*Category: Clinical Trial Operations – Work in Progress*

**From Take-Off to Landing: The Creation and Implementation of a CCPS Navigator Resource**

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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 and also provides infrastructure for the Protocol Review and Monitoring System (PRMS) process. The CRO quickly identified that Cancer Control and Population Sciences (CCPS) study teams needed additional support to navigate the UFHCC review process and centrally report protocol status updates and subject accrual information. The CRO historically has relied upon CCPS investigators/staff for these functions with resulting inconsistencies when capturing CCPS study activity. In December 2018, the CRO responded by creating a full-time CCPS navigator position to provide assistance and guidance in an effort to address the inconsistencies noted and improve research efficiencies throughout the protocol lifecycle.

**2. Goals**

- Enhance CCPS investigators' understanding of ancillary review processes
- Improve protocol review efficiency during the two-stage PRMS process
- Improve capture of subject accrual entry and data maintenance
- Streamline distribution of information

**3. Solutions and Methods**

- Creation and integration of "navigator" position
    - Direct contact for study activation, including triage through PRMS review process
    - Liaison between CRO; CCPS research program; and Community Outreach, Engagement, and Equity program (COEE)
    - Support for integrating CCPS interventions into clinical settings (workflow, logistics)
- CCPS protocol template development and deployment
    - Resource for more efficient PRMS review of CCPS protocols
    - Template captures key areas of review required by PRMS and IRB
- CCPS data management plan
    - Clearly defined CRO expectations for data capture and accrual entry
- CCPS navigator webpage
    - Central distribution of resources and relevant clinical research information

**4. Outcomes**

- Enhanced connections between CCPS investigators, COEE program, CRO, and the clinicians → Use of navigator service to connect lead investigators to disease-site clinicians relevant to study design and patient population needed for recruitment
- Decrease review timeline with SRMC → Creation and distribution of a protocol template to reduce SRMC queries and requested revisions

- Improved efficiency of data collection, capture, and protocol activation

The CCPS navigator facilitates CCPS study activation, regulatory maintenance, and timely data collection and entry. With deployment of this resource, CCPS investigators now demonstrate an improved understanding of the PRMS review process; increased logistical support for deployment of interventional studies in clinical areas; and improved, routine (monthly) capture of accrual activity and protocol status allowing for accurate, real-time analysis of the CCPS research portfolio.

**5. Lessons Learned**

- Integration of a new resource must be organic and develop from invested stakeholder needs
    - CCPS leadership advocacy for navigator use is key, as are investigator testimonials regarding efficiencies gained and overall value of the resource
    - New CCPS needs assessment planned for late 2021
- Creation of educational modules specific to CCPS faculty and staff needs
    - General information about the cancer diagnosis and treatment lifecycle
- Extension of CCPS support into other, already established areas of the CRO
    - Extend enhanced assistance with protocol authoring and study development/activation through the Project Management Office

**Figure:**