Not for publication or presentation

A G E N D A
CIBMTR WORKING COMMITTEE FOR LYMPHOMA
Salt Lake City, UT
Friday, February 6, 2026, 1:00 – 3:00 PM (MT)

Co-Chair:	**Alex Herrera, MD; City of Hope National Medical Center, Duarte, CA; Telephone: 626-256-4673; E-mail: aherrera@coh.org**
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Co-Chair:	**Peter Riedell, MD; University of Chicago, Chicago, IL; Telephone: 773-702-8412; E-mail: priedell@medicine.bsd.uchicago.edu**
Scientific Director:	**Mehdi Hamadani, MD; CIBMTR® (Center for International Blood and Marrow Transplant Research), Milwaukee, WI; Telephone: 414-805-0643; E-mail: mhamadani@mcw.edu**
Scientific Director:	**Samantha Jaglowski, MD, MPH, MBA; CIBMTR® (Center for International Blood and Marrow Transplant Research), Milwaukee, WI; Telephone: 414-955-3746; E-mail: sjaglowski@mcw.edu**
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Statistical Director:	**Di Wang, PhD; CIBMTR® (Center for International Blood and Marrow Transplant Research), Milwaukee, WI; Telephone: 414-805-0700; E-mail: diwang@mcw.edu**
Statistician:	**Jinalben Patel, MPH; CIBMTR® (Center for International Blood and Marrow Transplant Research), Milwaukee, WI; Telephone: 414-955-3774; E-mail: jipatel@mcw.edu**

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1. **Introduction**
   a. Minutes from February 2025 (**Attachment 1**)

2. **Accrual summary** (**Attachment 2**)

3. **Presentations, Publications or Submitted papers**
   a. **LY20-02** Perales MA, Awan FT, Boumendil A, Patel J, Castagna L, Angelucci E, Finel H, Kulagin A, Glass B, Corradini P, Herrera AF, Blaise D, Kharfan-Dabaja MA, Halahleh K, Ahmed S, Martinez C, Giebel S, Montoto S, Jones RJ, Ahmed N, Lynch RC, de Lima MJ, Shadman M, Sauter CS, Ahn KW, Hamadani M, Bazarbachi A, Sureda A. Outcomes of allogeneic HCT in Hodgkin lymphoma in the era of checkpoint inhibitors: A joint CIBMTR and EBMT analysis. **Blood. 2025 Aug 21; 146(8):1011-1029. doi:10.1182/blood.2024027197. Epub 2025 Jul 7. PMC12530899.**
   b. **LY22-01b** Furqan F, Ahn KW, Kaur M, Patel J, Ansell S, Awan FT, Baird J, Bezerra E, Farooq U, Fung H, Khurana A, Lekakis L, Lutfi F, McCarty J, Mukherjee D, Nath R, Romancik J, Schuster SJ, Smith M, Winter A, Turtle C, Sauter C, Shadman M, Herrera A, Hamadani M. Autologous transplant or CAR-T as consolidation options in MYC rearranged large B-cell lymphoma patients in remission

after salvage treatments. **American Journal of Hematology. doi:10.1002/ajh.27687. Epub 2025 Apr 15. PMC12270545.**

c. **LY22-02c** Thiruvengadam SK, Ahn KW, Patel J, Lian Q, Hertzberg M, Epperla N, Metheny L, Hong S, Jain T, Aljurf M, Beitinjaneh A, Vaughn J, Gopal A, Iqbal M, Wirk B, Manjappa S, Oliver C, Mohty R, Shadman M, Turtle C, Hamadani M, Herrera AF. CD19 directed CAR T therapy for transformed follicular lymphoma: A CIBMTR Analysis. **American Journal of Hematology. 2025 Oct 1; 100(10):1803-1812. doi:10.1002/ajh.70027. Epub 2025 Aug 5. PMC12582634.**

d. **LY22-02d** Nadiminti KV, Ahn KW, Patel J, Lian Q, Bezerra E, Chen A, Ganguly S, Gergis U, Hashmi H, Kharfan-Dabaja MA, Kuruvilla J, Lekakis L, Locke FL, Murthy H, Mousthafa MA, Perales MA, Pophali P, Riedell PA, Shah NN, Wang T, Pasquini M, Hamadani M, Turtle CJ, Herrera AF, Shadman M. Chimeric antigen receptor T-cell therapy for richter transformation: A CIBMTR analysis. **Transplantation and Cellular Therapy. S2666-6367(25):01334-X. doi:10.1016/j.jtct.2025.07.02. Epub 2025 Aug 1.**

e. **LY22-02e** Gauthier J, Ahn KW, Patel J, Lian Q, Badawy S, Cairo MS, Delgado J, Grover N, Haverkos B, de Lima M, Malone A, Mussetti A, Nieto Y, Pawarode A, Pearson L, Solh M, Sureda A, Tun AM, Wudhikran K, Yamshon S, Shadman M, Turtle CJ, Hamadani M, Herrera AF. CD19 CAR T-cell therapy for primary mediastinal large B-cell lymphoma: a CIBMTR analysis. **American Journal of Hematology. 2025 Sep 28; 100(10):17. doi:10.1002/ajh.70033. Epub 2025 Aug 11. PMC12608806.**

f. **LY22-02f** Hossain NM, Ahn KW, Patel J, Lian Q, Bilal Abid M, Al Nughmush A, Bacher U, Bi X, Hashmi SK, Hilal T, Husnain M, Khimani F, Maziarz RT, Modi D, Ram R, Rizzieri D, Sica RA, Steinberg A, Vij R, Shadman M, Turtle C, Hamadani M, Herrera AF. Chimeric antigen receptor T-cell therapy for high grade B-cell lymphoma NOS. **British Journal of Haematology. 2025 Sep 1; 207(3):1011-1018. doi:10.1111/bjh.70020. Epub 2025 Jul 22.**

g. **LY22-02h** Patel J, Gopal A, Cherniawsky H, Ram R, Kamble R, Hamadani M. CD19 directed CAR T therapy for intravascular large B-cell lymphoma. **Haematologica. doi:10.3324/haematol.2025.288838. Epub 2025 Nov 6.**

h. **LY22-02c** CD19-Directed CAR-T Therapy for Transformed Follicular Lymphoma: A CIBMTR Analysis (S Kambhampati/ K Nadimenti/ A Herrera). ***Poster Presentation, Tandem Meetings 2025.***

i. **LY22-02d** CD19-Directed CAR-T Therapy for Richter Transformation: A CIBMTR Analysis (M Shadman/ M Hamadani). ***Poster Presentation, Tandem Meetings 2025.***

j. **LY22-02e** Real-World Outcomes of CD19 CAR T-Cell Therapy in Patients with Primary Mediastinal B-Cell Lymphoma and Impact of Prior ICI Treatment: A CIBMTR Analysis (J Gauthier/ A Herrera). ***Poster Presentation, Tandem Meetings 2025.***

k. **LY22-02f** CAR T Outcomes in Patients with High-Grade B-Cell Lymphoma Not Otherwise Specified (HGBL-NOS): A CIBMTR Analysis (S Ahmed/ S Mercadal/ H Hashmi/ C J Lee/ N Epperla). ***Poster Presentation, Tandem Meetings 2025.***

4. Studies in progress (**Attachment 3**)

a. **LY23-01** Efficacy of hematopoietic stem cell transplantation in patients with plasmablastic lymphoma (S Ahmed/ T Al-Juhaishi)**. Manuscript Preparation.**

b. **LY24-01a** Role of Hematopoietic Cell Transplantation in Rare Peripheral T-cell Lymphoma Subtypes – Hepatosplenic T-cell lymphoma (M Iqbal / A Tun). **Datafile Preparation.**

c. **LY24-01b** Role of Hematopoietic Cell Transplantation in Rare Peripheral T-cell Lymphoma Subtypes - Monomorphic epitheliotropic intestinal T-cell lymphoma and enteropathy-associated
T-cell lymphoma (T Brooks/ Y Pang). **Datafile Preparation.**

d. **LY24-01c** Role of Hematopoietic Cell Transplantation in Rare Peripheral T-cell Lymphoma Subtypes **–** Extra-nodal NK/T-cell lymphoma, nasal type (A Desai/ K Rechache). **Datafile Preparation.**

e. **LY24-01d** Role of Hematopoietic Cell Transplantation in Rare Peripheral T-cell Lymphoma Subtypes – Nodal T-follicular helper cell lymphoma (I Muhsen/ C Poh). **Datafile Preparation.**
f. **LY24-01e** Role of Hematopoietic Cell Transplantation in Rare Peripheral T-cell Lymphoma Subtypes – Subcutaneous panniculitis-like T-cell lymphoma (D Reef/ A Stack). **Datafile Preparation.**
g. **LY24-01f** Role of Hematopoietic Cell Transplantation in Rare Peripheral T-cell Lymphoma Subtypes – Adult T-cell leukemia/lymphoma (A Sica/ R Stuver). **Datafile Preparation.**
h. **LY24-01g** Role of Hematopoietic Cell Transplantation in Rare Peripheral T-cell Lymphoma Subtypes – Mycosis fungoides/Sezary syndrome (A Goyal/ E Yilmaz). **Datafile Preparation.**
i. **LY25-01** Axi-cel vs. Liso-cel in Second line in DLBCL (A Mian/ B T Hill/ D Reef/ N Grover). **Protocol Pending.**
j. **LY25-02** Real-world Outcomes Following Anti-CD19 Chimeric Antigen Receptor T Cell Therapy in Older Patients with Large B Cell Lymphoma. (M Di/ M Shadman/ S Gupta/ V Bachanova/ P Jain/ A Lionel). **Protocol Pending.**

5. Future/proposed studies

a. **PROP 2508-01** Novel Composite Endpoints Toxicity-free/Progression-free survival (tfPFS100) and Toxicity-free Complete Remission (tfCR100) after CAR T cell therapy for diffuse large B cell lymphoma (V Bachanova) (**Attachment 4**)
b. **PROP 2508-05** Optimizing approaches to Allotransplant for Non-Hodgkin Lymphoma patients relapsing after second line CART therapy (N Hossain/ P Munshi) (**Attachment 5**)
c. **PROP 2509-33; 2509-105** Lisocabtagene maraleucel for the treatment of relapsed or refractory mantle cell lymphoma: a CIBMTR analysis (J Huang/ T Brooks) (**Attachment 6**)
d. **PROP 2509-88; 2509-136** The role of bridging radiation therapy prior to CD19 CAR T for non-Hodgkin lymphoma (M Alhomoud/ M Scordo/ R Mailhot/ E Mobley) (**Attachment 7**)
e. **PROP 2509-115** Late Relapses After CD19 CAR-T Cell Therapy for Diffuse Large B-Cell Lymphoma: Cumulative Incidence, Predictors, and Post-Relapse Outcomes (J Desroches/ A Khurana) (**Attachment 8**)
f. **PROP 2509-225** Outcomes of Chimeric Antigen Receptor (CAR) T-Cell Therapy in Post-Transplant Lymphoproliferative Disorders (P Thazin Myint/ G Hildebrandt) (**Attachment 9**)

Proposed studies; not accepted for consideration at this time

g. **PROP 2412-03** Autologous HCT in Secondary CNS lymphoma (A Kidwell/ B Gattas/ N Shah/ U Gergis). ***Dropped due to small sample size.***
h. **PROP 2503-01** Impact of Prior Mogamulizumab Therapy on Allogeneic Stem Cell Transplantation Outcomes in Patients with T-Cell Lymphomas: A CIBMTR Analysis (Y Choi). ***Dropped due to small sample size.***
i. **PROP 2508-08** Outcomes of Allogenic HSCT in patients with secondary hematological malignancies (SHM) following CAR T Cell therapy. (R Faramand/ S Hamid). ***Dropped due to low scientific impact.***
j. **PROP 2509-09** Outcomes of Allogeneic vs Autologous Stem Cell Transplant in First CR for PTCL (C Peterson/ M Herr). ***Dropped due to low scientific impact.***
k. **PROP 2509-20** Impact of Time from Relapse to Apheresis (TRA) on Outcomes of Autologous Anti-CD19 CAR T-Cell Therapy in Patients with Relapsed/Refractory Large B-Cell Lymphoma (LBCL) (C Zhang/ P Strati). ***Dropped due to low scientific impact.***
l. **PROP 2509-41** Real World Outcomes of Anti-CD19 CAR-T Cell Therapy in Follicular Lymphoma: Comparing Products and Exploring the Impact of Prior Therapies and Line of Therapy (S Franco/ N Grover). ***Dropped due to low scientific impact.***

m. **PROP 2509-48** Outcomes of post-CAR T salvage therapies in relapsed/refractory mantle cell lymphoma (A Xiao/ T Phillips). ***Dropped due to low scientific impact.***
n. **PROP 2509-51** Chimeric antigen receptor T-cell therapy in immunodeficiency-associated aggressive B-cell non-Hodgkin lymphomas: A CIBMTR analysis (A Tun/ P Johnston). ***Dropped due to small sample size.***
o. **PROP 2509-54** Autologous versus Allogeneic Stem Cell Transplantation for large B cell lymphomas patients who failed anti-CD19 CAR T-cell as first or second-line of therapy (A Mussetti/ A Kanate). ***Dropped due to small sample size.***
p. **PROP 2509-61** An international study comparing the efficacy and utility of anti-CD19 CAR-T versus allogeneic stem cell transplantation for Richter Transformation (G Wehymeyer/ A Kittai). ***Dropped due to low scientific impact.***
q. **PROP 2509-66** Autologous or allogeneic stem cell transplant as consolidation in fit patients with relapsed/refractory DLBCL responding to bi-specific antibodies. (A Oliver/ V Irigoin). ***Dropped due to small sample size.***
r. **PROP 2509-78** Risk of Graft-Versus-Host Disease After Anti-CD19 CAR-T Therapy in Recipients of Prior Allogeneic Stem Cell Transplants (G O Dannehy/ N Wagner-Johnston). ***Dropped due to low scientific impact.***
s. **PROP 2509- 90** A Comparative Analysis of Clinical Outcomes of CD19 Directed CAR T-cell therapy versus autologous bone marrow transplantation in patients with relapsed/refractory post-transplant lymphoproliferative disorder (PTLD) (C Duarte/ B Haverkos). ***Dropped due to small sample size.***
t. **PROP 2509-94** Impact of Clonal Hematopoiesis on Clinical Outcomes Following CAR-T Cell Therapy (A Kishtagari). ***Dropped due to low scientific impact.***
u. **PROP 2509-95** Impact of previous exposure to CD3/CD20 bispecific antibodies on outcomes post CD19 CAR T in R/R large B-cell lymphoma and R/R follicular lymphoma patients (S Thiruvengadam/ A Herrera). ***Dropped due to small sample size.***
v. **PROP 2509-96** Matched Analysis of CD19 CAR T and Bispecific Antibodies in R/R large B-cell lymphoma and R/R follicular lymphoma (S Thiruvengadam/ A Herrera). ***Dropped due to low scientific impact.***
w. **PROP 2509-97** The Durability of Consolidative Transplant in Mediastinal Gray Zone Lymphoma (N Amirmokhtari/ F Lutfi). ***Dropped due to small sample size.***
x. **PROP 2509-140** Sequencing Bispecific Antibodies and CAR-T Cell Therapy in Diffuse Large B-cell Lymphoma (S Franco/ N Grover). ***Dropped due to low scientific impact.***
y. **PROP 2509-141** Patient-Reported Outcomes (PROs) Following Anti-CD19 Chimeric Antigen Receptor T-Cell Therapies for Aggressive B-Cell Lymphomas: A Comparative Analysis of Axicabtagene Ciloleucel and Lisocabtagene Maraleucel Utilizing CIBMTR Data (G Fatobene/ V Rocha). ***Dropped due to low scientific impact.***
z. **PROP 2509-149** Characterization of patients with DLBCL and a history of HBV infection undergoing cellular therapy or HCT (A Binder/ D Russ). ***Dropped due to low scientific impact.***
aa. **PROP 2509-154** Efficacy and Toxicity of Lisocabtagene Maraleucel vs Brexucabtagene autoleucel in Older patients with Mantle cell lymphoma (M Iqbal/ M Karfan-Dabaja). ***Dropped due to low scientific impact.***
bb. **PROP 2509-158** Allogeneic hematopoietic stem cell outcomes in previous CAR-T therapy recipients (F Lutfi/ S Dahiya). ***Dropped due to low scientific impact.***
cc. **PROP 2509-163** Comparative Outcomes of CAR-T Therapy Versus Autologous Stem Cell Transplant in Relapsed/Refractory PMBCL in the second line settings (early relapse)- A CIBMTR Study (A Khurana/ A Falade). ***Dropped due to small sample size.***

dd. **PROP 2509-165** Long-Term Outcomes and Predictors of Progression-Free Survival at 12 Months Following CAR-T Therapy for Diffuse Large B-Cell Lymphoma (A Ravindra/ U Farooq). ***Dropped due to overlap with current study/publication.***

ee. **PROP 2509-171** Real-World Comparison of Safety and Efficacy of Brexucabtagene Autoleucel versus Lisocabtagene Maraleucel for Relapsed or Refractory Mantle Cell Lymphoma (S Gupta/ V Bachanova/ A Lionel/ P Jain). ***Dropped due to small sample size.***

ff. **PROP 2509-192** Outcomes of pediatric, adolescent, and young adult patients with relapsed or refractory ALK-positive anaplastic large cell lymphoma post consolidation with autologous or allogeneic hematopoietic cell transplant. (A Xavier/ M Cairo). ***Dropped due to low scientific impact.***

gg. **PROP 2509-221** Impact of Lenalidomide Exposure on CAR T-Cell Therapy in Diffuse Large B-cell Lymphoma (DLBCL) (P T Myint/ M Yasir). ***Dropped due to low scientific impact.***

6. Other business

MINUTES
CIBMTR WORKING COMMITTEE FOR LYMPHOMA
Honolulu, HI
Friday, February 14, 2025, 1:00 – 3:00 PM HST

Co-Chair:	**Cameron Turtle, MBBS, PhD; University of Sydney, Sydney, NSW, Australia; E-mail: cameron.turtle@sydney.edu.au**
Co-Chair:	**Alex Herrera, MD; City of Hope National Medical Center, Duarte, CA; Telephone: 626-256-4673; E-mail: aherrera@coh.org**
Co-Chair:	**Mazyar Shadman, MD, MPH; Fred Hutchinson Cancer Research Center, Seattle, WA; Telephone: 206-667-5467; E-mail: mshadman@fredhutch.org**
Scientific Director:	**Mehdi Hamadani, MD; CIBMTR® (Center for International Blood and Marrow Transplant Research), Milwaukee, WI; Telephone: 414-805-0643; E-mail: mhamadani@mcw.edu**
Statistical Director:	**Kwang Woo Ahn, PhD; CIBMTR® (Center for International Blood and Marrow Transplant Research), Milwaukee, WI; Telephone: 414-456-7387; E-mail: kwooahn@mcw.edu**
Statistician:	**Jinalben Patel, MPH; CIBMTR® (Center for International Blood and Marrow Transplant Research), Milwaukee, WI; E-mail: jipatel@mcw.edu**

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1. **Introduction**
   a. Minutes from February 2024 (Attachment 1)

2. **Accrual summary** (Attachment 2)

3. **Presentations, Publications or Submitted papers**
   a. **LY22-01c** Wang TP, Ahn KW, Shadman M, Kaur M, Ahmed N, Bacher U, Cerny J, Chen A, Epperla N, Frigault M, Grover N, Haverkos B, Hill B, Hossain N, Iqbal M, Jain T, Krem MM, Maakaron J, Modi D, Alhaj Moustafa M, Riedell P, Savani B, Sica RA, Sureda A, Wudhikarn K, Herrera AF, Sauter C, Hamadani M, Jimenez Jimenez A. Chimeric antigen receptor T-cell infusion for large B-cell lymphoma in complete remission: A Center for International Blood and Marrow Transplant Research analysis. ***Leukemia. 2024 Jul 1; 38(7):1564-1569. doi:10.1038/s41375-024-02242-6. Epub 2024 May 15. PMC11271761.***
   b. **LY22-02a** Epperla N, Hashmi H, Ahn KW, Chen AI, Wirk B, Kanakry JA, Lekakis L, Lekakis L, Kharfan-Dabaja MA, Scordo M, Riedell PA, Jain T, Shadman M, Sauter C, Hamadani M, Herrera AF, Ahmed S. Outcomes of patients with secondary central nervous system lymphoma treated with chimeric antigen receptor T-cell therapy: A CIBMTR analysis. ***British Journal of Haematology. 2024 Sep 1; 205(3):1202-1207. doi:10.1111/bjh.19569. Epub 2024 May 26. PMC11499028.***
   c. **LY22-01a** Shadman M, Ahn KW, Kaur M, Lekakis L, Beitinjaneh A, Iqbal M, Ahmed N, Hill B, Hossain NM, Riedell P, Gopal AK, Grover N, Frigault M, Brammer J, Ghosh N, Merryman R, Lazaryan A, Ram R, Hertzberg M, Savani B, Awan F, Khimani F, Ahmed S, Kenkre VP, Ulrickson M, Shah N, Kharfan-Dabaja MA, Herrera A, Sauter C, Hamadani M. Autologous transplant vs. CAR-T therapy in patients

with DLBCL treated while in complete remission. ***Blood Cancer Journal. 14(1):108. doi:10.1038/s41408-024-01084-w. Epub 2024 Jul 8. PMC11231252.***

d. **LY22-01b** Pophali PA, Fein JA, Ahn KW, Allbee-Johnson M, Ahmed N, Awan FT, Farhan S, Grover NS, Hilal T, Iqbal M, Maakaron J, Modi D, Nasrollahi E, Schachter L, Sauter CS, Hamadani M, Herrera AF, Shouval R, Shadman M. CD19-directed CART therapy for T cell/histiocyte rich large B-cell lymphoma. ***Blood Advances. 2024 Oct 22; 8(20):5290-5296.doi:10.1182/bloodadvances.2024013863. Epub 2024 Jul 14. PMC11497379.***

e. **LY22-01a** Mercadal S, Ahn KW, Allbee-Johnson M, Ganguly S, Ramakrishnan Geethakumari P, Hong S, Malone A, Murthy H, Pawarode A, Sica AR, Solh M, Ustun C, Shadman M, Sauter CS, Hamadani M, Herrera AF, Lee CJ. Outcomes of patients with primary central nervous system lymphoma following CD19-targeted chimeric antigen receptor T-cell therapy. ***Haematologica. doi:10.3324/haematol.2024.285613. Epub 2024 Sep 5.***

f. **LY22-02b** Outcomes of autologous HCT and CD19 CAR-T in MYC+ large B-cell lymphoma patients. (M Hamadani/ F Furqan). ***Submitted.***

g. **LY20-02** Outcomes of allogeneic transplants in patients with hodgkin lymphoma in the era of checkpoint inhibitors: A joint CIBMTR and EBMT analysis. (M-A Perales/ A Sureda/ F Awan/ S Montoto). ***Submitted.***

4. Studies in progress (Attachment 3)

a. **LY22-02c** Efficacy and safety of CD19 directed CAR T-cell therapy for transferred follicular lymphoma (S Kambhampati/ K Nadiminti/ A Herrera). **Manuscript Preparation.**

b. **LY22-02d** Efficacy and safety of CD19 directed CAR T-cell therapy for Richter's transformation (M Shadman/ M Hamadani). **Manuscript Preparation.**

c. **LY22-02e** Efficacy and safety of CD19 directed CAR T-cell therapy for primary mediastinal B-cell lymphoma (J Gauthier/ A Herrera). **Manuscript Preparation.**

d. **LY22-02f** Efficacy and safety of CD19 directed CAR T-cell therapy for high grade B-cell lymphoma. (S Ahmed/ S Mercadal/ H Hashmi/ C Lee/ N Epperla). **Manuscript Preparation.**

e. **LY23-01** Efficacy of hematopoietic stem cell transplantation in patients with plasmablastic lymphoma (S Ahmed/ T Al-Juhaishi)**. Protocol Development.**

f. **LY24-01** Hematopoietic cell transplantation for rare mature T-cell lymphomas (M Hamadani/ A Herrera). **Protocol Development.**

5. Future/proposed studies

a. **PROP 2410-44; 2410-168** Axi-cel vs. Liso-cel in Second line in DLBCL (A Mian/ B T. Hill/ D Reef/ N Grover) (Attachment 4)

Dr. Reef presented.

- ***Hypothesis:*** *Axicel and Lysocel have different efficacy and toxicity profiles in second-line treatment for relapsed/refractory DLBCL.*
- ***Objectives:*** *Estimate progression-free survival, overall response rate, overall survival, complete response rates, and toxicity measures.*

b. **PROP 2410-66** A Matching Adjusted Indirect Comparison (MAIC) Analysis Comparing the Clinical Outcomes of Patients with Follicular Lymphoma Treated with Anti-CD19 Chimeric Antigen Receptor T Cell Therapy (CART) and Bispecific T Cell Engager (M Di/ M Shadman) (Attachment 5)

Dr. Dai presented.

- ***Hypothesis:*** *CAR T cells have better efficacy compared to bispecific T cell engagers in relapsed/refractory follicular lymphoma.*
- ***Objectives:*** *Compare progression-free survival, overall survival, response rates, and safety outcomes between CAR T cells and bispecific antibodies.*

c. **PROP 2410-67** Real-world Outcomes Following Axicabtagene Ciloleucel and Lisocabtagene Maraleucel in Older Patients with Large B Cell Lymphoma (M Di/ M Shadman) (Attachment 6)

Dr. Dai presented.

- ***Hypothesis:*** *Lysocel has similar efficacy but better safety compared to Axicel in older patients with relapsed/refractory large B-cell lymphoma.*
- ***Objectives:*** *Compare progression-free survival, overall survival, and safety endpoints between Axicel and Lysocel.*

d. **PROP 2410-72; 2410-239** Brux-cel in older MCL patients (S Gupta/ V Bachanova/ P Jain/ A Lionel) (Attachment 7)

Dr. Gupta presented.

- ***Hypothesis:*** *Older patients with relapsed/refractory mantle cell lymphoma treated with Brexucel demonstrate comparable response rates and survival outcomes.*
- ***Objectives:*** *Compare objective and complete response rates, progression-free survival, overall survival, and cumulative incidence of grade 3 or higher CRS and ICANS.*

e. **PROP 2410-100** Incidence and Risk factors for Non-relapse Mortality after anti-CD19 CAR T-cell therapy for Lymphoma (D Modi) (Attachment 8)

Dr. Modi presented.

- ***Hypothesis:*** *Non-relapse mortality is a significant complication of CAR T-cell therapy for B-cell non-Hodgkin lymphoma.*
- ***Objectives:*** *Estimate cumulative incidence of non-relapse mortality, identify timing and risk factors, and evaluate association with different CAR T-cell products.*

f. **PROP 2410-120; 2410-194** AutoHCT in Secondary CNS lymphoma (B Gattas/ U Gergis/ A Kidwell/ N N. Shah) (Attachment 9)

Dr. Kidwell presented.

- ***Hypothesis:*** *Consolidated autologous stem cell transplant improves outcomes for patients with secondary CNS lymphoma.*
- ***Objectives:*** *Compare progression-free survival, overall survival, and subgroup analyses based on frontline therapy and conditioning regimen.*

Proposed studies; not accepted for consideration at this time.

g. **PROP 2401-01** Impact of mogamulizumab on GVHD in patients receiving post-transplantation cyclophosphamide based GVHD prophylaxis (C Sterling). ***Dropped due to small sample size.***

h. **PROP 2407-01** Outcome of CART therapy post allogenic HSCT (J L Wagner). ***Dropped due to low scientific impact.***

i. **PROP 2408-07** Real world outcomes of second chimeric antigen receptor T cell (CAR T-cell) therapy for lymphoma (J Joseph). ***Dropped due to low scientific impact.***
j. **PROP 2409-13** Autologous stem cell transplant vs chimeric antigen receptor T-cell therapy in older patients with chemosensitive late relapsed diffuse large B-cell lymphoma (A Tun/ P Johnston). ***Dropped due to low scientific impact.***
k. **PROP 2409-14** Autologous stem cell transplant vs chimeric antigen receptor T-cell therapy in follicular lymphoma with early treatment failure (A Tun/ C Sauter). ***Dropped due to low scientific impact.***
l. **PROP 2409-32** The impact of TP53 genomic alterations in large B-cell lymphoma treated with CD19-CAR-T (R Shouval). ***Dropped due to supplemental data needed.***
m. **PROP 2410-12** Outcomes of HIV+ Lymphoma treated with Chimeric Antigen Receptor T-Cell Therapy (M Iqbal/ H Murthy). ***Dropped due to overlap with current study/publication.***
n. **PROP 2410-13** Outcomes and Utilization Trends of Autologous Hematopoietic Cell Transplantation for Classical Hodgkin Lymphoma (M Iqbal/ M Kharfan-Dabaja). ***Dropped due to low scientific impact.***
o. **PROP 2410-15** Evaluating Outcomes of Allogeneic Hematopoietic Cell Transplantation in Cutaneous T Cell Lymphoma in the Contemporary Era (M Iqbal/ M Kharfan-Dabaja). ***Dropped due to low scientific impact.***
p. **PROP 2410-19** Use of PD1 Inhibitors as Salvage Therapy Prior to Autologous Stem Cell Transplantation (ASCT) in Hodgkin Lymphoma (Y Berry/ S Farhan). ***Dropped due to low scientific impact.***
q. **PROP 2410-42** Outcomes of CAR-T in DLBCL Based on Remission Status (A Sindel). ***Dropped due to low scientific impact.***
r. **PROP 2410-64** Real world comparison of efficacy of bispecific antibodies (BsAbs) and chimeric antigen receptor T-cell therapies (CART) in large B-cell lymphoma (LBCL) (T Zhuang/ P Strati). ***Dropped due to small sample size.***
s. **PROP 2410-65** Impact of checkpoint inhibitors on outcomes after autologous stem cell transplant for relapsed Hodgkin's lymphoma (P Pophali/ D Trotier). ***Dropped due to low scientific impact.***
t. **PROP 2410-68** CD19 Directed CAR-T therapy Outcomes in Patients with Relapsed/Refractory Diffuse Large B Cell Lymphoma (DLBCL) as Determined by Tumor Size (& burden) and Lactate Dehydrogenase Enzyme (LDH) (A Desai/ R Maziarz). ***Dropped due to overlap with current study/publication.***
u. **PROP 2410-83** The impact of novel therapies and modern antiretroviral therapy on outcomes after autologous stem cell transplant in patients with relapsed and refractory HIV-associated lymphoma (K Lurain/ A Herrera). ***Dropped due to overlap with current study/publication.***
v. **PROP 2410-88** Predictive Modeling for CAR-T Therapies in Relapsed/Refractory Follicular Lymphoma Using Machine Learning (N Ahmed/ S Irfan). ***Dropped due to low scientific impact.***
w. **PROP 2410-98** Outcomes of Hematopoietic Cell Transplantation and CAR T-Cell Therapy for Denovo CD5+ Diffuse Large B-Cell Lymphoma (B Wirk). ***Dropped due to small sample size.***
x. **PROP 2410-105** Outcomes of CD3/CD20 bispecific antibodies and other targeted therapies post CD19 CAR T therapy in relapsed refractory diffuse large B-cell lymphoma (S Thiruvengadam/ A Herrera). ***Dropped due to small sample size.***
y. **PROP 2410-108** Outcomes of R/R large B-cell lymphoma patients treated with CD19 CAR T cell therapy previously exposed to bispecific antibody with propensity score matching comparison to those naïve to bispecific antibody (S Thiruvengadam/ A Herrera). ***Dropped due to small sample size.***

z. **PROP 2410-110** Outcomes of R/R FL patients treated with CD19 CAR T cell therapy previously exposed to bispecific antibody with propensity score matching comparison to those naïve to bispecific antibody (S Thiruvengadam/ A Herrera). ***Dropped due to small sample size.***

aa. **PROP 2410-112** Comparative efficacy of CD19+CAR-T vs autoHCT in 2L DLBCL based on the putative cell of origin (ABC vs GCB) (M Abid/ S Ahmed). ***Dropped due to low scientific impact.***

bb. **PROP 2410-113** Efficacy of a second CAR-T infusion in patients with relapsed/refractory B-cell malignancies (M Abid/ S Ahmed). ***Dropped due to low scientific impact.***

cc. **PROP 2410-114** Outcomes of Burkitt lymphoma Patients Undergoing Autologous and Allogeneic hematopoientic cell transplantation: A contemporary analysis (I Muhsen/ M Aljurf). ***Dropped due to low scientific impact.***

dd. **PROP 2410-115** Real-World Outcomes of CD19+CAR-T and Comparison of Axi-cel vs Tisa-cel for Relapsed/refractory Follicular Lymphoma (M Abid/ S Ahmed). ***Dropped due to low scientific impact.***

ee. **PROP 2410-116** Efficacy of Autologous Stem Cell Transplant in DLBCL Patients Who Relapse After CAR T-Cell Therapy (M Abid/ S Ahmed). ***Dropped due to low scientific impact.***

ff. **PROP 2410-117** Analysis of Commercial CD19+CAR-T Therapy for Patients with relapsed/refractory Aggressive Large B Cell Lymphoma in the real-world third line Setting (M Abid/ S Ahmed). ***Dropped due to low scientific impact.***

gg. **PROP 2410-127** Real-world non-relapse mortality and early mortality after brexucabtagene autoleucel (brexu-cel) CAR T-cell therapy for mantle cell lymphoma (P Jain/ A Lionel). ***Dropped due to low scientific impact.***

hh. **PROP 2410-132** Comparative outcome analysis of patients with primary refractory or early relapsed aggressive B-cell lymphoma treated with axicabtagene ciloleucel versus lisocabtagene maraleucel (X Bi/ U Gergis). ***Dropped due to low scientific impact.***

ii. **PROP 2410-150** Outcomes of autologous stem cell transplantation in DLBCL relapsed/refractory to CD19 CAR T (S Thiruvengadam/ E Bezerra). ***Dropped due to low scientific impact.***

jj. **PROP 2410-162** A comparison of the safety and efficacy of anti-CD19 CAR T-cell therapy versus autologous stem cell transplantation (ASCT) in follicular lymphoma experiencing early therapy failure (POD12 and POD24) (H Wolfe/ P Ramakrishnan). ***Dropped due to low scientific impact.***

kk. **PROP 2410-164** Outcomes of subsequent transplant or cellular therapy for relapse after CD19 autologous CAR T-cell therapy in large B-cell lymphoma (H Cherniawsky/ R J Stubbins). ***Dropped due to low scientific impact.***

ll. **PROP 2410-166** Real-world Outcomes Following Lisocabtagene Maraleucel in Patients with Mantle Cell Lymphoma (J Huang/ M Shadman). ***Dropped due to small sample size.***

mm. **PROP 2410-170** Optimizing CAR-T in Follicular Lymphoma: Identifying the Best Line of Therapy to Maximize Survival (D Reef/ N Grover). ***Dropped due to low scientific impact.***

nn. **PROP 2410-171** Effect of Prior CD19-Targeted Therapies and CD3xCD20 Bispecific Antibodies on Subsequent Anti-CD19 CAR T-Cell Therapy Outcomes in Diffuse Large B-cell Lymphoma (E Yilmaz/ F Awan). ***Dropped due to small sample size.***

oo. **PROP 2410-185** Efficacy and Toxicity of CAR T-Cell Therapy in Patients with Large B-Cell Lymphoma Previously Treated with Bispecific Antibodies (J Huang/ M Shadman). ***Dropped due to small sample size.***

pp. **PROP 2410-189** Efficacy of a second CAR T-cell therapy in patients with Relapse/Refractory B-cell non-Hodgkin lymphoma (A Kidwell/ N Shah). ***Dropped due to low scientific impact.***

qq. **PROP 2410-197** Efficacy and safety of CD19 CAR T cell therapy in EBV-positive diffuse large B-cell lymphoma (M Alhomoud/ M Scordo). ***Dropped due to small sample size.***

rr. **PROP 2410-198** Evaluating outcomes of Hematopoietic Cell Transplantation in Hepatosplenic T Cell Lymphoma (M Iqbal/ H Murthy). ***Dropped due to overlap with current study/publication.***

ss. **PROP 2410-215** Real-world efficacy of anti-CD19-chimeric antigen receptor T cell therapy in the second-line setting for late-relapsed large B cell lymphoma (S Ahmed/ K Chohan). ***Dropped due to low scientific impact.***

tt. **PROP 2410-216** Post-autologous stem cell transplant outcomes of primary mediastinal B-cell lymphoma patients with prior exposure to checkpoint inhibitors (S Larson/ J Timmerman). ***Dropped due to overlap with current study/publication.***

uu. **PROP 2410-219** Outcomes of chimeric antigen receptor T-cell therapy (CAR-T) for patients with relapsed/refractory large B cell lymphoma with testicular involvement – an efficacy analysis of CAR-T for a rare sanctuary site (G Hildebrandt/ M Yasir). ***Dropped due to small sample size.***

vv. **PROP 2410-226** A Matched Adjusted Indirect Comparision of Safety and Efficacy of CD20-directed BiTE therapy versus CD19-directed CAR-T therapy in LBCL (K Chetlapalli/ L Gowda). ***Dropped due to low scientific impact.***

ww. **PROP 2410-236** Real-world analysis of brexucabtagene autoleucel as compared to allogeneic transplant for patients with high-risk mantle cell lymphoma (S Ahmed/ K Chohan). ***Dropped due to low scientific impact.***

xx. **PROP 2410-238** Outcomes of Subsequent CD19-directed CAR-T infusion after relapse from prior CAR-T cell therapy for B cell malignancies (S Mirza/ L Gowda). ***Dropped due to low scientific impact.***

yy. **PROP 2410-243** Efficacy and toxicity of allogeneic transplantation post-chimeric antigen receptor T cell therapy failure in large B cell lymphoma Cri (S Ahmed/ K Chohan). ***Dropped due to low scientific impact.***

zz. **PROP 2410-244** Impact of BTK Inhibitor Maintenance Therapy on Outcomes Following CAR T-Cell Therapy in Mantle Cell Lymphoma (O Jarallah/ S Mirza). ***Dropped due to supplemental data needed.***

aaa. **PROP 2410-252** Outcomes and toxicity of autologous stem cell transplant for patients with Primary CNS Lymphoma associated with HIV (L Schachter/ J Cleveland). ***Dropped due to small sample size.***

bbb. **PROP 2410-263** Survival Outcomes of Allogeneic Transplants (allo-SCT) in comparison to Chimeric Antigen Receptor (CAR T) therapy for Relapsed Refractory Mantle Cell lymphoma (MCL) (S Naik/ C Annageldiyev). ***Dropped due to low scientific impact.***

6. Other business

Accrual Summary for Hodgkin and Non-Hodgkin Lymphoma Working Committee: 2000-2025						
	HLA-Identical Sibling		Alternative Donor		Autologous	
	TED only	Research	TED only	Research	TED only	Research
Anaplastic large cell	362	60	609	190	2384	220
PIF	66 (18)	9 (15)	94 (15)	34 (18)	311 (13)	21 (10)
CR1	55 (15)	11 (18)	84 (14)	29 (15)	1110 (47)	95 (43)
Rel 1	31 (9)	10 (17)	45 (7)	14 (7)	188 (8)	24 (11)
CR2	116 (32)	17 (28)	214 (35)	51 (27)	547 (23)	53 (24)
Other/Unknown	94 (26)	13 (22)	172 (28)	62 (33)	228 (10)	27 (12)
Burkitt/small non-cleaved	206	59	166	113	751	157
PIF	37 (18)	8 (14)	19 (11)	22 (19)	118 (16)	32 (20)
CR1	45 (22)	15 (25)	39 (23)	16 (14)	266 (35)	62 (39)
Rel 1	28 (14)	7 (12)	18 (11)	16 (14)	63 (8)	14 (9)
CR2	51 (25)	21 (36)	59 (36)	39 (35)	192 (26)	38 (24)
Other/Unknown	45 (22)	8 (14)	31 (19)	20 (18)	112 (15)	11 (7)
Diffuse large cell/immunoblastic	1838	331	2049	920	22474	2636
PIF	422 (23)	90 (27)	482 (24)	271 (29)	3872 (17)	455 (17)
CR1	201 (11)	53 (16)	314 (15)	102 (11)	4081 (18)	501 (19)
Rel 1	280 (15)	44 (13)	211 (10)	89 (10)	3829 (17)	474 (18)
CR2	254 (14)	32 (10)	345 (17)	113 (12)	6624 (29)	774 (29)
Other/Unknown	681 (37)	112 (34)	697 (34)	345 (38)	4068 (18)	432 (16)
Follicular	1473	518	1341	732	5425	928
PIF	251 (17)	93 (18)	229 (17)	147 (20)	790 (15)	109 (12)
CR1	109 (7)	38 (7)	95 (7)	43 (6)	647 (12)	115 (12)
Rel 1	199 (14)	106 (20)	159 (12)	103 (14)	954 (18)	171 (18)
CR2	194 (13)	73 (14)	185 (14)	80 (11)	1438 (27)	219 (24)
Other/Unknown	720 (49)	208 (40)	673 (50)	359 (49)	1596 (29)	314 (34)
Lymphoblastic	172	49	125	106	266	35
PIF	18 (10)	7 (14)	8 (6)	12 (11)	14 (5)	1 (3)
CR1	50 (29)	11 (22)	21 (17)	18 (17)	118 (44)	19 (54)
Rel 1	28 (16)	8 (16)	10 (8)	16 (15)	23 (9)	1 (3)
CR2	32 (19)	12 (24)	35 (28)	34 (32)	32 (12)	6 (17)
Other/Unknown	44 (26)	11 (22)	51 (41)	26 (25)	79 (30)	8 (23)
Mantle	949	205	1197	490	10096	1005
PIF	173 (18)	44 (21)	162 (14)	84 (17)	1408 (14)	132 (13)
CR1	194 (20)	40 (20)	232 (19)	80 (16)	7167 (71)	694 (69)
Rel 1	140 (15)	34 (17)	161 (13)	80 (16)	268 (3)	34 (3)

Accrual Summary for Hodgkin and Non-Hodgkin Lymphoma Working Committee: 2000-2025						
	HLA-Identical Sibling		Alternative Donor		Autologous	
	TED only	Research	TED only	Research	TED only	Research
CR2	183 (19)	31 (15)	343 (29)	95 (19)	491 (5)	63 (6)
Other/Unknown	259 (27)	56 (27)	299 (25)	151 (31)	762 (8)	82 (8)
Marginal	98	25	112	40	422	44
PIF	16 (16)	8 (32)	32 (29)	10 (25)	76 (18)	12 (27)
CR1	9 (9)	3 (12)	20 (18)	5 (13)	74 (18)	5 (11)
Rel 1	11 (11)	1 (4)	13 (12)	6 (15)	55 (13)	3 (7)
CR2	14 (14)	3 (12)	12 (11)	4 (10)	93 (22)	10 (23)
Other/Unknown	48 (49)	10 (40)	35 (31)	15 (38)	124 (29)	14 (32)
NK T cell	311	52	480	127	909	89
PIF	74 (24)	12 (23)	104 (22)	29 (23)	158 (17)	17 (19)
CR1	85 (27)	13 (25)	156 (33)	47 (37)	429 (47)	40 (45)
Rel 1	27 (9)	6 (12)	27 (6)	10 (8)	65 (7)	5 (6)
CR2	60 (19)	5 (10)	108 (23)	29 (23)	138 (15)	14 (16)
Other/Unknown	65 (21)	16 (31)	85 (18)	12 (9)	119 (13)	13 (15)
T cell	1082	268	1919	681	4586	470
PIF	356 (33)	101 (38)	602 (31)	283 (42)	729 (16)	69 (15)
CR1	222 (21)	58 (22)	454 (24)	139 (20)	2749 (60)	254 (54)
Rel 1	123 (11)	27 (10)	203 (11)	65 (10)	300 (7)	45 (10)
CR2	166 (15)	33 (12)	367 (19)	81 (12)	454 (10)	53 (11)
Other/Unknown	215 (20)	49 (18)	293 (15)	113 (17)	354 (8)	49 (10)
NHL not specified	180	24	102	120	857	44
PIF	15 (8)	4 (17)	7 (7)	31 (26)	92 (11)	8 (18)
CR1	13 (7)	0 (0)	5 (5)	13 (11)	107 (12)	11 (25)
Rel 1	28 (16)	2 (8)	7 (7)	18 (15)	63 (7)	5 (11)
CR2	15 (8)	2 (8)	18 (18)	19 (16)	111 (13)	5 (11)
Other/Unknown	109 (61)	16 (67)	65 (64)	39 (33)	484 (56)	15 (34)
Other	844	208	1608	468	12252	1110
PIF	213 (25)	61 (29)	406 (25)	123 (26)	2238 (18)	212 (19)
CR1	167 (20)	40 (19)	413 (26)	145 (31)	4218 (34)	401 (36)
Rel 1	85 (10)	19 (9)	129 (8)	38 (8)	1386 (11)	101 (9)
CR2	127 (15)	17 (8)	313 (19)	59 (13)	3464 (28)	270 (24)
Other/Unknown	252 (30)	71 (34)	347 (22)	103 (22)	946 (8)	126 (11)
Hodgkin	1386	376	1701	1321	22173	2546
PIF	259 (19)	67 (18)	297 (17)	188 (14)	3972 (18)	551 (22)
CR1	76 (5)	27 (7)	130 (8)	112 (8)	3089 (14)	347 (14)

Accrual Summary for Hodgkin and Non-Hodgkin Lymphoma Working Committee: 2000-2025						
	HLA-Identical Sibling		Alternative Donor		Autologous	
	TED only	Research	TED only	Research	TED only	Research
Rel 1	163 (12)	58 (15)	186 (11)	147 (11)	3862 (17)	466 (18)
CR2	156 (11)	55 (15)	233 (14)	198 (15)	7391 (33)	776 (30)
Other/Unknown	732 (53)	169 (45)	855 (50)	676 (51)	3859 (17)	406 (16)
Graft type	8901	2175	11409	5308	82595	9284
BM	887 (10)	194 (9)	1784 (16)	1055 (20)	717 (1)	74 (1)
PB	7952 (89)	1976 (91)	8998 (79)	3606 (68)	81124 (98)	9151 (99)
Other/Unknown	62 (1)	5 (0)	627 (5)	647 (12)	754 (1)	59 (1)

Unrelated Donor HCT Research Sample Inventory - Summary for First Allogeneic Transplants in CRF and TED with biospecimens available through the CIBMTR Repository stratified by availability of paired samples, recipient only samples and donor only samples, Biospecimens include: whole blood, serum/plasma and limited quantities of viable cells and cell lines (collected prior to 2006), Specific inventory queries available upon request through the CIBMTR Immunobiology Research Program

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
Number of patients	5495	2208	1248
Source of data			
CRF	2685 (49)	816 (37)	487 (39)
TED	2810 (51)	1392 (63)	761 (61)
Number of centers	212	163	217
Disease at transplant			
Non-Hodgkin lymphoma	4508 (82)	1890 (86)	1018 (82)
Hodgkin lymphoma	987 (18)	318 (14)	230 (18)
NHL Disease status at transplant			
CR1	668 (15)	426 (23)	157 (15)
CR2	865 (19)	391 (21)	169 (17)
CR3+	405 (9)	186 (10)	93 (9)
PR	446 (10)	111 (6)	99 (10)
Advanced	2031 (45)	750 (40)	466 (46)
Missing	73 (2)	18 (1)	31 (3)
Recipient age at transplant			
0-9 years	63 (1)	14 (1)	19 (2)
10-17 years	165 (3)	44 (2)	37 (3)

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
18-29 years	730 (13)	237 (11)	159 (13)
30-39 years	770 (14)	282 (13)	175 (14)
40-49 years	1024 (19)	361 (16)	254 (20)
50-59 years	1491 (27)	558 (25)	309 (25)
60-69 years	1125 (20)	581 (26)	271 (22)
70+ years	127 (2)	131 (6)	24 (2)
Median (Range)	50 (2-81)	53 (3-79)	50 (2-77)
Recipient race			
White	4918 (92)	1925 (90)	952 (88)
Black or African American	288 (5)	119 (6)	74 (7)
Asian	105 (2)	58 (3)	52 (5)
Native Hawaiian or other Pacific Islander	9 (<1)	3 (<1)	1 (<1)
American Indian or Alaska Native	10 (<1)	12 (1)	3 (<1)
Other	1 (<1)	4 (<1)	1 (<1)
More than one race	27 (1)	13 (1)	3 (<1)
Unknown	137 (N/A)	74 (N/A)	162 (N/A)
Recipient ethnicity			
Hispanic or Latino	379 (8)	178 (9)	93 (8)
Non Hispanic or non-Latino	4519 (91)	1832 (91)	811 (74)
Non-resident of the U.S.	43 (1)	10 (<1)	197 (18)
Unknown	554 (N/A)	188 (N/A)	147 (N/A)
Recipient sex			
Male	3462 (63)	1437 (65)	803 (64)
Female	2033 (37)	771 (35)	445 (36)
Karnofsky score			
10-80	1894 (34)	844 (38)	419 (34)
90-100	3332 (61)	1272 (58)	775 (62)
Missing	269 (5)	92 (4)	54 (4)
HLA-A B DRB1 groups - low resolution			
<=3/6	4 (<1)	15 (1)	0
4/6	17 (<1)	21 (1)	13 (1)
5/6	692 (13)	256 (12)	154 (13)
6/6	4707 (87)	1806 (86)	1022 (86)
Unknown	75 (N/A)	110 (N/A)	59 (N/A)
High-resolution HLA matches available out of 8			
<=5/8	47 (1)	21 (1)	4 (<1)
6/8	137 (3)	37 (2)	31 (3)
7/8	1027 (20)	298 (16)	201 (21)
8/8	3971 (77)	1455 (80)	708 (75)
Unknown	313 (N/A)	397 (N/A)	304 (N/A)

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
HLA-DPB1 Match			
Double allele mismatch	1045 (28)	290 (22)	118 (23)
Single allele mismatch	2076 (55)	689 (53)	291 (56)
Full allele matched	634 (17)	332 (25)	109 (21)
Unknown	1740 (N/A)	897 (N/A)	730 (N/A)
High resolution release score			
No	2864 (52)	2204 (>99)	1224 (98)
Yes	2631 (48)	4 (<1)	24 (2)
KIR typing available			
No	4713 (86)	2206 (>99)	1246 (>99)
Yes	782 (14)	2 (<1)	2 (<1)
Graft type			
Marrow	1076 (20)	302 (14)	242 (19)
PBSC	4416 (80)	1881 (85)	1004 (80)
BM+PBSC	1 (<1)	3 (<1)	0
PBSC+UCB	2 (<1)	22 (1)	1 (<1)
Others	0	0	1 (<1)
Conditioning regimen			
Myeloablative	2091 (38)	624 (28)	389 (31)
RIC/Nonmyeloablative	3362 (61)	1571 (71)	843 (68)
TBD	42 (1)	13 (1)	16 (1)
Donor age at donation			
To Be Determined/NA	11 (<1)	69 (3)	15 (1)
18-29 years	2683 (49)	1209 (55)	581 (47)
30-39 years	1570 (29)	564 (26)	362 (29)
40-49 years	965 (18)	289 (13)	219 (18)
50+ years	266 (5)	77 (3)	71 (6)
Median (Range)	30 (18-69)	28 (18-68)	31 (18-61)
Donor/Recipient CMV serostatus			
+/+	1278 (23)	542 (25)	291 (23)
+/-	667 (12)	316 (14)	186 (15)
-/+	1624 (30)	595 (27)	342 (27)
-/-	1861 (34)	670 (30)	403 (32)
CB - recipient +	2 (<1)	16 (1)	1 (<1)
CB - recipient -	0	6 (<1)	0
Missing	63 (1)	63 (3)	25 (2)
GvHD Prophylaxis			
No GvHD Prophylaxis	25 (<1)	12 (1)	9 (1)
TDEPLETION alone	4 (<1)	4 (<1)	1 (<1)
TDEPLETION +- other	52 (1)	8 (<1)	14 (1)

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
CD34 select alone	0	1 (<1)	1 (<1)
CD34 select +- other	54 (1)	21 (1)	6 (<1)
Cyclophosphamide alone	6 (<1)	3 (<1)	7 (1)
Cyclophosphamide +- others	502 (9)	651 (29)	167 (13)
FK506 + MMF +- others	858 (16)	244 (11)	167 (13)
FK506 + MTX +- others(not MMF)	2309 (42)	798 (36)	385 (31)
FK506 +- others(not MMF,MTX)	319 (6)	134 (6)	81 (6)
FK506 alone	171 (3)	54 (2)	24 (2)
CSA + MMF +- others(not FK506)	549 (10)	123 (6)	121 (10)
CSA + MTX +- others(not MMF,FK506)	413 (8)	97 (4)	169 (14)
CSA +- others(not FK506,MMF,MTX)	73 (1)	19 (1)	30 (2)
CSA alone	50 (1)	7 (<1)	35 (3)
Other GVHD Prophylaxis	81 (1)	24 (1)	16 (1)
Missing	29 (1)	8 (<1)	15 (1)
Donor/Recipient sex match			
Male-Male	2467 (45)	971 (44)	534 (43)
Male-Female	1257 (23)	446 (20)	243 (19)
Female-Male	988 (18)	437 (20)	267 (21)
Female-Female	772 (14)	311 (14)	200 (16)
CB - recipient M	0	13 (1)	0
CB - recipient F	2 (<1)	9 (<1)	1 (<1)
Missing	9 (<1)	21 (1)	3 (<1)
Year of transplant			
1986-1990	3 (<1)	1 (<1)	1 (<1)
1991-1995	47 (1)	11 (1)	15 (1)
1996-2000	254 (5)	63 (3)	54 (4)
2001-2005	818 (15)	157 (8)	202 (17)
2006-2010	1430 (26)	257 (13)	235 (19)
2011-2015	1633 (30)	434 (22)	301 (25)
2016-2020	790 (15)	499 (25)	244 (20)
2021-2025	520 (8)	786 (29)	196 (13)
Follow-up among survivors, Months			
N Eval	2310	1270	589
Median (Range)	68 (0-315)	24 (0-291)	37 (0-296)

Unrelated Cord Blood Transplant Research Sample Inventory - Summary for First Allogeneic Transplants in CRF and TED with biospecimens available through the CIBMTR Repository stratified by availability of paired, recipient only and cord blood only samples, Biospecimens include: whole blood, serum/plasma and limited quantities of viable cells and cell lines (collected prior to 2006-recipient only), Specific inventory queries available upon request through the CIBMTR Immunobiology Research Program

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
Number of patients	522	139	177
Source of data			
CRF	388 (74)	90 (65)	97 (55)
TED	134 (26)	49 (35)	80 (45)
Number of centers	94	42	68
Disease at transplant			
Non-Hodgkin lymphoma	418 (80)	112 (81)	142 (80)
Hodgkin lymphoma	104 (20)	27 (19)	35 (20)
NHL Disease status at transplant			
CR1	66 (16)	12 (11)	28 (20)
CR2	80 (19)	28 (25)	36 (26)
CR3+	47 (11)	11 (10)	12 (9)
PR	68 (16)	12 (11)	16 (11)
Advanced	154 (37)	48 (43)	46 (33)
Missing	0	1 (1)	3 (2)
Recipient age at transplant			
0-9 years	25 (5)	8 (6)	6 (3)
10-17 years	29 (6)	6 (4)	12 (7)
18-29 years	75 (14)	17 (12)	26 (15)
30-39 years	92 (18)	20 (14)	32 (18)
40-49 years	94 (18)	36 (26)	33 (19)
50-59 years	125 (24)	22 (16)	41 (23)
60-69 years	77 (15)	28 (20)	25 (14)
70+ years	5 (1)	2 (1)	2 (1)
Median (Range)	45 (1-73)	45 (5-78)	44 (2-73)
Recipient race			
White	357 (71)	94 (69)	107 (71)
Black or African American	100 (20)	31 (23)	30 (20)
Asian	36 (7)	9 (7)	11 (7)
Native Hawaiian or other Pacific Islander	2 (<1)	0	1 (1)
American Indian or Alaska Native	6 (1)	0	0
More than one race	3 (1)	3 (2)	2 (1)
Unknown	18 (N/A)	2 (N/A)	26 (N/A)

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
Recipient ethnicity			
Hispanic or Latino	78 (15)	14 (11)	27 (15)
Non Hispanic or non-Latino	431 (85)	116 (89)	122 (70)
Non-resident of the U.S.	0	0	26 (15)
Unknown	13 (N/A)	9 (N/A)	2 (N/A)
Recipient sex			
Male	308 (59)	85 (61)	99 (56)
Female	214 (41)	54 (39)	78 (44)
Karnofsky score			
10-80	153 (29)	41 (29)	41 (23)
90-100	346 (66)	91 (65)	129 (73)
Missing	23 (4)	7 (5)	7 (4)
HLA-A B DRB1 groups - low resolution			
<=3/6	27 (5)	15 (12)	4 (2)
4/6	260 (51)	62 (49)	92 (56)
5/6	186 (37)	42 (33)	63 (38)
6/6	36 (7)	8 (6)	6 (4)
Unknown	13 (N/A)	12 (N/A)	12 (N/A)
High-resolution HLA matches available out of 8			
<=5/8	282 (66)	67 (71)	87 (69)
6/8	94 (22)	15 (16)	29 (23)
7/8	40 (9)	10 (11)	8 (6)
8/8	14 (3)	3 (3)	3 (2)
Unknown	92 (N/A)	44 (N/A)	50 (N/A)
HLA-DPB1 Match			
Double allele mismatch	53 (32)	7 (22)	18 (46)
Single allele mismatch	100 (60)	22 (69)	19 (49)
Full allele matched	15 (9)	3 (9)	2 (5)
Unknown	354 (N/A)	107 (N/A)	138 (N/A)
High resolution release score			
No	438 (84)	136 (98)	175 (99)
Yes	84 (16)	3 (2)	2 (1)
KIR typing available			
No	445 (85)	139 (100)	175 (99)
Yes	77 (15)	0	2 (1)
Graft type			
UCB	472 (90)	117 (84)	169 (95)
PBSC+UCB	47 (9)	22 (16)	6 (3)
Others	3 (1)	0	2 (1)
Number of cord units			

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
1	407 (78)	0	118 (67)
2	115 (22)	0	59 (33)
Unknown	0 (N/A)	139 (N/A)	0 (N/A)
Conditioning regimen			
Myeloablative	217 (42)	59 (42)	64 (36)
RIC/Nonmyeloablative	305 (58)	79 (57)	111 (63)
TBD	0	1 (1)	2 (1)
Donor age at donation			
To Be Determined/NA	381 (73)	44 (32)	136 (77)
0-9 years	99 (19)	70 (50)	36 (20)
10-17 years	4 (1)	5 (4)	3 (2)
18-29 years	12 (2)	4 (3)	0
30-39 years	8 (2)	3 (2)	1 (1)
40-49 years	7 (1)	6 (4)	1 (1)
50+ years	11 (2)	7 (5)	0
Median (Range)	5 (0-68)	5 (0-68)	4 (1-43)
Donor/Recipient CMV serostatus			
CB - recipient +	327 (63)	84 (60)	105 (59)
CB - recipient -	189 (36)	49 (35)	65 (37)
CB - recipient CMV unknown	6 (1)	6 (4)	7 (4)
GvHD Prophylaxis			
No GvHD Prophylaxis	2 (<1)	0	1 (1)
TDEPLETION +- other	4 (1)	1 (1)	1 (1)
CD34 select +- other	35 (7)	14 (10)	2 (1)
Cyclophosphamide +- others	1 (<1)	1 (1)	1 (1)
FK506 + MMF +- others	190 (36)	44 (32)	55 (31)
FK506 + MTX +- others(not MMF)	14 (3)	5 (4)	2 (1)
FK506 +- others(not MMF,MTX)	31 (6)	7 (5)	9 (5)
FK506 alone	26 (5)	10 (7)	3 (2)
CSA + MMF +- others(not FK506)	183 (35)	52 (37)	84 (47)
CSA + MTX +- others(not MMF,FK506)	3 (1)	1 (1)	2 (1)
CSA +- others(not FK506,MMF,MTX)	12 (2)	1 (1)	7 (4)
CSA alone	0	0	2 (1)
Other GVHD Prophylaxis	16 (3)	2 (1)	5 (3)
Missing	5 (1)	1 (1)	3 (2)
Donor/Recipient sex match			
CB - recipient M	308 (59)	85 (61)	99 (56)
CB - recipient F	214 (41)	54 (39)	78 (44)
Year of transplant			
1996-2000	1 (<1)	0	0

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
2001-2005	6 (1)	7 (5)	3 (2)
2006-2010	155 (30)	34 (25)	52 (30)
2011-2015	260 (50)	53 (39)	68 (39)
2016-2020	77 (15)	23 (17)	46 (26)
2021-2025	23 (3)	22 (14)	8 (4)
Follow-up among survivors, Months			
N Eval	237	62	68
Median (Range)	69 (0-166)	54 (0-194)	49 (0-144)

Related Donor HCT Research Sample Inventory - Summary for First Allogeneic Transplants in CRF and TED with biospecimens available through the CIBMTR Repository stratified by availability of paired, recipient only and donor only samples, Biospecimens include: whole blood, serum/plasma and limited quantities of viable cells and cell lines (collected prior to 2006), Specific inventory queries available upon request through the CIBMTR Immunobiology Research Program

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
Number of patients	1344	252	130
Source of data			
CRF	416 (31)	65 (26)	47 (36)
TED	928 (69)	187 (74)	83 (64)
Number of centers	75	39	24
Disease at transplant			
Non-Hodgkin lymphoma	1106 (82)	208 (83)	101 (78)
Hodgkin lymphoma	238 (18)	44 (17)	29 (22)
NHL Disease status at transplant			
CR1	225 (20)	49 (24)	25 (25)
CR2	211 (19)	40 (19)	17 (17)
CR3+	115 (10)	26 (13)	7 (7)
PR	71 (6)	14 (7)	7 (7)
Advanced	475 (43)	78 (38)	45 (45)
Missing	5 (<1)	0	0
Recipient age at transplant			
0-9 years	13 (1)	5 (2)	0
10-17 years	57 (4)	8 (3)	1 (1)
18-29 years	172 (13)	41 (16)	12 (9)
30-39 years	149 (11)	35 (14)	22 (17)
40-49 years	226 (17)	38 (15)	25 (19)
50-59 years	375 (28)	66 (26)	39 (30)
60-69 years	328 (24)	51 (20)	26 (20)
70+ years	24 (2)	8 (3)	5 (4)
Median (Range)	52 (3-77)	50 (2-75)	51 (13-75)
Recipient race			
White	1022 (79)	167 (72)	98 (79)
Black or African American	172 (13)	41 (18)	22 (18)
Asian	65 (5)	21 (9)	2 (2)
Native Hawaiian or other Pacific Islander	7 (1)	1 (<1)	1 (1)
American Indian or Alaska Native	10 (1)	1 (<1)	0
More than one race	11 (1)	1 (<1)	1 (1)
Unknown	57 (N/A)	20 (N/A)	6 (N/A)
Recipient ethnicity			

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
Hispanic or Latino	238 (18)	49 (20)	22 (17)
Non Hispanic or non-Latino	1083 (82)	197 (80)	103 (82)
Non-resident of the U.S.	7 (1)	0	1 (1)
Unknown	16 (N/A)	6 (N/A)	4 (N/A)
Recipient sex			
Male	854 (64)	155 (62)	79 (61)
Female	490 (36)	97 (38)	51 (39)
Karnofsky score			
10-80	449 (33)	95 (38)	47 (36)
90-100	822 (61)	144 (57)	73 (56)
Missing	73 (5)	13 (5)	10 (8)
HLA-A B DRB1 groups - low resolution			
<=3/6	288 (23)	77 (33)	38 (32)
4/6	95 (7)	15 (6)	10 (8)
5/6	26 (2)	2 (1)	6 (5)
6/6	863 (68)	137 (59)	65 (55)
Unknown	72 (N/A)	21 (N/A)	11 (N/A)
High-resolution HLA matches available out of 8			
<=5/8	361 (31)	85 (40)	44 (41)
6/8	16 (1)	4 (2)	3 (3)
7/8	20 (2)	2 (1)	4 (4)
8/8	758 (66)	124 (58)	56 (52)
Unknown	189 (N/A)	37 (N/A)	23 (N/A)
HLA-DPB1 Match			
Single allele mismatch	1 (<1)	0	0
Full allele matched	292 (48)	64 (83)	33 (70)
Unknown	320 (52)	13 (17)	14 (30)
Unknown	731 (N/A)	175 (N/A)	83 (N/A)
High resolution release score			
No	928 (69)	252 (100)	127 (98)
Yes	416 (31)	0	3 (2)
Graft type			
Marrow	181 (13)	36 (14)	21 (16)
PBSC	1161 (86)	215 (85)	109 (84)
BM+PBSC	2 (<1)	1 (<1)	0
Conditioning regimen			
Myeloablative	486 (36)	74 (29)	32 (25)
RIC/Nonmyeloablative	853 (63)	174 (69)	96 (74)
TBD	5 (<1)	4 (2)	2 (2)
Donor age at donation			

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
To Be Determined/NA	4 (<1)	1 (<1)	1 (1)
0-9 years	21 (2)	1 (<1)	0
10-17 years	62 (5)	8 (3)	2 (2)
18-29 years	232 (17)	59 (23)	30 (23)
30-39 years	214 (16)	46 (18)	25 (19)
40-49 years	249 (19)	49 (19)	23 (18)
50+ years	562 (42)	88 (35)	49 (38)
Median (Range)	46 (0-81)	42 (0-71)	43 (0-74)
Donor/Recipient CMV serostatus			
+/+	550 (41)	114 (45)	50 (38)
+/-	180 (13)	23 (9)	14 (11)
-/+	247 (18)	48 (19)	33 (25)
-/-	345 (26)	59 (23)	28 (22)
Missing	22 (2)	8 (3)	5 (4)
GvHD Prophylaxis			
No GvHD Prophylaxis	33 (2)	1 (<1)	3 (2)
TDEPLETION alone	2 (<1)	3 (1)	0
TDEPLETION +- other	9 (1)	2 (1)	2 (2)
CD34 select alone	0	1 (<1)	0
CD34 select +- other	5 (<1)	1 (<1)	0
Cyclophosphamide alone	9 (1)	1 (<1)	0
Cyclophosphamide +- others	498 (37)	114 (45)	61 (47)
FK506 + MMF +- others	117 (9)	13 (5)	3 (2)
FK506 + MTX +- others(not MMF)	468 (35)	60 (24)	44 (34)
FK506 +- others(not MMF,MTX)	114 (8)	44 (17)	13 (10)
FK506 alone	10 (1)	0	0
CSA + MMF +- others(not FK506)	9 (1)	5 (2)	0
CSA + MTX +- others(not MMF,FK506)	25 (2)	0	1 (1)
CSA +- others(not FK506,MMF,MTX)	14 (1)	5 (2)	1 (1)
CSA alone	3 (<1)	0	0
Other GVHD Prophylaxis	25 (2)	1 (<1)	2 (2)
Missing	3 (<1)	1 (<1)	0
Donor/Recipient sex match			
Male-Male	513 (38)	97 (38)	50 (38)
Male-Female	248 (18)	48 (19)	25 (19)
Female-Male	340 (25)	58 (23)	29 (22)
Female-Female	242 (18)	49 (19)	26 (20)
Missing	1 (<1)	0	0
Year of transplant			
2006-2010	120 (9)	16 (7)	14 (11)

Variable	Samples Available for Recipient and Donor N (%)	Samples Available for Recipient Only N (%)	Samples Available for Donor Only N (%)
2011-2015	499 (38)	70 (29)	35 (28)
2016-2020	445 (34)	83 (34)	42 (34)
2021-2025	280(19)	83 (31)	39 (27)
Follow-up among survivors, Months			
N Eval	855	161	88
Median (Range)	37 (0-148)	36 (0-123)	37 (0-145)

TO: Lymphoma Working Committee Members

FROM: Mehdi Hamadani, MD; Samantha Jaglowski, MD, MPH, MBA; Scientific Directors for the Lymphoma Working Committee

RE: 2025-2026 Studies in Progress Summary

LY23-01 Efficacy of hematopoietic stem cell transplantation in patients with plasmablastic lymphoma (S Ahmed/ T Al-Juhaishi) This study will evaluate outcomes of autologous and allogenic HCT with plasmablastic lymphoma.

Status: **Manuscript Preparation** Goal: **Submission**

LY24-01a Role of Hematopoietic Cell Transplantation in Rare Peripheral T-cell Lymphoma Subtypes – Hepatosplenic T-cell lymphoma (M Iqbal / A Tun) This study will evaluate outcomes of HCT with rare peripheral T-cell lymphoma (PTCL) subtypes such as hepatosplenic T-cell lymphoma (HSTCL)

Status: **Data File Preparation** Goal: **Submission**

LY24-01b Role of Hematopoietic Cell Transplantation in Rare Peripheral T-cell Lymphoma Subtypes - Monomorphic epitheliotropic intestinal T-cell lymphoma and enteropathy-associated T-cell lymphoma (T Brooks/ Y Pang). This study will evaluate outcomes of HCT with rare peripheral T-cell lymphoma (PTCL) subtypes such as Monomorphic epitheliotropic intestinal T-cell lymphoma and enteropathy-associated T-cell lymphoma.

Status: **Data File Preparation** Goal: **Submission**

LY24-01c Role of Hematopoietic Cell Transplantation in Rare Peripheral T-cell Lymphoma Subtypes – Extra-nodal NK/T-cell lymphoma, nasal type A Desai/ K Rechache). This study will evaluate outcomes of HCT with rare peripheral T-cell lymphoma (PTCL) subtypes such as Extra-nodal NK/T-cell lymphoma, nasal type

Status: **Data File Preparation** Goal: **Submission**

LY24-01d Role of Hematopoietic Cell Transplantation in Rare Peripheral T-cell Lymphoma Subtypes – Nodal T-follicular helper cell lymphoma (I Muhsen/ C Poh) This study will evaluate outcomes of HCT with rare peripheral T-cell lymphoma (PTCL) subtypes such as Nodal T-follicular helper cell lymphoma

Status: **Data File Preparation** Goal: **Submission**

LY24-01e Role of Hematopoietic Cell Transplantation in Rare Peripheral T-cell Lymphoma Subtypes – Subcutaneous panniculitis-like T-cell lymphoma (D Reef/ A Stack) This study will evaluate outcomes of HCT with rare peripheral T-cell lymphoma (PTCL) subtypes such as Subcutaneous panniculitis-like T-cell lymphoma

Status: **Data File Preparation** Goal: **Submission**

LY24-01f Role of Hematopoietic Cell Transplantation in Rare Peripheral T-cell Lymphoma Subtypes – Adult T-cell leukemia/lymphoma (A Sica/ R Stuver) This study will evaluate outcomes of HCT with rare peripheral T-cell lymphoma (PTCL) subtypes such as Adult T-cell leukemia/lymphoma (ATLL)

Status: **Data File Preparation** Goal: **Submission**

LY24-01g Role of Hematopoietic Cell Transplantation in Rare Peripheral T-cell Lymphoma Subtypes – Mycosis fungoides/Sezary syndrome (A Goyal/ E Yilmaz) This study will evaluate outcomes of HCT with rare peripheral T-cell lymphoma (PTCL) subtypes such as Mycosis fungoides/Sezary syndrome (MF/SS)

Status: **Data File Preparation** Goal: **Submission**

LY25-01 Axi-cel vs. Liso-cel in Second line in DLBCL (A Mian/ B T Hill/ D Reef/ N Grover). This study will compare outcomes of products of CT in DLBCL

Status: **Protocol Pending.** Goal: **Submission**

LY25-01 Real-world Outcomes Following Anti-CD19 Chimeric Antigen Receptor T Cell Therapy in Older Patients with Large B Cell Lymphoma. (M Di/ M Shadman/ S Gupta/ V Bachanova/ P Jain/ A Lionel). This study will evaluate outcomes of CT with Large B Cell Lymphoma in older age.

Status: **Protocol Pending.** Goal: **Submission**

Field	Response
Proposal Number	2508-01-BACHANOVA
Proposal Title	Novel Composite Endpoints Toxicity-free/Progression-free survival (tfPFS100) and Toxicity-free Complete Remission (tfCR100) after CAR T cell therapy for diffuse large B cell lymphoma
Key Words	DLBCL, CAR-T, composite endpoint
Principal Investigator #1: - First and last name, degree(s)	Veronika Bachanova, MD, PhD
Principal Investigator #1: - Email address	bach0173@umn.edu
Principal Investigator #1: - Institution name	University of Minnesota
Principal Investigator #1: - Academic rank	Professor of Medicine
Junior investigator status (defined as 幼、5 years from fellowship)	No
Do you identify as an underrepresented/minority?	No
Please list any ongoing CIBMTR projects that you are currently involved in and briefly describe your role.	Chair of leukemia WG no active projects with lymphoma WG
Do any of the PI(s) within this proposal have a CIBMTR WC study in manuscript preparation >6 months?	No
PROPOSED WORKING COMMITTEE:	Lymphoma
Please indicate if you have already spoken with a scientific director or working committee chair regarding this study.	No
RESEARCH QUESTION:	The success of CAR T is typically assessed by disease response and rates of immune complications like Cytokine Release Syndrome (CRS) and Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS). Given the variability in both efficacy andof toxicity among available CD19 CAR T products in relapsed/refractory large B-cell lymphoma (LBCL), traditional outcomes may not fully capture the overall clinical impact of this therapy. We aim to examine the composite end-points which may yield novel insights into net clinical benefit and optimal therapeutic index.

Field	Response
RESEARCH HYPOTHESIS:	We hypothesize that novel composite endpoints will differentiate 3 commercial products in their net clinical benefit. To evaluate the combined contribution of efficacy and toxicity in the first 100 days post CAR T, we defined novel composite end-points: toxicity-free complete response at day 100 (tfCR100) and toxicity-free, progression free survival at day 100 (tfPFS100). Toxicity will be characterized as experiencing grade 3 CRS or grade 3ICANS. tfCR100 will be defined as the proportion of patients achieving a complete response (CR) at day 100 post-infusion and without toxicity; tfPFS100 will be defined as the proportion of patients alive, free of lymphoma progression at day 100 post-infusion, and without toxicity. We compared outcomes between tfCR100 and CR100wt (patients in CR with gr 3 CRS or gr 3 ICANS). We then compared 3-yr PFS and OS by tfCR100 overall and by product. Relapse and non-relapse mortality at 2 years were estimated using cumulative incidence function using competing risks.
SPECIFIC OBJECTIVES/OUTCOMES TO BE INVESTIGATED (Include Primary, Secondary, etc.):	To evaluate the combined contribution of efficacy and toxicity in the first 100 days post CAR T, we defined novel composite end-points: toxicity-free complete response at day 100 (tfCR100) and toxicity-free, progression free survival at day 100 (tfPFS100). CR at day 100 with toxicity CR100-wt) will be defined as CR with either gr 3 CRS or gr 3 ICANS or both. No CR100 will be a group of patients who do not achieve CR at day 100 regardless of toxicity. Primary Objective: Evaluate tfPFS100 and tfCR100 in patients with R/R DLBCL treated with commercial CAR-T product and compare Axi-cel, Tisa-cel and Liso-cel. Secondary Objective: 1.Evaluate 2 year PFS and OS in tfCR100 patients compared to CR100-wt group 2. Evalute 2 year PFS and OS of no CR100 group 3. Evaluate cumulative incidence of NRM at 2 year in tfCR100 group compared to CR100-wt 4. Evaluate cumulative incidence of relapse at 2 years in tfCR100 group compared to CR100-wt 5. Evaluate 2-year PFS and OS of tfCR100 patients by CAR-T product 6. Evaluate 2 year PFS and OS of CR100-wt patients by CAR-T product 7. Evaluate all composite endpoints and objective 1-6 limited to cohort of R/R DLBCL treated with 2nd line Axicel vs Liso-cell

Field	Response
SCIENTIFIC IMPACT: Briefly state how the completion of the aims will impact participant care/outcomes and how it will advance science or clinical care.	As novel composite endpoints, tfCR100 and tfPFS100 measure freedom from progression and from serious immune effectors toxicity and morbidity including less corticosteroid use and associated complications. CIBMTR large dataset is an optimal data source to investigate these important questions. Composite endpoints can reveal the impact of serious toxicity, steroid use for ICANS on relapse risk as well as risk of mortality. The impact of this study is substantial as it will validate and reveal the emergence of novel clinical research tools for CAR-T evaluation in oncology. The applications are broad and potentially go beyond lymphoma. Composite end-points can be valuable in benchmarking cell therapies, design of clinical trials, health economic modeling, and guiding future strategies to optimize both safety and efficacy of CAR-T therapy.
SCIENTIFIC JUSTIFICATION: Provide a background summary of previous related research and their strengths and weaknesses, justification of your research and why your research is still necessary.	We have develop a dataset as part of Cell Therapy Consortium and examined novel composite end-points in cohort of 627 patients mostly treated in 3rd line therapy for R/R DLBCL with one of 3 available commercial CAR-T products. Our data have beed submitted to ASH and currently under embargo.
PARTICIPANT SELECTION CRITERIA: State inclusion and exclusion criteria.	Patients with R/R DLBCL treated with commercial CAR-T product in any line of therapy Age >18 Data available for disease response Data available for CRS and ICANS including grade Survival status
Does this study include pediatric patients?	No
If this study does not include pediatric patients, please provide justification:	CAR-T does not have approval for patients <18
DATA REQUIREMENTS: After reviewing data on CIBMTR forms, list patient-, disease- and infusion- variables to be considered in the multivariate analyses. Outline any supplementary data required.	all data is available on routine forms
Types of cellular therapy data this proposal includes:	Chimeric Antigen Receptor (CAR) T-Cell Therapy (CAR-T)
PATIENT REPORTED OUTCOME (PRO) REQUIREMENTS: If the study requires PRO data collected by CIBMTR, the proposal should include: 1) A detailed description of the PRO domains, timepoints, and proposed analysis of PROs; 2) A description of the hypothesis speci	N/A
MACHINE LEARNING: Please indicate if the study requires methodology related to machine-learning and clinical predictions.	N/A
SAMPLE REQUIREMENTS: If the study requires biologic samples from the CIBMTR Repository, the proposal should also include: 1) A detailed description of the proposed testing methodology and sample requirements; 2) A summary of the investigator's previous e	N/A

Field	Response
NON-CIBMTR DATA SOURCE: If applicable, please provide: 1) A description of external data source to which the CIBMTR data will be linked; 2) The rationale for why the linkage is required.	N/A
REFERENCES:	N/A
CONFLICTS OF INTEREST: Do you have any conflicts of interest pertinent to this proposal concerning?	No, I do not have any conflicts of interest pertinent to this proposal

Characteristics of adults with Relapsed/refractory DLBCL treated with CAR-T infusion reported to the CIBMTR

Characteristic	N (%)
No. of patients	6800
No. of centers	142
Level Age at CT Treatment, median (range), years	65.3 (18.0-91.2)
Age group - no. (%)	
18-39	377 (6)
40-69	4286 (63)
>=70	2137 (31)
Recipient Sex - no. (%)	
Male	4265 (63)
Female	2534 (37)
Not reported	1 (0)
Recipient race - no. (%)	
White	5527 (81)
Black or African American	397 (6)
Asian	380 (6)
Native Hawaiian or other Pacific Islander	13 (0)
American Indian or Alaska Native	35 (1)
Other	41 (1)
More than one race	301 (4)
Not reported	106 (2)
Ethnicity - no. (%)	
Hispanic or Latino	780 (11)
Non-Hispanic or Latino	5718 (84)
Non-resident of the U.S.	35 (1)
Not reported	267 (4)
Karnofsky performance score prior to CT - no. (%)	
90-100	2617 (38)
<90	3399 (50)
Not reported	784 (12)
ECOG prior to CT - no. (%)	
Asymptomatic	2728 (40)
Symptomatic but completely ambulatory	3269 (48)
Symptomatic, < 50% in bed during the day	317 (5)
Symptomatic, > 50% in bed, but not bedbound	31 (0)
Bedbound	3 (0)
Not reported	452 (7)

Characteristic	N (%)
HCT-CI Score - no. (%)	
0	1826 (27)
1	1347 (20)
2	957 (14)
3+	2600 (38)
Not reported	70 (1)
Disease status prior to CT for lymphoma - no. (%)	
CR	539 (8)
PR	1520 (22)
Resistant	3968 (58)
Untreated	427 (6)
Unknown	344 (5)
Not reported	2 (0)
Lymphodepleting regimen - no. (%)	
Fludarabine + Cyclophosphamide	4777 (70)
Bendamustine only	515 (8)
Others	1504 (22)
Not reported	4 (0)
Bridging therapy - no. (%)	
No	2215 (33)
Yes	2807 (41)
Not reported	1778 (26)
Time from initial diagnosis to CT - no. (%)	
>= 0 to < 12 months	767 (11)
>= 12 to < 36 months	2117 (31)
>= 36 to < 60 months	3914 (58)
Not reported	2 (0)
Product - no. (%)	
Tisagenlecleucel	967 (14)
Axicabtagene ciloleucel	4698 (69)
Lisocabtagene maraleucel	1128 (17)
Other	7 (0)
PET (or PET/CT) scan positive - no. (%)	
No	89 (1)
Yes	3529 (52)
Not reported	3182 (47)
No. of lines of prior therapies (including HCT and CT) - no. (%)	
median (min-max)	3.0 (1.0-18.0)
1	371 (5)
2	1641 (24)

Characteristic	N (%)
>=3	3182 (47)
Not reported	1606 (24)
Prior HCT - no. (%)	
No	5583 (82)
Yes	1205 (18)
Not reported	12 (0)
Types of prior HCTs - no. (%)	
No prior HCT	5583 (82)
Prior allo-HCT	51 (1)
Prior auto-HCT	1137 (17)
Prior auto and allo-HCT	8 (0)
Not reported	21 (0)
Year of CT - no. (%)	
2017	6 (0)
2018	366 (5)
2019	742 (11)
2020	849 (12)
2021	848 (12)
2022	1303 (19)
2023	1289 (19)
2024	1154 (17)
2025	243 (4)
Follow-up among survivors - median (range)	24.5 (0.9-89.2)

Field	Response
Proposal Number	2508-05-HOSSAIN
Proposal Title	Optimizing approaches to Allotransplant for Non-Hodgkin Lymphoma patients relapsing after second line CART therapy
Key Words	AlloSCT, CART, Relapse, GVHD, Infection, Conditioning, Immunosuppression
Principal Investigator #1: - First and last name, degree(s)	Nasheed Hossain, MD
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Principal Investigator #1: - Institution name	University of Pennsylvania
Principal Investigator #1: - Academic rank	Assistant Professor of Medicine
Junior investigator status (defined as 玆、5 years from fellowship)	No
Do you identify as an underrepresented/minority?	No
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Principal Investigator #2 (If applicable): - Institution name:	University of Pennsylvania
Principal Investigator #2 (If applicable): - Academic rank:	Associate Professor of Medicine
Junior investigator status (defined as 玆、5 years from fellowship)	No
Do you identify as an underrepresented/minority?	No
We encourage a maximum of two Principal Investigators per study. If more than one author is listed, please indicate who will be identified as the corresponding PI below:	Nasheed M. Hossain; Note PI#3 - Alison Loren (Professor of Medicine. University of Pennslyvania

Field	Response
Please list any ongoing CIBMTR projects that you are currently involved in and briefly describe your role.	Nasheed Hossain: LY22-02 - Co Investigator - protocol development, data analysis, manuscript preparation CT22-02 - Co Investigator - leading in concept design, protocol development and will be involved in data analysis and final manuscript/abstract preparation CT21-01 - protocol development CT20-03 - protocol development, CK21-01 = protocol development GV210-2 - protocol development LK21-01- protocol development and review GV18-01a-protocol development, manuscript review GV18-01b-protocol development, manuscript review MM20-02a - protocol development, data review, manuscript review Pashna Munshi: GV23-01: Co-investigator, protocol development, data analysis, manuscript preparation (this protocol is in initial stages and we are awaiting the data set).
Do any of the PI(s) within this proposal have a CIBMTR WC study in manuscript preparation >6 months?	No
PROPOSED WORKING COMMITTEE:	Lymphoma
Please indicate if you have already spoken with a scientific director or working committee chair regarding this study.	No
RESEARCH QUESTION:	What are the utilization patterns and outcomes for allogeneic stem cell transplant in lymphoid malignancy patients with disease relapse following CAR T cell therapy and can the use of allogeneic transplant be optimized to minimize non-treatment related mortality while optimizing disease control?
RESEARCH HYPOTHESIS:	We hypothesize that AlloSCT will be utilized in a younger population and preferentially in patients who have relapsed after CAR T cell therapy in the third line setting and the use of RIC regimens will be associated with decreased non-relapse mortality but increased rates of disease relapse post alloSCT. We also hypothesize that use of RIC conditioning may also may alloSCT a more feasible option for older patient populations (age 65+). We also hypothesize in that in the post CAR setting, having treatment response of disease at time of transplant translates into improved outcomes and lower rates of relapse in multivariate analysis. We also hypothesize that the rates of GVHD, infection and graft failure in this population will compare favorably to what has been observed in the established literature for the use of AlloSCT in B-cell malignancies.

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SPECIFIC OBJECTIVES/OUTCOMES TO BE INVESTIGATED (Include Primary, Secondary, etc.):	1. Tabulate current practice patterns with regards to AlloSCT in the post-CART setting for B-cell malignancies including donor source, conditioning and immunosuppressive regimens utilized. One area of special interest will be the impact MAC vs RIC conditioning has on outcomes. 2. Determine non-relapse mortality, progression free survival, overall survival and rates of relapse post AlloSCT 3. Determine rates of acute and chronic GVHD and responses to therapy and compared that to typical rates seen for AlloSCT in B cell malignancies. Specific focus will be placed on the impact adoption of pTCY has had on outcomes 4. Determine rates of infection post AlloSCT and compared that to typical rates seen for AlloSCT in B cell malignancies
SCIENTIFIC IMPACT: Briefly state how the completion of the aims will impact participant care/outcomes and how it will advance science or clinical care.	As the population of patient's receiving CAR T cell therapy grows, there is quickly growing population of patients who have experienced post CAR-t relapsed. Currently there is great uncertainty on how to best proceed in this patient population. AlloSCT represents one of the most potent immunotherapeutic options but one associated with increased Non-relapse mortality. Given the growing need further insight and guidance is required for clinicians. This study will help highlight current practice patterns and help determine guidelines on who should be offered an allogeneic stem cell transplant and how it best can be carried out (graft source, conditioning, immunosuppressive regimen). Furthermore - many of the practice patterns in terms of approach to AllOSCT, specifically intensity of conditioning, is extrapolate from previous patient populations who had undergone multiple lines of intense chemotherapy. In the current era- there is overall less chemotherapy and more lines immunotherapy (CAR, BiTEs etc) that patients undergo before being referred for AlloSCT. In this new pateint population it would be crucial to determine if MAC regimens may provide additional outcomes benifits as compared to RIC regimens.

SCIENTIFIC JUSTIFICATION: Provide a background summary of previous related research and their strengths and weaknesses, justification of your research and why your research is still necessary.	Standard DLBCL induction therapy provides approximately 60% of DLBCL patients long-term remissions.1 Unfortunately, 10-15% of DLBCL patients have primary refractory disease (and an additional 20-25% have relapsed disease after initial response to therapy.2 A recent meta-analysis of over 600 patients (SCHOLAR-1) demonstrated that patients refractory to chemotherapy have a CR rate of only 7%, median OS of 6.3 months and 1 year OS of 23%.3 The North American retrospective study (REFINE) of over 300 patients also highlighted dismal outcomes in patients with relapsed or refractory disease and that patients with MYC rearranged DLBCL are prone to primary treatment failure and less success with salvage therapies; including ASCT and allogeneic stem cell transplantation.4 Taken together, SCHOLAR-1 and REFINE established that chemotherapy refractory DLBCL represents a critical unmet medical need, with approximately 5,400 patients seeking improved therapeutic options annually. Chimeric Antigen Receptor (CAR) therapy targeting CD19 has recently emerged as a potential treatment option for lymphoid malignancies, specifically ALL and NHL. Multiple groups have reported complete remission (CR) rates 70% in patients with B-cell ALL and 75% in NHL.5, 6 Durable response (lasting >6months) seen primarily in patients with an initial CR but not those who achieve a PR following CAR therapy. Furthermore, initial insights into CAR dynamics indicate that effective therapy is characterized by initial robust CAR T-cell expansion and persistence of the CARs beyond the 6-month mark. Similar observations are seen in MCL, FL and MM. The current trends have fueled great interest in the future direction for clinical management of patient's with post CAR disease relapse. One of the largest recent analysis by J Speigel et al, looked at 100 patients treated with Axi-cel who experience disease relapse and had subsequent therapy. They reported that the most widely used follow therapies where checkpoint inhibitor based (n = 30), lenalidomide based (n = 27), chemotherapy (n = 17), and radiation (n = 10). Other options alkso included use of venetoclax (n = 1), brentuximab vedotin (n = 2) or ibrutinib (n = 2), novel therapies (n = 8), steroids (n = 1), second CAR-T on clinical trial (n = 1). Disappointingly, the Overall, best response rates for these patients were 29% ORR, with 17% CR, and median PFS was 55 days (95% CI, 47-86). Given these observations there is ongoing interest at looking at other approaches. The SWOG cooperative group is in

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	the midst of formulating a study (S2114) to determine the role of pre-emptive subsequent therapy in patients not achieving a CR withing the first 30 days post-CAR. However, to date there has been no analysis on the role of an allogeneic transplant. This proposal would not only look at trends in the use of alloSCT but more closely look at aspects of AlloSCT, including graft source, conditioning regimen, immunosuppressive regimen, age group of recipient/donor and outcomes (response, GVHD rates, infection rates) to elucidate trends and highlight practice patterns that may optimize AlloSCT for this growing patient population. There is clearly a clinical need for such guidance and given the CIBMTRs resources it stands in the strongest position for such a analysis.
PARTICIPANT SELECTION CRITERIA: State inclusion and exclusion criteria.	Any patient with a history of B-cell malignancy who is underwent CAR-T therapy with subsequent relapse and then underwent an AlloSCT.
Does this study include pediatric patients?	No
If this study does not include pediatric patients, please provide justification:	In general - a lower population of pediatric patients develop B-cell lymphomas. It is postulated they may have a very different biology compared to their adult counterparts and as such would warrant a separate analysis

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DATA REQUIREMENTS: After reviewing data on CIBMTR forms, list patient-, disease- and infusion-variables to be considered in the multivariate analyses. Outline any supplementary data required.	Age Gender Stage at Diagnosis IPI score at diagnosis (if applicable) Presence of bulky disease (if applicable), at diagnosis and at time of CAR-T) Disease status at CAR-T treatment Prior History of Auto or AlloSCT CART product received Type of CART product (CD28 co-stim versus 4-1bb co-stim) LDH, Ferritin, CRP at time of CAR-T treatment at each follow up date Blood counts at treatment (WBC, Platelets, Hemoglobin, ANA, ALC) and at each subsequent follow up date when response assessed D28 Response D90 Response D120 Response Month 6 Response Month 9 Response Month 12 Response Maximum grade of CRS Maximum grade of Neurotoxity Duration of cytopenias Timing of disease relapse Time to AlloSCT post CAR Donor Source (MUD, Sib, Haplo, Cord) CMV status (D/R) Donor Gender Conditioning Regimen (MAC, RIC, NMA) Immunosuppressive Regimen (Tac/MTX, Post-transplant Cy, Tac/MMF, Other) Time to WBC engraftment Time to platelet engraftment Best Disease response post AlloSCT Time to Relapse Rates of aGVHD -systems impacted and stage -maximum overall grade -treatment given Rates of cGVHD -systems impacted -maximum grade -treatments given Rates of Infection (Viral, Fungal, Bacterial)
Types of cellular therapy data this proposal includes:	Hematopoietic Cell Transplantation (HCT)
PATIENT REPORTED OUTCOME (PRO) REQUIREMENTS: If the study requires PRO data collected by CIBMTR, the proposal should include: 1) A detailed description of the PRO domains, timepoints, and proposed analysis of PROs; 2) A description of the hypothesis speci	no
MACHINE LEARNING: Please indicate if the study requires methodology related to machine-learning and clinical predictions.	no
SAMPLE REQUIREMENTS: If the study requires biologic samples from the CIBMTR Repository, the proposal should also include: 1) A detailed description of the proposed testing methodology and sample requirements; 2) A summary of the investigator's previous e	no

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NON-CIBMTR DATA SOURCE: If applicable, please provide: 1) A description of external data source to which the CIBMTR data will be linked; 2) The rationale for why the linkage is required.	A description of the external data source to which the CIBMTR data will be linked. The rationale for why the linkage is required, i.e., neither database contains all the data required to answer the study question.
REFERENCES:	1. Sehn LH, Gascoyne RD. Diffuse large B-cell lymphoma: optimizing outcome in the context of clinical and biologic heterogeneity. Blood. 2015;125(1):22-32. doi:10.1182/blood-2014-05-577189. 2. Friedberg JW. Relapsed/refractory diffuse large B-cell lymphoma. Hematol Am Soc Hematol Educ Progr. 2011;2011:498-505. doi:10.1182/asheducation-2011.1.498. 3. Crump M, Neelapu SS, Farooq U, et al. Outcomes in refractory diffuse large B-cell lymphoma: results from the international SCHOLAR-1 study. Blood. August 2017. doi:10.1182/blood-2017-03-769620. 4. Epperla N, Maddocks KJ, Salhab M, Chavez JC, Reddy N, Karmali R, Umyarova E, Bachanova V, Costa C, Glenn M, Calzada O, Xavier AC, Zhou Z, Hossain NM, Hernandez-Ilizaliturri FJ, Al-Mansour Z, Barta SK, Chhabra S, Lansigan F, Mehta A, Jaglal MV, Evans A, Fl CL. C-MYC-positive relapsed and refractory, diffuse large B-cell lymphoma: Impact of additional “hits” and outcomes with subsequent therapy. Cancer. 2017;123(22):4411-4418. doi:10.1002/cncr.30895. 5. Maude SL, Frey N, Shaw PA, et al. Chimeric antigen receptor T cells for sustained remissions in leukemia. N Engl J Med. 2014;371(16):1507-17. 6. Neelapu SS, Locke FL, Bartlett NL, et al. Axicabtagene Ciloleucel CAR T-Cell Therapy in Refractory Large B-Cell Lymphoma. N Engl J Med. December 2017. doi:10.1056/NEJMoa1707447. 7. Abramson JS, Siddiqi T, Palomba ML, Gordon LI, Lunning MA, Arnason JE, Wang M, Forero-Torres A, Albertson T, Dehner C, Garcia J, Li Daniel, Xie B MD. R/R Aggressive B-NHL (TRANSCEND NHL 001 Study): A Defined Composition CD19-Directed CAR T Cell Product with Potential for Outpatient Administration. In: 2018 BMT Tandem Meetings. ; 2018. 8. Spiegel JY, Dahiya S, Jain MD, et al. Outcomes of patients with large B-cell lymphoma progressing after axicabtagene ciloleucel therapy. Blood. 2021;137(13):1832-1835.

Field	Response
CONFLICTS OF INTEREST: Do you have any conflicts of interest pertinent to this proposal concerning?	No, I do not have any conflicts of interest pertinent to this proposal

Characteristics of US allo Adult patients (age ≥18)who have prior CT with DLBCL/FL/MCL

Characteristic	**N (%)**
Number of patients	377
No. of centers	90
Patient age, median (range), years	58.7 (20.0-78.9)
Age group, no. (%)	
18-39	46 (12)
40-69	302 (80)
>=70	29 (8)
Sex, no. (%)	
Male	268 (71)
Female	109 (29)
TED or RES (RF) track determined for this event, no. (%)	
TED	339 (90)
CRF (RES)	38 (10)
Race, no. (%)	
White	322 (85)
Black or African American	22 (6)
Asian	20 (5)
More than one race	2 (1)
Not reported	11 (3)
Ethnicity, no. (%)	
Hispanic or Latino	37 (10)
Non-Hispanic or Latino	331 (88)
Non-resident of the U.S.	2 (1)
Not reported	7 (2)
HCT-CI, no. (%)	
0	88 (23)
1	64 (17)
2	68 (18)
3+	72 (19)
Not reported	85 (23)
Karnofsky Score, no. (%)	
90-100	189 (50)
<90	172 (46)
Not reported	16 (4)
Conditioning regimen intensity, no. (%)	
MAC	59 (16)
RIC/NMA	303 (80)
Not reported	15 (4)

Characteristic	N (%)
Conditioning regimen, no. (%)	
TBI/Cy	11 (3)
TBI/Cy/Flu	99 (26)
TBI/Cy/Flu/TT	2 (1)
TBI/Cy/VP	1 (0)
TBI/VP	1 (0)
TBI/Mel	31 (8)
TBI/Flu	36 (10)
TBI/other(s)	1 (0)
Bu/Cy	4 (1)
Flu/Bu/TT	5 (1)
Flu/Bu	82 (22)
Flu/Mel/TT	5 (1)
Flu/Mel	80 (21)
Cy/Flu	4 (1)
BEAM	2 (1)
Mel alone	1 (0)
TLI	4 (1)
Other(s)	6 (2)
Not reported	2 (1)
Primary disease, no. (%)	
NHL	377 (100)
Specify ALL classification, no. (%)	
NHL follicular,predominantly small cleaved cell:	3 (1)
NHL follicular,mixed,small cleaved and large cell:	7 (2)
NHL diffuse, large B-cell:	86 (23)
NHL mantle cell:	52 (14)
Follicular, predominantly large cell Grade IIIA (2400v4):	12 (3)
Follicular, predominantly large cell Grade IIIB (2400v4):	1 (0)
Follicular unknown grade:	1 (0)
Follicular, predominantly large cell (Grade IIIA vs IIIB not specified)	3 (1)
Diffuse, large B-cell lymphoma- Germinal center B-cell type	121 (32)
Diffuse, large B-cell lymphoma- Activated B-cell type	88 (23)
EBV+ DLBCL, NOS (1823)	3 (1)
Donor type, no. (%)	
HLA identical sibling	85 (23)
Haploidentical donor	92 (24)
Other related	5 (1)
Well-matched unrelated (8/8)	152 (40)
Partially-matched unrelated (7/8)	28 (7)

Characteristic	N (%)
Mismatched unrelated (<= 6/8)	1 (0)
Multi-donor	1 (0)
Unrelated (matching cannot be determined)	10 (3)
Cord blood	3 (1)
Year of current transplant, no. (%)	
2018-2022	186 (49)
2023-2025	191 (51)
Follow-up of survivors, median (range), months	23.8 (3.0-74.7)

CIBMTR TBD

Lisocabtagene maraleucel for the treatment of relapsed or refractory mantle cell lymphoma: a CIBMTR analysis

Version 1.8.2026

Key Words: Mantle cell lymphoma; lisocabtagene maraleucel; Real-world; Relapsed or refractory

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1.0 RESEARCH QUESTION

1.1 What are the characteristics and outcomes of patients with relapsed or refractory mantle cell lymphoma (r/r MCL) treated with commercial lisocabtagene maraleucel (liso-cel) among centers submitting data to CIBMTR?

2.0 HYPOTHESIS

2.1 Liso-cel will observe similar response rates, survival outcomes, and toxicities (e.g., cytokine release syndrome [CRS], immune-effector cell-associated neurotoxicity syndrome [ICANS], and infections) to those described in the pivotal TRANSCEND NHL 001 trial despite its application to a broad population of patients with r/r MCL, including a substantial proportion of whom would not have been eligible from the trial.

3.0 SPECIFIC OBJECTIVES/OUTCOMES TO BE INVESTIGATED

3.1 Objectives:

- 3.1.1 Assess real-world effectiveness of liso-cel in a large population of patients with r/r MCL and compare these outcomes to those of TRANSCEND NHL 001.
- 3.1.2 Describe safety outcomes of liso-cel use among patients with r/r MCL, including rates of cytokine release syndrome (CRS), immune effector cell-associated neurotoxicity syndrome (ICANS), and infectious complications.
- 3.1.3 Characterize non-relapse mortality (NRM) among patients with MCL treated with liso-cel.
- 3.1.4 Ascertain the relationship between treatment history (e.g., prior Bruton's tyrosine kinase inhibitor [BTKi], bendamustine, autologous hematopoietic cell transplant, and number of prior lines of systemic therapy) and outcomes.
- 3.1.5 Perform a comparative analysis of liso-cel and brexucabtagene autoleucel (brexu-cel) utilizing a target trial emulation (TTE) framework

3.2 Outcomes:

Outcomes of patients treated with brexu-cel and those treated with liso-cel will be analyzed separately.

- 3.2.1 Overall survival (OS, Primary): time to death. Death from any cause will be considered an event. Surviving patients will be censored at time of last follow-up.
- 3.2.2 Progression-free survival (PFS, Secondary): survival without disease progression or relapse. Progression, relapse, and death are considered events. Patients who are alive and in remission are censored at time of last follow-up.
- 3.2.3 Hematopoietic recovery (Secondary): The primary measures for hematopoietic recovery will be:
  - 3.2.3.1 Time to neutrophils (ANC) > 0.5 $x10^9$/L sustained for three consecutive days within 28 and 100 days post-transplant. This endpoint does not specify whether recovery is engraftment of donor cells or autologous reconstitution.

3.2.3.1.1 Time to achieve a platelet count of (a) >20 x 10^9/L independent of platelet transfusions for 3 consecutive days.

3.2.4 NRM (Secondary): Cumulative incidence of NRM. NRM is defined as death without preceding disease relapse/progression. Relapse and progression are competing events.

3.2.5 Relapse/Progression (Secondary): Cumulative incidence of disease relapse/progression with NRM as competing event.

3.2.6 Cause of death (Secondary): Descriptive only.

4.0 SCIENTIFIC IMPACT

4.1 Real-world experience has confirmed the safety and efficacy of brexu-cel, but data are limited in relation to commercial liso-cel in r/r MCL. This study aims to characterize the efficacy and toxicity profile among a broad population of individuals treated with liso-cel in clinical practice. The results of this study may aid clinicians in choosing the optimal cellular therapy product for patients with r/r MCL.

5.0 SCIENTIFIC JUSTIFICATION

5.1 Prior research into chimeric antigen receptor (CAR) T-cell therapy for r/r MCL has primarily focused on brexu-cel, with several real-world studies and registry analyses involving diverse population of patients across dozens of treatment centers. These studies have provided valuable insights into its clinical performance and toxicity profile in patients who were not eligible for enrollment for the initial studies of brexu-cel in r/r MCL.

Similar research into the real-world use of liso-cel for r/r MCL is lacking. Patients enrolled on the initial TRANSCEND trial that led to its approval consisted of a highly curated population due to the relatively strict inclusion and exclusion criteria of clinical trials. This often leads to a trial population that differs from the population of individuals to which approved products are applied, which may then lead to differences in outcomes and in potential toxicities.

Considering these gaps, a CIBMTR analysis of the safety and efficacy of liso-cel in the real-world setting is both timely and necessary. Such an analysis would provide real-world evidence to validate the safety and efficacy of liso-cel in a broader population, including patients with high-risk features and those who might not qualify for clinical trials. It would also allow for meaningful comparisons with brexu-cel, helping clinicians make informed decisions about which CAR T-cell product to use based on individual patient characteristics. Direct comparisons could be accomplished using the target trial emulation framework, an emerging methodological approach to reducing bias in observational research and enhancing the ability of researchers to make causal inferences from retrospective data. Furthermore, since liso-cel approval was based on

early-phase data, post-marketing surveillance through a registry like CIBMTR is essential to confirm its continued safety and effectiveness in routine practice.

6.0 PARTICIPANT SELECTION CRITERIA

6.1 Inclusion criteria:

- 6.1.1 Adults (age ≥18 years) patients with a histologically confirmed diagnosis of MCL treated with liso-cel as standard-of-care for r/r disease
- 6.1.2 Infused with liso-cel between June 2024 and June 2026
- 6.1.3 Provided informed consent for participation in the CIBMTR research database

6.2 Exclusion Criteria:

- 6.2.1 Patients enrolled in clinical trials
- 6.2.2 Patients with prior non-transplant cellular therapy (including prior CAR T-cell therapy)

7.0 DATA REQUIREMENTS

7.1 Patient related:

- 7.1.1 Form 4000
  - 7.1.1.1 Ethnicity
  - 7.1.1.2 Race
  - 7.1.1.3 Is this the first time the recipient is being treated using a cellular therapy?
  - 7.1.1.4 Has the recipient ever had a prior HCT?
    - 7.1.1.4.1 Name of cellular therapy product
  - 7.1.1.5 LDH (report most recent LDH value within 30 days of lymphodepleting therapy)
  - 7.1.1.6 What scale was used to determine the recipient's functional status prior to the cellular therapy
    - 7.1.1.6.1 Karnofsky Scale
    - 7.1.1.6.2 ECOG score
  - 7.1.1.7 HCT-CI score
- 7.1.2 Form 2018R
  - 7.1.2.1 Mantle cell lymphoma histology (at diagnosis)
  - 7.1.2.2 Were immunohistochemical stains obtained?
    - 7.1.2.2.1 Ki-67
      - 7.1.2.2.1.1 Positive/Negative/Unknown
      - 7.1.2.2.1.2 Percent positivity
  - 7.1.2.3 Were cytogenetics tested via FISH?
    - 7.1.2.3.1 T(11;14)
    - 7.1.2.3.2 Del(17p) / 17p-
    - 7.1.2.3.3 P53 deletion
    - 7.1.2.3.4 Other abnormality
  - 7.1.2.4 Were cytogenetics tested via karyotyping?
    - 7.1.2.4.1 Specify abnormalities
  - 7.1.2.5 WBC (mantle cell and all Hodgkin histologies)
    - 7.1.2.5.1 Number
  - 7.1.2.6 LDH (all histologies)
    - 7.1.2.6.1 Number

7.1.2.7 Stage of organ involvement
7.1.2.8 Was there any extranodal or splenic involvement?
7.1.2.8.1 Specify site(s) of involvement
7.1.2.9 ECOG score (at diagnosis)
7.1.2.9.1 NumberAge at HCT
7.1.3 Gender: Male vs. Female
7.1.4 Karnofsky performance score: 90-100% vs. Not reported
7.1.5 HCT Co-morbidity index: 0 vs. 1-2 vs. ≥3 vs. Not reported vs. N/A
7.1.6 Race: Caucasian vs. Asian vs. African-American vs. Pacific Islander vs. Other vs. Not reported
7.1.7 Ethnicity: Hispanic or non-Hispanic

7.2 Disease related:
7.2.1 Disease stage at diagnosis: I/II vs. III/IV
7.2.2 Elevated LDH at diagnosis: Yes vs. No vs. Not reported
7.2.3 Bone marrow involvement at any time before HCT: Yes vs. No vs. Not reported
7.2.4 History of CNS involvement: At diagnosis vs. At relapse/progression vs. No vs. Unknown vs. Not reported
7.2.5 Type of first-line therapy: Chemotherapy alone vs. Radiation alone vs. Chemoradiation vs. Surgery vs. Unknown vs. Not reported
7.2.6 Response to first-line therapy: Complete response (CR) vs. <CR vs. Not reported
7.2.7 Number of prior therapy lines received before cellular therapy: Continuous
7.2.8 Response to last therapy line before cellular therapy: CR vs. PR vs. <PR vs. Not reported
7.2.9 Time from diagnosis to cellular therapy: <1 year vs. ≥1 year

7.3 Pre-infusion Therapy:
7.3.1 Form 2018R
7.3.1.1 Was therapy given?
7.3.1.1.1 Systemic therapy
7.3.1.1.1.1 Date therapy started
7.3.1.1.1.2 Date therapy stopped
7.3.1.1.1.3 Number of cycles
7.3.1.1.1.4 Was a standard drug regimen given?
7.3.1.1.1.5 Were systemic drugs given?
7.3.1.1.1.6 Intrathecal therapy
7.3.1.1.1.6.1 Reason for intrathecal therapy
7.3.1.1.1.6.2 Specify intrathecal therapy
7.3.1.1.1.7 Radiation therapy
7.3.1.1.1.7.1 What was the extent of the radiation field?
7.3.1.1.1.7.2 Specify the site of radiation
7.3.1.1.1.7.3 Specify technique
7.3.1.1.1.8 Cellular therapy
7.3.1.1.1.9 Best response to line of therapy by CT criteria
7.3.1.1.1.10 Best response to line of therapy by PET criteria
7.3.1.1.1.11 Wat this line of therapy maintenance/consolidation?

7.3.1.1.1.12 Did disease relapse/progression occur following this line of therapy?
7.3.1.1.1.12.1 Date of relapse/progression
7.3.1.1.1.13 Did the recipient have known nodal involvement? (at last evaluation)
7.3.1.1.1.14 Was there any extranodal or splenic involvement? (at lats evaluation)
7.3.1.1.1.14.1 Specify site(s) of involvement

7.3.2 Form 4001
7.3.2.1 In what setting is this cell therapy product infusion being planned?
7.3.2.2 Drug (lymphodepleting therapy prior to cellular therapy)
7.3.2.3 Therapy given for the prevention of CRS
7.3.2.4 Therapy given for the prevention of neurotoxicity

7.3.3 Form 4003
7.3.3.1 Name of cellular therapy product
7.3.3.1.1 Is the product out of specification?
7.3.3.1.2 Date of cell product collection

7.3.3.2 Form 4006
7.3.3.2.1 Date of this product infusion
7.3.3.2.2

7.4 <u>Post-infusion:</u>
7.4.1 Form 2118R
7.4.1.1 What was the best response by CT (radiographic) criteria to HCT or cellular therapy since the date of the last report?
7.4.1.1.1 Was the date of best response previously reported?
7.4.1.2 What was the best response by PET (metabolic) criteria to HCT or cellular therapy since the date of the last report?
7.4.1.2.1 Was the date of best response previously reported?
7.4.1.3 Was therapy given since the date of the last report for reasons other than relapse or progressive disease?
7.4.1.4 Did the recipient experience a relapse or progression since the date of the last report? (by any method)
7.4.1.5 Was intervention given for relapsed disease, progressive disease, or minimal residual disease? (since the date of the last report)
7.4.1.6 What is the current disease status? (by CT (radiographic) criteria)
7.4.1.7 What is the current disease status? (by PET (metabolic) criteria)

7.4.2 Form 4100R92
7.4.2.1 Date of actual contact with the recipient to determine medical status for this follow-up report:
7.4.2.2 Specify the recipient's survival status at the date of last contact
7.4.2.3 Was the date of best response previously reported?
7.4.2.4 Was there evidence of initial recovery?
7.4.2.4.1 Date ANC >/= 500/mm^3 (first of 3 consecutive lab values)
7.4.2.5 Was an initial platelet count >/= 20 x 10^9/L achieved?
7.4.2.5.1 Date platelets >/= 20 x 10^9/L
7.4.2.6 Was a disease relapse or progression detected since the date of last report?

7.4.2.6.1 Date of relapse or progression
7.4.2.7 Did a new malignancy, myelodysplastic, myeloproliferative, or lymphoproliferative disease/disorder occur that is different from the disease/disorder for which the infusion was performed?
7.4.2.8 Did the patient experience CRS?
7.4.2.8.1 Was the date of diagnosis previously reported?
7.4.2.8.1.1 Date of CRS diagnosis
7.4.2.8.2 Specify therapy given for CRS
7.4.2.8.3 Indicate the symptoms of CRS
7.4.2.8.3.1 Specify the therapy given for hypotension
7.4.2.8.4 Were features resembling macrophage activation syndrome (MAS)/hemophagocytic lymphohistiocytosis (HLH)-like toxicities present?
7.4.2.8.4.1 Specify therapy given for MAS/HLH-like toxicities
7.4.2.8.5 Did the recipient experience neurotoxicity?
7.4.2.8.5.1 Specify therapy given for neurotoxicity
7.4.2.8.6 Has the recipient experienced grade 3 organ toxicity?
7.4.2.8.6.1 Specify organ
7.4.2.8.6.2 Specify the toxicity
7.4.2.8.7 Has the recipient experienced grade 4 organ toxicity?
7.4.2.8.7.1 Specify organ
7.4.2.8.8 Did the recipient develop a clinically significant infection since the date of last report?
7.4.2.8.8.1 Organism
7.4.2.8.8.2 Site

7.4.3 Form 4101R1
7.4.3.1 Was the recipient admitted to the hospital post-infusion
7.4.3.2 Were B-cell counts monitored after infusion/was there B-cell recovery
7.4.3.2.1 Date of B-cell recovery

8.0 PATIENT-REPORTED OUTCOME (PRO) REQUIREMENTS

8.1 Not applicable.

9.0 MACHINE LEARNING

9.1 Not applicable.

10.0 SAMPLE REQUIREMENTS

10.1 Not applicable.

11.0 NON-CIBMTR DATA SOURCE

11.1 Not applicable.

12.0 REFERENCES

Characteristics of adults with Relapsed or refractory mantle cell lymphoma treated with liso-cel CAR-T infusion reported to the CIBMTR between June 2024 and June 2026

Characteristic	N (%)
No. of patients	80
No. of centers	45
Level Age at CT Treatment, median (range), years	72.6 (45.9-85.1)
Age group - no. (%)	
<60	10 (13)
60+	70 (88)
Recipient Sex - no. (%)	
Male	56 (70)
Female	24 (30)
Recipient race - no. (%)	
White	70 (88)
Black or African American	5 (6)
Asian	2 (3)
More than one race	3 (4)
Ethnicity - no. (%)	
Hispanic or Latino	6 (8)
Non-Hispanic or Latino	72 (90)
Not reported	2 (3)
Karnofsky performance score prior to CT - no. (%)	
90-100	32 (40)
<90	28 (35)
Not reported	20 (25)
ECOG prior to CT - no. (%)	
Asymptomatic	39 (49)
Symptomatic but completely ambulatory	35 (44)
Symptomatic, < 50% in bed during the day	4 (5)
Not reported	2 (3)
HCT-CI Score - no. (%)	
0	14 (18)
1	16 (20)
2	11 (14)
3+	39 (49)
Disease status prior to CT for lymphoma - no. (%)	
CR	13 (16)
PR	18 (23)
Resistant	41 (51)

Characteristic	N (%)
Untreated	2 (3)
Unknown	6 (8)
Lymphodepleting regimen - no. (%)	
Fludarabine + Cyclophosphamide	71 (89)
Bendamustine only	7 (9)
Others	2 (3)
Bridging therapy - no. (%)	
No	22 (28)
Yes	54 (68)
Not reported	4 (5)
Time from initial diagnosis to CT - no. (%)	
>= 12 to < 36 months	6 (8)
>= 36 to < 60 months	74 (93)
Product - no. (%)	
Lisocabtagene maraleucel	80 (100)
No. of lines of prior therapies (including HCT and CT) - no. (%)	
median (min-max)	4.0 (1.0-12.0)
1	2 (3)
2	13 (16)
3	62 (78)
Not reported	3 (4)
Prior HCT - no. (%)	
No	64 (80)
Yes	16 (20)
Types of prior HCTs - no. (%)	
No prior HCT	64 (80)
Prior allo-HCT	1 (1)
Prior auto-HCT	14 (18)
Prior auto and allo-HCT	1 (1)
Year of CT - no. (%)	
2024	49 (61)
2025	31 (39)
Follow-up among survivors - median (range)	6.0 (2.9-12.0)

Field	Response
Proposal Number	2509-136-MAILHOT and 2509-88-ALHOMOUD
Proposal Title	The role of bridging radiation therapy prior to CD19 CAR T for non-Hodgkin lymphoma
Key Words	Lymphoma, CAR T, radiation
Principal Investigator #1: - First and last name, degree(s)	Mohammad Alhomoud, MD
Principal Investigator #1: - Email address	alhomom@mskcc.org
Principal Investigator #1: - Institution name	Memorial Sloan Kettering Cancer Center
Principal Investigator #1: - Academic rank	Assistant Professor
Junior investigator status (defined as 㑊、5 years from fellowship)	Yes
Do you identify as an underrepresented/minority?	Yes
Principal Investigator #2 (If applicable): - First and last name, degree(s):	Raymond Mailhot, MD MPH
Principal Investigator #2 (If applicable): - Email address:)	rbm143@med.miami.edu
Principal Investigator #2 (If applicable): - Institution name:	University of Miami
Principal Investigator #2 (If applicable): - Academic rank:	Associate Professor
Junior investigator status (defined as 㑊、5 years from fellowship)	No
Do you identify as an underrepresented/minority?	Yes
We encourage a maximum of two Principal Investigators per study. If more than one author is listed, please indicate who will be identified as the corresponding PI below:	Mohammad Alhomoud
Please list any ongoing CIBMTR projects that you are currently involved in and briefly describe your role.	Dr. Alhmoud and Dr. Scordo has no ongoing work with CIBMTR. Drs. Mailhot and Mobley are MPIs for R37CA288560 with a novel data linkage between CIBMTR and PCORnet in collaboration with CIBMTR contact Dr. Heather Stefanski. Dr. Mailhot also has submitted a PCORI grant with CIBMTR leader Dr. Rachel Phelan serving as a stakeholder.
Do any of the PI(s) within this proposal have a CIBMTR WC study in manuscript preparation >6 months?	No
PROPOSED WORKING COMMITTEE:	Lymphoma
Please indicate if you have already spoken with a scientific director or working committee chair regarding this study.	No

Field	Response
RESEARCH QUESTION:	What are the clinical efficacy and safety of bridging radiation therapy prior to CD19 CAR T-cell for Non-Hodgkin's lymphoma?
RESEARCH HYPOTHESIS:	Bridging radiation therapy is safe and effective in the context of CD19 CAR T-cell for Non-Hodgkin's lymphoma compared to radiation-free bridging regimen.
SPECIFIC OBJECTIVES/OUTCOMES TO BE INVESTIGATED (Include Primary, Secondary, etc.):	Primary: Determine the clinical efficacy and safety of bridging radiation therapy (BRT) prior to CD19 CAR T-cell for Non-Hodgkin's lymphoma by assessing overall response rates (ORR), rates of complete response (CR), incidence of relapse, progression-free survival (PFS), overall survival (OS), rates of cytokine release syndrome (CRS), and immune-effector cell neurotoxicity syndrome (ICANS). Secondary: Compare 1. Compare the clinical efficacy and safety profile of BRT to radiation-free bridging regimen. 2. Dose-response evaluation (given the heterogeneity of doses prescribed). 3. Evaluate clinical and sociodemographic factors associated with RT receipt as a bridging strategy.
SCIENTIFIC IMPACT: Briefly state how the completion of the aims will impact participant care/outcomes and how it will advance science or clinical care.	CAR T-cell therapy has yet to achieve its full therapeutic potential in Non-Hodgkin's lymphoma. While two thirds of patients are cured following first line chemoimmunotherapy, those not cured front-line have poor outcomes. CD19-directed CAR T-cell therapy achieves response rates exceeding 80% in relapsed or refractory DLBCL, with approximately one-third of patients attaining durable remissions. Nonetheless,treatment failure occurs in nearly two-thirds of patients. Hence, there is a great need for improving efficacy and remission durability for patients who receive CAR T-cells. Successful execution of the proposed aims will benefit clinical practice by informing practitioners of the benefit (or lack thereof) of RT as a bridging strategy for patients receiving CAR T for relapse/refractory aggressive NHL.

SCIENTIFIC JUSTIFICATION: Provide a background summary of previous related research and their strengths and weaknesses, justification of your research and why your research is still necessary.	Our combined teams have assembled a strong justification using both pre-clinical and clinical data, emphasizing the significance of executing this proposal. Herein, we provide rationale with preclinical and clinical evidence emphasizing the need to answer the current gap in knowledge regarding BRT efficacy. Preclinically, our team previously showed that radiation could significantly boost the efficacy of CD19 CAR-T cells, particularly when given in a close proximity to CAR T-cell infusion. In a syngeneic mouse model, we showed that low-dose radiation enhances the cytotoxicity of CD19 CAR-T cell by improving peripheral peak expansion,persistence, intra-humoral trafficking, T-cell subset phenotypic composition, and antigen-indecent mediated killing through Fas and TRAIL-R2 death receptor pathways (Alhomoud et al. bioRxiv 2025). Clinically, despite the lack of prospective evidence, many single institution reports have been published regarding the effectiveness of RT as a bridging strategy for patients with relapsed/refractory aggressive NHL. In the largest meta-analysis to date,including 538 NHL patients (one-third with bulky disease), our group demonstrated that BRT achieved promising efficacy, with PFS and OS rates of 55% and 71%, respectively, in a cohort enriched with adverse risk features (Alhomoud et al. Haematologica 2025).Contrary to our initial hypothesis that BRT might increase toxicity, grade 3/4 CRS rates were low (3.6%) with pooled ICANS incidence of 11%, comparable or lower than pivotal CAR T-cell trials. The recent 2025 publication by Yegya-Raman in Blood Advances further illustrates the value of such a a multicentered analysis, highlighting the signal detected in a multicenter retrospective study for how RT as a local therapy affects patterns of failure. Without bridging RT, local treatment failure was a predominant pattern of disease progression after CAR-T with nearly all patients having a component of local failure (86%) at the time of progression and approximately one-third (36%) exhibiting strictly local treatment failures. In the Blood Advances report, most treatment failures (71%) occurred outside of the Br-RT fields, and only 6% of treatment failures were isolated in-field. Different radiation doses were used in this 10 center study. The weaknesses of the current research are a result of the nature of those single institutions which limit the sample size for statistical analysis and also creates heterogeneity in patient selection, radiation therapy dose, and delivery.

Field	Response
	More recently, our group developed a novel radiomics-based approach to quantify disease burden pre- and post-BRT in a large real-world cohort of patients with large B-cell lymphoma (Hubbeling et al.Clin Cancer Res 2024). We showed that effective cytoreduction with BRT enabled high-disease-burden patients to achieve outcomes after CAR T-cell comparable to those with initially low burden,underscoring not only the cytoreductive benefit of BRT but also the immunomodulatory role of radiation in enhancing CAR T-cell efficacy. Based on these findings, there is growing interest in incorporating BRT and other low-dose radiation platforms as bridging or lymphodepletion strategies in CD19-directed CAR T-cell therapy, with the aim of enhancing efficacy without compromising safety. However, large-scale, registry-level data supporting the efficacy and safety of BRT in this context remain lacking. A retrospective CIBMTR study is justified in that a larger sample size reflective of clinical practice would be better suited to detect a difference in NHL outcomes for those receiving BRT versus those not, and the size of CIBMTR allows for the evaluation of secondary objectives including understanding what patients may benefit, what volumes should be targeted, and what doses may be beneficial.
PARTICIPANT SELECTION CRITERIA: State inclusion and exclusion criteria.	- Adult and pediatric patients who have undergone treatment with FDA-approved CD-19 CAR T therapy between 2017-2024 for NHL. - Patients who have received bridging therap, with or without radiation therapy.
Does this study include pediatric patients?	Yes
If this study does not include pediatric patients, please provide justification:	

DATA REQUIREMENTS: After reviewing data on CIBMTR forms, list patient-, disease- and infusion-variables to be considered in the multivariate analyses. Outline any supplementary data required.	Data collected by CIBMTR before and after CD19 CART,including essential forms such as Forms 2000, 2018, 2118, 4000, 4001, 4003, 4006, 4100, 4101. Patient-specific characteristics, including: -Date of birth (2400: 1) -Sex (2400: 2) -Ethnicity (4000R10: 1) -Race (4000R10: 2) -Country of residence (4000R10: 3) -Insurance (2000R6: 111) -Zip code (4000R10: 7) -All socioeconomic information (4001R1: 34-45) -Comorbid conditions (4000R10: 81-90) -Karnofsky performance status (4000R10: 77-80) Disease-specific factors, including: -Name of cellular therapy product (4000: 51) -HCT History (4000: 27-32) -Cellular Therapy History (4000: 18-26) -Non Hodgkin Lymphoma diagnosis and treatment including PET scan results, therapies received and particularly radiation (2018R6: 1-288) -Date of diagnosis (4000: 53-54) -Number of prior lines of therapy -Disease risk [second line age-adjusted International Prognostic Index (IPI)] -Disease stage at the time of apheresis and pre-infusion (if available) -Extranodal disease(Y/N), and sites (if available) -Disease status at CD19 CAR T infusion (CR/CRu, PR, etc) -Lactate dehydrogenase level prior to CAR T (if available) Bridging therapy-specific characteristics,including: -Radiation therapy details: timing, dose in Gy, number of fractions, mode (comprehensive vs. involved-field radiation therapy, and number of involved sites (if available). -Non-radiation bridging agents (I.e. chemotherapy, immunotherapy agents). -Radiographic response to bridging therapy (if available). Infusion-specific characteristics, including: -Lymphodepletion regimen used

Field	Response
	-CD19 CAR T product used -Year of CD19 CART -Interval from diagnosis to CD19 CAR T -Interval from most recent relapse to CD19 CAR T Outcome measures, including: -ORR -CR -PFS -OS -Cumulative incidence of CRS -Cumulative incidence of ICANS -Cumulative incidence of relapse -Cumulative incidence of NRM -Cause of death Follow-up data regarding survival, disease response, etc. obtained from: 4100R9 and 4101R1.
Types of cellular therapy data this proposal includes:	Chimeric Antigen Receptor (CAR) T-Cell Therapy (CAR-T)
PATIENT REPORTED OUTCOME (PRO) REQUIREMENTS: If the study requires PRO data collected by CIBMTR, the proposal should include: 1) A detailed description of the PRO domains, timepoints, and proposed analysis of PROs; 2) A description of the hypothesis speci	N/A
MACHINE LEARNING: Please indicate if the study requires methodology related to machine-learning and clinical predictions.	N/A
SAMPLE REQUIREMENTS: If the study requires biologic samples from the CIBMTR Repository, the proposal should also include: 1) A detailed description of the proposed testing methodology and sample requirements; 2) A summary of the investigator's previous e	N/A
NON-CIBMTR DATA SOURCE: If applicable, please provide: 1) A description of external data source to which the CIBMTR data will be linked; 2) The rationale for why the linkage is required.	N/A

REFERENCES:	1) Yegya-Raman N, Plastaras JP, Wright CM, Chelius M, Zhang S, Baron JA, Hubbeling H, Sim AJ, Robinson TJ, Jain MD, Imber B, Fregonese B, Yahalom J, Ladbury C, Dandapani S, Pinnix CC, Gunther JR, Fang PQ, Wu SY, Dabaja BS, Yang JC, Chew J, Braunstein S, Sinha S, Delinger NM, Sun S, Terezakis SA, Sakthivel G, Constine LS, Chowdhry AK, Reagan PM, Burke S, Tseng YD, LaRiviere MJ, Maity A, Schuster SJ, Chong EA, Figura NB. Bridging radiotherapy before chimeric antigen receptor T cells for B-cell lymphomas: an ILROG multicenter study. Blood Adv. 2025 Jul 8;9(13):3293-3303. doi: 10.1182/bloodadvances.2025015855. PMID: 40203192; PMCID: PMC12268022. 2) Manzar GS, Pinnix CC, Dudzinski SO, Marqueen KE, Cha EE, Nasr LF, Yoder AK, Rooney MK, Strati P, Ahmed S, Nze C, Nair R, Fayad LE, Wang M, Nastoupil LJ, Westin JR, Flowers CR, Neelapu SS, Gunther JR, Dabaja BS, Wu SY, Fang PQ. Outcomes with bridging radiation therapy prior to chimeric antigen receptor T-cell therapy in patients with aggressive large B-cell lymphomas. Front Immunol. 2025 Jan 31;16:1517348. doi: 10.3389/fimmu.2025.1517348. PMID: 39958356; PMCID: PMC11825444. 3) Ababneh HS, Ng AK, Wan J, Walburn T, Zhu L, Bobi M, Johnson PC, Bredtfeld J, Leeman J, Soumerai J, Abramson JS, Barnes J, Takvorian R, Frigault MJ, Pursley J, Patel CG. 5-5-5 ABRT (Dose of 5 Gy per Fraction for up to 5 Fractions Over 5 Weeks Adaptive Bridging Radiation Therapy)-Artificial Intelligence Enters the CAR (-T) (Chimeric Antigen Receptor-T) in Relapsed/Refractory Large B Cell Lymphoma. Int J Radiat Oncol Biol Phys. 2025 Jul 15;122(4):936-948. doi: 10.1016/j.ijrobp.2025.03.023. Epub 2025 Apr 3. PMID: 40178467. 4) Laverdure E, Mollica L, Ahmad I, Cohen S, Lachance S, Veilleux O, Bernard M, Marchand EL, Delisle JS, Bernard L, Boileau M, Petrella T, Pilon SJ, Bouchard P, Roy DC, Busque L, Fleury I. Enhancing CAR-T Efficacy in Large B-Cell Lymphoma with Radiation Bridging Therapy: A Real-World Single-Center Experience. Curr Oncol. 2025 Mar 17;32(3):173. doi: 10.3390/curroncol32030173. PMID: 40136377; PMCID: PMC11941054. 5) Saifi O, Breen WG, Lester SC, Rule WG, Stish B, Rosenthal A, Munoz J, Herchko SM, Murthy HS, Lin Y, Bansal R, Hathcock MA, Bennani NN, Paludo J, Wang Y, Khurana A, Bisneto JCV, Johnston PB, Ansell SM, Iqbal M, Tun H, Ayala E, Kharfan-Dabaja MA, Hoppe BS, Peterson JL. Does bridging radiation therapy affect the pattern of failure after CAR T-cell therapy in non-Hodgkin lymphoma?

Field	Response
	Radiother Oncol. 2022 Jan;166:171-179. doi: 10.1016/j.radonc.2021.11.031. Epub 2021 Dec 7. PMID: 34890736.
CONFLICTS OF INTEREST: Do you have any conflicts ofinterest pertinent to this proposal concerning?	No, I do not have any conflicts of interest pertinent to this proposal

Characteristics of patients who underwent CAR-T for Lymphoma with bridging therapy reported to the CIBMTR

Characteristic	No-Radiation as bridging	Yes-Radiation as bridging	Radiation and other therapy as bridging
No. of patients	3269	629	536
No. of centers	141	94	95
Patient Related			
Level Age at CT Treatment, median (range)	65.0 (18.3-91.2)	64.8 (18.2-87.6)	64.0 (19.0-90.8)
Age category at infusion, years, no. (%)			
18-59	1084 (33)	222 (35)	204 (38)
>59	2185 (67)	407 (65)	332 (62)
Sex, no. (%)			
Female	1146 (35)	230 (37)	193 (36)
Male	2123 (65)	399 (63)	343 (64)
Recipient race, no. (%)			
White	2619 (80)	494 (79)	417 (78)
Black or African American	192 (6)	16 (3)	19 (4)
Asian	170 (5)	34 (5)	44 (8)
Native Hawaiian or other Pacific Islander	8 (0)	0 (0)	0 (0)
American Indian or Alaska Native	7 (0)	0 (0)	3 (1)
Other	14 (0)	0 (0)	7 (1)
Missing	259 (8)	85 (14)	46 (9)
Recipient ethnicity, no. (%)			
Hispanic or Latino	332 (10)	54 (9)	58 (11)
Not Hispanic or Latino	2677 (82)	478 (76)	426 (79)
NA, not a US resident	154 (5)	72 (11)	34 (6)
Unknown	106 (3)	25 (4)	17 (3)
Not reported	0 (0)	0 (0)	1 (0)
Karnofsky performance score prior to CT, no. (%)			
90-100	1157 (35)	250 (40)	145 (27)
<90	1823 (56)	302 (48)	323 (60)
Not Reported	289 (9)	77 (12)	68 (13)
CT-CI, no. (%)			
0	858 (26)	193 (31)	134 (25)
1 - 2	1132 (35)	207 (33)	188 (35)

Characteristic	No-Radiation as bridging	Yes-Radiation as bridging	Radiation and other therapy as bridging
3+	1245 (38)	226 (36)	209 (39)
Not reported	34 (1)	3 (0)	5 (1)
Disease related			
Extranodal involvement at diagnosis, no. (%)			
No	813 (25)	168 (27)	122 (23)
Yes	2109 (65)	398 (63)	369 (69)
99	347 (11)	63 (10)	45 (8)
No. of lines of prior therapies (excluding CT), median (range)	3.0 (1.0-16.0)	3.0 (1.0-14.0)	4.0 (1.0-20.0)
Disease status prior to CT, no. (%)			
CR	257 (8)	39 (6)	23 (4)
PR	783 (24)	126 (20)	111 (21)
Resistant	1999 (61)	409 (65)	375 (70)
Untreated	48 (1)	6 (1)	9 (2)
Unknown	182 (6)	49 (8)	17 (3)
Not reported	0 (0)	0 (0)	1 (0)
CAR-T related			
Time from initial diagnosis to CT, months, median (range)	14.7 (0.4-405.8)	12.6 (1.5-356.0)	11.2 (1.1-322.2)
Time from initial diagnosis to CT, no. (%)			
< 12 months	1329 (41)	296 (47)	293 (55)
>= 12 months	1939 (59)	332 (53)	243 (45)
Not appropriate	1 (0)	1 (0)	0 (0)
Types of prior HCTs, no. (%)			
No	2589 (79)	524 (83)	467 (87)
Yes	670 (20)	105 (17)	69 (13)
Prior alloHCT	44 (1)	9 (1)	6 (1)
Prior autoHCT	607 (19)	90 (14)	61 (11)
Prior auto and alloHCT	12 (0)	3 (0)	2 (0)
Not reported	7 (0)	3 (0)	0 (0)
Unknown	1 (0)	0 (0)	0 (0)
Not reported	9 (0)	0 (0)	0 (0)
Bridging therapy, no. (%)			
Yes			
Multi agent chemotherapy therapy given as bridging therapy	1418 (43)	0 (0)	190 (35)

Characteristic	No-Radiation as bridging	Yes-Radiation as bridging	Radiation and other therapy as bridging
Single agent chemotherapy therapy given as bridging therapy	556 (17)	0 (0)	121 (23)
Monoclonal antibodies therapy given as bridging therapy	599 (18)	0 (0)	105 (20)
BTKi/IMID therapy given as bridging therapy	158 (5)	0 (0)	32 (6)
Intrathecal/Intraocular therapy given as bridging therapy	70 (2)	0 (0)	19 (4)
Radiation therapy given as bridging therapy (exclusively)	0 (0)	629 (100)	0 (0)
Other therapy given as bridging therapy	245 (7)	0 (0)	69 (13)
Not reported bridging therapy	223 (7)	0 (0)	0 (0)
Type of CAR-T, no. (%)			
Tisagenlecleucel	604 (18)	126 (20)	98 (18)
Axicabtagene ciloleucel	1701 (52)	357 (57)	289 (54)
Brexucabtagene autoleucel	403 (12)	42 (7)	63 (12)
Lisocabtagene maraleucel	541 (17)	103 (16)	81 (15)
Not reported	20 (1)	1 (0)	5 (1)
Year of CT, no. (%)			
2017	5 (0)	0 (0)	1 (0)
2018	159 (5)	26 (4)	28 (5)
2019	366 (11)	61 (10)	56 (10)
2020	447 (14)	81 (13)	65 (12)
2021	570 (17)	114 (18)	107 (20)
2022	806 (25)	196 (31)	135 (25)
2023	582 (18)	101 (16)	82 (15)
2024	334 (10)	50 (8)	62 (12)
Follow-up of survivors, median (range), months	25.2 (1.0-94.4)	25.2 (0.5-84.3)	26.2 (1.5-75.4)

Field	Response
Proposal Number	2509-115-DESROCHES
Proposal Title	Late Relapses After CD19 CAR-T Cell Therapy for Diffuse Large B-Cell Lymphoma: Cumulative Incidence, Predictors, and Post-Relapse Outcomes
Key Words	Late relapses, CD19 CAR-T, DLBCL, cumulative incidence, predictors, outcomes
Principal Investigator #1: - First and last name, degree(s)	Justin Desroches, M.D., C.M.
Principal Investigator #1: - Email address	desroches.justin@mayo.edu
Principal Investigator #1: - Institution name	Mayo Cinic Rochester
Principal Investigator #1: - Academic rank	Advanced hematology fellow, clinical cellular therapy
Junior investigator status (defined as 玆、5 years from fellowship)	Yes
Do you identify as an underrepresented/minority?	No
Principal Investigator #2 (If applicable): - First and last name, degree(s):	Arushi Khurana
Principal Investigator #2 (If applicable): - Email address:)	khurana.arushi@mayo.edu
Principal Investigator #2 (If applicable): - Institution name:	Mayo Clinic Rochester
Principal Investigator #2 (If applicable): - Academic rank:	Assistant Professor of Medicine
Junior investigator status (defined as 玆、5 years from fellowship)	No
Do you identify as an underrepresented/minority?	No
We encourage a maximum of two Principal Investigators per study. If more than one author is listed, please indicate who will be identified as the corresponding PI below:	Justin Desroches
Please list any ongoing CIBMTR projects that you are currently involved in and briefly describe your role.	None
Do any of the PI(s) within this proposal have a CIBMTR WC study in manuscript preparation >6 months?	No
PROPOSED WORKING COMMITTEE:	Lymphoma
Please indicate if you have already spoken with a scientific director or working committee chair regarding this study.	No
RESEARCH QUESTION:	Among patients with diffuse large B-cell lymphoma (DLBCL) who achieve event-free survival at 12 months after CD19-directed CAR-T cell therapy, what is the cumulative incidence, pattern, and outcome of late relapses?

Field	Response
RESEARCH HYPOTHESIS:	In patients with diffuse large B-cell lymphoma who achieve event-free survival at 12 months after CAR-T cell therapy, a subset will experience late relapses, which are associated with distinct clinical features and inferior survival compared with patients who remain in remission.
SPECIFIC OBJECTIVES/OUTCOMES TO BE INVESTIGATED (Include Primary, Secondary, etc.):	Primary Objective - To determine the cumulative incidence of late relapse after CD19 CAR-T therapy in patients with DLBCL who achieve event-free survival at 12 months (EFS12). To present cumulative incidence at 1, 2, and 5 years after the landmark (i.e., months since EFS12). Secondary Objectives - To identify clinical and biological predictors of late relapse. - To describe the phenotype of late relapse (histology, CD19 status, relapse sites). - To compare cumulative incidence of late relapse by CAR-T product, baseline histology, cell of origin and line of therapy. - To evaluate survival after late relapse. - To describe salvage strategies and outcomes after late relapse (if data available).
SCIENTIFIC IMPACT: Briefly state how the completion of the aims will impact participant care/outcomes and how it will advance science or clinical care.	Impact on participant Care and outcomes: This study will improve patient counseling and risk stratification by determining the cumulative incidence of late relapse in patients who achieve EFS12 post CAR-T and by identifying patients who remain at high risk of late relapse. It will inform tailored surveillance strategies, reducing follow-up burden for low-risk patients while enabling earlier detection in high-risk groups. Additionally, understanding outcomes of different salvage approaches will guide optimal treatment decisions for those who relapse. Advancement of Science and Clinical Care: By filling a critical knowledge gap on long-term outcomes after CAR-T, this study will establish benchmarks for late relapse incidence and survival, provide biological insights regarding late relapses, and inform the design and endpoints of future CAR-T trials. Findings may also shape clinical guidelines by defining appropriate duration and intensity of post-CAR-T monitoring and identifying subgroups who could benefit from extended surveillance or novel interventions.

Field	Response
SCIENTIFIC JUSTIFICATION: Provide a background summary of previous related research and their strengths and weaknesses, justification of your research and why your research is still necessary.	Background In diffuse large B-cell lymphoma (DLBCL), most relapses occur within the first 12 24 months after frontline immunochemotherapy. Patients who achieve event-free survival at 24 months (EFS24) after immunochemotherapy have an excellent prognosis, but a minority experience late relapse [1]. The landmark study by Wang et al. characterized late relapses after frontline chemoimmunotherapy using an EFS24 definition [2]. This helped establish benchmarks for long-term surveillance and survivorship planning after immunochemotherapy. However, their applicability is limited to patients treated with chemoimmunotherapy in the pre-CAR-T era. CD19-directed CAR-T cell therapy has transformed the treatment of relapsed/refractory DLBCL, with durable remissions in a subset of patients. Most published CAR-T trials have demonstrated that most relapses occur within the first year post-infusion, but data on the frequency, biology, and prognosis of late relapses (after durable remission) remain sparse [3]. There is lack of systematic capture of late relapse events, and insufficient detail on relapse biology and salvage strategies. Justification for the Proposed Research As more patients are living beyond one year post-CAR-T in both trial and real-world settings, understanding the incidence and outcomes of late relapse is clinically relevant. Event-free survival at 12 months (EFS12) has emerged as an important landmark in DLBCL post CAR-T, with several studies showing that patients who remain event-free at this point experience a marked flattening of the survival curve and durable remission in most cases [4-9]. Without systematic data on late relapse beyond EFS12, clinicians lack evidence-based guidance for long-term surveillance, counseling, and management. Moreover, identifying risk factors and relapse patterns will help refine patient selection, survivorship care, and strategies to prevent or treat late relapse. Why This Research is Still Necessary Despite advances, there is no published study characterizing late relapse in DLBCL patients after CAR-T therapy after achieving a predefined landmark (EFS12). By defining the incidence, risk factors, and outcomes of late relapse in this population, the proposed research will fill an important gap and inform clinical practice guidelines regarding post-CAR-T follow-up and survivorship care.

Field	Response
PARTICIPANT SELECTION CRITERIA: State inclusion and exclusion criteria.	Inclusion - Age 18 years. - Histologically confirmed DLBCL (including transformed indolent histologies). - Treated with CD19 CAR-T therapy (axi-cel, tisa-cel, liso-cel, or other) at participating sites. - Achieved event-free survival at 12 months (EFS12). Exclusion - Non-DLBCL histologies without evidence of transformation. - Disease progression before 12 months.
Does this study include pediatric patients?	No
If this study does not include pediatric patients, please provide justification:	Focus on adult patients treated with commercial CAR-T
DATA REQUIREMENTS: After reviewing data on CIBMTR forms, list patient-, disease- and infusion-variables to be considered in the multivariate analyses. Outline any supplementary data required.	Patient Demographics - Age at CAR-T infusion (years) - Sex (M/F/Other) - ECOG at infusion (0 4) Baseline Disease Features - Initial diagnosis date - Stage (I IV) - Extranodal involvement (Y/N; specify site) - CNS involvement at any time (Y/N) - LDH at infusion (normal/elevated) - Cell of origin (GCB/non-GCB/unknown) - Double-/triple-hit status (Y/N/unknown) - Concurrent indolent lymphoma (Y/N; type if yes) - Prior lines of therapy (numeric) - Prior autologous SCT (Y/N) - Prior allogeneic SCT (Y/N) CAR-T Treatment - CAR-T product (axi-cel, tisa-cel, liso-cel) - Line of CAR-T (2nd, 3rd, later) - Bridging therapy (Y/N; specify) - Infusion date Response & Toxicities - Best response (CR/PR/SD) - Date of best response - CRS grade (0 4) - ICANS grade (0 4) Follow-Up & Relapse - Relapse/progression (Y/N) - Date of relapse - Histology at relapse (DLBCL, indolent, other) - CD19 status at relapse (positive/negative/unknown) - Site(s) of relapse (nodal, extranodal, CNS, marrow, other) - Date of last follow-up - Vital status (alive/dead) - Date of death (if applicable) Post-Relapse Management (if data available) - Salvage therapy type(s) (bispecific, chemo, transplant, 2nd CAR-T, other) - Response to salvage (CR/PR/SD/PD) - Date of salvage response assessment
Types of cellular therapy data this proposal includes:	Chimeric Antigen Receptor (CAR) T-Cell Therapy (CAR-T)
PATIENT REPORTED OUTCOME (PRO) REQUIREMENTS: If the study requires PRO data collected by CIBMTR, the proposal should include: 1) A detailed description of the PRO domains, timepoints, and proposed analysis of PROs; 2) A description of the hypothesis speci	N/A

Field	Response
MACHINE LEARNING: Please indicate if the study requires methodology related to machine-learning and clinical predictions.	N/A
SAMPLE REQUIREMENTS: If the study requires biologic samples from the CIBMTR Repository, the proposal should also include: 1) A detailed description of the proposed testing methodology and sample requirements; 2) A summary of the investigator's previous e	N/A
NON-CIBMTR DATA SOURCE: If applicable, please provide: 1) A description of external data source to which the CIBMTR data will be linked; 2) The rationale for why the linkage is required.	N/A
REFERENCES:	1. Maurer, M.J., et al., Event-free survival at 24 months is a robust end point for disease-related outcome in diffuse large B-cell lymphoma treated with immunochemotherapy. J Clin Oncol, 2014. 32(10): p. 1066-73. 2. Wang, Y., et al., Late Relapses in Patients With Diffuse Large B-Cell Lymphoma Treated With Immunochemotherapy. J Clin Oncol, 2019. 37(21): p. 1819-1827. 3. Zinzi, A., et al., Late relapse after CAR-T cell therapy for adult patients with hematologic malignancies: A definite evidence from systematic review and meta-analysis on individual data. Pharmacol Res, 2023. 190: p. 106742. 4. Neelapu, S.S., et al., Axicabtagene Ciloleucel CAR T-Cell Therapy in Refractory Large B-Cell Lymphoma. N Engl J Med, 2017. 377(26): p. 2531-2544. 5. Locke, F.L., et al., Long-term safety and activity of axicabtagene ciloleucel in refractory large B-cell lymphoma (ZUMA-1): a single-arm, multicentre, phase 1-2 trial. Lancet Oncol, 2019. 20(1): p. 31-42. 6. Abramson, J.S., et al., Lisocabtagene maraleucel for patients with relapsed or refractory large B-cell lymphomas (TRANSCEND NHL 001): a multicentre seamless design study. Lancet, 2020. 396(10254): p. 839-852. 7. Schuster, S.J., et al., Tisagenlecleucel in Adult Relapsed or Refractory Diffuse Large B-Cell Lymphoma. N Engl J Med, 2019. 380(1): p. 45-56. 8. Nastoupil, L.J., et al., Standard-of-Care Axicabtagene Ciloleucel for Relapsed or Refractory Large B-Cell Lymphoma: Results From the US Lymphoma CAR T Consortium. J Clin Oncol, 2020. 38(27): p. 3119-3128. 9. Jacobson, C.A., et al., Real-World Evidence of Axicabtagene Ciloleucel for the Treatment of Large B Cell Lymphoma in the United States. Transplant Cell Ther, 2022. 28(9): p. 581.e1-581.e8.

Field	Response
CONFLICTS OF INTEREST: Do you have any conflicts of interest pertinent to this proposal concerning?	No, I do not have any conflicts of interest pertinent to this proposal

Characteristics of patients who underwent CAR-T for DLBCL reported to the CIBMTR

Characteristic	N (%)
No. of patients	3653
No. of centers	160
Patient Related	
Level Age at CT Treatment, median (range)	64.4 (18.2-91.2)
Age category at infusion, years, no. (%)	
18-59	1326 (36)
>59	2327 (64)
Sex, no. (%)	
Female	1462 (40)
Male	2190 (60)
Not reported	1 (0)
Recipient race, no. (%)	
White	2741 (75)
Black or African American	168 (5)
Asian	225 (6)
Native Hawaiian or other Pacific Islander	9 (0)
American Indian or Alaska Native	28 (1)
Other	19 (1)
Missing	463 (13)
Recipient ethnicity, no. (%)	
Hispanic or Latino	426 (12)
Not Hispanic or Latino	2753 (75)
NA, not a US resident	357 (10)
Unknown	116 (3)
Not reported	1 (0)
Karnofsky performance score prior to CT, no. (%)	
90-100	1659 (45)
<90	1593 (44)
Not Reported	401 (11)
CT-CI, no. (%)	
0	1158 (32)
1 - 2	1258 (34)
3+	1194 (33)
Not reported	43 (1)
Disease related	
Extranodal involvement at diagnosis, no. (%)	
No	792 (22)
Yes	1532 (42)

Characteristic	N (%)
Not reported	1329 (36)
No. of lines of prior therapies (excluding CT), median (range)	3.0 (1.0-18.0)
Disease status prior to CT, no. (%)	
CR	351 (10)
PR	906 (25)
Resistant	1943 (53)
Untreated	258 (7)
Unknown	194 (5)
Not reported	1 (0)
CAR-T related	
Time from initial diagnosis to CT, months, median (range)	14.8 (0.4-446.2)
Time from initial diagnosis to CT, no. (%)	
< 12 months	1446 (40)
>= 12 months	2205 (60)
Not appropriate	2 (0)
Types of prior HCTs, no. (%)	
No	2843 (78)
Yes	804 (22)
Prior alloHCT	36 (1)
Prior autoHCT	744 (20)
Prior auto and alloHCT	8 (0)
Not reported	16 (0)
Unknown	2 (0)
Not reported	4 (0)
Bridging therapy, no. (%)	
Yes	
Multi agent chemotherapy therapy given as bridging therapy	472 (13)
Single agent chemotherapy therapy given as bridging therapy	165 (5)
Monoclonal antibodies therapy given as bridging therapy	232 (6)
BTKi/IMID therapy given as bridging therapy	47 (1)
Intrathecal/Intraocular therapy given as bridging therapy	19 (1)
Radiation therapy given as bridging therapy	222 (6)
Other therapy given as bridging therapy	68 (2)
Not reported bridging therapy	34 (1)
No bridging therapy	1295 (35)
Not reported bridging therapy	1099 (30)
Type of CAR-T, no. (%)	
Tisagenlecleucel	493 (13)
Axicabtagene ciloleucel	2800 (77)
Brexucabtagene autoleucel	4 (0)

Characteristic	**N (%)**
Lisocabtagene maraleucel	336 (9)
Not reported	20 (1)
Year of CT, no. (%)	
2013	1 (0)
2016	1 (0)
2017	5 (0)
2018	197 (5)
2019	397 (11)
2020	397 (11)
2021	490 (13)
2022	800 (22)
2023	981 (27)
2024	384 (11)
Follow-up of survivors, median (range), months	24.9 (12.0-96.3)

Field	Response
Proposal Number	2509-225-THAZINMYINT
Proposal Title	Outcomes of Chimeric Antigen Receptor (CAR) T-Cell Therapy in Post-Transplant Lymphoproliferative Disorders
Key Words	Post-transplant lymphoproliferative disorder (PTLD), Chimeric Antigen Receptor (CAR) T-cell therapy
Principal Investigator #1: - First and last name, degree(s)	Phyo Thazin Myint, MD, MS
Principal Investigator #1: - Email address	phyothazinmyint@gmail.com
Principal Investigator #1: - Institution name	University of Missouri, Columbia
Principal Investigator #1: - Academic rank	Hematology and Oncology Fellow, PGY-6
Junior investigator status (defined as 㑊、5 years from fellowship)	Yes
Do you identify as an underrepresented/minority?	Yes
Principal Investigator #2 (If applicable): - First and last name, degree(s):	Gerhard Hildebrandt, MD, FACP
Principal Investigator #2 (If applicable): - Email address:)	gchhrb@health.missouri.edu
Principal Investigator #2 (If applicable): - Institution name:	University of Missouri, Columbia
Principal Investigator #2 (If applicable): - Academic rank:	Division Chief, Hematology & Medical Oncology Director, Bone Marrow Transplant and Cellular Therapy Program
Junior investigator status (defined as 㑊、5 years from fellowship)	No
Do you identify as an underrepresented/minority?	No
We encourage a maximum of two Principal Investigators per study. If more than one author is listed, please indicate who will be identified as the corresponding PI below:	Phyo Thazin Myint
Do any of the PI(s) within this proposal have a CIBMTR WC study in manuscript preparation >6 months?	No
PROPOSED WORKING COMMITTEE:	Lymphoma
Please indicate if you have already spoken with a scientific director or working committee chair regarding this study.	No

Field	Response
RESEARCH QUESTION:	To assess efficacy (Overall response rate, complete response rate, progression free survival and overall survival) and safety including toxicities (CAR T cell related: cytokine release syndrome (CRS), immune effector cell associated neurotoxicity syndrome(ICANS), hypogammaglobulinemia; prolonged cytopenia; patient transplant outcome related: acute and chronic graft versus host disease, engraftment failure and secondary graft loss or graft rejection) related to CD19 CAR T-cell therapy in patients with post-transplant lymphoproliferative disorders (PTLD).
RESEARCH HYPOTHESIS:	CD19-directed CAR T-cell therapy provides meaningful clinical efficacy in PTLD while maintaining an acceptable safety profile, without excessive toxicity or increased risk of graft rejection.
SPECIFIC OBJECTIVES/OUTCOMES TO BE INVESTIGATED (Include Primary, Secondary, etc.):	To evaluate the outcomes of CD19 CAR T in PTLD: Primary Objective - Overall response rate (ORR) Secondary Objectives Secondary Efficacy Objectives: - Complete response rate (CR) - Progression free survival (PFS) - Overall survival (OS) Secondary Safety Objectives: - Incidence and severity of adverse events such as cytopenias, cytokine release syndrome (CRS) and immune effector cell- associated neurotoxicity syndrome (ICANS). - Non-relapse mortality - Incidence of graft rejection - Incidence of secondary graft failure - Incidence and severity of acute and chronic GVHD - Incidence of hypogammaglobulinemia - Incidence of prolonged cytopenias
SCIENTIFIC IMPACT: Briefly state how the completion of the aims will impact participant care/outcomes and how it will advance science or clinical care.	While CAR T-cell therapy has become the standard of care for relapsed/refractory large B-cell lymphoma, its role in PTLD remains insufficiently defined due to limited available evidence. Our proposed study seeks to systematically evaluate the efficacy and toxicity of CAR T-cell therapy in PTLD. Data from this study will allow us for compare response rates, survival outcomes, and adverse events with both historical PTLD therapies and established CAR T data for B cell lymphoma outside of PTLD. Importantly, this analysis will provide critical information to guide transplant physicians in balancing disease control with graft preservation and other toxicities, and will serve as a foundation for future prospective studies of CAR T-cell therapy in PTLD.

SCIENTIFIC JUSTIFICATION: Provide a background summary of previous related research and their strengths and weaknesses, justification of your research and why your research is still necessary.	Post-transplant lymphoproliferative disorders (PTLD) are serious and potentially life-threatening complications following solid organ transplantation (SOT) and allogeneic hematopoietic stem cell transplantation (allo-HCT). The pathogenesis is strongly linked to chronic immunosuppression and Epstein Barr virus (EBV) infection, which together impair immune surveillance(1). The incidence of PTLD varies by type of organ transplant, with the highest rates observed in heart, lung, and multiorgan recipients (up to 20%), and the lowest in kidney transplant recipients (0.8 2.5%)(2 4). Clinical presentation is heterogeneous, ranging from benign lymphoid hyperplasia to aggressive, monomorphic or polymorphic lymphomas. Extranodal involvement is particularly frequent(2). Treatment approaches depend on disease biology and severity. For early, non-destructive forms (plasmacytic hyperplasia, florid follicular hyperplasia), reduction of immunosuppression may be sufficient. In contrast, destructive or monomorphic PTLD often requires systemic therapy, including rituximab, chemoimmunotherapy or, in selected patients, autologous stem cell transplantation(5). Despite therapeutic advances, outcomes remain limited: in an Australian series of liver transplant recipients, the 3-year overall survival was approximately 50%(6). Chimeric antigen receptor (CAR) T-cell therapy has transformed the treatment landscape for relapsed/refractory B-cell lymphomas, and early reports suggest potential efficacy in PTLD. However, published data remain sparse, consisting mainly of case reports and small case series (7,8). Unique challenges exist in this setting such as immunosuppressive drugs (particularly corticosteroids and calcineurin inhibitors) may impair CAR T efficacy(9), while cytokine release syndrome (CRS) and associated inflammation may increase the risk of graft dysfunction or rejection. In a recent meta-analysis of CAR T-cell therapy in PTLD (n=29), the pooled objective response rate was 70%, with a complete response rate of 46%. Toxicity was comparable to non-transplant populations, with grade 3 CRS in 5% and grade 3 immune effector cell-associated neurotoxicity syndrome (ICANS) in 40% of patients(10). However, the small sample size and retrospective nature of available data highlight the urgent need for larger, systematic analyses. By utilizing the Center for International Blood and Marrow Transplant Research (CIBMTR) cellular

Field	Response
	therapy database, which compiles comprehensive real-world outcomes across multiple centers, we aim to systematically evaluate the safety, efficacy, and outcomes of CAR T-cell therapy in patients with PTLD.
PARTICIPANT SELECTION CRITERIA: State inclusion and exclusion criteria.	● Inclusion Criteria - Patients with PTLD who underwent a CD19 CAR T cell therapy from 1/1/2017 to 7/31/2025 - Age more than or equal to 18 years at the time of CAR T cell therapy. ● Exclusion Criteria - Pregnant patients.
Does this study include pediatric patients?	No
If this study does not include pediatric patients, please provide justification:	Most likely very few pediatric patients would have been treated with CD19 CAR T for PTLD.

DATA REQUIREMENTS: After reviewing data on CIBMTR forms, list patient-, disease- and infusion-variables to be considered in the multivariate analyses. Outline any supplementary data required.	Data Forms to be Used - Pre-cellular Therapy Essential Data Pre-cellular Therapy Baseline Data Hodgkin and Non-Hodgkin Lymphoma Pre-infusion Data Hodgkin and Non-Hodgkin Lymphoma Post-infusion Data Cellular Therapy Infusion Post-cellular Therapy Follow-up Patient's Baseline Characteristics - Age at the time of cellular therapy - Gender: Male vs. Female - Ethnicity: Caucasian, Hispanic, African American, Asian Pacific Islander - ECOG score - Hematologic findings prior to lymphodepleting therapy: White blood cell (WBC) count, neutrophil count, platelet count, creatinine, lactate dehydrogenase (LDH). Data related to PTLD and prior treatment - Histological type of PTLD - Immunohistochemical stains, cytogenetics, Ki-67, if available - Stage of disease. - Systemic therapy given prior to CAR T: yes or no. - Type of systemic therapy, cycles, duration, timing of last systemic therapy prior to apheresis, timing of last systemic therapy prior to CAR T-cell therapy infusion - Radiation therapy given prior to apheresis or CAR T-cell infusion: yes or no. If yes, timing, site of radiation and dose. - Number of prior lines of treatments and best last response. - Chemosensitive /-refractory disease - Best response to systemic therapy right before cellular therapy, MRD status if available - Stage at time of cellular therapy - Bridging therapy between leukapheresis and CAR T treatment CAR T-Cell Related Data - Lymphodepletion Regimen for CAR T cells - Type of CAR T cell product - CAR T cell dose Data Related to Prior Transplantation - History of prior allogeneic hematopoietic cell transplantation (HCT) (CIBMTR data). If yes, * Time from transplant to CAR T cell therapy * Indication for transplant * HLA compatibility: Matched, Mismatched, Haploidentical * Donor-Patient Relationship: Sibling, Unrelated, Parental, Cord blood * Conditioning regimen: MAC or RIC, ATG given or T cell-depleted regimen * T cell-depleted or not * If available (for CIBMTR registry HCTs): active or history of acute GVHD, chronic GVHD, EBV reactivation * On active immunosuppression

Field	Response
	(medication) for GVHD prophylaxis or treatment yes or no - History of prior solid organ transplantation (non-CIBMTR data) If yes, * Transplanted organ type * Immunosuppression for graft rejection prophylaxis * EBV reactivation * On active immunosuppression (medication) or not * Dose and last date of immunosuppressant prior to cellular therapy (if available) * Dose and date of resuming immunosuppressant post-cellular therapy (if available) * Occurrence of transplant rejection Outcome Data - Progression free survival, overall survival, non-transplant-related mortality. - Best response (complete response, partial response or no response) - Cytokine release syndrome (CRS) yes or no - If yes to CRS, grade of CRS. - ICAN yes or no - If yes to ICAN, grade of ICANS. - Any grade 3 organ toxicity yes or no. If yes, specify organ. - Any grade 4 organ toxicity yes or no. If yes, specify organ. - Cytopenias/hematologic values at Day 30 and Day 100 - Prolonged cytopenia: counts below thresholds (neutropenia with absolute neutrophil count <500/µL and/or thrombocytopenia with platelets < 50 × 10 /L) still present at Day 100.
Types of cellular therapy data this proposal includes:	Chimeric Antigen Receptor (CAR) T-Cell Therapy (CAR-T)
PATIENT REPORTED OUTCOME (PRO) REQUIREMENTS: If the study requires PRO data collected by CIBMTR, the proposal should include: 1) A detailed description of the PRO domains, timepoints, and proposed analysis of PROs; 2) A description of the hypothesis speci	Not required.
MACHINE LEARNING: Please indicate if the study requires methodology related to machine-learning and clinical predictions.	Not required.
SAMPLE REQUIREMENTS: If the study requires biologic samples from the CIBMTR Repository, the proposal should also include: 1) A detailed description of the proposed testing methodology and sample requirements; 2) A summary of the investigator's previous e	Not required.

Field	Response
NON-CIBMTR DATA SOURCE: If applicable, please provide: 1) A description of external data source to which the CIBMTR data will be linked; 2) The rationale for why the linkage is required.	We would need a brief supplemental survey to be distributed to transplant and cellular therapy centers that reported cases of PTLD. The survey will collect information on the transplant history that preceded PTLD, including: - Type of solid organ transplant - EBV reactivation - On active immunosuppression (medication) or not - Immunosuppressive agent(s) used immediately prior to cellular therapy - Dose and last date of immunosuppressant prior to cellular therapy (if available) - Dose and date of resuming immunosuppressant post-cellular therapy (if available) - Occurrence of transplant rejection This supplemental data is essential to characterize the type of organ transplant, immunosuppressant modification, and incidence of transplant rejection in patients with PTLD treated with CAR T-cell therapy. These factors are not captured in CIBMTR data but are important to understand the interplay between immunosuppression, graft outcomes, and CAR T-cell efficacy in this population.

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Field	Response
	Hawkins MC, Johnson NA, Singh P, Mistry H, Johncy S, Adkins S, Kebriaei P, Shpall EJ, Green MR, Flowers CR, Westin J, Neelapu SS. Prognostic impact of corticosteroids on efficacy of chimeric antigen receptor T-cell therapy in large B-cell lymphoma. Blood. 2021 Jun 10;137(23):3272-3276. doi: 10.1182/blood.2020008865. PMID: 33534891; PMCID: PMC8351896. 10. Yamshon S, Gribbin C, Chen Z, Demetres M, Pasciolla M, Alhomoud M, Martin P, Shore T. Efficacy and Toxicity of CD19 Chimeric Antigen Receptor T Cell Therapy for Lymphoma in Solid Organ Transplant Recipients: A Systematic Review and Meta-Analysis. Transplant Cell Ther. 2024 Jan;30(1):73.e1-73.e12. doi: 10.1016/j.jtct.2023.05.018. Epub 2023 Jun 4. PMID: 37279856.
CONFLICTS OF INTEREST: Do you have any conflicts of interest pertinent to this proposal concerning?	No, I do not have any conflicts of interest pertinent to this proposal

Characteristics of patients who underwent CAR-T for PTLD reported to the CIBMTR

Characteristic	No (%)
No. of patients	36
No. of centers	24
Patient Related	
Level Age at CT Treatment - median (min-max)	42.5 (18.2-73.4)
Age category at infusion, years - no. (%)	
18-59	29 (80.6)
>59	7 (19.4)
Sex - no. (%)	
Female	14 (38.9)
Male	22 (61.1)
Recipient race - no. (%)	
White	22 (61.1)
Black or African American	1 (2.8)
Asian	3 (8.3)
Missing	10 (27.8)
Recipient ethnicity - no. (%)	
Hispanic or Latino	4 (11.1)
Non Hispanic or non-Latino	22 (61.1)
Non-resident of the U.S.	9 (25.0)
Unknown	1 (2.8)
Karnofsky performance score prior to CT - no. (%)	
90-100	12 (33.3)
<90	17 (47.2)
Not Reported	7 (19.4)
CT-CI - no. (%)	
0	4 (11.1)
1 - 2	7 (19.4)
3+	21 (58.3)
Not reported	4 (11.1)
Disease related	
Sub - Disease, no. (%)	
Polymorphic PTLD (1874)	4 (11)
Monomorphic PTLD (B- and T- / NK-cell types) (1875)	31 (86)
Classical Hodgkin lymphoma PTLD (1876)	1 (3)
The size of the largest nodal mass - no. (%)	
Size < 5 cm	10 (27.8)
Size >= 5 cm	4 (11.1)

Characteristic	No (%)
Not reported	22 (61.1)
Extranodal involvement at diagnosis - no. (%)	
No	5 (13.9)
Yes	20 (55.6)
Not reported	11 (30.6)
No. of lines of prior therapies (excluding CT) - median (min-max)	3.0 (1.0-9.0)
Disease status prior to CT - no. (%)	
CR	3 (8.3)
PR	9 (25.0)
Resistant	23 (63.9)
Unknown	1 (2.8)
CAR-T related	
Time from initial diagnosis to CT, months - median (min-max)	9.8 (0.4-226.3)
Time from initial diagnosis to CT - no. (%)	
< 12 months	21 (58.3)
>= 12 months	15 (41.7)
Types of prior HCTs - no. (%)	
No	24 (66.7)
Yes	12 (33.3)
Prior allo-HCT	6 (16.7)
Prior auto-HCT	5 (13.9)
Prior auto and allo-HCT	1 (2.8)
Bridging therapy - no. (%)	
Yes	
Multi agent chemotherapy therapy given as bridging therapy	2 (5.6)
Single agent chemotherapy therapy given as bridging therapy	3 (8.3)
Monoclonal antibodies therapy given as bridging therapy	1 (2.8)
Radiation therapy given as bridging therapy	4 (11.1)
Other therapy given as bridging therapy	3 (8.3)
No bridging therapy	10 (27.8)
Not reported bridging therapy	13 (36.1)
Type of CAR-T - no. (%)	
Tisagenlecleucel	4 (11.1)
Axicabtagene ciloleucel	20 (55.6)
Lisocabtagene maraleucel	6 (16.7)
Not reported	6 (16.7)
Year of CT - no. (%)	
2017	1 (2.8)
2018	2 (5.6)
2019	5 (13.9)

Characteristic	No (%)
2020	3 (8.3)
2021	5 (13.9)
2022	4 (11.1)
2023	6 (16.7)
2024	10 (27.8)
Follow-up of survivors, months - median (range)	23.4 (1.7-62.4)