

WHITE PAPER

Thriving in Uncertainty: How Real-World Data Powers Life Sciences Resilience

The life sciences industry has always been complex, but today's environment is uniquely unstable. Regulatory divergence, pricing reform, AI disruption, and shifting consumer expectations are reshaping the industry.

In fact, 40-60% of recent pharmaceutical launches have underperformed financially¹, underscoring the need for data-driven strategies and faster feedback loops.

Real-world data (RWD) in healthcare is the foundation for success in research. When used effectively, it enables companies to anticipate policy shifts, personalize engagement, defend product value, and accelerate innovation.

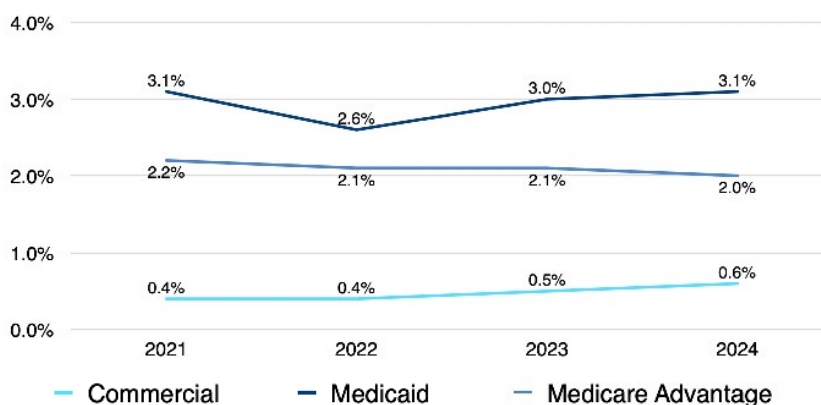
Understanding the Forces of Uncertainty

Drivers of uncertainty fall into four key domains: policy and regulatory shifts, market fragmentation and access limitation, technology acceleration and data complexity, and consumer behavior and societal shifts. These areas overlap and intensify one another, creating a cycle of disruption that requires proactive, data-powered responses.

Policy and regulatory shifts

Regulatory dynamics are in flux at every level. FDA staffing disruption and delayed guidance for AI and [devices](#) create unpredictability in review timelines. Additionally, legislative moves, such as potential cuts to opioid recovery programs or reinstatement of the “Most Favored Nation” drug pricing policy, threaten both patient outcomes and innovation incentives.

Figure 1: Percent of Individuals with Opioid Use Disorder Diagnosis, by Payer and Year



1. “Drug launches reflect overall company performance,” Deloitte, August 25, 2023, <https://www.deloitte.com/us/en/insights/industry/health-care/key-factors-for-successful-drug-launch.html>

Rates of [opioid use disorder](#) (OUD) diagnosis are consistently higher among Medicaid (2.6–3.1%) and Medicare Advantage (MA) (2.0–2.2%) populations compared to the commercially insured population (0.4–0.6%). Given this higher prevalence among government-insured groups, legislative cuts to opioid recovery programs would disproportionately impact Medicaid and Medicare beneficiaries – populations already at greater risk and more reliant on public coverage for treatment access compared to commercially insured groups.

Meanwhile, investor and societal expectations regarding environmental, social, and governance (ESG) frameworks, particularly clinical trial diversity and sustainability, are adding further complexity, emphasizing the continued priority on compliance.

Market fragmentation and access pressures

Market access has become increasingly disorganized. Biosimilar competition and patent expiries are accelerating portfolio pressures, while proposed import tariffs of up to 200% could raise manufacturing costs and limit availability². Supply chain fragility adds another layer of risk, with raw material shortages and geopolitical tensions threatening continuity.

To [manage these pressures](#), companies need to understand patient access down to the local community level, have adaptable pricing strategies, and receive real-time visibility into payer dynamics – all supported by robust RWD.

Technology acceleration and data complexity

Rapid advancement of AI and digital health technologies holds transformative potential for the healthcare industry. However, regulatory oversight has struggled to keep pace. Initiatives like the FDA's [cdERGPT](#), an AI-based drug review pilot, represents progress, yet they also underscore lingering uncertainties related to validation standards, accountability, and liability.

At the same time, cybersecurity vulnerabilities continue to expose critical weaknesses in the healthcare system. [High profile incidents](#) compromised the data of up to 190 million individuals and inflicted severe financial strain on the healthcare system. Similarly, the attack on Episource exposed the data of over five million people including health insurance details (plans, policies, member/group IDs, and government payor IDs), medical information (records, diagnoses, medications, test results, images, and treatments), and personal identifiers such as birth dates and Social Security numbers.

Compounding these risks is the exponential growth of healthcare data from EHRs, claims, and pharmacy records, social drivers of health (SDOH), genomic, and device-generated data. Without effective harmonization, this data deluge risks leading to “insight paralysis,” where the sheer volume and fragmentation of information hinder timely, actionable decision-making.

2. “US tariffs: What’s the impact on global trade and the economy?” J.P.Morgan, August 11, 2025, <https://www.jpmorgan.com/insights/global-research/current-events/us-tariffs>

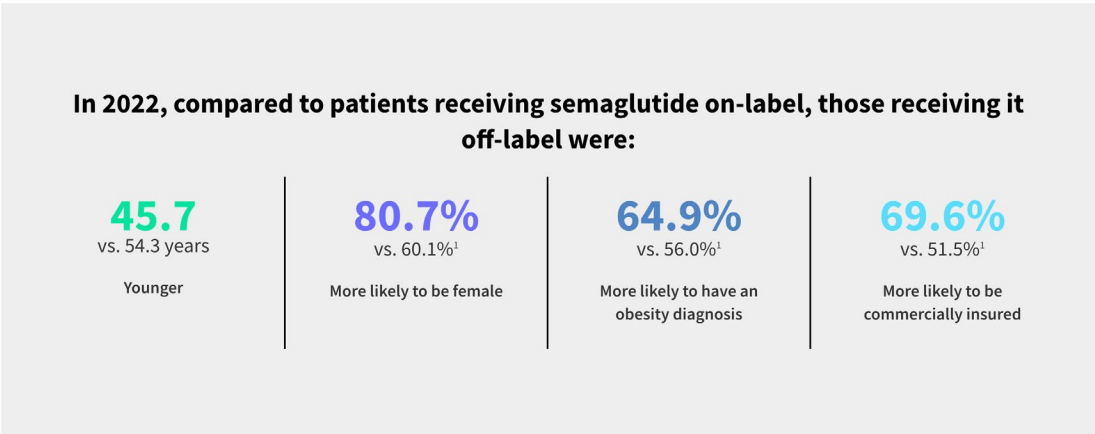
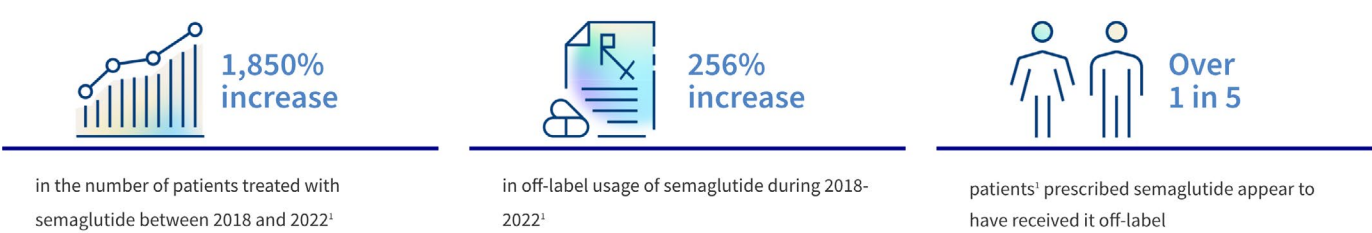
Consumer behavior and societal shifts

Consumer-driven healthcare is redefining expectations. Direct-to-consumer platforms offer convenience and rapid feedback to consumers, while blurring traditional care pathways. This shift raises new regulatory and reputational risks, such as off-label utilization that companies may not anticipate through conventional channels.

Data from 2022–2023



Key Insights from 2018–2022



The rapid expansion of telehealth and direct-to-consumer care models has reshaped patient demand, likely contributing to rising off-label GLP-1 use. These shifts have accelerated adoption patterns that drug manufacturers may not have anticipated, with younger, commercially insured, and predominantly female patients driving much of the increase.

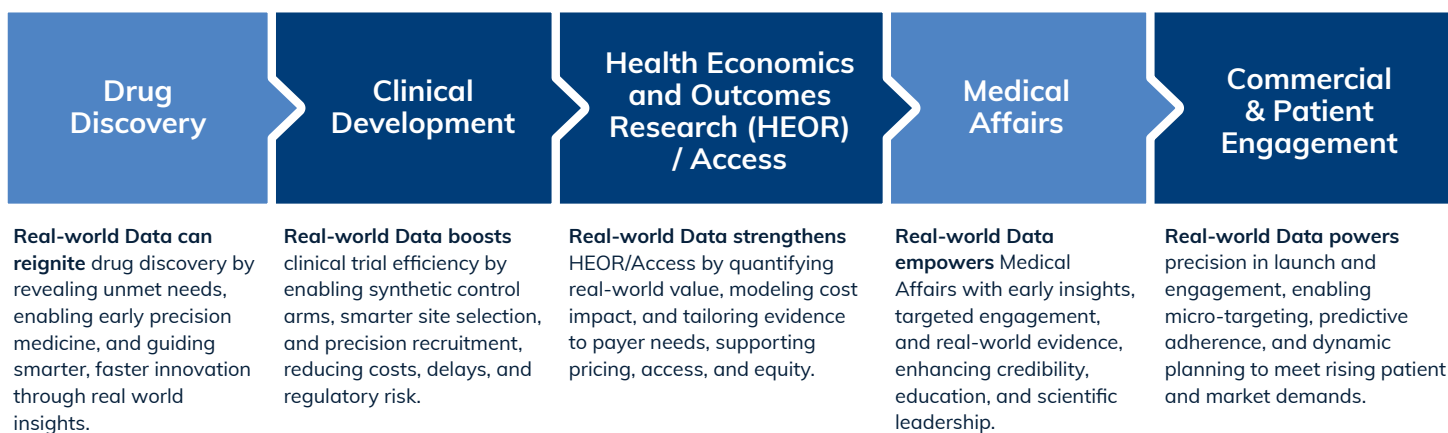
Generational diversity further complicates engagement. Younger cohorts demand seamless digital experiences and subscription-based care, while older cohorts rely on traditional provider-driven models. Internally, workforces spanning four generations bring differing expectations for culture and flexibility, adding another dimension of organizational complexity.

A Converging Challenge

These domains – policy, access, technology, and society – do not operate in isolation. A cybersecurity breach can stall digital trials, regulatory shifts can destabilize pricing models, consumer demands can undermine traditional engagement, and strategic resilience requires data-powered agility.

The following sections will explore how RWD, powered by claims, EHR, specialty pharmacy, and SDOH, can act as both a lens to anticipate disruption and a lever to respond effectively.

Strategic Responses Across the Life Sciences Value Chain



Clinical Development Deep Dive

Regulatory volatility, rising development costs, and persistent enrollment delays continue to challenge trial success. More than 11% of trial sites fail to enroll any patients³, and 55% of trials miss their enrollment targets⁴, delaying critical therapies and increasing costs. Lack of real-time visibility into site performance compounds these issues. Sponsors often cannot track progress or identify bottlenecks quickly, and fragmented IT systems disrupt collaboration between trial sites and sponsors.

Real-world data in healthcare helps overcome these challenges. Synthetic control arms built from claims and EMR data could potentially reduce reliance on placebo groups. Real-world care pathways inform protocol design, hybrid trial models, and site selection. Sponsors can also pre-screen trial-eligible populations with claims and EHR data, improving recruitment accuracy and accelerating enrollment. This data-driven approach streamlines development and increases the likelihood of regulatory and commercial success.⁶

Inovalon's [Clinical Research Patient Finder™](#) speeds up trial enrollment by scanning EHRs directly at research sites, automating bulk pre-screening without compromising patient privacy. This reduces site burden, shortens enrollment timelines, and boosts diversity by surfacing patients who might otherwise be missed.

Looking forward, the next frontier is an intelligent clinical trial platform that integrates open and closed claims, EHR, and SDOH data. The platform could offer AI-powered modules to support every phase of the trial lifecycle:

- **The intelligent protocol design module:** analyze comorbidities, refine inclusion/exclusion criteria, predict feasibility, and minimize patient burden.
- **The smart site selection and optimization module:** profile and rank sites, run diversity gap analyses, and generate AI-driven recommendations.
- **Patient engagement and retention:** personalize patient journeys, identify barriers such as transportation or cost, and use real-time sentiment analysis to support retention.

3. "Benchmarking Site Activation and Patient Enrollment," Lambert, M.J., Dirks, A., Kikuchi, N. et al., Ther Innov Regul Sci, April 3, 2024, <https://doi.org/10.1007/s43441-024-00638-1>

4. "Successes and Challenges in Clinical Trial Recruitment: The Experience of a New Study Team," Successes and Challenges in Clinical Trial Recruitment: The Experience of a New Study Team, Hung, M., Mohajeri, A., Almpani, K., Carberry, G., Wisniewski, J. F., Janes, K., Janes, B., Hardy, C., Zakeri, G., Raymond, B., Trinh, H., Bretner, J., Cheever, V. J., Garibyan, R., Bachstein, P., & Licari, F. W., Medical sciences (Basel, Switzerland), August 14, 2024, <https://doi.org/10.3390/medsci12030039> Hung, M., Mohajeri, A., Almpani, K., Carberry, G., Wisniewski, J. F., Janes, K., Janes, B., Hardy, C., Zakeri, G., Raymond, B., Trinh, H., Bretner, J., Cheever, V. J., Garibyan, R., Bachstein, P., & Licari, F. W., Medical sciences (Basel, Switzerland), August 14, 2024, <https://doi.org/10.3390/medsci12030039>

5. Utilization of EHRs for clinical trials: a systematic review, Kalankesh, L.R., Monaghesh, E., BMC Med Res Methodol, March 18, 2024, <https://doi.org/10.1186/s12874-024-02177-7>

6. Externally Controlled Studies Using Real-World Data in Patients With Hematological Cancers: A Systematic Review," Hermans, S.J.F., van der Maas, N.G., van Norden, Y. et al., JAMA Oncol, Oct 1, 2024, <https://doi.org/10.1001/jamaoncol.2024.3466>

These innovations could deliver value to every stakeholder. Sponsors can cut costs and dropouts, research sites can boost enrollment with less effort, and patients can access trials that are more inclusive and better suited to their needs. Ultimately, therapies can reach the market faster and reflect the diversity of real-world populations.

HEOR and Market Access

Uncertainty regarding pricing reform, payer cost containment, fragmented health technology assessment (HTA) requirements, and reimbursement variability have made traditional approaches insufficient. To succeed, health economics and outcomes research (HEOR) and market access teams must ground their strategies in RWD.

Longitudinal claims and EHR data reveal the total cost of care, treatment effectiveness, and utilization trends. Combined with SDOH, these insights help contextualize value, highlight disparities, and support regionally tailored dossiers. Real-world data in healthcare can also model budget impact under both MA and Fee-for-Service (FFS), map geographic access gaps, and run comparative effectiveness studies that validate trial endpoints and strengthen payer negotiations.

With access to the industry's [largest primary source dataset](#), companies can analyze patient characteristics, social drivers, and regional disparities in high-cost therapies.

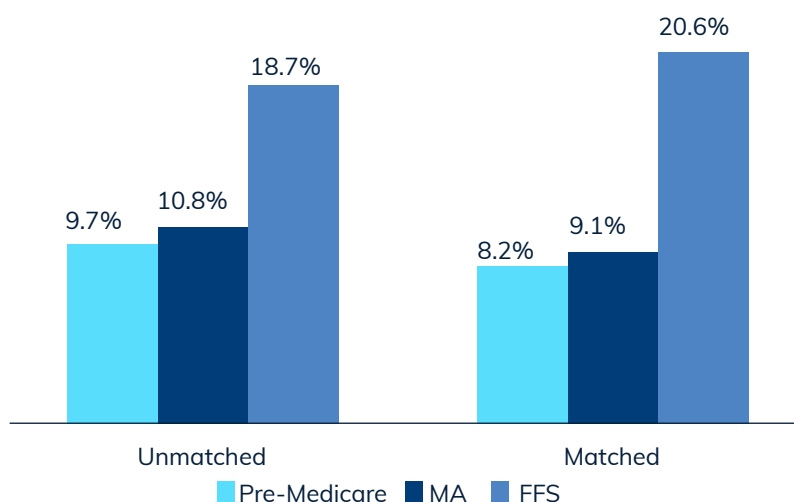
Several use cases highlight the power of real-world data in healthcare:

- **[Advanced Parkinson's Disease \(aPD\) and DAT utilization](#):** RWD showed that Medicare beneficiaries often faced low utilization of device-aided therapies (DATs), even in states with more facilities. Distance to treatment centers, gender, race, and socioeconomic status were significant barriers. These insights helped address equity concerns and supported strategies to improve access for underserved populations.
- **[Hyperkalemia \(HK\) in long-term care \(LTC\)](#):** Analysis found high prevalence and recurrence among Medicare patients in LTC, with HK linked to significantly greater clinical and economic burden during and after stays. Findings informed contracting strategies and identified opportunities for cost containment.
- **[CAR T vs. non-CAR T therapies in relapsed/refractory MCL \(mantle cell lymphoma\)](#):** RWD compared patient characteristics, treatment patterns, and outcomes across payer types. Results showed non-CAR T (Chimeric Antigen Receptor-T cell) regimens were associated with earlier progression, higher use of subsequent therapies, and greater costs. Evidence suggested earlier adoption of CAR T could reduce resource utilization and financial burden for both patients and health systems.

Beyond specific therapies, RWD can challenge long-standing assumptions in health policy. A recent analysis conducted by Inovalon and Harvard, comparing MA and FFS at age 65, found meaningful differences in utilization, costs, and outcomes after adjusting for sociodemographic, geographic, clinical, and SDOH variables. These findings cast doubt on prior MedPAC comparisons based solely on FFS data and reinforced the efficiency of MA. The results may inform strategies for Medicare program design, policy proposals, and [future research](#).

- Quality outcomes: 30-day readmissions
- Unplanned 30-day readmissions often stem from poor care coordination and discharge planning, driving up costs and worsening outcomes.
- The HEDIS® PCR measure tracks these readmissions as a key quality indicator.
- FFS patients show significantly higher readmission rates than MA:
 - +76% higher before matching
 - +126% higher after adjusting for pre-Medicare differences
- Implication: MA plans may deliver more effective transitional care and better manage post-discharge risk.

Figure 2: Plan 30-Day All Cause Readmissions (PCR)



All quality measure statistics reflect the published HEDIS or CMS metrics and vary from measure to measure according to the measure specifications.

The next evolution is an integrated HEOR and payer value platform. Built on harmonized claims, EHR, SDOH, and clinical trial data, the platform could apply AI and natural language processing (NLP) to extract structured insights from unstructured EHR notes, detect anomalies, and fill gaps. Predictive cost-effectiveness models, health equity impact analyses, and AI-assisted value dossier generation streamline payer engagement and make evidence communication more dynamic.

For life sciences companies, this would speed up market access by aligning robust real-world evidence with payer expectations and improve the speed and strength of reimbursement negotiations. Market access teams can gain compelling, data-backed arguments to support stronger pricing and coverage decisions. Beyond traditional HEOR, these strategies would integrate real-world outcomes and SDOH insights to deliver a richer understanding of therapeutic value, while also positioning products as solutions for reducing disparities and advancing health equity.

For payers and HTA bodies, detailed real-world evidence improves decision-making, resource allocation, and visibility into how therapies perform across diverse populations. For patients, the outcome is earlier access to innovation and more equitable care delivery that reflects the needs of historically underserved groups.

Commercial and patient engagement

Underperforming launches, digital fragmentation, and rising patient expectations are putting pressure on commercial and support teams to rethink their strategies. Real-world data in healthcare provides the precision needed to succeed, transforming fragmented approaches into insight-driven engagement.

Claims and SDOH data can micro-segment prescriber behavior and personalize outreach, while EHR and pharmacy data help detect non-adherence risks and tailor patient interventions. Dynamic forecasting models, grounded in real-world response rates, improve launch planning and territory optimization. At the same time, predictive adherence models and omnichannel engagement strategies aligned to generational preferences ensure relevance across diverse patient populations. Benchmarking against external comparator cohorts helps refine and validate patient support programs, transforming commercial and engagement functions into agile, insight-driven growth engines.

The next step for using RWD in commercial and patient engagement is solutions connecting commercial strategy with patient care, creating an ecosystem that aligns business objectives and patient well-being. Capabilities include:

- **Segmentation and micro-targeting:** Enable deep insights into prescriber behavior, geographic trends, and patient demographics, combined with micro-targeting tools that enhance sales territories and personalize marketing content delivery.
- **Proactive patient support:** Identify at-risk patients using clinical triggers, medication fill patterns, and SDOH. Interventions include customized education resources, care coordinator alerts, financial support pathways, and telehealth integration.
- **Connected engagement:** Enhance adherence, reduce dropout rates, and support a more equitable and connected patient experience with real-time progress tracking and multi-channel communication.



The New Wave of Technology

Innovation in life sciences reaches beyond molecular discovery and clinical development. It now spans the entire value chain, from early research through commercialization and patient engagement.

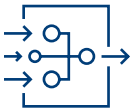
The most resilient organizations are those that use data and technology to anticipate and transform uncertainty into opportunity.

To lead in this new era, companies must master three core drivers:



AI and RWD synergy

Artificial intelligence is only as strong as the data behind it. Out of 519 studies reviewed, only 5% used real patient care data (i.e., RWD such as EMRs or claims) to evaluate LLMs⁷. RWD provides the diversity, scale, and clinical relevance needed to train and operationalize AI responsibly. Together, AI and RWD unlock real-time insights that power precision medicine, adaptive trial design, dynamic market access, and targeted commercial engagement.



Data harmonization

Data locked in silos is wasted potential. To unlock value, EHR, claims, genomics, and patient-reported outcomes must be integrated into a single intelligence layer. Standardization, interoperability, and advanced analytics are the keys to transforming disparate datasets into actionable insight, enabling life sciences companies to personalize strategies and respond quickly to changing conditions.



Organizational agility

Technology alone is not enough. Companies must also use data literacy, agile governance, and cross-functional collaboration in their operating models. Agile organizations can respond faster to policy changes, competitive threats, and patient needs. It's not about doing more – it's about learning faster, acting smarter, and scaling what works.

7. Shah NH, Entwistle D, Pfeffer MA. Creation and Adoption of Large Language Models in Medicine. JAMA. 2023;330(9):866–869. doi:10.1001/jama.2023.14217

From Reactive to Resilient: A Blueprint for the Future

By using RWD and AI in every layer of decision-making, companies can:

- Anticipate market and regulatory shifts
- Personalize commercial and clinical engagement
- Defend and communicate product value
- Speed up innovation across the lifecycle
- Create enterprise-wide agility and responsiveness

This is more than modernization. It is a blueprint for thriving in uncertainty.

The next decade won't be defined by stability, but by how well companies adapt. Those that combine RWD with AI, break down data silos, and embed agility into their culture will redefine what it means to innovate.

The leaders of tomorrow will be both data-rich and data-smart, turning complexity into clarity and uncertainty into opportunity. They'll set the standard for a more resilient, adaptive, and equitable industry.

This is the new frontier. And the future belongs to those who are ready for it.



About us

Inovalon is a leading provider of data and solutions empowering data-driven healthcare. The Inovalon ONE® Platform brings together national-scale connectivity, real-time primary source data access, and advanced analytics into a sophisticated cloud-based platform empowering improved outcomes and economics across the healthcare ecosystem. The company's analytics and capabilities are used by nearly 50,000 active, licensed customers. For more information, visit www.inovalon.com.

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Broderick's expertise is in strategy development, AI-driven innovation, and business transformation. He has an exceptional record — building high-performing teams to deliver significant business results. He is recognized for integrating business and technology solutions and driving operational efficiency, enabling clients to achieve breakthrough outcomes.

Prior to joining Inovalon, Broderick has worked for leading management consulting & technology firms focused on creating value across the entire healthcare value chain, leveraging digital customer analytics and information management capabilities resulting in substantial business benefits and better patient outcomes. Broderick earned his certification in Artificial Intelligence from the Wharton School of Business at University of Pennsylvania and a Bachelor of Arts in Business Administration from LaSalle University.

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