Not for publication or presentation

A G E N D A
CIBMTR WORKING COMMITTEE FOR LYMPHOMA
San Antonio, TX
Wednesday, February 21, 2024, 1:00 – 3:00 PM CST

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1. **Introduction**

   a. Minutes and Overview Plan from February 2023 meeting (Attachment 1)

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

3. **Presentations, Published or Submitted papers**

   a. **LY22-01a** Outcomes of CD19 CAR-T in patients who achieve complete remission prior to lymphodepletion in patients with aggressive non-Hodgkins lymphoma (Mazyar Shadman / Mehdi Hamadani). ***Oral presentation at ASH 2023; Manuscript under review.***

   b. **LY22-01c** Outcomes of CD19 CAR-T in patients who achieve complete remission prior to lymphodepletion in patients with aggressive non-Hodgkins lymphoma (Trent Wang / Antonio martin Jimenez Jimenez). ***Oral presentation ASH 2023; Manuscript under review.***

   c. **LY22-02a** Efficacy and safety of CD19 directed CAR T-cell therapy for non-Hodgkin B-cell lymphomas with primary and secondary central nervous system involvement (Narendranath Epperla / Hamza Hashmi / Sairah Ahmed / Santiago Mercadal / Catherine Lee). ***Oral presentation at Tandem 2024; currently in manuscript preparation phase.***

   d. **LY22-02b** Efficacy and safety of CD19 directed CAR T-cell therapy for T-cell rich histiocyte rich B-cell lymphoma (Priyanka Pophali / Roni Shouval /Mazyar Shadman). ***Poster presentation, Tandem Meetings 2024; Manuscript circulated within writing committee.***

4. Studies in progress (Attachment 3)

a. **LY20-02** Outcomes of allogeneic transplants in patients with hodgkin lymphoma in the era of checkpoint inhibitors: A joint CIBMTR and EBMT analysis (Miguel-Angel Perales/Ana Maria Sureda). **Manuscript preparation.**

b. **LY22-01b** Outcomes of autologous HCT and CD19 CAR-T in MYC+ large B-cell lymphoma patients (Fateeha Furqan / Mehdi Hamadani). **Data File Preparation.**

c. **LY22-02c** Efficacy and safety of CD19 directed CAR T-cell therapy for transferred follicular lymphoma (Swetha Kambhampati / Kalyan Nadiminti / Alex Herrera). **Waiting hours assignment.**

d. **LY22-02d** Efficacy and safety of CD19 directed CAR T-cell therapy for Richter's transformation. Data File preparation (Mazyar Shadman / Mehdi Hamadani). **Waiting hours assignment.**

e. **LY22-02e** Efficacy and safety of CD19 directed CAR T-cell therapy for primary mediastinal B-cell lymphoma (Jordan Gauthier / Alex Herrera). **Waiting hours assignment.**

f. **LY22-02f** Efficacy and safety of CD19 directed CAR T-cell therapy for high grade B-cell lymphoma (Nasheed Hossain / Alex Herrera). **Waiting hours assignment.**

g. **LY23-01** Efficacy of hematopoietic stem cell transplantation in patients with plasmablastic lymphoma. **Protocol Development.**

5. Future/proposed studies

a. **PROP 2310-99** A Matching Adjusted Indirect Comparison (MAIC) Analysis Comparing the Clinical Outcomes of Patients with Follicular Lymphoma Treated with Anti CD19 Directed CAR-T Therapy vs. the Bispecific Antibody, Mosunetuzumab (CAR T) (M Shadman/ M Hamadani) (Attachment 4)

b. **PROP 2308-04** Autologous Stem Cell Transplant vs Chimeric Antigen Receptor T-Cell Therapy in Patients with Relapsed Secondary Central Nervous System Lymphoma (CAR T) (A Tun/ S Ansell) (Attachment 5)

c. **PROP 2310-142/2310-258/2310-23** Real-world outcomes of second line CD19 CAR T-cell therapy for large B-cell lymphoma (CAR T) (S Kambhampati/ A Herrera/ M S Odstrcil Bobillo/ CJ Lee/ C Lee/ S Dahiya/ M Shadman) (Attachment 6)

d. **PROP 2310-177** Hematopoietic Cell Transplantation for Rare Mature T-Cell Lymphomas. A Basket – Mentoring Study Proposal (M Hamadani/ A Herrera) (Attachment 7)

e. **PROP 2310-24/2310-209/2310-231** Outcomes of autologous stem cell transplantation in DLBCL relapsed/refractory to CD19 CAR T (S Kambhampati/ A Herrera/ E Bezerra/ S Jaglowski/ B Wirk) (Attachment 8)

f. **PROP 2310-130** Comparative Effectiveness of Glofitamab and Axicabtagene Ciloleucel in Large B Cell Lymphoma: A CIBMTR-Based Matching-Adjusted Indirect Comparison Analysis (CAR T) (M Di/ M Shadman) (Attachment 9)

Proposed studies; not accepted for consideration at this time

a. **PROP 2305-02** Autologous and Allogeneic Hematopoietic Cell Transplantation for ALK+ Diffuse Large B-Cell Lymphoma. *Dropped – low scientific impact.*

b. **PROP 2305-06** Chimeric Antigen Receptor T-Cell Therapy vs. Autologous Transplant in Relapsed DLBCL After Complete Remission. *Dropped – overlap with current study/publication.*

c. **PROP 2309-03** Clinical Outcome and Impact of Fludarabine Lymphodepletion Dose Prior to CD19 CAR T Cell Therapy in Aggressive Non-Hodgkin's Lymphoma Patients. *Dropped – low scientific impact.*
d. **PROP 2309-04** Impact of Donor age on Post-SCT Outcomes in Patients with Acute Myeloid Leukemia. *Dropped – low scientific impact.*
e. **PROP 2309-05** Outcomes of Haplo vs MUD vs Umbilical Cord vs Matched Related Allogeneic Stem Cell Transplant in Patients with Cutaneous T-Cell Lymphomas. *Dropped – low scientific impact.*
f. **PROP 2309-08** Role of Induction Chemotherapy Regimen in Relapse Free Survival Following Autologous Bone Marrow Transplant Among Mantle Cell Lymphoma Patients. *Dropped – low scientific impact.*
g. **PROP 2309-14** The Impact of Salvage Therapy on Outcomes After Autologous Stem Cell Transplant in Patients with Relapsed and Refractory Hodgkin Lymphoma. *Dropped – low scientific impact.*
h. **PROP 2309-16** Fludarabine Lymphodepletion Exposure as a Driver of Outcomes After Car-T. *Dropped – supplemental data needed.*
i. **PROP 2310-16** Incidence of Second Primary Malignancies and Related Survival Outcomes in Lymphoma Patients Undergoing CAR-T Therapy. *Dropped – supplemental data needed.*
j. **PROP 2310-20** Real-World Outcomes of CD19 CAR T for Relapsed/Refractory Follicular Lymphoma. *Dropped – low scientific impact.*
k. **PROP 2310-22** Real-World Outcomes of Novel Therapies Post CD19 CAR T Therapy in Relapsed Refractory Diffuse Large B-Cell Lymphoma. *Dropped – low scientific impact.*
l. **PROP 2310-51** Evaluating Outcomes of Hematopoietic Cell Transplantation in Hepatosplenic T Cell Lymphoma. *Dropped – low scientific impact.*
m. **PROP 2310-70** Efficacy and Safety of CD19-Directed CAR-T Cell Therapy in NHL Patients Who Did Not Meet Clinical Trial Criteria for Second-Line or Third-Line Setting, Including Those with Prior CD19 Therapy Exposure. *Dropped – low scientific impact.*
n. **PROP 2310-76** Real-Word Efficacy of Lisocabtagene Maraleucel (Liso-cel) Therapy in Patients with Relapsed or Refractory Large B Cell Lymphoma. *Dropped – low scientific impact.*
o. **PROP 2310-77** Optimal Monitoring Period for Lymphoma Patients Who Are Recipients of Commercial CD19 CAR-T Therapy. *Dropped – low scientific impact.*
p. **PROP 2310-85** Outcomes of HIV-Associated Large B-Cell Lymphoma Treated with Chimeric Antigen Receptor T-Cell Therapy. *Dropped – low scientific impact.*
q. **PROP 2310-100** Autologous Transplant vs Chimeric Antigen Receptor T-Cell Therapy for DLBCL Achieving a Partial Remission to Frontline Chemoimmunotherapy. *Dropped – low scientific impact.*
r. **PROP 2310-108** Real World Outcomes of Axi-cel and Tisa-Cel in Patients with Relapsed/Refractory Follicular Lymphoma. *Dropped – low scientific impact.*
s. **PROP 2310-112** Effect of Diabetes on the Outcomes of Diffuse Large B Cell Lymphoma Patients Treated with CAR T-Cells. *Dropped – low scientific impact.*
t. **PROP 2310-134** Determination of the Optimal Conditioning Regimen for Non-Hodgkin Lymphoma with Secondary CNS Involvement. *Dropped – low scientific impact.*
u. **PROP 2310-135** Comparative Outcomes Analysis of Patients with Aggressive B- Cell Lymphoma Treated with Axicabtagene Ciloleucel vs. Lisocabtagene Maraleucel. *Dropped – low scientific impact.*
v. **PROP 2310-137** Impact of Lymphodepleting Chemotherapy on Outcomes After CAR-T Cell Therapy for Relapsed Refractory Non-Hodgkin's Lymphoma. *Dropped – low scientific impact.*
w. **PROP 2310-139** Can the Outcome of a CAR T-Cell Treatment be Predicted Before the Treatment Starts? *Dropped – low scientific impact.*
x. **PROP 2310-145** Outcomes of CAR-T Therapy in Large B-Cell Lymphoma Patients with History of CNS Involvement. *Dropped – low scientific impact.*
y. **PROP 2310-151** A Comparison of Chemotherapy versus Non-chemotherapy-based Salvage regimens Leading to Autologous Hematopoietic Cell Transplant (autoHCT) for the Treatment of Relapsed/Refractory Hodgkin Lymphoma. *Dropped – supplemental data needed.*

z. **PROP 2310-153** A Comparison Between Chemotherapy-Based and Non-Chemotherapy-Based Salvage Regimens for Large B Cell Lymphomas (LBCL) Prior to Autologous Stem Cell Transplantation. *Dropped – supplemental data needed.*
aa. **PROP 2310-156** The Predictive Role of Cytopenia Recovery on Outcome Following CAR-T Cell Therapy in Lymphoma. *Dropped – overlap with current study/publication.*
bb. **PROP 2310-162** Outcomes of Hematopoietic Stem Cell Transplantation (HSCT) in Rare T Cell Lymphoma (TCL) Subtypes – Hepatosplenic TCL (HSTCL) and Enteropathy Associated TCL (EATL). *Dropped – low scientific impact.*
cc. **PROP 2310-165** Impact of Novel Agent-Based Salvage Therapies on Outcomes in Classical Hodgkin Lymphoma Patients Undergoing Autologous Hematopoietic Cell Transplantation. *Dropped – supplemental data needed.*
dd. **PROP 2310-167** Impact of prior cellular immunotherapy on outcomes post CD19 CAR-T cell therapy for relapsed refractory NHL. *Dropped – low scientific impact.*
ee. **PROP 2310-182** The Impact of Conditioning Regimens on Outcomes of Autologous Hematopoietic Stem Cell Transplantation (HSCT) in Peripheral T Cell Lymphomas (PTCL). *Dropped – low scientific impact.*
ff. **PROP 2310-191** Risk Factors and Outcomes of Patients with Lymphoid Malignancies Receiving out of Specification Autologous Cell Therapy Products. *Dropped – low scientific impact.*
gg. **PROP 2310-193** Comparative Efficacy of CD19 CAR-T Cell Therapy in Extra-Nodal versus Nodal-Only Large B-Cell Lymphoma. *Dropped – supplemental data needed.*
hh. **PROP 2310-197** Outcomes in Late Relapse Aggressive B-Cell Lymphoma. *Dropped – low scientific impact.*
ii. **PROP 2310-204** Efficacy of a Second CAR T-Cell Therapy in Patients with Relapse/Refractory B-Cell Malignancies. *Dropped – low scientific impact.*
jj. **PROP 2310-220** Chimeric Antigen Receptor T (CAR T) Cell Therapy in Non-Hodgkin's B Cell Lymphoma Patients with Pre-Existing Active Autoimmune Rheumatological Diseases – Safety and Efficacy Analysis. *Dropped – supplemental data needed.*
kk. **PROP 2310-223** CAR-T and Allogeneic Transplant in Relapsed Mantle Cell Lymphoma: A Contemporary Real-World Data in the Era of Novel Drugs. *Dropped – low scientific impact.*
ll. **PROP 2310-230** Comparing the Efficacy and the Safety of CD19 CAR T Cell Therapy in EBV-Positive versus EBV-Negative Diffuse Large B-Cell Lymphoma. *Dropped – low scientific impact.*
mm. **PROP 2310-234** Prognostic Impact of Corticosteroids Following CAR-T Cell Therapy in Large B-Cell Lymphoma: Assessing Infection Risk and Clinical Outcomes. *Dropped – low scientific impact.*
nn. **PROP 2310-238** Outcomes of Donor Lymphocyte Infusion in Patients with Hodgkin Lymphoma that Received Checkpoint Inhibitors. *Dropped – low scientific impact.*
oo. **PROP 2310-252** Comparative Outcomes of Large B Cell Lymphoma Patients Treated with Lisocabtagene Maraleucel (liso-cel) Compared to Axicabtagene Ciloleucel (axi-cel). *Dropped – low scientific impact.*
pp. **PROP 2310-253** Impact of Pre-Existing Autoimmune Disease on Outcomes After CAR-T Cell Therapy. *Dropped – supplemental data needed.*
qq. **PROP 2310-256** Outcomes of Bispecific Immune Effector Engager Antibodies BITEs Before and After CD19 CAR-T for Patients with Large B-Cell Lymphomas. *Dropped – low scientific impact.*
rr. **PROP 2310-259** Comparative Outcomes of Patients with Follicular Lympyhoma Treated with Lisocabtagene Maraleucel (liso-cel) Compared to Axicabtagene Ciloleucel (axi-cel). *Dropped – low scientific impact.*
ss. **PROP 2310-265** CAR-T cell therapy versus salvage/auto-transplant for patients with primary refractory Mantle Cell Lymphoma. *Dropped – low scientific impact.*
tt. **PROP 2310-267** Liso-Cabtagene Comparison to Axi-Cel and Tisa-Cel. *Dropped – low scientific impact.*

MINUTES AND OVERVIEW PLAN
CIBMTR WORKING COMMITTEE FOR LYMPHOMA
Orlando, Florida
Wednesday, February 15, 2023, 1:00-3:00 pm

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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1. Introduction

The CIBMTR Hodgkin and Non-Hodgkin Lymphoma Working Committee was called to order at 1 pm on Wednesday, February 15, 2023, by Dr. Mehdi Hamadani. Dr. Alex Herrera introduced the working committee leadership, and highlighted leadership's conflict of interest disclosures per CIBMTR policy. Dr. Herrera emphasized the process of becoming a Working Committee member. Then outlined the Working Committee goals, expectations, limitations, and the voting guidelines. The guidelines are based on a scale from 1 to 9; 1=high scientific impact, 9=low scientific impact. In addition, emphasized the rules of authorship: 1) substantial and timely contributions to conception and design, or acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; 3) final approval for the version to be published. Then encouraged junior faculty, fellows, and assistant professors to collaborate actively with the Lymphoma Writing Committee. Dr. Herrera also detailed the LYWC study life cycle and introduced PRO data collection effort of CIBMTR to audience followed by encouragement to propose studies that can encompass PRO data. Then Dr. Hamadani provided gratitude to outgoing chair - Dr. Kharfan Dabaja for his contributions to LYWC on behalf of CIBMTR. Dr. Hamadani provided an update on the Working Committee productivity including 2 publications, 2 presentations at EBMT 2022 meetings. Dr. Hamadani went over the three studies in progress and detailed the goals for these studies. Then indicated the availability of publicly available dataset for secondary analyses and explained the difference between the TED and CRF data collection forms.

2. Presentations, published or submitted papers

(a) **LY18-01e** Munshi PN, Chen Y, Ahn KW, Awan FT, Cashen A, Shouse G, Shadman M, Shaughnessy P, Zurko J, Locke FL, Goodman AM, Bisneto JCV, Sauter C, Kharfan-Dabaja MA, Meyers G, Jaglowski S, Herrera A, Hamadani M. Outcomes of autologous hematopoietic cell transplantation

in older patients with diffuse large B-cell lymphoma. ***Transplantation and Cellular Therapy. 2022 Aug 1; 28(8):487.e1-487.e7. doi:10.1016/j.jtct.2022.05.029. Epub 2022 May 21. PMCID:PMC9375438. Presentation: EBMT 2022***

(b) **LY19-01c** Furqan F, Ahn KW, Chen Y, Kaur M, Abutalib SA, Ahmed N, Ahmed S, Kharfan-Dabaja MA, Friedberg J, Gregory T, Hill L, Sterling C, Barta SK, Shadman M, Perales M-A, Zain J, Herrera AF, Sauter C, Hamadani M. Allogeneic haematopoietic cell transplant in patients with relapsed/refractory anaplastic large cell lymphoma. ***British Journal of Haematology. 2023 Jan 1; 200(1):54-63. doi:10.1111/bjh.18467. Epub 2022 Sep 19. PMCID:PMC9772096. Presentation: EBMT 2022***

3. Studies in progress

(a) **LY20-02** Outcomes of Allogeneic HCT in patients with Hodgkin Lymphoma in the era of Checkpoint Inhibitors: A joint CIBMTR and EBMT analysis. (Miguel-Angel Perales/Ana Maria Sureda) **Manuscript Preparation.**

(b) **LY22-01** Comparing CAR vs. Auto-HCT in Aggressive B-cell lymphomas: Addressing questions unanswered by randomized trials (Mazyar Shadman/Mehdi Hamadani/Trent Wang/ Antonio Martin Jimenez Jimenez/Zurko Joanna) **Data File Preparation.**

(c) **LY22-02** CAR-T Outcomes in Rare Lymphoma Subtypes: A Basket Protocol (Hamza Hashmi/Naren Epperla/Sairah Ahmad/Santiago Mercadal/Catherine Lee/Priyanka Pophali/Joshua Fein/Roni Shouval/Mazyar Shadman/Swetha Kambhampati/Kalyan Nadiminti/Alex Herrera/Mehdi Hamadani/Jordan Gauthier) **Protocol Development.**

4. Research Datasets Available for Secondary Analysis, Introduction to TED (Transplant Essential Data) vs CRF (Comprehensive Report Form)

Dr. Mehdi Hamadani emphasized the availability of published datasets freely available to the public for secondary analysis. Also, explained the difference between the TED and CRF databases. It was emphasized that CRF is a subset of the TED database, and that the CRF forms collect all disease specific information such as lines of therapy, extranodal involvement, and prior radiation. If a study needs any of this information, CRF level data is needed on the study.

Dr. Hamadani finished the introduction slides by inviting the members to attend the Collaborative Study Proposal Session.

5. Future/proposed studies

Dr. Kharfan-Dabaja presented the first three proposed concepts and emphasized that all presentations are in-person. Finally encourage the virtual attendants to submit their questions on the chat.

(a) **Xia Bi:** Outcomes of allogenic stem cell transplant for large B-cell lymphoma progression after CAR T-cell therapy (Xia Bi/Dipenkumar Modi/Baldeep Wirk/Usama Gergis)
Dr Bi presented the concept in-person. The proposed study wants to look the outcomes of allo-HCT for large B-cell lymphoma (LBCL) progressing after commercial CAR-T cell therapy with the hypothesis that allo-HCT can provide long-term disease control and remains a viable option in selected patients with LBCL progressing after anti-CD19 CAR-T cell therapy. A total of 58 cases met the selection criteria for the study but impact of database transitioning on small number of cases found in retrieval was emphasized for which information for actual data file preparation

and study analysis was also provided that data for all cases reported to CIBMTR meeting eligibility criteria for study will be used if proposal is accepted.
The proposal was opened for questions from the audience. A clarification was requested if study is only focusing on allo-HCTs performed post CAR-T therapy relapse only and not with intent of consolidation which was responded as allo-HCT performed after relapse will be focused only. Another question raised was if therapies given to patients between post CAR-T therapy relapse and prior to auto-HCT will be looked upon. Frequencies of TED and CRF track patients for sample size was brought into attention. Requested data for CRF track patients can be provided. In addition to this, data collection on all CAR-Ts was also discussed with pivotal point that not all CAR-Ts are captured by CIBMTR but if they are captured followed by collection of subsequent transplant information, requested information will be available based on TED or CRF track assigned to the recipient**.** A suggestion from audience was received to wait for some years to get a greater number of patients and to avoid overlapping of patient data because there could be a possibility of data for these patients being reported to multi-centers. Another question was raised regarding identification of denominator which is not addressed in Dr. Zurko's paper about how many patients progressing after CAR-T infusion are receiving transplant. Dr. Hamadani emphasized importance of finding denominator number along with difficulties associated in the possible ways of finding it by prioritizing CAR-T over HCT database or by prioritizing HCT over CAR-T database along with limitation that not all CAR-Ts are reported to CIBMTR.

(b) **Razan Mohty**: Outcomes following CD19 Directed Chimeric Antigen Receptor (CAR) T-cell Therapy for Relapsed Refractory Follicular Lymphoma (Razan Mohty/ Aleksandr Lazaryan/ Swetha Kambhampati/ Alex Herrera)
Dr. Razan presented the proposal on behalf of study group. The proposed study hypothesizes that real-world safety and efficacy outcomes of CD19 CAR-T cell therapy as standard of care for relapsed/refractory follicular lymphoma are similar to data from pivotal clinical trials; and predictors of toxicity and efficacy following anti-CD19 CAR-T cell therapy for follicular lymphoma might be different from other types of non-Hodgkin lymphoma. A total of 333 patients met the eligibility criteria for the study.
The proposal was opened for questions from the audience. A member of audience asked about grades of follicular lymphoma included in the study. It includes patients of all grades of follicular lymphoma except transformed follicular lymphoma cases. A suggestion was received to present numbers in categories of follicular lymphoma grade for better understanding. Another question was raised regarding shorter median follow-up times and was answered as by the time study will be analyzed, there will be longer follow-up time. A question regarding assignment of 6 months' time-period for toxicity-free, progression free survival (TPFS) was raised. Dr. Mohty brought up toxicities included for TPFS outcome which are only grade III CRS and grade III ICANS that usually develops within specified time-period. A suggestion was received to include B-cell cytopenia aplasia in this outcome. Another question raised was if there are enough TED or CRF patients to perform study which was answered as cellular therapy cases are all research level patients so there is no categorization of TED and CRF track for cellular therapy cases. Question from virtual audience was also addressed regarding very few patients for Tisa-cell product in study which got excluded due to a contract with manufacturing company but can be added into the study once permission is received. Another question was raised if outcomes in research performed at Moffitt center were evaluated at earlier time-points of 3 and 6 months. Dr. Mohty responded that outcomes were only evaluated for diffuse large B-cell lymphoma (DLBCL) at earlier time-points and were also found strongly associated.

(c) **Amrita Goyal:** Allogeneic hematopoietic stem cell transplantation for advanced mycosis fungoides and Sezary syndrome (Amrita Goyal/Firas Safa/Nakhle Saba/ Francine Foss)
Dr. Goyal presented the concept to the audience. This study hypothesizes that allogenic HSCT is an effective treatment and curative modality for advanced mycosis fungoides (MF) and Sezary syndrome (SS). Advances in donor selection, GVHD prophylaxis, and supportive care over the last decade have resulted in improved outcomes of allo-transplant for MF/SS. A total of 349 and 150 cases were found for MF and SS respectively in CIBMTR database which were eligible for the study.
Study was opened for questions. A suggestion was received to start study years from 2008 instead of 2001 since there has been a lot of change in clinical practice since then and there were only 5% cases from those years so exclusion of those cases will not even cause much loss of follow-up. A concern was raised regarding frequencies of conditioning regimen where a very few cases received Myeloablative conditioning regimen and could be for younger patients only; all of which implies concern on the type and timing of complete or partial remission achieved corresponding to conclusion longer the time to transplant, more likely the response is slow. Dr. Hamadani responded that lines of therapies on CRF track and time interval from diagnosis to transplant can address this issue. A suggestion was received that looking on TBI and non-TBI frequencies can also be helpful for this. Dr. Goyal also informed that study would exclude CDA-positive aggressive epidermotropic CTCL. A suggestion was received that keeping transformation of disease can be an important factor to consider during the final analysis if that information is collected. Another question was asked if CRF forms collect MOGA usage and if that data will be included to shed light on GVHD. Dr. Hamadani informed about a pharma-funded study related to MOGA use in process and mentioned that required information related to MOGA can also be obtained from that study once complete.

Dr. Sauter presented last 3 proposal concepts.

(d) **Swetha Kambhampati:** Outcomes of novel therapies post CD19 CAR-T in DLBCL (Swetha Kambhampati/ Alex Herrera)
Dr. Kambhampati presented the proposal. The study hypothesizes that novel standard of care therapies such as Lonca-T, Pola-BR, Tafa-len, and Selinexor will be safe and efficacious in the post CT19 CAR-T setting but with limited duration of benefit. A total of 520 patients were eligible for study. The proposal was opened for questions and discussions.
A question was raised regarding quality of data collection for this topic since this data has never been looked before. Dr. Herrera answered that from collection of lines of therapies and sequencing data, response to each line of therapies can be looked upon. Dr. Hamadani explained forms capture response to therapy but how well that response is capture is unknown because of less usage of that data in CIBMTR research studies. Timeline at which forms are collected by CIBMTR was described and information related to consideration of 90% completeness index for research study was also provided. Another question was raised regarding collection of data on CD19 target biopsy results which was answered as no. It was discussed as a relevant topic because in practice, all cases go through biopsy, but no data collection of this result is one of the limitations. Dr. Dabaja suggested to look on number of patients who relapsed post CAR-T, survived for 12-18 months and got allogeneic transplant. A

question was asked by virtual audience if all prior lines of therapies are captured by CIBMTR which was answered as yes.

(e) **Sairah Ahmed:** Outcomes of Hematopoietic stem cell transplantation in patients with plasmablastic lymphoma (Adeel Masood/Sairah Ahmed)
Dr. Ahmed presented the concept to the audience that role of stem cell transplantation (SCT) is unclear with conflicting data of which patients may benefit from SCT as consolidation in first complete remission or in the salvage setting. The study hypothesize that analysis of patient and disease-related factor may help predict the patients who have improved outcomes after SCT for plasmablastic lymphoma. A total of 133 patients were eligible for study. The proposal was opened for questions and discussions.
Clarification was made that all transplants will be selected including first and beyond at patient level. A concern was raised on short duration of time from diagnosis to auto transplant. Dr. Ahmed proposed the possibility of transplant in first complete remission. She mentioned as per recent studies early-stage disease which has been found having better overall response post-transplant than overall survival and progression-free-survival. She also proposed the possibility of quick relapse post-transplant after achieving complete remission. Dr. Hamadani brought up lines of therapies and disease status prior to transplant for lymphoma captured on TED track from 2018 onwards and mentioned that information is accessible though TED track database.

(f) **Sushanth Gouni:** Secondary malignancies after CD-19 CAR-T cell therapy in Large B cell Lymphoma (Sushanth Gouni/Sairah Ahmed)
Dr. Gouni presented the concept to the audience. The study hypothesizes that the analysis of patient and disease-related factors may help predict the later development of secondary malignant neoplasms\subsequent myeloid neoplasms after CAR-T cell therapy. A total of 4751 patients met the eligibility criteria for the proposal. The proposal was opened for questions and discussions.
A comment was made for consideration of causation and association of events to ascertain correct recognition of secondary malignancies on carried-over malignancies for centralizing the analysis. A question was raised regarding which lines of therapies will be considered for the study for which a suggestion was that lines of therapies can be added in risk models. Another question was asked about ways to find out if secondary malignancies are developing causatively or co-incidentally. Shorter follow-up among cases was also a concern and was discussed. Another question was if forms are contemporary enough to capture next generation sequencing (NGS) data. Dr. Hamadani reported that NGS data is not collected but biopsy results can be requested from centers. Such reports are usually submitted to CIBMTR and in case of missingness, centers can be contacted via emails. Another question was raised if specificity of neoplasms will be reported in the results which was answered as yes.

Ongoing study presentation:

Mazyar Shadman: LY22-01- Outcome of patients with large cell lymphoma receiving ASCT vs. CAR-T therapy while in CR (Mazyar Shadman/Mehdi Hamadani):
The study hypothesizes that in patients with large B-cell lymphoma who are in a complete remission, autologous hematopoietic cell transplant (auto-HCT) consolidation provides a better progression-free survival (PFS) and overall survival (OS) compared to chimeric antigen receptor

(CAR) T-cell therapy (CAR-T). Primary objectives of the study are to evaluate PFS and OS along with secondary objectives looking at hematopoietic recovery, non-relapse mortality, cumulative incidence of disease relapse or progression and causes of death. A total of 79 and 282 patients met criteria for CAR-T and ASCT cohorts in study respectively.
Question was raised regarding validation of final numbers (n=79) out of around 6000 people who underwent cellular therapy. Attention was brought to non-CR exclusions in the selection criteria and was related to real-world scenarios of CR and non-CR disease status prior to transplant. Another question was raised regarding possible biasing based on difference in CR for ASCT and CAR-T which even goes beyond for partial remission patients. Dr. Hamadani mentioned it as one of the limitations but also suggested a way to look at nodal mass at time of transplant for determination. Other suggestion was received to monitor lines of therapies, response to last line of therapy, timings of therapies, and scanning results along with nodal mass monitoring. Another suggestion was provided regarding safety of lumping Kymriah and Yescarta in one cohort against ASCT because both products have different efficacy in the real-world.

Proposed studies; not accepted for consideration at this time
Dr. Hamadani thanked all the investigators who submitted their concepts but were not accepted from presentation.

a. PROP 2205-03 Impact of peri-transplant radiation therapy in relapsed or refractory Hodgkin Lymphoma undergoing autologous stem cell transplantation
b. PROP 2210-18 Comparison of clinical outcomes of patients with large B-cell lymphomas who relapse or progress after anti-CD19 CART during 2nd line of therapy versus 3rd line of therapy
c. PROP 2210-56 Real-world outcomes of second line CD19 CAR T for primary refractory/early relapse diffuse large B-cell lymphoma
d. PROP 2210-59 Outcomes of autologous stem cell transplantation after CD19 CAR T in patients with relapsed refractory DLBCL
e. PROP 2210-65 The impact of TP53 genomic alterations in large B-cell lymphoma treated with CD19-CAR-T
f. PROP 2210-78 Outcomes and Utilization Trends of Autologous Hematopoietic Cell Transplantation for Classical Hodgkin Lymphoma
g. PROP 2210-82 The Impact of Bridging Therapy on the Safety and Efficacy of CAR T-cells for Large B-cell Lymphoma
h. PROP 2210-86 Outcomes of Hematopoietic Cell Transplant Strategies in Patients with CLL and Hodgkin Lymphoma variant Richter's Syndrome
i. PROP 2210-88 Optimal Transplant Strategy for Patients with Non-Hodgkin Lymphoma Who Relapse After 2nd-line CAR T cell therapy
j. PROP 2210-94 EFS6, EFS12 and EFS24 as predictors of long-term outcomes in patients with diffuse large B-cell lymphoma treated with chimeric antigen T cell receptor therapy
k. PROP 2210-100 Outcomes of CAR T therapy in LBCL patients with CNS involvement
l. PROP 2210-109 Outcomes of Hematopoietic Stem Cell Transplantation (HSCT) in Rare T Cell Lymphoma (TCL) Subtypes – Hepatosplenic TCL (HSTCL) and Enteropathy Associated TCL (EATL)
m. PROP 2210-111 Outcomes of Mantle Cell Lymphoma Patients Undergoing Autologous Stem Cell Transplant Based on Initial Induction Regimen
n. PROP 2210-115 Stratified comparison of CD19-directed CAR-T cell products in lymphoma patients who receive and do not receive bridging therapy
o. PROP 2210-140 Allogeneic Transplant for PTCL in Partial Remission or Less

p. PROP 2210-145 Outcomes of Salvage AHCT in Double Hit DLBCL
q. PROP 2210-153 Outcomes of Mantle Cell Lymphoma (MCL) Beyond First Relapse with Chimeric Antigen Receptor (CAR) T-Cell Therapy compared to Autologous and Allogenic Stem Cell Transplant
r. PROP 2210-168 Outcomes of patients with aggressive B-cell lymphomas after CD19 CAR T-cells that required bridging therapy prior to infusion
s. PROP 2210-171 CAR-T outcomes after prior CD19-directed therapy in large B-cell lymphoma
t. PROP 2210-174 A Comparison of HLA-matched Allogeneic versus CART for Diffuse Large B Cell Lymphoma
u. PROP 2210-177 Comparative outcomes of patients with B cell lymphomas treated with Lisocabtagene maraleucel (liso-cel) compared to Axicabtagene ciloleucel (axi-cel) and Tisagenlecleucel (tisa-cel)
v. PROP 2210-192 Autologous transplant following second line CAR T- cell therapy failure for Large B-cell lymphoma
w. PROP 2210-197 Comparative safety and efficacy of CD19-CAR T cell therapy for patients with transformed follicular lymphomas
x. PROP 2210-200 Compare outcomes of high-risk Mantle cell with Cellular therapy vs autologous vs allogeneic stem cell transplant.
y. PROP 2210-229 Outcomes of Relapsed-refractory Post-Transplant Lymphoproliferative Disorder after Cellular Therapies
z. PROP 2210-242 Outcomes of Mantle Cell Lymphoma (MCL) Beyond First Relapse with Chimeric Antigen Receptor (CAR) T-Cell Therapy compared to Autologous and Allogenic Stem Cell Transplant
aa. PROP 2210-260 Comparison of Autologous Stem Cell Transplant and CAR T-Cell Therapy for Relapsed Follicular Lymphoma
bb. PROP 2210-266 Allogeneic hematopoietic cell transplantation versus chimeric antigen receptor T-cell therapy for relapsed refractory mantle cell lymphoma.
cc. PROP 2210-278 Impact of immune checkpoint inhibitors on outcomes of autologous HCT for classical Hodgkin lymphoma
dd. PROP 2210-291 Impact of CAR-T and allogeneic transplant in Relapsed Mantle Cell Lymphoma: A Contemporary CIBMTR analysis

7. Other Business

After the proposals were presented, the voting process was reiterated, and the working committee leadership invite the attendees to rate each new proposal using the Tandem App. Without additional comments, the meeting was adjourned at 3:52 pm.

Working Committee Overview Plan 2023-2024		
Study number and title	**Status**	**Chairs priority**
LY20-02: Outcomes of allogeneic transplants in patients with hodgkin lymphoma in the era of checkpoint inhibitors: A joint CIBMTR and EBMT analysis.	Manuscript preparation	1
LY22-01: Outcomes of CD19 CAR-T in patients who achieve complete remission prior to lymphodepletion in patients with aggressive non-Hodgkins lymphoma.	Data file preparation	2
LY22-02: Efficacy and safety of CD19 directed CAR T-cell therapy for non-Hodgkin B-cell lymphomas with primary and secondary central nervous system involvement.	Protocol development	3
LY23-01: Efficacy of hematopoietic stem cell transplantation in patients with plasmablastic lymphoma.	Protocol development	4

Accrual Summary for Hodgkin and Non-Hodgkin Lymphoma Working Committee: 2000-2023						
	HLA-Identical Sibling		Alternative Donor		Autologous	
	TED only	Research	TED only	TED only	Research	TED only
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
Anaplastic large cell	335	61	498	183	2117	208
PIF	63 (18.8)	10 (16.4)	81 (16.3)	34 (18.6)	286 (13.5)	21 (10.1)
CR1	50 (14.9)	11 (18.0)	70 (14.1)	29 (15.8)	935 (44.2)	88 (42.3)
Rel 1	32 (9.6)	10 (16.4)	34 (6.8)	14 (7.7)	182 (8.6)	23 (11.1)
CR2	100 (29.9)	17 (27.9)	164 (32.9)	51 (27.9)	492 (23.2)	51 (24.5)
Other/Unknown	90 (26.9)	13 (21.3)	149 (29.9)	55 (30.1)	222 (10.5)	25 (12.0)
Burkitt/small non-cleaved	199	60	142	112	718	155
PIF	35 (17.6)	8 (13.3)	17 (12.0)	21 (18.8)	116 (16.2)	32 (20.6)
CR1	45 (22.6)	15 (25.0)	30 (21.1)	17 (15.2)	254 (35.4)	61 (39.4)
Rel 1	28 (14.1)	7 (11.7)	16 (11.3)	16 (14.3)	58 (8.1)	14 (9.0)
CR2	48 (24.1)	21 (35.0)	52 (36.6)	38 (33.9)	179 (24.9)	37 (23.9)
Other/Unknown	43 (21.6)	9 (15.0)	27 (19.0)	20 (17.9)	111 (15.5)	11 (7.1)
Diffuse large cell/immunoblastic	1786	318	1863	851	21924	2600
PIF	405 (22.7)	82 (25.8)	435 (23.3)	247 (29.0)	3815 (17.4)	450 (17.3)
CR1	185 (10.4)	51 (16.0)	242 (13.0)	85 (10.0)	3931 (17.9)	482 (18.5)
Rel 1	278 (15.6)	44 (13.8)	195 (10.5)	86 (10.1)	3756 (17.1)	473 (18.2)
CR2	248 (13.9)	32 (10.1)	320 (17.2)	123 (14.5)	6379 (29.1)	761 (29.3)
Other/Unknown	670 (37.5)	109 (34.3)	671 (36.0)	310 (36.4)	4043 (18.4)	434 (16.7)
Follicular	1467	517	1300	738	5278	921
PIF	251 (17.1)	93 (18.0)	226 (17.4)	152 (20.6)	780 (14.8)	106 (11.5)
CR1	108 (7.4)	38 (7.4)	92 (7.1)	42 (5.7)	614 (11.6)	113 (12.3)
Rel 1	198 (13.5)	106 (20.5)	153 (11.8)	107 (14.5)	932 (17.7)	170 (18.5)
CR2	191 (13.0)	72 (13.9)	179 (13.8)	82 (11.1)	1368 (25.9)	216 (23.5)
Other/Unknown	719 (49.0)	208 (40.2)	650 (50.0)	355 (48.1)	1584 (30.0)	316 (34.3)
Lymphoblastic	172	49	125	106	266	35
PIF	18 (10.5)	7 (14.3)	8 (6.4)	12 (11.3)	14 (5.3)	1 (2.9)
CR1	50 (29.1)	11 (22.4)	21 (16.8)	18 (17.0)	118 (44.4)	19 (54.3)
Rel 1	28 (16.3)	8 (16.3)	10 (8.0)	16 (15.1)	23 (8.6)	1 (2.9)
CR2	32 (18.6)	12 (24.5)	35 (28.0)	34 (32.1)	32 (12.0)	6 (17.1)

Accrual Summary for Hodgkin and Non-Hodgkin Lymphoma Working Committee: 2000-2023						
Other/Unknown	44 (25.6)	11 (22.4)	51 (40.8)	26 (24.5)	79 (29.7)	8 (22.9)
Mantle	935	204	1128	490	9573	987
PIF	170 (18.2)	44 (21.6)	154 (13.7)	88 (18.0)	1359 (14.2)	132 (13.4)
CR1	190 (20.3)	40 (19.6)	208 (18.4)	89 (18.2)	6718 (70.2)	678 (68.7)
Rel 1	141 (15.1)	34 (16.7)	156 (13.8)	81 (16.5)	258 (2.7)	33 (3.3)
CR2	178 (19.0)	29 (14.2)	329 (29.2)	97 (19.8)	477 (5.0)	61 (6.2)
Other/Unknown	256 (27.4)	57 (27.9)	281 (24.9)	135 (27.6)	761 (7.9)	83 (8.4)
Marginal	95	26	108	40	408	42
PIF	15 (15.8)	8 (30.8)	33 (30.6)	10 (25.0)	73 (17.9)	13 (31.0)
CR1	8 (8.4)	3 (11.5)	18 (16.7)	5 (12.5)	73 (17.9)	4 (9.5)
Rel 1	11 (11.6)	1 (3.8)	13 (12.0)	6 (15.0)	54 (13.2)	2 (4.8)
CR2	14 (14.7)	3 (11.5)	10 (9.3)	4 (10.0)	85 (20.8)	10 (23.8)
Other/Unknown	47 (49.5)	11 (42.3)	34 (31.5)	15 (37.5)	123 (30.1)	13 (31.0)
NK T cell	282	52	400	124	840	85
PIF	67 (23.8)	11 (21.2)	93 (23.3)	28 (22.6)	149 (17.7)	16 (18.8)
CR1	75 (26.6)	14 (26.9)	128 (32.0)	48 (38.7)	383 (45.6)	38 (44.7)
Rel 1	24 (8.5)	6 (11.5)	20 (5.0)	9 (7.3)	62 (7.4)	5 (5.9)
CR2	55 (19.5)	5 (9.6)	83 (20.8)	28 (22.6)	128 (15.2)	14 (16.5)
Other/Unknown	61 (21.6)	16 (30.8)	76 (19.0)	11 (8.9)	118 (14.0)	12 (14.1)
T cell	1019	254	1583	620	4162	450
PIF	333 (32.7)	95 (37.4)	502 (31.7)	266 (42.9)	686 (16.5)	67 (14.9)
CR1	205 (20.1)	55 (21.7)	354 (22.4)	117 (18.9)	2419 (58.1)	238 (52.9)
Rel 1	111 (10.9)	26 (10.2)	173 (10.9)	64 (10.3)	286 (6.9)	45 (10.0)
CR2	156 (15.3)	32 (12.6)	296 (18.7)	74 (11.9)	424 (10.2)	52 (11.6)
Other/Unknown	214 (21.0)	46 (18.1)	258 (16.3)	99 (16.0)	347 (8.3)	48 (10.7)
NHL not specified	180	24	102	120	857	44
PIF	15 (8.3)	4 (16.7)	7 (6.9)	31 (25.8)	92 (10.7)	8 (18.2)
CR1	13 (7.2)	0 (0.0)	5 (4.9)	13 (10.8)	107 (12.5)	11 (25.0)
Rel 1	28 (15.6)	2 (8.3)	7 (6.9)	18 (15.0)	63 (7.4)	5 (11.4)
CR2	15 (8.3)	2 (8.3)	18 (17.6)	19 (15.8)	111 (13.0)	5 (11.4)
Other/Unknown	109 (60.6)	16 (66.7)	65 (63.7)	39 (32.5)	484 (56.5)	15 (34.1)
Other	766	195	1224	408	10064	1027
PIF	193 (25.2)	61 (31.3)	331 (27.0)	110 (27.0)	1867 (18.6)	199 (19.4)
CR1	150 (19.6)	33 (16.9)	294 (24.0)	108 (26.5)	3308 (32.9)	369 (35.9)

Accrual Summary for Hodgkin and Non-Hodgkin Lymphoma Working Committee: 2000-2023						
Rel 1	75 (9.8)	18 (9.2)	107 (8.7)	35 (8.6)	1185 (11.8)	97 (9.4)
CR2	109 (14.2)	14 (7.2)	223 (18.2)	55 (13.5)	2824 (28.1)	240 (23.4)
Other/Unknown	239 (31.2)	69 (35.4)	269 (22.0)	100 (24.5)	880 (8.7)	122 (11.9)
Hodgkin	1360	345	1635	1207	20636	2487
PIF	260 (19.1)	59 (17.1)	290 (17.7)	181 (15.0)	3807 (18.4)	542 (21.8)
CR1	74 (5.4)	25 (7.2)	123 (7.5)	101 (8.4)	2692 (13.0)	339 (13.6)
Rel 1	160 (11.8)	57 (16.5)	180 (11.0)	137 (11.4)	3689 (17.9)	461 (18.5)
CR2	148 (10.9)	53 (15.4)	224 (13.7)	171 (14.2)	6704 (32.5)	745 (30.0)
Other/Unknown	718 (52.8)	151 (43.8)	818 (50.0)	617 (51.1)	3744 (18.1)	400 (16.1)
Graft type	8596	2105	10108	4999	76843	9041
BM	871 (10.1)	190 (9.0)	1671 (16.5)	1035 (20.7)	719 (0.9)	72 (0.8)
PB	7663 (89.1)	1911 (90.8)	7861 (77.8)	3300 (66.0)	75372 (98.1)	8909 (98.5)
Other/Unknown	62 (0.7)	4 (0.2)	576 (5.7)	664 (13.3)	752 (1.0)	60 (0.7)

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

	Samples Available for Recipient and Donor	Samples Available for Recipient Only	Samples Available for Donor Only
Variable	**N (%)**	**N (%)**	**N (%)**
Number of patients	5246	1770	1156
Source of data			
CRF	2624 (50)	692 (39)	477 (41)
TED	2622 (50)	1078 (61)	679 (59)
Number of centers	206	157	208
Disease at transplant			
Non-Hodgkin lymphoma	4284 (82)	1493 (84)	940 (81)
Hodgkin lymphoma	962 (18)	277 (16)	216 (19)
NHL Disease status at transplant			
CR1	613 (14)	290 (20)	133 (14)
CR2	800 (19)	296 (20)	153 (16)
CR3+	371 (9)	131 (9)	86 (9)
PR	449 (11)	111 (7)	94 (10)

	Samples Available for Recipient and Donor	Samples Available for Recipient Only	Samples Available for Donor Only
Variable	**N (%)**	**N (%)**	**N (%)**
Advanced	1959 (46)	637 (43)	440 (47)
Missing	72 (2)	20 (1)	31 (3)
Recipient age at transplant			
0-9 years	60 (1)	12 (1)	17 (1)
10-17 years	154 (3)	38 (2)	32 (3)
18-29 years	711 (14)	201 (11)	151 (13)
30-39 years	739 (14)	235 (13)	161 (14)
40-49 years	988 (19)	303 (17)	234 (20)
50-59 years	1429 (27)	461 (26)	289 (25)
60-69 years	1062 (20)	448 (25)	252 (22)
70+ years	103 (2)	72 (4)	20 (2)
Median (Range)	50 (2-79)	52 (3-78)	50 (2-77)
Recipient race			
White	4727 (92)	1549 (90)	912 (90)
Black or African American	255 (5)	93 (5)	58 (6)
Asian	96 (2)	47 (3)	36 (4)
Native Hawaiian or other Pacific Islander	8 (<1)	2 (<1)	0
American Indian or Alaska Native	10 (<1)	10 (1)	2 (<1)
Other	1 (<1)	4 (<1)	1 (<1)
More than one race	26 (1)	13 (1)	3 (<1)
Unknown	123 (N/A)	52 (N/A)	144 (N/A)
Recipient ethnicity			
Hispanic or Latino	347 (7)	136 (8)	86 (9)
Non Hispanic or non-Latino	4305 (92)	1455 (91)	751 (74)
Non-resident of the U.S.	43 (1)	11 (1)	173 (17)
Unknown	551 (N/A)	168 (N/A)	146 (N/A)
Recipient sex			
Male	3292 (63)	1160 (66)	746 (65)
Female	1954 (37)	610 (34)	410 (35)
Karnofsky score			
10-80	1800 (34)	664 (38)	392 (34)
90-100	3184 (61)	1020 (58)	712 (62)
Missing	262 (5)	86 (5)	52 (4)
HLA-A B DRB1 groups - low resolution			
<=3/6	4 (<1)	9 (1)	0
4/6	12 (<1)	12 (1)	4 (<1)
5/6	621 (12)	174 (11)	132 (12)
6/6	4497 (88)	1407 (88)	973 (88)
Unknown	112 (N/A)	168 (N/A)	47 (N/A)
High-resolution HLA matches available out of 8			

	Samples Available for Recipient and Donor	Samples Available for Recipient Only	Samples Available for Donor Only
Variable	**N (%)**	**N (%)**	**N (%)**
<=5/8	46 (1)	14 (1)	2 (<1)
6/8	127 (3)	22 (2)	23 (3)
7/8	984 (20)	225 (16)	190 (21)
8/8	3874 (77)	1127 (81)	688 (76)
Unknown	215 (N/A)	382 (N/A)	253 (N/A)
HLA-DPB1 Match			
Double allele mismatch	975 (28)	181 (22)	101 (24)
Single allele mismatch	1922 (56)	430 (52)	234 (55)
Full allele matched	548 (16)	219 (26)	94 (22)
Unknown	1801 (N/A)	940 (N/A)	727 (N/A)
High resolution release score			
No	2636 (50)	1766 (>99)	1131 (98)
Yes	2610 (50)	4 (<1)	25 (2)
KIR typing available			
No	4464 (85)	1768 (>99)	1154 (>99)
Yes	782 (15)	2 (<1)	2 (<1)
Graft type			
Marrow	1060 (20)	285 (16)	236 (20)
PBSC	4184 (80)	1463 (83)	918 (79)
PBSC+UCB	2 (<1)	22 (1)	1 (<1)
Others	0	0	1 (<1)
Conditioning regimen			
Myeloablative	2044 (39)	558 (32)	373 (32)
RIC/Nonmyeloablative	3160 (60)	1199 (68)	769 (67)
TBD	42 (1)	13 (1)	14 (1)
Donor age at donation			
To Be Determined/NA	83 (2)	103 (6)	23 (2)
10-17 years	0	1 (<1)	0
18-29 years	2481 (47)	885 (50)	525 (45)
30-39 years	1491 (28)	453 (26)	332 (29)
40-49 years	934 (18)	253 (14)	208 (18)
50+ years	257 (5)	75 (4)	68 (6)
Median (Range)	30 (18-69)	29 (12-68)	31 (18-61)
Donor/Recipient CMV serostatus			
+/+	1204 (23)	430 (24)	261 (23)
+/-	633 (12)	254 (14)	170 (15)
-/+	1528 (29)	465 (26)	311 (27)
-/-	1740 (33)	528 (30)	373 (32)
CB - recipient +	2 (<1)	16 (1)	1 (<1)
CB - recipient -	0	6 (<1)	0

	Samples Available for Recipient and Donor	Samples Available for Recipient Only	Samples Available for Donor Only
Variable	**N (%)**	**N (%)**	**N (%)**
Missing	139 (3)	71 (4)	40 (3)
GvHD Prophylaxis			
No GvHD Prophylaxis	18 (<1)	4 (<1)	5 (<1)
TDEPLETION alone	2 (<1)	4 (<1)	2 (<1)
TDEPLETION +- other	52 (1)	8 (<1)	14 (1)
CD34 select alone	0	2 (<1)	1 (<1)
CD34 select +- other	54 (1)	21 (1)	5 (<1)
Cyclophosphamide alone	6 (<1)	3 (<1)	6 (1)
Cyclophosphamide +- others	309 (6)	282 (16)	109 (9)
FK506 + MMF +- others	847 (16)	231 (13)	164 (14)
FK506 + MTX +- others(not MMF)	2276 (43)	757 (43)	380 (33)
FK506 +- others(not MMF,MTX)	316 (6)	132 (7)	80 (7)
FK506 alone	169 (3)	53 (3)	25 (2)
CSA + MMF +- others(not FK506)	549 (10)	117 (7)	119 (10)
CSA + MTX +- others(not MMF,FK506)	413 (8)	96 (5)	156 (13)
CSA +- others(not FK506,MMF,MTX)	77 (1)	19 (1)	25 (2)
CSA alone	49 (1)	7 (<1)	34 (3)
Other GVHD Prophylaxis	80 (2)	25 (1)	16 (1)
Missing	29 (1)	9 (<1)	15 (1)
Donor/Recipient sex match			
Male-Male	2368 (45)	783 (44)	500 (43)
Male-Female	1217 (23)	362 (20)	228 (20)
Female-Male	907 (17)	342 (19)	238 (21)
Female-Female	726 (14)	227 (13)	177 (15)
CB - recipient M	0	13 (1)	0
CB - recipient F	2 (<1)	9 (1)	1 (<1)
Missing	26 (<1)	34 (2)	12 (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 (4)	54 (5)
2001-2005	818 (16)	157 (9)	202 (17)
2006-2010	1433 (27)	257 (15)	229 (20)
2011-2015	1633 (31)	433 (24)	299 (26)
2016-2020	790 (15)	499 (28)	241 (21)
2021-2023	268 (5)	349 (20)	115 (10)
Follow-up among survivors, Months			
N Eval	2126	950	526
Median (Range)	72 (0-315)	25 (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

	Samples Available for Recipient and Donor	Samples Available for Recipient Only	Samples Available for Donor Only
Variable	**N (%)**	**N (%)**	**N (%)**
Number of patients	513	134	170
Source of data			
CRF	388 (76)	88 (66)	94 (55)
TED	125 (24)	46 (34)	76 (45)
Number of centers	92	42	66
Disease at transplant			
NHL	410 (80)	107 (80)	134 (79)
Hodgkins Lymphoma	103 (20)	27 (20)	36 (21)
NHL Disease status at transplant			
CR1	65 (16)	13 (12)	25 (19)
CR2	76 (19)	24 (22)	35 (26)
CR3+	45 (11)	11 (10)	12 (9)
PR	68 (17)	12 (11)	16 (12)
Advanced	153 (38)	45 (42)	42 (32)
Missing	0	2 (2)	3 (2)
Recipient age at transplant			
0-9 years	23 (4)	7 (5)	3 (2)
10-17 years	28 (5)	4 (3)	12 (7)
18-29 years	76 (15)	17 (13)	25 (15)
30-39 years	91 (18)	18 (13)	31 (18)
40-49 years	92 (18)	35 (26)	32 (19)
50-59 years	123 (24)	23 (17)	40 (24)
60-69 years	75 (15)	28 (21)	25 (15)
70+ years	5 (1)	2 (1)	2 (1)
Median (Range)	45 (1-73)	46 (5-78)	44 (7-73)
Recipient race			
White	352 (71)	92 (70)	103 (71)
Black or African American	100 (20)	29 (22)	29 (20)
Asian	36 (7)	8 (6)	10 (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	14 (N/A)	2 (N/A)	25 (N/A)
Recipient ethnicity			

	Samples Available for Recipient and Donor	Samples Available for Recipient Only	Samples Available for Donor Only
Variable	**N (%)**	**N (%)**	**N (%)**
Hispanic or Latino	76 (15)	13 (10)	25 (15)
Non Hispanic or non-Latino	426 (85)	111 (90)	118 (70)
Non-resident of the U.S.	0	0	25 (15)
Unknown	11 (N/A)	10 (N/A)	2 (N/A)
Recipient sex			
Male	302 (59)	82 (61)	95 (56)
Female	211 (41)	52 (39)	75 (44)
Karnofsky score			
10-80	148 (29)	40 (30)	38 (22)
90-100	342 (67)	87 (65)	125 (74)
Missing	23 (4)	7 (5)	7 (4)
HLA-A B DRB1 groups - low resolution			
<=3/6	23 (5)	8 (8)	4 (3)
4/6	234 (50)	50 (51)	75 (52)
5/6	179 (38)	34 (35)	59 (41)
6/6	32 (7)	6 (6)	7 (5)
Unknown	45 (N/A)	36 (N/A)	25 (N/A)
High-resolution HLA matches available out of 8			
<=5/8	284 (66)	57 (73)	81 (65)
6/8	91 (21)	12 (15)	30 (24)
7/8	42 (10)	8 (10)	9 (7)
8/8	14 (3)	1 (1)	4 (3)
Unknown	82 (N/A)	56 (N/A)	46 (N/A)
HLA-DPB1 Match			
Double allele mismatch	51 (34)	5 (25)	15 (50)
Single allele mismatch	84 (55)	14 (70)	14 (47)
Full allele matched	17 (11)	1 (5)	1 (3)
Unknown	361 (N/A)	114 (N/A)	140 (N/A)
High resolution release score			
No	430 (84)	131 (98)	169 (99)
Yes	83 (16)	3 (2)	1 (1)
KIR typing available			
No	436 (85)	134 (100)	169 (99)
Yes	77 (15)	0	1 (1)
Graft type			
UCB	466 (91)	112 (84)	162 (95)
PBSC+UCB	45 (9)	22 (16)	6 (4)
Others	2 (<1)	0	2 (1)
Number of cord units			
1	402 (78)	0	112 (66)

	Samples Available for Recipient and Donor	Samples Available for Recipient Only	Samples Available for Donor Only
Variable	**N (%)**	**N (%)**	**N (%)**
2	111 (22)	0	58 (34)
Unknown	0 (N/A)	134 (N/A)	0 (N/A)
Conditioning regimen			
Myeloablative	209 (41)	56 (42)	58 (34)
RIC/Nonmyeloablative	304 (59)	77 (57)	110 (65)
TBD	0	1 (1)	2 (1)
Donor/Recipient CMV serostatus			
CB - recipient +	323 (63)	81 (60)	101 (59)
CB - recipient -	184 (36)	47 (35)	64 (38)
CB - recipient CMV unknown	6 (1)	6 (4)	5 (3)
GvHD Prophylaxis			
No GvHD Prophylaxis	2 (<1)	0	1 (1)
TDEPLETION +- other	4 (1)	1 (1)	1 (1)
CD34 select +- other	32 (6)	14 (10)	2 (1)
Cyclophosphamide +- others	1 (<1)	1 (1)	1 (1)
FK506 + MMF +- others	186 (36)	37 (28)	50 (29)
FK506 + MTX +- others(not MMF)	14 (3)	5 (4)	2 (1)
FK506 +- others(not MMF,MTX)	32 (6)	7 (5)	8 (5)
FK506 alone	26 (5)	10 (7)	4 (2)
CSA + MMF +- others(not FK506)	179 (35)	54 (40)	83 (49)
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	1 (<1)	0	1 (1)
Other GVHD Prophylaxis	16 (3)	2 (1)	5 (3)
Missing	5 (1)	1 (1)	3 (2)
Donor/Recipient sex match			
CB - recipient M	302 (59)	82 (61)	95 (56)
CB - recipient F	211 (41)	52 (39)	75 (44)
Year of transplant			
1996-2000	1 (<1)	0	0
2001-2005	6 (1)	7 (5)	3 (2)
2006-2010	157 (31)	34 (25)	49 (29)
2011-2015	260 (51)	53 (40)	68 (40)
2016-2020	77 (15)	23 (17)	46 (27)
2021-2023	12 (2)	17 (13)	4 (2)
Follow-up among survivors, Months			
N Eval	231	59	64
Median (Range)	72 (0-166)	60 (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

	Samples Available for Recipient and Donor	Samples Available for Recipient Only	Samples Available for Donor Only
Variable	**N (%)**	**N (%)**	**N (%)**
Number of patients	1208	218	111
Source of data			
CRF	389 (32)	64 (29)	38 (34)
TED	819 (68)	154 (71)	73 (66)
Number of centers	71	38	23
Disease at transplant			
NHL	994 (82)	177 (81)	84 (76)
Hodgkins Lymphoma	214 (18)	41 (19)	27 (24)
NHL Disease status at transplant			
CR1	197 (20)	41 (23)	18 (21)
CR2	188 (19)	35 (20)	11 (13)
CR3+	104 (11)	21 (12)	6 (7)
PR	69 (7)	13 (7)	6 (7)
Advanced	427 (43)	66 (38)	43 (51)
Missing	5 (1)	0	0
Recipient age at transplant			
0-9 years	11 (1)	5 (2)	0
10-17 years	47 (4)	9 (4)	1 (1)
18-29 years	150 (12)	35 (16)	10 (9)
30-39 years	126 (10)	30 (14)	21 (19)
40-49 years	204 (17)	31 (14)	23 (21)
50-59 years	347 (29)	57 (26)	31 (28)
60-69 years	301 (25)	43 (20)	23 (21)
70+ years	22 (2)	8 (4)	2 (2)
Median (Range)	52 (3-76)	50 (2-75)	51 (12-75)
Recipient race			
White	935 (81)	146 (73)	86 (80)
Black or African American	151 (13)	35 (18)	18 (17)
Asian	54 (5)	17 (9)	2 (2)
Native Hawaiian or other Pacific Islander	5 (<1)	1 (1)	0
American Indian or Alaska Native	8 (1)	1 (1)	0
More than one race	7 (1)	0	1 (1)
Unknown	48 (N/A)	18 (N/A)	4 (N/A)
Recipient ethnicity			

	Samples Available for Recipient and Donor	Samples Available for Recipient Only	Samples Available for Donor Only
Variable	**N (%)**	**N (%)**	**N (%)**
Hispanic or Latino	209 (18)	42 (20)	18 (17)
Non Hispanic or non-Latino	978 (82)	171 (80)	89 (82)
Non-resident of the U.S.	5 (<1)	0	2 (2)
Unknown	16 (N/A)	5 (N/A)	2 (N/A)
Recipient sex			
Male	767 (63)	141 (65)	70 (63)
Female	441 (37)	77 (35)	41 (37)
Karnofsky score			
10-80	406 (34)	77 (35)	32 (29)
90-100	745 (62)	131 (60)	69 (62)
Missing	57 (5)	10 (5)	10 (9)
HLA-A B DRB1 groups - low resolution			
<=3/6	227 (21)	61 (33)	22 (26)
4/6	79 (7)	13 (7)	5 (6)
5/6	23 (2)	2 (1)	4 (5)
6/6	751 (70)	111 (59)	55 (64)
Unknown	128 (N/A)	31 (N/A)	25 (N/A)
High-resolution HLA matches available out of 8			
<=5/8	286 (29)	68 (38)	24 (30)
6/8	14 (1)	4 (2)	3 (4)
7/8	19 (2)	2 (1)	2 (3)
8/8	668 (68)	103 (58)	50 (63)
Unknown	221 (N/A)	41 (N/A)	32 (N/A)
HLA-DPB1 Match			
Single allele mismatch	2 (<1)	0	0
Full allele matched	222 (30)	45 (48)	15 (39)
Unknown	526 (70)	49 (52)	23 (61)
Unknown	458 (N/A)	124 (N/A)	73 (N/A)
High resolution release score			
No	814 (67)	218 (100)	108 (97)
Yes	394 (33)	0	3 (3)
Graft type			
Marrow	164 (14)	33 (15)	18 (16)
PBSC	1042 (86)	184 (84)	93 (84)
BM+PBSC	2 (<1)	1 (<1)	0
Conditioning regimen			
Myeloablative	441 (37)	67 (31)	31 (28)
RIC/Nonmyeloablative	762 (63)	147 (67)	79 (71)
TBD	5 (<1)	4 (2)	1 (1)
Donor age at donation			

	Samples Available for Recipient and Donor	Samples Available for Recipient Only	Samples Available for Donor Only
Variable	**N (%)**	**N (%)**	**N (%)**
To Be Determined/NA	6 (<1)	0	1 (1)
0-9 years	18 (1)	2 (1)	0
10-17 years	51 (4)	10 (5)	2 (2)
18-29 years	197 (16)	47 (22)	19 (17)
30-39 years	178 (15)	39 (18)	22 (20)
40-49 years	228 (19)	44 (20)	19 (17)
50+ years	530 (44)	76 (35)	48 (43)
Median (Range)	47 (0-81)	42 (0-71)	47 (0-74)
Donor/Recipient CMV serostatus			
+/+	493 (41)	99 (45)	42 (38)
+/-	156 (13)	21 (10)	12 (11)
-/+	227 (19)	40 (18)	26 (23)
-/-	313 (26)	51 (23)	25 (23)
Missing	19 (2)	7 (3)	6 (5)
GvHD Prophylaxis			
No GvHD Prophylaxis	5 (<1)	0	0
TDEPLETION alone	1 (<1)	3 (1)	0
TDEPLETION +- other	9 (1)	2 (1)	1 (1)
CD34 select alone	0	1 (<1)	0
CD34 select +- other	5 (<1)	1 (<1)	0
Cyclophosphamide alone	9 (1)	1 (<1)	0
Cyclophosphamide +- others	401 (33)	88 (40)	42 (38)
FK506 + MMF +- others	113 (9)	12 (6)	2 (2)
FK506 + MTX +- others(not MMF)	450 (37)	58 (27)	46 (41)
FK506 +- others(not MMF,MTX)	107 (9)	41 (19)	13 (12)
FK506 alone	11 (1)	0	0
CSA + MMF +- others(not FK506)	9 (1)	4 (2)	0
CSA + MTX +- others(not MMF,FK506)	22 (2)	0	1 (1)
CSA +- others(not FK506,MMF,MTX)	14 (1)	4 (2)	1 (1)
CSA alone	3 (<1)	0	0
Other GVHD Prophylaxis	24 (2)	1 (<1)	2 (2)
Missing	25 2)	2 (<1)	3 (3)
Donor/Recipient sex match			
Male-Male	459 (38)	85 (39)	46 (41)
Male-Female	225 (19)	35 (16)	20 (18)
Female-Male	307 (25)	56 (26)	24 (22)
Female-Female	216 (18)	42 (19)	21 (19)
Missing	1 (<1)	0	0
Year of transplant			
2006-2010	118 (10)	15 (7)	15 (14)

	Samples Available for Recipient and Donor	Samples Available for Recipient Only	Samples Available for Donor Only
Variable	**N (%)**	**N (%)**	**N (%)**
2011-2015	493 (41)	65 (30)	34 (31)
2016-2020	435 (36)	84 (39)	43 (39)
2021-2023	162 (13)	54 (25)	19 (17)
Follow-up among survivors, Months			
N Eval	759	144	78
Median (Range)	39 (0-148)	26 (0-123)	48 (0-145)

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CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

TO: Lymphoma Working Committee Members

FROM: Mehdi Hamadani, MD; Scientific Director for the Lymphoma Working Committee

RE: Studies in Progress Summary

LY20-02 Outcomes of allogeneic transplants in patients with hodgkin lymphoma in the era of checkpoint inhibitors: A joint CIBMTR and EBMT analysis (Miguel-Angel Perales/Ana Maria Sureda). This study is in collaboration with EBMT. The PIs are currently working on the manuscript preparation. **Manuscript preparation.**

LY22-01a Outcomes of CD19 CAR-T in patients who achieve complete remission prior to lymphodepletion in patients with aggressive non-Hodgkins lymphoma (Mazyar Shadman / Mehdi Hamadani). This study compares outcomes of patients with DLBCL in CR after salvage therapy who received auto-HCT vs those who received CAR-T therapy. **Manuscript submitted.**

LY22-01b Outcomes of autologous HCT and CD19 CAR-T in MYC+ large B-cell lymphoma patients (Fateeha Furqan / Mehdi Hamadani). This study compares outcomes of patients with DLBCL with MYC-rearrangement or high-grade b-cell lymphoma with MYC and BCL2 and/or BCL6 rearrangements who receive either commercial CAR T-cell therapy or auto-HCT after achieving a CR or PR after second or subsequent line therapies for R/R disease. **Data File Preparation phase.**

LY22-01c Outcomes of CD19 CAR-T in patients who achieve complete remission prior to lymphodepletion in patients with aggressive non-Hodgkins lymphoma (Trent Wang / Antonio Martin Jimenez Jimenez). This study describes survival outcomes of all patients with R/R LBCL in CR after salvage therapy who receive CAR T-cell therapy (including patients with prior auto-HCT). **Manuscript submitted.**

LY22-02a Efficacy and safety of CD19 directed CAR T-cell therapy for non-Hodgkin B-cell lymphomas with primary and secondary central nervous system involvement (Narendranath Epperla / Hamza Hashmi / Sairah Ahmed / Santiago Mercadal / Catherine Lee). This study evaluates outcomes of patients undergoing CAR-T for primary and secondary CNS lymphoma. **Manuscript submitted.**

LY22-02b Efficacy and safety of CD19 directed CAR T-cell therapy for T-cell rich histiocyte rich B-cell lymphoma (Priyanka Pophali / Roni Shouval /Mazyar Shadman). This study evaluates outcomes of patients undergoing CAR-T for T-cell rich histiocyte rich B-cell lymphoma. **Manuscript about to be submitted.**

LY22-02c Efficacy and safety of CD19 directed CAR T-cell therapy for transferred follicular lymphoma (Swetha Kambhampati / Kalyan Nadiminti / Alex Herrera). This study evaluates outcomes of patients undergoing CAR-T for follicular lymphoma. **Waiting hours assignment.**

LY22-02d Efficacy and safety of CD19 directed CAR T-cell therapy for Richter's transformation. Data File preparation (Mazyar Shadman / Mehdi Hamadani). This study evaluates outcomes of patients undergoing CAR-T for Richter's transformation. **Waiting hours assignment.**

LY22-02e Efficacy and safety of CD19 directed CAR T-cell therapy for primary mediastinal B-cell lymphoma (Jordan Gauthier / Alex Herrera). This study evaluates outcomes of patients undergoing CAR-T for primary mediastinal B-cell lymphoma. **Waiting hours assignment.**

LY22-02f Efficacy and safety of CD19 directed CAR T-cell therapy for high grade B-cell lymphoma (Nasheed Hossain / Alex Herrera). This study evaluates outcomes of patients undergoing CAR-T for high grade B-cell lymphoma. **Waiting hours assignment.**

LY23-01 Efficacy of hematopoietic stem cell transplantation in patients with plasmablastic lymphoma. This study will evaluate outcomes of autologous and allogenic HCT with plasmablastic lymphoma (Taha Al-Juhaishi / Sairah Ahmed / Krina Patel). **Protocol Development**

Field	Response
Proposal Number	2310-99-SHADMAN
Proposal Title	A Matching Adjusted Indirect Comparison (MAIC) Analysis Comparing the Clinical Outcomes of Patients with Follicular Lymphoma treated with anti CD19 directed CAR-T therapy vs. the Bispecific antibody, Mosunetuzumab.
Key Words	Follicular lymphoma, CAR-T therapy, Bispecific antibody, mosunetuzumab
Principal Investigator #1: - First and last name, degree(s)	Mazyar Shadman, MD MPH
Principal Investigator #1: - Email address	mshadman@fredhutch.org
Principal Investigator #1: - Institution name	Fred Hutch Cancer Center
Principal Investigator #1: - Academic rank	Associate Professor
Junior investigator status (defined as ≤5 years from fellowship)	No
Do you identify as an underrepresented/minority?	No
Principal Investigator #2 (If applicable): - First and last name, degree(s):	Mehdi Hamadani, MD
Principal Investigator #2 (If applicable): - Email address:)	mhamadani@mcw.edu
Principal Investigator #2 (If applicable): - Institution name:	Medical College of Wisconsin
Principal Investigator #2 (If applicable): - Academic rank:	Professor
Junior investigator status (defined as ≤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.	Mazyar Shadman is a co-chair of the lymphoma committee and PI for LY22-01 and CT-1902 Mehdi Hamadani is the scientific director of the CIBMTR lymphoma committee
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.	Yes
If you have already spoken with a scientific director or working committee chair regarding this study, then please specify who:	The proposal is written by one of the co-chairs and the scientific director
RESEARCH QUESTION:	In patients with FL with 2 or more prior lines of treatment, are clinical outcomes different in patients who received commercial CD19 directed CAR-T (either tisa-cel or axi-cel) vs. in those who received the CD20/CD3 bispecific antibody mosunetuzumab?
RESEARCH HYPOTHESIS:	CD19 directed CAR-T (with either tisa-cel or axi-cel) therapy is associated with an improved clinical efficacy compared to mosunetuzumab in patients with r/r FL after 2 or more prior lines of treatment.

Field	Response
SPECIFIC OBJECTIVES/OUTCOMES TO BE INVESTIGATED (Include Primary, Secondary, etc.):	Primary objectives: 1) To compare the progression-free survival (PFS) between tisa-cel and mosunetuzumab 2) To compare the PFS between axi-cel and mosunetuzumab Secondary objectives 1) To compare the overall survival (OS) between tisa-cel and mosunetuzumab 2) To compare the OS between axi-cel and mosunetuzumab 3) To compare the rate of infections between tisa-cel and mosunetuzumab 4) To compare the rate of infections between axi-cel and mosunetuzumab 5) To compare the rate of non-relapse mortality (NRM) between tisa-cel and mosunetuzumab 6) To compare the rate of NRM between axi-cel and mosunetuzumab 7) To compare causes of death between tisa-cel and mosunetuzimab 8) To compare causes of death between axi-cel and mosunetuzimab
SCIENTIFIC IMPACT: Briefly state how the completion of the aims will impact participant care/outcomes and how it will advance science or clinical care.	Both CAR-T therapy (tisa-cel and axi-cel) and bispecific antibody (mosunetuzumab) are approved for treatment of patients with FL after 2 or prior lines of treatment.(1) Both approaches have high efficacy with the current follow-up based on single arm studies but there is no prior, ongoing or planned head-to-head clinical trial to compare the clinical efficacy and safety of the 2 treatment modalities.(2-4) CIBMTR is in the unique position of using the detailed and high-quality CAR-T clinical database and perform a Matching Adjusted Indirect Comparison (MAIC) analysis to compare the patient level data from the CIBMTR after adjustment for the baselines characteristics obtained from the published data from the mosunetuzumab.(5) The results will be important and informative for clinical practice. Findings may indicate clinical benefit for one of the 2 modalities and regardless, will have an impact the clinical practice.
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.	This analysis is justified as there is no clinical trial to compare CAR-T and bispecific antibodies for patients with FL and there is no expectation to have such studies at least in foreseeable future to best of our knowledge. With two effective immunotherapy approaches available, it is important to make the best effort to make this comparison. CIBMTR is in a unique position for this MAIC analysis and such comparison is not otherwise feasible for the lymphoma community to perform.
PARTICIPANT SELECTION CRITERIA: State inclusion and exclusion criteria.	1) Patients with a diagnosis of FL 2) Treatment with either tisa-cel or axi-cel 3) At least 2 prior lines of treatment 4) No history of histologic transformation 5) No prior history of other CAR-T therapy
Does this study include pediatric patients?	No

Field	Response
If this study does not include pediatric patients, please provide justification:	CAR-T is not approved for pediatric population
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.	a. Age b. Sex c. Ethnicity d. ECOG at treatment e. An arbor stage at treatment f. Bulky disease at treatment g. FLIPI risk factor if available at treatment h. Number of prior lines of therapy i. Prior autologous transplant j. Refractoriness to last previous therapy k. Refractoriness to previous anti-CD20 therapy (if available) l. Refractoriness to previous alkylator therapy (if available) m. Progressive disease withing 24 months from first line of therapy Using the CIBMTR database, a cohort of patients with FL will be selected after matching with the published baselines characteristics of patients who were treated with mosunetuzumab on he pivotal clinical trial.(2) Two separate cohorts will be selected from the patients who received axi-cel and tisa-cel, separately. There is no plan to compare the 2 CAR-T cohorts together. The selected axi-cel and tisa-cel cohorts using the patient level data will be compared to mosunetuzaumab cohort separately. The baseline characteristics and outcomes are described above.
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 desc	NA
MACHINE LEARNING: Please indicate if the study requires methodology related to machine-learning and clinical predictions.	NA
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 o	NA
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.	NA

Field	Response
REFERENCES:	1. Jacobsen E. Follicular lymphoma: 2023 update on diagnosis and management. Am J Hematol. 2022;97(12):1638-51. 2. Budde LE, Sehn LH, Matasar M, Schuster SJ, Assouline S, Giri P, et al. Safety and efficacy of mosunetuzumab, a bispecific antibody, in patients with relapsed or refractory follicular lymphoma: a single-arm, multicentre, phase 2 study. Lancet Oncol. 2022;23(8):1055-65. 3. Fowler NH, Dickinson M, Dreyling M, Martinez-Lopez J, Kolstad A, Butler J, et al. Tisagenlecleucel in adult relapsed or refractory follicular lymphoma: the phase 2 ELARA trial. Nat Med. 2022;28(2):325-32. 4. Jacobson CA, Chavez JC, Sehgal AR, William BM, Munoz J, Salles G, et al. Axicabtagene ciloleucel in relapsed or refractory indolent non-Hodgkin lymphoma (ZUMA-5): a single-arm, multicentre, phase 2 trial. Lancet Oncol. 2022;23(1):91-103. 5. Signorovitch JE, Sikirica V, Erder MH, Xie J, Lu M, Hodgkins PS, et al. Matching-adjusted indirect comparisons: a new tool for timely comparative effectiveness research. Value Health. 2012;15(6):940-7.
CONFLICTS OF INTEREST: Do you have any conflicts of interest pertinent to this proposal concerning?	Yes, I have conflicts of interest pertinent to this proposal
If yes, provide detail on the nature of employment, name of organization, role, entity, ownership, type of financial transaction or legal proceeding and whether renumeration is >$5000 annually.	Mazyar Shadman: Consulting, Advisory Boards, steering committees or data safety monitoring committees: Abbvie, Genentech, Genmab, AstraZeneca, Beigene, Bristol Myers Squibb, Morphosys/Incyte, Kite Pharma, Eli Lilly, Fate therapeutics. Research Funding: Mustang Bio, Celgene, Bristol Myers Squibb, Pharmacyclics, Gilead, Genentech, AbbVie, TG Therapeutics, Beigene, AstraZeneca, Genmab, Morphosys/Incyte, Vincerx. Employment (spouse): BMS. Dr. Hamadani's COI is on file

PROP 2310-99: A matching adjusted indirect comparison (MAIC) analysis comparing the clinical outcomes of patients with follicular lymphoma treated with anti CD19 directed CAR-T therapy vs. the bispecific antibody, mosunetuzumab

Table 1. Characteristics of adult patients who underwent CAR-T for follicular lymphoma with tisa cel or axi-cel

Characteristic	**N (%)**
No. of patients	449
No. of centers	91
Age group, years - no. (%)	
Median (min-max)	61.8 (26.9-86.8)
18-40	12 (2.7)
41-60	177 (39.4)
>60	260 (57.9)
Recipient Sex - no. (%)	
Male	274 (61)
Female	175 (39)
Recipient race - no. (%)	
White	380 (85)
African-American	28 (6)
Asian	14 (3)
Native American	2 (0)
Unknown	18 (4)
Not reported	7 (2)
Ethnicity - no. (%)	
Hispanic or Latino	52 (12)
Non-Hispanic or non-Latino	377 (84)
Not reported	20 (4)
Karnofsky performance score prior to CT - no. (%)	
90-100	214 (48)
80	143 (32)
< 80	61 (14)
Not reported	31 (7)
Disease status prior to CT - no. (%)	
CR	18 (4)
PR	75 (17)
Resistant	277 (62)

Characteristic	**N (%)**
Untreated	47 (10)
Unknown	32 (7)
Time from initial diagnosis to CT - no. (%)	
< 6 months	13 (3)
6 to 12 months	15 (3)
> 12 months	421 (94)
Product - no. (%)	
tisa-cel	6 (1)
Axi-cel	443 (99)
Total number of lines of therapy - no. (%)	
2	67 (15)
>= 3	307 (68)
Not reported	75 (17)
Prior HCT - no. (%)	
No	379 (84)
Yes	70 (16)
Year of CT - no. (%)	
2018	9 (2)
2019	6 (1)
2020	10 (2)
2021	143 (32)
2022	166 (37)
2023	115 (26)
Follow-up among survivors - median (range)	12.3 (0.5-60.0)

Field	Response
Proposal Number	2308-04-TUN
Proposal Title	Autologous stem cell transplant vs chimeric antigen receptor T-cell therapy in patients with relapsed secondary central nervous system lymphoma
Key Words	secondary central nervous system lymphoma; diffuse large B-cell lymphoma; relapsed/progrossive; high dose chemotherapy and autologous stem cell transplant; chimeric antigen receptor T-cell therapy
Principal Investigator #1: - First and last name, degree(s)	Aung Tun
Principal Investigator #1: - Email address	atun@kumc.edu
Principal Investigator #1: - Institution name	KUMC
Principal Investigator #1: - Academic rank	Assistant Professor
Junior investigator status (defined as ≤5 years from fellowship)	Yes
Do you identify as an underrepresented/minority?	Yes
Principal Investigator #2 (If applicable): - First and last name, degree(s):	Stephen Ansell
Principal Investigator #2 (If applicable): - Email address:)	ansell.stephen@mayo.edu
Principal Investigator #2 (If applicable): - Institution name:	Mayo Clinic, Rochester
Principal Investigator #2 (If applicable): - Academic rank:	Professor
Junior investigator status (defined as ≤5 years from fellowship)	No
Do you identify as an underrepresented/minority?	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:	Should fit patients with relapsed/progressive secondary central nervous system lymphoma (SCNSL) optimally be treated with autologous stem cell transplant (ASCT) or chimeric antigen receptor T-cell (CAR-T) therapy?
RESEARCH HYPOTHESIS:	ASCT is associated with superior survival and better toxicity profiles than CAR-T therapy in patients with relapsed SCNSL
SPECIFIC OBJECTIVES/OUTCOMES TO BE INVESTIGATED (Include Primary, Secondary, etc.):	Primary: 1. To compare progression free survival (PFS) rates between ASCT and CAR-T therapy in patients with aggressive relapsed/progressive SCNSL Secondary: 1. Response rates between two groups 2. Overall survival (OS) 3. Relapse vs nonrelapse mortality 4. Toxicities of ASCT vs CAR-T therapy

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.	CAR-T cell therapy is currently FDA approved for patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), and fit patients with relapsed/progressive SCNSL are being offered CAR-T therapy, instead of ASCT, despite limited clinical evidence. The results of this study will help clinicians when determining optimal treatment strategies in patients with relapsed/progressive SCNSL.

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.	Relapsed/progressive SCNSL is an uncommon but devastating complication of DLBCL, and there is no effective prophylactic strategy (Puckrin et al, Am J Hematol, 2021 and Orellana-Noia et al, Blood, 2022). It may be diagnosed simultaneously with systemic disease, at systemic relapse, or as an isolated site of relapse. The central nervous system (CNS) site at relapse/progression occurs mainly in the brain parenchyma, but can also take place in the leptomeninges, intraocular/vitreoretinal sites, or a combination. Patients with CNS-only disease are typically treated with high dose methotrexate based regimens often in combination with cytarabine, thiotepa, ifosfamide, or temozolomide (Ferreri et al, Lancet, 2009) and those with synchronous systemic disease are treated with regimens such as rituximab, methotrexate, cytarabine, and thiotepa (MATRix), followed by rituximab, ifosfamide, carboplatin and etoposide (R-ICE) or rituximab, dexamethasone, cytarabine, and cisplatin (R-DHAP) alternating with high dose methotrexate (Ferreri et al, Lancet Haematol, 2021 and Doorduijn et al, Hematol Oncol, 2017). Appropriate patients with chemosensitive disease are then consolidated with ASCT using BCNU and thiotepa as a conditioning regimen achieving long term remission in ~ 50% of patients (Ferreri et al, Lancet Haematol, 2021). On the other hand, emerging data on CAR-T indicate promising clinical activities, without an increase in the risk of neurotoxicity, in patients with SCNSL (Cook et al, Blood Adv, 2023). A study of 7 patients treated at Medical College of Wisconsin showed a complete response (CR) in 6 (85.7%) patients though most patients received bridging whole brain radiation therapy (Ahmed et al, Blood Adv, 2021). Another study of 8 patients with SCNSL treated with tisagenlecleucel at Dana Faber Cancer Institute reported that 3 patients achieved CR and 1 had PR (Frigault et al, Blood, 2019). An analysis from the US Lymphoma CAR-T Consortium included 5 patients with active CNS disease at the time of CAR-T infusion with 2 achieving CR and 1 resulting in PR (Bennani et al, Blood, 2019). Similar response rates had been seen with other studies, but achieving a durable response remains a major challenge (Li et al, Front Oncol, 2020; Ghafouri et al, Bone Marrow Transplant, 2021; Wu et al, Blood Cancer J, 2021; and Liu et al, Hum Gene Ther, 2022). Most CAR-T registration trials in relapsed or refractory DLBCL excluded patients with known CNS involvement at enrollment. However, 8 patients with known SCNSL in TRANSCEND and TRANSFORM received CAR-T, yet clinical data remains limited for clinical application (Abramson et al, Lancet, 2020 and Kamdar et al, Lancet, 2022). Thus, a large

Field	Response
	CIBMTR database analysis is necessary to determine an optimal therapeutic strategy in patients with SCNSL.
PARTICIPANT SELECTION CRITERIA: State inclusion and exclusion criteria.	Patients with SCNSL who underwent ASCT and/or CAR-T therapy
Does this study include pediatric patients?	No
If this study does not include pediatric patients, please provide justification:	It is a disease of older patients.
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 and disease related: Age at ASCT or CAR-T Performance status – KPS prior to ASCT or CAR-T Sex Ethnicity Stage at diagnosis High grade B-cell non Hodgkin lymphoma (double - or triple – hit DLBCL) LDH elevated at diagnosis Extranodal involvement at diagnosis Refractory to first line therpay Time from diagnosis to ASCT or CAR-T (≤12 months vs >12 months) Time from completion of firseline chemotherapy to ASCT or CAR-T (≤12 months vs >12 months) Lines of therapy before ASCT or CAR-T Type of salvage therapy before ASCT or CAR-T Site of CNS involvment (parenchyma and/or leptomeninges) Synchronous systemic relapse (yes or no) LDH before ASCT or CAR-T Disease status before ASCT or CAR-T (CR vs PR vs stable disease (SD)) ASCT related: Year of ASCT Conditioning regimen CAR-T related: Year of CAR-T Type of CAR-T (name and construct) Bridging therapy Lymphodepletion regimen CRS with maximal grade Neurotoxicity with maximal grade Cytopenia at day 28 (yes or no) Long term complication related: Relapse date Site of relapse (CNS and/or systemic relapse) Nonrelapse mortality Vital status at last follow up Cause of death
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 desc	not applicable
MACHINE LEARNING: Please indicate if the study requires methodology related to machine-learning and clinical predictions.	not applicable

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.	not applicable

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Field	Response
	T, Zhao L, Zhang Y, et al. CAR T-Cell Therapy Is Effective but Not Long-Lasting in B-Cell Lymphoma of the Brain. Front Oncol. 2020;10:1306. doi:10.3389/fonc.2020.01306 11. Ghafouri S, Timmerman J, Larson S, Mead MD. Axicabtagene Ciloleucel CAR T-cell therapy for relapsed/refractory secondary CNS non-Hodgkin lymphoma: comparable outcomes and toxicities, but shorter remissions may warrant alternative consolidative strategies? Bone Marrow Transplant. 2021;56(4):974-977. doi:10.1038/s41409-020-01099-4 12. Wu J, Meng F, Cao Y, et al. Sequential CD19/22 CAR T-cell immunotherapy following autologous stem cell transplantation for central nervous system lymphoma. Blood Cancer J. 2021;11(7):131. doi:10.1038/s41408-021-00523-2 13. Liu R, Cheng Q, Kang L, et al. CD19 or CD20 CAR T Cell Therapy Demonstrates Durable Antitumor Efficacy in Patients with Central Nervous System Lymphoma. Hum Gene Ther. 2022;33(5-6):318-329. doi:10.1089/hum.2021.249 14. Abramson JS, Palomba ML, Gordon LI, et al. Lisocabtagene maraleucel for patients with relapsed or refractory large B-cell lymphomas (TRANSCEND NHL 001): a multicentre seamless design study. Lancet (London, England). 2020;396(10254):839-852. doi:10.1016/S0140-6736(20)31366-0 15. Kamdar M, Solomon SR, Arnason JE, et al. Lisocabtagene Maraleucel (liso-cel), a CD19-directed chimeric antigen receptor (CAR) T cell therapy, versus standard of care (SOC) with salvage chemotherapy (CT) followed by autologous stem cell transplantation (ASCT) as second-line (2L) treatment in pati. Blood. 2021;138:91.
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

PROP 2308-04: Autologous stem cell transplant vs chimeric antigen receptor T-cell therapy in patients with relapsed secondary central nervous system lymphoma

Table 1. Characteristics of adult patients who underwent auto-HCT/CAR-T for SCNS

Characteristic	HCT	CT	Total
No. of patients	74	182	256
No. of centers	47	62	82
TED or CRF track - no. (%)			
CRF	74 (100)	0 (0)	74 (29)
CT	0 (0)	182 (100)	182 (71)
Age group - no. (%)			
Median (min-max)	55.6 (20.4-74.6)	60.2 (22.7-82.8)	59.0 (20.4-82.8)
18-40	12 (16.2)	20 (11.0)	32 (12.5)
41-60	35 (47.3)	71 (39.0)	106 (41.4)
>60	27 (36.5)	91 (50.0)	118 (46.1)
Recipient Sex - no. (%)			
Male	48 (65)	117 (64)	165 (64)
Female	26 (35)	65 (36)	91 (36)
Recipient race - no. (%)			
White	52 (70)	147 (81)	199 (78)
African-American	7 (9)	8 (4)	15 (6)
Asian	11 (15)	10 (5)	21 (8)
Native American	1 (1)	0 (0)	1 (0)
More than one race	0 (0)	1 (1)	1 (0)
Unknown	3 (4)	9 (5)	12 (5)
Not reported	0 (0)	7 (4)	7 (3)
Ethnicity - no. (%)			
Hispanic or Latino	8 (11)	16 (9)	24 (9)
Not Hispanic or Latino	60 (81)	150 (82)	210 (82)
Non-resident of the U.S.	5 (7)	0 (0)	5 (2)
Not answered	1 (1)	16 (9)	17 (7)
Region - no. (%)			
US	61 (82)	174 (96)	235 (92)
Canada	6 (8)	3 (2)	9 (4)

Characteristic	HCT	CT	Total
Europe	0 (0)	4 (2)	4 (2)
Asia	4 (5)	0 (0)	4 (2)
Mideast/Afric	1 (1)	1 (1)	2 (1)
Central/South America	2 (3)	0 (0)	2 (1)
Transplant type - no. (%)			
Autologous	74 (100)	0 (0)	74 (29)
N/A, CT	0 (0)	182 (100)	182 (71)
Karnofsky score prior to HCT - no. (%)			
90-100%	33 (45)	51 (28)	84 (33)
< 90%	36 (49)	110 (60)	146 (57)
Not reported	5 (7)	21 (12)	26 (10)
Disease status prior to transplant - no. (%)			
CR	39 (53)	6 (3)	45 (18)
PR	29 (39)	41 (23)	70 (27)
Resistant	4 (5)	123 (68)	127 (50)
Untreated	1 (1)	7 (4)	8 (3)
Unknown	1 (1)	5 (3)	6 (2)
Time from diagnosis to transplant(months) - no. (%)			
<6-month	17 (23)	23 (13)	40 (16)
6-month-12-month	29 (39)	61 (34)	90 (35)
>=12-month	28 (38)	98 (54)	126 (49)
Product - no. (%)			
tisa-cel	0 (0)	44 (24)	44 (17)
Axi-cel	0 (0)	133 (73)	133 (52)
Liso-cel	0 (0)	5 (3)	5 (2)
N/A, HCT	74 (100)	0 (0)	74 (29)
Year of current transplant/CAR-T - no. (%)			
2008	8 (11)	0 (0)	8 (3)
2009	5 (7)	0 (0)	5 (2)
2010	1 (1)	0 (0)	1 (0)
2011	1 (1)	0 (0)	1 (0)
2013	5 (7)	0 (0)	5 (2)
2014	6 (8)	0 (0)	6 (2)

Characteristic	HCT	CT	Total
2015	5 (7)	0 (0)	5 (2)
2016	5 (7)	0 (0)	5 (2)
2017	6 (8)	0 (0)	6 (2)
2018	11 (15)	14 (8)	25 (10)
2019	8 (11)	31 (17)	39 (15)
2020	0 (0)	44 (24)	44 (17)
2021	6 (8)	45 (25)	51 (20)
2022	4 (5)	34 (19)	38 (15)
2023	3 (4)	14 (8)	17 (7)
Follow-up among survivors - median (range)	57.8 (0.03-170)	23.8 (1.51-60.2)	29.2 (0.03-170)

I. Study Title

Real-world outcomes of second line CD19 CAR T-cell therapy for large B-cell lymphoma

II. Key words
CD19 CAR T, standard of care, relapsed refractory diffuse large B-cell lymphoma

III. Principal Investigator Information

IV.

Names:

Swetha Kambhampati (junior investigator), Alex Herrera (senior investigator)
Maria Silvina Odstrcil Bobillo (junior investigator), Catherine Joy Lee (senior investigator)
Caroline Lee (junior investigator), Saurabh Dahiya (Senior Investigator), Mazyar Shadman (Senior Investigator)

Institution Names: City of Hope, University of Utah, Fred Hutchinson, Stanford

V. Proposed working committee
Lymphoma Group

VI. Research Question
What is the efficacy and safety of standard of care CD19 CAR T-cell therapy (CAR T) in second line setting for diffuse large B-cell lymphoma

VII. Research Hypothesis
With the increasing utilization of CAR T for the treatment of relapsed or refractory (R/R) LBCL in the second line in the past couple of years, we hypothesize that the efficacy of CAR T-cell therapy in real world is similar to that published in clinical trials.

We predict that CD19 CAR T in the second-line setting is effective and safe for primary refractory/early relapse DLBCL with real-world outcomes that are similar to those reported in the clinical trials ZUMA 7 and TRANSFORM and in late relapse transplant-ineligible patients with outcomes that are similar to those reported in the PILOT study

VIII. Specific Objectives/Outcomes to be Investigated

Primary objective:

- To evaluate the efficacy of second-line CAR T in patients with R/R LBCL by measuring progression free survival of SOC second line CD19 CAR T in R/R LBCL

Secondary objectives:
-To evaluate the efficacy by overall survival, event free survival, overall response rate (defined as rate of patients who achieve PR or CR), duration of response, and best CR rate of patients with R/R LBCL receiving second-line CAR-T.
-To evaluate efficacy outcomes stratified by primary refractory/early relapse (axi-cel and liso-cel) and late relapse (liso-cel)
-To assess safety by evaluating any grade and grade III/IV toxicities, specifically cytokine release syndrome (CRS), immune effector cell-associated neurotoxicity syndrome (ICANS), cytopenias, and infection rate as well as non-relapse mortality
- To identify predictive risk factors on outcome variables of toxicity, response rate, and survival outcomes of patients with R/R receiving second-line CAR-T. The variables of interest/risk factors include age, histological type of disease (DLBCL vs high grade DLBCL NOS vs double hit/triple hit DLBCL), co-existing disease, disease burden/stage, ECOG PS, disease holding therapy (defined as therapy between frontline chemotherapy and apheresis), bridging therapy, response to initial treatment (primary progressive vs primary refractory with partial response vs early relapse vs late relapse), and CAR-T product (axi-cel vs liso-cel).

Primary Endpoints:
- progression-free survival of SOC second-line CAR T

Secondary Endpoints:
- overall response rate, event free survival, overall response rate (CR + PR), best CR rate, duration of response, and overall survival
-safety as measured by rate of incidence and severity of adverse events and non-relapse mortality
-efficacy and safety endpoints stratified by primary refractory/early relapse and late relapse as well as CAR T product
-odds ratio and hazard ratio for ORR, CRR, PFS, OS, DOR, and safety outcomes of interest by predictive risk factors

IX. Scientific Impact

Diffuse large B-cell lymphoma is the most common aggressive form of NHL. CD19-directed CAR T cell therapy has recently transformed the landscape of DLBCL with initial approval of three products (axicabtagene ciloleucel (axi-cel), tisagenlecleucel (tisa-cel), and lisocabtagene maraleucel (lisa-cel)) in the third-line setting based on pivotal ZUMA-1,[1] BELINDA,[2] and TRANSCEND[3] trials respectively. More recently, axi-cel and liso-cel have also received approval for primary refractory/early relapse DLBCL patients based on ZUMA-7[4] and TRANSFORM[5] studies respectively. The ZUMA 7[4]

demonstrated that at a median follow-up of 24.9 months, the median event-free survival (EFS) was 8.3 months in the axi-cel group and 2.0 months in the standard of care group. The estimated overall survival at 2 years was 61% in the axi-cel group and 52% in the standard-care group. In the TRANSFORM study,[5] at a median follow-up of 6.2 months, the median EFS was significantly improved in the liso-cel group compared to SOC group (10.1 months vs 2.3 months). The PILOT trial is a phase 2 study demonstrating safety and efficacy of second line liso-cel in transplant ineligible patients.[6]

Given clinical trials often have stringent eligibility criteria, the outcomes observed in these trials may not be reflective of real-world practice. It is important to understand the safety and efficacy of second line standard of care (SOC) CD19 CAR T in primary refractory and early relapse DLBCL patients as well as in late relapse DLBCL patients in real-world clinical practice. To our knowledge there are no current published data describing this. Given the knowledge gap, analysis of a large retrospective cohort can provide valuable information to answer this question.

To that end, we propose a retrospective study using the CIBMTR database to delineate the characteristics and outcomes of patients treated with commercially available second line axi-cel or liso-cel CAR T and to evaluate its safety and efficacy outside the confines of a clinical trial. We also propose to analyze the risk factors predictive of response, differences in outcome with product type, and the effect of disease response to initial chemoimmunotherapy treatment on outcomes post CAR T.

X. Scientific Justification

We propose to use CIBMTR database to evaluate the safety and efficacy of standard of care second line CD19 CAR T for patients with relapsed DLBCL in the real-world practice. Through this retrospective analysis, we hope to not only describe response and toxicity outcomes of second line CD19 CAR T in R/R DLBCL but we hope to also better understand real-world differences between axi-cel and liso-cel outcomes and safety, risk factors predictive of response to CAR T, and how disease response to initial chemoimmunotherapy treatment may impact outcomes after CAR T. To determine its efficacy and safety in a broad population, our proposed study will include all patients receiving SOC second-line CAR-T commercially and collect outcome variables such as age, co-existing disease, disease burden, disease holding therapy, and bridging therapy, to see how these variables influence clinical outcomes in the real world. Completion of this proposal will further support the efficacy and clinical outcomes of patients with R/R LBCL receiving CAR-T as the second-line therapy. It is important to understand how therapies work in the real-world setting and if the results mirror those demonstrated in clinical trials, as trials often have strict eligibility criteria that leads to selective bias in the patients who are enrolled.

XI. Participant Selection Criteria

Inclusion Criteria

- Adult patients (age greater than or equal to 18)
- Diagnosis of any LBCL including diffuse large B cell lymphoma, primary mediastinal large B cell lymphoma, T-cell/histiocyte-rich large B cell lymphoma, transformed lymphoma from any indolent lymphoma (including Richter's syndrome), and high-grade B cell lymphoma, not otherwise specified
- Primary refractory disease after first-line systemic therapy
- Any relapsed disease after the first line of therapy (early relapse within 12 months of initial chemoimmunotherapy or late relapse after 12 months of initial chemoimmunotherapy)
- Received axi-cel or liso-cel (commercial) as SOC second-line therapy for R/R LBCL (excluding disease holding therapy and bridging therapy)

Exclusion Criteria
-patients with any histology other than DLBCL
-treatment-naïve patients or patients who receive CD19 CAR T third-line or after
-patients who received CD19 CAR T on clinical trial
-patients who received prior CD19 CAR T

XII. Data Requirements

We will utilize data collected by CIBMTR from #2018 (Hodgkin and Non-Hodgkin Lymphoma Pre-infusion), #4000 (Pre-Cellular Therapy Essential Data), #4001 (Pre-Cellular Therapy Baseline Data), #4101 (Post-Cellular Therapy Follow-Up), #2900 (Recipient Death Data), and #2006 (Hematopoietic Stem Cell Transplant Infusion). The summary of data will be analyzed:

Patient and disease related variables (Baseline characteristics):

- Age < 60, ≥ 60, median age
- Sex (female vs male)
- Race (White, Black, Asian, American Indian, or Native Hawaiian)
- Ethnicity (Hispanic vs. non-Hispanic)
- Disease (based on the list of B cell neoplasms in the form #2018)
- Immunohistochemical testing (double expressor or non-double expressor)
- Molecular testing (double hit or non-double hit)
- Molecular subgroup (germinal center B (GCB) cell-like vs non-GCB)
- Bulky disease (greater than or equal to 10 cm vs. <10cm)

- LDH (greater than normal limit vs. normal)
- Stage (I, II, III, IV)
- B-symptoms at time of infusion (Y/N)
- Extra-nodal disease (Y/N)
- Bone marrow involvement (Y/N)
- CNS involvement (Y/N)
- IPI and R-IPI score (low, intermediate, and high)
- First-line systemic therapy
- Prior lines of therapy: median # and range of prior lines
- Response to initial chemoimmunotherapy (primary refractory primary progressive, primary refractory with partial response, early relapse within 12 months of completion of treatment, late relapse after 12 months of initial treatment)
- Disease status at infusion (refractory vs relapse)
- Time between remission and relapse if relapsed
- ECOG Performance Status
- Karnofsky performance status
- Co-existing disease or organ impairment (based on the list of diseases in the form #4000)

Infusion-related variables:

- Name of CAR T product (axi-cel vs liso-cel)
- Any disease holding therapy given between progression and apheresis (Y/N)
- Type of disease holding therapy (chemoimmunotherapy, radiation therapy, steroids)
- Any bridging therapy (Y/N)
- Type of bridging therapy (chemoimmunotherapy, radiation therapy, steroids)
- Lymphodepleting agents used
- Time from cell diagnosis to CAR-T infusion
- Time from apheresis to CAR-T infusion

Safety:

- CRS (maximum grade, date of onset, last day of CRS)
- ICANS (maximum grade, date of onset, last day of ICANS)
- Baseline and days +30, +90, +180 cytopenia
- Significant infection (organism, date)
- Hospitalization post CAR-T (Y/N, duration)
- ICU stay post CAR T (Y/N, duration)
- Tocilizumab use (Y/N)
- Steroid Use (Y/N)

Efficacy Outcomes:

- date of best response
- date of progression
- date of best response
- date of last response
- date of death
- date of last contact
- Antigen escape by flow or IHC at relapse post CAR-T

Outcomes:

- PFS
- OS
- EFS
- ORR (PR+CR)
- Duration of response
- Best CR rate
- Any grade of adverse event
- Any adverse event with grade 3 or higher
- Rate of hospitalization
- Rate of infection
- Non-relapse mortality
- Cell therapy utilization post CAR T progression (Autologous SCT, Allogeneic SCT and other cell therapies)

XIII. PRO Requirements
-study does not have any PRO requirements

XIV. Sample Requirements
-study does not have any sample requirements

XV. Non-CIBTMR Data Source
N/A

XVI. References
See below

XVII. Conflicts of Interest
-SK: research funding: GNE, Genmab, and ADC-T
-AH:
Bristol Myers Squibb – research funding, consultancy

Genentech – research funding, consultancy
Merck – research funding, consultancy
Seattle Genetics - research funding, consultancy
KiTE Pharma - research funding
Gilead Sciences – research funding
AstraZeneca – research funding, consultancy
Karyopharm – consultancy
ADC Therapeutics – research funding, consultancy
Takeda – consultancy
Tubulis - consultancy
Regeneron - consultancy
Genmab - consultancy
Pfizer - consultancy
Caribou - consultancy
Adicet Bio - consultancy
Abbvie – consultancy
-DL: none
-SD: research funding from Kite and BMS
-MS: consultancy for Kite. Employent (spouse) for BMS

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2. Bishop MR, Dickinson M, Purtill D, et al: Second-Line Tisagenlecleucel or Standard Care in Aggressive B-Cell Lymphoma. N Engl J Med 386:629-639, 2022
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PROP 2310-23; 2310-142; 2310-258: Real-world outcomes of second line CD19 CAR T-cell therapy for large B-cell lymphoma

Table 1. Characteristics of adult patients who underwent second line CAR-T for LBCL with axi-cel or liso-cel

Characteristic	**N (%)**
No. of patients	447
No. of centers	101
Age group - no. (%)	
Median (min-max)	63.6 (20.4-86.0)
18-40	41 (9.2)
41-60	141 (31.5)
>60	265 (59.3)
Recipient Sex - no. (%)	
Male	274 (61)
Female	173 (39)
Recipient race - no. (%)	
White	358 (80)
African-American	27 (6)
Asian	22 (5)
Native American	1 (0)
More than one race	2 (0)
Unknown	21 (5)
Not reported	16 (4)
Ethnicity - no. (%)	
Hispanic or Latino	54 (12)
Non-Hispanic or non-Latino	362 (81)
Not reported	31 (7)
Karnofsky performance score prior to CT - no. (%)	
90-100	180 (40)
80	149 (33)
< 80	89 (20)
Not reported	29 (6)
Disease status prior to CT - no. (%)	
CR	17 (4)
PR	112 (25)

Characteristic	**N (%)**
Resistant	278 (62)
Untreated	18 (4)
Unknown	22 (5)
Time from initial diagnosis to CT - no. (%)	
< 6 months	57 (13)
6 to 12 months	258 (58)
> 12 months	132 (30)
Product - no. (%)	
Axi-cel	444 (99)
Liso-cel	3 (1)
Prior HCT - no. (%)	
No	423 (95)
Yes	24 (5)
Year of CT - no. (%)	
2018	6 (1)
2019	17 (4)
2020	28 (6)
2021	23 (5)
2022	233 (52)
2023	140 (31)
Follow-up among survivors - median (range)	6.5 (1.0-60.8)

Field	Response
Proposal Number	2310-177-HAMADANI
Proposal Title	Hematopoietic Cell Transplantation for Rare Mature T-cell Lymphomas. A basket – mentoring Study Proposal.
Key Words	Mature T-cell lymphomas, allogeneic, autologous
Principal Investigator #1: - First and last name, degree(s)	Mehdi Hamadani
Principal Investigator #1: - Email address	mhamadani@mcw.edu
Principal Investigator #1: - Institution name	MCW
Principal Investigator #1: - Academic rank	Professor
Junior investigator status (defined as ≤5 years from fellowship)	No
Do you identify as an underrepresented/minority?	Yes
Principal Investigator #2 (If applicable): - First and last name, degree(s):	Alex Herrera
Principal Investigator #2 (If applicable): - Email address:)	aherrera@coh.org
Principal Investigator #2 (If applicable): - Institution name:	City of Hope
Principal Investigator #2 (If applicable): - Academic rank:	Associate Professor
Junior investigator status (defined as ≤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:	Mehdi Hamadani
Please list any ongoing CIBMTR projects that you are currently involved in and briefly describe your role.	Proposal on behalf of LYWC Leadership as a mentoring / outcomes strategy
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.	Yes
If you have already spoken with a scientific director or working committee chair regarding this study, then please specify who:	Mehdi Hamadani self
RESEARCH QUESTION:	Limited contemporary data are available for outcomes of autologous or allogeneic hematopoietic cell transplantation (HCT), in rare (define in eligibility section) mature T-cell lymphomas. The LYWC propose a basket protocol to report outcomes of rare T-cell lymphomas as a platform for mentoring junior faculty through an open invitation selection process.

Field	Response
RESEARCH HYPOTHESIS:	Autologous and allogeneic HCT provide durable disease control in rare T-cell lymphomas.
SPECIFIC OBJECTIVES/OUTCOMES TO BE INVESTIGATED (Include Primary, Secondary, etc.):	Primary objectives: 1) To determine the progression-free survival (PFS) of rare T-cell lymphomas post HCT Secondary objectives 1) Hematopoietic engraftment kinetics 2) Cumulative incidence of acute and chronic GVHD (for allogeneic subset) 3) Overall survival (OS) 4) Non-relapse mortality (NRM) 5) Cumulative incidence of Relapse 6) Causes of Death

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.	Mature T-cell lymphomas are a heterogenous group of non-Hodgkin lymphomas (NHL) with varied morphological and clinical features and an overall prognosis that is generally worse than their B-cell counterparts (Armitage JO, AJH 2017). The most common subtypes of mature T-cell lymphoma are peripheral T-cell lymphoma not otherwise specified (PTCL-NOS), angioimmunoblastic T-cell lymphoma (AITL), and anaplastic large cell lymphoma (ALCL). In the relapsed/refractory setting available pharmacological options typically do not provide long term disease control, and adoptive immunotherapy in the form of allogeneic hematopoietic cell transplantation (allo-HCT) remains the only curative option for all three subtypes (Smith S. JCO 2013, Schmitz N. Blood 2021), and autologous HCT is applied on a case by case basis. In fact, with the recent decline in allo-HCT utilization for diffuse large B-cell lymphoma, T-cell NHL now constitutes the most common indication of allo-HCT for lymphomas in the United States and Europe. A recent transatlantic collaboration between CIBMTR and EBMT evaluated the contemporary outcomes of allo-HCT relative to established donor sources, in the three most common nodal variants of mature T-cell lymphomas (PTCL-NOS, AITL and ALCL; Hamadani et al. Blood Advances 2022). However, with the possible exception of extranodal NK/T-cell lymphoma, nasal type (Kanate et al. BJH 2018), While small series and case series are reported (Bojanini L, CLML 2021; Foss F, AJH 2020; Phillips BMT 2019); CIBMTR data has not examined the role of either autologous or allogeneic HCT in patients with rare mature T-cells lymphoma including; hepatosplenic T-cell lymphoma, monomorphic epitheliotropic intestinal T-cell lymphoma / enteropathy-type T-cell lymphoma, extranodal NK / T-cell lymphoma, nasal type, aggressive NK cell leukemia, nodal peripheral T-cell lymphoma with TFH phenotype and subcutaneous panniculitis-like T-cell lymphoma. Hence we propose a mainly descriptive analysis examining contemporary outcomes of either autologous or allogeneic HCT in rare / uncommon mature T-cell lymphomas in basket protocol setting, with secondary aim to involve junior investigators in observational research.

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.	A retrospective multicenter study will be conducted utilizing CIBMTR dataset. Patients will be eligible if they satisfied the criteria detailed in the "Study population" section. The objective of this study is to evaluate the post-HCT PFS and OS of patients with rare T-cell lymphomas. Patient-, disease- and transplant- related factors will be described. PFS and OS will be estimated using the Kaplan-Meier method. Cumulative incidence of non-relapse mortality (NRM) and relapse/progression (CIR) will be calculated reflecting time to non-relapse death and time to relapse, respectively, as competing risks. For neutrophil and platelet recovery, acute GVHD and chronic GVHD (for alloHCT cohort), death without the event will be the competing event. Data on patients without an event will be censored at last follow up. Depending on the number of patients with data available, multivariable analysis using Cox models for PFS and OS with stepwise variable selection will be performed using the patient-, disease- and transplant-related variables described in section XI.

Field	Response
PARTICIPANT SELECTION CRITERIA: State inclusion and exclusion criteria.	1) Patients with a histological diagnosis of a. Hepatosplenic T-cell lymphoma b. Monomorphic epitheliotropic intestinal T-cell lymphoma / Enteropathy-type T-cell lymphoma c. Extranodal NK / T-cell lymphoma, nasal type d. Aggressive NK cell leukemia e. Nodal peripheral T-cell lymphoma with TFH phenotype f. Subcutaneous panniculitis-like T-cell lymphoma 2) Time period 2002-22 3) Adult patient (age 18 years or older) 4) For allogeneic cohort: any donor, graft source, conditioning, GVHD prophylaxis platform 5) Exclusion will include cord blood transplants, allogeneic HCT after a prior 1st allogeneic HCT, patients from embargoed centers or non consented patients Selection of Junior PI: • LYWC is committed to promoting and mentoring junior faculty. Provided the LYWC membership receives the proposal positively and ranks this proposal high, the LYWC leadership will announce an open period for inviting junior faculty to apply a letter of interest to be considered as lead PI for this study. Junior PI is defined as Hematology Oncology physician in their fellowship training for, faculty within first three years of their appointment. The faculty should ideally have a demonstrable lymphoma-focus in the clinical practice. • If a junior faculty from a LYWC chairs'/Sci Dri institution applies to join this team, the corresponding chair and Scientific director will recuse themselves from PI selection process • LYWC is also sensitive to the fact that many mid career and senior faculty may have proposed some of these histologies in the past to LYWC consideration, and such faculty if chose to will be considered for writing committees of this study.
Does this study include pediatric patients?	No

Field	Response
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.	Standard CIBMTR TED plus CRF level data. No supplement data required. Autologous and allogenic HCT cohorts will be analyzes separately without formal statistical comparisons. Patient-related: • Age at transplant: continuous & by age group: decades • Patient sex: male vs. female • Karnofsky performance status at transplant: ≥ 90 vs. < 90 vs. missing • HCT comorbidity index at transplant: 0 vs 1-2 vs ≥ 3 vs. missing • Race: Caucasian vs. others vs. missing Disease-related: • Remission status at HCT: CR vs PR vs. resistant vs. untreated/unknown • History of autologous transplant (for alloHCT cohort): no vs. yes • Time from diagnosis to HCT: ≥ 12 months vs. < 12 months vs. missing • Number of lines of prior therapy, median range Transplant-related: • Graft source: peripheral blood vs bone marrow vs. cord blood • Transplant donor type (for alloHCT cohort): MRD vs MUD vs. Mismatched unrelated donor vs. vs. Mismatched related donor (haplo) • Conditioning regimen (for autoHCT cohort): TBI-based vs chemotherapy only • Conditioning regimen (for alloHCT cohort): MAC vs. NMA/RIC • Graft type: Bone marrow vs. Peripheral blood • Year of HCT: Continuous • GVHD prophylaxis (for alloHCT cohort): TBD
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 desc	None
MACHINE LEARNING: Please indicate if the study requires methodology related to machine-learning and clinical predictions.	None
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 o	None
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.	None
REFERENCES:	Reference are embedded in the justification text.
CONFLICTS OF INTEREST: Do you have any conflicts of interest pertinent to this proposal concerning?	Yes, I have conflicts of interest pertinent to this proposal

Field	Response
If yes, provide detail on the nature of employment, name of organization, role, entity, ownership, type of financial transaction or legal proceeding and whether renumeration is >$5000 annually.	Mehdi Hamadani: Research Support/Funding: ADC Therapeutics; Spectrum Pharmaceuticals; Consultancy: ADC Therapeutics, Omeros, CRISPR, BMS, Kite, Abbvie, Caribou, Genma. Speaker's Bureau: ADC Therapeutics, AstraZeneca, BeiGene, Kite. DMC: Inc, Genentech (2022), Myeloid Therapeutics (2023), CRISPR (2023)

PROP 2310-177: Hematopoietic cell transplantation for rare mature T-cell lymphomas. A basket – mentoring study proposal.

Table 1. Characteristics of adult patients who underwent HCT for rare mature T-cell lymphoma

Characteristic	ALL Aggressive NK-cell Lk:	Enteropathy-type T-cell lymphoma:	Extranodal NK-T-cell:	Hepatosplenic gamma-delta T-cell:	Subcutaneous panniculitis T-cell:	Monomorphic epitheliotropic intestinal T-cell lymphoma	Nodal peripheral T-cell lymphoma with TFH phenotype	Total
No. of patients	43	155	477	273	126	42	63	1179
No. of centers	35	81	146	121	67	34	38	217
TED or CRF track - no. (%)								
TED	34 (79)	140 (90)	411 (86)	203 (74)	88 (70)	39 (93)	55 (87)	970 (82)
CRF	9 (21)	13 (8)	62 (13)	64 (23)	35 (28)	2 (5)	6 (10)	191 (16)
Not reported	0 (0)	2 (1)	4 (1)	6 (2)	3 (2)	1 (2)	2 (3)	18 (2)
Transplant type - Auto/Allo - no. (%)								
Allogeneic	38 (88)	31 (20)	220 (46)	222 (81)	71 (56)	10 (24)	20 (32)	612 (52)
Autologous	5 (12)	124 (80)	257 (54)	51 (19)	55 (44)	32 (76)	43 (68)	567 (48)
Age group - no. (%)								
Median (min-max)	46.9 (18.7-73.1)	60.1 (22.0-75.6)	47.1 (18.1-78.7)	40.0 (18.1-77.0)	37.8 (18.6-71.2)	62.6 (22.7-77.6)	59.7 (31.8-77.6)	48.1 (18.1-78.7)
18-40	17 (39.5)	13 (8.4)	147 (30.8)	137 (50.2)	73 (57.9)	5 (11.9)	5 (7.9)	397 (33.7)
41-60	19 (44.2)	64 (41.3)	243 (50.9)	107 (39.2)	41 (32.5)	9 (21.4)	28 (44.4)	511 (43.3)
>60	7 (16.3)	78 (50.3)	87 (18.2)	29 (10.6)	12 (9.5)	28 (66.7)	30 (47.6)	271 (23.0)
Sex - no. (%)								
male	28 (65)	104 (67)	317 (66)	184 (67)	52 (41)	32 (76)	41 (65)	758 (64)
female	15 (35)	51 (33)	160 (34)	89 (33)	74 (59)	10 (24)	22 (35)	421 (36)
Race - no. (%)								
White	25 (58)	102 (66)	238 (50)	158 (58)	52 (41)	23 (55)	38 (60)	636 (54)
Black or African American	3 (7)	5 (3)	21 (4)	49 (18)	15 (12)	2 (5)	5 (8)	100 (8)
Asian	7 (16)	18 (12)	127 (27)	22 (8)	21 (17)	14 (33)	7 (11)	216 (18)

Characteristic	ALL Aggressive NK-cell Lk:	Enteropathy-type T-cell lymphoma:	Extranodal NK-T-cell:	Hepatosplenic gamma-delta T-cell:	Subcutaneous panniculitis T-cell:	Monomorphic epitheliotropic intestinal T-cell lymphoma	Nodal peripheral T-cell lymphoma with TFH phenotype	Total
Native Hawaiian or other Pacific Islander	1 (2)	0 (0)	2 (0)	1 (0)	12 (10)	0 (0)	0 (0)	16 (1)
American Indian or Alaska Native	1 (2)	0 (0)	11 (2)	1 (0)	1 (1)	0 (0)	1 (2)	15 (1)
More than one race	0 (0)	0 (0)	3 (1)	1 (0)	3 (2)	0 (0)	2 (3)	9 (1)
Not reported	6 (14)	30 (19)	75 (16)	41 (15)	22 (17)	3 (7)	10 (16)	187 (16)
Ethnicity - no. (%)								
Hispanic or Latino	6 (14)	15 (10)	87 (18)	27 (10)	7 (6)	3 (7)	11 (17)	156 (13)
Non Hispanic or non-Latino	27 (63)	100 (65)	287 (60)	178 (65)	83 (66)	28 (67)	40 (63)	743 (63)
Non-resident of the U.S.	10 (23)	36 (23)	97 (20)	62 (23)	34 (27)	10 (24)	11 (17)	260 (22)
Not reported	0 (0)	4 (3)	6 (1)	6 (2)	2 (2)	1 (2)	1 (2)	20 (2)
Current CCN region of patient - no. (%)								
US	27 (63)	101 (65)	322 (68)	193 (71)	81 (64)	31 (74)	50 (79)	805 (68)
Canada	2 (5)	16 (10)	27 (6)	23 (8)	10 (8)	2 (5)	7 (11)	87 (7)
Europe	3 (7)	7 (5)	22 (5)	19 (7)	4 (3)	0 (0)	0 (0)	55 (5)
Asia	4 (9)	10 (6)	74 (16)	10 (4)	16 (13)	7 (17)	4 (6)	125 (11)
Australia/New Zealand	5 (12)	7 (5)	6 (1)	12 (4)	12 (10)	0 (0)	0 (0)	42 (4)
Mideast/Afric	1 (2)	1 (1)	8 (2)	5 (2)	1 (1)	1 (2)	0 (0)	17 (1)
Central/South America	1 (2)	13 (8)	18 (4)	11 (4)	2 (2)	1 (2)	2 (3)	48 (4)
Calculated Graft (Product) type or all the products in the transplant - no. (%)								
Bone marrow	2 (5)	4 (3)	17 (4)	23 (8)	7 (6)	1 (2)	1 (2)	55 (5)
Peripheral blood stem cells	37 (86)	148 (95)	440 (92)	224 (82)	117 (93)	41 (98)	61 (97)	1068 (91)
Umbilical cord blood	4 (9)	3 (2)	17 (4)	26 (10)	2 (2)	0 (0)	1 (2)	53 (4)
Not reported	0 (0)	0 (0)	3 (1)	0 (0)	0 (0)	0 (0)	0 (0)	3 (0)

Characteristic	ALL Aggressive NK-cell Lk:	Enteropathy-type T-cell lymphoma:	Extranodal NK-T-cell:	Hepatosplenic gamma-delta T-cell:	Subcutaneous panniculitis T-cell:	Monomorphic epitheliotropic intestinal T-cell lymphoma	Nodal peripheral T-cell lymphoma with TFH phenotype	Total
Donor type - no. (%)								
Autologous	5 (12)	124 (80)	257 (54)	51 (19)	55 (44)	32 (76)	43 (68)	567 (48)
HLA-identical sibling	16 (37)	8 (5)	79 (17)	55 (20)	27 (21)	2 (5)	3 (5)	190 (16)
Twin	0 (0)	0 (0)	1 (0)	1 (0)	0 (0)	0 (0)	0 (0)	2 (0)
Other related	3 (7)	4 (3)	40 (8)	52 (19)	13 (10)	1 (2)	4 (6)	117 (10)
Well-matched unrelated (8/8)	5 (12)	12 (8)	61 (13)	62 (23)	15 (12)	7 (17)	9 (14)	171 (15)
Partially-matched unrelated (7/8)	3 (7)	1 (1)	10 (2)	11 (4)	3 (2)	0 (0)	0 (0)	28 (2)
Mis-matched unrelated (<= 6/8)	0 (0)	0 (0)	1 (0)	2 (1)	0 (0)	0 (0)	0 (0)	3 (0)
Multi-donor	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	1 (0)
Unrelated (matching not reported)	7 (16)	3 (2)	11 (2)	9 (3)	9 (7)	0 (0)	3 (5)	42 (4)
Cord blood	4 (9)	3 (2)	17 (4)	26 (10)	2 (2)	0 (0)	1 (2)	53 (4)
Not reported	0 (0)	0 (0)	0 (0)	4 (1)	1 (1)	0 (0)	0 (0)	5 (0)
Karnofsky score prior to HCT - no. (%)								
90-100%	23 (53)	95 (61)	301 (63)	168 (62)	83 (66)	27 (64)	39 (62)	736 (62)
< 90%	19 (44)	56 (36)	166 (35)	95 (35)	37 (29)	15 (36)	23 (37)	411 (35)
Not reported	1 (2)	4 (3)	10 (2)	10 (4)	6 (5)	0 (0)	1 (2)	32 (3)
Disease status prior to transplantation - no. (%)								
CR	30 (70)	108 (70)	329 (69)	155 (57)	66 (52)	32 (76)	40 (63)	760 (64)
PR	9 (21)	37 (24)	105 (22)	76 (28)	42 (33)	8 (19)	20 (32)	297 (25)
Resistant	3 (7)	7 (5)	29 (6)	32 (12)	15 (12)	2 (5)	3 (5)	91 (8)
Untreated	0 (0)	0 (0)	2 (0)	5 (2)	0 (0)	0 (0)	0 (0)	7 (1)
Unknown	1 (2)	3 (2)	12 (3)	5 (2)	3 (2)	0 (0)	0 (0)	24 (2)

Characteristic	ALL Aggressive NK-cell Lk:	Enteropathy-type T-cell lymphoma:	Extranodal NK-T-cell:	Hepatosplenic gamma-delta T-cell:	Subcutaneous panniculitis T-cell:	Monomorphic epitheliotropic intestinal T-cell lymphoma	Nodal peripheral T-cell lymphoma with TFH phenotype	Total
Time from diagnosis to transplant(months) - no. (%)								
<6-month	22 (51)	42 (27)	102 (21)	134 (49)	14 (11)	11 (26)	7 (11)	332 (28)
6-month-12-month	12 (28)	85 (55)	160 (34)	89 (33)	51 (40)	24 (57)	37 (59)	458 (39)
>=12-month	9 (21)	28 (18)	213 (45)	48 (18)	60 (48)	7 (17)	19 (30)	384 (33)
Not reported	0 (0)	0 (0)	2 (0)	2 (1)	1 (1)	0 (0)	0 (0)	5 (0)
Year of current transplant - no. (%)								
2008	2 (5)	5 (3)	27 (6)	13 (5)	7 (6)	0 (0)	0 (0)	54 (5)
2009	5 (12)	8 (5)	15 (3)	11 (4)	11 (9)	0 (0)	0 (0)	50 (4)
2010	5 (12)	9 (6)	33 (7)	9 (3)	8 (6)	0 (0)	0 (0)	64 (5)
2011	1 (2)	8 (5)	33 (7)	13 (5)	7 (6)	0 (0)	0 (0)	62 (5)
2012	6 (14)	15 (10)	37 (8)	16 (6)	8 (6)	0 (0)	0 (0)	82 (7)
2013	3 (7)	18 (12)	28 (6)	19 (7)	12 (10)	0 (0)	0 (0)	80 (7)
2014	6 (14)	10 (6)	35 (7)	20 (7)	6 (5)	0 (0)	0 (0)	77 (7)
2015	3 (7)	12 (8)	26 (5)	17 (6)	7 (6)	0 (0)	0 (0)	65 (6)
2016	0 (0)	17 (11)	32 (7)	17 (6)	11 (9)	0 (0)	0 (0)	77 (7)
2017	0 (0)	12 (8)	30 (6)	24 (9)	7 (6)	0 (0)	0 (0)	73 (6)
2018	3 (7)	10 (6)	26 (5)	23 (8)	5 (4)	8 (19)	7 (11)	82 (7)
2019	0 (0)	9 (6)	38 (8)	16 (6)	7 (6)	4 (10)	8 (13)	82 (7)
2020	2 (5)	6 (4)	28 (6)	21 (8)	8 (6)	9 (21)	8 (13)	82 (7)
2021	2 (5)	4 (3)	33 (7)	17 (6)	4 (3)	6 (14)	14 (22)	80 (7)
2022	1 (2)	7 (5)	36 (8)	22 (8)	10 (8)	6 (14)	11 (17)	93 (8)
2023	4 (9)	5 (3)	20 (4)	15 (5)	8 (6)	9 (21)	15 (24)	76 (6)
Follow-up among survivors - median (range)	73.3 (0.03-140)	61.0 (0.03-152)	44.6 (0.03-177)	48.6 (0.03-173)	49.3 (0.03-176)	24.7 (0.03-36.3)	12.4 (0.03-59.7)	44.6 (0.03-177)

I. Study Title

Outcomes of autologous stem cell transplantation in DLBCL relapsed/refractory to CD19 CAR T

II. Key words
CD19 CAR T, autologous stem cell transplant, relapsed refractory DLBCL

III. Principal Investigator Information
Name: Swetha Kambhampati (junior investigator), Alex Herrera (senior investigator)
Degree: MD
Email: skambhampati@coh.org, aherrera@coh.org
Institution name: City of Hope
Academic rank: Assistant Professor (Dr. Kambhampati), Associate Professor (Dr. Herrera)
Junior Investigator status: Assistant Professor at City of Hope
Current ongoing work with CIBMTR: PI of study evaluating outcomes of CAR T for transformed DLBCL, Dr. Herrera is Co-chair of Lymphoma Working Group

Principal Investigator Information
Name: Evandro Bezerra (junior investigator), Samantha Jaglowski (senior investigator)
Degree: MD
Email: evandro.bezerra@osumc.edu, sjaglowski@mcw.edu
Institution name: Junior investigator from The Ohio State University and senior investigator from Medical College of Wisconsin
Academic rank: Assistant Professor (Dr. Evandro Bezerra), Professor (Dr. Jaglowski)
Junior Investigator status: Assistant Professor at The Ohio State University
Current ongoing work with CIBMTR:
PI of Real world data of tecartus for B-ALL - presented oral abstract at ASH
Co-author of Bridging therapy to CART19 in DLBLC - co-author of oral abstract at ASH
Co-PI of Factor associated with outcomes of 2nd allograft for relapsed disease - co-author - ongoing
Co-PI of Outcomes of salvage therapies after CART19 in DLBCL and B-ALL - co-author – ongoing

Prinicipal Investigator: Baldeep Wirk, MD
Email baldeep.wirk@vcuhealth.org
Institution name: Virginia Commonwealth University Massey Comprehensive Cancer Center, Cellular Immunotherapy and Transplant Program, Richmond, Virginia
Academic Rank: Professor
Current ongoing work at CIBMTR: LK 22-01 Co-PI

IV. Proposed working committee
Lymphoma Group

V. Research Question
What is the feasibility, safety, and efficacy of autologous stem cell transplant after CD19 chimeric antigen receptor (CAR) T-cell therapy in patients with relapsed refractory DLBCL

VI. Research Hypothesis

We hypothesize that autologous stem cell transplant is feasible and safe in DLBCL relapsed/refractory to CART19, and a subset of patients can achieve durable remission with ASCT even after CAR T.

VII. Specific Objectives/Outcomes to be Investigated

Primary objective: Assess feasibility of auto-SCT after CD19 CAR T in R/R DLBCL

Secondary objectives:
1) Assess safety efficacy of auto-SCT after CD19 CAR T in R/R DLBCL
2) Assess efficacy of auto-SCT after CD19 CAR T in R/R DLBCL
3) To demonstrate underutilization of ASCT after CART19 in R/R DLBCL if proven to be feasible, safe and effective

Primary Endpoints:
-Feasibility as measured by median stem cell count collected, median number of apheresis collections needed, and number of patients requiring plerixafor

Secondary Endpoints:
- Safety measured by non-relapse mortality, time to engraftment and rate of incidence and severity of adverse events in the 100 days post auto-SCT
-efficacy as measured by progression-free survival, overall survival, and overall response rate of auto-SCT after CD19 CAR T

VIII. Scientific Impact

This is a novel study that aims to assess the feasibility, safety, and efficacy of auto-SCT after CD19 CAR T in patients with relapsed refractory DLBCL. Until 2022, second-line treatment of DLBCL consisted of platinum based chemotherapy regimens such as rituximab plus ifosfamide, carboplatin, and etoposide (R-ICE) or rituximab plus dexamethasone, cytosine arabinoside, and cisplatin (R-DHAP) followed by high-dose chemotherapy with auto-SCT in eligible patients. CD19 CAR T, initially approved in the third-line setting, more recently has transformed the second-line treatment landscape of DLBCL with the approval of axi-cel and liso-cel in

primary refractory or early relapsed DLBCL based on the ZUMA 7 and TRANSFORM studies respectively.[3,4] Results from ZUMA7 and TRANSFORM show a marked difference in median EFS between CAR T cells and standard treatments (8.3 months in ZUMA7 and 10 months in TRANSFORM vs 2 months with standard treatments).[3,4] Based on this data, CD19 CAR T became the standard-of-care as second line setting for DLBCL patients with primary refractory or early relapsed disease (relapse within 12 months of initial chemoimmunotherapy). Despite improved outcomes of R/R DLBCL with CART19 as second-line, most of the patients still relapse (~60%)[5,6]. Since incorporation of CART19 as standard of care as 2nd line therapy, the numbers of ASCT for R/R DLBCL have significantly declined. (CIBMTR slides of trends of ASCT in DLBCL). However, 50-70% of the patients with chemosenstive R/R DLBCL could still be cured with ASCT (50-70%).[7] That being said, a significant subset of patients is no longer being considered to a potential curative therapy option.

At this time, there is no known data regarding the feasibility, safety, and efficacy of auto-SCT after CD19 CAR T. This becomes an important question as CD19 CAR T is increasingly replacing auto-SCT in the second line setting in clinical practice and patients who relapse after CD19 CAR T have limited treatment options. We have abundant data demonstrating that CD19 CAR T is safe and effictive after auto-SCT[8-10] but there is no published data to our knowledge evaluating outcomes of auto-SCT after CD19 CAR T.[6,11,12]

Because of the known prolonged myelotoxicity effect from CART19, it is unknown their impact on hematopoietic stem cell mobilization and engraftment, and thus subsequently in the feasibility and safety of auto-SCT.[13,14] Also, given the different mechanism of action of CART19, immunotherapy, and auto-SCT, high-dose chemotherapy, we speculate that the mechanism of disease resistance may not overlap, and a subset of patients may be sensitive to auto-SCT despite resistance to CART19.[15,16]

Therefore, here we propose to assess the feasibility, safety, and efficacy of auto-SCT after CD19 CAR T, and if demonstrated feasible, safe and effective, we also aim to demonstrate the underutilization of auto-SCT as therapy resource for post-CART19 R/R DLBCL. These are novel research questions with significant clinical importance based on the changing paradigm in management of R/R DLBCL. Given the CIBMTR is the largest registry of both CART19 and auto-SCT, and also the current rare use of auto-SCT following CART19, the CIBMTR is the ideal data source to address the above clinically relevant research questions.

IX. Scientific Justification

Traditionally, second-line treatments for relapsed refractory (R/R) DLBCL consisted of high dose chemotherapy followed by autologous stem cell transplantation (auto-SCT) in chemosensitive patients. However more than half of the patients relapsed after auto-SCT.[2] CD19-directed CAR T cell therapy has recently

transformed the landscape of DLBCL with initial approval of three products (axicabtagene ciloleucel (axi-cel), tisagenlecleucel (tisa-cel), and lisocabtagene maraleucel (lisa-cel)) in the third-line setting based on pivotal ZUMA-1,[17] BELINDA,[18] and TRANSCEND[10] trials respectively. More recently, axi-cel and lisa-cel have also received approval for primary refractory/early relapse DLBCL patients based on ZUMA-7[3] and TRANSFORM[4] studies respectively. As CD19 CAR T therapy is increasingly used in clinical practice in the second line setting for patients with primary refractory or early relapsed DLBCL, the role of auto-SCT in these patients is coming into question. The feasibility, safety, and efficacy of auto-SCT after CD19 CAR T is unknown at this time. Patients who relapse after CD19 CAR T have limited treatment options, and it will be important to understand the outcomes of salvage chemotherapy followed by auto-SCT in the post CD19 CAR T setting to better understand if auto-SCT remains a treatment option for patients who relapse after second line CAR T. This CIBMTR study will assess retrospectively the feasibility, safety, and efficacy of auto-SCT after in CD19 CAR T in real-world clinical practice in patients with relapsed refractory DLBCL.

X. Participant Selection Criteria

Inclusion Criteria
-adult relapsed refractory DLBCL patient who have received autologous stem cell transplant after disease relapse/refractory to CD19 CAR T therapy

Exclusion Criteria
-patients who did not receive auto-SCT after CD19 CAR T
-patients with any underlying histology other than DLBCL (transformed DLBCL or FL Grade 3B is ok)
-treatment naïve patients

XIII. Data Requirements

-disease state: relapsed refractory DLBCL
-treatment: auto-SCT after CD19 CAR T

Baseline and treatment characteristics:
-gender
-age
-disease stage at diagnosis
-FISH BCL2, MYC, BCL6 gene rearrangements
-TP53 mutations
-DOUBLE HIT yes versus no
-prior lines of therapy prior to auto-SCT (including CD19 CAR T)

-bulky disease (< 5 cm vs ≥5 cm)
-IPI
-HCT-CI comorbidity index
-disease status prior at time of prior CD19 CAR T
-best response to prior CD19 CAR T
-disease status at time of auto-SCT
-interval from prior CAR T to auto-SCT
-history of CNS disease
-Bone marrow involvement by lymphoma: yes versus no
-type of prior CD19 CAR T (Axi-cel, Tisa ~~o~~-cel, Liso-cel)
-Lines of prior chemotherapy (median and range)
-salvage chemotherapy regimen prior to auto-SCT: yes versus no
-conditioning regimen for auto-transplant: BEAM vs other

Post treatment characteristics:
- CD34+ per kg stem cell count ~~collected and~~ infused
-number of apheresis collections needed for stem cell mobilization
-plerixafor needed (yes/no)
- Time to neutrophils engraftment
- Time to platelets engraftment
- Rate of engraftment failure (yes/no)
- Non-relapse mortality
-best response and date of best response to auto-SCT
-date of progression, date of last response assessment
-cumulative incidence of relapse
-date of death or last contact post auto-SCT
-any grade and ≥ grade 3 adverse events in first 100 days post auto-SCT
Causes of death: relapse versus other

-Yearly number of ASCT done prior to CART19 approval as 3rd line, after approval as 3rd line and since approval as 2nd line.

XI. PRO Requirements
-study does not have any PRO requirements

XII. Sample Requirements
-study does not have any sample requirements

XIII. Non-CIBTMR Data Source
N/A

XIV. References
See below

XV. Conflicts of Interest

-Swetha Kambhampati:
Research funding: GNE, Genmab, and ADC-T, Advisory: Ipsen
-Alex Herrera:
Bristol Myers Squibb – research funding, consultancy
Genentech – research funding, consultancy
Merck – research funding, consultancy
Seattle Genetics - research funding, consultancy
KiTE Pharma - research funding
Gilead Sciences – research funding
AstraZeneca – research funding, consultancy
Karyopharm – consultancy
ADC Therapeutics – research funding, consultancy
Takeda – consultancy
Tubulis - consultancy
Regeneron - consultancy
Genmab - consultancy
Pfizer - consultancy
Caribou - consultancy
Adicet Bio - consultancy
Abbvie – consultancy

Evandro Bezerra:
Novartis: consultancy
Kyverna therapeutics: consultancy

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10. CIBMTR slides of trend of ASCT in DLBCL after CART19: https://cibmtr.org/CIBMTR/Resources/Summary-Slides-Reports

PROP 2310-24; 2310-209; 2310-231: Outcomes of autologous stem cell transplantation in DLBCL relapsed/refractory to CD19 CART

Table 1. Characteristics of patients who underwent auto HCT post-CAR-T

Characteristic	N (%)
No. of patients	41
No. of centers	28
TED or CRF track - no. (%)	
TED	39 (95)
CRF	1 (2)
Not reported	1 (2)
Age group - no. (%)	
Median (min-max)	53.7 (18.0-77.8)
18-40	8 (19.5)
41-60	17 (41.5)
>60	16 (39.0)
Sex - no. (%)	
Male	30 (73)
Female	11 (27)
Race - no. (%)	
White	33 (80)
Black or African American	1 (2)
Asian	1 (2)
American Indian or Alaska Native	1 (2)
Not reported	5 (12)
Ethnicity - no. (%)	
Hispanic or Latino	7 (17)
Not Hispanic or Latino	30 (73)
Non-resident of the U.S.	1 (2)
Not reported	3 (7)
Current CCN region of patient - no. (%)	
US	40 (98)
Canada	1 (2)
Calculated Graft (Product) type or all the products in the transplant - no. (%)	
Peripheral blood stem cells	41 (100)

Characteristic	**N (%)**
Karnofsky score prior to HCT - no. (%)	
90-100%	18 (44)
< 90%	21 (51)
Not reported	2 (5)
Disease status prior to transplantation - no. (%)	
CR	21 (51)
PR	10 (24)
Resistant	7 (17)
Unknown	3 (7)
Time from diagnosis to transplant(months) - no. (%)	
<6-month	2 (5)
6-month-12-month	3 (7)
>=12-month	36 (88)
Year of current transplant - no. (%)	
2018	3 (7)
2019	4 (10)
2020	11 (27)
2021	7 (17)
2022	7 (17)
2023	9 (22)
Follow-up among survivors - median (range)	18.7 (0.03-49.0)

Field	Response
Proposal Number	2310-130-DI
Proposal Title	Comparative Effectiveness of Glofitamab and Axicabtagene Ciloleucel in Large B Cell Lymphoma: A CIBMTR-based Matching-adjusted Indirect Comparison Analysis
Key Words	Large B cell lymphoma, CAR-T therapy, Bispecific antibody, glofitamab, axicabtagene ciloleucel
Principal Investigator #1: - First and last name, degree(s)	Mengyang Di, MD PhD
Principal Investigator #1: - Email address	mydi@fredhutch.org
Principal Investigator #1: - Institution name	Fred Hutch Cancer Center
Principal Investigator #1: - Academic rank	Assistant professor
Junior investigator status (defined as ≤5 years from fellowship)	Yes
Do you identify as an underrepresented/minority?	No
Principal Investigator #2 (If applicable): - First and last name, degree(s):	Mazyar Shadman, MD MPH
Principal Investigator #2 (If applicable): - Email address:)	mshadman@fredhutch.org
Principal Investigator #2 (If applicable): - Institution name:	Fred Hutch Cancer Center
Principal Investigator #2 (If applicable): - Academic rank:	Associate professor
Junior investigator status (defined as ≤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:	Mengyang Di, MD PhD
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.	Yes
If you have already spoken with a scientific director or working committee chair regarding this study, then please specify who:	Mehdi Hamadani, MD
RESEARCH QUESTION:	In patients with large B cell lymphoma who received at least two prior lines of therapy, what is the relative effectiveness of a recently approved bispecific antibody drug, glofitamab, compared with axicabtagene ciloleucel (axi-cel)?

Field	Response
RESEARCH HYPOTHESIS:	In the third line setting and beyond, glofitamab is likely associated with an inferior efficacy in patients with relapsed/refractory large B cell lymphoma, compared with axi-cel.
SPECIFIC OBJECTIVES/OUTCOMES TO BE INVESTIGATED (Include Primary, Secondary, etc.):	Primary objective: 1) To compare progression free survival between glofitamab and axi-cel Secondary objectives: 1) To compare overall survival between glofitamab and axi-cel 2) To compare non-relapse mortality between glofitamab and axi-cel 3) To compare cause of death between glofitamab and axi-cel 4) To compare response (including objective and complete response) and duration of response (if available) between glofitamab and axi-cel 5) To compare grade ≥3 adverse events (cytokine release syndrome, immune effector cell-associated neurotoxicity syndrome, infection) between glofitamab and axi-cel
SCIENTIFIC IMPACT: Briefly state how the completion of the aims will impact participant care/outcomes and how it will advance science or clinical care.	Glofitamab was recently approved by the FDA to treat patients with large B cell lymphoma (LBCL) who have received at least two prior lines of therapy given its high efficacy and acceptable safety profile in a single-arm trial (1). The approval adds an efficacious treatment option in the relapsed/refractory (r/r) setting. However, it is unclear how glofitamab best fits into the current treatment paradigm for r/r LBCL. Particularly, the clinical effectiveness and safety of glofitamab relative to other commonly used therapies in the r/r setting remains largely unknown. Axi-cel was the first chimeric antigen receptor T (CART) cell therapy approved for r/r LBCL (2, 3) and remains one of the most used therapies in this population. To compare these two treatments (e.g, for the same line of therapy) can provide valuable data to potentially inform how to sequence these therapies for the future. The results of this analysis will likely impact clinical practice.

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.	Glofitamab was recently approved by the FDA to treat patients with LBCL who have received at least two prior lines of therapy (1). The approval was based on a single-arm trial (1). It is unclear on the relative clinical efficacy of glofitamab, compared with other commonly used therapies for the relapsed/refractory setting, such as chimeric antigen receptor T (CART) cell therapy. Such comparisons (e.g., glofitamab vs. axi-cel proposed in this study) has the potential to inform clinical practice. To date, there have not been head-to-head comparisons in clinical trials; there will unlikely be a trial of such in foreseeable future. CIBMTR data provides a very unique opportunity for such an important comparison using the matching-adjusted indirect comparison (MAIC) method (4).
PARTICIPANT SELECTION CRITERIA: State inclusion and exclusion criteria.	1) Patients with a diagnosis of LBCL, including diffuse large B cell lymphoma, NOS, transformed follicular lymphoma, high grade B cell lymphoma, and primary mediastinal B cell lymphoma 2) Treatment with axi-cel 3) At least 2 prior lines of treatment 4) No prior history of other CAR-T therapy
Does this study include pediatric patients?	No
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.	Following patient characteristics are required for patients: a. Age b. Sex c. Ethnicity d. ECOG at treatment e. Ann arbor stage at treatment f. Bulky disease at treatment g. Number of prior lines of therapy h. Prior autologous transplant i. Refractoriness to any therapy j. Refractoriness to last previous therapy k. Primary refractoriness l. Refractoriness to previous anti-CD20 therapy (if available) Using the CIBMTR database, a cohort of patients with large B cell lymphoma who received axi-cel will be selected after matching with the published baselines characteristics of patients who were treated with glofitamab on the phase II clinical trial (1). The selected cohort using the patient level data will be compared to the glofitamab cohort separately. The baseline characteristics and outcomes are described above.
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 desc	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 o	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
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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

PROP 2310-130: Comparative effectiveness of glofitamab and axicabtagene ciloleucel in large B cell lymphoma: a CIBMTR-based matching-adjusted indirect comparison analysis

Table 1. Characteristics of adult patients who underwent CAR-T for LBCL with axi-cel

Characteristic	**N (%)**
No. of patients	4468
No. of centers	141
Age groupings - no. (%)	
Median (min-max)	62.5 (18.0-90.8)
18-69 years old	3451 (77.2)
>=70 years old	1017 (22.8)
Recipient Sex - no. (%)	
Male	2819 (63)
Female	1648 (37)
Not reported	1 (0)
Recipient race - no. (%)	
White	3418 (76)
African-American	236 (5)
Asian	249 (6)
Pacific Islander	11 (0)
Native American	20 (0)
More than one race	24 (1)
Unknown	233 (5)
Not reported	277 (6)
Ethnicity - no. (%)	
Hispanic or Latino	534 (12)
Non-Hispanic or non-Latino	3473 (78)
Not reported	461 (10)
Karnofsky performance score prior to CT - no. (%)	
90-100	1759 (39)
80	1394 (31)
< 80	876 (20)
Not reported	439 (10)
Disease status prior to CT - no. (%)	

Characteristic	**N (%)**
CR	231 (5)
PR	951 (21)
Resistant	2818 (63)
Untreated	255 (6)
Unknown	212 (5)
Not reported	1 (0)
Time from initial diagnosis to CT - no. (%)	
>= 0 to < 6 months	534 (12)
6 to 12 months	1543 (35)
> 12 months	2390 (53)
Not reported	1 (0)
Total number of lines of therapy - no. (%)	
2	1249 (28)
>= 3	2405 (54)
Not reported	814 (18)
Prior HCT - no. (%)	
No	3526 (79)
Yes	927 (21)
Not reported	15 (0)
Year of CT - no. (%)	
2017	5 (0)
2018	385 (9)
2019	662 (15)
2020	698 (16)
2021	644 (14)
2022	1163 (26)
2023	911 (20)
Follow-up among survivors - median (range)	14.1 (0.9-62.3)