



Trial Recruitment & Disparities Research: How multicenter institutional studies can improve enrollment.

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Problem

Trial recruitment remains an issue among many sites around the country and world. Frequently, sites are not meeting recruitment expectations set at study start-up by the sponsor or institution. Accrual is slow and/or goals are not met resulting in extra work to open and maintain sites for little return. Institutional studies (investigator-initiated trials or IITs) are often a priority for Cancer Centers, but trial recruitment continues to be a challenge for these trials where the infrastructure available to support the trials is small when compared to a large pharma company with more staff and resources.

Goal

Develop multicenter infrastructure to support engagement and recruitment from outside sites: Outside institutions may include affiliates associated with the institutional hospital system or satellite sites within the institution itself that the PI has oversight of.

Method

Worked with administration and Cancer Center leadership to write job descriptions for new or existing positions to support management of outside sites and developed relationships with hospital partners to engage the research teams.

Outcome

Since implementing the strategies outlined above, **accrual has increased over the past years for multicenter institutional trials from 2016 to 2018 by 39%**. Several trials have met accrual goals since the implementation of these plans in 2016.

Develop systems and processes to streamline study start-up and maintenance

Standardized procedures, guidance documents and SOP's were created to streamline multicenter coordination.

Indiana University's Clinical Trial Office currently manages 9 multicenter IITs with 24 active sites.

Meet realistic accrual goals: Identify potential studies to open at additional sites.

Considered opening trials at a multisite level. This allowed a PI to reach larger geographical areas and therefore have a larger patient population to offer their trial as an option. Sent newsletters as reminders that the trial was still ongoing.

Conclusions

While enrollment can be improved with the implementation discussed previously, there is always room for further growth. Streamlined processes and consistent systems should be considered for the best results. New policies and expectations take time to implement before an accrual growth is realized. Be aware the processes are always evolving and plan to adjust and refine current policies and develop new policies as required to meet the demands of an ever-changing oncology world. Have realistic expectations and understand the patient populations as well as the institutions you plan to work with prior to proceeding and including them in the trial. The use of advertising can be developed further with institutional policies considered prior to implementation.

Systematically increase predictability for accrual when selecting sites

Created a feasibility checklist for sites to complete that requested accrual numbers for the patient population to support recruitment prior to selecting a site. The feasibility checklist also determined if enough resources were available for site participation.

Make institutional PIs aware of such programs: PIs may not be aware that multicenter programs are available at their institution or an institution they may know colleagues.

Made PIs aware of such programs via email, standing meetings, or teleconferences.

