

THAW – The Holistic Approach for Working in Cellular and Gene Therapy Clinical Trials

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1. Background

Execution of cellular and gene therapy trials is highly complex and requires multidisciplinary interactions (cell therapy/transplant program, transfusion medicine, oncologic sub-disciplines, inpatient and outpatient patient care units) for which the research team is the core. The rapidly growing number of clinical trials in this area and their diversity across hematologic and solid tumor indications are some of the challenges that face an organization that wishes to operate in this innovative field. The Clinical Protocol and Data Management (CPDM) office began this cutting edge cancer and non-cancer research with its first gene therapy protocol in 2016. Since then, CPDM has developed a dedicated research team facilitating the execution of Cellular and Gene therapy protocols for varying indications from Sickle Cell to large cell carcinoma.

2. Goals

- Solidify processes with workflow guidance documents and standard operating procedures specific to cellular and gene therapy protocols
- Create a dedicated feasibility committee to thoroughly review potential studies to ensure success in clinical trial facilitation and selection
- Create a dedicated research cell therapy lab focused on clinical trials
- Further expand by placing CPDM personnel in partnering departments to facilitate collaboration
- Collaboration of different oncologists throughout the hospital and CPDM office

3. Solutions and Methods

CPDM recognized the need for a team dedicated to the cellular and gene therapy protocols. As such, a senior CRC position was created and a data coordinator was assigned to supplement the efforts of the initial research nurses, CRC, and CRM. Detailed tracking mechanisms were implemented by the Clinical Research Manager to monitor all protocol processes from start-up through overall trial progress. Weekly meetings to review the tracker and protocol progress supplement the weekly disease team meetings. Updates are discussed surrounding current patients as well as study start-up specifics for new trials.

Additionally, Outlook calendar entries were created to house all information pertaining to patient visits for cellular therapy/gene therapy protocols. All manuals, subject documents, protocol documents, and visit information are located on this calendar for cross-departmental simultaneous viewing. The calendar entry is distributed to all personnel (leukapheresis nurses, physicians, research nurses, CRCs, etc.) prior to the study visit.

Furthermore, a departmental SOP outlining the roles and responsibilities when facilitating cellular and gene therapy clinical trials was developed. The SOP references supplemental workflow documents created to assist and reinforce trial procedures.

4. Outcomes and Future Directions

Since its inception and implementation in 2016, 8 cellular therapy and gene therapy protocols have been opened, 17 patients have been enrolled, and 12 patients have been treated. With each enrollment, the study team continues to grow and assess the new processes set forth by the department. We anticipate opening 8 new trials in the coming year.

The implementation of the aforementioned processes streamlines communication, minimizes confusion, and provides structure for protocols with cross-departmental responsibilities. With that said, the processes are still in the beginning phases of execution. The cross-communication techniques will continue to be refined to ensure each subject's clinical trial experience goes as seamlessly as possible. In anticipation of opening protocols with solid tumor disease origin, we anticipate doubling those numbers by the end of 2020.