



**How real-world evidence
transforms the entire
healthcare ecosystem**

From drug development to value-based care, there is a huge opportunity to tap into real-world data (RWD) to improve patient outcomes. Knowing how a medicinal product is actually used by patients can help stakeholders across the healthcare ecosystem make important and potentially life-saving real-time decisions.

RWD has the potential to break down inefficiencies and fill gaps in information silos among stakeholders throughout the healthcare ecosystem of providers, payers, manufacturers, government entities and patients. This information sharing, in turn, enables all parties to derive new insights, support value-based care and deliver better health outcomes (See Figure 1).

Who is using RWE?

Manufacturers

From identifying unmet needs to clinical trials optimization to market access and pharmacovigilance, the industry actors are high “consumers” of RWE.



Healthcare providers

They gain the ability to “augment” their intelligence on patient profiles, diagnosis, treatment pathway and potential adverse events. They are able to leverage more efficient clinical decisions through evidence-based methodologies and systems.



Regulators

FDA and EMA use the data traditionally for post-market safety and benefit/risk studies. FDA with the 21st Century Act clearly puts RWE as a key enabler for regulatory decisions and market approvals.



Patients

As an integral participant to their own healthcare, patients will benefit from more data openness and availability enabling next-generation healthcare such as “personalized medicine.”



Payers

They can manage cost of care and good usage. RWE also enables insights and decisions for personalized reimbursement models based on usage, value and outcome.



Figure 1. Who is using RWE?

Real-world evidence (RWE) — evidence acquired from real-world data — is used by different stakeholders in many different ways.

- It gives life sciences companies insight into how their drugs are being used.
- It helps providers improve the delivery of care.
- It enables regulatory authorities to monitor post-market safety and adverse events.
- It helps payers assess outcomes from treatments.

RWD, in combination with artificial intelligence (AI), can also be used to optimize clinical trial design and improve patient recruitment. AI turns this RWD into actionable information, which can drive precision medicine.

Understanding real-world data

RWD is observational data typically gathered when an approved medical product is on the market and used by “real” patients in real life, as opposed to clinical trials. The U.S. Food and Drug Administration (FDA) cites several potential sources of RWD, including electronic health records (EHRs), claims, disease and product registries, patient-generated data, and data gathered from additional sources that can shed light on a patient’s health status. These additional sources include the internet of things (IoT), social media forums and blogs.

Real-world evidence (RWE) refers to evidence about the risks and benefits of a product derived from analysis of the RWD. For example, the FDA has used RWD and RWE, derived from its Sentinel system for monitoring the safety of regulated products, in place of post-marketing studies. It has carried this out for nine potential safety issues involving five products.

The U.S. Congress has defined RWE as data that supports the use and potential benefits or risks of a drug whose efficacy and safety data were derived from sources beyond traditional clinical trials.

According to the FDA, there are three main uses for RWE. The first is from a regulatory authority standpoint, particularly with regard to monitoring post-market safety and adverse events and to make regulatory decisions. Second, providers use RWE to support care decisions and to develop guidelines and tools that can aid clinical practice. And third, life sciences companies use the data to support clinical trial designs and observational studies to advance treatment approaches.



RWE in life sciences

As more countries battle to contain healthcare costs, and as the population ages and the number of patients with chronic diseases increases, the need to remove inefficiencies and upgrade the delivery of coordinated care that improves outcomes is more pressing. At the same time, life sciences companies are facing tumultuous times. Industry globalization, the end of the blockbuster era, and an increasingly complex regulatory environment all add to the difficulty of bringing products to market. And across the board, companies are moving toward a patient-centric and outcome-focused model.

In this environment, RWE can be transformative for the industry when RWD is combined with the right technology framework and the regulatory intelligence to make sense of it. As data is consumed across life sciences in different ways and by different stakeholders, it can provide valuable insights and “evidence” across the product life cycle (See Figure 2).

From RWD to RWE

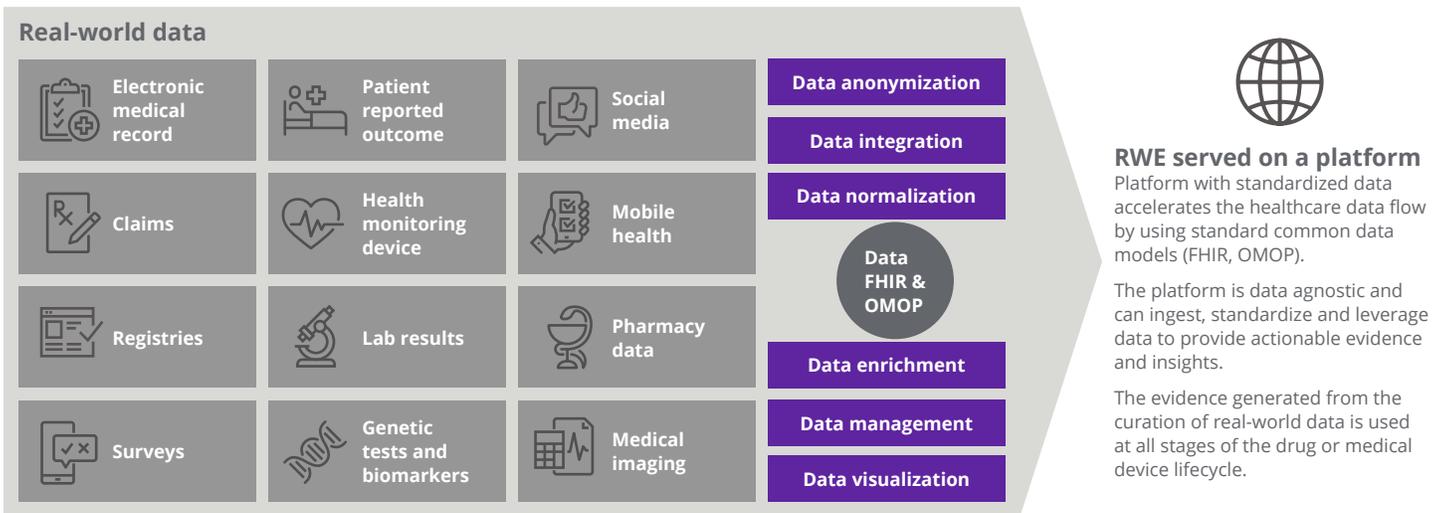


Figure 2. From RWD to RWE

Use cases along the drug life cycle

RWE can be used to make clinical trials more effective and efficient, for example in patient recruitment or label extension. During clinical trials, RWE gathered from other studies or from currently marketed products in a similar category, for example, can have a positive effect on the product portfolio by exposing positive side effects as new potential indications. The most famous example is Viagra, which was initially studied as a drug to lower blood pressure, but an unexpected side effect led to the drug ultimately being approved for erectile dysfunction (See Figure 3).

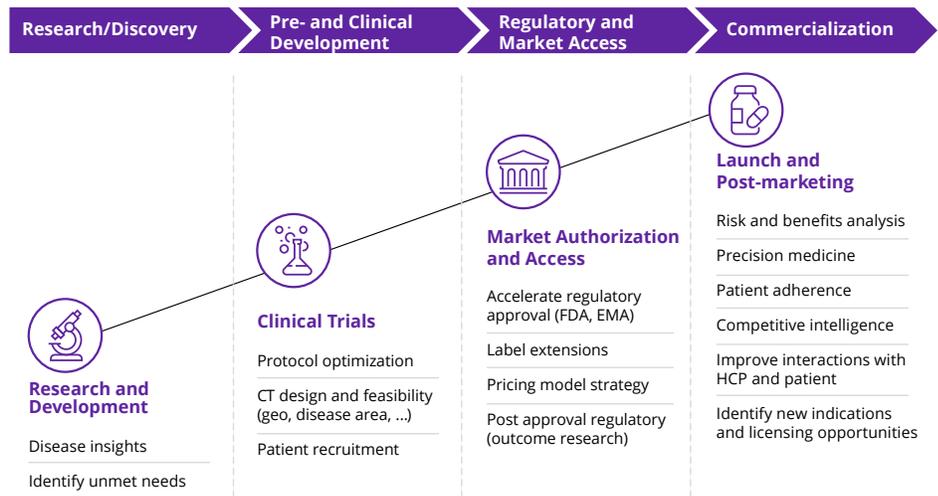


Figure 3. Examples of “RWE use cases” along the drug life cycle

Life sciences companies can also use this type of data for real-time decision making to protect public safety, such as taking swift action if RWD — that is, the data used to derive RWE — shows adverse events that weren’t detected in clinical trials. The course of action will be dictated by what RWE is gathered and by what regulatory authorities require.

RWE can also be leveraged for real-time strategic decision making to support a brand. For example, IoT data or data held by regulatory authorities might show a weakness in a competitor’s product in the market — perhaps a gap in a region the company has begun targeting. Using this “real-time” intelligence, companies can quickly act and, for example, identify their medical product as a better alternative to a competitor’s or adjust recently launched product strategy to reflect the RWE gathered in real life.

RWE — a regulatory imperative

The benefits of RWE derived from RWD are increasingly being recognized by regulatory authorities. The U.S. Food and Drug Administration (FDA) released a framework for using RWE to support the process of drug regulation and submission. This is a major step toward recognizing that clinical trials, while still relevant, are not the only way to assess the efficacy and safety of a product. Indeed, the FDA is soon expected to conduct its first full post-market safety approval using only RWE.

RWE is now accepted as a reliable source of information for regulatory decision making in certain circumstances. A primary rationale for the FDA to use RWE is to help support the approval of a new or extended use for a drug approved under the Federal Food, Drug, and Cosmetic Act (FD&C) and to help support or satisfy post-approval study requirements — always with the proviso that the data quality is up to the standard required. In a recent statement, the FDA even notes: “Recently, new tools for capturing data in the post-market period, including more sophisticated use of real world data and real-world evidence (RWE), are providing new approaches to address important questions about the safety and benefits of new drugs in real

world settings. These approaches have the potential to do so more rapidly and with greater efficiency than traditional methods (See Figure 4)."

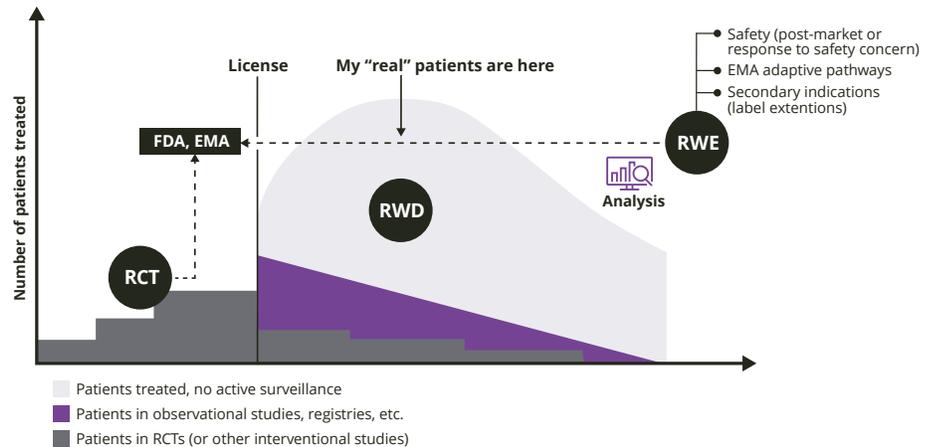


Figure 4. The contrast between randomized clinical trial (RCT), observational studies and RWD

The use of RWE and RWD is also an increasing priority for other regulatory authorities other than the FDA.

A 2018 paper by Dr. Hans-Georg Eichler, the chief medical officer of the European Medicines Agency (EMA), discussed the importance of a learning healthcare system to “harness the full potential of RWD.” The authors argue that the shortcomings of randomized controlled trials — the limited number of trials carried out due to cost, complexity and time, as well as the inability to detect rare serious adverse events — make RWD an important complementary source of data.

The EMA has also stated in its Regulatory Science to 2025 document that one of its objectives is to promote the use of RWD in decision making. For example, to improve the scientific quality of evaluations the agency notes that “data could be more widely and efficiently collected throughout the lifecycle of a medicine, from preclinical development, through the clinical trial process, and into real-world use,” adding that improved evidence generation would also make the clinical development and regulation process more cost-effective, which in turn would reduce the burden on healthcare systems.

Changing the treatment protocol

Beyond the potential regulatory benefits, RWE can be used today to enhance decisions about what to prescribe for particular patient cohorts. Various companies are already providing clinical decision support that gathers RWE on treatment outcomes along with genomics data to allow clinicians to assess outcomes by patient cluster. Networks of clinicians also report the outcomes of treatments they have prescribed, ensuring that the data is constantly updated.

RWE is also of relevance to the payers, who by definition have this data through the claims they receive. But there is growing pressure from payers to gather more outcomes-based RWE to help them determine what they should continue to pay for.

Within the broader healthcare ecosystem, the emphasis is increasingly on breaking down the inefficiencies and information silos between the different players. The goal is to streamline processes in order to support value-based care and develop new pharmaceutical and medical devices to improve outcomes and reduce costs. But for this to happen, healthcare organizations must achieve more efficient data integration to realize a true and complete view of patients and their data.

The future of RWE across the value chain

When analysis is performed using RWD, it's possible for life sciences companies to have a higher success rate with better outcomes in practically all of the critical stages of product development. This, however, will require high quality data, as well as overcoming challenges related to access and interoperability.

The same is true from the provider perspective, where health records provide a data mine that can be used to better understand how medicine works in the real world and measure the impact biopharma products and devices have on patients. Because of their high level of accuracy, claims data has become a commodity, but the real focus lies in being able to leverage EHR data as well.

Efforts are underway across healthcare to make it easier to leverage health records, but doing so in a compliant way that respects patient privacy. Companies such as Flatiron Health have paved the way by their collaboration with the FDA to support regulatory decision making using unidentified EHRs.

Global health research networks are optimizing clinical research and discoveries by providing a platform to exchange RWD combined with AI and analytics to health research and medical centers. And there is a move by integrated delivery networks to set up their own data analytics platforms in order to offer RWD access to relevant stakeholders, including the processes and tools needed to manage patient privacy and consent.

Overcoming RWE challenges

Achieving actionable RWE is not without its challenges. These include the quality of the data, which can be affected by how busy clinicians are capturing information, availability (the right data is often hard to source) and ownership of patient data, combined with privacy requirements (HIPAA, GDPR, and so on). At a regulatory level, the FDA is well aware of these weaknesses and casts a critical eye over the data submitted.

New user interfaces will also have to be developed to enable clinicians to capture data in a more efficient way, removing the cumbersome pull-down lists that reduce the quality of RWE. AI and other capabilities can be leveraged to enhance data quality.

Another barrier to deriving value from RWE lies in problems around interoperability. Here the answer lies in leveraging common data models, which are at the forefront of many initiatives by providers and life sciences companies. Increasingly, integrated delivery networks are looking at how they might adopt the research-centric Observational Medical Outcomes Partnership (OMOP) common data model, as well as the Clinical Data Interchange Standards Consortium's (CDISC) Study Data Tabulation Model (SDTM) standard for regulatory submission. And across all of healthcare, the Fast Healthcare Interoperability Resources (FHIR) specification is gaining greater traction to enable the exchange of EHRs. Linking these standards efficiently to enable better data access, improved data quality and greater insights at speed will be a game changer in the RWE world.

The objective of all stakeholders is to gain actionable insights that advance health outcomes. By bringing together the RWD from the life sciences value chain with the healthcare ecosystem, it will become increasingly possible to deliver multichannel value in innovative and unforeseen new ways.

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