Development of a Clinical Trials Screening Coordinator Role and Workflow to Improve Recruitment

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Background:

A survey of oncologists from the Eastern Cooperative Oncology Group identified practical limitations such as excessive paperwork or additional time required as barriers that decreased physician clinical trial participation[1]. Yet, Campillo-Gimenez concluded that prescreening for clinical trial enrollment could be improved by a systematic review of medical reports.[2] Many institutions utilize clinical research coordinators (CRC) to assist in patient recruitment; however, studies show that many CRCs are already working more than their scheduled 40-hour work week managing patient care and the core responsibilities of the CRC[3].

Rationale:

The role of the Clinical Trials Screening Coordinator (CTSC) was developed at Moffitt Cancer Center (MCC) to improve the identification of potential clinical trial participants and increase physician engagement in clinical trials.

Methods:

- The CTSC position is stationed in the clinic as a central liaison and may be available to present informed consent if the CRC is otherwise engaged in other activities.
- The CTSC role requires experience in oncology clinical research and disease-specific knowledge.
- CTSCs collaborate closely with the trial's principal investigator and CRC to understand trial slot availability.
- This workflow has alleviated the stress of the CRC needing to see new patients at the same time as active trial patients.

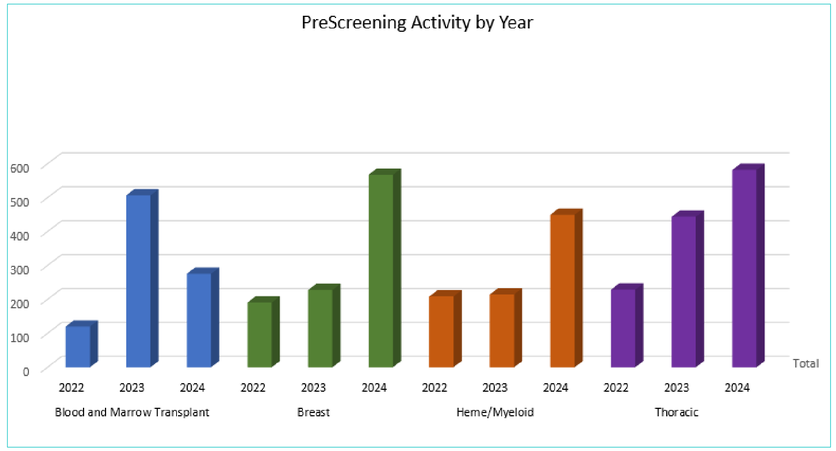
CTSC reviews physician schedule for new/potentially progressing patients against open clinical trial menu

Clinical team is notified of potential eligibility and barriers to enrollment on trial, such as pending genomic results

Physician presents clinical trial option during patient appointment

Outcomes

- This initiative was piloted in 2015 within a large disease program at MCC.
    - In 2022, two disease programs utilized CTSCs. As of January 2024, the number has increased to six disease programs who have CTSC roles.
- Programs with CTSCs have benefited from the timely identification of potential trial patients and improved communication among providers and research staff in determining patient eligibility.
    - There has been a greater than 50% increase in the number of pre-screened patients in these programs.
    - CTSCs also report a 24–48-hour turnaround time regarding eligibility.



Lessons Learned and Future Direction:

- The CTSCs convene monthly to discuss challenges, find solutions to common issues, and promote cohesiveness.
- The CTSC role has been proven to increase physician awareness of clinical trial availability and their satisfaction with accruing new patients to trial.
- CTSCs are shifting their prescreening to additional ambulatory centers.
- CTSCs have also begun to develop mitigation plans with research leadership for underperforming trials.
- CTSCs are working toward accrual strategies focused on underserved communities.

[1] Chen, L., Grant, J., Cheung, W. Y., & Kennecke, H. F. (2013). Screening intervention to identify eligible patients and improve accrual to phase II-IV oncology clinical trials. *J Oncol Pract*, *9*(4), e174-181. https://doi.org/10.1200/JOP.2012.000763

[2] Campillo-Gimenez, B., Buscail, C., Zekri, O., Laguerre, B., Le Prise, E., De Crevoisier, R., & Cuggia, M. (2015). Improving the pre-screening of eligible patients in order to increase enrollment in cancer clinical trials. *Trials*, *16*, 15. https://doi.org/10.1186/s13063-014-0535-7

[3] Speicher, L. A., Fromell, G., Avery, S., Brassil, D., Carlson, L., Stevens, E., & Toms, M. (2012). The critical need for academic health centers to assess the training, support, and career development requirements of clinical research coordinators: recommendations from the Clinical and Translational Science Award Research Coordinator Taskforce. *Clin Transl Sci*, *5*(6), 470-475. https://doi.org/10.1111/j.1752-8062.2012.00423.x