Disclosure

- No conflicts to disclose
Research saves lives. Every advancement made in treatment, prevention or care of hereditary cancer has come from research.

Yet only 0.2% of patients are referred to clinical trials and only 3% of adult cancer patients participate in clinical trials.

An analysis of over 500 National Cancer Institute treatment clinical trials showed that 40% didn’t achieve their enrollment goals.

Without participants, studies close early. Incomplete research costs society millions of dollars, thousands of hours of researcher effort, thousands of volunteers taking risks, and countless lives lost, all in vain.

Why Participate in Research?
# Myths About Research Participation

<table>
<thead>
<tr>
<th>Myth</th>
<th>Fact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research is only for people who have exhausted all options.</td>
<td>There are risk, prevention, detection, quality of life, and treatment studies enrolling people with early stage, late stage, and high risk for cancer.</td>
</tr>
<tr>
<td>Participating in research is dangerous.</td>
<td>There are strict safety measures built in to clinical trials.</td>
</tr>
<tr>
<td>Participating in research means you may be denied treatment or be treated like a guinea pig.</td>
<td>Patients in clinical trials are typically monitored very closely.</td>
</tr>
<tr>
<td>There are plenty of others who will participate. If I don’t do it, the next person will.</td>
<td>Only 3% of adult cancer patients participate in clinical trials.</td>
</tr>
<tr>
<td>My doctor didn’t refer me to a clinical trial, so I must not qualify for one.</td>
<td>Doctors may not be aware of, or refer patients to studies outside of their facility.</td>
</tr>
</tbody>
</table>
Matching HBOC Patients to HBOC Research

Study open only to people with HBOC

Study open to any person facing cancer
Matching HBOC Patients to HBOC Research

Study open only to people with HBOC

Study open to any person facing cancer
1. Focus on hereditary cancer studies
2. Personalized clinical trial search
3. Studies summarized in plain language
4. Additional clinical trial resources
Studies Focused on HBOC-Related Cancers

ATHENA - Rucaparib and Nivolumab for Maintenance in Ovarian Cancer
Clinicaltrials.gov identifier: NCT03522246
Treatment: Ovarian
More Info

POLO - Olaparib in BRCA-Associated Pancreatic Cancer
Clinicaltrials.gov identifier: NCT02184195
Treatment: Pancreatic
More Info

TRITON3 - Rucaparib vs. Physician Choice for Castration Resistant Prostate Cancer
Clinicaltrials.gov identifier: NCT02975934
Treatment: Prostate
More Info

Women Choosing Surgical Prevention (WISP) Trial
Clinicaltrials.gov identifier: NCT02760849
Prevention: Ovarian
Quality of Life: High Risk But No Cancer
More Info

Metformin for Risk Reduction
Metformin to Lower Breast Cancer Risk in High Risk Women
Clinicaltrials.gov identifier: NCT01905046
Prevention: Breast
More Info

OlympiA - Olaparib Adjuvant Therapy for BRCA-related Breast Cancer
Clinicaltrials.gov identifier: NCT02032823
Treatment: Breast
More Info

IMPRES - Improving Memory after RRSO
Clinicaltrials.gov identifier: NCT03187353
Quality of Life: Breast Cancer Survivor
High Risk But No Cancer
More Info

PROMPT
Clinicaltrials.gov identifier: NCT02665195
Surveys, Registries, Interviews
More Info
Tools That Personalize Your Search

Search for Hereditary Pancreatic Cancer Treatment Research Studies

Pancreatic cancers are often identified based on the cell type that comprises the cancer. Most pancreatic cancers caused by a BRCA or other inherited mutation are adenocarcinomas. Pancreatic cancer treatment studies are frequently divided into studies for people who are newly-diagnosed versus people with recurrent cancers. Some studies are enrolling people with early stage vs those with locally advanced or metastatic cancers. Other studies may be open specifically to people with a BRCA or other mutations. You can use the search below to look for studies based on these criteria. If you need assistance getting started, visit our How to Search for Research Studies page.

Pick one or more of the criteria below to narrow down your search, or leave blank to see all trials.

Stage: Any stage
Genetic test/marker: Any marker
Keyword: 

Search

Search for Hereditary Ovarian Cancer Treatment Research Studies

Ovarian cancers are often identified based on the cell type that comprises the cancer. Most ovarian cancers caused by a BRCA mutation are the serous subtype of ovarian cancer. Ovarian cancer treatment studies are frequently divided into studies for women who are newly-diagnosed versus women with recurrent cancers. Some studies are enrolling women with inherited mutations such as BRCA or Lynch Syndrome, or markers within the tumor. You can use the search below to look for studies based on these criteria. If you need assistance getting started, visit our How to Search for Research Studies page.

Pick one or more of the criteria below to narrow down your search, or leave blank to see all trials.

New/recurrent: Any
Genetic test/marker: 
Keyword: 

Search
Clinicaltrials.gov

Matching Tool

Olaparib in gBRCA Mutated Pancreatic Cancer Whose Disease Has Not Progressed on First Line Platinum-Based Chemotherapy (POLO)

About the Study

POLO is a clinical trial enrolling people with metastatic (advanced) pancreatic cancer patients with BRCA mutations to determine whether adding the PARP inhibitor, olaparib, after first line chemotherapy improves survival.

Patients who enroll in the study will be randomly assigned to one of two groups once they have completed chemotherapy. One group will receive olaparib, a type of medication known as a PARP inhibitor, a category of medication that has been studied in people BRCA mutations and certain types of cancer. The other group will receive a placebo, also known as a sugar pill.

Visit the study website for more information.

Type of Study:

Randomized, Double-blinded, Placebo-controlled, Maintenance Study

- The study has two arms. This means that patients in the study are placed in one of two different groups. One group will receive the PARP inhibitor olaparib and the other group will receive a placebo.
- This is a randomized study, which means that patients will be placed into one of the two treatment groups by chance. Neither patients nor the research doctor will choose the group they are placed in. This randomizing is 3:2.
- This means that patients will have a slightly greater chance of being placed in the treatment group than the placebo group.
- The study is double-blinded. This means that participants will be randomly selected to one of two groups. Neither the participants nor their doctors will know whether they are receiving olaparib or the placebo while participating in the study.
- The study is placebo-controlled. Placebos are harmless sugar pills.

This study is open to:

- Patients with advanced (metastatic) pancreatic cancer who:
  - have a documented mutation in BRCA1 or BRCA2.
  - are on treatment with a first line platinum-based chemotherapy regimen for metastatic pancreas cancer and have no evidence of disease progression.
- can be at a point in chemotherapy where both they and their doctor believe having a pause or break in chemotherapy treatment is appropriate.

This study is not open to:

- Patients are excluded if they:
  - have progression of tumor between start of first line platinum based chemotherapy for metastatic pancreas cancer and randomization for the clinical trial.
  - have been previously treated with...
Eligibility In Plain Language

The Women Choosing Surgical Prevention (WISP) Trial

About the Study
The goal of the WISP Study is to compare whether removal of fallopian tubes only, delaying removal of the ovaries can safely improve sexual functioning and menopausal symptoms compared to standard risk-reducing removal of the ovaries and fallopian tubes (also known as risk-reducing salpingo-oophorectomy or RRSO).

What the Study Entails
This is a non-randomized study. Women who participate in this study will be able to choose which type of ovarian procedure they wish to undergo:
- Fallopian tube removal (salpingectomy) followed later by a second surgery to remove their ovaries later.
- Removal of the ovaries and tubes immediately. This is the current standard-of-care recommendation for women at high risk for ovarian cancer.

Background
Removal of the ovaries and fallopian tubes (also known as Risk-Reducing Salpingo-Oophorectomy or RRSO) is the recommended way for high-risk patients with certain types of genetic mutations to lower their risk for ovarian cancer. With RRSO, the fallopian tubes and ovaries are removed at the same time and women who have not yet reached menopause may experience symptoms and long-term side effects of early-onset menopause. New research suggests that many ovarian cancers may actually begin in the fallopian tubes leading patients and researchers to wonder if they could keep the ovaries until closer to natural menopause and still lower their risk by removing the fallopian tubes (with or without one ovary) only, followed by ovarian removal several years later.

This study is open to:
Women who are at increased risk of ovarian cancer who:
- are between age 30 and 50 years of age.
- are premenopausal, with a documented deleterious mutation in one of the following ovarian cancer genes: BRCA1, BRCA2, BRIPI, PALB2, RAD51C, RAD51D, BARD1, MSH2, MSH6, MLH1, PMS2, or EPCAM.
- are willing to undergo two surgical procedures (if participant chooses the ISDO arm)
- have at least 1 fallopian tube and 1 ovary.

This study is not open to:
Patients are excluded if they:
- have a personal history of ovarian cancer
- are pregnant
- are currently being treated with Tamoxifen or Aromatase Inhibitors
Additional Resources

1. Tips for searching studies
2. Once you find a study
3. Other resources
Other Resources

1. FAQ
2. Glossary
3. Peer Navigation Program
4. Other Websites

Frequently Asked Questions
Cancer is a complicated disease. And hereditary cancers are different than other cancers. Many articles about cancer are not focused on hereditary cancers. It can be confusing determining which facts apply to you. We will be posting and answering Frequently Asked Questions about topics related to hereditary breast and ovarian cancer. Check back frequently for more questions and answers.

- What happens if I change my mind about participating in a research study?
- I want to enroll in a study that is not open at a facility close to where I live. What can I do?
- What is a placebo? Are studies using placebos safe?

Peer Navigation Program
Our free Peer Navigation Program connects cancer survivors, people at high risk and their caregivers to support and resources personalized for their situation.

Definitions
- Advanced-stage: Stage is a term used to describe how much a cancer has spread. Cancers are staged from stage 0 (cancerous cells can be removed) to stage 4. Although staging varies by cancer type, usually the lower the number, the less the cancer has spread. Advanced-stage cancers usually refer to stage 4 or metastatic cancers.
- ATM: ATM is a gene found on chromosome 11. Mutations in ATM increase the risk for female breast, pancreatic, prostate and possibly other cancers.
- BARD1: BARRD is a gene found on chromosome 2. Mutations in BARRD increase the risk for female breast cancer and possibly other cancers.
- BART: BART stands for Breast Analysis Rearrangement Test. This is an expanded panel looking for mutations in BRCA1.
Outreach, Support & Awareness

1. Volunteer training
2. Incorporation into other programs
3. Promotion of tool and individual studies
4. Print collateral
Key Takeaways

• Studies are open and enrolling people across the entire HBOC community
• Participating in studies is a way that you can help accelerate research
• FORCE has tools to help you find studies enrolling people like you
  • www.facingourrisk.org/research
  • www.facingourrisk.org/pnp
Connect

Websites:
FacingOurRisk.org

Research Tool:
FacingOurRisk.org/research

Email:
info@FacingOurRisk.Org

Phone:
1-866-288-7475

Get Social:
@FacingOurRisk
Victoria Seewaldt has no financial conflict of interest to declare.
Research studies at City of Hope

- City of Hope is off the Gold Line in Duarte. Parking is free.
- We have High Risk Clinics at our Main Clinica in Pasadena.
- Where to find studies on the City of Hope website (link)
  - [https://www.cityofhope.org](https://www.cityofhope.org)
- Types of studies:
  - Early detection, Prevention, Genetics, Healthy Living
  - Treatment for TNBC, pancreatic, and lung cancer.
- How to get a referral: call **800-826-4673**
  - Or go to the City of Hope web site and request on line.
  - For High Risk Clinic referral: kherold@coh.org
<table>
<thead>
<tr>
<th>Name</th>
<th>Cancer type/State/Subtype</th>
<th>Phase</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALLIANCE A211102 Metformin Hydrochloride in Patients With Atypical Hyperplasia or In Situ Breast Cancer to Placebo in Decreasing Atypical Cells in Patients With Atypical Hyperplasia or in Situ Breast Cancer</td>
<td>Prevention study for women with atypia who are at high risk for breast cancer including any woman who carries a gene mutation (e.g. BRCA1)</td>
<td>Phase III</td>
<td>Metformin</td>
</tr>
<tr>
<td>Alliance 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</td>
<td>Stage 2 – stage 3a breast cancer</td>
<td>Phase III</td>
<td>Axillary lymph node dissection Axillary radiation</td>
</tr>
<tr>
<td>A SU2C Catalyst Randomized Phase II Trial of the PD1 Inhibitor Pembrolizumab (Keytruda) With or Without a Vitamin D Receptor Agonist Paricalcitol (Zemplar) in Patients With Stage IV Pancreatic Cancer Who Have Been Placed in Best Possible Response</td>
<td>Metastatic pancreatic cancer</td>
<td>Phase II</td>
<td>Pembrolizumab (Immunotherapy agent) Paricalcitol</td>
</tr>
<tr>
<td>NIH Early Detection Trial: Testing for signaling networks that predict rapidly growing breast cancer growing breast cancer</td>
<td>Women undergoing breast MRI screening.</td>
<td>Phase 0</td>
<td>Contribute breast core biopsy (at time of clinical biopsy) and blood.</td>
</tr>
<tr>
<td>Eat Move Live: A community based healthy living program to reduce cancer, diabetes, and heart disease. Mayra Serrano Leader; Spanish Translation</td>
<td>Any: Sister of high risk, survivor, previvor. All are welcome</td>
<td>Phase 0</td>
<td>Community based healthy living, exercise, and diet</td>
</tr>
</tbody>
</table>
Study detail – Metformin Hydrochloride in Patients With Atypical Hyperplasia or In Situ Breast Cancer to Placebo in Decreasing Atypical Cells in Patients With Atypical Hyperplasia or in Situ Breast Cancer

- Women at high risk for breast cancer and a diagnosis of atypia on breast biopsy
- Randomized, placebo-controlled study
- Metformin is a drug already approved for treating diabetes
- After one year in the study, women receiving placebo will have the opportunity to “cross-over” and take metformin
Coming in the future:
Collaboration with Caltech – Lihong Wang, Ph.D.
Non-contrast imaging using light and ultrasound
PACT – imaging of blood flow

PACT imaging of normal breast blood flow

PACT imaging of a cancer that mammogram cannot detect

Lin et al. *Nature Communication*, 2018
Therapeutic Trials at Cedars-Sinai Medical Center

- Wide variety of therapeutic studies run through Samuel Oschin Comprehensive Cancer Center
Non-therapeutic studies at Cedars-Sinai Medical Center

- Population-based studies
  - *BRCA* Founder OutReach Study
- Epidemiologic studies
  - Gilda Radner Hereditary Cancer Program
  - HealthCare Outcomes after Risk-Reducing Oophorectomy
BRCA Founder OutReach Study

• Purpose:
  • Develop a new model for genetic testing
  • Reduce cancer risks and improve outcomes for BRCA+ individuals
  • Identify best practices for incorporating PCPs in genetic testing
• Men and women age 25 and older with at least one Ashkenazi Jewish grandparent
• Must live in designated zip code area of New York City, Boston, Philadelphia or Los Angeles
• Includes genetic testing for the Ashkenazi Jewish BRCA1 and BRCA2 founder mutations.
Gilda Radner Hereditary Cancer Program

- **Purpose:**
  - Identify factors that influence cancer risk
  - Better understand precursors to cancer
  - Identify preventative interventions for individuals with and without inherited mutations.
  - Anyone who has had genetic testing can participate!
  - Annual questionnaire and blood/saliva sample

The Gilda Radner Hereditary Cancer Program Newsletter
A Project of the Women’s Cancer Program at the Samuel Oschin Comprehensive Cancer Institute

**A Gift of Love**
How The Gilda Radner Hereditary Cancer Program Got Its Name

The Cedars-Sinai Gilda Radner Hereditary Cancer Program officially began in 1991. But the gift of love that established naming of the program began two years earlier as one of America’s most beloved comedienes lost her fight with ovarian cancer.

Gilda Radner and her husband Gene Wilder began their cancer journey in 1986 when Gilda first began to feel something was wrong with her body. The symptoms she experienced were warning signs that today are more widely recognized as signals of ovarian cancer. After multiple non-cancer diagnoses, they sought care at Cedars-Sinai, where Gilda’s Stage IV ovarian cancer was identified. Sadly, despite surgery and chemotherapy, she would eventually lose her fight.
HealthCare Outcomes after Risk Reducing Oophorectomy

• **Purpose:**
  • Understand impact of surgical menopause on:
    • Cognitive function
    • Bone health
    • Cardiovascular disease
    • Quality of life
  • Female mutation carriers who are planning risk reducing BSO
  • Questionnaires to be completed prior to surgery and then 6, 12, 18, and 24-months after surgery.
  • DEXA scan and blood work prior to surgery and repeated once during 2 year follow up period.

Health Outcomes Following Risk-Reducing Salpingo-Oophorectomy in Women at High Risk of Ovarian Cancer

While there is some information on the benefits of undergoing risk-reducing surgery in women who are at a higher risk of ovarian cancer, there have been few studies that have addressed the long-term effect of surgical menopause on cognitive function, bone health, cardiovascular disease and quality of life in women who are at an elevated risk of ovarian cancer due to a genetic predisposition.

Ilana Cass, MD, a gynecologic oncologist in the Women’s Cancer Program and investigator in the Gilda Radner Hereditary Cancer Program, is studying the effects of surgical menopause on cognitive function, bone health, cardiovascular disease, quality of life and frequency of screening procedures in women who have a positive genetic mutation and elect to have risk-reducing surgery to remove their ovaries. The purpose of this research is to develop a better understanding of how to properly counsel women at elevated risk of ovarian cancer who are thinking about getting risk-reducing surgery.
We would love to have you as part of research efforts!

Contact info:
Email: gildaprogram@cshs.org
Phone: 310-423-9966
About Us

- UCLA Jonsson Comprehensive Cancer Center is a leader in cancer prevention, diagnosis and treatment.
- With a membership of nearly 500 researchers and clinicians, we offer hundreds of clinical trials each year.
- In the past four years, there have been 11 FDA drug approvals based on research conducted, including new indications for existing treatments.
- Examples of therapies developed at UCLA Jonsson Comprehensive Cancer Center include:
  - Herceptin, the first targeted therapy to treat HER2+ breast cancer that has helped extend the lives of countless women.
  - Keytruda, a first-of-its-kind immunotherapy to treat advanced melanoma.
<table>
<thead>
<tr>
<th>Name</th>
<th>Cancer type/State/Subtype</th>
<th>Phase</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>NATALEE – Phase III open label ribociclib X 3 years; 1:1 randomization</td>
<td>ER-positive breast cancer</td>
<td>Phase III</td>
<td>Ribociclib</td>
</tr>
<tr>
<td>A Safety, Pharmacokinetic, Pharmacodynamic and Anti-Tumor Study of PF-06873600 as a Single Agent and in Combination with Endocrine Therapy</td>
<td>Metastatic TNBC or ER-pos. breast cancer/Male breast cancer/Platinum resistant ovarian cancer</td>
<td>Phase II</td>
<td>PF-06873600- A CDK inhibitor</td>
</tr>
<tr>
<td>GOG 3015 – Atezolizumab Versus Placebo in Combo With Paclitaxel, Carboplatin, and Bevacizumab in Participants with Newly-Diagnosed Stage III or Stage IV Ovarian, Fallopian Tube, or Primary Peritoneal Cancer</td>
<td>Newly diagnosed advanced ovarian cancer</td>
<td>Phase III</td>
<td>Paclitaxel and Cisplatinum (chemotherapy) Atezolizumab – immunotherapy agent Bevacizumab (Avastin)</td>
</tr>
<tr>
<td>TRIO 026 – Phas II randomized study of pembro with or without epigenetic modulation with CC-486 in patients with platinum-resistant ovarian, fallopian tube or primary peritoneal cancer</td>
<td>Platinum-resistant ovarian cancer</td>
<td>Phase II</td>
<td>Pembrolizumab – immunotherapy agent CC-486 (new agent)</td>
</tr>
<tr>
<td>OPAL – Phase 2 Study to Evaluate the Safety and Efficacy of Novel Treatment Combinations in Patients with Recurrent Ovarian Cancer</td>
<td>Platinum resistant recurrent ovarian cancer</td>
<td>Phase II</td>
<td>Niraparib (PARP inhibitor) TSR-042 (immunotherapy agent) Bevacizumab (Avastin)</td>
</tr>
<tr>
<td>OVARIO – The phase 2, single-arm, open-label study of maintenance therapy with niraparib and bevacizumab in patients with advanced ovarian cancer following response on frontline platinum-based chemotherapy</td>
<td>Newly diagnosed, platinum sensitive ovarian cancer</td>
<td>Phase II</td>
<td>Maintenance therapy with Niraparib (PARP inhibitor) Bevacizumab (Avastin)</td>
</tr>
</tbody>
</table>
UCLA Research Study for Young Women Survivors of Breast Cancer

- UCLA is conducting a study to examine two group programs for young breast cancer survivors:
  - Mindfulness-meditation classes
  - Survivorship education classes

- We would like to compare these two group programs on meeting the common needs of young survivors.

- Classes will meet for six weeks and are held at UCLA. We will also ask you to come to UCLA for three in-person appointment throughout the duration of the study.

- You may be eligible to participate if you were diagnosed with breast cancer at age 50 or younger and are within five years of your diagnosis.

- If you are interested in participating or would like more information, please contact the study staff at:
  - bkahnmills@mednet.ucla.edu or 310-825-2520
Thank you!

To learn more:

Please visit the UCLA Jonsson Comprehensive Cancer Center’s booth. Our Genetic Counselors will be on hand during morning and afternoon breaks on Friday and Saturday to answer your questions. Please also visit https://clinicaltrials.gov/ and cancer.ucla.edu.
Research studies at UCSD

- Established in 1978, Moores Cancer Center is one of just 49 National Cancer Institute-Designated Comprehensive Cancer Centers in the United States, and the only one in the San Diego region.
- Moores Cancer Center is part of the UC Health System, with locations across San Diego County including La Jolla, Hillcrest, Encinitas, and Vista.
- To search for studies at UCSD studies please visit https://clinicaltrials.ucsd.edu/
- The Clinical Trials Office has over 400 trials of all types, including treatment, prevention, palliative, and observational.
- To get a referral or inquire about UCSD trials, please contact us by calling 858-822-5354 or emailing us at cancercto@ucsd.edu.
## Research studies at UCSD

<table>
<thead>
<tr>
<th>Name</th>
<th>Cancer type/State/Subtype</th>
<th>Phase</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>ATHENA WISDOM STUDY</td>
<td>Women between the ages of 40-74 who have never had breast cancer or mastectomies.</td>
<td>N/A</td>
<td>Genetic testing and risk-based screening vs. guideline-based screening</td>
</tr>
<tr>
<td>IRONMAN</td>
<td>Advanced prostate cancer registry</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A Randomized Phase 2 Study of Cediranib in Combination with Olaparib versus Olaparib Alone in Men with Metastatic Castration Resistant Prostate Cancer</td>
<td>Metastatic, castration resistant Prostate cancer</td>
<td>II</td>
<td>Olaparib (PARP inhibitor) Cediranib (Blood supply inhibitor)</td>
</tr>
<tr>
<td>Olaparib With or Without Cediranib in Treating Patients With Metastatic Castration-Resistant Prostate Cancer</td>
<td>Metastatic castration-resistant prostate cancer</td>
<td>II</td>
<td>Olaparib (PARP inhibitor) Cediranib (Blood supply inhibitor)</td>
</tr>
<tr>
<td>PREDICT- Profile-Related Evidence Determining Individualized Cancer Therapy</td>
<td>All cancer patients, ages 18 and over. Rady Children’s Hospital allows patients ages 7 and over.</td>
<td>N/A</td>
<td>Observational</td>
</tr>
<tr>
<td>An Open Label Navigational Investigation of Molecular Profile-Related Evidence Determining Individualized Cancer Therapy for Patients With Incurable Malignancies and Poor Prognoses (I-PREDICT)</td>
<td>Cancer patients, ages 18+ newly diagnosed or previously treated</td>
<td>Pilot</td>
<td>Varies; open-label navigational</td>
</tr>
</tbody>
</table>
Study detail – Wisdom Study

- Prevention study
- Open to women without breast cancer who have not had mastectomy
- Looking at risk-based breast cancer screening compared to general population screening
- Includes genetic testing in the risk-based arm
I cannot find any information on the NATALEE study including the NCT number.
Sue Friedman, 9/9/2018
I-PREDICT: An Open Label Navigational Investigation of Molecular Profile-Related Evidence Determining Individualized Cancer Therapy for Patients With Incurable Malignancies and Poor Prognoses

What the Study Entails

• This is for patients of all tumor types.
• The trial offers customized combinations with matching drugs, including immunotherapy.
• This treatment is designed just for you!

About the Study:

• The purpose of this study is to learn more about personalized cancer therapy including response to treatment and side effects. Information from the patient’s medical record regarding the tests and treatments they have received, or will receive, for their cancer will be collected.
• Genomic testing on tissue from the primary tumor or metastases will be used to match therapy recommendations.
• Patients in which there is no appropriate matched therapy will receive systemic chemotherapy according to their treating physician’s discretion. This information will be used to describe whether or not patients respond better when their physicians choose to treat them according to the genetic makeup of their tumor.

Study Contact Information

• Shuks Sulaiman
  ssulaiman@ucsd.edu
• (858) 246-2073
• NCT02534675
• PI: Dr. Jason Sicklick
• The trial is open at UC San Diego and Avera Cancer Institute

You CAN join if:

• Male or female, age 18+
• Incurable malignancy that is either unresectable, metastatic, medically unfit for surgical resection, or no conventional therapy is available
• Actionable alterations determined by FoundationOne assay

You can’t join if:

• Disagreement of two oncologists on prognosis or resectability.
• Severe or uncontrolled medical disorder that would, in the investigator's opinion, confound study analyses of treatment response.
**PREDICT:** Moores PREDICT (Profile Related Evidence Determining Individualized Cancer Therapy)

**What the Study Entails:**
- All cancer types are eligible
- Multiple molecular alterations are evaluated
- Blood draws with optional biological samples such as urine or ascites fluid.

**Study Contact Information:**
- Suzanna Lee
- Email
- Phone
- NCT2478931
- PI: Razelle Kurzrock
- The trial is open at UC San Diego, Rady Children’s Hospital San Diego, Eisenhower Medical Center

**About this study:**
- This study is being conducted to learn more about personalized cancer therapy, including response and toxicity.
- No therapy is included in this study
- If you have a tumor “profile” the researchers will look at whether or not your doctors has treated you with drugs that are matched to genetic abnormalities that may have been found in your profile.

**What is Personalized Cancer Therapy?**
- The practice of making decisions about what kind for treatment patients should receive based on the genetic makeup of their tumor.
- If a patient’s tumor has a gene abnormality, their cancer may respond better to a drug that targets that specific abnormality.

**You CAN join if:**
- 18+ years for consent or written consent from legal guardian and written assent from patients 7+
- Confirmed cancer or cancer-related diagnosis

**You can’t join if:**
- You have recent hemoglobin levels of less than 10 g/dL
USC Norris Comprehensive Center/ Keck Medicine of USC

- USC Norris is part of the Keck School of Medicine and is designated by the National Cancer Institute as one of the nation’s 49 comprehensive cancer centers.
  - Link to clinical trials at USC
    - https://cancer.keckmedicine.org/patients/clinical-trials/
  - To refer a patient, please call 323-865-3050.
## Enrolling Research Trials at USC

<table>
<thead>
<tr>
<th>Name</th>
<th>Cancer type/State/Subtype</th>
<th>Phase</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial 1B-16-5</strong></td>
<td>Any patient referred to the breast cancer genetic risk counseling clinics.</td>
<td>Observational</td>
<td></td>
</tr>
<tr>
<td><strong>Trial 0S-12-12</strong></td>
<td>All cancer types</td>
<td>Observational</td>
<td></td>
</tr>
<tr>
<td><strong>Norris ORIEN Total Cancer Care</strong></td>
<td>This research trial collects biological samples and clinical information to create a repository of data from patients with cancer or a predisposition for cancer.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Trial CTSU-EAY131</strong></td>
<td>Advance refractory Solid tumors, lymphomas or multiple myeloma</td>
<td>Phase II</td>
<td></td>
</tr>
<tr>
<td><strong>Trial 1B-17-8</strong></td>
<td>Stage 4 breast cancer. Also enrolling healthy patients.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Homing Study**
Harvest of Circulating Tumor Cells (CTCs) from Patients with Metastatic Breast Cancer (MBC) using the Parsortix™ PC1 System.
## Enrolling Research Trials at USC

<table>
<thead>
<tr>
<th>Name</th>
<th>Cancer type/State/Subtype</th>
<th>Phase</th>
<th>Intervention</th>
</tr>
</thead>
</table>
| **Trial 0S-12-4**  
USC Norris Comprehensive Cancer Center - Cancer Genetics Registry. | Any individual with multiple primary cancers, diagnosed with cancer under age 50, a known hereditary cancer syndrome |  |  |
| **Trial 0C-14-2**  
Neratinib HER Mutation Basket Study (SUMMIT)  
An open-label, multicenter, multinational, Phase 2 study exploring the efficacy and safety of neratinib therapy in patients with solid tumors with activating HER2, HER3 or EGFR mutations or with EGFR gene amplification. | Malignant Solid Tumor  
Fibrolamellar Carcinoma | Phase II | Neratinib |
| **Trial GOG-0225**  
Diet and Physical Activity Change or Usual Care in Improving Progression-Free Survival in Patients With Previously Treated Stage II, III, or IV Ovarian, Fallopian Tube, or Primary Peritoneal Cancer | Ovarian cancer  
Fallopian cancer  
Primary peritoneal cancer | Phase III |  |
| **Trial 0C-15-5**  
A Clinical Trial of Pembrolizumab (MK-3475) Evaluating Predictive Biomarkers in Subjects with Advanced Solid Tumors (KEYNOTE 158) | Advance solid tumors | Phase II | Pembrolizumab |
# Enrolling Research Trials at USC

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<tr>
<td><strong>Trial 1B-14-5</strong></td>
<td>Breast cancer Stage I-III</td>
<td>Pilot</td>
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<tr>
<td>High-Intensity Interval Training for Stage I-III Breast Cancer Patients during Trastuzumab or Anthracycline Use</td>
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<tr>
<td><strong>Trial 1B-10-3</strong></td>
<td>Invasive breast cancer</td>
<td>Phase II</td>
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<tr>
<td>Investigation of Serial Studies to Predict Your Therapeutic Response with Imaging And molecular Analysis 2.</td>
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Research Studies at USC

Stephen Gruber MD, PhD, MPH
• Dr. Gruber’s focus is the genetic epidemiology of cancer with an emphasis on colorectal cancer, the molecular pathogenesis of cancer integrated with genetic epidemiology, methods in genetic and molecular epidemiology, clinical cancer genetics, and translational research in cancer prevention.
• Numerous prior publications on topics including mismatch repair gene mutations, clinical presentation of Hispanic individuals with Lynch syndrome, and increased yield of actionable mutations using multi-gene panels to assess hereditary cancer susceptibility in an ethnically diverse clinical cohort.

John Carpten PhD
• Dr. Carpten’s research focuses on the developments and application of cutting edge genomic technologies and bioinformatics analysis in search of germline and somatic alterations that are associated with cancer risk and tumor characteristics, specifically related to prostate cancer.
• Lead author on the first genome wide scan for hereditary prostate cancer genes.
• Involved in the identification of HOXB13 as the first true hereditary prostate cancer gene.
Research Studies at USC

Gregory Idos MD – Hereditary Cancer Research Projects

Multiplex Gene Panel Testing in the Diagnosis of Hereditary Cancer
• Advances in genetic sequencing have expanded germline genetic analysis for hereditary cancer risk assessment far beyond the single gene tests. Yet the benefits and harms of gene panel testing are unknown. This is a multi-center prospective cohort study of hereditary cancer testing to measure the benefits, harms, and patient experiences of multiplex gene panel testing.

Inherited Susceptibility to Pancreatic Cancer
• Inherited genetic factors account for 5% to 10% of all pancreatic cancer. The USC Norris Comprehensive Cancer Center is home to the Cancer Surveillance Program of Los Angeles County, and has developed a diverse biorepository of pancreatic cancers. This study evaluates a diverse cohort of pancreatic cancer samples for germline mutations.

Inherited colorectal cancer risk variants: from association to biology
• Chemoprevention is an approach to reducing mortality using a variety of medications that can prevent cancer from developing in the colon. In this study, we utilize organoid and stromal cell models to study the chemopreventative effect of statins on Lynch syndrome organoids that increase the risk of colorectal cancer.

Contact Information
• Genetics office: 323-865-0991
Research Studies at USC

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I-SPY 2 Study

- Multicenter Trial
- Primary Endpoints:
  - Pathological complete response (pCR)
  - Defined as no residual invasive cancer in breast or lymph nodes
  - Assessed using the Residual Cancer Burden (RCB) method
  - Highly reproducible between local and central pathologist review
- I-SPY 2 To Date
  - >1000 patients completed surgery
  - 11 investigational agents/combinations
Pathological Complete Response Predicts Event-Free and Distant Disease Free Survival in the I-SPY 2 TRIAL

Douglas Yee, MD
Masonic Cancer Center, University of Minnesota

On behalf of I-SPY2 Investigators and authors:


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**HOMING Study**

- Women with either newly diagnosed metastatic breast cancer who are about to start a new line of therapy or those with currently progressive or recurrent disease
- Blood drawn from each subject will be run through the Parsortix system to capture circulating tumor cells (CTC)
- Harvested CTC’s will be evaluated through cytopathology, FISH, qPCR, RNAseq to determine their diagnostic efficacy
THANK YOU

QUESTIONS?