Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Work in Progress

Expansion of Clinical Trials to the Moffitt Ambulatory Centers

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1. Background
Moffitt Cancer Center is focused on growing services through the introduction of Moffitt Ambulatory Centers (MACs), designed to expand our network of ambulatory clinics across the Tampa Bay area. The Clinical Trials Office (CTO) has brought the expansion of clinical trial opportunities to the forefront of this mission. To do so, it is important to develop and stabilize a priority pathway for identifying and activating research studies that continue to offer hope with more convenience and accessibility to patients.

2. Goals
Maximizing access to clinical trials closer to home, achieved by:

- Enhancing clinical trial portfolio performance through investigator engagement, feasibility assessment and workflow optimization
- Developing site management plans and clinical trial prioritization
- Supporting study team growth, cross-training and multi-specialty collaboration
- Clinical research integration, education, and adaptability into clinical pathways
- Maximizing prescreening efforts and upscaling research-related clinical encounters
- Providing optimal patient care, offering consistency and flexibility in scheduling, per patient preference, at each Moffitt location

3. Solutions and Methods
The CTO developed a MAC trial evaluation process, accomplished through a 3-phase approach consisting of a) protocol assessment and feasibility review, b) operational review, and c) an implementation checklist. This trial selection and priority pathway is a standardized mapping tool that illustrates opportunities and limitations in what trials can be operationalized at the MACs.

4. Outcomes
Expansion of clinical trials at the MACs requires additional clinical trial resources that better help the CTO align process workflows from the perspective of MAC operations, allowing the CTO to analyze and further optimize best practices that promote patient care satisfaction and understanding of their clinical trial participation.

- Creation of resources: Site Management Plan, Clinical Trials Dashboards, Referral Tools, Work Instructions, Procedures Matrix, Trial Priority Table/Score
- Approximately 274 clinical trial protocol assessments conducted
- Standardized integration plan of clinical trial workflows and workspace into future MAC building designs and clinic layouts
- Increased clinical trial activity at the locations with 12 treatment trials opened, 31 patients referred and enrolled resulting in a 31% increase in number of trial treatments occurring at a MAC, with 1.4 percent of research-related clinical encounters occurring at a MAC

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5. Lessons Learned and Future Directions

Initially, only clinical trials that were already open at primary locations were operationalized at the MACs. Through exploration, we learned there is greater efficiency in evaluating the suitability of MAC trial opportunities during the site activation process. We have gained further insight in better understanding patient populations seen at the MAC locations through investigator engagement and development of clinical trial provider champions, which we anticipate will increase clinical trial opportunities, activity and accruals. To understand effectiveness and productivity, we will introduce a fourth phase in reassessing clinical trial activity at 90-day intervals to determine future refinements.