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Future of medical science

Medical science is currently being transformed by scientific discoveries that will dramatically advance the way we diagnose and treat different diseases. Breakthroughs in digital medicines, nanomedicine, genomics, microbiometrics/metabolomics, and others are occurring at an unprecedented and exponential pace, building on transformed clinical trial structures and timing, disruptive market entrants, and increased consumer participation.

Also shaping the future of medical science is the health ecosystem's exponentially increased capacity for data capture and analysis. Organizations are using insights derived from interoperable data and platforms supported by deep learning capabilities, "always on" biosensors, and behavioral research to shape consumer beliefs and actions. They are also applying virtual care, artificial intelligence (AI), and other technologies to personalize medicine, enable real-time care interventions, and provide behavioral nudges.[1]

Advances in medical science are being propelled by significant investment and research across the public and private sectors—government, biopharmaceutical companies, technology giants and startups, and academic institutions—bringing new innovations to the masses and driving more predictive, preventative, personalized, and participatory (4P) medicine.

Transformational innovations

Digital medicine–The last few years have witnessed a proliferation of digital medicine products, evidence-based software and hardware products that measure and/or intervene in the service of human health.[2] These include digital therapeutics (i.e., regulated products that employ software to deliver evidence-based therapeutic interventions) and digital companions (i.e., products that provide additional services and insights for patients to improve their experience, knowledge, and outcomes of their existing drug therapy). Among current examples:

- **Digital therapeutics:** AppliedVR is a provider of therapeutic virtual reality for pain management. Using head-mounted devices, the AppliedVR platform creates an immersive experience that helps people overcome their discomfort. Through gamification, patients learn evidence-based pain management skills and mindfulness strategies. Having been successfully used for acute pain in health care settings, the technology is starting to be used for chronic pain management at home, specifically for chronic lower back or fibromyalgia pain.[3]

- **Digital companions:** In 2020, Teva launched ProAir® Digihaler®, a sensor-laden albuterol dispenser pump for treatment and prevention of obstructive airway disease. The dispenser records and sends inhaler event data to the companion mobile app via Bluetooth. The app can use this data to instruct patients on their inhaler techniques or adherence. With patient consent, the app can share the data with their provider to inform treatment decisions and care management.[4]

Nanomedicine–Nanomedicine is the improvement and preservation of human health with the help of molecular tools, or nanotechnology.[5] Promising applications include targeted drug delivery; nanorobots to detect and repair infections and body damages; controlled protein and peptide delivery; and gene therapy, in which the expression of a defective gene may be altered and corrected.[6] The pharmaceutical industry is already engineering new molecules at nano-scale. In one example, NaNotics, a nanomedicine company, builds subtractive nanoparticles that remove specific disease-causing molecules from the human body. NaNots are injected into the body like a drug and modulate cellular behavior by depleting specific signal molecules or their inhibitors from blood—without disturbing normal cell signaling.[7]

Genomics–The field of genomics is a significant disruptive force that could redefine health care, and we are only beginning to tap its potential. The whole human genome was sequenced 15 years ago after more than a decade of research and at a cost of about $2.7 billion.[8] A patient's DNA can now be sequenced for a few hundred dollars in about a day.[9] A person's DNA can help identify a predisposition to certain diseases; sequencing the genomes of multiple patients can provide researchers with a richer knowledge about diseases, which can help them develop more effective personalized therapies. Application areas include direct-to-consumer (DTC) genetic testing, cancer diagnostics and therapy, and gene editing. Advances in genomic sequencing could make it possible to use a blood test to identify traces of cancer DNA and the genetic mutations that cause it. A gene-editing platform could be used to reprogram the patient's immune system to identify these mutations and attack the cancer cells.[10] Researchers in the United States and the United Kingdom have used genetic sequencing of the coronavirus genome to understand how it's changing, and then build on that knowledge at scale to improve COVID-19 vaccines so that they can respond better to delta and other emerging variants (see below).

Unlocking the power of mRNA vaccines and therapies[11]

Vaccine developers are using a variety of technologies and techniques—from the tried and tested to completely novel approaches—to battle COVID-19 and prevent severe disease, hospitalization, and COVID-related death. The first vaccine to receive emergency use authorization in the US was a first-in-class synthetic messenger RNA (mRNA) vaccine,[12] making RNA a household term.

As background, DNA and RNA are the two naturally occurring varieties of nucleic acids, which are the main information-carrying molecules in our cells. DNA is a long, double-stranded molecule that stores the genetic instructions your body's cells need to make proteins. These instructions are translated from nucleic acid into protein through an intermediate messenger, mRNA. The mRNA carries that protein-encoding DNA information from the nucleus to the cytoplasm and activates the cell machinery to make fully functional proteins.[13] Discoveries in the 1990s demonstrated that synthetic mRNA molecules can be used to deliver genetic information to the translational machinery to generate the encoded proteins. RNA technology can potentially be used for:

- **Replacement therapy:** mRNA is administered to the patient to compensate for a defective gene/protein, or to supply therapeutic proteins

- **Vaccines:** mRNA encoding specific antigen(s) are administered to elicit protective immunity

- **Cell therapy:** mRNA is transfected into the cells ex vivo to alter cell phenotype or function, and these modified cells are subsequently delivered into the patient.[14]

At present, most mRNA-based therapeutics are being used as vaccines against infectious diseases like COVID-19 or to develop personalized cancer vaccines.[15] Ongoing research is also exploring whether this technology can be used as a protein-replacement therapy, particularly for rare diseases such as the blood-clotting disorder hemophilia.[16] By February 2021, there were more than 520 clinical trials testing mRNA therapeutics across more than 20 disease categories with investment growing considerably.[17]

Artificial intelligence and big data–While drug discovery has led to many life-saving and life-enhancing clinical treatments, it is also a long, expensive, and often unsuccessful process, with many areas of unmet need. AI-enabled solutions are transforming the process and enabling the development of more precise targeted treatments. This is shifting health care toward a future where medicine is more personalized, predictive, preventative, and participatory.[18]

AI algorithms can extract concepts and relationships from data and learn independently from data patterns, augmenting what humans do. AI also helps cross-reference published scientific literature with alternative information sources. By mining such data, AI applications in drug discovery have already delivered new candidate medicines, in some cases in months rather than years.[19]

While current AI-enabled solutions are focused primarily on transforming the process of small molecule research, they are also showing potential in identifying new biologics such as therapeutic antibodies against cancer, fibrosis and other diseases. UK-based BenevolentAI is combining advanced AI/ML with cutting-edge science to interpret, classify, and extrapolate biomedical data; decipher complex disease biology; and discover new therapeutic interventions.[20] Alphabet Inc.'s AI research lab DeepMind Technologies announced in late 2020 that it has created software that solves the "protein folding problem," a breakthrough that could solve one of biology's biggest challenges and pave the way for a better understanding of diseases and new drug discoveries.[21]

> Today we are using big data and applying AI to discover new science and feeding that science back to consumers in a virtuous loop of discovery. For example, COVID symptom tracking is providing data that is contributing to the science of vaccine development in real time and continually updating insights. It's a continuous loop of science and consumers working together.
>
> **George Hadjigeorgiou**, co-founder of health science company ZOE

Microbiometrics/metabolomics–Current medical approaches to address diabetes, heart disease, and other chronic health issues view weight gain as the problem, rather than a symptom of poor metabolic health. They also generally treat patients the same when, in reality, bodies are all very different. Startups including Viome[22] and ZOE[23] (see sidebar) use data and AI platforms to analyze the interaction between food and an individual's microbiome to develop precision nutrition programs, with the goal of improving gut health and reducing inflammatory responses caused by diet.[24]

Trust your gut: Microbiome test uses AI/ML to create personalized dietary programs to reduce inflammation and improve gut health

An interview with George Hadjigeorgiou, co-founder, ZOE.

Health science company ZOE (www.joinzoe.com), named after the Greek word for 'life,' was founded in 2017 by Professor Tim Spector of King's College London, data science leader Jonathan Wolf, and entrepreneur George Hadjigeorgiou. The US- and UK-based startup combines large-scale human studies with artificial intelligence/machine learning technology and metagenomic sequencing to analyze individual responses to specific foods and provide a personalized nutrition program that can potentially help reduce dietary inflammation and improve gut health to unlock energy, manage hunger and weight, and enhance overall health. ZOE is also behind the hugely popular ZOE COVID app, the world's largest ongoing study of COVID-19 with more than 5 million members that has helped to save lives.

Q: George, what do you think is driving the growing interest in gut health and the idea that every person's biology reacts differently to food? People have a right to understand how their body responds to food, to take control of their health, and to live a better life. All three of ZOE's co-founders had a personal journey around the impact of food on their health. I read about the topic, including The Diet Myth, Tim's book about gut microbes, which led me to a process of experimentation. In three months, I lost 15 kilos and dropped my cholesterol levels by 40%. I was shocked by that because I didn't realize that by changing my diet, I can have an impact on my weight and my metabolic health. We offer a very personalized program to help individuals do that.

Q: Following this program requires a lot of accountability on the consumer's part. Have you found that people that start the program remain engaged? How do you keep them motivated? We believe our approach is, by design, sustainable because it teaches people to be more aware of the impact of food on their body. We want them to understand the connection between what they eat and what happens in their gut and make it second nature: If you eat a certain way your body is going to act a certain way. There will be people who can master that and go on their own, others will master it but need extra support. For these people we provide coaches that help them stay engaged, learning, and accountable. We already see most of our members mastering these connections as in addition to weight loss they feel less hungry and more energetic and tell us that ZOE has changed their life!

Q: How does ZOE's feedback loop enable you to improve and evolve the program? We see ZOE as a platform that improves over time as our dataset and scientific studies expand. The data set we're building around the microbiome, "good" and "bad" gut bacteria, and the connection to and how people eat, live, and feel is the most comprehensive in the world. With more and more people joining the ZOE community and providing feedback on their experience, data becomes our core asset. We use the most advanced tests and cutting-edge science available to help people understand how their body works so they can reduce dietary inflammation and improve their gut health naturally.

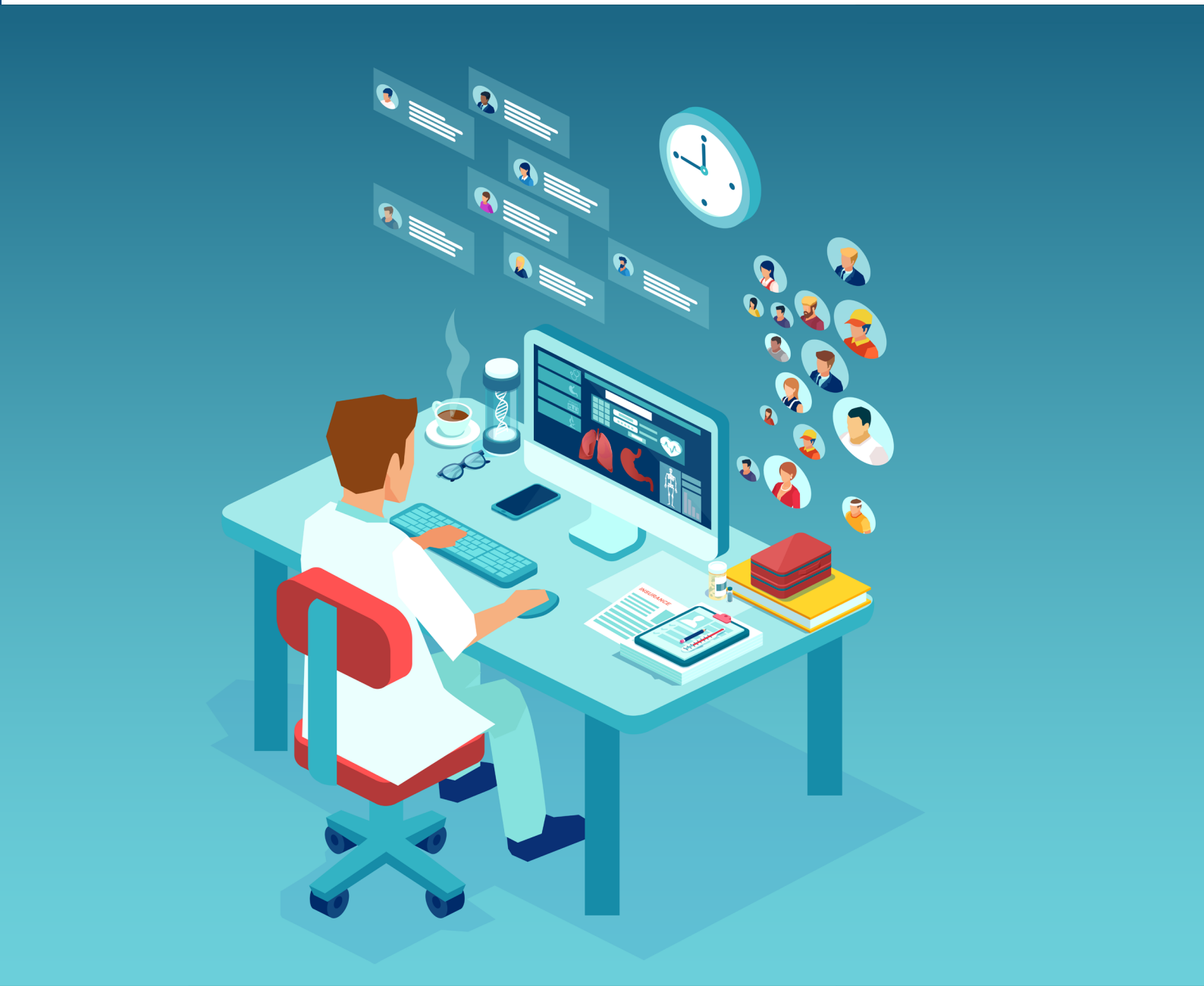
Q. What are the challenges of scaling personalized products for the masses? Because the ZOE community is young but growing rapidly, the first challenge is being able to scale our operational abilities; to onboard customers, send tests, process the resulting data, and support members in our program with the highest quality. The second challenge is being able to personalize their program even more by accounting for an individuals' unique lifestyle so they can make best use of the program—and to repeat this process for increasing numbers of users. I think both of these challenges are solvable with technology.

Obstacles to innovation: Cost, scale, trust

How do the health care and life sciences sectors overcome cost, scale, and trust issues to bring medical science innovations to the masses? The high R&D cost of new immunotherapies, digital medicine products, and precision/personalized medicine is a significant point of concern—especially in light of the already rising cost of health care diagnosis and treatment—and places many promising innovations beyond the reach of poor and middle-class sections of society.

Another challenge is developing business and operating models to tap into medical science opportunities at scale. There are many great ideas that are too impractical and/or expensive in their current form. How can innovations be translated from the academic into the practical at scale and at speed?

Finally, health care providers, insurers, and patients may be reluctant to engage with new medical interventions, even after they have been cleared by regulatory authorities. The COVID-19 vaccine hesitancy is a very recent example; there are many groups of people that don't want to engage with things of a scientific basis, including medicines and treatments. If you build it, will they come?



Questions/actions health care leaders should consider for 2022

How can scientific innovation help stakeholders control health care costs while also improving overall public health?

Medical science innovations continually shape and reshape the health care sector, shifting the focus toward prevention and well-being, moving care outside of health facilities, and putting consumers at the center of their own care. Even today, digital medicine products are beginning to transform health research and care models, and the COVID-19 pandemic has accelerated the process.[25] But scientific discovery, development and commercialization is expensive—especially for personalized therapies.

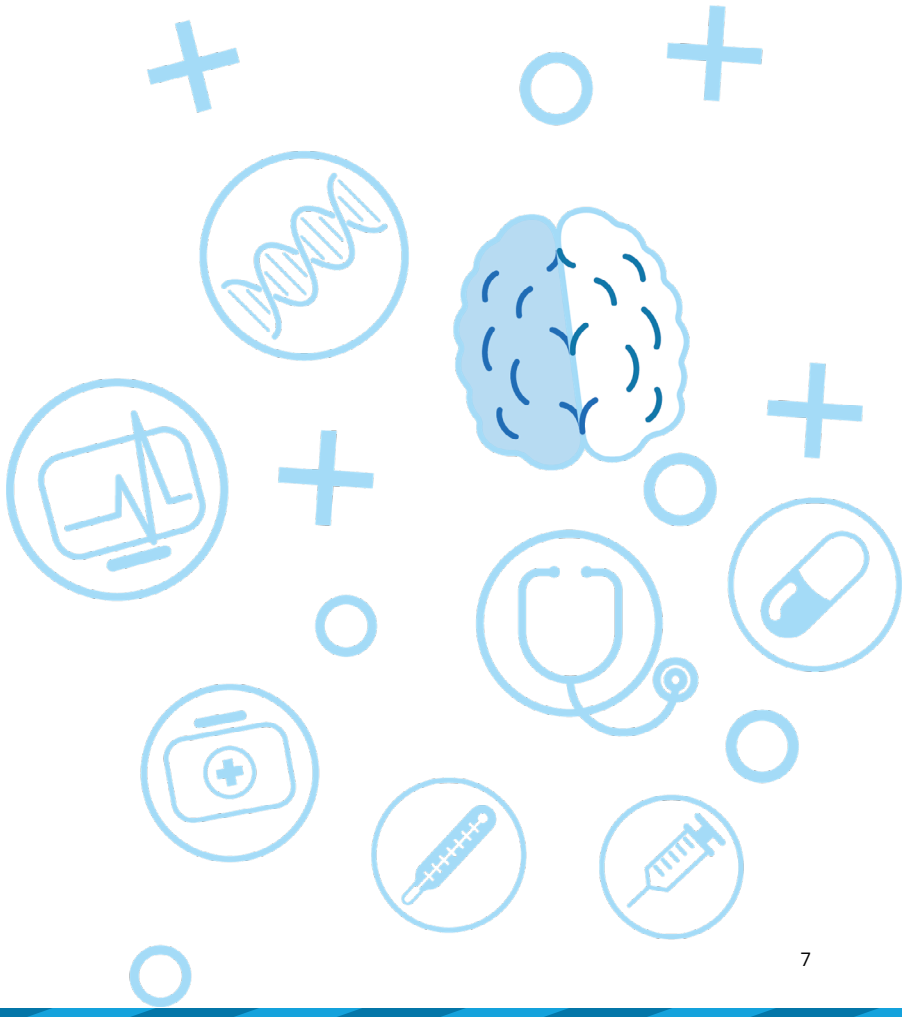
And health care is costing more and more each year. The following actions may help health care leaders balance the tremendous benefits of medical technology innovation with the practicalities of controlling health care spending.

Tap into consumer empowerment. More and more consumers are demanding access to data and tools that will empower them with knowledge and ability to understand what's happening with their bodies, make informed health decisions, and take appropriate preventative and/or therapeutic actions. Smartphone technology, over-the-counter diagnostic tests, and personalized health data are democratizing medical science and putting more power—and responsibility—in consumers' hands. Already, we can measure our DNA, microbes, blood sugar levels, exercise, and sleep patterns. And we are applying new technologies to make sense of, expand, and leverage this data in a virtuous loop that continuously updates the science. Digital medicine products, for example, offer the opportunity to influence patient adherence and outcomes, better understand the patient experience of disease, and generate real-world data that is relevant to customers. A growing number of biopharma companies, large technology players, and digital health startups are introducing innovative digital medicine products to enable patients to take greater control of their health.[26]

Making it easy for empowered consumers to experience medical innovations first-hand is an important driver of adoption. Ochsner Health's O Bar, located in the health systems' facilities throughout Louisiana (there's also a mobile version), offers the latest in cutting-edge, interactive health technology to help consumers seamlessly manage their health and wellness. The O Bar's full-time technology specialist helps consumers select and set up the digital products or apps they need to participate in Ochsner programs such as digital medicine, which helps patients manage their high blood pressure and/or Type 2 diabetes from home while staying connected to a dedicated care team. The O Bar sells a variety of physician-recommended products, such as activity trackers, wireless blood pressure monitors, and scales. They also feature a state-of-the-art iPad® bar that allows patients to test drive more than 100 Ochsner-approved health apps that focus on wellness, nutrition, fitness, diabetes, women's health, smoking cessation and more.[27]

Establish health system innovation hubs. The biopharma industry has long used innovation hubs as incubators for medical science advances that, biopharmas hope, will become future revenue-generators. Now health systems are modeling the practice. Ireland's first health innovation hub, launched at University College Cork, is a partnership of clinicians, academics, innovators, and entrepreneurs from across Ireland to accelerate health care innovation and commercialization, improve outcomes for patients, and create jobs and exports for Ireland.[28] In the United States, the Henry Ford Innovation Institute (HFII) in Detroit, Michigan, provides Henry Ford Health System innovators access to an array of intellectual asset-related resources and programs that include technological opportunity assessment, engineering services for prototypes, seminars designed to convey opportunities, programs aimed at developing specific medical products and broad educational offerings in the realms of translational medicine and the entrepreneurial arts. The Institute is organized as an independent scientific research and educational entity, allowing it to operate flexibly and rapidly. HFII's operating philosophy is simple: Use innovation to improve health care and the patient experience.[29]

Explore collaborative funding and development models. Companies are experimenting with various business and operating models to offset the considerable expense and time involved in developing, obtaining regulatory approval, and commercializing medical science innovations. For example, pharma companies are partnering with technology companies, consultancies, and digital health startups to access the expertise to build digital medicine products. Internal teams from biopharma companies (where the digital function exists) assess the tech landscape to identify potential partners that best suit their needs.[30] Partnerships can involve access to a propriety technology platform that is often TA-specific. For instance, BMS has partnered with Voluntis to use its Theraxium Oncology platform to build a digital companion for self-management of symptoms related to cancer therapy.[31] Sanofi partnered with an established mental health digital therapeutics firm, Happify Health, to build a digital therapeutic to help multiple sclerosis patients manage anxiety and depression.[32] Technology companies are likely to remain important partners for biopharma as a source of expertise and innovation in medical science products.



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