TRIANGLE INSIGHTS GROUP
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Insights and Perspectives Series

September 2020

Applying Stakeholder Understanding to Design Digital Health Commercial Models

- Digital innovations are being introduced across the healthcare landscape
- While digital healthcare products have generally succeeded from a technical perspective, many have failed to achieve large scale commercial adoption or to meet financial targets
- The degree to which the commercial model aligns to the roles of multiple stakeholders is a key factor that distinguishes the successful programs
- Designers of digital health commercial models should organize their efforts within three steps:
  - Understand the product category
  - Describe where in the patient journey the product is used
  - Map the links between stakeholder benefit and adoption influence
- The answers to three stakeholder adoption influence questions drive the success of the commercial model
  - Which stakeholders are involved in the buying process?
  - Which of those stakeholders, if any, act as a "gatekeeper" to product adoption?
  - For each stakeholder, to what extent does the product provide net benefit?

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1 Introduction

With the advent of the digital revolution in healthcare, those responsible for developing product strategies are finding that previously reliable frameworks for designing and evaluating commercial models are inconsistently successful in this new environment. This should not be surprising as digital health covers a vast range of technologies, medical devices, therapeutics, and algorithms.

As the range of digital health applications expands, planners will need to apply increased attention to designing commercial models that are tailored to the product characteristics and the interplay among the range of stakeholders who influence adoption. Those stakeholders include patients, caregivers, providers, payers, and employers. This white paper provides a framework for designing approaches to facilitate product adoption that is based on identifying how this range of stakeholders receive benefit from a digital health innovation and understanding the level of influence each of those stakeholders exerts over product adoption.

In healthcare, adoption decisions may be separated from the stakeholder that derives direct benefit from the product. This is observed in the traditional pharmaceutical market where insurance companies (payers) act as gatekeepers controlling whether a therapy is presented as an option and physicians act as the key decision-maker in whether a patient receives the treatment. Some digital healthcare products will follow this model. Other products, designed to bring new information to stakeholders and to empower alternative means of decision making influence will follow a different path. A digital healthcare product's success depends on establishing a commercial model that is matched to the influence and interplay of these stakeholders.

We recommend a three-step approach to building digital health commercial models:

1. Understand the Product Category
2. Describe Where in the Patient Journey the Product is Used
3. Map the Links Between Stakeholder Benefit and Adoption Influence

Supporting this sequence, in the following discussion, we will begin by establishing the scope of digital health technology applications and review where they provide benefit across the patient journey. Then, we will describe the *Stakeholder Benefit Map* and use example digital health technologies to demonstrate its utility in identifying drivers and barriers to adoption and in informing commercial model strategy.

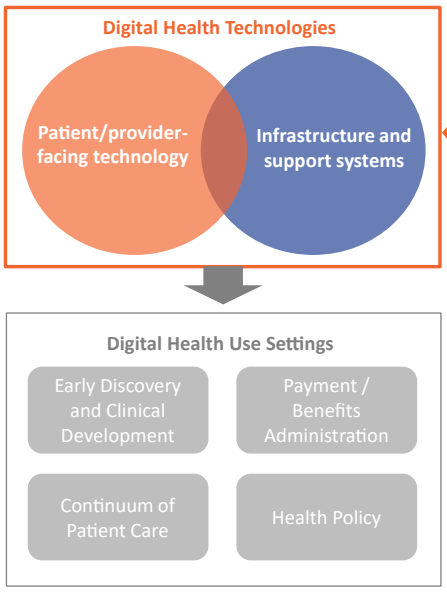
2 Understanding the Product Category

2.1 Defining Digital Health Technologies

Digital health encompasses a variety of technology offerings. Commercial planning teams must start by clarifying where a product fits within the broad digital health landscape.

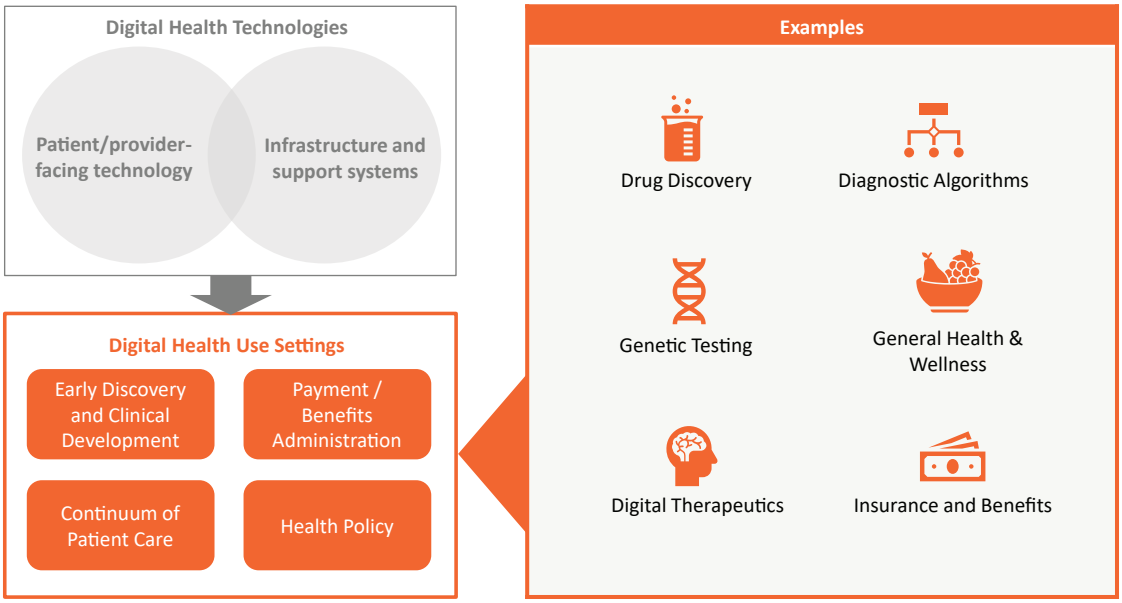
The first step is to separate products that are patient and provider facing from those targeting enhancements or efficiencies in the healthcare infrastructure and support systems. Even within these groupings, there is a rich variety of innovations. In Figure 1, we have provided a framework using the most common patient and provider facing digital health technology categories: Mobile Apps, Wearables, Implants, Technology Augmented Pharmaceutical Solutions (TAPS), and Internet of Things (IoT) solutions. Figure 2 outlines areas where digital health technology is being applied in the upstream infrastructure and support system areas. With so many entry points, the digitization of healthcare continues to expand and the requirement to establish effectively aligned commercial models becomes ever more important.

Figure 1. Examples of digital health technologies that tend to be more patient and/or provider-facing, though at times may overlap with technologies traditionally associated with infrastructure or "back-end" systems.



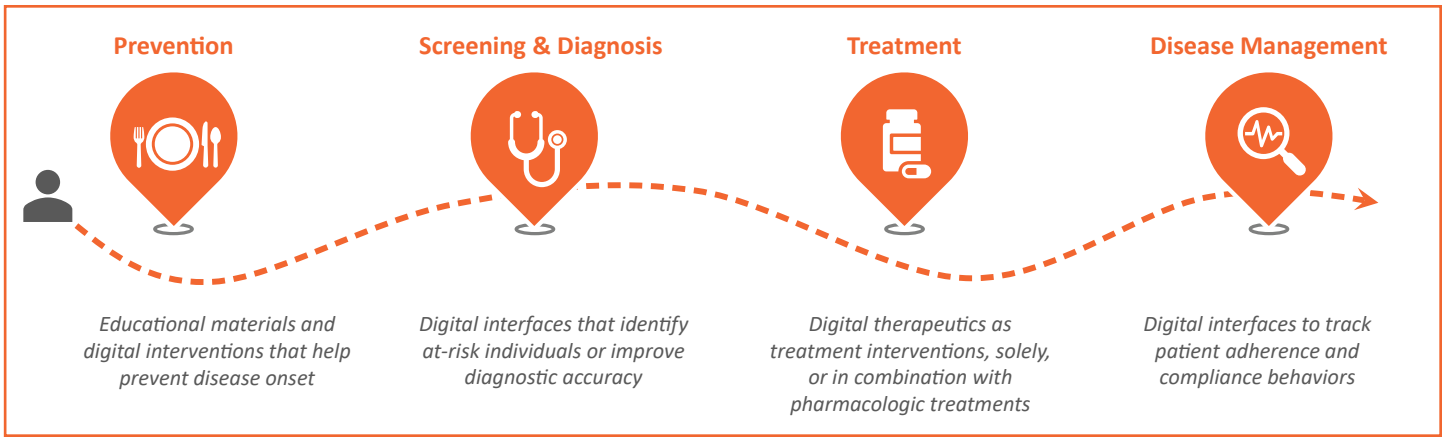
Example Digital Health Technologies (Not Exhaustive)	Description
Technology-Augmented Pharmaceutical Solution (TAPS)	Technology additions to enhance pharmaceutical or medical device delivery or efficacy, including on-device and on-treatment solutions ***Examples: Teva ProAir/AirDuo Digihaler, Otsuka Abilify MyCite***
Wearables / Portables	Devices worn for monitoring a user's physiologic parameters, designed for minimal interruption or limitation of the user's activities ***Examples: Apple Watch***
Implants	Medical device that is partly or wholly introduced into the body and designed to provide treatment and/or external communication of physiologic ***Examples: Pacemaker + Medtronic MyCareLink***
User-Facing Applications	Software applications that run on user-facing platforms (e.g. smartphones) and are intended for use along the continuum of care ***Examples: Pear reSET-O***
Internet of Things	Network of physical objects supported by embedded technology for internal and external data communication ***Examples: CYCORE remote monitoring systems (weight scale)***

Figure 2. Categorization of digital health technology solutions by their various applications



2.2 Categorizing Digital Health Technologies

Figure 3. Categorization of digital health technology solutions by their various applications



A framework to understand where stakeholders derive benefit from digital health innovations requires framing these technologies within the stages of the patient journey. Digital health technology applications can be bucketed into four predominant use cases: **Prevention, Screening & Diagnosis, Treatment, and Adherence & Disease Management** (Figure 3). Large pharmaceutical and biotech companies are applying the types of digital technologies described in Figure 1 to improve experiences at all points of the patient journey, and across multiple therapeutic areas.

PREVENTION

By equipping end-users with educational material and app-based behavioral interventions, digital technologies empower patients' healthier and more educated choices. Wearables and mobile applications allow users to interact with their own health data and even gamify this experience. Notably, gamified exercises have shown the potential to reduce the risk of developing chronic conditions. Mobile applications have been synced with wearables to guide personalized fitness and diet plans for users. They may also track activity and caloric intake to minimize the risk of developing obesity and diabetes. Perhaps the most familiar example of a wearable is the Apple Watch. By providing early warning notifications based on pulse rate, heart rhythm, and ECG readings, end-users are empowered with the data and information to take early preventive health measures.

SCREENING & DIAGNOSIS

Digital health tools may improve diagnostic accuracy and facilitate early identification of at-risk individuals. Wearables and mobile apps that track end-user behavior and health data may alert patients to get screened or inform potential diagnoses when levels cross clinical thresholds. In other instances, algorithms have enabled physicians' therapeutic decisions through imaging-based technology that is leveraged to aid identification and prioritization of the most imminent risks to patient health.

TREATMENT

Therapeutic digital interventions may work independently or in combination with molecular therapies. Examples include prescription and direct to consumer digital therapeutic applications that leverage evidence-based Cognitive Behavioral Therapy (CBT) to tackle clinical depression. Woebot, for example, uses algorithms to power an app-based chatbot that provides personalized CBT to improve end-user mood and mental health.

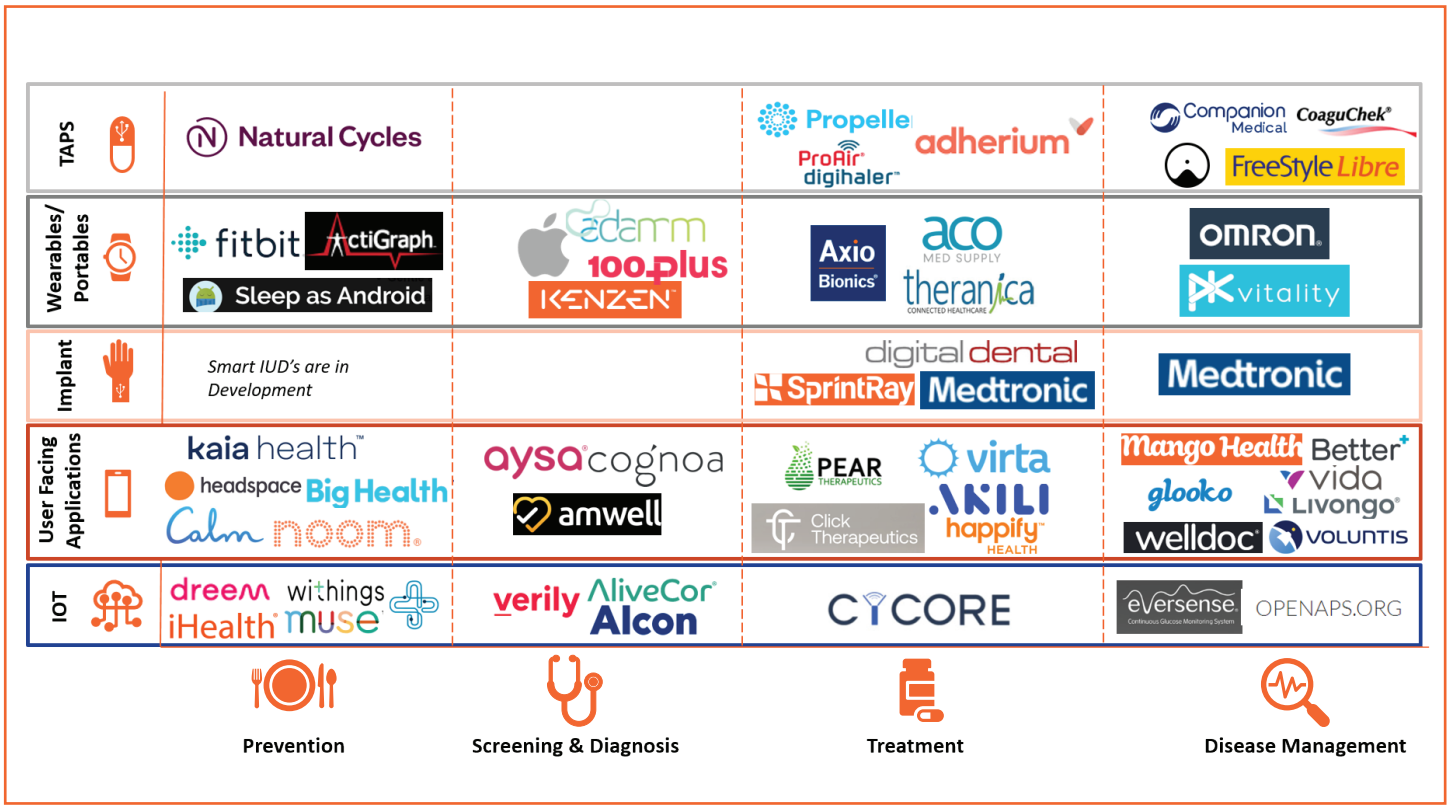
DISEASE MANAGEMENT

Digital health allows patients to keep track of their treatment regimen, as well as monitor disease progression. Providers can leverage data to record patient adherence to a treatment plan and make adjustments that are tailored to patient needs. Examples include technologies that are built-in to molecular therapeutics, wherein providers can track whether a patient has taken their medication. Patient compliance data is aggregated to assess overall adherence and suggest changes to treatment regimens. Proteus Digital Health offers an ingestible sensor and a wearable patch that can track medication adherence, patient activity, and rest. Data from these sensors is sent to the patient's mobile device and can be leveraged to inform disease management.

Some digital technologies provide benefits at multiple points on the patient journey. For example, mobile applications that provide therapeutic interventions also have features that enable screening, diagnosis, and disease management. Also crossing multiple points, algorithms exemplify a technology that allows for use cases along the patient journey. They have already demonstrated value in improving diagnostic speed and accuracy, as well as supporting physicians' therapeutic decisions. With the burgeoning opportunities presented by digital health technologies, the selection and design of commercial models is highly influenced by where in the patient journey the product provides value.

The robust landscape of digital health innovation is evident in Figure 4. Here we map a variety of products based on how they are used and the point in the patient journey where they provide benefit.

Figure 4. Categorization of digital health technology solutions by the patient journey



3 Digital Health Technology Adoption Through the Lens of Stakeholder Benefit

Each digital health technology is unique in terms of stakeholder interaction and individual benefit. In evaluating a product's commercial potential, commercial model designers must fully characterize stakeholder involvement across the buying process and patient/end-user journey of the product. While the same is generally true for pharmacologic treatments, digital health technologies and stakeholder dynamics are generally less easily characterized in broad strokes due to greater variability in product-stakeholder interaction and the relative nascency of digital technology.

Patient and HCP (health-care provider) modes of interaction with digital health technologies are often more complex, and may involve novel paradigms (e.g. CBT for opioid addiction delivered via digital apps). Furthermore, given the relatively recent rise in digital health technologies, the body of health economic and outcomes evidence in support of their adoption is smaller, and payers are only beginning to derive a similar level of experience in assessing value.

To assess a digital health product within the *Stakeholder Benefit Map*, one must answer the following questions:

- Which stakeholders are involved in the buying process and/or interactions with the digital health technology?
- Which of the stakeholders identified, if any, act as "gatekeepers" to product uptake?
- For each stakeholder, to what extent does the product feature provide a net benefit?

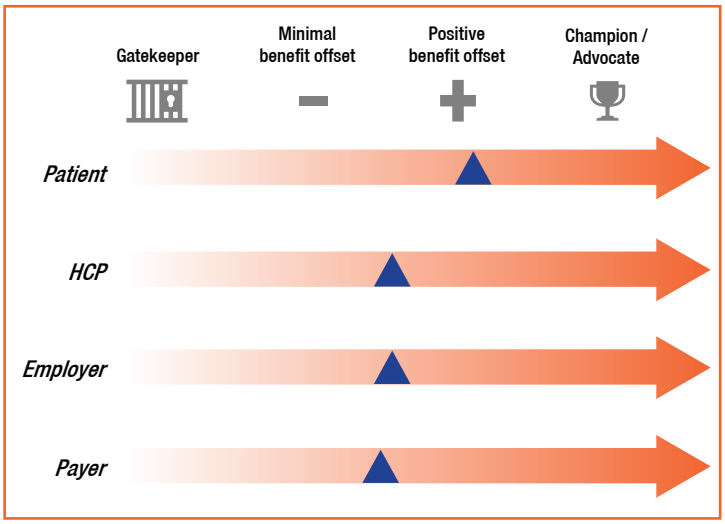
EXAMPLE 1: Single Stakeholder (Patient) Focused Benefit and Adoption

Digital innovation has enabled a transformation of patient responsibility in healthcare. The introduction of the Apple Watch Series 4 and 5 ECG, an application that measures heart rhythm via electrodes on the rear of the smartwatch and on the digital crown, represents an opportunity for patients to be self-informed and manage their own health status. While the ECG application's potential is presently limited to the detection of atrial fibrillation through an early algorithm, the technology may revolutionize a cardiology diagnostic landscape that is burdened by the use of unwieldy and slow Holter monitors. Despite employers, payers, and even physicians receiving minimal benefit from the adoption of the Apple Watch ECG in its present form, individuals seeking to take control of their own health management are drawn to the application's convenience and are championing the product's adoption going forward (Figure 5).

EXAMPLE 2: Multi-Stakeholder Benefit with Gatekeeper Endorsement

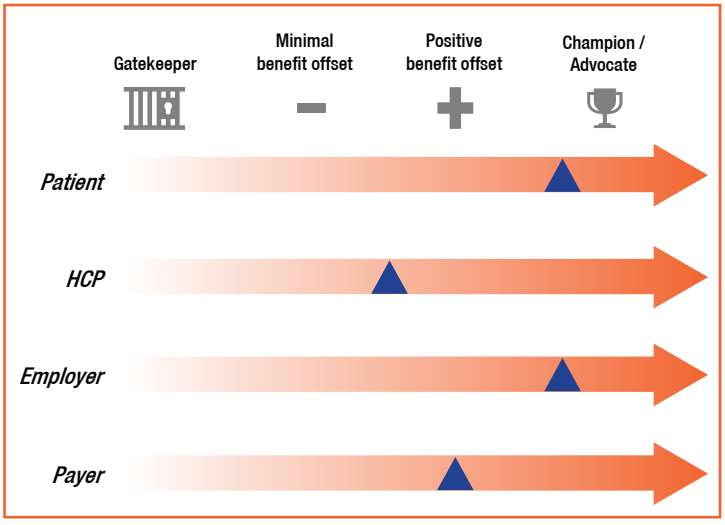
User-facing on-device applications have created platforms for the convergence of treatment, monitoring, and care integration. Livongo is a digital health platform designed for the management of chronic disease, both metabolic and behavioral. Through integrated smart devices, personalized treatment plans and access to expert coaching, Livongo has demonstrated clinical outcomes and cost savings for both patients and payers. Their

Figure 5. Apple Watch Series 4/5 ECG AF Detection Algorithm – positive, though potentially minimal, net benefit across all stakeholders may be realized by the technology and facilitate its widespread adoption.



model enables partnerships with employers, health plans and health systems through which members are enrolled based on eligibility. Payers, patients, and their caregivers (family and friends) derive a net positive benefit from Livongo's application, with demonstrated cost savings and reduction in total diabetes spend, as well as positive clinical outcomes for the patient, with reduced HbA1C levels (Figure 6).

Figure 6. Livongo Platform – clinical and health economic outcomes data are directly impactful to patients and payers, respectively. HCPs and caregivers benefit from additional tracking of physiological parameters.



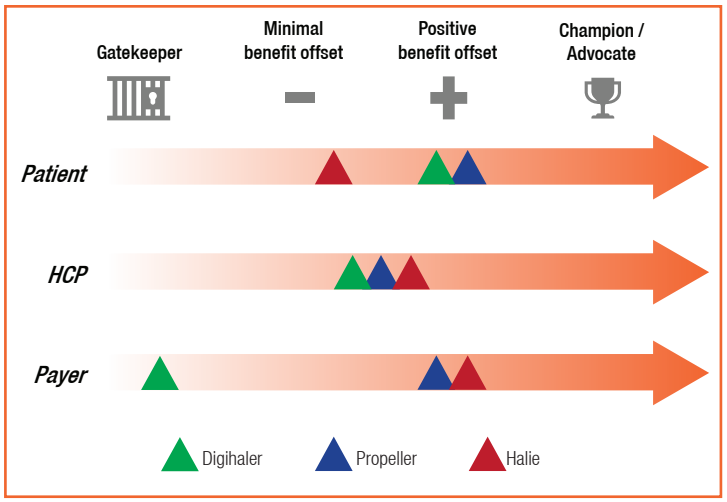
EXAMPLE 3: Multi-Stakeholder Benefit Overcoming Gatekeeper Resistance

Respiratory disorders like asthma and COPD present an opportunity for digital health technologies to improve medication delivery and adherence. Given the difficulty in managing these conditions, TAPS (technology-augmented pharmaceutical solutions) have emerged to provide augmentation to existing respiratory devices (e.g. MDI inhaler) resulting in "smart inhalers". These inhalers use sensors to assess adherence to proper inhaler technique, spirometry to track lung function, and connectivity to provide physicians with real time monitoring of patient status. In outcomes studies, inhaler sensors have been shown to improve disease control, reduce rescue inhaler use, and lower overall cost in various treatment settings.

Multiple commercial selling models exist among digital inhalers, resulting in unique positioning of stakeholder benefit (Figure 7). Teva's Digihaler is expected to launch as a pharmaceutical product with a traditional approach where an insurance claim and copay would likely be required to obtain the medication. Given the availability of non-digital generics the development of outcomes data is likely to play a role in payer value assessment and approach to formulary management. Ongoing outcomes studies with the Digihaler device seek to provide such data and assist payers in recognizing the net positive benefit of providing patient access to the device.

Alternative inhaler selling models can result in dramatically different stakeholder benefit assessment. Resmed's Propeller Health inhaler is funded by foundations and manufacturers and is provided at no cost to the patient, thus bypassing the payer "gate" and eliminating cost burden on the patient. Adherium's Halie Symbicort is an aftermarket inhaler attachment where patients assume the cost of the product, which places the lever for driving uptake more squarely on patient targeting.

Figure 7. Digital inhaler technologies – positioning within the Stakeholder Benefit Map varies depending on the selling model utilized by each product.



4 Conclusion

As the healthcare system embraces digital solutions, developers and investors will increasingly seek to understand how to evaluate the commercial potential for these new health technologies and products. With multiple stakeholders potentially deriving benefit from the innovations, and with those benefits being derived at different points in the patient journey, leaders must be careful to draw lessons only from examples that reflect relevant, comparable context. Whether tasked with designing the commercial model or with evaluating whether a product can survive the healthcare adoption gauntlet, we recommend beginning with the tools described above. First, clarify the category of the digital innovation. Then use the *Stakeholder Benefit Map* to quickly assess which stakeholders will be most influential in driving or restricting adoption. When the answers are not obvious, deeper levels of market research are warranted.

The current analysis suggests that digital health technologies succeed when the commercial model is paired to the market circumstance in one of three ways:

1. When the benefits are concentrated within a single stakeholder, value messages and product positioning is concentrated on that stakeholder. When that stakeholder is the consumer/patient, commercial model designs follow patterns established in the consumer packaged goods (CPG) industry. Companies like Headspace or Mango Health apply a direct-to-consumer model focusing on general health and wellness. Success for these types of products is contingent upon strong DTC efforts to improve consumer knowledge.

2. When the benefits are received from one stakeholder, but others can act as gatekeepers, the commercial model must first address the gatekeeper's economic concerns. Then, communications can be addressed to the original target of the product benefits (often the consumer/patient). Frameworks for planning for these circumstances can be found in the traditional pharmaceutical market where insurers act as gatekeepers and individuals receive product benefits. Companies including Pear Therapeutics, Proteus Health, and Natural Cycles have approached the FDA with the hope of registering certified digital therapeutics. Further, the proposed value of the offering has been substantiated through outcomes data or a clinical trial. Accordingly, these technologies are pursuing a commercial model relying on payer-driven reimbursement channels or physician guided adoption.

3. In circumstances where the benefits are distributed across multiple stakeholders with no clear gatekeeper, the commercial model must be designed to balance benefits with related costs at each point of influence. These circumstances are the most likely to require a segmented understanding of each stakeholder group and the degree to which segments of one stakeholder are aligned to segments of the others. When considering these digital health assets, commercial model designers must also consider how the data are made available to each stakeholder. While some digital health technologies exist within a closed ecosystem, those that will continue to drive incremental value to healthcare stakeholders are technologies where value can easily be seen by all parties. EHR integration allows technologies like Propeller to display the improvement to critical success factors in respiratory disease including rescue inhaler utilization, controller medication adherence, and inhaler technique. If stakeholders are able to see this benefit without leaving the system, they may be more likely to continue to use the digital health technology.

Already, the diverse nature of digital health innovations and the wide range of circumstances where they are applied preclude reliance on a single template for commercial model development. However, patterns are emerging in how to draw lessons from the industry's pioneers. Armed with an understanding of how to categorize where and how a product provides benefits, and matching it with an appreciation for the roles of key stakeholders, commercial model designers can more effectively plan for their products' success.

About Triangle Insights Group

Headquartered in Research Triangle Park, Triangle Insights Group, LLC is a strategy consulting firm providing guidance on the most critical business issues to leaders in life sciences organizations. The firm's approach combines deep knowledge of the industry across therapeutic areas and functional groups, with a dedication to creativity and disciplined critical thinking. Recommendations from Triangle Insights Group are original, relevant to the industry environment, and supported by rigorous analytics. Clients of Triangle Insights Group include large pharmaceutical companies, emerging biotechnology firms, diagnostics manufacturers, medical device companies, and private equity investors.

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Gautam has provided strategic advice to a wide range of clients, spanning Top-5 pharmaceutical manufacturers, emerging biotechnology manufacturers, bio-pharmaceutical investors, and service providers to bio-pharmaceutical companies. He has spoken at several industry conferences (LES, CED, EBD, BIO-Windhover, CHLA, Banff Venture Forum) and has published a peer-reviewed article on deal timing.

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While at GlaxoSmithKline, Chris's scientific accomplishments led to multiple patent authorships and peer-reviewed publications, as well as discoveries resulting in over $30 million in company cost savings. In business development roles, Chris was responsible for corporate strategy and reviewing in-licensing and out-licensing opportunities. Chris earned an M.B.A. from the University of North Carolina Kenan-Flagler Business School as a member of Beta Gamma Sigma academic honor society. He has an M.S. from the University of Buffalo and a B.S. in Biochemistry from the University of Rochester.

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Recent by-lined articles have appeared in Pharmaceutical Executive, InVivo, Nature Biotech, RPM Report, and Scrip. In addition, Ben's case studies on the pharmaceutical industry have been used in graduate business programs.

Ben is the chairman of the Life Sciences Sector of the Licensing Executive Society. He has also been a member of the program committee for the BIO International Convention. Prior to the founding of Triangle Insights Group, Ben was the leader of the Business Development Practice at Campbell Alliance and a partner in the Strategy practice at Oliver Wyman (formerly Mercer Management Consulting/Strategic Planning Associates). Ben earned an M.B.A. from the Stanford Graduate School of Business and a B.S. from Duke University.

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