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Real-world data

The key to a deeper, more precise understanding of cancer progression and treatment efficacy

According to the World Health Organization, cancer is the second leading cause of death in the world, with about one in six deaths attributed to the disease.[1] Cancer is the No. 2 killer in the U.S. as well.[2] But you knew that. That's why you do what you do to contribute to the global search for — and delivery of — effective cancer treatments and solutions. What you might not know is that you may not be taking full advantage of all the data available that can help you reach your goals.

Missing pieces

Historically, the oncology data available to researchers has either been too narrow (focusing on cancer alone), too shallow (composed of just one type of data, such as claims data), or some combination of the two. This is problematic for several reasons, most notably:

- Some cancers are treated outside of the oncology setting. For example, many skin cancers are treated by dermatologists.
- Treatment for many other cancers is often split between oncologists and other specialists. Urologists, for example, often diagnose and treat early-stage prostate cancer.
- Cancer treatment produces a lot of side effects. Other providers, such as cardiologists, often care for cancer patients' comorbid conditions and treat the aftereffects of cancer therapy.
- Using incomplete data restricts the scope of the research that can be conducted. Researchers — and the professionals using their research — are unable to see the whole picture.

By focusing entirely on what happens in the oncologist's office or relying only on a specific type of data, researchers can miss an incredible amount of important information that is necessary to assess how a particular cancer and its treatments impact patients.

Is what the oncologist is doing helping the patient, or is it something else in the patient's care? Are outcomes better for patients who started at point A versus those who started at point B? Why did a patient switch from one treatment to another?

There are other considerations as well as you strive to answer these types of questions. Geographic and demographic diversity, longitudinality and adequate sample size are all critical to researchers who are trying to detect and understand the differences in outcomes between cohorts. The job of oncological researchers is complicated even further by the need to identify patients by genetic drivers of cancer, other molecular details, pathology findings and radiographic data in order to understand the etiology and progression of a cancer, as well as the patients' responses to therapy. To gather the detail they need, many life sciences companies must often run lengthy and costly patient-recruited clinical trials or source the data from many different data aggregators, which can be cumbersome and time-consuming.

A real, powerful solution

To take a more holistic — and realistic — view of a cancer's progression and treatments, researchers must examine the entire clinical journey patients take in real-world settings. This can be done by adding de-identified, real-world data (RWD) featuring claims and electronic health record (EHR) information. Such RWD can provide the breadth and depth necessary to obtain a more complete picture of a treatment's effectiveness and a patient's experience.

RWD facilitates longitudinal outcomes research by capturing data all along the continuum of care. That includes data from pre-cancer clinical appointments, labs, diagnostics and assessments, data from diagnosis and treatment encounters, and post-surgical care data. This end-to-end view allows researchers to gain invaluable insights about:

- Risk factors for — and precursors to — developing cancer
- Treatment selection and line of therapy
- Short- and long-term clinical outcomes, including progression, response, remission, relapse, recurrence and death
- Complications and adverse events that require supportive care

Essential components of real-world data

Claims and EHR data are the foundation of real-world data (RWD) because they provide insight into a patient's record of health care utilization and the associated costs through encounters such as:

- Clinical assessments
- Diagnostic tests
- Labs
- Diagnoses
- Interventions

Using natural language processing to dig deep into patient records and provider notes is especially valuable in providing a better understanding of the progression of cancer and patients' responses to therapies.

A very versatile tool

Since RWD can provide a robust, longitudinal view of the cancer patient's path from the start, it easily lends itself to use by stakeholders throughout the health care system. FDA is using RWD and the real-world evidence (RWE) that comes from that data to keep an eye on postmarket safety and adverse events and to make regulatory decisions. The health care community is using RWD to make coverage decisions and to develop guidelines and decision support tools for use in clinical practice. And medical product developers are using RWD and RWE to support clinical trial designs and observational studies to generate innovative, new treatment approaches.[3] Increasingly, RWD is also being used for label expansions and to demonstrate to payers and providers the value of products for clinically precise groups of patients.

This growing acceptance and usage of RWD has created a watershed moment for life sciences companies and the medical community since the collection and curation of data is far less costly and time-consuming than the execution of organic, randomized control trials. In fact, Optum estimates that use of RWD for RWE will cut the cost of phase I, II, III and IV studies by one-third to half.

RWD can put you in the enviable position of being able to track the cancer patient's experience from pre- to post-diagnosis and beyond. This can lead to the comprehensive understanding of product efficacy and safety required by payers, providers and regulators for approval. By embracing RWD, you can obtain a complete grasp of how your product performs, is viewed and is deployed throughout its entire lifecycle from development to utilization.

1. World Health Organization. Cancer key facts. who.int/news-room/fact-sheets/detail/cancer.
2. CDC. National Center for Health Statistics. Mortality in the United States, 2018. cdc.gov/nchs/products/databriefs/db355.htm.
3. FDA. Real world evidence. fda.gov/science-research/science-and-research-special-topics/real-world-evidence.

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What to look for in real-world data

If you're interested in putting real-world data to work, make sure you use high quality data. That means using data that:

- Is derived from a large population of patients
- Includes relevant patient populations across demographics, geography and numerous types of cancers with defining genetic mutations and biomarkers
- Is properly de-identified and directly sourced from providers
- Includes documented provenance and automated mapping of variables
- Includes data from clinical encounters in other specialties like dermatology, urology, pulmonology, gynecology, cardiology and neurology
- Is comprised of various types of data – such as claims, EHR, and patient reported data – that can be easily integrated and used together

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