

# Real-world evidence's evolution into a true end-to-end capability

Find out how biopharmaceutical companies are embedding real-world data and evidence use across the enterprise—and why now is the time.

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# Executive summary

SINCE 2017, DELOITTE'S real-world evidence (RWE) benchmarking studies have signaled the biopharmaceutical industry's efforts to expand the use of real-world data (RWD) and RWE across the product life cycle.<sup>1</sup> Beyond satisfying postmarketing requirements, for instance, biopharma companies have expanded their inclusion of RWE in regulatory submissions. During the COVID-19 pandemic, RWD/E played a key role in enabling biopharma companies to innovate and bring novel vaccines and therapies against this highly contagious disease to market in record time. RWD/E was invaluable to the scientific community to understand the efficacy of COVID-19 diagnostic tests and repurpose on-market drugs to save lives. Major regulatory agencies across the globe also have stepped up their efforts to advance RWE use in regulatory submissions, further expanding its importance.<sup>2</sup>

Real-world data (RWD) is data that relates to patient health status and/or the delivery of health care routinely collected from a variety of sources. Real-world evidence (RWE) is the clinical evidence about the usage and potential benefits or risks of a medical product derived from analysis of RWD.

Given these trends, the Deloitte Center for Health Solutions surveyed 17 executives from global biopharma companies and interviewed 10 leaders

from industry groups, research organizations, and RWE organizations in 2022. We found:

- RWE has now evolved into a true “end-to-end” capability. Ninety percent of survey respondents stated their organization is attempting to leverage RWE for decision-making across the product life cycle today.
- The growing traction around integrated evidence planning (IEP) has expanded the incorporation of RWE in evidence generation plans for assets. Half of the survey respondents reported their organization is actively undertaking IEP for one or more assets.
- More than two-thirds of survey respondents said recent technology investments have created efficiencies in RWE generation (e.g., reduced time to insight) and encouraged the use of new analysis methodologies (e.g., the use of artificial intelligence (AI)).
- Adoption of RWD/E in research and development (R&D) continues to accelerate, and there has been an expansion of RWD/E use in commercial. More than half of surveyed executives expect their companies to apply RWD/E for innovative R&D use cases such as building regulatory-grade synthetic control arms or designing adaptive trials in the next two to three years.

- AI-enabled RWE generation is picking up pace. Top use cases among companies we surveyed include enabling a data-driven understanding of disease progression, understanding patient behavior, and segmenting patients to match them to trials.

No matter how far companies have come in harnessing RWD/E, there are steps they can take to embed RWD/E across the enterprise:

- **Set an enterprisewide strategy**, if not in place already, and frequently revisit this strategy to change how RWD/E is utilized across the enterprise.
- **Continue to invest** in RWE capabilities given the pace of technological change,

availability of new RWD sources, and demand for talent.

- **Integrate RWE into relevant processes**, such as clinical operations or commercial analytics across the drug life cycle, wherever possible. IEP is a great example of integrating RWE into asset evidence generation plans.
- **Create enterprise governance** to ensure that the right stakeholders have frictionless access to RWD for the right purpose. As AI-enabled RWE generation grows, define governance to manage the ethical risks associated with AI use.
- **Encourage teams to be bold and agile** to challenge orthodoxies and to experiment, gain hands-on experience, learn, and iterate with RWD/E to potentially spark new ways of working across the enterprise.

# Real-world evidence: How it's being used and regulated is changing

**T**O SAY THE relevance and application of RWE have expanded since our last [RWE benchmarking study](#) would be an understatement. One indication of this shift is how sponsors are increasingly including RWE in regulatory submissions to demonstrate product safety and effectiveness, provide therapeutic context (e.g., contextualize the natural history of a disease), and expand label indications.<sup>3</sup> At the end of 2020, 90% of new drug approvals in the United States had RWE as part of the submission.<sup>4</sup>

Major regulatory agencies also have stepped up their efforts to advance RWE use in regulatory submissions, further expanding its importance: Over the past two years, the FDA has released guidelines on use of claims, electronic health records, and registry data in submissions.<sup>5</sup> As part of its RWE strategy, the FDA is working on projects exploring the role RWE could play in regulatory decision-making.<sup>6</sup> The European Medicines Agency and the National Medical Products Association in China also are attempting to expand RWE use to expedite patient access to innovative therapies.<sup>7</sup>

In parallel, the pandemic highlighted the utility of RWD/E in understanding and combating a novel

disease. RWD/E helped biopharma companies answer many questions, including what repurposed drugs can effectively treat the infection? How did COVID-19 impact care for specific patient populations such as cancer patients? How long do COVID-19 antibodies last?<sup>8</sup> Additionally, initiatives such as the Reagan-Udall Foundation's COVID-19 Evidence Accelerator brought together multiple stakeholders to advance methods to convert RWD into actionable COVID-19 insights.<sup>9</sup> The learnings from this initiative are being applied to other conditions such as Alzheimer's disease.<sup>10</sup>

## RESEARCH METHODOLOGY:

Between March and May 2022, the Deloitte Center for Health Solutions surveyed 17 executives from large biopharma companies across the globe to benchmark their organizations' RWD/E aspirations, investments, capabilities, use cases, and ability to harness RWD/E. We also interviewed 10 leaders from industry groups, research organizations, and RWE organizations to understand how COVID-19 impacted the use and acceptance of RWD/E and what is needed to expand the utility of RWD/E in the coming years.

# RWE has evolved into a true end-to-end capability

SINCE 2017, OUR RWE benchmarking studies have signaled biopharma's growing focus on building capabilities to leverage RWE across the product life cycle.<sup>11</sup> This year's survey results suggest RWE has evolved into a true end-to-end capability, with 90% of survey respondents saying their organization is attempting to use RWE for decision-making across the product life cycle.

Historically, biopharma's health economics and outcomes research (HEOR), epidemiology, and medical affairs experts have used RWE to understand disease progression, monitor patient safety, and assess clinical and cost-effectiveness. Not surprisingly, our survey data shows the bulk of RWE is generated for these functions even today. However, beyond these traditional uses, more than 30% of survey respondents reported that R&D and commercial are the top two functions that their organizations generate RWE for. Top use cases include informing the clinical trial design and site selection, understanding the heterogeneity of treatment effects, and informing pricing and forecasting assumptions.

The growing traction around IEP has also expanded the incorporation of RWE in the evidence planning process for assets. IEP enables cross-functional collaboration to create a common plan to leverage randomized clinical trial data and RWE approaches to meet the evidence needs of multiple stakeholders including HCPs, regulators, and payers, across the product life cycle. This enables companies to look at evidence planning holistically, make more strategic choices, and use

resources efficiently to generate the most impactful RWE. Half of our survey respondents said their organization is actively undertaking IEP for one or more assets (figure 1).

Furthermore, future end-to-end evidence generation approaches could be modeled on the industry's use of RWD/E during the pandemic, which expedited patient access to novel vaccines and therapies (see sidebar, "RWD/E during the pandemic," for more information).

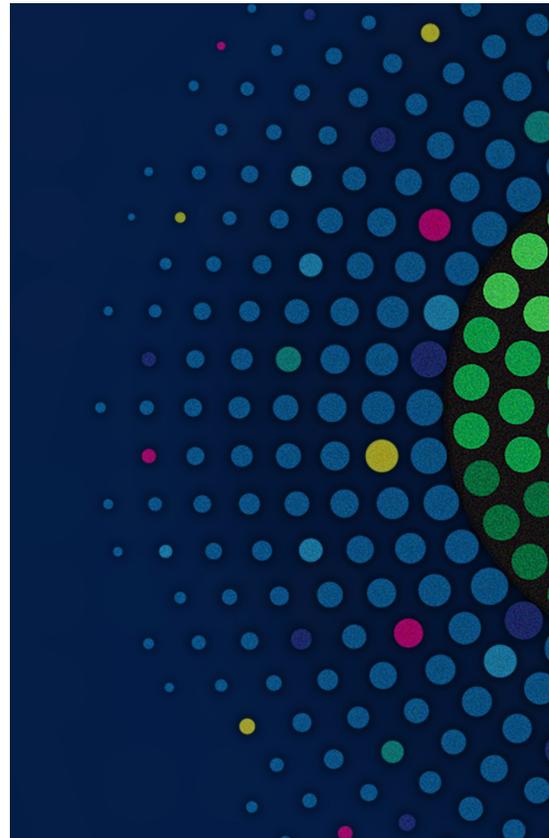
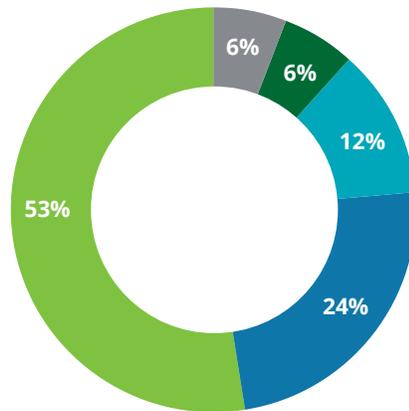


FIGURE 1

## Adoption of integrated evidence planning

- We are actively using it within our company (could be for one or multiple brands)
- This has been discussed but there are no plans to move to an integrated evidence plan model
- There is strong interest within the company in moving to this model
- I'm not familiar with this model
- Don't know



Question: Some companies may be taking an integrated approach to evidence planning where cross-functional groups work together to develop an "integrated evidence plan." This combines randomized clinical trials and RWE approaches together with the goal of having one integrated plan that meets the needs of all stakeholders (regulators, payers, patients, and providers). Which statement below best represents your company's view on this?

Note: Total number of respondents = 17.

Source: Deloitte's 2022 RWE benchmarking study.

### RWD/E DURING THE PANDEMIC

The unprecedented challenge posed by COVID-19 propelled the industry to leverage RWD/E to innovate faster than ever. More than half of the companies we surveyed used RWD/E to understand the incidence and severity of COVID-19 and its variants for vaccine and drug development. Vaccine developers such as Johnson & Johnson analyzed RWD to predict COVID-19 hotspots across geographies to optimize site selection and collect data from diverse racial and ethnic groups.<sup>12</sup> RWE also played a critical role in understanding vaccine effectiveness across demographics such as age, gender, race, and ethnicity and determining the need for boosters.<sup>13</sup>

Beyond new vaccines and therapies, biopharma companies turned to RWD/E to understand how the pandemic impacted care or treatment patterns for patients suffering from other diseases, such as cancer. More than 80% of our survey respondents reported using RWD/E to understand how COVID-19 impacted care for certain populations or diseases.

*"The real-time information about real-world COVID-19 cases, vaccine effectiveness over time, and against new variants, etc., have opened people's eyes to the possibility of RWD. Without RWD, we would be in the dark." – Head of RWE, large biopharma company*

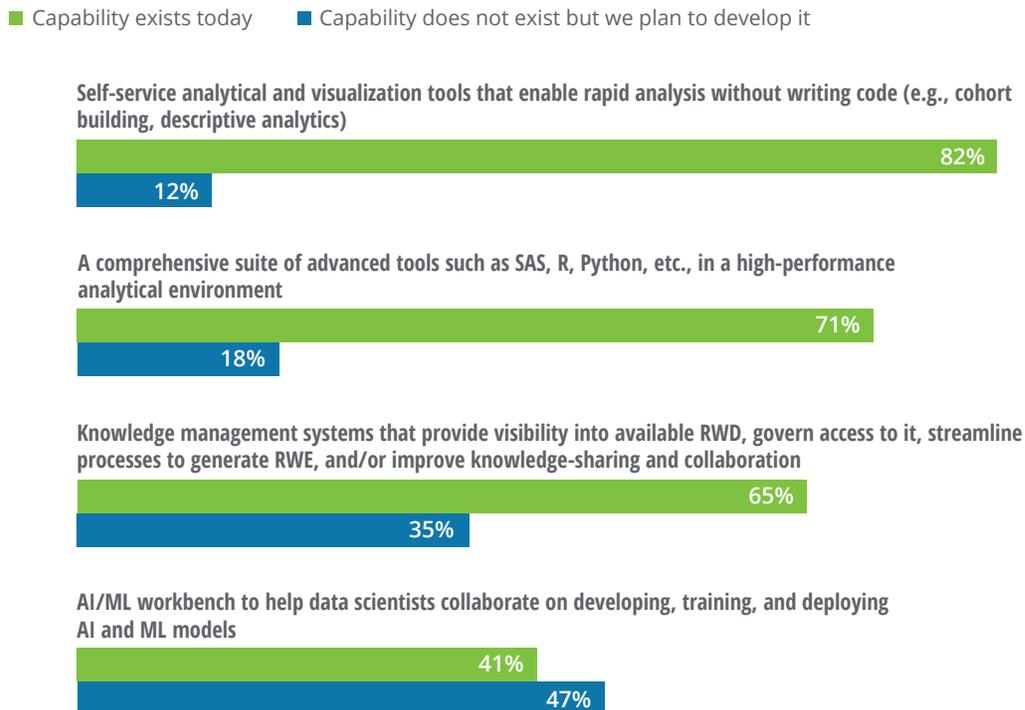
# Technology investments have enabled scaling the use of RWD/E

**A**S PART OF building an end-to-end RWE capability, biopharma companies have invested in technology capabilities (e.g., RWE platforms and tools) that are beginning to pay off. Our survey data suggests such capabilities

are becoming increasingly common, enabling new ways to generate insights and evidence, scaling to more use cases, and reaching a broader user community.

FIGURE 2

## RWE technology capabilities companies have in place or plan to develop



Question: Which RWD/E technologies/capabilities does your organization have in place or plan to implement?

Notes: Total number of respondents = 17; some figures do not add up to a total of 100% because some respondents say their organizations do not plan to develop these capabilities or are unaware of their current status.

Source: Deloitte's 2022 RWE benchmarking study.

Advanced analytical tools, self-service applications, and knowledge management systems are central components of a mature RWE capability, and most survey participants report that their organizations already have these in place today. More than two-thirds of surveyed respondents stated that their organizations provide a comprehensive suite of analytical tools for statisticians, data scientists, and analysts. The greater availability of self-service analytical applications also has enabled business and citizen data scientists (who are data-savvy but can't necessarily write code to generate insights) to quickly run RWD analyses (e.g., cohort creation, descriptive statistics, etc.) through user-friendly interfaces. In this year's survey, more than 80% of respondents reported that their organizations have self-service analytical and visualization tools compared to 58% in the 2020 survey.<sup>14</sup>

Over the last several years, we have observed a growing use of knowledge management systems across the industry that are democratizing RWD/E use across the product life cycle. These valuable

solutions provide transparency into RWD assets and the corresponding RWE that's generated, enable consistent use of business rules and methods, and streamline reviews and workflows critical to evidence generation. About 65% of this year's survey respondents reported having a knowledge management system compared with just 35% in our previous study.<sup>15</sup> Furthermore, the remaining respondents indicated that their organizations plan to develop knowledge management systems, which are essential to increasing visibility into available RWD assets and making RWD analysis more transparent across the organization.

Survey findings also show that technology investments have laid the foundation for organizations to realize more significant benefits from using RWD/E. More than three-fourths of respondents reported that their organization's technology investments have created efficiencies in RWE generation (e.g., reducing time to insight) and enabled the use of new analysis methodologies (e.g., the use of AI).

# Adoption of RWD/E in R&D has accelerated as the application in commercial expands

IN OUR [PREVIOUS RWE benchmarking study](#), most respondents expected the importance and application of RWD/E in R&D to increase significantly over the next two years. This year's survey data shows organizations have already realized benefits from RWD/E use across several R&D use cases (figure 3). More than half of our survey respondents have used RWD/E to enable a data-driven understanding of disease progression in populations of interest, support label revisions related to safety, and make better decisions on development strategy.

Additionally, nearly two-thirds of survey respondents reported that their organization had used RWD/E to assess disease incidence across socioeconomic, racial, and ethnic groups to improve trial diversity. The disproportionate impact of COVID-19 on racial and ethnic minorities fueled an ongoing need for trial populations that better mirror the real-world demographic of the populations affected.<sup>16</sup> [Deloitte's research with Pharmaceutical Research and Manufacturers of America](#) highlighted a sustained commitment among biopharma companies to address clinical trial diversity. Relatedly, the FDA recently released guidance on enhancing clinical trial diversity, making improving research equity a pressing imperative for all sponsors.<sup>17</sup> To ensure that [research is diverse and representative](#), industry leaders should consider taking bold steps to establish data-driven and inclusive trial recruitment processes.

Most of the interviewees opined that the pivotal role of RWE during the pandemic, coupled with the increased regulatory openness to its use, is likely to accelerate RWD/E application in R&D. During the next two to three years, more than half of the respondents expect their organizations to leverage RWD/E more frequently for more innovative and impactful R&D use cases. These include building regulatory-grade external control arms (ECAs), supporting label revisions related to product effectiveness, designing adaptive trials, and tokenizing data for long-term patient follow-ups (see sidebar, "Two ways that biopharma is leveraging RWD/E," for more information). Doing so requires collaboration between industry stakeholders to help streamline RWE use for regulatory submissions (see sidebar, "Developing a collective experience to evolve RWE use," for more information).

**“Regulatory openness and acceptance have greatly accelerated the generation and use of RWE for drug development. There is no going back from this point.”**

— *Global head of HEOR, large biopharma company*

FIGURE 3

### Expected versus realized benefits from the use of RWD/E in R&D



Questions: What benefits is your organization realizing through the use of RWD/E in R&D today? What benefits does it expect to realize over the next two to three years?

Notes: Total number of respondents = 17; some figures do not add up to a total of 17 because some respondents don't expect to realize this benefit or are unaware.

Source: Deloitte's 2022 RWE benchmarking study.

## TWO WAYS THAT BIOPHARMA IS LEVERAGING RWD/E

### 1. Building an external control arm to expedite access to a lifesaving therapy<sup>18</sup>

A biopharma company was conducting a phase 2 single-arm trial of its investigational therapy for relapsed refractory multiple myeloma (RRMM). The company worked with COTA, an RWE organization, to build an ECA to assess real-world treatment patterns for RRMM that were included in its submission packages to the FDA and EMA. In the United States, the company's application was accepted for priority review.

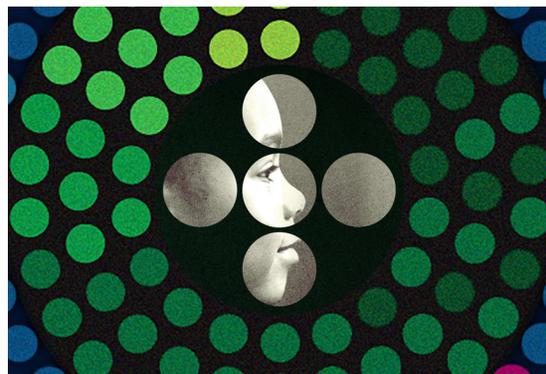
### 2. Using RWE to support label revisions for a cancer drug<sup>19</sup>

Eli Lilly collaborated with Flatiron Health to fill evidence gaps in its submission package to the FDA for a new dosing regimen of cetuximab to treat metastatic colorectal cancer (CRC). Analysis of RWD from Flatiron Health's database found no significant differences in the survival of CRC patients receiving weekly or biweekly doses of cetuximab. This RWD analysis was critical to the FDA's decision to approve the biweekly doses of cetuximab.<sup>20</sup> As a result, cetuximab infusions can now be scheduled alongside other biweekly treatments, reducing the number of patient visits to infusion centers.

As companies develop more targeted therapies focused on narrower patient populations, enrolling patients in a traditional control arm is becoming increasingly complex from a cost, time, and ethical standpoint. Constructing regulatory-grade ECAs using data collected from a patient's electronic health record (EHR), administrative claims, and other sources is of particular interest to cut development time, reduce costs, and ensure participant access to lifesaving therapies.<sup>21</sup> Such external control arms could create a more representative dataset to study drug effectiveness by enabling the [inclusion of patient data across diverse populations](#). However, embedding ECAs more systemically in development processes requires cultivating an appetite for risk-taking among development teams and investing in technologies and processes for ECA design and implementation.<sup>22</sup>

Enabling many of the most impactful R&D use cases requires linking disparate data sources (EHR, claims, and clinical trial data) together at the patient level to

create a more robust long-term view of the patient. Tokenization technologies enable biopharma companies to anonymously link disparate data sources together at the patient level, creating a rich dataset while maintaining HIPAA compliance. To date, most linkages have been one-off projects within biopharma companies. But some organizations are developing systems and processes to scale this capability across the enterprise. It will be interesting to see the results of these bold moves over the next few years.



Postlaunch, organizations have been expanding the use of RWD/E to better understand how therapies perform in the real world and their impact on patient health outcomes. Most survey respondents reported that their organization had used RWD/E to understand current treatment patterns and patient behavior, such as switching patterns and adherence. For instance, Eli Lilly analyzed registry data to demonstrate higher patient adherence and longer persistence of its diabetes drug Trulicity compared to other type 2 diabetes medications.<sup>23</sup>

Half of the survey respondents reported using RWD to understand factors impacting HCP decision-making to better position their products. Some biopharma companies are already analyzing RWD to determine the impact of their marketing outreach to patients and HCPs (see sidebar, “Analyzing RWD to determine brand marketing effectiveness,” for more information).

### DEVELOPING A COLLECTIVE EXPERIENCE TO EVOLVE RWE USE

Many interviewees highlighted the need for biopharma companies to collaborate with regulators and RWD/E organizations to develop a collective experience that will eventually evolve today's guidance to a point where RWE use cases can be better regulated. They also noted that recent regulatory guidance has created a baseline for RWE acceptance in regulatory filings. In the near term, regulatory submissions using RWE would continue to require frequent and meaningful engagement with regulators. Two-thirds of survey respondents also cited the need for criteria to define fit-for-purpose RWD for regulatory use cases and best practices to engage with regulators around study conduct.

*“It’s too soon to write a guidance that says, here’s exactly the dos and don’ts. But we have to work on this together to develop a collective experience.” – Associate Director for Real-World Evidence Analytics, regulatory agency<sup>24</sup>*

### ANALYZING RWD TO DETERMINE BRAND MARKETING EFFECTIVENESS

A biopharmaceutical company leveraged an AI-powered platform to analyze RWD to assess marketing campaign effectiveness and increase prescriptions for one of its brands. This solution integrated marketing data (including display advertising, online video, search, and website traffic) with medical and prescription claims data to measure the quality of audience reached, and net conversions to the promoted brand. This also enabled better brand decisions around targeting and resource allocation, allowing the brand to grow more efficiently.

# AI-enabled RWE generation is picking up pace

**G**IVEN THE EXPANDING volume and increasing access to RWD, companies are exploring advanced analytics, including machine learning (ML), deep learning, and natural language processing, to generate RWE. The survey data suggests the application of AI is becoming more common for RWE use cases. Top use cases for AI include understanding patient behaviors, segmenting patients for trial matching, and enabling a data-driven understanding of disease progression. However, the interviewees commented that the use of AI for RWD analysis is still nascent, with biopharma companies having yet to derive true value from its use.

More concerted efforts to apply AI for RWE generation require a strong leadership commitment to AI as a long-term strategic priority. Most survey respondents stated that their organizations either have or plan to build an AI/

ML workbench to enable data scientists to build, train, and deploy AI/ML models for RWD analysis. Beyond the availability of such tools, many of the interviewees stressed the need for biopharma companies to form partnerships to access high-quality RWD and build expertise in training AI/ML models (see sidebar, “Expanding access to high-quality RWD,” for more information).

Even more vital to scaling AI/ML use is broadening the internal acceptance of such techniques in the RWE space. RWE studies traditionally have involved biostatisticians, epidemiologists, and other experts using time-tested statistical approaches to validate causal relationships between data points. Opening the proverbial AI black box or at least creating an understanding of how AI arrived at a particular decision can help change perceptions around AI use.

FIGURE 4

### Top 10 use cases for AI in RWD analysis



Question 1: What benefits is your organization realizing through the use of RWD/E in R&D today? What benefits does it expect to realize over the next two to three years? (For R&D and commercial)

Question 2: Has your organization used AI/ML to achieve these? (For R&D and commercial)

Notes: Total number of respondents = 17; this figure includes the top 10 use cases for AI included in our survey; figures for each bar represents percentage of total responses.

Source: Deloitte's 2022 RWE benchmarking study.

## EXPANDING ACCESS TO HIGH-QUALITY RWD

More than 50% of our survey respondents cited access (both within and outside the United States) to high-quality RWD as the key to realizing RWE's full potential. Through a thoughtful strategy, companies could create a cost-effective mix of RWD assets to support their evidence-generation needs, including:<sup>25</sup>

**Foundational data:** Large, representative datasets that can be used across a wide range of disease areas to understand treatment patterns, disease incidence, disease prevalence, and health care resource utilization.

**Disease-specific data:** Highly curated datasets focused on a particular disease of interest. In many instances, unstructured data is curated and/or additional data is linked at the patient level for such datasets.

**Fit-for-purpose data:** Created to meet a specific research need or objective, such data needs to be of sufficient quality to confidentially identify the cohort of interest, the intervention, and the right outcomes. Biopharma companies often partner with RWE organizations or data vendors to curate such datasets.

The interviewees also opined that doubling down on partnerships with RWE organizations is vital to access or build high-quality RWD in disease areas beyond oncology. All survey participants believe spending on partnerships to access new types of RWD from nontraditional sources (including health systems, startups, and patient groups) likely will increase in the next two to three years.

Thinking beyond traditional data sources to better understand the patient population a therapeutic is meant to serve will be important. New data types, including those collected from wearables, patient reports, and drivers of health (otherwise known as social determinants of health, including race, ethnicity, education status, access to transportation, etc.), and behavioral data likely will be leveraged more moving forward. Taking full advantage of the next wave of RWD entails managing RWD as a strategic asset by proactively assessing opportunities and identifying potential partners to access data. A data strategy coupled with the right governance and infrastructure to support partnerships will be key.

# Call to action: Embedding RWD/E use across the enterprise

**T**HIS YEAR'S SURVEY results suggest a continued evolution of RWD/E within the biopharma industry. There are several key principles that companies can pursue to further expand their RWE capabilities:

**Set an enterprisewide strategy.** Developing an enterprisewide strategy could help change how companies utilize RWD/E. For those organizations that already have a strategy in place, it should be revisited frequently, given how quickly this area is evolving.

**Continue to invest.** In our last survey, we saw that the companies that invested early were starting to see returns on those investments. With the pace at which technology is evolving, new sources of data, demand for talent, and continued investments also will be key to taking an organization's RWE capability to the next level.

**Integrate RWE into processes.** While expanding the use of RWE across the organization, it is important to embed it in the relevant processes wherever possible, making it a standard part of the ways of working within the organization. IEP is a great example of embedding RWE into an asset's evidence planning process.

**Govern for the enterprise.** This year's survey results show organizations have defined processes for RWE study design and dissemination of results. However, embedding RWE use across the drug life cycle requires enterprise governance to ensure that

stakeholders have frictionless access to data for the right purpose.

As AI-enabled RWE generation grows, it'll become crucial to define governance to manage the ethical risks associated with AI use. Ensuring AI models are built with a thorough understanding of the disease and patient population being studied can improve the fairness of outputs and avoid biases toward certain subgroups. Algorithm validation should check training data to ensure its representativeness and correct biases that may reflect outputs. Human decision-makers should be given the discretion to override model decisions to promote ethical decision-making.

**Be bold and agile.** As RWE becomes a critical organizational capability, leaders should encourage teams to experiment with RWD/E to challenge orthodoxies within their companies. For instance, in R&D, leaders could encourage development teams to explore using RWD/E in drug development programs and present ideas at stage-gate meetings. Allowing teams to experiment, gain hands-on experience, learn, and iterate with RWD/E could create an environment that encourages innovation and sparks new ways of working.

As RWE becomes a key future capability, now is the time for organizations to consider steps to embed its use more extensively across the enterprise. Organizations that do so are likely to emerge as leaders and differentiate themselves as they win with RWE as an end-to-end capability.

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