BUSINESS MODEL BASICS

Learning Objectives

After reading this brief, you will be able to…

I. Recognize different business models in the health technology field
II. Understand the payment models that typically are associated with different business models
III. Evaluate the pros and cons of different business models to help you choose an appropriate model for your technology

Getting Started

Your business model, or how you capture value from the market, is an important part of the overall strategy for your health technology. Throughout the need research process you were likely given "clues" as to what possible business models you could pursue. Specifically, you gathered information about who you might sell to (the economic buyer), how you might sell to them (your channel), and what and how they would pay. In healthcare, business models are especially complicated because the economic buyer is not always the same as the end user, and the number of different channels is proliferating rapidly. The key is to think critically about the best model to support your technology and then validate it with the key stakeholders to ensure a good match.

What Is a Business Model?

Michael Lewis, financial journalist and business author, defines a business model as "the way a company makes money."[1] According to management expert Peter Drucker, a business model answers the following questions: Who is your customer, what does the customer value, and how do you deliver value at an appropriate cost?[2]

When people think about healthcare and how it's paid for, they often think of traditional reimbursement – where providers are reimbursed by public and/or private insurance companies for the provision of a product or service. If your company becomes a healthcare "provider" it can file a claim for and receive reimbursement directly from insurance companies. Otherwise, you'll sell your technology to a healthcare provider that recommends or offers your product using one of the approaches to generating revenue that are described below. Then the provider will seek reimbursement for the purchase of your product and/or the services they provide in combination with your product, if the technology or related service is covered by public/private insurers. For more detail on reimbursement and insurance-based models, see the Reimbursement Basics toolkit.

Two of the key ingredients of getting paid for a health technology are revenue stream and price. Revenue stream refers to how income is generated for the company and when payments are made by the buyer. Price is how much the buyer is willing to pay and, in turn, how much the company can

charge for its products or services. While companies are getting increasingly creative about revenue and pricing models, the most common methods are outlined below:

- **One-time fee/license**
  Company receives a single fee as payment for their technology.

- **Service/support/maintenance fees**
  A recurring fee that entitles the customer to ongoing support for the technology purchased. It often accompanies the one-time fee/license approach.

- **Recurring/subscription fees**
  Company receives monthly, quarterly, or annual fees for use of the whole product or some component of the product.

- **Program fees**
  Company receives fees for services that accompany the healthcare solution. This often includes fees paid by partners for marketing your product to their member-base.

- **Freemium**
  A product is offered for free for a period of time so the user can "try before they buy."

- **Ancillary fees (or in-app purchases)**
  Company receives fees for additional features/components that offer additional value to the user.

However, beyond revenue stream and price, there are other essential considerations that should be taken into account when deciding on an optimal business model, as summarized in Table 1.

Table 1 – Business Model Factors to Consider

Factor	Explanation
Margin structure	The profit to the company from sales (revenue minus costs).
Sales investment	How much it costs the company to get the innovation into the user's hands.
Customer training requirements	How much specialized training is required for the user to put the innovation to use.
IP	How important IP protection is to the success of the business model.
Clinical/regulatory hurdles	The clinical trials/evidence required to support the adoption of the innovation and the regulatory burden before commercialization can begin.
Financial requirements	The level of overall investment needed to develop and commercialize the innovation.

When deciding on a business model, one way to bring all of these factors together is to evaluate:

- The innovation
- The customer
- And they way that they interact to create mutual value

Each of these three components is covered in the sections below.

The Innovation

Many of the factors listed above are specific to the type of innovation you've developed. In health technology, there a number of common product categories – although companies are increasingly combining these categories into blended offerings:

- **Low-cost disposables**
  Inexpensive technologies that are used once and then discarded (e.g., syringes, medical tubing). Require high sales volume to offset low profit margins. Must be easy to use so they can be sold through low-cost distribution channels. Recurring revenue stream.

- **High-cost disposables**
  Single-use products that have greater competitive differentiation and can therefore command higher prices and gross margins (e.g., blood clot retrieval devices). These typically require specialized training to use and comprehensive IP protection. Recurring revenue stream.

- **Implantables**
  Single-use technologies implanted in the body (e.g., stents). Due to their clinical/regulatory hurdles, they're highly differentiated and command relatively healthy prices and gross margins. Require specialized training and advanced IP protection. Recurring revenue stream. Can be bundled with a service (e.g., pacemaker with post-procedure monitoring service).

- **Reusables**
  Technologies that can be used multiple times for a defined period before they need to be replaced (e.g., endoscopes). Pricing and gross margins are reasonable but not high enough to support specialized training. Revenue driven by initial acquisition and eventual replacement unless combined with a disposable (e.g., surgical shaver with disposable blades).

- **Capital equipment**
  High-end technologies that are repeatedly used over an extended period of time (e.g., CT scanners). Often considered infrastructure, requiring administrative approval and a capital investment by the purchaser. Typically has a high "switching cost." Revenue driven by initial acquisition and eventual replacement unless combined with a disposable or service (e.g., an MRI maintenance contract).

- **Software**
  Technologies that can be used perpetually, are updated frequently, and are often accessed via the cloud on computers or mobile devices (e.g., digital health apps like Headspace, Livongo, or Pear Therapeutics.) Often have recurring subscription pricing and a high margin structure since they can serve millions of users simultaneously with the same software instance.

- **Wearables**
  Accessories that are typically worn by an individual to capture personal biometrics like steps, heart rate, glucose, and more. Some wearables also deliver a "digital therapeutic," which is designed to prevent, manage, or treat a medical disorder or disease (e.g., neuro peripheral therapy delivered through a smart watch.) Wearables are frequently connected to a mobile app, which then transmits collected data to the cloud for analysis. While the margins are typically lower on devices, wearables are often sold along with high margin software that garners recurring subscription revenue.

- **Services**
  Work performed by one individual or group for the benefit of another. Often bundled with a technology (e.g., MRI maintenance contracts) or enabled by one (e.g., digital patient monitoring systems). Recurring revenue stream. Often not eligible for IP protection or other barriers to entry.

Figure 1 summarizes the business model challenges and opportunities typically associated with each different type of innovation.

Figure 1 - Business Model Challenges and Opportunities by Type of Technology

Type of Technology	Margin Structure	Sales Investment	Importance of IP	Barriers to Entry	Customer Training	Clinical/ Regulatory Hurdles	Financial Requirements
Disposable – High Cost	HIGH	HIGH	HIGH	HIGH	HIGH	MEDIUM	MEDIUM
Disposable – Low Cost	LOW	LOW	LOW	LOW	LOW	LOW	MEDIUM
Reusable – Pure	LOW	LOW	LOW	LOW	LOW	MEDIUM	LOW
Implantable – Mid to High Cost	HIGH	HIGH	HIGH	HIGH	HIGH	HIGH	HIGH
Capital Equipment – Pure or Combined	HIGH	NEUTRAL	HIGH	HIGH	LOW	MEDIUM	HIGH
Software	HIGH	MEDIUM	MEDIUM	LOW	LOW	MEDIUM	MEDIUM
Wearables	LOW	MEDIUM	MEDIUM	HIGH	LOW	MEDIUM	MEDIUM
Service – Pure or Attached to Product	LOW	LOW	LOW	LOW	MEDIUM	LOW	MEDIUM

Take a look at the videos called Early Business Model Considerations for a Digital Technology and Early Business Model Considerations for Medical Equipment for two examples of how business model issues can vary by type of technology.

The Customer

In health technology, the number of potential customers is expanding. Globally, consumers are taking more control over their healthcare, quantifying everything from their exercise, to their diet, to their relevant therapies. This makes the sales of certain products more appropriate for direct-to-consumer business models. Yet, the vast majority of health technologies continue to be sold to public or private healthcare providers, as well as other types of businesses, who then use the solutions to drive improved outcomes and efficiencies. Different categories of customers are outlined below, along with some of the benefits and challenges of working with each type.

Consumers

One option is to sell directly to the "patient" or individual using the health technology. Health technology companies that sell directly to consumers often get experts (clinicians, super users, or even famous users) to try and then recommend their products. In addition to reaching out to individuals directly via online, mail, or telephone methods, direct-to-consumer (DTC) businesses also can leverage retail relationships. Examples of retail distribution include both digital and brick-and-mortar retailers such as Amazon, Walmart, Target, or drug stores like CVS and Walgreens.

DTC companies often adopt tiered pricing models, where an individual can buy a base subscription for one price and then add features in exchange for extra monthly fees. If your solution is made up of software and either a hardware component (e.g., blood glucose monitor) or a supply (e.g., blood glucose strip), you can offer the hardware/supplies for a one-time fee or include them as part of the subscription to your software. When health technology companies offer a hardware solution as the primary offering, they also might sell that product for a one-time fee and offer maintenance/support for a monthly or annual fee.

The benefit of a DTC approach is that you can carefully control your messaging and sales process. In addition, since your relationship is directly with the customer, you have the opportunity to learn from them first-hand and use those learnings to improve your products and come up with new offerings. If you don't need to train or engage partners in your sales process, you might also have the opportunity to test new ideas more rapidly. Sometimes health technology companies will make their product available to consumers first as a way to prime the market and gather initial feedback before focusing their sales efforts on other businesses that can help them scale more quickly in terms of distribution/market access (e.g., OneDrop, AliveCor, Kardia Medical).

Challenges with this business model include the extensive investment required to build a brand and develop/execute on advertising programs. In addition, since healthcare in the United States historically has been covered by either private or public healthcare insurance, patients are not accustomed to paying for their own healthcare products and often are hesitant to do so. However, consumers are becoming more amenable to spending some of their discretionary income on health solutions as they purchase everything from step counting and exercise/calorie management systems to glucose, heart rate, and blood pressure trackers.

Quick Example: Emme

Emme's mission is to put "women's health in women's hands." Their technology-enabled pill case ensures that women stay on schedule when taking their birth control pills. It's marketed directly to the consumer for a one-time hardware purchase and includes a free mobile app for health tracking and engagement (reminders, tips, etc.). The company also provides pharmacy services for women's health medications, starting with birth control. They take a percent of pharmacy sales with each prescription filled through Emme to create a recurring revenue stream for the company and charge $20 per month that is reimbursable to people with pharmaceutical coverage. They also offer a telemedicine application for $20 per year. Their business model is decidedly consumer-driven, relying on the patient to find value in their technology and associated services, which have evolved to managing a wide range of women's healthcare issues.

Businesses/Enterprises

Another approach is to sell your product directly to a healthcare "enterprise" that then uses the product to treat a defined patient population. One benefit of selling to enterprises is that they get your solution to patients on your behalf, offering significant patient access and the ability to scale usage. In most cases, this approach also allows the payment to flow through a provider rather than requiring the patient to pay out-of-pocket. In addition, enterprises usually compete for patient "business" and may seek to leverage new technologies as a way to improve patient satisfaction and outcomes.

Challenges with selling to enterprises include the extensive investment required to build an expert direct salesforce and the related sales tools required for successful sales, the need to find and develop key opinion leaders, and traditionally long sales cycles.

There are a number of different types of entities that fall into the enterprise category. Your company might choose to sell to one or many of these organizations. Your sales approach will differ slightly when selling to each of the following segments.

Physician Offices/Providers and Health Systems

Physician offices/providers are individual or small medical practices, while health systems are larger healthcare organizations that offer healthcare services to broader communities of patients (Sutter Health, Dignity Health, Cleveland Clinic, etc.). Both purchase health technologies to better serve their patients. They typically are paid through a "fee for service" model that garners reimbursement for covered medical services and products through private or public insurance. If your solution is reimbursable, they will prescribe it, receive reimbursement, and pay your company a fee for it. If the solution is not reimbursable, they will recommend it to a patient and pay you for it because they believe it will be mutually beneficial to the practice/system (additional billings, cost savings) and to the patient (outcomes), or they'll ask the patient to cover the cost directly. With larger health systems, you also may be able to charge program, set-up, and/or maintenance fees, if applicable.

Sales to these customers are typically direct. Some companies are able to sell to smaller practices through digital means, like telephone sales and advertising. But sales to larger practices and health systems almost always involve an expert direct sales force, require extensive clinical data to validate the technology, and benefit from the support of key opinion leaders (KOLs).[3] Sometimes you can work with a channel partner or other healthcare company (device, pharma, supplies, telehealth) to distribute your product to these customers.

Accountable Care Organizations

Accountable care organizations (ACOs) are groups of hospitals and clinicians that voluntarily work together to provide coordinated care to a defined population of patients with a focus on saving time and money. The concept of the ACO was first introduced in the Patient Protection and Affordable Care Act[4] (also known as the ACA or Obama Care) as a way to incentivize providers to optimize care delivery. Through better coordination, ACOs help ensure that patients receive both preventive care and the right acute care at the right time, with the goal of avoiding unnecessary expenditures linked to the duplication of services and emergency care situations. ACOs use a payment model called capitation, through which they're paid a specific amount to care for a patient and any part of that payment that is not utilized in the delivery of care goes to their bottom line – called "shared savings."

As this type of "value-based" care proves to be effective in improving outcomes while lowering costs, more health systems are adopting the ACO model. In some cases, health systems will offer capitated services to part of their population as a result of an agreement with either public or private insurance companies. If your technology provides preventative care, has strong clinical

validation, and/or improves outcomes at a lower cost, ACOs may be interested in including your product among their offerings. If your solution is reimbursable, ACOs will claim reimbursement and pay your company a fee for it [one-time or subscription on a per-patient, per-month (PPPM) basis]. You can also charge ACOs program, set-up, and/or maintenance fees if these services are required.

Integrated Delivery Systems

Integrated delivery systems (IDNs) are healthcare organizations that manage the complete healthcare value chain – from health insurance to primary, specialty and acute care, pharmacy, and ancillary services – for a defined population. As with ACOs, these organizations seek to optimize preventative care to deliver improved clinical outcomes at a lower cost. Examples of vertically-integrated delivery systems include Kaiser Permanente, Intermountain West, and Geisinger.

Much like health systems and ACOs, sales to IDNs usually involve an expert, direct sales force, extensive clinical validation, and the support of KOLs. If the IDN chooses to include your solution in its healthcare offerings, they will pay your company a fee for your solution (one-time or subscription on a PPPM basis). You also can charge an IDN program, set-up, and/or maintenance fees if these services are required.

Quick Example : iRhythm Technologies

Traditionally, when a patient complained of an abnormal heart rhythm, they would have to get a referral to a heart specialist, who would prescribe a device called a Holter monitor to try to detect and diagnose the problem. However, Holter monitors were inconvenient and uncomfortable to wear, and they only provided surveillance for ~48 hours. And because arrhythmias are episodic and unpredictable, the monitors often failed to return useful data.

Seeking to improve this care paradigm, iRhythm created the ZIO patch, which is a small, discrete continuous heart monitoring device that can be comfortably worn for up to 14 days. As a result, it captures more complete and conclusive diagnostics information. Additionally, because it's less expensive, front-line providers (rather than specialists) can provide it, streamlining the diagnostics workflow.

iRhythm sells the technology to a wide variety of enterprise customers based on the value proposition that it improves outcomes and reduces the overall cost of diagnosis. These facilities, in turn, are reimbursed for the technology by private and public health insurance companies.

Private Health Insurance Companies

Private insurers are organizations that provide coverage to individuals for health services. This coverage may be purchased directly by the individual or by the individual's employer. Examples of private health insurance companies include United Healthcare Group, Blue Cross Blue Shield, and Aetna.

As healthcare costs continue to mount, health insurance companies have become more engaged in providing preventative care and related ancillary products and services that improve customer outcomes. Some even provide their customers with health technologies, such as digital health apps and wearables, at no additional expense to support lower-cost preventative care. In some cases, health insurance companies also may directly purchase or partner with health technology companies on a larger scale. For example, Florida Blue Shield bundled Teladoc/Livongo with its

health insurance offerings, enabling any member, whether they purchase coverage directly or receive insurance through an employer, to use the telemedicine services provided by Teladoc/Livongo. Another emerging trend is for private insurers to implement capitated coverage programs to incentivize healthcare providers via a shared risk/reward model to deliver better outcomes at lower costs (e.g., Oncology Care Model).

Sales to health insurance companies are typically direct. Clinical validation is a key requirement of the sales process (e.g., study results that prove improved outcomes). If your health technology has been proven to significantly improve outcomes and/or prevent expensive acute care, it might be attractive for healthcare insurance companies to bundle with their offerings.

Self-Insured Employers

With self-insured employers (SIEs) or self-funded health plans, employers directly assume the financial risk for providing healthcare benefits to their employees. This approach requires them to use their own financial resources to cover their employees' medical claims. Most self-insured employers contract with an insurance company or independent third party administrator for plan management, however, the actual cost for medical services are paid for by the employer. Since SIEs bear the financial risk associated with their employees' health, they are interested in providing preventative and chronic care management offerings to reduce high per-employee costs associated with acute and emergency care. Examples of SIEs include General Electric, Albertsons Companies, Marriott International, and Walmart.

In certain sectors of healthcare, self-insured employers have been active direct buyers of health technologies. As SIEs are cost sensitive, they are increasingly offering their employees telemedicine, digital health, mental health, chiropractic, wellness, and other health solutions that they purchase directly on behalf of their employees.

Quick Example: Livongo Health

Chronic diseases present challenges to patients 24 x 7 x 365 days a year. However, these patients typically only see their clinicians 2-4 times a year. In between, they're expected to self-manage. Unfortunately, inconsistent health management causes higher absenteeism and lower productivity among employees with a chronic disease.[5] In addition, people with chronic disease are at a higher risk for comorbidities, further contributing to their reduced productivity in the workforce.

Livongo, now a part of Teladoc Health, offers a chronic disease management system that includes monitoring software, wearables, supplies, and coaching to help patients better self-manage conditions such as diabetes and hypertension. Using Livongo, patients also can share their health data with physicians and other members of the care team.

Through studies, Livongo has proven that people using their services maintain better health. As a result, they're able to sell their solution to self-insured employers, who in turn provide it as a benefit to their employees at no cost. These employers pay for the Livongo service on a PPPM subscription basis.

Government Entities

In the United States (and many other countries around the world), health services are subsidized or paid for entirely by public government funds. The US government offers the following health coverage options:

- Medicare – Federally-funded health insurance for people 65 years or older, certain young people with disabilities, and those with chronic kidney disease requiring long-term dialysis or kidney transplantation.
- Medicaid – Health insurance for low-income families and individuals. Jointly funded federally and by each state.
- Government employer plan – Health insurance provided to government employees, including those actively serving in the US military.
- Veterans Affairs – Health insurance provided to US military veterans.

Selling into government entities requires specific sales knowledge about government purchasing processes, and buying decisions can be slow. To be considered for adoption by Medicare and/or Medicaid, a company must be a "CMS Accredited Supplier," which involves sponsorship among other requirements (instructions for becoming accredited are available online[6]). Engaging KOLs to support your technology is also important. However, government programs include millions of people, which potentially offers health technology companies significant patient access and the ability to scale quickly. And, once you gain access and certification by a government entity, you generally have the ability to sell broadly across these groups.

As with private insurance, government entities invest in health technologies that provide comparable or better outcomes at a lower cost. Beyond providing reimbursement, they also will directly purchase certain healthcare innovations to offer directly to the citizens they cover. In 2020, the US Department of Health and Human Services spent over $4 trillion on healthcare services, and a quarter of that went to various "technologies." For more information, checkout the latest budget available on the HHS website.[7]

Partners

In a partnership, a health technology company enters into an agreement with a larger entity like a medical device, biotech, telehealth, or pharmaceutical company that then distributes your technology to their customers. Companies in these categories often are looking for ways to improve adoption, increase adherence, and/or extend the value of their offerings. Many add ancillary products to their core offerings by partnering with other healthcare technology companies. Some of these organizations may also use your healthcare innovation as part of an intervention in a clinical study.

The benefits of selling with or through partners is that they typically have expert sales forces and KOLs that you can readily access and train on your technology. Partnering also allows you to interact with a large number of clinicians and health systems that can help you quickly achieve more significant scale. On the other hand, when selling through partners, it can be time consuming to develop relationships and negotiate mutually beneficial agreements. These companies are also known for having stringent requirements for extensive clinical and technical validation. In addition, you run the risk of losing some control over your technology and how it's positioned, as well as becoming dependent on just a few partners for your revenue stream.

Quick Example: Glooko

Almost 30 million Americans have diabetes and must use various devices and medications to help stabilize their condition. 100% of people with type 1 and 30% of people with type 2 diabetes become insulin dependent.[8]

Glooko set out to help people with diabetes track their disease, understand drivers of poor blood sugar, and increase actions that improve health, including exercise, diet, and medication adherence. Because Glooko helps individuals adhere to their care plans – by achieving better control of their blood sugar and remembering to take critical medications – manufacturers of diabetes devices and pharmaceuticals saw value in collaborating with the company.

As a result, Glooko's partners distribute the Glooko system in combination with their own products, providing the company with access to patients and physicians who specialize in diabetes at a greater scale than the company could achieve on its own. These partners also pay Glooko for each of their patients who uses the Glooko digital health app. In addition, they pay Glooko for de-identified patient data and related analytics with patient consent (see Box 1 for more information about sharing and using patient data).

BOX 1

Sharing and Using Patient Data

When selling direct to the patient or through the various entities discussed in this brief, your buyer will have an interest in the end-user data that your product may capture. This data can be used for everything from providing customer support to the patient, to conducting research for product improvements and extensions. Health technology companies have the opportunity to provide raw data, as well as tabulated insights (with patient consent), as part of their business model. Patient data, and the associated insights it provides, can be a highly valuable component of your product portfolio.

Just remember that the Health Insurance Portability and Accountability Act (HIPAA) protects sensitive patient health information from being disclosed without the patient's consent. These protections are critical for your organization to follow. No matter what business model you choose, you should consider developing and publishing a patient "bill of rights" that specifically addresses the patient's rights to the information your product captures. HIPAA's Privacy Rule gives patients the right to an electronic copy of their healthcare data/records, if those records are kept digitally (such as in an electronic medical record) or are "readily producible" electronically (for example, the provider can easily scan a paper record and create a PDF). The Privacy Rule also gives patients the right of access, right to request the amendment of their protected health information (PHI), right to accounting of disclosures, right to request restrictions of PHI, right to request confidential communications, and ~~the~~ right to complain of Privacy Rule violations. Learn more online. [link to https://www.hhs.gov/hipaa/for-professionals/privacy/index.html]

Mutual Value

In addition to the innovation and the customer, the last critical component to consider when choosing a business model is how you bring those two together to create mutual value. Your health technology should deliver value to the economic buyer, direct user (e.g., clinician), and beneficiary (e.g., patient) by filling an unmet or poorly met need. The onus is on your company to identify where the value lies, and to prove that value to the customer. Health technology companies typically measure value in three ways: outcomes, economics, and engagement.

- **Outcomes**
  Measurable and proven clinical outcomes are critical for health technology adoption. Simply put, does your technology deliver the improved results you set out to provide? And do you have the clinical research and data in place to demonstrate these desired outcomes to your customer(s)?

- **Economics**
  Demonstrating economic value enables customers to justify their decision to buy your solution. If your technology lowers costs or increases the ability for a healthcare enterprise to generate new sources of revenue, customers can make a reasonable business case to support their purchasing decision.

- **Engagement**
  While it seems somewhat obvious, targeted user engagement, is important to all business models. Engagement often takes the form of repeat and frequent use, or active recommendations from the users of your product. Not all innovations offer equal engagement opportunities, and each type of innovation category will likely measure engagement differently. For example, with an implant, the clinical results associated with your technology are an important engagement proxy. But with software, recency and frequency of use are important measures of engagement.

Which Business Model to Choose?

For some technologies, the choice of a business model is clear. For others, there's no "right answer" so you must evaluate different options and choose the model that makes the most sense.

When making this important decision, carefully consider the characteristics of the technology you've invented, identify the entity that's most motivated to become your first customer, and then define a value proposition (and supporting business model) that will be mutually compelling. In many cases, starting with a "beachhead" market, made up of early adopters[9] who are highly motivated to try the technology, is a smart strategy for an early-stage technology company. This singular focus provides an unambiguous target for prioritizing activities and directing company resources, which can be helpful on a lean budget and when first getting started.

Other factors to consider include:

- **Precedent**
  What is the closest model you can use as a benchmark? Have others been successful at this model? Even if the answer is no, what can you learn from others who have tried it the past? Does a payment construct exist for this model?

- **Validation**
  Has the purchaser told you they understand the value of your technology and are willing to compensate you for it? If not, what steps do you need to take to demonstrate value that the customer will pay for? Who can you talk with to test/confirm that the business model you've chosen makes sense from a mutual value perspective?

- **Repeatability/scale**
  Are there enough decision makers and/or end-users in your beachhead market who are motivated to adopt? If not, what would your expansion strategy look like? Are there adjacent customer segments you could target to achieve your required scale? How much different is the fundamental value proposition for these other customer segments?

Keep in mind that your business model is not static. You might start with one model as a way to get the company off the ground, but then evolve your approach over time. Business models often morph as the company acquires more clinical data (see the Building Evidence toolkit), achieves new regulatory approvals that change the claims the company is able to make about its technology, qualifies for reimbursement coverage, "wins over" KOLs, and/or as incentives shift in the external environment. No matter what you decide initially, it's essential to continually monitor your need area for changes that may create new business model challenges and opportunities. Watch the video called Leveraging a Staged Business Model: Self-Pay While Seeking Reimbursement for an example of how one early-stage company approached business model evolution.

If you've invented a digital technology, check out the videos called Considerations for Digital Health Business Models and Decision Tree for Digital Health Business Models for additional guidance on choosing an optimal approach. You can access the Decision Tree referenced in the video under Additional Resources.

Credits

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Notes

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