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

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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.

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.