Development of a Navigation Tool to Guide Investigators from the study Concept, through the First Stage Review to the Cancer Center Scientific Review

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BACKGROUND

Scientific review of clinical protocols is an NCI expectation for cancer centers[1]. Processes as to which types of protocols required first-stage review, which types of protocols were exempt from the protocol review and monitoring committee (PRMC) review, and how these operations and composition differed were poorly defined at the **University of Vermont Cancer Center (UVMCC).**

This led to confusion and frustration on the part of investigators, delays in study development and evaluation, and a breakdown in collaboration among investigators and clinical trials office (CTO) staff.

GOALS

To develop a navigation tool for investigators and transdisciplinary team (TDT, disease-focused first stage review groups) leaders that:

- define and improve the efficiency of protocol review,
- shortens study processing times, reduces stakeholder confusion and frustration, and
- supports and improves collaboration among investigators and clinical trials office staff.

Figure 1: UVMCC PRMS Pathways Overview

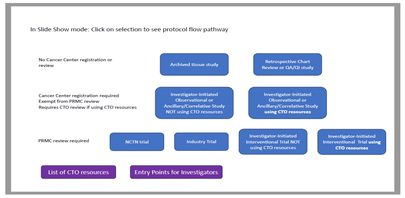


Figure 2: UVMCC PRMS Pathways for NCTN Trials

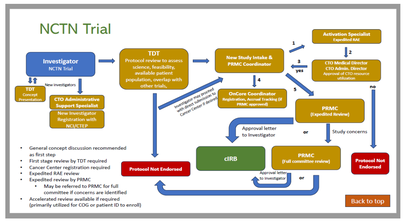


Figure 3: UVMCC PRMS Pathways for Industry-Sponsored Trials

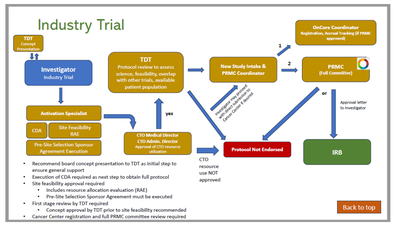


Figure 4: UVMCC PRMS Pathways for Interventional Investigator-Initiated Trials with CTO Resources

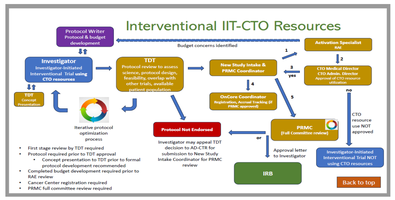
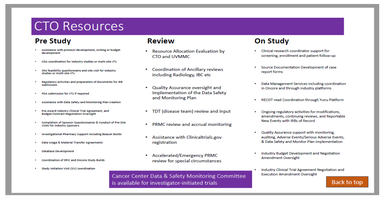


Figure 5: List of UVMCC CTO Trial Resources for Investigators



METHODS & SOLUTIONS

We developed a user-friendly web-based navigation tool that clearly defined delineated pathways of study review for investigator-initiated, national cooperative group, and industry trials, and it guided appropriate review pathways for non-interventional and correlative research studies.

OUTCOMES

Immediate implementation outcomes included:

1) investigators and TDT leaders developed an improved understanding and acceptance of NCI review processes;
2) investigators developed an improved understanding of the role of the clinical trials office in the protocol review process;
3) a clearly defined and delineated point of entry to the protocol review and monitoring system.

Anticipated outcomes for which data is currently being collected:

1) improved process review timelines for studies, particularly investigator-initiated trials;

2) greater acceptance of TDT leadership role and responsibilities in the first stage review process.

LESSONS LEARNED & FUTURE DIRECTIONS

- Before the navigation tool implementation, investigators were not cognizant of the various activities performed by the clinical trials office staff or the amount of effort in shepherding protocols through the system.
- Confusion about the processes led to frustration and reduced enthusiasm to develop and activate trials.
- Since this time, investigators have had less confusion and frustration, and improved collaboration among the clinical trials office staff.
- Further, the navigation tool has resulted in an increased number of protocols in development. When implementing new tools, early investigator education is pivotal to enhancing engagement, collaboration, and robust clinical trials efforts.

ACKNOWLEDGEMENTS

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- UVMCC Clinical Trials Office
- UVM Institutional Review Board
- Faculty & Staff across TDTs participating in the implementation

REFERENCES

1. https://grants.nih.gov/grants/guide/pa-files/PAR-21-321.html