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Unlocking the value of healthcare's Real-World Data in the era of Generative AI

How to capitalize on the dynamic opportunity at the intersection of RWD and GenAI.

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Introduction: Why RWD matters more today

If data-driven healthcare is the future, can companies afford to fall behind?

Healthcare and life sciences (HCLS) organizations are increasingly realizing that the health data they generate has tremendous value. And the benefits of this data are both internal facing, to help better understand patient outcomes and prescriber behavior, and externally enabling, as an asset to support life sciences partners such as biopharma, medical device firms, and artificial intelligence (AI)/machine learning (ML) companies. Several factors are further amplifying the demand for this data, including the emergence and widespread availability of Generative AI (GenAI) models, increasingly complex clinical development programs (e.g., precision medicine), FDA guidance for industry to incorporate Real-World Data (RWD) into regulatory submissions, and shifts towards value-based delivery and payment models.

On the data supply side, investments in infrastructure and interoperability over the last several decades (e.g., electronic health record systems, cloud storage, de-identification tools) have enabled healthcare providers to accumulate a critical mass of high-quality, multi-modal, longitudinal RWD. Early adopters are leveraging this data to drive innovation, improve clinical and operational workflows, and pursue new industry partnerships—creating differentiation from organizations unable to fully embrace data.

At the same time, the rise of GenAI is providing new opportunities for HCLS organizations to analyze and share data insights. Emerging ML, AI, and GenAI applications are shining a light on data quality and reliability—with new models emerging constantly, stakeholders are asking questions about where data is coming from, and what sources can provide the most relevant data. Given a scarcity of high-quality data, companies that collect and organize data efficiently are attracting considerable interest from industry partners and further differentiating themselves from their competitors.

These dynamics are driving more and more HCLS organizations to evaluate how they should transform data strategies during an era of AI-powered technological leaps. The innovators are figuring out how to best leverage RWD to advance patient-centered care initiatives, with a clear focus on uncovering insights that improve outcomes. However, unlocking the full potential of RWD and avoiding common risks require a clear and cohesive approach.

The time is now for healthcare "data generators" to invest in capabilities, infrastructure, and strategies.

The goal of this paper is to assess the emerging impact of GenAI on the RWD landscape and help HCLS organizations unlock the value of their data. Topics include:

01

What is RWD and how can it be best used?

02

Why is health RWD demand increasing?

03

How will emerging AI applications evolve the need for RWD?

04

How can businesses unlock the value behind RWD?

05

How can KPMG help?

01 What is RWD and how can it be best used?

RWD definition and key stakeholders

RWD is a broad term defined as information and measurements collected from various sources outside controlled experiments or trials. RWD, such as consumer purchase histories, traffic patterns, social media user data, and environmental measurements, help organizations across all industries make decisions, innovate, optimize operations, and/or enhance consumer experiences.

Health RWD, encompassing clinical, imaging, molecular, and other data captured throughout the patient care journey, is the focus of this paper. Healthcare providers including health systems, hospitals, physician offices, urgent care clinics, labs, imaging centers, and pharmacies, as well as patients through wearable devices and patient-reported outcomes, are the key generators of health RWD. Life sciences companies (e.g., biopharmaceutical, medical device, diagnostics), AI/ML platforms, and payers account for most of the demand and use cases for health RWD.

Health RWD's wide range of use cases

Clinical data, including patient demographics, provider notes, medications, patient outcomes, and other electronic health record (EHR) information, is the most common type of data used internally by healthcare providers and payers to improve care pathways and value-based care performance. Historically, medical claims data collected from processing billing codes was one of the original sources used for Real-World Evidence (RWE). Today, clinical data encompasses claims data and significantly more information, thanks to EHRs and electronic patient-reported outcomes. Externally, clinical data supports a wide range of applications across product discovery, pre-clinical, clinical development, and commercialization phases for life sciences companies. Additionally, imaging data (both radiology and pathology) and actual images and videos recorded during care delivery are used by providers internally for training healthcare professionals and quality improvement as well as externally for assessing and improving products and treatment approaches. Molecular data includes the structure, function, and interactions of molecules, including genomic, proteomic, and epigenomic data. Molecular data encompasses biomarker tests, such as polymerase chain reaction (PCR) tests for KRAS), sequencing-based tests for germline mutations such as BRCA in oncology, CFTR genetic tests in cystic fibrosis, and other tests for rare genetic diseases.

Multi-modal health RWD that integrates multiple sources of clinical, imaging, and/or molecular data is highly valuable for HCLS organizations and demand is rapidly increasing.

02 Why is health RWD demand increasing?

There are three key drivers increasing global health RWD market demand across the HCLS ecosystem: 1. Technology advancements and clinical decision support (CDS) tools powered by RWD, 2. Greater R&D complexity and regulations, and 3. Precision medicine and treatment personalization.

01 » Technology advancements and CDS tools powered with RWD

Today's CDS tools are at the forefront of integrating health RWD to revolutionize patient care. Over 690 AI/ML-enabled medical devices have been approved by the FDA as of October 2023,[1] and with many more in development, CDS developers and practitioners will continue to drive significant demand for well-curated RWD. This surge in CDS tools allows providers to train professionals and standardize care across diverse healthcare settings, ensuring that patient access to high-quality outcomes is not confined to select academic health systems, further enabling health equity across a variety of care settings. The growing demand for health RWD is rooted in its unparalleled ability to reflect the complexities of real-world clinical scenarios.

In contrast, synthetic data, while useful in certain contexts such as manufacturing and packaging, falls short in consistently capturing complex patterns in real-world interactions and variability in outcomes necessary for optimizing treatment protocols. Health RWD is indispensable for developing effective CDS tools that can adapt to the unique and complex needs of healthcare delivery.

02 » Greater R&D complexity and regulations

The landscape of R&D within HCLS subsectors is becoming increasingly complex. This complexity arises from the need to understand more nuanced patient outcomes, the demand for innovative treatments, and regulatory requirements safeguarding product safety and efficacy. Health RWD supports these complex R&D processes, and demand continues to increase for biopharmaceutical companies and medical device manufacturers as they seek to speed up development processes, improve the efficiency of clinical trials, and assess efficacy of interventions in the post-approval setting to ensure cost effectiveness and value. Furthermore, regulatory bodies worldwide are recognizing the value of RWD, and there is a shift towards the acceptance of RWD in regulatory submissions for drug approval and post-market surveillance, particularly in the development of novel therapeutics for orphan conditions. This shift is evident in the FDA's framework for evaluating the use of RWD and RWE to support regulatory decision-making.[2] As regulations evolve to accommodate RWD, an increase in demand and use cases across the R&D lifecycle, from early-stage research to post-market studies, is expected.

[1] Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices, U.S, Food and Drugs Administration, (May 13, 2024)

[2] Real-World Evidence, U.S, Food and Drugs Administration, (May 02, 2023)

03» Precision medicine and treatment personalization

As patient care continues to shift away from a "one-size-fits-all" approach toward precision medicine, health RWD will continue to be used to identify patterns that inform treatment decisions at the individual level. As treatment plans in the future become highly personalized, based on a patient's genetics, lifestyle, and environment, the already high demand will grow for multi-modal health RWD. Originally, precision medicine was based on tailing dosage of therapeutics based on a patient's weight. As precision medicine matured, it became more common to tailor therapeutics based on prior therapeutics that failed, such as changing treatments approaches for a cancer patient post-chemotherapy. As precision medicine continued to evolve, treatments were based on a single biomarker (e.g., HER2). Today, precision medicine is using multi-model data to account for more factors, including patient demographics, prior lines of therapy, protein expression levels, clinical pathology, multiple DNA-based biomarkers, pharmacogenomics, and even gene expression.

03 How will emerging AI applications evolve the need for health RWD?

Impact of AI on healthcare delivery

The advent of AI in healthcare delivery is changing the way clinicians diagnose, treat, and monitor patients, by helping understand patterns that cannot be seen with the naked eye, linking data that historically couldn't be linked before. Healthcare organizations (HCOs) are not only consumers of AI-informed healthcare delivery tools, such as clinical decision support agents and AI-guided radiology tools, but also are in the business of developing these tools themselves to maximize performance within their four walls, and potentially beyond them.

As the volume of AI applications in healthcare continues to grow, the need for high-quality RWD to inform hypotheses, validate algorithmic quality, and continue to improve performance will only increase.

The volume of data required is increasing in order to satisfy the needs for this explosion in AI applications, but the types of data modalities required to inform novel algorithms are also increasing. While 75% of FDA approvals for AI/ML-enabled medical devices have been in radiology to date (531 total), we are seeing increased R&D in areas such as pathology images, DNA-based analysis, biosensors, and care pathway intelligence platforms, highlighting the expanding reach of these technologies and the potential for a wider range of HCOs to contribute valuable real-world data.[3]

Impact of life sciences applications

If we consider AI applications in healthcare delivery as one use-case for AI, pharmaceutical manufacturers and biotech companies (collectively, biopharma) have their own independent initiatives to discover, develop, and commercialize therapeutic assets leveraging AI.

However, for different use cases across the continuum, each AI application is powered by its own set of data to draw inferences and recognize patterns. As such, the AI applications for identifying novel drug targets, or stratifying patients that are more or less likely to respond to a drug, are only as powerful as the core, underlying data.

[3] Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices, U.S, Food and Drugs Administration, (May 13, 2024)

High-quality RWD needed, even amidst GenAI boom

For healthcare, biopharma, and medical device AI applications, the fuel that powers algorithms is real, well-curated, actual patient data. This data is not without its challenges—data is often missing, it may live in silos, it may live in different systems—but to draw clinical-grade conclusions, it is important that the foundation of these models is actual patient data.

For this reason, even amidst the rise of GenAI applications in healthcare and life sciences, the need for RWD is getting even stronger. As GenAI tools enable summation of information and exponential increases in data processing speed, often they produce "hallucinations" (i.e., outcomes not actually existing in the data). When placed within the scope of health data, these hallucinations may represent patient outcomes that did not take place, rendering clinical AI applications unusable. There are myriad excellent use cases for GenAI applications across healthcare and life sciences, but when it comes to developing clinical-grade AI tools, RWD and conventional AI/ML have a stronger foothold and are poised to continue to expand, without significant risk of displacement for GenAI models.

What does the shifting technology/ GenAI landscape mean?

As the need for RWD to power AI applications continues to increase, both for HCOs and for life sciences partners, many organizations are implementing strategies and tactics to maximize the value of their data. And as AI continues to enter the zeitgeist for corporate initiatives across HCLS, it becomes more difficult to ignore.

This means that the HCOs themselves that manage patient interactions—whether a hospital, pharmacy, distributor, insurance company, pharmacy benefit manager (PBM), home health provider, or other care setting—are now implementing measures to better curate and prepare their data for downstream uses, both within their care center and externally.

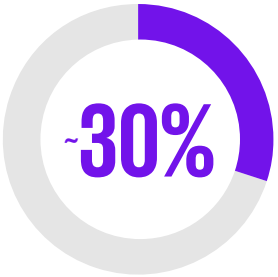
From a RWD demand perspective, customer appetite is increasing, but scrutiny and savviness is increasing accordingly as more RWD options become available. There are additional questions being raised by customers around appropriate patient representation within the data (e.g., age, race, demographic factors, geographic location), consistency in data capture, ease of manipulation, and confidence that data will be viewed as appropriate in nature when dealing with state and federal regulators.

04 How can businesses unlock the value behind RWD?

Believing the hype around RWD opportunities

An enormous amount of HCLS data is being generated. Approximately 30 percent of the world's data volume is generated by the HCLS industry, and the amount of HCLS data is increasing by 36 percent per year.[4] This includes large quantities of longitudinal and tokenized text, images, audio, and video, across an expanding range of data modalities (e.g., radiology, labs, genomics, wearables). The average hospital alone is now generating over 50 petabytes of data annually.[5]

However, as much as 95 percent of data generated by hospitals remains unstructured and goes unused, highlighting the opportunity for HCOs to better deploy RWD towards optimizing care management decisions and making more intelligent business decisions.[6] And with the democratization of high-quality GenAI tools unlocking new avenues for analyzing data, it has become increasingly critical for HCOs to understand the types of data they are generating, the value of this data, and how it is currently being used versus how it could be deployed both internally and externally.



of the world's data volume is generated by the HCLS industry

Determining the benefits of investing in RWD capabilities

As more HCOs look to capitalize on their data, one of the first questions that tends to be asked is, *"What exactly would the payback be and is it 'worth it' given the potential risks?"* While the specific benefits will vary across each HCO, the ability to clearly identify and communicate these benefits to key decision makers remains a key springboard in many organizations' RWD journey.

The benefits of a comprehensive RWD strategy are multifaceted, and include:

Clinical excellence

Delivering exceptional, decentralized patient care is often the primary driver for HCOs to develop RWD capabilities, and a way to gather internal alignment around what guiding principles should be. Quality of care can be enhanced through robust AI-supported data analytics, monitoring long-term patient outcomes beyond the clinic, and the introduction of new scientific discoveries powered by RWD, as examples.

[4] The healthcare data explosion, RBC Capital Markets, Greg Wiederrecht, Ph.D., Andrew Callaway

[5] Hospitals only use 3% of data, Microsoft says, Becker's Healthcare, Giles Bruce, (October 18, 2023)

[6] Managing Unstructured Big Data in Healthcare System, National Library of Medicine, Hyoun-Joong Kong, (January 31, 2019)

Prestige and rankings

Developing a formal RWD roadmap strengthens industry partnerships and fosters new types of collaboration models such as co-development and data sharing. HCOs investing in GenAI and RWD are positioning themselves at the forefront of cutting-edge research, which helps recruit world-class physicians and scientists and maximize research grant funding. This, in turn, generates new opportunities for publications and press releases, optimizing collaboration across departments of the organization. Early adopters have achieved tangible differentiation from competitors while laggards may risk extinction.

Financial opportunities

While quantifying the full value captured through data can be challenging given the far-reaching impact, RWD unlocks revenue streams beyond traditional clinical means. Potential benefits include licensing deals, spinouts, optimized value-based care performance, cost reductions through automation, increased patient volumes into the HCO (e.g., via reputational gains), and accelerated clinical trial enrollment.

Setting course on the RWD journey

HCOs are no strangers to the hurdles of project approvals and go-to-market (GTM) planning. Many have witnessed promising initiatives falter due to a lack of structure from the outset. The intersection of RWD and GenAI presents exciting possibilities, but the market is a whirlwind of rapid evolution and increasing competition. This dynamic landscape demands a thoughtful and forward-looking approach from HCOs to effectively leverage RWD.

KPMG has worked with a variety of HCOs to craft tailored RWD strategies that optimize value capture and accelerate GTM capabilities. Our demonstrated approach helps HCOs secure buy-in effectively, establish guiding principles, bridge departmental divides, and help maximize operational efficiencies.

A successful roadmap will look different for every organization. However, several common themes tend to exist across HCOs embarking on RWD initiatives, summarized in these three steps:

Step 1: Establish RWD vision and gather internal alignment

RWD success hinges on vision and alignment—do not underestimate the importance of Step 1. Without a clear vision for RWD and buy-in from all stakeholders, your goals could quickly fizzle. Key considerations include:

Establishing the north star:
Establishing the tenets that will determine how data opportunities are evaluated and pursued, and creating specific guardrails for RWD partnerships, helps set the overall direction for RWD initiatives and keep teams progressing towards a common goal.

Designing data infrastructure, governance, and manipulation:
At the onset, HCOs should determine key data decision-makers, establish clear governance processes, map existing data management projects and systems, and define roles and accountabilities for all stakeholders involved in RWD activities.

Achieving executive and cross-functional buy-in:
Failing to secure full leadership buy-in around RWD sharing models, and/or effectively socializing guiding principles with cross-functional stakeholders involved in execution, can delay RWD projects.

Step 2: Uncover data strengths and gaps

An internal data assessment can take on many forms, but generally involves determining what assets exist internally and which infrastructure gaps need to be addressed to enhance RWD assets.

Data asset inventory:
Compiling a comprehensive inventory of data assets across departments, modalities, therapeutic areas, and customer channels is critical to understanding areas of strength and relative differentiation. It is also foundational for shaping a GTM approach.

Technical data systems inventory:
Determine which on-premises and cloud-based storage systems exist to store and manage data, plus which systems are used to de-identify the data and enable physician researchers to understand data today. This serves as the starting point to evaluate investments necessary to support a robust health RWD capability.

Risk evaluation and mitigation plan:
This is essential before data sharing to protect patient privacy, ensure data security, and avoid potential legal or financial repercussions.

Gap assessment and infrastructure needs:
Evaluating "build" versus "partner" versus "buy" decisions across infrastructure gaps ensures sufficient technical capacity and processes to securely manage RWD partnerships. This also allows for efficient scaling of commercial efforts.

Step 3: Develop roadmap for execution

The final part of formalizing a RWD strategy involves development of a roadmap and setting near- and long-term objectives (both non-financial and financial). Key considerations include:

Differentiation and market positioning:
Prioritize different data sharing models, customer channels, and distribution frameworks based on areas of differentiation, organizational right to win, and market attractiveness of different RWD opportunities.

Operating model:
To execute on RWD opportunities, changes to existing operating models are likely needed, with the ultimate goal of "adopting a commercial mindset."

KPIs/performance evaluation:
Develop financial projections, key performance indicators (KPIs), and metrics to monitor performance with ample flexibility to adapt with the strategic direction long-term.

Don't let a lack of planning hinder your progress.

KPMG can help you navigate strategic business planning with confidence and embark on a successful RWD journey.

This content outlines initial considerations meriting further consultation with life sciences organizations, healthcare organizations, clinicians, and legal advisors to explore feasibility and risks.

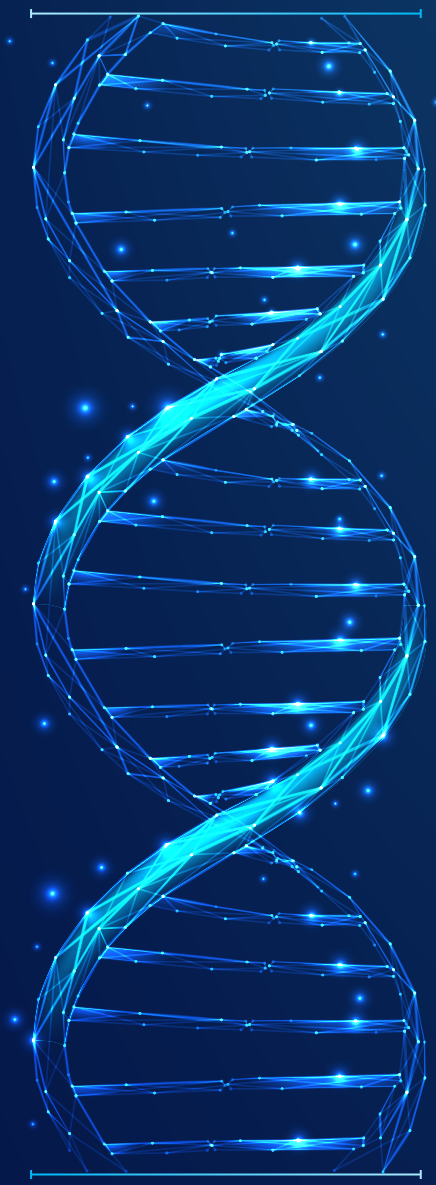
05 How KPMG can help

Our firm is well positioned to assist companies across the HCLS landscape, leveraging our strategic partnerships and insights into how GenAI is poised to revolutionize RWD. Through the various services summarized below, we have helped guide clients in navigating the complex realm of RWD, identifying trends, assessing potential impacts, and developing strategies to capitalize on opportunities and threats driven by the emergence of GenAI.

Strategic advisory
helps clients develop their overall GenAI in RWD strategies by identifying trends, assessing how these trends could impact their business, and helping the client develop business plans to capitalize on these trends.

Commercial due diligence
included the evaluation of a target company's market position, business model, customer relationships, and growth prospects.

Integration planning and post-merger integration
happens after a deal is completed and involves helping a client integrate the acquired company or assets emphasizing the seamless integration of technologies, including GenAI. This could involve identifying potential synergies, developing an integration plan, or helping manage the integration process.



Deal sourcing and evaluation
to identify potential acquisition, partnership, and product licensing opportunities specifically within the intersection of RWD and generative AI. Factors taken into account include market positioning, portfolio synergies, financial projections, alignment with advanced generative AI initiatives, and anticipated return on investment.

Market and competitive intelligence
involves continuous monitoring of advancements in generative AI, including implications on the RWD landscape. Provides clients with insights on evolving market trends, competition adaptation to GenAI in RWD, regulatory shifts influenced by GenAI advancements, and other pivotal dynamics shaping their business environment.

Lighthouse & data analytics
help clients to create the infrastructure and technological tools to bring new capabilities to market and implement data strategies efficiently.

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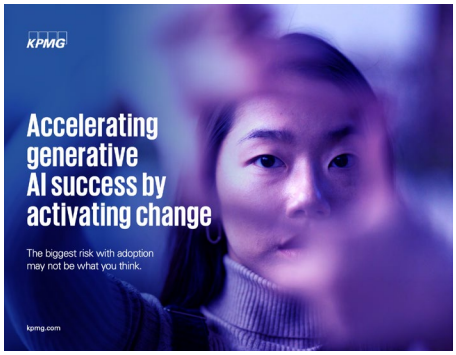

Accelerating generative AI success by activating change

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