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How New Therapies Reach Patients Faster

A New Beginning: RWD and Non–Small-Cell Lung Cancer Patients

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What if real-world data (RWD) sources can increase the speed of getting therapies to market? Instead of waiting five years for a clinical trial to be designed, enrolled, and completed, we could do it in 1/5 of the time?

That journey is underway.

Many organizations—academia, public and private companies, health policy groups, patient associations, medical societies, and the FDA—are working to establish best practices for generating and evaluating RWD. In fact, Friends of Cancer Research (FOCR) brought together six organizations with oncology-focused healthcare data. Their goal was to conduct a pilot study project to agree on and execute a common protocol using diverse RWD. They also wanted to explore how real-world end points could rapidly address clinically relevant questions about treatment effectiveness.

The resulting paper, "An Exploratory Analysis of Real-World End Points for Assessing Outcomes Among Immunotherapy-Treated Patients With Advanced Non–Small-Cell Lung Cancer (aNSCLC)," published in JCO® Clinical Cancer Informatics, outlines how the project extracted and used RWD to examine real-world end points from many different healthcare organizations. They also assessed how these related to end points in clinical trials for immunotherapy-treated aNSCLC.

Researchers used non-identified patient data from sources such as administrative claims and electronic health records (EHRs) to assess real-world end points. They found the end points were not only consistent with each other, they also aligned with outcomes observed in randomized clinical trials (RCTs). As a result, researchers said they believe this "substantiates the potential validity of real-world data to support regulatory and payer decision making."

> "RWE will be an important tool for continued learning about treatment outcomes over time, which benefits future patients."

RWE data sourcing

Inteliquet contributed deidentified data on 9,118 NSCLC patients, of which 3,478 had a NSCLC. Within that cohort, 477 patients had been treated with PD1 inhibitors in the real-world setting. This data source contribution, taken from diversified oncology EMRs, is similar in size to that of other organizations participating in the study. Because the findings were consistent with each other and with outcomes observed in RCTs, the case can be made that using such aggregated RWD and real-world evidence (RWE) can benefit a number of groups.

As I recently discussed with my colleague Marie E. Lamont, VP of Integrated Health Practice, Real World Technology Solutions at IQVIA, we see value for each of these four industry segments regarding data and RCTs:

- **For Life Science/Sponsors/Pharma:**
  There is an opportunity to potentially shorten the time involved in bringing new therapies to patients, as well as to streamline trial design. It also shows the value of using RWE to measure and quantify the comparative benefits and risks of various medical products.
- **For CROs:**
  They are in a better position to work with Sponsors to develop new therapies by sharing and using their own data. This allows them to be a more strategic partner and collaborator.
- **For Providers:**
  RWE will be an important tool for ongoing learning about treatment outcomes, which will benefit future patients.
- **For Patients:**
  Usage of RWE will provide access to safer therapies more quickly. Importantly, it also can provide important information on smaller and more diverse patient populations, including those often excluded from clinical trials.

RWD and RWE over RCTs?

Currently RCTs are the standard practice to test new treatments and show efficacy and safety of experimental drugs and are frequently head-to-head studies. But they are time-consuming and challenging to design and conduct. A further limitation exists around the failure of results that may not correlate to patients treated in the real-world settings. While RCTs are the best method to demonstrate effects between treatments and outcomes, the researchers concede that RCTs "are often slow to accrue and expensive or are difficult to conduct because of practical or ethical reasons. Moreover, their results may not generalize to patients who are treated in the real-world setting." RWE can play a role in helping advance therapies and treatments, as well as continuing the process of learning about treatments following RCTs.

Inteliquet: A Melting Pot of Data. More Representative

Data that Inteliquet contributed is representative of the patient diversity from many types of oncology practices across the U.S. Not only does this eliminate biases, it provides a more complete representation of data due to the broad spectrum of sites and patients. Larger data sets can be restrictive when they only focus on one section of the country, one type of care setting, or only insurance claims.

Inteliquet's software is EMR-agnostic; it can extract and ingest data from any source. This includes many systems such as EMRs, practice management systems, laboratory information systems, and tumor registries. It also includes many types of diagnostic reporting, including pathology, radiology, and molecular results, among others. Along with being representative, another benefit of EMR data is the longitudinal ability to observe the entire patient journey with real results, which can bring a new level of clarity to the clinical trial process.

This is the first step on a long path, and Inteliquet will continue to contribute to such endeavors under the auspices of FOCR and other groups as they look for ways to improve the cancer research process.

You can read the full paper here or if you'd like to learn more about OncWeb, check out our website.