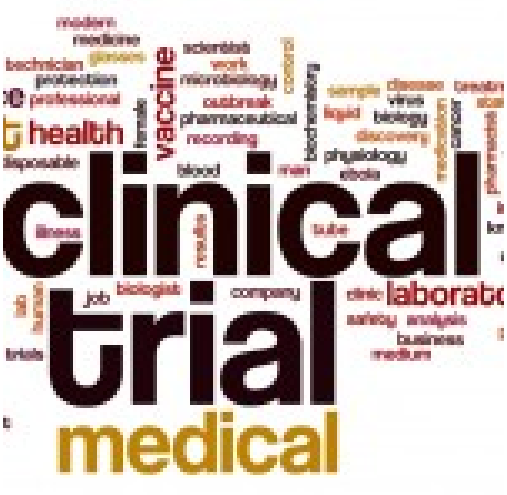
Cancer Trials Fall Short on Recruitment

By Lila Abassi — January 4, 2016



clinical trial via shutterstock [1]

Clinical trials are the best tool we have to evaluate new therapeutic drugs. To be able to do so, each trial must enroll a target number of patients to ensure the efficacy of the study drug. A report published in the *Journal of the National Cancer Institute* [2] found that one in every five publicly-funded clinical cancer trials fell short of recruiting enough participants in order to establish statistically-reliable results.

The need to enroll sufficient number of patients into oncology clinical trials has been a long-running issue. The critical aim of any drug trial is to determine whether the results are valid, if the drug shows efficacy (generalizable to the population) and what the side effects are.

Generally, in Phase II/III clinical trials [3] where the study drug is given to large groups of people the number of target participants has already been calculated. In this report, researchers from the University of Washington and the Fred Hutchinson Cancer Research Center reviewed 787 phase II/III studies sponsored by the National Clinical Trials Network (NCTN) between the years 2000 and 2011, and found that 145 trials ended with less than 50 percent of target three years or more after initiation.

Such trials represent a waste of scarce human and economic resources and contribute little to medical knowledge, a researcher said, according to *Medical News Today* [4].

There are specific factors of the trials themselves that limit participation. For example, if the study required an invasive procedure such as a biopsy or tissue sample, fewer individuals will enroll. Another factor in low recruitment is if the patient knows that he/she potentially may (or may not) receive a new drug /therapy.

(They are more likely to receive the study drug in phase II than in phase III.) Phase III trials will randomize individuals to current treatment versus new drug.

As soon as you add in randomization, where patients may or may not get [the investigational treatment], it wipes away the higher accrual rates we found among trials studying new treatments, said Dr. Carrie Bennette, the study s lead author.

The investigators were able to identify 12 possible factors accounting for the low recruitment levels in studies. Knowing this will help future NCTN trials account for these factors, as well as help attract more participants. Predictors allow investigators to direct resources toward trials that are higher priority that are more likely to achieve target recruitment goals.

In the absence of a sufficient number of participants, investigators cannot determine with confidence whether the investigational drug truly had the desired therapeutic effect. Additionally, these studies end up being a waste of valuable resources (i.e. effort to recruit, find participating sites) and up costing more [5] than anticipated because they tend to remain open for longer than planned times, while producing unreliable results.

What that means is a clinical trial is started, a tremendous amount of resources are invested in designing the trial and finding sites to begin to enroll patients, " Dr. Bennette adds, and "then that trial doesn t get used to help advance science or improve clinical practice.

Knowing what challenges to anticipate enables proper planning. It is disheartening for any investigator to go through the tremendous effort required to conduct clinical trials, only to end up with results that either show nothing, or an effect that may or may not be real. This, of course, hurts patients too, by slowing progress. It is possible that the investigational drug that failed to show reliable results in a limited patient population might have done far better in a proper trial.
