

Trials and Triumphs! Implementation of a Phase I Clinical Trial Program in a Community-based Hospital

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Trials and Triumphs! Implementation of a Phase I Clinical Trial Program in a Community-based Hospital

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SIGNIFICANCE AND BACKGROUND

Lehigh Valley Cancer Institute (LVCI) is a rapidly growing cancer center located in a community-based setting. Through the inception of pharmaceutical clinical trials in 2010 and a longstanding history with cooperative-group studies, LVCI has been a mainstay for patients seeking innovative clinical trial treatments. With the determination to offer the highest quality, state-of-the-art cancer care to our local community, LVCI recognized the need for expansion into Phase 1 clinical trials. Phase 1 clinical trials require immense knowledge and clinical coordination in order to be conducted safely and in protocol compliance. They are very sophisticated studies and involve multiple pharmacokinetics, cardiac monitoring, and rigorous nursing assessments.

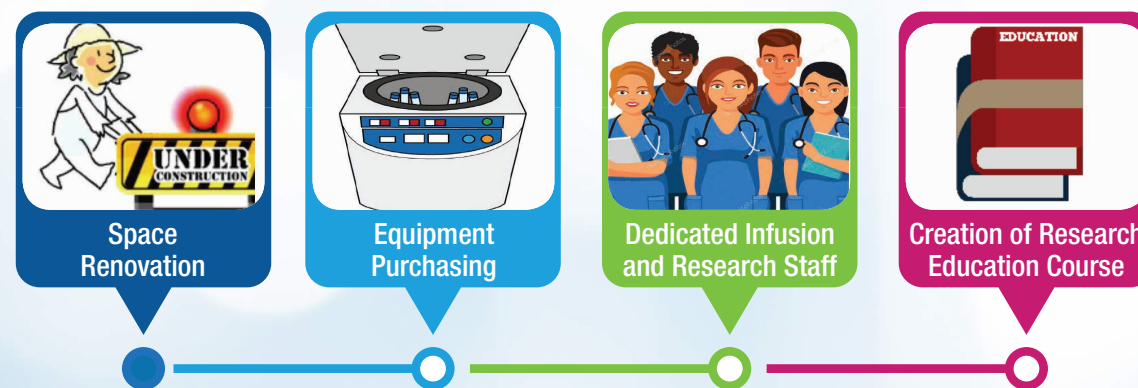
PURPOSE

LVCI has successfully conducted over 100 clinical trials in phases II-IV. Therefore, it became evident the implementation of a Phase I program would be the next step to continue to bring breakthrough care to our patients in the community setting. LVCI understood the comprehensive care that Phase 1 clinical trials demand, but determined it was imperative to offer this to our patients closer to home. The implementation of the Phase 1 program required complete infrastructure development, including space construction and equipment purchasing, creation of a core nursing team and development of research-specific education.

INTERVENTION

A Phase 1 Work Group was created and included nurse leaders from Clinical Trials, staff from the Cancer Institute and the Physician-in-Chief. The work group first determined that dedicated space was needed for the Phase 1 patient. Three private phase-1 infusion rooms now include cardiac and vital sign monitoring and a phase-1 lab work room was constructed. Equipment for the work room was purchased and contains a -20C freezer, refrigerated centrifuge, and a designated area for research lab technicians.

STEPS TO IMPLEMENTATION OF A SUCCESSFUL PHASE I PROGRAM



The success of this program was also in choosing dedicated staff nurses, in both clinical research and infusion, to lead the phase I program. A core team of expert oncology nurses were nominated to operate the Phase 1 clinical trial program. A continuing education course was created by the Oncology Clinical Trials Supervisor RN and Clinical Nurse Specialist focusing on research basics, navigation of a research protocol, toxicity management and grading for nurses, documentation requirements, and case discussion. The course is offered quarterly to infusion and clinical research RNs as a requirement to participate in care of the Phase 1 patient.

RESEARCH EDUCATION COURSE OUTLINE

Introduction to Research	<ul style="list-style-type: none"> • Introduction to Research • Types and Phases of Research • Lehigh Valley Cancer Institute Specific Research Process
Navigation of a Research Protocol: The Basics	<ul style="list-style-type: none"> • Protocol Scavenger Hunt • Disease Response Assessments
Toxicity Management and CTCAE Grading Criteria	<ul style="list-style-type: none"> • CTCAE Criteria • Serious Adverse Events
Documentation Requirements	<ul style="list-style-type: none"> • Informed Consent • Electronic Medical Record Review
Case Scenarios	<ul style="list-style-type: none"> • Group Discussion of Research Patients • Application of Protocol Guidelines to Patient Scenarios

RESULTS AND CONCLUSION

There are multiple layers to implementing a Phase 1 program in the community setting. Proper facilities to perform clinical research is key in early phase trials. Dedicating space, core nurses, and research specific education is imperative to successful delivery of expert patient care in a safe and protocol compliant environment.

As a result of proper planning, our program passed our Resources and Capabilities survey. The program is now equipped and staff is properly trained to conduct Phase I clinical trials.