Project EXTRA with USF: Community Partnerships for Patient Empowerment and the Improvement of Breast Cancer Care

Bethany Jowers, B.S. & B.A. candidate
Marleah Dean Kruzel, PhD
Sue Friedman, DVM

January 25, 2024
Undergraduate Humanities Symposium
University of South Florida

FORCE

Disclosures

This work is supported by a cooperative agreement from the Centers for Disease Control and Prevention (NU58DP006677)

- Co-Principal Investigators: Sue Friedman and Marleah Dean
- Project Title: “Expanding XRAYS ThRough Alliances: Project EXTRA.”

Agenda

- Acronyms/Definitions
- Introduction
- Project EXTRA Overview
- FORCE Overview
- USF Involvement
- Lessons Learned

Important Acronyms/Definitions

- **BC** = breast cancer
- **mBC** = metastatic breast cancer, or breast cancer that has spread to other parts of the body
- **YBCS** = young breast cancer survivor
- **HCP** = healthcare provider
- **POC** = person/people of color
- **CEU** = continuing education unit
- **Previvor** = an individual with inherited genetic risk for cancer but no active or past cancer diagnosis

Introduction

BC previvors, patients, and survivors face challenges in gathering information and making healthcare decisions.

What are some of these challenges?

Challenges

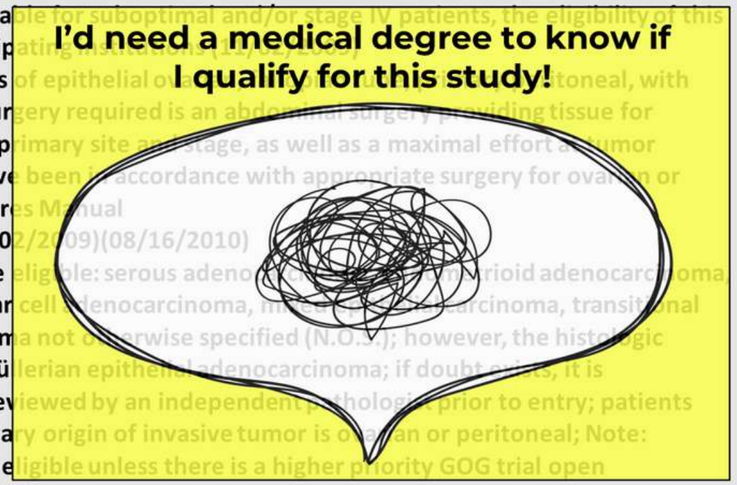
- Barriers to communication with HCPs

Challenges

- Incomprehensible scientific study results or enrollment requirements

Inclusion Criteria:

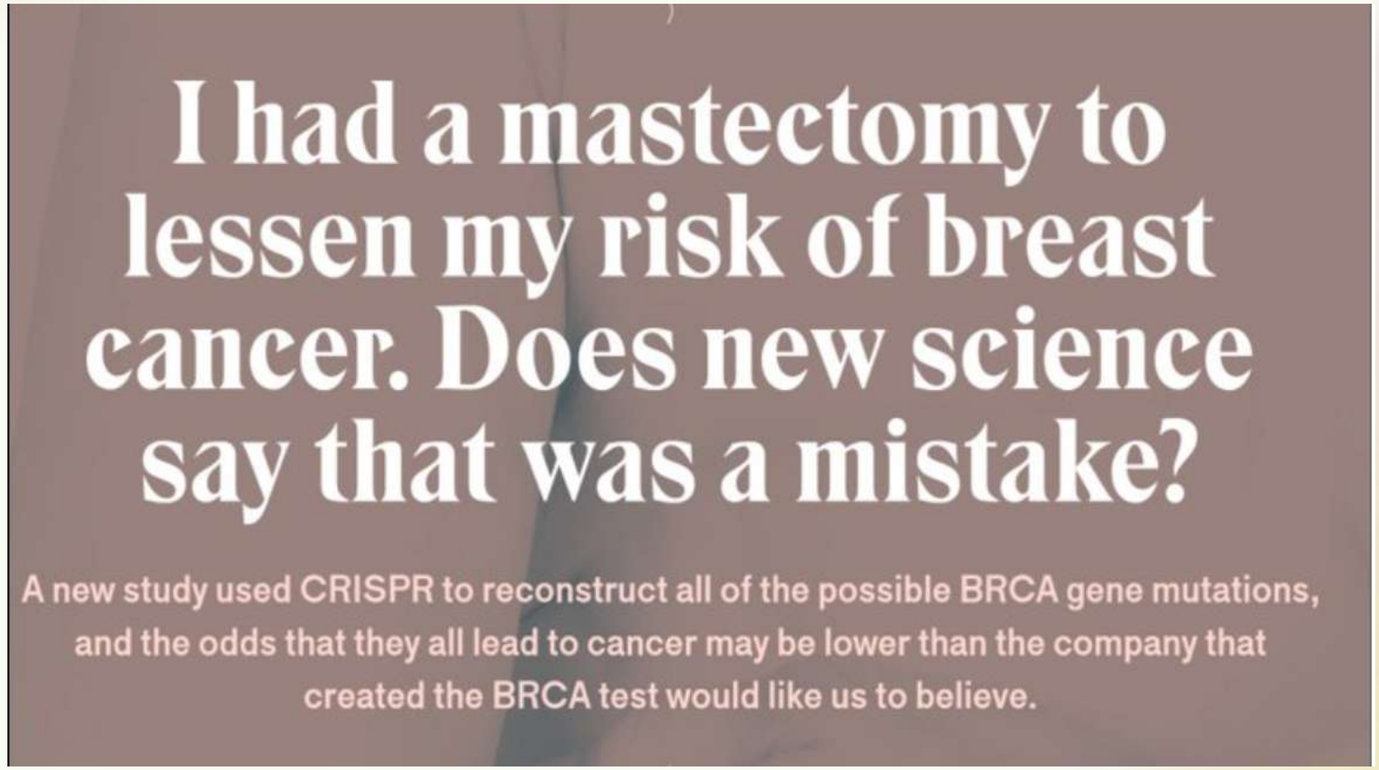
- **Patients with a histologic diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal carcinoma, stage II, III, or IV with either optimal (=< 1 cm residual disease) or suboptimal residual disease; in the event of a higher priority Phase III Gynecologic Oncology Group (GOG) protocol becoming availa ble for suboptimal and/or stage IV patients, the eligibility of this study will narrow and exclude those patients at those particip ating institutions that enroll**
- **All patients must have a procedure for determining diagnosis of epithelial ov an or peritoneal, with appropriate tissue for histologic evaluation; the minimum sur gery required is an abdominal surgery providing tissue for histologic evaluation and establishing and documenting the p imary site and stage, as well as a maximal effort at tumor debulking; if additional surgery was performed, it should hav been in accordance with appropriate surgery for ova n or peritoneal carcinoma described in the GOG Surgical Procedur s Manual (https://www.gog.fccc.edu/manuals/pdf/surgman.pdf) (11/0 /2009)(08/16/2010)**
- **Patients with the following histologic epithelial cell types are eligible: serous adeno carcinoma, endometrioid adenocarc noma, mucinous adenocarcinoma, undifferentiated carcinoma, clear cell adenocarcinoma, m xed cell carcinoma, transitional cell carcinoma, malignant Brenner's Tumor, or adenocarcinom a not otherwise specified (N.O.S.); however, the histologic features of the tumor must be compatible with a primary Mü lerian epithelial adenocarcinoma; if doubt exists, it is recommended that the investigator should have the slides re viewed by an independent pathologist prior to entry; patients may have co-existing endometrial cancer so long as the prima y origin of invasive tumor is ovarian or peritoneal; Note: patients with mucinous, low grade and clear cell disease are e igible unless there is a higher priority GOG trial open (11/02/2009) (08/16/2010)**
- **Absolute neutrophil count (ANC) greater than or equal to 1,500/mcl, equivalent to Common Terminology Criteria for Adverse Events v3.0 (CTCAE) grade 1; this ANC cannot have been induced or supported by granulocyte colony stimulating factors**



Focus group participant when asked if she thought she was eligible for this study.

Challenges

- Misinformation from the media



What does this mean?

Difficult to make informed decisions regarding:

- Genetic testing
- BC surveillance plans
- BC treatment options
- Healthy lifestyle
- Which HCP(s) to see
- Communicating risk/diagnoses with loved ones

Additional Challenges

- Women with mBC
- Young BC previvors, patients, survivors
- POC
    - Barriers to healthcare access
    - HCP communication struggles
    - Low research involvement

Project EXTRA

Expanding XRAYS ThRough Alliances

- 2019 - 2024
- Funding from the U.S. Center for Disease Control and Prevention
- Extension of previous grant: XRAYS, eXamining the Relevance of Articles for Young Survivors
- Over 45 partners across the U.S.
  - Susan G. Komen
  - Univ. of South Florida
  - Nat'l Alliance for Hispanic Health
  - Individual researchers/health professionals
- Spearheaded by FORCE: Facing our Risk of Cancer Empowered

Project EXTRA

Expanding XRAYS ThRough Alliances

- Target populations:
  - Women diagnosed with or at increased, hereditary risk of developing BC
    - YBCS / patients (<45 years old)
    - mBC patients / survivors
    - POC
- Areas of interest:
  - Health literacy / patient communication
  - Lifestyle / healthcare-related services:
    - Healthy lifestyle
    - Mental health
    - Sexual health
    - Treatment options
    - Survivorship

FORCE:

Facing Our Risk of Cancer Empowered

- Founded in 1999 by Dr. Sue Friedman, DVM
- Resource hub for people with hereditary cancer/risk:
  - Education
    - Website
    - Community events
  - Advocacy
    - Ex. AMP v. Myriad Genetics
  - Research
    - Results
    - Enrollment in ongoing studies

FORCE

The XRAY tool: EXamining the Relevance of Articles for You

Nature. 2018 Oct;562(7726):217-222. doi: 10.1038/s41586-018-0461-z. Epub 2018 Sep 12.

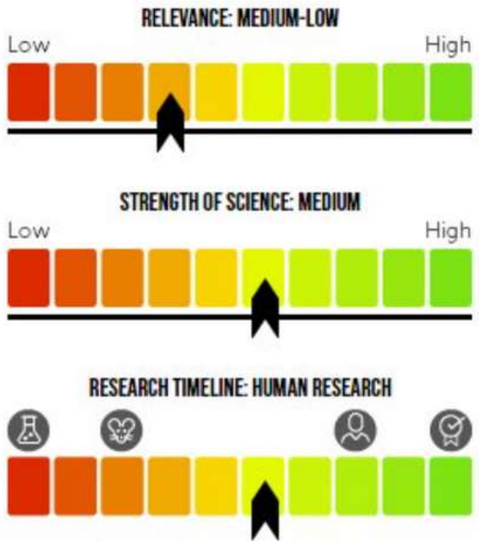
Accurate classification of BRCA1 variants with saturation genome editing

Abstract

Variants of uncertain significance fundamentally limit the clinical utility of genetic information. The challenge they pose is epitomized by BRCA1, a tumour suppressor gene in which germline loss-of-function variants predispose women to breast and ovarian cancer. Although BRCA1 has been sequenced in millions of women, the risk associated with most newly observed variants cannot be definitively assigned. Here we use saturation genome editing to assay 96.5% of all possible single-nucleotide variants (SNVs) in 13 exons that encode functionally critical domains of BRCA1. Functional effects for nearly 4,000 SNVs are bimodally distributed and almost perfectly concordant with established assessments of pathogenicity. Over 400 non-functional missense SNVs are identified, as well as around 300 SNVs that disrupt expression. We predict that these results will be immediately useful for the clinical interpretation of BRCA1 variants, and that this approach can be extended to overcome the challenge of variants of uncertain significance in additional clinically actionable genes.

FORCE

The XRAY tool: EXamining the Relevance of Articles for You



Study : A new method for determining whether genetic variants in BRCA1 increase cancer risk

Most relevant for: People who have a Variant of Uncertain Significance in a gene associated with cancer risk.

Ever since BRCA1 was discovered, researchers have been trying to understand which of the thousands of possible DNA changes in this gene increase cancer risk and which are harmless changes. A new study in Nature reports how a cutting-edge technology called "genome editing" may be used to classify changes—known as variants of uncertain significance-in BRCA1 as harmful or harmless. Once validated, this same technology may be used to classify variants in other genes. (9/29/18)

Read More

FORCE
Facing Hereditary Cancer EMPOWERED

FORCE

Search and Enroll Tool

Eligibility Criteria

Description

Inclusion Criteria:

- Participants with LS defined as one of the following:
  - Mutation positive: MLH1, MSH2/EPCAM and MSH6 genotypes with prior history of >= 1 adenoma(s) and/or >= 1 advanced adenoma(s) and/or colon cancer(s) (but no active cancer for 6 months) OR
  - PMS2 genotype with prior history of colon cancer(s) (but no active cancer for 6 months)
- Participants must have at least part of the descending/sigmoid colon and/or rectum intact
- Participants must be at least 6 months from any cancer-directed treatment (such as surgical resection, chemotherapy, immunotherapy or radiation)
- Participants >= 18 years will be enrolled. Because the risk of LS related cancers is very low in participants < 18 years of age, children and adolescents are excluded from this study
- Eastern Cooperative Oncology Group (ECOG) performance status =< 1 (Karnofsky >= 70%)
- Leukocytes >= 3,000/microliter
- Absolute neutrophil count >= 1,500/microliter
- Platelets >= 100,000/microliter
- Total bilirubin within normal institutional limits
- Aspartate aminotransferase (AST) (serum glutamic-oxaloacetic transaminase [SGOT])/alanine aminotransferase (ALT) (serum glutamate pyruvate transaminase [SGPT]) =< 1.5 x institutional upper limit of normal
- Creatinine within normal institutional limits
- The effects of the Tri-Ad5 vaccines and N-803 on the developing human fetus at the recommended therapeutic dose are unknown. For this reason, women of child-bearing potential and men must agree to use adequate contraception (hormonal or barrier method of birth control; abstinence) prior to study entry and for the duration of study participation. Should a woman become pregnant or suspect she is pregnant while participating in this study, she should inform her study physician immediately
- Ability to understand and the willingness to sign a written informed consent document
- Participants must be willing and able to space coronavirus disease (COVID) vaccines at least 2 weeks prior to and 2 weeks after receipt of study agent

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Exclusion Criteria:

- History of organ allograft or other history of immunodeficiency
- Known human immunodeficiency virus (HIV) with CD4 count < 540, hepatitis B virus (HBV), or hepatitis C virus (HCV) infection. Subjects with laboratory evidence of cleared HBV and HCV infection will be permitted. Poorly controlled HIV may prevent an adequate immune response to the vaccine and will be an exclusion criterion
- Subjects requiring systemic treatment with corticosteroids (> 10 mg daily prednisone equivalents) or other immunosuppressive medications within 3 months of vaccination
- Participants may not be receiving any other investigational agents
- History of allergic reactions attributed to compounds of similar chemical or biologic composition to adenovirus-based vaccines and N-803
- Uncontrolled intercurrent illness or psychiatric illness/social situations that would limit compliance with study requirements
- Pregnant women are excluded from this study because of the unknown effects of the vaccine and N-803 on the fetus. Because there is an unknown but potential risk for adverse events (AEs) in nursing infants secondary to treatment of the mother with the vaccine plus N-803, breastfeeding should be discontinued if the mother is treated with the vaccine plus N-803
- History of untreated thrombotic disorders
- Participants who experienced severe side effects or allergic reactions to previous adenovirus-based vaccines (such as Johnson and Johnson COVID vaccine) will be excluded

FORCE

Search and Enroll Tool

Printer Friendly Page

Testing A Combination Of Vaccines For Cancer Prevention In Lynch Syndrome

Clinicaltrials.gov identifier:
NCT05419011

Prevention
Testing A Combination Of Vaccines For Cancer Prevention In Lynch Syndrome

Study Contact Information:
For more information, please contact ncpc@northwestern.edu

Lynch Syndrome Vaccine Study

About the Study

Lynch Syndrome (LS) increases the risk of colon cancer and other cancers, including cancer of the uterus, ovaries, small bowel, stomach, pancreas, urinary tract, skin, and brain.

This study is being done to assess the safety and effectiveness of a series of vaccines (Tri-Ad5), together with another drug (N-803) that magnifies the body's response to vaccines, to see if there is an effect on the risk of developing colon and other cancers in LS patients.

For more Information, visit https://bit.ly/ihavelynch

What the Study Entails

THIS STUDY IS OPEN TO:

People 18 years or older who:

- Have been diagnosed with Lynch syndrome and have had abnormal growths in their colon or rectum.
- Have not had any cancer treatment in the past 6 months.
- Are not pregnant or planning to get pregnant.

THIS STUDY IS NOT OPEN TO:

People who do not meet the eligibility criteria defined above and those who:

- Have experienced severe side effects or allergic reations to previous vaccines.
- Have a blood clotting disorder.
- Have had organ transplants.
- Are pregnant or breastfeeding.

FORCE

Spot the BOAST!

When you're reviewing health information online, ask yourself:

Is it trustworthy, or is it a B O A S T ?

BIASED

OVERBLOWN

AMATEUR

SALES-FOCUSED

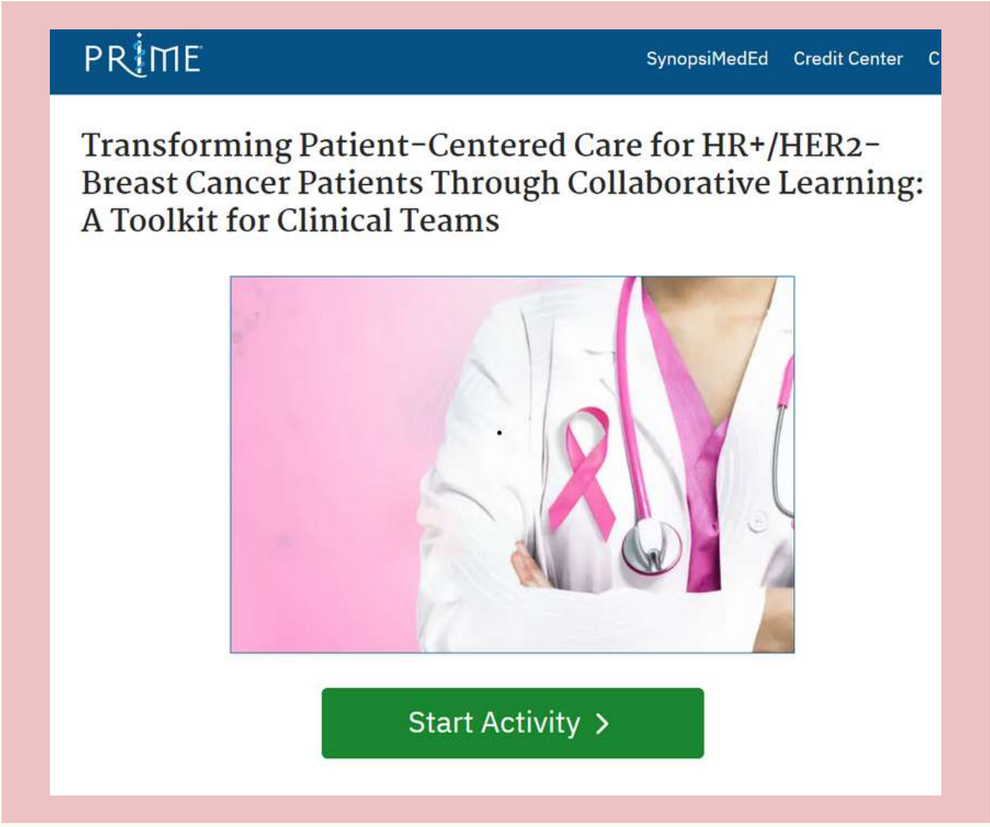
TAKEN OUT OF CONTEXT
TOO SOON TO BE USEFUL

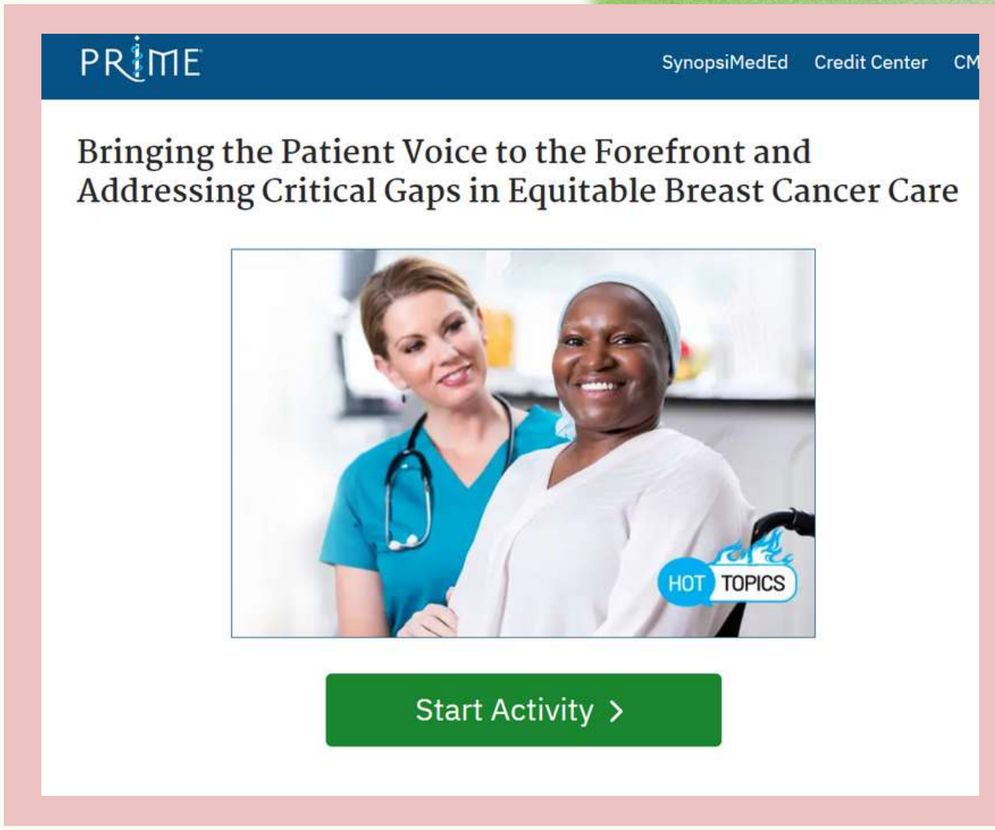
Where does USF come in?

What do I do as an
Undergraduate Research Assistant?

USF Involvement

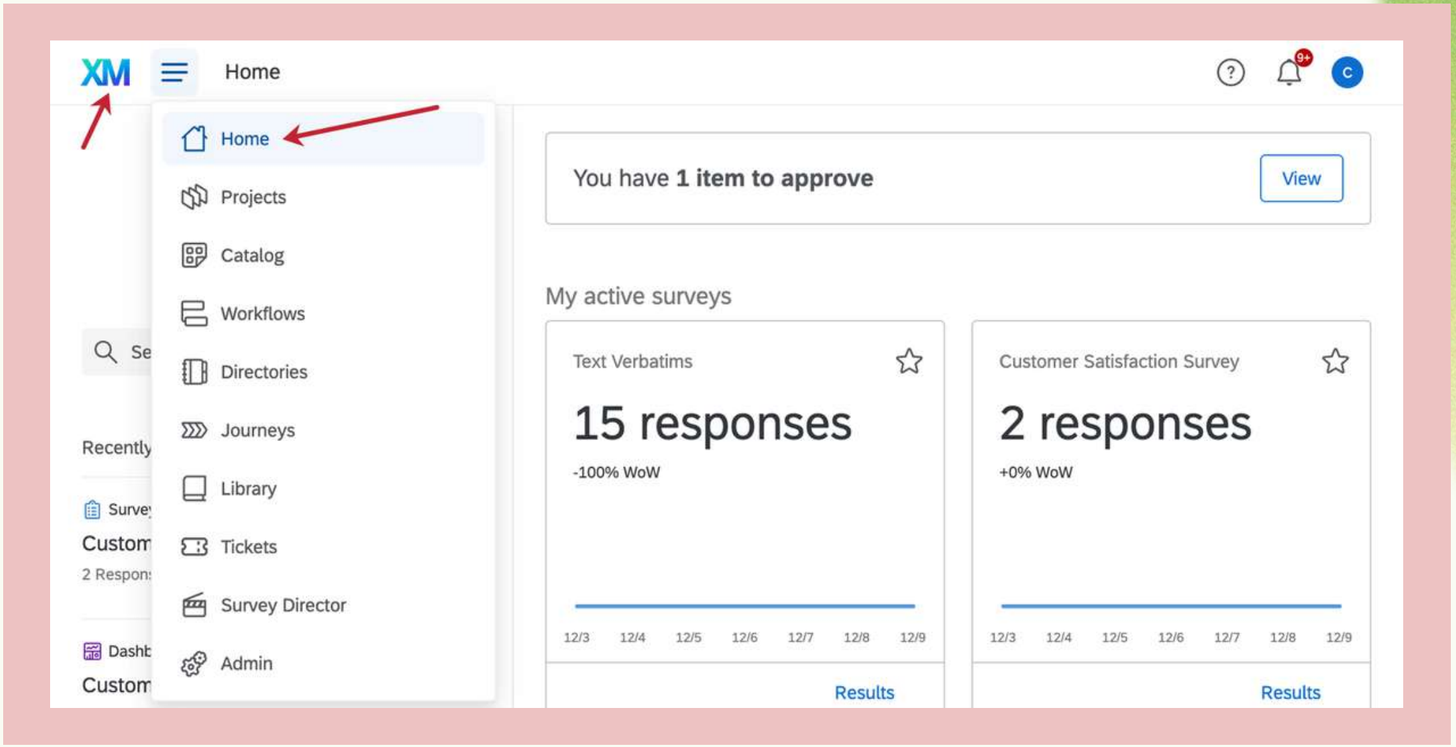
- Collecting CEU opportunities





USF Involvement

- Manage Qualtrics data
  - Needs assessments, focus group recruitment



Recent Publications

- Owens, K., Dean, M., Bourquardez Clark, E., DeBeck, D., Conaty, J., Friedman, S. J., Pugh Yi, R. H., & Klemp, J. R. (Online). **Results of a needs assessment of oncology nurse navigators providing navigation services to breast cancer patients.** Journal of Oncology & Navigation Services.

- Clark, E. B., Bonini, K. E., Yi, R. H. P., Kuhn, E., Klemp, J. R., Rose, D., & Dean, M. (2023). **Experiences of genetic counselors in referring young and metastatic breast cancer patients to support services: A needs assessment.** Patient Education and Counseling, 107946.

USF Involvement

- Assist with creation of digital HCP education

Lessons Learned

- Partnerships
- Community mobilization
- Accessible research
- Translational research
- Targeted efforts → diverse populations
- Continuous improvement on care

References

Parker, P. A., Aaron, J., & Baile, W. F. (2009). Breast cancer: Unique communication challenges and strategies to address them. The Breast Journal, 15(1), 69–75. https://doi.org/10.1111/j.1524-4741.2008.00673

Boumis, J. K., & Dean, M. (2023). The BRCA1/2 previvor information journey: Understanding what helps or hinders. Health Communication, 1–13. https://doi.org/10.1080/10410236.2023.2248677

Zupello S., I had a mastectomy to lessen my risk of breast cancer. Does new science say that was a mistake? TheOutline.com. https://theoutline.com/post/6257/i-had-a-mastectomy-to-lessen-my-risk-of-breast-cancer-does-new-science-say-that-was-a-mistake

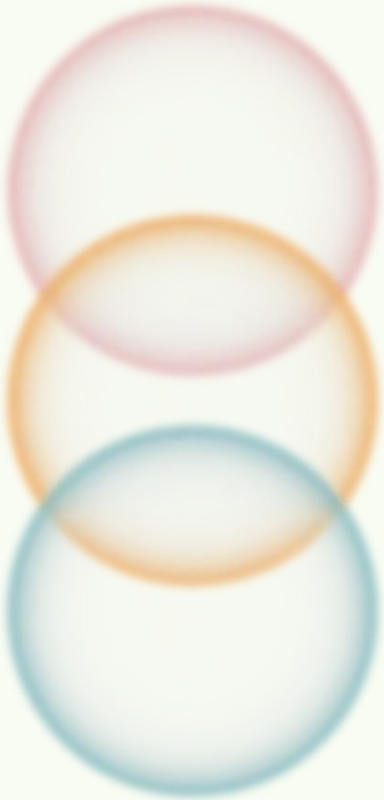
https://www.facingourrisk.org/

Owens, K., Dean, M., Bourquardez Clark, E., DeBeck, D., Conaty, J., Friedman, S. J., Pugh Yi, R. H., & Klemp, J. R. (Online). Results of a needs assessment of oncology nurse navigators providing navigation services to breast cancer patients. Journal of Oncology & Navigation Services.

Clark, E. B., Bonini, K. E., Yi, R. H. P., Kuhn, E., Klemp, J. R., Rose, D., & Dean, M. (2023). Experiences of genetic counselors in referring young and metastatic breast cancer patients to support services: A needs assessment. Patient Education and Counseling, 107946.

https://www.facingourrisk.org/research-clinical-trials/study/273/testing-a-combination-of-vaccines-for-cancer-prevention-in-lynch-syndrome

https://clinicaltrials.gov/study/NCT05419011



Acknowledgements

My sincere thanks to Dr. Marleah Dean Kruzel, Dr. Sue Friedman, Ms. Elizabeth Clark, the Project EXTRA Executive Committee, and the USF Communications Department for giving me the opportunity to support this important work!

Thank you!

Do you have any questions?

FORCE

USF Comm