

Deployment of a Cancer Population Science Clinical Research Navigator to Improve Engagement with CPS Investigators

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1. Background

The UF Health Cancer Center (UFHCC) Clinical Research Office (CRO) is responsible for tracking and reporting all cancer relevant research activity, including Cancer Population Science (CPS) research. Historically, the CRO had limited interactions with CPS investigators and study staff, and therefore CPS study activity was not routinely captured. In 2017, a new requirement for all cancer research to undergo Scientific Review and Monitoring Committee (SRMC) review led to improved knowledge of new studies in the CPS area. However, obtaining ongoing updates for study progress proved difficult and some CPS investigators expressed frustration with navigating the regulatory processes. As a result, CRO established a designated CPS Navigator team to assist investigators with navigating study activation and ongoing review processes while simultaneously fostering working relationships with CPS staff.

2. Goals

- Improve the capture of protocol status and accrual information within the Clinical Trials Management System (CTMS), OnCore
- Enhance communications with CPS staff by providing support to navigate institutional research requirements to deploy and maintain study portfolios

3. Solutions and Methods

During SRMC review, periodic updates were sought by CRO staff by contacting CPS teams for protocol status and accrual updates. In early 2018, a dedicated Regulatory Specialist was hired to help navigate CPS trials through protocol activation and the IRB process. This incremental hire allowed management of IRB submissions for CPS investigators as long as accrual updates were provided on a regular basis. This hire also supported entry of accruals and study status updates into OnCore. This dedicated resource subsequently led to increased requests for trial support. A second staffer was hired shortly thereafter who possessed both regulatory and study coordination experience, given the diversity of CPS-style studies conducted at UFHCC. Together, this CPS Navigator team utilizes a shared email address so that all messages are shared allowing for improved communication and cross coverage.

4. Outcomes and Future Directions

From January 2017 through May 2018, only 23 new CPS studies were known to the center and accrual updates were non-existent. Upon deploying the CPS Navigator team, we identified and logged roughly 750 accruals associated with these studies. An additional 16 new CPS trials were subsequently activated with cumulative enrollments exceeding 3800 subjects by the end of 2018. Through efforts of the CPS Clinical Research Navigator team, the number of studies identified and accruals tracked increased exponentially due to the CPS study accruals actively being entered into OnCore. Communications and

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engagement between the CRO and CPS investigators through the CPS Navigator Team have similarly improved.

Early on we discovered that many CPS and UFHCC CRO staff members did not share a common research lexicon. CPS Navigator staff had to modify messaging and reduce technical language/acronyms with CPS staff who were unfamiliar with UFHCC and NCI reporting requirements. Reciprocating, CRO staff needed to expand their working knowledge of clinical research study types and interventions. Clarity regarding accrual reporting was also provided, to prevent under and/or over reporting of accruals, especially for trials that were multisite. A future goal is to scale the program services to offer more bandwidth as CPS program faculty ranks expand.