

The background is an abstract, textured composition. It features a dark teal or blue base color, overlaid with intricate, organic patterns in shades of gold, bronze, and light blue. These patterns resemble marbled paper, liquid splatters, or perhaps microscopic biological structures. The overall effect is dynamic and futuristic. In the bottom right corner, there is a subtle grid of small white plus signs (+) on a dark blue background.

Venture Capital Ecosystems

A Report on Digital Health in the United States

CONTENTS

SECTION ONE

Introduction 03

SECTION TWO

**Industry Trends: US Digital Health
Venture Ecosystem** 05

SECTION THREE

The Investment and Market Landscape 07

SECTION FOUR

Methodology 24

Introduction

A watershed moment for the digital health industry, 2021 and 2022 revealed new paths forward for many companies and set the scene for a more favorable regulatory environment.

As the COVID-19 pandemic's ripple effects spread throughout the world, digital health technology became a necessary tool for meeting people's health care needs. This proved to be a massive accelerant to both funding and innovation across the sector.

In response, many digital health companies expanded, and deal values soared for early- and growth-stage investments. These developments introduced opportunities for digital health, but they also revealed new challenges, including increased competition, new operational demands, and a need for more judicious spend on capital.

Below is a look at what the early- and growth-stage venture ecosystem looks like and steps your company can take to stay competitive in the changing environment. We hope you find this report useful.



RICH CROGHAN

National Practice Leader
Life Sciences Practice

EARLY-STAGE VENTURE ECOSYSTEM AT A GLANCE

Throughout the 2010s, venture investment **rose steadily with scarcely a slowdown**, in both count and aggregate value.

In 2020, **deal value spiked as invested venture capital (VC) hit \$14.7 billion**—a staggering surge over the previous high of \$10.2 billion in 2019.

A flood of capital into the digital health start-up environment enabled companies to stay private longer; however, it also led to intensifying competition as the population of large, heavily funded, privately held digital health companies expanded.

Against a competitive market backdrop, the **challenges that digital health companies face across their life cycles range** from judicious spend on capital to liquidity options to fine-tuning operations to optimizing controls.

Investors in **early-stage digital health companies primarily focus on breaking financings into portions** tied to specific milestones, often including terms related to future liquidity events.

Many more **mature, growth-stage companies largely focus on proving out truly scalable systems** and processes at a level that public listings or prospective acquirers require in the face of soaring valuations.

Although **early-stage businesses saw competition accelerate**, they can help ease transitions by preparing in advance for regulatory and tax issues before revenue rolls in.

An expansion and diversification of the active investor population partly fueled growth in late-stage venture investment. Corporate players participated at a quickening pace throughout the 2010s as they joined in some of the larger financings on record, accounting for nearly \$6 billion of the total capital invested in 2020.

Striking partnerships with key publicly traded players and academia is another option that will pose fertile, if fraught, opportunities for early-stage digital health companies as well as helpful competitive differentiation for more mature businesses.

Holistic integration across systems—both technical and procedural—will aid in establishing necessary levels of sophistication across controls, whether pertaining to cybersecurity and critical health information on the part of users or more general processes.

The liquidity environment remains quite favorable, although firms should use caution as they assess the degree of preparation required, regardless of exit type. This is especially true given how rich valuations are and the high degree of competition within private financial markets.

Industry Trends: US Digital Health Venture Ecosystem

The COVID-19 pandemic proved to be a massive accelerant to both funding and innovation across the digital health sector.

“The pandemic shone a bright light on the need for increased collaboration across public and private spheres to better monitor the spread of diseases, manage stores and availability of supplies and therapeutics, and prioritize in times of crisis.”

– Jeremy Kuhlmann, Partner, Life Sciences Practice

The technical frontier of digital health includes more sophisticated wearables, a greater variety of diagnostics that people can use at home or on the go, and applications with user-friendly capabilities that are predicated on holistic care.

Especially in the United States, digital health start-ups will likely face considerable pressure to strike partnerships and consolidate given their need to integrate into existing health care systems.

Significant investment and innovation opportunities remain as health care systems work to solve conversion and integration issues caused by antiquated back-end digital infrastructure and other legacy technical systems.





In terms of policy, the pace of legislation and regulatory changes can be slow and at times unpredictable. However, it’s likely the signal achievement of the accelerated COVID-19 vaccine program will be the reappraisal of approval timelines for new therapies, especially those that are noninvasive and consumer-friendly, such as digital health.

As capital continues to flow into the digital health space, it’s likely that academic-industry partnerships will continue to flourish, with early-stage investors looking for a larger pipeline of investment opportunities and founders engaging with groundbreaking intellectual property.

Venture Capital and Investment Developments

<h3>\$14.7 BILLION</h3> <p>2020 saw record influx of VC into the US digital health ecosystem.</p>	<h3>388</h3> <p>Foreign investors piled into US digital health investment opportunities, joining in close to 400 completed rounds in 2020 alone.</p>
<h3>\$67.5 MILLION</h3> <p>The median late-stage VC valuation notches a new high in 2021 to date, closing in on \$70 million.</p>	<h3>\$9.3 BILLION</h3> <p>Investors have been rewarded with a surge in liquidity, with \$9.3 billion in exit value already achieved in 2021.</p>

Digital Health Ecosystem Innovations

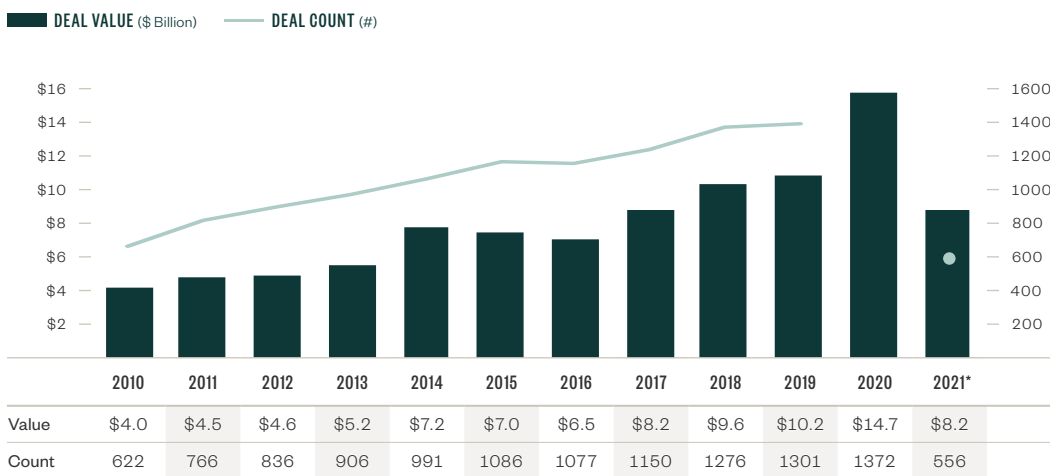
	INNOVATION IN ARTIFICIAL INTELLIGENCE (AI) -powered imaging, as well as sensors, helps improve the viability of home diagnostics kits and tools, with the goal of matching the accuracy of basic lab tests.
	NEW PROGRAMS such as the Digital Health Center of Excellence at the Center for Devices and Radiological Health launched to better coordinate governmental efforts within the space.
	PERSONAL-DATA SECURITY will be critical for winning the trust of consumers.
	HOME DIAGNOSTICS AND KITS continue to grow in popularity. Health care consumers will need to be educated in their proper use. Careful controls will be necessary to provide valid results, especially as investment in and focus on preventive care continues to intensify.

The Investment and Market Landscape

OVERVIEW

Even prior to the onset of COVID-19, which accelerated sectors critical to containing the coronavirus, digital health steadily grew in popularity among VCs.

FIGURE 1: US Venture Activity by Year for Digital Health



* As of May 11, 2021

Throughout the 2010s, venture investment rose steadily—in both deal count and aggregate value—with scarcely a slowdown. In 2020, deal value spiked, with VC invested hitting \$14.7 billion in a staggering surge over the previous high of \$10.2 billion in 2019. Volume also closed in on nearly 1,400 completed transactions.

2021 has yet to see a slowdown, with \$8.2 billion invested already as of mid-May across well over 500 financings.

“There was significant positive momentum within digital health prior to the onset of the COVID-19 pandemic, but the sheer array of products and services that can be provided remotely grew, stretching the boundaries of what’s feasible and accelerating innovation across the entire space.”

– Jeremy Kuhlmann

Multiple factors explain the decade-long, persistent rise in venture activity, but the following are the chief macrofactors:

- Falling costs in critical components such as sensors
- Rising health care costs, which incentivize providers and consumers to find more cost-effective solutions, especially in preventive care
- Aging demographics and the growing incidence of chronic disease, which combine to produce a clear need for continuous monitoring
- The proliferation of smartphones and wearables with sufficient power and capabilities to serve as diagnostic tools

“As the COVID-19 pandemic evolved, it became clear that health care consumers preferred digital communication.

Digital health’s development facilitated that shift in preference by expanding potential resources; however, as care becomes more personalized, it’s important that access be readily available to even those who aren’t technically well-versed, particularly in the preventative and diagnostic realms.”

– Rucha Bhatt, Senior Manager, Technology and Life Sciences Practices

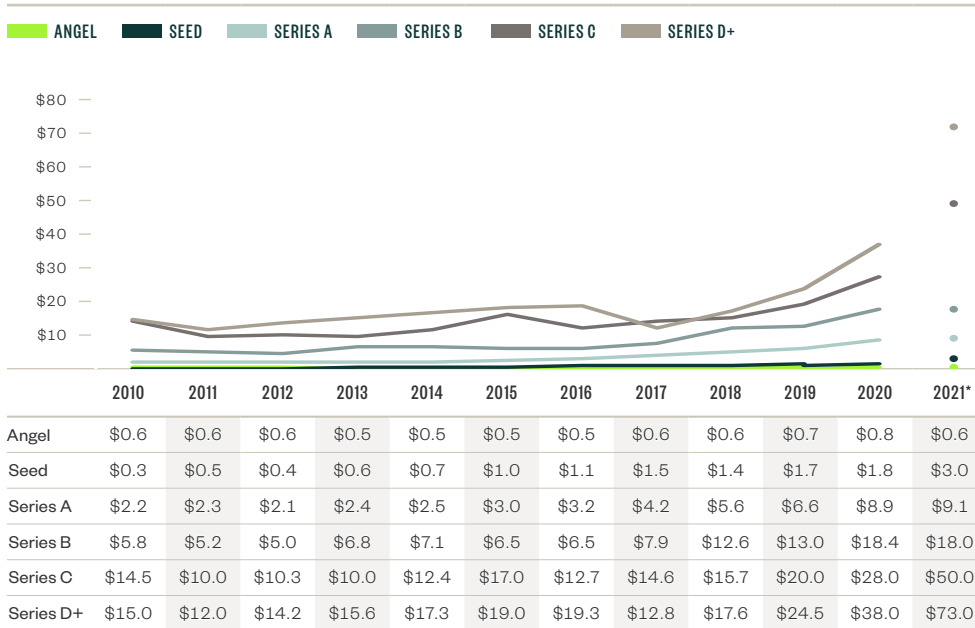
There are other drivers at play, but the confluence of those primary factors has enabled significant growth in both founder interest and investor activity. This is true across the digital health arena, with the expanse of market opportunities and creation of new segments in health care value chains.

As the 2020s unfold, the challenges that digital health companies face across their life cycles range from judicious spend on capital to liquidity options, fine-tuning operations, and enhancing controls.

MATURATION ACROSS THE LIFE CYCLE: EARLY STAGE

The robust growth in venture investment has also been reinforced by companies' successes as they continue to raise larger sums. Rapidly mounting VC overhang caused by the asset class's success as well as the growing popularity of alternative investments also enabled scaling.

FIGURE 2: Median US Venture Deal Size (\$ Millions)
by Series and Year in Digital Health

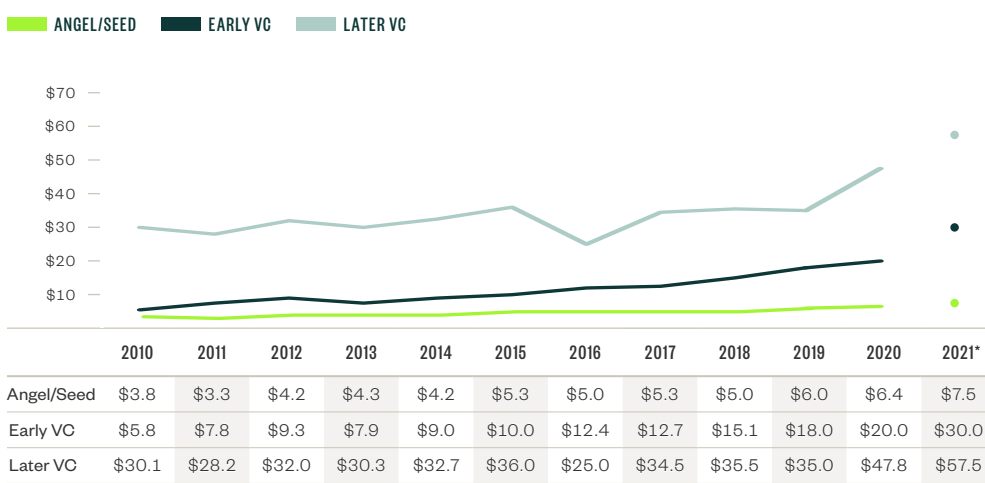


* As of May 11, 2021

Nearly every type of financing saw at least a gradual increase in median size, with the late stage seeing significant jumps to \$38 million in 2020 and \$73 million in 2021 to date—although at a non-normative population size of less than 30.

Valuations rose in tandem, surging to \$30 million thus far in 2021.

FIGURE 3: Median US Venture Pre-Money Valuation (\$ Millions) by Stage Over Type and Year in Digital Health

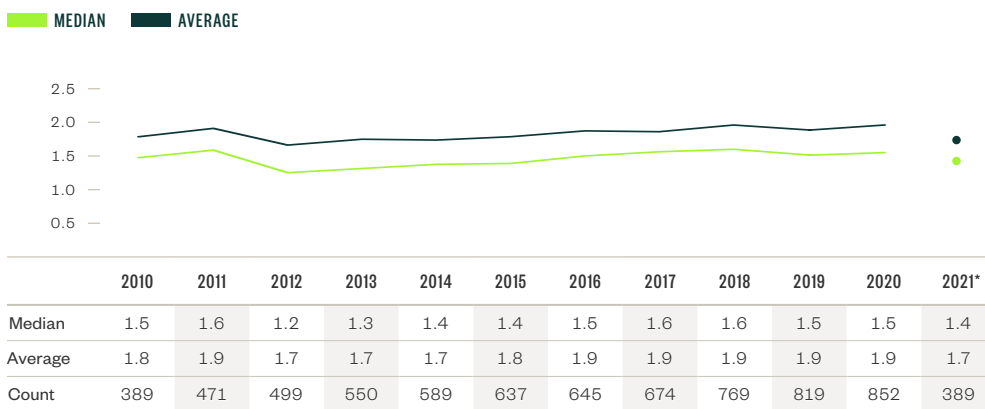


* As of May 11, 2021

As capital continues to flow into the digital health space, it's enabled companies to stay private longer and fundraise less frequently. At least, that was the case until 2021, when the time between rounds declined due to opportunistic fundraising on the part of founders.

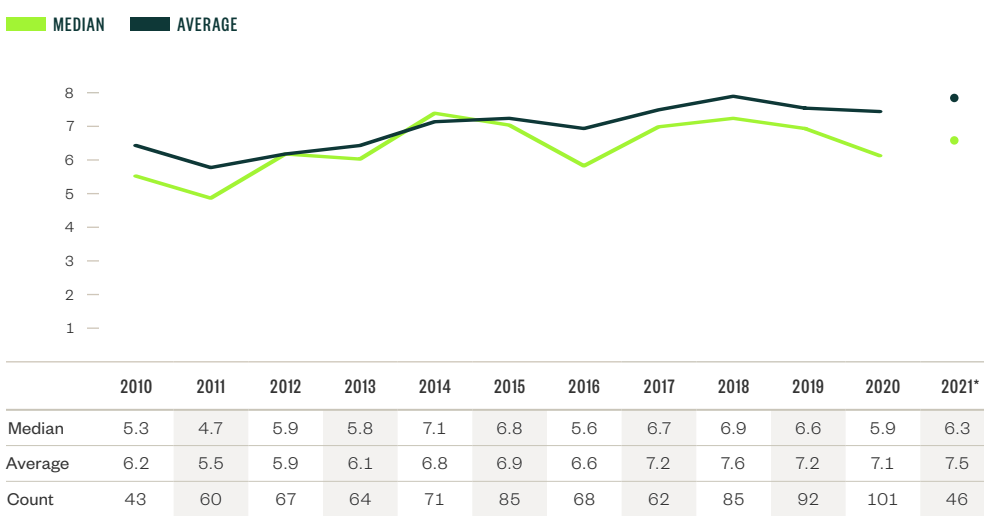
Moreover, the maturation of multiple digital health companies led to a tilt toward larger and later-stage financings relative to overall volume, and the average company age consistently exceeds seven years since 2017.

FIGURE 4: Median and Average Time (Years) Between Venture Rounds of US Companies in Digital Health



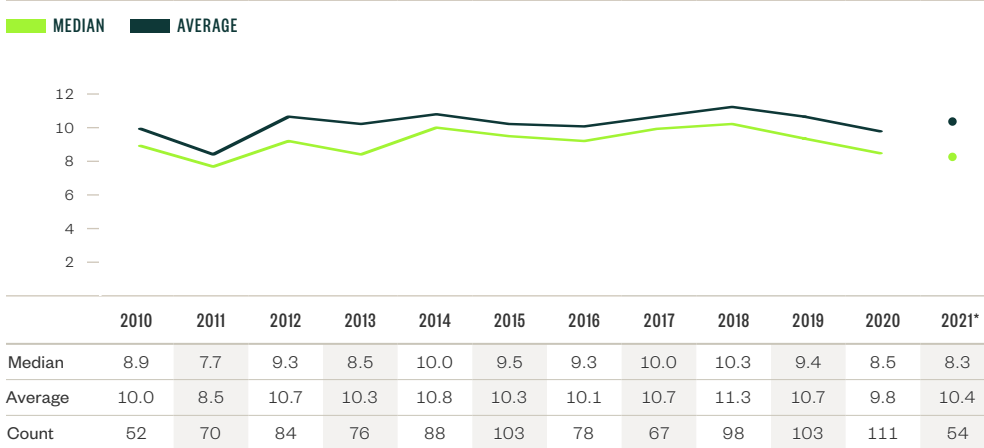
* As of May 11, 2021

FIGURE 5: Median and Average Time (Years) Since First Venture Round of US Companies in Digital Health



* As of May 11, 2021

FIGURE 6: Median and Average Time (Years) Since Founding of US Companies in Digital Health



* As of May 11, 2021

A less-explored aspect of digital health that’s highly important from a controls perspective is overall security of personal health information—especially as patient information proliferates across multiple systems. As a result, data integrity and accuracy will be paramount.

– Joan Taylor, Senior Manager, Internal Audit Services

What this entails for early-stage digital health companies is preparation for a wider variety of scenarios, depending on the types of financing events or transactions that seem most desirable or most likely.

Depending on the business model and overall availability of private capital, digital health companies arguably have more financing options than ever, but that in turn entails additional upfront work in assessing the best options. Beyond that, striking partnerships with key players may pose fertile opportunities for early-stage digital health companies.

“Finding investors that will provide more than just capital is critical in a rich environment. Especially at the early stage, companies need strong, experienced investors that can offer expertise in relevant areas.”

– Jeremy Kuhlmann

For investors in early-stage digital health companies, the primary focus is on breaking financings into tranches tied to specific milestones—often including terms related to future liquidity events.

Given that valuations rose significantly and companies can opt to stay private longer, scenario-based plans for differing rates of growth—even exponential rates—should be considered.

Rapid growth can often create challenges across organizations when innovation outpaces infrastructure. Especially at the early stage, a head start in preparatory planning can pay dividends later.

Key areas of focus through a capital deployment lens include required resources for personnel, compliance, and IT infrastructure. Other focus areas that can apply to digital health companies at all stages, but are best tackled in advance, span risks and associated controls, particularly as they relate to personal health information.

It can be expensive to set up proper controls and security protocols, but breaches are likely to be far more costly. It’s also easier to set up these processes from the beginning.

“It’s never too early for a digital health company to plan for enterprise risk assessments, particularly with an eye toward a privacy perspective, as regulations continue to tighten around personal data.”

– Joan Taylor

Beyond capital deployment across those focus areas, companies looking to form partnerships will need to be prepared for unique terms in collaboration agreements.

Especially for fledgling businesses, sculpting the commercial terms with customers to align with preferred patterns of revenue recognition can help eliminate ambiguity and confusing, subjective estimation.

It’s also best to prepare early in a company’s existence for client-base expansions and any possible partnerships across multiple jurisdictions.

Beyond simpler matters such as registration, the administrative burden of taxes and general business operations across regions can be significant—especially as states continue to evolve their various approaches. As companies continue to expand into more mature growth stages, federal legal requirements play a significant role as well.

“Digital health companies are increasingly subject to sales as well as indirect and income taxes across state boundaries. Digital health companies can cross borders easily as they expand markets, so they should be ready for these issues and any indirect tax burdens. Moreover, states are now more aggressive in pursuing companies that are subject to this overall tax burden, which raises the stakes for compliance and proper reporting.”

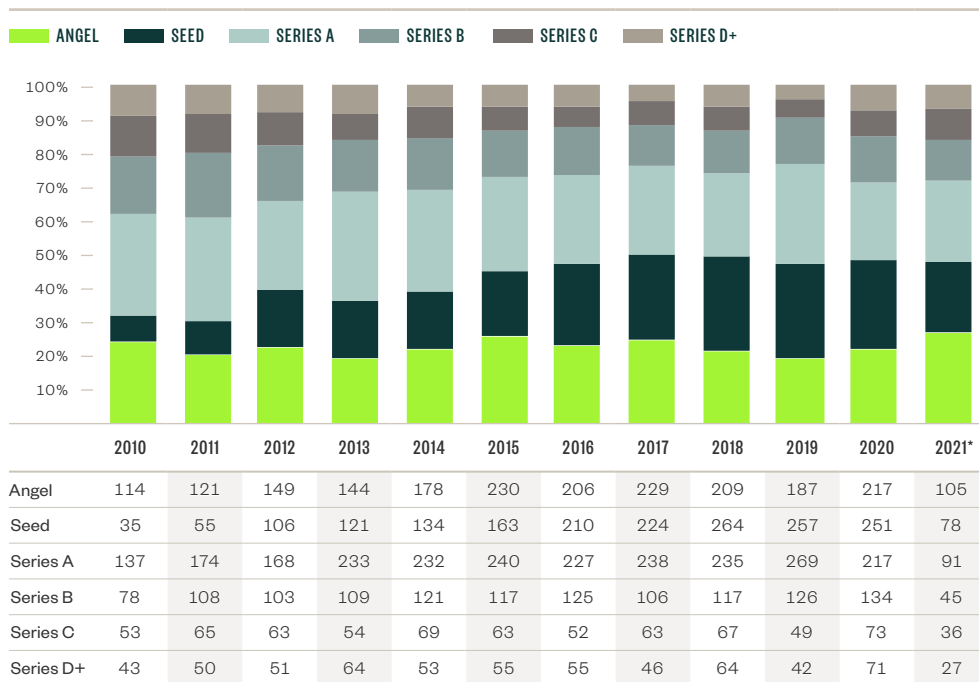
– Rucha Bhatt

MATURATION ACROSS THE LIFE CYCLE: LATE STAGE

The increased amount of cash investors devoted in the late stage of companies’ life cycles was fueled in part by expansion and diversification of the active investor population.

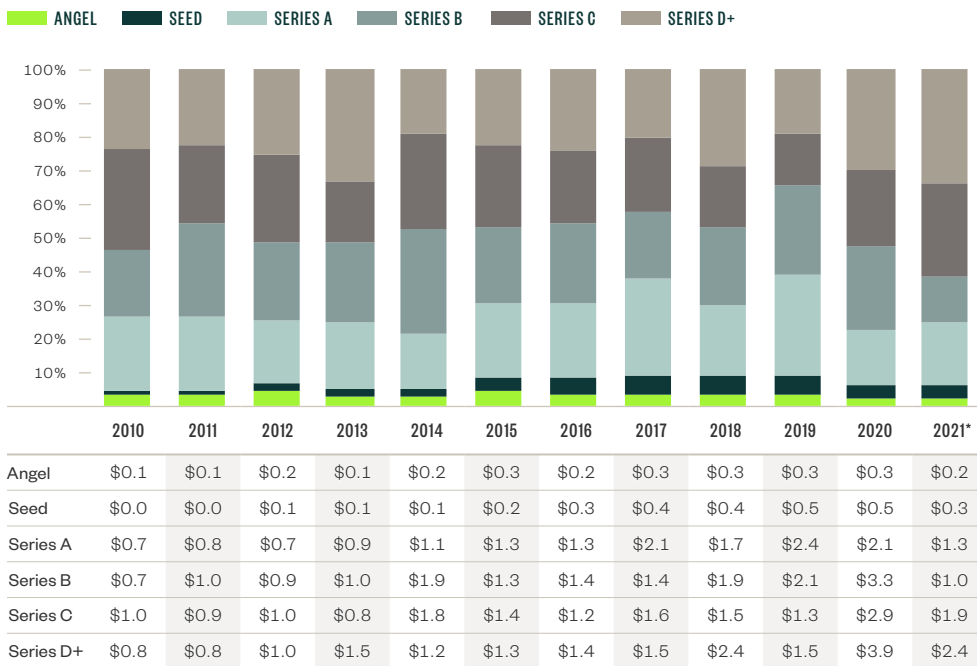
Corporate players participated at a quickening pace throughout the 2010s as they joined in some of the larger financings on record, accounting for nearly \$6 billion of the total capital invested last year.

FIGURE 7: US Venture Activity (Number) by Series in Digital Health



* As of May 11, 2021

FIGURE 8: US Venture Activity (\$ Billions) by Series in Digital Health

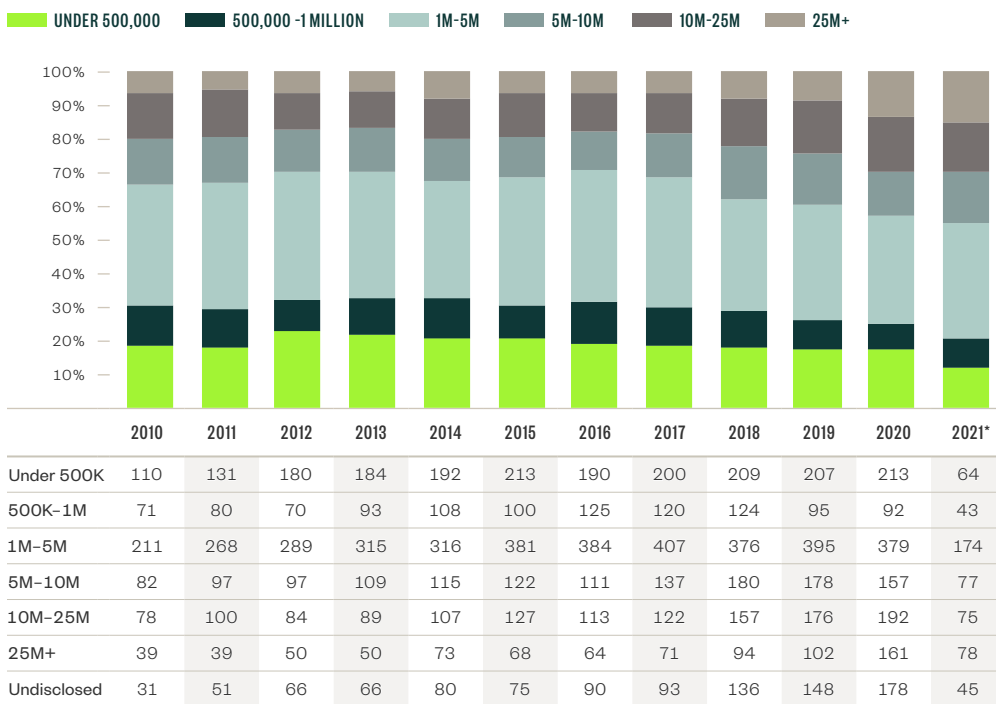


* As of May 11, 2021

Nontraditional investors such as hedge funds or private equity (PE) firms also became more active, boosting activity. This was especially true at later stages, in which company sizes and growth rates better suited their investment mandates.

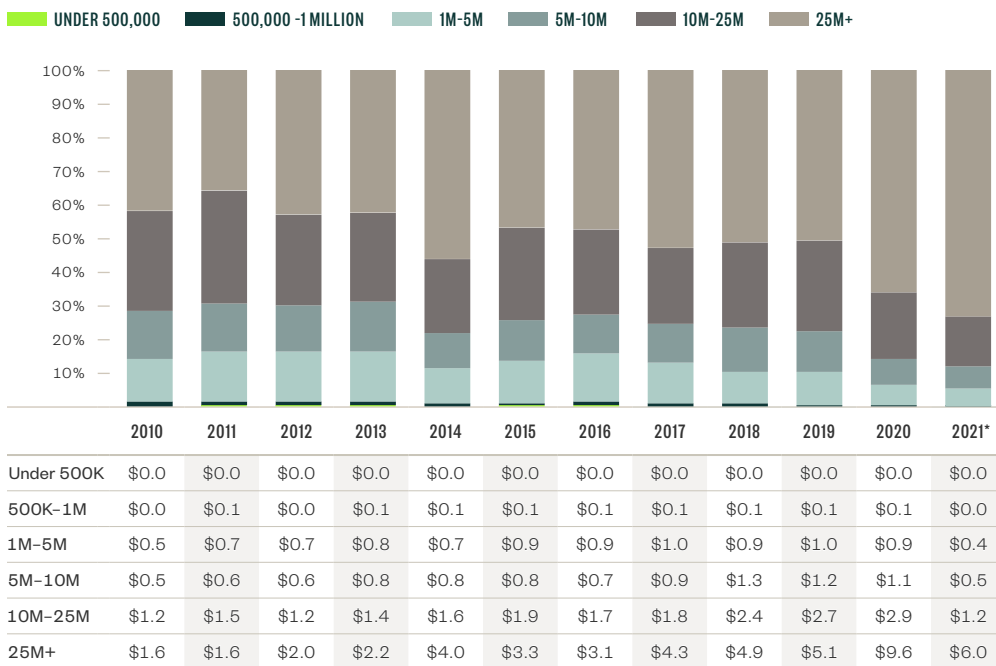
This activity fueled a consistent shift in the proportion of deal value in later-stage stock series, with Series D or later rounds already seeing no less than \$2.4 billion as of mid-May. Additionally, 2021 has already recorded close to 80 rounds of \$25 million or more, eclipsing 2017's entire output.

FIGURE 9: US Venture Activity (Number) by Size in Digital Health



* As of May 11, 2021

FIGURE 10: US Venture Activity (\$ Billions) by Size in Digital Health



* As of May 11, 2021

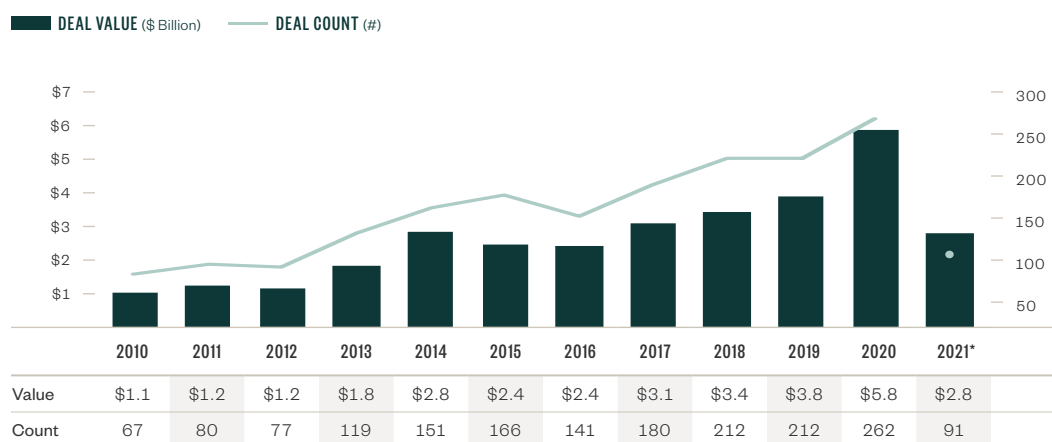
“Companies scaling rapidly introduce a new strategy that might not consider the strain placed on current resources. Focuses can too often become about meeting an imposed rollout rather than ensuring adequate organizational structure for support. The benefits sought, even if achieved, aren’t necessarily sustainable if people, processes, and systems struggled significantly to keep up.”

– Joan Taylor

With this maturity comes increasing expectations from investors and boards regarding scale and timelines to liquidity. Additionally, the challenges early-stage companies tend to face carry over into later stages, but they’re amplified across geographies, markets, and customer bases.

Even some larger companies in digital health face a landscape of heightened competition, given how much capital has flown into the space—not to mention heavy investment into R&D and consumer-centric improvements to existing products by incumbent health care companies.

FIGURE 11: US Venture Activity with Corporate Participation by Year in Digital Health



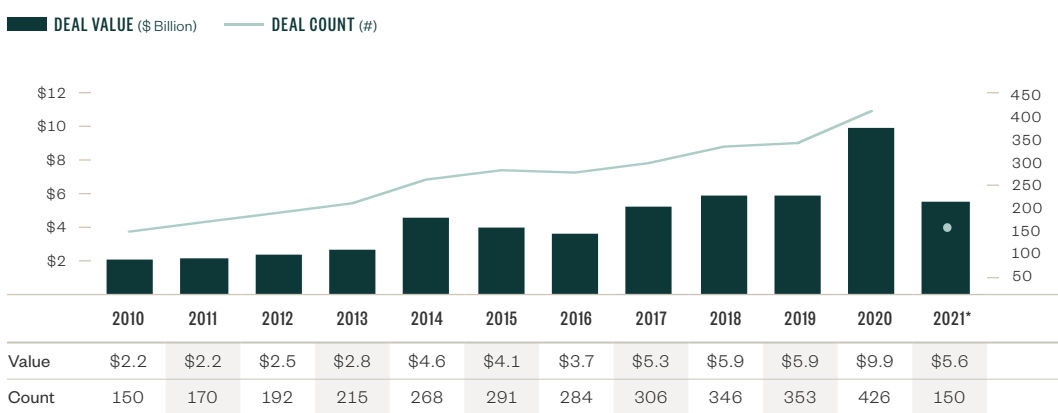
* As of May 11, 2021

While increased wealth in the digital health space has benefits, accounting becomes more challenging as capital structures grow more complex in later funding rounds.

To find the best approach, companies must analyze in depth the implications of fundraising vehicles. These include convertible notes and preferred stock, versus the potential for venture debt given increasingly stable, recurrent cash flows.

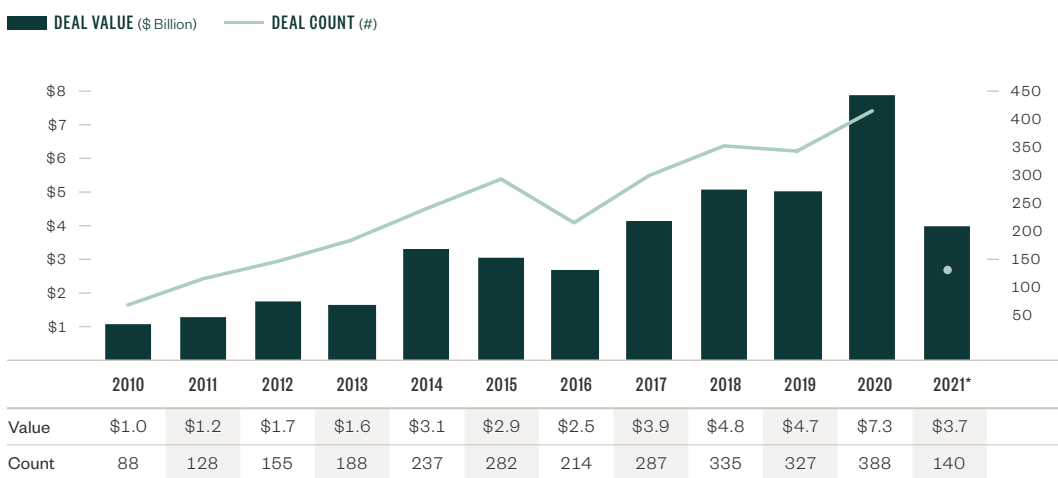
Talent grows increasingly expensive as companies look for teams that can take them to the next level. This means planning for stock-based compensation as liquidity events loom on the horizon for many companies. And all the while, competitors perform the same preparations and tap into the same capital markets as previous years.

FIGURE 12: US Venture Activity with Nontraditional Investor Participation by Year in Digital Health



* As of May 11, 2021

FIGURE 13: US Venture Activity with Foreign Investor Participation by Year in Digital Health



* As of May 11, 2021

“Many companies have such high valuations and expectations within the market that it can be difficult to remain disciplined as competitors raise even more capital. Taking the more conservative approach by choosing select advisors and partners and being judicious with the right investor mix, especially at the mature growth stages, can ultimately produce better cash flow management and maintain trust.”

– Rucha Bhatt

However, the critical distinction for mature, growth-stage companies—as opposed to earlier-stage digital health companies—is balancing maintenance with preparation, all at much greater scale.

Fine-tuning operations across a more complex organizational structure requires more sensitivity to strategy and longer-term implications.

For example, the stakes surrounding cybersecurity only rise in tandem with scale and consumer base growth. This requires establishing better integration across tech stacks and clear best practices across teams.

At a certain enterprise size, companies must consider the trade-off between in-house development versus outsourcing certain processes to trusted third parties. This decision should largely be contingent on available resources and potential efficiency gains from decentralizing procedures such as system testing, product-market fit, and more.

“As the organization grows, it only becomes more challenging to capitalize on internal software stacks against the backdrop of software that’s to be sold or marketed—in addition to ongoing external product and website development. This is because rolling out new tools, either externally or internally, comes with greater potential business implications and consequent logistical hurdles.”

– Jeremy Kuhlmann

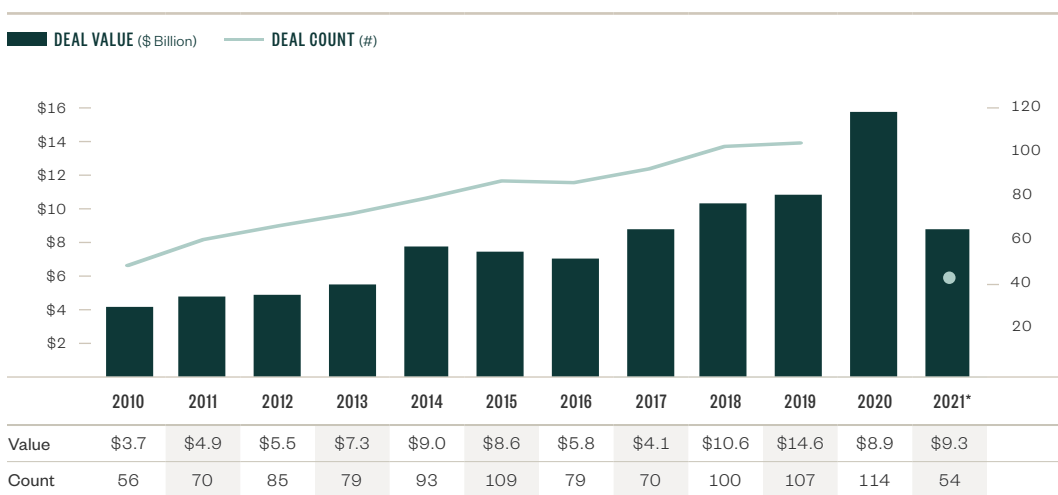
However, mature digital health companies can continue to focus on business expansion once they can maintain interoperability and achieve consistency of scalable processes. At a certain point, rapid-yet-sustainable growth should lead to an opportunity to prepare for liquidity scenarios that best suit the business.

LIQUIDITY PREPARATION

Liquidity for digital health companies has been remarkably robust from 2017 to 2021, although even the mid-2010s saw robust peaks. Between 2018 and 2020, 100 or more completed exits occurred, aggregating just over \$38.2 billion in exit value.

Moreover, 2021 has already experienced a surge in exits across the digital health space, with total exit value handily eclipsing the entirety of last year’s tally. Volume is paced to set a similar record.

FIGURE 14: US Venture Exits by Year in Digital Health



* As of May 11, 2021

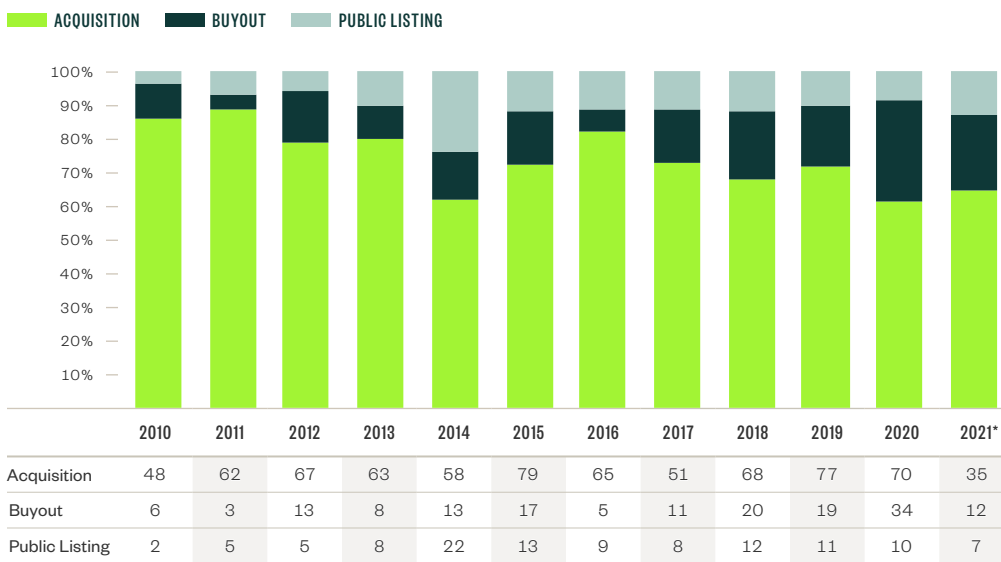
In short, it’s a welcoming exit climate by all metrics. Breaking down exits by type, it’s apparent that the remarkable run in publicly traded equities over the last few years boosted the debuts of a handful of digital health companies. Those exits accounted for close to half of all 2020 exit value alone—notwithstanding the proliferation of additional exit avenues.

“Going public is often the best option for a truly large capital raise, but the degree of preparation and timeline of public listings can seem daunting given the amount of administrative, operational, and marketing preparation. There have been recent signs of change in alternative access routes, such as direct listings or special purpose acquisition companies (SPACs). However, neither necessarily diminishes the amount of work that must be done, which often brings unexpected administrative challenges.”

– Rucha Bhatt

In the early 2010s, acquisitions accounted for the bulk of exit volume. Since then, the relative proportion of buyouts by PE players grew steadily. Last year saw a new high of 34 completed buyouts of digital health enterprises.

FIGURE 15: US Venture Exits (Number) by Type in Digital Health

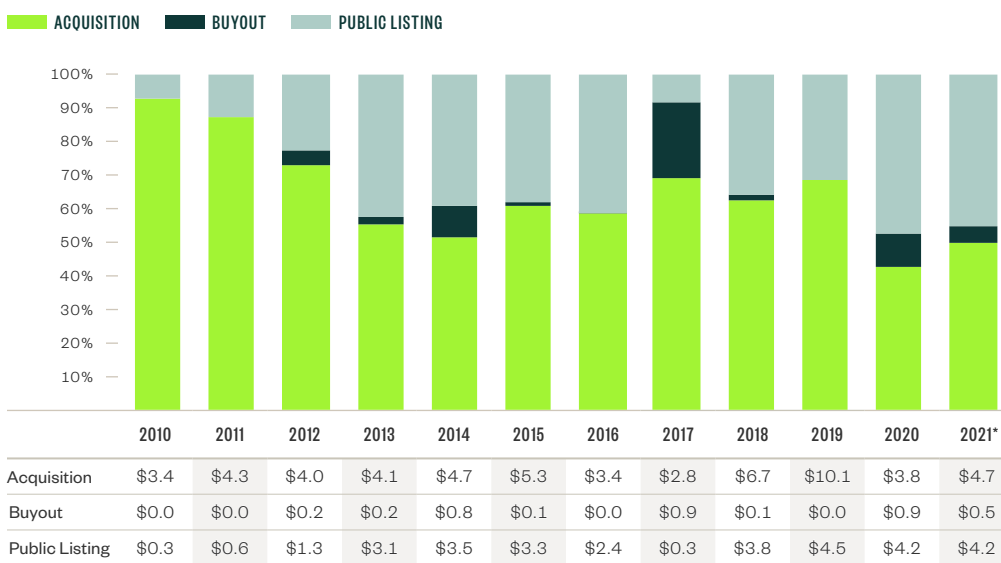


* As of May 11, 2021

The macrotrend of PE firms pushing into the software space definitely acted as an invigorating backdrop to this surge and broadened the variety of liquidity options for digital health companies.

In turn, the SPAC phenomenon produced ample pools of capital that are likely to intensify the pace of acquisitions of privately held companies over the next 18–24 months. Privately held digital health companies past a certain size threshold may well come into the acquisitive scope of SPACs hunting for targets.

FIGURE 16: US Venture Exits (\$ Billions) by Type in Digital Health

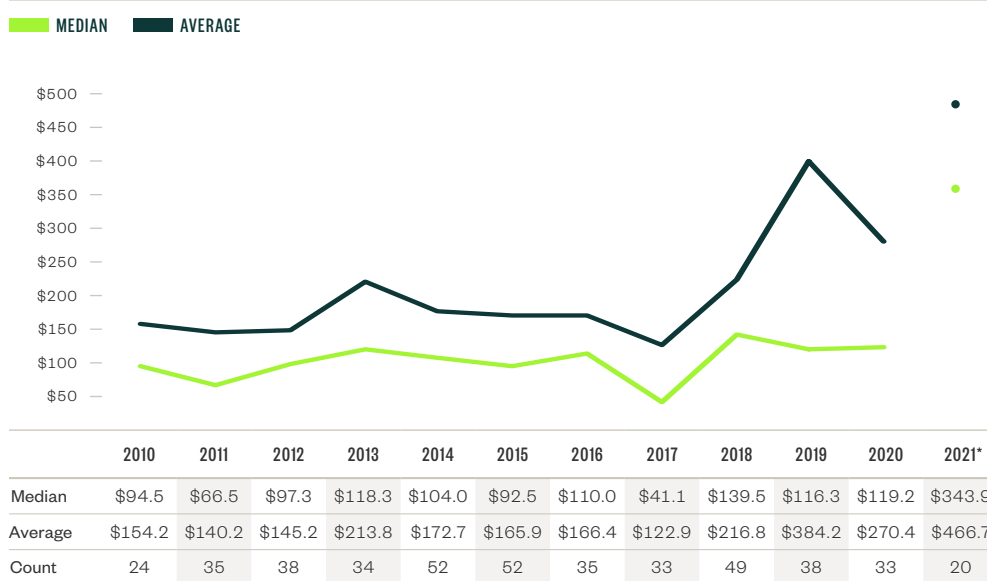


* As of May 11, 2021

Granted, there are ongoing implications regarding potential changes in warrants for SPACs—plus the hurdle of Sarbanes-Oxley-related requirements tied to the de-SPAC event itself—that must be noted with caution.

Growth in the average exit size for digital health companies suggests that select businesses could command premiums upon liquidity events. Premiums would have to be predicated on clear demonstration of sustainable, scalable processes and infrastructure as well as proven metrics—especially given the highly competitive nature of the digital health environment.

FIGURE 17: Average and Median US Venture Exit Size (\$ Million) in Digital Health

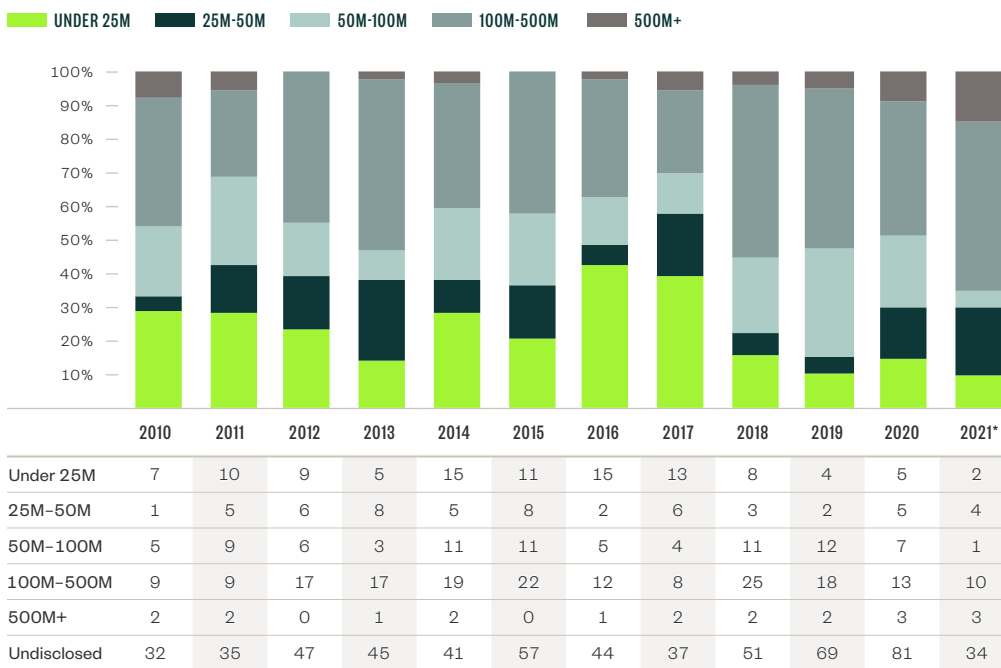


* As of May 11, 2021

That said, as exits have generally trended larger of late, the outlook is promising for both financial backers and the businesses themselves. Key points of differentiation will include proven interoperability across patients’ entire continuum of care.

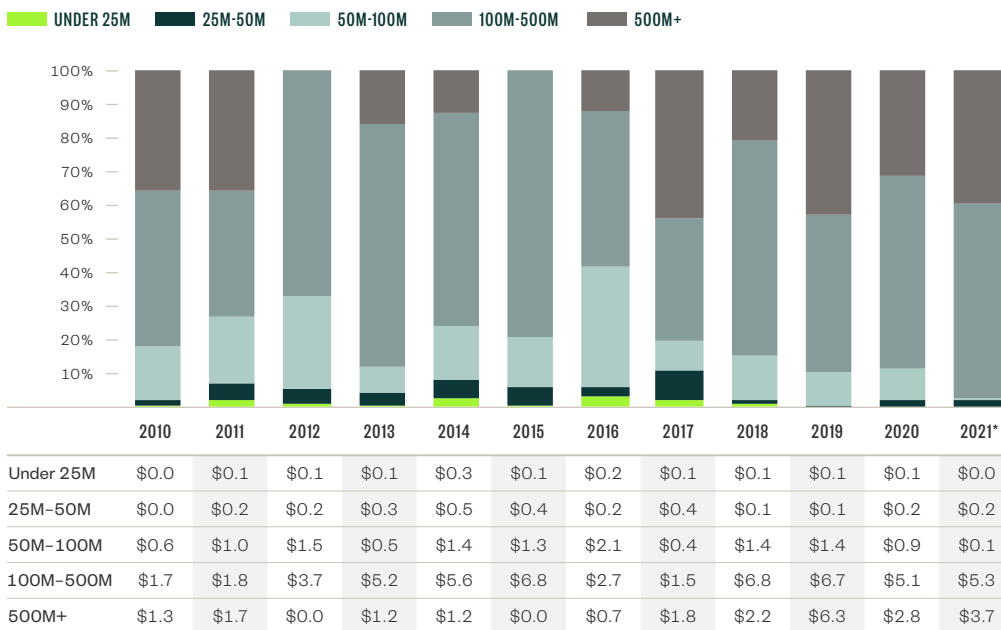
The ability to scale across multiple markets will help deflect questions around merging with established rivals. Using tested controls and monitoring tracking systems for risks could also be differentiating factors, signaling both maturity and sophistication.

FIGURE 18: US Venture Exits (Number) by Size in Digital Health



* As of May 11, 2021

FIGURE 19: Figure 21: US Venture Exits (\$ Billions) by Size in Digital Health



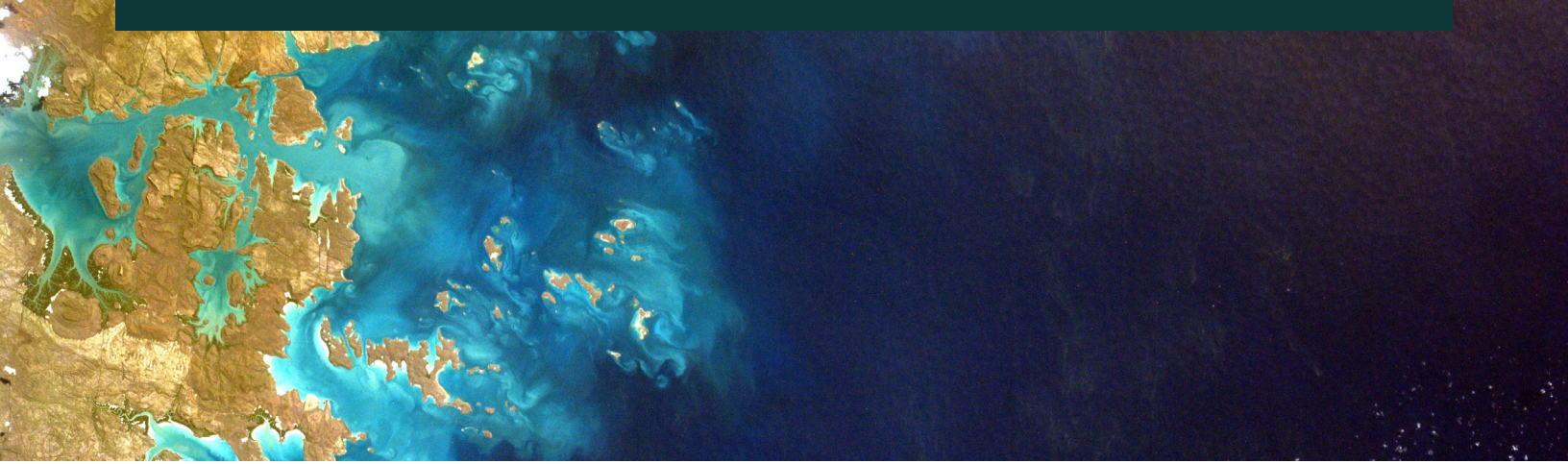
* As of May 11, 2021

“Even as competition for good businesses accelerated valuations, prospective acquirers still expect even early-stage companies to exhibit full-scale preparation, including audited financial statements. Clearing this hurdle could require a sprint on the part of the company.”

– Joan Taylor

Digital health businesses remain poised to grasp significant growth opportunities given acceleration of the digital health ecosystem throughout the 2010s as well as the unprecedented push for remote health care caused by the COVID-19 pandemic.

However, the odds of success are high if companies sufficiently invest and prepare across operations, finance, sales, and personnel. They should also fine-tune how they approach challenges such as cybersecurity, integration, and interoperability.



SECTION FOUR

Methodology

- *Digital health* is defined using the PitchBook industry codes of Healthcare Technology Systems and Healthcare Devices and Supplies.
- Each company in the underlying population had to have at least one of those industry codes tagged as its primary industry code.
- Standard PitchBook methodology regarding venture transactions and venture-backed exits used for all datasets.
- All data is as of May 11, 2021.

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