PERSPECTIVE

Trial-level variables influencing enrollment and completion in cancer clinical trials

Sonali Bharti

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ABSTRACT

In the United States, cancer ranks as the second most common cause of death. Clinical trials convert discoveries made in basic science into cancer treatments that patients require. One of the major obstacles to the conclusion of oncology clinical trials is the inadequate accrual of study participants. This study sought to fill knowledge gaps and provide areas for future research by looking into trial-level variables that influence the enrollment and/or completion of oncology clinical trials.

Key Words: *Hepatobiliary; Surgical care; Oncology, Brest cancer; Vascular surgery*

INTRODUCTION

With an anticipated death toll of 606,520, cancer is the second-leading cause of death in the US. The rising number of oncology clinical trials and the astronomical expenses associated with conducting these studies have created obstacles to their completion as pressure has intensified to swiftly transfer fundamental scientific discoveries into therapies that are urgently required by cancer patients. Oncology clinical trials began in around 2800, according to ClinicalTrials.gov, in 2015. In 2019, it increased to more than 4600. Lackluster trial participant recruitment has emerged as one of the biggest obstacles to the completion of clinical trials due to the rise in the number of oncology clinical trials and the limited resources available to support the conduct of these trials. Only 3-8% of adults with cancer take part in clinical trials. A 20% failure rate for oncology clinical trials is also common due to insufficient accrual. As obtaining the specified sample size is necessary for valid results, patient accrual is a critical statistic in assessing the success of a clinical study. Too often, incomplete accrual results in the early termination of clinical trials or their extension. This hurts the financial and other resources of the sponsors and participating sites for cancer trials. The ultimate objective of offering innovative, effective cancer medicines to people who urgently require them is hampered most significantly by trials that are postponed or canceled early. A significant improvement in the effectiveness, completion, and prioritization of clinical trials was demanded by the Institute of Medicine in 2010. In the current period of constrained research funding for governmental, academic, and business groups, accurate projections about the accrual and completion of a study are essential to achieving these objectives. The only way to make these exact forecasts and achieve the Institute of Medicine's goals is to thoroughly understand the variables influencing the enrollment and completion of oncology clinical trials. The body of research shows that factors influencing enrollment and completion in oncology clinical trials take place at the individual, interpersonal, organizational, community, and policy levels. Even though numerous researchers have looked at these characteristics and created interventions like patient navigation and communication training to address barriers, enrollment in and completion of clinical trials still fall short. It is not obvious from research if aspects including eligibility requirements, anticipated sample sizes, study phases, study designs, and the use of randomization that may have an impact on successful accrual and trial completion have been sufficiently examined. To fill in any gaps in the literature and suggest relevant areas for future research, this review looked at the empirical literature to investigate trial-level characteristics that affect trial enrollment and/or completion in oncology clinical trials. The following research query served as the review's compass: Which trial-level variables affected the enrollment and/or completion of oncology trials was one of the topics covered in research that examined big data sets of clinical trials. Sponsor, number

Editorial Office, Journal of Surgical Research, United Kingdom

Correspondence: Bharti S, Editorial office, Journal of Surgical Research, United Kingdom, e-mail id: jsugresarch@theresearchpub.com

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and location of participating institutions, competing for trials, time of trial opening, and fast-track status were among the background variables that were examined about cancer clinical trial accrual and/or completion. Annual incidence and the type(s) of targeted cancer were two disease-related parameters. The trials looked at a variety of treatments, including prescription medications, radiation therapy, and surgery. The length of the study, the eligibility requirements, randomization, sample size, trial phase, the use of placebos, and the scheduling of the necessary protocol procedures were all variables in the design of the experiment. Identifying and solving trial-level issues affecting accrual is crucial because patient participation rates in oncology clinical trials, which show promise for future medicines, are low. This will make it easier to complete trials. In order to decide how to most effectively search the literature for pertinent studies, the authors spoke with a medical reference librarian. The systematic selection of the literature for the sample was guided by the PRISMA declaration, and the procedure was laid out in a flow chart. On February 24, 2020, relevant publications were looked for in the Scopus and PubMed databases. No date separators were present. Study design, population, type of cancer, sample size, trial phase, and database were just a few of the trial-related criteria that were looked at in relation to how they affect a study's accrual and/or completion. There was 15 quantitative research, and 1 study used a mixed-methods methodology. All investigations were at level (for instance, retrospective cohort study). Additionally, only three research included pediatric oncology clinical trials; the other studies primarily focused on adult oncology trials. Most studies did not restrict their research to one or more particular cancer types. Multiple cancer kinds were mentioned in three studies. The literature revealed background factors influencing the accrual and/or completion of oncology clinical trials. One of the background factors that was looked at was the sponsor or funder. Industry-sponsored trials had some of the quickest accumulating phase III cancer clinical trials released. Additionally, industry-supported immune checkpoint inhibitor studies were much less likely to terminate early compared to those that were sponsored by the federal government and academic institutions, with low accrual being the most common reason for early clinical trial terminations. Worldwide, industry-sponsored studies were also noticeably more likely than government-funded trials to reach accrual sufficiency. Consequently, the failure of randomized clinical trials in radiation oncology was predicted by the presence of government support. Time spent developing clinical trials was another background element that was studied. Calculated trial development time from the time the study was first submitted to the NCI Cancer Therapy Evaluation Program (CTEP) until it started. Compared to those developed in 12 to 18 months, oncology clinical trials developed in 12 months were considerably more likely to reach their enrollment goals. On the other hand, compared to studies created in 12 and 12-18 months, oncology clinical trials created in 24 months were considerably less likely to reach their accrual goals. The quantity and location of participating institutions both had an impact on the accrual and/or completion of oncology clinical trials. Compared to clinical trials conducted at numerous universities, those conducted at a single institution had a higher failure rate. According to data from one study, trials that were done outside of the United States or that were conducted both inside and outside of the United States had a higher completion rate than trials that were only conducted within the United States. According to the results of a different investigation, the lead investigator's continental residence and trials that were carried out abroad had no appreciable impact on the outcome of the study. One of the quickest-accumulating trial types was international trials. But there were no appreciable variations in accrual times between phase III cancer clinical trials conducted in the US and those in Europe. Background variables such as competing trials, the time of trial initiation, and fast-track status were examined in connection to oncology clinical trial enrollment and/or completion. The number of competing trials was a predictor of low accrual among adult National Clinical Trials Network cancer clinical trials, with a higher number of competing trials being related to low accrual. Identified radiation oncology randomised clinical trials that started in successive time periods and were either full or partial. Each successive time period saw a significant increase in the number of failed trials. Trials that began before 2003 had a smaller accrual of elderly adults, it was discovered. Low accrual was not linked to the Food and Drug Administration's fast-track review status. Low accrual was predicted by a lower yearly incidence of the targeted type of cancer and a higher necessary enrolment percentage of the eligible patient population. Fewer breast cancer phase III clinical trials in the NCI Cooperative Group were stopped due to insufficient accrual. Discovered that among phase III oncology clinical trials, breast cancer studies had the fastest accumulating trials. However, Hernandez-Torres et al. showed that fewer older persons were enrolled in breast cancer clinical trials. Clinical trials for malignancies of the central nervous system were linked to increased accrual among the older population. Between urological and neurological studies, sufficient accrual did not significantly differ. However, among urological trials, kidney cancer trials had the best accruals, whereas bladder cancer trials had the poorest. Trials with inclusion criteria that targeted various types of cancer and those that focused on typical solid cancers rather than unusual solid or liquid tumors were predictors of low accrual. The correlation between accumulation and metastatic disease produced a variety of results. Metastatic disease was a predictor of low accrual in two studies when compared to no metastatic disease. Additionally, the registration of older people was substantially correlated with early-stage cancer. In contrast, another study found that trials involving advanced disease accumulation performed better. The literature looked at treatment-related aspects. Comparing immune checkpoint inhibitors to other types of cancer medications, immune checkpoint inhibitor clinical trials had a lower early termination rate, but the difference was not statistically significant. Radiation therapy and non-targeted therapy were predictors of low accretion. Compared to other cooperative groups and multimodality studies that did not focus largely on systemic therapy, accrual was worse for trials conducted by the Radiation Therapy Oncology Group. Others found no statistically significant difference in inadequate accrual between clinical trials involving a novel investigational medication and those that did not, whereas some found the use of an experimental new drug to be a predictor of low accrual. Clinical trials that included standard therapy, whether it was combined with a new drug or not, had higher accrual rates than those that did not. Low accrual and/or trial failure were linked to studies that compared surgery to other therapies such as medications, and low

accrual was linked to multimodality clinical trials. Oncology clinical trials' accrual and/or completion are impacted by the following factors: eligibility requirements, randomization, sample size, trial phase, use of placebos, and mandatory protocol procedures and their timing. Phase I cancer clinical trials' sluggish accrual was mostly attributed to safety/toxicity, design/protocol difficulties, and eligibility requirements. Additionally, eligibility requirements and design/protocol concerns such as needed procedures, treatment schedules, and overall trial complexity were the main causes of the poor accrual for phase II cancer clinical trials. Low accrual was linked to increased trial complexity, which was defined by a higher number of targeted disorders in inclusion criteria, therapies, and study locations. Despite conflicting findings in research, sample size and clinical trial phase were two trial design elements that affected enrollment and/or completion of oncology clinical trials. The bigger sample size was a predictor of low accrual, it was discovered. However, showed that for completed trials with a median sample objective, the sample size target (not stated) was larger than for terminated trials with a median. Additionally, they discovered that phase II and phase III studies had much lower early termination rates compared to phase I trials, with poor accrual accounting for the majority of early terminations across all trials. However, limited accretion was predicted by the proven phase III. In other research, accrual by trial phase was not seen to vary. Another aspect of the trial design that influences accrual in oncology clinical trials is eligibility. In general, low accrual was linked to eligibility requirements that stress patients, like those that demand the collection of samples unrelated to regular medical care. The total number of eligibility requirements was strongly correlated with the length of the recruitment period in studies that enrolled patients in study of phase I through III molecular trials. Trial development duration, eligibility requirements, randomization, sample size, trial phase, use of placebos, and necessary protocol procedures and their timing were all elements that were looked into. The factor that was looked into the most frequently was eligibility requirements. Although they are required to keep out individuals with poor prognoses and a high risk of adverse events, eligibility requirements can negatively affect enrollment and/or trial completion. It is necessary to assess each eligibility requirement to make sure it is supported by the scientific literature and isn't included just because it was in earlier protocols. Further suggests lowering eligibility standards once a We now know more about the toxicity profile of the medicine.