1. **Introduction**
   Dr. Mark Litzow called the meeting to order at 12:15 PM, introduced the members of the LKWC leadership, and mentioned that Dr. Brenda Sandmaier was unable to attend the meeting. Dr. Litzow introduced the incoming Co-Chair, Dr. Christopher Hourigan, who will be replacing Dr. Sandmaier in the upcoming year. The attendees were reminded to have their badges scanned to be included in the working committee email list and to fill out the voting sheets and evaluations. Dr. Litzow explained the voting criteria and scoring, prioritization of accepted studies, rules for authorship on CIBMTR studies, and the advisory committee metrics. The differences between TED and CRF sources of data were briefly reviewed.

2. **Accrual summary**
   The accrual summary was not presented due to time constraints but was made available to attendees as an attachment.

3. **Presentations, published or submitted papers**
   Details regarding presentations and publications were not presented due to time constraints but was made available to attendees as an attachment.


e. LK16-01 Reduced Intensity Conditioning (RIC) regimens for Acute Myeloid Leukemia (AML): A comparison of Busulfan (B) and Melphlan (M) based regimens from the CIBMTR database (PI: Z Gul/ G Ahmed/M Khan/G Hilderbrandt/H Akhateeb/M Damlaj/M Patnaik/R Nath/Z Zhou/J Cerny; MS: Hai-Lin Wang; PhD: Hai-Lin Wang; oversight assignment: Brenda Sandmaier; Sci Dir: Saber) *Submitted*

f. LK15-03 Comparison of outcomes of older adolescents and young adults with Philadelphia-chromosome/BCR-ABL1-negative acute lymphoblastic leukemia receiving post-transplant consolidation chemotherapy with pediatric-inspired chemotherapy on CALGB 10403 or myeloablative allogeneic hematopoietic cell transplantation (M Wieduwilt/W Stock/D Weisdorf) *Presented at ASH 2019, manuscript in preparation*

g. LK16-02 DRI-guided Choice of Conditioning Intensity for Allogeneic Hematopoietic Cell Transplantation in Adults with Acute Myeloid Leukemia and Myelodysplastic Syndromes (N Bejanyan/ E Warlick/C Brunstein/D Weisdorf) *Presented at ASH 2019, manuscript in preparation*

h. LK16-03 Allogeneic transplantation to treat therapy related acute myeloid leukemia and myelodysplastic syndromes (N Callander/L Metheny/M De Lima/A Hall) *Presented at ASH 2019, manuscript in preparation*

i. LK17-01 Outcomes of acute myeloid leukemia patients who undergo allogeneic transplant stratified by depth of clinical response (M Percival/B Sandmaier/E Estey) *Presented at ASH 2019, manuscript in preparation*

j. LK17-02 Allogeneic Hematopoietic Transplant Outcomes in Adult Patients with MLL-rearranged Acute Myeloid Leukemia (K Menghrajani/M Tallman) *Presented at TCT 2020, manuscript in preparation*

4. Studies in progress
Dr. Litzow gave an overview of the status of currently active studies.

a. LK17-03 Impact of post-transplant maintenance therapy with BCR-ABL tyrosine kinase inhibitors on outcomes of Philadelphia chromosome-positive acute lymphoblastic leukemia (Z DeFilipp/YB Chen) *Manuscript preparation*

b. LK18-01 Prognostic Impact of the new European LeukemiaNet Genetic Risk Stratification Categories in Predicting Outcomes for Adults with Acute Myeloid Leukemia undergoing Allogeneic Hematopoietic Stem Cell Transplantation (A Jimenez/T Wang/M de Lima/K Komanduri) *Data file preparation*

c. LK18-02 Comparison of outcomes of HCT with matched-related donor or matched-unrelated donor alloHCT for adults with acute lymphoblastic leukemia (M Wieduwilt/L Metheny/M de Lima) *Data file preparation*

d. LK19-01 Evaluating outcomes of hematopoietic cell transplantation in blastic plasmacytoid dendritic cell neoplasm (H Murthy/M Kharfan-Dabaja) *Protocol development*

e. LK19-02 Evolving significance of Ph-positive status on ALL post-transplant outcomes in the TKI era (M Krem/R Maziarz) *Protocol development*
f. **LK19-03** Outcomes of allo-HCT in AML patients who achieved complete remission after two or more cycles of induction chemotherapy (M Boyiadzis/M de Lima) **Protocol development**

5. **Future/proposed studies**

Drs. Litzow and Partow Kebriaei led this session. Presenters were reminded to limit their presentations to 5 minutes to ensure time for discussion (5 minutes).

a. **PROP 1909-01** Comparison of Reduced-Intensity Conditioning Regimens for Older Patients with AML and MDS: A propensity score analysis (S O Ciurea/P Kongtim/M Al Malki/N Bejanyan/B Sandmaier)

Dr. Stefan Ciurea presented the proposal. The main objective of the proposed study is to compare the progression-free survival of elderly patients with AML and MDS receiving allo-HCT using FM100 with other RIC and NMA conditioning regimens. A total of 3,649 patients aged 60 and older underwent first allo-HCT for AML/MDS in 2008-2018, with 89 receiving FM100 and 3560 receiving another type of RIC/NMA regimen.

Comments were received about potential confounding due to the effect of GVHD prophylaxis on toxicity of Flu/Mel and disease status on conditioning intensity choice. Suggestions were made to limit the patient population to MDS due to the small number of AML patients, to not include FM140 in the comparison to other RIC regimens, and to look at center effect for those receiving FM100 regimen.


Dr. Fevzi Yalniz presented the proposal. The primary objective of the proposed study is to assess the outcomes of adult patients who underwent a second allo-HCT for relapsed AML/MDS/ALL and to identify risk factors associated with survival. The secondary aim is to establish the impact of using haploidentical donors for second allo-HCT. There are 790 patients who received a second allo-HCT for relapsed AML, ALL, or MDS in 2000-2018.

The attendees made several suggestions including separating the AML/MDS and ALL populations, checking which patients had the same donor for the first and second transplants, and extending the population to include those transplanted after 2018. Concerns were raised about the feasibility of the second aim since very few patients received a second transplant from a haploidentical donor.

c. **PROP 1910-20** Evaluating outcomes of allogeneic hematopoietic cell transplantation in T-cell acute lymphoblastic leukemia (H Murthy/M Iqbal/M Kharfan-Dabaja)

Dr. Madiha Iqbal presented the proposal. The study objectives are to describe clinical outcomes of patients with T-cell ALL undergoing allo-HCT and to evaluate the impact of patient, disease, and transplant related factors on these outcomes. There are 1144 patients who received first allo-HCT for T-cell ALL in 2000-2017.

Questions were asked about availability of the following data: MRD status, cytogenetics, nelarabine use, extramedullary involvement, and ATG use. An attendee suggested including T-cell lymphoblastic lymphoma patients in the study.

d. **PROP 1911-18/1911-83/1911-191/1911-224** Acute myeloid leukemia (AML) with chromosome 17 abnormalities with or without TP53 abnormalities and outcomes after hematopoietic stem cell transplantation (A Dias/J Yared/A Gomez-Arteaga/R Shallis/M Byrne/B McClune/A Rapoport/A Jakubowski/L Gowda/B Skikne/N Hardy/S Dahiya/T Lin/S Giralt/M Litzow)

Dr. Jean Yared presented the proposal. The proposed study aims to identify patient, disease, and transplant related variables that can be predictors of outcomes in AML patients with chromosome
17 (ch17) abnormalities. There are 632 patients with ch17 abnormalities who received a first allo-

Questions were asked about the availability of post-HCT maintenance therapy data (particularly
about venetoclax and IDH inhibitors), if it is possible to identify mono/bi-allelic TP53 mutations, if
samples are available for TP53 typing, MRD data availability, and post-transplant maintenance
therapy. Due to small number of patients with reliable TP53 typing, one attendee suggested
comparing complex and/or monosomal karyotypes with and without 17p deletion.

e. **PROP 1911-73/1911-205** Comparison of outcomes of myeloablative versus reduced-intensity
conditioning for allogeneic hematopoietic cell transplant in adults with B-cell acute lymphoblastic
leukemia (M Schwartz/M Wieduwilt/M Mei/R Nakamura/I Aldoss)

Dr. Marc Schwartz presented the proposal. The proposed study aims to compare outcomes
between ALL patients who received MAC and those who received RIC; within the RIC population,
outcomes of patients receiving Flu/Mel vs FluBu2 will be compared. A total of 2526 adult patients
undergoing first allo-HCT for ALL in 2000-2017 received either MAC (2276) or RIC (250) prior to
transplant; out of the 250 RIC patients, 68 received FluBu2 and 117 received Flu/Mel.

Comments were made about taking age into account since the median age of patients in MAC and
RIC groups differ greatly. Another commenter suggested accounting for year of transplant because
therapy regimens have changed over the past decade.

f. **PROP 1911-078** Busulfan based conditioning in ALLO-HCT for acute myeloid leukemia or
myelodysplastic syndromes from HLA matched related and unrelated donors (M Sobh/C
Bredeson)

Dr. Christopher Bredeson presented the proposal. The primary objective of the study is to
compare post-transplant outcomes of AML and MDS patients receiving different busulfan-based
conditioning regimens, specifically in the dose ranges of 6.4 mg/kg, 9.6 mg/kg, and 12.8 mg/kg. A
total of 873 patients undergoing first allo-HCT for AML or MDS in 2008-2017 received busulfan-
based conditioning with doses in the described categories; specifically, 458 received 6.4 mg/kg,
49 received 9.6 mg/kg, and 366 received 12.8 mg/kg.

Questions were asked about the number of centers using the 9.6 mg/kg dose and about
clarifying if the goal of the study is to determine if a higher busulfan dose can be used in older
patients or if a lower dose can be used in younger patients. An attendee commented that a
similar study was proposed in the EBMT working group. One suggestion was to include
population based pharmacokinetic modeling for inference of busulfan exposure.

g. **PROP 1911-162/1911-194/1911-242** Outcomes of second allogeneic hematopoietic cell
transplant vs donor lymphocyte infusion in patients with relapsed acute lymphoblastic leukemia
relapse after the first allogeneic hematopoietic cell transplant (B Dholaria/A Jimenez/B Wirk/B
Savani/K Komanduri/T Wang/M de Lima)

Dr. Bhagirathbhai Dholaria presented the proposal. The primary objective of the proposed study
is to compare progression-free and overall survival of patients who received DLI vs. second allo-
HCT for relapsed ALL. Out of 275 adult patients undergoing first allo-HCT for ALL in 2000-2018
and relapsed, 155 received a second allo-HCT and 120 received DLI.

Questions were asked about the number of patients receiving CAR T-cell therapy, availability of
data on Ph status, how to address patients who received both treatments, and how to account
for possible selection bias due differing disease status between patients receiving second allo-
HCT and DLI. A suggestion was made to include relapsed patients who did not receive second
allo-HCT or DLI for comparison.

h. **PROP 1911-190** Outcomes of allogeneic hematopoietic cell transplantation (HCT) among
germline RUNX1 mutation carriers with acute myeloid leukemia (AML) (P Liu/W Saber/L
Cunningham)
Dr. Wael Saber presented the proposal. The objective of the proposed study is to identify patient, disease, and transplant related factors that affect post-transplant outcomes in AML patients with germline RUNX1 mutations. There are 180 patients who received first allo-HCT for AML with a RUNX1 mutation in 2013-2019 and have samples available for typing in the CIBMTR biorepository.

Questions were asked about the availability of donor samples. Suggestions from the audience consisted of expanding the study to examine other germline mutations, including MDS patients, and including late effects as outcomes.

**Proposed studies; not accepted for consideration at this time**

Dr. Litzow mentioned that the committee received many proposals and briefly discussed common reasons for declining proposals such as feasibility issues, overlap with ongoing studies, and potential scientific impact.

a. **PROP 1906-01** Outcomes of allogeneic hematopoietic stem cell transplantation in Philadelphia chromosome positive acute myeloid leukemia

b. **PROP 1910-04** Compare outcomes of allogeneic hematopoietic cell transplantation (allo-HCT) in patients with acute lymphoblastic leukemia (ALL) with or without central nervous system disease involvement

c. **PROP 1910-05** Evaluating outcomes of allogeneic hematopoietic cell transplantation in acute myeloid leukemia with central nervous system involvement

d. **PROP 1910-06** Outcomes and predictors of outcomes of adult patients with therapy-related acute lymphoblastic leukemia after allogeneic hematopoietic stem cell transplantation

e. **PROP 1910-08** Impact of donor lymphocyte infusion (DLI) on mixed chimerism and minimal residual disease (MRD) and association with the CD3+ cell dose

f. **PROP 1910-11** Impact of the intensity of the conditioning regimen in adults between 55-65 years diagnosed with high-risk acute myeloid leukemia

g. **PROP 1910-14** Clinical implication of morphologic complete remission following targeted therapy in AML patients undergoing allogeneic hematopoietic stem cell transplantation.

h. **PROP 1910-17** Hematopoietic stem cell transplantation (HCT) for patients with active acute leukemia

i. **PROP 1911-09** Comparison of Flu/2GY TBI vs. Flu/4GY TBI reduced-intensity conditioning regimen in Leukemia/MDS patients undergoing allogeneic HCT

j. **PROP 1911-48** Comparison of post-transplant outcomes for patients with acute myeloid leukemia treated with higher intensity chemotherapy versus lower intensity targeted therapy

k. **PROP 1911-64** Influence of molecular and cytogenetic risk factors in myeloid sarcoma

l. **PROP 1911-82** Transplant outcomes of myeloid/lymphoid neoplasms with 8p11 syndrome (8p11 chromosomal translocation; FGFR1 molecular rearrangement)

m. **PROP 1911-91** The impact of allogeneic stem cell transplantation on acute myeloid leukemia and myelodysplastic syndrome with chromosome 3 abnormalities

n. **PROP 1911-111** Allogeneic hematopoietic cell transplantation for adult acute lymphoblastic leukemia: survival and outcomes in the modern era

o. **PROP 1911-112** Prophylactic CNS therapy after allogenic hematopoietic stem cell transplantation in adult acute lymphoblastic leukemia: A CIBMTR study

p. **PROP 1911-127** Impact of second cell therapy on the outcomes of patients with acute myeloid leukemia or myelodysplastic syndrome relapsed after a first allogeneic hematopoietic cell transplantation

q. **PROP 1911-131** Outcomes of patients with myeloid sarcoma and isolated CNS leukemia post-allogeneic stem cell transplant: a potential trans-Atlantic collaboration with EBMT
r. **PROP 1911-146** Outcomes of allogeneic hematopoietic cell transplantation for early T-precursor acute lymphoblastic leukemia

s. **PROP 1911-161** A new prognostic model for post-transplant AML outcomes

t. **PROP 1911-164** Impact of baseline absolute lymphocyte count on outcomes in patients with acute leukemia who underwent allo-HCT with anti-thymocyte globulin

u. **PROP 1911-179** Clinical outcomes in AML patients carrying isocitrate dehydrogenase (IDH1-2) mutations undergoing allogeneic hematopoietic stem cell transplantation

v. **PROP 1911-184** Allogeneic hematopoietic cell transplant outcomes in adult patients with Philadelphia chromosome like acute lymphoblastic leukemia

w. **PROP 1911-217** Comparison of reduced intensity conditioning regimens for allogeneic hematopoietic stem cell transplant with post-transplant cyclophosphamide

x. **PROP 1911-232** Impact of asparaginase containing versus non-asparaginase containing induction regimen on allogeneic transplantation outcomes for acute lymphoblastic leukemia

y. **PROP 1911-243** Comparison of graft failure rate between acute lymphoblastic leukemia vs myeloid neoplasm patients who undergo busulfan-based myeloablative haploidentical stem cell transplant

z. **PROP 1911-246** Exploring the impact of upfront induction therapy intensity in high risk myelodysplastic syndromes and acute myeloid leukemia on post-allogeneic stem cell transplant outcomes in older patients

aa. **PROP 1911-247** Incidence of therapy-related myelodysplastic syndrome and acute myeloid leukemia in the recipients of prior autologous hematopoietic cell transplantation (HCT) and their outcomes after allogeneic HCT

ab. **PROP 1911-263** Impact of systemic immunosuppressive therapy on recurrent malignancy following allogeneic hematopoietic cell transplantation in acute myeloid leukemia

ac. **PROP 1911-271** Mixed chimerism in post hematopoietic stem cell transplant high risk hematologic malignancies: incidence, management and outcomes

ad. **PROP 1912-05** The impact of HLA-B35 expression on the incidence and outcomes of acute myeloid leukemia with IDH2-R140Q mutation

6. Other business

- Dr. Kebriaei presented an updated definition of primary induction failure (PIF) based on recent publications and answered questions from the audience. The working definition of PIF is: No complete remission (CR) after 2 cycles of conventional combination chemotherapy or no CR after 4 cycles of hypomethylating based therapy.
- Advisory committee member Dr. Bart Scott attended the pre- and post-meetings, as well as the working committee meeting.
- It was suggested to clearly indicate the data source (TED or CRF) in the proposal demographic tables provided to presenters.
- After the new proposals were presented, each participant in the meeting had the opportunity to rate each proposal using paper ballots. Based on the voting results, current scientific merit, available number of relevant cases, and the impact of the study on the field, the following studies will move forward in the committee’s research portfolio for the upcoming year:
  - **PROP 1911-18/1911-83/1911-191/1911-224** Acute myeloid leukemia with chromosome 17 abnormalities with or without TP53 abnormalities and outcomes after hematopoietic stem cell transplantation (A Dias/J Yared/A Gomez-Arteaga/R Shallis/M
PROP 1911-190 Outcomes of allogeneic hematopoietic cell transplantation among germline RUNX1 mutation carriers with acute myeloid leukemia (P Liu/W Saber/L Cunningham)

The following study has been accepted but will be deferred until July 2021 due to limited statistical hours:

- PROP 1910-20 Evaluating outcomes of allogeneic hematopoietic cell transplantation in T-cell acute lymphoblastic leukemia (H Murthy/M Iqbal/M Kharfan-Dabaja)

- An additional proposal, PROP 1912-04: Impact of older age in allogeneic HCT for AML in CR1, was accepted based on the timeliness of the topic and the minimal amount of statistical hours required for completion.

### Working Committee Overview Plan for 2020 – 2021

<table>
<thead>
<tr>
<th>Proposal</th>
<th>Title</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>LK17-03</td>
<td>Impact of post-transplant maintenance therapy with BCR-ABL tyrosine kinase inhibitors on outcomes of Philadelphia chromosome-positive acute lymphoblastic leukemia</td>
<td>Analysis is underway. The goal is to complete the analysis and start manuscript preparation by July 2020 and have the manuscript submitted by July 2021. 130 statistical hours have been allocated to accomplish these goals.</td>
</tr>
<tr>
<td>LK18-01</td>
<td>Prognostic impact of ELN risk group in alloHCT for adult AML in CR1/CR2</td>
<td>Data file preparation is underway. The goal is to complete the data file and analysis and begin manuscript preparation by July 2020. We expect to have the manuscript submitted by July 2021. 170 statistical hours have been allocated to accomplish these goals.</td>
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<tr>
<td>LK18-02</td>
<td>Comparison of outcomes of HCT with matched-related donor or matched-unrelated donor alloHCT for adults with acute lymphoblastic leukemia</td>
<td>Data file preparation is underway. The goal is to complete the data file and analysis and begin manuscript preparation by July 2020. We expect to have the manuscript submitted by July 2021. 150 statistical hours have been allocated to accomplish these goals.</td>
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<tr>
<td>LK19-01</td>
<td>Evaluating outcomes of Hematopoietic Cell Transplantation in Blastic Plasmacytoid Dendritic Cell Neoplasm</td>
<td>Protocol development is underway. The goal is to finalize the protocol and start data file preparation by July 2020. We expect to finish the analysis and start manuscript preparation by July 2021. 260 statistical hours have been allocated to accomplish these goals.</td>
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<tr>
<td>LK19-02</td>
<td>Evolving significance of Ph-chromosome status on ALL prognosis in the TKI era</td>
<td>Protocol development is underway. The goal is to finalize the protocol and start data file preparation by July 2020. We expect to finish the analysis and start manuscript preparation by July 2021. 260 statistical hours have been allocated to accomplish these goals.</td>
</tr>
<tr>
<td>LK19-03</td>
<td>Outcomes of alloHCT in AML patients who achieved complete remission after two or more cycles of induction chemotherapy</td>
<td>Protocol development is underway. The goal is to finalize the protocol and start data file preparation by July 2020. We expect to finish the analysis and start manuscript preparation by July 2021. 210 statistical hours have been allocated to accomplish these goals.</td>
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<tr>
<td>LK20-01</td>
<td>Acute myeloid leukemia with chromosome 17 abnormalities with or without TP53 abnormalities and outcomes after hematopoietic stem cell transplantation (Ajoy Dias, Jean Yared, Alexandra Gomez-Artega et al.)</td>
<td>The plan is to begin protocol development in July 2020</td>
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</table>
and finalize the protocol and begin data file preparation by July 2021. 120 statistical hours have been allocated to accomplish these goals.

h. **LK20-02** Outcomes of allogeneic hematopoietic cell transplantation among germline RUNX1 mutation carriers with acute myeloid leukemia (Paul Liu, Wael Saber, Lea Cunningham)
   The plan is to begin protocol development in July 2020 and finalize the population and begin sample typing by July 2021. 10 statistical hours have been allocated to accomplish these goals.

i. **LK20-03** Evaluating outcomes of allogeneic hematopoietic cell transplantation in T-cell acute lymphoblastic leukemia (Hemant Murthy, Madiha Iqbal, Mohamed Kharfan-Dabaja)
   This study has been deferred until July 2021.

j. **LK20-04** Impact of older age in allogeneic HCT for AML in CR1 (Joseph Maakaron, Daniel Weisdorf)
   The goal is to begin manuscript preparation by July 2020 and have the manuscript submitted by July 2021. 70 statistical hours have been allocated to accomplish these goals.

<table>
<thead>
<tr>
<th>Oversight Assignments for Working Committee Leadership (March 2020)</th>
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<tbody>
<tr>
<td><strong>Partow Kebriaei</strong></td>
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<tr>
<td><strong>LK18-02</strong>: Comparison of outcomes of haploidentical hematopoietic cell transplantation (HCT) with matched-related donor or matched-unrelated donor allogeneic HCT for adults with Ph-negative acute lymphoblastic leukemia</td>
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<td><strong>LK19-02</strong>: Evolving significance of Ph-chromosome status on ALL prognosis in the TKI era</td>
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<td><strong>LK20-02</strong>: Outcomes of allogeneic hematopoietic cell transplantation among germline RUNX1 mutation carriers with acute myeloid leukemia</td>
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<td><strong>Christopher Hourigan</strong></td>
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## Appendix: Overview Plan

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<th>Study number and title</th>
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