



MASTER TRIAL LIST

MAY 2024

 New or ReOpened Trials
 No Trials Currently Available

JUST IN TIME TRIALS (JIT)

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

5.7.24

RADIATION LOCATIONS:
 OSF Glen Oak - OSF main hospital
 OSF Route 91 (attached to Illinois CancerCare)
 Carle Health Greater Peoria)
 SJMC - St Joseph Medical Center



JUST IN TIME (JIT) TRIALS

*Contact Disease Specific Navigator

Multi-Disease Site: Advanced/Metastatic Solid Tumors

<u>EAY191- (Combomatch) E5</u>	A Randomized Phase II Study of AMG 510 (Sotorasib) With or Without Panitumumab in Advanced Solid Tumors: A ComboMATCH Treatment Trial
<u>EAY191 - (Combomatch) N5</u>	A Randomized Trial of Neratinib, A Pan-ERBB Inhibitor, Alone or in Combination With Palbociclib, a CDK4/6 Inhibitor, in Patients With HER2+ Gynecologic Cancers and Other Solid Tumors: A ComboMATCH Treatment Trial
<u>EAY191 (Combomatch) - S3</u>	A Phase II Study of Paclitaxel + Ipatasertib In Taxane-Refractory Participants with AKT-Altered Advanced Non-Breast Solid Tumors)
<u>RAIN-3202</u>	A Phase 2 Basket Study of Milademetan in Advanced/Metastatic Solid Tumors

ALL

<u>EA9213</u>	A Phase II Study of Daratumumab-Hyaluronidase for Chemotherapy-Relapsed/Refractory Minimal Residual Disease (MRD) in T Cell Acute Lymphoblastic Leukemia (T-ALL)
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AL Amyloidosis

<u>S2213</u>	A Phase III, Randomized Study of Daratumumab, Cyclophosphamide, Bortezomib and Dexamethasone (Dara-VCD) Induction Followed by Autologous Stem Cell Transplant or Dara-VCD Consolidation and Daratumumab Maintenance in Patients With Newly Diagnosed AL Amyloidosis
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Biliary

<u>EAY191 (ComboMatch) -A6</u>	FOLFOX in Combination With Binimetinib as 2nd Line Therapy for Patients With Advanced Biliary Tract Cancers With MAPK Pathway Alterations: A ComboMATCH Treatment Trial
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Breast

<u>EAY191 (Combomatch) - N2</u>	<i>Molecular Analysis for combination Therapy Choice</i> (SUBSTUDY- N2 : Phase II Trial of Fulvestrant and Binimetinib in Patients With Hormone Receptor-Positive Metastatic Breast Cancer With A Frameshift or Nonsense Mutation or Genomic Deletion in NF1)
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Gynecological

<u>GY026</u>	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
Genitourinary - Rare	
<u>A031702</u>	Phase II Study of Cabozantinib in Combination with Nivolumab and Ipilimumab in Rare Genitourinary Tumors <i>Enrolling cohorts: renal collecting duct, bladder plasmacytoid, sarcomatoid bladder, urethral carcinoma (which allows any histology urothelial, squamous, clear cell, or adenocarcinoma), and Bone only (which allows for any GU histology, except prostate).</i>
Head & Neck	
<u>EA3191</u>	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
<u>EA3211</u>	Phase III Randomized Trial of Immunotherapy With or Without Consolidative Radiotherapy for Oligometastatic Head and Neck Squamous Cell Carcinoma
<u>HN010</u>	A Controlled, Randomized Phase II Trial of Docetaxel Plus Trastuzumab Versus Ado-Trastuzumab Emtansine for Recurrent, Metastatic, or Treatment-Naive, Unresectable HER2-Positive Salivary Gland Cancer
Liposarcoma	
<u>A092107</u>	A Randomized Phase 2 Trial With a Safety Lead-In to Evaluate Palbociclib Versus Palbociclib and Cemiplimab for the Treatment of Advanced Dedifferentiated Liposarcoma
Melanoma	
<u>A091903</u>	A Randomized Phase II Trial of Adjuvant Nivolumab With or Without Cabozantinib in Patients With Resected Mucosal Melanoma
Multiple Myeloma	
<u>A062102</u> <small>SCHEMA</small>	NEW! Randomized Phase 2 Study of Iberdomide Maintenance Therapy Following Idecaptogene Vicleucel CAR-T in Multiple Myeloma Patients
<u>EAA173</u> <small>SCHEMA</small>	Daratumumab to Enhance Therapeutic Effectiveness of Revlimid in Smoldering Myeloma (DETER-SMM)

<p><u>S2209</u></p> <p>SCHEMA</p>	<p>A Phase III Randomized Trial for Newly Diagnosed Multiple Myeloma (NDMM) Patients Considered Frail or in a Subset of "Intermediate Fit" Comparing Upfront Three-Drug Induction Regimens Followed by Double or Single-Agent Maintenance</p>
<p style="text-align: center;">Neuroendocrine</p>	
<p><u>S2104</u></p>	<p>Randomized Phase II Trial of Postoperative Adjuvant Capecitabine and Temozolomide Versus Observation in High-Risk Pancreatic Neuroendocrine Tumors</p>
<p style="text-align: center;">Pancreas</p>	
<p><u>A022106</u></p>	<p>Phase II/III Second-Line NABPLAGEM vs. Nab-Paclitaxel/Gemcitabine in BRCA1/2 or PALB2 Mutant Metastatic Pancreatic Ductal Adenocarcinoma (PLATINUM)</p>
<p><u>S2104</u></p>	<p>Randomized Phase II Trial of Postoperative Adjuvant Capecitabine and Temozolomide Versus Observation in High-Risk Pancreatic Neuroendocrine Tumors</p>
<p style="text-align: center;">Rectal</p>	
<p><u>EA2201</u></p>	<p>Temporarily Closed (RT at Glen Oak, UPHM) A Phase II Study of Neoadjuvant Nivolumab Plus Ipilimumab and Short-Course Radiation in MSI-H/dMMR Locally Advanced Rectal Adenocarcinoma</p>



ILLINOIS
CANCERCARE, P.C.

Specializing in Cancer and Blood Disorders

MASTER TRIAL LIST

MAY 2024



MENU

AML

Navigator - Heather x3661

[Moonshot \(NCI 10323\)](#)

[SCHEMA](#)

Coming Soon! Cancer Moonshot Biobank Research Protocol



MASTER TRIAL LIST

MAY 2024



MENU

ANAL

Navigator - Carrie x3621

EA2176

A Randomized Phase III Study of Immune Checkpoint Inhibition With Chemotherapy in Treatment-Naive Metastatic Anal Cancer Patients



ILLINOIS
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MASTER TRIAL LIST

MAY 2024

[MENU](#)

APL

Navigator - Heather x3661

There are no trials available at this time



MASTER TRIAL LIST

MAY 2024



ACUTE LYMPHOBLASTIC LEUKEMIA

Navigator - Heather x3661

[EA9213 - JIT Trial](#)

A Phase II Study of Daratumumab-Hyaluronidase for Chemotherapy-Relapsed/Refractory Minimal Residual Disease (MRD) in T Cell Acute Lymphoblastic Leukemia (T-ALL)



MASTER TRIAL LIST

MAY 2024



BILIARY

Navigator - Carrie x3621

<p>EAY191 (ComboMatch) -A3</p> <p>SCHEMA</p>	<p>Palbociclib and Binimetinib in RAS-Mutant Cancers: A ComboMATCH Treatment Trial</p>
<p>EAY191 (ComboMatch) -A6</p> <p>(JIT)</p>	<p>FOLFOX in Combination With Binimetinib as 2nd Line Therapy for Patients With Advanced Biliary Tract Cancers With MAPK Pathway Alterations: A ComboMATCH Treatment Trial</p>



MASTER TRIAL LIST

MAY 2024



BLADDER / UROTHELIAL

Navigator - Carrie x3621

ADJUVANT / NEOADJUVANT

[A032103](#)

SCHEMA

An Integrated Phase 2/3 and Phase 3 Trial of MRD-Based Optimization of Adjuvant Therapy in Urothelial Cancer (MODERN)

METASTATIC

[SGNDV001](#)

SCHEMA

An Open-label, Randomized, Controlled Phase 3 Study of Disitamab Vedotin in Combination With Pembrolizumab Versus Chemotherapy in Subjects With Previously Untreated Locally Advanced or Metastatic Urothelial Carcinoma That Expresses HER2 (IHC 1+ and Greater)



MASTER TRIAL LIST

MAY 2024



BRAIN

Navigator - Carrie x3621

<p><u>A071702</u></p> <p><small>SCHEMA</small></p>	<p>Temporarily Suspended A Phase II Study of Checkpoint Blockade Immunotherapy in Patients With Somatically Hypermethylated Recurrent WHO Grade 4 Glioma</p>
<p><u>BN010</u></p> <p><small>SCHEMA</small></p>	<p>(RT pending at Carle and OSF) A Safety Run-In and Phase II Study Evaluating the Efficacy, Safety, and Impact on the Tumor Microenvironment of the Combination of Tocilizumab, Atezolizumab, and Fractionated Stereotactic Radiotherapy in Recurrent Glioblastoma</p>
<p><u>BN011</u></p> <p><small>SCHEMA</small></p>	<p>(RT at SJMC) 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 Carle) 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

No trials at this time

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

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

Neo/Adjuvant - Hormone Receptor Positive / HER2 Negative

BR007

SCHEMA

(RT at Glen Oak, Rt 91, Carle, 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

BR009

SCHEMA

A Phase III Adjuvant Trial Evaluating the Addition of Adjuvant Chemotherapy to Ovarian Function Suppression Plus Endocrine Therapy in Premenopausal Patients With pN0-1, ER-Positive/HER2-Negative Breast Cancer and an Oncotype Recurrence Score Less Than or Equal to 25 (OFSET)

J2J-MC-JZLH / EMBER-4

SCHEMA

(Peoria, Bloomington, Galesburg, Pekin, Washington, Ottawa, Peru) A Randomized, Open-Label, Phase 3 Study of Adjuvant Imlunestrant vs Standard Adjuvant Endocrine Therapy in Patients Who Have Previously Received 2 to 5 Years of Adjuvant Endocrine Therapy for ER+, HER2- Early Breast Cancer With an Increased Risk of Recurrence

S2206

SCHEMA

Phase III Trial of Neoadjuvant Durvalumab (NSC 778709) Plus Chemotherapy Versus Chemotherapy Alone for MammaPrint Ultrahigh (MP2) Hormone Receptor (HR) Positive / Human Epidermal Growth Factor Receptor (HER2) Negative Stage II-III Breast Cancer

Neo/Adjuvant - Triple Negative

A012103

SCHEMA

OptimICE-PCR: De-Escalation of Therapy in Early-Stage TNBC Patients Who Achieve pCR After Neoadjuvant Chemotherapy With Checkpoint Inhibitor Therapy

S2212 / SCARLET

SCHEMA

Shorter Anthracycline-Free Chemo Immunotherapy Adapted to Pathological Response in Early Triple Negative Breast Cancer (SCARLET), A Randomized Phase III Study

METASTATIC TREATMENT

**EAY191
(Combomatch) - E4**

SCHEMA

Temporarily Closed | A ComboMATCH Treatment Trial **E4**: Nilotinib and Paclitaxel in Patients With Prior Taxane-Treated Solid Tumors

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

Metastatic - Hormone Receptor Positive / HER2 Negative

**EAY191
(Combomatch) - N2
(JIT)**

Molecular Analysis for combination Therapy Choice (**SUBSTUDY- N2**: Phase II Trial of Fulvestrant and Binimetinib in Patients With Hormone Receptor-Positive Metastatic Breast Cancer With A Frameshift or Nonsense Mutation or Genomic Deletion in NF1)

S1703

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 Carle*)

CANCER CONTROL (Breast only)

A211901

SCHEMA

Not Actively Screening - Contact Navigator | Reaching Rural Cancer Survivors Who Smoke Using Text-Based Cessation Interventions

CC011

SCHEMA

Cognitive Training for Cancer Related Cognitive Impairment in Breast Cancer Survivors: A Multi-Center Randomized Double-Blinded Controlled Trial

EAQ202

SCHEMA

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

S2010

SCHEMA

A Randomized Phase III Trial Comparing Active Symptom Monitoring Plus Patient Education Versus Patient Education Alone to Improve Persistence With Endocrine Therapy in Young Women With Stage I-III Breast Cancer (ASPEN)

<p><u>S2108CD</u></p> <p>SCHEMA</p>	<p>(Peoria, Bloomington, Galesburg, Canton, Ottawa, Pekin) 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>S1912CD</u></p> <p>SCHEMA</p>	<p><u>Not Actively Screening - Contact Navigator</u> A Randomized Trial Addressing Cancer-Related Financial Hardship Through Delivery of a Proactive Financial Navigation Intervention (CREDIT) <i>(spouse participation no longer required)</i></p>
<p><u>S2013</u></p> <p>SCHEMA</p>	<p>Temporarily Closed (Peoria, Bloomington, Galesburg, Pekin, Washington) Immune Checkpoint Inhibitor Toxicity: A Prospective Observational Study (I-CHECKIT)</p>
<p><u>URCC-18007</u></p>	<p>Randomized Placebo Controlled Trial of Bupropion For Cancer Related Fatigue- <i>at least 2 months out from surgery/tx/radiation</i></p>
<p><u>URCC 19185</u></p> <p>SCHEMA</p>	<p>(Peoria, Bloomington, Canton, Galesburg, Ottawa, Pekin, Peru, Washington) Multicenter Randomized Controlled Trial Comparing Brief Behavioral Therapy for Cancer Related Insomnia (BBT-CI) and Healthy Eating Education Learning (HEAL)</p>
<p><u>URCC 21038</u></p> <p>SCHEMA</p>	<p>(Peoria, Bloomington, Galesburg, Pekin, Washington) 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>SCHEMA</p>	<p>Internet-delivered Management of Pain Among Cancer Treatment Survivors (IMPACTS)</p>
<p><u>WF-2202</u></p> <p>SCHEMA</p>	<p>NEW! Optimizing Psychosocial Intervention for Breast Cancer-Related Sexual Morbidity:The Sexual Health and Intimacy Education (SHINE) Trial</p>
<p>GYNECOLOGICAL</p>	
<p>Navigator - Angie x3613</p>	
<p><u>NRG - GY023</u></p> <p>SCHEMA</p>	<p>Temporarily Closed 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</p>
<p><u>EAY191 (ComboMATCH) - A3</u></p> <p>SCHEMA</p>	<p>Palbociclib and Binimetinib in RAS-Mutant Cancers: A ComboMATCH Treatment Trial</p>
<p><u>EAY191 (ComboMATCH) - N4</u></p>	<p><i>Molecular Analysis for combination Therapy Choice</i> (SUBSTUDY- N4: A Randomized Trial of Selumetinib and Olaparib or Selumetinib Alone in Patients with Recurrent or Persistent RAS Pathway Mutant Ovarian and Endometrial Cancers)</p>



CANCER CONTROL

SURVIVORSHIP

<u>CC011</u> SCHEMA	Cognitive Training for Cancer Related Cognitive Impairment in Breast Cancer Survivors: A Multi-Center Randomized Double-Blinded Controlled Trial
<u>EAQ211</u> SCHEMA	Social Genomic Mechanisms of Health Disparities Among Adolescent and Young Adult (AYA) Survivors of Hodgkin and Non-Hodgkin Lymphoma
<u>URCC-18007</u>	Randomized Placebo Controlled Trial of Bupropion For Cancer Related Fatigue - <i>at least 2 months out from surgery/tx/radiation</i>
<u>WF-1901</u> SCHEMA	Internet-delivered Management of Pain Among Cancer Treatment Survivors (IMPACTS)
<u>WF-2202</u> SCHEMA	Optimizing Psychosocial Intervention for Breast Cancer-Related Sexual Morbidity: The Sexual Health and Intimacy Education (SHINE) Trial

MULTI-DISEASE SITES

<u>A211901</u> SCHEMA	Not Actively Screening - Contact Navigator Reaching Rural Cancer Survivors Who Smoke Using Text-Based Cessation Interventions
<u>EAQ202</u> SCHEMA	Improving Adolescent and Young Adult Self-Reported Data in ECOG-ACRIN Trials (<i>breast, leukemia, lymphoma, and white non-hispanic cohorts closed to accrual</i>)
<u>S1912CD</u> SCHEMA	Not Actively Screening - Contact Navigator A Randomized Trial Addressing Cancer-Related Financial Hardship Through Delivery of a Proactive Financial Navigation Intervention (CREDIT) (<i>spouse participation no longer required</i>)
<u>S2013</u> SCHEMA	Temporarily Closed (Peoria, Bloomington, Galesburg, Pekin, Washington) Immune Checkpoint Inhibitor Toxicity: A Prospective Observational Study (I-CHECKIT)
<u>S2108CD</u> SCHEMA	(Peoria, Bloomington, Galesburg, Canton, Ottawa, Pekin) A Cluster Randomized Trial Comparing an Educationally Enhanced Genomic Tumor Board (EGTB) Intervention to Usual Practice to Increase Evidence-Based Genome-Informed Therapy
<u>URCC-18007</u>	Randomized Placebo Controlled Trial of Bupropion For Cancer Related Fatigue - <i>at least 2 months out from surgery/tx/radiation</i>
<u>URCC 19185</u> SCHEMA	(Peoria, Bloomington, Canton, Galesburg, Ottawa, Pekin, Peru, Washington) Multicenter Randomized Controlled Trial Comparing Brief Behavioral Therapy for Cancer Related Insomnia (BBT-CI) and Healthy Eating Education Learning (HEAL)
<u>URCC 21038</u> SCHEMA	(Peoria, Bloomington, Galesburg, Pekin, Washington) 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>URCC 22063</u> SCHEMA	Longitudinal Observational Trial to Uncover Subtypes of Cancer Cachexia
<u>WF-1901</u> SCHEMA	Internet-delivered Management of Pain Among Cancer Treatment Survivors (IMPACTS)
BREAST	
<u>CC011</u> SCHEMA	Cognitive Training for Cancer Related Cognitive Impairment in Breast Cancer Survivors: A Multi-Center Randomized Double-Blinded Controlled Trial
<u>S2010</u> SCHEMA	A Randomized Phase III Trial Comparing Active Symptom Monitoring Plus Patient Education Versus Patient Education Alone to Improve Persistence With Endocrine Therapy in Young Women With Stage I-III Breast Cancer (ASPEN)
<u>WF-2202</u> SCHEMA	Optimizing Psychosocial Intervention for Breast Cancer-Related Sexual Morbidity: The Sexual Health and Intimacy Education (SHINE) Trial
LYMPHOMA	
<u>EAQ211</u> SCHEMA	Social Genomic Mechanisms of Health Disparities Among Adolescent and Young Adult (AYA) Survivors of Hodgkin and Non-Hodgkin Lymphoma
REGISTRY	
Navigator - Heather 243-3661	
<u>Connect MM</u>	Connect MM: The Multiple Myeloma Disease Registry (<i>new cohort : relapsed/refractory MM to 1st line, initiated / planning 2nd line tx</i>)
<u>Connect Myeloid</u> SCHEMA	The Myelofibrosis (MF), Myelodysplastic Syndromes (MDS) and Acute Myeloid Leukemia (AML) Disease Registry. (<i>enrolling cohorts : low risk MDS, Treated MF, Treated MF cytopenias - includes CMML, aCML, MDS/MPN-RS-T, MDS/MPN unclassifiable</i>)
<u>NHLBI-MDS</u>	Temporarily Closed (Peoria, Bloomington and Galesburg only) -The National Myelodysplastic Syndromes (MDS) Study



MASTER TRIAL LIST

MAY 2024



CLL

Navigator - Heather x3661

1st Line

BGB-11417-301

SCHEMA

NEW! (Peoria, Bloomington, Galesburg, Pekin, Peru, Ottawa, Washtington) A Phase 3, Open-Label, Randomized Study of Sonrotoclax (BGB-11417) Plus Zanubrutinib (BGB-3111) Compared With Venetoclax Plus Obinutuzumab in Patients With Previously Untreated Chronic Lymphocytic Leukemia

2nd Line, 3rd Line, etc.

No trials at this time



MASTER TRIAL LIST

MAY 2024



CML

Navigator - Heather x3661

<p>Novartis CABL001J12302</p> <p>SCHEMA</p>	<p>(Peoria, Bloom, Gburg, Ottawa, Pekin, Peru, Wash) A Phase IIIb, Multi-center, Open-label, Randomized Study of Tolerability and Efficacy of Oral Asciminib Versus Nilotinib in Patients With Newly Diagnosed Philadelphia Chromosome Positive Chronic Myelogenous Leukemia in Chronic Phase.</p>



MASTER TRIAL LIST

MAY 2024



COLON / RECTAL

Navigator - Carrie x3621

Adjuvant

<p>A022004 <small>SCHEMA</small></p>	<p>Randomized Trial of Consolidation Targeted Adjuvant Therapy With Encorafenib and Cetuximab Versus Usual Care for Patients With Stage II/III BRAF V600E Colon Cancer</p>
<p>C-14</p>	<p>(Peoria, Bloomington, Canton, 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)</p>
<p>EA2201 - JIT</p>	<p>Temporarily Closed (RT at Glen Oak, Carle) A Phase II Study of Neoadjuvant Nivolumab Plus Ipilimumab and Short-Course Radiation in MSI-H/dMMR Locally Advanced Rectal Adenocarcinoma</p>
<p>GI008 <small>SCHEMA</small></p>	<p>Colon Adjuvant Chemotherapy Based on Evaluation of Residual Disease</p>

Metastatic

<p>S2107 <small>SCHEMA</small></p>	<p>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</p>
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CANCER CONTROL (Colorectal only)

<p>A211901 <small>SCHEMA</small></p>	<p><u>Not Actively Screening - Contact Navigator</u> Reaching Rural Cancer Survivors Who Smoke Using Text-Based Cessation Interventions</p>
<p>EAQ202 <small>SCHEMA</small></p>	<p>Improving Adolescent and Young Adult Self-Reported Data in ECOG-ACRIN Trials (<i>breast, leukemia, lymphoma, and white non-hispanic cohorts closed to accrual</i>)</p>

<p><u>S1912CD</u></p> <p>SCHEMA</p>	<p><u>Not Actively Screening - Contact Navigator</u> A Randomized Trial Addressing Cancer-Related Financial Hardship Through Delivery of a Proactive Financial Navigation Intervention (CREDIT) (<i>spouse participation no longer required</i>)</p>
<p><u>S2013</u></p> <p>SCHEMA</p>	<p>Temporarily Closed (Peoria, Bloomington, Galesburg, Pekin, Washington) Immune Checkpoint Inhibitor Toxicity: A Prospective Observational Study (I-CHECKIT)</p>
<p><u>S2108CD</u></p> <p>SCHEMA</p>	<p>(Peoria, Bloomington, Galesburg, Canton, Ottawa, Pekin) 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-18007</u></p>	<p>Randomized Placebo Controlled Trial of Bupropion For Cancer Related Fatigue - <i>at least 2 months out from surgery/tx/radiation</i></p>
<p><u>URCC 19185</u></p> <p>SCHEMA</p>	<p>(Peoria, Bloomington, Canton, Galesburg, Ottawa, Pekin, Peru, Washington) Multicenter Randomized Controlled Trial Comparing Brief Behavioral Therapy for Cancer Related Insomnia (BBT-CI) and Healthy Eating Education Learning (HEAL)</p>
<p><u>URCC 21038</u></p> <p>SCHEMA</p>	<p>(Peoria, Bloomington, Galesburg, Pekin, Washington) 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>URCC 22063</u></p> <p>SCHEMA</p>	<p>Longitudinal Observational Trial to Uncover Subtypes of Cancer Cachexia</p>
<p><u>WF-1901</u></p> <p>SCHEMA</p>	<p>Internet-delivered Management of Pain Among Cancer Treatment Survivors (IMPACTS)</p>



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MAY 2024



ESOPHAGEAL- GASTRIC

Navigator - Carrie x3621

<p>A022102</p> <p><small>SCHEMA</small></p>	<p>Randomized Phase III Trial of mFOLFIRINOX vs. FOLFOX With Nivolumab for First-Line Treatment of Metastatic HER2- Gastroesophageal Adenocarcinoma</p>
<p>EAY191 (Combomatch) - E4</p> <p><small>SCHEMA</small></p>	<p>Temporarily Closed A ComboMATCH Treatment Trial E4: Nilotinib and Paclitaxel in Patients With Prior Taxane-Treated Solid Tumors</p>
<p>EA2212</p> <p><small>SCHEMA</small></p>	<p>A Randomized Phase II Study of Perioperative Atezolizumab +/- Chemotherapy in Resectable MSI-H/dMMR Gastric and Gastroesophageal Junction (GEJ) Cancer</p>

HEAD & NECK

Navigator - Ashton x3611

<p><u>EA3161</u></p> <p>SCHEMA</p>	<p>(RT at Glen Oak, Carle) 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>EA3211 - JIT</u></p>	<p>Phase III Randomized Trial of Immunotherapy With or Without Consolidative Radiotherapy for Oligometastatic Head and Neck Squamous Cell Carcinoma</p>
<p><u>EAY191 (Combomatch) - E4</u></p> <p>SCHEMA</p>	<p>Temporarily Closed A ComboMATCH Treatment Trial E4: Nilotinib and Paclitaxel in Patients With Prior Taxane-Treated Solid Tumors</p>
<p><u>HN005</u></p> <p>SCHEMA</p>	<p>Temporarily Closed (RT at Glen Oak; Carle) 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 Carle and SJMC) 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>
<p><u>HN010 - JIT</u></p>	<p>A Controlled, Randomized Phase II Trial of Docetaxel Plus Trastuzumab Versus Ado-Trastuzumab Emtansine for Recurrent, Metastatic, or Treatment-Naive, Unresectable HER2-Positive Salivary Gland Cancer</p>
<p><u>S2101</u></p>	<p>Biomarker Stratified CaboZantinib (NSC#761968) and NivOlumab (NSC#748726) (BiCaZO) - A Phase II Study of Combining Cabozantinib and Nivolumab in Patients With Advanced Solid Tumors (IO Refractory Melanoma or HNSCC) Stratified by Tumor Biomarkers - an immunoMATCH Pilot Study</p>



MASTER TRIAL LIST

MAY 2024

MENU

Navigator - Heather x3661

LYMPHOMA

HL

No HL trials at this time

NHL

No NHL trials at this time



MASTER TRIAL LIST

MAY 2024



MDS/MPN

Navigator - Heather x3661

<p><u>Connect Myeloid</u></p> <p>SCHEMA</p>	<p>The Myelofibrosis (MF), Myelodysplastic Syndromes (MDS) and Acute Myeloid Leukemia (AML) Disease Registry. (<i>enrolling cohorts</i> : newly diagnosed low risk MDS, Treated low risk-MDS, Treated MF, Treated MF cytopenias - includes CMML, aCML, MDS/MPN-RS-T, MDS/MPN unclassifiable)</p>
<p><u>NHLBI-MDS</u></p>	<p>Temporarily Closed (Peoria, Bloomington and Galesburg only) -The National Myelodysplastic Syndromes (MDS) Study</p>



MASTER TRIAL LIST

MAY 2024



MELANOMA

Navigator - Carrie x3621

<p><u>A091903 - JIT Trial</u></p>	<p>A Randomized Phase II Trial of Adjuvant Nivolumab With or Without Cabozantinib in Patients With Resected Mucosal Melanoma</p>
<p><u>S2101</u></p> <p>SCHEMA</p>	<p>Biomarker Stratified CaboZantinib (NSC#761968) and NivOlumab (NSC#748726) (BiCaZO) - A Phase II Study of Combining Cabozantinib and Nivolumab in Patients With Advanced Solid Tumors (IO Refractory Melanoma or HNSCC) Stratified by Tumor Biomarkers - an immunoMATCH Pilot Study</p>



MASTER TRIAL LIST

MAY 2024

MENU

MERKEL

Navigator - Carrie x3621

<p><u>EA6174</u></p>	<p>Temporarily Closed (RT at Glen Oak, Carle) A Phase III Randomized Trial Comparing Adjuvant MK3475 (Pembrolizumab) to Standard of Care Observation in Completely Resected Merkel Cell Carcinoma</p>
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MASTER TRIAL LIST

MAY 2024

MENU

MOLECULAR STUDIES

*Contact Disease Specific Navigator

Moonshot (NCI 10323)	Coming Soon! Cancer Moonshot Biobank Research Protocol
SCHEMA	
S1823	Closing 5/20/24 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>)
SCHEMA	
TP-CA-003 (Sculptor)	(Peoria, Blm, Canton, Gburg, Ottawa, Pekin, Peru, Washington) A Tissue and Longitudinal Circulating Tumor DNA (ctDNA) Biomarker Profiling Study of Patients with Small Cell Lung Cancer (SCLC) Using Comprehensive Next-Generation Sequencing (NGS) Assays (TEMPUS)
EAY191 - COMBOMATCH	Targeted Therapy Directed by Genetic Testing in Treating Patients With Locally Advanced or Advanced Solid Tumors, The ComboMATCH Screening Trial (<i>multiple substudies available</i>)
EAY191 (ComboMatch) -A3	Palbociclib and Binimetinib in RAS-Mutant Cancers: A ComboMATCH Treatment Trial
SCHEMA	
EAY191 (ComboMatch) -A6	FOLFOX in Combination With Binimetinib as 2nd Line Therapy for Patients With Advanced Biliary Tract Cancers With MAPK Pathway Alterations: A ComboMATCH Treatment Trial
EAY191 (Combomatch) - E4	Temporarily Closed A ComboMATCH Treatment Trial E4: Nilotinib and Paclitaxel in Patients With Prior Taxane-Treated Solid Tumors
SCHEMA	
EAY191- (Combomatch) E5	NEW! A Randomized Phase II Study of AMG 510 (Sotorasib) With or Without Panitumumab in Advanced Solid Tumors: A ComboMATCH Treatment Trial
EAY191 (Combomatch) - N2	<i>Molecular Analysis for combination Therapy Choice</i> (SUBSTUDY- N2: Phase II Trial of Fulvestrant and Binimetinib in Patients With Hormone Receptor-Positive Metastatic Breast Cancer With A Frameshift or Nonsense Mutation or Genomic Deletion in NF1)
EAY191 - (Combomatch) N5	NEW! A Randomized Trial of Neratinib, A Pan-ERBB Inhibitor, Alone or in Combination With Palbociclib, a CDK4/6 Inhibitor, in Patients With HER2+ Gynecologic Cancers and Other Solid Tumors: A ComboMATCH Treatment Trial

EAY191 (Combomatch) -
S3

A Phase II Study of Paclitaxel + Ipatasertib In Taxane-Refractory Participants with AKT-Altered Advanced Non-Breast Solid Tumors)

MULTIPLE MYELOMA

Navigator - Heather x3661

<p><u>A062102 - JIT</u> SCHEMA</p>	<p>NEW! Randomized Phase 2 Study of Iberdomide Maintenance Therapy Following Idecaptogene Vicleucel CAR-T in Multiple Myeloma Patients</p>
<p><u>Connect MM</u></p>	<p>Connect MM: The Multiple Myeloma Disease Registry (<i>new cohort : relapsed/refractory MM to 1st line, initiated / planning 2nd line tx</i>)</p>
<p><u>EAA173 - JIT</u> SCHEMA</p>	<p>Daratumumab to Enhance Therapeutic Effectiveness of Revlimid in Smoldering Myeloma (DETER-SMM)</p>
<p><u>Moonshot (NCI 10323)</u> SCHEMA</p>	<p>Coming Soon! Cancer Moonshot Biobank Research Protocol</p>
<p><u>S2209 - JIT</u> SCHEMA</p>	<p>A Phase III Randomized Trial for Newly Diagnosed Multiple Myeloma (NDMM) Patients Considered Frail or in a Subset of "Intermediate Fit" Comparing Upfront Three-Drug Induction Regimens Followed by Double or Single-Agent Maintenance</p>

MASTER TRIAL LIST

MAY 2024

MENU

NEUROENDOCRINE

Navigator - Carrie x3621

<u>A021804</u>	A Prospective, Multi-Institutional Phase II Trial Evaluating Temozolomide vs. Temozolomide and Olaparib for Advanced Pheochromocytoma and Paraganglioma
<u>S2104 - JIT Trial</u>	Randomized Phase II Trial of Postoperative Adjuvant Capecitabine and Temozolomide Versus Observation in High-Risk Pancreatic Neuroendocrine Tumors

NSCLC

Navigator - Ashton x3611

ADJUVANT / NEOADJUVANT

<p>A081801 SCHEMA</p>	<p>Actively Screening for TB only - Contact Navigator Integration of Immunotherapy Into Adjuvant Therapy for Resected NSCLC: ALCHEMIST Chemo-IO (ACCIO)</p>
<p>E4512 SCHEMA</p>	<p>A Randomized Phase III Trial for Surgically Resected Early Stage Non-small Cell Lung Cancer: Crizotinib Versus Observation for Patients With Tumors Harboring the Anaplastic Lymphoma Kinase (ALK) Fusion Protein (ALCHEMIST substudy)</p>
<p>LU008 SCHEMA</p>	<p>(RT at Carle, SJMC, [pending Rt 91 and Glen Oak]) Phase III Prospective Randomized Trial of Primary Lung Tumor Stereotactic Body Radiation Therapy Followed by Concurrent Mediastinal Chemoradiation for Locally Advanced Non-Small Cell Lung Cancer</p>
<p>S1914</p>	<p>(RT at Glen Oak, Carle, SJMC) 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>(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>

METASTATIC - 2nd/3rd Line

<p>EAY191 (Combomatch) - E4 SCHEMA</p>	<p>Temporarily Closed A ComboMATCH Treatment Trial E4: Nilotinib and Paclitaxel in Patients With Prior Taxane-Treated Solid Tumors</p>
<p>LUNGMAP</p>	<p>A Master Protocol To Evaluate Biomarker-Driven Therapies and Immunotherapies in Previously-Treated NSCLC. <i>(SUB-STUDIES: 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 - co-mutation with TP53 cohort now closed); S1900G - A Randomized Phase II Study of INC280 (Capmatinib) Plus Osimertinib With or Without Ramucirumab in Participants With EGFR-Mutant, MET-Amplified Stage IV or Recurrent Non-Small Cell Lung Cancer; S1900K (NEW substudy!) - A Randomized Phase II Study of Tepotinib with or without Ramucirumab in Participants with MET Exon 14 Skipping Positive Stage IV or Recurrent Non-Small Cell Lung Cancer</i></p>
<p>S2302 (Pragmatica) SCHEMA</p>	<p>A Prospective Randomized Study of Ramucirumab (LY3009806; NSC 749128) Plus Pembrolizumab (MK-3475; NSC 776864) Versus Standard of Care for Participants Previously Treated With Immunotherapy for Stage IV or Recurrent Non-Small Cell Lung Cancer (Pragmatica-Lung)</p>

CANCER CONTROL (NSCLC Only)

<p>A211901 SCHEMA</p>	<p>Not Actively Screening - Contact Navigator Reaching Rural Cancer Survivors Who Smoke Using Text-Based Cessation Interventions</p>
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<p><u>EAQ202</u> </p>	<p>Improving Adolescent and Young Adult Self-Reported Data in ECOG-ACRIN Trials (<i>breast, leukemia, lymphoma, and white non-hispanic cohorts closed to accrual</i>)</p>
<p><u>S2108CD</u> </p>	<p>(Peoria, Bloomington, Galesburg, Canton, Ottawa, Pekin) 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>S1912CD</u> </p>	<p><u>Not Actively Screening - Contact Navigator</u> A Randomized Trial Addressing Cancer-Related Financial Hardship Through Delivery of a Proactive Financial Navigation Intervention (CREDIT) (<i>spouse participation no longer required</i>)</p>
<p><u>S2013</u> </p>	<p>Temporarily Closed (Peoria, Bloomington, Galesburg, Pekin, Washington) Immune Checkpoint Inhibitor Toxicity: A Prospective Observational Study (I-CHECKIT)</p>
<p><u>URCC-18007</u></p>	<p>Randomized Placebo Controlled Trial of Bupropion For Cancer Related Fatigue - <i>at least 2 months out from surgery/tx/radiation</i></p>
<p><u>URCC 19185</u> </p>	<p>(Peoria, Bloomington, Canton, Galesburg, Ottawa, Pekin, Peru, Washington) Multicenter Randomized Controlled Trial Comparing Brief Behavioral Therapy for Cancer Related Insomnia (BBT-CI) and Healthy Eating Education Learning (HEAL)</p>
<p><u>URCC 21038</u> </p>	<p>(Peoria, Bloomington, Galesburg, Pekin, Washington) 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>URCC 22063</u> </p>	<p>Longitudinal Observational Trial to Uncover Subtypes of Cancer Cachexia</p>
<p><u>WF-1901</u> </p>	<p>Internet-delivered Management of Pain Among Cancer Treatment Survivors (IMPACTS)</p>



MASTER TRIAL LIST

MAY 2024



PANCREATIC

Navigator - Carrie x3621

<p><u>A022106 - JIT</u></p>	<p>Phase II/III Second-Line NABPLAGEM vs. Nab-Paclitaxel/Gemcitabine in BRCA1/2 or PALB2 Mutant Metastatic Pancreatic Ductal Adenocarcinoma (PLATINUM)</p>
<p><u>EA2192</u> <small>SCHEMA</small></p>	<p>A Randomized Phase II Double-Blind Study of Olaparib Versus Placebo Following Curative Intent Therapy in Patients With Resected Pancreatic Cancer and a Pathogenic BRCA1, BRCA2 or PALB2 Mutation (APOLLO)</p>
<p><u>EAY191 (ComboMATCH) - A3</u> <small>SCHEMA</small></p>	<p>Palbociclib and Binimetinib in RAS-Mutant Cancers: A ComboMATCH Treatment Trial</p>
<p><u>EAY191 (Combomatch) - E4</u></p>	<p>Temporarily Closed A ComboMATCH Treatment Trial E4: Nilotinib and Paclitaxel in Patients With Prior Taxane-Treated Solid Tumors</p>
<p><u>S2001</u> <small>SCHEMA</small></p>	<p>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</p>
<p><u>S2104 - JIT Trial</u></p>	<p>Randomized Phase II Trial of Postoperative Adjuvant Capecitabine and Temozolomide Versus Observation in High-Risk Pancreatic Neuroendocrine Tumors</p>

MASTER TRIAL LIST

MAY 2024



PROSTATE

Navigator - Carrie x3621

ADJUVANT

<p><u>GU008</u></p> <p>SCHEMA</p>	<p>(RT at Glen Oak and Carle) 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, Carle, 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 Carle) Parallel Phase III Randomized Trials of Genomic-Risk Stratified Unfavorable Intermediate Risk Prostate Cancer: De-Intensification and Intensification Clinical Trial Evaluation (GUIDANCE)</p>
<p><u>GU013</u></p> <p>SCHEMA</p>	<p>(RT credentialing pending) The Phase III 'High Five Trial' Five Fraction Radiation for High-Risk Prostate Cancer</p>

METASTATIC

<p><u>EAY191 (Combomatch) - E4</u></p> <p>SCHEMA</p>	<p>Temporarily Closed A ComboMATCH Treatment Trial E4: Nilotinib and Paclitaxel in Patients With Prior Taxane-Treated Solid Tumors</p>
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MASTER TRIAL LIST

MAY 2024



RENAL CELL

Navigator - Carrie x3621

<p><u>A031704</u></p> <p><small>SCHEMA</small></p>	<p>Temporarily suspending on 5/15/24 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>EA8211</u></p> <p><small>SCHEMA</small></p>	<p>(RT at Rt 91, Glen Oak) Phase III Randomized Trial of Stereotactic Ablative Radiotherapy (SAbR) for Oligometastatic Advanced Renal Carcinoma (SOAR)</p>
<p><u>S2200</u></p> <p><small>SCHEMA</small></p>	<p>A Phase II Randomized Trial of Cabozantinib (NSC #761968) With or Without Atezolizumab (NSC #783608) in Patients With Advanced Papillary Renal Cell Carcinoma (PAPMET2)</p>

MASTER TRIAL LIST








MAY 2024

MENU

RADIATION TRIALS

Navigator - Jessica x3615

BRAIN	
<u>BN011</u>	(RT at SJMC) A Phase III Trial of Gleostine® (Lomustine)-Temozolomide Combination Therapy Versus Standard Temozolomide in Patients With Methylated MGMT Promoter Glioblastoma
<u>N0577</u>	(Glen Oak, RT 91, and Carle) 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>BN010</u>	NEW! (RT pending at Carle and OSF) A Safety Run-In and Phase II Study Evaluating the Efficacy, Safety, and Impact on the Tumor Microenvironment of the Combination of Tocilizumab, Atezolizumab, and Fractionated Stereotactic Radiotherapy in Recurrent Glioblastoma
<u>BN012</u>	(RT at Carle) A Randomized Phase III Trial of Pre-Operative Compared to Post-Operative Stereotactic Radiosurgery in Patients with Resectable Brain Metastases
<u>CCTG CE.7</u>	(Glen Oak, Carle) - A Phase III Trial of Stereotactic Radiosurgery Compared with Whole Brain Radiotherapy (WBRT) for 5-15 Brain Metastases
<u>WF-2201</u>	(Glen Oak; Pending at Rt 91) - Hypofractionated Radiotherapy vs Single Fraction Radiosurgery For Brain Metastasis Patients On Immunotherapy (HYPOGRYPHE)
BREAST	
<u>BR007</u>	(Glen Oak, Rt 91, Carle, 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) Tailor RT: A Randomized Trial of Regional Radiotherapy in Biomarker Low Risk Node Positive Breast Cancer
HEAD & NECK	

<u>EA3161</u> 	(Glen Oak and Carle) A Phase II/III Randomized Study of Maintenance Nivolumab Versus Observation in Patients With Locally Advanced, Intermediate Risk HPV Positive OPSCC
<u>EA3211 - JIT</u>	Phase III Randomized Trial of Immunotherapy With or Without Consolidative Radiotherapy for Oligometastatic Head and Neck Squamous Cell Carcinoma
<u>HN005</u> 	Temporarily Closed (Glen Oak; Carle) 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 Carle and SJMC) 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)
NSCLC	
<u>LU008</u> 	(RT at Carle, SJMC, pending rt 91 and Glen Oak) Phase III Prospective Randomized Trial of Primary Lung Tumor Stereotactic Body Radiation Therapy Followed by Concurrent Mediastinal Chemoradiation for Locally Advanced Non-Small Cell Lung Cancer
<u>S1914</u>	(Glen Oak, Carle and SJMC) 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 and Carle) 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, Carle, 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> 	(RT at Carle) Parallel Phase III Randomized Trials of Genomic-Risk Stratified Unfavorable Intermediate Risk Prostate Cancer: De-Intensification and Intensification Clinical Trial Evaluation (GUIDANCE)

<p><u>GU013</u></p> <p><small>SCHEMA</small></p>	<p>(RT credentialing pending) The Phase III 'High Five Trial' Five Fraction Radiation for High-Risk Prostate Cancer</p>
<p>RENAL</p>	
<p><u>EA8211</u></p> <p><small>SCHEMA</small></p>	<p>(RT at Rt 91, Glen Oak) Phase III Randomized Trial of Stereotactic Ablative Radiotherapy (SAbR) for Oligometastatic Advanced Renal Carcinoma (SOAR)</p>
<p>SCLC</p>	
<p><u>NRG CC009</u></p> <p><small>SCHEMA</small></p>	<p>(Glen Oak, Carle) - 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>S1827</u></p>	<p>(Glen Oak, SJMC, Carle) A Randomized Phase III Trial of MRI Surveillance With or Without Prophylactic Cranial Irradiation (PCI) in Small-Cell Lung Cancer</p>

MASTER TRIAL LIST

MAY 2024

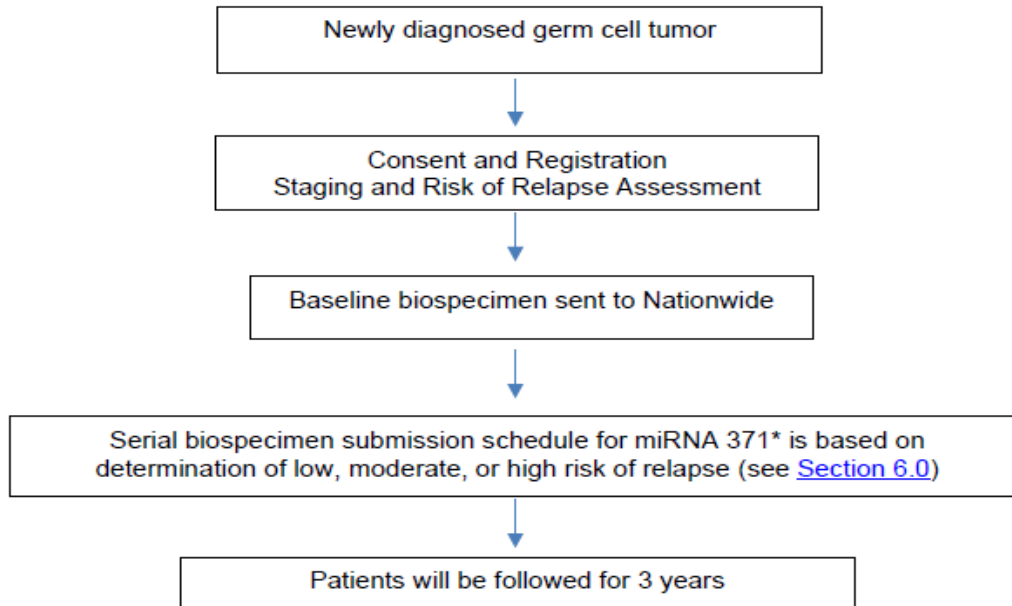
MENU

SMALL CELL LUNG CANCER

Navigator - Ashton x3611

<p><u>NRG CC009</u></p> <p>SCHEMA</p>	<p>(RT at Glen Oak, Carle) - 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>S1827</u></p>	<p>(RT at Glen Oak, SJMC, Carle) A Randomized Phase III Trial of MRI Surveillance With or Without Prophylactic Cranial Irradiation (PCI) in Small-Cell Lung Cancer</p>
<p><u>TP-CA-003 (Sculptor)</u></p>	<p>(Peoria, Blm, Canton, Gburg, Ottawa, Pekin, Peru, Washington) A Tissue and Longitudinal Circulating Tumor DNA (ctDNA) Biomarker Profiling Study of Patients with Small Cell Lung Cancer (SCLC) Using Comprehensive Next-Generation Sequencing (NGS) Assays (TEMPUS)</p>

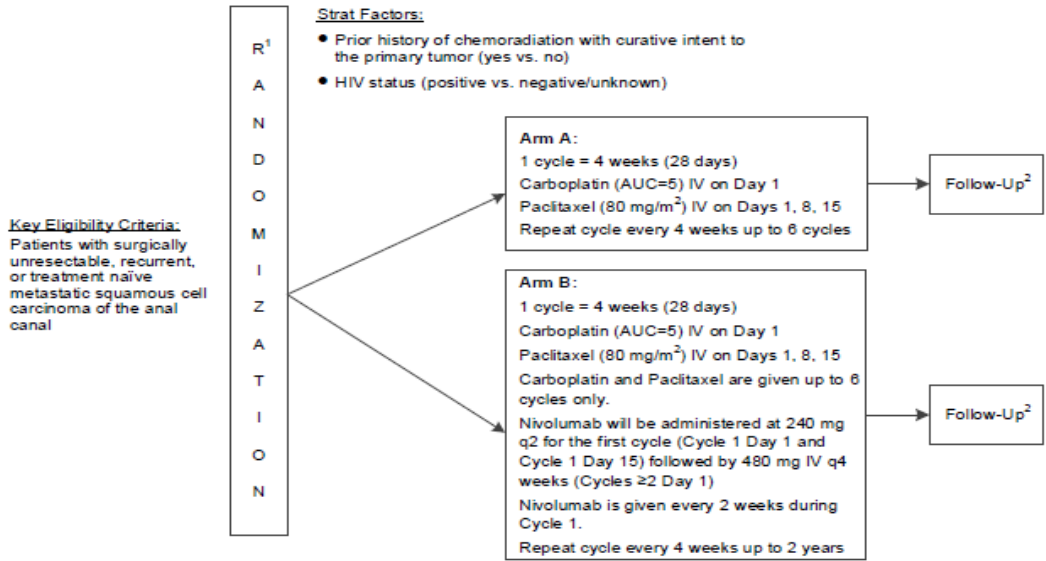
SCHEMA



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

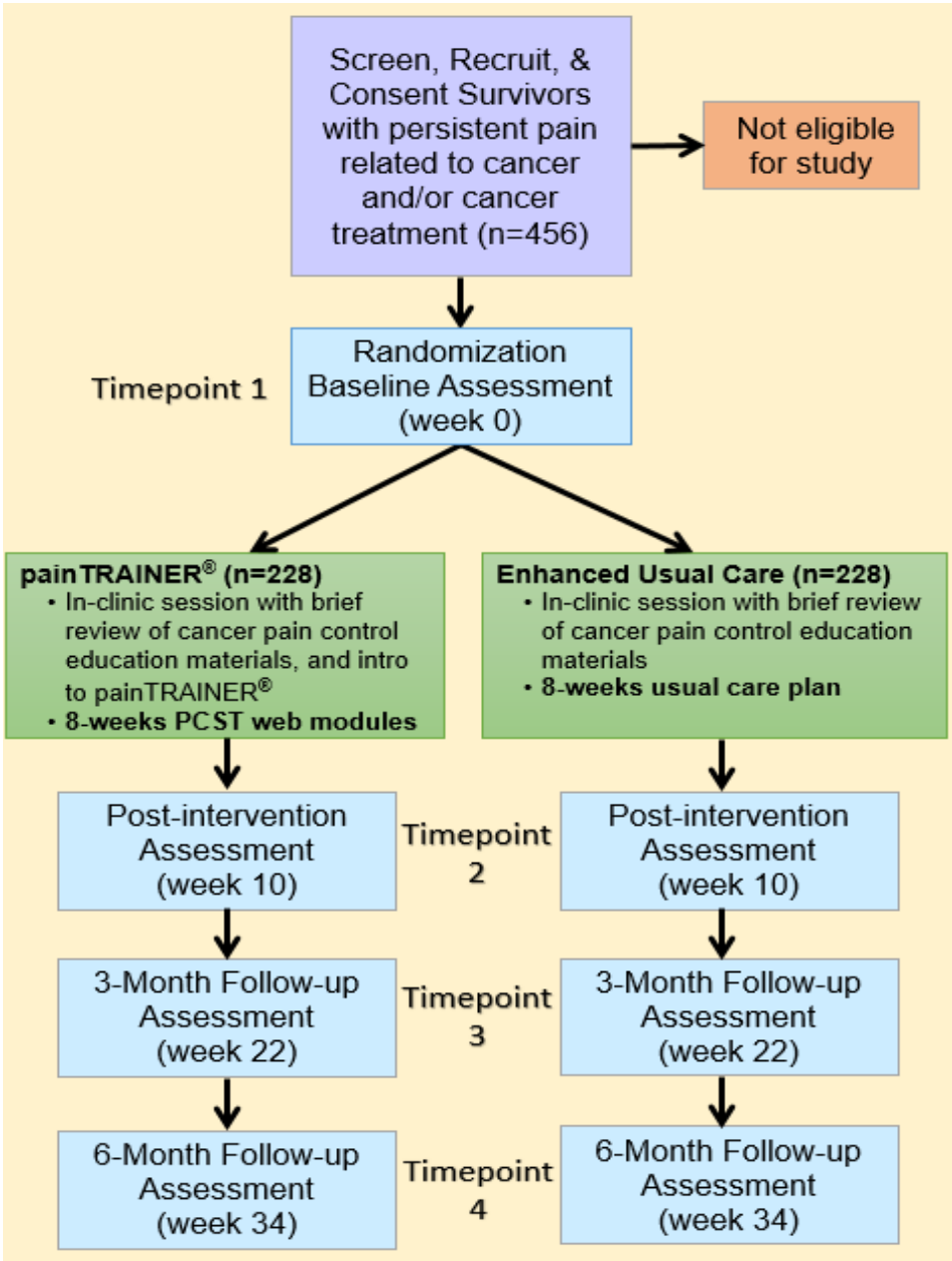
EA2176
Navigator -Carrie x3621

MENU



1. Randomization is 1:2 (A:B).

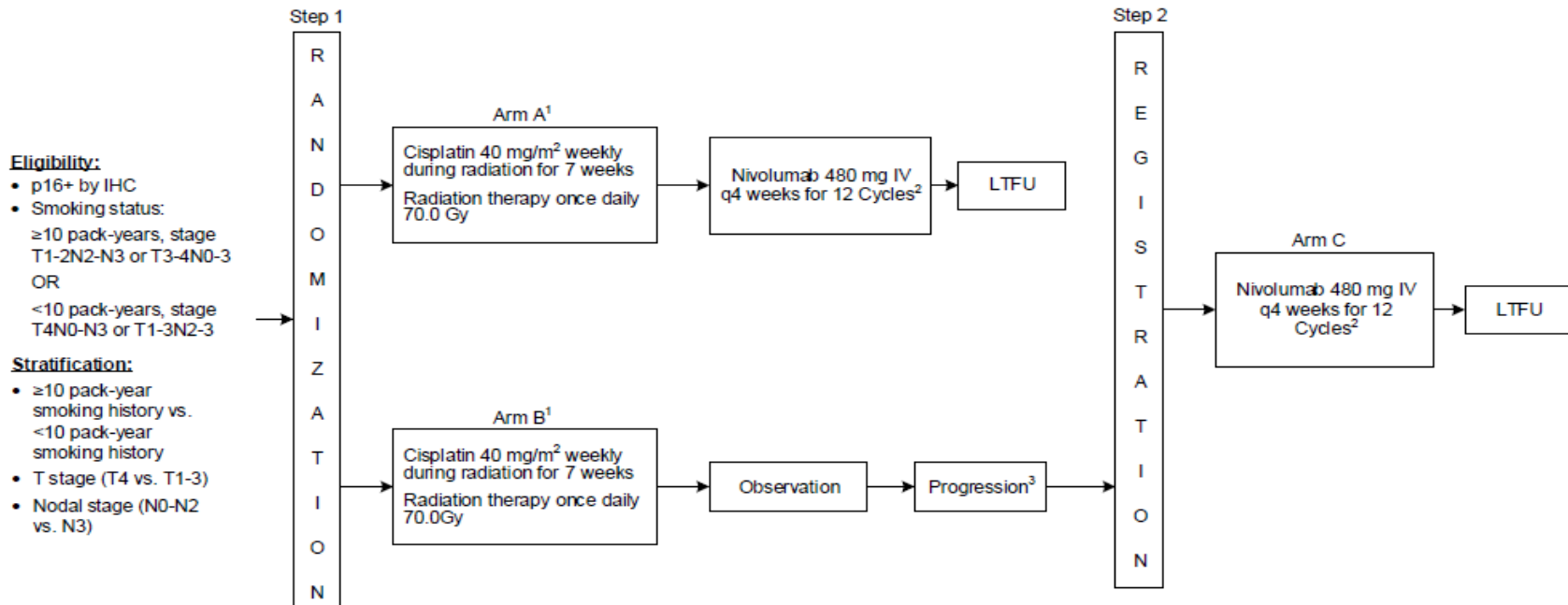
2. For this protocol, all patients, including those who discontinue protocol therapy early, will be followed for response until disease progression, even if non-protocol therapy is initiated, and for survival every 3 months for two years from the date of randomization. All patients must also be followed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



EA3161
Navigator -Ashton x3611

MENU

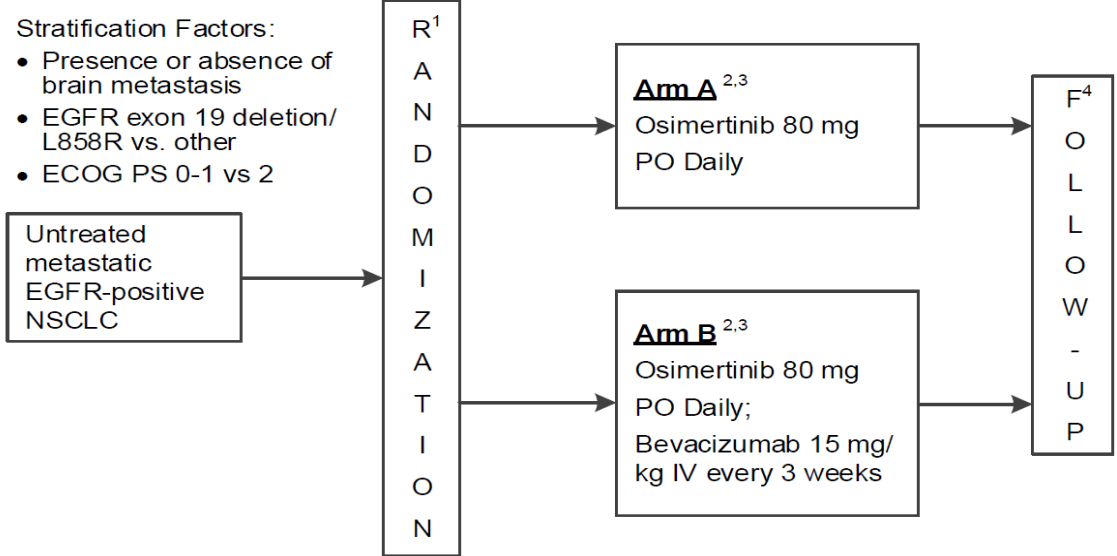
Schema



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.

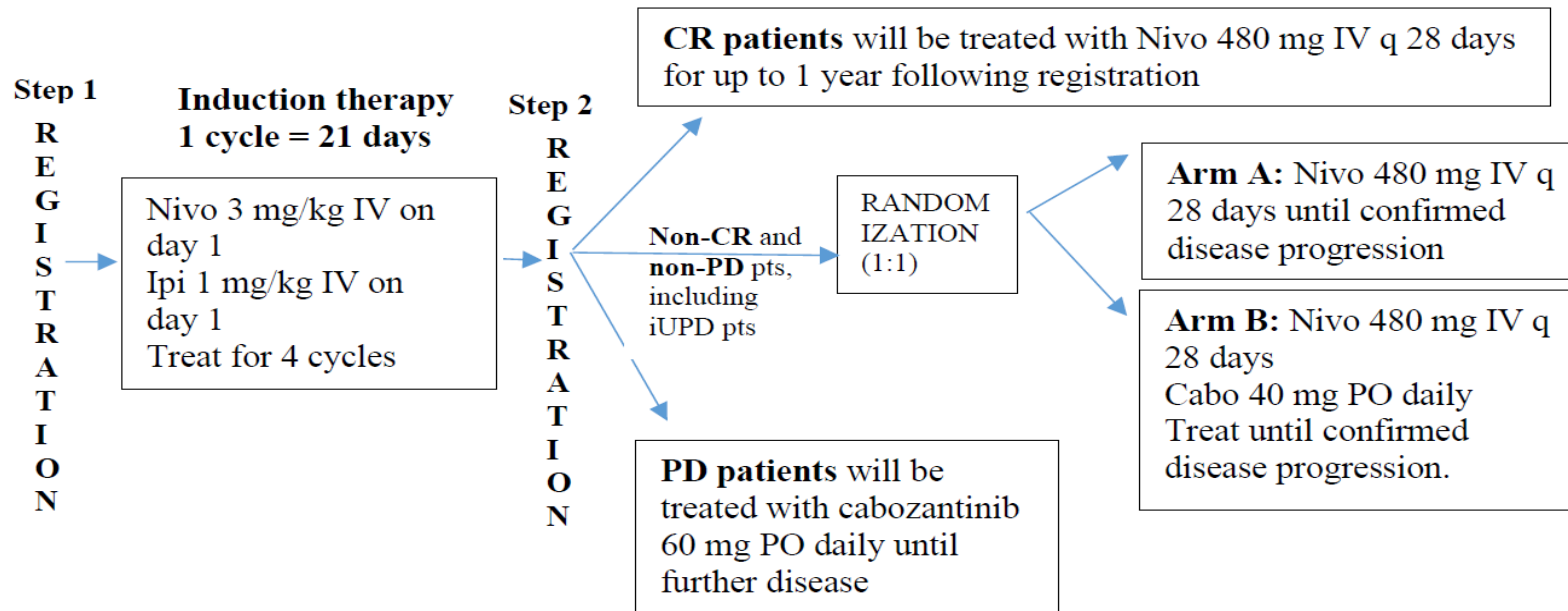
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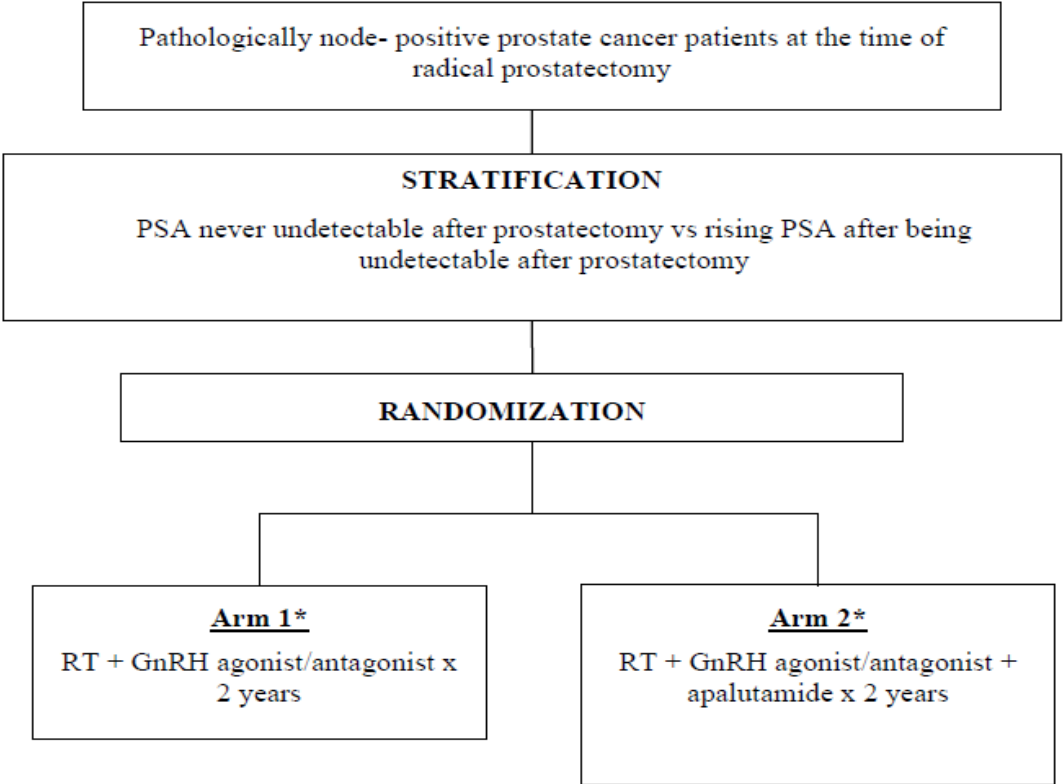


Accrual Goal = 300 patients
Cycle = 3 weeks (21 days)

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

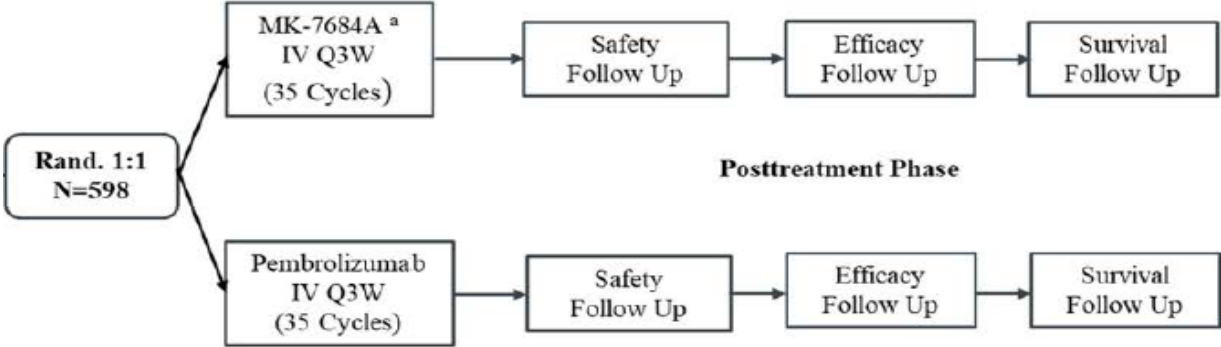
Arm 4
RT
+
24 mos ADT
+24 mos Apalutamide

* 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)

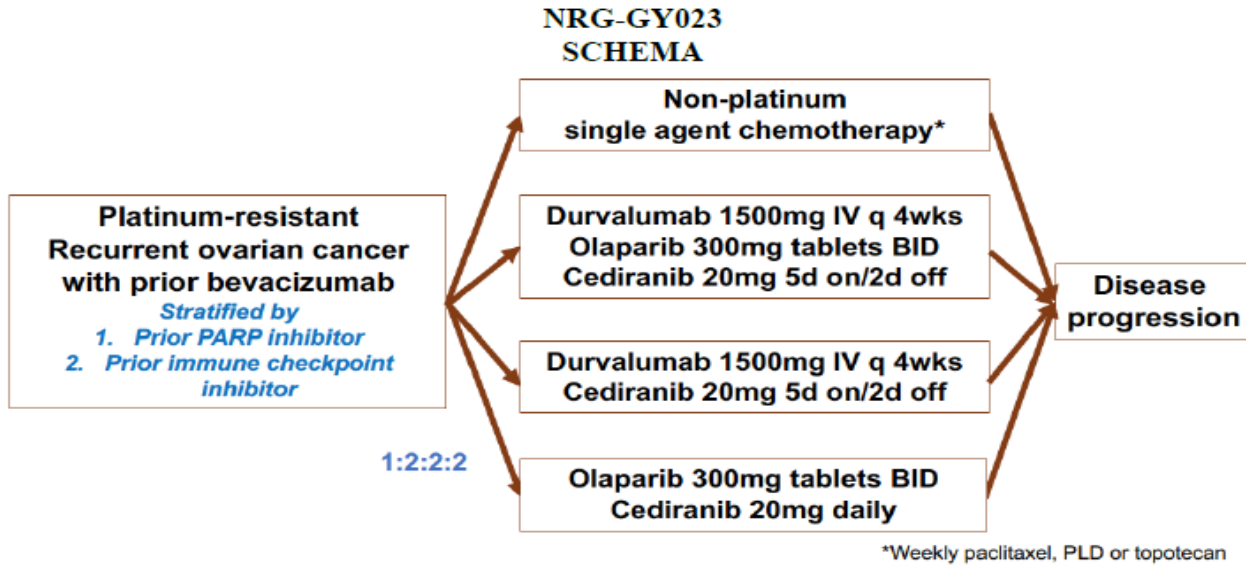
Step 2-RANDOMIZATION*

Arm 1**

Breast Radiation Therapy
+
Endocrine Therapy

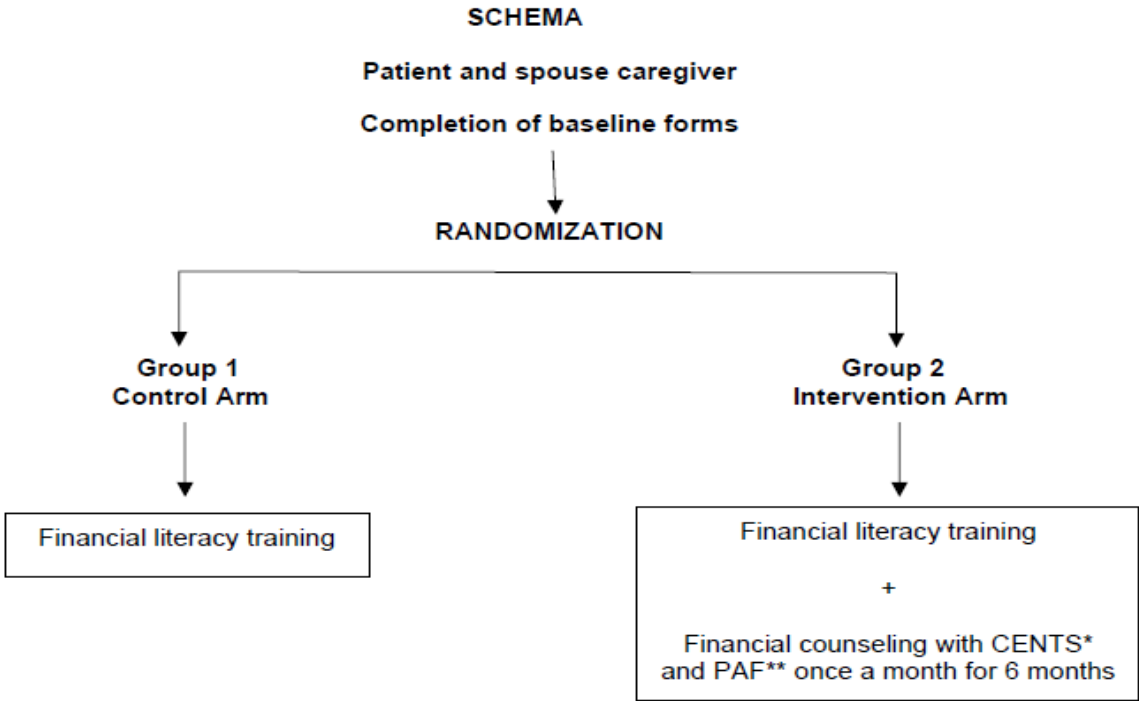
Arm 2**

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

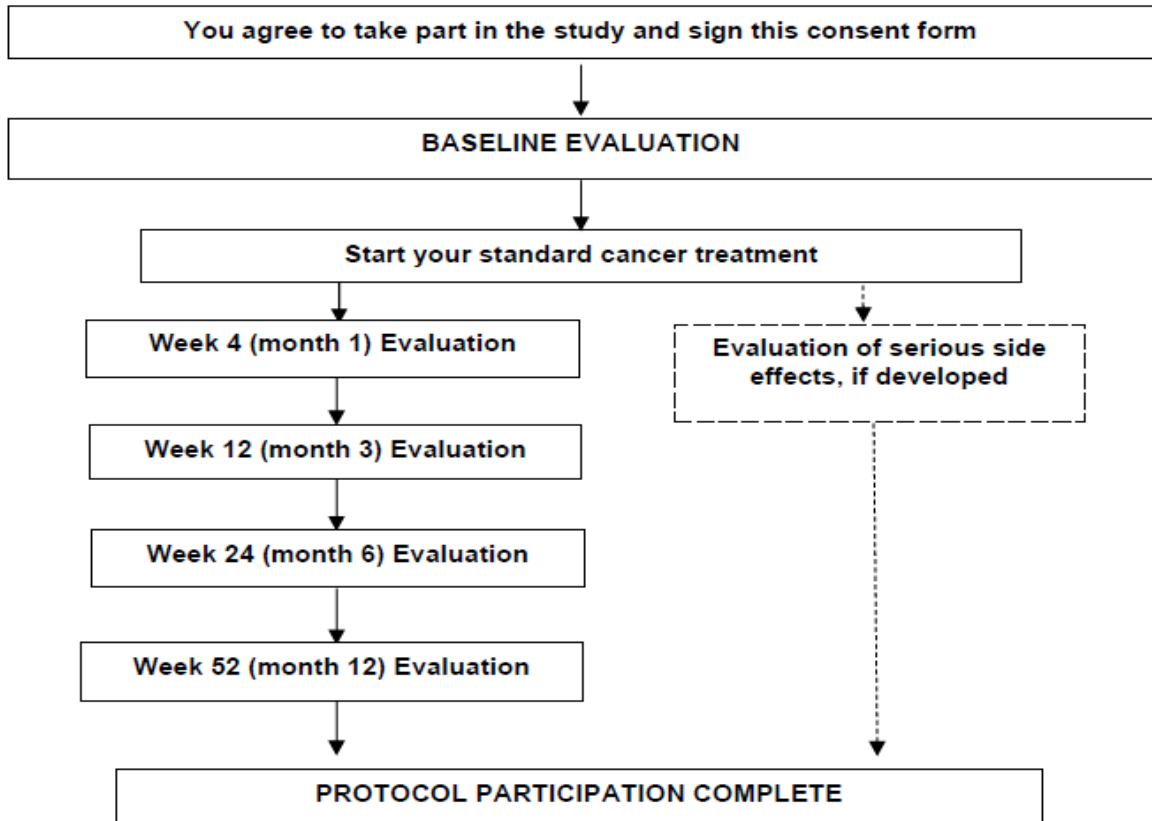


In order to participate, CCD Research sites must complete the **S1912CD** Site Implementation Survey and upload the completion certificate to the CTSU Regulatory Portal as described in [Section 13.4](#).

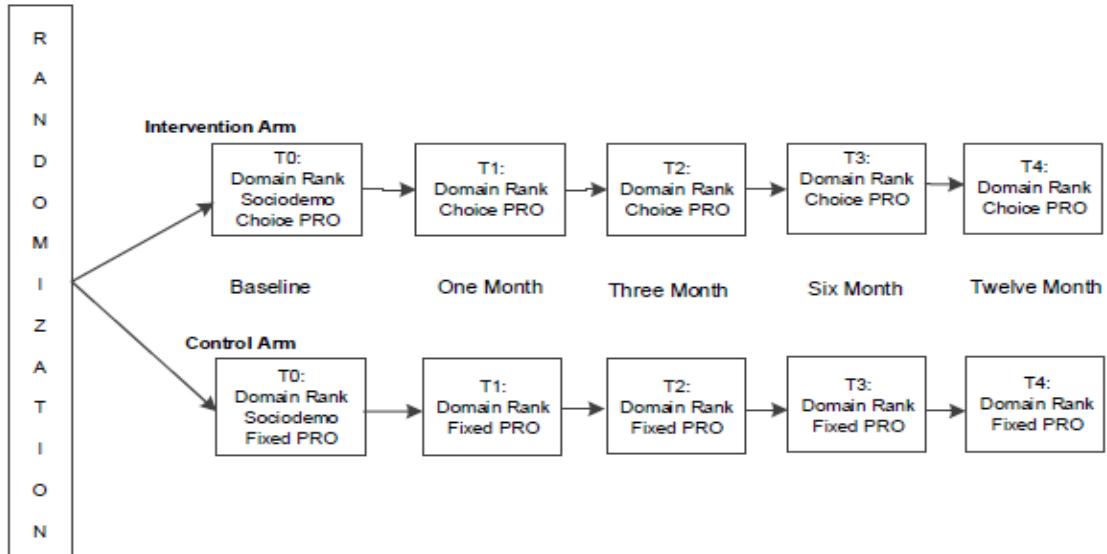
* Consumer Education and Training Services (CENTS)

** Patient Advocate Foundation (PAF)

SCHEMA



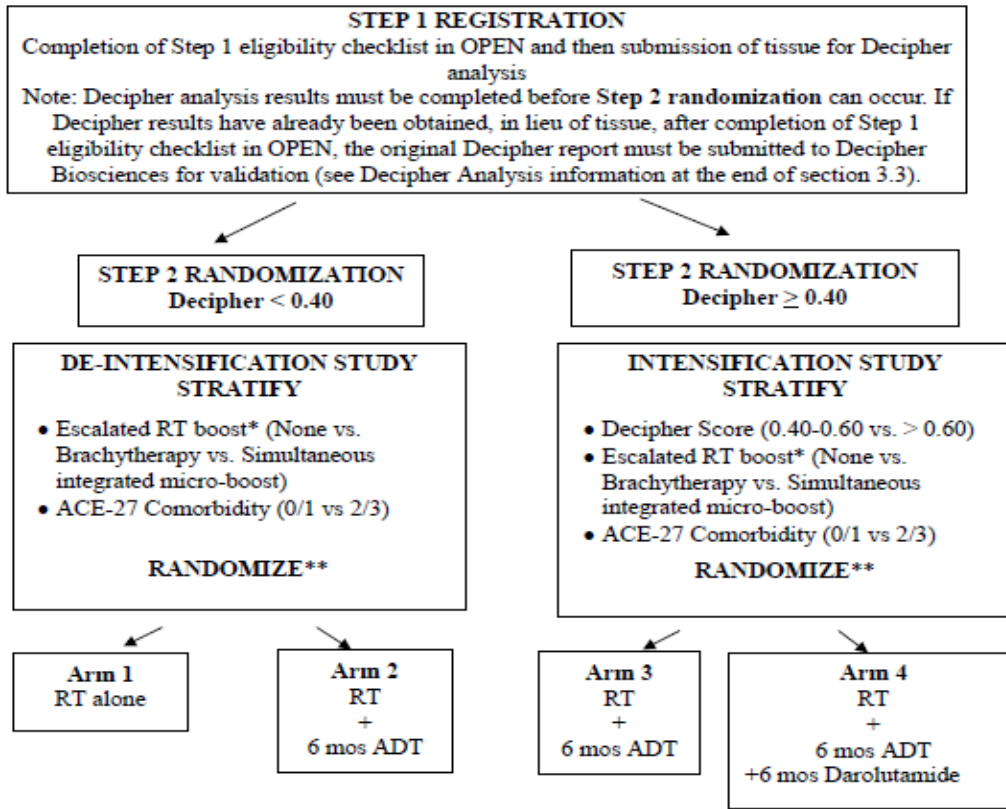
Schema



<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>
---	---	--

Accrual Goal = 400

SCHEMA

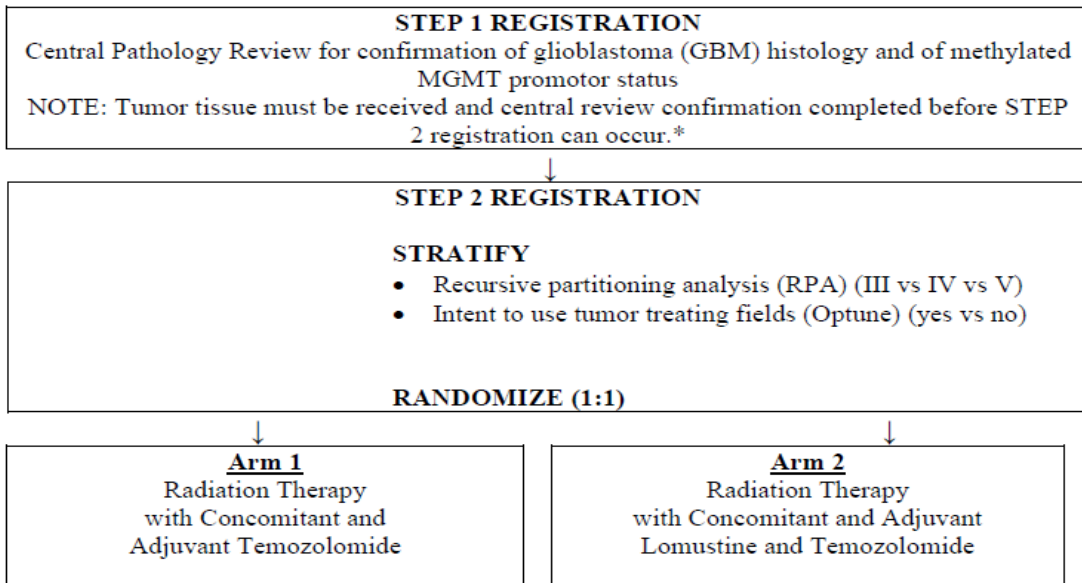


*For Escalated RT boost definition see Section 5.2 Establishing Treatment Approaches

**Randomization is 1:1

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

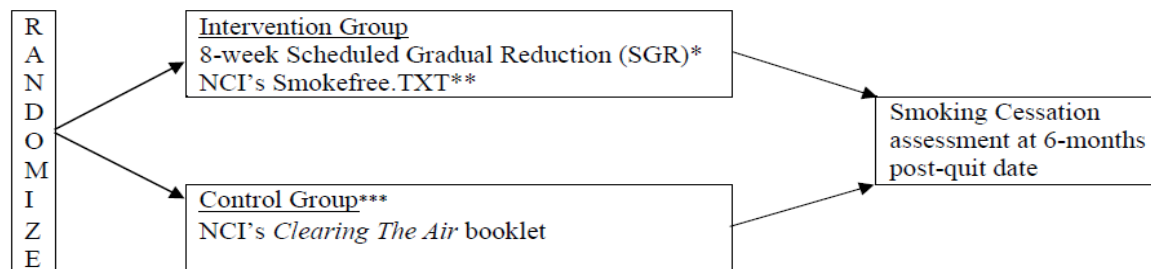
NRG-BN011
SCHEMA



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.

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.

**NSABP C-14
Navigator -Carrie x3621**

MENU

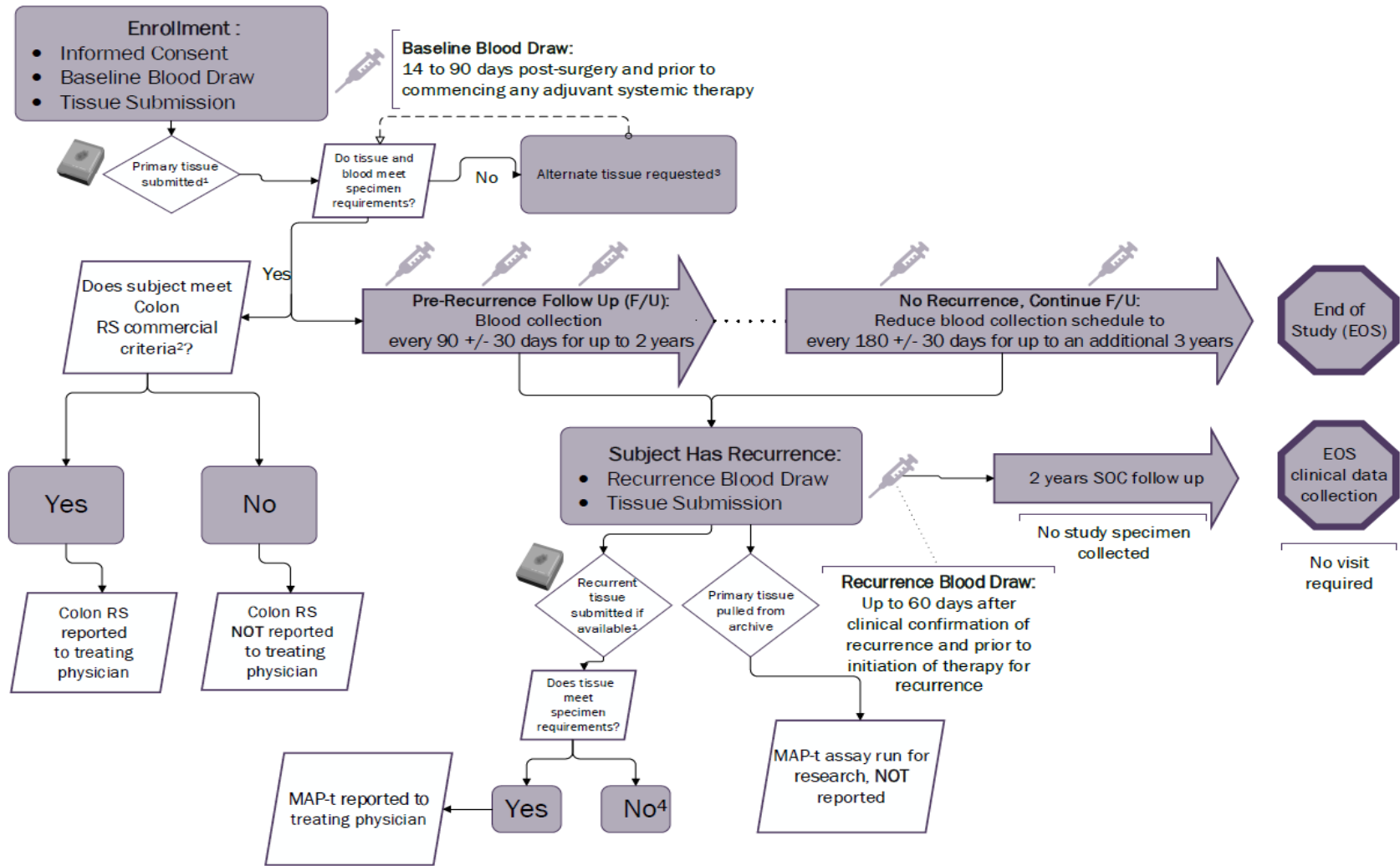
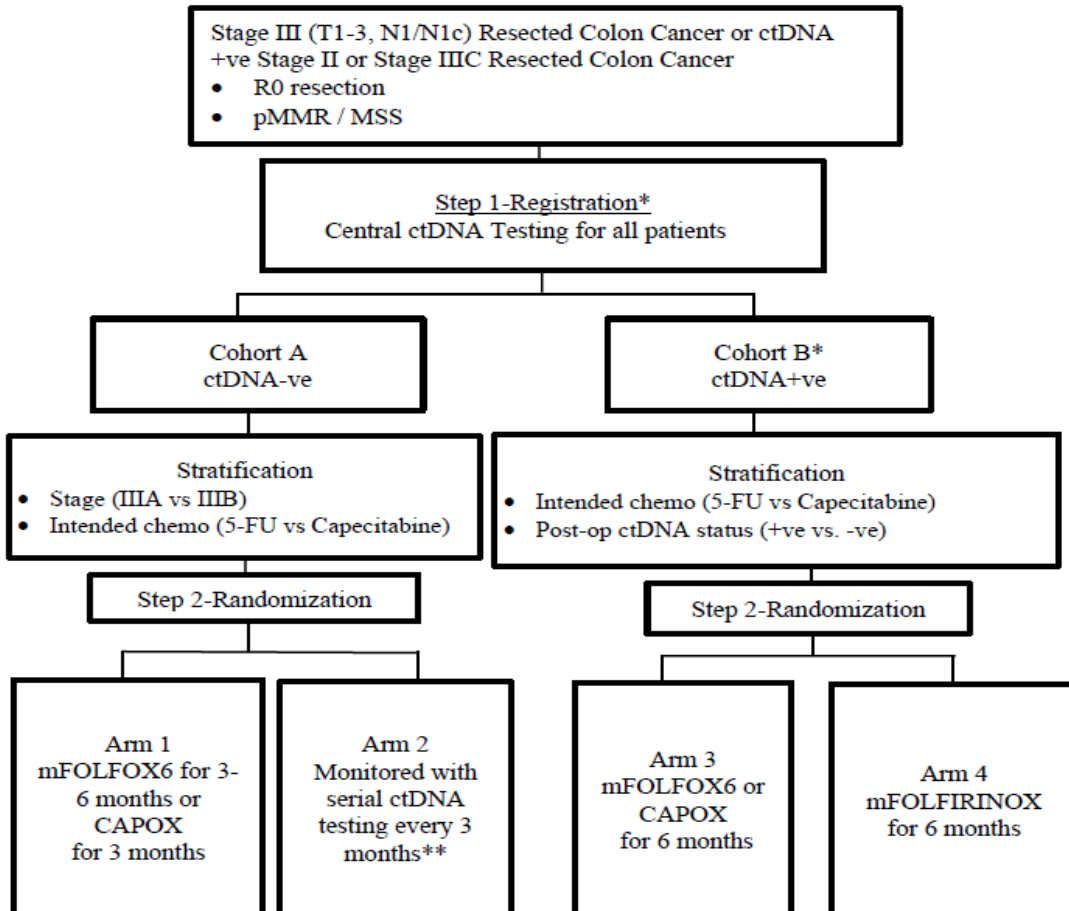


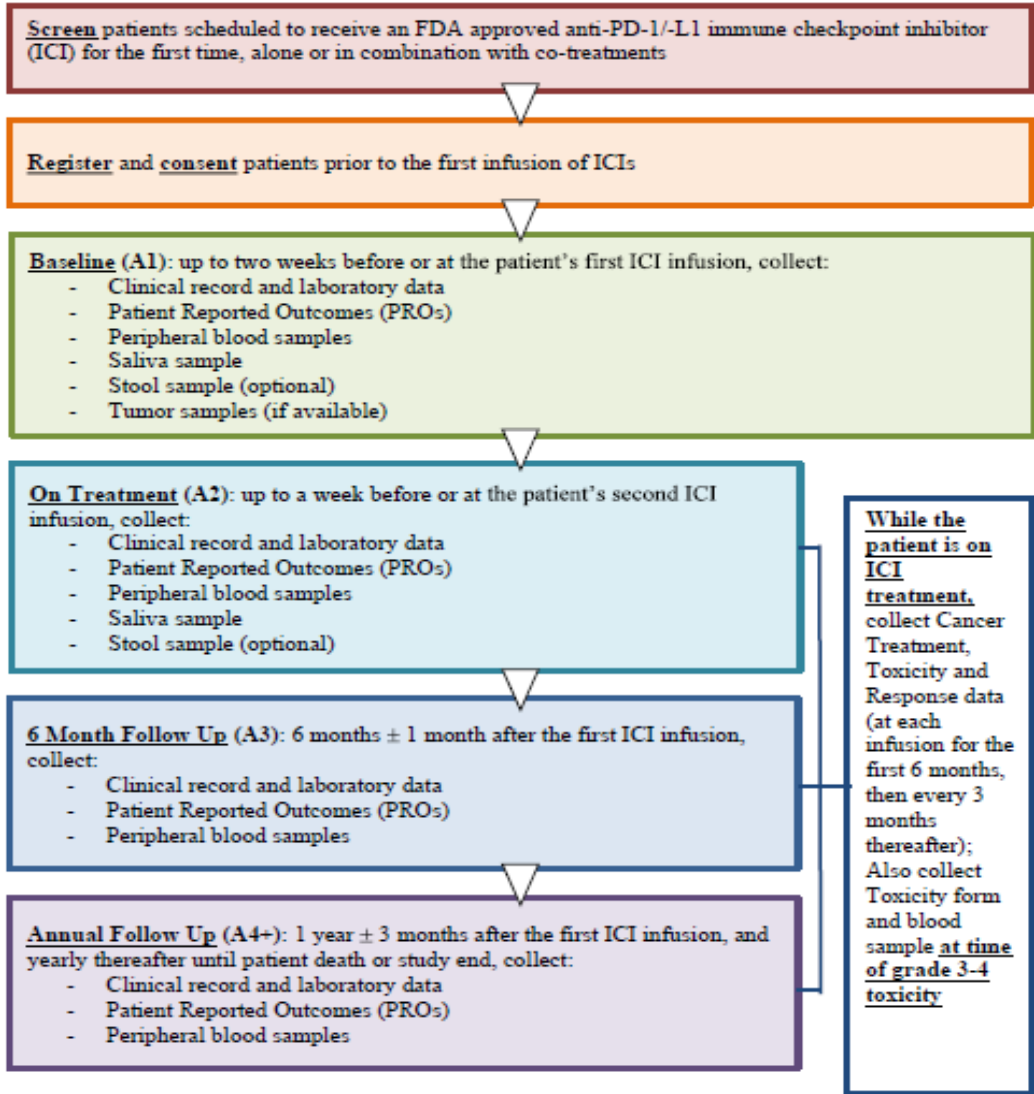
Figure 1.
NRG-GI008 SCHEMA



*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



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



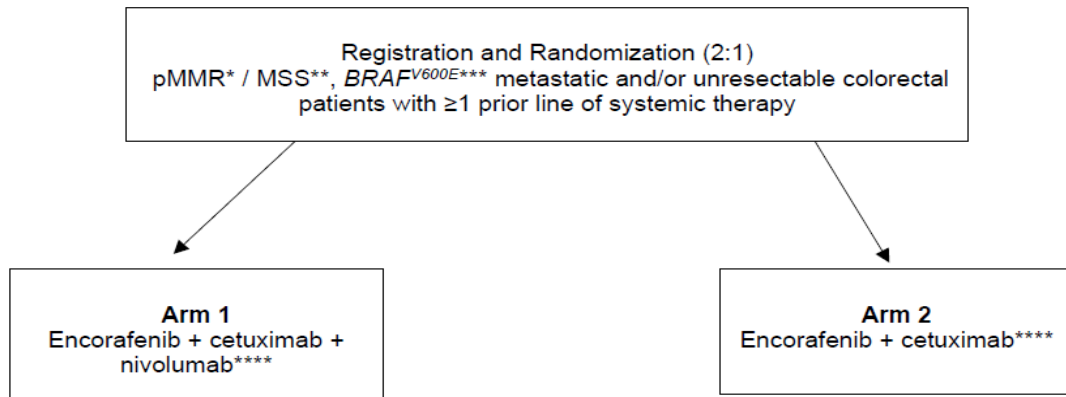
p16-positive OPC/CUP Cohort

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

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

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})

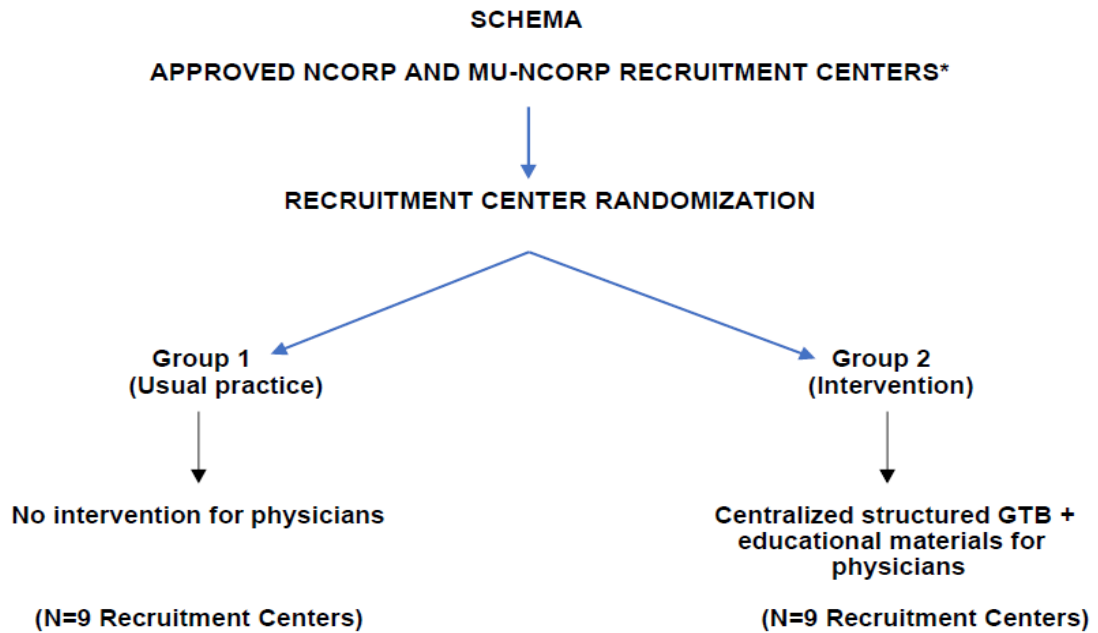
****Treatment continues until participant meets one of the criteria listed in [Section 7.7](#).

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.

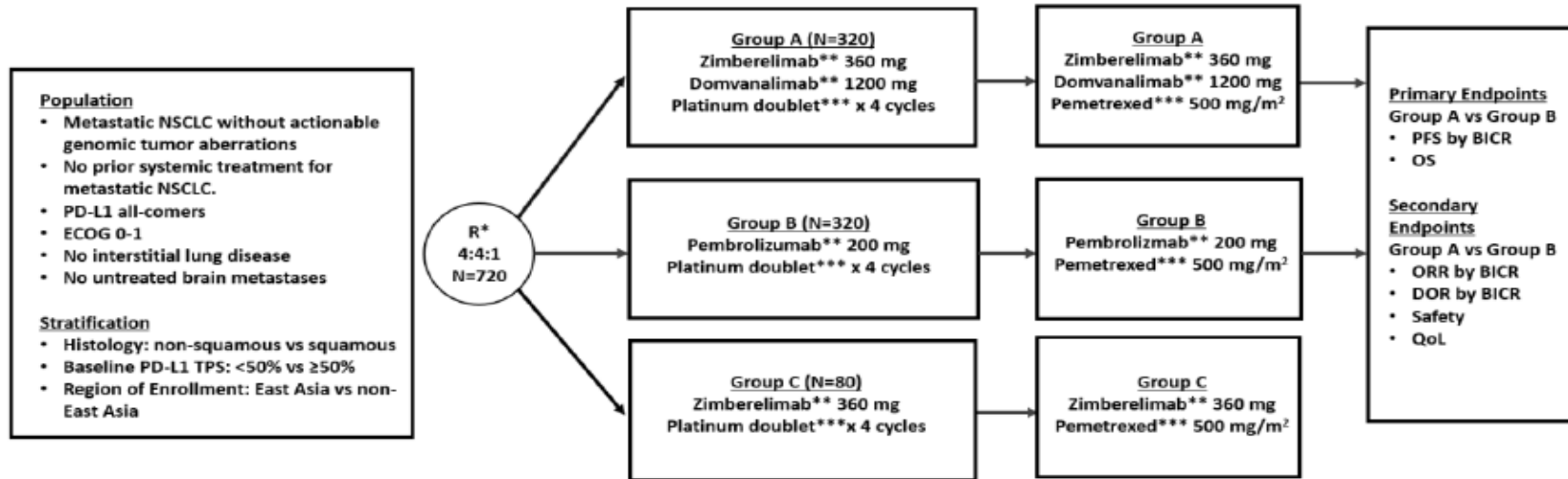
Treatment is to continue until disease progression, unacceptable toxicity, or withdrawal of consent. Patients will be followed for survival and progression every 3 weeks during Cycle 1-4 and every 4 weeks after Cycle 5 until progression, and then for survival every 3 months until 3 years after registration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



* A Recruitment Center is defined as an outpatient clinic, or group of clinics, belonging to the same NCORP or MU-NCORP, that will be contributing physician and patient participants to the study. Each clinic within the Recruitment Center must have a CTEP Site ID. All Recruitment Centers must have completed a S2108CD Recruitment Center Application and received approval for participation.

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

MENU

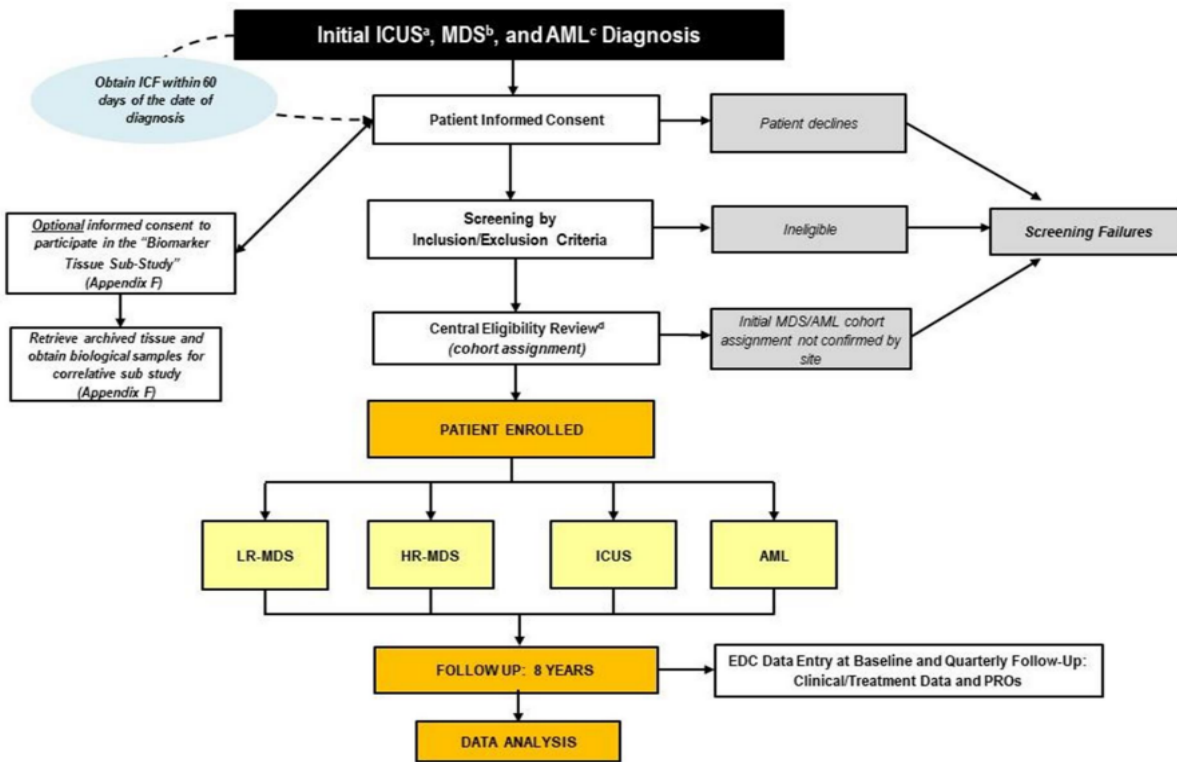


AUC = area under the curve; BICR = blinded independent central review; DOR = duration of response; ECOG = Eastern Cooperative Oncology Group; eDMC = external Data Monitoring Committee; NSCLC = non-small cell lung cancer; ORR = objective response rate; OS= overall survival; PD-L1 = programmed cell death 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.

Figure 2: Study Schema: Treated MF⁹ Cohort

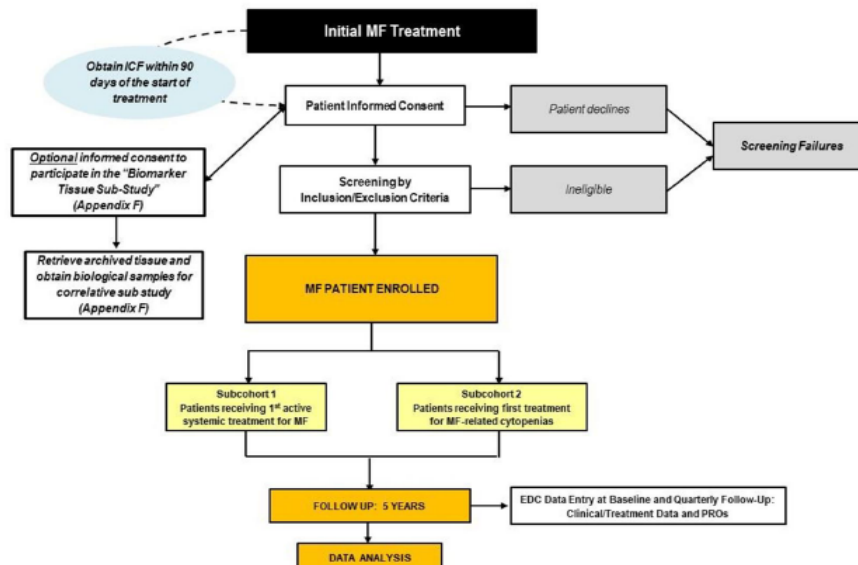
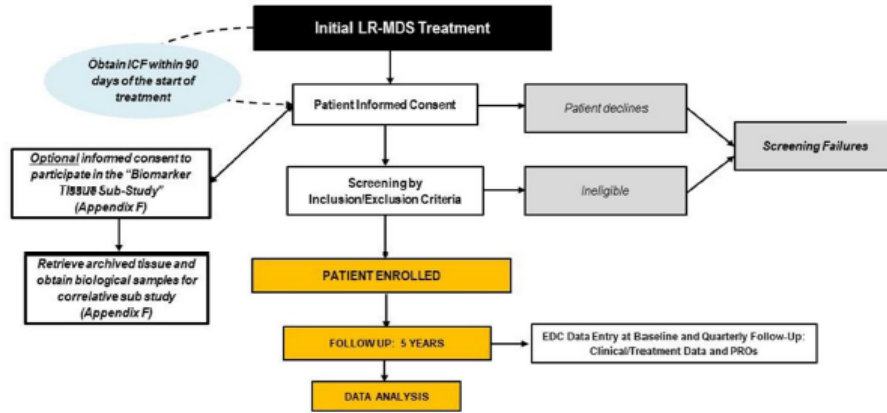
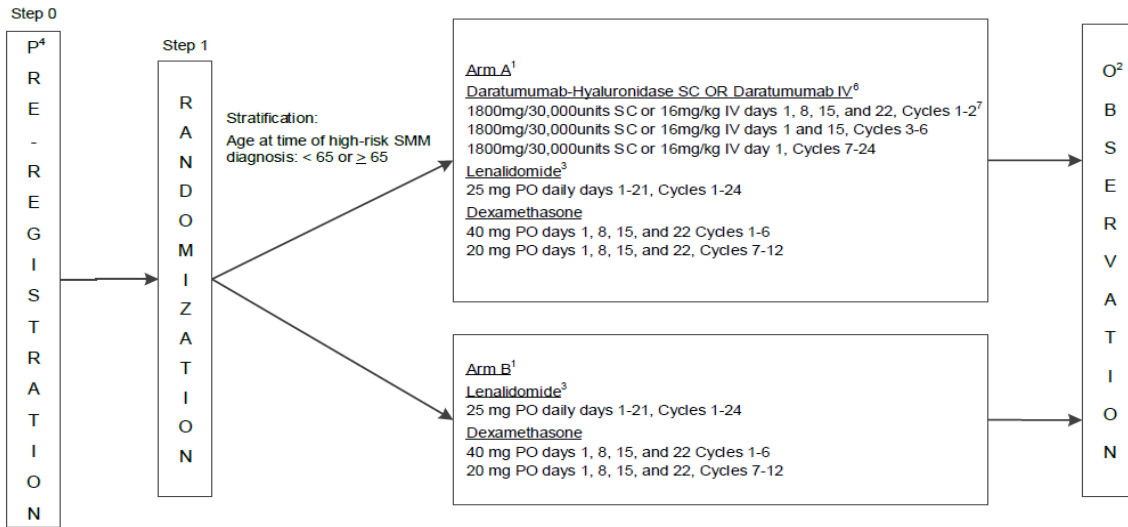


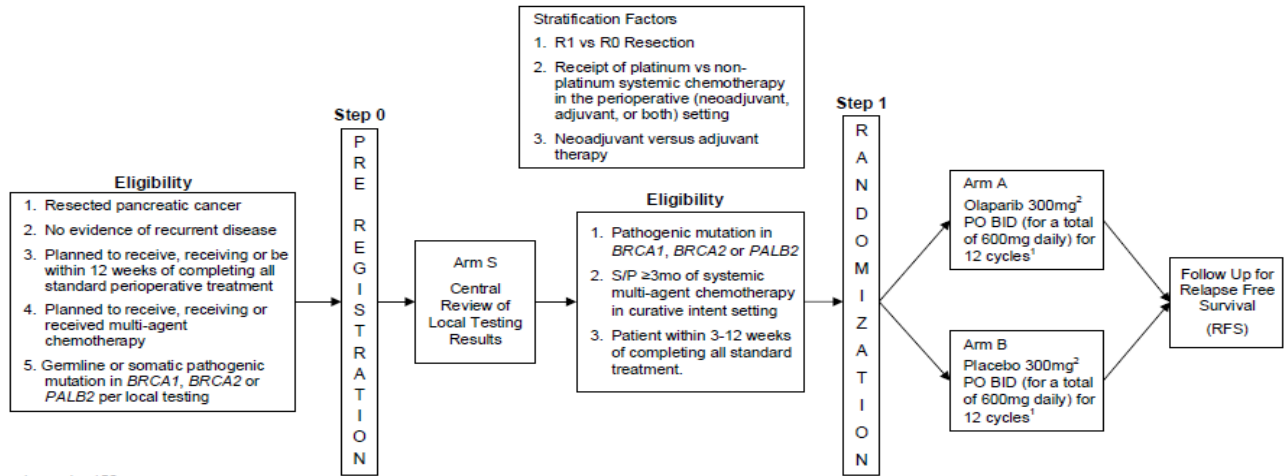
Figure 3: Study Schema: Treated LR-MDS Cohort





Accrual Goal: 288 patients with high-risk smoldering multiple myeloma.⁵
Cycle: 28 days

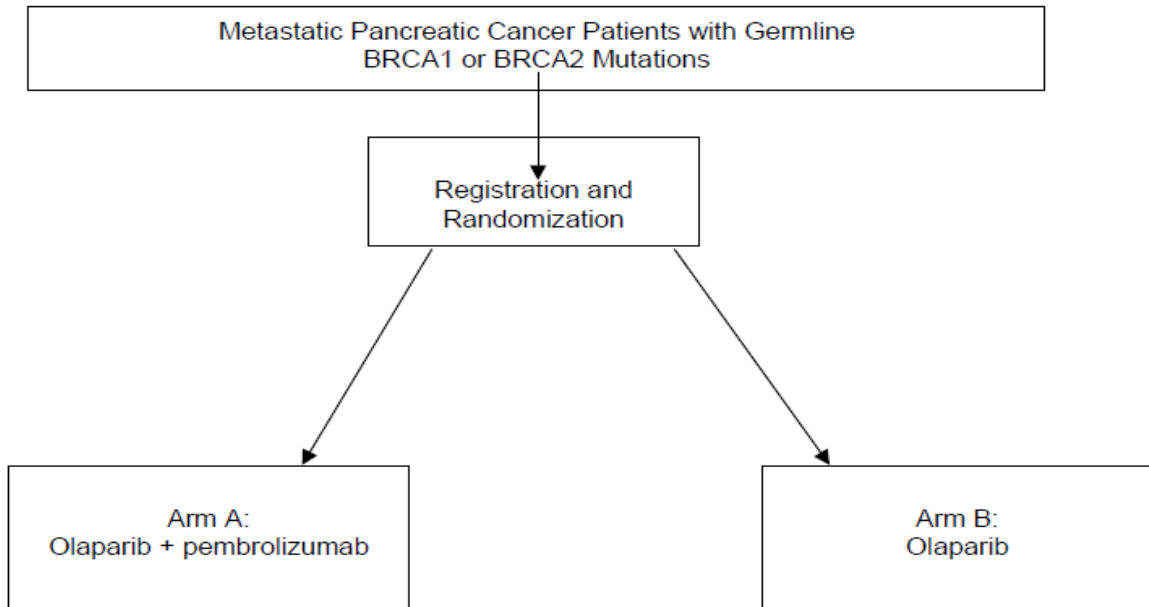
1. Peripheral blood stem cells for future transplants should be collected between cycles 4-6 of therapy. Therapy may be interrupted for up to 6 weeks to allow for PBSC collection. While collection following 4-6 weeks of therapy is strongly suggested, it is not required for protocol participation.
2. 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



¹ One cycle = 4 weeks

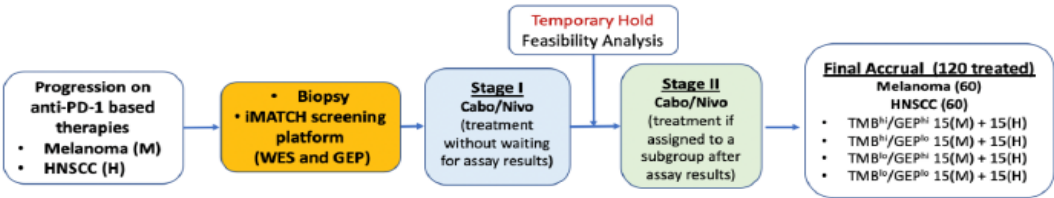
² Olaparib is supplied in either 100 mg or 150 mg tablets

NOTE: Please note that when a patient has been successfully randomized, the confirmation of randomization will indicate that the patient is on Arm X. The patient will actually be randomized to Arm A or B, but as this is a double-blind trial, that information cannot be displayed.



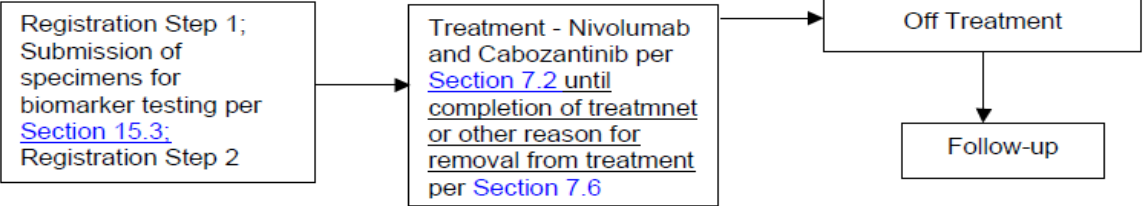
S2101
 Navigator - Carrie x3621
 Navigator - Ashton x3611

MENU

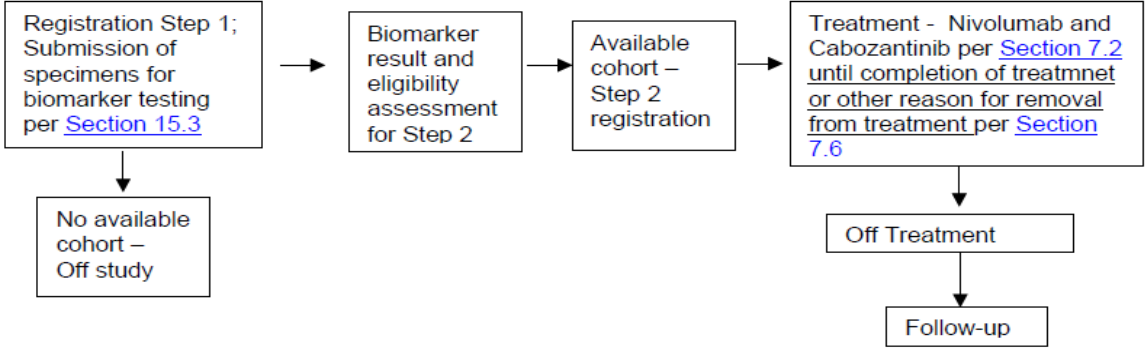


- TMB= tumor mutational burden; GEP = gene expression profiling for tumor inflammation score; WES = whole exome sequencing for tumor mutational burden
- Participants will be stratified into cohorts by disease type and biomarker status (TMB^{hi}/GEP^{hi}; TMB^{hi}/GEP^{lo}; TMB^{lo}/GEP^{hi}; TMB^{lo}/GEP^{lo})

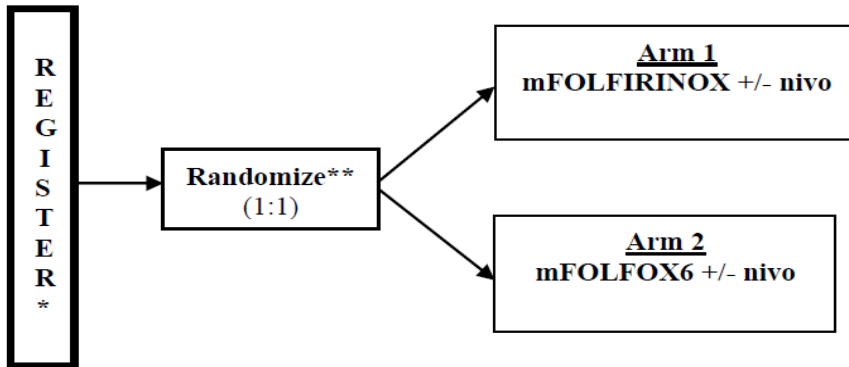
Stage I – Sites will order specimen kits per [Section 15.2](#) one week prior to registration. Sites will register participants to Step 1 registration. Sites must submit specimens for biomarker testing via the SWOG Specimen Tracking System within one day after Step 1 registration. Sites will register participants to Step 2 registration. Participants will begin treatment prior to availability of results. Participants will be assigned to their biomarker cohort retrospectively. Sites will be informed when the trial progresses to Stage II.



Stage II – Sites will order specimen kits per [Section 15.2](#) one week prior to registration. Sites will register participants to Step 1 registration. Sites will submit specimens for biomarker testing via the SWOG Specimen Tracking System within one day after Step 1 registration. Sites will receive the biomarker results and will register participants to Step 2 registration only if a slot in an available biomarker cohort is available. Sites will be informed when the trial progresses to Stage II.



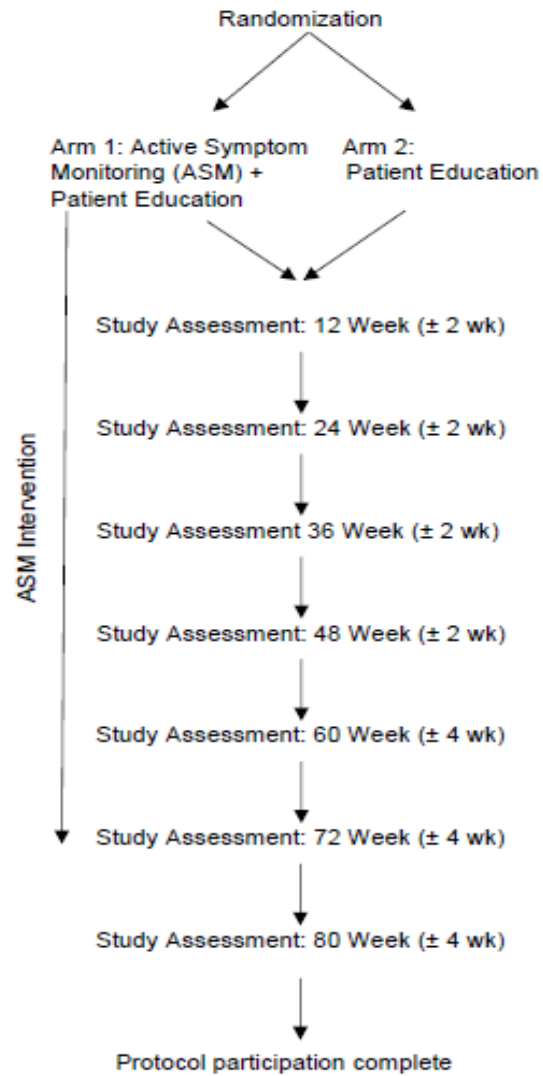
Schema



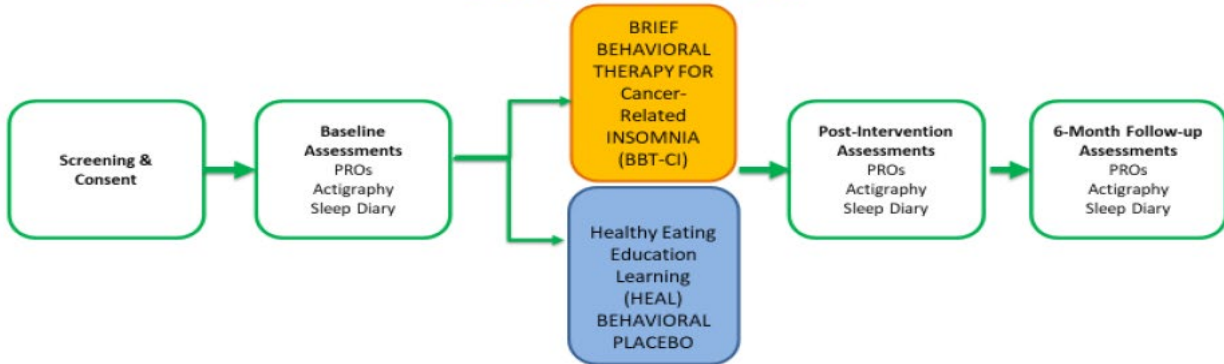
* Patients with newly diagnosed advanced unresectable or metastatic HER2 negative gastric, GEJ, esophageal adenocarcinoma

** Stratification: Tumor location (gastric vs GEJ vs esophagus); Measurable disease vs not; planned nivo use vs not; PD-L1 CPS ≥ 5 vs < 5 .

Patients will be treated using 14-day cycles until disease progression or discontinuation of treatment for other reasons (e.g. unacceptable adverse events, withdrawal, etc.); oxaliplatin will be given up to 12 cycles.



Study Schema



SCHEMA

Patients with Stage IV or recurrent non-small cell lung cancer



Randomization

Arm A

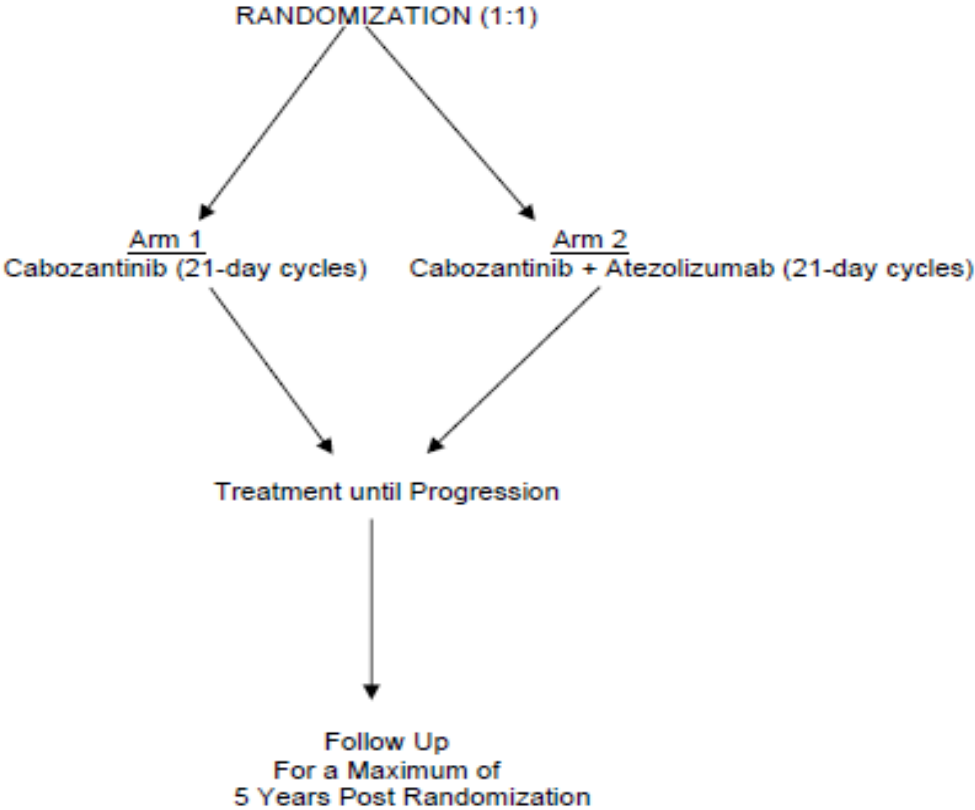
Arm B

Investigator's Choice
of Standard of Care ^A

Ramucirumab +
Pembrolizumab

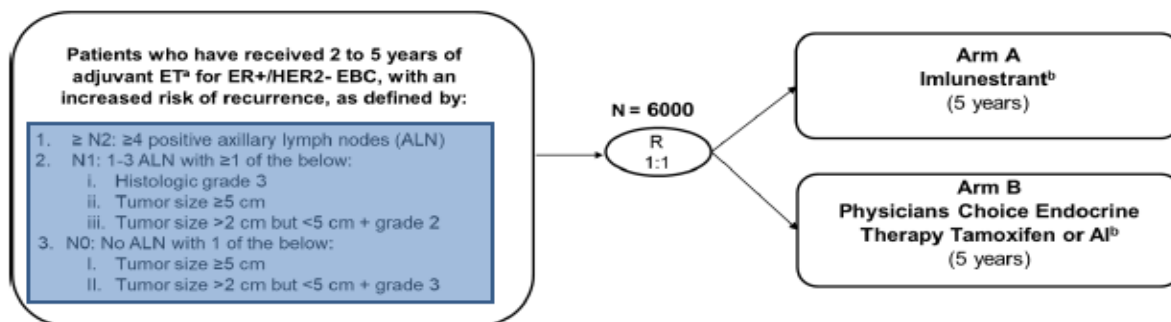
^A For guidance on Investigator's Choice of Standard of Care, see [Section 7.2](#).

Metastatic Type I or II Papillary
Renal Cell Carcinoma



EMBER-4
Navigator - Angie x3613

MENU

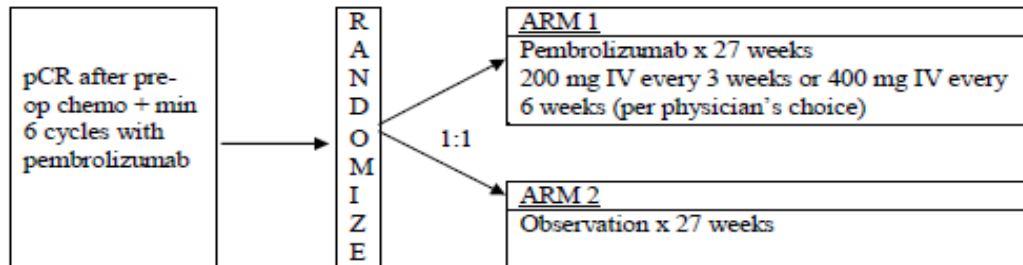


Abbreviations: AI = aromatase inhibitor; ALN = axillary lymph nodes; CDK4/6 = cyclin-dependent kinase 4/6; EBC = early breast cancer; ER = estrogen receptor; ET = endocrine therapy; GnRH = gonadotropin-releasing hormone; HER2- = human epidermal growth factor receptor 2 negative; R = randomization.

^a Prior adjuvant therapy with a CDK4/6 or PARP inhibitor is permitted.

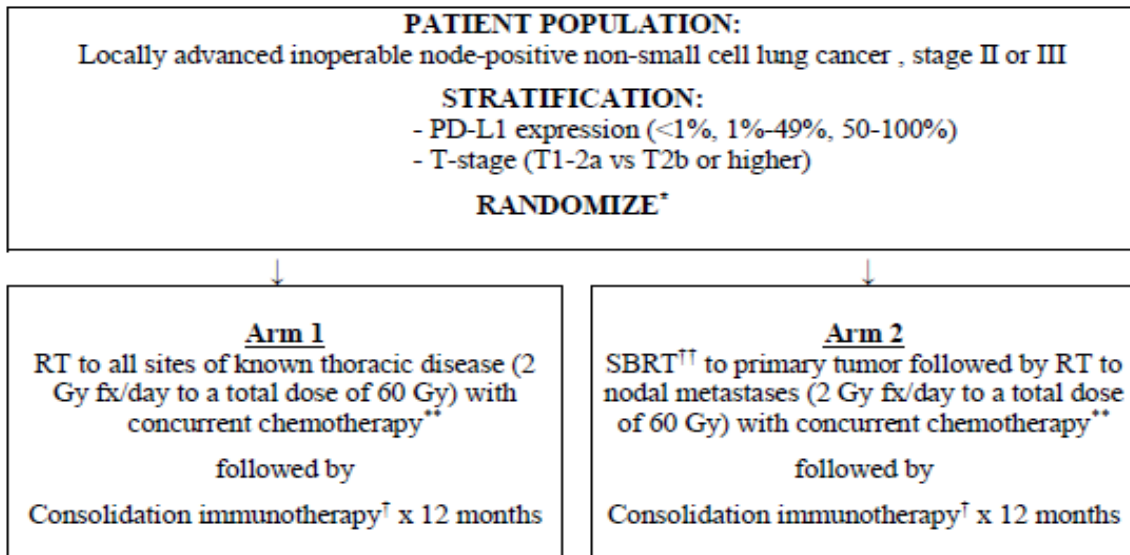
^b GnRH agonist is required in men and pre-/peri-menopausal women receiving imlunestran or AI and is given at the investigator's discretion in patients receiving tamoxifen, per standard practice.

Schema



Treatment or observation is to continue for 27 weeks or until unacceptable adverse event. Patients will be followed for 5 years after registration or recurrence. Thereafter, patients will be followed annually (+/- 3 months) for overall survival for a total of 10 years after registration.

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



*Randomization is 1:1.

**Chemotherapy is given concurrently with radiotherapy (RT). See Section 5.1.1 for details.

††See Section 5.1 for allowable stereotactic body radiation therapy (SBRT) fractionation.

†Consolidation immunotherapy for up to 12 months or alternative consolidation regimens may be given per the treating physician. See Section 5.1.2 for details.

- Oropharyngeal squamous cell carcinoma, p16-positive
- ≤ 10 pack-year history of smoking
- 8th ed. clinical stages T1-2N1M0 or T3N0-N1M0 (8th ed. stage I-II excluding T0, T1-2N0, or any N2)



STRATIFICATION
Zubrod Performance Status: 0 vs.1

RANDOMIZE*



Arm 1**

70 Gy radiation in 6 weeks using 6
fractions per week
+
Cisplatin



Arm 3**

60 Gy radiation in 5 weeks using 6 fractions
per week + Nivolumab

*Randomization is 1:1

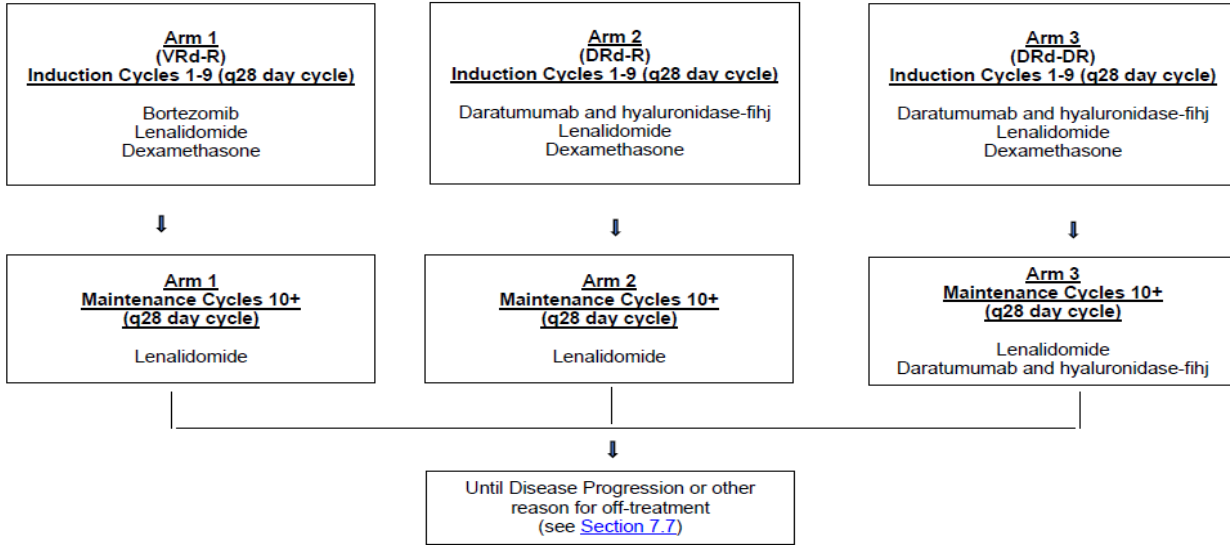
**See Section 5 for radiation and systemic therapy treatment details.

Note: Arm 2 (see prior schema) eliminated after phase II interim futility analysis.

SCHEMA

Frail or Selected Intermediate Fit Newly Diagnosed Multiple Myeloma
Participants

RANDOMIZATION



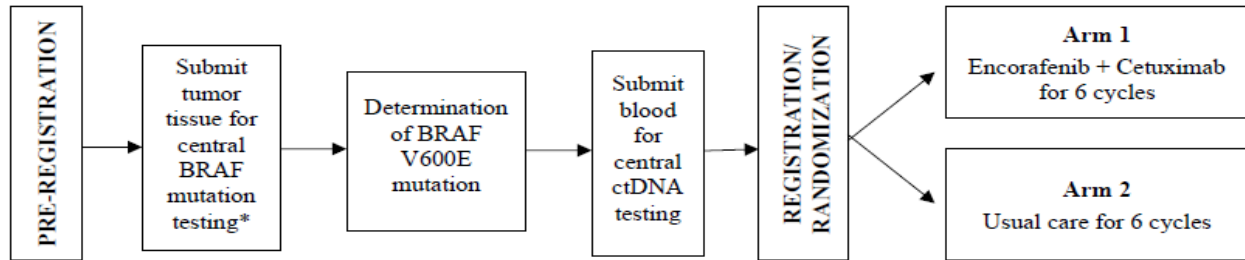
Schema



N = 40

1. Repeat cycles until disease progression or unacceptable toxicity.
2. Restaging scans will be performed every 2 cycles.
3. Whole exome sequencing and RNAseq (on tissue) will be performed at baseline and at disease progression. Germline Whole Exome analysis (in blood) will be performed at baseline. Longitudinal ctDNA monitoring will be performed at baseline, Cycle 2 Day 1, and at progression. See Section [7.2](#) and Section [10](#) for more information.
4. 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 3 years from the date of registration.

Schema
1 Cycle = 28 Days



SCHEMA

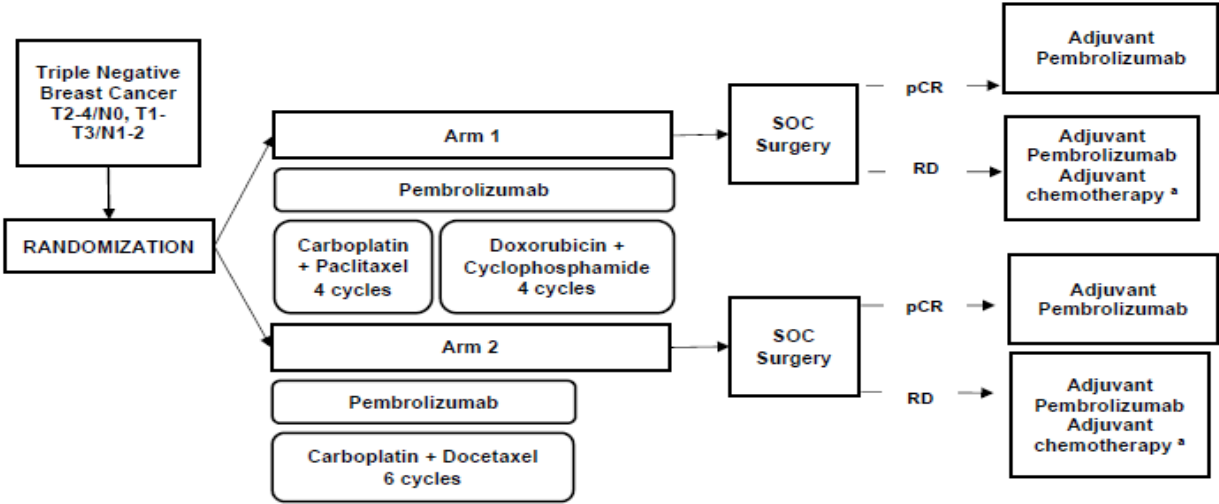
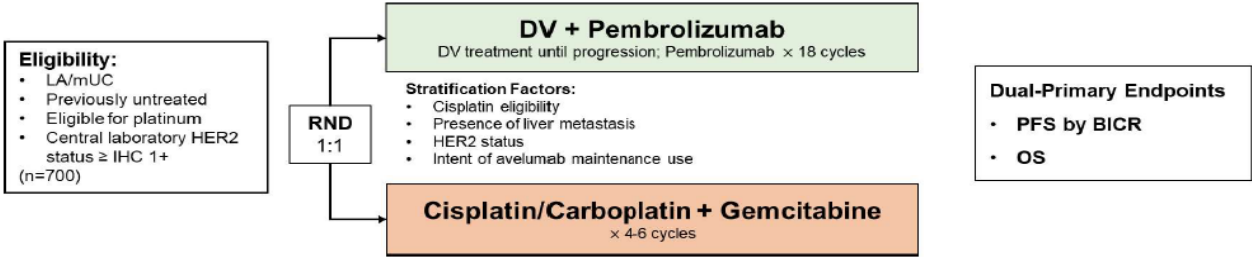
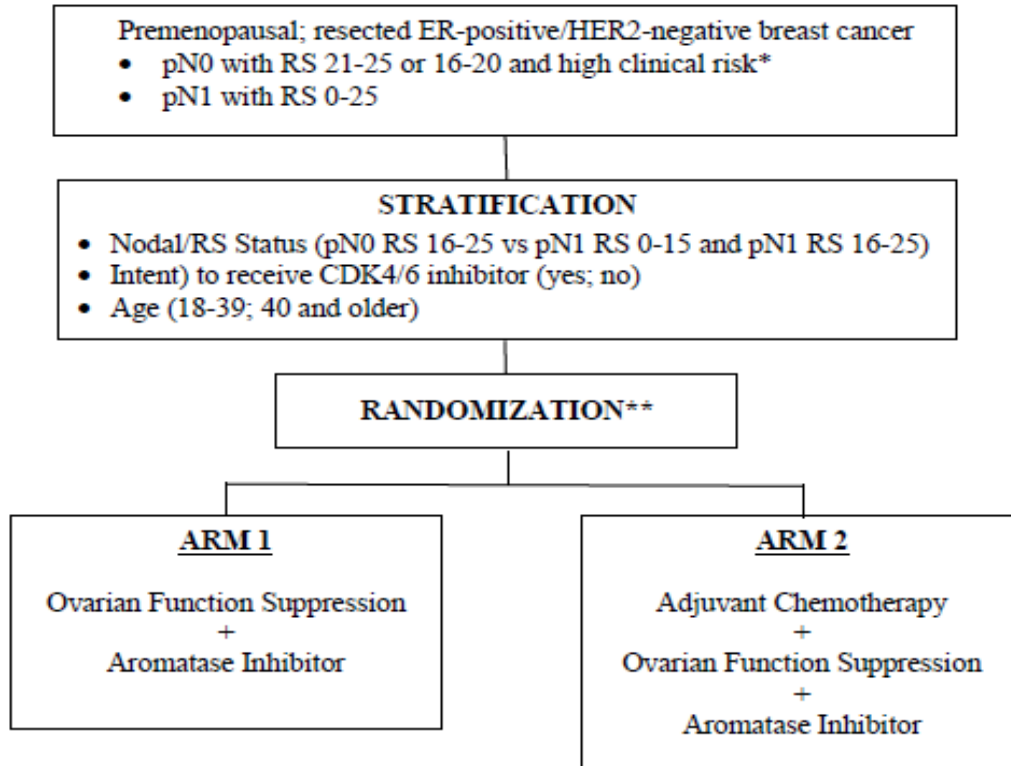


Figure 1: Study Schema



BICR=blinded independent central review; DV=disitamab vedotin; HER2=human epidermal growth factor receptor 2; IHC=immunohistochemistry; LA/mUC=locally advanced unresectable or metastatic urothelial carcinoma; OS=overall survival; PFS=progression-free survival; RND=randomization.

Figure 1. NRG-BR009 Schema



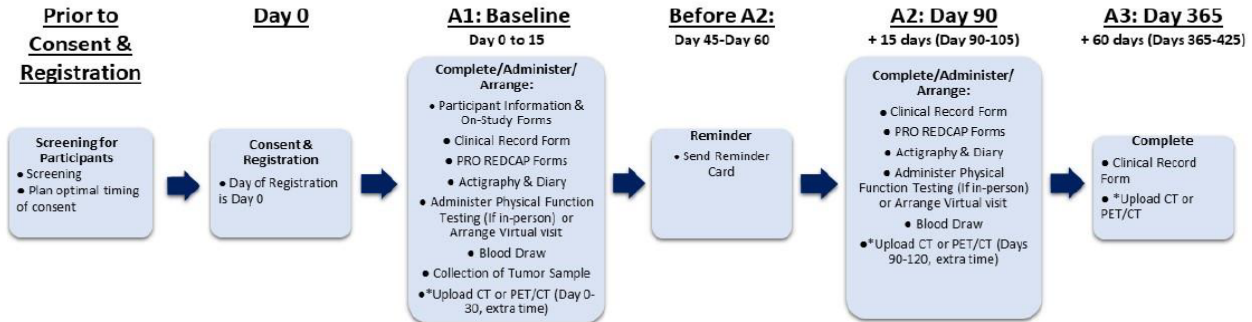
* **High clinical risk defined as:**

- 1) low histologic grade with primary tumor size > 3 cm, OR
- 2) intermediate histologic grade with primary tumor size > 2 cm, OR
- 3) high histologic grade with primary tumor size > 1 cm

** Randomization is 1:1.



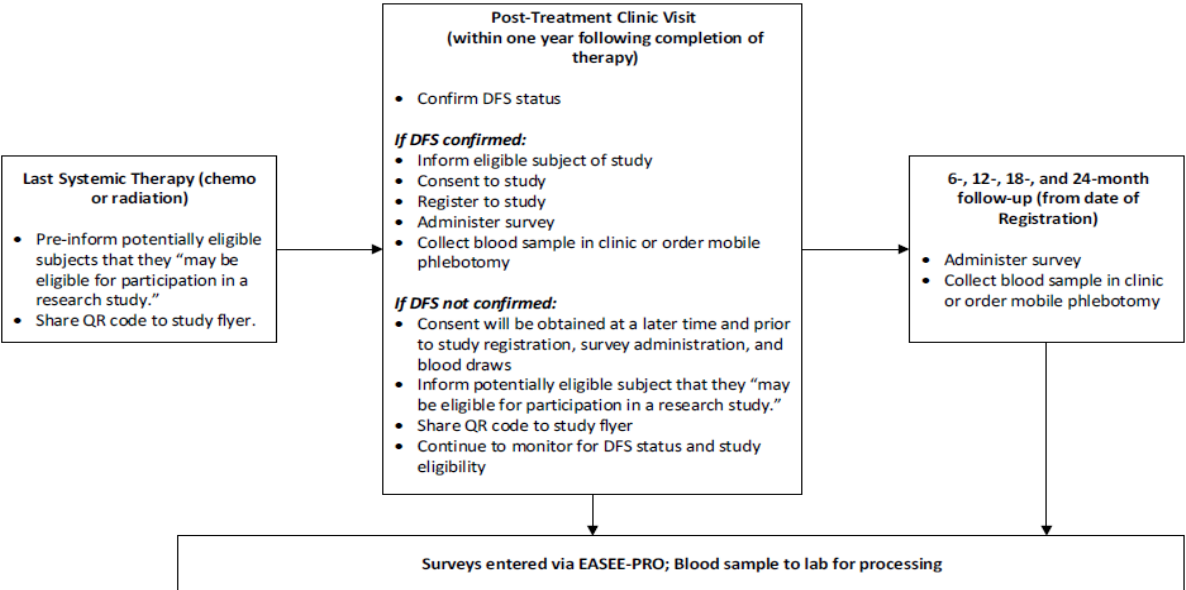
TIMELINE OF STUDY STAFF ACTIVITIES



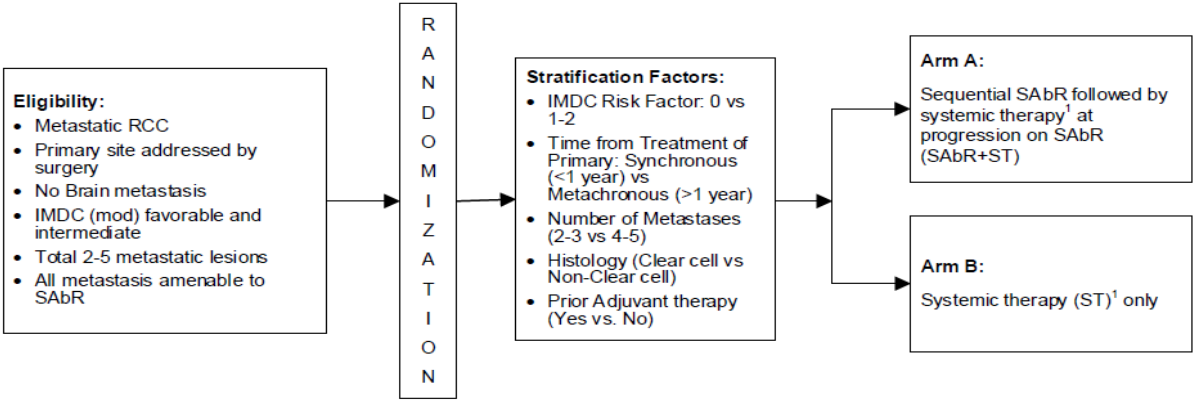
Abbreviations: PROs- Patient-reported outcomes; CT- Computed Tomography; PET- Positron Emission Tomography

*Study uses standard-of-care scans. Extra time allocated for imaging upload during A1 and A2; Wider A3 window allows ample time for imaging upload.

Schema



Schema

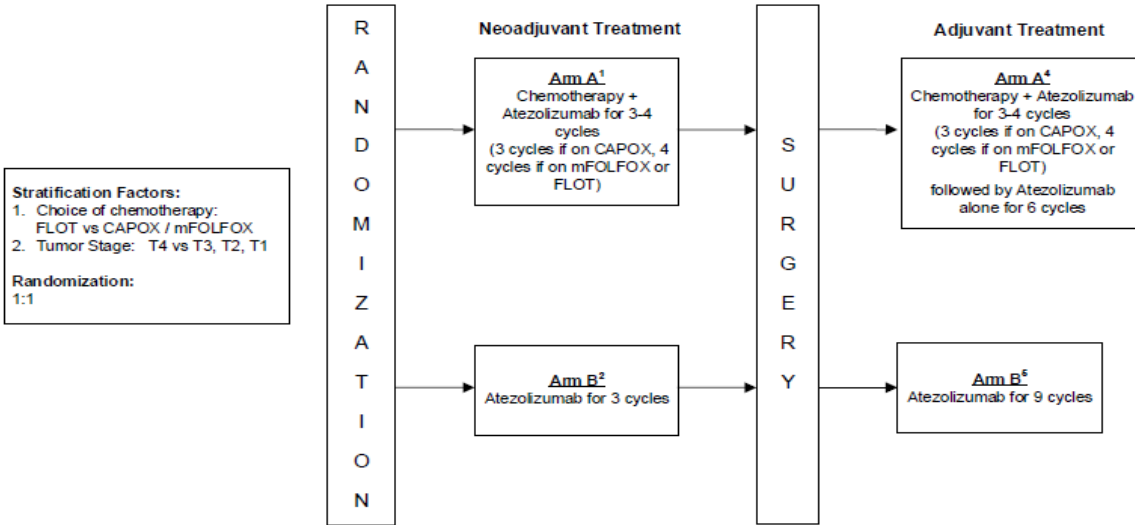


Accrual Goal = 472

Cycle Length = assessments will be done every 3 months

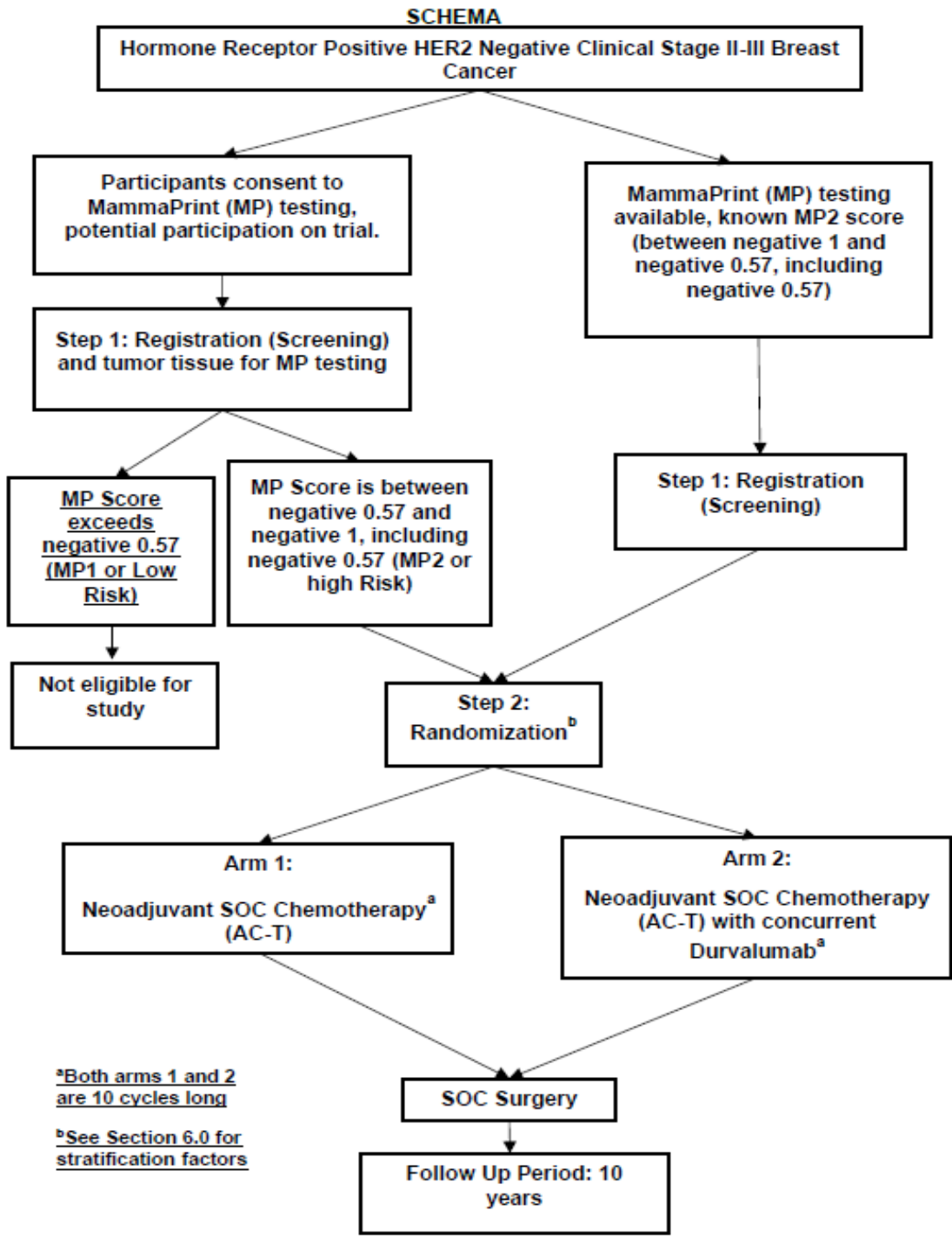
1. Systemic therapy will consist of standard FDA approved first line systemic therapy for renal cell carcinoma, as per NCCN guidelines and with the options outlined in Section 5.1.2. The selection of the systemic therapy regimen used is at the discretion of the treating physician and in agreement with the patient. Once the regimen has been declared and started, patients may not switch to another regimen option.

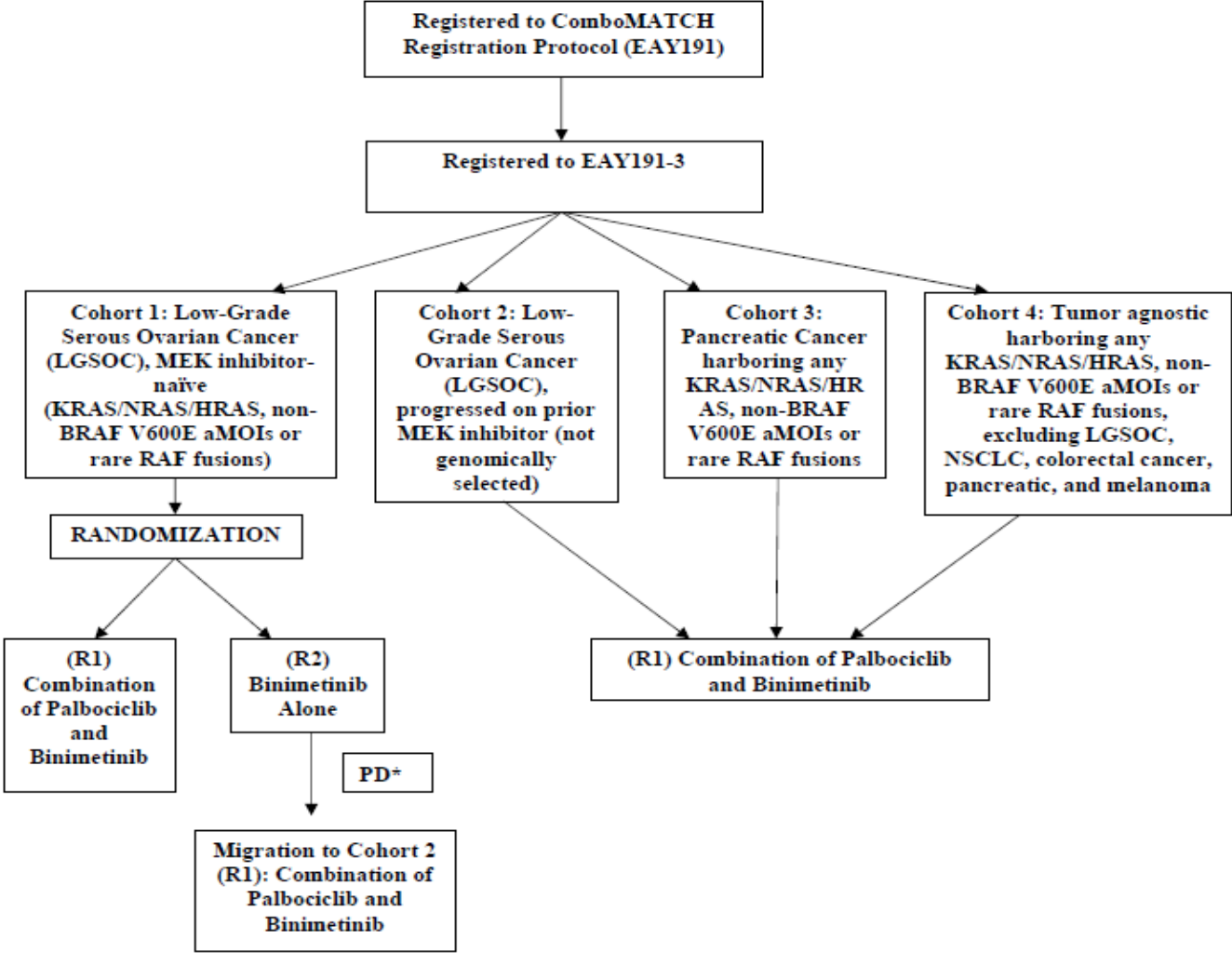
Schema



N = 240

1. Arm A Neoadjuvant: Prior to randomization, the treatment physician must select one of the following chemotherapy regimens outlined below (see Section 5.2 for detailed administration guidelines).
 Arm A Option 1 FLOT: Day 1 Docetaxel 50 mg/m² IV, Oxaliplatin 85 mg/m² IV, Leucovorin 200 mg/m² IV, Fluorouracil (5-FU) 2600 mg/m² IV continuous infusion over 24 hours, Atezolizumab 840mg mg IV. Repeat cycle every 14 days for 4 cycles.
 Arm A Option 2 mFOLFOX: Day 1 Oxaliplatin 85 mg/m² IV, Leucovorin 400 mg/m² IV, Fluorouracil (5-FU) bolus of 400 mg/m² followed by Fluorouracil (5-FU) 2400 mg/m² IV continuous infusion over 46 hours, Atezolizumab 840mg mg IV. Repeat cycle every 14 days for 4 cycles.
 Arm A Option 3 CAPOX: Day 1 Oxaliplatin 130 mg/m² IV infusion and Atezolizumab 1200mg IV; Capecitabine 1000 mg/m² twice a day by mouth on Days 1-14 of each cycle. Repeat cycle every 21 days for 3 cycles.
2. Arm B Neoadjuvant: Day 1 Atezolizumab 1200 mg IV. Repeat cycle every 21 days for 3 cycles.
3. Surgery: Refer to Section 5.2.4 for details for those patients that do not go on to surgery
4. Arm A Adjuvant: The same regimen used in the neoadjuvant setting will be used in the adjuvant setting. Repeat cycle every 14 days for 4 cycles for FLOT +Atezolizumab or mFOLFOX + Atezolizumab and repeat cycle every 21 days for 3 cycles for CAPOX + Atezolizumab. After adjuvant Chemotherapy + Atezolizumab is complete, patient will receive Atezolizumab 1200mg mg IV alone for 6 cycles.
5. Arm B Adjuvant: Day 1 Atezolizumab 1200 mg IV. Repeat cycle every 21 days for 9 cycles.





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

*If patients that had been randomized to Cohort 1 Regimen 2, Binimetinib alone are interested in being migrated to Cohort 2, Combination of Palbociclib and Binimetinib upon documentation of disease progression, they will be eligible to migrate to Cohort 2, Combination of Palbociclib and Binimetinib.

NRG-GU013
SCHEMA

Pathologically (histologically or cytologically) proven diagnosis of adenocarcinoma of prostate cancer



STRATIFY

- Treating pelvic lymph nodes (yes vs. no)
- Length of ADT (< 18 months vs. ≥ 18 months)
- 2nd generation anti-androgen (yes vs. no)
 - Microboost (yes vs. no)

RANDOMIZE*



Arm 1

SBRT (ultrahypofractionation)
5 fractions



Arm 2

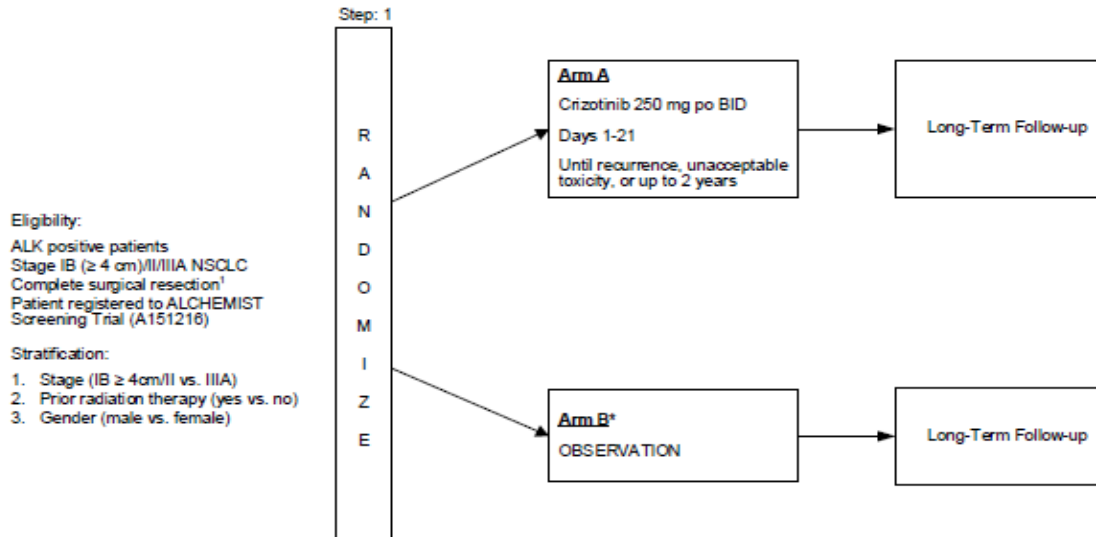
Conventional or moderate hypofractionation
20-45 fractions

*Randomization is 1:1

**E4512 (Alchemist Substudy)
Navigator - Ashton x3611**

MENU

Schema



Accrual Goal: 168 patients
Cycle= 3 weeks (21 days)

1. Patients must have completed any prior surgery 4 or more weeks prior to randomization and be adequately recovered at time of randomization. Maximum time between surgery and randomization is 4 months if no adjuvant chemotherapy was administered, 9 months if adjuvant chemotherapy was administered, and 11 months if adjuvant chemotherapy and radiation therapy were administered.

*Prior to activation of Addendum 8, Arm B patients were receiving placebo

*Patients enrolled on previous addendums will have been enrolled based on AJCC v7 and patients enrolled after amendment #12 and on will be based on AJCC v8

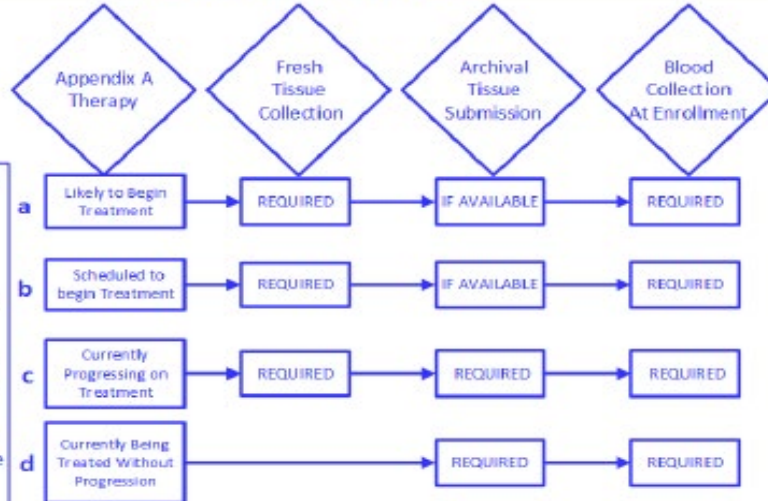
Scenarios for Enrollment into the Cancer Moonshot Biobank

Refer to Protocol Section 4.1

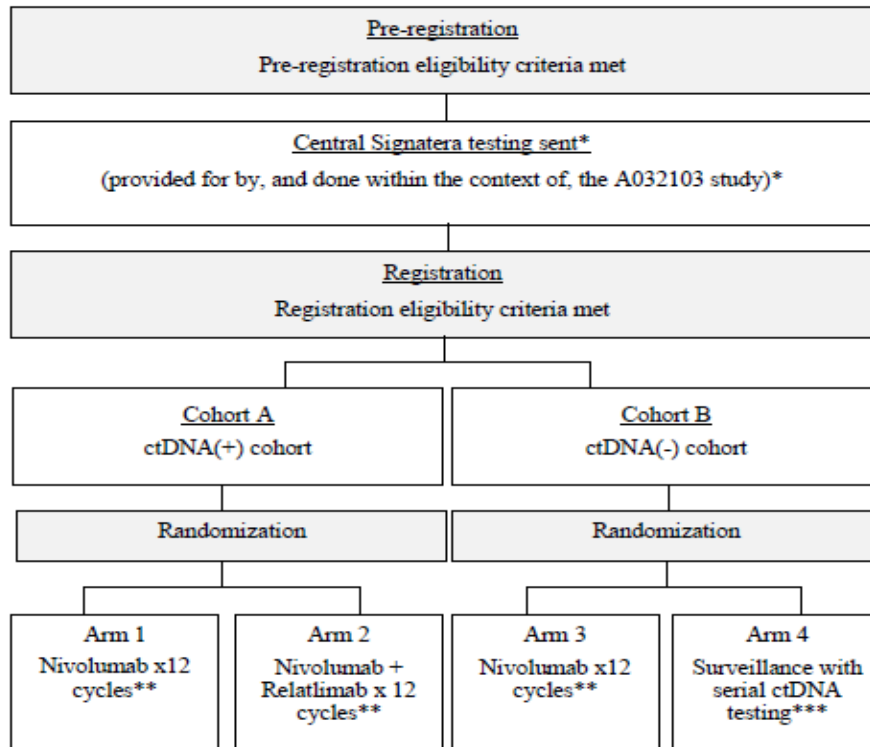
Cancer Type and Stage

Patient has clinical presentation consistent with OR has been diagnosed with a listed cancer:

- Colorectal cancer: Stage IV
- Non-small cell or small cell lung cancer: Stage III/IV
- Prostate cancer: metastatic castration-resistant prostate cancer
- Gastroesophageal cancer: Stage IV
- Melanoma: Clinical Stage IV with Pathologic Stage III OR Clinical Stage IV
- Acute myeloid leukemia
- Multiple myeloma



* Appendix A therapies may be given as a singular/monotherapy or in combination with any other therapies that constitute an FDA-approved treatment regimen.

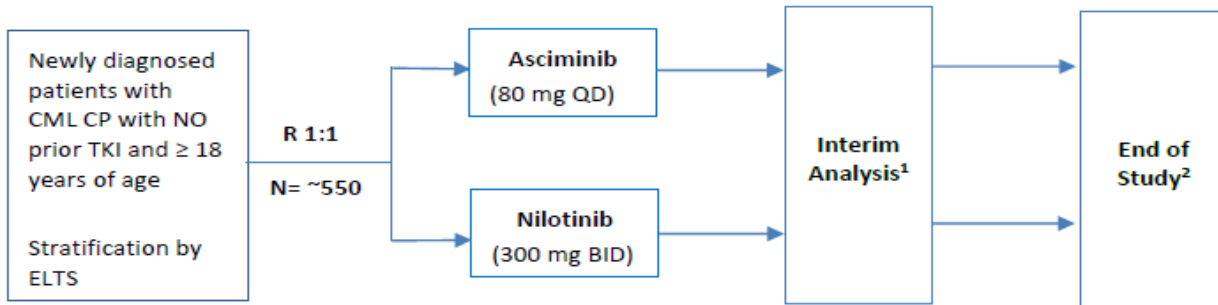


*Patients who pre-registered based on pT2N0 urothelial cancer with ctDNA(+) Signatera testing based on routine standard testing are only eligible if central testing confirms ctDNA(+) result. Note: This is distinct from patients with ypT2N0 urothelial cancer (i.e., after neoadjuvant chemotherapy) who are eligible with either ctDNA(+) or ctDNA(-) testing.

** 1 cycle = 28 days

***Patients in Cohort B (Arm 4) who develop a ctDNA(+) assay during serial monitoring may be eligible to be re-registered and receive or initiate nivolumab. A re-registration step is required.

Treatment is to continue until disease progression or unacceptable adverse event or completion of 12 cycles nivolumab +/- relatlimab. Patients will be followed for 5 years or until death, whichever comes first.

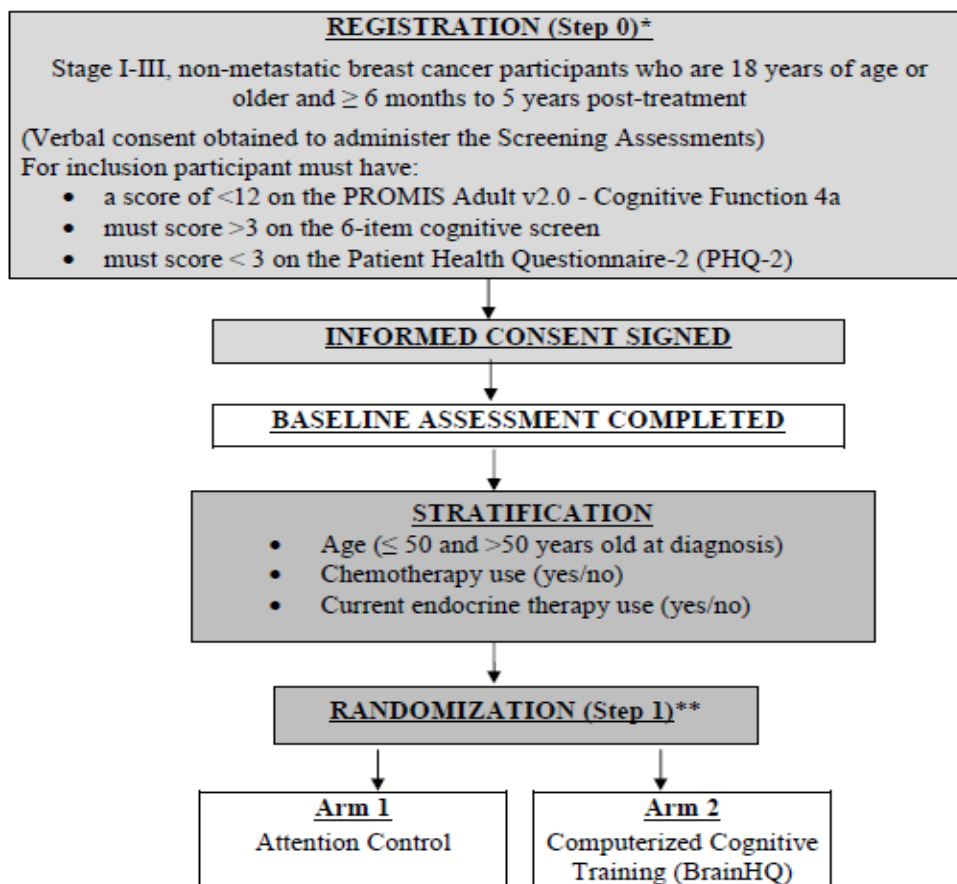


¹A single interim analysis will take place when 46 discontinuations due to AE have occurred. If statistical significance is reached, the IA will be used to allow for an early assessment of the benefits of asciminib. Refer to [Section 9.8 Interim Analysis](#) for details.

²Participants can be treated in the study until 65 discontinuations of study treatment due to AE (TTDAE) are met. End of study is defined as when the necessary number of events for the primary analysis has been reached and when end of treatment and the last assessments as per [Table 1-1](#) are completed. Refer to [Section 6.1.5 Treatment Duration](#) for additional details.

N= Approximate number of participants required to achieve 65 events (refer to [Section 9.9](#))

NRG-CC011 SCHEMA



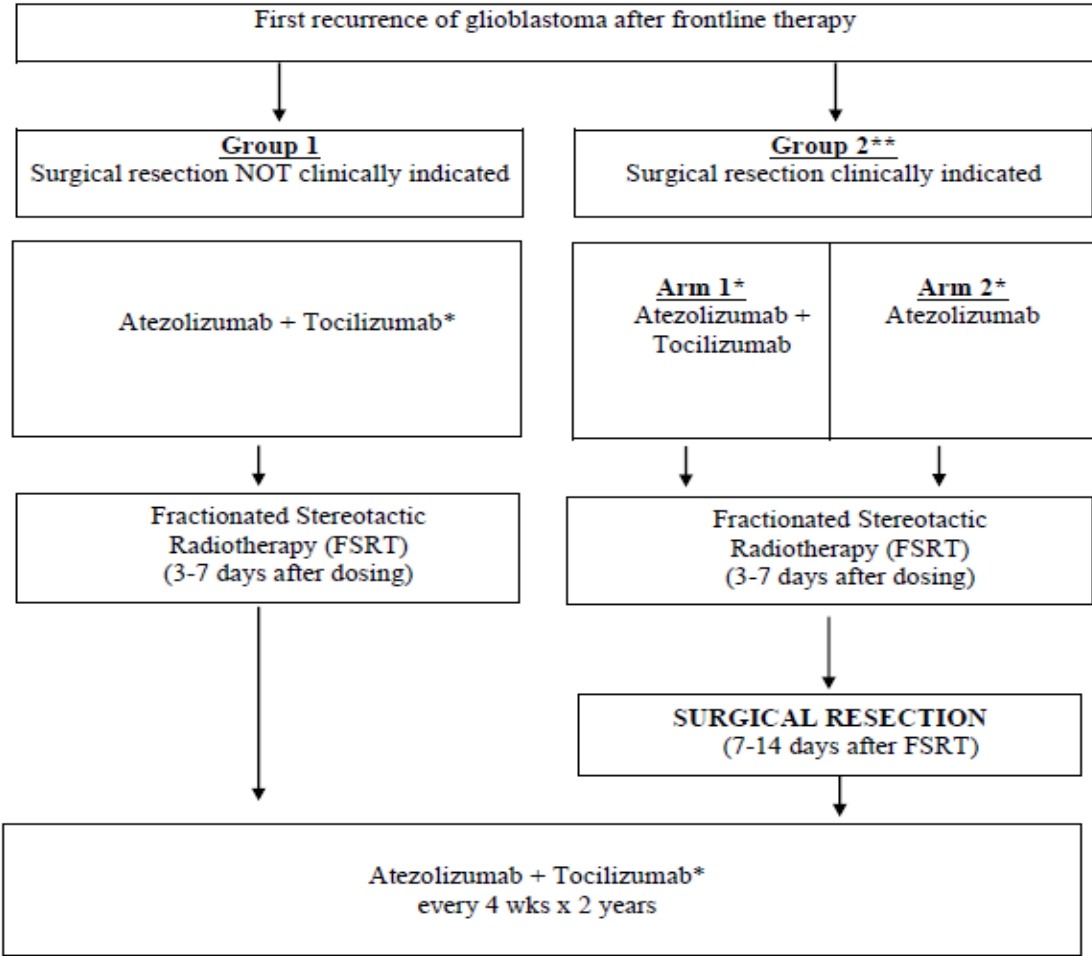
*All potential participants will be registered in Step 0.

**If a participant meets all eligibility requirements, provides written informed consent, and completes the baseline assessment (both surveys via VTOC tool and neuropsychological assessment), the participant will be randomized in Step 1.

**Randomization is 1:1

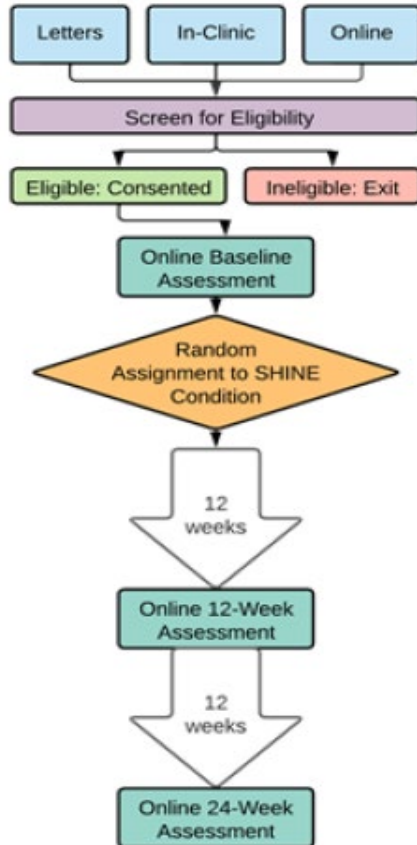
Registration (Step 0) and Randomization (Step 1) are a collaboration of NRG Oncology sites, NRG SDMC, and Ohio State University (shading represents the steps where sites are involved). The baseline assessment is a function of the NRG Oncology SDMC and Ohio State University only.

NRG-BN010
PHASE II SCHEMA (20-DEC-2023)
OPENED TO ACCRUAL WITH PROTOCOL AMENDMENT 3



WF-2202
Navigator -Courtney x3660

MENU



There are four SHINE intervention **components**: (1) psychoeducation about cancer-related sexual morbidity (“Sexual Health Essentials”), (2) training for communication with clinicians (“Health Care Discussions”), (3) training for communication with partners (“Partner Conversations”), and (4) physical intimacy promotion (“Intimacy Insights”). In total, there are 16 SHINE **conditions**, or combinations of four SHINE intervention **components**. See Table 1 for the detailed list of conditions.

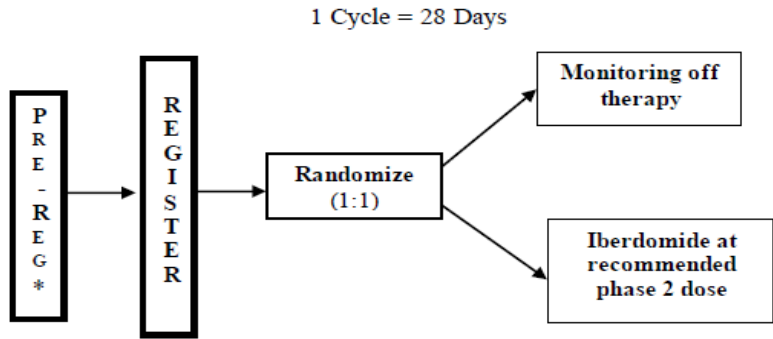
Sample Size: n=320 (20 participants randomized into each of the 16 conditions)

Study Duration: 24 weeks

Table 1: Study Factorial Design

Condition	Sexual Health Essentials	Health Care Discussions	Partner Conversations	Intimacy Insights	N
1	Enhanced	On	On	On	20
2	Enhanced	On	On	Off	20
3	Enhanced	On	Off	On	20
4	Enhanced	On	Off	Off	20
5	Enhanced	Off	On	On	20
6	Enhanced	Off	On	Off	20
7	Enhanced	Off	Off	On	20
8	Enhanced	Off	Off	Off	20
9	Standard	On	On	On	20
10	Standard	On	On	Off	20
11	Standard	On	Off	On	20
12	Standard	On	Off	Off	20
13	Standard	Off	On	On	20
14	Standard	Off	On	Off	20
15	Standard	Off	Off	On	20
16	Standard	Off	Off	Off	20

Alliance A062102
Randomized Phase II Schema

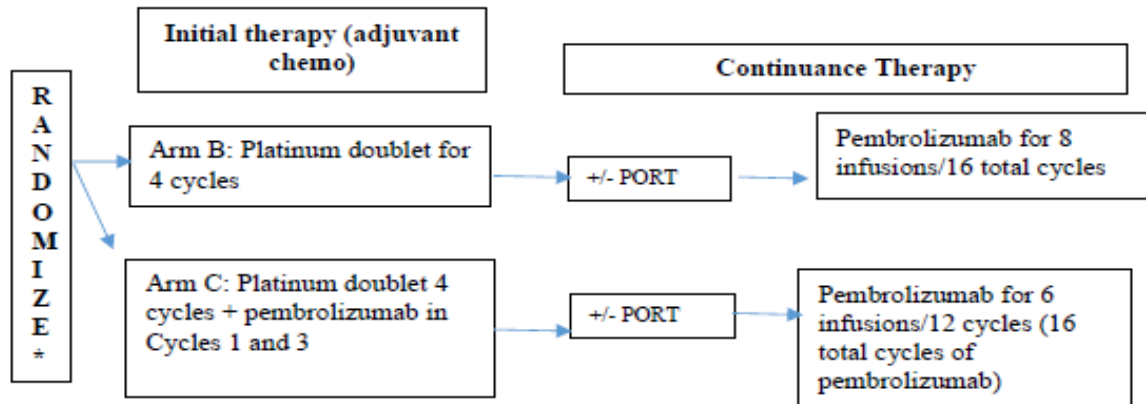


* All patients must be pre-registered in order to submit the required bone marrow and blood specimens to the Alliance HEME Biorepository (see [Sections 4.4](#) and [6.2](#)).

Treatment is to continue until disease progression or unacceptable adverse event. Patients will be followed for 4 years or until death, whichever comes first.

SCHEMA

1 cycle = 21 days



After the release of Update 07 patients will be randomized to Arms B and C. A081801 previously had an Arm A, in which patients receive a platinum doublet followed by observation.

Patients will be followed for up to 10 years or until death, whichever comes first.

