TrustCoLab

Trust or Consequences 2040

Will innovations in health and medicine deliver?

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usp®

MIT CENTER FOR COLLECTIVE INTELLIGENCE

United States Pharmacopeia

Since 1820, the U.S. Pharmacopeia (USP) has built trust where it matters most: in the world's medicines, dietary supplements and foods.

As an independent, nonprofit, scientific organization that collaborates with the world's top experts in health and science, USP helps protect and improve the health of people worldwide through our scientific rigor and the public quality standards we set. Through standards setting, advocacy and education, USP helps increase the availability of quality medicines, dietary supplements and food for billions of people.

The practice of health and medicine is changing fast, and we're working to ensure tomorrow's remarkable innovations can be trusted in the same way quality medicines have been trusted over the past 200 years.

Central to our achievements are the contributions of more than 800 independent volunteer scientists and other experts from around the world, who contribute their expertise to develop and approve USP's standards and who are solely committed to the public interest. These independent scientists and other experts provide integrity by developing the quality standards that help build trust in medicines around the world.

The *United States Pharmacopeia–National Formulary (USP–NF)* includes over 6,800 quality standards for medicines, both chemical and biologic; active pharmaceutical ingredients; and excipients (inactive ingredients). It is the most comprehensive source in the world for medicine quality standards, which are used to help ensure the quality of medicines and their ingredients, and to protect the safety of patients. *USP–NF* is utilized in over 150 countries worldwide and integrated into the laws of more than 40 countries, including in the U.S.

The year 2020 marks the 200th anniversary of the founding of USP. Throughout the past two centuries, USP has evolved its science and public quality standards to anticipate and address innovations in health and medicine. Our focus on quality fuels our outlook for USP's third century and the incredible medical breakthroughs that will come with it.

For more information, visit www.usp.org.

MIT Center for Collective Intelligence (MIT CCI)

The MIT Center for Collective Intelligence (MIT CCI) brings together faculty from across MIT CCI to conduct research on how advances in information technology are changing the way people work together.

This first-of-its-kind research effort draws on the strengths of many diverse organizations across the Institute, including the MIT Media Lab, the Computer Science and Artificial Intelligence Laboratory, the Department of Brain and Cognitive Sciences, and the MIT Sloan School of Management.

Our mission is to understand collective intelligence at a deep level so we can create and take advantage of the new possibilities it enables. Our hope is that the work in this Center will lead to both new scientific understanding in a variety of disciplines and practical advances in many areas of business and society.

CCI's CoLab platforms, including Climate CoLab and Futures CoLab, engage large groups of people online to address complex problems of significance to the world.

Inspired by Thomas W. Malone's *Superminds: The Surprising Power of People and Computers Thinking Together*, CCI's Collective Intelligence Design Lab helps groups design innovative new kinds of collectively intelligent systems—superminds—to solve important problems.

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Executive summary

In June 2000, a White House press conference announced the successful sequencing of the first "working draft" of the human genome. It was one of the greatest scientific breakthroughs in history and has made possible a string of transformative subsequent discoveries.

Scientific advances like sequencing the genome are vital to progress, and the innovations that followed have brought remarkable improvements to the human condition. But for innovations to be widely adopted, people have to trust that they are safe and will do what they promise. This is especially true in the domain of health and medicine.

Today, 20 years after the mapping of the human genome, the prospect of genetic information being paired with new information technologies—specifically, the ability to gather, process and analyze immense stores of data with the help of artificial intelligence—offers the promise of even more groundbreaking medical advances in coming decades.

What will the next 20 years bring? Will the envisioned medical discoveries materialize, or will our high hopes be disappointed? What will happen to the disparities in access to care that exist today, both within and between countries? Will these continue, or will access broaden? What will be the health impact of forces outside of medicine and health care, like climate change and political polarization? What influence might economic and technological trends, like online commerce and social media, have in medicine and health care? Twenty years from now, in the wake of the changes that might have happened, will people be able to trust that the health care they receive, and the medicines they take, are safe and effective?

To answer these questions, U.S. Pharmacopeia (USP) and the MIT Center for Collective Intelligence (MIT CCI) jointly launched Trust CoLab, an online platform that engaged more than 100 global experts, representing a broad range of disciplines, to reflect on the future of trust in health care. The exercise was undertaken as a centerpiece of USP's 200th Anniversary Celebration.

Trust CoLab participants were taken through a structured four-week process. First, they identified drivers of change that could shape the future and evaluated which of those drivers have the greatest potential to influence medicine and health care. Participants then contributed ideas about how these forces could play out over the next 20 years. Their contributions served as inputs for constructing scenarios—a set of alternative storylines—about potential ways medicine and health care might evolve between now and 2040.

Imagining 2020
from the vantage point of 1992: USP's previous scenario work

The Trust CoLab isn't USP's first effort to take a thoughtful and creative look at the future.

In 1992, the USP 2020 Strategic Context of Drug Standards and Drug Information Conference brought together 60 leaders from science, medicine, government, industry and consumer groups, as well as health futurists, to forecast the future of health and medicine. The year 2020 was chosen as the focus since it would be the 200th anniversary of USP's founding. A summary of the meeting is captured in *2020 Visions: Health Care Information Standards and Technologies*, a book published by USP.

Participants sought to answer the question, "If you were designing the ideal systems for standards and information for health technologies in 2020, what would they be?" Participants' responses, supplemented by interviews with experts from USP and other entities, drove the creation of four scenarios suggesting how the future might unfold.

Read more about how 1992's conference participants envisioned health and medicine in 2020 at **usp.org/trustorconsequences**.

From the exercise came four scenario narratives, which describe potential futures:

Scaling the tried and true.

A series of rolling crises spur effective global collaboration to address health concerns broadly. Meanwhile, medical advances based on big data and artificial intelligence occur gradually and are implemented incrementally. As a result, the focus is on baseline care, provided to all.

Dangerous uncertainty.

Problems with big data and artificial intelligence lead to devastating health care failures. Unequal distribution of access means only the rich receive the most advanced treatments while people of modest means turn to therapies informed by traditional folkways. The efficacy and safety of science-based medicine is called into question.

A world of difference.

The successful application of big data and artificial intelligence leads to rapid advances in personalized medicine and prevention, diagnosis, and treatment informed by genetic information. Not everyone has access to the fruits of these innovations. Disparities between and within nations perpetuate a "haves" versus "have nots" dynamic.

Solving tomorrow's problems.

Smart and deliberate innovation is broadly distributed. Advances in big data and artificial intelligence help create effective, inexpensive genetic diagnostic tools that are applied globally. Diseases become more predictable and, informed by new insights about why illness occurs, the focus of health care evolves to emphasize prevention. New treatments also emerge. Technological advances not only lead to remarkable new therapies but contribute to curbing increases in health care costs.

These scenarios are not predictions about what will happen; rather, they are narratives about what could happen. They are intended to open up people's minds and expand their thinking about future possibilities, to prompt better decision making in the present.

After the scenario narratives were developed, a summary outlined what each potential future might bring in four areas of particular relevance: the focus of medical innovation, the position of regulators, leveraging standards and the status of trust.

The focus of innovation ranges from a "Wild West" pursuit of the most advanced therapies, at one extreme, to an emphasis on creative ways to deliver tried-and-true therapies, at the other. The position of regulators and standards-setting organizations varies widely across the scenario narratives as well. In some futures they are central, building the institutional infrastructure that enables broad global cooperation; in others they become marginalized, fighting a rearguard action against the proliferation of unsafe, ineffective medical treatments. In some of the scenarios, trust remains high among all stakeholders; in others, it becomes bifurcated or fragmented.

In conclusion, the exercise suggested a broad range of ways standards—including standards in realms outside the ones that are now important—could contribute to securing trust in health and medicine in the 21st century.

USP and MIT CCI's goal with this report, and with the activities planned as part of USP's 200th Anniversary Celebration, is to encourage a robust and enlightening dialogue about trust in medicine and to spur reflection among health care stakeholders on how we all can work together to ensure the continuation of this trust in the future.

Introduction

As we prepare for the next wave of dramatic breakthroughs, we must work to ensure that trust and quality remain cornerstones of these advances.

In 2020, on the 20th anniversary of the sequencing of the human genome, we are experiencing profound and rapid advances in medicine. New technologies and treatments—like gene and stem cell therapies, precision medicine, immunotherapy, diagnosis by artificial intelligence, digital therapeutics and 3D printing—have arrived or are on their way. As we prepare for the next wave of dramatic breakthroughs, we must work to ensure that trust and quality remain cornerstones of these advances.

Today, trust is in a precarious position across many sectors, including science and medicine. Recent headlines have reported on the largest U.S outbreak of measles in 25 years, driven in part because many parents have not had their children vaccinated for this disease. Concern about rising drug costs is a major topic of discussion on the U.S. campaign trail in this election year. To help people embrace discovery and to encourage development of the next generation of therapies, we must work collectively to build trust in the future of medicine.

That's why U.S. Pharmacopeia (USP) and the MIT Center for Collective Intelligence (MIT CCI) joined together to launch Trust CoLab, an online platform that brought together a group of more than 100 global leaders in science and medicine to engage in a structured conversation about developments that could shape people's health between now and the year 2040. The goal of the project is to gain a deeper understanding of the importance of trust in ensuring the scale and broad availability of future innovation in health and medicine, with the promise of improved health outcomes around the globe.

Editor's note: The Trust CoLab main exercise took place October-November 2019, before the novel coronavirus (COVID-19) outbreak.

USP and MIT CCI, working closely with Jonathan Star, an experienced scenarios facilitator, invited the experts to address this question:

What developments will shape people's health between now and 2040, and how will trust be critical in making sure these developments help people everywhere live longer and healthier?

There was a specific rationale behind each part of the question:

What developments will shape people's health ...

Participants were asked to imagine the many factors that could shape future heath: not only technology and scientific advances but also potential changes in people's behavior or economic and environmental developments.

... between now and 2040 ...

Participants were asked to explore possibilities for the next 20 years. Some developments might be predictable or likely within that timeframe. Others could be highly uncertain or difficult to imagine right now. USP and MIT CCI wanted to capture all of these possibilities.

... and how will trust be critical ...

Participants were asked to consider how trust in medicine and health care may evolve alongside possible developments that will shape people's health. USP and MIT CCI invited participants to look across sectors and geographies and reflect on what factors might affect trust in medicine and health care in the future.

... in making sure these developments help people everywhere live longer and healthier?

Participants were asked to consider the following key questions: What will trust in medicine and health care look like across the globe in 20 years? How can we ensure the tremendous breakthroughs in science, medicine and health will be accessible and bring the maximum benefits to everyone around the world?

USP and MIT CCI guided participants through a structured, four-phase process that invited them to suggest drivers of change that could affect the future of trust in medicine and health care and to vote on which they felt would have the greatest impact. Based on these inputs, participants were then asked a series of structured questions that could serve to flesh out storylines about potential futures that might emerge. The contributions submitted throughout the exercise were then synthesized in this report.

What follows has four main parts:

- Specific drivers of change that participants envisioned will shape trust in health and medicine over the next two decades
- Scenario narratives—four storylines about possible futures that could emerge—based on participants' responses to structured questions
- Scenario perspective on innovation, regulations, standards and trust
- Conclusions from the exercise on potential ways to leverage science-based standards in the 21st century

Drivers of change

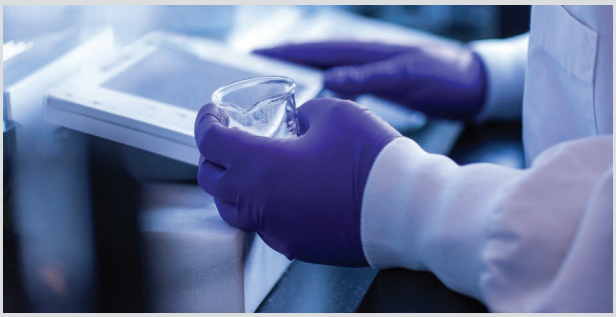
During the second phase of the exercise, participants were presented with 29 groups of drivers that had been organized into four overarching categories:

External forces

Broad forces that will shape the future and are also likely to have a big impact on health care/medicine

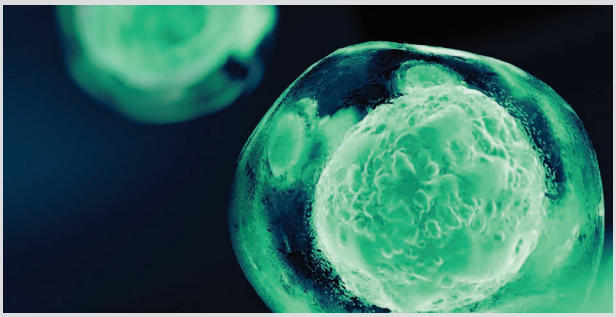
Non-health care technologies

Technologies developed in other sectors with significant potential to impact health care/medicine



Health care trends

Future developments expected to occur within the medical field/health care system



New therapies

New ways of treating patients that are expected to emerge, including traditional drug-based therapies and modalities such as gene modification, cell therapies and sensor/app bundles

2 Participants were invited to vote on the groups of drivers they believed would have the most impact on people's health through the year 2040. Eighteen items were judged to have the greatest potential impact.

External forces

- Environmental pressures and responses
- Inequality between and within countries
- Shifts in the global economy
- Demographic shifts, migration and urbanization

Non-health care technologies

- Big data's potential benefits
- Artificial intelligence for diagnosis and treatment
- Wearables and miniaturized sensors
- "Amazonization" in health care (i.e., delivery of care online/at the patient's home or office)
- Web-enabled self-care

Health care trends

- Drug development and approval processes
- Health care workforce
- Health care reform
- Health care industry structure

New therapies

- Genetic diagnostics and therapies
- Personalized medicine
- Wellness, prevention and holistic care
- Mental health
- Nutrition and food

Figure 1: Groups of drivers identified by participants as having the greatest potential future impact

Drivers of change

External forces

Participants highlighted four groups of broad forces outside of health care/medicine that they viewed as likely to have major impacts on health. The first two were seen as having the most impact and attracted the most contributions by participants; the last two, while also seen as important, did not attract the same level of attention.

First was **environmental pressures and responses**. Many contributors identified how climate change could affect health and medicine in the future. Insect-borne diseases could become more prevalent in formerly temperate regions, and there may be more illnesses tied to dehydration caused by water shortages and increased cases of skin cancer due to ozone depletion and greater ultraviolet exposure. Also anticipated were outbreaks of communicable disease among climate migrants in crowded refugee camps. More climate disasters, or heightened conflicts between nations caused by climate change, could place significant strains on health care systems.

Extreme weather could also make people more sedentary, resulting in increased cardiovascular disease, obesity and diabetes. Newly virulent pests and reduced acreage suitable for agriculture have the potential to lead to food shortages. One other disturbing possibility was mentioned: What if higher levels of disease among chicken populations could cause a lack of healthy eggs for the supply chain, resulting in shortages of the vaccines for flu, yellow fever and MMR (measles, mumps, rubella)?

Beyond climate change, some participants noted how pollution—notably microplastics and toxins present in electronic waste—could affect future health.

While environmental challenges are anticipated over the next 20 years, we should also expect many potential responses. One might be a shift toward a circular economy, reliant on re-use, rather than producing goods anew from raw materials. This could affect the health care system specifically by restricting single-use plastics. This could also force providers and medical device manufacturers to develop biodegradable materials or rely on recycling. We could also see the replacement of toxic/hazardous chemicals with greener/sustainable alternatives in medical labs and the adoption of measures to reduce the impact of pharmaceuticals in the waste stream.

Participants also identified **inequality between and within countries** as a source of future health impacts. Drivers in this category cut in two broad directions: some participants envisioned a future of increased disparities; others foresaw greater equity.

Participants identified a number of drivers that suggest we could see greater inequality in the future. Disparities in wealth, education and health coverage might continue, affecting access to care. Poorer regions might experience a slower diffusion of medical advances. Research data used to develop new breakthroughs might exhibit bias (e.g., at present 80 percent of the genetic data available to researchers is about Caucasians). We might continue to see a lack of awareness about health impacts (e.g., the benefits of a healthy diet) among the less privileged.

In addition, the economics of health care could incentivize medical researchers and pharma companies to neglect diseases, such as Dengue and Chikungunya, that are prevalent in certain developing countries but not in developed nations. Finally, many participants were concerned about a future of "class" divisions based on people's DNA, with discrimination against people seen as having "unfit" genomic profiles due to their being susceptible to particular diseases. Participants also noted that inequalities existing outside of the health care system, such as the availability of clean air and access to clean water/adequate sanitation, will continue to influence health.

Alternatively, participants identified some developments that could contribute toward greater equality in health outcomes. Over the next 20 years, we might see successful activism that promotes greater economic justice; richer countries helping subsidize health advances in developing countries; new models for developing drugs to address neglected diseases and antimicrobial resistance; uptake by national governments on the United Nations' push to achieve universal health care and health-related Sustainable Development Goals; use of online platforms to foster open, participatory dialogue that could facilitate development of more inclusive policies; and more gender equality, which is associated with better health outcomes in populations as a whole, especially in developing nations.

The third group of drivers, **shifts in the global economy**, focuses primarily on the predicted faster economic growth in emerging economies. Several participants noted that with the rise of a large middle class in China, South Asia, Africa and Latin America, health care spending is expected to grow significantly in those nations over the next two decades. The world's poorest countries also show the fastest population growth, so demand for health care will no doubt rise in those nations as well. China is likely to become the world's largest health care market; some participants wondered if it might also become the world's center of gravity for medical innovation. Looking across the world as a whole, some participants raised the prospect of a truly global market for pharmaceuticals, enabled by harmonized international standards.

The final group of drivers in this category, **demographics, migration and urbanization**, focuses on the age and settlement patterns of populations. In advanced economies, aging populations, driven by increasing life expectancy, will lead to more chronic disease and challenges in providing elder care. Developing countries, by contrast, can be expected to have a growing cadre of young people. Participants identified how migration is creating cultural fissures and a reaction against diversity in some countries while urbanization is reshaping attitudes and lifestyles throughout the world. One example of the latter is the growing adoption of Western diets by citizens in developing countries who move from the countryside into cities. ●

Drivers of change

Non-medical technologies

Technologies developed outside of the medical field were seen as having a big potential impact because participants foresaw them being applied directly in the health care sector. The three technologies participants saw as having the greatest potential impact on people's health are **big data, artificial intelligence (AI), and wearables and miniaturized sensors.** Because these technologies are closely connected, participants envisioned them being used in combination.

Big data and AI—deployed in tandem—have the potential to enable far more efficient and accurate diagnosis and treatment, as well as more effective preventive health measures. AI will query repositories of genetic and electronic health record data to find new patterns, leading to the development of new therapies.

Early applications of AI already assist care providers in diagnosing illnesses and recommending treatment plans. AI has the potential to reduce errors and the human effort required to reach decisions. This could lead, over the long term, to shifts in the composition of the field of medical professionals. We should expect that all medical professionals will need to become more conversant with data, and that there will be growing opportunities for new kinds of professionals to work with data in the health care field. For example, participants anticipated that fewer radiologists might be needed, while there will be more data professionals and machine learning experts to create and update algorithms that physicians rely on.

AI may also allow for more accurate predictions about people's future behavior that could encourage improved compliance with treatment regimens and better treatment of mental health problems. In the face of these developments, participants noted that a new set of rules would need to be established to govern the use of AI in health care. In particular, concerns were expressed about data privacy and ethical questions that arise with the use of AI systems.

People's health could be transformed by wearables and touchless or implanted sensors. Ubiquitous sensors would enable continuous monitoring of a patient's health condition (e.g., ongoing tracking of glucose levels for diabetics or collection of data on the condition of a cardiac patient's heart). Embedded sensors could react to changing internal conditions, such as pH, and alter the way a drug is released so it is most likely to have a positive effect.

Some participants even foresaw a future where a person's handheld device could serve as a mini-lab for undertaking blood tests or validating the quality of a prescription. The widespread presence of wearable/embedded sensors could make it easier to recruit and enroll subjects in virtual clinical trials. Recent mobile apps are an early example that demonstrates the potential of this approach.

Some participants noted that many of these opportunities will be realized only if steps are taken to facilitate the collection and appropriate use of medical data and ensure data integrity and interoperability. Data would have to be housed in the cloud (instead of siloed in individual providers' systems) and in repositories that are openly accessible, with appropriate privacy protections, to parties who promise to make good use of it.

A world of big data, however, poses privacy risks to patients. We might expect new governance frameworks to enhance rules for collection, storage and use of medical data. To be most effective, these frameworks will eventually have to be extended to work on a global scale. Cybersecurity will be critical; some important medical data will be collected and stored on personal devices, designed for consumers, that are not currently set up to allow for stringent security protections.

The combination of big data, AI and ubiquitous sensors creates the prospect of a far more information-rich environment. This could lead to radically new business models in the health care sector. One can imagine providers offering subsidized health services in exchange for patient data. Insurers could set their pricing based on people's measured health habits, the way auto insurers now offer "safe driver discounts" to customers willing to have their driving habits tracked by a mobile app.

Some participants looked at these developments and identified a potentially significant unintended consequence. If AI applications become as powerful as promised, this could lead to significant reduction in the number of jobs in medium- to high-earning categories outside of the health care sector. In countries that rely extensively on private health insurers, this could erode the size of the middle-class risk pool, whose insurance premiums are needed to keep the health care system viable.

Two other groups of drivers focus on how patients could access health care more immediately and conveniently. The first is the prospect that people's health might be shaped by **"Amazonization" in health care**, a push by providers to deliver convenience to patients by making care accessible at locations close to homes and offices or via virtual interactions. Tech companies like Amazon have created remarkably powerful and immediate user experiences for their customers. The expectation that other companies will offer similar experiences is flowing through into other parts of the economy, as consumers expect more customized and responsive services.

Participants highlighted how telemedicine is expected to become increasingly prevalent, especially in low- and middle-income countries where traveling to health care centers may be difficult due to lack of transportation infrastructure. The prospect of remote robotic surgery in such settings is another possibility. Similarly, more pharmacy customers in the future may have drugs delivered to them the same way a package is delivered by Amazon—by truck or by drone.

The second is **web-enabled self-care**, which refers to the explosion of health care information available online. Patients are increasingly aware of health conditions and illnesses based on what they read on the web. Participants envisioned the prospect of a subset of patients, over time, adopting a do-it-yourself mentality about health care, with the result that they would feel less dependent on professional care providers. This effect could be enhanced if we see the emergence of local biohackers, able to synthesize therapeutic substances locally and inexpensively. Such self-care could be further encouraged by apps that rely on information from wearables and small sensors.

More online information is also expected to heighten the risk of misinformation being spread. We already see this danger as it relates to vaccinations. Health care could be affected as malign actors prey on gullible patients by promoting ineffective treatments—the 21st century equivalents of the snake oil cures sold to gullible customers in the 19th century. Given these risks, there may be a counter-push, resulting in a demand for third parties that serve as neutral arbiters, validating which web-based health information is reliable and which is not.

Drivers of change

Health care trends

Participants identified four main trends within health care that are likely to drive change and ultimately affect people's health: a movement from binary to conditional drug approval processes, changes in the health care workforce, policy reform and shifts in industry structure.

One group of drivers pertains to **drug development and approval processes**. Many participants foresaw a shift from the current binary (approved/not approved) approach to a more conditional, graduated process. They imagined how incremental authorizations could occur for ever larger groups of patients, informed by data collected and analyzed at each stage. Patients would have more ability to volunteer for trials and provide their own data in real-world evidence trials, which would deliver outcomes more quickly than in traditional trials. Regulatory agencies could then use this information to evaluate new medicines. Some participants, however, expressed concern that allowing patients access to therapies in the early stages of development could lead to unanticipated safety problems.

Clinical trials could also be transformed by AI and genetic modeling. These technologies might reduce the need for human subjects to participate in trials by undertaking sophisticated software-based simulations to predict the likely impact of proposed new therapies. Both iterative and modeling-based approval processes could significantly reduce drug development costs.

Participants also identified the possibility of a more globally integrated approval process, involving cooperation, first among regulators in North America, Europe and Asia, and eventually in Latin America and Africa. They envisaged simultaneous global approvals, based on Totality of Evidence in Multi-Regional Clinical Trials and growth in membership in the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use. This would address the lag that exists today in some emerging economies, particularly Asia. Participants also expected governments to optimize the regulatory process for emerging digital health technologies.

In the future, discovery processes might also be transformed by bio-innovators working in local labs. The availability of community-based lab space and the spread of an open-source ethos, of the kind pioneered by software developers, might allow citizen bio-scientists to make important breakthroughs. This locally based discovery could be enabled and enhanced by the emergence of micro-manufacturing

capabilities, where small labs could synthesize bio-remedies and 3D print traditional pharmaceuticals on site.

The next group of drivers seen as having a major impact concerns the changing **health care workforce**. Several participants saw real potential for future shortages of health care workers, which would, in turn, affect people's health. In developed countries, this could be driven by a growing demand from aging populations, coupled with compensation issues and burnout affecting the supply of primary care providers. One participant specifically identified the problem of the high cost of medical school in the U.S., noting that a potential remedy could be philanthropically funded programs recently started at several medical schools that obviate the need for massive loans. Developing countries might also face shortages in caregivers due to a lack of training infrastructure.



The comments of some participants, however, cut in the opposite direction; they noted that telemedicine could address localized provider shortages. Technology was also seen as potentially helping with staffing shortages. AI tools and robots could take over some tasks currently performed by health care professionals, freeing people to do tasks requiring skills that only humans possess. Community pharmacists have also demonstrated that they could assume a larger role in ensuring patients comply with treatment regimens.

Another group of drivers, **health care reform**, describes how many countries' health systems are under pressure, with this pressure only expected to grow in the years ahead. In some countries, the biggest challenges will involve the need to provide access to care at a lower cost for those of modest means; in others, the primary impetus to reform will be budget pressures, especially in light of expensive new therapies and the growing needs of aging populations.

Many approaches to reform are already under consideration. These include patient-centered care, value-based care (i.e., cost structure based on improved health outcomes), measures to reduce the cost of pharmaceuticals (particularly in the U.S.), steps to reduce medical litigation, greater reliance on health technology assessment, new compensation models and equitable remuneration. Other participants noted the importance of shifting the focus to prevention, not only in dealing with individual patients but also in how public funds to improve health are allocated, including proactive investments that can improve social determinants of health such as improved employment opportunities, education and affordable housing. Participants expected that most health systems will undertake some combination of these reforms over the next decade or two.

A final group of trends related to the health care system addresses questions of **health care industry structure**. Participants imagined several developments that could lead to major changes in the industry. These include more employers self-insuring their workers, peer-to-peer insurance co-ops and a shift in the U.S. to a single-payer health care model. Concerns were expressed about the potential for big data to create the capacity to segment the patient base very finely, thereby allowing insurers to cherry pick the most attractive customers, which would have ill effects. Participants also foresaw pressure for more transparent hospital pricing.

The pharmaceutical industry will be expected to face pressure to reduce drug costs, especially for biologically based products. 3D printing and continuous manufacturing for biotherapeutic products could help in this quest. In a price-pressured market, some participants expressed concern about what might happen to producers of generic drugs. Might they thrive or could they struggle to make sufficient returns on investment, which could reduce the supply of lower-cost drugs?

Some participants foresaw the potential for policymakers in some countries to impose mandatory price caps on drugs. Policymakers in emerging economies could mandate low-cost licensing of patented drugs in their regions, and regulators may step in to curb patent evergreening—the practice of making small changes to drugs that are going off patent to secure another round of patent protection. Some participants also foresaw the end of direct-to-consumer marketing of pharmaceuticals in the U.S.

Drug supply chains could also be reconfigured, based on shortages of materials, restrictions imposed by importing countries and the emergence of new regions (e.g., Africa) to serve as the location for low-cost manufacturing.

Drivers of change

New therapies

The first two groups of drivers in the category of new therapies, **genetic diagnostics and therapies** and **personalized medicine**, are closely interrelated.

There is likely to be growing reliance on "omics" profiling (e.g., genome, transcriptome, proteome, metabolome, exposome, microbiome), assisted by AI, which will increasingly inform individualized risk reduction, prevention and treatment plans. This development might be enabled by small-batch, in-home manufacturing of "designer drugs," using micro-fabrication units that could fit in a patient's kitchen or den. Participants also envisioned online patient monitoring by wearables and embedded sensors. A key enabler will be the ever-lower cost of gene sequencing.

The proliferation of new testing and treatment methods could be taken a step further. We are likely to see treatments to modify patients' DNA. These methods already show promise of addressing a wide range of diseases, including lymphoma and other cancers as well as diseases such as Alzheimer's, Parkinson's, celiac, multiple sclerosis and even obesity.

Gene-based therapies will raise ethical issues if they are used to enhance human capabilities. Participants also saw the dangers of a biased genetic knowledge base (e.g., current genomic databases significantly overrepresent people of European descent and the

privileged). As genetic therapies become more commonly used, such issues will need to be addressed.

The next group of drivers does not actually involve new therapies, but rather represents a way to prevent the need for them: **wellness, prevention and holistic care**. In the future, we can expect greater focus on measures that address health challenges before disease strikes and an emphasis on treating each patient as a whole person, who has an identity beyond his or her status as someone battling an illness.

As one part of this push, participants foresaw health care systems coming to rely on a broader set of metrics to gauge health outcomes; for example, tracking quality of life in addition to life expectancy. Others envisioned health care systems adopting metrics that reflect some of the social determinants of health, such as environment, self-image, the character of professional and personal interactions, and the extent to which people feel they are part of a community.

These new metrics could, importantly, allow for new ways to evaluate the return on investments and interventions designed to enhance health. Some participants felt that such a shift would make the benefits of preventive care more apparent. More generally, instead of countries' overall policies focusing on gross domestic product growth, participants imagined some governments could also place the wellness of their nation's population as a top policy goal, since better health raises productivity and reduces dependence on government benefits.

Participants also envisioned key actors incentivizing individual behaviors that enhance wellness. To reduce health care costs, we are likely to see more employers compensating staff for adopting healthier lifestyles that include exercise, weight loss and getting adequate sleep.

Participants also foresaw a complementary development: growing emphasis on treating the whole person in an integrated way once illness strikes. Providers will increasingly recognize that patients want to be considered as people and not be defined by their illness. There was also an expectation that future therapeutic regimens would combine drugs with diet and exercise programs in an integrated way. This could involve care teams expanding to include additional disciplines, for example, experts in nutrition or stress management working alongside experts in the traditional medical specialties.

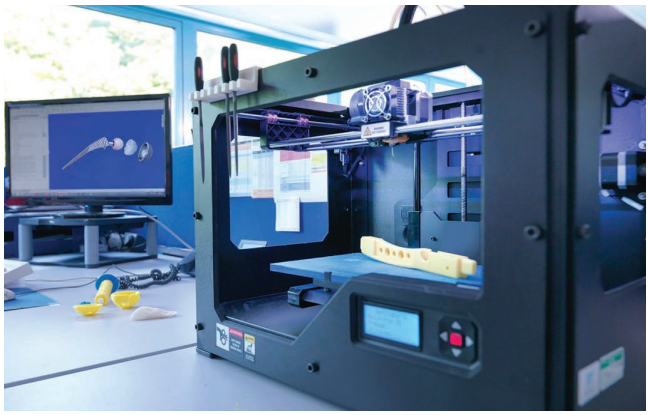
The next group of drivers focuses on emerging new therapies to address **mental health**. Advances in brain science can be expected to lead to new, better-targeted treatments for mental health problems. In particular, drug addiction, dementia/Alzheimer's and problems associated with the stresses of modern life—such as social media and video game addictions, information overload and 24/7 workplace expectations. All of these areas of focus were anticipated in the near- and mid-term. Such advances could also help address diseases that are tied to the brain and affect other parts of the body. Increased access to services and a reduction in the stigma tied to mental health problems were also anticipated.

A final group of drivers was called out in this category as having a large potential impact: **nutrition and food**, which was seen emerging as a more important form of medical treatment. Food is also likely to undergo significant changes in the decades ahead—for example, several participants anticipated new kinds of plant-based meat—and this will have a major impact on people's health.

Some of these developments may be driven by government policies targeted at reducing obesity and the high health care costs associated with it. Others, like plant-based diets, may be adopted based on policies to curb climate change or evolving consumer preferences. New foods, such as alternative forms of protein made possible by genetic engineering and production with microorganisms, will emerge.

New modes of consumption could also arise to address health challenges. One example cited was people being prescribed personalized diet plans based on their microbiome. Participants also envisioned a world where engineered foods, tailored to the genome of the patient, could incorporate bio-modifying interventions that treat illness, with compliance confirmed by microbiome monitoring.

Several other groups of drivers were also noted by participants, though in lesser measure than the themes listed above. But these drivers also describe interesting potential developments that could shape people's health in the future. For some patients, the emergence of low-cost **cell therapies** shows promise as a replacement for traditional pharmaceuticals. This could lead to more patients banking their stem cells and more aggressive embryonic research in the future.



Engineered body parts, produced using traditional materials via bioengineering (in vivo or by 3D bio-printing), could become prevalent. Such developments could improve overall health and life expectancy by mitigating donor backlogs for the highest-need organs, tissue or even blood. Ethical issues will arise should these engineered parts be used for augmentation and not just replacement.

Other novel therapeutic methods were also seen as playing a growing role in the future. These methods include nanotechnology for targeted imaging and drug delivery, therapies based on modulating the gut microbiome, polymolecule therapies that rely on using multiple drugs at once and theranostics (diagnostics and therapy using targeted radioactive drugs).

The final group of drivers covers **new therapies for specific health challenges**. These include therapies to address trauma and emerging diseases (e.g., Zika, Ebola, HIV), as well as long-established diseases (e.g., hypercholesterolemia associated with coronary heart disease, Alzheimer's disease, malaria, cancer), therapies targeting patients who face multiple concurrent health conditions, new approaches for responding to mass-casualty situations that arise due to natural disasters or conflict and health problems that may arise in the course of space travel.


97%


CAS9

Scenarios

Participants' voting and comments on the groups of drivers served as the basis for 14 scenario axes. A scenario axis depicts two quite different outcomes that could occur along a key dimension.

For example: Will big data lead to more effective treatments and lower costs or might the difficulty in achieving clearer insights with data, combined with privacy concerns, prevent major benefits from being realized? The goal of setting out an axis like this is to describe the range of uncertainty about the future along that dimension.

During the third phase of the exercise participants were invited to comment on the uncertainties described by the axes and to support (an action on the platform similar to liking a post on Facebook) the ones they thought could make the most interesting scenarios. Based on that input, organizers chose two axes that had attracted much attention from participants and also showed potential to serve as the basis for an interesting set of scenarios. They arrayed those two uncertainties onto orthogonal axes, thereby outlining four potential future worlds that could emerge by the year 2040 (see **Figure 2**).

The first axis is about big data/AI and how these technologies could facilitate radical medical advances in personalized medicine and gene-based prevention, diagnostics and treatment. At one extreme, these anticipated innovations would deliver on their promise; at the other, the future would bring disappointments and slower-than-expected advances.

The second uncertainty relates to how broadly distributed new medical advances and access to care will be. At one extreme, the future would bring widened health disparities, with the most advanced treatments available only to the privileged; at the other extreme, the future would bring widespread, relatively equal access.

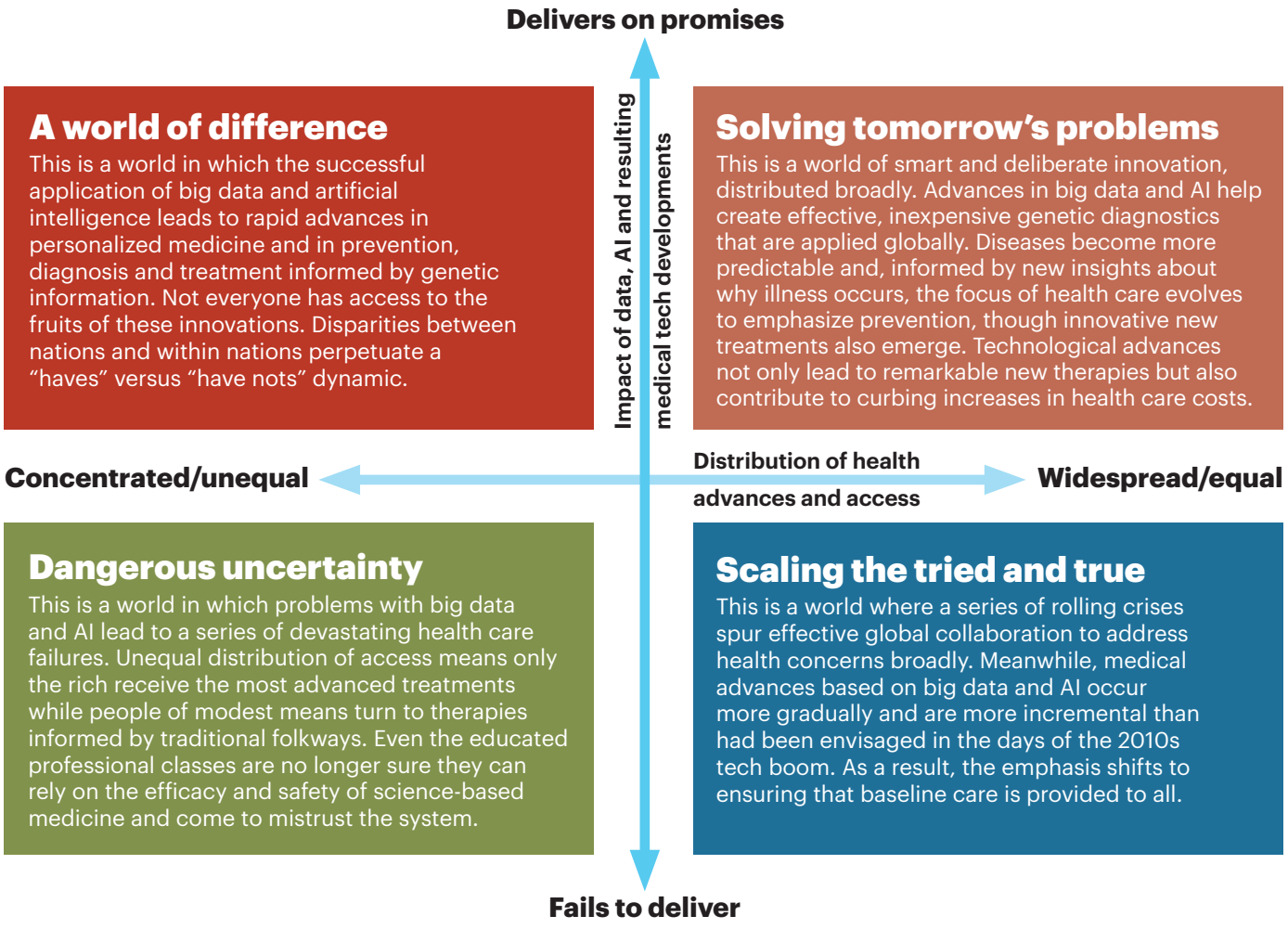


Figure 2: Scenarios developed in the Trust CoLab exercise

Scenario

Scaling the tried and true

This is a world where a series of rolling crises spur effective global collaboration to address health concerns broadly. Meanwhile, medical advances based on big data and artificial intelligence occur gradually and are implemented incrementally. As a result, the focus is on baseline care, provided to all.

In the first half of the 2020s, a series of health crises occur. Climate emergencies create large numbers of disaster victims; heretofore less recognized environmental threats like micro-particulates in the air and plastics in water are recognized as posing severe health risks; viruses and microbes that are resistant to antibiotics emerge, leading to outbreaks of newly virulent infectious diseases; and mosquito-borne diseases (e.g., malaria, West Nile, Eastern Equine Encephalitis, Zika) become increasingly prevalent in what were once more temperate regions.

In parallel, while the application of big data and AI contributes to some medical advances, these occur more slowly than had initially been expected. They are also less than revolutionary and apply to only small numbers of people.

Many of the health problems that trouble the world span national boundaries—for example, plastics waste in Indonesia affects health in Japan—so it's not enough for countries to police themselves. Instead, effective action requires broad cooperation. At first, nationalism and polarization driven by social media manipulation prevent nations from effectively working together. The initial response to the wave of health crises is fear and an impulse to close ranks.

But nothing focuses the mind more than a crisis—or a series of them. Over time, high-profile successful collaborations emerge. When a major outbreak of Ebola spreads from sub-Saharan Africa to Western Europe, the non-governmental organizations (NGOs) Partners in Health and Médecins Sans Frontiers jump in. Working closely with the World Health Organization and a consortium of pharmaceutical companies—and assisted by young biohackers based at a university in Liberia—they manage to curb the contagion. Similar efforts, involving health-focused NGOs, the medical research establishment, large foundations and groups of dedicated physicians, succeed in staunching an outbreak of malaria in the southern U.S. and a major occurrence of tuberculosis in East Asia.

Global media coverage draws attention to the success of these heroic efforts. It also shows how close the world came, in several instances, to facing large-scale pandemics. The global community gets very pragmatic. A broad range of collaborations is forged across nations and between the private and public sectors to address emerging health challenges. These collaborations focus on using technology to scale up global delivery of tried-and-true solutions rather than cutting-edge advances.

The nature of the new threats also leads to recognition that everyone is in it together. As the crises show, it only takes a few unprotected people for a virulent illness to spread widely. Providing adequate health care to all members of society comes to be seen as an imperative for ensuring the safety of the population of a country—and the world as a whole. As a result, there is a new emphasis on equity and guaranteeing broad access to care.

One important element of the global collaboration among nations and other organizations is the codifying of responses to major health crises such as treatments used, protocols for patient care, innovative new practices, and real-world trial and error. After recovering from a major global health crisis, leaders conduct after-action reviews based on lessons learned in order to create standardized approaches that are deployed around the world in subsequent emergencies. On-the-ground experimentation with new treatments becomes real-world clinical trials, which lead to streamlined regulatory approvals, providing flexibility in the up-front stages balanced by real-world feedback loops.

Genetic research emphasizes understanding the genetics and life cycle of pathogens and the genetic makeup of people able to resist them. This focus leads to development of new vaccines and genetic treatments.

While these breakthroughs are important, implementation science becomes the center of health care innovation efforts, to ensure that resources are used in the most effective way. One element of this is disseminating preventive measures at scale. Another is a push to accelerate the pace with which proven therapeutic approaches are implemented. As a result, the timetable for adoption of best medical practices shrinks from seven years to nine months.

Novel modes of delivering health services, relying on information technology, also play a big role. A large Chinese tech company launches a health care venture that comes to span the globe. It provides patients around the world with low-cost access to doctors based in China. The system is powered by web-based telepresence and real-time voice translation, with mobile payments allowing access to these services even in rural parts of developing countries.

Low-cost medicines and preventive measures, delivered at scale, are core to this world. Companies active in the health care sector adjust their business models so they can deliver well-established therapies while still providing an adequate return on investment.

Advanced economies are no longer the main place where medical innovations arise. New approaches in Sierra Leone for delivering care quickly and at scale may be as important—or even more important—than a new cell therapy developed in a lab in Western Europe.

Through a combination of new preventive/therapeutic measures, innovative new approaches for delivering them and faster adoption, several diseases—measles, malaria, yellow fever and HIV/AIDS—are effectively eradicated globally.

Trust is crucial in this future. Memories of the crises that swept the world in the early 2020s remain fresh and ensure that broad cooperation remains in place across the entire global health care system. The success of cooperative models is proved time and again, making trusting partnerships the bedrock of global health care in 2040.

Scenario

Dangerous uncertainty

This is a world where problems with big data and artificial intelligence lead to devastating health care failures. Unequal distribution of access means only the rich receive the most advanced treatments while people of modest means turn to therapies informed by traditional folkways. The efficacy and safety of science-based medicine is called into question.

The high hopes that applying big data and AI would unlock new therapies are not fulfilled—far from it. Instead, a series of major missteps fosters deep, widespread disillusionment.

In one high-profile instance from 2022, algorithms mis-prescribe drugs to a group of African American patients at a large hospital in Los Angeles, leading to hundreds of deaths. Investigations reveal that errors were caused by data-gathering flaws and algorithmic biases, since minorities and less-powerful groups have been systematically underrepresented in clinical research studies.

A group of startups based in San Francisco seeks to develop a range of IT-enabled therapies, such as diagnostic AI, sensor/app bundles and telemedicine bots. With their venture capital investors pushing them to reach scale quickly, these companies skirt regulatory requirements (much as Uber did in the ride-sharing domain) and field products before their safety and efficacy have been fully proved. This leads to a series of high-profile accidents and ensuing skepticism.

Many other disasters follow. Dozens of patient deaths are tied to software bugs in a cutting-edge smart sensor/insulin pump device. An elective CRISPR-based vision enhancement procedure developed in Japan, which promised to let people perceive colors outside the visible spectrum, instead causes blindness in numerous patients within five years. Sympathy for the victims is tempered because they chose to undergo an elective procedure that

was not medically necessary, but the incident undermines confidence in therapies based on genetic modification.

The backlash against AI grows stronger when investigative journalists report that, at some major hospitals in the U.S., algorithms were tuned to maximize revenues and profits rather than patient outcomes. Disillusionment deepens further when hackers from enemy countries seek to corrupt medical algorithms in a set of concerted cyberattacks. Several of these attacks are focused on top-ranked medical centers in North America and Europe, which were aggressive early adopters of data- and AI-enabled medicine.

Other scandals are tied to medical advances used for nefarious social or political purposes. Some authoritarian governments institute mandatory DNA sampling, so as to be able to identify and arrest protesters with technology that can project how people's faces look based on their genetic makeup. By finding traces of DNA at the site and matching them against the national genetic database, authoritarian rulers can detect who was present at a demonstration even in the absence of video images.

These developments lead to a near halt by the mid-2020s in large-scale application of big data and AI in health care. The slowdown is exacerbated by lack of interoperability and failure to achieve broadly agreed-upon standards. Medical researchers in Western countries reexamine the sampling practices they have long used in early stage drug development and clinical trials, with the goal of eradicating bias. This leads to a chaotic period in which long-established practices are reassessed and progress is slowed even more.

In parallel, policymakers deliberate about what new rules should be established to protect the privacy of patient data and govern the use of AI in health care. The process gets bogged down in dysfunctional bickering between groups hoping to foster continued medical progress and populists who don't take the time to understand the technical issues and seek to gain political advantage from prior missteps.

The inability of people of modest means to access the best medical care leads to widely publicized cases in which gullible patients are victimized by medical counterfeiters. Counterfeiting medicine reaches the scale seen in the 2010s in the luxury goods markets. Regulators and standards-setting bodies increasingly devote their attention to detecting and removing substandard and counterfeit medicines from circulation and debunking ineffective/unsafe alternative therapies. As a result, they are able to devote less time and resources to evaluating new science-based treatments, further slowing advancement.

Most people come to mistrust the health care system and the scientific ethos on which it is based. Increasing tribalism in society leads some people to rely less on credentialed experts and more on peers. Among such groups, there is a turn away from science-based medicine and growing usage of remedies with ties to traditional cultures, which are promoted by adherents on social media. For example, more people come to rely on acupuncture and Chinese herbal remedies as their sole treatment regimen, not simply as a complement to Western medicine. There is also growing use of food- and nutrition-based therapies for patients who cannot afford conventional medical treatments.

In some cases, this has salutary effects: A return to traditional ways of eating, like the Mediterranean diet or consumption of the oily fish eaten by the Inuit people of the Arctic, improves health outcomes for some. Certain people, who possess the right genetic characteristics or are naturally resistant to disease, do well in a survival-of-the-fittest environment. These lucky survivors become convinced of the correctness of their ways, and their folk-based approaches to medicine become seen as increasingly legitimate within certain subpopulations. In some instances, charismatic individuals and their eccentric health recommendations, amplified by the megaphone of social media, achieve cult leader status among their true-believing followers.

Yet, unfortunately, reliance on folk medicine leads to troubling outcomes for many. Some of a health cult's followers may not have the right genetic endowment for the prescribed regimen and thus experience negative consequences. Since there is no science-based evidence to turn to, it becomes impossible to predict who is likely to benefit and who is not. Anti-vaxxer beliefs become even more widespread, leading to localized instances where illnesses formerly thought to have been eradicated reoccur.

Sales of alternative medicines come to exceed those of patented/approved medicines in the U.S., yet life expectancy declines. Widespread mistrust of science among the public means there is no support for objective studies to find the causes of this decline, which only reinforces the vicious cycle.

The educated professional classes also lose trust in the health care system but for different reasons. Daunted by high-profile failures centered in leading research hospitals, they turn against care informed by data and AI. They guard their own medical records closely, and those with the means turn to a new kind of primary care physician, who offers highly personalized care, informed by science, but is hesitant about recommending any measures that are not well established and rigorously vetted. Some of these physicians work with trusted, locally based community biotech labs, which are able to synthesize drugs that are known to be sound.

This world is one where trust in the health care system has become fragmented. For the few who can afford the most advanced treatments, high-tech medicine offers big benefits. Much of the educated middle class comes to feel suspicious about the medical establishment and trust only a small coterie of locally based health care providers. The less affluent rely increasingly on traditional folk medicine and food-based cures, recommended by people they trust from their local communities or those they engage with on social media.

Scenario

A world of difference

This is a world in which the successful application of big data and artificial intelligence leads to rapid advances in personalized medicine and prevention, diagnosis and treatment informed by genetic information. Not everyone has access to the fruits of these innovations. Disparities between and within nations perpetuate a "haves" versus "have nots" dynamic.

In 2040, all babies except those born in remote rural regions get their DNA sequenced, as do people at airports seeking to enter affluent countries. Distributed mini-testing labs make widespread gene sequencing fast and convenient for most.

Ensuring the health of the population is seen as a way for rich nations to maintain their economic power and influence. It's also a way to restrain the growth of health care costs, which are an increasing strain on public budgets in nations with aging populations. As a result, governments seek to exclude newcomers, and even visitors, whose DNA could make them susceptible to illnesses that have the potential to spread to citizens. The problem of noncitizens hoping to enter wealthy countries becomes acute in the 2030s, as climate refugees from the Pacific islands and low-lying nations like Bangladesh increase.

People share all of their health genetic data with large providers, drug development firms and tech companies active in the health care industry—it is a requirement to obtain care. This includes not only genetic data and electronic health records but also information about daily life, including eating and exercise habits, gathered by the complex array of wearable and embedded sensors most people use.

Large Western tech companies and their counterparts in China, which previously took the lead in exploiting data for targeted advertising and selling, apply their knowledge about working with data to assume a major role in health care. Big tech harvests health information from developing countries and rural/remote areas in advanced countries and works with pharmaceutical companies to test new therapies in those places first. Residents in these areas are happy to volunteer, since it is often their only chance to access advanced therapies.

Health insurance premiums are adjusted based on genetic characteristics and data on people's habits. Since the affluent have more money to buy better food and more leisure to exercise, ironically, their health insurance premiums are lower. People of modest means eat fewer healthy foods, exercise less and are more susceptible to a range of chronic diseases, so their insurance premiums are higher.

Access to health care is determined not by the country in which people live but rather by disparities in access tied to regional differentials within countries. People living near Shanghai or San Francisco, for example, are able to get the same advanced treatments, with the richest taking advantage of cutting-edge breakthroughs that border on science fiction.

Some countries are initially more aggressive in development of genetic therapies and attract wealthy patients from around the world, not only for genetic therapies but also for genetic enhancements. The countries that move first are able to capture valuable intellectual property and also generate revenues by treating wealthy patients who want to be early adopters of the latest advances. These funds can then pay for the next round of research. This dynamic eventually draws other advanced countries, which had initially proceeded more slowly due to ethical concerns, into a global genetic therapy "arms race."

Media reports about the "6 billion dollar man" (a name that riffs on the title of a 1970s American television series about an astronaut whose body was enhanced with bionic implants that cost 6 million dollars) tell of a Silicon Valley titan who, in his quest for immortality, spends huge sums on research and testing of genetic enhancements designed exclusively for him.

Genetic tinkering, albeit on a less elaborate scale, becomes the norm for the most affluent. As a result, in some countries the life expectancy gap between the top 1 percent and the bottom 80 percent comes to exceed 50 years.

In the 2030s, the first babies are born whose DNA includes sequences taken from other people. Some parents choose DNA sequences taken from the reconstructed genomes of great geniuses from prior eras, like Albert Einstein and Leonardo da Vinci. Leather goods grown in labs from skin cells of prominent 21st century celebrities become a hot fashion item.

In parallel, gene harvesting—which acquires DNA snippets associated with desirable traits, like immunities, reproductive health and even height and beauty—becomes a major industry. The concept of the genetic lottery takes on a new meaning when the best genetic material can be obtained for the right price.

In areas outside of major cities, such as Appalachia or Western China, only the most affluent have access to advanced treatments. High-priced therapies are out of reach for those of modest means, and 1 billion people in urban slums cannot access even basic care. Those in poorer regions who struggle to access care are at the same time more likely to suffer disproportionately from the negative health effects of climate change. Responses to this situation are varied.

In the late 2020s, insurers in the U.S. begin to sell plans that offer lower premiums but rely on medical tourism. Patients can file claims only if they have the most advanced treatments in foreign countries, where they are provided at lower cost. In 2030, a California bank offers the first mortgage to fund the cost of medical treatment. Over time, medical loans become prevalent and are treated much as educational loans are handled in the U.S. today, with borrowers unable to declare bankruptcy to escape repayment. Wall Street is able to bundle these medical loans and sell securities comprising tranches of patients with similar medical conditions. Patients who obtain well-established treatments for chronic diseases are bundled to create AAA-rated bonds; those who receive experimental treatments for rare diseases are bundled into bonds that are riskier but offer higher returns. The prices of these securities are volatile, shifting quickly as new discoveries arise and new knowledge emerges about the likely outcomes of therapies.

With so many people unable to access the latest medical advances, growing resentment spurs massive demonstrations across the world. Some developing countries invalidate patents or enforce licensing to reduce the costs of new therapies. Rich countries respond by introducing complex security measures to prevent unauthorized copying of new therapies. Counterfeiting of traditional pharmaceuticals and newer biologics becomes increasingly common and small-scale. Local labs begin to synthesize medicines in a do-it-yourself (DIY) way, compromising quality and safety in order to provide low-cost therapies to patients in need. These labs are unable to share data and best practices effectively and also cannot absorb the costs associated with standard quality processes and safety testing. As a result, such DIY efforts often cause harm to patients by not providing effective treatments or exposing them to toxic substances.

Broad public support for government investment in medical innovation wanes, since it is seen to benefit the few and not the many. Regulations on therapies are loosened, since the richest are able to vet new treatments themselves and jet around the world to wherever the research related to their condition is most advanced. Their social media posts, which tell of the advanced treatments they receive, only make more apparent the gulf between the care the wealthiest receive and that which other members of society can access.

Given these dynamics, the affluent maintain strong trust in medicine and the health care system, as might be expected, since they are the beneficiaries of remarkable new treatments. When the less affluent can obtain top-line treatment, they still trust that it is sound. Trust in the health care system as a whole, however, understandably erodes overall for those who lack access since they are often subject to predatory practices such as highly risky clinical trials or unproven and unsafe DIY therapeutic approaches.

Scenario

Solving tomorrow's problems

This is a world where smart and deliberate innovation is broadly distributed. Advances in big data and artificial intelligence help create effective, inexpensive genetic diagnostic tools that are applied globally. Diseases become more predictable and, informed by new insights about why illness occurs, the focus of health care evolves to emphasize prevention. New treatments also emerge. Technological advances not only lead to remarkable new therapies but contribute to curbing increases in health care costs.

In the early 2020s, governance and regulatory mechanisms are at first overwhelmed by technological advances and have difficulty adapting quickly enough. Over time, government entities at the international, national and local levels catch up and put in place policies and regulatory approaches to ensure the benefits of medical advances are broadly distributed and risks minimized. Indeed, big data and AI help inform development of evidence-based policy frameworks that are at the heart of these new governance mechanisms.

This doesn't happen overnight. In the mid-2020s, a series of experiments around the world leads to new governance structures emerging, first in small countries and then at the provincial/state level in large nations. California assumes a leadership role, and its practices come to be widely adopted by other states in America and some medium-sized countries. Some innovations also come from middle-income countries that have invested heavily in information technology and thus possess the infrastructure needed to implement broad-based digital health strategies on a national scale. Once success is demonstrated in smaller settings, new governance measures get adopted broadly around the world.

People's genetic data and health histories come to be collected and curated as a public good. The tagline "23 and Me for Free" comes to be widely used, since the price of genetic testing drops enough that governments can offer testing for all citizens and more than defray the modest costs

by selling data to stakeholders in the health care system. The All of Us project, launched by the National Institutes of Health in 2015, spreads globally, first in the European Union and later throughout East Asia, and becomes the global repository for health data. Subsidiary organizations in each region establish rules about how data is collected, translated, shared and then accessed. These efforts not only involve setting protocols that allow data sets to be interoperable across regions but also encourage harmonization on privacy regulations and security approaches, so citizens can be assured that their data will be used for their benefit and only by authorized researchers.

Individuals have ultimate control over their own information and can choose to share it on a true opt-in basis, with appropriate protections. A variety of mechanisms emerge for patients to receive some of the benefits generated by the use of their data. In some cases, corporations that access the global repository and develop innovations based on it share a percentage of the revenues from their discoveries with the people who provided their data. In other cases, funds generated by the use of data help to pay for the national data banks that feed into the global repository.

The widespread availability of vast stores of data allows for rapid advances in personalized medicine and new approaches to prevention, diagnosis and treatment based on genetic information. Artificial intelligence also plays a big role in helping health care professionals make decisions about what to do for a particular patient.

These developments quickly raise a series of vexing ethical issues. Should genetic knowledge be used only to alert people that they are susceptible to serious rare diseases or also to let them know they have a predisposition to common chronic diseases? How much genetic alteration is proper? Should modifications to improve mental or physical performance be allowed? Are designer babies okay? Similar questions arise around the use of AI, specifically regarding what AI algorithms should optimize for: health of the individual patient, health of the population as a whole or cost? An additional question that arises relates to how reliable the treatment recommendations made by AI algorithms are.

The cooperative governance mechanisms put in place to establish standards for the handling of genetic data allow the global health care system to address these ethical challenges. Society decides not to implement certain medical advances even though they are technically feasible, since they are judged to be socially undesirable. Similarly, rules governing what AI can—and cannot—do in connection with patient care are established. These deliberations also generate a consensus that providing broad access to care is a worthy societal goal.

The emphasis overall is on advances that can help large numbers of people rather than ones that will enhance the lives of a select few. This is accomplished through a combination of formal legal constraints, standards and widely held agreement among medical professionals about what is and isn't okay. These rules and universally held norms prevent ethically questionable pathways from being pursued even in the lab.

These same collaborative mechanisms lead to innovations in the approval process for new therapies. Computer simulations come to be substituted for human trials in some parts of the approval process. Individual patients have a "digital twin"—which replicates, in silico, the workings of an individual's body based on his or her particular genetic endowment—that can be used to test their likely reaction to a regimen under consideration. Once the safety of a new therapy has been established, widespread testing is permitted, with real-world evidence then used to evaluate efficacy and validate or improve simulation models. Greater genetic knowledge also allows more elaborate protocols for prevention, so approval processes related to prevention emerge.

The new focus on prevention helps to contain costs. Preventive measures and treatments become more effective thanks to the proliferation of personal sensors, which are paired with apps that provide positive reinforcement to help people adhere to healthier lifestyles and follow therapeutic regimes after they've been diagnosed—or even before. These apps are augmented by AI algorithms and rely on new insights into the workings of human behavior developed by researchers armed with rich genetic data. As overall costs fall, funds become available for further investment in innovation, which in turn further reduces costs, thereby setting a virtuous cycle in motion. Lower costs also help to achieve the goal of providing broad access to health care. By 2040, life expectancy exceeds 100 years in most countries.

However, the explosion of new knowledge creates complexity for individuals facing decisions about what treatments to undertake and even which preventive measures to try. In response, requirements for a growing profession—health care advocate—emerge to help patients weigh the benefits and risks of the array of choices they face in this brave new world. Primary care providers, with some of their duties now assumed by AI algorithms, also provide counsel of this sort.

Widespread genetic profiling also has impacts outside of health care. Uploading a DNA sequence becomes a routine part of signing up for dating apps, and startup companies help people find others who have compatible genetic profiles. At first, this genetic matching is controversial and the companies entering this domain get accused of trying to "engineer love." Other critics note that DNA matching echoes the eugenics movement that swept across the United States and Western Europe in the early 20th century, with disastrous consequences in Germany. Much as online dating was met with resistance initially and then came to be widely adopted, over time the practice of DNA matching as one aspect of the quest to find a suitable mate comes to be seen as routine.

This world is one of widespread cooperation: to create globally accepted standards for the handling of health data (including strict privacy and cybersecurity measures), to establish the boundaries of where genetic interventions may (and may not) occur and to set rules governing the use of AI. The presence of these standards serves to create broad trust in the health care system. Indeed, deep trust between key stakeholders—providers and patients, government officials and executives at the corporations that serve the health care sector—is a cornerstone of this future.

Scenario perspectives on innovation, regulators, standards and trust

After the four scenario narratives were developed, the next step in the process was to summarize what they revealed about four areas of particular relevance:

- **The focus of medical innovation**
- **The position of regulators**
- **The leveraging of standards**
- **The status of trust in medicine and health care**

	Focus of medical innovation	Position of regulators	Leveraging of standards	Status of trust in medicine and health care
Scaling the tried and true	Focus is on new processes to get tried-and-true remedies to those who need them.	Regulators, collaborating globally, prioritize health care delivery and best practices.	The primary objective is to standardize medical practices.	High levels of trust, zealously guarded, avoid recurrence of early 2020s health crises.
Dangerous uncertainty	Disparate local efforts emerge to serve the needs of particular communities.	Regulators fight rearguard action against substandard and counterfeit medicines and folk remedies.	New standards are needed for traditional and food-based therapies.	Fragmented trust, based on belief that only locally based care providers and like-minded people are trustworthy.
A world of difference	Innovation is geared toward new therapies for patients who can pay full price.	Regulators are less powerful, with a greater role for large companies.	Market-based outcomes, rather than commons-based standards, shape health care.	Bifurcated trust: the affluent trust the health care system; the poor trust treatments (when they get them) but not the system overall.
Solving tomorrow's problems	Emphasis is on omics-based medicine (e.g., genomics, microbiomics) that can do the best for the most people.	There is broad global cooperation among regulators.	Standards developed alongside product innovations; standards in place to guide data and privacy.	High levels of trust in health care for all, based on durable global cooperation and standards.

Figure 3: What the scenarios tell us about innovation, regulators, standards and trust

Implications

Scaling the tried and true

In this future, the focus of innovation shifts from developing new therapies to identifying new ways to deliver proven preventive measures and cures. New discoveries continue. The emphasis is not on pushing the envelope with the novel and exotic, but rather, on what can serve the largest number in a cost-effective way. Another new form of innovation is ensuring that, when new approaches are developed, they are disseminated into medical practice as quickly as possible. Given all these changes, innovation is no longer dominated by the United States and Western Europe, as it was before 2020. Instead, new ideas arise from all around the world, with innovation often coming from developing countries.

Regulators shift from focusing on approval of new therapies to establishing process standards that ensure broad distribution and adoption of already proven medical practices and products. There is more cross-cooperation between national regulators. International groups working in the health sector, both governmental and non-governmental, increasingly seek to bring in more representatives from developing and emerging economies.

Standards that ensure the quality of medicines remain very important, especially in a world where many emerging economies need to be able to access generic drugs on a large scale and at affordable cost. New standards are also developed—not only for the quality of the chemical and biological substances people rely on but also for the processes that ensure effective treatments can be delivered broadly. Examples include methods to ensure new vaccines, drug-linked devices, and digital therapeutics that are widely deployed and campaigns that enable broad and rapid diffusion of genetic testing and new medical practices.

In this future, trust is elusive at the outset as the world faces a series of serious health care crises; the initial reaction is mistrust and suspicion. Close cooperation between physicians, pharmaceutical and medical technology companies, standards-setting organizations and government entities at the local, national and international levels successfully addresses the challenges. As a result, the public sees the value of health care collaboration and regains a sense of trust in the overall system. In subsequent years, an institutional framework is built to support a global, cross-sector network that delivers tried-and-tested modes of health care to all who need it. While there are temptations to defect from collaborative agreements, memories of the crises of the early 2020s remain strong and are invoked to ensure cooperation continues. The result is broad trust in medicine and health care at all levels—patients, caregivers, corporations and policymakers.

In short, the world depicted in this scenario relies on pragmatic, scientific, evidence-based approaches that are focused on results. The benefits of collaboration are clearly and continually articulated so the prospect of achieving them outweighs the challenges of working across disciplinary, organizational and national boundaries.

Implications

Dangerous uncertainty

In this fragmented, fractious world, the rich support continued incremental medical breakthroughs but at a slower pace than had been expected. The middle class finds its own trusted local providers. Those with less education and lower incomes are vulnerable. Regulators and standards setters fill a void by seeking to eradicate substandard and counterfeit drugs and providing sound recommendations about which alternative remedies are safe and effective.

Innovation slows in this future, due to widely publicized failures of IT-based medicine and genetic modification. This creates a strong backlash. Any health care initiatives that have associations with Silicon Valley or established biotech companies come to be seen in a highly negative light. Ironically, there is a great deal of innovation in areas for which the benefit to patients is at best uncertain. Proponents of folk remedies and food-based cures use social media creatively to gain adherents. Counterfeiters proliferate, preying on unsuspecting patients who cannot afford to pay the full price and seek to purchase medicines on the cheap.

In the face of a dizzying array of substandard and counterfeit chemically and biologically based drugs and a broad range of newly launched "alternative" therapies, regulators initially get swamped. They focus their resources on preventing damage that could be caused by potentially dangerous substances, but this leaves less bandwidth for vetting new science-based therapies. To protect public health, governments need to provide additional resources to help regulators staunch the flow of substandard and counterfeit medicines and launch educational campaigns to notify the public about the potential dangers.

Efforts to create standards for the use of big data and AI flounder, which serves to slow advances in IT-based and genetically based medicine. Standards setting for drugs becomes more challenging as well, in the face of ingenious and adaptive counterfeiting operations. Standards-setting organizations recognize that they need to play a role in evaluating the folk remedies and food-based cures that are all the rage in some communities and on social media. By evaluating which of these approaches are effective—and for whom—and then communicating that information through trusted sources, standards setters reduce the uptake of regimens that don't work or have the potential to cause harm.

In this future, the foundations of trust become fragmented. The very affluent—the global elite and those in their close professional circles—benefit from leading-edge treatments and continue to trust the science-based medical establishment. Members of the middle classes, however, grow skeptical of high-tech medicine after they witness high-profile failures of IT-enabled gene-based therapies at prestigious medical centers. They come to rely mostly on people they know for their care. This creates demand for locally based physicians and community bio-labs that develop drugs to serve this set of patients. The least affluent use folk medicines and food-based therapies based on recommendations from members of their face-to-face and virtual communities.

Implications

A world of difference

In this future, the focus of medical innovation is on finding breakthrough treatments that can extend or enhance life, even if they come at a great cost. Researchers seek to push the envelope, with the knowledge that wealthy patients will pay what is required.

Regulators find their role circumscribed as compared with the past. Large corporations dominate innovation processes, effectively privatizing what were formerly government-based approaches for approving new medical practices. Regulators end up merely rubber stamping advances sought by rich patients and big companies. Regulators find themselves strapped for resources, since their government funding bases are squeezed. This is a world where the rich are able to reduce their tax burden and the broader public is less willing to support government activities that they don't see as benefiting them directly. Regulators can, however, keep in place safety and efficacy requirements for the legacy treatments upon which the majority of people rely.

Similarly, standards-setting bodies have a more circumscribed role. They continue to protect the public by ensuring standards for mature remedies remain in place. For cutting-edge treatments, however, a "Wild West" mentality prevails, with countries and companies seeking to become first movers in the realms where they are active so their proprietary approach can become the de facto industry standard.

In this future, individuals' trust in the health care system is shaped by their place on the economic ladder. The affluent, who receive cutting-edge treatments that extend their lifespans and enhance their mental and physical capabilities, understandably have great trust in the health care system. Those at the lower end of the economic scale see the benefits of these treatments and trust they are safe and efficacious. That is, they trust in medicine itself, but they do not trust a health care system in which they cannot access its full benefits.

In sum, this is a future of impressive medical advances, mostly made by large private companies and mostly for the benefit of the wealthy. It's a world tailored to advancing the health of the wealthiest one percent. Less-affluent members of society respect the value of these medical advances; they know they work well, sometimes almost miraculously so, and wish they could receive them for themselves. But most people must make do with the legacy treatment options they are able to afford. This stirs resentment and mistrust of the health care system overall. Regulators and standards setters play a smaller part in overseeing breakthrough advances than in the past. They do, however, play a salutary role in ensuring the safety and efficacy of mature treatments upon which most people rely.

Implications

Solving tomorrow's problems

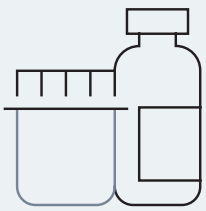
Regulators and standards setters are central in establishing the rules and protocols that enable this future. Benefits are widely shared, so there is broad public support for the organizations—primarily governments and NGOs—that take the lead in establishing the rules of the game that govern health care. The health care system as a whole is seen favorably, since it delivers broad benefits for most.

In this world, innovation initially focuses on developing data protocols and security mechanisms that allow patient data to be widely shared while still ensuring privacy. This certainly requires technical development but also innovative governance mechanisms that ensure data is used ethically for the benefits of patients. Once a global data repository is in place, a flowering of new developments in genetic diagnostics, treatment and prevention takes place. A round of innovations in the use of AI, especially in diagnostics, occurs in parallel. Needed innovation also occurs in the development of ethical frameworks to determine which genetic treatments and which applications of AI are allowed.

Regulators play a big role in this future by establishing the rules of the game for data, genetically based medicine and use of AI. Getting these rules in place is a big task and requires cooperation of government entities with stakeholders in the health care sector at many levels, from local to national and international. New approaches get developed first at local levels, and those that work see broad adoption. Over time, a set of harmonized, global rules comes to be in place for data, genetic medicine and AI.

Data standards are crucial and are the cornerstone on which this future is built. While regulators need to establish certain legal mandates (for example privacy protections), standards-setting bodies working with industry also play an important role. Data standards allow protocols that encourage globally dispersed systems to collect and exchange the relevant data. Standards are also needed to ensure that complex genetic therapies are delivered safely and effectively. Standards-setting bodies also play a key role in another important realm: establishing protocols for synthesizing the vast array of patient data—genetic profile, health history and lab tests—as it gets interpreted and translated into a recommended treatment plan by AI algorithms.

This is a future of high trust, made possible by successful mobilization to establish globally accepted standards around the handling of genetic data, which genetic modifications/alterations are acceptable and how AI ought to be deployed to assist human judgment in health care. Because access to care is broadly shared and the system focuses on doing the best for the most, everyone trusts in the system because all believe it is working to benefit them.



Conclusion

Leveraging quality standards in the 21st century

In the 20th century, great strides were made in building trust in the medicines patients took. The world went from one where pharmacists formulated drugs on a small scale to one where multinational companies produced medicines in vast quantities and distributed them through a complex global supply chain. Ensuring that medicines were safe and did what they promised became a matter of validating the mix of chemicals inside each pill. Standards for manufacturing and testing finished medicines achieved a remarkable result: Today, when people use a prescription medicine, most feel confident that what they're taking won't harm them and will address their illness. USP has played a crucial role in developing and gaining acceptance for these standards.

Drug standards of this kind will remain important in the 21st century. These standards will continue to evolve to reflect advances in science and technology: They will address next-generation manufacturing, including analytical methods and supply chain considerations, and also incorporate predictive tools to anticipate emerging health challenges.

There will also be a need for new kinds of standards. The Trust CoLab exercise identified four areas for which new kinds of standards could be required.

First, the coming decades will likely see the proliferation of new modes of treatment, not only biologics but also genome-informed and other "-ome-" based therapies (e.g., microbiome, proteome). Ensuring the quality of these new therapies will be far more complex than validating that a pill has its stated chemical composition. New quality and safety standards will be needed for these new medicines.

Second, the intertwining of information technology and medicine will create other challenges. These will require validating not only the quality of treatment but also the quality of the analytic and decision-making process that leads to the prescribing of a treatment. For genomic medicine to work, vast repositories of DNA data will have to be gathered, stored and then, in real time, accessed and synthesized. At that crucial juncture at which a human caregiver interacts with a patient and considers a range of possible diagnoses, the caregiver must be able to cross-reference the repository of genomic data against the individual patient's genetic profile, medical history and test results. To manage this, he or she will need assistance from artificial intelligence algorithms or, at the very least, powerful decision support software.

At every step in this chain—from the collection of genomic data to the storage and interpretation in the caregiver's interaction with a patient—potential errors can be introduced. Establishing a set of agreed-upon practices in the data and IT domain thus represents a new frontier for medical standards settings. Establishing formats and practices for health data and AI could do for safety and efficacy in the 21st century what standards for medicines did in the 20th century.

Third, standards that enable faster dissemination of best medical practices may be another important frontier to explore. This would involve identifying the most effective means of setting and communicating best-practice guidelines. Standards in this realm would not be hard technical protocols, of the kind needed to ensure quality of chemical drugs or procedures for working with data. Instead, they would focus on the human realm and involve health information and how it is shared to guide clinician and organizational behaviors that have proved to drive the greatest health improvements.

A final realm in which standards could play an important future role is by expanding the quality checks now employed to validate the safety and efficacy of chemical drugs into two other areas likely to grow in importance: alternative therapies informed by traditional cultural practices and food-based therapies. It may be challenging to obtain the same level of scientific consensus about alternative and food-based treatments as now exists for chemically based drugs. In the face of growing reliance on these treatment modes by patients, however, developing recommendations based on the best available scientific evidence could help consumers make sense of the myriad competing claims present online and in social media feeds.

Health care standards can serve to sustain and strengthen trust and deliver the greatest benefits to the greatest number of people. Standards effectively advocate for the most vulnerable, who may not be able to vet the potential treatments they use as reliably as members of society who possess greater resources. No one entity will be able to develop the standards, or the oversight required, to ensure the safety and effectiveness of future medicine. Setting the quality standards of the 21st century will require involvement by caregivers, government entities, commercial providers active in the health care sector and standards-setting organizations like USP. Collaboration and partnerships will be critical to ensure trust in 21st century medicine and in the global health care system.

These reflections emerged from the Trust CoLab exercise. USP and MIT CCI hope the discussions that ensue can explore further frontiers for enhancing patients' confidence in the care and therapies they receive and ultimately lead to a healthier world. ●

Appendix

Scenario development process

Trust CoLab relied on two techniques that have emerged in recent decades: scenario planning and crowdsourcing.

Scenario planning is used by organizations to think systematically about the future, in order to reflect on how possible developments in years to come could affect the decisions they need to make now. Scenarios do not seek to predict the future; rather, they attempt to sketch out what might happen, with the goal of expanding the range of possibilities decision makers consider. Developing scenarios can help an organization's leaders prepare for an uncertain, changing future.

Scenario-planning exercises are typically conducted using face-to-face workshops. Meetings like these allow for rich interaction but also involve significant travel costs and require participants to be away from their daily work for an extended time.

Online crowdsourcing engages participants over a web platform and invites them to contribute knowledge and insights, often in short bursts of time, to accomplish a clearly delineated goal. Trust CoLab relied on crowdsourcing to engage geographically diverse experts in a scenario exercise at less expense and disruption than would have been the case with a face-to-face meeting. An online approach allows for contributions by many individuals, from all around the world and from many relevant fields, all participating during brief intervals as their schedules allow.

Trust CoLab elicited contributions from health care providers, researchers working to discover new drugs and therapies, patient/consumer advocates and policymakers, as well as executives from pharmaceutical companies, health insurers and standards-setting organizations.

The map (**Figure 4**) shows the geographic distribution of the participants and the chart (**Figure 5**) shows the types of organizations with which they were affiliated.

Figure 4

Participants by region

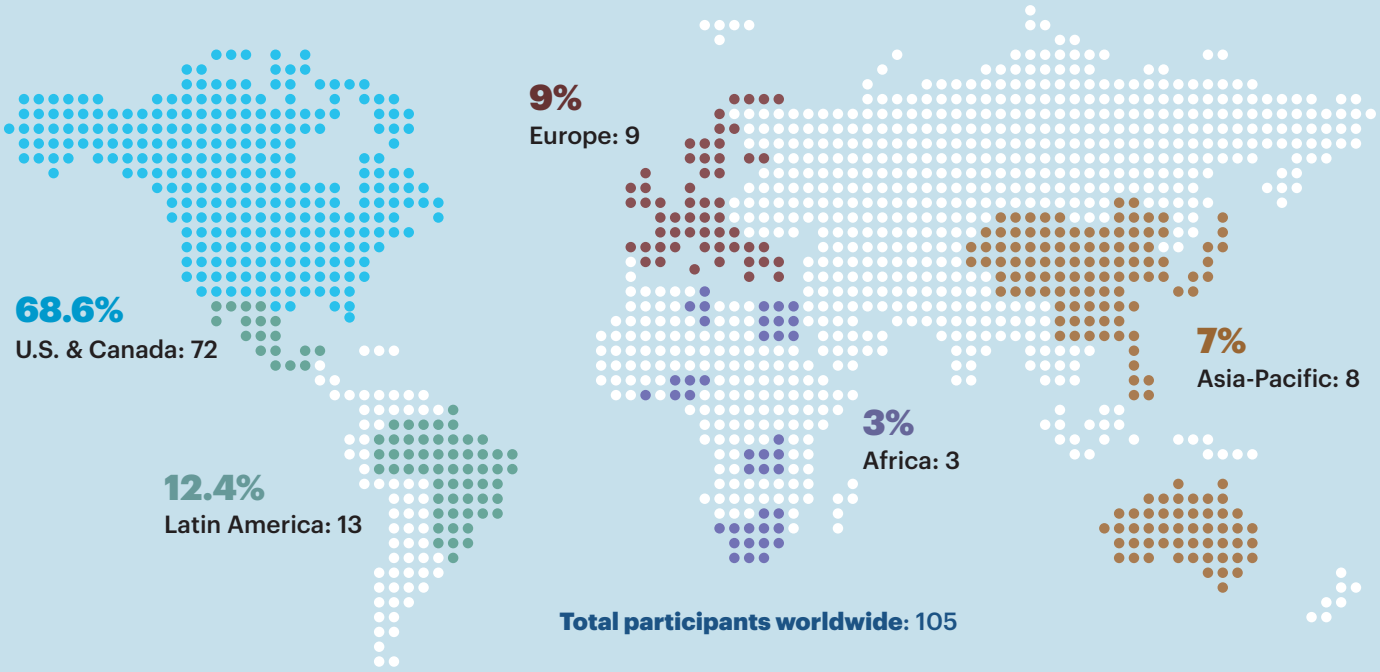
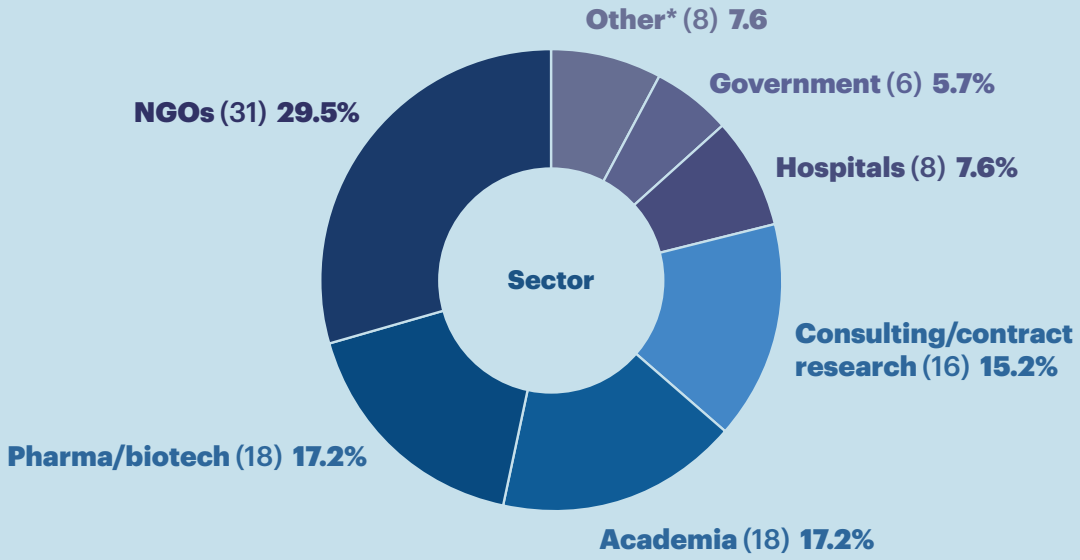


Figure 5

Participants by sector



Total participants by sector: 105

*Other includes information technology, payers, think tanks, international organizations and venture capital.

By bridging geographic and disciplinary boundaries with technology and inviting experts to engage when it was most convenient for them, Trust CoLab made it possible for a diverse crowd of experts to generate deep insights into the future role of trust in health care.

Insights for this report were gathered during a pilot September 18–October 4, 2019, and a full exercise October 28–November 24, 2019.

The scenario development process was led by an organizing group that included Robert Anderson and Jennifer Strohm from USP; Robert Laubacher, Annalyn Bachmann, Carlos Botelho, and Kathleen Kennedy from MIT CCI; and Jonathan Star of Scenario Insight, a facilitator with extensive experience leading face-to-face and online scenario exercises.

A steering committee from USP also provided advice and oversight (for a list of the members of the steering committee, see the next appendix, Acknowledgments).

The scenario development process involved four phases.

During the first phase, participants were asked to contribute drivers of change that could shape people's health between now and 2040 (for a definition of drivers of change, and other key scenario-planning terms, see **Figure 6**). Participants were invited to submit drivers in six categories: patient demand and behavior; politics and policy; economics and business; medical technologies; other technologies; and environment. Participants submitted 278 drivers.

Drivers of change	Forces within and beyond the health care system/medicine that could shape people's health between now and 2040.
Groups of drivers	Clusters of similar drivers created to provide participants with a manageable number of choices when they were invited to assess which could have the most future impact.
Scenario axis	A pair of highly divergent future outcomes, defined by the two ends of the axis, that could plausibly occur by 2040. By setting out two extreme potential outcomes, a scenario axis defines the range of future uncertainty that exists along a key dimension.
Scenario	A story that paints a plausible picture of the world at a designated future date. Scenario exercises typically sketch out three to four such stories. Taken together, the scenario narratives seek to depict the full array of potential future developments.

Figure 4: Definitions of key terms

Scenarios do not seek to predict the future; rather, they attempt to sketch out what might happen, with the goal of expanding the range of possibilities decision makers consider. Developing scenarios can help an organization's leaders prepare for an uncertain, changing future.

Before the second phase began, the organizing team, assisted by a natural language processing tool, clustered the 278 submitted drivers into 29 groups of drivers. They were categorized into four overarching groups, starting with drivers that are outside of medicine/health care and moving to ones that are part of that domain: broad external forces, non-medical technologies with applications in health care, health care trends and new therapies.

Participants were then invited to vote and comment on the groups of drivers they believed could have the greatest impact on the future. They were also invited to create combinations of drivers that could occur at the same time or instances in which the emergence of one driver could trigger the emergence of another. These combinations were the seeds of storylines that could eventually be incorporated into scenarios that emerged at the end of the process.

Before the third phase, the organizing team noted which groups of drivers received the most votes and created 14 scenario axes—forces with uncertain outcomes that could have major impact. Each scenario axis outlined a pair of potentially quite different outcomes that could arise in the future. Participants were then invited to support (akin to a Facebook like) and comment on the axes they found most interesting.

Before the fourth phase began, the organizing team arrayed one axis on the horizontal dimension and another on the vertical. This pair of axes defined a set of quadrants, which created four different scenarios to consider. The organizers prepared a brief sketch of a narrative for each of these possible futures and also posed a series of questions about them. Participants were invited to respond to the questions, and their answers provided key details that enriched and enlivened the narratives.

After the exercise was completed, the organizing team synthesized the contributions of the participants in this report, paying particular attention to especially stimulating or thought-provoking ideas that had been submitted.

Appendix

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