

**Questions? 800-78-CANCER, 909-558-CANCER, or 909-558-4050**  
**Adult Open Studies**

**Biology**

LLUC-BIOSPECIMEN  
LABORATORY - SPECIMEN  
COLLECTION

Loma Linda University Cancer Center Biospecimen Laboratory Specimen Collection  
Protocol

C.S. Chen, M.D., Ph.D.

Radiation Medicine

Cytogenetic damage as a biomarker of radiation sensitivity in prostate cancer

Marcelo Vasquez, MD, PhD

**Breast**

SWOG-S1007

A Phase III, Randomized Clinical Trial of Standard Adjuvant Endocrine Therapy +/- Chemotherapy in Patients with 1-3 Positive Nodes, Hormone Receptor-Positive and HER-2 Negative Breast Cancer with Recurrence Score (RS) of 25 or Less. RxPONDER: A Clinical Trial Rx for Positive Node, Endocrine Responsive Breast Cancer  
<http://www.clinicaltrials.gov/ct2/show/NCT01272037>

Gayathri Nagaraj, M.D.

SWOG-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  
<http://www.clinicaltrials.gov/ct2/show/NCT01674140>

Gayathri Nagaraj, M.D.

SWOG-A011106

ALTERNate approaches for clinical stage II or III Estrogen Receptor positive breast cancer NeoAdjuvant TrEatment (ALTERNATE) in postmenopausal women: A Phase III Study  
<https://clinicaltrials.gov/ct2/show/NCT01953588>

Gayathri Nagaraj, M.D.

NSABP-B52

A Randomized Phase III Trial Evaluating Pathologic Complete Response Rates in Patients with Hormone Receptor-Positive, HER2-Positive, Large Operable and Locally Advanced Breast Cancer Treated with Neoadjuvant Therapy of Docetaxel, Carboplatin, Trastuzumab, and Pertuzumab (TCHP) with or Without Estrogen Deprivation  
<https://clinicaltrials.gov/ct2/show/NCT02003209>

Gayathri Nagaraj, M.D.

SWOG-A011202

A Randomized Phase III Trial Comparing Axillary Lymph Node Dissection to Axillary Radiation in Breast Cancer Patients (cT1-3 N1) Who Have Positive Sentinel Lymph Node Disease After Neoadjuvant Chemotherapy  
<https://clinicaltrials.gov/ct2/show/NCT01901094>

Sharon Lum, M.D.

**GI**  
**Colon**

SWOG-S0820

A Double Blind Placebo-Controlled Trial of Eflornithine and Sulindac to Prevent Recurrence of High Risk Adenomas and Second Primary Colorectal Cancers in Patients with Stage 0-III Colon Cancer, Phase III - Preventing Adenomas of the Colon with Eflornithine and Sulindac (PACES)  
<http://www.clinicaltrials.gov/ct2/show/NCT01349881>

Chung-Tsen Hsueh, M.D., Ph.D.

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**GI**  
**Esophagus**

Radiation Medicine	A phase II trial of proton-chemotherapy (PCT) for resectable esophageal or esophagogastric junction cancer <a href="https://clinicaltrials.gov/ct2/show/NCT01684904">https://clinicaltrials.gov/ct2/show/NCT01684904</a>	<a href="#">Gary Yang, MD</a>
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**GI**  
**Liver**

Radiation Medicine	Randomized controlled trial of transarterial chemoembolization versus proton beam radiotherapy for the treatment of hepatocellular carcinoma <a href="https://clinicaltrials.gov/ct2/show/NCT00857805">https://clinicaltrials.gov/ct2/show/NCT00857805</a>	<a href="#">David Bush, MD &amp; Michael De Vera, MD</a>
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Radiation Medicine	Randomized controlled trial of proton beam radiotherapy plus Sorafenib vs Sorafenib for patients with hepato-cellular carcinoma exceeding San Francisco criteria <a href="https://clinicaltrials.gov/ct2/show/NCT01141478">https://clinicaltrials.gov/ct2/show/NCT01141478</a>	<a href="#">David Bush, MD &amp; Michael De Vera, MD</a>
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Radiation Medicine	Phase I/II Trial of Stereotactic Body Proton Therapy (SBPT) for Patients with Liver Metastases <a href="https://clinicaltrials.gov/ct2/show/NCT01697371">https://clinicaltrials.gov/ct2/show/NCT01697371</a>	<a href="#">Gary Yang, MD</a>
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**GI**  
**Pancreas**

Radiation Medicine	A phase II trial of gemcitabine and erlotinib (GB) plus proton-chemotherapy (PCT) and capox for locally advanced pancreatic cancer (LAPC) <a href="https://clinicaltrials.gov/ct2/show/NCT01683422">https://clinicaltrials.gov/ct2/show/NCT01683422</a>	<a href="#">Gary Yang, MD</a>
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**GU**  
**Prostate**

SWOG-S1216	A Phase III Randomized Trial Comparing Androgen Deprivation Therapy + TAK-700 with Androgen Deprivation Therapy + Bicalutamide in Patients with Newly Diagnosed Metastatic Hormone Sensitive Prostate Cancer <a href="http://www.clinicaltrials.gov/ct2/show/NCT01809691">http://www.clinicaltrials.gov/ct2/show/NCT01809691</a>	<a href="#">C.S. Chen, M.D., Ph.D.</a>
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Radiation Medicine	Phase I-II trial of hypofractionated conformal proton beam radiation therapy for favorable-risk prostate Cancer <a href="https://clinicaltrials.gov/ct2/show/NCT00831623">https://clinicaltrials.gov/ct2/show/NCT00831623</a>	<a href="#">Jerry D. Slater, MD</a>
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**Adult Open Studies**

**Dermatologic Toxicities**

SWOG-S1013	A Prospective Study of Epidermal Growth Factor Receptor (HER-1/EGFR) Inhibitor-Induced Dermatologic Toxicity: Validation of the Functional Assessment of Cancer Therapy - EGFR18 (FACT-EGFR18) Questionnaire for EGFR-Induced Skin Toxicities <a href="http://www.clinicaltrials.gov/ct2/show/NCT01416688">http://www.clinicaltrials.gov/ct2/show/NCT01416688</a>	<a href="#"><u>Hamid Mirshahidi, M.D.</u></a>
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**GYN**

GOG-0277	A Phase III Randomized Trial of Gemcitabine (NSC # 613327) plus Docetaxel (NSC # 628503) followed by Doxorubicin (NSC # 123127) versus Observation for Uterus-Limited, High-Grade Uterine Leiomyosarcoma <a href="http://clinicaltrials.gov/ct2/show/NCT01533207">http://clinicaltrials.gov/ct2/show/NCT01533207</a>	<a href="#"><u>Yevgeniya Ioffe, M.D.</u></a>
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GOG-0275	A Phase III Randomized Trial of Pulse Actinomycin-D versus Multi-Day Methotrexate for The Treatment of Low-Risk Gestational Trophoblastic Neoplasia <a href="https://clinicaltrials.gov/ct2/show/NCT01535053">https://clinicaltrials.gov/ct2/show/NCT01535053</a>	<a href="#"><u>Yevgeniya Ioffe, M.D.</u></a>
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GOG-0263	Randomized Phase III Clinical Trial of Adjuvant Radiation Versus Chemoradiation in Intermediate Risk, Stage I/IIA Cervical Cancer Treated with Initial Radical Hysterectomy and Pelvic Lymphadenectomy <a href="https://clinicaltrials.gov/ct2/show/NCT01101451">https://clinicaltrials.gov/ct2/show/NCT01101451</a>	<a href="#"><u>Yevgeniya Ioffe, M.D.</u></a>
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**Lung**

CALGB-140503	A Phase III Randomized Trial of Lobectomy versus Sublobar Resection for Small (d2 cm) Peripheral Non-Small Cell Lung Cancer <a href="http://www.clinicaltrials.gov/ct2/show/NCT00499330">http://www.clinicaltrials.gov/ct2/show/NCT00499330</a>	<a href="#"><u>Jason Wallen, M.D.</u></a>
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CALGB-30901	Randomized Phase II Study of Maintenance Pemetrexed versus Observation for Patients with Malignant Pleural Mesothelioma Without Progression After First-line Chemotherapy <a href="http://www.clinicaltrials.gov/ct2/show/NCT01085630">http://www.clinicaltrials.gov/ct2/show/NCT01085630</a>	<a href="#"><u>Hamid Mirshahidi, M.D.</u></a>
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SYNTA-9090-14	A Randomized, Phase 3 Study of Ganetespib in Combination with Docetaxel versus Docetaxel Alone in Patients with Advanced Non-Small-Cell Lung Adenocarcinoma <a href="https://clinicaltrials.gov/ct2/show/NCT01798485">https://clinicaltrials.gov/ct2/show/NCT01798485</a>	<a href="#"><u>Hamid Mirshahidi, M.D.</u></a>
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SWOG-S1400	Phase II/III Biomarker-Driven Master Protocol for Second Line Therapy of Squamous Cell Lung Cancer <a href="http://clinicaltrials.gov/ct2/show/NCT02154490">http://clinicaltrials.gov/ct2/show/NCT02154490</a> ***Sub-Study E only is permanently closed to enrollment effective 11/25/14	<a href="#"><u>Hamid Mirshahidi, M.D.</u></a>
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SWOG-A151216	Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST) <a href="https://clinicaltrials.gov/ct2/show/NCT02194738">https://clinicaltrials.gov/ct2/show/NCT02194738</a>	<a href="#"><u>Hamid Mirshahidi, M.D.</u></a>
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**Adult Open Studies**

SWOG-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) <a href="https://clinicaltrials.gov/ct2/show/NCT02194738">https://clinicaltrials.gov/ct2/show/NCT02194738</a>	<u>Hamid Mirshahidi, M.D.</u>
SWOG-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 <a href="https://clinicaltrials.gov/ct2/show/NCT02201992">https://clinicaltrials.gov/ct2/show/NCT02201992</a>	<u>Hamid Mirshahidi, M.D.</u>
AstraZeneca-D5160C00003	A Phase III, Open Label, Randomized Study of AZD9291 versus Platinum-Based Doublet Chemotherapy for Patients with Locally Advanced or Metastatic Non-Small Cell Lung Cancer whose Disease has Progressed with Previous Epidermal Growth Factor Receptor Tyrosine Kinase Inhibitor Therapy and whose Tumours harbour a T790M mutation within the Epidermal Growth Factor Receptor Gene (AURA3) <a href="https://clinicaltrials.gov/ct2/show/NCT02151981">https://clinicaltrials.gov/ct2/show/NCT02151981</a>	<u>Hamid Mirshahidi, M.D.</u>
Eli Lilly & Co-I3Y-MC-JPBK	JUNIPER: A Randomized Phase 3 Study of Abemaciclib plus Best Supportive Care versus Erlotinib plus Best Supportive Care in Patients with Stage IV NSCLC with a Detectable KRAS Mutation Who Have Progressed After Platinum-Based Chemotherapy <a href="https://clinicaltrials.gov/ct2/show/NCT02152631">https://clinicaltrials.gov/ct2/show/NCT02152631</a>	<u>Hamid Mirshahidi, M.D.</u>
Novartis-CLDK378A2112	A multi-center, randomized open label study to assess the systemic exposure, efficacy, and safety of 450 mg ceritinib taken with a low-fat meal and 600 mg ceritinib taken with a low-fat meal as compared with that of 750 mg ceritinib taken in the fasted state in adult patients with ALK rearranged (ALK-positive) metastatic non-small cell lung cancer (NSCLC) <a href="https://clinicaltrials.gov/ct2/show/NCT02299505">https://clinicaltrials.gov/ct2/show/NCT02299505</a>	<u>Hamid Mirshahidi, M.D.</u>

**Lymphoma**

SWOG-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 <a href="http://clinicaltrials.gov/ct2/show/NCT01856192">http://clinicaltrials.gov/ct2/show/NCT01856192</a>	<u>C.S. Chen, M.D., Ph.D.</u>
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**Melanoma**

SWOG-S1320	A Randomized Phase II Trial of Intermittent Versus Continuous Dosing of Dabrafenib (NSC-763760) and Trametinib (NSC-763093) in BRAFV600E/K Mutant Melanoma <a href="http://clinicaltrials.gov/ct2/show/NCT02196181">http://clinicaltrials.gov/ct2/show/NCT02196181</a>	<u>Frank D. Howard, IV, M.D., Ph.D.</u>
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**Multiple**

BCT-BCT-100-005	Recombinant Human Arginase 1 (rhArg1) in Patients with Advanced, Arginine Auxotrophic Solid Tumors: Dose Escalation, Safety, and PK/PD <a href="https://clinicaltrials.gov/ct2/show/NCT02285101">https://clinicaltrials.gov/ct2/show/NCT02285101</a>	<u>C.S. Chen, M.D., Ph.D.</u>
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**Soft Tissue Sarcoma**

Radiation Medicine

A phase II study of preoperative proton therapy in soft tissue sarcomas of the extremities and body wall  
<https://clinicaltrials.gov/ct2/show/NCT01819831>

Gary Yang, MD

**Registry**

Radiation Medicine

Radiation Medicine Patient Registry  
<https://clinicaltrials.gov/ct2/show/NCT02436941>

Jerry D. Slater, MD