Advisory Board

Optum

The 11 Things Life Sciences Leaders Need to Know in 2022

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We're only four months into 2022, and it's clear the year ahead is going to be just as bumpy and unpredictable for life sciences organizations as 2021 was.

All signs point to a waning of the two-year-old COVID-19 pandemic, but there's no shortage of new uncertainties impacting health care, global trade, and innovation.

Recently, life sciences market experts from Advisory Board and Optum Life Sciences came together to consider the trends poised to have the greatest impact on the market for life sciences data and evidence in 2022. Drawing on conversations with 200+ decision-makers across the health care ecosystem—as well as a series of executive roundtables and cross-industry events for life sciences medical, health economics and outcomes research (HEOR), and market access leaders—we identified **11 trends** worth watching this year.

About this report

As the market for evidence continues to evolve, we encourage life sciences leaders to keep asking three critical questions to inform planning and prioritization.

1. When it comes to engaging with real-world data, generating evidence, and articulating the value of your products: What are you doing to monitor the most salient market shifts and stakeholder priorities?
2. How are sources, uses, and applications of medical evidence evolving to meet customers' demands for "value"?
3. What internal investments, organizational structures, and skills will be most necessary for life sciences organizations to succeed in an increasingly complex market for evidence?

To answer these questions and help you distill signal from noise, we've picked out the trends that we think matter most.

11 trends life sciences leaders need to know

Situational context

Coming wave of next-gen therapies

The impending launch of numerous "next-gen therapies"—inclusive not only of ultra-high-cost **cell and gene therapies but also biomarker-based precision treatments as well as digital therapeutics**—will **disrupt traditional treatment paradigms** and require stakeholders to take a more coordinated, expansive approach to **data collection, evidence-generation, outcomes monitoring, and value assessment** over time.

Life sciences' pipelines are increasingly shifting toward more narrowly targeted precision therapies, ranging from cell and gene therapies to CRISPR, CAR-T, and other treatments that leverage patients' biomarkers and genomic makeup to treat disease. In fact, there are over 1,764 cell and gene therapies in development. But beyond such new-in-kind drugs, investors and life sciences organizations are also pouring money into innovative digital therapeutics (DTx) and digital health tools, many of which leverage technology such as apps, telehealth platforms, and even video games to treat disease. In 2021, investors poured $29.1B into U.S.-based digital health startups, and investments in digital therapeutics increased 2.6x between 2020 and 2021.

Despite promising clinical advancements, many of these treatments carry a high price tag (ranging from tens of thousands to millions of dollars). This raises the bar for the evidence and proof of "value" that payers, providers, and regulators will require for product coverage and use. Yet next-gen therapies and digital therapeutics create two novel challenges for innovators focused on evidence generation and outcomes monitoring.

First, many next-gen therapies are durable and/or curative in nature, with safety and efficacy profiles that require long periods of monitoring to prove value for each patient. However, today's value assessments typically rely on randomized clinical trial (RCT) data spanning shorter (one-

Situational context

Coming wave of next-gen therapies

to three-year) time horizons. Most health care organizations are just starting to develop the infrastructure needed to track and evaluate more longitudinal outcomes. Additionally, these therapies are pushing payer and provider organizations to expand the scope of their clinical value assessments to consider a greater range of pharmacoeconomic outcomes and impacts on total costs of care.

Second, the broad classes of cell/gene therapies and digital therapeutics are, together, starting to illuminate the industry-wide need for value assessments that consider an expanded range of clinical endpoints, not to mention the need for manufacturers to generate stronger evidence dossiers overall. For example, some customers may place greater weight on patient-reported outcomes (PROs) that help illuminate patient experiences, quality of life impacts, and preferences over time. To help stakeholders evaluate digital therapeutics, manufacturers may need to collect digital-first endpoints via wearable devices or smartphones, and they'll need to provide greater proof of adherence and clinical impact over time.

It's also worth noting how cell/gene therapies and digital therapeutics are disrupting the care continuum and dispersing the most common places for treatment, albeit in very different ways. Notably, patients are still funneled to just a handful of Centers of Excellence for initial cell/gene therapy, even if follow-up care and monitoring happens closer to home. Conversely, most digital therapeutics meet the definition of "everywhere care"—supporting patients at home, at the office, virtually, etc. In either case, clinical innovators will need to develop compelling ways to track safety, efficacy, and durability across a wide range of clinical and home-based settings.

Explore the implications for life sciences leaders and questions to consider for this trend on the following page.

Situational context

Implications for life sciences leaders

Life sciences leaders will need to expand where and from whom they generate evidence. They'll also need to broaden the kinds of data sources that can provide insight into endpoints customers may require. Doing so will require heightened collaboration across medical affairs, HEOR, market access, and other internal functions, as well as with cross-industry stakeholders. Such efforts will not only enable smarter, more coordinated evidence generation, but they may also pave the way for new opportunities in value-based contract design, especially for high-cost cell and gene therapy drugs.

Life sciences leaders must also recognize how payers and providers are broadening the set of treatment options they consider as comparators. Drugs are no longer evaluated in isolation. With heightened cost pressures and limited insight into longitudinal outcomes, decision-makers may expand their evaluations from just drug vs. drug to drug vs. digital therapeutic or drug vs. non-medical intervention. As a result, customers will have new demands for comparative effectiveness studies or real-world data showing meaningful differences among treatment options.

Questions to consider

1. How are you working cross-functionally to identify and prepare for your customers' future evidence needs? Are you thinking about endpoints that customers might require three to five years from now and incorporating those endpoints into study designs today?
2. What real-world data sources (e.g., claims, EHR data, data from wearable devices, patient reported outcomes) can you leverage to better demonstrate the value of your products?
3. Are you generating evidence that shows how your products impact a broader range of metrics beyond safety and efficacy, such as total cost of care, absenteeism, or patient satisfaction?

Situational context

Continued battles over drug pricing

While federal drug pricing proposals wither on the vine, **state governments and disruptive for-profit innovators** will continue to pressure both manufacturers and PBMs with **new models of value assessment, transparency, and price control.**

Drug pricing is likely to remain a hot topic in 2022. But the federal government isn't likely to be the driving force behind any meaningful change. While (as of this writing) President Biden tries to revive interest in federal drug pricing reform, the Build Back Better Act—which included several initiatives aimed at slowing drug cost growth and reducing patients' out-of-pocket costs—seems unlikely to re-emerge in anything close to its original form. Senator Joe Manchin (D-W.Va.) has recently expressed renewed interest in negotiating revised legislation that would include some efforts to lower drug costs (for the government and for consumers), but it's unclear how that will ultimately play out. Payer/provider price transparency mandates have exposed the profits many hospitals and physicians generate from "buy and bill" and 340B pricing models, but political realities and competing stakeholder incentives make further federal scrutiny here unlikely.

All that activity may obfuscate the more likely threat to current drug pricing models and incentives. Across the past year, several for-profit innovators have positioned themselves as potential disruptors to the PBMs' prevailing rebate-centered model—most notably, EQRx, EmsanaRx, GoodRx, and Mark Cuban's CostPlus drug company. Some, like EQRx, present themselves as a simpler kind of PBM, while others, like CostPlus, are trying to disintermediate PBMs entirely. Their business models vary, but all claim to lower consumers'

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Continued battles over drug pricing

out-of-pocket drug costs by injecting more transparency and simpler fee structures into their approach. While it's too early to predict these companies' lasting impact, their efforts to lower consumers' drug prices by "disrupting from within" the industry are worth watching.

Meanwhile, several states continue to push forward with drug pricing regulations of their own. In 2021, 22 states passed more than 40 prescription drug pricing laws, and they are poised to do even more in 2022. Fueled by guidance and resources from the National Academy for State Health Policy (NASHP), these states are establishing independent drug price review boards, penalties for "unjustified" price increases, price caps, and price transparency requirements. Many of the state-level bills target PBMs as well as manufacturers. Perhaps not coincidentally, NASHP is a nonpartisan advocacy group funded by Arnold Ventures, the same organization that contributes millions of dollars to the Institute for Clinical and Economic Review, the organization better known as ICER. And ICER has been getting more involved in state-level initiatives as well. In early March, ICER announced receipt of a grant from the California Health Care Foundation (CHCF) to develop "two annual unsupported price increase reports specific to California and a policymaker guide outlining how to use comparative effectiveness research to ensure that patients have fair access to fairly priced drugs" (ICER press release, March 3, 2022). As early adopters of such initiatives and regulations begin to generate data about the impact of their efforts, interest in replicating or refining their models may grow.

Explore the implications for life sciences leaders and questions to consider for this trend on the following page.

Situational context

Implications for life sciences leaders

Even without an urgent need to respond to official federal drug pricing reforms, life sciences leaders must not become complacent or assume that today's dominant pricing models are set in stone. Any cracks in traditional pricing models (be they rebate-based, buy-and-bill, or ASP+) open the door to more experimentation with value-based contracting, value-based benefit designs, and other innovative approaches to pricing and access. These newer models will almost certainly require broader use of real-world evidence to demonstrate differentiated clinical outcomes and/or lower total cost of care.

Any truly disruptive changes to today's pricing models (e.g., if CMS starts to negotiate drug prices for even a handful of high-cost therapies) could force a broad, cross-industry reckoning with legacy business models. To minimize the impact on research, innovation, and commercial growth, manufacturers would almost certainly need to reimagine long-established approaches to drug discovery, clinical development, and physician engagement. While such disruption may appear unlikely in the near term, it's never too early to begin planning for such scenarios.

Questions to consider

1. Do you have sufficient resources monitoring federal, state, and startup business activities that could impact pricing, contracting, and transparency requirements?
2. Have you sufficiently modeled different pricing scenarios for your most promising products in the pipeline?
3. What are you doing today to foster the kind of agility, innovation, and cross-sector collaboration that may be required to succeed with more value-centered approaches to pricing and access?

Situational context

The pursuit of health equity

Across all sectors of the health care economy, progressive organizations will collaborate to leverage **real-world data** not only to identify health disparities, but also to **prioritize, shape, modify, and assess multi-stakeholder interventions over time**.

The outsized impact of COVID-19 on racial and ethnic minorities laid bare the limited progress we've made in reducing health disparities since the Institute of Medicine's seminal 2003 report, Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care. Since the summer of 2020, nearly every health care company operating in the United States has publicly identified health equity as an executive priority. Many organizations have appointed chief diversity officers or chief equity officers, donated to organizations addressing social determinants of health, and/or kicked off internal initiatives targeting health disparities that align with their organizations' areas of focus.

Academics, policymakers, and researchers have also been hard at work, unpacking histories and analyzing data to help the industry understand the scale and scope of the problems at hand. Through webinars, podcasts, conferences, and journal articles, these research and policy leaders have increased awareness of health disparities and their root causes, which has stimulated important conversations about how to narrow those gaps. Among the biggest areas of focus: lack of diversity in clinical trials, unequal access to diagnosis and treatment, racial bias in care delivery, and the need to address social determinants such as food/housing insecurity, technology/transportation access, and available social support.

Situational context

The pursuit of health equity

Broad access to high-quality, longitudinal real-world data has been instrumental to these efforts. While projects in 2020 and 2021 skewed heavily toward descriptive analyses highlighting evidence of disparities and illuminating root causes, initiatives in 2022 must pivot more toward action. Such efforts to drive meaningful, sustainable change will require focused cross-industry collaboration—life sciences companies partnering with providers, payers working with health tech companies, and large multinationals collaborating with local community nonprofits. Real-world data will continue to power these efforts. But instead of just providing evidence of disparities, rich combinations of clinical, cost, behavioral, and socioeconomic data will help cross-industry leaders prioritize their efforts, pilot various interventions, and (importantly) track the impact of their work over time.

Explore the implications for life sciences leaders and questions to consider for this trend on the following page.

Situational context

Implications for life sciences leaders

Life sciences companies will face increasing pressure to demonstrate their commitment to reducing health disparities in tangible ways. This is true not only as it relates to diversifying clinical trial participation, but also as it relates to ensuring equitable access to appropriate diagnostics and treatments.

To do this work, life sciences companies will need trusted data and insights that can help them prioritize opportunities and develop meaningful, measurable pilot programs. They'll need to identify aligned payer, provider, and community partners willing to contribute the resources needed to test, measure, and scale programs that can move the dial on health equity. In the short term, the "sweet spots" for alignment likely cluster around programs that help address disparities in the following areas: trial participation, disease prevention, appropriate screening, earlier diagnosis, simplified access, and improved adherence to recommended treatments.

Questions to consider

1. Do you have clear visibility into the nature of health disparities in the populations you aim to support with your therapies?
2. Has your organization invested in the real-world data most "fit for purpose" to help drive meaningful action against the disparities you are best positioned to address?
3. How might you use real-world data as a potential shared source of truth to fuel conversations with payers, providers, and other stakeholders about health disparities in the populations they serve?
4. Have you identified the attributes of partner organizations best positioned to help your firm address health inequities?

Situational context

Efforts to democratize clinical trials

Our ability to truly democratize clinical trials will depend on the extent to which we can **harness ongoing technological and operational innovations** to address the **non-clinical exclusions** built into the current system that **limit patient and investigator diversity.**

Sponsors and clinical research organizations (CROs) have a unique opportunity to translate recent efforts to decentralize clinical trials into structural change that meaningfully democratizes evidence generation and ensures equitable representation of both patients and investigators. The virtualization of trials is a necessary but not wholly sufficient step to accomplishing this goal, as success will require time, true partnership with communities, and the learning and unlearning of processes that stand in the way of progress.

One necessary shift is that stakeholders must recognize the current approach to clinical trials too often excludes participants on more than just clinical dimensions. Stakeholders must acknowledge the ways in which social determinants like transportation, physical location, and education status impact trial participation but are not fully accounted for in trial design. Unless sponsors do more to account for these kinds of "hidden" exclusions that often begin at the point of protocol design, it will be hard for the industry to realize the full potential of data and technologies designed to improve patient finding and patient/investigator experience during trials. At best, these tools can help expand access, diversify participation, and broaden the kinds of data collected. But without a commitment to rethinking protocol design and process flows, these same tools run the risk of adding complexity, increasing costs, and exacerbating inequities.

Situational context

Efforts to democratize clinical trials

Progressive organizations across the ecosystem are recognizing that a similar approach can help address the challenge of expanding participation of investigators from marginalized communities. These organizations are using technology not only to reduce the non-clinical burden on investigators, but also to identify ways for clinicians who do not wish to be investigators to maintain continuity of care with their patients.

Explore the implications for life sciences leaders and questions to consider for this trend on the following page.

Situational context

Implications for life sciences leaders

Life sciences organizations must do more to demonstrate their commitment to making trials more diverse and inclusive—even amid continued pressures on costs and speed-to-market. Meaningful changes will require sponsors to revisit assumptions around existing timelines and procedures as well as partnerships with contract research organizations (CROs), community trust brokers, digital vendors, and others. Leaders must be vigilant to ensure that the vital work required to reduce patient barriers to participation does not overshadow the work needed to broaden the pool of potential investigators.

The benefits of improved clinical trials participation (both in terms of patient recruitment and patient experience) extend beyond the impact on trial operations. The whole health care ecosystem can benefit as well. Purchasers, HCPs, and patients are eager to understand how treatments vary across patient demographics in order to support shared decision-making and appropriate utilization.

Questions to consider

1. How will you identify and engage with established trust brokers to foster partnerships in local communities?
2. Has your organization integrated the right patient, clinician, and community perspectives to minimize the non-clinical burdens of trial participation?
3. What steps have you taken to ensure that digital technology is being used to close gaps in participation and doesn't just increase costs/timelines or exacerbate inequities?

Sources and uses of evidence

Pushing beyond the tipping point for RWE

Now that real-world evidence has garnered **industry-wide acceptance** and the FDA has issued **draft guidelines** on RWE use in regulatory decisions, life sciences leaders cannot afford to wait passively for further direction or support. Progressive organizations will **invest more aggressively in using sources of real-world data** to support clinical development, payer/provider engagement strategies, and a range of market access programs (including outcomes-based contracts.)

The industry is at a tipping point in its comfort with and use of real-world data across the product lifecycle. Diagnosing, treating, and vaccinating against COVID-19 has required health systems and governments to make public health decisions via the near-real-time collection and analysis of real-world data. In December 2021, the FDA issued draft guidance on use of RWD and RWE in regulatory decisions and has publicly signaled that it will continue to release additional guidance on RWE sources and study design.

Additionally, FDA appears to be signaling a greater openness to conversation and collaboration with industry stakeholders. In fact, in the draft guidance, FDA suggests that "Sponsors should engage with FDA in the early stages of designing a non-interventional 135 study intended to support a marketing application."

Sources and uses of evidence

Pushing beyond the tipping point for RWE

Beyond recent regulatory changes, investors continue to pour billions of dollars into technologies and consortiums that can aggregate, integrate, and safely de-identify disparate real-world data sets for more sophisticated analyses. And although buzz around real-world evidence has existed for years, it's now fully in the public spotlight—and top-of-mind for all health care leaders.

As a result, real-world evidence is past its tipping point on acceptance. Hesitation to invest beyond claims and registries is getting harder to justify, as regulators are beginning to offer more clarity, impactful use cases are proliferating, technology platforms are enabling greater ways to link disparate data sets, and stakeholders are raising the bar for demonstrating value.

Explore the implications for life sciences leaders and questions to consider for this trend on the following page.

Sources and uses of evidence

Implications for life sciences leaders

Life sciences leaders can no longer take a passive or reactive approach to investment in and use of real-world evidence.

However, as investment and interest in RWE intensify, the bar for real-world evidence is evolving. Increased scrutiny on data quality, scale, and relevance—coupled with increased pressure from stakeholders to see ROI on RWD investments—means that life sciences leaders need to proactively (and aggressively) evolve their RWE strategy. Life sciences leaders must identify opportunities to invest in tools and platforms that support secure and lawful data linkages for longitudinal analysis, trusted AI applications, and near-real-time analytics. They must work with payers and providers to make better sense of the abundant cost, utilization, and clinical data available. And they must put that real-world data to use in ways that better align stakeholders on improving outcomes, lowering total cost of care, and delivering value. Medical and HEOR leaders must continue to work with their R&D colleagues to identify appropriate use cases for utilizing RWD earlier in the product lifecycle and for leveraging the wealth of data they already have.

As a case in point, several progressive life sciences organizations have started to use RWE to inform clinical pipeline prioritization, protocol design, market access strategies, and business development decisions.

Yet a comprehensive RWE strategy isn't just about data collection and evidence generation. Life sciences leaders must change how and when they communicate real-world evidence with key stakeholders. Clinicians and other medical product gatekeepers will demand answers to questions about the validity of data and analytic algorithms, assumptions underlying data analyses, and any possible holes in data due to disrupted care during COVID-19. Stakeholders may also need help making sense of the sheer volume of real-world data that continues to emerge so that they can curate data based on quality, business need, and context. Some customers may even ask life sciences leaders for help analyzing their own data, which could create new opportunities for personalized, data-driven engagements between sales or medical liaisons and their key customers.

To avoid falling behind competitors, life sciences leaders should be actively engaging regulators and key customers to discuss real-world evidence needs, adapting and preparing for upcoming regulatory guidance, and identifying opportunities to expand use cases for existing data sets.

Sources and uses of evidence

Questions to consider

1 How are you staying up to date on the latest RWE regulatory guidance and changes? Is your organization proactively working with regulators, and across internal stakeholders, to incorporate any guidance into evidence-generation strategies?

2 How can you better understand your customers' real-world evidence needs? What opportunities exist for collaborative evidence-generation partnerships?

3 Are your teams working across the product lifecycle to leverage RWE in a range of clinical and nonclinical decisions? What additional internal stakeholders should you engage to ensure your organization's RWE strategy is proactive and comprehensive?

Sources and uses of evidence

Proliferating sources of RWD

The RWE landscape will need to account for **delivery and clinical innovations** such as whole genome testing, telehealth, and home-based care. This will raise the bar for **integrating data from increasingly fragmented care sites** and highly varied data sources into reliable, trusted, quality data sets.

The broad acceptance of RWE and the growing interest in additional applications of data are happening concurrent with an unprecedented shift in care delivery from inpatient to outpatient settings, and from outpatient to home/virtual settings. 2021 saw unprecedented investments in digital health, home-based care, and innovations that support care delivery in non-acute settings.

While many experts have touted the benefits of these innovations, especially from the patient perspective, few people are talking about the ripple effects of this care fragmentation. Notably, this transition to "everywhere care" makes care coordination and data integration much, much harder. Manufacturers will face new challenges in ensuring that the longitudinal real-world data sets they use are sufficiently robust across multiple sites of care. And they'll also face new customer demands to measure and demonstrate value of their products when used in a wider range of clinical (or non-clinical) settings.

Explore the implications for life sciences leaders and questions to consider for this trend on the following page.

Implications for life sciences leaders

Life sciences leaders need to understand how new care models impact clinician decision-making, especially about diagnosis, prescribing, and product use. This information is particularly important given the efforts of payers and primary care innovators to influence clinicians' decisions as a way of reducing unnecessary downstream utilization. But it's not just about the provider. Life sciences leaders should also strive to understand their top integrated delivery network (IDN) customers' long-term site-of-care strategies. Which IDNs are investing in ambulatory surgery centers? Which are building out infusion centers or partnering with home care agencies to enable more acute care at home? These plans will have significant implications on product purchasing, distribution, use, and real-world data collection (e.g., for symptom/side effect or adherence tracking).

These site-of-care shifts also raise questions around the safety, quality, and cost of providing care in atypical settings. Life sciences leaders are asking questions like: "What are the right metrics to track?" Or, "What are the appropriate benchmarks?" Such data does not readily exist for many treatments and interventions, thus requiring manufacturers to gather additional RWD they can share with providers, payers, and IDN leaders. Doing this important work requires access to data sources that these stakeholders trust as accurately reflecting real world practice and outcomes.

There is also an emerging need for organizations to gather new and different kinds of data, either because the source is novel (like wearables or connected devices) or because the data itself is relatively novel and untested (like social determinants of health or internet search histories). Life sciences leaders must gather input cross-functionally, and across key customer groups, to ensure that they are investing in data sources and evidence-gathering initiatives that meaningfully contribute to conversations about value in a world of fragmented "everywhere care."

Questions to consider

1. For which of your products, and in which markets, are site-of-care shifts likely to be most impactful?
2. Do you have sufficient data to understand both the magnitude of changes in care delivery and the impacts on cost, quality, and safety?
3. What novel data sources are worth your time to investigate, and which represent noise?

Sources and uses of evidence

Anxiety over data privacy and security

Life sciences leaders must balance their **thirst for connecting disparate real-world data sets** with very real institutional and individual responsibilities for ensuring the **privacy and security of the underlying patient information.**

There are more data sources than ever to gain a holistic understanding of patient journeys and diseases themselves. The life sciences research community can now leverage a diverse array of deidentified information sources by linking traditional medical data (like EHR and claims data) with emerging resources like social determinants of health (SDOH), patient-generated wearables data, genomics, and consumer data. And new data interoperability mandates in the next few years will further reduce the barriers that hinder the creation and maintenance of longitudinal patient histories.

But the life sciences community must move forward with care. When tasked with solving a business problem, well-intentioned researchers design analyses and identify their data needs. Often, researchers may wish to connect different forms of data. For example, researchers may combine deidentified information from a clinical trial with a publicly available data source. But they need to be careful that such data-linking doesn't inadvertently increase the risk of reidentification of individual patients.

When tasked with solving a business problem, well-intentioned researchers design analyses and identify their data needs. In many cases, they may desire to connect different forms of data together—for example, by combining deidentified information from a clinical trial with a publicly available data source. Researchers must accompany this type of data linking with careful due diligence to assess the resultant data set and ensure it does not inadvertently increase the risk of reidentification, because as more attributes are known about a deidentified person, the risks of reidentification increase.

Sources and uses of evidence

Anxiety over data privacy and security

When individuals' health data is exposed, they may confront reimbursement fraud, personal financial risks or unwanted stigma. For life sciences manufacturers, data reidentification could violate their own protocols for IRB-approved studies or their contractual obligations with third parties. They may also face scrutiny and penalties from a variety of state and federal regulators for any resulting breach from an exposure as well as financial exposure from the individuals impacted by a breach. Business leaders can safeguard the outputs and protect against misuse or privacy breaches by making sure the right compliance and governance processes are in place.

Chief information security officers and chief privacy officers cannot be the only ones who are concerned with privacy and data security. The risk of patient re-identification, coupled with ever-more-sophisticated cyberattacks, means that life sciences organizations must take steps to protect their own reputations along with the security and privacy of the patients, payers, and provider organizations generating and sharing real-world data for research purposes. Leaders must cultivate a culture of preserving confidentiality—everyone touching data must understand his or her obligation to ensure the information remains deidentified and secure.

Explore the implications for life sciences leaders and questions to consider for this trend on the following page.

Sources and uses of evidence

Implications for life sciences leaders

Recent miscues by social media platforms and Big Tech have cast a spotlight on the misuse of personal information, and that spotlight is unlikely to fade away anytime soon. Several times each year, the newswires decry the latest data breach or ransomware attack on a health care organization. Cultivating a cross-functional data governance team that includes data, analytics, legal, security and privacy experts can help your organization acquire, curate, and deploy data securely to keep your organization out of the headlines.

Leaders must be aware of the regulatory obligations and public perceptions around data access, because cross-sector partners will be protective of their own institutional obligations and reputational risk. This risk aversion may make it more difficult to pursue innovative projects that depend on multiple forms of real-world data.

These challenges are particularly acute outside of the United States, where European privacy laws and regulations make decentralized trials or remote data collection for research purposes particularly difficult.

Questions to consider

1. Have your data privacy and security policies kept pace with technological innovation?
2. Who in your organization decides what data to acquire and how different sets of data are used?
3. What steps does your organization take to deidentify data and ensure it cannot be reidentified?
4. If you source data from a third party, what mechanisms do they have to help protect and prevent reidentification of that data?

Sources and uses of evidence

Harnessing the power of AI

Massive investments in data science partnerships suggest that pharma leaders have bought into AI's promise to make drug discovery more efficient—but life sciences companies won't realize the full potential of this technology unless they take deliberate steps **to embed AI applications into day-to-day workflows** in ways that empower employees and **exercise caution to minimize unintended bias.**

Some of the biggest players in the life sciences space have placed nine- or ten-digit bets on companies that promise to use artificial intelligence (AI) to discover new medicines more efficiently, leading to better returns on R&D dollars and less time spent on potential treatments that are ultimately unsuccessful. Should these endeavors prove successful, they have the potential to mark a turning point in the history of drug development, as the promise of these capabilities to reduce waste and increase speed to market finally comes to fruition.

Applying AI to identify druggable targets or model molecular structures is an activity that occurs well before clinical trials in actual humans begin. The hypotheses formed from AI-driven insights are tested in a lab, where researchers can readily observe the outcomes of controlled experiments. If and when these initial tests are successful, the rigors of the regulatory approval process require that any treatment coming out of an AI-informed process meets safety and efficacy thresholds.

The use cases for AI expand well beyond drug discovery, though. Life sciences manufacturers can adopt well-established forms of AI to personalize consumer experiences, as the retail and banking industries have done. They can select appropriate administrative processes to automate which, when paired with appropriate human oversight, can streamline operations and help employees be more productive. And they can analyze real-world data in new ways: for example,

Sources and uses of evidence

Harnessing the power of AI

a machine learning algorithm could analyze medical claims data and potentially identify label expansion opportunities. Researchers can also use natural language processing (NLP) to transform unstructured data from clinical notes into research-ready discrete data that other forms of AI can ingest and examine.

While all these applications have the potential to streamline operations and increase both consumer and employee satisfaction, they nonetheless come with a cost—and in many ways, it's a harder one to swallow than the high-dollar investments in pre-lab discovery. Laws and regulations are emerging in this space, and organizations must be mindful to have proper controls and governance models in place to reduce risk of unintended consequences, such as the introduction, persistence or exacerbation of bias. The recommendations or predictions made by AI-driven models must be presented to the human end users in ways that build trust, fit seamlessly into workflows, enable responsible use and arrive at moments when they can take action to influence outcomes. It takes sustained effort, a commitment to building a culture that embraces technological change and the awareness that human oversight is needed to minimize any unintentional negative impacts to the people affected by the model's predictions or recommendations.

Explore the implications for life sciences leaders and questions to consider for this trend on the following page.

Sources and uses of evidence

Implications for life sciences leaders

Many of these data science partnerships are in their infancies, and we are only months removed from DeepMind's decision to make their AlphaFold protein-folding prediction technology publicly available. The industry seems to be on the cusp of significant scientific breakthroughs that could create meaningful changes for patients, providers and payers—but those advances won't be realized for many years to come.

More immediately, two macro trends are converging that force life sciences leaders to examine their AI strategies: first, the emphasis on equality and equity, and second, the societal distrust of AI. Much of the media focus on AI in health care has scrutinized the ethical or practical constraints of AI in clinical practice. As such, the burden of proof is understandably high when it comes to illustrating the benefits of any program that uses AI-driven recommendations. When collaborating with providers or other patient-facing entities on clinical programs that incorporate these insights, decisionmakers must take steps to limit unintended consequences.

Other parts of health care have already discovered that it takes an incredible effort to close the last mile between the potential and the practical when it comes to embedding AI into operations, even when there's broad agreement that AI can offer observable value (either monetarily or by improving patient outcomes). That means it's likely easier to judge the ROI on efforts to increase efficiency in early discovery—despite the high price tag—because the downstream gains of AI applications show up in ways that are harder to measure.

As leaders assess the ROI on downstream AI applications, they should evaluate a mix of hard costs (i.e., dollars and time) and soft costs (i.e., sustained effort and persuasion). That appraisal is further complicated by the time lag between when the technology investment is made and when the benefits accrue to patients and staff. But in an increasingly competitive landscape, leaders must examine every lever they can pull to offer exceptional consumer experiences, operate as efficiently possible and deploy human talent where it can make the most impact. Organizations must consider how different forms of AI can help achieve those goals.

Sources and uses of evidence

Questions to consider

1. How does your organization stay abreast of emerging laws and regulations relating to the use of AI?
2. How does your organization provide oversight and governance on the responsible development and use of AI?
3. Which parts of your workforce could benefit from the right technology applications that take redundant or menial tasks off their plates?
4. Which cross-industry AI best practices could help you create more consumer-centric experiences?

Expanding platforms for HCPs' consumption and circulation of evidence

The **growing online presence of clinicians,** coupled with their heightened demands for real-time consultation and evidence, are changing the evidence dissemination paradigm from **the traditional one-way push of information** to a **real-time circulation of knowledge.**

Online clinician communities for medical information sharing—both open social media channels (e.g., Twitter, LinkedIn) and physician-only digital platforms (e.g., Doximity, Sermo, epocrates, Figure 1)—have evolved to become top destinations for clinicians to discuss clinical evidence, network with their peers, and extend their own reach and "influence" within the health care community.

Clinicians are becoming more comfortable seeking and reviewing clinical information (including, but not limited to, peer-reviewed journal articles) and anecdotes online. This became especially important during the COVID-19 pandemic, when traditional access to information from pharma representatives, conferences, and traditional channels was restricted. Further, the pandemic spurred questions about drugs, vaccines, and conditions faster than researchers could generate evidence, so clinicians relied on crowdsourced answers from experts around the world. While the digitization of medical information has existed for years, COVID-19 and the acceleration of online information exchange have made medical consensus-building more transparent and accessible than ever.

As HCPs are increasingly debating evidence studies and engaging in rich discussions with their peers online, those conversations are directly informing treatment selection and care decisions—becoming part of a dynamic body of evidence in the process. This is creating fundamental shifts the evidence communication paradigm, moving it from one traditionally focused on evidence dissemination to one focused on the circulation of evidence at unprecedented scale. As a result, evidence dissemination is no longer a static, one-way street from life sciences organizations to HCPs.

Explore the implications for life sciences leaders and questions to consider for this trend on the following page.

Sources and uses of evidence

Implications for life sciences leaders

Changes to the ways evidence is generated and disseminated will require many life sciences leaders to rethink their traditional strategies for disseminating medical information—including publications, conference presentations, use of key opinion leaders (KOLs), and use of MSLs. Evidence dissemination is no longer a static, one-way activity. Life sciences leaders need to understand and capitalize on the discussions surrounding their studies, as well as the subsequent consequences these discussions have on how clinicians practice medicine.

As interest in online clinician communities grows, life science leaders must recognize that such discussions can create new opportunities for real-world evidence generation and insight about unmet medical needs, physicians' clinical decision-making processes, and gaps in research/clinical evidence. For example, online debates can provide insight into physicians' perceptions of standards of care and treatment options, how clinicians decide what medical products to use, and how the current evidence base (or lack thereof) informs actual treatment decisions.

However, life science leaders must also prepare for the unintended ripple effects these platforms create. With COVID-19 accelerating the pace of evidence generation, researchers and HCPs are now demanding new data and evidence at an unprecedented pace. Whether life science leaders can keep up with these heightened demands, or will need to temper their customers' expectations, remains to be determined.

Further, the rapid pace and proliferation of evidence discussion means that conversations are happening outside of life science leaders' control—making medical misinformation or disinformation more likely to arise. As clinicians typically congregate online by specialty or background, some clinicians may start to resist changing their perspective or opinions, as online "echo chambers" of discussion can amplify preexisting biases or opinions. To adapt, life sciences leaders need to not only actively monitor these communities and the influential voices on them, but also understand how discussions impact product use, perceptions, and decisions.

Sources and uses of evidence

Questions to consider

1. How are clinicians engaging with your evidence in online clinician communities? Where are discussions about your company's products or therapeutic areas happening?
2. What opportunities exist to use data mining and social listening to generate real-world evidence in online clinician communities?
3. How can you use conversations from online clinician communities to better understand HCPs' uses and perceptions of your products as well as current evidence needs?

Organizational impacts

Evolving role of medical sciences liaisons

Continued restrictions on pharmaceutical representatives' in-person interactions with HCPs, coupled with clinicians' growing comfort accessing medical information online, are causing many life sciences organizations to **reorganize** both their sales and medical outreach teams. This is raising new questions about **optimal ways to leverage MSLs** as part of a broader evidence-generation and evidence-engagement strategy.

Even as the most recent Omicron wave of the COVID-19 pandemic subsides, continued restrictions on in-person HCP interactions, local surges, and clinician burnout are all causing life sciences organizations to question the future of the traditional sales representative and consider the expertise needed to interact with clinical customers.

On one hand, the pandemic illuminated the need for more medical/scientific expertise, along with reps who can field complex questions about products, evidence, and value. As a result, some companies are looking to expand the purview of the MSL beyond traditional off-label and science-centered conversations.

They're looking to leverage RWD and HEOR research in new ways, such as helping HCPs understand their patient populations more discretely or engaging new kinds of customers (e.g., employers). Other companies, like Pfizer and Amgen, are cutting back on the number of reps. These companies are reallocating some of those funds toward more digital-first content creation in recognition of the greater presence of HCPs searching for and discussing evidence online.

On the other hand, gaining the attention of HCPs is more difficult than ever. Providers are still restricting most reps from in-person interactions. Individual HCPs continue to suffer from burnout and trauma and are turning down virtual visits.

Organizational impacts

Evolving role of medical sciences liaisons

More HCPs are utilizing online channels to access and discuss clinical evidence and products, which is calling the traditional MSL role into question and causing life sciences leaders to rethink what value such a clinically trained field force can provide to their customers. In fact, a recent survey published by Reuters for Within3 found that 40% to 49% of medical affairs and life science engagements are expected to be virtual in the next three years. And this doesn't just impact current customer engagements. It's also becoming increasingly difficult for life sciences leaders to identify the right decision-makers to target in the future, and to understand who has influence in the digital world.

Explore the implications for life sciences leaders and questions to consider for this trend on the following page.

Organizational impacts

Implications for life sciences leaders

The role of the rep has been at an inflection point for years, but the future will be determined by whether life sciences leaders can take advantage of emerging opportunities to leverage real-world data more effectively answer HCPs' and customers' open questions. In fact, a new report from Accenture found that 65% of oncologists want pharma reps to be able to discuss real-world data with them, and 51% "will need more discussion" on real-world data from reps in the future.

Moving forward, field teams may look for opportunities to generate localized, RWD-derived insights about individual customers' patient populations, disparities, and care gaps. Field teams can use personalized analysis to take their interactions to the next level and help customers identify eligible patients in their population, understand appropriate use cases, and support the creation of clinical guidelines and standards. As real-world data and technology companies continue to invest in and expand access to new and linked sources of RWD, many other potential use cases may arise that could support MSL-to-HCP engagement.

Questions to consider

1. How can your field teams support customers by providing provide data-driven, tailored analysis?
2. Are your reps fully trained in the needed data and communication skills to be able to explain RWE to customers and to field complex questions?
3. How are your field teams adding value to your customers, who are increasingly burned out and have limited time to meet with reps?

Organizational impacts

Busting silos to maximize the ROI of RWD

Rapidly expanding sources and accepted uses of real-world data will force most life sciences companies to **invest in the necessary governance, infrastructure, and talent** required to support **collaborative, cross-functional RWD initiatives** across portfolios and product lifecycles.

Together, the ten previously discussed trends are fueling unprecedented investments in real-world data and analytics. Many life sciences companies appear to be locked in a virtual "arms race" for data. They are accumulating new data assets through a combination of licenses, partnerships, and proprietary tools in the hope of generating insights that can fuel innovation and growth. Not surprisingly, the number of data and analytics vendors has expanded rapidly as well, leaving many life sciences companies with a massive swath of disparate and disconnected data sets. Complicating matters further, that data is often housed in multiple, separate silos and owned by a variety of different functional or therapeutically focused teams.

Real-world data and evidence-generation are no longer the exclusive purview of HEOR or medical affairs leaders. Market access teams (and a burgeoning, integrated function known as medical access) are expanding their interest in a variety of real-world data sources to support more value-centered conversations with payers, PBMs, and employers. And as the FDA looks to establish clearer guidelines about the use of real-world evidence for regulatory purposes, the use cases for RWD in R&D are likely to expand as well. To avoid redundant data purchases or underutilized data assets, life sciences companies will need to develop enterprise-wide models for evaluating vendors, purchasing data, scoping projects, managing cross-functional RWE initiatives, and sharing critical research insights across the firm.

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Organizational impacts

Implications for life sciences leaders

The role of the rep has been at an inflection point. Just as the past few years showcased a growing cross-industry acceptance of real-world data, the coming years will be marked by an increasingly urgent need for companies to integrate and optimize the use of all these data sets. Doing so will require visionary leaders who can design the structures, processes, and staffing models that can support the RWE use cases of today—and tomorrow. It will require the commitment of additional capital (above and beyond the investments in data) to ensure teams have the right talent, analytical tools, and data sharing/storage infrastructure to generate the insights that can fuel decisions, actions, and impactful changes in care. And it will require the careful selection of data and consulting partners to ensure that life sciences companies not only work with high-quality, representative, fit-for-purpose data, but also ask the questions likely to yield the most salient, actionable results.

While the following list of infrastructure elements and required expertise may seem obvious, it differentiates the more sophisticated organizational consumers of real-world data from those still trying to figure it out:

- Data strategy that is clearly linked to enterprise strategy
- Centralized data infrastructure and governance
- Enterprise-wide data access
- Easily accessible educational resources that define contents and limitations of available data sets
- Early cross-functional input into RWE project design and scope
- Broad and clear firm-wide visibility into past and current projects
- Appropriate analytical talent (either in-house or through consulting partners) to analyze the data

Organizational impacts

Questions to consider

1. Can you (and your colleagues) clearly articulate your firm's real-world data strategy?
2. Are you doing enough to break down the technical and organizational silos that can hinder optimal use of real-world data assets?
3. Does your firm have a centralized function or team fully focused on real-world data (e.g., RWE Center of Excellence)? If not, should you?
4. Do you have processes in place to ensure you get early, cross-functional input on RWD projects that could have multiple applications across the product lifecycle?
5. Does your organization make it easy for colleagues from different functional areas to explore sources, methods, and results of past RWD projects to avoid repeating past mistakes and increase the likelihood of future success?

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