PHARPOINT RESEARCH

Maximizing Enrollment Potential for Solid Tumor Clinical Trials

3 Things PharPoint's Oncology Experts Suggest

OVERVIEW

Less than 5% of adult cancer patients enroll in a clinical trial. Meeting enrollment goals while maintaining study timelines and budgets can be tough if a study hasn't been properly planned and supported.

PharPoint is a mid-sized CRO with expertise within oncology. While every study is different and can benefit from individualized input and approaches, the following suggestions are commonly used by our team to maximize enrollment potential in solid tumor clinical trials.

1. Optimizing and de-risking your protocol

If you're planning to bring in a contract research organization (CRO), be sure that CRO is capable of providing an additional layer of expertise to catch small details and allow for an even more powerful, effective clinical trial.

Some of the questions that should be asked during this process include:

- How will those involved in your study (including investigators, site coordinators, and study subjects) perceive your study protocol?
- Are there any changes that can be made to improve protocol clarity?
- How does your study protocol compare with other protocols in similar indications?
- How are your study processes set up to handle obstacles and predicted challenges?

PharPoint has extensive experience in assisting clients as they optimize, de-risk and operationalize oftentimes complex protocols. For solid tumor trials, we provide clients with input from our oncology experts in clinical operations and biometrics along with input from our on-team Oncologist.

2. Selecting the right sites

Selecting the right sites is key to maximizing enrollment. As you look at potential sites, it's important to perform a thorough feasibility process.

PharPoint suggests identifying sites in an objective manner by using an extensive database of historical clinical trial data. The most popular or well-known sites are not always the most suitable for every study. Additionally, we typically implement a tiered site selection and activation strategy and leverage a mix of both academic and non-academic institutions.

For solid tumor studies especially, part of the site selection process includes **ensuring investigators can consistently evaluate response criteria** throughout a study per protocol requirements.

3. Properly supporting sites

After selecting the right sites, it's important to set them up for study success through effective site management and support.

Solid tumor studies often utilize RECIST criteria, which can be complex to standardize. To assist in this effort, the study's biometrics team should prioritize the creation of eCRFs that minimize site burden while still providing everything needed for analysis. Oftentimes this may include using flexible design for cycle delays and building pathways in visit structure to push forms as needed.

Sponsors should also consider engagement with relevant support communities. These communities and relevant organizations should be vetted to determine how they can best assist with study success. For many oncologic indications, it may be possible to partner with groups that maintain complete patient databases that may help sites directly find and connect with patients.

About PharPoint

PharPoint Research is an award-winning and client-focused contract research organization (CRO) that supports innovative clients of all sizes. Founded in 2007, PharPoint's team has participated in over 1,000 clinical trials with a high business repeat rate.

Our services include:

- Clinical Operations
- Site Feasibility
- Medical Monitoring
- Project Management
- Data Management
- Biostatistics
- Statistical Programming
- Medical Writing
- Study Rescue
- DMC Support