



**One Size Doesn't Fit All:
A New Age in Healthcare**

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Personalized medicine is an aspiration of the modern healthcare system, yet, when we look at existing medicines used today, drug therapy is rarely dose optimized for the individual, resulting in variable efficacy and tolerability.¹

Successful outcome driven patient care should combine dose optimized drug therapy with non-drug digital interventions like lifestyle, exercise and behavior change. We now have the potential to ensure individual treatments are available for every unique patient at a population health scale.

As we continue to witness the growing intersection between science and technology, drug and digital, we envision a future where drug therapy that is tailored for the individual becomes a reality.

“Personalizing the dosing side of medicine would be a huge step forward toward the holy grail of personalized and precision medicine.”

– Paul Simms, chief executive at Impatient Health

The personalized medicine movement

Most therapies and medical devices are approved based on the overall safety and efficacy demonstrated in large-scale clinical trials. In real life, however, the efficacy and tolerability of any given intervention may vary between people from different subgroups (race, gender, age, etc), from one individual to the next, and even in the same individual over time. Clearly, one size doesn't fit all when it comes to medicine. Yet from 2013 to 2017, 78% of the drugs the FDA approved had only 1 dosing regimen. Of the drugs considered to be amenable to response-guided treatment, only 39% provided relevant dosing instructions in the labeling.¹

We are witnessing the dawn of a new age in healthcare, one in which personalized treatment will eventually become the norm. There is an increasing appetite, particularly among younger people, for access to their health data and engagement with their treatment. New technologies that enable real-time monitoring of patients in the community are creating a huge opportunity to collect real-world data to enable optimized dosing linked to outcome improvements. Today, patients take a pill at the recommended dose and assume it works. Tomorrow, they may be able to track its outcome and work with their healthcare provider to work out the right dose for them.

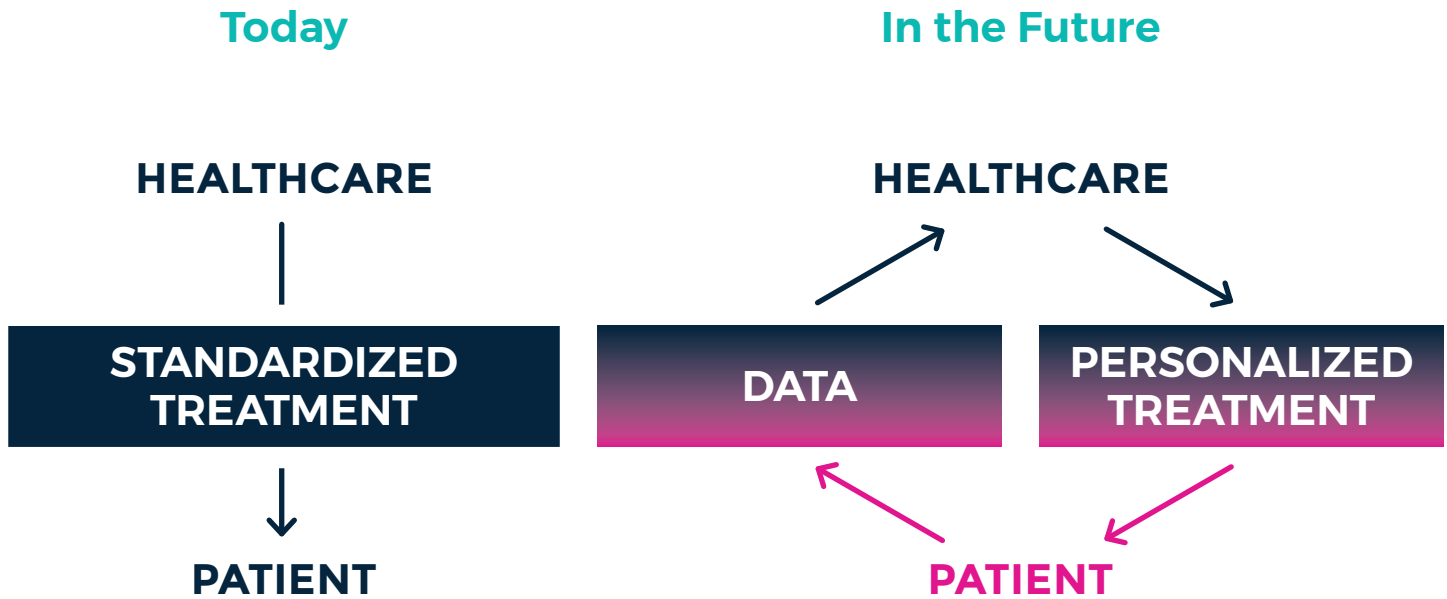


Figure 1. The Shift From Standardized to Personalized Treatment

Optimizing dosing not only has the potential to improve efficacy and safety outcomes and minimize medication wastage for the individual, it could also save healthcare systems and governments huge amounts of money. In 2016, the annual US cost of drug-related morbidity and mortality resulting from nonoptimized medication was \$528.4 billion—equating to 16% of US healthcare expenditures.²

Advances in diagnostics and genomics, as well as real-world data capture by empowered and educated patients, will propel the movement toward personalized healthcare. As more effective, tailored interventions emerge, incumbents and their products may face shrinking demand unless they evolve and stay relevant.

“People are used to how they’ve been trained. They’ve been trained on the basis that 1 dose fits all, which is not correct. We need to move away from that paradigm window to more personalized medicine.”

— Professor Sir Munir Pirmohamed, David Weatherall
Chair of Medicine at the University of Liverpool

The cost of healthcare inequality

Precision medicine, where healthcare treatments are tailored to the individual, has, until now, only been applied to a handful of medical conditions. What if it could be applied more widely and made more accessible? The ability to put software as a medical device app in the hands of any patient with a smartphone creates an opportunity for digital companions to be prescribed alongside traditional therapeutics. Thus, enabling real-world data integration into care regimens for individuals regardless of their level of access to healthcare treatment options. This approach has the ability to level the healthcare playing field, providing wider access to the highest quality care, usually only accessible to the few.

Committing to equity in healthcare is not only a humanitarian imperative; it makes economic sense at both a healthcare system and government level. In the state of Texas alone, it is estimated that racial health disparities have resulted in \$2.7 billion in excess medical spending, \$5 billion in lost productivity, and 452,000 life years lost due to premature deaths, conservatively valued at \$22.6 billion.³ That represents a staggering increase of 60% in excess medical spending and 72% in lost productivity due to a lack of equity in healthcare since 2016.⁴

The COVID-19 pandemic has certainly exacerbated, but is by no means entirely responsible for, these costs. A study conducted in England before the pandemic (2011-12) found a steep social gradient in overall inpatient hospital admissions, with much higher rates in deprived neighborhoods. The total associated cost of this inequality was £4.8 billion.⁵

“By not broadening the lens of who they are serving, major industries are leaving trillions of dollars on the table every year. And when you specifically see the dynamics of how the population will shift in the United States and the individual power of economic availability, I believe that number is underestimated.”

— Aurora Archer, cofounder of The Opt-In

Using hypertension as an example, a disease that impacts a third of the adult population in the US and disproportionately impacts those of lower socio-economic standing, it is costing the US \$131 to \$198 billion a year.⁶ This number includes the cost of healthcare services and medications to treat high blood pressure, as well as the loss of productivity from premature death. The ability to better deploy standard of care across patients with hypertension could prevent up to 91,900 heart attacks, 139,000 strokes, and 115,400 cardiovascular deaths in 5 years—saving the US healthcare system hundreds of millions of dollars every year.^{7,8} By saving human lives, healthcare systems and the country can save money.

The current system fails to deploy personalized healthcare solutions more widely and, as a result, misses the ability to treat all people early, effectively, and equitably. Generation after generation, nations lose millions of lives and billions of dollars. But these costs are avoidable, and the path forward is clear. A move toward an inclusive and agile system that works for everyone will benefit all of us.

**“Personalized
medicine is about
patient empowerment.
With more insights,
individuals have
more control over
the medications
they are taking.”**

— Professor Shafi Ahmed, MD, The Royal London Hospital

Digital health ≠ telehealth

Stakeholders across healthcare, including payors, providers, physicians, and, most importantly, patients, now realize that digitization in healthcare doesn't just provide access via technology, but also a complete reimagination of what healthcare fundamentally means to them. Many providers have already started to reorganize their practices and processes around new ways of working—some of which do not involve one-to-one interaction, but instead new solutions and linked devices that patients can use from the comfort of their own home. However, this is just the start. With mandatory growth in digital health and telemedicine, fueled by COVID-induced necessity, the future is even more exciting.

Digital health startup investment is setting new records: By mid 2021, more money had been raised in this category than in the whole of 2020, around \$15 billion.⁹ Remote, person-centered healthcare has become not just normalized, but expected. The COVID-19 pandemic necessitated a mass experimentation of new ways of working toward the digitization of consumer and business behavior.

From education to banking, we are now far more likely to choose providers and services that give us the option to share and benefit from data remotely. According to a McKinsey global survey, executives are now 3x more likely to say at least 80% of their customer interactions are digital than before the pandemic.¹⁰ The same is true of healthcare, with digital services reaching far more people than traditional models ever could. In the Global Strategy on Digital Health 2020-2025 report, the WHO recognizes “that the strategic and innovative use of digital and cutting-edge information and communications technologies will be an essential enabling factor towards ensuring that 1 billion more people benefit from universal health coverage, that 1 billion more people are better protected from health emergencies, and that 1 billion more people enjoy better health and well-being.”¹¹

Instead of confining interactions to office visits, where the average face-to-face time spent in the US between a doctor and their patient is only around 17 minutes, digital tools allow healthcare to extend the engagement window, capturing the real-world view between appointments.¹² Integrating various digital health strategies will allow the healthcare industry to actively provide personalized attention to patients, from pre-appointment preparations through consultation and, importantly, into more tailored and better-suited care regimens based on the reality of that patient's individual experience and reaction to their treatment course. The opportunity to remotely check in, optimize treatment regimens, and increase trust becomes far more accessible. For the collective global population, this is progress, but for the younger generations, this is expected.

“Historically, we’ve studied and prescribed medications for their average effects in a population, rather than how they perform for each individual in daily life. With new technologies, we’re likely to realize the benefits of personal optimization in dosing.”

— David van Sickle, Co-Founder and Ex CEO
of Propeller Health

As each new generation enters adulthood, they also become the consumers and providers of healthcare. We now have a whole generation of people who don’t remember a world without smartphones, to whom the touchscreen is the most natural interface. Gen Z are digital natives who would much prefer to receive healthcare online, often have no local primary care provider and, in many cases, don’t want one. They also don’t see online communication as inferior to in-person for most conversations.

The rise of digital therapeutics

Digital therapeutics (DTx) are increasingly challenging the historical disease- and symptom-management paradigm. Early results from studies of behavior-altering therapeutics are promising, with innovations such as insomnia treatment through gamification of digitally administered, cognitive behavioral therapy proving successful.¹³ Clinical applications are abundant, and preventive DTx will have a long runway and support from cost-minded payers. Importantly these new digital therapy modalities have the ability to be tailored and modified, based on patient experience, to create patient journeys that are more bespoke to the individual. With greater data and access, this personalization will only get better and be of more value to patients and physicians.

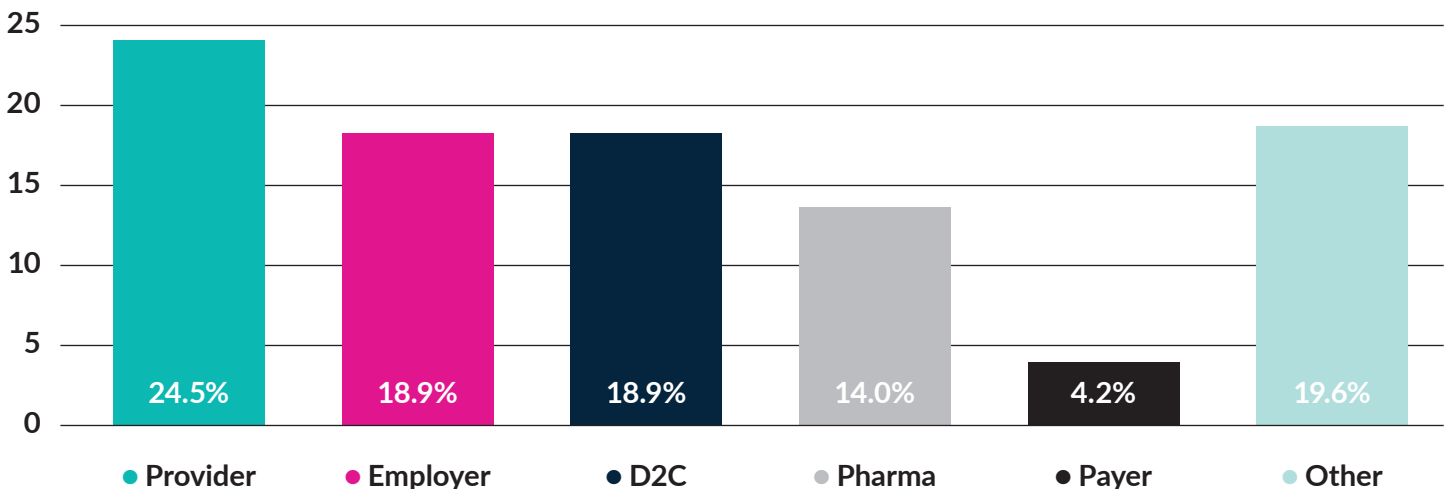
The challenges payers face in delivering accessible high-quality care outside of traditional office-based visits have been exposed and exacerbated by the global COVID-19 pandemic.¹⁴ We have seen a sharp rise in mental health concerns, opioid addiction, and insomnia since 2020.^{15,16} DTx offers an attractive option for patients with limited access to in-person healthcare, helping drive adoption.

In 2021, digital health companies catalyzing research and development in biopharma and medtech topped the investment chart, securing \$5.8 billion in funding. This staggering growth was stimulated by the COVID-accelerated acceptance of real-world evidence and decentralized trials as valid and valuable. Investments in digital products supporting disease treatment grew 2.6x between 2020 and 2021 as insurance coverage pathways for prescription DTx widened. Healthcare marketplaces also experienced a 3.2x year-over-year funding growth, driven by upticks in direct-to-consumer marketplaces (Mindbody: \$500 million), caregiver marketplaces (Honor: \$370 million), and clinical job boards (Trusted Health: \$149 million across 2 rounds).¹⁷

Regulation is, of course, essential for ensuring consumer safety, especially when it comes to healthcare. With that said, regulatory considerations and reluctance from payers to approve reimbursement have been the biggest hurdles in bringing new DTx to market. Thankfully regulators are increasingly willing to adapt and accelerate the approval pathways for DTx. The FDA recently launched a digital health pre-certification program designed to “provide more streamlined and efficient regulatory oversight of software-based medical devices developed by manufacturers who have demonstrated a robust culture of quality and organizational excellence and who are committed to monitoring real-world performance of their products once they reach the US market.”¹⁸

Devising and implementing a successful go-to-market strategy remains a key challenge for DTx companies. We’ve seen a lot of trial and error and migration between different commercialization pathways. There is no silver bullet. Provider, employer, and direct-to-consumer (D2C) are currently the leading route to market strategies for the commercialization of DTx (Figure 2).¹⁹

Figure 2. Route to Market Strategies for Commercialization of DTx



Adapted from HealthXL. Digital Therapeutics: routes to market. October 2021 report.

“ Digital therapeutics need to coexist in supporting drug therapy—they must be additive or synergistic.”

— Professor Shafi Ahmed, MD, The Royal London Hospital

Among healthcare providers, there is a significant gap between theory and practice when it comes to digital solutions. While over 80% of providers believe there are advantages to integrating DTx in patient care, adoption of remote monitoring and patient engagement tools remains below 35%.^{20,21} Healthcare providers are notoriously time poor, so it's not surprising that administrative concerns, such as ease of integration with current workflows and electronic health records (EHRs), are high on their list of priorities when evaluating DTx. To be successful in clinical practice, DTx must be designed with the user experience of both the patient and provider front of mind.

Given the financial cost of nonoptimized medication to individuals, healthcare systems, and governments (as previously described, the annual US cost of drug-related morbidity and mortality resulting from nonoptimized medication was \$528.4 billion), it is perhaps surprising that only 4.2% of DTx companies have adopted the payer route to market.^{22,23} Partnerships between DTx companies and payers have the potential to dramatically improve outcomes for patients and reduce medication waste, saving funds that can be invested elsewhere in the healthcare system.

The economic opportunity

Healthcare is entering a new age thanks to global advances in technology, human behavior, and the arrival of digital health. It is no surprise that investing in innovative products and services has become the priority for life sciences companies seeking organic growth. By recognizing the seismic shifts in the market and adjusting accordingly, companies can develop business models that diversify their revenue streams and keep pace with evolving consumer and market trends.

A 2022 McKinsey survey found that 74% of life science companies with new business as their primary growth strategy outgrew the market, compared with 58% of companies with other organic growth strategies. Organizations that rely primarily on new business are 2.5x more likely to grow at more than 10% above the market rate than those organizations that execute other organic growth strategies: 35% versus 13%, respectively.²⁴

Corporate strategies focused on building business are better equipped to absorb volatility and economic shock. Just like diversification in an investment portfolio, strategies focused on revenue expansion help mitigate exposure to unsystematic risk and hedge against internal business model inefficiencies or miscalculations. At the same time, this allows companies to proactively incorporate assets optimized for a rapidly changing world.

In 2021, Deloitte surveyed 150 leaders across the value chain from large biopharma companies (revenue of US \$1 billion and above) across the United States, Europe, and Asia. Respondents overwhelmingly stated that their organizations are currently prioritizing investments in AI (81%) and cloud (71%).²⁵ The implications suggest an industry focus on establishing an interconnected ecosystem of data that can utilize machine learning to execute advanced analytics. This investment creates a clear platform for cross business and industry collaboration—where relevant consensual data may be utilized from business to business, industry to industry, and corporate to individual.

Historically, the life sciences industry has seen innovation equate to growth. More than half of life sciences companies surveyed by McKinsey reported making 20% or more of their revenue from new-business building in the past decade. For an industry designed to be calculated, pragmatic, and reactive, having one-fifth of its revenue stream come from new services or products is notable. With that said, this margin is more than capable of growing, meaning there is still a lot of money on the table up for grabs.

Start-ups turned unicorns

When considering the instability in global markets and events along with the rapid evolution of medical technologies and increased market demand, sticking to the status quo is a good way to get left behind. The titans of pharma and life sciences have already seen young start-ups enter the fray and assume market share at a remarkable rate. Skyrocketing direct-to-consumer companies like Ro, Nurx, Keeps and Hims have been able to raise billions of dollars in funding at billion-dollar multiple evaluations in just the past 5 years. Ro alone has raised \$847 million in its lifetime, resulting in a \$5 billion valuation.²⁶

Prescription DTx has also seen a surge in investment. Mahana Therapeutics, who developed a DTx for irritable bowel syndrome, announced that they had raised \$81 million in August 2021.²⁷ Boston-based prescription DTx developer Pear Therapeutics is predicting that their revenue will more than quintuple in 2022, to around \$22 million.²⁸

With young start-ups grabbing market share by the billions, trillion-dollar companies like Amazon taking larger and larger steps into life sciences, and healthcare systems losing millions of dollars a year in wasted medication, established pharma companies and payers cannot afford to be complacent. Any player not just looking to survive, but to compete, must prepare to be agile, tactical, and assertive. To do this, they must overhaul archaic business models and look outward for investments that modernize global health to match the worldwide shift of needs, interests, and capabilities. While innovation in healthcare should ultimately lead to better health outcomes for every human on the planet, advances in this sector also create tremendous economic possibilities.

“Pharma needs to be agile. Agility is about trying stuff and going through a feedback loop as quickly as possible to then iterate the next version of that, as opposed to waiting for 6 months or a year. Agility is about learning.”

— Paul Simms, chief executive at Impatient Health

A survey of 15 major pharma companies found that, in response to the COVID-19 pandemic, research and development saw a significant uptick, and their internal rate of return (IRR) is the highest since 2014—increasing from 2.7% in 2020 to 7.0% in 2021.²⁹ Interestingly, this same survey found that companies continue to increase the proportion of external sources of innovation—from 33% in 2017 to 71% in 2021. This investment from big pharma, coupled with generational shifts toward digital fluency, is fueling the US DTx market, which is projected to see compound annual growth rate (CAGR) of 26.1% from 2022 to 2030—from \$5.09 billion today to over \$32.5 billion in 2030.³⁰ The projected growth reflects technological advancements and optimizations. This forecast illustrates that healthcare is entering its next chapter—a chapter that is driven by this industry’s capacity to integrate innovative technology as well as an individual’s desire to experience more advanced and personalized care.

Today

Drug screening and development are human-driven.

Medication is often one-size-fits-all. Patients are resigned to mass market therapeutics.

Disease prevention, detection and treatment are primarily managed through episodic in-person consultations.



In the Future

Machine learning and AI will lead the way and expand our capabilities dramatically.

Advances in genomic sequencing, precision dosing and data analytics will enable optimization and personalization of treatment, saving money for patients and healthcare systems.

Healthcare will tap into the accessibility afforded by technology, taking advantage of DTx, genomics, machine learning and telehealth to proactively analyze health risks.

Figure 3. Healthcare Today and in the Future

CONCLUSION

Historically, healthcare has taken an umbrella approach. Treatments were designed for the masses rather than the individual. But one size does not fit all. Society is now on the cusp of an exciting new age in healthcare. Considering the waste that stems from impersonal and imprecise medication, it is essential and seemingly inevitable that healthcare will innovate to overcome these challenges and stay relevant.

Precision medicine is entering a chapter with new capabilities, where technology works in parallel with prescribed therapeutics—at the individual drug level. These digital and drug combination offerings have the potential to accelerate the movement toward personalized medicine and optimized dosing, promoting improved outcomes for patients and offering support to time-poor healthcare providers.

Combination products flip the process of data collection and value on its head. This type of technology collects data at the individual level, rather than starting with the generalized majority. Data sets can now be inherently disaggregated and socially representative. The capacity of combination product technologies to collect individual real-world data in real time allows for unrealized data to inform agile research and development pipelines as well as better real-world care.

Early signs have indicated that life science companies and other stakeholders proactively recognizing and responding to this shift have already seen economic benefits. Those who refuse to adapt have seen their potential market share decrease by the billions and risk missing out on a significant opportunity.

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