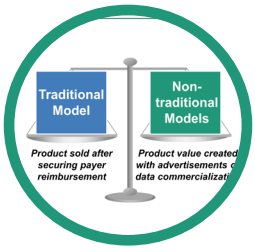
Forging New Paths for the Digital Revolution in Healthcare

The digital revolution is underway but its full implications in healthcare are not yet understood. Digital health holds promise to transform care delivery and management. But how will this idea turn into reality and where is it now? In this white paper, we outline both the current state and future trajectory of digital health by evaluating the current unmet needs of our healthcare system and the actionable ways in which digital health can be uniquely leveraged to fill those voids.

THE BRIEF

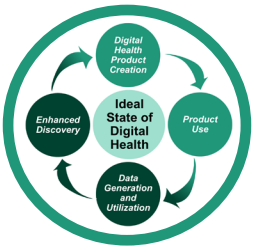
Mapping Clinical Applications

Outlining use cases for digital tools to uniquely fill unmet clinical needs



Evaluating Business Models

Analyzing value drivers of digital tools for manufacturers



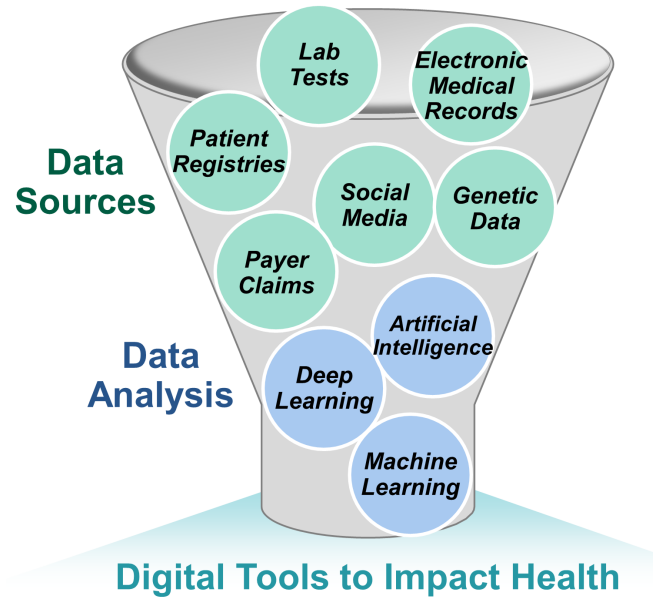
Identifying Paths to Harness Value

Delineating steps for innovators and drug makers to improve healthcare

Simplifying Digital Health

Healthcare today is awash with novel technologies innovating in the ways patient health data is both collected and analyzed. The marriage of precise, accurate data collection and robust analytics constitutes a digital health tool. Digital health tools are poised to impact patients and disrupt the healthcare space.

FIGURE 1 - Defining Digital Health



Today, data is collected through various avenues – electronic medical records, patient registries, lab tests, payer claims databases – even social media. Facebook has tracked posts for suicide risks and partnered with first responders to conduct wellness checks; the UK National Health Service has leveraged Tinder to promote organ donation to people who swipe right on celebrities' profiles.

Digital health companies are innovating novel technologies to improve data collection. For example, Verily Life Sciences is improving the constancy and accuracy of data collection by developing an adhesive patch with miniaturized sensors monitoring glucose 24/7 for diabetes patients.

While new data collection technologies are being developed, innovation in novel data analysis methods is also underway. Recently, the digital revolution in healthcare has capitalized on learning-based algorithms, or "artificial intelligence," to substantially optimize the value and use of collected health data. For example, HealthTap has developed AI that learns from each patient interaction and cyclically improves its own functions, which are to provide an analysis of a user's health based on reported symptoms.

The confluence of the data collection and analysis ecosystem creates the ideal environment to foster digital health products. Digital health companies have the potential to leverage these data collection and analysis capabilities to fill a myriad of unmet needs in the healthcare space. ClearView delineates six nodes along the patient clinical journey by unmet needs today and examples of how digital health technologies can successfully be integrated to add technology-driven value to the nexus of clinical care.

Mapping Applications for Digital Health Across Clinical Needs

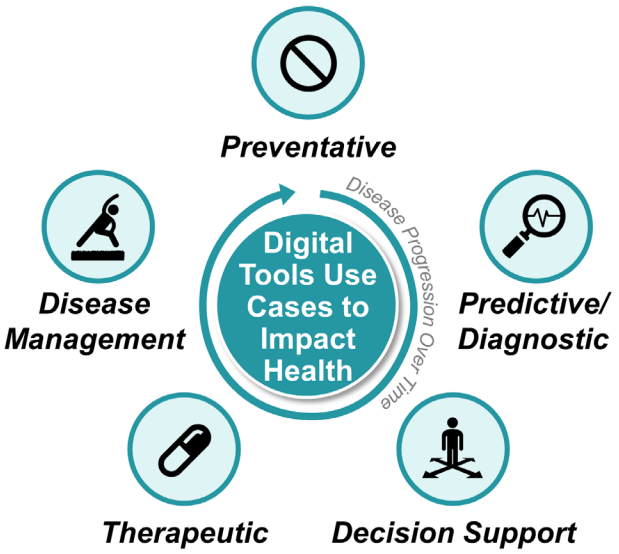
Segment 1: Preventative

Inherently, medicine targets curing rather than preventing. Although medicine is trending towards preventative care, the onset of disease is heavily influenced by an individual's social determinants of health. Preventative digital health technologies are aimed at addressing these environmental contributors to lower the risk of disease through wellness and lifestyle management. For example, Lark is a research-backed app available for $20 per month (and reimbursed by some payers). Lark is synced with 23andMe genotype data and AI to tailor lifestyle choices in a personalized fashion to prevent type II diabetes and promote general wellness. The FDA-approved 23andMe $199 out-of-pocket genotype report has evaluated over 500 million users' risk for diseases, heritability of traits, and ancestry information after testing saliva samples and pairing them with phenotypic data from online user health surveys. If 23andMe's Lactose Intolerance Report shows a patient is lactose intolerant, Lark can filter out lactose-containing diet options within its AI-based coaching to prevent obesity and concomitant chronic disorders. Noom is another preventative app for pre-diabetic patients allowing patients to log meals, track weight, engage with coaches, and interact with a peer support network for $59 per month out of pocket. Demonstrated outcomes rival traditional in-person diabetes prevention programs while attenuating cost and recruitment barriers.

Segment 2: Predictive/Diagnostic

While the best means of treating a disease is often early-stage detection, unfortunately, the majority of physician

FIGURE 2 - Mapping Clinical Applications



visits occur too late. This issue is exacerbated in diseases that are asymptomatic in early stages. Digital health technologies have the potential to predict or identify early warning signals of disease that a patient cannot. Similar in purpose to Verily's glucose monitoring device is AliveCor's KardiaMobile, a $99 FDA-cleared fingertip EKG device that clips onto the back of phones. It is paired with a free Kardia App, which uses AI to help predict cases of atrial fibrillation and hyperkalemia. Data is transmitted virtually through customized reports to both patients and physicians. Kardia is FDA-validated as a breakthrough device in predicting hyperkalemia and has secured its position as the world's most clinically-validated around-the-clock personal EKG device.

Segment 3: Decision Support

In a world with a shortage of physicians and an average doctor visit length of 17.5 minutes, face-to-face time between physicians and patients is limited. As such, efficiencies in information transfer, especially for information outside an office visit, are critical for physicians to make accurate decisions. Digital health technologies are not only able to provide this raw information transfer, but also progress a step further to analyze the information to aid physician treatment decisions. HealthTap is a free or $99 per month AI-driven telemedicine app. Patients first speak to the AI "doctor," which then is analyzed to inform the connected physician's decisions. The AI possesses capabilities to analyze treatment decisions from over 140,000 physicians against self-reported health issues from over 350 million patients to continually improve the decision support it provides to physicians.

Segment 4: Therapeutic

The quintessential tradeoff for pharmacotherapies is efficacy versus tolerability. However, digital therapeutics offer an alternative: treating conditions without concern for pharmacokinetic side effects. Digital therapeutics can be positioned to substitute traditional drugs or can serve as add-ons to traditional pharmacotherapies, such as Akili's video game therapeutic in development for ADHD, which can potentially be utilized in conjunction with pharmacotherapies such as Adderall. Digital therapeutics can also replace provider-mediated therapies, such as Deprexis, Gaia Healthcare's AI-based cognitive behavioral therapy for depression, or Sleepio, Big Health's AI-based cognitive behavioral therapy for insomnia.

Segment 5: Disease Management

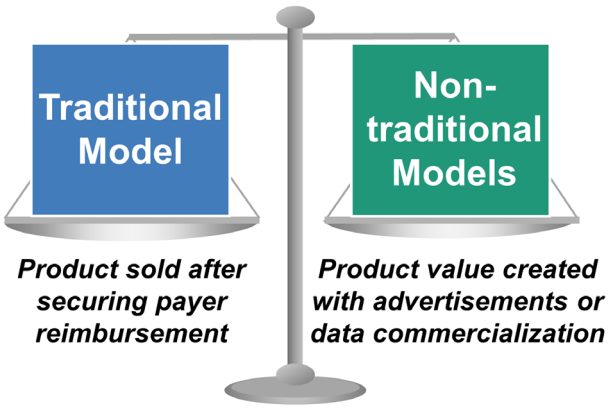
A traditional hurdle for healthcare providers has been poor patient compliance. Sometimes, a patient needs additional assistance, such as when social determinants of health serve as barriers to following a provider's recommendations. Ensuring proper adherence in these circumstances may necessitate efforts or check-ins outside of the office visit that physicians may not have the time or resources to conduct. Digital health products can fill this unmet need. For example, Livongo is an app that for a monthly fee (and reimbursed by several states' and major insurers' health plans such as Blue Cross Blue Shield of Kansas City) provides an AI coaching program for diabetes. Livongo shares data measured through a paired smart touch glucose meter and blood pressure cuff with Certified Diabetes Educators to receive feedback in real-time – for example, a call or text to make sure patients are stable if their blood sugar dips below 50 mg/dL or daily check-ins to discuss meals, exercise, and pharmacotherapy management.

Digital health technologies are not limited to augmenting care in only one of the clinical use parameters this paper outlines. For example, AliveCor's Kardia App has medication tracking support as well, classifying the technology as serving both disease management and predictive/diagnostic needs. These categories, therefore, serve as a continuum of functions across which digital health can extend its reach to better serve patients.

Evaluating Business Models

Digital health technologies can provide value not only to patients and providers, but also to investors and innovators of these technologies. However, questions remain about the feasible and ideal business models to pursue. Innovators have the optionality to pursue the traditional revenue model of payer reimbursement (i.e., "drug/medical device-like") as well as non-traditional models (e.g., "software-like") for their products. Equal value may be derived from both approaches.

FIGURE 3 - Evaluating Business Models



Traditional Model

The traditional model of payer reimbursement is utilized for drugs and medical devices and involves CPT/DRGs, contracting, and rebates. This model is generally more difficult to pursue for digital products given the nascency of the digital health industry and payer unfamiliarity with its value proposition. Digital therapeutics are likeliest to find success with the traditional method of payer reimbursement utilized for drugs and medical devices, as these tools may supplant highly-priced payer-covered drugs. For example, Sleepio is reimbursed to treat insomnia by the National Health Service in the UK and CVS Caremark pharmacy benefit management clients in the U.S. given its cost savings over in-person therapy. Innovators may also pursue this model for products unable to sustain an infinitely expanding user pool. For example, Livongo is a disease management product but also pairs patients with a finite supply of human coaches. Digital therapeutics are not the only segment that can pursue traditional reimbursement. For example, Lark is a preventative app that has successfully achieved payer coverage given its proven downstream cost offset.

Although revenue is driven by price rather than quantity of patients in this model, a key consideration is that the burden of proof is much higher for traditional reimbursement, given the barrier of convincing skeptical payers of a significant added clinical benefit or cost offset. Innovators should be aware that this may lead to slower launches from regulatory hurdles on the pathway to approval, costly R&D (e.g., payer pilots, randomized control trials akin to pivotal drug trials, HEOR), and more effortful post-launch market development.

Non-traditional Models

The focus thus far for many digital products, most of which have been digital therapeutics, has been to secure payer reimbursement. However, non-traditional models may maximize return on investment to the same degree as a payer-reimbursed model by leveraging successful methods from the software or electronics industries. Primary revenue drivers for these models may range from direct-to-consumer product sales to Software as a Service (SaaS) models, which may look to non-product-driven revenue generation measures such as monetizing patient data or selling advertisements. For example, one model may be to price a digital app with a free or "freemium" (i.e., nominal) out-of-pocket cost in order to attract a sizable user pool. Revenue in this case may be generated by quantity of product sales. Fitbit charges from $60 to $250 out of pocket for the same base product with incremental "nice-to-have" add-on features to capture the widest user pool. Ancillary measures can also serve as key revenue drivers. 80% of 23andMe's 5 million users opt in to the company selling their deidentified data to pharmaceutical companies to aid therapeutic discovery, which has become the company's primary revenue source.

A key consideration for companies pursuing non-traditional models is who should serve as the target customer. If it is employers or patients, commercialization may bypass the high burden of proof required by payers and innovators can spend less time and capital on R&D, enabling a quicker launch. Innovators should instead invest more in direct-to-consumer marketing (e.g., Noom's Instagram advertisements), user experience, real-world evidence generation, and education.

For both traditional and non-traditional models, innovators should consider the value proposition of recurring (e.g., per member per month, monthly subscription service) versus one-time payments, as it has been proven successful. For example, KardiaMobile is a one-time payment, Sleepio can be purchased

for year-long use, and Noom offers monthly and a discounted two-month and four-month plan in addition to a two-week free trial. Time taken for the product to demonstrate a clinically meaningful benefit should be front-of-mind for innovators deciding on an optimal payment frequency for their products.

Identifying Paths for Innovators and Drug Makers to Harness the Value of Digital Tools

Given the variety of pathways for clinical use and business models for digital health companies, the digital revolution and the continued integration of data in healthcare possesses separate implications for both digital innovators and traditional drug makers.

Innovators

Innovators should not miss out on opportunites to pioneer advancements in patient health before diagnosis and after treatment. These areas of healthcare have been relatively untouched and pose a natural barrier of entry to biopharmaceutical companies. Pharmaceutical companies aiming to treat disease may naturally have less interest in preventative care. As a result, budding digital health companies have an opportunity to trailblaze channels to augment today's healthcare system and add value in previously under-innovated areas.

As discussed, there is lucrative revenue potential for digital apps and products that focus on preventative health, predicting disease, and managing treatment, as these products can be potentially marketed to a wide patient pool. The data collected from these products can also be used not only to improve patient experience, patient health, or improve the product itself, but also can be sold to pharmaceutical companies that may have no other means of collecting this important health data.

Given the lower burden of proof required for digital health products focused on pre-diagnosis and post-treatment, there may be fewer restrictive regulatory pathways and less need for securing private/public reimbursement as compared to a digital therapeutic. As a result of this lower burden of proof and larger patient pool, digital innovation in these comparatively overlooked areas of healthcare could prove highly profitable.

Drug Makers

Drug makers should also seek to dive into the rising tide of digital revolution. While there may not be an incentive to invest in, for example, decision support tools or lifestyle/wellness apps, drug makers could glean benefits from partnering, acquiring, or developing in-house disease management or discovery tools.

Compliance remains an unsolved issue for patients, providers, and pharmaceutical companies. Digital tools may be better able to improve compliance to challenging treatment regimens as well as track patient adherence at a larger scale. Similarly, monitoring devices can optimize trial compliance and data collection efforts to improve discovery. The clinical trial market is exponentially growing in scale; in the year 2000, ClinicalTrials.gov listed 2,119 active studies, but today, this number has skyrocketed to over 280,000. With this expanding number of trials, recruiting eligible patients in need of novel therapies is a greater challenge than ever. Digital health products such as Clinical Trial Connect is an online finder platform that can be integrated into patient advocacy groups' or trial sponsors' websites to connect interested patients with trials in minutes by analyzing patient health data. Digital health can also improve trial accuracy and operations, such as Philips Actiwatch devices to collect patient health data. These devices can monitor patient safety (e.g., heart rate) and collect efficacy endpoints (e.g., steps taken per day) minute by minute. They can also track or promote adherence in trials, for example, by sounding an alarm each day to remind patients to take their medication. Companies such as Evidation Health have created platforms to streamline analysis of raw data through pre-built connectors that normalize, anonymize, and quarantine questionable device data before summarizing key insights.

Drug makers can either rely on existing nimble digital health companies to independently develop and market these tools or strategically partner with select companies that are best positioned to directly improve disease management for their patients. Direct provision of these technologies can greatly augment patient trust in a therapy, if paired with a specific technology, or towards the pharmaceutical company as a whole.

As with any paradigm shift, digitization may face challenges in unlocking widespread multi-stakeholder buy-in, particularly in healthcare, an industry historically slow in adopting technology. Key drivers of broad public reticence are the widely publicized failed digital health technologies and ubiquity of unvalidated or inaccurate digital tools marketed to consumers.

IBM Watson for Oncology's failure in China typifies the former case. An AI decision support tool recommending treatment plans for oncology patients and backed by Memorial Sloan Kettering Cancer Center, Watson was expected to attenuate worldwide physician shortages, particularly apt for China, one of the world's most populous countries. However, physicians quickly recoiled from the tool after realizing it was targeting therapeutic recommendations at patients directly contraindicated for those therapies. Analysis revealed that this was a result of deep learning developed from a small sample of hypothetical cases rather than robust real patient data. In addition to inaccurate analyses rooted in problematic data, IBM Watson lacked adoption due to poor commercial planning. It was touted as applicable to patients worldwide but was unable to read Chinese databases, resulting in recommendations directly opposing Chinese national treatment guidelines. Its access was also significantly narrowed by its prohibitive cost, with a $1,000 USD price per inquiry resulting in use in a mere 10 patients in China.

Wearables are an example of a niche within digital health saturated with unreliable products. Digital health tools are advertised as improving health and fitness, but many lack strong validation, clinical evidence demonstrating effectiveness, or consistency between devices.

To overcome these barriers, galvanizing broad adoption of digital health and promoting use of quality tools over a sea of unreliable and unvalidated products, drug makers and innovators must accurately validate and carefully plan access and logistical integration into existing infrastructure before launch. Only with these conditions in place can digital health can improve patient care and health outcomes through the methods outlined in this paper.

Healthcare has significant limitations. Though improvements are in development, today's system emphasizes treatment rather than prevention and misses opportunities to optimize disease management or clinical discovery. If we are able to align the unique data collection and analysis tools of digital health to the clinical needs identified in this paper, we have the potential to create a virtuous cycle. The application of tools combined with real-world data collection can foster the creation of more digital health products.

While drug makers can improve compliance and discovery with advanced data collection tools and monitoring devices, innovators can complement traditional healthcare companies by focusing on improving patient health before and after treatment in addition to developing digital therapeutics to supplant or add on to traditional drugs.

With drug makers and innovators driving this digital revolution forward, both complementing each other in new and unique ways, a future "ideal" state in healthcare is portended:

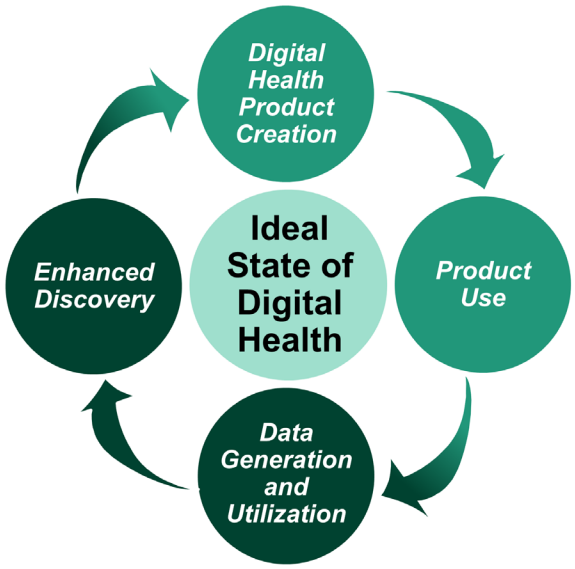
1. Collection and analysis of data leads to creation of a novel digital product

2. Novel product is used by patients/physicians

3. Data is collected and analyzed

4. Through data insights, companies take action to (1) directly impact clinical care, (2) improve user experience and capabilities of digital products, (3) aid discovery of novel pharmacotherapies

FIGURE 4 - Harnessing Value of Digital Tools



This paper has strategized specific novel paths by which digital innovators and pharmaceutical companies can integrate digital technologies into the healthcare system and address previously-ignored aspects of care. The onus is on medical device and pharmaceutical companies, however, to truly embrace the proper digital tools and drive forward the digital revolution if this ideal state of healthcare is to be achieved. Only then can shortcomings in clinical care be truly ameliorated by the digital forces permeating our world today.

About ClearView Healthcare Partners

Founded in 2007, ClearView Healthcare Partners is a global strategy consulting firm serving the life science sector.

The firm combines international industry knowledge and deep scientific expertise across a range of therapeutic areas with an extensive network of external stakeholders to deliver practical and actionable recommendations to our clients' most complex challenges. The firm's projects include cross-functional support at the corporate, franchise, and product levels for pharmaceutical, biotech, medtech and digital, and diagnostics companies worldwide.

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