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Turning The Dial Up On Digital

by Jo Shorthouse

The maturation of digital offerings, coupled with commercially and clinically successful partnerships, has enabled huge investments in the digital health industry.

The reasons driving alliances and deals between pharma and digital health have been well documented; the need for innovation without internal capability, the need to remain commercially competitive through the addition of data and analytics, the weight of evidence to prove value to regulators and payers, and the evolution into patient-centric organizations through new forms of engagement.

Indeed, some companies are investing in complete internal digital transformation to become value-driven innovators. In December, Japanese pharma major *Astellas Pharma, Inc.* detailed its digital transformation strategy, which it described as the "best mix of digital and people."

This overhaul is underpinned by figures from Deloitte's Japanese consulting team that estimated the use of digital technology could reduce the cost of drug R&D by 60%, reduce the time to market by 2.4 years, and advanced analytics could improve pretax earnings for pharma by 45%-75%.

"We are at a turning point where there is a commercial perspective," Adrien Rousset, *Amgen, Inc.*'s head of augmented diagnostics, told to *In Vivo*. "Before, it was just ideas. Now that pharma can see clinical applications and potential revenue, there is an acceleration in dealmaking and partnerships."

Rousset was behind one of the first major digital deals – a collaboration with French American startup Owkin – when artificial intelligence was "just a concept" in 2016. Amgen was Owkin's first pharma client.

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For five years, the pair have been collaborating on projects across cardiology, hematology and oncology to develop clinical applications for AI, and have recently announced the results of a three-year project to use AI to predict cardiovascular risk more accurately. This study, the results of which were published in the European Heart Journal in December 2021, demonstrates the ability of AI to improve the way that clinicians predict patients' risk of suffering major cardiovascular events, such as strokes and myocardial infarctions.

There was industry skepticism about the use of AI in 2016, but to Rousset it was clear that something huge was happening. “Every time you pitch at a pharma company, they want to see evidence that it has worked before. Amgen allowed innovation and risk taking to happen,” said Jean-Frédéric Petit-Nivard, Owkin’s senior vice-president of commercial and product strategy. “Adrien had to convince people internally at Amgen, managing expectations and concerns was an essential part of the project in the beginning.”

A Natural Maturation

Five years down the track, and the maturation of digital health offerings coupled with commercially and clinically successful partnerships, has enabled huge investments in the digital health industry, and not just from the biopharmaceutical industry.

In 2021, Biomedtracker recorded 53 deals and alliances between pharma and digital health companies. The industry has been experimenting with many different approaches to integrating digital methods into a variety of therapeutic areas, as well as augmenting and streamlining manufacturing methods, and internal processes.

Indeed, Paris-based Owkin has also been a beneficiary of this accelerated investment. In November 2021, it became a ‘unicorn’ – a startup valued at over $1bn – through a $180m equity investment from *Sanofi*, announced alongside an exclusivity deal to work on four types of cancers, worth $90mupfront.

“The industry is maturing. Pharma companies understand that there is a novel way of working which can find fresh and enhanced results by leveraging AI in a different way,” Owkin’s Petit-Nivard told *In Vivo*. Of course, the interest in digital health companies is not unique to pharma, investment in the space is at an all-time high, according to figures from Rock Health.

Stellar Investment

In its end of year update, 2021 year-end digital health funding: Seismic shifts beneath the surface, Rock Health research found that 2021's total funding among US-based digital health startups amounted to $29.1bn across 729 deals, with an average deal size of $39.9m. Overall investment nearly doubled 2020's $14.9bn former record haul.

Rock Health figures show that corporate venture capital firms (CVCs) participated in 296 US digital health funding deals in 2021. Provider CVCs participated in 106 deals, while biopharma CVCs participated in 27 investment deals. Investor Michael Greeley, co-founder and general partner at Boston, MA-based Flare Capital, described the investment activity around digital health in 2021 as "frenetic, borderline frothy, but terribly exciting."

Valuations for digital health companies are certainly high. In many cases, these valuations anticipate exceptional performance, explained Megan Zweig, chief operating officer at Rock Health. "It's an extraordinary market right now. There will be winners, but there will also be companies which do not hit those growth targets, and that is going to be a really tough time for both investors and companies."

Digital health companies catalyzing R&D in biopharma and medtech topped the investment charts, with $5.8bn in funding, stimulated by the COVID-accelerated adoption of real-world evidence and decentralized trials. Investments in digital products supporting disease treatment grew 2.6 times between 2020 and 2021 as coverage pathways for prescription digital therapeutics widened.

In addition to this rising tide of investment, there was also an uptick in alliances and dealmaking between pharma and digital health companies. In 2021, the US saw 272 merger and acquisition deals in which a digital health company was the target. Biopharma companies were the acquirers in eight of these deals, while health care provider organizations were the acquirers in three.

Rock Health's mission is "making health care massively better for every human being" through its advisory firm, investment fund, and non-profit. Zweig oversees the company's corporate membership program, advising companies strategizing their digital health moves. Anecdotally, Zweig has noticed that pharma has increasingly taken a more strategic and intentional approach to digital innovation. "In the early days of digital health, pharma companies were dipping their toes with a partnership here or there. Now, there is a more curated strategy for these pharma companies to get deeper into digital health. They are making intentional decisions about which innovation models to leverage to pursue their strategic aims — from investment to accelerators to joint development partnerships to acquisitions," she highlighted.

The COVID-19 Effect

Flare Capital's Greeley emphasized the "COVID effect" on the stellar investment numbers. In a

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short period of time, the health care system had to become virtual, real time, on-demand, much more intelligent and responsive. All those capabilities required innovative new technologies. "There was extraordinary reprioritization of budgets to enable that in the face of the pandemic, and the downstream effect is that a number of entrepreneurs get excited, start companies and raise capital to build companies," he said.

Zweig expects to see strong and continued investment in the R&D space. "COVID has brought heightened visibility and opportunity to this [digital] space. Pharmaceutical companies that may have had hybrid or virtual clinical trials on their strategic map in a few years' time have pulled those hybrid trials forward."

Policy dynamics are also changing. COVID was a really important time around regulation for decentralized, hybrid and remote clinical trials. The industry is seeing investment in lock step with those regulatory changes.

Digital solutions for pharma companies that may adopt a hybridized work stream in the future are receiving considerable investment, explained Adriana Krasniansky, health researcher and author of the Rock Health report. While some of the world could work remotely during the pandemic, many laboratories had to continue – increasing interest in companies that offer hybrid collaboration tools or automated execution software for pharmaceutical manufacturers, such as digital health startup Apprentice.

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The pandemic caused a lot of people to focus on their mental health and wellbeing, in addition to exacerbating symptoms in those already living with mental health conditions. This has not gone unnoticed by investors. Flare Capital is "crawling all over" potential investments, Greeley told *In Vivo*, along with many other interested parties.

Indeed, according to Rock Health figures, digital health startups offering mental health care raised $5.1bn in 2021, $3.3bn more than any other clinical indication last year, and nearly double 2020's funding total. This has been driven by the integration of mental health services into broader virtual care platforms, as well as the rise of virtual options for intensive mental and behavioral health needs, led by companies like Lyra Health, NOCD and Equip Health.

For pharma it was no different, 2021 was bookended by alliances showing the industry's appetite for digital applications in the mental health space. In early 2021, Otsuka Pharmaceuticals and digital therapeutics (DTx) company *Click Therapeutics, Inc.* announced a new remote clinical trial to measure DTx interventions effectiveness on adults with depression. Fast forward to December 2021, and *Biogen, Inc.* and *TheraPanacea* inked a $15m neuroscience collaboration to leverage machine learning analysis to develop digital health solutions that may improve patient care and accelerate drug development.

Consolidation And Cannibalization

With so many digital health startups in many categories, consolidation is not far from the minds of investors like Greeley, who provide seed and early round funding for young companies with good ideas and the technology to back them up. The industry is in a market-defining era of investment, he believes, not a bubble.

Rock Health's Zweig concurred: "Cannibalization may happen in some spaces. But currently, there's a lot of win-win in terms of partnering with virtual care, monitoring and navigation solutions because they can be so complementary to traditional therapeutics. It makes offerings more competitive and differentiated relative to competitors."

Greeley believes the digital startup space is in an "anoint the winner" phase, whereby companies are raising very large rounds of capital to differentiate in the market, in part to recruit, but also to show real distinction from the pack. Certain digital health categories, FemTech, for example, may have up to 40 startups, some of which have raised $100m rounds and are looked at just very differently from the rest of the pack. "If you just looked at other industries that go through these cycles, out of these cycles come enduring big companies, and I think we're in that phase right now," Greeley explained. "There's real urgency to become a category leading company."

The health care industry will be able to absorb the small companies "quite productively," he said, unlike the dot-com crisis from 20 years ago or clean tech from 10 years ago.

2022 And Beyond

In its 2022 deals outlook, PricewaterhouseCoopers (PwC) said it expects M&A investments to reach $350bn to $400bn this year, driven by all subsectors. The continuation of the $5bn to $15bn biotech deals, combined with medium-sized pharma ($50bn) and medical device ($25bn) deals is expected to drive significant investment dollars in M&A.

Investments will remain high in all subsectors, it predicts, not just in procuring digital health capabilities. However, the ever-changing regulatory landscape, the potential for US and global tax reform, and the continued focus on the affordability of drugs will remain issues that the sector will need to consider when executing deals in 2022 and beyond.

Specific to digital health companies, there are three forces mixing to make 2022 another significant year for investment – even if it is not as frenzied as 2021. The "Great Resignation," not only in the US, will leave companies looking for new talent acquisition strategies, venture-backed startup companies rich with capital will have to make good on their growth expectations, and competition between digital health companies will intensify as players seek to win their subsector.

Overarching all these factors is the fact that health care is changing, and the future of medicine is personalized. Amgen's Rousset believes that "only data-driven precision medicine can integrate the huge amount of data that is required to have a full understanding of the patient. AI is game changing and will support this shift."

Personalized, in a different sense of the word, is the potential in novel care delivery, care in non-traditional settings such as virtual care in the home. "We're very excited," Greeley told *In Vivo*. "The home is one of the great frontiers. We believe that people really want to be cared for in their homes."

Patent empowerment, whether it be through precision medicine, home therapies, or the consumerization and retailization of health care all need a digital switch. AI, apps and digital therapeutics, to name just a few participants, all have a huge part to play in patients taking ownership of their own medical journeys. Data liquidity and automation will catalyze this movement.

Undoubtedly there will be more to come in pharma's digital journey as it seeks to modernize and become truly patient-centric in its offering. The future of pharma is digital.