CREATING THE STANDARD FOR SPECIALIZED NURSE TRAINING IN THE PHASE I CLINICAL TRIALS SETTING

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Phase I Unit Overview

- 15 Private Treatment Rooms
- 4 Private Clinic Rooms
- 3 Fast Track Areas
- Collaborative Care Team Stations
- Translational Lab
- Multidisciplinary cohesive clinic and infusion care integration
- “One Stop Shop” Care Model
- Designed with unique integrated facility design emphasizing integration of high quality patient care and accurate research conduct
- 200 + patients enrolled to Phase I Trials annually

Phase I RN Role Summary

- Advanced certification required
- (i.e.: OCN, BMTCN)
- CITI Training and Good Clinical Practice (GCP)
- Phase I Trial specific orientation
- Comprehensive understanding of protocol navigation
- Detailed assessment and documentation to allow accurate CTCAE grading
- Conceptual understanding of the importance of quality data collection within mandated protocol time points

Advanced Training

- Collaboration during each patient visit: research coordinator, lab specialist, pharmacist, RN, APP, MD
- Creation of nursing considerations documents outlining data collection time points during treatment visits
- Required RN training prior to study opening
- Pre trial huddle with nursing staff and research team to review research procedures and pharmacy orders prior to first patient enrolled on a new study
- Comprehensive review of protocol navigation: contraindicated medications, windows within data collection time points and safety precautions associated with investigational drugs
- Review of study drug mechanisms of actions

Plans for Future Growth

- Further development of a standard training manual and training classes for phase 1 orientation
- Development of educator role, specific to phase 1 clinical trials
- Development and monitoring of metrics to track quality control, patient satisfaction and clinical practice