

Leadership
Chair:
Vice-Chair:Young Kwang Chae, MD, MPH
Executive Officer:
Statisticians: Megan Othus, PhD
Anna B. Moseley, MS
Sara Threlkel, BS
Designates
Data Coordinator:
Veterans Affairs:
Oncology Research Professionals:
CRAs:
Nurse: TBD
Pharmaceutical Science:
Sun "Coco" Yang, PharmD, PhD
Patient Advocate:
Protocol Project Manager: Catrina De Los Santos-Mireles
Clinical Trials Program Manager: Laura Gildner, MS
Early Therapeutics Liaisons
Breast Committee Liaison: Stephanie L. Graff, MD
Cancer Control Liaison:
Lara E. Davis, MD (Survivorship)
Genitourinary Committee Liaison:
Imaging:TBD
Lung Committee Liaison:Shirish M. Gadgeel, MD
Lymphoma Committee Liaison:Nasheed Mohammad Hossain, MD
Melanoma Committee Liaison:
Myeloma Committee Liaison: Frits van Rhee, MD, PhD

#### Time/Location

Thursday, September 18, 2025 11:00 a.m. - 1:30 p.m. Room: Regency C (Ballroom Level, West Tower)

### **Agenda**

11:00 - 11:10 am	Welcome and Introduction - Razelle Kurzrock, MD
11:10 - 11:35 am	ComboMATCH - James M. Ford, MD, FASCO
11:35 - 11:55 am	CNS Working Group and DART CNS Data - Manmeet Ahluwalia, MD
11:55 - 12:15 pm	S2012, "Randomized Phase II/III Trial of First Line Platinum/Etoposide with or without Atezolizumab (NSC#783608) in Patients with Poorly Differentiated Extrapulmonary Neuroendocrine Carcinomas" - David Zhen, MD

12:15 - 12:40 pm	Overview of Clinical Outcomes of DART - Sandip Patel, MD
12:40 - 1:00 pm	Updates from Sarcoma Working Group - Lara Davis, MD
1:00 - 1:20 pm	Translational Studies for DART - Cara Haymaker, PhD

Wrap Up - Razelle Kurzrock, MD

#### **Active Studies**

1:20 - 1:30 pm

**S2012**, "Randomized Phase II/III Trial of First Line Platinum/Etoposide with or without Atezolizumab (NSC#783608) in Patients with Poorly Differentiated Extrapulmonary Small Cell Neuroendocrine Carcinomas (NEC)." Drs. Zhen, Chiorean, Burgess, Swisher. Activated: 12/2/21.

CTSU/A071401, "Phase II Trial of SMO/AKT/NF2/CDK Inhibitors in Progressive Meningiomas with SMO/AKT/NF2/CDK Pathway Mutations." Dr. Brastianos. SWOG Champion: Dr. Piccioni. Activated: 8/28/2015. New patient registration (Step 1) to the NF2, CDKN2A, CDK4, CDK6, CCND1, CCND2, CCND3, and CCNE1 Cohort (Abemaciclib Cohort) is closed to accrual as of 10/3/22.

CTSU/A092001, "Phase 2 Randomized Trial of Neoadjuvant or Palliative Chemotherapy with or Without Immunotherapy for Peritoneal Mesothelioma". SWOG Champion: Dr. P.S.K. Raghav. Activated: 10/15/21.

CTSU/AGCT1531, "A Phase III Study of Active Surveillance for Low Risk and a Randomized Trial of Carboplatin vs. Cisplatin for Standard Risk Pediatric and Adult Patients with Germ Cell Tumors" SWOG Champion: Dr. D'Souza Activated: 5/8/17. Stratum 2 is temporarily closed to accrual 12/17/24.

CTSU/AOST2031, "A Phase 3 Randomized Controlled Trial Comparing Open vs Thoracoscopic Management of Pulmonary Metastases in Patients with Osteosarcoma" SWOG Champion: Dr. Hofstetter. Activated: 2/15/22

CTSU/AOST2032, "A Feasibility and Randomized Phase 2/3 Study of the VEFGR2/MET Inhibitor Cabozantinib in Combination with Cytotoxic Chemotherapy for Newly Diagnosed Osteosarcoma" SWOG Champion: Dr. J. A. Livingston. Activated: 2/17/23 Temporarily Closed to Accrual as of 9/6/23

CTSU/ HN.11 (CCTG-HN11), "SPECT-CT Guided Elective Contralateral Neck Treatment (SELECT) for Patients with Lateralized Oropharyngeal Cancer: A Phase III Randomized Controlled Trial SWOG" Champion: Dr. Paul Swiecicki. Activated: 9/29/22

# **Studies in Development**

- SN2426, "A Randomized Phase II Study of Amivantamab versus Cetuximab in Immunocompromised Patients with Recurrent Inoperable or Metastatic Cutaneous Squamous Cell Carcinoma". Dr. Swiecicki. Anticipated activation date: 8/15/25
- **S2505**, "Phase III Randomized Study Testing Non-Inferiority of Short-Course Ultra-Fractionated Radiation (UHRT-5) Versus Standard Fractionation (RT-25) for High-Risk, Resectable Soft Tissue Sarcoma. Dr. Harris

#### **Closed Studies**

- CTSU/A071702, "A Phase II Study of Checkpoint Blockade Immunotherapy in Patients with Somatically Hyper-mutated Recurrent Glioblastoma." SWOG Champion: Dr. M. Ahluwalia. Activated: 10/30/20. Pre-Registration is temporarily Closed to accrual 12/12/23. Closed: 6/2/25.
- CTSU/EA2183, "A Phase III Study of Consolidative Radiotherapy in Patients with Oligometastatic HER2 Negative Esophageal and Gastric Adenocarcinoma." Dr. Uboho. SWOG Champion: Dr. Saeed. Activated: 2/6/20. Closed: 5/23/25
- CTSU/A071601, "Phase II Trial of BRAF/MEK Inhibitors in Papillary Craniopharyngiomas." Dr. Brastianos. SWOG Champion: Dr. Ahluwalia. Activated: 8/4/17. Temporarily Closed (Cohort A): 9/8/20. Closed: 5/10/24
- <u>\$1609</u>, "DART: Dual Anti-CTLA-4 and Anti-PD-1 blockade in Rare Tumors." Drs. Patel, Chae, and Kurzrock. Activated: 1/13/17. Closed: 3/15/23.
- CTSU/NRG-GY006, "A Randomized Phase III Trial of Radiation Therapy and Cisplatin Alone or in Combination with Intravenous Triapine in Women with Newly Diagnosed Bulky Stage IB2, Stage II, IIIB, or IVA Cancer of the Uterine Cervix or Stage II-IVA Vaginal Cancer." Dr. Leath. SWOG Champion: Dr. Robinson. Activated: 1/15/16. Closed: 9/22/22
- CTSU/NRG-GY020, "A Phase III Randomized Trial of Radiation +/Pembrolizumab (MK-3475) for Newly Diagnosed Early Stage High
  Intermediate Risk Mismatch Repair Deficient (dMMR) Endometrioid
  Endometrial Cancer." Dr. Backes. SWOG Champion: Dr. Robinson.
  Activated: 2/7/20. Closed: 8/29/22.
- NCICOVID, "NCI COVID-19 in Cancer Patients Study (NCCAPS): A Longitudinal Natural History Study." Dr. Karim. Activated: 5/21/20. Closed: 2/1/22.
- CTSU/NRG-GY009, "A Randomized, Phase II/III Study of Pegylated Liposomal Doxorubicin and CTEP-Supplied Atezolizumab versus

- Pegylated Liposomal Doxorubicin, CTEP-Supplied Bevacizumab and CTEP-Supplied Atezolizumab versus Pegylated Liposomal Doxorubicin and CTEP-Supplied Bevacizumab in Platinum Resistant Ovarian Cancer." Dr. O'Cearbhaill. SWOG Champion: Dr. Robinson. Activated: 5/12/17. Closed 10/14/21
- CTSU/NRG-HN007, "An Open-Label, Phase III Study of Platinum-Gemcitabine with or without Nivolumab in the First-Line Treatment of Recurrent or Metastatic Nasopharyngeal Carcinoma." Dr. Brigette B. Y. Activated: 9/8/20; Closed: 10/28/21
- CTSU/EAY131, "Molecular Analysis for Therapy Choice (MATCH)."
  Activated: 8/12/15. Closed: 12/23/22
- CTSU/NRG-BN007, "A Randomized Phase II/III Open-Label Study of Ipilimumab and Nivolumab versus Temozolomide in Patients with Newly Diagnosed MGMT (Tumor O-6-Methylguanine DNA Methyltransferase) Unmethylated Glioblastoma." Dr. Lassman. SWOG Champion: Dr. Ahluwalia. Activated: 8/6/20. Closed: 3/29/23.
- CTSU/EA3163, "Phase II Randomized Trial of Neoadjuvant Chemotherapy Followed by Surgery and Post-Operative Radiation versus Surgery and Post-Operative Radiation for Organ Preservation of T3 and T4a (and Selected T4b) Nasal and Paranasal Sinus Squamous Cell Carcinoma (NPNSCC)." Dr. Saba. SWOG Champion: Dr. Swiecicki. Activated: 3/28/18. Closed: 11/7/23

#### **Proposed Studies**

- NRG-BN1803, "NRG-COG Phase II Trial of Radiation Plus Concurrent and Adjuvant ONC201 for Newly Diagnosed, H3 K27M-Mutant Gliomas." SWOG Champion: Dr. Ahluwalia.
- NRG-OV1821, "A Randomized Phase II Trial of Olaparib Versus Olaparib + Tremelimumab in Platinum-Sensitive Recurrent Ovarian Cancer." Dr. Robinson.
- NRG-BN1855, "A Randomized Phase II/III Open Label Study of Ipilimumab and Nivolumab Vs Te-mozolomide in Patients with Newly Unmethylated MGMT (Tumor O-6-Methylguanine DNA Methyltransfer-ase) Glioblastoma." Dr. M. Ahluwalia.
- NRG-HN1854, "An Open-label, Phase III Study of Platinum-Gemcitabine with or Without Nivolumab in the First-line Treatment of Recurrent or Metastatic Nasopharyngeal Carcinoma." Dr. P. Swiecicki.
- NRG-UC1805, "Randomized Phase III Trial of Radiation +/- Pembrolizumab for High Intermediate Risk Mismatch Repair Deficient (dMMR)

  Endometrioid Endometrial Cancer." Dr. W. Robinson.

#### **ComboMATCH**

### **Proposed Studies**

**EAY191-S7**, "A Phase 2 Study Investigating Safety and Efficacy of Trastuzumab Deruxtecan (DS8201/T-DXd) and ATR Inhibitor, Ceralasertib (AZD6738) in Human Epidermal Growth Factor Receptor 2 (HER2) Positive Advanced Solid Tumors." Dr. K. Raghav.

#### **Active Studies**

**EAY191-S3**, "Phase 2 Study of Paclitaxel + Ipatasertib in Taxane-Refractory Participants with AKT-Altered Advanced Non-Breast Solid Tumors.". Study Chairs: Reva Basho, M.D., Haider Mahdi, M.

### **Clinical Trials Partnerships (CTP)**

### **Developing Studies**

**21CTP. HN01, CAPT-HN**, "A Phase II Study of Combined Amivantamab, Carboplatin and Paclitaxel in Unresectable Locally Recurrent or Metastatic Head and Neck Cancer." Drs. Swiecicki, Rodriguez, and Brenner.

#### **Publications**

The publications listed below were received by the Group Chair's Office as published (including online), accepted, or submitted since the SWOG Spring 2025 Group Meeting. Conference abstracts are not included.

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

## **Published/Accepted Manuscripts**

S1609 A Phase II Basket Trial of Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors (DART) SWOG S1609: Pancreatic Neuroendocrine Neoplasm (PNEN) Cohort. Patel S, Fisher J, Chae Y, Soto L, Kasi A, Konda B, Walshauser M, Parra E, Zhang J, Duault C, Gonzalez-Kozlova E, Manyam G, Holmes T, Zhang J, Chen H, Duose D, Laberiano Fernandez C, Luthra R, Al-Atrash G, Kim-Schulze S, Maecker H, Wistuba I, Gnjatic S, Lee J, Zhang J, Magner C, Chen H, Sharon E, Othus M, Ryan C, Blanke C, Haymaker C, Kurzrock R. Journal of Immunotherapy of Cancer Jun 30;13(6):e011760, 2025. https://pubmed.ncbi.nlm.nih.gov/40588371/

S1609 A phase II basket trial of dual anti-CTLA-4 and anti-PD-1 blockade in rare tumors (DART) SWOG S1609: durable responses and delayed pseudoprogression in small cell carcinoma of the ovary, hypercalcemic type cohort. Chae YK, Othus M, Patel SP, Aljumaily R, Win K, Pejovic T, Thomas S, Robinson W, Kim H, Chung L, McLeod C, Chen H, Sharon E, Streicher H, Ryan, C, Blanke C, Kurzrock R. Accepted.

#### **Submitted Manuscripts**

S1609 A Phase II Basket Trial of Dual Anti-CTLA-4 and Anti-PD-1
Blockade in Rare Tumors (DART) SWOG S1609: The Salivary Gland Tumor
Cohort. Chae Y, Sun R, Patel S, Giles F, Ohr J, Worden F, Suga J, Naing
A, Cohen E, Wallace J, Fenton S, II-Young Chung L, Kang H, McLeod C,
Chen H, Sharon E, Streicher H, Ryan C, Othus M, Blanke CD, Kurzrock R.
Submitted, 2025.

S1609 DART/SWOG/NCI Phase II Anti-CTLA-4/PD-1 Trial: Clear Cell Carcinomas of Ovary, Endometrium, Cervix. Chae Y, Othus M, Patel S, Backes F, O'Malley D, Cristea M, Naing A, Kurnit K, Eskander R, Goodrich S, Robinson W, Kim H, Il-Young Chung L, McLeod C, Chen H, Sharon E, Streicher H, Ryan C, Blanke CD, Kurzrock R. Submitted, 2025.

# Accrual from trials that are open as of 6/30/2025 or have closed in the prior 18 months, by Institution and Study

Cancer Research Consortium of West Michigan NCORP  Cancer Research for the Ozarks NCORP  Cancer Research for the Ozarks NCORP  1		EAY191-S3	<i>S2012</i>	A071401	AGCT1531	EAY191	EAY191A3	EAY191A6	EAY191E4
Cedars-Sinai Medical Center         1         -         -         2         -<	Cancer Research Consortium of West Michigan NCORP	-	1	-	-	-	-	-	-
CommonSpirit Health Research Institute	Cancer Research for the Ozarks NCORP	-	2	-	-	-	-	-	-
Duke University - Duke Cancer Institute LAPS         1         - <td>Cedars-Sinai Medical Center</td> <td>1</td> <td>-</td> <td>-</td> <td>-</td> <td>2</td> <td>-</td> <td>-</td> <td>-</td>	Cedars-Sinai Medical Center	1	-	-	-	2	-	-	-
Fred Hutchinson Cancer Research Center LAPS         -         111         - </td <td>CommonSpirit Health Research Institute</td> <td>-</td> <td>1</td> <td>1</td> <td>-</td> <td>-</td> <td>-</td> <td>-</td> <td>-</td>	CommonSpirit Health Research Institute	-	1	1	-	-	-	-	-
Froedtert and the Medical College of Wisconsin LAPS  Gulf South Minority Underserved NCORP  - 2 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1	Duke University - Duke Cancer Institute LAPS	1	-	-	-	-	-	-	-
Gulf South Minority Underserved NCORP	Fred Hutchinson Cancer Research Center LAPS	-	11	-	-	-	-	-	-
Hawaii Minority Underserved NCORP	Froedtert and the Medical College of Wisconsin LAPS	-	1	-	-	-	-	-	-
Heartland Cancer Research NCORP	Gulf South Minority Underserved NCORP	-	2	-	-	-	-	-	-
Henry Ford Hospital	Hawaii Minority Underserved NCORP	-	1	-	-	1	-	1	-
Kaiser Permanente NCI Community Oncology Research Program  Michigan Cancer Research Consortium NCORP  Moffitt Cancer Center  Mount Sinai Hospital  Northwestern University LAPS  Ohio State University Comprehensive Cancer Center LAPS  Regents of the University of Michigan  Southeast Clinical Oncology Research Consortium NCORP  The Don and Sybil Harrington Cancer Center  UCI Irvine Health/Chao Family Comprehensive Cancer Center  UNiversity of Colorado Cancer Center LAPS  The University of Texas Health Science Center at San Antonio  University of Texas MD Anderson Cancer Center LAPS  Wisconsin NCI Community Oncology Research Program  Yale University - Yale Cancer Center LAPS  NRG  NRG	Heartland Cancer Research NCORP	-	1	-	-	-	-	-	-
Michigan Cancer Research Consortium NCORP       1       4       - </td <td>Henry Ford Hospital</td> <td>-</td> <td>2</td> <td>-</td> <td>-</td> <td>-</td> <td>-</td> <td>-</td> <td>-</td>	Henry Ford Hospital	-	2	-	-	-	-	-	-
Moffitt Cancer Center         -         8         -	Kaiser Permanente NCI Community Oncology Research Program	-	5	-	-	-	-	-	-
Mount Sinai Hospital         -         -         -         1         -	Michigan Cancer Research Consortium NCORP	1	4	-	-	-	-	-	-
Northwestern University LAPS	Moffitt Cancer Center	-	8	-	-	-	-	-	-
Ohio State University Comprehensive Cancer Center LAPS Pacific Cancer Research Consortium NCORP 1	Mount Sinai Hospital	-	-	-	1	-	-	-	-
Pacific Cancer Research Consortium NCORP  Regents of the University of Michigan  - 2	Northwestern University LAPS	-	5	1	-	-	-	-	-
Regents of the University of Michigan  Southeast Clinical Oncology Research Consortium NCORP  The Don and Sybil Harrington Cancer Center  UC Irvine Health/Chao Family Comprehensive Cancer Center  UC San Diego Moores Cancer Center  University of Colorado Cancer Center  University of Colorado Cancer Center 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 Center LAPS  Vanderbilt University - Ingram Cancer Center LAPS  Vanderbilt University - Ingram Cancer Center LAPS  Vale University - Yale Cancer Center LAPS  ALLIANCE  Southeast Clinical Oncology Research Program  Concert Center LAPS  All Concert Center Cent	Ohio State University Comprehensive Cancer Center LAPS	-	8	-	-	-	-	-	-
Southeast Clinical Oncology Research Consortium NCORP  - 1	Pacific Cancer Research Consortium NCORP	1	-	-	-	-	-	-	-
The Don and Sybil Harrington Cancer Center	Regents of the University of Michigan	-	2	-	-	-	-	-	-
UC Irvine Health/Chao Family Comprehensive Cancer Center 1 - 4 - 1 3  UC San Diego Moores Cancer Center 2 1	Southeast Clinical Oncology Research Consortium NCORP	-	1	-	-	-	-	-	-
UC San Diego Moores Cancer Center University of Colorado Cancer Center LAPS	The Don and Sybil Harrington Cancer Center	-	-	-	1	-	-	-	-
University of Colorado Cancer Center LAPS  1	UC Irvine Health/Chao Family Comprehensive Cancer Center	-	-	1	-	4	-	1	3
University of Texas Health Science Center at San Antonio  University of Texas MD Anderson Cancer Center LAPS  University of Utah - Huntsman Cancer Institute LAPS  Iniversity of Utah - Huntsman Cancer Institute LAPS  University - Ingram Cancer Center LAPS  University - Ingram Cancer Center LAPS  University - Ingram Cancer Center LAPS  University - Yale Cancer Center LAPS	UC San Diego Moores Cancer Center	-	-	2	1	-	-	-	-
University of Texas MD Anderson Cancer Center LAPS 3 10 2 University of Utah - Huntsman Cancer Institute LAPS - 1	University of Colorado Cancer Center LAPS	-	-	1	-	-	-	-	-
University of Utah - Huntsman Cancer Institute LAPS - 1	University of Texas Health Science Center at San Antonio	-	3	-	-	-	-	-	-
University of Utah - Huntsman Cancer Institute LAPS - 1	University of Texas MD Anderson Cancer Center LAPS	3	-	-	-	10	2	-	-
Wisconsin NCI Community Oncology Research Program       -       2       -	·	-	1	-	-	-	-	-	-
Wisconsin NCI Community Oncology Research Program       -       2       -	Vanderbilt University - Ingram Cancer Center LAPS	-	2	-	-	-	-	-	-
Yale University - Yale Cancer Center LAPS       -       7       2       - </td <td></td> <td>-</td> <td>2</td> <td>-</td> <td>-</td> <td>-</td> <td>-</td> <td>-</td> <td>-</td>		-	2	-	-	-	-	-	-
ALLIANCE       3       14       -		-	7	2	-	-	-	-	-
NRG 4 10	·	3	14	-	-	-	-	-	-
	ECOG-ACRIN	8	11	-	-	-	-	-	-
Total 22 105 8 3 17 2 2 3	NRG	4	10	-	-	-	-	-	-
	Total	22	105	8	3	17	2	2	3

