

MENU

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

JUST IN TIME TRIALS (JIT)		TPX-0005-01 (TRIDENT-1) <i>MULTI-DISEASE SITES</i>
AML	ANAL	APL
BILIARY	BLADDER-UROTHELIAL	BRAIN
BREAST	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 3.12.21

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

Endometrial

Genitourinary - Rare

[A031702](#)

Phase II Study of Cabozantinib in Combination with Nivolumab and Ipilimumab in Rare Genitourinary Tumors *(temp closed - small cell carcinoma of bladder and adenocarcinoma of bladder)*

Gastrointestinal

[EA2197](#)

NEW! 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

[EA2187](#)

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

Head & Neck

[EA3191](#)

NEW! (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

[E4412](#)

A Phase I Study with an Expansion Cohort/Randomized Phase II Study of the Combinations of Ipilimumab, Nivolumab and Brentuximab Vedotin in Patients with Relapsed/Refractory Hodgkin 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
Multiple Myeloma	
<u>Nasopharngeal</u>	
<u>NRG-HN007</u>	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. suspended)</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
Prostate	
<u>67652000PCR3002 / AMPLITUDE</u>	A Phase 3 Randomized, Placebo-controlled, Double-blind Study of Niraparib in Combination with Abiraterone Acetate and Prednisone Versus Abiraterone Acetate and Prednisone for the Treatment of Participants with Deleterious Germline or Somatic Homologous Recombination Repair (HRR) Gene-Mutated Metastatic Castration-Sensitive Prostate Cancer (mCSPC)
<u>GU008</u>	<i>(Credentialing pending)</i> 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
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

MARCH 2021

MENU

Multi-Disease Sites

Navigator - Heather x3661

[TPX-0005-01 \(TRIDENT-1\)](#)

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)**



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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)*



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ANAL

Navigator - Carrie x3621

<u>EA2176</u> <small>SCHEMA</small>	A Randomized Phase III Study of Immune Checkpoint Inhibition With Chemotherapy in Treatment-Naive Metastatic Anal Cancer Patients
<u>EA2182</u>	(RT at UPHM only; Glen Oak pending) A Randomized Phase II Study of De-Intensified ChemoRadiation for Early-Stage Anal Squamous Cell Carcinoma (DECREASE)
<u>EA2165</u>	(RT at RT-91, Glen Oak, UPHM, and Galesburg) A Randomized Phase II Study of Nivolumab After Combined Modality Therapy (CMT) in High Risk Anal Cancer



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APL

Navigator - Heather x3661

<u>EA9131</u>	A Simplified Patient Care Strategy to Decrease Early Deaths in Acute Promyelocytic Leukemia (APL)



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BILIARY

Navigator - Carrie x3621

No trials at this time



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BLADDER / UROTHELIAL

Navigator - Carrie x3621

<p><u>A031501</u></p>	<p>Phase III randomized “Adjuvant study of MK-3475 (pembrolizumab) in muscle invasive and locally advanced urothelial carcinoma” (AMBASSADOR) versus observation</p>
<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>S1806</u></p>	<p>(RT at Glen Oak, UPHM and Galesburg) Phase III Randomized Trial of Concurrent Chemoradiotherapy with or without Atezolizumab in Localized Muscle Invasive Bladder Cancer</p>
<p><u>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>SCHEMA</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>



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MARCH 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

NEW! 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

No trials at this time.

Neo/Adjuvant - Triple Negative

B-59/GBG 96

SCHEMA

A Randomized, Double-Blind, Phase III Clinical Trial of Neoadjuvant Chemotherapy with Atezolizumab or Placebo in Patients with Triple-Negative Breast Cancer Followed by Adjuvant Continuation of Atezolizumab or Placebo. (*ILCC Clinics: Bloomington, Peoria, Ottawa, Pekin, Peru, and Galesburg Only*)

S1418 / BR006

SCHEMA

REOPENED! A Randomized Phase III Trial to Evaluate Efficacy and Safety of MK-3475 (Pembrolizumab) as Adjuvant Therapy for Triple Receptor-Negative Breast Cancer with ≥ 1 cm Residual Invasive Cancer or Positive Lymph Nodes (ypN1mi, ypN1-3) After Neoadjuvant Chemotherapy.

METASTATIC TREATMENT

Metastatic - HER2 Positive

BR004

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

<u>EFC15935</u> <small>SCHEMA</small>	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
<u>SMX 20-001</u> <small>SCHEMA</small>	An Open-label, Multicenter Study Evaluating the Safety of Lasofoxifene in Combination With Abemaciclib for the Treatment of Pre- and Postmenopausal Women With Locally Advanced or Metastatic ER+/HER2- Breast Cancer and Have an ESR1 Mutation (ELAINEII) ILCC Clinics: Galesburg

Metastatic - Triple Negative

<u>IPI-549-03</u>	A Phase 2, Multi-arm, Multicenter, Open-label Study to Evaluate the Efficacy and Safety of IPI-549 Administered in Combination With Front-line Treatment Regimens in Patients With Locally Advanced and/or Metastatic Triple-Negative Breast Cancer or Renal Cell Carcinoma (*JIT TRIAL - expect ≥ 2 week delay to consent pt)
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SURGERY / RADIATION ONLY

<u>A011202</u> <small>SCHEMA</small>	A Randomized Phase III Trial Evaluating the Role of Axillary Lymph Node Dissection in breast Cancer Patients (cT1-3 N1) Who Have Positive Lymph Node Disease After Neoadjuvant Chemotherapy. (RT: Glen Oak, Rt 91, UPHM, Galesburg)
<u>A221505</u>	Phase III Randomized Trial of Hypofractionated Post Mastectomy Radiation with Breast Reconstruction (RT: Glen Oak, Rt 91, UPHM, Galesburg)
<u>BR002</u>	Temporarily Closed (RT at SFMC and UPH)- 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 (RT: Glen Oak, UPHM)
<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)

<u>A191901</u> <small>SCHEMA</small>	NEW! Optimizing Endocrine Therapy Through Motivational Interviewing and Text Interventions
<u>A221602</u>	Olanzapine with or without Fosaprepitant for the Prevention of CINV in Patients Receiving Highly Emetogenic Chemotherapy: A Phase III Randomized, Double-Blind, Placebo- Controlled Trial.

<p><u>ACCRU SC-1601</u></p> <p>SCHEMA</p>	<p>(Peoria, Bloomington, Galesburg, Peru, Pekin and Ottawa only)-A Phase III, Randomized, Controlled, Dose-Evaluation Study Evaluating the Safety of Two Doses of Apixaban For Secondary Prevention of Cancer Related Venous Thrombosis in Subjects Who Have Completed at Least Six Months of Anticoagulation Therapy</p>
<p><u>URCC 16070</u></p>	<p>Treatment of Refractory Nausea- for breast cancer patients.</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>URCC-18007</u></p>	<p>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></p>
<p><u>WF-1901</u></p>	<p>Coming Soon! Internet-delivered Management of Pain Among Cancer Treatment Survivors (IMPACTS)</p>
<p><u>WF-97116</u></p>	<p>(Peoria, Galesburg, Bloomington, Ottawa, Peru and Pekin) Phase III Placebo Controlled Trial of Donepezil in Chemotherapy Exposed Breast Cancer Survivors with Cognitive Impairment.</p>

CANCER CONTROL

MULTI-DISEASE SITES

<u>A221602</u>	Olanzapine with or without Fosaprepitant for the Prevention of CINV in Patients Receiving Highly Emetogenic Chemotherapy: A Phase III Randomized, Double-Blind, Placebo- Controlled Trial.
<u>ACCRU SC-1601</u> <small>SCHEMA</small>	(Peoria, Bloomington, Galesburg, Peru, Pekin and Ottawa only) -A Phase III, Randomized, Controlled, Dose-Evaluation Study Evaluating the Safety of Two Doses of Apixaban For Secondary Prevention of Cancer Related Venous Thrombosis in Subjects Who Have Completed at Least Six Months of Anticoagulation Therapy
<u>URCC 16092</u>	(Peoria only) - Phase II Study of Low-Dose Ibuprofen for Cognitive Impairment in Cancer Patients Receiving Chemotherapy
<u>WF-1901</u> <small>SCHEMA</small>	Coming Soon! Internet-delivered Management of Pain Among Cancer Treatment Survivors (IMPACTS)

BREAST

<u>A191901</u> <small>SCHEMA</small>	NEW! (Peoria, Bloomington, Galesburg, Ottawa, Pekin, and Peru) Optimizing Endocrine Therapy Through Motivational Interviewing and Text Interventions
<u>URCC 16070</u>	Treatment of Refractory Nausea- for breast cancer patients.
<u>URCC-18007</u>	Randomized Placebo Controlled Trial of Bupropion For Cancer Related Fatigue in stage I-III Breast cancer pts.- <i>at least 2 months out from surgery/tx/radiation</i>
<u>WF-97116</u>	(Peoria, Galesburg, Bloomington, Ottawa, Peru and Pekin) Phase III Placebo Controlled Trial of Donepezil in Chemotherapy Exposed Breast Cancer Survivors with Cognitive Impairment.

LUNG

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

<u>A221805</u> <small>SCHEMA</small>	Duloxetine to Prevent Oxaliplatin-Induced Chemotherapy-Induced Peripheral Neuropathy: A Randomized, Double-Blind, Placebo-Controlled Phase II to Phase III Study
<u>S1820</u>	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)
<u>WF-1806</u>	(M&M Study) Myopenia and Mechanisms of Chemotherapy Toxicity in older Adults with Colorectal Cancer

BRAIN

<u>WF-1801</u>	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

[Connect MDS/AML](#)

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

[NHLBI-MDS](#)

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



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MARCH 2021

[MENU](#)

CARCINOID

Navigator - Ashton x3611
Carrie x3621

No trials at this time



MASTER TRIAL LIST

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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 <i>(tx naïve arm temporarily closed - relapsed open)</i></p> <p><i>*NOTE: Medicare will not authorize Venetoclax</i></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>
<p><u>EA9161</u></p>	<p>A Randomized Phase III Study of the Addition of Venetoclax to Ibrutinib and Obinutuzumab Versus Ibrutinib and Obinutuzumab in Untreated Younger Patients 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 <i>(tx naïve arm temporarily closed - relapsed open)</i></p>
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MASTER TRIAL LIST

MARCH 2021



MENU

CML

Navigator - Heather x3661

No trials at this time

MASTER TRIAL LIST

MARCH 2021

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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>Temporarily Closed 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>REOPENED! 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>A221602</u></p>	<p>Olanzapine with or without Fosaprepitant for the Prevention of CINV in Patients Receiving Highly Emetogenic Chemotherapy: A Phase III Randomized, Double-Blind, Placebo- Controlled Trial.</p>
<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>ACCRU SC-1601</u></p> <p><small>SCHEMA</small></p>	<p>(Peoria, Bloomington, Galesburg, Peru, Pekin and Ottawa only)-A Phase III, Randomized, Controlled, Dose-Evaluation Study Evaluating the Safety of Two Doses of Apixaban For Secondary Prevention of Cancer Related Venous Thrombosis in Subjects Who Have Completed at Least Six Months of Anticoagulation Therapy</p>
<p><u>S1820</u></p> <p><small>SCHEMA</small></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>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>Coming Soon! 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

MARCH 2021



<i>ESOPHAGEAL- GASTRIC</i>		Navigator - Carrie x3621
<u>EA2174</u> SCHEMA	NEW! (RT Credentialing Pending) A Phase II/III Study of Peri-Operative Nivolumab and Ipilimumab in Patients With Locoregional Esophageal and Gastroesophageal Junction Adenocarcinoma	
<u>EA2183</u> SCHEMA	(RT at UPHM only) A Phase III Study of Consolidative Radiotherapy in Patients With Oligometastatic HER2 Negative Esophageal and Gastric Adenocarcinoma (EGA)	

HEAD & NECK

Navigator - Ashton x3611

<p><u>EA3161</u></p> <p><small>SCHEMA</small></p>	<p>NEW! (RT at Glen Oak) A Phase II/III Randomized Study of Maintenance Nivolumab Versus Observation in Patients With Locally Advanced, Intermediate Risk HPV Positive OPSCC</p>
<p><u>HN004</u></p>	<p>(RT at Glen Oak and UPHM)-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 & 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>
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<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>
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NHL

<p><u>C2321001</u></p> <p>SCHEMA</p>	<p>(Peoria only) A Phase I Dose Escalation and Expanded Cohort Study of PF-06821497 in the Treatment of Adult Patients with Relapsed/Refractory Small Cell Lung Cancer (SCLC), Castration Resistant Prostate Cancer (CRPC) and Follicular Lymphoma (FL) (FL cohort open)</p>
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<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>
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<p><u>TG-1501-101</u></p>	<p>(Peoria only)-A Phase 1 Study of TG-1501 in Subjects with Relapsed or Refractory Lymphoma</p>
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<p><u>UTX-TGR-205</u></p>	<p>(Peoria, Bloomington, Galesburg, Peru, Ottawa) A Phase 2b Randomized Study to Assess the Efficacy and Safety of the Combination of Ublituximab + Umbralisib With or Without Bendamustine and Umbralisib Alone in Patients With Previously Treated Non-Hodgkin's Lymphoma</p>
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DLBCL



MASTER TRIAL LIST

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MDS

Navigator - Heather x3661

<p><u>Connect MDS/AML</u></p>	<p>REOPENED! 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>



MASTER TRIAL LIST

MARCH 2021



MELANOMA

Navigator - Carrie x3621

<p><u>MK 7902-003</u></p> <p>SCHEMA</p>	<p>(Bloomington, Galesburg, Pekin, Peoria) A Phase 3 Randomized, Placebo-controlled Trial to Evaluate the Safety and Efficacy of Pembrolizumab (MK-3475) and Lenvatinib (E7080/MK-7902) Versus Pembrolizumab Alone as First-line Intervention in Participants With Advanced Melanoma (LEAP-003)</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

MARCH 2021

MENU

MERKEL

Navigator - Carrie x3621

<p><u>EA6174</u></p>	<p>(RT at UPHM, and Galesburg; 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</p>
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MASTER TRIAL LIST

MARCH 2021



MOLECULAR STUDIES

*Contact Disease Specific Navigator

<u>2215-MA-3297 / CLEVO</u>	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
<u>64091742PCR0002 / Prevalence</u>	Biomarker Study to Determine Frequency of DNA-repair Defects in Men with Metastatic Prostate Cancer (Prevalence)
<u>A151804</u>	Establishment of a National Biorepository to Advance Studies of Immune-Related Adverse Events
<u>ACCRU 2018-01</u>	Temp. suspended (Peoria and Ottawa only) - Blood Sample Collection to Evaluate Biomarkers in Subjects with Untreated Solid Tumors(Bladder, Colorectal, Esophageal, Kidney/Renal pelvis, Ovarian, Pancreas, Stomach and Uterine.
PCR PICI009(Parker Institute)	An Exploratory Biomarker Study of Checkpoint Inhibitors (PD-1, PD-L1 and CTLA-4) used as Monotherapy or in Combination in Patients with Cancer
<u>S1823</u>	A Study of miRNA 371 in Patients With Germ Cell Tumor

SCHEMA

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MARCH 2021



MULTIPLE MYELOMA

Navigator - Heather x3661

S1803

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

NSCLC

Navigator - Ashton x3611

ADJUVANT / NEOADJUVANT

<p><u>A081801</u> 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><u>A151216</u></p>	<p>Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST).</p>
<p><u>EA5181</u> 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><u>GO40241</u> SCHEMA</p>	<p>(Peoria, Bloomington, Galesburg, Pekin, Peru) A Phase III, Double-Blinded, Multicenter, randomized Study Evaluating The Efficacy and Safety of Neoadjuvant Treatment with Atezolizumab or Placebo in Combination with Platinum-Based Chemotherapy in Patients with Resectable Stage II, IIIA, or Select IIIB Non-Small Cell Lung Cancer</p>
<p><u>GO41854</u> 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><u>S1914</u></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><u>S1933</u> 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><u>ADXS-503-101</u> SCHEMA</p>	<p>(Peoria only) - Phase 1-2, Open Label Study of ADXS-503 Alone and in Combination with Pembrolizumab in Subjects with Metastatic Squamous or Non-Squamous NSCLC (Part A closed)</p>
<p><u>EA5182</u> SCHEMA</p>	<p>NEW! 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><u>LU002</u></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><u>MK 7684A-003</u></p>	<p>Activation Planned March 2021 - (Bloomington, Galesburg, Ottawa, Pekin, Peoria, Peru) 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><u>TH-138</u> 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 (non smokers)</p>

METASTATIC - 2nd/3rd Line

<p><u>ADXS-503-101</u></p> <p>SCHEMA</p>	<p>(Peoria only) - Phase 1-2, Open Label Study of ADXS-503 Alone and in Combination with Pembrolizumab in Subjects with Metastatic Squamous or Non-Squamous NSCLC (Part A closed)</p>
<p><u>CA209-79X</u></p>	<p>Activation Planned April/May 2021- (Bloomington, Pekin, Galesburg, Peoria) A Phase 1/2, Randomized Study Evaluating Multiple Nivolumab Combination Therapies in Patients With Stage IV or Recurrent Non-Small Cell Lung Cancer (NSCLC) After Failure of Platinum-Based Chemotherapy and Anti-PD-1 (L)1 Immunotherapy (CheckMate 79X)</p>
<p><u>LUNGMAP</u></p>	<p>A Master Protocol To Evaluate Biomarker-Driven Therapies and Immunotherapies in Previously-Treated NSCLC.</p>
<p><u>MK 7684A-002</u></p>	<p>Activation Planned March 2021 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>
<p><u>TH-138</u></p> <p>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 (EGFR mutants)</p>
<p style="text-align: center;">CANCER CONTROL (NSCLC Only)</p>	
<p><u>A221602</u></p>	<p>Olanzapine with or without Fosaprepitant for the Prevention of CINV in Patients Receiving Highly Emetogenic Chemotherapy: A Phase III Randomized, Double-Blind, Placebo- Controlled Trial.</p>
<p><u>ACCRU SC-1601</u></p> <p>SCHEMA</p>	<p>(Peoria, Bloomington, Galesburg, Peru, Pekin and Ottawa only)-A Phase III, Randomized, Controlled, Dose-Evaluation Study Evaluating the Safety of Two Doses of Apixaban For Secondary Prevention of Cancer Related Venous Thrombosis in Subjects Who Have Completed at Least Six Months of Anticoagulation Therapy</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>SCHEMA</p>	<p>Coming Soon! Internet-delivered Management of Pain Among Cancer Treatment Survivors (IMPACTS)</p>



MASTER TRIAL LIST

MARCH 2021

MENU

PANCREATIC

Navigator - Carrie x3621

<u>A021806</u> SCHEMA	A Phase III Trial of Perioperative Versus Adjuvant Chemotherapy for Resectable Pancreatic Cancer
<u>EA2186</u> SCHEMA	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)
<u>D-US-60010-001</u> SCHEMA	An Open-label, Randomised, Multicentre, Phase III Study of Irinotecan Liposome Injection, Oxaliplatin, 5-fluorouracil/Leucovorin Versus Nab-paclitaxel Plus Gemcitabine in Subjects Who Have Not Previously Received Chemotherapy for Metastatic Adenocarcinoma of the Pancreas (NAPOLI3)

MASTER TRIAL LIST

MARCH 2021



PROSTATE

Navigator - Carrie x3621

ADJUVANT

<p><u>C2321001</u></p> <p>SCHEMA</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) <i>(FL cohort open)</i></p>
<p><u>EA8183</u></p>	<p>RT Credentialing Pending 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)</p>
<p><u>GU002</u></p>	<p>(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</p>
<p><u>GU005</u></p>	<p>(RT at Glen Oak & UPHM)-Phase II IGRT and SBRT vs. IGRT and hypofractionate IMRT for Localized Intermediate Risk Prostate Cancer.</p>
<p><u>GU009</u></p>	<p>(RT Credentialing Pending - Glen Oak, RT 91) Parallel Phase III Randomized Trials for High Risk Prostate Cancer Evaluating De-Intensification for Lower Genomic Risk and Intensification of Concurrent Therapy for Higher Genomic Risk With Radiation (PREDICT-RT*)</p>
<h3>METASTATIC</h3>	
<p><u>64091742PCR0002 / Prevalence</u></p>	<p>Biomarker Study to Determine Frequency of DNA-repair Defects in Men with Metastatic Prostate Cancer</p>

<p><u>A031902 / CASPAR</u></p> <p><small>SCHEMA</small></p>	<p><i>Temporarily Suspended!</i> A Phase III Trial of Enzalutamide and Rucaparib as a Novel Therapy in First-Line Metastatic Castration-Resistant Prostate Cancer</p>
<p><u>EA8153</u></p>	<p><i>Closing March 26th!</i> Cabazitaxel with Abiraterone versus Abiraterone Alone Randomized Trial for Extensive Disease Following Docetaxel: The CHAARTED2 Trial</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

MARCH 2021



RENAL CELL

Navigator - Carrie x3621

<p><u>A031704</u></p>	<p><i>(Temporarily Closed)</i> 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>EA8143</u></p>	<p>A Phase 3 Randomized Study Comparing PERioperative Nivolumab vs. Observation in Patients with Localized Renal Cell Carcinoma Undergoing Nephrectomy (PROSPER RCC)</p>
<p><u>MK 6482-011</u></p> <p>SCHEMA</p>	<p>(Peoria only) 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

<p><u>A071801</u></p>	<p>(UPHM & Glen Oak) Phase III Trial of Post-Surgical Single Fraction Stereotactic Radiosurgery (SRS) Compared With Fractionated SRS for Resected Metastatic Brain Disease</p>
<p><u>BN007</u></p> <p><small>SCHEMA</small></p>	<p>(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>CCTG CE.7</u></p>	<p>(UPHM & Glen Oak)- A Phase III Trial of Stereotactic Radiosurgery Compared with Whole Brain Radiotherapy (WBRT) for 5-15 Brain Metastases</p>
<p><u>EA2183</u></p> <p><small>SCHEMA</small></p>	<p>(UPHM only) A Phase III Study of Consolidative Radiotherapy in Patients With Oligometastatic HER2 Negative Esophageal and Gastric Adenocarcinoma (EGA)</p>
<p><u>EA3161</u></p> <p><small>SCHEMA</small></p>	<p>NEW! (RT at Glen Oak) A Phase II/III Randomized Study of Maintenance Nivolumab Versus Observation in Patients With Locally Advanced, Intermediate Risk HPV Positive OPSCC</p>
<p><u>EA5181</u></p> <p><small>SCHEMA</small></p>	<p>(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)</p>
<p><u>GU005</u></p>	<p>(Glen Oak and UPHM) -Phase II IGRT and SBRT vs. IGRT and hypofractionate IMRT for Localized Intermediate Risk Prostate Cancer.</p>

<u>GU009</u>	(RT Credentialing Pending - Glen Oak, 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>HN005</u>	(UPHM & 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>LU007 / RAPTOR</u>	(Glen Oak & UPHM) – Randomized Phase II/III Trial of Consolidation RT + Immunotherapy for ES-SCLC
<u>MA.39</u>	(Glen Oak and UPHM) - Tailor RT: A Randomized Trial of Regional Radiotherapy in Biomarker Low Risk Node Positive Breast Cancer
<u>NRG CC003</u> <small>SCHEMA</small>	(Glen Oak only) Randomized Phase II/III Trial of Prophylactic Cranial Irradiation with or without Hippocampal Avoidance for Small Cell Lung Cancer
<u>NRG LU007</u>	(Glen Oak & UPHM) – Randomized Phase II/III Trial of Consolidation RT + Immunotherapy for SCLC
<u>S1827</u>	(Glen Oak and UPHM) A Randomized Phase III Trial of MRI Surveillance With or Without Prophylactic Cranial Irradiation (PCI) in Small-Cell Lung Cancer
<u>S1933</u> <small>SCHEMA</small>	(UPHM only) A Pilot Study of Hypofractionated Radiotherapy Followed by Atezolizumab Consolidation in Stage II or III NSCLC Patients With Borderline Performance Status
<u>WF-1802</u>	(Glen Opak, Rt-91, UPHM, Galesburg) Influence of Primary Treatment for Prostate Cancer on Work Experience (PCW)
CANCER CONTROL (RT specific)	
<u>WF-1801</u>	A Single Arm, Pilot Study of Ramipril for Preventing Radiation-Induced Cognitive Decline in Glioblastoma (GBM) Patients Receiving Brain Radiotherapy

SMALL CELL LUNG CANCER

Navigator - Ashton x3611

<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) – Randomized Phase II/III Trial of Consolidation RT + Immunotherapy for ES-SCLC</p>
<p><u>NRG CC003</u></p> <p><small>SCHEMA</small></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>S1827</u></p>	<p>(RT at Glen Oak and UPHM) 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><small>SCHEMA</small></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
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Specializing in Cancer and Blood Disorders

MASTER TRIAL LIST

MARCH 2021



MENU

VULVA

Navigator - Angie x3613

Figure 1-1: Study Design Schematic

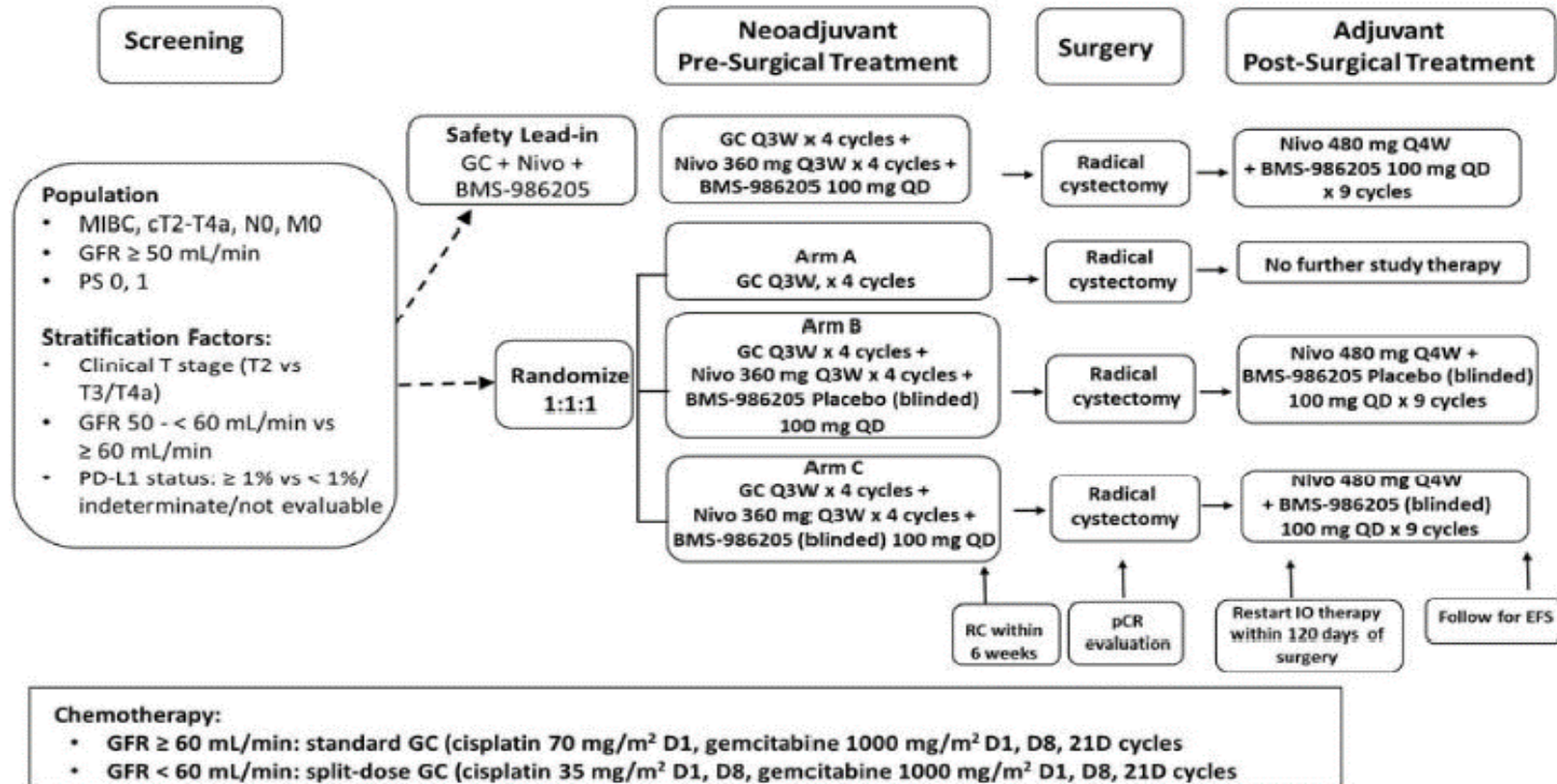
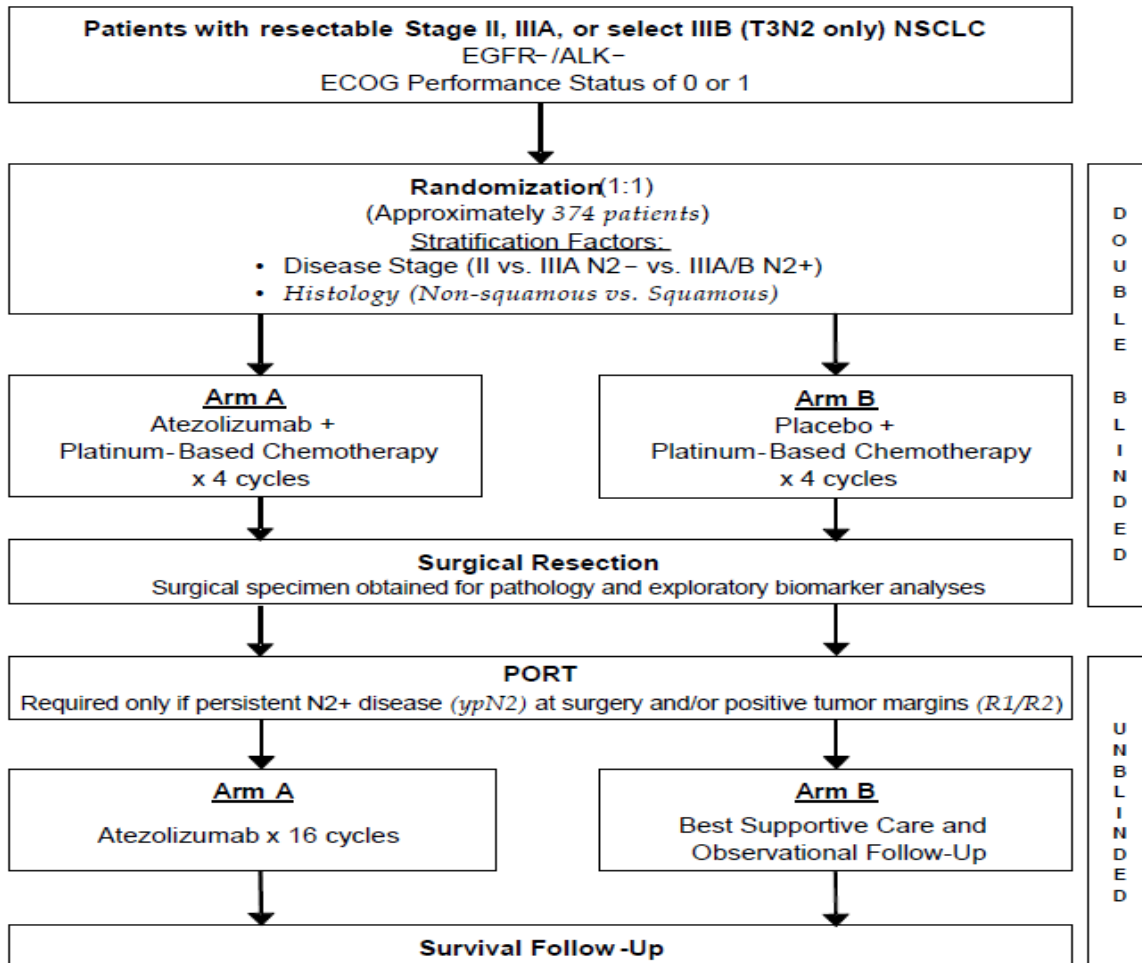


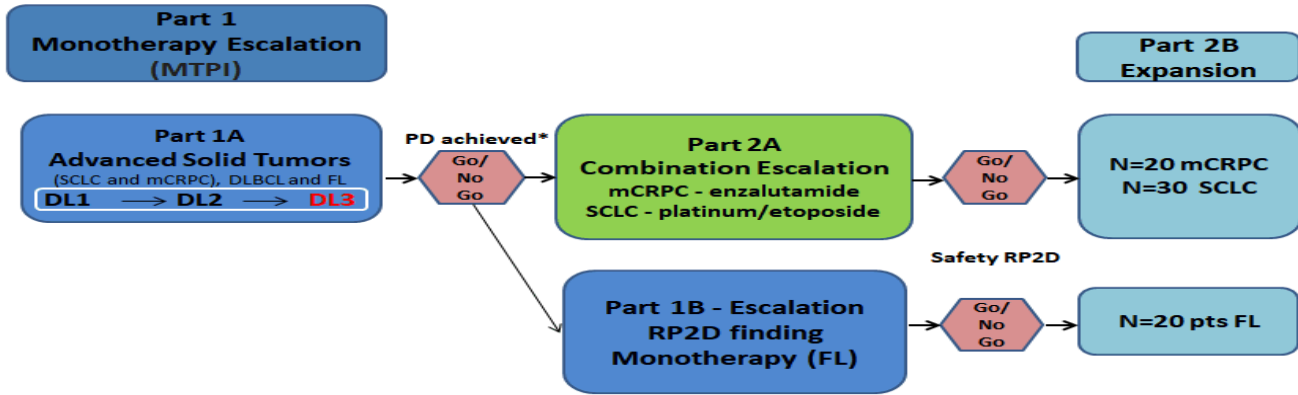
Figure 1 Study Schema



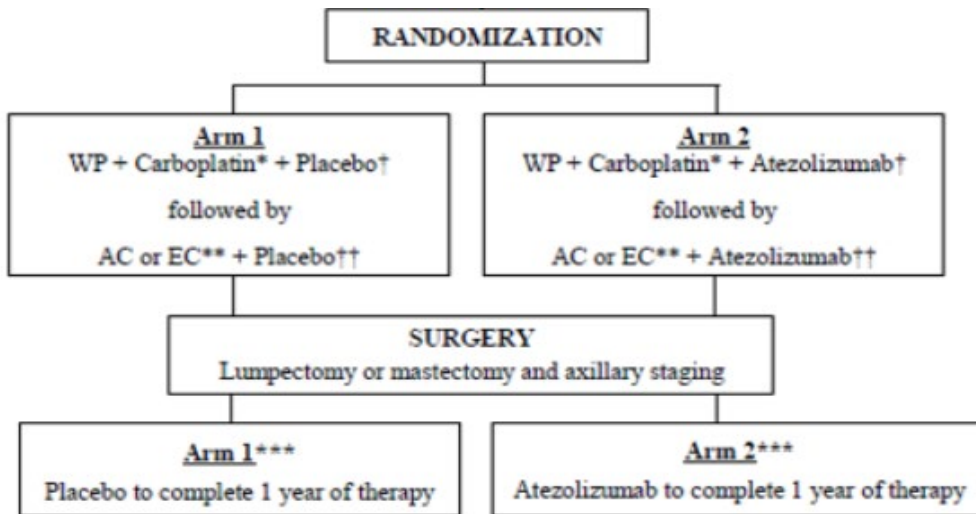
ALK = anaplastic lymphoma kinase; EGFR = epidermal growth factor; NSCLC = non-small cell lung cancer; PORT = post-operative radiation therapy; PS = performance status.

C2321001 SCHEMA
Contact Disease Specific Navigator

MENU



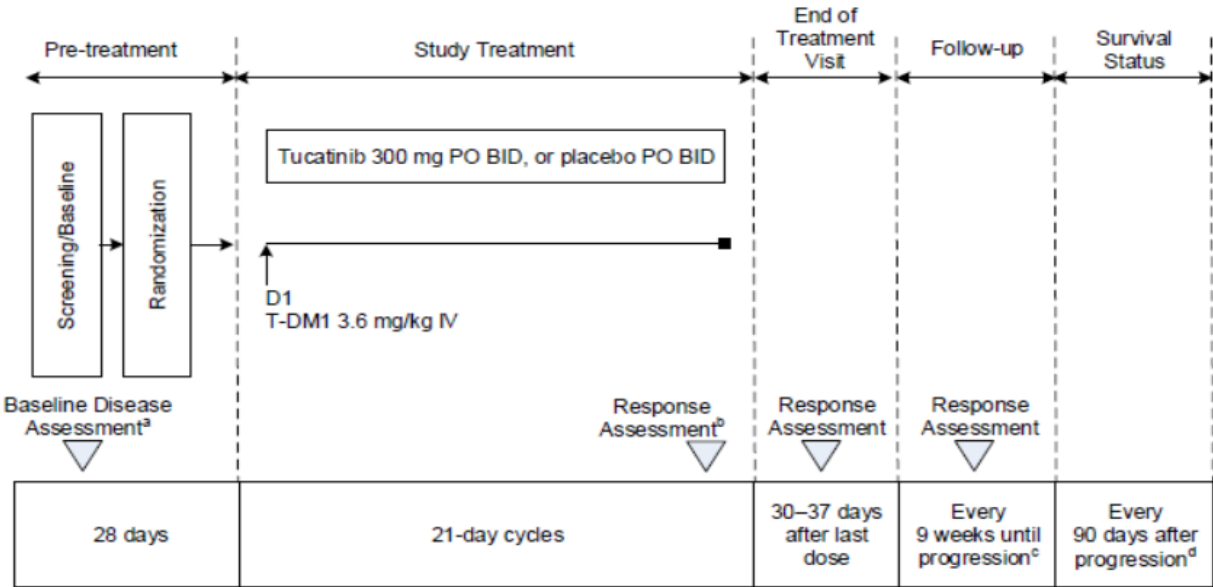
*50-70% down modulation of H3K27me3



- * Paclitaxel 80 mg/m² IV weekly x 12 doses (WP) + Carboplatin AUC of 5 IV Day 1 every 3 weeks for 4 cycles.
- ** Doxorubicin (A) 60 mg/m² IV + cyclophosphamide (C) 600 mg/m² IV Day 1 every 2 or 3 weeks for 4 cycles OR Epirubicin (E) 90 mg/m² IV + cyclophosphamide (C) 600 mg/m² IV Day 1 every 2 or 3 weeks for 4 cycles. Choice of anthracycline and schedule per investigator discretion.
- † Atezolizumab 1200 mg or placebo IV Day 1 every 3 weeks for 4 doses.
- †† Atezolizumab 1200 mg or placebo IV Day 1 every 3 weeks for 3 to 4 doses depending on AC/EC schedule used.
- *** Atezolizumab 1200 mg or placebo IV Day 1 every 3 weeks after surgery until 1 year after the first dose.

SGNTUC-016 SCHEMA
 Navigator - Angie x3613

MENU



ADXS-503-101 SCHEMA
Navigator - Ashton x3611

MENU

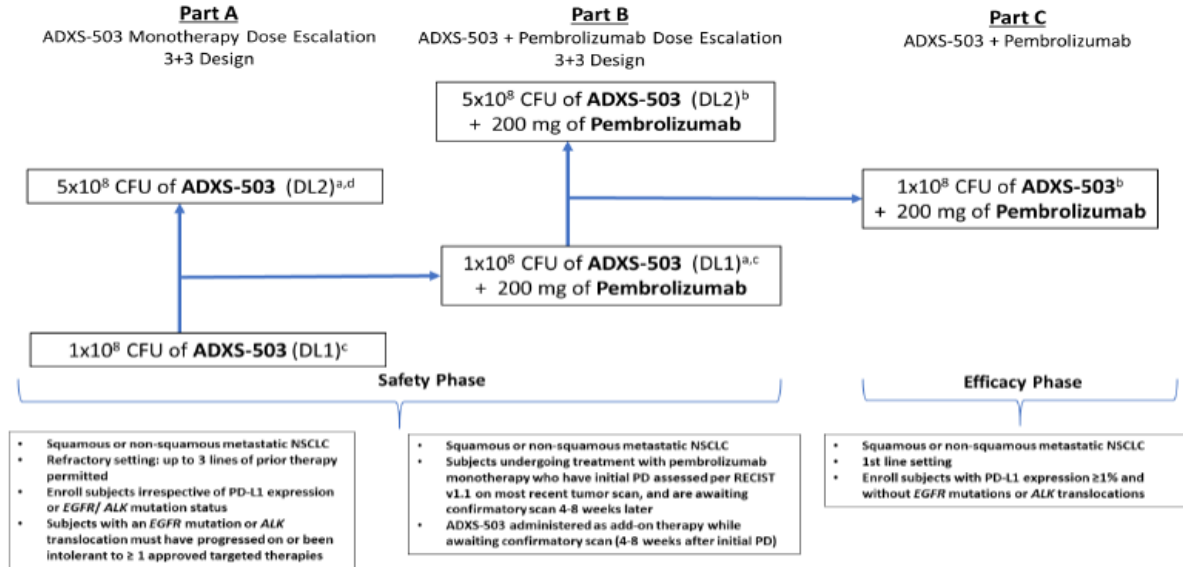
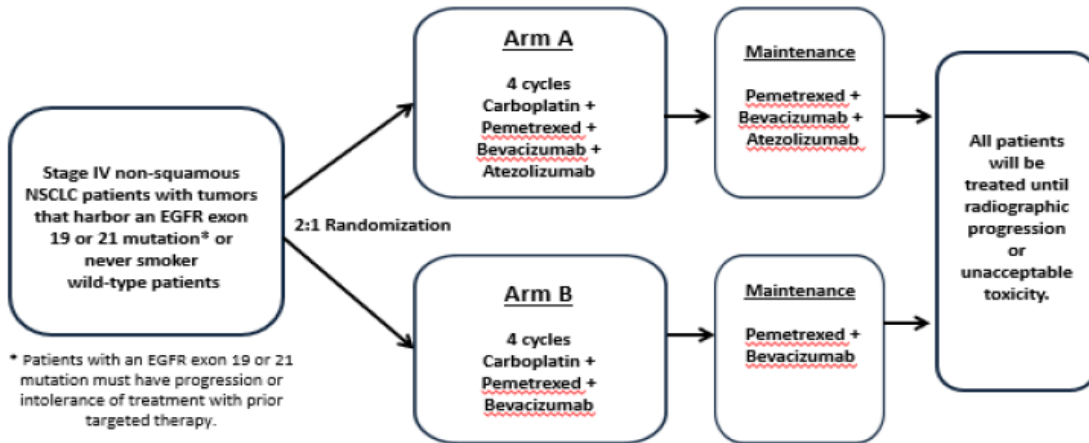


Figure 1. Study Design

- Escalation to DL2 in Part A will occur in parallel with accrual at DL1 in Part B
- Escalation to DL2 in Part B will occur in parallel with accrual in Part C
- If treatment is not safe/tolerable at DL1 in Part A or Part B, a lower dose level (DL-1; 0.5x10⁸ CFU of ADXS-503) will be evaluated before proceeding with Part B and Part C, respectively.
- Upon completion of dose escalation in Part A, ADXS-503 monotherapy may be evaluated in an expansion cohort.

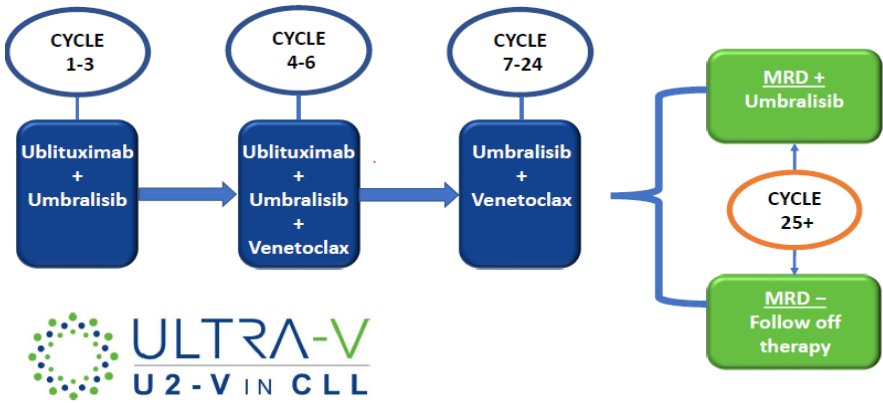
Abbreviations: DL: dose level.

Study Design



US-VEN-207 (ULTRA-V) Schema
Navigator - Heather x3661

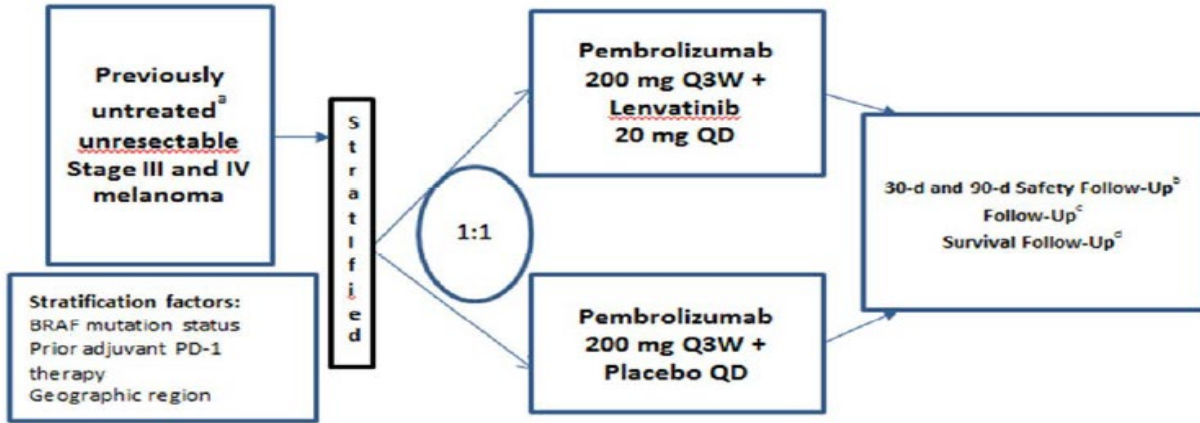
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US-VEN-207

MK 7902-003 (LEAP-003) Schema
Navigator - Carrie x3621

MENU



MK 6482-011 Schema
Navigator - Carrie x3621

MENU

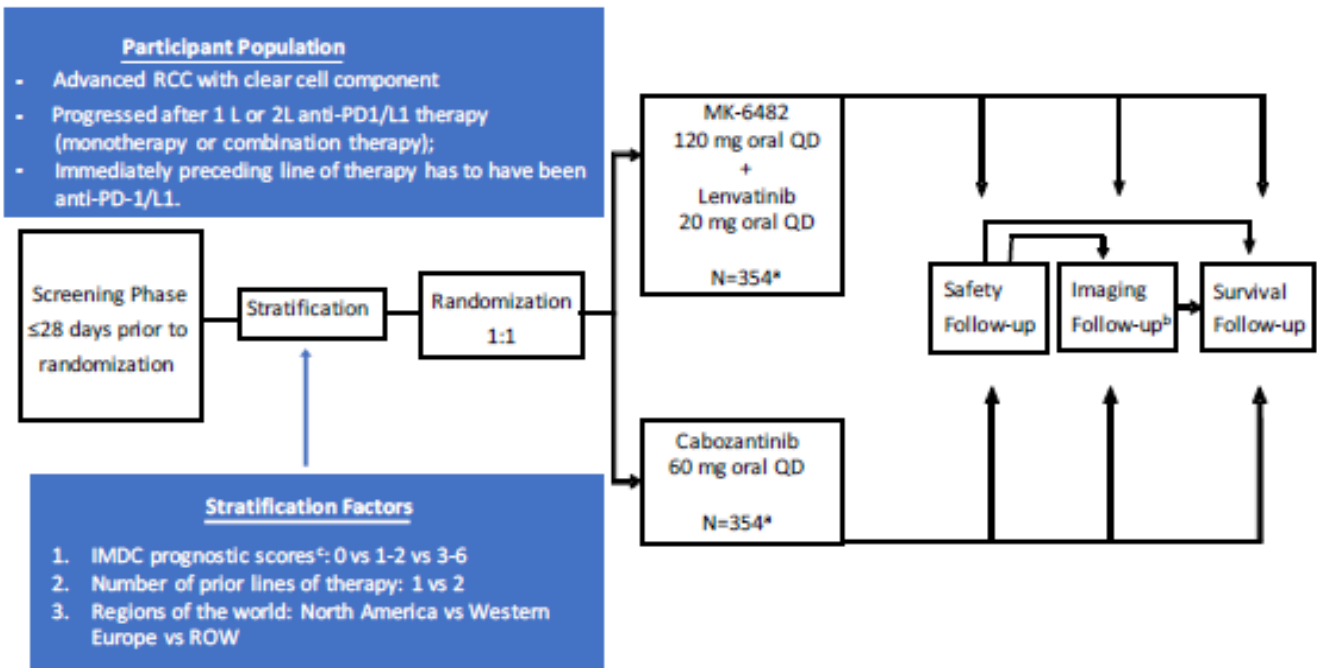
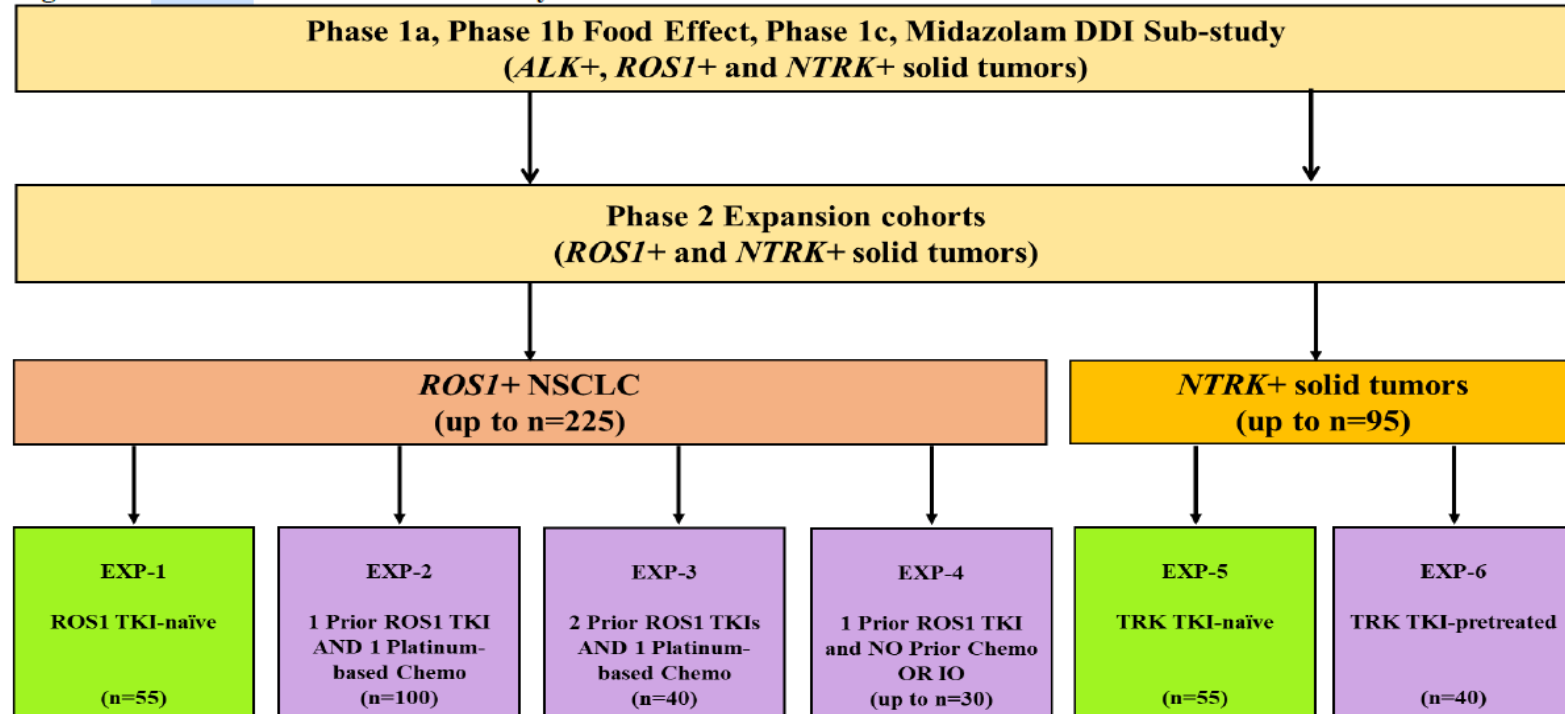
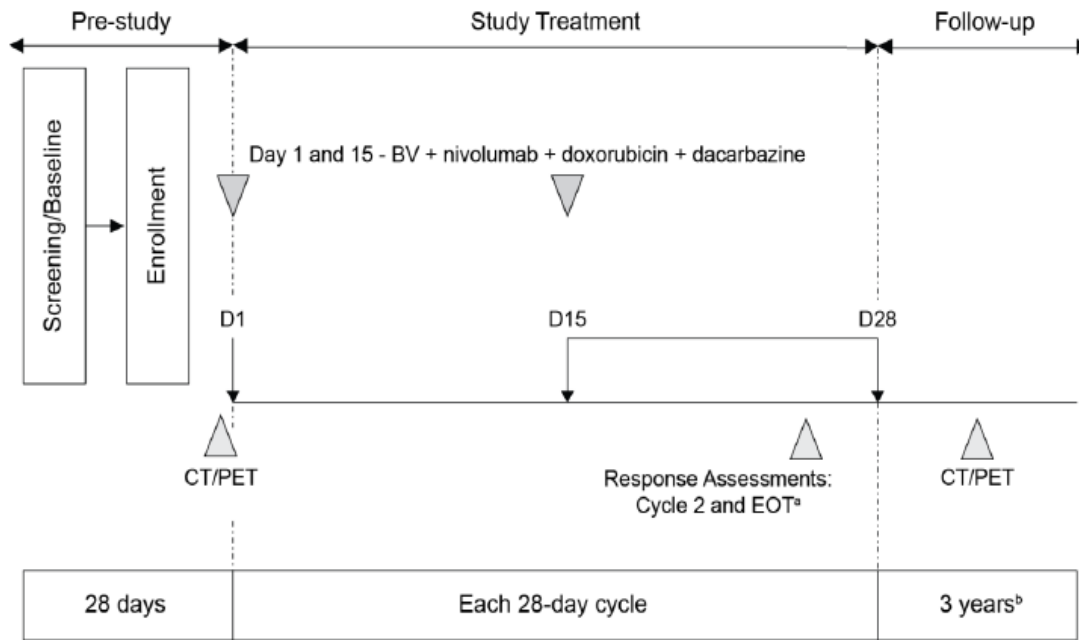


Figure 2. Schema of TPX-0005-01 Study



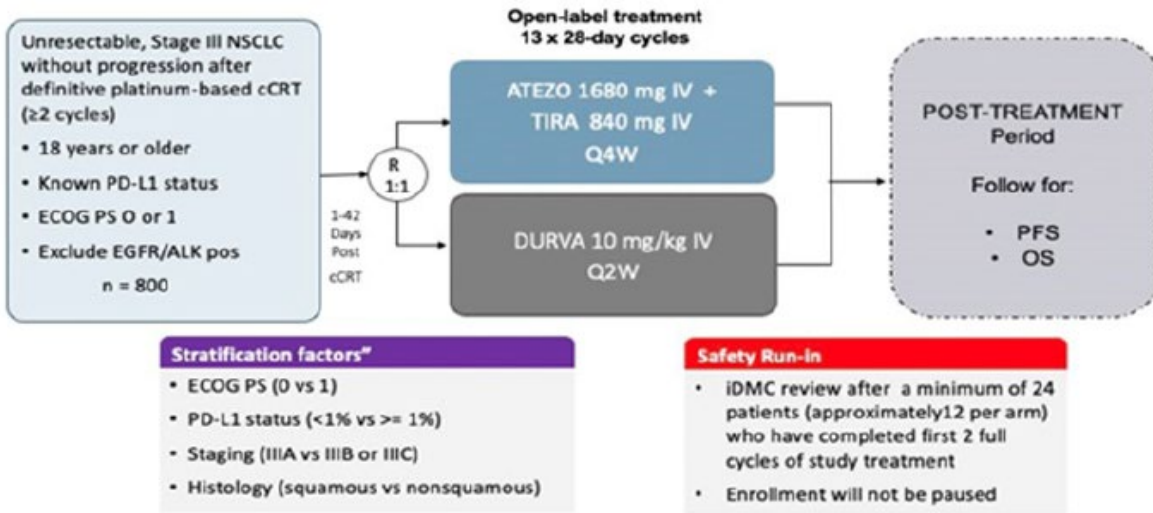


a Response assessments will include PET and diagnostic-quality CT scan on Day 25-28 of Cycle 2, and at EOT.

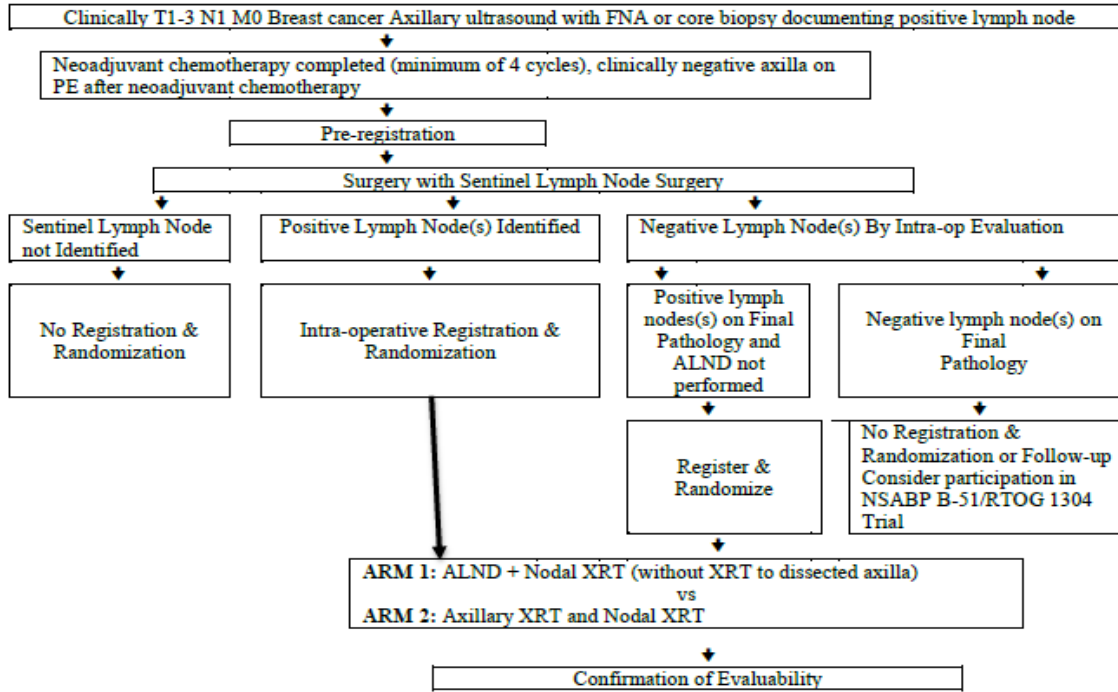
b Part C follow-up period includes 2 additional years (5 years total).

GO41854 Schema
Navigator - Ashton x3611

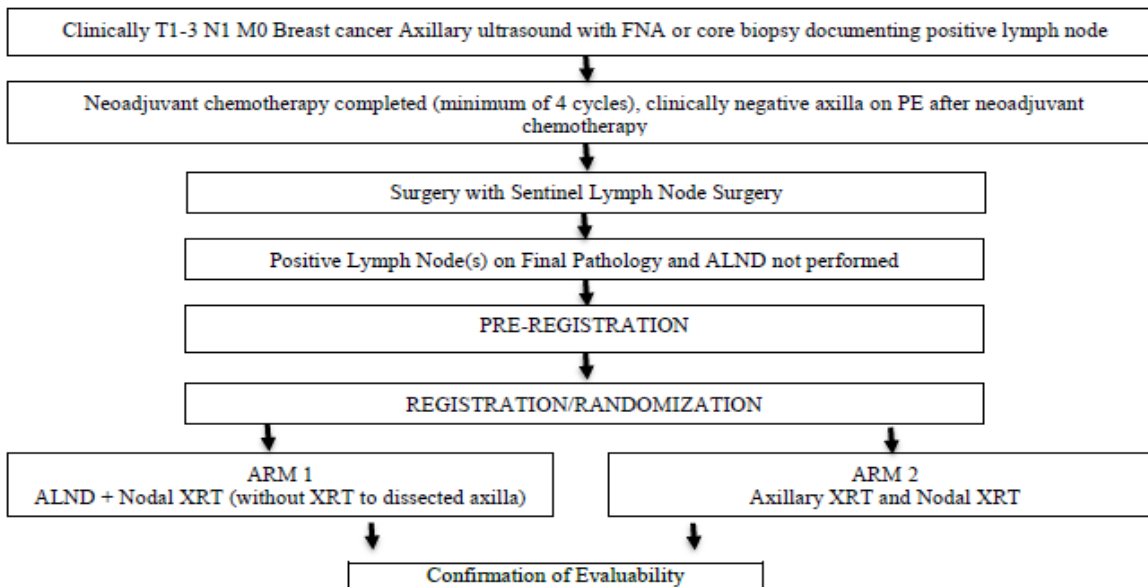
MENU



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

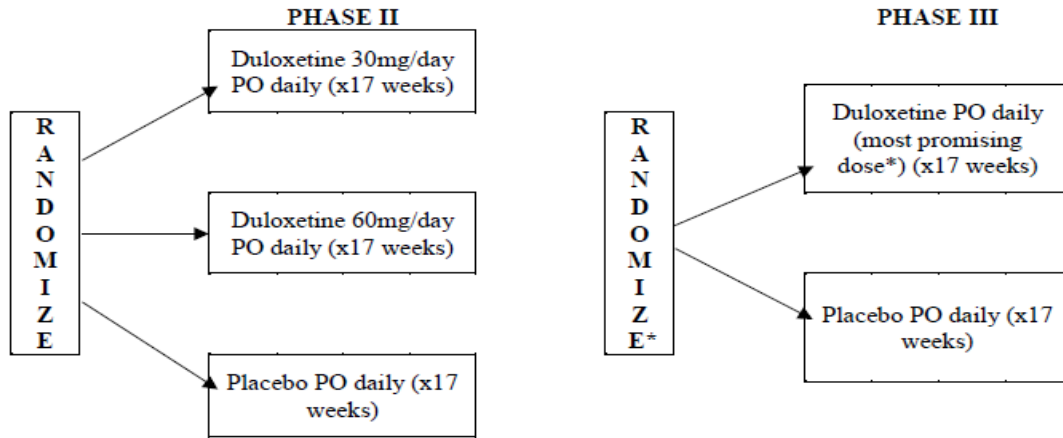


Schema for patients who pre-register AFTER surgery* (where SLN surgery was performed but ALND was NOT performed):



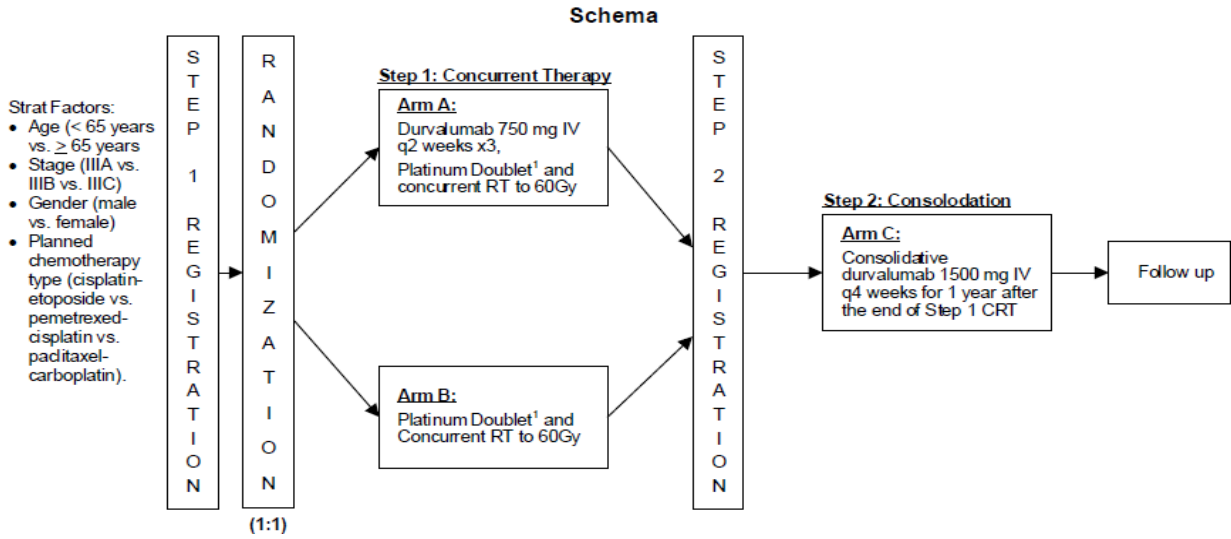
* Patients who are pre-registered after SLN surgery are NOT eligible to enroll onto the Arm Lymphedema Companion Study (A011201-S11)

Schema

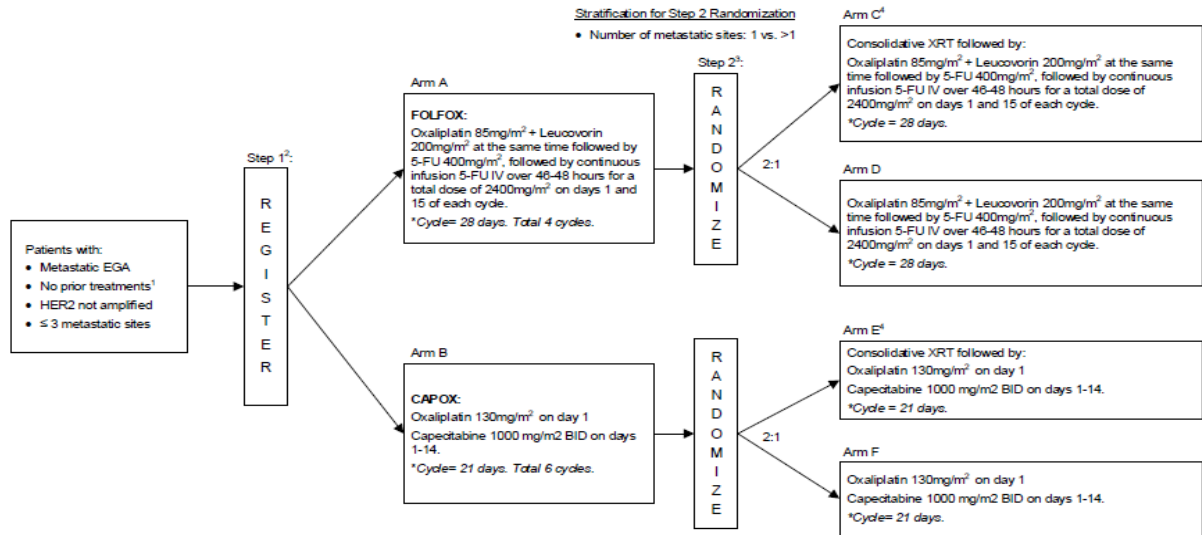


All patients will receive oxaliplatin on both phases of the trial. Further, for all patients the 17th week of study drug will be a tapering period.

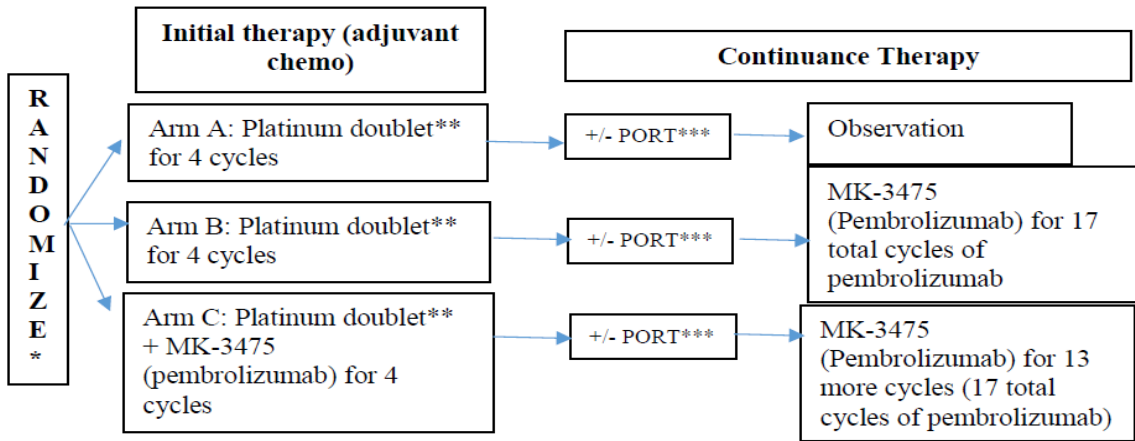
* Additional patients will be recruited to the Phase III trial. The most promising dose of duloxetine will be determined after initial Phase II, and this dose will be used for Phase III for patients randomized to the duloxetine arm.



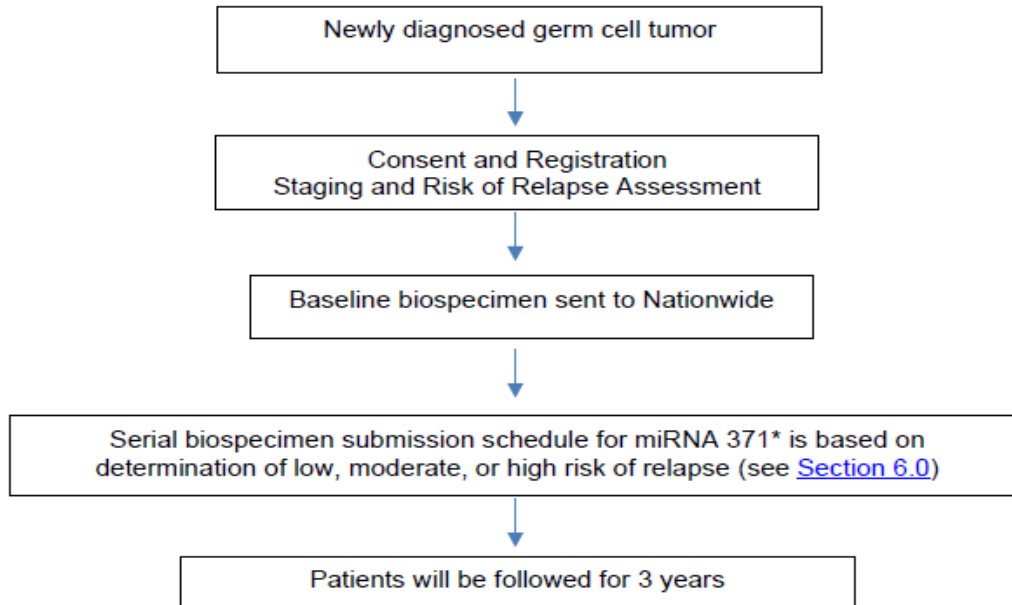
Schema



Schema: 1 cycle = 21 days



SCHEMA



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

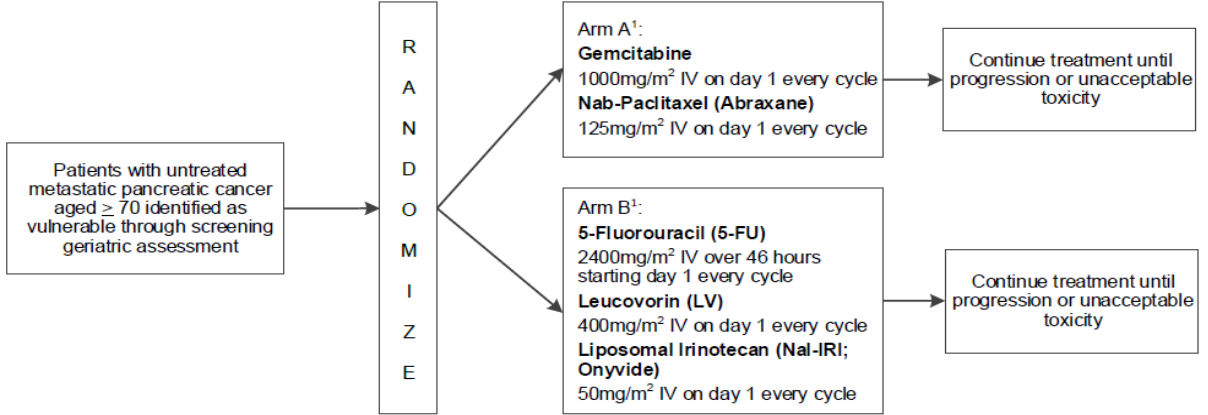
EA2186 SCHEMA
Navigator - Carrie x3621

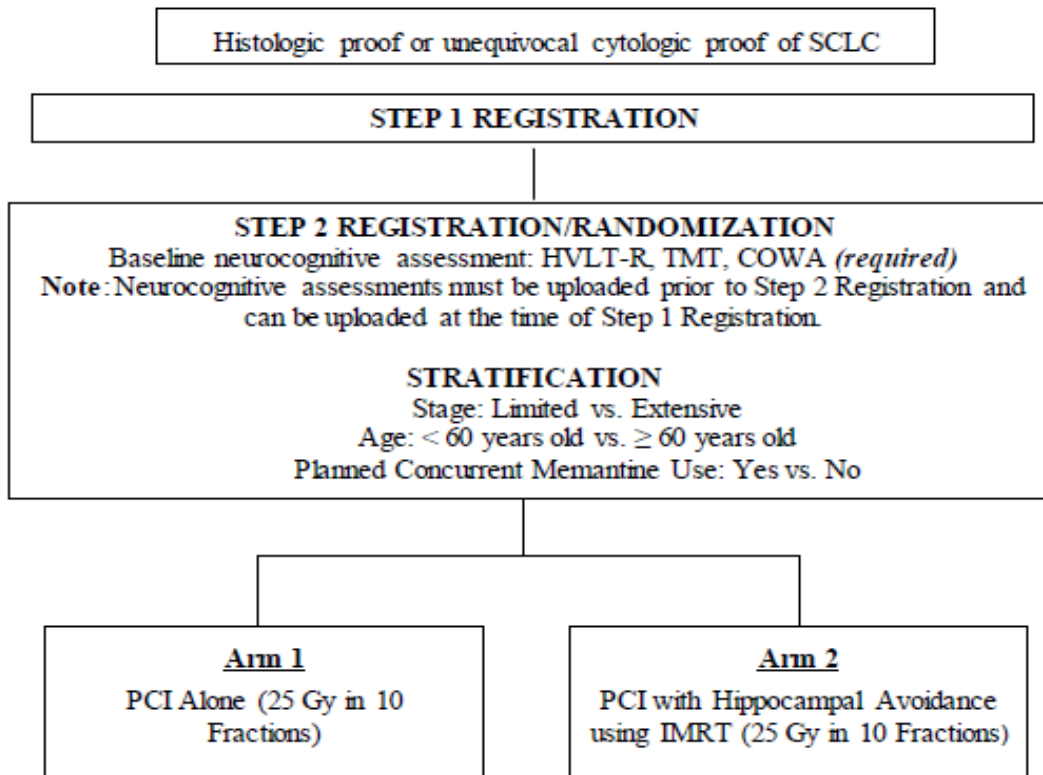
MENU

Schema

Stratification:

- ECOG: 0-1 vs 2
- Age 70-74 vs ≥ 75





SCHEMA

REGISTRATION STEP 1



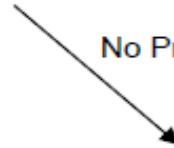
60 Gy hypofractionated radiotherapy in 15 fractions over 3 weeks



2-5 weeks after completion of radiotherapy:
disease assessment

Progression

No Progression



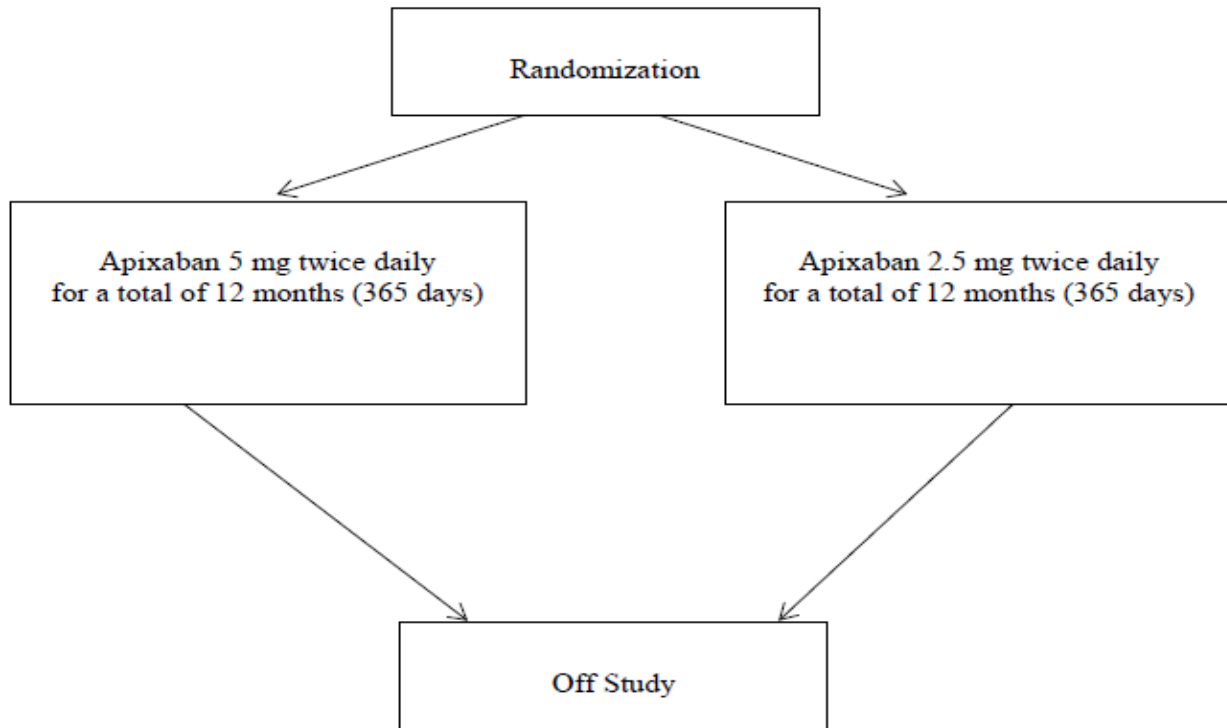
Off protocol treatment

REGISTRATION STEP 2



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

Schema



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

MENU

Key Inclusion Criteria

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

Stratification Factors:

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

R
1:1:1

Olaparib Oral +
Bevacizumab
(until progression)

Olaparib Oral
(until progression)

5-FU + Bevacizumab
(until progression)

STEP 1 REGISTRATION
Central Pathology Review for confirmation of glioblastoma (GBM) histology and of unmethylated MGMT promotor status
NOTE: Tumor tissue must be received and central review confirmation completed before STEP 2 registration can occur.

STEP 2 REGISTRATION

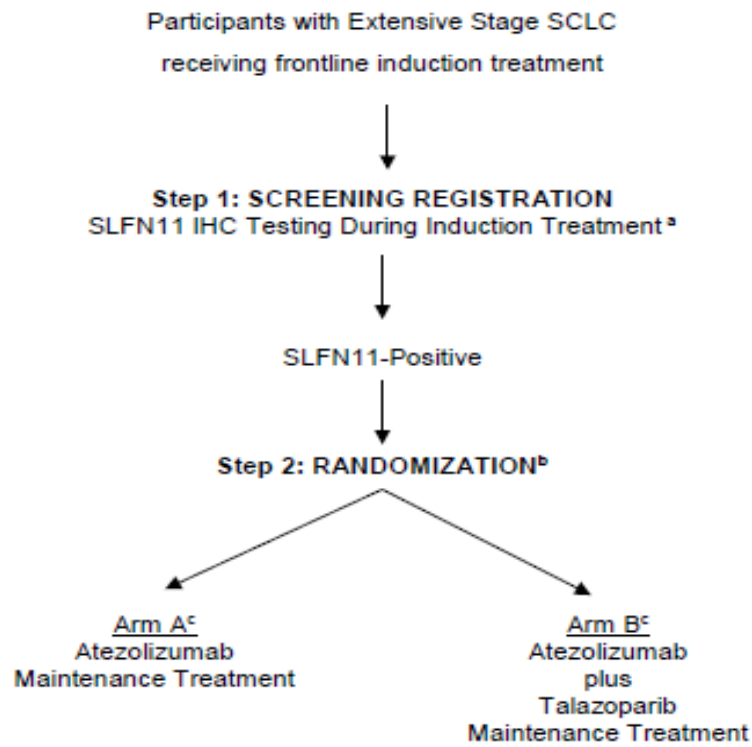
STRATIFY

- Recursive partitioning analysis (RPA) (III vs IV vs V)
- Intent to use Optune (yes vs no)

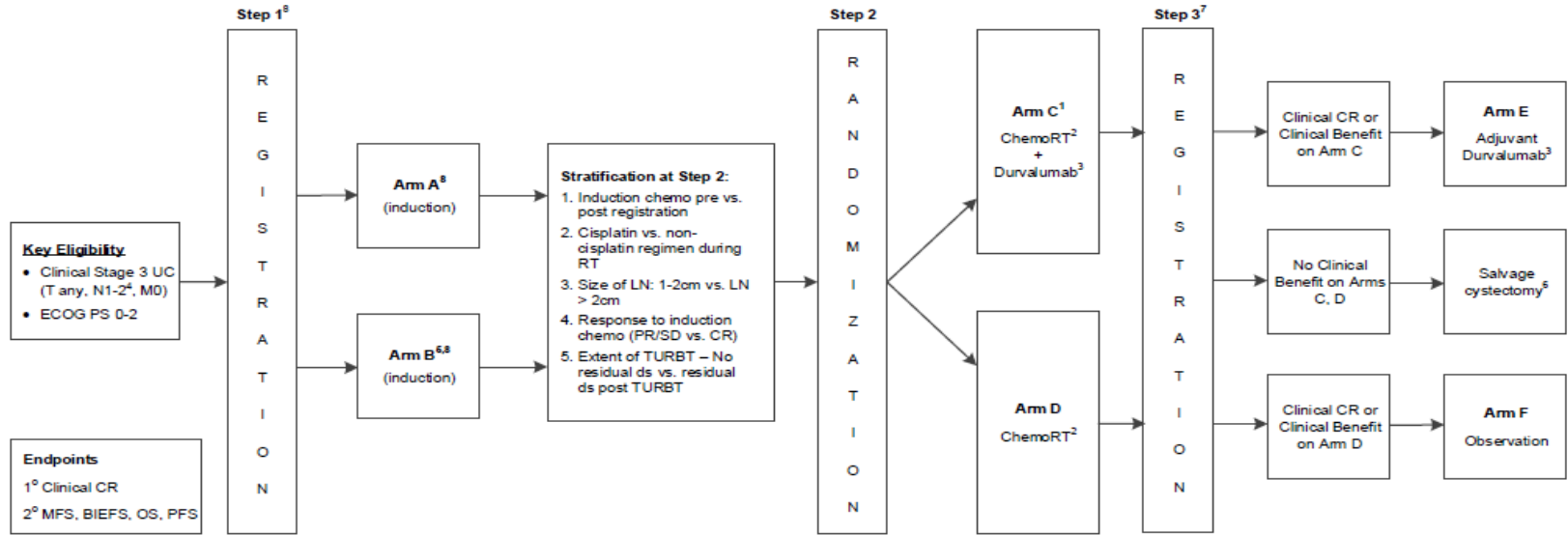
RANDOMIZE (1:1)

Arm 1
Radiation Therapy
plus
Concomitant temozolomide
plus
Adjuvant temozolomide
(Optune allowed)

Arm 2
Radiation Therapy
plus
Concomitant ipilimumab and nivolumab
plus
Adjuvant ipilimumab and nivolumab
(Optune not allowed)

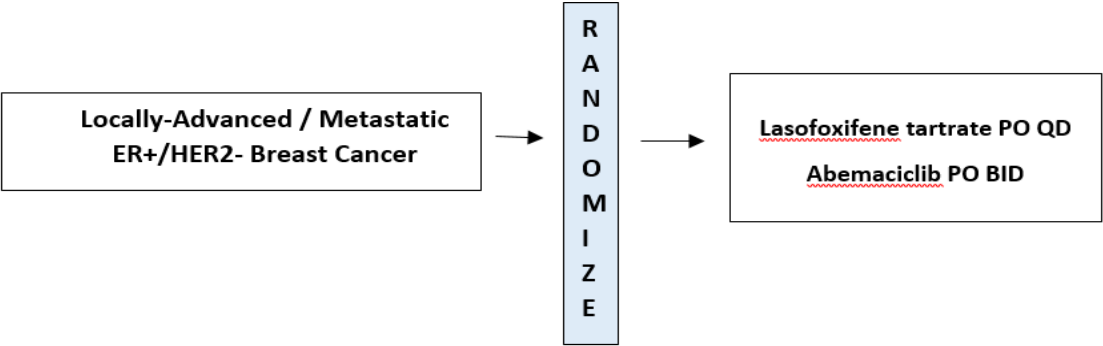


Schema



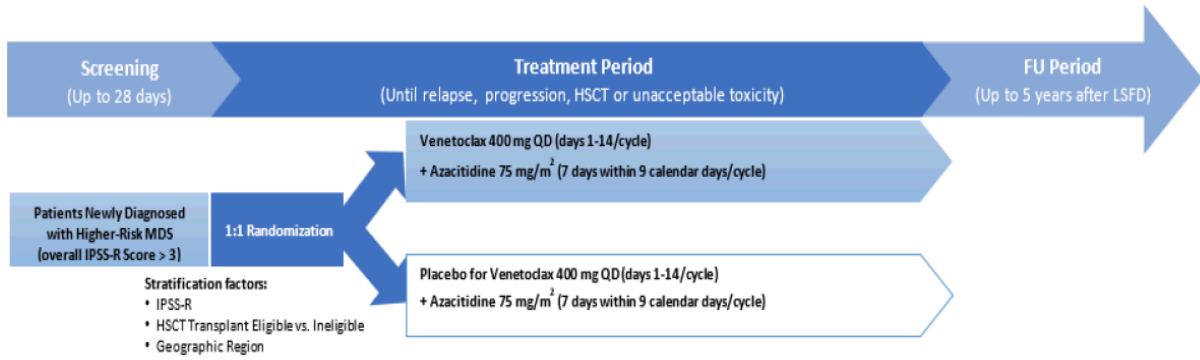
SMX 20-001
Navigator -Angie x3613

MENU

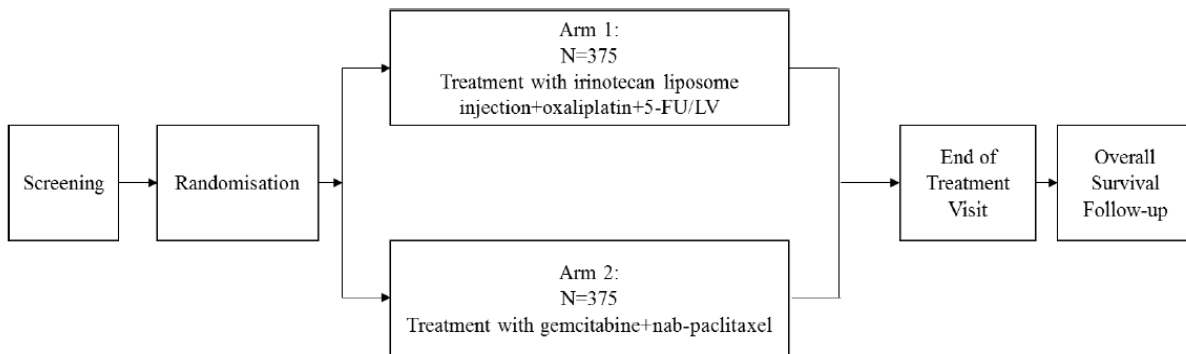


M15-954
Navigator -Heather x3661

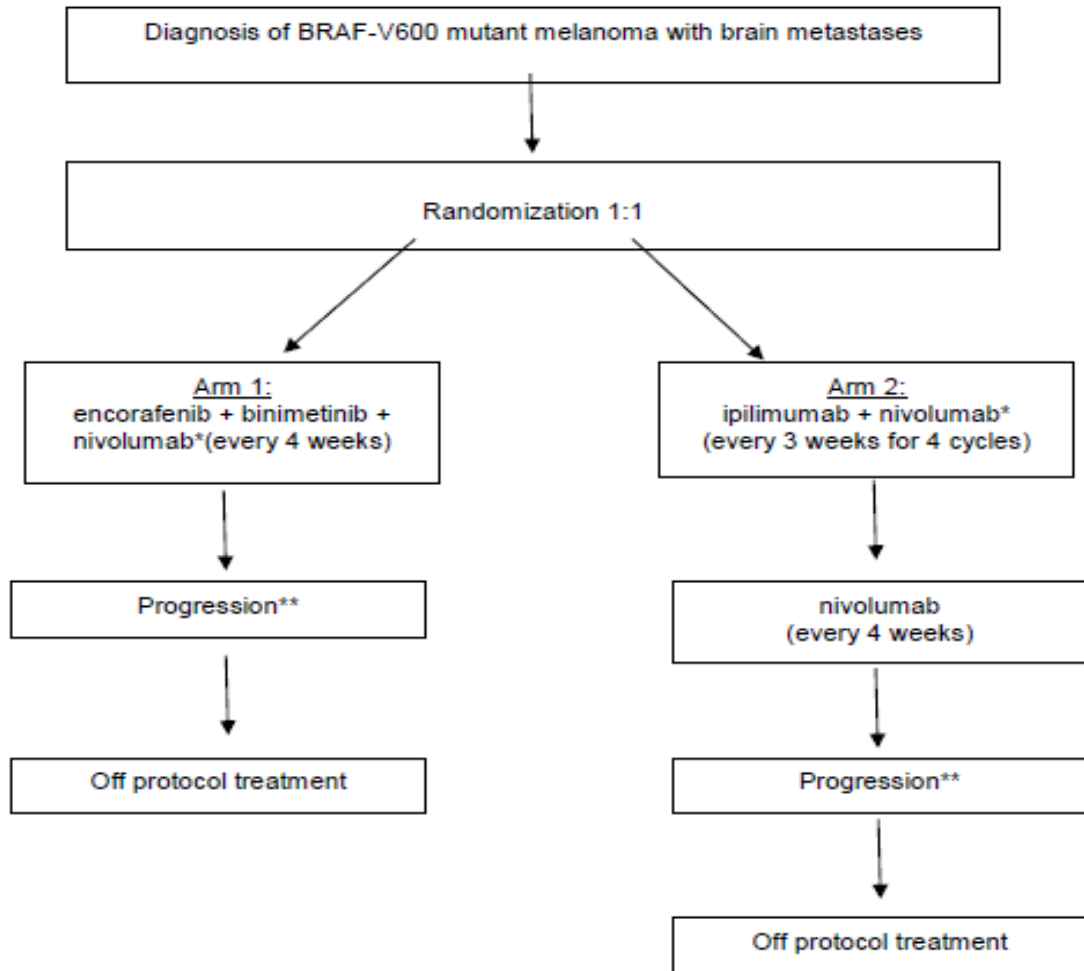
MENU



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

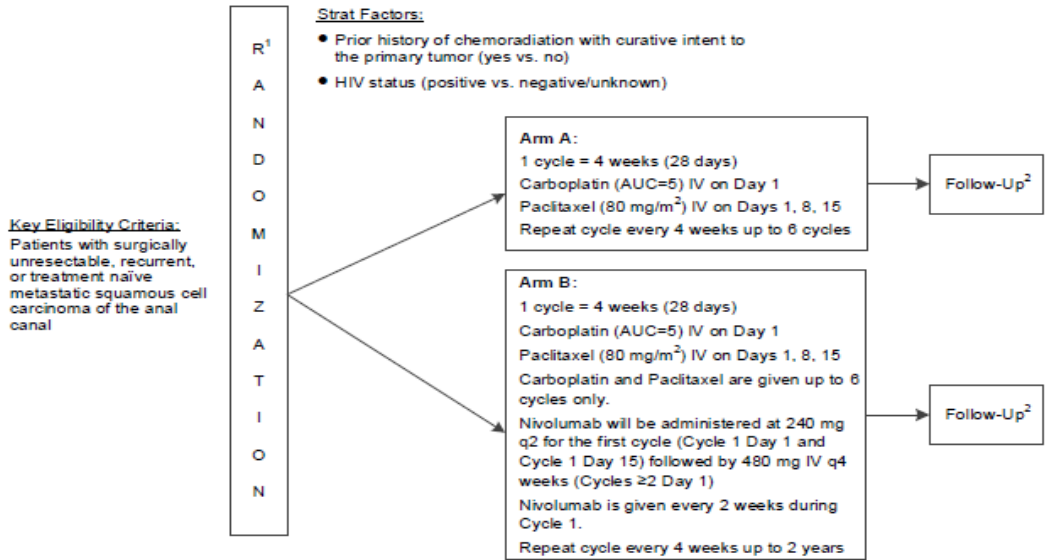


SCHEMA

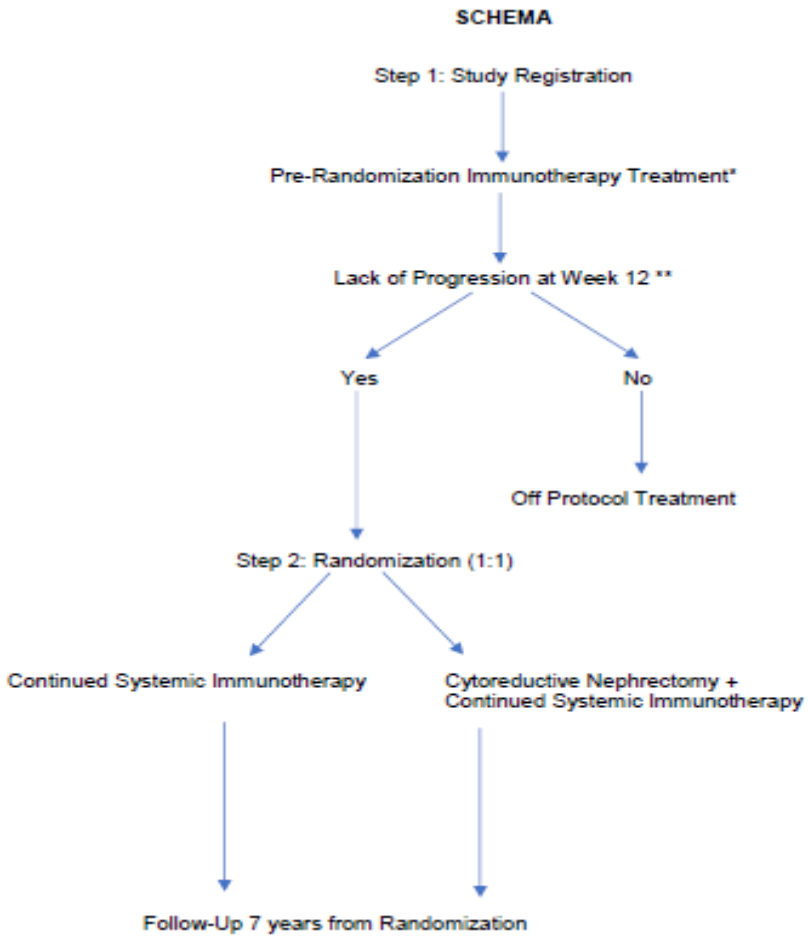


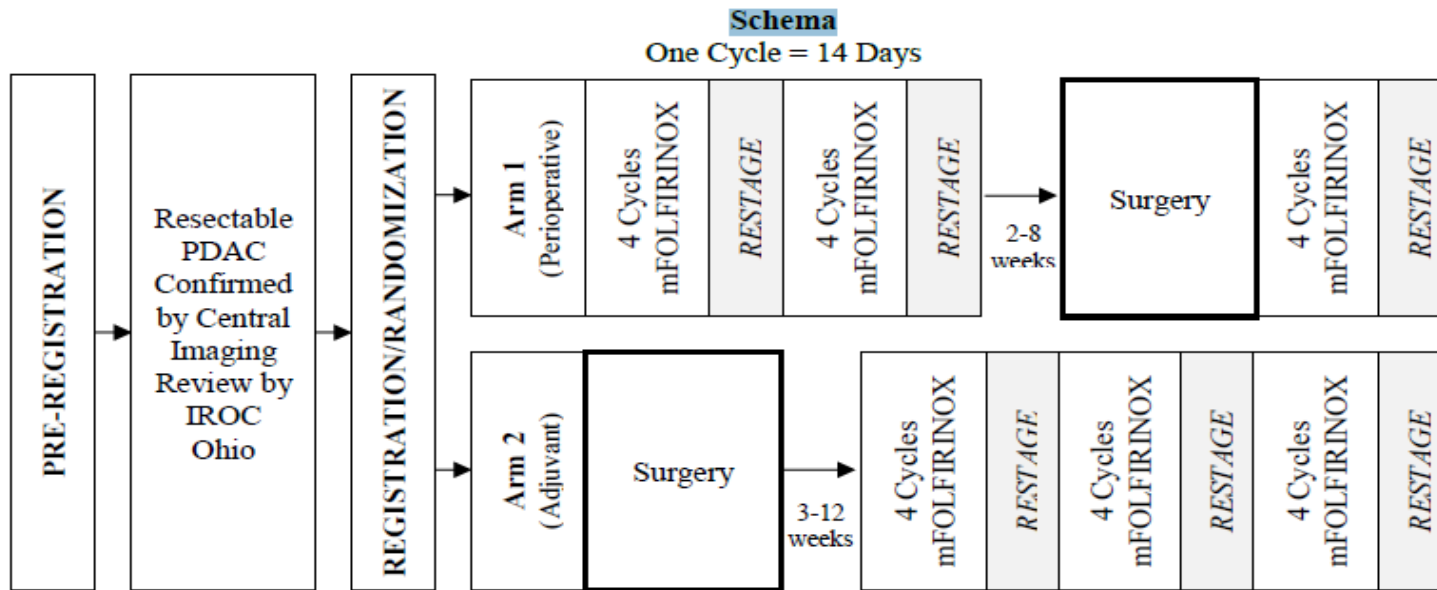
EA2176
Navigator -Carrie x3621

MENU

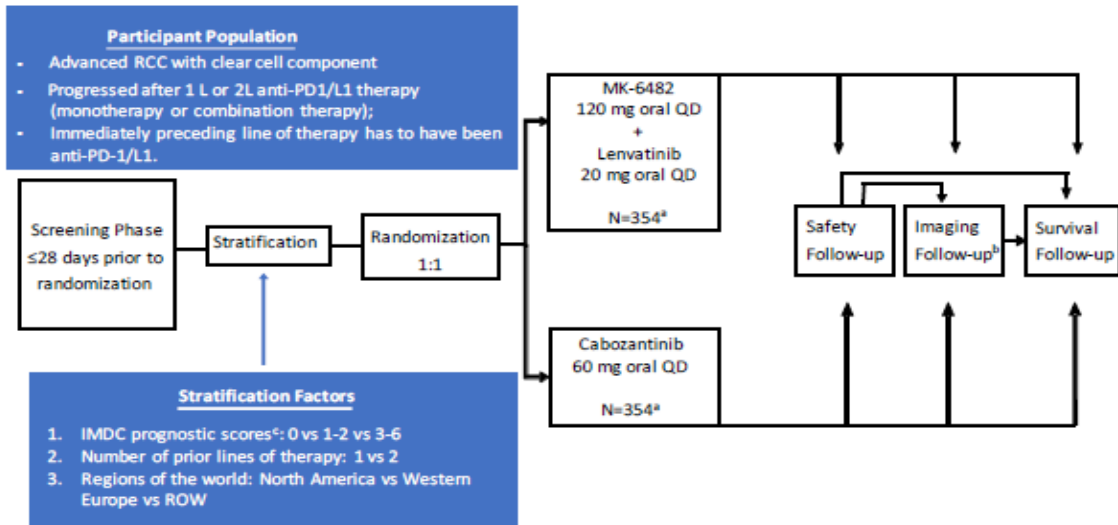


1. Randomization is 1:2 (A:B).
 2. For this protocol, all patients, including those who discontinue protocol therapy early, will be followed for response until disease progression, even if non-protocol therapy is initiated, and for survival every 3 months for two years from the date of randomization.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





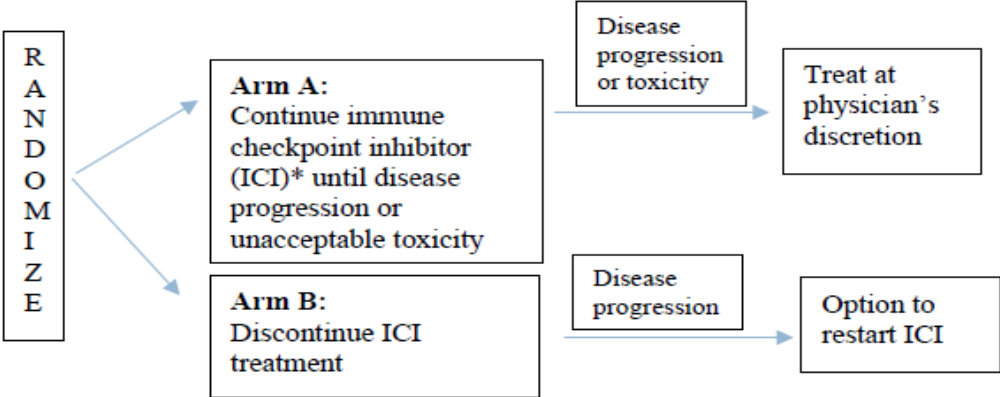
Treatment/intervention is to continue as outlined above or until disease recurrence, unacceptable toxicity, or withdrawal of consent. Patients will be followed for 6 years or until death, whichever comes first.



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

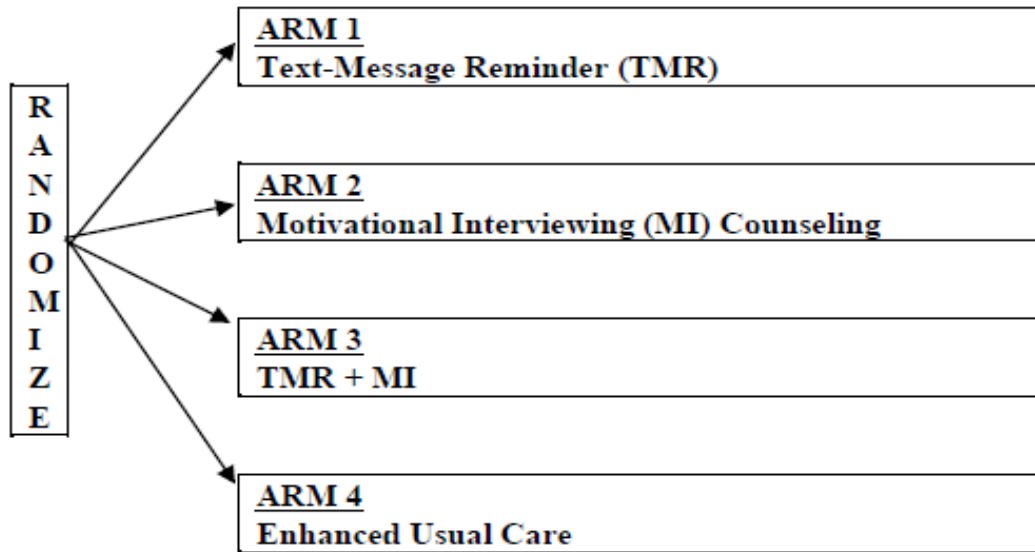
Cycle definition is based on ICI cycle length



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

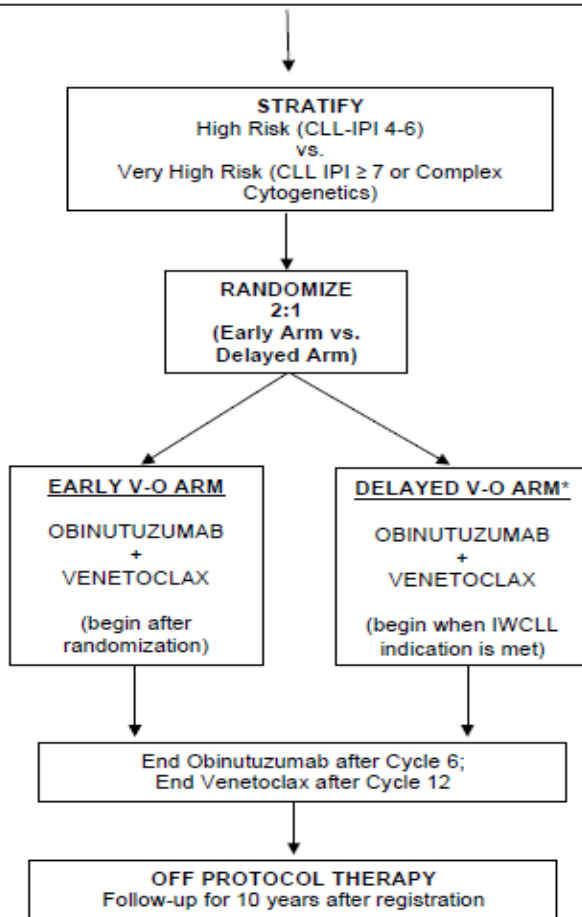
Patients will be followed for 5 years or until death or withdrawal of consent, whichever occurs first.

Schema

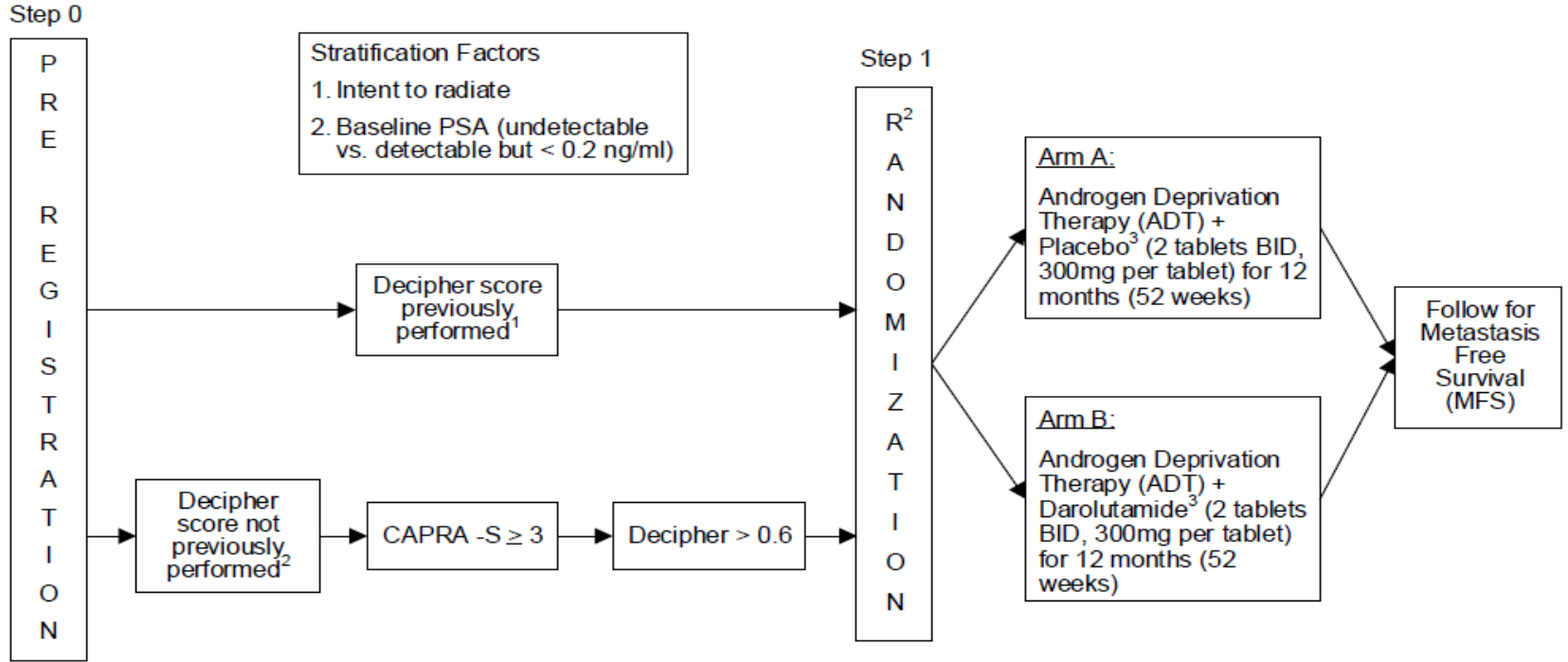


SCHEMA

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]



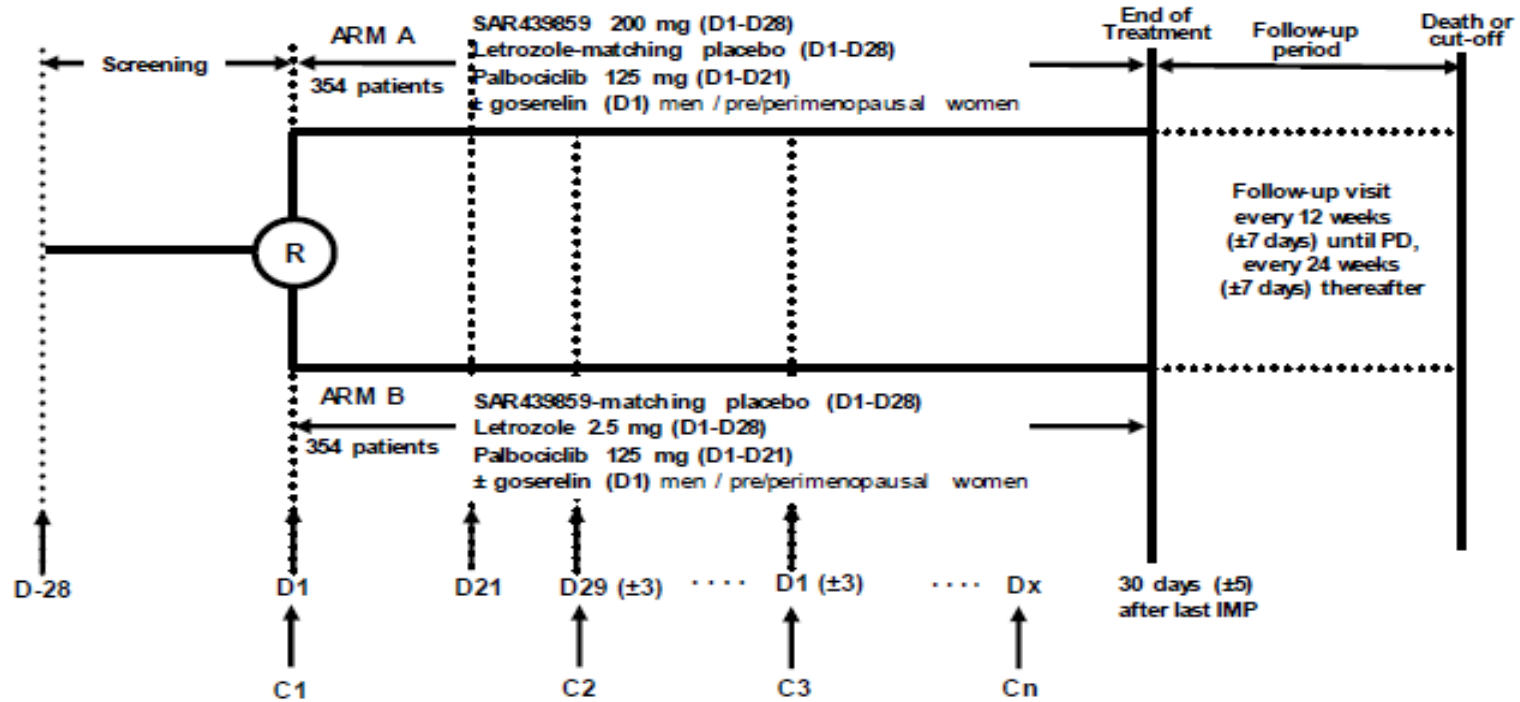
Schema



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.

S1418 / BR006
Navigator -Angie x3613

MENU

Patients with TNBC*, ≥ 1 cm residual invasive breast cancer, or any + LN (including ypN1mi) after neoadjuvant chemotherapy, followed by surgery

Step 1 Registration

Submit slides to central laboratory for PD-L1 evaluation.
SWOG Statistics and Data Management Center will notify sites when PD-L1 testing is completed.

Step 2 Registration (RANDOMIZATION)

Randomization stratification factors will include:

- Nodal Stage: ypN0 vs. ypN+
- Residual tumor size: ≤ 20 mm vs. > 20 mm
- PD-L1: positive vs. negative (blinded to sites)
- Prior post-operative (adjuvant) chemotherapy: yes vs. no

Arm 1**

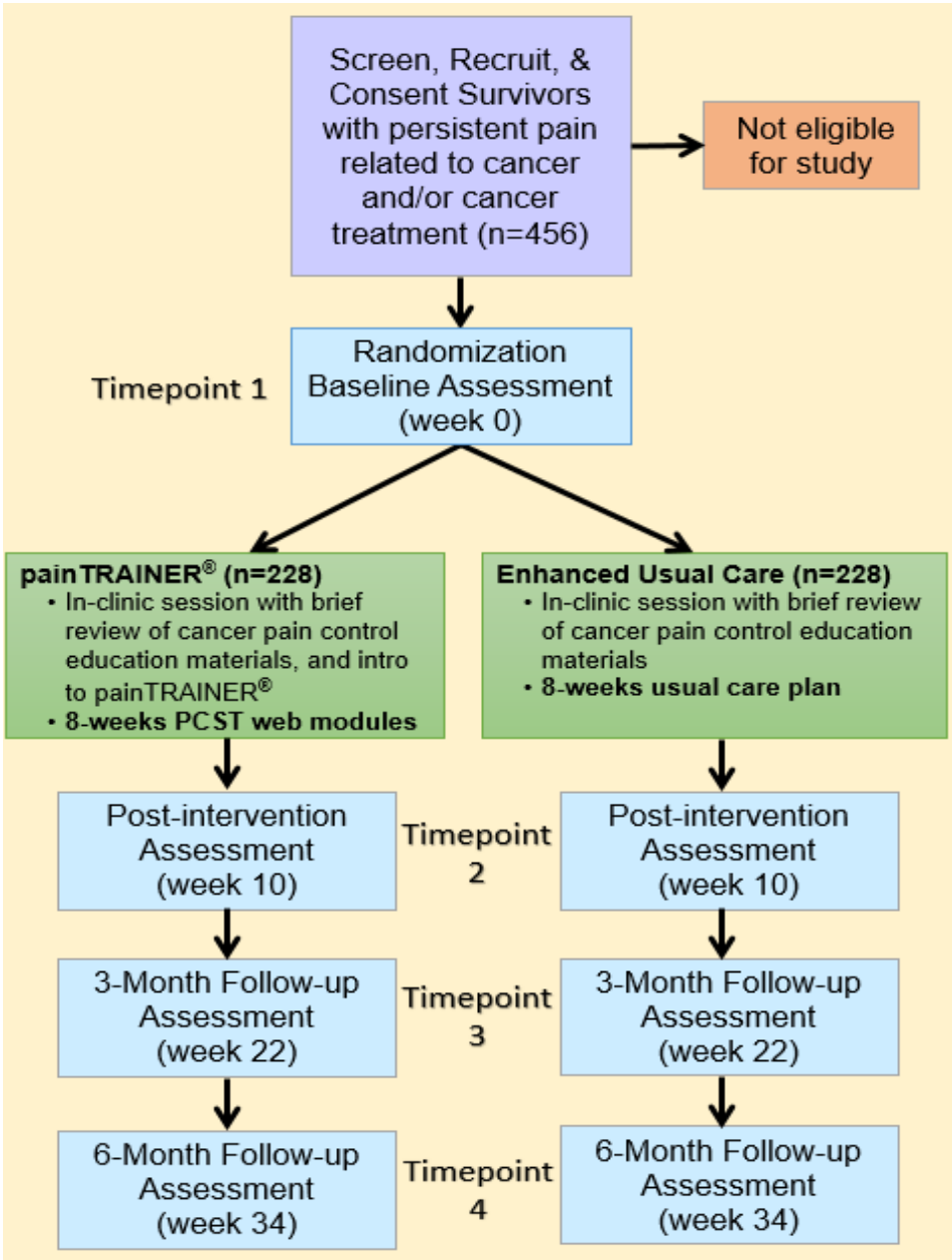
Observation

Arm 2**

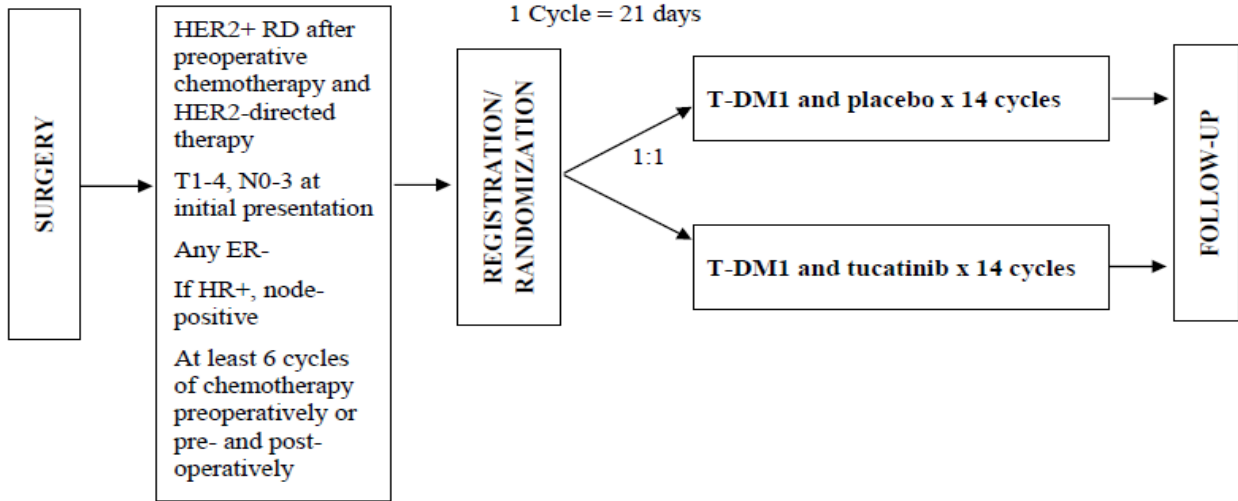
Pembrolizumab
(MK-3475)
IV
every 3 weeks for 52
weeks

* Patients with low ER- and/or PR- positive cancers (less than or equal to 5% positivity) and/or HER2 borderline cancers by ASCO CAP guidelines are also eligible.

** Patients must complete adjuvant chemotherapy, if given, prior to Step 1 Registration. Radiation therapy may be given concurrently with protocol treatment on Arm 1 or Arm 2 (see [Section 7.0](#)).



Schema



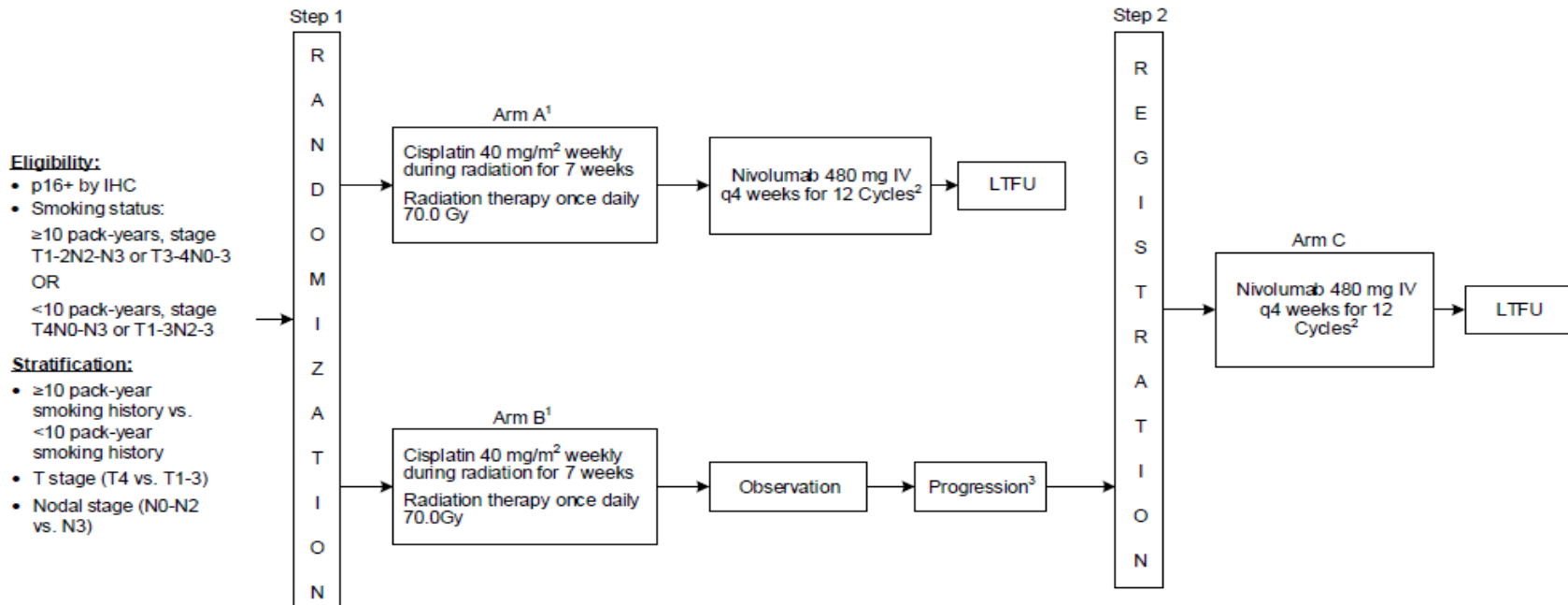
Note: HR stands for “hormone-receptor.”

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

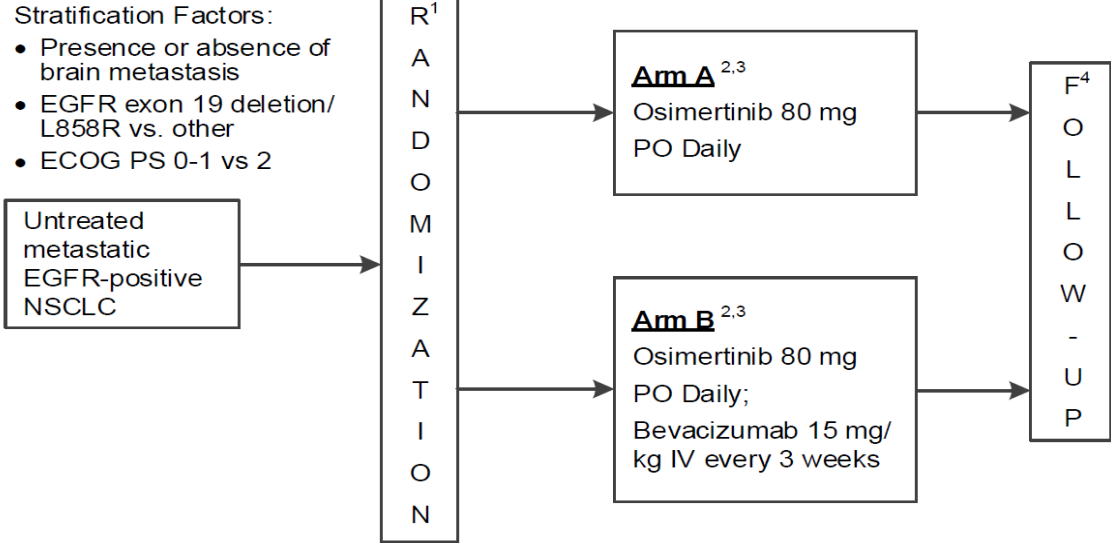
Schema



Accrual Goal: 744

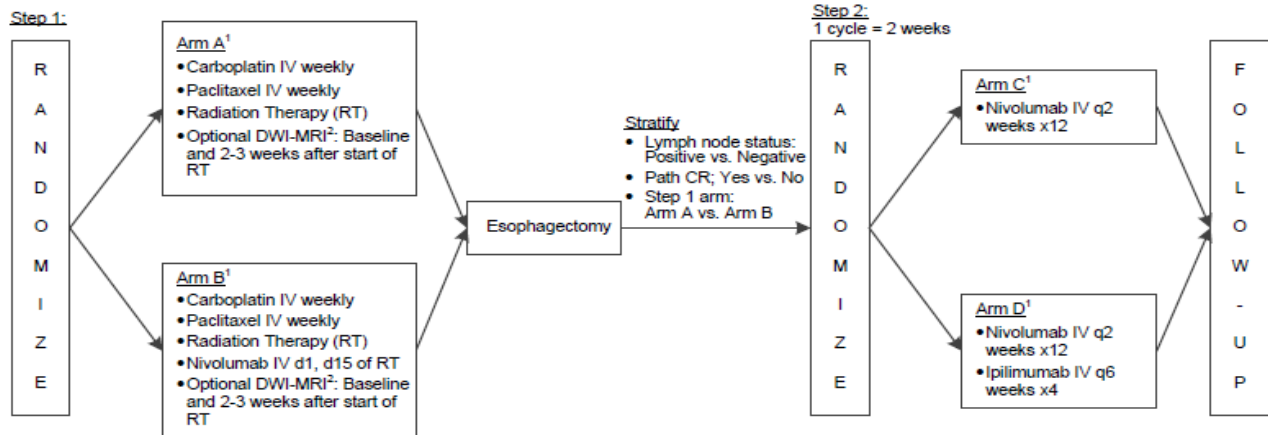
1. Submit tissue for PD-L1 testing.
2. Cycle length = 28 days
3. Patients who were randomized to observation will be offered the option to cross over if they have clearly documented progression by the RECIST criteria and tissue-proven progression within 12 months from the end of cisplatin/radiation therapy.

Schema



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

Schema

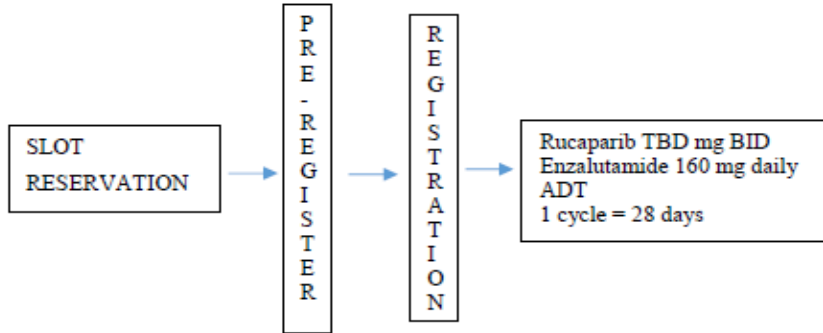


N=278

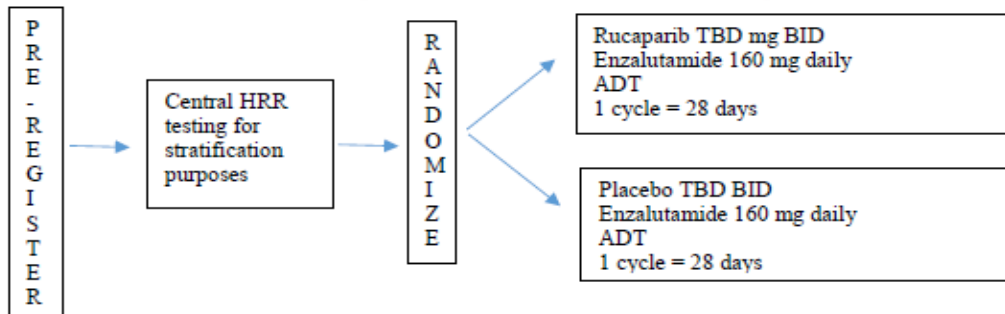
1. Please reference Section 5.1 for treatment dosing specifics.
2. Optional Diffusion weighted imaging-MRI (DWI-MRI) should be obtained at step 1 baseline and 2-3 weeks after initiation of protocol treatment.

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.