Practical and Logistics of Clinical Care for Cell Therapy Patients

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MOFFITT CANCER CENTER

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 [Abecma]	Lifileucel [Amtagvi]	Afamitresgene [Tecelra]	CAR T
Obecabtagene [Aucatzyl]			TCR
Lisocabtagene [Breyanzi]			TIL
Ciltacabtagene [Carvykti]			Cytokine infusion +/- monoclonal antibodies
Tisagenlecleucel [Kymriah]			
Brexucabtagene [Tecartus]			
Axicabtagene [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

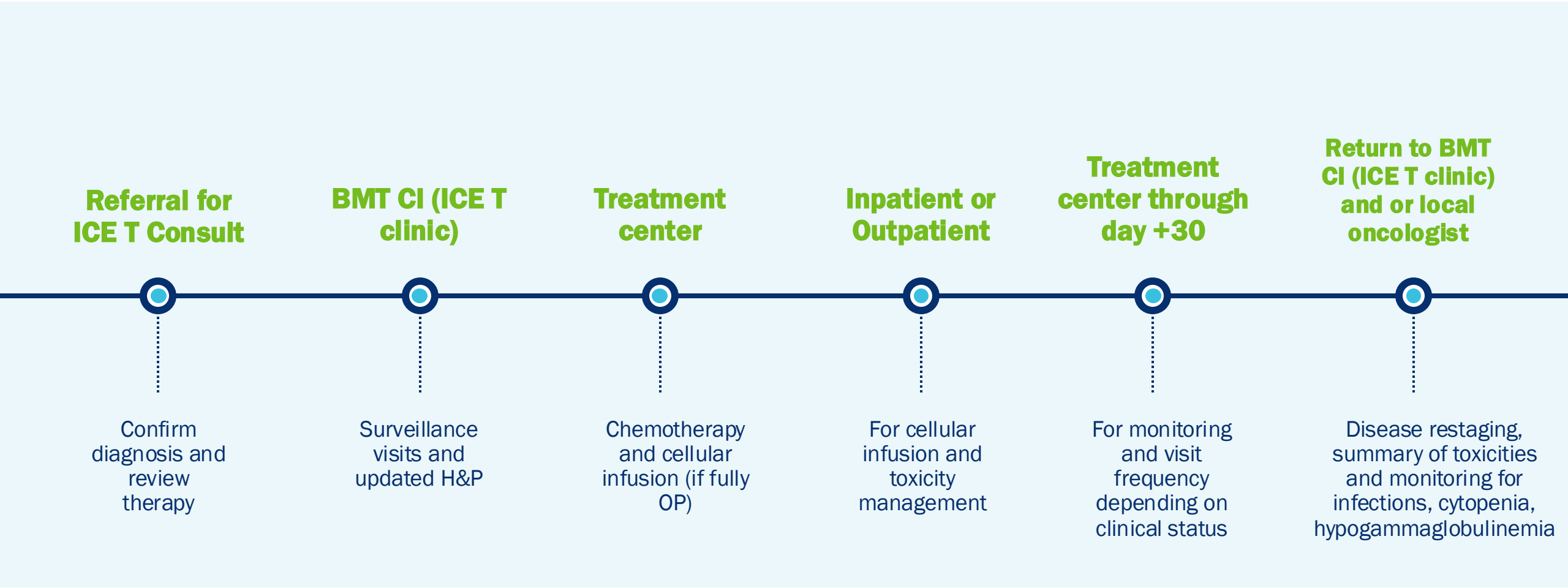
CAR-T: Chimeric antigen receptor therapy T- cell therapy
IEC = Other Immune Effector Cell therapies

Challenges with delivery of quality care

- Lack of interoperability
- Optimizing clinical workflows
- Personnel shortages and specialty training
- Scheduling
- Keeping up with advances in medical science and protocols
- Patient access and safety

Wolters Kluwer (2025)

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)

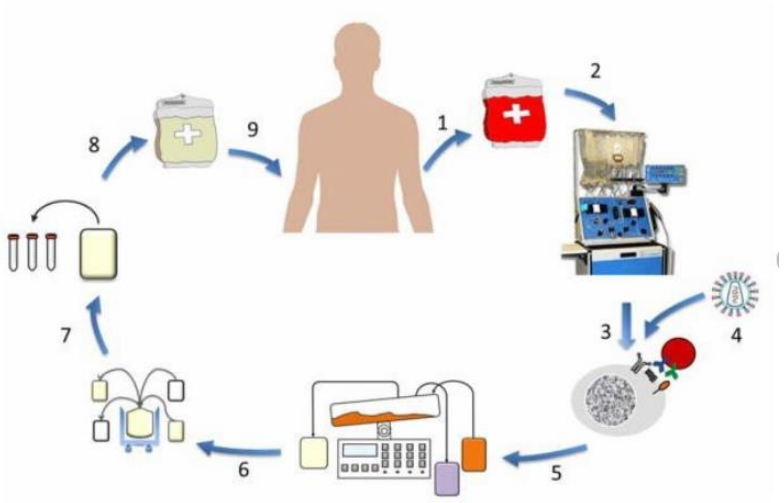
5. ICE T reevaluation and testing

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

Preparations

Apheresis

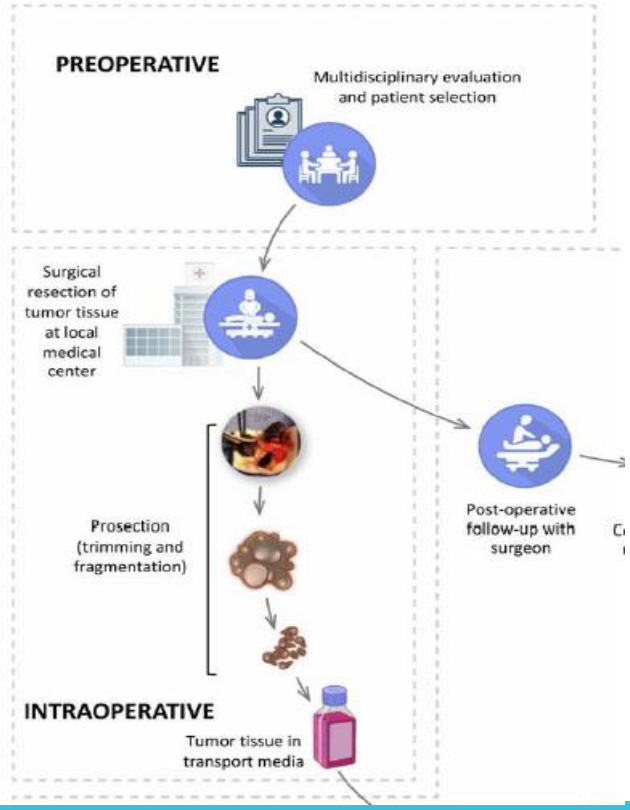
- Mononuclear cell collection
  - CAR T
  - TCR
- IR coordination (non tunneled line)
  - PIV (vein assessment)
- Cell Product logistics
  - Estimated cell readiness date



Fesnak et al. (2016)

Surgery (TIL Harvest)

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



Mullinax et al. (2022)

Patient and caregiver education

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

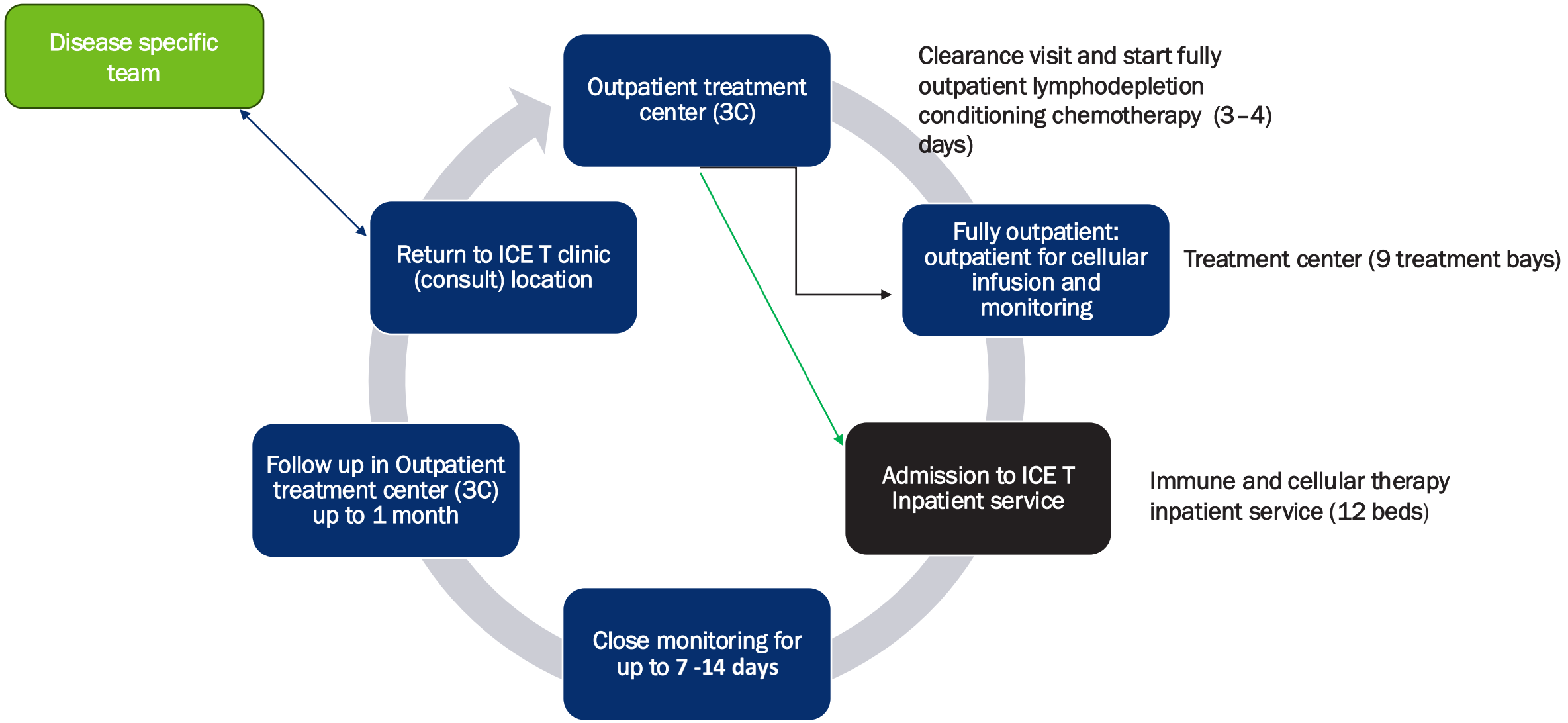
BMT CI Coordination Calendar

- 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 2 admissions	Black 3 infusions	2 admissions 3 Infusions	ICE-T Admission	ICE-T Admission	ICE-T	All ICE-T cell types **Except "BsAb Commercial"**	ICE-T IP
Black As above	Black 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 Up to 2 Clearances*	Gray 1 infusion*	1 Clearance 1 infusion **(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 Up to 2 Clearances		2 Clearances **(Overbooks need approval)**	ICE-T Clearance	N/A	ICE-T	Includes Chemo	ICE-T OP
Green/Yellow Up to 2 Clearances		2 Clearances **(Overbooks automatic-**	ICE-T Immunother-apy Clearance	N/A	ICE-T	Includes IL, Vaccine, Research BsAB & other	ICE-T OP

ICE T - JA- 001

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)**

CTF: Cell Therapy Facilities

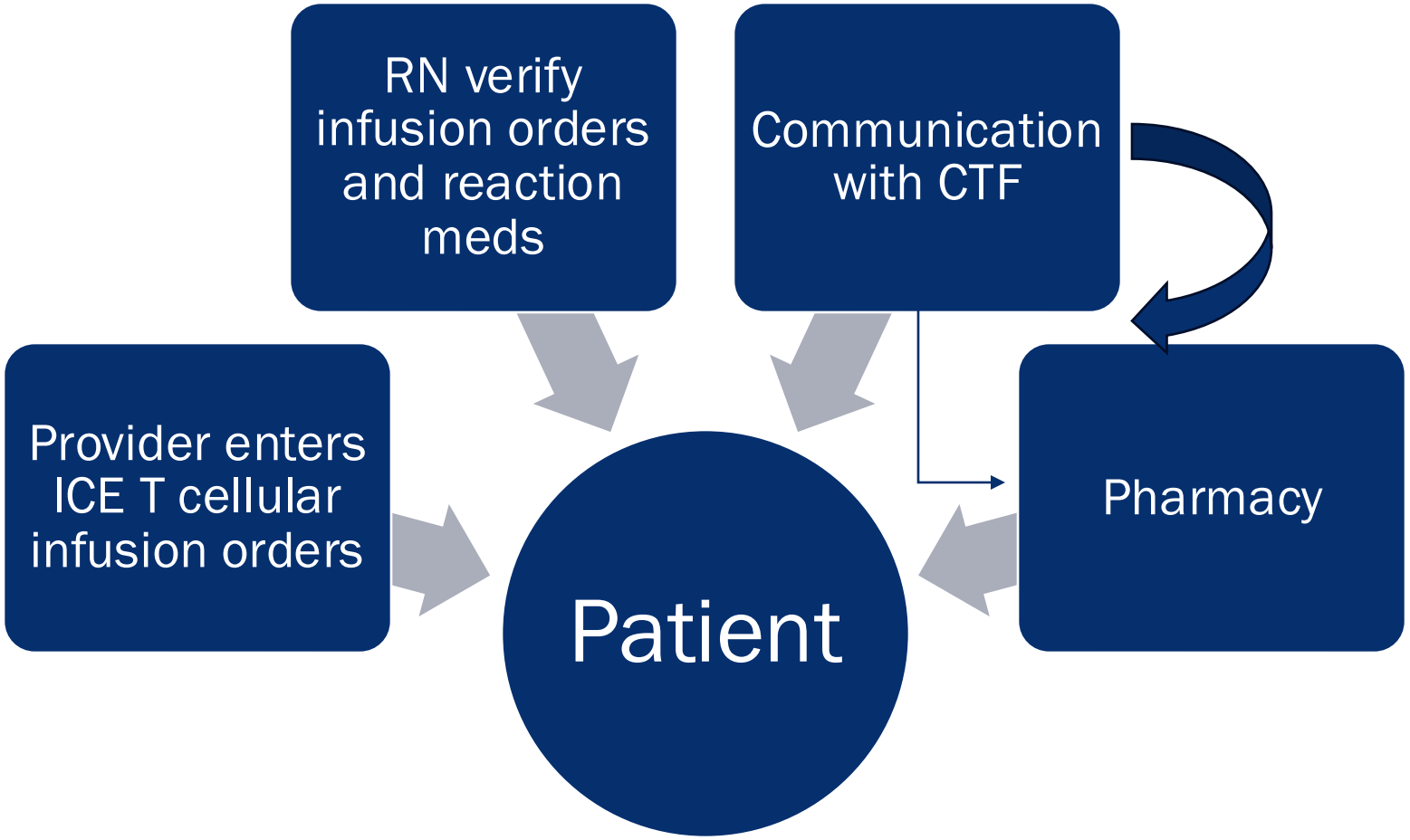
Resource

Chemotherapy schedules

Commerical CAR T	Clearance Day	Chemo Schedule
Lymphoma		
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
Multiple Myeloma		
Carvykti	D-6 Clearance + line clear	Chemo D-5 through D-3 If OP daily chairs D0 through D10
Abecma	D-6 Clearance + line clear	Chemo D-5 through D-3
B- ALL		
Kymriah	D-7 clearance + line clear	Chemo D-6 through D-3
Tecartus	D-5 clearance + line clear D-6 Enhanced Cla/Cy + line	Chemo D-4 through D-2 Chemo D-5 through D-3
Aucatzyl	D-7 clearance + line clear	Chemo D-6 through D-3
Solid tumor		
Tecelra TCR	D-8 clearance + line clear	Chemo D-7 through D-4
Amtagvi TIL	D-6 clearance + line clear 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



CTF: Cell Therapy Facilities

AUCATZYL (obe-cel) CAR T

Split dose infusion

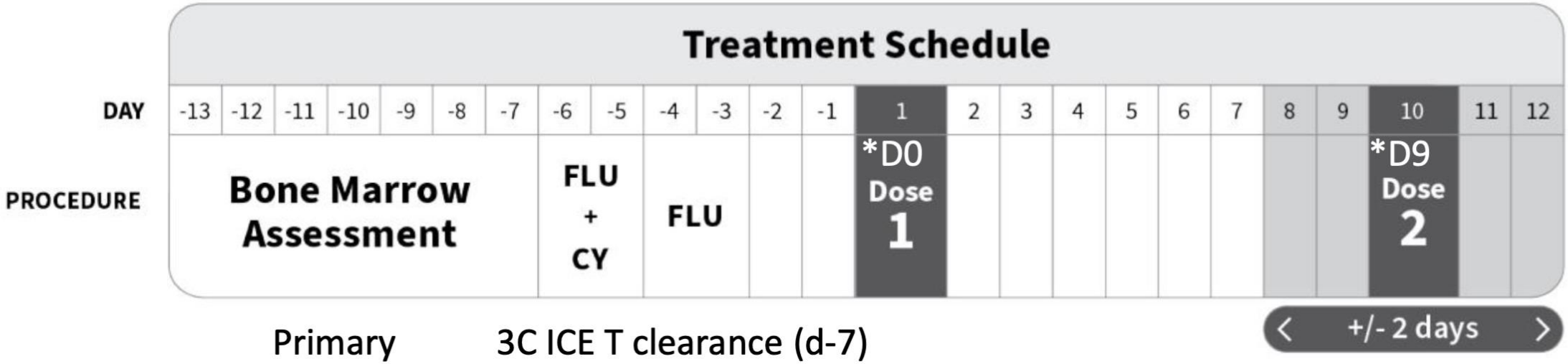
Dose selection

Cell therapy facility notification

ICE T Cell infusion orders (for both days)

Aucatzyl (obe-cel) CAR T

Figure 1: AUCATZYL Treatment Schedule



Primary team visit and cell dose selection prior to LD clearance

3C ICE T clearance (d-7)

Commercial cell infusion date
Day 0
Day 9

Final location INPT/OP per MD

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

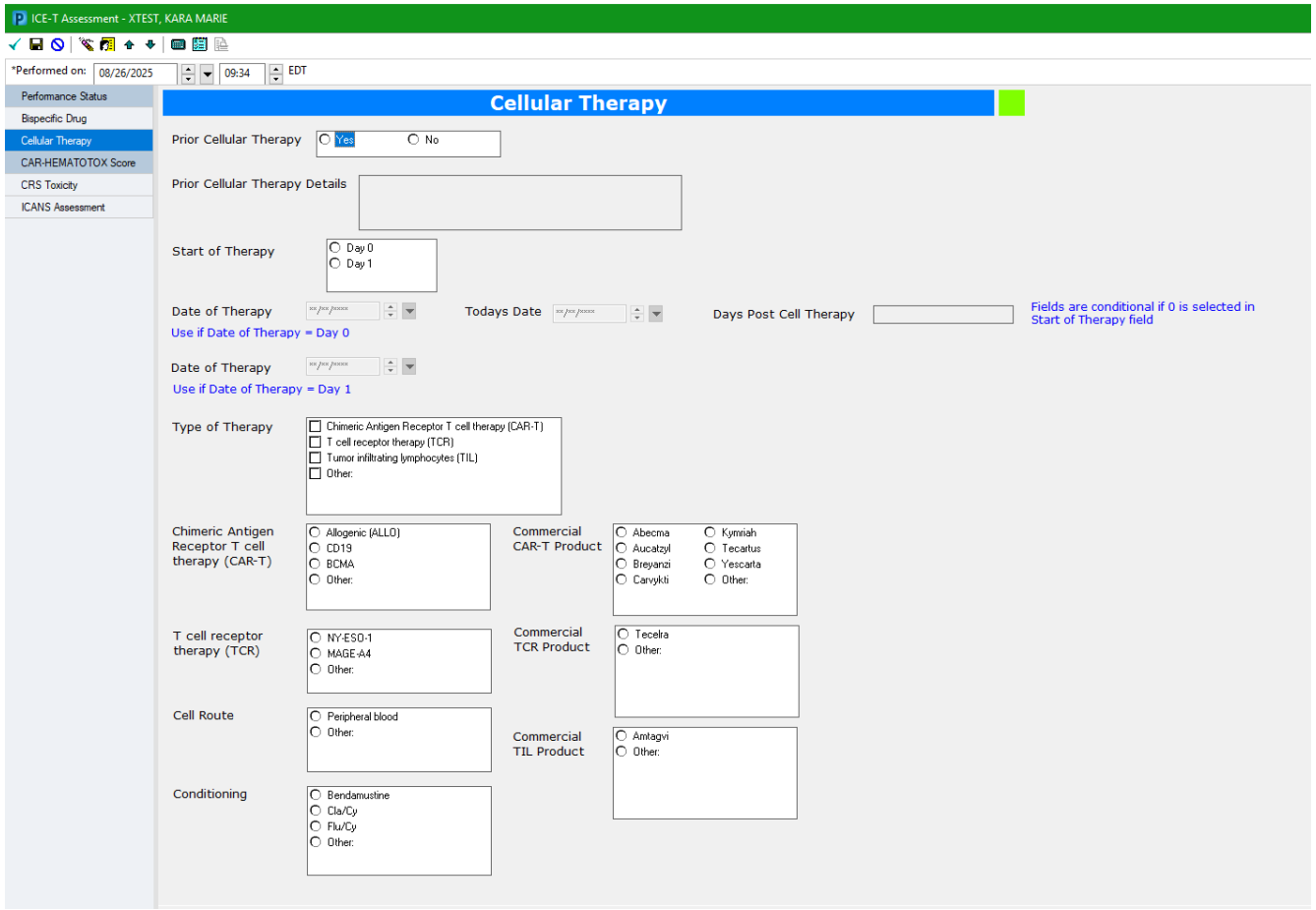
Lee, Daniel W. et al. Biology of Blood and Marrow Transplantation (2019), 25:4

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)

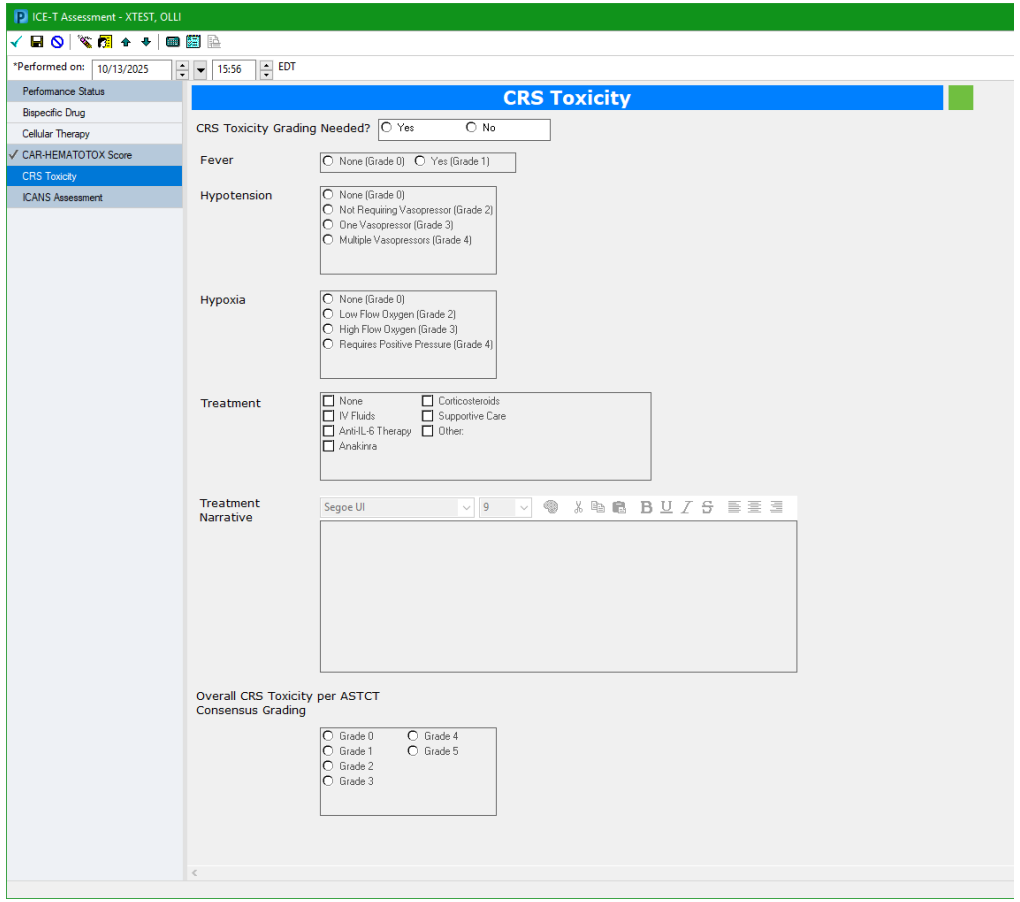
Documentation

ICE T Documentation - Therapy

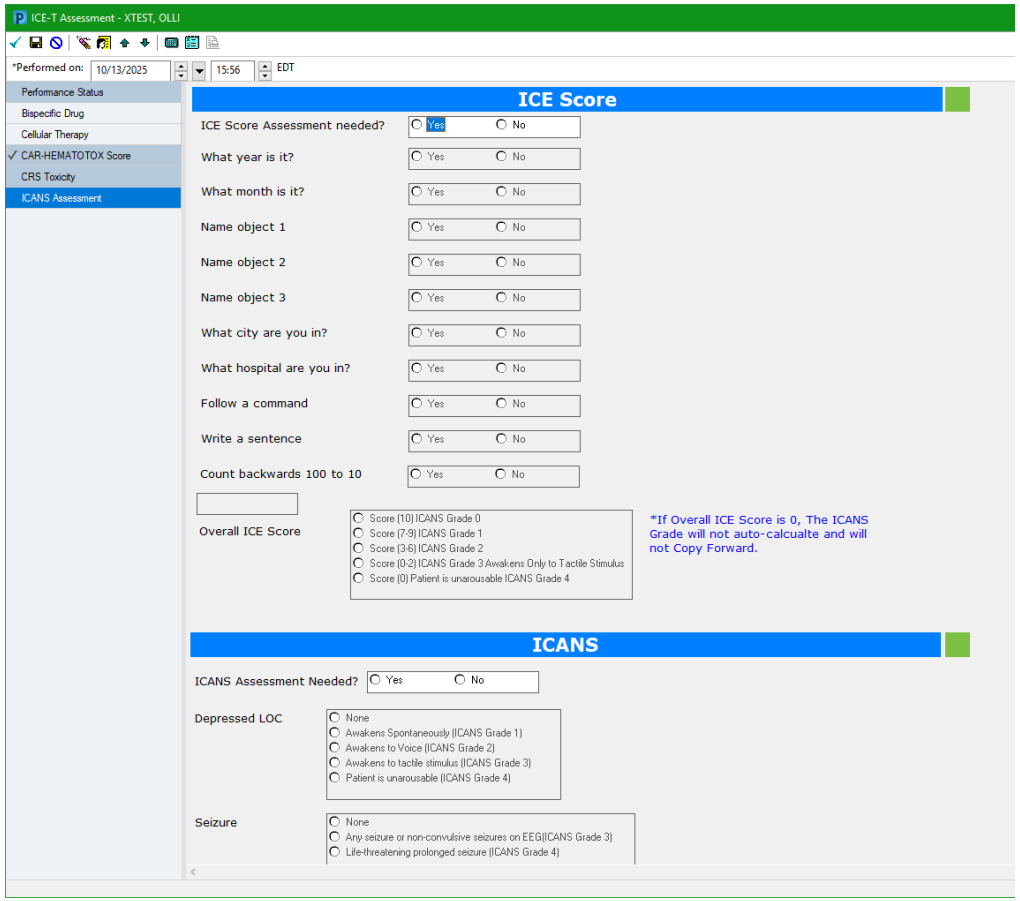


ICE T Documentation – CRS & ICANS

ASTCT: CRS



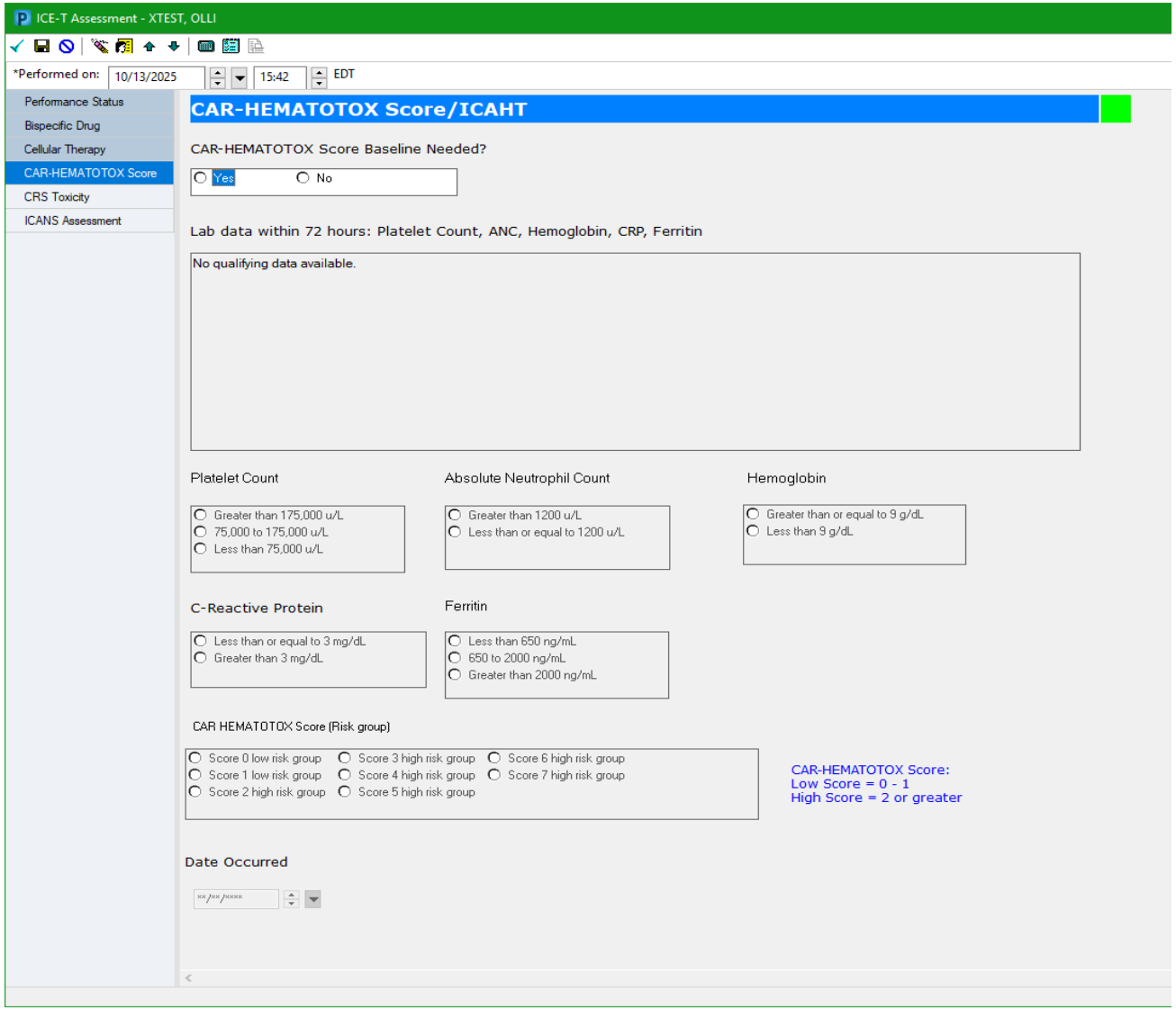
ASTCT: ICANS



ASTCT: American Society for Transplantation and Cellular Therapy

CRS: Cytokine Release Syndrome
ICANS: Immune Effector Cell–Associated Neurotoxicity Syndrome

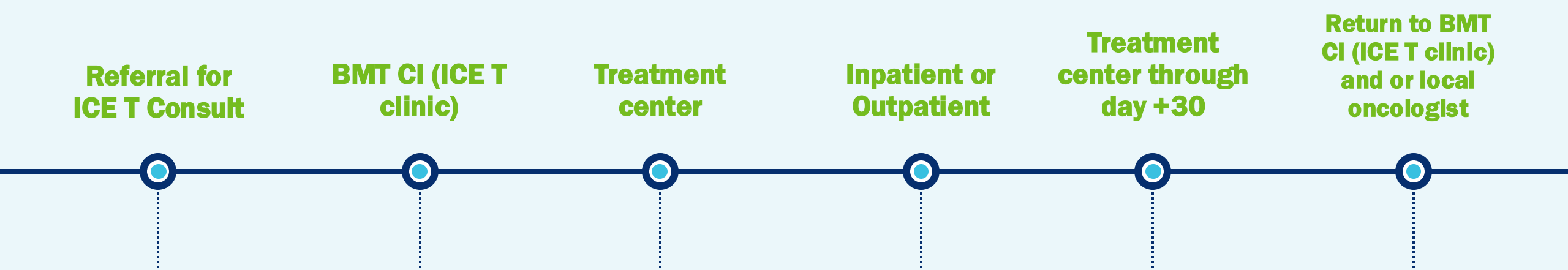
ICE T Documentation- CAR HEMATOTOX



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 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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