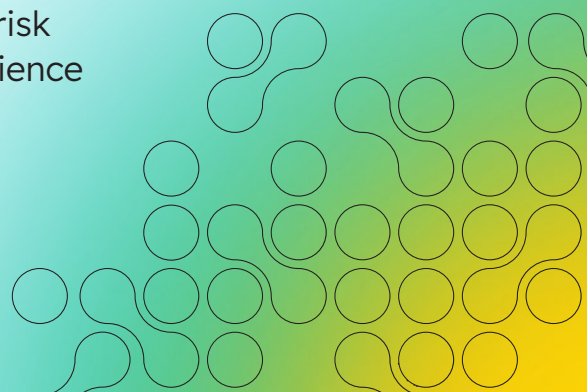


Volpara® Risk Pathways®

Complete cloud-based risk assessment



Volpara® 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. For programs that span both imaging and high-risk workflows, Risk Pathways integrations connect the experience across departments.



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.

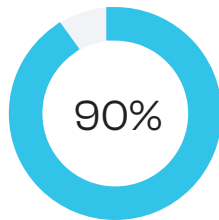
Leading screening guidelines now recommend clinical risk assessment as the basis for which women are screened and what imaging modalities are used.² In addition, various industry and regulatory changes all signal the heightened importance placed on assessing breast cancer risk.

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.

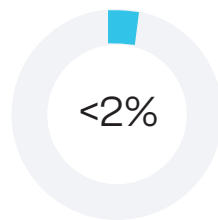
That's where Volpara Risk Pathways can help.



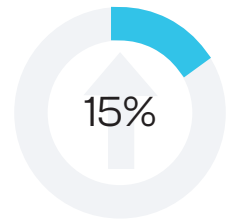
US women over age 40 with high breast density³



Women with hereditary risk not yet identified⁴



Women at high risk offered an MRI and undergo exam⁵



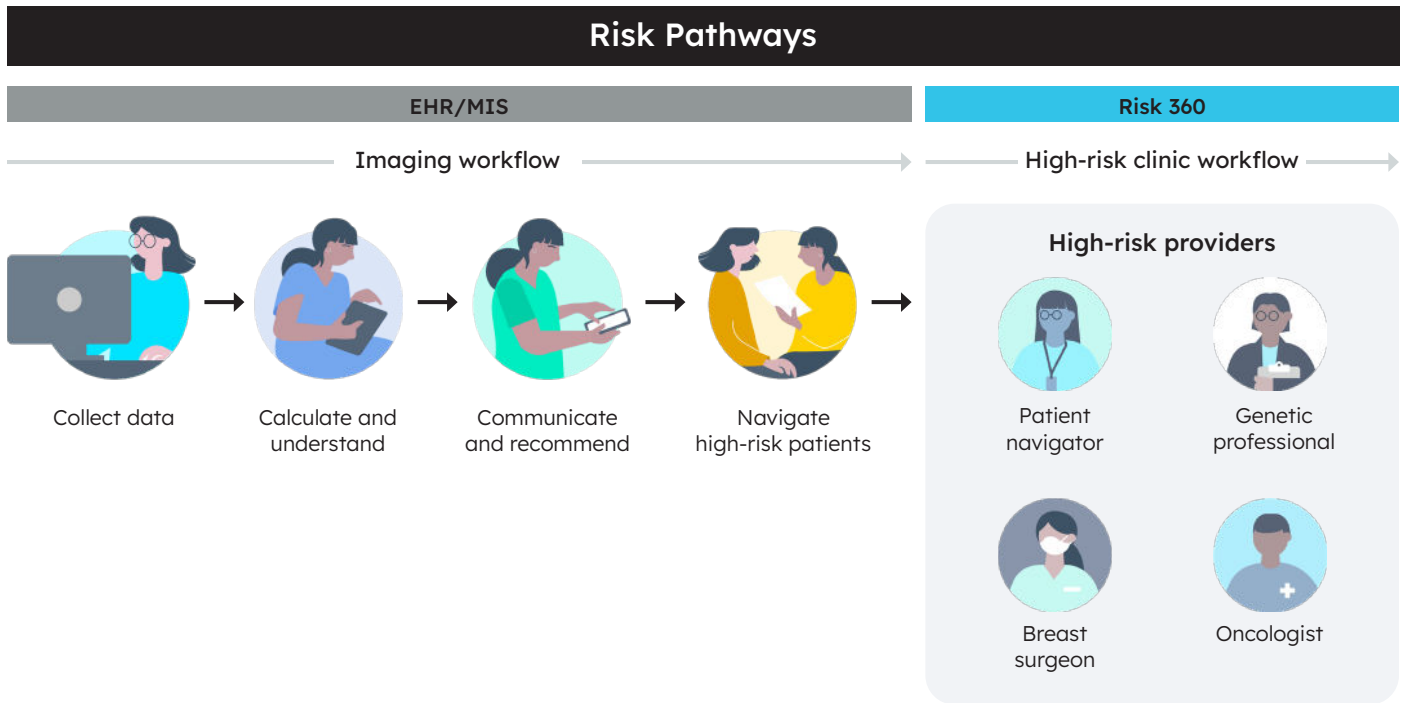
Increase in screening adherence when women know their risk⁶

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 'Schedule' interface. At the top, there are filters for Appointment Date (8/21/2023), Clinic (Azeroth and 4 more...), Appointment Provider (All), and Risk Data Status (New and 2 more...). Below the 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. Three appointments are listed for 08/21/2023.

S	P	Q	AS	Date and Time	Patient Name	MRN	DOB	Appointment Provider
☐	☐	☐	☐	08/21/2023 05:00 PM	Test, Invitae	1414bahblahlah	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	

Overlaid on the bottom right is a 'Health Questionnaire' form. It includes a 'Logout' button, the Volpara logo, and language options: English (selected), Français, Español, and Português. The text 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 at the bottom.



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.



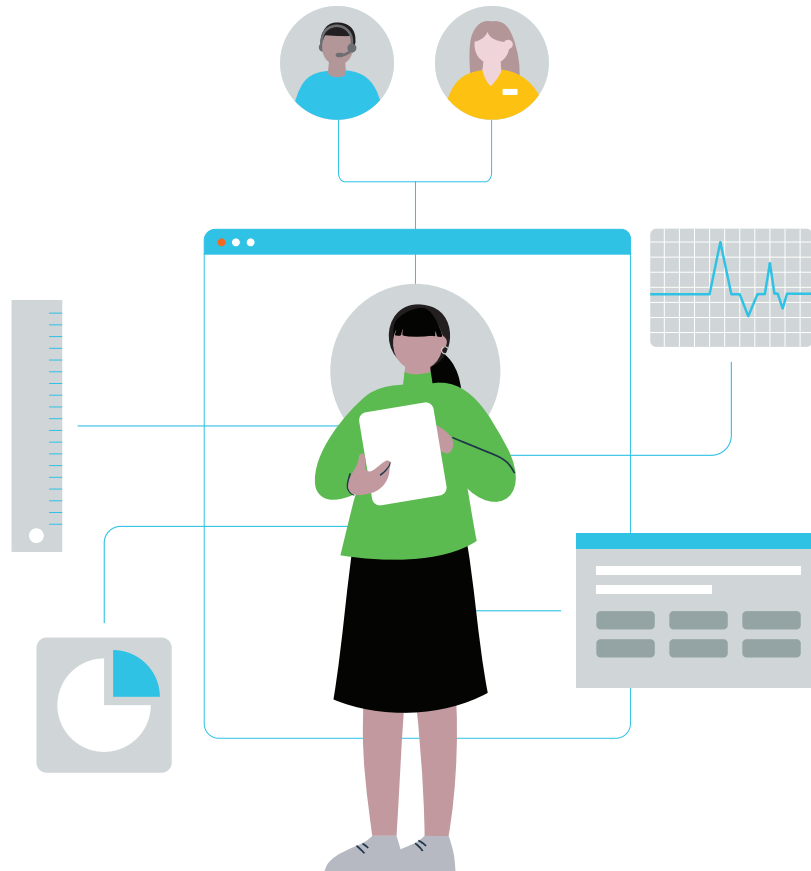
Administrator

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		Genetic testing referral
	NCCN		
Pancreatic	PancPRO		
	NCCN		
Prostate	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.

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.

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%
Tyrer-Cuzick v6	2.8%	6.16%	25.49%		
Tyrer-Cuzick v7	1.29%	6.08%	34.42%		
Tyrer-Cuzick v8	1.29%	6.05%	34.28%		
Claus		3.6%	13.7%		
Gail		4.16%	23.32%		

Explain Tyrer-Cuzick v8 Lifetime Breast Cancer Risk	
Risk Category	Lifetime Risk
For people with patient's age and gender	0.34%
Including above and patient's race and ethnicity	0.34%
Including above and patient's hormonal and reproductive risk factors	3.62%
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	34.28%
Including above and patient's breast density	34.28%
Risk score	34.28%

Colon/Endometrial Risk					
Model	HNPCC Mutation	5-Year Colorectal Cancer	Lifetime Colorectal Cancer	5-Year Endometrial Cancer	Lifetime
MURPRO	0.02%	0.31%	2.82%		0.5%
CCRAT		0.18%	2.49%		

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

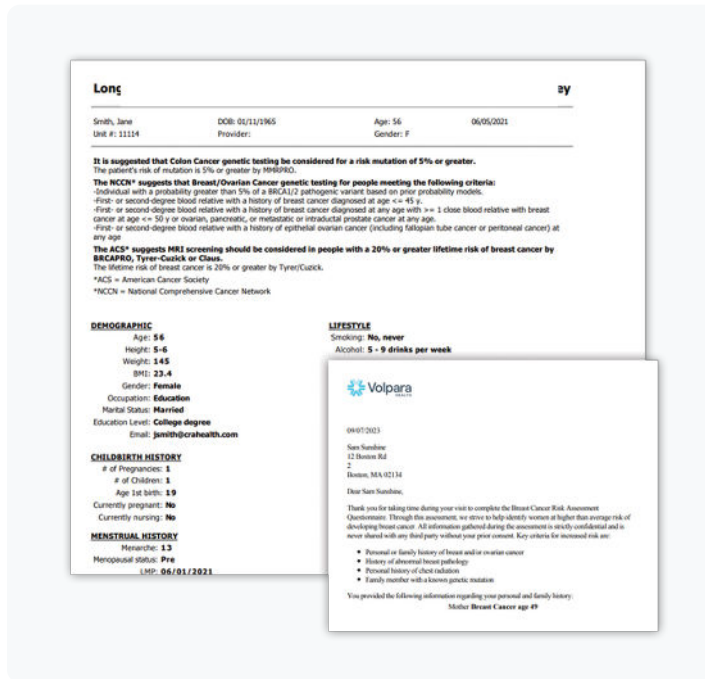
Tyrer-Cuzick v8 Lifetime Risk by Density	
Breast Composition	Lifetime Risk
RISATK A - Almost entirely fatty	16.49%

Close

Customizable patient and referrer communications

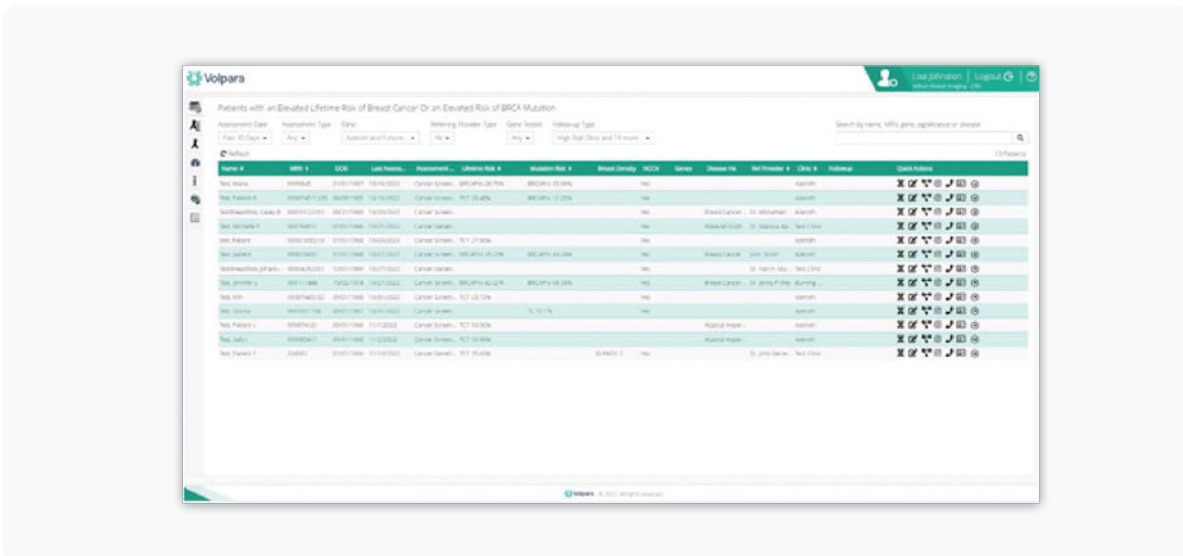
Staying in touch with your patients is critical to their understanding and participation in their healthcare journey. In Risk Pathways, you can produce communications with customized messaging, including patient result letters, primary care provider letters, and questionnaire summaries.

Letters can be generated on demand, batch printed, or sent outbound to your EHR system.



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.

Lab Connect for efficient administration

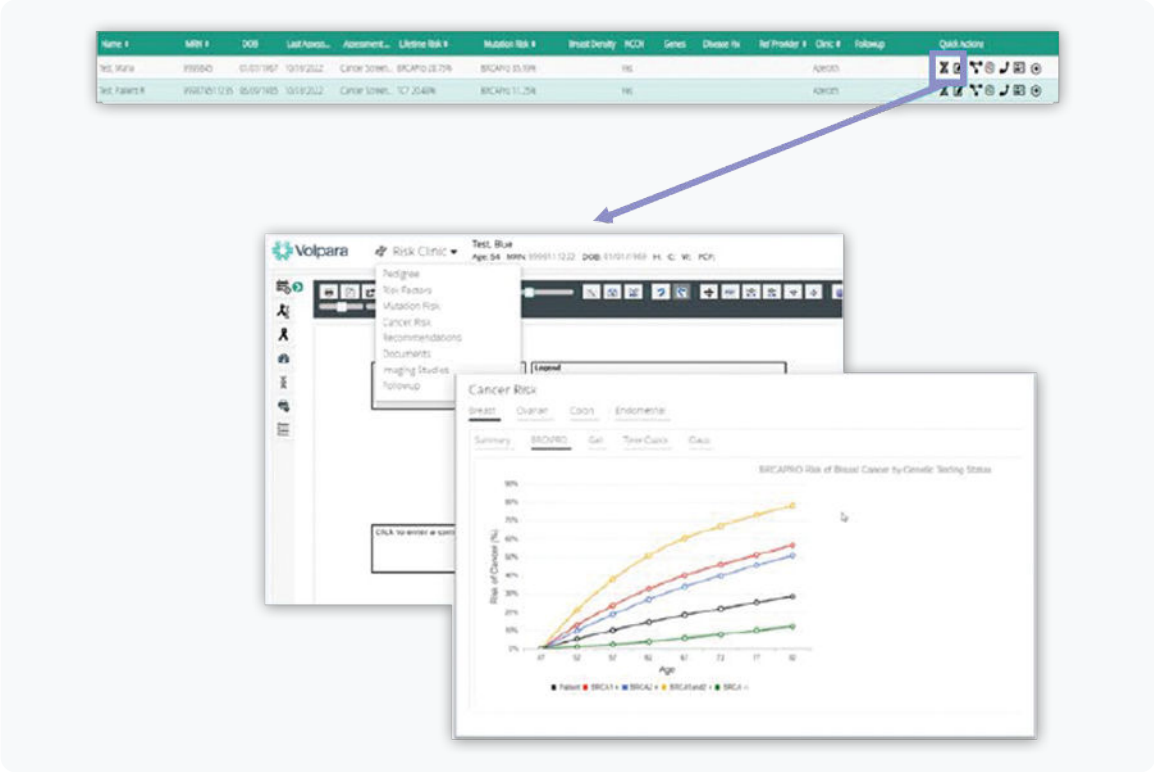
Making sure patients understand their risks and options is a big part of the work you do. So is gaining the trust of referring providers and clinical staff. Lab Connect streamlines your genetic testing services with electronic ordering or pre-populated test request forms (TRFs) and return results. For 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.

The image shows a screenshot of the Natera Empower patient information form. The form is titled 'natera | Empower' and includes a QR code and a note to 'Please place collection kit barcode here.' The form is divided into several sections: 'PATIENT INFORMATION', 'ORDERING CLINICIAN - REPORT RECIPIENT', 'PATIENT HISTORY OF CANCER', and 'PATIENT'S PERSONAL HISTORY'. The 'PATIENT INFORMATION' section includes fields for patient name, date of birth, gender, and ethnicity. The 'ORDERING CLINICIAN' section includes fields for name, title, and contact information. The 'PATIENT HISTORY OF CANCER' section includes a table for recording cancer history. The 'PATIENT'S PERSONAL HISTORY' section includes fields for smoking status, alcohol consumption, and other medical conditions. The form also includes a 'STATEMENT OF MEDICAL NECESSITY' section and a 'FAMILY TESTING PROGRAM & INITIATIONS APPLY. SEE BACK' section.

Genetic Lab	Sending Order	Receiving Results
	<input checked="" type="checkbox"/> Pre-populated TRF	<input checked="" type="checkbox"/> Results returned as PDF - manual entry to Risk 360
	<input checked="" type="checkbox"/> Pre-populated TRF	<input checked="" type="checkbox"/> Return of results as discrete data in Risk 360
	<input checked="" type="checkbox"/> Pre-populated TRF	<input checked="" type="checkbox"/> Return of results as discrete data in Risk 360
	<input checked="" type="checkbox"/> E-ordering to Ambry Genetics Clinician can see relevant order in AmbryPort	<input checked="" type="checkbox"/> Return of results as discrete data in Risk 360

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.



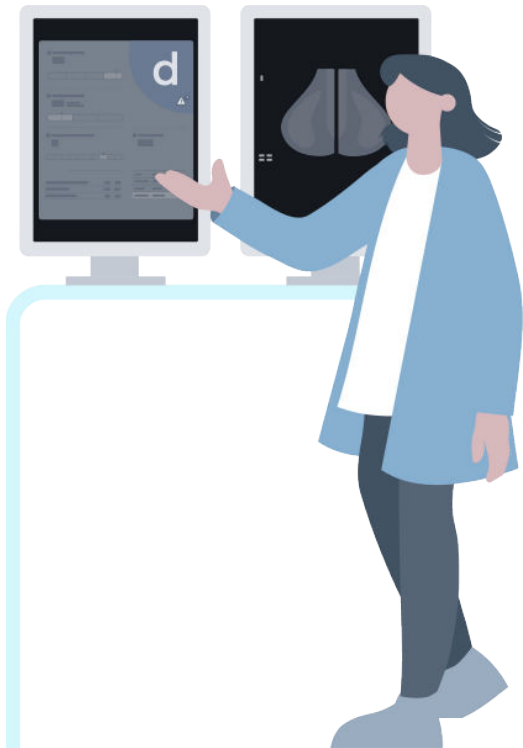
Administrator

- 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.



Lunit Professional Services

Lunit'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.

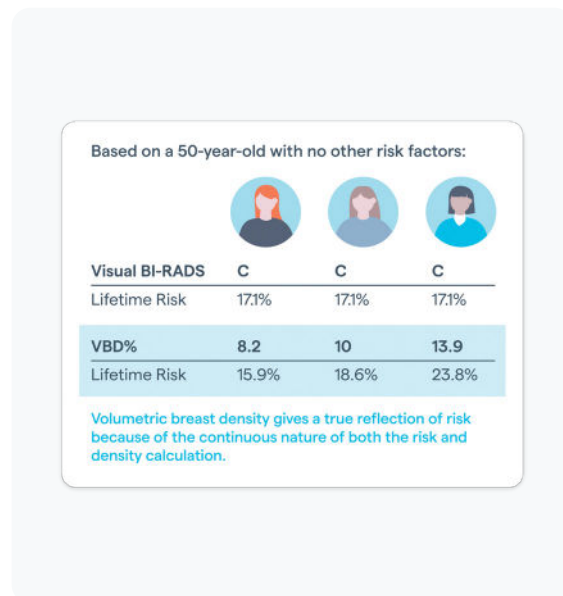
The Scorecard option is based on the Volpara® TruDensity™ algorithm, which calculates volumetric breast density (VBD), fibroglandular tissue volume, and breast volume to assign a breast density category for an objective, consistent, and repeatable assessment.⁷ It can be sent to PACS to support radiologists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

- Availability of TC8 display on Scorecard may vary by region and licensing requirements. Please contact your representative for details.
- For sites with Scorecard, Myriad PES can receive the VBD%.



References: 1 <https://ascopubs.org/doi/full/10.1200/CCI18.00072>. / 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/CCI18.00072>. / 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. / 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).

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