

2030 – Life Sciences and Health Go Digital



This report is intended for all members and friends of the Pistoia Alliance, and any others interested in its work supporting cross-industry collaboration and innovation. It sets out to consider what the life science, biopharma R&D and healthcare ecosystem might look like in 2030.

The objective is to ensure that the Pistoia Alliance, its members, and the industry as a whole, are prepared and agile enough to respond to the changes that will occur over the next ten years or so in the life science/biopharma/healthcare ecosystem.

The sophistication of technology is increasing exponentially; enhancements are enabling the development of scientific method and consequently scientific insight. This combination of advances in technology, medical science and healthcare is empowering society to progress from a “one-size-fits-all” management and palliation of disease, to a personalized, preventive and predictive approach – even to the cure of previously incurable disease.

However, these healthcare developments come at a cost. Society will need to think of new ways of valuing, calculating and funding the costs of healthcare delivery. The key stakeholders must evolve to become an integrated community embracing all aspects of healthcare (patients, disease prevention and diagnosis, treatment and monitoring) that collaborates, educates, and informs.

To support this evolution, we have produced this “futurescape” set around the year 2030. It looks back at the changes experienced by the world and its demand for healthcare and is written from this retrospective point of view. There are many scenarios we could legitimately put forward and challenge, choosing just one was a lengthy process involving many industry experts. It is not to say it will be correct. However, in presenting these scenarios it is hoped that they might stimulate debate and help identify signals that identify the likely drivers of change over the next decade.

“In times of political and social upheaval, maintaining our links across borders and working closely together is more important than ever. We must focus on science, not geography!”

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Socio-Economic and Political Trends From 2020 to 2030

Looking back on the last decade, the world experienced a difficult time between 2019 and 2023. Recessionary economic forces and austerity had dominated, yet government deficits had skyrocketed. However, after 2023 some growth thankfully resumed, trade normalized, and market stability returned.

By the late 2020s, the disruptions caused by Brexit and the US/China trade wars had receded and the predictions of global economic growth meltdowns had been avoided. China had cemented itself as the world's leading economy and became a

stabilizing force in global business. India was not far behind, having become the third largest consumer economy². Indeed, its population had risen to over 1.5 billion, overtaking China. Overall, growth markets in Asia continued to outperform the West.

The emergence of this trend was already visible in 2018 where the global innovation index showed Singapore, the lead economy in the Association of Southeast Asian Nations (ASEAN), and China improving their positions. Now, in 2030 the flow of new technologies from the East rivals those from the West.

“Today, the East leads in many sectors and former wealthy, Western-based nations are increasingly reliant on innovation from these countries³.”

Table 1: Global Innovation Index 2018

Rank in 2018	Country	Rank in 2017	Rank in 2018	Country	Rank in 2017
1	Switzerland	1	11	Israel	17
2	Netherlands	3	12	Korea, Republic of	11
3	Sweden	2	13	Japan	14
4	United Kingdom	5	14	Hong Kong (China)	16
5	Singapore	7	15	Luxembourg	12
6	United States of America	4	16	France	15
7	Finland	8	17	China	22
8	Denmark	6	18	Canada	18
9	Germany	9	19	Norway	19
10	Ireland	10	20	Australia	23

www.wipo.int/pressroom/en/articles/2018/article_0005.html

During this decade, Africa had moved towards a period of improved political and economic stability⁴. Physical terror-related events largely disappeared, replaced with chronic, low-level cyber-crime. Today, displaced populations from unrest in

the Middle East and Africa are starting to return home. The poor condition of those war-torn countries has improved considerably, and the diseases and malnutrition suffered in the early 2020s are no longer a major global issue.

Socio-Economic and Political Trends From 2020 to 2030

Overall in 2030, the world is currently enjoying a prolonged period of sustained growth. Economic prosperity has allowed for an increase in investment in many social projects. Healthcare as a fundamental human right⁵ has become one of the new generation's principles, along with the now widely accepted requirement to care for the global environment. This translated to a societal movement, led by millennials and Generation X, that strived toward fairness across societies and regions. As a result, while environmental issues such as global warming remain a challenge⁶, the severe predictions made between 2000 and 2020 have not materialized as fully as was feared following the implementation of new legislation agreed at successful global climate summits held between 2021 and 2025.

However, significant challenges remain in 2030. Some nations have failed to meet basic societal demands⁷, such as ensuring adequate clean water supplies and unpolluted air⁸, commodities which are now being supplied by private companies to those who can afford them. At the same time, access to medicines remains a political juggling act – with governments and healthcare providers facing increasing demand for new vaccines, diagnostics and therapies.



Governments and healthcare providers face increasing demand for new vaccines, diagnostics and therapies

The Pharma Industry

From a healthcare perspective, underfunding was a chronic problem for the last decade in many of the more established economies; diseases that had been assumed to be under control had started to re-emerge – not least caused by the spread of misinformation about vaccines on social media⁹.

The previously inexorable rise of healthcare costs in relatively rich economies is now under control. Now, in 2030, in the USA, Medicare and Medicaid¹⁰ reimbursements have been trimmed to align with average OECD levels¹¹. In Europe, the Beneluxa¹² initiative on pharmaceutical pricing, along with the “Valletta Declaration”¹³, has reduced expenditure on medicines. Alongside other pharmaceutical price control activities¹⁴ these measures have lowered revenues for the Western-based biopharmaceutical and life science industry, resulting in a decrease in R&D expenditure and a subsequent challenge to innovation.

The industry had accepted the need to evolve from an R&D and manufacturing business to one embracing healthcare delivery including disease prediction, prevention, management and indeed cure, along with diagnostics and monitoring. New, highly personalized and expensive therapeutic modalities such as gene and cell therapy caused the reimbursement model to evolve from the traditional one-size-fits-all, “pay per pill” to “payment for outcomes”.

Many of the advances in technology and medical science made throughout the 2020s had in part been enabled by significantly increased collaboration within the industry; record keeping also regained the trust of the regulators and indeed the public by the deployment of tamper-proof, blockchain documentation systems.

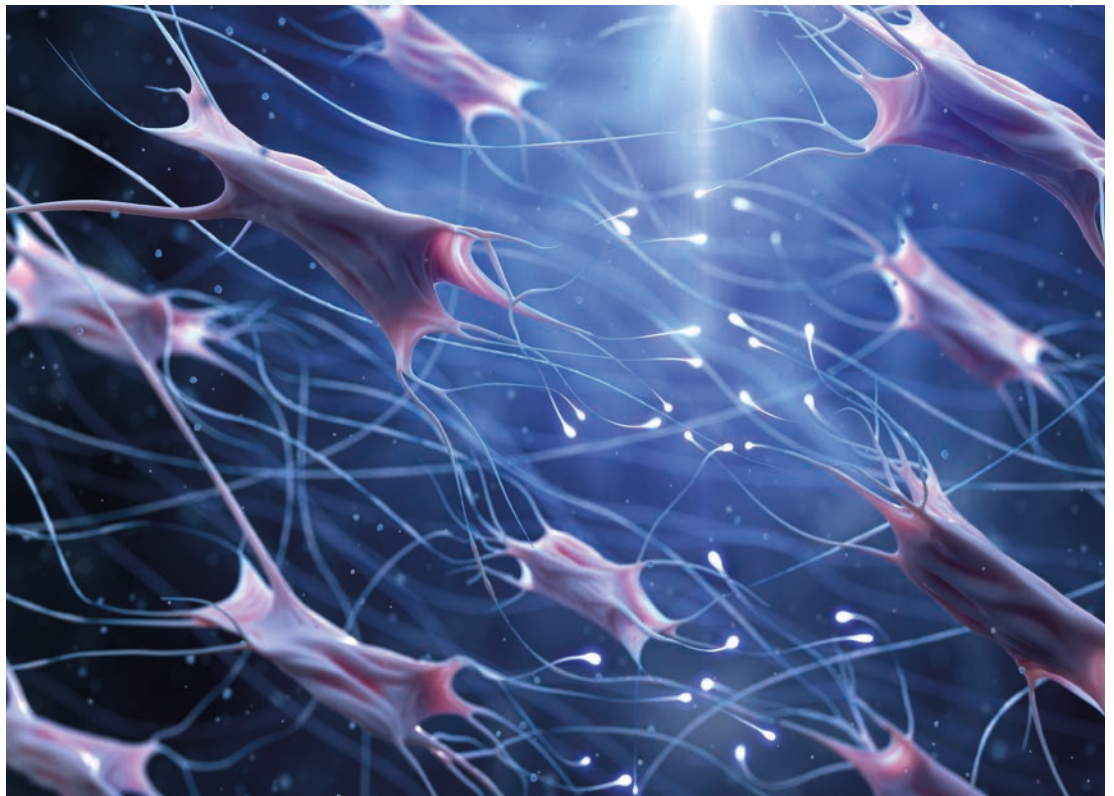
“Consolidation in the industry continued in part due to technology giants swallowing some of the traditional research-based biopharma companies¹⁵.”

The Pharma Industry

These dramatic medical scientific innovations, along with enhanced healthcare delivery capabilities, helped improve the reputation of the pharmaceutical industry – which had been severely tarnished by some not infrequent egregious marketing and sales behaviors.

Outside of the West, Chinese pharmaceutical companies had been significantly more successful during this period than previously and are now among the top tier global players¹⁶ – having disrupted the *status quo* with high-quality, low-priced innovative healthcare solutions, including many traditional Chinese medicines (TCMs). This had driven an overall improvement in access to healthcare in China and an expansion of healthcare markets.

Today, patient empowerment is fully embedded into the healthcare industry and the ability to compare treatments with outcomes is actively promoted. The prevention of disease has become an inter-governmental initiative with trillions of dollars being invested in fundamental research promising breakthroughs in many chronic, debilitating diseases¹⁷. The use of vast data resources is having a positive impact on discovery and the Real World Data (RWD) feedback loop is now an established part of discovery research in health-related industries. This had led to a notable increase in true cross-industry and within-industry pre-competitive collaboration^{18 19 20}.



Dramatic medical scientific innovations helped improve the reputation of the pharmaceutical industry

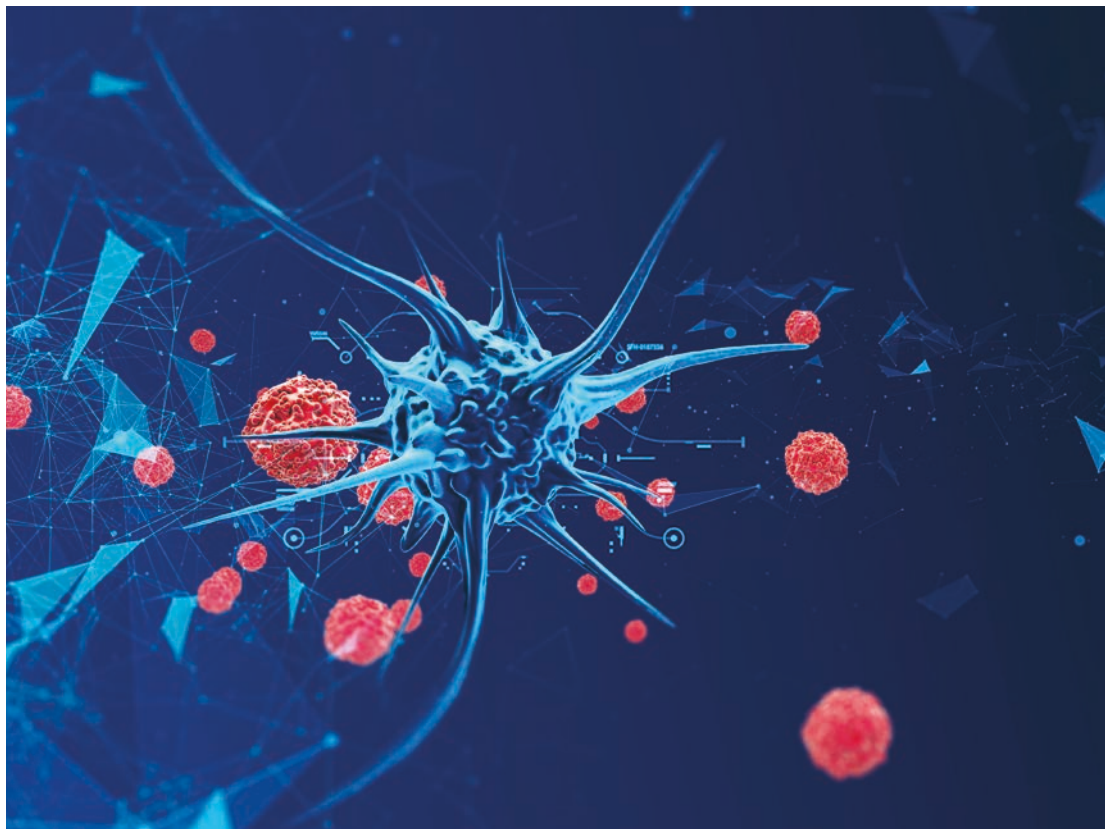
Technology and Healthcare

This was a revolutionary decade for the development of technology. By the early 2020s, technology like AI-powered search saw patients arriving for appointments at their clinician's office knowing more about their own morbidity than their doctor²¹. Soon, diagnosis, treatment, and prognosis were largely being determined by AI. Healthcare providers started experiencing a serious shortage of physicians, with talented students' no longer viewing medicine as a quality career²².

However, despite advances made during this time in the field of quantum computing and AI and Machine Learning (ML)²³ progress in, and the widespread deployment of, automated diagnosis had failed to live up to its early expectations after lives had been lost due to algorithms making 'stupid' errors.

Drug discovery has been transformed thanks to pharma companies using hybrid machines – high-performance classical computers tightly coupled with quantum computers – and advanced AI/ML algorithms. These hybrid machines have enabled *ab initio* drug design, coupled with advanced modelling to design innovative drugs of high specificity and low toxicity. The fundamental requirement of AI/ML – i.e. access to sufficient data of sufficient quality – remains a significant hurdle but is being overcome today in part by the use of AI federated learning (FL) techniques²⁴.

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These hybrid machines have enabled ab initio drug design, coupled with advanced modelling to design innovative drugs

Population Health Trends

From the early 2000s onwards, many predictions had been made about the increase in HONDA trends occurring in the Baby Boomer generation. By 2030, these concerns have not materialized as extensively as had been expected; nonetheless HONDAs are imposing a significant burden on world healthcare resources, along with a few other notable conditions.

HONDAs

Hypertension: As predicted by the World Health Organization (WHO)²⁵, a significant percentage (35 percent – 45 percent) of the world population over the age of 25 continues to suffer from hypertension, particularly in less mature economies.

Obesity: Back in 2016, the WHO reported that approximately 39 percent of people over 18 years old were overweight, with 13 percent of them being obese²⁶; more than 1 in 20 cancer cases were caused by excess weight²⁷. Obesity in 2030 remains a global health challenge with many more diet-associated disease states becoming symptomatic at younger ages.

Non-Compliance: Depending on definitions, reported non-adherence rates in cancer patients ranges from 16 percent to 100 per cent, illustrating a serious problem²⁸. Although technology has enabled progress on this front, through innovations like continuous monitoring and patient reminders, the compliance challenge remains unchecked, especially in poorer economies.

Diabetes: In 2014, it was estimated that 422 million people world-wide were living with diabetes (a major cause of blindness, kidney failure, heart attacks, stroke and lower limb amputation)²⁹. This was approximately 1 in 11 of the world's adult population and the figure is expected to rise to around 642 million people by 2040³⁰.

Asthma: The incidence of asthma (in 2017 approximately eight percent of

the UK population was asthmatic³¹ with a similar percentage estimated in the USA³²) remains significant. Environmental pollution and continued use of fossil fuels in emerging economies had not reduced sufficiently and the occurrence of asthma, particularly in the young, continued to rise throughout the 2020s.

Cancer: In 2018, cancer was the second leading cause of mortality globally, responsible for an estimated 9.6 million deaths³³. The economic impact of cancer was significant, it remains so and is increasing. The total annual economic cost of cancer in 2010 was estimated at approximately US\$1.16 trillion. Today, the number of global cancer deaths has increased by 45 percent with about 70 percent of those deaths occurring in low - and middle-income economies.

Mental Health: Mental health issues have continued to dominate, in particular depression, anxiety, schizophrenia, bipolar disorder³⁴, and the dementias. These conditions have driven huge increases in cost pressures on social care across the world. The current cost of Alzheimer's alone is estimated to be around US\$2 trillion annually³⁵. However, the use of digital technologies (e.g. in-dwelling biosensors, monitoring, diagnostics, therapeutics, robotics, and the implementation of social care initiatives, such as the intelligent home) are helping to deliver significant, cost-effective support for patients³⁶.

Population Health Trends

Anti-Microbial Resistance (AMR):

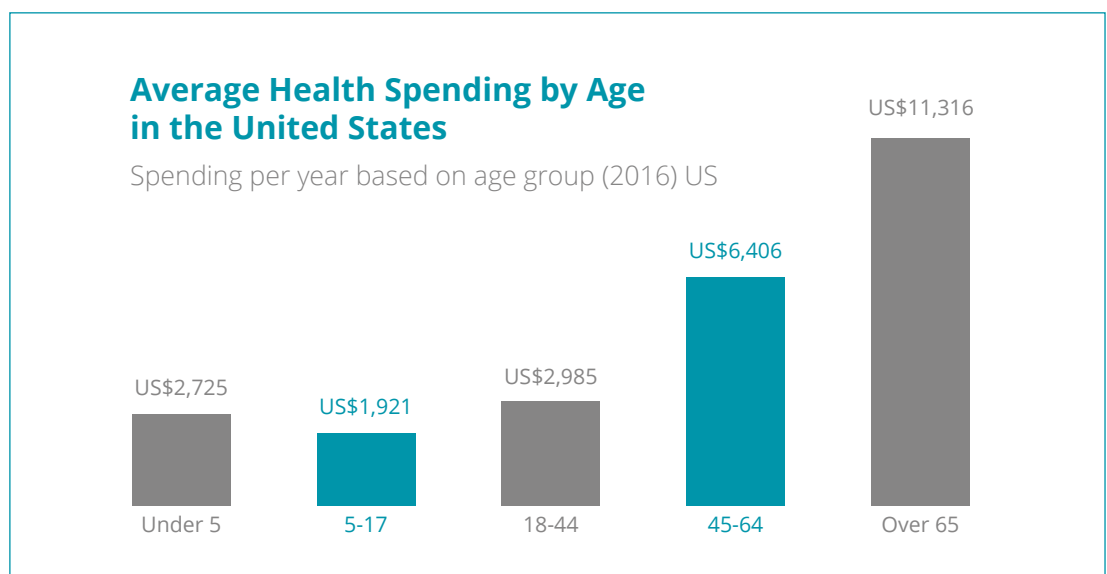
The predictions of AMR causing a meltdown in routine medical procedures was narrowly averted by using breakthroughs in phage therapy³⁷ and anti-bacterial monoclonal antibodies³⁸. The challenging economic issues that had prevented the pharmaceutical industry from diverting resources into AMR were overcome during a global summit in the mid-2020s when a new reward structure was implemented giving substantial tax advantages to companies that brought anti-microbial molecules to the market. Today, managing and curing pathologies related to ageing has become the next unconquered field^{39,40}.

Ageing: The WHO reported⁴¹ that the world's population over 60 years old will double from 12 to 22 percent over the period from 2015 to 2050, and that all countries were facing major challenges to ensure their health and social systems were prepared for this demographic shift. The WHO report said, "...common

conditions in older age include hearing loss, cataracts and refractive errors, back and neck pain and osteoarthritis, chronic obstructive pulmonary disease, diabetes, depression, and dementia. Furthermore, as people age, they are more likely to experience several conditions at the same time." The WHO "Global Strategy and Action Plan on Ageing and Health" recommended five priority areas for action:

- Commitment to healthy ageing
- Aligning health systems with the needs of older populations
- Developing systems for providing long-term care
- Creating age-friendly environments
- Improving measurement, monitoring and understanding

The potential financial impact of this demographic trend can readily be seen in the figure below⁴².



Innovative Technology

The last decade also saw numerous technological advances which have profoundly transformed the pharmaceutical and healthcare industries today:

AI & Machine Learning: AI has long been seen as integral to the healthcare industry. By 2018, more than a third of healthcare providers had made investments into healthcare AI and medical predictive analytics, preparing for the next generation of automated healthcare. For example, in pathology, the extensive use of whole-slide imaging aligned with pattern recognition methods based on deep learning, as well as incorporating clinical, radiologic and genomic data, allowed highly-sophisticated, rapid and accurate diagnosis and prognosis⁴³.

Throughout the last decade, big data analytics and machine learning algorithms were also widely deployed to analyze large scale data of Electronic Medical Records (EMR), automatically learning how physicians treated patients in real-world settings. When newly written prescriptions deviated from the spectrum of typical treatment patterns, they were flagged as a potential error prompting the physicians to double check. Such technologies reduced the burden of adverse events and

medically-induced deaths, estimated by a Johns Hopkins study to be the third largest cause of death in the USA⁴⁴.

By the mid-2020s, it was clear that the role of the physician was changing. The physician was becoming more like a technician, a patient/carer educator, and a counsellor, while high-powered, RWD-driven, AI/ML-based systems performed the differential diagnoses and provided treatment suggestions.

Robotics: Robotics began supporting many areas of care, especially for the aged⁴⁵. The Japanese Ministry of Economy, Trade and Industry estimated that the Japanese robot industry alone would grow to JP¥400 billion (US\$3.8 billion) by 2035, by which point a third of Japan's population would be 65 or older⁴⁶.

As a result of this transformative decade, today in 2030, pharma, healthcare and digital are deeply intertwined⁴⁷. Working with other industry verticals has become critical and those with the business skills to do so are highly valued. Care delivery has significantly improved in present times under the influence of AI/ML, robotics, automation, breakthrough services, and adjunct therapies.

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Innovative Technology

Blockchain: In recent years, blockchain technology has transformed healthcare, placing the patient at the center of the healthcare ecosystem and increasing the security, privacy, and interoperability of health data. This technology provided a new model for Health Information Exchanges by making EMRs more efficient, disintermediated, and secure. While not a panacea, this rapidly evolving field provided fertile ground for experimentation, investment, and proof-of-concept testing⁴⁸.

Cloud Computing: The adoption of cloud computing by biopharma R&D was steady but slow throughout the 2020s. The PRISME Forum – the *de facto* R&D IT leadership group of the biopharmaceutical industry – explored this topic as long ago as 2010⁴⁹, yet by 2019, some biopharma companies were still nervous of the unstoppable encroachments of this widespread technology, not least in the implementation of GxP solutions⁵⁰. But today, in 2030, the cloud has been accepted as the platform of choice for the life science ecosystem, significantly improving the efficiency and effectiveness of biopharma R&D.

Devices: Advances in medical devices, wearables and multi-dimensional imaging⁵¹ led to diagnostic insights in numerous previously untreatable conditions. The increase in reliability and accuracy of implantable monitoring devices for serious disease⁵² in the general population, and for most of the common health-related issues, meant that real-time monitoring of patients undergoing therapy was possible. Furthermore, outcomes

data was used routinely to demonstrate the health-economic value of drugs, procedures and devices.

As a result, clinical trials were transformed during this time by researchers employing digital solutions; companies such as Science 37 worked effectively with big pharma⁵³ to exploit wearables and simplify the clinical trial patient experience. Some CROs have now developed platforms to securely capture, transmit and visualize medical device data; these platforms have been specifically built to support the volumes of data collected by modern sensors⁵⁴.

Internet of Things (IoT): Nanotech and associated non-invasive implantable surgery⁵⁶ has delivered huge advantages to the medical device industry and sensors have become self-powered (from the human body)⁵⁷. Lab automation revolutionized the life science industry. In particular it empowered clinical testing laboratories experiencing unprecedented demand from the age-related morbidities of Baby Boomers⁵⁸, and also enhanced the processes of drug discovery.

Many tasks that used to require human skills are now no longer needed, allowing the industry to reduce costs significantly. 3D-printing, organ regeneration⁵⁹, and targeted therapeutics working at the nucleic acid level⁶⁰ emerged, with the potential to change the face of medicine. In 2030, we have entered an era where tissue and whole organ regeneration is no longer experimental but available to those who can afford it, although costs remain high.

“Adoption of the IoT continued apace in the 2020s, and today, the IoT has matured to the point where it can handle trillions of devices generating zettabytes (10^{21}) of data⁵⁵; the predictive capabilities of AI/ML have improved based on such vast amounts of data, enabling new avenues of research to be identified.”

Innovative Technology

Digital Biomarkers: Digital biomarkers are defined as objective, quantifiable physiological and behavioral data that are collected and measured by digital devices such as portables, wearables, implantables or ingestibles/digestibles. The data is typically used to explain, influence and/or predict health-related outcomes. Digital biomarkers also represented an opportunity to capture clinically meaningful, objective data⁶¹ and have become commonly used in R&D today.

Liquid Next Generation Sequencing (NGS): Developments in the ability to accurately analyze circulating DNA and circulating tumor DNA (ctDNA) provided the opportunity to screen patients cost effectively and with considerably less stress. Analysis of ctDNA generates better information than that acquired from a single biopsy of a tumor, which is limited and fails to reflect its heterogeneity. Improvement in such screening allowed early detection of cancers before overt symptoms are expressed, transforming the treatment and management of cancers. Today, in 2030, we've entered an era where cancer is no longer feared as a death sentence. For some it's curable, and for many others it's a long-term disease which can be managed and successfully treated.

Quantum Computing: Quantum computing (QC) created the potential to revolutionize several computational use-cases within life sciences R&D and medicine, such as quantum energy calculations for molecules and some aspects of machine learning – advances that are still being explored today. In the early 2020s, some Pistoia Alliance members were already exploring QC applications and the Pistoia Alliance supported a cross-industry community of interest, especially for its many members from smaller organizations who were not equipped to navigate this complex journey alone.

Therapeutic Molecule Synthesis: The smaller, specialized markets that resulted from the explosion in genomics-based precision medicine have become very significant in the new healthcare delivery system. Biotechnology, micro-fluidics, nanotechnology, and other advancements in chemical technologies continue to open new frontiers today.

Broad application of DNA-encoded libraries⁶², containing hundreds of billions of compounds⁶³, effected a streamlined search for chemical matter and drug candidates. This rapidly reduced the time and costs associated with discovery and preclinical development while increasing transition probabilities to preclinical and clinical development.

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Patient-Centric Innovations

As well as technological advances, the last decade has seen several important scientific advances which have significantly improved patient care:

Real World Data: Defined as ‘data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources’, RWD has been transformative for the pharma industry – particularly in its approach to clinical trials supporting external control arms, disease models and natural histories, site selection, patient recruitment, etc⁶⁴. The improved quality, availability and accessibility of RWD, due to the increasing deployment of the FAIR data principles⁶⁵, enabled more precise *in silico* clinical trials to increase the efficiency and effectiveness of clinical development programs to tackle unmet medical needs^{66 67}.

RWD began to be used extensively to inform Health Technology Assessment (HTA) and the value of therapies. Projects such as the MIT Leaps project⁶⁸ used AI and Machine Learning (ML) to enable patients to receive timely access to the most appropriate therapeutics for their needs, while providing key stakeholders with the Real World Evidence (RWE) needed to improve decisions related to the development, access, and use of therapeutics for the target disease.

Patient Registries: Patient registries have been a long-term facilitator of patient-centric research, and continued to be widely used throughout the 2020s. By 2030, in today’s era of “very big real world data”, they are harmonized to align with commonly agreed standards so that patient registries can effectively be mined to promote research – helping organizations efficiently find the right patients in the right places with the right inclusion criteria, and the right principal investigators for clinical trials.

Fully Connected Healthcare: Today, the promise of the digital revolution has been realized in healthcare allowing secure, real-time connection between patients and providers, medical records being updated continuously allowing outcomes to be monitored, adverse events to be rapidly alerted and assessed, and patients eligible for clinical trials seamlessly contacted, consented and enrolled.

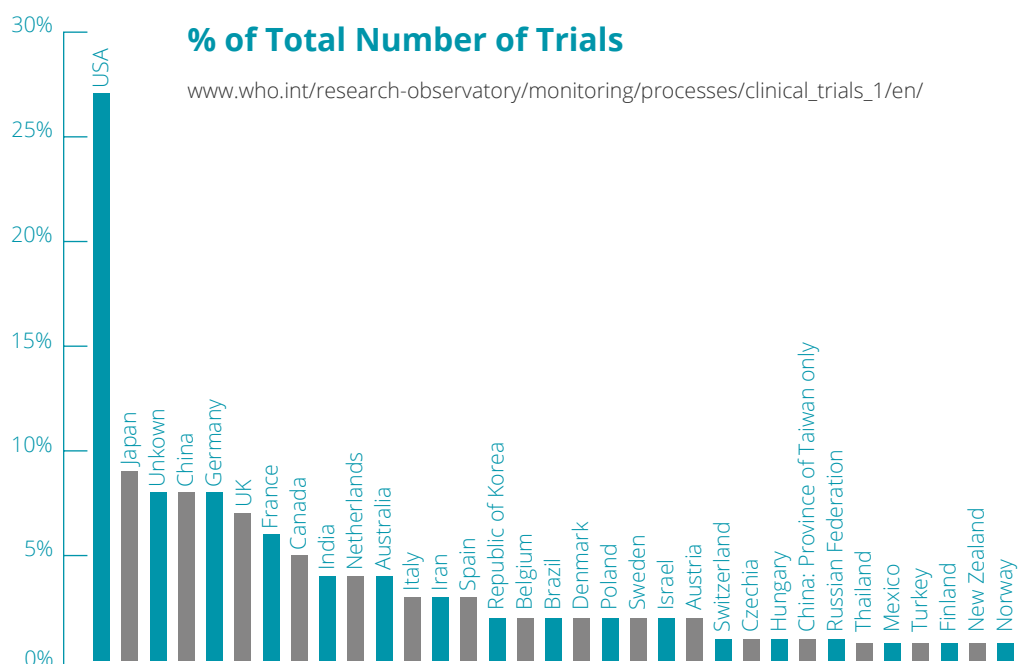
Precision Medicine: The potential of genomics-based precision medicine came to fruition in the 2020s, enhanced by the increasing scientific understanding and targeting of combination therapies⁶⁹.

Patient-Centric Innovations

The fundamental work of organizations such as UK Biobank⁷⁰, Genomics England⁷¹, and the NIH All of Us Research Program⁷² provided much-needed insight into the correlation between phenotype and genotype. By the mid-2020s, the age of patient empowerment had arrived, with a handful of start-up companies leading the way through secure, patient-friendly applications allowing patients to choose whether or not to participate in research and share elements of their medical records with participants in the healthcare ecosystem.

The improved data security offered by companies decreased the cost of end-user sequencing by moving some of the cost to the researchers who accessed the data, and then compensated the end-users when researchers accessed their data. By the early 2020s, it was possible to get one's genome sequenced and to retain ownership and control of the data. This could be achieved via web-based, blockchain-based, third-party providers; Nebula Genomics⁷³ being one example, Shivom⁷⁴ being another. The UK too harbored similar ambitions for its NHS data⁷⁵. The breakthroughs in medical devices, monitoring, and diagnostics (including companion diagnostics) continue to rapidly expand and show considerable promise, although often their deployment is based on the ability to pay⁷⁶.

Diversity Challenges In Clinical Trials: One of the major challenges in drug development during the last decade had been an historic under representation of patients recruited into clinical trials from regions other than the USA and Europe. For example, 15 percent of the worldwide population lived in Africa yet represented only 2-3 percent of the worldwide patients recruited into clinical trials; 57 percent of the worldwide population lived in APAC⁷⁷ yet they too were significantly underrepresented in clinical trials. The chart below reveals that the USA, with about 5 percent of the world's population, was carrying out over 25 percent of the world's clinical trials – whereas China and India, housing approximately 35 percent of the world's population, performed only ~12 percent of the world's clinical trials collectively.



Patient-Centric Innovations

Today, through improved patient registries in those regions of the world, and with the deployment of digitally-enabled clinical trials, substantially more patients as a percentage of their population are able to participate in clinical trials and gain access to innovative medicines.

Stem Cell Therapy: In the late 2010s, stem cell therapy had developed to an extent where various diseases of the blood and immune system, including the need to restore the blood system after treatments for specific cancers, could be managed with blood stem cells. Indeed, some skin grafts for patients with severe burns were grown from stem cells and there had been some success with repairing corneas⁷⁸.

Furthermore, stem cells were being used to grow organoids – three-dimensional (3D) *in vitro* tissue models that incorporated many of the physiologically relevant features of the *in vivo* tissue. By the mid-2020s, organoids representing over a dozen different organs of the body were being applied to a wide variety of research fields, including drug discovery. This allowed, in large part, the elimination of the need for animal testing and some human testing thereby improving the accuracy of the experimental models and the ethics of drug discovery and development.

Organoids can model healthy and diseased organs as well as cancers and as such were providing robust platforms

for patient-specific drug screening, cancer and immunology studies, and the pathogenesis of infectious agents. Today, in the 2030's, significant contributions to regenerative medicine are being delivered by stem cell therapy.

Gene Therapy: The promise of gene, DNA/RNA editing and autologous, allogeneic and stem cell therapies is being realized today, providing significant advances in multiple disease areas globally. Disease segmentation and patient-centric treatment algorithms, built on the opportunities provided by “big data” and computational biology during the 2020s, transformed the historic small molecule, biologics drug discovery model. Supply chain and reimbursement concerns of 2018 have been largely addressed through payment on outcomes.

Beginning in the mid-teens, gene therapy emerged as an important therapeutic modality for a variety of rare genetic disorders, including severe combined immunodeficiency due to adenosine deaminase deficiency (ADA-SCID)⁷⁹, spinal muscular atrophy (SMA), RPE65⁸⁰ mutation-associated retinal dystrophy, and the GBA-form of Parkinson's disease⁸¹. DNA and RNA editing technologies evolved from primarily research tools to agents in clinical developments for a variety of liver and retinal diseases.

“Digital technologies have helped overcome the challenges of clinical trial enrollment by empowering physicians – and indeed patients themselves – to find relevant clinical trials based on disease, age, gender, location, and biomarkers.”

Initial reports in 2012 described how CRISPR could cut DNA in specific locations; cuts could be used to remove troublesome DNA or disable certain genes. The technology generated tremendous interest during subsequent years in the academic community and venture companies, and a number of companies and academic institutions started to advance agents towards clinical development for indications ranging from sickle-cell disease and beta-thalassemia, to multiple myeloma and inherited forms of blindness. In addition to evaluating efficacy, these initial studies were critical to understanding the impact of unwanted edits and off-target effects.

In contrast to DNA base editing, which is permanent, the effects of RNA base editing are reversible. A number of companies emerged from stealth mode

in 2018 and 2019 with ambitions to treat diseases ranging from cystic fibrosis, to Rett syndrome.

Genomics: Genetics moved center-stage in the last decade, and by the end of the 2020s personalized medicine was available across the globe. Today, the markets for cell and gene therapy⁸² are immense; CAR-T⁸³ and stem cell therapy⁸⁴ have matured and become available for treating serious disease. The vastly improved knowledge in the field of genomics coupled with phenomics has allowed the understanding, tackling and the cure of some polygenic diseases to be contemplated.

Cure as a primary endpoint for some new therapies was possible. However, it came at a cost (see Table 4).

“Genetics moved center-stage in the last decade, and by the end of the 2020s personalized medicine was available across the globe.”

Table 4: Figures relate to the late 2010s

Disease	Drug	Treatment Cost US\$
Hepatitis C	Solvadi	84,000
ADA-SCID (“boy in the bubble syndrome”)	Strimvelis	665,000
Inherited retinal disease	Luxturna	850,000
Beta thalassaemia	Zynteglo	1,800,000
Infant spinal muscular atrophy	Zolgensma	2,125,000

Patient-Centric Innovations

The business model for such curative therapies had been difficult to implement. As *Bloomberg Opinion* noted in 2018, “Wall Street Wants the Best Patents, Not the Best Drugs”⁸⁵.

These breakthrough treatments have been criticized for being unaffordable - just as the cost of antibody-based cancer treatments in the 1990s were declared out of reach for most. However, experiments with new healthcare systems, including outcomes-based, annuity-based reimbursements^{86 87}, aimed to reward the biopharmaceutical industry for these new breakthrough drugs.

Oncology: Today, tumors are treated with well-established, mainstream chronic therapies, including immunotherapy⁸⁸, and most cancers are being identified and treated earlier – not least due to further progress in Liquid NGS made during the 2020s. Research initiatives, such as ASCO’s Center for Research & Analytics (CENTRA)⁸⁹, provided the infrastructure to analyze the RWD and deliver deep insights into the etiology, diagnosis, treatment and prognosis of cancers. However, as with other breakthroughs made in recent years, the ongoing cost pressures of therapeutics remains an issue and new pricing models are being experimented with. Proteolysis-targeting

chimeric molecules (PROTACs)⁹⁰, protein-slaying drugs, look destined to become the next wave of blockbusters.

Microbiome: The human microbiome has an estimated 100 trillion microbes, the bulk of which live in the gut. By the early 2020s, researchers were pursuing the potential of the microbiome and had moved beyond gut-related inflammation, such as Crohn’s disease and colitis, to central nervous system and cardiovascular diseases.

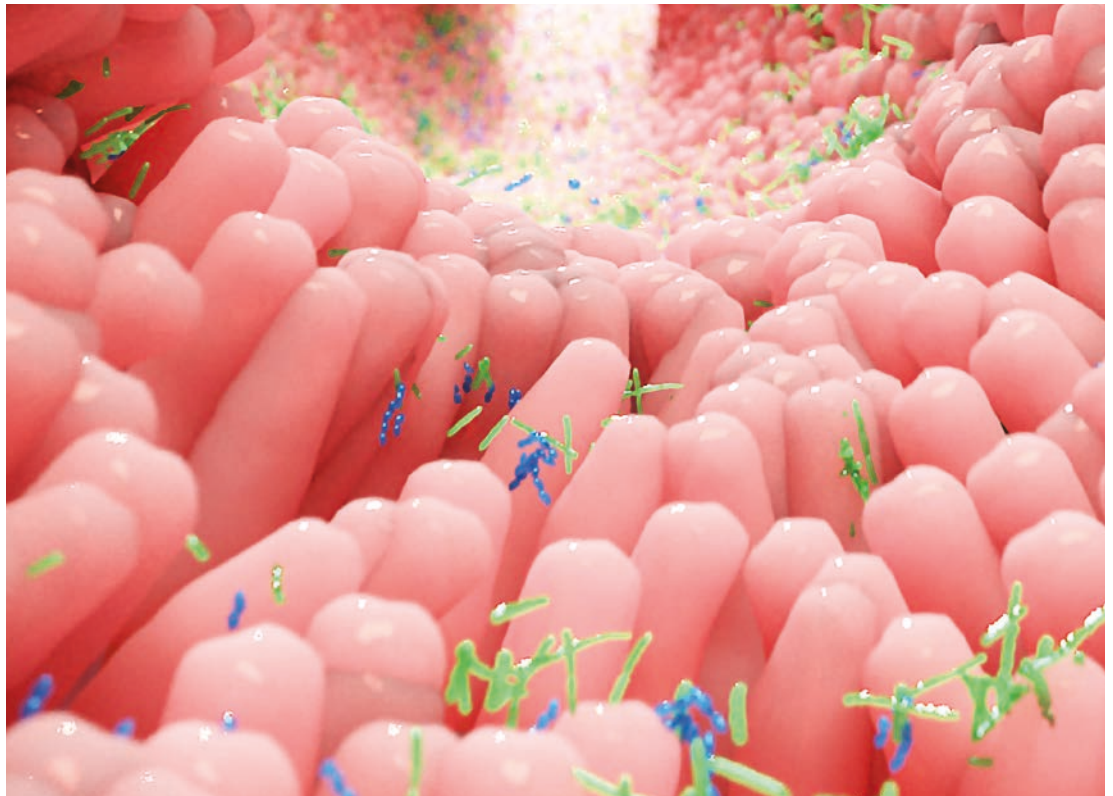
A greater understanding emerged in the early 2020s on how to balance the gut microbiome and test the effects on multiple disease phenotypes. However, researchers struggled to make headway due to the plethora of data sets published on microbiome experiments as enabled by the genomics era, until universal data and tools emerged on the molecular interactions between microbiome and host physiology. These developments, along with advances made in genome sequencing technologies and metagenomic analysis have greatly increased our present understanding of the microbiome⁹¹. In 2030, this has led to a whole new field of medicine with as much potential as genomics held 25 years ago.

Patient-Centric Innovations

Diagnostic Pill: The paucity of knowledge about gut microbiota higher up the GI tract was resolved by researchers at Tufts University developing a “diagnostic pill” which could be swallowed, and which recorded bacterial samples while passing through the gut^{92,93}. Such “lab-on-a-pill” devices revolutionized understanding during this era of the spatial diversity of the gut microbiome and its response to medical conditions and treatments.

Skin Microbiome: Continued research showed that skin microorganisms were discovered to have important roles in educating the cutaneous immune system. Some skin diseases had been associated with an altered microbial state of the skin. Reversion of this dysbiosis had helped prevent and/or treat the disease⁹⁴. Indeed, some studies had indicated that bacteria in the skin microbiome could inhibit skin cancers⁹⁵.

“In the early 2020s, many organizations suffered delays in their R&D programs due to a shortage of relevant skills and this continues to be a challenge in 2030⁹⁶.”



The human microbiome has an estimated 100 trillion microbes, the bulk of which live in the gut

Skills for 'R&D Technology'

Over the past decade, the relevant skills needed by the biopharma industry have evolved constantly due to the impact of new and emerging technologies.

Today, the executive leadership of the biopharmaceutical industry has widely recognized the importance of the technology-biology interface to innovation. R&D IT – or R&D technology as it has increasingly become known – is now seen as a strategic discipline and, importantly, different from the IT that supports line of business activities.

Management has largely accepted that the rate of change of the technology-science continuum is so rapid that extra effort has to be expended to keep the workforce's skills up-to-date. As such, increased investment in training, development and education keeps up-skilling personnel, allowing new technologies to be brought in without causing unnecessary redundancies in the workforce.

Leading up to 2030, digital experts needed to be encouraged to join the biopharma industry and biopharma needed to compete against other industry sectors, such as the well-funded fintech, as every company was fishing in the same limited talent pool. One of the key hurdles to overcome in recruiting talented young people was the negative perception held by society of the biopharma industry, caused by many serious and on-going issues to do with transparency (for example Humphrey Rang's review of Ben Goldacre's book "Bad Pharma: How drug companies mislead doctors and harm patients"⁹⁷), and high-profile problems of pricing⁹⁸.

As highlighted in the PwC Pharma 2005, 2010 and 2020 reports, the perception that society had of the pharmaceutical industry continued to be very poor. Even in 2030, the industry has only partially got to grips with this fundamental problem and society is yet to be fully convinced. As the industry attempts to become more patient-centric, so this fundamental trust issue needs constantly to be addressed. In part societal trust will be solicited by the delivery of "cures" for some hitherto untreatable and distressing conditions, using gene editing and cell therapy. These breakthrough treatments are stimulating more positive thinking in society and an appreciation of the impressive biomedical capabilities of the industry

Table 5: Impact of New Technologies in R&D Value Chain

Discovery	AI/ML/NLP (including text mining), RWD, data validation and cleaning tools, quantum computing
Development	New development modalities e.g. virtual trials, AI/ML, digital / wearables, blockchain, RWD
Medical Practice	AI/ML, digital / wearables, digitally-enhanced patient engagement, automatically produced PROs, intelligent home, RWD
Clinical Outcomes	Digital / wearables, blockchain, RWD
Regulatory Policy and Compliance	Predicting regulatory policy evolution and streamlining compliance to regulatory change, RWD
Business Development and Licensing	Augmenting search, evaluation and licensing with AI/ML, RWD

Skills for 'R&D Technology'

Another hurdle is the comparatively conservative, slow-moving nature of biopharma compared to the dynamic and agile nature of digital technology innovation and development. 21st century Agile development methodologies do not sit well with the constraints of 20th century regulation, controlling the deployment of computer-based technologies in the regulated domains of the biopharma industry.

Today, the industry is more confident in its recruitment of data scientists. Although the tools with which data science is executed continue to develop, the requirement for biopharma/life science/healthcare domain knowledge, along with the data analytical and statistical skills, is now accepted as the *sine qua non* for carrying out the required tasks.

Table 6: Skills Required for Pharma R&D Data Science⁹⁹

A strong educational background: 88% of Data Scientists have a Master's degree and 46% have PhDs		
Typical Data Scientist tasks	Business skills	Technical skills required in the year 2020
Collecting large amounts of structured and unstructured data and transforming it into a usable analytics-ready format.	Domain knowledge such as molecular biology, medicinal chemistry, clinical R&D, regulatory affairs, epidemiology, pharmaco-economics.	R programming (43% of data scientists use R).
Solving business problems using data-driven techniques.	Intellectual curiosity, creative problem-solving and strategic thinking.	Medical statistics / pharmaceutical statistics ¹⁰⁰ .
Staying on top of analytical techniques such as machine learning, deep learning and text analytics, including benchmarking of methods.	Relevant business acumen and awareness of industry trends.	Procedural and compiler coding; database query languages: SQL SPARQL; data modeling in relational and RDF form.
Communicating and collaborating with both IT and the business.	Communication skills to different levels of audience.	Familiarity with cloud-based environments (AWS, Google, Microsoft).
Looking for order and patterns in data, as well as spotting trends that generate value.	Relationship-building, teamwork and conflict resolution.	Data visualization techniques.
Validating models and analysis.	Understanding of legal, regulatory and ethical issues.	Machine Learning and AI.
		Text mining and related ontology use in semantic based text mining.

Regulation

In the years leading to 2030, regulatory agencies have been striving to adopt processes, such as adaptive licensing¹⁰¹, that allow them to get good drugs into the market while continuing their important vigilance to ensure bad drugs do not get approved.

For example, in the USA, it had been predicted that by 2025, the FDA would be approving 10 to 20 cell and gene therapy products a year. This statistic was based on an assessment of the pipeline and the clinical success rates of these products and as such the FDA expanded its workforce including additional Marketing Authorization Applications reviewers.

During the late 2010s, major regulatory agencies (e.g. CFDA, FDA, EMA, PDMA) delivered strategy reports embracing the need to support and expedite the development and marketing approval process for many new treatments. For example, the EMA Regulatory Science to 2025 Strategic Reflection¹⁰² identified the need for five key objectives:

- Catalyzing the integration of science and technology in medicines development
- Driving collaborative evidence generation - improving the scientific quality of evaluations
- Advancing patient-centered access to medicines in partnership with healthcare systems
- Addressing emerging health threats and availability/therapeutic challenges
- Enabling and leveraging research and innovation in regulatory science

Furthermore, the FDA produced several guidelines to help drive clarity in the processes of the deployment of regenerative medicine¹⁰³ and cellular and gene therapy¹⁰⁴ including the longer term follow-up of gene therapy patients.

The Chinese FDA also implemented considerable change in their regulatory environment designed to reform the administration of clinical trials, accelerate the evaluation and approval process, and the promotion of drugs innovation and the development of generic drugs¹⁰⁵.

The Japanese Pharmaceuticals and Medical Devices Agency (PMDA) had similarly been working on its efficiency to ensure new drugs got to market safely and effectively and in a timely manner. Indeed, by the mid-2010s the average number of days between an NDA filing and approval of a standard drug in Japan was 306 days, compared to 322 days in the USA (FDA) and 366 days in the UK (MHRA).

Nonetheless, despite all these efforts, the rate of change of drug discovery and development and the impact of new, precision-medicine research modalities, have continued to stretch the resources of the regulatory agencies.

Regulation

Health Technology Assessment (HTA): For many years, HTAs had been used to help assess the value (and indeed affordability) of therapies. The pharmaceutical industry regarded the HTA assessment as the “4th hurdle”; the first three hurdles being the need to demonstrate to the regulatory agencies that a therapy was safe, effective and could be manufactured with consistent quality¹⁰⁶. Overcoming the 4th hurdle was essential to obtain reimbursement from many payers in many regions. NICE¹⁰⁷ (the National Institute for Health and Care Excellence), the HTA in England and Wales provides a useful exemplar of the role of a HTA.

However, now in 2030, global RWD standards¹⁰⁸ are in place that allow outcomes measurement to be useful and the many disparate Health Technology Assessment Agencies, including NICE, are aligned into a global consortium (similar in concept to EUnetHTA¹⁰⁹ but with global reach) which provides support and advice to the life science and medical device industries. The development of such HTA methodologies has been instrumental in the migration of the reimbursement paradigm from “payment per pill” to “outcomes-based payment”.

Pre-Competitive Collaboration

Another key development in the last decade has been that all major biopharmaceutical and life science businesses have been closely aligned and have been collaborating openly in pre-competitive programs that delivered cross-industry results¹¹⁰. The multi-company, multi-year Open Targets¹¹¹ initiative, launched in 2014, provided one example of many of these pre-competitive collaborations that have transformed the efficiency and increased the innovation of biopharma R&D. KPMG predicted in its 2018 report, “Reinvent innovation and become an R&D front-runner by 2030”¹¹² that new market dynamics would lead to R&D funding by cost and resource sharing among multiple healthcare stakeholders and even crowdfunding that included the wider public to distribute the financial risk.

During this time, the multiple regulatory agencies agreed to try to move beyond The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) model of standardization and move towards establishing a global regulatory body. The WHO took a leading role in these negotiations as indicated in their report “Towards Access 2030”¹¹³.

Conclusion

Our work to imagine the future of the health ecosystem in the year 2030 has involved 75 subject matter experts drawn from 65 different organizations. What emerges is a life sciences and healthcare industry with tremendous opportunities for development, and for contribution to world health and the public good.

We do not expect all the predictions to be accurate, in fact we are certain time will show that some are not. However, we are confident that many of the signals we have noticed will deliver the expected changes. Socio-political changes are certainly moving in the direction of healthcare being seen as a human right; macroeconomic analyses say that overall healthcare costs as a percentage of GDP cannot continue to rise as they have, and the mechanisms that we have to pay for healthcare require a radical rethink. Our agenda must shift from treatment of disease to prevention and cure and with that, the reward systems we have to promote these solutions must flex to encompass the new agenda.

However, such opportunities will only be realized if the industry embraces the rapidly developing and substantial technical and scientific advances we are seeing in the life sciences. In the next ten years, new research modalities such as cell and gene therapy, the new wave of digital technologies supporting biomarkers, diagnostics, monitoring, therapeutics and health devices, and the profound developments in capability of AI/ML/NLP and robotics, will deliver exciting progress.

Further, the analysis of very big data generated by this digital revolution, when powered by the next generation

of high-performance computing, including quantum computing, and undertaken in collaboration with all stakeholders in the ecosystem, will make a profound contribution to the understanding of disease, the delivery of new therapies and the palliation of the human condition. Importantly, in the years ahead, the industry will need to find the staff with the right skill set which will evolve rapidly; never has training, development and education, which has always been fundamental to our industry, been so important.

In many instances, these predicted advances over the next decade will be found at the intersection of technologies and the intersection of technologies and science. These dramatic developments in scientific-technological progress will continue to create stress for social and political institutions. We cannot sweep under the carpet the legitimate concerns society has regarding the security of personal health data, nor can we overlook the lack of trust that already exists with many players in the healthcare ecosystem and with some of the newer technology businesses. However, the large multinational companies, with their awareness of world-wide challenges, along with their understanding of the opportunities that collaboration across industries and geographies create, will become increasingly effective in helping to calm these concerns.

As such, the Pistoia Alliance, along with many other organizations, should reconfigure to ensure that they reflect and promote these developments and by so doing, increase the chances of success.

Background

The Pistoia Alliance is a global, not-for-profit (Type 501 (c) (6)) alliance of life science companies, vendors, publishers, and academic groups that work together to lower barriers to innovation in life science R&D and healthcare <http://www.pistoiaalliance.org>. The Pistoia Alliance Board of Directors and its Advisory Board undertook to help the members of the Pistoia Alliance get ready for our predictions of some of the profound changes that will occur in the life science and healthcare ecosystem over the next decade.

Today, it is becoming increasingly clear that a host of scientific and medical advances across numerous disciplines are happening in parallel. “The Life Sciences Innovation Report”¹⁴, produced by the Pistoia Alliance & Clarivate Analytics in 2018, reviewed the innovation that had occurred across all aspects of healthcare and the cure and/or management of disease. In this report, by “futurecasting” developments in these areas, the Pistoia Alliance will be able to prepare its members for the challenges and opportunities that will present over time. The Pistoia Alliance will lay out its view of the future of life science R&D and healthcare as it relates to its membership and the skills that they will require.

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