Long-term Follow-up of Patients Receiving CAR T Cell Therapy

The CAR T Academy Modules are intended to provide a high-level overview of select adverse events and are not meant to be a comprehensive discussion of all adverse events contemplated for CAR T cell therapy.

Bristol Myers Squibb™

Patient Journey Through the CAR T Cell Therapy Process

Patient selection → Patient consent & education → Patient screening → Leukapheresis and cell transport → CAR T manufacturing → Bridging and lymphodepleting chemotherapy → CAR T infu & patien monitori → Post hospital discharge monitoring → Long-term monitoring

1 Patient Identification

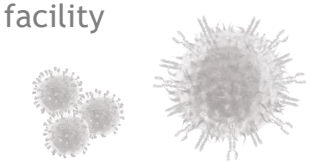
- Appropriate patients will be identified for treatment at qualified treatment sites or referring sites
- Company will be notified and leukapheresis and treatment dates will subsequently be scheduled

2 Leukapheresis

- Patient will undergo apheresis, which involves collection of white blood cells
- Collected apheresis product will be sent to the manufacturer for production

3 Manufacturing

The CAR T cell product is created at a manufacturing facility



4 Prep

- Patients may require bridging therapy to maintain disease control while the CAR T cell product is being manufactured
- Shortly prior to CAR T cell administration, the patient is prepared for treatment with lymphodepletion

5 Treat

- The CAR T cell product is delivered to the treatment site
- Product is administered

6 Monitor

- The patient is monitored closely for at least 4 weeks and side effects are promptly managed. Caregiver support is critical during this time
- Thereafter, the patient is periodically monitored long term

Reference: Beaupierre A, et al. *Clin J Oncol Nurs*. 2019;23:27-34.

Need for Long-term Follow-up

- CAR T cells may persist for multiple years in some patients, underscoring the need for long-term monitoring for late effects of treatment[1,2]
- Long-term patient monitoring should occur from 30 days through 15 years post-infusion[3,4]
- Patients should be monitored life-long for the development of secondary malignancies[5-9]

References: 1. Hartmann J, et al. *EMBO Mol Med*. 2017;9(9):1183-1197. **2.** Boyiadzis MM, et al. *J Immunother Cancer*. 2018;6(1):1-12. **3.** Lee DW, et al. *Biol Blood Marrow Transplant*. 2019;25(4):625-638. **4.** Beaupierre A, et al. *Clin J Oncol Nurs*. 2019;23(2):27-34. **5.** National Institutes of Health. DailyMed. Accessed August 10, 2021. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=594bb413-af3b-4b97-afb3-bfe2b174f2ed. **6.** National Institutes of Health. DailyMed. Accessed August 10, 2021. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=b90c1fe7-f5cc-464e-958a-af36e9c26d7c. **7.** National Institutes of Health. DailyMed. Accessed August 10, 2021. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=aad3ba54-dfd3-4cb3-9e2b-c5ef89559189. **8.** National Institutes of Health. DailyMed. Accessed August 10, 2021. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=9b70606e-b99c-4272-a0f1-b5523cce0c59. 9. National Institutes of Health. DailyMed. Accessed October 25, 2021. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=a16108c2-7ca7-45af-965e-54bda4713022.

Transfer Back to the Referring Provider

After at least 4 weeks, or when toxicities resolve, patients can be transferred back to the referring provider

Recommended Information to Be Shared With the Referring Provider

- Results of all baseline tests performed prior to CAR T cell infusion
- Clinical summary of the patient's progress, including information regarding the risk for adverse events (AEs) and recommended interventions
- Current disease staging information
- Information regarding specific laboratory orders and how often they should be performed
- Recommendations for monitoring late-onset cytopenias
- Recommendations for possible administration of blood products, if necessary
- Medication list (eg, prophylactic antibiotics and antiviral medications)
- CAR T cell product information (United States Prescribing Information [USPI] and medication guide)
- Copy of patient wallet card listing symptoms that may occur post-treatment
- List of approximate dates when the patient should follow up with the treating center

AEs, adverse events; USPI, United States Prescribing Information.

Reference: Beaupierre A, et al. *Clin J Oncol Nurs*. 2019;23(2):27-34.

CAR T Academy: Considerations for Long-term Follow-up

01 Post-treatment Complications

02 Relapse

03 Psychosocial Factors

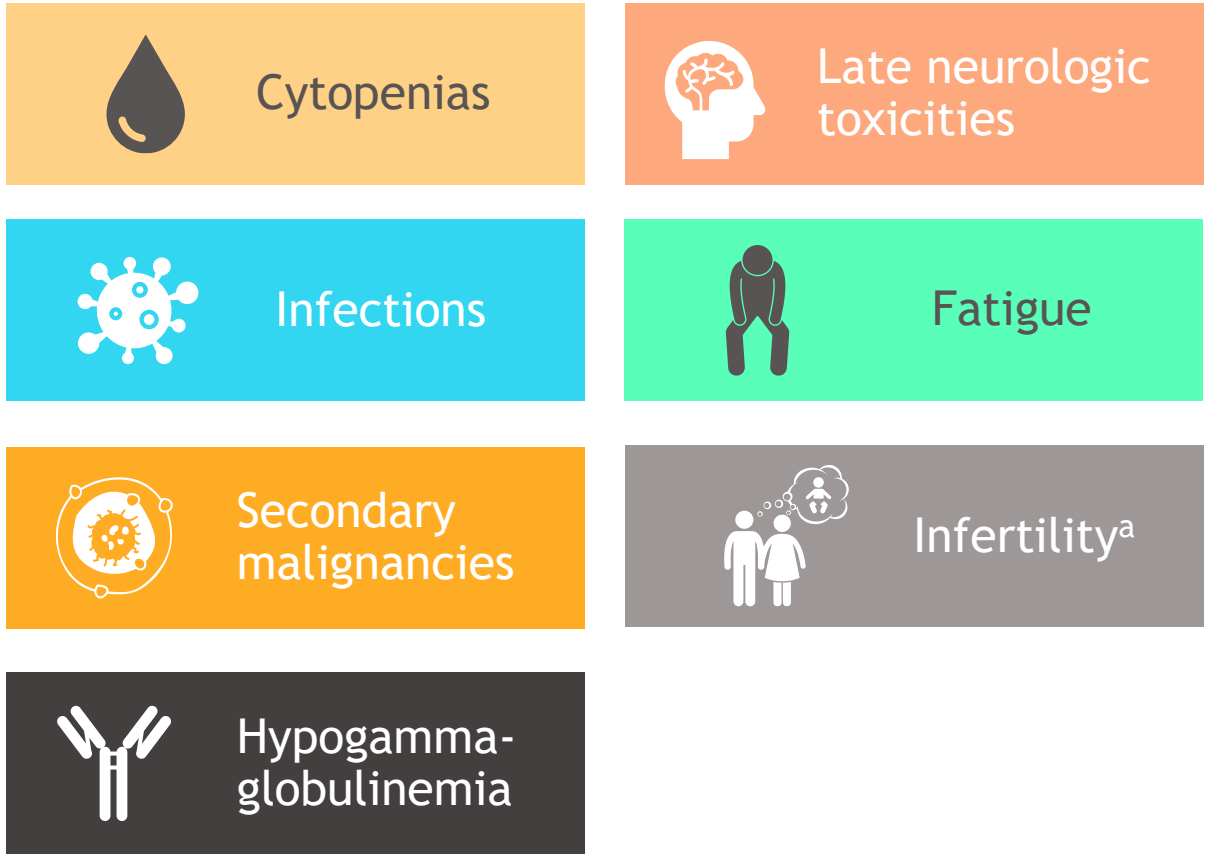
04 Logistical Considerations

05 Registry

The Physiologic Effects of Post-CAR T Cell Therapy

- The physiologic effects of CAR T cell therapy are becoming better understood as the pool of patients who receive such therapy grows
- Several interventions can be utilized to address the physiologic effects of CAR T cell therapy, which underscores the need for long-term monitoring to ensure long-term patient safety

Example Physiologic Effects



[a]Infertility is not a known physiologic effect of commercial CAR T cell therapies.

Reference: Buitrago J, et al. *Clin J Onc Nurs*. 2019;23(2):42-48.

Cytopenias

Understanding the Risk

- Cytopenias including grade 3/4 anemia, thrombocytopenia, leukopenia, and neutropenia, occur frequently following CAR T cell infusion[1]
- Evidence suggests that CAR T cell therapy can induce myelosuppression via cytokine-mediated and perhaps other mechanisms[1]
- Lymphodepleting chemotherapy administered prior to CAR T cell therapy may also induce myelosuppression[1]
- Cytopenias may persist for long durations[2]
  - Cytopenias have been observed in patients up to 24 months following CAR T cell infusion[3,4]
  - In a report of patients with NHL, ALL, and CLL (n=86) who received CAR T cell therapy and were followed long term (median duration of follow-up, 28.1 mo; range, 12.5–62.6 mo), 16% (n=3/19 patients with ongoing complete remission) had severe cytopenias lasting beyond 90 days post-infusion (up to 21.7 months)[3]

ALL, acute lymphocytic leukemia; CLL, chronic lymphocytic leukemia; NHL, non-Hodgkin lymphoma.

References: 1. Brudno JN, Kochenderfer JN. *Blood*. 2016;127(26):3321-3330. **2.** Brudno JN, Kochenderfer JN. *Blood Rev*. 2019;34:45-55. **3.** Cordeiro A, et al. *Biol Blood Marrow Transplant*. 2020;26(1):26-33. **4.** Munshi NC, et al. *N Engl J Med*. 2021;384(8):705-716.

Cytopenias (cont.)

Monitoring and Follow-up Care

- Monitor blood counts weekly through 60 days post-infusion or as indicated until recovery[1]
- Provide transfusion and/or growth factor support to patients with severe cytopenias, when appropriate.[1] Support may include:
  - Red blood cell transfusions[2]
  - Platelet transfusions[2]
  - Filgrastim[2]

Note: Institutional and product guidelines may vary.[3]

ANC, absolute neutrophil count.

References: 1. Buitrago J, et al. *Clin J Onc Nurs*. 2019;23(2):42-48. **2.** Brudno JN, Kochenderfer JN. *Blood*. 2016;127(26):3321-3330. **3.** Brudno JN, Kochenderfer JN. *Blood Rev*. 2019;34:45-55

Infections

Understanding the Risk

- Immunosuppression is common in patients who receive CAR T cell therapy and may be due to:[1]
  - Underlying malignancy
  - Lymphodepleting chemotherapy
  - CAR T cell therapy
- Infections can occur following CAR T cell infusion
  - These may include, but are not limited to: bacteremia, *Salmonella*, urinary tract infections, and viral infections such as influenza, respiratory syncytial virus, herpes zoster virus, Epstein Barr virus, and cytomegalovirus[2,3]
  - One study demonstrated that ~25% of patients developed infections during first 28 days post-infusion, typically within the first 10 days[2]
  - Other trials found that 14%-33% of patients developed infections within 30-180 days post-infusion[2,4,5]
- Factors that may be associated with increased risk for infection include:[2]
  - Type of malignancy
  - ≥4 prior lines of therapy
  - Higher CAR T cell dose
  - Higher grade of cytokine release syndrome (CRS)

References: **1.** Brudno JN, Kochenderfer JN. *Blood Rev*. 2019:34:45-55. **2.** Hill JA, et al. *Blood*. 2018;131(1):121-130. **3.** Brudno JN, Kochenderfer JN. *Blood*. 2016;127(26):3321-3330. **4.** Park JH, et al. *Clin Infect Dis*. 2018;67:533-540. **5.** Munshi NC, et al. *N Engl J Med* 2021;384:705-16.

Infections (cont.)

Monitoring and Follow-up Care

- Closely monitor patients who become febrile after infusion for signs of infection. Keep in mind that fever may also be a sign of CRS[1]
- Since no standard antimicrobial prophylaxis recommendations have been developed for patients who receive CAR T cell therapy, healthcare providers should use their best medical discretion and consider following recommendations for antimicrobial prophylaxis for patients with cancer-related immunosuppression[2]
- No current guidelines exist for revaccination after infusion.[3] Healthcare providers should use their best medical discretion regarding revaccination
  - Consider revaccination ≥6 months after CAR T cell infusion for inactivated vaccines and ≥1 year after infusion for live vaccines, provided the patient is no longer immunocompromised[3]
  - Consider offering flu vaccination ≥30 days post-infusion, particularly in patients who are neutropenic[2]

CRS, cytokine release syndrome

References: 1. Brudno JN, Kochenderfer JN. *Blood Rev*. 2019:34:45-55. **2.** Buitrago J, et al. *Clin J Onc Nurs*. 2019;23(2):42-48. **3.** Hill JA, Seo SK. *Blood*. 2020;136(8):925-935.

Hypogammaglobulinemia

Understanding the Risk

- B cells produce antibodies that recognize foreign antigens and protect against infection[1]
- CAR T cells can kill healthy B cells in addition to malignant B cells (on-target, off-tumor effect)[1]
- This activity can lead to B-cell aplasia, chronic immunodeficiency, and hypogammaglobulinemia (IgG <400 mg/dL)[1]
- In select clinical trials, hypogammaglobulinemia has been reported to occur in 9%-53% of patients that received CAR T cell therapy[2-6]
- Two studies have suggested that ~25%-75% of patients have hypogammaglobulinemia at 30 days post-infusion, up to day 90 and beyond[7,8]
- B-cell aplasia and hypogammaglobulinemia can last months to years after treatment and predispose patients to infection[1,9]

Monitoring and Follow-up Care

- Check immunoglobulin G (IgG) levels monthly[10]
- Consider monthly immunoglobulin infusions for patients who develop frequent infections, especially those with IgG <400 mg/dL[1]
- Given how long this complication can last, IgG replacement may be necessary[1]

Note: Institutional and product guidelines may vary[1]

IgG, immunoglobulin G.

References: 1. Buitrago J, et al. *Clin J Onc Nurs*. 2019;23(2):42-48. **2.** Munshi NC, et al. *N Engl J Med* 2021;384:705-16. **3.** Abramson JS, et al. *Lancet*. 2020;396(10254):839-852. **4.** Locke FL, et al. *Lancet Oncol*. 2019;20(1):31-42. **5.** National Institutes of Heath. DailyMed. Accessed August 5, 2021. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=aad3ba54-dfd3-4cb3-9e2b-c5ef89559189. **6.** National Institutes of Heath. DailyMed. Accessed October 25, 2021. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=a16108c2-7ca7-45af-965e-54bda4713022. **7.** Hill JA, et al. *Blood*. 2018;131(1):121-130. **8.** Cordeiro A, et al. *Biol Blood Marrow Transplant*. 2020;26(1):26-33. **9.** Beaupierre A, et al. *Clin J Oncol Nurs*. 2019;23(2):27-34. **10.** Callahan C, et al. *Clin J Onc Nurs*. 2019;23(2):35-41.

Secondary Malignancies

Understanding the Risk

- Because genetic alteration is used to create CAR T cells, there is a small possibility that these products can cause insertional mutagenesis, resulting in secondary malignancies[1]
- In a small cohort of patients followed up to 5.25 years, 15% (n=13/86)[2] developed subsequent malignancies
  - These included nonmelanoma skin cancer, myelodysplastic syndromes (MDS), melanoma, bladder cancer, and multiple myeloma (MM)
  - The median time from first infusion to diagnosis for subsequent malignancies was 2 to 16 mo, depending on the type of malignancy
  - No replication-competent lentivirus was detected in CAR T cell products before infusion or in blood samples after CAR T cell infusion

Monitoring and Follow-up Care

- Healthcare providers need to follow patients who receive CAR T cell therapy life-long for secondary malignancies, per FDA requirements[3-8]
  - In the event that a secondary malignancy occurs:
    - Notify the CAR T cell therapy manufacturer[3-8]
    - Report the event to the FDA via MedWatch[4-8]
- Secondary malignancies should be treated per disease-specific protocols[2]

FDA, US Food and Drug Administration; MDS, myelodysplastic syndromes; MM, multiple myeloma.

References: 1. Buitrago J, et al. *Clin J Onc Nurs*. 2019;23(2):42-48. **2.** Cordeiro A, et al. *Biol Blood Marrow Transplant*. 2020;26(1):26-33. **3.** Beaupierre A, et al. *J Adv Pract Oncol*. 2019;10(Suppl 3):29-40. 4. National Institutes of Heath. DailyMed. Accessed August 5, 2021. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=594bb413-af3b-4b97-afb3-bfe2b174f2ed. **5.** National Institutes of Health. DailyMed. Accessed August 5, 2021. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=b90c1fe7-f5cc-464e-958a-af36e9c26d7c. 6. National Institutes of Health. DailyMed. Accessed August 10, 2021. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=aad3ba54-dfd3-4cb3-9e2b-c5ef89559189. **7.** National Institutes of Health. DailyMed. Accessed August 10, 2021. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=9b70606e-b99c-4272-a0f1-b5523cce0c59. **8.** National Institutes of Health. DailyMed. Accessed October 25, 2021. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=a16108c2-7ca7-45af-965e-54bda4713022.

Late Neurologic Toxicities

Understanding the Risk

- Neurologic toxicities can arise several weeks following infusion, including seizures, weakness, confusion, aphasia, and coordination problems[1]
- In select CAR T cell clinical trials, the incidence of neurotoxicity was 18%-63%[a,2-6]
- In a small cohort of patients followed up to 5.25 years, 10% had neurologic events that occurred 90 days post-infusion or beyond[7]
  - These included stroke, peripheral neuropathy, and dementia

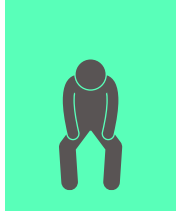
Monitoring and Follow-up Care

- Given the potential for neurologic toxicity, patients should not drive for at least 8 weeks post-infusion[1]
- Seizure prophylaxis (eg, levetiracetam) may be prescribed to prevent seizure[1]
- Patient caregivers should be educated about possible neurologic toxicities and monitor for any changes so they can be immediately addressed[1]

[a]Grading criteria for neurotoxicity varies amongst clinical studies.

References: 1. Buitrago J, et al. *Clin J Onc Nurs*. 2019;23(2):42-48. **2.** Munshi NC, et al. *N Engl J Med* 2021;384:705-16. **3.** Abramson JS, et al. *Lancet*. 2020;396(10254):839-852 **4.** Locke FL, et al. *Lancet Oncol*. 2019;20(1):31-42. **5.** Schuster SJ, et al. *N Engl J Med*. 2019;380(1):45-56. **6.** Wang M, et al. *N Engl J Med*. 2020;382(14):1331-1342. **7.** Cordeiro A, et al. *Biol Blood Marrow Transplant*. 2020;26(1):26-33.

Fatigue



Understanding the Risk

- Fatigue can be a common and difficult-to-manage side effect of CAR T cell therapy[1]
- In select CAR T cell clinical trials, the incidence of fatigue ranged from 25% to 53%[2-6]
- Fatigue has been reported to resolve in some patients within 4-6 weeks post-infusion[1]

Monitoring and Follow-up Care

- Rule out any contributing factors (eg, anemia, hypothyroidism)[7]
- Steroids should be avoided due to potential T cell suppression that might limit the activity of CAR T cell therapy[1]
- Nonpharmacologic interventions include exercise, yoga, meditation, Pilates, and massage therapy[1]

References: 1. Buitrago J, et al. *Clin J Onc Nurs*. 2019;23(2):42-48. **2.** Munshi NC, et al. *N Engl J Med* 2021;384:705-16. **3.** Abramson JS, et al. *Lancet*. 2020;396(10254):839-852. **4.** Locke FL, et al. *Lancet Oncol*. 2019;20(1):31-42. **5.** Schuster SJ, et al. *N Engl J Med*. 2019;380(1):45-56. **6.** Wang M, et al. *N Engl J Med*. 2020;382(14):1331-1342. **7.** American Cancer Society. Accessed August 10, 2021. https://www.cancer.org/treatment/treatments-and-side-effects/physical-side-effects/fatigue/what-is-cancer-related-fatigue.html.

Infertility

Understanding the Risk

- Effects of CAR T cell therapy on fertility and childbearing outcomes are not yet known[1]
- However, data suggest that lymphodepleting chemotherapy could affect reproductive capacity[1]

Monitoring and Follow-up Care

- Pregnancy and effective contraception should be discussed as part of the treatment plan, particularly for patients who are adolescents or young adults[2]
- Persons of childbearing age should be advised to consult with a fertility preservation specialist prior to lymphodepleting chemotherapy[1]
- Fertility counseling should ideally be scheduled prior to the start of first-line therapy and should continue throughout all lines of treatment[1]

References: 1. Buitrago J, et al. *Clin J Onc Nurs*. 2019;23(2):42-48. **2.** Callahan C, et al. *Clin J Onc Nurs*. 2019;23(2):35-41.

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Restaging Scans

After a patient undergoes CAR T cell infusion, periodic follow-up is necessary to restage disease and determine the response to treatment.

- Restaging PET/CT scans are typically performed:
  - 30 to 90 days post-infusion
  - Every 3 months for the first 2 years post-infusion
- Reimaging should also be performed for patients with signs/symptoms of disease recurrence (such as unexplained fever or chills, new pain, lymphadenopathy)

PET/CT, positron emission tomography/computed tomography

Reference: Beaupierre A, et al. *Clin J Oncol Nurs*. 2019;23(2):27-34.

Managing Relapse

- Relapse can occur for many reasons[1,2]
  - Loss of the antigen of interest
  - Lack of persistence or function of CAR T cells
  - CAR T cells may become exhausted, thereby limiting their anticancer effects
  - Tumors can develop compensatory mechanisms that lead to immune evasion
- In certain settings, consolidation therapy with allogeneic stem cell transplantation or participation in a clinical trial (if eligibility criteria are met) can be considered[3,4]

When relapse occurs, alternative treatment strategies specific to the patient's disease are necessary (eg, chemotherapy, targeted therapy, clinical trial, etc)[4]

References: 1. Perica K, et al. *Biol Blood Marrow Transplant*. 2018;24:1135-1141. **2.** Abramson JS, et al. *Am Soc Clin Oncol Educ Book*. 2019;39:446-453. **3.** Beaupierre A, et al. *Clin J Oncol Nurs*. 2019;23(2):27-34. **4.** Byrne M, et al. *Biol Blood Marrow Transplant*. 2019;25(11):e344-e351.

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Psychosocial Effects of CAR T Cell Therapy

Patients may experience:

- Heightened anxiety or fear of recurrence
- Changes in physical functioning that impact quality of life
- Other mental stressors associated with the therapeutic process (eg, consistent caregiver support, financial concerns) resulting in compromised coping

Reference: Buitrago J, et al. *Clin J Onc Nurs*. 2019;23(2):42-48.

Strategies for Managing Psychosocial Effects

Survivorship programs are resources that can provide:

- Ongoing communication between patients and treating providers
- Interventions that enable patients to recognize and manage anxiety and that promote positive coping
- Opportunities to engage with other survivors through support groups

- Additional avenues of support can include:
  - Social workers, chaplains, clinical psychologists/psycho-oncologists, and community-based organizations
  - Online forums (eg, social media, online support groups specifically for patients who have received CAR T cell therapy)
- Ensuring adequate caregiver support may also prove beneficial

Reference: Buitrago J, et al. *Clin J Onc Nurs*. 2019;23(2):42-48.

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Logistical Considerations for CAR T Cell Therapy

The total cost of CAR T cell therapy and all medical-related expenses is considerable[1,2]

- Emergency care or hospitalization for adverse events
- Follow-up appointments for disease and side effects monitoring
- Insurance-related expenses

References: 1. Perica K, et al. *Biol Blood Marrow Transplant*. 2018;24:1135-1141. **2.** Buitrago J, et al. *Clin J Onc Nurs*. 2019;23(2):42-48.

Strategies for Managing Logistics

Have transparent conversations with patients and caregivers about treatment costs upfront

Regularly assess for financial constraints and psychosocial sequelae like any other adverse event, and provide support as appropriate

Connect patients to financial assistance programs

Reference: Buitrago J, et al. *Clin J Onc Nurs*. 2019;23(2):42-48.

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Patient Registry and Data Capture

- FDA recommends 15 years of observation for patients who receive CAR T cell therapies[1]
- FDA requires REMS programs for commercial CAR T cell therapies[2]

- **Center for International Blood and Marrow Transplant Research**[1]
  - (CIBMTR) launched a database dedicated to cellular therapy outcomes in 2016
  - Used to capture long-term data for patients who receive CAR T cells or other cellular therapies aside from hematopoietic stem cell transplantation

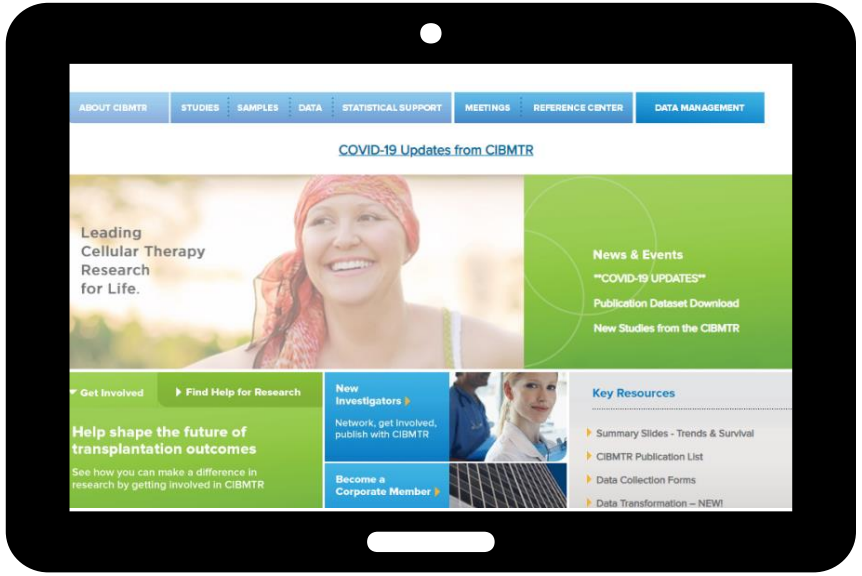
FDA, US Food and Drug Administration; REMS, Risk Evaluation and Mitigation Strategy

References: 1. Lee DW, et al. *Biol Blood Marrow Transplant*. 2019;25:625-638. **2.** US Food & Drug Administration. Accessed August 10, 2021. https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm.

Patient Registry and Data Capture (cont.)

The CIBMTR Cellular Therapy Registry:

- Offers a platform for standardized, comprehensive data collection
  - After infusion, data captured at 3 months, 6 months, 1 year, and yearly thereafter



- Aligns with FDA regulatory recommendations to capture relevant CAR T cell–associated toxicities
  - Specific outcomes captured include CRS, neurotoxicities, neutrophil and platelet recovery, hypogammaglobulinemia, severe infections, nonhematologic grade 4 toxicities, death from any cause
  - Event-driven forms can be used to report subsequent neoplasms and pregnancies

CIBMTR, Center for International Blood and Marrow Transplant Research; CRS, cytokine release syndrome; FDA, US Food and Drug Administration

Reference: Lee DW, et al. *Biol Blood Marrow Transplant*. 2019;25:625-638.

Summary

- Several physiologic effects can arise following CAR T cell therapy
  - Many of these may be successfully managed with prophylactic treatment, close monitoring, and prompt intervention, when necessary
- Psychosocial effects and financial constraints associated with CAR T cell therapy should not be overlooked
  - Several avenues of support can help patients cope with these issues, including survivorship programs, support groups, etc
- Periodic imaging is necessary to determine the response to treatment, restage disease, and monitor for relapse
  - When relapse occurs, alternative disease-specific treatment strategies are necessary
- FDA recommends 15 years of observation and long-term AE reporting for patients who receive CAR T cell therapies
  - This can be accomplished by utilizing the CIBMTR Cellular Therapy Registry

AE, adverse event; CIBMTR, Center for International Blood and Marrow Transplant Research;
FDA, US Food and Drug Administration.

Thank you for completing this module of CAR T Academy

We hope you found it informative and educational

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