



AI that works in breast imaging

The Volpara Health approach to trusted, effective AI



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Breast care AI confidence gap

Introduction

Artificial intelligence (AI) is all around us, but why has adoption in healthcare—and breast imaging in particular—been slower than in other industries?

The value AI can bring to breast imaging has evolved significantly since the early days of computer-aided detection (CAD). AI has already shown tremendous potential to help increase early breast cancer detection and improve workflow management as the industry faces radiologist shortages and increasing study volume.

Yet there is a confidence gap that is slowing the adoption of AI and productivity and quality for breast imaging.

To deliver on AI's promise in breast imaging—speed, simple workflow, consistency, and ROI—the AI confidence gap must be closed. To build trust and adoption, quality and rigor for AI development and validation need to be elevated to a much higher standard.

This eBook elaborates on Volpara's approach to AI innovations that automate a range of tasks and bring value to breast imaging—from speeding US Food & Drug Administration (FDA) quality audits to objective analysis of mammography quality and precise breast density measurement. We provide guidance on how to evaluate AI for your practice and provide a glimpse at developments on the horizon.

Part One: Evaluation and optimization





Evaluating AI for breast imaging

Whether you're considering your first breast imaging AI tool implementation, or you've been using AI since the early days of CAD, how do you properly evaluate your options?

- Consider well-established, big-name vendors?
- Remain in the comfort of established vendor relationships?
- Wait for validation studies in peer-reviewed journals?
- Rely on AI developed at your institution or by trusted peers?

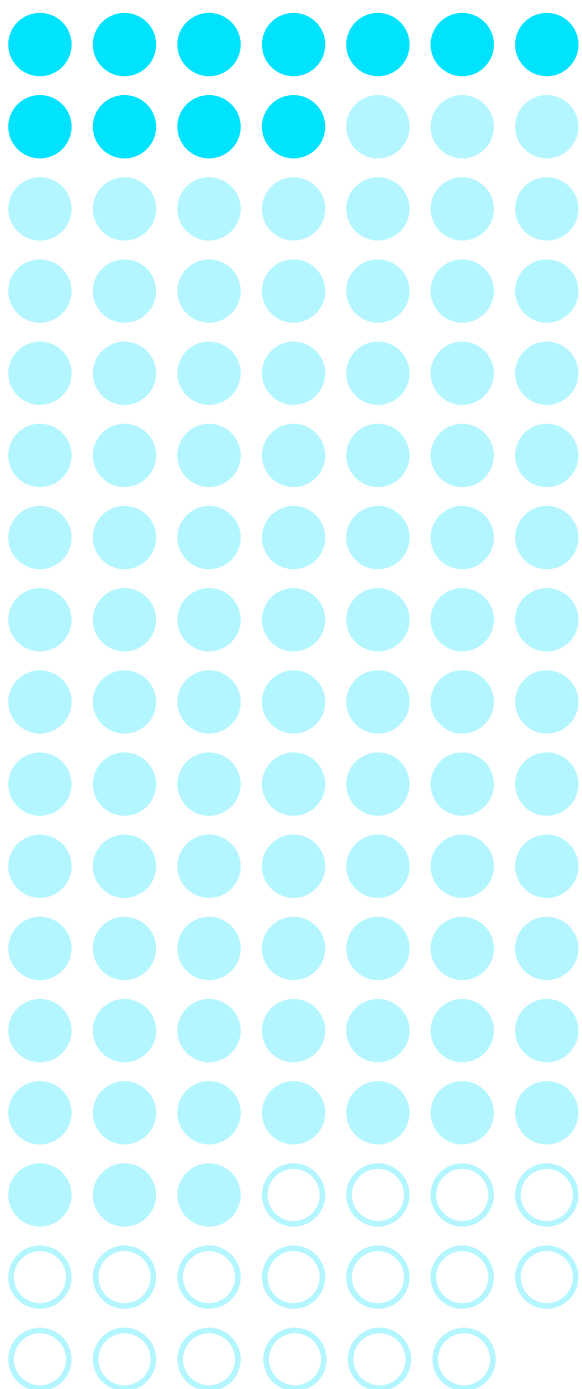
Choosing the right AI tool is an important decision for the productivity and reputation of your practice, as well as for improving outcomes for your patients. At Volpara Health, we develop AI to support, not replace, the clinical judgment of radiologists and to bring consistency to the very subjective tasks of breast imaging.

In this chapter, Volpara's approach to establishing best practices for the creation of AI tools for breast imaging will be outlined.



View your breast imaging AI checklist

Are you confident in what to ask a potential AI vendor? To help you evaluate how an AI tool may work in your practice, we've developed a series of questions to ask each vendor about how it was designed and validated.



Defining standards

As imaging societies and government regulators work on standards for design and validation, we understand if you're a little shy about getting started. With the ongoing introduction of breast imaging AI tools, it's not uncommon to find that algorithms are tested on only a few hundred—or even a few dozen—cases.¹

In a study published in *Academic Radiology* in September 2021, researchers found that **only 11 of 118 FDA-cleared algorithms used validation datasets of over 1,000 patients.** Nine used datasets of between 500 and 1,000 patients, and 45 out of the 118 had fewer than 500 patients. Most lacked any patient demographic information and **17 didn't post publicly accessible data.**²

In addition to sufficient datasets, it is critical to understand how an algorithm was built and trained. For example, for a breast density assessment AI tool, does the algorithm assess density the same way radiologists make a visual assessment? This method is subjective and has been shown to result in only a 60 percent agreement in scoring category b and c breast density.³ Or, does it use a quantitative and objective method, such as Volpara® TruDensity™, which uses a combination of x-ray physics and AI to generate accurate volumetric measurements of breast composition, showing high correlation to breast MRI—considered the source of ground truth in breast density?

Ongoing and proactive algorithm improvements as well as continuous testing and independent validation are critical to addressing these challenges and ensuring accurate and consistent results.

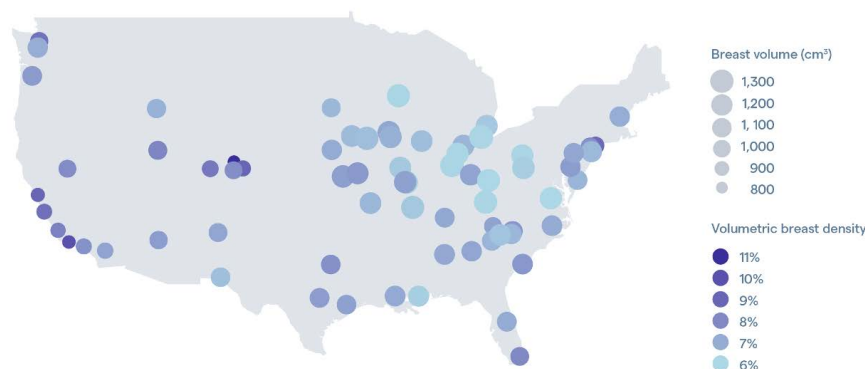


Challenges for breast imaging AI



Each patient is unique

Breast size and tissue composition vary across countries and regions. More than 13 million women attend a Volpara breast clinic annually, which enables robust data collection and helps ensure that **Volpara AI is applicable to different breast size and tissue composition.**

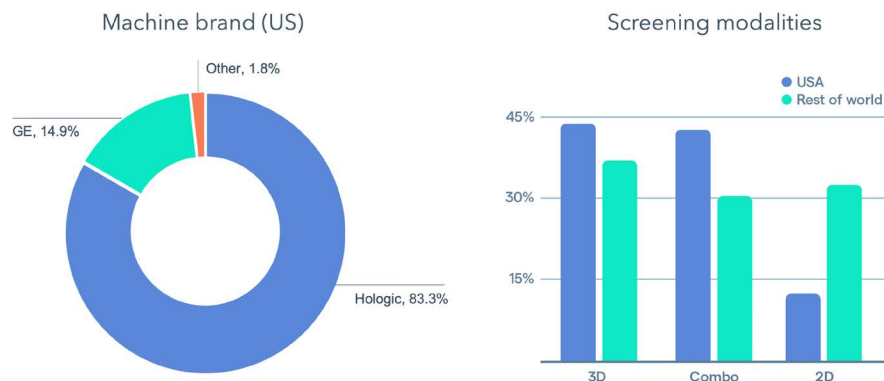


The size of the circle represents the average breast volume, the color of the circle represents the average volumetric breast density.

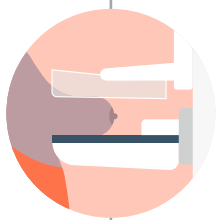


Vendor system differences

Each mammography system has different settings and software updates may not be synced. This presents a challenge for most AI to work across all of them. Volpara regularly monitors updates and new introductions and conducts thorough testing to accommodate for these changes.

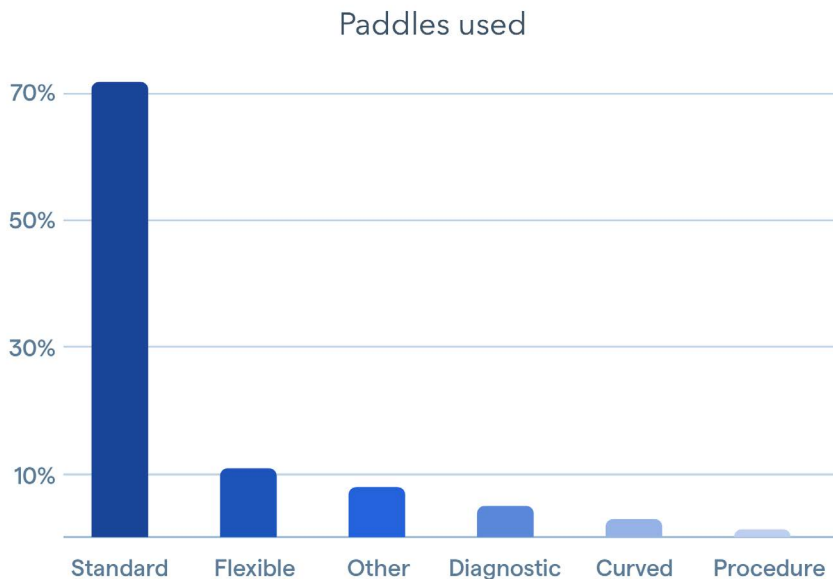


Data from 2021 onwards



Variation from paddles

Paddles can create significant artifacts the AI must take into account. Volpara's physics-based AI allows the user to correct for most issues prior to AI processing.

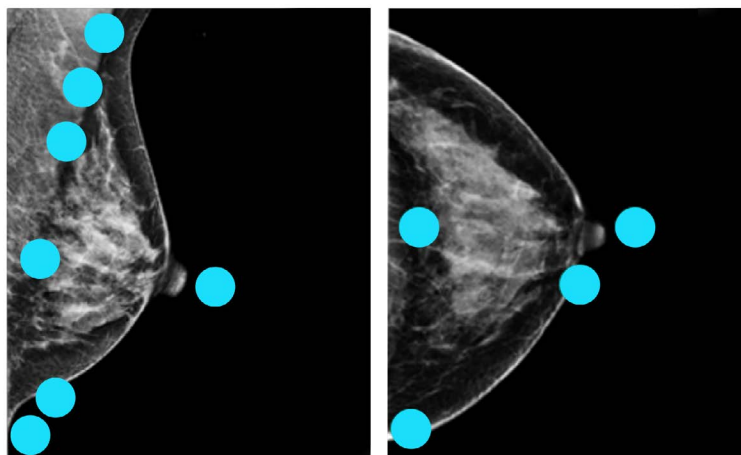


Data from 2021 onwards.



Technologist performance impact

Mammography quality is subjective due to lack of standardization and specific guidance from accrediting bodies. Technologists perform different techniques to position and compress a breast, so AI needs to adapt to those different processes.



Volpara® TruPGMI™ uses AI to analyze 11 markers of proper positioning objectively and automatically on every mammogram to guide technologists where they're proficient and where they can improve.

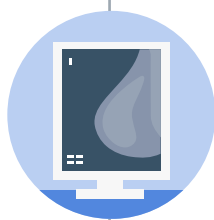
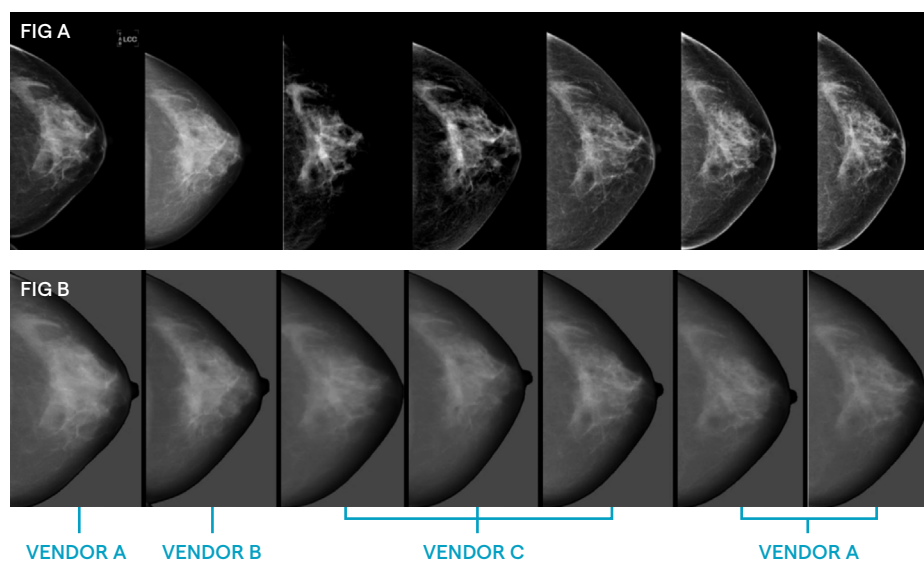


Image processing differences

Mammography gantry manufacturers process 2D/3D images in different, proprietary ways. Processing variability due to manufacturer, model, and site make it difficult for AI to work reliably and be generalizable on “presentation images”. Volpara uses For Processing/Raw Images to retain correct physics data, enabling the algorithm to accurately measure the relationship between pixel intensity and x-ray attenuation.



Images from Fig A and Fig B are from the same woman over 7 years.

Fig A shows 2D mammography presentation images from multiple vendors; Fig B show quantitative images, standardized by Volpara from raw, X-ray data.

Breast imaging AI algorithms must be applicable to the broad population, accounting for a wide range of variables:

- Breast size and tissue composition
- Mammography system types, settings, and software versions
- Technologist performance, e.g., positioning, compression, artifacts
- Image processing (if not using raw x-ray images)

Volpara’s philosophy is to adhere to scientific principles and ground truth, which led us to create robust development guidelines and validation processes. With more than 10 years of AI experience, Volpara technology has been used to assess the breast composition of more than 17.3 million women across 41 countries. Our dataset includes nearly 100 million (at time of publication), and this ever-expanding database allows for continuous improvement of our algorithms. Furthermore, our AI software is delivered via Software as a Service (SaaS), which helps healthcare providers avoid obsolescence and facilitates quick updates.

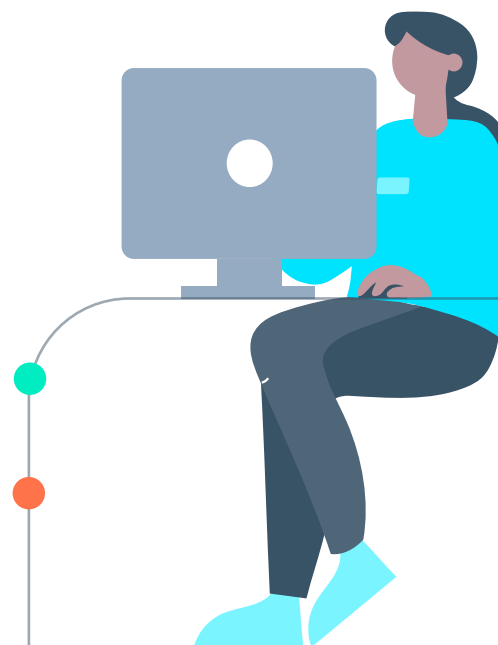


Optimizing AI acceptability and trust

Leveraging a blend of medical physics, computer vision, and deep learning, Volpara’s approach to AI is to take subjective decisions and make them objective. We focus on areas where AI can be used to improve patient care while increasing productivity and quality.

We also focus on areas where users typically struggle, such as repetitive quantification including image-quality analytics and audit preparations, automated breast density assessment, and evidence-based risk assessment. Our AI tools have been featured in over 200 peer-reviewed studies as well as over 500 scientific works, making it the most independently validated AI tool of its kind.

The paper “Artificial intelligence in radiology: 100 commercially available products and their scientific evidence” validates this claim, as Volpara was shown to have the most independent peer-reviewed papers of any vendor included across all clinical radiology product types.⁴



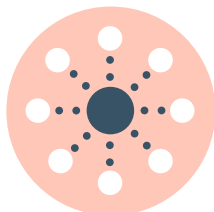
Paper comparisons

Vendor (Breast)	Product	Papers	Independent	Level of efficacy						
				1c	1t	2	3	4	5	6
Competitor One		1	1	0	0	1	0	0	0	0
Competitor Two		17	13	1	3	14	0	0	0	0
Competitor Three		1	1	0	0	0	1	0	0	0
Competitor Four		4	0	0	0	3	1	0	0	0
Volpara Health	VolparaDensity	35	21	5	8	20	4	2	0	0



Using a Software as a Service (SaaS) model allows us to seamlessly deliver updates and upgrades to the algorithms. This process enhances clinical confidence and provides protection from obsolescence as we regularly improve our algorithms.

Volpara Health has taken steps to establish best practices for the creation of our AI, abiding by the following guiding principles: sufficient dataset, rigorous testing processes, external validation, explainability, and reliability.



Explainability



Large, diverse datasets



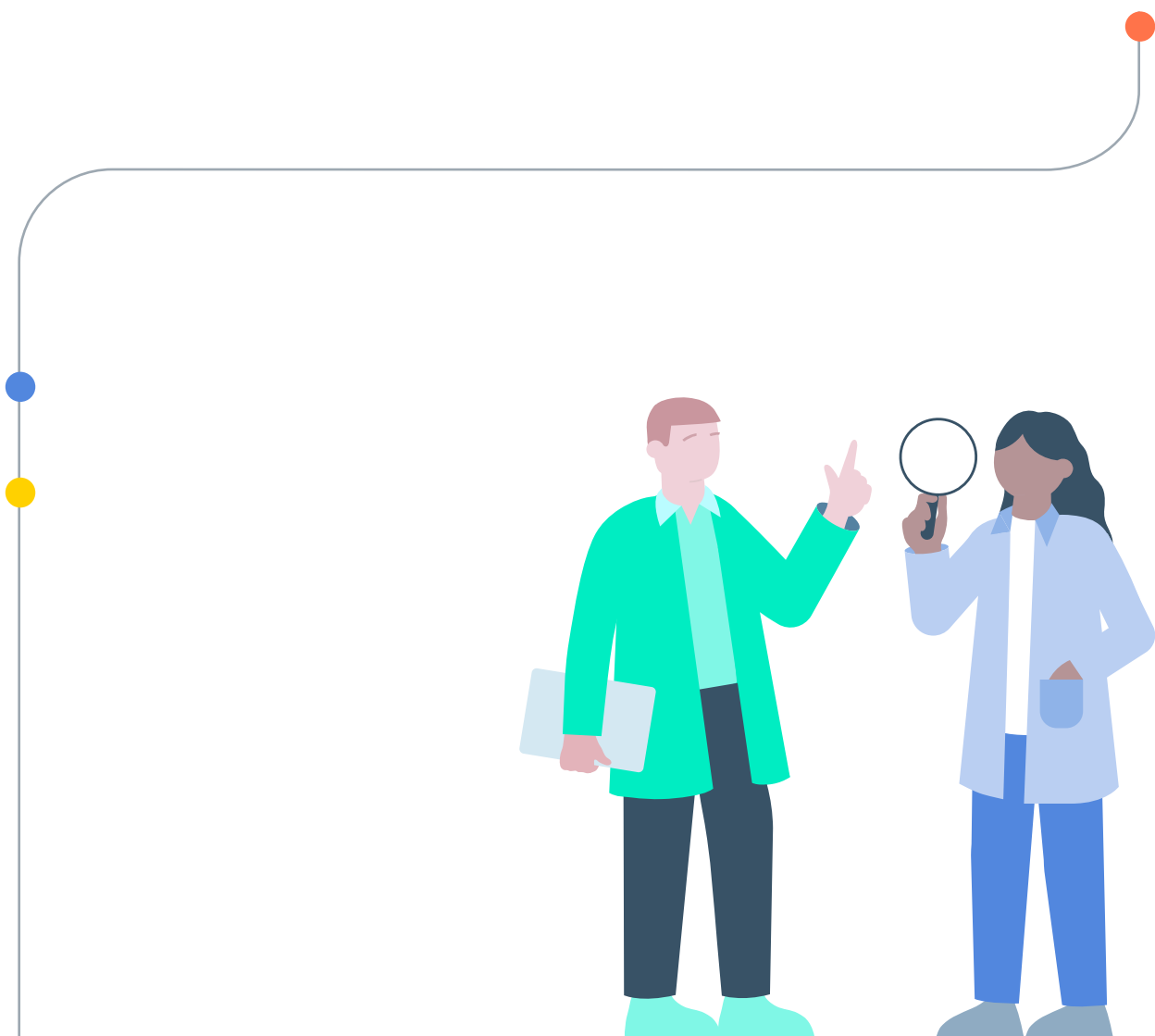
Rigorous testing



External validation



Reliability





Explainability

In order to trust an algorithm, users need to understand how it generates results.

- For example, if a physician uses an AI tool to help guide screening decisions for a patient, she could disagree with the AI's low risk scoring for the patient because she has seen similar cases where patients developed cancer.
- A second example is an AI tool designed to help detect malignancies. The AI tool could provide a malignancy score for an image without showing what led to that decision. Alternatively, the AI tool could show the microcalcifications and lesions it detected and identify the image as potentially malignant. The second approach is more explainable.

Without understanding how the AI tool scored the patient's risk, it is difficult to trust whether the recommendation is correct or not.



Large, diverse datasets

To avoid bias, training data needs to be broad enough to ensure that it includes all expressions of the disease as well as normal subjects. In addition, the datasets used for testing need to represent the screening population to ensure generalizability.

This is where most AI tools for mammography fall short: they have algorithms built on small, homogenous datasets. The algorithm may perform well on a small dataset but fails when applied to a larger population.

To build trust that AI improves breast imaging, AI products must be appropriately designed and validated with both large databases and third-party testing. To ensure a robust, generalizable algorithm that is unbiased, Volpara Health uses more than 70 datasets with patients and cases from facilities around the world, including New Zealand, Australia, the United States, China, Japan, Chile, the United Kingdom, and the Netherlands, to name a few.



Rigorous testing

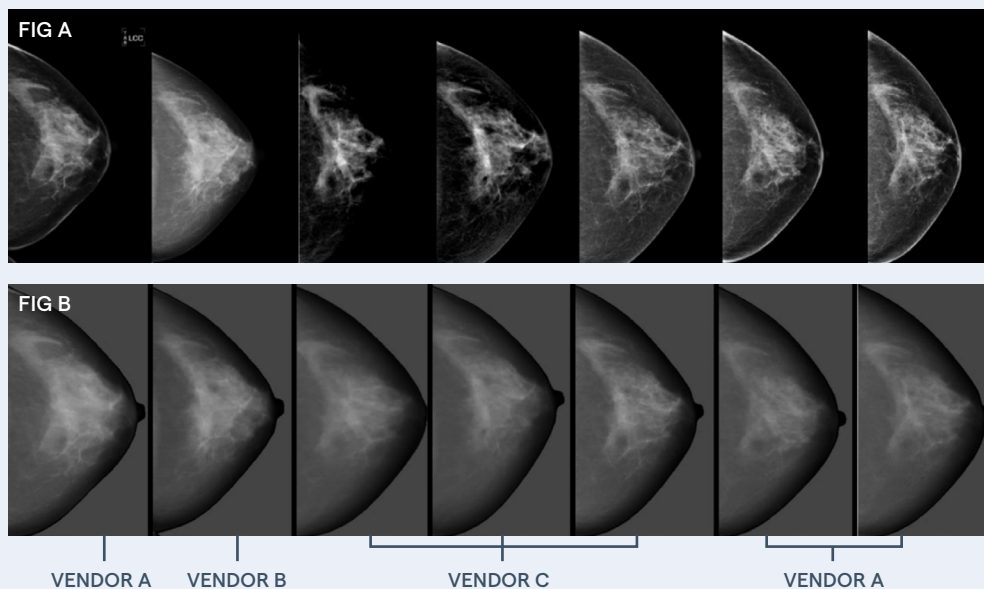
A clinician using an AI tool with insufficient understanding of how it was tested and validated will have difficulty trusting the algorithm and assessing clinical efficacy since generalizability to the patient population and presence of bias cannot be judged.

Volpara works to ensure performance and accuracy through our proven, rigorous processes. For example, to validate the performance of our TruDensity algorithm, we perform 21 tests to confirm that it works with 36 FDA-approved mammography system and that it can resolve implants, pacemakers, image quality issues, and other “noise” that clinicians see in the real world but are generally not included in validation datasets or “clean” training datasets and test sets. In addition, we perform tests to compare how the AI performs on the following:

- Digital 2D mammography versus 3D tomosynthesis
- Scoring the same woman when the exam is conducted on different mammography systems
- Comparing AI performance to radiologists

Without this type of rigorous testing, the AI could work perfectly for some exams, and fail for all or some areas in other exams. Volpara has relationships with some of the world’s largest, best curated mammography datasets for our validation exercises.

Addressing imaging processing differences



Images from Fig A and Fig B are from the same woman over 7 years.

Fig A shows 2D mammography presentation images from multiple vendors;
Fig B show quantitative images, standardized by Volpara from raw, X-ray data.



External validation

Independent validation testing is critical to ensure that AI performs as expected.

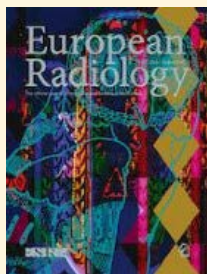
For example, an algorithm is trained on a dataset that includes images from a high-risk breast center that uses a 3D tomosynthesis system, and a general imaging center that uses a 2D mammography system.

Has the AI detected cancers, or has it simply learned that the 3D images are from the high-risk clinic and therefore more likely to have suspicious findings?

Whether required by regulators or not, AI developers should encourage completion of external, third-party validation studies. The accuracy of Volpara TruDensity has been validated by multiple independent studies^{5,6,7} showing a high correlation to breast MRI—considered the source of ground truth in breast density.

Although external validation is one of the most important parts of AI creation, this is often where shortcuts are taken and inadequate testing occurs. Volpara's relationships with esteemed breast centers around the globe assist in our external validation process and help ensure that the AI is highly functioning in clinical practice.

Impact of AI to the EUSOBI



New EUSOBI guidelines are based on [Project DENSE](#), an independent, 10-year randomized controlled trial.

The study used Volpara® Scorecard™ to identify—quantitatively and objectively—women with extremely high breast density.

The results of this study provided critical data towards the March 2022 updated recommendation that women with extremely dense breasts receive MRI supplemental screening.



Reliability

Introducing new software into a breast imaging center creates a potential vulnerability. AI implementation requires the approval and partnership of your IT department, as the new software must pass multiple security checkpoints.

Your selection of a competent vendor that holds data handling protocols and PHI protection as paramount is a key to success. [Volpara Health has partnered with Microsoft](#) and their world-class Azure Cloud computing system to provide our users confidence in their Volpara software experience. We have clear, preventative measures in place as well as active monitoring to secure your patient data and make sure that our AI models perform as expected in every environment. Our tools are designed to integrate into healthcare system IT ecosystems with the goal of providing a streamlined AI experience. Our SaaS model provides a high standard of secure software delivery and convenient software updates.

MAYFAIR[®] DIAGNOSTICS

“There is something comforting about having the quality assessed on every mammogram I take. It gives me constant and very specific reminders about what I can do to improve and provides me with a rewarding feeling when I’m doing a good job. I can’t imagine doing mammography without Volpara Analytics.”

Kate Kaminski Mammography Coordinator, Mayfair Diagnostics

Part Two: Volpara AI





Why select Volpara AI for your breast center?

Confident decision-making for efficient breast screening

Clinically validated by researchers and trusted by breast imaging centers, Volpara's algorithms are built on proven science. Volpara® Science™ has analyzed nearly 100 million mammography images and has assessed the breast composition of more than 17.3 million women across 41 countries (at time of publication).

Trusted insight

Volpara Health is the preferred partner of leading clinical sites, including top cancer centers. Renowned researchers use Volpara Scorecard and Volpara Analytics to provide reliable, consistent measures for their academic studies.

Continuous improvement

Every image we analyze has the potential to help improve our algorithms for the early detection of breast cancer. This affords Volpara users regular software improvements, and our SaaS model of software delivery provides these convenient updates at no additional cost while under contract.

Precise intelligence

Our AI is grounded in science to enhance clinician expertise. It is designed to provide accurate, objective assessments to inform radiologist decision-making.

Medical necessity

Through consistent measurement of breast density and mammography quality, Volpara provides decision support that makes the subjective objective. For example, Volpara TruDensity aids clinicians with volumetric precision to help them advocate for additional screening for patients with dense breasts.



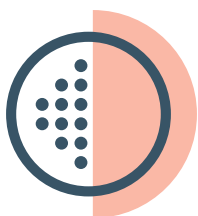
“Volpara’s constant innovation and drive to improve health outcomes is impacting the lives of millions of people around the world, and truly making a difference.”

Vanessa Sorenson
Chief Partner Officer, Microsoft ANZ



Volpara Health’s approach to AI for breast imaging is a blend of medical physics, computer vision, and deep learning that we use to take subjective decisions and make them objective. **Volpara algorithms** work in concert across products to deliver the clinical decision support and practice management tools radiologists, administrators, and technologists need to improve mammographic quality, detect cancer earlier, and maximize resource utilization.

Click the icons below to view short informational videos about our algorithm functionality.



TruDensity



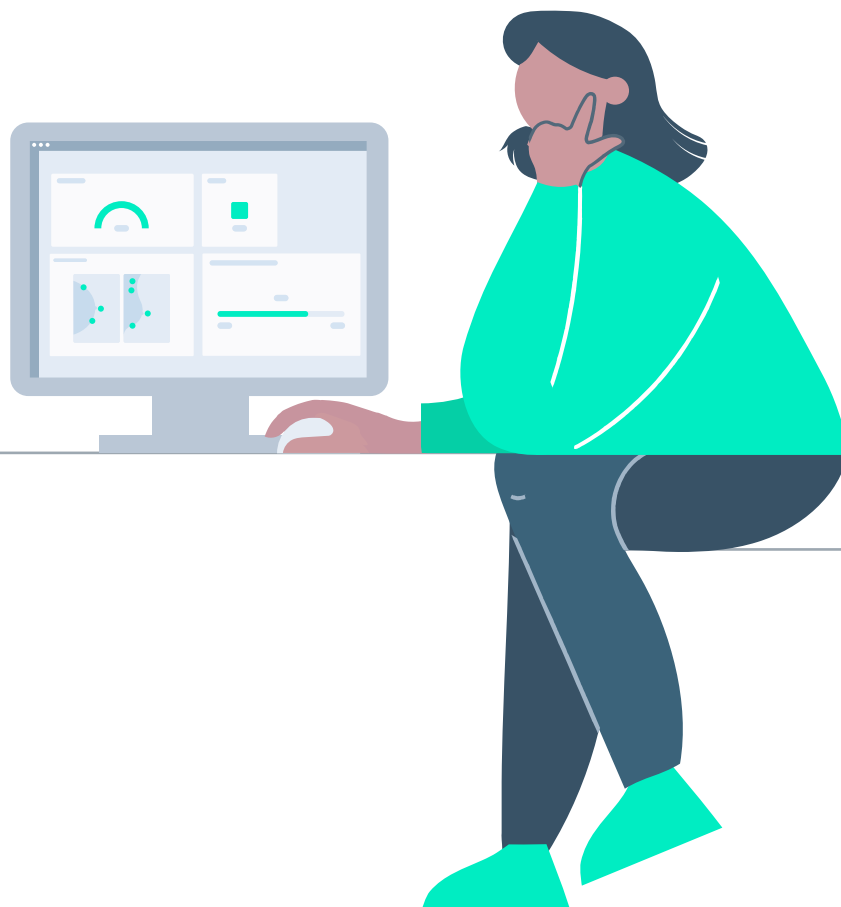
TruPressure



TruPGMI



TruRadDose



Performance use cases

Reduction of recalls/quality improvement: Volpara Analytics

The FDA established national quality standards for the United States through the Mammography Quality Standards Act (MQSA). The standards include proper positioning, x-ray dose, and breast compression. Though the FDA states that “poor positioning has been found to be the cause of most clinical image deficiencies and most failures of accreditation,”⁵ no specific guidance has been provided on how to achieve the requisite high quality in either positioning or the other included areas, nor on how to sustain or improve performance.

Volpara Analytics software provides a vendor-neutral approach for assessing mammography positioning, compression, and dose, and helps technologists improve to consistently achieve high-quality exams. Use of Volpara Analytics enables easy MQSA EQUIP compliance preparation through the generation of EQUIP reports with objective Volpara quality data to show inspectors. It enables users to rapidly find and fix image-quality issues.



Optimized mammography program performance

Mayfair Diagnostics in Canada decided to implement Volpara Analytics software to drive a quality improvement program using breast imaging analytics. Since their adoption of the software, they have been impressed by the broad impact the software is having across their network of 10 breast imaging facilities.

A Calgary-based multi-modality imaging practice that takes over 50,000 mammograms annually, Mayfair Diagnostics saw a 60% reduction in time searching for cases within six months of using Volpara Analytics—in addition to a 37% reduction in Inadequate images.⁶ Other benefits included the following:

Volpara Analytics benefits



Streamlining the compliance process

Being able to automatically generate a list of studies that are relevant for compliance reviews has saved Mayfair's Infrastructure Specialist **4–6 hours** in the image selection process.



Advancing technologists' skills

Monitoring technologists' positioning skills for every patient and every image allowed Mayfair's Mammography Coordinator to identify ways in which technologists can strengthen their skills for improved image quality.



Reducing technical recalls

The focus on quality improvement had financial benefits for Mayfair; they measured a **14% reduction** in the number of technical recalls, which directly influences cost savings in rescheduling patients, the use of x-ray equipment time, and technologist and radiologist labor.

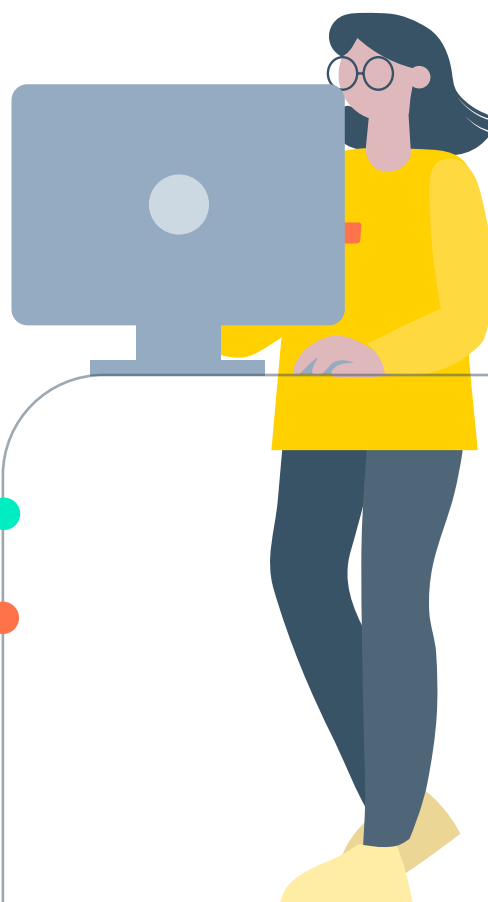


The future of AI for mammography quality

Peter R. Eby, MD, of Virginia Mason Medical Center presented the results of the largest mammographic image quality evaluation to date at RSNA 2022, “Reduction in technical repeat and recall rate after implementation of artificial intelligence driven quality improvement software.”

With a dataset of over 48,000 exams conducted by 42 technologists over nine clinics, the study found that, in the 12 months following the installation of Analytics, there were significant improvements in breast positioning and compression quality—6% and 8%, respectively. This led to an associated reduction in technical repeats and recalls of 78%.

AI used to assess mammography quality should provide women confidence in their mammography provider’s performance and their exam’s ability to afford them the best chance of early detection.



“This study highlights the potential for AI in revolutionizing what has traditionally been a very manual process, by providing continuous mammography image quality feedback to technologists on an unprecedented scale.”

Peter R. Eby, MD, Virginia Mason Medical Center



Accurate identification for supplemental imaging: Volpara Scorecard

The accuracy of Volpara TruDensity has been validated by multiple independent studies, showing a high correlation to breast MRI—considered the source of ground truth in breast density.⁷

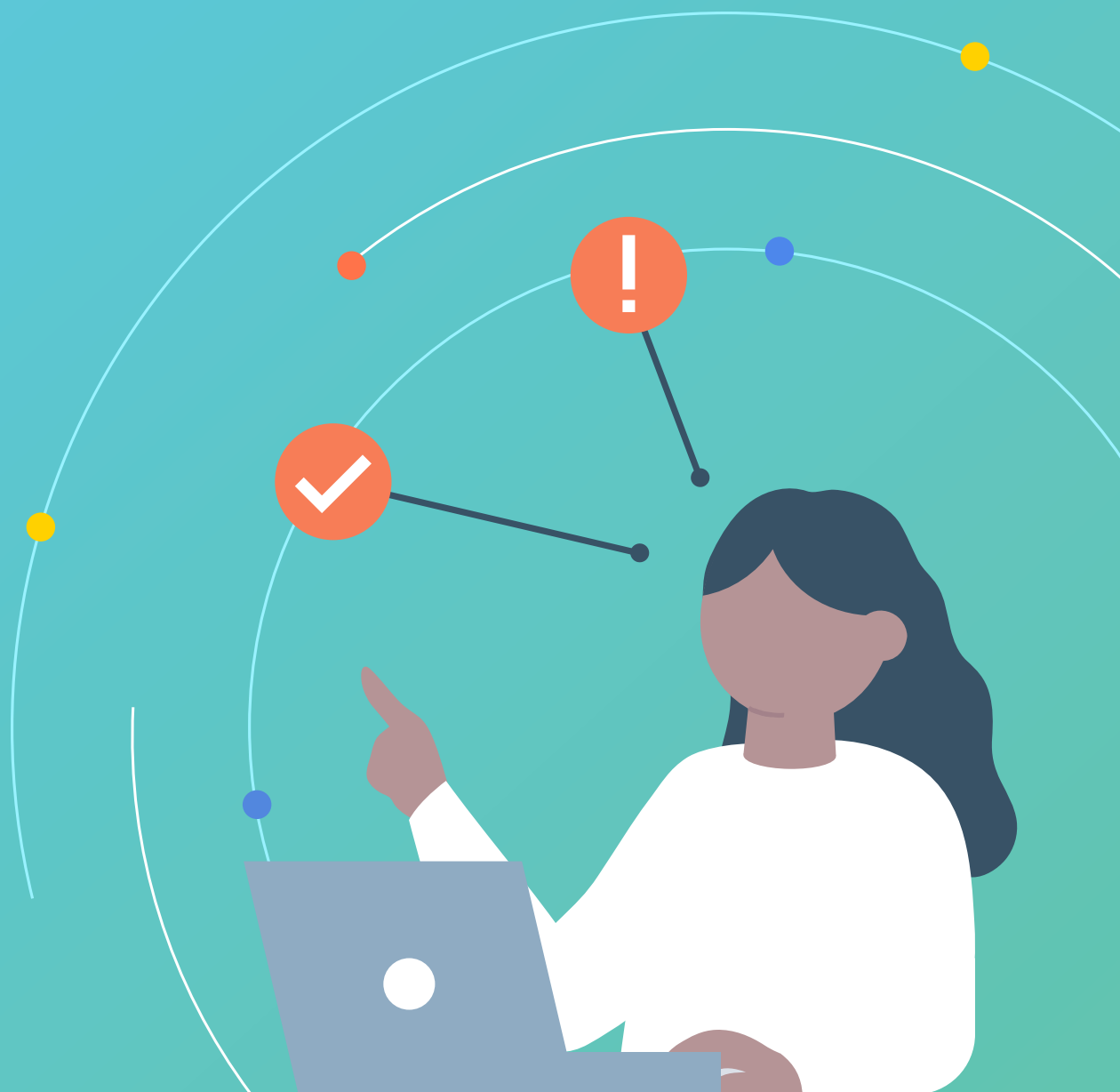
The European Society of Breast Imaging recently published new [guidelines](#) recommending that all women in Europe be told their breast density and that those at the higher density be offered breast MRI every 2-4 years.⁸ Those guidelines were based on results of several large trials such as DENSE trial, which showed that screening women with extremely dense breasts using MRI in addition to mammography dramatically [reduced the number of interval cancers](#)⁹ and a study result showed a [reduction in false positives](#).¹⁰

Volpara was heavily involved in the DENSE trial with our objective, quantitative, AI-based TruDensity scoring system, which automatically assesses breast density volumetrically on a continuous scale. Its accuracy has been validated by many independent studies, showing high correlation to breast MRI, which is considered the source of truth in breast density. Because TruDensity is quantitative and continuous rather than grouped into broad categories, screening programs can flex how they personalize screening according to resources.

	DENSE trial round one screening	DENSE trial round two screening
Additional cancer detection rate (CDR)	16.5 per 1000 exams	5.8 per 1000 exams
False-positive (FPR)	79.8 per 1000 exams	26.3 per 1000 exams

Results of the “Supplemental Breast MRI for Women with Extremely Dense Breasts: Results of the Second Screening Round of the DENSE Trial”

Part Three: The future





The evolving role of AI in breast imaging

Using AI to predict and prevent

Early breast cancer detection leads to the best outcomes for patients—with five-year relative survival rates in the United States dropping from 99% for “localized”-stage cancer to 29% for “distant”-stage cancer that has metastasized to other areas of a patient’s body.¹¹ As AI continues to prove its role within the field of breast imaging, its benefit in early cancer detection is becoming more prominent. But it can also be used to predict cancer before it occurs and help send patients down a path to prevention.

In breast cancer imaging, AI like Volpara’s TruDensity is often thought of as decision support when reading mammograms and characterization of suspicious tissue.¹² But AI can also help clinicians predict who may likely develop cancer. Researchers are continuing to study AI for automatic, objective, and precise breast density assessment as a means to aid in prediction and prevention.¹³





Quantitative breast density to inform risk assessment

Not only has use of Volpara's volumetric density assessment AI tool, Scorecard, demonstrated its ability to objectively assess breast density, it has also proven to be a good mechanism for personalizing care and triaging patients to supplemental screening using alternate screening modalities such as MRI.¹⁴

Change in medical management toward personalized screening regimens gives patients with dense breasts a higher chance of successfully catching breast cancers earlier and preventing late-stage diagnosis, and this starts with a risk assessment.

The Tyrer-Cuzick v8 risk model (TC8) assesses a patient's 10-year and lifetime risk of developing breast cancer based on personal and family histories of cancer, as well as other personal risk factors, including their breast density in version 8 of the model. Density inputs to the risk model include the results of visual assessment (BI-RADS® 4th ed., or visual analog scale) or Volpara Breast Density % (the only vendor density assessment technology integrated with the model).¹⁵

According to one study in a US screening setting, using Volpara volumetric density score in the TC risk model resulted in more women being identified as high risk than through 'classical risk factors alone', making them eligible for additional screening with reimbursement.¹⁶

In the United States, the 2023 introduction of the FDA mandate to inform all women of their breast density in their mammography letters is an opportune event for AI.

Volpara Scorecard is the number-one AI tool for automated breast density assessment that precisely estimates the volume of dense tissue. It is the only density software to provide a continuous measure of breast density as an input to the TC8 lifetime risk model.



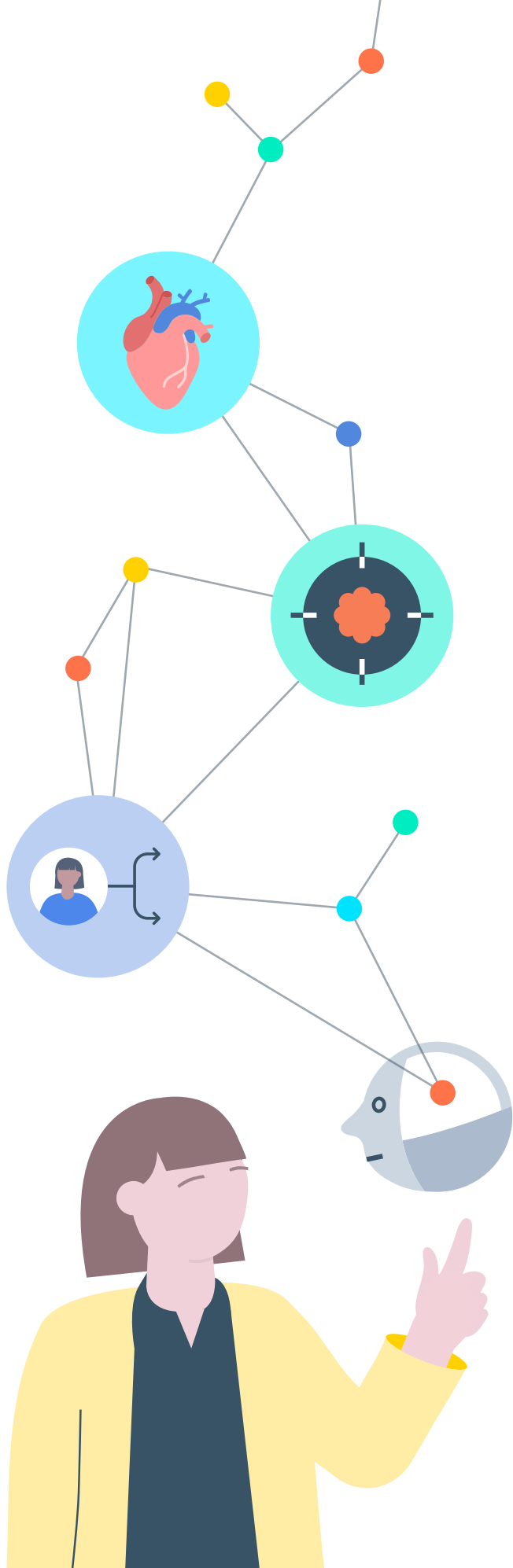


Future applications

Image-based risk

AI's role is constantly evolving. Many researchers are beginning to develop methods to predict risk and breast health analysis from images,^{17,18} and to study an individual's mammography images over successive screening rounds to identify changes over time and whether those changes should indicate the need for a specialized care pathway.^{19,20,21} The meaning of these changes still isn't clear, such as how to elucidate the distinction between early signs of cancer and patterns indicating risk²²—but AI will be a way to track them and help define them.

AI holds a promising role in the future of breast cancer prediction and prevention, from reaching patients earlier to raising the standard of care. Prevention will only be possible when the effort is taken to assess breast cancer risk at an early age so that appropriate screening regimens and other interventions can be offered and applied to high-risk patients.



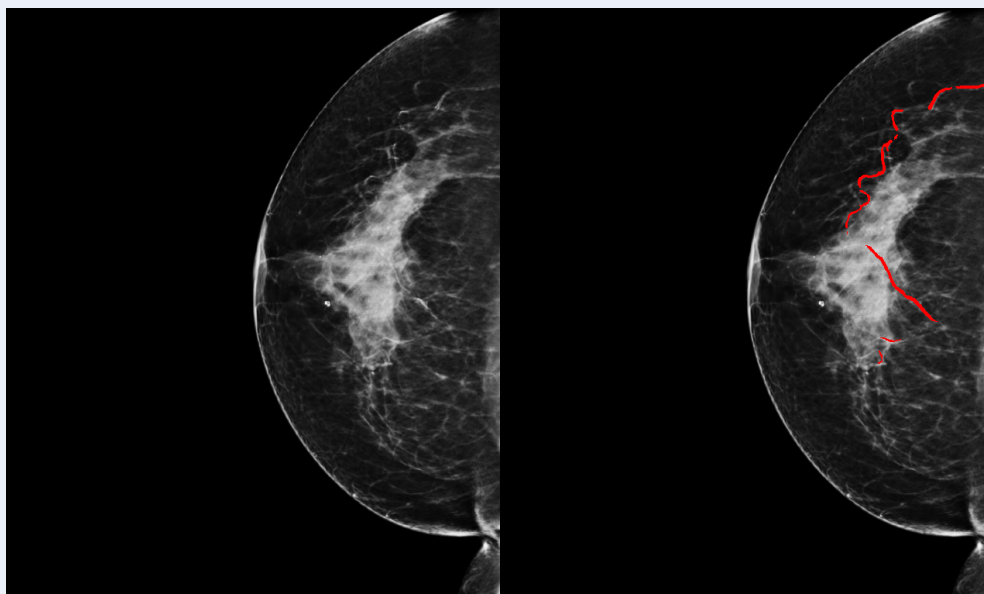


AI to help predict cardiovascular health

Breast arterial calcifications (BAC) are often observed on mammograms and are usually considered an incidental finding without increased risk for breast cancer but which may indicate arteriosclerosis. Building on Volpara's approach to quantitative and objective breast density scoring using AI, Volpara and Microsoft are working on algorithms to create a tissue composition map that identifies and quantifies BAC to help radiologists identify the need to take steps toward prevention of heart disease.

Volpara's BAC model is continuing to evolve, with work underway on how to operationalize this critical information into the breast imaging workflow.

Volpara's BAC model



Left image: mammogram with breast arterial calcification

Right image: same mammogram with Volpara BAC detection algorithm

Part Four: Selecting your vendor





Choosing the right AI partner

As breast cancer screening continues to become more personalized and the paradigm shifts from early detection toward prevention, new uses of AI and the cloud are emerging. To address radiologist shortages and increasing study volume, AI that improves workflow and precision will be critical. AI can take on the tasks where users typically struggle, such as repetitive quantification in areas such as image-quality analytics, audit preparations, automated breast density assessment, and evidence-based risk assessment.

Volpara Health's approach to AI for breast imaging is a blend of medical physics, computer vision, and deep learning that we use to take subjective decisions and make them objective. We focus on areas where AI can be used to improve patient care while increasing productivity and quality.

We see the breast imaging industry struggling to find their way in embracing AI, and we have taken steps to address the lack of standards. Volpara Health has established best practices for the creation of our AI that every radiologist can use to measure the quality of other vendors' AI tools. Based on our volume of publications and scientific works, AI tools developed by Volpara are the most independently validated AI tools of their kind.

We encourage you to hold us to these best practices as you evaluate and use our AI tools, and to use the [Breast Imaging AI Checklist](#) as you consider AI from any vendor. We believe that choosing the right AI technology—and partner—will enable you to focus on what matters most—providing the best breast care to patients.





Your breast imaging AI checklist

Questions to ask your vendor:

- How does it improve patient care?
- What is its regulatory status?
- What's the return on investment?
- Does the vendor have information security certification?
- How well can it integrate into my workflow?

Advanced questions: How do you trust the AI?

Explainability

- Is it logical?
- Is there an explanation of how it works and when it might not?

Generalizability

- Is it representative of the global population?
- Does the dataset contain millions of images?
- Is raw data used, not processed display image sets?

Validation

- Is it rigorously tested on mammographic images from multiple vendors?
- Is it lab tested and clinically validated?
- Is it attuned to the intricacies of breast imaging?
- Is it available for independent testing?

Reliability

- How does it secure PHI?
- Does it actively monitor the safety of your data?
- How well does it integrate with your IT systems?
- Is it regularly and automatically updated?





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