

## IO Trials Are Accruing: Where Are the Patients?

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I have been a research nurse at Johns Hopkins Medical Institution since 2010. Within six months of starting my position, I began working with checkpoint inhibitors. From my vantage point in clinical trials research, I've seen many changes in immuno-oncology trials patient selection over the last eight years. All studies define the population to be evaluated and questions the study hopes to answer. Each study defines the disease, the stage, the line of therapy, the performance status, and wash out periods from prior therapy. (The wash out period is a specified amount of time that must go by after the last dose of previous therapy.) In the case of checkpoint inhibitors, as our knowledge about these agents has grown, we've seen study requirements and eligibility criteria become much more specific.

### *How are you talking to your patients about IO clinical trial opportunities?*

Before a patient can be considered as a trial candidate, the patient, caregiver, or provider must be aware of study's existence and feasibility. It is up to the study team to get the information out. At Hopkins, the primary investigator or a study team member will attend tumor boards to explain upcoming trials and eligibility criteria to providers. More recently, genomic testing results have started to list actionable mutations and clinical trials associated with those mutations, which can assist providers and patients in the search for treatment. Sponsors have been advertising trial enrollment opportunities on TV, referring viewers to websites for more information. All of this takes time and dedicated communication.

My first checkpoint inhibitor study was a phase 1 trial, open to five different disease groups. The study required archival tissue or biopsy for testing at screening. The description of the sample was more flexible than many of my current studies. Today multiple biopsies at different points during a study are the norm. Core specimen size is

clearly defined; studies require larger samples and more core biopsies. Fine needle aspiration specimens are not permitted. If large-gauge core specimens are needed, the method of obtaining biopsies may be dictated. For example, with lung biopsies, obtaining cores via a bronchoscopy may be possible with special needles, but may also not be a possibility. CT-guided specimens can have an element of risk depending on the location of the mass. Increasing the core gauge and number of cores may increase the risk of pneumothorax. The fixative, temperature, and fixation times for specimens have become more defined. Laboratories running these studies have had to adjust practices. Baseline samples may require evaluation by a central lab prior to enrollment. Others require pathologist confirmation that a certain percentage of tumor is present in block or slides. Some of these changes have led to prescreening periods and procedures.

Besides tissue, study protocols outline the scans, labs, EKGs, ECHOs, prior treatments allowed or prohibited, and the time frame permitted before enrollment. Ordering and scheduling multiple tests can lead to a lengthier screening period.

Before patient consent to participate in a study can be obtained, insurance clearance is necessary. Depending on the payer's process, this can take days or weeks. Other challenges to enrollment may include travel and expenses, as well as the patient/caregiver's ability to conform to the protocol's schedule.

Despite our progress, many different types of cancer need more effective and tolerable treatments. Clinical trials continue to be the path to advance our understanding of cancers and to improve patient care.



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