



MASTER TRIAL LIST

JUNE 2022

*****NEW & REOPENED TRIALS HIGHLIGHTED IN GREEN!*****

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 6.7.22

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



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

Brain

[A071702](#)

A Phase II Study of Checkpoint Blockade Immunotherapy in Patients With Somatically Hypermutated Recurrent Glioblastoma

Carcinoid

[S2104](#)

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

Endometrial

[GY014](#)

(Temp. suspended) Phase II Study of Tazemetostat (EPZ-6438) (IND # 138671) in Recurrent or Persistent Endometrioid or Clear Cell Carcinoma of the Ovary, and Recurrent or Persistent Endometrioid Endometrial Adenocarcinoma

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](#)

Temporarily Closed (RT at Route-91) 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

<u>S1934</u>	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
Ovarian	
<u>GY014</u>	<i>(temp closed)</i> Phase II Study of Tazemetostat (EPZ-6438) (IND # 138671) in Recurrent or Persistent Endometrioid or Clear Cell Carcinoma of the Ovary, and Recurrent or Persistent Endometrioid Endometrial Adenocarcinoma
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
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>	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

JUNE 2022

[MENU](#)

AML

Navigator - Heather x3661



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ANAL

Navigator - Carrie x3621

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



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APL

Navigator - Heather x3661

There are no trials available at this time



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MENU

ACUTE LYMPHOBLASTIC LEUKEMIA

Navigator - Heather x3661

[EA9152](#)

Temporarily Closed | A Phase IB/II Study of Venetoclax (ABT-199) in Combination With Liposomal Vincristine in Patients With Relapsed or Refractory T-Cell or B-Cell Acute Lymphoblastic Leukemia



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JUNE 2022



BLADDER / UROTHELIAL

Navigator - Carrie x3621

ADJUVANT / NEOADJUVANT

<p><u>BMS CA017-078</u></p>	<p>(Peoria, Bloomington, Galesburg, and Peru) -A Phase 3, Randomized, Study of Neoadjuvant Chemotherapy alone versus Neoadjuvant Chemotherapy plus Nivolumab or Nivolumab and BMS-986205, Followed by Continued Post-Surgery Therapy with Nivolumab or Nivolumab and BMS-986205 in Participants with Muscle-Invasive Bladder Cancer (<i>BMS-986205/placebo tablets discontinued</i>)</p>
<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>(RT at Glen Oak, 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>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>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>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>

A032002

(RT at Glen Oak) Phase II Randomized Trial of Atezolizumab Versus Atezolizumab and Radiation Therapy for Platinum Ineligible/Refractory Metastatic Urothelial Cancer (ART)



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BRAIN

Navigator - Carrie x3621

<u>BN007</u>	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
<u>BN011</u>	(RT credentialing pending) A Phase III Trial of Gleostine® (Lomustine)-Temozolomide Combination Therapy Versus Standard Temozolomide in Patients With Methylated MGMT Promoter Glioblastoma
<u>N0577</u>	(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



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

Neo/Adjuvant - HER2 Positive

[EA1181](#)

Preoperative THP and Postoperative HP in Patients Who Achieve a Pathologic Complete Response (CompassHER2-pCR)

Neo/Adjuvant - Hormone Receptor Positive / HER2 Negative

[BR007](#)

(RT at Galesburg, Glen Oak, Rt 91, UPHM) 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

METASTATIC TREATMENT

Metastatic - HER2 Positive

Metastatic - Hormone Receptor Positive / HER2 Negative

Metastatic - Triple Negative

SURGERY / RADIATION ONLY

[A011202](#)

Temporarily Closed- A Randomized Phase III Trial Evaluating the Role of Axillary Lymph Node Dissection in breast Cancer Patients (cT1-3 N1) Who Have Positive Lymph Node Disease After Neoadjuvant Chemotherapy. (RT: Glen Oak, Rt 91, UPHM, Galesburg)

[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](#)

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

<u>A211901</u>	Reaching Rural Cancer Survivors Who Smoke Using Text-Based Cessation Interventions
<u>A222004</u>	A Randomized Phase III Trial of Olanzapine Versus Megestrol Acetate for Cancer-Associated Anorexia
<u>EAQ202</u>	Improving Adolescent and Young Adult Self-Reported Data in ECOG-ACRIN Trials
<u>S1912CD</u>	A Randomized Trial Addressing Cancer-Related Financial Hardship Through Delivery of a Proactive Financial Navigation Intervention (CREDIT)
<u>S2013</u>	(Peoria, Bloomington, Galesburg, Pekin, Washington) Immune Checkpoint Inhibitor Toxicity: A Prospective Observational Study (I-CHECKIT)
<u>URCC 16070</u>	Treatment of Refractory Nausea- for breast cancer patients.
<u>URCC-18007</u>	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>
<u>URCC 21038</u>	(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
<u>WF-1901</u>	Internet-delivered Management of Pain Among Cancer Treatment Survivors (IMPACTS)

GYNECOLOGICAL

Navigator - Angie x3613

<u>NRG - GY023</u>	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	Reaching Rural Cancer Survivors Who Smoke Using Text-Based Cessation Interventions
A222004	A Randomized Phase III Trial of Olanzapine Versus Megestrol Acetate for Cancer-Associated Anorexia
EAQ202	Improving Adolescent and Young Adult Self-Reported Data in ECOG-ACRIN Trials
S1912CD	A Randomized Trial Addressing Cancer-Related Financial Hardship Through Delivery of a Proactive Financial Navigation Intervention (CREDIT)
S2013	(Peoria, Bloomington, Galesburg, Pekin, Washington) Immune Checkpoint Inhibitor Toxicity: A Prospective Observational Study (I-CHECKIT)
URCC 21038	(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	Internet-delivered Management of Pain Among Cancer Treatment Survivors (IMPACTS)

BREAST

A191901	(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 - <i>See Multi-Disease Cancer Control trials ABOVE .</i>
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COLORECTAL

A221805	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
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REGISTRY

Contact Disease Specific Navigator



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[MENU](#)

CARCINOID

Navigator - Ashton x3611
Carrie x3621

No trials at this time



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CLL

Navigator - Heather x3661

1st Line

<p><u>A041702</u></p>	<p>Temporarily closing on 6/14/22 A Randomized Phase III Study of Ibrutinib Plus Obinutuzumab Versus Ibrutinib Plus Venetoclax and Obinutuzumab in Untreated Older Patients (≥ 65 Years of Age) With Chronic Lymphocytic Leukemia (CLL)</p>
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2nd Line, 3rd Line, etc.

no trials at this time



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CML

Navigator - Heather x3661

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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	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	Temporarily Closed Colon Adjuvant Chemotherapy Based on Evaluation of Residual Disease

Metastatic

MK 7339-003	(Peoria, Bloomington, Galesburg, Peru) A Phase 3 Randomized, Open-label Study to Evaluate the Efficacy and Safety of Olaparib Alone or in Combination With Bevacizumab Compared to Bevacizumab with 5-FU in Participants with Unresectable or Metastatic Colorectal Cancer who Have Not Progressed Following First-line Induction of FOLFOX With Bevacizumab (LYNK-003)
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CANCER CONTROL (Colorectal only)

A211901	Reaching Rural Cancer Survivors Who Smoke Using Text-Based Cessation Interventions
A221805	Duloxetine to Prevent Oxaliplatin-Induced Chemotherapy-Induced Peripheral Neuropathy: A Randomized, Double-Blind, Placebo-Controlled Phase II to Phase III Study
A222004	A Randomized Phase III Trial of Olanzapine Versus Megestrol Acetate for Cancer-Associated Anorexia
EAQ202	Improving Adolescent and Young Adult Self-Reported Data in ECOG-ACRIN Trials
S1912CD	A Randomized Trial Addressing Cancer-Related Financial Hardship Through Delivery of a Proactive Financial Navigation Intervention (CREDIT)
S2013	(Peoria, Bloomington, Galesburg, Pekin, Washington) Immune Checkpoint Inhibitor Toxicity: A Prospective Observational Study (I-CHECKIT)
URCC 21038	(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

<u>WF-1901</u>	Internet-delivered Management of Pain Among Cancer Treatment Survivors (IMPACTS)
<u>WF-1806</u>	(M&M Study) Myopenia and Mechanisms of Chemotherapy Toxicity in older Adults with Colorectal Cancer



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ESOPHAGEAL- GASTRIC

Navigator - Carrie x3621

[EA2174](#)

(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>(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>Temporarily Closed (RT at Route-91) 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>(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>



Navigator - Heather x3661

LYMPHOMA

HL

<u>S1826</u>	(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 >= 12 Years) With Newly Diagnosed Advanced Stage Classical Hodgkin Lymphoma
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NHL

<u>EA4181</u>	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 ≤ 70 Years Old With Untreated Mantle Cell Lymphoma
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SLL



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MENU

MDS

Navigator - Heather x3661

<u>NHLBI-MDS</u>	(Peoria, Bloomington and Galesburg only) -The National Myelodysplastic Syndromes (MDS) Study
<u>M15-954</u>	(Peoria, Bloomington, Galesburg, Pekin) A Randomized, Double-Blind, Phase 3 Study Evaluating the Safety and Efficacy of Venetoclax in Combination With Azacitidine in Patients Newly Diagnosed With Higher-Risk Myelodysplastic Syndrome (Higher-Risk MDS)



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MELANOMA

Navigator - Carrie x3621

CA224098

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



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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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MENU

MOLECULAR STUDIES

*Contact Disease Specific Navigator

<u>64091742PCR0002 / Prevalence</u>	Biomarker Study to Determine Frequency of DNA-repair Defects in Men with Metastatic Prostate Cancer (Prevalence)
<u>A151804</u>	Establishment of a National Biorepository to Advance Studies of Immune-Related Adverse Events
<u>NSABP C-14</u>	Second Colorectal Cancer Clinical Validation Study to Predict Recurrence Using A Circulating Tumor DNA Assay To Detect Minimal Residual Disease (CORRECT-MRD II)
<u>S1823</u>	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>)
<u>TPX-0005-01 (TRIDENT-1)</u>	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)

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MULTIPLE MYELOMA

Navigator - Heather x3661

S1803

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)

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NEUROENDOCRINE

Navigator - Carrie x3621

[A021804](#)

A Prospective, Multi-Institutional Phase II Trial Evaluating Temozolomide vs. Temozolomide and Olaparib for Advanced Pheochromocytoma and Paraganglioma

NSCLC

Navigator - Ashton x3611

ADJUVANT / NEOADJUVANT

<u>A081801</u>	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>).
<u>A151216</u>	Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST).
<u>EA5181</u>	(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)
<u>GO41854</u>	(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)
<u>S1914</u>	(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
<u>S1934 (JIT)</u>	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)

METASTATIC - 1st Line

<u>EA5182</u>	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)
<u>MK 7684A-003</u>	(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
<u>TH-138</u>	(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 (non smokers)

METASTATIC - 2nd/3rd Line

<u>LUNGMAP</u>	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)
<u>MK 7684A-002</u>	(Peoria only) A Phase II, Multicenter, Randomized Study to Compare the Efficacy and Safety of MK-7684A or MK-7684A Plus Docetaxel Versus Docetaxel Monotherapy in the Treatment of Participants With Metastatic NSCLC With Progressive Disease After Treatment With a Platinum Doublet Chemotherapy and Immunotherapy.

<u>TH-138</u>	(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 (EGFR mutants)
CANCER CONTROL (NSCLC Only)	
<u>A211901</u>	Reaching Rural Cancer Survivors Who Smoke Using Text-Based Cessation Interventions
<u>A222004</u>	A Randomized Phase III Trial of Olanzapine Versus Megestrol Acetate for Cancer-Associated Anorexia
<u>EAQ202</u>	Improving Adolescent and Young Adult Self-Reported Data in ECOG-ACRIN Trials
<u>S1912CD</u>	A Randomized Trial Addressing Cancer-Related Financial Hardship Through Delivery of a Proactive Financial Navigation Intervention (CREDIT)
<u>S2013</u>	(Peoria, Bloomington, Galesburg, Pekin, Washington) Immune Checkpoint Inhibitor Toxicity: A Prospective Observational Study (I-CHECKIT)
<u>URCC 21038</u>	(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
<u>WF-1901</u>	Internet-delivered Management of Pain Among Cancer Treatment Survivors (IMPACTS)



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PANCREATIC

Navigator - Carrie x3621

PROSTATE

Navigator - Carrie x3621

ADJUVANT

GU008

(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): *Intensifying Treatment for Node Positive Prostate Cancer by Varying the Hormonal Therapy*

GU009

(RT at Glen Oak, Galesburg, UPHM) 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***)

GU010

(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)

METASTATIC

**64091742PCR0002 /
Prevalence**

Biomarker Study to Determine Frequency of DNA-repair Defects in Men with Metastatic Prostate Cancer

C2321001

(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)

A031902 / CASPAR

A Phase III Trial of Enzalutamide and Rucaparib as a Novel Therapy in First-Line Metastatic Castration-Resistant Prostate Cancer

<u>GU011</u>	(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)
<u>S1802</u>	(RT at Glen Oak & 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

MASTER TRIAL LIST

JUNE 2022



RENAL CELL

Navigator - Carrie x3621

<p><u>A031704</u></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>(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, 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>A071801</u>	(UPHM & Glen Oak) Phase III Trial of Post-Surgical Single Fraction Stereotactic Radiosurgery (SRS) Compared With Fractionated SRS for Resected Metastatic Brain Disease

<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>A011202</u>	<i>Temporarily Closed</i> (Glen Oak, Rt 91, UPHM, Galesburg) A Randomized Phase III Trial Evaluating the Role of Axillary Lymph Node Dissection in breast Cancer Patients (cT1-3 N1) Who Have Positive Lymph Node Disease After Neoadjuvant Chemotherapy.
<u>BR007</u>	(Galesburg, Glen Oak, Rt 91, UPHM) 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>	(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>	(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>	(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>	(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>	(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>	(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>	(RT at Glen Oak, Galesburg, UPHM) 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>	(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>	(RT at Glen Oak & UPHM) A Phase II Double-Blinded, Placebo-Controlled Trial of PROstate OligoMETastatic RadiotherErapy With or Without ANdrogen Deprivation Therapy in Oligometastatic Prostate Cancer (NRG Promethean)
<u>S1802</u>	(Glen Oak & 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 CC003</u>	(Glen Oak only) Randomized Phase II/III Trial of Prophylactic Cranial Irradiation with or without Hippocampal Avoidance for Small Cell Lung Cancer
<u>NRG CC009</u>	(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>LU005</u>	(Glen Oak, UPHM and Galesburg) Limited Stage Small Cell Lung Cancer (LS-SCLC): A Phase II/III Randomized Study of Chemoradiation Versus Chemoradiation Plus Atezolizumab
<u>S1827</u>	(Glen Oak, UPHM, Galesburg) A Randomized Phase III Trial of MRI Surveillance With or Without Prophylactic Cranial Irradiation (PCI) in Small-Cell Lung Cancer

SMALL CELL LUNG CANCER

Navigator - Ashton x3611

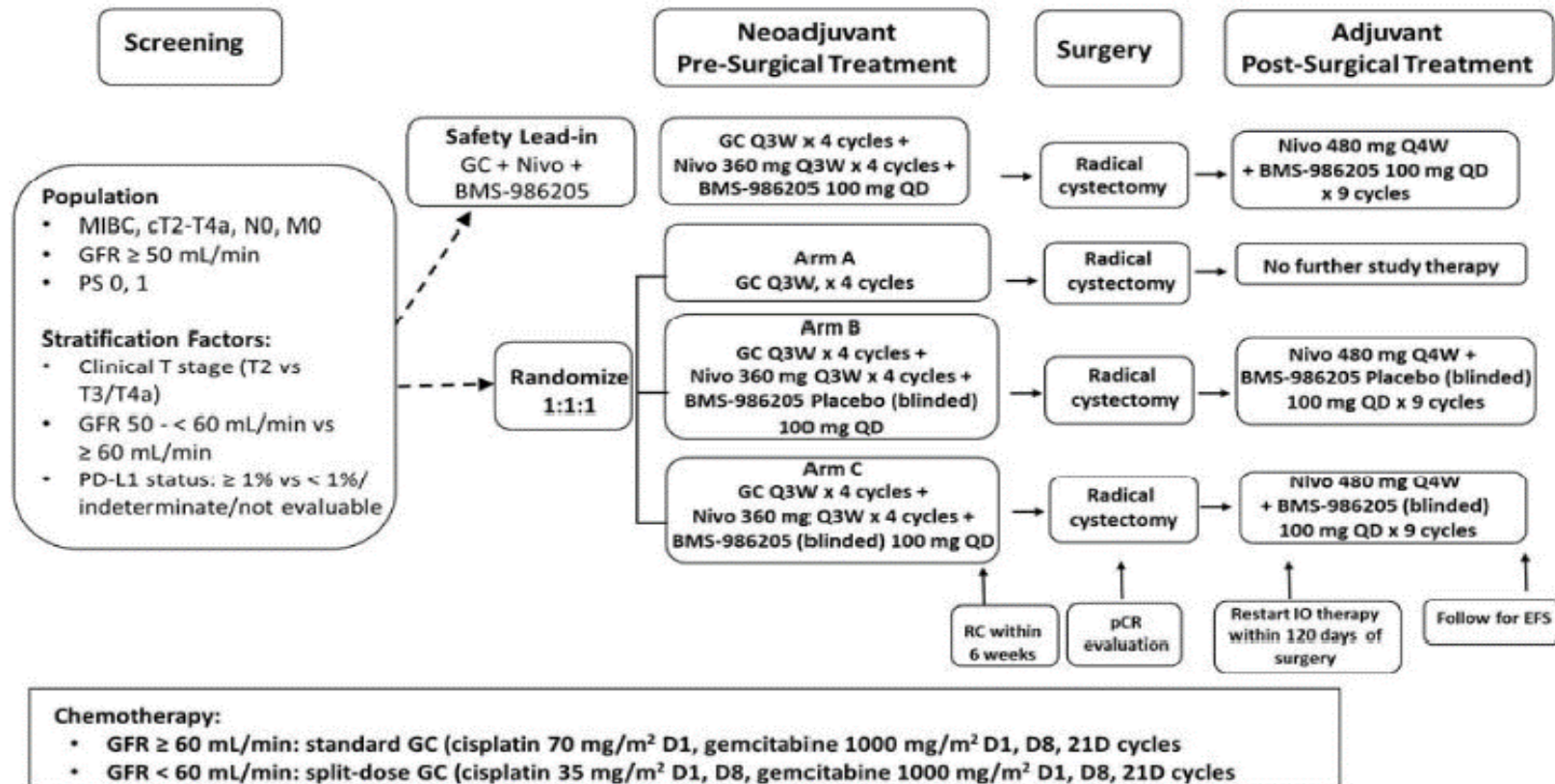
<p><u>NRG CC003</u></p>	<p>(RT at Glen Oak only) Randomized Phase II/III Trial of Prophylactic Cranial Irradiation with or without Hippocampal Avoidance for Small Cell Lung Cancer</p>
<p><u>NRG CC009</u></p>	<p>(RT at Glen Oak, UPHM) - Phase III Trial of Stereotactic Radiosurgery (SRS) versus Hippocampal-Avoidant Whole Brain Radiotherapy (HA-WBRT) for 10 or fewer Brain Metastases from Small Cell Lung Cancer</p>
<p><u>GO43104</u></p>	<p>(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) Following First-Line Induction Therapy With Carboplatin, Etoposide and Atezolizumab</p>
<p><u>LU005</u></p>	<p>(RT at Glen Oak, UPHM and Galesburg) Limited Stage Small Cell Lung Cancer (LS-SCLC): A Phase II/III Randomized Study of Chemoradiation Versus Chemoradiation Plus Atezolizumab</p>
<p><u>S1827</u></p>	<p>(RT at Glen Oak, UPHM, Galesburg) A Randomized Phase III Trial of MRI Surveillance With or Without Prophylactic Cranial Irradiation (PCI) in Small-Cell Lung Cancer</p>
<p><u>S1929</u></p>	<p>Phase II Randomized Study of Maintenance Atezolizumab Versus Atezolizumab in Combination With Talazoparib in Patients With SLFN11 Positive Extensive Stage Small Cell Lung Cancer (ES-SCLC) <i>Tissue screening allowed during induction chemotherapy</i></p>

**BMS-986205/placebo tablets have been discontinued.*

Clinical Protocol
BMS-986205

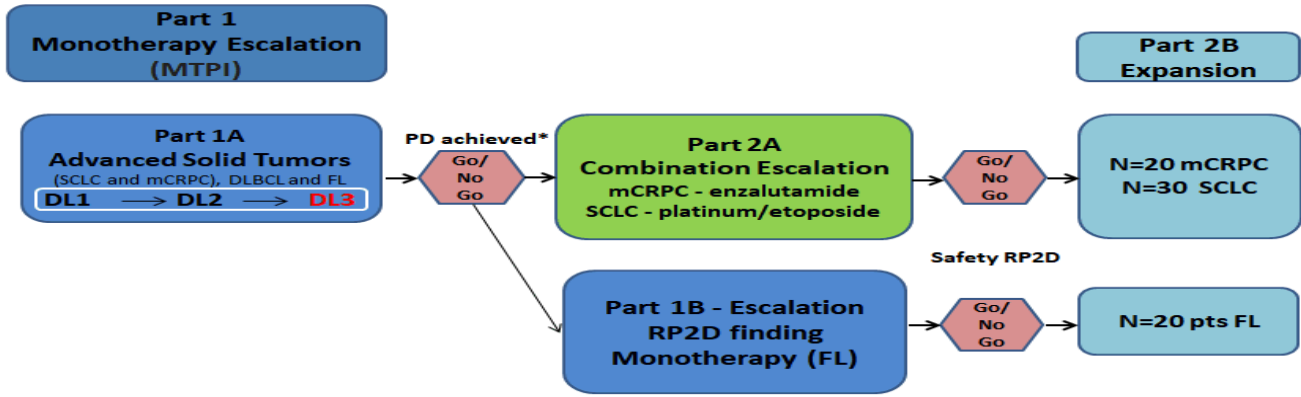
CA017078
IDO1 inhibitor

Figure 1-1: Study Design Schematic



C2321001 SCHEMA
Contact Disease Specific Navigator

MENU



*50-70% down modulation of H3K27me3

Study Design

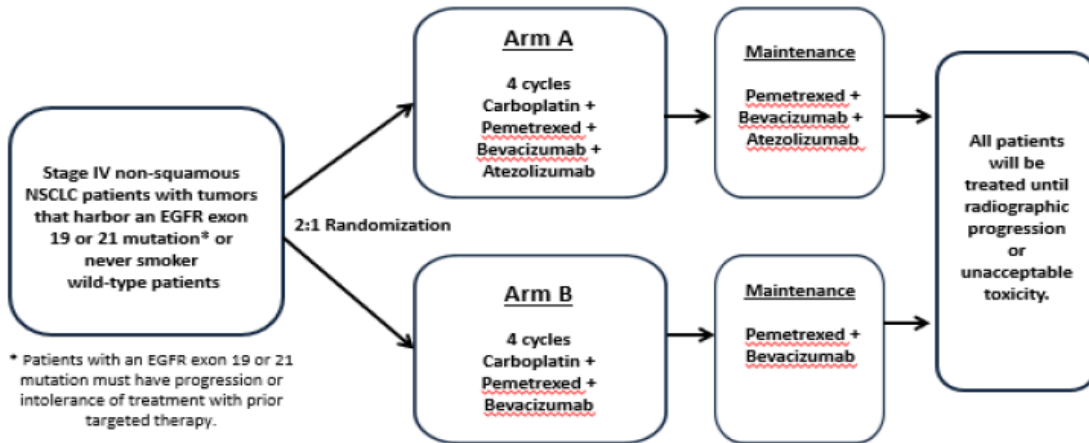
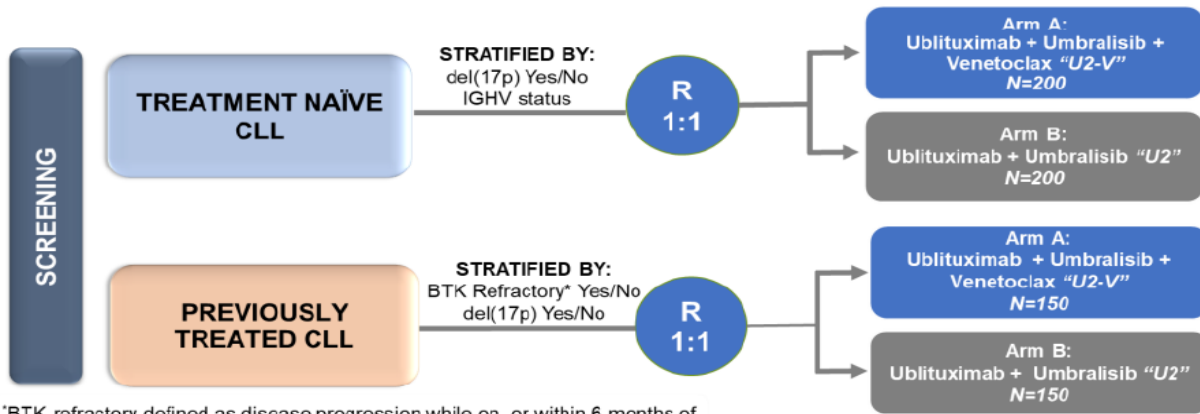


FIGURE 2: PHASE 3 STUDY DESIGN



MK 6482-011 Schema
Navigator - Carrie x3621

MENU

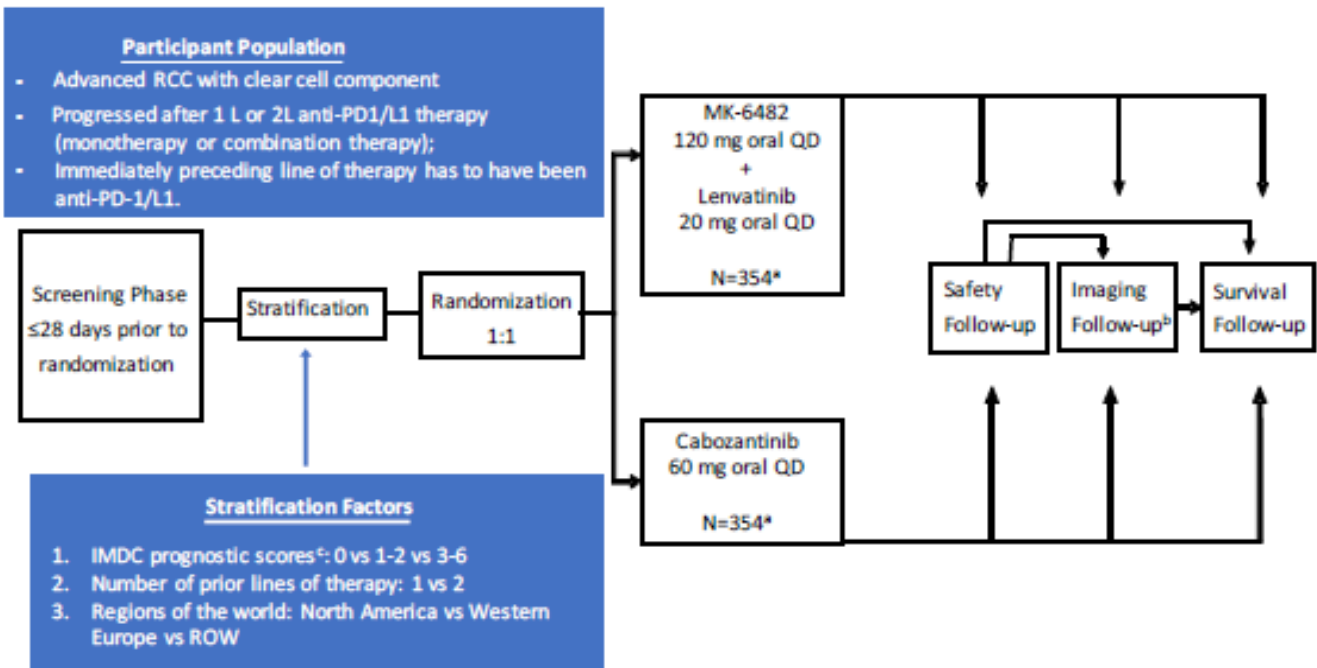
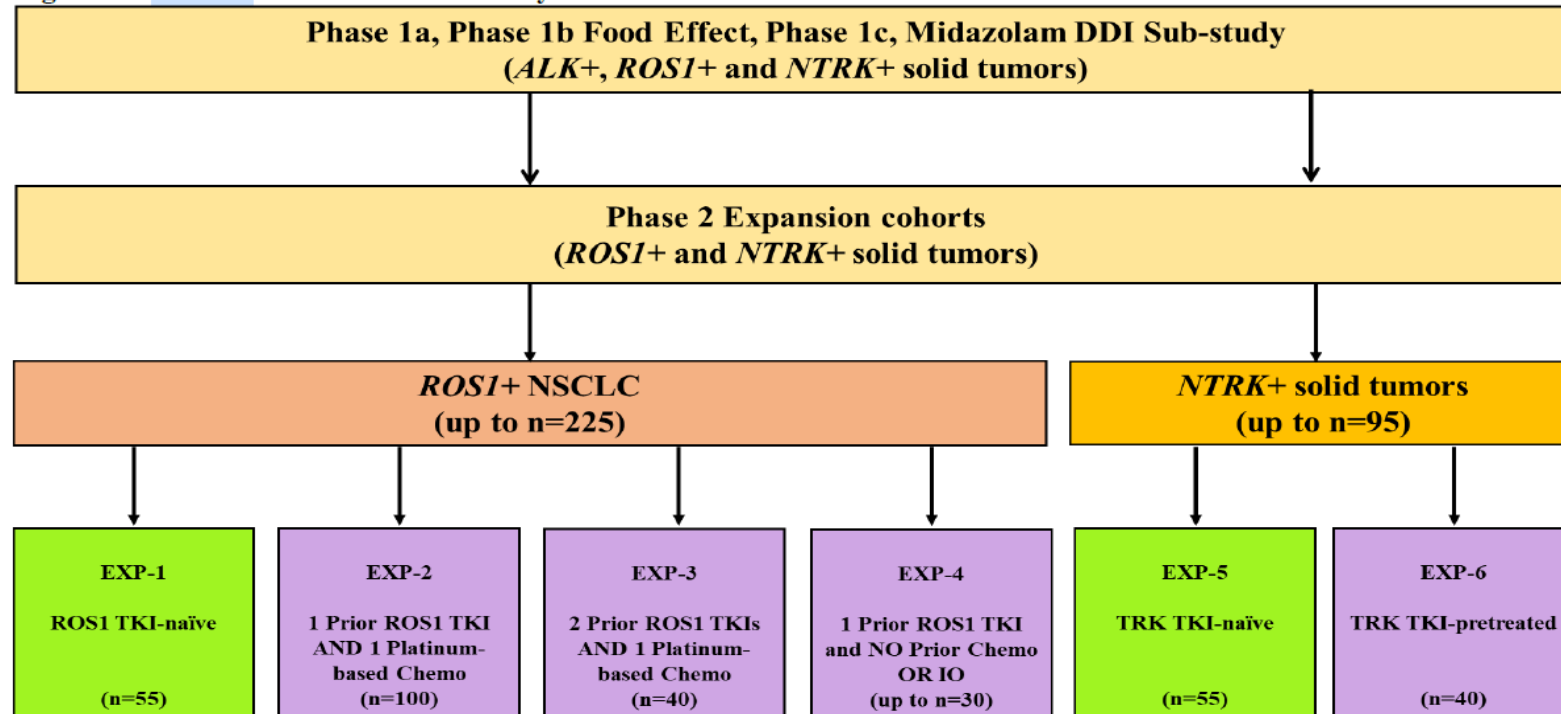
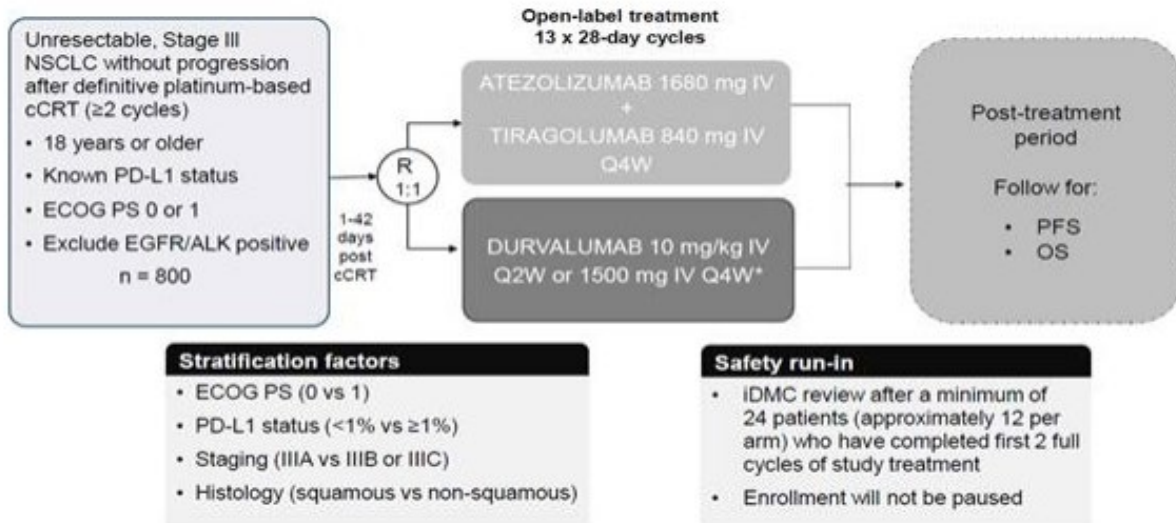


Figure 2. Schema of TPX-0005-01 Study



GO41854 Schema
Navigator - Ashton x3611

MENU

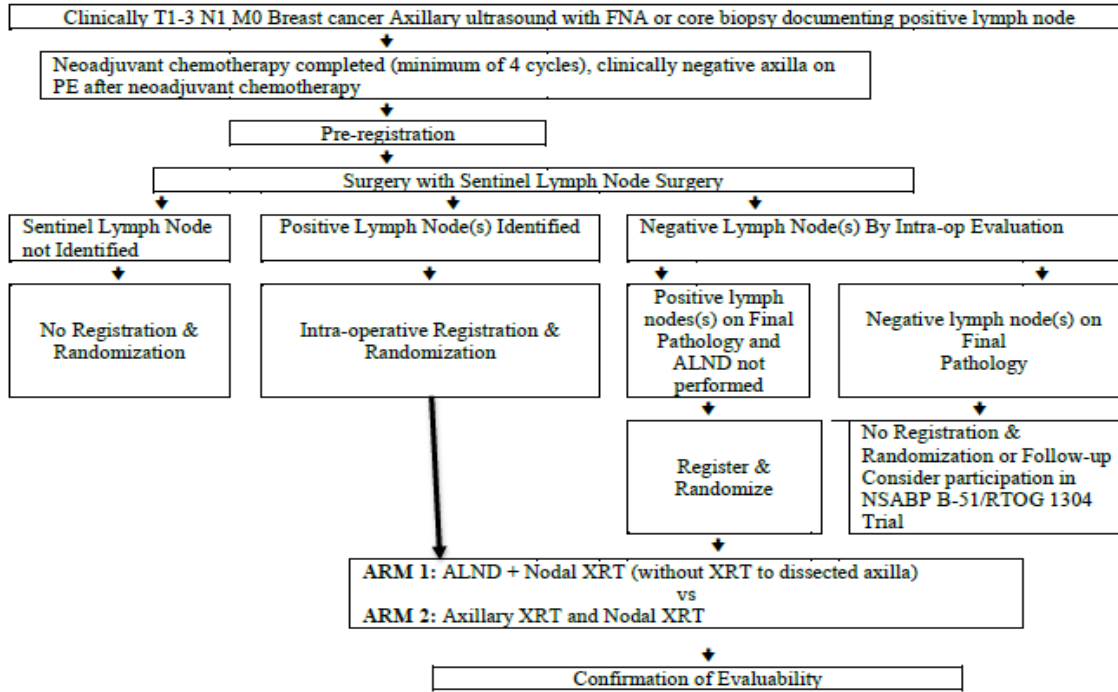


*For patients whose weight ≥30 kg

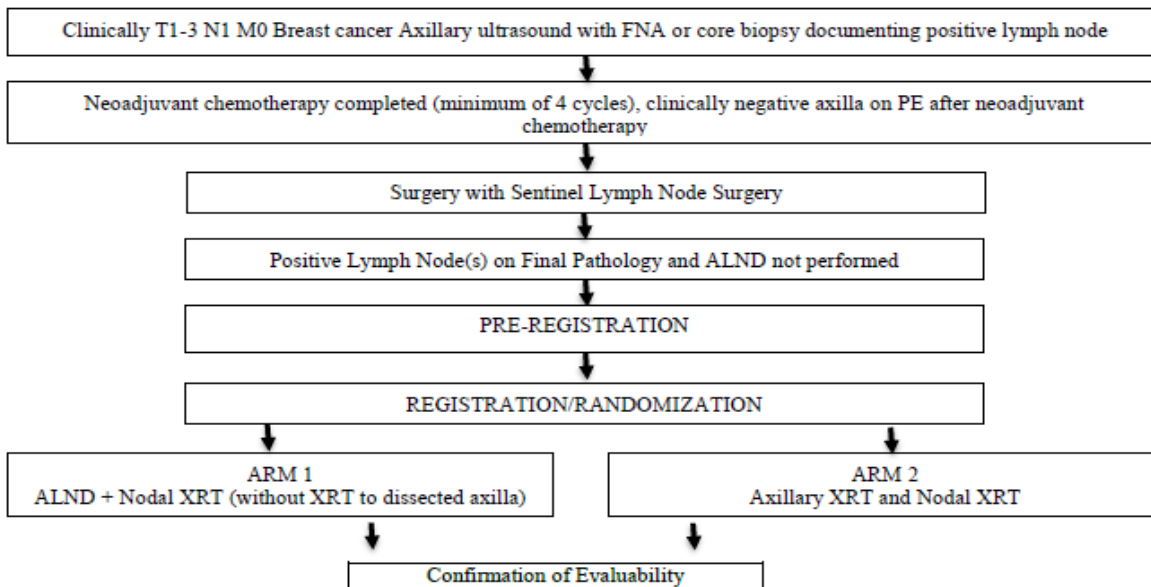
A011202 SCHEMA
Navigator Angie x3613

MENU

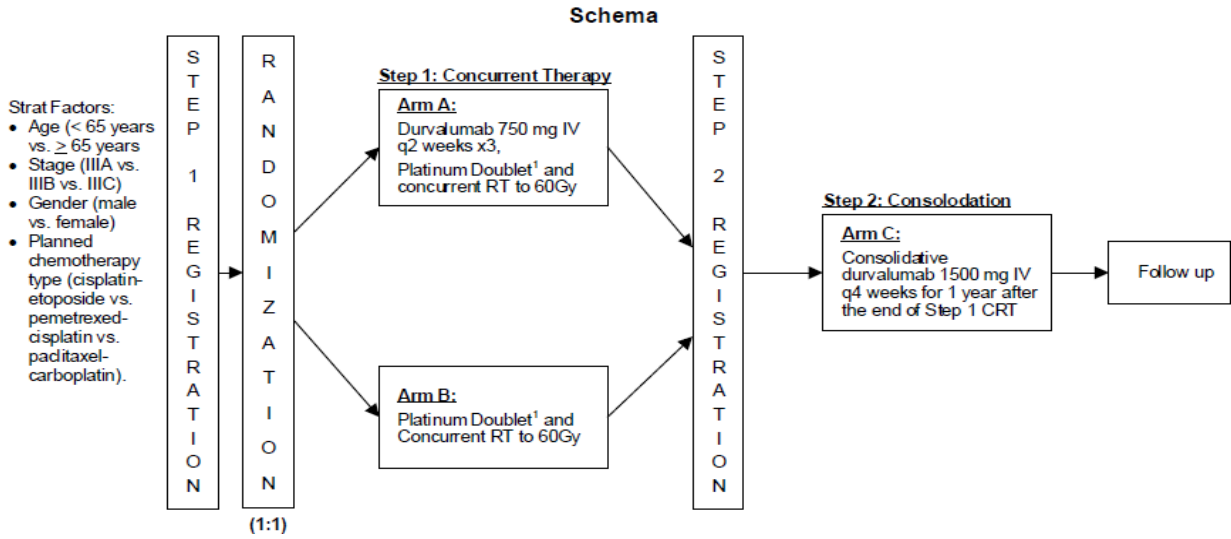
Schema for patients who pre-register prior to SLN surgery:



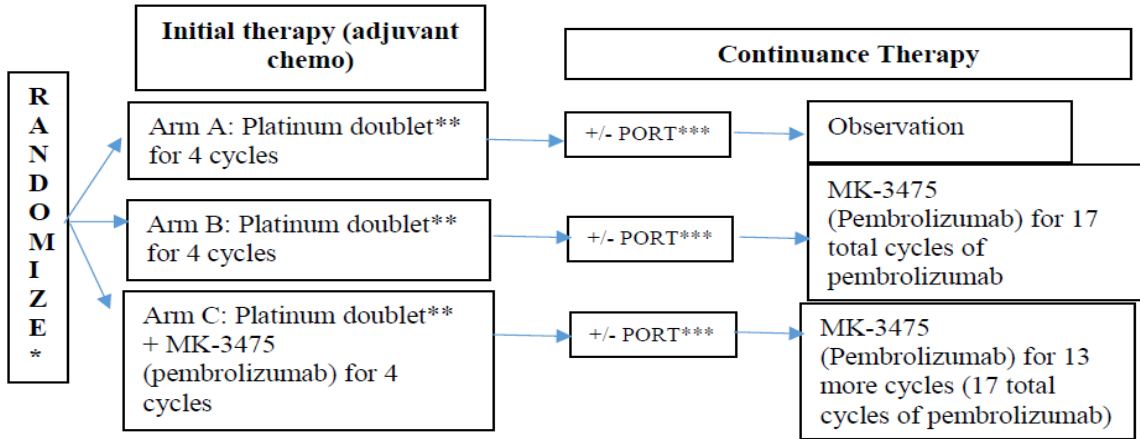
Schema for patients who pre-register AFTER surgery* (where SLN surgery was performed but ALND was NOT performed):



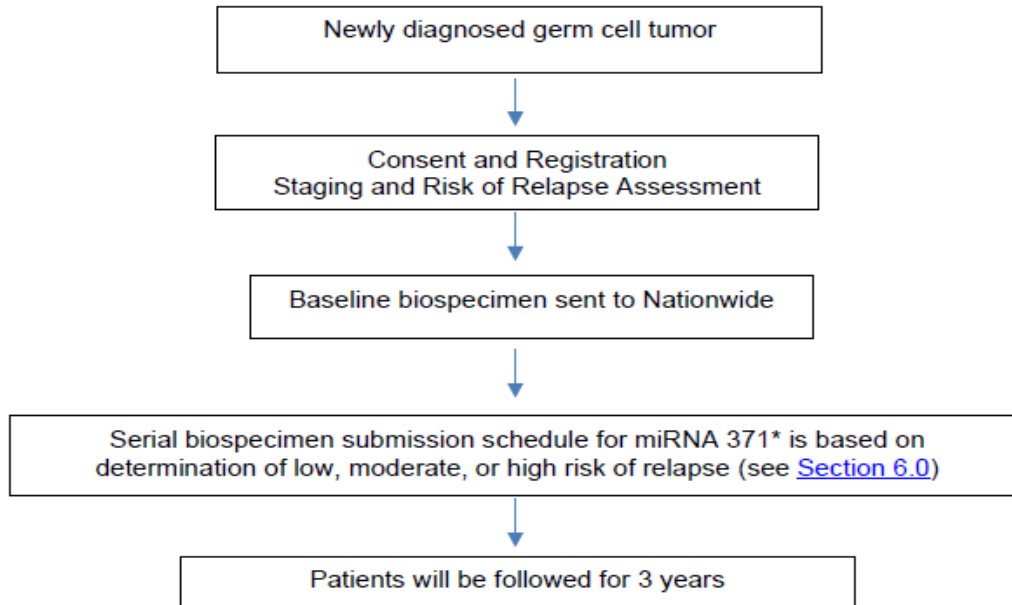
*** Patients who are pre-registered after SLN surgery are NOT eligible to enroll onto the Arm Lymphedema Companion Study (A011201-SII)**



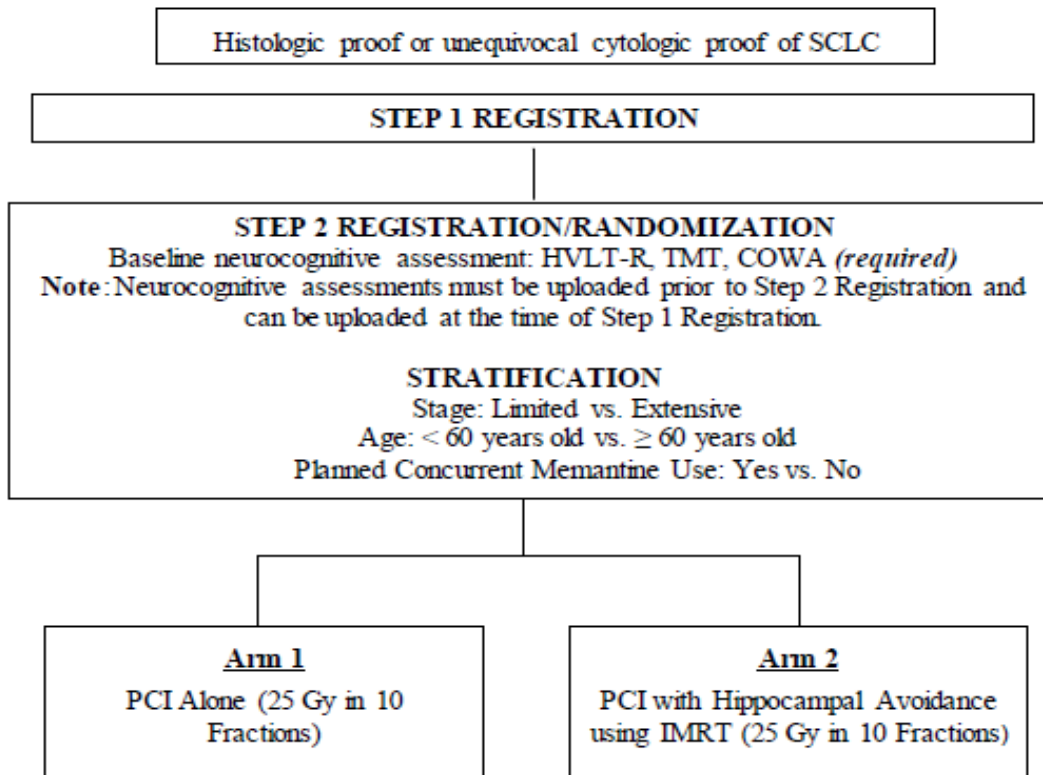
Schema: 1 cycle = 21 days



SCHEMA



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



Merck 7339-003 / LYNK-003 SCHEMA
Navigator -Carrie x3621

MENU

Key Inclusion Criteria

- Unresectable or metastatic CRC
- Has not progressed after completing at least 6 prior induction cycles of FOLFOX + bevacizumab and can no longer tolerate oxalliplatin
- ECOG 0-1

Stratification Factors:

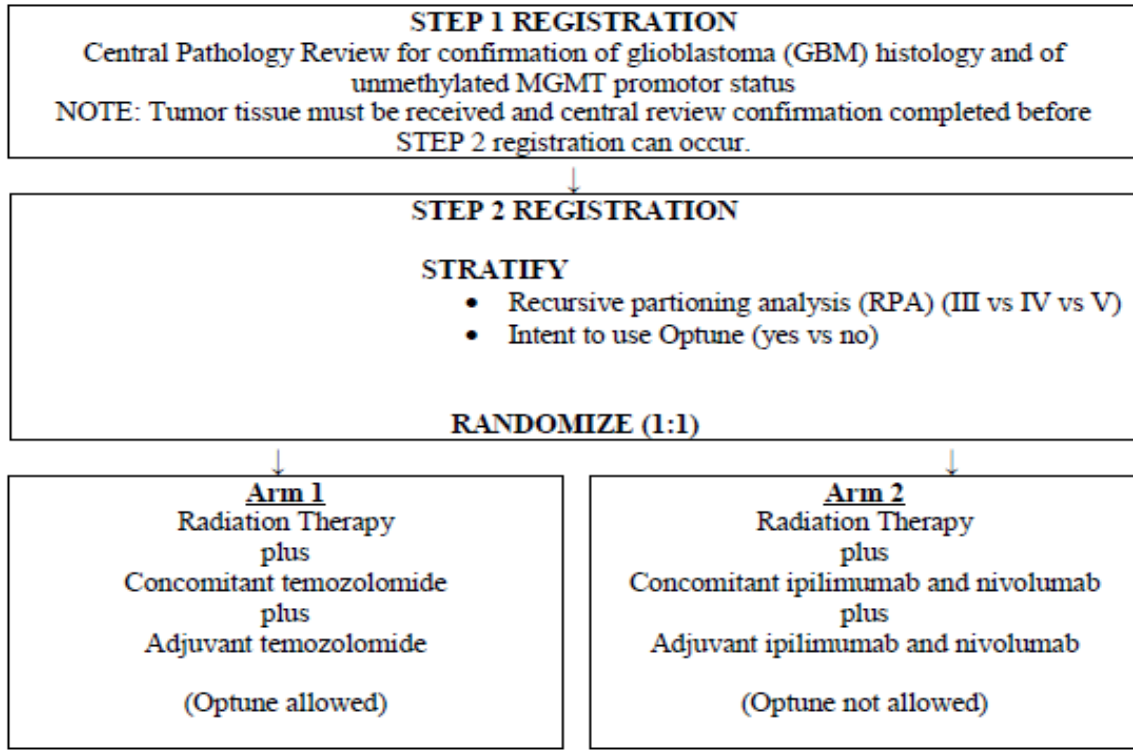
- SD vs. PR/CR to prior FOLFOX induction
- BRAF_{mut} and/or Ras_{mut} vs. BRAF_{wt} + Ras_{wt}
- 6-8 cycles vs. >8 cycles of FOLFOX induction

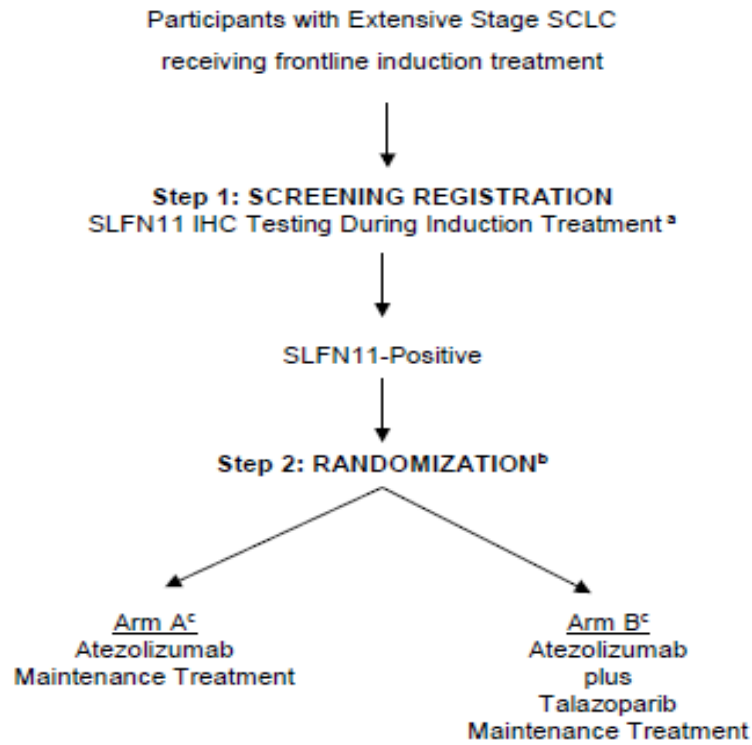
R
1:1:1

Olaparib Oral +
Bevacizumab
(until progression)

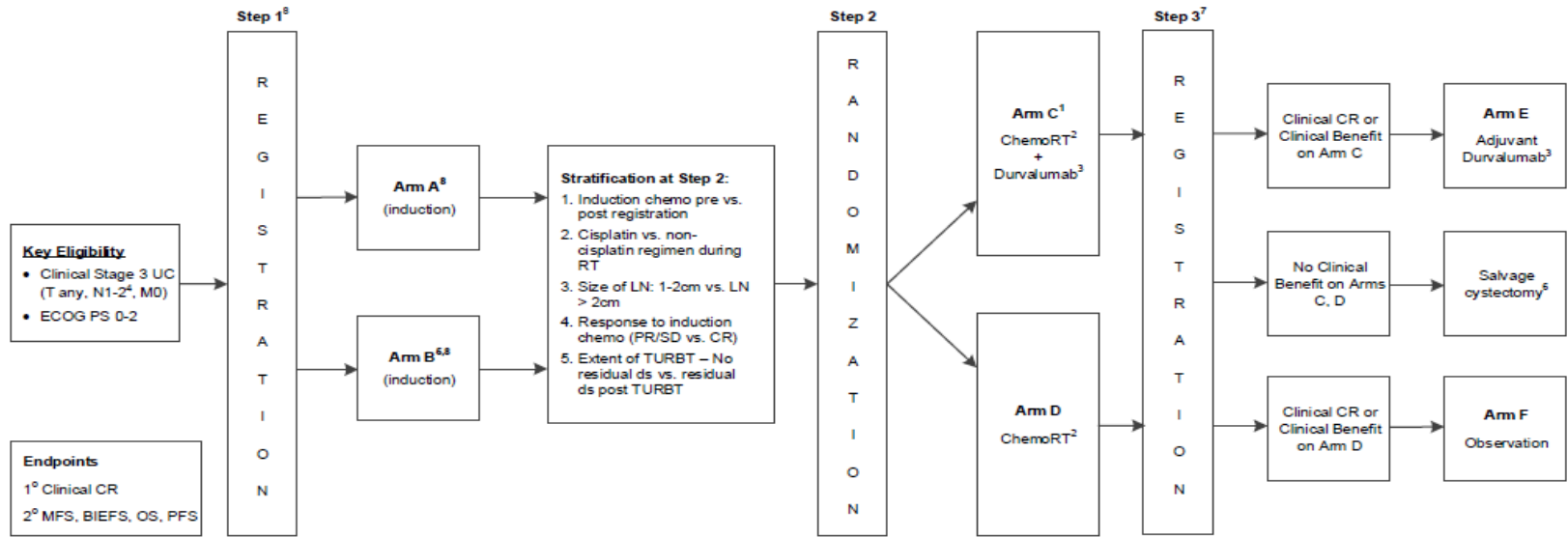
Olaparib Oral
(until progression)

5-FU + Bevacizumab
(until progression)



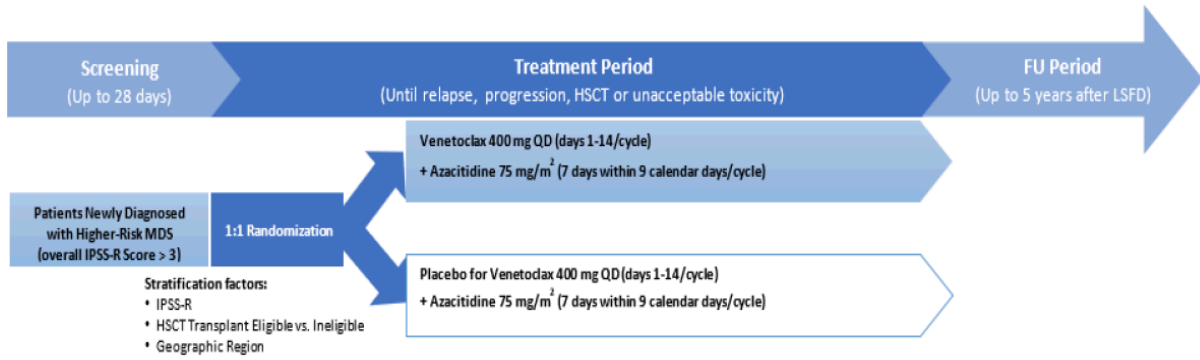


Schema



M15-954
Navigator -Heather x3661

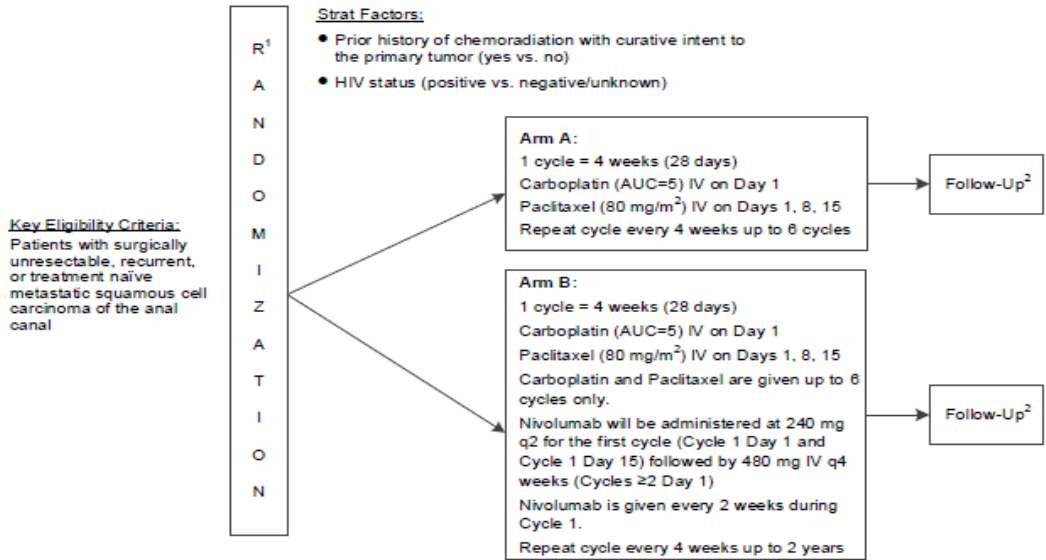
MENU



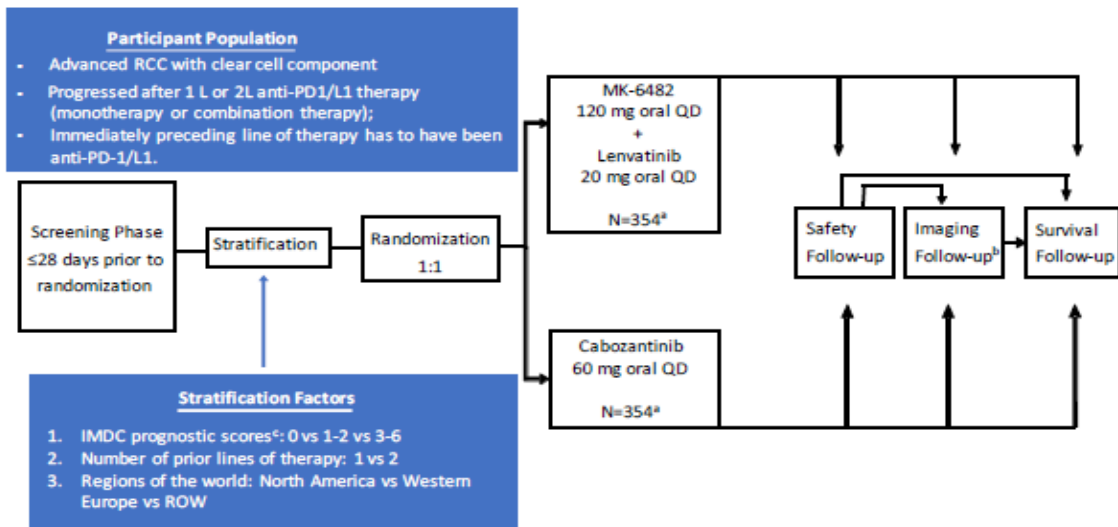
FU = follow up; HSCT = hematopoietic stem cell transplant; IPSS-R = Revised International Prognostic Scoring System; LSFD = last subject first dose; MDS = myelodysplastic syndrome; QD = once daily

EA2176
Navigator -Carrie x3621

MENU



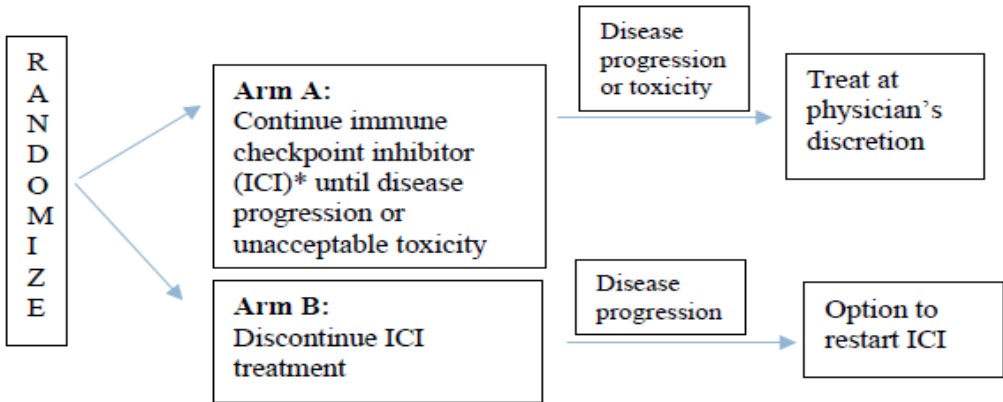
1. Randomization is 1:2 (A:B).
 2. For this protocol, all patients, including those who discontinue protocol therapy early, will be followed for response until disease progression, even if non-protocol therapy is initiated, and for survival every 3 months for two years from the date of randomization.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

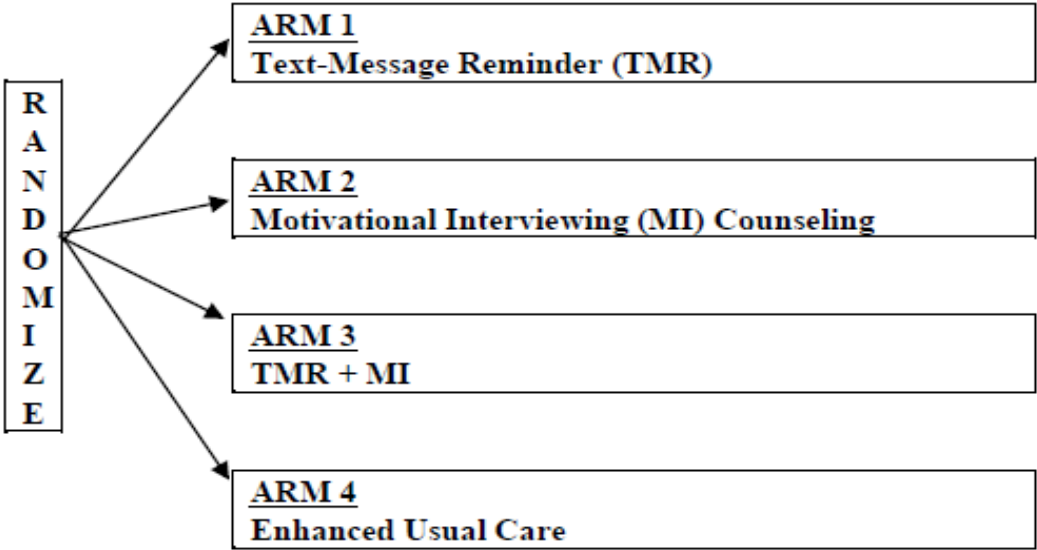
Cycle definition is based on ICI cycle length

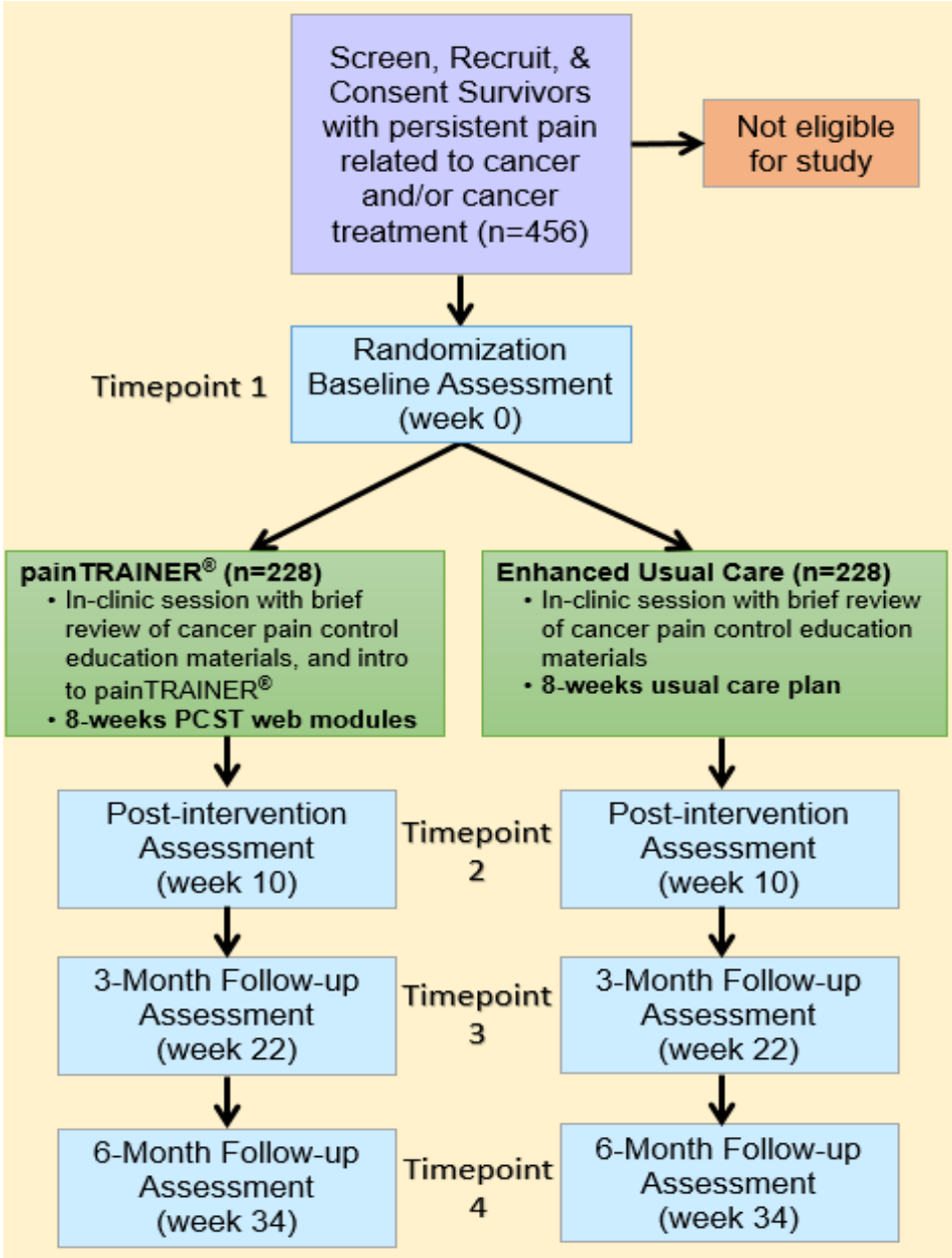


* ICI agents include pembrolizumab, nivolumab, atezolizumab, durvalumab and avelumab

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

Schema

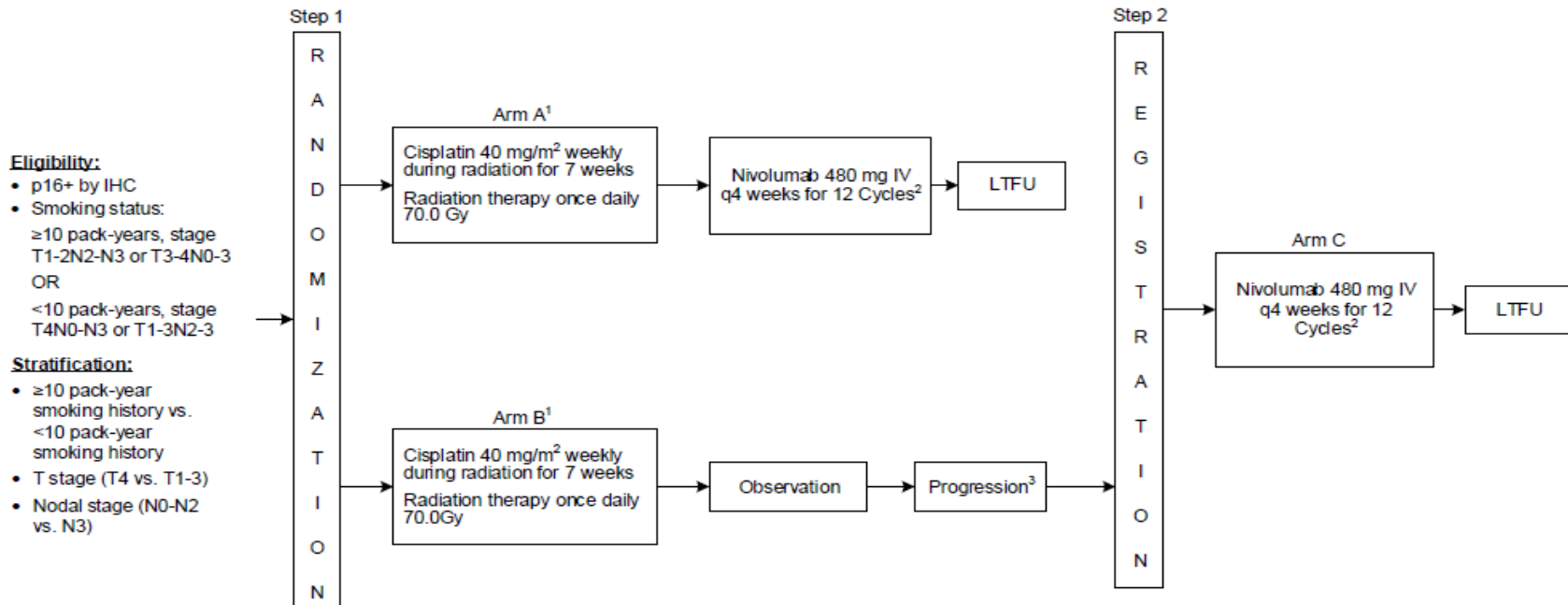




EA3161
Navigator -Ashton x3611

MENU

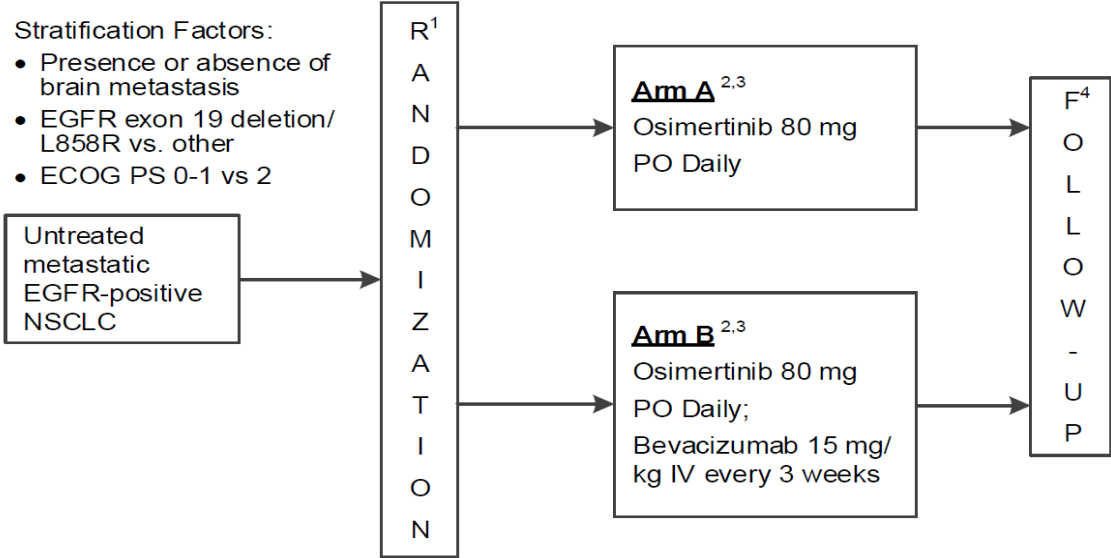
Schema



Accrual Goal: 744

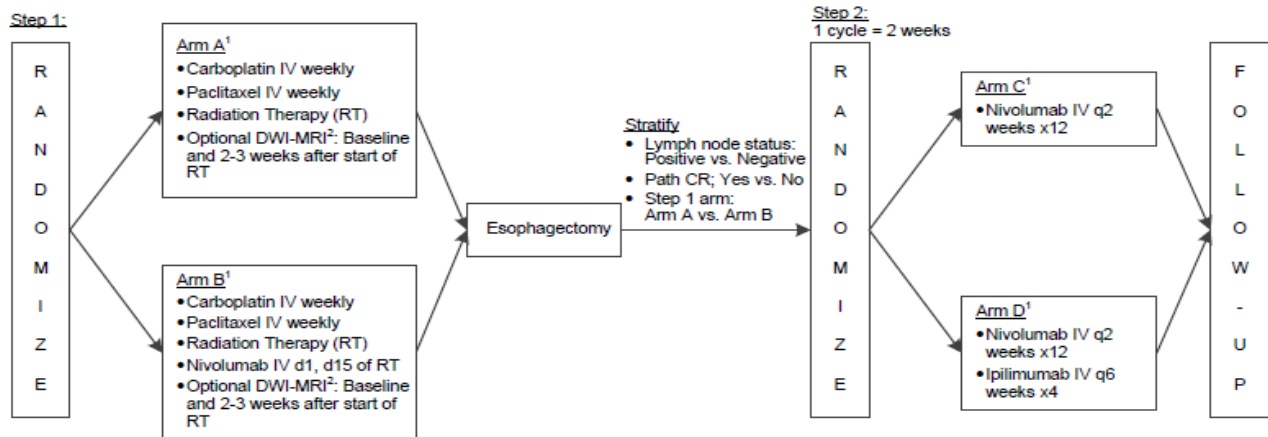
1. Submit tissue for PD-L1 testing.
2. Cycle length = 28 days
3. Patients who were randomized to observation will be offered the option to cross over if they have clearly documented progression by the RECIST criteria and tissue-proven progression within 12 months from the end of cisplatin/radiation therapy.

Schema



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

Schema

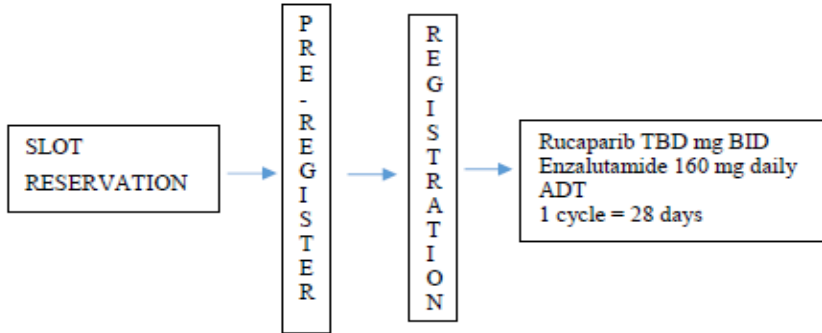


N=278

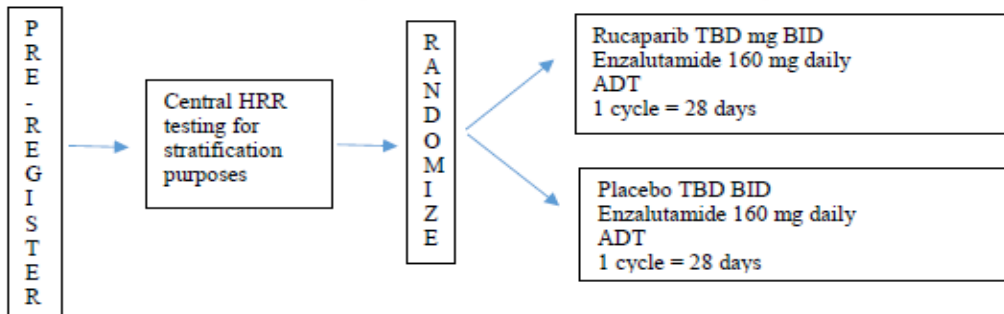
1. Please reference Section 5.1 for treatment dosing specifics.
2. Optional Diffusion weighted imaging-MRI (DWI-MRI) should be obtained at step 1 baseline and 2-3 weeks after initiation of protocol treatment.

Schema

PK Substudy (Dose Finding Portion) Only

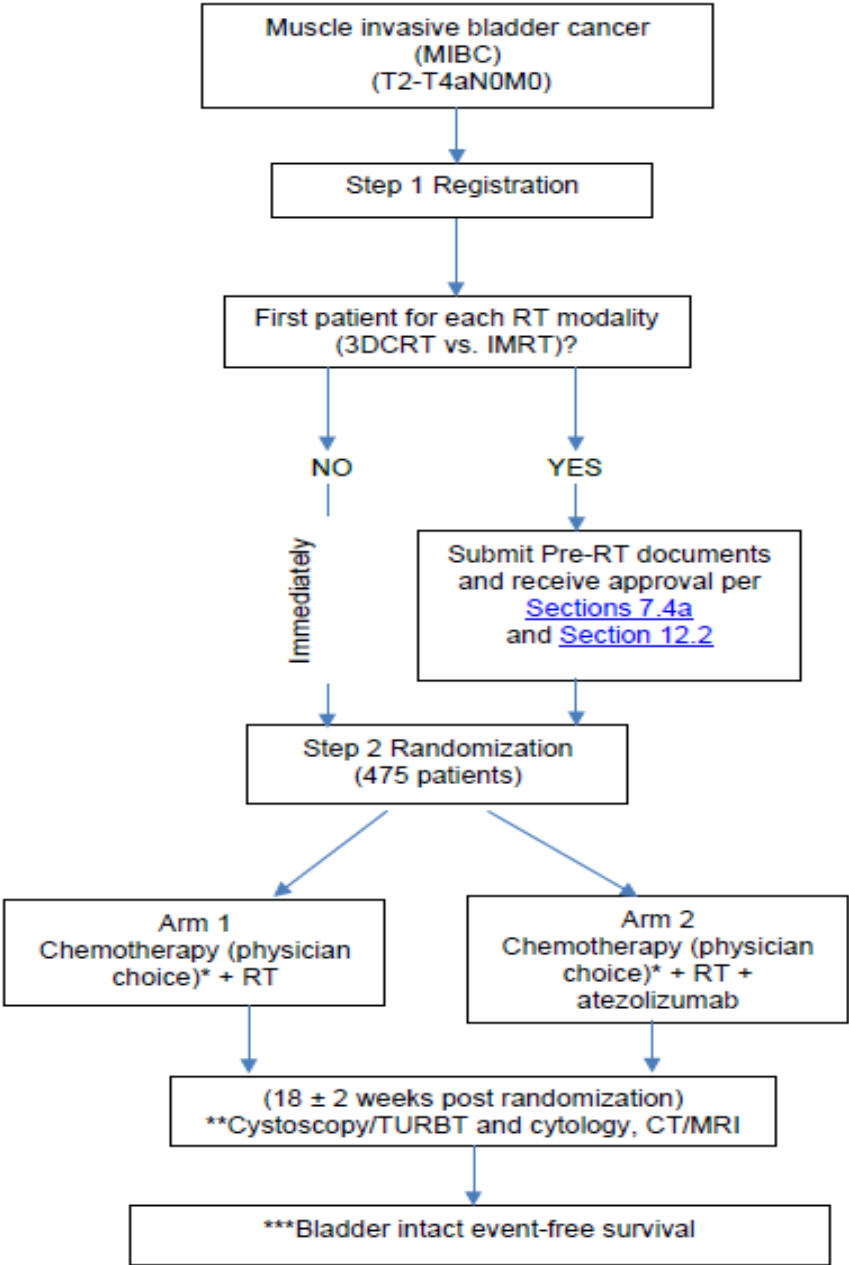


Phase III (Double-Blinded, Placebo-Controlled) Portion



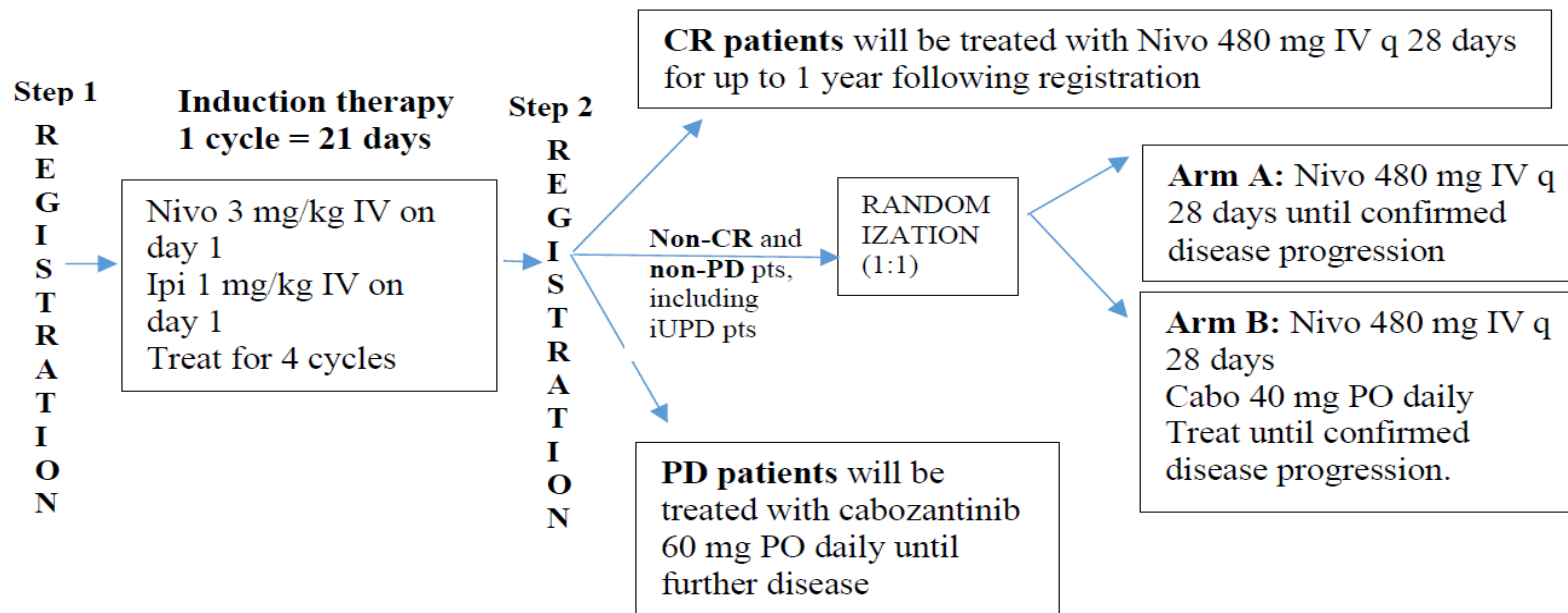
For all patients, treatment is to continue until disease progression or unacceptable adverse event.
Patients will be followed for 5 years or until death, whichever comes first.

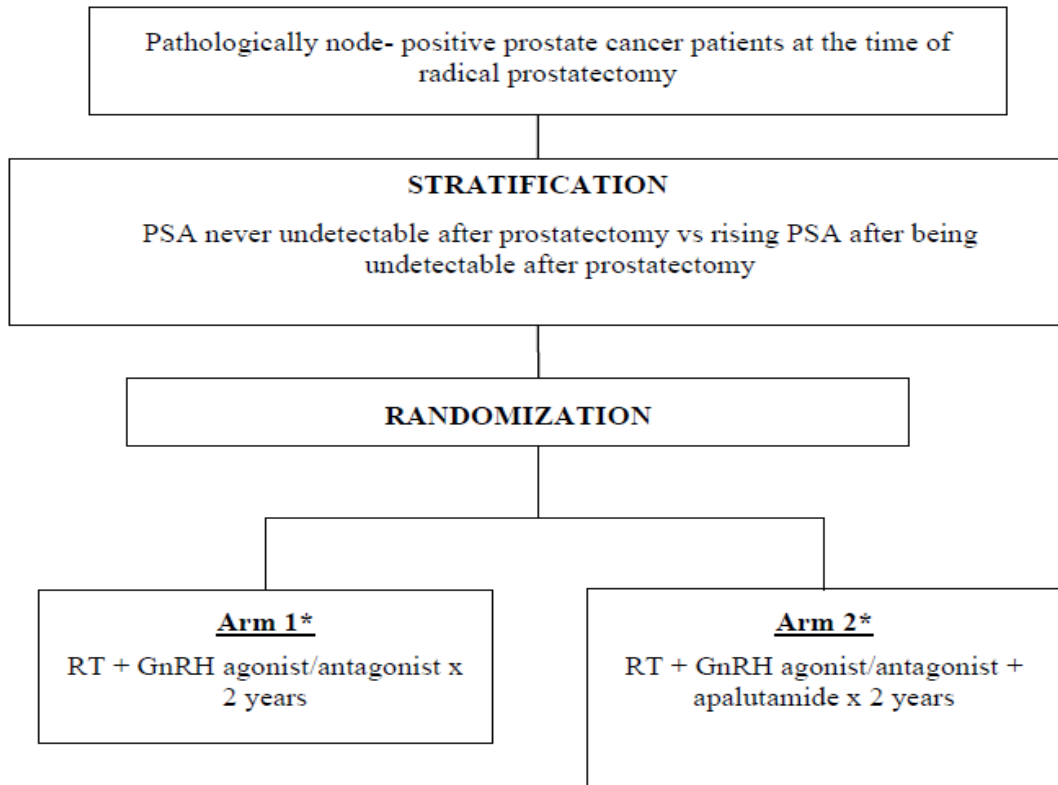
Please refer to the full protocol text for a complete description of the eligibility criteria and treatment plan.



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.

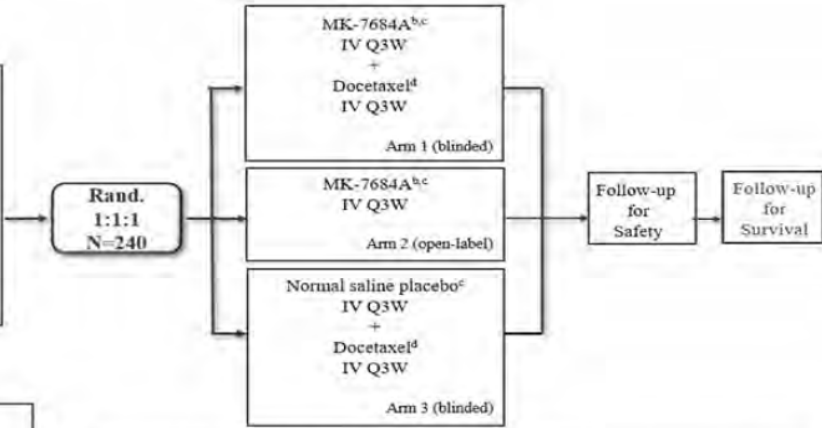
RT = radiation therapy; ADT = androgen deprivation therapy

Key Eligibility Criteria^a

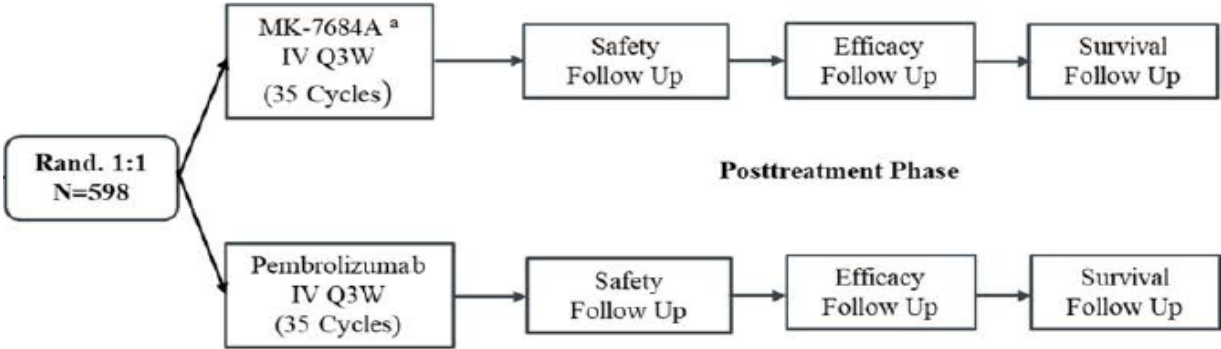
- Stage IV NSCLC with any histology
- PD after platinum doublet chemotherapy and one prior anti-PD-1/PD-L1 inhibitor
- Must not have received prior docetaxel
- EGFR-, ALK- or ROS1-directed therapy not indicated
- Newly obtained/archival tumor tissue for PD-L1 TPS
- Measurable disease based on RECIST 1.1
- ECOG performance status 0 or 1
- No untreated or unstable brain metastasis

Stratification

- ECOG performance status (0 vs 1)
- Prior anti-PD-1/PD-L1 mAb (immediate prior treatment vs not immediate prior treatment)
- PD-L1 TPS (<50% vs ≥50%)



^a See full list of inclusion and exclusion criteria in Section 5.1 and Section 5.2.
^b MK-7684 and pembrolizumab are co-formulated and referred to in this protocol as MK-7684A. The components of MK-7684A are MK-7684 200 mg/pembrolizumab 200 mg.
^c Treatment with MK-7684A may continue until a discontinuation criteria is met, or completion of 35 cycles.
^d Treatment with docetaxel may continue until a discontinuation criterion is met or as per approved local label.



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)

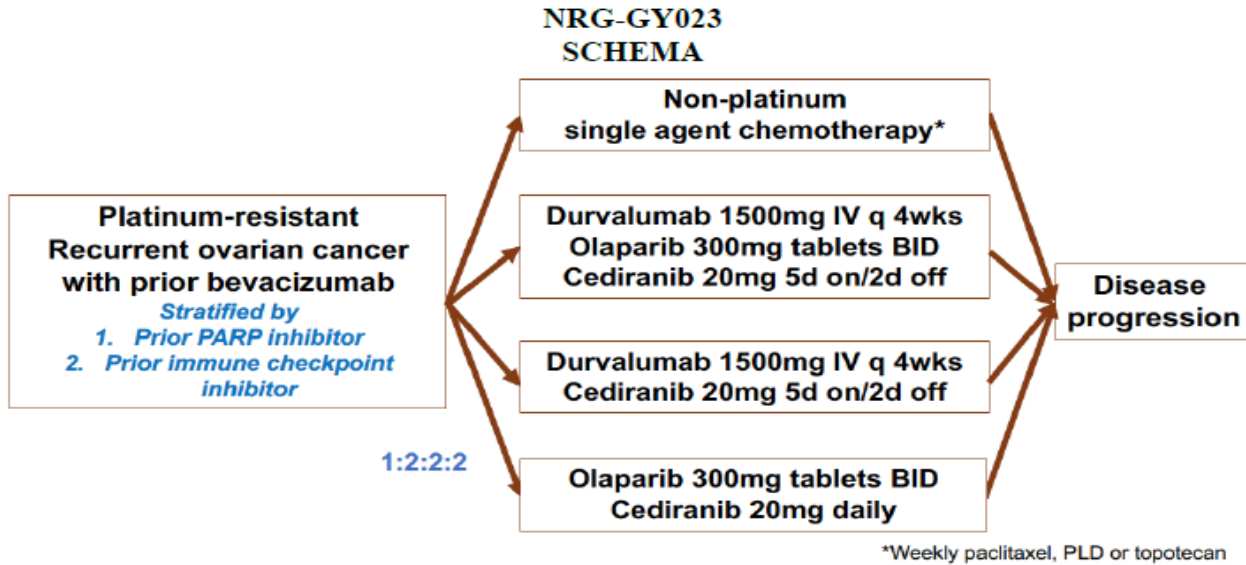
Step 2-RANDOMIZATION*

Arm 1**

Breast Radiation Therapy
+
Endocrine Therapy

Arm 2**

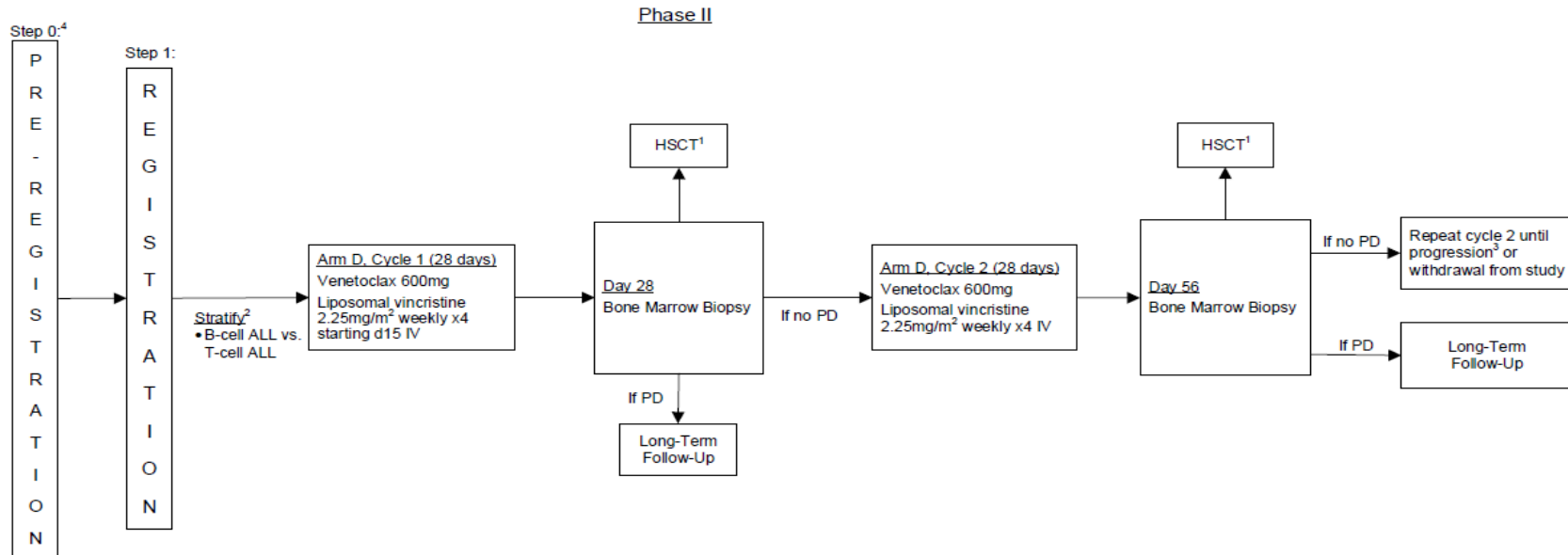
No Breast Radiation Therapy
+
Endocrine Therapy



*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.

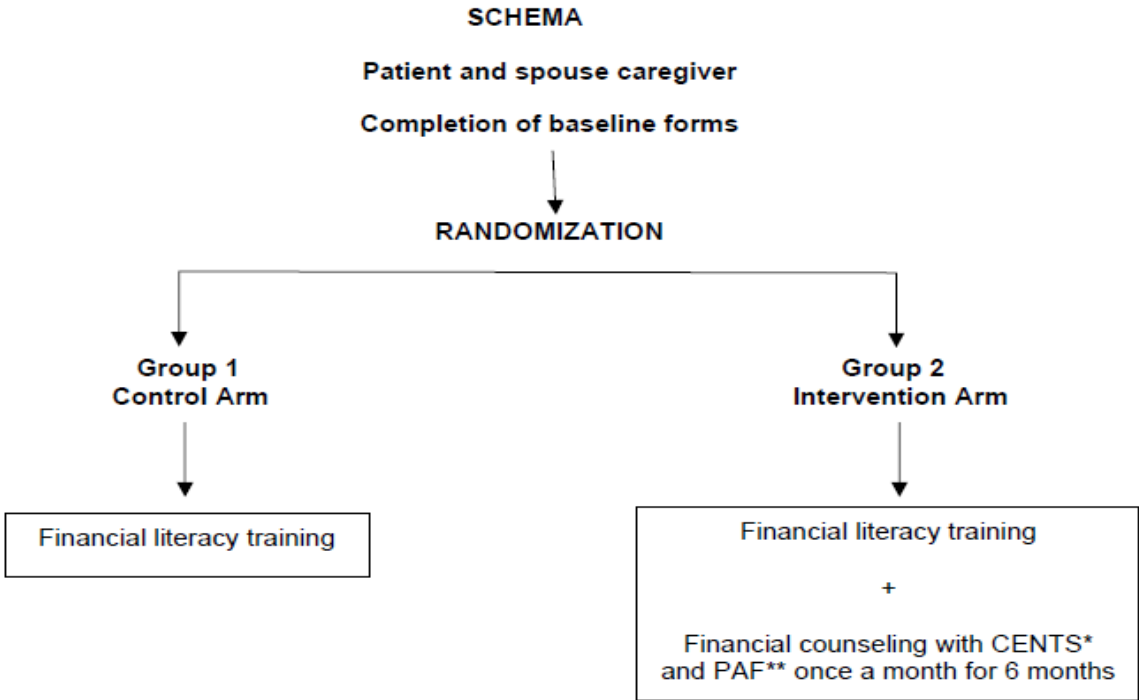
Randomization is 1:2:2:2

Schema



Phase II Accrual Goal: 56 patients (including the patients from the Phase I arm with the MTD dose)

1. If patient demonstrates CR or Cri at day 28 or day 56 bone marrow biopsies, they may continue on combination therapy or proceed to HSCT if deemed fit for transplant and advised by treating physician. Patient may proceed to HSCT at any point at treating physician's discretion (if not day 28 or 56).
2. Patients will be stratified by immunophenotype: "B-cell ALL" vs. "T-cell ALL".
3. If patient does not demonstrate any signs of progression, they may continue on combination therapy as long as they are receiving benefit per treating physician. Patients, if in CR/Cri by the end of cycle 2 may continue on combination or single agent venetoclax at the discretion of the treating physician.
4. Bone marrow and peripheral blood specimens must be submitted for mandatory central review.

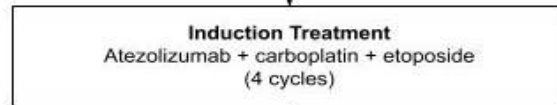
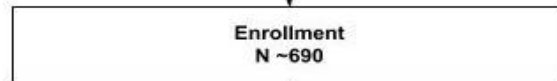
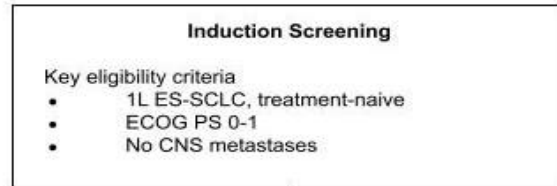


In order to participate, CCD Research sites must complete the **S1912CD** Site Implementation Survey and upload the completion certificate to the CTSU Regulatory Portal as described in [Section 13.4](#).

* Consumer Education and Training Services (CENTS)

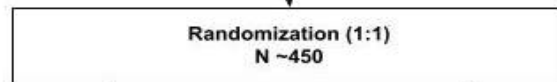
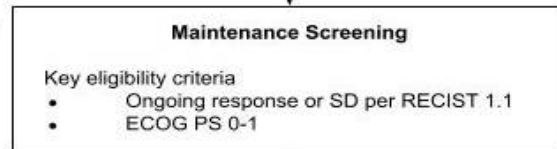
** Patient Advocate Foundation (PAF)

Baseline Induction



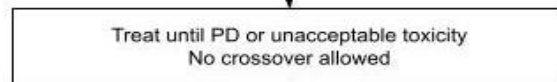
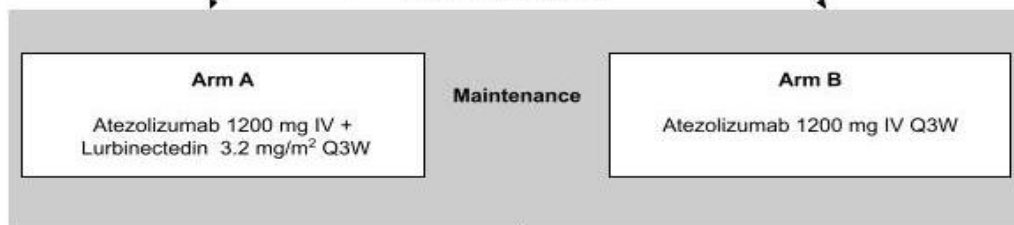
Optional PCI
(Investigator's discretion)

Baseline Maintenance

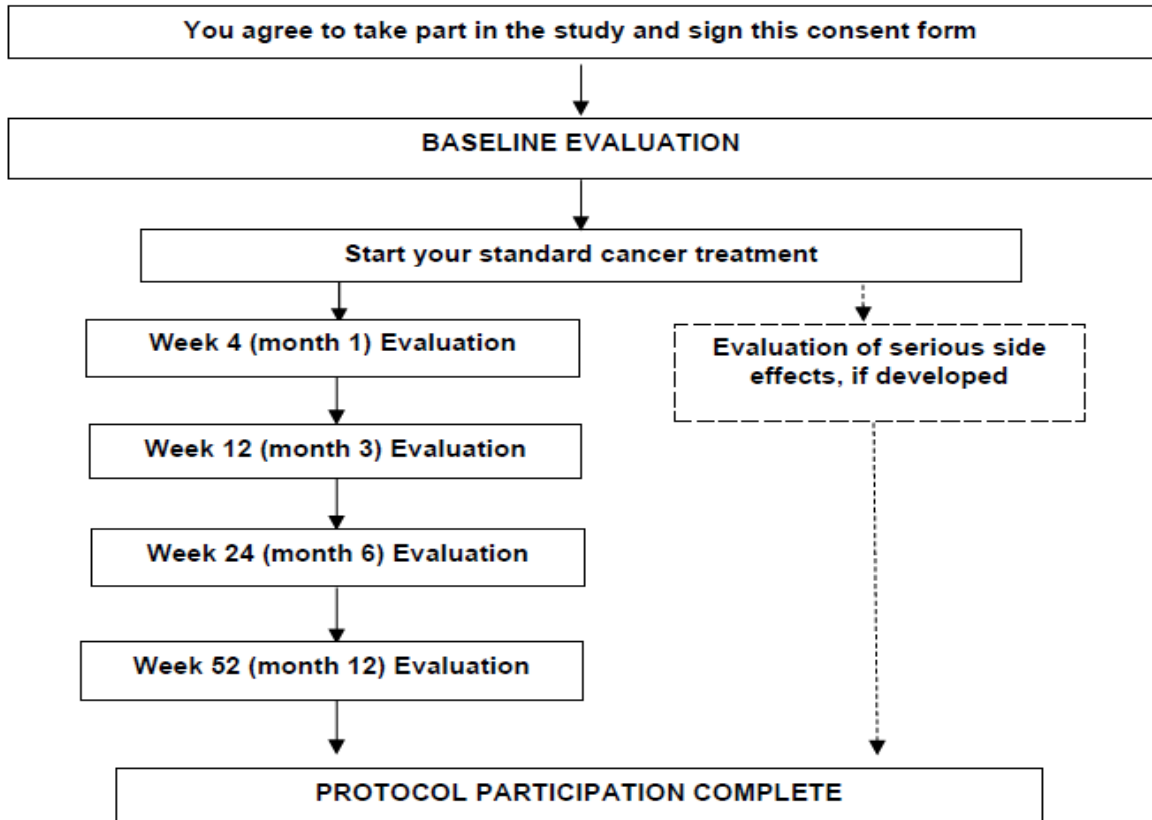


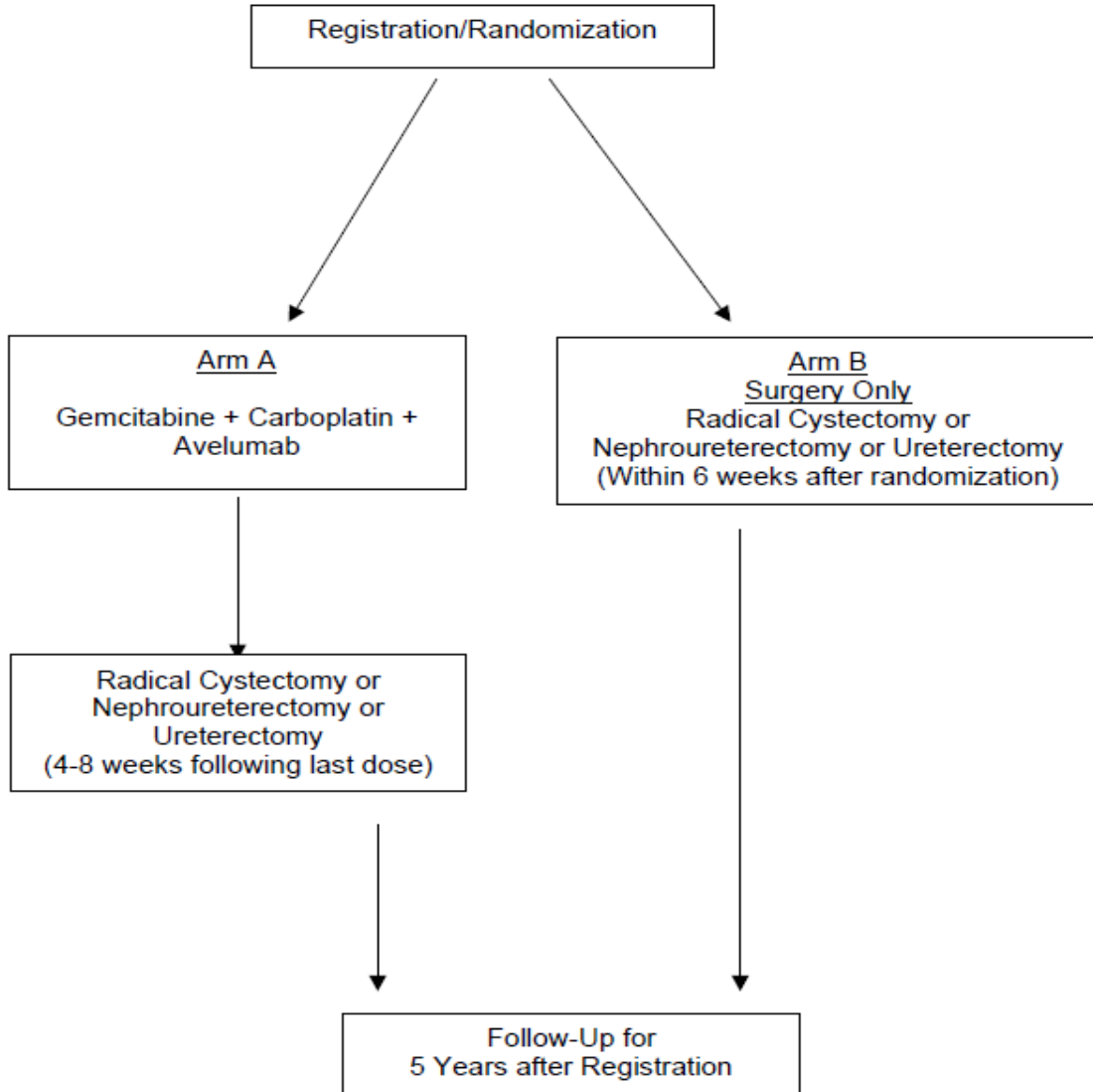
Stratification Factors

- 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





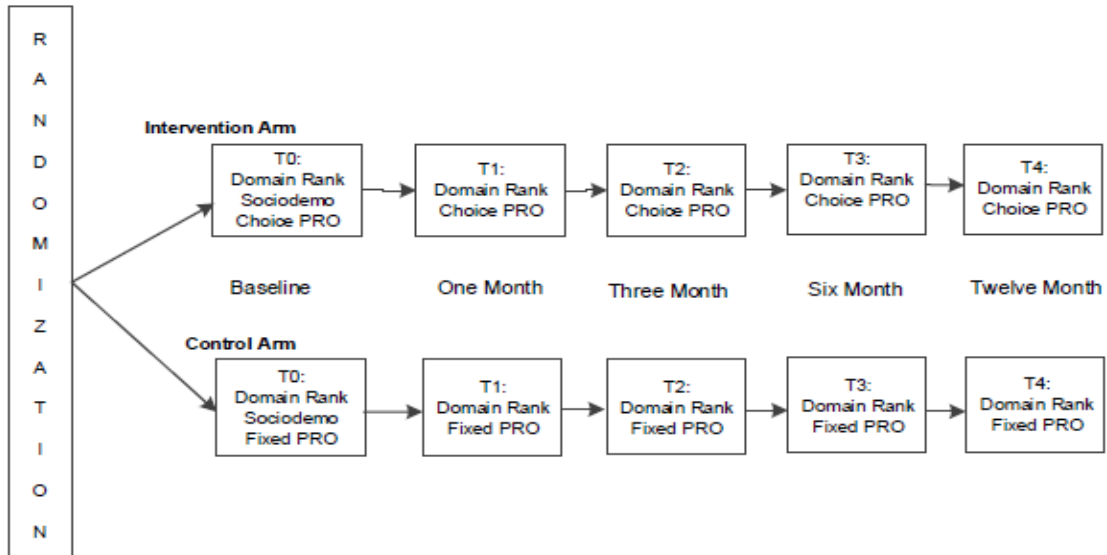
R
A
N
D
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E

ARM 1
Olanzapine 5 mg once per day orally qhs x 4 weeks

ARM 2
Megestrol acetate 600 mg/d oral suspension x 4 weeks

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

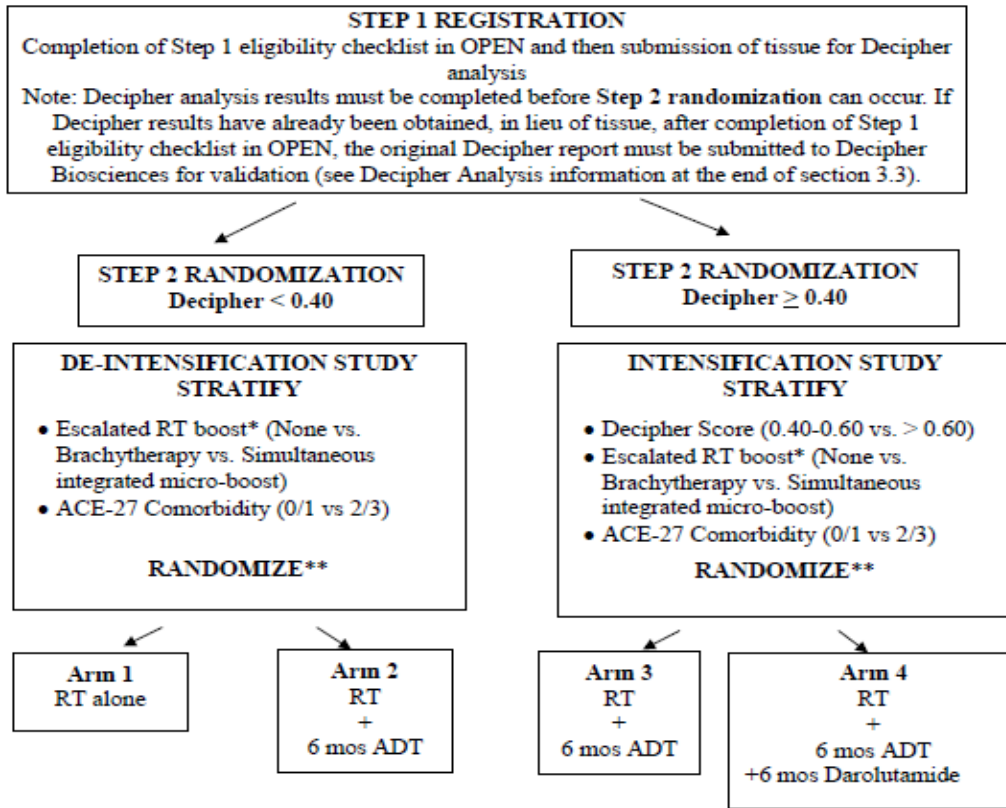
Schema



<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

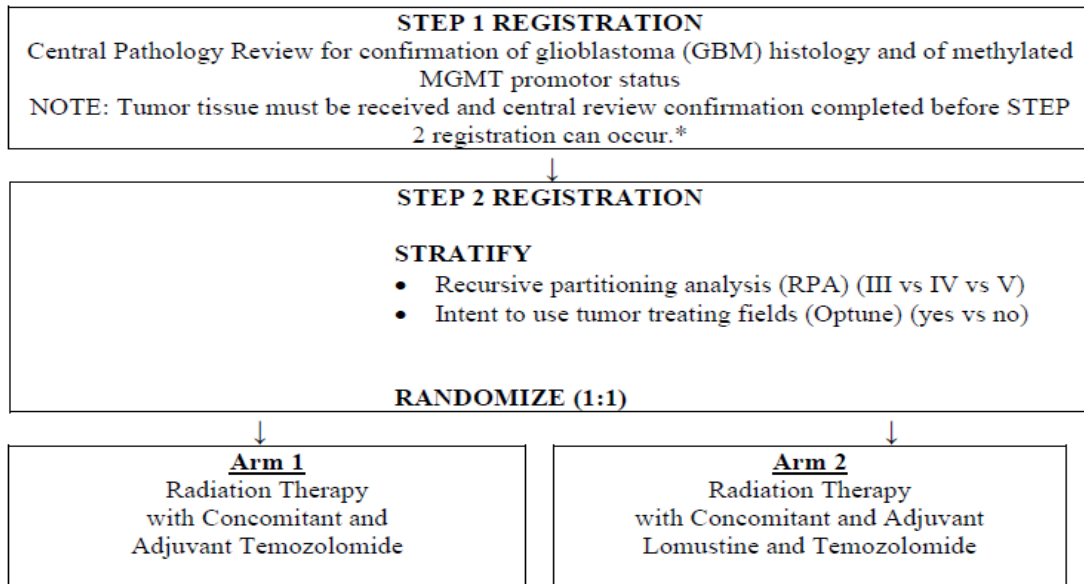


*For Escalated RT boost definition see Section 5.2 Establishing Treatment Approaches

**Randomization is 1:1

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

NRG-BN011
SCHEMA



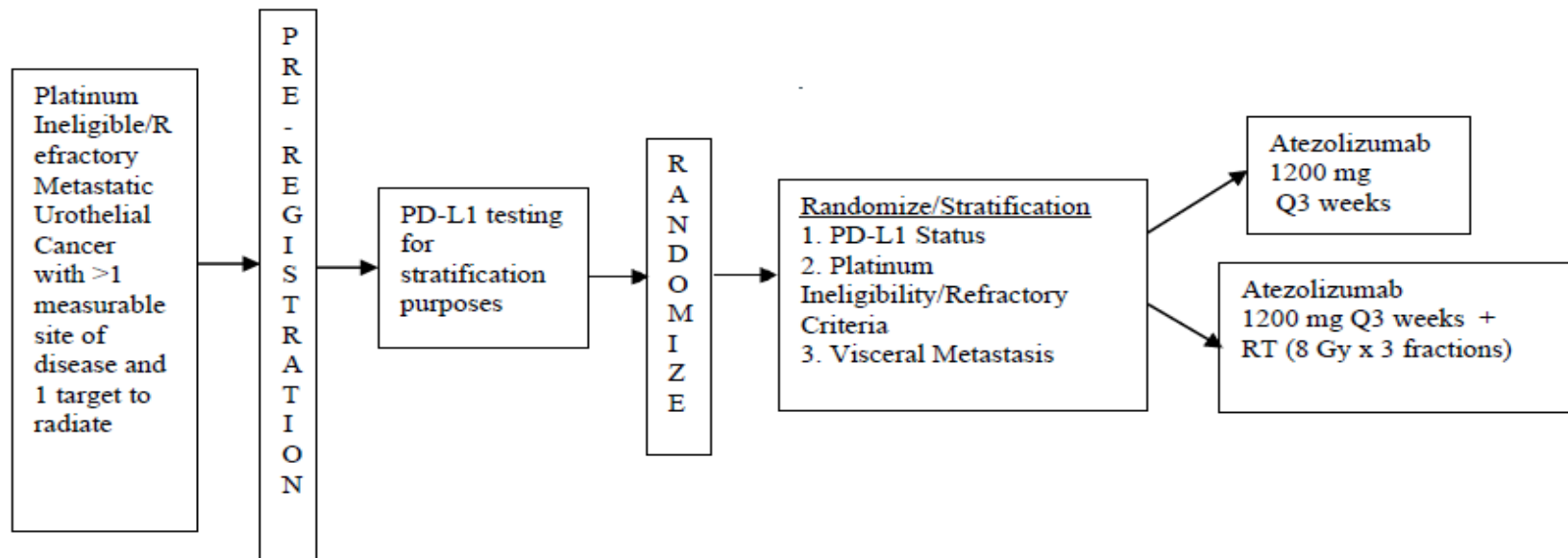
See [Section 5.1](#) for agent treatment details and [Section 5.2](#) for radiation therapy details.

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

Alliance A032002

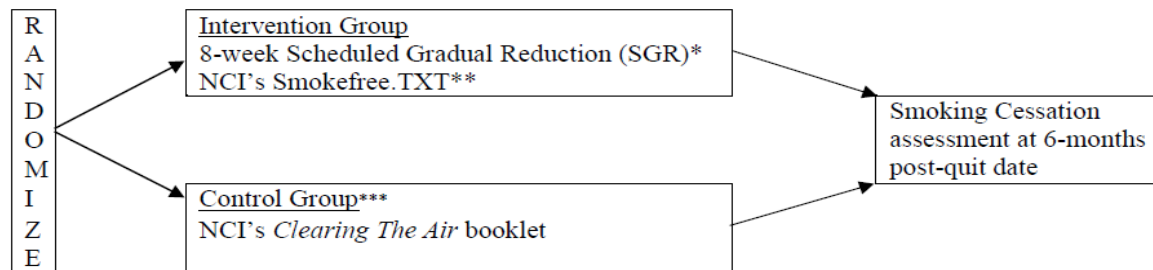
Schema

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



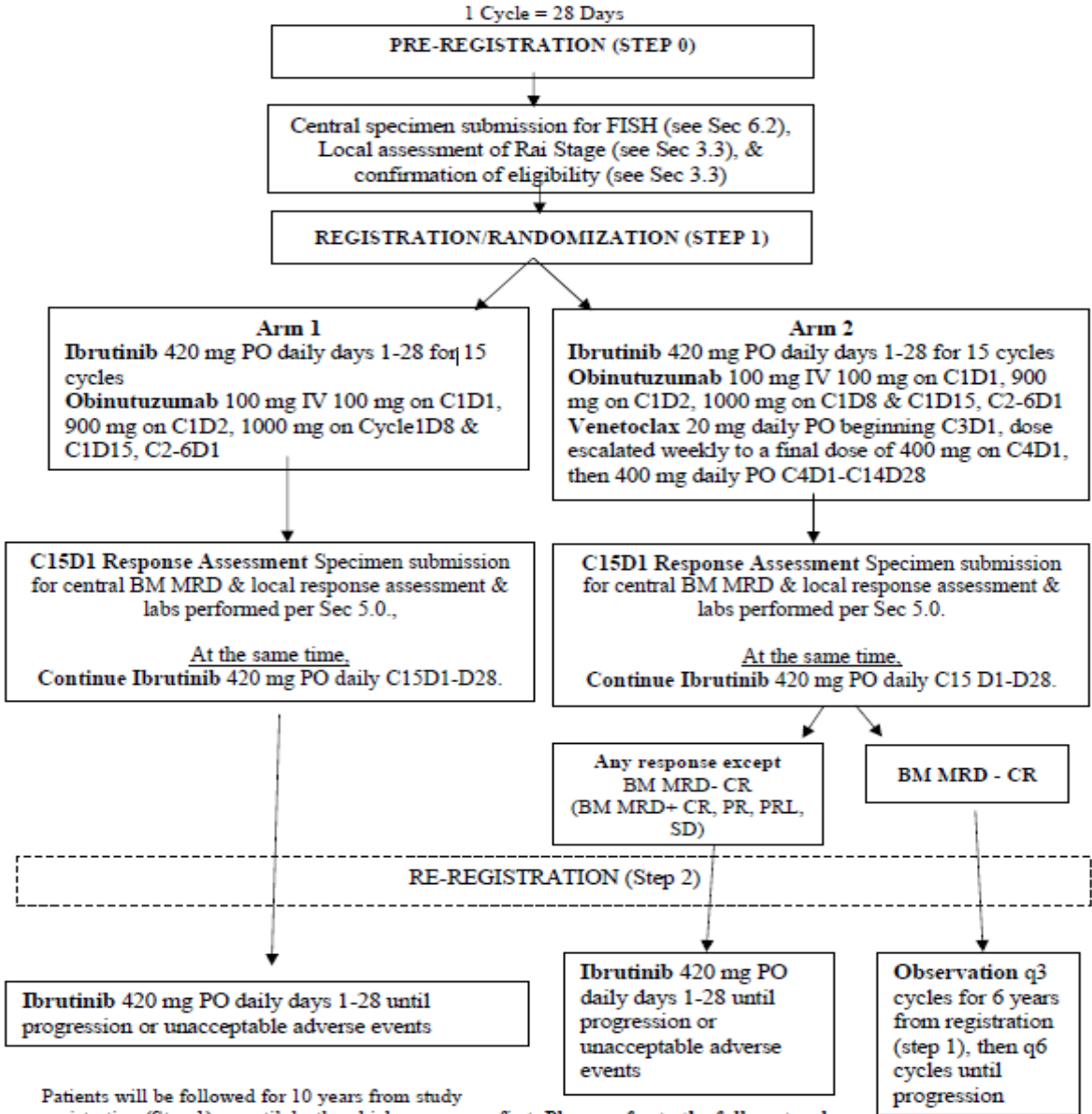
Arm 2
SABR + blinded relugolix** for 6 months

*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.

A041702

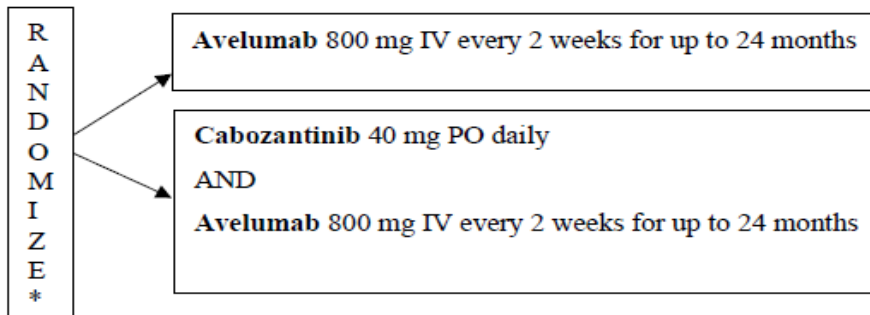
SCHEMA



Patients will be followed for 10 years from study registration (Step 1) 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



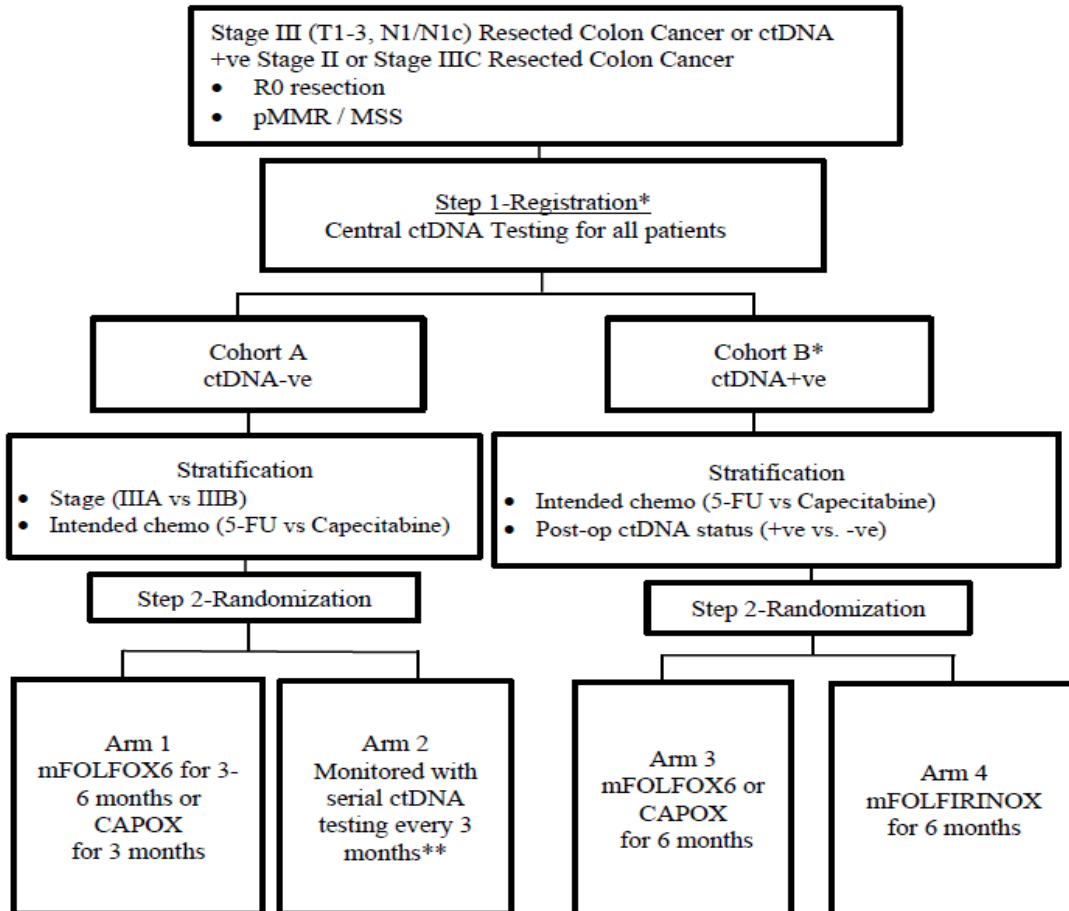
*Randomization is to occur 3-10 weeks after last dose of 1st-line treatment

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

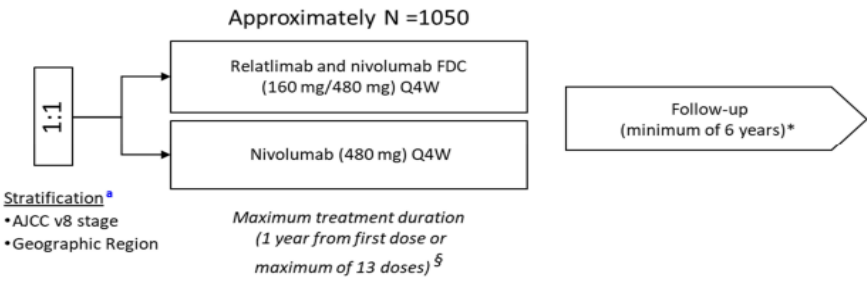


p16-positive OPC/CUP Cohort

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.

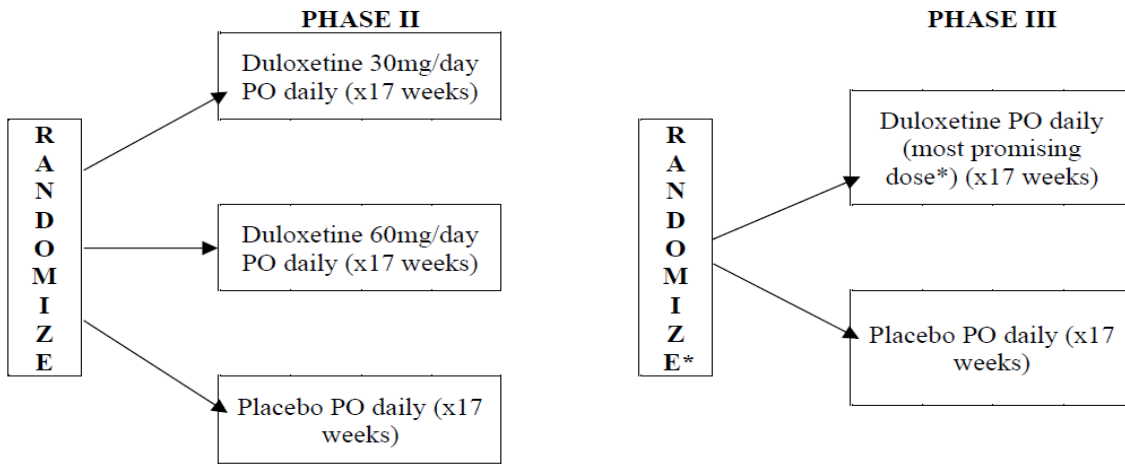


[§] All participants will be treated until recurrence of disease (except melanoma in situ), unacceptable toxicity, participant withdrawal of consent, or a maximum duration of 1 year from first-dose (maximum of 13 doses), whichever occurs first.

* 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.