

## Leadership Chair: ...... Harry P. Erba, MD, PhD Vice-Chair: ...... Aniali S. Advani, MD Statisticians: ..... Megan Othus, PhD ......Anna Moseley, MS ...... Allison Hayes, BS **Scientific Leadership** Translational Medicine: ...... Jerald P. Radich, MD Pathology: ......David R. Head, MD Cytogenetics Liaison: ..... Min Fang, MD, PhD **Designates** Cancer Control: ...... Stephanie B. Tsai, MD Veterans Affairs:...... Tsewang Tashi, MD Data Coordinators:.....Louise Highleyman, BA ......Roula Bustami Oncology Research Professionals: CRA: . . . . . TBD Patient Advocate:......Gail Sperling, MPH Pharmaceutical Science: ...... Holly O. Chan, PharmD ......lla M. Saunders, PharmD Protocol Project Manager: ..... Amy Doyle Sr. Protocol Project Manager: ..... Sarah Cantu (MyeloMATCH)

### Time/Location

Thursday, May 1, 2025 5:15 p.m. - 7:15 p.m. Room: Garden Room (Atrium Lobby Level)

#### **Agenda**

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

- 1. Updates in Leukemia Translational Medicine
- 2. Updates in MyeloMATCH
- 3. Updates in Acute Lymphoblastic Leukemia
- 4. Updates in MPN
- 5. Updates in CLL

#### **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. Closed: 9/16/24.

#### **Closed Studies**

- **S1612**, "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; Complete: 6/26/24.
- **S0919**, "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: 03/29/22.

### **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: 05/24/22.

### **Developing Studies**

**S2507**, "A Phase II Randomized Study of Blinatumomab with or without Revumenib for Patients with KMT2Ar B-ALL with persistent measurable residual disease (MRD)." Drs. I. Aldoss, A. Advani, W. Stock, J. McNeer, 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: 11/01/09.

**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: 9/29/21.

### **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**

**S2504**, "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: 7/15/22.

#### **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**

**<u>\$2502</u>**, "A Phase I/II study of Nuvisertib (TP-3654) in Combination with oral decitabine plus cedazuridine 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: 05/16/24.

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: 05/16/24.

## **Developing Studies**

MM10A-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 Substudy." 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 Fall 2024 Group Meeting. Conference abstracts are not included.

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

#### **Published/Accepted Manuscripts**

S1203 Probability of remission with reinduction with 7+3 versus high-dose ara-C: Analysis of SWOG Trial S1203. Othus M, Garcia-Manero G, Appelbaum F, Erba H, Estey E, Percival M. Leukemia Mar;39(3):752-754, 2025. https://pubmed.ncbi.nlm.nih.gov/39870766/

myeloMATCH Evaluating the impact of stratification on the power and cross-arm balance of randomized Phase 2 clinical trials. Moseley A, LeBlanc M, Freidlin B, Shallis R, Zeidan A, Sallman D, Erba H, Little R, Othus M. Clin Trials Jan 15:17407745241304065, 2025.

https://pubmed.ncbi.nlm.nih.gov/39815460/

E1912 Tolerability and long-term disease control by IGHV mutation status among patients with CLL on ibrutinib arm of E1912. Shanafelt TD, Wang XV, Hanson CA, Paietta E, O'Brien S, Barrientos J, Jelinek DF, Braggio E, Leis JF, Zhang CC, Barr PM, Cashen AF, Mato AR, Singh AK, Mullane MP, Little RF, Erba H, Stone RM, Litzow M, Tallman M, Kay NE. Blood Adv Jan 14;9(1):224-228, 2025.

https://pubmed.ncbi.nlm.nih.gov/39163612/

#### **Submitted Manuscripts**

None this cycle



## Accrual from trials that are open as of 12/31/2024 or have closed in the prior 18 Months by Institution and Study

	MM1YA-S01	MYELOMAT	TCH \$1905	S1925	A041501	A041701	A041703	A042001
Banner University Medical Center - Tucson	_	2	-	-	-	-	-	-
Baptist Mem Health Care/Mid South Minority Underserved NCORP	-	2	-	-	-	-	-	-
CWRU Case Comprehensive Cancer Center LAPS	_	-	2	7	4	-	-	_
Cancer Research for the Ozarks NCORP	-	_	-	1	-	-	-	-
Carle Cancer Center NCI Comm Oncology Research Program	_	-	-	1	-	-	-	-
Cedars-Sinai Medical Center	_	1	_	-	-	-	_	_
City of Hope Comprehensive Cancer Center	-	-	3	1	-	-	-	_
Duke University - Duke Cancer Institute LAPS	-	_	-	1	-	-	-	-
Fred Hutchinson Cancer Research Center LAPS	-	_	4	2	-	-	-	_
Froedtert & the Medical College of Wisconsin LAPS	-	4	-	-	-	-	-	-
Georgia Cares Minority Underserved NCORP	-	1	-	-	-	-	-	_
Hawaii Minority Underserved NCORP	_	-	_	_	-	-	_	_
Heartland Cancer Research NCORP	-	1	-	-	-	-	_	_
Henry Ford Hospital	_	-	_	3	-	4	_	_
Intermountain Medical Center		_	-	-	2	-	_	_
Kaiser Permanente NCI Comm Oncology Research Program	_	_	_	1	-	_	_	_
Loyola University Medical Center		_	-	1	_	_		_
	_	1	_	-	-	-	-	-
Massachusetts Vets Epidemiology Research & Information Center		-		3	-	-	-	-
Medical U of South Carolina Minority Underserved NCORP	-		-	<i>7</i>	-	-	-	-
Michigan Cancer Research Consortium NCORP	-	8			-	-	-	-
Montana Cancer Consortium NCORP	-	1	-	-	-	-	-	-
NCORP of the Carolinas	-	1	-	-	-	-	-	-
Northwell Health NCORP	-	-	-	-	-	2	-	-
Northwestern University LAPS	-	3	-	1	3	1	-	1
Oregon Health & Science University	1	3	1	-	8	-	-	-
Pacific Cancer Research Consortium NCORP	-	4	-	-	-	-	-	-
STCC at DHR Health Institute for Research & Development	-	-	-	1	-	-	-	-
Southeast Clinical Oncology Research Consortium NCORP	-	-	-	1	-	-	-	-
Stanford Cancer Institute Palo Alto	-	-	-	-	8	-	-	2
UC Davis Comprehensive Cancer Center LAPS	-	-	-	4	2	-	-	-
UC Irvine Health/Chao Family Comprehensive Cancer Center	-	-	-	2	3	-	1	-
UC San Diego Moores Cancer Center	-	-	-	-	-	-	-	-
U of Alabama at Birmingham/Deep South Research Consortium LAF	S -	-	-	-	1	-	-	2
University of Arkansas for Medical Sciences	-	-	-	-	-	4	-	-
University of Cincinnati Cancer Center-UC Medical Center	-	-	2	-	-	-	1	-
University of Kansas Cancer Center- MCA Rural MU NCORP	1	15	-	-	-	-	-	-
University of Oklahoma Health Sciences Center LAPS	-	3	-	-	-	-	-	-
University of Rochester LAPS	1	24	2	12	7	27	3	3
University of Utah - Huntsman Cancer Institute LAPS	-	3	-	18	1	-	-	-
Wayne State University - Karmanos Cancer Institute LAPS	-	-	-	-	-	-	-	-
Western States Cancer Research NCORP	-	-	-	-	-	-	-	-
Wisconsin NCI Comm Oncology Research Program	-	2	-	-	-	-	-	-
Yale University - Yale Cancer Center LAPS	-	5	-	-	5	-	-	-
ALLIANCE	1	56	2	30	-	-	-	-
CCTG	-	5	-	11	-	-	-	-
ECOG-ACRIN	1	50	2	14	-	-	-	-
NRG								
MIG	-	2	-	4	-	-	-	-



## Accrual from trials that are open as of 12/31/2024 or have closed in the prior 18 Months by Institution and Study

	EA9152	EA9171	EA9181	EA9213	MM10AEA02	MM1YACTG01
Banner University Medical Center - Tucson	-	-	-	-	-	-
Baptist Mem Health Care/Mid South Minority Underserved NCORP	-	-	-	-	-	-
CWRU Case Comprehensive Cancer Center LAPS	-	-	-	-	-	-
Cancer Research for the Ozarks NCORP	-	-	-	-	-	-
Carle Cancer Center NCI Comm Oncology Research Program	-	-	-	-	-	-
Cedars-Sinai Medical Center	-	-	-	-	-	-
City of Hope Comprehensive Cancer Center	-	-	-	-	-	-
Duke University - Duke Cancer Institute LAPS	-	-	3	-	-	-
Fred Hutchinson Cancer Research Center LAPS	-	-	-	3	-	-
Froedtert & the Medical College of Wisconsin LAPS	-	-	-	-	-	-
Georgia Cares Minority Underserved NCORP	-	-	-	-	-	-
Hawaii Minority Underserved NCORP	-	-	4	-	-	-
Heartland Cancer Research NCORP	-	-	-	-	-	-
Henry Ford Hospital	-	-	-	-	-	-
Intermountain Medical Center	-	-	-	-	-	-
Kaiser Permanente NCI Comm Oncology Research Program	-	-	-	-	-	-
Loyola University Medical Center	-	-	2	-	-	-
Massachusetts Vets Epidemiology Research & Information Center	-	-	-	-	-	-
Medical University of South Carolina Minority Underserved NCORP	-	-	-	-	-	-
Michigan Cancer Research Consortium NCORP	-	-	-	-	-	-
Montana Cancer Consortium NCORP	-	-	-	-	-	-
NCORP of the Carolinas	-	-	-	-	-	-
Northwell Health NCORP	-	-	-	-	-	-
Northwestern University LAPS	-	-	4	-	-	-
Oregon Health & Science University	-	-	-	-	-	-
Pacific Cancer Research Consortium NCORP	-	-	-	-	-	-
STCC at DHR Health Institute for Research & Development	-	-	-	-	-	-
Southeast Clinical Oncology Research Consortium NCORP	-	-	-	-	-	-
Stanford Cancer Institute Palo Alto	-	-	-	-	-	-
UC Davis Comprehensive Cancer Center LAPS	-	-	-	-	-	-
UC Irvine Health/Chao Family Comprehensive Cancer Center	-	-	11	-	-	-
UC San Diego Moores Cancer Center	-	-	1	-	-	-
U of Alabama at Birmingham/Deep South Research Consortium LAPS	-	-	-	-	-	-
University of Arkansas for Medical Sciences	-	-	-	-	-	-
University of Cincinnati Cancer Center-UC Medical Center	-	-	4	-	-	-
University of Kansas Cancer Center- MCA Rural MU NCORP	-	-	-	-	-	2
University of Oklahoma Health Sciences Center LAPS	-	-	-	-	-	-
University of Rochester LAPS	-	-	8	-	1	-
University of Utah - Huntsman Cancer Institute LAPS	-	-	-	-	-	-
Wayne State University - Karmanos Cancer Institute LAPS	-	-	3	-	-	-
Western States Cancer Research NCORP	-	2	-	-	-	-
Wisconsin NCI Comm Oncology Research Program	-	-	-	-	-	-
Yale University - Yale Cancer Center LAPS	3	2	1	-	1	-
ALLIANCE	-	-	-	-	-	-
CCTG	-	-	-	-	-	-
ECOG-ACRIN	-	-	-	-	-	-
NRG	-	-	-	-	-	-
<b>Total</b>	3	4	41	3	2	2





