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RECRUITMENT & RETENTION

Accelerating Oncology Trial Recruitment by Identifying Patients at Diagnosis

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Oncology researchers face a sizable patient recruitment challenge. The numbers alone paint a revealing picture: roughly 14,000 oncology trials are actively recruiting,{1} garnering participation rates estimated at a mere 3% to 8% of possible candidates, with even more limited numbers in minority and geriatric populations.{2}

Low enrollment rates pose risks to more than just the success of individual clinical trials; they may hinder treatment advances and corresponding benefits to outcomes.{3} Despite the promise that trials hold to improve cancer care, most oncology researchers find themselves in fierce competition for patients who have little awareness of the opportunities that exist, or due to real or perceived barriers from a site perspective, which make the perception and reality that recruitment is a labor- and time-intensive process.

However, it should be noted, cancer treatments are fast approaching an inflection point, and fortunately, technology innovations are starting to offer new ways to overcome historic oncology recruitment barriers and disrupt the status quo. One example of technology rising to meet this need combines advanced clinical trial design with a digital pathology platform to help accelerate recruitment by identifying trial-eligible patients at the time of diagnosis.

Current Recruitment Obstacles

Current and traditional recruitment workflows rely heavily on oncologists' knowledge of their patient base, as well as their awareness of active clinical trials. Patients are rarely tracked as potential trial candidates until after they've failed a first-line therapy, and it as at this point that oncologists may propose study options, particularly those available in nearby academic institutions offering a wider variety of clinical trial options than a typical community-based site.

Given the growing movement toward precision medicine, however, more detailed clinical diagnostics are required to qualify patients for some trials. Based on the eligibility criteria for specific protocols, patients may need to obtain additional tumor samples or biomarkers. Consequently, oncologists are increasingly reliant on the diagnostic team—often pathology—for new assays or secondary review, or must rely on historic samples from outside institutions to verify for review. This somewhat retroactive approach is not only cumbersome for oncologists' and pathologists' case flows, it can also delay entry into active treatment protocols.

In addition to the emotional impact of treatment delays on patients, timing is of the essence in cancer trial recruitment. Clinical research coordinators have narrow windows of time to work within due to the complexity of diagnosing patients with specific inclusion/exclusion criteria. Currently, it is often challenging to obtain even baseline information in a consolidated fashion.

As noted previously, sites need to find patients who have appropriate tumor types *and* who are at the right juncture within various lines of therapy. Additional protocol eligibility considerations may require patients who are refractory to a certain class of drug, for example, or in relapse. That forces coordinators and physicians to identify candidates "in the gap"—after they've failed one therapy, but before they've started on another course of treatment—versus proactive identification and tracking of patients earlier on in lines of therapy.

The pressing need for information at precisely the right time is why it's beneficial for researchers to move upstream from the oncologist to the pathologist. Rather than wait for data to be entered into an electronic health record (EHR) or lab information system, they can leverage cloud-based pathology technology to identify and track trial-eligible patients at the time of diagnosis.

New Opportunities and Benefits

The sooner we can identify eligible oncology trial candidates after a diagnosis, the faster we can achieve value for researchers, providers, and—most importantly—patients.

To explain the efficacy of such a process, let's consider a scenario in which a patient is diagnosed with a cancer and goes on a standard line of therapy. A cloud-based, pathology-focused platform that allows tracking to begin at the time of diagnosis helps ensure the patient is not overlooked by study coordinators just because multiple inclusion/exclusion criteria have not yet been met.

From a site management perspective, contract research organizations (CROs) typically see 15% to 20% of sites underrecruit or not recruit at all. The situation is multifactorial, however, a large portion of this percentage comes from the inability to identify appropriate patients at the right time, or at all, to approach about participating in trials. Easing cumbersome workflows increases the likelihood patients will be identified for appropriate trials, alleviating the frustration of enrolling few recruits after completing months of upfront preparation.

Researchers and sponsors also can benefit from the compressed timelines possible through technology-supported trial designs. Fast-track enrollment can help alleviate delays that cost as much as $8 million per day.{4} In addition, the sooner patients are enrolled in a study, the longer the efficacy and safety data will have to mature. That, in turn, can help shorten the trial duration.

For pathologists, accelerating digitization and streamlining complex data management through algorithms and artificial intelligence (AI) presents two-fold benefits. First, it can strengthen trial recruitment and care coordination. Second, it can optimize workflows and free more time to work on a top-of-license basis.

For example, AI tools can enable more accurate mitotic index calculations almost instantly, thereby simplifying and improving secondary review. Technology platforms can quickly track down historical samples, as well as auto-generate forms and ease quality assurance, quality control, and tumor board requirements.

Furthermore, by leveraging the full value of the diagnosis, pathologists can assume a more integral role in the care team. Enhancing pathologists' ability to make oncologists more aware of trial potential at the time of diagnosis may deepen their collaborative relationships.

For oncologists and patients, timelier awareness of clinical research as a care option allows earlier, clearer, and more informed decision-making. Every percentage increase in cancer study participation represents new prospects to save lives.

Conclusion

The historic challenges associated with oncology trial recruitment—low enrollment rates amidst stiff competition—can be overcome. Identifying and tracking trial-eligible patients at the time of diagnosis is a new mechanism to get the best care for patients.

There is immense satisfaction, especially for study coordinators and clinicians, when cancer patients are appropriately enrolled in beneficial trials. By removing the friction points that can impede achievement of enrollment goals all along the continuum of care, we can help researchers, sponsors, and clinicians work together to improve the participant experience.

References

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