

Leadership Chair: Harry P. Erba, MD, PhD Vice-Chair: Aniali S. Advani, MD Statisticians: Megan Othus, PhDAnna Moseley, MS Scientific Leadership Translational Medicine: Jerald P. Radich, MD Cytogenetics Liaison: Min Fang, MD, PhD **Designates** Cancer Control: Stephanie B. Tsai, MD Veterans Affairs:..... Tsewang Tashi, MD Data Coordinators:.....Louise Highleyman, BARoula BustamiTaylor Vlaming (MyeloMATCH) Oncology Research Professionals: CRA: Heather A. Thulean, BS Pharmaceutical Science: Holly O. Chan, PharmDlla M. Saunders, PharmD

Time/Location

Friday, October 18, 2024 9:45 a.m. - 11:45 a.m. Room: Crystal C (Lobby Level, West Tower)

Agenda

Protocol Project Manager: Amy Doyle
Sr. Protocol Project Manager: Sarah Cantu (MyeloMATCH)

Clinical Trials Program Manager:Sharon Palmer

Clinical Trials Program Manager: Mariah Norman, MS (MyeloMATCH)

- Updates in Leukemia Translational Medicine Cecilia Yeung (20 minutes)
- 2. Updates in MyeloMATCH Tara Lin & Laura Michaelis (40 minutes)
- Updates in Acute Lymphoblastic Leukemia Kristen O'Dwyer (20 minutes)
- 4. Updates in MPN Alex Coltoff (20 minutes)
- 5. Updates in CLL Deb Stephens & Mazyar Shadman (20 minutes)

AML/MDS Studies

Active Studies

CTSU/A041701, "A Randomized Phase II/III Study of Conventional Chemotherapy +/- Uproleselan (GMI-1271) in Older Adults with Acute Myeloid Leukemia Receiving Intensive Induction Chemotherapy." Dr. L. Liesveld. Activated: 1/16/19. Temporarily closed to accrual 11/19/21

Closed Studies

- <u>\$1612</u>, "A Randomized Phase II/III Trial of "Novel Therapeutics" Versus Azacitidine in Newly Diagnosed Patients with Acute Myeloid Leukemia (AML) or High-Risk Myelodysplastic Syndrome (MDS), Age 60 or Older." Drs. L. Michaelis, R. Walter, S. Assouline, et al. Activated: 12/22/17; Closed: 9/3/20.
- **50919**, "A Phase II Study of Idarubicin and Ara-C in Combination with Pravastatin for Poor-Risk Acute Myelogenous Leukemia (AML)." Dr. A. Advani. Re-Activated: 4/1/13; Closed: 9/15/17; Complete: 10/21/21.
- S1203, "A Randomized Phase III Study of Standard Cytarabine Plus Daunorubicin (7+3) Therapy or Idarubicin with High Dose Cytarabine (IA) versus IA with Vorinostat (NSC-701852) (IA+V) in Younger Patients with Previously Untreated Acute Myeloid Leukemia (AML)." Drs. Garcia-Manero and Pagel. Activated: 12/15/12; Closed: 11/4/15; Complete: 3/29/22.

ALL Studies

Active Studies

- **S1905**, "A Phase I/II Study of AKR1C3-Activated Prodrug OBI-3424 (OBI-3424) in Patients with Relapsed/Refractory T-Cell Acute Lymphoblastic Leukemia (T-ALL) / T-Cell Lymphoblastic Lymphoma (T-LBL)." Drs. A. Advani, N. Papadantonakis, and C. Yeung. Activated: 8/17/20.
- CTSU/A041501, "A Phase III Trial to Evaluate the Efficacy of the Addition of Inotuzumab Ozogamicin (a Conjugated Anti-CD22 Monoclonal Antibody) to Frontline Therapy in Young Adults (Ages 18-39 Years) with Newly Diagnosed Precursor B-Cell ALL." Dr. A. Advani. Activated: 6/1/17. Temporarily closed to accrual: 5/24/22.

Developing Studies

S2434, "A Phase 1B Study of Revumenib (SNDX-5613) in Combination with Age-Guided Chemotherapy and Blinatumomab in Newly Diagnosed Patients with KMT2Ar ALL or ALAL." Drs. I. Aldoss, A. Advani, W. Stock, and C. Saygin.



Closed Studies

S0333, "A Phase II Study of Double Induction Chemotherapy for Newly Diagnosed Non-L3 Adult Acute Lymphoblastic Leukemia with Investigation of Minimal Residual Disease and Risk of Relapse Following Maintenance Chemotherapy." Drs. Forman and O'Donnell. Activated: 4/15/05; Closed: 11/1/09.

S1312, "A Phase I Study of Inotuzumab Ozogamicin in Combination with CVP (Cyclophosphamide, Vincristine, Prednisone) for Patients with Relapsed/Refractory CD22-Positive Acute Leukemia (Including B-ALL, Mixed Phenotypic Leukemia, and Burkitt's Leukemia)." Drs. A. Advani and Liedtke. Activated: 4/1/14; Closed: 8/2/19.

S1318, "A Phase II Study of Blinatumomab and POMP (Prednisone, Vincristine, Methotrexate, 6-Mercaptopurine) for Patients ≥ 65
Years of Age with Newly Diagnosed Philadelphia-Chromosome
Negative (Ph-) Acute Lymphocytic Leukemia (ALL) and of Dasatinib,
Prednisone and Blinatumomab for Patients ≥ 65 Years of Age with
Newly Diagnosed Philadelphia-Chromosome Positive (Ph+) ALL
and Philadelphia-Chromosome-Like Signature (Ph-like) ALL (Newly
Diagnosed or Relapsed/Refractory) with Known or Presumed
Activating Dasatinib-Sensitive Mutations or Kinase Fusions (DSMKF)."
Drs. A. Advani and K. O'Dwyer. Activated: 1/12/15; Closed: 4/15/21.

CLL Studies

Active Studies

S1925, "Randomized, Phase III Study of Early Intervention with Venetoclax and Obinutuzumab Versus Delayed Therapy with Venetoclax and Obinutuzumab in Newly Diagnosed Asymptomatic High-Risk Patients with Chronic Lymphocytic Leukemia / Small Lymphocytic Lymphoma (CLL): EVOLVE CLL/SLL Study." Drs. D. Stephens, B. Hill, J. Pagel, et al. Activated: 12/14/20.

Developing Studies

S2421, "A Randomized Phase II Study of Pirtobrutinib Plus R-CHOP vs. R-CHOP for Patients with Previously Untreated Richter Transformation (RT)." Drs. M. Shadman, D. Stephens, and A. Danilov.

Closed Studies

CTSU/EA9161, "A Randomized Phase III Study of the Addition of Venetoclax to Ibrutinib and Obinutuzumab Versus Ibrutinib and Obinutuzumab in Untreated Younger Patients with Chronic Lymphocytic Leukemia (CLL)." Dr. M. Shadman. Activated: 1/3/19. Closed: 4/30/21.

CTSU/A041702, "A Randomized Phase III Study of Ibrutinib Plus

Obinutuzumab Versus Ibrutinib Plus Venetoclax and Obinutuzumab
in Untreated Older Patients (≥ 70 Years of Age) with Chronic

Lymphocytic Leukemia (CLL)." Dr. B. Hill. Activation: 1/4/19. Closed:
1/4/19.

CML Studies

Closed Studies

51712, "A Randomized Phase II Study of Ruxolitinib (NSC-752295) in Combination with BCR-ABL Tyrosine Kinase Inhibitors in Chronic Myeloid Leukemia (CML) Patients with Molecular Evidence of Disease." Drs. K. Sweet and J. Radich. Activated: 7/20/18. Closed: 10/20/22.

MDS/MPN Studies

Developing Studies

52502, "A Phase I/II Study of TP-3654 in Combination with Decitabine for Myelodysplastic Syndrome/Myeloproliferative Neoplasm Overlap Syndromes (MDS/MPNs) and Accelerated- or Blast-Phase MPNs (MPN-AP/BP)." Drs. A. Coltoff, A. Gerds, and U. Borate.

MyeloMATCH

Active Studies

MYELOMATCH, "Master Screening and Reassessment Protocol (MSRP) for Tier Advancement in the NCI MyeloMATCH Clinical Trials." Drs. J. Radich and S. Jiwani. Activated: 5/16/24.

MM1YA-S01, "A Randomized Phase II Study Comparing Cytarabine + Daunorubicin (7+3) vs. (Daunorubicin and Cytarabine) Liposome, Cytarabine + Daunorubicin + Venetoclax, Azacitidine + Venetoclax, and (Daunorubicin and Cytarabine) Liposome + Venetoclax in Patients Aged 59 or Younger who are Considered High-Risk (Adverse) Acute Myeloid Leukemia as Determined by myeloMATCH; A myeloMATCH Clinical Trial." Drs. P. Shami and T. Lin. Activated: 5/16/24.

Developing Studies

MM1OA-S03, "A Randomized Phase II trial of C-DEC, Venetoclax, and Enasidenib Compared with Azacitidine and Venetoclax for Newly Diagnosed Older Adults with IDH2 mutant AML: A myeloMATCH Treatment Trial." Drs. U. Borate and E. Huselton.



Publications

The publications listed below were received by the Group Chair's Office as published (including online), accepted, or submitted since the SWOG Spring 2024 Group Meeting. Conference abstracts are not included.

Because of journal embargo policies, journal names are omitted for submitted or accepted manuscrips.

Published/Accepted Manuscripts

S1203 Association between class III obesity and overall survival in previously untreated younger patients with acute myeloid leukemia enrolled on SWOG S1203. Zhang M, Othus M, McMillen K, Erba H, Garcia-Manero G, Patel J, Sorror M, Percival M. <u>Leukemia</u> Jul;38(7):1488-1493, 2024. https://pubmed.ncbi.nlm.nih.gov/38830960/

Submitted Manuscripts

myeloMATCH Moseley A, LeBlanc M, Freidlin B, Shallis R, Zeidan A, Sallman D, Erba H, Little R, Othus M. Evaluating the impact of stratification on the power and cross-arm balance of randomized Phase 2 clinical trials. Submitted 2024.



Accrual from trials that are open as of 6/30/2024 or have closed in the prior 18 Months by Institution and Study

	MYELOMATC	H _{S1905}	51925	A041501	A041701	A041703	A042001	EA9152	EA9171	EA9181	EA9213
CWRU Case Comprehensive Cancer Center LAPS	-	1	7	4	-	-	-	-	-	-	-
Cancer Research for the Ozarks NCORP	-	-	1	-	-	-	-	-	-	-	-
City of Hope Comprehensive Cancer Center	-	3	1	-	-	-	-	-	-	-	-
Duke University - Duke Cancer Institute LAPS	-	-	1	-	-	-	-	-	-	2	-
Fred Hutchinson Cancer Research Center LAPS	-	4	2	-	-	-	-	-	-	-	3
Hawaii Minority Underserved NCORP	-	-	-	-	-	-	-	-	-	3	-
Henry Ford Hospital	-	-	2	-	4	-	-	-	-	-	-
Intermountain Medical Center	-	-	-	2	-	-	-	-	-	-	-
Loyola University Medical Center	-	-	1	-	-	-	-	-	-	1	-
Medical University of South Carolina Minority Underserved NCORP	-	-	3	-	-	-	-	-	-	-	-
Michigan Cancer Research Consortium NCORP	-	-	7	-	-	-	-	-	-	-	-
Northwell Health NCORP	-	-	-	-	2	-	-	-	-	-	-
Northwestern University LAPS	-	-	-	3	1	-	1	-	-	4	-
Oregon Health and Science University	-	1	-	8	-	-	-	-	-	-	-
STCC at DHR Health Institute for Research and Development	-	-	1	-	-	-	-	-	-	-	-
Southeast Clinical Oncology Research Consortium NCORP	-	-	1	-	-	-	-	-	-	-	-
Stanford Cancer Institute Palo Alto	-	-	-	8	-	-	-	-	-	-	-
UC Davis Comprehensive Cancer Center LAPS	-	-	4	2	-	-	-	-	-	-	-
UC Irvine Health/Chao Family Comprehensive Cancer Center	-	-	1	3	-	1	-	-	-	10	-
UC San Diego Moores Cancer Center	-	-	-	-	-	-	-	-	-	1	-
U of Alabama at Birmingham/Deep South Research Consortium LAPS	-	-	-	1	-	-	1	-	-	-	-
University of Arkansas for Medical Sciences	-	-	-	-	4	-	-	-	-	-	-
University of Cincinnati Cancer Center-UC Medical Center	-	2	-	-	-	1	-	-	-	3	-
University of Rochester LAPS	-	2	11	7	27	3	-	-	-	6	-
University of Utah - Huntsman Cancer Institute LAPS	-	-	16	1	-	-	-	-	-	-	-
Wayne State University - Karmanos Cancer Institute LAPS	-	-	-	-	-	-	-	-	-	3	-
Western States Cancer Research NCORP	-	-	-	-	-	-	-	-	2	-	-
Yale University - Yale Cancer Center LAPS	-	-	-	5	-	-	-	3	2	1	-
ALLIANCE	1	2	22	-	-	-	-	-	-	-	-
CCTG	-	-	10	-	-	-	-	-	-	-	-
ECOG-ACRIN	4	-	11	-	-	-	-	-	-	-	-
NRG	-	-	3	-	-	-	-	-	-	-	-
Total	5	15	105	44	38	5	2	3	4	34	3



