

Factors predicting low patient accrual in cancer clinical trials

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Nearly one in four publicly sponsored cancer clinical trials fail to enroll enough participants to draw valid conclusions about treatments or techniques. Such trials represent a waste of scarce human and economic resources and contribute little to medical knowledge. Although many studies have investigated the perceived barriers to accrual from the patient or provider perspective, very few have taken a trial-level view and asked why certain trials are able to accrue patients faster than expected while others fail to attract even a fraction of the intended number of participants. According to a study published December 29 in the *JNCI: Journal of the National Cancer Institute*, a number of measurable trial characteristics are predictive of low patient accrual.

Caroline S. Bennette, M.P.H., Ph.D., of the Pharmaceutical Outcomes Research and Policy Program, University of Washington, Seattle, and colleagues from the University of Washington and the Fred Hutchinson Cancer Research Center analyzed information on 787 phase II/III [clinical trials](#) sponsored by the National Clinical Trials Network (NCTN; formerly the Cooperative Group Program) launched between 2000 and 2011. After excluding trials that closed because of toxicity or interim results, Bennette et al. found that 145 (18%) of NCTN trials closed with low accrual or were accruing at less than 50% of target accrual 3 years or more after opening.

The authors identified potential risk factors from the literature and interviews with clinical trial experts and found multiple trial-level factors that were associated with poor accrual to NCTN trials, such as increased

competition for patients from currently ongoing trials, planning to enroll a higher proportion of the available patient population, and not evaluating a new investigational agent or targeted therapy. Bennette et al. then developed a multivariable prediction model of low accrual using 12 trial-level risk factors, which they reported had good agreement between predicted and observed risks of low accrual in a preliminary validation using 46 trials opened between 2012 and 2013.

The researchers conclude that "Systematically considering the overall influence of these factors could aid in the design and prioritization of future clinical trials..." and that this research provides a response to the recent directive from the Institute of Medicine to "improve selection, support, and completion of publicly funded [cancer clinical trials](#)."

In an accompanying editorial, Derek Raghavan, M.D., Levine Cancer Institute, writes that the focus needs to be on getting more patients involved in [trials](#), saying, "we should strive to improve trial enrollment, giving the associated potential for improved results. Whether the basis is incidental, because of case selection bias, or reflects the support available to trial patients has not been determined, but the fact remains that outcomes are better."

Provided by Oxford University Press

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