

## **Moving Cellular Therapy Clinical Trials in the Outpatient Setting: Aligning With Institutional Standards and FACT**

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### **1. Background**

Until recently, cellular therapies (CT) were mostly administered inpatient with around-the-clock care, staff familiar with Foundation for the Accreditation of Cellular Therapy (FACT) standards and trained in FDA required Risk Evaluation and Mitigation Strategy (REMS). Providing safe patient care can be challenging with complicated CT trials and requires detailed patient education and monitoring. Converting investigational CT to the outpatient setting and aligning with FACT standards, creates many obstacles. With a plan to grow CT research, City of Hope (COH) recently transitioned multiple CT trials to the Briskin Center for Clinical Research (BCCR), an outpatient oncology research unit providing therapeutic first-in-human (FIH) through Phase 3 trials.

Challenges included: process development to align with standard of care (SOC), FACT knowledge gaps of BCCR treatment staff, numerous investigational CT treatments, and advanced planning for CT study requirements.

### **2. Goals**

To meet these challenges, BCCR aimed to:

1. Innovatively adjust BCCR schedule for growing needs of CT studies.
2. Align SOC and research CT policies, ensuring safety and FACT requirements.
3. Manage resources associated of new outpatient CT studies.
4. Collaborate with the Clinical Trials Office (CTO) to streamline CT study initiation.

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

1. BCCR leadership limited CT patient assignments to experienced registered nurses (RN) and developed a licensed vocational nurse (LVN) position to assist with the CT studies. To accommodate schedules for CT study patients, the service line director updated scheduling procedures with CT trial scheduling guidelines.
2. Most FACT policies are not always appropriate for outpatient or research settings as they may not conform with study requirements, including post treatment assessments or discharge. To ensure consistency with SOC, the BCCR and clinical research nurses (CRNs), reviewed all CT research protocols, determined necessary processes and added protocol specific requirements to SOC policies. The CTO created a research-specific FACT wallet card and revised the after-visit summary to conform with the SOC.
3. The physician or advanced practice providers (APP) usually administers the CT for investigator-initiated CT studies after the BCCR RN premedicates the patients. To reduce RN expense, the CT dedicated LVN will manage and premedicate patients prior to CT product arrival. Upon arrival, the RN will perform product check and evaluation. This eliminates the cost of an RN on stand-by

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for several hours until product arrival. Additionally, trial supplies, including personal protective equipment (PPE), were updated for cost reduction.

4. To streamline activation, the BCCR assigned a lead RN to CT studies. This allows the lead RN early access to the protocol and lab delivering the CT product to assist CRNs align protocol required procedures with SOC and ensure treatment plans are accurately updated.

**4. Outcomes**

The process was recently fully integrated. We will evaluate the ability to schedule more research patients, reduce nursing time and supply costs and ensure alignment with SOC.

**5. Lessons Learned**

The disconnect between SOC and research CT policies and processes offered an opportunity to collaborate and educate our SOC partners. Plans include training all BCCR nurses to care for patients on CT studies. Teams will partner on detailed CT study in-services, monitoring volume for staffing and space needs, and cost saving opportunities.