



MASTER TRIAL LIST

OCTOBER 2022

 New or ReOpened Trials
 No Trials Currently Available

JUST IN TIME TRIALS (JIT)

AML	ANAL	ALL
APL	BLADDER-UROTHELIAL	BRAIN
BREAST/ GYN	CANCER CONTROL	
CLL	CML	COLON-RECTAL
ESOPHAGEAL - GASTRIC	HEAD & NECK	LYMPHOMA
MDS	MELANOMA	MERKEL
MOLECULAR STUDIES	MULTIPLE MYELOMA	NEUROENDOCRINE
NSCLC	PANCREATIC	PROSTATE
RADIATION TRIALS	RENAL CELL	SMALL CELL LUNG CANCER

Updated 10.26.22

RADIATION LOCATIONS:

OSF Glen Oak - OSF main hospital
OSF Route 91 (attached to Illinois CancerCare)
UPHM - Unity Point Health Methodist
Galesburg - Western Illinois Cancer Treatment Center
SJMC - St Joseph Medical Center



JUST IN TIME (JIT) TRIALS

*Contact Disease Specific Navigator

Multi-Disease Site: Advanced/Metastatic Solid Tumors

[RAIN-3202](#)

A Phase 2 Basket Study of Milademetan in Advanced/Metastatic Solid Tumors

Carcinoid

[S2104](#)

Randomized Phase II Trial of Postoperative Adjuvant Capecitabine and Temozolomide Versus Observation in High-Risk Pancreatic Neuroendocrine Tumors

Endometrial

[GY026](#)

NEW! A Phase II/III Study of Paclitaxel/Carboplatin Alone or Combined With Either Trastuzumab and Hyaluronidase-Oysk (HERCEPTIN HYLECTA) or Pertuzumab, Trastuzumab, and Hyaluronidase-Zzxf (PHESGO) in HER2 Positive, Stage I-IV Endometrial Serous Carcinoma or Carcinosarcoma

Gastrointestinal

[EA2187](#)

Temporarily closed Phase II study of Pevonedistat in Combincatoin with Carbo and paclitaxel in advanced intrahepatic cholangiocarcinoma.

Genitourinary - Rare

[A031702](#)

Phase II Study of Cabozantinib in Combination with Nivolumab and Ipilimumab in Rare Genitourinary Tumors (*temp closed cohorts - small cell carcinoma/neuroendorine & adenocarcinoma of bladder, penile, and misc GU tract variants, renal medullary carcinoma, and rare GU*)

Head & Neck

[EA3191](#)

A Phase II Randomized Trial of Adjuvant Therapy With Pembrolizumab After Resection of Recurrent/Second Primary Head and Neck Squamous Cell Carcinoma With High Risk Features

Lung

[S1934](#)

Randomized Phase II Trial of Trimodality +/- Atezolizumab in Resectable Superior Sulcus Non-Small Cell Lung Cancer. **NASSIST** (Neoadjuvant Chemoradiation +/- Immunotherapy Before Surgery for Superior Sulcus Tumors)

Multi-Disease	
<u>S1614</u>	<i>(temp closed)</i> A Phase III Randomized Trial of Prophylactic Antiviral Therapy in Patients with Current or past hepatitis B Virus Infection Receiving Anti-Cancer Therapy for Solid Tumors
Pancreas	
<u>S2001</u>	Randomized Phase II Clinical Trial of Olaparib + Pembrolizumab vs. Olaparib Alone as Maintenance Therapy in Metastatic Pancreatic Cancer Patients with Germline BRCA1 or BRCA2 Mutations
<u>S2104</u>	Randomized Phase II Trial of Postoperative Adjuvant Capecitabine and Temozolomide Versus Observation in High-Risk Pancreatic Neuroendocrine Tumors
Rectal	
<u>EA2201</u>	(RT at Glen Oak, UPHM, Galesburg) A Phase II Study of Neoadjuvant Nivolumab Plus Ipilimumab and Short-Course Radiation in MSI-H/dMMR Locally Advanced Rectal Adenocarcinoma
Renal Cell Carcinoma	
<u>S2200</u>	A Phase II Randomized Trial of Cabozantinib (NSC #761968) With or Without Atezolizumab (NSC #783608) in Patients With Advanced Papillary Renal Cell Carcinoma (PAPMET2)
Sarcoma	
<u>A091902</u>	A Multicenter Phase II Trial of Paclitaxel With and Without Nivolumab in Taxane Naive, and Nivolumab and Cabozantinib in Taxane Pretreated Subjects With Angiosarcoma <i>(closed to taxane pre-treated pts only)</i>
Skin	
<u>A091802</u>	Phase II randomized Trial of Avelumab plus cetuximab versus avelumab alone in advanced cutaneous Squamous cell carcinoma of skin
Thymoma	
<u>S1701</u>	<i>Closing 9/29/22</i> A Randomized Phase II Trial of Carboplatin-Paclitaxel with or without Ramucirumab in Patients with Unresectable Locally Advanced, Recurrent, or Metastatic Thymic Carcinoma

MASTER TRIAL LIST

OCTOBER 2022

[MENU](#)

AML

Navigator - Heather x3661



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ANAL

Navigator - Carrie x3621

<p><u>EA2176</u></p> <p>SCHEMA</p>	<p>A Randomized Phase III Study of Immune Checkpoint Inhibition With Chemotherapy in Treatment-Naive Metastatic Anal Cancer Patients</p>
<p><u>EA2182</u></p>	<p>(RT at UPHM and Glen Oak) A Randomized Phase II Study of De-Intensified ChemoRadiation for Early-Stage Anal Squamous Cell Carcinoma (DECREASE)</p>



ILLINOIS
CANCERCARE, P.C.

Specializing in Cancer and Blood Disorders

MASTER TRIAL LIST

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[MENU](#)

APL

Navigator - Heather x3661

There are no trials available at this time



ILLINOIS
CANCERCARE, P.C.

Specializing in Cancer and Blood Disorders

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ACUTE LYMPHOBLASTIC LEUKEMIA

Navigator - Heather x3661



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BLADDER / UROTHELIAL

Navigator - Carrie x3621

ADJUVANT / NEOADJUVANT

<p><u>EA8185</u></p>	<p>(RT pending at Glen Oak & Rt-91) Phase 2 Study of Bladder-Sparing Chemoradiation With MEDI4736 (Durvalumab) in Clinical Stage 3, Node Positive Bladder Cancer (INSPIRE)</p>
<p><u>S1806</u></p> <p>SCHEMA</p>	<p>(RT at Glen Oak, SJMC, UPHM and Galesburg) Phase III Randomized Trial of Concurrent Chemoradiotherapy with or without Atezolizumab in Localized Muscle Invasive Bladder Cancer</p>
<p><u>S2011</u></p> <p>SCHEMA</p>	<p>Randomized Phase II Trial of Gemcitabine, Avelumab and Carboplatin vs. No Neoadjuvant Therapy Preceding Surgery for Cisplatin-Ineligible Muscle-Invasive Urothelial Carcinoma: SWOG GAP TRIAL</p>
<h3>METASTATIC</h3>	
<p><u>A031901</u></p> <p>SCHEMA</p>	<p>Duration of Immune Checkpoint Therapy in Locally Advanced or Metastatic Urothelial Carcinoma: A Randomized Phase 3 Non-Inferiority Trial</p>
<p><u>A032001</u></p> <p>SCHEMA</p>	<p>Phase III Randomized Trial of Maintenance Cabozantinib and Avelumab vs Maintenance Avelumab After First-Line Platinum-Based Chemotherapy in Patients With Metastatic Urothelial Cancer</p>
<p><u>A032002</u></p> <p>SCHEMA</p>	<p>(RT at Glen Oak) Phase II Randomized Trial of Atezolizumab Versus Atezolizumab and Radiation Therapy for Platinum Ineligible/Refractory Metastatic Urothelial Cancer (ART)</p>



MASTER TRIAL LIST

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BRAIN

Navigator - Carrie x3621

<p><u>A071702</u></p> <p><small>SCHEMA</small></p>	<p>A Phase II Study of Checkpoint Blockade Immunotherapy in Patients With Somatically Hypermethylated Recurrent WHO Grade 4 Glioma</p>
<p><u>BN007</u></p> <p><small>SCHEMA</small></p>	<p>Temporarily Closed (RT at UPHM, Glen Oak, Galesburg) A Randomized Phase II/III Open-Label Study of Ipilimumab and Nivolumab Versus Temozolomide in Patients With Newly Diagnosed MGMT (Tumor O-6-Methylguanine DNA Methyltransferase) Unmethylated Glioblastoma</p>
<p><u>BN011</u></p> <p><small>SCHEMA</small></p>	<p>(RT credentialing pending) A Phase III Trial of Gleostine® (Lomustine)-Temozolomide Combination Therapy Versus Standard Temozolomide in Patients With Methylated MGMT Promoter Glioblastoma</p>
<p><u>N0577</u></p>	<p>(RT at Glen Oak, RT 91, and UPHM) Phase III Intergroup Study of Radiotherapy with Concomitant and Adjuvant Temozolomide versus Radiotherapy with Adjuvant PCV Chemotherapy in Patients with 1p/19q Co-deleted Anaplastic Glioma or Low Grade Glioma</p>



BREAST

Navigator - Angie x3613

DCIS

AFT-25

Comparing an Operation to Monitoring, With or Without Endocrine Therapy Trial For Low Risk DCIS: A Phase III Prospective Randomized Trial (**COMET**)

NEO/ADJUVANT TREATMENT

S1706*

Not Actively Screening - Contact Navigator - A Phase II Randomized Trial of Olaparib (NSC-747856) Administered Concurrently with Radiotherapy versus Radiotherapy Alone for Inflammatory Breast Cancer (**All biomarker subgroups eligible**) | *JIT TRIAL - expect 1 week delay to consent pt

Neo/Adjuvant - HER2 Positive

A011801

Not Actively Screening - contact Navigator - The CompassHER2 Trials (Comprehensive Use of Pathologic Response Assessment to Optimize Therapy in HER2-Positive Breast Cancer) CompassHER2 Residual Disease (RD), a Double-Blinded, Phase III Randomized Trial of T-DM1 Compared With T-DM1 and Tucatinib

EA1181

Preoperative THP and Postoperative HP in Patients Who Achieve a Pathologic Complete Response (CompassHER2-pCR) (*Closed to Her2+/ER+ w/ tumor 2.1-3cm and node negative*)

Neo/Adjuvant - Hormone Receptor Positive / HER2 Negative

BR007



(RT at Galesburg, Glen Oak, Rt 91, UPHM, SJMC) Phase III Clinical Trial Evaluating De-Escalation of Breast Radiation for Conservative Treatment of Stage I, Hormone Sensitive, HER-2 Negative, Oncotype Recurrence Score Less Than or Equal to 18 Breast Cancer

Neo/Adjuvant - Triple Negative

no

METASTATIC TREATMENT

Metastatic - HER2 Positive *(no trials at this time)*

Metastatic - Hormone Receptor Positive / HER2 Negative

S1703

Not Actively Screening - contact Navigator - Randomized Non-Inferiority Trial Comparing Overall Survival of Patients Monitored with Serum Tumor Marker Directed Disease Monitoring (STMDDM) Versus Usual Care in Patients with Metastatic Hormone Receptor Positive HER-2 Negative Breast Cancer

S2007

Not Actively Screening - contact Navigator- A Phase II Trial of Sacituzumab Govitecan (IMMU-132) (NSC #820016) for Patients With HER2-Negative Breast Cancer and Brain Metastases

Metastatic - Triple Negative (no trials at this time)

SURGERY / RADIATION ONLY

[MA.39](#)

Tailor RT: A Randomized Trial of Regional Radiotherapy in Biomarker Low Risk Node Positive Breast Cancer (RT: *Glen Oak and UPHM*)

CANCER CONTROL (Breast only)

[A191901](#)

[SCHEMA](#)

(Peoria, Bloomington, Galesburg, Ottawa, Pekin, and Peru) Optimizing Endocrine Therapy Through Motivational Interviewing and Text Interventions (*only enrolling African American women*)

[A211901](#)

[SCHEMA](#)

Reaching Rural Cancer Survivors Who Smoke Using Text-Based Cessation Interventions

[A212102](#)

[SCHEMA](#)

(Peoria, BLM, Canton, Gburg, Pekin, Peru, Ottawa, Wash) Blinded Reference Set for Multicancer Early Detection Blood Tests

[A222004](#)

[SCHEMA](#)

A Randomized Phase III Trial of Olanzapine Versus Megestrol Acetate for Cancer-Associated Anorexia

[EAQ202](#)

[SCHEMA](#)

Improving Adolescent and Young Adult Self-Reported Data in ECOG-ACRIN Trials (*breast, leukemia, and lymphoma cohorts closed to accrual*)

[S2108CD](#)

[SCHEMA](#)

(Peoria, Bloomington, Galesburg, Canton, Ottawa) A Cluster Randomized Trial Comparing an Educationally Enhanced Genomic Tumor Board (EGTB) Intervention to Usual Practice to Increase Evidence-Based Genome-Informed Therapy

[S1912CD](#)

[SCHEMA](#)

A Randomized Trial Addressing Cancer-Related Financial Hardship Through Delivery of a Proactive Financial Navigation Intervention (CREDIT)

[S2013](#)

[SCHEMA](#)

(Peoria, Bloomington, Galesburg, Pekin, Washington) Immune Checkpoint Inhibitor Toxicity: A Prospective Observational Study (I-CHECKIT)

[URCC 16070](#)

Treatment of Refractory Nausea- for breast cancer patients.

[URCC-18007](#)

Randomized Placebo Controlled Trial of Bupropion For Cancer Related Fatigue in stage I-III Breast cancer pts.- *at least 2 months out from surgery/tx/radiation*

[URCC 21038](#)

[SCHEMA](#)

(Peoria Only) Disparities in Results of ImmuneCheckpoint Inhibitor Treatment (DiRECT): A Prospective Cohort Study of Cancer Survivors Treated With anti-PD-1/anti-PD-L1 Immunotherapy in a Community Oncology Setting

[WF-1901](#)

[SCHEMA](#)

Internet-delivered Management of Pain Among Cancer Treatment Survivors (IMPACTS)

NRG - GY023

SCHEMA

A Randomized Phase II Trial of Triplet Therapy (a PD-L1 Inhibitor (Durvalumab) MEDI4736 in Combination With Olaparib and Cediranib) Compared to Olaparib and Cediranib or (Durvalumab) MEDI4736 and Cediranib or Standard of Care Chemotherapy in Women With Platinum-Resistant Recurrent Epithelial Ovarian Cancer, Primary Peritoneal or Fallopian Cancer Who Have Received Prior Bevacizumab

CANCER CONTROL

MULTI-DISEASE SITES

A211901 SCHEMA	Reaching Rural Cancer Survivors Who Smoke Using Text-Based Cessation Interventions
A212102 SCHEMA	(Peoria, BLM, Canton, Gburg, Pekin, Peru, Ottawa, Wash) Blinded Reference Set for Multicancer Early Detection Blood Tests
A222004 SCHEMA	A Randomized Phase III Trial of Olanzapine Versus Megestrol Acetate for Cancer-Associated Anorexia
EAQ202 SCHEMA	Improving Adolescent and Young Adult Self-Reported Data in ECOG-ACRIN Trials (<i>breast, leukemia, and lymphoma cohorts closed to accrual</i>)
S1912CD SCHEMA	A Randomized Trial Addressing Cancer-Related Financial Hardship Through Delivery of a Proactive Financial Navigation Intervention (CREDIT)
S2013 SCHEMA	(Peoria, Bloomington, Galesburg, Pekin, Washington) Immune Checkpoint Inhibitor Toxicity: A Prospective Observational Study (I-CHECKIT)
S2108CD SCHEMA	(Peoria, Bloomington, Galesburg, Canton, Ottawa) A Cluster Randomized Trial Comparing an Educationally Enhanced Genomic Tumor Board (EGTB) Intervention to Usual Practice to Increase Evidence-Based Genome-Informed Therapy
URCC 21038 SCHEMA	(Peoria only) Disparities in Results of ImmuneCheckpoint Inhibitor Treatment (DiRECT): A Prospective Cohort Study of Cancer Survivors Treated With anti-PD-1/anti-PD-L1 Immunotherapy in a Community Oncology Setting
WF-1901 SCHEMA	Internet-delivered Management of Pain Among Cancer Treatment Survivors (IMPACTS)

BREAST

A191901 SCHEMA	(Peoria, Bloomington, Galesburg, Ottawa, Pekin, and Peru) Optimizing Endocrine Therapy Through Motivational Interviewing and Text Interventions (<i>only enrolling African American women</i>)
URCC 16070	Treatment of Refractory Nausea- for breast cancer patients.
URCC-18007	Randomized Placebo Controlled Trial of Bupropion For Cancer Related Fatigue in stage I-III Breast cancer pts.- <i>at least 2 months out from surgery/tx/radiation</i>

LUNG

Nothing currently available for Lung only - *See Multi-Disease Cancer Control trials ABOVE.*

COLORECTAL

A221805 SCHEMA	Duloxetine to Prevent Oxaliplatin-Induced Chemotherapy-Induced Peripheral Neuropathy: A Randomized, Double-Blind, Placebo-Controlled Phase II to Phase III Study
WF-1806	(M&M Study) Myopenia and Mechanisms of Chemotherapy Toxicity in older Adults with Colorectal Cancer

BRAIN

WF-1801

A Single Arm, Pilot Study of Ramipril for Preventing Radiation-Induced Cognitive Decline in Glioblastoma (GBM) Patients Receiving Brain Radiotherapy

REGISTRY

Navigator - Heather 243-3661

Connect Myeloid

SCHEMA

REOPENED! The Myelofibrosis (MF), Myelodysplastic Syndromes (MDS) and Acute Myeloid Leukemia (AML) Disease Registry. *(enrolling low risk MDS only)*

NHLBI-MDS

(Peoria, Bloomington and Galesburg only) -The National Myelodysplastic Syndromes (MDS) Study



MASTER TRIAL LIST

OCTOBER 2022

[MENU](#)

CARCINOID

Navigator - Ashton x3611
Carrie x3621

<u>A021602</u>	Randomized, Double-Blinded Phase III Study of Cabozantinib Versus Placebo In Patients With Advanced Neruodenocrine Tumors After progression on Prior Therapy (CABINET)
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MASTER TRIAL LIST

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CLL

Navigator - Heather x3661

no trials at this time

1st Line

2nd Line, 3rd Line, etc.



MASTER TRIAL LIST

OCTOBER 2022



CML

Navigator - Heather x3661

No trials at this time

Adjuvant

A021502	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
C-14	(Peoria, Bloomington, Galesburg, Ottawa, Pekin, Peru, Washington) Second Colorectal Cancer Clinical Validation Study to Predict Recurrence Using A Circulating Tumor DNA Assay To Detect Minimal Residual Disease (CORRECT-MRD II)
GI005	Phase II/III Study of Circulating Tumor DNA as a Predictive Biomarker in Adjuvant Chemotherapy in Patients With Stage IIA Colon Cancer (COBRA)
GI008 SCHEMA	REOPENED Colon Adjuvant Chemotherapy Based on Evaluation of Residual Disease

Metastatic

S2107 SCHEMA	Randomized Phase II Trial of Encorafenib and Cetuximab With or Without Nivolumab (NSC #748726) for Patients With Previously Treated, Microsatellite Stable, BRAFV600E Metastatic and/or Unresectable Colorectal Cancer
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CANCER CONTROL (Colorectal only)

A211901 SCHEMA	Reaching Rural Cancer Survivors Who Smoke Using Text-Based Cessation Interventions
A212102 SCHEMA	Blinded Reference Set for Multicancer Early Detection Blood Tests
A221805 SCHEMA	Duloxetine to Prevent Oxaliplatin-Induced Chemotherapy-Induced Peripheral Neuropathy: A Randomized, Double-Blind, Placebo-Controlled Phase II to Phase III Study
A222004 SCHEMA	A Randomized Phase III Trial of Olanzapine Versus Megestrol Acetate for Cancer-Associated Anorexia
EAQ202 SCHEMA	Improving Adolescent and Young Adult Self-Reported Data in ECOG-ACRIN Trials <i>(breast, leukemia, and lymphoma cohorts closed to accrual)</i>
A212102 SCHEMA	(Peoria, BLM, Canton, Gburg, Pekin, Peru, Ottawa, Wash) Blinded Reference Set for Multicancer Early Detection Blood Tests
S1912CD SCHEMA	A Randomized Trial Addressing Cancer-Related Financial Hardship Through Delivery of a Proactive Financial Navigation Intervention (CREDIT)
S2013 SCHEMA	(Peoria, Bloomington, Galesburg, Pekin, Washington) Immune Checkpoint Inhibitor Toxicity: A Prospective Observational Study (I-CHECKIT)

<p><u>S2108CD</u></p> <p></p>	<p>(Peoria, Bloomington, Galesburg, Canton, Ottawa) A Cluster Randomized Trial Comparing an Educationally Enhanced Genomic Tumor Board (EGTB) Intervention to Usual Practice to Increase Evidence-Based Genome-Informed Therapy</p>
<p><u>URCC 21038</u></p> <p></p>	<p>(Peoria Only) Disparities in Results of ImmuneCheckpoint Inhibitor Treatment (DiRECT): A Prospective Cohort Study of Cancer Survivors Treated With anti-PD-1/anti-PD-L1 Immunotherapy in a Community Oncology Setting</p>
<p><u>WF-1901</u></p> <p></p>	<p>Internet-delivered Management of Pain Among Cancer Treatment Survivors (IMPACTS)</p>
<p><u>WF-1806</u></p>	<p>(M&M Study) Myopenia and Mechanisms of Chemotherapy Toxicity in older Adults with Colorectal Cancer</p>



MASTER TRIAL LIST

OCTOBER 2022



ESOPHAGEAL- GASTRIC

Navigator - Carrie x3621

[EA2174](#)

[SCHEMA](#)

(RT at Glen Oak, RT-91, UPHM, Galesburg) A Phase II/III Study of Peri-Operative Nivolumab and Ipilimumab in Patients With Locoregional Esophageal and Gastroesophageal Junction Adenocarcinoma

HEAD & NECK

Navigator - Ashton x3611

<p><u>EA3161</u></p> <p>SCHEMA</p>	<p>(RT at Glen Oak, UPH, Galesburg) A Phase II/III Randomized Study of Maintenance Nivolumab Versus Observation in Patients With Locally Advanced, Intermediate Risk HPV Positive OPSCC</p>
<p><u>EA3191 - JIT</u></p>	<p>A Phase II Randomized Trial of Adjuvant Therapy With Pembrolizumab After Resection of Recurrent/Second Primary Head and Neck Squamous Cell Carcinoma With High Risk Features</p>
<p><u>HN005</u></p>	<p>(RT at UPHM, Galesburg, Glen Oak) A Randomized Phase II/III Trial of De-Intensified Radiation Therapy for Patients With Early-Stage, P16-Positive, Non-Smoking Associated Oropharyngeal Cancer</p>
<p><u>HN009</u></p> <p>SCHEMA</p>	<p>(RT at UPHM) Randomized Phase II/III Trial of Radiation With High-Dose Cisplatin (100 mg/m²) Every Three Weeks Versus Radiation With Low-Dose Weekly Cisplatin (40 mg/m²) for Patients With Locoregionally Advanced Squamous Cell Carcinoma of the Head and Neck (SCCHN)</p>



LYMPHOMA

HL

S1826

(RT at Glen Oak, Rt-91, UPHM) A Phase III, Randomized Study of Nivolumab (Opdivo) Plus AVD or Brentuximab Vedotin (Adcetris) Plus AVD in Patients (Age \geq 12 Years) With Newly Diagnosed Advanced Stage Classical Hodgkin Lymphoma

NHL

EA4181

Temporarily Closed | 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 \leq 70 Years Old With Untreated Mantle Cell Lymphoma

SLL



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MDS

Navigator - Heather x3661

[Connect Myeloid](#)

SCHEMA

REOPENED! The Myelofibrosis (MF), Myelodysplastic Syndromes (MDS) and Acute Myeloid Leukemia (AML) Disease Registry. *(enrolling low risk MDS only)*

[NHLBI-MDS](#)

(Peoria, Bloomington and Galesburg only) -The National Myelodysplastic Syndromes (MDS) Study



MASTER TRIAL LIST

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MENU

MELANOMA

Navigator - Carrie x3621

CA224098

SCHEMA

A Randomized, Double-Blind Phase 2/3 Study of Relatlimab Combined With Nivolumab Versus Nivolumab in Participants With Previously Untreated Metastatic or Unresectable Melanoma



MASTER TRIAL LIST

OCTOBER 2022

MENU

MERKEL

Navigator - Carrie x3621

EA6174

(RT at Glen Oak, UPHM, Galesburg) A Phase III Randomized Trial Comparing Adjuvant MK3475 (Pembrolizumab) to Standard of Care Observation in Completely Resected Merkel Cell Carcinoma



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MOLECULAR STUDIES

[*Contact Disease Specific Navigator](#)

<p><u>64091742PCR0002 / Prevalence</u></p>	<p>Biomarker Study to Determine Frequency of DNA-repair Defects in Men with Metastatic Prostate Cancer (Prevelence)</p>
<p><u>A151804</u></p>	<p>Establishment of a National Biorepository to Advance Studies of Immune-Related Adverse Events</p>
<p><u>NSABP C-14</u></p>	<p>Second Colorectal Cancer Clinical Validation Study to Predict Recurrence Using A Circulating Tumor DNA Assay To Detect Minimal Residual Disease (CORRECT-MRD II)</p>
<p><u>S1823</u></p> <p>SCHEMA</p>	<p>A Study of miRNA 371 in Patients With Germ Cell Tumor (<i>closed to high risk pts or pts on chemo for testicular cancer</i>)</p>
<p><u>TPX-0005-01 (TRIDENT-1)</u></p> <p>SCHEMA</p>	<p>A Phase 1/2, Open-Label, Multi-Center, First-in-Human Study of the Safety, Tolerability, Pharmacokinetics, and Anti-Tumor Activity of TPX-0005 in Patients with Advanced Solid Tumors Harboring ALK, ROS1, or NTRK1-3 Rearrangements (TRIDENT-1)</p>

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MULTIPLE MYELOMA

Navigator - Heather x3661

EAA173 SCHEMA	NEW! Daratumumab to Enhance Therapeutic Effectiveness of Revlimid in Smoldering Myeloma (DETER-SMM)
<u>S1803</u>	Phase III Study of Daratumumab/rHuPH20 (NSC- 810307) + Lenalidomide or Lenalidomide as Post-Autologous Stem Cell Transplant Maintenance Therapy in Patients with Multiple Myeloma (MM) Using Minimal Residual Disease to Direct Therapy Duration (DRAMMATIC Study)

MASTER TRIAL LIST

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MENU

NEUROENDOCRINE

Navigator - Carrie x3621

<u>A021602</u>	Randomized, Double-Blinded Phase III Study of Cabozantinib Versus Placebo In Patients With Advanced Neuroendocrine Tumors After progression on Prior Therapy (CABINET)
<u>A021804</u>	A Prospective, Multi-Institutional Phase II Trial Evaluating Temozolomide vs. Temozolomide and Olaparib for Advanced Pheochromocytoma and Paraganglioma

NSCLC

Navigator - Ashton x3611

ADJUVANT / NEOADJUVANT

<p>A081801 SCHEMA</p>	<p>Integration of Immunotherapy Into Adjuvant Therapy for Resected NSCLC: ALCHEMIST Chemo-IO (ALCHEMIST substudy- <i>Must be enrolled on ALCHEMIST and this substudy prior to start of tx</i>).</p>
<p>A151216</p>	<p>Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST).</p>
<p>EA5181 SCHEMA</p>	<p>(RT at UPHM and Galesburg) Randomized Phase III Trial of MEDI4736 (Durvalumab) as Concurrent and Consolidative Therapy or Consolidative Therapy Alone for Unresectable Stage 3 NSCLC (credentialing pending at Glen Oak & Rt-91)</p>
<p>GO41854 SCHEMA</p>	<p>(Bloomington, Galesburg, Pekin, Peoria, Peru) A Phase III, Open Label, Randomized Study of Atezolizumab and Tiragolumab Compared With Durvalumab in Patients With Locally Advanced, unresectable Stage III Non-Small Cell Lung Cancer Who Have Not Progressed After Concurrent Platinum-Based Chemoradiation (SKYSCRAPER-03)</p>
<p>S1914</p>	<p>(RT at Glen Oak, UPHM, Galesburg) Randomized Phase III Trial of Induction/Consolidation Atezolizumab (NSC #783608) + SBRT Versus SBRT Alone in High Risk, Early Stage NSCLC</p>

METASTATIC - 1st Line

<p>EA5182 SCHEMA</p>	<p>Randomized Phase III Study of Combination AZD9291 (osimertinib) and Bevacizumab versus AZD9291 (osimertinib) Alone as First-Line Treatment for Patients with Metastatic EGFR-Mutant Non-Small Cell Lung Cancer (NSCLC)</p>
<p>GS-US-626-6216 (STAR-121) SCHEMA</p>	<p>(Peoria, Bloomington, Galesburg, Ottawa, Pekin, Peru, Washington) A Randomized, Open-Label, Phase 3 Study to Evaluate Zimberelimab and Domvanalimab in Combination With Chemotherapy Versus Pembrolizumab With Chemotherapy for the First-Line Treatment of Patients With Metastatic Non-Small Cell Lung Cancer With No Epidermal Growth Factor Receptor or Anaplastic Lymphoma Kinase Genomic Tumor Aberrations</p>
<p>MK 7684A-003 SCHEMA</p>	<p>Screening by referral only (Peoria only) A Phase 3, Multicenter, Randomized, Double-Blind Study of MK-7684 with Pembrolizumab as a Coformulation (MK-7684A) Versus Pembrolizumab Monotherapy as First Line Treatment for Participants With PD-L1 Positive Metastatic Non-Small Cell Lung Cancer</p>
<p>TH-138 SCHEMA</p>	<p>Screening by referral only (Peoria, Bloomington, Galesburg, Pekin) Phase II Randomized Trial of Carboplatin + Pemetrexed+ Bevacizumab, With or Without Atezolizumab in Stage IV Non-Squamous NSCLC Patients Who Harbor a Sensitizing EGFR Mutation or Have Never Smoked (<i>non smokers</i>)</p>

METASTATIC - 2nd/3rd Line

<p>ADXS-503-101 SCHEMA</p>	<p>A Phase 1/2, Open-Label Study of ADXS-503 Alone and in Combination With Pembrolizumab in Subjects With Metastatic Squamous or Non-Squamous Non-Small Cell Lung Cancer (Part 2B)</p>
<p>LUNGMAP</p>	<p>A Master Protocol To Evaluate Biomarker-Driven Therapies and Immunotherapies in Previously-Treated NSCLC. (SUB-STUDIES: S1800D - A Phase II/III Study of N-803 (ALT-803) plus Pembrolizumab versus Standard of Care in Participants with Stage IV or Recurrent Non-Small Cell Lung Cancer Previously Treated with Anti-PD-1 or Anti-PD-L1 Therapy; S1900E - A Phase II Study of AMG 510 in Participants With Previously Treated Stage IV or Recurrent KRAS G12C Mutated Non-Squamous Non-Small Cell Lung Cancer); S1900F- A Randomized Phase II Study of Carboplatin and Pemetrexed w/ or w/o Selpercatinib in Participants With Non-Squamous RET Fusion-Positive Stage IV Non-Small Cell Lung Cancer and Progression of Disease on Prior RET Directed Therapy)</p>

<p>TH-138</p> <p>SCHEMA</p>	<p>Screening by referral only (Peoria, Bloomington, Galesburg, Pekin) Phase II Randomized Trial of Carboplatin + Pemetrexed+ Bevacizumab, With or Without Atezolizumab in Stage IV Non-Squamous NSCLC Patients Who Harbor a Sensitizing EGFR Mutation or Have Never Smoked (<i>EGFR mutants</i>)</p>
<p>CANCER CONTROL (NSCLC Only)</p>	
<p>A211901</p> <p>SCHEMA</p>	<p>Reaching Rural Cancer Survivors Who Smoke Using Text-Based Cessation Interventions</p>
<p>A212102</p> <p>SCHEMA</p>	<p>(Peoria, BLM, Canton, Gburg, Pekin, Peru, Ottawa, Wash) Blinded Reference Set for Multicancer Early Detection Blood Tests</p>
<p>A222004</p> <p>SCHEMA</p>	<p>A Randomized Phase III Trial of Olanzapine Versus Megestrol Acetate for Cancer-Associated Anorexia</p>
<p>EAQ202</p> <p>SCHEMA</p>	<p>Improving Adolescent and Young Adult Self-Reported Data in ECOG-ACRIN Trials (<i>breast, leukemia, lymphoma cohorts closed to accrual</i>)</p>
<p>S2108CD</p> <p>SCHEMA</p>	<p>(Peoria, Bloomington, Galesburg, Canton, Ottawa) A Cluster Randomized Trial Comparing an Educationally Enhanced Genomic Tumor Board (EGTB) Intervention to Usual Practice to Increase Evidence-Based Genome-Informed Therapy</p>
<p>S1912CD</p> <p>SCHEMA</p>	<p>A Randomized Trial Addressing Cancer-Related Financial Hardship Through Delivery of a Proactive Financial Navigation Intervention (CREDIT)</p>
<p>S2013</p> <p>SCHEMA</p>	<p>(Peoria, Bloomington, Galesburg, Pekin, Washington) Immune Checkpoint Inhibitor Toxicity: A Prospective Observational Study (I-CHECKIT)</p>
<p>URCC 21038</p> <p>SCHEMA</p>	<p>(Peoria Only) Disparities in Results of ImmuneCheckpoint Inhibitor Treatment (DiRECT): A Prospective Cohort Study of Cancer Survivors Treated With anti-PD-1/anti-PD-L1 Immunotherapy in a Community Oncology Setting</p>
<p>WF-1901</p> <p>SCHEMA</p>	<p>Internet-delivered Management of Pain Among Cancer Treatment Survivors (IMPACTS)</p>



ILLINOIS
CANCERCARE, P.C.
Specializing in Cancer and Blood Disorders

MASTER TRIAL LIST

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[MENU](#)

PANCREATIC

Navigator - Carrie x3621

No trials at this time.

PROSTATE

Navigator - Carrie x3621

ADJUVANT

<p><u>GU008</u></p> <p>SCHEMA</p>	<p>(RT at Glen Oak, UPHM) Randomized Phase III Trial Incorporating Apalutamide and Advanced Imaging Into Treatment for Patients With Node-Positive Prostate Cancer After Radical Prostatectomy (INNOVATE): <i>Intensifying Treatment for Node Positive Prostate Cancer by Varying the Hormonal Therapy</i></p>
<p><u>GU009</u></p> <p>SCHEMA</p>	<p>(RT at Glen Oak, Galesburg, UPHM, Rt 91) 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*)</p>
<p><u>GU010</u></p> <p>SCHEMA</p>	<p>(RT at UPHM) Parallel Phase III Randomized Trials of Genomic-Risk Stratified Unfavorable Intermediate Risk Prostate Cancer: De-Intensification and Intensification Clinical Trial Evaluation (GUIDANCE)</p>

METASTATIC

<p><u>64091742PCR0002 / Prevalence</u></p>	<p>Biomarker Study to Determine Frequency of DNA-repair Defects in Men with Metastatic Prostate Cancer</p>
<p><u>A032101</u></p> <p>SCHEMA</p>	<p>A Phase 2 Trial of ADT Interruption in Patients Responding Exceptionally to AR-Pathway Inhibitor in Metastatic Hormone-Sensitive Prostate Cancer (MHSPC): A-DREAM</p>
<p><u>C2321001</u></p> <p>SCHEMA</p>	<p>(Peoria only) A Phase I Dose Escalation and Expanded Cohort Study of PF-06821497 in the Treatment of Adult Patients with Relapsed/Refractory Small Cell Lung Cancer (SCLC), Castration Resistant Prostate Cancer (CRPC) and Follicular Lymphoma (FL)</p>

<p><u>A031902 / CASPAR</u></p> <p><small>SCHEMA</small></p>	<p>A Phase III Trial of Enzalutamide and Rucaparib as a Novel Therapy in First-Line Metastatic Castration-Resistant Prostate Cancer</p>
<p><u>GU011</u></p> <p><small>SCHEMA</small></p>	<p>(RT at Glen Oak and UPHM) A Phase II Double-Blinded, Placebo-Controlled Trial of PROstate OligoMETastatic RadiothERapy With or Without ANdrogen Deprivation Therapy in Oligometastatic Prostate Cancer (NRG Promethean)</p>
<p><u>S1802</u></p>	<p>(RT at Glen Oak, SJMC & UPHM) 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</p>

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RENAL CELL

Navigator - Carrie x3621

<p><u>A031704</u></p> <p>SCHEMA</p>	<p>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)</p>
<p><u>MK 6482-011</u></p> <p>SCHEMA</p>	<p>(Peoria, Bloomington, Galesburg, Pekin) An Open-label, Randomized, Phase 3 Study of MK-6482 in Combination with Lenvatinib (MK-7902) vs Cabozantinib for Second-line or Third-line Treatment in Participants with Advanced Renal Cell Carcinoma Who Have Progressed After Prior Anti-PD-1/L1 Therapy</p>

RADIATION TRIALS

Navigator - Jessica x3615

CANCER CONTROL	
<u>WF-1801</u>	A Single Arm, Pilot Study of Ramipril for Preventing Radiation-Induced Cognitive Decline in Glioblastoma (GBM) Patients Receiving Brain Radiotherapy
ANAL	
<u>EA2182</u>	(UPHM and Glen Oak) A Randomized Phase II Study of De-Intensified ChemoRadiation for Early-Stage Anal Squamous Cell Carcinoma (DECREASE)
BLADDER	
<u>A032002</u>	(RT at Glen Oak) Phase II Randomized Trial of Atezolizumab Versus Atezolizumab and Radiation Therapy for Platinum Ineligible/Refractory Metastatic Urothelial Cancer (ART)
<u>EA8185</u>	(RT pending at Glen Oak & Rt-91) Phase 2 Study of Bladder-Sparing Chemoradiation With MEDI4736 (Durvalumab) in Clinical Stage 3, Node Positive Bladder Cancer (INSPIRE)
<u>S1806</u>	(Glen Oak, SJMC, UPHM and Galesburg) Phase III Randomized Trial of Concurrent Chemoradiotherapy with or without Atezolizumab in Localized Muscle Invasive Bladder Cancer
BRAIN	
<u>BN007</u>	Temporarily Closed (UPHM, Glen Oak, Galesburg) A Randomized Phase II/III Open-Label Study of Ipilimumab and Nivolumab Versus Temozolomide in Patients With Newly Diagnosed MGMT (Tumor O-6-Methylguanine DNA Methyltransferase) Unmethylated Glioblastoma
<u>N0577</u>	(Glen Oak, RT 91, and UPHM) Phase III Intergroup Study of Radiotherapy with Concomitant and Adjuvant Temozolomide versus Radiotherapy with Adjuvant PCV Chemotherapy in Patients with 1p/19q Co-deleted Anaplastic Glioma or Low Grade Glioma
BRAIN METS	
<u>CCTG CE.7</u>	(UPHM & Glen Oak)- A Phase III Trial of Stereotactic Radiosurgery Compared with Whole Brain Radiotherapy (WBRT) for 5-15 Brain Metastases
BREAST	

<u>BR007</u> <small>SCHEMA</small>	(Galesburg, Glen Oak, Rt 91, UPHM, SJMC) Phase III Clinical Trial Evaluating De-Escalation of Breast Radiation for Conservative Treatment of Stage I, Hormone Sensitive, HER-2 Negative, Oncotype Recurrence Score Less Than or Equal to 18 Breast Cancer
<u>MA.39</u>	(Glen Oak and UPHM) Tailor RT: A Randomized Trial of Regional Radiotherapy in Biomarker Low Risk Node Positive Breast Cancer
ESOPHAGEAL/GASTRIC	
<u>EA2174</u> <small>SCHEMA</small>	(Glen Oak, Rt 91, UPHM, Galesburg) A Phase II/III Study of Peri-Operative Nivolumab and Ipilimumab in Patients With Locoregional Esophageal and Gastroesophageal Junction Adenocarcinoma
HEAD & NECK	
<u>EA3161</u> <small>SCHEMA</small>	(Glen Oak, UPH, Galeburg) A Phase II/III Randomized Study of Maintenance Nivolumab Versus Observation in Patients With Locally Advanced, Intermediate Risk HPV Positive OPSCC
<u>HN005</u>	(UPHM, Galesburg, Glen Oak) A Randomized Phase II/III Trial of De-Intensified Radiation Therapy for Patients With Early-Stage, P16-Positive, Non-Smoking Associated Oropharyngeal Cancer
<u>HN009</u> <small>SCHEMA</small>	(RT at UPHM) Randomized Phase II/III Trial of Radiation With High-Dose Cisplatin (100 mg/m ²) Every Three Weeks Versus Radiation With Low-Dose Weekly Cisplatin (40 mg/m ²) for Patients With Locoregionally Advanced Squamous Cell Carcinoma of the Head and Neck (SCCHN)
HODGKIN'S LYMPHOMA	
<u>S1826</u>	Temporarily Closing 10.5.22 (Glen Oak, Rt-91, UPHM) A Phase III, Randomized Study of Nivolumab (Opdivo) Plus AVD or Brentuximab Vedotin (Adcetris) Plus AVD in Patients (Age >= 12 Years) With Newly Diagnosed Advanced Stage Classical Hodgkin Lymphoma
MERKEL CELL	
<u>EA6174</u>	(Glen Oak, UPHM and Galesburg) A Phase III Randomized Trial Comparing Adjuvant MK3475 (Pembrolizumab) to Standard of Care Observation in Completely Resected Merkel Cell Carcinoma
NSCLC	
<u>EA5181</u> <small>SCHEMA</small>	(UPHM and Galesburg) Randomized Phase III Trial of MEDI4736 (Durvalumab) as Concurrent and Consolidative Therapy or Consolidative Therapy Alone for Unresectable Stage 3 NSCLC (credentialing pending at Glen Oak)
<u>S1914</u>	(Glen Oak, UPHM, Galesburg) Randomized Phase III Trial of Induction/Consolidation Atezolizumab (NSC #783608) + SBRT Versus SBRT Alone in High Risk, Early Stage NSCLC

PROSTATE	
<u>GU008</u> <small>SCHEMA</small>	(RT at Glen Oak, UPHM) Randomized Phase III Trial Incorporating Apalutamide and Advanced Imaging Into Treatment for Patients With Node-Positive Prostate Cancer After Radical Prostatectomy (INNOVATE): <i>Intensifying Treatment for Node Positive Prostate Cancer by Varying the Hormonal Therapy</i>
<u>GU009</u> <small>SCHEMA</small>	(RT at Glen Oak, Galesburg, UPHM, Rt 91) 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*)
<u>GU010</u> <small>SCHEMA</small>	(RT at UPHM) Parallel Phase III Randomized Trials of Genomic-Risk Stratified Unfavorable Intermediate Risk Prostate Cancer: De-Intensification and Intensification Clinical Trial Evaluation (GUIDANCE)
<u>GU011</u> <small>SCHEMA</small>	(RT at Glen Oak & UPHM) A Phase II Double-Blinded, Placebo-Controlled Trial of PROstate OligoMETastatic RadiothERapy With or Without ANDrogen Deprivation Therapy in Oligometastatic Prostate Cancer (NRG Promethean)
<u>S1802</u>	(Glen Oak, SJMC & UPHM) 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
<u>WF-1802</u>	(Glen Oak, Rt-91, UPHM, Galesburg) Influence of Primary Treatment for Prostate Cancer on Work Experience (PCW)
SCLC	
<u>NRG CC009</u> <small>SCHEMA</small>	(Glen Oak, UPHM) - Phase III Trial of Stereotactic Radiosurgery (SRS) versus Hippocampal-Avoidant Whole Brain Radiotherapy (HA-WBRT) for 10 or fewer Brain Metastases from Small Cell Lung Cancer
<u>S1827</u>	(Glen Oak, UPHM, Galesburg, SJMC) A Randomized Phase III Trial of MRI Surveillance With or Without Prophylactic Cranial Irradiation (PCI) in Small-Cell Lung Cancer

MASTER TRIAL LIST

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SMALL CELL LUNG CANCER

Navigator - Ashton x3611

<p><u>NRG CC009</u></p> <p>SCHEMA</p>	<p>(RT at Glen Oak, UPHM) - Phase III Trial of Stereotactic Radiosurgery (SRS) versus Hippocampal-Avoidant Whole Brain Radiotherapy (HA-WBRT) for 10 or fewer Brain Metastases from Small Cell Lung Cancer</p>
<p><u>GO43104</u></p> <p>SCHEMA</p>	<p>(Peoria, Bloomington, Galesburg, Ottawa, Pekin, Peru, Washington) A Phase III, Randomized, Open-Label, Multicenter Study of Lurbinectedin In Combination With Atezolizumab Compared With Atezolizumab As Maintenance Therapy In Participants With Extensive-Stage Small-Cell Lung Cancer (ES-SCLC) Followiing First-Line Induction Therapy With Carboplatin, Etoposide and Atezolizumab</p>
<p><u>S1827</u></p>	<p>(RT at Glen Oak, UPHM, Galesburg, SJMC) A Randomized Phase III Trial of MRI Surveillance With or Without Prophylactic Cranial Irradiation (PCI) in Small-Cell Lung Cancer</p>

Study Design

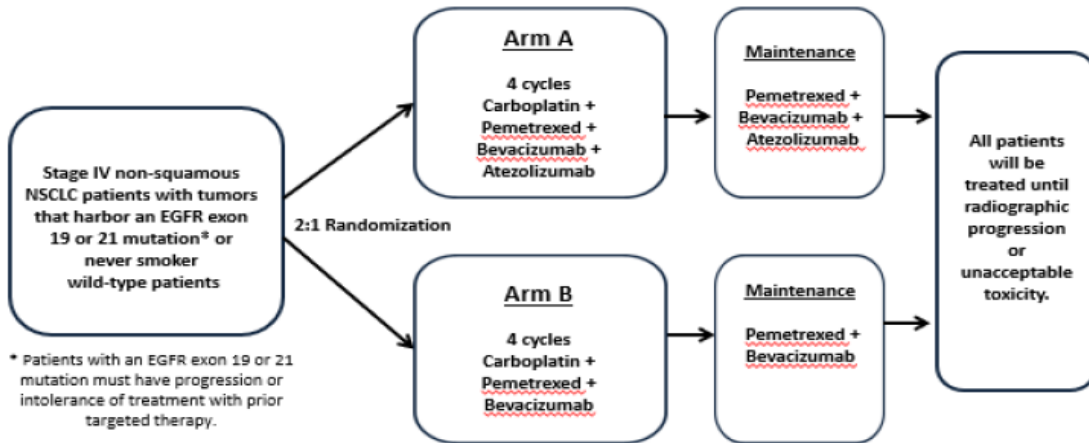
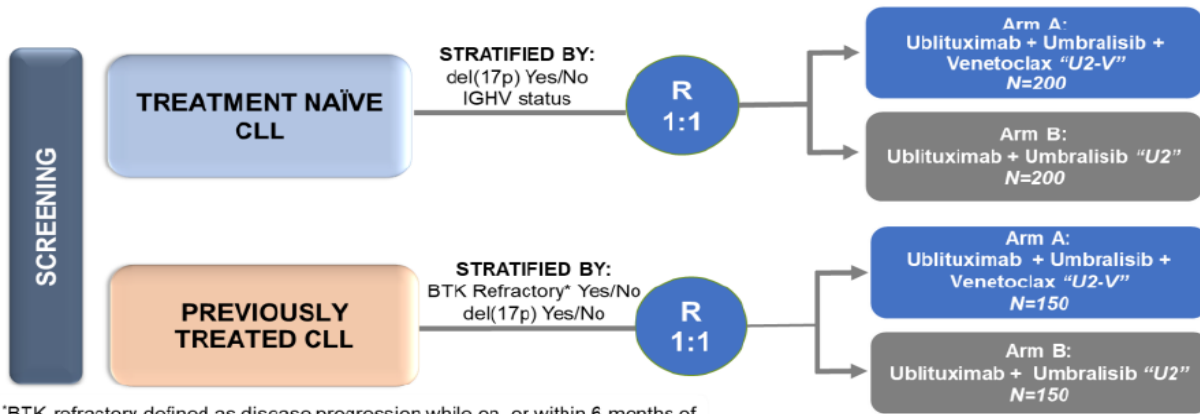


FIGURE 2: PHASE 3 STUDY DESIGN



*BTK-refractory defined as disease progression while on, or within 6 months of the last dose of a BTK inhibitor (e.g., ibrutinib, acalabrutinib, etc)

MK 6482-011 Schema
Navigator - Carrie x3621

MENU

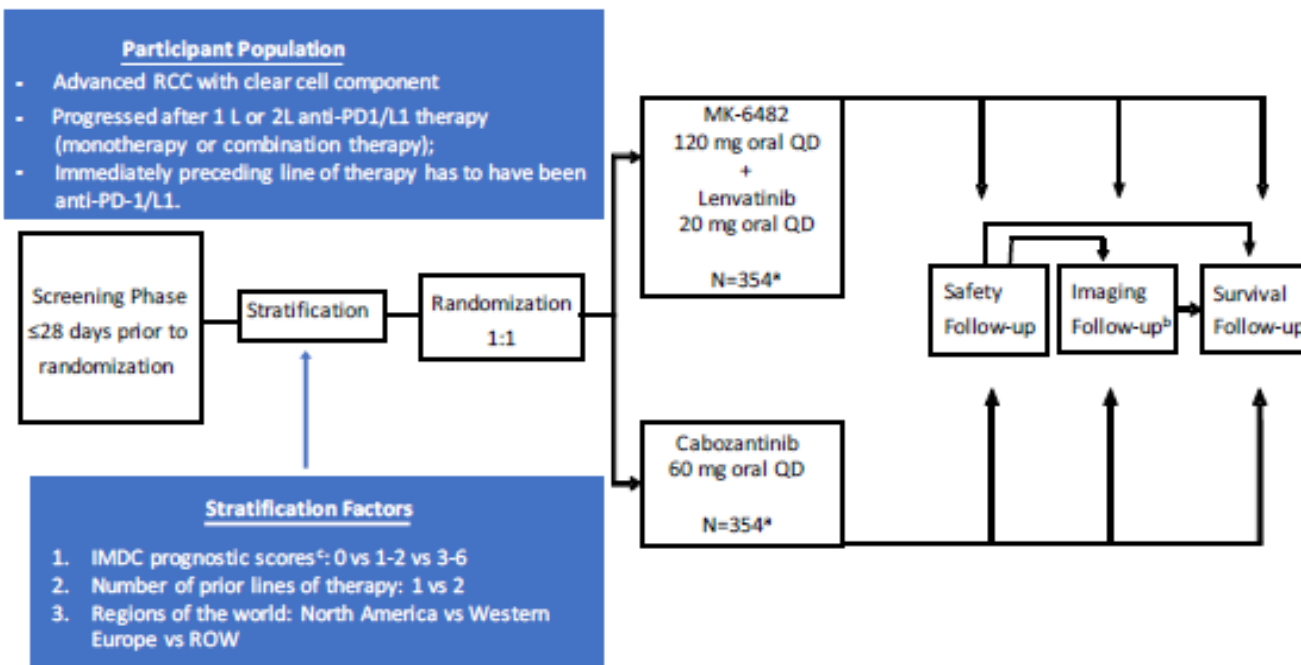
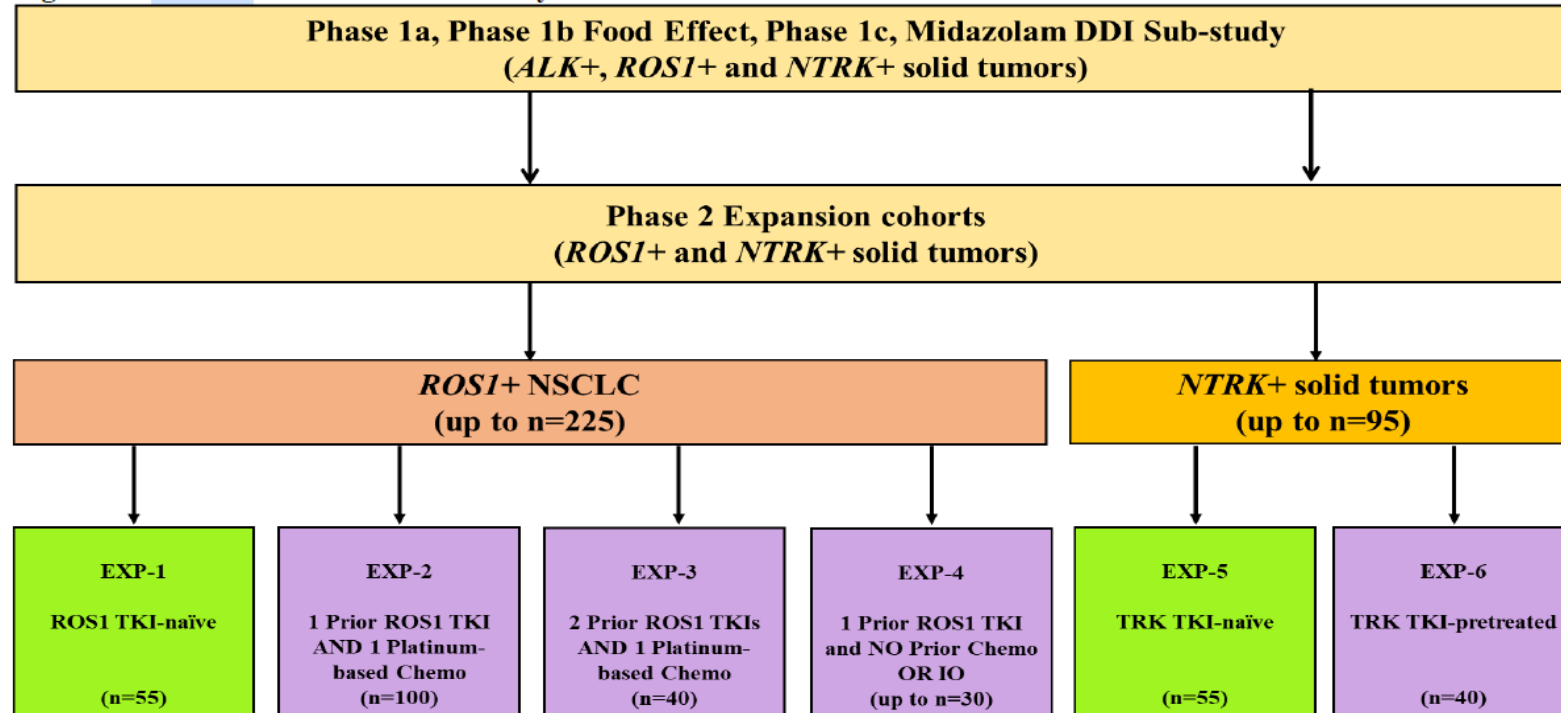
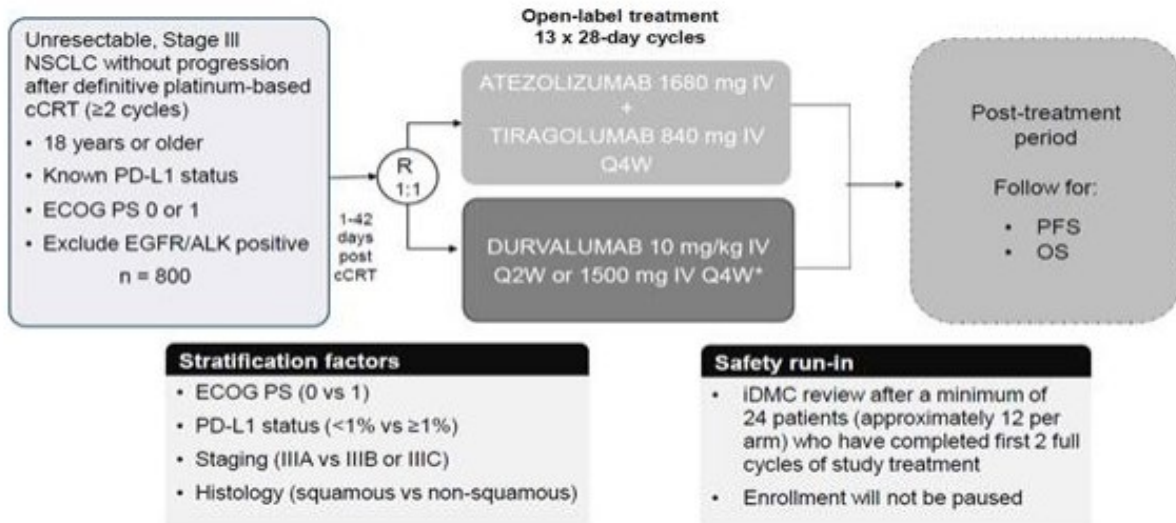


Figure 2. Schema of TPX-0005-01 Study

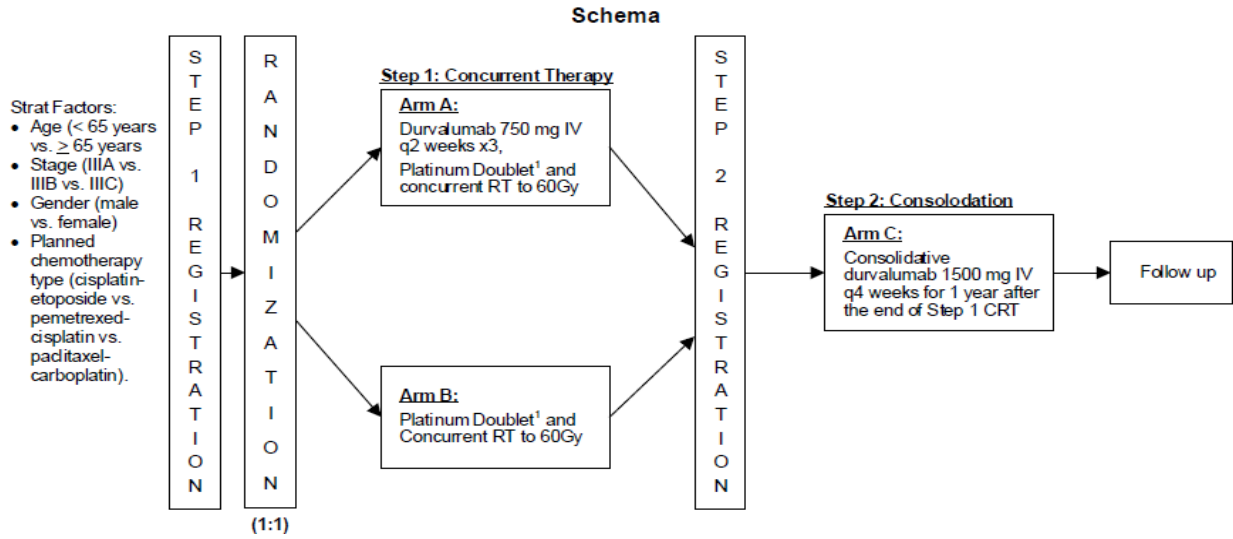


GO41854 Schema
Navigator - Ashton x3611

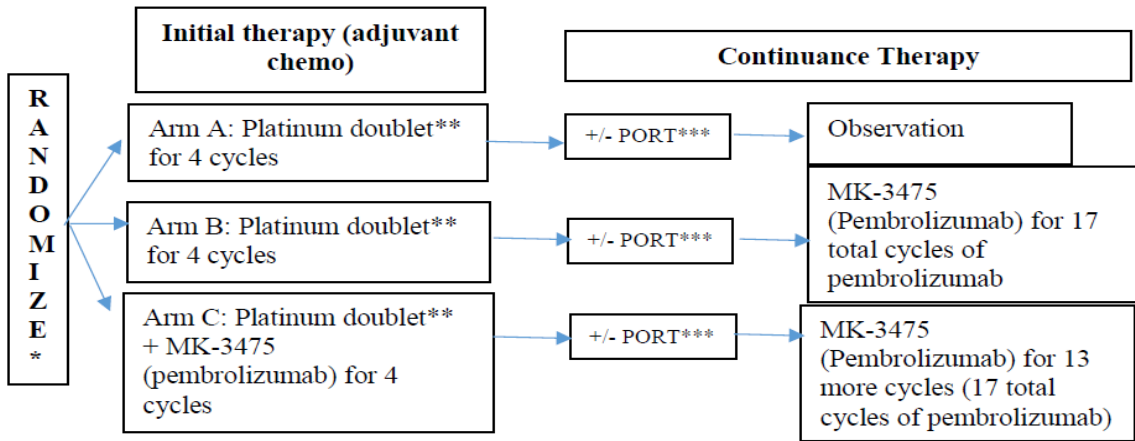
MENU



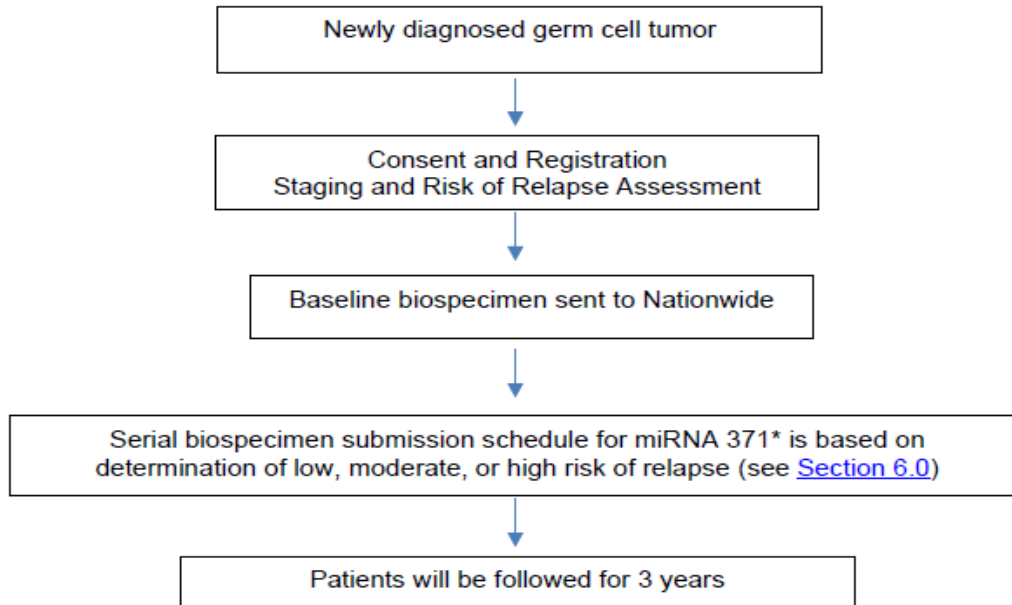
*For patients whose weight ≥30 kg



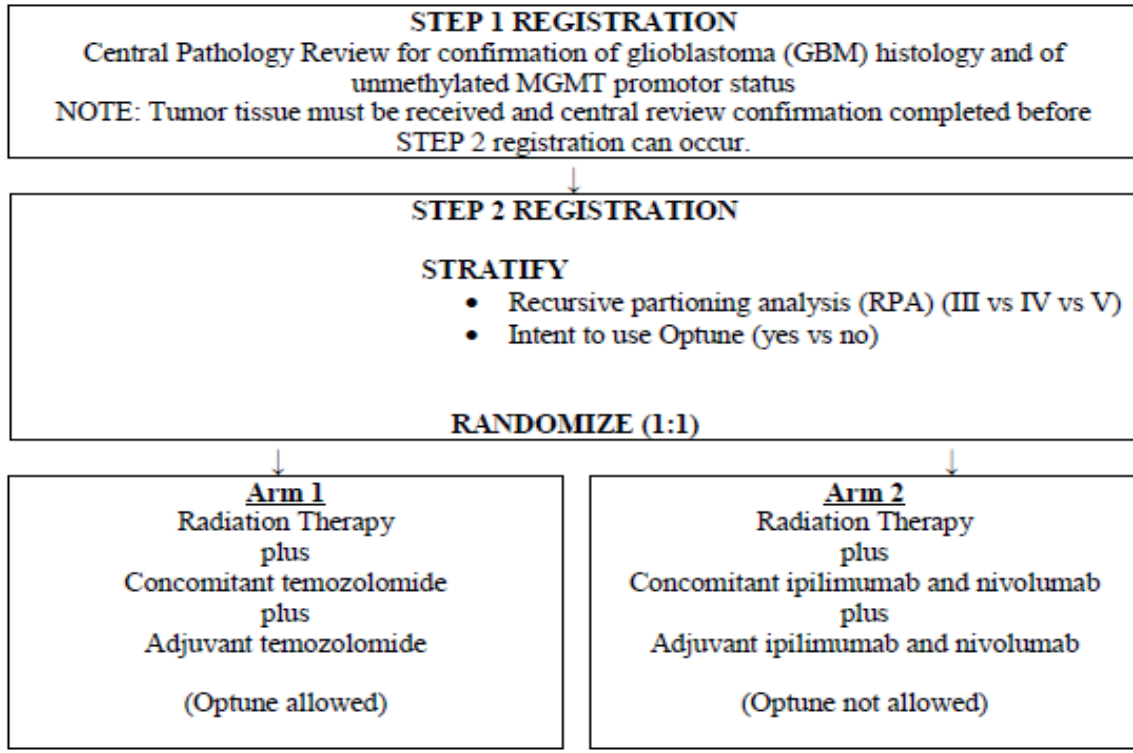
Schema: 1 cycle = 21 days



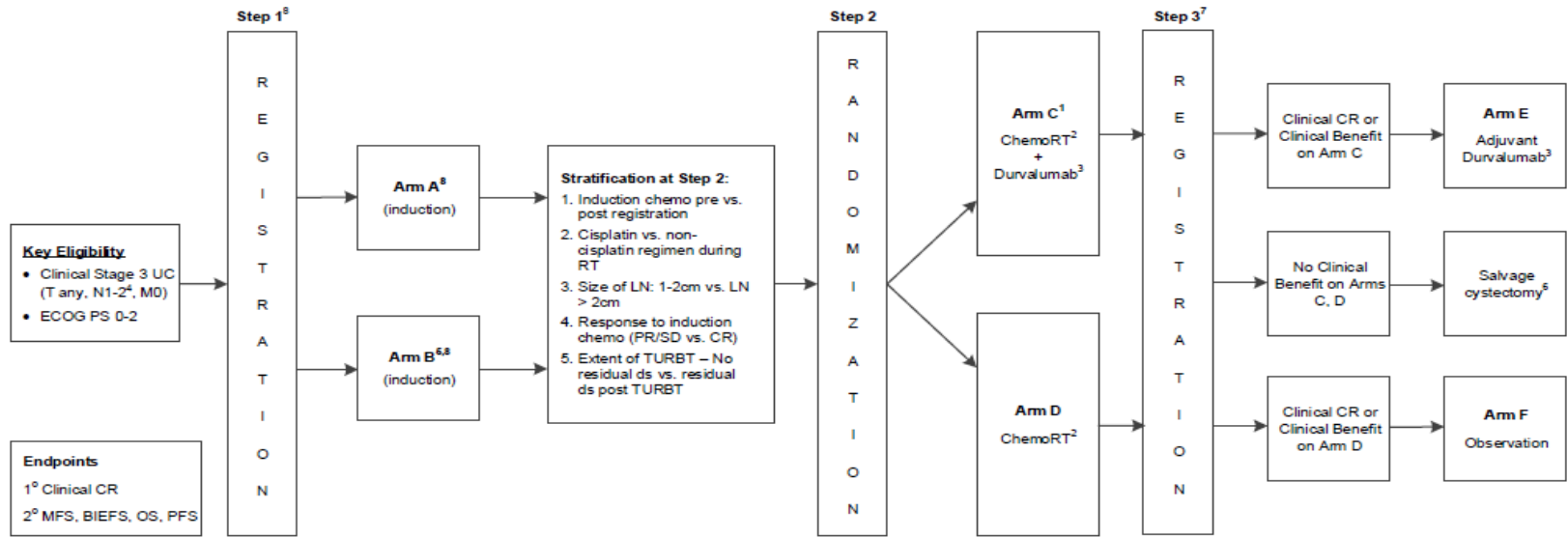
SCHEMA



* Patients and providers will not have knowledge of the results of the miRNA 371 analysis.

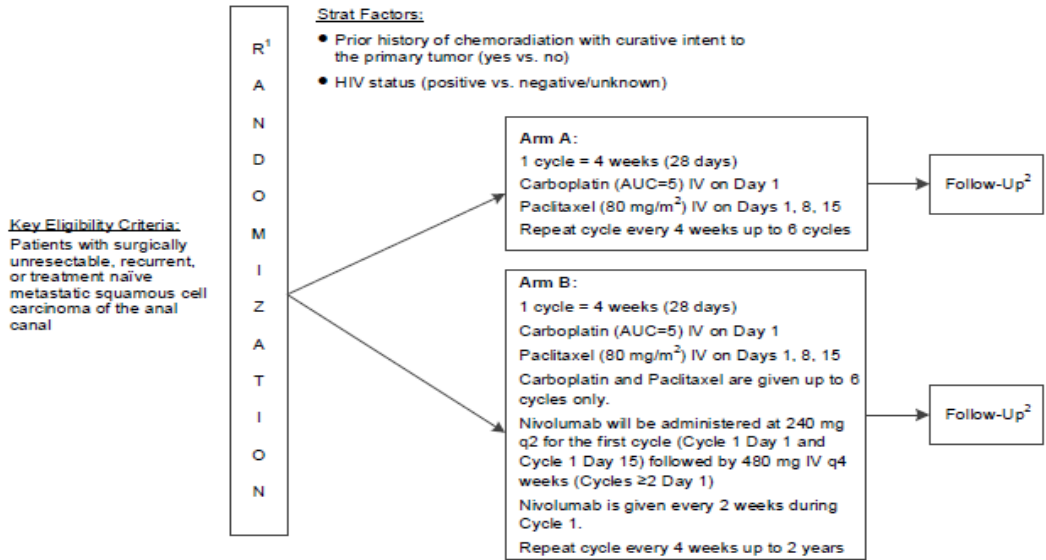


Schema

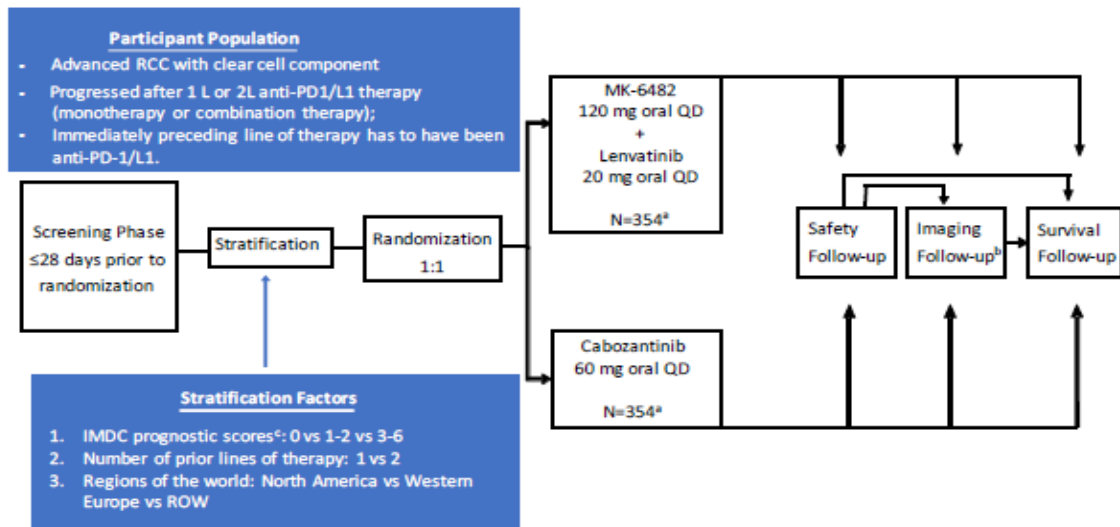


EA2176
Navigator -Carrie x3621

MENU



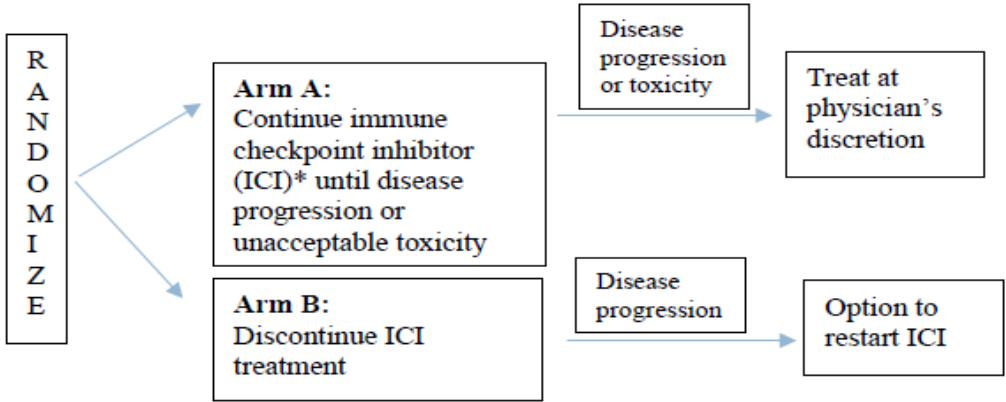
1. Randomization is 1:2 (A:B).
 2. For this protocol, all patients, including those who discontinue protocol therapy early, will be followed for response until disease progression, even if non-protocol therapy is initiated, and for survival every 3 months for two years from the date of randomization. All patients must also be followed through completion of all protocol therapy.



BICR=blinded independent central review; DMC=Data Monitoring Committee; IMDC=International Metastatic Renal Cell Carcinoma Database Consortium; QD=once daily; RCC=renal cell carcinoma; ROW=rest of world; TKI=tyrosine kinase inhibitor; US=United States; VEGF=vascular endothelial growth factor.

Schema

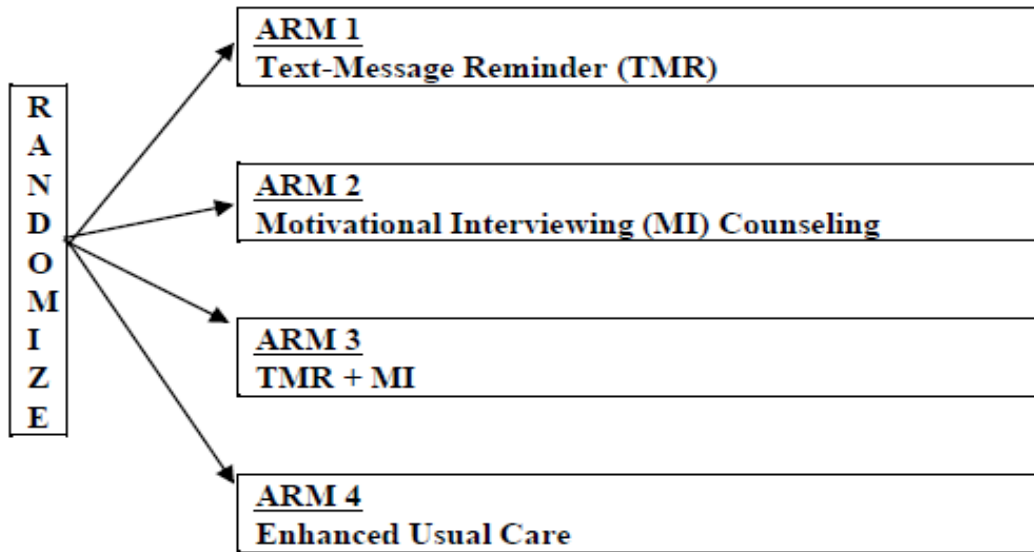
Cycle definition is based on ICI cycle length

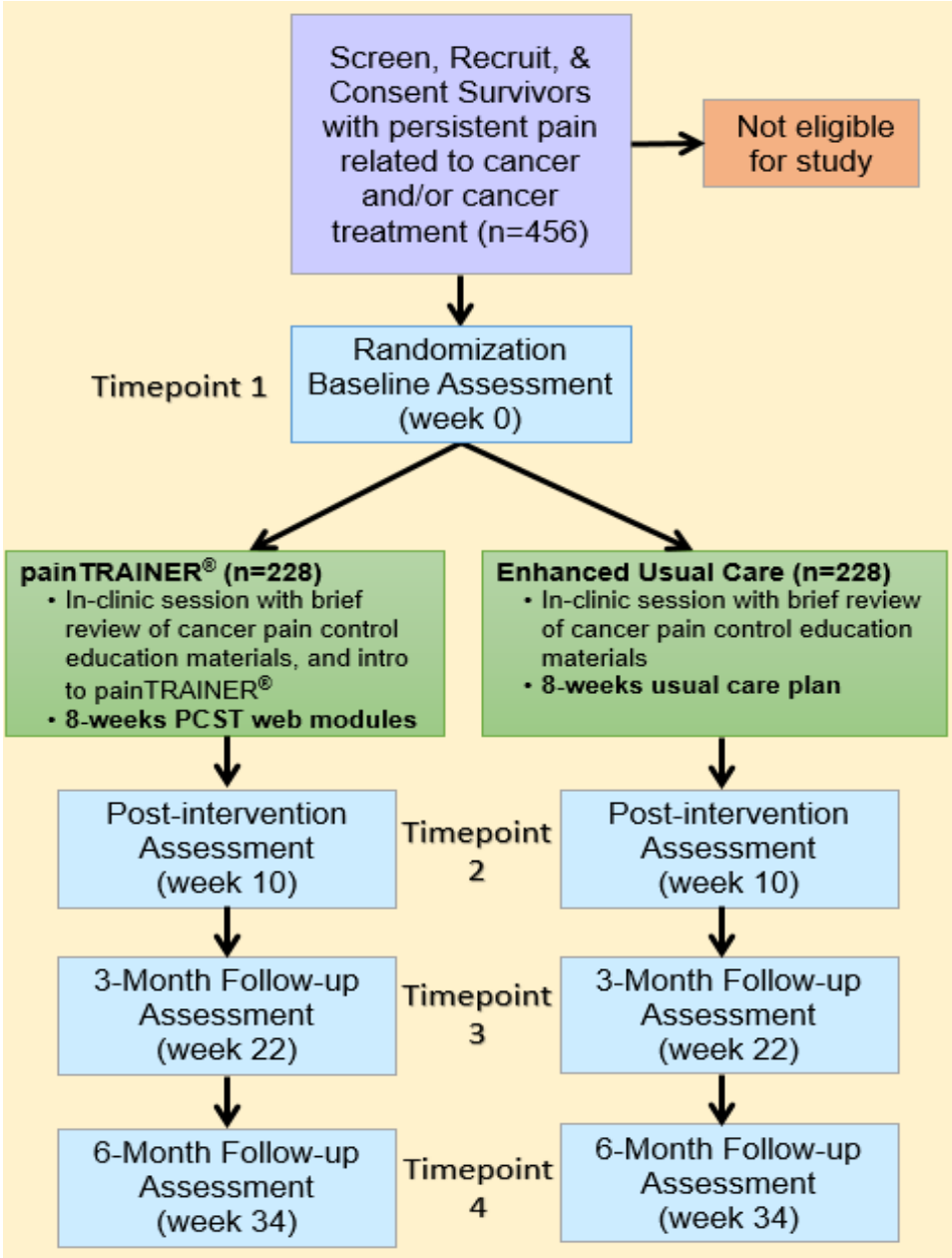


* ICI agents include pembrolizumab, nivolumab, atezolizumab, durvalumab and avelumab

Patients will be followed for 5 years or until death or withdrawal of consent, whichever occurs first.

Schema

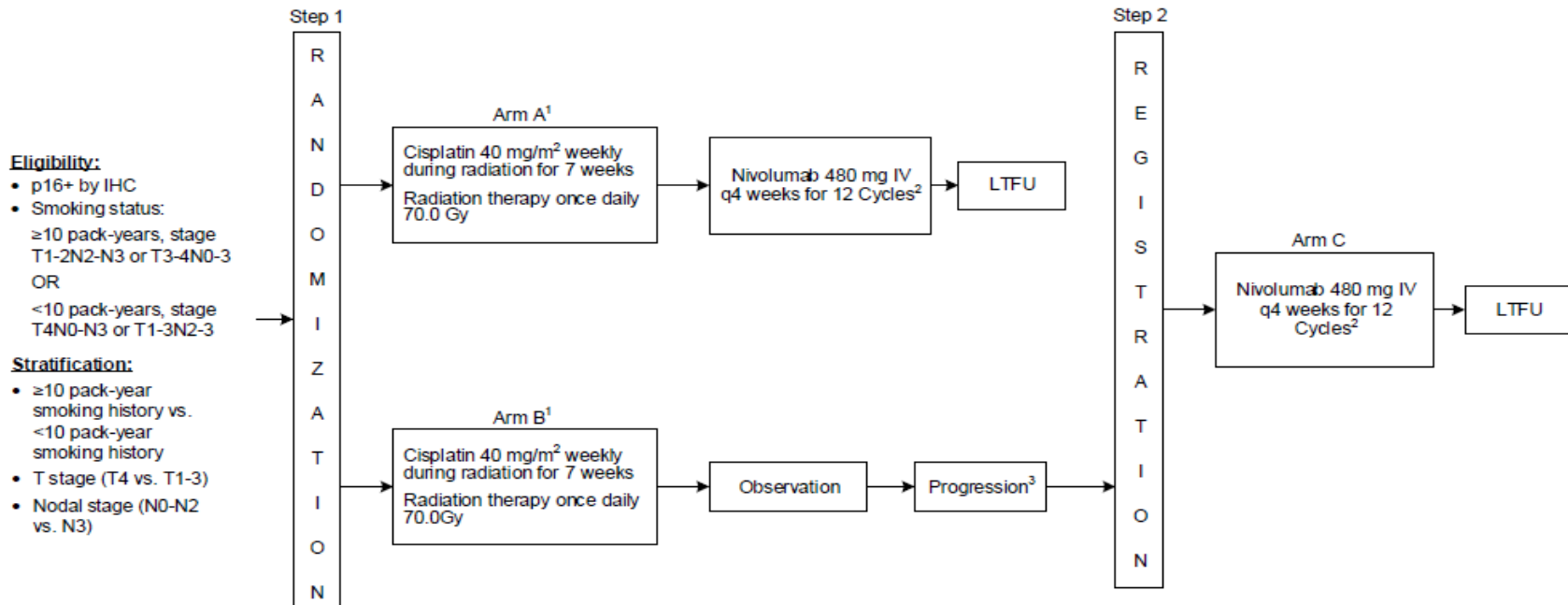




EA3161
Navigator -Ashton x3611

MENU

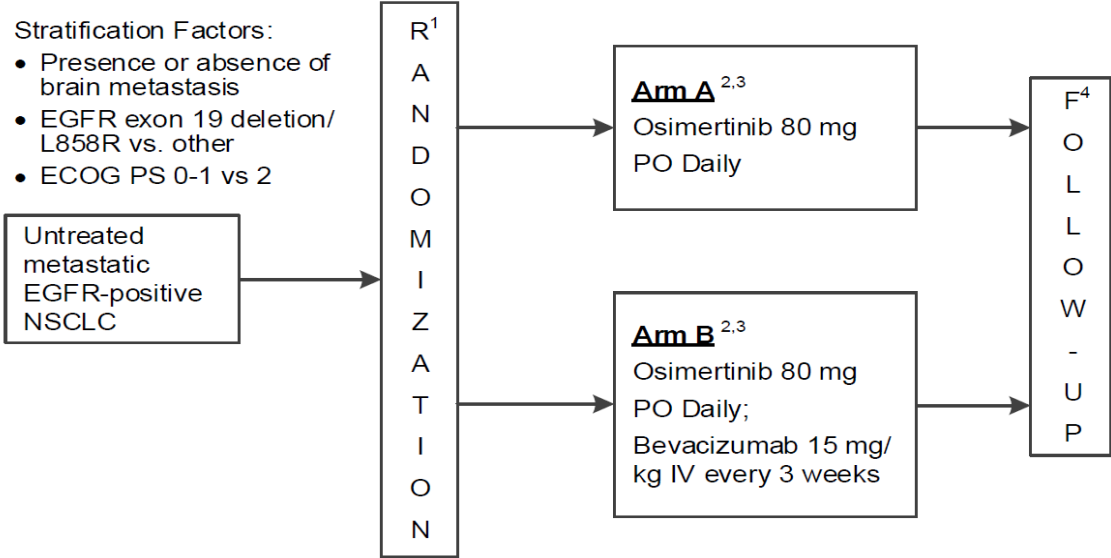
Schema



Accrual Goal: 744

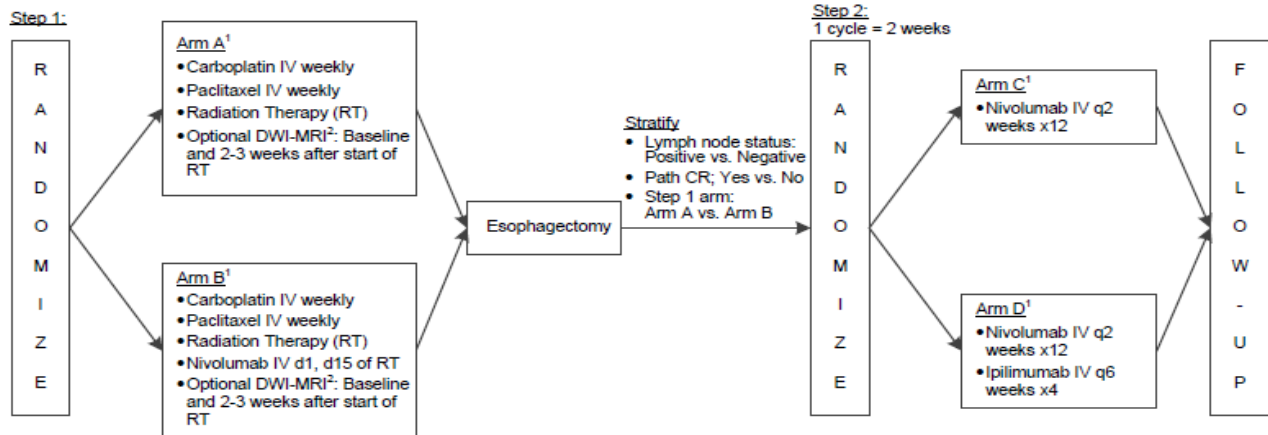
1. Submit tissue for PD-L1 testing.
2. Cycle length = 28 days
3. Patients who were randomized to observation will be offered the option to cross over if they have clearly documented progression by the RECIST criteria and tissue-proven progression within 12 months from the end of cisplatin/radiation therapy.

Schema



Accrual Goal = 300 patients
Cycle = 3 weeks (21 days)

Schema

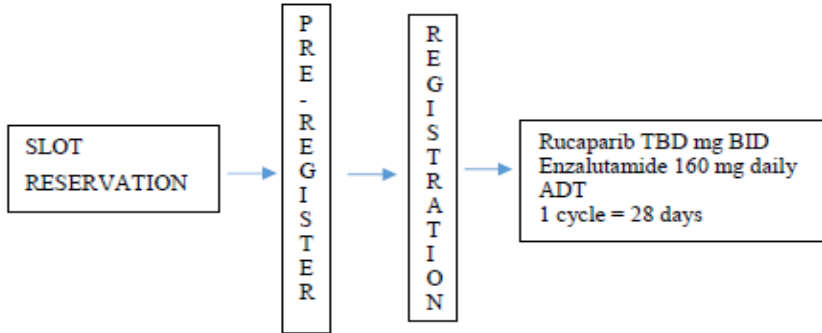


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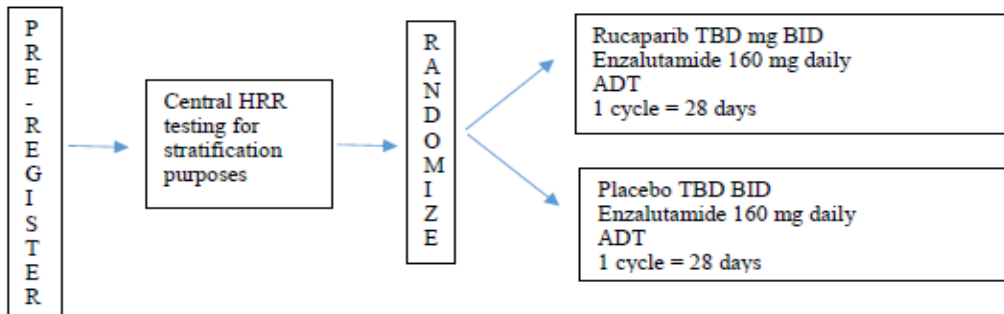
1. Please reference Section 5.1 for treatment dosing specifics.
2. Optional Diffusion weighted imaging-MRI (DWI-MRI) should be obtained at step 1 baseline and 2-3 weeks after initiation of protocol treatment.

Schema

PK Substudy (Dose Finding Portion) Only

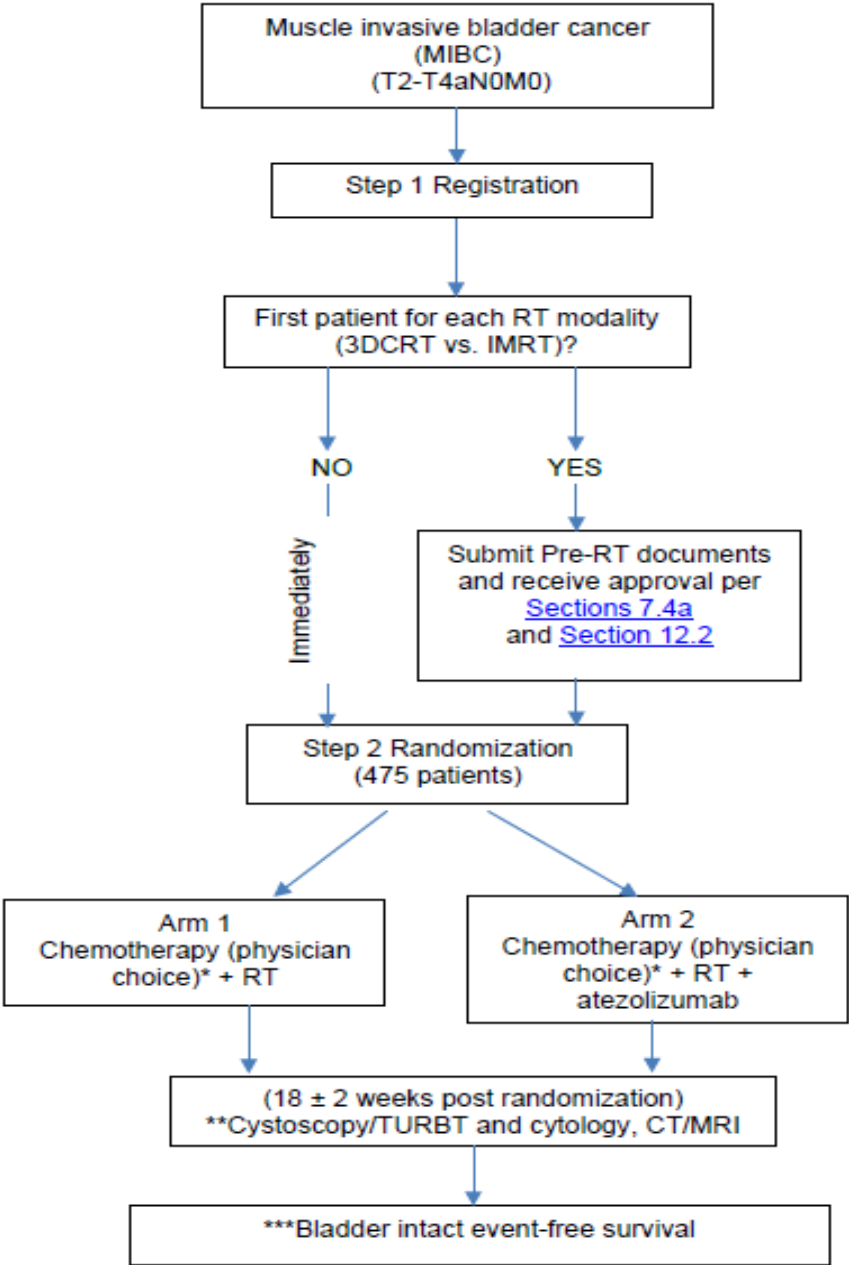


Phase III (Double-Blinded, Placebo-Controlled) Portion



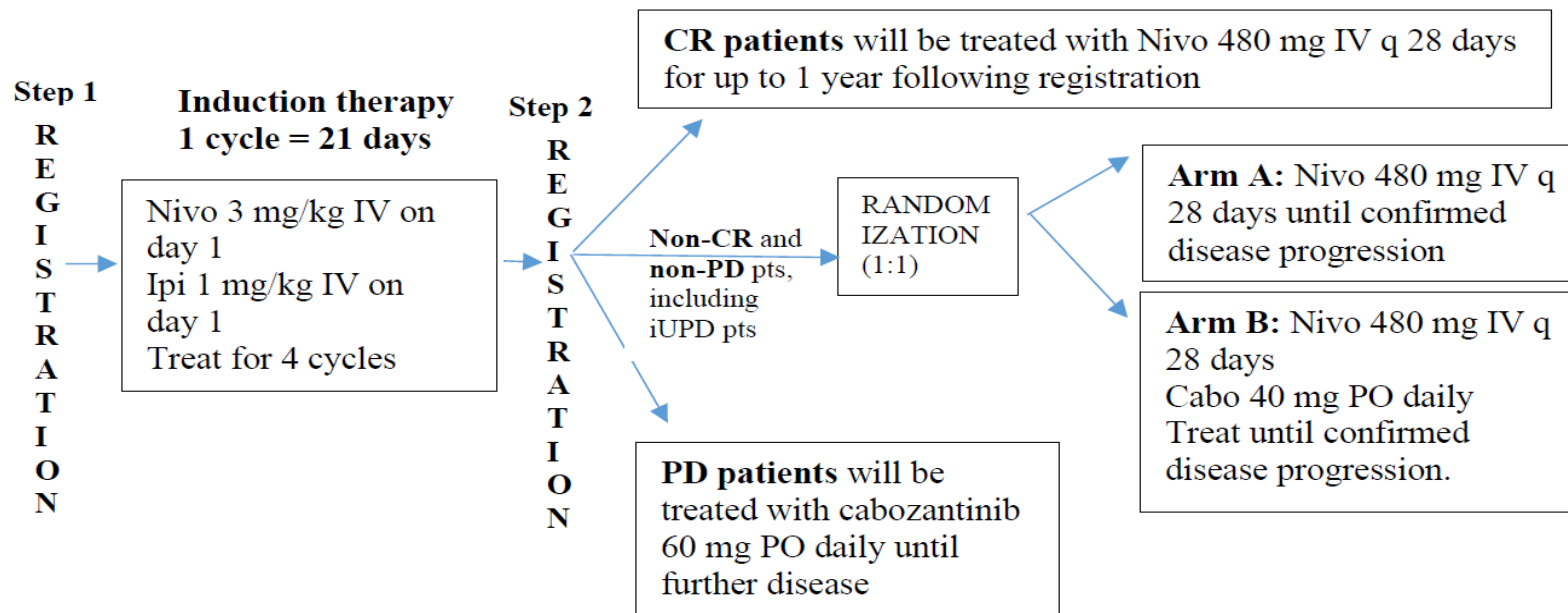
For all patients, treatment is to continue until disease progression or unacceptable adverse event.
Patients will be followed for 5 years or until death, whichever comes first.

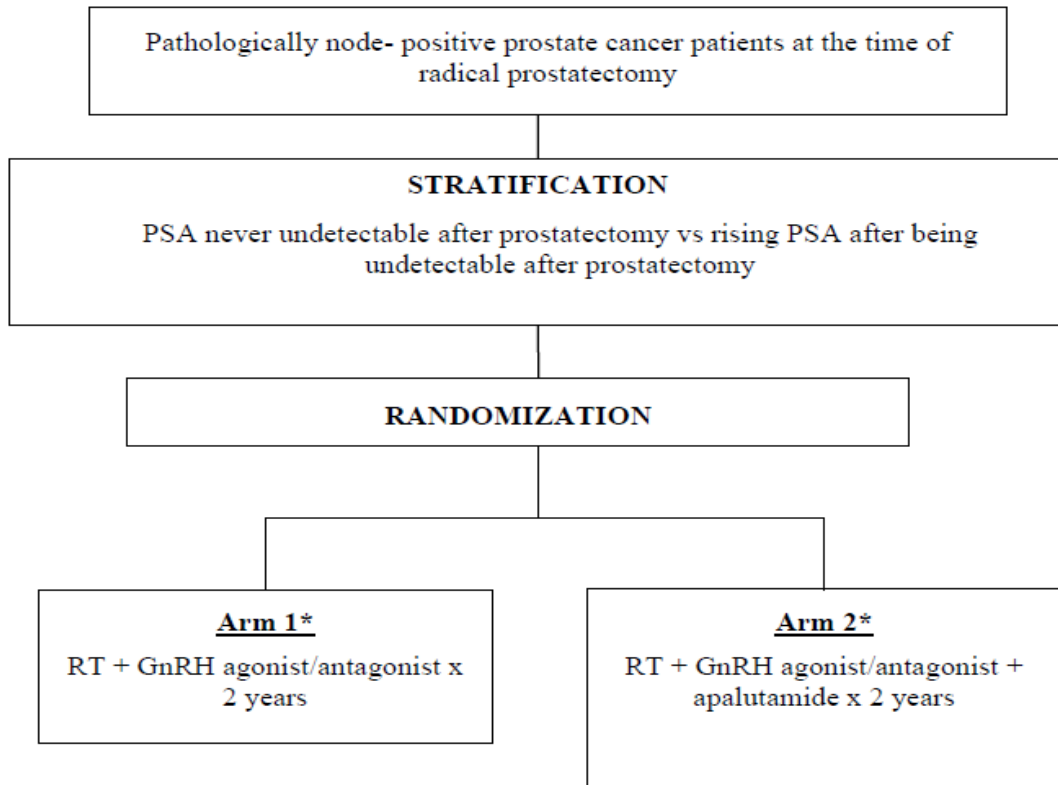
Please refer to the full protocol text for a complete description of the eligibility criteria and treatment plan.



Schema

1 cycle = 28 days





NRG-CC009
SCHEMA

STEP 1 REGISTRATION



STEP 2 REGISTRATION/RANDOMIZATION

Baseline neurocognitive function (NCF) tests: HVLT-R, TMT, COWA (*required*)
Note: NCF testing scores must be uploaded into Rave prior to Step 2 Registration and can be uploaded at the time of Step 1 Registration

STRATIFY

Disease-Specific Graded Prognostic Assessment (DS-GPA)²:

- 1. 0.5-2.0
- 2. 2.5-4.0

Prior exposure to NCF testing on SWOG S1827³:

- 1. Yes
- 2. No

RANDOMIZE¹



Arm 1

Stereotactic radiosurgery (SRS)



Arm 2

Whole brain radiotherapy with hippocampal avoidance (HA-WBRT)+ Memantine

¹Randomization is 1:1

NRG-GU009
SCHEMA

STEP 1 REGISTRATION

Completion of Step 1 eligibility checklist in OPEN and then submission of tissue for Decipher analysis
Note: Decipher analysis results must be completed before Step 2 randomization can occur. If Decipher results have already been obtained, in lieu of tissue, after completion of Step 1 eligibility checklist in OPEN, the original Decipher report must be submitted to Decipher Biosciences for validation (see Decipher Analysis information at the end of section 3.0).

STEP 2 RANDOMIZATION
Decipher \leq 0.85

DE-INTENSIFICATION STUDY
STRATIFY

- Decipher Score (Low/Int v High*)
- Boost type (EBRT vs. Brachy)
- Pelvic Treatment (Yes/No)
- ACE-27 Comorbidity (0/1 vs 2/3)**

RANDOMIZE 1:1

Arm 1
RT
+
24 mos ADT

Arm 2
RT
+
12 mos ADT

STEP 2 RANDOMIZATION
Decipher $>$ 0.85 or Node Positive

INTENSIFICATION STUDY
STRATIFY

- Boost type (EBRT vs. Brachy)
- Pelvic Treatment (Yes/No)
- Nodal Status (Positive/Negative)

RANDOMIZE 1:1

Arm 3
RT
+
24 mos ADT

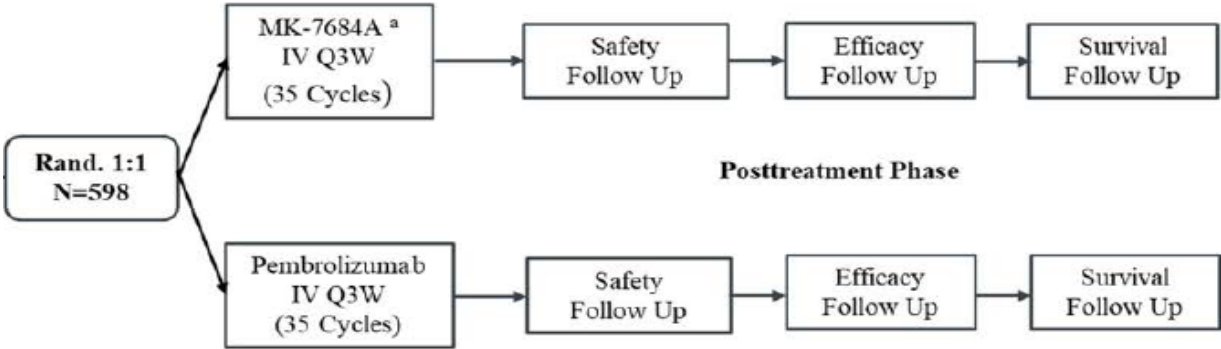
Arm 4
RT
+
24 mos ADT
+24 mos Apalutamide

* Low/Intermediate = Decipher $<$ 0.6 and High = Decipher 0.6-0.85

** http://comogram.org/assets/files/ace-27_ctr_ver_rtog_web.pdf

Note: A radiation treatment approach change post registration involving the pelvic lymph node treatment or prostate boost type stratification factors will result in a protocol deviation.

RT = radiation therapy; ADT = androgen deprivation therapy



Patients with resected pT1N0M0, HER2-Negative,
ER and/or PgR-Positive Breast Cancer
and Oncotype-DX Recurrence Score ≤ 18

Step 1 – Pre-entry registration

If patients with a *T1a tumor* (≤ 0.5 cm in size) do **not** have an Oncotype DX Recurrence Score, a tissue sample must be sent to the Genomic Health centralized laboratory

STRATIFICATION

- Age (< 60 ; ≥ 60)
- RS (≤ 11 , > 11)
- Tumor size (≤ 1 cm; 1.1–2 cm)

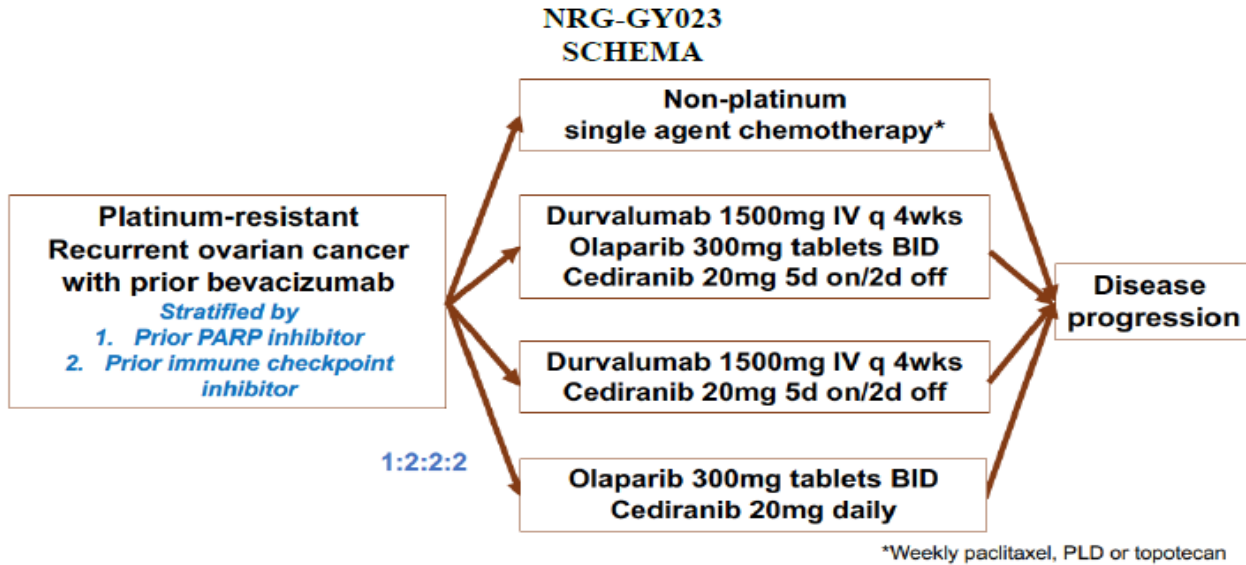
Step 2-RANDOMIZATION*

Arm 1**

Breast Radiation Therapy
+
Endocrine Therapy

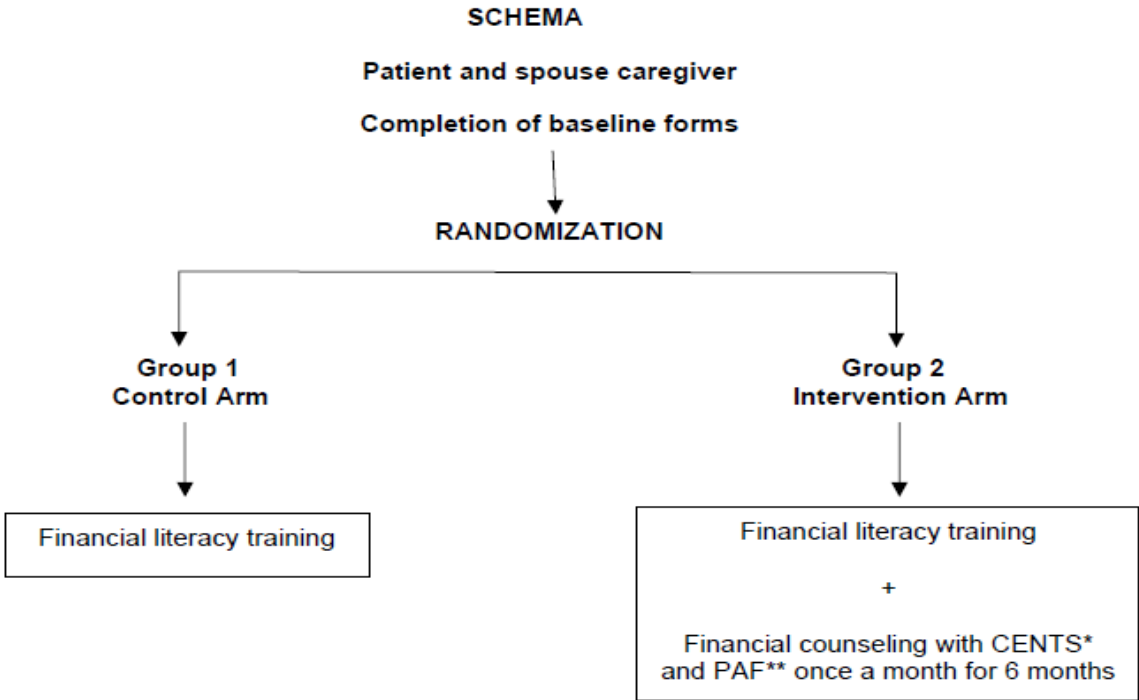
Arm 2**

No Breast Radiation Therapy
+
Endocrine Therapy



*Non-platinum single agent chemotherapy includes weekly paclitaxel, topotecan or pegylated liposomal doxorubicin (PLD). There can be no deviance from the prescribed regimens, e.g. addition of bevacizumab or other agents.

Randomization is 1:2:2:2

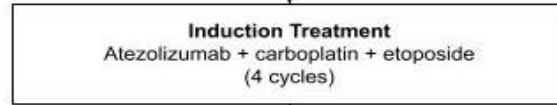
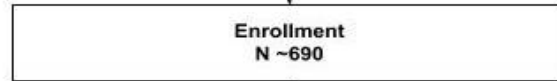
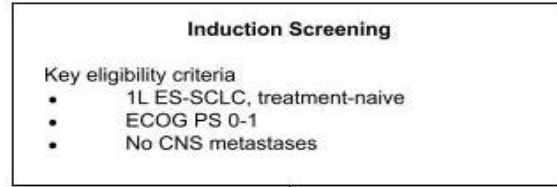


In order to participate, CCD Research sites must complete the **S1912CD** Site Implementation Survey and upload the completion certificate to the CTSU Regulatory Portal as described in [Section 13.4](#).

* Consumer Education and Training Services (CENTS)

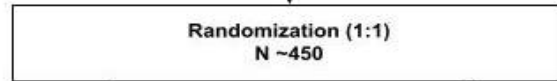
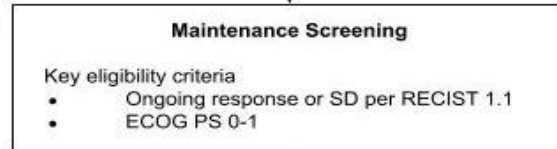
** Patient Advocate Foundation (PAF)

Baseline Induction



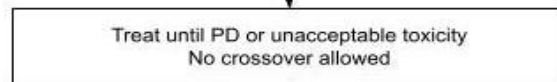
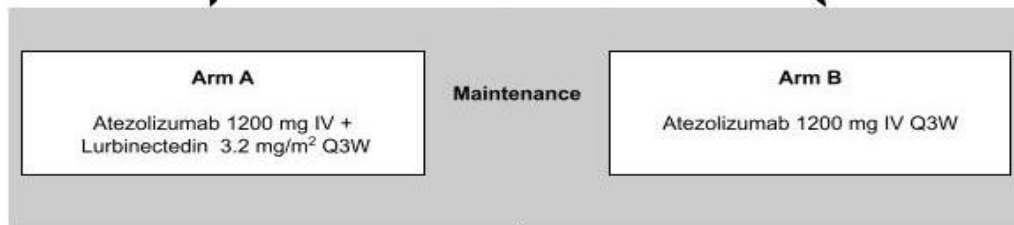
Optional PCI
(Investigator's discretion)

Baseline Maintenance

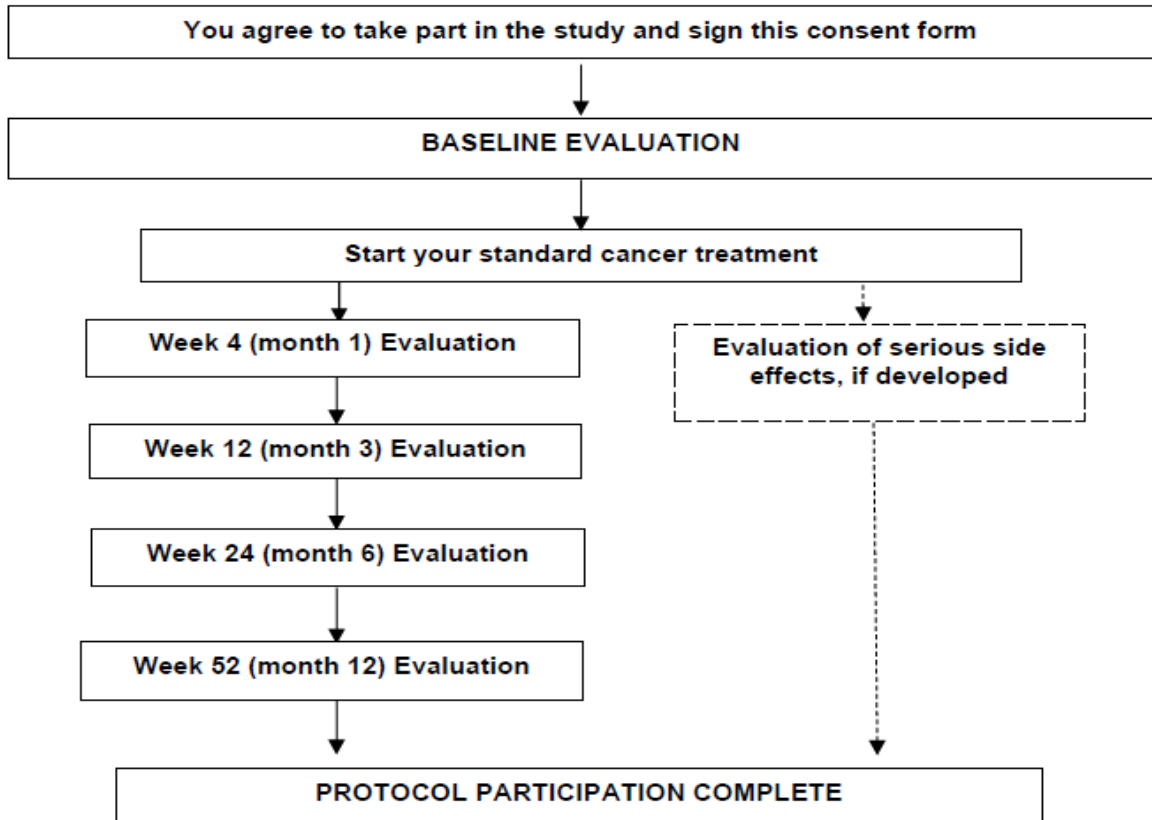


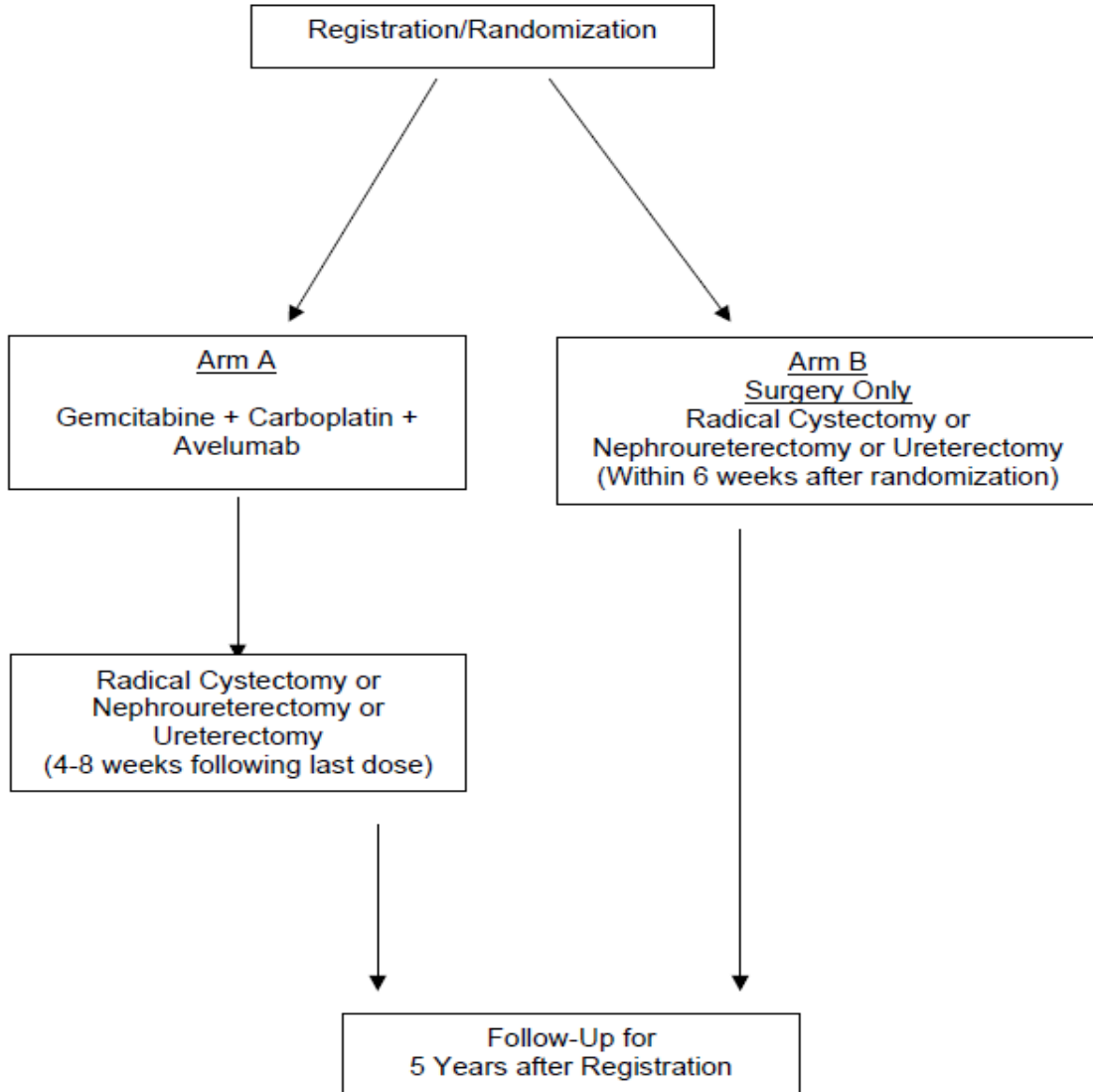
Stratification Factors

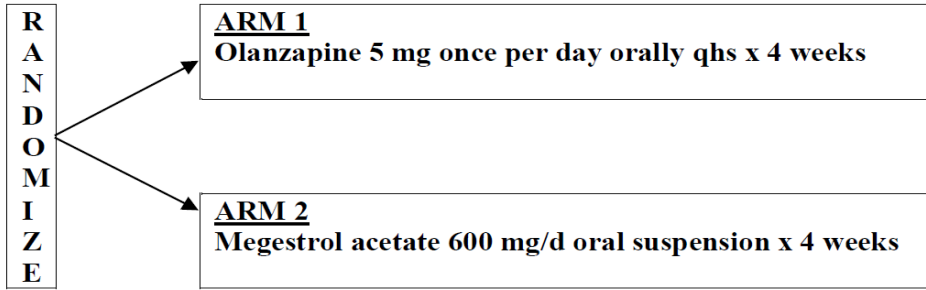
- ECOG PS at maintenance baseline (0 vs. 1)
- LDH at maintenance baseline (\leq ULN vs. $>$ ULN)
- Presence of liver metastases at induction baseline (yes vs. no)
- Prior PCI (yes vs. no)



SCHEMA

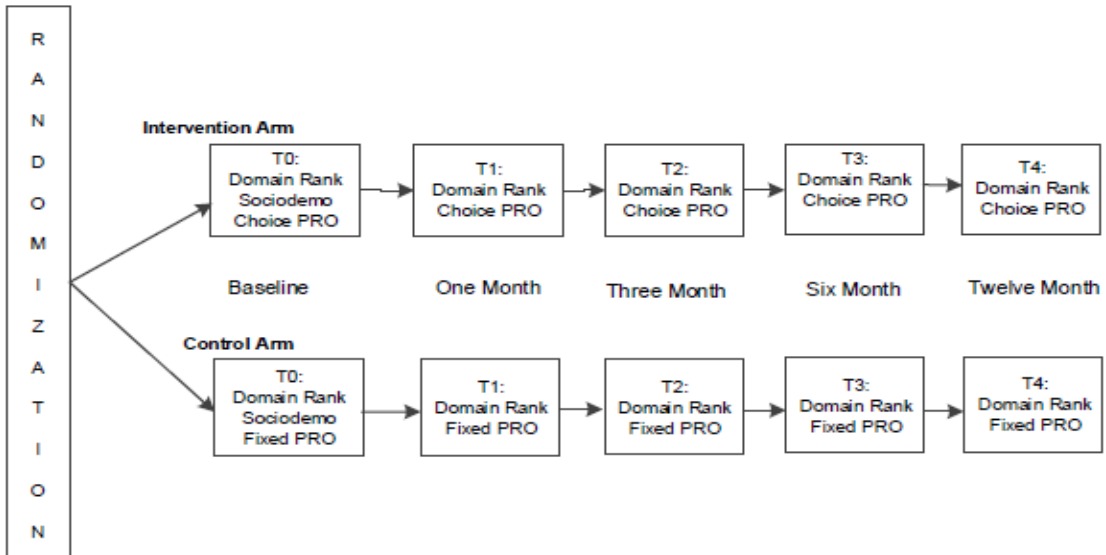






Treatment will continue for up to 4 weeks, unless the patient declines therapy or has unacceptable adverse events.

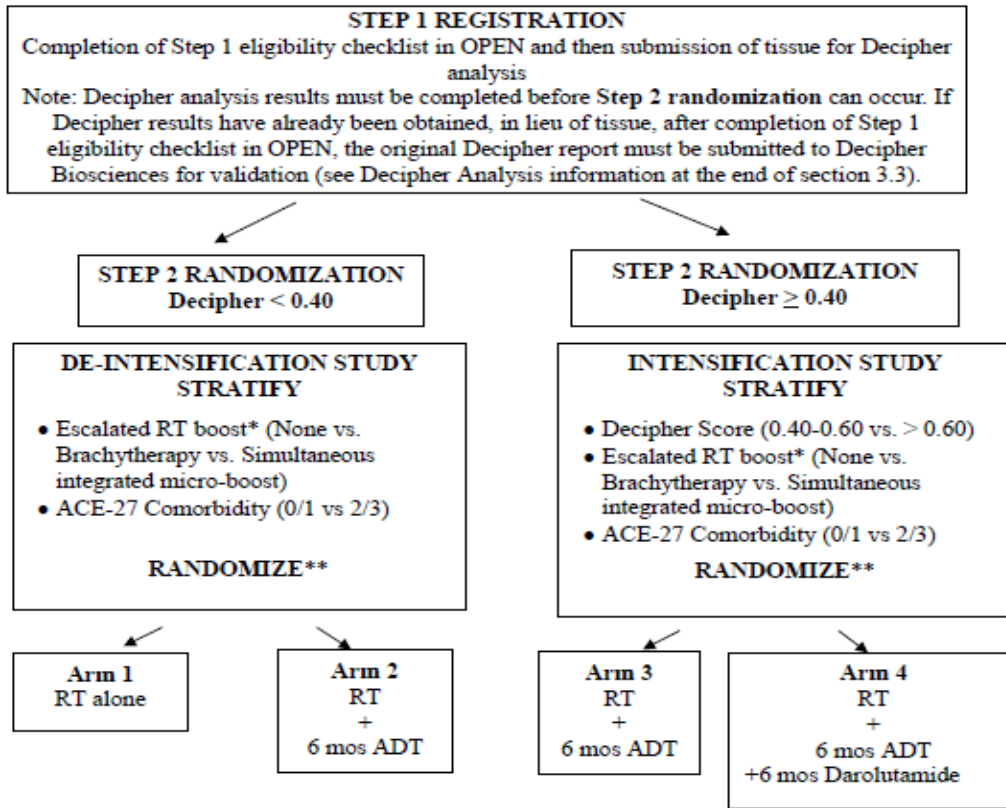
Schema



<p>Eligibility: -Age 18 to 39 -Within 12 weeks of diagnosis -Performance Status 0-3 -Any stage of cancer -Favorable prognosis</p>	<p>Randomization: Stratified by sex, race, ethnicity, and age (emerging adults 18-25-year-old vs young adults 26-39-year-old)</p>	<p>Domain Rank: Participant Ranks Domain by personal priority at each time point Fixed PRO: PROMIS Global, PROMIS standard AYA 5 domains, Common Items Choice PRO: PROMIS Global, 5 ranked AYA domains, Common Items</p>
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Accrual Goal = 400

SCHEMA

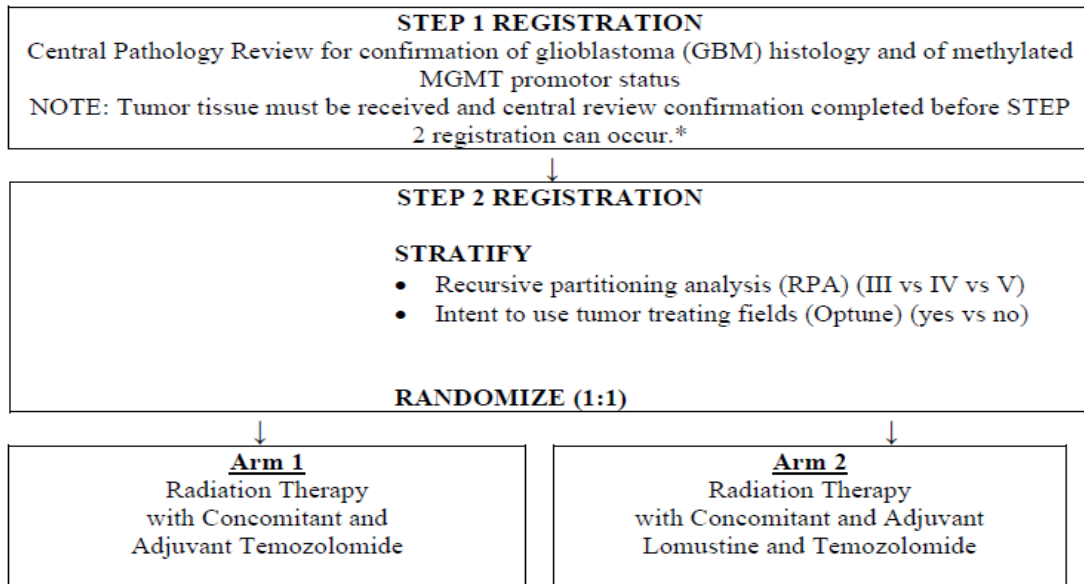


*For Escalated RT boost definition see Section 5.2 Establishing Treatment Approaches

**Randomization is 1:1

RT = radiation therapy; SBRT = stereotactic body radiotherapy; ADT = androgen deprivation therapy

NRG-BN011
SCHEMA



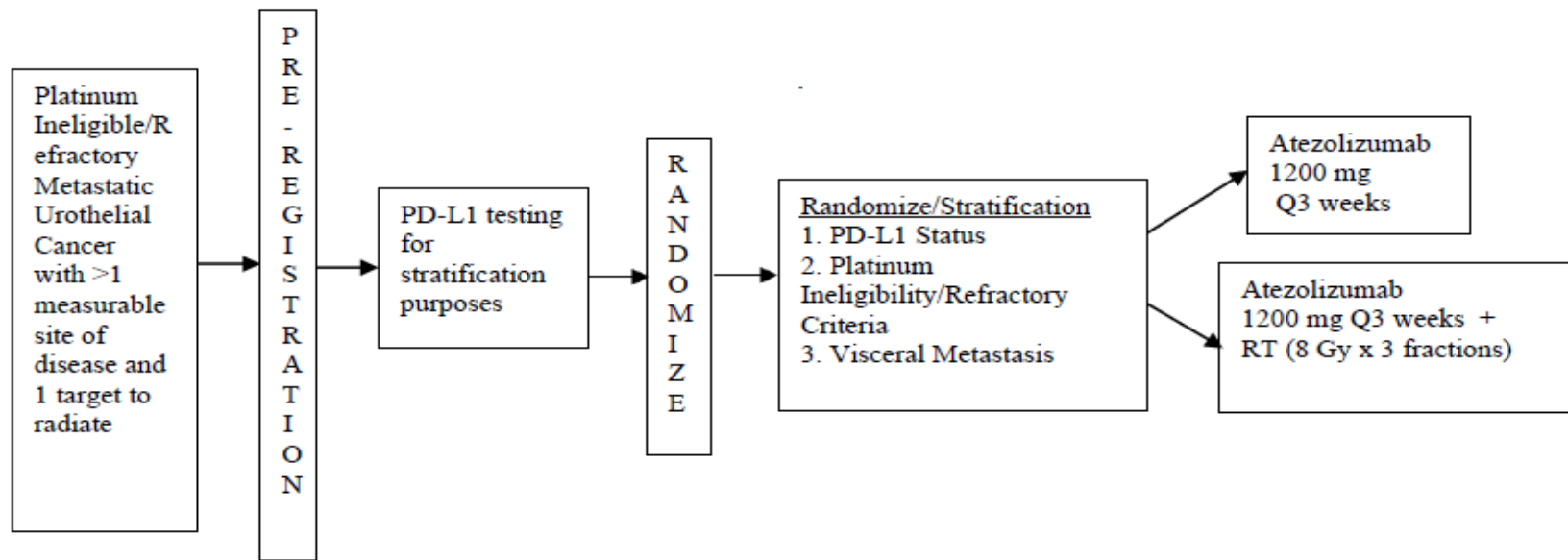
See [Section 5.1](#) for agent treatment details and [Section 5.2](#) for radiation therapy details.

*Patients with unmethylated MGMT may be considered for enrollment on NRG-BN007. Please see [Section 10.2](#) for additional information.

Alliance A032002

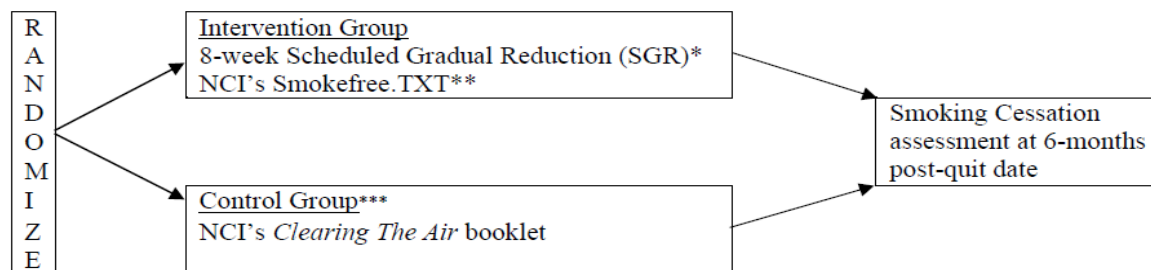
Schema

1 Cycle = 21 Days



Treatment is to continue until disease progression or unacceptable adverse event. Patients will be followed for 3 years or until death, whichever comes first.

Schema



- * Target quit date will be 8 weeks following enrollment.
- ** NCI's Smokefree.TXT messages will start 2 weeks before quit date and extend for 4 weeks after quit date.
- *** Quit date must be within 8 weeks of receiving the *Clearing The Air* cessation booklet

Please refer to the full protocol text for a complete description of the eligibility criteria and intervention plan.

**NRG-GU011
SCHEMA**

Recurrent Oligometastatic Prostate Cancer (detected by PET) after RT to Prostate or Radical Prostatectomy +/- Post-Operative Radiotherapy

STRATIFY

- Extrapelvic node(s) only vs Bone +/- node(s) [pelvic/extrapelvic]
 - PSA Doubling Time <12 mos vs \geq 12mos
 - Fluciclovine PET vs PSMA PET

RANDOMIZE*



Arm 1
SABR + blinded placebo** for 6 months



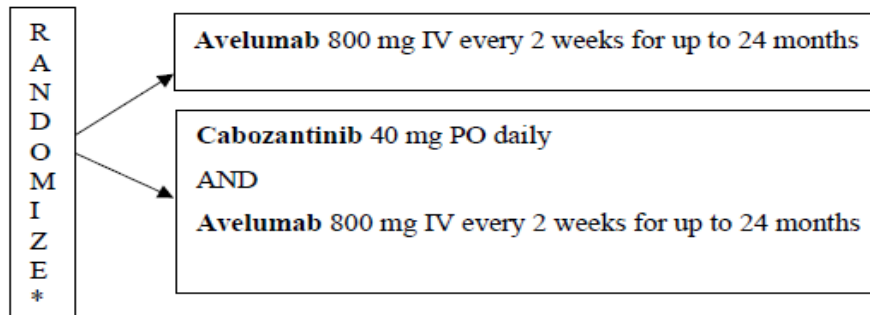
Arm 2
SABR + blinded relugolix** for 6 months

*Randomization is 1:1

** Monitor according to Test Schedule; see Sections 4.2, 4.3, and 5.3.1 for progression. Salvage ADT should be delayed until metastatic progression by conventional imaging.

Schema

1 Cycle = 28 Days



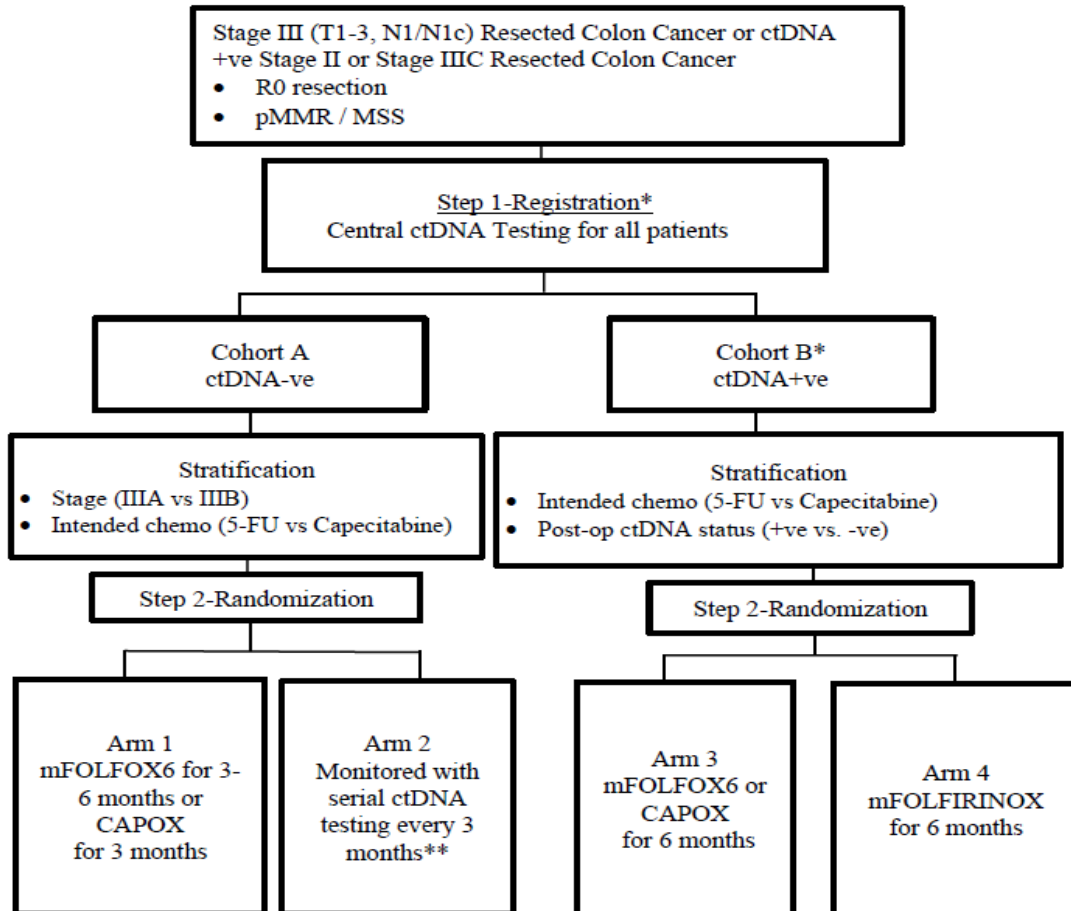
*Randomization is to occur 3-10 weeks after last dose of 1st-line treatment

Stratification:

- Best response to 1st-line chemo (SD vs PR vs CR)
- Visceral metastases: present versus absent

Please refer to the full protocol text for a complete description of the eligibility criteria and treatment plan.

Figure 1.
NRG-GI008 SCHEMA



*Patients with completely resected stages II or IIIC colon cancer who are ctDNA +ve as determined by a Signatera™ ctDNA test performed outside of the trial through routine clinical care and who otherwise meet all eligibility criteria for Step 1-Registration are eligible for enrollment into Cohort B.

**Patients in Cohort A (Arm 2) who develop a ctDNA +ve assay during serial monitoring may transition to the ctDNA+ve cohort (Cohort B) and undergo a second randomization.

STUDY SCHEMA

Screen patients scheduled to receive an FDA approved anti-PD-1/-L1 immune checkpoint inhibitor (ICI) for the first time, alone or in combination with co-treatments

Register and **consent** patients prior to the first infusion of ICIs

Baseline (A1): up to two weeks before the patient's first ICI infusion, collect:

- Clinical record and laboratory data
- Patient Reported Outcomes (PROs)
- Peripheral blood samples
- Saliva sample
- Tumor samples (if available)

During Treatment (A2): up to a week before the patient's second ICI infusion (usually 2-3 weeks after A1), collect:

- Clinical record and laboratory data
- Patient Reported Outcomes (PROs)
- Peripheral blood samples
- Saliva sample

6 Month Follow Up (A3): 6 months \pm 1 month after the first ICI infusion, collect:

- Clinical record and laboratory data
- Patient Reported Outcomes (PROs)
- Peripheral blood samples

Annual Follow Up (A4+): 1 year \pm 3 months after the first ICI infusion, and yearly thereafter until patient death or study end, collect:

- Clinical record and laboratory data
- Patient Reported Outcomes (PROs)
- Peripheral blood samples

At each infusion while the patient is on ICI treatment, collect Cancer Treatment, Toxicity and Response data

For patients with oropharyngeal cancer (OPC) or cancer of unknown primary (CUP):
Local p16 determination by immunohistochemistry is required.

For patients with laryngeal and hypopharyngeal primaries:
Analysis of p16 status is **not required**.



STRATIFY

- Zubrod (ECOG) performance status: 0 vs. 1
- Smoking status: ≤ 10 pack-year vs. > 10 pack-year history
 - T stage: T0-3 vs. T4
 - Age: ≤ 50 vs. > 50 years

RANDOMIZE (1:1 in each cohort)



Non-OPC/p16-negative OPC Cohort

Arm 1: IMRT/IMPT + High-dose cisplatin
Q 3 weeks

Arm 2: IMRT/IMPT + Low-dose cisplatin
weekly

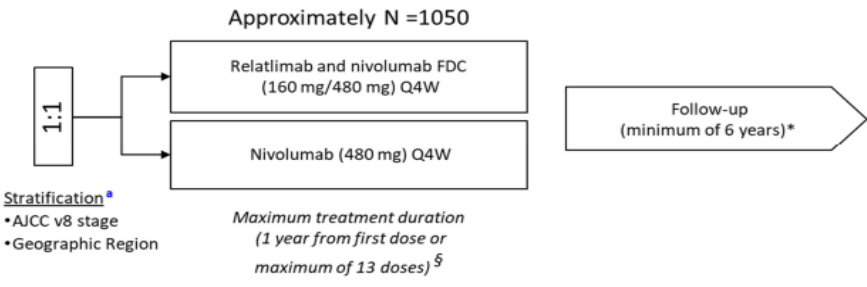


p16-positive OPC/CUP Cohort

Arm 3: IMRT/IMPT + High-dose cisplatin
Q 3 weeks

Arm 4: IMRT/IMPT + Low-dose cisplatin
weekly

- Key Eligibility Criteria**
- ≥ 18 Years of Age
 - Completely Resected Melanoma
 - Stage IIIA (>1 mm tumor in LN), Stage IIIB/C/D, or Stage IV NED Melanoma
 - No prior immuno-oncology agents
 - ECOG Performance Status ≤ 1
 - Submission of FFPE tissue block or 20 unstained slides from surgical/biopsy specimen within 3 months of randomization.

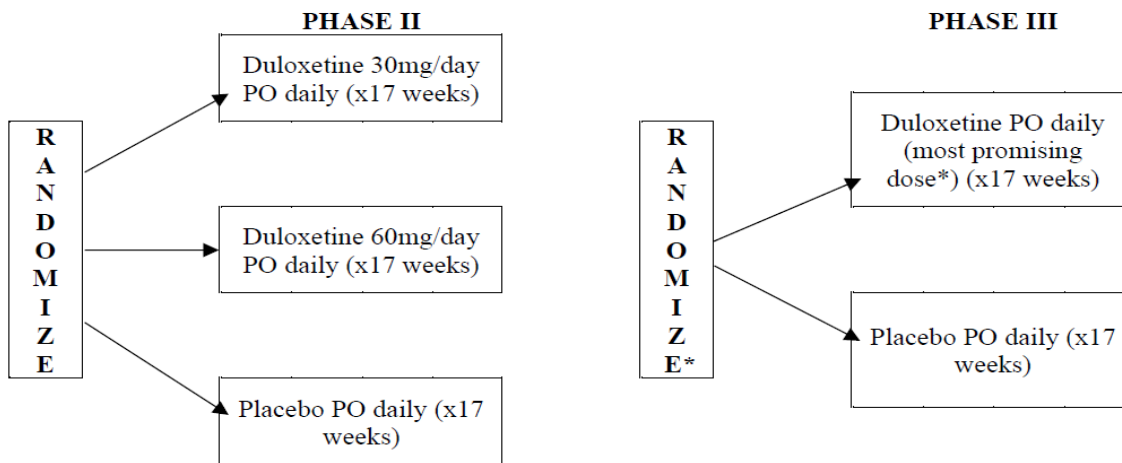


[§] All participants will be treated until recurrence of disease (except melanoma in situ), unacceptable toxicity, participant withdrawal of consent, or a maximum duration of 1 year from first-dose (maximum of 13 doses), whichever occurs first.

* Participants will be followed until death, lost to follow-up, withdrawal of consent, conclusion of the study, or a minimum of 6 years.

Abbreviations: AJCC v8, American Joint Committee on Cancer, version 8; ECOG, Eastern Cooperative Oncology Group; FDC, fixed dose combination; FFPE, formalin-fixed paraffin-embedded; LN, lymph node; NED, no evidence of disease; ROW, rest of the world; Q4W, every 4 weeks.

Schema

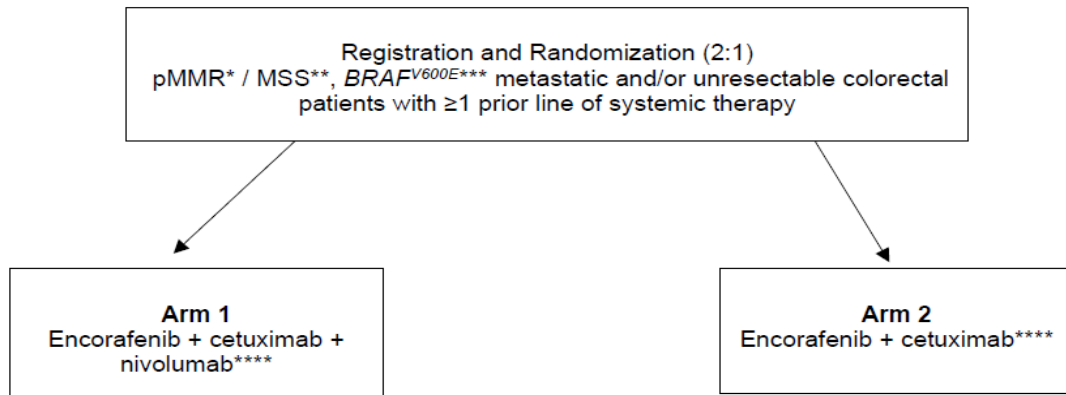


All patients will receive oxaliplatin on both phases of the trial. Further, for all patients the 17th week of study drug will be a tapering period.

* Additional patients will be recruited to the Phase III trial. The most promising dose of duloxetine will be determined after initial Phase II, and this dose will be used for Phase III for patients randomized to the duloxetine arm.

S2107 SCHEMA
Navigator - Carrie x3621

MENU



* Proficient mismatch repair (pMMR)

** Microsatellite stable (MSS)

***An activating missense mutation in codon 600 of exon 15 B-Raf proto-oncogene (*BRAF*^{V600E})

****Treatment continues until participant meets one of the criteria listed in [Section 7.7](#).

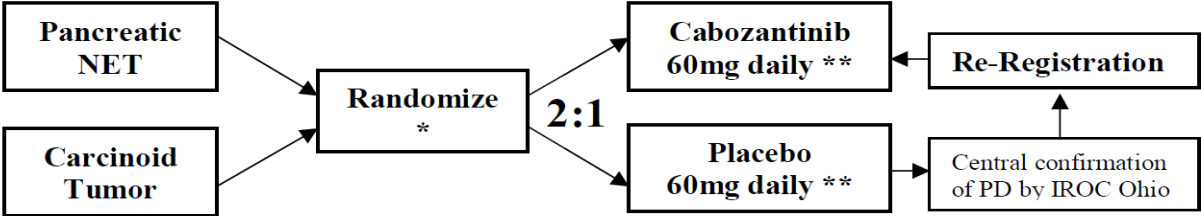
A071702 SCHEMA
Navigator - Carrie x3621



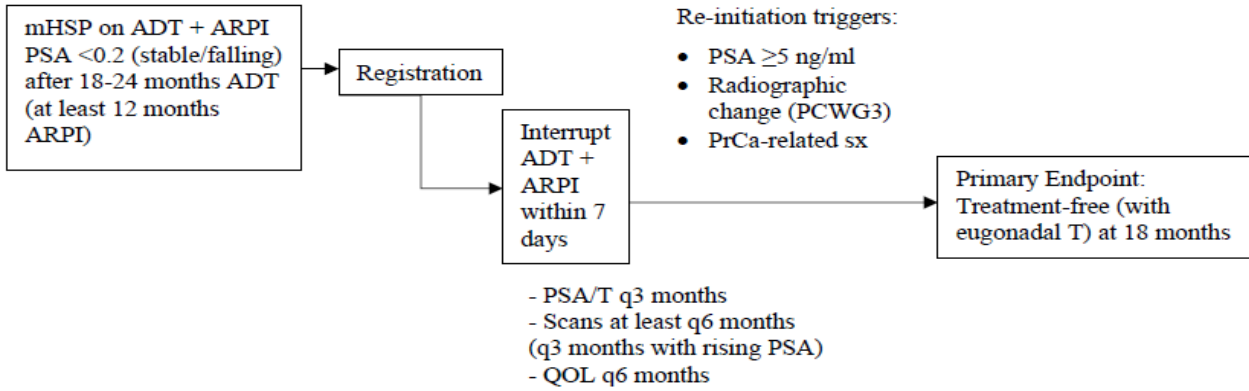
* During Cycles 1-4, one cycle is defined as 3 weeks. Beginning at Cycle 5, one cycle is defined as 4 weeks.

Treatment is to continue until disease progression, unacceptable toxicity, or withdrawal of consent. Patients will be followed for survival and progression every 3 weeks during Cycle 1-4 and every 4 weeks after Cycle 5 until progression, and then for survival every 3 months until 3 years after registration or until death, whichever comes first.

1 Cycle = 28 Days



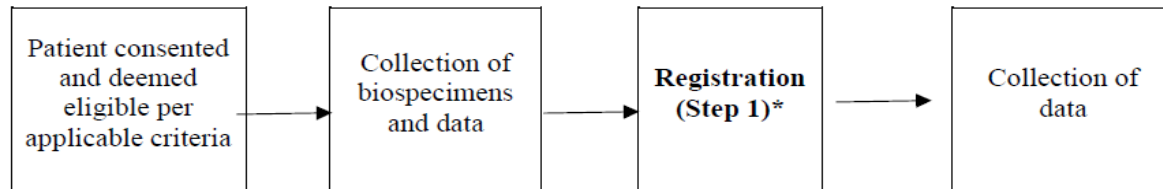
Schema



Treatment is re-initiated per the pre-specified triggers (PSA increase to ≥ 5 ng/ml, radiographic change [PD on CT/MRI imaging per modified RECIST 1.1 or PDu on bone scintigraphy per PCWG3], or symptoms attributable to prostate cancer). Subsequent management is per physician discretion. Patients undergo protocol assessments until a new treatment is initiated after the initial ARPI is permanently discontinued (i.e. at time to next treatment [TTNT]), and are subsequently followed until withdrawal of consent or death.

**At the time of
registration****

**12 months (+/-
60 days) after
registration**

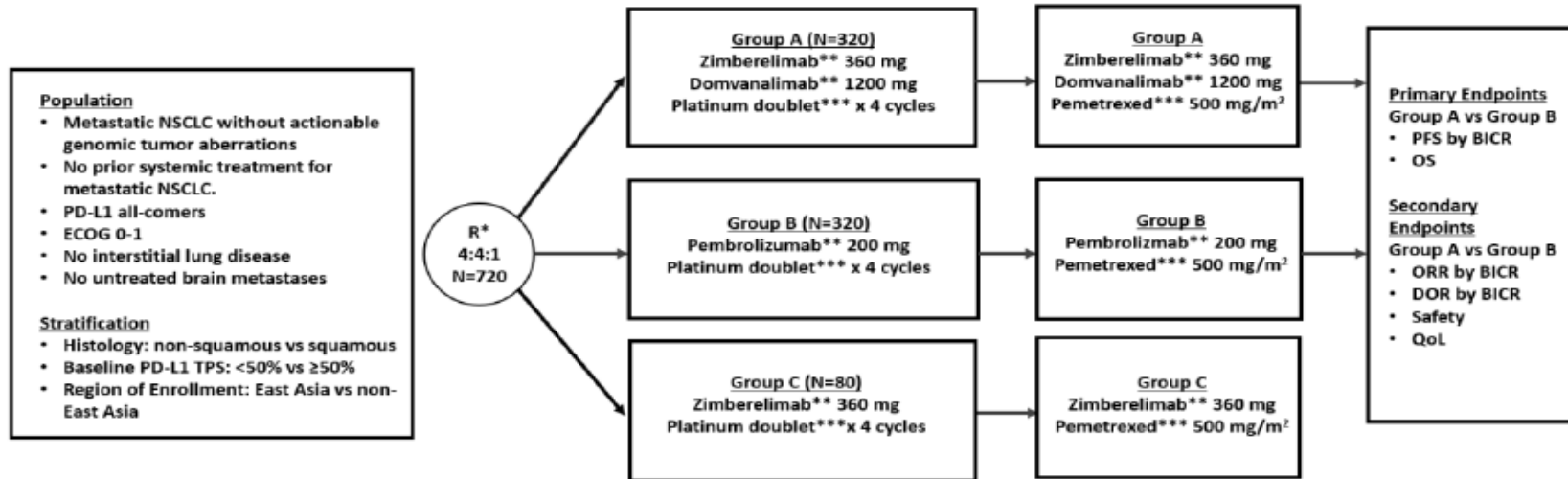


* Slot reservation required (see [Section 4.3](#)).

** For patients with a cancer diagnosis, biospecimens and data should be collected prior to any definitive therapy for the cancer.

GS-US-626-6216 (STAR-121)
Navigator -Ashton Todd x3611

MENU

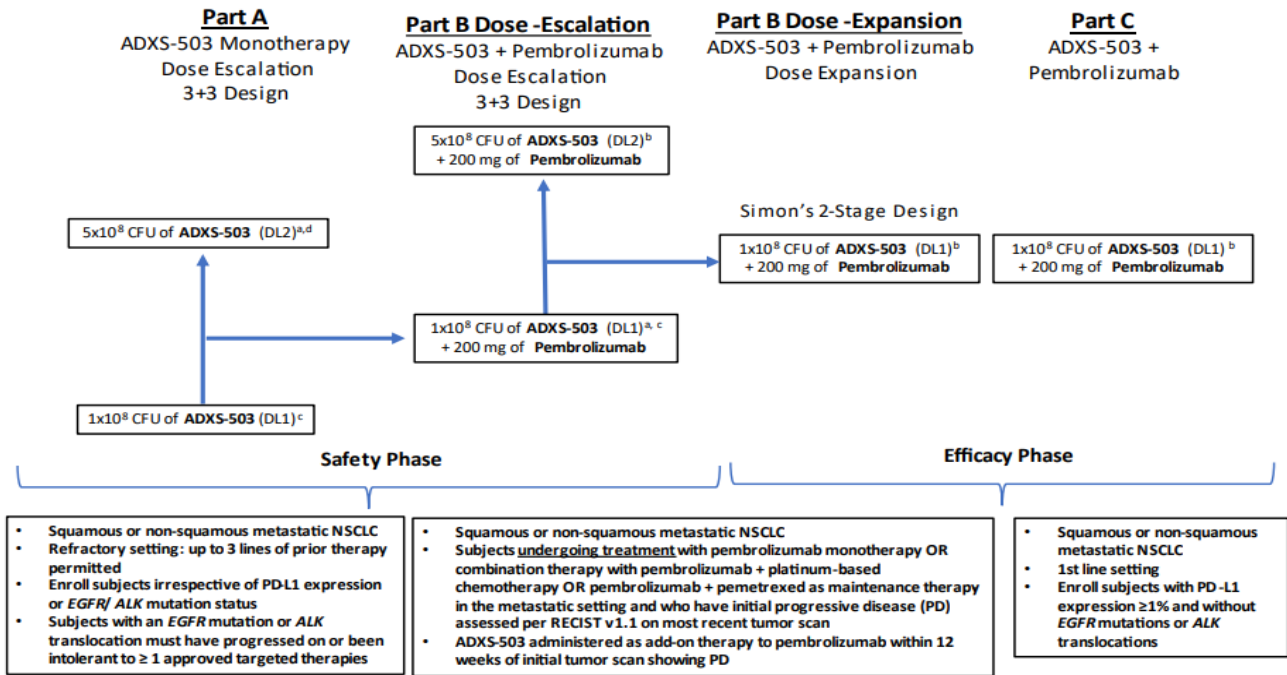


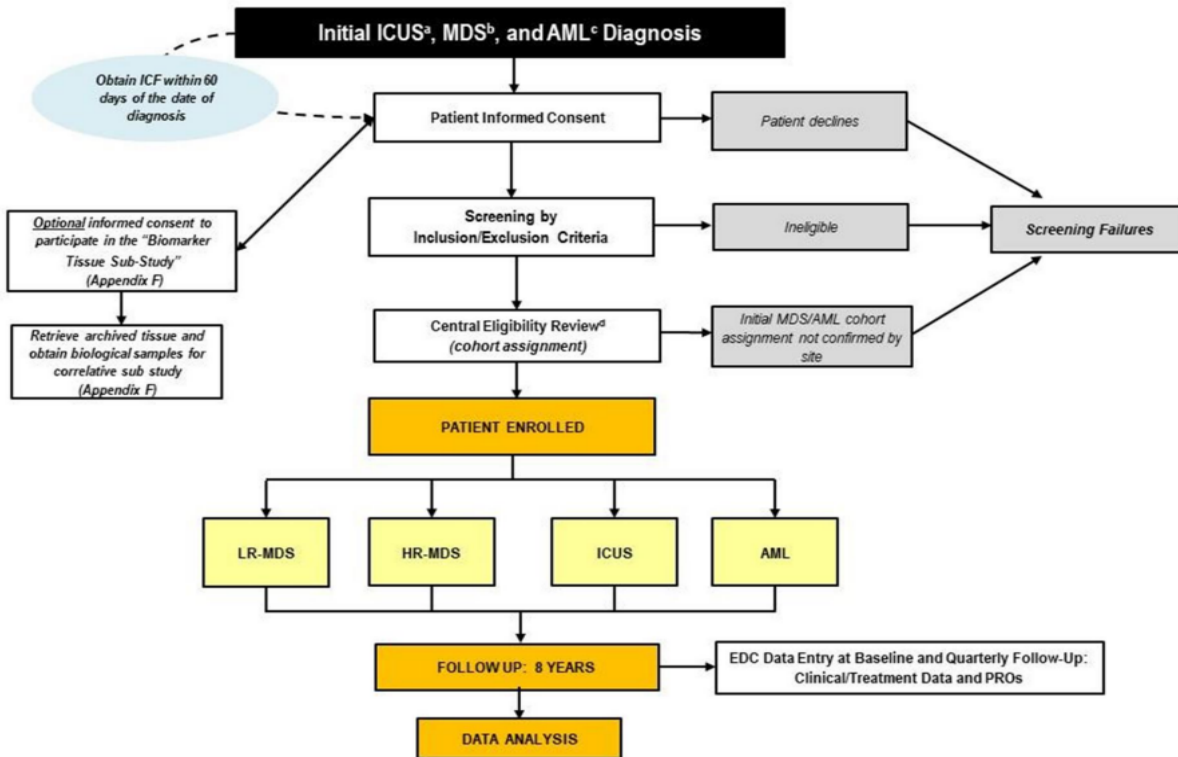
AUC = area under the curve; BICR = blinded independent central review; DOR = duration of response; ECOG = Eastern Cooperative Oncology Group; eDMC = external Data Monitoring Committee; NSCLC = non-small cell lung cancer; ORR = objective response rate; OS= overall survival; PD-L1 = programmed cell death ligand 1; PFS = progression-free survival; Q3W = every 3 weeks; QOL = quality of life; QW = weekly; R = randomized; TPS = tumor proportion score

*The first eDMC review is planned after a safety run-in period, defined as approximately 20 participants randomized in Group A completing at least 1 full study cycle.

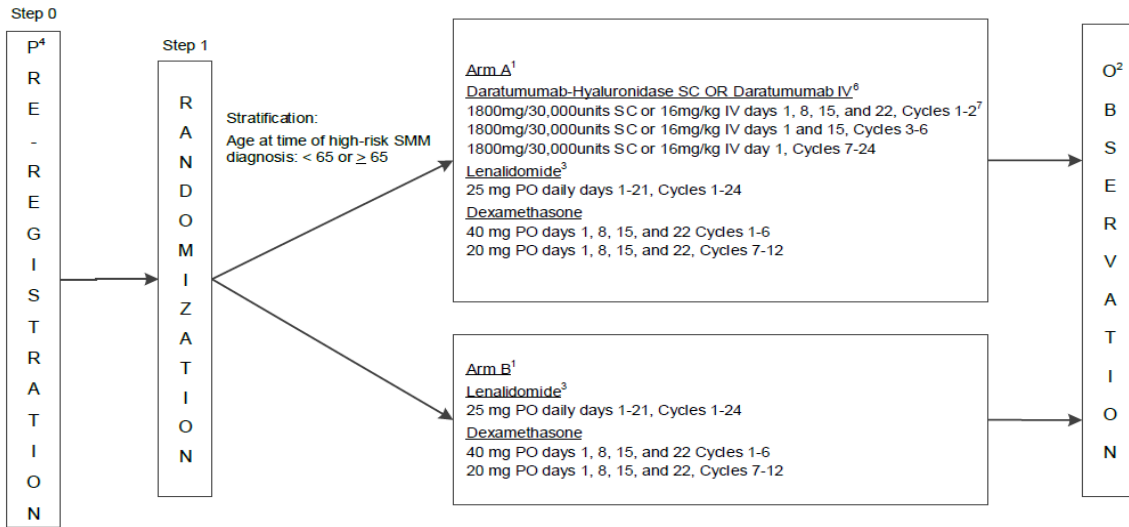
**Zimberelimab, domvanalimab, and pembrolizumab are given Q3W for a maximum of 35 doses.

***Choice of chemotherapy is dependent on histology. Participants with nonsquamous histology will receive cisplatin 75 mg/m² or carboplatin AUC 5 with pemetrexed 500 mg/m² Q3W. Those with squamous histology will receive carboplatin AUC 6 Q3W with paclitaxel 200 mg/m² Q3W or nab-paclitaxel 100 mg/m² QW. For participants with nonsquamous histology, pemetrexed 500 mg/m² Q3W is continued after 4 cycles of induction chemotherapy until PD or intolerable toxicities.





- ICUS diagnosis: refers to the date of either (a) the most recent BM aspirate/biopsies, or (b) the date of the laboratory assessment documenting cytopenia(s) consistent with the severity and length of time required for an ICUS diagnosis
- MDS Diagnosis: refers to the date of initial BM aspirate/biopsies for patients with classified risk of MDS.
- AML Diagnosis: refers to the date of initial BM aspirate/biopsies or the date of initial peripheral blood sample that led to the suspected diagnosis (not the date of subsequent samples)
- Diagnosis reports to be submitted for the Central Eligibility Review (CER) should include (not limited to) BM aspirate/biopsies report, cytogenetic report, peripheral laboratory results (including the percentage of blasts, if available), and any other laboratory results or reports that led to the diagnosis of MDS, ICUS or AML.



Accrual Goal: 288 patients with high-risk smoldering multiple myeloma.⁵

Cycle: 28 days

1. Peripheral blood stem cells for future transplants should be collected between cycles 4-6 of therapy. Therapy may be interrupted for up to 6 weeks to allow for PBSC collection. While collection following 4-6 weeks of therapy is strongly suggested, it is not required for protocol participation.
2. All patients, including those who discontinue protocol therapy early, will be followed for response until progression, even if non-protocol therapy is initiated, and for survival for 15 years from the date of randomization.
3. In patients with calculated (Cockcroft-Gault) creatinine clearance of 30-59 ml/min, starting dose of lenalidomide should be reduced to 10 mg. If the clearance improves to ≥ 60 ml/min, the dose can be increased to 25 mg provided the patient has not experienced any of the toxicities that would require a dose reduction for lenalidomide.
4. Submission of pre-study specimens per patient consent.
5. Patients must be diagnosed within the past 12 months. See Section 3.2.2 for the definition of high-risk SMM.
6. Patients currently receiving IV daratumumab should cross over to SC daratumumab-hyaluronidase unless they do not tolerate daratumumab-hyaluronidase. Patients intolerant of SC daratumumab-hyaluronidase may remain on or cross over to IV daratumumab. Please refer to section 5.1.1 for daratumumab treatment details.
7. For patients receiving IV daratumumab, split-dosing schedule may be used for first IV infusion, and will consist of 8mg/kg given on Cycle 1, days 1 and 2 only