

SPRING GROUP MEETING

Seattle

Genitourinary Committee

APRIL 3-6, 2024 | SEATTLE, WASHINGTON

Genitourinary Committee

Leadership

Chair: Seth P. Lerner, MD
 Vice-Chair: Daniel P. Petrylak, MD
 Chair Emeritus: Ian M. Thompson, Jr., MD
 Executive Officer: Christopher W. Ryan, MD
 Statisticians: Cathy M. Tangen, DrPH
 Melissa Plets, MS
 Sam Callis, MS

Scientific Leadership

Translational Medicine: David J. McConkey, PhD (GU Chair)
 Joshua J. Meeks, MD, PhD (Bladder)
 Amir Goldkorn, MD (Prostate)
 Sumanta “Monty” K. Pal, MD (Renal)
 Radiation Oncology: James B. Yu, MD
 Daniel A. Hamstra, MD
 Imaging: Evan Y. Yu, MD
 Hiram Shaish, MD
 John D. Hazle, PhD
 Immunotherapeutics: Shuchi Gulati, MD (Medical Onc)
 Robert Svatek, MD (Urologic Onc)
 Pathology: M. Scott Lucia, MD
 Surgery: Kelly L. Stratton, MD
 Early Therapeutics: Parminder Singh, MD
 Bladder Organ Site Chairs: Siamak Daneshmand, MD (Localized)
 Thomas W. Flaig, MD (Advanced)
 Prostate Organ Site Chairs: Daniel W. Lin, MD (Localized)
 Tanya B. Dorff, MD (Advanced)
 Renal Organ Site Chairs: Brian Shuch, MD (Localized)
 Ulka N. Vaishampayan, MD (Advanced)

Designates

Cancer Control: Clara Hwang, MD
 Sarah P. Psutka, MD, MSC
 DEI Champion: Jessica D. McDermott, MD
 Digital Engagement: Neema Navai, MD
 NCORP: Scott Edward Delacroix, Jr., MD
 Helen Heng-Shan Moon, MD
 Veterans Affairs: Michael M. Goodman, MD
 Data Coordinators: Laura Wells, BA
 Michele Counts, BS
 Tonya Johnson, BS
 Oncology Research Professionals:
 CRAs: Abigail L. Cornette, MS
 Cheryl Farlow, RN, OCN
 Nurse: Gary Lee Duvall, RN

Patient Advocates: Rick Bangs, MBA (Emeritus, Bladder)
 Darrell Nakagawa (Bladder)
 Tony Crispino (Emeritus, Prostate)
 Karen Costello, MSS, LSW (Prostate)
 Lee Henry Moultrie (Prostate)
 Laura B. Esfeller, MA (Renal)
 Pharmaceutical Science: Joyce Lee, PharmD
 Allison Schepers, PharmD
 Protocol Project Manager: Megan Keim
 Clinical Trials Program Manager: Mariah Norman, MS

Time/Location

Friday, April 5, 2024 9:30 a.m. - 12:00 p.m.
 Room: Elwha AB (Level 5)

Agenda

9:30 - 9:45 am: Chair’s Welcome and Opening Remarks - Seth Lerner
 9:45 - 10:15 am: Cancer Control - Clara Hwang and Sarah Psutka
 10:15 - 12:00 pm: Review of open approved trials - all organ site chairs
 Prostate – Dan Lin and Tanya Dorff
 Renal – Brian Shuch and Ulka Vaishampayan
 Bladder – Sia Daneshmand and Tom Flaig

Bladder

Organ Site Chairs: Dr. Thomas Flaig (Advanced) and Dr. Siamak Daneshmand (Local).

Priority Study

S1937, “A Phase III Trial of Eribulin (NSC #707389) with or Without Gemcitabine Versus Standard of Care (Physician’s Choice) for Treatment of Metastatic Urothelial Carcinoma Refractory to, or Ineligible for, Anti PD1/PDL1 Therapy.” Drs. S. Sadeghi and P. Lara. Activated: 2/16/21. Temporary Closure: 5/30/23. Re-opened Arms 1&3 to accrual and permanently closed Arm 2 on 2/15/24.

Concepts in Development

S2427, “Bladder preservation with chemoradiotherapy or immunoradiotherapy after a good response to neoadjuvant chemotherapy in patients with muscle invasive bladder cancer (BRIGHT).” Dr. L. Ballas. Presented to SWOG triage 2/5/24. Triage approved with recommendations 2/13/24.

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Active Studies

S1806, “Phase III Randomized Trial of Concurrent Chemoradiotherapy with or Without Atezolizumab in Localized Muscle Invasive Bladder Cancer.” Drs. P. Singh, S. Lerner, J. Efstathiou, et al. Activated: 4/19/19. Step 1 accrual closed 3/1/24.

CTSU/A031701, “A Phase II Study of Dose-Dense Gemcitabine Plus Cisplatin (ddGC) in Patients with Muscle-Invasive Bladder Cancer with Bladder Preservation for Those Patients Whose Tumors Harbor Deleterious DNA Damage Response (DDR) Gene Alterations.” Drs. A. Gupta and S. Gupta. Activated: 8/1/18.

CTSU/A031803, “Phase II Trial of Intravesical Gemcitabine and MK-3475 (Pembrolizumab) in the Treatment of Patients with BCG-Unresponsive Non-Muscle Invasive Bladder Cancer.” Drs. D. Tyson and C. Ramamurthy. Activated: 1/6/20.

CTSU/EA8185, “Phase II Study of Bladder-Sparing Chemoradiation with MEDI4736 (Durvalumab) in Clinical Stage III, Node Positive Bladder Cancer (INSPIRE).” Drs. T. Mitin and J. Meeks. Activated: 8/25/20.

CTSU/EA8192, “A Phase II/III Trial of MED14736 (Durvalumab) and Chemotherapy for Patients with High Grade Upper Tract Urothelial Cancer Prior to Nephroureterectomy” Drs. S. Psutka and A. Tripathi. Activated: 5/6/21.

Closed Studies

S1011, “A Phase III Surgical Trial to Evaluate the Benefit of a Standard Versus an Extended Pelvic Lymphadenectomy Performed at Time of Radical Cystectomy for Muscle Invasive Urothelial Cancer.” Drs. S. Lerner, A. Alva, and T. Koppie, et al. Activated: 8/1/11; Permanently Closed: 4/15/17.

S1602, “A Phase III Randomized Trial to Evaluate the Influence of BCG Strain Differences and T Cell Priming with Intradermal BCG Before Intravesical Therapy for BCG Naïve High-Grade Non-Muscle Invasive Bladder Cancer.” Drs. R. Svatek, A. Alva, and S. Lerner. Activated: 2/7/17; Permanently Closed: 12/15/2020.

S1605, “Phase II Trial of Atezolizumab in BCG-Unresponsive Non-Muscle Invasive Bladder Cancer.” Drs. P. Black, P. Singh, and S. Lerner. Activated: 2/7/17; Permanently Closed: 7/5/19.

S2011, “Randomized Phase II Trial of Gemcitabine, Avelumab, and Carboplatin vs. No Neoadjuvant Therapy Preceding Surgery for Cisplatin Ineligible Muscle-Invasive Urothelial Carcinoma.” Drs. Sonpavde, M. Liss, and S. Lerner, et al. Activated: 10/6/21. Closed to Accrual: 11/15/23.

Renal

Organ Site Chairs: Dr. Ulka Vaishampayan (Advanced) and Dr. Brian Shuch (Local).

Priority Study

S1931, “Phase III Trial of Immunotherapy-Based Combination Therapy with or Without Cytoreductive Nephrectomy for Metastatic Renal Cell Carcinoma (PROBE Trial).” Drs. H. Kim and U. Vaishampayan. Activated: 11/16/20.

Concepts in Development

S2419, “Phase III Double Blinded Trial of Immune-Based Therapy with a Live Biotherapeutic CBM588, or Placebo for Frontline Therapy of Advanced Clear Cell Renal Cell Carcinoma [BioFront Trial].” Drs. P. Barata and U. Vaishampayan. Development and submission to GUSC placed on hold until June (pending dose finding study results from Osel).

Active Studies

S2200, “A Phase II Randomized Trial of Cabozantinib (NSC #761968) with or without Atezolizumab (NSC #783608) in Patients with Advanced Papillary Renal Cell Carcinoma (PAPMET2)” Drs. B. Maughan and S. Pal. Activated 9/19/22.

CTSU/AREN1721, “A Randomized Phase 2 Trial of Axitinib/Nivolumab Combination Therapy vs. Single Agent Nivolumab for the Treatment of TFE/Translocation Renal Cell Carcinoma (tRCC) Across All Age Groups.” Dr. M. Parikh. Activated: 10/9/18; Temporarily Closed: 3/24/21; Re-activated: 2/7/22.

CTSU/A031704, “PD-Inhibitor (Nivolumab) and Ipilimumab Followed by Nivolumab vs. VEGF TKI Cabozantinib with Nivolumab: A Phase III Trial in Metastatic Untreated Renal Cell Cancer [PDIGREE].” Dr. T. Zhang. Activated: 5/9/19; Step 1 temporarily closed: 3/8/21; Step 1 re-activated: 3/26/21.

CTSU/A031801, “A Phase II Randomized Trial of Radium-223 Dichloride and Cabozantinib in Patients with Advanced Renal Cell Carcinoma with Bone Metastasis (Radical).” Dr. M. Parikh. Activated: 12/13/19.

CTSU/A031901, “Duration of Immune Checkpoint Therapy in Locally Advanced or Metastatic Urothelial Carcinoma: A randomized Phase 3 non-inferiority Trial.” Dr. D. Vaena. Activated: 12/10/20.

Closed Studies

S1500, “A Randomized, Phase II Efficacy Assessment of Multiple MET Kinase Inhibitors (Cabozantinib [NSC #761968], Crizotinib [NSC #749005],

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Savolitinib [NSC #785348], and Sunitinib [NSC #736511] in Metastatic Papillary Renal Carcinoma (PAPMET).” Drs. S. Pal and P. Lara. Activated 4/5/16; Permanently closed: 12/15/19.

S0931, “EVEREST: Everolimus for Renal Cancer Ensuing Surgical Therapy, A Phase III Study.” Drs. C. Ryan, E. Heath, P. Lara, et al. Activated: 4/1/11; Permanently Closed: 9/15/16.

CTSU/E2810, “Randomized, Double-Blind Phase III Study of Pazopanib vs. Placebo in Patients with Metastatic Renal Cell Carcinoma Who Have No Evidence of Disease Following Metastatectomy.” Dr. S. Pal. Activated: 8/8/12; Permanently closed: 7/25/17.

CTSU/A031501, “Phase III Randomized Adjuvant study of Pembrolizumab in Muscle Invasive and Locally Advanced Urothelial Carcinoma (AMBASSADOR) Versus Observation.” Dr. G. Sonpavde. Activated: 9/21/17; Permanently Closed: 8/24/21.

CTSU/EA8143, “A Phase 3 Randomized Study Comparing Perioperative Nivolumab vs. Observation in Patients with Renal Cell Carcinoma Undergoing Nephrectomy (PROSPER RCC).” Drs. P. Lara and B. Shuch. Activated: 2/2/17; Permanently Closed: 6/9/21.

Prostate

Organ Site Chairs: Dr. Tonya Dorff (Advanced) and Dr. Daniel W. Lin (Local).

Priority Study

S2210, “Targeted neoadjuvant treatment for patients with localized prostate cancer and germline DNA repair deficiency.” Dr. H. Cheng. Activated 8/14.

Concepts in Development

S2312, “A Phase III Study of Cabazitaxel with or without Carboplatin in Patients with metastatic castrate-resistant prostate cancer (mCRPC), Stratified by Aggressive Variant Signature.” Dr. Paul Corn. Will submit protocol and MCF to CTEP by end of February.

Active Studies

S1802, “Phase III Randomized Trial of Standard Systemic Therapy (SST) Versus Standard Systemic Therapy Plus Definitive Treatment (Surgery or Radiation) of the Primary Tumor in Metastatic Prostate Cancer.” Drs. B. Chapin, A. Aparicio, and R. Valicenti. Activated: 9/17/18.

CTSU/A031102, “A Randomized Phase III Trial Comparing Conventional-Dose Chemotherapy Using Paclitaxel, Ifosfamide, and Cisplatin (TIP) with High-Dose Chemotherapy Using Mobilizing Paclitaxel Plus Ifosfamide Followed by High-Dose Carboplatin and Etoposide (TI-CE) as First

Salvage Treatment in Relapsed or Refractory Germ Cell Tumors.” Dr. D. Quinn. Activated: 7/1/15.

CTSU/EA8171, “Multiparametric MRI (mpMRI) for Preoperative Staging and Treatment Planning for Newly-Diagnosed Prostate Cancer.” Dr. M. Liss. Activated: 7/9/18.

CTSU/EA8184, “A Phase II Randomized Double Blinded Study of Green Tea Catechins (GTC) vs. Placebo in Men on Active Surveillance for Prostate Cancer: Modulation of Biological and Clinical Intermediate Biomarkers.” Dr. R. Kopp. Activated: 5/10/21.

CTSU/NRG-GU002, “Phase II-III Trial of Adjuvant Radiotherapy and Androgen Deprivation Following Radical Prostatectomy with or Without Adjuvant Docetaxel.” Dr. D. Raben. Activated: 12/30/16.

CTSU/NRG-GU008, “Randomized Phase III Trial Incorporating Abiraterone Acetate with Prednisone and Apalutamide and Advanced Imaging into Salvage Treatment for Patients with Node-Positive Prostate Cancer After Radical Prostatectomy (INNOVATE*) *Intensifying Treatment for Node Positive Prostate Cancer by Varying the Hormonal Therapy.” Dr. D. Lin. Activated: 3/5/20; Temporarily Closed: 6/24/21; Re-activated: 12/1/21.

CTSU/NRG-GU009, “Parallel Phase III Randomized Trials for High Risk Prostate Cancer Evaluating De-Intensification for Lower Genomic Risk and Intensification of Concurrent Therapy for Higher Genomic Risk with Radiation (PREDICT-RT*).” Dr. S. Zhang. Activated: 10/15/20; Temporarily Closed: 6/24/21; Re-activated: 12/15/21.

Closed Studies

S1216, “A Phase III Randomized Trial Comparing Androgen Deprivation Therapy + TAK-700 with Androgen Deprivation Therapy + Bicalutamide in Patients with Newly Diagnosed Metastatic Hormone Sensitive Prostate Cancer.” Drs. N. Agarwal, A. Goldkorn, S. Gupta, et al. Activated: 3/6/13; Permanently Closed: 7/15/17.

CTSU/NRG-GU005, “Phase III IGRT and SBRT Vs IGRT and Hypofractionated IMRT for Localized Intermediate Risk Prostate Cancer.” Dr. A. Solanki. Activated: 11/16/17; Closed to accrual: 6/8/22.

CTSU/NRG-GU006, “A Phase II, Double-Blinded, Placebo-Controlled Randomized Trial of Salvage Radiotherapy with or Without Enhanced Anti-Androgen Therapy with Apalutamide in Recurrent Prostate Cancer.” Dr. J. Zeng. Activated: 4/27/18; Permanently Closed: 5/19/20.

CTSU/RTOG-0924, “Androgen Deprivation Therapy and High Dose Radiotherapy with or Without Whole-Pelvic Radiotherapy in Unfavorable Intermediate or Favorable High Risk Prostate Cancer: A

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Phase III Randomized Trial. Dr. T. Marshall. Activated: 7/7/11; Permanently Closed: 6/24/19.

CTSU/NRG-GU007, “Randomized Phase II Trial of Niraparib with Standard Combination Radiotherapy and Androgen Deprivation Therapy (ADT) in High Risk Prostate Cancer (with Initial Phase I) (NADIR*) *Randomized Phase II Trial of Niraparib With Standard Combination Androgen Deprivation Therapy (ADT) and Radiotherapy In High Risk Prostate Cancer (With Initial Phase I).” Dr. D. VanderWeele. Activated: 6/3/19; Temporarily Closed: 5/5/21; Reactivated of dose level 2 (phase I) for 1 additional patient: 9/14/21; Temporarily closed to accrual for phase I dose level 2: 11/4/21; Re-activated to accrual for phase I/dose level 3: 12/6/21; Temporarily Closed: 7/11/2022.

CTSU/EA8153, “Cabazitaxel with Abiraterone Versus Abiraterone Alone Randomized Trial for Extensive Disease Following Docetaxel: The CHARTED2 Trial.” Dr. P. Corn. Activated: 2/8/18; Permanently Closed: 4/2/21; Tobacco use assessment sub-study permanently closed: 10/8/21.

CTSU/AGCT1531, “A Phase 3 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.” Dr. A. D’Souza. Activated: 5/8/17; PRO study Temporarily Closed: 2/12/21.

Translational Medicine

Chair: Dr. David McConkey

Co-Chair: Dr. Joshua Meeks

Bladder Chair: Dr. Joshua Meeks

Prostate Chair: Dr. Amir Goldkorn

Renal Chair: Dr. Sumanta “Monty” Pal

Cancer Control

Liaisons: Drs. Clara Hwang and Sarah Psutka

Active Studies

S1600, “A Randomized Phase III Double-Blind Clinical Trial Evaluating the Effect of Immune-Enhancing Nutrition on Radical Cystectomy Outcomes.” Drs. J. Hamilton-Reeves and J. Holzbeierlein. Activated: 2/21/19.

S1823, “A Prospective Observational Cohort Study to Assess miRNA 371 for Outcome Prediction in Patients with Early Stage Germ Cell Tumors”, PI: Craig Nichols– Activated 6/1/2020 GU Champions: Thomas Frye & Anishka D’Souza

S1931, (Companion Study): Examining Psychosocial and Emotional Issues for Metastatic Kidney Cancer. PI: Cristiane Bergerot.

S1937, (Companion Study): Assessment of Quality of Life for S1937: A Phase III Randomized Trial of Eribulin with or without Gemcitabine Versus Standard of Care (Physician’s Choice) for Treatment of Metastatic Urothelial Carcinoma Refractory to, or Ineligible for, Anti PD1/PDL1 Therapy. QoL Study Chair: Dr. Afsaneh Barzi. On hold until accrual picks up on S1937.

Diverse Studies of Interest

S1609, “DART: Dual Anti-CTLA-4 and Anti-PD-1 blockade in Rare Tumors.” Drs. S. Patel, Y. Chae, R. Kurzrock, et al. Activated: 1/13/17; Permanently Closed: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 13, 14, 15, 16, 17, 18, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 39, 41, 42, 43, 44, 45, 48, 51, 52, and 53; Temporarily Closed: 38, 40, 46, and 51.

CTSU/A031702, “A Phase II Study of Ipilimumab, Cabozantinib, and Nivolumab in Rare Genitourinary Cancers (ICONIC)” Dr. S. Liu. Activated: 4/12/19; Temporarily Closed: Cohort A, B, C, E, F, G, I.

CTSU/EAY 131, “Molecular Analysis for Therapy Choice (MATCH).” Dr. V. Villalobos. Activated: 8/12/15; EAY131 (MATCH) Subprotocol Z1C, EAY131-Z1C, is permanently Closed to Accrual: 5/25/21; EAY131 (MATCH) Subprotocol M, or EAY131-M, is suspended, effective immediately: 8/3/21; AY131 Subprotocols A, C1, C2, E, L, V, Z1E, and Z1G are closed to accrual: 1/31/22; Subprotocol Z1G reactivated: 2/23/22

CTSU/EA8134, “InPACT- International Penile Advanced Cancer Trial (International Rare Cancers Initiative Study).” Dr. C. Pettaway. Activated: 9/8/17.

Publications

The publications listed below were received by the Group Chair’s Office as published (including online), accepted, or submitted since the SWOG Fall 2023 Group Meeting. Conference abstracts are not included.

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

Note: All PCPT and SELECT publications are listed under Cancer Control & Prevention Committees

Published/Accepted Manuscripts

S1314 Association of Molecular Subtypes with Pathologic Response, PFS, and OS in a Phase II Study of COXEN with Neoadjuvant Chemotherapy for Muscle-invasive Bladder Cancer. Lerner S, McConkey

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DJ, Tangen C, Meeks JJ, Flaig T, Hua X, Daneshmand S, Alva A, Lucia MS, Theodorescu D, Goldkorn A, Milowsky M, Choi W, Bangs R, Gustafson D, Plets M, Thompson IM. *Clinical Cancer Research* Nov 15. doi: 10.1158/1078-0432.CCR-23-0602. Online ahead of print, 2023.

<https://pubmed.ncbi.nlm.nih.gov/37966367/>

S1216 Markers of bone metabolism and overall survival in men with bone-metastatic hormone sensitive prostate cancer (HSPC): a subset analysis of SWOG S1216, a phase III trial of androgen deprivation with or without orteronel. Lara P, Mayerson E, Gertz E, Tangen C, Goldkorn A, Van Loan M, Hussain M, Gupta S, Zhang J, Parikh M, Twardowski P, Quinn D, LeBlanc M, Thompson I, Agarwal N. *Prostate Cancer Prostatic Dis.* Feb 29. doi: 10.1038/s41391-024-00813-3, 2024.

<https://pubmed.ncbi.nlm.nih.gov/38424319/>

Submitted Manuscripts

S0931 Association of adjuvant everolimus with outcomes in patients with localized non-clear cell renal cell carcinoma (RCC): Subgroup analysis from the phase-III EVEREST trial (SWOG S0931). Gulati S, Tangen C, Ryan C, Vaishampayan U, Shuch B, Barata P, Pruthi D, Bergerot C, Tripathi A, Lerner S, Thompson I, Lara P, Pal S. Submitted, 2024.

S0931 Adjuvant everolimus in patients with completely resected very high-risk renal cell cancer and clear cell histology: results from the phase III placebo-controlled SWOG S0931 (EVEREST) trial. Lara P, Tangen C, Heath E, Gulati S, Stein M, Meng M, Alva A, Pal S, Puzanov I, Clark J, Choueiri T, Agarwal N, Uzzo R, Haas N, Synold T, Plets M, Vaishampayan U, Shuch B, Lerner S, Thompson I, Ryan C. Submitted, 2024.

S1011 Standard vs. Extended Lymphadenectomy for Muscle Invasive Bladder Cancer. Lerner S, Tangen C, Svatek R, Daneshmand S, Pohar K, Skinner E, Schuckman A, Sagalowsky A, Smith N, Kamat A, Kassouf mW, Plets M, Bangs R, Koppie T, Alva A, La Rosa F, Pal S, Kibel A, Canter D, Thompson I. Submitted, 2024.

S1216 Baseline circulating tumor cell count as a prognostic marker of overall survival in metastatic hormone sensitive prostate cancer (SWOG S1216). Goldkorn A, Tangen C, Plets M, Bsteh D, Xu T, Pinski J, Ingles S, Triche T, MacVicar G, Vaena D, Crispino A, McConkey D, Lara P, Jr., Hussain M, Quinn D, Dorff T, Thompson I, Jr, Agarwal N. Submitted 2024.

S1216 Three- and seven- month prostate-specific antigen levels as prognostic markers for overall survival in metastatic hormone sensitive prostate cancer (mHSPC): Results from SWOG S1216, a phase III randomized trial of androgen deprivation plus orteronel or bicalutamide. Parikh M, Tangen C, Hussain M, Gupta S, Jo Y, Callis S,

Harzstark A, Paller C, George S, Zibelman M, Cheng H, Maughan B, Zhang J, Pachynsk R, Bryce A, Lin D, Quinn D, Thompson I, Lerner SP, Dorff T, Lara P, Agarwal N. Under review following resubmission 2024.

S1314 S1314 correlative analysis of ATM, RB1, ERCC2 and FANCC mutations and pathologic complete response after neoadjuvant chemotherapy in patients with muscle-invasive bladder cancer. Plimack E, Tangen C, Plets M, Kokate R, Xiu J, Nabhan C, Ross E, Grundy E, Choi W, Dinney C, Lee I, Fong M, Lucia M, Daneshmand S, Theodorescu D, Goldkorn A, Lerner S, Flaig T, McConkey D. Submitted, 2024.

S1314 DNA Damage Response Gene Alterations Predict for Neoadjuvant Chemotherapy Sensitivity in Muscle-Invasive Bladder Cancer: A Correlative Analysis of the SWOG S1314 Trial. Iyer G, Tangen C, Sarfaty M, Regazzi A, Lee I, Fong M, Choi W, Dinney C, Flaig T, Thompson I, Lerner S, McConkey D, Rosenberg J. Submitted, 2024.

E3805 Effect of Metformin and Body Mass Index on Quality of Life and Survival in the E3805 CHARTED Trial. Jerrard D, Chen Y, Morgans A, Carducci M, Liu G, Eisenberger M, Wong Y-N, Hahn N, Bryce A, Cooney M, Dreicer R, Vogelzang N, Picus J, Shevrin D, Hussain M, Garcia J, DiPaola R, Sweeney C. Submitted 2023.

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Accrual from trials that are open as of 12/31/2023 or have closed in the prior 18 Months by Institution and Study

	S1802	S1806	S1931	S1937	S2011	S2200	A031102	A031701	A031702	A031704
Ascension Providence Hospitals - Southfield	-	-	-	-	-	-	-	-	-	3
Audie L Murphy VA Hospital	-	-	-	-	-	-	-	-	-	-
Banner MD Anderson Cancer Center	6	-	1	-	-	-	-	-	-	-
Banner University Medical Center - Tucson	7	-	1	-	-	-	-	-	-	-
Baylor College of Medicine/Duncan Comprehensive Cancer Center	2	6	-	-	-	-	-	-	-	-
CWRU Case Comprehensive Cancer Center LAPS	-	-	-	-	-	-	-	7	-	-
Cancer Research Consortium of West Michigan NCORP	2	7	-	-	-	-	-	-	-	-
Cancer Research for the Ozarks NCORP	1	5	-	-	-	-	-	-	-	-
Cancer Research of Wisconsin and Northern Michigan Consortium	1	6	-	-	-	-	-	-	-	-
Carle Cancer Center NCI Community Oncology Research Program	1	1	1	-	-	-	-	-	-	-
Cedars-Sinai Medical Center	-	10	2	-	-	-	-	-	-	-
City of Hope Comprehensive Cancer Center	3	-	2	-	-	-	-	-	-	-
Columbia University Minority Underserved NCORP	2	4	-	-	-	-	-	-	-	-
CommonSpirit Health Research Institute	3	4	-	3	-	-	-	-	-	-
Dayton NCI Community Oncology Research Program	5	2	-	-	-	-	-	-	-	1
Desert Regional Medical Center	1	-	-	-	-	-	-	-	-	-
Fred Hutchinson Cancer Research Center LAPS	19	-	-	-	-	-	-	-	-	-
Georgia Cares Minority Underserved NCORP	1	-	-	-	-	-	-	-	-	-
Grupo Oncologico Cooperativo de Investigacion	2	-	-	-	-	-	-	-	-	-
Gulf South Minority Underserved NCORP	80	73	1	-	-	1	-	-	-	-
Hawaii Minority Underserved NCORP	-	4	-	-	-	-	-	-	-	-
Heartland Cancer Research NCORP	8	8	1	-	4	1	-	1	-	-
Henry Ford Hospital	25	4	-	1	-	-	-	-	2	6
Instituto Nacional De Cancerologia	1	-	-	-	-	-	-	-	-	-
Instituto Nacional De Cancerologia de Mexico	1	-	-	-	-	-	-	-	-	-
Kaiser Permanente NCI Community Oncology Research Program	18	-	2	-	-	-	-	-	-	60
Lahey Hospital and Medical Center	-	-	-	-	-	-	-	-	6	-
Loyola University Medical Center	9	6	1	2	-	-	-	-	1	1
Mass Veterans Epidemiology Research and Information Center	-	-	-	-	-	-	-	-	-	-
Medical University of South Carolina Minority Underserved NCORP	6	-	-	1	-	-	-	-	-	-
Mercy Medical Center - Des Moines	-	1	-	-	-	-	-	-	-	-
Michigan Cancer Research Consortium NCORP	9	18	-	2	-	1	-	1	-	-
Montana Cancer Consortium NCORP	3	-	-	-	-	-	-	-	-	-
NCORP of the Carolinas (Prisma Health NCORP)	10	-	-	-	-	-	-	-	-	1
Nevada Cancer Research Foundation NCORP	1	-	-	-	-	-	-	-	1	-
New Mexico Minority Underserved NCORP	-	-	1	-	-	-	-	-	-	-
Northwell Health NCORP	-	3	-	-	-	-	-	-	-	1

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Accrual from trials that are open as of 12/31/2023 or have closed in the prior 18 Months by Institution and Study

	S1802	S1806	S1931	S1937	S2011	S2200	A031102	A031701	A031702	A031704
Northwestern University LAPS	-	8	1	-	-	-	-	-	-	2
Ohio State University Comprehensive Cancer Center LAPS	2	3	-	-	-	-	-	-	-	-
Oregon Health and Science University	-	1	-	-	-	1	-	-	5	5
SCL Health Saint Joseph Hospital	2	-	-	-	-	-	-	-	-	-
Southeast Clinical Oncology Research Consortium NCORP	8	1	-	-	-	-	-	-	-	-
Sutter Cancer Research Consortium	-	3	-	-	-	-	-	-	-	-
Tulane University School of Medicine	-	-	9	-	-	-	-	-	-	1
UC Davis Comprehensive Cancer Center LAPS	12	9	2	3	-	-	-	9	-	3
UC Irvine Health/Chao Family Comprehensive Cancer Center	6	6	-	-	-	-	-	-	-	-
UC San Diego Moores Cancer Center	4	3	-	-	-	-	-	-	-	-
UCLA / Jonsson Comprehensive Cancer Center	-	-	3	-	-	-	-	-	-	-
UPMC Hillman Cancer Center LAPS	-	5	2	-	-	-	-	-	-	-
USC Norris Comprehensive Cancer Center LAPS	5	-	-	3	-	-	12	-	5	-
Univ. of Alabama at Birmingham / Deep South Research Consort LAPS	-	-	3	-	-	-	-	-	1	-
University of Arkansas for Medical Sciences	2	-	-	-	-	-	-	-	-	-
University of Cincinnati Cancer Center-UC Medical Center	6	6	3	-	-	-	-	-	-	5
University of Colorado Cancer Center LAPS	5	6	-	3	1	-	-	-	-	11
University of Kansas Cancer Center - MCA Rural MU NCORP	7	7	-	-	-	-	-	-	1	7
University of Kentucky/Markey Cancer Center	-	3	-	-	-	-	-	-	-	-
University of Michigan Comprehensive Cancer Center LAPS	2	-	17	-	-	-	-	-	-	-
University of Mississippi Medical Center	1	-	-	1	-	1	-	-	1	-
University of Oklahoma Health Sciences Center LAPS	29	15	4	-	-	2	-	-	-	-
University of Rochester LAPS	24	-	2	-	-	-	-	-	3	8
University of Texas Health Science Center at San Antonio	9	-	2	-	-	-	-	-	-	-
University of Texas MD Anderson Cancer Center LAPS	81	-	-	-	-	-	-	-	-	-
University of Utah - Huntsman Cancer Institute LAPS	19	-	1	-	-	-	-	-	-	-
Upstate Carolina Consort Community Oncology Research Program	3	2	-	-	-	-	-	-	-	-
Vanderbilt University - Ingram Cancer Center LAPS	6	5	-	-	-	-	-	-	-	-
Virginia Mason Medical Center	-	-	-	-	-	-	-	-	-	-
Wayne State University - Karmanos Cancer Institute LAPS	1	-	-	-	-	-	-	-	-	-
Western States Cancer Research NCORP	-	2	-	-	-	-	-	-	-	-
Wisconsin NCI Community Oncology Research Program	10	6	-	-	-	-	-	-	-	-
Yale University - Yale Cancer Center LAPS	1	4	-	-	-	-	-	-	-	1
ALLIANCE	103	32	4	1	-	1	-	-	-	-
ECOG-ACRIN	84	41	10	2	1	1	-	-	-	-
NRG	92	132	7	1	-	-	-	-	-	-
Total	751	462	83	23	6	9	12	18	26	116

Genitourinary Committee

Accrual from trials that are open as of 12/31/2023 or have closed in the prior 18 Months by Institution and Study

	A031801	A031803	A031901	A031902	A032001	A032101	A222001	EA8134	EA8171	EA8183
Ascension Providence Hospitals - Southfield	-	-	-	-	-	-	-	-	-	-
Audie L Murphy VA Hospital	-	1	-	-	-	-	-	-	48	-
Banner MD Anderson Cancer Center	-	-	-	-	-	-	-	-	-	-
Banner University Medical Center - Tucson	-	-	-	-	-	-	1	-	-	-
Baylor College of Medicine/Duncan Comprehensive Cancer Center	-	4	-	-	-	-	-	-	-	-
CWRU Case Comprehensive Cancer Center LAPS	-	-	-	4	12	-	-	-	-	-
Cancer Research Consortium of West Michigan NCORP	-	-	-	-	-	-	-	-	-	-
Cancer Research for the Ozarks NCORP	-	-	-	-	-	-	-	-	-	-
Cancer Research of Wisconsin and Northern Michigan Consortium	-	-	-	-	-	-	-	-	-	-
Carle Cancer Center NCI Community Oncology Research Program	-	-	-	-	-	-	-	-	-	-
Cedars-Sinai Medical Center	-	-	-	-	-	-	-	-	-	-
City of Hope Comprehensive Cancer Center	-	-	-	-	-	-	-	-	-	-
Columbia University Minority Underserved NCORP	-	-	-	-	-	-	-	-	-	-
CommonSpirit Health Research Institute	-	-	-	-	-	-	-	-	-	-
Dayton NCI Community Oncology Research Program	-	-	-	-	-	-	-	-	-	-
Desert Regional Medical Center	-	-	-	-	-	-	-	-	-	-
Fred Hutchinson Cancer Research Center LAPS	-	-	-	-	-	-	-	-	-	-
Georgia Cares Minority Underserved NCORP	-	-	-	-	-	-	-	-	-	-
Grupo Oncologico Cooperativo de Investigacion	-	-	-	-	-	-	-	-	-	-
Gulf South Minority Underserved NCORP	1	16	-	-	-	-	-	-	11	-
Hawaii Minority Underserved NCORP	-	-	-	-	-	-	-	-	2	-
Heartland Cancer Research NCORP	-	-	-	-	-	-	-	-	-	-
Henry Ford Hospital	-	-	2	-	-	-	-	-	1	-
Instituto Nacional De Cancerologia	-	-	-	-	-	-	-	-	-	-
Instituto Nacional De Cancerologia de Mexico	-	-	-	-	-	-	-	-	-	-
Kaiser Permanente NCI Community Oncology Research Program	-	-	-	-	-	-	-	-	-	-
Lahey Hospital and Medical Center	-	-	-	-	-	-	-	-	-	4
Loyola University Medical Center	-	-	-	-	-	-	-	-	-	-
Mass Veterans Epidemiology Research and Information Center	-	-	-	1	-	-	-	-	-	-
Medical University of South Carolina Minority Underserved NCORP	-	-	-	-	-	-	-	-	-	-
Mercy Medical Center - Des Moines	-	-	-	-	-	-	-	-	-	-
Michigan Cancer Research Consortium NCORP	-	-	-	-	-	-	-	-	-	-
Montana Cancer Consortium NCORP	-	-	-	-	-	-	-	-	-	-
NCORP of the Carolinas (Prisma Health NCORP)	-	-	-	-	-	-	-	-	-	-
Nevada Cancer Research Foundation NCORP	-	-	-	-	-	-	-	-	-	-
New Mexico Minority Underserved NCORP	-	-	-	-	-	-	-	-	-	-
Northwell Health NCORP	-	-	-	-	-	-	-	-	-	-

Genitourinary Committee

Accrual from trials that are open as of 12/31/2023 or have closed in the prior 18 Months by Institution and Study

	A031801	A031803	A031901	A031902	A032001	A032101	A222001	EA8134	EA8171	EA8183
Northwestern University LAPS	-	-	-	-	-	1	-	-	-	-
Ohio State University Comprehensive Cancer Center LAPS	-	-	-	-	-	-	-	-	-	-
Oregon Health and Science University	-	-	-	-	-	-	-	-	12	-
SCL Health Saint Joseph Hospital	-	-	-	-	-	-	-	-	-	-
Southeast Clinical Oncology Research Consortium NCORP	-	-	-	-	-	-	-	-	-	-
Sutter Cancer Research Consortium	-	-	-	-	-	-	-	-	-	-
Tulane University School of Medicine	-	-	-	-	-	-	-	-	-	-
UC Davis Comprehensive Cancer Center LAPS	7	5	-	-	2	-	-	-	-	-
UC Irvine Health/Chao Family Comprehensive Cancer Center	-	-	-	-	-	-	-	-	-	-
UC San Diego Moores Cancer Center	-	-	-	-	-	1	-	-	-	-
UCLA / Jonsson Comprehensive Cancer Center	-	-	-	-	-	-	-	-	-	-
UPMC Hillman Cancer Center LAPS	-	-	-	-	-	-	-	-	-	-
USC Norris Comprehensive Cancer Center LAPS	-	-	-	-	-	-	-	11	-	-
Univ. of Alabama at Birmingham / Deep South Research Consort LAPS	1	8	-	-	-	-	-	-	-	-
University of Arkansas for Medical Sciences	-	-	-	-	-	-	-	-	-	-
University of Cincinnati Cancer Center-UC Medical Center	-	-	-	-	-	-	-	-	-	-
University of Colorado Cancer Center LAPS	-	-	-	-	-	2	-	1	-	-
University of Kansas Cancer Center - MCA Rural MU NCORP	-	-	-	-	-	-	-	-	-	-
University of Kentucky/Markey Cancer Center	-	-	-	-	-	-	-	-	-	-
University of Michigan Comprehensive Cancer Center LAPS	-	-	-	-	-	8	-	-	-	-
University of Mississippi Medical Center	-	-	-	-	-	-	-	-	-	-
University of Oklahoma Health Sciences Center LAPS	-	-	-	-	-	-	-	-	-	-
University of Rochester LAPS	-	-	-	-	1	-	-	-	-	-
University of Texas Health Science Center at San Antonio	-	6	-	-	-	-	-	-	13	-
University of Texas MD Anderson Cancer Center LAPS	-	-	-	-	-	-	-	-	-	-
University of Utah - Huntsman Cancer Institute LAPS	4	-	-	-	-	-	1	-	-	-
Upstate Carolina Consort Community Oncology Research Program	-	-	-	-	-	-	-	-	-	-
Vanderbilt University - Ingram Cancer Center LAPS	-	-	-	-	-	-	-	-	-	-
Virginia Mason Medical Center	-	-	-	-	-	-	-	-	-	-
Wayne State University - Karmanos Cancer Institute LAPS	-	-	-	-	-	-	-	-	-	-
Western States Cancer Research NCORP	-	-	-	-	-	-	-	-	-	-
Wisconsin NCI Community Oncology Research Program	-	-	-	-	-	-	-	-	-	-
Yale University - Yale Cancer Center LAPS	-	-	-	-	-	-	-	-	-	-
ALLIANCE	-	-	-	-	-	-	-	-	-	-
ECOG-ACRIN	-	-	-	-	-	-	-	-	-	-
NRG	-	-	-	-	-	-	-	-	-	-
Total	13	40	2	5	15	12	2	12	87	4

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Accrual from trials that are open as of 12/31/2023 or have closed in the prior 18 Months by Institution and Study

	EA8185	EA8191	EA8192	EA8212	NRGGU002	NRGGU008	NRGGU009	NRGGU010	NRGGU011
Ascension Providence Hospitals - Southfield	-	-	-	-	-	-	-	-	-
Audie L Murphy VA Hospital	-	-	-	-	-	-	-	-	-
Banner MD Anderson Cancer Center	-	-	-	9	-	-	-	-	-
Banner University Medical Center - Tucson	-	-	-	-	-	-	-	-	-
Baylor College of Medicine/Duncan Comprehensive Cancer Center	-	-	-	3	-	-	-	-	-
CWRU Case Comprehensive Cancer Center LAPS	-	-	-	-	-	-	-	-	-
Cancer Research Consortium of West Michigan NCORP	-	-	-	-	-	-	-	-	-
Cancer Research for the Ozarks NCORP	-	-	-	-	-	-	-	-	-
Cancer Research of Wisconsin and Northern Michigan Consortium	-	-	-	-	-	-	-	-	-
Carle Cancer Center NCI Community Oncology Research Program	-	-	-	-	-	-	-	-	-
Cedars-Sinai Medical Center	-	-	-	-	-	-	-	-	-
City of Hope Comprehensive Cancer Center	-	-	-	-	-	-	-	-	-
Columbia University Minority Underserved NCORP	-	-	-	-	-	-	-	-	-
CommonSpirit Health Research Institute	-	-	-	-	-	-	-	-	-
Dayton NCI Community Oncology Research Program	-	-	-	-	-	-	-	-	-
Desert Regional Medical Center	-	-	-	-	-	-	-	-	-
Fred Hutchinson Cancer Research Center LAPS	-	17	-	1	-	-	-	-	-
Georgia Cares Minority Underserved NCORP	-	-	-	-	-	-	-	-	-
Grupo Oncologico Cooperativo de Investigacion	-	-	-	-	-	-	-	-	-
Gulf South Minority Underserved NCORP	1	-	-	42	1	4	14	6	2
Hawaii Minority Underserved NCORP	-	-	-	-	-	-	-	-	-
Heartland Cancer Research NCORP	-	-	-	-	-	-	-	-	-
Henry Ford Hospital	-	-	-	-	-	-	-	-	-
Instituto Nacional De Cancerologia	-	-	-	-	-	-	-	-	-
Instituto Nacional De Cancerologia de Mexico	-	-	-	-	-	-	-	-	-
Kaiser Permanente NCI Community Oncology Research Program	-	-	-	-	-	-	-	-	-
Lahey Hospital and Medical Center	-	-	-	-	-	-	-	-	-
Loyola University Medical Center	-	-	-	-	-	-	-	-	-
Mass Veterans Epidemiology Research and Information Center	-	-	-	-	-	-	-	-	-
Medical University of South Carolina Minority Underserved NCORP	-	-	-	-	-	-	-	-	-
Mercy Medical Center - Des Moines	-	-	-	-	-	-	-	-	-
Michigan Cancer Research Consortium NCORP	-	-	-	-	-	-	-	-	-
Montana Cancer Consortium NCORP	-	-	-	-	-	-	-	-	-
NCORP of the Carolinas (Prisma Health NCORP)	-	-	-	1	-	-	-	-	-
Nevada Cancer Research Foundation NCORP	-	-	-	-	-	-	-	-	-
New Mexico Minority Underserved NCORP	-	-	-	-	-	-	-	-	-
Northwell Health NCORP	-	1	-	-	-	3	6	2	-

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Accrual from trials that are open as of 12/31/2023 or have closed in the prior 18 Months by Institution and Study

	EA8185	EA8191	EA8192	EA8212	NRGGU002	NRGGU008	NRGGU009	NRGGU010	NRGGU011
Northwestern University LAPS	-	-	-	-	-	-	-	4	-
Ohio State University Comprehensive Cancer Center LAPS	-	-	-	-	-	-	-	-	-
Oregon Health and Science University	-	6	-	3	-	-	-	-	2
SCL Health Saint Joseph Hospital	-	-	-	-	-	-	-	3	-
Southeast Clinical Oncology Research Consortium NCORP	-	-	-	-	-	-	-	-	-
Sutter Cancer Research Consortium	-	-	-	-	-	-	1	3	-
Tulane University School of Medicine	-	-	-	-	-	-	-	-	-
UC Davis Comprehensive Cancer Center LAPS	-	-	-	-	-	-	1	-	-
UC Irvine Health/Chao Family Comprehensive Cancer Center	-	-	-	-	-	2	-	-	-
UC San Diego Moores Cancer Center	-	-	-	1	-	-	-	-	-
UCLA / Jonsson Comprehensive Cancer Center	-	-	-	-	-	-	-	-	-
UPMC Hillman Cancer Center LAPS	-	-	-	-	-	-	-	-	-
USC Norris Comprehensive Cancer Center LAPS	-	-	-	3	-	-	-	-	-
Univ. of Alabama at Birmingham / Deep South Research Consort LAPS	-	-	-	-	-	-	-	-	-
University of Arkansas for Medical Sciences	-	-	-	-	-	-	-	-	-
University of Cincinnati Cancer Center-UC Medical Center	-	-	-	-	-	-	-	-	-
University of Colorado Cancer Center LAPS	-	-	2	-	1	-	4	-	-
University of Kansas Cancer Center - MCA Rural MU NCORP	-	-	-	-	-	1	3	1	-
University of Kentucky/Markey Cancer Center	-	-	-	1	-	-	-	-	-
University of Michigan Comprehensive Cancer Center LAPS	-	-	-	-	-	-	-	1	-
University of Mississippi Medical Center	-	-	-	-	1	-	1	-	-
University of Oklahoma Health Sciences Center LAPS	-	1	-	-	-	-	-	-	-
University of Rochester LAPS	-	-	-	-	-	-	-	4	-
University of Texas Health Science Center at San Antonio	-	2	-	-	-	-	-	-	-
University of Texas MD Anderson Cancer Center LAPS	-	-	-	-	-	-	-	-	-
University of Utah - Huntsman Cancer Institute LAPS	-	-	-	-	-	-	-	-	-
Upstate Carolina Consort Community Oncology Research Program	-	-	-	-	-	-	-	-	-
Vanderbilt University - Ingram Cancer Center LAPS	-	-	-	-	-	-	-	-	-
Virginia Mason Medical Center	-	-	-	-	-	-	4	2	-
Wayne State University - Karmanos Cancer Institute LAPS	-	-	-	-	1	-	-	-	-
Western States Cancer Research NCORP	-	-	-	-	-	-	1	1	-
Wisconsin NCI Community Oncology Research Program	-	-	-	-	-	-	-	-	-
Yale University - Yale Cancer Center LAPS	-	-	-	-	-	-	-	-	-
ALLIANCE	-	-	-	-	-	-	-	-	-
ECOG-ACRIN	-	-	-	-	-	-	-	-	-
NRG	-	-	-	-	-	-	-	-	-
Total	1	27	2	64	4	10	35	27	4

