The 7 Trends Shaping Life Sciences Strategies

in 2023

Enter

Optum | Advisory Board

If we've learned anything in the last 3 years, it's that the only reasonable prediction is more unpredictability. Undaunted by this reality, life sciences market experts from Optum and Advisory Board came together once again to find a signal in the noise — offering our take on 7 trends shaping life sciences strategies in 2023.

This analysis is rooted in conversations with over 100 evidence generators, data scientists, researchers, clinicians and decision-makers across the health care ecosystem. The insights and recommendations captured here are intended to provoke thought, challenge conventional wisdom and stimulate the kinds of cross-functional conversations that can catalyze meaningful industry change.

Read more to:

- See the trends we've identified as most likely to shape life sciences leaders' real-world data (RWD) and real-world evidence (RWE) strategies in the year ahead.
- Consider the implications of these trends on different stakeholders within the health care ecosystem.
- Gather ideas for thoughtful questions to ground strategic planning meetings with your team, cross-functional colleagues and important business partners.
- Challenge your own assumptions. Or challenge ours. We'd welcome the conversation.

The 7 trends shaping life sciences strategies

1. Writing the next chapter in RWE's history
2. Targeting the opportunities in precision medicine
3. Unlocking the value of providers' clinical data for a broader set of users
4. Navigating the promise and peril of consumer data
5. Pushing beyond the biosimilar tipping point
6. Building the case for more evidence to support "everywhere care"
7. Monitoring the ripple effects of the clinical workforce staffing crisis

About this report

This report is intended for life sciences leaders interested in the evolving market for real-world data and evidence.

As you read through these trends, we encourage you to ask yourself and your colleagues 4 questions:

1 What more can we do to monitor the most salient market shifts and stakeholder priorities?

2 How can we stay more attuned to the impact of major economic, demographic, clinical and operational trends for our primary customers?

3 How can we best ensure that the clinical and technological innovations our organizations develop reach the patients and families most likely to benefit?

4 How can we expand our sources and uses of RWD to better address customers' evolving demands for value?

Trend 1

Writing the next chapter in RWE's history

The **expanded guidance from the U.S. Food and Drug Administration (FDA)** on the use of RWE in regulatory decision-making has opened the door for more pragmatic approaches to trial design, more inclusive methods for participant recruitment and **earlier stakeholder input** into clinical programs writ large. With clear guidance but no hard-and-fast rules, life sciences organizations must push forward — balancing innovation with scientific rigor and pragmatic discipline. Capitalizing on these new clinical development opportunities will require life sciences companies to nurture more **cross-functional collaboration,** develop more **holistic evidence plans,** coordinate an **enterprise-wide approach to RWE** and enrich their **understanding of each RWD asset** they deploy.

The FDA's latest guidance is simultaneously an affirmation of RWE's value and a call to action for manufacturers and other stakeholders to innovate and collaborate in the absence of a perfectly mapped-out regulatory playbook. It is no longer a question of if, but rather how, real-world data and evidence can best support clinical development and regulatory decision-making. While it's imperative that manufacturers' early RWD-based submissions meet an appropriately high bar for data quality and analytical rigor, the bigger challenge lies in making sure new, RWD-enhanced study designs don't simply replicate the problems weighing down so many clinical trials today.

Today's clinical trial models are clearly ripe for disruption. Patient enrollment challenges and tedious data-entry processes have plagued the industry for decades. Shifts toward precision therapies and demands for greater participant diversity only exacerbate these problems. With increased government and health plan price pressures, manufacturers must find smarter ways to generate high-quality, trusted clinical evidence for their products. The FDA's RWE guidelines may provide just the tailwind the industry needs to change.

Such changes cannot focus solely on evidence generation for regulatory approval. Rather, the FDA's increased openness to RWE-supported regulatory submissions should encourage manufacturers, clinical research organizations (CROs), and data vendors to take a more holistic approach to evidence planning writ large. Such approaches should consider both traditional and more innovative trial designs, like hybrid trials and external control arms, as well as traditional and emerging sources of real-world data, such as wearables, genomics or social determinants of health. With more diverse data sources and study designs now available for both regulatory-grade and post-marketing studies, life sciences companies may finally find it easier to structure trials that reduce patient and investigator burden, while also generating evidence that demonstrates value to a range of stakeholders.

As with any expansion of use cases for RWD, life sciences companies will need to guard against the risks of re-identification and systemic bias. They also need to take greater ownership of enterprise-wide understanding of data quality and provenance — enough to confidently answer questions from regulators and other stakeholders about how the data and analytical methods support approval, coverage or use of a particular product. Life sciences data and analytics teams must work more fluidly across their organizations to educate colleagues about these assets at a much more granular level than in the past. They must be able to answer questions about what's in the data sets and what's not — and why.

All of this points to a greater need for cross-functional and cross-industry collaboration. Specifically, manufacturers should:

- Coordinate across functions to maximize the value of RWD investments for the enterprise and over the duration of product lifecycles.
- Partner with regulators and purchasers around endpoint selection and data collection methods to strike an appropriate balance among clinical outcomes (safety and efficacy), patient-defined value and purchaser-defined value.
- Consult early and often with key stakeholders to align on meaningful measures of value, and the analytical methods for demonstrating it.

From January 2021 to June 2022, 65% of FDA approvals included RWE in their submissions to support safety and/or effectiveness.

Approvals included New Drug Applications (NDAs) Types 1 and 9 (New Molecular Entities (NMEs), new indication or claim) and Biologics License Applications (BLAs, excluding assays, solutions and blood products).

Source: The Role of Real-World Evidence in FDA-Approved New Drug and Biologics License Applications. American Society for Clinical Pharmacology & Therapeutics. November 2021.

Implications for life sciences leaders

It is unlikely that regulators and health technology assessors (HTAs) across the globe will reach consensus around every element of fit-for-purpose RWD. However, by studying RWD adoption across a range of global markets, manufacturers can identify important themes and recurring questions that may impact market access and commercial success. While there is no going back to pre-pandemic views of RWD, these next few years will likely shape strategies for decades to come. Life sciences leaders should view this as a reason for excitement, even as they exercise due diligence.

The future will require additional investments in RWD and trial innovation. But manufacturers must still work to avoid creating new trial designs that end up increasing complexity and cost, especially as patient privacy regulations and RWD availability still vary widely across the globe.

Increasingly complex trials won't just create financial and business challenges, they could also complicate the industry's ambition to make both clinical trials and subsequent care more equitable across social, ethnic and demographic lines. Partnerships with data vendors, communities, patient advocacy groups and others will be necessary to deliver on the promise of innovation in a sustainable manner.

Questions to consider

1. What structures, processes or incentives will best facilitate coordination across your enterprise?
2. What sources of data beyond claims and electronic health records (EHRs) will allow you to create the most compelling narratives for all stakeholders?
3. What kinds of real-world education of regulators, health plans and clinicians are still necessary?
4. What are the non-negotiable attributes for data vendors? How can you best hold a consistent bar for data partners across the enterprise?

Trend 2

Targeting the opportunities in precision medicine

Despite biopharma companies' massive pipeline shift toward *precision therapies*, most organizations continue to **underestimate** what's required for market success. With patient-finding for clinical trials at a premium and pricing pressures mounting from multiple stakeholders, it's never been more important for life sciences companies to invest in the **data and insight that can inform *precision strategies*.** From market sizing to metric selection, from improved diagnostic testing access to value-based contract enablement — strategic investments in **real-world genomic, economic, clinical and behavioral intelligence** can help life sciences companies optimize the opportunity and promise of precision medicine.

Gone are the days when industry analysts reported on the "coming wave" of precision therapies. Yes, there are still at least 800 cell, gene and next-generation therapies in development pipelines. And most industry analysts project global spend on precision therapies to exceed $85 billion by 2030. But the era of precision medicine is already here. Consider that:

- Two mRNA vaccines have successfully helped quell the worst of the COVID-19 pandemic.
- More than 80 targeted oncology treatments are currently available in the U.S. market.
- In 2021, 33 of the 50 new drugs approved by the FDA were considered precision therapies.
- Two new gene therapies were approved for rare blood disorders in the second half of 2022, each with a price tag over $2.5 million.
- Whole genome sequencing (WGS) is now available to anyone in the U.S. for less than $1,000.

Despite these remarkable clinical advances, the health care industry is just starting to grapple with the ways that precision medicine disrupts legacy models of evidence generation, diagnosis, treatment selection and reimbursement. It's still too hard for sponsors to find enough eligible patients for their clinical trials. Too many patients and physicians still make treatment decisions without the benefit of appropriate genetic or genomic tests. And neither payers nor employers are eager to embrace frontloaded multimillion-dollar price tags for one-time, potentially curative therapies without some financial protection if the drugs don't work as well as hoped.

Between the Inflation Reduction Act's looming drug price regulations, the expanding market for biosimilars and potential recessionary pressures on all health care stakeholders, life sciences executives are already taking a hard look at precision pipelines and portfolios to maximize return on investment (ROI). But continued success with precision medicines will require those leaders to examine their portfolios with a fresh perspective — one that not only accounts for scientific and market opportunity, but also considers how new sources of RWD may be deployed in innovative ways to enhance critical business decisions.

Implications for life sciences leaders

Life sciences manufacturers should approach commercial innovation to support precision medicines as creatively and rigorously as they approach scientific innovation. Without a more holistic approach to product strategy and stakeholder insight, too many precision tests and treatments may fail to reach their full market potential. And worse, too many patients may miss out on the promise of fuller, healthier lives available to them with access to targeted therapies.

Somewhat ironically, the most significant commercial and analytical innovations necessary to support precision medicines should begin during early discovery and development. For example, by leveraging more clinicogenomic data — linking WGS data with other de-identified clinical data sets — researchers can refine hypotheses more efficiently and identify populations more likely to see outsized benefits or undue harm from targeted therapies. But that's just the start. Life sciences leaders from across the organization must challenge each other early and often with difficult questions about market opportunity and demonstrable clinical impact, then seek out the data, analytics and insight to help answer those questions with confidence. And there's no shortage of opportunity to do so:

- Clinical development leaders can now take advantage of new analytical tools — built off large, de-identified clinical data sets — to refine protocol designs before they go searching for hard-to-find patients. They can also now partner with a growing number of provider consortia and collaboratives to identify and enroll those patients in trials.
- Medical and clinical development teams can view genomically rich RWD sets through an equity lens in search of potential variations in certain biomarkers' prevalence based on ethnic or racial heritage. This will reduce the risk of "missing" diagnoses in certain subpopulations because assumed genetic or genomic markers of risk or disease aren't as prevalent as they are in other groups.
- Product teams can meet with regulators and payers earlier in the clinical development process to incorporate vital stakeholder input on hybrid trial designs and studies incorporating RWD, including prospective EHR-based studies and the use of external control arms, according to new FDA guidelines. Such conversations will be vital not only to trial innovation, but also to manufacturers' efforts to launch precision products with clear evidence of medical value.

> "We're still in the nascent stages of unlocking the potential of both precision medicine and RWE, and there will be even more opportunity to improve health as both of these worlds start to converge. We haven't even begun to reimagine what the new clinical care and research paradigms could or should look like.
>
> **Chris Boone**, Vice President and Global Head, Health Economics and Outcomes Research (HEOR) AbbVie

- Market access leaders can leverage RWD-derived insights about patient journeys, provider workflows and payer economics not only to support value messaging and lower access barriers, but also to evaluate different outcomes-based contracting models.
- Medical affairs leaders can capitalize on their expanding knowledge of real-world health care professional (HCP) behavior and clinical decision-making to help their product teams identify opportunities to alleviate some of the barriers hindering appropriate, evidence-based use of precision tests and therapies.
- Brand and product leaders can continue efforts to break down internal silos to guide more cross-functional and holistic approaches to RWD investments, holistic evidence generation and outcomes-based contracting enablement.

Given the potential positive health impact of precision tests and treatments, it behooves any life sciences manufacturer to continue seeking data-driven answers to the difficult and important questions that can improve value-centered access to these potentially life-changing therapies.

Questions to consider

1. Are you deploying all of your RWD assets — especially those incorporating relevant genomic information — to help refine your target selection and populations of interest?
2. How can you incorporate diversity and equity considerations as you develop therapeutics, diagnostics and strategies to support precision care?
3. Are you leveraging RWD to help refine protocol designs and improve precision patient finding as early and comprehensively as possible?
4. How well do you understand all the reasons patients may not end up on an appropriate targeted therapy, even if it's on the formulary and the companion diagnostics are available?
5. Do you have a clear plan for generating the longer-term evidence that payers and employers will demand to support coverage and access to high-cost precision therapies?

Trend 3

Unlocking the value of providers' clinical data for a broader set of users

Providers are increasingly conscious of **the inherent value of their clinical practice data.** Many are actively evaluating opportunities to maximize that value in innovative, secure and scalable ways. But the vast majority of organizations **lack the IT bandwidth and data management resources** needed to extract, normalize and package the information in formats that can support clinical and operational research. **Trusted third-party vendors** specializing in data science can help these provider organizations **optimize the data's quality and potential use cases** – both for themselves and for other ecosystem stakeholders.

RWE's move from health care's fringes to the mainstream has caused provider organizations of all shapes and sizes to rethink their own relationship with the data they generate. They see the growth of big data companies in this space and wonder how they too might capture some of that value for themselves. While a few large and well-known institutions, like Mayo Clinic, may be able to commercialize access to their de-identified, proprietary clinical data, most health systems are unlikely to pursue this path, in part because they lack the necessary infrastructure and expertise.

In fact, EHR-based clinical data is structured in ways that make it difficult for most providers to use those resources for research and quality improvement initiatives without significant work. Increasingly, providers are looking to a long list of partners who can help them transform their data into insights that will help address their organizations' strategic and clinical priorities.

While health systems are open to the idea of partnerships with other stakeholders to derive value from their data, this idea is still relatively new. Life sciences leaders should take time to understand the trade-offs from the care delivery organizations' perspective. Most health systems are keen to partner in ways that either allow them to leverage RWE-derived insights to address market-specific challenges or generate new research. But they have a lot of questions and concerns.

Even if they fully appreciate the value of having someone else extract, normalize, package and return their data for easier internal analysis, health system leaders don't just want to "give away" their data without understanding how others (including life sciences manufacturers) may benefit from that data as well. They also want to know that the data will come back to them in formats and via platforms their own teams can use and benefit from. For many health system business applications, this will require regular and timely data refreshes. And they need a lot of added reassurance that anyone else accessing this data will hold patient privacy in the highest regard. That last one is non-negotiable.

Between recent pandemic-induced financial troubles and the continued pressure by payers to assume more financial risk, leaders of provider organizations are keen to leverage any available data that can help them find opportunities to capitalize on clinical innovations, reduce unnecessary variation and deliver more cost-effective care. A lot of that data — especially if integrated with other available sources into larger de-identified, RWD assets — has been sitting within their own organizations, yet is unavailable for use. With the recent expansion of third-party aggregators, health systems will have several options to consider, and many will likely take action in the coming few years.

These collaboratives won't explode overnight, but provider organizations' greater openness to using and sharing their de-identified data is absolutely a trend to watch in 2023.

Implications for life sciences leaders

As health systems grow more comfortable with third-party aggregators and collaborative models for pooling de-identified clinical data, the opportunities for life sciences researchers to dive into this data will expand rapidly. Many hope that such collaboratives will bring forth more diverse, representative data sets — especially if health systems serving a high percentage of historically marginalized or underrepresented patients agree to participate.

Such collaboratives or consortia may also unlock new opportunities for cross-industry research and innovation. Organizations open to contributing their de-identified clinical data for research purposes may also be interested in expanding their participation in clinical trials, population health initiatives, outcomes-based contracts, or tech-enabled patient engagement and adherence programs.

And even those not participating in data aggregation programs may be more receptive to RWE generated from de-identified clinical data drawn from populations more similar to their own. This may unlock new ways for life sciences medical teams to engage HCPs with data and insights about the local populations they serve.

> "Don't be fooled into thinking that since providers have an enormous amount of data, our problems of evidence are simply solved by liberating it for other users. Providers often need external support to capture data accurately and to make sure they're answering questions with the data they need, not just the data they have.
>
> **John League,** Managing Director, Digital Health Research, Advisory Board

Questions to consider

1. How might your organization leverage its relationships with HCPs and health systems to help them see the value of pooling their clinical data with others in ways that can support research while still protecting privacy?
2. How should your organization evaluate different options for leveraging de-identified clinical data sets in light of the growing number of consortia, collaboratives and third-party aggregators?
3. Beyond accessing data, how might third-party aggregators streamline your efforts to partner with health systems – especially those serving more marginalized or underrepresented populations – for innovative trials or population health initiatives?

Trend 4

Navigating the promise and peril of consumer data

The “retailization” of primary care, coupled with the increasing presence of out-of-industry health care disruptors, is fueling **greater interest** among all major industry stakeholders in **leveraging consumer data** to develop products and programs that can meaningfully improve whole patient health. However, companies interested in these resources must balance their potential with the **operational, financial, equity and reputational risks** associated with consumer data integration and management.

Investments in and acquisitions of primary and home care by the likes of Walgreens, Amazon, CVS and Walmart dominated health care headlines in 2022. These companies consistently tout their deep relationships with consumers and their geographic reach as differentiators relative to health care incumbents. Each has a different investment thesis, but all believe that they can positively disrupt clinical trials, care delivery and payment models.

The consequences of their successes and failures will be felt for decades. But one clear consequence has been a renewed interest in nonclinical consumer data that organizations may use to better understand both individual health and key aspects of many common diseases.

Consumer data sets introduce a huge swath of information about individual behavior and health status that can provide powerful insights about disease incidence and prevalence. This information also helps a range of health care companies design better health care products, promote positive behavior change and proactively manage patients. For instance, in 2016, Microsoft researchers claimed that search queries might improve early detection of pancreatic cancer. And digital surveillance tools consistently help public health officials detect the flu or COVID-19 hot spots.

Walmart stores host about **230 million** weekly customer visits around the world.

Source: Statista. Number of weekly customer visits to Walmart stores worldwide from fiscal year 2017 to 2022. Last reviewed March 25, 2022. Accessed January 9, 2023.

Consumer data could also theoretically help retailers promote nutritionally appropriate foods for patients with diabetes. It could help larger payers and providers target educational messaging and even coupons to motivate healthy behavior changes. Retail and health plan disruptors in the care delivery space increasingly believe that this data can help them succeed in value-based arrangements and cannibalize volumes from legacy providers. This is prompting health systems and medical groups to consider how they can then leverage consumer data to maintain their market positions.

But any use of such data — whether by health plans, providers, health tech companies or life sciences manufacturers — raises a host of legal and privacy concerns. Although most consumer data is not protected by the Health Insurance Portability and Accountability Act (HIPAA), some states have laws or are drafting laws that attempt to close that gap. In addition, the ways that companies choose to use or share consumer data may expose them to significant reputational and financial risks.

Recently, major news outlets reported that several health systems shared patients' sensitive health information with Facebook, via their online scheduling tools. Such news stories, coupled with increased public awareness over data privacy after the Dobbs Supreme Court decision, have tested assumptions that some data previously believed to be protected by HIPAA may not be as private as originally thought. Use of this data also potentially exposes companies to actions and fines from the Federal Trade Commission (FTC).

Implications for life sciences leaders

The past few years have made it clear that life sciences manufacturers must embrace new ways to understand and engage with their end users, be they clinicians or consumers. Much of this focus has been on omnichannel outreach strategies, but many organizations are dialing up their interest in analyzing consumer data for both clinical and commercial purposes.

Beyond gleaning new insights into how patient behaviors, environments and unmet social needs may impact adherence and outcomes, responsible use of consumer data may help health care organizations of all shapes and sizes unlock new ways of recruiting patients into clinical trials, detecting disease, expanding care access and managing health. Despite its promise, any health care use of consumer data requires intentionality and caution to minimize the risks of re-identification or other privacy violations.

Life sciences leaders should look for lessons from early movers and signs of emerging consensus around areas of promise as well as pitfalls to avoid. The involvement of many organizations with expertise in consumer data who are now entering the clinical trials space also deserves close monitoring.

Questions to consider

1. How can your organization identify the consumer data with the greatest salience for the patient populations and conditions you support?
2. What policy and legislative movements should you be monitoring at the state, local and federal level that might impact how consumer data is used in health care?
3. How might your organization need to think differently about partnerships with health tech and retailers in order to maximize opportunities and minimize reputational risk?
4. How would patients, HCPs and regulators respond to your potential uses of consumer data if they found out?

Trend 5

Pushing beyond the biosimilar tipping point

The **coming era of biosimilar competition** will focus less on payer coverage and adoption than on efforts to build **patient and provider trust.** To do this, biosimilar manufacturers must **engage a broader network of pharmacists, nurses and patient advocacy groups** to inform ongoing research and adherence programs, while also generating the kinds of evidence that can reassure patients and providers about the value of their medication choices.

This year is shaping up to be a seminal year for the U.S. biosimilar market. In December 2022, Fresenius Kabi's Idacio® became the eighth FDA-approved biosimilar for AbbVie's blockbuster, Humira® (Adalimumab). But none of these biosimilars hit the market until Amgen's AMJEVITA™ launched earlier this year.

In late 2022, Optum Rx®, Express Scripts® and other pharmacy benefit managers (PBMs) announced plans to cover several of the Humira biosimilars. Payment and incentive models vary, but patients and physicians will now have more choices to consider. How will this market evolve? No one knows for sure, but everyone interested in a healthy biologic or biosimilar competitive marketplace is watching.

By the end of 2022, the FDA had approved 40 biosimilars in the U.S., with 25 on the market and 4 deemed "interchangeable" with the reference biologic. Unlike Europe, U.S. regulators require biosimilar manufacturers to conduct additional, costly switching studies in order to secure an interchangeable designation. This is one of several reasons the U.S. lags Europe and other countries in biosimilar uptake. If passed, the Biosimilar Red Table Elimination Act – proposed late last year by Sen. Mike Lee, R-Utah – would eliminate these studies, paving the way for more biosimilar competition. Should Congress take up this or similar proposals, 2023 could be even more of a game-changing year for biosimilars than expected.

On the policy front, the passing of last year's Inflation Reduction Act also has implications for biosimilar investments and commercial activity. While it's too early to know how things will play out, once CMS can negotiate prices on a subset of high-priced specialty medications lacking sufficient competition starting in 2024, industry analysts like Adam Fein have simply noted that biosimilar launches may "get weird."

In some instances, manufacturers in the hot seat may welcome biosimilar competition to stave off government-mandated price negotiations. While in other instances, manufacturers may see CMS price negotiations as a way to make market entry less appealing for potential biosimilar competitors. Look for signals in 2023 for how this may take shape in subsequent years.

With so much change and uncertainty, what can we learn from the competitive landscape of the 11 biologics already facing biosimilar competition in the U.S.? In the last few years, payers and PBMs have become much more open to including at least one biosimilar for these products on formularies, but cost-tiering incentives for consumers vary widely. Some branded biologics are still preferred or offered at equal cost to biosimilars, while other branded biologics have lost status and share in favor of lower-priced biosimilar options. At a macro level, launched biosimilars have introduced healthy price competition contributing to over $21 billion in savings on specialty medications in the last 6 years.

In specialty biologic categories now facing increased biosimilar competition, expanded choice introduces new complexities for physicians and consumers. In a recent survey, only 9% of consumers were familiar with biosimilars.[1] There's still plenty of educational work to be done. When at least one biosimilar is offered on an equivalent price tier as its reference biologic, consumers and their clinicians may not know how to choose. They may need new kinds of clinical evidence to guide their choice. In categories with multiple biosimilar options, physicians and patients may clamor for even more evidence to help them determine if one option is better for them than the others.

Implications for life sciences leaders

While payers, PBMs and employers seem to have fully embraced biosimilars, some patients and physicians may still be confused or skeptical, especially if they're confronted with multiple biologic and biosimilar options to consider.

In newly-competitive categories, manufacturers of both established biologics and emerging biosimilars will need to double down on outreach and education efforts — not only with patients and physicians, but also with the nurses, physician assistants and pharmacists increasingly involved in addressing patient concerns and monitoring adherence. Because so many of the newer biosimilars treat patients with cancer or chronic conditions, patient advocacy and support groups will also be important stakeholders to engage.

12.4% to 22.5%

biosimilar utilization increase from 2020 to 2021.

Source: American Journal of Managed Care. Specialty drug trend is strong but may shift with biosimilars. Last reviewed September 8, 2022. Accessed January 19, 2023.

1. CivicScience, November 3, 2022, U.S. Adults 18+, n=3,061-2,632

However, this next wave of outreach needs to be about more than just education. Manufacturers should consider investing in more real-world studies comparing the safety, effectiveness and adherence of different biologic and biosimilar options. This is particularly relevant in categories where doctors and patients may consider switching from one comparable product to another.

Fortunately, Europe has a wealth of data to analyze here since their biosimilar market is more mature. But many patients and physicians will want similar analyses to help determine when switching makes sense — and whether certain demographic or disease characteristics may help guide therapy selection and management in these increasingly complex therapeutic categories.

Questions to consider

1. How can your evidence help you articulate the value of biosimilars to patients and providers when they may not see immediate, direct savings from choosing that product?
2. Regardless of whether you manufacture a reference biologic or a biosimilar, what more can you do to help patients and physicians understand and evaluate their options?
3. How can you expand education and support for the nurses, pharmacists, physician assistants and patient advocates who are taking on greater responsibility for answering patient questions and, in some cases, administering biosimilar medications?
4. What new real-world research and surveillance may help clinicians better understand relative differences in adherence and potential side effects among biologic and biosimilar options?

Trend 6

Building the case for more evidence to support “everywhere care”

While the **continued shift of care to virtual, home and retail settings** may lower episodic costs and increase consumer convenience, it is **disrupting patient journeys and clinical information flows** in potentially problematic ways. Life sciences companies should consider **what may be missing i**n even their most robust RWD assets, while also making efforts to **generate new evidence and expand both patient and provider education** in ways that can fill critical knowledge gaps about diagnosis, drug administration and adherence monitoring in these “nontraditional” care settings.

Continuing the trend we’ve now seen for several years, payers, providers, retailers and digital health companies are converging on a patient experience rooted in the concept of “everywhere care.” That is to say, patients are not only able, but often encouraged, to combine virtual and in-person care through various touch points in the home, ambulatory care facilities, hospitals, retail and urgent care clinics, and even their own mobile devices.

When coupled with the compelling recent innovations in at-home diagnostics, digital biomarkers, virtual mental health support and remote monitoring, it’s not just care delivery that’s happening anywhere and everywhere. Health care data is now collected 24/7, across multiple sites and virtual platforms, and stored in many different places.

This exploding variety of care sites and delivery models should, in theory, improve patient access and convenience. And on many levels, it has. But it’s also created some unintended consequences that could impact RWE generation and consumption.

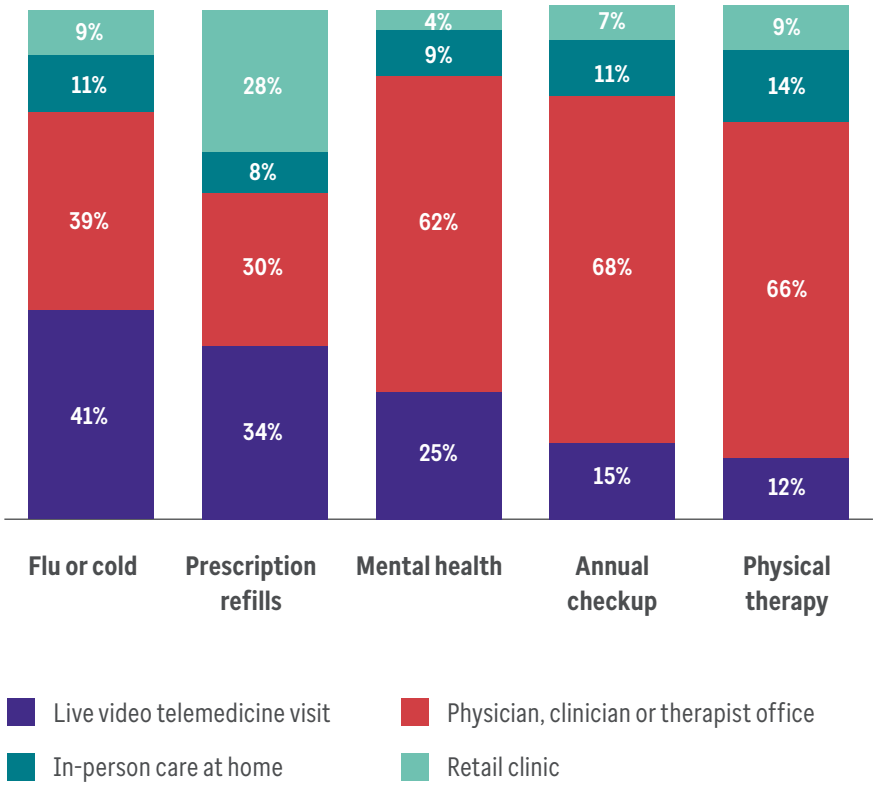
Patient journeys have become more fragmented and varied. Even the most robust RWD sets may have some gaps reflecting care received outside what’s traditionally collected in claims or EHRs (case in point: at-home COVID-19 tests). That’s to be expected, but this reality does require RWD users to account for such gaps when conducting research and analyzing data. But there’s a potential silver lining as well.

As organizations look to fill some of those gaps by examining data from different sources, they may unlock new ways to account for those who too often don't show up in any RWD sets because they historically haven't accessed health care through traditional channels – typically, those from marginalized or under-resourced communities. Any progress here would be welcome by leaders across the health care ecosystem.

In a world where more patients are taking diagnostic tests, injecting and infusing medications, tracking daily activities and managing symptoms at home, medical evidence and educational resources may no longer meet the needs of patients, physicians or even payers. Addressing these needs will require organizations to understand the new questions patients and physicians are asking, such as:

- What should patients and caregivers look out for when administering specialty medications at home that may not have been as apparent in the initial controlled clinical trials?
- What new evidence may be required to support the safe and effective use of tests and treatments traditionally delivered in medical facilities?
- How can physicians help educate patients about different diagnostic tests and treatment options when interacting with them primarily through telehealth visits?

Preferred method of accessing care by care need



Source: Rock Health Advisory. Consumer adoption of telemedicine in 2021. Last reviewed December 12, 2021. Accessed December 15,2022.

Implications for life sciences leaders

The shift to everywhere care has huge implications for life sciences manufacturers' use of RWD and generation of RWE. As noted above, executives managing RWD asset portfolios will need to understand what those resources may miss in their data capture models, and then develop ways to account for those gaps in their analysis. Data leaders should also continue scanning the horizon for innovators offering new data sources or analytical methods – including the use of artificial intelligence (AI) and machine learning (ML) – to offer more complete pictures of population health and patient journeys.

On that note, prior models of common patient journeys for diseases like type 2 diabetes, depression or rheumatoid arthritis may also need to be revisited given the greater use of home infusion, virtual care and at-home testing. Further, the demographic profiles of those more comfortable with telehealth and app-based care support – younger, more educated, more affluent – suggest that some patient segmentation models may need a refresh. Large, integrated de-identified RWD sets can help.

Holistic evidence plans must account for these more recent shifts in patient journeys and the new questions patients, providers and payers may have around treatments whose primary safety and efficacy data stems from randomized, controlled trials conducted in traditional clinical settings. Organizations able to demonstrate real-world safety and efficacy in today's everywhere care reality may have a competitive edge. Those who can generate evidence showing fewer side effects to monitor remotely or better ease of self-administration may also stand out in the market, particularly when talking with HCPs.

Finally, life sciences medical leaders should engage field medical science liaison (MSL) teams to understand how HCPs have changed approaches to treatment decisions and patient education. Virtual and at-home care options disrupt many clinicians' means of moving a patient through the diagnostic and treatment initiation process. This disruption almost certainly creates new opportunities for MSLs and population health teams to help providers fill care gaps, educate patients and monitor early treatment results.

Questions to consider

1. How might your pre- and post-launch study designs need to evolve to better reflect the more diverse ways patients may access care?
2. How might you work with data partners to fill some of the gaps in understanding patient journeys as a result of the more fragmented ways patients are accessing care?
3. How might your teams compliantly support the efforts of HCPs to educate and monitor patients in this new environment?

Trend 7

Monitoring the ripple effects of the clinical workforce staffing crisis

Leaders of health care delivery organizations cannot achieve a **sustainable workforce environment** without structural and technological changes across clinical and nonclinical roles. The net result will **redefine patient journeys and clinical decision-making** in ways that will impact the "who" and "how" of clinical product utilization for years to come.

The dire state of the clinical workforce has been making headlines since the start of the COVID-19 pandemic. Across the country, it's had a huge impact on health system finances writ large and on many provider organizations' ability to remain operational. Median labor expense per discharge has increased from $4,009 in 2019 to $5,494 in March 2022, and is contributing to the toughest financial climate for health systems in recent memory. But today's crisis is about more than labor expense. Turnover across all clinical roles outside of physicians has made it difficult for many health systems to maintain their quality and efficiency standards.

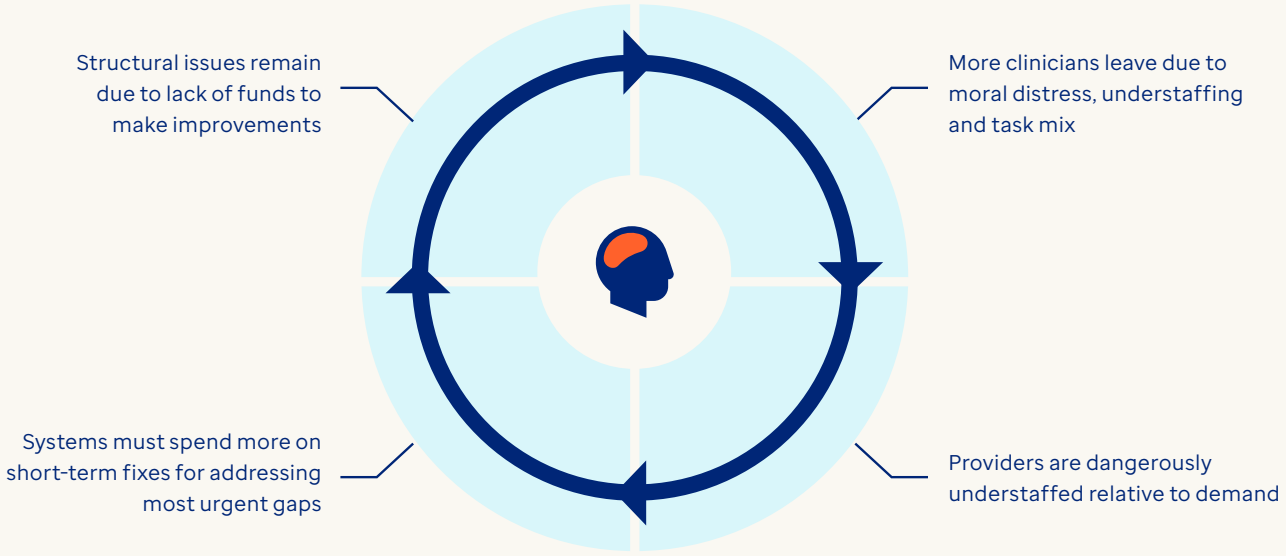
Despite the ways that this turnover has disrupted workflows and increased workloads for many clinicians, physicians aren't leaving the workforce at the rates some industry analysts feared at the start of the pandemic. But health system executives remain vigilant. While greater than 50% of physicians continue to express a desire for a career change, those numbers are consistent with pre-pandemic numbers, as is the 7% of physicians who eventually make this change.

Meanwhile, the nursing workforce is undergoing a generational shift that predates the pandemic and has resulted in the loss of decades of clinical expertise. Data from 2022 indicate that nurses under the age of 35 are 4 times more likely to leave than any other age demographic, creating a squeeze at both tenure extremes. Many who aren't leaving are moving from acute care and skilled nursing facilities to more flexible, and often more lucrative, options in home health, telehealth and surgery centers. A growing number of health system leaders recognize the financial and clinical value of workforce stability and reduced stress, and they're investing in a combination of administrative, operational and technological changes as a result.

Technological investments will focus on both administrative and clinical areas, with a shared goal of addressing burnout across the entire workforce. The use of robots and software, a subset of which will deploy machine learning, will enable care team transformations that broaden and diversify who's on the team, while simultaneously shifting more tasks away from doctors' purview. AI and renewed investments in value-based care are likely to further reduce clinician autonomy, both real and perceived, as greater standardization becomes vital to clinical and financial success.

Vicious turnover cycle is difficult for health systems to escape

Clinician shortage creates a treacherous feedback loop



Source: The cost of nurse turnover in 2022: How the great resignation impacts your organization. Roar for Good, 2022.

Implications for life sciences leaders

Clinical decision-making is shifting from a memory-based task to a technologically-assisted one. This could prove beneficial if it allows clinicians to apply the latest clinical evidence in shared decision-making with patients. But success hinges on the ability of life sciences manufacturers to collaborate with digital health companies in finding new ways to integrate evidence into clinical workflows. This is a vital but daunting challenge, given the high levels of burnout across the health care workforce, a significant amount of which is attributed to administrative burdens often associated with technological adoption.

Life sciences companies can also start supporting future nurses and pharmacists before they even enter the clinical setting. The younger workforce is particularly nimble with technology, but academic institutions often don't have the bandwidth to teach students the technologies that they will encounter in practice. Teaching students how to use existing and emerging technologies could cut down on onboarding time. It could also help get the next generation of caregivers comfortable with the tools and techniques that support cost-effective patient care. It may also illuminate new ways that life sciences manufacturers can compliantly engage and educate these broader care teams.

Questions to consider

1. What existing trainings and resources can you make available to provider organizations that may help them minimize the loss of knowledge and expertise?
2. What roles are poised to grow in clinical and operational influence as clinicians trade autonomy for sustainability and care teams are redesigned?
3. How might you help clinical and nonclinical staff separate signal from noise when reviewing medical evidence so they're more likely to incorporate it into their practice?
4. How might new kinds of predictive models, algorithms and patient education resources allow manufacturers to alleviate provider burdens while also closing care gaps and improving evidence-based care?

Optum

At Optum Life Sciences, we connect data. We connect ideas. We connect life sciences firms with the rest of the health care ecosystem to catalyze innovation and impact.

We help our clients:

Generate evidence by unlocking insights from the industry's largest repository of longitudinal, linked real-world data

Elevate your value story by anticipating and addressing the demands of payers, providers, patients and regulators throughout the product lifecycle

Put theory into practice by leveraging our enterprise connections across all sectors of health care to accelerate clinical development and improve population health

Visit us at optum.com/lifesciences

Advisory Board

Advisory Board offers a subscription-based research service for commercial, medical, RWE and HEOR executives at leading life science, medical device and health tech firms. Our deep relationships span the health care ecosystem. We work not only with leaders of hospitals, health systems, medical groups and post-acute care providers, but also with digital health companies and health plans.

We leverage this longstanding network and our rigorous objective research to help life science leaders better understand customers, market dynamics and cross-industry challenges to inform strategy.

We enable you to:

- Understand how shifts in the market impact your organization and your role today, and in the future
- Anticipate how HCP and payer decision-making is evolving and the associated implications and open questions
- Influence internal and external stakeholders through objective educational material

Visit us at advisory.com/memberships/life-sciences

Want to continue the conversation?

Contact us.

Brandi Greenberg
Vice President, Market Strategy
and Customer Insight
Optum Life Sciences
brandi.greenberg@optum.com

Solomon Banjo
Managing Director,
Life Sciences Research
Advisory Board
banjos@advisory.com

Anna Gefroh
Associate Director, Marketing
Optum Life Sciences
anna.gefroh@optum.com

Michael Mejia
Director, Life Sciences Research
Advisory Board
mejiam@advisory.com