IS YOUR ONCOLOGY PATIENT POOL A SEA OF SAMENESS?

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As our population ages and medical advances increase life expectancy, drug developers are facing an emerging gap in clinical research: lack of evidence to guide treatment decisions for people over 65. Almost a year ago, the Food and Drug Administration held a public meeting asking for suggestions on how to include more older people in clinical trials. Since then, a number of experts around the world have expressed similar concern that there is little evidence to tell them what drug or treatment works in elderly patients.

Researchers from the National Cancer Institute estimate that the number of U.S. women diagnosed with breast cancer will increase nearly 50 percent by 2030. This growth is mainly due to aging female baby boomers, those born between 1946 and 1964. When these women reach 70 to 85 years old, the number of American women with breast cancer will jump from 24 to 35 percent.

Trials for new cancer drugs commonly test subjects in their 40s and 50s who do not have other ailments and who are only receiving the trial treatment. The clinical results may be valid for the study group, but how confident are we that those results will be the same for a patient in her 80s who may be managing a number of other chronic conditions besides cancer?

It's important to study older patients because their bodies are less efficient at clearing drugs out of the system and they tend to be taking on average more than 10 different drugs at the same time, which puts them at risk of treatment mistakes and side effects.

In addition to the clinical need to understand how older people respond to new treatments, there is an increasing business need to recruit older patients. Based on the analysis by the National Cancer Institute, cancer rates in younger women will go down at the same time as baby boomers mature, thus shrinking the size of the patient pool from which most companies currently source women for trial.

An evaluation published by the British Medical Journal revealed that elderly patients were part of the exclusion criteria for nearly a third of trial protocols. But elderly patients make up more than a third of the population who would ultimately benefit from the use of these drugs.

Most R&D functions follow a well established process for crafting clinical studies, but researchers at a top pharmaceutical company are questioning convention and embracing new information in the hopes of improving clinical trial design. For a recent study, trial authors decided to do something quite different. They invited patients into the organization to see if there was anything they could learn from them that would impact the way they architected the study. It turned out there was. And from the patient interaction, they redesigned the study.

What the company did was to make a strategic decision to move away from a "group think" mentality. Rather than relying on the same sources of data, the same assumptions and the same processes, they listened to a broader set of stakeholders to acquire information for better decision-making. Rather than piling on requirements, they highlighted an opportunity for research organizations to innovate. Rather than taking a "kitchen sink" approach, they encouraged their research partners to carefully prioritize and select based on what makes sense in the real world.

Diversity in patient pools is important. According to FDA Commissioner Margaret Hamburg, "One of the core tenets of rigorous biomedical research … is the importance of encouraging diversity in clinical trials. When a more diverse population participates in clinical trials, we increase the potential to know more about the extent to which different subgroups—males and females, young and old, people of various racial and ethnic backgrounds and patients with differing comorbid diseases and conditions—might respond to a medical product …" The result, she says, is greater assurance in the safety and effectiveness of the treatments that ultimately will be used by a broad, diverse population that clinical trials should attempt to mimic.

About PALIO

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