

## **Optimizing Clinical Trial Conduct for CART Therapies Improves Trial Efficiency**

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### **1. Background**

There is exponential growth in clinical trials investigating chimeric antigen receptor (CAR) T-cell therapy to treat cancer in the recent years. At Mayo Clinic, the number of trials has grown six fold over the last 4 years with more on the way. CART trials have complexities not traditionally found with other pharmaceutical protocols due to the multi-disciplinary teams involved with the individualized manufacturing of CAR-T cells, the highly specialized expertise for clinical management, and complex data reporting.

### **2. Goals**

We created a CART clinical trial standardized operation process (SOP) with the intent of improving efficiency in the trial conduct and improving the overall experience for the study team and clinical providers. We examined CART trial cases prior to 2019 in order to identify areas of need for a CART trial SOP, and implemented the practice in January of 2019. Our goals were to reduce deviations and data reporting delays, as well as increase provider and sponsor satisfaction during the time period of January 2019 to July 2019.

### **3. Solutions and Methods**

We examined trial requirements including data reporting time constraints and monitoring visits, and inspected trial outcomes such as coordinator efforts for each stage of the trial conduct, the number of deviations, and effort spent clearing queries. We interviewed study monitors, sponsors, and clinical providers regarding challenges for efficient patient care and study conducts. In our assessment, we identified challenges in these common areas: scheduling logistics, meeting study specific requirement in addition to complex standard of care practice, and complex data entry. We worked with the CART program medical director, clinical lab personnel, and providers to develop an SOP for CART trial conduct. This SOP documents the expectations and responsibilities of the different roles in CART trial conduct. Contracts have been updated to allow more monitors per visit, increased number of visits, and additional monitor rooms at our site. In order to continually advance the practice, touch point meetings with key members of the inpatient clinical staff are scheduled monthly.

### **4. Outcomes**

Deviations per accrual decreased from 2.24 for CART trials prior to 2019 to 0.857 after implementation in January 2019 ( $p = 0.031$ ). The data entry efficiency improved along with query responses, and we are able to more effectively stay on schedule for task completion. Better reporting outcomes led to an increase in the sponsor and monitor satisfaction. Providers reported an increase in satisfaction due to improved communication among the inpatient and outpatient clinical staff, as well as the reduction in repetitive communication amongst the care team.

## **5. Lessons Learned**

Despite the novel complexities involved with CART, we discovered ways to standardize the approach and improve trial efficiency. The standardization of communication practices and continual meetings with all involved departments proved to be necessary for the success of a CART trial. Lessons learned from this practice can be extended to other trials with complex processes. The SOP, in fact, is being implemented at our institution to other trials requiring coordinated inpatient and outpatient care and serves as the groundwork for new complex trial development in the immunotherapy space.