

Volpara Risk Pathways

Complete cloud-based risk assessment



A full program for identifying, tracking, and managing patients at high risk of developing cancer.

The care your patients need. Simpler, better.

Risk assessment can be a complex process involving numerous stakeholders, systems, and software products. Volpara® Risk Pathways® software simplifies this process so you can more effectively deliver the care your patients deserve.

Risk Pathways provides a holistic view of risk assessment for several common cancers: breast, colorectal, endometrial, ovarian, and pancreatic. It recommends the appropriate high-risk care paths—such as genetic tests, risk-reducing medications, lifestyle modifications, and changes to screening protocols—so you can offer patients a comprehensive, personalized experience.

With Risk Pathways, your multidisciplinary team—including imaging staff and high-risk clinic nurse navigators, genetic counselors, surgeons, and oncologists—have shared, essential tools for coordinated workflow.

Getting started with a breast cancer risk program

Assessing risk of developing breast cancer has never been more important—for women of all ages. As most women are unaware of their risk status¹, it's a real opportunity for healthcare providers to fulfill a growing need.

Leading screening guidelines now recommend clinical risk assessment as the basis for which women are screened and what imaging modalities are used.² In addition, various industry and regulatory changes all signal the heightened importance placed on assessing breast cancer risk.

For example, the National Accreditation Program for Breast Centers (NAPBC) will soon require proof of risk assessment at screening for facilities to attain accreditation or renewal. This expanding emphasis on risk assessment means that imaging departments stand to benefit from the increased revenue generated by MRI. At the same time, however, these imaging departments and high-risk clinics, will need help managing their high-risk workflow.

That's where Volpara Risk Pathways can help.

~50%

US women over age 40 with high breast density³

90%

Women with hereditary risk not yet identified⁴

<2%

Women at high risk offered an MRI and undergo exam⁵

15%

Increase in screening adherence when women know their risk⁶

¹ <https://ascopubs.org/doi/full/10.1200/CCI.18.00072>.

² Siu AL; US Preventive Services Force. Screening for Breast Cancer: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med. 2016;164(4):279-296.

³ <https://www.mayoclinic.org/tests-procedures/mammogram/in-depth/dense-breast-tissue/art-20123968>

⁴ <https://ascopubs.org/doi/full/10.1200/CCI.18.00072>.

⁵ Drohan B, Roche CA, Cusack JC Jr, Hughes KS. "Hereditary breast and ovarian cancer and other hereditary syndromes: using technology to identify carriers." Ann Surg Oncol. 2012 Jun; 19(6):1732-7.

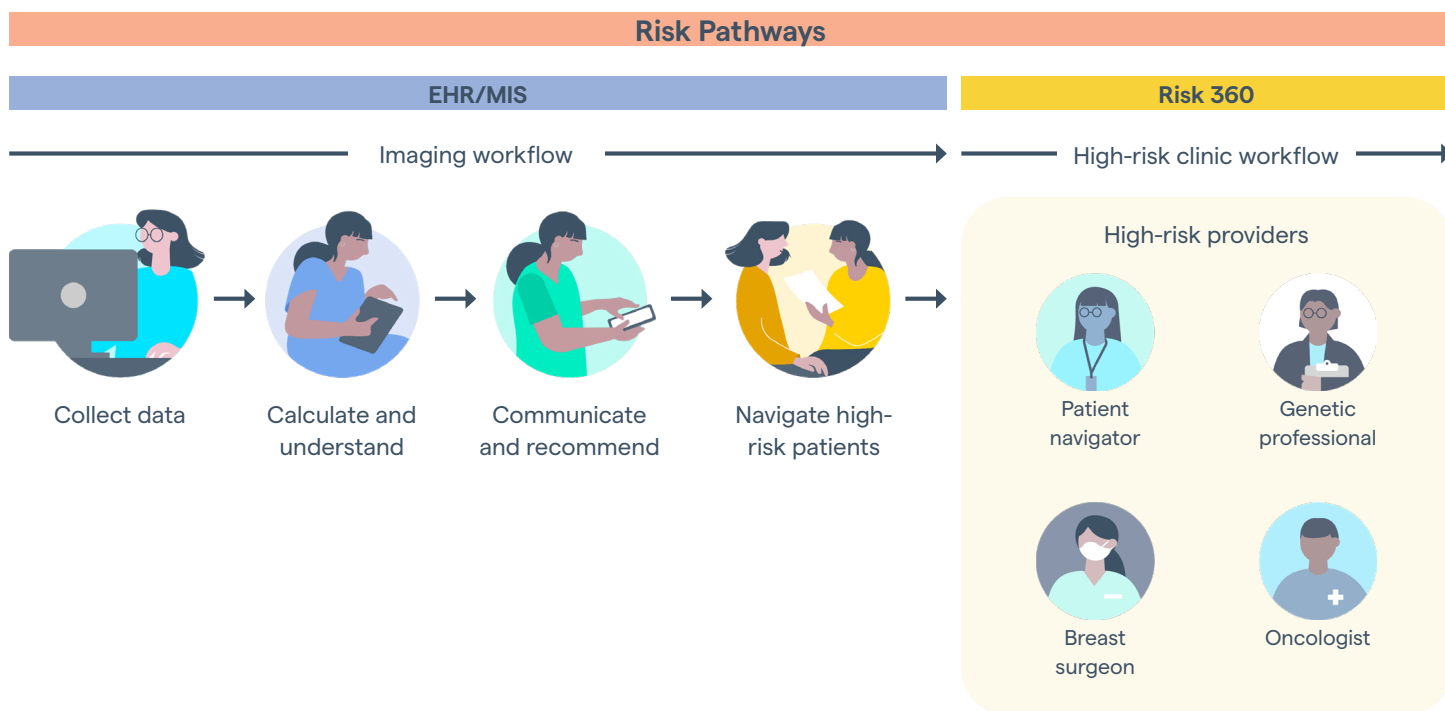
⁶ Wernli KJ, DeMartini WB, Ichkawa L, et al. "Patterns of breast magnetic resonance imaging use in community practice" [published online November 18, 2013]. JAMA Intern Med.

Volpara Risk Pathways

Complete risk assessment, step by step

Risk Pathways is a risk assessment application that lives in the cloud. It's a convenient, easy-to-use system that tracks patient identification and progress, updates risk profiles, generates communication, and triggers follow-up actions.

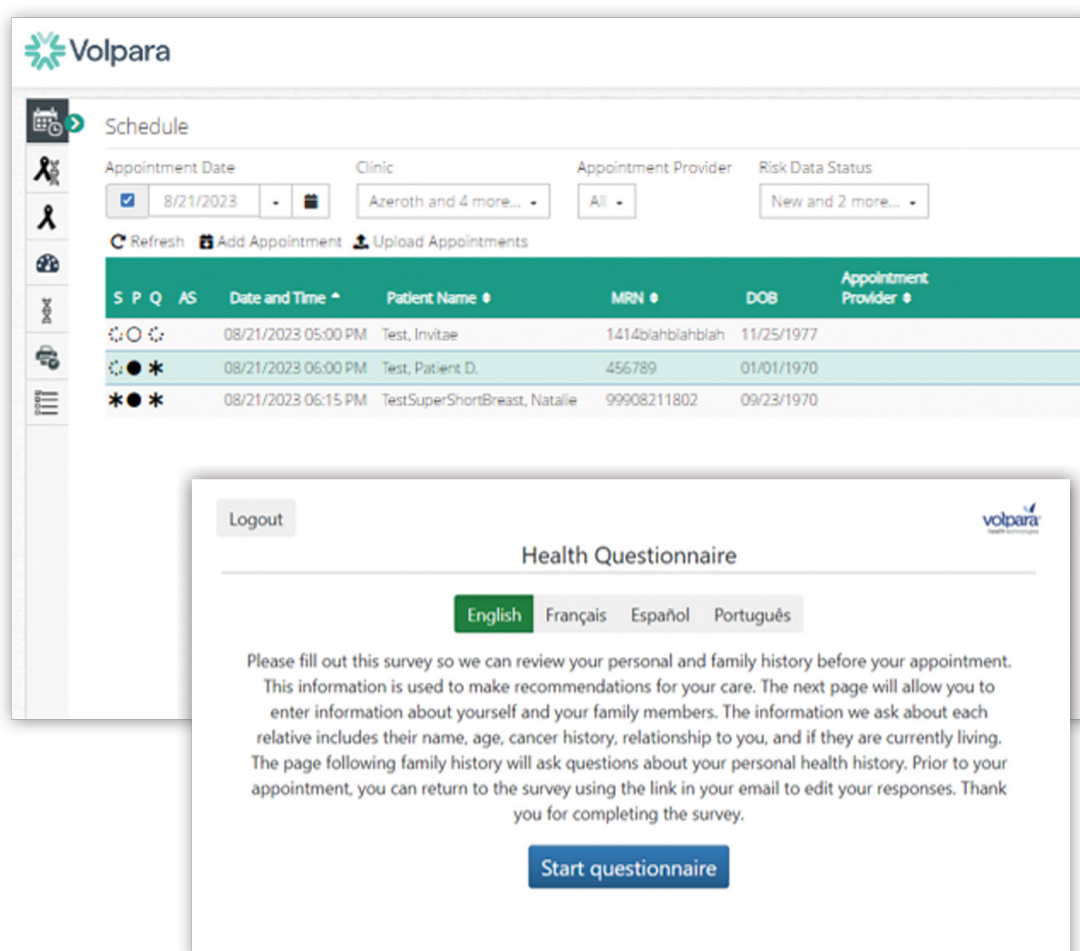
Whether your team works in imaging or is part of a high-risk clinic, Risk Pathways meets the needs of your workflow, covering all the steps of the risk-assessment process. For programs that span both imaging and high-risk workflows, Risk Pathways integrations connect the experience across departments.



> Efficient, empowering online questionnaire

As personalized cancer screening programs become the standard of care, providing a good experience for patients is more important than ever. Using our online questionnaire to collect your patients' risk factors and medical history is an opportunity to empower them and help determine their individual pathway for early detection.

The more accurate and comprehensive your information, the more effective and successful your program will be. Our online questionnaire enables you to collect the data you need—either before the appointment or in your facility, freeing your staff from administration tasks. Plus, medical history on record is pre-populated for smoother patient engagement, greater adherence, and improved accuracy from year to year.



The screenshot displays the Volpara app interface. The top section is titled 'Schedule' and includes filters for Appointment Date (8/21/2023), Clinic (Azeroth and 4 more...), Appointment Provider (All), and Risk Data Status (New and 2 more...). Below these filters are buttons for Refresh, Add Appointment, and Upload Appointments. A table lists appointments with columns for S, P, Q, AS, Date and Time, Patient Name, MRN, DOB, and Appointment Provider. The table contains three rows of appointment data.

Overlaid on the bottom right is a 'Health Questionnaire' screen. It features a 'Logout' button, the Volpara logo, and language selection options: English (selected), Français, Español, and Português. The text on the questionnaire screen reads: 'Please fill out this survey so we can review your personal and family history before your appointment. This information is used to make recommendations for your care. The next page will allow you to enter information about yourself and your family members. The information we ask about each relative includes their name, age, cancer history, relationship to you, and if they are currently living. The page following family history will ask questions about your personal health history. Prior to your appointment, you can return to the survey using the link in your email to edit your responses. Thank you for completing the survey.' A 'Start questionnaire' button is located at the bottom.

S	P	Q	AS	Date and Time	Patient Name	MRN	DOB	Appointment Provider
○	○	○		08/21/2023 05:00 PM	Test, Invitee	1414blahblahblah	11/25/1977	
○	●	●		08/21/2023 06:00 PM	Test, Patient D.	456789	01/01/1970	
●	●	●		08/21/2023 06:15 PM	TestSuperShortBreast, Natalie	99908211802	09/23/1970	



Patient

Access the online questionnaire from home—ahead of the screening mammogram appointment or visit to the high-risk clinic—for more time to complete family history and reduced wait times during the appointment.



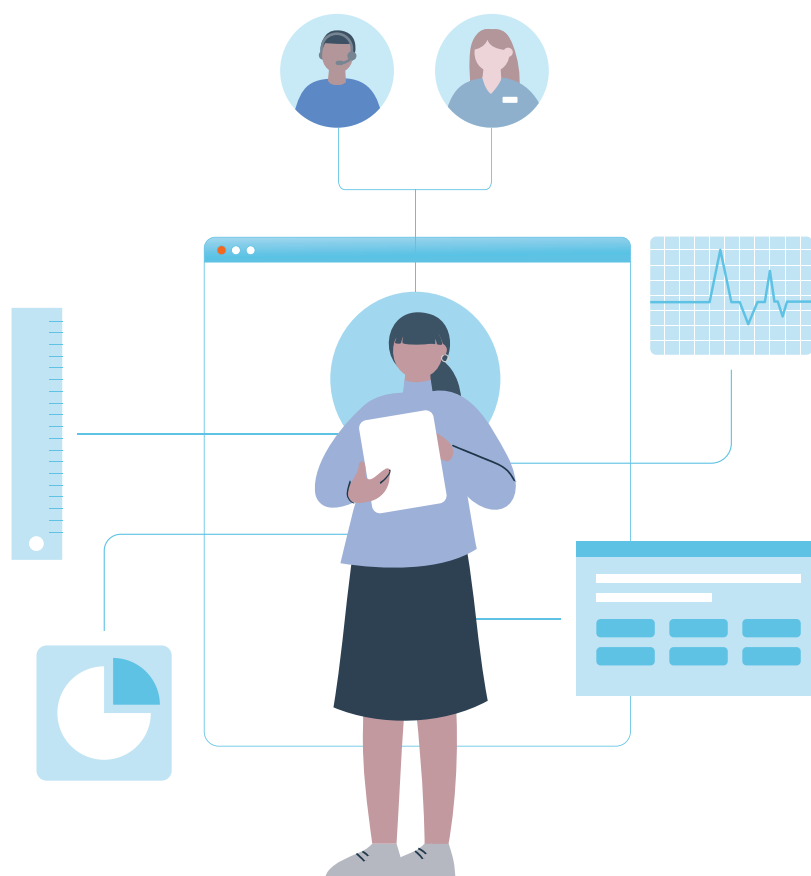
Administrator

Monitor patients' progress with the online questionnaire, whether performed at home or in the office, and track their engagement.



Technologist or Nurse Navigator

- Check medical history from the online questionnaire to support accurate risk assessment.
- Spend less time helping patients collect personal and family history and more time validating new information.



> Comprehensive risk calculation and decision support

Risk Pathways features the major risk models and guidelines for breast, colorectal, endometrial, ovarian, and pancreatic cancers. You can assess the risk of multiple cancers during any patient interaction for a faster risk-stratified approach to early detection. By identifying the patients at high risk of developing cancer, you can engage them in shared decision-making around the care path most appropriate for them, whether that means genetic testing, risk-reduction strategies, ultrasound, or breast MRI.

Breast cancer	
Models or guidelines	Notes
BRCAPRO™	Genetic testing (BRCA 1/2 genes) and/or MRI referral
Claus	Lifetime risk; high-risk referral for MRI
Gail	Risk-reducing medicine
NCCN®	Genetic testing referral
Tyrer-Cuzick v8	Lifetime risk; high-risk referral for MRI; genetic testing (BRCA 1/2 genes)

Other cancers		
Cancer	Models or guidelines	Notes
Colorectal	CCRAT	Guideline-appropriate screening regimens
	MMRpro	
	NCCN	
Endometrial	MMRpro	
	NCCN	
Ovarian	BRCAPRO	
Pancreatic	PancPRO	
	NCCN	

In addition, recommendations and guidelines from the American Cancer Society® guidelines and NCCN Guidelines for Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic (NCCN Guidelines®) transform risk models next steps, supporting clinical decisions, reducing clinicians' mental load, and creating standards across your organization. They also enable you to support your facility's accreditation with the NAPBC, showing how and why a patient goes on a particular care path.

Available EHR & mammography reporting system integrations

If your program uses electronic health record (EHR) software other than Epic or mammography information systems (MIS) other than Volpara® Patient Hub™ software, these risk-model insights can be delivered to your system of choice. From there, radiologists can easily access the insights for triage and referral to the correct care path.

> Comprehensive tools for patient management

Keeping patients informed, educated, and up to date on their cancer risk is one of the most powerful services your program can provide. Risk Pathways offers several tools to help you facilitate both patient and referrer understanding.



Nurse Navigator

- Interpret risk scores.
- View the impact of individual risk factors following calculation for greater understanding, transparency, and troubleshooting.
- Create customized patient and referrer communications.
- Track how well your program's patients follow their individualized care pathways.

Patient Summary

MRN: 234567

Maternal Grandfather: Pancreatic Cancer age 88, Prostate Cancer
 Paternal Grandfather: Lymphoma (Non-Hodgkins) age 66
 Paternal Aunt: Liver Cancer age 40

RISK CALCULATIONS

Date of Analysis: 05/23/2023

Breast/Ovarian Risk					
Model	BRCA 1/2 Mutation	5-Year Breast Cancer	Lifetime Breast Cancer	5-Year Ovarian Cancer	Lifetime
BRCAPRO	0.47%	1.57%	10.12%	0.14%	
Tyler-Cuzick v6	2.8%	6.16%	25.43%		
Tyler-Cuzick v7	1.29%	6.08%	34.42%		
Tyler-Cuzick v8	1.29%	6.05%	34.28%		
Claus		3.6%	13.7%		
Gail		4.16%	23.32%		

Explain Tyler-Cuzick v8 Lifetime Breast Cancer Risk	
Risk Category	Lifetime Risk
For people with patient's age and gender	10.34%
Including above and patient's race and ethnicity	10.34%
Including above and patient's hormonal and reproductive risk factors	13.62%
Including above and patient's medical history	12.71%
Including above and patient's family history	32.84%
Including above and patient's personal family genetic testing	32.84%
Including above and patient's breast density	34.28%
Final score	34.28%

Colon/Endometrial Risk					
Model	HNPCC Mutation	5-Year Colorectal Cancer	Lifetime Colorectal Cancer	5-Year Endometrial Cancer	Lifetime Endometrial
MMRPRO	0.02%	0.31%	2.82%	0.3%	
CCRAT		0.18%	2.43%		

The following scores are based on the patient's risk factors and for a given breast density composition.

Tyler-Cuzick v8 Lifetime Risk by Density	
Breast Composition	Lifetime Risk
BIRADS 4 - Almond, anteriorly fatty	16.49%

Close

> Clear patient summary of risk results

Beginning a risk program or expanding to new care paths always comes with questions. The patient summary's clear breakdown of cancer risk by model helps elicit confidence from your patients, providers, and clinical specialists.

In the case of TC8 risk scores, Risk Pathways shows the exact factors driving the number.

Long ay

Smith, Jane DOB: 01/11/1965 Age: 56 06/05/2021
 Unit #: 11114 Provider: Gender: F

It is suggested that Colon Cancer genetic testing be considered for a risk mutation of 5% or greater.
 The patient's risk of mutation is 5% or greater by MMR2/PRO.

The NCCN* suggests that Breast/Ovarian Cancer genetic testing for people meeting the following criteria:
 -Individual with a probability greater than 5% of a BRCA1/2 pathogenic variant based on prior probability models.
 -First- or second-degree blood relative with a history of breast cancer diagnosed at age <= 45 y.
 -First- or second-degree blood relative with a history of breast cancer diagnosed at any age with >= 1 close blood relative with breast cancer at age <= 50 y or ovarian, pancreatic, or metastatic or intraductal prostate cancer at any age.
 -First- or second-degree blood relative with a history of epithelial ovarian cancer (including fallopian tube cancer or peritoneal cancer) at any age.

The ACS* suggests MRI screening should be considered in people with a 20% or greater lifetime risk of breast cancer by BICAPRO, Tyrer-Cuzick or Claus.
 The lifetime risk of breast cancer is 20% or greater by Tyrer/Cuzick.

*ACS = American Cancer Society
 *NCCN = National Comprehensive Cancer Network

DEMOGRAPHIC
 Age: **56**
 Height: **5-6**
 Weight: **145**
 BMI: **23.4**
 Gender: **Female**
 Occupation: **Education**
 Marital Status: **Married**
 Education Level: **College degree**
 Email: **jsmith@crahealth.com**

LIFESTYLE
 Smoking: **No, never**
 Alcohol: **5 - 9 drinks per week**

CHILD BIRTH HISTORY
 # of Pregnancies: **1**
 # of Children: **1**
 Age 1st birth: **19**
 Currently pregnant: **No**
 Currently nursing: **No**

MENSTRUAL HISTORY
 Menarche: **13**
 Menopausal status: **Pre**
 LMP: **06/01/2021**

Volpara

09/07/2023
 Sam Sundine
 12 Boston Rd
 2
 Boston, MA 02134

Dear Sam Sundine,

Thank you for taking time during your visit to complete the Breast Cancer Risk Assessment Questionnaire. Through this assessment, we strive to help identify women at higher than average risk of developing breast cancer. All information gathered during the assessment is strictly confidential and is never shared with any third party without your prior consent. Key criteria for increased risk are:

- Personal or family history of breast and/or ovarian cancer
- History of abnormal breast pathology
- Personal history of chest radiation
- Family member with a known genetic mutation

You provided the following information regarding your personal and family history:
 Mother Breast Cancer age 49

➤ Customizable patient and referrer communications

Staying in touch with your patients is critical to their understanding and participation in their healthcare journey. In Risk Pathways, you can produce communications with customized messaging, including patient result letters, primary care provider letters, and questionnaire summaries. Letters can be generated on demand, batch printed, or sent outbound to your EHR system.

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Patients with an Elevated Lifetime Risk of Breast Cancer Or an Elevated Risk of BRCA Mutation

Assessment Date: [Any] Assessment Type: [Any] Referring Provider Type: [Any] Follow-up Type: [Any] Search by name, NPI, gene, signature or address

Assessment ID	Assessment Date	Assessment Type	Referring Provider	Referring Provider Type	Follow-up Type	Search by name, NPI, gene, signature or address
1000000001	10/01/2023	Assessment	Dr. John Doe	Physician	Follow-up	10/01/2023
1000000002	10/01/2023	Assessment	Dr. John Doe	Physician	Follow-up	10/01/2023
1000000003	10/01/2023	Assessment	Dr. John Doe	Physician	Follow-up	10/01/2023
1000000004	10/01/2023	Assessment	Dr. John Doe	Physician	Follow-up	10/01/2023
1000000005	10/01/2023	Assessment	Dr. John Doe	Physician	Follow-up	10/01/2023
1000000006	10/01/2023	Assessment	Dr. John Doe	Physician	Follow-up	10/01/2023
1000000007	10/01/2023	Assessment	Dr. John Doe	Physician	Follow-up	10/01/2023
1000000008	10/01/2023	Assessment	Dr. John Doe	Physician	Follow-up	10/01/2023
1000000009	10/01/2023	Assessment	Dr. John Doe	Physician	Follow-up	10/01/2023
1000000010	10/01/2023	Assessment	Dr. John Doe	Physician	Follow-up	10/01/2023
1000000011	10/01/2023	Assessment	Dr. John Doe	Physician	Follow-up	10/01/2023
1000000012	10/01/2023	Assessment	Dr. John Doe	Physician	Follow-up	10/01/2023
1000000013	10/01/2023	Assessment	Dr. John Doe	Physician	Follow-up	10/01/2023
1000000014	10/01/2023	Assessment	Dr. John Doe	Physician	Follow-up	10/01/2023
1000000015	10/01/2023	Assessment	Dr. John Doe	Physician	Follow-up	10/01/2023
1000000016	10/01/2023	Assessment	Dr. John Doe	Physician	Follow-up	10/01/2023
1000000017	10/01/2023	Assessment	Dr. John Doe	Physician	Follow-up	10/01/2023
1000000018	10/01/2023	Assessment	Dr. John Doe	Physician	Follow-up	10/01/2023
1000000019	10/01/2023	Assessment	Dr. John Doe	Physician	Follow-up	10/01/2023
1000000020	10/01/2023	Assessment	Dr. John Doe	Physician	Follow-up	10/01/2023

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➤ Patient adherence tracking

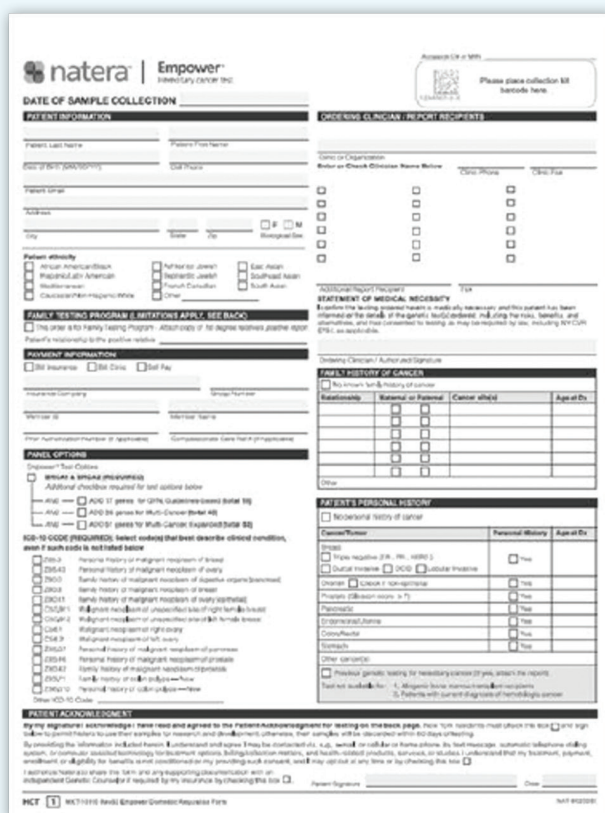
Risk Pathways allows you to access worklists, clinical notes, and follow-up actions all in one place. Patient adherence metrics inform overall program performance (see the "supporting your risk assessment program" section).

> High-risk patient tools for genetic professionals



Genetic Counselor

- Order, track, and understand genetic tests with your lab of choice: Ambry, Myriad, Invitae, or Natera.
- Order tests without any double entry of data, saving time and reducing errors.
- Facilitate and document patient conversations and follow-up.
- Dive deeper into hereditary cancer risk and cascade testing.

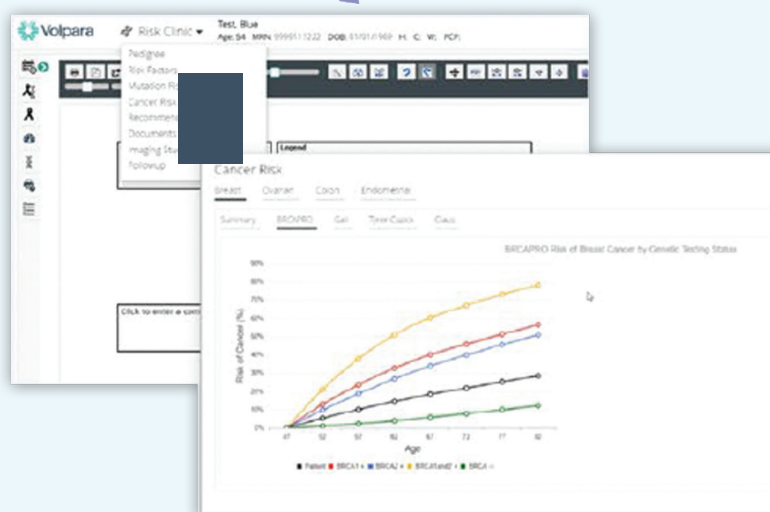


Genetic Lab	Sending Order	Receiving Results
	 Pre-populated TRF	 Results returned as PDF - manual entry to Risk 360
	 Pre-populated TRF	 Return of results as discrete data in Risk 360
	 Pre-populated TRF	 Return of results as discrete data in Risk 360
	 E-ordering to Ambry Genetics Clinician can see relevant order in AmbryPort	 Return of results as discrete data in Risk 360

> Lab Connect for efficient administration

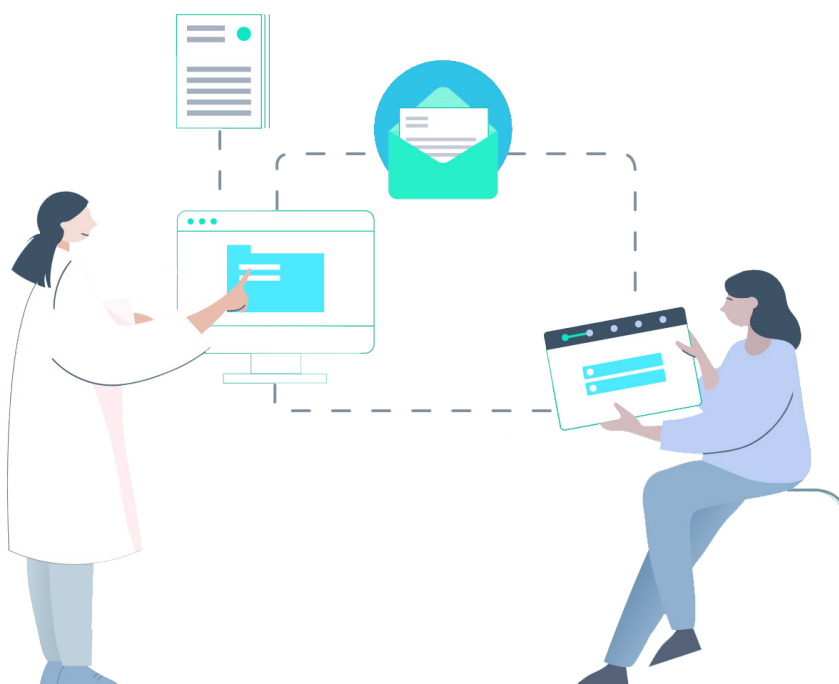
Making sure patients understand their risks and options is a big part of the work you do. So is gaining the trust of referring providers and clinical staff. Lab Connect streamlines your genetic testing services with electronic ordering or pre-populated test request forms (TRFs) and return results. For additional genetic counselor resources, Risk Pathways also supports the Myriad Patient Education Service (PES) with electronic sending of data to Myriad to support education. Ordering is faster, paperless, and complete—so your lab gets the information it needs the first time.

Name	MRN	DOB	Last Appoint...	Assessment...	Lifetime Risk	Mutation Risk	Breast Density	PCDR	Genes	Disease Ris	Ref Provider	Clinic	Followup	Quick Actions
Test Maria	999840	01/01/1967	10/19/2022	Cancer Screen...	BRECAPO 03.79%	BRECAPO 03.19%	19%					Agnes		
Test Patient	999874011215	06/09/1985	10/19/2022	Cancer Screen...	TCT 20.48%	BRECAPO 11.25%	19%					Agnes		



> Robust pedigree tool

Volpara's pedigree tool enhances hereditary cancer risk calculation with multiple risk models and a detailed pedigree drawing that can be shared with patients and their families.



Supporting your risk assessment program

As your team manages patients' progress through their designated care paths, you'll need to understand your program's performance over time. Use the application's metrics to track organizational progress or Volpara's optional Professional Services to get the most out of your risk assessment program.



Administrator

- Monitor health outcomes.
- Plan your program's expansion into new care path offerings.
- Engage Volpara's Professional Services team as your program matures.

> Powerful metrics to measure your success

Track engagement and return on investment with our comprehensive reporting. Understand and report out your success to leadership and peers.

As with all programs, we recommend that you keep tweaking your processes as you learn—identify areas you can invest in further and build the right business cases.

> Volpara Professional Services

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.



Volpara Scorecard

Software add-on for supercharged density assessment

Optimizing your risk assessment program is easy with Volpara® Scorecard™ software's objective, automated breast density assessment, the key to early detection of breast cancer.

The Scorecard option is based on the Volpara® TruDensity™ algorithm, which calculates volumetric breast density (VBD), fibroglandular tissue volume, and breast volume to assign a breast density category for an objective, consistent, and repeatable assessment.⁷ It can be sent to PACS to support radiologists in reading workflows.

The Scorecard VBD% calculation:

- Is the only validated, automated breast density measurement used as an input to the TC8 risk model;
- Provides the most accurate TC8 score for a more accurate assessment of lifetime risk of developing breast cancer;⁸ and
- Populates the cloud dashboards, worklists, reports, and TRFs.

Notes:

- Scorecard does not display TC8 scores. This functionality may become available in a future enhancement.
- For sites with Scorecard, Myriad PES can receive the VBD%.

Based on a 50-year-old with no other risk factors:

			
Visual BI-RADS	C	C	C
Lifetime Risk	17.1%	17.1%	17.1%
VBD%	8.2	10	13.9
Lifetime Risk	15.9%	18.6%	23.8%

Volumetric breast density gives a true reflection of risk because of the continuous nature of both the risk and density calculation.

About Volpara Health

Volpara Health has been supporting risk assessment programs for over 15 years. Its 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. Each year, these providers rely on Risk Pathways to conduct over 3 million risk assessments. In turn, Volpara Health's world-class experts in risk, genetics, and breast imaging use customer feedback and market dynamics to continuously improve Risk Pathways, now in its third generation, with regular, biweekly software updates.

⁷ Gubern-Merida, A., Kallenberg, M., Platel, B., Mann, R.M., Marti, R. and Karssemeijer, N. (2014) Volumetric Breast Density Estimation from Full-Field Digital Mammograms: A Validation Study. PLoS ONE; 9: e85952.

⁸ Brentnall, A.R. et al. A Case-Control Study to Add Volumetric or Clinical Mammographic Density into the Tyrer-Cuzick Breast Cancer Risk Model. Journal of Breast Imaging (2019).

Contact

info@volparahealth.com AUS +61 1800 370 623 Europe +44 203 051 1029
support@volparahealth.com NZ +64 0800 444 148 USA +1 800 305 3865

Connect

 @VolparaHealth  @volpara  Volpara Health