Virtual integrated care delivery networks (Medically Home) • Robotic surgery/medical procedures • Virtual diagnostics and clinical decision-making tools • Big data (population analytics for the early detection of health threats, personalized medicine)	• Wearables for real-time safety and outcome monitoring • Social media platform for creating patient communities

PREVENTION AND WEL-BEING

Mental health and counseling services

Physical fitness and cardiovascular health management (online personal training, body composition management)

Behavioral modification programs (addiction management, smoking cessation support)

Clinical Trials

With the development of novel, innovative cell and gene therapies (CGTs), clinical trial design and execution has become increasingly complex. This poses a number of new challenges for the pharmaceutical industry, research and development teams, trial sites, and vendors. Digital technology can play a role in alleviating these concerns, but organizations must go beyond simply digitizing existing processes. They must also think critically to redesign and update the entire experience with the patient in mind and using digital technology as a driver.

The widespread use of digital technology in clinical trials can help to solve common challenges — patient recruitment, compliance and data management, and difficulty translating outcomes into the real world — while encouraging innovation and managing patient expectations.

- **Patient recruitment:** Clinical trials often struggle to recruit patients, particularly for rare diseases. Digital technology can speed up and improve patient access to relevant trials. Mobile apps and telemedicine services can be used to remotely enroll patients and expand the geographical footprint of studies. This technology can also be used to identify more eligible patients for trial recruitment by leveraging data collected as part of routine care, in electronic health records (EHRs) or insurance claims.

- **Compliance and data management:** Clinical trials rely on protocol compliance from many sites, partners, vendors, patients, providers, etc. This requires using different tracking systems to validate the data is collected and captured correctly. Using mobile apps, wearable devices and/or in-home sensor technology, providers can enable remote, continuous collection of data. In real time, they can confirm compliance, monitor patient adherence and mitigate adverse events, thus improving data quality and reporting. To further enhance efficiencies, clinical trials should consider using other emerging technologies such as artificial intelligence (AI) to collect and analyze data.

- **Trial setting not reflective of the real-world experience:** For clinical trials to be effective, the trial should mimic patients' daily life and therapies should be representative of the individuals who will use them. Alignment between clinical trial findings and real-world outcomes will become increasingly important to assess the value of highly specialized, expensive therapies such as CGT. Using the right combination of digital health technology, pragmatic clinical trials can enable two-way, real-time communication between researchers and patients to ensure the evidence collected

aligns with real-world experiences. This promotes continuity of care from clinical trial into a post-launch real-world setting. The digital technology utilized will need to be engaging and easy to use to ensure continued use even after the trial has concluded.

Treatment Delivery and Patient Management

A small percentage of patients with the most severe chronic conditions accrue a disproportionate share of healthcare expenditures (75% in North America). Sixty percent of U.S. adults have at least one chronic illness, and 40% have two or more. The treatment of these individuals accounts for $3.3 trillion in healthcare costs every year.

At the same time, the healthcare industry is moving to adopt outcomes-based payment models that reward providers for improved patient outcomes. New technologies are smoothing the path by making patient data collection and monitoring easier than it's ever been.

One example of a successful digital health intervention is Omada's digital behavioral counseling application, which can be used for the management of obesity and related chronic conditions. The app was shown to be effective in patients with pre-diabetes and those at risk for cardiovascular diseases, and a 2016 Centers for Disease Control and Prevention (CDC) study found that, on average, participants enrolled in the program lost more than 5% of their body weight.

There are three primary classifications of digital therapeutics that can improve clinical outcomes and reduce costs associated with traditional care delivery models — mobile apps, remote monitoring devices and telehealth.

MOBILE APPS

- Helps patients improve their conditions through self-management
- Available for all types of patients
- Low barriers for tech companies to produce and release
- Subscription-based models
- Allows for self-collection and management of data
- Example: Happify, a digital therapeutics platform for behavioral health

REMOTE MONITORING DEVICES

- Generates insights into patients' disease management
- Targeted to patients with moderate to severe disease conditions
- Medium barrier for tech companies to produce and release
- Subscription-based models
- Facilitates real-time reporting of outcomes and promotes adherence
- Example: One Drop, a glucose meter that monitors diabetes management

TELEHEALTH AND HOME CARE

- Provides expert guidance and clinical interventions from providers
- Targeted to patients with severe disease conditions
- Very few players in the market
- Subscription-based and population health models
- Increases patient access to providers for close management and promotes patient engagement in their own care
- Examples: Medically Home, Babylon

MEDICALLY HOME: A Case Study in Effective Treatment Delivery for High-Acuity Patients

Several factors are shifting patient care and treatment delivery away from hospitals. Emerging technologies have made it easier and safer for providers to interact with patients and collect biometric data remotely. Healthcare systems have become increasingly decentralized to reduce facility-based overhead and improve patient access challenges. Payors are driving an increased focus on outcomes-based care. And patients, especially in light of the COVID-19 pandemic, have an increased fear of hospitals.

The response to these trends has been to innovate care delivery for the home setting. One of the leading innovators in this space is Medically Home. Their model focuses on enabling health systems to build virtual hospitals to deliver high-acuity hospital level care in the home. Through the model that leverages a telemedical command center paired with a suite of in-home services across 18 different categories (e.g., paramedic, infusion nursing, mobile imaging), Medically Home estimates that 20% of current inpatient episodes could qualify to receive this type of acute care at home.

Medically Home's physician-led and nurse-powered model is enabled by a state-of-the-art technology platform, Cesia® Continuum, which allows the care team to manage patients virtually through an integrated medical command center that operates around the clock and ensures patients and families can connect with providers on demand at the push of a button. It supports the complex logistics of decentralized hospital care with real-time decision support to guide order fulfillment and scheduling for in-home services and back-end insights into the utilization and quality of services performed.

From an operations perspective, this model is also innovating the traditional supply chain. With a centralized, coordinated mobile network built on the key elements of a hospital, Medically Home enables quick, seamless delivery of patient care services, ensuring patients and providers get the tools and equipment they need when they need them.

Prior to the outbreak of COVID-19, at-home care delivery models struggled to prove to payors that these innovative methods would work. As positive outcomes data rolled in and Medically Home showed cost savings of 15% to 20%, payors began to change their thinking. Now, in the midst of an unprecedented global pandemic, the same payors recognize and value the opportunity that a model like Medically Home's presents.

Digital Health Integration

What will it take for these stakeholders to accept digital technology as a solution to their current challenges?

Digital health adoption is occurring at an exponential rate, accelerated by the COVID-19 pandemic, but there is still more work to be done to achieve large-scale acceptance as a core, long-term solution rather than just a stopgap measure leveraged as part of health system responses to the pandemic.

ADOPTION CHALLENGES	DIGITAL HEALTH SOLUTIONS
Fragmented Data Collection Infrastructure Without access to sufficient, uniform data, digital health will be prevented from reaching its full potential. Yet medical data is vast, heterogenous and siloed.	To encourage industrywide adoption, digital technology should be converted into a universal model that can manage and track all healthcare data.
Sensitive, Protected Digital Health Data Digital therapeutics companies must adhere to stringent confidentiality procedures as they collect sensitive patient data.	There will be trade-offs in the creation of a universal model that prioritizes performance over privacy. Privacy-preserving models offer a high level of protection but fall short in terms of performance and accuracy. To continue to make strides in digital technology, laws and regulations should be updated to allow increased access to data.
Stakeholder Perceptions Key stakeholders have been slow to accept novel digital health solutions. To promote wider adoption of digital health, health systems must seek to shift the attitudes of those accustomed to more traditional approaches.	Digital health companies must work collaboratively with key stakeholders to create new pathways and incentives to encourage the use of digital health technology platforms (e.g., mobile devices that integrate with EHRs). Recently the FDA did just that when it revamped and expedited evaluation procedures for digital health products.

Digital health is here to stay as the growing enthusiasm of patients and providers continues to drive the acceptance of these technologies. These innovations are critical to reducing costs and better managing data across the care continuum while also improving patient access, compliance and outcomes. Innovative therapies like CGT hold the promise of life-changing treatments for critically ill patients, but that future is only possible if the industry is able to expand access and demonstrate the durability of clinical effects in the real world. Digital health can offer the transformative solutions necessary to manifest that reality.

Realizing the Benefits of Digital Health in CGT

CGT has the potential to offer highly durable outcomes in a single short-term treatment, but these therapies are coming to the market with limited data to support value claims and steep price tags. Regulators are mandating additional data collection, and payors are requiring more proof to engage in outcomes-based contracts. For CGT developers, digital health can be used to resolve many of the challenges inherent in their current delivery models.

- **Limited data to support value claims:** Digital health technology can be used to help providers assess performance in the real world and monitor disease progression. By using mobile apps, wearable devices and/or in-home sensor technology, they can enable remote, continuous collection of data that allows them to analyze the data and obtain results in real time while also mitigating negative side effects and disease progression.

- **Long-term data collection and tracking:** Digital health can supply the technology needed for long-term post-treatment tracking across multiple payors, sites of care and providers via mobile apps that integrate with EHRs. These solutions provide the evidence providers need to satisfy regulator requirements and enter into outcomes-based contracts and outcomes-based reimbursement designs with payors, which might increase access to these types of therapies for more patients.

- **Limited CGT treatment delivery expertise and patient access:** Digital technology can expand CGT capabilities and increase patient access to treatment by democratizing the specialized infrastructure and expertise required to deliver and monitor these innovative therapies. With a solution that is part telehealth and part virtual monitoring, patients can connect remotely with CGT centers without geographical or logistical constraints. An example of this type of delivery model is integrated virtual healthcare (IVHC), which allows providers to integrate their EHRs with telehealth to engage and monitor patients, create reports for payors and regulatory bodies, and enroll patients in programs immediately at assessment for CGT so they can be followed and monitored in real time.

Andrew Hobbs, managing partner at Axian Consulting Ltd., helped to moderate the roundtable on which this piece is based.

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