



Mission critical

Biopharma companies are accelerating real-world evidence adoption, investment, and application

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Second annual Real-World Evidence (RWE) Benchmarking Survey (2018)

Executive summary

SINCE the publication of Deloitte's first survey on the life sciences industry's real-world evidence (RWE) capabilities in 2017, the use and importance of RWE have evolved. Health care data—including patient-generated data—has proliferated, technology and analytics capabilities have advanced, regulators have increased their focus on the use of RWE, and a heightened scrutiny of drug prices has elevated the need to use real-world data (RWD) to track and better understand value. This year's survey sheds light on how biopharmaceutical companies' approach to optimize the use of RWE across the enterprise is changing through investments, functional applications, and technology.

This year, we found that the visibility and importance of RWE initiatives are increasing at the executive level. Most respondents are leveraging RWD across the enterprise to not just generate evidence but also support other research, corporate, and commercial objectives. They report that this is being driven by pressure to demonstrate value for access and reimbursement, the need to better understand the patient journey, increased data availability, and greater acceptance of RWE among regulators.

We found that:

- Almost all respondents (90 percent) reported they have either established or are currently investing in building RWE capability for use across the entire product life cycle. The top future application areas for RWE include supporting value-based contracting arrangements,

regulatory submissions, and improving clinical trial design and execution.

- Companies are planning to bring more of their RWE activities in house: 70 percent of respondents reported building or increasing capabilities to conduct a greater proportion of RWE studies internally. As a result, RWE spending on talent and technology in the future is anticipated to increase.
- The data landscape is rapidly evolving. There is a growing desire among respondents to use non-traditional data sources such as purpose-built linked data (for example, clinical data linked to molecular data), connected devices, and health apps.
- The future data landscape is likely to be shaped by an increase in strategic data partnerships and new ways of procuring data.
- Respondents noted that health care stakeholder receptivity to industry-generated RWE and lack of an internal understanding of where RWE analyses can be applied are the key barriers to RWE initiatives.

These trends are beginning to challenge biopharma's traditional operating model across the product life cycle. To remain competitive and differentiated in a value-based, personalized health care system, biopharma companies are likely to benefit from establishing end-to-end evidence-management strategies supported by the right talent, platforms, partnerships, and operating model.

Introduction

WHAT is real-world data (RWD) and real-world evidence (RWE)? Real-world data refers to health care data gathered from a variety of sources, outside of randomized controlled clinical trials. These data sources can include electronic medical records (EMRs), health insurance claims, genomic data, and data from health apps, wearables, and other biometric devices. Real-world evidence refers to the insights that are generated from these data. The Food and Drug Administration (FDA) refers to RWE as “the clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of RWD.”¹ For a detailed discussion about what RWE is, what it does, and how it helps biopharma companies develop products safely and effectively, refer to our inaugural RWE benchmark survey from 2017, *Getting real with real-world evidence*.²

Since the publication of our first survey in Spring 2017, regulators have advanced RWE initiatives (see sidebar, “The advancing regulatory science of RWE”), and some companies have been aggressive in their strategy to access RWD and generate RWE. For instance, in February 2018, Roche announced the acquisition of Flatiron Health, a health care technology company with a large oncology-EMR system, for US\$2 billion. Roche cited the possibility of harnessing the EMR data for research purposes—potentially speeding up and improving drug development—as a key driver of the decision.³

For this year’s survey, we sought to understand more about what’s inspiring companies to take such bold steps to access and use RWD and what investments they are making in this area (for more

THE ADVANCING REGULATORY SCIENCE OF RWE

The FDA has taken steps to advance guidelines around the use of RWE. Under the provisions of both the 21st Century Cures Act and the Prescription Drug User Fee Act (PDUFA VI), the FDA has established timetables for developing guidance on using RWE within its regulatory framework. The agency will continue to seek input in the coming months and years with as much external collaboration as possible.⁴ The FDA is collaborating with the industry to explore the uses of RWE. Together with Flatiron, the FDA is seeking to understand how immunotherapies can better treat cancer, for example.⁵

The European Medicines Agency (EMA) is also embracing novel ways of getting treatments to market. Among them is PRIME (PRiority MEdicines),⁶ which recognizes patient registries, health records, and other sources of data as ways to identify unmet medical needs. Developers of promising treatments to address these needs can receive accelerated assessment and may potentially receive expedited approval.

detail on this year’s survey see the sidebar, “Survey methodology”).

Our survey results reveal that:

- RWE is being used to achieve key strategic priorities across the product life cycle.

SURVEY METHODOLOGY

Deloitte conducted its second annual real-world evidence (RWE) survey to explore the perceived value, capabilities, and barriers to utilizing RWE. Between January and April 2018, Deloitte surveyed and conducted interviews with RWE, IT, scientific, medical, and business executives from global life sciences companies. The 2018 study includes 20 respondents, up from 15 respondents in 2017. The larger sample enabled us to create a broader understanding of RWE investments, applications, and operationalization across the industry.

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- Companies are investing in people, data, and technology (including machine learning) to build internal capabilities.
- Increasing use of nontraditional data sources will likely require external strategic partnerships.
- Internal and external barriers threaten the success of RWE initiatives.



RWE is being used to achieve key strategic priorities across the product life cycle

Executive leadership considers RWE to be an important priority

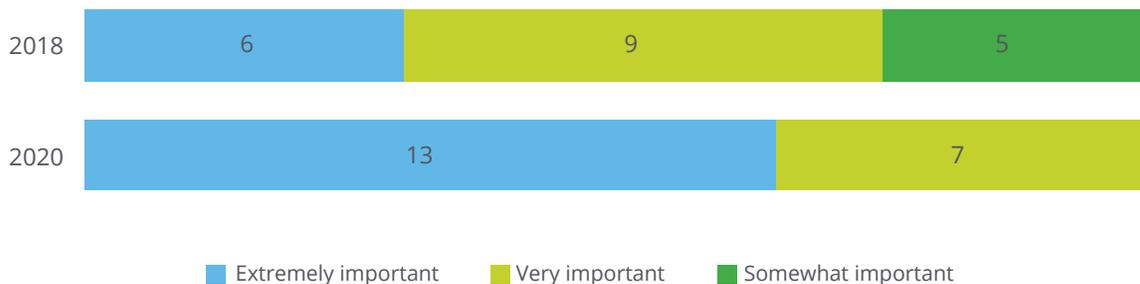
Twice as many respondents believe RWE will be extremely important to their executive leadership teams in 2020 versus today (figure 1). New business imperatives are helping drive this focus, including value-based contracting, clinical trial design and execution, and supporting regulatory submissions. Specifically, respondents cite stakeholder pressure to demonstrate the value of treatments, the shift toward personalized care, and growing regulatory acceptance of RWE as the main drivers of this trend. RWE can offer deeper insights into the patient journey, influence treatment pathways, and help differentiate products through both clinical and economic evidence. Rapid technological and data science advances are helping to make it possible to generate quick insights from real-world data, which can en-

able executive leaders to use RWE in strategy and decision-making.

Notably, the 13 who responded that RWE will be a mission critical capability (extremely valuable to their executive leadership teams by 2020) also, not surprisingly, say that their companies are investing significantly more money than others. This investment is going toward procurement of data through vendors as well as through novel external partnerships with health systems, payers, advocacy groups, and technology companies. Moreover, these companies were more likely to say that:

- Transforming clinical trials is an extremely valuable application of RWE.
- They are already using RWE to support value-based contracting.
- They are using machine learning for RWE analytics more than others.
- The use of health apps and connected devices will continue to grow.

Figure 1. What level of importance do members of the executive leadership team place on the use of RWE as part of the organization's strategy? How important will they consider it to be in the next two years?



Source: Deloitte's 2018 RWE Benchmarking Survey.

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The growth in importance of RWE reflects an expectation that companies will be able to apply RWE to product design, development, and commercialization. This year, 90 percent of respondents (figure 2) reported having either already established or currently investing in building RWE capabilities for use across the entire product life

cycle. This indicates greater intent to harness RWE as a core asset for adoption of an end-to-end evidence management approach (see sidebar, “RWE in end-to-end evidence management”). But, less than half (45 percent) reported having RWE capabilities in place that are mature enough to leverage RWE across the entire product life cycle.

Figure 2. Which statement best represents the status of your RWE capabilities?



Source: Deloitte’s 2018 RWE Benchmarking Survey.

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RWE IN END-TO-END EVIDENCE MANAGEMENT

Real-world data has been used for years in health economic and other observational contexts. However, with the proliferation of digital and electronic health care data, we are entering a new era of RWE where organizations can use RWD to answer the “hard questions” in health care—what works, for whom, in what context, and at what cost. Increasingly, data and evidence are generated and used for multiple purposes across biopharmaceutical organizations—from drug discovery all the way through commercialization.

An end-to-end (E2E) evidence management strategy breaks down the traditional evidence siloes using platforms and processes to access data and knowledge assets across the organization to support data-driven decision making.⁷

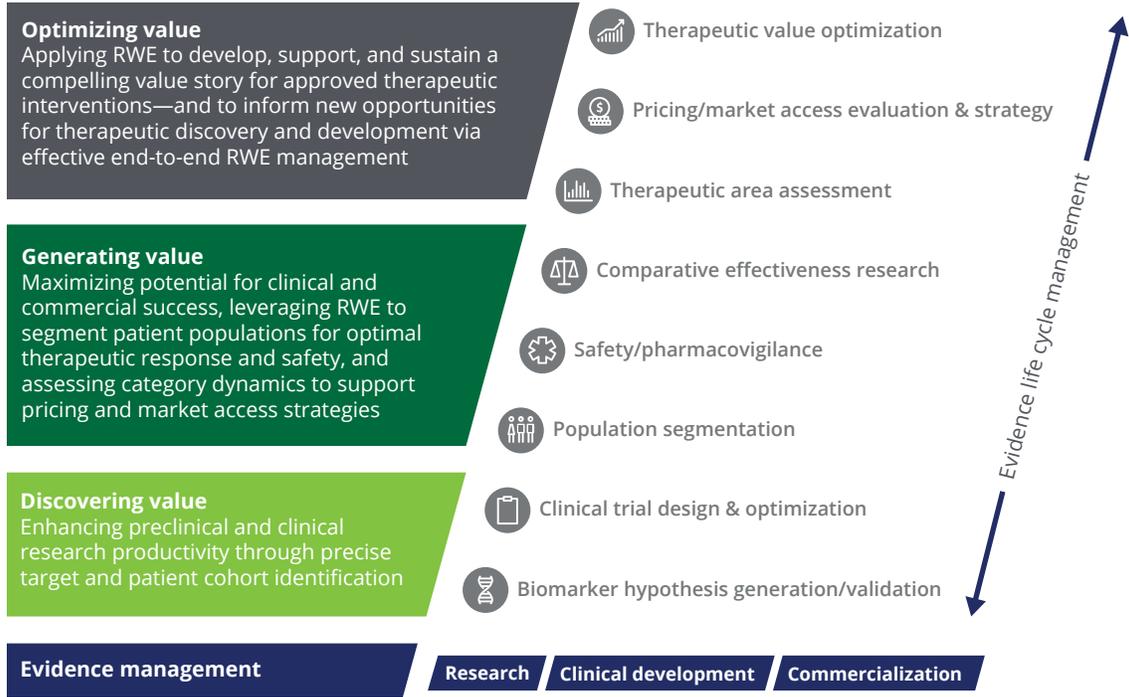
By adopting E2E evidence management strategies, companies can use RWE to discover, generate, and optimize product value (figure 3). This could not only enhance research productivity and assessment of drug effectiveness but also support pricing, customer engagement, and marketing. As a result, companies should consider making digital patient engagement strategies a critical component of end-to-end evidence-generation. Many leading biopharma companies are beginning to link their digital initiatives with their data and analytics objectives.

Eventually, E2E evidence management strategies could enable companies to create compelling value stories and digital engagement strategies for each of their therapies. This in turn can enable more meaningful conversations with customers and other stakeholders.

Crafting and implementing such strategies, however, will likely require companies to assess and re-align their current infrastructure, governance, operating models, people, and processes. While this may be complex, time-consuming, and resource-intensive, the efficiency, innovation, and commercial benefits they offer may justify the investment.

Figure 3. End-to-end evidence management approach

Pharma companies can maximize the value of their data by using it for decision-making at an enterprise level (vs. traditional siloed approaches)



Source: Deloitte analysis.

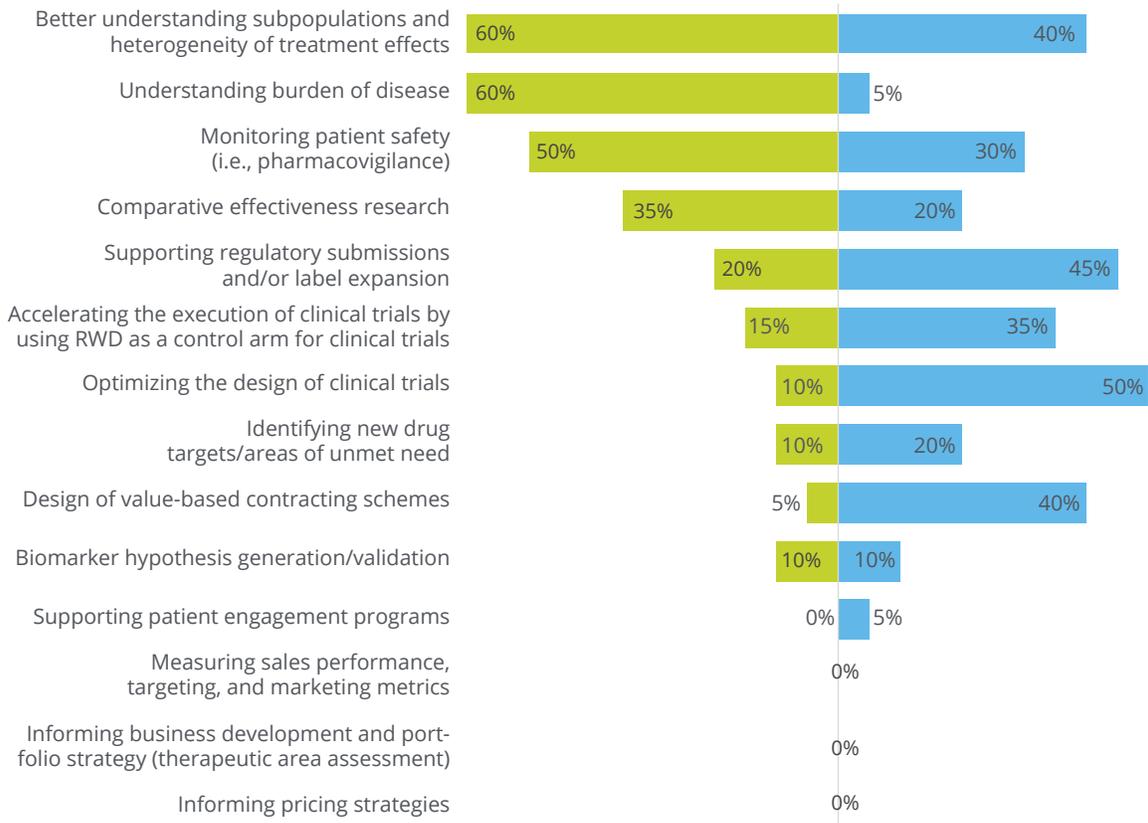
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RWD and RWE applications are expanding across the life cycle

Consistent with an expected increase in the executive-level importance of RWE, respondents also expect an expansion of RWE’s impact across key

strategic objectives (figure 4). Most respondents identified understanding treatment effects in sub-populations (see case study 1 in the sidebar “Current priority areas of application for respondents”), understanding disease burden (case study 2), and monitoring patient safety as the most impactful areas of RWE application today.

Figure 4. Please rank the three most impactful areas of current and future RWE application within your organization



Note: The figure denotes current and future application areas ranked amongst the top three by respondents and expressed as a percentage.

Source: Deloitte's 2018 RWE Benchmarking Survey.

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CURRENT PRIORITY AREAS OF APPLICATION FOR RESPONDENTS

Case study 1: Analyzing treatment impact across subpopulations⁸

A large biopharma company is undertaking a registry-based study to analyze the safety and efficacy of breast cancer treatments on postmenopausal women. The study will enroll 320 Canadian breast cancer patients receiving either endocrine therapy alone or a combination of endocrine and targeted therapies. Outcomes assessed will include prevention and management of treatment-emergent adverse events, patient-reported quality of life, work-related productivity, and survival status.

Case study 2: Better understanding NASH⁹

Allergan is running a five-year observational study of nonalcoholic steatohepatitis (NASH), an area of high unmet clinical need, impacting 5 percent of the US population. The study will collect data on NASH diagnosis and current management practices as well as outcomes of/safety data on new treatments as they enter the market. This data will help the company as it develops and launches its own therapies for the disorder.

While these areas are likely to continue to remain important, the use of RWE for the following areas are expected to have the highest business impact in the next two to three years as per our respondents: optimizing clinical trial design, supporting regulatory submissions/label expansions (see case study 3 in sidebar “Future priority areas of application for respondents”), and designing value-based contracts (case study 4).

Leveraging RWE across such a wide range of business objectives can require looking beyond

traditional methods of study design and data collection. Advances in wearables, smartphones, and even cognitive technologies are helping enable new means for patient-generated data to be captured in real time (see case study 5 and 6 in the sidebar “Novel methods of collecting and analyzing RWE”). Evidence generated from these approaches could provide quicker and deeper insights into disease progression, treatment pathways, and actual patient benefit.

FUTURE PRIORITY AREAS OF APPLICATION FOR RESPONDENTS

Case Study 3: Synthetic control arms for quicker market access¹⁰

Using Flatiron’s oncology RWE repository, Roche was able to create synthetic control arms to gain quick market access for its non-small cell lung cancer (NSCLC) drug in more than 20 countries. These control arms contained data on drug use, uptake, and patient outcomes for medications used as standards of care in different countries. Roche then compared this data to clinical trial results for its NSCLC drug trials and used the finding to answer questions from regulators and payers in different countries.

Case Study 4: Quantifying treatment outcomes for value-based contracting¹¹

Using an “effectiveness algorithm” based on several criteria (patient compliance, dose escalation, switching or adding drugs to the therapy, and steroid interventions) Harvard Pilgrim is able to quantify the real-world effectiveness of Amgen’s rheumatoid arthritis drug. This algorithm analyzes pharmacy and claims data for these criteria to generate a score that is then used to determine the amount paid to Amgen for the drug.

NOVEL METHODS OF COLLECTING AND ANALYZING RWE

Case Study 5: Collecting patient-reported outcomes to study cardiovascular health

Using Apple Inc.’s ResearchKit®, an open-source application development platform, Stanford created an app to collect RWD to study the impact of physical activity on cardiac health. The app enabled Stanford to enroll 11,000 study participants within 24 hours across the United States, a task that would otherwise have taken several months.¹²

The app can continuously collect data on a participant’s physical activity (sleep, exercise routines, etc.) using the Apple iPhone® mobile digital device. The app also asked patients to enter data on cardiac risk factors including readings from basic lab tests (cholesterol, blood pressure, etc.). Machine learning was then used to cluster participants and find associations between their physical activity and cardiovascular health.¹³

Case Study 6: Leveraging AI to process patient-reported data

Doc.ai, an artificial intelligence company, has built a platform leveraging blockchain to develop insights based on personal data. Users provide access to health records, wearable device data, and/or social media accounts. Doc.ai then uses AI to process the information and start drawing inferences between the data sets.

Doc.ai, Deloitte, and a large national health plan company have teamed up to use machine learning capabilities to accelerate research trials for predictive and preventative health programs.

Spotlight on value-based contracting

Pressure on pharmaceutical pricing has helped spur an increased focus on the value therapeutics provide to patients and the health system. Advances in science and personalization of care have led to some specialty therapies costing thousands of dollars a month.¹⁴ As a result, biopharma companies have been experimenting with value-based contracts to mitigate the cost and share the risk of these innovative and expensive treatments. Executing such contracts requires an ability to measure and track patient outcomes in the real world.

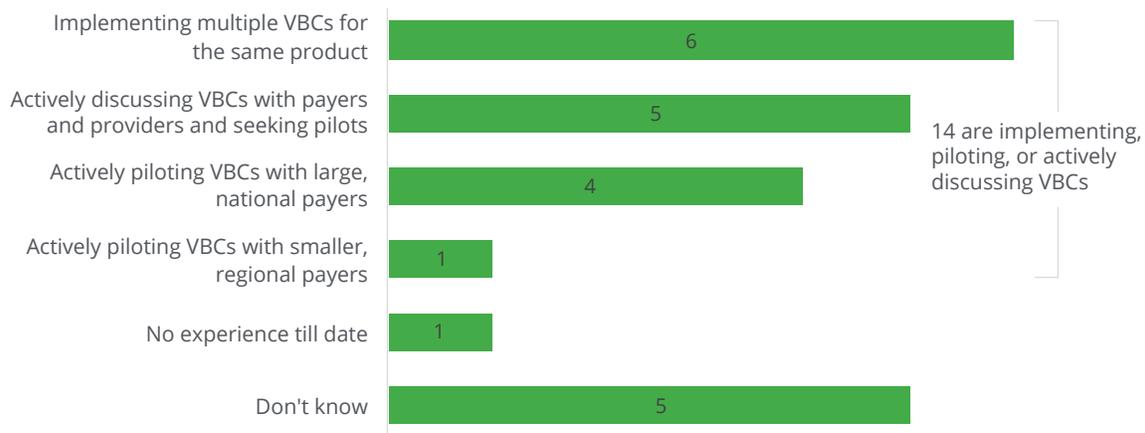
Despite the recent buzz and publicity around value-based contracting arrangements between life sciences companies and payers, the scale-up of

value-based contracts has been relatively slow. This year’s survey went into greater depth on current and future use of value-based contracts, barriers, and opportunities.

We asked survey participants to describe the current state of the use of value-based contracts within their organizations. Results showed that 14 of 15 respondents (who were able to provide an answer) stated their companies are implementing, piloting, or actively discussing value-based contracts (figure 5). Furthermore, of these 14 respondents, nine (65 percent) stated their companies are using RWE in contract design and support.

Despite this level of value-based contracting activity, there are barriers preventing widespread adoption and realization of these arrangements in the market. The two biggest barriers identified by

Figure 5. Which statement best describes your organization's current use of value-based contracts? Is your organization using RWE to design and support value-based contracting?



Source: Deloitte’s 2018 RWE Benchmarking Survey.

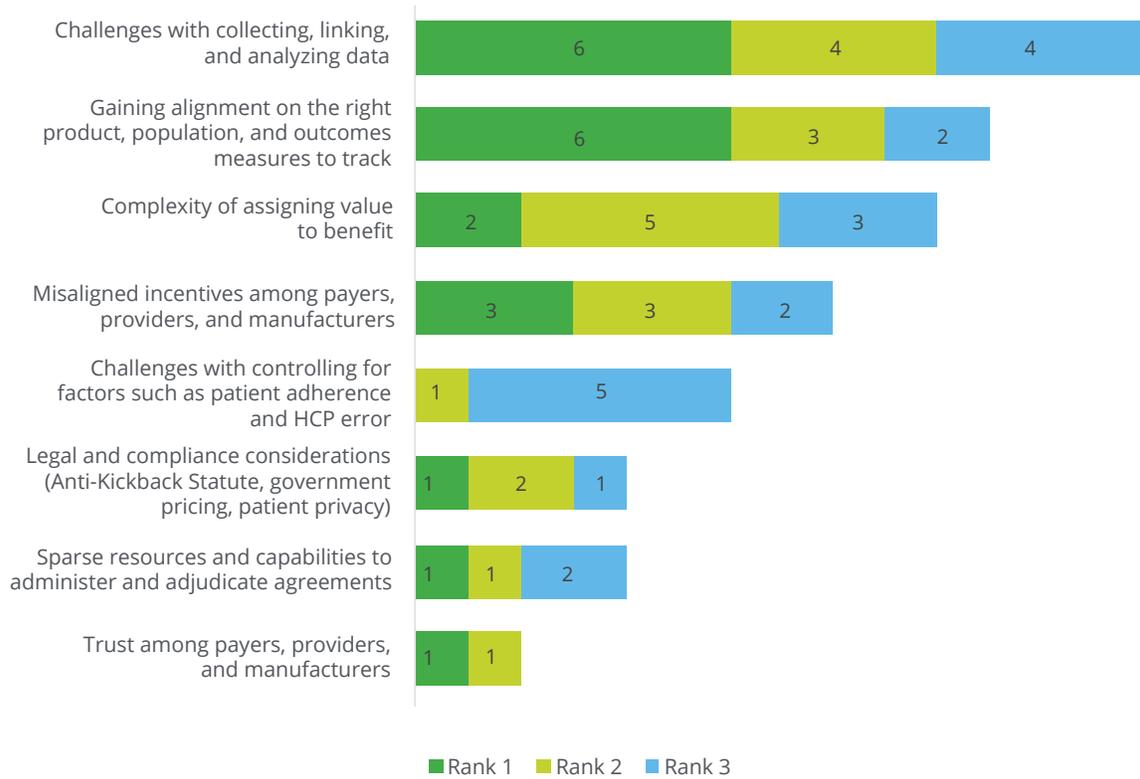
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survey respondents were challenges with collecting, linking, and analyzing the necessary health care data, and objectively gaining alignment on how to structure the arrangement (that is, defining the population and outcomes) (figure 6).

Survey respondents appear to be confident that the industry will overcome these barriers. All 14 respondents believe the number of value-

based contracts their organizations will enter will increase over the next 2–3 years. To move value-based contracts beyond the stage of experimentation, stakeholders will likely need to come together to set goals and objectives, develop standardized definitions for measuring outcomes, and invest in the necessary technology to capture the patient data in an efficient and sustainable manner.

Figure 6. What do you believe is the biggest barrier to value-based contracting (rank top 3)?



Source: Deloitte’s 2018 RWE Benchmarking Survey.

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Building for the future: Creating an internal RWE engine

Many respondents are shifting from outsourcing to more internalized capabilities

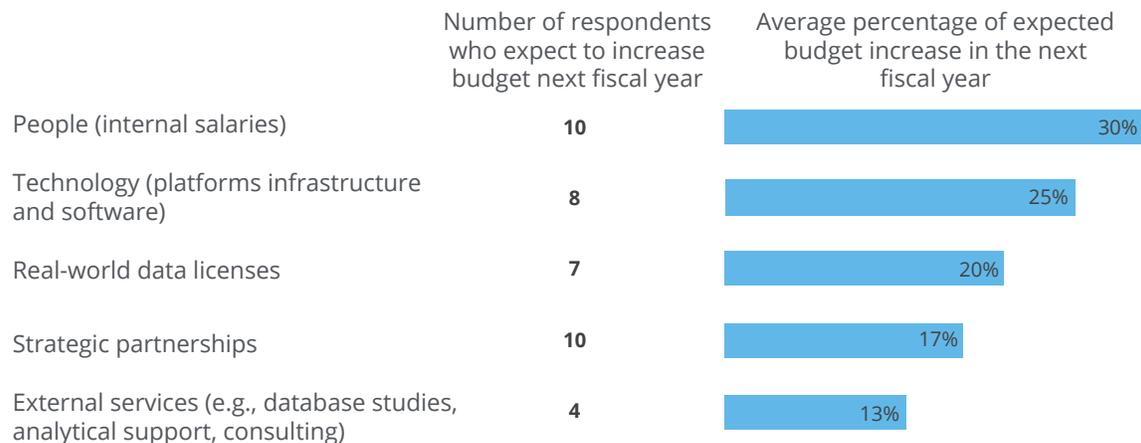
Traditionally, biopharma companies relied heavily on external vendors to conduct a majority of their analyses and research with RWD. Now the trend is shifting toward internalizing more of this work: 70 percent of respondents reported building or increasing capabilities to conduct more of their RWE studies internally, and 15 percent are building capabilities to exclusively resource studies internally. This increase in reliance on internal capabilities is likely to drive the need for institutional governance, organizationwide standards, and new platforms to work with RWE.

The investments and predicted future spend on RWE capabilities also align with this trend toward an internal RWE engine. According to our respondents,

the two biggest increases in investment over the next year are expected to be on people and technology platforms to support the organization’s RWE capability (figure 7).

Investing in new talent or upskilling existing resources could help build teams with diversified skills to analyze and interpret RWD. Hiring experts to build and implement advanced systems (such as machine learning systems) can help existing talent derive insights from structured and unstructured disparate RWD sources. But attracting this talent could prove difficult, given the current market demand for data scientists. Beyond data scientists, companies could benefit from making RWD and analytics accessible to a broad range of internal stakeholders. It will likely be crucial to supplement this talent pool with the right technology platforms and external partnerships to access and assess RWD sets.

Figure 7. By what percent do you estimate the budget will increase in the next fiscal year?



Source: Deloitte’s 2018 RWE Benchmarking Survey.

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MEASURING THE ROI ON RWE INVESTMENT

Given increased investment in RWE capabilities, we asked respondents how they were measuring the return on that investment. Most respondents are still trying to define a consistent and effective means of tracking returns on RWE spending. However, some respondents are currently experimenting with multiple financial and nonfinancial metrics for both short-term and long-term returns. For example:

- For the short term (0–2 years), some respondents are evaluating nonfinancial metrics such as the number of studies published and the use of RWE in support of health technology assessments (HTA). For financial impact, some respondents are defining short-term success as the ability to decrease spending (in many cases duplicative) on external vendors.
- In the long run (> 2 years) respondents are looking for methods to quantify RWE impact on topline sales and/or clinical development productivity (for example, getting to market faster or lower clinical trial costs). A few respondents plan to track the use of RWE in regulatory submissions or value-based contracts as nonfinancial metrics over the next two to five years.

Centralized enterprise analytics, knowledge management, and collaboration platforms are cited as critical components of the RWE engine

As they continue to expand the use of RWE across the enterprise, organizations are commonly using integrated analytics, knowledge management, and collaboration platforms to improve data management and access, empower a range of internal stakeholders to analyze RWD, and foster knowledge sharing and collaboration. Most respondents—65 percent—are using a central analytics platform. Of these, 77 percent are using a cloud-based one.

Many organizations are overhauling their IT landscapes by combining open-source, open-standards, virtualization, and containerization. This trend is not unique to RWE. In fact, Deloitte’s 2017 Tech Trends survey identified this shift to the “inevitable architecture” across all industries.¹⁵ Many companies are also leveraging automation aggressively, coupling existing and new platforms more loosely, and often embracing a “cloud first” mindset.

These steps are part of an emerging trend that some see as inevitable: the standardization of a flexible architecture model that:

- Drives efficiency;
- Reduces hardware and labor costs; and
- Foundationally supports speed, flexibility, and rapid outcomes.

Nineteen out of 20 respondents say that it is important to have a central knowledge management system. These management systems can assist with ingesting and integrating data, advanced analytics, visualization (e.g., patient journey, geospatial), and knowledge management. Self-service analytical tools—which enable specific analyses such as defining a cohort, generating descriptive statistics, and understanding treatment patterns without writing the underlying code—are also growing in importance. Among these self-service analytical capabilities, cohort building topped the list. One hundred percent of respondents said cohort building was important. This is likely because traditional methods of iterating through complex cohort definitions and feasibility assessments can be time-consuming. Market players are increasingly using such platforms to drive efficiencies (see case study 7).

TECHNOLOGY EXPEDITES RWD ANALYSIS

Case study 7. Cloud helps Celgene achieve workflow and cost efficiencies

Celgene Corporation won the Cloud Pioneer Award at Cloudera’s 2017 Strata Big Data Conference for its implementation of a cloud platform called Synapse as part of a corporate initiative to support big data initiatives including RWE.¹⁶ Celgene, which manufactures drug therapies for cancer and inflammatory disorders, worked with Deloitte to achieve 99 percent savings in process run times for real-world patient data analysis and a 70 percent reduction in operating costs by migrating legacy workloads via Cloudera Enterprise.¹⁷

The rise of machine learning in RWE

Machine learning automates analytical model building and uses statistical techniques to give computers the ability to “learn” (i.e., progressively improve performance on a specific task). This set of technologies can help identify patterns in data that humans cannot.

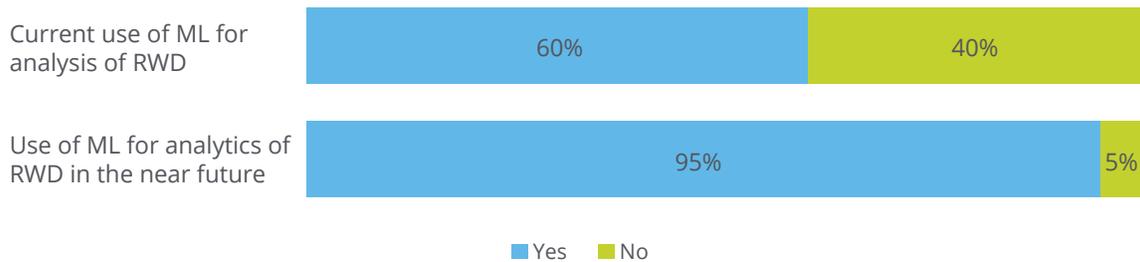
As the volume, variety, and velocity of both structured and unstructured data grows, machine learning may be required to adequately capitalize on the potential of big health care data to generate

life-saving insights, such as identifying patients with undiagnosed or underdiagnosed diseases.

In our survey, 60 percent of respondents report currently using machine learning, but almost all—95 percent—expect to use it for RWE in coming years (figure 8).

Merck, for instance, through a partnership with the Regenstrief Institute, used machine learning to improve the ability to identify patients with peripheral arterial disease (PAD) from EMR records. Using natural language processing, Merck sorted through structured and unstructured EMR data to find four times the number of patients with PAD than possible through conventional data analysis.¹⁸

Figure 8. Is your organization currently using any machine learning (ML) approaches to analyze real-world data? Do you anticipate an increase in the use of ML in the coming years?



Source: Deloitte’s 2018 RWE Benchmarking Survey.

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Fueling the engine: Increasing the use of nontraditional data sources

Many respondents are moving beyond traditional RWD toward digital data sources

Traditional RWD sources such as claims and EMR have primarily been the foundation of RWE studies. Though they are likely to continue to be important, they are also likely to become insufficient to meet the demand for a nuanced understanding of the patient journey, disease progression, and treatment pathways.

Nontraditional data sources such as purpose-built-linked data (such as clinical data linked to molecular data) and patient-generated data from health apps and wearables represent the “next generation” of RWD. Less than 60 percent of companies are currently using these data sources, but several expect to increase their use in the next 12–18 months (figure 9).

Another nontraditional source, genomic-linked data, is becoming increasingly available and can be used to understand treatment effects in patient sub-populations. This level of granularity is especially important in oncology, where tumor profiles are used to target treatments. Eighty-five percent of our survey respondents expect to use genomic-linked data in the next 12–18 months. The majority of companies currently using or expecting to use genomic-linked data in our survey ranked oncology among their top two priority focus area for RWE initiatives.

As patients become more active in their care decisions and empowered through technology and the digital health ecosystem, they are creating a new rich source of RWD. Some of our survey re-

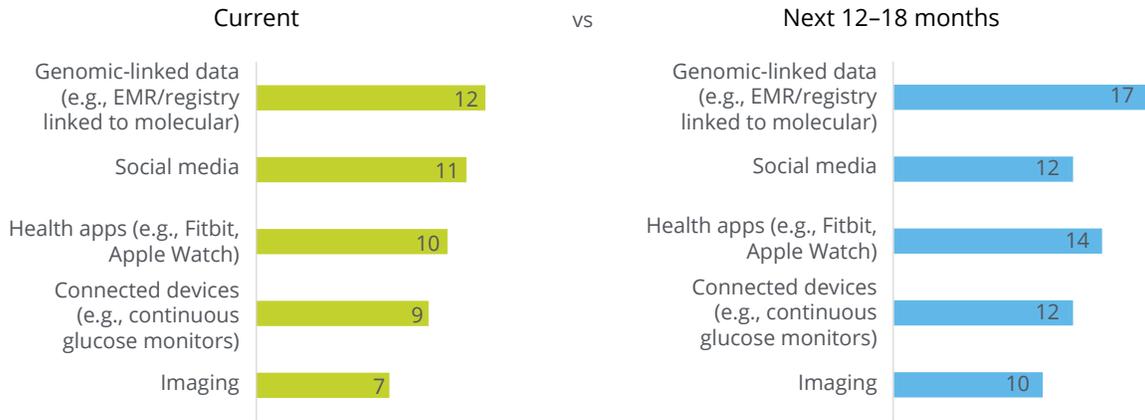
spondents expect data collected directly from patients or consumer-directed technology companies (e.g., Amazon and Apple) to play a bigger role in the health care data landscape moving forward. They expect an increase in the use of data from digital sources—including health apps, social media, and data from connected devices—in the next 12–18 months (figure 9).

Consumer-generated data could be a rich source of patient-centered information on areas such as activity, lifestyle, and biometrics. In fact, half the respondents in Deloitte’s *2018 Survey of US Health Care Consumers* said they used technology to track their health information.¹⁹ For companies, this also means that internally driven digital engagement strategies could be generating meaningful data that could support RWE studies.

Strategic partnerships are likely to shape the future data landscape

Data access strategies at some companies are moving away from “vendor” relationships toward “partnerships,” driven by technological advances and the availability of RWD from disparate sources. A majority of respondents believe strategic data partnerships will have the highest impact on the future data landscape (figure 10), though they also seem to be skeptical of the value of cross-industry collaboration, perhaps because of the complexity of organizing and governing such initiatives. Interestingly, respondents ranked reliance on data from their own studies as the least impactful in the future.

Figure 9. What types of nontraditional real-world data sets is your organization currently using? Will your organization's use of this data set type increase or decrease in the next 12-18 months?

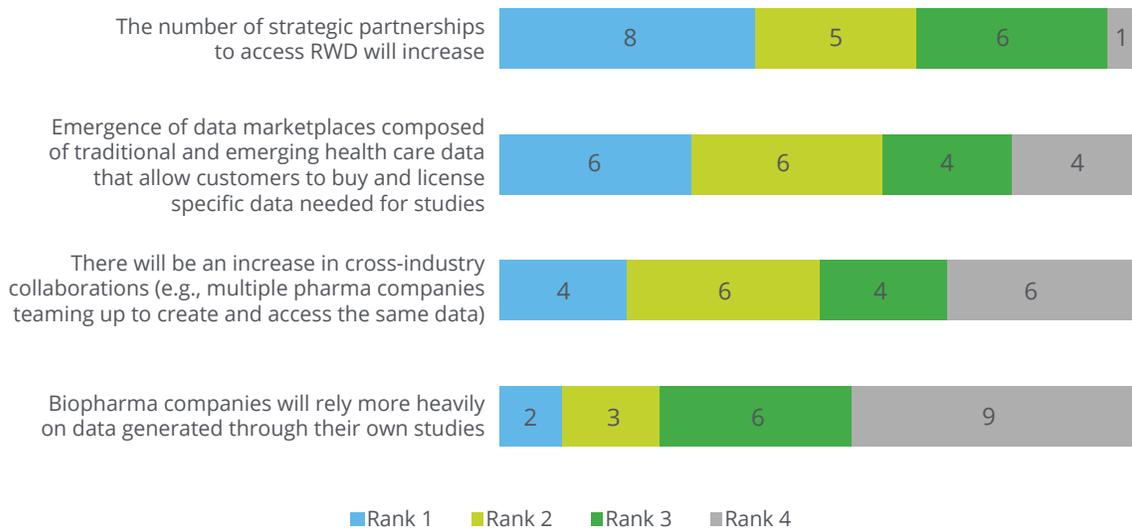


Note: Figure shows the number of respondents that currently use the data source and expect to continue, as well as new users (i.e., those don't use the source currently but intend to increase use in future).

Source: Deloitte's 2018 RWE Benchmarking Survey.

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Figure 10. Which of the following scenarios might have the biggest impact on the future data landscape?



Source: Deloitte's 2018 RWE Benchmarking Survey.

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As biopharma companies increasingly enter into strategic partnerships across traditional (e.g., health plans, integrated delivery networks (IDNs)) and nontraditional organizations (for example, patient advocacy groups, technology companies) they should consider aligning their priorities and defining governance clearly to derive maximum value. In

the future, networks of partnerships and contractual relationships are likely to become increasingly intertwined and prolific. Looking externally to access RWD is likely to become table stakes, and organizations should consider creating alliance management functions to manage these relationships effectively.

Internal and external barriers threaten to slow down the progress of RWE capabilities

External stakeholders, change management, and a lack of data access can pose challenges

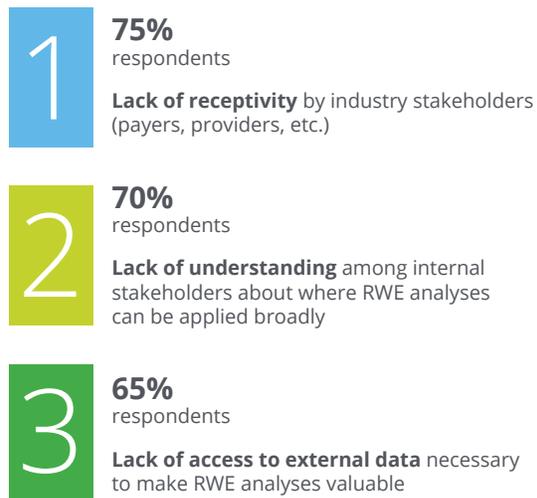
Strategic intent is critical, but execution might not be easy. Our survey respondents cited the following as the top hurdles they need to overcome to realize the success of RWE capability (figure 11):

Lack of receptivity to industry-generated RWE by external stakeholders (e.g., payers and providers). Respondents perceive health care stakeholders, primarily health insurers and health systems, as reluctant to embrace RWE generated by industry. How strong is this resistance, and can stakeholder education on the value of RWE help overcome this challenge? Are there new ways of partnering that can provide a level of objectivity and trust?

Surveys have shown that there continues to be a lack of trust among IDNs, managed care organizations (MCOs), and pharmacy benefit managers (PBMs) in pharma-generated RWE, possibly due to a lack of transparency on data sourcing and analytics.²⁰ Companies should communicate the limitations and applicability of the data to their intended use.²¹

Lack of internal understanding on how to use RWE. There is often a learning curve to understanding the biases and different ways of working with RWD across the organization, and how to best

Figure 11. What are the top three challenges to the success of your RWE efforts?



Note: Chart shows top three barriers calculated as the percentage of respondents who ranked the barrier in the top three.

Source: Deloitte's 2018 RWE Benchmarking Survey.
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use the insights generated from it. Market leaders have demonstrated that visible buy-in and support from executive-level leadership can be necessary to change the company's mindset, and drive data literacy and broader adoption of evidence generation practices across the enterprise.

Data access. As discussed above, companies are increasingly using data sources that could

complement claims and EMR data and provide a more complete picture of the patient journey. Increasingly, engaging in strategic partnerships to secure this data could be critical in providing access to useful data sets.

Addressing these challenges with new operating models and governance. RWE is likely to disrupt traditional biopharma processes, requiring a shift in cultural mindset, breaking down organizational siloes, and challenging data literacy at multiple levels of the organization. Many companies are experimenting with multiple operating models to address this challenge. Eighty-five percent of respondents report that setting strategy and making decisions about RWE is done globally rather than regionally. Just over half—55 percent—say that the decision-making authority rests with a cross-functional decision-making body. For the remaining companies, authority sits with the RWE Center of Excellence (CoE) leader (20 percent), a functional leader (15 percent), or a hybrid (10 percent).



The path forward

Enterprise, end-to-end, and external

As the importance of RWE continues to rise, biopharmaceutical companies should consider the following: think enterprisewide, develop an end-to-end evidence management strategy, look externally to partner for data access, and leverage advancements in technology and data science capabilities.

Think enterprisewide. An enterprisewide mindset may be important to maximize insights from RWD, avoid duplicative investments, establish data governance, optimize external engagement strategies, and best utilize data science talent. Executives should consider educating themselves and internal stakeholders on the application of RWD for different questions. This can help in overcoming a key barrier to RWE initiative success—lack of internal stakeholder understanding of how to use RWD in various contexts to generate evidence and insights. Further, defining a mechanism for appropriately budgeting and measuring ROI for RWE initiatives can help nurture and grow these programs and help ensure the organization can keep pace with market and regulatory developments.

Develop an E2E evidence management strategy. Organizations should consider developing an E2E evidence management strategy and operating model to break down functional silos that prevent the application of RWD across the product life cycle. This approach can be particularly useful in highly personalized, orphan, or specialty therapeutic areas—where the pace of clinical practice

change, complexity of the patient journey, and cost of therapies require a focus on end-to-end value. Supporting these strategies will likely require embracing the “inevitable architecture” of open, standards-based, cloud platforms across the enterprise. The development and use of self-service tools can enable executives and staff across the enterprise to leverage RWE for decision-making. In addition to technology considerations, appropriate talent, process, and operating model changes are likely to be needed to encourage this E2E mentality.

Look externally to partner for data access. The data landscape is evolving rapidly, and biopharma companies should consider looking externally to identify sources of RWD to fill evidence gaps. The “information asymmetry” in the biopharmaceutical industry, with regard to its products relative to other health care stakeholders, is shifting. Strategic partnerships with IDNs, technology companies, or industry consortia will likely be required to access a more comprehensive set of data to understand the complete patient journey. Accessing RWD is no longer an activity that can be sourced through vendors in a transactional relationship. Companies should consider developing alliance teams to identify, execute, and manage RWD partnerships—just as much of the industry did over a decade ago when it recognized external product innovation was critical to future success. Like scientific alliance management, sourcing strategic RWD partnerships may require new organizations, unique talent, and a specific alliance model aligned to the business.

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