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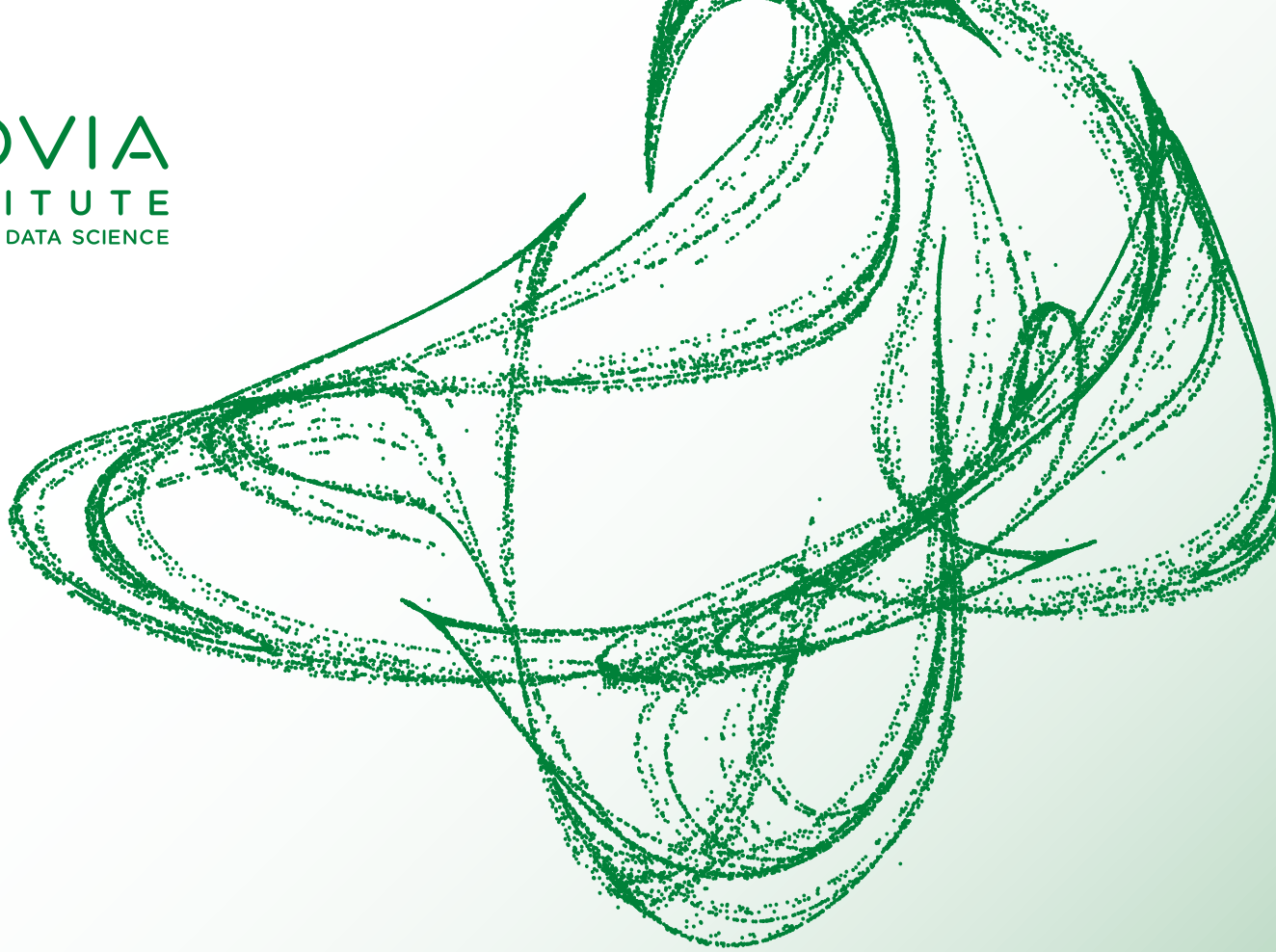

Pathways to Overcome Challenges to CAR T-cell Therapy Readiness

Summary highlights from a webinar organized by the IQVIA Institute on April 29, 2025

JULY
2025

WEBINAR

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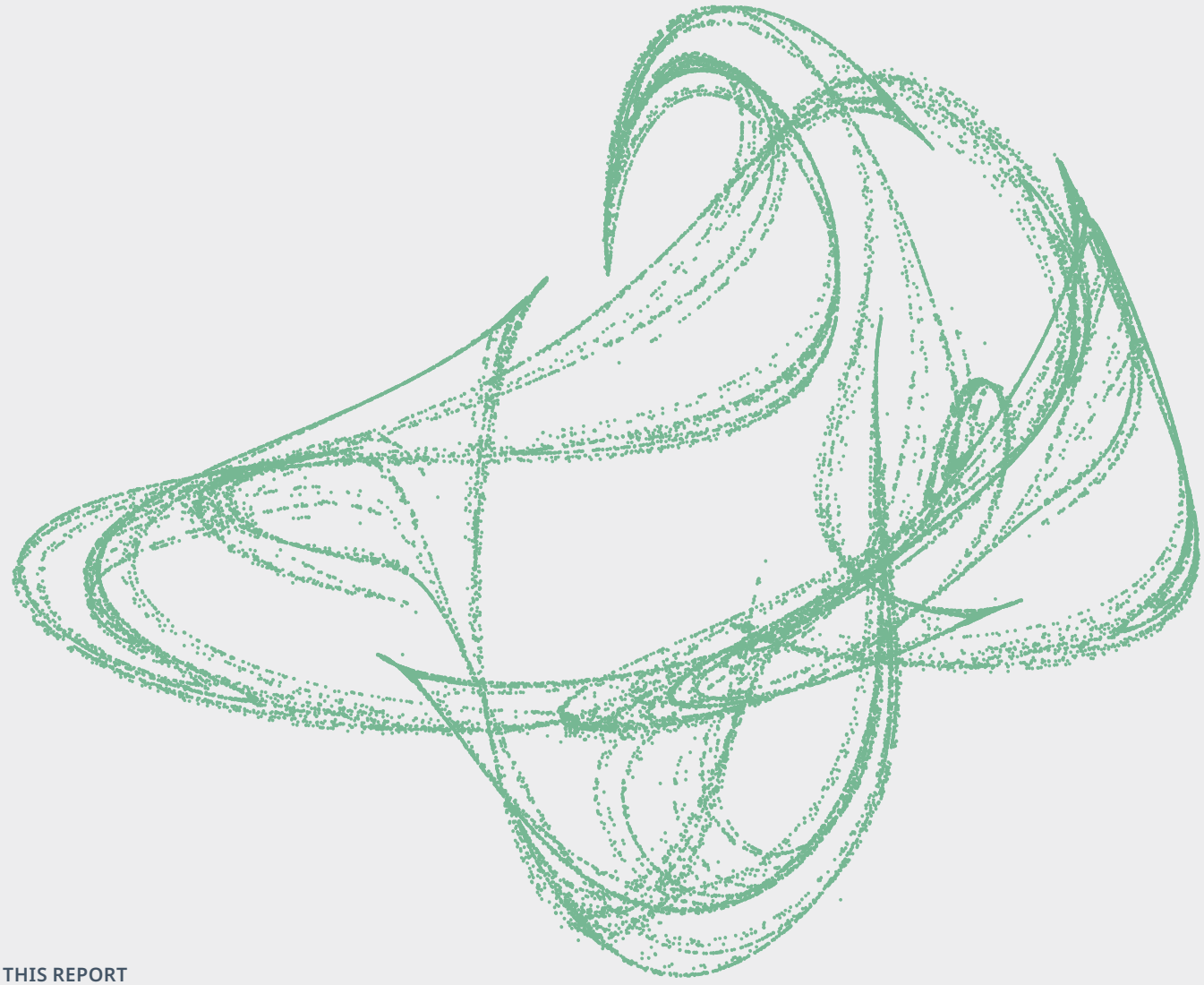

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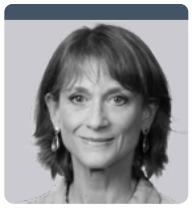
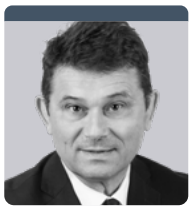
Panelists

EXTERNAL SPEAKERS



NATACHA BOLANOS
Head, Membership and Alliances, Lymphoma Coalition



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Former Chair of the EBMT Cellular Therapy & Immunobiology Working Party and founder of the GoCART Coalition

CARMEN SANGES
EU Initiatives Scientific Project Lead, Universitätsklinikum Würzburg and Lead coordinator of T2Evolve

MODERATOR

MURRAY AITKEN
Executive Director, IQVIA Institute for Human Data Science

Introduction

The IQVIA Institute for Human Data Science convened a multi-stakeholder webinar on April 29, 2025, titled, *Pathways to overcome challenges to CAR T-cell therapy health system readiness*. This webinar covered the state of CAR T-cell therapy innovation and its impact on cancer care, current state of readiness of the CAR T-cell therapy journey in different geographies, key barriers and best practices, and healthcare policies and investments needed to ensure equitable and timely access to CAR T-cell therapy. Building on the IQVIA Institute's published report on *Achieving CAR T-cell Therapy Health System Readiness: An Assessment of Barriers and Opportunities*, the aim of this session was to further the ongoing discussion about the state of readiness across different countries to provide CAR T- cell therapies in a timely manner.

The panelists represented abroad range of stakeholders including from patient advocacy, policy, and hematology.

The following summary provides highlights from the discussion along with calls to action that were discussed during the webinar.

The webinar was organized as a public service with funding from Gilead and Kite.

Background

The webinar opened with an overview of the research findings from the report published by IQVIA Institute in March 2025 as an introduction to the themes of the panel discussion. These findings covered the overall CAR T-cell system and patient journey, current state of CAR T-cell therapy provision, and an analysis of several dimensions of health system readiness in selected countries.

CAR T-cell therapies belong to the category of advanced therapy medicine products (ATMPs). These therapies have significantly expanded treatment options for hematological malignancies such as acute lymphoblastic leukemia (ALL), diffuse large B-cell lymphoma (DLBCL), high grade B-cell lymphoma (HGBCL), primary mediastinal large B-cell lymphoma (PMBCL), mantle cell lymphoma (MCL), follicular lymphoma (FL), and multiple myeloma (MM). CAR T-cell therapies involve modifying T-cells, which are white blood cells that play a crucial role in the immune system. Scientists can program T-cells to identify specific proteins, such as CD19 or B-cell maturation antigen (BCMA), two antigens present on the surface of transformed B-cells at various stages of differentiation. CAR T-cell therapies are considered to be highly successful immunotherapies. They demonstrate notable efficacy in certain relapsed or refractory (R/R) hematological malignancies and are being studied in several other hematological indications and solid tumors, as well as in non-cancer indications such as certain auto-immune or chronic inflammatory diseases.

CAR T-cell therapy provision is complex and requires a coordinated multi-disciplinary team, including physicians, nurses, pharmacists, and other stakeholders, varying by location. Treatment centers can often need infrastructure upgrades, such as ICU expansion for severe adverse events and organizational training. Policymakers play a crucial role in funding and shaping processes. The complexity of reimbursement, administration, and patient care can hinder optimal therapy provision, affecting patient outcomes.[1,2]

An IQVIA analysis of CAR T-cell therapy utilization in Italy, France, Germany, Spain, and the UK showed an increasing trend in LBCL 2L+ R/R CAR T-cell therapy use in 2022–2023, though shares varied by country. France led in 2023 with 30% of patients being treated with CAR T-cell therapy followed by Spain (18%), Germany (17%), the UK (15%), and Italy (11%) . Factors influencing uptake include treatment center availability, referral, and administration processes, and reimbursement dynamics. These variations underscore the need to address barriers and explore solutions for optimal therapy use.

Disparities and overall sub-optimal provision of CAR T-cell therapy utilization can be driven by barriers across several dimensions of the CAR T-cell therapy journey, namely:

- National or regional policy strategies for CAR T-cell therapies, cell and gene therapies, and advanced therapeutics
- Availability of CAR T-cell therapy treatment sites
- Patient identification and referral processes
- Reimbursement and funding of CAR T-cell therapy administration and associated procedures
- Practices for treatment initiation and administration
- Typical short-term and long-term monitoring and data collection

Seven countries — Australia, Canada, Italy, France, Germany, Spain, and the UK — were assessed on these dimensions. For example:

- CAR T-cell treatment sites can be concentrated in certain regions leading to greater need for patient travel, as is the case in Italy.
- Referral process is a major challenge in some countries, such as Italy and Germany, with the lack of standardization leading to delays. Referring physicians across countries report the need for more information about CAR T-cell therapy and associated processes.
- Reimbursement and funding approval timelines can also be an issue, especially when patients are travelling from other regions within a country.
- Capacity issues, such as apheresis slots, ICU beds, staff, and other challenges, remain a concern across all countries.

Along with the approved indications, CAR Ts and other cell-based immunotherapies are being studied in several other hematological and solid tumors as well as in non-cancer indications such as autoimmune diseases.[3] As demand for CAR T-cell therapies increases, there is likely to be increased pressure on the existing health system. Understanding the existing barriers and developing solutions to overcome them is critical to ensure that optimal patient outcomes are achieved.

Disparities and overall sub-optimal provision of CAR T-cell therapy utilization can be driven by barriers across several dimensions of the CAR T-cell therapy journey.

Highlights and calls to action

The panelists agreed with the issues raised in the key findings presentation based on the IQVIA Institute report. In particular, they highlighted several key areas where action is required:

PLAN FOR FUTURE DEMAND AND CAPACITY EXPANSION THROUGH HORIZON SCANNING AND APPROPRIATE INVESTMENTS

CAR T-cell therapy is expanding beyond hematological cancers into autoimmune diseases and potentially solid tumors. This growth will bring new patient populations and healthcare providers into the CAR T ecosystem.

The panelists stated that there is a pressing need to:

- Monitor capacity constraints (e.g., ICU beds, apheresis slots, trained staff)
- Invest in infrastructure and workforce development
- Anticipate future demand across therapy areas

"We are not geared up to face a growing number of patients coming from several different medical fields."

— Christian Chabannon

"If we want to unlock the full power of CAR T-cell therapies, we must build pathways that are as innovative as the therapies themselves. Equity means every patient, no matter who they are or where they live, has a fair chance to benefit. And that only happens if we listen to patients, work together across sectors, and commit to do better, year after year"

— Natacha Bolanos

BUILD A CROSS-STAKEHOLDER ECOSYSTEM FOR SHARED LEARNING

Panelists emphasized the importance of a collaborative, pan-European ecosystem (including clinicians, researchers, regulators, industry, and patient advocates) building on initiatives such as T2EVOLVE and GoCART, which are already fostering practical collaboration and shared learning.

A joint approach by stakeholders should:

- Facilitate knowledge exchange across countries and therapy areas
- Standardize areas of common interest such as referral pathways and data collection across countries, if feasible
- Align on key measures to assess progress in terms of providing CAR T-cell therapy to the right patient in a timely manner
- Support long-term collaboration through sustained funding

In Europe, initiatives such as T2EVOLVE and GoCART are working to address these challenges by building collaborative frameworks that harmonize CAR T-cell therapy data and best practices, facilitating readiness across diverse healthcare systems.

"Too many patients still slip through the cracks because their doctor doesn't have clear information or because the referral process itself is so bureaucratic that it adds unnecessary burden and eats up precious time. Let's make it simple and practical: clear eligibility criteria, user-friendly referral tools, and direct contact points for advice when needed."

— Natacha Bolanos

"We need to learn from each other and recognize that there is no single pathway to access. Instead, multiple temporary solutions must coexist if we are to truly serve patients across different countries and healthcare systems."

— Christian Chabannon

"T2EVOLVE and GoCART are working to establish a core, consensus-driven CAR-T data set across Europe. This initiative is essential for building a foundational backbone to support future learning and promote sustainable advancement in the field."

— Carmen Sanges

"We need to shine a light on the real barriers behind the numbers. It's not just about which regions have certified centres, it's also about social and economic obstacles. It's about families who can't afford to travel or take time off work. It's about people who live far from cities, or who don't know how to navigate the system at all."

— Natacha Bolanos

INTEGRATE PATIENT VOICES AND DATA INTO SYSTEM DESIGN

Panelists noted that patient advocacy groups must be equal partners in shaping CAR T-cell therapy pathways as this can support patient and caregiver decision making and ease their overall burden.

The patient advocate emphasized that patient data should extend beyond patient counts and standard clinical outcomes to capture how patients truly live after undergoing treatment. This necessitates the inclusion of real-world data that reflects long-term outcomes — not just survival rates, but also measures of quality of life.

> *"More than ever, patient advocacy groups need to be an equal partner — and ideally with decision power. These systemic gaps are not just inconveniences — they are life-altering for patients."*
>
> *— Natacha Bolanos*

Key actions discussed by panelists include:

- Incorporating patient-reported outcomes and quality-of-life data
- Supporting patient navigation and education
- Designing systems that reflect real-world patient experiences

DEVELOP AND MAINTAIN DYNAMIC TREATMENT ALGORITHMS

The treatment landscape is evolving rapidly, with bispecific antibodies and other modalities also available along with CAR T-cell therapies.

> *"We are living in a very complex world… we need more resources to offer access to those different treatments and to design appropriate strategies."*
>
> *— Christian Chabannon*

Actions discussed to support decision-making include:

- Develop evidence-based algorithms that reflect current options
- Regularly update them with input from all stakeholders
- Ensure they are accessible to both referring and treating physicians and accessible by patients and their caregivers

INNOVATE TO REDUCE BURDEN AND IMPROVE EFFICIENCY

Best practices such as outpatient monitoring can ease pressure on healthcare systems and should continue to be incorporated where feasible. Changes to the overall pathway should also be considered while these refinements are being made.

> *"We need to identify each critical step that contributes to the vein-to-vein turnaround time or even the brain-to-vein time which is from the moment HCP are thinking of treating patients [with CAR T-cells] to the time when the medicinal product is received and available for infusion at the treating hospital."*
>
> *— Christian Chabannon*

Recommendations discussed include:

- Reassess and redesign the CAR T-cell therapy pathway
- Implement scalable innovations that reduce bottlenecks
- Use digital tools and AI to streamline administrative tasks and communication

> *"We do not have the luxury of wasting that [healthcare professional] capacity on administrative work."*
>
> *— Natacha Bolanos*

SECURE LONG-TERM, MILESTONE-BASED INVESTMENT

Short-term project funding is insufficient to support the scale and complexity of CAR T-cell therapy implementation. Stakeholders — and in particular, country and local governments — need to plan ahead to provide long-term milestone-based funding.

> *"We need to move to collaborative funding frameworks that bring together all stakeholders to assess real-world needs. This starts with national governments committing to long-term investment, so no one's care depends on the postcode lottery of next year's budget."*
>
> *— Natacha Bolanos*

Priorities include:

- Multi-year, milestone-driven funding programs
- Investment in infrastructure, workforce, and data systems
- Support for initiatives like T2EVOLVE and the GoCART Coalition that promote harmonization and sustainability

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3. IQVIA Institute for Human Data Science. Achieving CAR T-cell therapy Health System Readiness: An Assessment of Barriers and Opportunities. March, 2025. Available from www.iqviainstitute.org

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

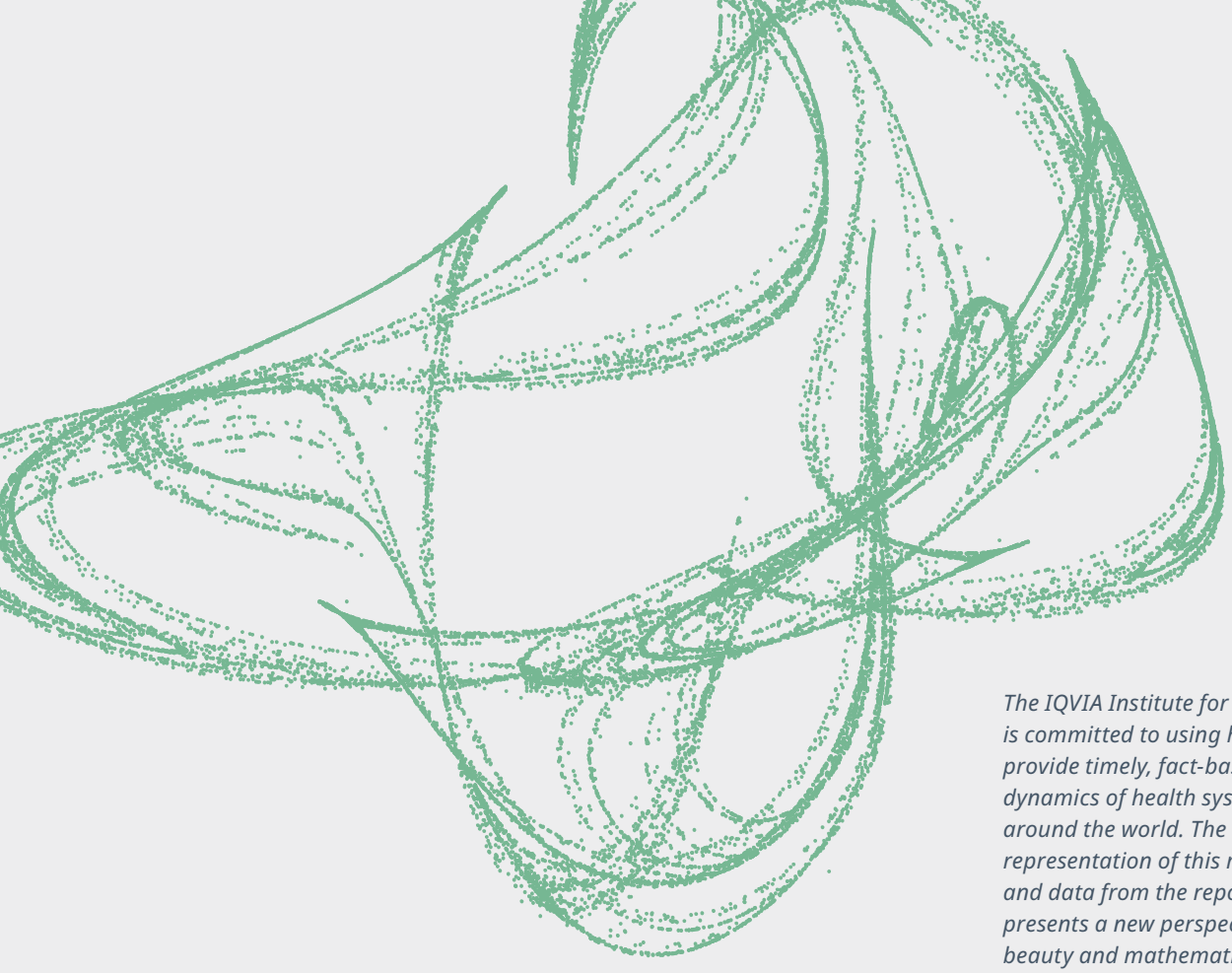
The research agenda for the Institute centers on five areas considered vital to contributing to the advancement of human health globally:

- 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.

The artwork on this report cover is based on the share of patients treated with CAR T-cell therapies in 2022 and 2023 and key referrering and treating provider data on CAR T-cell therapy use.

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