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Investment & Corporate Banking

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# Digital Horizons: Healthcare

Precision Decisions: How personalized  
medicine is shaping the future of healthcare



# Precision Decisions: How Personalized Medicine is Shaping the Future of Healthcare

A six-year-old girl was diagnosed with a fatal neurological disorder with no known treatment. By the time she received her diagnosis, she was already unable to see, speak or walk. Her outlook was considered grim – until doctors in Boston were able to, in just a few months' time, determine the genetic cause of her disease and design a personalized injection. Dozens of researchers, scientists and medical professionals across the public and private sectors banded together to create the treatment which involved sequencing the girl's genome, finding abnormalities in a specific gene and designing and manufacturing a therapy to repair the genetic error.

## What is personalized medicine?

Imagine a world where instead of a “one-size-fits-all” approach, medical treatments are customized for each individual patient. Vital information – including genetic composition, vital signs and specific biomarkers – which has become increasingly available to healthcare practitioners through digitization and data collection, combined with exponential advances in the speed and efficiency with which that information can be applied, is being used to customize the development of novel therapeutics. We are entering this world and while today the focus is on acute disease, the numerous benefits of personalized medicine range from disease prevention and predicting susceptibility to environmental factors, improving detection and reducing the side effects of medication associated with chronic diseases.

Today, customized therapies are incorporated across the continuum – into the field of drug discovery, the planning and delivery of care, and the way in which patients interact with healthcare companies and providers. This progression has been aided by investment from both government and private sector, and a continued shift in traditional business models is a requisite for progress in this new paradigm of healthcare treatment.

Personalized medicine is emerging as one of the fastest evolving frontiers within patient treatment and the field of healthcare. While still in its infancy, customized therapies will become the standard of care over the next few decades. The personalized medicine market size was valued at US\$ 2.1 trillion in 2021 and is projected to grow at an 11.6% CAGR to US\$ 5.7 trillion by 2030.<sup>1</sup>



**Drug  
Development**



**Oncology**



**Gene  
Therapy**



**Patient  
Connection**



**Wearables**



**Consumer  
Healthcare**

<sup>1</sup> Source: Biospace. <https://www.biospace.com/article/personalized-medicine-market-size-to-worth-around-us-5-7-trillion-by-2030/?keywords=Achieve#:~:text=The%20personalized%20medicine%20market%20size,to%20be%20effective%20among%20individuals.>



## Personalized medicine is poised to be an industry disruptor that will change how patients interact with the healthcare system.

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### Who are the players?

On-the-ground stakeholders will determine the infrastructure, business models and wider rollout of personalized medicine. These include medical diagnostics companies expanding access to real time information and data, pharmaceutical companies partnering and negotiating with healthcare practitioners and providers, and biotech companies evaluating industry resources and constraints to develop viable business plans.

There is also a formidable role from the public sector including academic institutions, government agencies and regulators such as the Federal Drug Administration (FDA), National Institute of Health (NIH) and Center for Disease Control (CDC) in advancing research, sourcing funds and partnering with the private sector. Opportunities exist to foster and expedite research and approvals in ways that safeguard the public. Look no further than the development of the COVID vaccines mRNA technologies to find evidence of how the government can enable funding as well as remove the barriers of development through expedited review and approvals as well as reduction of manufacturing and market risks.

And let us not forget the payors. While cell and gene-based therapies have captured the imagination for their potential to cure disease, they come with unprecedented price tags, with some treatments costing as much as \$850,000 per usage.<sup>2</sup>

Existing payment methodologies are not set up to accommodate these emerging treatments and, in some instances, cures. Drug makers are introducing new deals and agreements with insurers and patients, and these payors must explore innovative reimbursement mechanisms such as rebates or payments based on therapeutic performance in treated patients over time, in some case decades.

Lastly and most significantly, there are the health practitioners and patients. Personalized medicine is poised to be an industry disruptor that will change how patients interact with the healthcare system. A key component in adoption of new technologies will be the undertaking between patients and their healthcare providers to understand and assess treatments options, available trials, outcomes, costs and benefits.

<sup>2</sup> Source: <https://www.fiercepharma.com/pharma/spark-prices-gene-therapy-luxturna-at-850k-grabbing-top-spot-pharma-s-costliest-drugs>



## Drug development: determining the pace of innovation

Although genomic testing is a recent phenomenon, today there are 200 drug labels that contain information involving pharmacogenomic biomarkers. Drug makers and scientists are increasingly relying on supercomputers and artificial intelligence in their research. Last year Nvidia launched Cambridge-1; the UK's most powerful supercomputer with the sole purpose to accelerate the development of genome sequencing, drug development and disease research. The super computers' ability to create A-I generated models of chemical structures and to analyze pathology slide images will greatly speed up the insights required during drug response research.<sup>3</sup> Additionally, a recent study at the Institute for Bioengineering of Catalonia, Barcelona demonstrated that using machine learning instead of traditional computation methods reduced microscope processing time from months to just seconds.<sup>4</sup>



## Oncology: first out of the gate

Broad based chemotherapy, which has been in existence for decades and often remains "first line" or "standard-of-care" treatment, is being displaced by more efficacious alternatives. Targeted or precision therapy, which works against actionable genetic mutations (those genetic aberrations occurring within patient's tumor cells) has demonstrated higher response rates and longer patient survival.

The promise of these targeted therapies was first realized in 1998 when Genetech's monoclonal antibody Herceptin was approved by the FDA for metastatic breast cancers that expressed the specific gene HER2. Data quickly demonstrated that treatment that included Herceptin cut the risk of cancer coming back by 50% compared to chemotherapy alone.<sup>5</sup> Ever since this 'quantum' shift in patient care 30 years ago, the field of personalized medicine has been considered the most important area of drug development.

Today, the Profile project at the Dana Farber Cancer Institute is considered one of the nation's most comprehensive precision cancer medicine initiatives – it has been able to analyze and categorize tens of thousands of genetic and molecular alterations that cause cancer. Over the past ten years, the cost of these identification processes has decreased from \$10 million per genome to \$1,000 per genome.<sup>6</sup> The field of cancer treatment has experienced the greatest advancement due to personalized medicine.

<sup>3</sup> Source: ComputerWeekly.com <https://www.computerweekly.com/news/252503571/The-Cambridge-1-switch-on-UKs-most-powerful-supercomputer-goes-live>

<sup>4</sup> Source: Institute for Bioengineering of Catalonia <https://ibecbarcelona.eu/machine-learning-reduces-microscope-data-processing-time-from-months-to-just-seconds/>

<sup>5</sup> Source: <https://www.gene.com/stories/her2/#:~:text=In%201998%20Herceptin%20was%20approved,HER2%2Dpositive%20metastatic%20breast%20cancer.>

<sup>6</sup> Source: McKinsey.



### Gene therapy: following closely behind

Gene therapy is also one of the fastest-developing segments within the space. It involves the replacement or repair of defective genetic material and has been enabled by the advent of gene editing technologies such as CRISPR and RNA-interference. In 2003, the human genome was mapped over a time frame of 10 years, costing \$1 billion. By 2015, the process took 6 hours and cost \$1,000.<sup>7</sup>

While the first gene therapy clinical trials began decades ago, in 2017 the FDA approved one of the first gene therapy medications called Luxturna, which treats a form of inherited blindness through a shot of DNA-filled viruses injected directly into the eye. This is intended for people with a mutation in the gene RPE65, which encodes an enzyme crucial to vision. Real world data proved the efficacy of this treatment, with 2 years of post-marketing data showing significant improvements in visual function and acuity.<sup>8</sup>



### Increased patient care connection

Biotechnology and pharmaceutical companies have made significant advances in the field of personalized medicine. At the same time, patients have more access to extensive information and technology and are more connected to their personal health information than ever before. As a result, they increasingly are taking ownership of their medical journey.

Telemedicine and telehealth also have improved access to healthcare and placed more agency on the patient. Previously considered a temporary measure during the COVID-19 pandemic, both have proven effective even as pandemic restrictions have largely been removed. Recently, Mayo Clinic researchers found that 87 percent of preliminary diagnoses made during video appointments at their centers were later confirmed during in-person appointments.<sup>9</sup>



### Wearables: personalized healthcare on your wrist

Adding to self-awareness and management of health and wellness, wearables have evolved from a consumer fitness category to become a principal instrument for the continual collection of personalized health data. Physiological and biochemical sensors feed crucial bioinformatics to researchers and medical practitioners on a 24-7 basis. The analysis of this data has led to work on a smart bandage, which is being developed by the collaborative team at Harvard Medical School, Tufts University and Purdue University.

<sup>7</sup> Source: Forbes. <https://www.forbes.com/dell/cloud-future-of-medicine/#699404c13df2>

<sup>8</sup> <https://www.cgtlive.com/view/real-world-luxturna-data-shows-good-efficacy-new-adverse-reaction-in-retinal-dystrophy>

<sup>9</sup> Source: U.S. News & World Report. <https://www.usnews.com/news/health-news/articles/2022-09-07/telemedicine-diagnoses-match-those-of-in-person-doctor-visits-most-of-the-time>

Smart glucose meters are one of the fastest growing wearables and are improving quality of care as well as an individual's quality of life. These devices are Bluetooth enabled and can monitor a patient's blood sugar at all times, sending test results directly to a smart phone or wirelessly to an insulin pump which can use the information to calculate a precise dose of insulin to be delivered at meals.<sup>10</sup> Smart glucose meters account for the largest share in the digital diabetes management industry which is expected to reach \$25.5 Billion by 2027.<sup>11</sup>

With consumers developing deeper understanding of and taking a more active role in monitoring their health, and companies leveraging wearable technology for treatment, this segment lies at the crucial intersection between consumer and personalized healthcare and is poised to continue its growth.



### Consumer healthcare: bringing the doctor's office to your home

Many people have seen ads for custom vitamins that can be delivered after completing a questionnaire or food sensitivity reports that can be sent based on a cheek swab. This type of consumer healthcare will continue to grow. New technologies and mobile medical apps enable patient's physiology to be tracked in real time. Established players in the technology space are taking a foothold, as well as startups such as Tempus, a patient portal that utilizes personal information combined with a warehouse of data to be used with a physician to design treatment plans and options.<sup>12</sup>

Consumers are already entrenched in the adoption of digital technologies – 79 percent use online health information, 24 percent use wearable devices and 19 percent use telemedicine.<sup>13</sup> In the future, mobile medical apps will accompany patients on every step of their healthcare journey.

<sup>10</sup> Source: <https://www.verywellhealth.com/choosing-glucose-meter-3289632>

<sup>11</sup> Source: <https://www.globenewswire.com/en/news-release/2022/10/28/2543747/28124/en/The-Worldwide-Digital-Diabetes-Management-Industry-is-Expected-to-Reach-25-5-Billion-by-2027.html>

<sup>12</sup> Source: Tempus. [www.tempus.com](http://www.tempus.com)

<sup>13</sup> Source: Rock Health. <https://rockhealth.com/insights/healthcare-consumers-in-a-digital-transition/>

## Hurdles to clear: challenges in deployment

Despite the benefits of personalized medicine and progress to date, challenges to rapid growth in this market remain. Individual governments will play a part in determining which groups should have treatments developed, and regulatory agencies will be required to evaluate the safety and benefits of drugs when dealing with specific subsets of the population. Payors/insurance companies will have to tackle the cost/benefit question when developing drugs for a small subpopulation, creating variables when determining profit for insurance companies.

Personalized medicine holds the promise to help millions of people worldwide, but the infrastructure of deploying it on a large scale brings challenges. Scaling these technology solutions will require data storage and tracking, modifications to regulatory processes, and a robust supply chain that has already seen recent struggles. Countries with universal healthcare will have to find a way to integrate personalized medicine into their system. Additionally, physicians will need to be incentivized and patients educated in order for both parties to be on board with this new technology.

## Conclusion

Personalized medicine is blazing a path through several sectors including pharmaceuticals, oncology, gene therapy, wearables and consumer healthcare. Although it will face some headwinds, it's a market poised for significant growth and opportunity to drive future returns for companies and outcomes for patients.

Business leaders should consider opportunities to accelerate access to technologies and innovations through strategic partnerships, licensing agreements or acquisitions. Our team of experienced healthcare bankers can help companies navigate the market landscape and provide strategic advisory and financing solutions to meet business objectives.



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## Beyond The Obvious Takeaways

### Multi-omics

Personalized medicine research has determined, individually, the importance of the immune profile, genomes, microbiomes and non-molecular metrics. These combined are considered “multi-omics” and are the next step at determining a more complete picture of the patient. These continued integrations and developments will lower costs and make these processes more approachable and accessible. This market is poised to hit nearly \$14 billion by 2030.<sup>14</sup> By combining individual omics analysis, a more comprehensive data set can be created to drive treatment plans as well as drug discovery.

### Rare disease targeting

The success in oncology has spurred researchers to find where else this technology can be applied.

Rare diseases are the next logical step, as many share genetic underpinnings similar to cancer. In contrast, more common diseases like diabetes, Alzheimer’s, and autism lack genomic predictability, as they involve many other factors, making application more complex.

### Large pharma is moving beyond the one-size-fits-all approach

Large pharma is pivoting their strategy to capture the trajectory of personalized medicine blazing a trail in the market. Previously dominated by “one size fits all” solutions, custom treatments will be the new frontier. Recently, Bristol Myers Squibb acquired Turning Point Therapeutics in order to bolster their pipeline of precision oncology medicines. Personalized medicine will continue to be a focus of investment as the opportunities grow.

<sup>14</sup> Source: Allied Market Research. <https://www.globenewswire.com/news-release/2021/07/14/2262912/0/en/Global-Single-Cell-Multiomics-Market-to-Hit-13-90-Billion-by-2030-Allied-Market-Research.html>

## Look Beyond The Obvious

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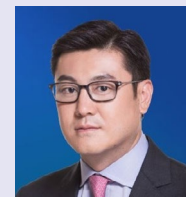
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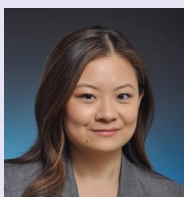
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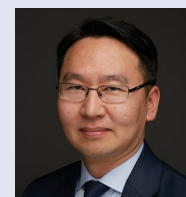
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The logo consists of the word "MIZUHO" in a bold, white, sans-serif font. Below the text is a white, curved line that starts under the 'M', arches over the 'I', 'Z', and 'U', and ends under the 'O'.