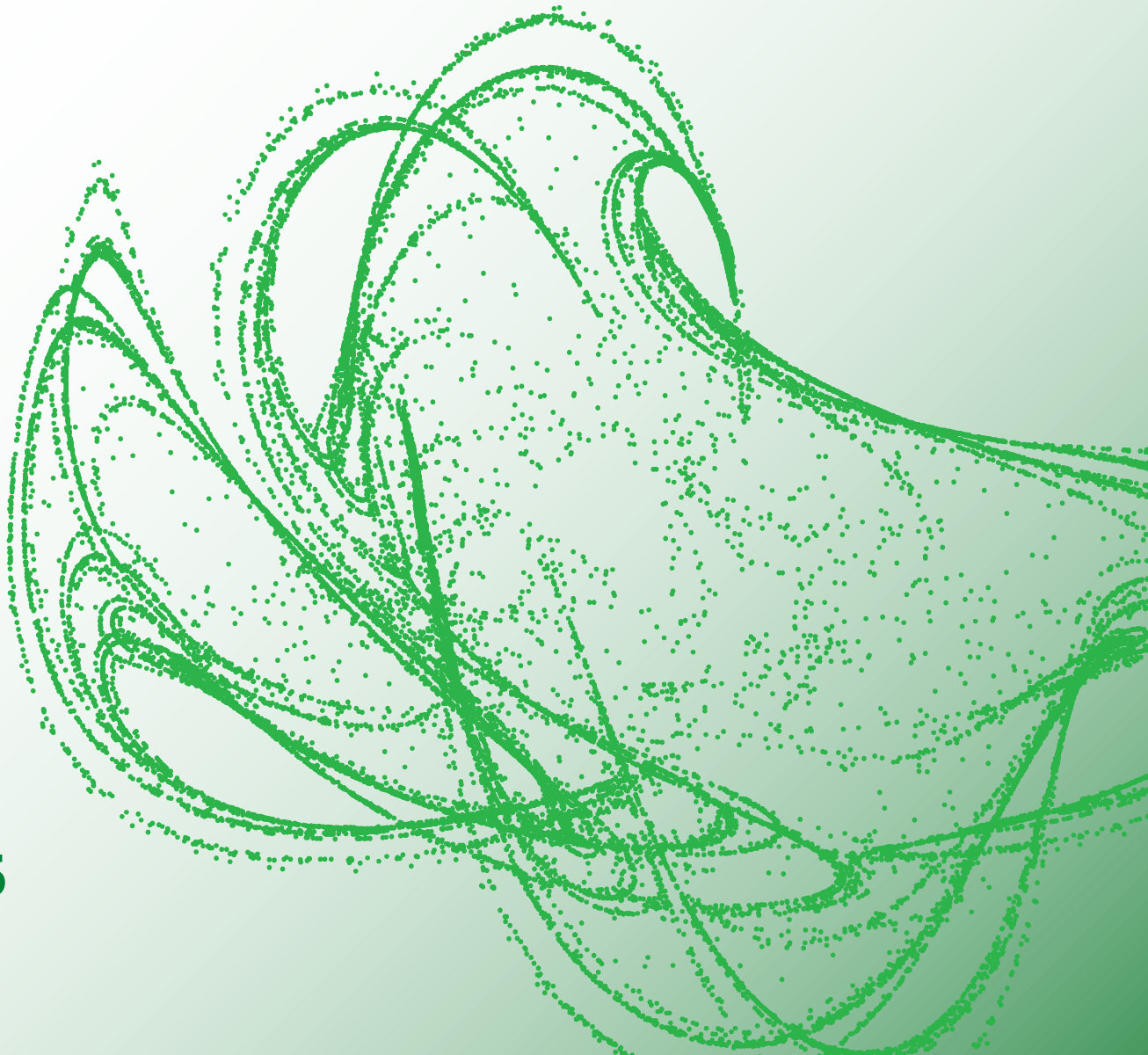
IQVIA INSTITUTE FOR HUMAN DATA SCIENCE

PERSPECTIVE

America's Greatness in the Biopharmaceutical Sector

Sustaining U.S. Leadership



MAY
2025

Introduction

The U.S. biopharmaceuticals sector — the collection of companies that discover, develop, and commercialize therapeutics and medicines for patients in the U.S. and around the world — contributes to the U.S. economy, healthcare system, and society through its focus on innovation and technology, while concurrently reducing mortality and morbidity from illness. The sector has developed an eco-system that combines a multitude of scientific discovery platforms with robust dissemination of information, intellectual property protection, a global talent pool, funding markets that provide liquidity, and a relatively transparent and responsive regulatory regime. This eco-system has delivered enormous value and has been a major net contributor to the U.S.; however, there are aspects of the current system that can be improved, and competition from other parts of the world is increasing. Addressing these issues — while maintaining or increasing the strengths of the existing eco-system — can contribute to the broader goals of enhancing America's global leadership and at the same time increase the contribution of this critical strategic sector.

This Perspective from the IQVIA Institute for Human Data Science is intended to contribute to the current discussion around several Executive Orders and policy proposals being discussed or implemented by the current U.S. Administration. It draws on recent research by the IQVIA Institute and others to bring a balanced and objective view of how the goals of the administration can be best supported by a vital and sustained biopharmaceutical sector. This Perspective is produced as a public service without external funding or support.

Find Out More

If you wish to receive future reports from the IQVIA Institute for Human Data Science or join our mailing list, visit iqviainstitute.org.

MURRAY AITKEN
Executive Director
IQVIA Institute for Human Data Science

REFERENCING THIS REPORT
Please use this format when referencing content from this report:
Source: IQVIA Institute for Human Data Science. America's Greatness in the Biopharmaceutical Sector: Sustaining U.S. Leadership. May 2025. Available from www.iqviainstitute.org

Biopharmaceuticals are a strategic sector for the U.S.

The U.S. biopharmaceutical sector contributes to the U.S. economy, healthcare system, and society in multiple ways:

1. Biomedical research leadership

- The U.S. has led the world in biomedical discovery and clinical research, focused on discovering and developing innovative treatments and cures for patients globally
- American companies have discovered, patented, and conducted clinical research to achieve regulatory approval for 46% of the 634 novel drugs approved globally over the past decade, twice the output of all companies headquartered in Europe[1]
- Scientists in America have achieved leadership in understanding genetics and molecular biology, immunology, cancer immunotherapy, infectious diseases, and many other disease areas, and deploying gene editing tools, immunotherapy, monoclonal antibodies, CAR T-cell therapies, and other mechanisms and modalities
- The research leadership is underpinned by a unique combination of public funding for basic research via the National Institutes for Health, university-led translational science, technology transfers from academic institutions to private sector entrepreneurs, venture capital funding, and larger company partnerships
- Major global pharmaceutical companies — over half of which are headquartered in the U.S. — invested $190 billion in research and development activities in 2024, an increase of 73% from the level five years ago, and representing over 25% of net revenue[2]
- The U.S. also has a regulatory agency and environment that is viewed as the gold standard by many other agencies around the world, providing essential guidance and support to speed innovations that make medical products more effective, safer, and more affordable, thereby contributing to the advancement of public health for all Americans

2. Economic contributions

- The direct and indirect economic contribution of the U.S. biopharmaceutical sector is estimated to be $1.65 trillion, including $800 billion in direct output in 2022, and an additional $850 billion through its suppliers and other sectors; this combined output impact represents 3.6% of all U.S. output[3]
- The sector is also responsible for direct and indirect employment of 4.9 million Americans, including more than 1 million workers directly employed by the U.S. biopharmaceutical industry and 3.8 million additional jobs based on a substantial employment multiplier of 4.69[3]
- The industry provides high paying jobs that averaged more than $157,000 per worker in annual wages and benefits in 2022, which is $60,000 more than the average U.S. manufacturing job, and more than twice the U.S. average across all industries[3]
- Total productivity per employee was more than $402,000 in 2022 based on the research and productive nature of the biopharmaceutical industry — more than twice that of the U.S. average manufacturing worker and more than three times that of the average U.S. worker[3]

American companies have led the world in biomedical discovery and clinical research, and bring substantial direct and indirect economic contributions to the U.S.

- There is broad distribution of activity — and economic contribution — by the industry across all 50 states, including the conduct of clinical trials, the manufacturing of medicines in more than 1,500 facilities certified under current Good Manufacturing Practice regulations across 47 states, research laboratories, and commercial business operations[3]
- This is a resilient sector that is largely recession-proof and provides stability relative to other sectors during times of financial downturn or other forms of economic disruption

3. Advanced patient care options

- Participation by U.S. patients in clinical trials provides an important care option, especially for patients with a rare or advanced disease where there may be few alternatives. Nearly 5,300 clinical trials of medicines are conducted with sites in the U.S, providing over 900,000 participants with the opportunity to consider clinical research as a care option, enabling them to access advanced treatments[4]
- More clinical trial sites — located at academic medical centers as well as community-based centers — are located in the U.S. than in any other country, and more patients are screened for participation in those trials
- The potential for enhanced medical care for participants in trials brings benefits to patients, including more frequent and detailed medical attention and better overall health monitoring, and greater empowerment for patients to take a more active role in their own healthcare

4. Patient access to newly approved drugs

- Patients in the U.S. gain access to more of the innovative drugs launched globally compared to those in other countries or regions. Over the five years 2020–24, 273 novel active substances (NAS) were launched in the U.S., compared to 204 in the EU4+UK, 199 in China and 164 in Japan[2]
- Americans have earlier availability of novel medicines compared to Europeans; since 2020, 110 NAS are available in the U.S. but not in Europe, while only 14 NAS are available in Europe but not in the U.S.[2]
- There is a high awareness and education of healthcare professionals and patients about newly approved drugs, which leads to a faster adoption of these treatments where appropriate in the U.S. and generally higher rates of use compared to other countries
- This earlier availability and use of pharmaceutical innovation is responsible for 66% of the increase in longevity in the U.S. between 2006 and 2016[5]

U.S. patients benefit from being able to participate in clinical trials and from earlier and broader access to innovative medicines than in other countries.

Opportunities to strengthen the global leadership of the U.S. biopharmaceutical eco-system

While the sector has made substantial contributions to the U.S., there are areas that could be strengthened and others that represent risks to the current leadership position:

1. Dependence on off-shore production sites for manufacturing of finished goods, active pharmaceutical ingredients (API), and key source materials for innovative medicines (which represent about 10% of U.S. medicine consumption by volume) and generics (about 90% of U.S. medicine consumption)

- There has been a shift of innovative medicines production capacity from the U.S. (including Puerto Rico) to Europe (particularly Ireland) due to tax and other financial incentives introduced over the past two decades, and following the phasing out by the U.S. of incentives from 1996 to 2006 that had been introduced in 1976 by Section 936 of the U.S. Internal Revenue Code, which allowed U.S companies operating in Puerto Rico to repatriate profits to the mainland without paying federal taxes
- API production volume for branded drugs is primarily sourced from the European Union (43%) and "other" countries (31%) while only 15% is produced in the U.S. and 5% in India and China together[6]
- The movement of generic medicines, API and finished goods production from the U.S. to lower cost countries, notably India and China, has occurred as costs of maintaining manufacturing capacity in the U.S. increased while competitive pricing pressures reduced margins in the U.S. market
- API production volume for generic drugs is now 35% sourced from India and 8% from China, 12% from the U.S., 18% from the EU, with the balance from other countries or unknown[6]

2. Over-dependence by biopharmaceutical companies on the U.S. market for sales of innovative medicines due to reimbursement and access constraints in other countries

- Global companies are now dependent on the U.S. market for 61% of total pharmaceutical sales of branded drugs, up 5 percentage points over the past decade[7]
- Many factors contribute to other countries being less attractive, including delays in registration, use of health technology assessments, imposition of pricing controls, caps on growth in spending on medicines, restrictions in access, and lack of access to diagnostics that are utilized in ex-U.S. markets

3. Rising out-of-pocket costs for many patients

- Total patient out-of-pocket payments by all Americans are estimated at $98 billion in 2024, an increase of 24% since 2019[7]
- Over 1 million Medicare Part D beneficiaries faced annual costs in excess of $2,000 in 2024, and almost 100 million new-to-product prescriptions were abandoned by patients (prescriptions written and filled but not taken from the pharmacy by the patient) and are highly correlated with the level of out-of-pocket payment required[8]

4. Increased barriers to access due to insurance design and pharmacy benefit restrictions

- Over 25% of all new retail prescriptions for brands and branded generic drugs — and over one-third for Medicaid beneficiaries — go unfilled due to payer rejections[8]
- Payers may not cover a medicine on its formulary or require prior authorization, completion of step therapy, or other documentation required from the prescriber

5. Reliance on treatments for symptom management and late-stage disease rather than disease prevention or early interception

- Most new medicine development is focused on therapeutics for symptom management or treatment of late-stage disease instead of disease-modifying treatments, cures, or early disease interception
- Most health service delivery is similarly focused on patients with the most advanced disease and life-threatening conditions
- Disease prevention and early interception of disease is being pursued but represents a small part of total public and private sector research activity and funding[9]
- Community-based wellness programs and primary care centers are generally under-funded and under-resourced with limited tools and proven interventions that will improve health outcomes at scale

6. Rising competition from China

- China-headquartered companies now sponsor 30% of all interventional industry-funded Phase I–III clinical trials globally, up from 5% in 2014 and only slightly behind U.S.-based companies, which represent 35% of the total[2]
- China has also seen rapid advancements in biotechnology, leveraging artificial intelligence; increasing public and private sector funding into life sciences; drawing on a large talent pool, including repatriated scientists trained in the U.S.; and a significant strengthening of its regulatory systems and intellectual property frameworks in recent years to protect innovation and attract global partnerships

7. Expanded efforts by Europe to strengthen global position in biopharmaceuticals

- The European Union (EU) is very aware of its declining relative contribution to innovation as measured by funding in support of early-stage companies, clinical trial activity, regulatory approval of NAS, and provision of attractive commercial markets for biopharmaceuticals. The EU's recent report by Mario Draghi focuses on Europe's urgent need to accelerate innovation and productivity growth to maintain global competitiveness[10]
- New efforts are underway to strengthen the EU position, including revision of the General Pharmaceutical Legislation to create a more innovation-friendly regulatory environment and to support small and mid-sized companies; preparation of a new strategy for European life sciences to strengthen research and innovation; the establishment of a unified framework for the use and exchange of electronic health data across the EU in the European Health Data Space; proposals from the European Commission for a Critical Medicines Act focused in part on supply resilience, and a Biotech Act focused on industrial policy for the sector; the creation of advanced opportunities for use of artificial intelligence based on large and accessible datasets; and streamlining regulatory requirements and support for the conduct of clinical trials in European sites

Specific initiatives to sustain U.S. leadership

America's existing global leadership in the biopharmaceutical sector can be strengthened — bringing economic growth, better healthcare for all Americans, and strategic strength — through a series of initiatives that address some of the identified issues and forestall competitor encroachment on U.S. leadership while preserving the core elements that have been successful to date:

1. **Maintain public funding for basic science through university-led and private sector-supported research** that will drive new focus on chronic disease, understanding disease etiology, early disease interception, and deeper understanding of the root causes of disease

- Ensure collaboration between public sector (such as NIH) and private sector (large and small biopharmaceutical companies) in a measurable shift in focus toward high-risk, high-impact research on the priority areas that will contribute to Make America Healthy Again
- Initiate new programs focused on disease etiology, including the underlying causes of obesity and chronic diseases such as diabetes, heart disease and mental health disorders, with a focus on early intervention and interception of disease
- Promote cross-collaboration across specialties in funding academic research and make electronic health records (EHR) and laboratory data more accessible and interchangeable in research settings
- Application of artificial intelligence and machine learning at scale to accelerate and support existing and new efforts at the nation's leading research centers in both the public and private sectors

2. **Manage the transition to more on-shore production of key materials, API, and finished products** through a staged transition program

- Provide tax or other incentives for manufacturers to move production on-shore and a realistic timetable for the construction and certification of new capacity
- Prioritize among generic and patent-protected medicines based on considerations of national security, availability of alternatives, and critical medical need
- Maintain close scrutiny of medicines vulnerable to supply shortages and disruptions

3. **Address "freeloading" of other countries through push and pull mechanisms**

- Provide incentives for companies to generate more than 40% of their global sales from branded drugs in countries outside the U.S., such as increased Medicare pricing or exemption from the Medicare Price Negotiation Program when a target level of ex-U.S. pricing and access is achieved
- Use America's negotiating power in trade relations to pressure other countries to abandon restrictive access policies and to fairly reward the risk and investment associated with the development of novel medicines, which average more than $2 billion per approved new drug[11]

4. **Promote provisions that simplify drug pricing, formulary plan design, and setting patient out-of-pocket costs**

- Align incentives across stakeholders involved in the market for medicines
- Address some of the gaps in the current funding of health systems that are currently being filled by drug pricing mechanisms, such as the 340(b) program

5. **Strengthen and modernize the FDA, clinical trial environment and real-world evidence guidelines** to better support innovation and clinical trial activity in biopharmaceuticals and maintain its position as the gold standard for manufacturing standards and clinical and safety evidentiary standards

- Adopt a more dynamic and responsive stance that is willing to take on more up-front risk (especially for areas of significant unmet need) balanced by better post-marketing studies and use of real-world data for monitoring safety and efficacy
- Drive interoperability EHR to allow better use of real-world data for digital twin studies and to augment/replace some studies, as well as for post approval effectiveness and safety monitoring and tracking of outcomes that can be linked to payment contracts
- Maintain or expand incentives for clinical research to be conducted in the U.S.
- Allow for participation in clinical research across state lines to facilitate remote study enrollment

6. **Enable the development of a "learning health system" that can improve system efficiency, enable value-based payments, and increase understanding of health outcomes for all Americans**

- Pursue the full development and implementation of interoperability standards across electronic health records and other relevant information sources
- Strengthen data security and handling standards to ensure ability to capture granular data and use it appropriately
- Foster development of artificial intelligence (AI) learning loops as part of the operation of health systems based on healthcare-grade AI foundation models

7. **Create an Industrial Policy to safeguard America's global leadership in biopharmaceuticals** and to ensure this benefits all Americans

- Pursue public and private collaboration to set the strategy for enduring strength of the sector
- Establish a monitoring system to ensure global competitive threats are recognized and addressed in advance of any impact on America's leadership
- Ensure pragmatic application of incentives and tools to address imbalances and maintain ethical and sound business practices across the sector

America's existing global leadership in the biopharmaceutical sector can be strengthened — bringing economic growth, better healthcare for all Americans, and strategic strength — through a series of initiatives that address some of the identified issues and forestall competitor encroachment on U.S. leadership while preserving the core elements that have been successful to date.

References

1. IQVIA Institute for Human Data Science. Unpublished research.

2. IQVIA Institute for Human Data Science. Global Trends in R&D 2025: Progress in Recapturing Momentum in Biopharma Innovation. Aitken M et. al. May 2024. Available from: https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/global-trends-in-r-and-d-2025

3. PhRMA and TEConomy Partners, LLC. The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates. Available from: https://cdn.aglty.io/phrma/global/blog/import/pdfs/The-Econ-Impact-of-US-Biopharma-Industry-2024-Report.pdf

4. PhRMA. New research: Industry sponsored clinical trials contribute billions to state economies. Reid Porter. March 6, 2025. Available from: https://phrma.org/blog/new-research-industry-sponsored-clinical-trials-contribute-billions-to-state-economies

5. Lichtenberg F. R. The effect of pharmaceutical innovation on longevity: Evidence from the U.S. and 26 high-income countries. Economics & Human Biology. August 2022; Vol 46. PMID: 31419866.

6. U.S. Pharmacopeia Medicine Supply Map. Available from: https://qualitymatters.usp.org/over-half-active-pharmaceutical-ingredients-api-prescription-medicines-us-come-india-and-european

7. IQVIA Institute for Human Data Science. 2025 Indicators of Progress for the Life Sciences Sector: How will we know if the sector is advancing in 2025? Available from: https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/2025-indicators-of-progress-for-the-life-sciences-sector

8. IQVIA Institute for Human Data Science. Understanding the Use of Medicines in the U.S. 2025: Evolving Standards of Care, Patient Access, and Spending. Aitken M et al. April 2025. Available from: https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/understanding-the-use-of-medicines-in-the-us-2025

9. IQVIA Institute for Human Data Science. October 2020. Evolving the Understanding of the Natural History of Disease. Available from: https://www.iqvia.com/library/publications/evolving-the-understanding-of-the-natural-history-of-disease

10. European Commission. The Future of European Competitiveness. Draghi, M. September 2024. Available from: https://commission.europa.eu/document/download/97e481fd-2dc3-412d-be4c-f152a8232961_en?filename=The%20future%20of%20European%20competitiveness%20_%20A%20competitiveness%20strategy%20for%20Europe.pdf

11. DiMasi JA, Grabowski HG, Hansen RW. Innovation in the pharmaceutical industry: New estimates of R&D costs. J Health Econ. 2016 May;47:20-33. doi: 10.1016/j.jhealeco.2016.01.012. Epub 2016 Feb 12. PMID: 26928437.

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 five areas considered vital to contributing to the advancement of human health globally:

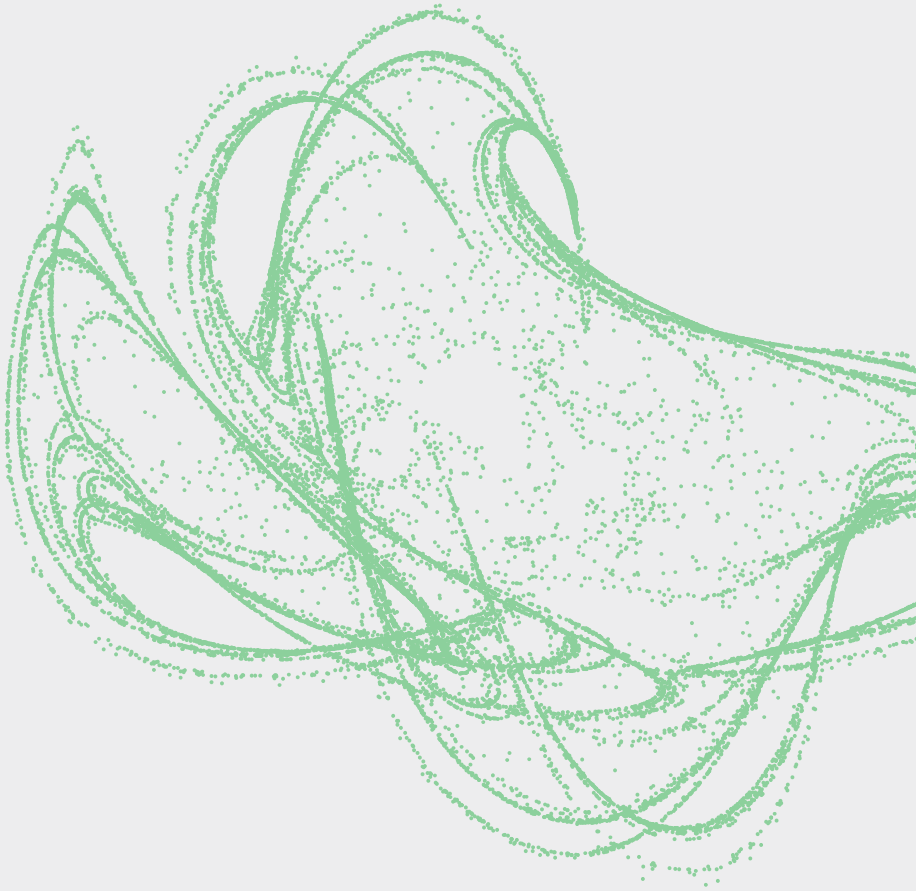
- Improving decision-making across health systems through the effective use of advanced analytics and methodologies applied to timely, relevant data.
- Addressing opportunities to improve clinical development productivity focused on innovative treatments that advance healthcare globally.
- Optimizing 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.



IQVIA INSTITUTE FOR HUMAN DATA SCIENCE

CONTACT US

100 IMS Drive

Parsippany, NJ 07054

United States

info@iqviainstitute.org

iqviainstitute.org