

Operationalizing a New Therapy Across Research Groups: A Team-Based Approach to Managing CAR T Clinical Trials

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1. Background

The expansion of CAR T-cell therapy in oncology research has been experienced by the Research Program at the Cleveland Clinic. As more cell therapy trials opened and patients enrolled, functional challenges of these complex trials were identified, and action plans were developed to address issues as they arose. At the beginning of 2020, momentum increased for CAR T therapy and a need to develop a formal team-based operations plan of starting up and managing these trials was identified.

2. Goals

The goal was to develop a Cellular therapy Assist Team (CAT), a core group of researchers with specialized CAR T clinical trial knowledge, as a means to assist research groups in running CAR T-cell therapy trials, increase collaboration across groups, provide education on cellular therapy, and ensure the research department has adequate resources and personnel in order to successfully run cellular therapy trials. A secondary goal was to increase the number of CAR T trials and increase the number of patients enrolled on these trials compared to previous years.

3. Solutions and Methods

The CAT is housed in the Blood and Marrow Transplant (BMT) research group and includes a lead physician, lead research nurse, and BMT data/regulatory supervisor. Department physicians alert the core team when there is interest in a new cell therapy trial. The CAT's involvement includes reviewing the protocol, assisting in completion of sponsor site feasibility questionnaires, participating in an internal feasibility review, involvement in cell therapy-specific budget creation, assisting with site Institutional Biosafety Committee application and approval, facilitating communication between research groups and the apheresis department and cell processing lab, coordinating location of infusions between inpatient and outpatient units, and training outpatient personnel on cell therapy infusion protocols and safety. The core group communicates frequently via email and meets every two weeks. A larger CAT group comprised of the core group along with physicians from the leukemia, myeloma, lymphoma, melanoma, Phase I, and thoracic oncology research groups meet every other month to review the cell therapy portfolio, assess any challenges/feedback, brainstorm new ideas and processes, and provide education opportunities.

4. Outcomes

From 2015-2019, six CAR T-cell clinical trials were opened to accrual within the Lymphoma and BMT Research Programs and 16 patients received treatment on these studies. In 2020 alone, there were eight clinical trials opened, a 400 percent increase compared to the two trials in 2019, and 18 patients enrolled, a 300 percent increase compared to the six patients enrolled in 2019. Additionally, there was expansion in the number of research groups that opened cell therapy trials. Groups that opened trials include BMT, lymphoma, myeloma, melanoma, and lung research groups.

5. Lessons Learned

As research in cellular therapy continues to grow, sites must continue to grow their resources and knowledge in order to operationalize these complex trials. The increase in both the number of clinical trials and patients enrolled to CAR T-cell clinical trials after formation of the CAT demonstrates the need for continuation and expansion of this team-based approach. Future efforts include incorporating CAR T budget specialists into the CAT and expanding cellular therapy infusions in the outpatient setting.

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