

BREAST CANCER STUDIES

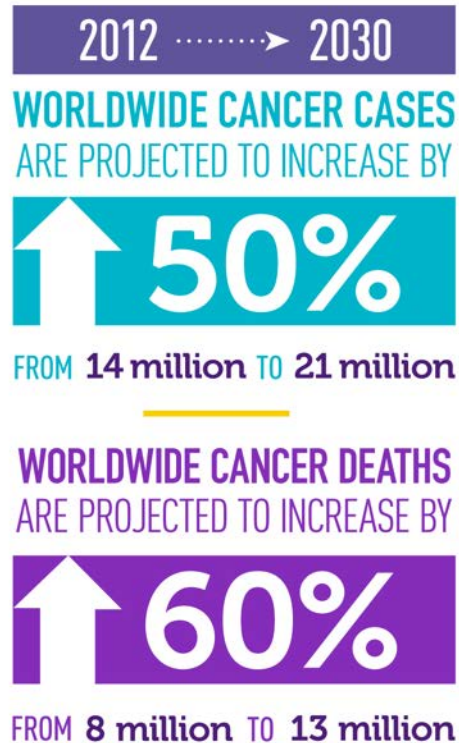
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UNIVERSITY OF HAWAII

CANCER CENTER

Importance of Clinical Trials



Source: American Cancer Society: Global Cancer Facts & Figures, Second Edition
cancer.gov

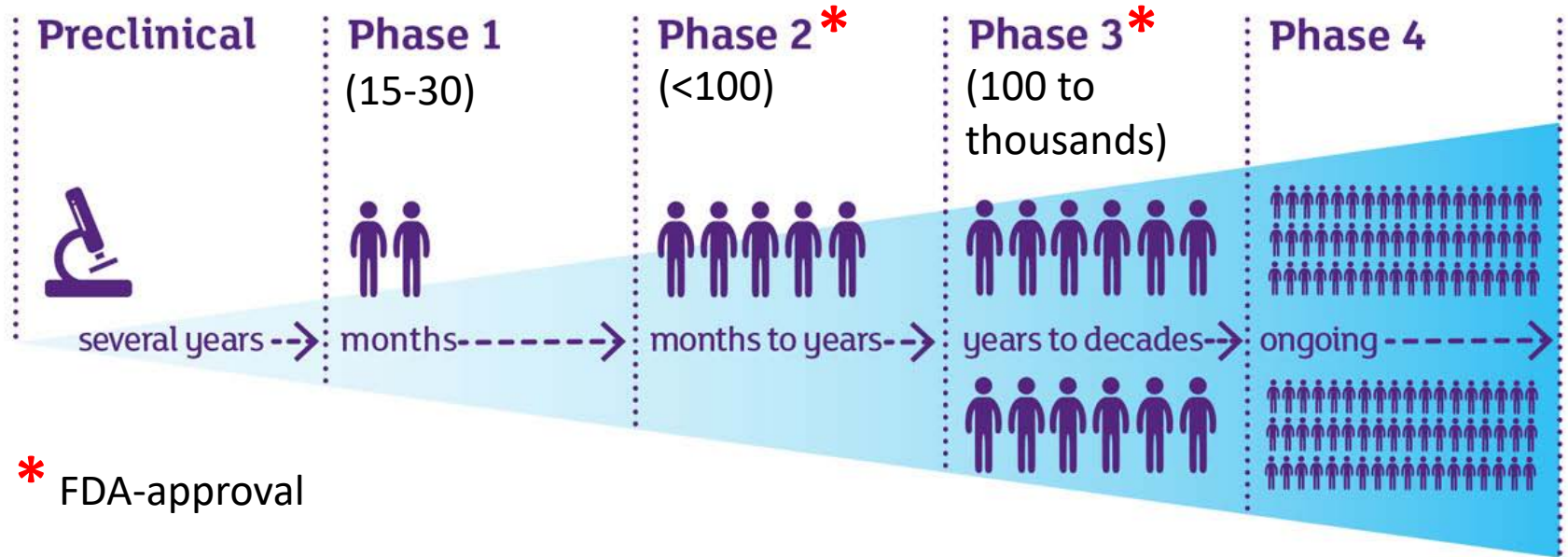
- Research brings hope for cures → key to making progress against cancer
- Today's treatments were clinical trials 5-10 years ago
- Today's clinical trials may be standard treatments in 5-10 years

Types of Cancer Clinical Trials

- Treatment
- Prevention
- Screening
- Supportive Care
- Correlative (laboratory science)
- Healthcare Delivery
- Diagnostic
- Quality of Life

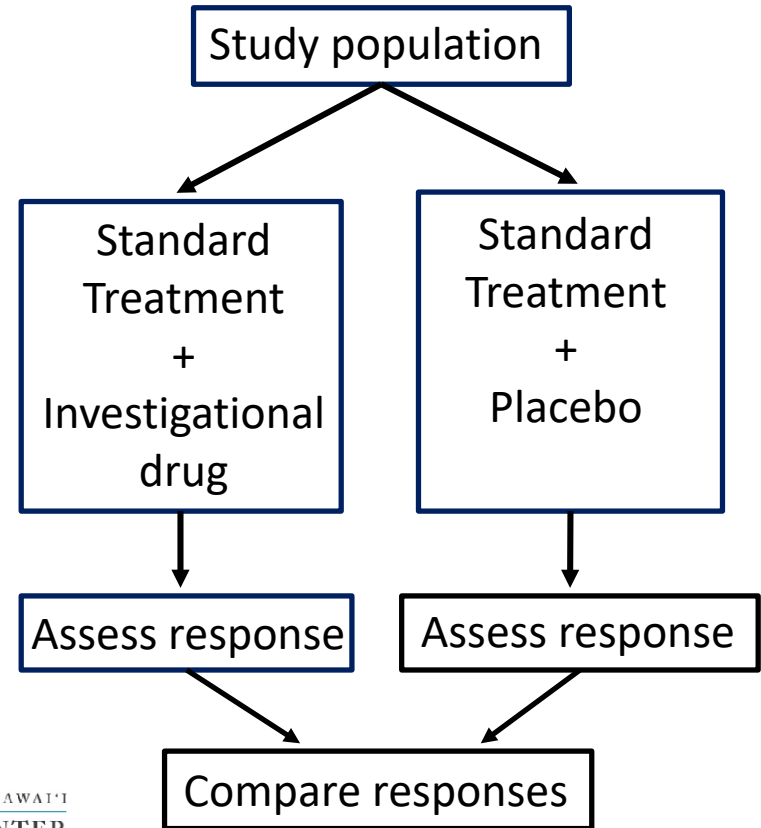


Phases of Cancer Clinical Trials



How Do Cancer Clinical Trials Work?

- Participants assigned to specific study group
- Level of medical attention and care same regardless of study group assigned



Benefits of Clinical Trials

- Access to new and novel treatments and approaches
- Contribute to cancer research
- Highest quality of care
 - Increased oversight
 - Standardized, scientifically reviewed treatments
 - Mandatory quality assurance

Research Team

- Principal investigator
- Research nurse
- Clinical research associate
- Data specialist
- Treating physician and nurse



CLINICAL TRIAL AWARENESS



85% OF CLINICAL TRIALS FAIL TO RETAIN ENOUGH PATIENTS



80% OF CLINICAL TRIALS FAIL TO FINISH ON TIME



50% OF SITES ENROLL ONE OR NO PATIENTS IN THEIR STUDIES



40% OF THE TOTAL US PHARMACEUTICAL CLINICAL TRIAL BUDGET GOES TOWARD RECRUITMENT (\$1.89B)



30% OF PATIENTS DROP OUT OF A CLINICAL TRIAL

SOURCE: NUTTAL, AIDAN, "CONSIDERATIONS FOR IMPROVING PATIENT RECRUITMENT INTO CLINICAL TRIALS," <id>CONSIDERATIONS FOR IMPROVING PATIENT RECRUITMENT INTO CLINICAL TRIALS</id>, RDP CLINICAL OUTSOURCING, 23 MAR, 2012. WEB: 17 NOV, 2015.



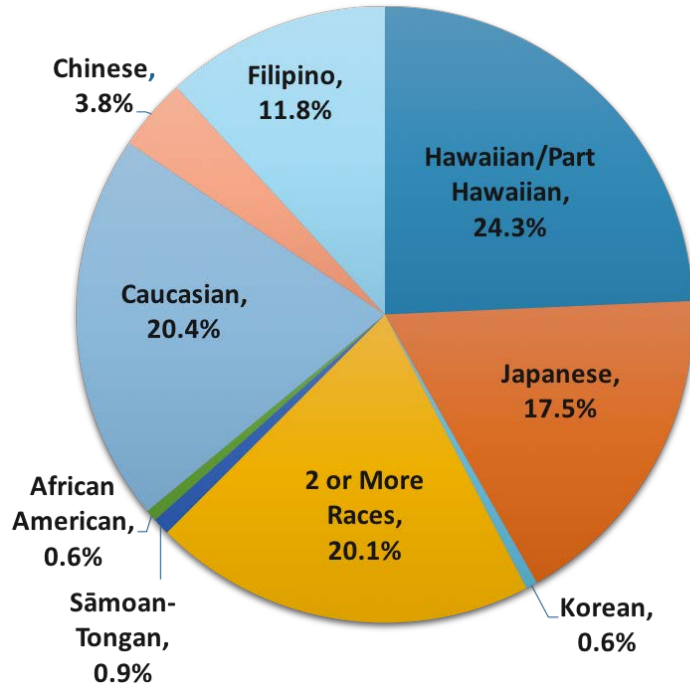
Statistics about clinical trials

- Children – nationally 70-75% of kids with cancer enroll onto a clinical trial
- Adults - ~3% of adults with cancer enroll on a clinical trial
- Reasons:
 - Lack of knowledge education
 - Concerns about effectiveness
 - Concerns about cost



ONE STEP CLOSER

Clinical Trials Lack Ethnic Diversity



Hawai'i population

- 95% clinical trials participants Caucasian
- Under-representation of racial/ethnic minorities
- Reduces generalizability of research findings

Hawaii's Cancer Health Disparities

Pacific Island Populations present with significant cancer health disparities compared to the US and other ethnic populations in Hawai'i and Guam.

Key statistics:

- From 2012-2016, breast cancer incidence and mortality rates were highest among Native Hawaiian women.
- Pacific Islanders represent the highest percentage of women that have never had a mammogram.
- Only 26% of Micronesian women 40 and older have ever had a mammogram.



Do you want to help doctors develop ways to personalize breast cancer screening for women in the future?

If so, will you consider participating in a breast cancer screening study?

We are currently recruiting women to TMIST, a clinical trial that will help us develop strategies that tailor breast cancer screening to the risks of individual women

In order to participate in the study:

You must be

- 45-74 years of age
- Scheduled for a screening mammogram

and

You must not

- Be pregnant, intend to be pregnant, or lactating
- Have symptoms of breast disease
- Have had a screening mammogram in the last 11 months
- Have a history of breast cancer
- Currently have breast implants or other breast enhancements

If you decide to participate, you will be involved in this research study for up to 8 years starting with your first mammogram. During this time:

- You will be randomized (assigned by a computer) to get either 3D or 2D mammograms for the first 5 years of the study
- Most women in the trial will be screened annually, but postmenopausal women with no high-risk factors will be screened every two years
- We will follow your breast cancer status for up to 8 years in total, including the screening years, by reviewing your medical records and, if needed, contacting you by phone

Mammography clinic participating in this study

Institution: The Queen's Medical Center - Women's Health Center

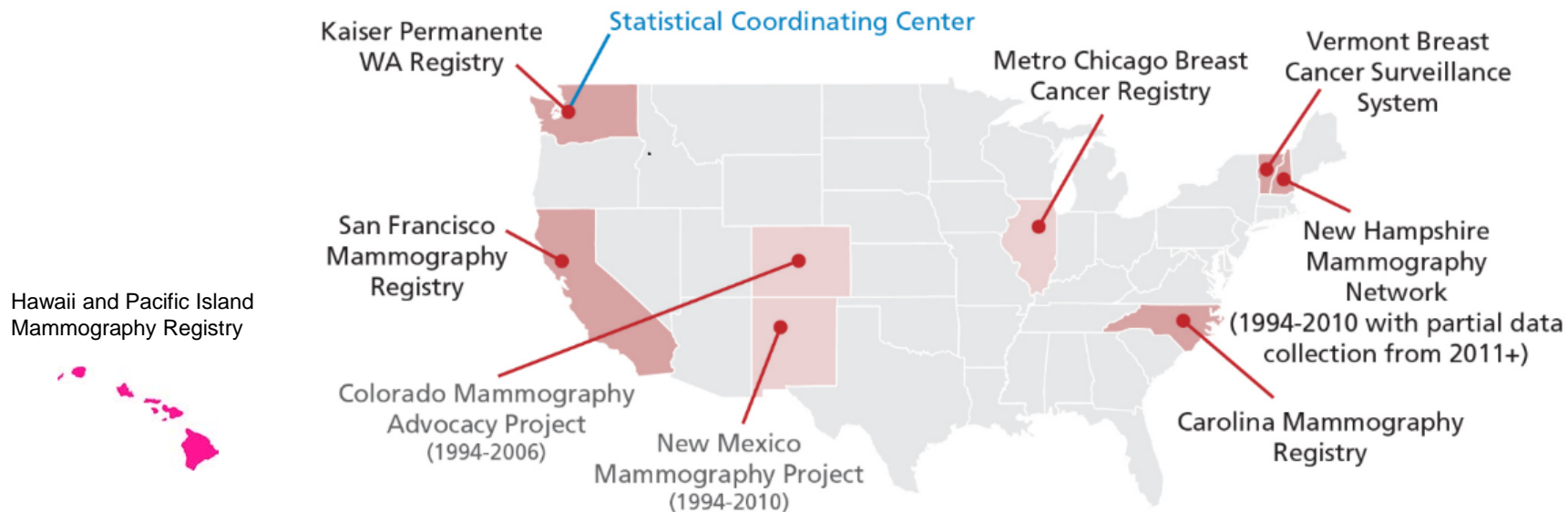
Address: 1301 Punchbowl Street, Honolulu, Hawaii 96813

To learn more about the TMIST breast cancer screening study, please contact:
Alanna Vance: 564-3993 Email: TMIST@cc.hawaii.edu



Hawaii and Pacific Islands Mammography Registry (HIPIMR)

Breast Cancer Surveillance Consortium

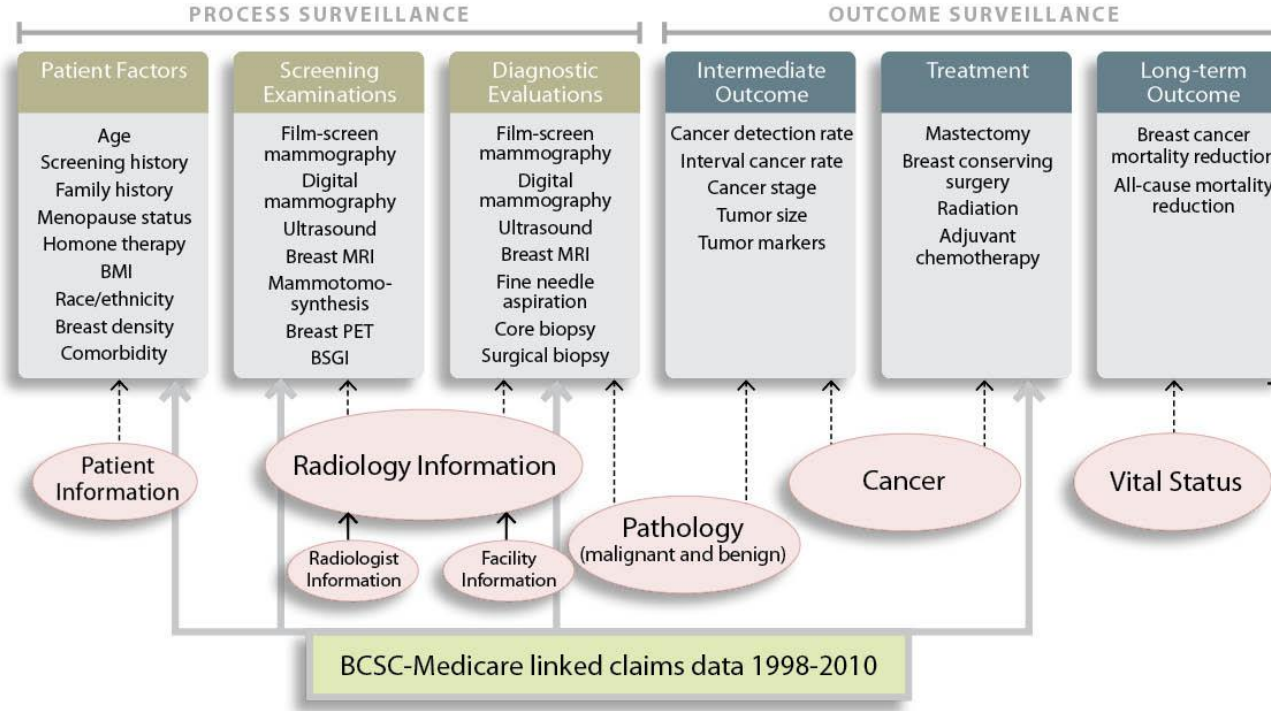


Active registries

Historic registries

CANCER CENTER

Comprehensive Data Resource



Unique Strengths

- Nation's largest longitudinal collection of breast imaging data
 - Risk factor ascertainment in healthy women through outcomes
 - 3.0 million women
 - 14.3 million breast imaging exams
 - 154,000 breast cancers
- Participation of community-based radiology facilities
- Data on diverse women, physicians, and facilities
- Complete capture of outcomes
 - Linkage to cancer registries
- Linkage to other data sources - Medicare

Breast Cancer Exercise Rehabilitation Research Study

The University of Hawaii Cancer Center, the Rehabilitation Hospital of the Pacific along with the University of Hawaii Kinesiology and Rehabilitation Science Department are collaborating in a study to show how exercise improves the health, fitness and quality of life for breast cancer patients and may lead to body composition changes.

REHAB Hospital of the Pacific, Hawaii's only premier, acute-care rehabilitation hospital, and the University of Hawaii's Kinesiology and Rehabilitation Science Department are collaborating in a study to show how exercise diminishes the toxic effects associated with cancer therapies. With your help, we can study how cancer exercise rehabilitation improves the health, fitness and quality of life for cancer patients.



WHY PARTICIPATE? <i>Benefits</i>	<ul style="list-style-type: none"> <input type="checkbox"/> Sessions are FREE! <input type="checkbox"/> 12 weeks of personalized training sessions (90 minutes each) with professional Kinesiology students (3x/week) <input type="checkbox"/> Continued 12 weeks of either personalized training sessions or group sessions (90 minutes each, 2x/week) <input type="checkbox"/> Copy of the DXA scan report (fat, lean and bone mass) <input type="checkbox"/> Complete blood count results
HOW DO I QUALIFY? <i>Requirements</i>	<ul style="list-style-type: none"> <input type="checkbox"/> A medical history of a diagnosis of breast cancer within 2 years, any type of past, current or scheduled medical intervention (surgery, chemotherapy, radiation therapy) <input type="checkbox"/> Clearance from your medical oncologist to participate <input type="checkbox"/> Able to lay flat on your back for up to 10 minutes <input type="checkbox"/> Able to stand without aid for 2 minutes <input type="checkbox"/> Do not have any metal implants and is not pregnant
WHAT TO EXPECT <i>Fitness Tests & Measurements</i>	<ul style="list-style-type: none"> <input type="checkbox"/> Several body composition measures will be completed for this study: whole-body DXA, blood draw, optical (2D and 3D) imaging and muscle strength <input type="checkbox"/> Lung function <input type="checkbox"/> Cardiorespiratory fitness training (treadmill) <input type="checkbox"/> Flexibility <input type="checkbox"/> Quality of life questionnaires and other related assessments
HOW TO PARTICIPATE: <i>Choose from any of these options:</i>	<ol style="list-style-type: none"> 1) Submit a registration form: http://bit.ly/CancerExerciseStudy1 And call Matthew Toyama-study coordinator (808) 564-3996 2) For the body composition only: <ul style="list-style-type: none"> ■ Contact UHCC Shape Up Study ■ Phone: (808) 440-5234 Email: bodycompstudies@cc.hawaii.edu 3) Call one of our Program Directors: <ul style="list-style-type: none"> ■ Cheri Teranishi-Hashimoto, DPT, MSPT, MS <ul style="list-style-type: none"> ○ Program Director - Women's Health & Cancer Rehabilitation ○ Ph: (808) 566-3428 Email: cheri.teranishi@rehabhospital.org ■ Paulette Yamada, PhD <ul style="list-style-type: none"> ○ Assistant Professor - Kinesiology & Rehabilitation Science, UH Manoa ○ Ph: (808) 956-3638 Email: pyamada@hawaii.edu

BENEFITS

- Sessions are FREE!
- 12 weeks of personalized training sessions (90 minutes each) with professional Kinesiology students (3x/week)
- Have fun while getting fit to fight cancer! (Optional: Participants may opt out of exercise training and elect to perform fitness test only)

REQUIREMENTS

- Must be 18-years of age or older
- A medical history with a diagnosis of any type of cancer with past, current or scheduled medical intervention (i.e. surgery for tumor removal, chemotherapy, radiation therapy, immunotherapy)
- Clearance from your medical oncologist to participate

FITNESS TESTS & MEASUREMENTS

Physical fitness and health testing will take approximately 3 hours for the initial and exit assessments, which includes:

- Vitals (blood pressure, HR, O₂ saturation)
- Body composition & circumference measurements
- Pulmonary function
- Cardiorespiratory fitness training (treadmill)
- Muscular strength & muscular endurance
- Flexibility
- Quality of life and other related assessments

HOW TO APPLY: ***Ongoing Enrollment***

Option 1
Scan QR Code



Option 2
Submit a registration form:
<http://bit.ly/CancerExerciseStudy1>



Option 3
Call one of our Program Directors:
Cheri Teranishi-Hashimoto, DPT, MSPT, MS
Women's Health & Cancer Rehabilitation Program Director
Ph: (808) 566-3428 Email: cheri.teranishi@rehabhospital.org

Paulette Yamada, PhD
Assistant Professor
Kinesiology & Rehabilitation Science, UH Manoa
Ph: (808) 956-3638 Email: pyamada@hawaii.edu

NCCN Guidelines

- National Comprehensive Cancer Network
- Recommendations/algorithms: prevention, diagnosis, management of cancer

”**Clinical Trials**: NCCN believes that the best management of any patient with cancer is in a clinical trial. Participation in clinical trials is especially encouraged.”

Take Home Message

- Best treatment option for cancer patients is a clinical trial
- Clinical trial participants receive highest level of care
- Most adult cancer patients do not enroll due to multitude of barriers at all levels – most can be overcome
- Clinical trials benefit participants, society, science

Resources

- UH Cancer Center Clinical Trials Office
(808) 586-2979
- NCI's Cancer Information Service
1-800-4220-6237 Hawaii and US trials