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Getting real with real-world evidence

Deloitte's Real-World Evidence Benchmark Survey shows life sciences companies have room for improvement

Executive summary

Life sciences companies should consider embracing new strategies, partnerships, and technologies to realize opportunities to discover, optimize, and demonstrate value through the application of real-world evidence (RWE). The industry-wide shift from volume- to value-based payment models and the move towards more personalized health care have helped fuel interest in using RWE to understand and demonstrate the value of pharmaceutical and medical device innovations. The bipartisan 21st Century Cures Act, signed by President Obama towards the end of his term in December 2016, charges the Food and Drug Administration (FDA) with evaluating the expanded use of RWE, including its potential to support the approval of new indications for previously approved drugs.

The new law and the growing imperative for life sciences companies to demonstrate value to payers and health authorities will likely shift research and development (R&D) and commercialization strategies towards those that develop innovative products and are effective in gaining coverage and optimal pricing. Many life sciences companies and other health care stakeholders (payers, providers, regulators, and patients) are increasingly making high-impact decisions using an expanding array of electronic real-world data (RWD) sets beyond traditional claims and electronic medical records (EMR) data.

Deloitte's 2017 Real-World Evidence Benchmark Survey shows that life sciences companies are making some progress in using RWE but still have opportunities to expand applications across the value chain, consider new channels to access RWD, and improve their overall capabilities.

Among our findings:

- Half (54 percent) of respondents are investing in their RWE programs to significantly increase their capability in this space.

- Many are targeting the use of RWE to support R&D in areas such as improving trial design and patient recruitment.

- Lack of access to the right RWD could hamper progress; new channels for data may be needed, including new external partnerships.

- As the demand for RWE increases, companies are turning to new technologies to compress the workflow and improve "time to insight."

To take advantage of new opportunities and thrive in today's technology-enabled, value-focused health care market, companies should consider embracing a new operating model based on end-to-end (E2E) evidence management from R&D through commercialization. This includes establishing an effective governance strategy, leveraging technologies such as the cloud and self-service analytics, and making sure that the organization has the ability to integrate data sets and understand the appropriate resources for the necessary analytics, as well as tactical issues around data access and quality.

Importantly, companies may also want to adopt new strategies and capabilities to support external partnerships and collaborations with health systems, patient advocacy groups, and other data aggregators in the near-term.

Introduction

The 21st Century Cures Act creates incentives for life sciences companies to invest in RWE and data strategies. Specifically, the FDA is charged with evaluating the expanded use of RWE to potentially support the approval of new indications for previously approved drugs.

This new regulatory opportunity—combined with the growing imperative for life sciences companies to demonstrate product value—is helping to drive commercialization strategies that result in broader insurance coverage, optimal pricing, and optimal formulary placement. Payers' shift in focus to outcomes- and value-based health care means that often companies need E2E evidence management capabilities across product development, launch, commercialization, and surveillance. In the past, companies' marketing strategies typically focused on claims-based messaging and scientific sound bites.

The new health care landscape calls for moving beyond simple marketing messaging to incorporate empirical evidence at the heart of the value conversation.[1]

21st Century Cures Act

Signed December 13, 2016, Public Law 114-255 includes key provisions accelerating drug and device development and approval:

- Requires FDA to hold a public meeting and issue guidance documents to assist sponsors in incorporating adaptive designs and statistical (quantitative and qualitative) modeling into new drug applications

- Requires FDA to evaluate the use of RWE to help support the approval of a new indication for a previously approved drug and to help support or satisfy post-approval study requirements

- Establishes a review pathway for biomarkers and other development tools to help shorten drug development times

- Allows FDA to rely upon qualified data summaries to support the approval of an application for a new indication of an already approved drug

- Requires FDA to include a statement regarding any patient experience data that was used at the time a drug is approved

- Requires FDA to issue guidance regarding how to collect patient experience data

- Establishes a breakthrough pathway for medical devices

- Identifies specific medical software categories that will not be regulated as a medical device unless there is found to be a safety concern

Source: Deloitte analysis

What is RWE and what is it good for?

RWE comes from secondary analysis of observational data from the health care system and, increasingly, patients themselves, as digital health and the Internet of Things become reality in many therapeutic areas. These data sources reflect the patient experience from a mix of individuals taking a drug or using a device in real world settings, as opposed to controlled clinical trials.

Traditional and emerging sources of RWD can include:

• Administrative claims data from insurers and government health programs

• Clinical data from medical records

• Surveys

• Patient registries

• Molecular and laboratory results data

• Social media and mobile technologies

• Health "apps" and other connected devices capturing health and lifestyle information

• Linked data sources (e.g., claims linked to electronic health records)

Uses of RWD may include:

• Learning about drug/device effectiveness in terms of both clinical and non-clinical impacts (as opposed to demonstrating efficacy—the main focus of randomized clinical trials); for example:
  – Outcomes (e.g., patient-reported outcomes, health care related quality of life, and symptoms) not traditionally collected in randomized control trials (RCTs)[2]
  – Comparisons of multiple alternative interventions (e.g., older vs. newer drugs) or clinical strategies to inform optimal therapy choices
  – Net clinical, economic, and patient impacts following implementation of coverage or payment policies or other health management programs (e.g., the kind of data CMS expects to collect under its Coverage with Evidence Development (CED) policy)[3]
  – Resource use for economic evaluation of health care services

• Estimating the evolving risk–benefit profile of a new intervention, including long-term (and rare) clinical benefits and harms, as well as proactive safety signal detection and monitoring[4]

• Learning how the drug or device performs in a variety of typical practice settings and populations, and among a diverse study population that reflects the range and distribution of patients observed in clinical practice, for example:
  – Seeing how a product is dosed and applied in clinical practice
  – Determining levels of patient adherence to therapy
  – Defining clinical practice standards and guidelines

• Expediting assessment when there is no time or opportunity to conduct a RCT; for example:
  – Advancing products to address narcotic abuse
  – Accelerating reimbursement for some therapies because it is the only available option and may be life-saving[5]
  – Providing interim evidence—in the absence of RCT data—upon which preliminary decisions can be made

• Substantiating data collected in more controlled settings

• Furthering additional R&D and business development, including:
  – Generating hypotheses to identify new drug targets or patient populations that may benefit and to facilitate drug repositioning

• Informing business development and portfolio strategies, including mergers and acquisition activity

RWD is neither a panacea nor a replacement for RCTs which, for the foreseeable future, are likely to remain the "gold standard" for demonstrating safety and efficacy. However, as outlined above, RWD sets can have a broad set of applications. As the use of RWD expands, we anticipate an associated acceleration in the improvement and confidence of the methodologies and regulatory science associated with its use.
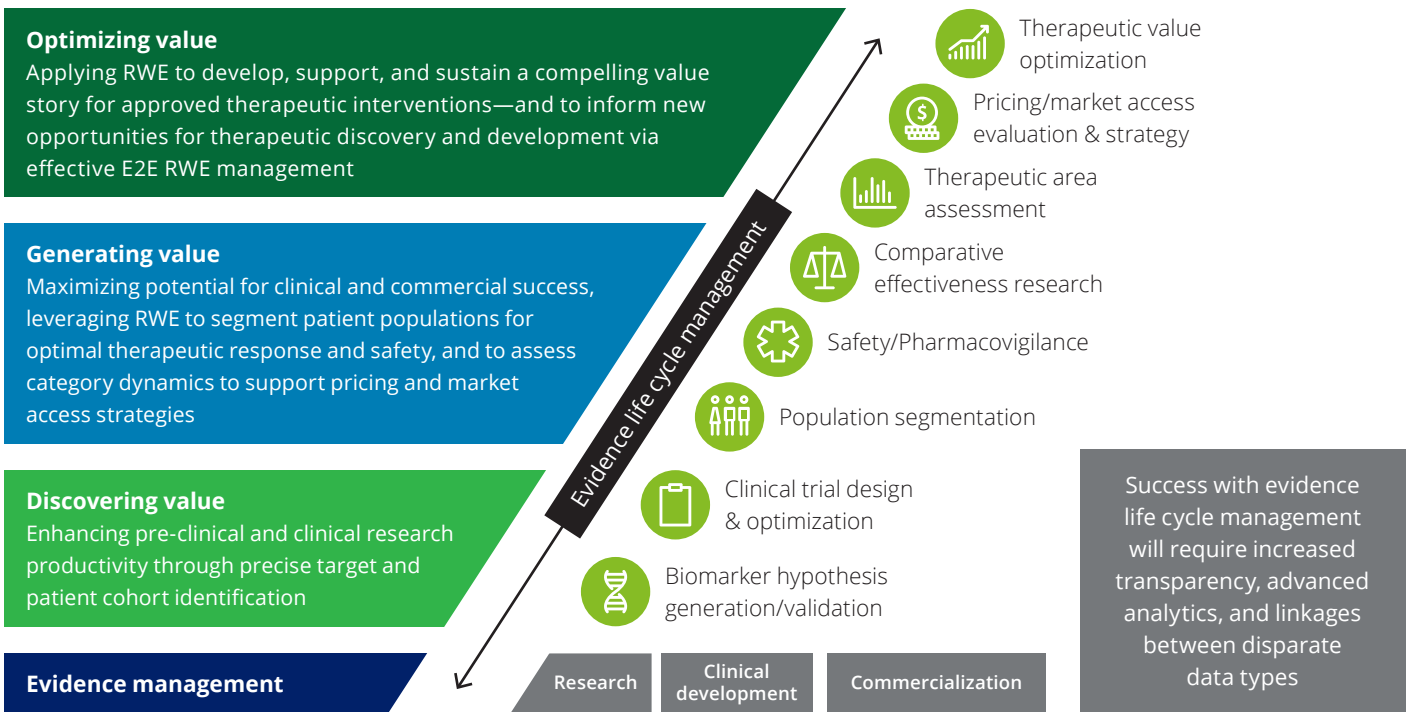
As health care technology advances and adoption increases, the volume, variety, and velocity of RWD is exploding. Life sciences companies can use this RWD to better understand what is happening during episodes of care at a much larger scale than is possible with clinical trials: it can enable researchers to characterize patient experience with a condition and therapy across millions of patients versus the few thousand that are part of a typical clinical trial. Insights generated from RWE may affect decisions across the entire product life cycle, from R&D through commercialization.

An E2E evidence management strategy could be a key ingredient in realizing RWE's potential because it helps decision makers act at an enterprise level based on rigorous, data-driven insights versus a traditional siloed approach. Using an E2E evidence management framework (Figure 1) can assist companies in identifying targeted breakthrough innovations, accelerating new products through development, and successfully launching and marketing them in a value-based care environment.

Figure 1. E2E evidence management framework

New paradigm of E2E evidence management
Life sciences companies should maximize the value of their data by using it for decision making at an enterprise level (vs. traditional siloed approaches)

Optimizing value
Applying RWE to develop, support, and sustain a compelling value story for approved therapeutic interventions—and to inform new opportunities for therapeutic discovery and development via effective E2E RWE management

Generating value
Maximizing potential for clinical and commercial success, leveraging RWE to segment patient populations for optimal therapeutic response and safety, and to assess category dynamics to support pricing and market access strategies

Discovering value
Enhancing pre-clinical and clinical research productivity through precise target and patient cohort identification

Evidence management

Evidence life cycle management

Therapeutic value optimization

Pricing/market access evaluation & strategy

Therapeutic area assessment

Comparative effectiveness research

Safety/Pharmacovigilance

Population segmentation

Clinical trial design & optimization

Biomarker hypothesis generation/validation

Research

Clinical development

Commercialization

Success with evidence life cycle management will require increased transparency, advanced analytics, and linkages between disparate data types

Source: Deloitte analysis

Leveraging RWD is not new to life sciences companies; however, today's stakes are higher, the opportunities are greater, and the data volume and quality have expanded. Many health economics and outcomes research, market access, and market research professionals have been using RWE for years although, historically, much of their work occurred within silos and they shared insights with limited audiences and for limited purposes. To fully realize the full potential of RWE, executives may want to take an enterprise approach that considers their organization's structure, processes, external collaborations, and technology investments.

How are life science companies leveraging RWE?

- **Comparing safety of alternative treatments for diabetes:** Astra Zeneca leveraged RWE to evaluate cardiovascular risk associated with the use of Dipeptidyl peptidase-4 (DPP4 inhibitors) as compared to sulfonylureas for diabetes treatment in 200,000 patients. For the study, the company created comparator groups on the basis of presence or absence of codes for CVD in claims data as well as similar demographic, clinical, and other risk factors from patient health records. It then calculated hazard ratios (probability of death ratios) for each group. This analysis showed no increased risk of heart failure from use of DPP-4 inhibitors compared with sulfonylureas.[6]

- **Accelerating clinical research:** In 2016, Celgene Corporation announced a collaboration with M2gen and the Oncology Research Information Exchange Network (ORIEN), an alliance of leading cancer centers throughout the United States. The collaboration will generate massive amounts of genetic and clinical data on patients that will accelerate the identification of eligible patients to participate in biomarker driven clinical trials helping match patients to therapies tailored to the unique molecular features of their disease.[7]

Leveraging real world data is not new to life sciences companies, however, today's stakes are higher.

## Survey results: Are companies delivering on the promise of RWE?

Have life sciences companies' investments, adoption, and results kept pace with the growing importance of RWE? Deloitte surveyed 15 leading life sciences companies in our first-ever RWE Benchmark Survey to understand the current state of their RWE capabilities. Our findings are summarized below.

Half of life sciences companies surveyed are significantly investing to expand their RWE capabilities

When we asked participants "what is the status of your RWE capability?," half of the respondents (54 percent) said they have a project underway to significantly improve their RWE capability (Figure 2). This suggests that many within the life sciences

industry are beginning to embrace the promise of RWE and are defining enterprise strategies to meet the growing needs of internal and external stakeholders. It is encouraging to see this level of interest in improving RWE capabilities. Time will tell if the companies investing substantially in RWE will leapfrog those whom have not made similar investments.

Figure 2. Status of RWE capabilities

13%

33%

54%
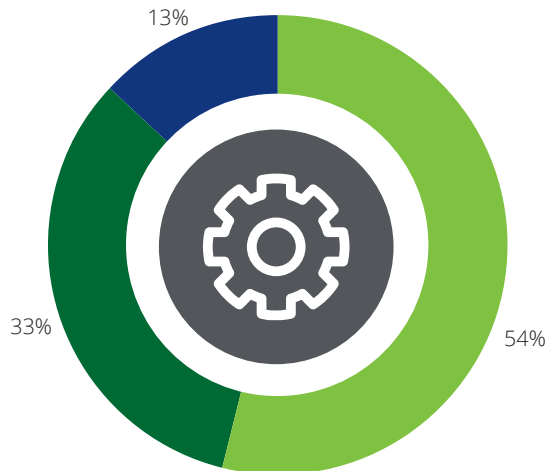
- A project is underway to develop and/or significantly improve this capability

- An RWE capability currently exists, only relatively minor updates/improvements needed

- Other

Source: Deloitte 2017 RWE Benchmark Survey

Methodology

To understand the current state of top life sciences companies RWE capabilities from an organizational, process, and technology perspective, as well as to gain insight into emerging trends, we surveyed 15 of the top life sciences companies by revenue globally. The survey was conducted over the phone and results were recorded in an online survey tool. All results were blinded during analysis and results were aggregated. The survey was conducted Q3-Q4 of 2016.

Many companies perceive that the biggest opportunities for RWE are in market access and R&D

We asked respondents where they are focusing RWE investments and where the biggest opportunities are to leverage RWE (Figure 3).

Survey participants ranked market access as the function with the greatest opportunity to realize RWE's potential benefits, followed by R&D. The fact that R&D ranked second may reflect the industry's desire to creatively address some of the challenges of increasing complexity of trials as more targeted, personalized therapies move their way through the pipeline.

As the drug development timeline lengthens (often exceeding a decade) and failure rate increases, it is unsurprising that the cost to develop and gain marketing approval for a new drug is approaching $2.6 billion.[8] How can life sciences companies reverse this trend?

Figure 3. Where are the biggest opportunities to leverage RWE?

■ Biggest opportunity   ■ Potential opportunity   ■ Some opportunity
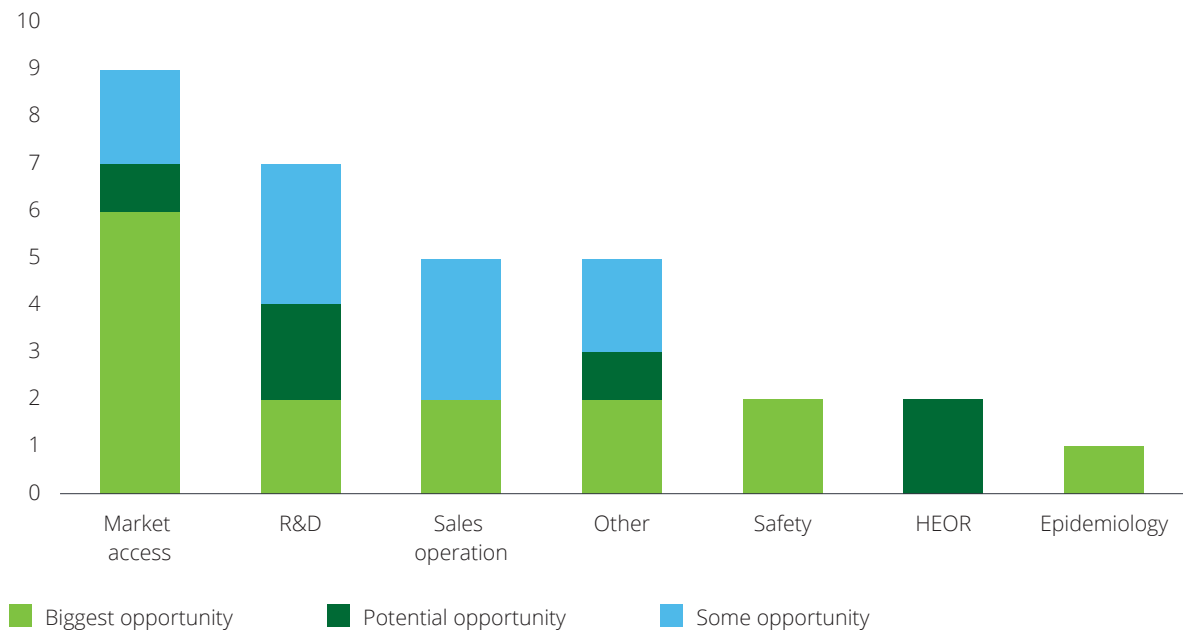
Source: Deloitte 2017 RWE Benchmark Survey

Survey participants ranked market access as the function with the greatest opportunity to realize RWE's potential benefits, followed by R&D.

As the volume of RWD grows and accessing it improves, companies have an opportunity to leverage RWE earlier in the product life cycle to help streamline development and drive down costs. When we asked survey participants to prioritize RWE use cases (Figure 4), comparative effectiveness topped the list across all respondents—likely because demonstrating real-world effectiveness is key to establishing the differential value a product delivers and gaining market access.

R&D specific use cases were two of the top three priority areas identified for companies that are currently investing in improving their RWE capabilities. This may signal that these companies are focusing their investments on driving efficiencies in R&D by improving protocol design and accelerating patient recruitment.

When thinking about two of the main drivers of drug development costs (time and failures),[9] RWE holds promise to address both if applied correctly. We heard from the survey respondents that companies are prioritizing the use of RWE to improve hypothesis development/trial design and accelerate trial recruitment.

Figure 4. Which RWE use cases are top priorities?

Cohort 1: Project underway to significantly improve capability

Cohort 2: Capability exists with only minor improvements needed

Legend: ■ Top priority ■ High priority ■ Medium-high priority ■ Medium-low priority ■ Priority

Source: Deloitte 2017 RWE Benchmark Survey

Hypothesis development is often anchored in understanding unmet needs. RWE can be an ideal source of this information. One important challenge will be how best to access the right RWD to inform this understanding.

With almost 80 percent of clinical trials failing to meet their initial enrollment projections,[10] delays in patient recruitment can cripple a trial and R&D program. How can RWE help? According to our survey, the industry is prioritizing trial patient recruitment as a RWE application. With many providers investing in health information technologies that allow them to better track and connect with their patients, patient trial enrollment can come to the point of care. This approach requires new partnership models, access to the right data, and innovative technology. While streamlining the trial recruitment process through an approach like this may seem daunting, doing so will likely be vital to realizing the full promise of personalized medicine.

Lack of access to data is the biggest challenge to implementing RWE programs

Our survey participants viewed lack of access to external data as the biggest challenge to implementing RWE programs (Figure 5). This helps underscore the need to define an enterprise RWE and data strategy to address data gaps and access challenges through novel business models and partnerships, and to provide the necessary expertise to generate insights from the data.

Data access challenges also demonstrate the limitations of the commercially available licensed real-world data sets, further underscoring the importance of new collaborations with health systems, patient advocacy groups, and other digital health constituents. As life sciences innovators define their data strategy, it is also imperative that they link it with their digital strategies (patient services, patient engagement, etc.), as digital presents an important opportunity to generate and fill evidence gaps.

Figure 5. What are the challenges to implementing RWE programs?

Major challenge   Challenging   Somewhat challenging
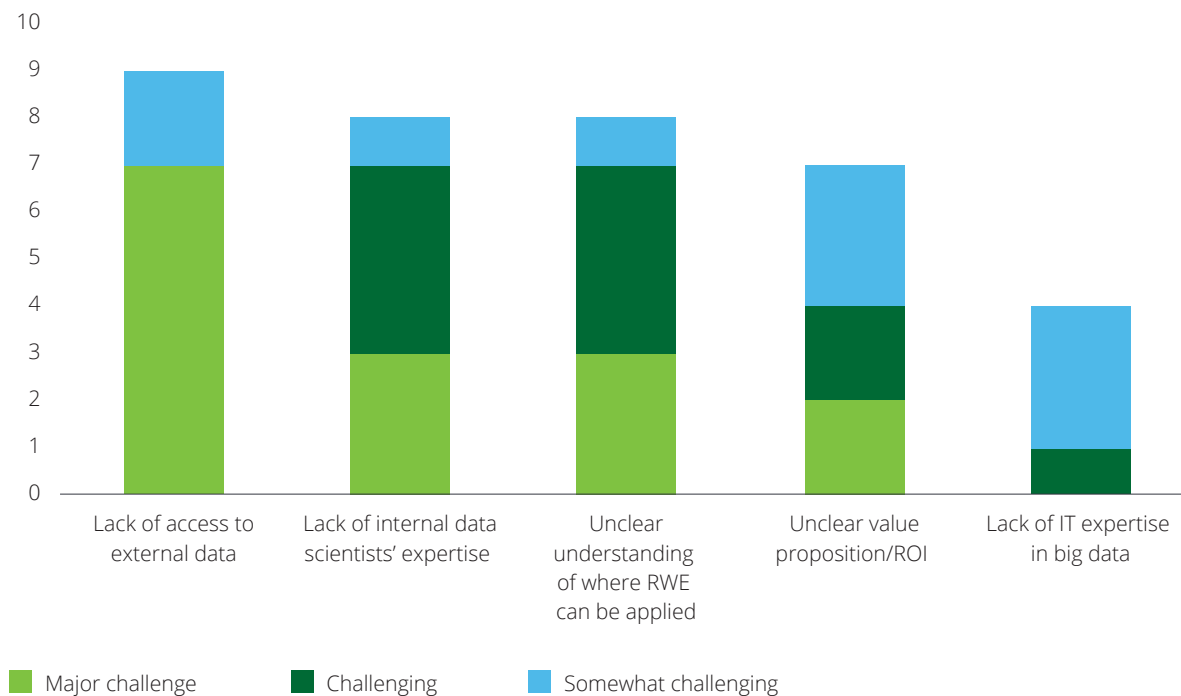
Source: Deloitte 2017 RWE Benchmark Survey

Potential barriers to accessing the right data for RWE

- *Data quality:* Researchers often have to clean RWD, especially from nontraditional sources, since most of it is not collected for research purposes. However, the cleaning methods that researchers use may not yet be widely accepted for statistical validity.[11]

- *Cost:* The cost of collecting and maintaining data from nontraditional sources such as patient groups, professional societies, and health care providers, is uncertain. If the process is not part of the regular course of doing business, investments may not be consistent or to the level required to obtain quality data. This is particularly true for organizations that may rely on government funding.[12]

- *Patient protection:* Data breaches in the health care industry continue to raise concerns around the security and privacy of patient data. These concerns could stifle the willingness of institutions to invest in RWE applications or of patients to consent to the use of their data.[13]

- *Data linkage restrictions:* When it comes to RWE, health care system fragmentation produces an incomplete picture of the patient. Linking various data sources (e.g., claims + EMR + patient-reported) provides a more accurate characterization of the patient. Unfortunately, the current data vendor landscape can make it difficult to bring data assets together.

Access to the right data is not likely to transform a company on its own. Other essential RWE program elements include data science talent, governance structure, technologies, and operating model.

Demand for data sciences talent is increasing

Increased demand for RWE-driven insights is creating increased demand for data scientists: experts in statistics, machine learning, and computer science with deep knowledge of various approaches to generate insights from disparate data sources. Survey participants cited lack of internal data science expertise as the second biggest RWE implementation challenge.

We asked survey participants which approaches they are using to build their data sciences team (Figure 6). The top three they identified are:

1. Recruiting from other life sciences companies
2. Recruiting from payers or providers
3. Recruiting from other industries

Figure 6. How are companies building a deep bench of data scientists?

Legend:
- Other
- Recruiting from competitors (other life sciences companies)
- Hire from graduate programs
- Recruiting from other industries
- Recruiting from payers or providers
- Training in-house statisticians from other departments
- Not sure
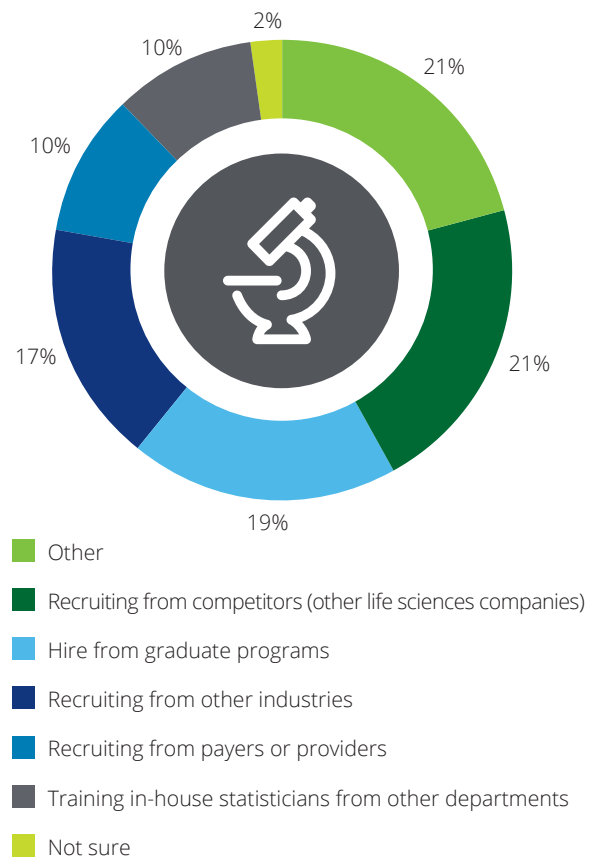
Source: Deloitte 2017 RWE Benchmark Survey

Recruiting from other life sciences companies is not surprising. These data scientists bring knowledge of the life sciences industry, which is vital because working with RWD can be complex and understanding the nuances of its application is rare. Data comes in a variety of formats, contains both structured and unstructured information, and has many potential biases. Previous experience dealing with these complexities can be extremely valuable.

Recruiting from payers or providers could add customers' perspective to the mix—a benefit to life sciences companies because it can provide a 'look under the hood' at how payers and providers analyze RWD and enable companies to incorporate those learnings into their overall approach.

Recruiting from other industries is the third most-cited approach, but it may offer the most potential to advance data science within life sciences. The industry is moving towards applying cognitive computing approaches to RWD so having a diverse team that applies learnings from other industries could help deliver new insights.

To accomplish a deep, diverse data science capability, life sciences companies should consider using a balanced talent strategy that could include hiring, partnering, co-sourcing and some capabilities outsourcing to keep pace with demand.

> To accomplish a deep, diverse data science capability, life sciences companies should consider using a balanced talent strategy.

Technology investments important to support RWE

The continued growth in data volume, variety, and velocity—as well as the need to quickly deliver insights derived from that data—makes the right technology an important element of an RWE program.

Many life sciences company functions are adopting cloud technologies because of the speed, scalability, flexibility, and security they provide. We asked survey participants about their use of the cloud to support RWE. Nearly 60 percent of survey respondents said they are using the cloud for RWE (Figure 7).

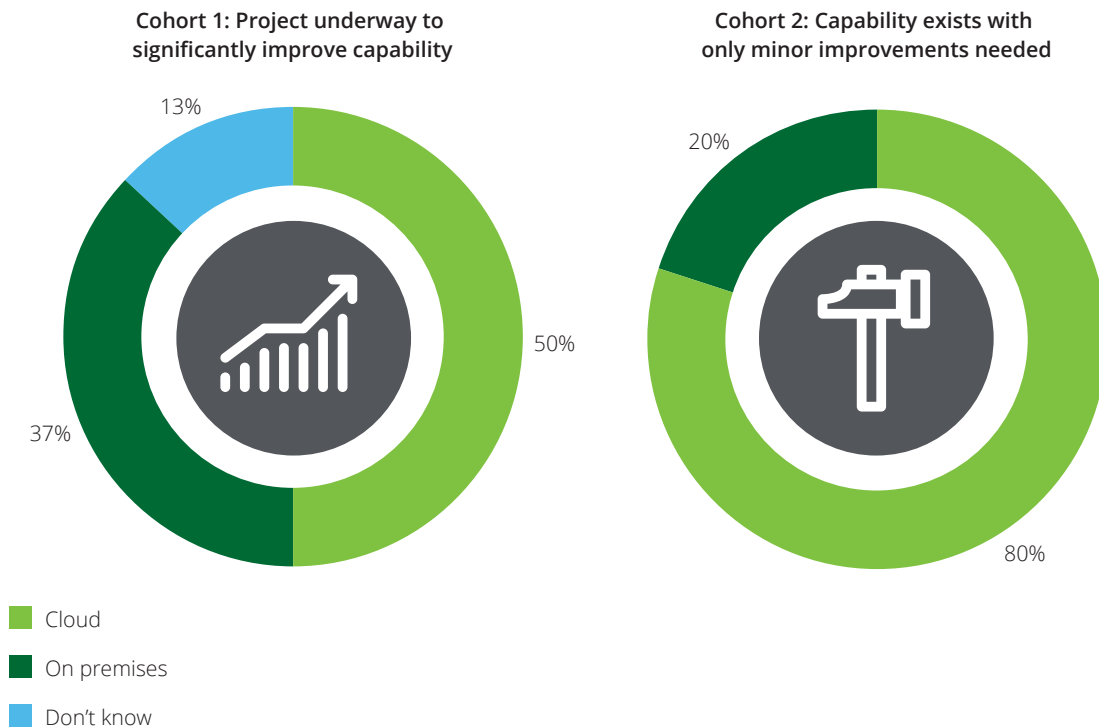**Figure 7. Is your organization using the cloud for RWE?**

- Cloud
- On premises
- Don't know

Source: Deloitte 2017 RWE Benchmark Survey

11
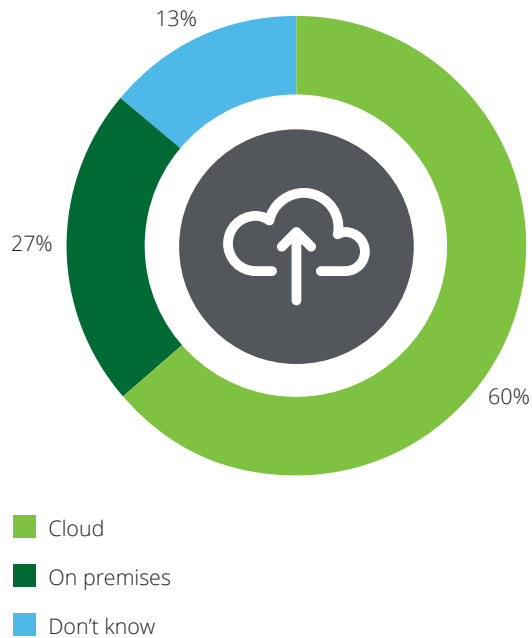
The cloud can provide important benefits to RWE functions:

- *Speed:* Cloud-based analytics can be stood-up extremely quickly.

- *Scalability:* As data volume grows, on-premise solutions often cannot scale fast enough. The cloud can provide flexibility and on-demand scale, and reduces or eliminates the need for large investments in hardware and the time it takes to procure and set it up.

- *Security:* Patient-level data, even in a de-identified format, must be protected at all times. The cloud can provide a highly secure environment for this data.

We saw some interesting differences between respondents whose organizations have RWE capability improvement projects underway and those who feel their existing capabilities are sufficient. Nearly 80 percent of the latter are using the cloud versus only 50 percent of the former (Figure 8). This may suggest that organizations investing in their RWE program are moving towards the cloud to improve the effectiveness of their program and capabilities, and that those who have a capability and are largely satisfied with that capability are already on the cloud.

Figure 8. Are you currently using the cloud for RWE?

Cohort 1: Project underway to significantly improve capability

13%

50%

37%

Cohort 2: Capability exists with only minor improvements needed

20%

80%

■ Cloud

■ On premises

■ Don't know

Source: Deloitte 2017 RWE Benchmark Survey

One of the key benefits of a cloud-based platform is having the ability to scale up or down based on demand because users can access computing and storage resources when needed. Combined with newer big data technologies such as Hadoop, Spark, MapReduce, Impala, Hive, etc., using the cloud can improve analytical systems' overall performance to manage RWD.

When we asked survey participants to rank the importance of a scalable environment, more than 60 percent said that having one is "most important" (Figure 9).

Figure 9. How important is a scalable environment?

Most important   Important   Not Important
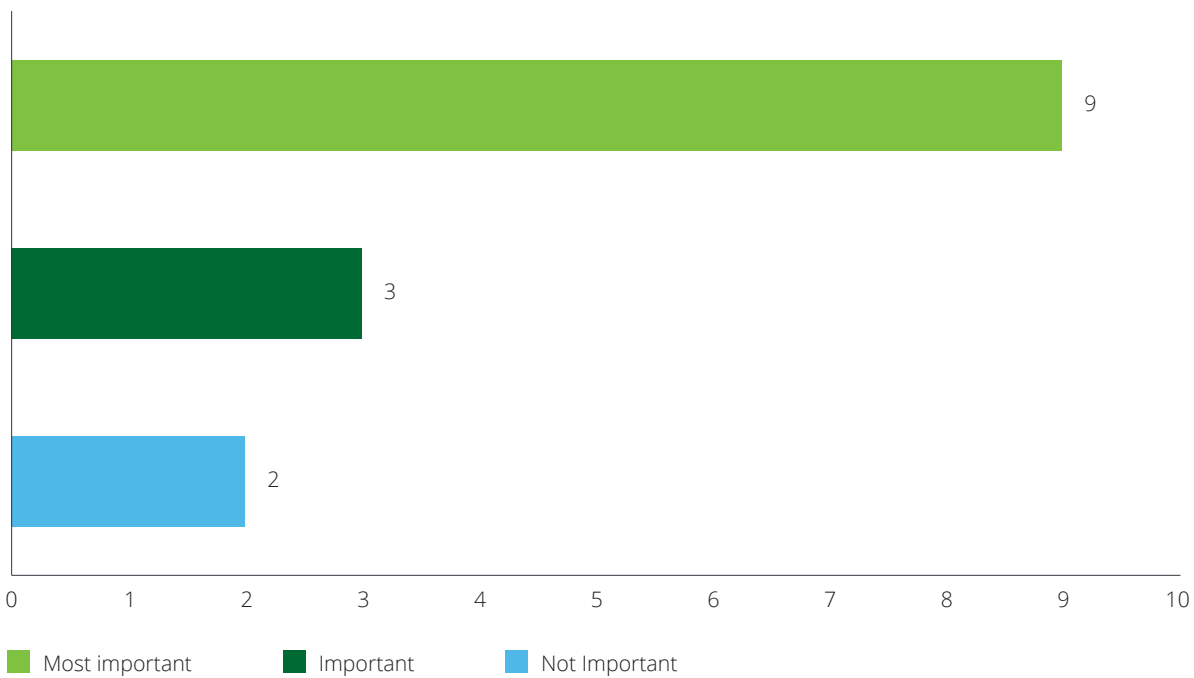
Source: Deloitte 2017 RWE Benchmark Survey

Using analytics to support RWE

As mentioned earlier, limited data science resources are not meeting growing demand. Many life sciences organizations are striving to find ways to streamline workflow and improve the efficiency of their analytics groups so that data scientists can focus their attention on answering the highest-impact and most-complicated research questions (vs. data wrangling and basic cohort selection).

Once a question is defined, one of the first steps in any analysis is to identify appropriate data sources. Researchers and data scientists can spend a lot of time trying to figure out what data sources exist, what

data they contain, and which studies and analyses have previously taken place. A centralized knowledge management system can provide visibility into all of an organization's data sources, capture relevant meta-data on each source, capture previous studies and analyses, and help connect stakeholders to better share knowledge.

We asked our participants how important it is to have a central knowledge management system that could help streamline this part of the analytics workflow. Over 90 percent of survey respondents said that this is a highly important component of their RWE capability (Figure 10).

Figure 10. How important are central knowledge management systems?

Most important   Important   Not important (NA)
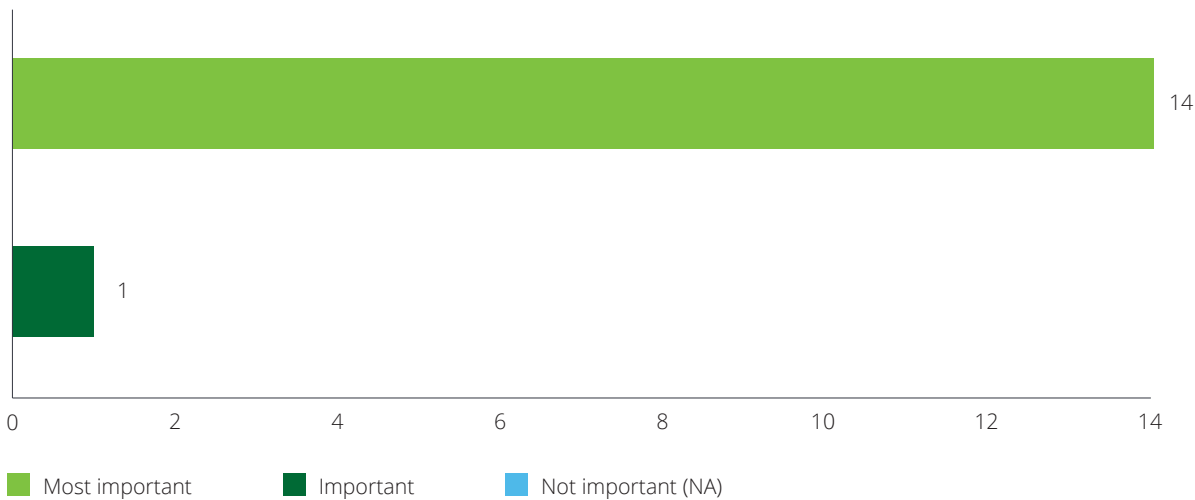
Source: Deloitte 2017 RWE Benchmark Survey

More than 90 percent of survey respondents said that a central knowledge management system to support an analytics workflow is a highly important component of their RWE capability.

Once a data scientist identifies a potential data source, the individual can spend considerable time iterating through business rules and cohort definitions to ensure an appropriate sample size to power their analysis. This step typically requires engaging stakeholders to work through the definitions and spending time writing code and running queries. The emergence of self-service applications (e.g., cohort selection tools, advanced data visualizations) that enable researchers, data scientists,

and domain experts to conduct complex feasibility queries without having to write the underlying code could dramatically condense this part of the workflow.

We asked survey participants how important tools like this are to their RWE capability and over 90 percent said they are either "important" or "most important" to their RWE capability (Figure 11).

Figure 11. How important are self-service tools for cohort building and descriptive characterization for non-technical users?

Legend:
- Most important
- Important
- Not Important
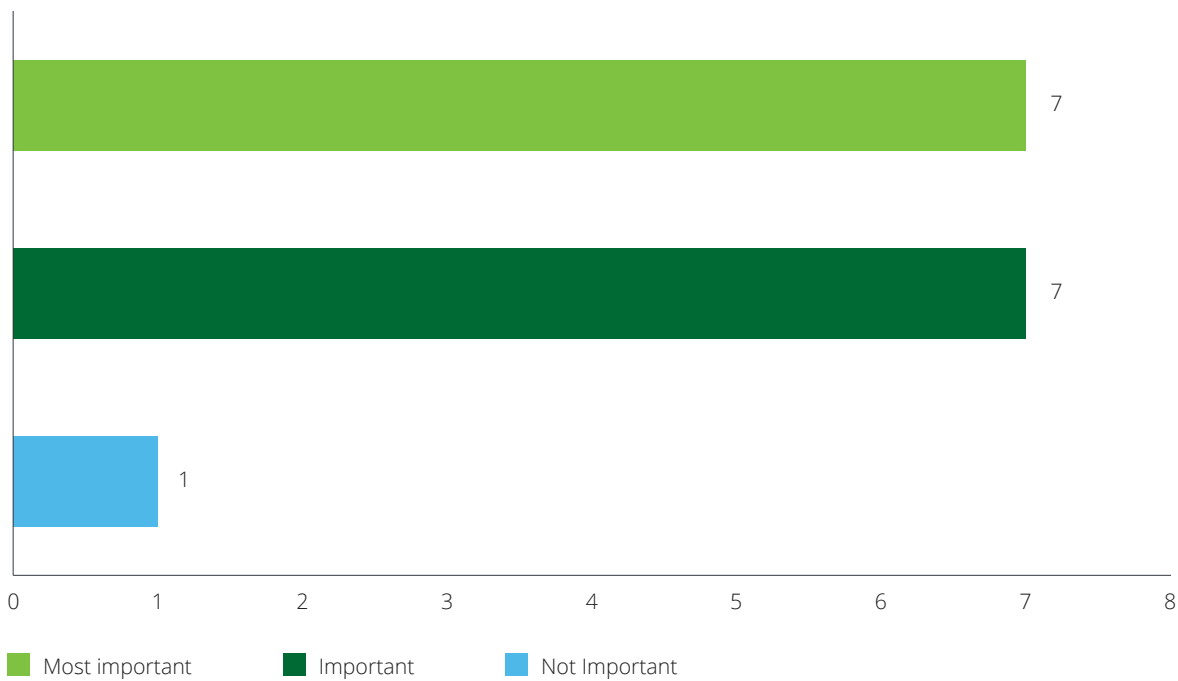
Source: Deloitte 2017 RWE Benchmark Survey

Conclusion

Our survey results shed light on how the life sciences industry is beginning to take advantage of RWE's promise. To effectively develop and implement a broad, enterprise-wide RWE capability, however, companies should take a holistic approach that spans traditional siloes and considers talent, technologies, governance, operating model, and external partnerships.

Some smart next steps that life sciences companies should consider include:

- Developing an E2E evidence strategy that cuts across the entire product life cycle

- Designing and implementing a platform and operating model that are grounded in an enterprise strategy to support working with RWE across functions and franchises

- Developing a data strategy and organizational capability to engage in external partnerships with

health care system stakeholders to gain access to the right data.

- Employing data scientists with diverse backgrounds to challenge conventional ways of doing things.

In our experience, transforming how life sciences companies incorporate RWE across the value chain and drive the development of innovative new therapies requires implementing an enterprise-level RWE strategy that spans multiple dimensions (Figure 12).

As health care data continues to proliferate, the need for and importance of advanced information management and analytics technologies to access, analyze, and act on RWE will likely grow exponentially. Results from our 2017 RWE Benchmark Survey show that life sciences companies are making some progress in strengthening their RWE capabilities but still have room for improvement.

Figure 12. Enterprise RWE capabilities require a strategy that spans multiple dimesions

Strategy	People & capabilities	Process & governance	Data	Technology
RWE vision	Leadership	Ideation & prioritization	Data strategy	Tech distributors & vendor strategy
Value rivers & business	Organization design	Agility & scalability	Data quality & management	Reference architecture
Stakeholder management	Talent	Process re-engineering & automation	Data analytics & modeling	Application development
Operation model	Change journey & process	Governance	Ethics & sharing	Cloud vs. on premise
Innovation	Knowledge management	Value realization	Regulation & complliance	Security, reliability, & continuity

Source: Deloitte analysis

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Endnotes

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