WHITEPAPER

Realizing the value of real-world evidence

Survey results show that barriers remain, but there's a path forward

PRESENTED BY: databricks

PUBLISHED BY: FIERCE Pharma

About the research

The debate about the value of real-world evidence (RWE) is over. Encouraged by their early successes, biopharma companies are now committed to investing in RWE to increase speed to market, reduce trial costs and realize a host of other benefits. Yet, companies continue to grapple with technology challenges that are impeding their efforts to deliver the benefits of RWE, creating an opportunity for organizations to adopt analytics strategies and platforms that enable the collation and analysis of different types of data.

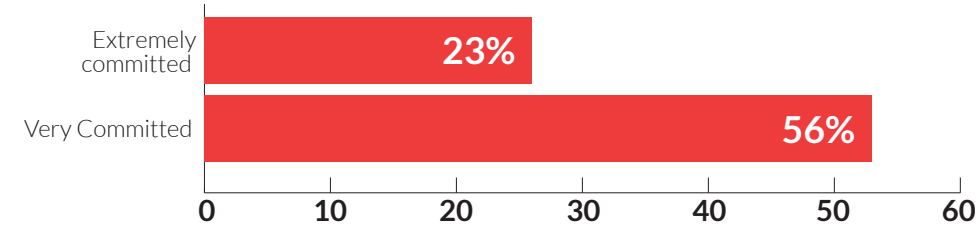
Recognizing the persistence of technology challenges, Databricks, the data and AI company, surveyed 109 biopharma executives to generate insights into how the industry is approaching RWE and the factors that are hindering efforts to realize its potential. The survey primarily captured the views of people working in R&D, analytics/data science and real-world evidence at the level of senior manager and above, making the results a snapshot of the thinking of RWE decision makers in the biopharma industry.

Making the case for RWE: What's driving investments

The top-line finding is that biopharma organizations are very committed to investing in RWE. Almost four fifths (79%) of respondents said they are very or extremely committed to investing in the space, with a further 20% being somewhat committed. The remaining 1% were not sure. No respondents voiced a lack of commitment to investing in RWE.

Biopharma organizations are committed to investing in Real-world Evidence

Four out of five biopharma executives (79%) report that their organizations are extremely or very committed to investing in Real-world Evidence.



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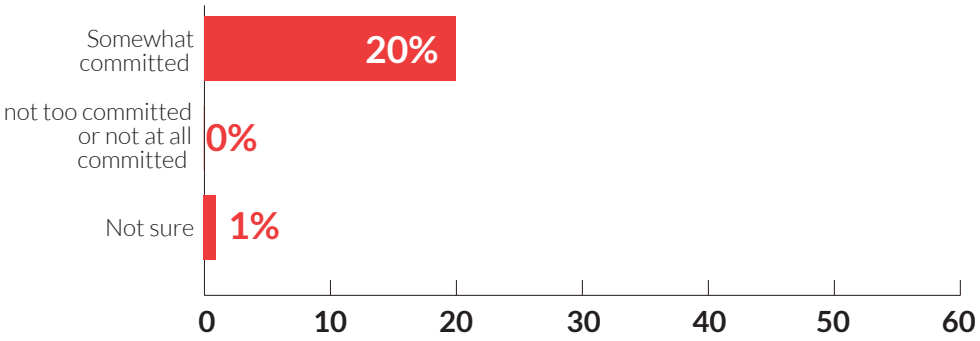
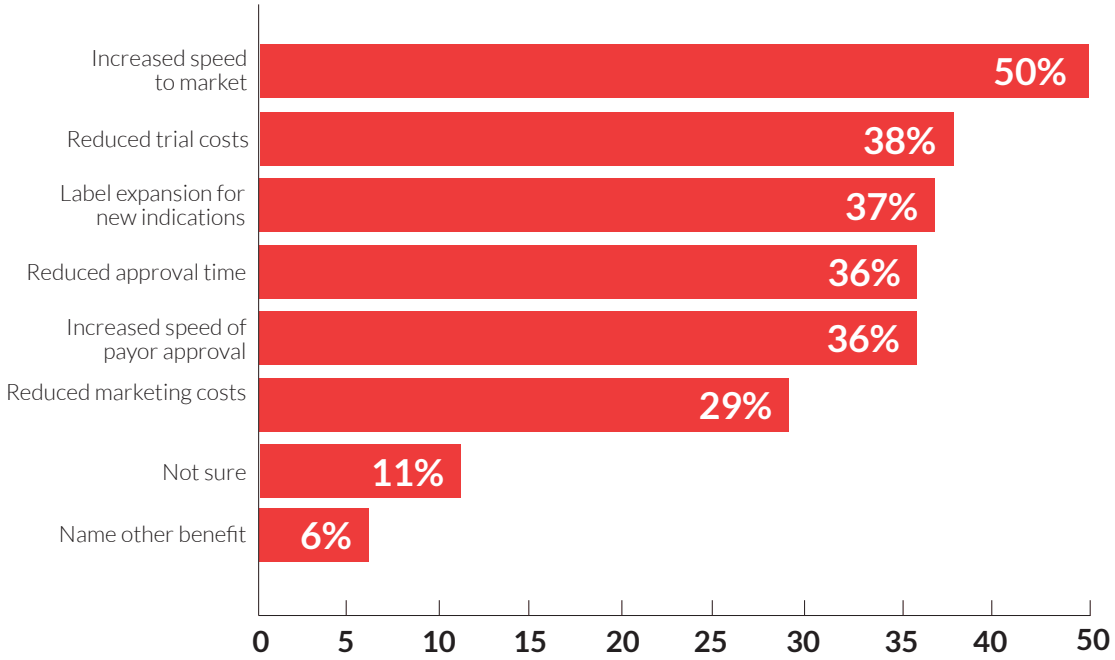


The widespread commitment to investing in RWE reflects a belief in its power to accelerate R&D. Half of the polled executives cited increased speed to market as a RWE benefit. Reduced trial costs (38%), label expansion for new indications (37%), reduced approval time (36%), increased speed of payor approval (36%) and reduced marketing costs (29%) were other popular choices.

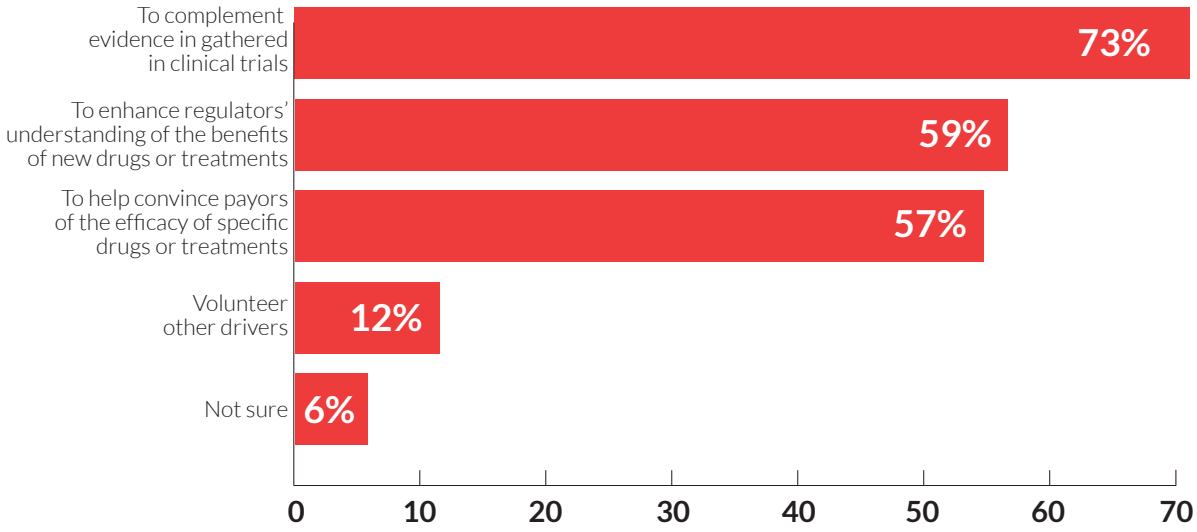
Increased speed to market is the top-mentioned benefit in using Real-world Evidence, but there also are other frequently mentioned benefits.



Some respondents also cited benefits beyond the options provided in the survey, revealing a recognition that RWE can improve market sizing and targeting, accelerate patient recruitment, increase sales, provide additional clinical markers or signals and deepen understanding of usage patterns.

The main driver for investing in RWE, as stated by 73% of respondents, is to complement evidence collected in clinical trials. Other common motivations included enhancing regulators' understanding of the benefits of new drugs or treatments (59%) and helping to convince payors of the efficacy of specific drugs or treatments (57%). The responses reflect the increasing willingness of regulators and payors to accept RWE.

The main driver of biopharma organizations' investments in Real-world Evidence is to complement evidence in gathered in clinical trials.

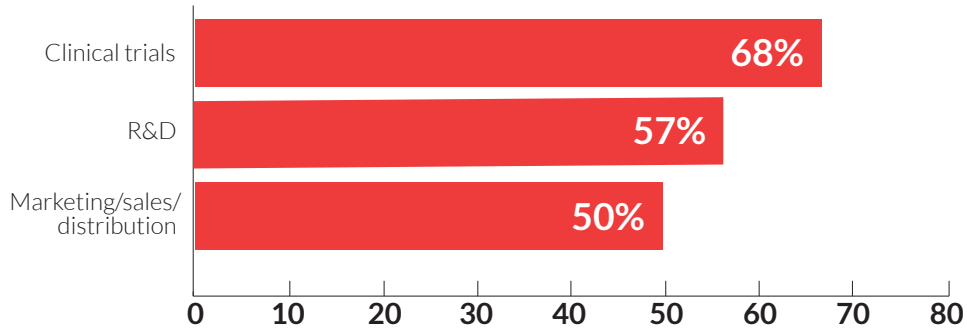


"The fact that the regulatory agencies are more open to considering real-world data is the biggest reason why a company might want to invest," Harini Gopalakrishnan, Executive Director at Syneos Health, said. "Moving from clinical to commercial, the biggest driver there is a shift in how payers and providers are looking at medicines and outcomes. There is also a shift towards what we call value-based pricing, more outcome based contracts, etc. that favors RWE."

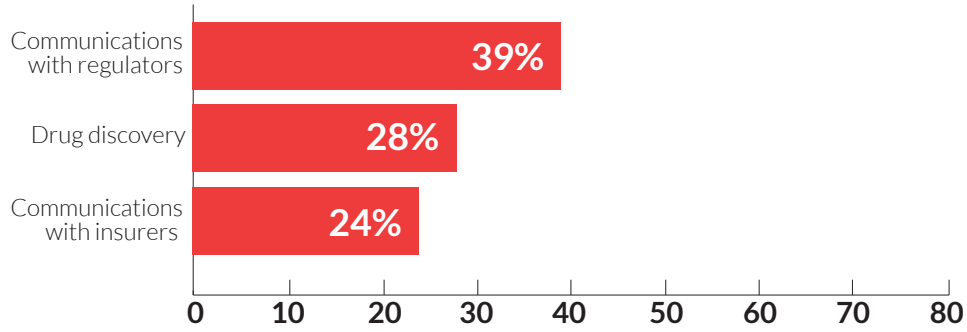
The pursuit of those benefits is shaping the targets of investment in RWE. More than two thirds (68%) of respondents are making RWE investments in clinical trials, making it the most active area of spending. Clinical research was joined in the top three areas of investment by R&D (57%) and marketing, sales and distribution (50%). The responses reveal the broad utility of RWE, with significant numbers of people investing in real-world evidence in relation to communications with regulators (39%), drug discovery (28%) and communications with insurers (24%).

Real-world Evidence investments are more heavily being made in clinical trials, R&D, and marketing/sales/distribution

Half or more of biopharma executives say their organizations are making investments in Real-world Evidence in three areas:



Other areas in which investments in Real-world Evidence are being made are:

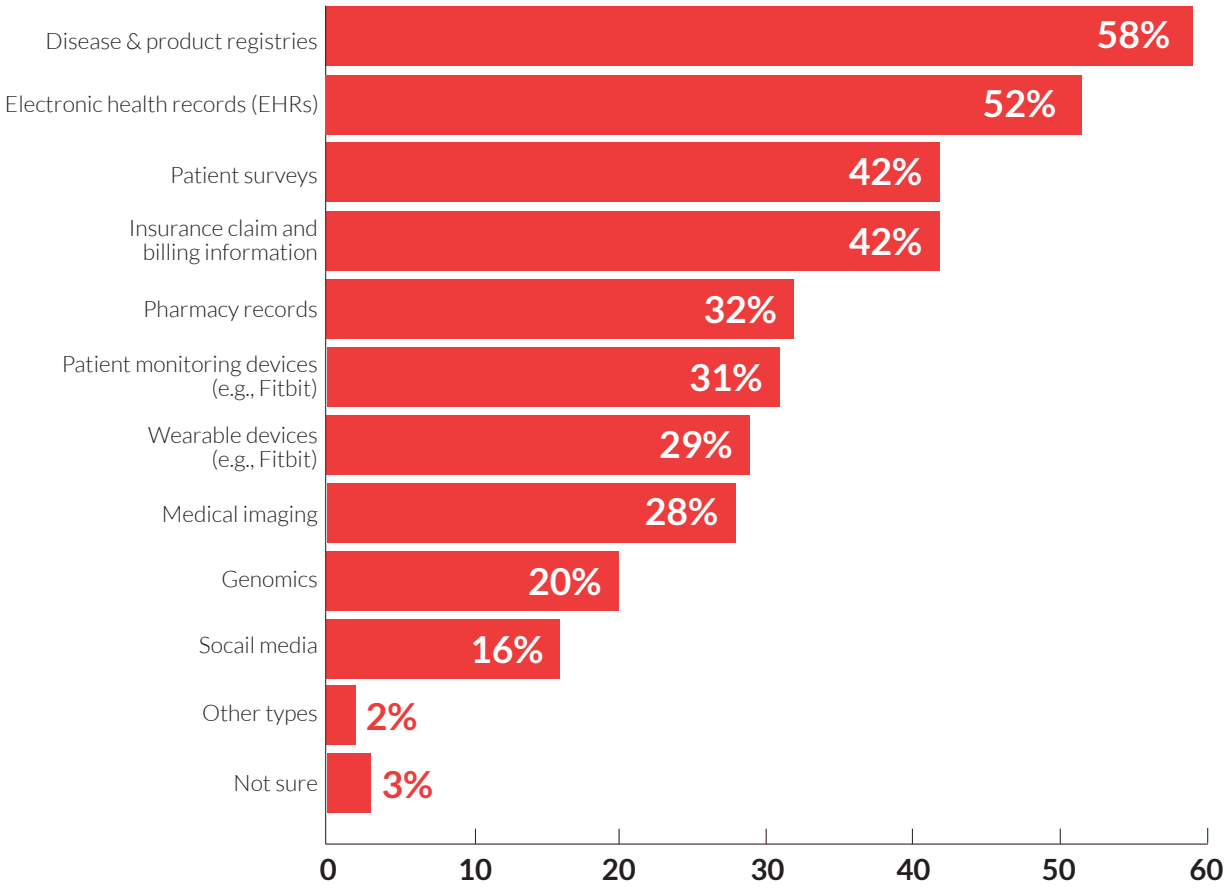


Six percent mention other areas where Real-world Evidence investments are being made and 3% are not sure.

The data behind real-world evidence

Biopharma executives are primarily looking to registries and electronic health records (EHRs) for the data they need to achieve their RWE objectives. Disease and product registries (58%) and EHRs (52%) topped the list of data sources, followed by a long tail of sources such as patient surveys, insurance claims and social media that are being used by between 16% and 42% of the respondents.

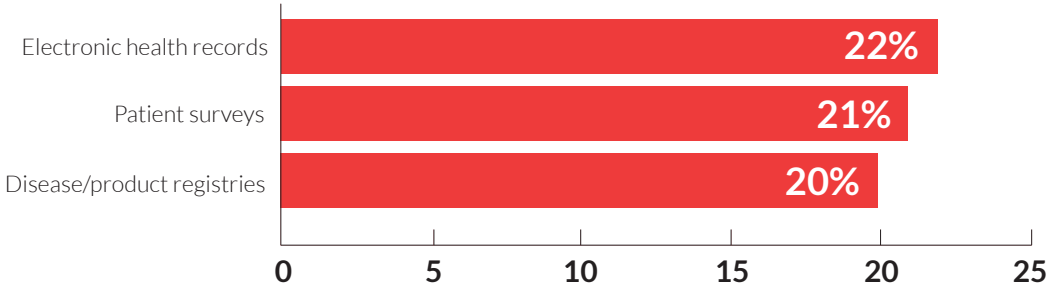
The most popular types of Real-world Data being used by biopharma organizations are disease/product registries and electronic health records



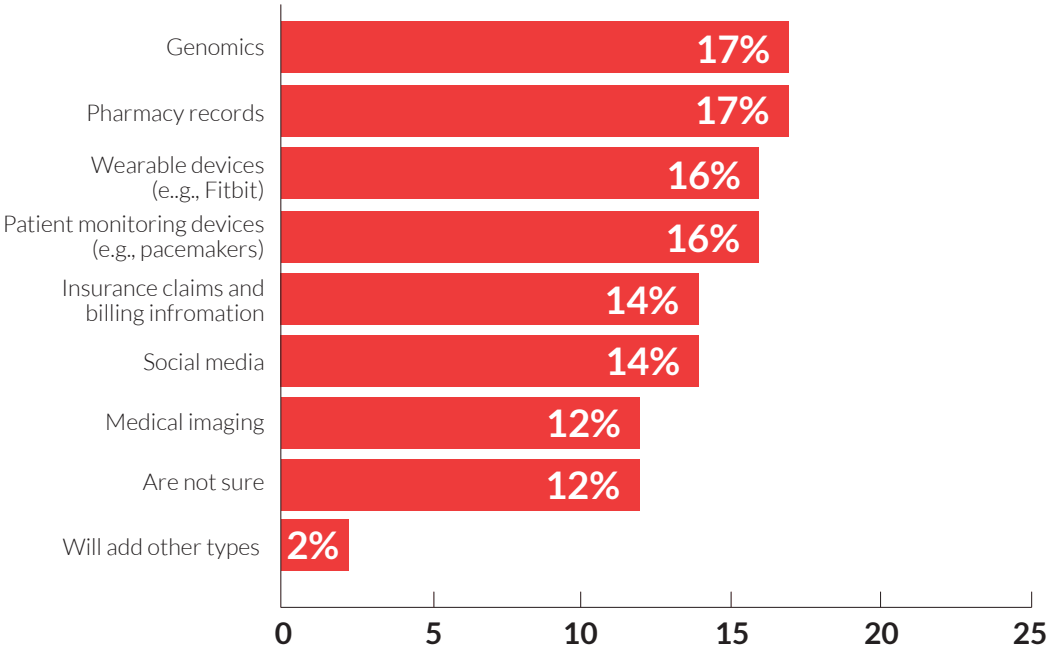
The survey suggests use of today's top sources will increase in the coming years. While half of the respondents said they will use the same sources over the next two years, around 20% are set to invest more in EHRs, patient surveys or disease and product registries. Those three data sources are the most commonly used by respondents today, and the survey suggests they will cement their positions at the top of the leaderboard over the next two years.

Biopharma organizations plan to use the same types of Real-world Data currently being used over the next two years. Many also are planning to add more types of data – especially electronic health records, patient surveys, and disease/product registries.

Half of biopharma executives (50%) say their organizations are planning to *use the same types of Real-world Data currently being used* over the next two years. But many are planning to add new types of data – especially:



Other types of Real-world Data that biopharma executives say their organizations will add in the next two years are:

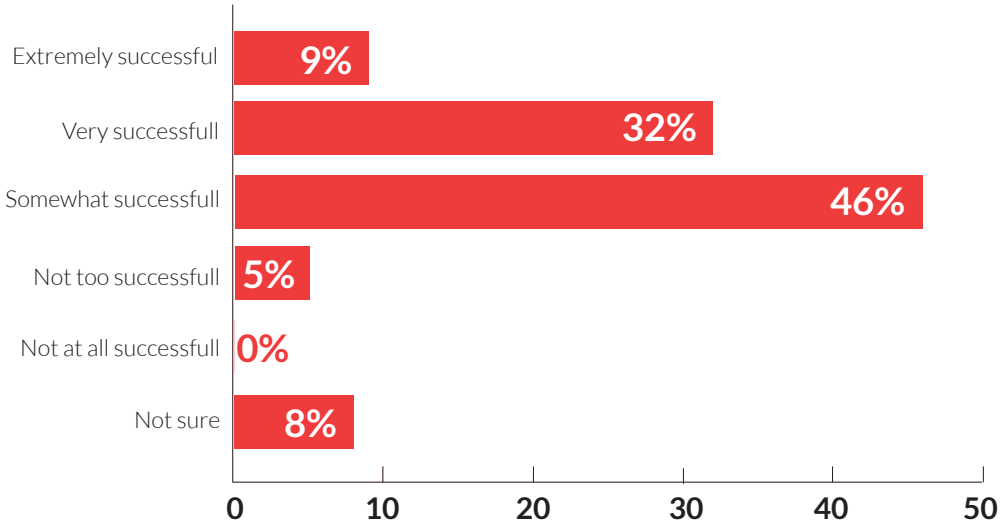


How persistent issues limit success in RWE

The expansion of current data acquisition strategies reflect the success biopharma companies have had using sources such as registries and EHRs to date. Most (87%) of respondents said their RWE strategies have been at least somewhat successful. Five percent of the polled biopharma executives admitted that they have not been too successful, but nobody has suffered a total failure.

Real-world Evidence strategies have been at least somewhat successful in producing measurable business outcomes.

Almost nine out of ten biopharma executives (87%) characterize their organizations' Real-world Evidence strategies as being at least somewhat successful in producing measurable business outcomes – 41% believe these strategies have been extremely or very successful. The full range of answers is as follows:



Yet, a closer look at the survey results reveals ample opportunity to improve. While failing RWE programs are rare, only 9% of the respondents said their strategies have been extremely successful. Almost half (46%) of the respondents have only experienced somewhat successful RWE campaigns. Given the vast potential of RWE, there is a world of difference between the impact of moderate successes and that of industry-leading real-world evidence programs. Too many programs are adequate rather than excellent.

The findings suggest that the business argument for RWE has been won, but companies continue to face technical barriers that are preventing them from running extremely successful campaigns and realizing the full value of real-world evidence.

"Everybody's bought into the concept, but what does it take to make it real?" Gopalakrishnan said. "The first question is how do we trust the data, so we can trust the outcome it delivers? For me, that has been the biggest barrier in the past. Then, is the organization ready to have a data scientist or data analyst who can work with newer programming languages or newer technologies to be able to analyze RWD?"

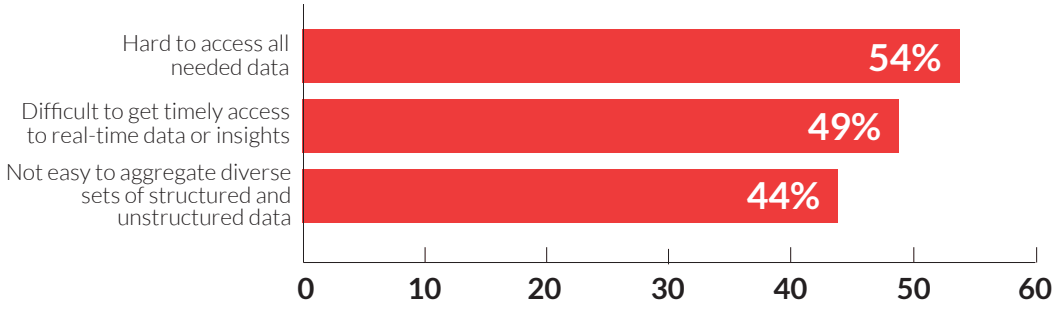
Many of the technical barriers stem from the fact RWE is based on a diverse mix of structured and unstructured data in various formats. Companies have traditionally used multiple different tools to manage the situation. The survey shows those tools are falling short. Data and technology are at the heart of the problem, with responses to questions about the remaining challenges confirming the technical issues. The main challenge, cited by 54% of executives, was accessing all the needed data.

Related challenges occupied the next few spots on the list of barriers to success in RWE. Difficulty getting timely access to real-time data or insights (49%), not easy to aggregate diverse sets of structured and unstructured data (44%) and the lack of consistent data structures (35%) were the next most common concerns. Other concerns included the difficulty of sharing across teams, vendors and partners (31%), complex and fragmented tools for analytics and machine learning (27%) and poor data quality (26%). The challenges reflect the nature of RWD.

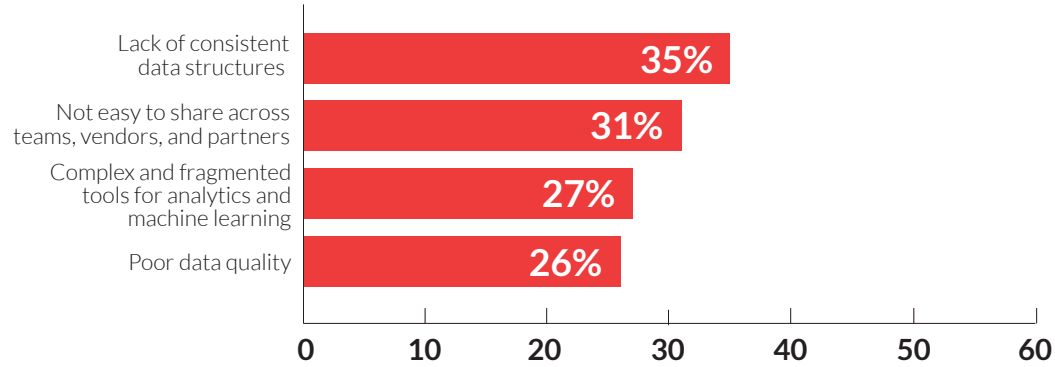
“Real-world data is not collected with the intent of evidence generation. It’s typically for billing or clinical documentation,” Michael Sanky, Global Healthcare and Life Sciences Leader at Databricks, said. “You need to go into those sources and have tooling to run things such as natural language processing pipelines, so you can really make sense of the clinical documentation, for example, measuring patient disease progression.”

Three factors are seen as primary challenges organizations are facing when trying to deliver on their Real-world Evidence initiatives: hard to access all needed data, difficult to get timely access to real-time data or insights, and not easy to aggregate diverse sets of structured and unstructured data.

About half of biopharma executives cite three challenges their organizations face when trying not deliver on their Real-world Evidence initiatives:



Other frequently mentioned challenges are:



What executives and their teams want from RWE programs and platforms

Wrestling with challenges has shown executives what they need from RWE programs. The surveyed executives believe success rests on five factors:

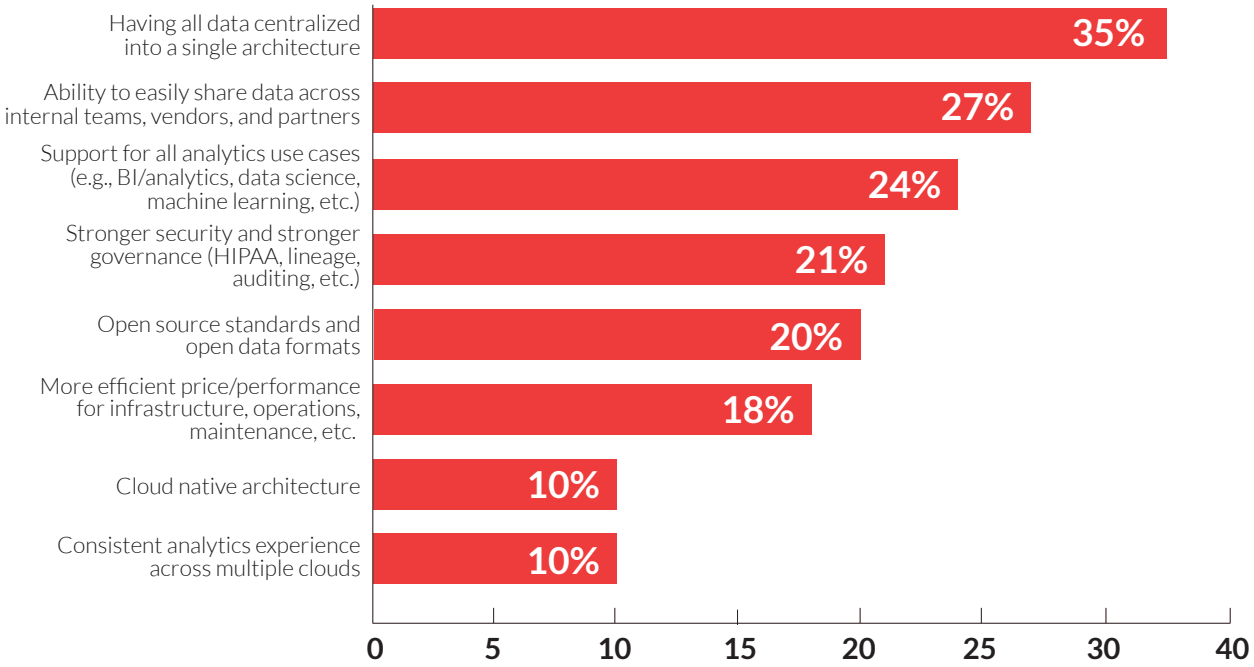
1. Timely access to large sets of reliable data
2. Leadership buy-in and support
3. Simple yet robust data management processes
4. Deep understanding of the regulatory environment
5. Expertise in building RWE programs

Fleshing those points out, the respondents explained that leadership needs to provide financial support for platforms and tools, and to help evangelize the benefits of RWE. As one respondent put it, success rests on "a strategic commitment from executive leadership to incorporate RWE into the entire value chain." Another respondent summarized the need for expertise by zeroing on the importance of "having internal experts or partners who understand the weaknesses and the strengths of the source data," and pairing that with "a robust and integrated data platform that spans the organization."

The discussion boiled down to a single question: If you could build the ideal data platform for RWE, what would you prioritize? The question revealed a wish to have all data centralized into a single architecture, with 35% of executives citing that as a critical advantage over existing architectures and 27% expressing a related desire to easily share data across internal teams, vendors and partners. Other popular choices for the ideal RWE system included support for all analytics use cases (24%), stronger security and stronger governance (21%) and open source standards and open data formats (20%).

If organizations could build a new data architecture for Real-world Data, having all data centralized into a single architecture would be the most important capability over existing architectures

Top factors mentioned as critical needs over existing Real-world Evidence architectures are:



Two percent volunteer other critical advantages, 15% are not sure and 6% do not have a data architecture for Real-world Data.

"The benefit of centralizing data, with the appropriate governance and access controls, is that you can begin to use the same data sources across multiple different departments. Once an appropriate system is in place, pharma companies can unlock a lot of value, for relatively little effort, by using data outside of its original application," Sanky said.

Enabling industry-leading RWE programs

The feedback on the ideal RWE platform illuminates the path to resolving the key question that came out of the survey results, namely: How do we close the big gap between the moderate success many companies are having today, and the industry-leading programs that remain a rarity? Databricks has developed an answer to that question.

With its Lakehouse Platform, Databricks is empowering biopharma companies to store all types of data in the cloud and power all types of analytics and machine learning use cases in a single, collaborative and open environment. The platform addresses the call for a system capable of centralizing data—the top demand of the polled biopharma executives—while providing a robust set of analytics tools to meet the diverse needs of different personas involved in evidence generation. Databricks thereby equips companies to maximize the value of their RWE programs and accelerate the development of life-changing medicines.

Learn how organizations like Sanofi, Biogen and Regeneron are delivering data-drive innovation across the entire drug lifecycle with the Databricks Lakehouse by visiting www.databricks.com/healthcare.

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