

# Office of Clinical Research

## Active Protocols

December 2015



**UVA Cancer Center**  
An NCI-Designated Cancer Center

Printed 12/11/15

### Studies Opened Since 11/1/15

#### Gynecologic Oncology

15-18433 GOG GOG3005

**A Phase 3 Placebo-Controlled Study of Carboplatin/Paclitaxel With or Without Concurrent and Continuation Maintenance Veliparib (PARP inhibitor) in Subjects with Previously Untreated Stages III or IV High-Grade Serous Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer**

Stages: III; IV CT.GOV ID: NCT02470585

Primary Investigator: Linda Duska MD

CRC: Anne Gabel

#### Melanoma

15-18174 UVA single-site MEL-64

**A trial to evaluate the safety, immunogenicity, and clinical activity of a helper peptide vaccine plus PD-1 blockade**

Stages: III B; III C; IV CT.GOV ID: NCT02515227

Primary Investigator: Craig Slingluff MD

CRC: Emily Allred

### All Studies Currently Open

#### Breast Oncology

00-8825 UVA single-site KOMEN-FOUNDATION

**Novel System for Dual Modality Tomographic Breast Imaging**

Stages: Not specified CT.GOV ID: Not specified

Primary Investigator: Mark Williams PhD

CRC: Joanne Gersbach

12-15885 UVA single-site BREAST43

**Building a better model: a comprehensive breast cancer risk model incorporating breast density to stratify risk and apply resources**

Stages: Not specified CT.GOV ID: Not specified

Primary Investigator: Jennifer Harvey MD

CRC: Kathy Repich

13-16686 BREAST-IMAGING

**Evaluation of Contrast Enhanced Mammography, Contrast Enhanced Breast Tomosynthesis, Breast Specific Gamma Imaging, and Gamma Emission Breast Tomosynthesis**

Stages: Not specified CT.GOV ID: Not specified

Primary Investigator: Mark Williams PhD

CRC: Joanne Gersbach

14-16921 PHAR NEWLINKNLG2101

**A Phase 2 Study of Docetaxel in Combination with 1-methyl-D-tryptophan indoximod) in Metastatic Breast Cancer**

Stages: IV CT.GOV ID: NCT01792050

Primary Investigator: Patrick Dillon MD

CRC: Lisa Malyn

#### Breast Oncology

14-16965 NRG NSABP-B-51

**A Randomized Phase III Clinical Trial Evaluating Post-Mastectomy Chestwall and Regional Nodal XRT and Post-Lumpectomy Regional Nodal XRT in Patients with Positive Axillary Nodes Before Neoadjuvant Chemotherapy Who Convert to Pathologically Negative Axillary Nodes After Neoadjuvant Chemotherapy**

Stages: II; III CT.GOV ID: NCT01872975

Primary Investigator: Shayna Showalter MD

CRC: Katie Rea

14-16966 Alliance A011202

**A Randomized Phase III Trial Comparing Axillary Lymph Node Dissection to Axillary Radiation in Breast Cancer Patients (cT1-3 N1) Who Have Sentinel Lymph Node Disease After Neoadjuvant Chemotherapy**

Stages: I; II; III CT.GOV ID: NCT01901094

Primary Investigator: Shayna Showalter MD

CRC: Katie Rea

14-17483 ECOG-ACRIN S1207

**Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating The Use of Adjuvant Endocrine Therapy +/- One Year of Everolimus in Patients With High-Risk Hormone Receptor-Positive and Her2/Neu Negative Breast Cancer**

Stages: I; II; III CT.GOV ID: NCT01674140

Primary Investigator: Patrick Dillon MD

CRC: Lisa Malyn

## Breast Oncology

15-17615 PHAR ABBVIEM14-011

**A Randomized, Placebo-Controlled, Double-Blind, Phase 3 Study Evaluating Safety and Efficacy of the Addition of Veliparib Plus Carboplatin Versus the Addition of Carboplatin to Standard Neoadjuvant Chemotherapy Versus Standard Neoadjuvant Chemotherapy in Subjects with Early Stage Triple Negative Breast Cancer (TNBC)**

Stages: II; III A CT.GOV ID: NCT02032277

Primary Investigator: Patrick Dillon MD

CRC: Lisa Malyn

15-17762 PHAR HER-NEU-VAX-2014-0443

**Phase II Trial of Combination Immunotherapy with nelipepimut-S + GM-CSF (NeuVax) and Trastuzumab in high-risk HER2+ Breast Cancer Patients**

Stages: I; II; III CT.GOV ID: NCT02297698

Primary Investigator: Patrick Dillon MD

CRC: Emily Allred

15-18004 UVA single-site BREAST-IORT-002

**A Prospective Single-Arm Phase II Study To Investigate The Efficacy Of Single-Fraction Intraoperative Radiation Treatment Using A Multi-Lumen Balloon Applicator And In-Room CT Imaging For The Treatment Of Early-Stage Breast Cancer**

Stages: 0; I CT.GOV ID: NCT02400658

Primary Investigator: Shayna Showalter MD

CRC: Katie Rea

15-18072 ECOG-ACRIN E2112

**A Randomized Phase III Trial of Endocrine Therapy plus Entinostat/Placebo in Men and Postmenopausal Women with Hormone Receptor-Positive Advanced Breast Cancer**

Stages: III; IV CT.GOV ID: NCT02115282

Primary Investigator: Christiana Brenin MD

CRC: Lisa Malyn

## Gastrointestinal Oncology

12-15934 PHAR TS-102

**A Phase III Clinical Trial Evaluating TheraSphere in Patients with Metastatic Colorectal Carcinoma of the Liver who have failed first line chemotherapy**

Stages: Any/all stages CT.GOV ID: NCT01483027

Primary Investigator: James Stone

CRC: Brigitte Kelly

12-16105 PHAR TS-103

**A Phase III Clinical Trial of Intra-arterial TheraSphere in the Treatment of Patients with Unresectable Hepatocellular Carcinoma (HCC)**

Stages: Not specified CT.GOV ID: NCT01556490

Primary Investigator: James Stone

CRC: Brigitte Kelly

12-16375 Alliance N1048

**A Phase II/III Trial of Neoadjuvant FOLFOX, with Selective Use of Combined Modality Chemoradiation versus Preoperative Combined Modality Chemoradiation for Locally Advanced Rectal Cancer Patients Undergoing Low Anterior Resection with Total Mesorectal Excision**

Stages: II A; III A; III B CT.GOV ID: NCT01515787

Primary Investigator: Traci Hedrick MD

CRC: Amy Harrigan

13-16678 UVA single-site PTP-01-001

**A Phase 0, Open Label Study to Evaluate the Biodistribution and Pharmacokinetics of a Single Intravenous Bolus Dose of PTP-01 in Subjects with Resectable Pancreatic Ductal Adenocarcinoma**

Stages: Any/all stages CT.GOV ID: NCT01962909

Primary Investigator: Reid Adams MD

CRC: Sandra Burks RN, BSN, CCRC

## Gastrointestinal Oncology

14-17434 PHAR ABI-007-PANC-003

**A Phase 3, Multicenter, Open-Label, Randomized Study of nab®-Paclitaxel Plus Gemcitabine Versus Gemcitabine Alone As Adjuvant Therapy In Subjects With Surgically Resected Pancreatic Adenocarcinoma**

Stages: I; II; III CT.GOV ID: NCT01964430

Primary Investigator: Osama Rahma

CRC: Julio Torres

15-17459 PHAR SONORHEOMETRY

**Sonorheometry to predict thrombotic risk in patients with cancer**

Stages: Not specified CT.GOV ID: Not specified

Primary Investigator: Hillary Maitland

CRC: Julio Torres

14-17493 PHAR NLG0505

**A Phase III Study of Chemotherapy With or Without Algenpantucel-(HyperAcute® - Pancreas) Immunotherapy in Subjects with Borderline Resectable or Locally Advanced Unresectable Pancreatic Cancer**

Stages: II; III CT.GOV ID: NCT01836432

Primary Investigator: Osama Rahma

CRC: Sarah Kelley

14-17546 PHAR EVOLUTION-STENT

**Evaluation of the Effectiveness of Evolution® Biliary Stent System-Fully Covered**

Stages: Not specified CT.GOV ID: NCT02104076

Primary Investigator: Andrew Wang

CRC: Sandra Oliphant RN, BSN, CCRC

15-17561 ECOG-ACRIN E2211

**A Randomized Phase II Study of Temozolomide or Temozolomide and Capecitabine in Patients with Advanced Pancreatic Neuroendocrine Tumors**

Stages: Not specified CT.GOV ID: NCT01824875

Primary Investigator: William Grosh MD

CRC: Julio Torres

15-17701 13-213

**A phase II multicenter randomized trial evaluating 3-year disease-free survival in patients with locally advanced rectal cancer treated with chemoradiation plus induction or consolidation chemotherapy, and total mesorectal excision or non-operative management**

Stages: II; III CT.GOV ID: NCT02008656

Primary Investigator: Charles Friel MD

CRC: Amy Harrigan

15-17801 UVA multi-site UVA-PC-PD101-UVA

**A Randomized Multicenter Phase Ib/II study to assess the safety and the immunological effect of chemoradiation therapy (CRT) in combination with MK-3475 (anti-PD1) to CRT alone in patients with resectable or borderline resectable pancreatic cancer**

Stages: Any/all stages CT.GOV ID: NCT02305186

Primary Investigator: Osama Rahma

CRC: Sarah Kelley

## Genitourinary Oncology

12-14266 UVA multi-site CARESS

**Couples Arousal Relationship Satisfaction Survey**

Stages: Not specified CT.GOV ID: Not specified

Primary Investigator: Tracey Krupski

CRC: Patricia Battle RN

## Genitourinary Oncology

13-16392 PHAR P10-3

### **A Registry of Sipuleucel-T Therapy in Men with Advanced Prostate Cancer**

Stages: Not specified CT.GOV ID: Not specified  
Primary Investigator: Tracey Krupski  
CRC: Patricia Battle RN

13-16604 UVA multi-site HYPO-FX-UVA

### **Hypofractionated post-prostatectomy radiotherapy for prostate cancer to reduce toxicity and improve patient convenience: A Phase I/II trial**

Stages: Any/all stages CT.GOV ID: NCT01868386  
Primary Investigator: Timothy Showalter  
CRC: Parchay Dalal

13-16946 UVA single-site PROSTATE-SURVIVAL

### **Evaluation of Survival in Patients with Metastatic Prostate Cancer undergoing Treatment of the Primary Tumor**

Stages: Not specified CT.GOV ID: Not specified  
Primary Investigator: Stephen Culp  
CRC: Elaine Woodson

13-17031 PHAR AGS-003-007

### **An International Phase 3 Randomized Trial of Autologous Dendritic Cell Immunotherapy (AGS-003) Plus Standard Treatment of Advanced Renal Cell Carcinoma (ADAPT)**

Stages: III; IV CT.GOV ID: NCT01582672  
Primary Investigator: Tracey Krupski  
CRC: Patricia Battle RN

14-17079 NRG RTOG0924

### **Androgen Deprivation Therapy and High Dose Radiotherapy With or Without Whole-Pelvic Radiotherapy in Unfavorable Intermediate or Favorable High Risk Prostate Cancer: A Phase III Randomized Trial**

Stages: I C; II; III; IV CT.GOV ID: NCT01856192  
Primary Investigator: Timothy Showalter  
CRC: Parchay Dalal

14-17456 UVA single-site PROSTATE-04

### **A pilot study to assess the combination of stereotactic body radiation therapy and CDX-1127 in modulating local and systemic T-cell responses against prostate cancer**

Stages: Any/all stages CT.GOV ID: NCT02284971  
Primary Investigator: James Larner MD  
CRC: Kristy Scott

15-17902 Alliance A031201

### **Phase III Trial of Enzalutamide (NSC# 766085) Versus Enzalutamide, Abiraterone and Prednisone for Castration Resistant Metastatic Prostate Cancer**

Stages: Not specified CT.GOV ID: NCT01949337  
Primary Investigator: Robert Dreicer  
CRC: Julio Torres

15-17959 ECOG-ACRIN S1314

### **A Randomized Phase II Study of Co-Expression Extrapolation (COXEN) With Neoadjuvant Chemotherapy for Localized, Muscle-Invasive Bladder Cancer**

Stages: Not specified CT.GOV ID: NCT02177695  
Primary Investigator: Robert Dreicer  
CRC: Julio Torres

15-18096 PHAR ASN001-101

### **A Phase 1/2, Open-Label, Uncontrolled, Multiple-Dose Escalation, Cohort Expansion And Extension Study To Evaluate The Safety, Tolerability, And Pharmacokinetics Of ASN001 In Subjects With Metastatic Progressive Castrate Resistant Prostate Cancer**

Stages: Not specified CT.GOV ID: NCT02349139  
Primary Investigator: Robert Dreicer  
CRC: Buki Akinola

## Genitourinary Oncology

15-18169 PHAR WO29636

### **A Phase III, Open-Label, Multicenter, Randomized Study of Atezolizumab (Anti-PD-L1 Antibody) Versus Observation as Adjuvant Therapy in Patients With PD-L1-Selected, High-Risk Muscle-Invasive Bladder Cancer After Cystectomy**

Stages: Not specified CT.GOV ID: NCT02450331  
Primary Investigator: Robert Dreicer  
CRC: Buki Akinola

15-18175 PHAR GU115

### **A Double-Blinded, Placebo-Controlled, Randomized Phase II Study of Enzalutamide With or Without the PI3 Kinase/mTOR Inhibitor LY3023414 in Men With Metastatic Castration Resistant Prostate Cancer**

Stages: IV CT.GOV ID: NCT02407054  
Primary Investigator: Robert Dreicer  
CRC: Julio Torres

## Gynecologic Oncology

08-13501 NRG GOG-0213

### **A Phase III Randomized Controlled Clinical Trial of Carboplatin and Paclitaxel Alone or in Combination With Bevacizumab (NSC #704865, IND #7921) Followed By Bevacizumab and Secondary Cytoreductive Surgery in Platinum-Sensitive, Recurrent Ovarian, Fallopian Tube and Peritoneal Primary Cancer**

Stages: Not specified CT.GOV ID: NCT00565851  
Primary Investigator: Susan Modesitt MD  
CRC: Sanja Arapovic

10-14864 NRG 9923

### **A Phase 1 Study of Carboplatin/Paclitaxel/CTEP-supplied Agent Bevacizumab and CTEP-supplied Agent ABT-888 in Newly Diagnosed Patients With Previously Untreated Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer**

Stages: II; III; IV CT.GOV ID: NCT00989651  
Primary Investigator: Linda Duska MD  
CRC: Timothy Howland

11-15391 UVA multi-site FRAILITY-ASSESSMENT

### **Frailty: An Outcome Predictor for Elderly Gynecologic Oncology Patients?**

Stages: Not specified CT.GOV ID: Not specified  
Primary Investigator: Leigh Cantrell MD  
CRC: Timothy Howland

12-16153 UVA multi-site OVA-7-UVA

### **A Randomized Phase II Evaluation Of Weekly Gemcitabine Plus Pazopanib Versus Weekly Gemcitabine Alone In The Treatment Of Persistent Or Recurrent Epithelial Ovarian, Fallopian Tube Or Primary Peritoneal Carcinoma**

Stages: Not specified CT.GOV ID: NCT01610206  
Primary Investigator: Linda Duska MD  
CRC: Sanja Arapovic

12-16337 NRG GOG225

### **Can Diet and Physical Activity Modulate Ovarian & Primary Peritoneal Cancer Progression Free Survival?**

Stages: Not specified CT.GOV ID: Not specified  
Primary Investigator: Susan Modesitt MD  
CRC: Anne Gabel

12-16411 NRG ANZGOG-0902-GOG-0274

### **A Phase III Trial of Adjuvant Chemotherapy as Primary Treatment for Locally Advanced Cervical Cancer Compared to Chemoradiation Alone: The Outback Trial (ANZGOG 0902/GOG-0274/RTOG 1174)**

Stages: I B; II; III B; IV A CT.GOV ID: NCT01414608  
Primary Investigator: Susan Modesitt MD  
CRC: Anne Gabel

## Gynecologic Oncology

14-16836 Non-UVA IUCRO-0383

**Determining the Sensitivity of Sentinel Lymph Nodes Identified with Robotic Fluorescence Imaging for Detecting Metastatic Endometrial and Cervical Cancer**

Stages: I; I A; I B CT.GOV ID: NCT01673022

Primary Investigator: Leigh Cantrell MD

CRC: Timothy Howland

13-17040 PHAR ARRAY-162-311

**The MILO Study (MEK Inhibitor in Low-grade Serous Ovarian Cancer): A Multinational, Randomized, Open-label Phase 3 Study of MEK162 vs. Physician's Choice Chemotherapy in Patients with Recurrent or Persistent Low-grade Serous Carcinomas of the Ovary, Fallopian Tube or Primary Peritoneum**

Stages: Not specified CT.GOV ID: NCT01849874

Primary Investigator: Leigh Cantrell MD

CRC: Sanja Arapovic

14-17366 UVA multi-site 17366

**Phase II Evaluation of BIBF 1120 in the Treatment of Bevacizumab-Resistant Persistent or Recurrent Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Carcinoma**

Stages: Not specified CT.GOV ID: NCT01669798

Primary Investigator: Linda Duska MD

CRC: Anne Gabel

14-17381 NRG GOG-0286B

**A Randomized Phase II/III Study of Paclitaxel/Carboplatin/Metformin (MSC#91485) versus Paclitaxel/Carboplatin/Placebo as Initial Therapy for Measurable Stage III or IVA, Stage IVB, or Recurrent Endometrial Cancer**

Stages: Not specified CT.GOV ID: NCT02065687

Primary Investigator: Susan Modesitt MD

CRC: Anne Gabel

15-17723 NRG 9671

**Exceptional Responders Pilot study: Molecular profiling of tumors from cancer patients who are Exceptional Responders**

Stages: Not specified CT.GOV ID: Not specified

Primary Investigator: Charles Landen

CRC: Heather Lothamer RN, MSN, CCRP

14-17782 UVA single-site ENDOMETRIAL-PATHOLOGY2

**Prospective evaluation of hormonal and glucose regulators in pre- and postmenopausal women with and without endometrial cancer undergoing hysterectomy**

Stages: Not specified CT.GOV ID: Not specified

Primary Investigator: Susan Modesitt MD

CRC: Anne Gabel

15-18064 PHAR PM1183

**Phase III Randomized Clinical Trial of Lurbinectedin (PM01183) versus Pegylated Liposomal Doxorubicin or Topotecan in patients with Platinum-resistant Ovarian Cancer (CORAIL Trial)**

Stages: Not specified CT.GOV ID: NCT02421588

Primary Investigator: Linda Duska MD

CRC: Anne Gabel

15-18121 PHAR MORAB-003-011

**A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study to Assess the Efficacy and Safety of Farletuzumab (MORAb-003) in Combination with Carboplatin plus Paclitaxel or Carboplatin plus Pegylated Liposomal Doxorubicin (PLD) in Subjects with Low CA125 Platinum-Sensitive Ovarian Cancer**

Stages: Not specified CT.GOV ID: NCT02289950

Primary Investigator: Linda Duska MD

CRC: Anne Gabel

## Gynecologic Oncology

15-18134 NRG NRG-CC002

**Pre-Operative Assessment and Post-Operative Outcomes of Elderly Women with Gynecologic Cancers**

Stages: Any/all stages CT.GOV ID: Not specified

Primary Investigator: Susan Modesitt MD

CRC: Sanja Arapovic

15-18203 NRG GOG-3008

**A Phase 1b study of CRLX101 in combination with weekly paclitaxel in patients with recurrent or persistent epithelial ovarian, fallopian tube or primary peritoneal cancer**

Stages: Any/all stages CT.GOV ID: Not specified

Primary Investigator: Linda Duska MD

CRC: Sanja Arapovic

15-18433 GOG GOG3005

**A Phase 3 Placebo-Controlled Study of Carboplatin/Paclitaxel With or Without Concurrent and Continuation Maintenance Veliparib (PARP inhibitor) in Subjects with Previously Untreated Stages III or IV High-Grade Serous Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer**

Stages: III; IV CT.GOV ID: NCT02470585

Primary Investigator: Linda Duska MD

CRC: Anne Gabel

## Head & Neck Oncology

13-16376 UVA single-site SCCA-TORS-2012

**A Single Arm Study of Efficacy and Functional Quality of Life in Patients Treated with Transoral Robotic Surgery for Oropharyngeal and Supraglottic Squamous Cell Carcinoma**

Stages: I; II; III CT.GOV ID: NCT01819480

Primary Investigator: Mark Jameson MD, PhD

CRC: BJ Ferrebee Ghamandi

13-16544 UVA single-site TC-P2-CALCITRIOL

**A Phase 2, placebo-controlled, randomized study to evaluate the effect of pre-operative vitamin D supplementation on hypocalcemia following total or near-total thyroidectomy**

Stages: Any/all stages CT.GOV ID: NCT01868750

Primary Investigator: David Shonka MD

CRC: BJ Ferrebee Ghamandi

15-17871 NRG NRG-HN002

**A Randomized Phase II Trial for Patients With p16 Positive, Non-smoking Associated, Locoregionally Advanced Oropharyngeal Cancer**

Stages: I; II; II B; III CT.GOV ID: NCT02254278

Primary Investigator: Paul Read MD

CRC: Parchayi Dalal

15-18172 PHAR MK3475-048

**A Phase 3 Clinical Trial of Pembrolizumab (MK-3475) in First Line Treatment of Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma**

Stages: IV CT.GOV ID: NCT02358031

Primary Investigator: Elizabeth Gaughan

CRC: Sarah Kelley

## Hematologic Malignancies

12-16260 ECOG-ACRIN E1411

**Intergroup Randomized Phase II Four Arm Study In Patients >= 60 With Previously Untreated Mantle Cell Lymphoma**

Stages: Any/all stages CT.GOV ID: NCT01415752

Primary Investigator: Michael Williams MD

CRC: Andrea Ruhsam BS, BA, CCRP



## Hematologic Malignancies

- 13-16706 UVA single-site BRETTCCELLCYTOTOXICITY  
**Effect of targeted therapies on leukemia and lymphoma cell cytotoxicity and signal transduction - Brett Cell Cytotoxicity**  
Stages: Not specified CT.GOV ID: Not specified  
Primary Investigator: Craig Portell  
CRC: Kim Underwood BS, CCRC
- 14-16770 PHAR SGN35-014  
**A randomized, double-blind, placebo-controlled, phase 3 study of brentuximab vedotin and CHP (A+CHP) versus CHOP in the frontline treatment of patients with CD30-positive mature T-cell lymphomas**  
Stages: Any/all stages CT.GOV ID: NCT01777152  
Primary Investigator: Michael Douvas MD  
CRC: Kim Underwood BS, CCRC
- 14-17063 ECOG-ACRIN E1412  
**Randomized Phase II Open Label Study of Lenalidomide R-CHOP (R2CHOP) vs RCHOP (Rituximab, Cyclophosphamide, Doxorubicin, Vincristine and Prednisone) in Patients with Newly Diagnosed Diffuse Large B Cell Lymphoma**  
Stages: Not specified CT.GOV ID: NCT01856192  
Primary Investigator: Michael Williams MD  
CRC: Andrea Ruhsam BS, BA, CCRC
- 14-17193 PrECOG PRE0401  
**Phase II Randomized Trial Comparing GA101 (Obinutuzumab) and Rituximab in Patients with Previously Untreated Low Tumor Burden Indolent Non-Hodgkin's Lymphoma**  
Stages: III; IV CT.GOV ID: NCT01889797  
Primary Investigator: Craig Portell  
CRC: Andrea Ruhsam BS, BA, CCRC
- 15-17748 PHAR BO29337  
**A Phase II, Open-Label Study Evaluating the Safety and Efficacy of GDC-0199 (ABT-199) Plus Bendamustine Plus Rituximab (BR) in Comparison with BR Alone or GDC-0199 Plus Rituximab (R) in Patients with Relapsed and Refractory Follicular Non-Hodgkin's Lymphoma**  
Stages: Not specified CT.GOV ID: NCT02187861  
Primary Investigator: Craig Portell  
CRC: Kim Underwood BS, CCRC
- 15-17750 Alliance A041202  
**A Randomized Phase III Study of Bendamustine Plus Rituximab Versus Ibrutinib Plus Rituximab Versus Ibrutinib Alone in Untreated Older Patients (>=65 Years of Age) With Chronic Lymphocytic Leukemia (CLL)**  
Stages: Not specified CT.GOV ID: NCT01886872  
Primary Investigator: Craig Portell  
CRC: Kim Underwood BS, CCRC
- 15-17983 UVA multi-site ABT199-MCL-UVA  
**Multi-institution Phase I/II study of ibrutinib with ABT-199 in relapsed/refractory mantle cell lymphoma**  
Stages: Any/all stages CT.GOV ID: NCT02419560  
Primary Investigator: Craig Portell  
CRC: Kim Underwood BS, CCRC

## Melanoma

- 13-16223 PHAR 103A-301  
**A Multicenter, Double-blind, Placebo-controlled, Adaptive Phase 3 Trial of POL-103A Polyvalent Melanoma Vaccine in Post-resection Melanoma Patients with a High Risk of Recurrence**  
Stages: II B; II C; III CT.GOV ID: NCT01546571  
Primary Investigator: Craig Slingluff MD  
CRC: Emily Allred

## Melanoma

- 13-16347 PHAR LUD2012-004  
**Phase I Study of NY-ESO-1 Vaccine in Combination with Ipilimumab in Patients with Unresectable or Metastatic Melanoma, for whom Treatment with Ipilimumab is Indicated**  
Stages: Not specified CT.GOV ID: NCT01810016  
Primary Investigator: Craig Slingluff MD  
CRC: Emily Allred
- 13-16416 PHAR CA209038  
**An Exploratory Study of the Biologic Effects of Nivolumab and Nivolumab in Combination with Ipilimumab Treatment in Subjects with Advanced Melanoma (Unresectable or Metastatic)**  
Stages: III B; III C; IV CT.GOV ID: NCT01621490  
Primary Investigator: Craig Slingluff MD  
CRC: Emily Allred
- 14-16952 Non-UVA ML28305  
**Analysis of the kinetics and effects of vemurafenib + cobimetinib on intratumoral and host immunity in patients with advanced BRAFV600 mutant melanoma: implications for combination with immunotherapy**  
Stages: Not specified CT.GOV ID: NCT01813214  
Primary Investigator: Craig Slingluff MD  
CRC: Sarah Kelley
- 14-16954 Non-UVA CITN-04  
**A Phase II Pilot Trial of an Indoleamine 2,3-dioxygenase-1 (IDO1) Inhibitor (INCB024360) Plus a Multipptide Melanoma Vaccine (MELITAC 12.1) in Patients with Advanced Melanoma**  
Stages: III; IV CT.GOV ID: NCT01961115  
Primary Investigator: Craig Slingluff MD  
CRC: Emily Allred
- 15-17780 UVA single-site MEL-62  
**A Phase I/II trial to evaluate the safety, immunogenicity, and clinical activity of a helper peptide vaccine plus CTLA-4 blockade in Advanced Melanoma (Mel62; 6PAC)**  
Stages: III B; III C; IV CT.GOV ID: NCT02385669  
Primary Investigator: Craig Slingluff MD  
CRC: Emily Allred
- 15-17860 UVA single-site MEL-63  
**A trial to evaluate the immunogenicity and safety of a melanoma helper peptide vaccine plus novel adjuvant combinations (MEL63)**  
Stages: II; III; IV CT.GOV ID: NCT02425306  
Primary Investigator: Craig Slingluff MD  
CRC: Emily Allred
- 15-18115 PHAR INTEGRATE  
**An ongoing, 5-year post market study to track clinical application, of DecisionDx-Melanoma gene expression profile (GEP) assay results and the impact on patient outcomes and health economics (INTEGRATE).**  
Stages: Any/all stages CT.GOV ID: Not specified  
Primary Investigator: Craig Slingluff MD  
CRC: Sarah Kelley
- 15-18174 UVA single-site MEL-64  
**A trial to evaluate the safety, immunogenicity, and clinical activity of a helper peptide vaccine plus PD-1 blockade**  
Stages: III B; III C; IV CT.GOV ID: NCT02515227  
Primary Investigator: Craig Slingluff MD  
CRC: Emily Allred

## Neuro-Oncology

## Neuro-Oncology

09-14665 ECOG-ACRIN E3F05

**Phase III Study of Radiation Therapy With or Without Temozolomide for Symptomatic or Progressive Low-Grade Gliomas**

Stages: Not specified CT.GOV ID: NCT00978458  
Primary Investigator: David Schiff MD  
CRC: Johanna Loomba BS

13-16463 Alliance N1174

**Phase I/Comparative Randomized Phase II Trial of TRC105 plus Bevacizumab Versus Bevacizumab in Bevacizumab-Naïve Patients with Recurrent Glioblastoma Multiforme**

Stages: Not specified CT.GOV ID: NCT01648348  
Primary Investigator: David Schiff MD  
CRC: Cara Hanby

13-17161 MC1281

**Phase I Trial of Pomalidomide for Patients with Relapsed/Refractory Primary CNS Lymphoma and Patients with Newly Diagnosed or Relapsed/Refractory Primary Vitreoretinal Lymphoma**

Stages: Not specified CT.GOV ID: NCT01722305  
Primary Investigator: David Schiff MD  
CRC: Cara Hanby

14-17466 PHAR STML-701-0114

**A phase 1/2 study of SL-701, a subcutaneously injected multivalent glioma-associated antigen vaccine, in adult patients with recurrent glioblastoma multiforme.**

Stages: Not specified CT.GOV ID: NCT02078648  
Primary Investigator: David Schiff MD  
CRC: Heather Tribout

14-17504 PHAR TPI-287-18

**Phase 2 Dose-Escalation Study of TPI 287 in Combination with Bevacizumab in Adults with Recurrent or Progressive Glioblastoma Following Bevacizumab Alone**

Stages: Not specified CT.GOV ID: NCT02047214  
Primary Investigator: David Schiff MD  
CRC: Heather Tribout

15-17897 Alliance A071102

**A Phase II/III Randomized Trial Of Veliparib Or Placebo In Combination With Adjuvant Temozolomide In Newly Diagnosed Glioblastoma With MGMT Promoter Hypermethylation**

Stages: Not specified CT.GOV ID: NCT02152982  
Primary Investigator: David Schiff MD  
CRC: Cara Hanby

15- Alliance A071401

**Phase II Trial of SMO/AKT/NF2 Inhibitors in Progressive Meningiomas With SMO/AKT/NF2 Mutations**

Stages: Not specified CT.GOV ID: NCT02523014  
Primary Investigator: David Schiff MD  
CRC: Cara Hanby

## Pediatric Oncology

99-8318 COG D9902

**A Group-Wide Protocol for Collecting and Banking Pediatric Cancer Research Specimens. an Intergroup Rhabdomyosarcoma Study Group Protocol**

Stages: Not specified CT.GOV ID: NCT00919269  
Primary Investigator: Kim Dunsmore MD  
CRC: Candace Hudspeth BA, CCRC

## Pediatric Oncology

01-9302 COG ANBL00B1

**Neuroblastoma Biology Studies: a Children's Oncology Group Study**

Stages: Not specified CT.GOV ID: NCT00904241  
Primary Investigator: Kim Dunsmore MD  
CRC: Candace Hudspeth BA, CCRC

08-13669 COG AREN03B2

**Renal Tumors Classification, Biology and Banking Study**

Stages: Not specified CT.GOV ID: NCT00898365  
Primary Investigator: Kim Dunsmore MD  
CRC: Candace Hudspeth BA, CCRC

10-14764 COG AHEP0731

**Treatment of Children With All Stages of Hepatoblastoma: A Groupwide Phase III Study**

Stages: I; II; III; IV CT.GOV ID: NCT00980460  
Primary Investigator: Kim Dunsmore MD  
CRC: Candace Hudspeth BA, CCRC

11-15479 COG AALL08B1

**Classification of Newly Diagnosed Acute Lymphoblastic Leukemia (ALL)**

Stages: Not specified CT.GOV ID: Not specified  
Primary Investigator: Kim Dunsmore MD  
CRC: Candace Hudspeth BA, CCRC

11-15583 COG AALL0932

**Treatment of Patients with Newly Diagnosed Standard Risk B-Precursor Acute Lymphoblastic Leukemia (ALL): A Groupwide Phase III Study**

Stages: Not specified CT.GOV ID: NCT01190930  
Primary Investigator: Kim Dunsmore MD  
CRC: Candace Hudspeth BA, CCRC

11-15896 COG AAML08B1

**Biology Study of Transient Myeloproliferative Disorder (TMD) in Children with Down Syndrome (DS)**

Stages: Not specified CT.GOV ID: NCT00959283  
Primary Investigator: Kim Dunsmore MD  
CRC: Candace Hudspeth BA, CCRC

13-15897 COG ACCL0933

**A Randomized Open-Label Trial of Caspofungin versus Fluconazole to Prevent Invasive Fungal Infections in Children Undergoing Chemotherapy for Acute Myeloid Leukemia (AML)**

Stages: Not specified CT.GOV ID: NCT01307579  
Primary Investigator: Kim Dunsmore MD  
CRC: Candace Hudspeth BA, CCRC

12-16462 COG AALL1131

**A Phase III Randomized Trial for Newly Diagnosed High Risk B-precursor Acute Lymphoblastic Leukemia (ALL) Testing Clofarabine (IND# 73789, NSC# 606869) in the Very High Risk Stratum**

Stages: Any/all stages CT.GOV ID: NCT01406756  
Primary Investigator: Kim Dunsmore MD  
CRC: Candace Hudspeth BA, CCRC

12-16468 COG ALTE07C1

**Neuropsychological, Social, Emotional and Behavioral Outcomes in Children with Cancer**

Stages: Not specified CT.GOV ID: NCT00772200  
Primary Investigator: Colleen Druzgal  
CRC: Jessica Pritchard

## Pediatric Oncology

- 13-16684 COG AEWS1031  
**Phase III Randomized Trial of Adding Vincristine-topotecan-cyclophosphamide to Standard Chemotherapy in Initial Treatment of Non-metastatic Ewing**  
Stages: Not specified CT.GOV ID: NCT01231906  
Primary Investigator: Kim Dunsmore MD  
CRC: Candace Hudspeth BA, CCRC
- 13-16951 COG ACNS1123  
**Phase 2 Trial of Response-Based Radiation Therapy for Patients with Localized Central Nervous System Germ Cell Tumors (CNS GCT)**  
Stages: Not specified CT.GOV ID: NCT01602666  
Primary Investigator: Colleen Druzgal  
CRC: Jessica Pritchard
- 14-17165 UVA single-site PEDSSOLIDTUMORDATABASE  
**Pediatric Relapsed Solid Tumor Database**  
Stages: Not specified CT.GOV ID: Not specified  
Primary Investigator: Aaron Quinlan  
CRC: Candace Hudspeth BA, CCRC
- 15-17264 COG ACCL0922  
**A Phase II Placebo-Controlled Trial of Modafinil to Improve Neurocognitive Deficits in Children Treated for a Primary Brain Tumor**  
Stages: Not specified CT.GOV ID: NCT01381718  
Primary Investigator: Colleen Druzgal  
CRC: Jessica Pritchard

## Thoracic Oncology

- 08-13622 Alliance CALGB-140503  
**A Phase III Randomized Trial of Lobectomy Versus Sublobar Resection for Small (<= 2 Cm) Peripheral Non-Small Cell Lung Cancer**  
Stages: I A CT.GOV ID: NCT00499330  
Primary Investigator: Benjamin Kozower MD  
CRC: Sandra Burks RN, BSN, CCRC
- 12-16005 UVA multi-site LCIS-R01  
**A Decision Aid with HRQL Assessment to Reduce Costs in the Treatment of NSCLC (LCIS-R01)**  
Stages: III B; IV CT.GOV ID: Not specified  
Primary Investigator: Patricia Hollen PhD, RN  
CRC: Bethany Coyne
- 14-17719 ECOG-ACRIN A151216  
**Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST)**  
Stages: Not specified CT.GOV ID: NCT02194738  
Primary Investigator: Richard Hall  
CRC: Galina Diakova
- 14-17720 ECOG-ACRIN A081105  
**Randomized Double Blind Placebo Controlled Study of Erlotinib or Placebo in Patients with Completely Resected Epidermal Growth Factor Receptor (EGFR) Mutant Non-Small Cell Lung Cancer (NSCLC)**  
Stages: I B; II; III A CT.GOV ID: NCT02193282  
Primary Investigator: Richard Hall  
CRC: Galina Diakova
- 14-17721 ECOG-ACRIN E4512  
**A Phase III Double-Blind Trial for Surgically Resected Early Stage Non-Small Cell Lung Cancer: Crizotinib versus Placebo for Patients with Tumors Harboring the Anaplastic Lymphoma Kinase (ALK) Fusion Protein**  
Stages: I B; II; III A CT.GOV ID: NCT02201992  
Primary Investigator: Richard Hall  
CRC: Galina Diakova

## Thoracic Oncology

- 15-17857 SWOG S1400  
**Phase II/III Biomarker-Driven Master Protocol for Second Line Therapy of Squamous Cell Lung Cancer**  
Stages: Not specified CT.GOV ID: NCT02154490  
Primary Investigator: Ryan Genzler  
CRC: Galina Diakova
- 15-17921 PHAR M14-360  
**A Phase 1 Dose Escalation and Phase 2 Randomized, Placebo-Controlled Study of the Efficacy and Tolerability of Veliparib in Combination with Paclitaxel/Carboplatin-Based Chemoradiotherapy Followed by Veliparib and Paclitaxel/Carboplatin Consolidation in Subjects with Stage III Non-Small Cell Lung Cancer (NSCLC)**  
Stages: III CT.GOV ID: NCT02412371  
Primary Investigator: James Larner MD  
CRC: Parchayi Dalal
- 15-17991 PHAR MERCK021  
**A Phase I/II Study of MK-3475 (SCH900475) in Combination with Chemotherapy or Immunotherapy in Patients with Locally Advanced or Metastatic Non-Small Cell Lung Carcinoma**  
Stages: Any/all stages CT.GOV ID: NCT02039674  
Primary Investigator: Ryan Genzler  
CRC: Gracie Tubbs
- 15-18173 PHAR LUN288  
**A Phase II Study of the Combination of LY302414 and Nectinmab after First-Line Chemotherapy for Metastatic Squamous Non-small Cell Carcinoma of the Lung**  
Stages: Not specified CT.GOV ID: NCT02443337  
Primary Investigator: Richard Hall  
CRC: Galina Diakova
- 15-18371 PHAR CO-1686-020  
**TIGER-3: A Phase 3, Open-label, Multicenter, Randomized Study of Oral Rociletinib (CO-1686) Monotherapy Versus Single-agent Cytotoxic Chemotherapy in Patients with Mutant EGFR Non-small Cell Lung Cancer (NSCLC) after Failure of at Least 1 Previous EGFR-directed Tyrosine Kinase Inhibitor (TKI) and Platinum-doublet Chemotherapy**  
Stages: Any/all stages CT.GOV ID: NCT02322281  
Primary Investigator: Richard Hall  
CRC: Gracie Tubbs
- 15-18446 PHAR CO-1686-022  
**TIGER 1: A Randomized, Open-label, Phase 2/3 Study of CO-1686 or Erlotinib as First-line Treatment of Patients with EGFR-Mutant Advanced/Metastatic Non-small Cell Lung Cancer (NSCLC)**  
Stages: III; IV CT.GOV ID: NCT02186301  
Primary Investigator: Ryan Genzler  
CRC: Gracie Tubbs

## Transplant

- 14-15670 Non-UVA 10-CBA  
**A multicenter access and distribution protocol for unlicensed cryopreserved cord blood units (CBUs) for transplantation in pediatric and adult patients with hematologic malignancies and other indications**  
Stages: Any/all stages CT.GOV ID: NCT01351545  
Primary Investigator: Tamila Kindwall-Keller DO  
CRC: Andrea Ruhsam BS, BA, CCRC

## Transplant

12-16168 PHAR 6637-01

**A multicenter safety study of unlicensed, investigational cryopreserved cord blood units (CBUs) manufactured by the National Cord Blood Program (NCBP) and provided for unrelated hematopoietic stem cell transplantation of pediatric and adult patients.**

Stages: Not specified CT.GOV ID: NCT01656603  
Primary Investigator: Tamila Kindwall-Keller DO  
CRC: Andrea Ruhsam BS, BA, CCRC

14-17215 UVA single-site MM-CD34

**A Prospective Observational Study of the Association Between CD34+ Cell-Dose Infused in Autologous Stem Cell Transplantation and Engraftment in Multiple Myeloma Patients**

Stages: Not specified CT.GOV ID: Not specified  
Primary Investigator: Tamila Kindwall-Keller DO  
CRC: Adam Schettler

15-17732 PHAR CELLDEX301-03

**A Pilot Study of CDX-301 (rhuFlt3L) with or without Plerixafor for the Mobilization and Transplantation of Allogeneic Blood Cell Grafts in HLA-Matched Donor/Recipient Sibling Pairs**

Stages: Not specified CT.GOV ID: NCT02200380  
Primary Investigator: Tamila Kindwall-Keller DO  
CRC: Andrea Ruhsam BS, BA, CCRC

## Other Oncology Trials

13-16964 UVA single-site STAT-RT-1/2

**A Phase III Single Arm Prospective Single Fraction Real-time Stereotactic Body Radiation Therapy Dose Escalation Trial of Rapid Helical TomoTherapy-based Radiation Therapy for Patients with Painful Osseous Metastatic Disease**

Stages: Any/all stages CT.GOV ID: NCT02145286  
Primary Investigator: Paul Read MD  
CRC: Parchayi Dalal

14-17038 PHAR BM-018

**A Phase IV Post Approval Clinical Study of ExAblate Treatment of Metastatic Bone Tumors for the Palliation of Pain**

Stages: Any/all stages CT.GOV ID: NCT01833806  
Primary Investigator: James Larner MD  
CRC: Parchayi Dalal

15-17576 UVA single-site AG-CDI

**Alanyl-Glutamine Supplementation of Standard Treatment for C. Difficile Infection: A Randomized, Double-Blind, Placebo-Controlled Trial**

Stages: Any/all stages CT.GOV ID: NCT02053350  
Primary Investigator: Cirle Warren  
CRC: Cirle Warren

12-2010017400 UVA single-site CANCER-PATIENT-NAVIGATION

**Cancer Patient Navigation: Training and Intervention Implementation and Evaluation**

Stages: Not specified CT.GOV ID: Not specified  
Primary Investigator: Randy Jones PhD, RN  
CRC: Randy Jones PhD, RN

14-2011017200 UVA single-site P3P-II

**Personal Patient Profile-Prostate II (P3P-II)**

Stages: Not specified CT.GOV ID: Not specified  
Primary Investigator: Randy Jones PhD, RN  
CRC: Elaine Woodson



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Jake	Boyd	434-243-3983		Beverly	Turner	434-982-3948	
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