

BIOREPOSITORY		
GU and Gyn	ROSSER-2014-1	Known GU and Gyn disorders. Urine Repository for BioMarker Research (URBR)
BRAIN		
Meningioma	NRG-BN003	Ph III; Newly diagnosed unifocal intracranial meningioma, gross totally resected (GTR); Grade II; GTR confirmed by modified Simpson grade and post MRI; Step 1 reg within 180 days of surgery; tissue submission required for path review and Step 2; Neurocognitive testing required. Tx: Observation vs RT (IMRT or Protons) 59.4Gy
GBM	ALLIANCE-A071102 on 5/18/2018	Closes Ph III; New Dx Grade IV intracranial GBM /gliosarcoma; Tissue for MGMT promoter hypermethylation testing; Completed RT & concomitant TMZ; Novo TTF-100a (Optune) device allowed. Tx: Veliparib/Placebo + Temozolomide
BREAST - POST Neoadjuvant		
N(+) Prior to NeoAdj	NSABP-B-51	Ph III; cT1-3N1 by FNA/Core Bx prior to 12 wks of NeoAdj tx; Tumor submission req; must have recvd 8 wks of neoadj.; N(-) post op. If (N+) see A011202 Tx: No regional RT vs regional nodal RT <= 12 wks of surgery or post op chemo.
N(+) Prior to & After Neoadj	ALLIANCE-A011202	PH III; cT1-3 N1 prior to <= 4 cycles of NeoAdj; Surgery <= 56 days of last dose of neoadj; >= 1(+) LN post op. Tx: ALND(+) nodal RT w/o RT to axilla vs Axillary RT & nodal RT
TNBC After NeoAdj	ECOG-ACRIN-EA1131	PIII; M/F; cStage II/III; completed neoadj taxane +/- anthracycline & residual Dz @ surgery; Tissue submitted for PAM50 analysis. Tx: Cisplatin or Carboplatin vs Capecitabine
BRCA1/2(+) & HR HER2(-)	NSABP-B-55	Ph III; M/F; >= 6 cycles NeoAdj/Adj Tx; Post NeoAdj: If TNBC: non-path CR, If ER &/or PR(+)/ HER2(-): non-pathCR, CPS & EG score >= 3. Post Adj: If TNBC: N(+) & any tumor size or N(-) & tumor >2cm, If ER &/or PR+/HER(-): >= N4(+); Tx: Olaparib vs Placebo
Stage II and IIIA Prior to NeoAdj	NRG-BR005	Ph II; M/F; operable focal or multifocal T1-T3, stage II and IIIA invasive ductal ca; CR by PE and radiologic CR by trimodality imaging (paid by insurance and done prior to enrollment- mammogram,US & MRI) after neoadjuvant tx (min 8 wks of anthracycline and/or taxane regimen); ER/PR and HER2 on primary tumor prior to neoadjuvant;bx marker placed prior to neoadj;no synchronous ipsilateral invasive breast ca or prior hx of; no invasive lobular ca or multicentric disease Tx: Image-Guided Core bx (utilizing a vacuum-assisted bx device) followed by Surgery (Lumpectomy)
BREAST - ADJUVANT		
TNBC, N(+) or Hi Risk Node (neg)	NRG-BR003	PhIII; M/F; pT1-3; if pN0 tumor must be >=3.0cm, pN1-N3; Neg. margins, Rand <= 60 days of last surgery. Tx: AC --> WP +/- Carboplatin
High Risk, ER/PR(+)/HER2(neg)	SWOG-S1207	PhIII; Adjuvant; High Risk, Hormone Receptor(+) & HER2(-); Adjuvant endocrine Tx planned; Inflammatory allowed; must be high-risk (See protocol for definitions) Tx: Everolimus/Placebo + endocrine therapy.
Breast N(+), HER2(-). Aspirin Breast Cancer (ABC) Trial	ALLIANCE-A011502 HIGH PRIORITY	Ph III; M/F; <70 yo; any ER/PR; Stage II/III; <= 1 yr of diagnosis; <= 60 days from prior chemo or RT; no contraindications to aspirin. Tx: Aspirin/Placebo x 5 years
Breast Cancer:HER2(-),ER & PR(-) or ER &/or PR(+)	ALLIANCE-A011401 (BWEL) HIGH PRIORITY	Ph III; Reg </=12 mos of 1st Dx; HER2(-), ER & PR(-) or ER &/or PR(+); all Tx completed <= 21 days prior to reg; BMI >=27kg/m2; Able to walk >= 2 blocks; no other wt loss, phys activity or dietary intervention clinical trial. Tx: 2 Yr Health Education +/- Supervised weight loss intervention
BREAST - ADVANCED		
ER &/or PR(+)/HER2(-) Met	ECOG-E2112	Ph III; M/F; Stage III/Locally Adv/Met; Measurable disease only; Failed/progress after one AI for advanced disease; no more than 1 prior chemo Tx for advanced disease. >= 3 wks prior. Tx: Exemestane + Entinostat/Placebo(HDAC inhibitor, prevent drug resistance to hormone trx)
BREAST - PREVENTION & SYMPTOM CONTROL		
DCIS w/o invasive cancer	AFT-25 (COMET) Only)	(HPH) PhIII; Women w/unilateral, bilateral, unifocal, or multifocal DCIS; Age >40 at diagnosis; Path dx within 90 days of reg; ER+ and/or PR+, HER2 -, 1+ or 2+; Randomization: Surgery +/- RT and endocrine therapy vs endocrine therapy. For those who are randomized but decline allocated arm: patient's choice of either arm
Breast Cancer Women Desiring Pregnancy	A221405 (POSITIVE Trial)	Women 18 -42yo; Stage I-III, ER and/or PR+; Rec'vd endocrine therapy >= 18mos but <=30mos for early breast ca; enocrine dc'd within 1mo prior to reg.; must be premeno.at dx; Intervention: 1) 3 month break before pregnancy attempt 2) 2 year pause to allow pregnancy, 3) Treatment Resumption of endocrine tx.
Breast Cancer Survivors - Improving memory performance	Wake Forest - WF97116 (NEW)	PhIII; Hx of invasive breast ca; completed at least 4 cycles of adjuvant/neo-adjuvant cytotoxic chemo between 1 and 5 yrs prior to enrollment; no recurrence or mets. Tx: Donepezil or placebo
Breast Cancer: ER &/or PR(+) Asian/Pacific Islanders ONLY	ECOG-E1Z11(AIMSS)	Stage I-III adenoca; post-meno; Local/Adj Tx completed; plan Tx w/anastrozole; No prior AI. Pain score <=4/10. Tx: Supportive Care Anastrozole
CANCER CARE DELIVERY RESEARCH		
Breast, NSCLC, Colorectal Ca - Effectiveness of Colony Stimulating Factor use as prophylaxis	S1415CD	Dx of breast, NSCLC, or colorectal ca; Met or non-met, at initial dx, recurrence and/or progression; registered prior to 1st cycle of chemo for current disease and stage; no prior therapy 180 days prior to registration;must be planning to receive protocol allowed neoadjuvant or adjuvant tx for their current disease. Cohort components: TAMC - Intermediate RISK-CSF, QMC - Intermediate Risk - No CSF
Colorectal QMC ONLY	SWOG-S1417CD	New Dx met or met recurrence after prior Tx for Stage I/III. Chemo &/or systemic biologics must be planned <=30 days after reg OR started <=60 days prior to reg. Tx must be at registering site. Intervention: Financial Assessment (Pt & Caregiver).
Prostate Ca - Decision Aid	Alliance - A191402CD	Newly dx prostate ca, T1-3N0M0, Gleason score 6-10; Prostate bx within 4 mos prior to reg;PSA <50ng/mL scheduled prostate ca consultation to be the first after dx; not concurrently enrolled on a clinical trial for cancer tx; Randomization: Decision Aids vs Usual Care
CANCER PREVENTION & SYMPTOM CONTROL		
Prevention of of Recurrent VTE	AFT-28 (NEW)	Dx of an advanced solid tumor, lymphoma, CLL, myeloma OR dx of early stage solid tumor, lymphoma, CLL or myeloma <= 12 months prior to enrollment; dx of VTE 30 days prior to enrollment; intention to put pt on anticoagulation therapy for at least 3 mos. Txt: Direct Oral AntiCoagulants (Intervention) vs LMWH/warfarin (Usual Care) [Not open at HPH]
Questionnaire Feasibility	ALLIANCE-A191401	Pilot; Open to ALL patients registered on another Alliance trial or any other national group protocol which is open to Alliance member; must be able to complete the questionnaires. Questionnaire Feasibility
Breast or Gyn - Sexual Desire	NRG-CC004	PH II; Postmenopausal women w/hx of breast or gyn ca, completed surgery, chemo, and/or RT at least 6 mos previously; Tx: Bupropion 150mg XL x 1wk, Bupropion 150mg XL x 8wks plus placebo followed by placebo x 1wk (titration) vs Bupropion 150mg XL x 1wk, Bupropion 300mg XL x 8wks then 150mg x1wk (titration) vs Placebo x 1wk, placebo x8 wks then placebo x 1wk (titration) followed by optional open label Bupropion
Colorectal - Prevention	SWOG-S0820 (PACES)	Ph III; Adjuvant; Hx of Stage 0/I/II/III colon or rectal adenoca; Tx completed; 6-15 months of surgery; (-) colonoscopy 180 days after colon resect or 120 days after rectal; PS 0-1; Tx: Prevention of recurrence - Eflornithine+sulindac vs Placebo/Placebo
Genetic Testing Education in Advanced Cancer	ECOG-ACRIN-EAQ152 (COMET)	Actionable mutation on MATCH or at MATCH expansion sites. Delivery of genetic testing education, communication and patient anxiety, distress, understanding, etc. Intervention: Pre-Test Genetic Education Vs Usual Care
Improving Reproductive Health Oncologic Survivorship	ECOG-E1Q11 (EROS)	Engendering Reproductive Health - w/in 3 mon of any cancer dx prior to any chemo or RT. Premeno; 18-55 yrs; pregnant women allowed; no prior hysterectomy, BSO, or other sterilization . Intervention: Standard Practice Assessments with or w/o Study-Specific Training Plan for Physicians. (Patient vs Physician perceptions)
Geriatric Assessment to Reduce Chemo Toxicity	URCC-13059	Age >=70. Stage IV or incurable St. III solid tumor or lymphoma. Planned chemo >=3 months.Age >= 70 Advanced Solid Tumor; Intervention: Geriatric Assessments (GA) plus GA driven recommendations vs Usual Care
Molecular Profiling, NCORP	DCP-002 HIGH PRIORITY	Molecular Profiling of Early Onset Malignancies (EOMs): Tumors (<age of dx): Breast(45), Prostate(55), Colorectal(55), Liver(55), Kidney(50), Multiple Myeloma(50). Fresh frozen tissue, non malignant tissue cores, blood, H&E slide; bone marrow for myeloma
Ovarian Ca - Diet/Exercise	GOG-0225	Ph III. Successful 1st line tx +/- consolidation > 6wk to <= 6mo & 2 wks post Tx. Intervention: General Health Education Vs Lifestyle Intervention
Trial Screening, NCORP	DCP-001	Trials include: symptom & toxicity management, prevention, screening, post-tx surveillance and comparative effectiveness. Screening Tool
Proleukin IL-2 Registry	PROMETHEUS-10PLK13	Prosepctive: Received IL-2 tx after 01/01/2013; Retrospective: Received IL-2 tx on or before 12/31/2012 . Observational Registry
Xerostomia H&N Ca	ACUPUNCTURE-WF-97115	Ph III; Prior bilat EBRT (>= 24 GY); Grade 2 or 3 xerostomia; Completed RT >= 12 mos prior to reg; intact parotid & submandibular glands; PS 0-2. Tx: Acupuncture vs Sham Tx
GASTROINTESTINAL		
Colorectal - Prevention	SWOG-S0820 (PACES)	PIII Adjuvant; Hx of Stage 0/I/II/III adenoca; Tx completed;6 - 15 months of surgery; (-) colonoscopy 180 days after colon resect or 120 days after rectal; PS 0-1; Tx: Prevention of recurrence - Eflornithine+sulindac vs Placebo/Placebo

Adjuvant Colon	A021502	Histo. Dx stage III colon adenoca; presence of DNA Mismatch Repair (dMMR) by IHC; completely resected; entire tumor in colon; no autoimmune disease; no active hep B or C; Tx: mFOLFOX 6 + atezolizumab x12 vs mFOLFOX6 (Note: 1 cycle of mFOLFOX6 allowed prior to reg)
Gastric/Gastroesophageal/Bladder	ACOBA-2015-1	Adenoca only; Seen @ QMC; Dx 01/01/2010-09/30/2014; HER2 assay; Tissue available. Retrospective data collection. PD-L1 Expression Analysis
Pancreatic- Unresectable/Met	ECOG-ACRIN-EA2161	Ph II; Histo. Low or intermediate grade pancreatic neuroendocrine; refractory to mTOR inhibitor; scans showing progression ≤ 12 months prior to reg; prior sunitinib ok. Tx: TAK-228 3mg po daily
Rectal-Neoadjuvant	NRG-GI002 (Temp suspended, awaiting Arm 3)	Ph II; Clinically locally advanced Stage II or III adenocarcinoma of the rectum w/major portion of tumor intact; ability to swallow oral meds;No cardiac disease. Tx:mFOLFX6 followed by RT+capecitabine with or w/o veliparib
Advanced/Metastatic Colorectal	S1613	Ph II; Met or locally advanced and unresectable colorectal cancer; KRAS & NRAS Wild Type; No BRAF V600E Wild Type; Step 1: Screening for HER-2 amplification. Step 2 (Randomization):At Least one prior regimen of chemo for met or locally advanced, unresectable disease. Not eligible if ≥ 3 lines of chemo. Tx: Trastuzumab + Pertuzumab (TP) vs Cetuximab + Irinotecan (CETIRI). Crossover to TP if progression on CETIRI
GENITOURINARY		
Bladder, non-muscle invasive	ROSSER-2015-6	Hx of non-muscle evasive OR muscle invasive tx by BST/not yet Tx and Dx ≤ 12 mos. Multiplex Elisa Assay for Surveilling Patients
Bladder	ROSSER-2015-8	Micro hematuria ≤/ = past 3 mos who are referred for cystoscopy. Multiplex ELISA Assay for Evaluating Pts
Bladder	ROSSER-2015-7	Gross hematuria ≤ = 3 mos who are referred for cystoscopy. Multiplex Elisa Assay for Evaluating Pts
Non-Muscle Invasive Bladder	ALTOR-CA-ALT-803-01-14	Non-Muscle Invasive Bladder Cancer (NMIBC) Tx: Intravesical BCG + ALT-803
Non-Muscle Invasive Bladder	Rosser- 2017-1 (CA-ALT-803-01-16-1)	Ph II; HG histo. confirmed non-muscle invasive bladder ca; Arm A (N=80) w/CIS, Arm B (N= 20) HG Ta or T1 disease w/o CIS; unresponsive to BCG;recurrence >6 mos after last BCG not eligible. Tx: BCG + ALT-803 x 6wks; If residual CIS and/or HG Ta, additional BCG+ALT-803 x 6 wks; if no further disease or Low Grade Ta, additional BCG=ALT-803 x 3wks. If CR or low grade Ta w/no CIS, continue BCG+ALT-803
Muscle invasive Bladder - Adjuvant	A031501	PH III; Histo confirmed muscle-invasive urothelial ca of the bladder or upper tract; radical resection ≤ 16 wks prior to registration; margins clear; measurable disease; no prior tx with PD-1 or PD-L1 axis; Central PD-L1 testing required; Tx: Pembrolizumab IV vs Observation
Prostate - Post prostatectomy	NRG-GU003	Ph III;pT2 or pT3, pN0, pNX, post radical prostatectomy; Positive surgical margins are eligible; PSA<2.0ng/mL; Must speak English - completed EPIC Questionnaire; limited androgen deprivation allowed; No pT2 w/neg surgical margin and PSA <0.1ng.mL; Tx: Hypofraction vs Conventional RT
Prostate	HUANG-2015-1	Ph II; VLR: <5% risk, cT1c, <3(+) Bx cores; LR: 10% risk, cT1-2a, Oncotype Dx; Gleason ≤6, PSA <10 ng.mL. Tx: Noni capsules
Prostate	RTOG-0924	Ph III; Unfavorable/Intermediate/Favorable HR. Tx: Androgen Deprivation Therapy & HDRT +/- Whole-Pelvic RT
Prostate - Castrate Resistant	ROSSER-2015-4	PhIb; Castrate resistant; Met adenoca w/o small cell features; Asymptomatic/Mildly symptomatic. Tx: Atezolizumab followed by Sipuleucel-T Vs Sipuleucel-T followed by Atezolizumab
Prostate - Recurrent	AFT-19 (NEW)	Ph III;Biochemically recurrent prostate cancer; PSA doubling time ≤ 9 months at the time of study entry; screening PSA >0.5 ng/mL; prior ADT and/or first generation anti-androgen in (neo)adjuvant and/or salvage setting in conjunction with RT or surgery is allowed if last dose of ADT and/or anti-androgen is > 9 months prior to date of randomization and prior therapy is ≤ 36 months. Txt: Degarelix vs Degarelix plus Apalutamide vs Degarelix plus Apalutamide plus Abiraterone/Prednisone
Metastatic Papillary Renal Cell	S1500 (NEW)	Ph II; Histo or cyto. papillary metastatic or locally advanced (not resectable) renalcell ca.; measurable dz; >28 days from surgery; may have rec'vd up to one prior systemic therapy for advanced or met RCC - exception another VEGF inhibitor; prior RT allowed. Txt: Sunitinib vs Cabozantinib vs Crizotinib vs Savolitinib
GYNECOLOGY		
Ovary/Fallopian Tube/Primary Peritoneal/Endometrial	NRG-GY005 (Temp closure - PH II met accrual)	Ph II/III HG serous/endometroid; Clear/mix epithelial/undiff/trans if BRCA1/2+; Progression on Platinum Tx or recur ≤ 6 mo of last plat tx; TX:PHII-Cediranib+ Olaprib vs Cediranib/Olaparib Alone vs Standard Non-plat chemo; PIII -Active PII Arm(s)
Ovarian, Fallopian tube or Primary Peritoneal	GOG-3015 (Roche YO39523)-NEW	Ph III; Stage III or IV ovarian, fallopian tube or primary peritoneal w/macrosopic residual disease postop or with planned neoadjuvant therapy followed by surgery; neg hepatitis B nd Hep C; tissue available for PD-L1 testing; Txt: Paclitaxel plus caroplatin plus bevacizumab with or w/o atezolizumab
Vulva	GOG-0279	PhII; Locally advanced squamous cell of the vulva. Tx: Cisplatin & Gemcitabine + IMRT
HEAD AND NECK		
Head and Neck Xerostomia	ACUPUNCTURE-WF-97115	Ph III; Prior bilat EBRT (>= 24 GY); grade 2 or 3 xerostomia; Completed RT >= 12 mos prior to reg; intact parotid & submandibular glands; PS 0-2. Tx: Acupuncture vs Sham Tx
Nasopharyngeal, EBV-DNA(+)	NRG-HN001	Ph II/III; Local dis; EBV(+). Tx: All pts: Cis/RT. Rand: after chemo/RT if EBV-DNA detectable Cis/5FU vs Gem/Taxol; If none: Cis/5FU vs Observation
Anaplastic Thyroid	ALLIANCE-A091305	PhII; Stage IVC/IVB; Meas Dz; No Tx ≤21 days prior; No prior taxane ≤ 6mos; PS ≤2. Tx: Paclitaxel + Efatutazone
LUNG		
NSCLC - Resected	ALLIANCE-A151216 (ALCHEMIST)	Resected NSCLC molecular screening. St. IB (T>=4cm), St.II-IIIa; Non-squamous cell pts tested for EGFR, ALK (-), PD-L1. Squamous cell only for PD-L1. Tissue block for central testing.
NSCLC - EGFR mutation	ALLIANCE-A081105	Ph III; Screened on A151216. EGFR exon 19 deletion/L858R mutation. After any adjuvant chemo/RT. Tx: Erlotinib/Placebo x 2 yrs.
NSCLC - ALK fusion (+)	ECOG-E4512	Ph III; Screened on A151216. EML4-ALK fusion tumors After any adjuvant chemo/RT. Tx: Crizotinib/Placebo x 2 yrs
NSCLC - +/-PD-L1 (+)	EA5142	Ph III; Screened on A151216; EGFR & ALK wild-type; PD-L1 tested. Tx: Nivolumab x 1 yr vs Observation
Squamous Cell St.IV	SWOG-S1400 (Lung-MAP)	Ph II/III; St.IV or Stage II-III that have progressed within 1 yr of adjuvant platinum; eligible to be screened at prog or prior to prog; adequate tissue. Progress after platinum rx. Tx: Dependent on Sub-study
NSCLC - SBRT for Limited mets	NRG-LU002	Ph II/III; St IV NSCLC after 1st line/induction chemo; with stable or partial resp.; ≤3 extracranial mets amenable to SBRT.w/in 35 days of last chemo. RX: Maintenance chemo +/- SBRT to mets.
MYELODYSPLASTIC SYNDROME		
MDS	ECOG-ACRIN-NHLBI-MDS	Suspected MDS or MDS/MPN undergoing BM Pcr OR MDS Dx ≤6 mos and UnTx; no Dx of solid tumor or hem. No Malignancy ≤ past 2 yrs except in situ ca; BM submission for central review. Natural Hx Study
MELANOMA		
Melanoma - Advanced	SWOG S1616	PH II; Path confirmed Stage IV or unresectable Stage III; Uveal (Ocular) not eligible; measurable dz;Treated CNS mets allowed; progressed either on or after stopping anti-PD1 or anti- PD-L1 agents; must not have a confirmed PR or CR to PD-1 or PD-L1 prior o progression; Tx: Ipilimumab (SOC) vs Ipilimumab + Nivolumab
Melanoma - Met./Unresectable	ECOG-EA6134	Ph III. Met or unresectable Stage III/IV; BRAF V600E/K; Meas Dz; prior Adj systemic therapy ok. Tx: Dabrafenib + Trametinib followed by Ipilimumab + Nivolumab vs Ipilimumab + Nivolumab followed by Dabrafenib + Trametinib (Ipilimumab Investigator Training is mandatory - short video)
Melanoma - Recurrent	SWOG-S1320	Ph II; Recur Stage III/IV; BRAF V600E/K Mutant ; +/- Meas Dz. Tx: Intermittent Versus Continuous Dosing of Dabrafenib & Trametinib
Melanoma - Recurrent/Unresectable	ECOG-ACRIN-EA6141 - Temporarily Closed (Interim Analysis)	Ph II/III; Recur Unresectable Stage III/IV; BRAF mutation:WT/mutated; Meas Dz; prior Adj Tx allowed; no prior ipilimumab &/or anti-PD-1/PD-L1. Tx: Nivolumab + Ipilimumab + Sargramostim Vs Nivolumab + Ipilimumab
MULTIPLE MYELOMA		
Multiple Myeloma	ECOG-E1A11 (ENDURANCE)	Ph III; New Dx; Sx standard risk MM; no t(14:20), t(14:16) or deletion 17p or LDH >2 xULN or >20% plasma cells; Meas/Eval Dz; ≤ 4 wks of prior chemo; ≤ 160mg prior Dex. Tx: Bortezomib, Lenalidomide & Dex vs Carfilzomib, Lenalidomide & Dex(CRd) Followed by Limit/Indefinite Lenalidomide
SARCOMA		
Sarcoma	ALLIANCE-A091401	Ph II; Locally advanced/unresect/met; >= 1 prior systemic Tx; FFPE or slides for central path review; Meas Dz. Tx: Nivolumab +/- Ipilimumab
TARGETED THERAPY-BASKET TRIALS		
Solid Tumors, Lymphoma or MM	ECOG-ACRIN-EAY131-MATCH	Step 0 (Screening closed);Prog on >=1 line of Tx & no other Tx available OR no standard Tx to prolong OS;Meas Dz; Tx: Based on specific actionable mutations or amplifications done in designated private sector labs
Solid Tumors	S1609 (DART)	Rare cancer and/or rare cancer of unknown primary; must have progressed on > 1 standard Tx w/no other therapy available or no standard Tx exists that has been shown to prologn overall survival. Tx: Ipilimumab, Nivolumab (Tumor Closures: Salivary gland, epithelial, neuroendocrine, mucinous adenoca of appendix and ovary, cholangio. - see protocol for complete list.)