Optum

Turning evidence into action

Maximize your investments with a more coordinated and connected real-world data strategy.

Explore more

According to the FDA's own website, "Real-world data (RWD) and real-world evidence (RWE) are playing an increasing role in health care decisions."[1]

How is your organization capitalizing on these vital resources?

If your claims and clinical data sets aren't integrated, if your data governance isn't centralized, or if the teams accessing the real-world data remain siloed, then your organization probably isn't maximizing the ROI of its RWD.

Now is the time for silo-busting. By connecting disparate data sets, centralizing data oversight and coordinating cross-team collaboration, your organization will be well on its way to enabling the connections that fuel insight, opportunity and improved patient care.

This e-book will prepare you for the conversations you'll want to have as you set a more coordinated and connected real-world data strategy. It includes a primer on the current real-world data landscape and offers some concepts you can use to evaluate your organization's investments and direction.

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1. U.S. Food & Drug Administration. Real-world evidence. Last updated May 20, 2022. Accessed June 10, 2022.

The best place to start

To get the most from your RWD investments, you first need to create an enterprise-wide data strategy. This will help you set a firm foundation that will reap benefits for years to come.

Consider these four steps as you craft a flexible, efficient, data-centric organization:

1. **Develop a clear plan.** Without a roadmap, many organizations build disjointed and inefficient systems. This lack of planning wastes time and money that you could use elsewhere.
2. **Build a network of internal and external partners who specialize in real-world data.** When your needs for data shift, you can leverage your partners to move more nimbly. Having a supportive network at the ready prepares you to maximize your time.
3. **Provide centralized data access across the organization.** Companies that silo or restrict their data limit their potential return on investment and may even waste resources by enabling redundant investments.
4. **Employ the right people and provide them with the appropriate tools to derive insights.** Data that sit on a server can't bring value to an organization. You need experts who can analyze and turn that information into useful insights. Bringing varying perspectives and experience into your projects will help ensure you're asking the right questions and unlocking richer insights.

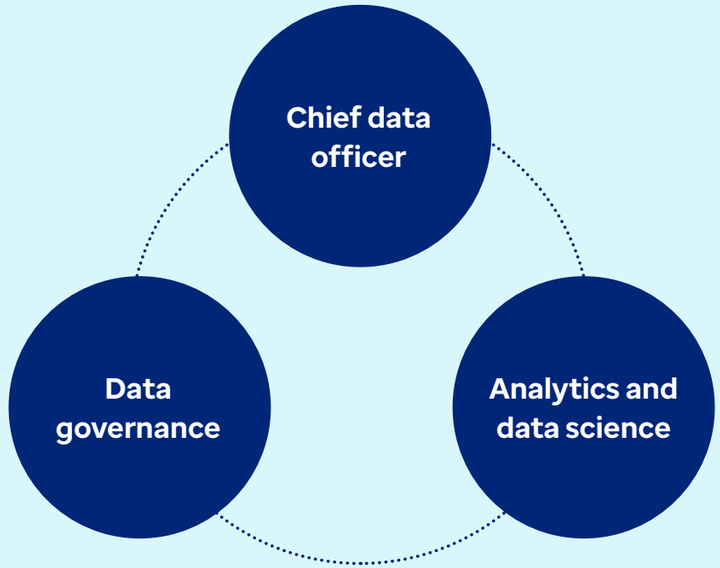
Ultimately, you need a single source of truth for your organization's real-world data, coupled with the proper processes, procedures and guidelines to ensure that the appropriate individuals and functions within the organization have access to the data when and how they need them.

Do you have the right teams in place?

The most progressive data-centric organizations have three centralized functions to help optimize data investments, access and insights.

- First, a **chief data officer** helps ensure an efficient and effective data environment
- Second, **data governance** teams help ensure appropriate use and security
- Finally, **analytics and data science** teams transform real-world data into real-world evidence through traditional and emerging forms of analytics

All three teams need to engage stakeholders throughout your enterprise to get the insights into the hands of the people who can use them.



Those silos are holding you back

To maximize the value of your organization's RWD investments, you need to bust some silos – technological ones (data silos) and organizational ones.

Siloed data can languish from underutilization. Let's say your clinical operations team licenses an EHR-based data set to help refine a study protocol so it doesn't unnecessarily exclude potential patients for the trial. Because the data set lives with the clinical development team, others may not know of its existence. But what if that same EHR data could help other teams answer important clinical and business questions?

- The health economics and outcomes research (HEOR) team could analyze those data to generate evidence about the demonstrated clinical value of approved products in the real world
- One of your brand teams could use the information to improve their targeting and messaging based on characteristics of patients on the branded therapy versus those who are not
- Your market access organization could leverage the data to better understand disease progression and likely ranges of outcomes to inform novel value-based contracting arrangements

In this scenario, four different parts of your organization are now leveraging the same data for important business activities, greatly increasing the value of the original clinical data investment.

Organizational silos can also lead to duplicative investments. Now imagine that two departments in the same organization license similar data from different sources to study a very similar topic. Not only does this fuel inefficient and duplicative spending, but it often yields answers to similar research questions that don't exactly line up. Perhaps the underlying populations are quite different, or the teams deploy different analytic methodologies.

Regardless, the misaligned results typically trigger months of further analysis to reconcile the two projects or "pick a winner." With enterprise-wide visibility into purchased data and potential projects, organizations can ensure teams are collaborating to ask the right questions, agree on methodologies and use the data that are truly fit for purpose.

Data silos

- Disparate data sources on different servers or platforms
- Difficult to integrate data for a complete picture of patient health

Organizational silos

- Separate data licensing or collection process across departments
- Using data for different purposes leads to missed opportunities for collaboration and value

The viable use cases for RWE are expanding

The FDA perspective on the use of real-world evidence in regulatory decision-making continues to evolve — the agency has published several new pieces of guidance and perspectives as of 2021 and 2022.[2, 3, 4] The agency clearly expects the use of RWE to proliferate in the coming years.

In the European Union, efforts are underway to better support the use of RWE there as well. The Data Analytics and Real World Interrogation Network (DARWIN EU) is developing a network to access and analyze health care data across the EU.[5]

Early use cases for RWE among life sciences companies focused on post-approval studies that enhanced value messaging for health care practitioners and payers, justified label expansions or surveilled long-term safety. Now, RWE is poised to support a wider range of critical activities across the product lifecycle. These activities include early-stage research through clinical development, launch planning, value-based contracting, long-term monitoring and ongoing patient activation. RWE can even play a role in strategic roadmapping, helping to determine how attractive potential markets can be.

Which parts of your organization are the most innovative in deploying RWE? Which teams may benefit most from reimagining how RWE can help them disrupt the status quo?

How are your teams leveraging RWE derived from linked clinical and claims data?

Roll over icons to learn more

- Medical strategy
- Market access
- Clinical development and clinical operations
- Epidemiology
- Health economics and outcomes research (HEOR)
- Brand

2. U.S. Food & Drug Administration. Real-world data: Assessing electronic health records and medical claims data to support regulatory decision-making for drug and biological products. Last updated September 2021. Accessed June 7, 2022.
3. U.S. Food & Drug Administration. FDA issues draft guidances on real-world evidence, prepares to publish more in future. Last updated January 31, 2022. Accessed June 7, 2022.
4. U.S. Food & Drug Administration. Perspective: Real-world evidence — Where are we now? Last updated April 30, 2022. Accessed June 7, 2022.
5. European Medicines Agency. A vision for use of real-world evidence in EU medicines regulation. Last updated November 24, 2021. Accessed June 7, 2022.

RWD that tell a complete story

Today, the most common types of real-world data fall into three buckets: claims data, clinical data and consumer or contextual data. They are inter-related, but they tell different stories.

- **Medical and pharmacy claims** contain information about diagnoses, utilization, sites of care, prescribers and treatments prescribed, and the associated costs of all services.
- **Clinical data** are predominantly housed in electronic health records (EHRs), which include clinical information captured in health care encounters. Examples of these data include vital signs and lab results, patient demographic information and unstructured clinical notes that often "fill in the gaps" by documenting patient histories, diagnoses, comorbidities, adherence patterns and more. Registries and approved remote monitoring devices (like Holter monitors for arrhythmias) provide additional sources of clinical data that may or may not be integrated into EHRs. Genomics data also fall into this category.
- Beyond claims and clinical data, there's a rapidly evolving and growing amount of **consumer and contextual data** that progressive organizations are actively trying to decipher, analyze and integrate. This includes data about social determinants of health (SDOH), such as food insecurity or transportation access, but it also extends to patient surveys, purchasing data and more.

Because the health system remains fragmented, it's difficult to find data sources that integrate and link these data together in reliable, meaningful ways.

RWD that tell a complete story

When you're able to make these connections, your teams can suddenly follow and understand patient journeys longitudinally and more deeply. At this point, a host of new insights become available to you:

- How symptoms, disease severity, reported side effects and decision-making affect medication choices and adherence
- How different treatment protocols compare clinically and economically in different populations
- How different underlying or situational patient characteristics correlate with differences in disease progression, prognosis, responses to treatment and the onset of any comorbid conditions
- How well different clinical and non-clinical interventions impact diagnosis, as well as adoption of (and adherence to) different treatments

Increasingly, next-generation RWD provide even greater levels of granularity. These data sources include social determinants of health (SDOH), genomic profiles, patient-reported outcomes (PROs) and patient-generated health data (PGHD) captured by internet-connected wearable devices.

How these emerging sources of data get incorporated into drug development and commercialization efforts will be a source of intense innovation and experimentation in the coming years. But research and technology leaders are determined to figure out how to connect these data with more established RWD sources in order to drive more nuanced, value-driven and patient-centered decision-making.

Data quality checklist

Having lots of data is not enough. It's important that the data be of high quality and fit for purpose. **Here's a checklist to consider** before you bring external data in-house:

Roll over questions to learn more

Are the data easy to use?

Are the data reliable?

Are the data relevant?

Are the data representative?

Where to turn for help

As the momentum toward real-world evidence adoption continues, you will almost certainly see more requests for real-world data from departments across your enterprise.

If and when you have unresolved questions about data sources, data quality, appropriate uses or advanced analytics, Optum data strategists, technologists and scientists are ready to help. Life sciences leaders trust our robust real-world data and experienced consultants to connect the dots in ways that answer tough questions, illuminate new possibilities and improve patients' lives.

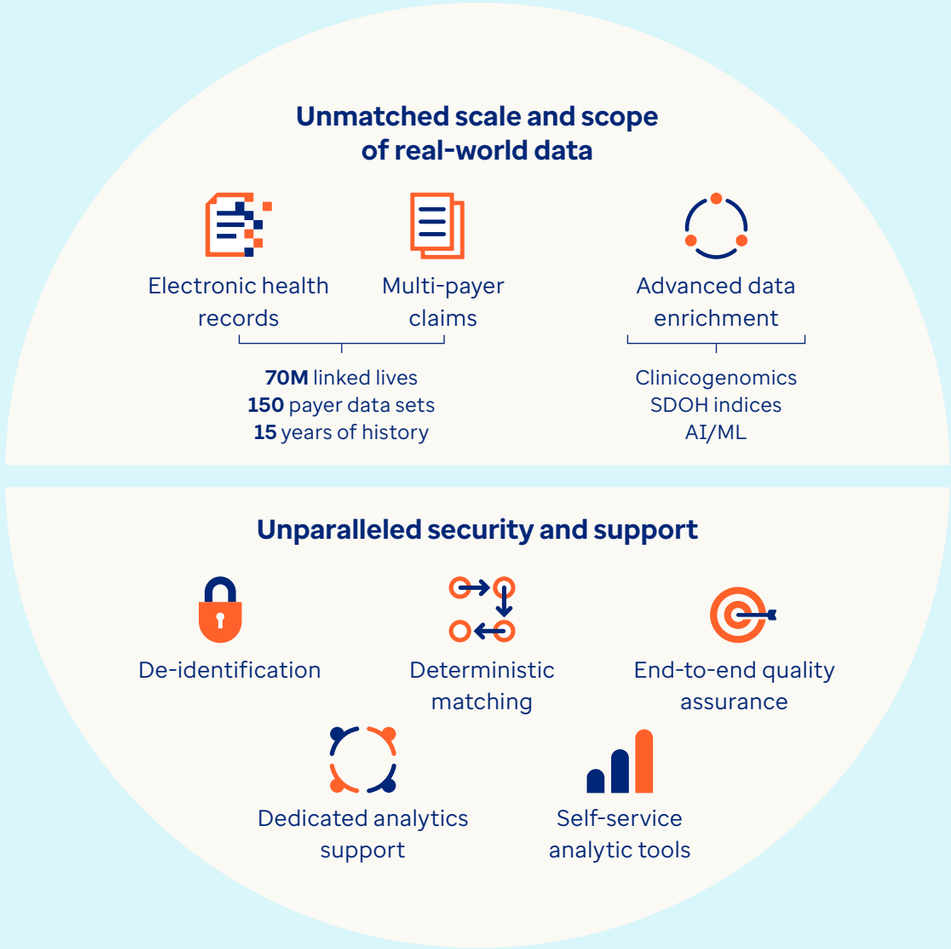
Our position at the center of the health care ecosystem means that we have a deep understanding of the people and institutions who will consume the RWE you generate – payers, pharmacies, providers and patients.

Our researchers can help your teams access the right real-world data to meet organizational business needs, thanks to our unparalleled Optum® Market Clarity Data. This rich data set integrates claims data from all payers across the United States with clinical data representing more than 70 million lives. Paired with cutting-edge analytics, this high-quality, linked, longitudinal data can help your organization:

- **Optimize** trial designs so you are generating the evidence you'll need in the populations you want to serve
- **Articulate** the value of your therapies in ways that are meaningful to payers, pharmacies, providers and patients
- **Track** crucial trends relating to patient outcomes, adherence rates and patient journeys once your drugs are out in the market

Your next scientific achievements may very well hold the keys to a better quality of life for patients and a more efficient, cost-effective health care system for all. We're here to help enable the data and organizational connections that can bring this vision to life.

Optum® Market Clarity Data brings together claims and clinical (EHR) data, advanced analytics and expertise in one place



At Optum® Life Sciences, we connect data. We connect ideas. We connect life sciences firms with the rest of the health care ecosystem to catalyze innovation and impact.

Let us help you connect the dots.

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