More than a mammogram

How Rush University Medical Center helps women understand their risk

Rush University Medical Center is one of the first academic medical centers in Illinois to make breast and ovarian cancer risk assessment a foundational component in their screening program. Rush screens approximately 24,000 patients annually.

Approximately 685,000 women globally die of breast cancer every year.[1] Catching cancers earlier is the key to increasing the survival rate. A risk-stratified approach is being recommended by a diverse group of healthcare organizations to determine the most effective care pathway for women who are at high risk of developing breast cancer.

Cancer risk assessment is part of every mammogram appointment at Rush to identify high-risk patients who are eligible for additional care. This personalized approach allows for the early detection of biologically aggressive cancers when they are most treatable.

"Our patients receive so much more than a mammogram. We help them understand their complete risk level and how to mitigate that risk with clinically proven strategies."

—Dr. Lisa Stempel, Division Chief of Breast Imaging at Rush University Cancer Center, Rush System for Health

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Comprehensive assessment and identification

A 3D mammogram, known as tomosynthesis, is the norm for all Rush patients. For those identified as being at a higher risk, additional screening and genetic testing are available to help to detect cancer sooner or inform preventative actions.

As part of the standard intake process, technologists ask patients a series of questions regarding personal and family history. The patient must consent to providing the information for risk modeling and the risk assessment is free of charge. This information, along with breast density, is used in risk model calculations to provide a comprehensive picture of the patient's cancer risk.

Rush uses the following in its risk assessment: the Tyrer-Cuzick v8 Risk Evaluation Tool (TC8), Gail 5-Year, and the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®).

MODELS INCORPORATED IN THE RUSH REPORTS

Tyrer-Cuzick v8

Most comprehensive and consistently accurate for predicting breast cancer risk

Data considered includes breast density, reproductive history, biopsy history, extended family history, and BMI

Threshold: ≥ 20% LIFETIME

Volumetric percent density measure from Volpara® Scorecard™ is the only automated density assessment validated for use in TC8 and improves risk stratification of patients

Gail 5-Year

Best studied indication for chemoprevention based on two large randomized trials

Data considered includes personal and hormonal factors

Threshold:

- ≥ 1.687 (ages 35–50)
- ≥ 2 (ages 50–59)
- ≥ 3 (ages 60–69)
- ≥ 4 (ages 70–79)

NCCN Guidelines®

Oncology recommendations to help health care professionals diagnose, treat, and manage cancer patient care; used for the indication for genetic testing

Data considered includes personal and extended family hereditary history

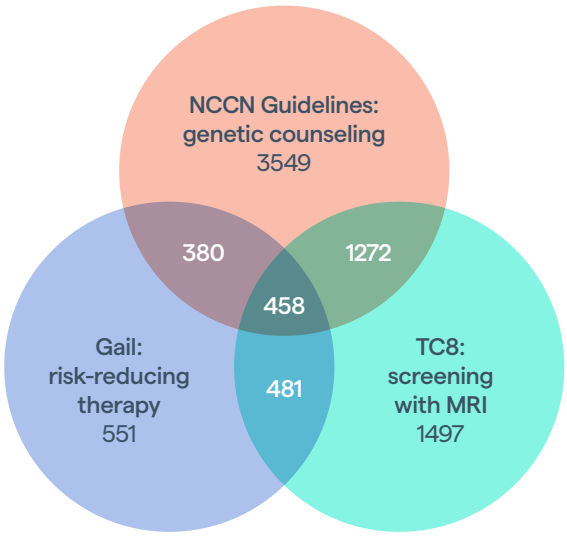
Threshold: 100%

Analysis of Rush's assessment program from July 2020–January 2023 showed that **8188 patients,* or 25.9% of all Rush patients, were identified at elevated risk** by at least one of the models:

- 22.8% with the Gail model
- 45.3% with TC8
- 69.1% with the NCCN Guidelines

This type of holistic approach is needed to set patients on the most appropriate path for prevention and early detection.

High-risk identification by model & intervention



* **Source:** Rush University Health System, N-8188 (25.9% of population assessed), 7/20/2020–1/31/2023

Personalized care pathways and medical management

Rush's high-risk protocol is well defined and based on guidance from accredited bodies.

"Technology is constantly changing," Dr. Stempel says. "As a system, Rush is at the forefront of the most advanced imaging and services. This allows our patients to make informed decisions about which screening pathway will offer them the best outcome with the lowest burden."

Dr. Stempel reports Rush's patient stratification found:

RISK LEVEL	% IDENTIFIED	RECOMMENDATION
Average	76.6%	Annual Mammogram and ABUS*
Intermediate	11.8%	Annual Mammogram and ABUS*
High	11.6%	Annual Mammogram and Fast MRI**

* ABUS recommended if breast density is category C or D.
**MRI performed at six-month interval from mammogram. Recommendation to Rush High-Risk Clinic.

Patients at unknown, average, or intermediate risk are advised to adhere to the annual mammogram schedule. An automated breast ultrasound, or ABUS, will be recommended for patients with heterogeneous and extremely dense breast tissue; this can often be performed on the same day as the mammogram.

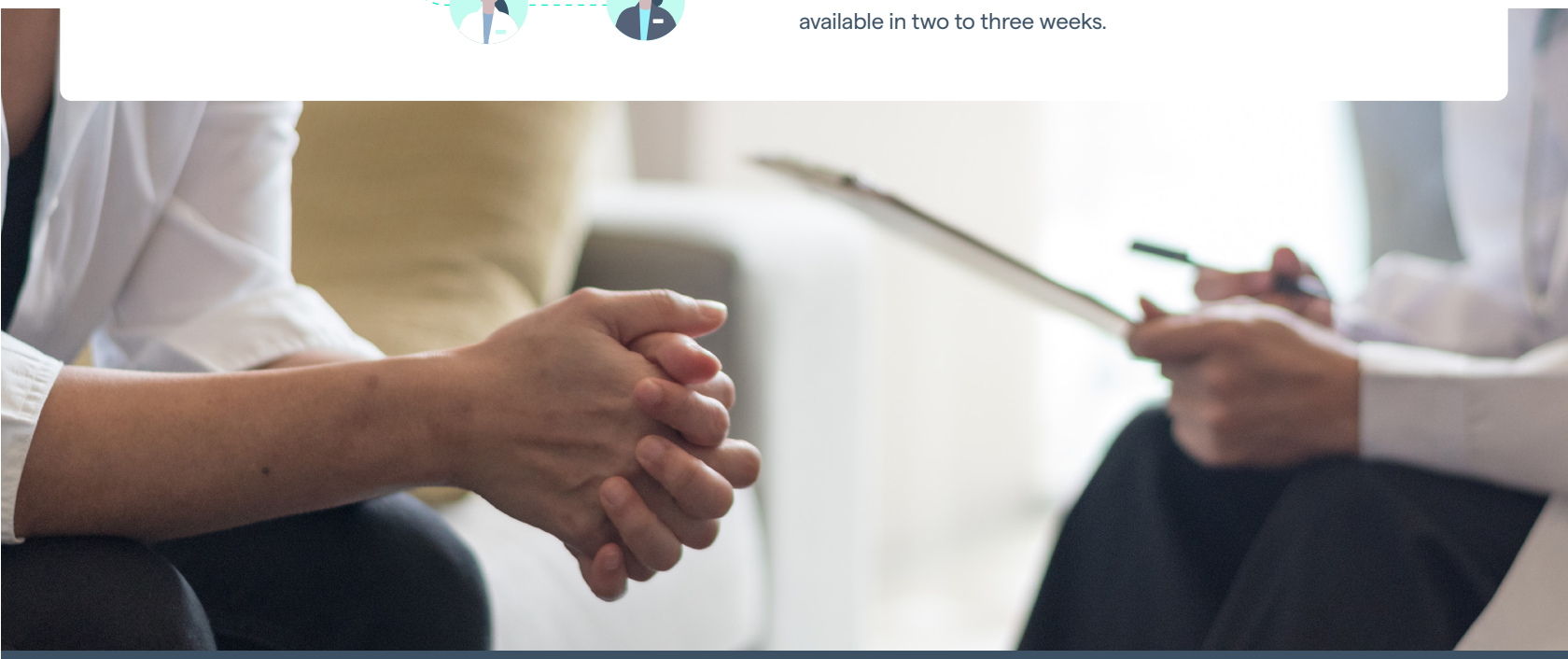
For patients identified as having a high lifetime risk (≥20%), a screening FAST breast MRI exam can be performed in just under 10 minutes of scan time. This exam is offered every year and typically scheduled six-months after the annual mammogram so that the high-risk patient is monitored twice a year.

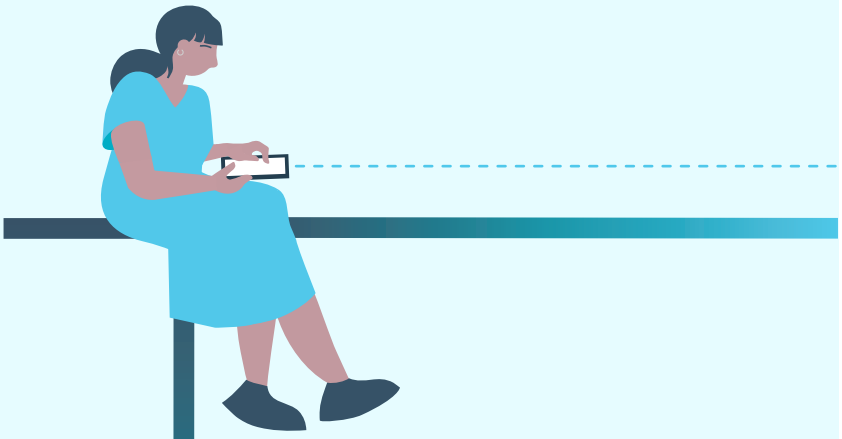
Rush is committed to applying the latest clinical evidence and recently further tailored their personalized screening program to recommend yearly breast MRIs for two groups at elevated risk:

- Patients with a personal history of breast cancer diagnosed before age 50 and treated with breast conserving therapy
- Patients with a personal history of breast cancer and dense breast tissue on the mammogram

All high-risk patients are also offered a referral to the Rush High-Risk Breast Clinic. There the patient receives a clinical breast exam, education, and information about other services, such as lab tests or guidance for a prevention strategy.

If a patient is identified as having an increased mutation risk, they may be a candidate for genetic testing and can schedule consultation. This appointment includes genetic counseling, a review of risk reduction strategies and, if warranted, genetic testing via a saliva sample. The cost of genetic testing and analysis is usually covered by insurance. However, if a patient will incur a cost, they are notified prior to the processing of the sample and given the option of canceling. Results of the testing are typically available in two to three weeks.





- Patient arrives for mammogram appointment and completes risk assessment survey
- Technologist confirms risk factors with patient
- Technologist enters data into Epic® Technologist Navigator

- Volpara Risk Pathways calculates the risk score using TC8, Gail, and the NCCN Guidelines
- Risk score is stored in Epic patient record using the Family Medical History Interface

- Risk score, explanation, and recommendations are populated in the Epic patient record, Technologist Navigator, and Reading Palette
- Reporting transparency removes uncertainty about medical necessity and guidelines, and fosters understanding about patient being deemed high risk

- Radiologists can access risk information in other systems integrated with Epic, such as dictation systems like PowerScribe®
- Radiologists select values from SmartLists in their result templates to "code" exams for the program audit; these values are stored in the impression field

- Patients with lifetime breast cancer risk of 20% or more get flagged in Epic as high risk
- High-risk patients receive results letter
- Patient's physician receives a report with risk recommendations

- Nurse navigator calls all high-risk patients to discuss the results and recommendations, and refers them to the high-risk clinic
- Physician referral created in Epic
- Nurse navigator uses the Epic high-risk center dashboard to track patient follow-up and recommended care status

- Nurse navigator records pathology on the pathology SmartForm for the program audit

Seamless clinical workflow with Epic integration

Risk-driven care requires more than simply knowing a patient's score. It requires a change in mindset. Crucial to widespread acceptance is a seamless workflow that eases collaboration among the patient's providers.

Rush chose Volpara® Risk Pathways™ software for its deep integration with Rush's Epic EHR. The bidirectional data flow enables risk assessment within existing workflows and maintains Epic as the source of truth on the patient's risk status. This keeps clinicians focused on informed and collaborative decision making in the EHR.

This EHR-driven cancer risk assessment workflow has not impacted appointment time or staffing because of the tight integration between Volpara Risk Pathways and Epic. In fact, the integration is so seamless that many of Rush's clinical users are unaware that Volpara powers their Epic risk workflows.

Another benefit to Rush is Volpara's ability to customize the risk models used, the cancers assessed, and the care pathways recommended to the organization's clinical, financial, and operational goals.

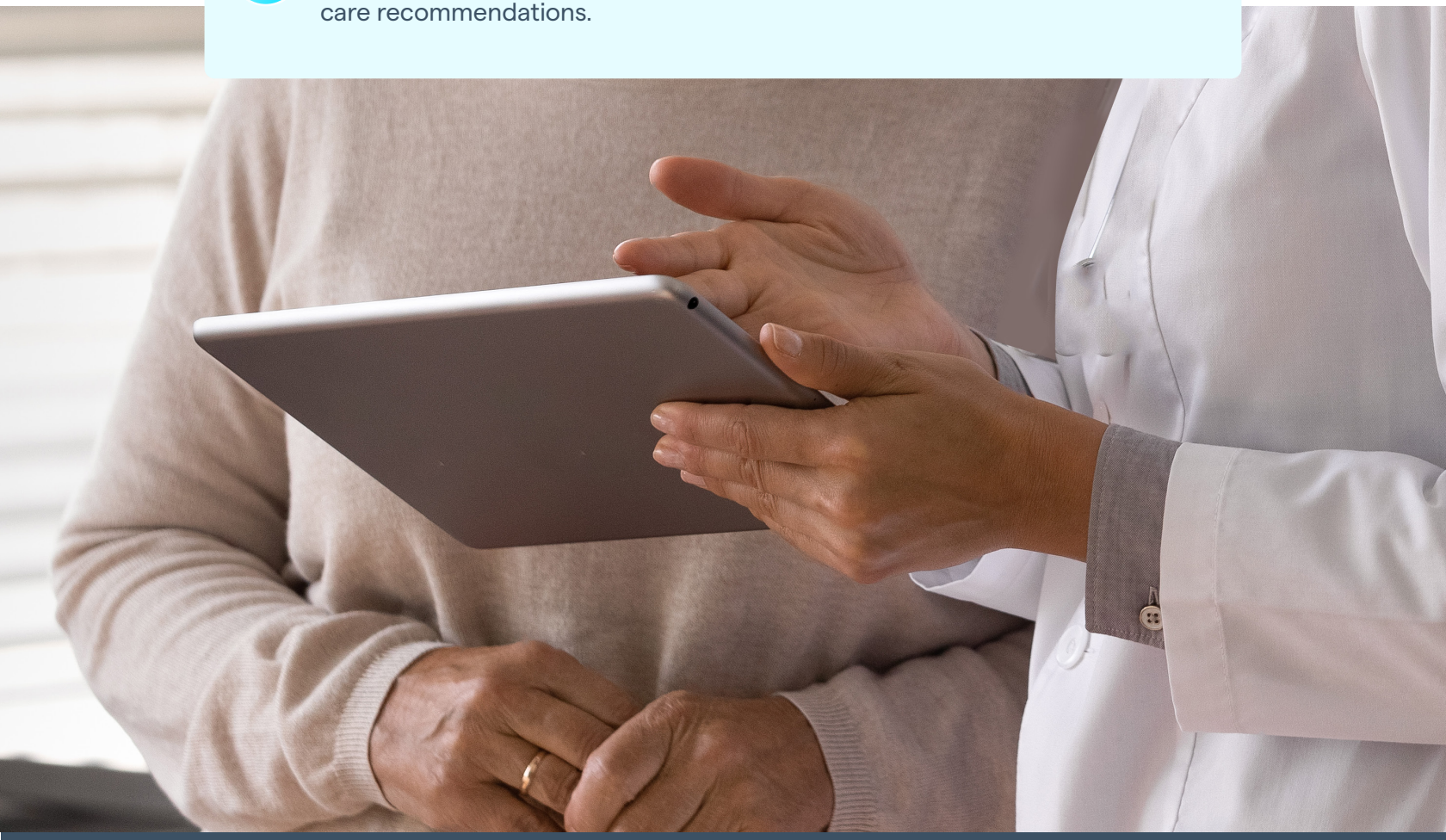
> "Epic and Volpara are in a unique position to work in concert to bring this vision to multiple medical centers and patients across the country."
>
> —Dr. Stempel

Risk program performance analysis

Rush also embraces the philosophy of a "learning healthcare system," a novel approach to the discovery and implementation of new knowledge in medicine. This method innovates clinical documentation methods to automatically extract research quality outcomes from data collected as part of the everyday routine care.

Volpara Risk Pathways uses discrete data fields in Epic, which enables Rush to audit the performance of their risk assessment program and generate reports, supporting **three** aims:

1. Develop automated methods to continuously measure the modality-specific cancer detection rate.
2. Develop automated methods to continuously measure the sub-population–specific cancer detection rate, including patients with and without a personal history of breast cancer, patients with dense breast tissue, and patients at different risk levels.
3. Develop statistical methods to compare the cancer detection rate within and across risk groups based on their respective adherence to care recommendations.



Patient impact drives the program

While the program audit findings highlight the impact on Rush's population, Dr. Stempel shares that it is the individual patient stories that motivate their staff.

"For example, we have a 56-year-old patient whose life was changed by understanding her risk and getting access to additional imaging beyond her annual mammogram," said Dr. Stempel.

The patient presented for her screening mammography and the 2D/tomosynthesis mammogram demonstrated heterogeneously dense breast tissue and was read as negative.

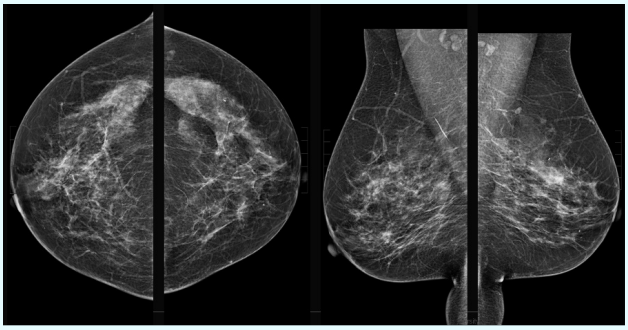
Risk assessment was performed at the time of the mammogram and the patient was found to have an elevated lifetime risk of breast cancer (Tyrer-Cuzick 8 = 23.16%) due to the family history of breast cancer in her mother at age 75 and maternal grandmother at age 35.

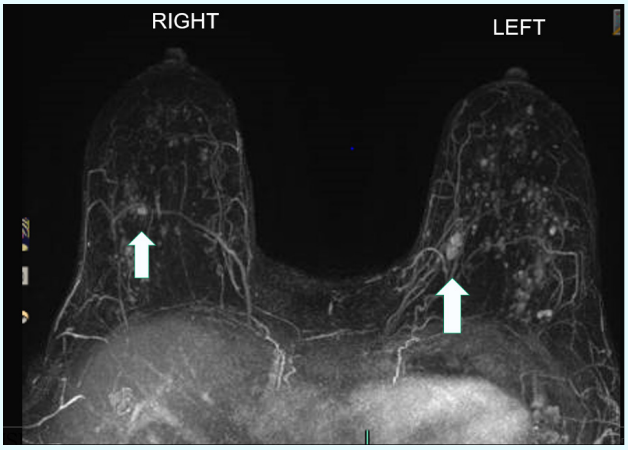
MRI screening was recommended in six months. The report from breast MRI advised core biopsies for a 1.7 cm enhancing mass in the superior medial left breast and a 0.7 cm irregular enhancing mass in the superior lateral right breast.

The bilateral core biopsies revealed invasive ductal carcinoma, grade 2.

At surgery, bilateral sentinel lymph nodes were negative.

This patient's cancer likely would have gone undetected and advanced had the risk assessment not identified her as eligible for additional imaging.





Future program optimizations

Rush is using their auditing program and clinician/patient feedback to identify short-term and long-term goals for the future of the program:

Self-survey completion

Currently, technologists interview patients and enter data into the Epic history at the beginning of the screening appointment. When patients complete their surveys at home, or any time prior to their screening, it saves staff time and shortens appointment times. Survey completion at home may also garner more comprehensive family history completion if there is better access to other family members.

Volumetric breast density score integrated into risk calculation

To more precisely integrate the risk associated with dense breast tissue into a risk model, a quantifiable measurement of breast density is needed. Volpara Scorecard density assessment software is the only tool validated for use with the Tyrer-Cuzick v8 risk model.

Primary care outreach

Most women are directed to have their first mammogram screening at the age of 40. New guidelines recommend that breast cancer risk assessment begin at 25–30 years old to identify at-risk women earlier. To reach younger women and identify those who need to begin breast care sooner, outreach needs to begin in primary care or OB/GYN offices. Volpara Risk Pathways can be used in any care setting via the Epic EHR.

This commitment to continued improvement reflects the quality of care delivered by Rush's personalized breast care pathways. This type of holistic approach is needed to give more patients the chance for prevention and early detection. Rush University Medical Center attributes the success of its program to efficient clinical workflow, comprehensive care management, and effective patient engagement that goes beyond the score to enable better patient outcomes.

About Rush

Rush University Health System is a national leader in outstanding patient care, education, research, community partnerships, and empowering a new generation of health care providers. Located in the Chicago metropolitan area, Rush comprises Rush University Medical Center, Rush Copley Medical Center, Rush Oak Park Hospital, and Rush University, as well as an extensive provider network and numerous outpatient care facilities. The Breast Imaging division at Rush University Cancer Center conducts over 54,000 breast imaging exams across their centers. Rush is designated as a Breast Imaging Center of Excellence by the American College of Radiology. At Rush, mammograms are read only by physicians specializing in breast imaging, offering the highest level of expertise and the best outcomes for patients. The breast imaging team works closely with the breast cancer team at Rush, which includes medical oncologists, breast surgeons, advanced practice providers, and other clinicians.

Lisa Stempel, MD, is the Division Chief of Breast Imaging at Rush University Cancer Center, Rush System for Health. She is a fellowship-trained radiologist specializing in all forms of breast imaging and performs various biopsy and preoperative localization procedures. Dr. Stempel is also the lead physician of the Automated Breast Ultrasound (ABUS) and Risk Assessment Programs.

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About Volpara Risk Pathways

Volpara Risk Pathways software has been used by more than 1,000 providers across the United States to identify, manage, and improve outcomes for patients at elevated risk for developing cancer. It conducts more than three million cancer risk assessments each year and can be deployed stand-alone or fully integrated with electronic health record systems, mammography reporting systems, and genetic laboratories.

Volpara's comprehensive Professional Services offering helps customers maximize the value of their high-risk cancer assessment programs. Our Professional Services team features experienced professionals who previously managed their own programs. They bring decades of expertise in supporting leading clinical sites around the world, skillfulness and dedication that can help programs at each step and empower them to keep pace with rapidly changing risk assessment and genetic landscapes.

References

1. World Health Organization – https://www.who.int/news-room/fact-sheets/detail/breast-cancer

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