Not for publication or presentation

MINUTES AND OVERVIEW PLAN
CIBMTR WORKING COMMITTEE FOR LYMPHOMA
San Antonio, TX
Wednesday, February 21, 2024, 1:00 - 3:00 PM CT

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1. Introduction

The CIBMTR Lymphoma Working Committee was called to order at 1 pm on Wednesday, February 21, 2024, by Dr. Craig Sauter, who introduced the working committee leadership, and highlighted leadership's conflict of interest disclosures per CIBMTR policy. He indicated the availability of publicly available dataset for secondary analyses and explained the difference between the TED and CRF data collection forms. Dr. Craig Sauter emphasized the process of becoming a Working Committee member and outlined the Working Committee goals, expectations, limitations, and the voting guidelines. In addition, rules of authorship were emphasized: 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. He encouraged junior faculty, fellows, and assistant professors to collaborate actively with the Lymphoma Writing Committee. Dr. Hamadani provided gratitude to outgoing chair - Dr. Craig Sauter for his contributions to LYWC on behalf of CIBMTR. Dr. Hamadani provided an update on the Working Committee productivity including publications, presentations at international conferences and went over the three studies in progress and detailed the goals for these studies.

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2. 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.***

3. Studies in progress

(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.**

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. Then Dr. Hamadani 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.

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

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5. Future/proposed studies

Dr. Alex Herrera 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) **Mazyar Shadman:** 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 (Mazyar Shadman/Mehdi Hamadani)

Dr Shadman presented the concept in-person. The proposed study wants to look at comparative efficacy and safety profile of cases treated with commercial CAR-T product axi-cel and bispecific agent - mosunetuzumab. CAR-T data will be obtained from CIBMTR registry and mosunetuzumab data will be obtained from GO29781 study followed by matching reweighting.
The proposal was opened for questions from the audience. A clarification was requested on matching of the 2 cohorts based on sample size which was responded as in following approach of careful consideration of number of variables for matching to find the balance as higher number of variables leads to over-adjustment in some instances. Statistical director of LYWC also contributed in answering the question and added propensity score calculation approach followed by weight application to create balance among CIBMTR and published data. Another question was raised regarding consideration of tisa-cel in the study and was answered that enrollment of tisa-cel for this particular indication is very slow and adding these cases into study will add heterogeneity to analysis. Additionally, follow-up of tisa-cell cases will not be long enough to be considered into analysis. A suggestion was also received to include ZUMA5 clinical trial cases as control to make study stronger. Another question was raised related to impact of transformation which was answered by providing the criteria of exclusion of reported transformed cases. Another suggestion was received to add hematopoietic recovery data as outcome. However, published data doesn't reported this outcome because of which this outcome cannot be compared among 2 cohorts. Last question was if CIBMTR collects data related to bispecific agents in registry. Dr. Hamadani responded that CIBMTR registry collects data mainly related to cellular therapies, however, there might be industry funded venues within CIBMTR where bispecific agents are compared with cellular therapies reported to CIBMTR.

(b) **Aung Tun**: Autologous stem cell transplant vs chimeric antigen receptor T-cell therapy (CAR-T) in patients with diffuse large B-cell lymphoma who relapsed or progressed in central nervous system (Aung Tun / Stephen Ansell)

Dr. Tun presented the proposal on behalf of study group. The proposed study hypothesizes that autologous stem cell transplantation is associated with superior progression-free survival (PFS) than CAR-T in patients with chemo-sensitive relapsed secondary Nervous System lymphoma (SCNSL). It also hypothesizes that CAR-T therapy is reasonably safe with a manageable toxicity profile in patients with SCNSL.
The proposal was opened for questions from the audience. A member of audience asked if bridging therapy or use of other modalities like ibrutinib will be captured in the study. Dr. Tun responded that reporting use of other modalities and bridging therapy will be helpful in the study even though this data is under-reported due to its complexity. A clarification was requested regarding criteria of conditioning regimen in transplant cohort which was answered by Dr. Tun

that all conditioning regimens will be looked on including BEAM. A suggestion was provided by a member of audience that comparing outcomes among primary/refractory cases and relapsed cases among these cohorts will be a better comparison to avoid potential biases in this study. Another suggestion was also received related to exclusion of CAR-T cases who received any prior autologous stem cell transplant to avoid overlapping.

(c) **Caroline Lee:** Real-world outcomes of second-line CD19 CAR T-cell therapy for large B-cell lymphoma (Caroline Lee / Saurabh Dahiya / Mazyar Shadman / Swetha Kambhampati / Alex Herrera / Maria Silvina Odstrcil Bobillo / Catherine Joy Lee)

Dr. Lee presented the proposal on behalf of study group. The rational of the study is that safety and efficacy of standard-of-care (SOC) second-line CD19 CAR T-cell therapy are unknown in the real-world population which includes patients with high-risk disease and/or comorbid conditions excluded from the registrational trials. The proposal hypothesize that the real-world safety and efficacy outcomes are similar to those reported in the registrational trials: ZUMA-7, TRANSFORM, and PILOT.
Study was opened for questions. A suggestion was received to parse out the patients who contact transplant centers after receiving treatment from primary physicians as it does not lead to a case where all the therapies received by patient are known to the center. Dr. Hamadani explained this as a complicated concept as data for bridging therapy is determined by CIBMTR and is not reported by centers as it is, however, it can be looked upon with handful data. Another suggestion was also received related to consideration of time to lines of therapies which can help determine intent, early therapy failure, and bridging therapy prior to infusion. Dr. Pasquini explained issues in determination of time of lines of therapies as centers sometimes do not report timings of lines of therapies and also have misunderstandings about definition of bridging therapy because of which a question related to collection of bridging therapy provision is not introduced on CIBMTR forms directly.

Dr. Shadman presented last 3 proposal concepts.

(d) **Mehdi Hamadani:** Hematopoietic cell transplantation for rare mature T-cell lymphomas. A Basket – mentoring study proposal (Mehdi Hamadani / Mazyar Shadman / Craig Sauter / Cameron Turtle / Alex Herrera)

Dr. Hamadani presented the proposal having objective of looking at survival outcomes, non-relapse mortality, relapse/progression and toxicity measures post HCT for rare mature T-cell lymphomas. Another goal of the study is to involve multiple junior investigators in leading a registry project. He also mentioned if LYWC members receives the proposal positively, the LYWC will seek guidance from CIBMTR Foster group for a fair way of identifying junior faculty to lead sub-projects.
The proposal was opened for questions. A suggestion was received to look on a cohort separately having cases which were treated with consolidation intent within 6 months of induction therapy for this study. Dr. Hamadani reflected the numbers of feasible cases among sub-diseases and agreed on looking consolidated cases separately. Another question was raised related to lumping of other DLI proposals having same criteria and objectives with this proposal. Dr. Hamadani responded that due to limited granularity of information for these sub-diseases data, lumping of

other DLI proposals is not that easy. However, publicly available datasets can be used to analyze such data if someone is interested.

(e) **Evandro Bezerra:** Outcomes of autologous stem cell transplant in large B-cell lymphoma related/refractory to CART19 (Evandro Bezerra / Samantha Jaglowski / Swetha Kambhampati / Alexa Herrera / Baldeep Wirk)

Dr. Bezzera presented the concept to the audience on behalf of group. The study hypothesizes that autologous stem cell transplant (ASCT) is feasible and safe if relapsed/refractory large B-cell lymphoma after CART 19, and may be effective in subset of patients. The study will determine the feasibility, safety, and effectiveness of ASCT post-CART19. If ASCT post-CART19 is proven to be feasible, safe, and effective, it may increase access to ASCT for a population for which currently the only curative therapy option is allogeneic stem cell transplant which is associated with high morbid-mortality.
The proposal was opened for questions. A question was raised if cases who receive pseudo bridging therapy can be separated from cases who receive real bridging therapy prior to infusion. Dr. Bezzera responded that just because study looks at autologous transplant post CAR-T infusion so lines of therapies prior to CAR-T infusion will not be looked upon. Another question was raised on feasibility of the study which was responded with conduction of descriptive analysis only. A clarification was requested if those cases will be included in the study who had autologous transplant prior to CAR-T and Dr. Bezzerra clarified by mentioning exclusion of those cases. Another clarification was made related to lines of therapies if CAR-T has to be given as second line post autologous transplant which was responded as CAR-T given in any line of therapies post-autologous stem cell transplant will be included in the study.

(f) **Mengyang Di:** Comparative effectiveness of glofitamab and axicabtagene ciloleucel in large B cell lymphoma: A CIBMTR-based matching-adjusted indirect comparison analysis (Mengyang Di / Mazyar Shadman)

Dr. Di presented the concept to the audience. The study hypothesizes better efficacy of axi-cel than glofitamab in lines of therapies. Matching-adjusted indirect comparison analysis will be performed for selecting patients from CIBMTR database. The results of study will cover the gap of knowledge pertaining to relative efficacy between CAR-Ts and bispecific agents and can lead to changes in clinical practice.
The proposal was opened for questions. A question was raised related to ways to deal with cases from glofitamab cohort that has received prior CAR-T which was responded by Dr. Di as one of the limitations. She also mentioned that progress-free survival at 2 years follow-up on 2 cohorts where one received prior CAR-T and other did not was similar in one of studies presented at ASH meeting. So, it is assumed that this factor will not impact the findings considering the caveat of comparing real-world data and clinical trial data. Another question was raised in regard to consideration of only one drug – glofitamab in the bispecific cohort which was answered as it was the first approved bispecific agent for the large B cell lymphoma indication and thus is the primary reason to be included solely in the study. Another question raised was related to finding out ways of unsuccessful CAR-T infusions due to factors like prolonged manufacturing where clinicians prefer to opt CAR-T infusion but change the treatment due to some factors as this is one of the biasing in the real-world clinical practice. Dr. Di mentioned this as one of the other

limitations of the study. An online question was also addressed related to explanation of results pertaining to sequencing of therapies. Dr. Di explained that based on hypothesis, axi-cel treatment should be more efficacious than glofitamab in the clinical settings. If axi-cel leads to more durable progression-free survival, it can be given prior to bispecific agents for large B cell lymphoma in second or greater line of therapy settings.

Proposed studies; not accepted for consideration at this time

Dr. Hamadani thanked all the investigators who submitted their concepts but were not accepted for presentation.

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.*

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.

Not for publication or presentation

Working Committee Overview Plan 2024-2025		
Study number and title	**Current 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 nonHodgkins 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
LY24-01: Hematopoietic cell transplantation for rare mature T-cell lymphomas.	Protocol Development	5