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Real-world evidence and Generative AI: A powerful platform for innovation

2025 RWE BENCHMARK SURVEY

Converge™
by Deloitte

Executive summary

Our latest survey of senior pharmaceutical leaders reveals a striking consensus: real-world evidence (RWE) is no longer a "nice to have"—it's a strategic imperative. At the same time, Generative AI (GenAI) is emerging as a powerful catalyst, transforming aspects of RWE planning, execution and dissemination.

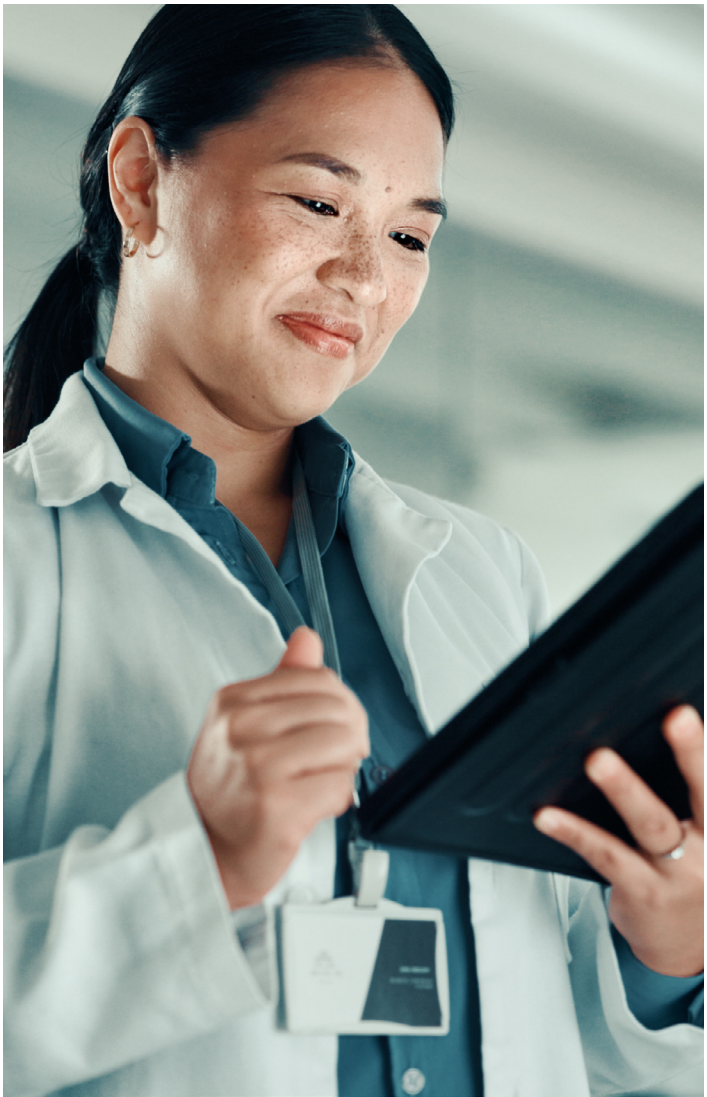
Deloitte has been at the forefront of modernizing biopharma's capabilities and scaling the use of RWE across the industry. We've periodically surveyed pharma executives since 2017 to understand the level of strategic importance, current state of capabilities, emerging trends, investments and use of real-world data (RWD) and RWE.

Today, the integration of RWD and RWE is increasingly critical to support regulatory acceptance, market access and reimbursement, clinical development, safety and competitive differentiation. While the value of RWE is widely accepted across the industry, quantifying its return on investment (ROI) remains elusive—not because the impact isn't real, but because it's often indirect, long-term, and difficult to isolate.

Without a clear framework for measuring ROI of RWE, organizations may struggle with the next great opportunity heading their way: harnessing the unprecedented power of GenAI, which will demand even greater clarity on value. The excitement around GenAI is palpable, yet companies with ambitious plans for it will need to have clear strategies, defined goals, and capabilities to measure impact—all before scaling investments.

Considering this upcoming inflection point, Deloitte surveyed executives from 25 global biopharma companies to gather their perspectives on the current and future state of RWD/E and the impact of GenAI in their organizations.

We are seeing a diversification of RWE applications where the most value is realized today, which suggests a growing maturity of capabilities across the biopharma value chain. Despite widespread adoption of RWD/E, leaders remain uncertain about their ability to measure the tangible ROI and are seeking more meaningful ways to capture its impact.



KEY STATISTICS:

96%
of biopharma companies believe RWD/E is very important or critical to their organizational strategy.

80%
of participants agree or strongly agree that GenAI will have a transformative impact on RWE generation in the next 12 months.

40%
of C-suite leaders consistently discuss RWD/E within their organization.

SURVEYED IMPACTS:

56%
Reducing costs and timelines

44%
Increasing efficiency and productivity

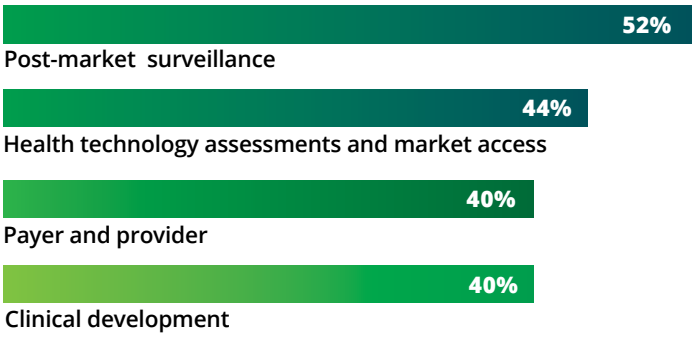
96%
of organizations will continue to invest in RWD/E over the next two to three years, in part to prepare for agentic AI.

Real-world evidence: An increasingly mature, embedded capability

Real-world evidence is derived from real-world data, a constellation of data sources that exist outside the controlled environment of clinical trials. RWD has evolved significantly, from traditional sources such as electronic health records (EHR) and claims data to a growing array of multimodal sources, such as genomics, digital health/wearables data, patient-generated health data, and social determinants of health data (SDoH). These diverse data types are increasingly linked to providing a more comprehensive and longitudinal view of the patient that cannot typically be gleaned from clinical trials alone.

Biopharma companies have come to widely recognize the strategic value of RWE. Survey participants were asked to select the top two areas where they see the most value from RWE today.

SURVEY RESPONSES WERE DIVERSIFIED ACROSS:



The diversification of RWE applications suggests a growing maturity of RWE capabilities across the biopharma value chain. Companies are planning to build on this foundation with additional investments as they prepare for the next phase of AI-enabled evidence generation to help them increase efficiency and productivity, reduce costs and timelines, and maximize the impact of RWE.

Over the next two to three years, 96% of respondents said they expect a moderate or significant increase in RWD/E investments.

CAPABILITIES THAT WERE CITED TO BE VERY IMPORTANT OR CRITICAL INCLUDE:

- **RWE study management systems:** Tools to manage and track the entire RWE generation process, from research concept to publication, dissemination and impact.
- **Advanced analytics and GenAI:** Utilization of AI tools, including GenAI to enhance analysis and interpretation of RWD.
- **Data linkage via tokenization:** Techniques to securely link data from different sources using tokenization.
- **RWE knowledge management systems:** Platforms to organize, store, and retrieve knowledge generated from RWE activities (e.g., inventory of RWD, inventory of RWE studies that have been executed, etc.).

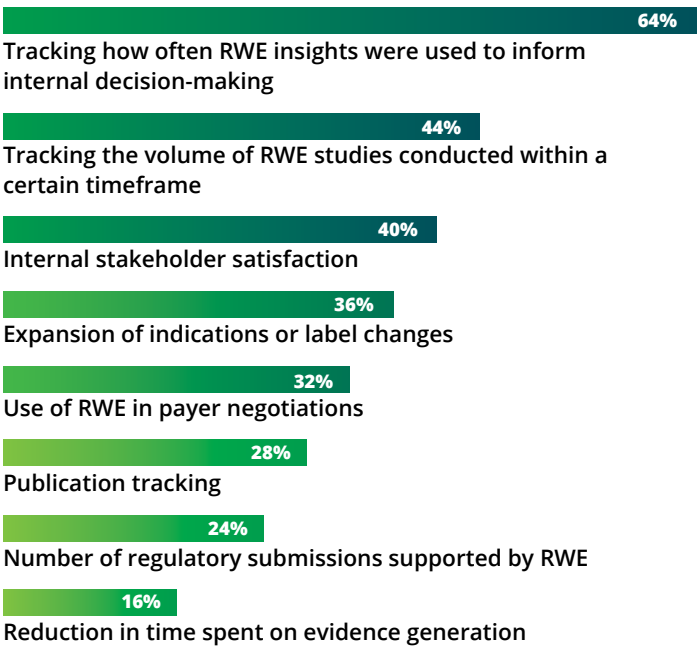
With the widespread adoption of RWE, continued investment, and preparation for the next wave of innovation powered by GenAI, it's increasingly important to measure RWE's impact and clearly articulate its value.

Answering the multi-million-dollar question: How to measure ROI of RWE

While the strategic value of RWE across the product lifecycle—from early development through commercialization—is widely recognized, accurately quantifying its ROI remains a complex challenge. Unlike traditional R&D investments that are tied to discrete milestones or financial metrics, RWE generates impact in more diffuse and interdependent ways. Its contributions—such as supporting regulatory decisions, informing trial design, accelerating market access, and strengthening payer negotiations often unfold over extended timeframes and are shared across multiple functions. Moreover, RWE can indirectly prevent costly missteps or shape long-term portfolio strategy, benefits that are difficult to isolate and attribute in financial terms. The lack of standardized methodologies, cross-functional silos, and inconsistent tracking of downstream outcomes further complicate efforts to measure ROI. As a result, while RWE clearly drives value, organizations often struggle to build a clear narrative linking RWE investments to measurable business outcomes.

There was little consensus between survey participants as to how to track ROI of their RWE capability. Strategies for measuring ROI run the gamut from quantitative to qualitative approaches.

THE MOST COMMONLY USED METHODS FOR MEASURING ROI:



The survey revealed misalignment between what's measured and what is most meaningful. For example, we also asked survey participants which methods would be the 'most effective' approach to measuring the ROI of RWE. While many respondents believe label expansion is a strong indicator of RWE's value (40%) as well as tracking the use in successful payer negotiations (40%), few currently use these metrics to measure ROI.

The discrepancies may result in underestimating RWE's impact and missed opportunities to align with strategic goals.

TO SHIFT TOWARDS MORE OUTCOME-ORIENTED VALUE TRACKING, ORGANIZATIONS SHOULD:

Develop systems to track the portfolio of RWE activities
At many organizations, RWE generation occurs in siloes, making it challenging to accurately monitor RWE activities across functions. Creating systems that track RWE studies and analyses, their intended use vs. actual use, cost and observed benefits (e.g., successful regulatory approval, positive access decision) is foundational to more precisely measuring ROI.

Develop an RWE value framework
Creating an RWE value framework that aligns with the stages of drug development and commercialization can help frame the value and ROI of RWE. It can assist leaders in making more informed decisions on future investments in RWE. These frameworks create a common language for discussing the value of RWE across the enterprise.

Align on key performance indicators (KPI) and metrics
Gaining alignment on KPIs and value metrics tied to RWE use cases is critical because it creates a shared understanding of what success looks like. They create a common language across functions to track performance and outcomes. These can be quantitative (e.g., cost and time savings, faster patient enrollment) and qualitative (e.g., internal stakeholder satisfaction, external stakeholder sentiment).

Companies will need to take a more comprehensive and systematic approach to measuring ROI that aligns with high-priority business goals, especially as new technologies like GenAI bring added complexity to the challenge of accurately accounting for the value of RWE across the biopharma ecosystem.

The transformative impact of GenAI on RWE

GenAI is a class of artificial intelligence models that can generate new content from massive volumes of structured and unstructured data. In the context of RWE, GenAI is already being piloted to draft abstracts, summarize study reports, support literature reviews, accelerate the analysis of RWD, and improve data ingestion and quality assessments

The advent of GenAI is creating a surge of optimism across the biopharma industry, particularly in the realm of RWE. As the demand for RWE continues to grow and companies are asked to do more with less, GenAI is emerging as a powerful enabler. In our survey, 80% of respondents agree or strongly agree that GenAI will transform how RWE is generated within the next year. This strong consensus underscores the belief that GenAI is not just a passing trend, but a catalyst for a new era of RWE—one marked by greater speed, scale, and scientific sophistication.

THE MOST PROMISING GENAI USE CASES EMERGING FROM THE SURVEY INCLUDE:

76% **believe GenAI will accelerate the analysis of RWD**

48% **anticipate they will use GenAI to automate the summary of real-world findings**

44% **stated they will use GenAI to support literature summarization**

GenAI can offer numerous benefits to a biopharma company through increased efficiencies, cost reduction, improved decision-making and enhanced experience for employees. Specific to RWE, the rewards could be significant, with leaders expecting to realize value through reduced costs and timelines (56%) and increased efficiency and productivity (44%). While the industry has spent the last two years on the GenAI learning curve—understanding what GenAI is and how it works and getting hands-on experience—we are now entering the stage of integrating it into daily workflows, ultimately scaling it.

Barriers to adoption: Talent, trust and technical complexity

Despite the promise, adoption of GenAI across the RWE landscape is not without its challenges.

WHEN ASKED ABOUT THE TOP BARRIERS PREVENTING BROADER USE OF GENAI, LEADERS CITED FOUR MAIN AREAS:

27% Data privacy and security

GenAI models are trained on massive amounts of data, which could present risks related to inadvertently revealing sensitive information and other potential compliance issues.

23% Model explainability and regulatory acceptance

To make safe, trustworthy and ethical decisions based on AI output, humans must be able to understand and verify the logic behind GenAI's decision-making. While there are emerging methods for opening the "black boxes" of GenAI models, companies may be wary of adopting technologies that aren't immediately transparent and explicable, especially when they plan to use the results for regulatory purposes. Agencies are currently working with industry to set guardrails for the use of GenAI in submissions, but the process is ongoing and uncertainty around expectations or requirements may slow adoption.

25% Lack of specialized resources

There is a limited pool of resources who have deep knowledge of GenAI coupled with RWE expertise. This hybrid skillset is critical, but hard to find today.

19% Integration with existing systems and workflows

Even when models perform well in isolation, embedding them into everyday ways of working is a challenge. Companies will need to consider issues of interoperability, scalability, and employee experience as they modernize workflows and upskill their teams.

Because of these challenges, a relatively limited number of respondents (17%) are taking a "wait and see" approach to GenAI and are less likely to adopt new capabilities until the technical and regulatory landscape mature sufficiently.

The shift from experimentation to execution

Piloting GenAI creates buzz, but scaling creates value. Companies are beginning to move from pilot projects to more deliberate investments in infrastructure, talent and scaling.

AMONG THOSE SURVEYED:

25% **are actively using GenAI to generate summaries, reports and publications**

23% **are building capabilities to analyze RWD using GenAI**

17% **are investing in internal training and capability building**

These early adopters are laying the foundation for broader organizational adoption by starting to embed GenAI into daily workflows, upskilling their teams and systematically monitoring and measuring the impact.

A path to the future of RWE for biopharma

RWD/E has evolved from emerging capabilities to core enablers of how biopharma companies discover, develop and commercialize their medicines. As regulatory expectations shift, payer demands intensify, and the pace of science accelerates, the ability to generate credible, high-quality RWE is no longer optional—it is essential.

At the same time, GenAI is creating a new way of how evidence is created, synthesized and applied. The convergence of RWE and GenAI offers a rare opportunity to modernize RWE generation, further enhance internal decision-making and unlock new sources of value across the product life cycle. However, realizing its potential requires more than the buzz.

IT REQUIRES A MULTI-FACETED APPROACH:

- **Develop a strategic blueprint:** The question is no longer if or when to scale GenAI, but how extensively to apply it. Defining the organization's ambition for the use of GenAI for RWE and anchor investments to these goals is an important first step.
- **Plan for scale:** Many biopharma companies have already invested in GenAI platforms internally. These should be leveraged, when possible, to ensure scalability and reuse of existing investments. RWE-specific GenAI applications require highly tuned models that should be incorporated into your GenAI ecosystem. Avoiding point solutions will improve scalability.
- **Measure and realize value:** Systematically measure outcomes and ROI of your GenAI investments and clearly articulate the impact.
- **Foster responsible AI use:** Embed trust, transparency, traceability and ethical use into all aspects of your GenAI workflows.
- **Build GenAI fluency:** Equip teams with the necessary trainings and tools needed to embed these capabilities at scale.

The future of RWE generation will be faster, smarter and more connected—and forward-thinking organizations are moving decisively to maximize its value.

Research methodology

Between November and December of 2024, Deloitte conducted its fifth RWE Benchmarking study, surveying executives from 25 biopharma companies across the globe to benchmark their organizations' RWD/E aspirations, investments, capabilities, use cases, and impact of GenAI on their RWD/E capabilities.

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