



# CAR T Cell Therapy Program Setup

Module 7

# CAR T Academy: CAR T Cell Therapy Program Setup



01 Program Oversight

02 Healthcare Professional Considerations

03 Logistical Considerations

# Section 01



01

Program Oversight

02

Healthcare Professional Considerations

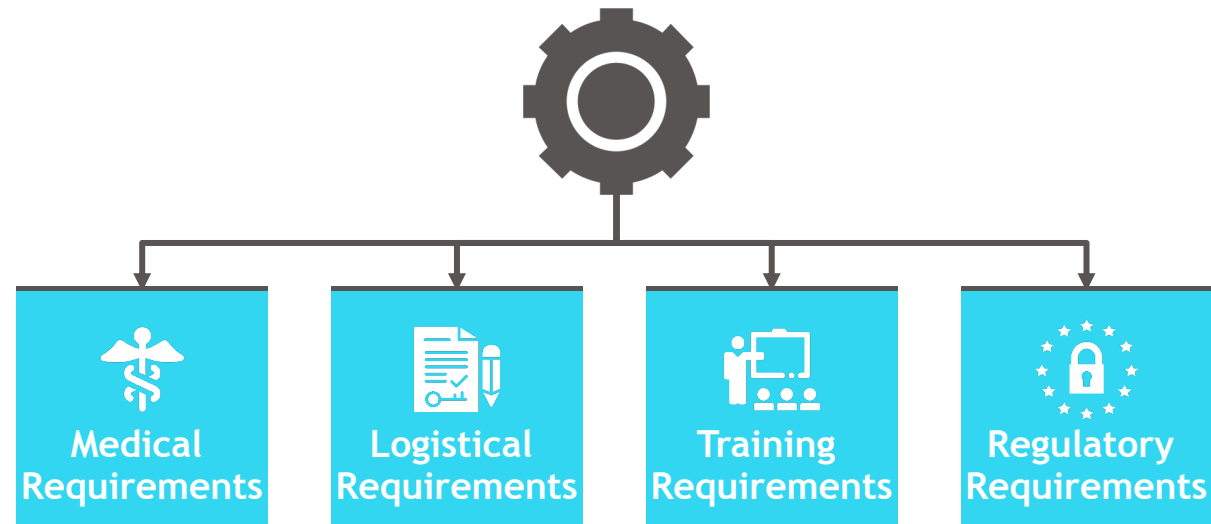
03

Logistical Considerations

# Institutional Infrastructure of CAR T Cell Programs Is Key

- One key factor to consider when establishing a chimeric antigen receptor (CAR) T cell program is oversight of the program
- All CAR T cell programs must have standards and systems in place for management of patients receiving CAR T therapy; however, operational approaches can vary

*Strong institutional infrastructure for the program is essential to ensure all of the complex requirements for CAR T cell therapy delivery are met*



Reference: 1. Taylor L et al. *Clin J Onc Nurs*. 2019;23(2):20-26.

# Factors to Consider when Determining Program Oversight

Given the high demand on institutional resources, oversight is a critical decision to the establishment of a CAR T cell therapy program

The type of program oversight is based on a number of factors but ultimately should aim to provide efficient delivery of CAR T cell therapy and patient support

Some factors to consider may include:

Number and types of CAR T cell therapies offered

Anticipated patient volume

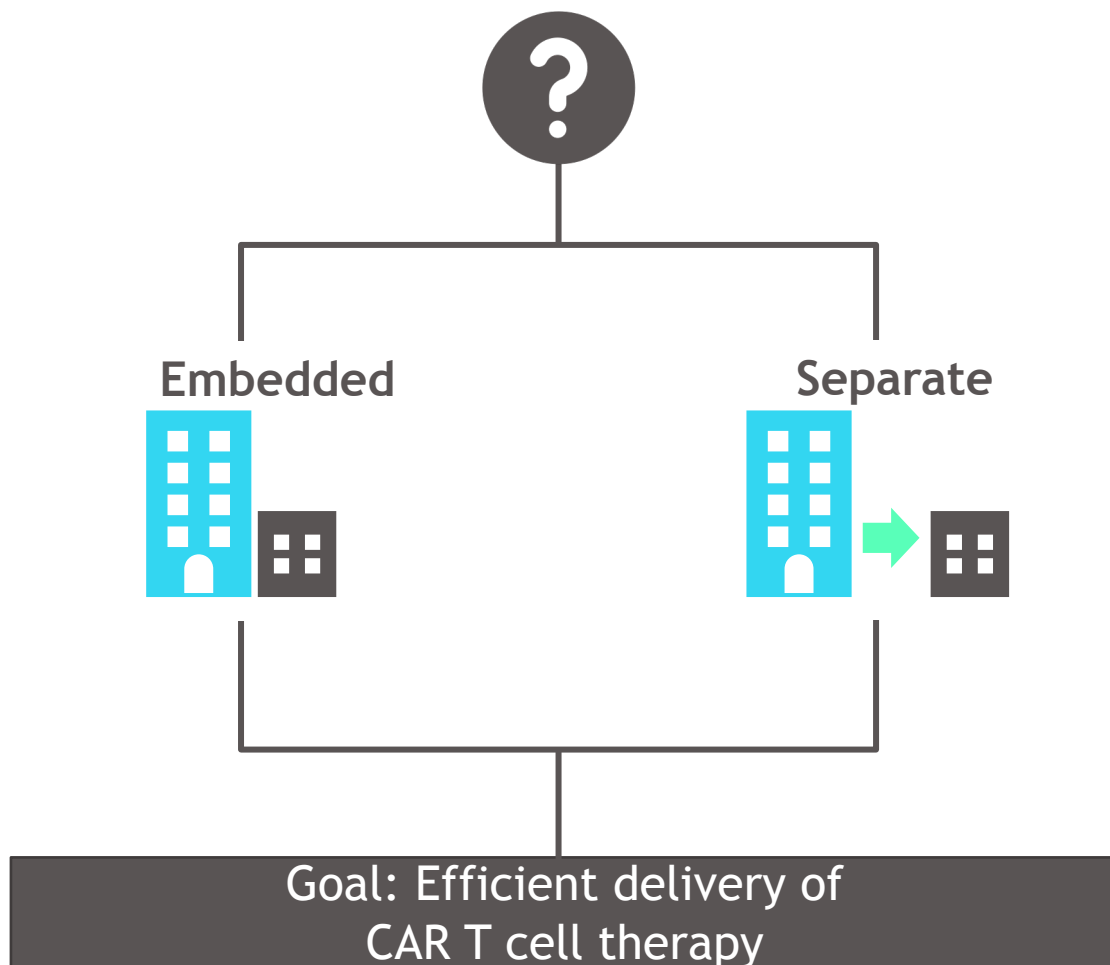
Inpatient/outpatient resources

Pre-existing service lines

BMT, blood and marrow transplantation.

Reference: 1. Taylor L et al. *Clin J Onc Nurs*. 2019;23(2):20-26.

# Determining the Type of Program Oversight



- CAR T cell therapy programs may be part of existing institutional blood and marrow transplantation (BMT) programs
- Other institutions may choose to develop distinct programs with a cell therapy focus, or based on primary disease service (eg, leukemia or lymphoma team)

BMT, blood and marrow transplantation.

Reference: 1. Taylor L et al. *Clin J Onc Nurs*. 2019;23(2):20-26.

# CAR T Cell Therapy Programs Embedded Within a Blood and Marrow Transplant (BMT) Program<sup>1</sup>



This type of program leverages existing BMT infrastructure, but requires additional features specific to CAR T programs, such as:

- Appropriate training of management of CAR T cell associated toxicities (eg, CRS, neurologic toxicity, infection)<sup>1</sup>
- REMS program training<sup>2</sup>

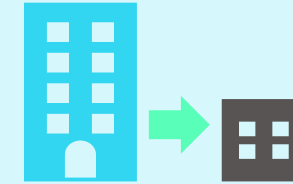
- Avoids system redundancy by utilizing systems that already meet similar requirements for BMT therapies
  - Data and quality management
  - Documentation methods and flow sheets
- Capitalizes on existing workflows and adapting to include CAR T-specific policies or support where needed
  - Apheresis support already meeting current standards
  - Existing policies for cell thaw and infusion
  - Existing policies for care and management of medically complex, immunocompromised patients

CRS, cytokine release syndrome; REMS, Risk Evaluation and Mitigation Strategies.

References: 1. Taylor L et al. *Clin J Onc Nurs*. 2019;23(2):20-26. 2. Beaupierre A et al. *Clin J Oncol Nurs*. 2019;23:27-34.

# CAR T Cell Therapy Programs that are Separate From BMT Programs

- May be able to accommodate increasing patient volume
- May be able to readily incorporate new CAR T cell products
- Patients are referred to CAR T cell therapy service from internal disease teams or from external HCPs for treatment and management
- CAR T cell evaluation, treatment, and posttreatment AE monitoring are managed entirely by an independent CAR T cell therapy service line
- Referrals are managed through coordination between administrative staff and HCPs/investigators to provide access to clinical care or relevant clinical trials



This type of program establishes an independent service line for CAR T cell therapy:

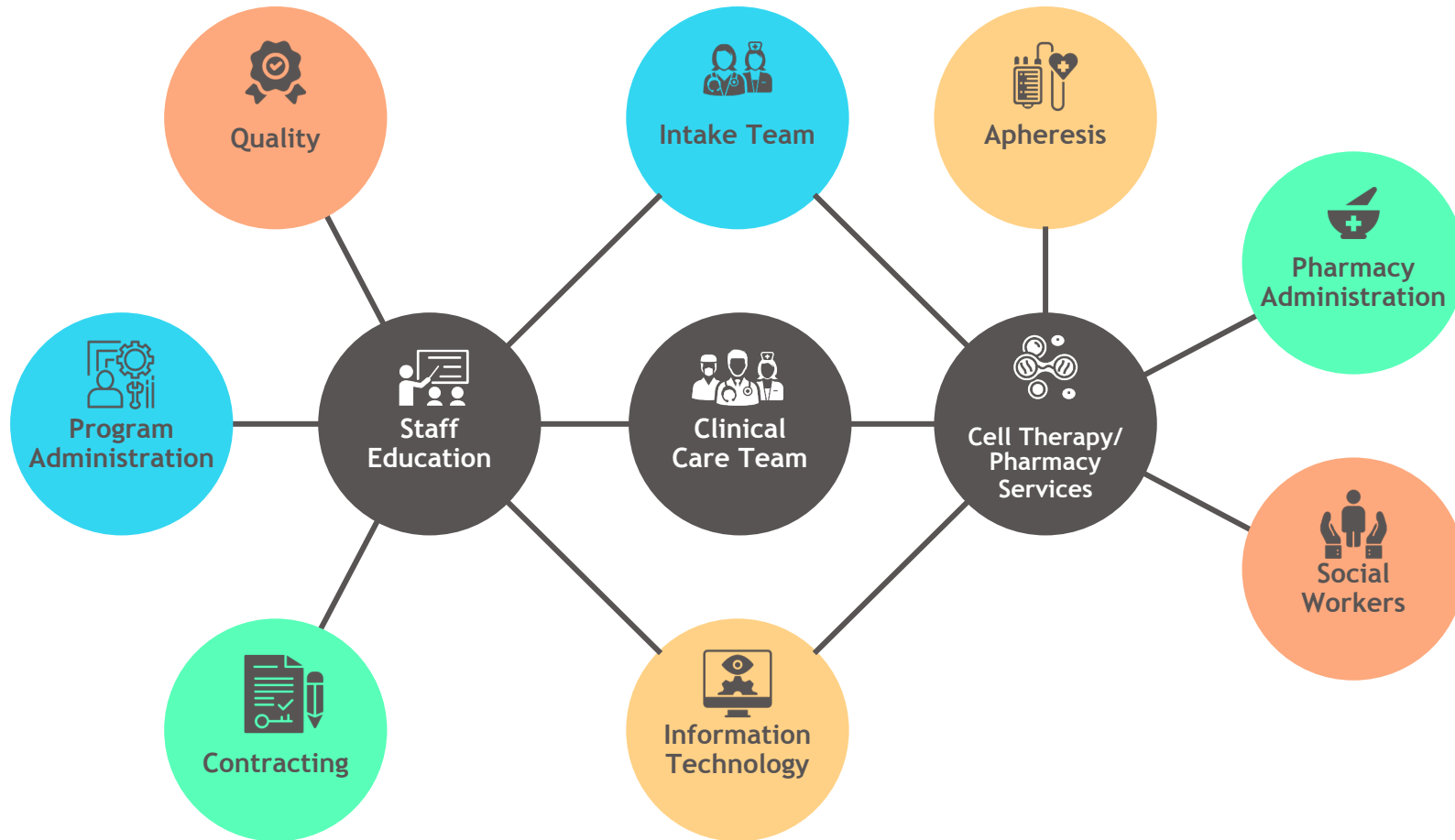
- Expert care from a dedicated care team for therapy delivery and AE management
- Separate from BMT programs

AE, adverse event; BMT, bone and marrow transplantation; HCPs, health care providers.

References: 1. Taylor L et al. *Clin J Onc Nurs*. 2019;23(2):20-26.



# Considerations for CAR T Cell Therapy Program Roles & Operations<sup>1-3</sup>



The same types of specialized interprofessional teams are needed to support the complex infrastructure and patient care needs for CAR T cell therapy delivery, regardless of the type of program oversight<sup>4</sup>

**References:** 1. McGuirk et al. *Cytotherapy*. 2017;19:1015-1024. 2. Perica K et al. *Biol Blood Marrow Transplant*. 2018;24(6):1135-1141. 3. Beupierre A et al. *Clin J Oncol Nurs*. 2019;23:27-34 4. Taylor L et al. *Clin J Onc Nurs*. 2019;23(2):20-26.

# CAR T Cell Therapy Program Roles & Operations



## 01 Program Admin

- Includes CAR T cell program director, program coordinator, REMS authorized representative
- Establish benchmarks
- Develop quality-care plans and manage SOPs
- Oversee program
- Plan and allocate resources



## 02 Quality

- Perform auditing and outcomes reporting
- Administer manufacturer REMS
- Transfer data for CIBMTR reporting, FDA adverse event reporting



## 03 Contracting

- Negotiate contractual agreements with manufacturers



## 04 Information Technology Services

- Create EHR documentation, alerts, and order sets
- Set up database infrastructure for quality reporting

CIBMTR, Center for International Blood and Marrow Transplant Research; EHR, electronic health record; FDA, US Food and Drug Administration; REMS, Risk Evaluation and Mitigation Strategies; SOPs, standard operating procedures.

References: 1. Taylor L et al. *Clin J Onc Nurs*. 2019;23(2):20-26. 2. Perica K et al. *Biol Blood Marrow Transplant*. 2018;24(6):1135-1141.

# CAR T Cell Therapy Program Roles & Operations



## 05 Staff Education

- Provide training on REMS programs and therapy-specific competencies



## 06 Intake Team

- Prescreen patients for eligibility
- Provide consultation and education
- Develop treatment plans
- Coordinate with patients, outside providers, and other services
- May identify housing and caregiver resources



## 07 Social Work

- Can arrange lodging and transportation
- Provide resources for patient support



## 08 Pharmacy

- Prepare plans for lymphodepleting chemotherapy
- Verify tocilizumab supply
- Track and register cell products
- Pharmacy billing
- Formulary oversight

REMS, Risk Evaluation and Mitigation Strategies.

References: 1. Taylor L et al. *Clin J Onc Nurs*. 2019;23(2):20-26. 2. Perica K et al. *Biol Blood Marrow Transplant*. 2018;24(6):1135-1141.

# CAR T Cell Therapy Program Roles & Operations



## 09 Apheresis

- Viral screening
- Cell collection
- Store and ship collected material to manufacturing facility
- Chain-of-custody tracking



## 10 Cell Therapy/ Pharmacy Services

- Receive and store CAR T cell product from manufacturer
- Prepare CAR T cell product for administration
- Chain-of-custody tracking



## 11 Clinical Care Team

- Provide patient care that requires cooperation across departments in potentially both the inpatient and outpatient settings (eg, hematology, BMT, ER, neurology, ICU, primary care)
- Communicate and coordinate between cross-functional care team, including physicians, nurses, pharmacists, nurse coordinators, administrators, etc.

BMT, bone and marrow transplantation; ER, emergency room; ICU, intensive care unit.

**References:** 1. National Institutes of Health. DailyMed. Available at <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=9b70606e-b99c-4272-a0f1-b5523cce0c59>. Accessed August 12, 2020. 2. National Institutes of Health. DailyMed. Available at <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=aad3ba54-dfd3-4cb3-9e2b-c5ef89559189>. Accessed August 12, 2020. 3. McGuirk et al. *Cytotherapy*. 2017;19:1015-1024. 4. Taylor L et al. *Clin J Onc Nurs*. 2019;23(2):20-26. 5. Perica K et al. *Biol Blood Marrow Transplant*. 2018;24(6):1135-1141.

# Section 02



01 Program Oversight

**02 Healthcare Professional Considerations**

03 Logistical Considerations

# Healthcare Professional Preparation

Healthcare professionals (HCPs) overseeing patients receiving CAR T cell therapy require training and proficiency in:

- Management of hematologic malignancies
- Immunotherapy principles
- Treatment timelines
- Cell infusion procedures
- AE management (eg, CRS, neurotoxicity)
- Management of immunocompromised patients
- Product-specific REMS training

CAR T Programs can help educate HCPs by:



- Creating, providing, and supporting therapeutic training and resources for foundational and continuing education
- Offering periodic competency assessment
- Providing updates about evidence-based delivery of care

AE, adverse event; CRS, cytokine release syndrome; REMS, Risk Evaluation and Mitigation Strategy.

Reference: Taylor L et al. *Clin J Onc Nurs*. 2019;23(2):20-26.

# Section 03



01 Program Oversight

02 Healthcare Professional Considerations

**03** Logistical Considerations

# Logistical Considerations for CAR T Cell Therapy<sup>1</sup>

- Although some sites may choose to treat appropriate patients in the outpatient setting, most patients will still require inpatient admission during therapy for monitoring and/or AE management
- Transportation and accommodation: patients will need to stay within 2-hours of the treating facility for 4 weeks or more after infusion
- Emergency care or hospitalization for AEs
- Follow-up appointments for disease and side effects monitoring

The CAR T cell therapy patient journey from evaluation through infusion should be timely and as streamlined as possible to help avoid treatment delays<sup>2</sup>

AEs, adverse events; ICU, intensive care unit

References: 1. Buitrago J et al. *Clin J Onc Nurs*. 2019;23(2):42-48. 2. McGuirk et al. *Cytotherapy*. 2017;19:1015-1024.



# Professional Guidance May Serve as a Roadmap for Potential Facilities

- Professional medical organizations may provide guidance to help facilities address care along the patient journey
- For example, FACT Standards provide a blueprint to help accommodate various models of patient care and use of cellular therapy products<sup>1</sup>
- Additional information about FACT standards is available at the FACT website: <http://www.factwebsite.org>

## Example FACT Standards for Cellular Therapy Products (2020)<sup>2</sup>

- A dedicated outpatient care area will be designated during treatment
- Access to an intensive care unit (ICU) or equivalent coverage must be available
- Prompt evaluation and treatment on a 24-hour basis to treat expected complications
- There shall be written guidelines for communication, patient monitoring, and transfer or triage of patients to ICU, ED, or equivalent when needed

**References:** 1. Smith S, Essell J. *J Clin Pathways*. 2018;4(8):42-47. 2. Foundation for the Accreditation of Cellular Therapy. FACT Standards for Immune Effector Cells. First Edition 1.1. <http://www.factwebsite.org/IECStandardsDownload/>. Accessed July 6, 2020.

# Summary

- Initiating programs for CAR T cell products requires significant specialized expertise, resources, and organization, as well as coordinated efforts from a multitude of cross-functional clinical and operational teams across an organization
- Adequate staffing, appropriate training, educational resources, and streamlined processes are key to establishing a well-functioning, comprehensive, and effective CAR T cell therapy program

# Thank you for completing this module of CAR T Academy

We hope you found it informative and educational



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