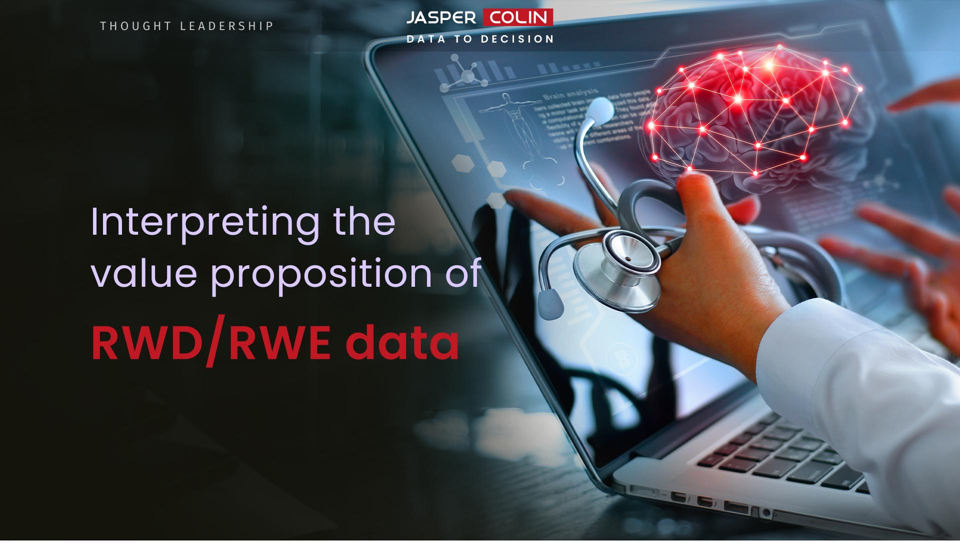
THOUGHT LEADERSHIP

JASPER COLIN
DATA TO DECISION



Interpreting the value proposition of RWD/RWE data

The pharmaceutical, healthcare, and insurance industries have undergone a significant change in how they gather, analyze, and publish data over the past 25 years.

The **fast acceptance and development** of technology has led to an explosion of data that can be carefully selected, aggregated, and analyzed to produce very helpful and timely information, not just in the health sciences but in all facets of our life.

Real-world data (RWD) and real-world evidence (RWE) are becoming more and more popular as **useful sources of information;** thus, it is important to talk about the **quality of data and its analysis, research design, and transparency of reporting** to gain the **confidence and acceptance of decision-makers.**

Real-World Data (RWD)

RWD is the data relating to patient health status and/ or the delivery of health care routinely collected from a variety of sources such as Electronic Health Records (EHRs), wearables, medical claims data, patient, and disease registries.

Real-World Evidence (RWE)

RWE is the clinical evidence about the usage and potential benefits, or risks of a medical product derived from analysis of RWD. It can be used to support Randomized Clinical Trials (RCTs)

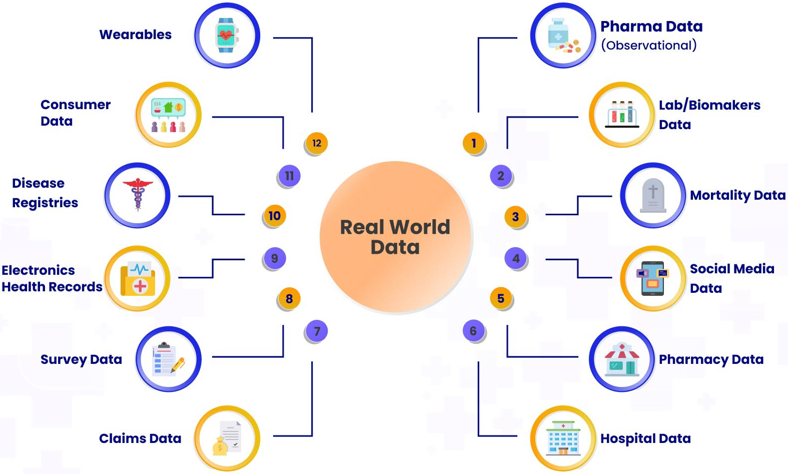
This paper educates stakeholders, including healthcare professionals, policymakers, and patients,

about the benefits of using RWD/RWE in healthcare decision-making. This information can be crucial for pharmaceutical companies to deep-dive this space and help them innovate better for the future.

Applications of RWD and RWE

RWD and RWE have diverse applications across healthcare research and decision-making.

- Safety and effectiveness of interventions
- Monitor real-world utilization patterns
- Comparing treatment outcomes
- Improved understanding of patient sub-populations
- Evaluate adherence and persistence to treatments



Real World Data

1. **Pharma Data** (Observational)
2. **Lab/Biomakers Data**
3. **Mortality Data**
4. **Social Media Data**
5. **Pharmacy Data**
6. **Hospital Data**
7. **Claims Data**
8. **Survey Data**
9. **Electronics Health Records**
10. **Disease Registries**
11. **Consumer Data**
12. **Wearables**

Strengths of RWD and RWE

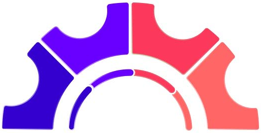
RWD and RWE offer several strengths that can be valuable inputs to support in healthcare research and decision-making.

- RWD/RWE provides a larger and more diverse patient population, reflecting real-world clinical practice, which enhances external validity and generalizability of findings.
- It can help capture long-term outcomes, real-world safety data and real-world treatment patterns which are often challenging to obtain in RCTs.

It can also generate evidence in a timely and cost-effective manner, as it utilizes existing data sources, reduces the need for resource-intensive prospective data collection.

Key considerations for using RWD & RWE

While utilizing RWD and RWE in healthcare research and decision-making, several key aspects should be considered

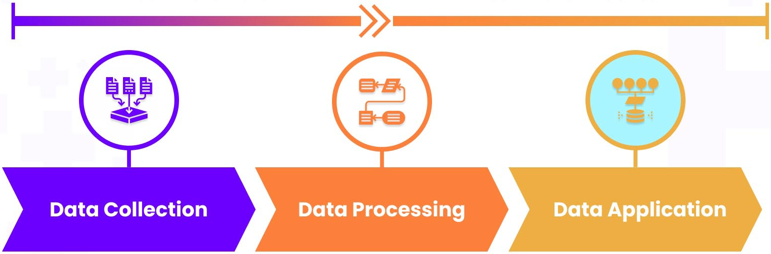


Data privacy and security
To be followed in accordance with relevant regulations and guidelines.

Study designs, statistical methods, and sensitivity analyze
To address potential biases and confounding.

Quality and completeness of the data
Data source should be evaluated, to ensure it is fit-for-purpose containing complete and accurate information.

Collaboration among stakeholders
To ensure the appropriate use and interpretation of RWD and RWE findings.



Real-World Data » **Real-World Evidence**

Data Collection

- Public Records
- Private Records

Data Processing

- Sharing Platforms
- Analytics Tools
- Data Standardisation
- Anonymization

Data Application

- Trial Optimization
- Evidence Based Medicine
- Secondary Indication
- Efficacy vs. Effectiveness

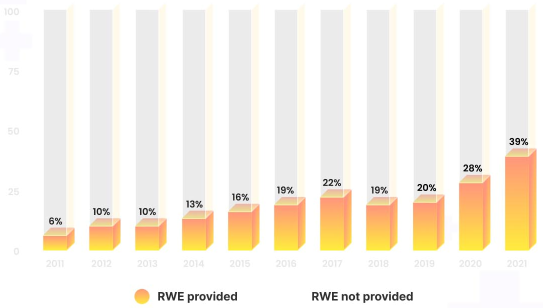
Process timeline of RWD and RWE in the pharmaceutical industry

The pharmaceutical industry is heading towards increased utilization of RWD and RWE due to several factors:

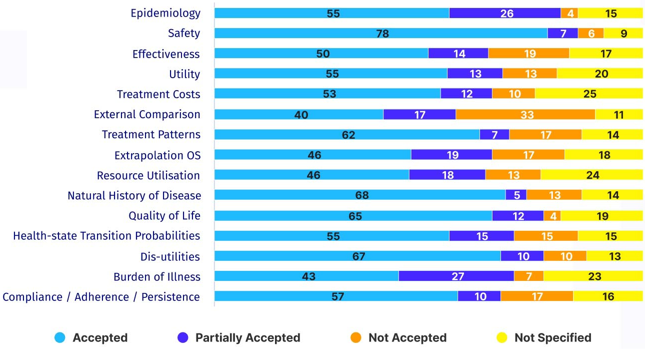
Expanded regulatory acceptance

Regulatory agencies, such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), have recognized the value of RWE in complementing traditional clinical trial data and have provided guidance on the use of RWE in drug development and regulatory decision-making. For instance;

Amgen Science got regulatory approval for a cancer drug based on single-armed Phase 2 study supported by RWE.



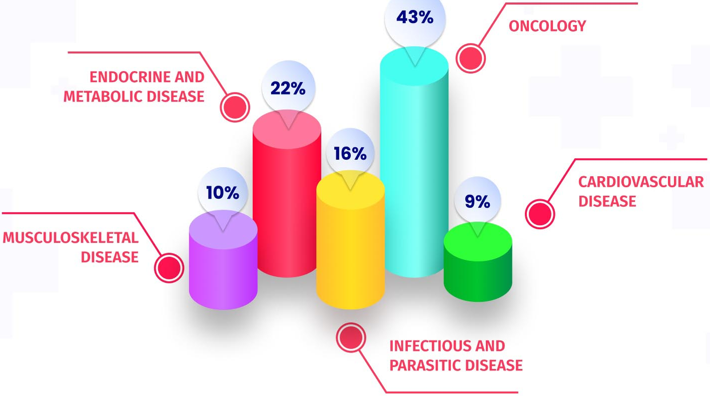
Evolution in the number of Health Technology Assessment (HTA) submissions leveraging RWE from 2011 to 2021



HTA ACCEPTANCE OF RWE (2011-2021)

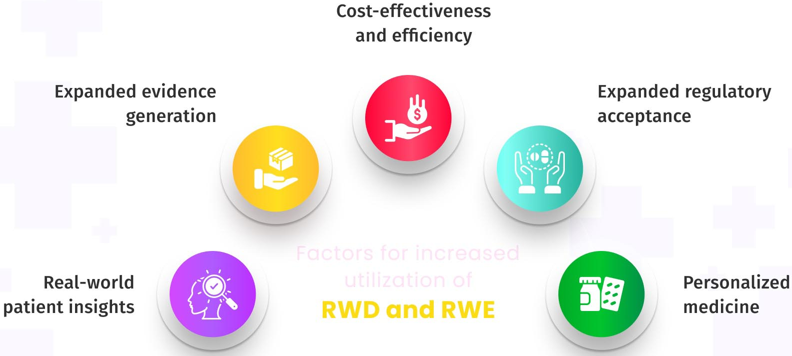
Since 2011, RWE has been commonly included in various HTA submissions. The highest number of submissions were

Oncology (942), followed by endocrine and metabolic diseases (480), infectious and parasitic diseases (342), musculoskeletal diseases (214), and cardiovascular diseases (200).



Real-world patient insight

RWD provides a rich source of data that reflects real-world patient experiences, diverse patient populations, comorbidities, and treatment patterns. This allows pharmaceutical companies to gain insights into real-world treatment outcomes, patient preferences, and unmet needs, and helping them in drug development strategies, patient access programs, and post-marketing activities


Cost-effectiveness and efficiency
Expanded evidence generation
Expanded regulatory acceptance
Real-world patient insights
Factors for increased utilization of
RWD and RWE
Personalized medicine

Cost-effectiveness and efficiency

Conducting randomized clinical trials (RCTs) can be time-consuming, resource-intensive, and costly. RWD, on the other hand, can be more cost-effective and efficient in generating evidence, as **it utilizes data collected during routine clinical practice by reducing the time and cost associated with traditional clinical trials.**

Expanded evidence generation

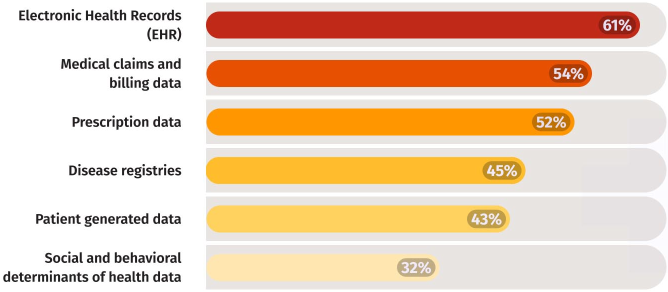
RWD allows for the generation of evidence beyond the controlled environment of clinical trials, capturing real-world effectiveness, and safety of drugs in routine clinical practice. This will help pharmaceutical companies to understand the value of their products in real-world settings, including sub-populations that may be under-represented in clinical trials.

Bristol-Myers Squibb and Pfizer alliance conducted real-world observational analysis of the effectiveness and safety of direct oral anticoagulants compared to warfarin in elderly patients with non-valvular atrial fibrillation.

Personalized medicine

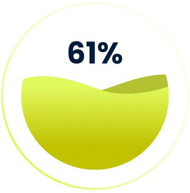
RWD can support the development of personalized medicine approaches by providing insights into patient characteristics, treatment patterns, and outcomes in real-world settings.

Demonstrating value to payers and providers

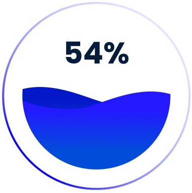


ACCORDING TO MEDI-INSIGHTS STUDY BY JASPER COLIN -

What types of real-world data are most important to demonstrate ***value to payers and providers*** *in addition to clinical trial data?*



Electronic Health Records



Medical Claims & Billing Data

Limitations of RWD and RWE

Despite their advantages, RWE and RWD have limitations that need to be carefully considered. The quality of RWD and RWE depends on the quality and completeness of the underlying data, which may vary across different sources and settings.

Bias and confounding

The biggest challenge of real-world studies is their potential for biases. These are broadly classified as confounding (lack of randomization), selection bias (process used to select study population) and information bias (measurement error).

Data Privacy and Security

Is an important consideration, as RWD and RWE often involve the use of personal health information. It is a special category of personal information and is subjected to use under strict guidelines of General Data Protection Regulation (GDPR).

Not suitable to study rare diseases

RWD and RWE may not be suitable for studying rare diseases or rare outcomes, as the sample sizes may be small.

RWE Market Dynamics

According to a recent report by Jasper Colin, the global RWE market is expected to reach

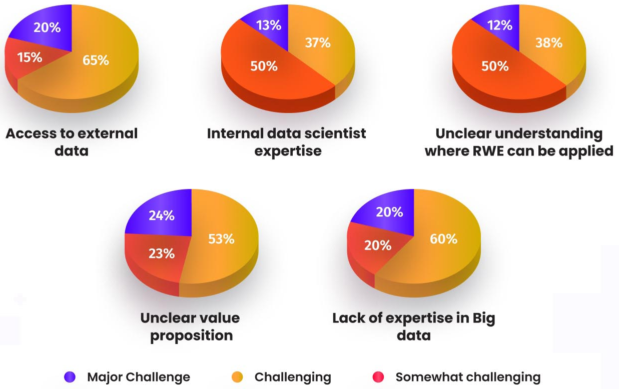
$5.2 billion

by 2030, with a compound annual growth rate (CAGR) of 13.9% from 2023 to 2026.

The growth is driven by the increasing adoption of RWE by pharmaceutical companies and healthcare providers, as well as the growing availability of RWD.

According to Medi-Insights study by Jasper Colin on identifying challenges to implement RWE programs. **Access to external data**, **unclear value proposition,** and **lack of expertise in big data** were the major challenges faced by the clients.

Challenges to implement RWE programs



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