Dying for Access

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We're dying to participate in clinical trials.

This was the message METUP delivered at the San Antonio Breast Cancer Symposium.

At a time when only 3 to 5 percent of eligible cancer patients enroll in clinical trials—and some trials are unable to get off the ground because of low accrual—reform of the clinical trial process is imperative.

For far too long, oncology trials have sought what we call "Olympians": the healthiest of the dying. These include patients who haven't undergone multiple prior lines of therapy; those without brain metastases (cancer spread to the brain); those who don't have comorbidities, like diabetes, high blood pressure or HIV; and those who aren't as old as the average patient who will use the drug under study.

In addition to restrictive eligibility requirements, there are logistical and financial barriers to participation in clinical trials. Although the majority of cancer patients in the United States are treated in community hospitals, most trials are conducted at big city academic centers. I recently talked to a woman in a trial who drove six hours round-trip for a five-minute blood draw at a large center!

Major players in the cancer research game are beginning to recognize that change is necessary. The American Society of Clinical Oncology, Friends of Cancer Research and the Food and Drug Administration recently examined eligibility requirements for clinical trials and made recommendations to facilitate enrollment of people who are more representative of the population that needs a new drug.

These recommendations include allowing enrollment of patients with stable treated brain metastases—and even those with active brain mets—if they could benefit and if brain metastases are common in the population; people with kidney or liver disease if the drug is not toxic to those organs; and patients with prior or concurrent cancers if this is unlikely to compromise the safety or efficacy of the drug.

In addition, trials should include patients in the age groups most affected by the cancer and work harder to enroll people of all races, ethnicities and socioeconomic statuses. And breast cancer trials should include men as well as women.

Trials should begin to move away from the brick-and-mortar mother-institution model and accept outside imaging and lab tests. When specialty labs are required, samples can be drawn locally and shipped to the research center. If FedEx can get the best seller I ordered from Amazon to me in a day, then surely a local lab can get blood to a research center promptly.

By broadening eligibility criteria, we will be able to get promising drugs to market faster. We, the metastatic and advanced cancer patients, want to help researchers help us live longer.

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