

MASTER TRIAL LIST

APRIL 2023



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

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

Updated 4.12.23

RADIATION LOCATIONS:

OSF Glen Oak - OSF main hospital

OSF Route 91 (attached to Illinois CancerCare)

UPHM - Unity Point Health Methodist ([NOW](#) Carle Health Greater Peoria)

Galesburg - Western Illinois Cancer Treatment Center

SJMC - St Joseph Medical Center



APRIL 2023

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

ALL

[EA9213](#)

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

Biliary

[EA2187](#)

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

Endometrial

[GY026](#)

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

[A031702](#)

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

Head & Neck

[EA3191](#)

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

[HN010](#)

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

Neuroendocrine

<u>S2104</u>	Randomized Phase II Trial of Postoperative Adjuvant Capecitabine and Temozolomide Versus Observation in High-Risk Pancreatic Neuroendocrine Tumors
Pancreas	
<u>S2104</u>	Randomized Phase II Trial of Postoperative Adjuvant Capecitabine and Temozolomide Versus Observation in High-Risk Pancreatic Neuroendocrine Tumors
Rectal	
<u>EA2201</u>	(RT at Glen Oak, UPHM, Galesburg) A Phase II Study of Neoadjuvant Nivolumab Plus Ipilimumab and Short-Course Radiation in MSI-H/dMMR Locally Advanced Rectal Adenocarcinoma
Renal Cell Carcinoma	
<u>S2200</u>	A Phase II Randomized Trial of Cabozantinib (NSC #761968) With or Without Atezolizumab (NSC #783608) in Patients With Advanced Papillary Renal Cell Carcinoma (PAPMET2)
Skin	
<u>A091802</u>	Phase II randomized Trial of Avelumab plus cetuximab versus avelumab alone in advanced cutaneous Squamous cell carcinoma of skin



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MASTER TRIAL LIST

APRIL 2023

[MENU](#)

AML

Navigator - Heather x3661



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ANAL

Navigator - Carrie x3621

[EA2176](#)

SCHEMA

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

[EA2182](#)

(RT at Carle 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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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)



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BILIARY

Navigator - Carrie x3621

[**EA9213 - JIT Trial**](#)

Temporarily closed | Phase II stud of Pevonedistat in Combincatoin with Carbo and Paclitaxel in advanced intrahepatic cholangiocarcinoma.



MASTER TRIAL LIST

APRIL 2023

MENU

BLADDER / UROTHELIAL

Navigator - Carrie x3621

ADJUVANT / NEOADJUVANT

[EA8185](#)

(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)

SCHEMA

[S1806](#)

(RT at Glen Oak, SJMC, Carle and Galesburg) Phase III Randomized Trial of Concurrent Chemoradiotherapy with or without Atezolizumab in Localized Muscle Invasive Bladder Cancer

SCHEMA

[S2011](#)

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

SCHEMA

METASTATIC

[A032001](#)

Phase III Randomized Trial of Maintenance Cabozantinib and Avelumab vs Maintenance Avelumab After First-Line Platinum-Based Chemotherapy in Patients With Metastatic Urothelial Cancer

SCHEMA

[A032002](#)

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

SCHEMA

MASTER TRIAL LIST

APRIL 2023

MENU

BRAIN

Navigator - Carrie x3621

<p><u>A071702</u></p> <p>SCHEMA</p>	<p>A Phase II Study of Checkpoint Blockade Immunotherapy in Patients With Somatically Hypermethylated Recurrent WHO Grade 4 Glioma</p>
<p><u>BN011</u></p> <p>SCHEMA</p>	<p>(RT credentialing pending) A Phase III Trial of Gleostine® (Lomustine)-Temozolomide Combination Therapy Versus Standard Temozolomide in Patients With Methylated MGMT Promoter Glioblastoma</p>
<p><u>N0577</u></p>	<p>(RT at Glen Oak, RT 91, and 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

EA1181

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

Neo/Adjuvant - Hormone Receptor Positive / HER2 Negative

BR007

SCHEMA

(RT at Galesburg, 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

JSJ-MC-JZLH / EMBER-4

Coming Apr/May 2023! (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

Neo/Adjuvant - Triple Negative (no trials at this time)

METASTATIC TREATMENT

Metastatic - HER2 Positive (no trials at this time)

Metastatic - Hormone Receptor Positive / HER2 Negative

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	<u>Not Actively Screening - contact Navigator</u> - A Phase II Trial of Sacituzumab Govitecan (IMMU-132) (NSC #820016) for Patients With HER2-Negative Breast Cancer and Brain Metastases
Metastatic - Triple Negative <i>(no trials at this time)</i>	
SURGERY / RADIATION ONLY	
<u>MA.39</u>	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)	
A211901 	<u>Not Actively Screening - Contact Navigator</u> Reaching Rural Cancer Survivors Who Smoke Using Text-Based Cessation Interventions
<u>A212102</u> 	(Peoria, BLM, Canton, Gburg, Pekin, Peru, Ottawa, Wash) Blinded Reference Set for Multicancer Early Detection Blood Tests (<i>healthy cohort closed</i>)
<u>A222004</u> 	<u>Not Actively Screening - Contact Navigator</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 (<i>breast, leukemia, and lymphoma cohorts closed to accrual</i>)
<u>S2010</u> 	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>S2108CD</u> 	(Peoria, Bloomington, Galesburg, Canton, Ottawa) A Cluster Randomized Trial Comparing an Educationally Enhanced Genomic Tumor Board (EGTB) Intervention to Usual Practice to Increase Evidence-Based Genome-Informed Therapy
<u>S1912CD</u> 	<u>Not Actively Screening - Contact Navigator</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- <i>at least 2 months out from surgery/tx/radiation</i>
<u>URCC 19185</u> 	<u>Not Actively Screening - Contact Navigator</u> (Peoria, Bloomington, Canton, Galesburg, Pekin, Washington) Multicenter Randomized Controlled Trial Comparing Brief Behavioral Therapy for Cancer Related Insomnia (BBT-CI) and Healthy Eating Education Learning (HEAL)

<p><u>URCC 21038</u></p> <p></p>	<p>(Peoria, Bloomington, Canton, 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></p>	<p>Internet-delivered Management of Pain Among Cancer Treatment Survivors (IMPACTS)</p>

GYNECOLOGICAL

Navigator - Angie x3613

<p><u>NRG - GY023</u></p> <p></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>
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CANCER CONTROL

MULTI-DISEASE SITES

A211901 SCHEMA	<u>Not Actively Screening - Contact Navigator</u> Reaching Rural Cancer Survivors Who Smoke Using Text-Based Cessation Interventions
A212102 SCHEMA	(Peoria, BLM, Canton, Gburg, Pekin, Peru, Ottawa, Wash) Blinded Reference Set for Multicancer Early Detection Blood Tests (<i>healthy cohort closed</i>)
A222004 SCHEMA	<u>Not Actively Screening - Contact Navigator</u> A Randomized Phase III Trial of Olanzapine Versus Megestrol Acetate for Cancer-Associated Anorexia
EAQ202 SCHEMA	Improving Adolescent and Young Adult Self-Reported Data in ECOG-ACRIN Trials (<i>breast, leukemia, and lymphoma cohorts closed to accrual</i>)
S1912CD SCHEMA	<u>Not Actively Screening - Contact Navigator</u> A Randomized Trial Addressing Cancer-Related Financial Hardship Through Delivery of a Proactive Financial Navigation Intervention (CREDIT)
S2013 SCHEMA	(Peoria, Bloomington, Galesburg, Pekin, Washington) Immune Checkpoint Inhibitor Toxicity: A Prospective Observational Study (I-CHECKIT)
S2108CD SCHEMA	(Peoria, Bloomington, Galesburg, Canton, Ottawa) A Cluster Randomized Trial Comparing an Educationally Enhanced Genomic Tumor Board (EGTB) Intervention to Usual Practice to Increase Evidence-Based Genome-Informed Therapy
URCC-18007	Randomized Placebo Controlled Trial of Bupropion For Cancer Related Fatigue - <i>at least 2 months out from surgery/tx/radiation</i>
URCC 19185 SCHEMA	<u>Not Actively Screening - Contact Navigator</u> (Peoria, Bloomington, Canton, Galesburg, Pekin, Washington) Multicenter Randomized Controlled Trial Comparing Brief Behavioral Therapy for Cancer Related Insomnia (BBT-CI) and Healthy Eating Education Learning (HEAL)
URCC 21038 SCHEMA	(Peoria, Bloomington, Canton, 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
WF-1901 SCHEMA	Internet-delivered Management of Pain Among Cancer Treatment Survivors (IMPACTS)

BREAST

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)
URCC 16070	Treatment of Refractory Nausea- for breast cancer patients.

LUNG

JOVIALITY 23289	(Peoria only) Safety and Acceptability: Virtual Reality for Psychotherapy Delivery in Lung Cancer Patients of Illinois CancerCare
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COLORECTAL	
WF-1806	(M&M Study) Myopenia and Mechanisms of Chemotherapy Toxicity in older Adults with Colorectal Cancer
BRAIN	
WF-1801	A Single Arm, Pilot Study of Ramipril for Preventing Radiation-Induced Cognitive Decline in Glioblastoma (GBM) Patients Receiving Brain Radiotherapy
REGISTRY	
Navigator - Heather 243-3661	
Connect Myeloid <div>SCHEMA</div>	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>)
NHLBI-MDS	(Peoria, Bloomington and Galesburg only) -The National Myelodysplastic Syndromes (MDS) Study



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MASTER TRIAL LIST

APRIL 2023

[MENU](#)

CARCINOID

Navigator - Ashton x3611
Carrie x3621

[A021602](#)

Randomized, Double-Blinded Phase III Study of Cabozantinib Versus Placebo In Patients With Advanced Neruodenocrine Tumors After progression on Prior Therapy (CABINET)



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MENU

CLL

Navigator - Heather x3661

no trials at this time

1st Line

2nd Line, 3rd Line, etc.

MASTER TRIAL LIST

APRIL 2023

MENU

CML

Navigator - Heather x3661

[Connect Myeloid](#)

SCHEMA

The Myelofibrosis (MF), Myelodysplastic Syndromes (MDS) and Acute Myeloid Leukemia (AML) Disease Registry. (enrolling cohorts : newly diagnosed low risk MDS, Treated low risk MDS, Treated MF, Treated MF cytopenias - includes CMML, aCML, MDS/MPN-RS-T, MDS/MPN unclassifiable)

MASTER TRIAL LIST

APRIL 2023

MENU

COLON / RECTAL

Navigator - Carrie x3621

Adjuvant

<u>C-14</u>	(Peoria, Bloomington, Galesburg, Ottawa, Pekin, Peru, Washington) Second Colorectal Cancer Clinical Validation Study to Predict Recurrence Using A Circulating Tumor DNA Assay To Detect Minimal Residual Disease (CORRECT-MRD II)
<u>EA2201 - JIT</u>	(RT at Glen Oak, Carle, Galesburg) A Phase II Study of Neoadjuvant Nivolumab Plus Ipilimumab and Short-Course Radiation in MSI-H/dMMR Locally Advanced Rectal Adenocarcinoma
<u>GI005</u>	Phase II/III Study of Circulating Tumor DNA as a Predictive Biomarker in Adjuvant Chemotherapy in Patients With Stage IIA Colon Cancer (COBRA)
<u>GI008</u> SCHEMA	Colon Adjuvant Chemotherapy Based on Evaluation of Residual Disease

Metastatic

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

<u>A211901</u> SCHEMA	<u>Not Actively Screening - Contact Navigator</u> Reaching Rural Cancer Survivors Who Smoke Using Text-Based Cessation Interventions
<u>A212102</u> SCHEMA	Blinded Reference Set for Multicancer Early Detection Blood Tests (<i>healthy cohort closed</i>)
<u>A222004</u> SCHEMA	<u>Not Actively Screening - Contact Navigator</u> A Randomized Phase III Trial of Olanzapine Versus Megestrol Acetate for Cancer-Associated Anorexia
<u>EAQ202</u> SCHEMA	Improving Adolescent and Young Adult Self-Reported Data in ECOG-ACRIN Trials (<i>breast, leukemia, and lymphoma cohorts closed to accrual</i>)
<u>A212102</u> SCHEMA	(Peoria, BLM, Canton, Gburg, Pekin, Peru, Ottawa, Wash) Blinded Reference Set for Multicancer Early Detection Blood Tests
<u>S1912CD</u> SCHEMA	<u>Not Actively Screening - Contact Navigator</u> A Randomized Trial Addressing Cancer-Related Financial Hardship Through Delivery of a Proactive Financial Navigation Intervention (CREDIT)
<u>S2013</u> SCHEMA	(Peoria, Bloomington, Galesburg, Pekin, Washington) Immune Checkpoint Inhibitor Toxicity: A Prospective Observational Study (II-CHECKIT)

<u>S2108CD</u> 	(Peoria, Bloomington, Galesburg, Canton, Ottawa) A Cluster Randomized Trial Comparing an Educationally Enhanced Genomic Tumor Board (EGTB) Intervention to Usual Practice to Increase Evidence-Based Genome-Informed Therapy
<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> 	<u>Not Actively Screening - Contact Navigator</u> (Peoria, Bloomington, Canton, Galesburg, Pekin, 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> 	(Peoria, Bloomington, Canton, 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>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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MENU

ESOPHAGEAL- GASTRIC

Navigator - Carrie x3621

A022102

SCHEMA

Randomized Phase III Trial of mFOLFIRINOX vs. FOLFOX With Nivolumab for First-Line Treatment of Metastatic HER2- Gastroesophageal Adenocarcinoma

MASTER TRIAL LIST

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MENU

HEAD & NECK

Navigator - Ashton x3611

<u>EA3161</u> 	<p>(RT at Glen Oak, Carle, Galesburg) A Phase II/III Randomized Study of Maintenance Nivolumab Versus Observation in Patients With Locally Advanced, Intermediate Risk HPV Positive OPSCC</p>
<u>EA3191 - JIT</u>	<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>
<u>HN005</u>	<p>Temporarily Closed (RT at 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>
<u>HN009</u> 	<p>(RT at Carle) 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>
<u>HN010 - JIT Trial</u>	<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>
<u>S2101</u> 	<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

APRIL 2023

MENU

Navigator - Heather x3661

LYMPHOMA

HL

No HL trials at this time

NHL



MASTER TRIAL LIST

APRIL 2023

MENU

MDS/MPN

Navigator - Heather x3661

[Connect Myeloid](#)

SCHEMA

The Myelofibrosis (MF), Myelodysplastic Syndromes (MDS) and Acute Myeloid Leukemia (AML) Disease Registry. (*enrolling cohorts : newly diagnosed low risk MDS, Treated low risk-MDS, Treated MF, Treated MF cytopenias - includes CMML, aCML, MDS/MPN-RS-T, MDS/MPN unclassifiable*)

[NHLBI-MDS](#)

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



MASTER TRIAL LIST

APRIL 2023

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MELANOMA

Navigator - Carrie x3621

S2101

SCHEMA

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



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APRIL 2023

MENU

MERKEL

Navigator - Carrie x3621

EA6174

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



MASTER TRIAL LIST

APRIL 2023

MENU

MOLECULAR STUDIES

*Contact Disease Specific Navigator

<u>A151804</u>	Establishment of a National Biorepository to Advance Studies of Immune-Related Adverse Events
<u>S1823</u> SCHEMA	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>TP-CA-003 (Sculptor)</u>	(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)
<u>TPX-0005-01 (TRIDENT-1)</u> SCHEMA	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)

MASTER TRIAL LIST

APRIL 2023

MENU

MULTIPLE MYELOMA

Navigator - Heather x3661

<p>EAA173</p> <p>SCHEMA</p>	<p>Daratumumab to Enhance Therapeutic Effectiveness of Revlimid in Smoldering Myeloma (DETER-SMM)</p>
<p><u>S1803</u></p>	<p>Temporarily Closed 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)</p>

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APRIL 2023

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NEUROENDOCRINE

Navigator - Carrie x3621

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

<u>A081801</u> SCHEMA	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> SCHEMA	(RT at Glen Oak, Carle 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 Rt-91)
<u>S1914</u>	(RT at Glen Oak, Carle, Galesburg) Randomized Phase III Trial of Induction/Consolidation Atezolizumab (NSC #783608) + SBRT Versus SBRT Alone in High Risk, Early Stage NSCLC

METASTATIC - 1st Line

<u>EA5182</u> SCHEMA	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>GS-US-626-6216 (STAR-121)</u> SCHEMA	(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
<u>MK 7684A-003</u> SCHEMA	Screening by referral only (Peoria only) A Phase 3, Multicenter, Randomized, Double-Blind Study of MK-7684 with Pembrolizumab as a Coformulation (MK-7684A) Versus Pembrolizumab Monotherapy as First Line Treatment for Participants With PD-L1 Positive Metastatic Non-Small Cell Lung Cancer
<u>S2302 (Pragmatica)</u> SCHEMA	NEW! 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)

METASTATIC - 2nd/3rd Line

<u>EA5162</u> SCHEMA	Phase II Study of AZD9291 (Osimertinib) in Advanced NSCLC Patients With Exon 20 Insertion Mutations in EGFR
<u>LUNGMAP</u>	A Master Protocol To Evaluate Biomarker-Driven Therapies and Immunotherapies in Previously-Treated NSCLC. (SUB-STUDIES: S1800D (CLOSED) - A Phase II/III Study of N-803 (ALT-803) plus Pembrolizumab versus Standard of Care in Participants with Stage IV or Recurrent Non-Small Cell Lung Cancer Previously Treated with Anti-PD-1 or Anti-PD-L1 Therapy; S1900E - A Phase II Study of AMG 510 in Participants With Previously Treated Stage IV or Recurrent KRAS G12C Mutated Non-Squamous Non-Small Cell Lung Cancer) ; S1900F - A Randomized Phase II Study of Carboplatin and Pemetrexed w/ or w/o Selpercatinib in Participants With Non-Squamous RET Fusion-Positive Stage IV Non-Small Cell Lung Cancer and Progression of Disease on Prior RET Directed Therapy)

CANCER CONTROL (NSCLC Only)

<u>A211901</u> SCHEMA	Not Actively Screening - Contact Navigator Reaching Rural Cancer Survivors Who Smoke Using Text-Based Cessation Interventions
------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------

<u>A212102</u> 	(Peoria, BLM, Canton, Gburg, Pekin, Peru, Ottawa, Wash) Blinded Reference Set for Multicancer Early Detection Blood Tests (<i>healthy cohort closed</i>)
<u>A222004</u> 	<u>Not Actively Screening - Contact Navigator</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 (<i>breast, leukemia, lymphoma cohorts closed to accrual</i>)
JOVIALITY 23289	NEW! (Peoria only) Safety and Acceptability: Virtual Reality for Psychotherapy Delivery in Lung Cancer Patients of Illinois CancerCare
<u>S2108CD</u> 	(Peoria, Bloomington, Galesburg, Canton, Ottawa) A Cluster Randomized Trial Comparing an Educationally Enhanced Genomic Tumor Board (EGTB) Intervention to Usual Practice to Increase Evidence-Based Genome-Informed Therapy
<u>S1912CD</u> 	<u>Not Actively Screening - Contact Navigator</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-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> 	<u>Not Actively Screening - Contact Navigator</u> (Peoria, Bloomington, Canton, Galesburg, Pekin, 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> 	(Peoria, Bloomington, Canton, 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>WF-1901</u> 	Internet-delivered Management of Pain Among Cancer Treatment Survivors (IMPACTS)

MASTER TRIAL LIST

APRIL 2023

MENU

PANCREATIC

Navigator - Carrie x3621

<p><u>EA2186</u></p> <p>SCHEMA</p>	<p>A Randomized Phase II Study of Gemcitabine and Nab-Paclitaxel Compared With 5-Fluorouracil, Leucovorin, and Liposomal Irinotecan in Older Patients With Treatment Naïve Metastatic Pancreatic Cancer (GIANT)</p>
<p><u>EA2192</u></p> <p>SCHEMA</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>S2001</u></p> <p>SCHEMA</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

APRIL 2023

MENU

PROSTATE

Navigator - Carrie x3621

ADJUVANT

[GU008](#)

SCHEMA

(RT at Glen Oak, Carle) 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](#)

SCHEMA

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

[GU010](#)

SCHEMA

(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)

METASTATIC

[A032101](#)

SCHEMA

A Phase 2 Trial of ADT Interruption in Patients Responding Exceptionally to AR-Pathway Inhibitor in Metastatic Hormone-Sensitive Prostate Cancer (MHSPC): A-DREAM

[C2321001](#)

SCHEMA

(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](#)

SCHEMA

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

<div><div><u>GU011</u></div><div>SCHEMA</div></div>	(RT at Glen Oak and Carle) 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, SJMC & Carle) 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

APRIL 2023

MENU

RENAL CELL

Navigator - Carrie x3621

<u>A031704</u> SCHEMA	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)
<u>MK 6482-011</u> SCHEMA	(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
<u>S2200</u> SCHEMA	A Phase II Randomized Trial of Cabozantinib (NSC #761968) With or Without Atezolizumab (NSC #783608) in Patients With Advanced Papillary Renal Cell Carcinoma (PAPMET2)

MASTER TRIAL LIST

APRIL 2023

MENU

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>	(Carle and Glen Oak) A Randomized Phase II Study of De-Intensified ChemoRadiation for Early-Stage Anal Squamous Cell Carcinoma (DECREASE)
BLADDER	
<u>A032002</u>	Temporarily Closed (RT at Glen Oak) Phase II Randomized Trial of Atezolizumab Versus Atezolizumab and Radiation Therapy for Platinum Ineligible/Refractory Metastatic Urothelial Cancer (ART)
<u>EA8185</u>	(RT pending at Glen Oak & Rt-91) Phase 2 Study of Bladder-Sparing Chemoradiation With MEDI4736 (Durvalumab) in Clinical Stage 3, Node Positive Bladder Cancer (INSPIRE)
<u>S1806</u>	(Glen Oak, SJMC, Carle and Galesburg) Phase III Randomized Trial of Concurrent Chemoradiotherapy with or without Atezolizumab in Localized Muscle Invasive Bladder Cancer
BRAIN	
<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>CCTG CE.7</u>	(Glen Oak)- A Phase III Trial of Stereotactic Radiosurgery Compared with Whole Brain Radiotherapy (WBRT) for 5-15 Brain Metastases
BREAST	
<u>BR007</u>	(Galesburg, 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> <small>SCHEMA</small>	(Glen Oak, Carle, Galesburg) A Phase II/III Randomized Study of Maintenance Nivolumab Versus Observation in Patients With Locally Advanced, Intermediate Risk HPV Positive OPSCC
<u>HN005</u>	Temporarily Closed (Galesburg, Glen Oak) A Randomized Phase II/III Trial of De-Intensified Radiation Therapy for Patients With Early-Stage, P16-Positive, Non-Smoking Associated Oropharyngeal Cancer
<u>HN009</u> <small>SCHEMA</small>	(RT at Carle) 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)
MERKEL CELL	
<u>EA6174</u>	Temporarily Closing 3.31.23 (Glen Oak, Carle and Galesburg) A Phase III Randomized Trial Comparing Adjuvant MK3475 (Pembrolizumab) to Standard of Care Observation in Completely Resected Merkel Cell Carcinoma
NSCLC	
<u>EA5181</u> <small>SCHEMA</small>	(Carle, Glen Oak 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 Rt 91)
<u>S1914</u>	(Glen Oak, Carle, Galesburg) Randomized Phase III Trial of Induction/Consolidation Atezolizumab (NSC #783608) + SBRT Versus SBRT Alone in High Risk, Early Stage NSCLC
PROSTATE	
<u>GU008</u> <small>SCHEMA</small>	(RT at Glen Oak, 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> <small>SCHEMA</small>	(RT at Glen Oak, Galesburg, 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)
<u>GU011</u> 	(RT at Glen Oak & Carle) A Phase II Double-Blinded, Placebo-Controlled Trial of PROstate OligoMETastatic RadiothERapy With or Without ANDrogen Deprivation Therapy in Oligometastatic Prostate Cancer (NRG Promethean)
<u>S1802</u>	(Glen Oak, SJMC & Carle) 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, Carle, Galesburg) Influence of Primary Treatment for Prostate Cancer on Work Experience (PCW)
SCLC	
<u>NRG CC009</u> 	(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
<u>S1827</u>	(Glen Oak, Galesburg, SJMC) A Randomized Phase III Trial of MRI Surveillance With or Without Prophylactic Cranial Irradiation (PCI) in Small-Cell Lung Cancer

MASTER TRIAL LIST

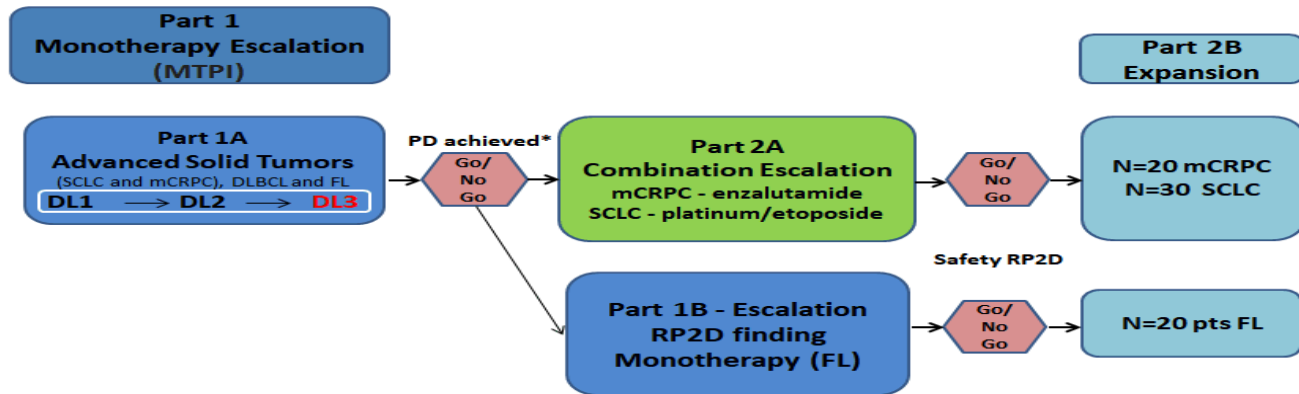
APRIL 2023

[MENU](#)

SMALL CELL LUNG CANCER

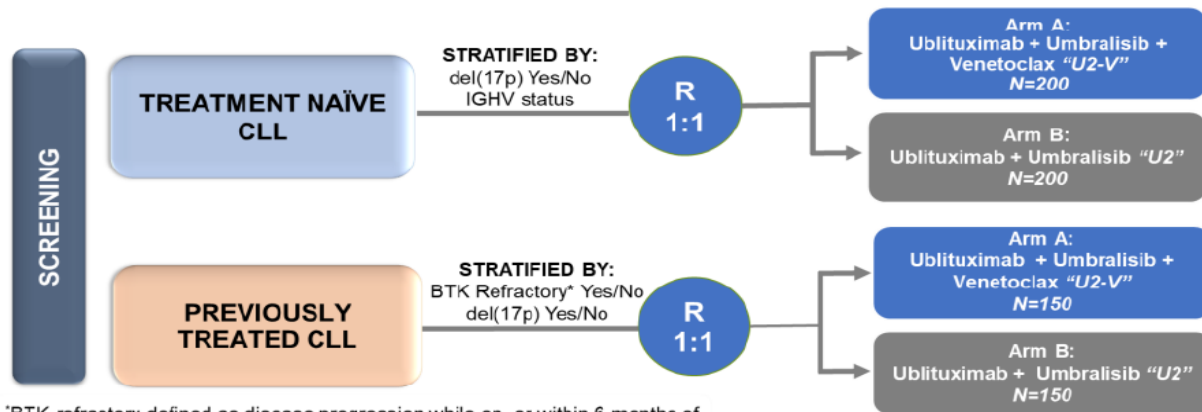
Navigator - Ashton x3611

<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>GO43104</u></p> <p>SCHEMA</p>	<p>(Peoria, Bloomington, Galesburg, Ottawa, Pekin, Peru, Washington) A Phase III, Randomized, Open-Label, Multicenter Study of Lurbinectedin In Combination With Atezolizumab Compared With Atezolizumab As Maintenance Therapy In Participants With Extensive-Stage Small-Cell Lung Cancer (ES-SCLC) Followiing First-Line Induction Therapy With Carboplatin, Etoposide and Atezolizumab</p>
<p><u>S1827</u></p>	<p>(RT at Glen Oak, Galesburg, SJMC) 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>



*50-70% down modulation of H3K27me3

FIGURE 2: PHASE 3 STUDY DESIGN



MK 6482-011 Schema
Navigator - Carrie x3621

MENU

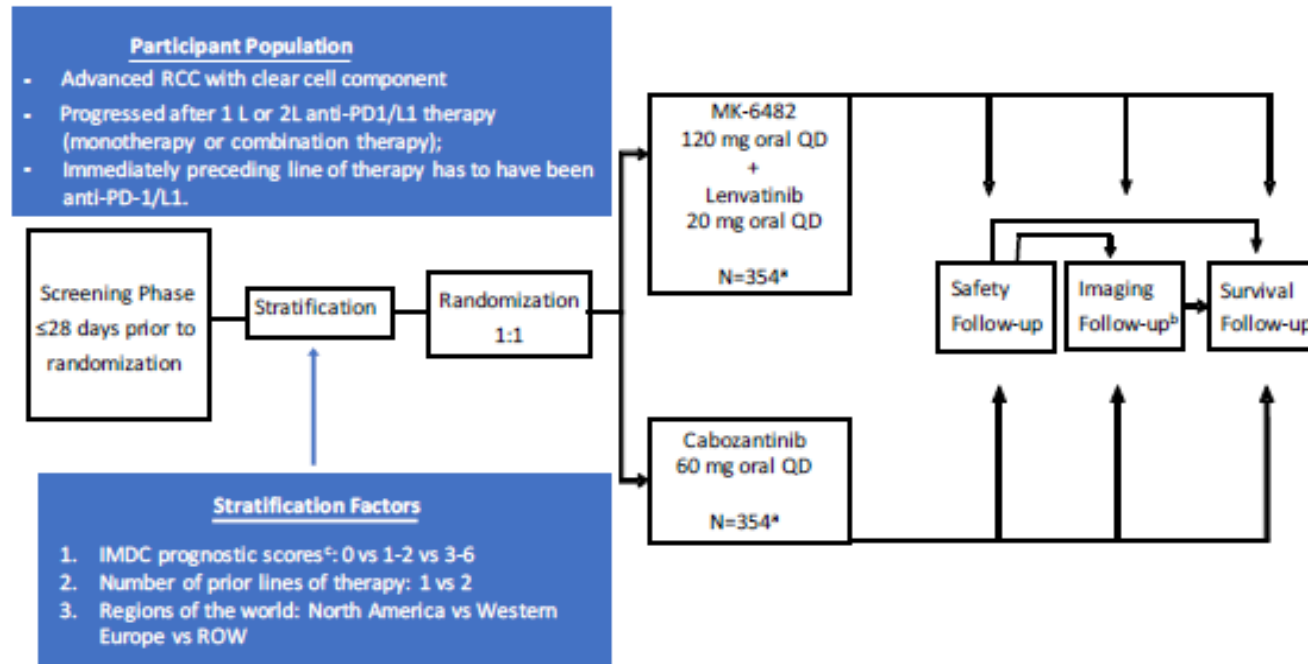
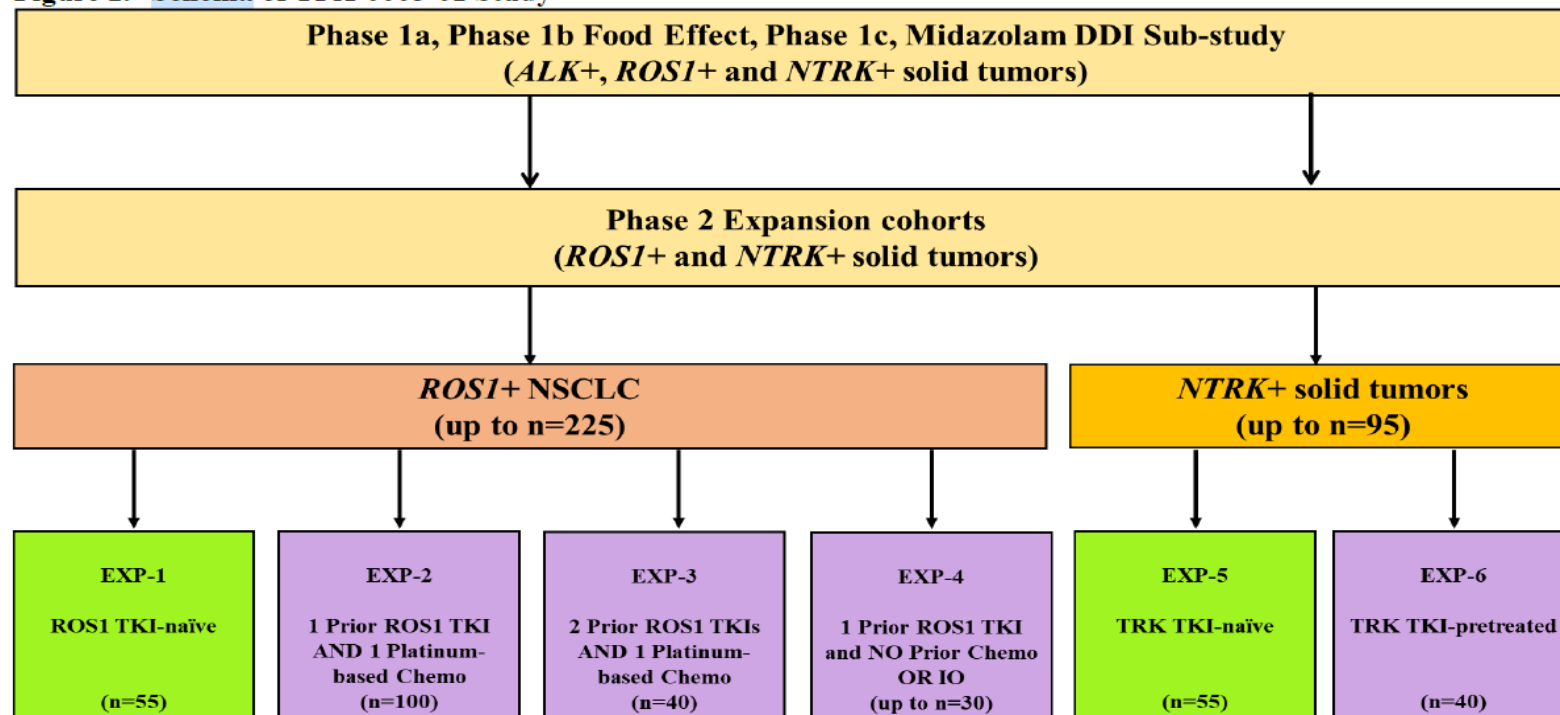
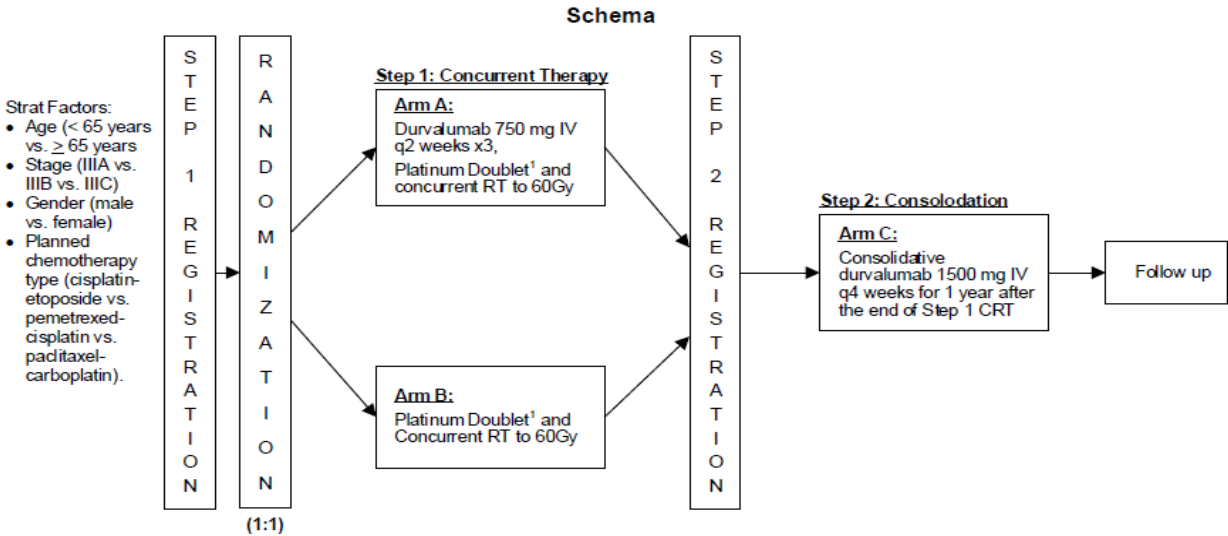
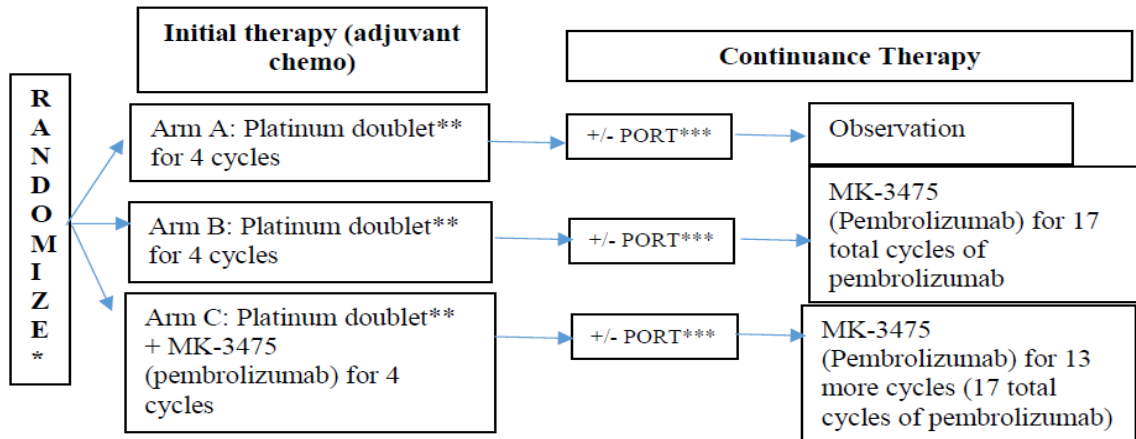


Figure 2. Schema of TPX-0005-01 Study

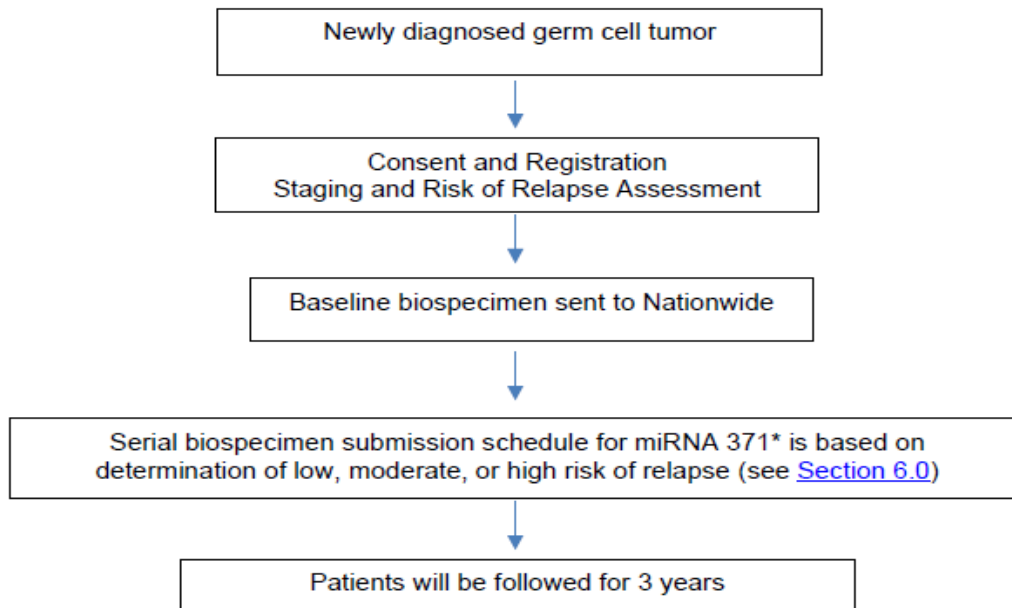




Schema: 1 cycle = 21 days

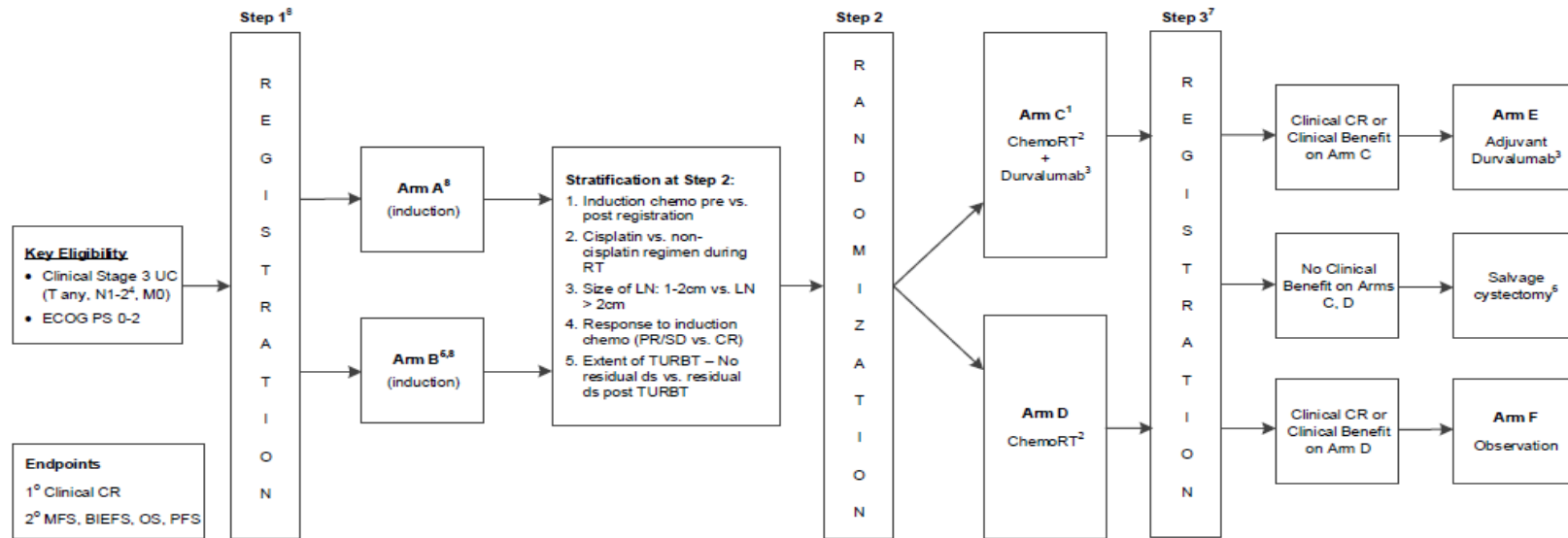


SCHEMA



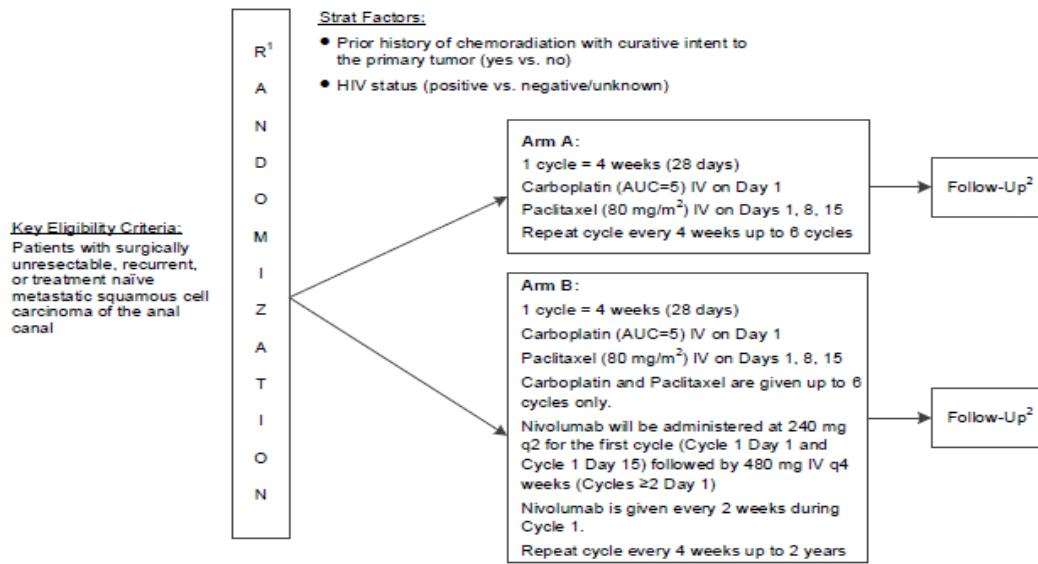
* Patients and providers will not have knowledge of the results of the miRNA 371 analysis.

Schema



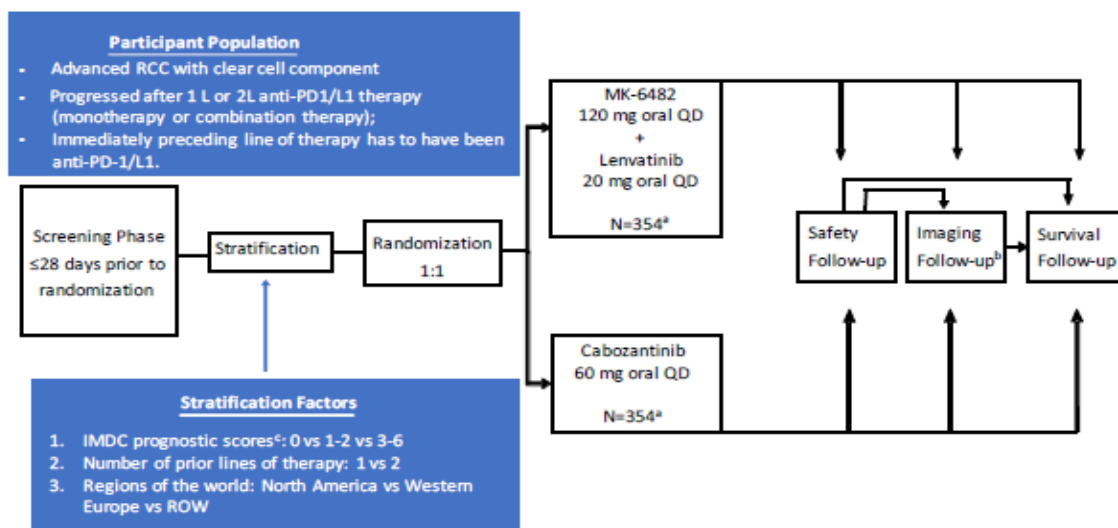
EA2176
Navigator -Carrie x3621

MENU

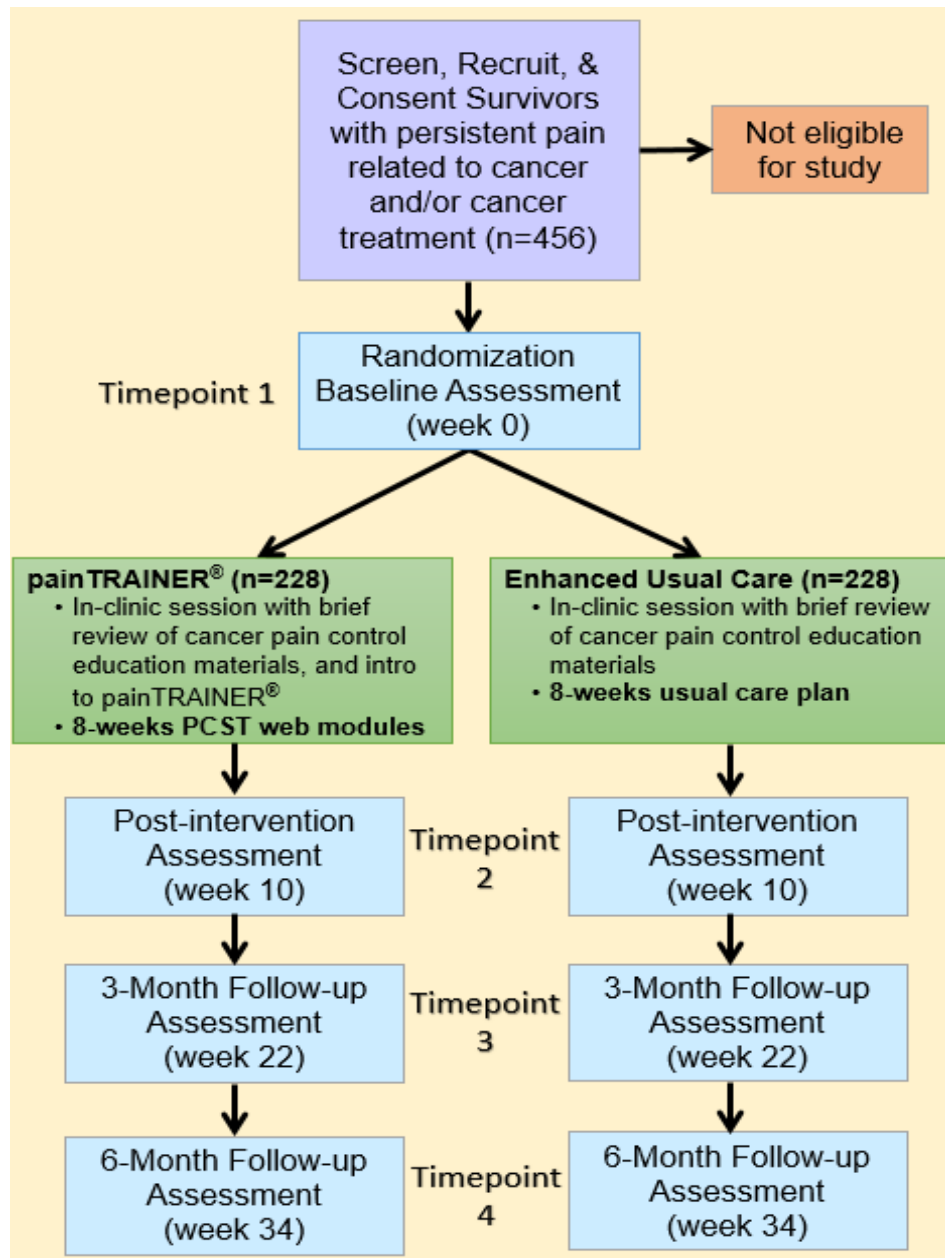


1. Randomization is 1:2 (A:B).

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



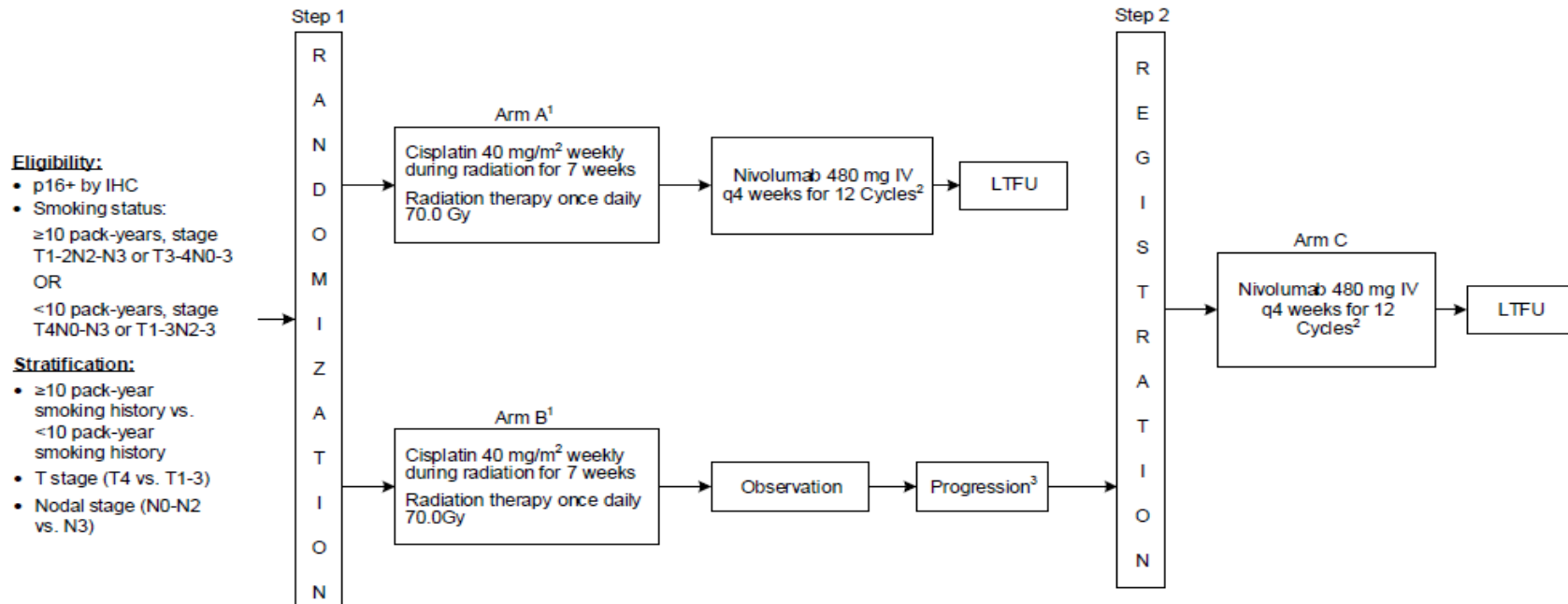
BICR=blinded independent central review; DMC=Data Monitoring Committee; IMDC=International Metastatic Renal Cell Carcinoma Database Consortium; QD=once daily; RCC=renal cell carcinoma; ROW=rest of world; TKI=tyrosine kinase inhibitor; US=United States; VEGF=vascular endothelial growth factor.



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

Stratification Factors:

- Presence or absence of brain metastasis
- EGFR exon 19 deletion/ L858R vs. other
- ECOG PS 0-1 vs 2

Untreated
metastatic
EGFR-positive
NSCLC

R¹
A
N
D
O
M
I
N
I
Z
A
T
I
O
N

Arm A^{2,3}

Osimertinib 80 mg
PO Daily

Arm B^{2,3}

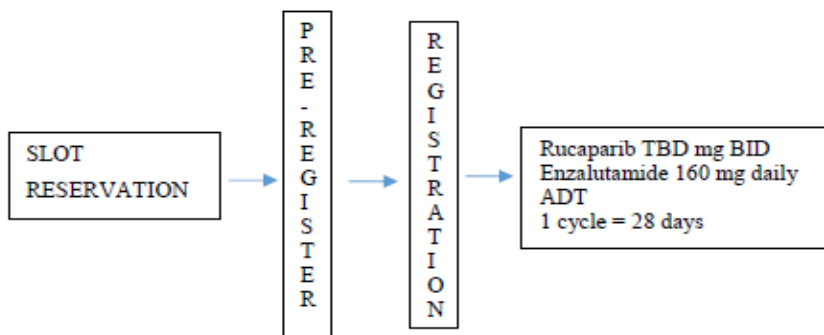
Osimertinib 80 mg
PO Daily;
Bevacizumab 15 mg/
kg IV every 3 weeks

F⁴
O
L
L
O
W
-
U
P

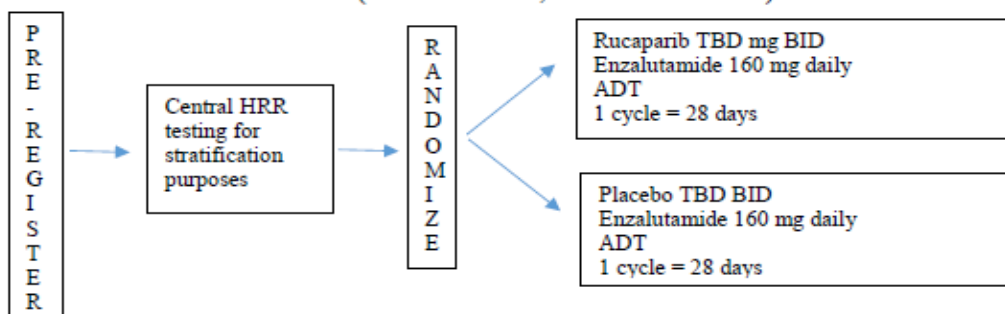
Accrual Goal = 300 patients
Cycle = 3 weeks (21 days)

Schema

PK Substudy (Dose Finding Portion) Only

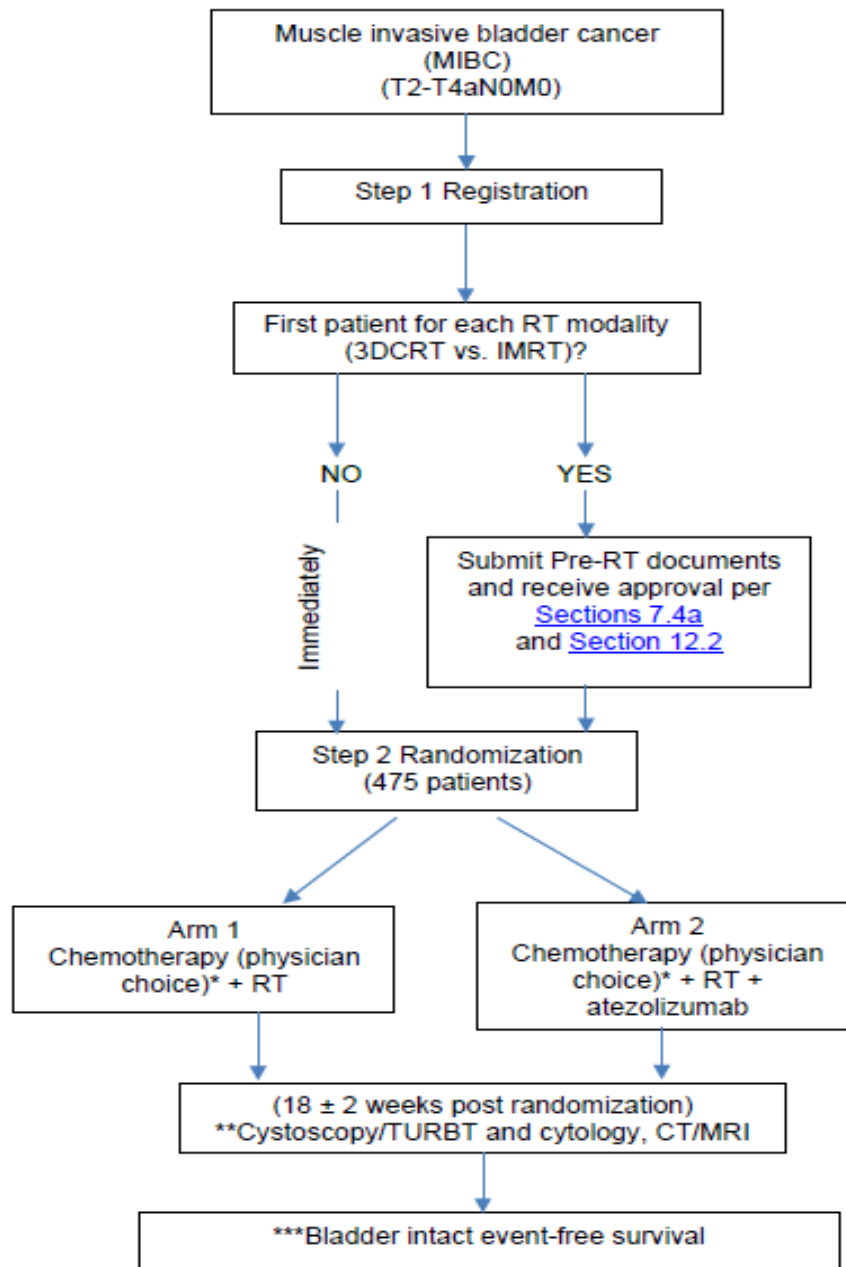


Phase III (Double-Blinded, Placebo-Controlled) Portion



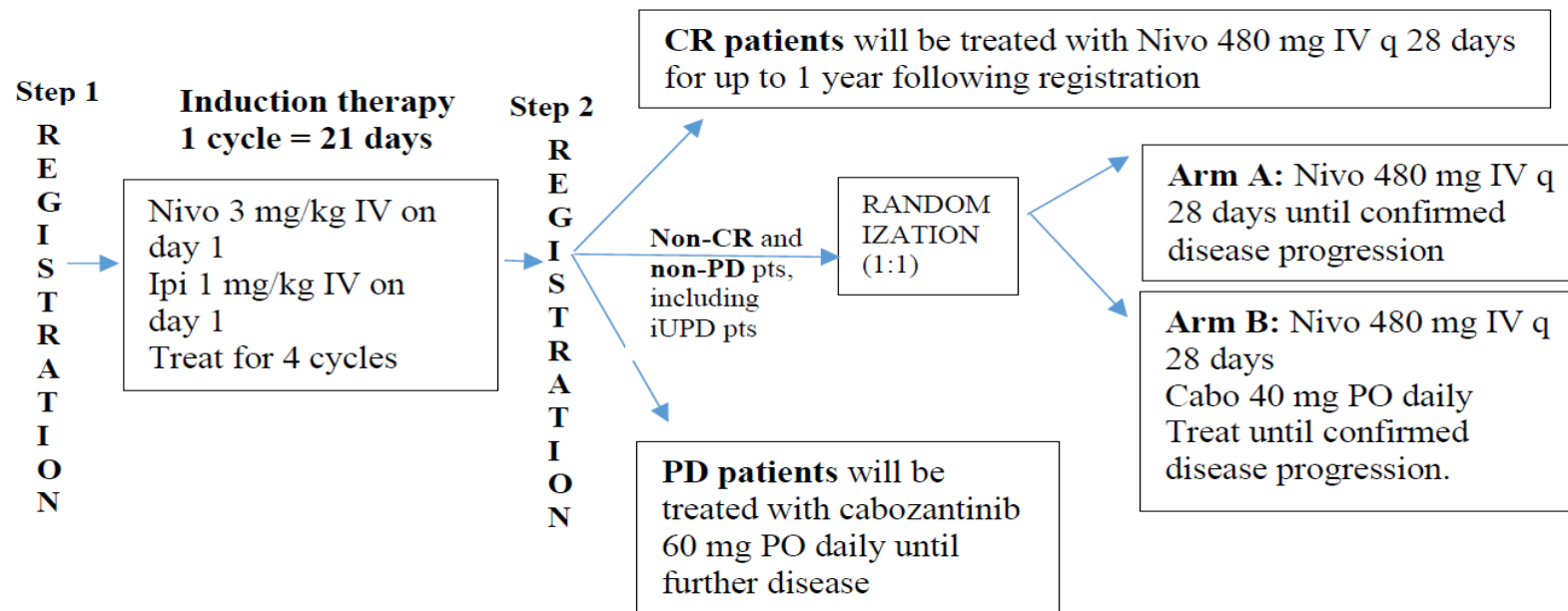
For all patients, treatment is to continue until disease progression or unacceptable adverse event.
Patients will be followed for 5 years or until death, whichever comes first.

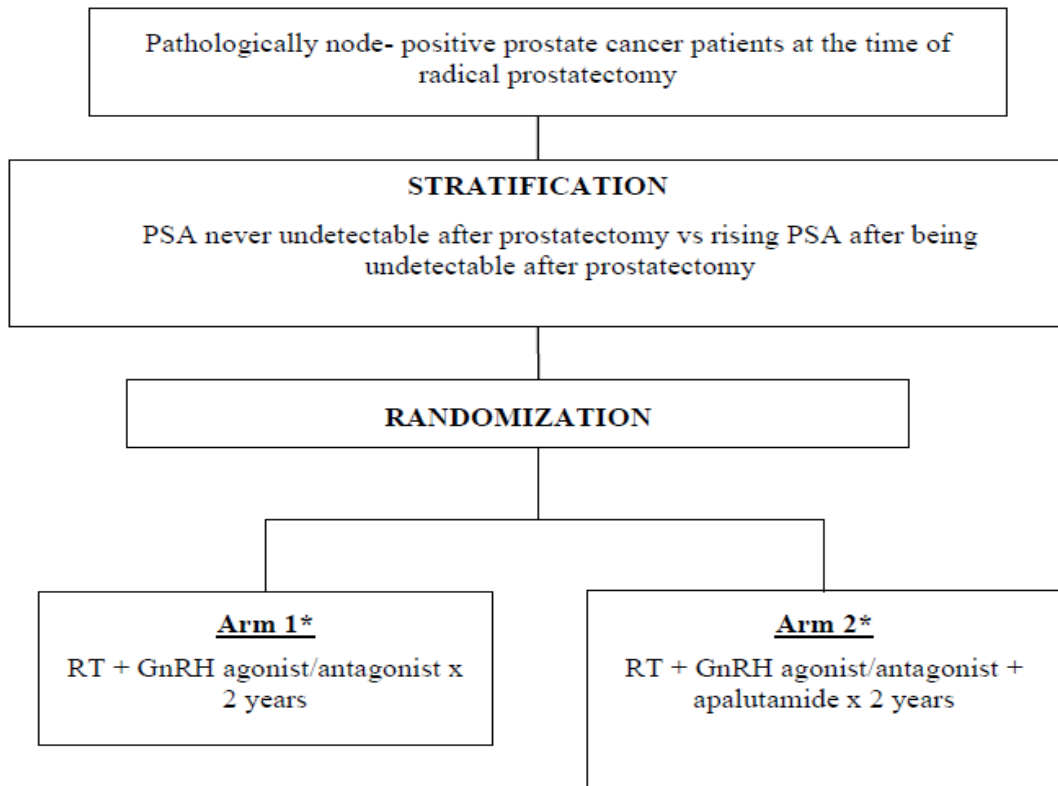
Please refer to the full protocol text for a complete description of the eligibility criteria and treatment plan.



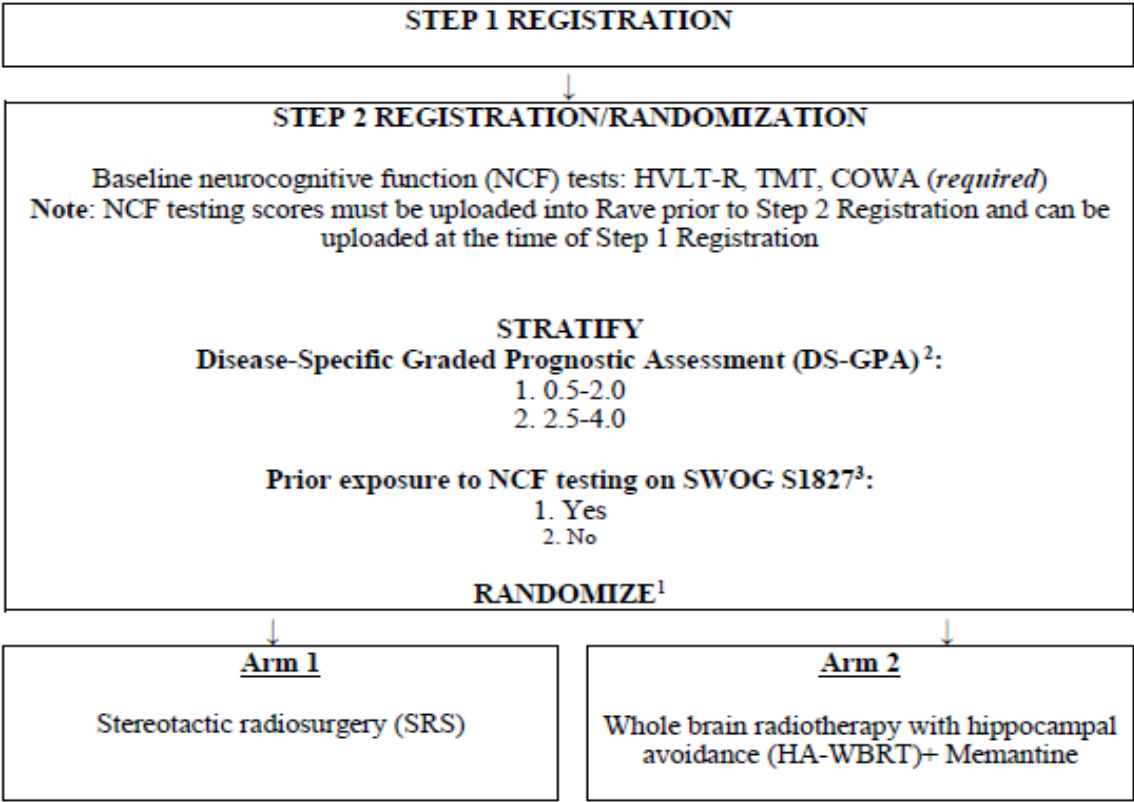
Schema

1 cycle = 28 days

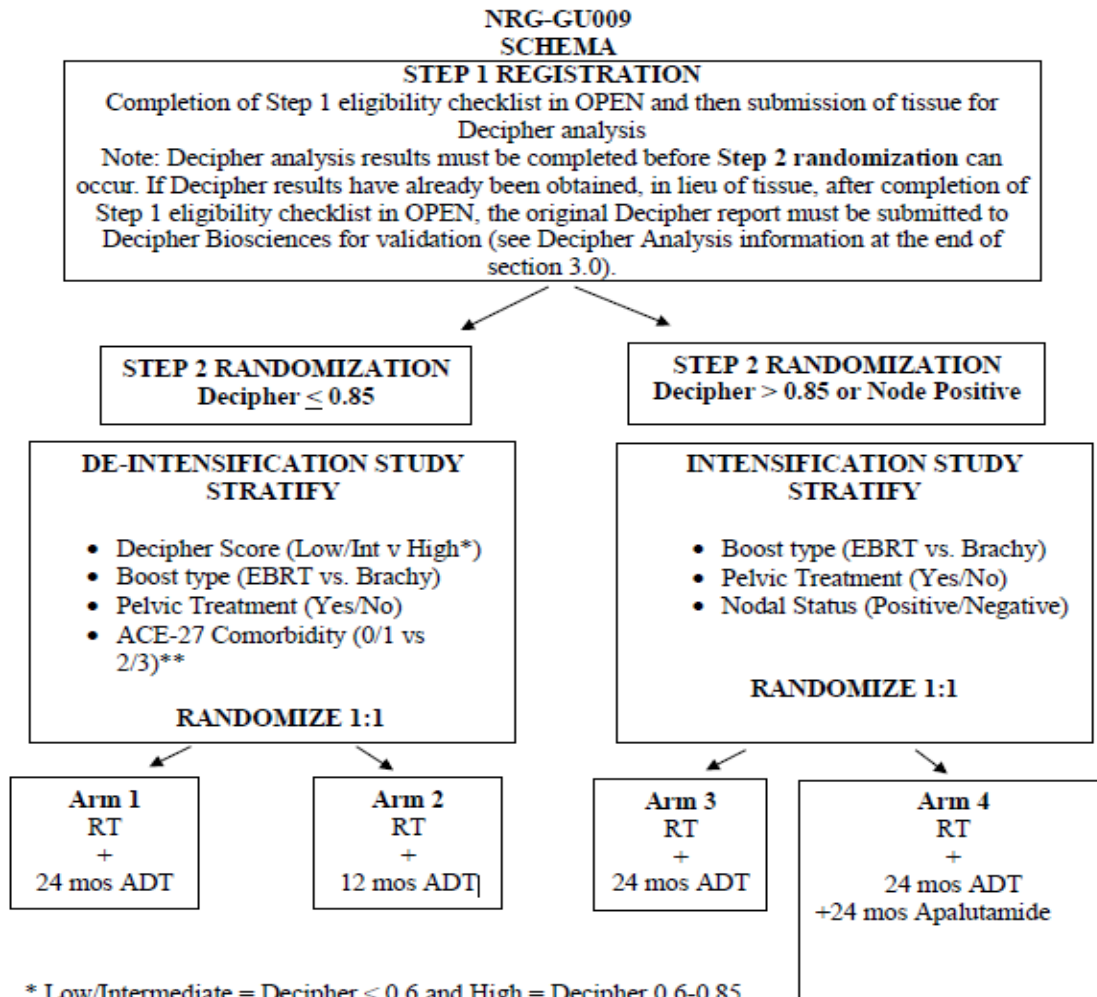




NRG-CC009
SCHEMA



¹Randomization is 1:1

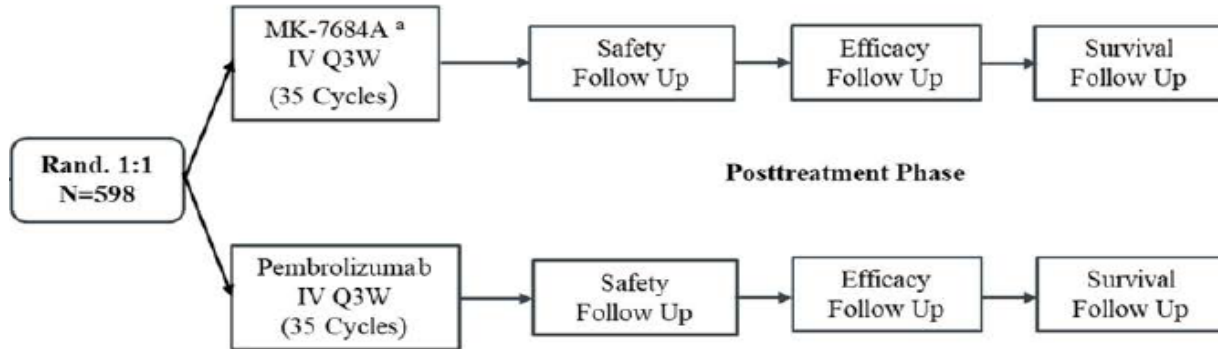


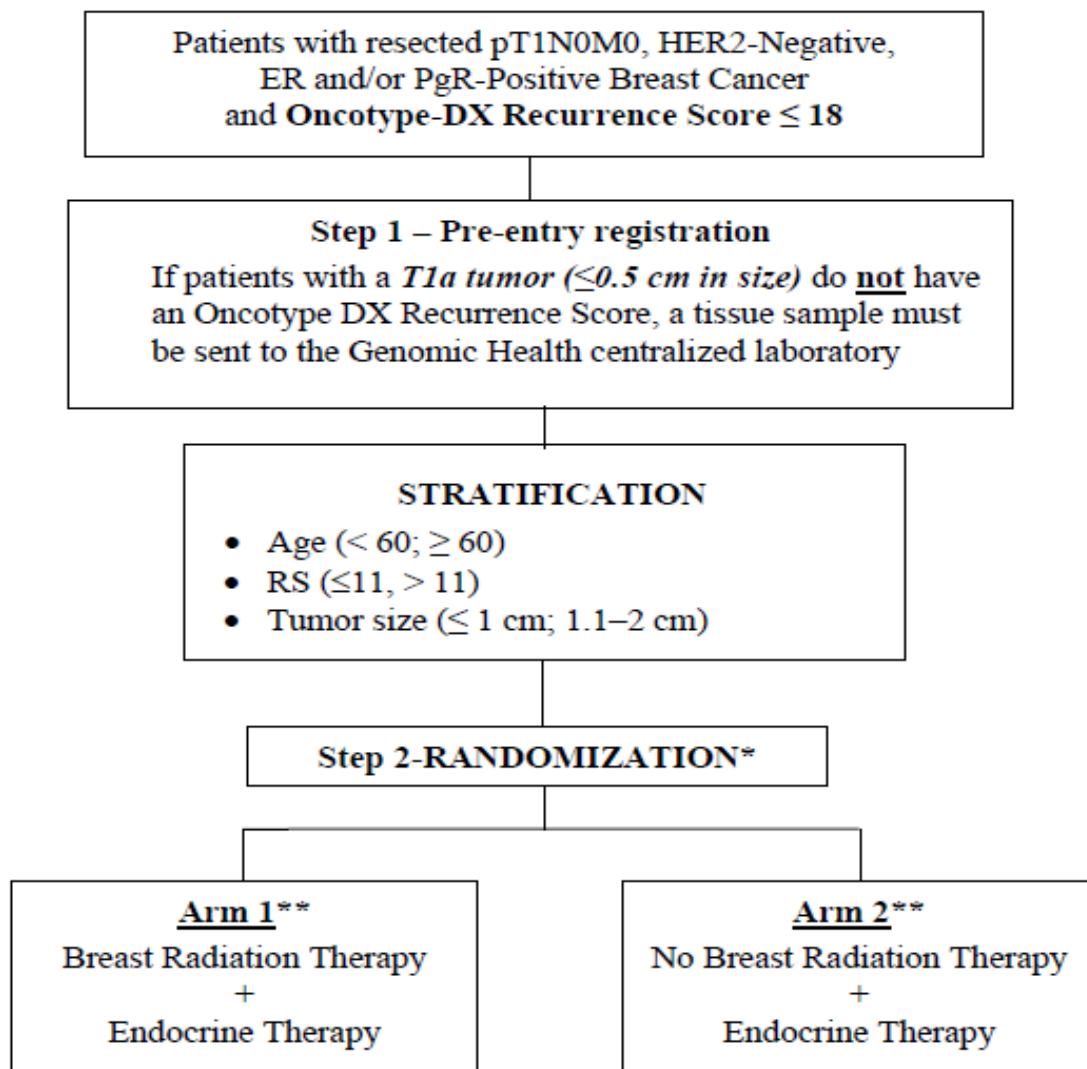
* Low/Intermediate = Decipher < 0.6 and High = Decipher $0.6-0.85$

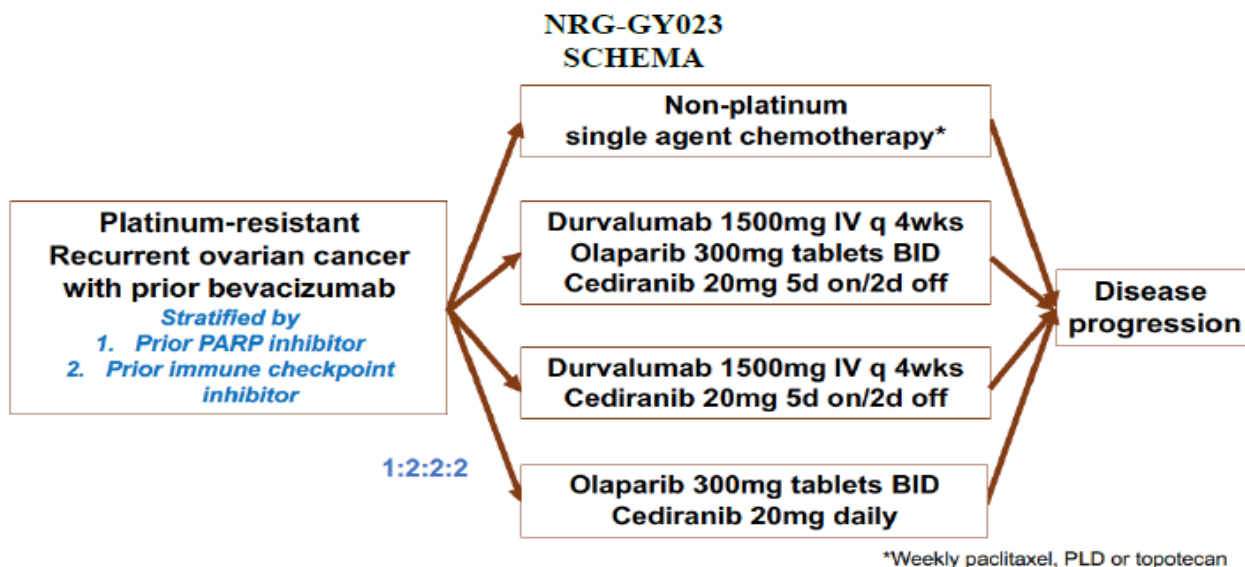
** http://comogram.org/assets/files/ace-27_ctr_ver_rtog_web.pdf

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







*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

Patient and spouse caregiver

Completion of baseline forms



RANDOMIZATION

Group 1
Control Arm



Financial literacy training

Group 2
Intervention Arm



Financial literacy training

+

Financial counseling with CENTS*
and PAF** once a month for 6 months

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

Induction Screening

Key eligibility criteria

- 1L ES-SCLC, treatment-naïve
- ECOG PS 0-1
- No CNS metastases

Enrollment
N ~690

Induction Treatment

Atezolizumab + carboplatin + etoposide
(4 cycles)

Optional PCI
(Investigator's discretion)

Baseline Maintenance

Maintenance Screening

Key eligibility criteria

- Ongoing response or SD per RECIST 1.1
- ECOG PS 0-1

Randomization (1:1)
N ~450

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)

Arm A

Atezolizumab 1200 mg IV +
Lurbinectedin 3.2 mg/m² Q3W

Maintenance

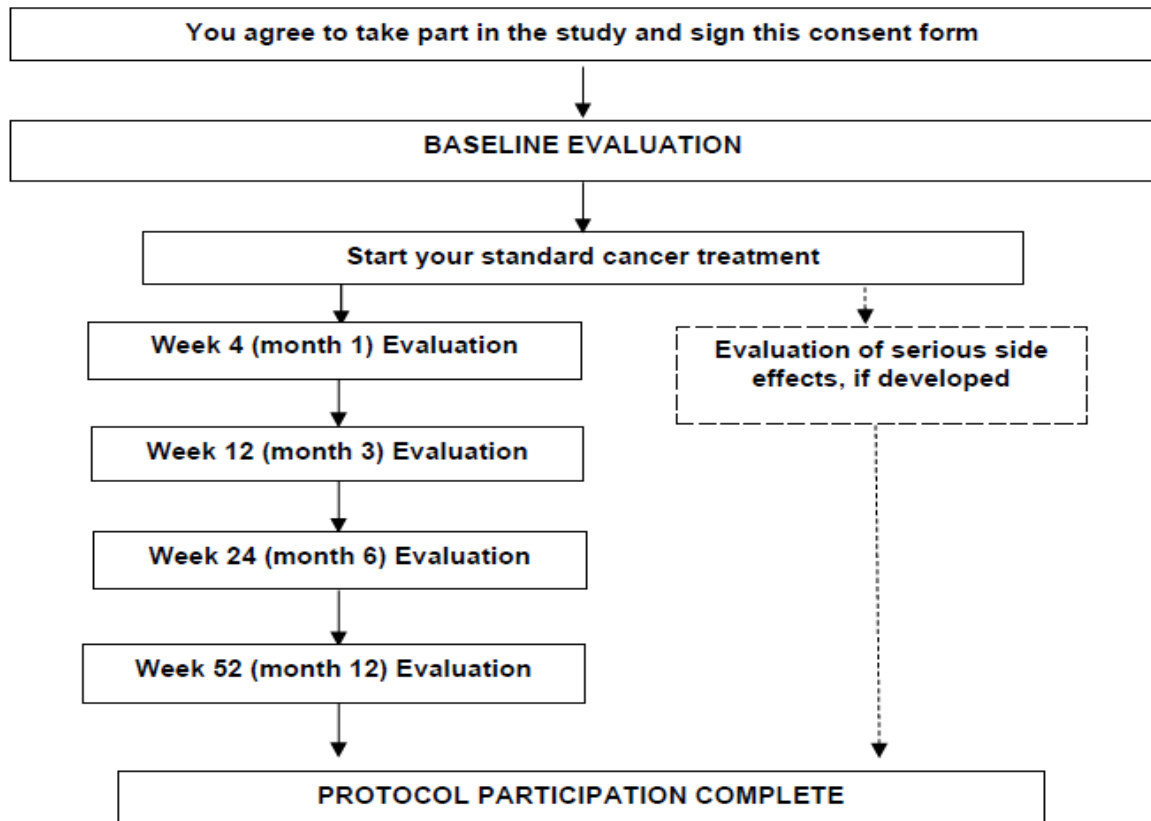
Arm B

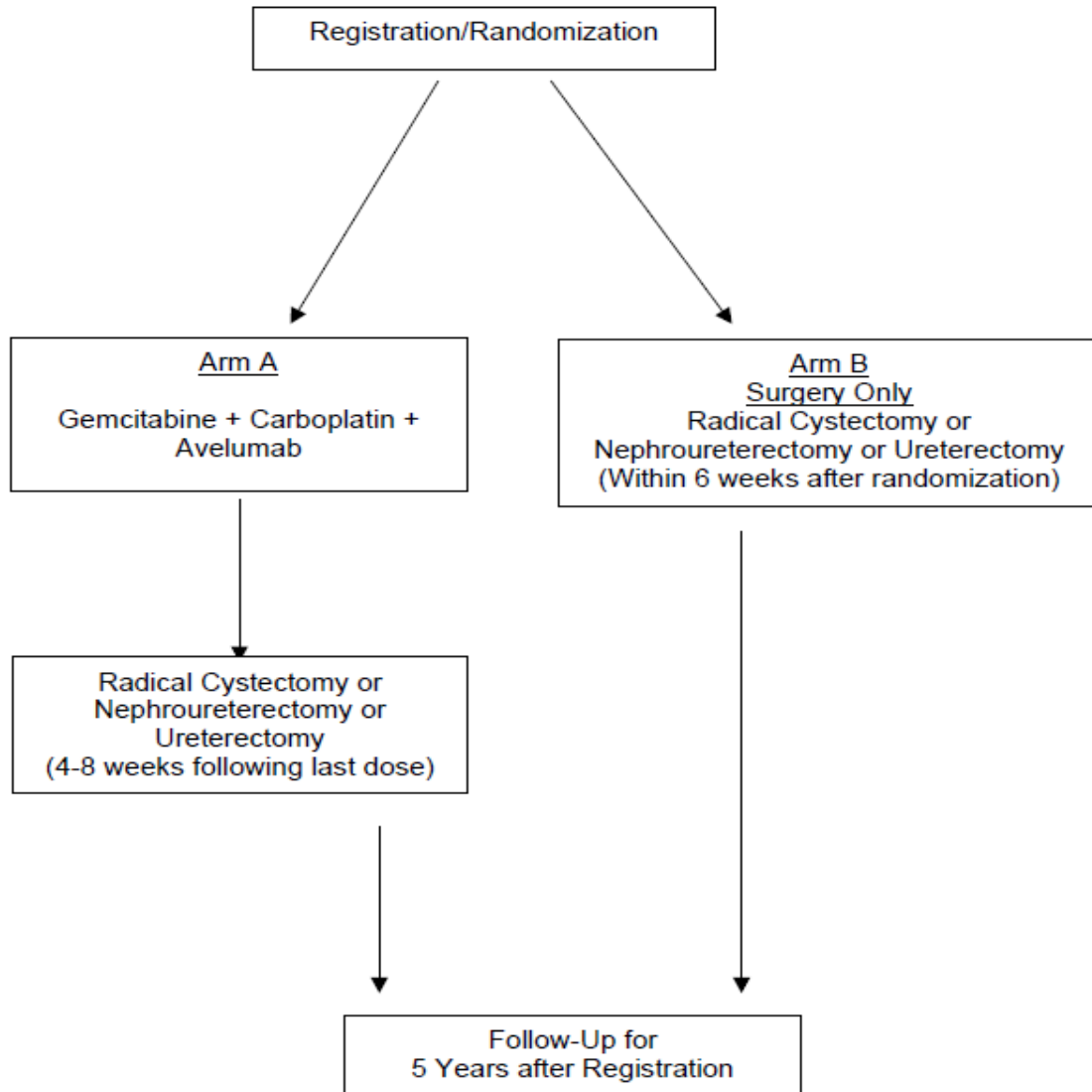
Atezolizumab 1200 mg IV Q3W

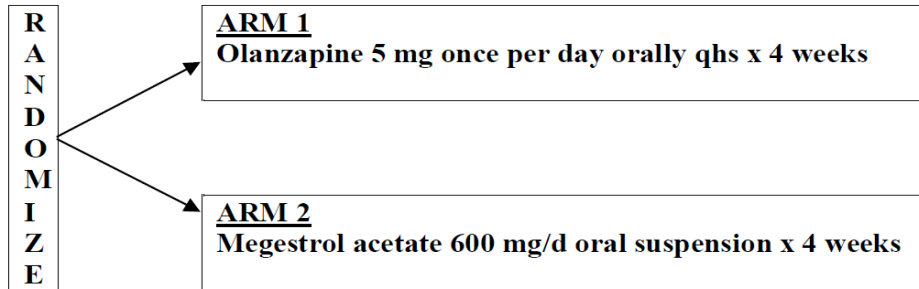
Treat until PD or unacceptable toxicity
No crossover allowed

Follow-Up

SCHEMA

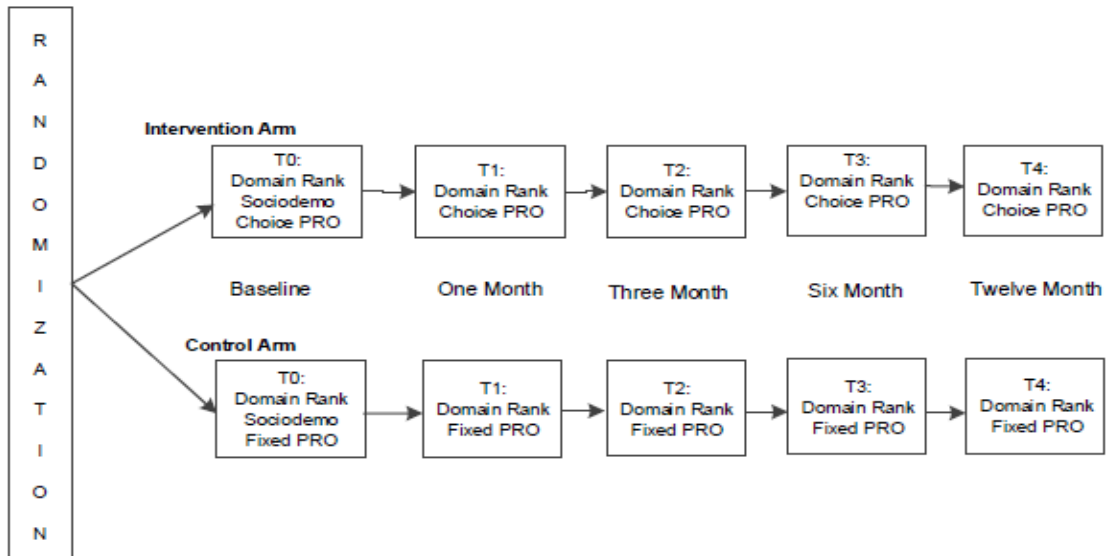






Treatment will continue for up to 4 weeks, unless the patient declines therapy or has unacceptable adverse events.

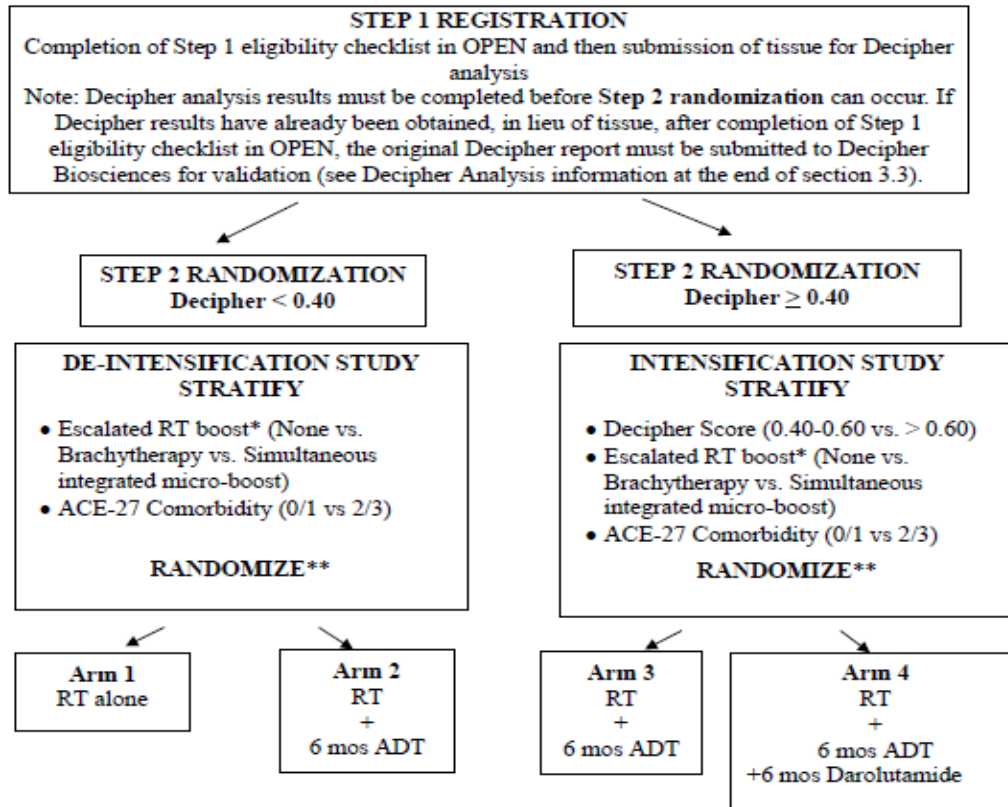
Schema



Eligibility: -Age 18 to 39 -Within 12 weeks of diagnosis -Performance Status 0-3 -Any stage of cancer -Favorable prognosis	Randomization: Stratified by sex, race, ethnicity, and age (emerging adults 18-25-year-old vs young adults 26-39-year-old)	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
--------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Accrual Goal = 400

SCHEMA

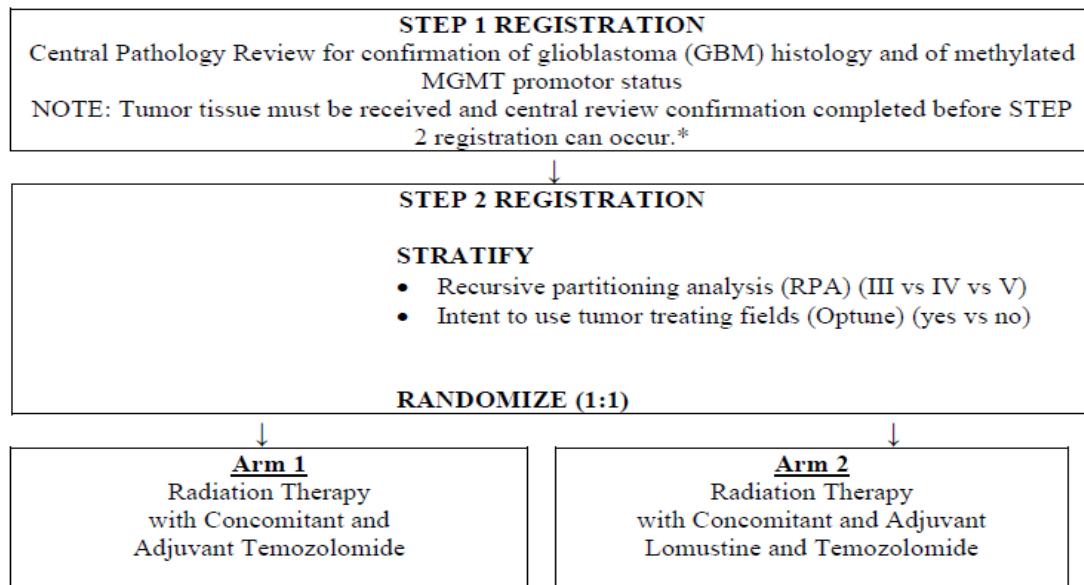


*For Escalated RT boost definition see Section 5.2 Establishing Treatment Approaches

**Randomization is 1:1

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

NRG-BN011
SCHEMA



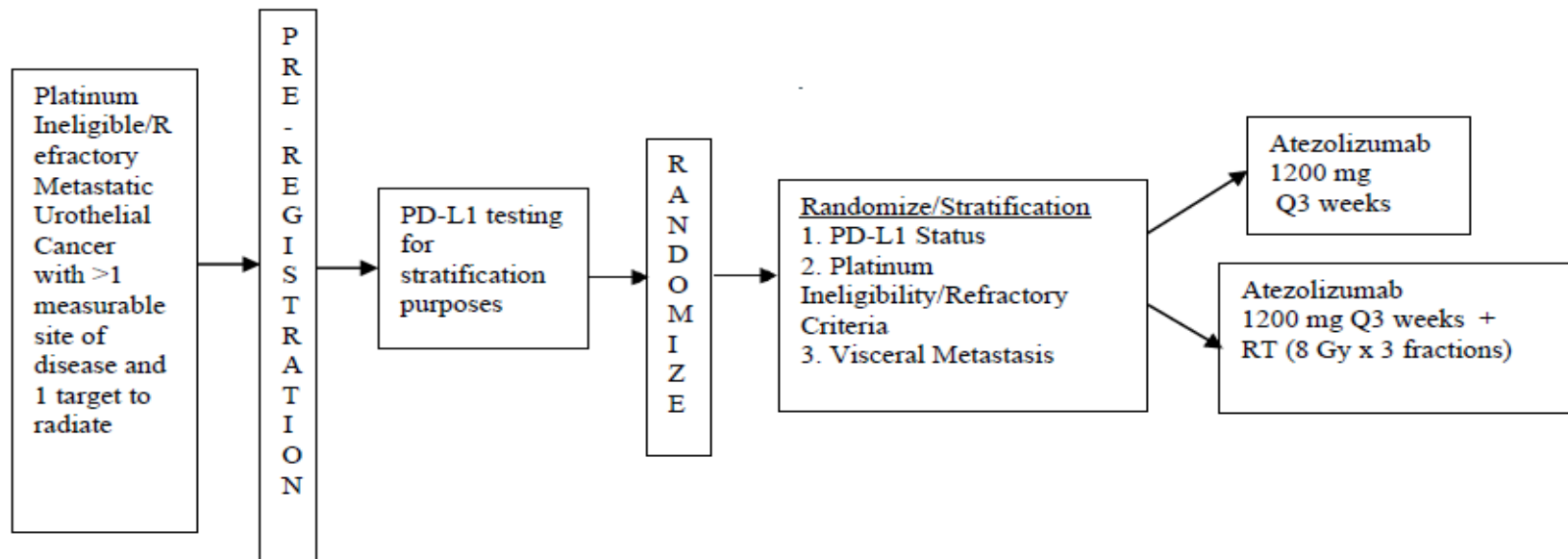
See [Section 5.1](#) for agent treatment details and [Section 5.2](#) for radiation therapy details.

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

Alliance A032002

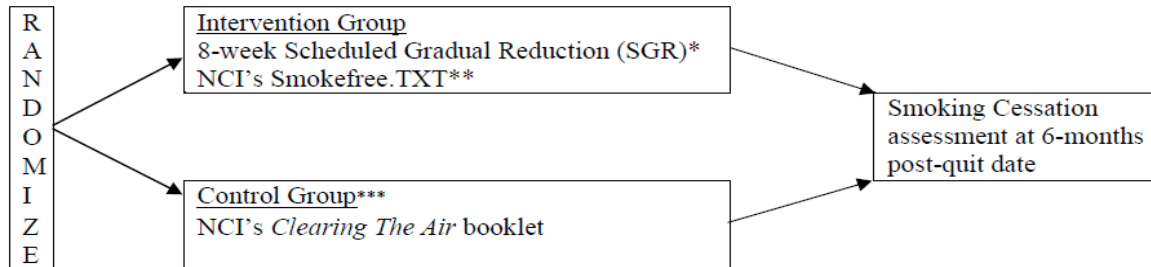
Schema

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.

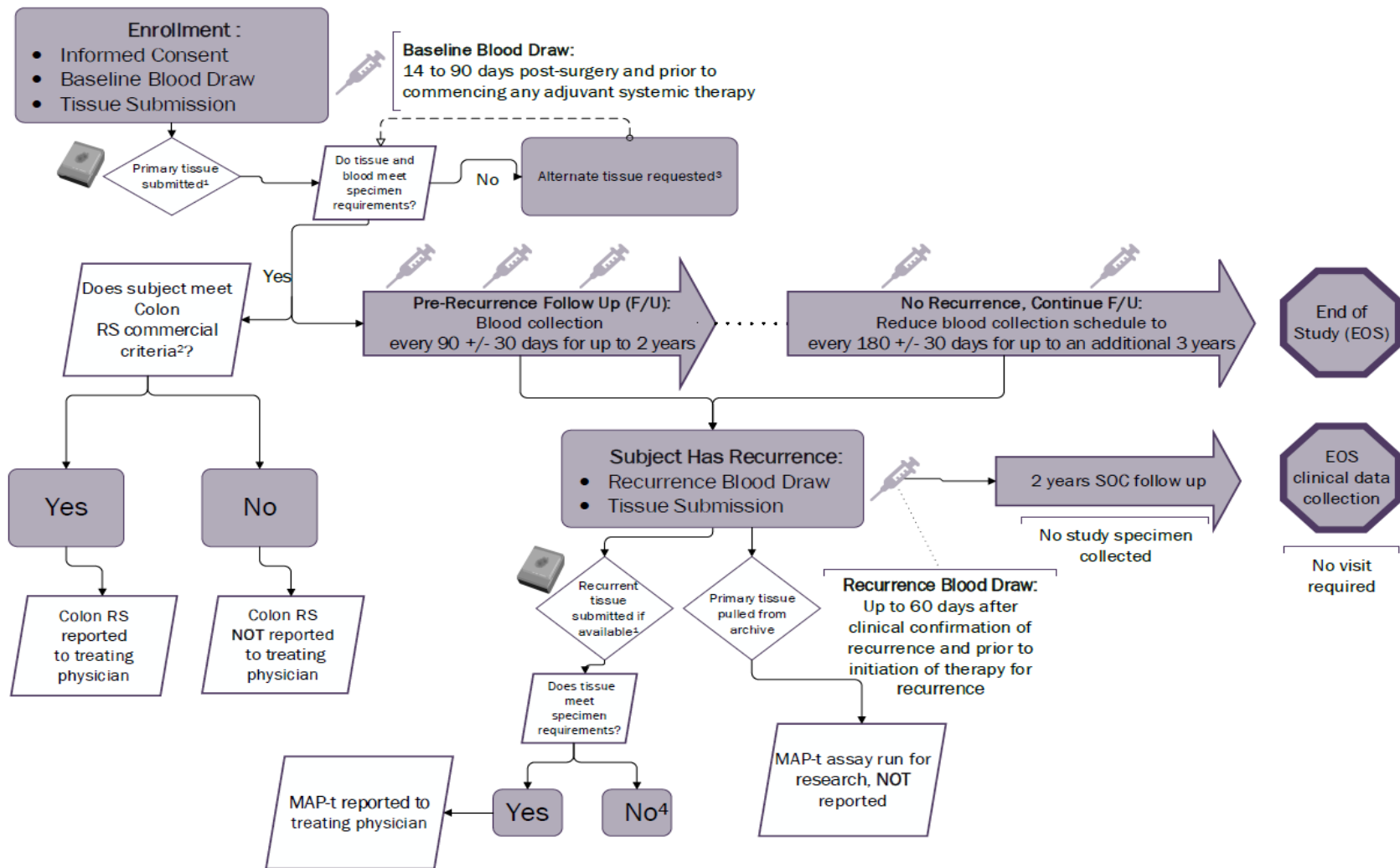
** NCI's Smokefree.TXT messages will start 2 weeks before quit date and extend for 4 weeks after quit date.

*** 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.

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

MENU



**NRG-GU011
SCHEMA**

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

STRATIFY

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

RANDOMIZE*



Arm 1
SABR + blinded placebo** for 6 months



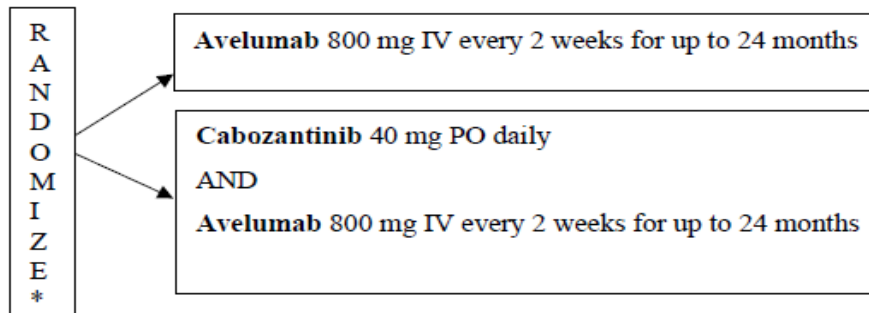
Arm 2
SABR + blinded relugolix** for 6 months

*Randomization is 1:1

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

Schema

1 Cycle = 28 Days



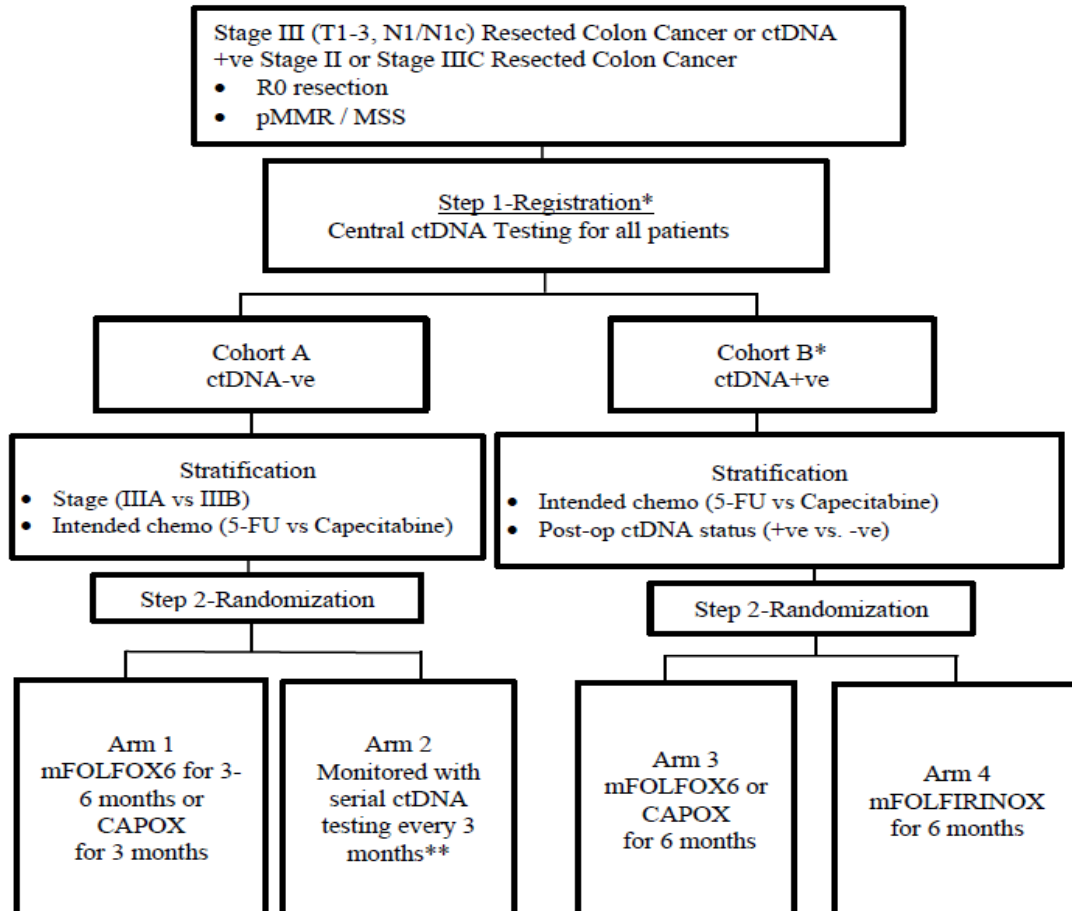
*Randomization is to occur 3-10 weeks after last dose of 1st-line treatment

Stratification:

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

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

Figure 1.
NRG-GI008 SCHEMA



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

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

STUDY SCHEMA

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

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

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

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

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

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

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

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

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

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

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

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

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



STRATIFY

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

RANDOMIZE (1:1 in each cohort)



Non-OPC/p16-negative OPC Cohort

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

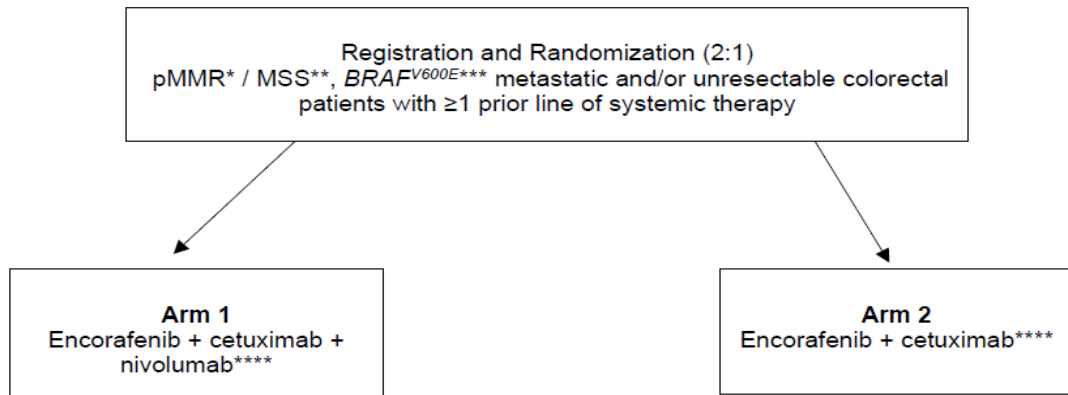
Arm 2: IMRT/IMPT + Low-dose cisplatin
weekly



p16-positive OPC/CUP Cohort

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

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



* 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

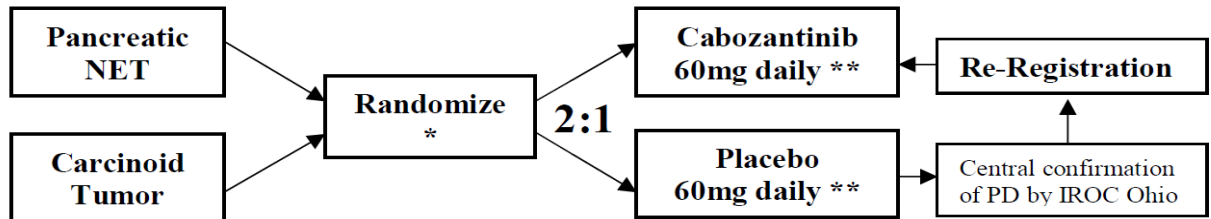
MENU



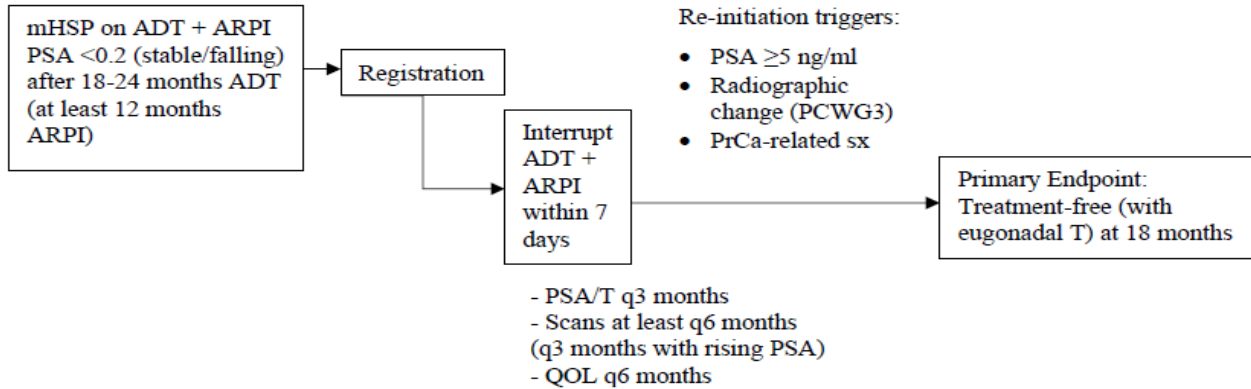
* During Cycles 1-4, one cycle is defined as 3 weeks. Beginning at Cycle 5, one cycle is defined as 4 weeks.

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

1 Cycle = 28 Days



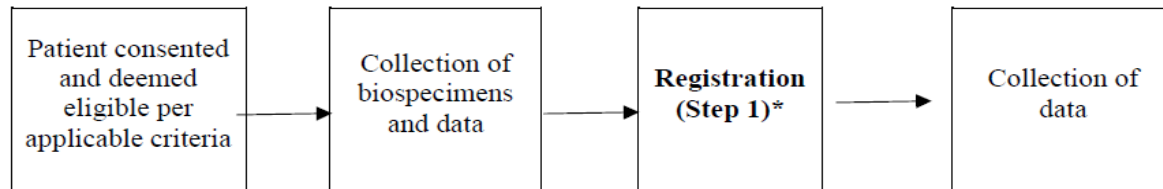
Schema



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

**At the time of
registration****

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

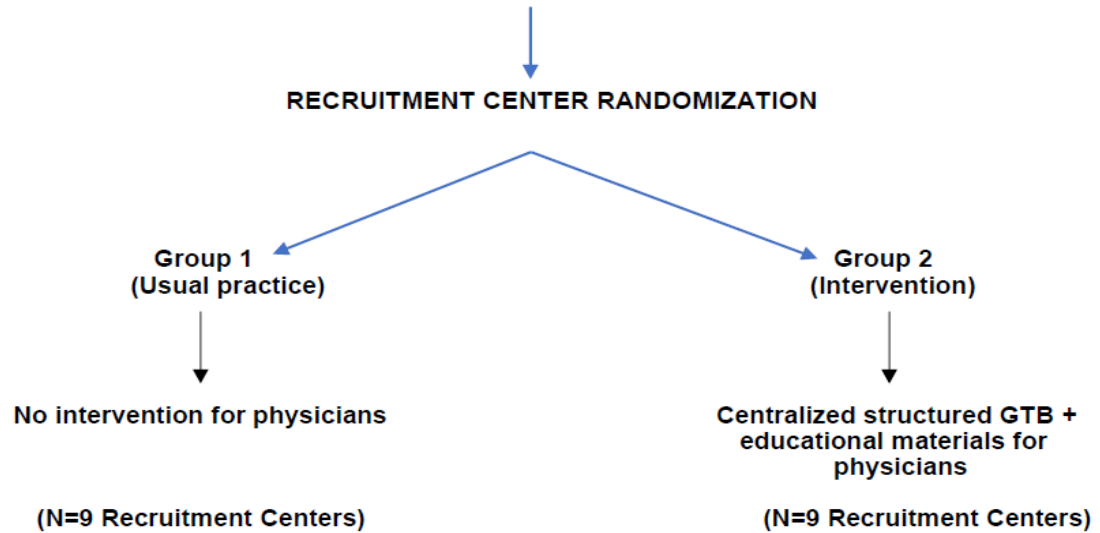


* Slot reservation required (see [Section 4.3](#)).

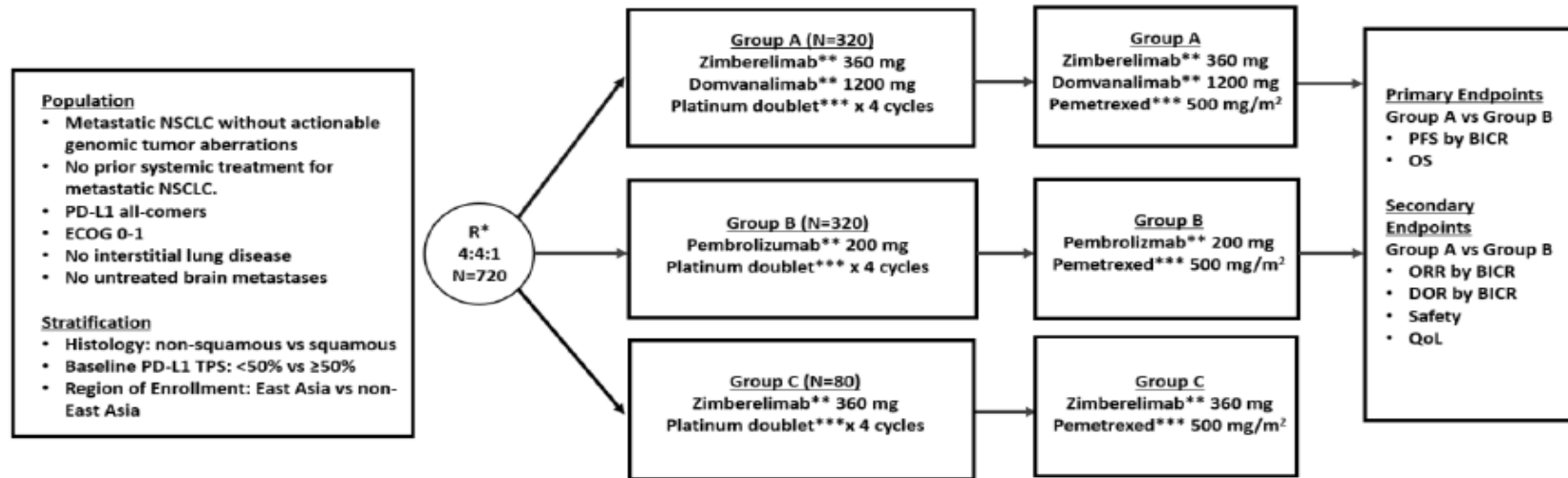
** For patients with a cancer diagnosis, biospecimens and data should be collected prior to any definitive therapy for the cancer.

SCHEMA

APPROVED NCORP AND MU-NCORP RECRUITMENT CENTERS*



* 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.

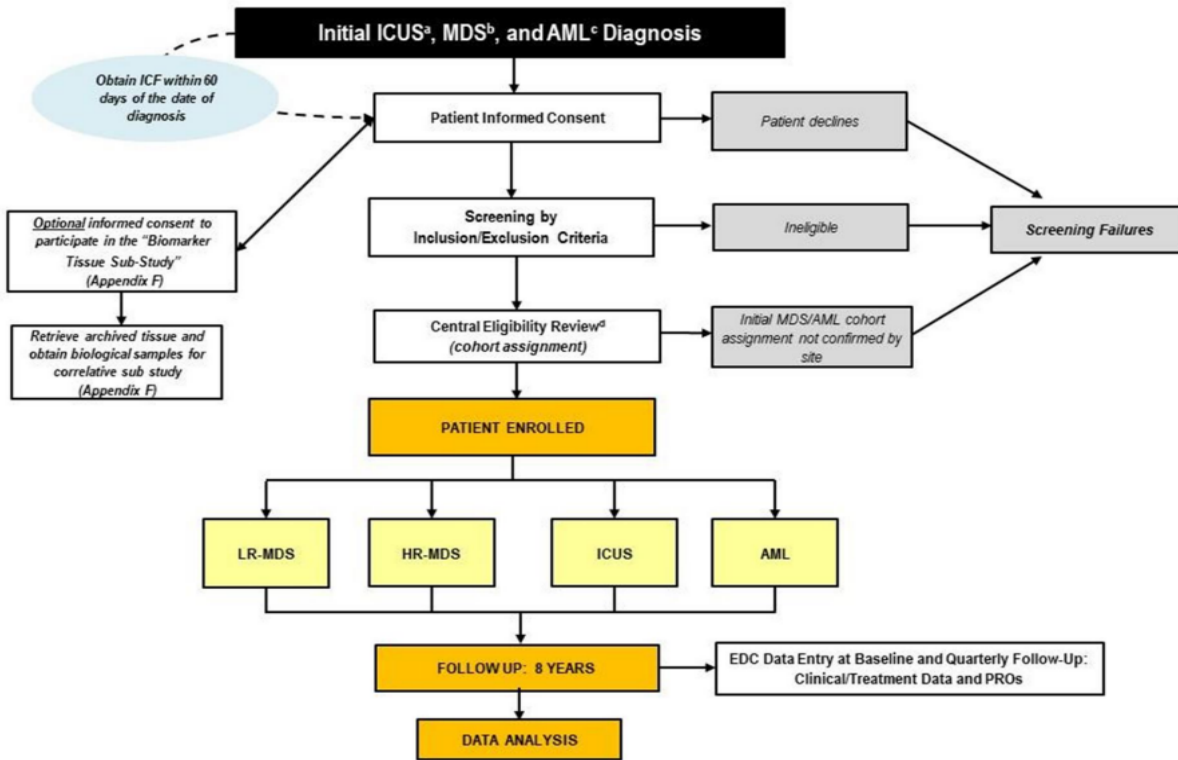


AUC = area under the curve; BICR = blinded independent central review; DOR = duration of response; ECOG = Eastern Cooperative Oncology Group; eDMC = external Data Monitoring Committee; NSCLC = non-small cell lung cancer; ORR = objective response rate; OS= overall survival; PD-L1 = programmed cell death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

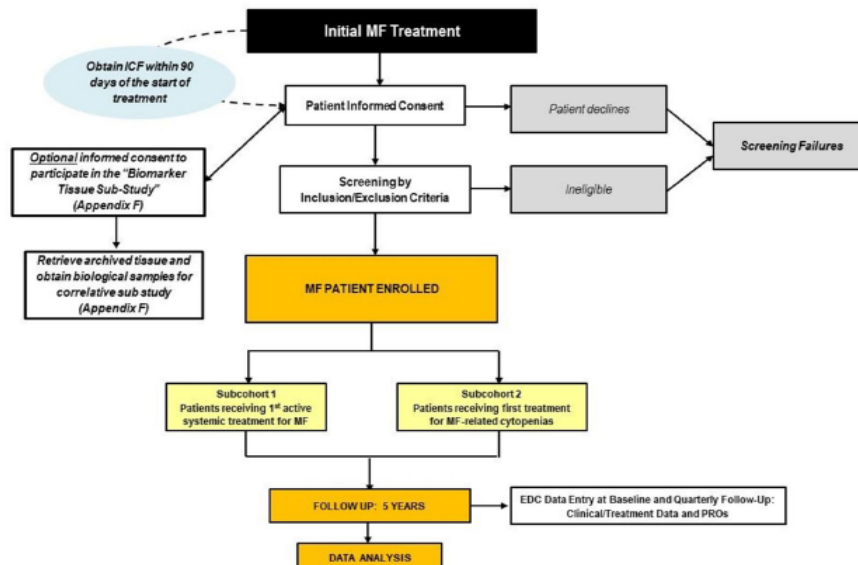
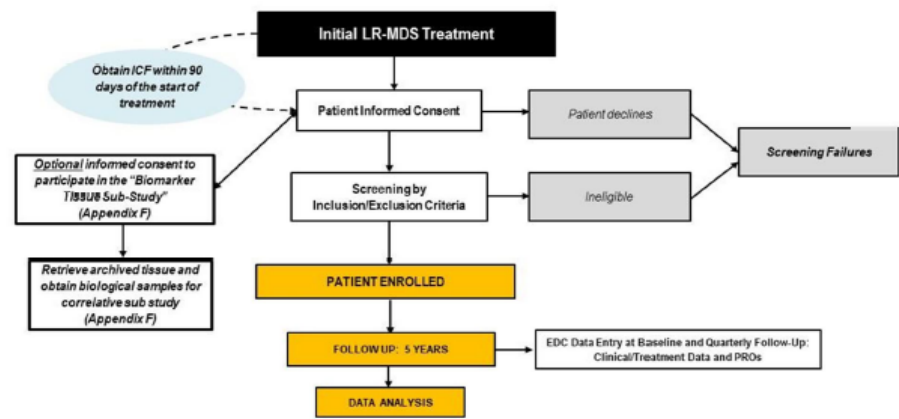
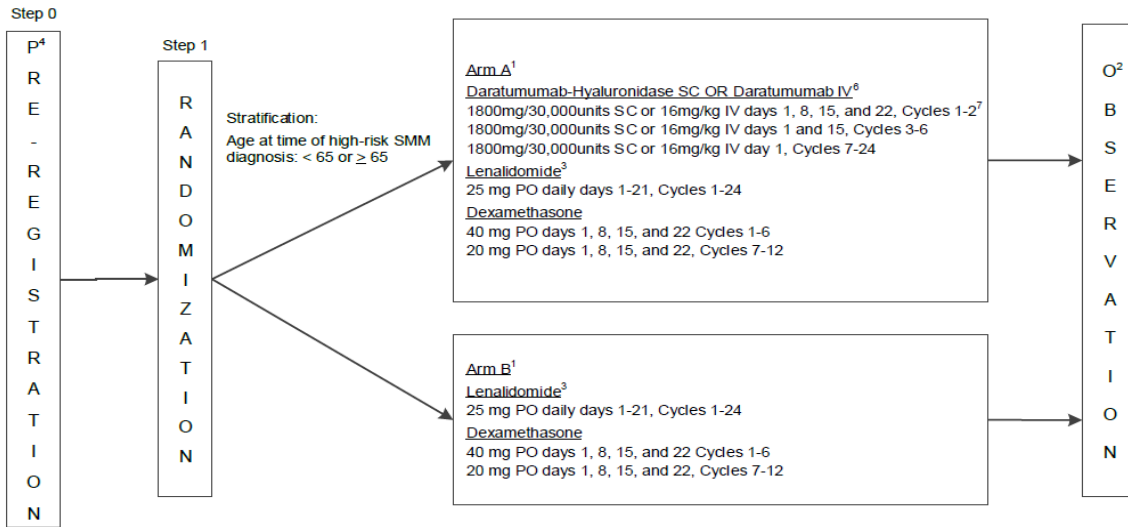


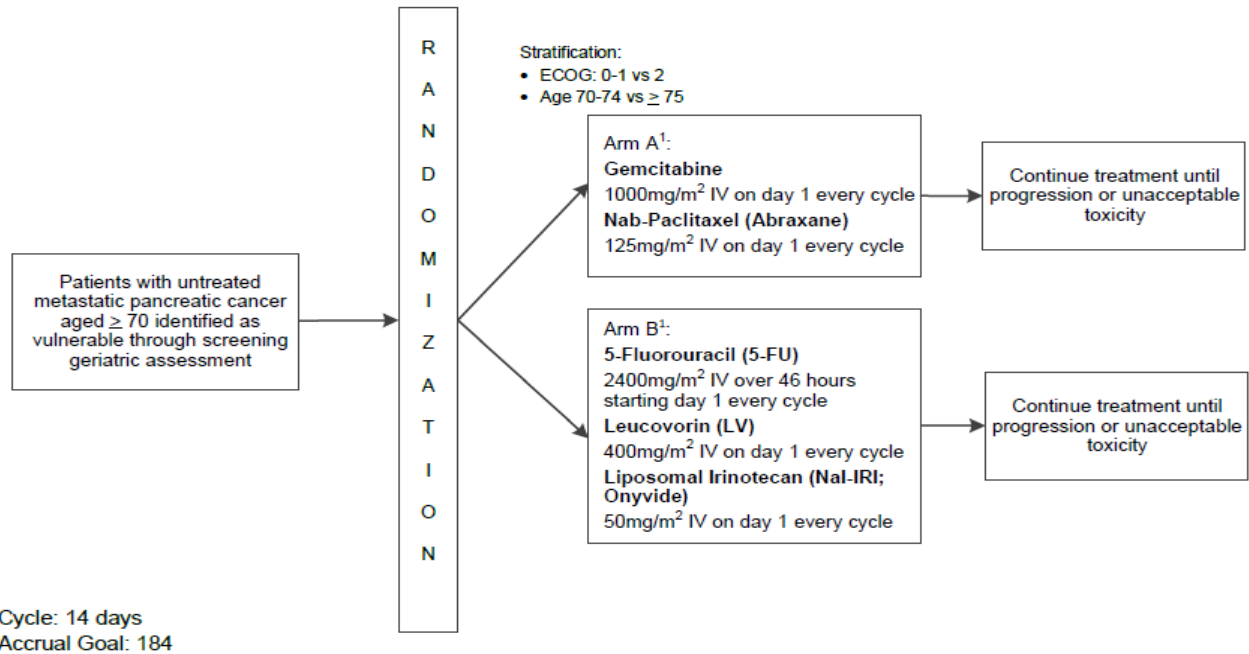
Figure 3: Study Schema: Treated LR-MDS Cohort



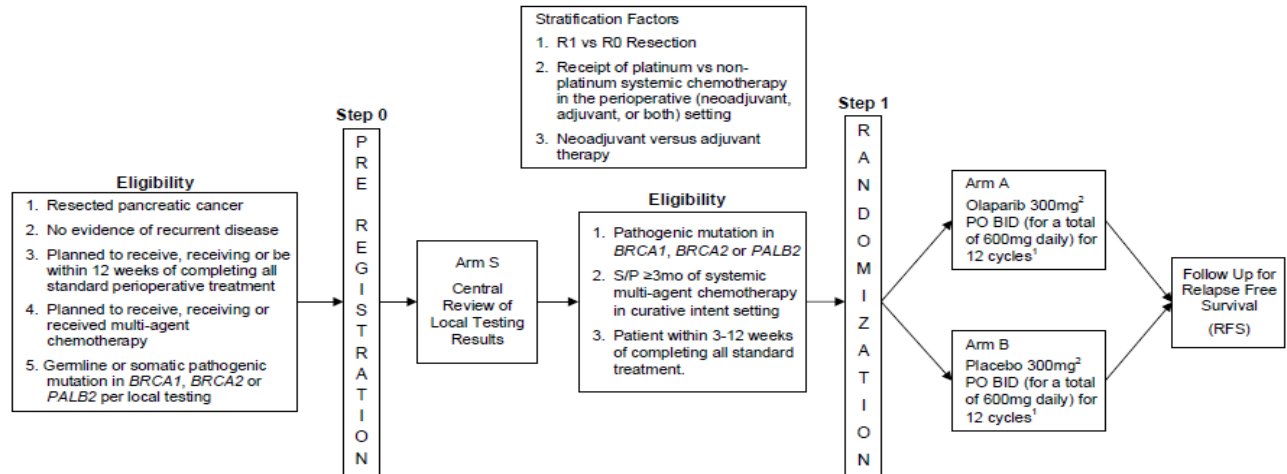


Accrual Goal: 288 patients with high-risk smoldering multiple myeloma.⁵
Cycle: 28 days

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



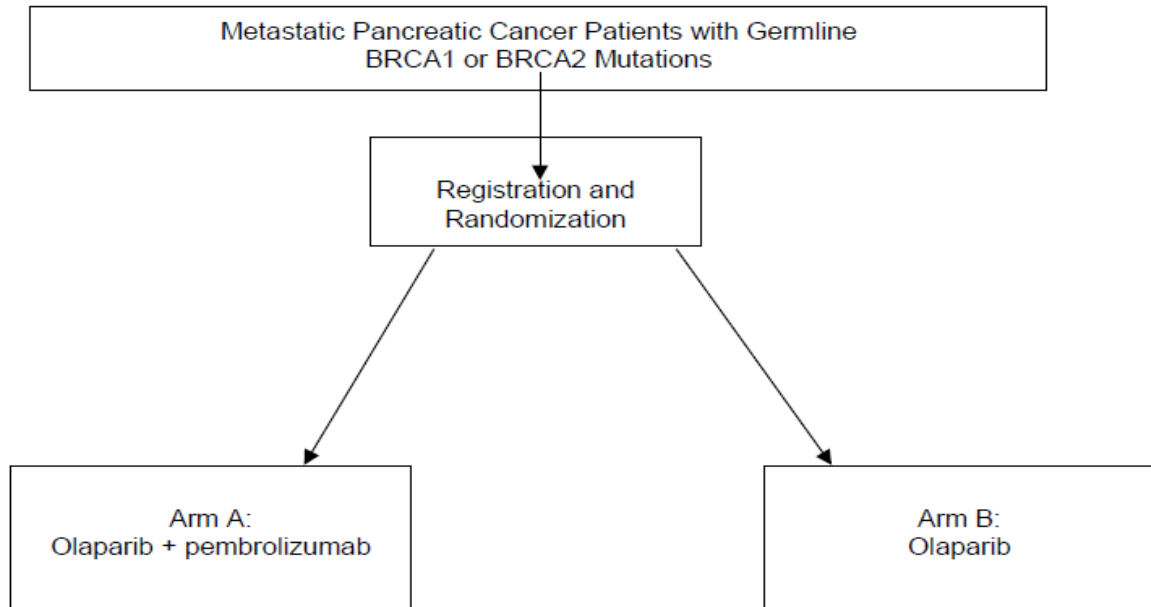
1. Patients will complete a comprehensive geriatric assessment and Quality of Life prior to starting treatment.

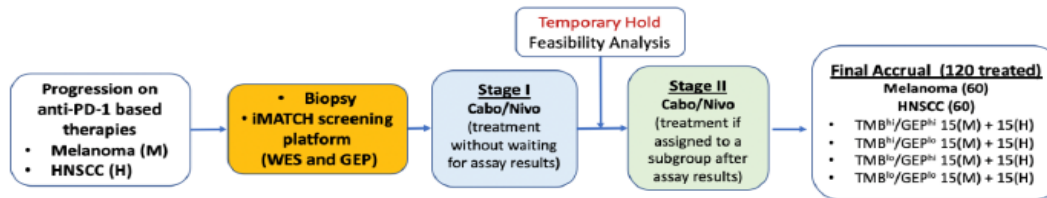


¹ One cycle = 4 weeks

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

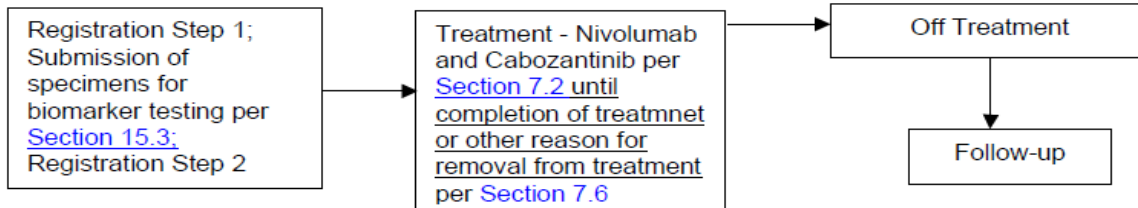
NOTE: Please note that when a patient has been successfully randomized, the confirmation of randomization will indicate that the patient is on Arm X. The patient will actually be randomized to Arm A or B, but as this is a double-blind trial, that information cannot be displayed.



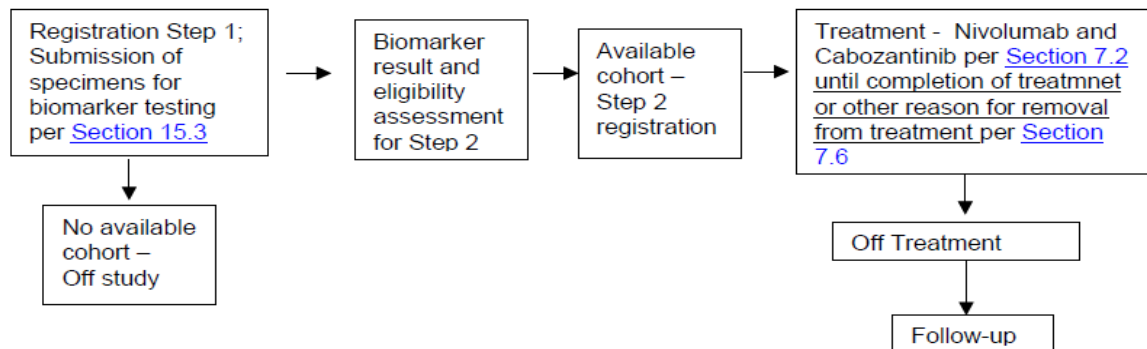


- TMB= tumor mutational burden; GEP = gene expression profiling for tumor inflammation score; WES = whole exome sequencing for tumor mutational burden
- Participants will be stratified into cohorts by disease type and biomarker status (TMB^{hi}/GEP^{hi}; TMB^{hi}/GEP^{lo}; TMB^{lo}/GEP^{hi}; TMB^{lo}/GEP^{lo})

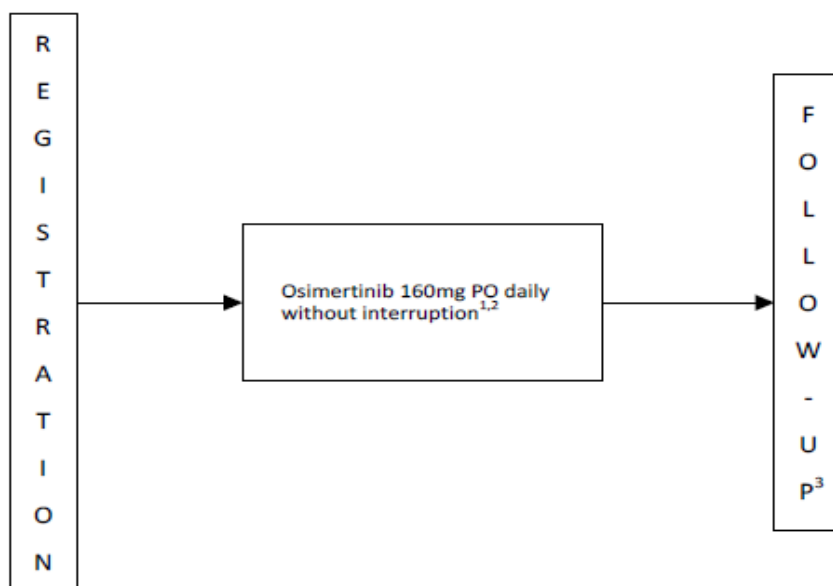
Stage I – Sites will order specimen kits per [Section 15.2](#) one week prior to registration. Sites will register participants to Step 1 registration. Sites must submit specimens for biomarker testing via the SWOG Specimen Tracking System within one day after Step 1 registration. Sites will register 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

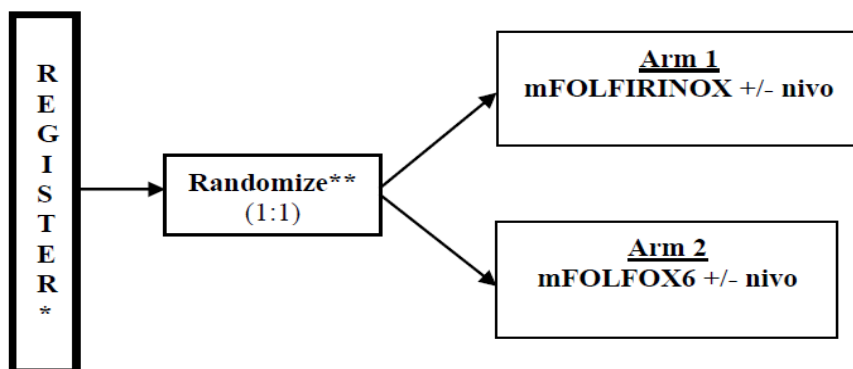


Cycle = 3 weeks (21 days)
Accrual = 20 patients

1. Until disease progression or unacceptable toxicities.
2. Restaging scans every 2 cycles (6 weeks).
3. Patients will be followed for 5 years from registration.

The primary endpoint is best objective response per RECIST 1.1, with confirmation of response required.

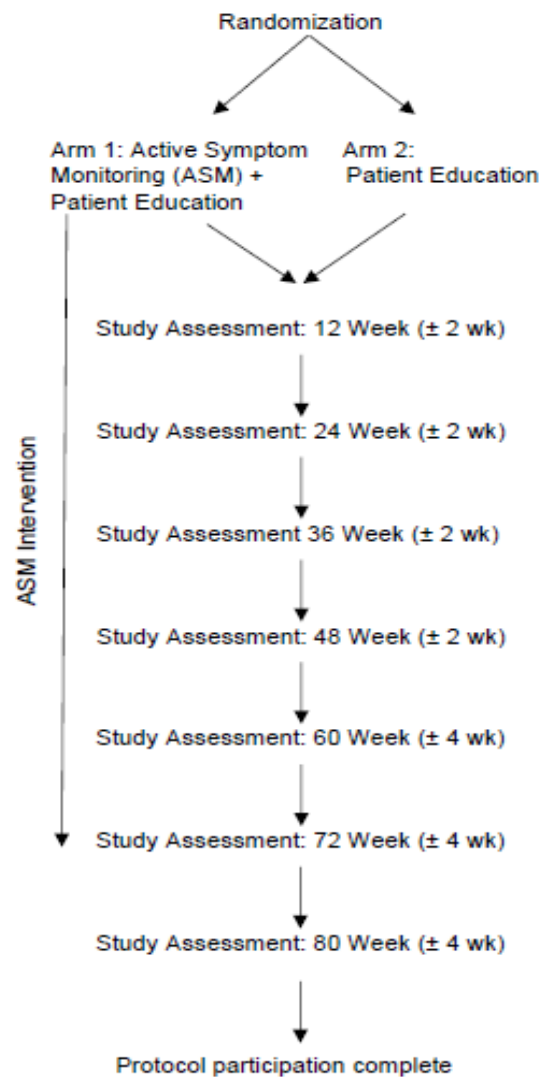
Schema



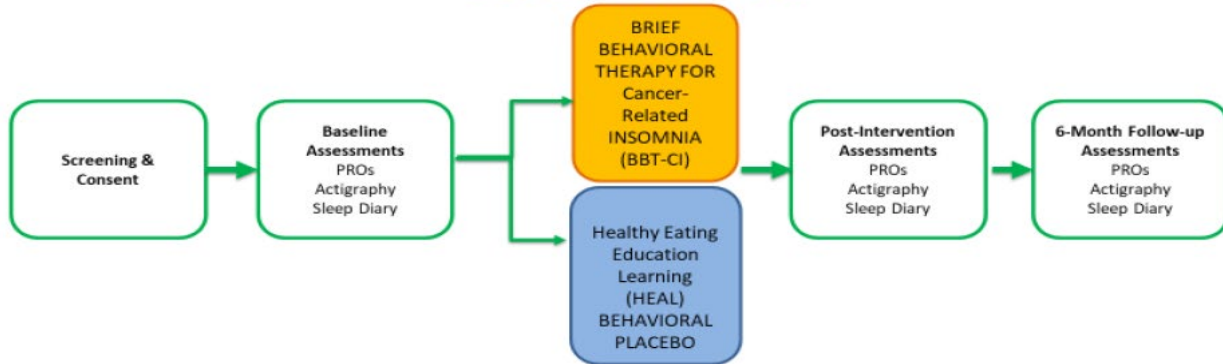
* Patients with newly diagnosed advanced unresectable or metastatic HER2 negative gastric, GEJ, esophageal adenocarcinoma

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

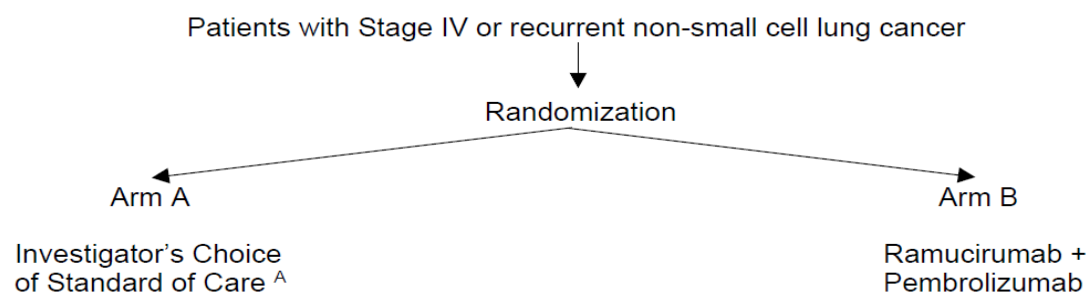
Patients will be treated using 14-day cycles until disease progression or discontinuation of treatment for other reasons (e.g. unacceptable adverse events, withdrawal, etc.); oxaliplatin will be given up to 12 cycles.



Study Schema



SCHEMA



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

Metastatic Type I or II Papillary
Renal Cell Carcinoma

