

# How to fix clinical trial accrual

Jame Abraham, MD, FACP

I was really excited to see Michelle in my follow-up clinic. She had driven more than 4 hours to come to see me. We talked about her two boys. When she was diagnosed with breast cancer 14 years back, they were 8 and 11. We compared stories about my two teenage boys, who were 1 year and 4 years when I met her. She was my first patient when I started out as an oncologist. We had practically “grown up” together. She was only 33 years old then, and was a successful computer professional. She was busy building her career and family. Breast cancer was not on her agenda.

But when she was diagnosed with a stage III ER/PR-positive, HER2-positive breast cancer, she did not ask “why me?”. She approached her diagnosis as she did with any other challenge she faced. She collected as much information as she could about her diagnosis and reviewed the different treatment options with me. After hours of discussion, she enrolled in the NSABP B-31 clinical trial. Back then, we did not know about the role of HER2 or HER2-targeted drugs in adjuvant breast cancer. She was randomized to the control arm. When the results of the study came out, like thousands of other patients on the control arm, she received trastuzumab, the study drug. She is doing very well.

Michelle was one of the 1,024 women who were assigned to the control arm. In all, there 3,676 mothers, sisters, and daughters enrolled in the study. NSABP B-31 and other studies include similar fascinating stories of survival, hope, disappointments, and frustrations. Over the last 50 years, many incredible men and women who have been diagnosed with cancer have agreed to go the extra mile to help someone else, and possibly themselves, by enrolling in a clinical trial. But in the United States, fewer than 5% of adult patients enroll in a clinical trial, and about 30% of national trials funded by the National Cancer Institute are closed because of insufficient accrual.<sup>1</sup>

As an academic oncologist, I have sat through many meet-

ings about clinical trial accrual. We have created new tools, technology, brochures, and even pins for physicians and nurses to wear to promote clinical trials. Yet I remain convinced that when there is appropriate clinical trial infrastructure, there is only one person, who can increase the clinical trial accrual, and that is the treating oncologist. Not the research nurse, not the patient, but the treating oncologist.



Patients, it seems, are open to joining a clinical trial, but doctors have perhaps not readily followed up on that willingness. In a poll conducted by Research America in 2010, more than 70% of the patients who were polled said they would likely or somewhat likely consider participating in a clinical trial, but only 6% of respondents said that their doctors had ever suggested they join a clinical trial.<sup>2</sup> Three years later, those numbers had barely shifted: in a poll of different patients, 72% of respondents said they would likely or somewhat likely consider participating in a trial, and just 8% said their doctors had suggested they do so.<sup>3</sup> Those findings seem to be consistent

across many studies that have shown that physicians play a key role in accrual.<sup>4,5</sup>

Well-designed clinical trials are the gold standard of cancer treatment. As oncologists, if we don't recommend clinical trials, we are accepting the status quo. From my personal experience, after reviewing the pros and cons of standard treatment versus trial treatment, if I recommend a clinical trial for a patient, there is a more than 80% chance that she will consider the trial. This is consistent with published literature, as Minasian and O'Mara have noted.<sup>6</sup>

Patients listen to us about trials because they trust us. It is up to us build that trust and ensure that we have the right trial for the right patient. Open the trials you believe in and encourage your patients to be part of the gold standard of cancer treatment. Once you build the clinical trial infrastructure, there is only one person who can increase the accrual – you, the doctor.

## References

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