ORACLE
Health Sciences

UNIFYING ACTION, ACCELERATING RESULTS.

BUSINESS BRIEF

Real World Data and Real World Evidence—The New Normal in Clinical Trials

Clinical research is in the midst of a data explosion, and that's a good thing. Biomarkers, electronic medical records, genomic data, imaging data, labs, social media, wearable sensors, and more provide enormous new sources of real world data (RWD) and real world evidence (RWE) that can quickly shed additional light on the quality, efficacy and safety of new therapies. But, before we can discuss value of this new information for clinical trials, we need to understand the difference between RWD and RWE and how they relate.

Terminology Matters

While clinical researchers welcome new sources of patient information, they often use the terms RWD and RWE interchangeably. Yet, they are not the same; and the distinctions are important. Broadly speaking, RWD is raw material and RWE is data that has been analyzed within a given set of circumstances.

Author and veteran data coach, Eduardo Valencia, explains, "RWD is data collected from sources outside of traditional clinical trials. RWE is the evidence derived from aggregating and analyzing RWD elements. As a result, between data and evidence, we put analytical processes into place that allow us to convert data into evidence."

Accenture's Jeff Elton says that RWD is information gathered "…from myriad of sources that when linked together provide a view of a patient's health history that can be acted upon using insights from advanced analytics." He, too, describes RWE as "a product of analyzed RWD."

In a co-authored article FDA Associate Deputy Commissioner Dr. Rachel Sherman and FDA Commissioner Dr. Robert M. Califf define RWD as raw measurements that are meaningless if observed without a framework. They go on to state, "Only when we add critical context about what is being measured and how, do they become information. That information can then be analyzed and combined to yield evidence, which in turn, can be used to guide decision-making. In other words, it's not enough merely to have data, even very large amounts of it. What we need, ultimately, is evidence that can be applied to answering scientific and clinical questions."

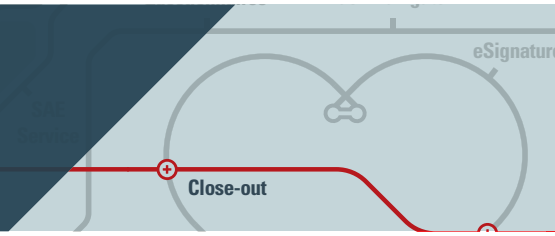
SRINIVAS KARRI
DIRECTOR, PRODUCT STRATEGY
ORACLE HEALTH SCIENCES

Srinivas Karri leads Oracle Health Sciences' Data Management capabilities, and brings years of experience consulting on and managing large data volumes in complex clinical trials

CID/2018/05.24

ORACLE

Oracle Health Sciences breaks down barriers and opens new pathways to unify people and processes, helping to bring new drugs to market faster.



The Real World View for Optimized Clinical Trial Results

So now that these distinctions have been identified, why are RWD and RWE valuable to the clinical trial process?

In a recent Clinical Information News piece, Sujay Jadhav, CEO of goBalto, observes that the use of RWD is becoming "the new normal" in clinical research because it extends the limited perspective that clinical trial results can provide. He adds that successful real world outcomes can validate a new drug's safety and efficacy with evidence that goes beyond the narrow world of trial results.

Drs. Califf and Sherman seem to agree. They note that most clinical trials take place in a "highly controlled setting" that may not reflect real life and often only include patients who might benefit from the new therapy. They explain that real-world information, when added to clinical trial results, can provide a more complete picture of how a new drug affects patients.

"…In other words," they write, "data gathered from [highly controlled clinical] studies may not actually depict the "real world" that many patients and care providers will experience, and this could lead to important limitations in our understanding of the effectiveness and safety of medical treatments. Clinicians and patients must be able to relate the results of clinical trials—studies that are done in controlled environments with certain patient populations excluded and which may therefore be challenging to generalize—to their own professional and personal experiences. It seems straightforward, then, to think that studies including a much fuller and more diverse range of individuals and clinical circumstances could ultimately lead to better scientific evidence for application to decisions about use of medical products and healthcare decisions."

Jadhav's opinion extends the leverage of RWD and RWE even farther, "[The use of RWD and RWE in clinical trials] also helps pharmas and biotechs differentiate their products in a saturated and competitive environment, while also satisfying the additional scrutiny and demands of regulators, insurance companies, healthcare providers, and individuals to whom the products will be prescribed."

RWD and RWE – the Potential for Enhanced Trial Results

RWD and RWE have enormous promise to improve medical care and offer more detailed answers to questions about patient health and safety.

Drs. Califf and Sherman add, "…The incorporation of 'real-world evidence'—that is, evidence derived from data gathered from actual patient experiences, in all their diversity— in many ways represents an important step toward a fundamentally better understanding of states of disease and health."

Are RWD and RWE making enhanced results possible for your clinical trials?

RWD

is raw material and RWE is data that has been analyzed within a given set of circumstances

"…It's not enough merely to have data, even very large amounts of it. What we need, ultimately, is evidence that can be applied to answering scientific and clinical questions."

DR. RACHEL SHERMAN AND DR. ROBERT M. CALIFF
FDA

ORACLE