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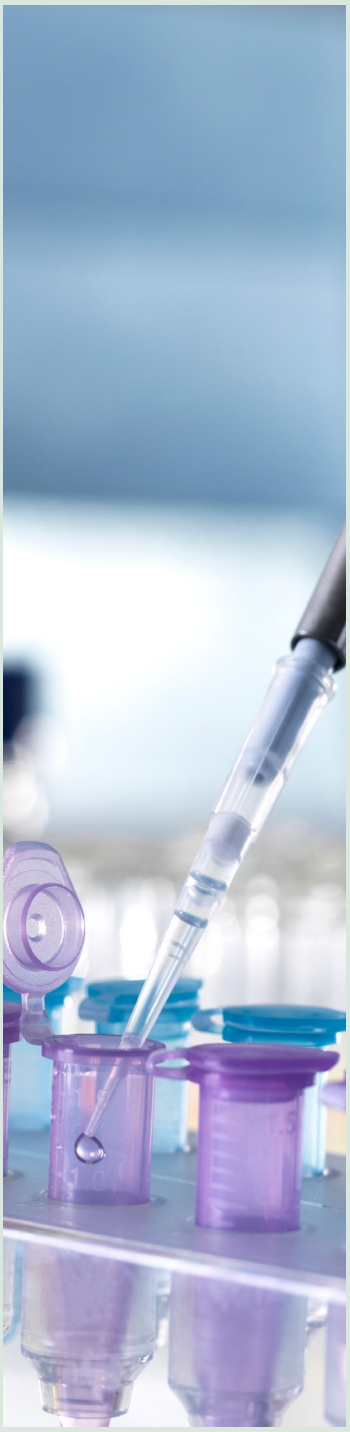

# REAL WORLD EVIDENCE: ANALYTICAL OPPORTUNITIES AND FUTURE SCOPE

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# Real World Evidence (RWE)

Real-world evidence is derived from real-world data, which is analyzed to ascertain the usage, current and expected pros and cons of a medical product. RWE combined with clinical trial data provides a 360-degree view of the product performance, both pre- and post-launch helping in making an informed decision. This brings us to an understanding of what Real-world data (RWD) is and how it gets generated.

## Real World Data

Real world data refers to the data pertaining to patient's health status which gets generated during routine healthcare delivery.

## Sources of Real-World Data

- **Clinical data:** Data present in the **electronic health records** and **case report forms.** This provides data regarding patient demographics, family history, treatment history, outcomes, prognosis, and comorbidities
- **Cost & Utilization data:** Data generated during claim adjudication process and billing activities e.g., claim data sets and public data sets from **Centers for Medicare and Medicaid Services (CMS) and American Healthcare Radiology Administrators (AHRA).** This data provides insights regarding utilization of healthcare services, population coverage and prescribing patterns.
- **Patient-generated data:** This data gets generated via **patient reported outcomes, biometrics data** and **health and treatment history data.** It provides information about what happens in real time scenarios like hospital visits, procedures, home care and hospital stays
- **Public Health data: Disease registries** maintained by various government sources

## Interrelation of real-world data and real-world evidence

The term real world evidence is closely related to real-world data, but they are often replaced. They are related but can be clearly distinguished from each other

| Real-world data | Real-world evidence |
|---|---|
| RWD can be collected from heterogeneous patient population in real-world settings or non-randomized controlled trial settings rather than data collected in randomized controlled trials | RWE is developed from RWD via analysis of accumulated data, and it supplements the data generated during the randomized clinical trials |

## Beneficiary of Real-World Data/Real-World Evidence

### Life Science Research & Biopharma Companies

- Expansion of the existing medication use for patients with different indications and age groups by reducing obligations for costly randomized controlled trials
- Drug development process streamlining by ensuring right patients are targeted for trials
- Reduction in research cost through formation of pre-trial study design by helping in identifying potential patients and creating appropriate inclusion criteria for clinical trials
- Facilitate value-based contracting structures by providing a mutually agreed measurement methodology for biopharmaceutical companies & providers. E.g., Novartis utilized an outcomes-based pricing contract with CMS for their Chimeric antigen receptor (CAR) T-cell therapy (Kymriah)

### Healthcare payers & Providers

- Assures patient safety and affordability via evaluation of medical products efficiency
- Cost reduction by empowering physicians to make more targeted and appropriate treatment plans for their patients
- Improved care outcomes and utilization management by leveraging RWE to further understand which clinical interventions can drive improved outcomes for patients
- Evaluation of value-based care outcomes by pinpointing which patients are experiencing gains

### Policy makers & Regulators

- Treatment guidelines can be refined and optimized by comparing outcomes for different treatment options utilizing RWE
- To make regulatory decisions by monitoring post market safety and adverse events via RWE
- Speedy approval for emergency drugs based on real-world evidence

## Analytical use cases for real-world evidence

| Application | 1. Medication adherence & Disease progression | | |
|---|---|---|---|
| Purpose | Tracking adherence rate of cancer or Psoriasis and Psoriatic Arthritis (PsO/PsA) patients | Evaluation of approaches to identify disease progression in cancer patients using RWE | Journey mapping of stenosis patients after Transcatheter Aortic Valve Implantation (TAVI) procedure |
| BU | Oncology; Dermatology/ Rheumatology | Oncology | Cardiology |
| Drug/Device Name | Lenalidomide & Pomalidomide (Oncology); Apremilast (Dermatology) | NA | Artificial heart valve |
| Type | Intravenous, Oral | NA | Device |
| Dataset | Patient data, Disease progression data | Electronic Health Record (EHR) data for disease progression | Patient data, Disease progression data |
| Analytics KPI | # Adherence rate= (No. of patients undergoing therapy at current cycle/No. of patients who underwent therapy at previous cycle) | # Overall Survival rate= (% of patients with the disease who are still alive/% of people alive in the general population of same sex & age)<br># Progression free survival rate= (% of people who did not have new tumor growth<br># Time to progression= Time from the start of treatment until the disease worsens | # Referral volume= (No. of patients referred to secondary health unit)<br># Follow-up diagnosis= (No. of patients in current stage/ No. of patients in previous stage) |
| Benefits | Detecting patients' tendency to deviate from therapy plan vs drug stage | Clinician-anchored technique along with the radiology data helped in predicting tumor progression matching for 90% of patients | Establishing correlation between follow-up diagnoses and success rate of TAVI procedure |

| Application | 2. Clinical Trial Optimization | | 3. Drug safety & Risk Management | 4. Market Segmentation | 5. Regulatory Approval |
|---|---|---|---|---|---|
| Purpose | Appropriate site selection and patient enrollment for clinical trial | Creation of a framework for inclusion of real-world evidence in clinical development planning | Compare the real-world effectiveness in routine care of an existing therapy for Chronic Obstructive Pulmonary Disease (COPD) and Asthma with a new investigational product | Evaluation of the potential of a pre-launch DM-II drug in a real-life setting | Expedited and streamline regulatory approval process by incorporating RWD to support decision-making |
| BU | Oncology | Immunosuppressant | Respiratory | Endocrinology | Neurology |
| Drug Name | NA | Fingolimod | Vilanterol/fluticasone furoate | NA | Brineura (Cerliponase alfa) |
| Drug Type | Intravenous | Oral | Dry Powder Inhaler (DPI) | Oral | Intraventricular |
| Dataset | Patient data, Historic clinical trial data | Clinical trial data | EHR data | Patient data | Patient data (Untreated) |
| Analytics KPI | # Enrollment rate = (Enrolled patients/ totals patients) | # % sample size reduction= (Estimated Size - Current size/ Estimated size)<br># Average recruitment rate= (Recruited patients/No. of sites)<br># Annualized relapsed rate= [(No. of relapses experienced by patient/ No. of days patient participated in the study)] *365.25 | # Exacerbation rate= (No. of exacerbations/ Time period) | # Prescription Probability in real life scenario= (Projected prescription of target drug/Total prescriptions) | # % decrease in the progression of symptoms of the disease = (Motor ability decline without drug-Motor ability decline with drug-/Motor ability decline without drug) |
| Benefits | Expedited site selection and patient enrollment for clinical trial | 40% sample size reduction across phase III studies, which translates to a time saving of at least 6 months | Reduction in moderate or severe exacerbations from 1.90 per year to 1.74, establishing increased efficacy of targeted drug | Insight generation & decision-making support for successful launch of new product | Annual rate of decline in motor activity deterioration increased to 2.43 score units per year from 1.81, thus was utilized for augmenting marketing authorization |

## Conclusion

Real-world evidence is existing in life sciences and healthcare domain since a long time but leveraging advanced technology it can be employed in several new ways. Food and Drug Administration (FDA) released draft guidance on the use of real-world evidence (RWE) to support regulatory decision-making in September 2021, while the draft guidance may appear unimpressive at first glance, it is an important step toward a larger, statewide plan that would eventually alter life sciences and healthcare. Organizations can accelerate their shift from product to patient-oriented approach by leveraging real-world evidence and advanced analytics. It gives an opportunity to the laggards to become leap froggers and leaders. Few of the existing leaders have already created a blueprint for its execution and now is the optimal time for the rest to capitalize on the horizon of real-world evidence analytics.

## About the Authors


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Sonika has more than 9 years of experience in clinical domain and has knowledge about the rising concept of real-world data and its application in clinical space. She specializes in US Healthcare, revenue cycle management and building analytical logics for Drugs & Biologics to ensure payment accuracy and prevent Fraud, waste and Abuse.

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