Merkel Cell Carcinoma Trials

PI	CRC	Protocol #/Title	Mechanism	Primary In/Ex Criteria	Status
Gao	Parvin Keshtmand	**EA6174**/A Phase III Randomized Trial Comparing Adjuvant MK-3475 (Pembrolizumab) To Standard of Care Observation in Completely **Resected Merkel Cell Carcinoma**	Pembrolizumab: Anti PD-1 Immunotherapy versus SOC	**Inclusion:** • Must have a histological confirmation of diagnosis of Merkel cell carcinoma (MCC), pathologic stages (AJCC version 8) I-IIIb • Primary tumor must have negative margins • **Must treat within 112 days of surgical resection** • **RT is allowed if completed 28 days prior to systemic tx or begins within 14 days of systemic tx** **Exclusion:** • Patients with distant metastatic disease (stage IV)	Open to Accrual Accrual: 7/8
Gao	Parvin Keshtmand	**UCI 18-84**/A Multicenter, Randomized, Double-Blinded, Placebo-Controlled, Phase III Trial of Adjuvant Avelumab (anti-PDL-1 Antibody) in Merkel Cell Carcinoma Patients with Clinically Detected Lymph Node Metastases [Orange]	PD-L1 Inhibitor	**Inclusion:** • Histologically confirmed MCC metastases in clinically detected lymph node(s) • Must have completed definitive treatment that included surgical removal of the clinically detected MCC metastases (with/without adjuvant radiation therapy as determined by the treating investigator). • **Must start the study treatment no more than 60 days from the last dose of RT (if administered) and no more than 120 days from the date of surgical removal of nodal metastases.** **Exclusion:** • Clinical or radiologic suspicion of residual MCC at the time of enrollment. • Suspicion or known history of distant metastatic MCC, which is not classifiable as local recurrence or regional metastasis. • Any prior systemic therapy (e.g. adjuvant, neo-adjuvant or concurrent use of chemotherapy, immunotherapy or an investigational agent) for MCC at any time • Any prior intra-lesional MCC therapy within 180 days from Day 1 of study treatment	Open to Accrual Accrual:6/7
Gao	TBD	**UCI 19-105/** A Phase II, Open Label, Multicenter Study to Investigate the Efficacy and Safety of Domatinostat in Combination With Avelumab in Patients with Treatment-Naïve Advanced Merkel Cell Carcinoma		**Inclusion:** • • **Exclusion:** • • •	New Accrual: 0/3

Dorothy Chang x 509-2199
Chang Shim x456-7242
Parvin Keshtmand x 509-2739
Celine Colmenares x 509-2172
Baoan Huynh x 509-6233
Erin Torrison x 456-6210
Keagan Buttigieg x456-7429

Merkel Cell Carcinoma Trials

PI	CRC	Protocol #/Title	Mechanism	Primary In/Ex Criteria	Status
Gao	Parvin Keshtmand	**UCI 19-104**/ A Phase II, Open Label Study to Investigate the Efficacy and Safety of Domatinostat in Combination with Avelumab in Patients with Advanced Unresectable/Metastatic Merkel Cell Carcinoma Refractory or Relapsed to Previous Anti-PD-(L)1 Antibody Therapy		Inclusion: • Progressing on previous anti-PD-(L)1 antibody monotherapy within the last 12 weeks before planned first administration of study medication fulfilling at least one of the following criteria: see protocol. • Pretreatment with avelumab monotherapy (cohort 1) or any anti-PD-1 antibody monotherapy (cohort 2) fulfilling the following minimum exposure criteria: • Anti-PD-(L)1 antibody given Q2W: at least 6 admins within the last 6m, last dose within 3m before planned first admin of study med. • Anti-PD-(L)1 antibody given Q3W: at least 4 administrations within the last 6m, last dose within 3m before planned first administration of study med. • Anti-PD-(L)1 antibody given Q4W: at least 3 admins within the last 6m, last dose within 3m before planned first admin of study med. • Anti-PD-(L)1 antibody given q6w: at least 2 adminis within the last 6m, last dose within 3m before planned first admin of study med. Exclusion: • More than one line of previous systemic anti-neoplastic therapy other than anti-PD-(L)1 antibody monotherapy • History of serious anti-PD-(L)1 therapy-related adverse reactions prohibiting further avelumab treatment: - Pneumonitis: Grade 3 or 4 or recurrent Grade 2 - Hepatitis: AST or ALT more than 5 times the upper limit of	open to accrual Accrual: 0/3

Yamamoto	Parvin Keshtmand	**ETCTN 10057**/ A Phase II Study of Talimogene Laherparepvec Followed by Talimogene Laherparepvec + Nivolumab in Refractory T Cell and NK Cell Lymphomas, Cutaneous Squamous Cell Carcinoma, Merkel Cell Carcinoma, and Other Rare Skin Tumors *Only enrolling to phase II (MCC)*	Tvec: replication in tumor tissue; normal cells are able to protect against talimogene laherparepvec infection as they contain intact anti-viral defense mechanisms. Deletion of ICP47 prevents down-regulation of antigen presentation molecules and increases the expression of HSV US11 gene, which enhances viral replication in tumor cells. GM-CSF recruits and activates antigen presenting cells which can process and present tumor-derived antigens to promote an effector T-cell response.	**Inclusion:** • PD while on or within 6 months of completing prior PD1/ PD-L1 therapy • at least 1 cutaneous, subcutaneous, or nodal lesion that is suitable for intralesional injection, with or without the use of ultrasound • able and willing to undergo serial biopsies of injected lesion **Exclusion:** • Untreated central nervous system (CNS) involvement • Previous treatment with talimogene laherparepvec or other herpes virus based therapy	Suspended Accrual: 1/3 Slot reservation required

Squamous Cell Carcinoma Trials

PI	CRC	Protocol #/Title	Mechanism	Primary In/Ex Criteria	Status
Fruehauf	Parvin Keshtmand	**UCI 20-116**/ A Randomized, Controlled, Open-Label, Phase II Study of Cemiplimab as a single agent and in Combination with RP1 in Patients with Advanced Cutaneous Squamous Cell Carcinoma	•Blockade of the PD-1 Checkpoint with Cemiplimab •RP1 (rHSV-1hGM-CSF/gibbon ape leukemia virus fusogenic glycoprotein [GALV-GP-R-]) is a selectively replication competent (HSV-1). Leads to cell fusion formation in infected tumor cells resulting in the death of the cells by membrane fusion & is intended to enhance the spread of the virus through the tumor.	**Inclusion:** • ≥ 1 measurable lesion + lesion(s) that are injectable, which individually or in aggregate are ≥ 1 cm in longest diameter • For locally advance scc: Surgery + RT must be deemed contraindicated or not appropriate **Exclusion:** • Prior tx w/ an oncolytic therapy • Prior tx w/ an agent that blocks (PD-1)/PD-L1 pathway. •Hx of myocarditis/ chf/ myocardial infarction within 6m of dosing	Open to accrual Accrual: 0/5
Dayyani	Jasmine Balangue x509-2948	**UCI 20-213**/ Phase 1 First-in-Human (FIH) Study of Leukocyte Immunoglobulin-Like Receptor B2 (LILRB2) Inhibitor Monoclonal Antibody (mAb) JTX-8064, as Monotherapy and in Combination with a Programmed Cell Death Receptor-1 (PD-1) Inhibitor, in Adult Subjects with Advanced Refractory Solid Tumor Malignancies	JTX-8064 is a humanized mAb, consisting of 2 identical hinge-stabilized gamma 4 (IgG4, with the S228P mutation) heavy chains and 2 identical kappa (Igκ) light chains, that specifically binds to human LILRB2 and is designed to block the interaction of LILRB2 with its known ligands, endogenous MHC I molecules and non-classical MHC I molecules. **JTX-4014** is a fully human mAb consisting of 2 identical hinge-stabilized gamma 4 (IgG4, S228P) heavy chains and 2 identical kappa (Igκ) light chains that specifically binds to and inhibits PD-1.	Skin cohort: 2L/3L cSCC; Subjects must have progressed on or after treatment with an anti-PD-(L)1 agent in their most recent prior line of therapy	Open to Accrual Accrual: 1/10

Cutaneous Melanoma: Metastatic Unresectable Previously Treated					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Fruehauf	Parvin Keshtmand	**UCI 17-73**/A Sequential 2-arm, Open-label Phase I Study to Evaluate the Effects of Encorafenib in Combination with Binimetinib on the Pharmacokinetics of Losartan, Midazolam, Caffeine, Omeprazole, and Dextromethorphan Administered in a Cocktail Approach an	Encorafenib BRAF kinase inhibitor and Binimetinib-MEK 1 and MEK 2 inhibitor	**Inclusion:** • Histologically confirmed diagnosis of locally advanced, unresectable or metastatic cutaneous melanoma or unknown primary melanoma American Joint Committee on Cancer (AJCC) Stage IIIB, IIIC or IV, or other BRAF V600 mutant advanced solid tumors • Presence of BRAF V600E and/or V600K mutation in tumor tissue • Evidence of measurable or non-measurable lesions (RECIST) • No prior treatment or progressed on or after other prior systemic therapy • Patient with other (non-melanoma) BRAF V600-mutant advanced solid tumors who has progressed on standard therapy or for whom there are no available standard therapies **Exclusion:** • Symptomatic brain metastasis.	Open to Accrual Accrual: 3/5
Moyers	Parvin Keshtmand	**ETCTN 9466**/ Phase I/II Study of Dabrafenib, Trametinib, and Navitoclax in BRAF Mutant Melanoma (Phase I and II) and Other Solid Tumors (Phase I Only) * Our site is only enrolling to phase II*	Navitoclax is a novel small molecule Bcl-2 (B-cell lymphoma-2) family protein inhibitor that binds with high affinity to multiple anti-apoptotic Bcl-2 family proteins including Bcl-XL (inhibition constant [Ki]<0.5 nM), Bcl-2 (Ki<1.0 nM), Bcl-w (Ki<1.0 nM), and Bcl-B (Ki<5.0 nM)	**Inclusion:** • BRAF-mutant (V600E/K) melanoma (molecularly confirmed using validated, commercially available assay performed in a CLIA-approved laboratory) that is metastatic or unresectable and for which standard curative measures do not exist or are no longer effective • Pts can also be tx naive **Exclusion:** • Prior navitoclax, BRAF inhibitor and/or MEK inhibitor therapy • Leptomeningeal or brain metastasis causing spinal cord compression that are symptomatic or untreated or not stable for ≥ 3 months (must be documented by imaging) • Anti-coagulation therapy	Open to accrual Accrual: 1/3
Fruehauf	Parvin Keshtmand	**UCI 20-169**/ A Phase IB, Open-Label, Multicenter Study to Evaluate the Safety, Pharmacokinetics, and Activity of Belvarafenib as a Single Agent and in Combination with Either Cobimetinib or Cobimetinib Plus Atezolizumab in Patients with NRAS-Mutant Advanced Melanoma Who Have Received Anti-PD-1/PD-L1 Therapy		**Inclusion:** • Metastatic or unresectable stage III, previously treated w up to 2 lines of systemic therapy that included anti-PD-1 or anti-PD-L1 therapy (previous tx in adjuvant setting is also permitted) • NRAS mutation positive **Exclusion:** • HIV, HCV, HBV • Prior allogeneic stem cell or solid organ transplantation • Untreated or actively progressing CNS lesions	RA signoff Accrual: 0/5
Valerin	Parvin Keshtmand	**UCI 20-174**/ PVSRIPO with and without Immune Checkpoint Blockade in Advanced PD-1 Refractory Melanoma	PVSRIPO is a recombinant rhinovirus/polio virus chimera that may affect anti-tumor activity through two mechanisms: direct tumor cell killing and induction of a secondary anti-tumor immune response	**Inclusion:** • ≥ 2 measurable lesions (one of which must be injectable: visible or palpable cutaneous, subcutaneous or nodal melanoma lesion) • PD after ≥ 6w of tx w/ anti-PD-1/anti-PD-L1 therapy (including adjuvant tx) or BRAF-targeted therapy (if BRAF+) **Exclusion:** • Ocular melanoma is excluded • Symptomatic, untreated, or actively progressing CNS metastases	Open to Accrual Accrual: 0/5

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Keagan Buttigieg x456-7429

Cutaneous Melanoma: Metastatic Unresectable Previously Treated

PI	CRC	Protocol #/Title	Mechanism	Primary In/Ex Criteria	Status
Valerin	Parvin Keshtmand	**UCI 21-40**/ A Phase I/II, First-in-Human, Multi-Part, Open-Label, Multiple-Ascending Dose Study to Investigate the Safety, Tolerability, Pharmacokinetics, Biological, and Clinical Activity of DF6002 as a Monotherapy and in Combination with Nivolumab in Patients with Locally Advanced or Metastatic Solid Tumors, and Expansion in Selected Indications	DF6002 is a monovalent human interleukin-12 (IL12)-constant fragment (Fc) fusion protein that binds to the IL12 receptor to stimulate interferon gamma (IFN secretion, proliferation of lymphocytes, and cytotoxicity of activated T cells and natural killer cells	**Inclusion:** • Previously tx melanoma, NSCLC, small cell lung, head and neck squamous cell, urothelial, gastric, esophageal, cervical, hepatocellular, Merkel cell, cutaneous squamous cell carcinoma, renal cell, endometrial, triple negative breast cancer (TNBC), ovarian, and prostate cancers • **Exclusion:** • Prior treatment with rhIL2 or with any drug containing an IL2 or IL12 moiety • •	Open to Accrual: 0/3 Slot request required prior to consenting

Cutaneous Melanoma: Resectable

PI	CRC	Protocol #/Title	Mechanism	Primary In/Ex Criteria	Status
Moyers	Parvin Keshtmand	**S1801**/A Phase II Randomized Study of Adjuvant Versus Neoadjuvant MK-3475 (Pembrolizumab) For Clinically Detectable Stage III-IV High Risk Melanoma	anti-PD-1	**Inclusion:** • must have resectable melanoma • must have clinically detectable **Stage III (clinically detectable N1b, N1c, N2b, N2c, N3b and N3c) or Stage IV resectable** melanoma	Open to Accrual Accrual: 3/4

Cutaneous Melanoma: Metastatic Unresectable Not Previously Treated

PI	CRC	Protocol #/Title	Mechanism	Primary In/Ex Criteria	Status
Fruehauf	Parvin Keshtmand	**UCI 18-64**/An Open-Label, Multicenter, Phase I/II Study of RP1 as a Single Agent and in Combination with PD1 Blockade in Patients with Solid Tumors	RP1 is a selectively replication competent HSV-1 Nivolumab	**Inclusion:** • Diagnosis of Stage IIIb-IV melanoma (ocular and mucosal allowed but no more than 10 patients each) **Exclusion:** • Prior treatment with an oncolytic therapy	Open to Acrrual Accrual: 0/5
Moyers	Parvin Keshtmand	**EA6141**/ Randomized Phase II/III Study of Nivolumab Plus Ipilimumab Plus Sargramostim Versus Nivolumab Plus Ipilimumab in Patients With Unresectable Stage III or Stage IV Melanoma	**Ipi:** Blocks the interaction of CTLA4 with the B7 ligand, resulting in a blockade of the inhibitory effect of T-cell activation. **Nivo**: Inhibits the binding of PD-1 to PD-L1 and PD-L2 which promotes immune and antigen-specific T-cell responses to both foreign antigens & self-antigens. **GM-CSF:** Affects the proliferation, differentiation, & activation	**Inclusion:** • Must have a known BRAF mutational status (WT or mutated) **Exclusion:** • Prior tx w/ PD1 or PD-L1 in the adjuvant or metastatic setting • Prior tx w/ ipilimumab in the metastatic setting • Active CNS mets • HIV + • Concurrent anti-coagulant therapy	Open to Accrual Accrual: 0/2

Cutaneous Melanoma: Metastatic Unresectable Not Previously Treated

PI	CRC	Protocol #/Title	Mechanism	Primary In/Ex Criteria	Status
Fruehauf	Parvin Keshtmand	**UCI 19-140**/ A Randomized Phase II, Open-Label, Active-Controlled, Multicenter Study Investigating the Efficacy and Safety of UV1 Vaccination in Combination with Nivolumab and Ipilimumab as First-line Treatment of Patients with Unresectable or Metastatic Melanoma (UV1-202)	UV1 is a therapeutic cancer vaccine consisting of 3 synthetically-produced peptides covering an epitope rich sequence within the active site of the human telomerase reverse transcriptase (hTERT). The mode of action of UV1 is to activate the immune system to induce T cells that recognize hTERT. The efficacy of the vaccine is thought to be mediated through these T cells.	**Inclusion:** - Histologically confirmed diagnosis of unresectable stage IIIB-D or unresectable stage IV malignant melanoma. Patient must have at least 1 measurable lesion at Screening according to the RECIST 1.1 criteria. - ECOG ps of 0 or 1 - Eligible for combination treatment with nivolumab and ipilimumab **Exclusion:** - Known brain metastases or leptomeningeal metastases. - Uveal or ocular melanoma - History of New York Heart Association class 3-4 congestive heart failure or history of MI within 6 months of starting study treatment - Known history of human immunodeficiency virus (HIV) (HIV 1/2 antibodies) - History of or active hepatitis B (hepatitis B surface antigen reactive) or active hepatitis C (hepatitis C virus antibody) - Prior systemic treatment for unresectable stage IIIB-D or unresectable stage IV malignant melanoma. Prior systemic BRAF/MEK inhibitors or immunotherapy as neoadjuvant or adjuvant or other setting treatment of stage I-IIIA, resectable IIIB-D, or resectable IV if patient progressed earlier than 6 months after last dose of such treatment	Open to Accrual Accrual: 1/7

Adjuvant Melanoma					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Fruehauf	Baoan Huynh	**UCI 20-57**/ A Phase III, Randomized, Open-Label Study of Adjuvant Immunotherapy with Bempegaldesleukin Combined with Nivolumab versus Nivolumab after Complete Resection of Melanoma in Participants at High Risk for Recurrence (PIVOT-12)	Bempegaldesleukin (NKTR-214) is a prodrug of a conjugated cancer immunotherapy cytokine that exerts its biological activity by binding to the IL-2 receptor and subsequent activation of effector T cells.	**Inclusion:** • Stage IIIA (LN metastasis > 1 mm [i.e., at least one LN metastasis measuring > 1 mm at greatest diameter]), IIIB/C/D, or IV (M1a/b/c/d) cutaneous melanoma by AJCC (8th edition) at study entry that has been completely surgically resected within 12 weeks prior to randomization. • Have PD-L1 expression classification (≥ 1%, < 1%, indeterminate, or not evaluable) prior to randomization (by central lab review). • Documented left ventricular ejection fraction (LVEF) > 45% **Exclusion:** • History of ocular/uveal melanoma or mucosal melanoma • Prior tx w/ interferon, talimogene laherparepvec (Imylgic®), IL-2 directed therapy, anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137, or anti-CTLA-4 antibody (including ipilimumab or any other antibody or drug specifically targeting T cell co-stimulation or checkpoint pathways). • Need for > 2 antihypertensive medications for management of hypertension (including diuretics). • HCV, HBV, HIV positive • History of leptomeningeal disease	Open to Accrual Accrual: 7/9

Miscellaneous & Phase 1 Clinical Trials					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Bota	Celine Colmenares	**UCI 19-38**/ A Phase IA/IB, Open-Label First-in-Human Study of the Safety, Tolerability, and Feasibility of Gene-Edited AUtologous NeoTCR-T Cells (NeoTCR-P1) Administered as a Single Agent or in Combination with Anti-PD-1 to Patients with Locally Advanced or Metastatic Solid Tumors	NeoTCR-P1 and anti-PD-1	•M1) Unresectable stage III or metastatic melanoma not amenable to local therapy •M2) Participants may not have a diagnosis of uveal or ocular melanoma. •M3) Prior treatment with pembrolizumab, nivolumab, or other approved anti-PD-1 or anti-PD-L1 agents. • Participants who received adjuvant PD-1 therapy who then develop measurable dx within 6 months of their last dose of PD-1 blockade are eligible and not required to receive PD-1 in the metastatic setting	Open to Accrual Accrual: 3/25
Ou	Keagan Buttigieg x456-7429	**UCI 19-64**/ A Phase I/II Study of MCLA-128, a full length IgG1 Bispecific Antibody Targeting HER2 and HER3, in Patients with Solid Tumors	MCLA-128 inhibits phosphorylation of HER3 and the downstream serine/threonine kinase Akt, inhibits HER2:HER3 dimerization, shows ADCC activity independent of FcγR receptor phenotype, and lacks CDC activity.	**Inclusion:** • At least one measurable lesion • Able to provide baseline mandatory tumor biopsy • Must have received prior standard therapy approprite for their tumor type and stage of disease, or would be unlikely to tolerate or derive clinically meaningful benefit from appropriate SOC therapy • Locally-advanced unresectable or metastatic solid tumor malignancy with documented NRG1 gene fusion, identified through molecular assays **Exclusion:** Symptomatic or unstable brain mets leptomeningeal mets NYHA Class III or IV congestive heart failure or LVEF <50% or history of significant cardiac disease, unstable angina, congestive heart failure,	Open to Accrual Accrual: 4/7

Skin Cancers: Epidemiologic/Correlative					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Meyskens	Meyskens	**UCI 09-17**/Biology of Human Melanocytes and Keratinocytes [UCIMC]	N/A	• Male babies • Foreskin available	Open to Accrual Accrual: 700/800
Yamamoto	Jennifer Chen	**UCI 15-40**/Prospective and Retrospective Study of Outcomes for Patients with Malignant Melanoma [UCIMC]	N/A	• Suspected or biopsy proven cutaneous melanoma • Exclusion: Patients whose final pathologic diagnosis does not reveal melanoma	Open to Accrual Accrual: 383/5000
Skin Cancers: Screening/Diagnostic					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Nam	Mashal Chhotani x509-2946	**NCICOVID**/ COVID-19 in Cancer Patients Study (N-CCaPS): A Longitudinal Natural History Study	N/A	**Inclusion:** • Previous COVID-19 diagnosis • Pts must be actively undergoing cancer treatment (chemotherapy, targeted therapy, immunotherapy, and/or radiation therapy) or follow-up care after treatment that requires them to regularly visit UCI Health (Orange or Newport)	Open to enrollment Accrual: 9/25
Kelly	Ata Sharif	**UCI 11-30**/Skin Imaging with Technologies in Development [Irvine]	N/A	**Inclusion:** • Age > 7 • Pt able to carry out study instructions	Open to Accrual Accrual: 540/750
Kelly	Ata Sharif & Mihaela Balu	**UCI 13-13**/Pilot study on in-vivo non-invasive skin imaging using multiphoton microscopy and multispectral imaging [Irvine]	N/A	**Inclusion:** • Age > 45 • Female • Skin type scale I to III **Exclusion:** • History of skin cancer, including squamous or basal cell carcinoma at the treatment site or history of malignant melanoma • Large amount of dark, coarse hair on the arms	Open to Accrual Accrual: 201/250
Yamamoto	Jennifer Chen	**UCI 19-135**/DecisionDx-Melanoma Impact on Sentinel Lymph Node Biopsy Decisions and Clinical Outcomes (DECIDE) [UCIMC and Irvine]	Patients who have newly diagnosed invasive cutaneous melanoma, are being considered for sentinel lymph node biopsy, and are undergoing DecisionDx-Melanoma GEP testing to inform this decision.	**Inclusion:** • Invasive cutaneous melanoma diagnosed within past 2 months • Being tested with the DecisionDx-Melanoma 31-GEP test as part of their clinical care • Pts being considered for sentinel lymph node biopsy **Exclusion:** • Stage lll or IV disease • Exclusion: Patients with a melanoma diagnosed in the same anatomical region in the last 5 years	Open to Accrual Accrual: 22/40

Dorothy Chang x 509-2199
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Skin Cancers: Screening/Diagnostic					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Linden	Jennifer Chen	**UCI 14-05**/ (mAID) Multicenter Diagnostic Imaging Study for the Melanoma Advanced Imaging Dermatoscope [UCIMC and Irvine]	The Melanoma Advanced Imaging Dermatoscope (mAID) manufactured RGB hyperspectral imaging of the lesion in 21 different colors	**Inclusion:** • Age > 18 • Normal appearing skin and a suspicious pigmented lesion **Exclusion:** • Self-reported history of photosensitivity • Self-reported history of vitiligo and/or other sun sensitive disease • Inaccessibility to lesion related to device: ears, toes, fingers, nailbeds, ankles, elbows	Suspended Accrual: 106/120
Yamamoto	TBD	**UCI 21-106**/ A Phase II Open-Label, Dose-Finding Study to Determine the Optimal Dose for Lymph Node Visualization Using ASP5354 in Participants with Breast Cancer or Melanoma Undergoing Sentinel Lymph Node Biopsy		**Inclusion:** • • • **Exclusion:** • •	PRMC approval Accrual: 0/20
Other					
PI	**CRC**	**Protocol #/Title**	**Mechanism**	**Primary In/Ex Criteria**	**Status**
Jakowatz	Erin Torrison	**UCI 21-35**/Outcomes of Cutaneous Melanoma Patients Clinically Tested DecisionDx - Melanoma (CONNECTION)		**Inclusion:** • Patients clinically tested with DecisionDx®-Melanoma between January 1, 2013 and December 31, 2017 • • **Exclusion:** • •	Open to Accrual Accrual: 0/56