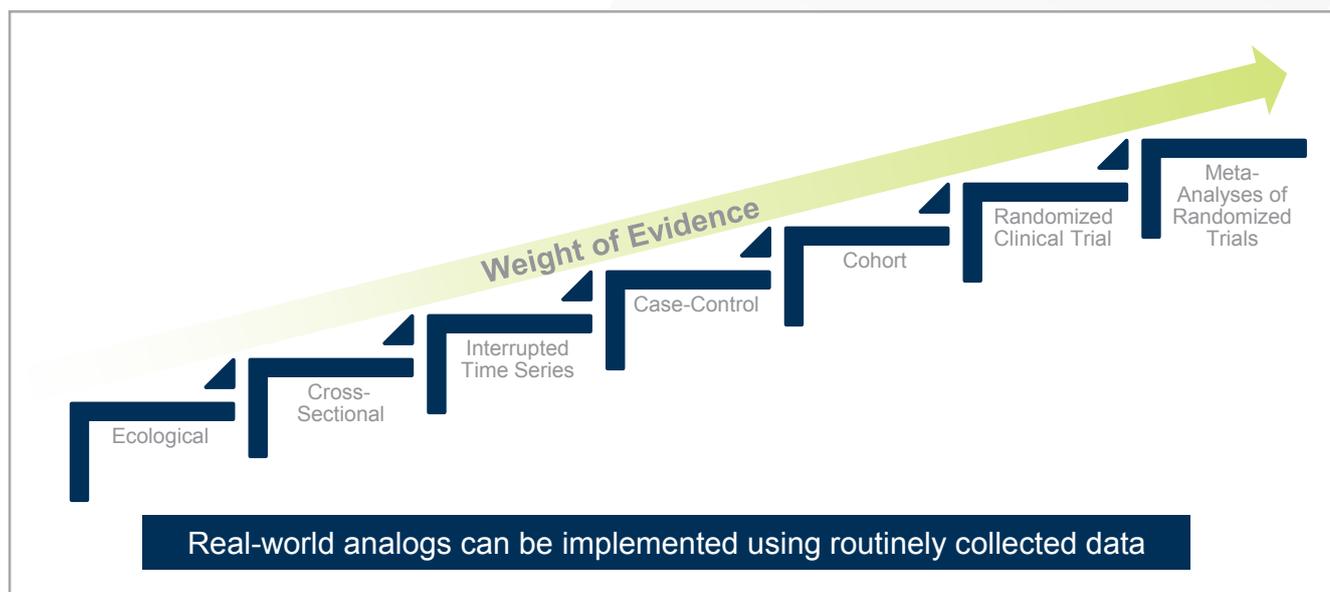


# THE ROLE OF REAL-WORLD EVIDENCE IN SUPPORTING A PRODUCT'S VALUE STORY

Randomized clinical trials (RCTs) are the gold standard for gaining regulatory approval for marketing authorization for medical products. RCTs typically measure short-term efficacy and safety of a product compared to placebo in a fairly homogeneous population and under ideal, controlled conditions. In contrast, the real world consists of a heterogeneous population in which patient care is much less controlled and thus, more complex. Treatment decisions made in this setting are predicated on a wider array of co-morbid conditions, competing medications, physician preference and risk of adverse events than those observed in RCT populations. Evidence generated from real-world settings reflects this complexity, complementing evidence derived from rigorously controlled RCTs.

Where routinely collected data exist, real-world studies can be implemented as analogs to study designs in the traditional evidence hierarchy.<sup>1,2</sup> For example, pragmatic trials can become real-world analogs to RCTs after patients are randomized and follow-up is conducted under routine care.

Figure 1. A Hierarchy of Research Designs



1. Concato J, Shah N, Horwitz RI. Randomized, controlled trials, observational studies, and the hierarchy of research designs. *N Engl J Med* 2000;342(25):1887-92.

2. Evans D, Hierarchy of evidence: a framework for ranking evidence evaluating healthcare interventions. *J Clin Nursing* 2003;12:77-84.

# Real-World Data Drives Real-World Evidence

Real-world evidence is dependent on data that are recorded by practitioners and administrators in the routine course of care. In the United States, these so-called “real-world data” come from a variety of sources. Each source features its own nuances that are critical for researchers to understand and consider when choosing data to support the development of real-world evidence.

Table 1. Common Real-World Data Sources in the United States

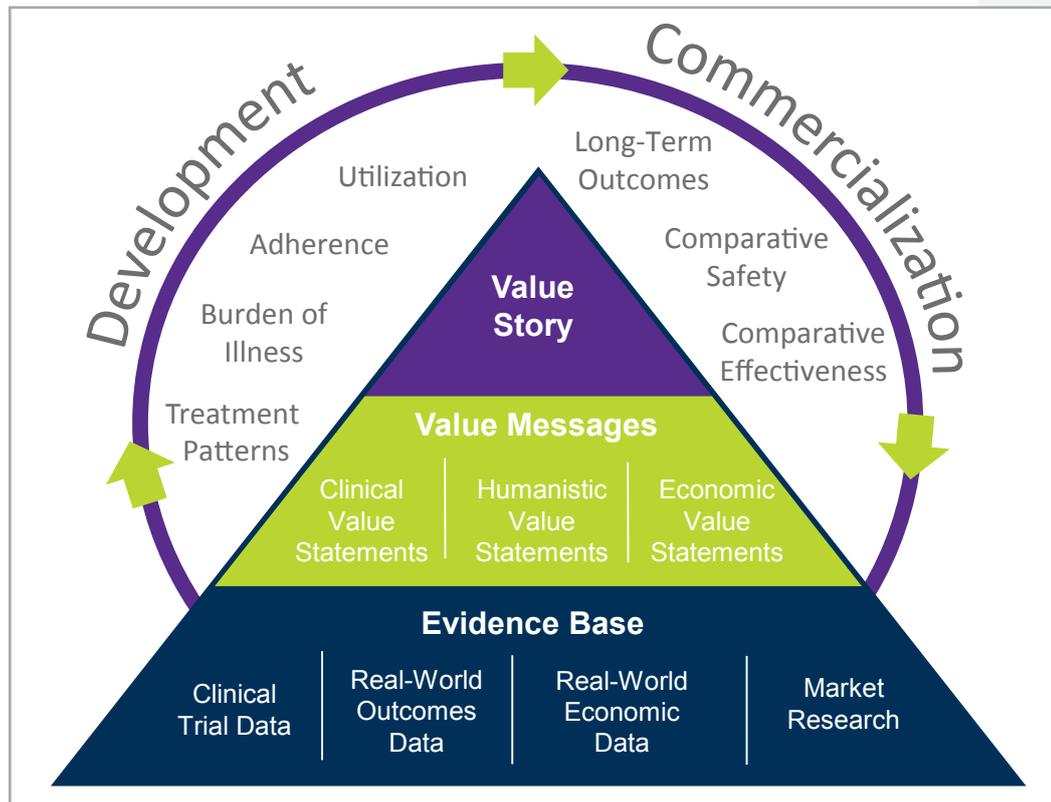
Real-World Data	Key Characteristics
<b>Hospital Administrative</b>	<ul style="list-style-type: none"><li>• Typically nationally representative</li><li>• Capture inpatient and outpatient hospital visits</li><li>• Often identify a brand of a device or novel procedure</li><li>• Do not capture inpatient labs or co-morbid conditions and events occurring outside of the facility</li></ul>
<b>Administrative Claims</b>	<ul style="list-style-type: none"><li>• Represent a general population</li><li>• Medicare claims are readily available</li><li>• Typically captures all settings of care</li><li>• Six to 12-month lag time</li><li>• Do not capture information on inpatient labs or medications</li></ul>
<b>Medical Records</b>	<ul style="list-style-type: none"><li>• Electronic medical records or paper-based charts</li><li>• Rich and efficient source of clinical information</li><li>• Current information</li><li>• Not comprehensive of a patient’s full continuum of care</li><li>• Lacks cost information</li></ul>
<b>Laboratory Tests</b>	<ul style="list-style-type: none"><li>• Contain diagnostic test results</li><li>• Provides clinical outcomes that can only be measured by lab tests</li><li>• Excellent source for near-real-time public health and safety monitoring data</li><li>• Can be linked to other data sources to obtain a more holistic view on patient exposures and outcomes</li></ul>

When developing real-world evidence, it is important to maximize its utility and meaning for stakeholders. Success requires a critical assessment of the optimal real-world data source as well as a thoughtful consideration of how stakeholders will receive and act on the evidence. If prospective data collection is impractical due to time and/or cost constraints and the patient population can be identified in a real-world data source, the decision framework outlined below can assist in selecting the best data source to support the desired evidence.

# Real-World Evidence Needs to Occur Throughout the Product Life Cycle

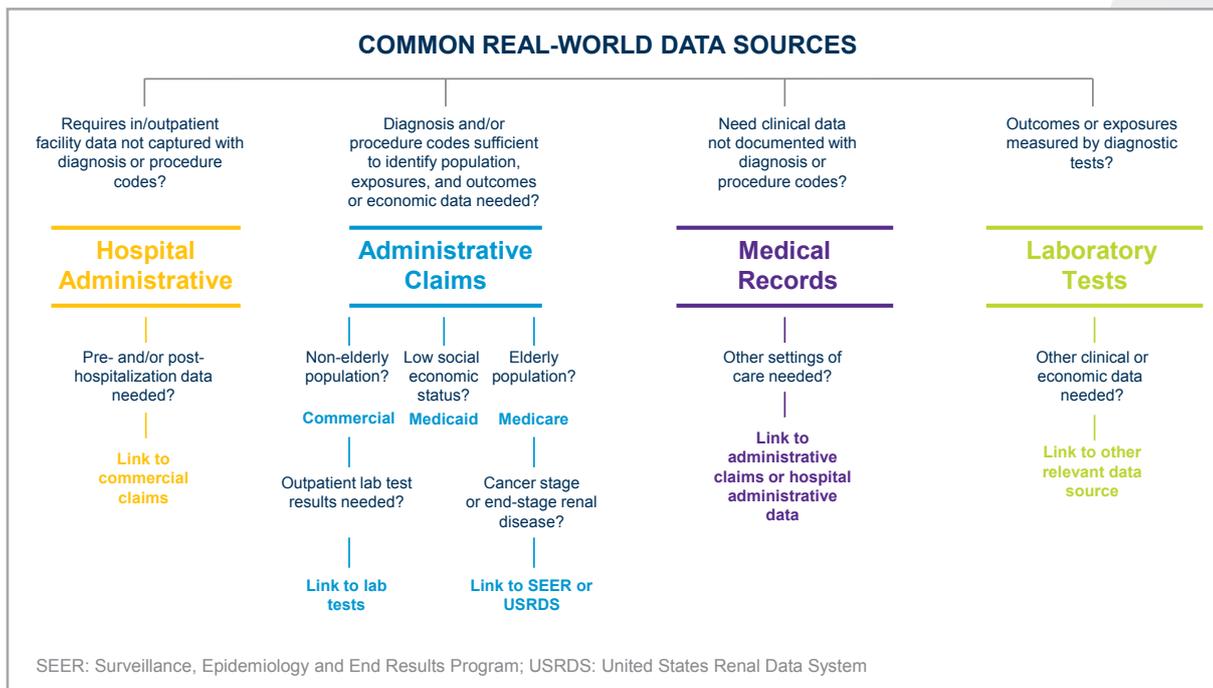
Real-world evidence should be incorporated into a product's value story throughout its life cycle to ensure successful product launch and commercialization. Real-world evidence needs vary throughout the life cycle and may include multiple components, such as an evaluation of unmet need during product development, as well as a comparative effectiveness study following launch.

Figure 2. Product Life Cycle Real-World Evidence Needs



Evidence generation does not end after product approval. Healthcare providers consider comparative effectiveness and safety information, particularly from real-world use, to assist in making treatment decisions at the point of care. Payers need real-world evidence to inform formulary and reimbursement decisions. These needs are illustrated by a recent survey published in the *Journal of Oncology Practice*, which found that payers valued retrospective analyses more highly than RCTs for comparisons of real-world costs and medication adherence. Real-world evidence thus plays a critical role in bridging gaps in information that are of interest to various stakeholders to support decision-making.

Figure 3. Decision Framework for Selecting Real-World Data



## Developing a Real-World Evidence Strategy

Identifying the required real-world evidence will help to formulate an effective strategy. Some key questions to consider include:

- ▶ Who are the stakeholders?
- ▶ What evidence is required at the different stages of product development and post launch?
- ▶ What events may cause a re-evaluation of the strategy (e.g., entry of competitor)?
- ▶ Is there support for developing real-world evidence throughout the organization?
- ▶ What is the best source of real-world data?
- ▶ Is the target evidence informative for stakeholder decision-making?
- ▶ Can the limitations of real-world data be addressed through epidemiologic study design or statistical methods?
- ▶ Are the correct experts and resources available to develop the evidence?

Maximized product success during commercialization is often dependent upon a thoughtful real-world evidence strategy, implementation and ongoing re-evaluation as events in the market unfold. Planning carefully throughout the product's life cycle is key to generating effective evidence that supports a product's value story.

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