

Smooth Sailing... Cellular Immunotherapy Trials Collaboration and Integration Process

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1. Background

The rapid expansion of cellular immunotherapy trials at our institute has required a new operational process involving the clinical trials office, clinical, and cell therapy groups.

Cellular Immunotherapy Trials involve CAR T, TIL, BITE and TCR cell therapies. These cellular immunotherapy trials present logistical challenges that require increased communication and planning. Responsibilities, training, and effective communication between all areas were lacking formality and definition. Therefore, focused improvements for these types of trials in particular were necessary.

Compared to the Huntsman Cancer Hospital (HCH) outpatient clinic staff, the HCH inpatient staff assignments frequently rotate shifts and providers, thus communication, education, and training of key personnel was critical to ensure patient safety and trial compliance.

2. Goals

- Provide education on operational processes to involved parties
- Integrate current workflows between the clinical trials office and clinical managers to enable patient care that adhere to protocol requirements
- Appoint clinical research nurse liaison to help facilitate the operational processes

3. Solutions and Methods

- Holding monthly cellular immunotherapy focused meetings with clinical trials office and clinic management to discuss upcoming/active trials, enrollments, issues, positive outcomes, and trends
- Developing a shared, trial specific cellular immunotherapy tracking spreadsheet used by all committee members was especially useful during the COVID-19 pandemic for communication between groups
- Holding clinical logistics meetings prior to a site initiation visit and at the time of first enrollment, attended by investigators, hospital, clinical research, and cell therapy groups
- Providing trial specific nursing instructions, fast fact sheets and contact information provided pre-site initiation visit
- Training clinical trials office clinical research coordinators and clinic nurses on the new process implemented
- Inpatient management identifying a skilled and focused nursing team to care for the clinical research immunotherapy trial patients with ongoing training provided
- Promoting a consistent theme across groups for our clinical trial patients' safety

4. Outcomes

- Increased cohesive, collaborative, and unified environment between all areas that care for patients enrolled to these complex trials
- Meeting regularly alleviates potential exacerbation of issues due to the consistent communication between meeting members
- Having an operational system solidified helps new staff know their role and responsibilities

Category: Trial Start-up, Activation, and Protocol Development – Work in Progress

- Clinical trials office has appointed a solid tumor physician liaison to ensure consistent collaboration and education between the BMT/inpatient teams and principal investigators

5. Lessons Learned and Future Directions

- Analyze deviation trends pre/post process implementation
- Develop a survey to measure process improvement
- Evaluate Report and Learn* trends since implementation

**Report and Learn = EMR (Epic) application to report issues contemporaneously for resolution, corrective action, and improvements.*