Welcome to the Fall 2012 issue of the Stanford Cancer Institute Clinical Research Newsletter! This quarterly publication is designed to inform our colleagues in the medical community, and especially physicians who are considering treatment options for their patients with cancer, about current clinical trials and research studies available at the Stanford Cancer Institute. Many of these trials provide access to novel therapies including new “targeted” agents, often not available in the community.

As the leader of the Stanford Cancer Genetics Program, I am pleased to introduce this special issue that presents information about clinical and translational research in Cancer Genetics, Women’s Cancers, and Urologic Oncology, as well as provides information about the genetic counseling, genetic testing, and cancer risk assessment and reduction services available at Stanford. This issue also introduces two new faculty clinicians who have recently joined Stanford in leadership positions. Eila Skinner, MD, is the new chair of the Department of Urology and leader of our Urologic Oncology Program. Dr. Skinner is a surgeon with expertise in urology and bladder cancer. Mark Pegram, MD, is our new director of the Breast Oncology Program. Dr. Pegram is a renowned breast medical oncologist and researcher who played a major role in the development of Herceptin.

The Stanford Women’s Cancer Center staff consists of a closely coordinated team of experts focused on eliminating breast and gynecologic cancers. Clinical trial offerings include combined modality treatment with advanced surgical and imaging techniques, as well as vaccines. In addition to cancer treatment and clinical trial offerings, the Stanford Women’s Cancer Center offers supportive services including on-site social services, psychological counseling and nutritional counseling.

The Urologic Oncology Program features cutting-edge clinical studies and treatment expertise for complex cancers of the prostate, kidney, bladder, and testis. Stanford offers minimally invasive laparoscopic and robotic surgery including nerve-sparing prostatectomy and cystectomy, and complex nephrectomy. The article highlights the scientific advances achieved by this program as well as its currently available clinical trials.

Each of the profiled disease programs offers weekly Tumor Boards. These provide an ideal mechanism to present challenging cases and discuss treatment options with all relevant subspecialists.

We hope that you will consider Stanford Cancer Institute for your patients who might be appropriate for clinical trials, multidisciplinary consultation, or genetic testing for inherited cancers. We, in turn, will make every effort to deliver great care to your patient, keep you informed of the patient’s treatment and response, and if clinical trial treatment is not appropriate for your patient, return them to your care.

James Ford, MD
Associate Professor of Medicine (Oncology) and Genetics
Director, Stanford Cancer Genetics Program
Established in 2000 as one of the first dedicated cancer genetics clinics on the West Coast, the Stanford Cancer Genetics Program is committed to detecting familial risk for cancer before the disease is diagnosed and becomes difficult to treat. With this focus, the Program concentrates on clinical and translational research of inherited cancer syndromes, genetic counseling and testing, and cancer risk assessment and reduction for patients with hereditary cancer syndromes. In addition, the Program provides educational outreach to health care professionals and the public.

The Stanford Cancer Genetics Program is led by James Ford, MD, Associate Professor of Medicine and Genetics, in the Division of Oncology. Faculty members include Allison Kurian, MD, MSc, Assistant Professor of Medicine and of Health Research and Policy, in the Divisions of Oncology and Epidemiology, who focuses on hereditary breast and ovarian cancers, and Uri Ladabaum, MD, MS, Associate Professor of Medicine, in the Division of Gastroenterology, who focuses on hereditary GI cancers. Staff includes three full-time certified genetic counselors, a program manager, and a research assistant.

CANCER GENETICS RESEARCH
The Stanford Cancer Genetics Program seeks to pinpoint genetic risks for hereditary cancer, create personalized cancer prevention, screening, and treatment strategies, and apply advances in personalized genomics to cancer prevention and treatment. Research features:

• Development of clinical protocols for the early detection and prevention of hereditary cancers. For example, the Program has a multidisciplinary clinical protocol for genetic testing, screening, and prophylactic surgery for Hereditary Diffuse Gastric Cancer caused by CDH1 mutations, and has become the primary referral center for this rare disorder in the US.

• Clinical trials and early adopters of breast MRI for early detection of breast cancer in women at high genetic risk.

• Major research efforts involving the study of individuals and families with hereditary BRCA1/2 mutations. For example, using the unique populations in California, the Program has modeled breast cancer genetic risk due to BRCA1/2 mutations across different racial/ethnic groups and tested these using collaborations with the Breast Cancer Family Registry (BCFR), and Hong Kong Breast Cancer Registry.

• Creation of the “Decision Tool for Women with BRCA Mutations,” a decision analysis and outcomes tool to predict survival of women with BRCA1/2 mutations based on various screening and prophylaxis interventions. This instrument was built and translated into a publicly available user-friendly website that has quickly gained wide use among cancer genetics professionals and patients to inform their clinical management. (To access this site, please visit brcatool.stanford.edu.)

• Translation of the Program’s laboratory expertise in DNA repair mechanisms into therapeutic trials of novel agents including poly (ADP-ribose) polymerase (PARP) inhibitors for triple-negative breast cancer, familial pancreatic cancers, and other tumors.

• The first large neoadjuvant trial of defective DNA repair directed chemotherapy in BRCA1/2 carriers with newly diagnosed breast cancer. This study demonstrated a remarkable clinical response rate.

• Use of ovarian tissue for studies of cancer risk and progression. The Program procures these specimens from 40-60 BRCA1/2 mutation carriers per year who undergo risk-reducing bilateral salpingo-oopherectomies (RRSO), and is currently planning a study of chemoprevention in this cohort of women using a PARP inhibitor and measuring tissue changes in these prophylactic ovarian resections.
• Examination of cost-benefit regarding medical outcomes and financial cost to “universal” screening of all resected colorectal and endometrial cancers for Lynch syndrome associated pathological changes (MSI), regardless of family history.

• Commitment to using advances in next-generation DNA sequencing to identify novel risk alleles and risk modifying variants in the germline of individuals and families with elevated cancer risk profiles. The Program has initiated numerous projects to sequence DNA from potentially informative families, as well as cohorts of patients to better define risk estimates based on identified SNPs.

• Application of genomics to tumor biology to provide personalized approach to targeted therapeutics.

CANCER GENETICS PROGRAM CLINIC FEATURES
The Program sees 600 to 700 new patients each year. Many Program patients have a family history of cancer, including breast, ovarian, colorectal, gastric, pancreatic, endometrial, and others. More than half the patients are considered for genetic testing for Breast/Ovarian Cancer Syndrome (BRCA1 and BRCA2 genes) or Lynch Syndrome (hereditary colorectal cancer caused by mutations in DNA mismatch repair genes).

Genetic Counseling and Testing Services for Those with Risk of Inherited Cancer include:

• Risk Assessment. Encompasses a complete personal and family medical history, including risk for cancer as well as possible predisposition for carrying a cancer gene. In individuals with a strong family cancer history, a major inherited cancer predisposition gene may be responsible. The characteristics of genetic cancers include: 1) diagnosis at an early age, 2) bilateral or multiple tumors, and 3) multiple generations affected on the same side of the family.

• Genetic Counseling. Specially trained genetic counselors provide:
  – Education regarding cancer susceptibility, risk assessment, and genetic testing.
  – Non-directive assistance with decision making.
  – Support in identifying and coping with the psychological and social concerns related to an increased cancer risk.
  – Discussion of the familial implications of hereditary cancers.

Genetic Testing and Results. If genetic testing is pursued, a second session will be scheduled to discuss results and plan management strategies. Genetic risks for other family members can be reassessed.

• Risk Reduction. Depending on personal and family medical history, the type of cancer in question and any applicable genetic test results, the clinic’s genetic oncology specialists offer options and recommendations for surveillance, preventative treatments, screening tests, and procedures. Options may include intensive monitoring, medications, or surgery. If appropriate, participation in research protocols and clinical trials will be offered.

• Psychological Support. Genetic cancer risks pose complex personal and family issues. Coping with the diagnosis of cancer or the potential risk of cancer is a major psychological challenge. With this in mind, the clinic staff may arrange referrals to professional counseling services and support groups.

CURRENT STUDIES INCLUDE:

**Breast Cancer**

• Genetic Studies of Blood and Tumor Samples from Patients with High Inherited Cancer Risk

• Measuring Real-World Breast Cancer Outcomes: The Oncoshare Project

• Developing a Decision Tool for Women with BRCA 1/2 Mutations

• Treatments and Outcomes of Women with BRCA1/2 Variants of Uncertain Significance

• The Comparative Effectiveness of Emerging Diagnostic Technologies in Breast Cancer Care

**Gastrointestinal Cancer**

• Molecular Genetic and Pathological Studies of Colorectal Tumors and Blood Samples (COR0005)

• The Gastric Cancer Foundation: A Gastric Cancer Registry (GI0005)

• Clinical & Pathological Studies of Upper Gastrointestinal Carcinoma (GIUPR0001)

**Other**

• Molecular Genetic Studies of Childhood Cancer and Blood Samples

• Stanford Cancer Genetics Database Study

  • highlighted studies are Stanford investigator initiated
As part of the Stanford Women’s Cancer Center, the Stanford Breast Oncology Program provides an array of innovative studies and treatment by a team of researchers and specialists whose expertise spans all breast cancer related disciplines and who test new treatments not yet available at other facilities. The Program conducts studies on a wide variety of promising new agents and procedures. Advanced imaging techniques, accelerated partial breast irradiation (APBI) including intra-operative radiation therapy (IORT) and 3D conformal radiation therapy are available. The Stanford Breast Oncology Program is a national leader in the evaluation of targeted therapy of triple negative breast cancer.

RENOWNED SCHOLAR AND CLINICIAN JOINS PROGRAM AS DIRECTOR

The Program is now led by Mark Pegram, MD, Professor of Medicine (Oncology) at the Stanford University Medical Center, who, in February this year, became the Program’s first director at the new Stanford Women’s Cancer Center; and co-leader of the Molecular Therapeutics Program, along with Stanford Cancer Institute member Amato Giaccia, PhD. A renowned clinician and scholar in breast cancer research and a leader in translational medicine, Dr. Pegram joined Stanford after five years at the University of Miami Miller School of Medicine, where he was a Sylvester Chair Professor of Medicine in the Braman Family Breast Cancer Institute and Associate Director for Clinical Research in the University’s Sylvester Comprehensive Cancer Center. In addition, while on the faculty of UCLA, he played a major role in the development of the drug Herceptin for the treatment of HER-2-positive breast cancer, which contributes to about 20 percent of all breast cancer cases.

STANFORD BREAST CANCER RESEARCH BREAKTHROUGHS

- DNA microarray technology that enabled Stanford Cancer Center investigators to use miniscule quantities of tumor tissue to classify breast cancers on a genetic basis. Stanford scientists are developing genomic signatures to better classify tumors as low or high risk and thus more accurately match patients to the right treatment.

- The MagSweeper, an automated device developed at Stanford that isolates and purifies cancer cells from blood with higher capture rates and purity than had been previously possible with commercial technology. Used to study the genetic profiles of circulating cancer cells, this invention is the result of the collaboration of Stanford physicians and basic scientists.

- Cancer stem cell research that analyzes and will ultimately target cancer stem cells. Working with breast cancer stem cells, Stanford scientists have found 186 genes that, together, predict the risk of recurrence in breast cancer patients.
Evaluation of improved visualization techniques for finding cancers in dense breast tissue, including ultrasound elastography.

National leader in evaluation of targeted therapy of triple negative breast cancer.

HIGHLIGHTS OF THE BREAST CANCER ONCOLOGY PROGRAM

- A multi-disciplinary tumor board that includes medical, radiation, and surgical oncologists, as well as dedicated breast radiologists, pathologists, cancer geneticists, nurses, social workers, and psychologists. This weekly tumor board of experts provides a thorough and collaborative review of patient records, radiographs, and pathology results, and discusses recommendations with the patient and family members on site.

- Advanced imaging capabilities, including non-contrast MRI.

- Accelerated, partial breast irradiation (APBI) including intra-operative radiation therapy (IORT) and 3D conformal radiation therapy.

- Poly (ADP-ribose) polymerase (PARP) inhibitors and immunotherapies.

- Breast reconstruction with innovative techniques, including transverse rectus abdominis myocutaneous (TRAM), deep inferior epigastric perforators (DIEP), and other specialized free-flaps that offer an alternative to patients who want options beyond implants.

- A wide array of supportive services, including help in overcoming sexual side effects and changes in body image; and collaborative programs with the Stanford Center for Integrative Medicine that explore the mind-body connection, combining complementary treatments such as meditation and acupuncture with traditional medical treatments.

CURRENT STUDIES INCLUDE:

Neoadjuvant Therapy

- Vitamin D and Breast Cancer: Does Weight Make a Difference? (BRSADJ0024)

- A Phase I Pharmacokinetic and Randomized Phase II Trial of Neoadjuvant Treatment with Anastrozole plus AZD0530 in Postmenopausal Patients with Hormone Receptor Positive Breast Cancer (BRSADJ0025) (SOON TO OPEN)
Clinical Research Newsletter for Colleagues in the Community

Stanford Breast Oncology Program continued

- A Phase II, Multi-Center, Open-Label, Neoadjuvant, Randomized Study of Weekly Paclitaxel with or without LCL161 in Patients with Triple Negative Breast Cancer (BRSADJ0026) (SOON TO OPEN)

Adjuvant Therapy
- A Randomized Phase III Trial of Adjuvant Therapy Comparing Chemotherapy Alone (Six Cycles of Docetaxel Plus Cyclophosphamide or Four Cycles of Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel) to Chemotherapy Plus Trastuzumab in Women with Node-Positive or High-Risk Node-Negative HER2-Low Invasive Breast Cancer (NSABPB47)
- A Phase III Clinical Trial Comparing the Combination of Docetaxel Plus Cyclophosphamide to Anthracycline-Based Chemotherapy Regimens for Women with Node-Positive or High-Risk Node-Negative, HER2-Negative Breast Cancer (NSABPB49)
- A Phase III Randomized Trial of Metformin versus Placebo on Recurrence and Survival In Early Stage Breast Cancer (ECOGMA32) (SOON TO OPEN)

Metastatic
- Radioactive Iodide (131I) Treatment of 124I PET/CT Detected Breast Cancers (BRSMTS0012)
- A Randomized, Phase 2 Study of the Efficacy and Tolerability of Veliparib (a PARP inhibitor) in Combination with Temozolomide or Veliparib in Combination with Carboplatin and Paclitaxel versus Placebo Plus Carboplatin and Paclitaxel in Subjects with BRCA1 or BRCA2 Mutation and Metastatic Breast Cancer (BRSMTS0017)
- A Two-Cohort, Open-Label, Multicenter Phase II Trial Assessing the Efficacy and Safety of Pertuzumab Given in Combination with Trastuzumab and Vinorelbine in First Line Patients with HER2-Positive Advanced (Metastatic or Locally Advanced) Breast Cancer (BRSMTS0018) (SOON TO OPEN)
- The BEACON Study (BrE Ast Cancer Outcomes with NKTR-102): A Phase 3 Open-Label, Randomized, Multicenter Study of NKTR-102 versus Treatment of Physician’s Choice (TPC) in Patients with Locally Recurrent or Metastatic Breast Cancer Previously Treated with an Anthracycline, a Taxane, and Capecitabine (BRSMTS0019) (SOON TO OPEN)
- A Phase Ib-Ila, Open-Label, Dose-Escalation Study of the Safety, Tolerability, and Pharmacokinetics of Trastuzumab Emtansine, Paclitaxel, and Pertuzumab Administered Intravenously to Patients with HER2-Positive, Locally Advanced or Metastatic Breast Cancer (BRSMTS0020) (SOON TO OPEN)
- A Randomized Phase III Trial of the Value of Early Local Therapy for the Intact Primary Tumor in Patients with Metastatic Breast Cancer (ECOGE2108) (SOON TO OPEN)

Radiation Oncology
- A Randomized Phase III Study of Conventional Whole Breast Irradiation (WBI) versus Partial Breast Irradiation (PBI) for Women with Stage 0, I, or II Breast Cancer (NSABPB39)

Imaging Protocols
- A Pilot Study to Determine Radiiodide Accumulation and Dosimetry in Breast Cancers Using 124I PET/CT (BRS0001)
- The Role of SPY Elite® Intra-Operative Angiography in Determining Adequate Skin Perfusion in Breast Cancer Related Procedures (BRS0005)
- Magnetic Resonance Imaging of Breast Cancer (BRSNSTU0004)

Biomarker & Molecular
- Immunohistochemical & Immunoblot Analysis of NIS (Na+/I-Symporter in Archival and Frozen Human Tissue Samples) (BRSNSTU0011)

Supportive Care
- Assessment and Treatment of Cognitive Deficits in Breast Cancer (BRS0002)
- Management of Insomnia in Breast Cancer Patients (BRS0008)
- A Single Arm Prospective Multicenter Study Evaluating the Biodesign® Plastic Surgery Matrix (BRS0015)

Observational
- A Study to Evaluate Different Decision-Making Approaches Used by Women Known to be at Increased Risk for Breast Cancer (NSABPDMP1)
Stanford Cancer Institute’s Developmental Therapeutics Group, led by Branimir I. Sikic, MD, offers Phase 1 and 2 clinical trials using novel therapeutics. Dr. Sikic’s clinical interests are mainly in ovarian cancers and cancers of unknown primary. Other faculty participating in this effort include Drs. Heather Wakelee and Joel Neal (lung cancers), Mark Pegram and Melinda Telli (breast cancers), Dimitri Colevas (head and neck cancers), George Fisher and Pamela Kunz (GI cancers), Sunil Reddy (melanoma), and Ranjana Advani and Holbrook Kohrt (lymphomas).

As a translational clinical studies program, Developmental Therapeutics brings together outstanding physicians with internationally regarded scientists to develop novel therapies and diagnostic modalities that utilize cutting-edge science and technologies. This research focuses on early clinical studies, investigator-initiated trials, the development of analytic approaches to enhancing the discovery of drugs and targets, and the analysis of clinical trials.

**RESEARCH HIGHLIGHTS INCLUDE**

- Running laboratory projects that study drug transporters, taxane resistance mechanisms including tubulin gene expression and epithelial to mesenchymal transition, and pharmacogenetic and genomic studies related to clinical trials in ovarian cancer, colorectal cancers, and pediatric leukemias.
- Directing Phase I and II trials of new tyrosine kinase inhibitors both as single agents and integrated with standard chemotherapies.
- Engaging in translational studies of molecular determinants of therapeutic response and toxicity.
- Developing novel immunotherapies for lymphomas and other cancers.

Below is a sampling of currently available Phase 1 and 2 studies.

**PHASE 1 STUDIES**

**Lymphomas**

- A Phase I Trial of an Anti-CD22 Monoclonal Antibody Conjugate DCDT2980S in Relapsed or Refractory B-Cell Non-Hodgkin’s Lymphomas (VAR0059)
- A Phase I Study of PF-05082566 as a Single Agent in Patients with Advanced Cancer, and in Combination with Rituximab in Patients with Non-Hodgkin’s Lymphoma (NHL) (LYMNHL0092)
- A Phase I Study of the Safety, Tolerability, Pharmacokinetics and Immunoregulatory Activity of BMS-663513 (Anti-CD137) in Subjects with Advanced and/or Metastatic Solid Tumors (VAR0071)

**Multiple/Variety**

- A Phase I, Open-Label, Multicenter Study to Assess the Safety, Tolerability, Pharmacokinetics, and Preliminary Anti-Tumor Activity of Ascending Doses of AZD4547 in Patients with Advanced Solid Malignancies (VAR0078) (SOON TO OPEN)
- A Phase 1, Open-label, Dose-escalation, Safety and Pharmacokinetic Study of CDX-1127 in Patients with Selected Refractory or Relapsed Hematologic Malignancies or Solid Tumors (VAR0081) (SOON TO OPEN)
- A Phase I, Open-Label, Dose-Escalation Study of the Safety and Pharmacokinetics of MPDL3280A Administered Intravenously as a Single Agent to Patients with Locally Advanced or Metastatic Solid Tumors (VAR0082) (SOON TO OPEN)

**PHASE 2 STUDIES**

**Thymic Cancers**

- A Phase 2 Study of Amrubicin in Relapsed or Refractory Thymic Malignancies (THOR0003)

**Gastric Cancers**

- A Phase 2 Study of Capecitabine, Carboplatin, and Bevacizumab for Metastatic or Unresectable Gastroesophageal Junction and Gastric Adenocarcinoma (GI0002)
The Stanford Gynecologic Oncology Program, which is part of the Stanford Women’s Cancer Center, offers treatments and clinical trials that utilize combined modalities and include advanced surgical techniques for ovarian, fallopian tube, cervical, endometrial, and other cancers of the female reproductive system.

**INNOVATIVE RESEARCH PROGRAMS**
This research is conducted through the Laurie Kraus Lacob Program for Gynecologic Oncology and Ovarian Cancer Research and Treatment, and the Cooperative Ovarian Cancer Group (COGi).

Based at Stanford, the Cooperative Ovarian Cancer Group (COGi), a national cooperative research group for specialized treatments in ovarian cancer, offers novel drugs, vaccines, and immunotherapies to patients treated in the gynecologic oncology program. The goal is to improve outcomes for this challenging disease.

**RESEARCH PROGRAMS INCLUDE:**
- Isolation of ovarian cancer stem cells and the development of stem-cell directed immunotherapy using monoclonal antibodies.
- Development of vaccines derived from tumor-associated antigens to prevent disease relapse, using a cell-base therapy with genetically-programmed dendritic cells.
- Refined methods for imaging ovarian cancer and studying biological markers that may improve detection—a program that is particularly important because ovarian cancer seldom reveals itself through early symptoms.
- Characterization of intracellular signaling pathways revealing new ways to classify ovarian tumors.
- Evaluation of the ability of therapeutic agents to help overcome resistance in ovarian cancers that appear to originate in stem cell-like cancer cells.
- Development of novel chemotherapies and investigations of fundamental biologic mechanisms of uterine tumors.
- Investigation of the mechanisms of HPV-induced malignancy and innovative prevention and detection strategies related to cervical cancer.

**SPECIAL CLINICAL PROGRAMS**
- A Multidisciplinary Tumor Board comprised of gynecologic oncologists, radiation oncologists, diagnostic and interventional radiologists, pathologists, cancer geneticists, nurse specialists, social workers, and psychologists. This team of experts meets weekly and provides a thorough and collaborative review of patient records, radiographs, and pathology results.
- Innovative treatments that combine modalities, including advanced surgical techniques and the most up-to-date chemotherapeutic agents.
  - Optimal cancer surgery involving the use of state-of-the-art techniques.
  - Advanced robotic surgery and other minimally invasive surgical techniques.
  - Use of leading-edge experimental treatments, including PARP inhibitors and immunotherapies such as dendritic cell therapy and vaccines against ovarian cancer.
  - Intraoperative radiation therapy (IORT).
- Fertility-conserving surgery and advanced assisted reproductive technology to help maximize childbearing options.
- A wide array of supportive services, focusing on psychological issues, sexual side effects, and changes in body image.

**CURRENT STUDIES INCLUDE:**
**Ovarian/Peritoneal/Fallopian**
- A Phase III, Randomized, Double-Blind Trial of Weekly Paclitaxel Plus AMG 386 or Placebo in Women with Recurrent Partially
Platinum Sensitive or Resistant Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Cancers (GYNOPF0008)

- Phase 2, Randomized Controlled Study on the Effectiveness of First-Line Chemotherapy (Carboplatin and Paclitaxel) versus Chemoimmunotherapy (Carboplatin-Paclitaxel-Oregovomab) in Patients with Advanced Epithelial Ovarian, Adnexal, or Peritoneal Carcinoma (GYNOPF0009) (SOON TO OPEN)

- A Randomized Double-Blind Phase 3 Trial Comparing EC145 and Pegylated Liposomal Doxorubicin (PLD/Doxil®/Caelyx®) in Combination versus PLD in Participants with Platinum-Resistant Ovarian Cancer (GYNOVA0017)

- A Phase I Study Evaluating the Efficacy and Toxicity of Stereotactic Body Radiation for Metastatic or Recurrent Platinum-Resistant Ovarian Cancer (GYNOVA0021)

- CANVAS: A Randomized, Double-Blinded, Placebo-Controlled Trial of Cvac (Autologous Dendritic Cells Pulsed with Recombinant Human Fusion Protein [Mucin 1-Glutathione S-Transferase] Coupled to Oxidized Polymannose) as Maintenance Treatment in Patients with Epithelial Ovarian Cancer (EOC) in Complete Remission Following First-Line Chemotherapy (GYNOVA0023) (SOON TO OPEN)

- A Randomized, Phase II Study Evaluating MK-1775 in Combination with Paclitaxel and Carboplatin versus Paclitaxel and Carboplatin Alone in Adult Patients with Platinum Sensitive p53 Mutant Ovarian Cancer (GYNOVA0025) (SOON TO OPEN)

- Does Palliative Chemotherapy Improve Symptoms in Women with Recurrent Ovarian Cancer? (GYNOVA0026) (SOON TO OPEN)

- A Phase III Randomized Controlled Clinical Trial of Carboplatin and Paclitaxel Alone or in Combination or with Bevacizumab (NSC #704865, IND #7921) followed by Bevacizumab and Secondary Cytoreduction Surgery in Platinum-Sensitive, Recurrent Ovarian, Peritoneal Primary, and Fallopian Tube Cancer (GOG0213)

- A Phase II Randomized, Double-Blind Trial of a Polyvalent Vaccine-KLH Conjugate (NSC 748933) + OPT-821 versus OPT-821 in Patients with Epithelial Ovarian, Fallopian Tube, or Peritoneal Cancer Who Are in Second or Third Complete Remission (GOG0255)

- Chemotherapy Toxicity in Elderly Women with Ovarian, Primary Peritoneal or Fallopian Tube Cancer (GOG0273)

- A Phase II Evaluation of the Poly (ADP-Ribose) Polymerase (PARP)-1 and -2 Inhibitor Veliparib (ABT-888) (IND #77840) (NSC #737664) in the Treatment of Persistent or Recurrent Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Patients Who Carry a Germline BRCA1 or BRCA2 Mutation (GOG0280)

Endometrial

- A Phase III Trial of Pelvic Radiation Therapy Versus Vaginal Cuff Brachytherapy Followed by Paclitaxel/Carboplatin Chemotherapy in Patients with High Risk, Early Stage Endometrial Carcinoma (GOG0249)

- A Randomized Phase III Trial of Cisplatin and Tumor Volume Directed Irradiation Followed by Carboplatin and Paclitaxel vs. Carboplatin and Paclitaxel for Optimally Debulked, Advanced Endometrial Carcinoma (GOG0258)

- A Randomized Phase III Trial of Paclitaxel Plus Carboplatin versus Ifosfamide Plus Paclitaxel in Chemotherapy-Naive Patients with Newly Diagnosed Stage I-IV, Persistent or Recurrent Carcinosarcoma (Mixed Mesodermal Tumors) of the Uterus (GOG0261)

Cervical

- Tissue and Plasma Biomarkers of Lymph Node Involvement in Cervical Cancer (GYNCVX0002)
The Stanford Urologic Oncology Program features cutting-edge clinical studies and treatment expertise in handling complex cases for patients with cancers of the prostate, kidney, bladder, and testis. Care among specialists is tightly integrated, with joint clinics that give patients access to sequential same-day appointments with medical, surgical, and radiation oncologists. This also allows continuity in patient management along the entire course of the disease, from early diagnosis through advanced disease.

NEW STANFORD CHAIR OF UROLOGY
The program is now led by newly appointed Chair Eila Skinner, MD, Professor of Urology, Stanford University Medical Center. Formerly Professor of Clinical Urology and Vice Chair of the Department of Urology, Keck School of Medicine, University of Southern California, Dr. Skinner is a urologic surgeon and a nationally known expert in urology and bladder cancer with research interests in cancer prevention, bladder cancer, and urinary tract reconstruction.

STANFORD BREAKTHROUGHS USED IN UROLOGIC CANCER RESEARCH
Stanford has made scientific advances that support urologic cancer research. These innovations include:

- DNA microarray technology that has enabled investigators to use miniscule quantities of tumor tissue to genetically classify urologic cancers. Stanford scientists are identifying genomic signatures to better classify tumors as low or high risk, which may allow for improved recommendations regarding treatment.
- The MagSweeper, an automated device developed at Stanford that isolates and purifies cancer cells from blood with higher capture rates and purity. Used to study the genetic profiles of circulating cancer cells, this invention is the result of the collaboration between Stanford physicians and basic scientists.
- Leading-edge cancer stem cell research. Working with bladder cancer stem cells, Stanford scientists and clinicians will be targeting stem cells as a novel treatment for bladder cancer.
- Evaluation of improved imaging techniques for early detection and evaluation of response to therapeutics.
- Important discoveries in the hedgehog signaling pathway in solid tumors, which have led to novel investigational treatments for prostate cancer.

STANFORD UROLOGIC ONCOLOGY PROGRAM FEATURES
The urologic oncology program includes a highly skilled team of individuals who exclusively focus on this area of oncology. The surgical team is adept at managing the most challenging minimally invasive and open cases. Features include:

- State-of-the-art cancer treatments, including:
  - Minimally invasive laparoscopic and robotic surgery for prostate, bladder, and kidney cancer. The surgical team has extensive experience with these surgeries and outstanding outcomes. This includes nerve-sparing prostatectomy and cystectomy and complex partial nephrectomy.
  - Urinary tract reconstruction with continent diversion and neobladder construction for many patients who require bladder removal for bladder cancer. The team has one of the largest experiences in the country in continent urinary diversion, and evaluates each cystectomy patient for the appropriateness of urinary reconstruction.
  - Management of complex patients with urinary tract malignancies, including the very elderly, those with significant other medical problems, and those who have had prior treatment such as pelvic radiation or chemotherapy. This includes management of some of the most challenging surgical cases in the field.
  - Advanced imaging capabilities using new tracers for the detection of early and advanced disease.
— An individualized, risk-adapted strategy for treatment of early bladder, kidney, and prostate cancer to optimize the outcome for each patient.
— Immunotherapies such as Provenge for castration-resistant prostate cancer and high dose interleukin-2 for advanced renal cell carcinoma.
— Clinical trials with novel therapeutics for early and advanced stage cancers of all types, including new biologic therapies.
— Cryoablation for small kidney cancers.
• A multidisciplinary tumor board that consists of medical, surgical, and radiation oncologists, as well as radiologists, pathologists, and nurses. This team of experts thoroughly reviews patient records, imaging, and pathologic specimens and provides a comprehensive treatment recommendation.
• Urologic cancer support group that holds monthly meetings offering lectures on state-of-the-art treatments, available clinical trials, and other patient care issues, and that conclude with an interactive panel discussion between the physicians and patients.

CURRENT STUDIES INCLUDE:

Bladder
• Open vs. Robotic-Assisted Radical Cystectomy: A Randomized Trial (BLDR0002)
• A Phase II Study of Pazopanib in Combination with Weekly Paclitaxel in Refractory Urothelial Cancer (BLDR0010)
• A Randomized, Phase 2, Open-Label Study Evaluating DN24-02 as Adjuvant Therapy in Subjects with High Risk HER2+ Urothelial Carcinoma (BLDR0013)
• A Randomized Doubled-Blinded Phase III Study Comparing Gemcitabine, Cisplatin, and Bevacizumab to Gemcitabine, Cisplatin, and Placebo in Patients with Advanced Transitional Cell Carcinoma (ECOGC90601)

Kidney
• A Randomized, Double-Blind, Placebo-Controlled Phase III Study to Evaluate the Efficacy and Safety of Pazopanib as Adjuvant Therapy for Subjects with Localized or Locally Advanced RCC Following Nephrectomy (RENAL0021)
• A Phase 1b, Open-Label, Dose-Escalation Study to Evaluate the Safety and Tolerability of SGN-75 in Combination with Everolimus in Patients with CD70-Positive Metastatic Renal Cell Carcinoma (RENAL0024) (SOON TO OPEN)
• A Randomized Phase II Trial of Sunitinib/Gemcitabine or Sunitinib in Advanced Renal Cell Carcinoma with Sarcomatoid Features (ECOGE1808)

Prostate
• Microarray Analysis of Gene Expression in Prostate Tissues (A Cancer Taxonomy Based on Gene Expression Patterns) (PROS0009)
• Quality of Life Following Radical Prostatectomy (PROS0012)
• Canary Prostate Active Surveillance Study Protocol (PROS0026)
• A Randomized Phase II Study to Assess the Activity of TroVax® (MVA-5T4) Plus Docetaxel versus Docetaxel Alone in Subjects with Progressive Hormone Refractory Prostate Cancer (PROS0041)
• A Phase 3, Randomized, Double-Blind, Controlled Trial of Cabozantinib (XL184) vs. Mitoxantrone Plus Prednisone in Men with Previously Treated Symptomatic Castration-Resistant Prostate Cancer (PROS0048) (SOON TO OPEN)
• Radium-223 Chloride (Alpharadin) in Castration-Resistant (Hormone-Refractory) Prostate Cancer Patients with Bone Metastasis (PROS0049) (SOON TO OPEN)
• A Randomized, Double-blind, Phase 3 Efficacy Trial of PROSTVAC-V/F ± GM-CSF in Men with Asymptomatic or Minimally Symptomatic Metastatic, Castrate-Resistant Prostate Cancer (PROS0050) (SOON TO OPEN)
• A Multicenter, Single-arm, Open Label Treatment Protocol to Provide Expanded Access to MDV3100 and Monitor Its Safety in Patients with Progressive Castration-Resistant Prostate Cancer Previously Treated with Docetaxel-Based Chemotherapy (PROS0051)
• Androgen Receptor Modulation Phase II, Randomized Study of MK-2206-Bicalutamide Combination in Patients with Rising PSA at High-Risk of Progression after Primary Therapy (ECOGE2809)

• highlighted studies are Stanford investigator initiated
RESOURCES:

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<th>Referral Center</th>
<th>Clinical Trials Web Search Engine</th>
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<td>1.866.742.4811</td>
<td>cancer.stanford.edu/trials</td>
</tr>
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