

Leadership

| Chair: | Robert Z. Orlowski, MD, PhD |
|----------------------------------|-------------------------------|
| Vice-Chair: | Sikander Ailawadhi, MD |
| Vice-Chair: | Jing Christine Ye, MD, MSc |
| Executive Officer | Susan M. O'Brien, MD |
| Statisticians: | |
| | Rachael Sexton, MS |
| | Adam Rosenthal, MS |
| | Sara Threlkel, BS |
| Scientific Leadership | |
| Translational Medicine: | Brian A. Walker, BSc, PhD |
| Radiation: | |
| Surgery: | TBD |
| Imaging: | Eric M. Rohren, MD, PhD |
| Pathology: | Pei Lin, MD |
| Early Therapeutics: | Frits van Rhee, MD, PhD |
| Designates | |
| Digital Engagement: | TBD |
| NCORP Representative: | Charles S. Kuzma, MD |
| Veterans Affairs: | Thomas R. Chauncey, MD, PhD |
| Data Coordinators: | Aubrey Gilmore, BA |
| | Daria Chugina, MD, CCRPS |
| | Pasarlai Ahmadzai, MD, MPH |
| Oncology Research Professionals: | |
| CRA: | Brandon Richard Labadie, CCRP |
| Nurse: | Teresa Witcher, BSN, RN |
| Patient Advocate: | Paul Gater, MPhil |
| Pharmaceutical Science: | Craig Elg, PharmD |
| | Ila M. Saunders, PharmD |
| Protocol Project Manager | A D I |
| Protocor Project Manager | Amy Doyle |
| Clinical Trials Program Manager: | |

Time/Location

Friday, May 2, 2025 4:30 p.m. - 6:30 p.m. Room: Pacific HI (Pacific Concourse Level)

Active Studies

S2005, "A Phase II Randomized Study Comparing Ibrutinib and Rituximab vs.Venetoclax and Rituximab in Previously Untreated Waldenström's Macroglobulinemia (WM) /Lymphoplasmacytic Lymphoma (LPL)" Drs. S. Ailawadhi and D. Bhutani. Activated: 6/24/21; Closed: 4/08/2022; Reactivated: 2/15/2024.

- **S2209**, "A Phase III Randomized Trial for Newly Diagnosed Multiple Myeloma (NDMM) Patients Considered Frail or Ineligible for Stem Cell Transplant Comparing Upfront Bortezomib-Lenalidomide-Dexamethasone-Lite (VRd-Lite) with Daratumumab-Lenalidomide-Dexamethasone (DRd)." Drs. S. Ailawadhi, J.C. Ye, B. Lipe, T. Chauncey, and K. Gowin. Activated 05/30/23.
- <u>S2213</u>, "Daratumumab, Cyclophosphamide, Bortezomib, and Dexamethasone (D-VCD) Induction Followed by Autologous Stem Cell Transplant or D-VCD Consolidation and Daratumumab Maintenance in Patients with Newly Diagnosed AL Amyloidosis." Drs. P. Hagen, T. Parker, and S. Sidana. Activated 12/01/2023
- A062102, "Randomized Phase II Study of Iberdomide Maintenance Therapy Following Idecabtagene Vicleucel CAR-T in Multiple Myeloma Patients." Dr. R. Banerjee. Activated: 04/04/2024
- **EAA173**, "Lenalidomide, and Dexamethasone With or Without Daratumumab in Treating Patients With High-Risk Smoldering Myeloma." Dr. E. Manasanch. Activated: 4/30/19.
- **EAA181**, "Testing the Use of Combination Therapy in Adult Patients With Newly Diagnosed Multiple Myeloma, the EQUATE Trial." Dr. K. Gowin. Activated: 10/27/20.

Developing Studies

S2508, "A Phase II Study of Optimal Induction and MRD Driven Maintenance Therapy for Patients with Newly Diagnosed High-Risk Multiple Myeloma (HRMM)." Drs. B. Lipe and J.C. Ye.

Closed Studies

- **<u>\$1803</u>**, "Phase III Study of Daratumumab/rHuPH20 (NSC- 810307) + Lenalidomide or Lenalidomide as Post-Autologous Stem Cell Transplant Maintenance Therapy in Patients with Multiple Myeloma (MM) Using Minimal Residual Disease to Direct Therapy Duration (DRAMMATIC Study)." Drs. A. Krishnan and S. Chhabra. Activated: 6/27/19. Registration Step 1 Closed to Accrual: 1/15/25.
- **S1211**, "A Randomized Phase I/II Study of Optimal Induction Therapy of Bortezomib, Dexamethasone and Lenalidomide with or Without Elotuzumab (NSC-764479) for Newly Diagnosed High Risk Multiple Myeloma (HRMM)." Drs. S. Usmani, S. Ailawadhi, and B. Lipe. Activated: 11/9/12. Closed: 6/2/16.
- **S1702**, "A Phase II Study of Isatuximab (SAR650984) (NSC-795145) for Patients with Previously Treated AL Amyloidosis." Drs. T. Parker and V. Sanchorawala. Activated: 3/08/18; Closed: 9/30/19.



- **<u>\$1304</u>**, "A Phase II Randomized Study Comparing Two Doses of Carfilzomib with Dexamethasone for Relapse/Refractory Multiple Myeloma." Dr. S. Ailawadhi. Activated: 10/18/13. Closed: 11/6/15.
- **S0777**, "Frontline Phase III Rev/Dex +/- Vel, no upfront transplant." Dr. B. Durie. Activated: 4/1/18. Closed: 2/2/12.
- **S0120**, "A prospective Observational Biologic Study of Asymptomatic Patients with Monoclonal Gammopathy and Plasmaproliferative Disorders." Dr. M. Dhodapkar. Activated: 6/1/02. Closed: 4/1/11.
- CTN 0702, "Single Autologous Transplant with or without RVD Consolidation versus Tandem Transplant and Maintenance Therapy." Dr. G. Somlo. Activated: 2/15/11. Closed: 11/15/13.
- A061402, "Ixazomib Citrate, Lenalidomide, Dexamethasone, and Zoledronic Acid or Zoledronic Acid Alone after Radiation Therapy in Treating Patients with Solitary Plasmacytoma of Bone." Dr. A. Kuman Mahindra. Activated: 12/23/15. Closed: 8/15/19.
- E1A11, "Randomized Phase III Trial of Bortezomib, LENalidomide and Dexamethasone (VRd) Versus Carfilzomib, Lenalidomide and Dexamethasone (CRd) Followed by Limited or Indefinite DURation Lenalidomide MaintenANCE in Patients with Newly Diagnosed Symptomatic Multiple Myeloma (ENDURANCE)." Drs. S. Kumar, A. Cohen, and J. Zonder. Activated: 11/22/13. Closed: 1/29/19.
- **E3A06** (was **S0909**), "High-risk AMM Revlimid." Dr. M. Dhodopkar. Activated: 1/17/11. Closed: 7/14/17.
- A061402, "Ixazomib Citrate, Lenalidomide, Dexamethasone, and Zoledronic Acid or Zoledronic Acid Alone after Radiation Therapy in Treating Patients with Solitary Plasmacytoma of Bone." Dr. A. Kumar Mahindra. Activated: 12/23/15. Closed: 8/15/19.
- E1A11, "Randomized Phase III Trial of Bortezomib, LENalidomide and Dexamethasone (VRd) Versus Carfilzomib, Lenalidomide and Dexamethasone (CRd) Followed by Limited or Indefinite DURation Lenalidomide MaintenANCE in Patients with Newly Diagnosed Symptomatic Multiple Myeloma (ENDURANCE)." Drs. S. Kumar, A. Cohen and J. Zonder. Activated: 11/22/13. Closed: 1/29/19.
- **EAA171**, "Optimizing Prolonged Treatment in Myeloma Using MRD Assessment (OPTIMUM)." Dr. S. Kumar. Activated: 6/1/21. Closed 03/03/23.

Proposed Studies-Pre-Triage/On Hold

- **SXXXX**, "A Phase III Study for Evaluation of Maintenance Cessation in Patients with Standard Risk Myeloma Achieving Minimal Residual Disease Negativity." Dr. M. Mohyuddin.
- **SXXXX**, "A Phase II Trial of BCMA Bi-Specific T-Cell Engager (BiTE)
 Teclistamab in Patients with Systemic Light Chain (AL) Amyloidosis." Drs.
 D. Bhutani and K. Dorritie.
- **SXXXX**, "An Open-Label Randomized Phase 2 Trial to Incorporate Venetoclax in Early Relapsed t(11;14) Multiple Myeloma." Dr. R. Chakraborty.
- **SXXXX**, Developing Smoldering Multiple Myeloma Concept. Drs. P. Hagen and A. Cowan.

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

S0777/S1211 Dexamethasone dose intensity does not impact outcomes in newly diagnosed multiple myeloma: a secondary SWOG analysis. Banerjee R, Sexton R, Cowan A, Rosenberg A, Ailawadhi S, Rajkumar V, Kumar S, Lonial S, Durie B, Richardson P, Usmani S, Hoering A, Orlowski R.. Blood. Jan 2;145(1):75-84, 2025.

https://pubmed.ncbi.nlm.nih.gov/39321347/

Submitted Manuscripts

S1702 Isatuximab in Relapsed AL Amyloidosis: Results of a Prospective Phase II Trial. Parker T, Rosenthal A, Sanchorawala V, Landau H, Campagnaro E, Kapoor P, Neparidze N, Girnius S, Hagen P, Scott E, Hoering A, Durie B, Orlowski R. (SWOG S1702). Submitted.



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

| | <i>\$1803</i> | <i>S2005</i> | <i>S2209</i> | <i>S2213</i> | EAA173 | EAA181 |
|---|---------------|--------------|--------------|--------------|--------|--------|
| Banner University Medical Center - Tucson | 11 | - | - | - | - | 5 |
| Boston Medical Center | 5 | - | - | 2 | - | - |
| CWRU Case Comprehensive Cancer Center LAPS | 27 | - | - | - | 8 | - |
| Cancer Research for the Ozarks NCORP | 2 | - | - | - | - | - |
| Cancer Research of Wisconsin and Northern Michigan Consortium | 5 | - | - | - | - | - |
| Carle Cancer Center NCI Community Oncology Research Program | - | - | 1 | - | - | - |
| Cedars-Sinai Medical Center | 6 | - | - | - | - | - |
| City of Hope Comprehensive Cancer Center | 118 | - | 3 | - | - | - |
| Columbia University Minority Underserved NCORP | - | - | 1 | 3 | - | - |
| Columbus NCI Community Oncology Research Program | 5 | - | - | - | - | - |
| CommonSpirit Health Research Institute | 1 | - | 3 | - | - | - |
| Dayton NCI Community Oncology Research Program | 5 | - | - | - | - | - |
| Duke University - Duke Cancer Institute LAPS | 3 | - | - | - | - | - |
| Fred Hutchinson Cancer Research Center LAPS | 5 | - | - | - | 8 | - |
| Froedtert and the Medical College of Wisconsin LAPS | 12 | - | - | - | - | - |
| Georgia NCI Community Oncology Research Program | 19 | - | - | - | - | - |
| Gulf South Minority Underserved NCORP | 4 | - | - | - | - | - |
| Heartland Cancer Research NCORP | 11 | - | 3 | - | - | - |
| Henry Ford Health Providence Southfield Hospital | 2 | - | - | - | 1 | 1 |
| Henry Ford Hospital | - | - | - | - | 2 | - |
| Houston Methodist Hospital | 10 | - | - | - | - | - |
| Kaiser Permanente NCI Community Oncology Research Program | 58 | - | 5 | - | - | - |
| Kansas City Veterans Affairs Medical Center | - | - | 2 | - | - | - |
| Lahey Hospital and Medical Center | 3 | - | - | - | - | - |
| Loyola University Medical Center | 26 | - | - | - | 3 | 1 |
| MU Health Care Goldschmidt Cancer Center | 3 | - | - | - | - | - |
| Massachusetts Veterans Epidemiology Research and Information Cntr | - | - | 1 | - | - | 2 |
| Medical University of South Carolina Minority Underserved NCORP | 54 | - | - | - | 1 | 1 |
| Mercy Medical Center - Des Moines | 1 | - | - | - | - | - |
| Michigan Cancer Research Consortium NCORP | 9 | - | 1 | - | - | - |
| Moffitt Cancer Center | 45 | - | - | - | - | - |
| Montana Cancer Consortium NCORP | 4 | - | - | - | - | - |

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

| New Mexico Minority Underserved NCORP 15 - - 1 - New Mexico Minority Underserved NCORP 15 - 4 - - Ohio State University Comprehensive Cancer Center LAPS 5 - - - - Oregon Health and Science University 33 - 1 - 3 9 Parker Adventist Hospital 2 - | | <i>\$1803</i> | S2005 | <i>S2209</i> | S2213 | EAA173 | EAA181 |
|--|--|---------------|-------|--------------|-------|--------|--------|
| New Mexico Minority Underserved NCORP Ohio State University Comprehensive Cancer Center LAPS 5 | NCORP of the Carolinas (Prisma Health NCORP) | - | - | 2 | - | - | - |
| Ohio State University Comprehensive Cancer Center LAPS Oregon Health and Science University 33 - 1 - 3 9 Pacific Cancer Research Consortium NCORP 16 - 6 Parker Adventist Hospital 2 Stanford Edit Hospital 3 Southeast Clinical Oncology Research Consortium NCORP 3 Stanford Cancer Institute Palo Alto Tulane University School of Medicine UC Davis Comprehensive Cancer Center LAPS 27 - 5 University of Arkansas for Medical Sciences University of Arkansas Gonzer Center-UC Medical Center University of Kantucky/Markey Cancer Center University of Michigan Comprehensive Cancer Center University of Michigan Comprehensive Cancer Center 4 University of Michigan Comprehensive Cancer Center LAPS 16 University of Texas Health Science Center at San Antonio 22 University of Texas MD Anderson Cancer Center LAPS 15 2 2 3 University of Texas MD Anderson Cancer Center LAPS 16 University of Utah - Huntsman Cancer Institute LAPS 17 University of Utah - Huntsman Cancer Institute LAPS 18 Wayne State University - Karmanos Cancer Institute LAPS 18 | Nevada Cancer Research Foundation NCORP | - | - | - | - | 1 | - |
| Oregon Health and Science University 33 - 1 - 3 9 Pacific Cancer Research Consortium NCORP 16 - 6 - - - Parker Adventist Hospital 2 - - - - - Riverside Methodist Hospital 3 - | New Mexico Minority Underserved NCORP | 15 | - | 4 | - | - | - |
| Pacific Cancer Research Consortium NCORP Parker Adventist Hospital 2 | Ohio State University Comprehensive Cancer Center LAPS | 5 | - | - | - | - | - |
| Parker Adventist Hospital 2 | Oregon Health and Science University | 33 | - | 1 | - | 3 | 9 |
| Riverside Methodist Hospital Southeast Clinical Oncology Research Consortium NCORP Stanford Cancer Institute Palo Alto Tulane University School of Medicine UC Davis Comprehensive Cancer Center LAPS UC Irvine Health/Chao Family Comprehensive Cancer Center University of Arkansas for Medical Sciences University of Cincinnati Cancer Center-UC Medical Center University of Kansas Cancer Center-UC Medical Center University of Kentucky/Markey Cancer Center University of Kentucky/Markey Cancer Center LAPS University of Michigan Comprehensive Cancer Center LAPS University of Michigan Comprehensive Cancer Center LAPS University of Rochester LAPS University of Rochester LAPS University of Rochester LAPS University of Texas Health Science Center at San Antonio University of Texas MD Anderson Cancer Center LAPS University of Utah - Huntsman Cancer Institute LAPS University of Utah - Huntsman Cancer Institute LAPS Wayne State University - Karmanos Cancer Institute LAPS Wayne State University - Karmanos Cancer Institute LAPS Wisconsin NCI Community Oncology Research Program 22 - 2 - 4 8 ALLIANCE CCTG ECOG-ACRIN NRG | Pacific Cancer Research Consortium NCORP | 16 | - | 6 | - | - | - |
| Southeast Clinical Oncology Research Consortium NCORP Stanford Cancer Institute Palo Alto | Parker Adventist Hospital | 2 | - | - | - | - | - |
| Stanford Cancer Institute Palo Alto Tulane University School of Medicine | Riverside Methodist Hospital | 3 | - | - | - | - | - |
| Tulane University School of Medicine 2 2 | Southeast Clinical Oncology Research Consortium NCORP | 3 | - | - | - | - | - |
| UC Davis Comprehensive Cancer Center LAPS UC Irvine Health/Chao Family Comprehensive Cancer Center 18 | Stanford Cancer Institute Palo Alto | - | - | 1 | - | - | - |
| UC Irvine Health/Chao Family Comprehensive Cancer Center University of Arkansas for Medical Sciences 3 - 3 University of Cincinnati Cancer Center-UC Medical Center 2 University of Kansas Cancer Center - MCA Rural MU NCORP 35 1 2 University of Kentucky/Markey Cancer Center 4 | Tulane University School of Medicine | - | - | - | - | 2 | - |
| University of Arkansas for Medical Sciences University of Cincinnati Cancer Center-UC Medical Center University of Kansas Cancer Center - MCA Rural MU NCORP 35 - 1 - 2 University of Kentucky/Markey Cancer Center University of Michigan Comprehensive Cancer Center LAPS 16 | UC Davis Comprehensive Cancer Center LAPS | 27 | - | 5 | - | - | - |
| University of Cincinnati Cancer Center-UC Medical Center University of Kansas Cancer Center - MCA Rural MU NCORP 35 - 1 - 2 University of Kentucky/Markey Cancer Center 4 | UC Irvine Health/Chao Family Comprehensive Cancer Center | 18 | - | - | - | - | - |
| University of Kansas Cancer Center - MCA Rural MU NCORP University of Kentucky/Markey Cancer Center University of Michigan Comprehensive Cancer Center LAPS 16 | University of Arkansas for Medical Sciences | - | - | 3 | - | - | 3 |
| University of Kentucky/Markey Cancer Center University of Michigan Comprehensive Cancer Center LAPS 16 | University of Cincinnati Cancer Center-UC Medical Center | - | - | - | - | - | 2 |
| University of Michigan Comprehensive Cancer Center LAPS University of Oklahoma Health Sciences Center LAPS University of Rochester LAPS University of Texas Health Science Center at San Antonio University of Texas MD Anderson Cancer Center LAPS University of Texas MD Anderson Cancer Center LAPS University of Utah - Huntsman Cancer Institute LAPS Upstate Carolina NCORP Upstate Carolina NCORP Wayne State University - Karmanos Cancer Institute LAPS Usiconsin NCI Community Oncology Research Program Vale University - Yale Cancer Center LAPS ALLIANCE 219 To community Oncology Research Program CCTG 20 | University of Kansas Cancer Center - MCA Rural MU NCORP | 35 | - | - | 1 | - | - |
| University of Oklahoma Health Sciences Center LAPS 15 2 2 - 3 University of Texas Health Science Center at San Antonio 22 - University of Texas MD Anderson Cancer Center LAPS University of Utah - Huntsman Cancer Institute LAPS Upstate Carolina NCORP Wayne State University - Karmanos Cancer Institute LAPS Wisconsin NCI Community Oncology Research Program 22 - Vale University - Yale Cancer Center LAPS ALLIANCE CCTG 20 | University of Kentucky/Markey Cancer Center | 4 | - | - | - | - | - |
| University of Rochester LAPS University of Texas Health Science Center at San Antonio 22 | University of Michigan Comprehensive Cancer Center LAPS | 16 | - | - | - | - | - |
| University of Texas Health Science Center at San Antonio University of Texas MD Anderson Cancer Center LAPS University of Utah - Huntsman Cancer Institute LAPS Upstate Carolina NCORP 4 | University of Oklahoma Health Sciences Center LAPS | 3 | - | - | - | - | - |
| University of Texas MD Anderson Cancer Center LAPS University of Utah - Huntsman Cancer Institute LAPS Upstate Carolina NCORP Wayne State University - Karmanos Cancer Institute LAPS Wisconsin NCI Community Oncology Research Program 22 | University of Rochester LAPS | 15 | 2 | 2 | - | - | 3 |
| University of Utah - Huntsman Cancer Institute LAPS Upstate Carolina NCORP 4 | University of Texas Health Science Center at San Antonio | 22 | - | - | - | - | - |
| Upstate Carolina NCORP Wayne State University - Karmanos Cancer Institute LAPS 18 | University of Texas MD Anderson Cancer Center LAPS | 27 | - | - | - | - | - |
| Wayne State University - Karmanos Cancer Institute LAPS 18 | University of Utah - Huntsman Cancer Institute LAPS | 16 | - | - | - | 4 | 2 |
| Wisconsin NCI Community Oncology Research Program 22 - | Upstate Carolina NCORP | 4 | - | - | - | - | - |
| Yale University - Yale Cancer Center LAPS 2 - 4 8 ALLIANCE 219 1 5 1 CCTG 20 ECOG-ACRIN 184 8 3 NRG 112 1 4 | Wayne State University - Karmanos Cancer Institute LAPS | 18 | - | - | - | - | - |
| ALLIANCE 219 1 5 1 CCTG 20 ECOG-ACRIN 184 8 3 NRG 112 1 4 | Wisconsin NCI Community Oncology Research Program | 22 | - | - | - | - | - |
| CCTG 20 - - - - ECOG-ACRIN 184 8 3 - - NRG 112 1 4 - - | Yale University - Yale Cancer Center LAPS | - | - | 2 | - | 4 | 8 |
| ECOG-ACRIN 184 8 3 NRG 112 1 4 | ALLIANCE | 219 | 1 | 5 | 1 | - | - |
| NRG 112 1 4 | ССТБ | 20 | - | - | - | - | - |
| | ECOG-ACRIN | 184 | 8 | 3 | - | - | - |
| Total 1,293 12 58 7 37 37 | NRG | 112 | 1 | 4 | - | - | - |
| | Total | 1,293 | 12 | 58 | 7 | 37 | 37 |



