

## FY'09-'16 APPROVED BIQSFP STUDIES

(10/31/16)

Type of Study	Integral/ Integrated	NCTN/NCORP Protocol ID	Phase	Protocol Title
Biomarker	Integral	Alliance A011106 (ACOSOG Z11103)	II-III	Alternate Approaches for Clinical Stage II & III Estrogen Receptor+ Breast Cancer Neoadjuvant Treatment (ALternate) Study
Biomarker	Integrated	Alliance A011401	III	Randomized Phase III Trial Evaluating the Role of Weight Loss In Adjuvant Treatment of Overweight and Obese Women with Early Breast Cancer
Imaging	Integral	Alliance A021302	II	Impact of Early FDG-PET Directed Intervention on Preoperative Therapy for Locally Advanced Gastric Cancer: A Random Assignment Phase II Study
Imaging	Integrated	Alliance A031201	III	Phase III Trial of MDV3100 vs. MDV3100 and Abiraterone and Prednisone for Castration Resistant Metastatic Prostate Cancer
Biomarker	Integral	Alliance A041501	III	A Phase III Trial to Evaluate the Efficacy of the Addition of Inotuzumab Ozogamicin to Frontline Therapy in Young Adults (Ages 16-39 years) with Newly Diagnosed Precursor B-Cell ALL
Biomarker	Integral	Alliance A051301	III	A Randomized Phase III Study of Ibrutinib During and Following Autologous Stem Cell Transplantation versus Placebo in Patients with Relapsed or Refractory Diffuse Large-Cell Lymphoma of the Activated-B-Cell Subtype
Biomarker	Integral	Alliance A071102	II-III	Randomized Trial of ABT-888 or Placebo in Combination with Adjuvant Temozolomide in Newly Diagnosed GBM with MGMT Promoter Hypermethylation
Biomarker	Integral	Alliance A151216	II-III	Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST)
Biomarker	Integral & Integrated	Alliance CALGB 30801	III	A Randomized Phase III Double Blind Trial Evaluating Selective COX-2 Inhibition in COX-2 Expressing Advanced Non-Small Cell Lung Cancer
Biomarker + Imaging	Integral	Alliance CALGB 80803	II	A Randomized, Phase 2 Trial of PET Scan-Directed Combined Modality Therapy in Esophageal Cancer
Biomarker	Integral	Alliance NCCTG N0577	III	Phase III Intergroup Study of Radiotherapy versus Temozolomide Alone versus Radiotherapy with Concomitant and Adjuvant Temozolomide for Patients with 1p/19q Codeleted Anaplastic Glioma

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Biomarker	Integrated	CABOZANTINIB STUDIES <b>GOG0186 + E1512 + A091201 + A031203</b>	II	Measurement of MET/IHC Across Patients with Ovarian, RCC, NSCLC, and Ocular Melanoma Cancers
Biomarker	Integral	COG AALL08B1/ AALL1131		Treatment of Newly Diagnosed High-Risk B-precursor Acute Lymphoblastic Leukemia (MRD Bridge Funding)
QOL	Integrated	COG AALL0932	QOL	Longitudinal assessment of vincristine-associated peripheral neuropathy
QOL-Imaging	Integrated	COG AALL1131	QOL	Incidence & Natural History of Osteonecrosis (ON) (PARENT STUDY: Treatment of Newly Diagnosed High-Risk B-precursor Acute Lymphoblastic Leukemia)
Biomarker	Integral	COG AALL1231	III	A Phase 3 Randomized Trial Investigating Bortezomib (PS-341, Velcade) on a Modified Augmented BFM (ABFM) Backbone in Newly Diagnosed T-cell Acute Lymphoblastic Leukemia (T-ALL) and T-cell Lymphoblastic Lymphoma (T-LL)
Biomarker	Integral & Integrated	COG AALL1331	III	Risk-Stratified Randomized Phase III Testing of Blinatumomab (IND# 100135, NSC# 765986) in First Relapse of Childhood B-Lymphoblastic Leukemia (B-ALL)
Biomarker	Integral	COG AALL1631	III	International Phase III Trial in Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia (Ph+ ALL) Testing Imatinib in Combination with Two Different Cytotoxic Chemotherapy Backbones
Biomarker	Integral & Integrated	COG AAML0531	III	A Phase III Randomized Trial of Gemtuzumab Ozogamicin Mylotarg® Combined with Conventional Chemotherapy for De Novo Acute Myeloid Leukemia (AML) in Children, Adolescents, and Young Adults
Biomarker	Integral & Integrated	COG AAML1031	III	A Phase III Randomized Trial for Patients with de novo AML Using Bortezomib and Lestaurtinib for Patients with FLT3 ITD
Biomarker	Integral	COG AAML1531	III	Risk-Stratified Therapy for Acute Myeloid Leukemia in Down Syndrome

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QOL-Biomarker	Integrated	COG ACCL0933	QOL	Prospective Evaluation of Galactomannan and (1→3)-β-D-glucan Assays as Diagnostic Tools for Invasive Fungal Infection in Children with Acute Myeloid Leukemia Receiving Fungal Prophylaxis
QOL-Biomarker	Integrated	COG ACCL0934	QOL	Prospective Surveillance of Resistance in Colonizing Bacteria from Stool or Perirectal Swab Cultures and in Bacterial Isolates from Sterile Site Cultures in Pediatric Patients Receiving Levofloxacin for Acute Leukemia
Biomarker	Integral	COG ACNS1422	II	A Phase II Study of Reduced Therapy for Newly Diagnosed Average-Risk WNT-Driven Medulloblastoma Patients
Imaging	Integral	COG AHOD1331	III	A Randomized Phase III Study of Brentuximab vedotin (Bv, IND #117117) for Newly Diagnosed High Risk Classical Hodgkin Lymphoma (cHL) in Children and Adolescents
Biomarker	Integral	COG ANBL1232	III	Utilizing Response-and Biology-Based Factors to Guide Therapy in Patients with Non-High-Risk Neuroblastoma
Biomarker	Integral	COG ANBL1531	III	A Phase III Study of 131IMetaiodobenzylguanidine (131I-MIBG) or Crizotinib Added to Standard Therapy for Children with Newly Diagnosed High-Risk Neuroblastoma (NBL)
Biomarker	Integrated	COG ARST13431	III	A Randomized Phase III Study of Vincristine, Dactinomycin, Cyclophosphamide (VAC) Alternating with Vincristine and Irinotecan (VI) Versus VAC/VI Plus Temozolomide (TEM) in Patients with Intermediate Risk (IR) Rhabdomyosarcoma (RMS)
Biomarker	Integral	COG ASCT1221	II	Randomized Phase II Study Comparing Two Different Conditioning Regimens Prior to Allogeneic Hematopoietic Cell Transplantation (HCT) for Children with Juvenile Myelomonocytic Leukemia (JMML)
Biomarker	Integral & Integrated	ECOG E1910	III	A Phase III Randomized Trial of Blinatumomab for Newly Diagnosed bcr-abl Negative B Acute Lymphoblastic Leukemia in Adults
Biomarker	Integral	ECOG-ACRIN EA1131	III	A Randomized Phase III Post-Operative Trial of Platinum Based Chemotherapy Vs. Observation in Patients with Residual Triple-Negative Breast Cancer Following Neoadjuvant Chemotherapy
Biomarker	Integrated	ECOG-ACRIN EA1412	II	Randomized Phase II Open Label Study of RCHOP with and without Lenalidomide in Newly Diagnosed Diffuse Large B Cell Lymphoma (DLBCL)

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Biomarker	Integral	ECOG-ACRIN EA2132	II	Randomized Phase I/II Study Of mFOLFOX6 +/- AMG 337 in the First Line Treatment of Patients with Her2Neu Negative and High c-Met Expressing Advanced Esophagogastric and Gastroesophageal Junction (GEJ) Adenocarcinoma
Biomarker	Integral	ECOG-ACRIN EA3132	II	Phase II Randomized Trial of Adjuvant Radiotherapy with or Without Cisplatin for p53 Mutated, Surgically Resected Squamous Cell Carcinoma of the Head and Neck (SCCHN)
Biomarker	Integral & Integrated	ECOG-ACRIN EA4151	III	A Randomized Phase III Trial of Consolidation with Autologous Hematopoietic Cell Transplantation Followed by Maintenance Rituximab vs. Maintenance Rituximab Alone for Patients with Mantle Cell Lymphoma In Minimal Residual Disease-Negative First Complete Remission
QOL	Integrated	GOG UC0604 (GOG 0249)	III	A Phase III Trial of Pelvic Radiation Therapy vs. Vaginal Cuff Brachytherapy Followed by Paclitaxel/Carboplatin Chemotherapy in Patients with High Risk Early Stage Endometrial Carcinoma
Biomarker	Integral	NRG NRG-BN001 (RTOG 1326)	II	Randomized Phase II Trial of Hypofractionated Dose-Escalated Particle Beam Therapy Versus Conventional Photon Irradiation with Concomitant and Adjuvant Temozolomide in Patients with Newly Diagnosed GBM
CEA	Integrated	NRG NRG-CC003	II-III	Randomized Phase II/III Trial of Prophylactic Cranial Irradiation with or without Hippocampal Avoidance (HA) for Small Cell Lung Cancer (SCLC)
Biomarker	Integral	NRG NRG-HN001 (RTOG 1305)	II-III	Randomized Phase II and Phase III Studies of Individualized Treatment for Nasopharyngeal Carcinoma Based on Biomarker Epstein Barr Virus (EBV) Deoxyribonucleic Acid (DNA)
Imaging	Integrated	NRG NRG-HN002 (RTOG 1221)	II	A Randomized Phase II Trial of Reduced-Dose IMRT with Weekly Cisplatin versus Mildly Accelerated Reduced-Dose IMRT Alone for p16 Positive, Non-Smoking Associated Oropharyngeal Cancer
QOL	Integrated	NRG NSABP-MA32.F	III	Biobehavioral Mechanisms of Fatigue in Patients Treated on MA 32: A Phase III Randomized Trial of the Effect of Metformin versus Placebo on Recurrence and Survival in Early Stage Breast Cancer (A Phase III Clinical Trial Comparing Adjuvant Sunitinib Malate to Placebo in Women with Residual Invasive Breast Cancer Following Neoadjuvant Chemotherapy)

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Imaging	Integrated	NRG RTOG 0825/ ACRIN 6686	III	Phase III Double-Blind Placebo-Controlled Trial of Conventional Concurrent Chemoradiation and Adjuvant Temozolomide Plus Bevacizumab Versus Conventional Concurrent Chemoradiation and Adjuvant Temozolomide in Patients with Newly Diagnosed Glioblastoma
Biomarker	Integral	NRG RTOG 1010	III	A Phase III Trial Evaluating the Addition of Trastuzumab to Trimodality Treatment of HER2 Overexpressing Esophageal Adenocarcinoma
Biomarker	Integral	NRG RTOG 1016	II-III	Phase II-III Trial of Moderate De-Escalation of Chemotherapy and Radiation in Favorable Risk, Locally Advanced, HPV-Associated Oropharynx Cancer
Biomarker	Integral	NRG RTOG 1201	II	A SMAD4-driven Phase II Randomized Trial of High Versus Standard Intensity Local or Systemic Therapy for Unresectable Pancreatic Cancer
Biomarker	Integral	NRG RTOG 1216	II-III	Randomized Phase II/III Trial of Surgery and Postoperative Radiation Delivered with Concurrent Cisplatin Versus Docetaxel Versus Cetuximab and Docetaxel for High-Risk Squamous Cell Cancer of the Head and Neck
Biomarker	Integral & Integrated	SWOG S0819	III	A Randomized , Phase 3 Study Comparing Carboplatin/ Paclitaxel/ Bevacizumab with or without Concurrent Cetuximab in Patients with Advanced Non-Small Cell Lung Cancer (NSCLC)
Biomarker	Integral	SWOG S1007	III	A Phase III, Randomized Clinical Trial of Standard Adjuvant Endocrine Therapy +/- Chemotherapy in Patients with 1-3 Positive Nodes, Hormone-responsive and HER2-negative Breast Cancer According to Recurrence Score (RS)
Biomarker	Integral	SWOG S1201	II	A Randomized Phase II Pilot Study Prospectively Assigning Treatment for Patients Based on ERCC1 for Advanced/Metastatic Gastric Cancer or Gastroesophageal (GE) Junction Cancer
Biomarker	Integrated	SWOG S1300	II	A Randomized, Phase II Trial of Crizotinib Plus Pemetrexed Versus Pemetrexed Monotherapy in ALK-Positive Non-Squamous NSCLC Patients who have Progressed Systemically after Previous Clinical Benefit from Crizotinib Monotherapy

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Biomarker	Integral & Integrated	SWOG S1314	II	A Randomized Phase II Study of CO-eXpression Extrapolation (COXEN)-Directed Neoadjuvant Chemotherapy for Localized, Muscle-Invasive Bladder Cancer
Biomarker	Integral & Integrated	SWOG S1416	II	Randomized Phase II Trial of Cisplatin +/- Veliparib in Metastatic TNBC and gBRCAm
Biomarker	Integrated	SWOG S1500	II	A Biomarker Analysis of MET Alterations and Papillary Subtype in S1500: A Randomized, Phase II trial of MET Inhibitors in Metastatic Papillary Kidney Cancer
Biomarker	Integrated	SWOG S1513	II	Randomized Phase II Study of 2nd Line Therapy with FOLFIRI with or without PARP Inhibitor Veliparib (ABT-888) in Metastatic Pancreatic Cancer
Biomarker	Integrated	SWOG S1602	III	A Randomized Trial to Evaluate (1) the Influence of BCG Strain Differences, and (2) T-cell Priming with Intradermal BCG Before Intravesical Therapy—for BCG-Naïve High-Grade Non-Muscle Invasive Bladder Cancer
Imaging	Integral	SWOG S1608	II	Randomized Phase II Trial in High-Risk Relapsed Refractory Follicular Lymphoma
Biomarker	Integral	SWOG S1612	II	A Randomized Phase II Study of CO-eXpression Extrapolation (COXEN)-Directed Neoadjuvant Chemotherapy for Localized, Muscle-Invasive Bladder Cancer
Biomarker	Integral	SWOG S1613	II	Randomized Phase II study of Pertuzumab and Trastuzumab compared to Cetuximab and Irinotecan in Advanced/ Metastatic Colorectal Cancer (mCRC) with HER2 Amplification