

# MINUTES AND OVERVIEW PLAN CIBMTR WORKING COMMITTEE FOR PLASMA CELL DISORDERS Orlando, FL

Thursday, February 16, 2023, 12:45 p.m. – 2:15 p.m. (EST)

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#### 1. Introduction

The Plasma Cell Disorders Working Committee (PCDWC) met on Thursday, February 16, 2023, at 12:45 p.m. The chairs, scientific director and statistician were all present at the meeting. Attendees were asked to have their name badges scanned at the front gate for attendance purpose and expressed that those members attending the meeting virtually will be part the committee membership roster.

As scientific director of the PCDWC, Dr. Marcelo Pasquini welcomed the attendees on behalf of the working committee leadership and started the welcome presentation by introducing each member of the working committee leadership, then explained how to gain and maintain membership, the goals, and expectations of the working committee. Dr. Pasquini acknowledged Dr. Nina Shah, for all her effort during the past years as Co-Chair and introduced Dr. Taiga Nishihori as the newly appointed Chair for the Working Committee starting May 1, 2023.

Dr. Pasquini discussed important details about how the working committee works and the committee goal and expectations. He emphasized the scoring process and scoring guide and discussed the rules of authorship. He informed the audience of the publicly available research dataset for secondary analysis in the CIBMTR webpage. Resources for additional information in the CIBMTR website was provided. Dr. Pasquini encouraged the attendance to the Collaborative Study Proposals Session scheduled for Saturday, February 18, 2023 at 12:15 p.m. The different sources of CIBMTR data collection were also shared with the audience.

Presentations, publications and submitted papers in 2022 were reviewed, and update on the status of ongoing studies and their goals for July 2023 was discussed. Dr. Pasquini continued with the productivity and engagement of the committee in the previous year. The voting process was reiterated, and it was emphasized that each proposal will be given 5 minutes for presentation and 7-10 minutes for discussion.

#### 2. Accrual summary

The accrual summary was referenced for review but not formally presented due to full agenda. The link to the full accrual summary was available online as part of the attachments. The accrual summary provides information about the number of patients available in the registration level and research level for potential studies. As of December 2022, 116,099 plasma cell disorder cases were reported at the TED level only and 16,478 cases at the research level to the CIBMTR for first autologous transplant. For first allogeneic transplants, these numbers are 5,214 cases and 2,126 cases respectively. For CAR T-cell infusion, 1,308 plasma cell disorders cases were reported to the CIBMTR between 2016-2022.

#### 3. Presentations, Published or Submitted Papers

The published or submitted papers as well as abstracts that have been presented at various conferences in 2022 are shown below demonstrating that it was a very productive year for our committee. These include:

- a. MM20-01 Ankit Kansagra, Angela Dispenzieri, Raphael Fraser, Noel Estrada-Merly, Surbhi Sidana, Taiga Nishihori, Doris K. Hansen, Larry D. Anderson, Rahul Banerjee, Naresh Bumma, Binod Dhakal, Jack Khouri, Heather Landau, Cindy Lee, Hira Mian, Sunita Nathan, Bipin Savani, Shaji Kumar, Muzaffar Qazilbash, Nina Shah, Anita D'Souza; Outcomes after autologous hematopoietic cell transplantation in POEMS syndrome and comparison with multiple myeloma. Blood Advances 2022 Jul 12; 6 (13): 3991-3995. doi: https://doi.org/10.1182/bloodadvances.2022007218
- b. **MM20-02A** Ragon BK, D'Souza A, Estrada-Merly N, Fraser R, George G, Gowda G, Shah N, Qazilbash MH, Kumar S, Horowitz MM, Usmani SZ, Shah MV. Impact of Second Primary Malignancy Post-Autologous Hematopoietic Stem Cell Transplantation on Outcomes of Multiple Myeloma: A CIBMTR Analysis. *Poster presentation, ASCO 2022.*
- c. MM20-02A Brittany Knick Ragon, Mithun Vinod Shah, Anita D'Souza, Noel Estrada-Merly, Lohith Gowda, Gemlyn George, marcos DeLima, Shahrukh Hashmi, Mohamed A Kharfan-Dabaja, Navneet S Majhail, Rahul Banerjee, Ayman Saad, Gerhard C. Hildebrandt, Hira Mian, Muhammad Bilal Abid, Minoo Battiwalla, Lazaros J. Lekakis, Sagar S. Patel, Hemant S. Murthy, Yago Nieto, Christopher S Strouse, Sherif M. Badawy, Samer Al Al Hadidi, Bhagirathbhai Dholaria, Mahmoud Aljurf, David H Vesole, Cindy H Lee, Attaphol Pawarode, Usama Gergis, Kevin Charles Miller, Leona A Holmberg, Aimaz Afrough, Melhem M Solh, Pashna Munshi, Taiga Nishihori, Larry D. Anderson, Baldeep Wirk, Gurbakhash Kaur, Muzaffar H Qazilbash, Nina Shah, Shaji K Kumar, Saad Z. Usmani; Impact of Second Primary Malignancy Post-Autologous Transplantation on Outcomes of Multiple Myeloma: A CIBMTR Analysis. Blood Advances 2023 Feb 24; bloodadvances.2022009138. doi: https://doi.org/10.1182/bloodadvances.2022009138
- d. **MM20-03** Bumma N, Dhakal B, Fraser R, Estrada-Merly N, Kumar S, Shah N, Qazilbash M, D'Souza A, Sidana S. Impact of bortezomib-based vs. lenalidomide maintenance therapy on outcomes of patients with high-risk multiple myeloma. (N Bumma et al.) *Oral presentation, Tandem Meetings 2022.*
- e. **MM21-01** L. Garderet, L. Grass, L. Koster, A. D'Souza, N. Estrada, H. Parameswaran, W. Saber, A. Cowan, M. Iida, O. Shin, H. Takamatsu, S. Mizuno, K. Kawamura, Y. Kodera, N. Hamad, B. Sheng Ko, C. Liam, H. Kim Wah, A. Sim Goh, S. Keat Tan, AM. Elhaddad, A. Bazarbachi, Q. Chaudhry, R. Alfar, A. Bekadja, M. Benakli, C. Frutos, E. Riva, S. Galaneo, F. Bass, H. Mian, A. McCurdy, F.R. Wang, D. Neumann, M. Koh, J. Snowden, S. Schoenland, I. Yakoub-Agka, H. Greinix, M. Aljurf, Y. Atsuta, D. Niederwieser. International Differences in Baseline Characteristics and Practice Patterns in Patients with Newly Diagnosed Multiple Myeloma Undergoing Upfront Autologous Stem Cell Transplantation. *Oral presentation, EBMT 2022 and ASH 2022.*
- f. MM21-01 L. Garderet, L. Grass, L. Koster, A. D'Souza, N. Estrada, H. Parameswaran, W. Saber, A. Cowan, M. Iida, O. Shin, H. Takamatsu, S. Mizuno, K. Kawamura, Y. Kodera, N. Hamad, B. Sheng Ko, C. Liam, H. Kim Wah, A. Sim Goh, S. Keat Tan, AM. Elhaddad, A. Bazarbachi, Q. Chaudhry, R. Alfar, A. Bekadja, M. Benakli, C. Frutos, E. Riva, S. Galaneo, F. Bass, H. Mian, A. McCurdy, F.R. Wang, D. Neumann, M. Koh, J. Snowden, S. Schoenland, I. Yakoub-Agka, H. Greinix, M. Aljurf, Y. Atsuta, D. Niederwieser. Worldwide

Network for Blood and Marrow Transplantation (WBMT) Global Study on Baseline Characteristics and Clinical Outcomes in NEWLY Diagnosed Multiple Myeloma Patients Undergoing Upfront Autologous STEM Cell Transplantation, a Study Off 61,725 Patients from 629 Centers. *Oral presentation, ASH 2022*.

# 4. Studies in Progress

Dr. Pasquini presented the summary of studies in progress.

- a. **MM20-02B** Risk factors for and characteristics of second primary malignancies following autologous hematopoietic cell transplant for multiple myeloma. (B Ragon/M Shah/S Usmani) **Deferred until longer follow-up of patients.**
- b. **MM20-03** Impact of bortezomib-based vs. lenalidomide maintenance therapy on outcomes of patients with high-risk multiple myeloma. (N Bumma/ S Sidana/ B Dhakal) **In Press.**
- c. **MM21-01** Differences in outcome on Myeloma treatment worldwide. (L Garderet) **Manuscript Preparation.**
- d. **MM22-01** Outcomes of autologous hematopoietic cell transplantation for light chain deposition disease. (H Hashmi/B Dhakal) **Protocol Development.**

#### 5. Future/Proposed Studies

Dr. Pasquini thanked the investigators whose proposals were submitted but not selected for presentation. This year, we had record of 43 proposals received, 7 of which were invited to present at the meeting. Majority were dropped due to overlaps with current studies and feasibility/data availability issues. Dr. Nina Shah introduced the presenter for the first proposal.

a. PROP 2208-03/2209-03/2209-04/2210-06/2210-08/2210-42/2210-51/2210-296 Combined proposal: Real world experience of Feasibility, Safety, and Outcomes Following anti-BCMA CAR T-cell Therapy for Patients with Relapsed or Refractory Multiple Myeloma (N Ahmed/ S Ganguly/ B Dhakal/ C Ferreri/ K Patel/ A Afrough/ L Anderson Jr./ H Hashmi/ S Usmani/ S Sidana/ D Hansen/ L Gowda/ S Mirza) Submitted proposals:

PROP 2208-03: Real-life experience and utilization of BCMA-directed CAR-T therapy in patients with Multiple Myeloma

PROP 2209-03: Real-world evidence of safety and efficacy of idecabtagene vicleucel in patients with multiple myeloma

PROP 2209-04: Real-world evidence of safety and efficacy of ciltacabtagene autoleucel in patients with multiple myeloma

PROP 2210-06: Assessment of Feasibility, Safety, and Efficacy of anti-BCMA CAR T-cell Therapy in the Real-World Setting for Patients with Relapsed or Refractory Multiple Myeloma

PROP 2210-08: Real World Experience of Abecma, Chimeric Antigen Receptor (CAR) T-Cells Targeting BCMA in Patients with Multiple Myeloma (MM)

PROP 2210-42: Characteristics and management of post-CAR T cell therapy toxicities in the real world for relapsed refractory multiple myeloma

PROP 2210-51: Real world outcomes with BCMA directed CAR-T cell therapy in multiple myeloma PROP 2210-296: BCMA CAR-T for Multiple Myeloma: Real World Evidence and Identifying Predictors of toxicity and Efficacy

Dr. Sidana presented the proposal on behalf of the group. This study hypothesizes that the standard of care ide-cel CAR-T therapy has a similar efficacy and toxicity profile as that observed with investigational ide-cel in a highly selected population of patients treated on clinical trial. The primary objective of this proposal is to determine the response rate per IMWG criteria for patients receiving ide-cel CAR T-cell

therapy in the real-world setting. The secondary objectives are to assess progression free survival (PFS), overall survival (OS), and safety - including incidence and severity of CRS, ICANS, other neurotoxicities, cytopenias, infections and second cancers. There are 786 patients who received first CAR T-cell infusion for multiple myeloma from 2016-2022 which includes 552 (70%) patients who received ide-cel.

#### **Comments from the Audience:**

Dr. Shah thanked Dr. Sidana for the presentation and welcomed questions from the audience. A question was asked about how representative the CIBMTR data is for the entire population of patients receiving ide-cel CAR-T therapy across the US especially with the issues related delayed reporting and fludarabine shortage. Dr. Pasquini responded saying this information is not available for ide-cel at this time; however, the data for some other CAR-T products (tisa-cel and axicel) showed 60-70% reporting rate when comparing the number of products shipped to the numbers reported to the CIBMTR. Based on this, it is believed that the data on ide-cel is representative or at least represents over 50% of the commercial ide-cel being used in the US.

Another question was asked about the availability of data on time from lymphocyte collection (apheresis) to cell infusion to see if this has an impact on outcomes. Dr. Pasquini confirmed that the data is available and agrees that this can be included in the proposal.

An attendee wanted to find out if all 786 patients who received first CAR T-cell infusion for multiple myeloma all received commercial product or clinical trial. Also, they wanted to know if the data can differentiate centers who perform high numbers of CAR T-cell therapies from those who do a few to determine if center-specific variables have an impact on outcomes. Dr. Pasquini confirmed that we have information on commercial products, clinical trials, and out-of-specification products. These differences will be considered in the analysis. Regarding center-effect, Dr. Pasquini mentioned that there is no specified standard way to analyze centers at this especially since there are no dedicated CAR-T centers yet. He mentioned that if center-effect will be included in the proposal, then its impact on outcomes can be analyzed.

Another member of the audience referenced a previous publication on a similar topic and wanted to know if this proposal will provide additional information that is not already available. Dr. Sidana responded saying the CIBMTR data can provide better statistical power given the high number of patients and important information can be derived from this data especially with the multi-variate analysis and assessment of predictors.

An attendee wanted to know if the data can provide information on the proportion of patients who did not receive cell infusion after cell collection. Dr. Sidana mentioned that the data is not available at this time. Another question was asked about availability of data on pre-infusion transplant. Dr. Sidana confirmed that the data is available.

Dr. Qazilbash then introduced the next presenter.

b. **PROP 2209-01:** Utility of urine testing in post-ASCT response assessments in multiple myeloma (**R Banerjee**/N Shah)

Dr. Banerjee presented the proposal on behalf of the group. This study hypothesizes that the presence versus absence of pre-ASCT urine immunofixation results will not significantly impact PFS, and a simplified set of CIBMTR response criteria that omits all urine testing (urine-free CIBMTR) will perform similarly to traditional CIBMTR response criteria in terms of predicting progression-free survival (PFS) based on pre-ASCT values. The primary objectives of this proposal are to assess the prognostic value of pre-ASCT urine immunofixation results (reported versus missing) on PFS, as analyzed by Cox regression using interaction testing; to determine the prognostic value of urine-free versus traditional pre-ASCT response criteria on PFS among patients with complete data, as analyzed by log-rank testing for PFS; and to evaluate the prognostic value of urine-free versus traditional pre-ASCT response criteria on PFS among all patients, as analyzed by log-rank testing for PFS.

There are 6935 patients who underwent HCT for multiple myeloma in the US from 2008-2019 with CRF level data. But only 2748 have known urine testing results.

#### Comments from the Audience:

A question was asked about the sub-group of patients who can only be assessed with urine testing. They suggested excluding these patients from the assessment. Dr. Banerjee agreed with this suggestion and mentioned that the focus will be on patients who can be assessed without urine testing.

Some attendees mentioned that 24hour urine is usually collected for other tests and wanted to find out if the aim of this study is to eliminate 24hour urine testing from clinical practice. Dr. Banerjee acknowledged the importance of 24hour urine collection for other tests and agrees to retaining those tests especially when the 24hour urine sample is readily available (for example in hospitalized patients). He mentioned that the aim of this proposal is to show that 24hour urine collection is not necessary when it may be an inconvenience to the patient.

For the question asking about the proportion of patients who have data on the 24hour urine test, Dr. Banerjee mentioned that there are ways the data can be used to determine this.

Dr. Landau introduced the next presenter.

c. PROP 2209-09/2210-20/2210-46/2210-66/2210-128 Combined proposal: Safety and efficacy of CAR T-cell therapy for relapsed/refractory multiple myeloma in areas of unmet need (B Dhakal/ D Hansen/ S Sidana/ H Hashmi/ S Usmani/ C Freeman/ O Akhtar) Submitted proposals:

PROP 2209-09: Impact of renal impairment on the safety and outcomes CAR T-cell therapy in multiple myeloma patients

PROP 2210-20: Outcomes of elderly patients receiving B-Cell Maturation Antigen (BCMA)-directed Chimeric Antigen Receptor (CAR) T-cell Therapy in the standard of care setting PROP 2210-46: Safety and efficacy of CAR T-cell therapy in areas of unmet need for relapsed refractory multiple myeloma

PROP 2210-66: Impact of obesity on outcomes following B-Cell Maturation Antigen (BCMA)-directed Chimeric Antigen Receptor (CAR) T cell therapy in the standard of care setting

PROP 2210-128: Safety and Efficacy of anti-BCMA CAR-T Therapy in Older Adults with Multiple Myeloma: An Analysis of Real-World Outcomes from the Center for International Blood and Marrow Transplant Research (CIBMTR) and Cellular Therapy Registry

Dr. Akhtar presented the proposal on behalf of the group. This study hypothesizes that CAR-T therapy will have comparable response rates and feasibility in patients within excluded / under-represented / unreported subgroups including patients with impaired renal function, older adults, frail patients (ECOG PS 2+ / KPS<80), and overweight/obese patients. For these patients with relapsed/refractory multiple myeloma in areas of unmet needs, the primary objective of this study is to determine:

- Response by IMWG Criteria
- Survival: Overall survival (OS); Progression-free survival (PFS); Relapse/Progression; Non-relapse mortality (NRM)
- Toxicity: CRS (all grades/grade ≥3), Neurotoxicity/ICANS (all grades/grade ≥3), Infections, Cytopenia There are 786 patients who received first CAR T-cell infusion for multiple myeloma from 2016-2022.

#### **Comments from the Audience:**

An attendee suggested combining this proposal with the previously presented CAR-T proposal since they have a similar theme and dataset. Dr. Pasquini responded saying that this suggestion will be considered when reviewing the proposals after the presentation, but each proposal should be voted separately based on their scientific impact. Another suggestion was made to include CrCl <60. Dr. Akhtar acknowledged that the suggestion will be considered.

Suggestions were made regarding other factors that should be considered in the analysis including difference in dosing of each CAR T-cell product, and socio-economic status. Some attendees made positive comments on the importance of this study and the use of CIBMTR data in answering the research question.

Dr. Shah then introduced the next presenter.

d. **PROP 2210-43/2210-44/2210-273** <u>Combined proposal</u>: Predictors of progression after CAR T-cell therapy for relapsed refractory multiple myeloma (**H Hashmi**/ S Usmani/ B Wirk) Submitted proposals:

PROP 2210-43: Predictors of efficacy and safety of CAR T-cell therapy in patients with relapsed refractory multiple myeloma

PROP 2210-44: Predictors of early progression after CAR-T cell therapy for relapsed refractory multiple myeloma

PROP 2210-273: Determinants of outcomes after chimeric antigen receptor T-cell therapy for multiple myeloma

Dr. Hashmi presented the proposal on behalf of the group. The hypothesis of this study is that analysis of patient, disease, and treatment-related variables will identify factors predicting progression/relapse after CAR T cell therapy for multiple myeloma. The study objectives are to determine patient, disease, and treatment-related factors associated with early (<3 mo) and late (>3 mo) progression after CAR T-cell therapy.

There are 786 patients who received first CAR T-cell infusion for multiple myeloma from 2016-2022.

#### Comments from the Audience:

A suggestion was made to consider including CAR T-cell data from pharmaceutical companies for better statistical power. There were some questions about the scientific importance of this study and what additional information the analysis will provide. Dr. Hashmi responded saying the findings of this study can be used as a guide to make informed decisions in clinical practice.

e. **PROP 2210-71/2210-72** <u>Combined proposal</u>: Outcomes of autologous hematopoietic cell transplantation for Multiple Myeloma with plasmacytoma(s) (**H Hashmi**) Submitted proposals:

PROP 2210-71: Outcomes of autologous hematopoietic cell transplantation for Macrofocal Multiple Myeloma

PROP 2210-72: Outcomes of autologous hematopoietic cell transplantation for Multiple Myeloma with plasmacytoma(s)

Dr. Hashmi presented this combined proposal. This study hypothesizes that autologous hematopoietic cell transplantation (AHCT) results in long-term disease control for patients with multiple myeloma with current or prior plasmacytoma(s). The objectives of this study are as follows:

- To determine overall survival (OS) after AHCT for multiple myeloma with prior or current plasmacytoma(s) and compare this outcome with patients with multiple myeloma without prior or current plasmacytomas.
- To determine disease response [hematological, radiological], progression-free survival (PFS), transplant-related mortality (TRM), cumulative incidence of relapse after AHCT for multiple myeloma with plasmacytoma(s) and compare these outcomes with patients with multiple myeloma without prior or current plasmacytomas.

There are 270 patients who received auto-HCT for multiple myeloma with current or previous plasmacytomas from 2000 - 2019 and have CRF level data.

#### **Comments from the Audience:**

There were concerns about the granularity of the CIBMTR data in answering the research question especially as it relates to distinguishing between bone and extramedullary plasmacytoma, determination of size, timing of diagnosis of plasmacytoma vs myeloma, identification of patients with macrofocal multiple myeloma etc. Dr. Hashmi responded saying while there are some limitations, the data provides high population size that provides a good statistical power to address the research question.

Dr. Landau introduced the next presenter.

f. **PROP 2210-170** Machine learning in predicting the factors associated with early relapse after autologous stem cell transplant in Multiple myeloma patients (S Vuyyala/ **S Farhan**)

Dr. Farhan presented the proposal on behalf of the group. This study hypothesizes that the data routinely collected for patients with multiple myeloma who undergo autologous stem cell transplant as part of the CIBMTR reporting contain predictive information which can be used to build predictive machine learning models that can provide physician and providers with more precise information regarding the risk of early relapse after autologous transplant for multiple myeloma. The primary objective is to assess early relapse within 2 years after autologous transplant. The secondary objective is

to determine PFS, OS after autologous transplant, identify which patients benefit the most from SCT especially high risk. There are 7600 patients who underwent HSCT for multiple myeloma in the US from 2008-2020 with CRF level data.

#### **Comments from the Audience:**

A member of the audience mentioned a previous CIBMTR study on a similar topic and wanted to know what additional information can be obtained from machine learning. Dr. Farhan mentioned that the result from this study is not aimed at invalidating the previous study that was done using regular analysis instead, the findings from both studies can be compared.

There were questions about how the validity of the machine learning analysis will be determined. Dr. Farhan explained that the data will be divided into 2 sub-groups - training and testing datasets. Multiple algorithms and models will be applied to the training dataset and then applied to the testing dataset afterward. External validation will also be done.

A concern was raised about the possibility of missing poor response patients who do not go on to receive a transplant. Dr. Farhan acknowledged that it will be better to work with patients without previous transplant. However, high risk patients (with early relapse after transplant) can also answer the research question.

Dr. Shah introduced the next presenter.

g. **PROP 2210-223** Comparison of survival outcomes for patients with relapsed multiple myeloma with salvage autologous SCT versus novel therapies (**S Devarakonda**/ Y Efebera)

Dr. Devarakonda presented the proposal on behalf of the group. This study hypothesizes that the outcomes of salvage ASCT are non-inferior to novel therapies for the management of relapsed multiple myeloma. The primary objective is to determine PFS and OS of patients with relapsed MM who received salvage ASCT as 2nd or 3rd line of therapy compared to patients with relapsed MM who received novel drugs as 2nd or 3rd line of therapy. The secondary objectives are to assess the proportion of patients with relapsed MM receiving salvage ASCT as part of 2nd or 3rd line of therapy relative to patients with relapsed MM receiving novel drugs as 2nd or 3rd line of therapy; and to determine the response rates (overall response rate, complete response, very good partial response, partial response, progression, and stable disease). There are 1725 patients who underwent salvage auto-HCT for relapsed multiple myeloma in the US from 2016-2022. About 212 patients with multiple myeloma received 2nd autologous SCT for relapse disease (salvage) and have CRF level data.

# **Comments from the Audience:**

There were questions about the relevance of 2nd autologous SCT for relapse disease (salvage) in the modern era with more interest in novel therapies such as CAR T-cell therapy and other alternative therapies. Dr. Devarakonda responded saying second transplant is still a valuable option when alternative therapies are not feasible.

Another question was asked about how outcomes of second HCT will be compared with the outcomes of patients who received alternative/novel therapies. Dr. Devarakonda mentioned that this comparison will be done using external data to supplement CIBMTR data.

Dr. Devarakonda also mentioned in response to a question that this study will differentiate patients with second transplant from patients with second salvage transplant.

# Seventeen additional proposals were submitted but not presented as listed below:

- a. **PROP 2210-53**: Outcomes of BCMA CAR T Therapy Among Patients with Multiple Myeloma who Relapse After Allogeneic Hematopoietic Cell Transplantation. *Dropped for small sample size*.
- b. **PROP 2210-73**: Upfront versus Delayed Autologous Hematopoietic Cell Transplantation in Newly Diagnosed Multiple Myeloma. *Dropped for low scientific impact among proposals*.
- c. **PROP 2210-97**: Clinical Outcome of Multiple Myeloma Patients with Renal Failure Treated with CD38-Targeting Monoclonal Antibody-Based Induction Therapy. *Dropped supplemental data needed*.
- d. **PROP 2210-98**: Trends in utilization of a delayed autologous transplant approach (ASCT) in Newly Diagnosed Multiple Myeloma (NDMM). *Dropped for low scientific impact among proposals*.
- e. **PROP 2210-99**: Stacking machine learning algorithms into an ensemble to predict treatment related mortality and overall survival in patients with systemic light chain amyloidosis at time of diagnosis and after autologous hematopoietic cell transplant. *Dropped supplemental data needed*.
- f. **PROP 2210-116**: Impact of prior B Cell Maturation Antigen (BCMA) directed therapy on outcomes of myeloma patients receiving BCMA Chimeric Antigen Receptor (CAR) T cell therapy in the standard of care setting. *Dropped for small sample size*.
- g. **PROP 2210-130**: Stacking machine learning algorithms into an ensemble to predict treatment related mortality and overall survival in patients with systemic light chain amyloidosis at time of diagnosis and after autologous hematopoietic cell transplant. *Duplicate*.
- h. **PROP 2210-139**: Role of allogenic hematopoietic stem cell transplants for multiple myeloma in the era of novel immunotherapeutics. *Dropped for low scientific impact among studies.*
- PROP 2210-156: Impact of Induction Therapy with anti-CD38 antibodies-based Regimen on outcomes in Patient with Multiple Myeloma Undergoing Autologous Stem Cell Transplantation. *Dropped - supplemental data needed*.
- j. **PROP 2210-160**: The role of autologous HSCT in the era of daratumumab for AL amyloidosis. *Dropped supplemental data needed*.
- k. **PROP 2210-182**: Real-world comparison of idecabtagene vicleucel (ide-cel) and ciltacabtagene autoleucel (cilta-cel) Chimeric Antigen Receptor (CAR) T-Cells versus clinical trial outcomes achieved by patients with Relapsed/Refractory Multiple Myeloma. *Dropped for small sample size; supplemental data needed*.
- I. **PROP 2210-206**: Evaluation of Patient, Disease and Social Factors/Characteristics That Predict Overall Survival Advantage with Early Autologous Transplantation in Multiple Myeloma. *Dropped for low scientific impact among studies*.
- m. **PROP 2210-208**: Outcomes of BCMA-directed CAR-T after prior BCMA directed therapy. *Dropped small sample size*.
- n. **PROP 2210-213**: BCMA-Targeted Chimeric Antigen Receptor (CAR) T-Cell Therapy for Relapsed/Refractory Multiple Myeloma after Allogeneic Hematopoietic Stem Cell Transplantation: Real-

- World Data from the Center for International Blood and Marrow Transplant Research (CIBMTR). Dropped for small sample size.
- PROP 2210-224: Impact of Dose-adjusted Melphalan in Obese and Non-obese Adults with Multiple Myeloma After an Autologous Hematopoietic Stem Cell Transplantation. *Dropped for low scientific impact among studies*.
- p. **PROP 2210-261**: Impact of cytogenetics and daratumumab containing induction on transplant outcomes of patients with light chain amyloidosis. *Dropped supplemental data needed*.
- q. **PROP 2210-262**: BCMA-directed Chimeric Antigen Receptor T-cell therapy for Relapsed Refractory Multiple Myeloma: Can we choose better between two products? *Dropped for small sample size;* supplemental data needed.

The instructions for voting through the Tandem2023 App was reiterated and the audience were thanked for being participants of the meeting. The meeting was adjourned on at **2:15** p.m. The Chairs and Scientific director stayed behind for extra time to meet and interact one on one with committee members.

#### 6. Other Business

The chairs of the working committee, scientific director and statistician had a post-WC meeting afterwards to discuss proposals. After the new proposals were presented, each attendee had the opportunity to vote the proposals using the provided voting sheets.

## **Scoring Results**

		Total #				
Proposal Number	Title	of votes	Mean	Median	Mode	Range
2208-03; 2209-03;	Real world experience of Feasibility, Safety, and	69	3.3	3	1	(1-9)
2209-04; 2210-06;	Outcomes Following anti-BCMA CAR T-cell					
2210-08; 2210-42;	Therapy for Patients with Relapsed or Refractory					
2210-51; 2210-296	Multiple Myeloma					
	Utility of urine testing in post-ASCT response	68	3.8	3	3	(1-9)
2209-01	assessments in multiple myeloma					
2209-09; 2210-20,	Safety and efficacy of CAR T-cell therapy for	69	3.3	3	1	(1-9)
2210-46, 2210-66,	relapsed/refractory multiple myeloma in areas of					
2210-128	unmet need					
	Machine learning in predicting the factors	67	4.5	4	4	(1-9)
	associated with early relapse after autologous					
2210-170	stem cell transplant in Multiple myeloma patients					
	Comparison of survival outcomes for patients with	71	4.3	4	1	(1-9)
	relapsed multiple myeloma with salvage					
2210-223	autologous SCT versus novel therapies					
2210-43; 2210-44;	Predictors of progression after CAR T-cell therapy	68	4.3	4	4	(1-9)
2210-273	for relapsed refractory multiple myeloma					
	Outcomes of autologous hematopoietic cell	68	5	5	4	(1-9)
	transplantation for Multiple Myeloma with					
2210-71; 2210-72	plasmacytoma(s)					

Based on the voting results, current scientific merit, and impact of the studies on the field, the following studies were decided to move forward as the committee's research portfolio as a combined study for the upcoming year:

**Combined study:** Real world experience of Feasibility, Safety, Efficacy, and Outcomes Following anti-BCMA CAR T-cell Therapy for Patients with Relapsed or Refractory Multiple Myeloma (N Ahmed/ S Ganguly/ B Dhakal/ C Ferreri/ K Patel/ A Afrough/ L Anderson Jr./ H Hashmi/ S Usmani/ S Sidana/ D Hansen/L Gowda/ S Mirza/ C Freeman/ O Akhtar)

Proposals:

PROP 2208-03/2209-03/2209-04/2210-06/2210-08/2210-42/2210-51/2210-296 Combined proposal: Real world experience of Feasibility, Safety, and Outcomes Following anti-BCMA CAR T-cell Therapy for Patients with Relapsed or Refractory Multiple Myeloma (N Ahmed/S Ganguly/B Dhakal/C Ferreri/K Patel/A Afrough/L Anderson Jr./H Hashmi/S Usmani/S Sidana/D Hansen/L Gowda/S Mirza)

PROP 2209-09/2210-20/2210-46/2210-66/2210-128 <u>Combined proposal</u>: Safety and efficacy of CAR T-cell therapy for relapsed/refractory multiple myeloma in areas of unmet need (B Dhakal/ D Hansen/ S Sidana/ H Hashmi/ S Usmani/ C Freeman/ O Akhtar)

Working Committee Overview Plan for 2023-2024					
Study number and title	Current status	Chairs' priority			
MM20-02B: Risk factors for and characteristics of secondary primary malignancies following autologous hematopoietic cell transplant for multiple myeloma	Deferred	2			
MM21-01: Differences in outcomes on myeloma treatment worldwide	Manuscript preparation	1			
MM22-01: Outcomes of autologous hematopoietic cell transplantation for light chain deposition disease	Protocol development	2			
MM23-01: Real world experience of Feasibility, Safety, Efficacy, and Outcomes Following anti-BCMA CAR T-cell Therapy for Patients with Relapsed or Refractory Multiple Myeloma	Protocol pending	1			

Working Assignments for Working Committee Leadership (May 2023)			
Heather Landau:	<b>MM20-02B:</b> Risk factors for and characteristics of secondary primary malignancies following autologous hematopoietic cell transplant for multiple myeloma		
Muzaffar Qazilbash:	<b>MM22-01:</b> Outcomes of autologous hematopoietic cell transplantation for light chain deposition disease		
Taiga Nishihori:	<b>MM23-01:</b> Real world experience of Feasibility, Safety, Efficacy, and Outcomes Following anti-BCMA CAR T-cell Therapy for Patients with Relapsed or Refractory Multiple Myeloma		