# Northern Light Cancer Research Clinical Trials

## Biliary Tract Cancers

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>SWOG S1815 NCT03768414</td>
<td>Temp. Susp. 03/5/20 A Phase III Randomized Trial of Gemcitabine, Cisplatin, and Nab-Paclitaxel vs Gemcitabine and Cisplatin in Newly Diagnosed Advanced Biliary Tract Cancers</td>
</tr>
</tbody>
</table>

## Breast - Neoadjuvant

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alliance A011202 NCT01901094</td>
<td>Temp. Susp. A Randomized Phase III Trial Evaluating the Role of Axillary Lymph Node Dissection in Breast Cancer Patients (cT1-3N1) Who Have Positive Sentinel Lymph Node Disease After Neoadjuvant Chemotherapy</td>
</tr>
<tr>
<td>DFCI 16-052 PELOPS NCT02764541</td>
<td>PELOPS: Palbociclib and Endocrine Therapy for Lobular Breast Cancer Preoperative Study: A Randomized Phase II Study of Palbociclib With Endocrine Therapy vs. Endocrine Therapy Alone for Invasive Lobular Carcinoma and Invasive Ductal Carcinoma</td>
</tr>
<tr>
<td>ECOG-ACRIN EA1131 NCT02445391</td>
<td>Randomized Phase III Post-Operative Trial of Platinum Based Chemotherapy Vs. Observation in Patients with Residual Triple-Negative Basal-Like Breast Cancer following Neoadjuvant Chemotherapy</td>
</tr>
</tbody>
</table>

## Breast - DCIS

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>AFT-25 COMET NCT02926911</td>
<td>Comparison of Operative to Monitoring and Endocrine Therapy (COMET) Trial for Low Risk DCIS: A Phase III Prospective Randomized Trial</td>
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</tbody>
</table>

## Breast - Adjuvant Triple Negative

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Details</th>
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</thead>
<tbody>
<tr>
<td>Alliance A211601 NCT03609021</td>
<td>Evaluation of Mammographic Breast Density Effect of Aspirin: A companion study to Alliance Study A011502</td>
</tr>
<tr>
<td>NRG-BR003 NCT02488967</td>
<td>A Randomized Phase III Trial of Adjuvant Therapy Comparing Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel with or without Carboplatin for Node-Positive or High-Risk Node-Negative Invasive Breast Cancer</td>
</tr>
<tr>
<td>ECOG-ACRIN EA1131 NCT02445391</td>
<td>A Randomized Phase III Post-Operative Trial of Platinum Based Chemotherapy Vs. Observation in Patients with Residual Triple-Negative Basal-Like Breast Cancer following Neoadjuvant Chemotherapy</td>
</tr>
<tr>
<td>SWOG S1418 NCT02954874</td>
<td>DTL Required A Randomized, Phase III Trial to Evaluate the Efficacy and Safety of MK-3475 (Pembrolizumab) as Adjuvant Therapy for triple Receptor-Negative Breast Cancer with &gt;/= 1 cm Residual Invasive Cancer or Positive Lymph Nodes (ypN+) after Neoadjuvant Chemotherapy</td>
</tr>
</tbody>
</table>
### BREAST - Adjuvant HR Positive

<table>
<thead>
<tr>
<th>Trial Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alliance A011401 NCT02750826</td>
<td>Randomized Phase III Trial Evaluating the Role of Weight Loss in Adjuvant Treatment of Overweight and Obese Women with Early Breast Cancer</td>
</tr>
<tr>
<td>Alliance A011502 NCT02927249</td>
<td>A randomized phase III double blinded placebo-controlled trial of aspirin as adjuvant therapy for node-positive, HER2 negative breast cancer: the ABC trial</td>
</tr>
<tr>
<td>DFCI 18-124 ATOP NCT03587740</td>
<td>Adjuvant Ado-Trastuzumab Emtansine (T-DM1) for Older Patients With Human Epidermal Growth Factor Receptor 2 (HER2)-Positive Breast Cancer</td>
</tr>
</tbody>
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### BREAST - Adjuvant HER2+

<table>
<thead>
<tr>
<th>Trial Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ECOG-ACRIN EA1181 NCT04266249</td>
<td>(CompassHER2-pCR): Preoperative THP and Postoperative HP in Patients Who Achieve a Pathologic Complete Response</td>
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</table>

### Breast - Adjuvant XRT

<table>
<thead>
<tr>
<th>Trial Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>CCTG MA.39 NCT03488693</td>
<td>A Randomized Trial of Regional Radiotherapy in Biomarker Low Risk Node Positive Breast Cancer</td>
</tr>
<tr>
<td>NSABP B-51 NCT01872975</td>
<td>A Randomized Phase III Clinical Trial Evaluating Post-Mastectomy Chestwall and Regional Nodal XRT and Post-Lumpectomy Regional Nodal XRT in Patients with Positive Axillary Nodes Before Neoadjuvant Chemotherapy Who Convert to Pathologically Negative Axillary Nodes After Neoadjuvant Chemotherapy</td>
</tr>
<tr>
<td>SWOG S1706 NCT03598257</td>
<td>A Phase II Randomized Trial of Olaparib (NSC-747856) Administered Concurrently with Radiotherapy versus Radiotherapy alone for Inflammatory Breast Cancer</td>
</tr>
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</table>

### Breast - Metastatic

<table>
<thead>
<tr>
<th>Trial Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>NRG BR004 NCT03199885 DTL Required</td>
<td>A Randomized, Double-Blind, Phase III Trial of Paclitaxel/Trastuzumab/Pertuzumab with Atezolizumab or Placebo in First-Line HER2-Positive Metastatic Breast Cancer</td>
</tr>
</tbody>
</table>

### Breast - Locally Advanced/Metastatic HER2+/HR+

<table>
<thead>
<tr>
<th>Trial Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>DFCI 17-318 NCT03289039</td>
<td>A Phase 2 Study of Neratinib With or Without Fulvestrant in HER2-Positive, ER-Positive Metastatic Breast Cancer</td>
</tr>
</tbody>
</table>
# Northern Light Cancer Research Clinical Trials

## ER+/HER2-

<table>
<thead>
<tr>
<th>Trial ID</th>
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</thead>
<tbody>
<tr>
<td>DFCI 17-101 PACE</td>
<td>Palbociclib After CDK and Endocrine Therapy (PACE): A Randomized Phase II Study of Fulvestrant, Palbociclib, and Avelumab for Endocrine Pre-Treated ER+/HER2- Metastatic Brest Cancer</td>
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<tr>
<td>NCT03147287</td>
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## Triple Negative

<table>
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<th>Trial ID</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>DFCI 17-512</td>
<td>A Randomized Phase 2 Trial of Carboplatin With or Without Nivolumab in First-Line Metastatic Triple-Negative Breast Cancer</td>
</tr>
<tr>
<td>NCT03414684</td>
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## Radiation

<table>
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<th>Trial ID</th>
<th>Description</th>
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<tbody>
<tr>
<td>DFCI 16-304</td>
<td>Study of Radiation Fractionation on Patient Outcomes After Breast Reconstruction (FABREC) for Invasive Breast Carcinoma</td>
</tr>
<tr>
<td>NCT03422003</td>
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## Children's Oncology Group Registry

<table>
<thead>
<tr>
<th>Trial ID</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>APEC14B1 (Patient's 25 and Younger)</td>
<td>Project EveryChild: A Registry, Eligibility Screening, Biology and Outcome Registry</td>
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</table>

## COLORECTAL

<table>
<thead>
<tr>
<th>Trial ID</th>
<th>Description</th>
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<tbody>
<tr>
<td>Alliance A021502</td>
<td>Randomized Trial of Standard Chemotherapy Alone or Combined with Atezolizumab as Adjuvant Therapy for Patients with Stage III Colon Cancer and Deficient DNA Mismatch Repair</td>
</tr>
<tr>
<td>NCT02912559</td>
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<tr>
<td>DTL Required</td>
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<tr>
<td>Alliance A021703</td>
<td>Randomized Double-Blind Phase III Trial of Vitamin D3 Supplementation in Patients with Previously Untreated Metastatic Colorectal Cancer (SOLARIS)</td>
</tr>
<tr>
<td>NCT04094688</td>
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<tr>
<td>NRG GI002</td>
<td>A Phase II Clinical Trial Platform of Sensitization Utilizing Total Neoadjuvant Therapy (TNT) in Rectal Cancer</td>
</tr>
<tr>
<td>NCT02921256</td>
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</tr>
<tr>
<td>Temp susp 05/13/19</td>
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<tr>
<td>NRG GI004</td>
<td>NRG-GI004/SWOG-S1610: Colorectal Cancer Metastatic dMMR Immuno-Therapy (COMMIT) Study: A Randomized Phase III Study of mFOLFOX6/Bevacizumab Combination Chemotherapy with or without Atezolizumab or Atezolizumab Monotherapy in the First-Line Treatment of Patients with Deficient DNA Mismatch Repair (dMMR) Metastatic Colorectal Cancer</td>
</tr>
<tr>
<td>NCT02997228</td>
<td></td>
</tr>
<tr>
<td>DTL Required</td>
<td></td>
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<tr>
<td>NRG-GI005</td>
<td>Phase II/III Study of Circulating tumor DNA as a Predictive Biomarker in Adjuvant Chemotherapy in Patients with Stage IIA Colon Cancer (COBRA)</td>
</tr>
<tr>
<td>NCT04068103</td>
<td></td>
</tr>
<tr>
<td>SWOG S1820</td>
<td>A Randomized Trial of the Altering Intake, Managing Symptoms Intervention for Bowel Dysfunction in Rectal Cancer Survivors Compared to a Healthy Living Education Control: A Feasibility and Preliminary Efficacy Study (AIMS-RC)</td>
</tr>
<tr>
<td>NCT04205955</td>
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<tr>
<td>SWOG S1922</td>
<td>Randomized Phase II Selection Study of Ramucirumab and Paclitaxel Versus FOLFIRI in Refractory Small Bowel Adenocarcinoma</td>
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<tr>
<td>NCT04205968</td>
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### Northern Light Cancer Research Clinical Trials

#### Gastrointestinal

<table>
<thead>
<tr>
<th>Code</th>
<th>Study Details</th>
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</thead>
<tbody>
<tr>
<td>ECOG-ACRIN EA2187 NCT04175912</td>
<td>A Phase 2 Study of Pevonedistat in Combination with Carboplatin and Paclitaxel in Advanced Intrahepatic Cholangiocarcinoma</td>
</tr>
</tbody>
</table>

#### Genitourinary

<table>
<thead>
<tr>
<th>Code</th>
<th>Study Details</th>
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</thead>
<tbody>
<tr>
<td>Alliance A031501 NCT03244384</td>
<td>Phase III randomized “Adjuvant study of MK-3475 (pembrolizumab) in muscle invasive and locally Advanced urothelial carcinoma” (AMBASSADOR) versus observation</td>
</tr>
<tr>
<td>PREVAIL NCT03788746</td>
<td>A Prospective, Non-Interventional Study to Assess the Prevalence of PD-L1 Expression in the First-Line Setting of Locally Advanced/Unresectable or Metastatic Urothelial Carcinoma</td>
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#### GYN

<table>
<thead>
<tr>
<th>Code</th>
<th>Study Details</th>
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<tbody>
<tr>
<td>NRG GY005 NCT02502266</td>
<td>A Randomized Phase II/III study of the combination of Cediranib and Olaparib compared to Cediranib or Olaparib alone, or Standard of care chemotherapy in women with recurrent platinum-resistant or -refractory ovarian, fallopian tube, or primary peritoneal cancer (COCOS)</td>
</tr>
<tr>
<td>NRG GY009 NCT02839707</td>
<td>A Randomized, Phase II/III Study of Pegylated Liposomal Doxorubicin and CTEP-Supplied Atezolizumab versus Pegylated Liposomal Doxorubicin/Bevacizumab and CTEP-Supplied Atezolizumab versus Pegylated Liposomal Doxorubicin/Bevacizumab in Platinum Resistant Ovarian Cancer</td>
</tr>
<tr>
<td>NRG GY014 NCT03348631</td>
<td>A Phase II Study of Tazemetostat (EPZ-6438) in Recurrent or Persistent Endometrioid or Clear Cell Carcinoma of the Ovary, and Recurrent or Persistent Endometrioid Endometrial Adenocarcinoma</td>
</tr>
<tr>
<td>NRG GY019 NCT04095364</td>
<td>A Randomized Phase III, Two-Arm Trial of Paclitaxel/Carboplatin /Maintenance Letrozole vs Letrozole Monotherapy in Patients with Stage II-IV, Primary Low-Grade Serous Carcinoma of the Ovary or Peritoneum</td>
</tr>
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#### Leukemia - Untreated/Newly Diagnosed

<table>
<thead>
<tr>
<th>Code</th>
<th>Study Details</th>
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</thead>
<tbody>
<tr>
<td>Alliance A041701 NCT03701308</td>
<td>A Randomized Phase II/III Study of Conventional Chemotherapy +/- Uproleselan (GMI-1271) in Older Adults with Acute Myeloid Leukemia Receiving Intensive Induction Chemotherapy</td>
</tr>
<tr>
<td>Alliance A041702 NCT03737981</td>
<td>A Randomized Phase III Trial of Ibrutinib Plus Obintuzumab versus Ibrutinib Plus Venetoclax and Obintuzumab in Untreated Older Patients (&gt; 70) Years of Age) with Chronic Lymphocytic Leukemia (CLL)</td>
</tr>
<tr>
<td>SWOG S1612 NCT03092674</td>
<td>A Randomized Phase II/III Trial of &quot;Novel Therapeutics&quot; versus Azacitidine in Newly Diagnosed Patients with Acute Myeloid Leukemia (AML) or High-Risk Myelodysplastic Syndrome (MDS), Age 60 or Older</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th><strong>Lung Cancer - Screening Adjuvant</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Alliance A151216</strong>&lt;br&gt;(ALCHEMIST)&lt;br&gt;NCT02194738</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Lung Cancer - Adjuvant</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Alliance A081105</strong>&lt;br&gt;(ALCHEMIST)&lt;br&gt;NCT02193282</td>
</tr>
<tr>
<td><strong>ECOG E4512</strong>&lt;br&gt;(ALCHEMIST)&lt;br&gt;NCT 02201992</td>
</tr>
<tr>
<td><strong>SWOG 1827</strong>&lt;br&gt;NCT04155034</td>
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<table>
<thead>
<tr>
<th><strong>Lung Cancer - 1st Line Metastatic</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ECOG-ACRIN EAS163</strong>&lt;br&gt;NCT03793179</td>
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<table>
<thead>
<tr>
<th><strong>Lung Cancer - 2nd Line Metastatic</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LUNGMAP</strong>&lt;br&gt;NCT02154490</td>
</tr>
<tr>
<td><strong>NRG-LU003</strong>&lt;br&gt;NCT03737994</td>
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<tr>
<td><strong>SWOG S1800A</strong>&lt;br&gt;NCT03971474</td>
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<tr>
<td><strong>SWOG S1900A</strong>&lt;br&gt;NCT03845296</td>
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# Northern Light Cancer Research Clinical Trials

## Lymphoma

<table>
<thead>
<tr>
<th>Study ID</th>
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<tbody>
<tr>
<td>Alliance A051701 NCT03984448</td>
<td>Randomized Phase II/III Study of Venetoclax (ABT 199) Plus Chemoimmunotherapy for MC/BCL2 Double-Hit and Double-Expressing Lymphomas</td>
</tr>
<tr>
<td>ECOG-ACRIN EA4181 NCT04115631</td>
<td>A Randomized 3 Arm Phase II Study Comparing 1) Bendamustine, Rituximab and High Dose Cytarabine (BR/CR), 2) Bendamustine, Rituximab, High Dose Cytarabine and Acalabrutinib (BR/CR-A), and 3) Bendamustine, Rituximab and Acalabrutinib (BR-A) in Patients &lt; 70 Years old with Untreated Mantle Cell Lymphoma</td>
</tr>
</tbody>
</table>

## Lymphoma - Relapsed

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>UTX-TGR-205-UNITY NCT02793583</td>
<td>A Phase 2b Randomized Study to Assess the Efficacy and Safety of the Combination of Ublituximab + TGR-1202 With or Without Bendamustine and TGR-1202 Alone in Patients With Previously Treated Non-Hodgkin’s Lymphoma</td>
</tr>
</tbody>
</table>

## Lymphoma - Locally Advanced Metastatic

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ECOG-ACRIN EA6141 NCT0239571</td>
<td>Randomized Phase II/III Study of Nivolumab plus Ipilimumab plus Sargramostim versus Nivolumab plus Ipilimumab in Patients with Unresectable Stage III or Stage IV Melanoma</td>
</tr>
<tr>
<td><strong>Temp. closed to accrual</strong></td>
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</tbody>
</table>

## Melanoma - Adjuvant

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Description</th>
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<tbody>
<tr>
<td>SWOG S1801 NCT03698019</td>
<td>A Phase II Randomized Study of Adjuvant vs. Neoadjuvant MK-3475 (Pembrolizumab) for Clinically Detectable Stage III-IV High-Risk Melanoma</td>
</tr>
</tbody>
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## Multiple Tumor Types

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Description</th>
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<tbody>
<tr>
<td>ECOG-ACRIN EAY131 (MATCH) NCT02465060</td>
<td>Molecular Analysis for Therapy Choice (MATCH)</td>
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</table>

## Myeloma

<table>
<thead>
<tr>
<th>Study ID</th>
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<tbody>
<tr>
<td>SWOG S1803 NCT04071457</td>
<td>Phase III Study of Daratumumab/HuPH20 (NSC-810307) + Lenalidomide or Lenalidomide as Post0Autologous Stem Cell Transplant Maintenance Therapy in Patients with Multiple Myeloma (MM) using Minimal Residual Disease to Direct Therapy Duration (DRAMMATIC STUDY)</td>
</tr>
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## Myeloma - Relapsed/Refractory

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>Alliance A061202 NCT002004275</td>
<td>A Phase I/II Study of Pomalidomide, Dexamethasone and Ixazomib VS. Pomalidomide and Dexamethasone for Patients with Multiple Myeloma Relapsing on Lenalidomide as Part of First Line Therapy</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th><strong>Prevention</strong></th>
<th><strong>Prostate</strong></th>
<th><strong>Rare Tumors</strong></th>
<th><strong>Renal</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AFT-28 CANVAS</strong>&lt;br&gt;NCT02744092</td>
<td><strong>Alliance A151804</strong>&lt;br&gt;NCT04242095</td>
<td><strong>SWOG S1609</strong>&lt;br&gt;NCT02834013</td>
<td><strong>ECOG ACRIN EA8143</strong>&lt;br&gt;NCT03055013&lt;br&gt;<strong>DTL Required</strong></td>
</tr>
<tr>
<td>Direct Oral Anticoagulants (DOACs) vs. LMWH +/- Warfarin for VTE in Cancer: A Randomized Effectiveness Trial (CANVAS Trial)</td>
<td>Establishment of a National Biorepository to Advance Studies of Immune-Related Adverse Events</td>
<td>A Phase 3 Study of Androgen Annihilation in High-Risk Biochemically Relapsed Prostate Cancer</td>
<td>A Phase 3 Randomized Study Comparing Perioperative Nivolumab vs. Observation in Patients with Localized Renal Cell Carcinoma Undergoing Nephrectomy (PROSPER RCC)</td>
</tr>
<tr>
<td><strong>Alliance A221701</strong>&lt;br&gt;NCT03839940</td>
<td><strong>SWOG S1802</strong>&lt;br&gt;NCT03678025</td>
<td><strong>NRG-GU006</strong>&lt;br&gt;NCT037371719&lt;br&gt;<strong>Temp. closed</strong></td>
<td><strong>Alliance A031704</strong>&lt;br&gt;(PDIGREE)&lt;br&gt;NCT03793166</td>
</tr>
<tr>
<td>Phase III Placebo-Controlled Trial to Evaluate Dexamethasone Use for Everolimus-Induced Oral Stomatitis: Prevention versus Early Treatment Approaches</td>
<td>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</td>
<td>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</td>
<td>PD-Inhibitor (Nivolumab) and Ipilimumab Followed by Nivolumab vs. VEGFTKI Cabozantinib with Nivolumab: A Phase III Trial in Metastatic Untreated Renal Cell Cancer (PDIGREE)</td>
</tr>
</tbody>
</table>

**DART:** Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors