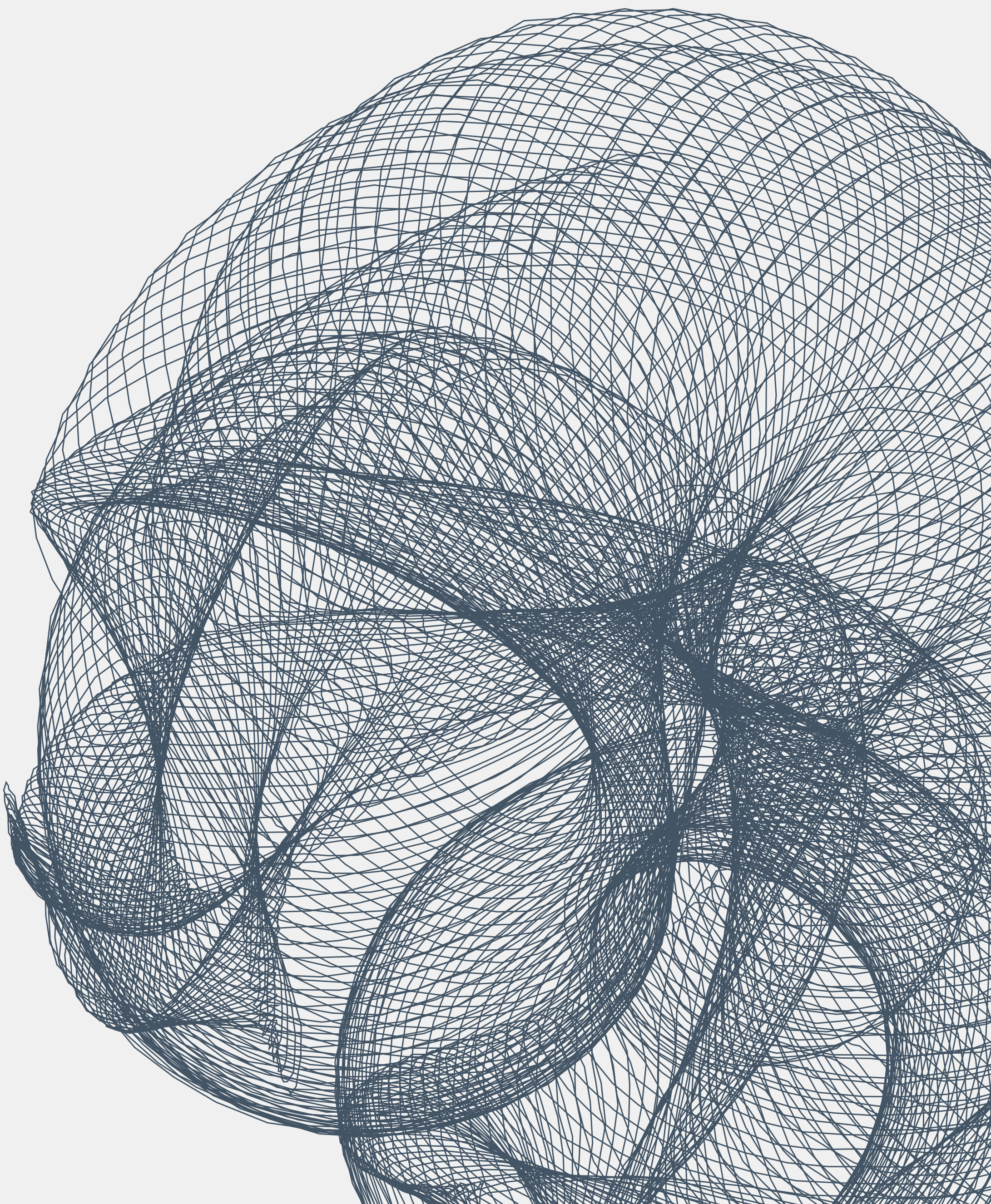
IQVIA INSTITUTE FOR HUMAN DATA SCIENCE

Advancing Human Data Science

A NEW APPROACH TO IMPROVING HUMAN HEALTH OUTCOMES



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Introduction

Advances in healthcare are accelerating as our understanding of genetic causes of disease, and other aspects of human science, grows. New therapeutic approaches like immune and gene therapies are being incorporated into clinical practice alongside new digital technologies to improve human health. The application of data science and analytics to big data in healthcare have further supported this progress. Analytics have been used to assess the value of these new therapies, speed innovative therapies to market, optimize health system performance, advance disease prevention and improve the treatment and delivery of human health services. This progress through data represents the emergence of a new discipline in healthcare — Human Data Science — which aims to advance understanding of human health and enable healthcare stakeholders to make better, more insightful, decisions. Through its use, stakeholders are working to drive better health outcomes and control the rise in healthcare costs.

This report introduces the emerging discipline of Human Data Science and its potential to tackle major gaps in healthcare. Today, scientists continue to grapple with holes in disease understanding that hinder their ability to develop treatments, and clinicians find that social determinants of health frustrate even their best care efforts. Health systems, too, struggle to combat the rise in chronic health conditions.

The report examines the innovation occurring at the crossroads of human data, human science and data science that can help combat these gaps. It presents three case studies representing the ways Human Data Science stands to improve health, advance disease prevention and treatment, and guide delivery of health services.

The principles that guide Human Data Science and elements that will shape what can be done in the future through its application are presented. Hurdles preventing the full potential of this discipline are explored and ways to address these discussed.

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Executive summary

For decades, scientific medical research and development have been the critical backbone of advances in health and healthcare. Breakthrough discoveries in the laboratory and the development and introduction of new therapies – from bench to bedside – have empowered the global medical community to more effectively combat, and in many cases conquer, life threatening and debilitating diseases, prevent unnecessary deaths, accelerate primary prevention and intercept asymptomatic conditions before they progress.

Notable achievements in medical science and discovery — such as the development of penicillin to eradicate infectious diseases; advances in therapies to treat cancer (moving from chemotherapy and hormonal treatments to targeted biologics, immuno-oncology drugs and CAR T-cell therapies); the impact of antihypertensives and statins to treat cardiovascular disease and prevent heart attacks and stroke; and breakthroughs in virology from life-sustaining combination therapies for HIV to curative therapies for hepatitis C — are continuing with the explosion of new frontiers in research and therapeutic breakthroughs stemming from molecular biology, biomarkers and the revolution in genomics, proteomics, nanotechnology and tissue-pathology. The rising volumes and quality of data and analytics, supported by digital technology, are also driving the application of real world evidence to speed therapeutic innovations to market and improve disease prevention, patient care and health system performance.

However, despite recent decades of tantalizing achievements, there are continued unmet needs and challenging gaps in healthcare that call for research in medical science, and gaps in healthcare data that call for advances in data science, to enable the healthcare ecosystem to fight these challenges and climb to even further heights.

While scientific and clinical advances have been achieved in medicine, and improvements have been made in data science and machine learning, challenges hinder the application of current methods to solve healthcare challenges and improve health outcomes and control the rising costs of healthcare services. These include issues around data collection — particularly on social factors that influence health — and the robustness and shareability of health data, a lack of common healthcare data structures, gaps in disease understanding, and a lack of focus on prevention and wellness globally marked by a rise in chronic diseases and multi-morbidities.

Failures to develop disease-modifying therapies for Alzheimer's disease, to effectively address social determinants of health and their impact on life expectancy, to tackle the rise in chronic diseases globally, or to effectively harness machine learning and artificial intelligence to guide medical practice, all show there is a need for a better approach to effectively address these gaps. They also illustrate the various challenges facing healthcare over the next 10 years and that, if solved, could enable better health outcomes.

Human Data Science, which integrates the life sciences with breakthroughs in data science and technology, is now advancing our understanding of human health and enabling healthcare stakeholders to make better, more insightful, decisions. Its three components — human data, human science and data science — acting together and guided by human expertise, can unleash innovative ways to solve healthcare's toughest problems. By combining scientific disciplines pertaining to human health (human science), data on the social and environmental conditions people face and their interactions with the health system (human data), and analysis of this information to obtain insights (data science), Human Data Science offers to provide enormous value in healthcare.

Applying a rigorous approach to the increasing amount of data in the healthcare environment, Human Data Science aims to improve health outcomes, the human experience of healthcare, and accelerate these improvements. By assessing what really works in healthcare and answering questions that have long plagued the health system, Human Data Science expands our ability to fight disease, maintain health and develop new treatments to address unmet needs.

The elements of Human Data Science are being applied to healthcare today, but holistic patient care, robust data science practices and an understanding of science behind diseases need to be incorporated as a whole to make improvements.

The potential promise of Human Data Science is significant in several ways: Through the application of advanced analytics to human data, Human Data Science can be used to optimize health system performance by guiding and improving policy decision-making and population health interventions. Disease prevention and treatment also stands to be advanced by Human Data Science by accelerating clinical development, analyzing and improving drug safety through data and supporting precision medicine treatment paradigms through analyses of patient biomarker data predicting patient response to therapy. Its approach to using social data further offers a deeper understanding of the patient experience to improve the delivery of human health services.

How do we link advances in human science with advances in data science? How do we bring them together to find new, better ways to close knowledge gaps and improve human health and wellness? That unique intersection is Human Data Science.

Answering healthcare questions by applying a lens of human-centricity and the rigor of data science is already having a positive impact on healthcare challenges. Human-informed and data-driven research offers to guide the health system to new solutions for problems that have not been solved through conventional means. This report presents examples of how the human-centricity that Human Data Science brings to decision-making, can be applied to specific health problems across three key domains — health system challenges, disease-specific issues and health-delivery services — and result in positive outcomes.

Six external factors will shape what can be done with Human Data Science in the future: human expertise to guide application; the availability of patient-level big data and data science methodologies to provide a foundation for inquiry; patient privacy and data security methods to ensure appropriate application; supportive policy and regulations to encourage new and insightful use; investment in discovery research and translational medicine to expand disease understanding; and technology to enable effective use of artificial intelligence and machine learning.

However, to maximize the value that can be derived from Human Data Science, stakeholders will need to support foundational elements underlying Human Data Science and apply principles to their research that increase its applicability and boost public confidence and trust. Protecting patient data privacy and security, reducing data bias and enabling greater transparency in research are necessary for the appropriate use of big data and advanced analytics, and as such, policies and methodologies that support these enable Human Data Science. Since Human Data Science solves healthcare problems by applying a lens of human-centricity to analyses, health policies that consider patient-defined outcomes of success and those that invest in basic research, human behavioral research and translational science, will support its future success. Data sharing from various multi-stakeholder datasets will power its advanced analytic algorithms and help address healthcare problems, thus investments in methodologies and policies that address and improve data sharing between stakeholders, as well as protect patient privacy and rights, will further the value Human Data Science can deliver.

While the challenges and gaps in healthcare worldwide are daunting and require a paradigm shift in our approach to data and science, this transformation through Human Data Science has already begun and offers reason to be optimistic. The powerful forces of human ingenuity, breakthrough science, and disruptive technology that Human Data Science has unleashed promises to power future healthcare advances and improve health outcomes for individuals and populations globally.

Framing the gaps

THE STATE OF HEALTHCARE

Healthcare is in the midst of positive transformation. Scientific advances are accelerating, and a record number of new active substances (NAS) were launched in the United States in 2018, bringing 59 new treatment options to patients. Almost half of these therapies carried an orphan drug designation and over a third of NAS launches were identified by the FDA as first-in-class; having mechanisms of action different from those of existing therapies. There is also growing investment in healthcare innovation with 1,308 life science venture capital deals closed in 2018 with an overall value greater than $23 billion.[1] The use of technologies such as artificial intelligence (AI) and machine learning (ML) is also becoming more mainstream in healthcare, though 85% of life science executives explain that AI is advancing faster than their organization's pace of adoption.[2] At the same time, information technology is being progressively incorporated into clinical practice to improve care and manage costs. The involvement of patients in their health (health activation), including engagement with wellness technologies and behaviors, and participation in healthcare decision-making are both increasing. Finally, health and wellness are being prioritized by a number of health stakeholders, with payers and employers supporting wellness programs to reduce obesity or lessen substance abuse of tobacco and alcohol, and wellness apps now accounting for the majority of health apps available to consumers.

GAPS IN HEALTHCARE

Despite this increased output and an acceleration in transformation within the healthcare sector, further challenges remain that suggest a better approach to health-related issues is needed. There are gaps in our understanding of underlying disease causes and molecular processes across therapy areas which are slowing the development of life-saving treatments. There are disparities in healthcare access and delivery related to an individual's environment and social factors. Despite existing policies and healthcare incentives intended to improve wellness, the number or patients with chronic diseases are rising globally.[3] Finally, gaps in data collection, data quality and data bias are impeding the full potential for advanced analytics to solve healthcare problems. Should these issues fail to be addressed, there is a risk that decades of advances in health and healthcare will stagnate and even in some cases lead to a decline — such as reduced life expectancy.

Gaps in disease understanding

Human disease understanding is a critical contributor to progress in clinical research and development. Despite some successes, a clear understanding of the underlying causes of certain diseases still eludes scientists and has hindered the development of breakthrough treatments. This lack of understanding is on full display in Alzheimer's disease where in the past sixteen years, 137 Alzheimer's development projects were discontinued, while only one medicine — a combination of two previously approved therapies — received

Despite scientific and clinical advances in medicine and improvements in advanced analytics, challenges remain. Gaps in disease understanding, health disparities, underutilized wellness and disease prevention strategies, and the availability of data call all hinder the ability to solve healthcare problems.

regulatory approval globally,[1] though the disease affects an estimated 50 million patients globally (see Exhibit 1).[4] Additionally, only a handful of symptomatic treatments are available for Alzheimer's patients.

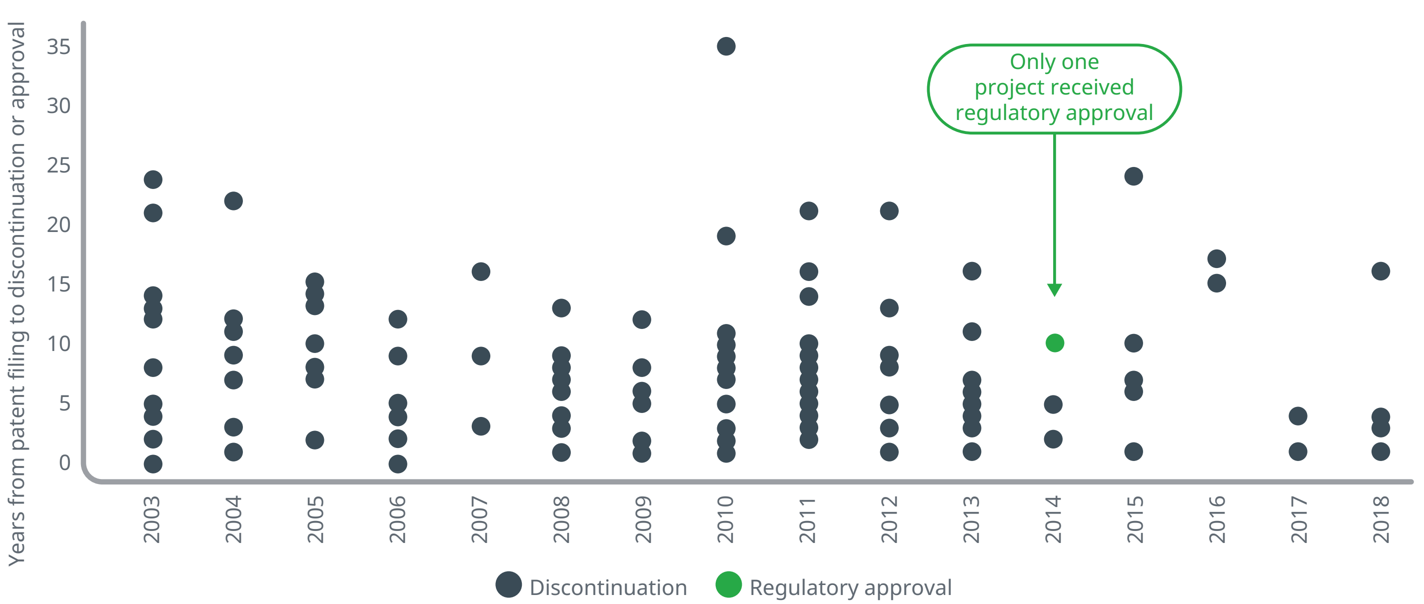
The lack of critical human disease understanding is on full display in Alzheimer's disease research; only one medicine has received regulatory approval in the last 16 years, even though more than 50 million patients are affected by the disease.

Predictive medicine can be used to determine which patients will respond best to a particular therapy, however, gaps in disease understanding limit its potential. Despite a paradigm shift in the treatment of multiple tumor types with the development of immune checkpoint inhibitors [i.e., programmed cell death protein 1/programmed cell death ligand 1 (PD-1/PD-L1) and CTLA-4 inhibitors] the percentage of patients estimated to respond to these medicines was only 12.5%[5] in 2018 though roughly 44% of U.S. patients with cancer were eligible for treatment with checkpoint inhibitors. Thus, challenges remain to determine which patients are truly benefiting from these life-saving medicines, as simply screening for the PD-L1 biomarker may not be sufficient. Understanding which patients will respond best to a therapy is only slowly being addressed by predictive medicine. Optimizing therapy in oncology faces additional challenges as there are numerous variations in cancer biomarker types that interact with an individual's genetic profile.

Social determinants working against health

Some aspects of public health are also moving backwards in developed countries, with life expectancies at birth stagnating in the United Kingdom and declining slightly in the United States over the past several years.[6,7]

Exhibit 1: Discontinuations versus regulatory approvals for Alzheimer's therapies

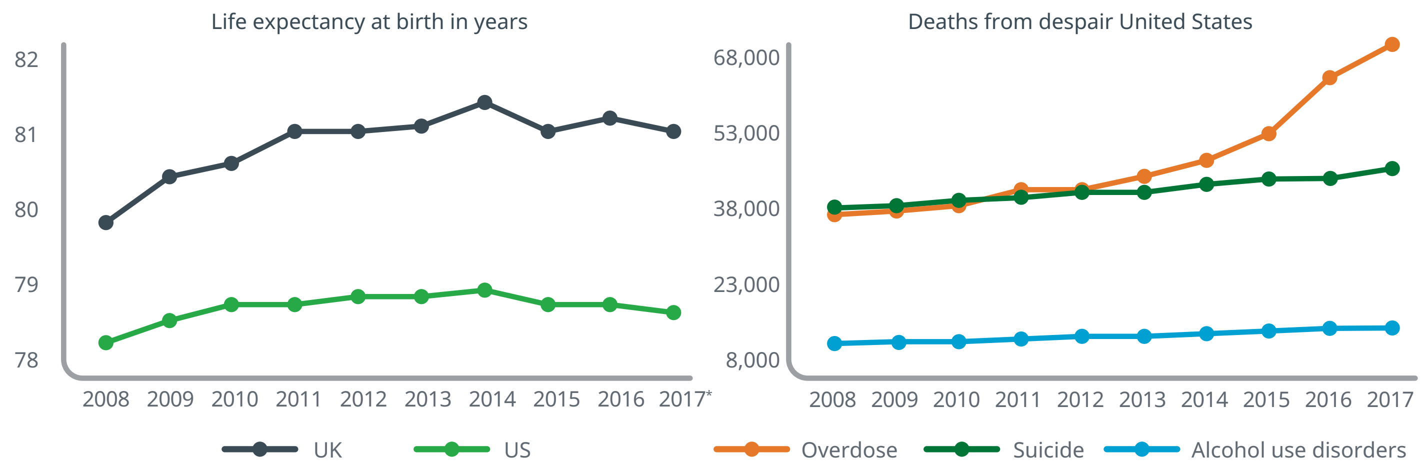


Source: The Changing Landscape of Research and Development - Innovation, Drives of Change, and Evolution of Clinical Trial Productivity. Report by the IQVIA Institute for Human Data Science

Notes: The exhibit shows the time from patent filing to the end of clinical development, whether that was a discontinuation of the program or market approval; this does not show a discontinuation of a single clinical trial. Line extensions of marketed therapies are included with original global approval of the molecule.

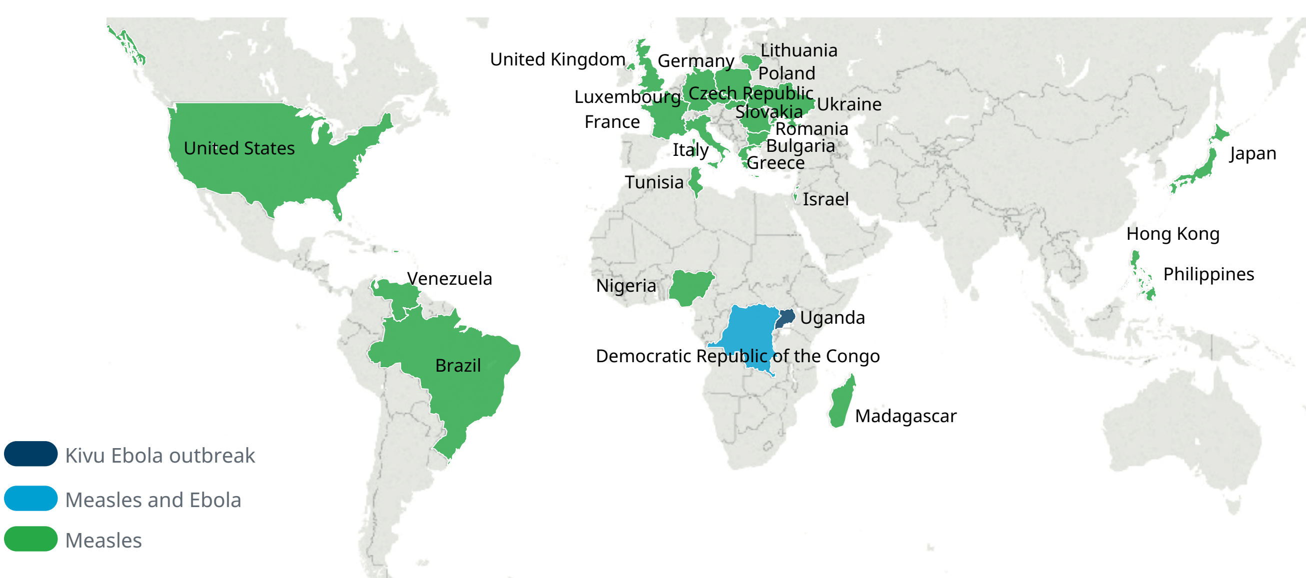
While the causes of this regression are not clear, so-called deaths from despair,[8] which include those related to drug and alcohol abuse and suicide, have been rising (see Exhibit 2). Specifically, suicide rates are climbing in the United States and the United Kingdom compared to other G7 and some BRIC countries,[9] and overdose deaths due to opioids have risen globally: between 2011 and 2016, opioid-related deaths increased by more than 20% on average in OECD countries.[10] Social factors or "social determinants" that influence these deaths may therefore be putting downward pressure on life expectancies in developed countries as well as globally. Social factors generally, such as material deprivation (e.g., food, housing, sanitation, and safe drinking water), social exclusion, lack of education, unemployment, low income and other living and working conditions,[11] and a lack of policies to address them, have been associated with negative aspects of health.

Exhibit 2: Life expectancy at birth and deaths from despair, 2008–2017



Source: OECD (2019), Life expectancy at birth (indicator), Accessed on 26 Jun 2019; National life tables, UK: 2015 to 2017. United States Life Tables. Arias E, Xu J. National Vital Statistics Report. 2019, 68(7). National Institute of Mental health. Suicide. Accessed Jul 2019. Available from: https://www.nimh.nih.gov/health/statis-tics/ suicide.shtml; NIH. Overdose Death Rates. Accessed Jun 2019. Available from: https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates
Notes: *Life expectancy analysis is from the OECD for the United Kingdom, with the exception of 2017, which is from the UK National Life Tables; data from the United States is from the National Vital Statistics report. Deaths from suicide have been calculated from suicide rates per 100,000 people in the United States.

Exhibit 3: Measles and Ebola outbreaks reported, 2018–2019



Source: CDC, WHO, and European Centre for Disease Prevention and Control publicly available websites. Accessed Jul 2019.

Infectious disease outbreaks, too, are intricately linked to the social, behavioral and environmental factors within the communities where they occur.[12] Despite vaccines being one of the greatest public health tools in the modern era, vaccination rates across communities and geographies vary. People are less likely to vaccinate if they receive misinformation, fear side effects or lack access, and vaccine programs in developing countries face challenges in affordability, logistics and credibility of stakeholders offering the vaccines.[13] These social and environmental actors have led to outbreaks of disease that could have been contained sooner, particularly for measles and even Ebola (see Exhiibit 3). For example, between 2018 and 2019, there were declared measles outbreaks across North and South America, Africa, Europe and Asia, and from January through July 2019, over 300,000 cases were reported to the World Health Organization (WHO).[14] Similarly, the Ebola virus has re-emerged in the Democratic Republic of Congo and Uganda with over 2,500 confirmed cases and 1,700 deaths as of July 2019.[15]

Although many of the complications that develop during pregnancy are treatable and preventable, health systems and communities are failing women. Maternal mortality is a primary concern in developing countries and is directly related to issues such as poverty and disparities in healthcare access. Although maternal mortality in developed countries accounts for only one percent of cases,[16] there remains a clear discrepancy in outcomes based on social factors. The maternal mortality rate is appallingly high in the United States, where approximately 700 women die every year from pregnancy or pregnancy related complications.[17]

According to the WHO, without addressing the underlying causes of chronic diseases like diabetes and cardiovascular disease, associated deaths are expected to increase by 17% over the next ten years, signaling a need for better chronic disease management strategies.

Harnessing artificial intelligence and machine learning methodologies for clinical decision support has not yet become routine, in part due to challenges around the healthcare data that trains these models. In particular, biased datasets can lead to flawed solutions that potentially exacerbate racial and gender disparities.

Underutilized wellness and disease prevention strategies

Chronic diseases, including cardiovascular disease, diabetes and cancer, are the leading causes of disability and death globally,[18] yet healthcare strategies to motivate, encourage and support individuals to avoid such chronic diseases remain poorly utilized. For example, according to the WHO, without addressing the underlying causes of chronic disease, associated deaths are expected to increase by 17% over the next ten years, making new approaches to wellness and prevention critical.[19] In addition, risks factors for these diseases are influenced by intrinsic social circumstances of the individual including preventable ones such as poor diet, lack of exercise, use of tobacco or alcohol consumption.[18]

Gaps in data science

Though artificial intelligence is increasingly used to guide clinical trials, the reported discontinuation of development and sales in 2019 of IBM's Watson for Drug Discovery,[20,21] a machine learning tool to speed the identification of drug candidates and drug targets, and challenges reported with application of Watson to clinical decision support in oncology (in achieving consistently accurate predictions for cancer treatments), illustrate the gaps that remain to apply data science and AI in the healthcare space.[22,23] This occurred, in part, due to the nature of unstructured healthcare datasets and the complex interactions between them, as well as challenges extracting variables from patient electronic health records, which often have missing or unstructured information.[22] Further, aside from imaging applications, few artificial intelligence-based tools have been approved for use by physicians in a clinical care setting.[22]

As the use of data science in healthcare increases, one serious challenge to the validity of insights generated is bias inherent in both datasets and analytic approaches applied to these. For instance, publication of studies describing clinical trials on medicines are biased towards studies with a positive outcome, which means stakeholders could be relying on an exaggerated benefit within data to make decisions.[24] Real world datasets may also have biases that need to be considered. For instance, electronic health records in a specific location will reflect the population bias and care delivery in that specific location, and payer data may reflect only patients able to afford coverage. Selection bias, too, can occur when enrolling patients for clinical studies leading to negative downstream effects. Bias in machine learning can be due to inherent flaws in the datasets used to train the models,[25] but can also be the result of how the algorithm is programmed and how it is used and could confirm pre-existing biases.[26,27] For example, a study of three commercially available facial-analysis software applications demonstrated an error rate of 34.7% for dark-skinned women compared to 0.8% for light-skinned men.[28] In another example, medical and genomic datasets are often racially biased: a meta-analysis from 2016 found that 81% of participants in genome-mapping studies were of European descent.[29]

The various gaps and failures of the healthcare system discussed in this section all show there is a need for a better approach to effectively address these challenges.

The combined application of data science, human data and human science supports progress by offering to guide and enable solutions to these problems. Improving our understanding of disease processes, harnessing the utility of social determinant data, enabling and supporting wellness efforts and addressing the challenges around the use of data science in healthcare can be achieved through a combination of human data, human science and data, known as Human Data Science.

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Human science meets data science

While the challenges and gaps in healthcare worldwide are daunting, we have reason to be optimistic about future advances in healthcare due to the emerging discipline of Human Data Science and its ability to unleash the powerful forces of human ingenuity, breakthrough science, and disruptive technology.

Human Data Science is a discipline that integrates the life sciences with breakthroughs in data science and technology to advance our understanding of human health and enable healthcare stakeholders to make better, more insightful, decisions. By combining scientific disciplines pertaining to human health (human science), data on the social and environmental conditions people face and their interactions with the health system (human data), and analysis of this information to obtain insights (data science), it offers to provide enormous value to healthcare. Its three components — human data, human science and data science — acting together and guided by human expertise, can unleash innovative ways to solve healthcare's toughest problems (see Exhibit 4).

Applying a rigorous approach to the increasing amount of data in the healthcare environment, Human Data Science aims to improve health outcomes, the health system and the human experience of healthcare, and accelerate these improvements. By assessing what really works in healthcare and answering questions that have long plagued the health system, Human Data Science expands our ability to fight disease, maintain health and develop new treatments to address unmet needs, as well as optimize allocation of resources in the health system.

WHY HUMAN DATA SCIENCE MATTERS

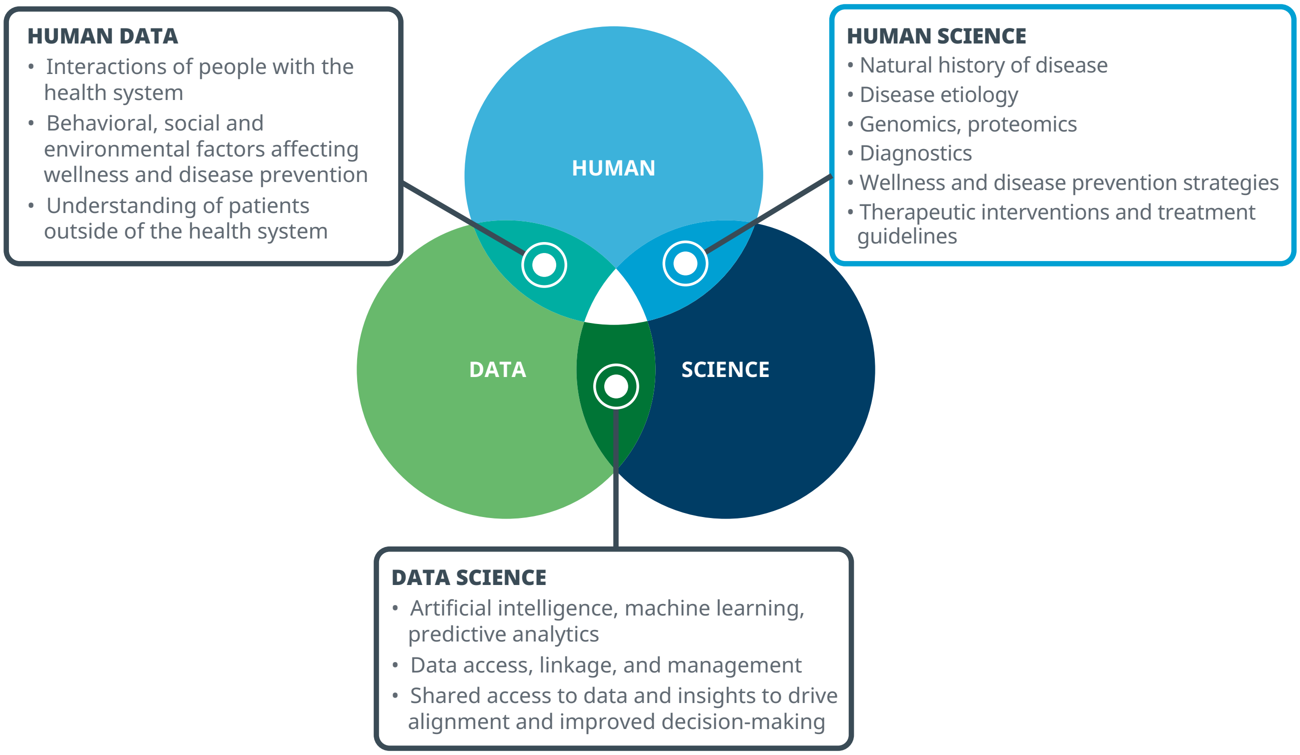
To realize the full potential of Human Data Science, each of the three elements — human science, human data and data science — are needed to gain a complete picture of factors influencing human health. In many instances, current health systems fail to apply one element and insights are impeded. To make improvements, the current ways patients are perceived by the health system, how their data is collected and used, and a basic understanding of the science underlying diseases need to evolve.

Current healthcare is focused on patients not humans
Human Data Science looks at human health in a new way by considering people and the human experience as a whole — rather than just patients. The collection of health data, scientific investigation and even patient care have typically focused on disease diagnoses and often failed to capture a holistic view of the person experiencing the disease. Those missing elements can include a patient's psychosocial state, their attitudes and beliefs,[30] level of health activation, and other social determinants of health like environment and housing security that can lead to disjointed and ineffective medical care if not taken into consideration. Patients treated only medically and not holistically can experience prolonged[31] or repeat hospitalizations that lead to increased treatment costs. When data science and analytics fail to consider social determinants of health, there is a missed opportunity to predict and address a person's susceptibility to disease or their risk for adverse

What is Human Data Science?

Human Data Science is a discipline that integrates human science with breakthroughs in data science and technology to advance our understanding of human health and enable healthcare stakeholders to make better, more insightful, decisions.

Exhibit 4: The elements of Human Data Science



Source: IQVIA Institute, Jul 2019

All three elements are needed to gain a complete picture of factors influencing human health and to find innovative ways to solve healthcare's toughest problems.

events. In order to treat the whole person and allow for greater creativity in problem solving, these attributes need to be considered by stakeholders more than they usually are today.

Healthcare data challenges traditional data science methods

Human Data Science applies rigorous data science methodologies to ensure the correct solutions to healthcare problems are produced through analytics.

In healthcare, more data is now being collected digitally than ever via electronic health records, insurance claims, an array of wearable sensors, online surveys and other digital tools, and includes newer data types like genomic data and biomarker test results. Big data analytics within large, complex healthcare databases can yield crucial discoveries, but there are challenges in collecting, standardizing and structuring data, and linking datasets — the process of data metamorphosis — needed to derive useful insights from this data. In some cases, parts of hospital systems may lack digital records entirely. For example, while the majority of hospitals in the United States have electronic health records (e.g., 96% overall and 99% of large non-federal acute care hospitals according to a 2017 study), among smaller rural networks (including critical access hospitals) only 93% do, leaving holes in our understanding of the health system.[32] In other cases, the datasets are not rigorous enough for effective data science, lacking standardized fields or input data, or having gaps in coverage across locations, ages, payers or provider types. As artificial intelligence and machine learning technologies mature, there will be a growing demand for ever more extensive and complex datasets, all of which must reach a standard of quality, connectedness and relevance. To arrive at accurate conclusions and derive useful insights, these standards must exist, and data science methodologies must be carefully applied.

Healthcare currently focuses on patients not humans. We need to turn our attention to total human health and evolve our basic understanding of disease.

Greater disease understanding is needed to improve data analytics

Human Data Science leverages and enhances scientific understanding and advanced analytics by enabling healthcare stakeholders to ask the right questions. Even with the application of rigorous data science to holistic human data, efforts to discover novel solutions are only as good as the science underlying study objectives. If a well-grounded understanding of human-science, based on the natural history of disease, genomics, proteomics, etc., is not incorporated, advances in healthcare will be limited. For example, for any machine learning algorithm to identify prospective, prodromal patients for Alzheimer's disease clinical trials, it would need to know the appropriate risk factors to use as the basis of that identification. Continued advances in basic science and the understanding of disease bio-processes are opening a wide range of new areas of investigation for Human Data Science as well as enabling the development of drugs with better-understood mechanisms of action and those targeted to specific pathways. Data initiatives, such as The Cancer Genome Atlas (TCGA) and the International Cancer Genome Consortium (ICGC), have generated genomes of more than 50 types or subtypes of cancers, and databases, such as the Catalogue of Somatic Mutations in Cancer (COSMIC), include large amounts of information on somatic mutations in both common and rare cancers.[33] With the ability to screen these cancer genome and protein structure databases, researchers are able to match novel drug targets to specific cancers and develop novel medicines.[34] The ability to link these and other such genomic databases to patient outcomes has also opened up a wide range of new areas of investigation for Human Data Science.

WHAT DO WE MEAN BY HUMAN DATA SCIENCE

Human data

Human data provides information about people and their health, both relating to their interactions with the health system and aspects of their health and wellness outside it. Gathering patient data and converting it into standardized, non-identified formats allows for comparisons between datasets, across populations, and across healthcare institutions to understand what is working best to support health. This data can power predictive analytic models to guide healthcare decisions and can also influence the research performed in human science to add to our understanding of disease.

Within Human Data Science, anonymized human data provides crucial information about people and their health, both relating to their interactions with the health system and aspects of their health and wellness outside it.

Human data comes from many sources and provide a means for Human Data Science to obtain answers to health questions. The most well-known are real world datasets that include electronic health records, diagnostic test results, payer claims, and physician billing activities and disease registries.[35] However, other sources like Patient Reported Outcomes Measures (PROMs), social data and digital health apps and wearable sensors are also finding emerging application in the healthcare space.

Social determinant data: Non-identified real world data that includes information on social determinants of a person's health — which have a profound effect on overall health, wellness and disease outcomes — can yield great insights in Human Data Science. This data includes information on psychosocial factors such as stress, daily experiences and mental health status; cultural influences including ethnic background; and social behaviors like lifestyle choices, profession and level of health engagement (see Exhibit 5).

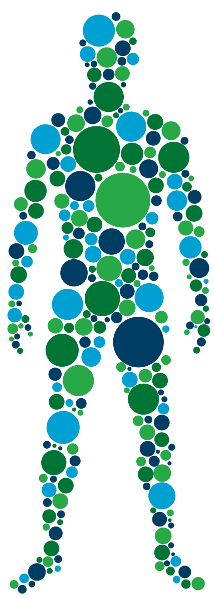
Understanding the whole person and the challenges they face outside of the healthcare system can help inform strategies to influence both an individual's health and population health as a whole. Addressing social issues, such as access to nutritious foods or stable housing, can also help to reduce health disparities within societies.[36]

Much of this data has not been effectively leveraged to-date, as patient health has not been considered holistically with all its influences, and current ICD-10 codes — when coded for in EHRs — do not currently trigger actions (see Exhibit 6). Social data on poverty, housing status and patient education, for example, may not be collected within a patient's electronic health records. Behavioral economics, which applies insights from psychology and economics to understand decision-making, has not been rigorously applied to improving population health, despite the potential to reduce the burden of chronic diseases or improve medication adherence.[37]

Exhibit 5: The full picture of human health – including social determinants alongside biology in human data

Biological health
- Genetic profile
- Disease state/risk
- Aging
- Access to healthcare
- Homeodynamics

Cultural influence
- Spiritual belief
- Socio-economic status
- Heritage / family
- Education
- Group history



Psychological factors
- Experience
- Stress
- Depression
- Insomnia

Social behavior
- Professional environment
- Personal activity/habits
- Engagement with technology

Source: Bortz WM. Biological basis of determinants of health. Am J Public Health. 2005 Mar;95(3):389-92; Macleod J, Davey Smith G. Psychosocial factors and public health: a suitable case for treatment? J Epidemiol Community Health. 2003 Aug;57(8):565-70; Healthfully. The Psychological Factors Affecting Medical Conditions. Updated 2017 Aug 14. Available from: https://www.livestrong.com/article/160946-the-psychological-factors-affecting-medical-conditions/

Exhibit 6: Selected ICD-10 codes currently associated with social determinants of health

ICD-10 CODE	CATEGORY	CODING INCLUDED IN THIS CATEGORY
Z55.0-Z55.9	Problems related to education and literacy	Illiteracy, schooling unavailable, underachievement in a school, educational maladjustment and discord with teachers and classmates.
Z56.0-756.9	Problems related to employment and unemployment	Unemployment, change of job, threat of job loss, stressful work schedule, discord with boss and workmates, uncongenial work environment, sexual harassment on the job, and military deployment status.
Z57.0-Z57.9	Occupational exposure to risk factors	Occupational exposure to noise, radiation, dust, environmental tobacco smoke, toxic agents in agriculture, toxic agents in other industries, extreme temperature and vibration.
Z59.0-Z59.9	Problems related to housing and economic circumstances	Homelessness, inadequate housing, discord with neighbors, lodgers and landlord, problems related to living in residential institutions, lack of adequate food and safe drinking water, extreme poverty, low income, insufficient social insurance and welfare support.
Z60.0-Z60.9	Problems related to social environment	Adjustment to life-cycle transitions, living alone, acculturation difficulty, social exclusion and rejection, target of adverse discrimination and persecution.
Z62.0-Z62.9	Problems related to upbringing	Personal history of physical and sexual abuse in childhood, other specified problems related to upbringing, parental overprotection, other upbringing away from parents, parent-child conflict, parent-foster child conflict, inadequate parental supervision and control, upbringing away from parents, inappropriate (excessive) parental pressure
Z63.0-Z63.9	Other problems related to primary support group, including family circumstances	Absence of family member, disappearance and death of family member, disruption of family by separation and divorce, dependent relative needing care at home, stressful life events affecting family and household, stress on family due to return of family member from military deployment, alcoholism and drug addiction in family.
Z64.0-Z64.4	Problems related to certain psychosocial circumstances	Unwanted pregnancy, multiparity, and discord with counselors.
Z65.0-Z65.9	Problems related to other psychosocial circumstances	Conviction in civil and criminal proceedings without imprisonment, imprisonment and other incarceration, release from prison, other legal circumstances, victim of crime and terrorism, and exposure to disaster, war and other hostilities.

Source: American Hospital Association, http://www.ahacentraloffice.org/PDFS/2018PDFS/value-initiative-icd-10-code-sdoh-0418.pdf; ICD-Codes, https://icd.codes/; Jul 2019
Notes: These are supplemental diagnostic codes

Digital health data tracking patient wellness and engagement: Overall, understanding patient activation and engagement provides valuable insights into factors that influence human health and disease and therefore is a valuable input for the applied methodologies of Human Data Science. Patients are becoming more involved in their health decisions and in maintaining wellness as digital technologies improve and become more mainstream. Technologies that help patients communicate with physicians and make health data accessible (e.g., patient portal websites for personal physicians), along with wearable sensors (e.g., activity trackers) and mobile apps (e.g., BlueStar® for diabetes management) encourage personal health awareness and behaviors to maintain wellness. Permissioned patient data or de-identified data generated from some of these mobile technologies and digital biomarkers can also track and reflect the activity of patients outside the clinic and can provide actionable insights into human health, which can be used to guide care decisions, affect population health and influence individual health outcomes.[38]

Human Science

Human science encompasses learnings about biological aspects of health such as the etiology and natural history of disease from diverse disciplines such as genomics, proteomics, immunology and cell biology. This fundamental knowledge guides current therapeutic interventions, in addition to wellness and disease-prevention strategies, and informs innovation. Within human science, understanding the early stages of disease makes it possible to better develop and launch disease-modifying drugs that interact with specific biological targets and pathways underlying disease and slow or halt disease progression. Insights into population-level genomics and proteomics allow for a greater understanding of disease etiology, progression and personal risk-factors that support the development of disease prevention strategies. Pharmacogenomic and pharmacokinetic information from diagnostic tests can suggest which patients might benefit from a precision medicine based on their predicted responses.

Within Human Data Science, scientific understanding ensures that analyses ask the right questions, include the right parameters and scope, and yield workable interventions and policies. The application of data science to human science also offers opportunities for innovation. For instance, exploring the existence of biomarkers tied to patient response to therapy (and outcomes) in data has helped identify narrower disease subsets based on a mutation and then helped guide strategies to target that mutation. The use of biomarkers to define more narrow disease subsets for treatment is also becoming ever more central to drug development to stratify patients for inclusion in trials. The full potential of human science discovery will therefore be realized alongside data science and information technology, which will manage and analyze large databases of scientific information, support biostatistics and predict protein structure and binding targets.

Data Science

Data science applies methodologies and technologies to extract valuable knowledge from data and answer questions. Through the application of statistics, computer science and advanced analytic methodologies — guided by human expertise in these domains — large, complex healthcare databases can be accessed and analyzed to solve problems in healthcare. Advanced analytic methodologies include artificial intelligence, which uses algorithms to analyze datasets; machine learning, where automated self-learning algorithms analyze data and make decisions; and a variety of other models and statistical methods. These methods can be applied to generate predictive analytics, which make predictions, including those about future outcomes, and prescriptive analytics, which often involves optimization and recommends actions, among others.

The application of statistics, computer science, and advanced analytic methodologies through data science extracts valuable knowledge from large, complex healthcare databases to improve understanding of the health system, make predictions, and advise actions.

The use of artificial intelligence in healthcare has been discussed in detail over the past few decades,[39] but truly began to have a measurable impact on healthcare with the emergence of machine learning. For instance, machine learning can be applied to patient data to determine when patients may be at risk of atrial fibrillation or hospital readmission for a chronic condition, or to optimize commercial practice by directing the assignment of pharmaceutical sales representatives, among other applications. Predictive analytics can be used to subdivide patients within datasets based on complex criteria, help identify undiagnosed and untreated patients, predict the optimal timing to initiate or change patient treatment, and provide lower-cost monitoring of patient progress and selection of treatment options over time.

Where will Human Data Science take us?

Applying the rigor of data science to human data is already having a positive impact in healthcare. Looking through the lens of human-centricity, data-driven research offers to guide the health system to solutions where they may have been lacking to date. Human Data Science is now bringing new assessments to data and impacting decision-making across three key domains — health system challenges, disease-specific issues and health-delivery services (see Exhibit 7). The following section presents examples of research seeking to impact each of these areas.

SETTING THE STAGE FOR IMPROVED HUMAN HEALTH

Optimizing health system performance

Health systems today face challenges regarding quality of care, transparency, efficiency, waste and expanding costs. According to the WHO, health system performance includes many aspects, such as its ability to promote population health, generate positive health outcomes from treatment, maintain high-levels of quality, responsiveness, productivity and appropriateness of care (e.g., waste reduction), as well as promote equity in care. Improvements in health system performance across these domains will depend on the collection and interpretation of data.

Health system stakeholders all measure health system performance in different ways, though most look to patient outcomes as the key aim. Comparing such performance measures across sites or actors through Human Data Science can yield critical insights about how to achieve performance improvements. For instance, the measurement of patient outcomes due to healthcare interventions over time or comparison of those outcomes by provider, can serve to monitor provider performance or understand the value of care.[40] Such outcomes measures can include survey-based tools like the patient-reported EQ-5D that measures

Human Data Science can be used to optimize health system performance by identifying waste, clarifying where social factors are creating health disparities within communities, and by guiding policies and actions by stakeholders to effectively address these.

Exhibit 7: Applying insights from human data science to improve health

Source: IQVIA

health-related quality of life and enables health systems like the U.K. National Health Service to compare benefits, cost, quality and efficiencies in delivering common procedures.[40,41]

Waste in the healthcare system occurs when money is spent on services that do not improve outcomes or quality of care and can include instances where specific patients receive large volumes of care without noticeably better outcomes. Some estimates show that the United States healthcare system wastes approximately 5% of GDP,[42] yet life expectancy in the United States is below most developed countries.[43] This suggests that despite Americans paying more for healthcare than other countries, they receive less value with poorer health outcomes.[44,45] Policymakers can help guide healthcare decisions away from wasteful practices while maintaining quality of care through Human Data Science (see Case Study: Guiding strategies to reduce healthcare waste).

Delivering population health

Population health refers to the health outcomes of a group of individuals, patterns of health determinants and health outcomes within that group, as well as the policies and interventions that link these two.[46] Elements influencing population health are the health services provided in a care delivery system along with the broader health and social systems that contribute to the overall health and wellness of a population.[47]

The discipline of Human Data Science aligns closely with the aims of population health to maximize health quality and care while minimizing cost. In the realm of population health, Human Data Science can integrate human expertise about local health systems and countries, along with social determinant data and other patient data sources to identify where inequalities exist and should be remedied, guide the creation of meaningful health interventions to address health disparities, and assess the efficacy of evidence-based wellness and prevention strategies that can be deployed in the community.

For example, real world data can be used to identify those at risk of poor health outcomes, such as communities and age groups not receiving adequate levels of vaccinations. This information can then be used to target educational programs about the benefits of vaccination to relevant physicians or populations to protect the health of the broader community, or guide deployment of resources to the communities and age groups that most need them.[48] In another example, interventions that aim to manage chronic disease or modify social determinants to influence population health can be examined for their downstream effects on health outcomes. For instance, the impact of programs, such as the CDC's HI-5 (Health Impact in 5 Years) health interventions, which focus on-clinical, community-wide approaches to facilitate healthier choices (e.g., tobacco control interventions and access to clean syringes) and address social determinants of health,[49] (such as providing early childhood education to protect against the future onset of adult disease and disability)[50] could be a target of data science to analyze program impact on population health.

However, not all stakeholders use analytics in population health, thus missing opportunities for improvements. One study found that just over 20% of surveyed healthcare organizations used analytics to inform decisions for population health management.[51] Achieving coordinated use of analytics for population health will also face challenges, in part due to the varying definitions of population health between stakeholders that each include different goals.[52]

Guiding policy decision-making

Health policies are the decisions, plans and actions that aim to fulfill specific healthcare goals within a society.[53] The ability for an individual's full health potential to be attained depends on the health influences of their local environment and community as well as the health policies of their government institutions. Human Data Science informs policy decision-making and the crafting of human-centric health solutions through data-driven analyses. These include policies that may work to influence social determinants of health, aim to address health disparities across communities, or support disease prevention and wellness or promote patient engagement. They may promote good nutrition or set out to revise transportation networks. For instance, transportation infrastructure focused on driving may create issues including limited access to healthy food and physical activity that can drive higher rates of illness, disability and premature death costing $142 billion, or air pollution estimated to cost $50–80 billion.[54]

Human Data Science advances disease prevention and treatment by accelerating clinical development through patient engagement and the collection and use of real world patient data.

ADVANCING DISEASE PREVENTION AND TREATMENT

Accelerating clinical development

The number of innovative medicines has been increasing over the past decade. This trend has been driven by advances across human science, data science and technology that are shifting the landscape of clinical development and influencing trial duration, complexity and likelihood of success.[1] Human Data Science approaches leveraging real world data — from electronic heath records, claims data and disease registries — have informed decisions on site selection and patient inclusion, guided trial design, and facilitated patient engagement. Analyses have even enabled new trial types like pragmatic and adaptive trials. In addition, Human Data Science applied to real world evidence,

- Enables manufacturers to design trials with optimal protocol specifications. For example, in rare diseases or cancers with narrowly-defined affected populations, real world evidence can right-size trials to detect a treatment effect by clarifying baseline disease progression and symptoms of untreated patients.
- Accelerates trial times by informing investigator and site selection and patient recruitment, for example, by identifying where eligible patients are located (especially valuable for hard-to-find patient populations) or where a group of patients with specific biomarkers have received care, or by providing an understanding of the value of care provided at candidate clinical trial sites.
- Enables adaptive trials by informing pre-specified protocol modifications through statistical procedures to occur in an ongoing trial based on data collected to avoid costly protocol amendments. Adaptive trials require fewer patients, enable more efficient dose selection and stakeholders can more quickly identify and discontinue unsuccessful trials.[55,56]
- Serves as comparators and virtual control arms in clinical trials when controls are ethically impossible or prohibitive — to thus provide additional data supporting or against approvals. For example, trials can reference historical control data or use data from patients represented in real world data sources, such as from electronic health records or disease registries (see Case Study: Clarifying the risk-benefit profile of innovative therapies through new trial designs).
- Informs and supports pragmatic trials which can evaluate the effectiveness of interventions in routine clinical care and provide value to stakeholders by determining the cost-effectiveness and health outcomes of treatments in real-life, heterogenous patient settings.[57]

Human Data Science also leverages advanced analytic techniques and models to accelerate innovations in clinical development (see Exhibit 9). Through modeling, Human Data Science can influence trial recruitment by identifying potential undiagnosed patients from registries or other data, or predicting which patients are early in their disease to increase patients eligible for trials testing preventative or disease-modifying medicines (e.g., Alzheimer’s disease). Advanced analytics can also identify subsets of patients with a known disease for precision medicine trials.

CASE STUDY

Guiding strategies to reduce healthcare waste

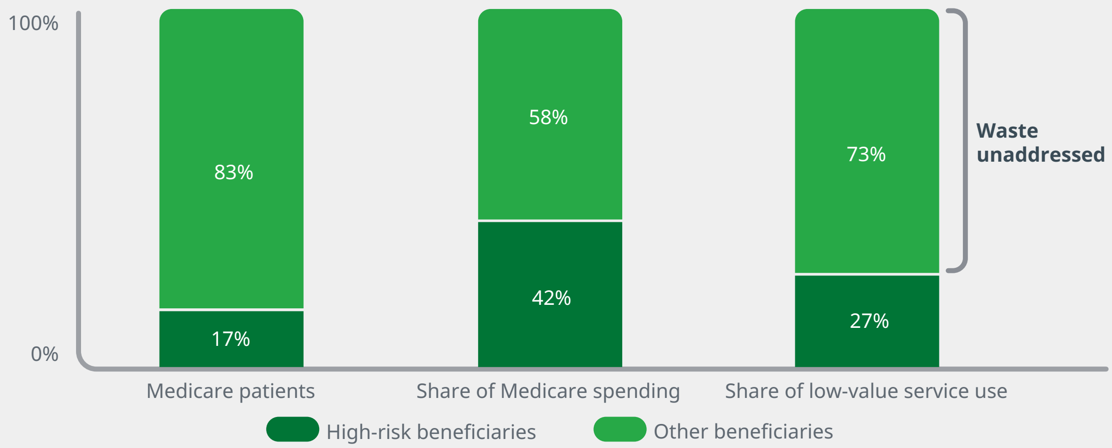
Accountable care organizations (ACOs) are groups of health providers that coordinate and share the responsibility for patient care. Human Data Science has been used to investigate whether strategies incentivized by global payment models that focus on reducing waste and lowering spending in high-risk patients is the best way to reduce waste and spending overall. By applying data science to a sample of anonymized patient-level claims data from Medicare Part A and B, the use of 31 'low-value services' considered wasteful or potentially harmful, as well as their associated costs, were assessed in both high-risk and other beneficiaries.[58]

High-risk beneficiaries were defined as having a Hierarchical Condition Category score (a risk-adjustment model that estimates future healthcare costs)[59] and a count of conditions in the Chronic Condition Data Warehouse (which incorporates Medicare and Medicaid beneficiary claims and assessment data on 66 chronic or potentially disabling conditions)[60] that fell in the top quartile of the distributions for those characteristics. Shared clinical and data science expertise of the healthcare community guided the selection of low-value screening, diagnostic, preventive and preoperative testing, imaging, and procedures.[61,62]

Overall, the 17% of Medicare beneficiaries that were high-risk cost nearly four times more per person than other beneficiaries — accounting for 42% of all Medicare spending — and received almost twice as many low value services (0.59 versus 0.33 services per patient). However, because they accounted for only 27% of low-value services (see Exhibit 8), a reduction in low-value services in only this patient population would still leave most waste unaddressed. It would miss opportunities to reduce waste and costs further and fail to reduce potentially harmful care across all beneficiaries.[58]

The authors conclude that focusing on high-risk patients may not effectively reduce spending and that a more effective strategy would be to reduce wasteful care for all patients, thereby creating a positive impact on the health and wellness of all patients — not just one sub-category — with the added benefits of greater cost-savings. The authors further make suggestions on how to reduce healthcare waste and cost rather, such as moving away from ACO budget models toward more piecemeal models with bundled payments for specific care, such as specialty or inpatient care, which would strengthen incentives to reduce spending for all patients.

Exhibit 8: Medicare patients share of spending and low-value service use in 2013 by patient risk of high spending



Source: McWilliams JM, Schwartz AL. Focusing on High-Cost Patients - The Key to Addressing High Costs? N Engl J Med. 2017 Mar 2;376(9):807-809
Notes: High-risk beneficiaries is calculated to identify patients at risk for high spending; they are the patients with the highest Hierarchical Condition Category (HCC) risk scores

Unnecessary services drive up costs and can expose patients to unnecessary risks and stress. Human Data Science can improve health system performance while improving human health. By comparing the cost impact of various strategies, this actionable use of Human Data Science recommended to foster patient wellness by reducing unnecessary, low-value treatments and tests for all patients, rather than just for the segment of at-risk, high-cost patients, which are often the focus of waste-reduction efforts. This data-driven insight can lead to a greater reduction in cost and help guide future strategies to combat waste.

- **Delivery of some low-value diagnostic services have been shown not to improve outcomes for patients and overuse of diagnostic tests and treatments can sometimes cause harm.**
- **Human Data Science offers data-driven decisions to improve patient wellbeing, for instance by assessing the most effective way to reduce healthcare overuse and waste.**
- **Analysis of Part A and B Medicare claims showed that although 17% of Medicare beneficiaries were considered at highest-risk of future costs and were significant drivers of overall cost, they accounted for only 27% of low-value service use so targeting them may miss opportunities for waste reduction.**
- **By offering routes to obtain the greatest positive impact on the health and wellness of patients, Human Data Science guides health policies to deliver greater human value and cost-savings.**

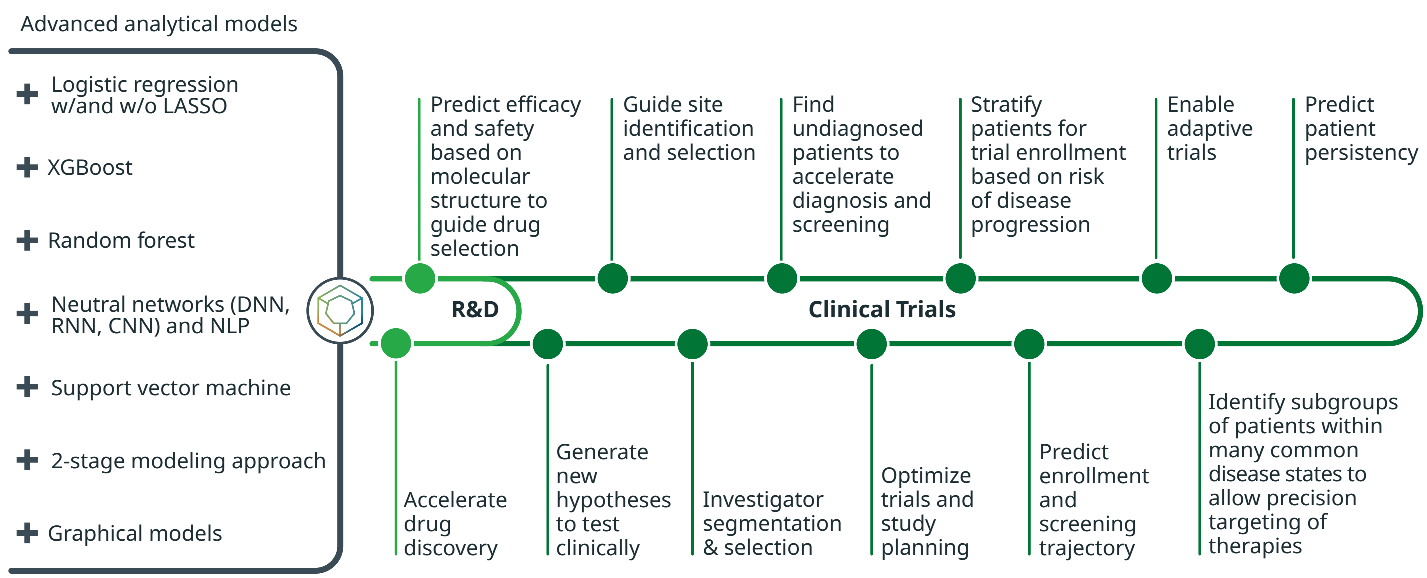
Advancing precision medicine

Human Data Science is an integral contributor to precision medicine, which offers treatment regimens tailored to a patient's unique genetic and metabolic profile, along with the improved efficacy, safety and dosing that such customization brings. Precision medicines offer improvements over conventional approaches by targeting medicines and interventions to the right patients and preventing waste and inappropriate use by patients who would otherwise not benefit, experience adverse events, or be harmed. In clinical development, precision medicine trials select eligible patients based on their predicted response to a therapy due to their genetic or pharmacokinetic profile, thus narrowing the size of trial patient populations as fewer patients are needed to power studies and offering increased trial success as patients have increased predictability of response.[1]

Existing clinical approaches for the use of precision medicines can be enhanced through Human Data Science to promote the maximum economic value of these medicines and refine treatment paradigms. A feedback loop of information from patients receiving precision medicines enables the health system to treat all patients more appropriately in routine clinical care leading to a reduction in waste and ensuring appropriate treatments. The current healthcare framework that supports precision medicines can also leverage data from clinical practice to feed information on successes and challenges with these therapies back to the healthcare system (see Exhibit 10).

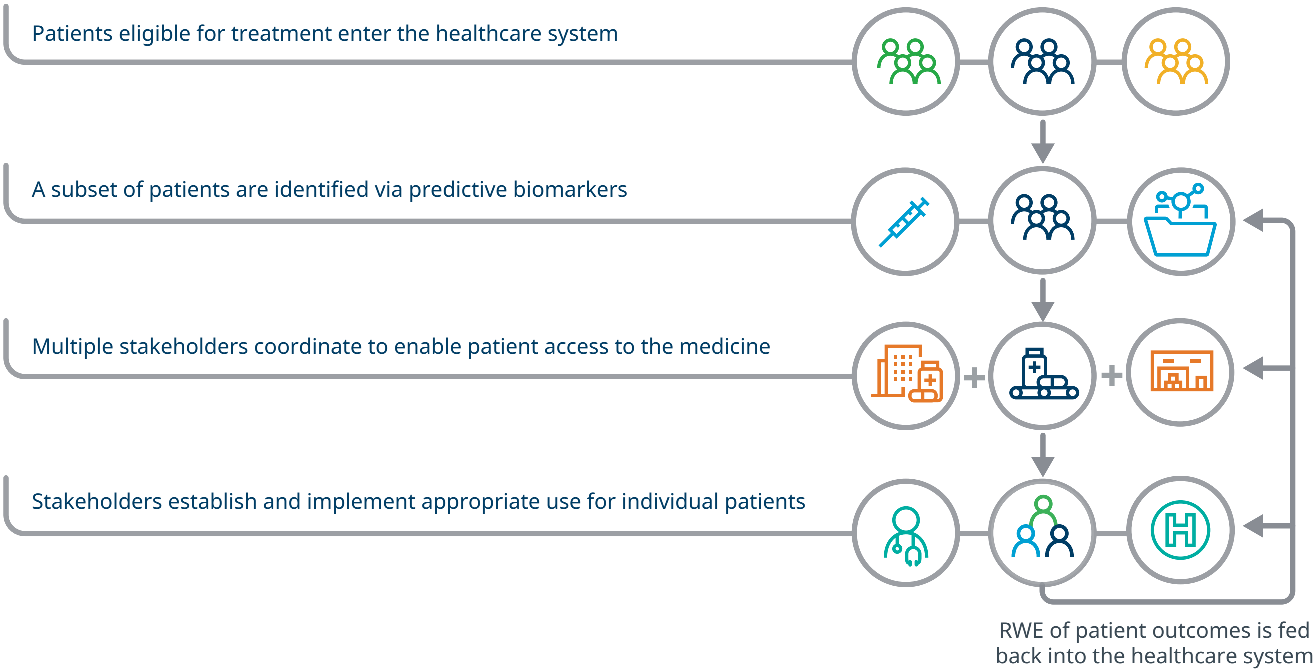
Human Data Sciences advances disease prevention and treatment through a feedback loop of real world data detailing beneficial outcomes or adverse events associated with specific therapies. This allows existing clinical approaches to be evolved, guides use of precision medicines, and powers pharmacovigilance systems.

Exhibit 9: Predictive analytics and AI driving value for clinical development



Source: IQVIA Advanced Analytics, Feb 2019; IQVIA Institute, Mar 2019
The Changing Landscape of Research and Development - Innovation, Drives of Change, and Evolution of Clinical Trial Productivity ~ Report by the IQVIA Institute

Exhibit 10: How healthcare systems support precision medicines



Source: IQVIA Institute for Human Data Science. Upholding the Clinical Promise of Precision Medicine. May 2017. Available from: https://www.iqvia.com/institute/reports/upholding-the-clinical-promise-of-precision-medicine-current-position-and-outlook

Ensuring drug safety

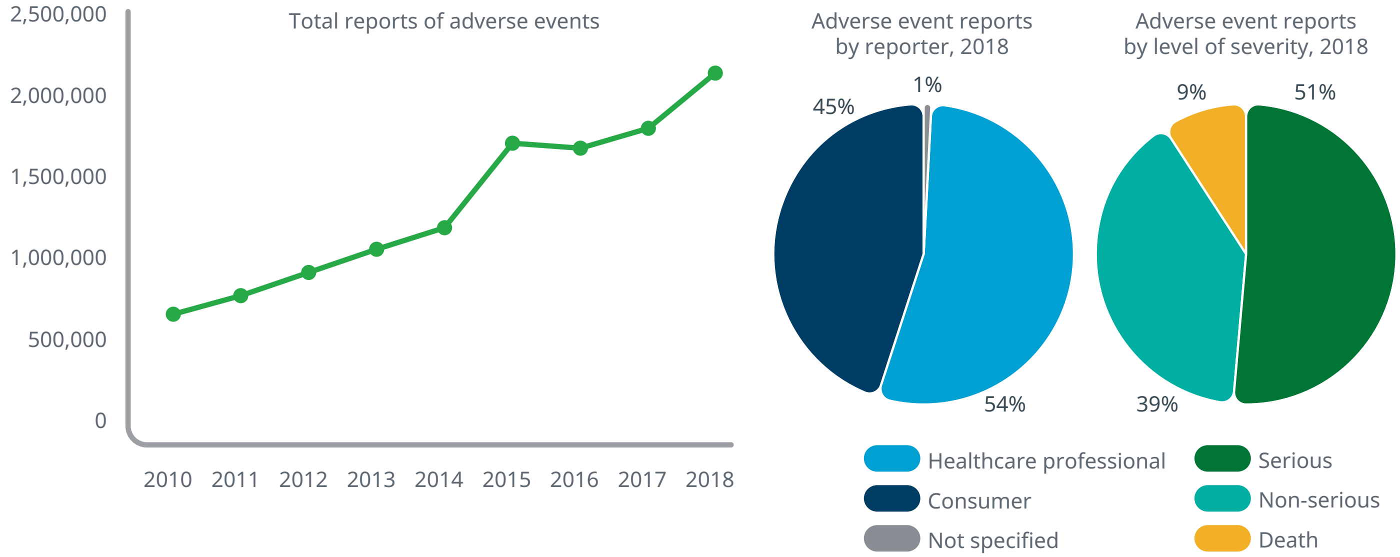
The monitoring of adverse drug reactions (ADRs) as well as adverse events (AEs) is integral to ensure the safety and benefits of medicines. In the case that drugs have unidentified health effects once introduced to the broader population, this information can allow authorities to take appropriate action to adjust product labels, include warnings or pull medicines from the market entirely. Human Data Science aids regulatory and clinical-care decisions through the capture, processing and analysis of drug adverse event information.

The FDA's Sentinel Initiative is an example of Human Data Science in action for pharmacovigilance. Sentinel is an active surveillance tool that leverages real world data and reusable query tools to answer questions around drug safety.[63] Within a privacy preserving "distributed data system," the Sentinel Initiative applies data science to patient data derived from health insurance companies, healthcare systems and academic institutions (with electronic health record systems). Sentinel allows the FDA to better understand post-market safety issues and inform regulatory decisions to improve patient safety.

In addition to Sentinel, the FDA's Adverse Event Reporting System (FAERS) database allows for passive surveillance and analysis of adverse events entered by healthcare stakeholders into FDA MedWatch. Reports of adverse events have been increasing since 2010, and in 2018, 45% of adverse events reported to the FDA were by consumers of healthcare, rather than clinicians, indicating the importance of patients feeding data into pharmacovigilance systems (see Exhibit 11). Potential future Human Data Science suggests that if FAERS were mapped to a common data model — such as by applying the Observational Medical Outcomes Partnership (OMOP) common data model and vocabulary maintained by Observational Health Data Sciences and Informatics (OHDSI)[64] — it would enable a range of applications,[65] and allow it to link or be compared to other real world datasets in the same format.

Other emerging applications of Human Data Science for pharmacovigilance combine advanced analytics and human expertise to automate previously routine, manual processes for healthcare stakeholders. For example, integration of natural language processing technology

Exhibit 11: FDA adverse event reporting



Source: FDA Adverse Events Reporting System (FAERS) Public Dashboard
Notes: Healthcare professionals include physicians, pharmacists, nurses, dentists and other medical professionals. Not specified includes reporters who are not healthcare professionals or consumers. Serious events include: hospitalization, life-threatening, disability, congenital anomaly, required intervention and/or other serious outcome. Death indicates the outcome was documented as a death. Non-serious includes outcomes not documented as serious or death.

can be used to read source documents and identify relevant information to build clinically relevant auto-narratives. This would reduce the need for manual data entry and report authoring by manufacturers.[66] Artificial intelligence and machine learning are already being used in technologies like the IQVIA™ Vigilance Platform to identify and evaluate safety signals by identifying patterns within structured data and unstructured data; thus reducing the effort of manual processing, review and assessment of single and groups of case safety reports by manufacturers and other stakeholders.

DELIVERING HUMAN HEALTH SERVICES

Furthering patient-centric health services

Patient-centered healthcare includes various strategies and approaches to delivering care that can improve disease-prevention, disease-management, diagnosis and treatment paradigms and customize this care for specific patients. These include coordinated care programs that facilitate the delivery of healthcare services from more than one provider and can improve real world clinical practice and patient outcomes, such as Accountable Care Organizations (ACOs). Patient-centered care also includes rehabilitation and palliative care services, as well as substance abuse and mental health services.[67]

Human Data Science supports patient-centric care models and improves real world clinical and patient-defined outcomes by analyzing how disease treatment strategies tie to patient outcomes.

Human Data Science enables improvements in patient-centered care by leveraging data science to measure the value of models of health delivery and assess interventions intended to improve patient outcomes and reduce health disparities.

Other hurdles to optimal delivery of patient care can also be addressed through Human Data Science. It can improve our understanding and,

- **Guide strategies to improve access to healthcare**, which is a main challenge in promoting human health, and can disproportionally affect patients living in rural areas, areas of poverty or specific countries.

Human Data Science can help assess the geographic availability of health services — a social determinant of health that ties to risk in patient outcomes — and guide strategies to improve access.

- **Assess how insurance quality impacts patient care** When insurance coverage is unavailable, or lacks in quality, it can be a barrier to care. Where a person lives and their income level often influence what their insurance coverage provides. Human Data Science can assess how insurance coverage ties to patient use of various services like preventative care, or how costs hinder their ability to access to health services.
- **Consider social factors to customize a patient's care and overcome barriers**. A patient's gender, age, ethnicity, literacy, level of education, income and access to transportation may all impact access to healthcare or cause disparities in the level of care received. Human Data Science can help inform strategies to identify and overcome the factors limiting patient ability to access care.
- **Compare the effectiveness of preventive services**, which are cost-effective ways to reduce morbidity and mortality of common diseases such as cancer, heart disease and diabetes, and to prevent infectious diseases such as HPV, polio, and measles. Human Data Science can improve the delivery and effectiveness of patient-centric health services.
- **Identify barriers and enablers of mental health and substance abuse services.** Mental health disorders are a significant source of global disability and impact patient quality life, employment and overall health. Human Data Science can assess patient access to programs and services that treat mental health and substance abuse, as well as the barriers to care. It may also be leveraged to measure the effectiveness of interventions that may emerge through digital health or delivery of coordinated care services.

Finally, in addition to improving the value and quality of care for patients by making care more patient-centric, Human Data Science has the added benefit of reducing costs. For example, if acute episodes or chronic conditions can be more effectively prevented, or disabilities from mental health and substance abuse more effectively managed, it would lead to a reduction in costs to hospitals, payers and safety net programs. According to one study by the U.S. Department of Health and Human Services, participants in Medicare's shared-savings program using ACOs generated approximately $1 billion in cost reductions in the first three years of the program.[68] (See Case Study: Proving the value of coordinated care)

Improving real world clinical and patient-defined outcomes

By analyzing how disease treatment strategies tie to patient outcomes, Human Data Science is able to help evolve care and even shift practice guidelines. For this reason, the collection, standardization and analysis of clinical outcome data, along with patient-reported outcomes and social determinant data, is becoming increasingly critical to healthcare stakeholders. In the United States and other countries, this data supports the movement from a volume-based health system to a value-based one that is based on evidence and effectiveness.[69]

Patient-centric care models, such as care delivery at ACOs, allow for the collection and sharing of an individual patient's data across specialists to inform personal treatment decisions. Within such health systems, such holistic patient data can generally be used for research purposes to understand how treatments have affected clinical outcomes and patient quality of life, inform future treatment decisions for other patients, and potentially expand disease understanding into new areas of research and treatment. Social determinant data can further be incorporated into these real world datasets and analyzed to make care more effective and accessible, thereby improving health outcomes of individual patients and populations. Patient-defined outcomes are also a growing part of the value story. When incorporated into clinical decision-making, patient-defined outcomes will improve both the quality of care delivered and patient perception of the value of care.

CASE STUDY

Clarifying the risk-benefit profile of innovative therapies through new trial designs

As big data gathered in real world healthcare settings becomes more prevalent, robust and more skillfully curated, there has been increasing acceptance of the use of real world evidence (RWE) and real world data (RWD) into clinical development programs. This data — which includes electronic health records (EHRs), claims data and disease registries, among other sources — can notably serve as controls or comparators in clinical trials to supply supportive evidence. RWE has been used for years to support post-marketing studies and in certain rare disease trials,[70,71] and this trend has moved earlier within clinical development programs to trials supporting regulatory approval. For example, the use of RWD as a control arm in clinical studies can be used in certain cases where randomized trial requirements would harm patients or would otherwise be problematic.[72] It can also be used to develop comparative benchmarks and track the natural course of the disease.

Two examples where Human Data Science was applied to RWD are those supporting regulatory submissions and initial approval of Roche's entrectinib (Rozlytrek) and line extension of Pfizer's palbociclib (Ibrance):

- The pre-registration applications and approvals of entrectinib for *ROS1* positive non-small cell lung cancer (NSCLC) were based on efficacy data from pivotal trials STARTRK-2, STARTRK-1, STARTRK-NG and ALKA-372-001[73] which included 53 patients with a *ROS1* rearrangement, but were additionally supported by evidence from a comparator arm created by Roche using their Flatiron Health RWE database. By isolating *ROS1* positive patients from a pool of over two million cancer patients in RWD (most of whom were treated with crizotinib as the best therapy available), and matching 54 of them to the patients in the study, they were able to offer greater comparative evidence of efficacy than would otherwise have been possible for this condition.[74] As of August 2019, entrectinib was registered in the United States for *ROS1*-positive NSCLC and pre-registered in Europe and Japan for the same indication, adding to its tissue agnostic approval for *NTRK* fusion-positive advanced recurrent solid tumors.

- Pfizer's palbociclib was approved in the United States, Canada, the EU and major Asian markets for the treatment of HR+/HER2- breast cancer in postmenopausal women in April 2019. Pfizer received a supplemental approval in the United States for the treatment of men with HR+/HER2- breast cancer based on a collaborative approach between Pfizer, IQVIA and Flatiron Health using real world datasets. While substantial evidence of efficacy was based on the pivotal trials conducted in women (PALOMA 2 and 3),[75] approval for the supplemental indication in males was supported by EHR data and post-marketing reports of real world palbociclib use in male patients from IQVIA's prescription and medical claims database, Flatiron Health's Breast Cancer database and Pfizer's global safety database.[76,77] There were two parts to the study supporting the use of palbociclib in this patient population: In one, pharmacy and medical claims data from IQVIA were retrospectively analyzed to describe the treatment patterns and prescribing duration of palbociclib plus an aromatase inhibitor or fulvestrant (i.e., endocrine therapy) compared to endocrine therapy alone in men with metastatic breast cancer.[78]

The second study was a retrospective analysis of EHR data from the Flatiron Health database providing supportive evidence of real world tumor response (i.e., efficacy) and safety to palbociclib plus endocrine therapy compared to endocrine therapy alone.[79] Results of the study demonstrated that men with metastatic breast cancer derive clinical benefit from the addition of palbociclib to an endocrine therapy. As breast cancer in men is rare, a traditional randomized-controlled prospective study would have been challenging to conduct in this patient population due to recruitment challenges and the use of RWD was thus able to support regulatory filings by increasing the pool of patients available for study and providing evidence corroborating efficacy and safety[78] as seen in traditional prospective trials.

Human Data Science incorporates disease understanding, advanced analytic methodologies and real world datasets to promote and enhance drug development. An actionable example of Human Data Science is the incorporation into clinical development programs of evidence informed by robust and curated real world datasets. In cases where conventional, randomized controlled trials are not feasible, the use of Human Data Science provides supportive evidence demonstrating the efficacy and safety of therapies within a clinical setting with speed in comparator design. Furthermore, in clinical development, the application of Human Data Science,

- **Provides a way to identify patients retrospectively for inclusion in a clinical trial in situations where utilizing a general pool of patients for prospective trials is not possible**
- **Can be accepted by regulatory bodies to support filing and approval of both new therapies and indications when its use is in line with current scientific approaches and rigor, and it offers the best route to provide supporting evidence**

CASE STUDY

Proving the value of coordinated maternity care

Patient-centered coordinated care programs facilitate the delivery of healthcare services from more than one provider and can improve real world clinical practice and patient outcomes. Maternal care, including pregnancy, labor, delivery and postpartum care, provides an opportunity to leverage longitudinal patient plans (integrated care plans that document important disease prevention and treatment goals)[80] and improve coordination across primary and specialty providers. The United States currently lacks uniform care in the postpartum period,[81] which is when more than 60% of global maternal deaths occur.[82] With maternity care representing nearly a quarter of all hospitalizations in the United States,[83] and continued poor patient outcomes nationally, maternity care has become a target for innovation in delivery and payment models. These include coordinated care, longitudinal patient care,[84] and bundled payment models.

Cigna, Humana and United Health, for instance, have recently offered bundled payment programs for maternity care to incentivize better care coordination and quality from the prenatal to postpartum period.[85,86,87] These payers were likely influenced by multiple studies leveraging Human Data Science suggesting that the adoption of bundled payment programs for maternal health can provide greater value to patients at lower costs for stakeholders. For instance, there is evidence that bundled payment programs offer lower rates of cesarean sections,[88,89] which can pose maternal health risks.[83,90] In 2018, 32% of all women in the United States underwent cesarean surgeries including 26% of women with low-risk births.[93] In one example, evidence from the Pacific Business Group on Health's 2014 implementation of flat blended payments for delivery in three Southern California hospitals reduced the number of cesarean deliveries by an average of 20% within a year.[91]

Another study using Human Data Science analyzed the impact of bundled episode-based payments (EBP) implemented by the Arkansas Health Care Payment Improvement Initiative (APII) for perinatal care, which includes delivery, prenatal and postpartum care.[92] Published in 2018, this study provided empirical evidence of EBP's impact on perinatal care and spending in the commercial market by comparing perinatal episodes in 2013 and 2014 after the policy was implemented, with pre-intervention episodes from 2010–2012, and comparing these further to neighboring states that used fee-for-service arrangements. The authors used Truven Health MarketScan Commercial Claims and Encounters data from 2009–2014, including information on actual payments to providers, to construct a database of perinatal episodes. Applying data science to this claims data, the authors identified all live births that occurred between 2010 and

2014, and then tracked the mothers across time flagging all other relevant claims for prenatal and postpartum care to determine aggregate spending.

Results showed that the EBP program in Arkansas led to a 3.8% decline in total episode spending in its first full year of implementation, or $396 per episode. To understand the drivers of decreased total episode spending, the authors further applied data science to categorize spending by service areas and distinguish between professional and facility spending. They determined that the drop was predominantly driven by declines in intrapartum facility spending during the hospitalization for childbirth, which dropped 6.6% relative to surrounding states ($332 per episode) and accounted for 80% of overall savings. They further concluded these savings were likely driven by changes in referral patterns to lower-priced hospitals. Finally, applying the expertise of human science to measure seven screening tests and services identified as quality markers, they were able to clarify that the cost savings occurred with only limited improvement in quality of care through chlamydia screening rates — a disappointment that should likely be confirmed through tracking in future years — and no significant impact on utilization such as cesarean section rates.

Gaps in longitudinal patient care, and particularly maternal care, are missed opportunities to support patients and mitigate health risk. They additionally hinder robust data collection on postpartum maternal morbidity that could be used to improve care. An actionable example of Human Data Science is the evidence creation that has supported the movement towards coordinated care programs, such as bundled episode-based payments. These programs facilitate delivery of healthcare services and are intended to incentivize better care coordination and quality. Data collected from these programs can then further be analyzed to determine if quality goals are being met and see if cost savings are being driven. They can also be used to refine and improve care and inform future decisions.

- **Conventional healthcare practices produce disparities in maternal care.**
- **Human Data Science, guided by expertise in data and human science, can be used to inform coordinated care programs through the analysis of payer-derived claims data.**
- **Bundled payment programs for maternity care have led to a decline in costs and may lower rates of cesarean sections.**
- **Although these programs are intended to incentivize improved care coordination and quality, initial data from year-one of a bundled payment program indicate that care and quality of care may be unaffected and further studies should be performed.**

Increasing wellness and prevention

The use of healthcare incentives to improve nutrition, exercise, and the delivery of supportive services (e.g., physical therapy), have the potential to create a significant impact on human wellness and reduce healthcare costs. For example, digital wellness and prevention apps along with their connected sensors can support patient efforts to set health goals, track daily lifestyle changes and monitor their data.[93] Wellness and prevention apps have become extremely popular. The company Under Armour — owner of MyFitnessPal, MapMyFitness and Endomondo apps — alone had more than 250 million registered users by 2019.[94]

Human Data Science can be used to analyze evidence from preventative health programs by identifying which wellness incentives create the greatest value.

Human Data Science can both incorporate novel sources of human data from patient apps and wearable sensors into analyses of the health system, as well as guide interventions focused on promoting health and wellness. Analytics applied to this and other real world data can help stakeholders understand or track patient adherence to see if interventions are working, among others. Human Data Science can even be built into apps themselves. For example, artificial intelligence has been built into devices to create "smart" versions of asthma inhalers, injectable insulin pens and pumps capable of identifying episodes, tracking usage and supporting adherence programs. In particular in the asthma space, pharmaceutical companies have both partnered with and bought leading adherence app and device developers to target the 30–70% of asthma patients who are non-adherent.[95,96]

Finally, Human Data Science can be used to analyze evidence from preventative health programs programs by identifying which wellness incentives create the greatest value. This data can then guide how to best affect behavioral change. A 2018 survey noted that 86% of employers in the United States offered financial incentives in their wellness programs, up 11% since 2017, and measures evaluating the value of these programs are beginning to include elements outside of traditional health and wellness measures, including social and emotional well-being and job satisfaction.[97]

Human Data Science can also help measure the impact of such interventions. In one example, in Japan, which historically had high levels of tobacco use, government legislation and employee actions and incentives were implemented to encourage smoking cessation, including banning smoking at company headquarters, converting smoking rooms and offering paid time off. Analysis of data from the Japan National Health and Wellness Survey (NHWS), showed this led to a 10.2% decline in lifetime smoking prevalence in the country since 2008.[98,99]

Increasing the relevance, confidence and applicability of Human Data Science

Human Data Science enables healthcare systems and its stakeholders to support human health. The opportunity to finally answer questions that have long plagued healthcare system brings stakeholders — driven by concern, interest, opportunity and excitement — to formulate approaches that further the path of Human Data Science. However, to maximize its value, stakeholders need to support the foundational elements underlying Human Data Science and apply principles to their research that increase its applicability and boost public confidence and trust.

WHAT ENABLES HUMAN DATA SCIENCE?

Six external elements will influence and advance what can be achieved through Human Data Science in the future. These include big data availability and data science methodologies, patient privacy and data security, technology enabling advanced analytics, investment in basic research and translational science, supportive policy and regulations and human expertise (see Exhibit 12).

Human expertise

Expertise across a number of domains is critical to guide the inquiries made through Human Data Science and to ensure that accurate answers enable smart decision-making. By applying knowledge and domain expertise, along with a holistic human-centric view of data, Human Data Science can drive superior health and analytic outcomes.

Exhibit 12: Elements and principles supporting human data science

Human Expertise	Big data availability and data science methodologies	Patient privacy and data security	Supportive policy and regulations	Investment in basic research and translational science	Technology enabling AI and ML
• Promote human-centricity through the use of data analytics to drive superior health outcomes • Apply a deep level of understanding of clinical care, human science, data and the healthcare environment	• Standardize and share data • Share advanced analytic, statistical, mathematical and programming • Identify and reduce data bias • Ensure advanced applications do not violate human rights	• Set policies and guidelines to ensure patient privacy including for social determinant and special categories data • Leverage and invest in privacy technologies • Permit the use of anonymized and permissioned data for research purposes	• Ensure the availability and proper use of data • Support open-health data sources • Promote data interoperability and transparency initiatives • Encourage use of meaningful patient experience measures • Invest in precision medicine initiatives	• Promote and support basic research • Expand understanding of human biology and behavior	• Invest in data management and IT infrastructure • Sponsor educational programs • Support transparency and intellectual property protection

These areas of expertise include,

- **Clinical expertise**, which can guide study hypotheses, refine data queries to ensure a full picture of care is obtained, or predict how solutions might play out in practice. For example, physicians, care providers and other individuals with an understanding of medical treatments provided in routine clinical care are able to identify how medical treatments seen in one dataset or in clinical trials differ from this norm.
- **Human science expertise**, which similarly serves to guide study hypotheses and drive smart decision-making in Human Data Science. For instance, understanding biochemical pathways, genomics, pharmacokinetics and other disciplines of human biology can help Human Data Science harness innovations in these fields to drive insights, as well as help guide research on disease progression and prevention strategies, drug development and disease-modifying treatments.
- **Data science expertise**, which helps guide study methodology through a deep understanding of advanced analytic approaches. Data scientists combine a deep knowledge of the subject area, mathematics and computer science with the ability to think differently about how healthcare data needs to be collected, studied, combined and protected.[100]

Knowledge and domain expertise, along with a holistic, human-centric view, enables Human Data Science to produce smart decisions and improve human health.

Human Data Science requires data sharing from various, multi-stakeholder datasets to power advanced analytic algorithms and address healthcare problems.

- **Healthcare environment expertise**, which provides an understanding of the policies and regulations of specific localities, the interactions between various stakeholders and actors, and the factors that influence pricing and reimbursement, care delivery, access to therapies and services and patient behavior, among others. All of these factors are needed for a clear understanding of the story being told by data.

Big data availability and data science methodologies
For Human Data Science to enable faster and better decision-making, diverse big data sources must be coordinated and be made available to query.

However, making this data available and usable for the application of Human Data Science poses some challenges. First, real world evidence data sources at times amount to petabytes of data — making this data a challenge to store, query and share. In the United States, such data may track more than 4.3 billion prescriptions, 1.5 billion visits to a doctor's office and the 370 million patient visits to a hospital that occur yearly in the United States, as well as data on diagnostic and genetic tests and digital biomarkers of health.

Depending on its use, data may further need to be de-identified and encrypted to protect patient privacy and data security and enable data to be shared (such as through federated databases). Such data sharing is critical to drive alignment between stakeholders and paint a full picture of the health system. Therefore, the use and development of methodologies to clean, structure and standardize healthcare data, as well as share these databases across stakeholders, are critical to enable Human Data Science and drive useful insights. Healthcare stakeholders would benefit by aligning on data management strategies and increasing investment in information technology infrastructure to facilitate the processing and sharing of data and the use of advanced analytics to guide decision-making. Without standardization across disparate datasets, new insights to problems cannot be discovered.

Reducing data bias, protecting patient data privacy and security, and enabling transparency are necessary components of big data and advanced analytics. Policies and methodologies behind these attributes support and enable Human Data Science.

Patient privacy and data security

The original sources of real world patient data can include personal identifiers, such as social security number or birthday, as well as social determinants data. Source data can also contain psychographic data or even sensitive special category data, like religion and race.[101] All data used for research purposes needs to be either anonymized or otherwise manipulated to protect patient privacy and ensure trust in data sharing, or explicitly permissioned for specified research purposes.

Appropriate legal and ethical use of big data protects patient privacy and data security and takes safeguards to ensure that an individual's identifiable health information is not distributed or revealed outside of permitted situations. For the general public and individual patients to trust that their data is being held private and protected, and to enable continued use of this data to improve human health and the health system, healthcare stakeholders have renewed efforts to codify privacy frameworks and guide implementation, taking their duty to protect patient data seriously in this era of big data.[102]

One of the most effective routes organizations can take to appropriately protect individual privacy when data is used for research purposes is the creation and use of non-identified healthcare information. Non-identified healthcare data has been stripped of personal identifiers and may undergo other privacy-protecting steps to allow data to be shared more widely and safely for research purposes. Techniques to render patient medical information appropriately non-identified include a combination of removing, generalizing and disguising some information, along with privacy and security safeguards (administrative, physical and technical) and contractual limitations to ensure there are sufficient controls over information to keep the information non-identified and ensure use in a responsible manner.[103] Security protections are also critical and need storage protections and technologies such as authentication, encryption, and access control to maintain the integrity of a dataset.[104]

Governments have taken the importance of data protection seriously and have legislated a number of policies and approaches to safeguard the anonymity and rights of patients and govern the use of their data including: the U.S. Health Insurance Portability and Accountability Act (HIPAA),[105] the EU's General Data Protection Regulation and Canada's Personal Information Protection and Electronic Documents Act,[104] all of which detail how healthcare organizations are responsible for managing and safeguarding personal information.

For patients to share personal information, such as their electronic health record data for use in research studies, individuals must trust that their personal information is secure and their privacy protected, and give consent to the use of their data, or that data must be anonymized prior to use. For this reason, investment and support of data privacy technologies, such as de-identification, encryption, or multi-factor authentication that can help protect patient data[106] is critical, as lack of public support for data sharing could negatively affect the applicability of Human Data Science. Policymakers and stakeholders can further encourage and normalize the use of privacy technologies through government initiatives and investments. Setting clear guidelines as to what methodologies adequately anonymize data can also further encourage the creation of such data sources.

Policies that improve data sharing between stakeholders while protecting patient privacy will further the value Human Data Science can deliver.

Supportive policy and regulations

Policies supporting data sharing through data interoperability and transparency initiatives, encouraging the use of meaningful patient experience measures, investment in precision medicine and maintaining open-health data sources will be crucial to healthcare stakeholders as they use data to guide health policy decisions. Specific areas of support include,

- **Health policies supporting data sharing and interoperability** – The successful uptake and approach of Human Data Science depends on stakeholders building policies that ensure and encourage the availability and sharing of data. In addition, policies that protect patient privacy, require validated datasets and promote transparency are critical components of data sharing initiatives. There are currently many disparate policies that support data sharing,[107] however, to allow the approach of Human Data Science to be the most efficacious, stakeholders need to collaborate and align on goals.

- **Data transparency** – Policies that support the transparent use of data by various healthcare stakeholders support patient trust and encourage the sharing of information. Such policies include the EMA's policy on the publication of clinical trial information and the United States' 21st Century Cures Act.[108] Health stakeholders also need to feel confidence in the methodologies and advanced analytic algorithms applied to data. A balance must be found between the need for transparency around the data and methods used in an analysis and the rights of stakeholders to protect their intellectual property.

- **Precision medicine** – Policies that support precision medicine typically encourage the creation and maintenance of population-wide genomic and epigenetic datasets that help advance our understanding of genetic influences. By furthering the use of genomic data, such policies enable analyses through Human Data Science as well as accelerate the discovery and development of novel precision therapies. Such precision medicine initiatives include the United Kingdom's 100,000 Genomes Project and the United States' All of Us research program.

- **Policies supporting patient experience measures and human-centricity** – Patient-defined outcomes engage patients in their health decisions and bring value to their care. These metrics can be used to influence clinical practice, inform clinical study endpoints, support updates to clinical guidelines and shift scientific research. Human Data Science can be used to identify new measures of patient experience in data as well as to analyze data captured from patient-defined outcomes. Moving forward, government and payer policymakers, as well as patient and professional and groups, like International Consortium for Health Outcomes Measurement (ICHOM)[109] and the European Organisation for Research and Treatment of Cancer (EORTC),[110] can further support this aim by developing and standardizing and supporting the uptake of patient outcome metrics.

To maximize the value that can be derived from Human Data Science, stakeholders will need to align and invest in these supportive elements and apply principles to their research that can boost public confidence and trust in its output and increase its applicability.

- **Policies enabling open-health data sources –** Open data sources are freely accessible and allow for the sharing and redistribution of data by all stakeholders. Access to these data platforms expands the number of stakeholders able to influence policy and improve health outcomes. For example, in the United States, the open FDA platform provides APIs and raw download access, to a number of structured datasets, including adverse events, drug product labeling and recall enforcement reports.[111] The CDC and HHS also supports a number of open source data platforms.[112,113] Other open sources of data analysis software and statistical computing, like R,[114] are also critical to ensuring broad application of Human Data Science.

Investment in basic research and translational science
Investment by various stakeholders (including policymakers) in discovery science and translational medicine ensures that ongoing innovation in healthcare and Human Data Science research is possible by continually advancing our understanding of human science. Discovery science is often conducted at an academic level and aims to answer basic scientific questions about human biology, diseases or behavior that enable new lines of inquiry into Human Data Science research.

Basic research, translational science, and digital technologies are foundational elements of Human Data Science.

Translational science, or translational medicine,[115] then takes these insights derived in the laboratory, clinic, or community, and furthers practical applications to improve human health, such as the creation of medicines or guiding clinical practice. This movement of discoveries, such as the disruptive genome-editing tool CRISPR-Cas9,[116] from bench to patient, patient to community or community to the broad public in the form of therapies,[117] not only spurs questions of how to best use these new discoveries to improve human health, but also produces evidence of the same through clinical trial, clinical practice and post-marketing study data captured on outcomes. For instance, as CRISPR-Cas9 gene editing is tested for conditions such as cancer, sickle-cell disease and beta-thalassemia,[118] benefits associated with these new technologies will provide data to impact community-level health policies and decisions.[119]

In the United States, government agencies funding research include the National Institutes of Health and the National Science Foundation. In the European Union, recently approved funding for the Horizon Europe program will support both academic and commercial research across its member states. Basic research and translational science conducted at academic institutions rely on funding from these and other government sources, but in recent years, industry, universities and private groups have even been contributing a higher share of basic research funding.

In 2014, investment by pharmaceutical companies in basic research grew to $8.1 billion from $3 billion in 2008; however, the bulk of R&D spending in the United States remains on development, rather than research of basic science.[120] This underscores the importance of continued funding of basic research, without which there can be no downstream innovations or products.

Technology to enable artificial intelligence and machine learning

Continued innovation in artificial intelligence, machine learning and predictive analytics will enable Human Data Science to further it its ability to provide smart decisions. AI and machine learning models are trained with huge amounts of data that needs to be secure, readily available and accurate. As the availability of large, complex datasets (e.g., biomarker results, pharmacokinetic profile data, electronic health records) grows, these will feed into existing models and improve current machine learning algorithms.[121]

These technologies are further supported by a vast range of infrastructure for data storage, processing, networking and cloud computing that enables complex statistical computations, along with teams of people working together, including data scientists, IT professionals, software developers, analysts, information security professionals and networking engineers. Institutions and companies that use artificial intelligence to answer healthcare questions or use machine learning or predictive analytics models to predict future outcomes require all of these components, as well as advanced analytic methods, and therefore require educational programs that support these high-level skills.

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About the authors

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Murray Aitken is Executive Director, IQVIA Institute for Human Data Science, which provides policy setters and decisionmakers in the global health sector with objective insights into healthcare dynamics. He led the IMS Institute for Healthcare Informatics, now the IQVIA Institute, since its inception in January 2011. Murray previously was Senior Vice President, Healthcare Insight, leading IMS Health's thought leadership initiatives worldwide. Before that, he served as Senior Vice President, Corporate Strategy, from 2004 to 2007. Murray joined IMS Health in 2001 with responsibility for developing the company's consulting and services businesses. Prior to IMS Health, Murray had a 14-year career with McKinsey & Company, where he was a leader in the Pharmaceutical and Medical Products practice from 1997 to 2001. Murray writes and speaks regularly on the challenges facing the healthcare industry. He is editor of Health IQ, a publication focused on the value of information in advancing evidence-based healthcare, and also serves on the editorial advisory board of Pharmaceutical Executive. Murray holds a Master of Commerce degree from the University of Auckland in New Zealand, and received an M.B.A. degree with distinction from Harvard University.

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Alana is Publications Manager for the IQVIA Institute and helps manage aspects of IQVIA Institute research projects and publications, as well as conducting research and analysis within global healthcare. Alana came to IQVIA in 2016 having previously worked at Decision Resources Group for over six years as a Principal Business Insights Analyst. At Decision Resources group, Alana authored a number of publications within multiple disease areas that included Alzheimer's disease, pain, bipolar disorder, schizophrenia and major depression. Alana has a Ph.D. in Chemistry from the University of Utah and completed a postdoctoral fellowship at Brandeis University, where part of her research involved structural investigation of a protein associated with Parkinson's disease.

About the Institute

The IQVIA Institute for Human Data Science contributes to the advancement of human health globally through timely research, insightful analysis and scientific expertise applied to granular non-identified patient-level data.

Fulfilling an essential need within healthcare, the Institute delivers objective, relevant insights and research that accelerate understanding and innovation critical to sound decision making and improved human outcomes. With access to IQVIA's institutional knowledge, advanced analytics, technology and unparalleled data the Institute works in tandem with a broad set of healthcare stakeholders to drive a research agenda focused on Human Data Science including government agencies, academic institutions, the life sciences industry and payers.

Research Agenda

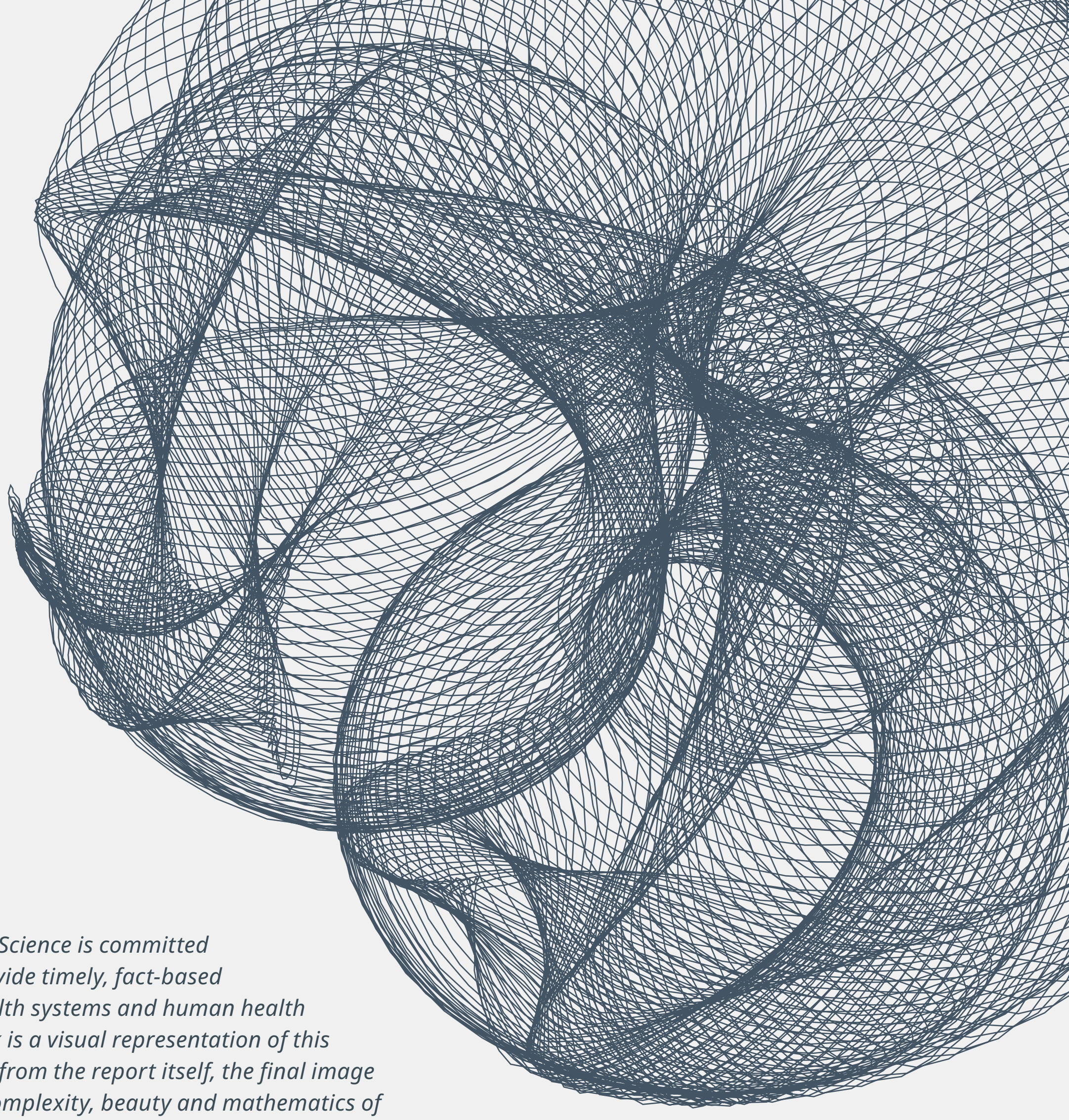
The research agenda for the Institute centers on 5 areas considered vital to contributing to the advancement of human health globally:

- Improving decision-making across health systems through the effective use of advanced analytics and methodologies applied to timely, relevant data.
- Addressing opportunities to improve clinical development productivity focused on innovative treatments that advance healthcare globally.
- Optimizing the performance of health systems by focusing on patient centricity, precision medicine and better understanding disease causes, treatment consequences and measures to improve quality and cost of healthcare delivered to patients.
- Understanding the future role for biopharmaceuticals in human health, market dynamics, and implications for manufacturers, public and private payers, providers, patients, pharmacists and distributors.
- Researching the role of technology in health system products, processes and delivery systems and the business and policy systems that drive innovation.

Guiding Principles

The Institute operates from a set of Guiding Principles:

- Healthcare solutions of the future require fact based scientific evidence, expert analysis of information, technology, ingenuity and a focus on individuals.
- Rigorous analysis must be applied to vast amounts of timely, high quality and relevant data to provide value and move healthcare forward.
- Collaboration across all stakeholders in the public and private sectors is critical to advancing healthcare solutions.
- Insights gained from information and analysis should be made widely available to healthcare stakeholders.
- Protecting individual privacy is essential, so research will be based on the use of non-identified patient information and provider information will be aggregated.
- Information will be used responsibly to advance research, inform discourse, achieve better healthcare and improve the health of all people.



The IQVIA Institute for Human Data Science is committed to using Human Data Science to provide timely, fact-based perspectives on the dynamics of health systems and human health around the world. The cover artwork is a visual representation of this mission. Using algorithms and data from the report itself, the final image presents a new perspective on the complexity, beauty and mathematics of Human Data Science and the insights within the pages.

Artwork on the cover of this Advancing Human Data Science report was generated using data about per capita antibiotic use and the number of antibiotic prescriptions written in the U.S. in 2017 and 2018.

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