MINUTES AND OVERVIEW PLAN
CIBMTR WORKING COMMITTEE FOR CELLULAR IMMUNOTHERAPY FOR CANCER
Orlando, Florida
Friday, February 21, 2020, 12:15 pm – 3:15 pm (break: 1:30 pm-1:45 pm)

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1. Introduction

The Committee chairs (Peiman Hematti, MD, Sarah Nikiforow MD) and the Scientific director (Marcelo Pasquini, MD) welcomed the committee and started the meeting at 12:20. After the brief introduction, Dr. Nikiforow talked about CIBMTR industry funding disclosure and CICWC leadership. She announced the incoming chair Cameron Turtle, MBBS, PhD from Fred Hutchinson Cancer Research Center. Then Dr. Nikiforow showed the goals: publishing high impact studies in a timely manner; expectations: providing current status of gonging studies and timelines, and members to assess and select proposals that would have a high impact on the field; and limitations of this working committee: early follow up, and data collected were part of an ongoing prospective study and early data could be embargoed until regulatory review.

Dr Pasquini introduced the new name of our working committee: Cellular immunotherapy for cancer working committee (CICWC), and some of updates of this working committee. Then he showed the voting process: scientific impact score, key questions, allocation of time, number of proposals that would be accepted and how long of the decision. He reminded committee members on the voting prioritization: scientific impact, priority of studies, and voting.

2. Accrual Summary (attachment 2)

Dr. Pasquini mentioned that this year we received many proposals, and we directed 9 to the infection committee and 2 to the lymphoma committee. Then, he briefly discussed the status of data that was available for cellular therapy with a brief overview of the milestones since the launch of the CT registry in the summer of 2016. The graph of number of CAR T cell infusions and CAR T cell indications from 2016 to 2019 was on the website. As January 2020, a total of 2058 CAR T cell recipients and 2217 infusions were reported to the CIBMTR. 79% were commercial CAR T cells, and the span of age was very broad from infants to 91-year-old patients. There are two industry-sponsored projects which are ongoing and target 1500 and 2500 patients as the accrual goal. He addressed the importance of industry collaborations, as without the implementation of these long term post approval studies the cellular therapy registry would not have accrued as many patients as

it did to date. The importance having the CIBMTR involvement it to facilitate data collection using a standard approach that centers are familiar and to have these data in the public domain so future studies can be performed.

Dr. Pasquini mentioned that collection of CAR T cell data remains voluntary as the regulatory requirement is imposed to manufacturer in order to follow patients long term. At the center level, reporting CAR T cells is voluntary which has an implication for the development of studies. It is important to ascertain consecutive reporting in order to minimize any bias on reporting.

3. Cellular Therapy Registry, CIDR and CICWC (M Pasquini)

Dr Pasquini introduced the CIDR, CT registry and CICWC update. The CIDR governance structure outlines the development of a working committee to oversee the utilization of this resource for research purposes. Dr Pasquini then mentioned the new restructure of this working committee, after the launch of the CIDR.

4. Presentations, Published or Submitted Papers

a. **SC17-07** Pasquini M, Locke FL, Herrera AF, Siddiqi T, Ghobadi A, Komanduri KV, Hu Z-H, Dong H, Hematti P, Nikiforow S, Steinert P, Purdum A, Horowitz MM, Hooper M, Kawashima J, Jacobson C. Post-marketing use outcomes of an anti-CD19 CAR T cell therapy, axicabtagene ciloleucel, for the treatment of large B cell lymphoma in the US. ***61st ASH Annual Meeting and Exposition.*** **Oral.**
b. **SC17-08** Jaglowski S, Hu Z-H, Zhang Y, Kamdar M, Ghosh M, Lulla P, Sasine J, Perales M-A, Hematti P, Nikiforow S, Steinert P, Jeschke M, Yi L, Chawla R, Pacaud L, Horowitz MM, Bleikardt E, Pasquini M. Tisagenlecleucel CAR T-cell therapy for adults with diffuse large B-cell lymphoma: real world experience from the CIBMTR Cellular Therapy Registry. ***61st ASH Annual Meeting and Exposition.*** **Oral.**
c. **SC17-08** Grupp S, Hu Z-H, Zhang Y, Keating A, Pulsipher MA, Philips C, Margossian SP, Rosenthal J, Salzberg D, Schiff DE, Yanik G, Curran KJ, Harris AC, Hematti P, Nikiforow S, Steinert P, Yi L, Chawla R, Horowitz MM, Bleikardt E, Pasquini M. Tisagenlecleucel CAR T-cell therapy for relapsed/refractory children and young adults with acute lymphoblastic leukemia: real world experience from the CIBMTR and Cellular Therapy Registry. ***61st ASH Annual Meeting and Exposition*****. Poster.**
d. **SC17-08** Pasquini M, Hu Z-H, Zhang Y, Crupp S, Hematti P, Jaglowski S, Keating A, Nikiforow S, Philips C, Pulsipher M, Shah S, Steinert P, Yanik G, Wang H, Horowitz M, Bleikardt E. Real world experience of tisagenlecleucel CAR T-cells targeting CD19 in patients with acute lymphoblastic leukemia and diffuse large B-cell lymphoma using the CIBMTR Cellular Therapy Registry. ***SOHO 2019 Annual Meeting.*** **2019, Houston, TX. Oral.**

5. Studies in progress

Dr. Pasquini briefly discussed the studies in progress before we started presenting the proposals.

e. **CT13-01** Utility of unmanipulated donor lymphocyte infusion (DLI) for the treatment of infections in allogeneic hematopoietic cell transplantation recipients (G Akpek) **Analysis**
f. **AC16-01** Pattern of use and outcomes with donor lymphocyte infusion (DLI) after HLA-haploidentical allogeneic hematopoietic stem cell transplant (E Gupta/J Foran/V Roy) **Data File Preparation**

g. **AC17-01** CD-19 chimeric antigen receptor T cells with or without hematopoietic cell transplantation for treatment of refractory ALL (S Nikiforow/J Park/M Perales) **Protocol Development.** Dr. Pasquini said that since we didn't have enough data at the beginning, we didn't move forward. However, the data is accumulated, we will work on this this year.
h. **AC18-01** Effect of stem cell boost and donor lymphocyte infusion on the incidence of GVHD (J Yoon/ E Waller) **Protocol Development**
i. **CT19-01** Allogeneic hematopoietic cell transplantation vs. chimeric antigen receptor T-cell therapy for DLBCL patients with a prior autologous transplant failure (M Hamadani/M Pasquini/F Locke/A Gopal) **Protocol Development**. Dr. Pasquini mentioned that this study is also going a little bit slow, since the follow up data is a little shorter of this year.
j. **CT19-02** Prolonged cytopenia following CD-19 targeted CAR-T therapy for diffuse large B-cell lymphoma (M Shadman) **Protocol Development**

6. Future/proposed studies

Dr. Pasquini briefly discussed we received 313 proposals this year and most of them came to cellular therapy. Overall, we have 52 proposals submitted for 2020. 16 proposals were dropped due to overlap with existent studies, due to feasibility or requiring long term follow up or needing supplemental information. Among the drop proposals the themes were comparing of CAR T cell that inpatients vs outpatients, cardiovascular toxicities and assessing the impact of bridging therapy. Updates on the CT forms released January 2020 will help answer these questions in the future. The investigators were invited to propose their studies next year.

Most accepted proposals were merged into 11 studies proposals based on the overlapping themes, which were correlation between CAR T cell manufacturing and outcomes, toxicities, comorbidities, comparisons between commercial CAR T cells or CAR T cells with HCT, health resource utilization, and predictors of disease response (ALL and DLBCL).

a. **PROP 1911-38/PROP 1911-67/PROP 1911-260** Comparative outcomes analysis of patients with aggressive B-cell lymphoma treated with axicabtagene ciloleucel vs. tisagenlecleucel (B Hill) (Attachment 4), Tisagenlecleucel (Kymriah®) versus axicabtagene ciloleucel (Yescarta®) in patients with relapsed/refractory diffuse large B cell lymphoma (M Pennisi/A Mussetti/M Perales) (Attachment 5), Comparative analysis of patient characteristics and efficacy of patients with aggressive B-cell lymphoma who received CD19 directed chimeric antigen receptor T-cell therapy (T Nishihori/M Jain/F Locke) (Attachment 6)

This study was presented by Martina Pennisi who started out by explaining that the hypothesis of this study were that Axi-Cel and Tisa-Cel shared clinical indication, and were considered largely equivalent in efficacy; different products (CD28 vs 41bb) with different response and toxicity rates; no direct comparison reported and randomized clinical trial unlikely. The aims of this study were describing baseline characteristics of patients treated with tisagenlecleucel vs axicabtagene ciloleucel and assessing their impact on the outcomes. There were 816 total patients that met the proposal eligibility criteria which were adults treated with commercially available anti-CD19 CAR T cells; diagnosing of DLBCL w/wo transformation from indolent, R/R after >2 lines of therapy.

b. **PROP 1911-53/PROP 1911-74/PROP 1911-77/PROP 1911-120/PROP 1911-258** Assessment of modified hematopoietic cell transplantation comorbidity index in non-Hodgkin lymphoma patients receiving chimeric antigen receptor T cell therapy (S Ahmed) (Attachment 7), A modified hematopoietic stem cell transplantation – comorbidity index for recipients of chimeric antigen receptor T cell therapy (M Sorror/M Bar) (Attachment 8), A model for predicting toxicity using the hematopoietic cell transplantation comorbidity index parameters in patients with

toxicity after chimeric antigen receptor T cell therapy (U Greenbaum/A Olson/E Shpall/P Kebriaei) (Attachment 9), Prognostic impact of comorbidities and on outcomes of patients with relapsed/refractory diffuse large B-cell lymphoma receiving chimeric antigen receptor T cell therapy (M Elsawy) (Attachment 10), Development of comorbidity scores that could impact the treatment related mortality and overall survival in patients receiving CD19 directed chimeric antigen receptor T-cell therapy (H Hashmi/T Nishihori/F Locke) (Attachment 11)

Dr. Hamza Hashmi presented this proposal starting with a question: were pre-treatment comorbidities predictive of CAR T cell therapy related toxicities and survival outcomes? This study could improve decision-making process and patient counselling prior to CAR T cell therapy and optimize the design of new clinical trials. The objectives of this study were evaluating the impact of individual comorbidities on development of severe toxicities after CAR T cell therapy; designing and validating a CAR-T specific comorbidity index. All CAR T recipients in the CIBMTR database was 1187 which included ALL (302) and NHL (885). Dr. Hashmi also mentioned the methods of this study design.

c. **PROP 1911-63/PROP 1911-89/PROP 1911-105** Pre-infusion risk score for incidence of cytokine release syndrome and CAR related encephalopathy syndrome in patients treated with CAR T-cell therapies (C Strouse/U Farooq/M Magalhaes-Silverman)(Attachment 12), Comprehensive assessment of CAR T cells' toxicities burden in patients with diffuse large B cell lymphoma treated with FDA approved anti-CD19 CAR T cells(axicabtagene ciloleucel or tisagenlecleucel) (M Pennisi/E Mead/M Perales) (Attachment 13), Development of a prognostic model of CAR-T cell therapy toxicity (R Shouval/M Pennisi/M Perales) (Attachment 14)

Dr. Roni Shouval presented this proposal, the hypothesis stated that baseline features collected before the time of Anti-CD19 CAR-T cells infusion were predictive of treatment toxicity. A weighted score, considering pre-infusion features, would reliably predict toxicity. The primary aim was developing a risk score for severe CAR T cell toxicity. The second aim were descriptive analysis of toxicities; incidence of CRS and ICANs by grading system; identification of risk factors for toxicities and correlation with duration; association between toxicities and survival/ short-term mortality; prediction of any CRS/ICANs grade. The population was 1024 which included ALL (208) and NHL (816). Then Dr. Shouval talked about the study design which included descriptive analysis of CAR T cell toxicities; Identification of predictors of individual toxicities; Construction of a risk score for composite toxicity; Independent validation. The prediction of severe toxicity would allow for risk stratification, toxicity prevention in high-risk patients, informed consent, adjustment tool in pro/retrospective analyses.

d. **PROP 1910-12** Correlation between CAR-T cell dose, disease response, cytokine release syndrome and acute neurotoxicity (M Salas/A Law/R Kumar) (Attachment 15)

Dr. Queralt Salas presented this proposal, explaining that CAR T cell was one of the most remarkable advances in cancer therapy in the last decades. However, CAR T cell therapy was associated with significant toxicities (CRS, ICANS), and adequate cell dose was crucial to achieve engraftment in alloHCT. It was reasonable to question if optimum CAR T cell dose range to achieve maximum therapeutic effect, and relation between CAR T cell dose and early toxicity. Then Dr. Salas mentioned the scientific justification that cell dose infused is a factor that can be adjusted to improve survival. This study exploring the impact of key product cellular attributes of tisagenlecleucel on clinical outcomes in patients diagnosed with DLBCL was presented at ASH. This study included 115 patients included in phase 2 JULET trial. The percentage and absolute number of

the subpopulation were analyzed and correlated with efficacy and safety. The aim of this study was correlation between CAR T cell dose and overall survival controlled by disease status.

e. **PROP 1911-33/PROP 1911-168/PROP 1911-206/PROP 1911-221** Predictive value of 1-month FDG-PET CT scan post CAR T cell therapy on outcome of aggressive B cell NHL (K Wudhikarn/M Perales/M Pennisi) (Attachment 16), Outcomes of CD19 CAR T cell therapy for large B cell lymphoma arising from a non-follicular transformation (M Jain/F Locke/T Nishihori) (Attachment 17), Outcomes in patients with double/ triple hit lymphoma post CAR T treatments (A Vallurupalli/S Ganguly) (Attachment 18), Analysis of the incidence of immune-effector cell toxicity and outcomes after anti-CD19 CAR-T cell therapy for B-cell lymphomas (P Ramakrishnan/ F Awan) (Attachment 19)

This study was presented by Kitsada Wudhikarn who started out by explaining that pivotal studies did not show response differences among key underlying characteristics but were underpowered. Early post-treatment PET response may not accurately reflect long term response and outcome. The hypothesis of this study was that disease characteristics determined response, toxicities and outcomes of aggressive large B-NHL patients treated with CAR T cells; immune-mediated toxicities were associated with treatment outcomes; early PET response to CAR T cells was an important surrogate for long-term outcomes. The aims were that Identify underlying lymphoma characteristics which can predict response and outcomes of aggressive large B-NHL patients treated with CAR T cells; evaluate the association between immune-mediated toxicities and outcomes; Explore prognostic implication of early PET response on long-term outcomes in aggressive large B-NHL treated with CAR T cells. This study included 869 patients who were adult with aggressive large B-NHL. Dr. Pasquini commented that we didn't capture the 30 days past, and we didn't know how the practice varied among different centers. He suggested that if the study moved forward, we could ask the practice of the 30 days past or we only include the centers which have the information.

f. **PROP 1911-145** Real world practice pattern and clinical outcomes of subsequent therapy after CAR-T treatment in patients with lymphoma (E Bezerra/G Nowakowski/Y Lin/S Hashmi) (Attachment 20)

Dr. Evandro Bezerra presented this proposal starting with the unmet need for NHL patients who don't achieve durable CR after CAR-T therapy. Survival is poor for patients who don't achieve durable CR after CAR-T1-3. The aims are comparing OS between who did and didn't receive subsequent therapies; comparing response rates, PFS and OS among different subsequent therapies; comparing OS between those who did and didn't receive subsequent allo-HCT. The hypothesizes are longer OS in those able to receive further therapies; similar outcomes across different therapies categories; patients not in CR post CAR T that received subsequent allo-HCT will have longer OS. This study included 875 patients, and 255 patients received subsequent systemic therapies.

g. **PROP 1911-41/PROP 1911-148** Assessing the outcomes of CAR T-cell therapy in patients who relapse within a year of autologous stem cell transplantation compared to patients who never undergo autologous stem cell transplantation: A CIBMTR analysis (P Johnson/A EI-Jawahri) (Attachment 21), Clinical outcomes of CAR-T cell therapy in transplant naïve patients versus CAR-T cell therapy post autologous transplant (N Shah/P Hari) (Attachment 22)

Dr. Connor Johnson presented this proposal, explaining that the aims were to compare PFS in patients with aggressive NHL receiving CAR-T cell therapy who were transplant naïve versus those who received an autologous HCT prior to CAR-T cell therapy; to characterize other outcomes among patients with aggressive NHL receiving CAR-T cell therapy who were transplant naïve versus those

who received an autologous HCT prior to CAR-T cell therapy. The hypothesis was the receipt of autologous HCT would be associated with lower PFS in patients receiving CAR-T cell therapy. Dr. Johnson stated the design of this study which was retrospective multicenter analysis of patients with NHL receiving anti-CD19 CAR T-cell therapy. There were 840 patients undergoing first CAR T for NHL with/without prior autologous transplant from 2016 to 2019.

h. **PROP 1911-149/PROP 1911-261** Patient derived donor origin CAR-T cell therapy for B cell malignancy patients who have relapsed post allogeneic transplant (N Shah/P Hari) (Attachment 23), Outcomes of CD-19 chimeric antigen receptor T cell therapy after allogeneic hematopoietic cell transplantation for relapsed B-cell lymphoid malignancies (A Mirza/H Elmariah/J Chavez) (Attachment 24)

This study was presented by Sayeef Mirza who started out by explaining that the background of CAR T cell post allogeneic transplant. Limited studies showed CAR-T cell therapy offers high remission rates for patients with relapsed B-cell malignancies post-transplant. A larger sample size may better assess the safety and efficacy of CAR-T cells against relapsed/refractory B cell malignancies post-allogeneic transplant. The hypothesis was CAR T cell therapy was safe and had improved outcomes in patients with relapsed B-cell malignancies post-transplant compared to other donor lymphocyte infusion/immunotherapy versus chemotherapy versus second transplant. The study design was A retrospective multicenter study utilizing the CIBMTR dataset involving patients with relapsed B-cell malignancies post allogeneic transplant who subsequently received CAR-T cell therapy. There were 133 patients who underwent first CAR T for ALL or NHL with prior allo-HCT.

i. **PROP 1911-110/PROP 1911-159/PROP 1911-216** Determinants of outcomes of acute lymphoblastic leukemia following the receipt of chimeric antigen receptor T-cell therapy (P Dhakal/V Bhatt) (Attachment 25), Outcome and prognostic significance of cytogenetic abnormalities in pediatric and adult patients with acute lymphoblastic leukemia post chimeric antigen receptor T-cell therapy (D Ragoonanan/K Mahadeo/P Kebriaei) (Attachment 26), Clinical features and outcomes in patients with acute lymphoblastic leukemia who relapse post-chimeric antigen receptor therapy (L Schultz/L Muffly) (Attachment 27)

This study was presented by Dristhi Ragoonanan who started out by explaining that we lack predictors of durable response, relapse, and survival. The hypothesis was that analysis of patient, disease and treatment variables would identify predictors of remission, relapse and survival following CAR T cell therapy. The primary aims were developing a model for predictors of outcomes post CAR T therapy; developing outcomes following CAR T therapy. Dr. Ragoonanan then mentioned the scientific impact of this study: improving risk stratification of patients allowing tailored management; understanding how to integrate CAR T cell therapy into current ALL management algorithms; identifying optimal candidates for CAR T cell therapy; recognizing modulable factors that impact outcomes of CAR T cell therapy; identifying patients who may benefit from consolidation therapy; evaluating long-term outcomes of CAR T-cell therapy. There were 302 patients including 208 commercial products and 94 noncommercial products.

j. **PROP 1911-115/PROP 1911-166/PROP 1911-187** Resource utilization with CAR-T cells (M Battiwalla/J Pantin) (Attachment 28), Real world experience of costs and healthcare utilization in children and young adults receiving Kymriah for acute lymphoblastic leukemia (H Rangarajan/P Satwani) (Attachment 29), Comparison of resource utilization patterns in adult patients receiving inpatient vs outpatient chimeric antigen receptor therapy for relapsed lymphoma (C Scheckel/ M Siddiqui/Y Lin/S Hashmi) (Attachment 30)

Dr. Caleb Scheckel presented this proposal starting with the background of CAR T cell therapy: two FDA approved therapies in NHL & ALL; future growth into other malignancies; high cost of therapy; no real-world data analysis on true cost and cost effectiveness. The goal of this study was describing and establishing "real world" cost and resource utilization in CAR-T recipients in first 60 days after infusion. The area of special focus was the cost of savings which included Inflammatory markers and treatment toxicity correlation with resource utilization; comparative CAR-T inpatient and outpatient resource utilization; CAR-T cost-effectiveness compared to other treatment strategies in pediatric ALL. Then Dr. Scheckel stated the methods of this study: currently can access via institutional licenses; critical data needed. The data had 1249 patients which included 302 patients of ALL and 886 patients of NHL.

k. **PROP 1911-92** Not everyone has access to care with CAR T cells for relapsed/refractory Diffuse Large B Cell Lymphoma (M Pennisi/M Pasquini/M Perales) (Attachment 31)

Dr. Martina Pennisi presented this proposal, showing the graph of socio-demographic disparities. The hypothesis was that there were disparities in access to care with CAR T cells in patients with R/R DLBCL based on varied characteristics. The aim was assessing rate of utilization of CAR T cells for patients with R/R DLBCL after auto-HCT, stratified by socio-economic, geographic and demographic data. There were 229 patients receiving CAR T cells after auto-HCT. The scientific impact of this study was a better definition of rates of utilization could provide important information on how to improve: access to care and health care policy.

Dropped proposed studies

Dr. Pasquini mentioned that the reasons for dropped studies were overlap or due to feasibility or requiring long term follow up or needing supplemental information.

a. **PROP 1909-05** Determining long term outcomes of CD19 directed autologous chimeric antigen receptor T-cell therapy in patients with B-cell acute lymphoblastic leukemia and diffuse large B-cell lymphoma. *Dropped due to supplemental data needed.*
b. **PROP 1910-15** Late-toxicity in long-term survivor patients treated with CAR-T cell therapies. *Dropped due to supplemental data needed.*
c. **PROP 1910-16** Comparison between patients who received consolidation with allo-HSCT vs not in acute lymphoblastic leukemia treated with CAR-T cell therapy. *Dropped due to overlap with current study/publication*.
d. **PROP 1911-55** Outcomes of allogeneic stem cell transplantation in patients with relapsed/refractory non-Hodgkin lymphoma after CAR T cell therapy. *Dropped due to small sample size.*
e. **PROP 1911-56** Outcomes of allogeneic stem cell transplantation in patients with relapsed/refractory acute lymphoblastic leukemia after CAR T cell therapy. *Dropped due to overlap with current study/publication.*
f. **PROP 1911-128** The impact of lymphodepletion regimen on CD19 CAR-T cell outcomes in patients with aggressive non-Hodgkin lymphoma. *Dropped due to small sample size.*
g. **PROP 1911-144** Outcomes of patients with aggressive B-cell lymphomas after CD19 CAR T-cells that required bridging therapy prior to infusion. *Dropped due to supplemental data needed.*
h. **PROP 1911-174** Matched-pair analysis of survival in patients with hematologic malignancies treated with haploidentical donor lymphocyte infusions compared to alternative donor lymphocyte infusions. *Dropped due to overlap with current study/publication.*
i. **PROP 1911-178** Age-based outcomes of chimeric antigen T-cell therapy for non-Hodgkin lymphoma. *Dropped due to overlap with current study/publication.*

j. **PROP 1911-199** Cardiovascular toxicity and clinical outcomes following chimeric antigen receptor T-cell infusion for B-cell lymphoid malignancies. *Dropped due to supplemental data needed*.
k. **PROP 1911-201** Outcomes in allogeneic hematopoietic cell transplant recipients with prior exposure to chimeric antigen receptor-T cell therapy for B cell malignancies. *Dropped due to overlap with current study/publication.*
l. **PROP 1911-207** Outcomes of allogeneic hematopoietic cell transplantation after CD-19 chimeric antigen receptor T cell therapy for B-cell acute lymphoblastic leukemia patients. *Dropped due to overlap with current study/publication.*
m. **PROP 1911-248** Outcome of CD-19 directed CAR T cell infusion on patients with secondary CNS lymphoma. *Dropped due to small sample size.*
n. **PROP 1911-251** Outcomes of allogeneic HCT in patients with B-cell non-Hodgkin lymphoma after prior chimeric antigen receptor – T cell therapy. *Dropped due to small sample size.*
o. **PROP 1911-259** Efficacy and safety of CD19 directed CAR T-cell therapy for aggressive non-Hodgkin B-cell lymphomas with secondary central nervous system involvement. *Dropped due to small sample size.*
p. **PROP 1911-264** Impact of prior blinatumomab exposure on efficacy and safety of CD19-targeted chimeric antigen receptor T cells in acute lymphoblastic leukemia. *Dropped due to small sample size.*
q. **PROP 1912-03** Outcomes of long-term survivors of Immune Effector Cell Therapy. *Dropped due to small sample size.*

Transfer to Infection and Immune Reconstitution Working Committee

a. **PROP 1911-34** Infectious disease patterns, clinical impacts and treatment in aggressive B cell non-Hodgkin lymphoma and precursor B acute lymphoblastic leukemia patients treated with CD19 CAR T cell therapy.
b. **PROP 1911-50** Impact of early infection in chimeric antigen receptor T (CAR-T) cell therapy outcomes in the first 100 days post-therapy.
c. **PROP 1911-76** Infectious complications after CAR-T cell immunotherapy in patients with B-cell malignancies.
a. **PROP 1911-155** Infections after CD19-targeted chimeric antigen receptor–modified (CAR) T-cell therapy for non-Hodgkin lymphoma.
b. **PROP 1911-158** Observational study of infectious complications among patients treated with anti-CD19 chimeric antigen receptor T cells (CAR-T cells).
c. **PROP 1911-209** Infectious complications and immune reconstitution following CD19-directed CAR-T cell therapy.
d. **PROP 1911-235** The role of intravenous immune globulins in patients after CAR-T therapy.
e. **PROP 1911-254** Patterns of infections post CD19 directed CAR-T cells infusions.
f. **PROP 1911-266** Risk factors for clinically significant infections following CD19-targeted CAR-T cells therapy for hematological malignancies.

Transfer to Lymphoma Working Committee

a. **PROP 1911-51** CAR-T cell therapy versus autologous transplant in early rituximab failure patients with diffuse large B-cell lymphoma.
b. **PROP 1911-267** Comparison of outcomes of DLBCL patients with partial response after salvage therapy who underwent CAR-T vs. ASCT.

The meeting adjourned at 3:00 pm.

Working Committee Overview Plan for 2020-2021						
Study number and Short title	Current status	Goal with date	Total hours to complete	Hours allocated to 6/30/2020	Hours allocated 7/1/2020-6/30/2021	Total Hours allocated
CT13-01: Utility of unmanipulated donor lymphocyte infusion (DLI) for the treatment of infections in allogeneic hematopoietic cell transplantation recipients	Analysis	Analysis -June 2020	110	0	0	**0**
AC16-01: Pattern of use and outcomes with donor lymphocyte infusion after HLA-haploidentical allogeneic hematopoietic stem cell transplant	Data File Prep	Manuscript Preparation -June 2020	130	60	70	**130**
AC17-01: CD-19 chimeric antigen receptor T Cells with or without hematopoietic cell transplantation for treatment of refractory Acute Lymphocytic Leukemia	Protocol Development	Analysis -June 20	260	130	60	**190**
AC18-01: Effect of stem cell boost and donor lymphocyte infusion on the incidence of GVHD	Protocol Development	Data File Preparation -June 20	330	100	160	**260**
CT19-01: Allogeneic hematopoietic cell transplantation vs chimeric antigen receptor t-cell therapy for dlbcl patients with prior autologous transplant failure or refractory disease	Protocol Development	Analysis -June 20	260	130	60	**190**
CT19-02: Prolonged cytopenia following CD-19 targeted CAR-T therapy for diffuse large b-cell lymphoma	Protocol Development	Manuscript Preparation -June 20	230	160	70	**230**

CT20-01: Comparative outcomes analysis of patients with aggressive B-cell lymphoma treated with axicabtagene ciloleucel vs. tisagenlecleucel	Protocol Pending	Protocol Development -June 20	330	0	260	**260**
CT20-02: Resource utilization with CAR-T cells	Protocol Pending	Protocol Development -June 20	370	0	240	**240**
CT20-03: Determinants of outcomes after CAR T cells for Lymphoma	Protocol Pending	Protocol Development -June 20	330	0	200	**200**
CT20-04: Determinants of outcomes after CAR T cells for ALL	Protocol Pending	Protocol Development -June 20	350	0	100	**100**

Oversight Assignments for Working Committee Leadership March 2020		
Sarah Nikiforow	**AC17-01**	CD19 CAR T cells without HCT for ALL
	CT19-01	ALLO vs CAR T DLBCL with prior Auto or refractory disease
	CT20-01	Comparison of commercial CAR T cells for DLBCL
	CT20-04	Determinants of outcomes after CAR T cells for ALL
Peiman Hematti	**CT13-01**	DLI for viral or fungal Infections in Allo HCT
	AC18-01	Effect of SCB and DLI on GVHD incidence
	AC16-01	DLI After HLA-haploidentical allogeneic transplant
Cameron Turtle	**CT19-02**	Prolonged Cytopenia Following CD-19 CAR-T Therapy for DLBCL
	CT20-02	Resource utilization with CAR-T cells
	CT20-03	Determinants of outcomes after CAR T cells for Lymphoma