Comprehensive Application of Supplemental Phantom Educational Resources (CASPER): A Friendly Phantom Patient to Guide the Way for New Study Coordinators

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Background

The Clinical Trial Office (CTO) at the Barbara Ann Karmanos Cancer Institute, an NCI-Designated Comprehensive Cancer Center, created an enhanced formal orientation program (EOP) in December, 2016 for all new employees. This program consists of 22 modules that review the basics of oncology, clinical trials, different research departments, and role specific topics. The EOP typically spans eight weeks and is designed to be completed prior to the coordinators starting individual study workloads. To date, 38 groups (over 200 employees) have completed the EOP. All orientation groups have been given a Post-Orientation Survey that asks what they liked about the program and allows for suggestions regarding how the program can improve. Multiple groups expressed a desire for more interactive modules to reinforce the instruction. In February 2021, it was decided to create a phantom patient to supplement the original EOP.

Methods Implemented

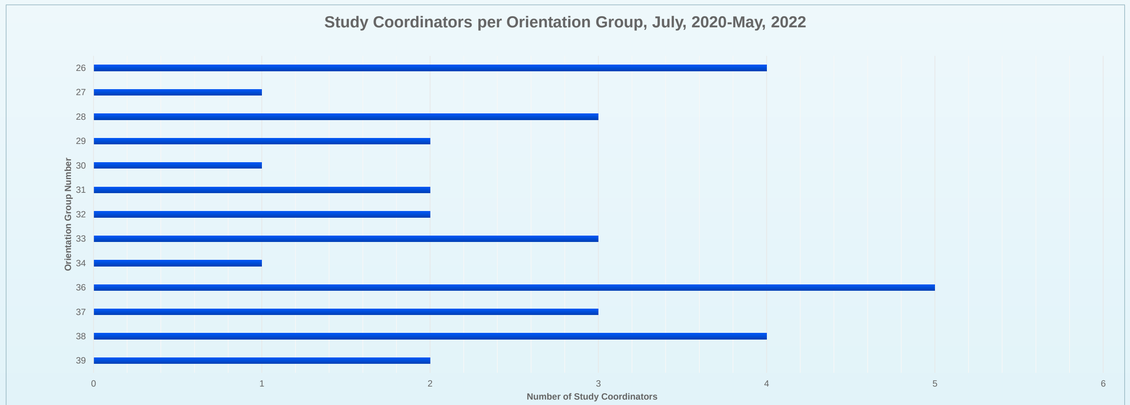
Three interactive Phantom Patient Modules (PPM) (introduction, informed consent, eligibility review and registration; deviations, tumor tracking, adverse events; source document creation, EMR exposure, and protocol treatments; with all modules reviewing applicable policies) were created. The PPM are attended in tandem with the EOP to allow Study Coordinators (SC) to become familiar with the processes introduced in the modules.

To ensure comprehensive exposure, three studies were chosen to represent a broad spectrum of disease types, treatment methods, and sponsor variety. The PPM follows three phantom patients through their respective studies to reinforce the instruction of the EOP. In order for SC to review the patient-specific study procedures, each phantom patient has a corresponding shadow chart that utilizes information from real patients, who have enrolled on these studies. The redacted shadow charts were uploaded into MS Teams and Veeva Site Vault in order to protect PHI.

Phantom Patient Module	EOP Module
Introduction to the Phantom Patient	Orientation Overview
	Introduction to Clinical Trials
	The Research Team
	Oncology 101 & Assessment of the Patient
	Self-Study: Moving Toward Better Cancer Treatment - Getting Involved with Clinical Trials
Phantom Patient Module #1	The Research Protocol & Review of Eligibility
	Regulatory "Human Research Protection & Review of the Regulatory Coordinator"
	Informed Consent
	Oncore Review
Phantom Patient Module #2	RECIST 1.1
	Shadow Charts & Source Documents
	CTCAE Toxicities
	Serious Adverse Events & Deviations
	Overview of NCI Studies
	Self-Study: Introduction to Vestigo
Phantom Patient Module#3	Central Data Management & The Network
	Quality Assurance & The DSMP
	90 Day Activation
	Pre & Post Awards
	Monitoring Visits
	End of Orientation Wrap Up

Goals

- Address repeated requests from orientees to follow a patient through the trial process
- Allow hands-on practice for new CTO SC, including review of patient documents for study-related procedures
- Promote greater familiarity with study processes in order to increase SC proficiency
- Provide examples of tools (adverse event, deviation, and medical history logs, emails to physicians, and note-to-file templates) to assist SC with developing personal methods and behaviors to comply with CTO expectations and policies



Results

The PPM were implemented in February 2022 with the initial group consisting of employees who recently completed the EOP. Throughout the course of the modules, positive feedback was received from participants, indicating they felt more comfortable with the eligibility and registration process and learned new ways to navigate the EMR. One participant's supervisor reached out in order to make special note of how the program positively impacted the SC comprehension of CTO processes and productivity. Further follow up with participants and their supervisors is planned to determine if there is a greater understanding of the CTO processes once the participant receives their workload.

Recommendations

Segments of the PPM were initially planned to be incorporated into the EOP modules; however, after discussion with EOP module presenters, it was determined that separate PPM would be more beneficial to the orientees.

After presenting the first module, an introduction session was created, in order to provide more in-depth instructions regarding expectations and the location of documents needed during the PPM. The creation of this stand-alone introduction module allows more time to be spent on the eligibility and registration process.

Conclusion

In April 2022, one series of the PPM was completed. In May 2022, the second series of PPM commenced with SCs currently undergoing the EOP.

Although the PPM is a new addition to the EOP, it does appear that these supplemental modules are making a positive impact on the overall competencies and confidence of the new SC.

In the ever-changing landscape of clinical trials, further follow-up and modifications to the program are planned, in order to keep the program current, beneficial, and relevant to the new orientees.