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ONCOLOGY ISSUES

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FROM THE EDITOR

Moving the Needle on Clinical Trial Accrual

BY JENNIE R. CREWS, MD, MMM, FACP



enrollment in clinical trials slow our progress and deny patients access to potentially life-saving treatments. Oncology literature is ripe with studies examining the reasons for this low accrual, many of which have focused on patient and provider barriers.

A recent meta-analysis provides us with some encouraging news and a fresh look at barriers.¹

First the good news. Though it is widely stated that only 2 to 3 percent of adult U.S. cancer patients participate in clinical trials, this meta-analysis finds trial participation to be 15.9 percent in academic settings and 7 percent in community settings. Given the multiple barriers surrounding clinical trial accrual, this is, indeed, encouraging news.¹

Unger et al. categorize enrollment barriers into four domains: structural (trial availability); clinical (trial eligibility); physician (trials discussion and offering); and patient (trial participation decision).¹ Structural and clinical barriers have received less attention but may be the most important barriers to overcome because they account for 77 percent of patients not enrolling in clinical trials.¹

Eligibility reform is underway thanks to efforts by a number of organizations in partnership with the National Cancer Institute. Much of this reform seeks to update eligibility requirements to allow inclusion of patients with brain metastases, prior malignancies, and comorbidities. Though this effort is laudable, it is not sufficient. Removing structural barriers is also necessary to achieve the goal of increased participation in clinical trials.

The root causes for structural barriers include the overhead costs associated with research, which disproportionately affect smaller community sites, and the lack of

The amazing advances seen in cancer care are the result of successful completion of clinical trials. But the fact is that we could do so much better. Persistently low rates of patient

access to clinical trials that some cancer programs face. In addition, more and more clinical trials involve drugs targeting rare mutations, which makes these studies less feasible for a smaller site to open. Finally, the overhead costs of research render clinical trials a loss leader that is increasingly vulnerable to budget constraints.

To move the needle on clinical trial accrual, we need both eligibility and structural reform, including:

- Correcting the unintended consequences of regulatory requirements that are necessary to keep patients safe but also must be feasible for cancer programs to comply with.
- Increasing opportunities to participate in precision medicine trials with more “just-in-time” approaches to enrollment.
- Exploring ways that digital technology can reduce overhead costs for cancer programs, particularly those in remote and underserved areas.
- Evaluating the use of real-world data to answer important clinical questions.

Hear more about how you can help in these efforts at the upcoming Association of Community Cancer Centers 36th National Oncology Conference, Oct. 30-Nov. 1, 2019, where author and journalist Mary Elizabeth Williams shares strategies for how patients and providers can work together to bring clinical trials to a more diverse patient population—based on her experience as a participant in a groundbreaking immunotherapy clinical trial. Until then, consider sharing what your cancer program or practice is doing to ensure that patients in your community have access to clinical trials by writing for ACCCBuzz (the association’s blog) or contributing an article to *Oncology Issues*. Interested? Email apatton@accc-cancer.org today and become a part of the solution!

Reference

1. Unger J, Vaidya R, Henderson DL, Minasian LM, et al. Systematic review and meta-analysis of the magnitude of structural, clinical, and physician and patient barriers to cancer clinical trial participation. *J Natl Cancer Inst.* 2019;111(3):1-11.