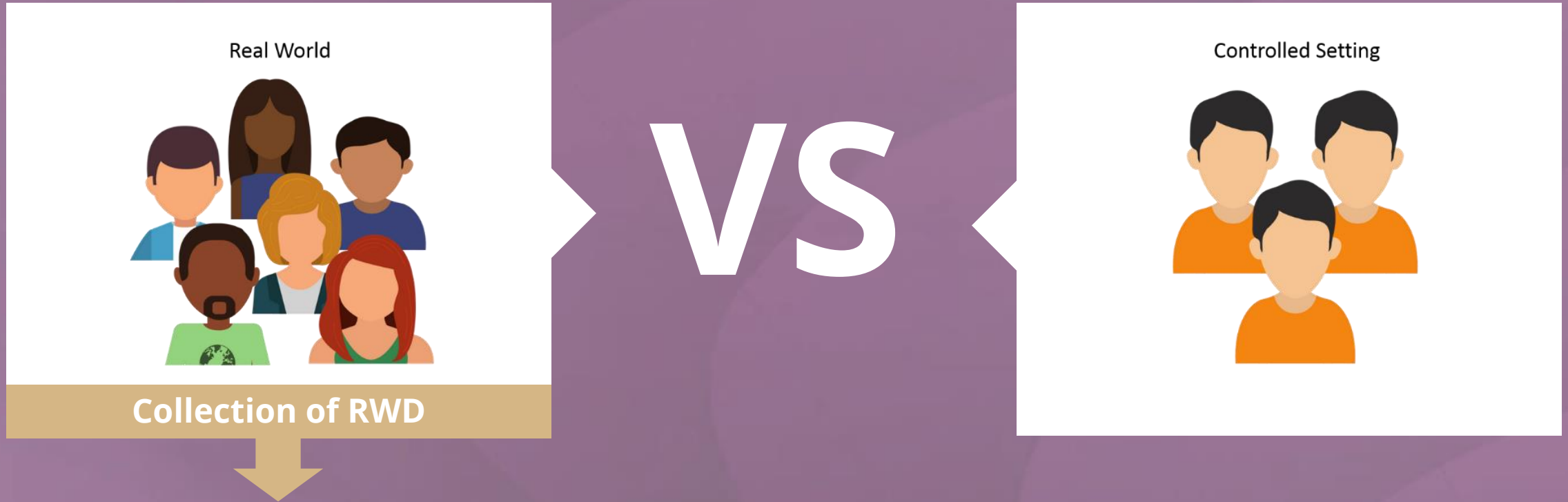


REAL WORLD EVIDENCE FOR REAL WORLD PROVIDERS



Recap: Real World Data and Real World Evidence



Analysis of RWD to generate RWE

RWD: Real World Data; RWE: Real World Evidence

Generation of Real World Evidence

RWE Uses Patient-Level Data

To better assess the clinical value of treatments and services based on actual health outcomes and the total cost of care



It is important to note that RWE does have limitations, including lack of randomization, less control over data collection, and less reliability/accuracy as compared to RCTs

Value of Real World Evidence

Real World Evidence has the potential...



- To break down **inefficiencies** and **fill gaps** in information silos among stakeholders throughout the healthcare ecosystem
- This information sharing enables all parties to derive new **insights**
- There is an opportunity to tap into RWE to better understand patient-level data
- Can help stakeholders across the healthcare ecosystem make important **real-time decisions**



It is important to note that RWE does have limitations, including lack of randomization, less control over data collection, and less reliability/accuracy as compared to RCTs

Stakeholders That Use Real World Evidence

Manufacturers

Provides pharma companies **insights into how their drugs are being utilized** From identifying unmet needs to clinical trials optimization to market access and pharmacovigilance, industry professionals are high “consumers” of RWE.



Healthcare providers

Helps HCPs to improve the standard of care 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

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



Patients

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



Payers

Supports payers in assessing outcomes from treatments They can manage cost of care and goods usage. RWE also enables insights and decisions for personalized reimbursement models based on usage and outcome.



How Stakeholders Use Real World Evidence

RWE can answer the questions of different stakeholders



Industry

- Meet commitments
- Add to the safety profile
- Secure formulary placement
- Enhance understanding of unmet patient needs
- Generate publications



Regulators

- Detect safety signals



Payers

- Determine coverage
- Monitor usage within criteria
- Cost-effectiveness



Providers

- Obtain locally relevant evidence
- Advance science
- Help improve care
- Ensure continued reimbursement
- Generate publications



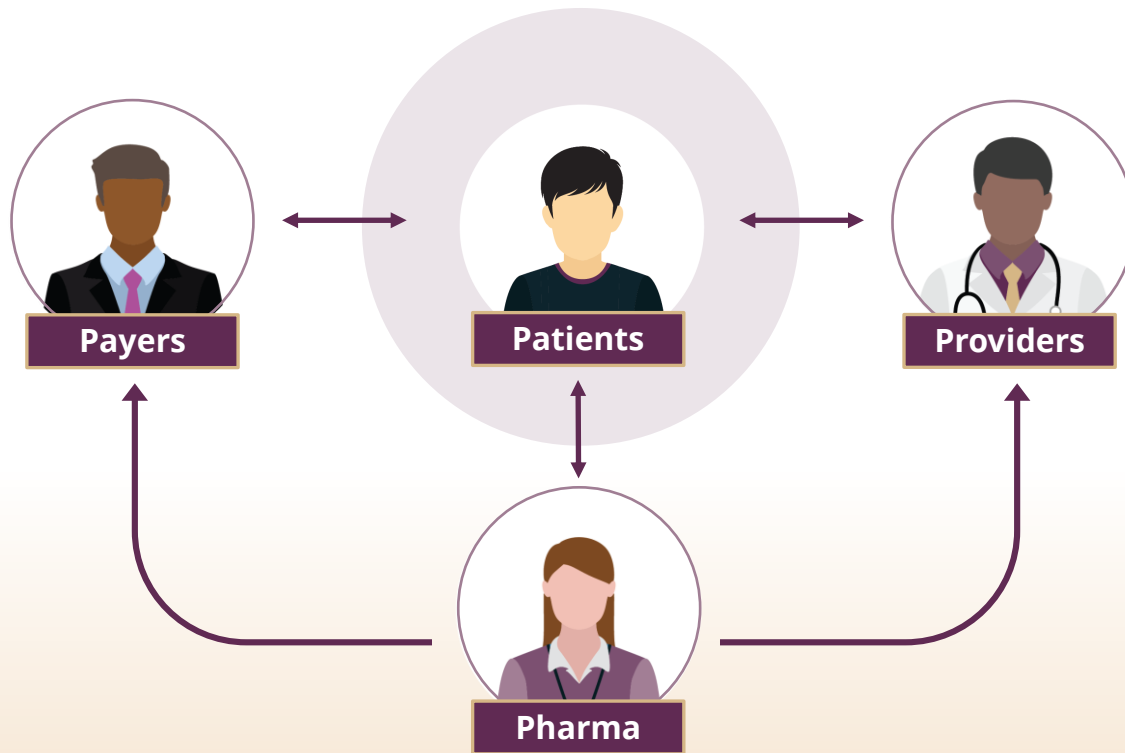
Patients

- My own health- what choices do I have?
- What are the risks/benefits?
- Which treatment is safer, more convenient and affordable?

Providers: Use of Real World Evidence

Patient Centered Evidence-Based Value

RWE can be an asset using objective understanding and robust analyses on health data and costs



For Providers, RWE allows them to:

- ✓ Obtain locally relevant evidence
- ✓ Advance science
- ✓ Improve care
- ✓ Ensure continued reimbursement
- ✓ Generate publications

It is important to note that RWE does have limitations, including lack of randomization, less control over data collection, and less reliability/accuracy as compared to RCTs

Real World Evidence – EXAMPLE 1

Prevalence and cost of HIV-associated weight loss in a managed care population

Javeed Siddiqui, Amy L. Phillips, Eric S. Freedland, Ami R. Sklar, Theodore Darkow and Carolyn R. Harley

EMD SERONO SPONSORED STUDY

OBJECTIVE:

- To estimate the prevalence of HIV-associated weight loss (2005-2007) among HIV patients in a US managed care population
- Compare demographic and clinical characteristics of HIV patients with and without evidence of HIV-associated weight loss

RESEARCH DESIGN AND METHODS:

- Retrospective observational study of health care claims data
- Continuously enrolled US managed care population
 - **Commercial enrollees only (N=22,535)** with HIV/AIDS from 1/1/2005–7/31/2007
- Based on a combination of HIV/AIDS diagnosis codes or antiretroviral treatment
 - HIV-associated weight loss status was defined according to an algorithm

RESULTS:

- HIV-associated Wasting prevalence 8.3%

Real World Evidence – EXAMPLE 2

Prevalence and risk factors of HIV-associated Wasting in patients with HIV: Retrospective US Health Care Claims Analysis*

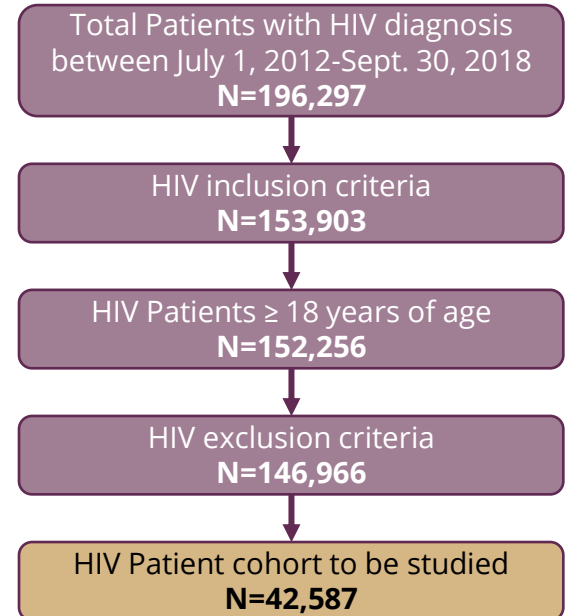
EMD SERONO SPONSORED STUDY

OBJECTIVES**:

- To identify the prevalence of HIV-associated Wasting (2012-2018) and understand the use of different HIV-associated Wasting diagnosis codes
- To compare demographic and clinical characteristics of patients with and without HIV-associated Wasting
- To identify risk factors associated with HIV-associated Wasting
- To compare healthcare resource utilization (HCRU) for patients with and without HIV-associated Wasting

RESEARCH DESIGN AND METHODS:

- Retrospective observational study of health care claims data
- Continuously enrolled US managed care population
 - **Commercial, Medicare, Medicaid**
- Based on a combination of HIV/AIDS diagnosis codes or antiretroviral treatment
 - HIV-associated weight loss status was defined according to an algorithm

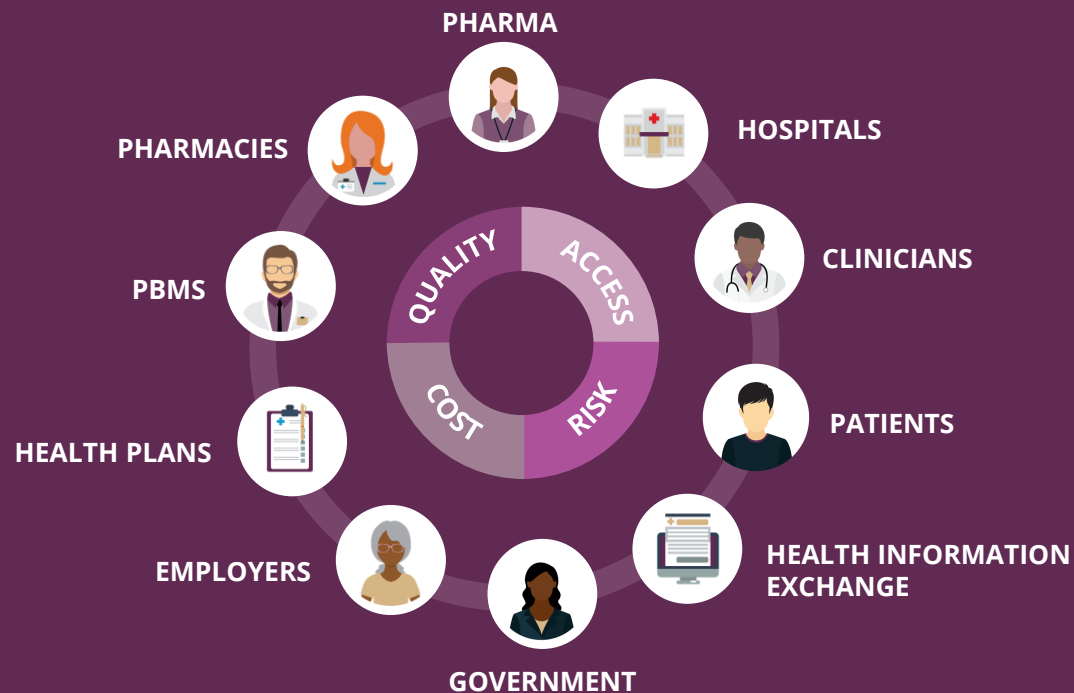


Real World Evidence Summary

RWE is the application of RWD to derive insights that can be generalized to further understand current care options

Seamless Total Healthcare

Many stakeholders asking the same questions



RWE is a valid source of information that represents the current patient treatment landscape by identifying unmet patient needs through:

- Better understanding of disease dynamics
- Drug safety and monitoring
- Meeting payer needs

RWE can be an asset using objective understanding and robust analyses on health data and costs



Q & A