



MASTER TRIAL LIST

SEPTEMBER 2021

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

JUST IN TIME TRIALS (JIT)

AML

ANAL

ALL

APL

BLADDER-UROTHELIAL

BRAIN

BREAST/ GYN

CANCER CONTROL

CARCINOID

CLL

CML

COLON-RECTAL

ESOPHAGEAL - GASTRIC

HEAD & NECK

LYMPHOMA

MDS

MELANOMA

MERKEL

MOLECULAR STUDIES

MULTIPLE MYELOMA

NSCLC

PANCREATIC

PROSTATE

RADIATION TRIALS

RENAL CELL

SMALL CELL LUNG CANCER

VULVA

Updated 9.7.21

RADIATION LOCATIONS:

OSF Glen Oak - OSF main hospital

OSF Route 91 (attached to Illinois CancerCare)

UPHM - Unity Point Health Methodist

Galesburg - Western Illinois Cancer Treatment Center



JUST IN TIME (JIT) TRIALS

*Contact Disease Specific Navigator

Brain

[A021804](#)

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

[A071702](#)

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

Breast

[S1706](#)

(RT not credentialed yet)-A Phase II Randomized Trial of Olaparib (NSC-747856) Administered Concurrently with Radiotherapy versus Radiotherapy Alone for Inflammatory Breast Cancer

CML

[S1712](#)

A Randomized Phase II Study of Ruxolitinib in Combination with BCR-ABL Tyrosine Kinase Inhibitors in Chronic Myeloid Leukemia Patients with Evidence of Molecular Disease.

Endometrial

[GY014](#)

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

Gastrointestinal

[EA2187](#)

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

[EA2197](#)

Optimal Perioperative Therapy for Incidental Gallbladder Cancer (OPT-IN): A Randomized Phase II/III Trial

[S1922](#)

Randomized Phase II Selection Study of Ramucirumab and Paclitaxel versus FOLFIRI in Refractory Small Bowel Adenocarcinoma

Genitourinary - Rare

[A031702](#)

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

Head & Neck	
<u>EA3191</u>	(RT at Route-91) A Phase II Randomized Trial of Adjuvant Therapy With Pembrolizumab After Resection of Recurrent/Second Primary Head and Neck Squamous Cell Carcinoma With High Risk Features
Lymphoma	
<u>S1608</u>	Randomized Phase II Trial in Early Relapsing or Refractory Follicular Lymphoma
Melanoma	
<u>EA6192</u>	A Phase II Study of Biomarker Driven Early Discontinuation of Anti-PD-1 Therapy in Patients With Advanced Melanoma (PET-Stop)
<u>S1801</u>	A Phase II Randomized Study of Adjuvant versus NeoAdjuvant MK-3475 (Pembrolizumab) for Clinically Detectable Stage III-IV High-Risk Melanoma
Multi-Disease	
<u>S1614</u>	<i>(temp closed)</i> A Phase III Randomized Trial of Prophylactic Antiviral Therapy in Patients with Current or past hepatitis B Virus Infection Receiving Anti-Cancer Therapy for Solid Tumors
Nasopharyngeal	
<u>NRG-HN007</u>	<i>(temp closed)</i> An Open-Label, Phase III Study of Platinum-Gemcitabine With or Without Nivolumab in the First-Line Treatment of Recurrent or Metastatic Nasopharyngeal Carcinoma
Ovarian	
<u>GY014</u>	<i>(temp closed)</i> Phase II Study of Tazemetostat (EPZ-6438) (IND # 138671) in Recurrent or Persistent Endometrioid or Clear Cell Carcinoma of the Ovary, and Recurrent or Persistent Endometrioid Endometrial Adenocarcinoma
Pancreas	
<u>S2001</u>	Randomized Phase II Clinical Trial of Olaparib + Pembrolizumab vs. Olaparib Alone as Maintenance Therapy in Metastatic Pancreatic Cancer Patients with Germline BRCA1 or BRCA2 Mutations
Rectal	
<u>EA2201</u>	(RT at Glen Oak, UPHM, Galesburg) A Phase II Study of Neoadjuvant Nivolumab Plus Ipilimumab and Short-Course Radiation in MSI-H/dMMR Locally Advanced Rectal Adenocarcinoma
Sarcoma	

<u>A091902</u>	A Multicenter Phase II Trial of Paclitaxel With and Without Nivolumab in Taxane Naive, and Nivolumab and Cabozantinib in Taxane Pretreated Subjects With Angiosarcoma
Skin	
<u>A091802</u>	Phase II randomized Trial of Avelumab plus cetuximab versus avelumab alone in advanced cutaneous Squamous cell carcinoma of skin
Thymoma	
<u>S1701</u>	A Randomized Phase II Trial of Carboplatin-Paclitaxel with or without Ramucirumab in Patients with Unresectable Locally Advanced, Recurrent, or Metastatic Thymic Carcinoma



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MASTER TRIAL LIST

SEPTEMBER 2021

MENU

AML

Navigator - Heather x3661

[Connect MDS/AML](#)

The Myelodysplastic Syndromes (MDS) and Acute Myeloid Leukemia (AML) Disease Registry This also included ICUS. *(enrolling low risk MDS only)*



MASTER TRIAL LIST

SEPTEMBER 2021



ANAL

Navigator - Carrie x3621

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



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APL

Navigator - Heather x3661

There are no trials available at this time



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SEPTEMBER 2021

MENU

ACUTE LYMPHOBLASTIC LEUKEMIA

Navigator - Heather x3661

EA9152

SCHEMA

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



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SEPTEMBER 2021



BLADDER / UROTHELIAL

Navigator - Carrie x3621

ADJUVANT / NEOADJUVANT

<p><u>BMS CA017-078</u></p> <p>SCHEMA</p>	<p>(Peoria, Bloomington, Galesburg, and Peru) -A Phase 3, Randomized, Study of Neoadjuvant Chemotherapy alone versus Neoadjuvant Chemotherapy plus Nivolumab or Nivolumab and BMS-986205, Followed by Continued Post-Surgery Therapy with Nivolumab or Nivolumab and BMS-986205 in Participants with Muscle-Invasive Bladder Cancer</p>
<p><u>EA8185</u></p>	<p>(RT pending at Glen Oak & Rt-91) Phase 2 Study of Bladder-Sparing Chemoradiation With MEDI4736 (Durvalumab) in Clinical Stage 3, Node Positive Bladder Cancer (INSPIRE)</p>
<p><u>EA8192</u></p> <p>SCHEMA</p>	<p>A Phase II/III Trial of MEDI4736 (Durvalumab) and Chemotherapy for Patients With High Grade Upper Tract Urothelial Cancer Prior to Nephroureterectomy</p>
<p><u>S1806</u></p> <p>SCHEMA</p>	<p>(RT at Glen Oak, UPHM and Galesburg) Phase III Randomized Trial of Concurrent Chemoradiotherapy with or without Atezolizumab in Localized Muscle Invasive Bladder Cancer</p>
<h3>METASTATIC</h3>	
<p><u>A031901</u></p> <p>SCHEMA</p>	<p>Duration of Immune Checkpoint Therapy in Locally Advanced or Metastatic Urothelial Carcinoma: A Randomized Phase 3 Non-Inferiority Trial</p>
<p><u>S1937</u></p> <p>SCHEMA</p>	<p>A Phase III Randomized Trial of Eribulin (NSC #707389) With or Without Gemcitabine Versus Standard of Care (Physician's Choice) for Treatment of Metastatic Urothelial Carcinoma Refractory to, or Ineligible for, Anti PD1/PDL1 Therapy</p>



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SEPTEMBER 2021



BRAIN

Navigator - Carrie x3621

<p><u>BN007</u></p> <p>SCHEMA</p>	<p>(RT at UPHM, Glen Oak, Galesburg) A Randomized Phase II/III Open-Label Study of Ipilimumab and Nivolumab Versus Temozolomide in Patients With Newly Diagnosed MGMT (Tumor O-6-Methylguanine DNA Methyltransferase) Unmethylated Glioblastoma</p>
<p><u>N0577</u></p>	<p>(RT at Glen Oak, RT 91, and UPHM) Phase III Intergroup Study of Radiotherapy with Concomitant and Adjuvant Temozolomide versus Radiotherapy with Adjuvant PCV Chemotherapy in Patients with 1p/19q Co-deleted Anaplastic Glioma or Low Grade Glioma</p>



BREAST

Navigator - Angie x3613

NEO/ADJUVANT TREATMENT

S1706*

RT credentialing pending - 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

SCHEMA

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)

Neo/Adjuvant - Hormone Receptor Positive / HER2 Negative

BR007

SCHEMA

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

Neo/Adjuvant - Triple Negative

No trials at this time.

METASTATIC TREATMENT

Metastatic - HER2 Positive

BR004

SCHEMA

A Randomized, Double-Blind, Phase III Trial of Paclitaxel/Trastuzumab/Pertuzumab with Atezolizumab or Placebo in First-Line HER2-Positive Metastatic Breast Cancer

SGNTUC-016

SCHEMA

Randomized, Double-blind, Phase 3 Study of Tucatinib or Placebo in Combination With Ado-trastuzumab Emtansine (T-DM1) for Subjects With Unresectable Locally-advanced or Metastatic HER2+ Breast Cancer (HER2CLIMB-02)

Metastatic - Hormone Receptor Positive / HER2 Negative

EFC15935

SCHEMA

A Randomized, Multicenter, Double-blind Phase 3 Study of SAR439859 Plus Palbociclib Versus Letrozole Plus Palbociclib for the Treatment of Patients With ER (+), HER2 (-) Breast Cancer Who Have Not Received Prior Systemic Anti-cancer Treatment for Advanced Disease | AMEERA-5 (**ILCC clinics: Peoria, Bloomington, Galesburg, Ottawa, Pekin, Peru**)

<u>S1703</u>	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
<u>S2007</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

SURGERY / RADIATION ONLY

<u>A011202</u> SCHEMA	A Randomized Phase III Trial Evaluating the Role of Axillary Lymph Node Dissection in breast Cancer Patients (cT1-3 N1) Who Have Positive Lymph Node Disease After Neoadjuvant Chemotherapy. <i>(RT: Glen Oak, Rt 91, UPHM, Galesburg)</i>
<u>BR002</u>	Temporarily Closed - A Phase IIR/III Trial of Standard of Care Therapy with or without Stereotactic Body Radiotherapy (SBRT) and/or Surgical Ablation for Newly Diagnosed Oligometastatic Breast Cancer <i>(RT: Glen Oak, UPHM)</i>
<u>MA.39</u>	Tailor RT: A Randomized Trial of Regional Radiotherapy in Biomarker Low Risk Node Positive Breast Cancer <i>(RT: Glen Oak and UPHM)</i>

CANCER CONTROL (Breast only)

<u>A191901</u> SCHEMA	Optimizing Endocrine Therapy Through Motivational Interviewing and Text Interventions
<u>PROT001/ BLUENOTE</u> SCHEMA	(Peoria, Bloomington, Galesburg, Peru, Pekin and Ottawa) Double-blinded, Randomized, Adaptive Registrational Trial to Compare Effectiveness of Two Digital Software Medical Devices (Attune™ and Cerena™) as Interventions for Physical and Emotional Health in Adjunctive Oncology Treatment
<u>S1912CD</u> SCHEMA	NEW! A Randomized Trial Addressing Cancer-Related Financial Hardship Through Delivery of a Proactive Financial Navigation Intervention (CREDIT)
<u>S2013</u> SCHEMA	NEW! Immune Checkpoint Inhibitor Toxicity: A Prospective Observational Study (I-CHECKIT)
<u>URCC 16070</u>	Treatment of Refractory Nausea- for breast cancer patients.
<u>URCC 16092</u>	(Peoria only) - Phase II Study of Low-Dose Ibuprofen for Cognitive Problems in Patients With Cancer
<u>URCC-18007</u>	Randomized Placebo Controlled Trial of Bupropion For Cancer Related Fatigue in stage I-III Breast cancer pts.- <i>at least 2 months out from surgery/tx/radiation</i>
<u>WF-1901</u> SCHEMA	Internet-delivered Management of Pain Among Cancer Treatment Survivors (IMPACTS)

GYNECOLOGICAL

<p><u>NRG-GY012</u></p> <p>SCHEMA</p>	<p>NEW! A Randomized Phase II Study Comparing Single-Agent Olaparib, Single Agent Cediranib, and the Combinations of Cediranib/Olaparib, Olaparib/Durvalumab (MEDI4736), Cediranib/Durvalumab (MEDI4736), Olaparib/AZD5363 (Capivasertib) in Women With Recurrent, Persistent or Metastatic Endometrial Cancer.: A Platform Trial for Women With Recurrent or Persistent Endometrial Cancer</p>
<p><u>NRG - GY023</u></p> <p>SCHEMA</p>	<p>NEW! 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>

CANCER CONTROL

MULTI-DISEASE SITES

PROT001/ BLUENOTE SCHEMA	(Peoria, Bloomington, Galesburg, Peru, Pekin and Ottawa) Double-blinded, Randomized, Adaptive Registrational Trial to Compare Effectiveness of Two Digital Software Medical Devices (Attune™ and Cerena™) as Interventions for Physical and Emotional Health in Adjunctive Oncology Treatment
S1912CD SCHEMA	NEW! A Randomized Trial Addressing Cancer-Related Financial Hardship Through Delivery of a Proactive Financial Navigation Intervention (CREDIT)
S2013 SCHEMA	NEW! Immune Checkpoint Inhibitor Toxicity: A Prospective Observational Study (I-CHECKIT)
URCC 16092	(Peoria only) - Phase II Study of Low-Dose Ibuprofen for Cognitive Impairment in Cancer Patients Receiving Chemotherapy
WF-1901 SCHEMA	Internet-delivered Management of Pain Among Cancer Treatment Survivors (IMPACTS)

BREAST

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

LUNG

	Nothing currently available for Lung only - <i>See Multi-Disease Cancer Control trials ABOVE.</i>
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COLORECTAL

A221805 SCHEMA	Duloxetine to Prevent Oxaliplatin-Induced Chemotherapy-Induced Peripheral Neuropathy: A Randomized, Double-Blind, Placebo-Controlled Phase II to Phase III Study
S1820	A Randomized Trial of the Altering Intake, Managing Symptoms Intervention for Bowel Dysfunction in Rectal Cancer Survivors Compared to a Healthy Living Education Control: A Feasibility and Preliminary Efficacy Study (AIMS-RC)
WF-1806	(M&M Study) Myopenia and Mechanisms of Chemotherapy Toxicity in older Adults with Colorectal Cancer

BRAIN

WF-1801	A Single Arm, Pilot Study of Ramipril for Preventing Radiation-Induced Cognitive Decline in Glioblastoma (GBM) Patients Receiving Brain Radiotherapy
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REGISTRY

Contact Disease Specific Navigator

Connect MDS/AML	The Myelodysplastic Syndromes (MDS) and Acute Myeloid Leukemia (AML) Disease Registry This also included ICUS. <i>(enrolling low risk MDS pts only)</i>
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MASTER TRIAL LIST

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[MENU](#)

CARCINOID

Navigator - Ashton x3611
Carrie x3621

No trials at this time



MASTER TRIAL LIST

SEPTEMBER 2021



CLL

Navigator - Heather x3661

1st Line

<p><u>S1925</u></p> <p><small>SCHEMA</small></p>	<p>Randomized, Phase III Study of Early Intervention With Venetoclax and Obinutuzumab Versus Delayed Therapy With Venetoclax and Obinutuzumab in Newly Diagnosed Asymptomatic High-Risk Patients With Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL): EVOLVE CLL/SLL Study</p>
<p><u>U2-VEN-207</u></p> <p><small>SCHEMA</small></p>	<p>(Bloomington, Galesburg, Pekin, Peoria) Phase 2 Study to Assess the Efficacy and Safety of Ublituximab in Combination With Umbralisib and Venetoclax (U2-V) in Subjects With Chronic Lymphocytic Leukemia (CLL) - ULTRA-V</p>
<p><u>A041702</u></p>	<p>A Randomized Phase III Study of Ibrutinib Plus Obinutuzumab Versus Ibrutinib Plus Venetoclax and Obinutuzumab in Untreated Older Patients (>= 70 Years of Age) with Chronic Lymphocytic Leukemia (CLL)</p>

2nd Line, 3rd Line, etc.

<p><u>U2-VEN-207</u></p>	<p>(Bloomington, Galesburg, Pekin, Peoria) Phase 2 Study to Assess the Efficacy and Safety of Ublituximab in Combination With Umbralisib and Venetoclax (U2-V) in Subjects With Chronic Lymphocytic Leukemia (CLL) - ULTRA-V</p>
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MASTER TRIAL LIST

SEPTEMBER 2021



CML

Navigator - Heather x3661

[S1712](#)

A Randomized Phase II Study of Ruxolitinib in Combination with BCR-ABL Tyrosine Kinase Inhibitors in Chronic Myeloid Leukemia Patients with Evidence of Molecular Disease.

SEPTEMBER 2021

COLON / RECTAL

Navigator - Carrie x3621

Adjuvant

<p><u>A021502</u></p>	<p>Randomized Trial of Standard Chemotherapy Alone or Combined With Atezolizumab as Adjuvant Therapy for Patients With Stage III Colon Cancer and Deficient DNA Mismatch Repair</p>
<p><u>NRG GI005</u></p>	<p>Phase II/III Study of Circulating Tumor DNA as a Predictive Biomarker in Adjuvant Chemotherapy in Patients With Stage IIA Colon Cancer (COBRA)</p>

Metastatic

<p><u>GI004</u></p>	<p>A Randomized Phase III Study of mFOLFOX6/Bevacizumab/Atezolizumab Combination versus Single Agent Atezolizumab in the First-Line Treatment of Patients with Deficient DNA Mismatch Repair (dMMR)/Microsatellite Instability High (MSI-H) Metastatic Colorectal Cancer</p>
<p><u>MK 7339-003</u></p> <p>SCHEMA</p>	<p>(Peoria, Bloomington, Galesburg, Peru) A Phase 3 Randomized, Open-label Study to Evaluate the Efficacy and Safety of Olaparib Alone or in Combination With Bevacizumab Compared to Bevacizumab with 5-FU in Participants with Unresectable or Metastatic Colorectal Cancer who Have Not Progressed Following First-line Induction of FOLFOX With Bevacizumab (LYNK-003)</p>

CANCER CONTROL (Colorectal only)

<p><u>A221805</u></p> <p>SCHEMA</p>	<p>Duloxetine to Prevent Oxaliplatin-Induced Chemotherapy-Induced Peripheral Neuropathy: A Randomized, Double-Blind, Placebo-Controlled Phase II to Phase III Study</p>
<p><u>S1820</u></p> <p>SCHEMA</p>	<p>A Randomized Trial of the Altering Intake, Managing Symptoms Intervention for Bowel Dysfunction in Rectal Cancer Survivors Compared to a Healthy Living Education Control: A Feasibility and Preliminary Efficacy Study (AIMS-RC)</p>

<p><u>S1912CD</u></p> <p><small>SCHEMA</small></p>	<p>NEW! A Randomized Trial Addressing Cancer-Related Financial Hardship Through Delivery of a Proactive Financial Navigation Intervention (CREDIT)</p>
<p><u>S2013</u></p> <p><small>SCHEMA</small></p>	<p>NEW! Immune Checkpoint Inhibitor Toxicity: A Prospective Observational Study (I-CHECKIT)</p>
<p><u>URCC 16092</u></p>	<p>(Peoria only) - Phase II Study of Low-Dose Ibuprofen for Cognitive Problems in Patients With Cancer</p>
<p><u>WF-1901</u></p> <p><small>SCHEMA</small></p>	<p>Internet-delivered Management of Pain Among Cancer Treatment Survivors (IMPACTS)</p>
<p><u>WF-1806</u></p>	<p>(M&M Study) Myopenia and Mechanisms of Chemotherapy Toxicity in older Adults with Colorectal Cancer</p>

MASTER TRIAL LIST

SEPTEMBER 2021



ESOPHAGEAL- GASTRIC

Navigator - Carrie x3621

<p>EA2174</p> <p>SCHEMA</p>	<p>(RT at Glen Oak, UPHM, Galesburg) A Phase II/III Study of Peri-Operative Nivolumab and Ipilimumab in Patients With Locoregional Esophageal and Gastroesophageal Junction Adenocarcinoma</p>
<p>EA2183</p> <p>SCHEMA</p>	<p><i>Temp Closed</i> (RT at UPHM only) A Phase III Study of Consolidative Radiotherapy in Patients With Oligometastatic HER2 Negative Esophageal and Gastric Adenocarcinoma (EGA)</p>

HEAD & NECK

Navigator - Ashton x3611

<p><u>EA3161</u></p> <p>SCHEMA</p>	<p>(RT at Glen Oak & Galesburg) A Phase II/III Randomized Study of Maintenance Nivolumab Versus Observation in Patients With Locally Advanced, Intermediate Risk HPV Positive OPSCC</p>
<p><u>EA3191 - JIT</u></p>	<p>Activation Pending (RT at Route-91) A Phase II Randomized Trial of Adjuvant Therapy With Pembrolizumab After Resection of Recurrent/Second Primary Head and Neck Squamous Cell Carcinoma With High Risk Features</p>
<p><u>HN004</u></p>	<p>Temp Closed (RT at Glen Oak, UPHM, Galesburg)-Randomized Phase II/III Trial of Radiotherapy with Concurrent MEDI4736 (Durvalumab) vs. Radiotherapy with Concurrent Cetuximab in Patients with Stage III-IVB Head and Neck Cancer with a Contraindication to Cisplatin</p>
<p><u>HN005</u></p>	<p>(RT at UPHM, Galesburg, Glen Oak) A Randomized Phase II/III Trial of De-Intensified Radiation Therapy for Patients With Early-Stage, P16-Positive, Non-Smoking Associated Oropharyngeal Cancer</p>



LYMPHOMA

HL

<p><u>S1826</u></p>	<p>(RT at Glen Oak, Rt-91, UPHM) A Phase III, Randomized Study of Nivolumab (Opdivo) Plus AVD or Brentuximab Vedotin (Adcetris) Plus AVD in Patients (Age >= 12 Years) With Newly Diagnosed Advanced Stage Classical Hodgkin Lymphoma</p>
<p><u>SGN35-027</u></p> <p>SCHEMA</p>	<p>(Bloomington, Galesburg, Ottawa, Pekin, Peoria, Peru) Multiple Part Clinical Trial of Brentuximab Vedotin in Classical Hodgkin Lymphoma Subjects</p>

NHL

<p><u>EA4181</u></p>	<p>A Randomized 3-Arm Phase II Study Comparing 1.) Bendamustine, Rituximab and High Dose Cytarabine (BR/CR) 2.) Bendamustine, Rituximab, High Dose Cytarabine and Acalabrutinib (BR/CR-A), and 3.) Bendamustine, Rituximab and Acalabrutinib (BR-A) in Patients ≤ 70 Years Old With Untreated Mantle Cell Lymphoma</p>
<p><u>TG-1501-101</u></p>	<p>(Peoria, Bloomington, Galesburg)-A Phase 1 Study of TG-1501 in Subjects with Relapsed or Refractory Lymphoma (<i>classic HL cohort closed</i>)</p>

DLBCL



MASTER TRIAL LIST

SEPTEMBER 2021



MDS

Navigator - Heather x3661

<p><u>Connect MDS/AML</u></p>	<p>The Myelodysplastic Syndromes (MDS) and Acute Myeloid Leukemia (AML) Disease Registry This also included ICUS. <i>(enrolling low risk MDS pts only)</i></p>
<p><u>NHLBI-MDS</u></p>	<p>(Peoria, Bloomington and Galesburg only) -The National Myelodysplastic Syndromes (MDS) Study</p>
<p><u>M15-954</u></p> <p>SCHEMA</p>	<p>(Peoria, Bloomington, Galesburg, Pekin) A Randomized, Double-Blind, Phase 3 Study Evaluating the Safety and Efficacy of Venetoclax in Combination With Azacitidine in Patients Newly Diagnosed With Higher-Risk Myelodysplastic Syndrome (Higher-Risk MDS)</p>



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MELANOMA

Navigator - Carrie x3621

<p><u>EA6194</u></p> <p>SCHEMA</p>	<p>Phase II Randomized Study of Neoadjuvant Pembrolizumab Alone or in Combination With CMP-001 in Patients With Operable Melanoma: Efficacy and Biomarker Study</p>
<p><u>S2000</u></p> <p>SCHEMA</p>	<p>A Randomized Phase 2 Trial of Encorafenib + Binimetinib + Nivolumab vs Ipilimumab + Nivolumab in BRAF-V600 Mutant Melanoma With Brain Metastases</p>



MASTER TRIAL LIST

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MENU

MERKEL

Navigator - Carrie x3621

EA6174

(RT at Glen Oak and Rt-91 pending) A Phase III Randomized Trial Comparing Adjuvant MK3475 (Pembrolizumab) to Standard of Care Observation in Completely Resected Merkel Cell Carcinoma



MASTER TRIAL LIST

MENU

SEPTEMBER 2021

MOLECULAR STUDIES

*Contact Disease Specific Navigator

<p><u>2215-MA-3297 / CLEVO</u></p>	<p>Activation Pending - A non-interventional cohort study of the CLonal EVolution of <i>FLT3</i> mutations during disease progression in patients with acute myeloid leukemia - CLEVO</p>
<p><u>64091742PCR0002 / Prevalence</u></p>	<p>Biomarker Study to Determine Frequency of DNA-repair Defects in Men with Metastatic Prostate Cancer (Prevelence)</p>
<p><u>A151804</u></p>	<p>Establishment of a National Biorepository to Advance Studies of Immune-Related Adverse Events</p>
<p><u>S1823</u></p> <p><small>SCHEMA</small></p>	<p>A Study of miRNA 371 in Patients With Germ Cell Tumor</p>
<p><u>TPX-0005-01 (TRIDENT-1)</u></p> <p><small>SCHEMA</small></p>	<p>A Phase 1/2, Open-Label, Multi-Center, First-in-Human Study of the Safety, Tolerability, Pharmacokinetics, and Anti-Tumor Activity of TPX-0005 in Patients with Advanced Solid Tumors Harboring ALK, ROS1, or NTRK1-3 Rearrangements (TRIDENT-1)</p>

MASTER TRIAL LIST

SEPTEMBER 2021

MENU

MULTIPLE MYELOMA

Navigator - Heather x3661

[EAA171](#)

SCHEMA

Optimizing Prolonged Treatment in Myeloma Using MRD Assessment (OPTIMUM)

[S1803](#)

Phase III Study of Daratumumab/rHuPH20 (NSC- 810307) + Lenalidomide or Lenalidomide as Post-Autologous Stem Cell Transplant Maintenance Therapy in Patients with Multiple Myeloma (MM) Using Minimal Residual Disease to Direct Therapy Duration (DRAMMATIC Study)

ADJUVANT / NEOADJUVANT

<p>A081801 SCHEMA</p>	<p>Integration of Immunotherapy Into Adjuvant Therapy for Resected NSCLC: ALCHEMIST Chemo-IO (ALCHEMIST substudy- <i>Must be enrolled on ALCHEMIST and this substudy prior to start of tx</i>).</p>
<p>A151216</p>	<p>Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST).</p>
<p>EA5181 SCHEMA</p>	<p>(RT at UPHM and Galesburg) Randomized Phase III Trial of MEDI4736 (Durvalumab) as Concurrent and Consolidative Therapy or Consolidative Therapy Alone for Unresectable Stage 3 NSCLC (credentialing pending at Glen Oak & Rt-91)</p>
<p>GO41854 SCHEMA</p>	<p>(Bloomington, Galesburg, Pekin, Peoria, Peru) A Phase III, Open Label, Randomized Study of Atezolizumab and Tiragolumab Compared With Durvalumab in Patients With Locally Advanced, unresectable Stage III Non-Small Cell Lung Cancer Who Have Not Progressed After Concurrent Platinum-Based Chemoradiation (SKYSCRAPER-03)</p>
<p>S1914</p>	<p>(RT at Glen Oak, UPHM, Galesburg) Randomized Phase III Trial of Induction/Consolidation Atezolizumab (NSC #783608) + SBRT Versus SBRT Alone in High Risk, Early Stage NSCLC</p>
<p>S1933 SCHEMA</p>	<p>(RT at UPHM only) A Pilot Study of Hypofractionated Radiotherapy Followed by Atezolizumab Consolidation in Stage II or III NSCLC Patients With Borderline Performance Status</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>LU002</p>	<p>(RT at Glen Oak, UPHM, Galesburg)- Maintenance Systemic Therapy Versus Consolidative Stereotactic Body Radiation Therapy (SBRT) Plus Maintenance Systemic Therapy for Limited Metastatic Non-Small Cell Lung Cancer (NSCLC): A Randomized Phase II/III Trial</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>
<p>TH-138 SCHEMA</p>	<p>(Peoria, Bloomington, Galesburg, Pekin) Phase II Randomized Trial of Carboplatin + Pemetrexed+ Bevacizumab, With or Without Atezolizumab in Stage IV Non-Squamous NSCLC Patients Who Harbor a Sensitizing EGFR Mutation or Have Never Smoked (<i>non smokers</i>)</p>

METASTATIC - 2nd/3rd Line

<p>EA5191</p>	<p>A Randomized Phase II Trial of Cabozantinib and Cabozantinib Plus Nivolumab Versus Standard Chemotherapy in Patients With Previously Treated Non-Squamous NSCLC</p>
<p>LUNGMAP</p>	<p>A Master Protocol To Evaluate Biomarker-Driven Therapies and Immunotherapies in Previously-Treated NSCLC.</p>
<p>MK 7684A-002 SCHEMA</p>	<p>(Peoria only) A Phase II, Multicenter, Randomized Study to Compare the Efficacy and Safety of MK-7684A or MK-7684A Plus Docetaxel Versus Docetaxel Monotherapy in the Treatment of Participants With Metastatic NSCLC With Progressive Disease After Treatment With a Platinum Doublet Chemotherapy and Immunotherapy.</p>

TH-138

SCHEMA

(Peoria, Bloomington, Galesburg, Pekin) Phase II Randomized Trial of Carboplatin + Pemetrexed+ Bevacizumab, With or Without Atezolizumab in Stage IV Non-Squamous NSCLC Patients Who Harbor a Sensitizing EGFR Mutation or Have Never Smoked (**EGFR mutants**)

CANCER CONTROL (NSCLC Only)

PROT001/ BLUENOTE

SCHEMA

(Peoria, Bloomington, Galesburg, Peru, Pekin and Ottawa) Double-blinded, Randomized, Adaptive Registrational Trial to Compare Effectiveness of Two Digital Software Medical Devices (Attune™ and Cerena™) as Interventions for Physical and Emotional Health in Adjunctive Oncology Treatment

S1912CD

SCHEMA

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

S2013

SCHEMA

NEW! Immune Checkpoint Inhibitor Toxicity: A Prospective Observational Study (**I-CHECKIT**)

URCC 16092

(Peoria only) - Phase II Study of Low-Dose Ibuprofen for Cognitive Problems in Patients With Cancer

WF-1901

SCHEMA

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



MASTER TRIAL LIST

SEPTEMBER 2021



PANCREATIC

Navigator - Carrie x3621

<p><u>A021806</u> SCHEMA</p>	<p>A Phase III Trial of Perioperative Versus Adjuvant Chemotherapy for Resectable Pancreatic Cancer</p>
<p><u>EA2186</u> 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> SCHEMA</p>	<p>A Randomized Phase II Double-Blind Study of Olaparib Versus Placebo Following Adjuvant Chemotherapy in Patients With Resected Pancreatic Cancer and a Pathogenic BRCA1, BRCA2 or PALB2 Mutation (APOLLO)</p>

MASTER TRIAL LIST

SEPTEMBER 2021



MENU

PROSTATE

Navigator - Carrie x3621

ADJUVANT

<u>EA8183</u>	(RT at UPHM only) A Phase III Double Blinded Study of Early Intervention After RADICAL ProstaTEctomy With Androgen Deprivation Therapy With or Without Darolutamide vs. Placebo in Men at Highest Risk of Prostate Cancer Metastasis by Genomic Stratification (ERADICATE)
<u>GU002</u>	(RT at Glen Oak, UPHM, and Rt-91) –Phase II-III Trial of Adjuvant radiotherapy and Androgen Deprivation Following radical Prostatectomy with or without Adjuvant Docetaxel
<u>GU005</u>	(RT at Glen Oak & UPHM) -Phase II IGRT and SBRT vs. IGRT and hypofractionate IMRT for Localized Intermediate Risk Prostate Cancer.
<u>GU008</u> SCHEMA	Temp Closed (RT at Glen Oak) Randomized Phase III Trial Incorporating Abiraterone Acetate With Prednisone and Apalutamide and Advanced Imaging Into Salvage Treatment for Patients With Node-Positive Prostate Cancer After Radical Prostatectomy
<u>GU009</u> SCHEMA	Temp Closed (RT at Glen Oak, Galesburg; Credentialing Pending @ 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*)
METASTATIC	
<u>64091742PCR0002 / Prevalence</u>	Biomarker Study to Determine Frequency of DNA-repair Defects in Men with Metastatic Prostate Cancer

<p><u>C2321001</u></p> <p></p>	<p><i>Prostate cohort temporarily closed (Peoria only)</i> A Phase I Dose Escalation and Expanded Cohort Study of PF-06821497 in the Treatment of Adult Patients with Relapsed/Refractory Small Cell Lung Cancer (SCLC), Castration Resistant Prostate Cancer (CRPC) and Follicular Lymphoma (FL)</p>
<p><u>A031902 / CASPAR</u></p> <p></p>	<p>A Phase III Trial of Enzalutamide and Rucaparib as a Novel Therapy in First-Line Metastatic Castration-Resistant Prostate Cancer</p>
<p><u>S1802</u></p>	<p>(RT at Glen Oak & UPHM) Phase III Randomized Trial of Standard Systemic Therapy (SST) versus Standard Systemic Therapy Plus Definitive Treatment (Surgery or Radiation) of the Primary Tumor in Metastatic Prostate Cancer</p>

MASTER TRIAL LIST

SEPTEMBER 2021

MENU

RENAL CELL

Navigator - Carrie x3621




<p><u>A031704</u></p> <p>SCHEMA</p>	<p>PD-Inhibitor (nivolumab) and Ipilimumab Followed by Nivolumab vs. VEGF TKI Cabozantinib with Nivolumab: A Phase III Trial in Metastatic Untreated Renal Cell Cancer (PDIGREE)</p>
<p><u>MK 6482-011</u></p> <p>SCHEMA</p>	<p>(Peoria, Bloomington, Galesburg, Pekin) An Open-label, Randomized, Phase 3 Study of MK-6482 in Combination with Lenvatinib (MK-7902) vs Cabozantinib for Second-line or Third-line Treatment in Participants with Advanced Renal Cell Carcinoma Who Have Progressed After Prior Anti-PD-1/L1 Therapy</p>
<p><u>S1931</u></p> <p>SCHEMA</p>	<p>Phase III Trial of Immunotherapy-Based Combination Therapy With or Without Cytoreductive Nephrectomy for Metastatic Renal Cell Carcinoma (PROBE Trial)</p>

RADIATION TRIALS

Navigator - Jessica x3615

CANCER CONTROL	
<u>WF-1801</u>	A Single Arm, Pilot Study of Ramipril for Preventing Radiation-Induced Cognitive Decline in Glioblastoma (GBM) Patients Receiving Brain Radiotherapy
ANAL	
<u>EA2182</u>	(UPHM and Glen Oak) A Randomized Phase II Study of De-Intensified ChemoRadiation for Early-Stage Anal Squamous Cell Carcinoma (DECREASE)
BLADDER	
<u>EA8185</u>	(RT pending at Glen Oak & Rt-91) Phase 2 Study of Bladder-Sparing Chemoradiation With MEDI4736 (Durvalumab) in Clinical Stage 3, Node Positive Bladder Cancer (INSPIRE)
<u>S1806</u>	(Glen Oak, UPHM and Galesburg) Phase III Randomized Trial of Concurrent Chemoradiotherapy with or without Atezolizumab in Localized Muscle Invasive Bladder Cancer
	SCHEMA
BRAIN	
<u>BN007</u>	(UPHM, Glen Oak, Galesburg) A Randomized Phase II/III Open-Label Study of Ipilimumab and Nivolumab Versus Temozolomide in Patients With Newly Diagnosed MGMT (Tumor O-6-Methylguanine DNA Methyltransferase) Unmethylated Glioblastoma
	SCHEMA
<u>N0577</u>	(Glen Oak, RT 91, and UPHM) Phase III Intergroup Study of Radiotherapy with Concomitant and Adjuvant Temozolomide versus Radiotherapy with Adjuvant PCV Chemotherapy in Patients with 1p/19q Co-deleted Anaplastic Glioma or Low Grade Glioma
BRAIN METS	
<u>A071801</u>	(UPHM & Glen Oak) Phase III Trial of Post-Surgical Single Fraction Stereotactic Radiosurgery (SRS) Compared With Fractionated SRS for Resected Metastatic Brain Disease
<u>CCTG CE.7</u>	(UPHM & Glen Oak)- A Phase III Trial of Stereotactic Radiosurgery Compared with Whole Brain Radiotherapy (WBRT) for 5-15 Brain Metastases
BREAST	

<u>A011202</u> <small>SCHEMA</small>	(Glen Oak, Rt 91, UPHM, Galesburg) A Randomized Phase III Trial Evaluating the Role of Axillary Lymph Node Dissection in breast Cancer Patients (cT1-3 N1) Who Have Positive Lymph Node Disease After Neoadjuvant Chemotherapy.
<u>BR007</u> <small>SCHEMA</small>	(Galesburg, Glen Oak, Rt 91, UPHM) Phase III Clinical Trial Evaluating De-Escalation of Breast Radiation for Conservative Treatment of Stage I, Hormone Sensitive, HER-2 Negative, Oncotype Recurrence Score Less Than or Equal to 18 Breast Cancer
<u>MA.39</u>	(Glen Oak and UPHM) Tailor RT: A Randomized Trial of Regional Radiotherapy in Biomarker Low Risk Node Positive Breast Cancer
ESOPHAGEAL/GASTRIC	
<u>EA2174</u> <small>SCHEMA</small>	(Glen Oak, UPHM, Galesburg) A Phase II/III Study of Peri-Operative Nivolumab and Ipilimumab in Patients With Locoregional Esophageal and Gastroesophageal Junction Adenocarcinoma
<u>EA2183</u>	<i>Temp Closed</i> (UPHM only) A Phase III Study of Consolidative Radiotherapy in Patients With Oligometastatic HER2 Negative Esophageal and Gastric Adenocarcinoma (EGA)
HEAD & NECK	
<u>EA3161</u> <small>SCHEMA</small>	(Glen Oak & Galeburg) A Phase II/III Randomized Study of Maintenance Nivolumab Versus Observation in Patients With Locally Advanced, Intermediate Risk HPV Positive OPSCC
<u>HN005</u>	(UPHM, Galesburg, Glen Oak) A Randomized Phase II/III Trial of De-Intensified Radiation Therapy for Patients With Early-Stage, P16-Positive, Non-Smoking Associated Oropharyngeal Cancer
HODGKIN'S LYMPHOMA	
<u>S1826</u>	(Glen Oak, Rt-91, UPHM) A Phase III, Randomized Study of Nivolumab (Opdivo) Plus AVD or Brentuximab Vedotin (Adcetris) Plus AVD in Patients (Age >= 12 Years) With Newly Diagnosed Advanced Stage Classical Hodgkin Lymphoma
MERKEL CELL	
<u>EA6174</u>	(UPHM and Galesburg) A Phase III Randomized Trial Comparing Adjuvant MK3475 (Pembrolizumab) to Standard of Care Observation in Completely Resected Merkel Cell Carcinoma
NSCLC	
<u>EA5181</u> <small>SCHEMA</small>	(UPHM and Galesburg) Randomized Phase III Trial of MEDI4736 (Durvalumab) as Concurrent and Consolidative Therapy or Consolidative Therapy Alone for Unresectable Stage 3 NSCLC (credentialing pending at Glen Oak)

<u>LU002</u>	(Glen Oak, UPHM, Galesburg) - Maintenance Systemic Therapy Versus Consolidative Stereotactic Body Radiation Therapy (SBRT) Plus Maintenance Systemic Therapy for Limited Metastatic Non-Small Cell Lung Cancer (NSCLC): A Randomized Phase II/III Trial
<u>S1914</u>	(Glen Oak, UPHM, Galesburg) Randomized Phase III Trial of Induction/Consolidation Atezolizumab (NSC #783608) + SBRT Versus SBRT Alone in High Risk, Early Stage NSCLC
<u>S1933</u> 	(UPHM only) A Pilot Study of Hypofractionated Radiotherapy Followed by Atezolizumab Consolidation in Stage II or III NSCLC Patients With Borderline Performance Status
PROSTATE	
<u>EA8183</u>	(RT at UPHM only) A Phase III Double Blinded Study of Early Intervention After RADICAL ProstaTEctomy With Androgen Deprivation Therapy With or Without Darolutamide vs. Placebo in Men at Highest Risk of Prostate Cancer Metastasis by Genomic Stratification (ERADICATE)
<u>GU002</u>	(RT at Glen Oak, UPHM, and Rt-91) –Phase II-III Trial of Adjuvant radiotherapy and Androgen Deprivation Following radical Prostatectomy with or without Adjuvant Docetaxel
<u>GU005</u>	(RT at Glen Oak & UPHM) –Phase II IGRT and SBRT vs. IGRT and hypofractionate IMRT for Localized Intermediate Risk Prostate Cancer.
<u>GU009</u> 	Temp Closed! (RT at Glen Oak & Galesburg) 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>S1802</u>	(Glen Oak & UPHM) Phase III Randomized Trial of Standard Systemic Therapy (SST) versus Standard Systemic Therapy Plus Definitive Treatment (Surgery or Radiation) of the Primary Tumor in Metastatic Prostate Cancer
<u>WF-1802</u>	(Glen Oak, Rt-91, UPHM, Galesburg) Influence of Primary Treatment for Prostate Cancer on Work Experience (PCW)
SCLC	
<u>NRG CC003</u> 	(Glen Oak only) Randomized Phase II/III Trial of Prophylactic Cranial Irradiation with or without Hippocampal Avoidance for Small Cell Lung Cancer

<p><u>NRG CC009</u></p> <p><small>SCHEMA</small></p>	<p>(Glen Oak) - 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>LU005</u></p>	<p>(Glen Oak, UPHM and Galesburg) Limited Stage Small Cell Lung Cancer (LS-SCLC): A Phase II/III Randomized Study of Chemoradiation Versus Chemoradiation Plus Atezolizumab</p>
<p><u>LU007 / RAPTOR</u></p>	<p>(Glen Oak, UPHM, Galesburg) – Randomized Phase II/III Trial of Consolidation RT + Immunotherapy for ES-SCLC</p>
<p><u>S1827</u></p>	<p>(Glen Oak, UPHM, Galesburg) A Randomized Phase III Trial of MRI Surveillance With or Without Prophylactic Cranial Irradiation (PCI) in Small-Cell Lung Cancer</p>

SMALL CELL LUNG CANCER

Navigator - Ashton x3611

<p><u>NRG CC003</u></p> <p>SCHEMA</p>	<p>(RT at Glen Oak only) Randomized Phase II/III Trial of Prophylactic Cranial Irradiation with or without Hippocampal Avoidance for Small Cell Lung Cancer</p>
<p><u>NRG CC009</u></p> <p>SCHEMA</p>	<p>(RT at Glen Oak; pending at Galesburg) - 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>SITE SELECTED A Phase III, Randomized, Open-Label, Multicenter Study of Lurbinectedin In Combination With Atezolizumab Compared With Atezolizumab As Maintenance Therapy In Participants With Extensive-Stage Small-Cell Lung Cancer (ES-SCLC) Following First-Line Induction Therapy With Carboplatin, Etoposide and Atezolizumab</p>
<p><u>LU005</u></p>	<p>(RT at Glen Oak, UPHM and Galesburg) Limited Stage Small Cell Lung Cancer (LS-SCLC): A Phase II/III Randomized Study of Chemoradiation Versus Chemoradiation Plus Atezolizumab</p>
<p><u>LU007 / RAPTOR</u></p>	<p>(RT at Glen Oak, UPHM, Galesburg) – Randomized Phase II/III Trial of Consolidation RT + Immunotherapy for ES-SCLC</p>
<p><u>S1827</u></p>	<p>(RT at Glen Oak, UPHM, Galesburg) A Randomized Phase III Trial of MRI Surveillance With or Without Prophylactic Cranial Irradiation (PCI) in Small-Cell Lung Cancer</p>
<p><u>S1929</u></p> <p>SCHEMA</p>	<p>Phase II Randomized Study of Maintenance Atezolizumab Versus Atezolizumab in Combination With Talazoparib in Patients With SLFN11 Positive Extensive Stage Small Cell Lung Cancer (ES-SCLC) <i>Tissue screening allowed during induction chemotherapy</i></p>



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

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SEPTEMBER 2021

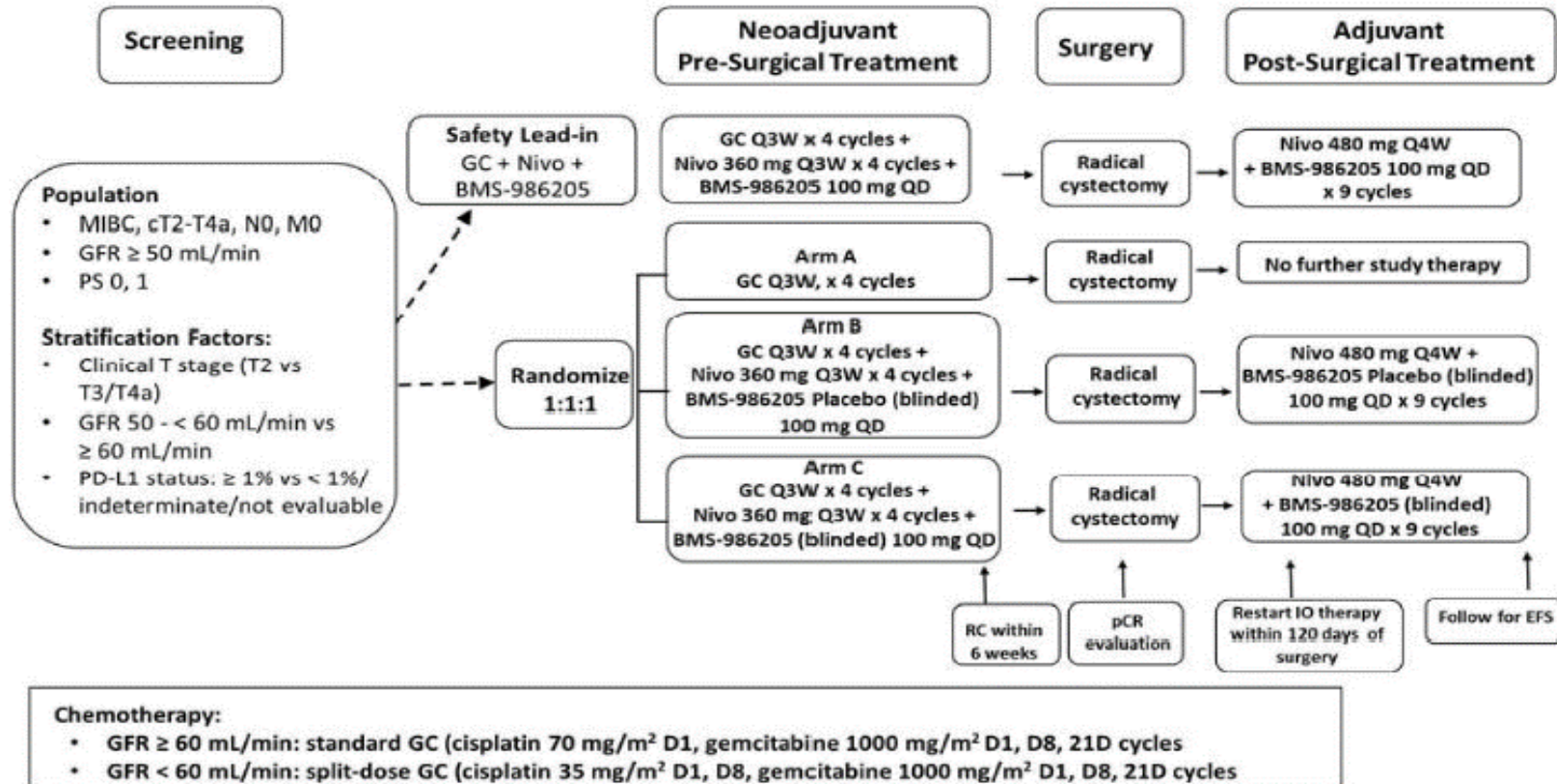


[MENU](#)

VULVA

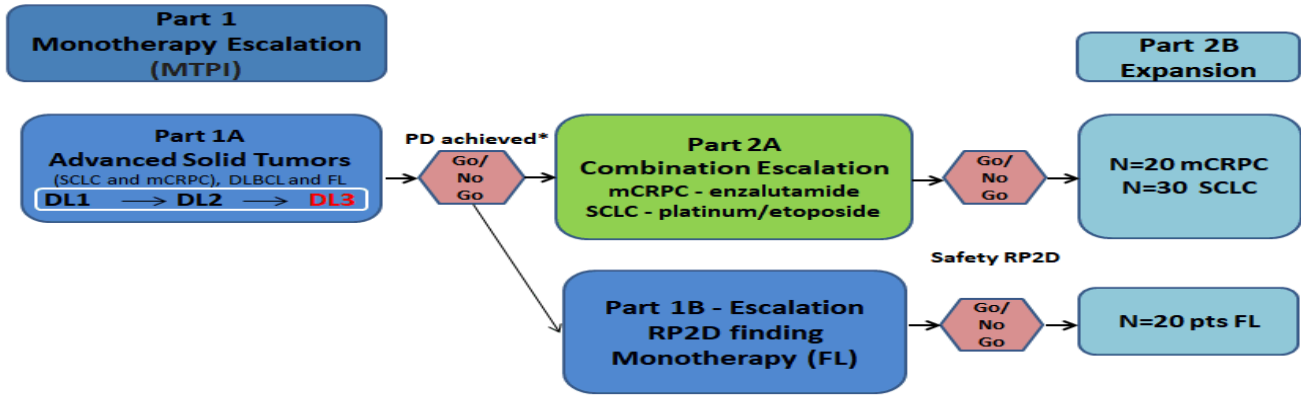
Navigator - Angie x3613

Figure 1-1: Study Design Schematic



C2321001 SCHEMA
Contact Disease Specific Navigator

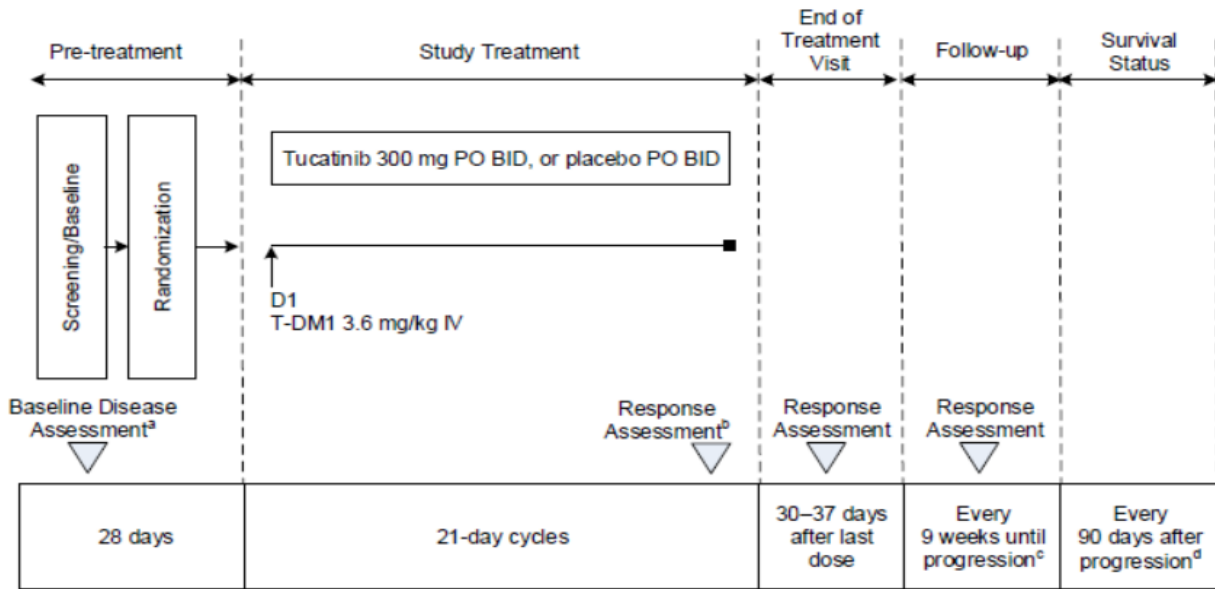
MENU



*50-70% down modulation of H3K27me3

SGNTUC-016 SCHEMA
 Navigator - Angie x3613

MENU



Study Design

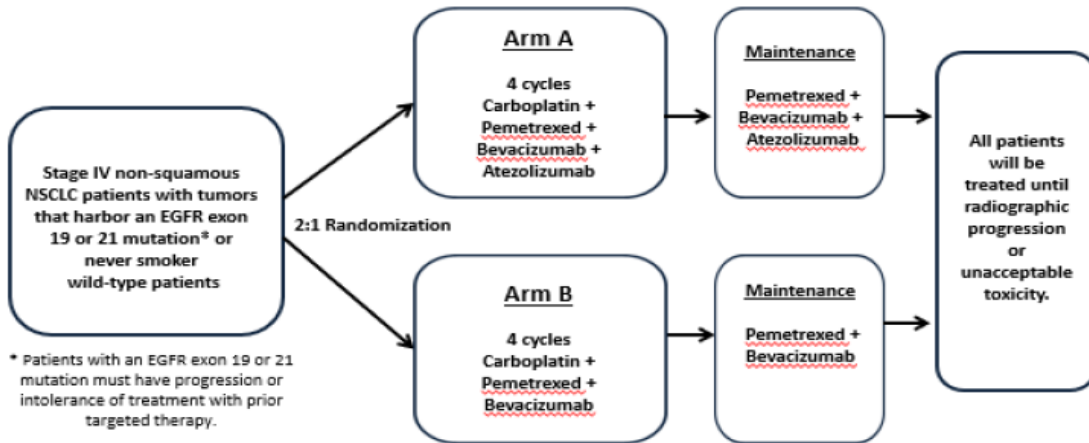
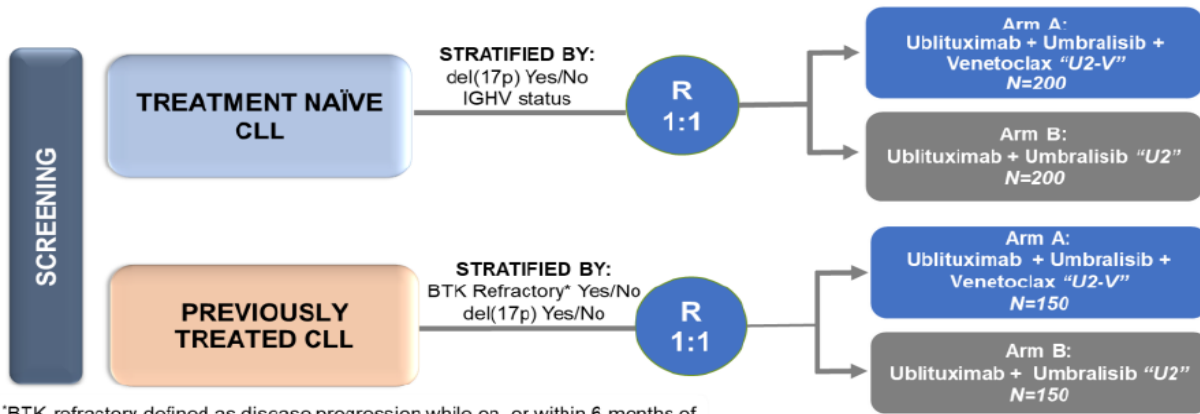


FIGURE 2: PHASE 3 STUDY DESIGN



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

MK 6482-011 Schema
Navigator - Carrie x3621

MENU

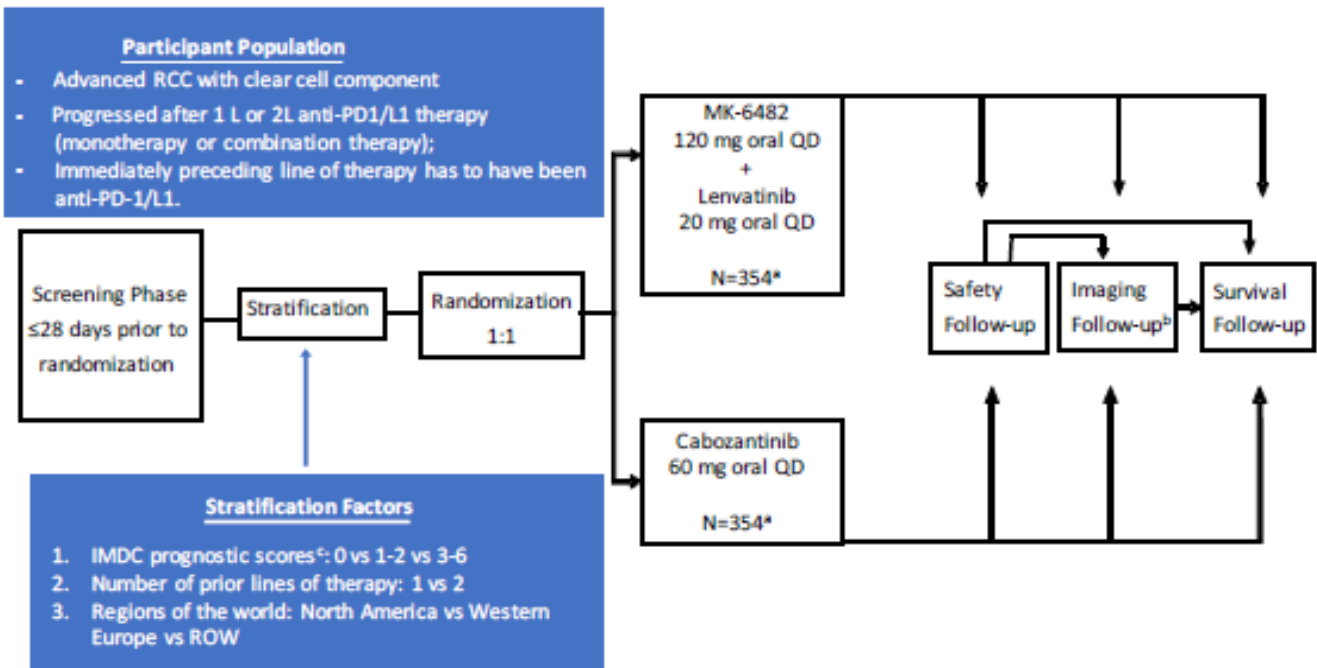
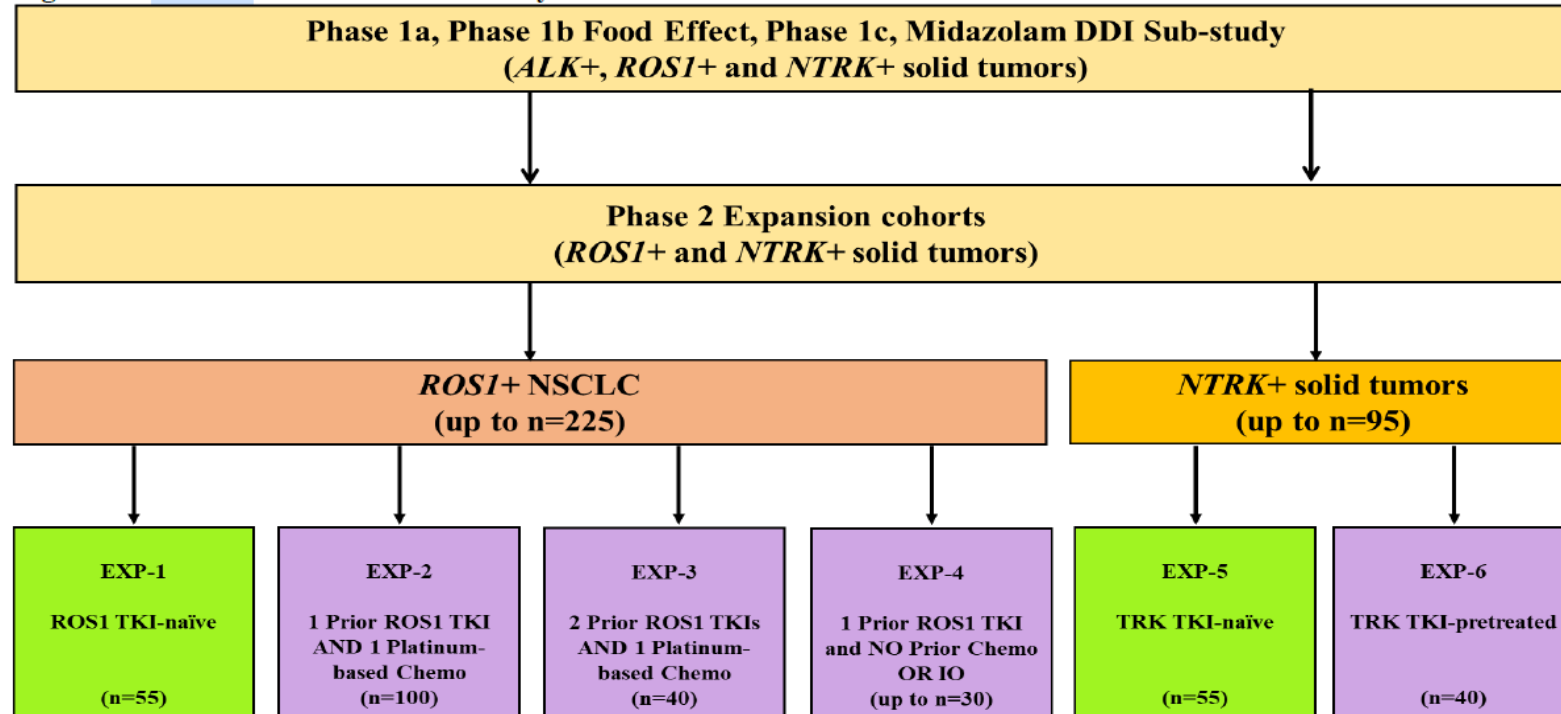
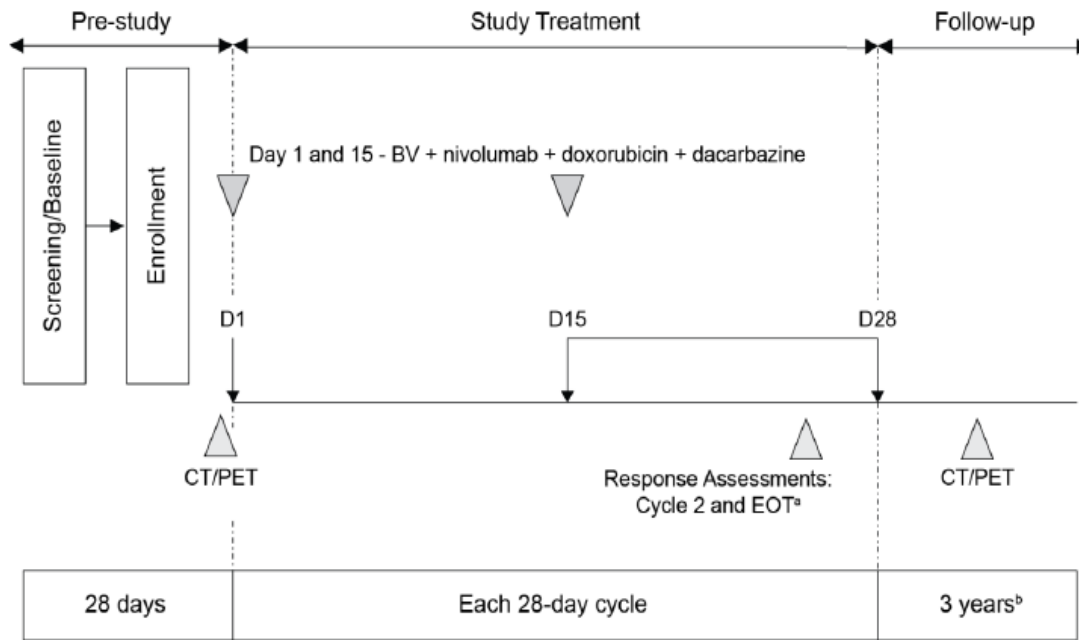


Figure 2. Schema of TPX-0005-01 Study



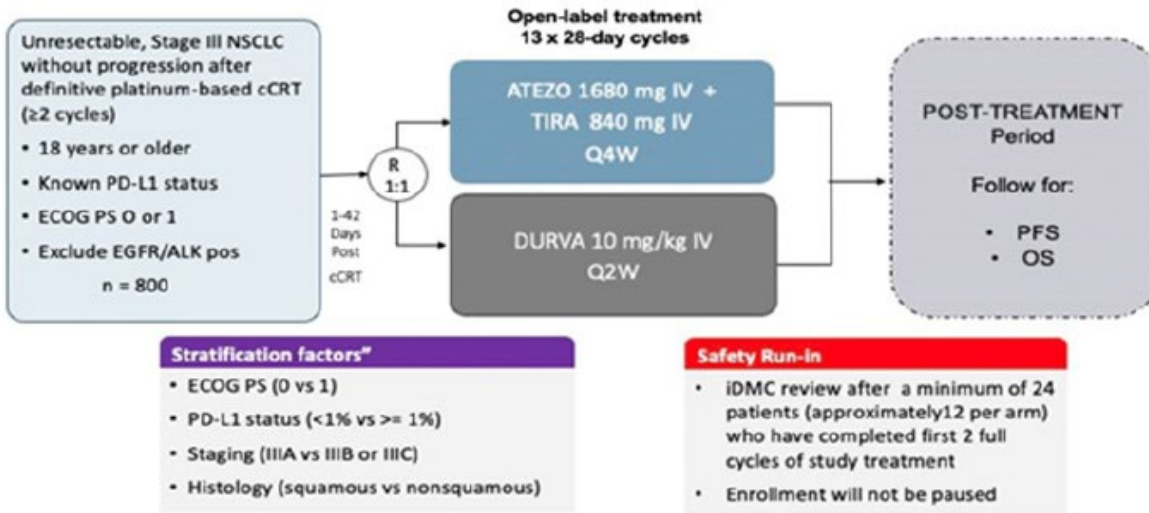


a Response assessments will include PET and diagnostic-quality CT scan on Day 25-28 of Cycle 2, and at EOT.

b Part C follow-up period includes 2 additional years (5 years total).

GO41854 Schema
Navigator - Ashton x3611

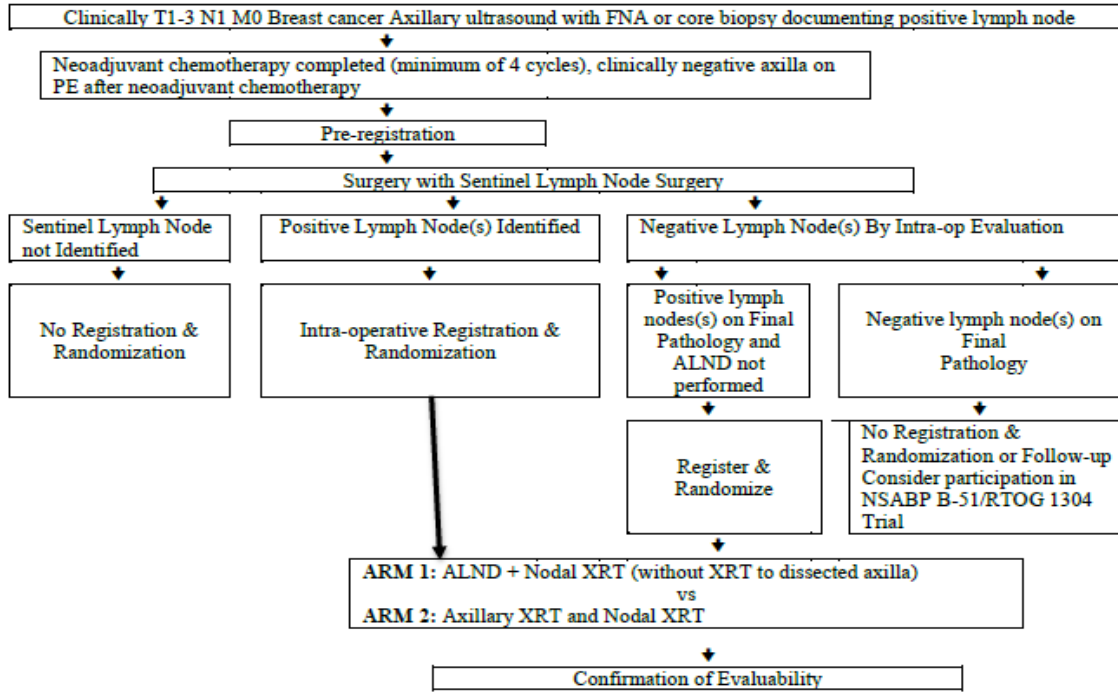
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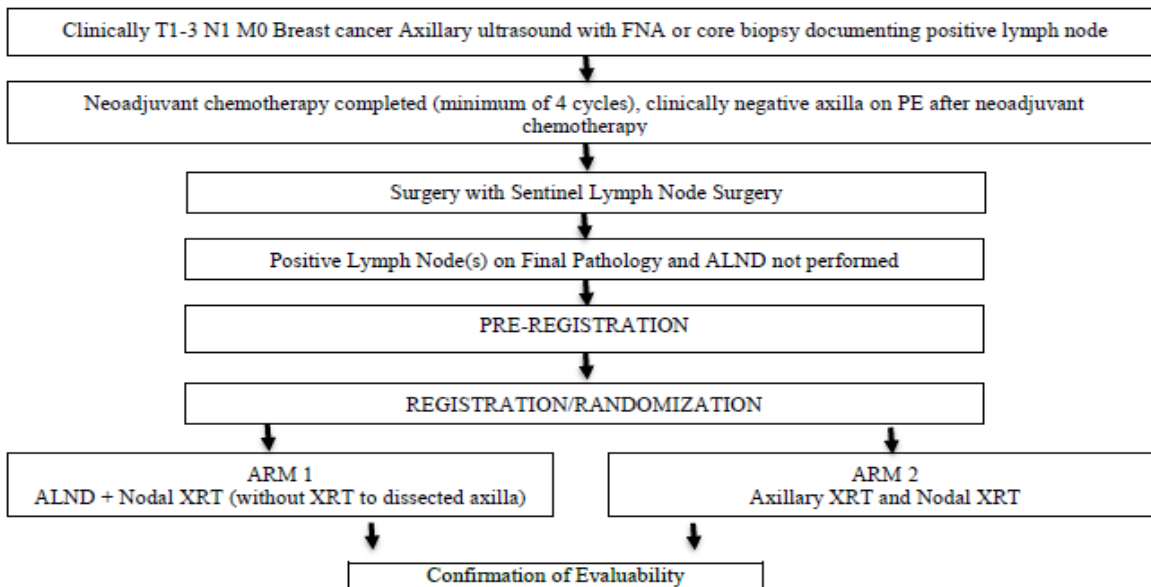
A011202 SCHEMA
Navigator Angie x3613

MENU

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

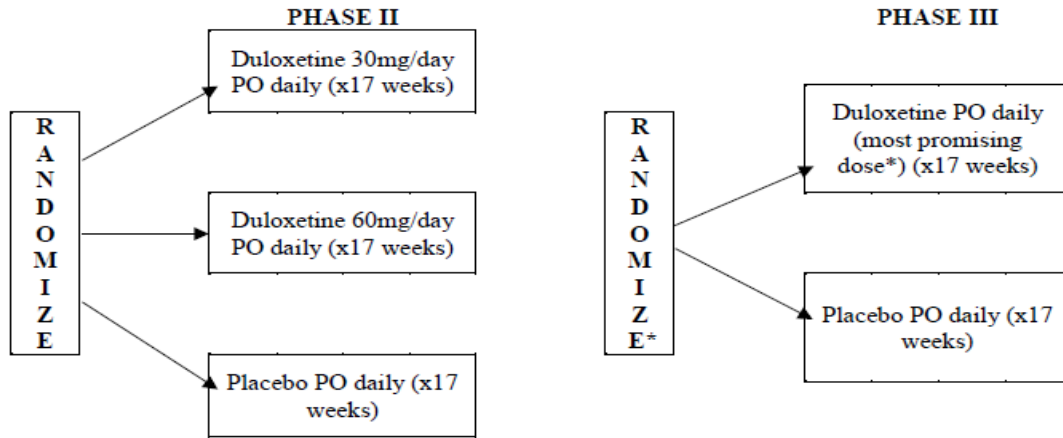


Schema for patients who pre-register AFTER surgery* (where SLN surgery was performed but ALND was NOT performed):



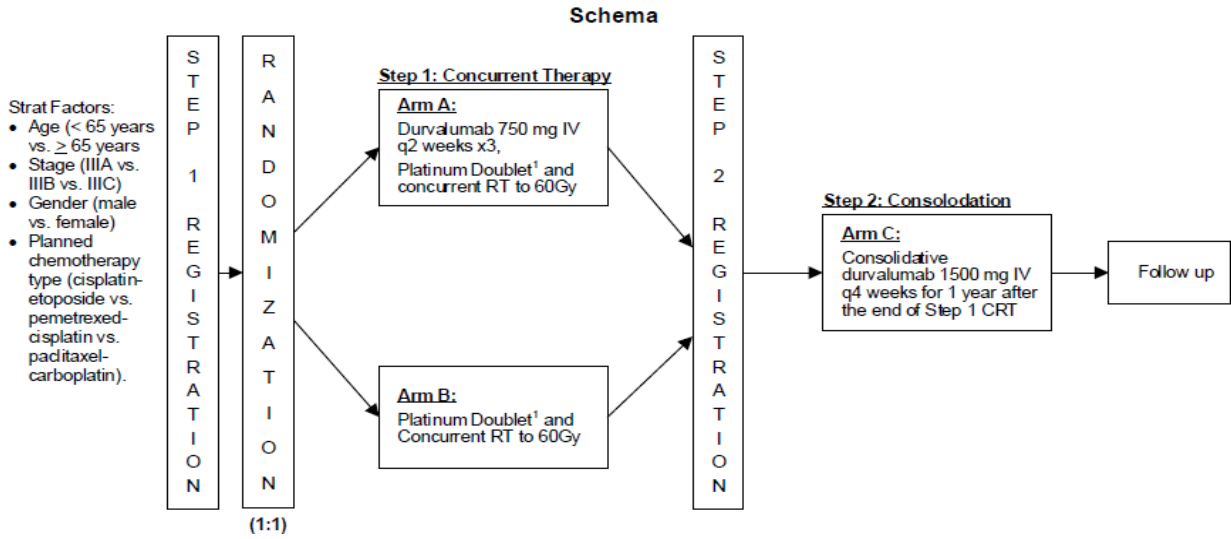
*** Patients who are pre-registered after SLN surgery are NOT eligible to enroll onto the Arm Lymphedema Companion Study (A011201-S11)**

Schema

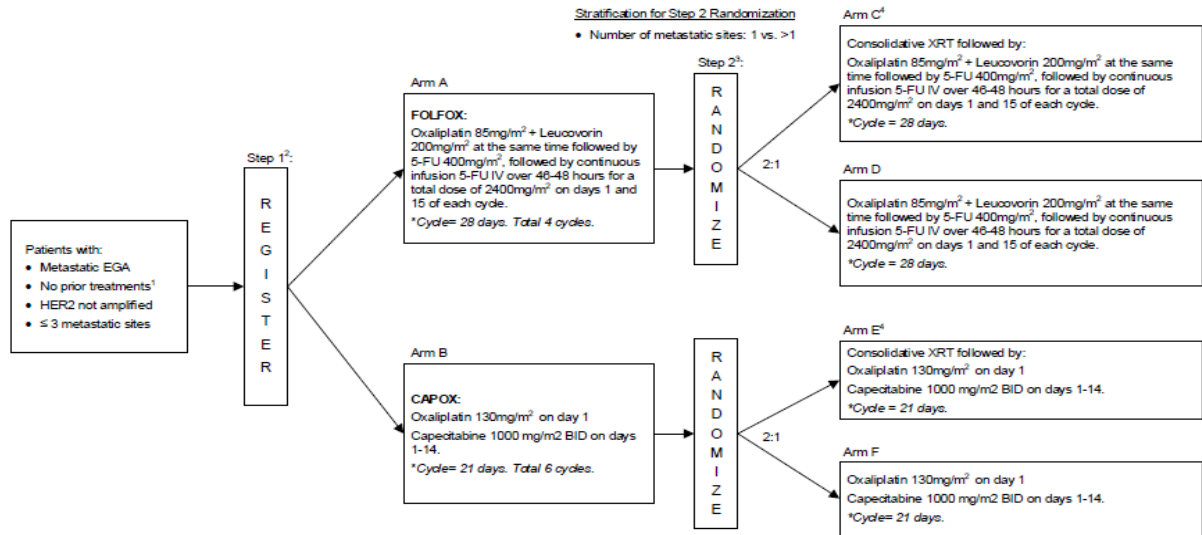


All patients will receive oxaliplatin on both phases of the trial. Further, for all patients the 17th week of study drug will be a tapering period.

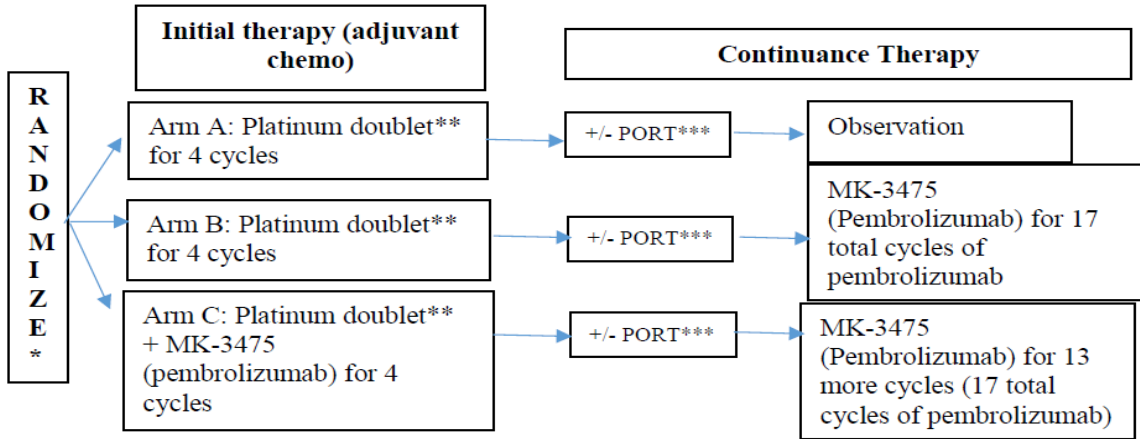
* Additional patients will be recruited to the Phase III trial. The most promising dose of duloxetine will be determined after initial Phase II, and this dose will be used for Phase III for patients randomized to the duloxetine arm.



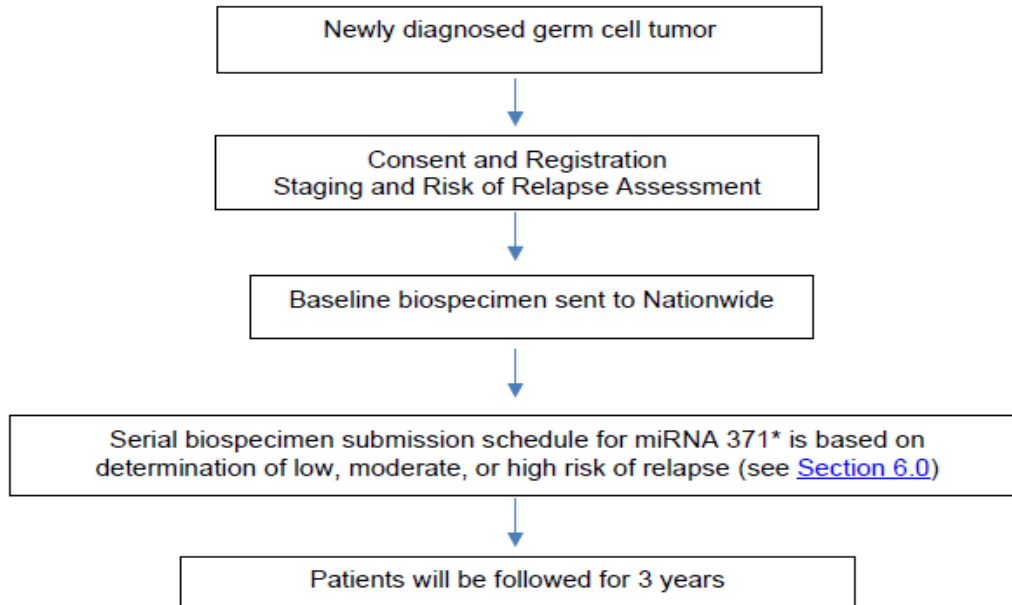
Schema



Schema: 1 cycle = 21 days



SCHEMA



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

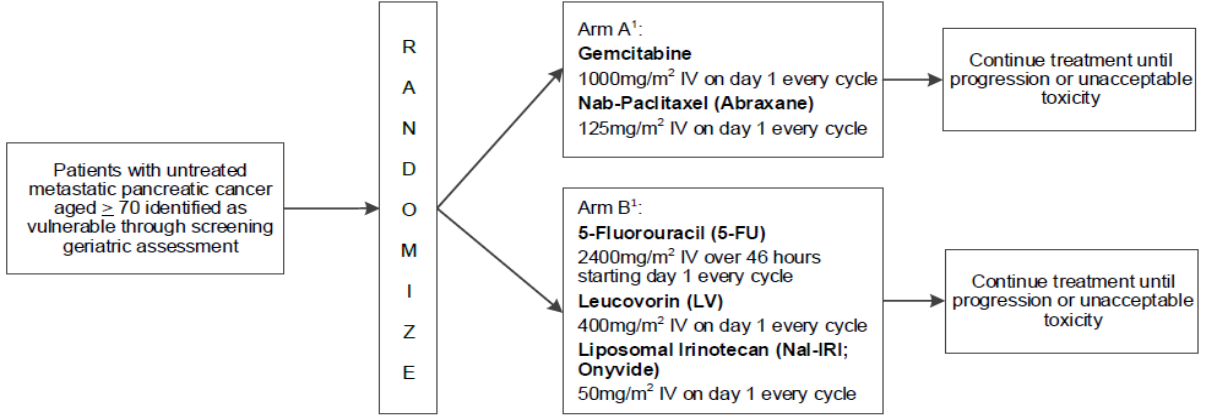
EA2186 SCHEMA
Navigator - Carrie x3621

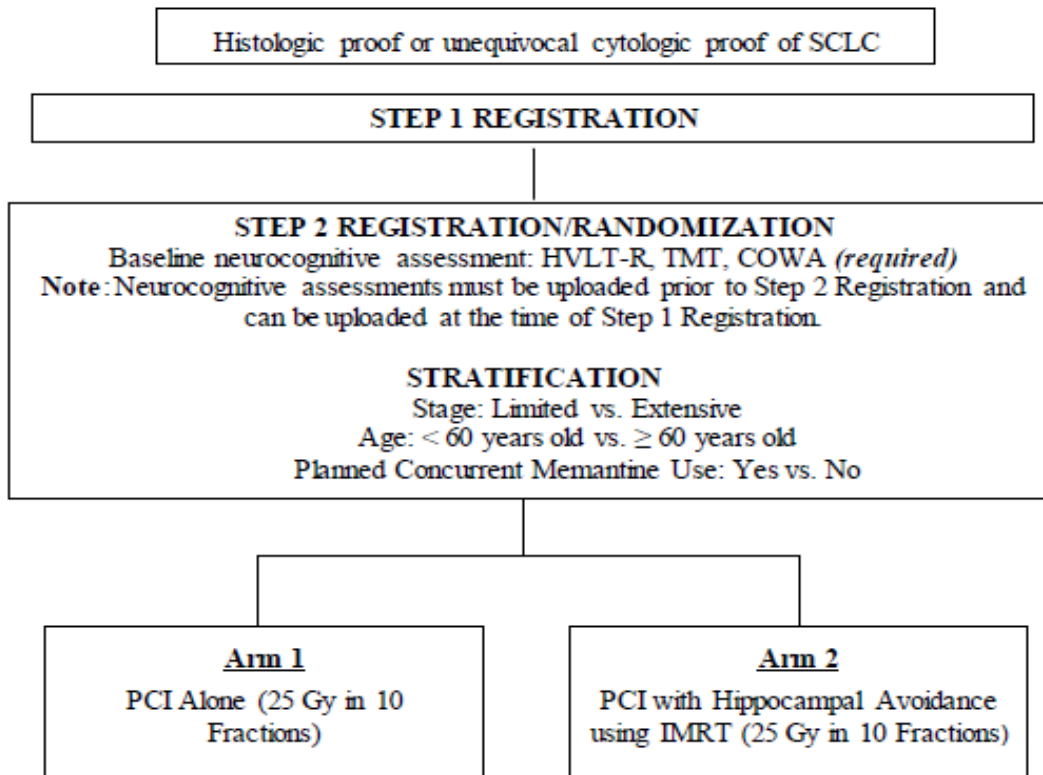
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Schema

Stratification:

- ECOG: 0-1 vs 2
- Age 70-74 vs ≥ 75





SCHEMA

REGISTRATION STEP 1



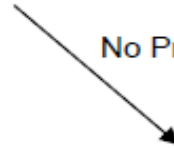
60 Gy hypofractionated radiotherapy in 15 fractions over 3 weeks



2-5 weeks after completion of radiotherapy:
disease assessment

Progression

No Progression



Off protocol treatment

REGISTRATION STEP 2



Atezolizumab consolidation
for up to 12 months
(maximum of 17 cycles)

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

MENU

Key Inclusion Criteria

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

Stratification Factors:

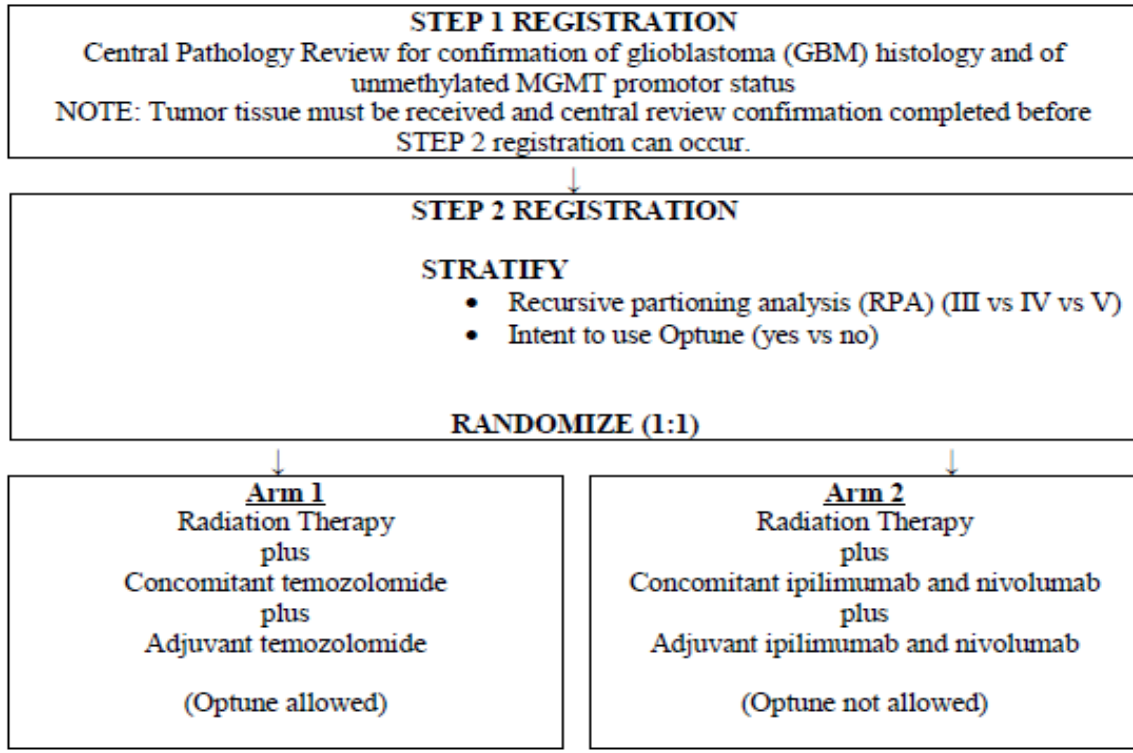
- SD vs. PR/CR to prior FOLFOX induction
- BRAF_{mut} and/or Ras_{mut} vs. BRAF_{wt} + Ras_{wt}
- 6-8 cycles vs. >8 cycles of FOLFOX induction

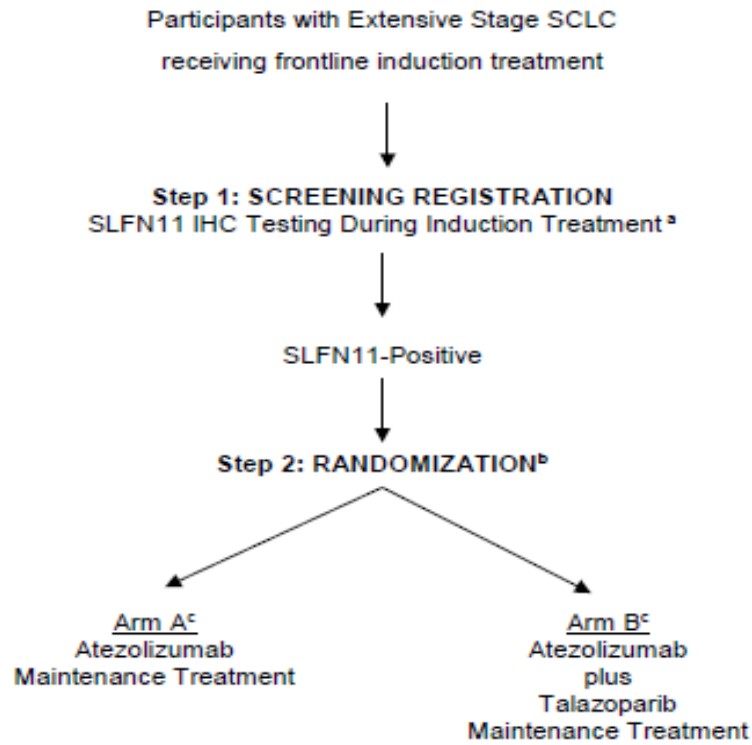
R
1:1:1

Olaparib Oral +
Bevacizumab
(until progression)

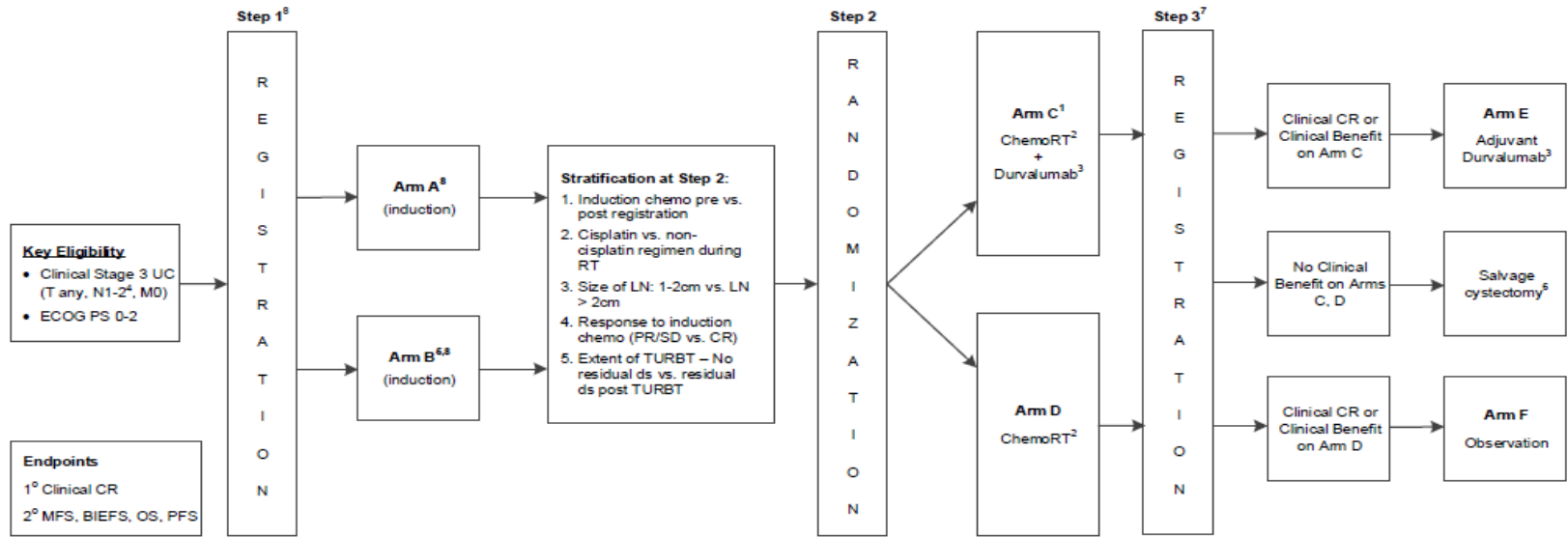
Olaparib Oral
(until progression)

5-FU + Bevacizumab
(until progression)



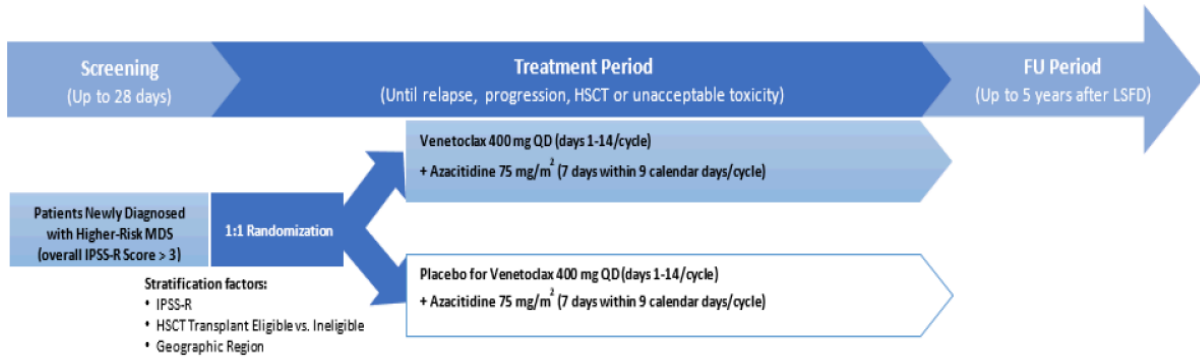


Schema



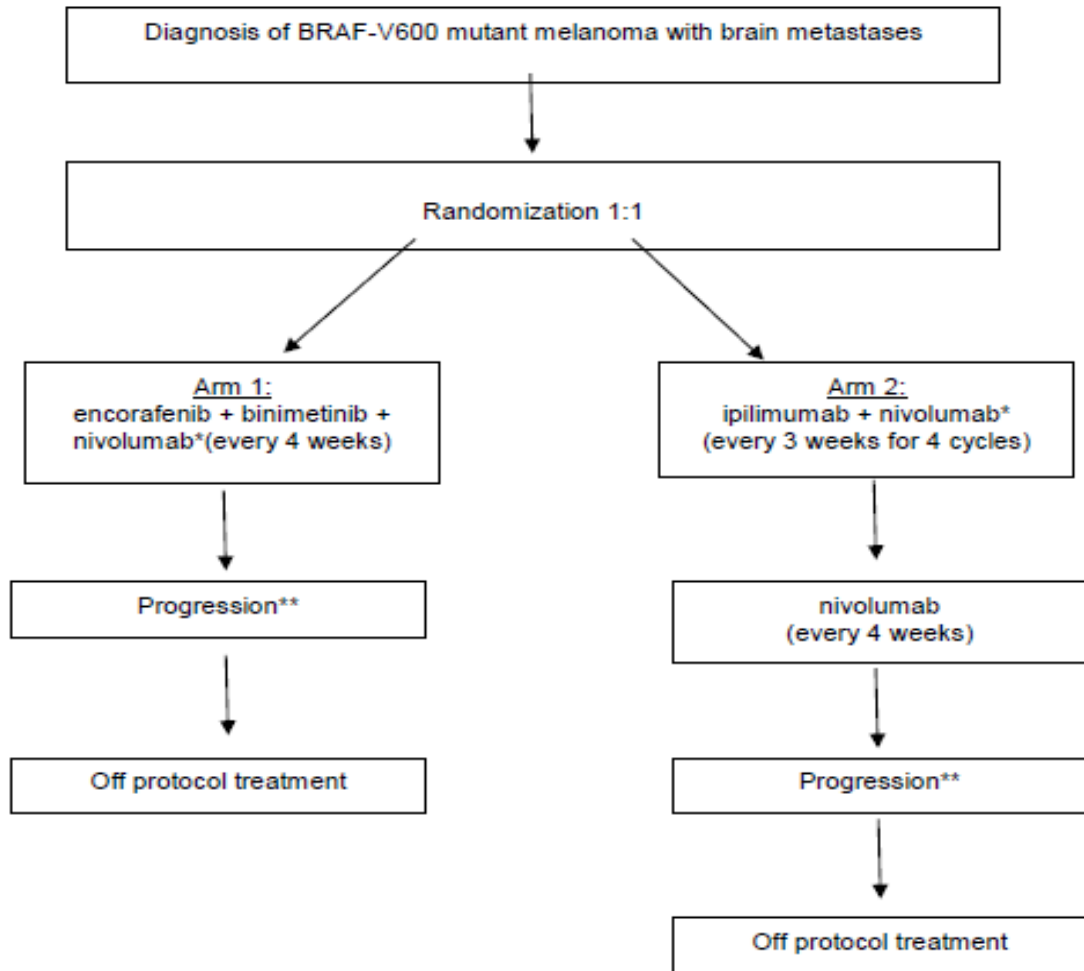
M15-954
Navigator -Heather x3661

MENU



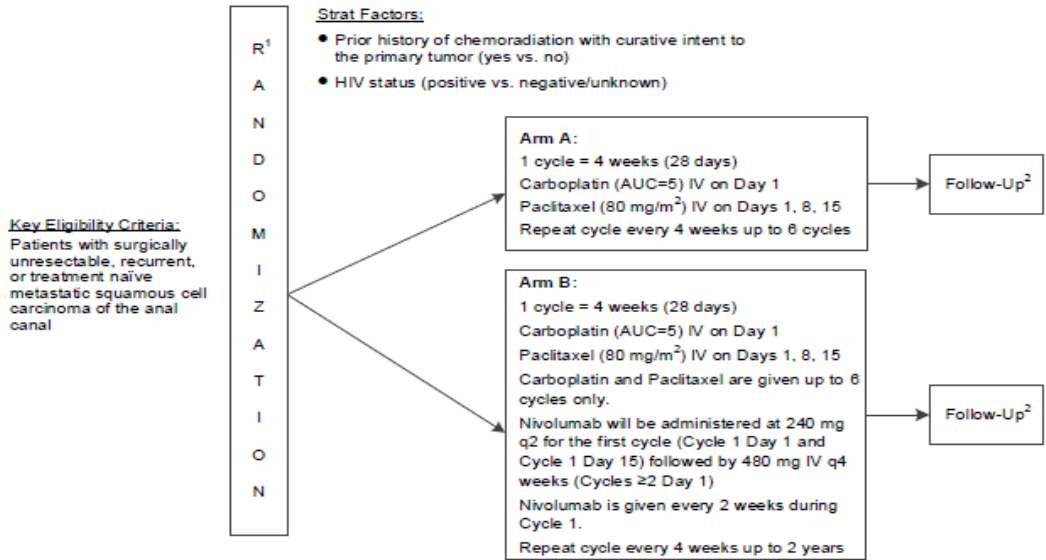
FU = follow up; HSCT = hematopoietic stem cell transplant; IPSS-R = Revised International Prognostic Scoring System; LSFD = last subject first dose; MDS = myelodysplastic syndrome; QD = once daily

SCHEMA

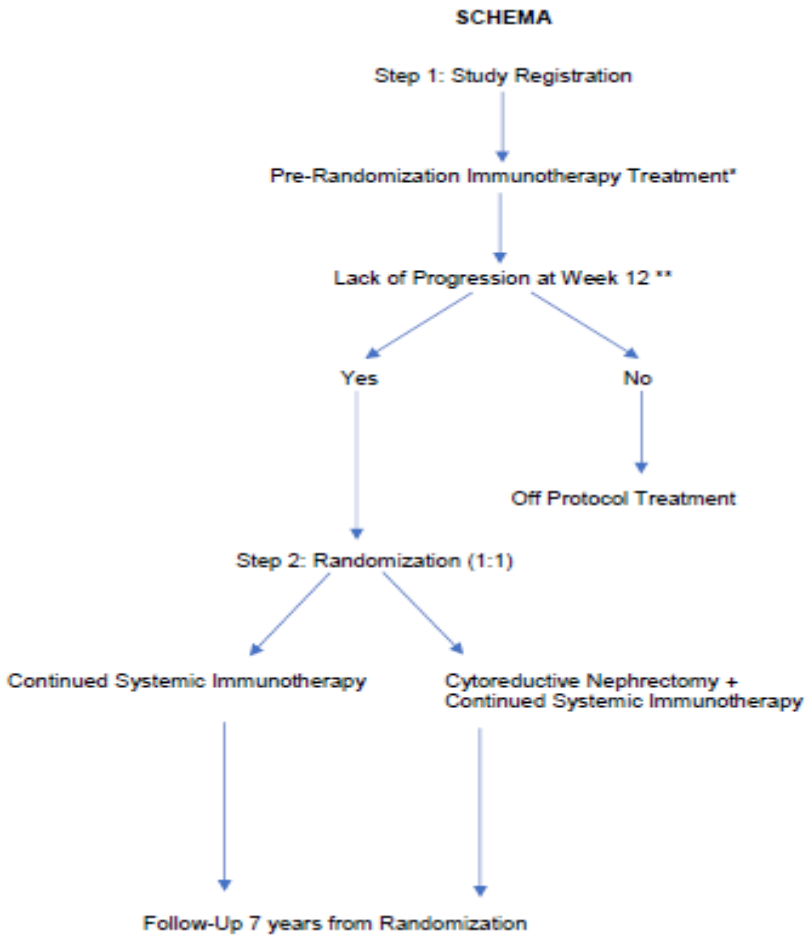


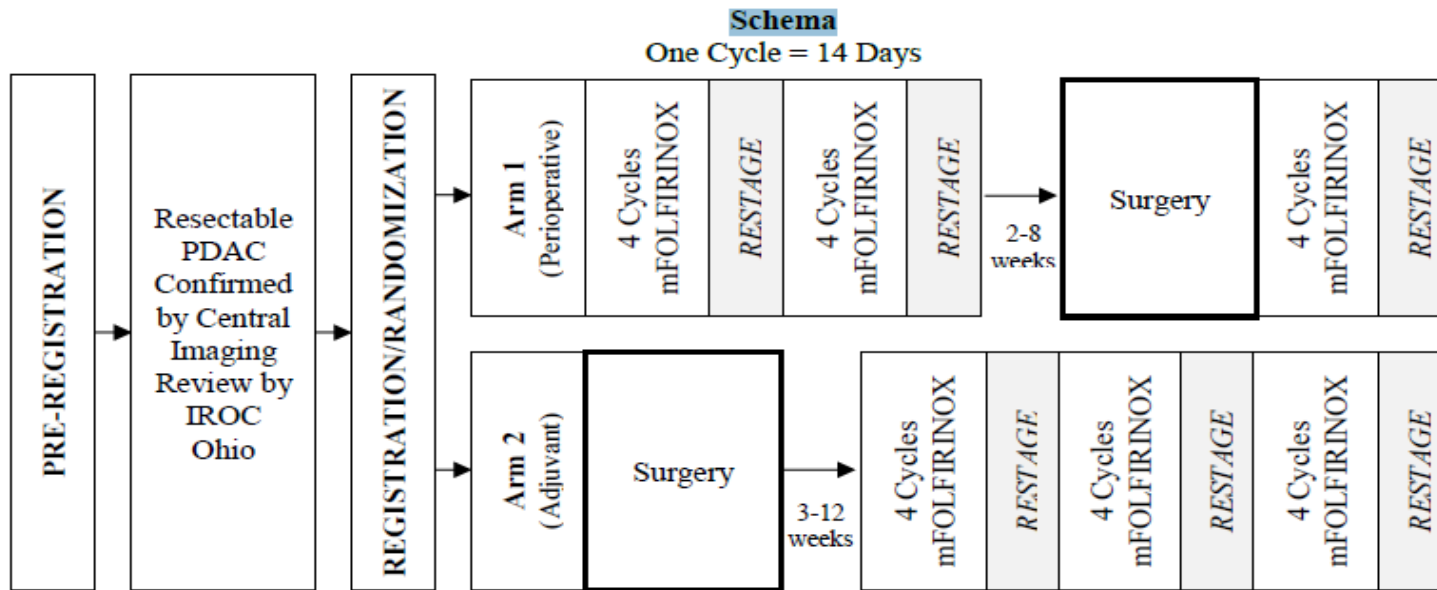
EA2176
Navigator -Carrie x3621

MENU

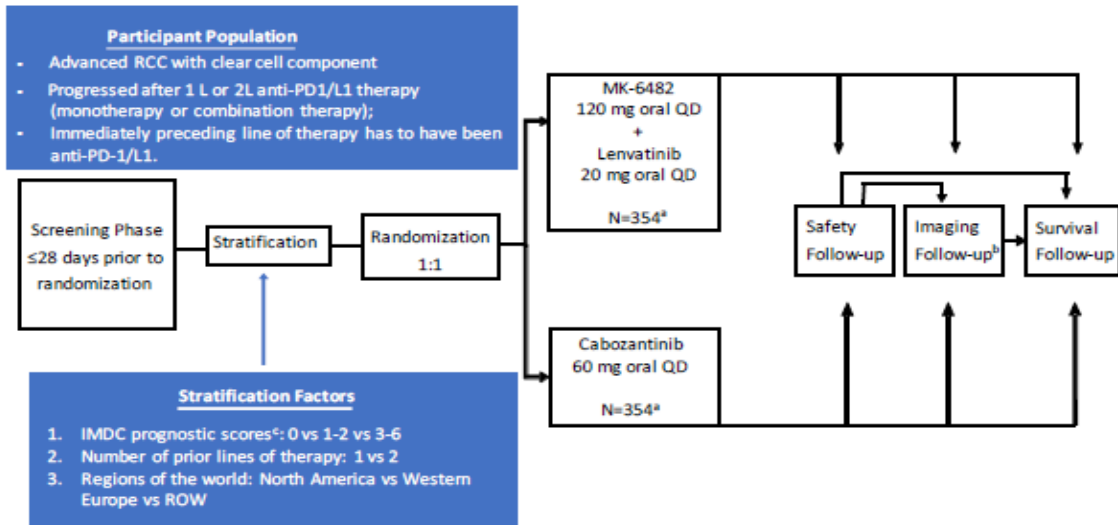


1. Randomization is 1:2 (A:B).
 2. For this protocol, all patients, including those who discontinue protocol therapy early, will be followed for response until disease progression, even if non-protocol therapy is initiated, and for survival every 3 months for two years from the date of randomization.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





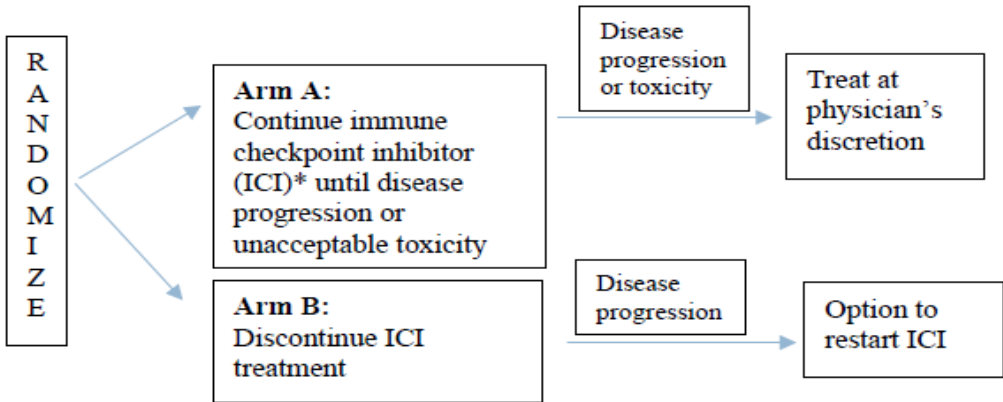
Treatment/intervention is to continue as outlined above or until disease recurrence, unacceptable toxicity, or withdrawal of consent. Patients will be followed for 6 years or until death, whichever comes first.



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

Schema

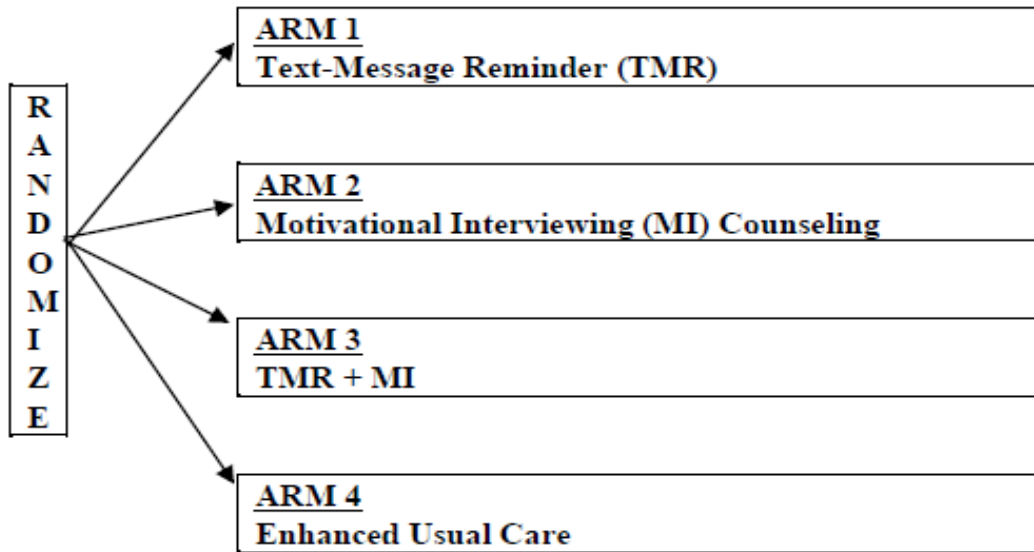
Cycle definition is based on ICI cycle length



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

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

Schema



SCHEMA

Newly Diagnosed, Early Stage, Asymptomatic, High-Risk Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) [CLL-International Prognostic Index (CLL-IPI) ≥ 4 and/or Complex Cytogenetics]

STRATIFY
High Risk (CLL-IPI 4-6)
vs.
Very High Risk (CLL IPI ≥ 7 or Complex Cytogenetics)

RANDOMIZE
2:1
(Early Arm vs. Delayed Arm)

EARLY V-O ARM

OBINUTUZUMAB
+
VENETOCLAX

(begin after randomization)

DELAYED V-O ARM*

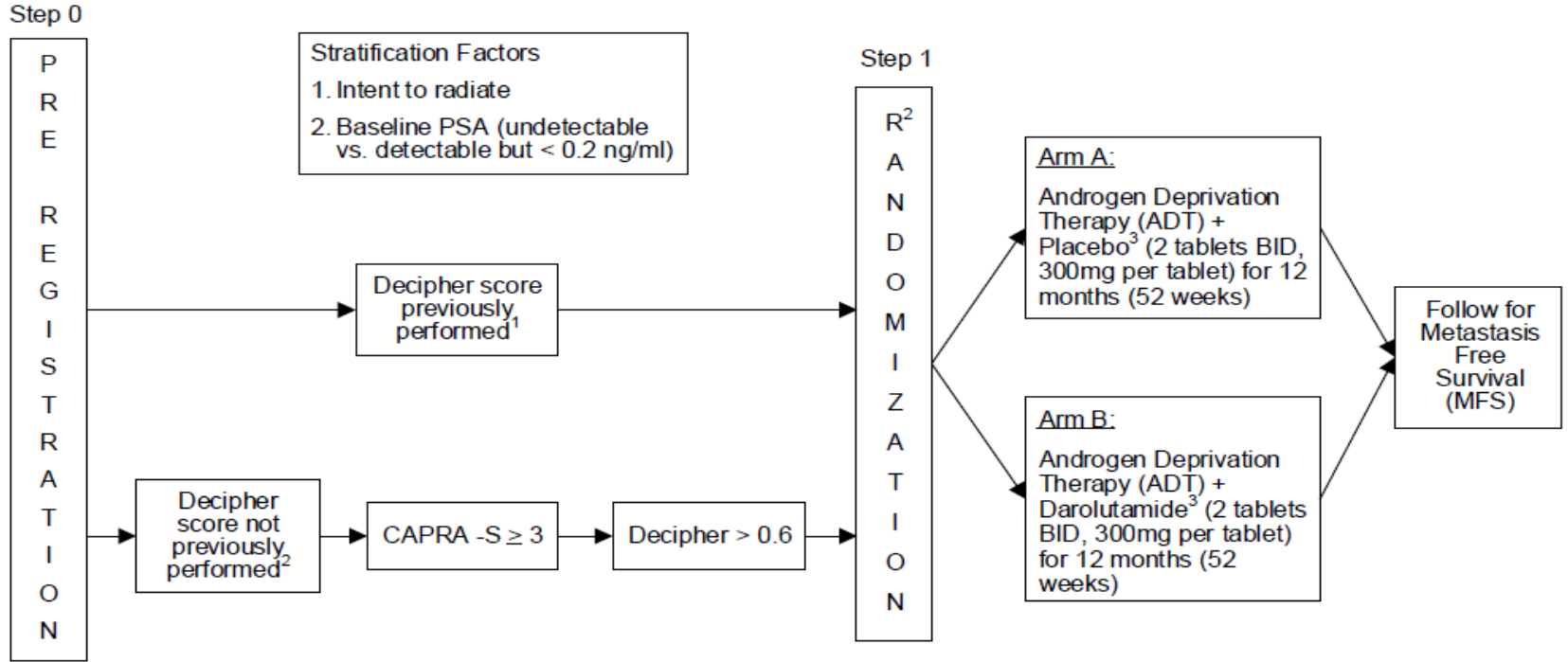
OBINUTUZUMAB
+
VENETOCLAX

(begin when IWCLL indication is met)

End Obinutuzumab after Cycle 6;
End Venetoclax after Cycle 12

OFF PROTOCOL THERAPY
Follow-up for 10 years after registration

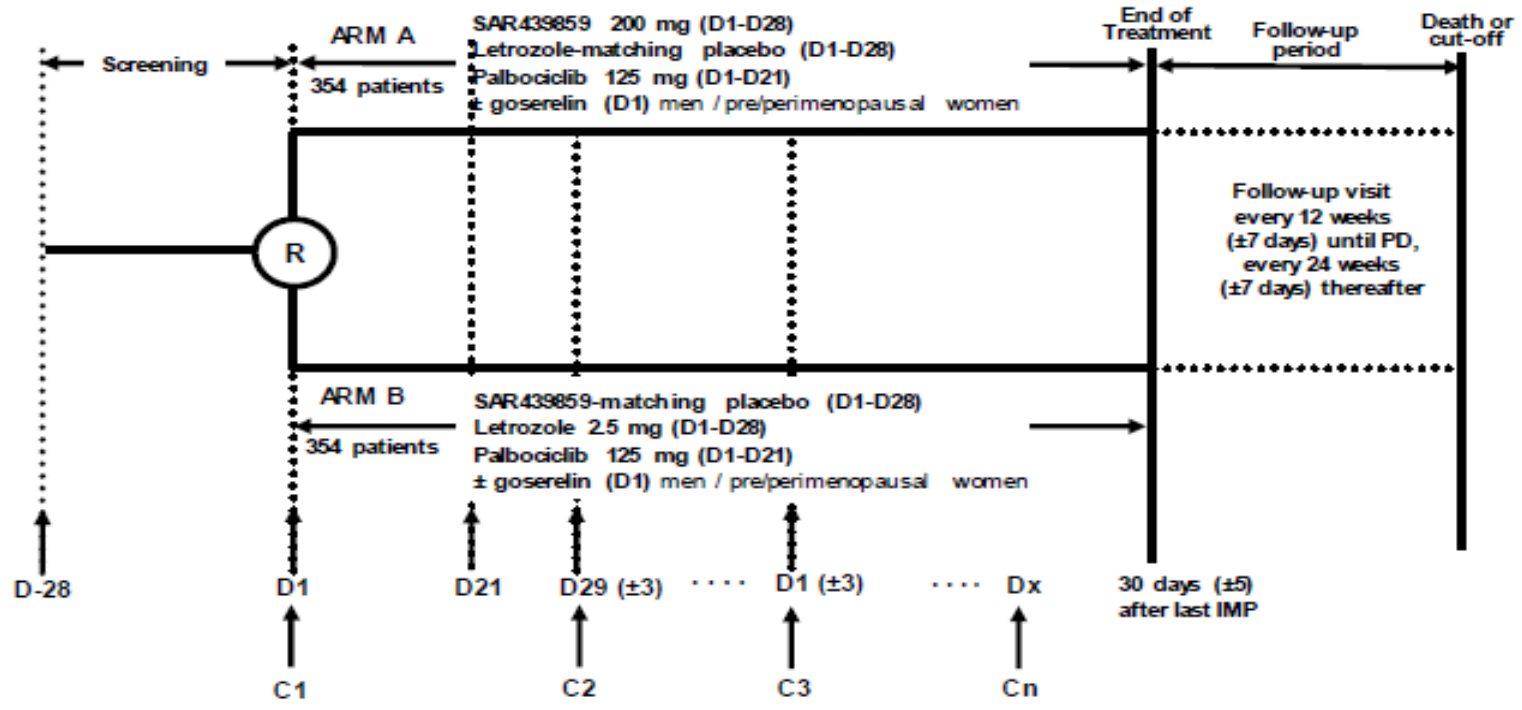
Schema



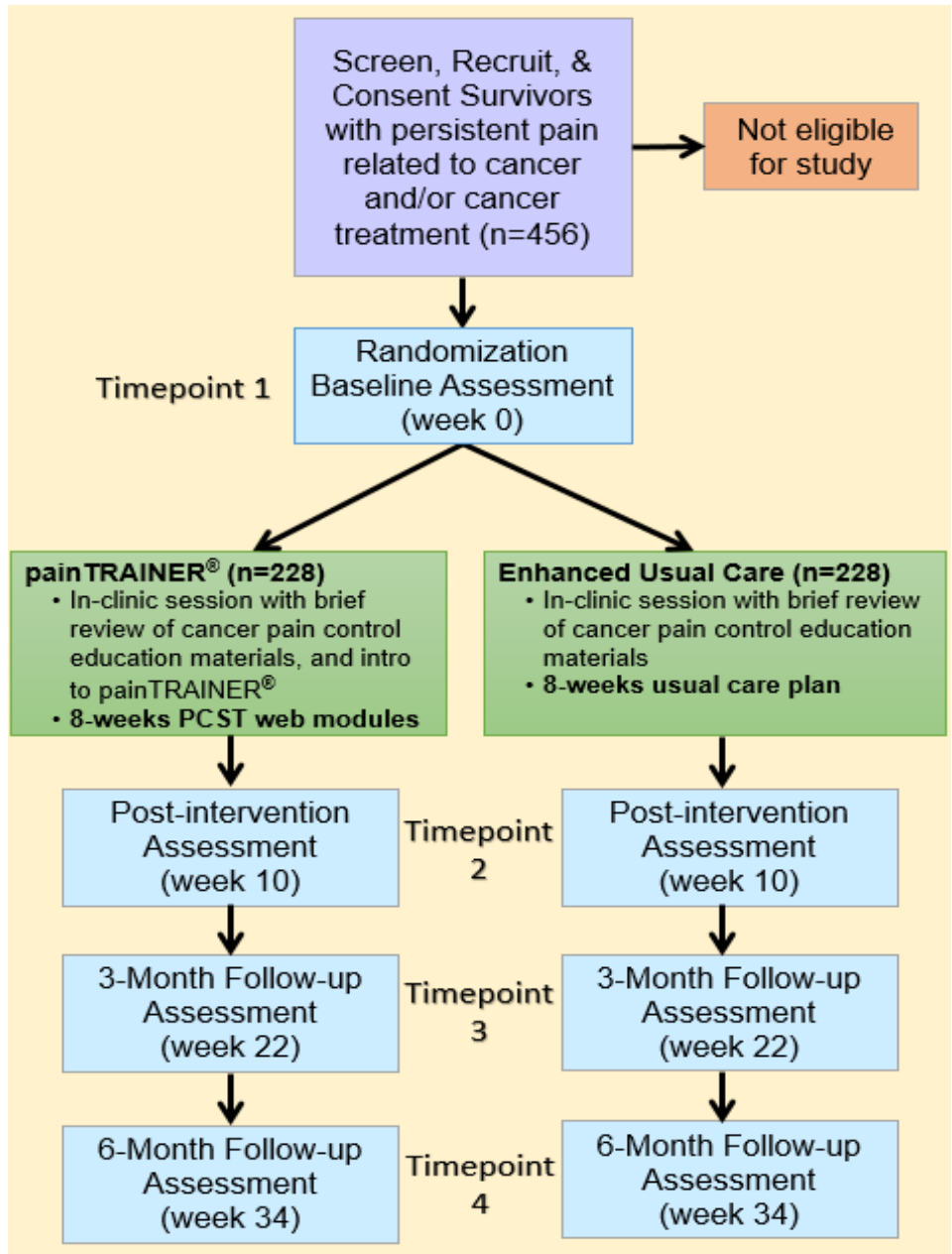
Accrual Goal: 810

1. Patients with a Decipher score previously performed by Decipher biosciences with a score of > 0.6 are eligible and may proceed from pre-registration directly to randomization after uploading Decipher score to Medidata Rave.
2. For patients who do not already have a completed Decipher test through standard of care testing the calculated CAPRA-S score must be ≥ 3 and the post registration Decipher Biosciences assessment must determine Decipher score to be > 0.6 .
3. Patients receiving post-operative adjuvant radiation (XRT) can receive it anytime within 52 weeks of prostatectomy.

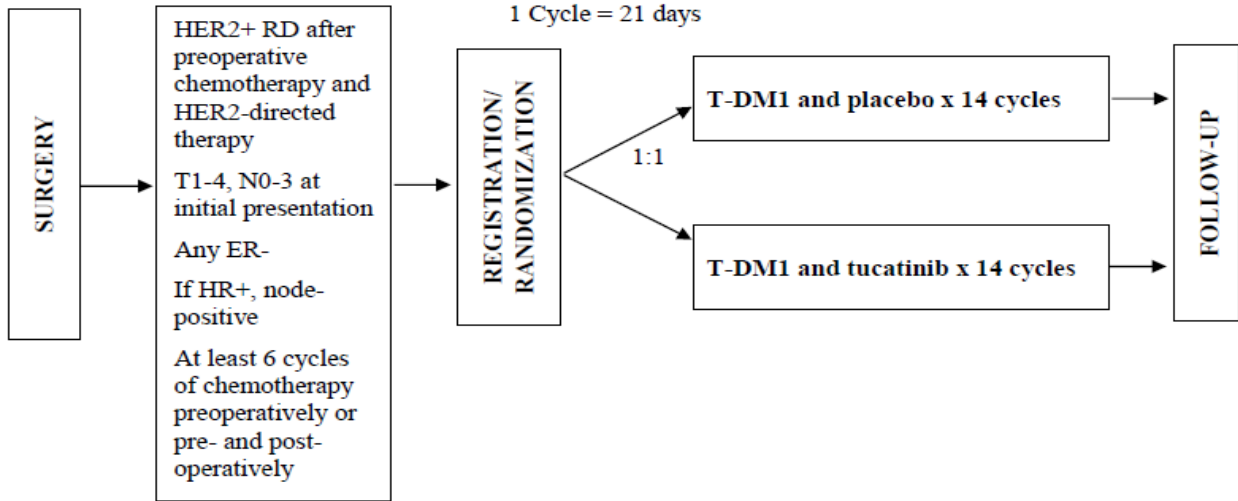
Figure 1 - Graphical study design



C = Cycle; D = day; IMP = Investigational medicinal product; PD = progressive disease; R = randomization.



Schema



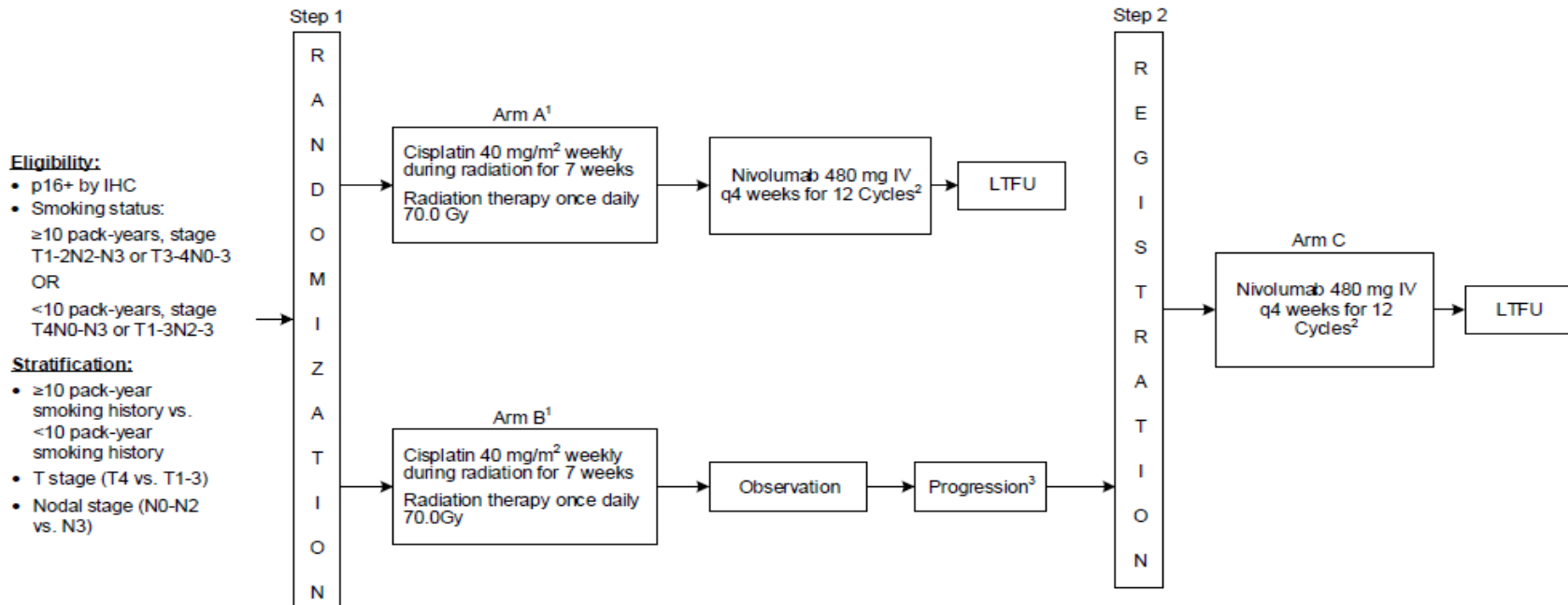
Note: HR stands for “hormone-receptor.”

Treatment is to continue until breast cancer recurrence, completion of 14 cycles, or unacceptable adverse event. Patients will be followed for 10 years after registration or until death, whichever comes first.

EA3161
Navigator -Ashton x3611

MENU

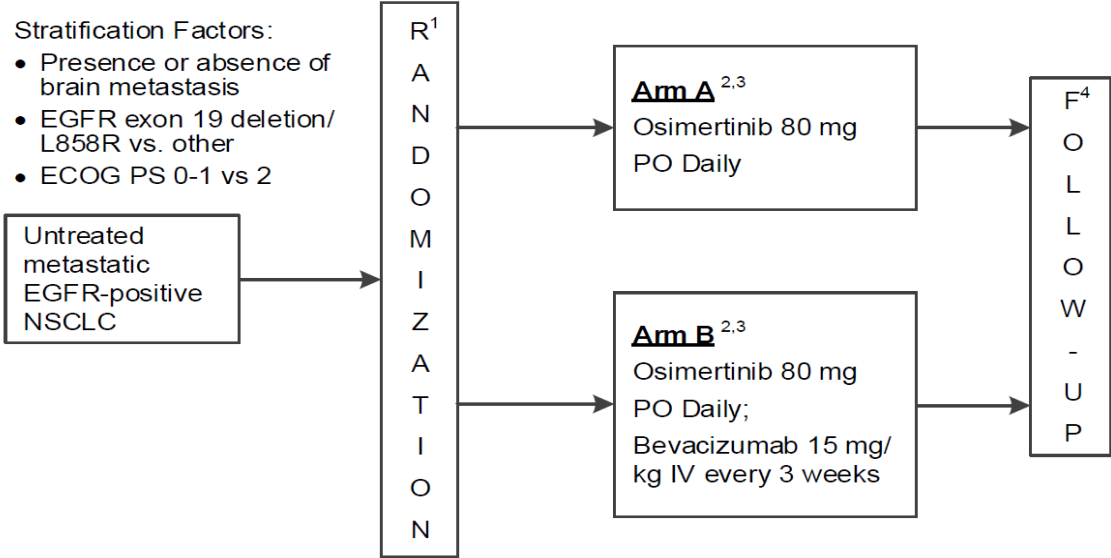
Schema



Accrual Goal: 744

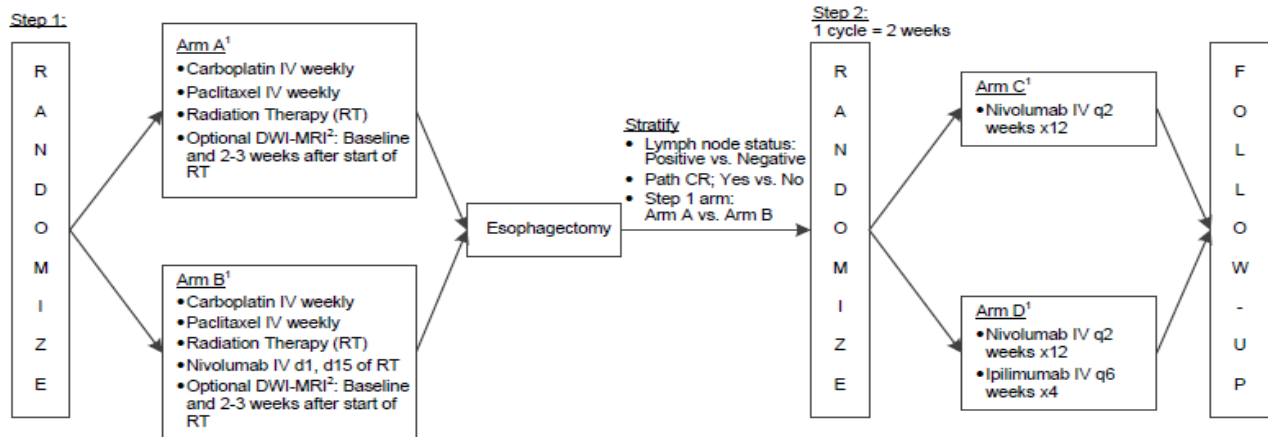
1. Submit tissue for PD-L1 testing.
2. Cycle length = 28 days
3. Patients who were randomized to observation will be offered the option to cross over if they have clearly documented progression by the RECIST criteria and tissue-proven progression within 12 months from the end of cisplatin/radiation therapy.

Schema



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

Schema

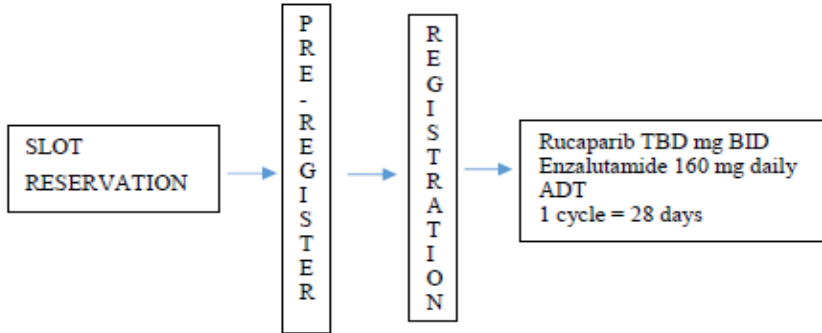


N=278

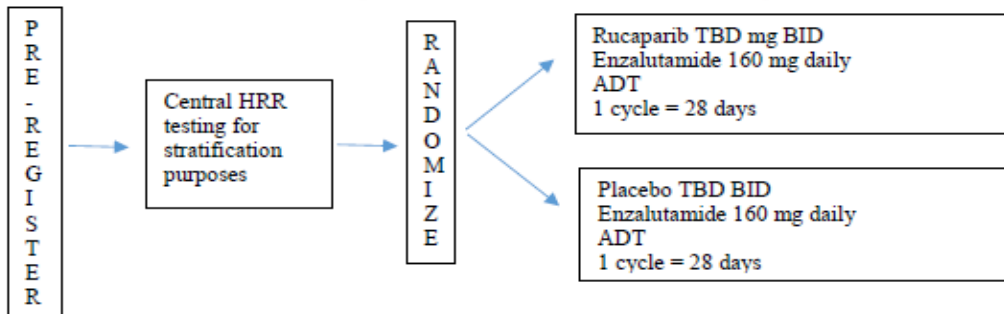
1. Please reference Section 5.1 for treatment dosing specifics.
2. Optional Diffusion weighted imaging-MRI (DWI-MRI) should be obtained at step 1 baseline and 2-3 weeks after initiation of protocol treatment.

Schema

PK Substudy (Dose Finding Portion) Only

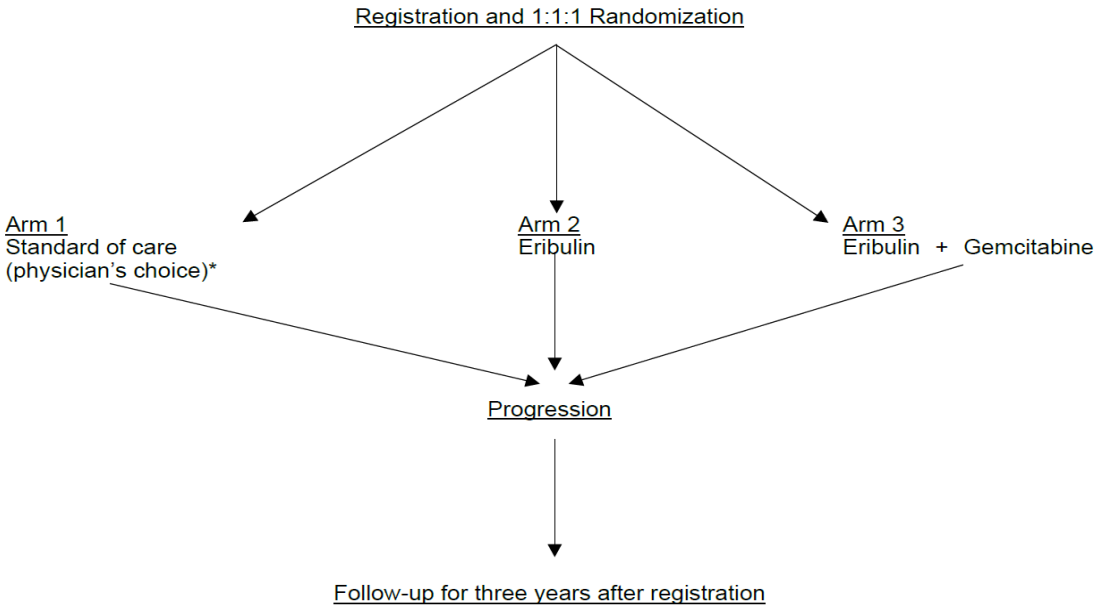


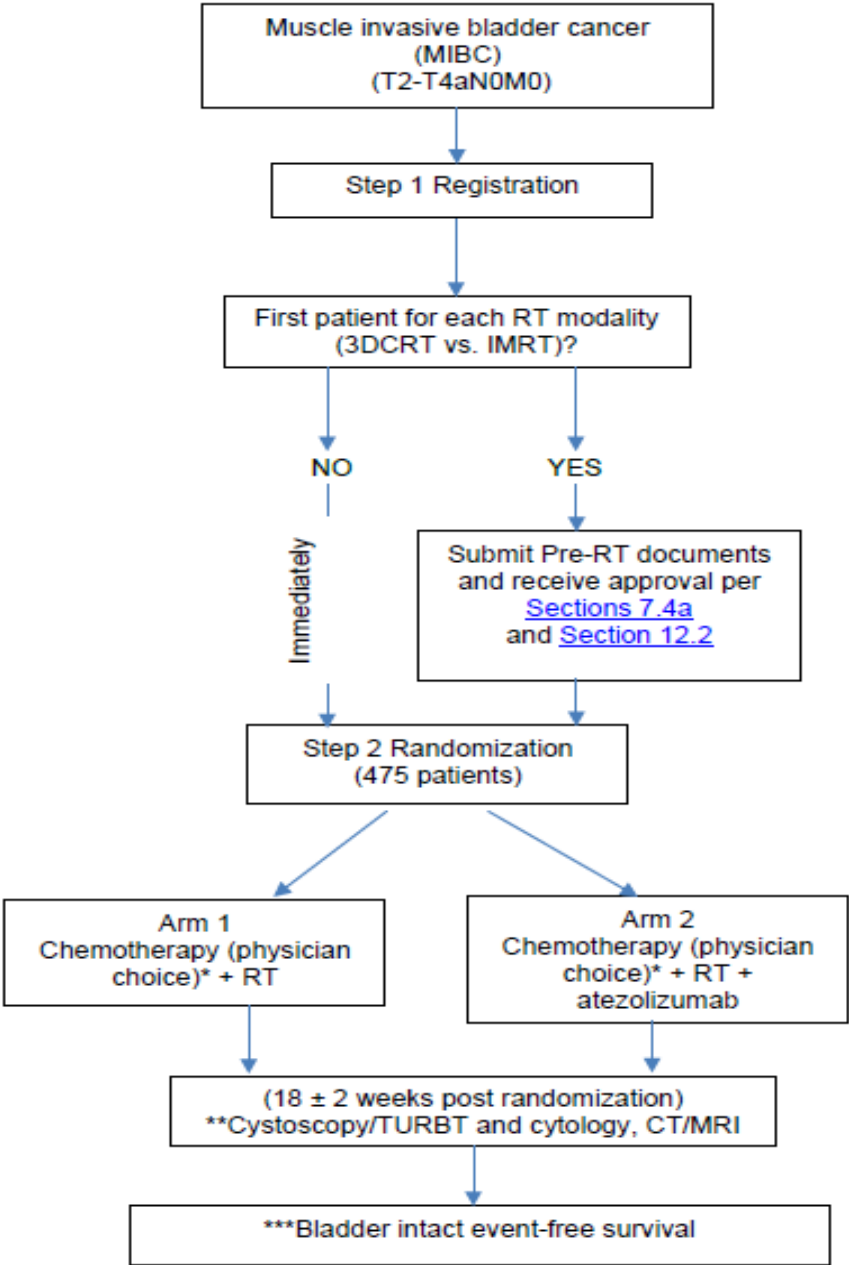
Phase III (Double-Blinded, Placebo-Controlled) Portion



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

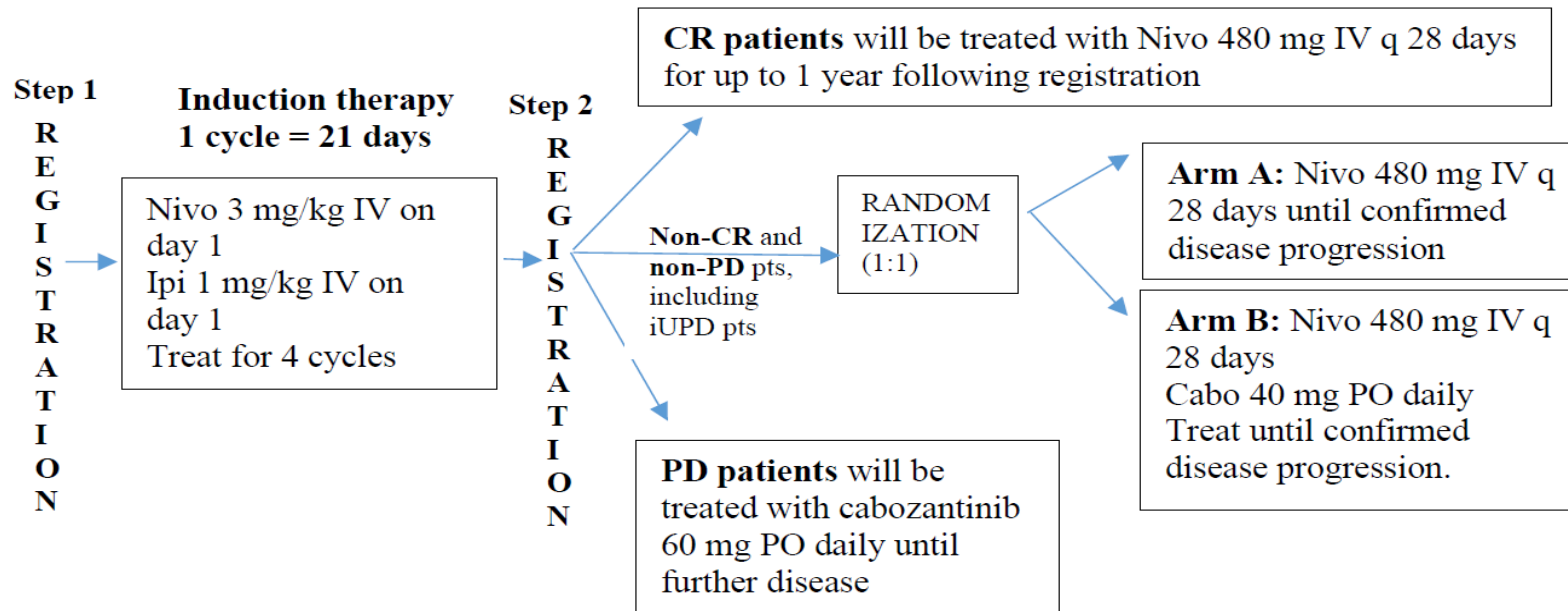
Please refer to the full protocol text for a complete description of the eligibility criteria and treatment plan.



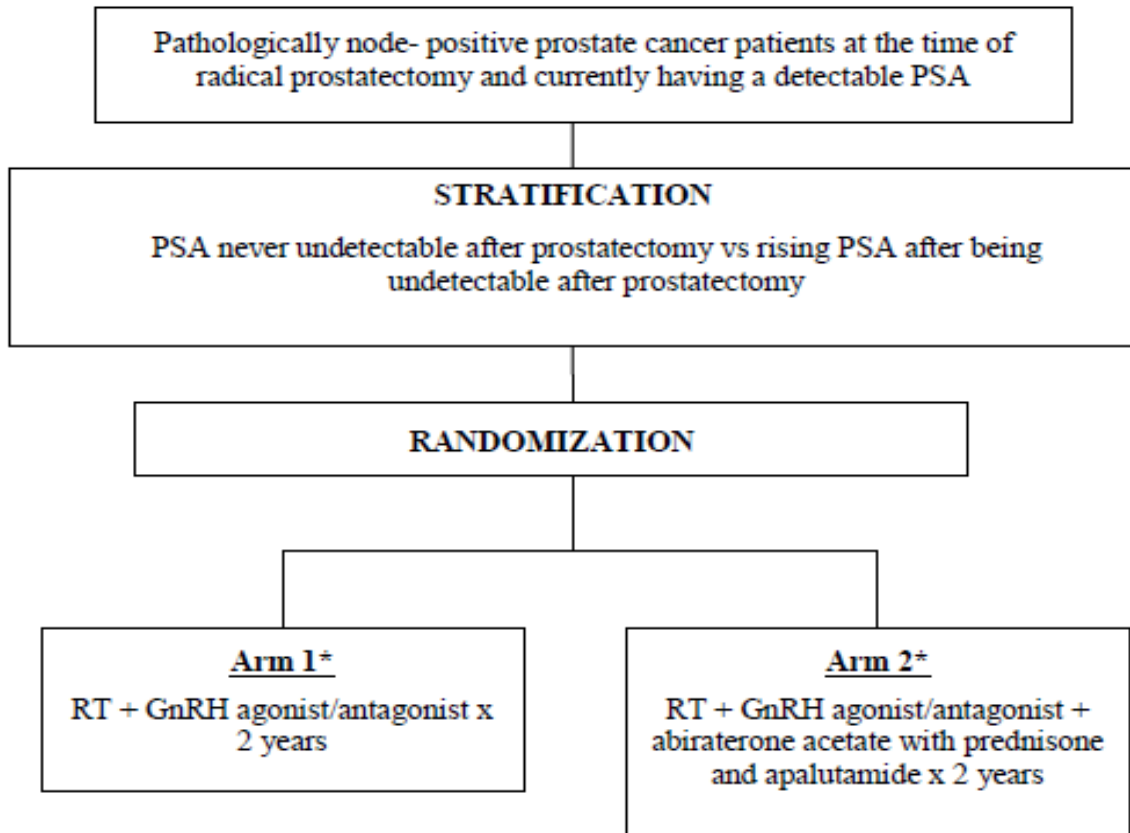


Schema

1 cycle = 28 days



**NRG-GU008
SCHEMA**



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)

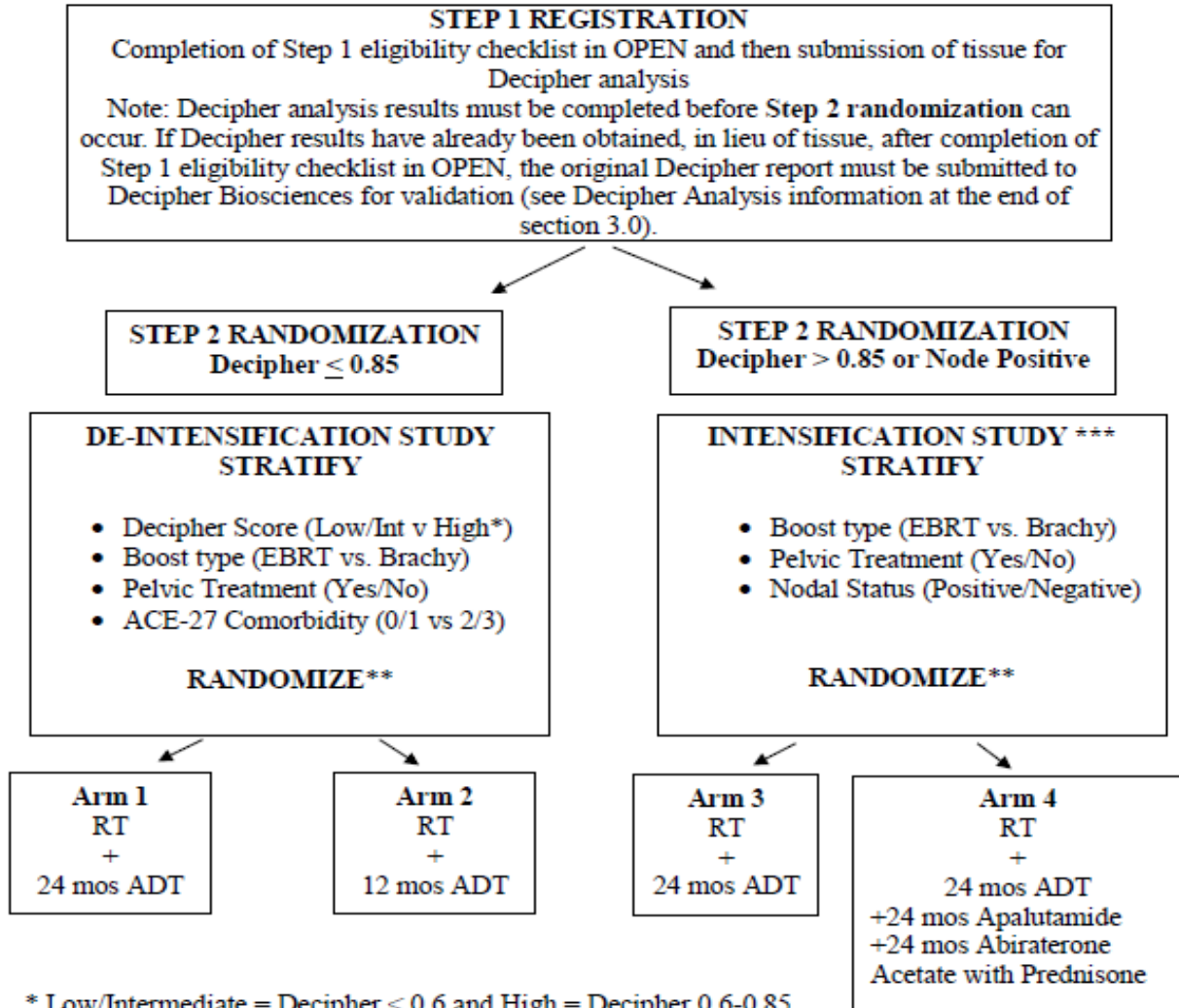


Arm 2

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

¹Randomization is 1:1

NRG-GU009
SCHEMA



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

**Randomization is 1:1

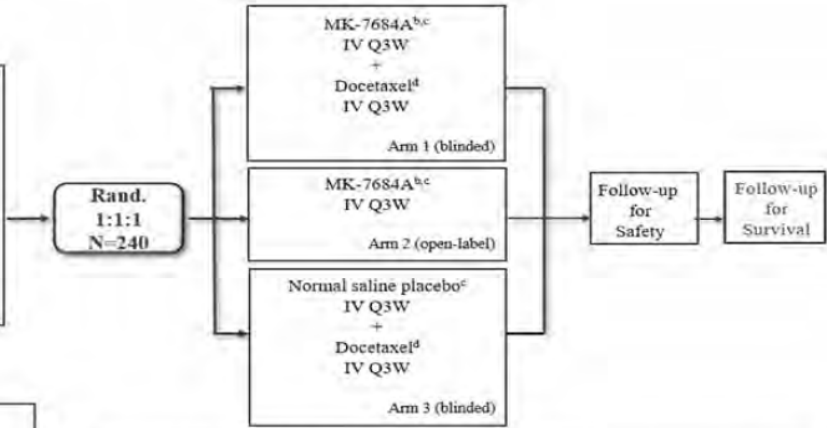
*** Up to 200 patients who consent to imaging sub study will receive F-18 PET. See Section 4.0 and 11.3 for more details and time points.

Key Eligibility Criteria*

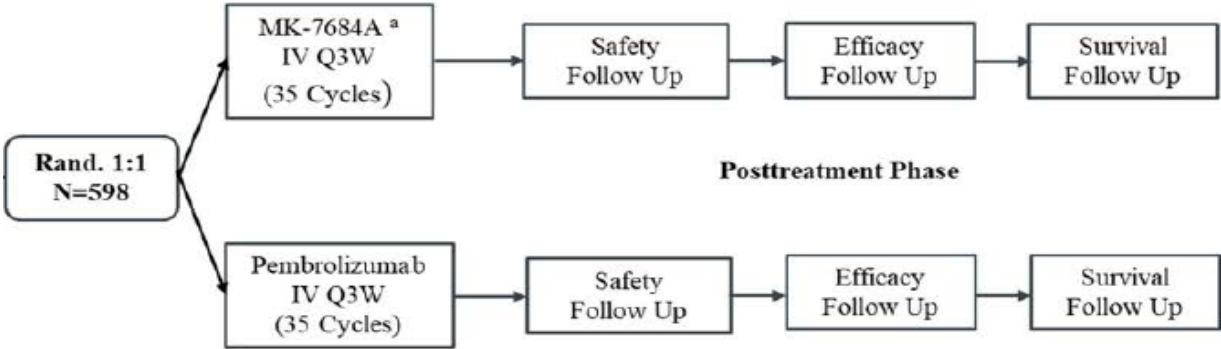
- Stage IV NSCLC with any histology
- PD after platinum doublet chemotherapy and one prior anti-PD-1/PD-L1 inhibitor
- Must not have received prior docetaxel
- EGFR-, ALK- or ROS1-directed therapy not indicated
- Newly obtained/archival tumor tissue for PD-L1 TPS
- Measurable disease based on RECIST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

Stratification

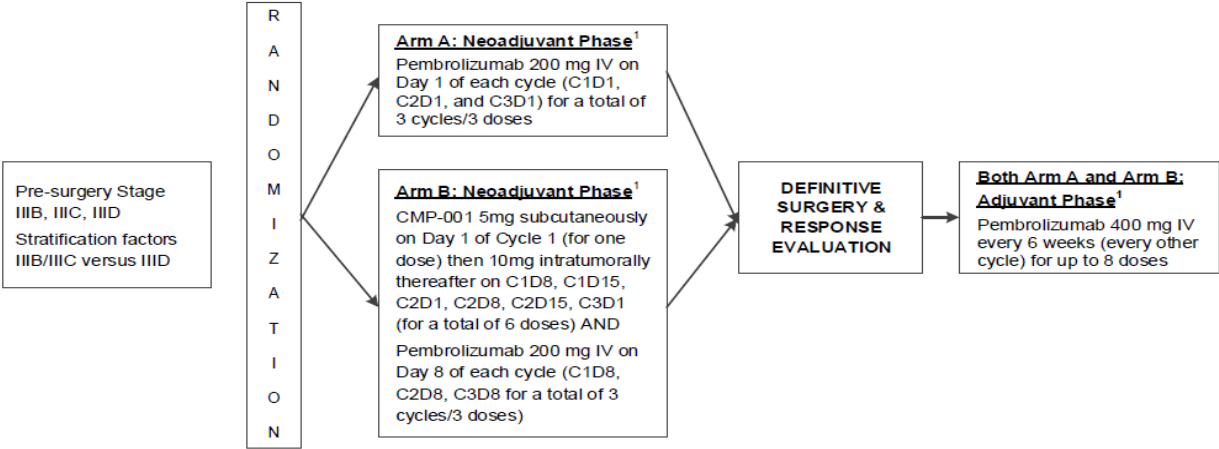
- ECOG performance status (0 vs 1)
- Prior anti-PD-1/PD-L1 mAb (immediate prior treatment vs not immediate prior treatment)
- PD-L1 TPS (<50% vs ≥50%)



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



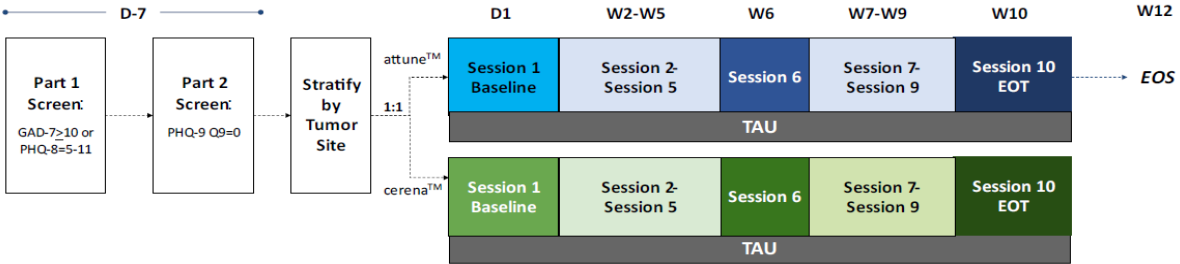
Schema



1. Neoadjuvant and Adjuvant cycle length: 1 cycle = 21 days

**PROT001/BLEU NOTE
Navigator -TBD**

MENU



Treatment-as-Usual (TAU)

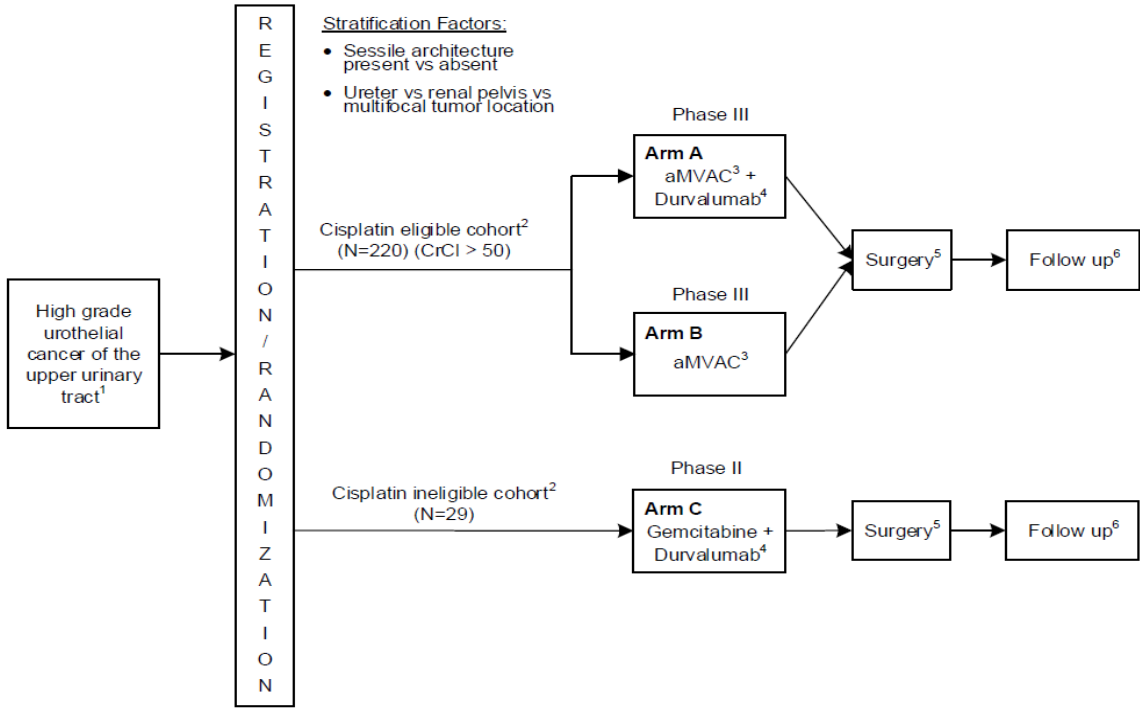
- None to minimal
- Pharmacotherapy for chemo side effects, e.g. antiemetics and SSRI, tricyclic antidepressants for pain or hot flashes

Assessments	Baseline	W6	W10 EOT	W12 EOS
Anxiety (PROMISA, CGI)	X	X	X	X
Depression (PROMIS-D, CGI)	X	X	X	X

Confidential

**BLUE NOTE
THERAPEUTICS**

Schema



Step 0

P
R
E
-
R
E
G
I
S
T
R
A
T
I
O
N

MRD Analysis¹

MRD positive

MRD negative

Off-study

Step 1

R
A
N
D
O
M
I
Z
A
T
I
O
N

- Stratification
- Molecular-based risk stratification: high vs. standard
 - Prior lenalidomide maintenance dose: 10 mg vs. > 10 mg

Arm A²
Lenalidomide:
10 mg PO daily days 1-28
Ixazomib:
4mg PO days 1, 8, 15

Continue treatment until progression or unacceptable toxicity

Arm B²
Lenalidomide:
10 mg PO daily days 1-28
Placebo:
4mg PO days 1, 8, 15

Continue treatment until progression or unacceptable toxicity

Cycle: 28 days

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**

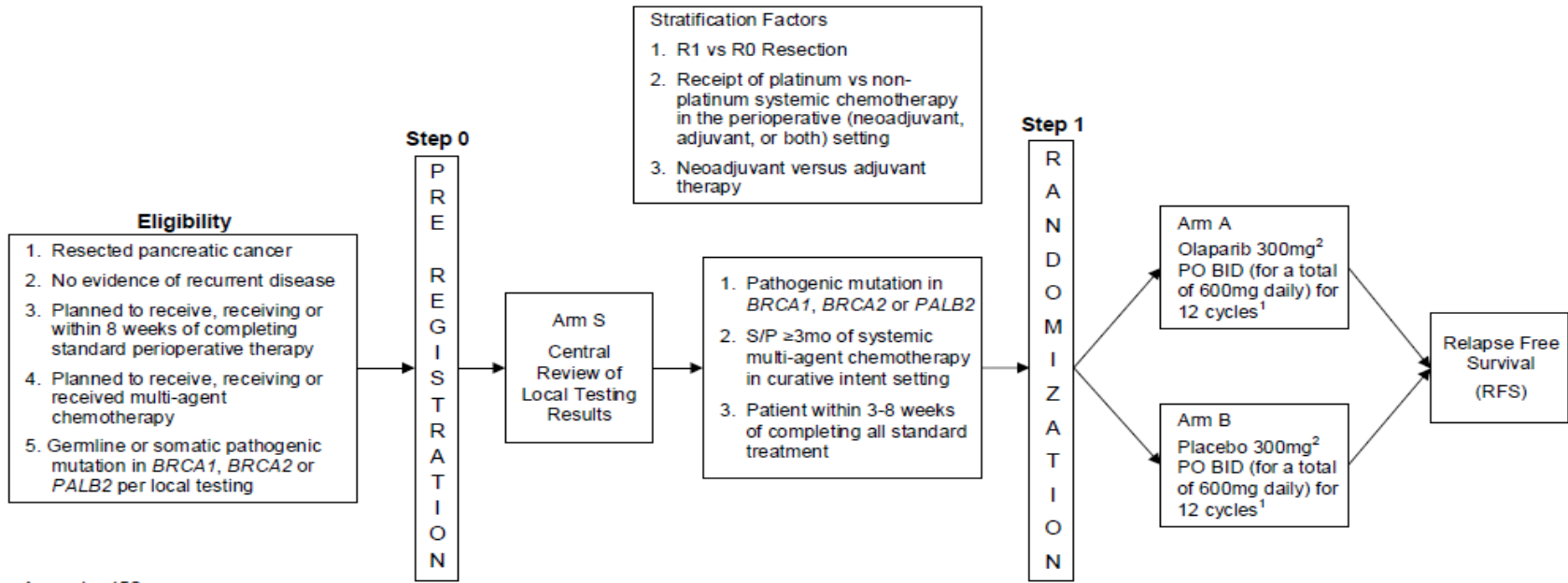
Breast Radiation Therapy
+
Endocrine Therapy

Arm 2**

No Breast Radiation Therapy
+
Endocrine Therapy

EA2192
Navigator -Carrie Geoffroy x3621

MENU

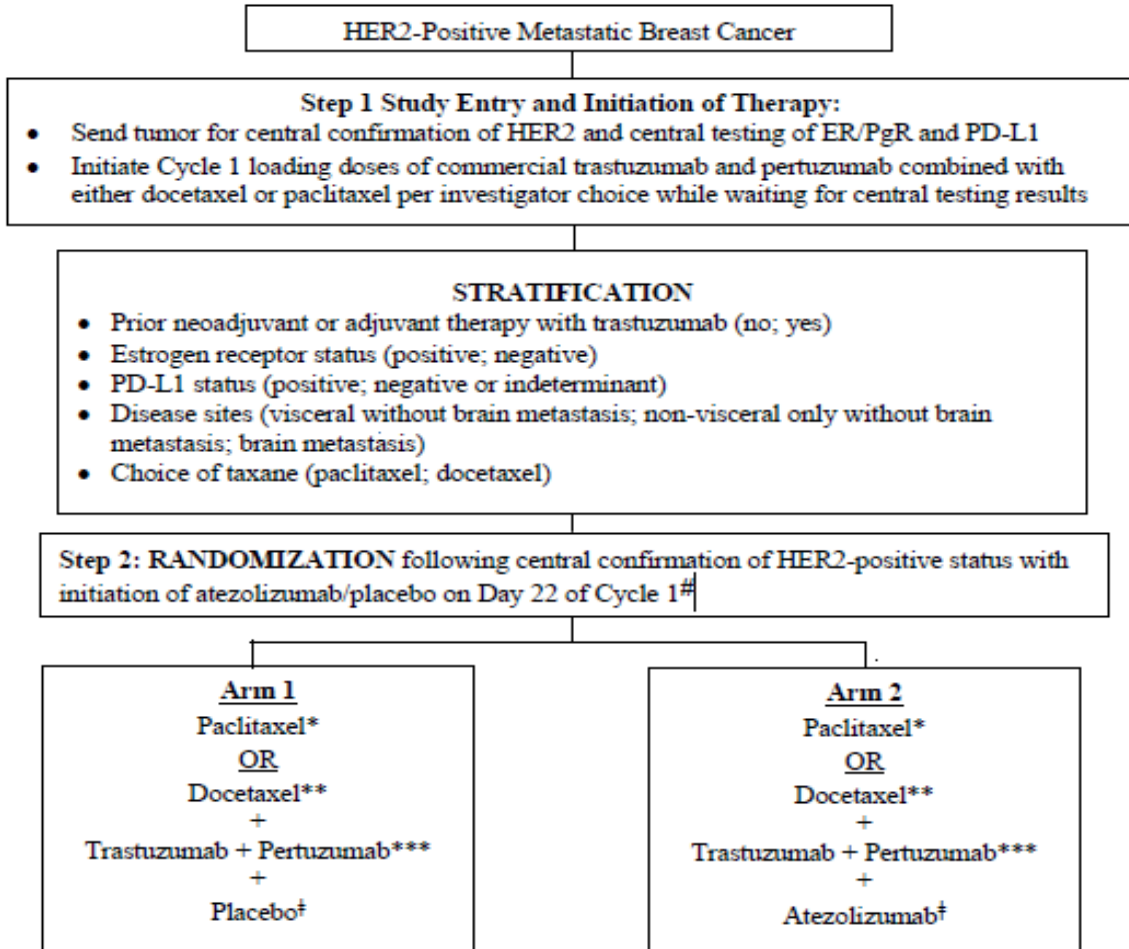


Accrual = 152

¹ One cycle = 4 weeks

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

Figure 1. NRG-BR004 SCHEMA



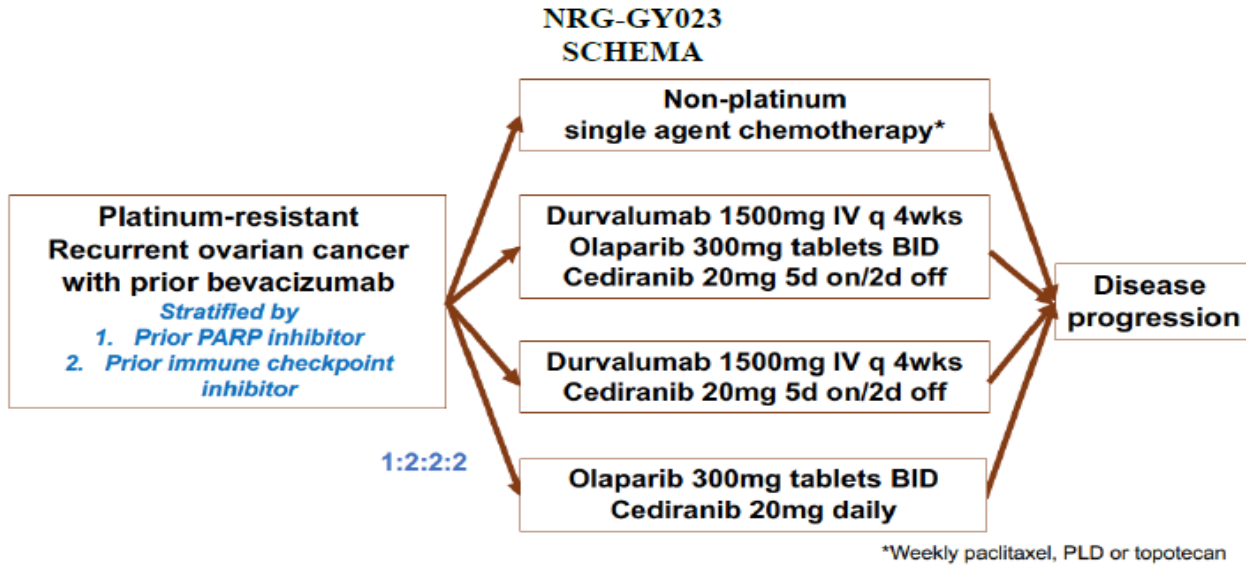
Randomization is 1:1.

* Paclitaxel: 80 mg/m² IV weekly on Days 1, 8, 15, 22, 29, and 36 of an every 6-week cycle for a minimum of 3 cycles with additional cycles at the investigator's discretion OR

** Docetaxel: 75 mg/m² IV on Days 1 and 22 of an every 6-week cycle for a minimum of 3 cycles with additional cycles at the investigator's discretion.

*** Trastuzumab + Pertuzumab: Trastuzumab 6 mg/kg IV with pertuzumab 420 mg IV Days 1 and 22 every 6 weeks until progression.

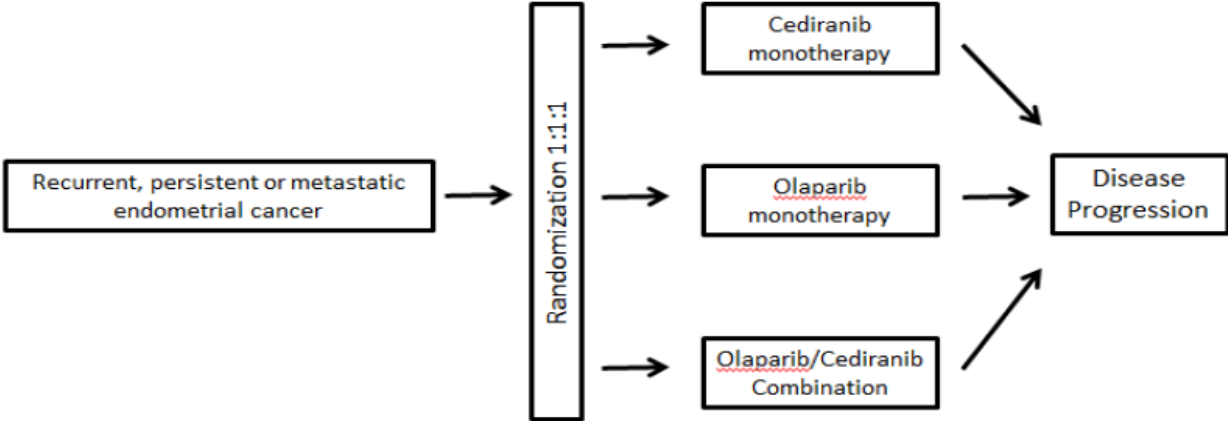
† Atezolizumab 1200 mg IV or placebo IV Days 1 and 22 every 6 weeks until progression or for 2 years.



*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.

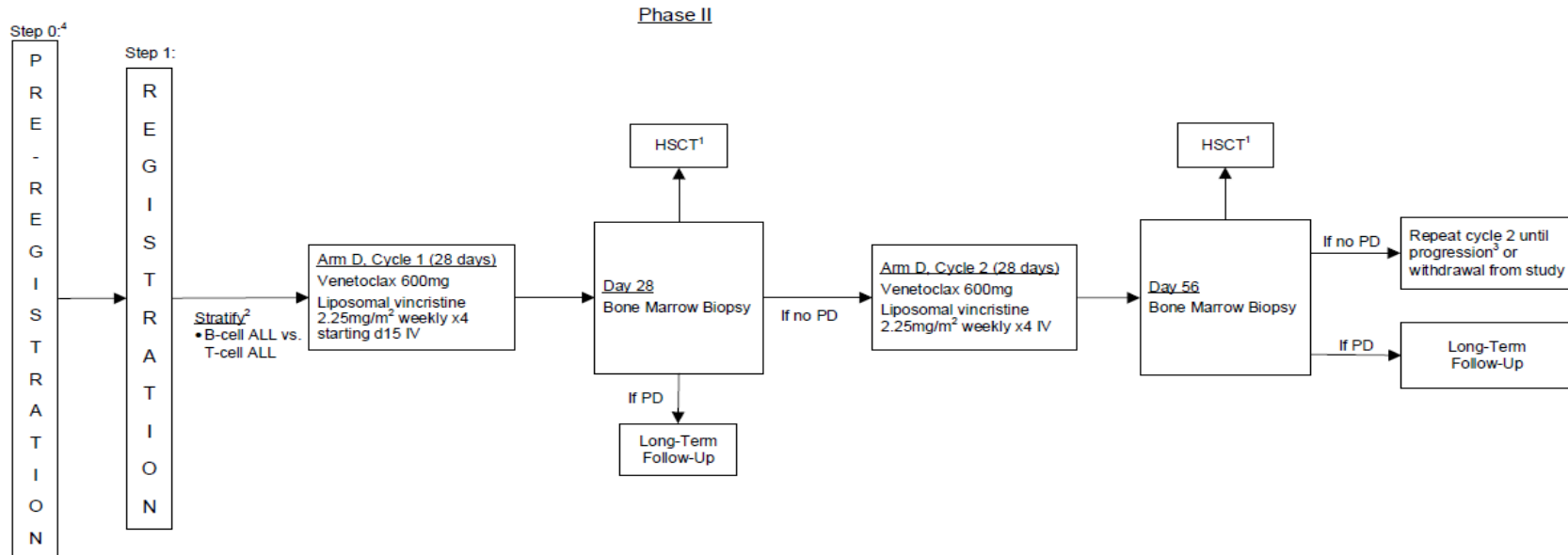
Randomization is 1:2:2:2

SCHEMA



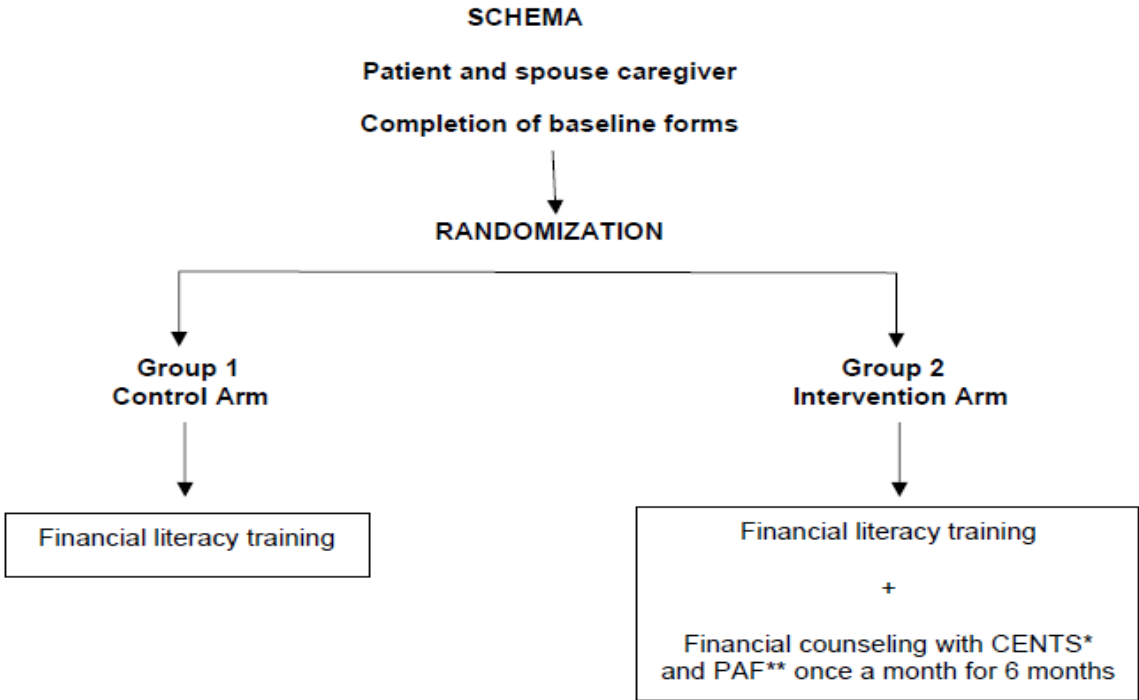
Schema changes as of Amendment 3 (24-MAY-2021):

Schema



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

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

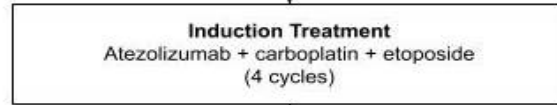
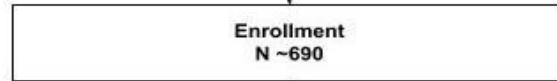
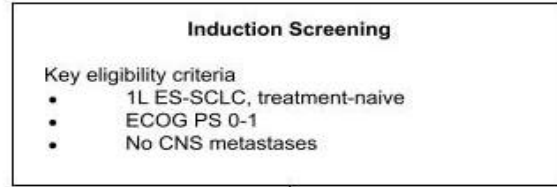


In order to participate, CCD Research sites must complete the **S1912CD** Site Implementation Survey and upload the completion certificate to the CTSU Regulatory Portal as described in [Section 13.4](#).

* Consumer Education and Training Services (CENTS)

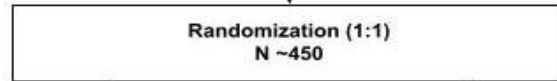
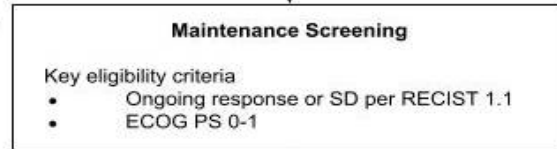
** Patient Advocate Foundation (PAF)

Baseline Induction



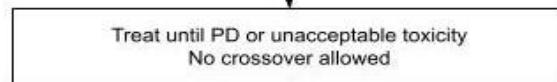
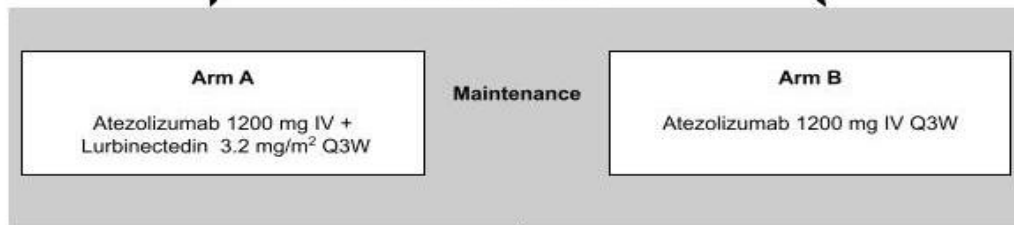
Optional PCI
(Investigator's discretion)

Baseline Maintenance



Stratification Factors

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



SCHEMA

