



Moving Cellular Therapy Clinical Trials in the Outpatient Setting: Aligning with Institutional Standards and FACT

Pam Herena, MSN, RN, OCN; Chris Krygsman, BSN, RN; Mary Shields, MSN, RN, OCN;

Meghan Licata, PhD, RN, ONP; Brenda Williams, BSN, RN; Adrine Chung; Ryan Chiechi, MBA, MHA

BACKGROUND

The Briskin Center for Clinical Research (BCCR) at City of Hope (COH) is a outpatient oncology research unit which provides therapeutic first-in-human (FIH) through Phase 3 clinical trial treatments. Recently, we were given the opportunity to integrate multiple cellular therapy (CT) trials into our unit.

There are over **300** treatment studies that utilize BCCR for outpatient treatments. The processes, training and orientation have been standardized to allow for easy adaptation for any oncology therapeutic study; however, CT trials brings new opportunities.

The recent trend of providing CT in the outpatient setting includes many challenges:

- Institutional Standards aligned with inpatient processes
- Foundation for the Accreditation of Cellular Therapy (FACT) standards
- Complex CT trials
- Knowledge gaps
- Training
- Patient safety

GOALS

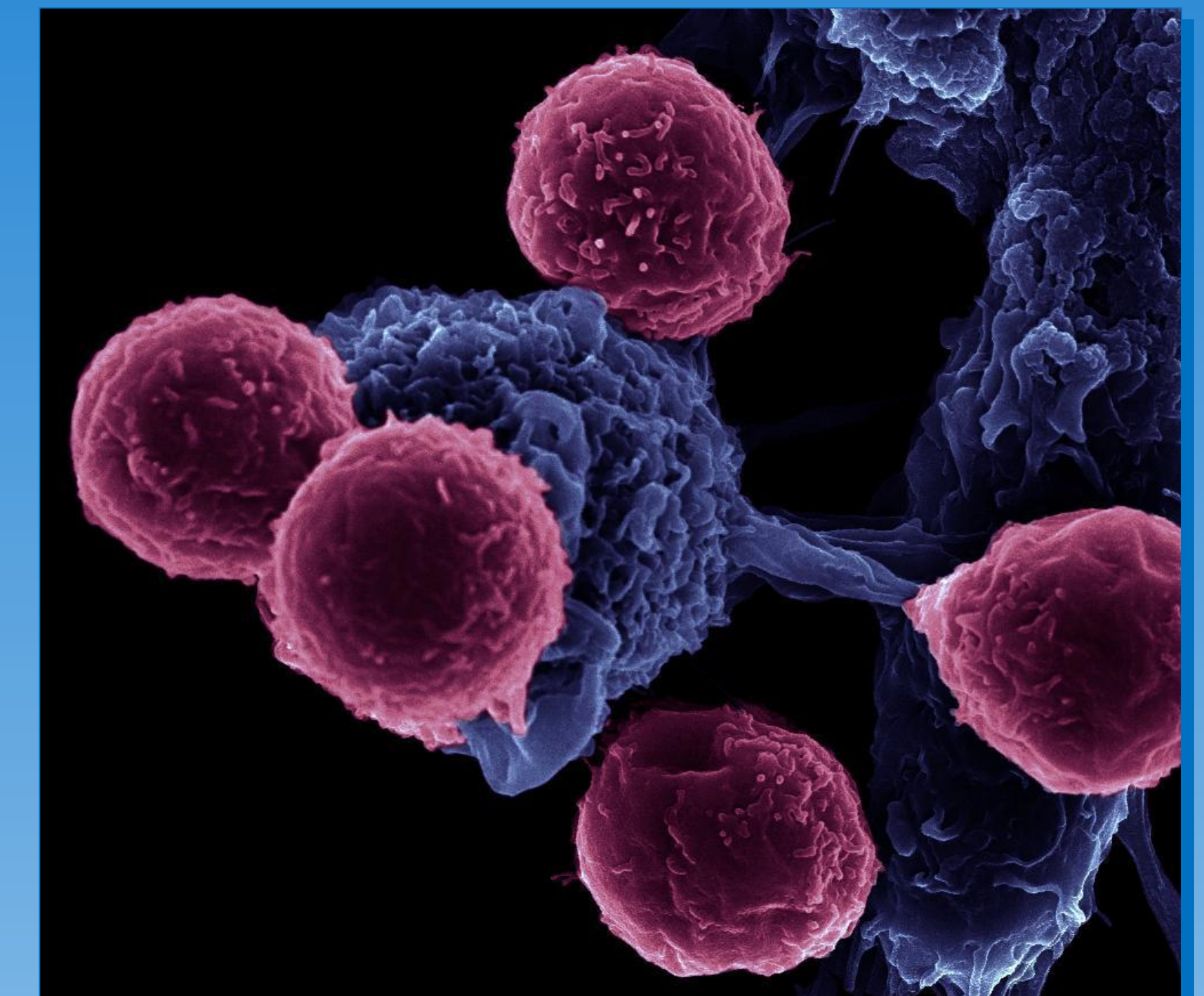
To meet the challenges, the BCCR team aimed to:

- Innovatively adjust BCCR schedule for growing needs of CT studies;
- Align standard of care and research CT policies, ensuring safety and FACT requirements;
- Responsibly manage resources associated with new outpatient CT studies; and
- Collaborate with the Clinical Trials Office (CTO) to streamline CT study initiations.

METHODS

In order to achieve success implementing CT in the outpatient setting, BCCR leadership:

1. Chose a select number of BCCR nurses to train and orient to CT infusion and patient care;
2. Implemented a Licensed Vocational Nurse (LVN) role to elevate some of the prep work (e.g. labs, oral medication);
3. Worked with the service line director to create scheduling guidelines for CT trials;
4. Added specific research CT trial information into our CT policies to ensure alignment and standardized processes; and
5. Streamlined study activation, by assigning a lead nurse to work with CTO in operationalizing CT trials and train and validate all newly trained BCCR nurses that join the CT treatment team.



FUTURE DIRECTIONS

We successfully implemented CT trials into the BCCR outpatient unit. There is a lot of collaboration required among different departments due to the complexity and varied CT trials protocols. This can slow down the processes and create department challenges.

We will continue to evaluate our space utilization to ensure we can support the continued growth in the CT trial space. Creating streamlined collaboration will help ensure we continue with our rapid activations. We also plan to role out the education, training and orientation to all the nursing staff in Briskin.

