MINUTES
CIBMTR WORKING COMMITTEE FOR ACUTE LEUKEMIA
Honolulu, HI
Thursday, February 13, 2025, 1:00 – 3:00 PM HST

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1. **Introduction**
    a. Minutes from February 2024 (Attachment 1)
    b. Introduction of incoming co-chair:
    Lori Muffly, MD; Stanford Health Care
    c. Acknowledgement of outgoing co-chair:
    Filippo Milano, MD; Fred Hutchinson Cancer Center
    d. Page Scholar participant
    Mariam Nawas, MD; The University of Chicago Medicine

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

3. **Presentations, Publications or Submitted papers**
    a. **LK19-02** Evolving significance of Ph-positive status on ALL post-transplant outcomes in the TKI era (M Krem / R Maziarz). ***Submitted.***

b. **LK20-02** Impact of Germline RUNX1 Mutations on Allogeneic Hematopoietic Stem Cell Transplant Outcomes in AML: A CIBMTR Analysis (L Cunningham). ***Oral Presentation, EBMT 2024.***
c. **LK21-01a** Pre-Allogeneic Transplantation Flow Cytometry Testing For Patients With AML In First CR, As Currently Performed, Has Limited Clinical Utility For Relapse And Survival Prediction: A CIBMTR Analysis (F El Chaer). ***Oral Presentation, EHA 2024.***
d. **LK21-01b** Measurable Residual NPM1 before Allogeneic Transplant for Acute Myeloid Leukemia (L Dillon/ C Hourigan). ***Poster Presentation, ASH 2024.***
e. **LK21-01d** Dillon LW, Gui G, Ravindra N, Andrew G, Mukherjee D, Wong ZC, Huang Y, Gerhold J, Holman M, D'Angelo J, Miller J, Higgins J, Salk JJ, Auletta JJ, El Chaer F, Devine SM, Jimenez-Jimenez AM, De Lima MJG, Litzow MR, Kebriaei P, Saber W, Spellman SR, Zeger SL, Page KM, Hourigan CS. Measurable residual FLT3 internal tandem duplication before allogeneic transplant for acute myeloid leukemia. **JAMA Oncology. doi:10.1001/jamaoncol.2024.0985. Epub 2024 May 2. PMC11066770.**
f. **LK21-01e** Hegde PS, Andrew G, Gui G, Ravindra N, Mukherjee D, Wong ZC, Auletta JJ, El Chaer F, Corner A, Devine SM, Jimenez-Jimenez AM, De Lima MJG, Litzow MR, Kebriaei P, Saber W, Spellman SR, Zeger SL, Page KM, Dillon LW, Hourigan CS. Measurable residual FLT3 tyrosine kinase domain mutations before allogeneic transplant for acute myeloid leukemia. **Bone Marrow Transplantation. doi:10.1038/s41409-024-02444-7. Epub 2024 Oct 18.**
g. **LK21-01f** Gui G, Ravindra N, Hegde PS, Andrew G, Mukherjee D, Wong ZC, Auletta JJ, El Chaer F, Chen EC, Chen Y, Corner A, Devine SM, Iyer SG, Jimenez Jimenez AM, De Lima MJG, Litzow MR, Kebriaei P, Saber W, Spellman SR, Zeger SL, Page KM, Dillon LW, Hourigan CS. Measurable residual mutated IDH2 before allogeneic transplant for acute myeloid leukemia. **Bone Marrow Transplantation. doi:10.1038/s41409-024-02449-2. Epub 2024 Oct 25.**
h. **LK21-01g** Gui G, Ravindra N, Hegde PS, Andrew G, Mukherjee D, Wong ZC, Auletta JJ, El Chaer F, Chen EC, Chen Y, Corner A, Devine SM, Iyer SG, Jimenez Jimenez AM, De Lima MJG, Litzow MR, Kebriaei P, Saber W, Spellman SR, Zeger S, Page KM, Dillon LW, Hourigan CS. Measurable residual mutated IDH1 before allogeneic transplant for acute myeloid leukemia. **Bone Marrow Transplantation. doi:10.1038/s41409-024-02447-4. Epub 2024 Nov 6.**

4. **Studies in progress** (Attachment 3)
   a. **LK20-01** Acute myeloid leukemia with chromosome 17 abnormalities with or without TP53 abnormalities and outcomes after hematopoietic stem cell transplantation (A Dias/J Yared). **Data File Preparation.**
   b. **LK20-02** Outcomes of allogeneic hematopoietic cell transplantation among germline RUNX1 mutation carriers with acute myeloid leukemia (P Liu/L Cunningham). **Manuscript Preparation.**
   c. **LK20-03** Evaluating outcomes of allogeneic hematopoietic cell transplantation in T-cell acute lymphoblastic leukemia (H Murthy/M Iqbal/M Kharfan-Dabaja). **Data File Preparation.**
   d. **LK21-01a** Impact of measurable residual disease status on outcomes of acute myeloid leukemia and patients 18-65 years old in first complete remission undergoing allogeneic hematopoietic cell transplantation (F El Chaer/C Hourigan). **Manuscript Preparation**
   e. **LK22-01** Impact of pre-allogeneic hematopoietic cell transplantation therapy in acute myeloid leukemia and myelodysplastic syndrome on post-transplant outcomes (Ali N). **Protocol Development**
   f. **LK23-01** The impact of allogeneic stem cell transplantation on acute myeloid leukemia and myelodysplastic syndrome with chromosome 3 abnormalities (A Datt Law). **Protocol Development.**

g. **LK23-02** Prognostic impact of cytogenetic and molecular risk classification in AML after hematopoietic stem cell transplant in adolescents and young adults (H Lust). **Protocol Development.**
h. **LK23-03** Impact of donor source in second allogeneic hematopoietic cell transplant in patients with acute leukemia/MDS who relapsed after prior allograft during the current era (2014-2020) (A Troullioud Lucas/ A Scaradavou). **Protocol Development.**
i. **LK24-01** Sequencing of chimeric antigen receptor T-cell therapy and allogeneic transplantation in adult patients with B-cell acute lymphoblastic leukemia (D Eng/ J Fein/ A Arteaga/ Luis Gonzalez Mosquera/ Kitsada Wudhikarn/ Muhammad Bilal Abid/ Abu-Sayeef Mirza). **Protocol Development**

5. Future/proposed studies

Proposed Studies to be presented for consideration at the Tandem WC Meeting

a. **PROP 2408-04** Outcomes after transplant in acute myeloid leukemia with t(6;9) (p23;q34) translocation (F Andreozzi) (Attachment 4)

Dr. Fabio Andreozzi presented.

- ***Key Points**:*
  - *AML with t(6;9)) is rare, accounting for 1-2% of cases.*
  - *Typically affects younger patients and is often chemotherapy resistant.*
  - *Study aims to assess outcomes post-transplant and correlate with various parameters like remission stage, HLA compatibility, conditioning intensity, FLT3-ITD mutations, and role of pre-transplant as well as post-transplant maintenance with FLT3 inhibitors.*
  - *Inclusion criteria: pediatric AML and MDS patients with t(6;9).*
  - *Classical endpoints: overall survival, incidence of relapse, non-relapse mortality, and graft-versus-host disease.*
  - *219 patients were identified from 2008 to 2019. Median age 37 and most were in CR1.*
  - *Key discussion points: 1) value of having a control arm, for e.g., those with FLT3 mutation but without t(6;9); 2) this question could have been pursued in other studies already and is not clear how the results will impact the practice; 3) EBMT already published on outcomes of these patients; 4) data availability and completeness in CIBMTR regarding FLT3 inhibitors use pre and post HCT*

b. **PROP 2408-06** Efficacy of hypomethylating agent/Venetoclax with or without donor lymphocyte infusion as management of post-transplant relapse acute myeloid leukemia and myelodysplastic syndrome (M Dandwani/ K Poonsombudlert) (Attachment 5)

Dr. Dandwani presented.

- ***Key Points**:*
  - *Study evaluates if adding DLI to hypomethylating agents and Venetoclax improves overall response rate and survival.*
  - *Focus on incidence of graft-versus-host disease, veno-occlusive disease, and hematological toxicity.*

- *Real-world evidence shows mixed results*
- *Key discussion points: 1) Most clinicians would tend to give DLI anyway or proceed to 2nd HCT; 2) concerns regarding selection bias among those chosen to get DLI vs. those who did not get DLI, and given retrospective nature, this will be hard to control; 3) heterogeneity in practice patterns among different centers*

c. **PROP 2410-06** Comparison of FluFTBI and other myeloablative Conditioning Regimens for Haploidentical and mismatched unrelated Hematopoietic Cell Transplant with Post-Transplant Cyclophosphamide in Patients with Acute Leukemia (S Arslan/ M Al Malki) (Attachment 6)

Dr. Arslan presented.

- ***Key Points**:*
  - *Evaluates outcomes of Fludarabine and TBI conditioning versus other myeloablative regimens.*
  - *Hypothesis: Fludarabine and TBI combinations may offer better outcomes.*
  - *Inclusion criteria: AML and ALL patients aged 18-60, undergoing haploidentical or mismatched unrelated transplants.*
  - *Large data set available for analysis.*
  - *Key discussion points: 1) concern whether TBI is mostly used with ALL rather than AML; 2) EBMT already published a similar study; 3) heterogeneity in regimens in control arm*

d. **PROP 2410-08; 2410-214; 2410-222** Survival Outcomes after allogeneic transplantation in Ph-like B-ALL (M Iqbal/ M Kharfan-Dabaja/ L Mendez/ L Gowda/ K V Nadiminti/ C Junge) (Attachment 7)

Dr. Chase Junge presented.

- ***Key Points**:*
  - *Compares outcomes in Ph-like ALL to Philadelphia positive and negative ALL.*
  - *Focus on overall survival, progression-free survival, and impact of novel immunotherapies.*
  - *Large cohort available for analysis, with stratification by age groups.*
  - *Key discussion points: 1) how Ph-like B-cell ALL is actually diagnosed is challenging across centers; 2) MRD data in CIBMTR forms have significant limitations; 3) how will results impact practice; 4) no value of including patients prior to 2014 because they did not have access to blinatumomab*

e. **PROP 2410-28** Comparison of reduced-intensity hematopoietic cell transplantation with CAR T cell therapy in patients age > 60 years with acute lymphoblastic leukemia (J Behman/ R Faramand) (Attachment 8)

Dr. John Behman presented.

- ***Key Points**:*
  - *Hypothesis: CAR T-cell therapy may offer improved survival compared to reduced intensity conditioning.*
  - *Focus on leukemia-free survival, MRD negativity, and treatment-related mortality.*

- *Data set includes patients aged 60 and older.*
- *Key discussion points: 1) the HCT cohort is mostly CR while the CAR-T cohort is mostly relapsed disease patients; 2) median FU among CAR-T patients is short*

f. **PROP 2410-70** Clinical Outcomes of Patients with Acute Lymphoblastic Leukemia with Measurable Residual Disease Who Receive CAR-T Cell Therapy vs Allogeneic Stem Cell Transplantation (G Sanchez-Petitto/ M de Lima) (Attachment 9)

Dr. Sanchez-Petitto presented.

- *Key Points:*
  - *What is the effectiveness of CAR-T cell therapy compared to allogenic stem cell transplant, in treating MRD positive patients with B-cell ALL*
  - *We hypothesize that for those patients who are 35 year old or older, or who have high cytogenetic risk, or advanced disease, allogenic transplant provides better outcomes.*
  - *Key discussion points: 1) CAR-T cohort is mostly comprised of pediatric and AYA patients, while allo-HCT cohort is mostly comprised of adult patients; 2) not clear how to handle post CAR allo-HCT; 3) how complete the data on blinatumomab is in CIBMTR*

g. **PROP 2410-199** Optimal Reduced Intensity Conditioning Regimen for Allogeneic Transplant in Measurable Residual Disease (MRD) Positive Acute Myeloid Leukemia (R Ramlal/ N Bejanyan) (Attachment 10)

Dr. Ramlal presented.

- *Key Points:*
  - *Hypothesis: Fludarabine and Melphalan may offer the best outcomes.*
  - *Focus on overall survival, leukemia-free survival, and relapse rates.*
  - *Large data set available for analysis.*
  - *Key points: 1) heterogeneity in regimens is a concern; 2) MRD definition; 3) completeness of post HCT maintenance therapies is a concern*

h. **PROP 2410-225** Comparison of myeloablative versus reduced intensity conditioning regimens in patients with Acute Lymphoblastic Leukemia achieving an MRD negative remission prior to allogeneic hematopoietic stem cell transplant (X Bi/ U Gergis) (Attachment 11)

Dr. Xia Bi presented.

- *Key Points:*
  - *Hypothesis: Reduced intensity conditioning may offer comparable outcomes with less toxicity.*
  - *Focus on overall survival, leukemia-free survival, and relapse rates.*
  - *Large data set available for analysis.*
  - *Key issues: 1) MRD data quality; 2) for PH +ve ALL, how complete the CIBMTR data on use of post HCT TKI is a concern*

i. **PROP 2410-259** Machine Learning–Based Model Development to Predict Acute Myeloid Leukemia Relapse after Allogeneic Transplantation (N Bejanyan/ G Valdes) (Attachment 12)

Dr. Nelli Bejanyan presented.

- *Key Points:*
  - *Aim to establish and validate a machine learning model using pre- and post-transplant covariates.*
  - *Focus on relapse, overall survival, and leukemia-free survival.*
  - *Large data set available for analysis.*
  - *Key issues: 1) impact on practice*

j. **PROP 2410-52; 2410-227** Determining optimal conosolidation for precursor Bcell Acute lymphoblastic leukemia in CR1. Comparing allogeneic hematopoietic cell transplantation to blinatumumab consolidation. A ECOG/CIBMTR comparitive study. (H S. Murthy/ M Litzow/ L Gowda/ K Chetlapalli) (Attachment 13)

Dr. Murthy presented.

- *Key Points:*
  - *Compares blinatumomab consolidation to allogeneic transplant.*
  - *Focus on overall survival, progression-free survival, and relapse rates.*
  - *Data set includes patients from the E1910 study and CIBMTR*
  - *Key issues: 1) true denominator is different between the two cohorts; 2) MRD data quality; 3) comparing RCT participants to real world evidence can be problematic*

Proposed studies; not accepted for consideration at this time

k. **PROP 2312-02** Do European Leukemia Net (ELN) 2017,2022 add to the Prognostic value of Disease Risk Index in Acute Myeloid Leukemia (AML) Patients in First Complete Remission who undergo Allogeneic Hematopoietic Stem Cell Transplant (A Masurekar). ***Dropped due to overlap with current study/publication.***
l. **PROP 2404-01** Maintenance Therapy after Allogeneic Stem Cell Transplant in Acute Myeloid Leukemia (A Sperotto/ M Gottardi). ***Dropped due to supplemental data needed.***
m. **PROP 2405-01** Real World Utilization Rates of Central Nervous System (CNS) Radiotherapy (RT) in Adult Acute Lymphoid Leukemia (ALL) (L Ballas/ S Zhang). ***Dropped due to small sample size and supplemental data needed.***
n. **PROP 2405-02** Outcomes of Ph+ ALL in CR1 MRD- status in the PostCy/RIC ERA (J Behman). ***Dropped due to overlap with current study/publication.***
o. **PROP 2408-03** Impact of post-transplant blinatumomab maintenance on outcomes of patients with B-cell acute lymphoblastic leukemia (P Vittayawacharin/ S Cirurea). ***Dropped due to low scientific impact.***
p. **PROP 2408-05** Looking beyond the HLA barrier; use of alternative donors for adverse risk acute myeloid leukemia (A Vegel/ K Poonsombudlert). ***Dropped due to overlap with current study/publication.***
q. **PROP 2409-07** Does prophylactic use of defibrotide lead to less incidence of TA-TMA (Y Choi). ***Dropped due to incomplete data in the CIBMTR database and need for supplemental data collection.***

r. **PROP 2409-08** Evaluation of Post-transplant Cyclophosphamide vs Calcineurin + Methotrexate Based Graft Versus Host Disease Prophylaxis in Acute Lymphoblastic Leukemia Patients (J Behman/ T Nishihori). ***Dropped due to overlap with current study/publication.***
s. **PROP 2409-09** Time to Allogeneic Transplant in Acute Myeloid Leukemia: Does it matter? (A Masurekar). ***Dropped due to overlap with current study/publication.***
t. **PROP 2410-05** Early donor chimerism is predictive of relapse and survival following allogeneic hematopoietic stem cell transplantation (P Munshi/ N Hossain). ***Dropped due to overlap with current study/publication.***
u. **PROP 2410-26** Real world data of SCT on TALL in the modern era (S Srikantan/ S Farhan). ***Dropped due to overlap with current study/publication.***
v. **PROP 2410-29** Mixed Donor Chimerism and its Impact on Relapse Rates and Relapse-Free Survival in Patients with Acute Leukemias Receiving PTCy versus Methotrexate-based GVHD Prophylaxis (C Graham/ H Alkhateeb). ***Dropped due to overlap with current study/publication.***
w. **PROP 2410-36** Biological Characteristics and Survival Outcomes in TP53-mutated Myelodysplastic Syndrome and Acute Myeloid Leukemia Patients Undergoing Allogeneic Stem Cell Transplantation: A CIBMTR Study (P Ramadas/ A Ananthaneni). ***Dropped due to overlap with current study/publication.***
x. **PROP 2410-50** Analyzing the Impact of Co-Mutations and Cytogenetics on Transplant Outcomes in NPM1- Mutated AML Using Machine Learning Models (J Wang/ M de Lima). ***Dropped due to overlap with current study/publication.***
y. **PROP 2410-62** Best Donor Type for Allogeneic Hematopoietic Cell Transplantation in High-Risk Acute Leukemia and Myelodysplastic Syndrome: Optimally Selected Haploidentical Donor, Double Unrelated Cord Blood or Matched Unrelated Donor? (G Fatobene/ V Rocha). ***Dropped due to overlap with current study/publication.***
z. **PROP 2410-81** Outcomes of Matched and mismatched unrelated allogeneic stem cell transplantation using posttransplant cyclophosphamide versus tacrolimus and methotrexate in patients with acute myeloid leukemia and myelodysplastic syndrome with TP 53 mutation and/or del(17p)/-17 (F Socola/ B Jonas). ***Dropped due to overlap with current study/publication.***
aa. **PROP 2410-84** Outcomes and Predictors of outcomes of adult patients with therapy-related acute lymphoblastic leukemia after allogeneic hematopoietic stem transplantation (R Nampoothir). ***Dropped due to limited data available in the CIBMTR database.***
bb. **PROP 2410-121** Prophylactic and preemptive donor lymphocyte infusion alone or in combination with hypomethylating agents after allogeneic stem cell transplantation for acute myeloid leukemia and myelodysplastic syndrome (N Tijaro Ovalle/ S Giralt). ***Dropped due small sample size.***
cc. **PROP 2410-130** Comparison of myeloablative versus reduced intensity conditioning regimens in patients with AML achieving an MRD negative remission prior to allogeneic hematopoietic stem cell transplant (X Bi/ U Gergis). ***Dropped due to overlap with current study/publication.***
dd. **PROP 2410-134** Comparison of outcomes between haploidentical, matched sibling, matched unrelated, and mismatched unrelated donor hematopoietic cell transplantation with post-transplant cyclophosphamide, mycophenolate mofetil, and a calcineurin inhibitor graft-versus-host disease prophylaxis in patients with acute myeloid leukemia (A Wofford/ M Wieduwilt). ***Dropped due to overlap with current study/publication.***
ee. **PROP 2410-155** Outcomes of allogeneic hematopoietic cell transplantation for de novo philadelphia chromosome-positive acute myeloid leukemia (N Sumransub/ M Juckett). ***Dropped due to limited availability of data in the CIBMTR database and small sample size.***

ff. **PROP 2410-156** Benefit of planned allogeneic stem cell transplant after CART cell therapy for B cell Acute lymphoblastic leukemia (R Nampoothiri/ N Kekre). ***Dropped due to overlap with current study/publication.***
gg. **PROP 2410-177** Allogeneic hematopoietic cell transplantation for patients with nucleophosmin (NPM1) mutant acute myeloid leukemia (AML) (L Gowda/ V Bhatt). ***Dropped due to overlap with current study/publication.***
hh. **PROP 2410-180** Impact of Clonal Evolution in Post-Transplantation Relapsed Myeloid Neoplasms (L Williams/ C Lai). ***Dropped due to small sample size.***
ii. **PROP 2410-184** Second Allogeneic Stem Cell Transplantation in Relapsed Myeloid Malignancies: Clinical Outcomes and Prognostic Insights (M Alhomoud/ B Shaffer). ***Dropped due to overlap with current study/publication.***
jj. **PROP 2410-190** Outcomes of T-Cell Depleted Allogeneic Stem Cell Transplant in Acute Myeloid Leukemia and High-Risk Myelodysplastic Syndrome (J L Reagan/ M R Christopher). ***Dropped due to overlap with current study/publication.***
kk. **PROP 2410-191** Characteristics and Post-Transplant Outcomes of Patients with Core-Binding Factor Acute Myeloid Leukemia (J L Reagan/ M R Christopher). ***Dropped due to low scientific impact and small sample size.***
ll. **PROP 2410-195** Maintenance Tyrosine Kinase Inhibitors Following Allogeneic Hematopoietic Cell Transplantation in Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia (Ph+ ALL) (J L Reagan/ M R Christopher). ***Dropped due to overlap with current study/publication.***
mm. **PROP 2410-202** Impact of pre-allogeneic stem cell transplantation salvage therapy in adult patients with relapsed and/or refractory (R/R) FLT3 internal tandem duplication (FLT3-ITD) acute myeloid leukemia on post-transplant outcomes (R Mohty/ M Kharfan-Dabaja). ***Dropped due to low scientific impact.***
nn. **PROP 2410-203** Outcomes of T-Cell Depleted Hematopoietic Stem Cell Transplant in Acute Myeloid Leukemia and High-Risk Myelodysplastic Syndrome (J L Reagan/ M R Christopher). ***Dropped due to overlap with current study/publication.***
oo. **PROP 2410-208** Impact of CD19-directed CAR T Dose on Outcomes in Relapsed/Refractory B-acute Lymphoblastic Leukemia (K McNerney/ L Schultz). ***Dropped due to low scientific impact.***
pp. **PROP 2410-220** Impact of Conditioning Intensity and Regimens Across Donor Types and GVHD Prophylactic Platforms in Adults with B-cell ALL Undergoing Allogeneic Hematopoietic Cell Transplantation (M Abid/ M Aljurf). ***Dropped due to overlap with current study/publication.***
qq. **PROP 2410-230** Impact of induction regimen intensity on post- allogeneic hematopoietic cell transplantation (allo-HCT) outcomes in older (age>=60) patients with acute myeloid leukemia (R Mohty/ M Kharfan-Dabaja). ***Dropped due to overlap with current study/publication.***
rr. **PROP 2410-231** Real World Analysis of the use of Maintenance Chemotherapy using Low-Dose HMA Agents in patients with Acute Leukemia and MDS to decrease the Risk of Relapse (C Graham). ***Dropped due to incomplete data in the CIBMTR database and supplemental data needed.***
ss. **PROP 2410-235** Outcomes of Allogeneic Hematopoietic Cell Transplantation for NF1-Mutated Myeloid Neoplasms (MDS and AML) (S Mirza). ***Dropped due to limited data available in the CIBMTR database and supplemental data needed.***
tt. **PROP 2410-247** Early versus late post-transplant maintenance for Patients with high-risk AML (S Mirza/ N Bejanyan). ***Dropped due to incomplete data in the CIBMTR database and supplemental data needed.***
uu. **PROP 2410-255;256** Outcomes of Flu/Bu Vs. Bu/Cy in adults with AML undergoing myeloablative allogeneic HCT for AML in morphologic remission with measurable residual disease (S Manjappa/ R B Walter). ***Dropped due to low scientific impact.***
ww. **PROP 2410-257** To compare the outcomes of different pre-transplant salvage regimens (FLT3i

combination therapy, conventional chemotherapy) in R/R FLT3mut AML (A R Kurup/ H Sibai). ***Dropped due to low scientific impact.***

xx. **PROP 2410**-**262** Evaluating Outcomes in Elderly Patients Undergoing Allogeneic Bone Marrow Transplant (BMT) with Different Pre-Transplant Treatment Regimens (A R Kurup/ H Sibai). ***Dropped due to overlap with current study/publication.***

yy. **PROP 2410**-**265** Impact of Transplant Characteristics on Outcomes in HCT for AML Patients in CRi (E Krieger/ A Toor). ***Dropped due to data available in the CIBMTR database and supplemental data needed.***

6. Other business