

Leadership	
Chair:	Seth P. Lerner, MD
Vice-Chair:	Daniel P. Petrylak, MD
Chair Emeritus:	lan M. Thompson, Jr., MD
Executive Officer:	Christopher W. Ryan, MD
Statisticians:	Cathy M. Tangen, DrPH
	Melissa Plets, MS
	Sam Callis, MS
	Sara Threlkel, BS
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
	Evan Y. Yu, MD
	Hiram Shaish, MD
	John D. Hazle, PhD
	Shuchi Gulati, MD (Medical Onc)
	Robert Svatek, MD (Urologic Onc)
Pathology:	M. Scott Lucia, MD
	Kelly L. Stratton, MD
	Parminder Singh, MD
•	. 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)
	Jlka N. Vaishampayan, MD (Advanced)
Designates	• • • • • • • • • • • • • • • • • • • •
_	Clara Hwang, MD
	Sarah P. Psutka, MD, MSC
	Jessica D. McDermott, MD
Digital Engagement:	Neema Navai, MD
NCORP:	Scott Edward Delacroix, Jr., MD
	Helen Heng-Shan Moon, MD
	Michael M. Goodman, MD
Data Coordinators:	
	Laura Wells, BA
	Michele Counts, BS
	Tonya Johnson, BS
Oncology Research Professionals:	•
= ·	Abagail L. Cornette, MS
	Gary Lee Duvall, RN
	,

Patient Advocates:	. Rick Bangs, MBA (Emeritus, Bladder))
	Darrell Nakagawa (Bladder)
	Tony Crispino (Emeritus, 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

10:15 - 12:00 pm:

Friday, October 18, 2024 9:30 a.m. - 12:00 p.m. Room: Regency D (Ballroom Level, West Tower)

Agenda

9:30 - 9:45 am: Chair's Welcome and Opening Remarks - Seth Lerner9:45 - 10:15 am: Cancer Control - Clara Hwang and Sarah Psutka

Review of open approved trials - all organ site chairs

Bladder – Sia Daneshmand and Tom Flaig Prostate – Dan Lin and Tanya Dorff

Renal – Brian Shuch and Ulka Vaishampayan

Cancer Control

Organ Site Chairs: Drs. Clara Hwang and Dr. 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", Pl: Craig Nichols – Activated 6/1/20 GU Champions: Thomas Frye & Anishka D'Souza

<u>\$1931</u> (Companion Study): Examining Psychosocial and Emotional Issues for Metastatic Kidney Cancer. Pl: Cristiane Bergerot.

<u>\$1937</u> (Companion Study): Assessment of Quality of Life for \$1937: 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.

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. Submitted to GUSC on 5/28. Received pending response. Response to GUSC comments due 8/7 for 8/21 GUSC meeting.

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 In-vasive Bladder Cancer." Drs. R. Svatek, A. Alva, and S. Lerner. Activated: 2/7/17; Permanently Closed: 12/15/20.
- <u>S1605</u>, "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. Son-pavde, M. Liss, and S. Lerner, et al. Activated: 10/6/21. Closed to Accrual: 11/15/23.

Prostate

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

Priority Study

52210, "Targeted neoadjuvant treatment for patients with localized prostate cancer and germline DNA repair deficiency." Dr. H. Cheng. Activated 8/14.

Concepts in Development

52312, "A Phase III Study of Cabazitaxel with or without Carboplatin in Patients with metastatic cas-trate-resistant prostate cancer (mCRPC), Stratified by Aggressive Variant Signature." Dr. Paul Corn. CIRB provided approval-on-hold 7/11. Awaiting CTEP full approval and completion of dry run. Target activation mid-September.

Active Studies

- **S1802**, "Phase III Randomized Trial of Standard Systemic Therapy (SST) Versus Standard Sys-temic 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. Revision #5 released 8/15.
- 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. Ouinn. 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 In-termediate 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 Pros-tate 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 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. Ac-tivated: 6/3/19; Temporarily Closed: 5/5/21; Reactivated of dose level 2 (phase I) for 1 additional pa-tient: 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: 7/11/22.

CTSU/EA8153, "Cabazitaxel with Abiraterone Versus Abiraterone Alone Randomized Trial for Exten-sive Disease Following Docetaxel: The CHAARTED2 Trial." Dr. P. Corn. Activated: 2/8/18; Permanent-ly 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.

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. Concept submitted to GUSC for 9/18 review.

Active Studies

52200, "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. Sin-gle 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; Reactivated: 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 [PDI-GREE]." 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 Urotheli-al 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], 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 Lo-cally 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.

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

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 ZIG reactivated: 2/23/22
- CTSU/EA8134, "InPACT- International Penile Advanced Cancer Trial (International Rare Cancers Initi-ative 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 Spring 2024 Group Meeting. Conference abstracts are not included.

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

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

Published/Accepted Manuscripts

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. <u>European Urology</u> May 28:50302-2838(24)02383-2, 2024.

https://pubmed.ncbi.nlm.nih.gov/38811313/

- S0931 Adjuvant Everolimus in Non-Clear Cell Renal Cell Carcinoma: A Secondary Analysis of a Randomized Clinical Trial. 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. JAMA Network Open Aug 1;7(8):e2425288, 2024. https://pubmed.ncbi.nlm.nih.gov/39106067/
- 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. Accepted July 2024.
- S1216 Bone Pain and Survival Among Patients With Metastatic,
 Hormone-Sensitive Prostate Cancer: A Secondary Analysis of the SWOG1216 Trial. Gebrael G, Jo Y, Swami U, Plets M, Hage Chehade C, Narang
 A, Gupta S, Myint ZW, Sayegh N, Tangen CM, Hussain M, Dorff T, Lara
 PN Jr, Lerner SP, Thompson I, Agarwal N. JAMA Netw Open. 2024 Jul
 1;7(7):e2419966. https://pubmed.ncbi.nlm.nih.gov/38980676/
- 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. <u>European Urology Oncology</u> Mar 23:S2588-9311(24)00054-3, 2024 https://pubmed.ncbi.nlm.nih.gov/38523017/
- S1216 Circulating tumor cell (CTC) count is prognostic of overall survival in metastatic hormone sensitive prostate cancer (mHSPC). 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. Accepted 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. European Urology Jul

12:S0302-2838(24)02453-9, 2024. https://pubmed.ncbi.nlm.nih.gov/39003201/

- S1314 DNA Damage Response 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. Accepted 2024
- S1500 Pathological concordance rate and outcomes by subtype in advanced papillary renal cell carcinoma. Tripathi A, Tangen C, Plets M, Li X, Tretiakova M, Humphrey P, Adeniran A, Barata P, Gulati S, Bergerot C, Pruthi D, Thompson I, Lerner S, Pal S, Shuch B. BJU Int. Jul 16. doi: 10.1111/bju.16403. Online ahead of print. 2024. https://pubmed.ncbi.nlm.nih.gov/39014969/
- S1500 Final overall survival analysis of S1500: A randomized, phase II study comparing sunitinib to cabozantinib, crizotinib and savolitinib in advanced papillary renal cell carcinoma. Barata P, Tangen C, Plets M, Thompson I, Narayan V, George D, Heng D, Shuch B, Stein M, Gulati S, Tripathi A, Bjarnason G, Vaishampayan U, Alva A, Zhang T, Cole S, Lara P, Balzer-Haas N, Lerner S, Pal S. Accepted 2024.
- <u>S1806</u> Eligibility and endpoints for clinical trials in trimodality therapy for bladder cancer. Singh P, Ballas L, Sonpavde G, Chen R, Bangs R, Bauman B, Nagar H, Delacroix S, Lerner S, Efstathiou J. Accepted 2024.
- EA8143 Perioperative nivolumab versus observation in patients with renal cell carcinoma undergoing nephrectomy (PROSPER ECOG-ACRIN EA8143): an open-label, randomised, phase 3 study. Allaf ME, Kim SE, Master V, McDermott DF, Harshman LC, Cole SM, Drake CG, Signoretti S, Akgul M, Baniak N, Li-Ning E, Palmer MB, Emamekhoo H, Adra N, Kaimakliotis H, Ged Y, Pierorazio PM, Abel EJ, Bilen MA, Ogan K, Moon HH, Ramaswamy KA, Singer EA, Mayer TM, Lohrey J, Margulis V, Gills J, Delacroix SE, Waples MJ, James AC, Wang P, Choueiri T, Michaelson MD, Kapoor A, Heng DY, Shuch B, Leibovich BC, Lara PN, Manola J, Maskens D, Battle D, Uzzo R, Bratslavsky G, Haas NB, Carducci MA. Lancet Oncology Aug;25(8):1038-1052, 2024.

https://pubmed.ncbi.nlm.nih.gov/38942046/

Submitted Manuscripts

<u>S1216</u> Correlation of body mass index with overall survival in patients with metastatic hormone-sensitive prostate cancer: Analysis of patient-level data from SWOG-1216 study. Swami U, Jo Y, Narang A, Plets M, Chehade C, Gebrael G, Gupta S, Myint Z, Tangen C, Lara P, Thompson I, Hussain M, Dorff T, Lerner S, Agarwal N. Submitted 2024.



E3805 Effect of Metformin and Body Mass Index on Quality of Life and Survival in the E3805 CHAARTED 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 2024.



	51802	51806	51931	51937	52011	52200	52210	A021804	A031701	A031702
Ascension Providence Hospitals - Southfield	-	-	-	-	-	-	-	-	-	-
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	8	-	-	-	-	-	-	-	-
CWRU Case Comprehensive Cancer Center LAPS	-	-	-	-	-	-	-	-	9	-
Cancer Research Consortium of West Michigan NCORP	2	8	-	-	-	-	-	-	-	-
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	-	11	4	-	-	-	-	-	-	-
City of Hope Comprehensive Cancer Center	4	-	2	-	-	5	-	-	-	-
Columbia University Minority Underserved NCORP	2	4	-	-	-	-	-	-	-	-
CommonSpirit Health Research Institute	3	4	-	3	-	-	-	-	-	-
Dayton NCI Community Oncology Research Program	5	2	-	-	-	-	-	-	-	-
Desert Regional Medical Center	1	-	-	-	-	-	-	-	-	-
Fred Hutchinson Cancer Research Center LAPS	21	-	-	-	-	-	1	-	-	-
Georgia Cares Minority Underserved NCORP	1	-	-	-	-	-	-	-	-	-
Grupo Oncologico Cooperativo de Investigacion	3	-	-	-	-	-	-	-	-	-
Gulf South Minority Underserved NCORP	83	<i>73</i>	1	-	-	1	-	-	-	-
Hawaii Minority Underserved NCORP	-	4	-	-	-	-	-	-	-	-
Heartland Cancer Research NCORP	11	8	1	-	4	2	-	-	2	-
Henry Ford Hospital	25	4	-	1	-	-	-	-	-	2
Houston Methodist Hospital	-	-	-	-	-	-	-	-	-	-
Instituto Nacional De Cancerologia	3	-	-	-	-	-	-	-	-	-
Instituto Nacional De Cancerologia de Mexico	11	-	-	-	-	-	-	-	-	-
Kaiser Permanente NCI Community Oncology Research Program	18	-	2	-	-	-	-	-	-	-
Lahey Hospital and Medical Center	-	-	-	-	-	-	-	-	-	6
Loyola University Medical Center	9	6	1	2	-	-	-	-	-	1
Mass Veterans Epidemiology Research and Information Cntr	-	-	-	-	-	-	-	-	-	-
Medical University of South Carolina Minority Underserved NCORP	7	-	-	1	-	-	-	-	-	-
Mercy Medical Center - Des Moines	-	1	-	-	-	-	-	-	-	-
Michigan Cancer Research Consortium NCORP	9	20	-	2	-	1	-	-	1	-
Montana Cancer Consortium NCORP	3	-	-	-	-	-	-	-	-	-
NCORP of the Carolinas (Prisma Health NCORP)	11	-	-	-	-	-	-	-	-	-
Nevada Cancer Research Foundation NCORP	1	-	-	-	-	-	-	-	-	1
New Mexico Minority Underserved NCORP	-	-	1	-	-	-	-	-	-	-
Northwell Health NCORP	-	3	-	-	-	-	-	-	-	-
Northwestern University LAPS	-	8	1	1	-	1	-	-	-	-



	51802	51806	51931	51937	52011	52200	52210	A021804	A031701	A031702
Ohio State University Comprehensive Cancer Center LAPS	2	3	-	-	-	-	-	-	-	-
Oregon Health and Science University	-	1	1	-	-	1	-	1	-	5
SCL Health Saint Joseph Hospital	2	-	-	-	-	-	-	-	-	-
Southeast Clinical Oncology Research Consortium NCORP	8	1	-	-	-	-	-	-	-	-
Sutter Cancer Research Consortium	-	3	-	-	-	-	-	-	-	-
The West Clinic - Wolf River	-	-	-	1	-	-	-	-	-	-
Tulane University School of Medicine	-	-	9	-	-	-	-	-	-	-
UC Davis Comprehensive Cancer Center LAPS	12	9	2	3	-	-	-	-	9	-
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	-	8	2	-	-	-	-	-	-	-
USC Norris Comprehensive Cancer Center LAPS	5	-	-	8	-	-	-	-	-	5
U of Alabama at Birmingham/Deep South Research Consortium LAPS	-	-	3	-	-	-	-	-	-	1
University of Arkansas for Medical Sciences	6	-	-	-	-	1	-	-	-	-
University of Cincinnati Cancer Center-UC Medical Center	7	6	3	-	-	-	-	-	-	-
University of Colorado Cancer Center LAPS	6	6	-	4	1	-	-	-	-	-
University of Kansas Cancer Center - MCA Rural MU NCORP	7	9	-	-	-	-	-	-	-	1
University of Kentucky/Markey Cancer Center	-	3	-	-	-	-	-	-	-	-
University of Michigan Comprehensive Cancer Center LAPS	2	-	20	-	-	-	-	-	-	-
University of Mississippi Medical Center	1	-	-	1	-	1	-	-	-	1
University of Oklahoma Health Sciences Center LAPS	34	15	4	-	-	2	-	-	-	-
University of Rochester LAPS	25	-	3	-	-	-	-	-	-	3
University of Texas Health Science Center at San Antonio	11	-	4	-	-	-	-	-	-	-
University of Texas MD Anderson Cancer Center LAPS	84	-	-	-	-	-	-	-	-	-
University of Utah - Huntsman Cancer Institute LAPS	19	-	1	1	-	3	-	-	-	-
Upstate Carolina Consortium Comm Oncology Research Program	3	2	-	-	-	-	-	-	-	-
Vanderbilt University - Ingram Cancer Center LAPS	8	6	-	-	-	-	-	-	-	-
Virginia Mason Medical Center	-	-	-	-	-	-	-	-	-	-
Wayne State University - Karmanos Cancer Institute LAPS	1	-	-	-	-	-	-	-	-	-
Western States Cancer Research NCORP	-	2	-	-	-	-	-	-	-	-
Wisconsin NCI Community Oncology Research Program	11	6	-	-	-	-	-	-	-	-
Yale University - Yale Cancer Center LAPS	1	6	-	-	-	-	-	-	-	-
ALLIANCE	106	34	4	3	-	1	-	-	-	-
ECOG-ACRIN	92	44	11	5	1	1	-	-	-	-
NRG	103	136	10	1	-	1	-	-	-	-
Total	817	485	96	37	6	21	1	1	21	26



	A031704	A031801	A031803	A031902	A032001	A032101	A032103	EA8134	EA8171	EA8183
Ascension Providence Hospitals - Southfield	3	-	-	-	-	-	-	-	-	-
Audie L Murphy VA Hospital	-	-	2	-	-	-	-	-	49	-
Banner MD Anderson Cancer Center	-	-	-	-	-	-	-	-	-	-
Banner University Medical Center - Tucson	-	-	-	-	-	-	-	-	-	-
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	1	-	-	-	-	-	-	-	-	-
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	6	-	-	-	-	-	-	-	1	-
Houston Methodist Hospital	-	-	-	-	-	-	-	-	-	-
Instituto Nacional De Cancerologia	-	-	-	-	-	-	-	-	-	-
Instituto Nacional De Cancerologia de Mexico	-	-	-	-	-	-	-	-	-	-
Kaiser Permanente NCI Community Oncology Research Program	66	-	-	-	-	-	-	-	-	-
Lahey Hospital and Medical Center	-	-	-	-	-	-	-	-	-	4
Loyola University Medical Center	2	-	-	-	-	-	-	-	-	-
Mass Veterans Epidemiology Research and Information Cntr	-	-	-	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)	1	-	-	-	-	-	-	-	-	-
Nevada Cancer Research Foundation NCORP	-	-	-	-	-	-	-	-	-	-
New Mexico Minority Underserved NCORP	1	-	-	-	-	-	-	-	-	-
Northwell Health NCORP	1	-	-	-	-	-	-	-	-	-
Northwestern University LAPS	2	-	-	-	-	1	-	-	-	-



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

	A031704	A031801	A031803	A031902	A032001	A032101	A032103	EA8134	EA8171	EA8183
Ohio State University Comprehensive Cancer Center LAPS	-	-	-	-	-	-	-	-	-	-
Oregon Health and Science University	5	-	-	-	-	-	-	-	13	-
SCL Health Saint Joseph Hospital	-	-	-	-	-	-	-	-	-	-
Southeast Clinical Oncology Research Consortium NCORP	-	-	-	-	-	-	-	-	-	-
Sutter Cancer Research Consortium	-	-	-	-	-	-	-	-	-	-
The West Clinic - Wolf River	-	-	-	-	-	-	-	-	-	-
Tulane University School of Medicine	1	-	-	-	-	-	-	-	-	-
UC Davis Comprehensive Cancer Center LAPS	3	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	-	-	-	-	-	-	-	12	-	-
U of Alabama at Birmingham/Deep South Research Consortium LAPS	-	1	10	-	-	-	-	-	-	-
University of Arkansas for Medical Sciences	2	-	-	-	-	-	-	-	-	-
University of Cincinnati Cancer Center-UC Medical Center	7	-	-	-	-	-	-	-	-	-
University of Colorado Cancer Center LAPS	11	-	-	-	-	2	-	1	-	-
University of Kansas Cancer Center - MCA Rural MU NCORP	8	-	-	-	-	-	-	-	-	-
University of Kentucky/Markey Cancer Center	-	-	-	-	-	-	-	-	-	-
University of Michigan Comprehensive Cancer Center LAPS	-	-	-	-	-	12	-	-	-	-
University of Mississippi Medical Center	-	-	-	-	-	-	1	-	-	-
University of Oklahoma Health Sciences Center LAPS	-	-	-	-	-	-	-	-	-	-
University of Rochester LAPS	9	-	-	-	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	-	6	-	-	-	-	-	-	-	-
Upstate Carolina Consortium Comm 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	1	-	-	-	-	-	-	-	-	-
ALLIANCE	-	-	-	-	-	-	-	-	-	-
ECOG-ACRIN	-	-	-	-	-	-	-	-	-	-
NRG	-	-	-	-	-	-	-	-	-	-
Total	130	15	43	5	15	16	1	13	89	4



	EA8185	EA8191	EA8192	EA8212	NRGGU008	NRGGU009	NRGGU010	NRGGU011	NRGGU012	VRGGU013
Ascension Providence Hospitals - Southfield	-	-	-	-	-	_	-	_	_	-
Audie L Murphy VA Hospital	_	-	-	-	_		-	-	-	-
Banner MD Anderson Cancer Center	_	_	-	14	-	1	-	_	_	_
Banner University Medical Center - Tucson	_	-	-	-	-		-	-	-	-
Baylor College of Medicine/Duncan Comprehensive Cancer Center	-	-	-	9	-	-	-	-	-	-
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	-	23	-	6	-	-	-	-	-	-
Georgia Cares Minority Underserved NCORP	-	-	-	-	-	-	-	-	-	-
Grupo Oncologico Cooperativo de Investigacion	-	-	-	-	-	-	-	-	-	-
Gulf South Minority Underserved NCORP	1	-	-	59	6	16	6	5	2	-
Hawaii Minority Underserved NCORP	-	-	-	-	-	-	-	-	-	-
Heartland Cancer Research NCORP	-	-	-	-	-	-	-	-	-	-
Henry Ford Hospital	-	-	-	-	-	-	-	-	-	-
Houston Methodist Hospital	-	-	-	2	-	-	-	-	-	-
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	-	-	-	1	-	-	-	-	-	-
Mass Veterans Epidemiology Research and Information Cntr	-	-	-	-	-	-	-	-	-	-
Medical University of South Carolina Minority Underserved NCORP	-	-	-	1	-	-	-	-	-	-
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	-	-	4	12	3	-	-	-
Northwestern University LAPS	-	-	-	-	-	-	4	-	-	-



	EA8185	EA8191	EA8192	EA8212	NRGGU008	NRGGU009	NRGGU010	NRGGU01	NRGGU012	NRGGU013
Ohio State University Comprehensive Cancer Center LAPS	-	-	-	-	-	-	-	-	-	-
Oregon Health and Science University	-	10	-	11	-	-	-	4	_	-
SCL Health Saint Joseph Hospital	-	-	-	-	-	-	3	-	-	-
Southeast Clinical Oncology Research Consortium NCORP	-	-	-	-	-	-	-	-	_	-
Sutter Cancer Research Consortium	-	-	-	-	-	1	4	-	-	-
The West Clinic - Wolf River	-	-	-	-	-	-	-	-	_	-
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	-	-	-	9	-	-	-	-	-	-
U of Alabama at Birmingham/Deep South Research Consortium LAPS	-	-	-	-	-	-	-	-	-	-
University of Arkansas for Medical Sciences	-	-	-	-	-	-	-	-	-	-
University of Cincinnati Cancer Center-UC Medical Center	-	-	-	-	-	-	-	-	-	-
University of Colorado Cancer Center LAPS	-	-	2	-	-	10	4	-	-	-
University of Kansas Cancer Center - MCA Rural MU NCORP	-	-	-	-	1	7	3	-	-	-
University of Kentucky/Markey Cancer Center	-	-	1	4	-	-	-	-	-	-
University of Michigan Comprehensive Cancer Center LAPS	-	-	-	-	-	-	1	-	-	-
University of Mississippi Medical Center	-	-	-	-	-	2	-	-	-	-
University of Oklahoma Health Sciences Center LAPS	-	4	-	2	-	3	-	-	1	2
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 Consortium Comm Oncology Research Program	-	-	-	-	-	-	-	-	-	-
Vanderbilt University - Ingram Cancer Center LAPS	-	-	-	-	-	-	-	-	-	-
Virginia Mason Medical Center	-	-	-	6	-	4	3	-	-	-
Wayne State University - Karmanos Cancer Institute LAPS	-	-	-	-	-	-	-	-	-	-
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	40	3	126	13	58	36	9	3	2



