



A G E N D A

CIBMTR WORKING COMMITTEE FOR GRAFT-VERSUS-HOST DISEASE

Salt Lake City, UT

Friday, February 6, 2026, 1:00 – 3:00 PM (MT)

Co-Chair:	Zachariah DeFilipp, MD; Massachusetts General Hospital, Boston, MA; Phone: 617-726-5765; E-mail: zdefilipp@mgh.harvard.edu
Co-Chair:	Nosha Farhadfar, MD; Methodist Hospital, San Antonio, TX; Phone: 972-974-8889; E-mail: nosha.farhadfar@hcahealthcare.com
Co-Chair:	Pooja Khandelwal, MD; Cincinnati Children's Hospital Medical Center, Cincinnati, OH; Phone: 513-803-9063; E-mail: pooja.khandelwal@cchmc.org
Co-Chair:	Fotios (Frank) Michelis, MD, PhD; Princess Margaret Cancer Centre, Toronto, Canada; E-mail: fotios.michelis@uhn.ca
Scientific Director:	Najla El Jurdi, MD; National Institutes of Health (NCI), Bethesda, MD; Phone: 612-624-5422; E-mail: Najla.eljurdi@nih.gov
Statistical Director:	Tao Wang, PhD; CIBMTR® (Center for International Blood and Marrow Transplant Research, Milwaukee, WI; Phone : 414-955-4339; E-mail : taowang@mcw.edu
Statistician:	Jakob Devos, MS; CIBMTR® (Center for International Blood and Marrow Transplant Research, Milwaukee, WI; Phone: 414-955-3726; E-mail : jdevos@mcw.edu
Page Scholar:	Arpita Ghandi, MD, MS, BS; Oregon Health and Science University, Portland, OR; E-mail: gandhiar@ohsu.edu

1. Introduction

- a. Minutes from February 2025 ([Attachment 1](#))

2. Accrual summary ([Attachment 2](#))

3. Presentations, Publications or Submitted papers

- a. **GV22-01** Nishitani M, Graham RT, Wang T, DeVos JD, Lee SJ, Spellman SR, Kitko CL, MacMillan ML, DeFilipp Z, Gray AN, Williams KM, Takahashi T, Schoettler ML, Hashem H, Rangarajan HG, Prestidge T, Ringden O, Hamilton BK, Sharma A, Nusrat R, El Jurdi N, Bhatt NS, Duncan CN, Qayed M. Impact of age on graft-vs-host disease and overall survival in pediatric hematopoietic cell transplant recipients. *Blood Advances*. doi:10.1182/bloodadvances.2025017393. Epub 2025 Dec 12.
- b. **GV22-02** Chronic GVHD Risk Index: A clinical risk assessment score for development of moderate-severe chronic graft-versus-host disease after hematopoietic cell transplantation (A Im/ S Pavletic). *Submitted*.
- c. **GV21-02** Determinants of Immune Suppression Discontinuation in the Modern Era: A CIBMTR Analysis of 18,642 Subjects. (J Pidala). *Oral Presentation, Tandem Meetings 2025*.
- d. **GV23-01a** The Effect of CNI- vs. PTCy-based GVHD Prophylaxis on HLA-Matched HCT in the MAC setting (P Munshi/ Z ZhouS McCurdy/ N Ranjeesh). *Oral Presentation, ASH 2025*.

- e. **GV23-02** Reduced chronic graft versus host disease after allogeneic HSCT with cryopreserved peripheral blood stem cell grafts: A CIBMTR analysis (R Soiffer/ K Maurer). **Oral Presentation, ASH 2025.**
- f. **GV23-01b** The Effect of CNI- vs. PTCy-based GVHD Prophylaxis on HLA-Matched HCT in the RIC setting (P Munshi/ Z Zhou/ S McCurdy/ N Ranjeesh). **Poster Presentation, Tandem Meetings 2026.**
- g. **GV24-01** PTCy/sirolimus versus PTCy/calcineurin-inhibitor-based graft-versus-host disease prophylaxis (R Mehta/ N Bejanyan/ J Pidala). **Poster Presentation, Tandem Meetings 2026.**

4. Studies in progress ([Attachment 3](#))

- a. **GV20-01** Machine learning models and clinical decision support tool for acute and chronic graft-versus-host disease in patients with acute myelogenous leukemia undergoing allogeneic transplants (T Kindwall-Keller/ B Lobo). **Manuscript Preparation.**
- b. **GV20-02** Prediction of graft-versus-host disease in recipients of hematopoietic cell transplant from a single mismatched unrelated donor using a highly-multiplexed proteomics assay: MHC-PepSeq (K Sandhu/ J Altin/ M Askar/ R Nakamura). **Manuscript Preparation.**
- c. **GV21-02** Determinants of successful discontinuation of immune suppression following allogeneic hematopoietic cell transplantation: A validation study (J Pidala/ B Logan/ M Martens). **Analysis.**
- d. **GV23-01a** The effect of CNI- vs. PTCy-based GVHD Prophylaxis on HLA-Matched HCT in the MAC setting (P Munshi/ R Nath/ Z Zhou/ S McCurdy). **Manuscript Preparation.**
- e. **GV23-01b** The effect of CNI- vs. PTCy-based GVHD Prophylaxis on HLA-Matched HCT in the RIC setting (P Munshi/ R Nath/ Z Zhou/ S McCurdy). **Analysis.**
- f. **GV23-02** Incidence of chronic graft versus host disease in cryopreserved versus fresh peripheral blood allogeneic hematopoietic stem cell grafts (R Soiffer/ K Maurer). **Manuscript Preparation.**
- g. **GV24-01** Post-transplantation cyclophosphamide (PTCy)/ sirolimus versus PTCy/calcineurin-inhibitor-based graft-versus-host disease prophylaxis (R Mehta/ N Bejanyan/ J Pidala). **Analysis.**
- h. **GV24-02** Effect of acute graft-versus-host disease on the outcome of hematopoietic cell transplantation with post-transplantation cyclophosphamide: a CIBMTR analysis (A Hadjis/ S McCurdy). **Data File Preparation.**
- i. **GV24-03** Differences in the characteristics of acute and chronic graft-versus-host disease after post-transplantation cyclophosphamide versus conventional calcineurin inhibitor-based graft-versus-host disease prophylaxis (R Mehta/ R Saliba). **Data File Preparation.**
- j. **GV25-01** Abatacept versus post-transplantation cyclophosphamide as GVHD prophylaxis after allogeneic hematopoietic stem cell transplantation for myeloid malignancies. (S Mirza/ J Pidala). **Protocol Development.**

5. Future/proposed studies

- a. **PROP 2508-10** Overall Survival after Post-Transplant Cyclophosphamide (PTCy) Peripheral Blood Hematopoietic Cell Transplantation (HCT) Differs by Race, Ethnicity, and Donor (M Herr) ([Attachment 4](#))
- b. **PROP 2509-46** Safety and Efficacy of Donor Lymphocyte Infusions following Mismatched Unrelated Donor Transplants in the Post Transplant Cyclophosphamide Era (P Munshi) ([Attachment 5](#))
- c. **PROP 2509-91** The Effect of PTCy versus Non-PTCY GVHD Prophylaxis in the AYA Population on GVHD Free Relapse Free Survival (N Amirmokhtari/ M Umair Mushtaq) ([Attachment 6](#))
- d. **PROP 2509-167** Real-World Outcomes of Post-Transplantation Cyclophosphamide Versus Calcineurin inhibitor-based Graft-Versus-Host Disease Prophylaxis for Second Allogeneic Hematopoietic Cell Transplantation (M Hameed/ T Nishihori) ([Attachment 7](#))

Proposed studies; not accepted for consideration at this time

- e. **PROP 2505-04** Related donor transplantation with posttransplant cyclophosphamide vs ATG for myelodysplastic neoplasms (L Siyi). ***Dropped due to overlap with current study/publication.***
- f. **PROP 2509-40** Early versus Standard Timing of Immunosuppression Taper Post-transplant and Its effect on outcomes after Allogeneic HCT for Malignant Hematological Disease (S Prem Sudha). ***Dropped due to need of supplemental data.***
- g. **PROP 2509-73** Identifying the ideal alemtuzumab dosing and timing (L J Arcuri). ***Dropped due to need of supplemental data.***
- h. **PROP 2509-137** Targeting mitochondrial metabolism for the treatment of Graft-versus host disease and tumor relapse after allogeneic bone marrow transplantation (H Nguyen). ***Dropped due to need of supplemental data.***
- i. **PROP 2509-195** Real-World Evaluation of Patient-Reported Outcomes in Chronic Graft-Versus-Host Disease Following Allogeneic Transplantation Using PTCy- or Calcineurin-Based GVHD Prophylaxis (C Graham). ***Dropped due to need of supplemental data.***

6. Other business



MINUTES

CIBMTR WORKING COMMITTEE FOR GRAFT-VERSUS-HOST DISEASE

Honolulu, HI

Friday, February 14, 2025, 1:00 – 3:00 PM

Co-Chair:	Carrie Kitko, MD; Vanderbilt University Medical Center, Nashville, TN; Phone: 615-936-2088; E-mail: carrie.l.kitko@vumc.org
Co-Chair:	Nosha Farhadfar, MD; Methodist Hospital, San Antonio, TX; Phone: 972-974-8889; E-mail: nosha.farhadfar@hcahealthcare.com
Co-Chair:	Zachariah DeFilipp, MD; Massachusetts General Hospital, Boston, MA; Phone: 617-726-5765; E-mail: zdefilipp@mgh.harvard.edu
Scientific Director:	Stephanie Lee, MD, MPH; Fred Hutchinson Cancer Research Center, Seattle, WA; Phone: 206-667-6190; E-mail: sjlee@fredhutch.org
Scientific Director:	Stephen Spellman, MBS; CIBMTR® (Center for International Blood and Marrow Transplant Research), Minneapolis, MN; Phone: 763-406-8334; E-mail: sspellma@nmdp.org
Statistical Director:	Tao Wang, PhD; CIBMTR® (Center for International Blood and Marrow Transplant Research, Milwaukee, WI; Phone : 414-955-4339; E-mail : taowang@mcw.edu
Statistician:	Jakob Devos, MS; CIBMTR® (Center for International Blood and Marrow Transplant Research, Milwaukee, WI; E-mail : jdevos@mcw.edu

1. Introduction

- a. Minutes from February 2024 (Attachment 1)

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3. Presentations, Publications or Submitted papers

- a. **GV18-02** Wallis W, Gulbis AM, Wang T, Wang T, Lee CJ, Sharma A, Williams KM, Nishihori T, Prestidge T, Gowda L, Byrne M, Krem MM, MacMillan ML, Kitko CL, Pidala J, Spellman SR, Lee SJ, Alousi AM. Incidence of bacterial blood stream infections in patients with acute GVHD. **Bone Marrow Transplantation. doi:10.1038/s41409-024-02426-9. Epub 2024 Oct 18.**
- b. **GV21-01/GV22-03** Farhadfar N, Rashid N, Chen K, DeVos JD, Wang T, Ballen KK, Beitinjaneh A, Bhatt VR, Hamilton BK, Hematti P, Gadalla SM, Solomon SR, El Jurdi N, Lee CJ, MacMillan ML, Rangarajan HG, Schoemans HM, Sharma A, Spellman SR, Wingard JR, Lee SJ. Racial, ethnic and socioeconomic diversity and outcomes of patients with graft-versus-host disease: A CIBMTR analysis. **Blood Advances. 2024 Sep 24; 8(18):4963-4976. doi:10.1182/bloodadvances.2024013074. Epub 2024 May 24. PMC11496972.**
- c. **GV18-04** Development of a risk score to predict the incidence of acute graft versus host disease after allogeneic hematopoietic cell transplantation. (C Ulschmid). **Submitted.**
- d. **GV22-01** Graft Vs Host Disease (GVHD) in Pediatric Hematopoietic Stem Cell Transplant (HCT) Recipients and Impact on Overall Survival: A CIBMTR Analysis (M Nishitani/ C Duncan/ R Graham/ M Qayed). **Oral Presentation, ASH 2024.**

- e. **GV21-02** Determinants of successful discontinuation of immune suppression following allogeneic hematopoietic cell transplantation: A validation study (J Pidala/ B Logan/ M Martens). **Oral Presentation, Tandem 2025.**

4. Studies in progress (Attachment 3)

- a. **GV20-01** Machine learning models and clinical decision support tool for acute and chronic graft-versus-host disease in patients with acute myelogenous leukemia undergoing allogeneic transplants (T Kindwall-Keller/ B Lobo). **Analysis.**
- b. **GV20-02** Prediction of graft-versus-host disease in recipients of hematopoietic cell transplant from a single mismatched unrelated donor using a highly-multiplexed proteomics assay: MHC-PepSeq (K Sandhu/ J Altin/ M Askar/ R Nakamura). **Manuscript Preparation.**
- c. **GV21-02** Determinants of successful discontinuation of immune suppression following allogeneic hematopoietic cell transplantation: A validation study (J Pidala/ B Logan/ M Martens). **Analysis.**
- d. **GV22-01** Acute and chronic graft versus host disease in infants and toddlers following hematopoietic cell transplantation (M Nishitani/ C Duncan/ R Graham/ M Qayed). **Manuscript Preparation.**
- e. **GV22-02** Chronic GVHD Risk Index: A clinical risk assessment score for development of moderate-severe chronic graft-versus-host disease after hematopoietic cell transplantation (A Im/ S Pavletic). **Manuscript Preparation.**
- f. **GV23-01** The effect of CNi- vs. PTCy- (with or without MMF) based GVHD prophylaxis on HLA-matched HCT (R Mehta/ P Munshi/ R Nath/ Z Zhou/ S Mccurdy). **Protocol Development.**
- g. **GV23-02** Incidence of chronic graft versus host disease in cryopreserved versus fresh peripheral blood allogeneic hematopoietic stem cell grafts (K Maurer). **Datafile Preparation.**
- h. **GV24-01** Post-transplantation cyclophosphamide (PTCy)/ sirolimus versus PTCy/calcineurin-inhibitor-based graft-versus-host disease prophylaxis (R Mehta/ N Bejanyan). **Protocol Development.**
- i. **GV24-02** Effect of acute graft-versus-host disease on the outcome of hematopoietic cell transplantation with post-transplantation cyclophosphamide: a CIBMTR analysis (A Hadjis/ S McCurdy). **Protocol Development.**
- j. **GV24-03** Differences in the characteristics of acute and chronic graft-versus-host disease after post-transplantation cyclophosphamide versus conventional calcineurin inhibitor-based graft-versus-host disease prophylaxis (R Mehta/ R Saliba). **Protocol Development.**

5. Future/proposed studies

- a. **PROP 2409-19** Impact of Ruxolitinib Treatment for Acute GVHD on the Incidence and Severity of Chronic GVHD (A Ali) (Attachment 4)

Dr. Ali from Georgetown University presented.

- *Objective: To assess whether the use of ruxolitinib for acute GVHD reduces the incidence and severity of chronic GVHD.*
- *Key Points:*
 - *Hypothesis: Ruxolitinib in acute GVHD may lower chronic GVHD incidence and severity.*
 - *Study involves 2,315 patients, with 541 receiving ruxolitinib.*
 - *Primary objective: Compare chronic GVHD incidence in ruxolitinib vs. other treatments.*

- *Secondary objectives: Assess severity, organ involvement, steroid responsiveness, and long-term survival.*
 - *Discussion:*
 - *Questions about steroid tapering and calcineurin inhibitor impact.*
 - *Concerns about the year of transplant and post-transplant cyclophosphamide (PTCy) impact.*
 - *Also concerns about limited information about duration of ruxolitinib treatment and details about administration.*
 - *Just compare second line ruxolitinib to other agents? Or also look at third, fourth line etc?*
 - *Ruxolitinib was used in more recent transplants and we know the rate of cGVHD is going down.*
- b. **PROP 2410-43; 2410-106** Impact of Post-Transplant Cyclophosphamide Dosing on Outcomes of Allogeneic Hematopoietic Cell Transplantation (H Elmariah/ A Rezvani/ C Shultz/ S Yu) (Attachment 5)
- *Objective: To determine the optimal dosing of PTCy for improved overall survival in allogeneic transplants.*
 - *Key Points:*
 - *PTCy is standard for GVHD prophylaxis but optimal dosing is unclear.*
 - *Study compares different PTCy doses (100 mg/kg, 60-80 mg/kg, 40-60 mg/kg, <40 mg/kg).*
 - *Primary endpoint: Overall survival.*
 - *Secondary endpoints: Disease-free survival, GVHD incidence, infections, and cardiac toxicities.*
 - *Discussion:*
 - *Won't we get the answer about lower dose PTCy from clinical trials like OPTIMIZE?*
 - *Concerns about confounding factors like cardiac toxicities and patient-related factors. Many people are dose-reducing for comorbidities.*
 - *Questions about actual vs. ideal body weight dosing.*
 - *Forms captured PTCy dosing differently – many values do not make sense.*
- c. **PROP 2410-254** Abatacept versus post-transplantation cyclophosphamide as GVHD prophylaxis after allogeneic hematopoietic stem cell transplantation for myeloid malignancies (S Mirza/ J Pidala) (Attachment 7)

Dr. Mirza from Moffitt Cancer Center presented.

- *Objective: To compare Abatacept and PTCy for GVHD prophylaxis in myeloid malignancies.*
- *Key Points:*
 - *Abatacept is increasingly used as an alternative to PTCy.*
 - *Retrospective analysis shows no significant difference in overall survival, relapse, or TRM.*
 - *Possible differences in acute and chronic GVHD rates.*
 - *Study focuses on 8/8 and 7/8 mismatched unrelated donors.*

- *Discussion:*
 - *Concerns about age distribution and follow-up times.*
 - *Suggestions to separate adult and pediatric populations for analysis. WC most interested in pediatric use*
- d. **PROP 2410-103** Impact of prior chimeric antigen receptor T-cell treatment on graft-vs-host disease and non-relapse mortality after allogeneic hematopoietic cell transplantation (T Othman/ M Al Malki) (Attachment 6)

Dr. Othman from UCSF Medical Center presented.

- *Objective: To assess if prior CAR T-cell therapy increases the risk of GVHD and NRM post-allogeneic transplant.*
- *Key Points:*
 - *CAR T-cells alter the immune environment, potentially increasing GVHD risk.*
 - *Study includes 633 patients with prior CAR T-cell therapy.*
 - *Primary endpoint: Grade 3-4 acute GVHD at day 100.*
 - *Secondary endpoints: Chronic GVHD, NRM, overall survival, and relapse.*
- *Discussion:*
 - *Questions about disease status at transplant and pre-transplant treatments.*
 - *Suggestions to adjust for disease status and consider CRF level data. Patients who get a CAR-T before transplant have aggressive disease.*
 - *Will knowledge that a patient received CAR-T before transplant affect how the transplant is done or how they are managed?*
 - *May be another study in the acute leukemia committee looking at CD19 CAR-T pre and post transplant.*

Proposed studies; not accepted for consideration at this time

- e. **PROP 2403-01** Recipient Age, Incidence, Non-Relapse Mortality, and Mortality in Acute and Chronic Graft-vs-Host Disease (W Ciurylo). ***Dropped due to lower scientific impact.***
- f. **PROP 2404-02** Rates of GVHD between myeloid and non hodgkin lymphoma patients undergoing Matched Unrelated Allogeneic Transplantation (L Mountjoy). ***Dropped due to lower scientific impact.***
- g. **PROP 2408-09** Incidence of Ocular Graft Versus Host Disease (oGVHD) Confirmed by Ophthalmologists According to CIBMTR Database (M Pamukcuoglu). ***Dropped due to lower scientific impact.***
- h. **PROP 2408-10** Has an Acute Graft Versus Host Disease Severity, Impact Chronic Graft Versus Host Disease Severity? (M Pamukcuoglu). ***Dropped due to overlap with current study/publication.***
- i. **PROP 2409-23** Post-transplant cyclophosphamide impact on survival and graft versus host disease in female-to-male allogeneic hematopoietic cell transplantation (A Law/ S Rodriguez). ***Dropped due to overlap with current study/publication.***
- j. **PROP 2410-21** Comparing Outcomes Between HLA-Haploidentical and Mismatched Unrelated Donor Transplantation Among Patients Receiving Reduced Intensity Conditioning With Posttransplant Cyclophosphamide-Based Graft Versus Host Disease Prophylaxis (V Agrawal/ M Al Malki). ***Dropped due to overlap with current study/publication.***

- k. **PROP 2410-24** Impact of Renal and Cardiac Function on the Selection of Graft-Versus-Host Disease Prophylaxis Strategies in Hematopoietic Cell Transplantation (R Shouval/ M Perales). ***Dropped due to supplemental data needed.***
- l. **PROP 2410-33** Outcomes in patients above the age of 70 undergoing allogeneic transplant for Acute Myeloid leukemia with post-transplant Cyclophosphamide (M R Pandey/ Y Lei). ***Dropped due to overlap with current study/publication.***
- m. **PROP 2410-90** Comparison of ATG vs PTCy based GVHD prophylaxis regimens in Allogeneic stem cell transplant using HLA matched unrelated and mismatched unrelated donors (R V Nampoothiri). ***Dropped due to overlap with current study/publication.***
- n. **PROP 2410-151** Clinical Outcomes of sex mismatch allogeneic hematopoietic stem cell transplant with the use of post-transplant cyclophosphamide for graft-versus-host disease prophylaxis in Acute Myeloid Leukemia and Myelodysplastic Syndrome (G Kaleka/ A Socola). ***Dropped due to overlap with current study/publication.***
- o. **PROP 2410-159** Chronic GVHD Risk Index: A clinical risk assessment score for development of moderate-severe chronic graft-versus-host disease (GVHD) after hematopoietic cell transplantation (HCT) (A Ramgopal/ S Pavletic). ***Dropped due to overlap with current study/publication.***
- p. **PROP 2410-163** Outcomes of Unmodified Allogeneic Hematopoietic Transplantation With Calcineurin-Inhibitor-Free GVHD Prophylaxis (G Raju/ D Ponce). ***Dropped due to supplemental data needed.***
- q. **PROP 2410-250** Impact of post-transplantation cyclophosphamide (PTCy) on graft-versus-host disease and relapse after subsequent donor lymphocyte infusion (M Hyder/ C Kanakry). ***Dropped due to supplemental data needed.***

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

Variable	<u>Samples</u>		
	<u>Available for</u>	<u>Samples</u>	<u>Samples</u>
	<u>Recipient and</u>	<u>Available for</u>	<u>Available for</u>
	<u>Donor</u>	<u>Recipient Only</u>	<u>Donor Only</u>
	N (%)	N (%)	N (%)
Number of patients	52147	28252	13886
Source of data			
CRF	26120 (50)	9911 (35)	6049 (44)
TED	26027 (50)	18341 (65)	7837 (56)
Number of centers	269	246	400
Disease at transplant			
AML	18232 (35)	10649 (38)	4659 (34)
ALL	7447 (14)	3394 (12)	2177 (16)
Other leukemia	1515 (3)	516 (2)	341 (2)
CML	3644 (7)	1331 (5)	1086 (8)
MDS	8027 (15)	5686 (20)	1874 (13)
Other acute leukemia	594 (1)	340 (1)	163 (1)
NHL	4508 (9)	1890 (7)	1018 (7)
Hodgkin Lymphoma	987 (2)	318 (1)	230 (2)
Plasma Cell Disorders, MM	960 (2)	310 (1)	215 (2)
Other malignancies	61 (<1)	14 (<1)	23 (<1)
Breast cancer	7 (<1)	3 (<1)	1 (<1)
SAA	1706 (3)	856 (3)	609 (4)
Inherited abnormalities erythrocyte diff fxn	733 (1)	256 (1)	226 (2)
Inherited bone marrow failure syndromes	79 (<1)	100 (<1)	47 (<1)
Hemoglobinopathies	48 (<1)	56 (<1)	27 (<1)
Paroxysmal nocturnal hemoglobinuria	6 (<1)	12 (<1)	6 (<1)
SCIDs	918 (2)	473 (2)	417 (3)
Inherited abnormalities of platelets	45 (<1)	22 (<1)	13 (<1)
Inherited disorders of metabolism	316 (1)	108 (<1)	172 (1)
Histiocytic disorders	415 (1)	164 (1)	150 (1)
Autoimmune disorders	36 (<1)	44 (<1)	18 (<1)
MPN	1811 (3)	1693 (6)	392 (3)
Others	52 (<1)	17 (<1)	22 (<1)
AML Disease status at transplant			
CR1	10313 (57)	7148 (67)	2436 (52)
CR2	3375 (19)	1683 (16)	904 (19)
CR3+	364 (2)	139 (1)	106 (2)
Advanced or active disease	3996 (22)	1639 (15)	1066 (23)

Refresh Date: Dec 2025

Variable	<u>Samples</u>		
	<u>Available for</u>	<u>Samples</u>	<u>Samples</u>
	<u>Recipient and</u> <u>Donor</u> N (%)	<u>Available for</u> <u>Recipient Only</u> N (%)	<u>Available for</u> <u>Donor Only</u> N (%)
Missing	184 (1)	40 (<1)	147 (3)
ALL Disease status at transplant			
CR1	3782 (51)	2059 (61)	945 (43)
CR2	2109 (28)	838 (25)	633 (29)
CR3+	614 (8)	214 (6)	201 (9)
Advanced or active disease	860 (12)	259 (8)	277 (13)
Missing	82 (1)	24 (1)	121 (6)
MDS Disease status at transplant			
Early	1664 (21)	1027 (18)	409 (22)
Advanced	5316 (66)	4226 (74)	1091 (58)
Missing	1047 (13)	433 (8)	374 (20)
NHL Disease status at transplant			
CR1	668 (15)	426 (23)	157 (15)
CR2	865 (19)	391 (21)	169 (17)
CR3+	405 (9)	186 (10)	93 (9)
PR	446 (10)	111 (6)	99 (10)
Advanced	2031 (45)	750 (40)	466 (46)
Missing	73 (2)	18 (1)	31 (3)
Recipient age at transplant			
0-9 years	4219 (8)	1566 (6)	1752 (13)
10-17 years	3346 (6)	1209 (4)	1237 (9)
18-29 years	6115 (12)	2470 (9)	1785 (13)
30-39 years	5730 (11)	2463 (9)	1603 (12)
40-49 years	7624 (15)	3311 (12)	1951 (14)
50-59 years	10532 (20)	5263 (19)	2375 (17)
60-69 years	11535 (22)	8488 (30)	2536 (18)
70+ years	3046 (6)	3482 (12)	647 (5)
Median (Range)	49 (0-84)	57 (0-84)	43 (0-84)
Recipient race			
White	45472 (91)	24731 (91)	10192 (87)
Black or African American	2540 (5)	1147 (4)	691 (6)
Asian	1405 (3)	859 (3)	661 (6)
Native Hawaiian or other Pacific Islander	80 (<1)	39 (<1)	48 (<1)
American Indian or Alaska Native	213 (<1)	127 (<1)	70 (1)
Other	49 (<1)	27 (<1)	28 (<1)
More than one race	320 (1)	184 (1)	74 (1)
Unknown	2068 (N/A)	1138 (N/A)	2122 (N/A)
Recipient ethnicity			
Hispanic or Latino	4496 (10)	2200 (9)	1302 (11)

Variable	<u>Samples</u>		
	<u>Available for</u>	<u>Samples</u>	<u>Samples</u>
	<u>Recipient and</u> <u>Donor</u> N (%)	<u>Available for</u> <u>Recipient Only</u> N (%)	<u>Available for</u> <u>Donor Only</u> N (%)
Non Hispanic or non-Latino	39733 (88)	23054 (90)	7386 (63)
Non-resident of the U.S.	894 (2)	312 (1)	2952 (25)
Unknown	7024 (N/A)	2686 (N/A)	2246 (N/A)
Recipient sex			
Male	30213 (58)	16592 (59)	8251 (59)
Female	21934 (42)	11660 (41)	5635 (41)
Karnofsky score			
10-80	18511 (35)	11453 (41)	4433 (32)
90-100	31769 (61)	16064 (57)	8777 (63)
Missing	1867 (4)	735 (3)	676 (5)
HLA-A B DRB1 groups - low resolution			
<=3/6	33 (<1)	129 (<1)	11 (<1)
4/6	336 (1)	196 (1)	95 (1)
5/6	7308 (14)	3629 (13)	2009 (15)
6/6	43950 (85)	23052 (85)	10876 (84)
Unknown	520 (N/A)	1246 (N/A)	895 (N/A)
High-resolution HLA matches available out of 8			
<=5/8	916 (2)	203 (1)	95 (1)
6/8	1918 (4)	342 (1)	285 (3)
7/8	9748 (19)	3950 (17)	2176 (22)
8/8	38113 (75)	19160 (81)	7403 (74)
Unknown	1452 (N/A)	4597 (N/A)	3927 (N/A)
HLA-DPB1 Match			
Double allele mismatch	12928 (28)	4490 (23)	1421 (24)
Single allele mismatch	24714 (54)	10180 (52)	3098 (53)
Full allele matched	8405 (18)	4749 (24)	1345 (23)
Unknown	6100 (N/A)	8833 (N/A)	8022 (N/A)
High resolution release score			
No	16427 (32)	28182 (>99)	13376 (96)
Yes	35720 (68)	70 (<1)	510 (4)
KIR typing available			
No	38299 (73)	28227 (>99)	13815 (99)
Yes	13848 (27)	25 (<1)	71 (1)
Graft type			
Marrow	17023 (33)	5857 (21)	5094 (37)
PBSC	34988 (67)	22130 (78)	8706 (63)
BM+PBSC	27 (<1)	34 (<1)	11 (<1)
PBSC+UCB	39 (<1)	197 (1)	11 (<1)
Others	70 (<1)	34 (<1)	64 (<1)

Refresh Date: Dec 2025

Variable	<u>Samples</u>	<u>Samples</u>	<u>Samples</u>
	<u>Available for</u>	<u>Available for</u>	<u>Available for</u>
	<u>Recipient and</u> <u>Donor</u> N (%)	<u>Recipient Only</u> N (%)	<u>Donor Only</u> N (%)
Conditioning regimen			
Myeloablative	30866 (59)	13348 (47)	8328 (60)
RIC/Nonmyeloablative	21046 (40)	14823 (52)	5380 (39)
TBD	235 (<1)	81 (<1)	178 (1)
Donor age at donation			
To Be Determined/NA	240 (<1)	573 (2)	172 (1)
0-9 years	4 (<1)	33 (<1)	1 (<1)
10-17 years	2 (<1)	11 (<1)	2 (<1)
18-29 years	26493 (51)	16448 (58)	6223 (45)
30-39 years	14635 (28)	7186 (25)	4164 (30)
40-49 years	8272 (16)	3074 (11)	2521 (18)
50+ years	2501 (5)	927 (3)	803 (6)
Median (Range)	30 (0-69)	28 (0-89)	31 (4-77)
Donor/Recipient CMV serostatus			
+/+	13243 (25)	7832 (28)	3717 (27)
+/-	6106 (12)	3591 (13)	1693 (12)
-/+	17148 (33)	8556 (30)	4247 (31)
-/-	14974 (29)	7541 (27)	3717 (27)
CB - recipient +	35 (<1)	154 (1)	10 (<1)
CB - recipient -	4 (<1)	50 (<1)	2 (<1)
CB - recipient CMV unknown	0	1 (<1)	0
Missing	637 (1)	527 (2)	500 (4)
GvHD Prophylaxis			
No GvHD Prophylaxis	224 (<1)	192 (1)	76 (1)
TDEPLETION alone	132 (<1)	51 (<1)	67 (<1)
TDEPLETION +/- other	1147 (2)	325 (1)	391 (3)
CD34 select alone	324 (1)	191 (1)	120 (1)
CD34 select +/- other	551 (1)	312 (1)	148 (1)
Cyclophosphamide alone	235 (<1)	99 (<1)	61 (<1)
Cyclophosphamide +/- others	6203 (12)	8638 (31)	1597 (12)
FK506 + MMF +/- others	5571 (11)	2339 (8)	1028 (7)
FK506 + MTX +/- others(not MMF)	21357 (41)	10248 (36)	3724 (27)
FK506 +/- others(not MMF,MTX)	2524 (5)	1438 (5)	512 (4)
FK506 alone	1206 (2)	547 (2)	235 (2)
CSA + MMF +/- others(not FK506)	3132 (6)	1059 (4)	1096 (8)
CSA + MTX +/- others(not MMF,FK506)	7032 (13)	1975 (7)	3594 (26)
CSA +/- others(not FK506,MMF,MTX)	1091 (2)	342 (1)	468 (3)
CSA alone	468 (1)	134 (<1)	406 (3)
Other GVHD Prophylaxis	769 (1)	306 (1)	229 (2)

Refresh Date: Dec 2025

Variable	<u>Samples</u>	<u>Samples</u>	<u>Samples</u>
	<u>Available for</u>	<u>Available for</u>	<u>Available for</u>
	<u>Recipient and</u> <u>Donor</u> N (%)	<u>Recipient Only</u> N (%)	<u>Donor Only</u> N (%)
Missing	181 (<1)	56 (<1)	134 (1)
Donor/Recipient sex match			
Male-Male	20961 (40)	11157 (39)	5327 (38)
Male-Female	12851 (25)	6690 (24)	3046 (22)
Female-Male	9136 (18)	5170 (18)	2851 (21)
Female-Female	8977 (17)	4769 (17)	2539 (18)
CB - recipient M	17 (<1)	112 (<1)	3 (<1)
CB - recipient F	22 (<1)	93 (<1)	9 (<1)
Missing	183 (<1)	261 (1)	111 (1)
Year of transplant			
1986-1990	347 (1)	47 (<1)	103 (1)
1991-1995	1838 (4)	439 (2)	745 (5)
1996-2000	3305 (6)	1184 (4)	1213 (9)
2001-2005	5347 (10)	1070 (4)	1880 (14)
2006-2010	9592 (18)	1921 (7)	1877 (14)
2011-2015	13348 (26)	3587 (13)	2650 (19)
2016-2020	10385 (20)	7194 (25)	2810 (20)
2021-2025	7985 (15)	12810 (45)	2608 (19)
Follow-up among survivors, Months			
N Eval	24194	17127	6810
Median (Range)	48 (0-384)	23 (0-362)	35 (0-385)

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

Variable	<u>Samples</u> <u>Available for</u> <u>Recipient and</u> <u>Donor</u> N (%)	<u>Samples</u> <u>Available for</u> <u>Recipient</u> <u>Only</u> N (%)	<u>Samples</u> <u>Available for</u> <u>Donor Only</u> N (%)
Number of patients	6535	1939	2412
Source of data			
CRF	4585 (70)	1190 (61)	1115 (46)
TED	1950 (30)	749 (39)	1297 (54)
Number of centers	156	145	231
Disease at transplant			
AML	2470 (38)	678 (35)	791 (33)
ALL	1345 (21)	417 (22)	530 (22)
Other leukemia	102 (2)	31 (2)	38 (2)
CML	140 (2)	38 (2)	61 (3)
MDS	594 (9)	184 (9)	193 (8)
Other acute leukemia	103 (2)	28 (1)	50 (2)
NHL	418 (6)	112 (6)	142 (6)
Hodgkin Lymphoma	104 (2)	27 (1)	35 (1)
Plasma Cell Disorders, MM	38 (1)	12 (1)	13 (1)
Other malignancies	12 (<1)	1 (<1)	3 (<1)
SAA	97 (1)	39 (2)	52 (2)
Inherited abnormalities erythrocyte diff fxn	171 (3)	51 (3)	45 (2)
Inherited bone marrow failure syndromes	10 (<1)	5 (<1)	7 (<1)
Hemoglobinopathies	3 (<1)	1 (<1)	1 (<1)
SCIDs	302 (5)	108 (6)	190 (8)
Inherited abnormalities of platelets	21 (<1)	6 (<1)	10 (<1)
Inherited disorders of metabolism	420 (6)	144 (7)	158 (7)
Histiocytic disorders	112 (2)	37 (2)	56 (2)
Autoimmune disorders	8 (<1)	0	6 (<1)
MPN	54 (1)	17 (1)	21 (1)
Others	11 (<1)	3 (<1)	10 (<1)
AML Disease status at transplant			
CR1	1311 (53)	398 (59)	410 (52)
CR2	654 (26)	164 (24)	198 (25)
CR3+	69 (3)	11 (2)	30 (4)
Advanced or active disease	428 (17)	102 (15)	147 (19)
Missing	8 (<1)	3 (<1)	6 (1)
ALL Disease status at transplant			

Refresh Date: Dec 2025

Variable	<u>Samples</u>	<u>Samples</u>	<u>Samples</u>
	<u>Available for</u>	<u>Available for</u>	<u>Available for</u>
	<u>Recipient and</u>	<u>Recipient</u>	<u>Donor Only</u>
	<u>Donor</u>	<u>Only</u>	<u>Donor Only</u>
	N (%)	N (%)	N (%)
CR1	599 (45)	179 (43)	230 (43)
CR2	515 (38)	154 (37)	189 (36)
CR3+	152 (11)	59 (14)	67 (13)
Advanced or active disease	78 (6)	24 (6)	42 (8)
Missing	1 (<1)	1 (<1)	2 (<1)
MDS Disease status at transplant			
Early	179 (30)	44 (24)	76 (39)
Advanced	358 (60)	123 (67)	92 (48)
Missing	57 (10)	17 (9)	25 (13)
NHL Disease status at transplant			
CR1	66 (16)	12 (11)	28 (20)
CR2	80 (19)	28 (25)	36 (26)
CR3+	47 (11)	11 (10)	12 (9)
PR	68 (16)	12 (11)	16 (11)
Advanced	154 (37)	48 (43)	46 (33)
Missing	0	1 (1)	3 (2)
Recipient age at transplant			
0-9 years	1989 (30)	704 (36)	872 (36)
10-17 years	683 (10)	184 (9)	278 (12)
18-29 years	781 (12)	173 (9)	256 (11)
30-39 years	626 (10)	183 (9)	240 (10)
40-49 years	690 (11)	185 (10)	228 (9)
50-59 years	885 (14)	229 (12)	299 (12)
60-69 years	757 (12)	237 (12)	218 (9)
70+ years	124 (2)	44 (2)	21 (1)
Median (Range)	27 (0-83)	23 (0-84)	20 (0-85)
Recipient race			
White	4580 (74)	1334 (73)	1456 (72)
Black or African American	966 (16)	271 (15)	306 (15)
Asian	389 (6)	144 (8)	179 (9)
Native Hawaiian or other Pacific Islander	38 (1)	5 (<1)	23 (1)
American Indian or Alaska Native	63 (1)	18 (1)	25 (1)
Other	1 (<1)	1 (<1)	1 (<1)
More than one race	138 (2)	42 (2)	40 (2)
Unknown	360 (N/A)	124 (N/A)	382 (N/A)
Recipient ethnicity			
Hispanic or Latino	1378 (22)	371 (20)	412 (18)
Non Hispanic or non-Latino	4938 (78)	1460 (78)	1422 (61)
Non-resident of the U.S.	53 (1)	31 (2)	512 (22)

Refresh Date: Dec 2025

Variable	<u>Samples</u>	<u>Samples</u>	<u>Samples</u>
	<u>Available for</u>	<u>Available for</u>	<u>Available for</u>
	<u>Recipient and</u>	<u>Recipient</u>	<u>Donor Only</u>
	<u>Donor</u>	<u>Only</u>	<u>Donor Only</u>
	N (%)	N (%)	N (%)
Unknown	166 (N/A)	77 (N/A)	66 (N/A)
Recipient sex			
Male	3628 (56)	1105 (57)	1375 (57)
Female	2907 (44)	834 (43)	1037 (43)
Karnofsky score			
10-80	1738 (27)	494 (25)	601 (25)
90-100	4547 (70)	1309 (68)	1588 (66)
Missing	250 (4)	136 (7)	223 (9)
HLA-A B DRB1 groups - low resolution			
<=3/6	197 (3)	124 (7)	63 (3)
4/6	2648 (41)	719 (40)	948 (41)
5/6	2736 (43)	706 (40)	953 (42)
6/6	809 (13)	236 (13)	324 (14)
Unknown	145 (N/A)	154 (N/A)	124 (N/A)
High-resolution HLA matches available out of 8			
<=5/8	3048 (54)	765 (55)	989 (54)
6/8	1352 (24)	333 (24)	434 (24)
7/8	809 (14)	196 (14)	270 (15)
8/8	389 (7)	109 (8)	141 (8)
Unknown	937 (N/A)	536 (N/A)	578 (N/A)
HLA-DPB1 Match			
Double allele mismatch	999 (37)	193 (31)	259 (36)
Single allele mismatch	1424 (53)	368 (59)	384 (54)
Full allele matched	263 (10)	58 (9)	70 (10)
Unknown	3849 (N/A)	1320 (N/A)	1699 (N/A)
High resolution release score			
No	5006 (77)	1889 (97)	2378 (99)
Yes	1529 (23)	50 (3)	34 (1)
KIR typing available			
No	5263 (81)	1933 (>99)	2383 (99)
Yes	1272 (19)	6 (<1)	29 (1)
Graft type			
UCB	6124 (94)	1734 (89)	2265 (94)
BM+UCB	1 (<1)	0	0
PBSC+UCB	378 (6)	197 (10)	132 (5)
Others	32 (<1)	8 (<1)	15 (1)
Number of cord units			
1	5485 (84)	0	2021 (84)
2	1048 (16)	0	390 (16)

Variable	<u>Samples</u> <u>Available for</u> <u>Recipient and</u> <u>Donor</u>	<u>Samples</u> <u>Available for</u> <u>Recipient</u> <u>Only</u>	<u>Samples</u> <u>Available for</u> <u>Donor Only</u>
	N (%)	N (%)	N (%)
3	1 (<1)	0	0
Unknown	1 (N/A)	1939 (N/A)	1 (N/A)
Conditioning regimen			
Myeloablative	4267 (65)	1244 (64)	1519 (63)
RIC/Nonmyeloablative	2250 (34)	689 (36)	872 (36)
TBD	18 (<1)	6 (<1)	21 (1)
Donor age at donation			
To Be Determined/NA	5148 (79)	814 (42)	1942 (81)
0-9 years	1076 (16)	868 (45)	372 (15)
10-17 years	60 (1)	98 (5)	23 (1)
18-29 years	75 (1)	46 (2)	17 (1)
30-39 years	66 (1)	45 (2)	27 (1)
40-49 years	52 (1)	30 (2)	13 (1)
50+ years	58 (1)	38 (2)	18 (1)
Median (Range)	5 (0-72)	5 (0-73)	4 (0-67)
Donor/Recipient CMV serostatus			
+/+	0	0	1 (<1)
-/-	0	0	1 (<1)
CB - recipient +	4108 (63)	1182 (61)	1472 (61)
CB - recipient -	2324 (36)	687 (35)	860 (36)
CB - recipient CMV unknown	103 (2)	70 (4)	78 (3)
GvHD Prophylaxis			
No GvHD Prophylaxis	25 (<1)	10 (1)	17 (1)
TDEPLETION alone	1 (<1)	0	0
TDEPLETION +- other	27 (<1)	9 (<1)	9 (<1)
CD34 select alone	0	2 (<1)	1 (<1)
CD34 select +- other	308 (5)	156 (8)	86 (4)
Cyclophosphamide alone	0	0	1 (<1)
Cyclophosphamide +- others	19 (<1)	11 (1)	13 (1)
FK506 + MMF +- others	1956 (30)	633 (33)	507 (21)
FK506 + MTX +- others(not MMF)	218 (3)	58 (3)	78 (3)
FK506 +- others(not MMF,MTX)	237 (4)	69 (4)	94 (4)
FK506 alone	148 (2)	42 (2)	27 (1)
CSA + MMF +- others(not FK506)	2956 (45)	760 (39)	1157 (48)
CSA + MTX +- others(not MMF,FK506)	100 (2)	30 (2)	51 (2)
CSA +- others(not FK506,MMF,MTX)	341 (5)	116 (6)	241 (10)
CSA alone	50 (1)	19 (1)	74 (3)
Other GVHD Prophylaxis	137 (2)	21 (1)	46 (2)
Missing	12 (<1)	3 (<1)	10 (<1)

Refresh Date: Dec 2025

Variable	<u>Samples</u>	<u>Samples</u>	<u>Samples</u>
	<u>Available for</u>	<u>Available for</u>	<u>Available for</u>
	<u>Recipient and</u>	<u>Recipient</u>	<u>Donor Only</u>
	<u>Donor</u>	<u>Only</u>	<u>Donor Only</u>
	N (%)	N (%)	N (%)
Donor/Recipient sex match			
Male-Female	0	0	1 (<1)
Female-Male	0	0	1 (<1)
CB - recipient M	3628 (56)	1105 (57)	1373 (57)
CB - recipient F	2907 (44)	834 (43)	1036 (43)
CB - recipient sex unknown	0	0	1 (<1)
Year of transplant			
1996-2000	1 (<1)	2 (<1)	5 (<1)
2001-2005	112 (2)	85 (4)	34 (1)
2006-2010	1847 (28)	427 (22)	623 (26)
2011-2015	2679 (41)	513 (26)	839 (35)
2016-2020	1340 (21)	528 (27)	553 (23)
2021-2025	556 (9)	384 (20)	358 (15)
Follow-up among survivors, Months			
N Eval	3247	1102	1277
Median (Range)	60 (0-196)	39 (0-213)	38 (0-240)

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 samples, recipient only samples and donor only samples, Biospecimens include: whole blood, serum/plasma and limited quantities of viable cells and cell lines (collected prior to 2006), Specific inventory queries available upon request through the CIBMTR Immunobiology Research Program

Variable	<u>Samples</u> <u>Available for</u> <u>Recipient and</u> <u>Donor</u>	<u>Samples</u> <u>Available for</u> <u>Recipient</u> <u>Only</u>	<u>Samples</u> <u>Available for</u> <u>Donor Only</u>
	N (%)	N (%)	N (%)
Number of patients	13687	2413	1156
Source of data			
CRF	4321 (32)	632 (26)	346 (30)
TED	9366 (68)	1781 (74)	810 (70)
Number of centers	97	80	69
Disease at transplant			
AML	4487 (33)	768 (32)	409 (35)
ALL	2299 (17)	490 (20)	209 (18)
Other leukemia	232 (2)	46 (2)	19 (2)
CML	396 (3)	59 (2)	28 (2)
MDS	1810 (13)	297 (12)	159 (14)
Other acute leukemia	214 (2)	39 (2)	12 (1)
NHL	1106 (8)	208 (9)	101 (9)
Hodgkin Lymphoma	238 (2)	44 (2)	29 (3)
Plasma Cell Disorders, MM	276 (2)	43 (2)	21 (2)
Other malignancies	25 (<1)	0	1 (<1)
Breast cancer	1 (<1)	0	0
SAA	679 (5)	106 (4)	45 (4)
Inherited abnormalities erythrocyte diff fxn	503 (4)	71 (3)	17 (1)
Inherited bone marrow failure syndromes	57 (<1)	7 (<1)	8 (1)
Hemoglobinopathies	319 (2)	57 (2)	20 (2)
Paroxysmal nocturnal hemoglobinuria	4 (<1)	1 (<1)	0
SCIDs	309 (2)	52 (2)	28 (2)
Inherited abnormalities of platelets	13 (<1)	0	0
Inherited disorders of metabolism	30 (<1)	8 (<1)	3 (<1)
Histiocytic disorders	79 (1)	11 (<1)	6 (1)
Autoimmune disorders	18 (<1)	0	0
MPN	577 (4)	104 (4)	41 (4)
Others	15 (<1)	2 (<1)	0
AML Disease status at transplant			
CR1	3007 (67)	529 (69)	265 (65)
CR2	673 (15)	97 (13)	50 (12)
CR3+	55 (1)	18 (2)	2 (<1)
Advanced or active disease	745 (17)	119 (15)	92 (22)

Refresh Date: Dec 2025

Variable	<u>Samples</u> <u>Available for</u> <u>Recipient and</u> <u>Donor</u>	<u>Samples</u> <u>Available for</u> <u>Recipient</u> <u>Only</u>	<u>Samples</u> <u>Available for</u> <u>Donor Only</u>
	N (%)	N (%)	N (%)
Missing	7 (<1)	5 (1)	0
ALL Disease status at transplant			
CR1	1355 (59)	298 (61)	131 (63)
CR2	697 (30)	130 (27)	56 (27)
CR3+	150 (7)	35 (7)	10 (5)
Advanced or active disease	97 (4)	27 (6)	12 (6)
MDS Disease status at transplant			
Early	312 (17)	44 (15)	27 (17)
Advanced	1425 (79)	230 (77)	123 (77)
Missing	73 (4)	23 (8)	9 (6)
NHL Disease status at transplant			
CR1	225 (20)	49 (24)	25 (25)
CR2	211 (19)	40 (19)	17 (17)
CR3+	115 (10)	26 (13)	7 (7)
PR	71 (6)	14 (7)	7 (7)
Advanced	475 (43)	78 (38)	45 (45)
Missing	5 (<1)	0	0
Recipient age at transplant			
0-9 years	1542 (11)	241 (10)	100 (9)
10-17 years	1443 (11)	199 (8)	83 (7)
18-29 years	1622 (12)	327 (14)	132 (11)
30-39 years	1042 (8)	213 (9)	122 (11)
40-49 years	1585 (12)	289 (12)	120 (10)
50-59 years	2706 (20)	506 (21)	232 (20)
60-69 years	3121 (23)	528 (22)	304 (26)
70+ years	626 (5)	110 (5)	63 (5)
Median (Range)	48 (0-82)	48 (0-81)	51 (0-83)
Recipient race			
White	10027 (78)	1626 (74)	837 (79)
Black or African American	1884 (15)	340 (15)	129 (12)
Asian	667 (5)	194 (9)	71 (7)
Native Hawaiian or other Pacific Islander	49 (<1)	9 (<1)	3 (<1)
American Indian or Alaska Native	95 (1)	16 (1)	9 (1)
More than one race	186 (1)	24 (1)	17 (2)
Unknown	779 (N/A)	204 (N/A)	90 (N/A)
Recipient ethnicity			
Hispanic or Latino	2664 (20)	594 (25)	260 (23)
Non Hispanic or non-Latino	10617 (79)	1729 (74)	841 (75)
Non-resident of the U.S.	133 (1)	28 (1)	18 (2)

Variable	<u>Samples</u> <u>Available for</u> <u>Recipient and</u> <u>Donor</u>	<u>Samples</u> <u>Available for</u> <u>Recipient</u> <u>Only</u>	<u>Samples</u> <u>Available for</u> <u>Donor Only</u>
	N (%)	N (%)	N (%)
Unknown	273 (N/A)	62 (N/A)	37 (N/A)
Recipient sex			
Male	8010 (59)	1414 (59)	680 (59)
Female	5677 (41)	999 (41)	476 (41)
Karnofsky score			
10-80	4910 (36)	955 (40)	502 (43)
90-100	8271 (60)	1384 (57)	591 (51)
Missing	506 (4)	74 (3)	63 (5)
HLA-A B DRB1 groups - low resolution			
<=3/6	3403 (26)	585 (26)	344 (34)
4/6	1015 (8)	196 (9)	105 (10)
5/6	295 (2)	56 (2)	31 (3)
6/6	8568 (65)	1444 (63)	529 (52)
Unknown	406 (N/A)	132 (N/A)	147 (N/A)
High-resolution HLA matches available out of 8			
<=5/8	4233 (33)	722 (33)	400 (44)
6/8	191 (1)	51 (2)	14 (2)
7/8	200 (2)	37 (2)	21 (2)
8/8	8264 (64)	1357 (63)	482 (53)
Unknown	799 (N/A)	246 (N/A)	239 (N/A)
HLA-DPB1 Match			
Double allele mismatch	15 (<1)	1 (<1)	4 (1)
Single allele mismatch	3612 (40)	491 (65)	287 (67)
Full allele matched	5377 (60)	261 (35)	136 (32)
Unknown	4683 (N/A)	1660 (N/A)	729 (N/A)
High resolution release score			
No	7234 (53)	2384 (99)	1143 (99)
Yes	6453 (47)	29 (1)	13 (1)
Graft type			
Marrow	3974 (29)	528 (22)	290 (25)
PBSC	9582 (70)	1840 (76)	856 (74)
UCB	2 (<1)	15 (1)	0
BM+PBSC	22 (<1)	7 (<1)	1 (<1)
BM+UCB	52 (<1)	15 (1)	3 (<1)
PBSC+UCB	1 (<1)	2 (<1)	4 (<1)
Others	54 (<1)	6 (<1)	2 (<1)
Conditioning regimen			
Myeloablative	7617 (56)	1319 (55)	587 (51)
RIC/Nonmyeloablative	6003 (44)	1077 (45)	551 (48)

Variable	<u>Samples</u> <u>Available for</u> <u>Recipient and</u> <u>Donor</u>	<u>Samples</u> <u>Available for</u> <u>Recipient</u> <u>Only</u>	<u>Samples</u> <u>Available for</u> <u>Donor Only</u>
	N (%)	N (%)	N (%)
TBD	67 (<1)	17 (1)	18 (2)
Donor age at donation			
To Be Determined/NA	15 (<1)	9 (<1)	2 (<1)
0-9 years	970 (7)	142 (6)	39 (3)
10-17 years	1156 (8)	188 (8)	78 (7)
18-29 years	2584 (19)	460 (19)	260 (22)
30-39 years	2165 (16)	433 (18)	222 (19)
40-49 years	2160 (16)	382 (16)	177 (15)
50+ years	4637 (34)	799 (33)	378 (33)
Median (Range)	40 (0-82)	40 (0-79)	39 (0-80)
Donor/Recipient CMV serostatus			
+/+	5561 (41)	1076 (45)	477 (41)
+/-	1467 (11)	209 (9)	115 (10)
-/+	3460 (25)	584 (24)	302 (26)
-/-	2958 (22)	478 (20)	229 (20)
CB - recipient +	32 (<1)	18 (1)	6 (1)
CB - recipient -	23 (<1)	14 (1)	1 (<1)
Missing	186 (1)	34 (1)	26 (2)
GvHD Prophylaxis			
No GvHD Prophylaxis	198 (1)	26 (1)	16 (1)
TDEPLETION alone	141 (1)	44 (2)	17 (1)
TDEPLETION +- other	144 (1)	39 (2)	19 (2)
CD34 select alone	91 (1)	29 (1)	12 (1)
CD34 select +- other	106 (1)	35 (1)	10 (1)
Cyclophosphamide alone	81 (1)	11 (<1)	10 (1)
Cyclophosphamide +- others	5079 (37)	841 (35)	507 (44)
FK506 + MMF +- others	897 (7)	114 (5)	34 (3)
FK506 + MTX +- others(not MMF)	4530 (33)	682 (28)	358 (31)
FK506 +- others(not MMF,MTX)	892 (7)	368 (15)	77 (7)
FK506 alone	127 (1)	19 (1)	6 (1)
CSA + MMF +- others(not FK506)	256 (2)	44 (2)	19 (2)
CSA + MTX +- others(not MMF,FK506)	773 (6)	105 (4)	46 (4)
CSA +- others(not FK506,MMF,MTX)	83 (1)	11 (<1)	3 (<1)
CSA alone	84 (1)	11 (<1)	3 (<1)
Other GVHD Prophylaxis	193 (1)	25 (1)	19 (2)
Missing	12 (<1)	9 (<1)	0
Donor/Recipient sex match			
Male-Male	4539 (33)	848 (35)	396 (34)
Male-Female	2908 (21)	498 (21)	248 (21)

Variable	<u>Samples</u> <u>Available for</u> <u>Recipient and</u> <u>Donor</u>	<u>Samples</u> <u>Available for</u> <u>Recipient</u> <u>Only</u>	<u>Samples</u> <u>Available for</u> <u>Donor Only</u>
	N (%)	N (%)	N (%)
Female-Male	3433 (25)	546 (23)	281 (24)
Female-Female	2748 (20)	488 (20)	224 (19)
CB - recipient M	34 (<1)	19 (1)	3 (<1)
CB - recipient F	21 (<1)	13 (1)	4 (<1)
Missing	4 (<1)	1 (<1)	0
Year of transplant			
2006-2010	613 (4)	74 (3)	56 (5)
2011-2015	3719 (27)	525 (22)	215 (19)
2016-2020	5089 (37)	910 (38)	403 (35)
2021-2025	4266 (31)	904 (37)	482 (42)
Follow-up among survivors, Months			
N Eval	8910	1577	753
Median (Range)	28 (0-150)	24 (0-124)	24 (0-148)



TO: Graft-Versus-Host Disease Working Committee Members

FROM: Najla El Jurdi, MD; Scientific Director for GVWC

RE: 2025-2026 Studies in Progress Summary

GV20-01 Machine learning models and clinical decision support tool for acute and chronic graft-versus-host disease in patients with acute myelogenous leukemia undergoing allogeneic transplants (T Kindwall-Keller/ B Lobo). This study aims to develop a machine learning model to predict the risk of developing acute and chronic GVHD in adult AML patients based on patient, disease and transplant-specific factors. The end goal is to create a tool that will provide information to both physician and patient to support clinical decision-making regarding transplant. The analysis was completed, but the data were insufficient to support the hypothesis. Plan to reframe this as a methodology paper focused on AI-based analysis of the dataset.

Status: **Manuscript Preparation**

GV20-02 Prediction of graft-versus-host disease in recipients of hematopoietic cell transplant from a single mismatched unrelated donor using a highly-multiplexed proteomics assay: MHC-PepSeq (K Sandhu/ J Altin/ M Askar/ R Nakamura). This study aims to evaluate the performance of a risk score derived from the MHC-PepSeq assay in predicting the development of acute and chronic GVHD in recipients of allogeneic HCT from either an 8/8 matched donor with mismatch in HLA-DP or a 7/8 mismatched donor. This study was presented at ASH 2023, manuscript preparation is ongoing.

Status: **Manuscript Preparation**

GV21-02 Determinants of successful discontinuation of immune suppression following allogeneic hematopoietic cell transplantation: A validation study (J Pidala/ B Logan/ M Martens). This study aims to develop and validate prediction models for immune suppression discontinuation and immune suppression discontinuation failure in patients who received allogeneic HCT for hematologic malignancies. The protocol was reviewed at the CIBMTR Statistical Meeting in January 2022. Additional work was completed over summer/fall 2023 to check for BMT CTN study population overlap and add new GVHD outcome variables. A data request was sent to centers regarding immunosuppression data relating to GVHD prophylaxis for patients that did not develop GVHD. This study was presented at TCT 2025 (oral). Data was received in the fourth quarter of 2025 and analysis is nearing completion.

Status: **Analysis**

GV22-02 Chronic GVHD Risk Index: A clinical risk assessment score for development of moderates/severe chronic graft-versus-host disease after hematopoietic cell transplantation (A Im/ S Pavletic). This study aims to develop and validate a risk score based on weighted clinical factors to predict the likelihood of developing moderate-severe chronic GVHD.

Status: **Manuscript under review**

GV23-01a The effect of CNI- vs. PTCy- (with or without MMF) based GVHD prophylaxis on HLA-matched HCT in the MAC setting (P Munshi/ R Nath/ Z Zhou/ S Mccurdy). This study aims to determine whether post-transplant cyclophosphamide is superior to CNI/methotrexate as GVHD prophylaxis, with and without ATG, in patients undergoing myeloablative HLA-matched related or unrelated donor transplantation. This study was presented at ASH 2025 (oral).

Status: **Manuscript Preparation**

GV23-01b The effect of CNI- vs. PTCy- (with or without MMF) based GVHD prophylaxis on HLA-matched HCT in the RIC setting (P Munshi/ R Nath/ Z Zhou/ S Mccurdy). This study aims to determine whether post-transplant cyclophosphamide is superior to CNI/methotrexate as GVHD prophylaxis, with and without ATG, in patients undergoing reduced intensity conditioning HLA-matched related or unrelated donor transplantation. A key subgroup analysis will focus on patients aged ≥ 70 years. This study will be presented at ASTCT 2026 (Poster).

Status: **Analysis**

GV23-02 Incidence of chronic graft versus host disease in cryopreserved versus fresh peripheral blood allogeneic hematopoietic stem cell grafts (K Maurer, R Soiffer). This study aims to determine whether cryopreservation of unrelated donor grafts is associated with a lower incidence of chronic GVHD compared to fresh products, and to evaluate other transplant outcomes. This study was presented at ASH 2025 (oral).

Status: **Manuscript Preparation**

GV24-01 Post-transplantation cyclophosphamide (PTCy)/ sirolimus versus PTCy/calcineurin-inhibitor-based graft-versus-host disease prophylaxis (R Mehta/ N Bejanyan/ J Pidala). The primary objective is to compare 1 year GVHD-free, relapse-free survival (GRFS) between those patients receiving PTCy/CNI vs PTCy/sirolimus GVHD prophylaxis. A subgroup analysis will test whether the addition of mycophenolate mofetil (MMF) to PTCy/CNI prophylaxis (triplet prophylaxis) confers additional benefit compared with PTCy/CNI prophylaxis alone (doublet prophylaxis). This study will be presented at ASTCT 2026 (Poster).

Status: **Analysis**

GV24-02 Effect of acute graft-versus-host disease on the outcome of hematopoietic cell transplantation with post-transplantation cyclophosphamide: a CIBMTR analysis (A Hadjis/ S Mccurdy). The aim of the study is to determine the impact of maximum grades II and grade III/IV aGVHD and cGVHD on NRM, relapse, relapse-free survival, and OS after haploidentical (haplo), matched sibling donor (MSD), and matched unrelated donor (MUD) HCT utilizing PTCy compared to grade 0-I and no cGVHD.

Status: **Data File Preparation**

GV24-03 Differences in the characteristics of acute and chronic graft-versus-host disease after post-transplantation cyclophosphamide versus conventional calcineurin inhibitor-based graft-versus-host disease prophylaxis (R Mehta/ R Saliba). The aim of this study is to determine the distribution and rates of organ involvement with acute and chronic GVHD with PTCy-based versus conventional CNI-based GVHD prophylaxis.

Status: **Data File Preparation**

GV25-01 Abatacept versus post-transplantation cyclophosphamide as GVHD prophylaxis after allogeneic hematopoietic stem cell transplantation for myeloid malignancies. (S Mirza/ J Pidala/P Khandelwal). This aim of the study is to compare 1-year graft-versus-host disease-free, relapse-free survival (GRFS) between abatacept- and post-transplant cyclophosphamide (PTCy)-based GVHD prophylaxis strategies across adult and pediatric allogeneic HCT populations.

Status: **Protocol Development**

Field	Response
Proposal Number	2508-10-HERR
Proposal Title	Overall Survival after Post-Transplant Cyclophosphamide (PTCy) Peripheral Blood Hematopoietic Cell Transplantation (HCT) Differs by Race, Ethnicity, and Donor
Key Words	Donor, race, survival, age, alloHCT
Principal Investigator #1: - First and last name, degree(s)	Megan Herr, PhD
Principal Investigator #1: - Email address	Megan.Herr@RoswellPark.org
Principal Investigator #1: - Institution name	Roswell Park Comprehensive Cancer Center
Principal Investigator #1: - Academic rank	Associate Professor
Junior investigator status (defined as 助、5 years from fellowship)	Yes
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.	LE21-01 - co-I, help with SEER analyses and pathology review. Four coauthored papers in the last 2 years.
Do any of the PI(s) within this proposal have a CIBMTR WC study in manuscript preparation >6 months?	No
PROPOSED WORKING COMMITTEE:	Donor and Recipient Health Services
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:	Heather Stefanski
RESEARCH QUESTION:	What is the association of race/ethnicity and donor type of overall survival.
RESEARCH HYPOTHESIS:	Overall survival differs by donor type and race/ethnicity
SPECIFIC OBJECTIVES/OUTCOMES TO BE INVESTIGATED (Include Primary, Secondary, etc.):	Primary outcomes: Overall survival (1-year and 2-year).
SCIENTIFIC IMPACT: Briefly state how the completion of the aims will impact participant care/outcomes and how it will advance science or clinical care.	These findings may help in donor selection.
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.	Hispanic and non-Hispanic Black (NHB) patients have worse HCT survival compared to non-Hispanic White (NHW) patients and were less likely to utilize an unrelated HCT donor (Khera et al. Blood Adv. 2024; Hahn et al. JAMA Netw Open. 2024), but this difference has not been evaluated in the PTCy era. PTCy reduces graft-versus-host disease (GvHD) and allows for increased availability of allogeneic donors in minority patients. It is important to know the best donor source for each ethnicity.
PARTICIPANT SELECTION CRITERIA: State inclusion and exclusion criteria.	Expanding on HS16-01 to include additional years and donor age. Inclusion criteria: 1. adults (>19 years) 2. Peripheral blood only 3. allogeneic HCT from 2013-2022 4. Treated with PTCy only
Does this study include pediatric patients?	No

Field	Response
If this study does not include pediatric patients, please provide justification:	NA
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.	Same as 16-01, expanding on years through 2022, and donor age.
Types of cellular therapy data this proposal includes:	Hematopoietic Cell Transplantation (HCT)
PATIENT REPORTED OUTCOME (PRO) REQUIREMENTS: If the study requires PRO data collected by CIBMTR, the proposal should include: 1) A detailed description of the PRO domains, timepoints, and proposed analysis of PROs; 2) A description of the hypothesis speci	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 of the investigator's previous e	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
REFERENCES:	Khera et al. Blood Adv. 2024; Hahn et al. JAMA Netw Open. 2024
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

Table 1.

Characteristic	Total
No. of patients	8922
No. of centers	144
Age, by decades, no. (%)	
Median (range)	58.2 (18.0-87.8)
18-29	834 (10)
30-39	844 (9)
40-49	1186 (13)
50-59	2043 (23)
60-69	2955 (33)
70+	1060 (12)
CCN region at transplant, no. (%)	
US	8922 (100)
Sex, no. (%)	
Male	5230 (59)
Female	3692 (41)
Race, no. (%)	
White	6829 (77)
Black	1017 (11)
Asian	418 (5)
Native Hawaiian or other Pacific Islander	19 (0)
American Indian or Alaska Native	47 (1)
More than one race	51 (1)
Non-resident of the U.S.	6 (0)
Missing	535 (6)
Ethnicity, no. (%)	
Hispanic or Latino	1364 (15)
Not Hispanic or Latino	7246 (81)
Non-resident of the U.S.	33 (0)
Not reported	279 (3)
Karnofsky score prior to HCT, no. (%)	
90-100%	4686 (53)
< 90%	4051 (45)
Not reported	185 (2)
Sorrer comorbidity score, no. (%)	
0	1686 (19)

Characteristic	Total
1	1314 (15)
2	1432 (16)
3	1620 (18)
4	1244 (14)
5	673 (8)
6	468 (5)
7	290 (3)
8	112 (1)
9	54 (1)
10	20 (0)
11	6 (0)
12	1 (0)
13	2 (0)
Primary disease, no. (%)	
AML	3874 (43)
ALL	1388 (16)
Other leukemia	75 (1)
CLL	67 (1)
CML	306 (3)
MDS	1835 (21)
Other acute leukemia	140 (2)
NHL	736 (8)
HD	92 (1)
MM	110 (1)
Other PCD	23 (0)
MPN	276 (3)
Graft source, no. (%)	
Peripheral blood stem cells	8922 (100)
Donor type, no. (%)	
HLA identical sibling	957 (11)
Haploidentical donor	4428 (50)
Well-matched unrelated (8/8)	2615 (29)
Partially-matched unrelated (7/8)	859 (10)
Mismatched unrelated ($\leq 6/8$)	63 (1)
Conditioning intensity, no. (%)	
Myeloablative	3558 (40)
Non-myeloablative (NST)	1767 (20)

Characteristic	Total
Reduced intensity (RIC)	3597 (40)
Conditioning regimen, no. (%)	
TBI/Cy	148 (2)
TBI/Cy/Flu	2495 (28)
TBI/Cy/Flu/TT	1 (0)
TBI/VP	16 (0)
TBI/Mel	573 (6)
TBI/Flu	1460 (16)
TBI/other(s)	232 (3)
Bu/Cy	495 (6)
Bu/Mel	3 (0)
Flu/Bu/TT	384 (4)
Flu/Bu	1681 (19)
Flu/Mel/TT	243 (3)
Flu/Mel	1088 (12)
FCR	1 (0)
Cy/Flu	62 (1)
BEAM	5 (0)
Mel alone	8 (0)
Mel/other(s)	6 (0)
Treosulfan	16 (0)
TLI	5 (0)
GVHD prophylaxis, no. (%)	
PtCy + other(s)	8922 (100)
Year of current transplant, no. (%)	
2017	982 (11)
2018	996 (11)
2019	1204 (13)
2020	1718 (19)
2021	1913 (21)
2022	2109 (24)
Follow-up of survivors, median (range), months	47.4 (1.4-99.6)

Field	Response
Proposal Number	2509-46-MUNSHI
Proposal Title	Safety and Efficacy of Donor Lymphocyte Infusions following Mismatched Unrelated Donor Transplants in the Post Transplant Cyclophosphamide Era
Key Words	DLI, Pt-Cy, mismatched unrelated donor
Principal Investigator #1: - First and last name, degree(s)	Pashna Munshi
Principal Investigator #1: - Email address	pashna.munshi@pennmedicine.upenn.edu
Principal Investigator #1: - Institution name	University of Pennsylvania
Principal Investigator #1: - Academic rank	Associate Professor
Junior investigator status (defined as 2-5 years from fellowship)	No
Do you identify as an underrepresented/minority?	Yes
Please list any ongoing CIBMTR projects that you are currently involved in and briefly describe your role.	Currently I am the co-PI in GV23-01 and we have submitted two abstracts from this study; one to ASH (Post-transplant cyclophosphamide based GVHD prophylaxis in HLA-matched related and unrelated donor hematopoietic cell transplantation in adults with hematologic malignancies undergoing myeloablative conditioning: A CIBMTR analysis of 8,272 participants) and one is being submitted to TCT/Tandem (Post-transplant cyclophosphamide based GVHD prophylaxis in HLA-matched related and unrelated donor hematopoietic cell transplantation in adults with hematologic malignancies undergoing reduced intensity conditioning (RIC): A CIBMTR analysis of 5950 participants)
Do any of the PI(s) within this proposal have a CIBMTR WC study in manuscript preparation >6 months?	No
PROPOSED WORKING COMMITTEE:	Morbidity, Recovery and Survivorship
Please indicate if you have already spoken with a scientific director or working committee chair regarding this study.	No
RESEARCH QUESTION:	Are donor lymphocyte infusion (DLI) safe and/or efficacious following mismatched unrelated donor transplants (MMUD).
RESEARCH HYPOTHESIS:	The rate of graft versus host disease (GVHD) using DLI following MMUDs is similar to historical controls (MUDs) with similar efficacy in the current era of using PYCy for GVHD prevention.

Field	Response
SPECIFIC OBJECTIVES/OUTCOMES TO BE INVESTIGATED (Include Primary, Secondary, etc.):	<p>Primary objective: To determine the incidence and degree of acute GVHD following DLI in HLA-mismatched (7/8 HLA match) unrelated allogeneic HCT in patients receiving PTCy, CNI/Methotrexate based regimens compared to MUD (8/8 HLA matched) transplants. Secondary objective: To determine GVHD-free-relapse-free survival (GRFS) and the overall survival (OS) in patients receiving DLI following an HLA-mismatched (unrelated) allogeneic HCT in patients receiving PTCy, CNI/Methotrexate based regimens</p>
SCIENTIFIC IMPACT: Briefly state how the completion of the aims will impact participant care/outcomes and how it will advance science or clinical care.	<p>GVHD prophylaxis using PTCy has widened the scope of alternate donor transplants, now most recently to even include MMUD transplants (7/8 HLA matched, &lt;7/8 HLA matched) showing similar efficacy to MUD transplants. However, relapse risk continues to remain a practical issue affecting the overall success of the transplant procedure. Donor lymphocyte infusion(s) (DLI) is often used either for prophylaxis, or when relapse is imminent (as seen by declining T-cell chimerisms), or in the face of active relapse often in tandem with chemo/immunotherapy albeit with limited successes depending on the disease characteristics. The dose of DLI has traditionally not shown to impact outcomes. However compelling evidence shows that there is 30-60% chance of patients developing GVHD further complicating post HCT management options in the face of relapse. Historically, MMUD transplants were fraught with poor outcomes due to increased GVHD risk. Data from recent studies incorporating PTCy shows feasibility and success of performing transplants safely in one and two antigen mismatched transplants. But there are limited data¹ indicating the safety and efficacy of DLI in the MMUD transplants when GVHD prophylaxis with PTCy is considered. The CIBMTR would have the largest numbers of these patients to study, and this is a timely question.</p>

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.

Allogeneic hematopoietic cell transplantation (allo-HCT) is a potentially curative therapy for many hematologic malignancies. For patients who lack a fully HLA-matched donor, transplantation from a mismatched unrelated donor (MMUD) is utilized, particularly important for those underrepresented racial and ethnic groups who are less likely to have access to matched donors. However, MMUD allo-HCT is associated with increased risks of graft-versus-host disease (GVHD), non-relapse mortality (NRM), and inferior survival compared to matched donor transplantation, primarily due to greater HLA disparity and heightened alloreactivity increasing risk of both acute and chronic GVHD. Historically, anti-thymocyte globulin (ATG) was the standard GVHD prophylaxis in this setting, but outcomes remained suboptimal, with high rates of severe GVHD and NRM especially compared to PTCy.² Recent multicenter trials and registry studies have shown that PTCy-based regimens, often combined with calcineurin inhibitors (CNI) and mycophenolate mofetil (MMF), yield 1-year OS rates approaching those seen with matched unrelated donors, with high grade (III-IV) acute GVHD rates as low as 8–10% and moderate/severe chronic GVHD rates below 15%.³⁻⁹ Furthermore, in attempts to reduce toxicity risk of PTCy, other trials are underway adjusting the dose of PTCy even in the MMUD setting.¹⁰ Therefore, PTCy is the practical new standard for GVHD prophylaxis in the MMUD setting.

Donor Lymphocyte Infusion: Rationale and Challenges in MMUD Allo-HCT Donor lymphocyte infusion (DLI) is a well-established strategy to enhance graft-versus-leukemia (GVL) effects to prevent or treat disease relapses after allo-HCT. The efficacy of DLI is predicated on the ability of donor T cells to recognize and eliminate residual malignant cells, most successfully noted in patients with CML compared to other hematologic malignancies.^{11,12} However, in the context of MMUD allo-HCT, the use of DLI is complicated by the heightened risk of severe GVHD due to greater HLA disparity. A study from a group in Israel¹³ shared their experience of treating 28 patients with DLI [prophylactic in 6 patients (9 DLIs) and therapeutic in 22 (50 DLIs)]. In the 6 patients receiving prophylactic DLI, complete remission was maintained in 5; however, 2 died from GVHD. Clinical responses to therapeutic DLI were seen in 6 of 22 (27.3%) patients; lower responses noted in high disease burden states. GVHD was noted in 13 of 28 patients. However, most

Field	Response
	<p>of these mismatched transplants were haploidentical (only 2 being unrelated). All patients received myeloablative conditioning and in patients with lower matching, GVHD prophylaxis was done using T cell depletion, not specified to PTCy. The timing of DLI is also a factor that could impact outcomes. Kulkarni and colleagues¹⁴ showed in patients who received dose escalating DLI following T-cell depleted transplants (with ATG/Campath) had overall better results for GVHD risk, and overall outcomes if given 9-12 months following allo-HCT. We would like to test if this holds true in this proposed CIBMTR analysis. In a more contemporary study from the National Cancer Institute (NCI)¹ of 38 DLIs given to 21 patients after 22 HCTs, few DLIs were associated with toxicities of acute GVHD (7.8%), cytokine release syndrome (CRS, 7.8%), or chronic GVHD (2.6%), and all occurred in those receiving serotherapy-containing pre-HCT conditioning (50% of HCTs). Notably the conditioning regimens had a mix of pentostatin/ATG/Campath prior to allo-HCT and there was only 1 MMUD participant. The authors concluded that DLIs given to PTCy-treated patients had low toxicity but limited efficacy, although pre-HCT serotherapy may modulate both toxicity and response. Other groups have found a modest risk of GVHD with DLI following PTCy compared to conventional CNI-based GVHD prophylaxis even when using HLA-partially mismatched donors.¹⁵⁻¹⁸ For this reason, when the need arises, many clinicians would subscribe to using DLI to PTCy-treated patients, but more data are needed to ascertain dose/timing/disease characteristics that it would be better suited for. There are many variations in practice, including starting dose or using fresh versus cryopreserved product. Using the CIBMTR platform will allow us to analyze all these confounding variables.</p>
PARTICIPANT SELECTION CRITERIA: State inclusion and exclusion criteria.	<p>All patients in the United States or Europe receiving an HLA-mismatched unrelated (MMUD) HCT with either PTCy, methotrexate and tacrolimus up through one year prior to the analysis. Transplant type: MAC or RIC/NMA allo-HCTs. Disease type: AML, MDS, ALL Graft: PB and Bone marrow Exclude patients with ex-vivo T cell depletion</p>
Does this study include pediatric patients?	No
If this study does not include pediatric patients, please provide justification:	<p>Typical donor pool studied is not often used in pediatric populations</p>

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.	<p>Outcomes shall be analyzed for the entire population and/or according to the following planned subgroups:</p> <p>1) Diagnosis; 2) stem cell source (peripheral blood vs. bone marrow); 3) Disease risk index; 4) Age and 5) HCT/CI</p> <p>Variables to be analyzed for inclusion in the multivariable analysis:</p> <p>Patient-related:</p> <p>Age at HCT, years: 18-49, 50-59, 60-65, 65-69, 70-75, 76+ and continuous</p> <p>Sex: male vs female</p> <p>Karnofsky performance score: 90% vs. <90%</p> <p>HCT</p> <p>comorbidity index at transplant 0, 1, 2, and 3</p> <p>Race: White vs. Black vs. Asian/pacific islander vs. others</p> <p>CMV status: seropositive vs. seronegative.</p> <p>Disease-related: Disease diagnosis</p> <p>Disease-Risk Index (low/intermediate vs. high/very high)</p> <p>Time from last treatment to allogeneic HCT</p> <p>Time from diagnosis to allogeneic HCT</p> <p>Remission status prior to allogeneic HCT</p> <p>Remission status following allogeneic HCT</p> <p>Transplant-related: Bone marrow vs. peripheral blood as a graft source</p> <p>Conditioning regimen: RIC vs. NMA (using standard CIBMTR definitions).</p> <p>Year of HCT</p> <p>Donor/Recipient gender (F-to-M vs. other)</p> <p>Donor/Recipient CMV status (CMV- D/CMV+ R vs. other)</p> <p>HLA match (degree of mismatch; 7/8HLA vs 6/8HLA vs less)</p> <p>Donor age continuous and in decades</p> <p>Donor relationship</p> <p>GVHD prophylaxis used (PTCy-based, ATG-based, or methotrexate/tacrolimus)</p> <p>Viable CD34+ cells/kg of recipient infused (if available)</p> <p>TNC/kg of recipient (if available)</p> <p>CD3+/kg of recipient before thawing (if available)</p> <p>Dose/frequency of DLI</p> <p>Cause of DLI (preventive versus treatment)</p> <p>Timing of DLI</p>
Types of cellular therapy data this proposal includes:	Hematopoietic Cell Transplantation (HCT)

Field	Response
PATIENT REPORTED OUTCOME (PRO) REQUIREMENTS: If the study requires PRO data collected by CIBMTR, the proposal should include: 1) A detailed description of the PRO domains, timepoints, and proposed analysis of PROs; 2) A description of the hypothesis speci	This study is not requesting PROs at this time
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 of the investigator's previous e	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.	We would be open to potential for collaboration with the EBMT if it is determined that additional patient numbers are needed for statistical power, but this is not a requirement for the study.

REFERENCES:

1. Shanmugasundaram K, Napier S, Dimitrova D, et al: Safety but limited efficacy of donor lymphocyte infusion for post-transplantation cyclophosphamide-treated patients. Bone Marrow Transplant 59:1513-1524, 2024
2. Battipaglia G, Labopin M, Hamladji RM, et al: Post-transplantation cyclophosphamide versus antithymocyte globulin in patients with acute myeloid leukemia undergoing allogeneic stem cell transplantation from HLA-identical sibling donors: A retrospective analysis from the Acute Leukemia Working Party of the European Society for Blood and Marrow Transplantation. Cancer 127:209-218, 2021
3. Al Malki MM, Bo-Subait S, Logan B, et al: Post-Transplant Cyclophosphamide-Based Graft-Versus-Host Disease Prophylaxis After Mismatched Unrelated Donor Peripheral Blood Stem Cell Transplantation. J Clin Oncol 43:2772-2781, 2025
4. Dybko J, Sobczyk-Kruszelnicka M, Sadowska-Klasa A, et al: Optimizing Outcomes in Mismatched Unrelated Donor Allogeneic Transplantation: Post-Transplant Cyclophosphamide's Dual Impact on Graft versus Host Disease Incidence and Overall Survival: Retrospective Analysis on Behalf of Polish Adult Leukemia Group. J Clin Med 13, 2024
5. Moiseev I, Abouqateb M, Peczynski C, et al: Post-transplantation cyclophosphamide and antithymocyte globulin in 8/10 HLA-mismatched unrelated donor transplantation: the analysis on behalf of the transplant complications working party of the EBMT. Bone Marrow Transplant, 2025
6. Pedraza A, Jorge S, Suarez-Lled M, et al: High-Dose Cyclophosphamide and Tacrolimus as Graft-versus-Host Disease Prophylaxis for Matched and Mismatched Unrelated Donor Transplantation. Transplant Cell Ther 27:619.e1-619.e8, 2021
7. Gaballa S, Ge I, El Fakih R, et al: Results of a 2-arm, phase 2 clinical trial using post-transplantation cyclophosphamide for the prevention of graft-versus-host disease in haploidentical donor and mismatched unrelated donor hematopoietic stem cell transplantation. Cancer 122:3316-3326, 2016
8. Arslan S, Desai A, Yang D, et al: Total Body

	<p>Irradiation and Fludarabine with Post-Transplantation Cyclophosphamide for Mismatched Related or Unrelated Donor Hematopoietic Cell Transplantation. Transplant Cell Ther 30:1013.e1-1013.e12, 2024 9. Dholaria B, Labopin M, Sanz J, et al: Allogeneic hematopoietic cell transplantation with cord blood versus mismatched unrelated donor with post-transplant cyclophosphamide in acute myeloid leukemia. J Hematol Oncol 14:76, 2021 10. Auletta</p> <p>JJ, Devine SM, Stefanski HE, et al: OPTIMIZE: A Phase II Study of Reduced Dose Post Transplantation Cyclophosphamide As GVHD Prophylaxis in Adult Patients with Hematologic Malignancies Receiving HLA-Mismatched Unrelated Donor Peripheral Blood Stem Cell Transplantation. Blood 144:3514.1-3514.1, 2024 11. Collins RH, Jr., Shpilberg O, Drobyski WR, et al: Donor leukocyte infusions in 140 patients with relapsed malignancy after allogeneic bone marrow transplantation. J Clin Oncol 15:433-44, 1997 12. Huff CA, Fuchs EJ, Smith BD, et al: Graft-versus-host reactions and the effectiveness of donor lymphocyte infusions. Biol Blood Marrow Transplant 12:414-21, 2006 13. Or R, Hadar E, Bitan M, et al: Safety and Efficacy of Donor Lymphocyte Infusions following Mismatched Stem Cell Transplantation. Biology of Blood and Marrow Transplantation 12:1295-1301, 2006 14. Kulkarni S, Bloor A, Dennis M, et al: Timely Use of Donor Lymphocyte Infusion (DLI) Improves Allogeneic Transplant Outcomes. Blood 144:7399-7399, 2024 15. Ghiso A, Raiola AM, Gualandi F, et al: DLI after haploidentical BMT with post-transplant CY. Bone Marrow Transplant 50:56-61, 2015 16. Goldsmith SR, Slade M, DiPersio JF, et al: Donor-lymphocyte infusion following haploidentical hematopoietic cell transplantation with peripheral blood stem cell grafts and PTCy. Bone Marrow Transplant 52:1623-1628, 2017 17. Jaiswal SR, Zaman S, Chakrabarti A, et al: Improved Outcome of Refractory/Relapsed Acute Myeloid Leukemia after Post-Transplantation Cyclophosphamide-Based Haploidentical Transplantation with Myeloablative Conditioning and Early Prophylactic Granulocyte Colony-Stimulating Factor-Mobilized Donor</p>
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Field	Response
	Lymphocyte Infusions. Biol Blood Marrow Transplant 22:1867-1873, 2016 18. Zeidan AM, Forde PM, Symons H, et al: HLA-haploidentical donor lymphocyte infusions for patients with relapsed hematologic malignancies after related HLA-haploidentical bone marrow transplantation. Biol Blood Marrow Transplant 20:314-8, 2014
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

Table 1.

Characteristic	Methotrexate and		Total
	PTCy	Tacrolimus	
No. of patients	1596	282	1878
No. of centers	129	74	142
Age, by decades, no. (%)			
Median (range)	59.0 (2.1-80.6)	47.3 (1.2-76.4)	57.8 (1.2-80.6)
0-9	10 (1)	30 (11)	40 (2)
10-19	23 (1)	31 (11)	54 (3)
20-29	115 (7)	26 (9)	141 (8)
30-39	175 (11)	35 (12)	210 (11)
40-49	201 (13)	29 (10)	230 (12)
50-59	322 (20)	47 (17)	369 (20)
60-69	509 (32)	65 (23)	574 (31)
70+	241 (15)	19 (7)	260 (14)
CCN region at transplant, no. (%)			
US	1590 (100)	281 (100)	1871 (100)
Europe	6 (0)	1 (0)	7 (0)
Sex, no. (%)			
Male	805 (50)	164 (58)	969 (52)
Female	791 (50)	118 (42)	909 (48)
Race, no. (%)			
White	1158 (73)	211 (75)	1369 (73)
Black	212 (13)	29 (10)	241 (13)
Asian	89 (6)	17 (6)	106 (6)
Native Hawaiian or other Pacific Islander	6 (0)	1 (0)	7 (0)
American Indian or Alaska Native	13 (1)	2 (1)	15 (1)
More than one race	10 (1)	0 (0)	10 (1)
Not reported	108 (7)	22 (8)	130 (7)
Karnofsky score prior to HCT, no. (%)			
90-100%	852 (53)	154 (55)	1006 (54)
< 90%	722 (45)	122 (43)	844 (45)
Not reported	22 (1)	6 (2)	28 (1)
Sorrer comorbidity score, no. (%)			
0	306 (19)	73 (26)	379 (20)
1	240 (15)	44 (16)	284 (15)

Characteristic	Methotrexate and		Total
	PTCy	Tacrolimus	
2	245 (15)	43 (15)	288 (15)
3	284 (18)	46 (16)	330 (18)
4	196 (12)	29 (10)	225 (12)
5	152 (10)	19 (7)	171 (9)
6	84 (5)	11 (4)	95 (5)
7	52 (3)	11 (4)	63 (3)
8	18 (1)	5 (2)	23 (1)
9	11 (1)	0 (0)	11 (1)
10	6 (0)	1 (0)	7 (0)
11	2 (0)	0 (0)	2 (0)
Primary disease, no. (%)			
AML	968 (61)	149 (53)	1117 (59)
ALL	300 (19)	77 (27)	377 (20)
MDS	328 (21)	56 (20)	384 (20)
Graft source, no. (%)			
Bone marrow	137 (9)	81 (29)	218 (12)
Peripheral blood stem cells	1459 (91)	201 (71)	1660 (88)
Donor type, no. (%)			
Partially-matched unrelated (7/8)	1448 (91)	280 (99)	1728 (92)
Mismatched unrelated (<= 6/8)	148 (9)	2 (1)	150 (8)
Conditioning intensity, no. (%)			
Myeloablative	613 (38)	189 (67)	802 (43)
Non-myeloablative (NST)	264 (17)	8 (3)	272 (14)
Reduced intensity (RIC)	718 (45)	85 (30)	803 (43)
Not reported	1 (0)	0 (0)	1 (0)
Conditioning regimen, no. (%)			
TBI/Cy	45 (3)	37 (13)	82 (4)
TBI/Cy/Flu	325 (20)	1 (0)	326 (17)
TBI/Cy/TT	2 (0)	13 (5)	15 (1)
TBI/Cy/VP	0 (0)	3 (1)	3 (0)
TBI/VP	5 (0)	13 (5)	18 (1)
TBI/Mel	99 (6)	3 (1)	102 (5)
TBI/Flu	257 (16)	5 (2)	262 (14)
TBI/other(s)	37 (2)	2 (1)	39 (2)
Bu/Cy/Mel	0 (0)	1 (0)	1 (0)
Bu/Cy	45 (3)	37 (13)	82 (4)
Bu/Mel	0 (0)	4 (1)	4 (0)

Characteristic	Methotrexate and		Total
	PTCy	Tacrolimus	
Flu/Bu/TT	92 (6)	4 (1)	96 (5)
Flu/Bu	365 (23)	97 (34)	462 (25)
Flu/Mel/TT	23 (1)	0 (0)	23 (1)
Flu/Mel	285 (18)	61 (22)	346 (18)
Cy/Flu	7 (0)	1 (0)	8 (0)
Mel/other(s)	3 (0)	0 (0)	3 (0)
Other(s)	6 (0)	0 (0)	6 (0)
GVHD prophylaxis, no. (%)			
PtCy + other(s)	1587 (99)	0 (0)	1587 (85)
PtCy alone	9 (1)	0 (0)	9 (0)
TAC + MTX +/- other(s) (except MMF, PtCy)	0 (0)	282 (100)	282 (15)
Year of current transplant, no. (%)			
2018	91 (6)	76 (27)	167 (9)
2019	124 (8)	63 (22)	187 (10)
2020	150 (9)	32 (11)	182 (10)
2021	193 (12)	24 (9)	217 (12)
2022	222 (14)	24 (9)	246 (13)
2023	347 (22)	29 (10)	376 (20)
2024	413 (26)	33 (12)	446 (24)
2025	56 (4)	1 (0)	57 (3)
Follow-up of survivors, median (range), months	24.0 (2.3-76.3)	49.0 (2.9-77.4)	24.3 (2.3-77.4)

Table 2. Patients who received a DLI from table 1

Characteristic	Methotrexate and Tacrolimus		Total
	PTCy		
No. of patients	18	5	23
No. of centers	15	5	20
Age, by decades, no. (%)			
Median (range)	55.6 (23.0-71.3)	42.2 (1.6-72.5)	53.7 (1.6-72.5)
0-9	0 (0)	2 (40)	2 (9)
20-29	2 (11)	0 (0)	2 (9)
30-39	2 (11)	0 (0)	2 (9)
40-49	1 (6)	2 (40)	3 (13)
50-59	7 (39)	0 (0)	7 (30)

Characteristic	Methotrexate		Total
	PTCy	and Tacrolimus	
60-69	4 (22)	0 (0)	4 (17)
70+	2 (11)	1 (20)	3 (13)
CCN region at transplant, no. (%)			
US	18 (100)	5 (100)	23 (100)
Sex, no. (%)			
Male	7 (39)	5 (100)	12 (52)
Female	11 (61)	0 (0)	11 (48)
Race, no. (%)			
White	15 (83)	4 (80)	19 (83)
Black	2 (11)	1 (20)	3 (13)
Not Reported	1 (6)	0 (0)	1 (4)
Karnofsky score prior to HCT, no. (%)			
90-100%	10 (56)	3 (60)	13 (57)
< 90%	8 (44)	2 (40)	10 (43)
Sorrer comorbidity score, no. (%)			
0	1 (6)	2 (40)	3 (13)
1	4 (22)	2 (40)	6 (26)
2	2 (11)	0 (0)	2 (9)
3	3 (17)	0 (0)	3 (13)
4	3 (17)	0 (0)	3 (13)
5	3 (17)	1 (20)	4 (17)
6	1 (6)	0 (0)	1 (4)
7	1 (6)	0 (0)	1 (4)
Primary disease, no. (%)			
AML	14 (78)	4 (80)	18 (78)
ALL	1 (6)	1 (20)	2 (9)
MDS	3 (17)	0 (0)	3 (13)
Graft source, no. (%)			
Bone marrow	0 (0)	1 (20)	1 (4)
Peripheral blood stem cells	18 (100)	4 (80)	22 (96)
Donor type, no. (%)			
Partially-matched unrelated (7/8)	18 (100)	5 (100)	23 (100)
Conditioning intensity, no. (%)			
Myeloablative	7 (39)	4 (80)	11 (48)
Non-myeloablative (NST)	1 (6)	0 (0)	1 (4)
Reduced intensity (RIC)	10 (56)	1 (20)	11 (48)
Conditioning regimen, no. (%)			

Characteristic	Methotrexate		Total
	PTCy	and Tacrolimus	
TBI/Cy/Flu	4 (22)	0 (0)	4 (17)
TBI/Flu	4 (22)	0 (0)	4 (17)
TBI/other(s)	2 (11)	0 (0)	2 (9)
Bu/Cy	0 (0)	2 (40)	2 (9)
Flu/Bu/TT	0 (0)	1 (20)	1 (4)
Flu/Bu	5 (28)	0 (0)	5 (22)
Flu/Mel	3 (17)	2 (40)	5 (22)
GVHD prophylaxis, no. (%)			
PtCy + other(s)	18 (100)	0 (0)	18 (78)
TAC + MTX +- other(s) (except MMF, PtCy)	0 (0)	5 (100)	5 (22)
Year of current transplant, no. (%)			
2019	1 (6)	1 (20)	2 (9)
2020	1 (6)	0 (0)	1 (4)
2021	6 (33)	0 (0)	6 (26)
2022	3 (17)	1 (20)	4 (17)
2023	5 (28)	3 (60)	8 (35)
2024	2 (11)	0 (0)	2 (9)
Follow-up of survivors, median (range), months	36.4 (12.7-36.4)	37.3 (24.0-37.3)	36.4 (12.7-37.3)

Table 3. Patients who received DLI after removal of PTCy- and methotrexate-based GVHD prophylaxis and MMUD inclusion criteria.

Characteristic	Total
No. of patients	628
No. of centers	116
Age, by decades, no. (%)	
Median (range)	58.4 (0.5-81.4)
0-9	40 (6)
10-19	32 (5)
20-29	43 (7)
30-39	42 (7)
40-49	59 (9)
50-59	119 (19)
60-69	206 (33)
70+	87 (14)
CCN region at transplant, no. (%)	
US	616 (98)
Europe	12 (2)
Sex, no. (%)	
Male	376 (60)
Female	252 (40)
Race, no. (%)	
White	508 (81)
Black	44 (7)
Asian	27 (4)
Native Hawaiian or other Pacific Islander	2 (0)
American Indian or Alaska Native	9 (1)
More than one race	2 (0)
Not reported	36 (6)
Karnofsky score prior to HCT, no. (%)	
90-100%	373 (59)
< 90%	245 (39)
Not reported	10 (2)
Sorrer comorbidity score, no. (%)	
0	119 (19)
1	117 (19)
2	98 (16)
3	119 (19)

Characteristic	Total
4	66 (11)
5	48 (8)
6	29 (5)
7	16 (3)
8	6 (1)
9	5 (1)
10	5 (1)
Primary disease, no. (%)	
AML	368 (59)
ALL	89 (14)
MDS	171 (27)
Graft source, no. (%)	
Bone marrow	60 (10)
Peripheral blood stem cells	568 (90)
Donor type, no. (%)	
HLA identical sibling	126 (20)
Haploidentical donor	141 (22)
Well-matched unrelated (8/8)	333 (53)
Partially-matched unrelated (7/8)	26 (4)
Mismatched unrelated ($\leq 6/8$)	1 (0)
Multi-donor	1 (0)
Conditioning intensity, no. (%)	
Myeloablative	262 (42)
Non-myeloablative (NST)	101 (16)
Reduced intensity (RIC)	265 (42)
Conditioning regimen, no. (%)	
TBI/Cy	31 (5)
TBI/Cy/Flu	88 (14)
TBI/Cy/TT	2 (0)
TBI/VP	4 (1)
TBI/Mel	18 (3)
TBI/Flu	56 (9)
TBI/other(s)	23 (4)
Bu/Cy/Mel	2 (0)
Bu/Cy	55 (9)
Bu/Mel	3 (0)
Flu/Bu/TT	19 (3)
Flu/Bu	192 (31)

Characteristic	Total
Flu/Mel/TT	32 (5)
Flu/Mel	101 (16)
Cy/Flu	1 (0)
TLI	1 (0)
GVHD prophylaxis, no. (%)	
Ex-vivo T-cell depletion	40 (6)
CD34 selection	3 (0)
PtCy + other(s)	307 (49)
PtCy alone	2 (0)
TAC + MMF +- other(s) (except PtCy)	36 (6)
TAC + MTX +- other(s) (except MMF, PtCy)	181 (29)
TAC + other(s) (except MMF, MTX, PtCy)	12 (2)
TAC alone	16 (3)
CSA + MMF +- other(s) (except PtCy,TAC)	17 (3)
CSA + MTX +- other(s) (except PtCy,TAC,MMF)	14 (2)
Year of current transplant, no. (%)	
2018	23 (4)
2019	37 (6)
2020	62 (10)
2021	111 (18)
2022	213 (34)
2023	166 (26)
2024	16 (3)
Follow-up of survivors, median (range), months	36.1 (5.1-86.9)

Field	Response
Proposal Number	2509-91-AMIRMOKHTARI
Proposal Title	The Effect of PTCy versus Non-PTCY GVHD Prophylaxis in the AYA Population on GVHD Free Relapse Free Survival
Key Words	AYA, PTCy, GVHD ppx, GVHD Free Relapse Free Survival
Principal Investigator #1: - First and last name, degree(s)	Neda Amirmokhtari, MD
Principal Investigator #1: - Email address	namirmokhtari@kumc.edu
Principal Investigator #1: - Institution name	University of Kansas Medical Center
Principal Investigator #1: - Academic rank	Fellow, PGY-5
Junior investigator status (defined as 助、5 years from fellowship)	Yes
Do you identify as an underrepresented/minority?	Yes
Principal Investigator #2 (If applicable): - First and last name, degree(s):	Muhammad Umair Mushtaq, MD
Principal Investigator #2 (If applicable): - Email address:)	mmushtaq@kumc.edu
Principal Investigator #2 (If applicable): - Institution name:	University of Kansas Medical Center
Principal Investigator #2 (If applicable): - Academic rank:	Associate Professor of Medicine
Junior investigator status (defined as 助、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:	Neda Amirmokhtari
Please list any ongoing CIBMTR projects that you are currently involved in and briefly describe your role.	None
Do any of the PI(s) within this proposal have a CIBMTR WC study in manuscript preparation >6 months?	No
PROPOSED WORKING COMMITTEE:	Graft vs. Host Disease
Please indicate if you have already spoken with a scientific director or working committee chair regarding this study.	No
RESEARCH QUESTION:	What is the effect of PTCy GVHD prophylaxis for allo-HCT on GVHD free relapse free survival in comparison to non-PTCy GVHD prophylaxis in the AYA population?
RESEARCH HYPOTHESIS:	Adolescent and young adult (AYA) patients who receive post transplant Cytoxan (PTCy) as graft versus host (GVHD) prophylaxis in comparison to non-PTCY GVHD prophylaxis will have improved GVHD free relapse free survival (GRFS).

Field	Response
SPECIFIC OBJECTIVES/OUTCOMES TO BE INVESTIGATED (Include Primary, Secondary, etc.):	The primary objective will be evaluating the impact of PTCy GVHD prophylaxis versus non-PTCy prophylaxis regarding GRFS in the AYA population who have underwent allogeneic hematopoietic stem cell transplant (allo-HCT). Secondary objectives will include comparing AYA patients and >40 years old patients who underwent PTCy GVHD prophylaxis regarding GRFS. Secondary objectives will also include assessing relapse free survival (RFS), overall survival (OS), time to engraftment, toxicities (in particular cardiac and genitourinary), non-relapse mortality (NRM), rates of relapse, incidence of acute and chronic GVHD and death between those who received PTCy GVHD prophylaxis versus non-PTCy prophylaxis.
SCIENTIFIC IMPACT: Briefly state how the completion of the aims will impact participant care/outcomes and how it will advance science or clinical care.	PTCy is an accepted standard GVHD prophylaxis in adults and has also been used in the pediatric population. However, data regarding the effects of PTCy in the AYA population is limited. Being able to further characterize the effects PTCy has on GRFS in the AYA population in comparison to non-PTCy GVHD prophylaxis would help further solidify its role in GVHD prophylaxis.
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.	PTCy has been shown to be efficacious and safe in adults and is the new standard of care for GVHD prophylaxis in allo-HCT. It not only has improved the incidence and severity of GVHD but has done so without impacting incidence of relapse. It has shown to increase GRFS in comparison to prior standard of care GVHD prophylaxis, tacrolimus with methotrexate ¹ . There is also evidence that PTCy is effective and safe in the pediatric and adolescent population ²⁻³ . However, there is limited evidence evaluating its impact on the AYA population, defined as patients ages 15-39 years old. One retrospective assessment suggested that the effect of PTCy GVHD prophylaxis in the AYA population may not be as significant as seen in other age groups ⁴ . Thus, with this study we aim to clarify the role PTCy GVHD prophylaxis plays within the AYA population, specifically in GRFS.
PARTICIPANT SELECTION CRITERIA: State inclusion and exclusion criteria.	This study will include patients ages 15-39 years old that are status post allo-HCT and received GVHD prophylaxis in the past 10 years (2015-2025). It will exclude patients aged less than 15 years old.
Does this study include pediatric patients?	Yes
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.	Will obtain baseline data at the time of allo-HCT, which would include socio-demographics, clinical and laboratory characteristics. Data will also include pre-transplant disease assessment and treatment, transplant-related factors (donor type/match, conditioning regimen, engraftment), and form of GVHD prophylaxis. Outcome measures will include GRFS, toxicities, infections, aGVHD, cGVHD, immune reconstitution, relapse, measurable residual disease (MRD), GvHD, NRM, death, RFS, GRFS, and OS. The majority of the data required should be available via post-transplant essential data form and recipient baseline data. No supplemental data will be required.

Field	Response
Types of cellular therapy data this proposal includes:	Hematopoietic Cell Transplantation (HCT)
PATIENT REPORTED OUTCOME (PRO) REQUIREMENTS: If the study requires PRO data collected by CIBMTR, the proposal should include: 1) A detailed description of the PRO domains, timepoints, and proposed analysis of PROs; 2) A description of the hypothesis speci	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 of the investigator's previous e	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:	<p>1. Bola os-Meade J, Hamadani M, Wu J, et al. Post-transplantation cyclophosphamide-based graft-versus-host disease prophylaxis. <i>New England Journal of Medicine</i>. 2023;388(25):2338-2348. doi:10.1056/nejmoa2215943</p> <p>2. Fierro-Pineda JC, Tsai H-L, Blackford A, et al. Prospective PTCTC trial of myeloablative Haplo-BMT with posttransplant cyclophosphamide for pediatric acute leukemias. <i>Blood Advances</i>. 2023;7(18):5639-5648. doi:10.1182/bloodadvances.2023010281</p> <p>3. Murphy M, Chen Dr A, Bonifant CL, et al. Post-transplant cyclophosphamide (ptcy) for HLA-matched HCT in pediatric and young adults with Acute Leukemias and MDS. <i>Transplantation and Cellular Therapy</i>. 2025;31(2). doi:10.1016/j.jtct.2025.01.463</p> <p>4. Stapor D, Shestovska Y, Styler M, et al. Effects of post-transplant cyclophosphamide on outcomes of allogeneic stem cell transplant are different between older and younger adult patients: A single institutional experience. <i>Blood</i>. 2024;144(Supplement 1):2165-2165. doi:10.1182/blood-2024-203886</p>
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

Table 1.

Characteristic	Non-PTCY	PTCY	Total
No. of patients	8990	5435	14425
No. of centers	306	277	328
Age, by decades, no. (%)			
Median (range)	27.6 (15.0-39.0)	28.2 (15.0-39.0)	27.9 (15.0-39.0)
15-19	1848 (21)	735 (14)	2583 (18)
20-29	3549 (39)	2404 (44)	5953 (41)
30-39	3593 (40)	2296 (42)	5889 (41)
CCN region at transplant, no. (%)			
US	5566 (62)	3809 (70)	9375 (65)
Canada	654 (7)	216 (4)	870 (6)
Europe	287 (3)	106 (2)	393 (3)
Asia	568 (6)	285 (5)	853 (6)
Australia/New Zealand	613 (7)	204 (4)	817 (6)
Mideast/Africa	442 (5)	128 (2)	570 (4)
Central/South America	860 (10)	687 (13)	1547 (11)
Sex, no. (%)			
Male	5211 (58)	3196 (59)	8407 (58)
Female	3779 (42)	2239 (41)	6018 (42)
Race, no. (%)			
White	5615 (62)	3255 (60)	8870 (61)
Black or African American	431 (5)	575 (11)	1006 (7)
Asian	689 (8)	375 (7)	1064 (7)
Native Hawaiian or other Pacific Islander	56 (1)	28 (1)	84 (1)
American Indian or Alaska Native	42 (0)	35 (1)	77 (1)
More than one race	154 (2)	127 (2)	281 (2)
Nos-resident of US	1476 (16)	616 (11)	2092 (15)
Not reported	527 (6)	424 (8)	951 (7)
Karnofsky score prior to HCT, no. (%)			
90-100%	6455 (72)	3904 (72)	10359 (72)
< 90%	2403 (27)	1413 (26)	3816 (26)
Not reported	132 (1)	118 (2)	250 (2)
Sorrer comorbidity score, no. (%)			
0	3352 (37)	1913 (35)	5265 (36)
1	1521 (17)	912 (17)	2433 (17)
2	1309 (15)	813 (15)	2122 (15)

Characteristic	Non-PTCY	PTCY	Total
3	1334 (15)	816 (15)	2150 (15)
4	798 (9)	515 (9)	1313 (9)
5	346 (4)	237 (4)	583 (4)
6	188 (2)	120 (2)	308 (2)
7	82 (1)	69 (1)	151 (1)
8	38 (0)	24 (0)	62 (0)
9	17 (0)	12 (0)	29 (0)
10	3 (0)	3 (0)	6 (0)
11	1 (0)	1 (0)	2 (0)
12	1 (0)	0 (0)	1 (0)
Primary disease, no. (%)			
AML	3512 (39)	2024 (37)	5536 (38)
ALL	3238 (36)	1925 (35)	5163 (36)
Other leukemia	25 (0)	12 (0)	37 (0)
CLL	12 (0)	6 (0)	18 (0)
CML	505 (6)	299 (6)	804 (6)
MDS	592 (7)	321 (6)	913 (6)
Other acute leukemia	229 (3)	138 (3)	367 (3)
NHL	494 (5)	362 (7)	856 (6)
HD	261 (3)	298 (5)	559 (4)
MM	45 (1)	15 (0)	60 (0)
Other PCD	8 (0)	5 (0)	13 (0)
MPN	69 (1)	30 (1)	99 (1)
Graft source, no. (%)			
Bone marrow	1994 (22)	1026 (19)	3020 (21)
Peripheral blood stem cells	6996 (78)	4409 (81)	11405 (79)
Donor type, no. (%)			
HLA identical sibling	3982 (44)	794 (15)	4776 (33)
Haploidentical donor	392 (4)	3222 (59)	3614 (25)
Well-matched unrelated (8/8)	4011 (45)	935 (17)	4946 (34)
Partially-matched unrelated (7/8)	596 (7)	422 (8)	1018 (7)
Mismatched unrelated (<= 6/8)	9 (0)	62 (1)	71 (0)
Conditioning intensity, no. (%)			
Myeloablative	7708 (86)	3926 (72)	11634 (81)
Non-myeloablative (NST)	339 (4)	544 (10)	883 (6)
Reduced intensity (RIC)	943 (10)	965 (18)	1908 (13)
Conditioning regimen, no. (%)			
TBI/Cy	2315 (26)	232 (4)	2547 (18)

Characteristic	Non-PTCY	PTCY	Total
TBI/Cy/Flu	147 (2)	720 (13)	867 (6)
TBI/Cy/Flu/TT	8 (0)	5 (0)	13 (0)
TBI/Cy/TT	205 (2)	3 (0)	208 (1)
TBI/Cy/VP	111 (1)	6 (0)	117 (1)
TBI/VP	653 (7)	79 (1)	732 (5)
TBI/Mel	114 (1)	260 (5)	374 (3)
TBI/Flu	486 (5)	1690 (31)	2176 (15)
TBI/other(s)	39 (0)	165 (3)	204 (1)
Bu/Cy/Mel	17 (0)	2 (0)	19 (0)
Bu/Cy	1824 (20)	474 (9)	2298 (16)
Bu/Mel	76 (1)	98 (2)	174 (1)
Flu/Bu/TT	124 (1)	284 (5)	408 (3)
Flu/Bu	1959 (22)	942 (17)	2901 (20)
Flu/Mel/TT	88 (1)	115 (2)	203 (1)
Flu/Mel	555 (6)	238 (4)	793 (5)
FCR	6 (0)	1 (0)	7 (0)
Cy/Flu	48 (1)	28 (1)	76 (1)
Cy alone	49 (1)	27 (0)	76 (1)
BEAM	22 (0)	1 (0)	23 (0)
BEAM like	3 (0)	0 (0)	3 (0)
Mel alone	3 (0)	12 (0)	15 (0)
Mel/other(s)	17 (0)	5 (0)	22 (0)
Treosulfan	95 (1)	44 (1)	139 (1)
TLI	26 (0)	4 (0)	30 (0)
GVHD prophylaxis, no. (%)			
Ex-vivo T-cell depletion	276 (3)	0 (0)	276 (2)
CD34 selection	116 (1)	0 (0)	116 (1)
PtCy + other(s)	0 (0)	5354 (99)	5354 (37)
PtCy alone	0 (0)	81 (1)	81 (1)
TAC + MMF +/- other(s) (except PtCy)	577 (6)	0 (0)	577 (4)
TAC + MTX +/- other(s) (except MMF, PtCy)	4182 (47)	0 (0)	4182 (29)
TAC + other(s) (except MMF, MTX, PtCy)	406 (5)	0 (0)	406 (3)
TAC alone	235 (3)	0 (0)	235 (2)
CSA + MMF +/- other(s) (except PtCy,TAC)	325 (4)	0 (0)	325 (2)
CSA + MTX +/- other(s) (except PtCy,TAC,MMF)	2755 (31)	0 (0)	2755 (19)
CSA + other(s) (except PtCy,TAC,MMF,MTX)	9 (0)	0 (0)	9 (0)
CSA alone	109 (1)	0 (0)	109 (1)
Year of transplant, no. (%)			

Characteristic	Non-PTCY	PTCY	Total
2015	1075 (12)	213 (4)	1288 (9)
2016	1118 (12)	268 (5)	1386 (10)
2017	999 (11)	393 (7)	1392 (10)
2018	899 (10)	315 (6)	1214 (8)
2019	933 (10)	404 (7)	1337 (9)
2020	812 (9)	574 (11)	1386 (10)
2021	800 (9)	653 (12)	1453 (10)
2022	786 (9)	658 (12)	1444 (10)
2023	772 (9)	883 (16)	1655 (11)
2024	689 (8)	905 (17)	1594 (11)
2025	107 (1)	169 (3)	276 (2)
Follow-up of survivors median (range), months	47.2 (0.0*-123.7)	25.1 (0.0*-121.8)	

*minimal follow-up, rounds to 0

Field	Response
Proposal Number	2509-167-HAMEED
Proposal Title	Real-World Outcomes of Post-Transplantation Cyclophosphamide Versus Calcineurin inhibitor-based Graft-Versus-Host Disease Prophylaxis for Second Allogeneic Hematopoietic Cell Transplantation
Key Words	Post-Transplantation, Cyclophosphamide, Tacrolimus, Methotrexate, Allogenic Hematopoietic Cell Transplantation
Principal Investigator #1: - First and last name, degree(s)	Maha Hameed
Principal Investigator #1: - Email address	mwhameed2016@gmail.com
Principal Investigator #1: - Institution name	Florida State University - Sarasota
Principal Investigator #1: - Academic rank	Internal Medicine Resident
Junior investigator status (defined as 助、5 years from fellowship)	Yes
Do you identify as an underrepresented/minority?	No
Principal Investigator #2 (If applicable): - First and last name, degree(s):	Taiga Nishihori
Principal Investigator #2 (If applicable): - Email address:)	Taiga.Nishihori@moffitt.org
Principal Investigator #2 (If applicable): - Institution name:	Moffit Cancer Center
Principal Investigator #2 (If applicable): - Academic rank:	Senior Member, Department of Blood & Marrow Transplant and Cellular Immunotherapy (BMT-CI)
Junior investigator status (defined as 助、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:	Maha Hameed
If you are a junior investigator and would like assistance identifying a senior mentor for your project please click below:	Yes, I am a junior investigator and would like assistance identifying a senior mentor for my project
Please list any ongoing CIBMTR projects that you are currently involved in and briefly describe your role.	None currently
Do any of the PI(s) within this proposal have a CIBMTR WC study in manuscript preparation >6 months?	No
PROPOSED WORKING COMMITTEE:	Graft vs. Host Disease

Field	Response
Please indicate if you have already spoken with a scientific director or working committee chair regarding this study.	No
RESEARCH QUESTION:	Does second allogeneic Hematopoietic cell transplantation (HCT) with post-transplant cyclophosphamide (PTCY) for Graft-Versus-Host Disease (GVHD) Prophylaxis have better efficacy and safety outcomes as compared to calcineurin-inhibitor (CNI) based GVHD prevention
RESEARCH HYPOTHESIS:	Second allogeneic HCT with PTCY-based GVHD Prophylaxis results in better GVHD control and would have better efficacy and safety and survival outcomes as compared to CNI based GVHD prophylaxis
SPECIFIC OBJECTIVES/OUTCOMES TO BE INVESTIGATED (Include Primary, Secondary, etc.):	The primary objective is to compare overall survival (OS) of second allogeneic HCT with those who received PTCY-based GVHD prophylaxis compared to those with CNI-based GVHD prevention. Secondary objectives include comparison of progression-free survival (PFS), non-relapse mortality (NRM), GVHD-free relapse-free survival (GRFS), chronic Graft Versus Host Disease-free relapse-free survival (CRFS), causes of death, and engraftment kinetics among adults with hematologic malignancies after allogeneic HCT with PTCY-based GVHD prophylaxis vs. CNI-GVHD prophylaxis. Exploratory analysis will evaluate the impact of age on all outcomes. Additionally, toxicities/organ failure post HCT will be compared between the two groups with a special attention to cardiac and renal complications.
SCIENTIFIC IMPACT: Briefly state how the completion of the aims will impact participant care/outcomes and how it will advance science or clinical care.	The completion of the primary and secondary objectives will highlight the impact of PTCY-based GVHD prophylaxis in second allogeneic HCT where patients have already undergone intensive therapy and comprehensive large-scale analyses of the real-world outcomes are lacking in this particular context. This study could illustrate the pattern of complications and safety, as well as it may uncover the influence of age on second allo HCT outcomes in the contemporary cohort. Limited data exists on the safety of repeat PTCY-based based GVHD for second allogeneic HCT, and this will lead to more personalized treatment strategies, ensuring elderly patients receive the most effective treatment as well.

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.	Several prospective and retrospective studies have explored PTCY versus CNI-based regimens, with results indicating that PTCy-based GvHD prophylaxis reduced the frequency and severity of both acute and chronic GvHD, in addition to a lower frequency of severe GI effects. However, these findings are noted to have been in the context of first allogeneic HCT with benefits. There has been no prior comprehensive analysis on the use of PTCY in second allogeneic HCT. CIBMTR data has a unique capability of evaluating this real-world data which allows transplant physicians to choose the best GVHD regimens in the context of second allogeneic HCT with confidence.
PARTICIPANT SELECTION CRITERIA: State inclusion and exclusion criteria.	<p>- Inclusion Criteria: - Adults 18 years with</p> <p>hematological malignancies (acute/chronic myeloid leukemia, acute/chronic lymphoblastic leukemia, myelodysplastic syndrome, myeloproliferative neoplasm/myelofibrosis), non-Hodgkin lymphoma, Hodgkin lymphoma who had undergone their second allogeneic HCT from any donor types (HLA-matched sibling, HLA-matched unrelated donors, HLA-mismatched unrelated donors, HLA-mismatched related donors, haploidentical donors)) with either peripheral blood or bone marrow graft between 2010 and 2025 - GVHD prophylaxis (for second allogeneic HCT) with one of the following GVHD prevention (they will be grouped as (A) PTCY-based vs. (B) CNI-based) o PTCY +/- tacrolimus +/- mycophenolate mofetil (MMF) o PTCY +/- sirolimus +/- MMF o Tacrolimus +/- methotrexate (MTX) o Tacrolimus +/- sirolimus +/- MTX o Tacrolimus +/- MMF o Cyclosporin +/- MTX o Cyclosporin +/- MMF - Exclusion Criteria: Pediatric patients, patients with non-hematological malignancies, umbilical cord graft, and those who received CD34-selected graft</p>
Does this study include pediatric patients?	No
If this study does not include pediatric patients, please provide justification:	The pediatric patient population is outside of the patient population/scope of clinical practice by both PI's.

<p>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.</p>	<p>- Data elements (relevant elements for both first and second allo HCT) and potential covariates: o Age (donor/recipient, first/second allo HCT) o Gender (donor/recipient, first and second allo HCT) o Race/ethnicity (recipient) o Donor type (first and second allo HCT) o Graft type (first and second allo HCT) o Diagnosis (hematologic malignancies) and DRI (disease risk index) o Disease status prior second allo HCT o HCT-comorbidity index (HCT-CI, first and second allo HCT) o Prior autologous HCT o Performance status (KPS) o Time from diagnosis to first transplant o Time from first allo HCT to relapse/progression o Time from first allo HCT to second allo HCT o CMV serostatus (donor/recipient) o ABO/Rh status (donor/recipient) o Conditioning regimens (first and second allo HCT) o Use of TBI o Conditioning regimen intensity (MAC vs. RIC/NMA, first and second allo HCT) o Use of ATG/campath (first and second allo HCT) o GVHD prophylaxis (see above, first and allo HCT) o Prior acute/chronic GVHD (with first allogeneic HCT) o Transplant year (first and second allo HCT) - Statistical analysis: o Patient-, disease-, and transplant-related characteristics will be described using descriptive statistics. Continuous variables will be summarized as medians with interquartile ranges, and categorical variables as frequencies and percentages. Baseline characteristics between groups (PTCY-based vs. CNI-based) will be compared using the chi-square test for categorical variables and the Wilcoxon rank-sum test for continuous variables. o OS, PFS, GRFS, CRFS will be estimated using the Kaplan Meier method, and survival curves compared with the log-rank test. Relapse, acute/chronic GHVD, NRM will be analyzed as competing risks, with cumulative incidence estimates calculated using the method of Fine and Gray; differences between groups will be assessed with Gray's test. Acute and chronic GVHD will also be analyzed using competing risk methodology, with</p>
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Field	Response
	<p>death and relapse as competing events. o Multivariable analyses will be conducted using Cox proportional hazards regression for time-to-event outcomes (OS, PFS, GRFS, CRFS) and Fine Gray subdistribution hazard models for competing-risk outcomes (relapse, NRM, GVHD). Variables to be considered are listed in the data elements. Covariates will be tested for proportional hazards assumption and collinearity. Toxicity and infection outcomes may be displayed in cumulative incidence curves. o Subgroup analysis may be conducted in those patients who received PTCY for both first and second allo HCTs. o Age-specific, KPS-specific, or HCT-CI-specific subgroup analyses will be conducted to evaluate the impact of age and comorbidities on outcomes of second allo HCT</p>
Types of cellular therapy data this proposal includes:	Hematopoietic Cell Transplantation (HCT)
PATIENT REPORTED OUTCOME (PRO) REQUIREMENTS: If the study requires PRO data collected by CIBMTR, the proposal should include: 1) A detailed description of the PRO domains, timepoints, and proposed analysis of PROs; 2) A description of the hypothesis speci	N/A
MACHINE LEARNING: Please indicate if the study requires methodology related to machine-learning and clinical predictions.	N/A
SAMPLE REQUIREMENTS: If the study requires biologic samples from the CIBMTR Repository, the proposal should also include: 1) A detailed description of the proposed testing methodology and sample requirements; 2) A summary of the investigator's previous e	N/A
NON-CIBMTR DATA SOURCE: If applicable, please provide: 1) A description of external data source to which the CIBMTR data will be linked; 2) The rationale for why the linkage is required.	N/A

Field	Response
REFERENCES:	<p>Redondo, S., García-Cadenas, I., Esquirol, A., Portos, J. M., Iranzo, E., Arguello-Tomas, M., ... & Martino, R. (2024). Severity and organ distribution of graft-versus-host disease with post-transplant cyclophosphamide versus calcineurin inhibitor plus methotrexate/mycophenolate mofetil or sirolimus in allogeneic HLA-matched or single-allele mismatched stem cell transplantation. <i>European Journal of Haematology</i>, 113(6), 776-787.</p> <p>Baranwal, A., Graham, C., Hassan, K., Kassis, R., Braun, J., Bartoo, G., ... & Alkhateeb, H. B. (2025). Comparison of Chimerism Kinetics and Associated Outcomes in Patients Receiving Post-Transplant Cyclophosphamide Versus Methotrexate based GVHD Prophylaxis Following Allogeneic Hematopoietic Cell Transplant. <i>Transplantation and Cellular Therapy</i>, Official Publication of the American Society for Transplantation and Cellular Therapy, 31(9), 670-e1.</p> <p>Munshi, P. N., Vesole, D., Jurczyszyn, A., Zaucha, J. M., St. Martin, A., Davila, O., ... & D'Souza, A. (2020). Age no bar: a CIBMTR analysis of elderly patients undergoing autologous hematopoietic cell transplantation for multiple myeloma. <i>Cancer</i>, 126(23), 5077-5087.</p>
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

Table 1.

Characteristic	PTCy-based	CNI-based	Total
No. of patients	2009	2416	4425
No. of centers	207	235	263
Age, by decades, no. (%)			
Median (range)	50.7 (18.1-78.8)	52.1 (18.0-81.5)	51.6 (18.0-81.5)
18-19	38 (2)	67 (3)	105 (2)
20-29	283 (14)	330 (14)	613 (14)
30-39	329 (16)	330 (14)	659 (15)
40-49	326 (16)	380 (16)	706 (16)
50-59	413 (21)	591 (24)	1004 (23)
60-69	494 (25)	597 (25)	1091 (25)
70+	126 (6)	121 (5)	247 (6)
CCN region at transplant, no. (%)			
US	1661 (83)	1851 (77)	3512 (79)
Canada	66 (3)	137 (6)	203 (5)
Europe	50 (2)	87 (4)	137 (3)
Asia	20 (1)	62 (3)	82 (2)
Australia/New Zealand	54 (3)	120 (5)	174 (4)
Mideast/Africa	22 (1)	61 (3)	83 (2)
Central/South America	136 (7)	98 (4)	234 (5)
Sex, no. (%)			
Male	1202 (60)	1365 (56)	2567 (58)
Female	807 (40)	1051 (44)	1858 (42)
Race, no. (%)			
White	1471 (73)	1807 (75)	3278 (74)
Black or African American	195 (10)	81 (3)	276 (6)
Asian	94 (5)	177 (7)	271 (6)
Native Hawaiian or other Pacific Islander	6 (0)	9 (0)	15 (0)
American Indian or Alaska Native	7 (0)	5 (0)	12 (0)
More than one race	22 (1)	19 (1)	41 (1)
Not reported	214 (11)	318 (13)	532 (12)
Karnofsky score prior to HCT, no. (%)			
90-100%	919 (46)	1134 (47)	2053 (46)
< 90%	1001 (50)	1201 (50)	2202 (50)
Not reported	89 (4)	81 (3)	170 (4)
Sorrer comorbidity score, no. (%)			
0	395 (20)	575 (24)	970 (22)
1	308 (15)	346 (14)	654 (15)
2	290 (14)	334 (14)	624 (14)

Characteristic	PTCy-based	CNI-based	Total
3	386 (19)	433 (18)	819 (19)
4	259 (13)	307 (13)	566 (13)
5	157 (8)	175 (7)	332 (8)
6	105 (5)	110 (5)	215 (5)
7	58 (3)	72 (3)	130 (3)
8	27 (1)	35 (1)	62 (1)
9	16 (1)	20 (1)	36 (1)
10	4 (0)	5 (0)	9 (0)
11	2 (0)	2 (0)	4 (0)
12	0 (0)	1 (0)	1 (0)
13	1 (0)	1 (0)	2 (0)
14	1 (0)	0 (0)	1 (0)
Primary disease, no. (%)			
AML	1062 (53)	1266 (52)	2328 (53)
ALL	315 (16)	345 (14)	660 (15)
Other leukemia	10 (0)	15 (1)	25 (1)
CLL	8 (0)	32 (1)	40 (1)
CML	66 (3)	67 (3)	133 (3)
MDS	291 (14)	386 (16)	677 (15)
Other acute leukemia	37 (2)	34 (1)	71 (2)
NHL	66 (3)	76 (3)	142 (3)
HD	36 (2)	17 (1)	53 (1)
MM	10 (0)	20 (1)	30 (1)
Other PCD	2 (0)	4 (0)	6 (0)
MPN	106 (5)	154 (6)	260 (6)
Graft type (first allo HCT), no. (%)			
Bone marrow	354 (18)	358 (15)	712 (16)
Peripheral blood stem cells	1444 (72)	1776 (74)	3220 (73)
Umbilical cord blood	105 (5)	45 (2)	150 (3)
Peripheral blood stem cells + Bone marrow	3 (0)	7 (0)	10 (0)
Bone marrow + Umbilical cord blood	0 (0)	1 (0)	1 (0)
Peripheral blood stem cells + Umbilical cord blood	5 (0)	6 (0)	11 (0)
Peripheral blood stem cells + Other	7 (0)	7 (0)	14 (0)
Umbilical cord blood + Other	3 (0)	0 (0)	3 (0)
Not reported	88 (4)	216 (9)	304 (7)
Donor group (first allo HCT), no. (%)			
HLA-identical sibling	411 (20)	825 (34)	1236 (28)
Twin	11 (1)	11 (0)	22 (0)
Other related	599 (30)	220 (9)	819 (19)
8/8 matched URD	568 (28)	875 (36)	1443 (33)

Characteristic	PTCy-based	CNI-based	Total
7/8 mismatched URD	171 (9)	132 (5)	303 (7)
<= 6/8 mismatched URD;	13 (1)	7 (0)	20 (0)
Multi-donor	8 (0)	14 (1)	22 (0)
Unrelated (matching under review)	27 (1)	64 (3)	91 (2)
Cord blood	113 (6)	52 (2)	165 (4)
Not reported	88 (4)	216 (9)	304 (7)
GVHD prophylaxis (first allo HCT), no. (%)			
None	25 (1)	23 (1)	48 (1)
Ex-vivo T-cell depletion	9 (0)	23 (1)	32 (1)
CD34 selection	28 (1)	56 (2)	84 (2)
PTCy + other(s)	968 (48)	347 (14)	1315 (30)
PTCy alone	22 (1)	14 (1)	36 (1)
TAC + MMF +/- other(s) (except PTCy)	168 (8)	198 (8)	366 (8)
TAC + MTX +/- other(s) (except MMF, PTCy)	408 (20)	819 (34)	1227 (28)
TAC + other(s) (except MMF, MTX, PTCy)	42 (2)	128 (5)	170 (4)
TAC alone	38 (2)	82 (3)	120 (3)
CSA + MMF +/- other(s) (except PTCy,TAC)	74 (4)	148 (6)	222 (5)
CSA + MTX +/- other(s) (except PTCy,TAC,MMF)	117 (6)	312 (13)	429 (10)
CSA + other(s) (except PTCy,TAC,MMF,MTX)	3 (0)	5 (0)	8 (0)
CSA alone	5 (0)	23 (1)	28 (1)
Other(s)	11 (1)	21 (1)	32 (1)
Missing	91 (5)	217 (9)	308 (7)
Conditioning intensity (first allo HCT), no. (%)			
Myeloablative	1052 (52)	1265 (52)	2317 (52)
Non-myeloablative (NST)	272 (14)	217 (9)	489 (11)
Reduced intensity (RIC)	527 (26)	526 (22)	1053 (24)
Not myeloablative, either NST or RIC	65 (3)	180 (7)	245 (6)
Not reported	93 (5)	228 (9)	321 (7)
Graft source, no. (%)			
Bone marrow	150 (7)	138 (6)	288 (7)
Peripheral blood stem cells	1859 (93)	2278 (94)	4137 (93)
Donor type, no. (%)			
HLA identical sibling	96 (5)	665 (28)	761 (17)
Haploidentical donor	1176 (59)	146 (6)	1322 (30)
Well-matched unrelated (8/8)	459 (23)	1371 (57)	1830 (41)
Partially-matched unrelated (7/8)	238 (12)	226 (9)	464 (10)
Mismatched unrelated (<= 6/8)	40 (2)	8 (0)	48 (1)
Conditioning intensity, no. (%)			
Myeloablative	423 (21)	818 (34)	1241 (28)
Non-myeloablative (NST)	588 (29)	459 (19)	1047 (24)

Characteristic	PTCy-based	CNI-based	Total
Reduced intensity (RIC)	998 (50)	1139 (47)	2137 (48)
Conditioning regimen, no. (%)			
TBI/Cy	24 (1)	131 (5)	155 (4)
TBI/Cy/Flu	789 (39)	161 (7)	950 (21)
TBI/Cy/Flu/TT	2 (0)	3 (0)	5 (0)
TBI/Cy/TT	0 (0)	5 (0)	5 (0)
TBI/Cy/VP	2 (0)	7 (0)	9 (0)
TBI/VP	3 (0)	41 (2)	44 (1)
TBI/Mel	201 (10)	120 (5)	321 (7)
TBI/Flu	171 (9)	323 (13)	494 (11)
TBI/other(s)	17 (1)	15 (1)	32 (1)
Bu/Cy/Mel	0 (0)	1 (0)	1 (0)
Bu/Cy	68 (3)	117 (5)	185 (4)
Bu/Mel	7 (0)	11 (0)	18 (0)
Flu/Bu/TT	60 (3)	24 (1)	84 (2)
Flu/Bu	176 (9)	444 (18)	620 (14)
Flu/Mel/TT	28 (1)	8 (0)	36 (1)
Flu/Mel	364 (18)	654 (27)	1018 (23)
FCR	0 (0)	2 (0)	2 (0)
Cy/Flu	25 (1)	54 (2)	79 (2)
Cy alone	1 (0)	12 (0)	13 (0)
BEAM	0 (0)	5 (0)	5 (0)
Mel alone	10 (0)	29 (1)	39 (1)
Mel/other(s)	3 (0)	38 (2)	41 (1)
Treosulfan	19 (1)	39 (2)	58 (1)
TLI	0 (0)	7 (0)	7 (0)
Other(s)	39 (2)	152 (6)	191 (4)
Missing	0 (0)	13 (1)	13 (0)
GVHD prophylaxis, no. (%)			
PtCy + other(s)	1988 (99)	0 (0)	1988 (45)
PtCy alone	21 (1)	0 (0)	21 (0)
TAC + MMF +/- other(s) (except PtCy)	0 (0)	506 (21)	506 (11)
TAC + MTX +/- other(s) (except MMF, PtCy)	0 (0)	963 (40)	963 (22)
TAC + other(s) (except MMF, MTX, PtCy)	0 (0)	210 (9)	210 (5)
TAC alone	0 (0)	154 (6)	154 (3)
CSA + MMF +/- other(s) (except PtCy,TAC)	0 (0)	221 (9)	221 (5)
CSA + MTX +/- other(s) (except PtCy,TAC,MMF)	0 (0)	297 (12)	297 (7)
CSA + other(s) (except PtCy,TAC,MMF,MTX)	0 (0)	7 (0)	7 (0)
CSA alone	0 (0)	58 (2)	58 (1)
Time from first allo HCT to second allo HCT (days)			

Characteristic	PTCy-based	CNI-based	Total
n / N	1921/2009	2200/2416	4121/4425
Mean (SD)	824.3 (877.40)	797.1 (837.82)	809.8 (856.50)
Median (25-75 percentile)	547.0 (234.0-1078.0)	509.0 (252.0-1020.5)	524.0 (244.0-1050.0)
Range	26.0-6216.0	-237.0-5768.0	-237.0-6216.0
Year of current transplant, no. (%)			
2010	2 (0)	46 (2)	48 (1)
2011	5 (0)	61 (3)	66 (1)
2012	7 (0)	73 (3)	80 (2)
2013	22 (1)	99 (4)	121 (3)
2014	61 (3)	197 (8)	258 (6)
2015	81 (4)	214 (9)	295 (7)
2016	81 (4)	189 (8)	270 (6)
2017	103 (5)	188 (8)	291 (7)
2018	146 (7)	208 (9)	354 (8)
2019	153 (8)	199 (8)	352 (8)
2020	203 (10)	182 (8)	385 (9)
2021	221 (11)	212 (9)	433 (10)
2022	210 (10)	209 (9)	419 (9)
2023	276 (14)	173 (7)	449 (10)
2024	342 (17)	140 (6)	482 (11)
2025	96 (5)	26 (1)	122 (3)
Follow-up of survivors, median (range), months	25.1 (0.0-170.0)	59.1 (0.0-169.9)	