RTI (h)(s)
Health Solutions

Real World Evidence (RWE) for Hypothesis Testing

Review examples of our expertise in utilization and safety studies from our searchable publications database.

An Example

A drug manufacturer discovers that one of their medications is being prescribed in clinical practice for a treatment that is not included on the label. They are interested in learning more and—based on their findings—may want to try to get approval for this additional indication. To do this, we perform formal comparative effectiveness and safety testing of this alternative use and provide them with evidence they can submit for regulatory consideration.

Before we begin an analysis for this type of hypothesis testing we recommend submitting the protocol for review by regulators, and posting it publicly (e.g., in clinicaltrials.gov). If there are multiple data sources available, when feasible we use a separate data source for the hypothesis testing study versus the characterization study. However, in many cases use of multiple data sources is required to address the study hypothesis.

To address any methods concerns up front, we include stakeholders who are experts in clinical practice and in the data source as part of the protocol development team. It may be difficult to pre-specify variable definitions and study design choices, so we complete validation of important variables as an early phase of the study.

By the time the protocol is finalized, we have study milestones and a preliminary publication plan in place. When the results **are** published, they include clarification on any deviations from the protocol and provide sufficient detail for other researchers to replicate the analysis.

It is our practice to publish **all** hypothesis testing studies, including those with a null result. If unexpected utilization patterns or safety signals arise, we can help assess and deal with them accordingly.

What is the difference between Real World Data (RWD) and Real World Evidence (RWE)?

RWD is all data collected **outside traditional clinical trial settings**

RWE is derived from RWD and allows for insight in the **actual setting of use**

Let's Talk

Let's talk about how the breadth and depth of our integrated teams can help you efficiently maneuver through gathering RWE during the entire lifecycle of your pharmaceutical. We'll show you the path to potential time and financial savings and help you relieve the strain of having to manage multiple vendors and timelines.

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