

# Genitourinary Disease-Oriented Team

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Clinical Research Treatment Trial Flowchart

## • 2025

■ Open to Accrual ■ Low Accruing ■ Pending Activation/Suspended

- UCI 25-32 (Mar): A Phase III, Randomized, Open-label Study of Belzutifan + Zanzalintinib Versus Cabozantinib for the Treatment of Participants with Locally Advanced or Metastatic RCC who Experienced Disease Recurrence During or After Prior Adjuvant Anti-PD-1/L1 Therapy (LITESPARK-033)
- UCI 25-33 (Mar): A Multicenter, Double-blind, Randomized Phase III Study of Belzutifan + Zanzalintinib Versus Belzutifan + Placebo in Participants with Locally Advanced or Metastatic RCC that have Progressed on or after both PD-1/L1 and VEGF-TKI Therapies in Sequence or in Combination (LITESPARK-034)
- UCI 25-99 (Gin; IIT): Single Dose CYTALUX (Pafolacianine, OTL38) for Intraoperative Imagein of Prostate Cancer - a Pilot Study
- UCI 25-100 (Daneshvar; IIT): Utilization of Flotufolastat 18F PET for Post-Focal Therapy Prostate Cancer Evaluation
- UCI 25-130 (Uchio): An Open-Label, International, Multicenter Phase II Study to Evaluate the Efficacy and Safety of Intravesical T3011 Injection in Participants with BCG-Unresponsive High Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) or BCG-Exposed, Chemotherapy Unresponsive Intermediate High-Risk NMIBC
- UCI 25-134 (Rezazadeh): A Phase Ib, 2-part, Multicenter, Single-arm, Open-label Study to Evaluate the Safety and Efficacy of a Nectin-4 Radiopharmaceutical ([<sup>225</sup>Ac]Ac-AKY-1189) in Patients with Previously Treated Locally Advanced or Metastatic Solid Tumors
- UCI 25-160 (Shahait): DIRECT-AI: Decision Impact Registry for Evaluation of Clinical Treatment with ArteraAI in Prostate Cancer

- 2026
  - UCI 26-19 (Exempt; Uchio): Validation of the Genomic Prostate Score (GPS) as a Predictive Biomarker of Oncologic Outcomes in Men with High-Risk Prostate Cancer (NCCN Guidelines v1.2025)
  - UCI 26-06 (EAP; Exempt; Daneshvar): ResQ132EX-NMIBC: Expanded Access Use of Recombinant Bacillus Calmette-Guérin in Nonmuscle Invasive Bladder Cancer



## SUPPORTIVE CARE

### UCI 20-59 (UCI)

6 Sessions of Goal-focused Emotion-Regulation Therapy (GET) or Individual Supportive Psychotherapy (ISP)

PI: Hoyt  
Coord: M. Haydon  
Accrual 78/175

### UCI 25-167 (UCI)

Understanding Adverse Biopsychosocial Outcomes and Unmet Needs Among Long-Term Young Adult Survivors of Testicular Cancer

PI: Hoyt  
Coord: M. Haydon  
Accrual 0/125



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**OBSERVATIONAL/RETROSPECTIVE**

**UCI 98-41 (UCI)**

Outcomes and Assessment of Prostate Cancer

PI: Ahlering  
Coord: J. Tran  
Accrual 2813/3380

**UCI 17-07 (UCI)**

(PROVOQ): Post-Radical Prostatectomy Outcome Assessment

PI: Ahlering  
Coord: J. Tran  
Accrual 1164/1875

**UCI 17-40 (UCI)**

Precision Medicine for Early Prostate Cancer

PI: Uchio  
Coord: D. Huttar  
Accrual 975/1027

**UCI 00-55 (UCI)**

Retrospective Evaluation of Prostate Cancer Clinical and Pathological Outcomes

PI: Ahlering  
Coord: L. Huynh  
Accrual 429/450

**UCI 23-159 (UCI)**

Prostate cancer and HPV

PI: Cozen  
Coord: TBD  
Accrual 0/240

**UCI 24-60 (UCI)**

Qualitative semi-structured interviews

PI: Hoyt  
Coord: TBD  
Accrual 17/20

**UCI 26-45(UCI)**

Health, Digital, and Numerical Literacy and Prostate-Related Knowledge in Men With Elevated PSA or With Prostate Cancer on Active Surveillance

PI: Shahait  
Coord: TBD  
Accrual 0/375



DIAGNOSTIC

UCI 23-223 (Curium)

Ph3 Cu64 PSMA I&T PETCT for newly dx prostate patients

PI: Uchio  
Coord: T. Cao, RN  
Accrual 6/10

UCI 25-54 (Clarity Pharmaceuticals)

64Cu-SAR-bisPSMA PET after biochemical recurrence

PI: Uchio  
Coord: A. Stelter  
Accrual 22/24

UCI 25-159 (UCI)

CTDNA-PSMA-BCR: A Single-Arm Trial of Circulating Tumor DNA-Guided Treatment Escalation and De-escalation in Biochemical Recurrent Prostate Cancer

PI: Shahait  
Coord: TBD  
Accrual 0/100

UCI 25-185 (Clarity Pharmaceuticals)

64Cu-SAR-bisPSMA PET prior to RARP

PI: Uchio  
Coord: TBD  
Accrual 0/10

UCI 25-100

Utilization of Flotufolostat 18F PET for Post-Focal Therapy Prostate Cancer Evaluation

PI: Daneshvar  
Coord: TBD  
Accrual 0/50



## SUPPORTIVE CARE/QUALITY OF LIFE

### UCI 24-70 (UCI)

Pre- and post-RT questionnaires

PI: Feinstein  
Coord: TBD  
Accrual 23/50

### UCI 24-128 (UCI)

Questionnaires, counseling, saliva collection

PI: Hoyt  
Coord: TBD  
Accrual 48/100

### UCI 25-31 (UCI)

QOL and cognitive effects of estradiol patch and darolutamide combination therapy for HSPC

PI: Rezazadeh  
Coord: TBD  
Accrual 0/50



RT

NRG GU013

Arm 1: SBRT (ultrahypofractionation) 5 fractions  
Arm 2: Conventional or moderate hypofractionation 20-45 fractions

PI: Hong  
Coord: J. Pon  
Accrual 6/10

SURGERY

UCI 23-137 (UCI)

Impact of Intraoperative ICG Use During Robotic-Assisted Radical Prostatectomy on Functional Outcomes

PI: Lee  
Coord: J. Go  
Accrual 74/400



## MULTIPLE LINES OF THERAPY

### ETCTN 10301

Ph1 completed, Ph2 open to accrual  
 A: 223Ra (bone-targeted alpha particle emitting radiopharmaceutical) IV x6  
 B: 223Ra IV x6 + M3814 (DNA-PK inhibitor) PO BID  
 C: 223Ra IV x6 + avelumab (anti-PD-L1 IgG1 Ab) IV x10 + M3814 PO BID

PI: Mar  
 Coord: J. Go  
 Accrual 17/25

### UCI 23-119 (Merck)

Arm 1: MK-5684 + HRT (appx. 600)  
 Arm 2: Alternative Abiraterone or Enzalutamide (appx. 600)

PI: Rezazadeh  
 Coord: J. Pon  
 Accrual 7/9

### UCI 23-204 (TELIX)

SUSPENDED

Cohort 1: TLX591 + abiraterone  
 Cohort 2: TLX591 + enzalutamide  
 Cohort 3: TLX591 + docetaxel

PI: Srinivas  
 Coord: A. Castro/A. Kote  
 Accrual 1/10

### UCI 24-79 (Amgen)

Phase 3 Study of Xaluritamig vs Cabazitaxel or Second ARDT in Subjects With mCRPC previously Treated With Chemotherapy

PI: Rezazadeh  
 Coord: A. Castro  
 Accrual 6/10

### SWOG S1802

Arm 1: SST Only  
 Arm 2: SST and Definitive Treatment of Primary Tumor

PI: Gin  
 Coord: J. Go  
 Accrual 2/10

### UCI 24-140A (Merck)

Phase 1/2 umbrella substudy of MK-2400-U01: ifinatamab deruxtecan (I-DXd)-based treatment combinations or I-DXd alone

PI: Mar  
 Coord: A. Castro  
 Accrual 0/7



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## MULTIPLE LINES OF THERAPY

### UCI 25-84

A Phase 3, Randomized Study of Xaluritamig Monotherapy, Xaluritamig Plus Abiraterone versus Investigator's Choice

PI: Rezazadeh  
Coord: TBD  
Accrual: 0/5

### UCI 24-34

Ph1 Dose Escalation and Expansion Study evaluating Safety, Tolerability and Anti-tumor Activity of [225Ac] Ac-FL-020, an anti-PSMA Radioconjugate (RDC)

PI: Srinivas  
Coord: R. Enaworu  
Accrual: 4/10

### UCI 24-158

A Phase III, Open-Label Study of Ifinatamab Deruxtecan Versus Docetaxel in Participants with Metastatic Castration-Resistant Prostate Cancer (mCRPC) (IDeate-Prostate01)

PI: Rezazadeh  
Coord: A. Kote  
Accrual: 1/8

### UCI 25-01

INV-9956 (CYP11A1 inhibitor) in mCRPC

PI: Uchio  
Coord: C. Thao/A. Stelter  
Accrual: 0/4

### CCTG-PR26

TRIPLE-SWITCH: Docetaxel + ARPI for mCRPC and suboptimal PSA response

PI: Yazdanpanah  
Coord: A. Kote  
Accrual: 0/5

### UCI 24-142 (KaliVir)

VET3-TGI +/- Pembrolizumab

PI: Uchio  
Coord: A. Stelter  
Accrual: 1/4



## MULTIPLE LINES OF THERAPY

### A032304

Radioligand Efficacy Compare by PSA-Response Outcome in MetCRPC wLutetium 177Lu PSMA RLT (RECIPROCAL)

PI: Yaz  
Coord: J. Go  
Accrual 0/8

### UCI 25-18

AcTFirst : AAA817+ARPI Versus Standard of Care in Adult Participants with PSMA-positive mCRPC

PI: Rezazadeh  
Coord: TBD  
Accrual 0/5

### UCI 26-81

First-in-Human VIR-5500 (AMX-500) in Participants With Prostate Cancer

PI: Rezazadeh  
Coord: TBD  
Accrual 0/6



## MUTATION-SPECIFIC

### Alliance A032102

Arm A: Valemetostat Tosylate(3201b)

Arm B: Cabazitaxel + Carboplatin

Arm C: Cabazitaxel or AR Targeting Agent or  
Lutetium Lu 177

PI: Rezazadeh

Coord: J. Go

Accrual 0/5

SINGLE LINE OF THERAPY



**NON-TREATMENT**

**ADJUVANT**

**UCI 13-03 (UCI)**  
Office-Based Percutaneous Ultrasound-Guided Renal Biopsy  
PI: Landman  
Coord: R. Yoon  
Accrual: 14/225



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MULTIPLE LINES OF THERAPY

UCI 22-130 (VUMC)

Ipi (anti-CTLA-4)/Nivo (anti-PD1) VS Nivo/Cabo (anti-VEGF TKI)

PI: Mar  
Coord: A. Castro  
Accrual 8/9

NRG GU012

Ph2 SABR for metastatic unresected RCC Standard Immunotherapy vs. SABR to primary (52Gy in 3 fracs) + Standard Immunotherapy

PI: Feinstein  
Coord: A. Castro  
Accrual: 1/5

SWOG S1931

Immunotherapy-Based Combination Therapy With or Without Cytoreductive Nephrectomy for Metastatic RCC

PI: Mar  
Coord: A. Kote  
Accrual 1/5

UCI 24-142 (KaliVir)

VET3-TGI +/- Pembrolizumab

PI: Uchio  
Coord: A. Stelter  
Accrual: 1/4

UCI 25-158

Orellanine treatment in patients with metastatic clear-cell or papillary renal cell carcinoma

PI: Mar  
Coord: TBD  
Accrual 0/3



**NON-INVASIVE: LOW GRADE**

Upper Tract

UCI 24-47 (Ferring Pharm)  
Nadofaragene Firadenovec vs. observation in IR NMIBC  
PI: Uchio  
Coord: A. Marinkovic  
Accrual 3/5

UCI 25-02 (UroGen)  
UGN-101 instillation for LG-UTUC  
PI: Uchio  
Coord: T. Cao, RN  
Accrual: 0/5

UCI 26-76 (UroGen)  
UGN 501 administered intravesically with recurrent (NMIBC)  
PI: Uchio  
Coord: TBD  
Accrual: 0/999



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## NON-INVASIVE – HIGH GRADE

### UCI 22-69 (enGene)

EG-70 for BCG-Unresponsive NMIBC and HR BCG-naïve or received incomplete treatment

PI: Uchio  
Coord: T. Cao, RN  
Accrual 1/5

### UCI 24-47 (Ferring)

Nadofaragene Firadenovec vs. observation in IR NMIBC

PI: Uchio  
Coord: A. Marinkovic  
Accrual 3/5

### Alliance A032303

Gemcitabine Alternating with BCG vs BCG alone for recurrent HG NMIBC

PI: Daneshvar  
Coord: J. Pon  
Accrual 1/10

### UCI 23-206

TARA-002 in HG NMIBC  
Cohort A: CIS +/- Ta/T1 BCG naïve/exposed  
Cohort B: CIS +/- Ta/T1 BCG unresponsive

PI: Uchio  
Coord: A. Marinkovic  
Accrual 4/12

### UCI 24-139 (CG Oncology)

Cretostimogene GRENADENOREPVEC in HR NMIBC

PI: Uchio  
Coord: A. Marinkovic  
Accrual 0/10

### UCI 24-46 (Ferring)

Nadofaragene firadenovec +/- gemcitabine and docetaxel or pembrolizumab in HG BCG-unresponsive NMIBC

PI: Uchio  
Coord: A. Marinkovic  
Accrual 2/5

### UCI 25-86 (ImmunityBio)

BCG + ALT-803 (N-803) for NMIBC

PI: Uchio  
Coord: TBD  
Accrual: 0/5



MUSCLE INVASIVE

UCI 23-72

Outcomes with use of multi parametric MRI (mpMRI) compared to diagnostic Transurethral Resection of Bladder Tumor (TURBT) in patients with suspected MIBC

PI: Mar  
Coord: A. Macaraeg  
Accrual 28/30

UCI 23-59

Adjuvant Sacituzumab Govitecan Plus Nivolumab in ctDNA Positive Patients

(USC and Hoag not yet open)

PI: Mar  
Coord: A. Castro  
Accrual 5/27

NRG-GU015

Phase III Adaptive Radiation for MIBC: Radiosensitizing chemotherapy

PI: Feinstein  
Coord: J. Pon  
Accrual 2/5

ETCTN 10636

Phase I Trial of CA-4948 in Combination With Pembrolizumab to Overcome Resistance to PD-1/PD-L1 Blockade in Metastatic Urothelial Cancer

PI: Mar  
Coord: J. Go  
Accrual: 4/5

UCI 26-73

Enfortumab Vedotin in Combination with Pembrolizumab for patients who are ineligible for or have Elected not to Undergo Cystectomy

PI: Mar  
Coord: TBD  
Accrual 0/5

UCI 26-74

Enfortumab Vedotin plus Pembrolizumab for Bladder Preservation in Participants with Muscle-invasive Bladder Cancer

PI: Mar  
Coord: TBD  
Accrual 0/5



ALL-COMERS

UCI 24-142 (KaliVir)

VET3-TGI +/- Pembrolizumab

PI: Uchio  
Coord: A. Stelter  
Accrual: 1/4

UCI 22-128 (Merck)

MK-2140 (Zilovertamab Vedotin) IV D1/D8 Q3W

PI: Rezazadeh  
Coord: A. Castro  
Accrual 0/3

ECOG-EA8231

A Phase III Randomized Trial of Pembrolizumab in Combination with Sacituzumab Govitecan vs Standard of Care in Anti-PD(L)1-Resistant Advanced Urothelial Cancer

PI: Mar  
Coord: A. Kote  
Accrual 2/5

UCI 24-191 (Daiichi Sankyo)

Phase 2/3 Dato-DXd + carboplatin or cisplatin vs. Gemcitabine + + Carboplatin or Cisplatin in la/mUC who progressed during or after EV+Pembro

PI: Rezazadeh  
Coord: A. Castro  
Accrual 0/5

UCI 25-184

An Interventional, Phase 1b/2, Open-Label Study to Investigate the Tolerability, Antitumor Activity, and Pharmacokinetics of PF-08634404 Monotherapy or in Combination With Enfortumab Vedotin

PI: Mar  
Coord: TBD  
Accrual 0/5



MUTATION-SPECIFIC

ETCTN 10144

Olaparib (PARP inhibitor) PO

Non-prostate GU tumors with DNA-repair defects (BRCA1, BRCA2, ATM, BAP1, MSH2, PALB2, and BRIP1 and others)

PI: Rezazadeh  
Coord: A. Castro  
Accrual 5/8

UCI 22-39 (SeaGen)

CLOSED Cohort A: DV (HER2-positive) IHC 3+, or IHC 2+ and ISH-positive  
CLOSED Cohort B: DV (HER2-low) IHC 2+ and ISH-negative, or IHC 1+  
OPEN Cohort C: Randomized arm open

PI: Mar  
Coord: A. Castro  
Accrual 6/10

UCI 24-159 (Eli Lilly)

Ph1a LOXO-435 monotherapy  
Ph1b LOXO-435 +/- pembro +/- EV  
B3 Pembro + LOXO-435  
B5 Pembro + EV + LOXO-435

PI: Mar  
Coord: A. Kote  
Accrual 3/10

UCI 25-183

Randomized, Double-blind, Placebo-controlled Study Evaluating the Efficacy and Safety of Vepugratinib Combined with EV/Pembro in Adults with an FGFR3 Genetic Alteration.

PI: Mar  
Coord: TBD  
Accrual 0/7



## PREVENTATIVE

## HEALTH SERVICES RESEARCH

### UCI 21-174 (UCI)

Preserving Medical Records After a Cancer Diagnosis for Subsequent Generations to Use

PI: Zell  
Coord: TBD  
Accrual: 0/100

## SUPPORTIVE CARE

## DIAGNOSTIC

### UCI 25-44 (UCI)

ctDNA using Northstar-Response and Northstar-Select for TRM in GU malignancies with bone or LN metastases

PI: Yazdanpanah  
Coord: TBD  
Accrual 0/24



MUTATION-SPECIFIC

UCI 22-87 (Revolution  
Med)

\*1L

Documented KRAS G12A, G12D, G12R, G12S,  
G12V

**SLOT RSVP REQ**

PI: Nagasaka  
Coord: J. Choe  
Accrual: 43/50



ALL-COMERS

**UCI 25-186**

First-In-Human, Open-Label, Dose Escalation Trial with Expansion Dose Cohorts to Evaluate the Safety, Pharmacokinetics and Efficacy of GEN1106 in Participants with Urothelial, Breast, Lung and Head and Neck Carcinomas

PI: Rezazadeh  
Coord: TBD  
Accrual: 0/5

**UCI 22-26 (Cosmo Technologies)**

**SUSPENDED**

Androgen and glucocorticoid receptor antagonist

Part 1 (dose esc): Relapsed/refractory adv/met solid tumor  
Part 2 (dose exp): Relapsed/refractory adv/met solid tumors TBD (likely prostate adeno)

PI: Dayyani  
Coord: B. Nguyen  
Accrual: 11/12

**UCI 24-142 (KaliVir)**

VET3-TGI +/- Pembrolizumab

PI: Uchio  
Coord: A. Stelter  
Accrual: 1/4

**NRG BN013**

Phase III: Single fraction Stereotactic Radiosurgery (SRS) vs Fractionated Stereotactic Radiosurgery (FSRS)

PI: Simon  
Coord: S. Beltran  
Accrual: 1/5



ALL-COMERS

UCI 25-14

Antineoplastic Therapy

PI: Rezazadeh  
Coord: J. Seneriches  
Accrual: 10/50

UCI 25-83

Mobile Health Intervention to Improve Adherence to Oral Anticancer Therapy

PI: Sadigh  
Coord: TBD  
Accrual: 34/35

UCI 24-176 (Daiichi Sankyo))

Evaluate Efficacy and Safety of Raludotatug Deruxtecan (R-DXd) in Participants with Advanced/Metastatic Solid Tumors

PI: Mar  
Coord: J. Go  
Accrual: 0/5