Smooth Sailing… Cellular Immunotherapy Trials Collaboration and Integration Process

Susan Sharry, BS, CCRP, Catherine Cromar, BS, Leanne Lujan, BS, CCRP, Jessica Moehle, BS, CCRP, and Karen Pena, CCRP

BACKGROUND

With the rapid increase in the number of cellular immunotherapy trials in the solid tumor and hematology areas at our institute, an apparent need was identified for a new operational process involving the clinical trials office, hospital/clinic and cell therapy groups.

Cellular Immunotherapy Trials involve CAR-T, TIL, BITE and TCR cell therapies. These cellular immunotherapy trials involve new complex science concepts and procedures that presented logistical challenges and the increased need for communication and planning on each new trial. Responsibilities were not clearly defined and training, education and effective communication between all areas were lacking formality and focused improvements for these types of trials in particular were necessary.

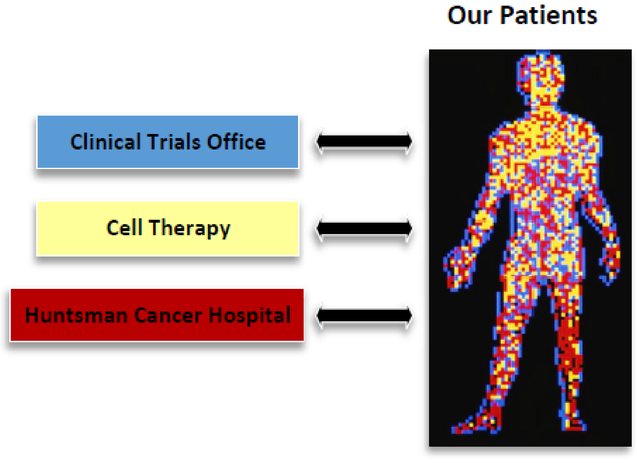
In comparison to the Huntsman Cancer Hospital (HCH) outpatient clinic staff, the HCH inpatient staff assignments rotate throughout the day/night and due to various health care providers, communication, education, and cross-training of key personnel was critical to ensure patient safety and trial compliance.

METHOD

- Provide education on departmental operational processes to the clinical trials office, hospital/clinic and cell therapy groups.
- Integrate current workflows between the clinical trials office and the hospital/clinic managers to enable seamless patient care while adhering to the complex protocol requirements.

RESULTS

- Monthly Clinical Trials Office Cellular Immunotherapy focused meetings with clinical trials office and hospital/clinic management to discuss updates on upcoming and active trials, issues, positive outcomes and trends.
- Development of a trial specific cellular immunotherapy tracking spreadsheet used by all committee members in Microsoft Teams was especially useful during the COVID pandemic for excellent communication between groups.
- Clinical logistics meetings were implemented to be held prior to a Site Initiation Visit and attended by PI, investigators, hospital, clinical research and cell therapy groups.
- Trial specific nursing instructions, Fast Fact Sheets on the protocol and contact information are provided pre-Site Initiation Visit.
- Training of clinical trials office Clinical Research Coordinators and clinic nurses on the new process implemented.
- Inpatient management identified a skilled and focused nursing team to treat and care for the clinical research immunotherapy trial patients with ongoing training provided.
- Promote a proactive and constant theme across groups for our clinical trial patients' safety.



CONCLUSIONS

- There is now a much better understanding of what challenges each group faces, while also seeing a more cohesive, collaborative and unified environment between all areas that care for patients enrolled to these complex treatment trials.
- The process is seamless and meeting regularly alleviates potential issues from growing into a problem due to the regular and consistent communication between meeting members.
- Cross training of staff continues and having an operational system solidified helps new staff know their role and responsibilities.
- Hospital administration will create the new position of inpatient/clinical research nurse liaison to help facilitate the operational processes on both sides.

FUTURE PLANS

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

**Report and Learn is a system in our EMR (Epic) where research and clinical staff may report issues in real time for resolution, corrective action and site-wide improvements.*

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