# The WISDOM Study

Breast cancer risk assessment & personalized screening plans



## The what & why of WISDOM

(Women Informed to Screen Depending on Measures of risk) began in 2016 as a preference-tolerant randomized clinical trial comparing annual breast cancer screening with personalized, risk-based screening recommendations. Starting in 2023, we launched our newest version of the trial, removing randomization, expanding eligibility to enroll younger women, and updating our genetic test methodology. The study is designed to test what we hope will be a transformative approach to breast cancer screening, detection & prevention – optimizing breast cancer detection for higher-risk women while reducing the unintended consequences of current screening practices for lower-risk women. We intend to show that personalized screening makes better use of available resources, screens women at intervals appropriate to their risk, improves compliance and decreases patient anxiety.

#### Who is involved

Founded by researchers at the University of California San Francisco, WISDOM is in partnership with the 5 University of California medical centers, UChicago, University of Alabama at Birmingham, Diagnostic Center for Women (Miami), and DHR Health (Texas). We are also partnered with insurers and employers to offer the benefits of breast cancer risk assessment & personalized screening recommendations to as many women as possible. Women nationwide can join the study even if they don't receive care from these partner institutions.

### How it works

- Women between the ages of 30-74, with no prior breast cancer or DCIS are eligible
- · Register and complete breast health questionnaire online at www.thewisdomstudy.org
- Choose study group (Annual screening or Personalized risk assessment & screening recommendations)
- Personalized group participants complete at-home genetic test
- Women at high risk have 1:1 consult with breast health expert, risk-reduction guidance, printable risk-report summary to share with provider
- Each year participants complete online questionnaire and receive updated risk assessment & screening recommendations
- Receive access to our web-based, personalized prevention tool
- Available in English & Spanish
- · No cost to participate

### Our risk assessment

#### Breast Cancer Surveillance Consortium (BCSC) model

- Age
- Race/ethnicity
- family Hx of breast cancer
- Hx of prior breast biopsies & benign breast disease
- Breast density (we collect mammogram reports)
- BMI
- Menopausal status



#### Saliva-based Genetic Testing

Personalized arm participants complete a test of 29 hereditary cancer genes including those that increase breast cancer risk (BRCA1, BRCA2, TP53, PTEN, STK11, CHD1, ATM, PALB2, CHEK2) plus millions of Single Nucleotide Polymorphisms using Low Pass Whole Genome Sequencing, resulting in a Polygenic Risk Score.



# Personalized screening recommendations

Screening recommendations for Personalized Arm participants are created by modifying the BCSC score with the polygenic risk score, then applying WISDOM risk thresholds to determine screening method and frequency (see Shieh et al, JNCI 2017). Risk thresholds and screening plans are updated throughout the trial, and aligned with international breast screening guidelines.