

DECEMBER 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 VULVA RENAL CELL SMALL CELL LUNG CANCER

Updated 12.8.21

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





DECEMBER 2021

	JUST IN TIME (JIT) TRIALS *Contact Disease Specific Navigator		
Mı	ulti-Disease Site: Advanced/Metastatic Solid Tumors		
<u>RAIN-3202</u>	A Phase 2 Basket Study of Milademetan in Advanced/Metastatic Solid Tumors		
	Brain		
<u>A021804</u>	A Prospective, Multi-Institutional Phase II Trial Evaluating Temozolomide vs. Temozolomide and Olaparib for Advanced Pheochromocytoma and Paraganglioma		
<u>A071702</u>	A Phase II Study of Checkpoint Blockade Immunotherapy in Patients With Somatically Hypermutated Recurrent Glioblastoma		
	Breast		
<u>\$1706</u>	(RT not credentialed yet)-A Phase II Randomized Trial of Olaparib (NSC-747856) Administered Concurrently with Radiotherapy versus Radiotherapy Alone for Inflammatory Breast Cancer		
	Carcinoid		
<u>\$2104</u>	Randomized Phase II Trial of Postoperative Adjuvant Capecitabine and Temozolomide Versus Observation in High-Risk Pancreatic Neuroendocrine Tumors		
CML			
<u>\$1712</u>	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		
<u>GY014</u>	(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		
<u>EA2187</u>	Temporarily closed Phase II study of Pevonedistat in Combincatoin with Carbo and paclitaxel in advanced intrahepatic cholonigocarcinoma.		
<u>EA2197</u>	Optimal Perioperative Therapy for Incidental Gallbladder Cancer (OPT-IN): A Randomized Phase II/III Trial		

<u>\$1922</u>	Randomized Phase II Selection Study of Ramucirumab and Paclitaxel versus FOLFIRI in Refractory Small Bowel Adenocarcinoma
	Genitourinary - Rare
<u>A031702</u>	Phase II Study of Cabozantinib in Combination with Nivolumab and Ipilimumab in Rare Genitourinary Tumors (temp closed cohorts - small cell carcinoma/neuroendorine & adenocarcinoma of bladder, penile, and misc GU tract variants, renal medullary carcinoma, and rare GU)
	Head & Neck
EA3191	Temporarily Closed (RT at Route-91) A Phase II Randomized Trial of Adjuvant Therapy With Pembrolizumab After Resection of Recurrent/Second Primary Head and Neck Squamous Cell Carcinoma With High Risk Features
	Lung
<u>\$1934</u>	Temporarily Closed Randomized Phase II Trial of Trimodality +/- Atezolizumab in Resectable Superior Sulcus Non-Small Cell Lung Cancer. NASSIST (Neoadjuvant Chemoradiation +/- Immunotherapy Before Surgery for Superior Sulcus Tumors)
	Lymphoma
<u>\$1608</u>	Randomized Phase II Trial in Early Relapsing or Refractory Follicular Lymphoma
	Melanoma
EA6192	A Phase II Study of Biomarker Driven Early Discontinuation of Anti-PD-1 Therapy in Patients With Advanced Melanoma (PET-Stop)
<u>\$1801</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>\$1614</u>	(temp closed) A Phase III Randomized Trial of Prophylactic Antiviral Therapy in Patients with Current or past hepatitis B Virus Infection Receiving Anti-Cancer Therapy for Solid Tumors
	Ovarian
<u>GY014</u>	(temp closed) 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

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<u>\$2001</u>	Randomized Phase II Clinical Trial of Olaparib + Pembrolizumab vs. Olaparib Alone as Maintenance Therapy in Metastatic Pancreatic Cancer Patients with Germline BRCA1 or BRCA2 Mutations	
<u>S2104</u>	Randomized Phase II Trial of Postoperative Adjuvant Capecitabine and Temozolomide Versus Observation in High-Risk Pancreatic Neuroendocrine Tumors	
	Rectal	
<u>EA2201</u>	(RT at Glen Oak, UPHM, Galesburg) A Phase II Study of Neoadjuvant Nivolumab Plus Ipilimumab and Short-Course Radiation in MSI-H/dMMR Locally Advanced Rectal Adenocarcinoma	
Sarcoma		
<u>A091902</u>	A Multicenter Phase II Trial of Paclitaxel With and Without Nivolumab in Taxane Naive, and Nivolumab and Cabozantinib in Taxane Pretreated Subjects With Angiosarcoma (closed to taxane pre-treated pts only)	
	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>\$1701</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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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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Navigator - Carrie x3621

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



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MENU

APL

Navigator - Heather x3661

There are no trials available at this time





DECEMBER 2021

ACUTE LYMPHOBLASTIC LEUKEMIA

Navigator - Heather x3661

EA9152

SCHEMA

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



MENU

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BLADDER / UROTHELIAL

Navigator - Carrie x3621

	ADJUVANT / NEOADJUVANT	
BMS CA017-078 SCHEMA	(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	
<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)	
EA8192 SCHEMA	A Phase II/III Trial of MEDI4736 (Durvalumab) and Chemotherapy for Patients With High Grade Upper Tract Urothelial Cancer Prior to Nephroureterectomy	
S1806 SCHEMA	(RT at Glen Oak, UPHM and Galesburg) Phase III Randomized Trial of Concurrent Chemoradiotherapy with or without Atezolizumab in Localized Muscle Invasive Bladder Cancer	
S2011 SCHEMA	Randomized Phase II Trial of Gemcitabine, Avelumab and Carboplatin vs. No Neoadjuvant Therapy Preceding Surgery for Cisplatin-Ineligible Muscle-Invasive Urothelial Carcinoma: SWOG GAP TRIAL	
METASTATIC		
A031901 SCHEMA	Duration of Immune Checkpoint Therapy in Locally Advanced or Metastatic Urothelial Carcinoma: A Randomized Phase 3 Non-Inferiority Trial	

<u>S1937</u>

SCHEMA

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





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Navigator - Carrie x3621

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



S2007

MASTER TRIAL LIST

MENU

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	BREAST	Navigator - Angie x3613
	DCIS	
<u>AFT-25</u>	Comparing an Operation to Monitoring, With or Without DCIS: A Phase III Prospective Randomized Trial (COM	• •
	NEO/ADJUVANT TREATMENT	Τ
<u>\$1706*</u>	RT credentialing pending - A Phase II Randomized Administered Concurrently with Radiotherapy versunflammatory Breast Cancer (All biomarker subgroweek delay to consent pt	sus Radiotherapy Alone for
Neo/Adjuvant - HE	R2 Positive	
A011801 SCHEMA	The CompassHER2 Trials (Comprehensive Use of P Optimize Therapy in HER2-Positive Breast Cancer) Double-Blinded, Phase III Randomized Trial of T-DI Tucatinib	CompassHER2 Residual Disease (RD), a
<u>EA1181</u>	Preoperative THP and Postoperative HP in Patient Response (CompassHER2-pCR)	s Who Achieve a Pathologic Complete
Neo/Adjuvant - <mark>Ho</mark>	rmone Receptor Positive / HER2 Negative	
BR007	(RT at Galesburg, Glen Oak, Rt 91, UPHM) Phase III Cli Radiation for Conservative Treatment of Stage I, Hormon Recurrence Score Less Than or Equal to 18 Breast Canc	one Sensitive, HER-2 Negative, Oncotype
Neo/Adjuvant - Tri	ple Negative	
No trials at this time.		
	METASTATIC TREATMENT	
Metastatic - HER2 I	Positive	
BR004	A Randomized, Double-Blind, Phase III Trial of Pacl Atezolizumab or Placebo in First-Line HER2-Positiv	
Metastatic - Hormo	one Receptor Positive / HER2 Negative	
<u>\$1703</u>	Randomized Non-Inferiority Trial Comparing Overa Serum Tumor Marker Directed Disease Monitoring Patients with Metastatic Hormone Receptor Positi	g (STMDDM) Versus Usual Care in

A Phase II Trial of Sacituzumab Govitecan (IMMU-132) (NSC #820016) for Patients With

HER2-Negative Breast Cancer and Brain Metastases

Metastatic - Triple	Negative
	no trials at this time
	SURGERY / RADIATION ONLY
A011202 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. (RT: Glen Oak, Rt 91, UPHM, Galesburg)
BR002	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 (RT: Glen Oak, UPHM)
MA.39	Tailor RT: A Randomized Trial of Regional Radiotherapy in Biomarker Low Risk Node Positive Breast Cancer (RT: Glen Oak and UPHM)
	CANCER CONTROL (Breast only)
A191901 ► SCHEMA	Optimizing Endocrine Therapy Through Motivational Interviewing and Text Interventions
A222004	A Randomized Phase III Trial of Olanzapine Versus Megestrol Acetate for Cancer-Associated Anorexia
EAQ202 SCHEMA	NEW! Improving Adolescent and Young Adult Self-Reported Data in ECOG-ACRIN Trials
PROT001/ BLUENOTE	(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	A Randomized Trial Addressing Cancer-Related Financial Hardship Through Delivery of a Proactive Financial Navigation Intervention (CREDIT)
S2013 ► SCHEMA	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 at least 2 months out from surgery/tx/radiation
WF-1901 SCHEMA	Internet-delivered Management of Pain Among Cancer Treatment Survivors (IMPACTS)

NRG-GY012	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
NRG - GY023	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



MENU

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Navigators - Courtney x3660 Hannah x3603

CANCER CONTROL		
MULTI-DISEASE SITES		
A222004 SCHEMA	A Randomized Phase III Trial of Olanzapine Versus Megestrol Acetate for Cancer-Associated Anorexia	
EAQ202	NEW! Improving Adolescent and Young Adult Self-Reported Data in ECOG-ACRIN Trials	
PROT001/ BLUENOTE	(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	A Randomized Trial Addressing Cancer-Related Financial Hardship Through Delivery of a Proactive Financial Navigation Intervention (CREDIT)	
S2013 SCHEMA	Immune Checkpoint Inhibitor Toxicity: A Prospective Observational Study (I-CHECKIT)	
<u>URCC 16092</u>	(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	
<u>URCC 16070</u>	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 at least 2 months out from surgery/tx/radiation	
	LUNG	
	Nothing currently available for Lung only - See Multi-Disease Cancer Control trials ABOVE.	
COLORECTAL		
A221805 SCHEMA	Duloxetine to Prevent Oxaliplatin-Induced Chemotherapy-Induced Peripheral Neuropathy: A Randomized, Double-Blind, Placebo-Controlled Phase II to Phase III Study	
<u>\$1820</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	
	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>	
NHLBI-MDS	(Peoria, Bloomington and Galesburg only) -The National Myelodysplastic Syndromes (MDS) Study	



DECEMBER 2021

Navigator - Ashton x3611 Carrie x3621

CARCINOID

No trials at this time

MENU





DECEMBER 2021

CLL

Navigator - Heather x3661

1st Line

S1925 SCHEMA	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	
U2-VEN-207	(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	
<u>A041702</u>	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)	
2nd Line, 3rd Line, etc.		
<u>U2-VEN-207</u>	(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	



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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.



Cancer

MASTER TRIAL LIST

MENU

DECEMBER 2021

COLON / RECTAL Navigator - Carrie x362		Navigator - Carrie x3621
Adjuvant		
A021502	Randomized Trial of Standard Chemotherapy Alone or Combined With Atezolizumab as Adjuvant Therapy for Patients With Stage III Colon Cancer and Deficient DNA Mismatch Repair	
NRG GI005	Phase II/III Study of Circulating Tumor DNA as a Predictive Biomarker in Adjuvant Chemotherapy in Patients With Stage IIA Colon Cancer (COBRA)	
	Metastatic	
<u>G1004</u>	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	
MK 7339-003	(Peoria, Bloomington, Galesburg, Peru) A Phase 3 Randomized, Oper Efficacy and Safety of Olaparib Alone or in Combination With Bevaciz Bevacizumab with 5-FU in Participants with Unresectable or Metastal Have Not Progressed Following First-line Induction of FOLFOX With B	umab Compared to cic Colorectal Cancer who
	CANCER CONTROL (Colorectal only)	
A221805	Duloxetine to Prevent Oxaliplatin-Induced Chemotherapy-Induced Pe Randomized, Double-Blind, Placebo-Controlled Phase II to Phase III St	
A222004	A Randomized Phase III Trial of Olanzapine Versus Megestrol Acetate for Cancer-Associated Anorexia	
EAQ202	NEW! Improving Adolescent and Young Adult Self-Reported Data in E	COG-ACRIN Trials
S1820	A Randomized Trial of the Altering Intake, Managing Symptoms Interin Rectal Cancer Survivors Compared to a Healthy Living Education Copreliminary Efficacy Study (AIMS-RC)	· · · · · · · · · · · · · · · · · · ·
S1912CD	A Randomized Trial Addressing Cancer-Related Financial Hardship The Financial Navigation Intervention (CREDIT)	rough Delivery of a Proactive
S2013 SCHEMA	Immune Checkpoint Inhibitor Toxicity: A Prospective Observational St	tudy (I-CHECKIT)
URCC 16092	(Peoria only) - Phase II Study of Low-Dose Ibuprofen for Cognitive Pro	oblems in Patients With

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



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	ESOPHAGEAL- GASTRIC	Navigator - Carrie x3621
<u>EA2174</u> ► SCHEMA	(RT at Glen Oak, RT-91, UPHM, Galesburg) A Phase II/III Study of Peri-Ope Ipilimumab in Patients With Locoregional Esophageal and Gastroesophage Adenocarcinoma	
EA2183 SCHEMA	Temp Closed (RT at UPHM only) A Phase III Study of Consolidative Radiot Oligometastatic HER2 Negative Esophageal and Gastric Adenocarcinoma (





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HEAD & NECK

Navigator - Ashton x3611

EA3161 SCHEMA	(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
<u>EA3191 - JIT</u>	Temporarily Closed (RT at Route-91) A Phase II Randomized Trial of Adjuvant Therapy With Pembrolizumab After Resection of Recurrent/Second Primary Head and Neck Squamous Cell Carcinoma With High Risk Features
<u>HN004</u>	Temporarily 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
<u>HN005</u>	(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
<u>HN009</u>	Coming Soon! Randomized Phase II/III Trial of Radiation With High-Dose Cisplatin (100 mg/m2) Every Three Weeks Versus Radiation With Low-Dose Weekly Cisplatin (40 mg/m2) for Patients With Locoregionally Advanced Squamous Cell Carcinoma of the Head and Neck (SCCHN)





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Navigator - Heather x3661

LYMPHOMA

HL	
<u>\$1826</u>	(RT at Glen Oak, Rt-91, UPHM) A Phase III, Randomized Study of Nivolumab (Opdivo) Plus AVD or Brentuximab Vedotin (Adcetris) Plus AVD in Patients (Age >/= 12 Years) With Newly Diagnosed Advanced Stage Classical Hodgkin Lymphoma
SGN35-027 SCHEMA	(Bloomington, Galesburg, Ottawa, Pekin, Peoria, Peru) Multiple Part Clinical Trial of Brentuximab Vedotin in Classical Hodgkin Lymphoma Subjects
	NHL
<u>EA4181</u>	A Randomized 3-Arm Phase II Study Comparing 1.) Bendamustine, Rituximab and High Dose Cytarabine (BR/CR) 2.) Bendamustine, Rituximab, High Dose Cytarabine and Acalabrutinib (BR/CR-A), and 3.) Bendamustine, Rituximab and Acalabrutinib (BR-A) in Patients ≤ 70 Years Old With Untreated Mantle Cell Lymphoma
TG-1501-101	(Peoria, Bloomington, Galesburg)-A Phase 1 Study of TG-1501 in Subjects with Relapsed or Refractory Lymphoma (classic HL cohort closed)
DLBCL	





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Navigator - Heather x3661

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





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MELANOMA

Navigator - Carrie x3621

EA6194 SCHEMA

Phase II Randomized Study of Neoadjuvant Pembrolizumab Alone or in Combination With CMP-001 in Patients With Operable Melanoma: Efficacy and Biomarker Study

\$2000 SCHEMA

A Randomized Phase 2 Trial of Encorafenib + Binimetinib + Nivolumab vs Ipilimumab + Nivolumab in BRAF-V600 Mutant Melanoma With Brain Metastases



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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





DECEMBER 2021

MOLECULAR STUDIES

*Contact Disease Specifc Navigator

2215-MA-3297 / CLEVO	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	
64091742PCR0002 / Prevalence	Biomarker Study to Determine Frequency of DNA-repair Defects in Men with Metastatic Prostate Cancer (Prevelence)	
<u>A151804</u>	Establishment of a National Biorepository to Advance Studies of Immune-Related Adverse Events	
NSABP C-14	Site Selected - Second Colorectal Cancer Clinical Validation Study to Predict Recurrence Using A Circulating Tumor DNA Assay To Detect Minimal Residual Disease (CORRECT-MRD II)	
<u>\$1823</u>	A Study of miRNA 371 in Patients With Germ Cell Tumor	
TPX-0005-01 (TRIDENT-1)	A Phase 1/2, Open-Label, Multi-Center, First-in-Human Study of the Safety, Tolerability, Pharmacokinetics, and Anti-Tumor Activity of TPX-0005 in Patients with Advanced Solid Tumors Harboring ALK, ROS1, or NTRK1-3 Rearrangements (TRIDENT-1)	



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MULTIPLE MYELOMA

Navigator - Heather x3661

EAA171	Optimizing Prolonged Treatment in Myeloma Using MRD Assessment (OPTIMUM)
<u>\$1803</u>	Phase III Study of Daratumumab/rHuPH20 (NSC- 810307) + Lenalidomide or Lenalidomide as Post-Autologous Stem Cell Transplant Maintenance Therapy in Patients with Multiple Myeloma (MM) Using Minimal Residual Disease to Direct Therapy Duration (DRAMMATIC Study)



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NSCLC

Navigator - Ashton x3611

ADJUVANT / NEOADJUVANT

A081801 SCHEMA	Temporarily closed Integration of Immunotherapy Into Adjuvant Therapy for Resected NSCLC: ALCHEMIST Chemo-IO (ALCHEMIST substudy- <i>Must be enrolled on ALCHEMIST and this substudy prior to start of tx</i>).
<u>A151216</u>	Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST).
EA5181 SCHEMA	(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)
GO41854 SCHEMA	(Bloomington, Galesburg, Pekin, Peoria, Peru) A Phase III, Open Label, Randomized Study of Atezolizumab and Tiragolumab Compared With Durvalumab in Patients With Locally Advanced, unresectable Stage III Non-Small Cell Lung Cancer Who Have Not Progressed After Concurrent Platinum-Based Chemoradiation (SKYSCRAPER-03)
<u>\$1914</u>	(RT at Glen Oak, UPHM, Galesburg) Randomized Phase III Trial of Induction/Consolidation Atezolizumab (NSC #783608) + SBRT Versus SBRT Alone in High Risk, Early Stage NSCLC
<u>S1933</u> ■ SCHEMA	(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

METASTATIC - 1st Line

EA5163/S1709 INSIGNA	Temporarily Closed A Randomized, Phase III Study of Firstline Immunotherapy alone or in Combination with Chemotherapy in Induction/Maintenance or Postprogression in Advanced Nonsquamous Non-Small Cell Lung Cancer (NSCLC) with Immunobiomarker SIGNature-driven Analysis				
EA5182	Randomized Phase III Study of Combination AZD9291 (osimertinib) and Bevacizumab versus AZD9291 (osimertinib) Alone as First-Line Treatment for Patients with Metastatic EGFR-Mutant Non-Small Cell Lung Cancer (NSCLC)				
<u>LU002</u>	Temporarily Closed (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				
MK 7684A-003	(Peoria only) A Phase 3, Multicenter, Randomized, Double-Blind Study of MK-7684 with Pembrolizumab as a Coformulation (MK-7684A) Versus Pembrolizumab Monotherapy as First Line Treatment for Participants With PD-L1 Positive Metastatic Non-Small Cell Lung Cancer				
<u>TH-138</u> ► 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 (non smokers)				

METASTATIC - 2nd/3rd Line

<u>EA5191</u>	A Randomized Phase II Trial of Cabozantinib and Cabozantinib Plus Nivolumab Versus Standard Chemotherapy in Patients With Previously Treated Non-Squamous NSCLC
LUNGMAP	A Master Protocol To Evaluate Biomarker-Driven Therapies and Immunotherapies in Previously-Treated NSCLC.

MK 7684A-002	(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.				
TH-138	(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)				
A222004 ► SCHEMA	NEW! A Randomized Phase III Trial of Olanzapine Versus Megestrol Acetate for Cancer-Associated Anorexia				
EAQ202	NEW! Improving Adolescent and Young Adult Self-Reported Data in ECOG-ACRIN Trials				
PROT001/ BLUENOTE	(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	A Randomized Trial Addressing Cancer-Related Financial Hardship Through Delivery of a Proactive Financial Navigation Intervention (CREDIT)				
<u>\$2013</u> ■ SCHEMA	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)				





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Navigator - Carrie x3621

A021806	A Phase III Trial of Perioperative Versus Adjuvant Chemotherapy for Resectable Pancreatic Cancer				
EA2186 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>Drug shortage:</u> Confirmation of Nab-Paclitaxel availability required prior to enrollment				
EA2192 SCHEMA	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)				



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	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.				
GU008	After Radical Prostatectomy (INNOVATE): Intensifying Treatment for Node Positive Prostate Cancer				
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*)					
GU010	Coming Soon! Parallel Phase III Randomized Trials of Genomic-Risk Stratification Intermediate Risk Prostate Cancer: De-Intensification and Intensification C (GUIDANCE)				
<i>METASTATIC</i>					

PROSTATE

64091742PCR0002 / Prevalence	Biomarker Study to Determine Frequency of DNA-repair Defects in Men with Metastatic Prostate Cancer
C2321001 SCHEMA	REOPENED! (Peoria only) A Phase I Dose Escalation and Expanded Cohort Study of PF-06821497 in the Treatment of Adult Patients with Relapsed/Refractory Small Cell Lung Cancer (SCLC), Castration Resistant Prostate Cancer (CRPC) and Follicular Lymphoma (FL)
A031902 / CASPAR	A Phase III Trial of Enzalutamide and Rucaparib as a Novel Therapy in First-Line Metastatic Castration-Resistant Prostate Cancer
<u>\$1802</u>	(RT at Glen Oak & UPHM) Phase III Randomized Trial of Standard Systemic Therapy (SST) versus Standard Systemic Therapy Plus Definitive Treatment (Surgery or Radiation) of the Primary Tumor in Metastatic Prostate Cancer



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Navigator - Carrie x3621

A031704	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)
MK 6482-011 SCHEMA	(Peoria, Bloomington, Galesburg, Pekin) An Open-label, Randomized, Phase 3 Study of MK-6482 in Combination with Lenvatinib (MK-7902) vs Cabozantinib for Second-line or Third-line Treatment in Participants with Advanced Renal Cell Carcinoma Who Have Progressed After Prior Anti-PD-1/L1 Therapy
S1931 SCHEMA	Phase III Trial of Immunotherapy-Based Combination Therapy With or Without Cytoreductive Nephrectomy for Metastatic Renal Cell Carcinoma (PROBE Trial)



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	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 Cell Carcinoma (DECREASE)	on for Early-Stage Anal Squamous	
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)		
S1806 SCHEMA	(Glen Oak, UPHM and Galesburg) Phase III Randomized Trial of Concurrent Chemoradiotherapy with or without Atezolizumab in Localized Muscle Invasive Bladder Cancer		
BRAIN			
BN007	(UPHM, Glen Oak, Galesburg) A Randomized Phase II/III Open-Label Study of Ipilimumab and Nivolumab Versus Temozolomide in Patients With Newly Diagnosed MGMT (Tumor O-6-Methylguanine DNA Methyltransferase) Unmethylated Glioblastoma		
<u>N0577</u>	(Glen Oak, RT 91, and UPHM) Phase III Intergroup Study of Radiotherapy with Concomitant and Adjuvant Temozolomide versus Radiotherapy with Adjuvant PCV Chemotherapy in Patients with 1p/19q Co-deleted Anaplastic Glioma or Low Grade Glioma		
BRAIN METS			
<u>A071801</u>	(UPHM & Glen Oak) Phase III Trial of Post-Surgical Single Fraction Stereotactic With Fractionated SRS for Resected Metastatic Brain Disease	Radiosurgery (SRS) Compared	
CCTG CE.7	(UPHM & Glen Oak)- A Phase III Trial of Stereotactic Radiosurgery Compared (WBRT) for 5-15 Brain Metastases	with Whole Brain Radiotherapy	
BREAST			

A011202 SCHEMA	(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.
BR007	(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	
EA2174 ► SCHEMA	(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>	Temp Closed (UPHM only) A Phase III Study of Consolidative Radiotherapy in Patients With Oligometastatic HER2 Negative Esophageal and Gastric Adenocarcinoma (EGA)
HEAD & NECK	
EA3161	(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
<u>HN009</u>	Coming Soon! Randomized Phase II/III Trial of Radiation With High-Dose Cisplatin (100 mg/m2) Every Three Weeks Versus Radiation With Low-Dose Weekly Cisplatin (40 mg/m2) for Patients With Locoregionally Advanced Squamous Cell Carcinoma of the Head and Neck (SCCHN)
HODGKIN'S LYMPHOMA	
<u>\$1826</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>	(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>	Temporarily Closed (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>\$1914</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 RADICAI 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.
GU009	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*)
GU010	Coming Soon! Parallel Phase III Randomized Trials of Genomic-Risk Stratified Unfavorable Intermediate Risk Prostate Cancer: De-Intensification and Intensification Clinical Trial Evaluation (GUIDANCE)
<u>\$1802</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	
NRG CC003	(Glen Oak only) Randomized Phase II/III Trial of Prophylactic Cranial Irradiation with or without Hippocampal Avoidance for Small Cell Lung Cancer
NRG CC009	(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
<u>LU005</u>	(Glen Oak, UPHM and Galesburg) Limited Stage Small Cell Lung Cancer (LS-SCLC): A Phase II/III Randomized Study of Chemoradiation Versus Chemoradiation Plus Atezolizumab
LU007 / RAPTOR	(Glen Oak, UPHM, Galesburg) – Randomized Phase II/III Trial of Consolidation RT + Immunotherapy for ES-SCLC
<u>\$1827</u>	(Glen Oak, UPHM, Galesburg) A Randomized Phase III Trial of MRI Surveillance With or Without Prophylactic Cranial Irradiation (PCI) in Small-Cell Lung Cancer



MASTER TRIAL LIST

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SMALL CELL LUNG CANCER

Navigator - Ashton x3611

NRG CC003	(RT at Glen Oak only) Randomized Phase II/III Trial of Prophylactic Cranial Irradiation with or without Hippocampal Avoidance for Small Cell Lung Cancer
NRG CC009	(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
GO43104 SCHEMA	NEW! (Peoria, Bloomington, Galesburg, Ottawa, Pekin, Peru, Washington) A Phase III, Randomized, Open-Label, Multicenter Study of Lurbinectedin In Combination With Atezolizumab Compared With Atezolizumab As Maintenance Therapy In Participants With Extensive-Stage Small-Cell Lung Cancer (ES-SCLC) Followiing First-Line Induction Therapy With Carboplatin, Etoposide and Atezolizumab
<u>LU005</u>	(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
LU007 / RAPTOR	(RT at Glen Oak, UPHM, Galesburg) – Randomized Phase II/III Trial of Consolidation RT + Immunotherapy for ES-SCLC
<u>\$1827</u>	(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
<u>\$1929</u> ▶ SCHEMA	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) Tissue screening allowed during induction chemotherapy



MASTER TRIAL LIST

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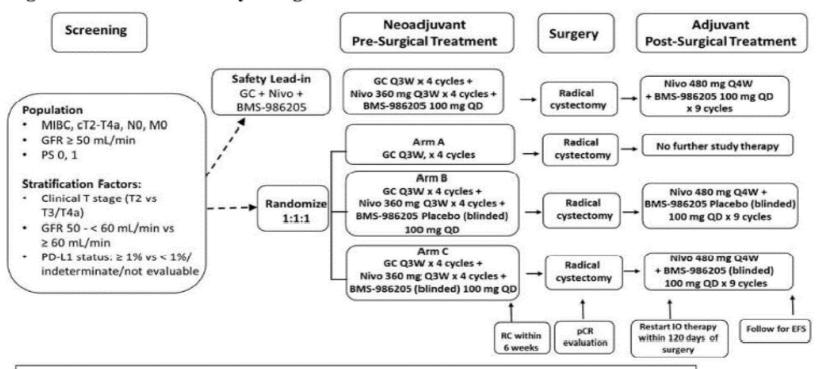
VULVA

Navigator - Angie x3613



Clinical Protocol BMS-986205 CA017078 IDO1 inhibitor

Figure 1-1: Study Design Schematic



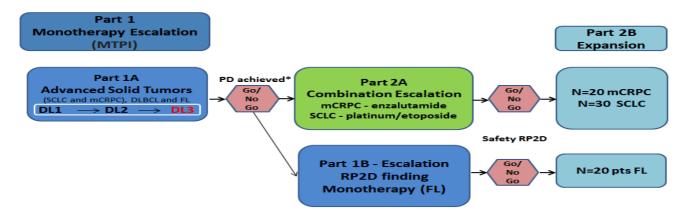
Chemotherapy:

- GFR ≥ 60 mL/min: standard GC (cisplatin 70 mg/m² D1, gemcitabine 1000 mg/m² D1, D8, 21D cycles
- GFR < 60 mL/min: split-dose GC (cisplatin 35 mg/m² D1, D8, gemcitabine 1000 mg/m² D1, D8, 21D cycles

C2321001 SCHEMA

Contact Disease Specific Navigator





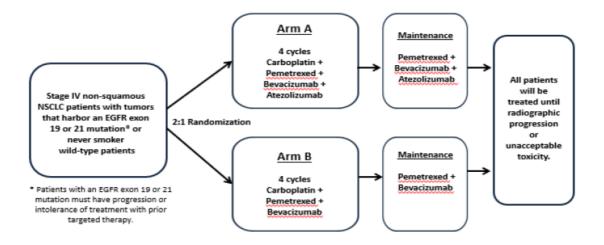
*50-70% down modulation of H3K27me3

TH-138 (NCCN) SCHEMA

Navigator - Ashton x3611

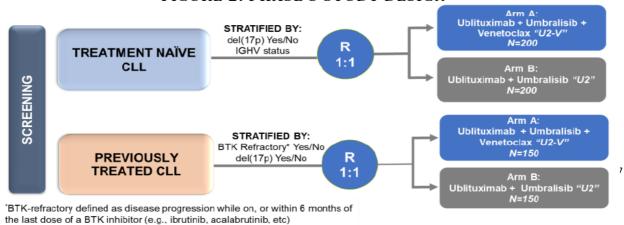


Study Design



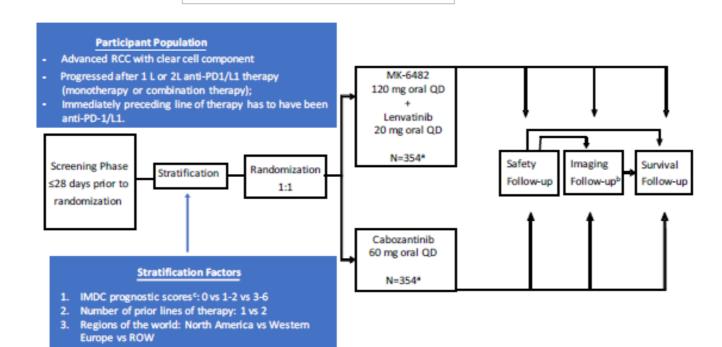
US-VEN-207 (ULTRA-V) Schema Navigator - Heather x3661 MENU

FIGURE 2: PHASE 3 STUDY DESIGN



MK 6482-011 Schema Navigator - Carrie x3621

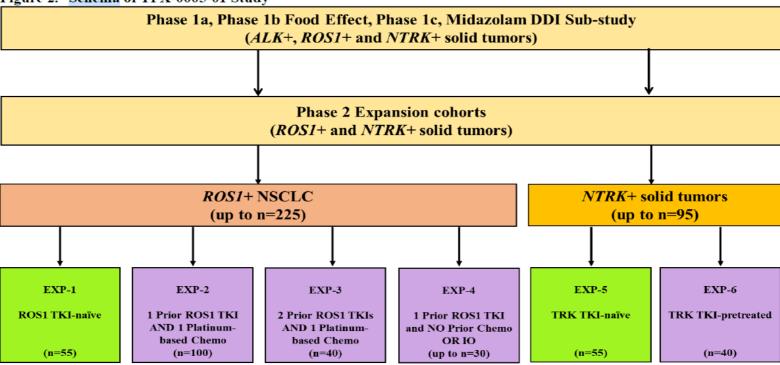


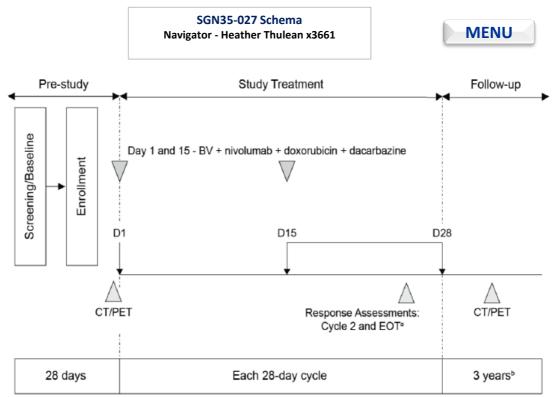


TPX-0005-01 Schema Contact Disease Site Specific Navigator



Figure 2. Schema of TPX-0005-01 Study





- 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).

MENU GO41854 Schema Navigator - Ashton x3611 Open-label treatment 13 x 28-day cycles Unresectable, Stage III NSCLC without progression after definitive platinum-based cCRT ATEZO 1680 mg IV + POST-TREATMENT TIRA 840 mg IV Period Q4W R 1:1 . Known PD-L1 status Follow for:

DURVA 10 mg/kg IV

Q2W

n = 800

(≥2 cycles)

· 18 years or older

· ECOG PS O or 1

· Exclude EGFR/ALK pos

- Stratification factors" . ECOG PS (0 vs 1)
- PD-L1 status (<1% vs >= 1%)
- Staging (IIIA vs IIIB or IIIC)
- · Histology (squamous vs nonsquamous)

1-42 Days Post

cCRT

Safety Run-in

· iDMC review after a minimum of 24 patients (approximately12 per arm) who have completed first 2 full cycles of study treatment

· PFS

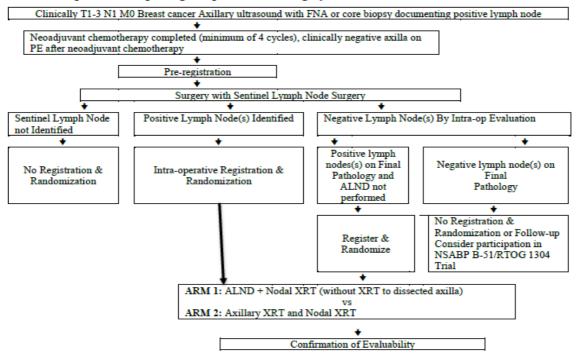
· OS

· Enrollment will not be paused

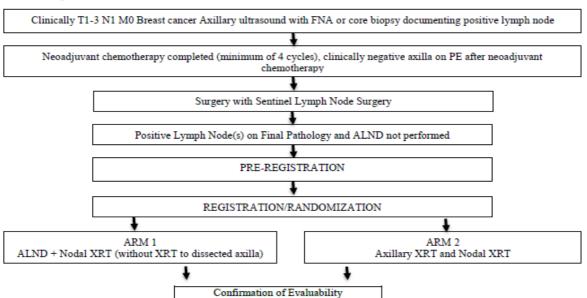
MENU

A011202 SCHEMA Navigator Angie x3613

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

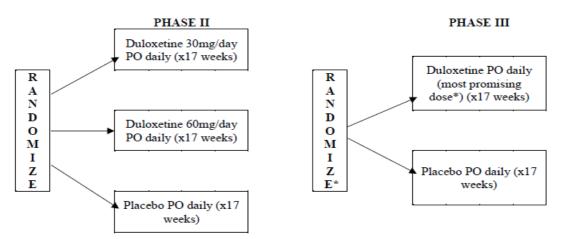


Schema for patients who pre-register AFTER surgery \star (where SLN surgery was performed but ALND was NOT performed):



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

Schema



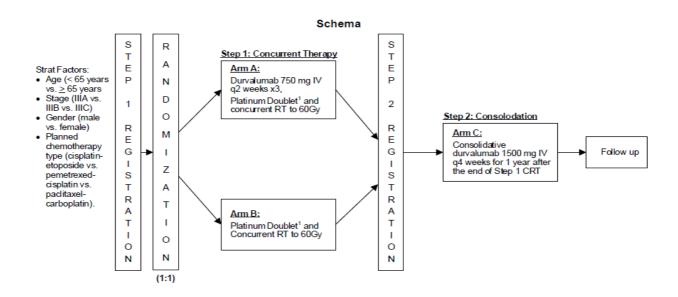
All patients will receive oxaliplatin on both phases of the trial. Further, for all patients the 17th week of study drug will be a tapering period.

* 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.

EA5181 SCHEMA

Navigator - Ashton x3611



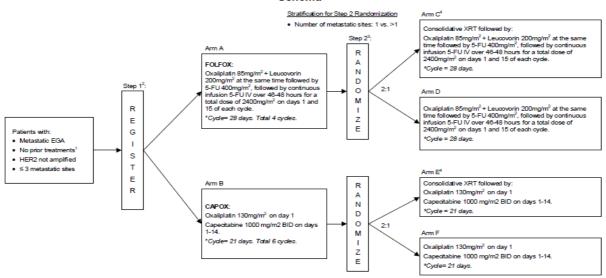


EA2183 SCHEMA

Navigator - Carrie x3621



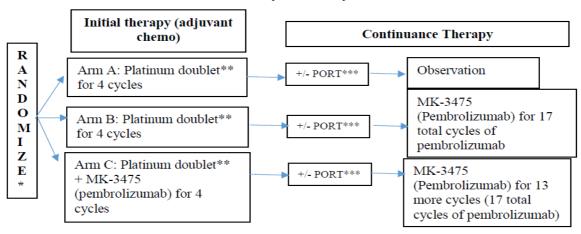
Schema



A081801 SCHEMA Navigator - Ashton x3611

MENU

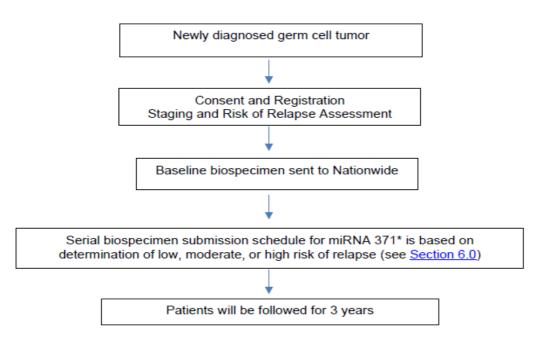
Schema: 1 cycle = 21 days



S1823 SCHEMA Navigator - Carrie x3621



SCHEMA

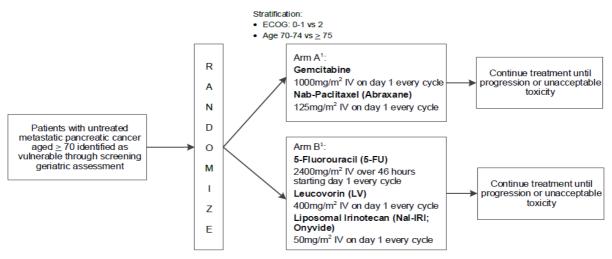


Patients and providers will not have knowledge of the results of the miRNA 371 analysis.

EA2186 SCHEMA Navigator - Carrie x3621

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Schema



NRG CC003 SCHEMA Navigator - Jessica x3615



Histologic proof or unequivocal cytologic proof of SCLC

STEP 1 REGISTRATION

STEP 2 REGISTRATION/RANDOMIZATION

Baseline neurocognitive assessment: HVLT-R, TMT, COWA (required)

Note: Neurocognitive assessments must be uploaded prior to Step 2 Registration and
can be uploaded at the time of Step 1 Registration.

STRATIFICATION

Stage: Limited vs. Extensive Age: < 60 years old vs. ≥ 60 years old Planned Concurrent Memantine Use: Yes vs. No

Arm 1

PCI Alone (25 Gy in 10 Fractions)

Arm 2

PCI with Hippocampal Avoidance using IMRT (25 Gy in 10 Fractions)

S1933 SCHEMA Navigator - Jessica x3615



SCHEMA

REGISTRATION STEP 1

60 Gy hypofractionated radiotherapy in 15 fractions over 3 weeks

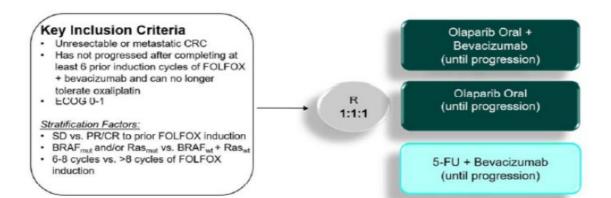
2-5 weeks after completion of radiotherapy: disease assessment

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





NRG BN007 Navigator -Carrie x3621



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 partioning 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

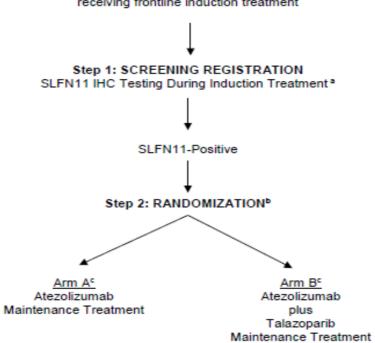
plus Adjuvant ipilimumab and nivolumab

(Optune not allowed)

S1929 Navigator -Ashton x3611

MENU

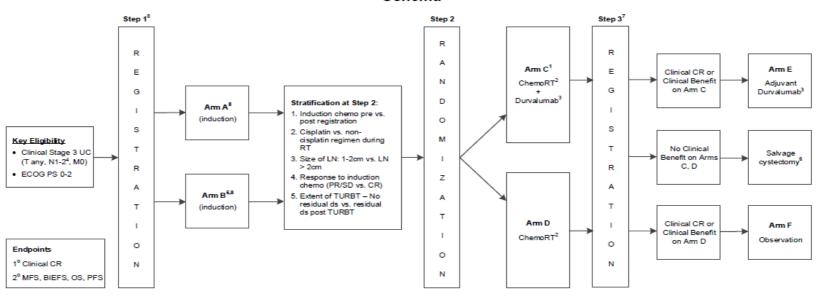
Participants with Extensive Stage SCLC receiving frontline induction treatment

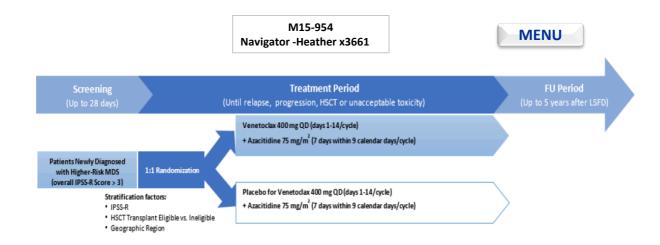


EA8185 Navigator -Carrie x3621



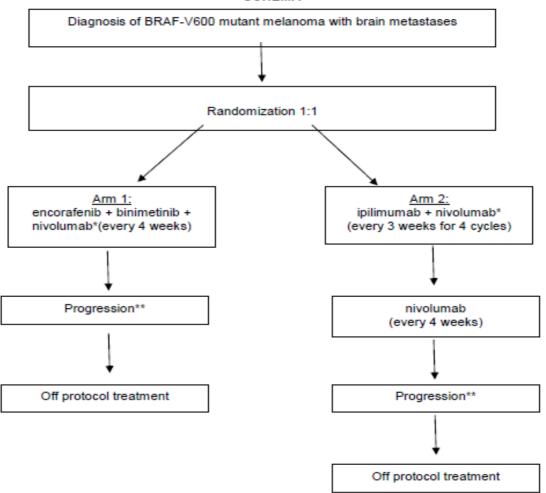
Schema





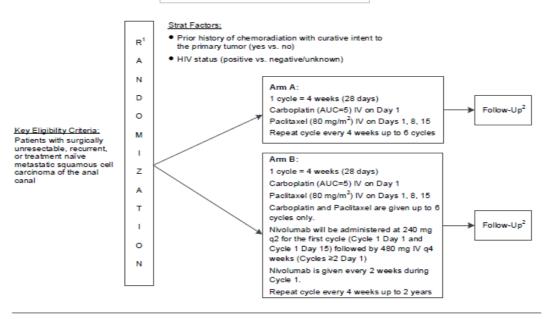
FU = follow up; HSCT = hematopoietic stem cell transplant; IPSS-R = Revised International Prognostic Scoring System; LSFD = last subject first dose; MDS = myelodysplastic syndrome; QD = once daily

SCHEMA



EA2176 Navigator -Carrie x3621





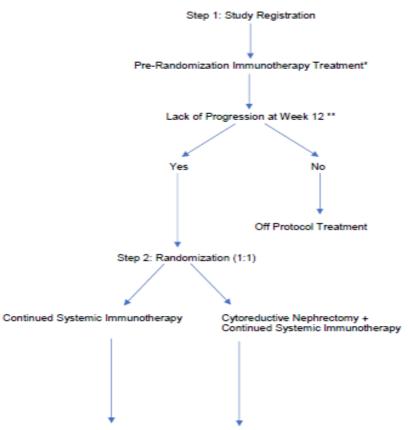
^{1.} Randomization is 1:2 (A:B).

^{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.

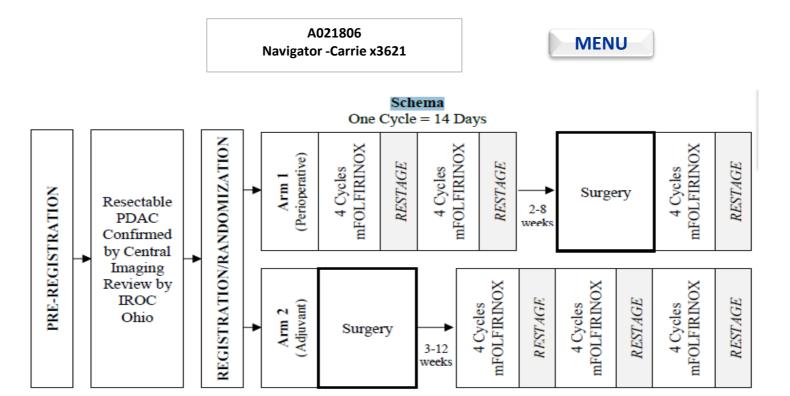
S1931 Navigator -Carrie x3621

MENU

SCHEMA



Follow-Up 7 years from Randomization



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.

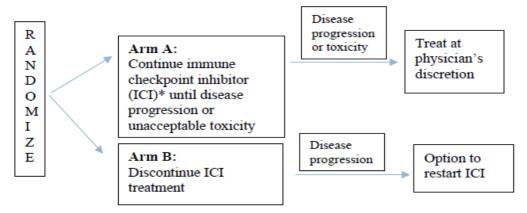
MK-6482-011 **MENU** Navigator - Carrie x3621 **Participant Population** Advanced RCC with clear cell component Progressed after 1 L or 2L anti-PD1/L1 therapy (monotherapy or combination therapy); MK-6482 120 mg oral QD Immediately preceding line of therapy has to have been anti-PD-1/L1. Lenvatinib 20 mg oral QD N=354^a Safety Imaging Survival Screening Phase Randomization Stratification Follow-up Follow-up Follow-up ≤28 days prior to 1:1 randomization Cabozantinib 60 mg oral QD Stratification Factors N=354a 1. IMDC prognostic scorese: 0 vs 1-2 vs 3-6 Number of prior lines of therapy: 1 vs 2 Regions of the world: North America vs Western Europe vs ROW

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.

A031901 Navigator -Carrie x3621

Schema

Cycle definition is based on ICI cycle length



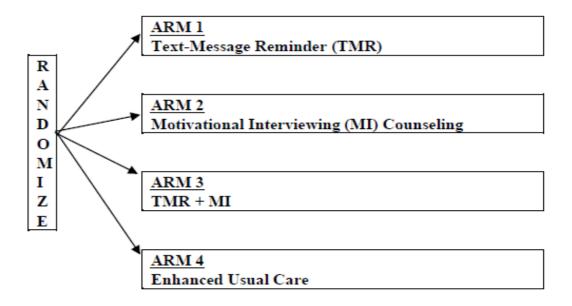
* ICI agents include pembrolizumab, nivolumab, atezolizumab, durvalumab and avelumab

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

A191901 Navigator -Hannah x3603



Schema

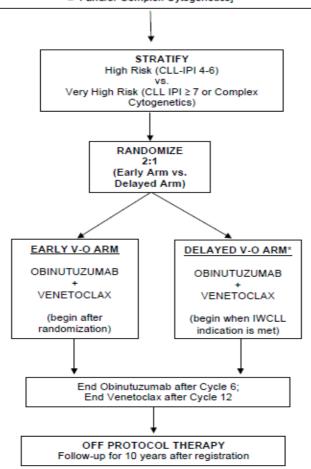


S1925 Navigator -Heather x3661



SCHEMA

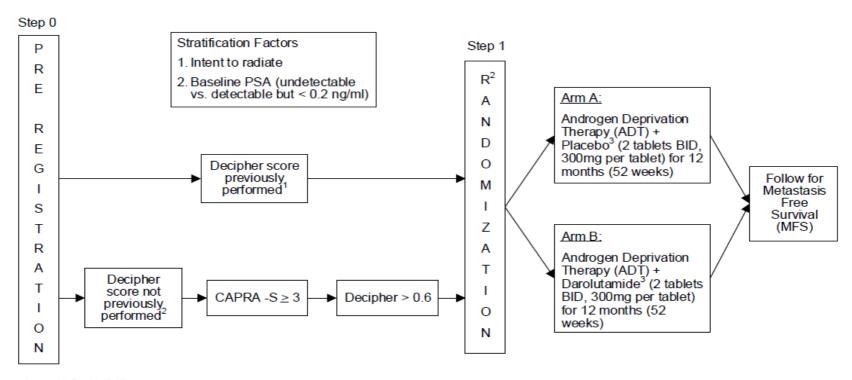
Newly Diagnosed, Early Stage, Asymptomatic, High-Risk Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) [CLL-International Prognostic Index (CLL-IPI) ≥ 4 and/or Complex Cytogenetics]



EA8183 Navigator -Carrie x3621



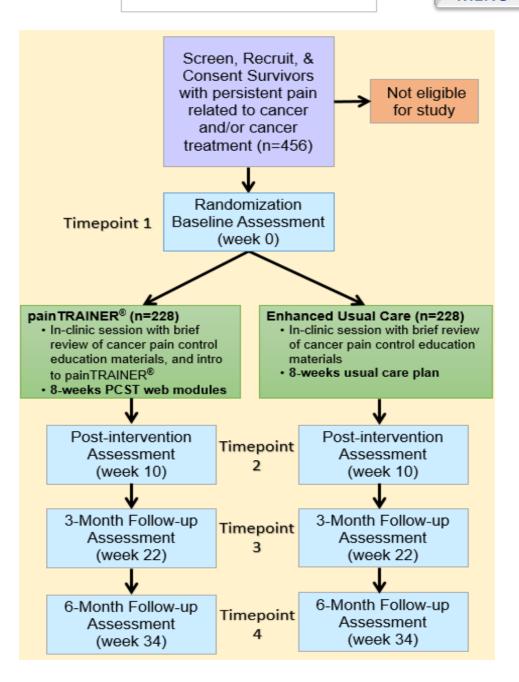
Schema



Accrual Goal: 810

- 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.
- 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.

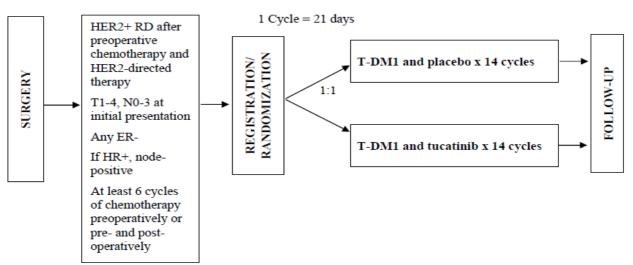
WF-1901 Navigator -Courtney x3660



A011801 Navigator -Angie x3613



Schema



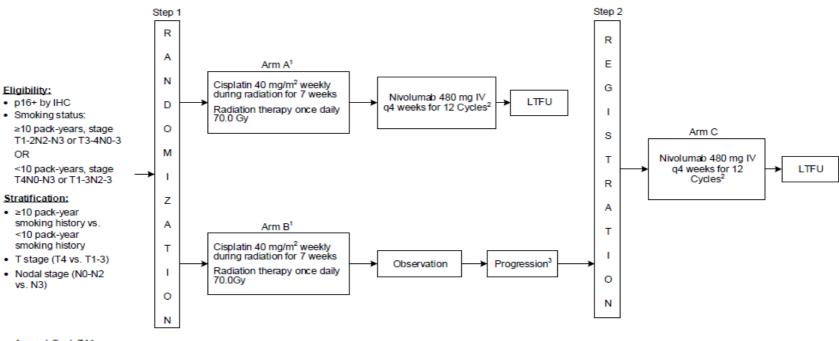
Note: HR stands for "hormone-receptor."

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.

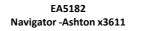
EA3161 Navigator -Ashton x3611

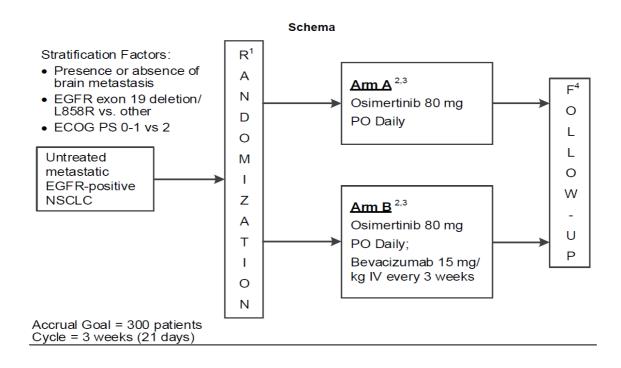


Schema



- 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.

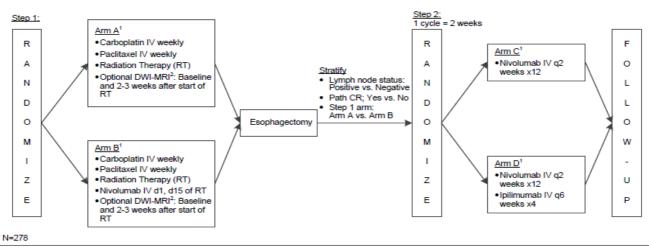




EA2174 Navigator - Carrie x3621



Schema



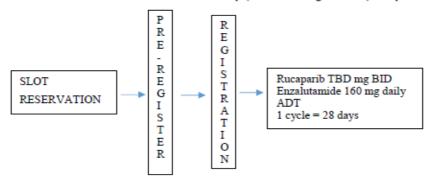
- Please reference Section 5.1 for treatment dosing specifics.
 Optional Diffusion weighted imaging-MRI (DWI-MRI) should be obtained at step 1 baseline and 2-3 weeks after initiation of protocol treatment.

A031902 Navigator -Carrie x3621

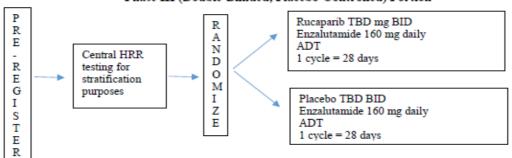
MENU

Schema

PK Substudy (Dose Finding Portion) Only



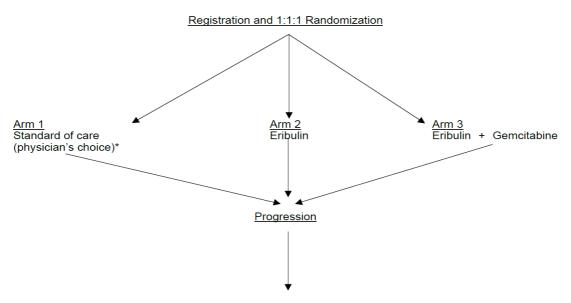
Phase III (Double-Blinded, Placebo-Controlled) Portion



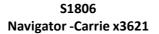
For all patients, treatment is to continue until disease progression or unacceptable adverse event.

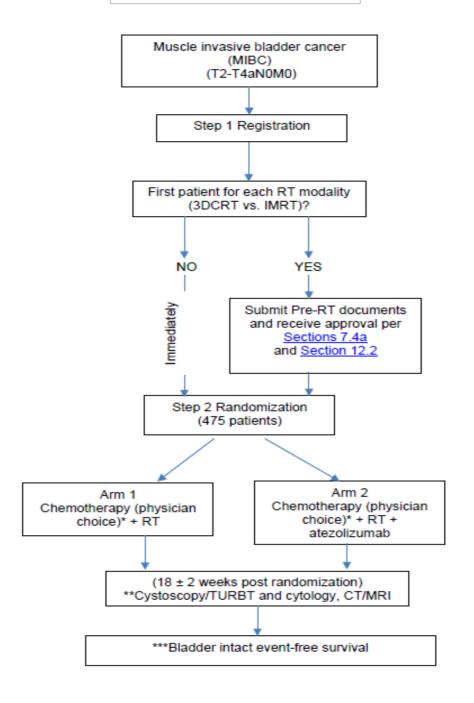
Patients will be followed for 5 years or until death, whichever comes first.

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



Follow-up for three years after registration



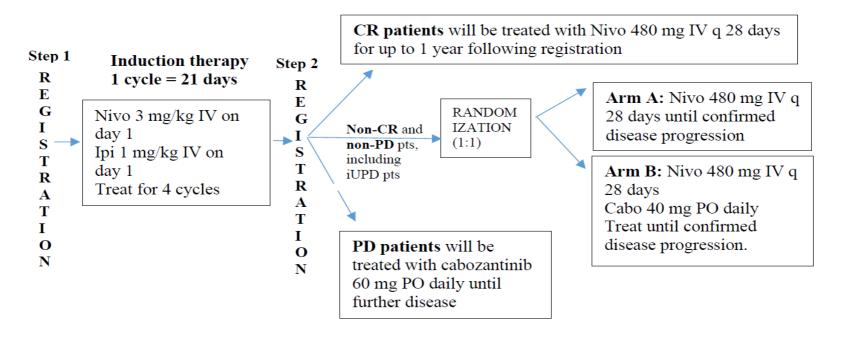


A031704 Navigator -Carrie x3621



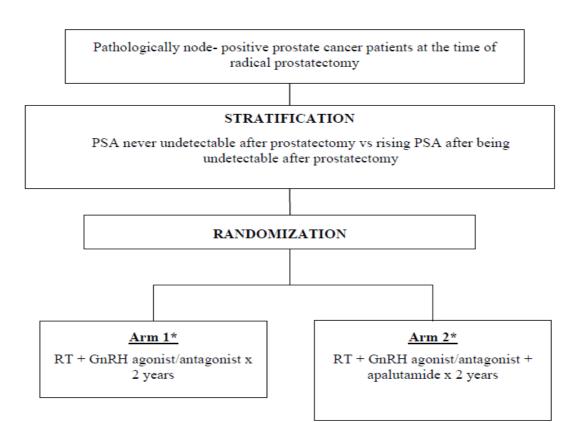
Schema

1 cycle = 28 days



GU008 Navigator -Carrie x3621





NRG-CC009 Navigator -Jessica x3615

MENU

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

GU009 Navigator -Carrie x3621



NRG-GU009 SCHEMA

STEP 1 REGISTRATION

Completion of Step 1 eligibility checklist in OPEN and then submission of tissue for Decipher analysis

Note: Decipher analysis results must be completed before Step 2 randomization can occur. If Decipher results have already been obtained, in lieu of tissue, after completion of Step 1 eligibility checklist in OPEN, the original Decipher report must be submitted to Decipher Biosciences for validation (see Decipher Analysis information at the end of section 3.0).

STEP 2 RANDOMIZATION STEP 2 RANDOMIZATION Decipher > 0.85 or Node Positive Decipher ≤ 0.85 INTENSIFICATION STUDY *** DE-INTENSIFICATION STUDY STRATIFY STRATIFY Decipher Score (Low/Int v High*) Boost type (EBRT vs. Brachy) Boost type (EBRT vs. Brachy) Pelvic Treatment (Yes/No) Pelvic Treatment (Yes/No) Nodal Status (Positive/Negative) ACE-27 Comorbidity (0/1 vs 2/3) RANDOMIZE** RANDOMIZE** Arm 1 Arm 2 Arm 3 Arm 4 RT RT RT RT 24 mos ADT 12 mos ADT 24 mos ADT 24 mos ADT +24 mos Apalutamide +24 mos Abiraterone Acetate with Prednisone

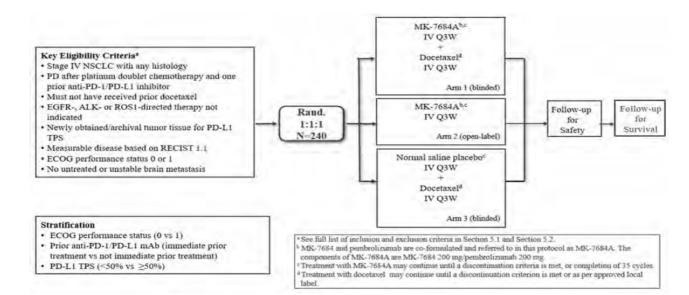
^{*} Low/Intermediate = Decipher < 0.6 and High = Decipher 0.6-0.85

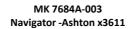
^{**}Randomization is 1:1

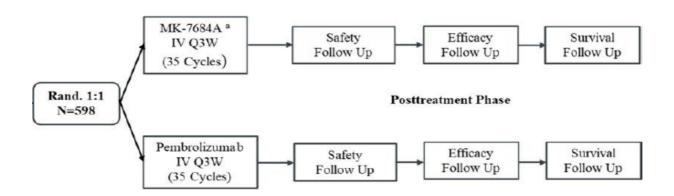
^{***} Up to 200 patients who consent to imaging sub study will receive F-18 PET. See Section 4.0 and 11.3 for more details and time points.

MK 7684A-002 Navigator -Ashton x3611



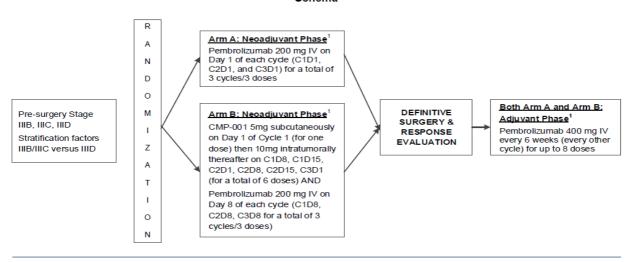








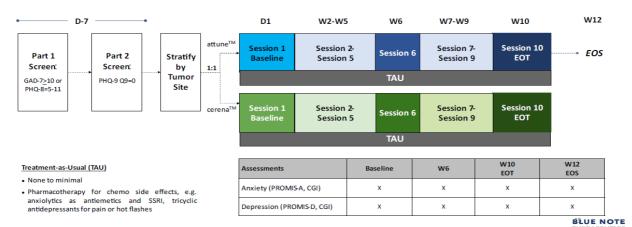
Schema



^{1.} Neoadjuvant and Adjuvant cycle length: 1 cycle = 21 days

PROT001/BLUE NOTE Navigator -TBD



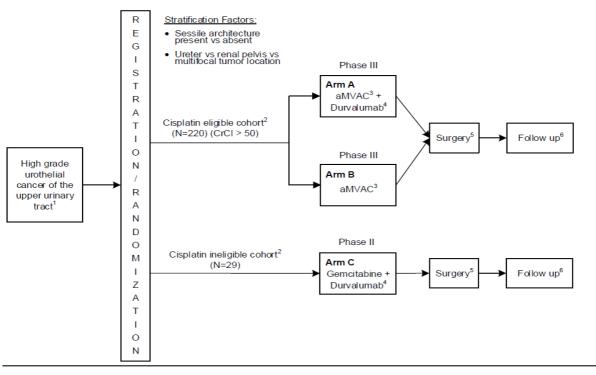


Confidential

EA8192 Navigator -Carrie Geoffroy x3621

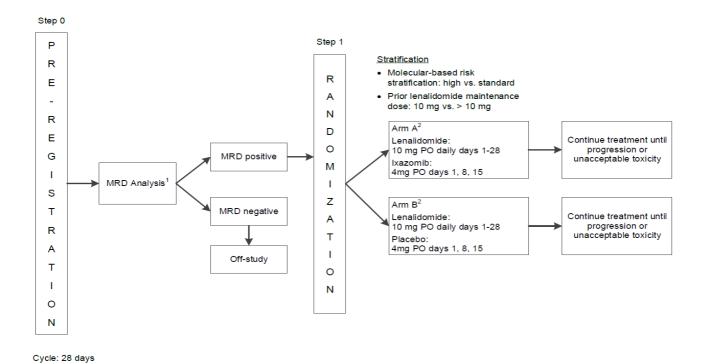
MENU

Schema



EAA171 Navigator -Heather Thulean x3661





BR007 Navigator -Angie Earles x3613



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 <u>not</u> 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

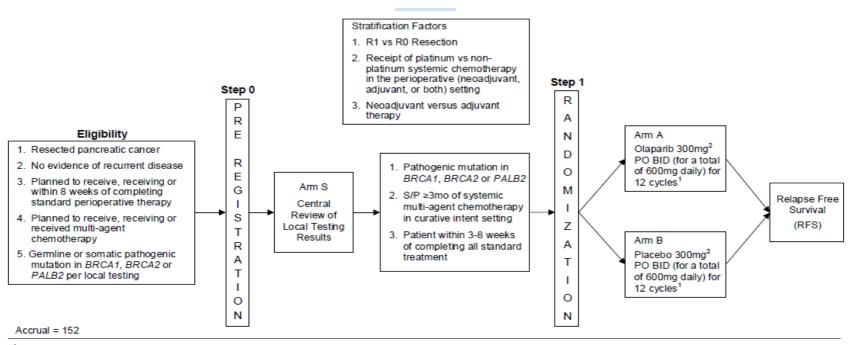
Endocrine Therapy

<u>Arm 2**</u>

No Breast Radiation Therapy

Endocrine Therapy

EA2192 Navigator -Carrie Geoffroy x3621



¹ One cycle = 4 weeks

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

BR004 Navigator -Angie Earles x3613



Figure 1. NRG-BR004 SCHEMA

HER2-Positive Metastatic Breast Cancer

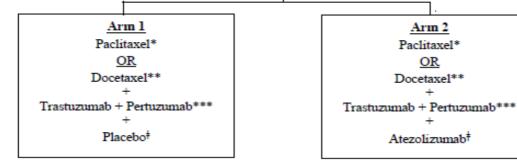
Step 1 Study Entry and Initiation of Therapy:

- Send tumor for central confirmation of HER2 and central testing of ER/PgR and PD-L1
- Initiate Cycle 1 loading doses of commercial trastuzumab and pertuzumab combined with either docetaxel or paclitaxel per investigator choice while waiting for central testing results

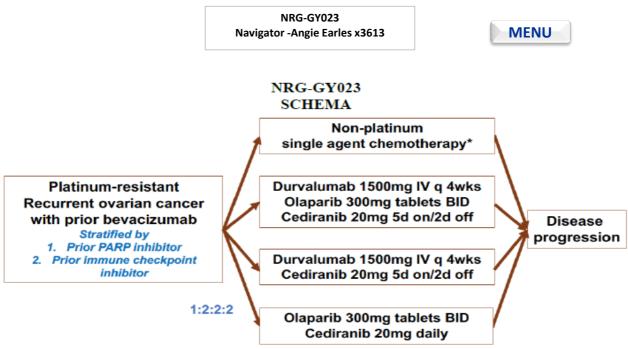
STRATIFICATION

- · Prior neoadjuvant or adjuvant therapy with trastuzumab (no; yes)
- · Estrogen receptor status (positive; negative)
- PD-L1 status (positive; negative or indeterminant)
- Disease sites (visceral without brain metastasis; non-visceral only without brain metastasis; brain metastasis)
- Choice of taxane (paclitaxel; docetaxel)

Step 2: RANDOMIZATION following central confirmation of HER2-positive status with initiation of atezolizumab/placebo on Day 22 of Cycle 1#



- # 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.



*Weekly paclitaxel, PLD or topotecan

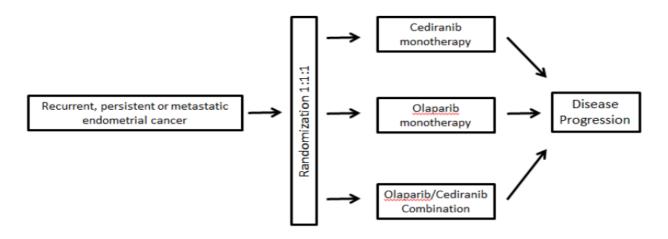
Randomization is 1:2:2:2

^{*}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.

NRG-GY012 Navigator -Angie Earles x3613

MENU

SCHEMA

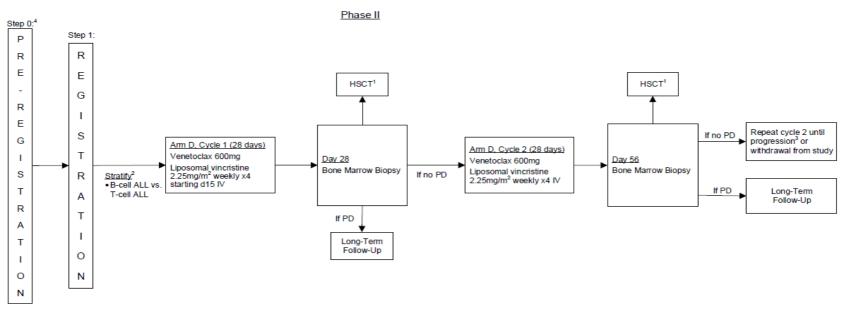


Schema changes as of Amendment 3 (24-MAY-2021):

EA9152 Navigator - Heather Thulean x3661



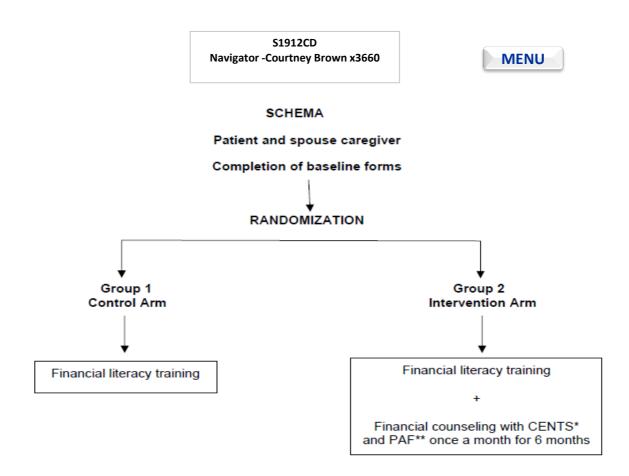
Schema



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

- 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). Patients will be stratified by immunophenotype: "B-cell ALL" vs. "T-cell ALL".
- 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.

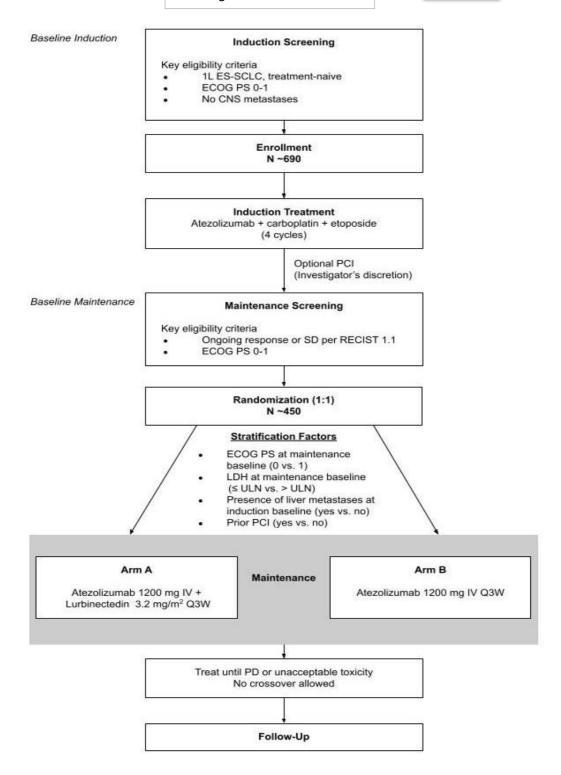


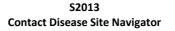
In order to participate, CCD Research sites must complete the **<u>\$1912CD</u>** Site Implementation Survey and upload the completion certificate to the CTSU Regulatory Portal as described in <u>Section 13.4</u>.

^{*} Consumer Education and Training Services (CENTS)

^{**} Patient Advocate Foundation (PAF)

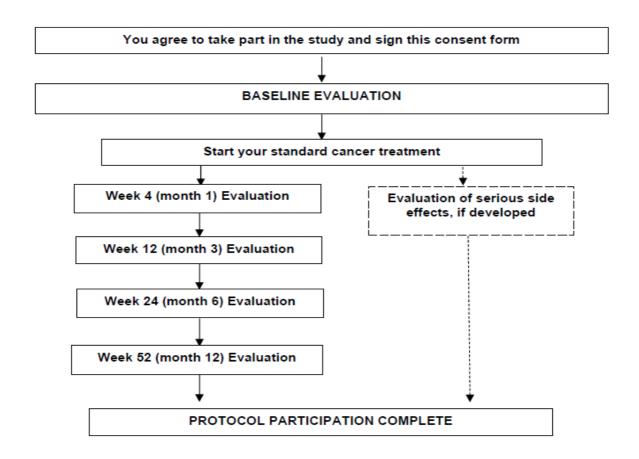
GO43104 Navigator -Ashton Todd 3611





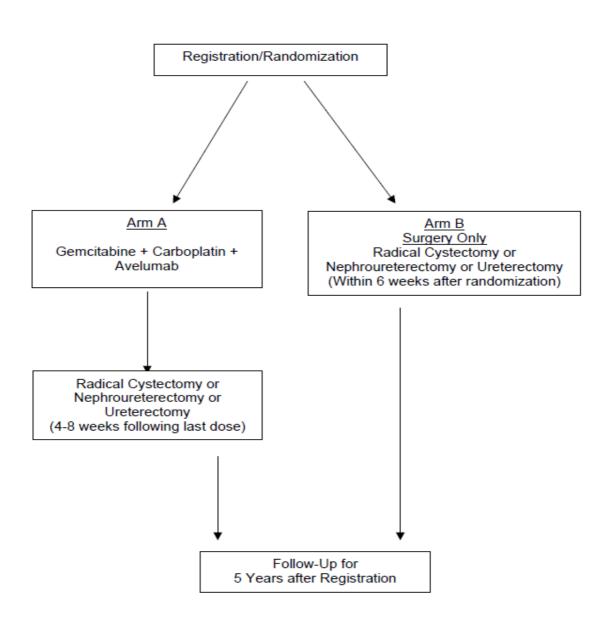


SCHEMA

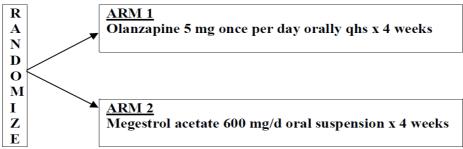


S2011 Navigator -Carrie Geoffroy x3621







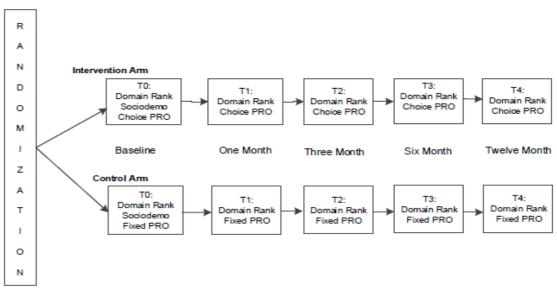


Treatment will continue for up to 4 weeks, unless the patient declines therapy or has unacceptable adverse events.

EAQ202 Navigator -Courtney Brown x3660



Schema



Eligibility: -Age 18 to 39 -Within 12 weeks of diagnosis -Performance Status 0-3 -Any stage of cancer -Favorable prognosis

Randomization: Stratified by sex, race, ethnicity, and age (emerging adults 18-25-year-old vs young adults 26-39year-old)

Domain Rank: Participant Ranks Domain by personal priority at each time point Fixed PRO:

PROMIS Global, PROMIS standard AYA 5 domains, Common Items

Choice PRO:

PROMIS Global, 5 ranked AYA domains, Common Items

Accrual Goal = 400

GU010 Navigator -Jessica Jones x3615



SCHEMA

STEP 1 REGISTRATION

Completion of Step 1 eligibility checklist in OPEN and then submission of tissue for Decipher analysis

Note: Decipher analysis results must be completed before Step 2 randomization can occur. If Decipher results have already been obtained, in lieu of tissue, after completion of Step 1 eligibility checklist in OPEN, the original Decipher report must be submitted to Decipher Biosciences for validation (see Decipher Analysis information at the end of section 3.3).

STEP 2 RANDOMIZATION STEP 2 RANDOMIZATION Decipher < 0.40 Decipher ≥ 0.40 DE-INTENSIFICATION STUDY INTENSIFICATION STUDY STRATIFY STRATIFY • Escalated RT boost* (None vs. Decipher Score (0.40-0.60 vs. > 0.60) Brachytherapy vs. Simultaneous • Escalated RT boost* (None vs. integrated micro-boost) Brachytherapy vs. Simultaneous integrated micro-boost) ACE-27 Comorbidity (0/1 vs 2/3) • ACE-27 Comorbidity (0/1 vs 2/3) RANDOMIZE** RANDOMIZE** Arm 1 Arm 2 Arm 3 Arm 4 RT RT alone RT RT 6 mos ADT 6 mos ADT 6 mos ADT +6 mos Darolutamide

 $RT = radiation \ therapy; \ SBRT = stereotactic \ body \ radiotherapy; \ ADT = and rogen \ deprivation \ therapy$

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

^{**}Randomization is 1:1