

**TORINO**

**DIPARTIMENTO DI BIOTECNOLOGIE  
MOLECOLARI E SCIENZE PER LA SALUTE**

**AULA ARISTOTELE**

Via Nizza, 52

**17 LUGLIO 2019**

## **IPOTESI SUI TRATTAMENTI REGIONALI PREVISTI**

**B. Bruno**

Dip. Biotecnologie Molecolari e Scienze per la  
Salute, Università di Torino –

Dip. Oncologia - Città della Salute e della Scienza di  
Torino

**ROAD MAP CAR-T**

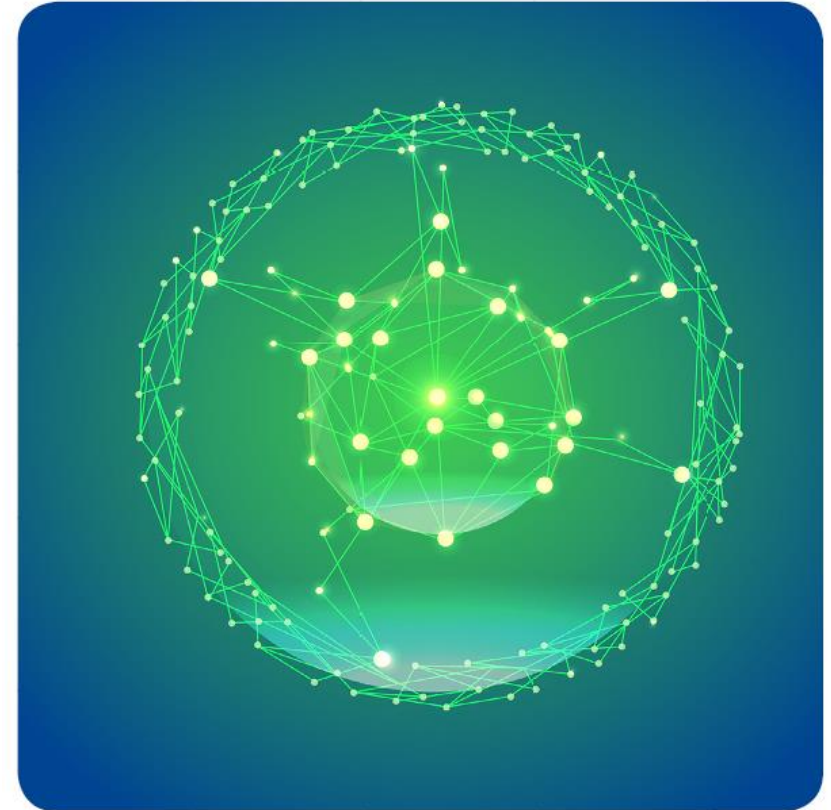
**PROSPETTIVE ATTUALI E FUTURE  
DELL'USO DELLE CAR-T IN ITALIA**

2019 **MOTORE**   
**SANITÀ**   
Gestire il Cambiamento

# Overview

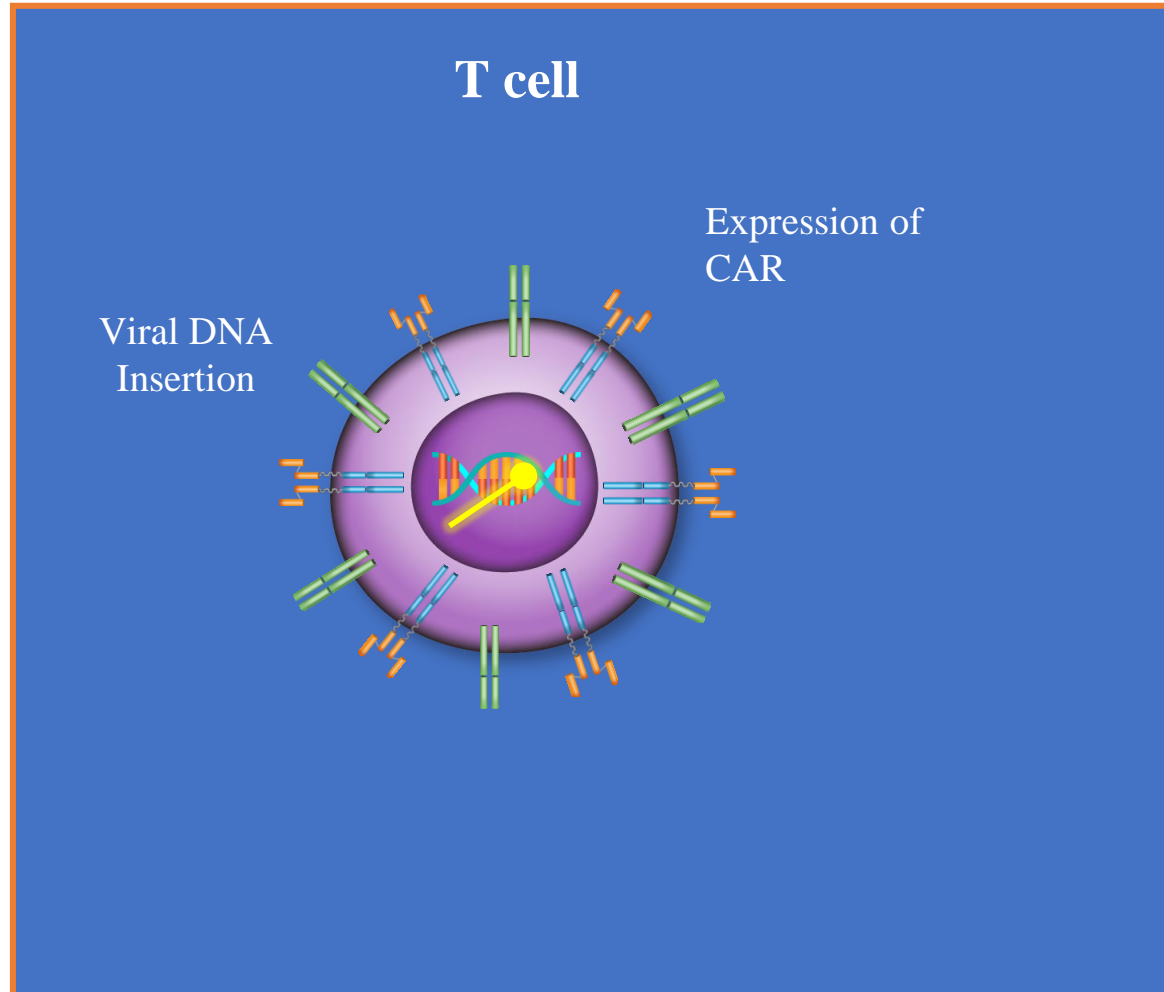
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1. **Clinical Trials *v**v***
2. **“In house” production *v**v***
3. **CAR T cells (Farmaci !) Commercial use**



# CAR T cells: Che tipo di Farmaco?

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*Terapia genica / O.G.M.*

*O.G.M.: Safety – Insurance*

*D.R.G. ??*

*Speciale/ super-speciale ??*

*Farmaco innovativo ??*

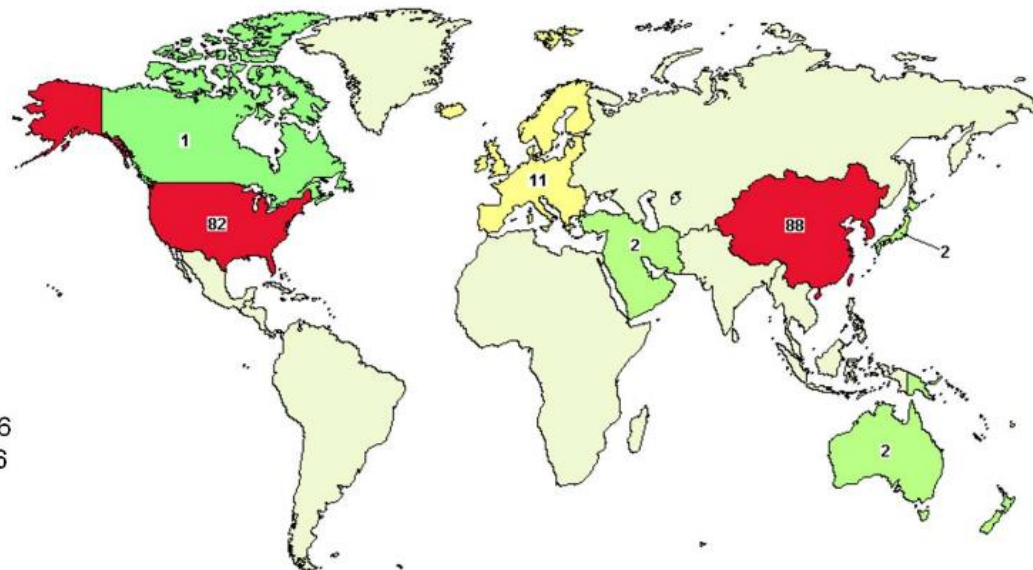


# CAR T Therapy is a Rapidly Growing Technology

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## CAR T Cell Trials Are Now Global

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123 – May 19, 2016  
102 – Feb 26, 2016  
88 – Dec 10, 2015  
77 – Sept, 2015  
<5 - 2010

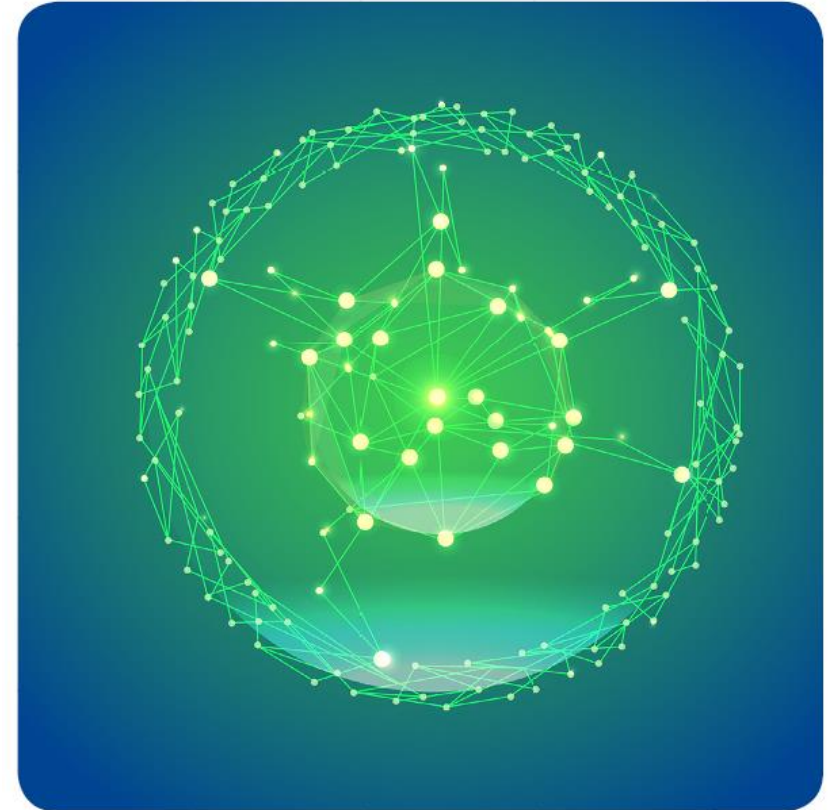
Clinical trials.gov search term “chimeric antigen receptor”  
183 trials ongoing as of April 23, 2017

Clinical trials.gov search term  
“CAR T” 792 trials ongoing as of June 2019  
“CAR T Cells” 415 trials ongoing as of June 2019

# Overview

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1. **In attesa di direttive A.I.F.A definitive**
2. **Competent Authorities A.I.F.A/C.N.T.**
3. **Società scientifiche (SIE; GITMO....)**
4. **Produttori (Companies): Qualificano il Centro**
5. **Realtà Locali**



# Quali Centri ?

- 1. Programmi Trapianto Accreditati J.A.C.I.E. (Vs >5)**
- 2. Reparto di Anestesia Rianimazione**



**J.A.C.I.E.:** The Joint Accreditation Committee ISCT-Europe & EBMT (JACIE) is Europe's only official accreditation body in the field of haematopoietic stem cell transplantation (HSCT) and cellular therapy.

# Quali Centri ?

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***Frequently Asked Questions: Effectively Transition to the  
7th Edition FACT-JACIE Hematopoietic Cellular Therapy Standards***

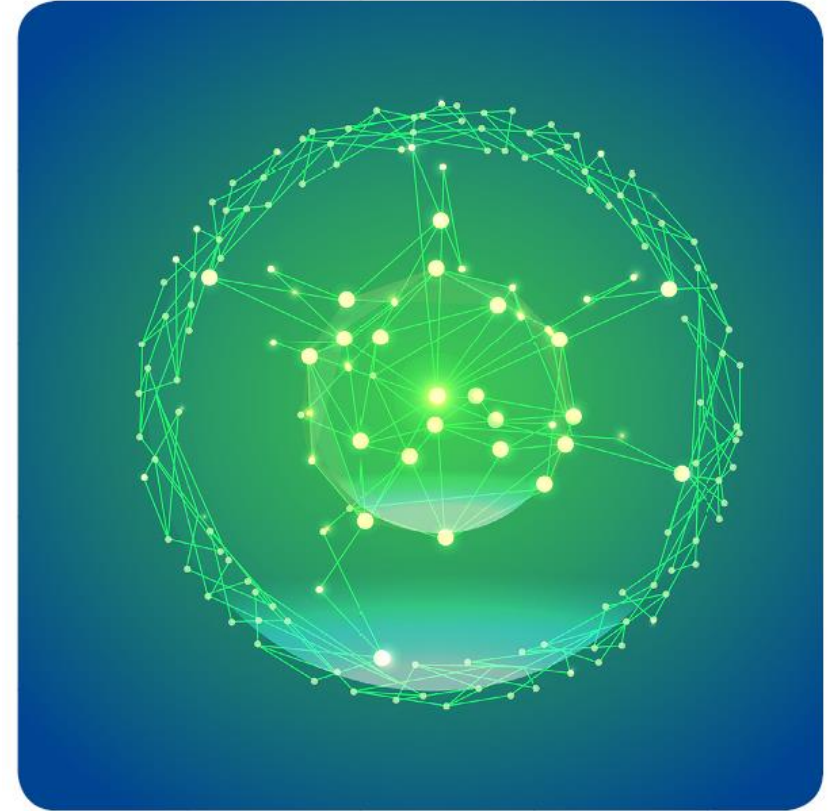


# Corretta Informazione !!!

## Quali Pazienti Candidabili?

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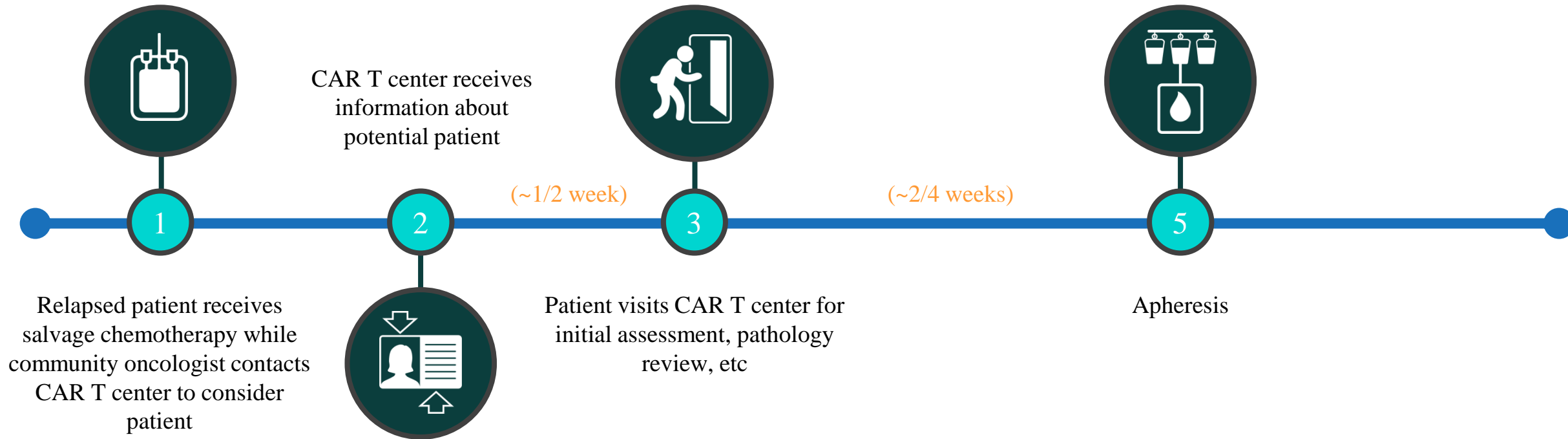
1. Poche patologie
2. Pazienti (fortemente) selezionati





# Patient Journey and Logistics: Part 1

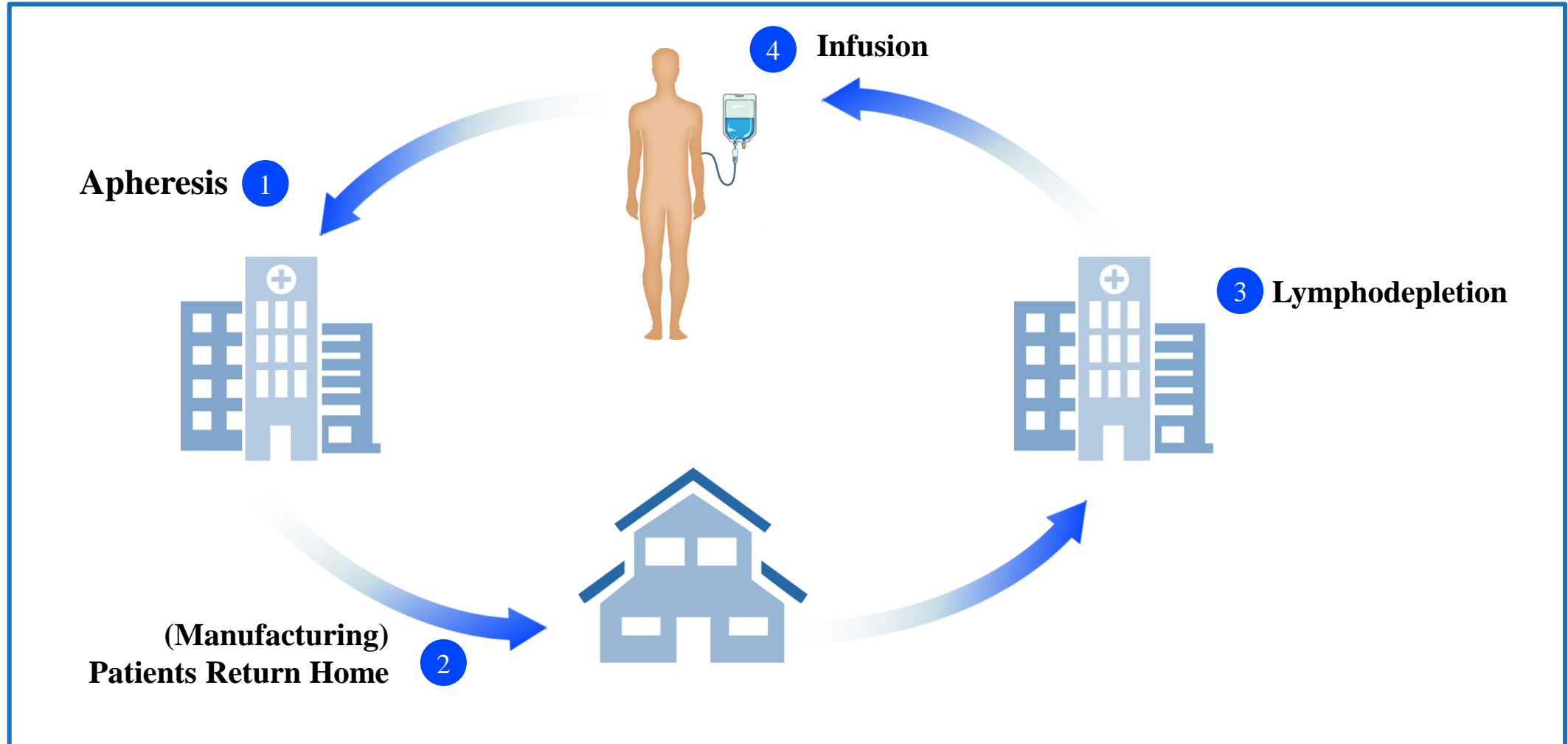
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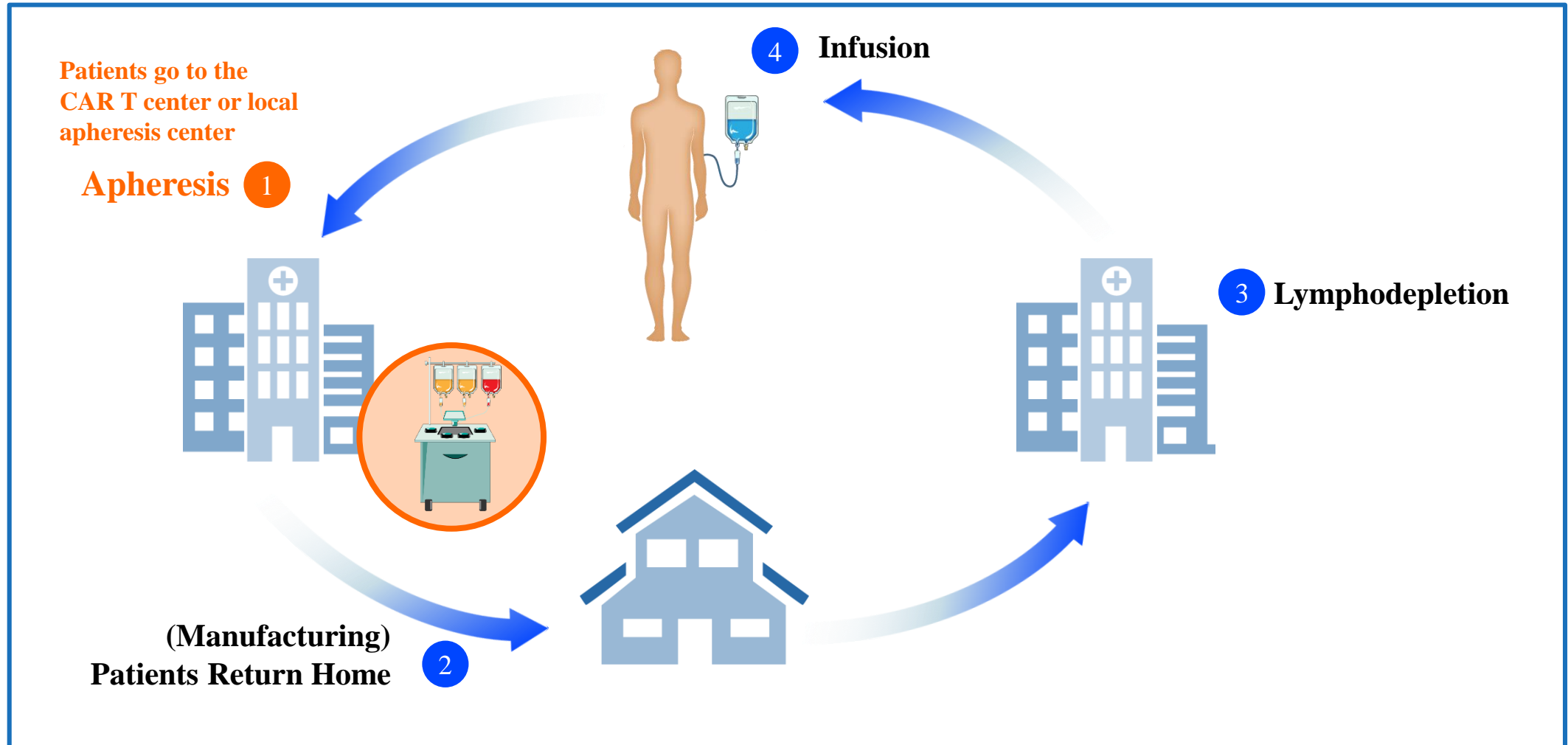
Due to the characteristics of patients who are treated with CAR T therapy, the time pressure from patient identification to apheresis is expected to be a significant constraint

# Patient Journey: Manufacturing to Infusion Part 2

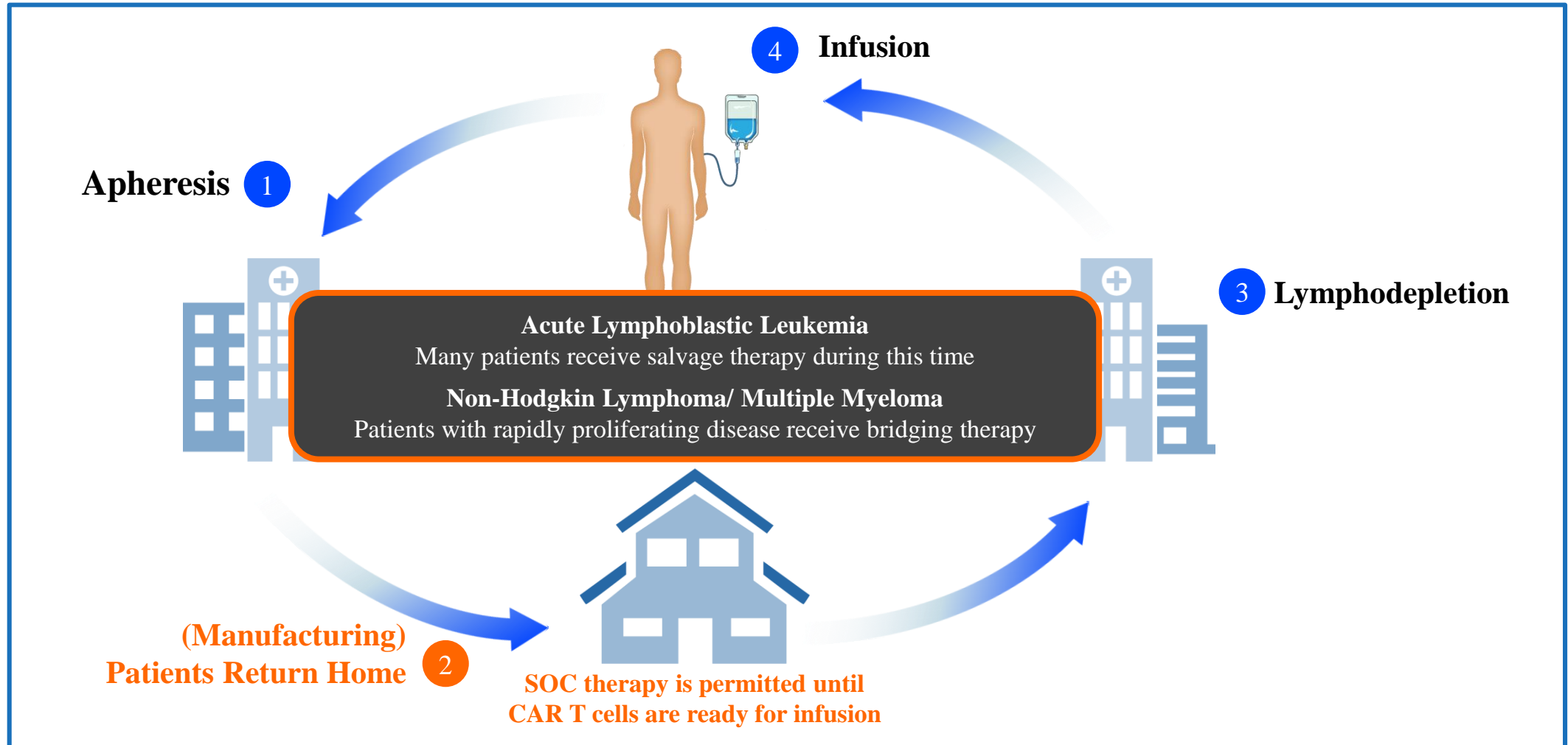
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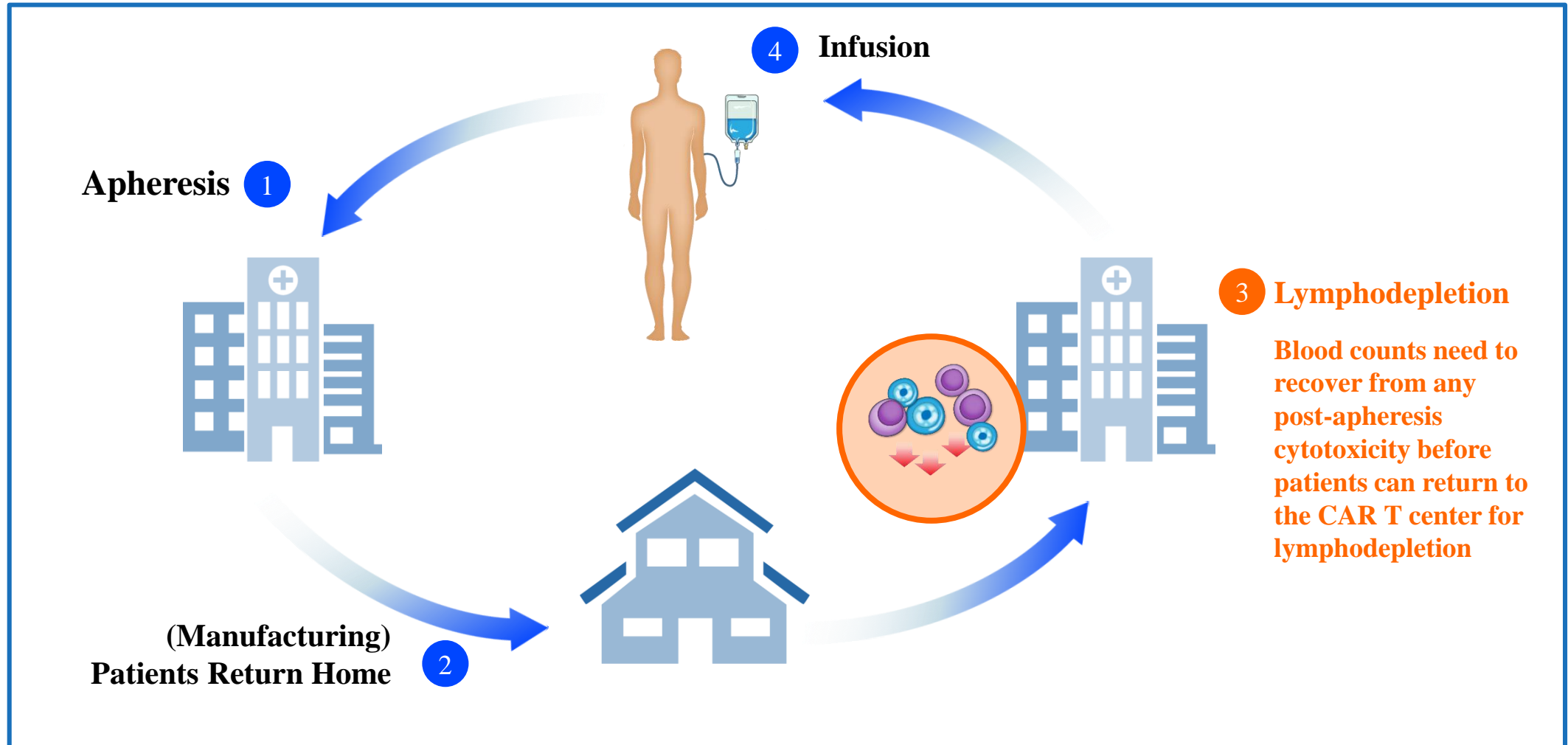
# Patient Journey: Manufacturing to Infusion Part 2



# Patient Journey: Manufacturing to Infusion Part 2

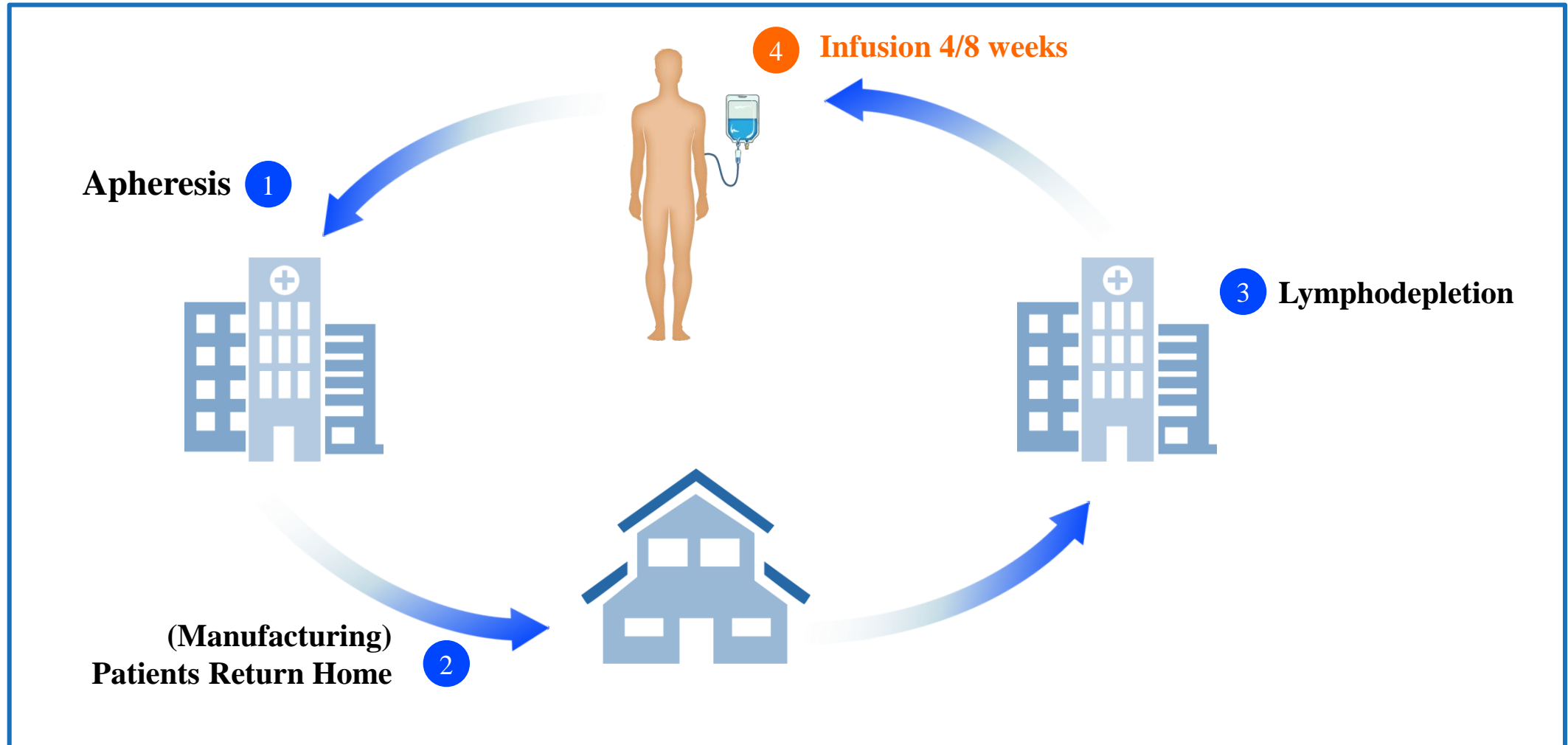


# Patient Journey: Manufacturing to Infusion Part 2



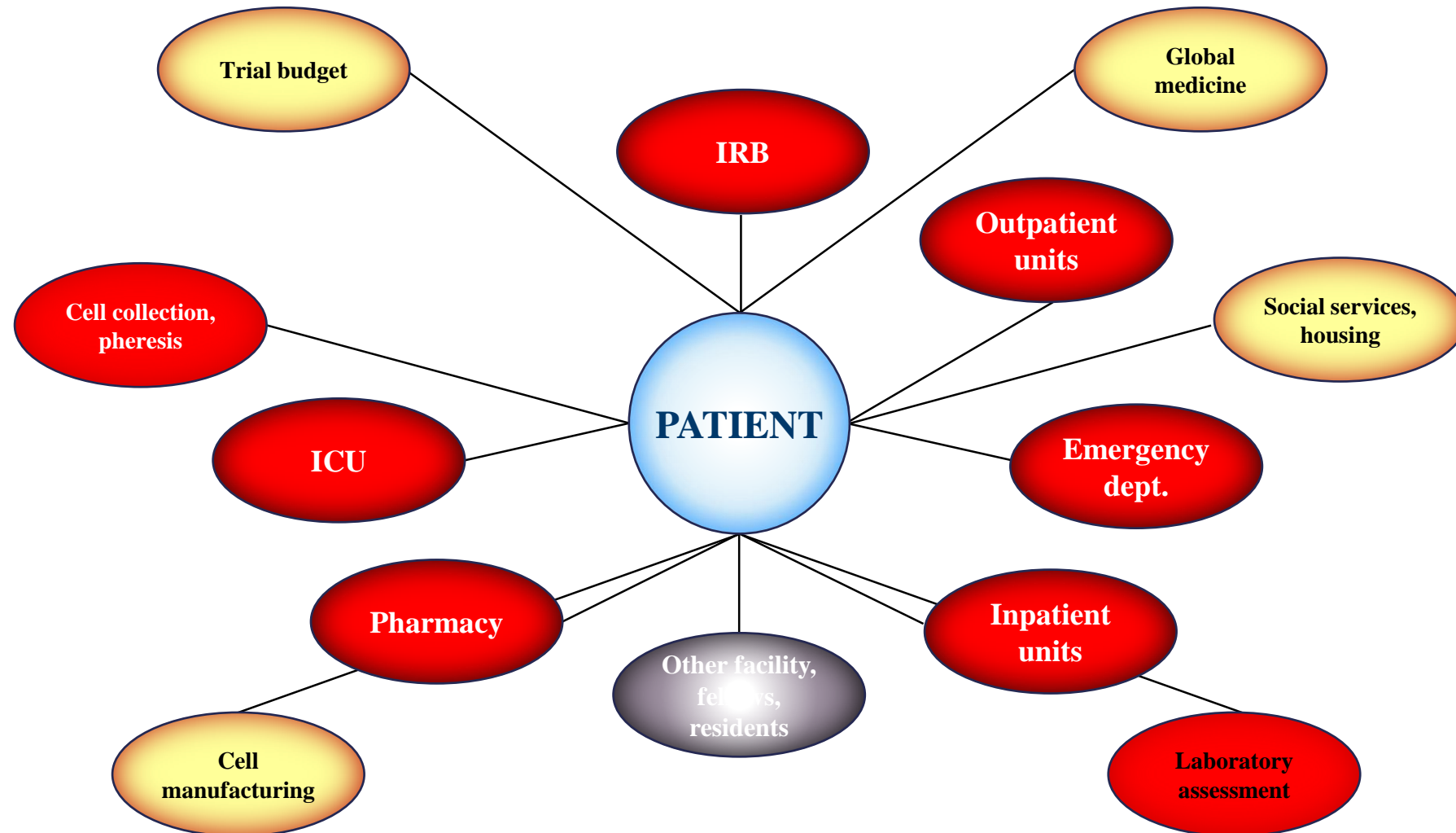
# Patient Journey: Manufacturing to Infusion Part 2

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# Best Practices: Ensure Crosstalk Between Clinical, Nursing, Financial, and Coordination Teams

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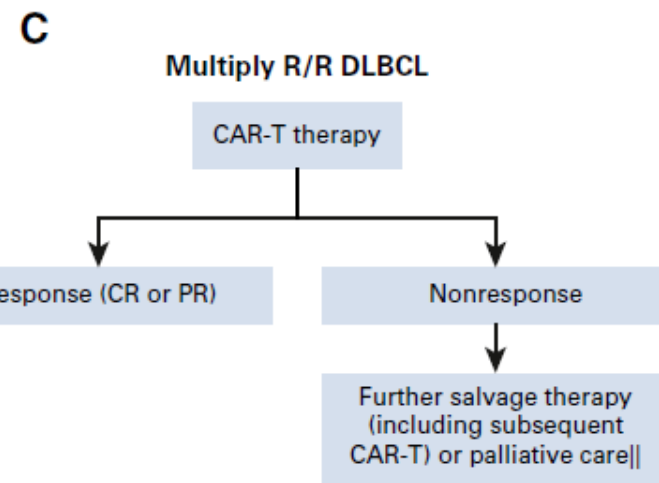
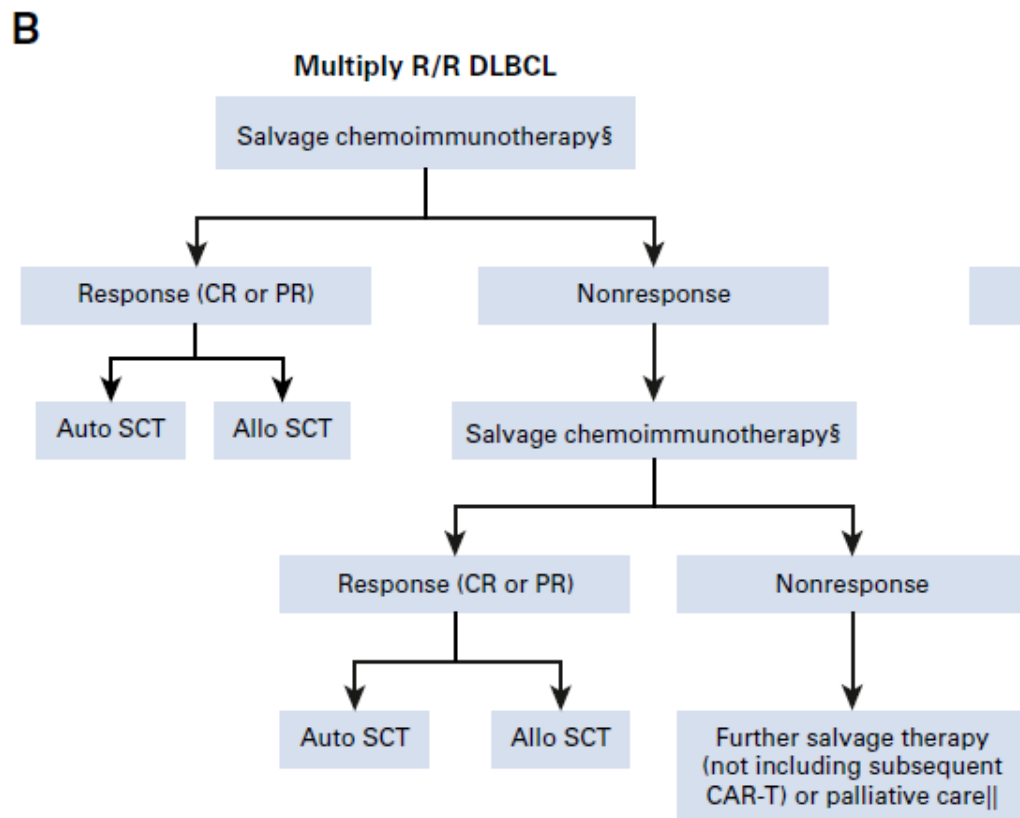
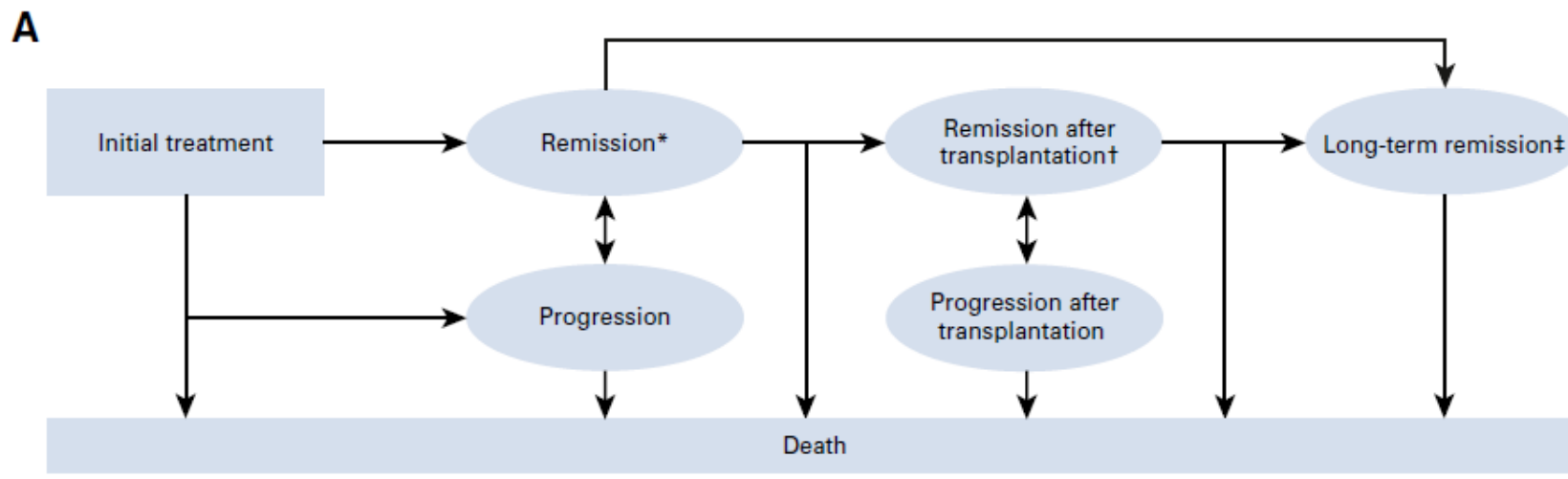


# Cost Effectiveness 1

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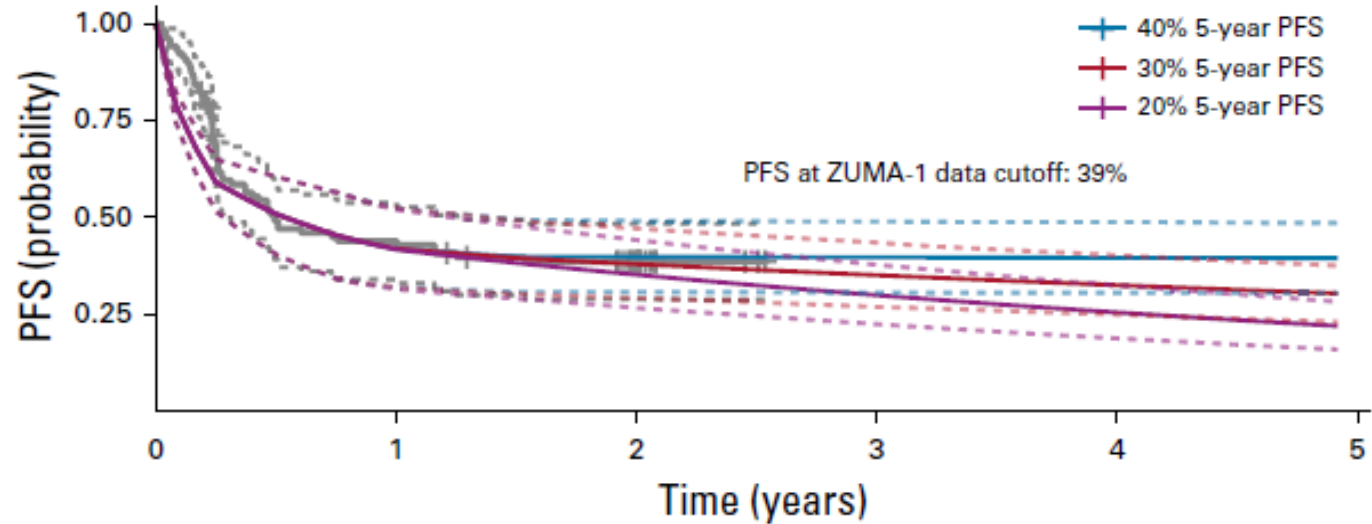
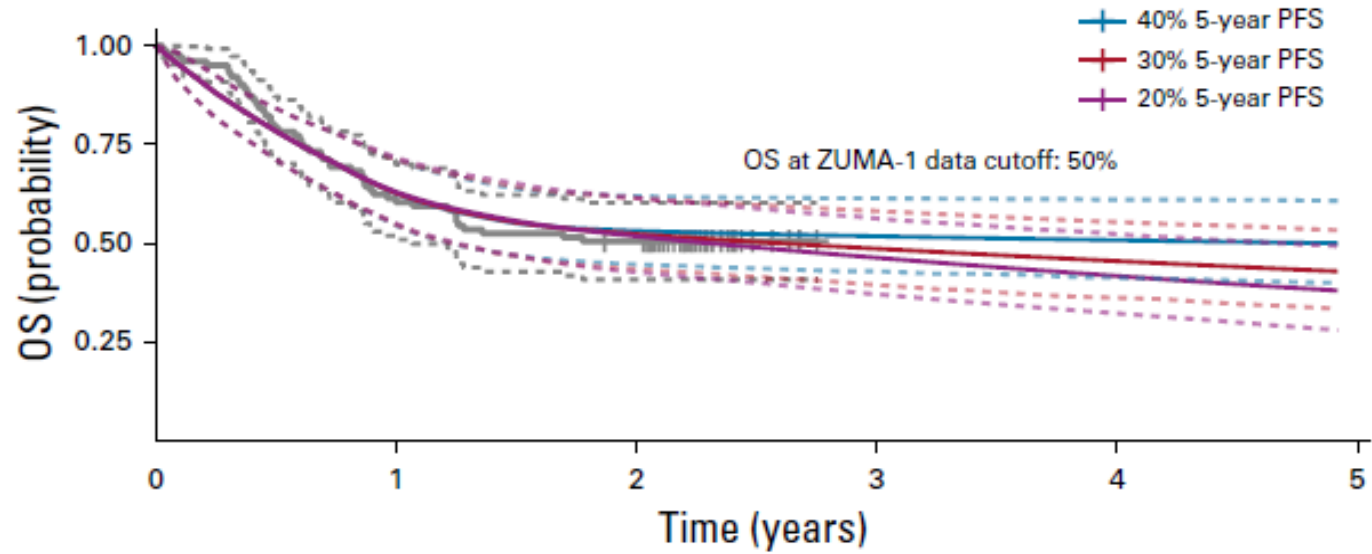
## Cost Effectiveness of Chimeric Antigen Receptor T-Cell Therapy in Multiply Relapsed or Refractory Adult Large B-Cell Lymphoma

John K. Lin, MD<sup>1,2</sup>; Lori S. Muffly, MS, MD<sup>3</sup>; Michael A. Spinner, MD<sup>3</sup>; James I. Barnes, MS, MD<sup>1,2</sup>; Douglas K. Owens, MD<sup>1,2</sup>; and Jeremy D. Goldhaber-Fiebert, PhD<sup>2</sup>

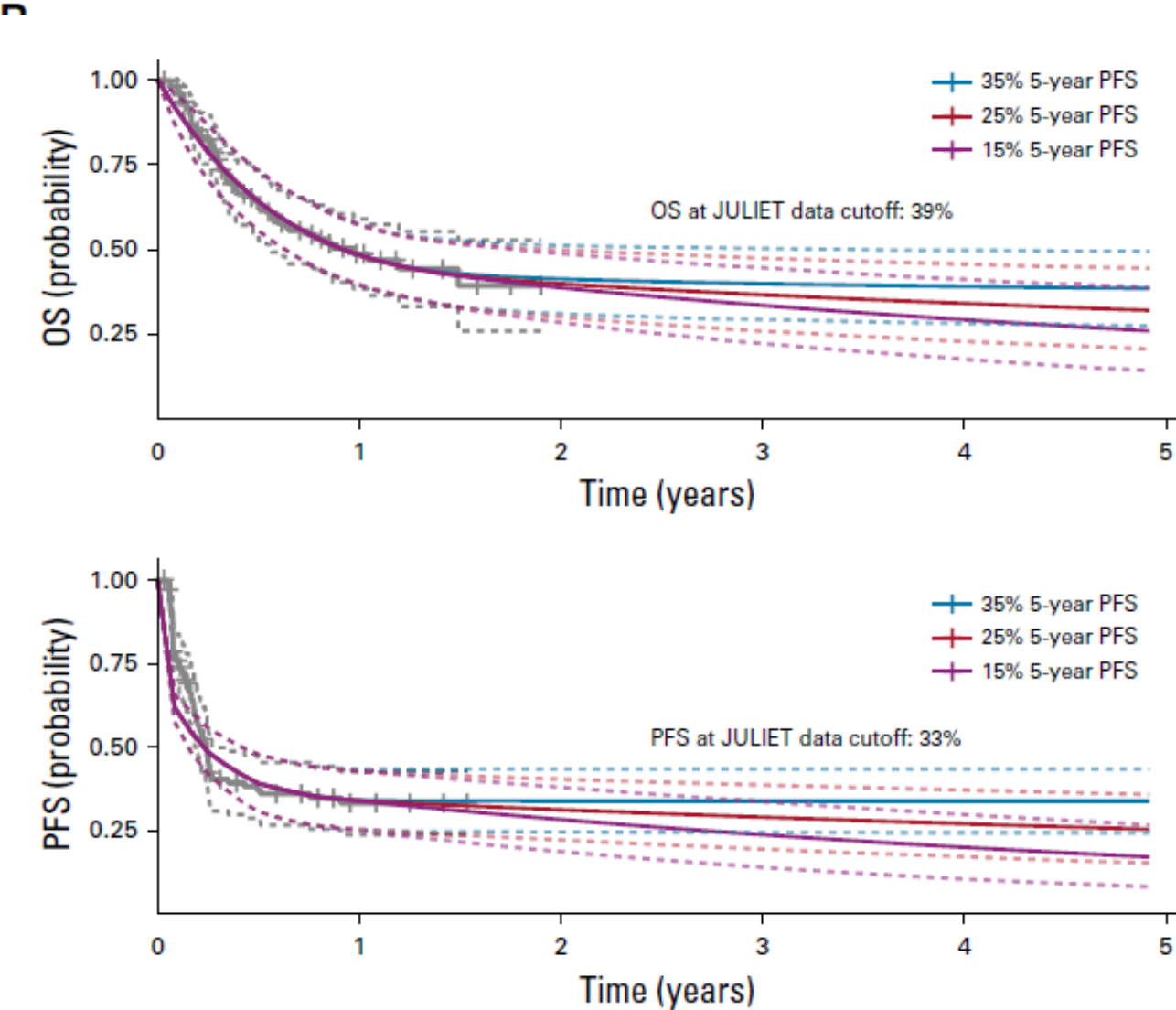


# Cost Effectiveness 1

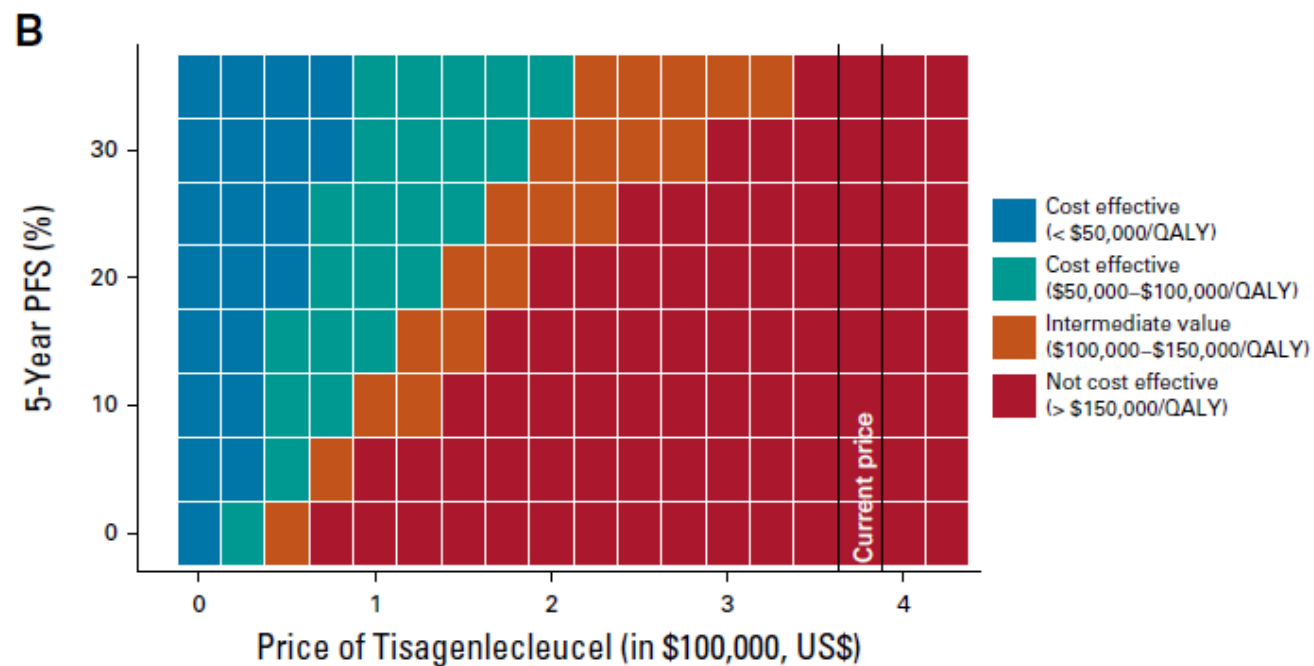
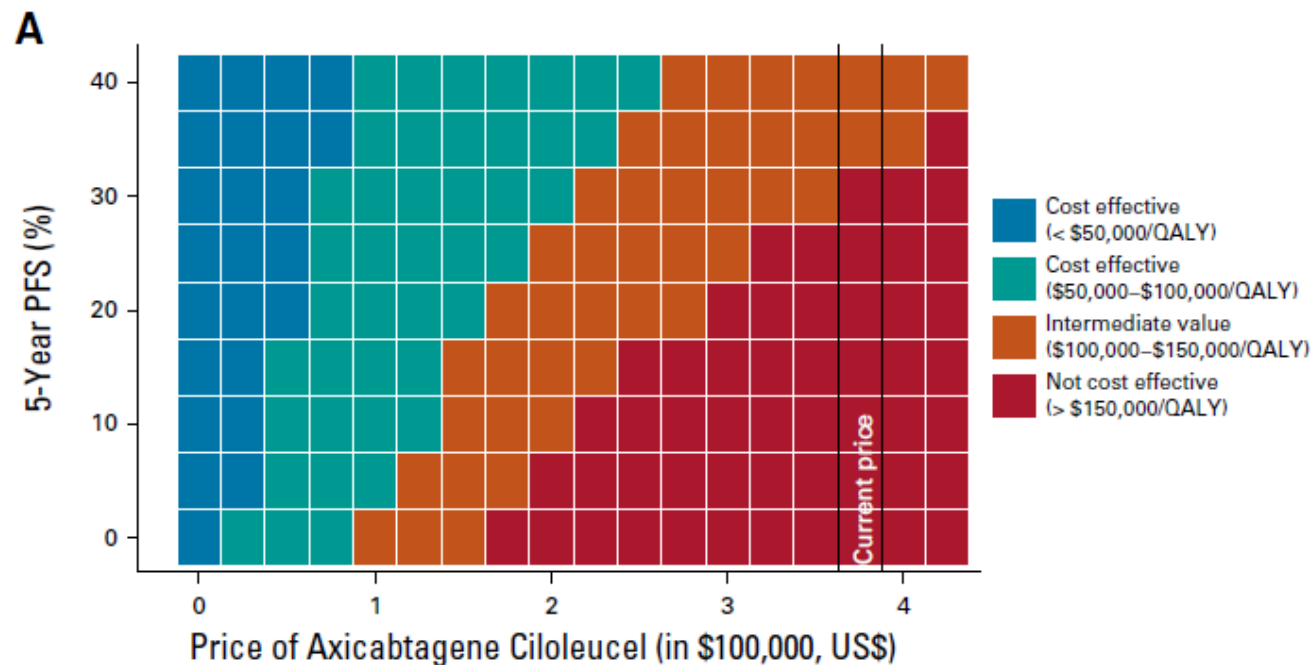
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# Cost Effectiveness 1



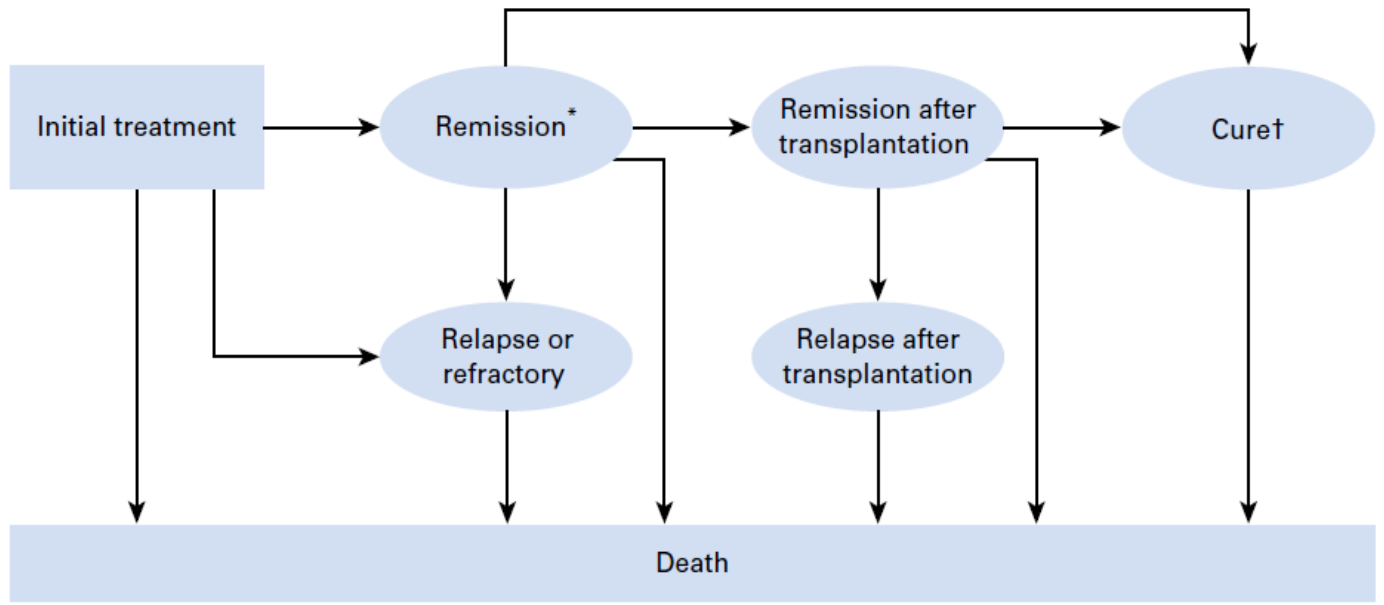
# Cost Effectiveness 1



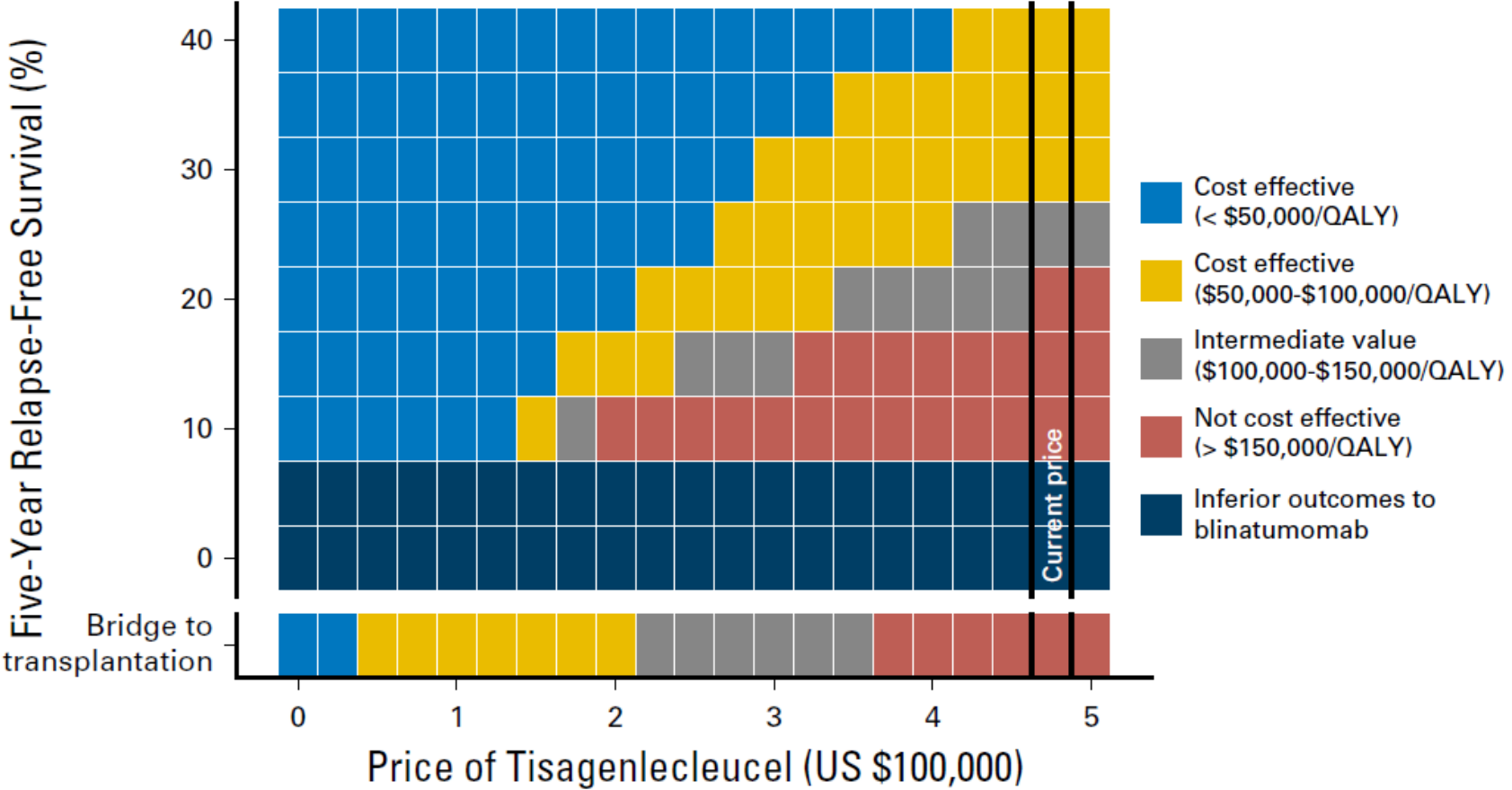
# Cost Effectiveness 2

## Cost Effectiveness of Chimeric Antigen Receptor T-Cell Therapy in Relapsed or Refractory Pediatric B-Cell Acute Lymphoblastic Leukemia

*John K. Lin, Benjamin J. Lerman, James I. Barnes, Brian C. Boursiquot, Yuan Jin Tan, Alex Q.L. Robinson, Kara L. Davis, Douglas K. Owens, and Jeremy D. Goldhaber-Fiebert*



# Cost Effectiveness 2





# Cost Effectiveness 2

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## **Conclusion**

The long-term effectiveness of tisagenlecleucel is a critical but uncertain determinant of its cost effectiveness. At its current price, tisagenlecleucel represents reasonable value if it can keep a substantial fraction of patients in remission without transplantation; however, if all patients ultimately require a transplantation to remain in remission, it will not be cost effective at generally accepted thresholds. Price reductions would favorably influence cost effectiveness even if long-term clinical outcomes are modest.

*J Clin Oncol 36:3192-3202. © 2018 by American Society of Clinical Oncology*

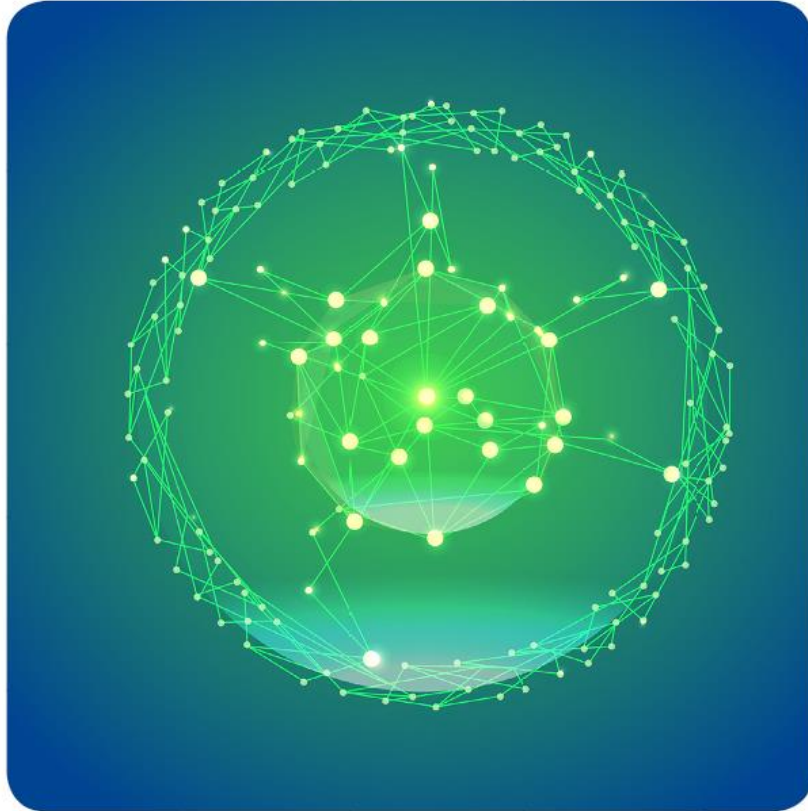


# Conclusions

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**Network !!**



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**GRAZIE PER L'ATTENZIONE**

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