

# Practical and Logistics of Clinical Care for Cell Therapy Patients

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# Objectives



Overview of BMT CI  
(ICE T Program) at  
Moffitt Cancer  
Center

Patient Journey

Toxicity  
management and  
documentation

Operational  
challenges and  
process  
improvement

# Disclosures

- None

# Overview of Cell Therapy in Clinical Practice



| CAR T                         | TIL                     | TCR                        | Clinical trials                                |
|-------------------------------|-------------------------|----------------------------|------------------------------------------------|
| Idecabtagene<br>[Abecma]      | Lifileucel<br>[Amtagvi] | Afamitresgene<br>[Tecelra] | CAR T                                          |
| Obecabtagene<br>[Aucatzyl]    |                         |                            | TCR                                            |
| Lisocabtagene<br>[Breyanzi]   |                         |                            | TIL                                            |
| Ciltacabtagene<br>[Carvykti]  |                         |                            | Cytokine infusion +/-<br>monoclonal antibodies |
| Tisagenlecleucel<br>[Kymriah] |                         |                            |                                                |
| Brexucabtagene<br>[Tecartus]  |                         |                            |                                                |
| Axicabtagene<br>[Yescarta]    |                         |                            |                                                |

# MOFFITT: BMT CI



-Dedicated ICE T unit to Immune Cell Therapy patients in 2020

## Total CAR-T

- FY24 = 281
- FY25 = 385
- Lifetime = 1758

## Total IEC (TIL, BsAb, CD8 DLI, TCR)

- FY24 = 74
- FY25 = 106

CAR-T: Chimeric antigen receptor therapy T- cell therapy

IEC = Other Immune Effector Cell therapies



## Challenges with delivery of quality care

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Lack of interoperability

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Optimizing clinical workflows

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Personnel shortages and specialty training

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Scheduling

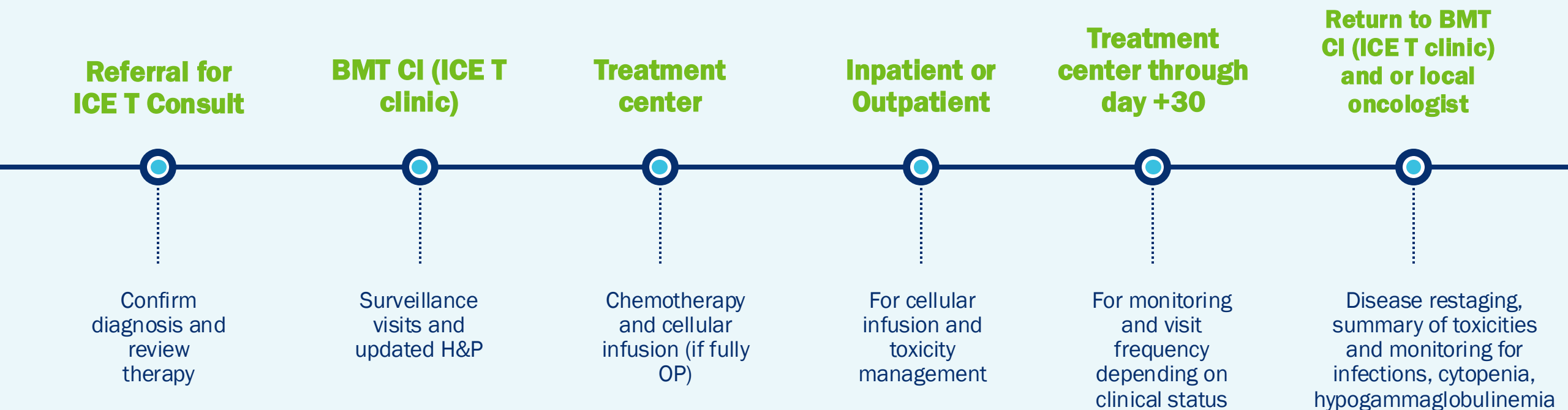
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Keeping up with advances in medical science and protocols

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Patient access and safety

# Patient Journey Overview



# Referral and Eligibility Assessment

## 1. Consult – ICE T Clinic (BMT CI)

- Confirm diagnosis
- Performance status & comorbidities
- Therapy selection (clinical trial or FDA approved therapy).
  - ICE T Tumor board

## 2. Insurance & Authorizations for testing and collection

Apheresis

Surgery

## 3. Review current therapy

Discuss holding therapy (bridging) with primary disease specific team

- Washout period

# Referral and Eligibility Assessment



## 4. ICE T surveillance clinic visits (virtual/in person)

## 5. ICE T reevaluation and testing

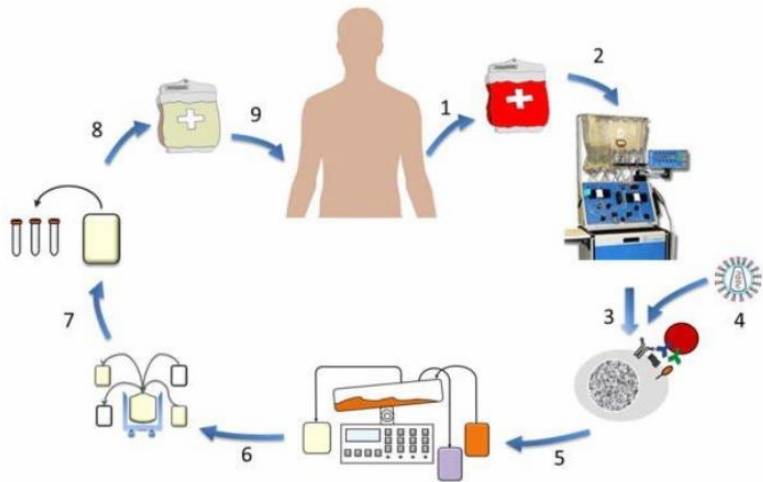
- Review risk and benefits
- Toxicity management considerations
- Informed consent

# Preparations



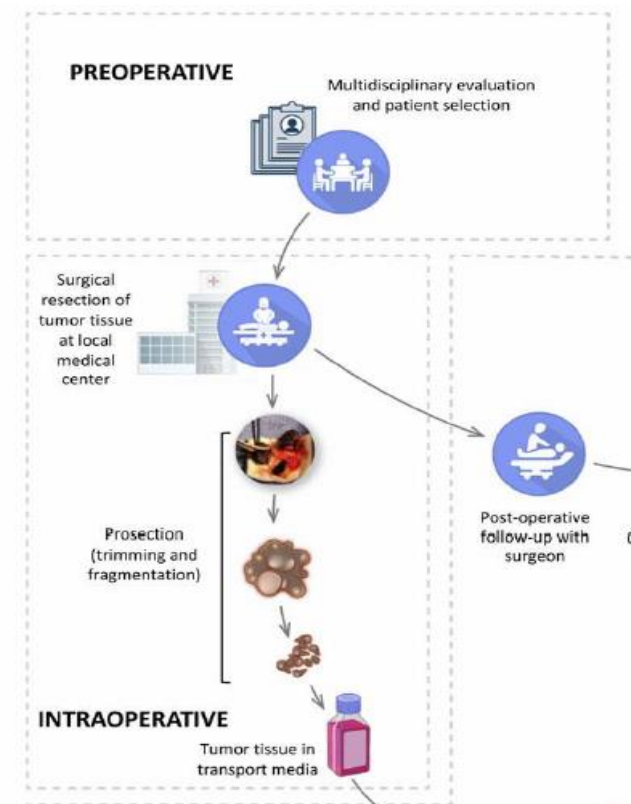
## Apheresis

- Mononuclear cell collection
  - CAR T
  - TCR
- IR coordination (non tunneled line)
  - PIV (vein assessment)
- Cell Product logistics
  - Estimated cell readiness date



## Surgery (TIL Harvest)

- Surgery Scheduling- TIL Surgeons
  - Based on tumor site/location
- Cell product logistics
  - Estimated cell readiness date





**BMT CI Education Class**  
**Appointment: ICE- T class**



**All patients attend prior to therapy start**

Review side effects & monitoring  
Caregiver role and responsibilities  
Local Lodging  
Reporting symptoms to direct line

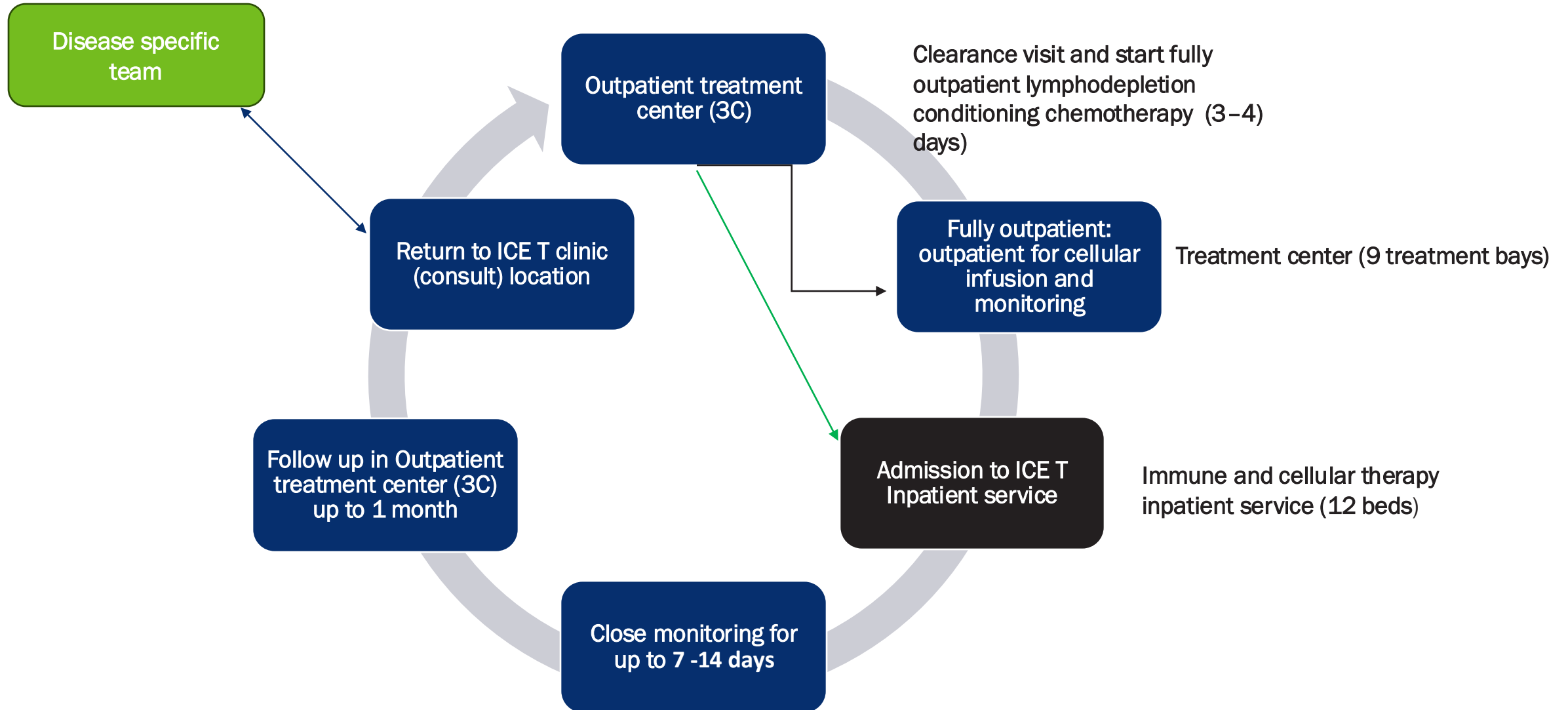


# BMT CI Coordination Calendar

- Shared coordination calendar
  - Capacity planning
  - Location (IP/OP)
  - Identification of patient population
    - Including (ICE T trials)

| Admission Calendar                  | Infusion Calendar    | BMT Calendar                                           | Admission Calendar            | Infusion Calendar  | Pending List | Pending List                                                   | Pending BMT          |
|-------------------------------------|----------------------|--------------------------------------------------------|-------------------------------|--------------------|--------------|----------------------------------------------------------------|----------------------|
| Colors And Limits                   | Colors And Limits    | Daily Limits                                           | Event Name                    | Event Name         | BMT Type     | Cell Type                                                      | Service Type         |
| Black<br>2 admissions               | Black<br>3 infusions | 2 admissions<br>3 Infusions                            | ICE-T Admission               | ICE-T Admission    | ICE-T        | All ICE-T cell types Except "BsAb Commercial"                  | ICE-T IP             |
| Black<br>As above                   | Black<br>As above    | Included in above limits                               | ICE-T Off Service             | ICE-T Off Service  | ICE-T        | Same as above                                                  | ICE-T Off Service    |
| Green/Purple<br>Up to 2 Clearances* | Gray<br>1 infusion*  | 1 Clearance<br>1 infusion<br>(Overbooks need approval) | OP ICE-T Clearance*           | Complete OP ICE-T* | ICE-T        | Includes ICE-T Cell Infusions done completely OP like Carvykti | Completely OP ICE-T* |
| Green/White<br>Up to 2 Clearances   |                      | 2 Clearances<br>(Overbooks need approval)              | ICE-T Clearance               | N/A                | ICE-T        | Includes Chemo                                                 | ICE-T OP             |
| Green/Yellow<br>Up to 2 Clearances  |                      | 2 Clearances<br>(Overbooks automatic-                  | ICE-T Immunotherapy Clearance | N/A                | ICE-T        | Includes IL, Vaccine, Research BsAB & other                    | ICE-T OP             |

# Therapy location – ICE T



# Clearance Visit – ICE T Treatment Center

- Treatment center team for ICE T patients
- Re evaluation and testing
  - Disease status
  - Virology
  - Echo/EKG
  - Optional PFTs/MRI brain w/wo contrast
  - Consults
- Central line confirmation (access)
- **Confirmation of cell therapy receipt (CTF)**

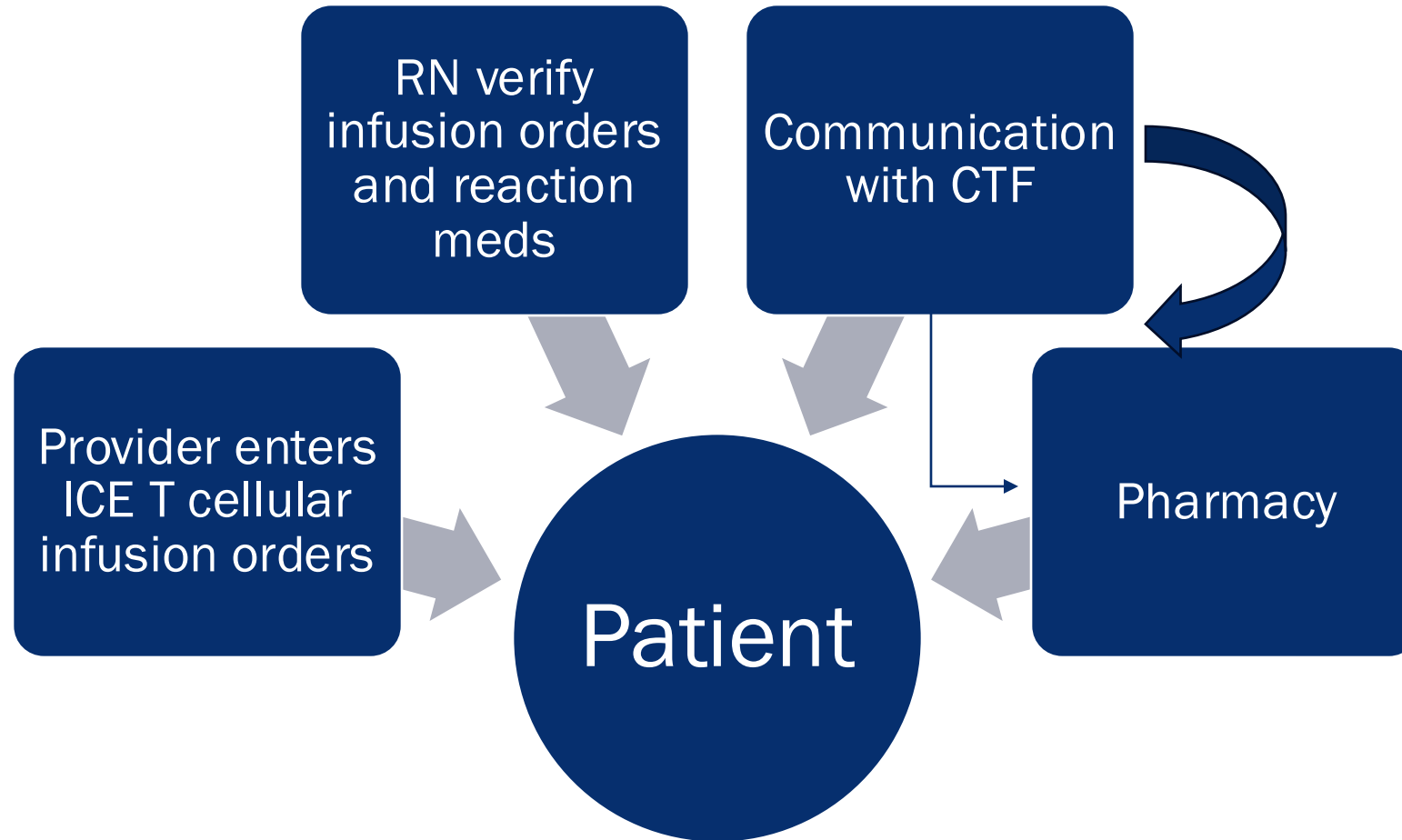
## Chemotherapy schedules

| Commerical CAR T                   | Clearance Day                                                                  | Chemo Schedule                                             |
|------------------------------------|--------------------------------------------------------------------------------|------------------------------------------------------------|
| <b>Lymphoma</b>                    |                                                                                |                                                            |
| Yescarta NHL                       | D-6 Clearance + line clear                                                     | Chemo D-5 through D-3                                      |
| Breyanzi NHL, MCL, CLL             | D-6 Clearance + line clear                                                     | Chemo D-5 through D-3                                      |
| Tecartus MCL                       | D-6 Clearance + line clear                                                     | Chemo D-5 through D-3                                      |
| Kymriah for LBCL                   | D-6 Clearance + line clear                                                     | Chemo D-5 through D-3                                      |
| NHL Bendamustine (LD) conditioning | D-6 Clearance + line clear                                                     | Chemo D-5 through D-4                                      |
| <b>Multiple Myeloma</b>            |                                                                                |                                                            |
| Carvykti                           | D-6 Clearance + line clear                                                     | Chemo D-5 through D-3<br>If OP daily chairs D0 through D10 |
| Abecma                             | D-6 Clearance + line clear                                                     | Chemo D-5 through D-3                                      |
| <b>B- ALL</b>                      |                                                                                |                                                            |
| Kymriah                            | D-7 clearance + line clear                                                     | Chemo D-6 through D-3                                      |
| Tecartus                           | D-5 clearance + line clear<br>D-6 Enhanced Cla/Cy + line                       | Chemo D-4 through D-2<br>Chemo D-5 through D-3             |
| Aucatzyl                           | D-7 clearance + line clear                                                     | Chemo D-6 through D-3                                      |
| <b>Solid tumor</b>                 |                                                                                |                                                            |
| Tecelra TCR                        | D-8 clearance + line clear                                                     | Chemo D-7 through D-4                                      |
| Amtagvi TIL                        | D-6 clearance + line clear<br>IP Chemo start, pt cleared on D-7, admit day D-6 | Chemo D-5 through D-1                                      |

Additional chair time: Pre fluids 500ml only on chemotherapy days (1hour)



# Cell infusion Day



# AUCATZYL (obe-cel) CAR T



## Split dose infusion



Dose selection



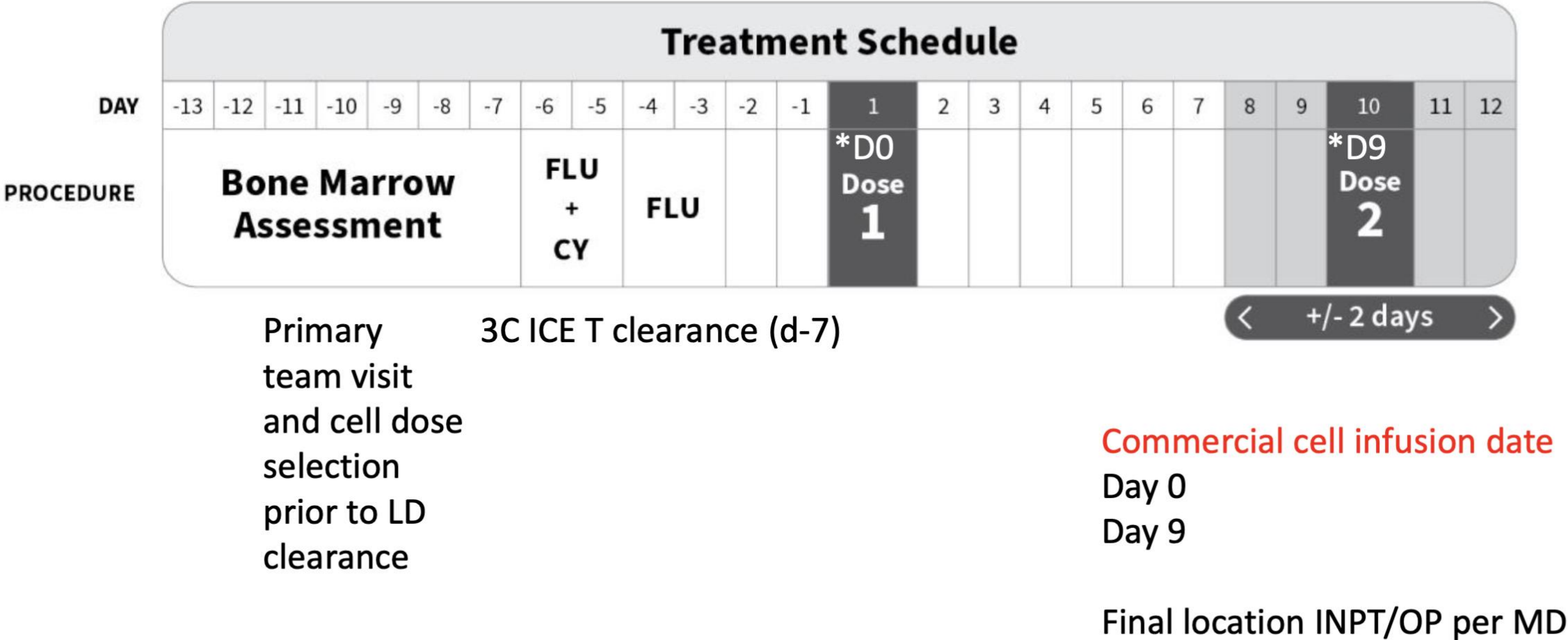
Cell therapy facility notification



ICE T Cell infusion orders (for both days)

# Aucatzyl (obe-cel) CAR T

**Figure 1: AUCATZYL Treatment Schedule**



# Toxicity considerations



## TIL (Tumor Infiltrating Lymphocytes)

Organ toxicity

### CTCAE (v5.0)

- Version v6.0 now available

Interleukin 2 (inpatient administration)

Toxicity management r/t IL2

## CAR T (Chimeric Antigen Receptor T Cell therapy)

CRS: ASTCT Toxicity  
Grading/management (IP/OP)

ICANS: Neuro checks

- Task order for ICE score

Anti seizure prophylaxis

Driving restrictions

## TCR (T cell receptor)

CRS: ASTCT Toxicity  
Grading/management (IP)

ICANS: Neuro checks (low risk for ICANS)

Anti seizure prophylaxis with clinical history

Driving restrictions

CTCAE: Common terminology criteria for adverse events

CRS: Cytokine Release Syndrome

ICANS: Immune Effector Cell–Associated Neurotoxicity Syndrome

Puzanov et al. Journal for Immunotherapy of Cancer (2017) 5:95

Lee, Daniel W. et al. Biology of Blood and Marrow Transplantation (2019), 25:4

# Continuity of care

- **Toxicity management:** Reviewed at time ICE T reevaluation visit, treatment center clearance and post infusion
- **Management guidance:** Specific instructions provided for covering day/overnight providers
  - ICE T Tumor board
- **Handoff communication:** For active ICE T patients (up to 30 days post- therapy)

# Documentation



# ICE T Documentation - Therapy



ICE-T Assessment - XTEST, KARA MARIE

\*Performed on: 08/26/2025 09:34 EDT

Performance Status  
Bispecific Drug  
**Cellular Therapy**  
CAR-HEMATOTOX Score  
CRS Toxicity  
ICANS Assessment

### Cellular Therapy

Prior Cellular Therapy ☒ Yes ☐ No

Prior Cellular Therapy Details

Start of Therapy ☐ Day 0 ☐ Day 1

Date of Therapy  Today's Date  Days Post Cell Therapy   
Fields are conditional if 0 is selected in Start of Therapy field  
Use if Date of Therapy = Day 0

Date of Therapy   
Use if Date of Therapy = Day 1

Type of Therapy

☐ Chimeric Antigen Receptor T cell therapy (CAR-T)  
☐ T cell receptor therapy (TCR)  
☐ Tumor infiltrating lymphocytes (TIL)  
☐ Other:

Chimeric Antigen Receptor T cell therapy (CAR-T)

☐ Allogenic (ALLD)  
☐ CD19  
☐ BCMA  
☐ Other:

Commercial CAR-T Product

☐ Abecma ☐ Kymriah  
☐ Axicatuzyl ☐ Tecartus  
☐ Breyanzi ☐ Yescarta  
☐ Carvykti ☐ Other:

T cell receptor therapy (TCR)

☐ NY-ESO-1  
☐ MAGE-A4  
☐ Other:

Commercial TCR Product

☐ Tecela  
☐ Other:

Cell Route

☐ Peripheral blood  
☐ Other:

Commercial TIL Product

☐ Antagvi  
☐ Other:

Conditioning

☐ Bendamustine  
☐ Clu/Cy  
☐ Flu/Cy  
☐ Other:

# ICE T Documentation – CRS & ICANS



## ASTCT: CRS

ICE-T Assessment - XTEST, OLLI

\*Performed on: 10/13/2025 15:56 EDT

Performance Status  
Bispecific Drug  
Cellular Therapy  
✓ CAR-HEMATOTOX Score  
CRS Toxicity  
ICANS Assessment

### CRS Toxicity

CRS Toxicity Grading Needed? ☐ Yes ☐ No

Fever ☐ None (Grade 0) ☐ Yes (Grade 1)

Hypotension ☐ None (Grade 0)  
☐ Not Requiring Vasopressor (Grade 2)  
☐ One Vasopressor (Grade 3)  
☐ Multiple Vasopressors (Grade 4)

Hypoxia ☐ None (Grade 0)  
☐ Low Flow Oxygen (Grade 2)  
☐ High Flow Oxygen (Grade 3)  
☐ Requires Positive Pressure (Grade 4)

Treatment ☐ None ☐ Corticosteroids  
☐ IV Fluids ☐ Supportive Care  
☐ Anti-IL6 Therapy ☐ Other:  
☐ Anakinra

Treatment Narrative  
Segoe UI

Overall CRS Toxicity per ASTCT Consensus Grading  
☐ Grade 0 ☐ Grade 4  
☐ Grade 1 ☐ Grade 5  
☐ Grade 2  
☐ Grade 3

## ASTCT: ICANS

ICE-T Assessment - XTEST, OLLI

\*Performed on: 10/13/2025 15:56 EDT

Performance Status  
Bispecific Drug  
Cellular Therapy  
✓ CAR-HEMATOTOX Score  
CRS Toxicity  
ICANS Assessment

### ICE Score

ICE Score Assessment needed? ☐ Yes ☐ No

What year is it? ☐ Yes ☐ No

What month is it? ☐ Yes ☐ No

Name object 1 ☐ Yes ☐ No

Name object 2 ☐ Yes ☐ No

Name object 3 ☐ Yes ☐ No

What city are you in? ☐ Yes ☐ No

What hospital are you in? ☐ Yes ☐ No

Follow a command ☐ Yes ☐ No

Write a sentence ☐ Yes ☐ No

Count backwards 100 to 10 ☐ Yes ☐ No

Overall ICE Score  
☐ Score (10) ICANS Grade 0  
☐ Score (7-9) ICANS Grade 1  
☐ Score (3-6) ICANS Grade 2  
☐ Score (0-2) ICANS Grade 3 Awakens Only to Tactile Stimulus  
☐ Score (0) Patient is unarousable ICANS Grade 4

\*If Overall ICE Score is 0, The ICANS Grade will not auto-calculate and will not Copy Forward.

### ICANS

ICANS Assessment Needed? ☐ Yes ☐ No

Depressed LOC ☐ None  
☐ Awakens Spontaneously (ICANS Grade 1)  
☐ Awakens to Voice (ICANS Grade 2)  
☐ Awakens to tactile stimulus (ICANS Grade 3)  
☐ Patient is unarousable (ICANS Grade 4)

Seizure ☐ None  
☐ Any seizure or non-convulsive seizures on EEG (ICANS Grade 3)  
☐ Life-threatening prolonged seizure (ICANS Grade 4)

CRS: Cytokine Release Syndrome

ICANS: Immune Effector Cell-Associated Neurotoxicity Syndrome

# ICE T Documentation- CAR HEMATOTOX



ICE-T Assessment - XTEST, OLLI

\*Performed on: 10/13/2025 15:42 EDT

Performance Status  
Bispecific Drug  
Cellular Therapy  
**CAR-HEMATOTOX Score**  
CRS Toxicity  
ICANS Assessment

### CAR-HEMATOTOX Score/ICAHT

CAR-HEMATOTOX Score Baseline Needed?  
☒ Yes ☐ No

Lab data within 72 hours: Platelet Count, ANC, Hemoglobin, CRP, Ferritin

No qualifying data available.

**Platelet Count**  
☐ Greater than 175,000 u/L  
☐ 75,000 to 175,000 u/L  
☐ Less than 75,000 u/L

**Absolute Neutrophil Count**  
☐ Greater than 1200 u/L  
☐ Less than or equal to 1200 u/L

**Hemoglobin**  
☐ Greater than or equal to 9 g/dL  
☐ Less than 9 g/dL

**C-Reactive Protein**  
☐ Less than or equal to 3 mg/dL  
☐ Greater than 3 mg/dL

**Ferritin**  
☐ Less than 650 ng/mL  
☐ 650 to 2000 ng/mL  
☐ Greater than 2000 ng/mL

**CAR HEMATOTOX Score (Risk group)**  
☐ Score 0 low risk group  
☐ Score 1 low risk group  
☐ Score 2 high risk group  
☐ Score 3 high risk group  
☐ Score 4 high risk group  
☐ Score 5 high risk group  
☐ Score 6 high risk group  
☐ Score 7 high risk group

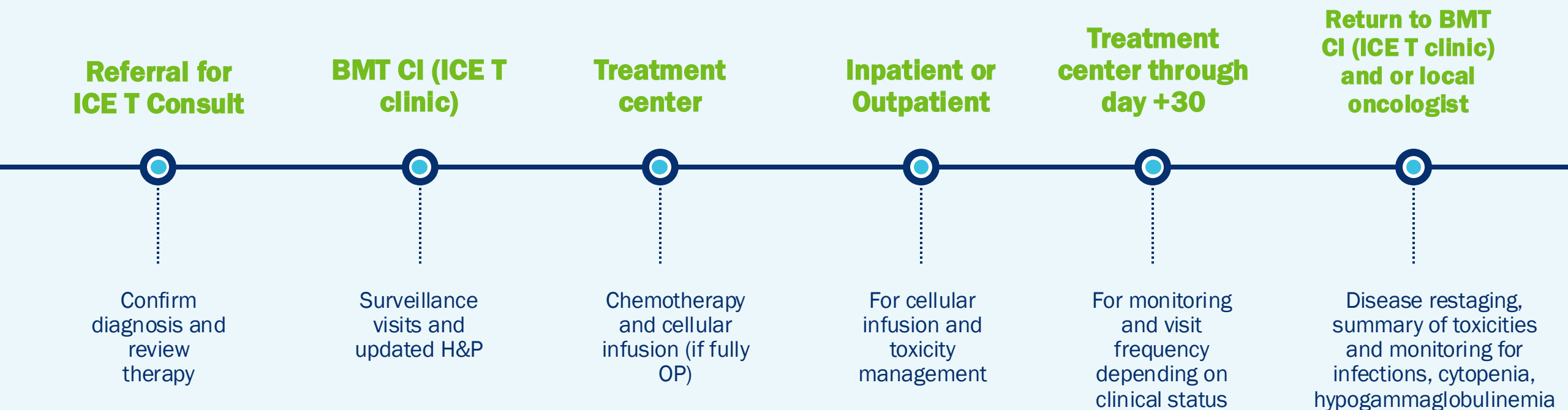
**CAR-HEMATOTOX Score:**  
Low Score = 0 - 1  
High Score = 2 or greater

**Date Occurred**  
no data found

# Operations and Process Improvement (BMT CI)

| Operations                                                                  | Process improvement                                                                                                                                  |
|-----------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|
| Lack of interoperability                                                    | Internal standard workflows and clinical informatics improvements for ICE T                                                                          |
| Optimizing clinical workflows                                               | Chart alert system for admission service, Triage & Admission algorithms                                                                              |
| Personnel shortages and specialty training                                  | Orientation for BMT CI APPs/RNs for additional ICE T specialty training                                                                              |
| Updates in clinical practice with advances in medical science and protocols | Lecture series, quick reference educational charts, checklists, tools, SOP sign off<br>Collaboration projects: Cardiology, Radiology, Neuro oncology |
| Patient access and safety                                                   | Triage line (BMT CI) staffed 24/7, addition of ICE T class for patients/caregivers, hospital wide meetings                                           |
| Scheduling                                                                  | Dedicated scheduling algorithms and patient provided calendar within BMT CI department                                                               |

# Patient Journey





# Questions

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