



IMPACT OF NOVEL TREATMENTS OF OBESITY ON HEALTHCARE ECONOMICS AND CLINICAL PRACTICE Summary highlights from a multi-stakeholder roundtable on December 7, 2023



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Re-thinking Obesity — roundtable speakers

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Introduction

The approval and launch of novel medications for the treatment of obesity have triggered an inflection point for rethinking the prevention and treatment of obesity as a complex, heterogeneous, chronic multidisease that is associated with many other health conditions, and which calls for a new framework for recognizing the value of obesity treatments on patient outcomes and health economics for individuals, health systems, and society. The advent of novel obesity medications is also driving disruptions in clinical practice, with elevated roles for obesity medicine specialists, primary care physicians, and new sites of care.

To discuss these changes, the IQVIA Institute for Human Data Science convened a virtual, public multi-stakeholder roundtable on December 7, 2023.

The roundtable, Rethinking Obesity: Impact on Healthcare Economics and Clinical Practice, covered the potentially transformative impact of new approaches for treating people with obesity, including:

- · Anti-obesity medications
- Healthcare economics
- Clinical practice
- Implications for patients, clinicians, payers, and other stakeholders

The roundtable featured a panel of experts from a variety of disciplines: global health, health economics, health policy, clinical practice, and the life sciences industry.

The following summary provides highlights from the discussion.

This roundtable was convened as a public service without external funding and intended to encourage dialogue on the consequences for health systems globally resulting from new approaches to treating patients with obesity.

Overview of the obesity landscape

The discussion opened with an overview of the obesity landscape as an introduction to the themes of the roundtable.

The interest in the new medications for the treatment of obesity is easy to understand in part because we have had more than 50 years of recognition that obesity is a global health and economic crisis of epidemic proportions. Alarms have been raised repeatedly about the devastating impact of obesity on individuals, on health systems, and society more broadly, and the burden of the disease in both in high-income and low- and middle-income countries.

A plethora of efforts have been introduced over the last several decades to address the crisis: pharmaco-therapy treatments, bariatric surgery, and efforts to change peoples' behavior through education, diet and exercise, and clinical counseling to reduce BMI scores.

However, despite the concerns about obesity, the efforts that have been taken for decades to address the epidemic have largely failed to deliver sustained results. Therefore, it is not surprising that the recent approvals of obesity treatments backed by compelling clinical efficacy data, and the robust pipeline of future therapies have created a lot of excitement and buzz, media headlines, and demand for these drugs. This enthusiasm has been driven not only by the clinical trials showing significant reductions in weight among people with obesity when taking these medications, but also emerging evidence of a positive impact on cardiac outcomes from the use of GLP-1s.¹

This all suggests that we are entering a new era that potentially will have transformative impact on healthcare economics and clinical practice.

The interest in obesity has also been matched by a surge in investments and activity regarding the development of additional therapeutics for the treatment of obesity. Unpublished research of the molecules in the pipeline conducted by the IQVIA Institute indicates that there are 124 new molecules under investigation for the development of new drugs for the treatment of obesity.² (Figure 1).

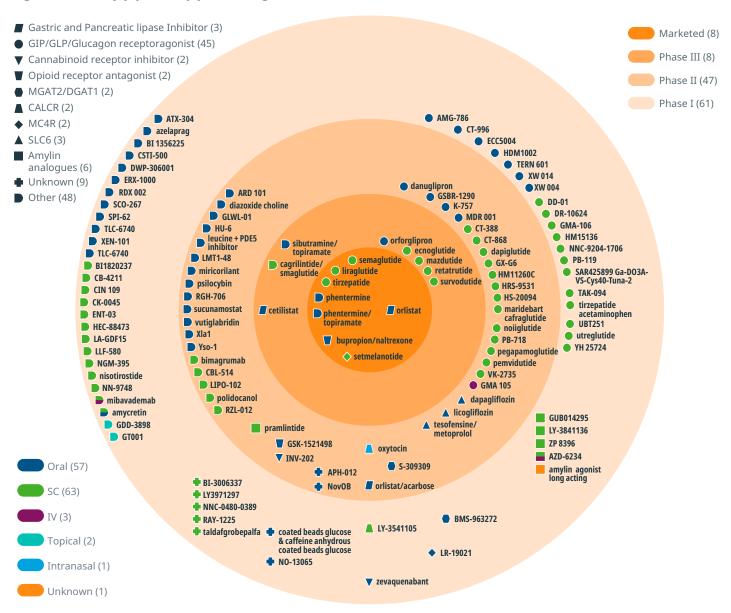


Figure 1: Obesity pipeline by phase, target and route of administration

We do appear to be on a transformational journey that will unfold over the next few years. Decisions on coverage and reimbursement for these medicines, and the impact on drug budgets and spending levels, are receiving attention at all levels, and questions about the affordability of these drugs — or whether we can afford not to use these drugs — are dominating current conversations about the healthcare expenditure.

As more patients access and use these drugs, the impact on clinical practice will unfold, including the changing role of primary care in treating obesity, other services needed to support people with obesity and the impact of downstream consequences of obesity. There is also a broader clinical aspect relating to cardio-metabolic management and the extent to which this represents a new paradigm for medicine now that we have these effective treatments for obesity and how that will play out in clinical practice as well.

Therefore, there is no better time to rethink obesity both through an economic lens and through a clinical lens.

Highlights from the roundtable discussion

The roundtable discussion centered on the following themes:

- · Health economics of obesity
- Impact on clinical practice
- Future research

HEALTH ECONOMICS OF OBESITY

The rising global burden of obesity

- It is estimated that one billion adult people will have obesity by 2030, according to the World Obesity Federation's Global Obesity Observatory.³ If children are added, the world may be close to the 1 billion number already. Due to the high likelihood that overweight is an indicator for later obesity, the World Obesity Federation estimates that as of 2035 more than half of the world's population will be living with overweight or obesity. Working with the Research Triangle Institute and supported by the World Bank and OECD, the World Obesity Federation created a methodology to estimate the economic impact of obesity of GDP. It was estimated that the direct and indirect medical costs of obesity and 27 related diseases, including diabetes, heart disease, and others, was about 2% of GDP in a number of pilot countries.
- Looking toward 2060, it was estimated that the percentage of GDP impacted by obesity would double and even higher in certain regions such as MENA.

The impact is highest in the areas in low- and middleincome countries where population growth is strongest.

- There is a growing interest in addressing the global burden of obesity, but there are still many gaps in research and knowledge. There are many unresolved questions to determine the best targets and develop coherent approaches to intervention, including the best pathways to change in health systems, food systems and particularly in the countries that have been late to recognize the challenge of obesity, especially the middle-income countries.
- There is also a clearer recognition of obesity as a disease and as a driver of other diseases, and the need for a coordinated and integrated global response, moving beyond a siloed approach. This broader effort is being supported by WHO's recommendations to address the obesity epidemic that were approved in 2022 with plans for accelerated action in key countries.

Understanding the direct medical costs of obesity

 When analyzing the economic costs of obesity, it is important to distinguish between the direct medical costs – those incurred within health systems for patient care associated with complications and consequences of obesity – and the indirect costs, including job absenteeism, people missing work because of obesity-related illnesses, job presenteeism that results in lower productivity, and impacts on worker wages.

"The growing numbers of economic impact from obesity are surreal, such as projections as high as \$10 trillion in China per year by 2060 if current growth rates continue. Globally, no country has been able to bend or even flatten the curve."

Johanna Ralston, CEO, World Obesity Federation

- Direct medical costs of obesity were estimated in the research conducted by John Cawley at Cornell University, Chad Meyerhofer at Ohio University, and Adam Biener at Lafayette College, who studied the causal impact of obesity on economic outcomes. Instead of looking at correlations between different factors and obesity, the researchers applied a method of instrumental variables where the researchers determined the causal impact of obesity by exploiting the so-called natural experiment of heritability of the genetic component.⁴
- The analysis shows that people's medical expenditures increase as BMI go up, but it is not a linear relationship (Figure 2). When looking at a BMI of 30, which is used as the threshold for defining obesity, medical expenditure is relatively low, but only when the BMI goes up to 35 and 40 does the level of medical expenditure begin to rise exponentially. Therefore, starting efforts to reduce obesity around the BMI 30 level does not generate significant savings. But starting efforts to reduce obesity around a BMI of 40 leads to savings.

"A lot of focus recently has been on the expense associated with new treatments for obesity, but it should not be lost that obesity in itself is very expensive and there are potentially big savings by reducing obesity and BMI." John Cawley, Cornell University

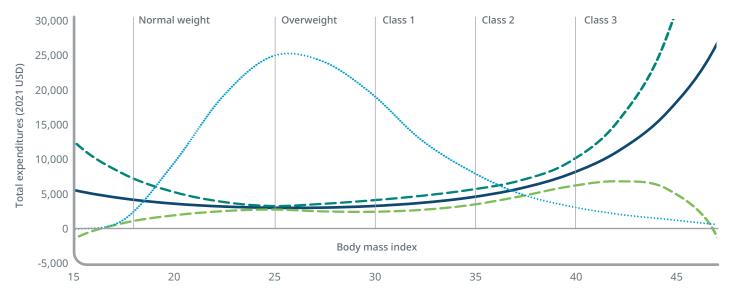


Figure 1: Obesity pipeline by phase, target and route of administration

Source: Biener, Cawley and Meyerhoefer (forthcoming), Handbook of Obesity, 5th Edition, ed. By GA Bray, C Bouchard & PT Katzmarzyk. Notes: Predicted medical expenditures denoted by the solid line are from an IV two-part model and are expressed in 2021 USD. Dashed lines represent the 90% confidence interval, which has been adjusted for the complex design of the MEPS. The distribution of individuals in the population is indicated by the dotted line. BMI is calculated using self-reports or proxy reports of height and weight. Data: MEPS 2006-2013. N = 31,591.

- When looking at the obesity categories based on BMI, obesity raises medical care costs by \$2,700-\$2,800 a year, a doubling relative to people with health weight. Class 1 obesity (a BMI between 30–35) raises medical costs by \$1,900 a year, Class 2 obesity (BMI 35-40) raises medical expenditures by \$3,800 a year, and Class 3 obesity (BMI 40 and above) raises medical expenditures by \$6,500 a year. The components that raise these medical costs are increased outpatient doctor visits, increased patient hospital stays, and increased prescription drug use. Obesity raises costs across many conditions, with diabetes among the big ones.
- Overall, a substantial amount of money is spent in the United States on obesity-related illnesses. Adding the costs of all categories, obesity-related illness costs United States \$289 billion a year, according to estimates for 2016.⁵ The majority of these costs is not paid directly by individuals with obesity but overall society through higher taxes to fund Medicare and Medicaid and higher health insurance premia through employer-provided health insurance.

Understanding the indirect costs of obesity

- Indirect costs of obesity were also estimated by John Cawley and colleagues using the same methodology. Indirect costs of obesity include the costs associated with absenteeism when employees miss work because they are sick. Relative to employees who are healthy, employees with obesity missed three more workdays per year due to poor health. The costs rise with the class of obesity, with 3.5 days extra missed with Class 2 of obesity and 7 additional days with Class 3 obesity. The aggregate costs of these missed workdays across the U.S. were estimated to between \$15 and 30 billion a year in 2016.⁶
- Another indirect category of costs associated with obesity is jobs presenteeism, where employees are coming to work but are less productive because of obesity-related illnesses. There are no reliable estimates to quantify the impact of jobs presenteeism.

Assessing the impact of weight on wages and the role of gender and race

- There are estimates for how obesity impacts wages. The estimate which looks at causal impact of weight on wages shows that it varies by gender. For men in the U.S., excess weight has no detectable impact on wages, but among women it is estimated that an additional 10 pounds lowers wages by 2.8%. By clinical weight classifications, women having overweight earn 4.5% less and women having obesity earn 11.9% less.
- There is also intersectionality at play showing that it is not only gender that matters but also race. The researchers found the strongest effect of obesity on wages among white females with no significant effect for African American females or Hispanic females. Subsequent research has confirmed these results in the U.S. and found very similar patterns in many other developed countries with greater penalty of obesity among women than men. Health is likely an answer at the higher end of the BMI, but wages are falling with BMI for women even at relatively lower levels of BMI, where we are not seeing any impact on healthcare costs, which seems to suggest that stigma and discrimination is part of the story.

Overcoming "short-termism" to recognize the longerterm health benefits of interventions

• While interventions such as the novel GLP-1 medications for the treatment of obesity have an immediate cost, it is important to recognize that healthcare benefits often are downstream and don't manifest themselves until three to five years after the start of intervention. There is a lot of data showing that there are benefits from reducing weight over time on cardiovascular disease and other obesity-related conditions, but there is a tendency among payers and employers to adhere to "short-termism" where they only look at costs and benefits within a limited time window. It is important to think about a framework that incorporates both the short-term costs and the longerterm benefits when looking at the effectiveness of a GLP-1 medication or a weight loss program such as the diabetes prevention program. "The bad news is that we have this persistent growth in spending largely linked to increasingly, medically complicated patients with chronic diseases. The good news is that many of these conditions are preventable through a combination of effective health coaching programs the new emerging technologies like GLP-1s."

Ken Thorpe, Emory University

 The changes in BMI over time and the growth in healthcare spending over the last two decades has been driven in large part by the prevalence of largely preventable, chronic disease. Research shows that 51% of the growth in per capita healthcare spending over the last decade is linked to the growth in the prevalence of chronic disease, particularly among medically complicated patients that have five or more chronic conditions, such as mental disorders, cardiovascular disease, Type 2 diabetes, cancer, and others. This is a prevalence-driven growth in per capita spending, which is largely preventable. Looking at this by condition in terms of spending over the last decade some of the key conditions are tied to obesity, including diabetes and heart disease.

- The interactions across chronic conditions linked to obesity are substantial. The person with Type 2 diabetes is probably also depressed, has hypertension and elevated cholesterol, and may have heart disease. Therefore, the opportunity is targeting changes in weight through effective health coaching programs that make a big difference in terms of weight loss, and in combination with these new GLP-1 medications can make an enormous impact on the growth trajectory of per capita spending, not only in the United States, but globally.
- The differences in the underlying prevalence of chronic disease, largely linked to BMI-rates, is one of the key reasons for the differences in healthcare

costs when comparing the U.S. and Europe. An analysis of patients at age 50 and above showed that if the U.S. had prevalence-rates of key chronic conditions, such as diabetes, hypertension, heart disease, and other illnesses, like Europe, per capitaspending rates healthcare spending in the U.S. would be about 17% lower.

Addressing reimbursement of obesity medications

• Access is a global barrier for patients to get the benefits from obesity medications. In the U.S., Medicare does not provide access to obesity medications, and less than half of the Medicaid state programs cover anti-obesity medications. Only half of all U.S. employers' health insurances cover obesity medications. One challenge in the U.S. is the difference between the business case from the perspective of the health insurer and the societal perspective that public health officials have in a potential cost-effectiveness study. In a cost-effectiveness case, you will need to look at all the costs and all the benefits to society, but the health insurer is focused on the company's profits. The business case may not be there to cover obesity treatments due to the turnover between enrollees and health insurance companies and the fact that many benefits of weight loss may be long-term some years down the pike. The health insurer can't recoup all the costs before the enrollee goes somewhere else. That does not explain why public health insurance such as Medicaid and Medicare that should take a long-term public health view don't provide coverage.

"Regarding access, we are hoping that we can dispel many of the myths that exist around the value in treating obesity. It is a cliché, but in the U.S., innovative medicines don't mean anything if you don't have access to them. Currently, only between 2-4% of people who are eligible for obesity medications actually take them and adherence issues are not well understood."

John Steele, Lilly Diabetes and Obesity

- In Europe, there is also a lot of the same frictions around access to obesity medications. In low- and middle-income countries, it is a fundamental problem that only about 20% of the countries even include obesity treatment in their health system.
- The ability for policymakers to take steps to address the crisis of obesity is also challenged by the fact that most countries don't track their health system costs by disease, and they don't track them by the underlying drivers of those diseases.
- Overall, the potential costs of obesity medications tend to be overstated in many recent predictions. As more companies enter the market with new medications, there will be more competition, which will drive down costs. The current problems with limited supply capacity will also be resolved. Currently, only between 2-4% of people who are eligible for obesity medications take them, and the potential limitations in use due to adherence issues are not well understood.

"From a global perspective, it is important to remember that the number of countries that have treatment of obesity in their health system is only around 20%. But it also indicates limitations of growth in demand shorter-term. On another note, I have not seen this level of scrutiny of costs in other disease areas, including MS and cancer. And I can't help wondering whether this is due to stigma and bias against obesity. It is hard to understand why it is so hard when you think about the long-term societal benefits and savings in relation to other conditions that are related to obesity."

Johanna Ralston, World Obesity Federation

IMPACT ON CLINICAL PRACTICE

Building clinical practice capacity to treat obesity as a complex, heterogenous, chronic disease

- It has long been a common belief that obesity was "just a lifestyle problem," that people gained weight by eating too much and exercising too little, and that people could lose weight by eating less and exercising more. It is now broadly understood that there are complex pathophysiological pathways, that many hormones are involved, and that obesity is a distinct, complex, heterogenous, and very difficult to treat chronic disease. Because of the complexity of obesity, effective sustainable treatment requires comprehensive evaluation, personalized treatment protocols, and extensive education.
- Due to the complex nature of the disease, good obesity care requires that the physician spends time with patients to identify every factor that has led to weight gain and every barrier that is preventing weight loss. The goal is to develop highly tailored management plans that address all these factors, optimize diet, optimize physical activity and behavior, and if necessary, incorporate advanced medical strategies, including pharmaco-therapy or bariatric surgery when needed. New obesity medications are now associated

with a 15–22%+ weight loss, which is dramatic and lifechanging for patients, but they are not magic bullets and need to be incorporated in a comprehensive treatment strategy.

• There are not enough trained obesity medicine providers to handle the magnitude of the obesity epidemic and deliver comprehensive obesity care. There are fewer than 120 fellowship-trained obesity medicine physicians in the entire U.S. and there are fewer than 7,000 physicians who have been board certified by the American Board of Obesity Medicine. Because of this, primary care doctors need to be part of the solution to get conversations started appropriately and to begin treatment to the extent they are comfortable. But it takes a lot of time, and a robust infrastructure is required for the evaluation, education, and support that is critically needed for patients to have success. Unfortunately, most PCPs don't have the luxury of time and infrastructure. Therefore, it is necessary to train more providers to deliver comprehensive obesity care, and nurse practitioners and physician assistants are also a crucial part of the solution.

"One of the biggest barriers to care is simply the lack of recognition that obesity is a complex, heterogenous, chronic disease that requires a comprehensive medical intervention for most individuals to be treated effectively and, more importantly, to manage their disease long-term. What people don't need to hear from their provider is just do more exercise or that Ozempic is the magic bullet. Individuals with obesity need empathy; they need to hear that their obesity isn't due to a lack of willpower; they need clinicians who give them hope."

Katherine H. Saunders, Weill Cornell College, Intellihealth

Advancing new opportunities for addressing chronic conditions with GLP-1s

- Recent promising studies have shown a reduction in cardiac events in patients being treated with GLP-1s. This is an important inflection point for more investments by life sciences companies in clinical studies that will potentially demonstrate that a reduction in obesity can lead to a decrease in all-cause mortality, and a reduction in kidney disease, NASH, sleep apnea, and a broad range of other diseases. It is a scientific revolution that is not only reducing obesity but many important non-communicable diseases that are ravaging not only developed, but also developing countries.
- Furthermore, several life sciences companies are working to develop oral medications that can provide benefits from a patient perspective for those who are afraid of needles. For low- and middle-income countries, this is also an important advancement to overcome the issues that are affecting injectable insulins in these countries with supply chain and cold storage requirements that are more expensive and complex than oral formulations.

FUTURE RESEARCH

In conclusion, the panelists considered investments in future research to continue to drive the field of obesity innovation forward. Key thoughts included the following suggestions:

 Sub-populations: It is important to understand different special sub-populations, and the unique impacts and barriers for these patients. There is a need for clinical trials to be more broadly representative of all the different sub-populations, which has not always been the case. In the past, many clinical trials have not included people with obesity, which has been a barrier in and of itself. In addition, racial and ethnic minorities that have been underrepresented in clinical trials should be incorporated. Furthermore, a more inclusive research agenda should also incorporate efforts to better understand health systems in low- and middleincome countries and how food systems impact the broader changes.

- Randomized clinical trials regarding co-morbidities: There is a significant need for ongoing, well-powered, randomized controlled trials (RCTs). RCTs should focus not only on how much weight loss was achieved by obesity drugs but go further to better understand their impact on obesity-related co-morbidities. These studies should also look at the impact on medical care costs, job absenteeism, and wages.
- · Studies about multiple interventions across patient types: There is a need for more information about outcomes of broad, multi-faceted programs that assess which combinations of interventions are most effective for different types of patients that present themselves with different combinations of chronic diseases and have different underlying health conditions. These studies should include the new GLP-1 medications, diet, exercise, and lifestyle medications to better understand what is most effective and in what combinations. As an example, studies should explore how effective health coaching is in combination with GLP-1s, without GLP-1s, and in collaboration with primary care and obesity medicine physicians. Recognizing that all patients are different, there should also be studies looking at different types of patient segments.

Key takeaways

- **Rethinking obesity**: The approval and launch of new effective obesity medications represent a landmark opportunity for rethinking obesity as a complex, heterogenous, chronic disease associated with multiple other health conditions and co-morbidities.
- Addressing obesity as a multi-disease:
 GLP-1 medications have demonstrated dramatic reductions of weight in people with obesity in addition to decreasing cardiac risk, and there is emerging evidence that these medications may also have positive outcomes on other diseases, including kidney disease and colon cancer. Therefore, these new obesity medications are becoming an inflection point for a new, comprehensive approach to preventing and treating obesity and its negative outcomes as a chronic multi-disease.
- Recognizing longer-term value: While there are health economic implications from the introduction and use of the new obesity medicines, a new framework is needed to recognize the longer-term value of these interventions in patient outcomes and savings to both health systems and society that exceed the initial costs of the medications.
- Expanding reimbursement of obesity medicines: Considering the significant improvement in patient outcomes through the reduction in weight and the longer-term savings from these medications, payers whether public payers such as Medicare and Medicare or private, employer-funded health plans — should reassess their approach to reimbursement to enable patient access to these critical therapeutics.
- Disrupting clinical practice: Preventing and treating obesity as a complex, heterogenous, chronic disease with multiple co-morbidities requires a comprehensive, multi-disciplinary approach, which disrupts the current

siloed approach in obesity care and calls for intensive collaboration between obesity medicine doctors, relevant specialties, and primary care physicians (PCPs) — with PCPs taking an elevated role in patient education, prevention, and treatment.

- Offering comprehensive obesity care: While obesity medications may be very effective in reducing weight and curbing longer-term health complications, they should be prescribed to people with obesity based on a thorough assessment of the individual patient and the application of comprehensive obesity care that combines pharmaco-therapy with other interventions, including education, diet, exercise, and other relevant lifestyle changes.
- Overcoming stigma and bias regarding obesity: The exaggerated concerns about uncontrolled costs of new obesity medications are not matched by the realities of barriers to access and hurdles for patient adherence. Similar scrutiny of costs has not been seen for other disease categories and suggest that stigma and bias around obesity are at play, which calls for an improved understanding of the serious health and economic burden of obesity on individuals, health systems, and society.
- Supporting integrated action in low- and middleincome countries: Obesity is an epidemic of global proportions affecting population health and economic prosperity in low- and middle-income countries (LMICs), and obesity rates are rising particularly rapidly in middle-income countries. Finding ways to curb the obesity epidemic should be an important priority for health systems in LMICs to accelerate the implementation of national plans that go beyond siloed and fragmented interventions to expedite comprehensive, integrated actions on obesity while also advancing access to novel cost-effective therapeutics and universal health coverage.

Key takeaways continued

- Advancing life sciences innovation: There are currently more than 124 molecules under investigation for the treatment of obesity, and investments should continue for even more effective and safe medications to treat obesity and associated chronic conditions, which also enable clinicians and patients to choose between different treatment options.
- **Investing in future research**: More clinical research, data, and evidence about the benefits of obesity therapies are required to address the complexities of obesity prevention, treatment, and care management. Future research efforts should aim to generate new insights regarding the prevention and treatment of

obesity in underrepresented populations, including African American and Hispanic people. Well-powered, randomized controlled clinical trials continue are required to understand the disease and the impact of obesity medications on obesity-related co-morbidities as well as the impact of on direct medical care costs and indirect costs, such as job absenteeism and wages. Large studies are also required that compare the impact of different interventions, drug therapy versus intensive health coaching, combinations of these interventions, and assessing the comparative impact of different modalities of intervention on separate population segments in real-world settings.

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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.

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