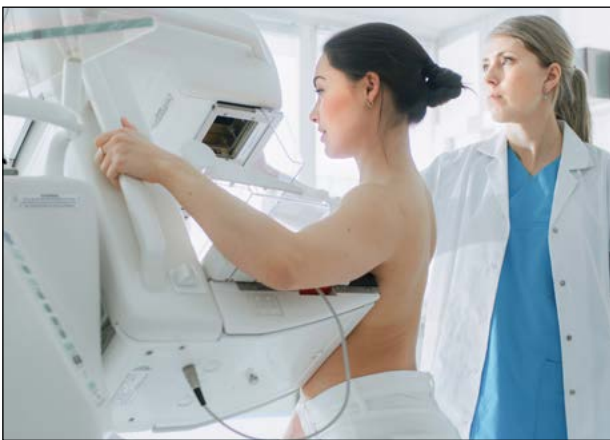# New era of breast imaging demands enterprise imaging strategy

An abundance of new technology and clinical research is emerging that is re-shaping diagnostic practices to establish new standards of breast care.

Introduction

Breast imaging is a rapidly evolving segment. New research, legislation and emerging technology is changing breast cancer detection and diagnosis, creating a more complex, multi-modality, multi-stakeholder care pathway. This more adaptive and personalised approach offers patients a higher quality of care. However, from an informatics perspective it also creates significant challenges for healthcare providers. Many "best of breed" software modules and tools in breast diagnosis and detection are proprietary or difficult to integrate with wider systems. Traditional radiology picture archiving and communication system (PACS) software can also lack breast specific tools and specialist reporting support; nor can it pull in patient data from other clinical IT systems to offer a complete view of patient history.

Consequently, few health providers have been successful in full integration of breast cancer detection and diagnosis data into broader imaging IT software and patient records. In this paper, we offer a summary of the main trends and technologies shaping the evolution of breast detection and diagnosis. We also explore how healthcare providers should tailor their imaging informatics strategy to be ready for the new era of breast detection and diagnosis.

Contents

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Signify
R E S E A R C H

Evolution of breast imaging

The diagnosis and treatment of breast cancer has improved markedly in the last two decades, supported by the emergence of a broad array of new diagnostic technologies. 2D Digital Mammography is an established base standard in terms of both screening and diagnosis for breast cancer today, with use across almost all mature healthcare markets. However, substantial clinical research in the last decade has identified the limitations of 2D digital mammography for some patient demographics and made clear that the "one-size-fits-all" approach has its limitations. Breast density has been identified as a major factor in the effectiveness of standard 2D digital mammography in diagnosis, prompting many healthcare providers to look to implement more adaptive and personalised diagnostic pathways. These often include using many different supplemental modalities, namely Digital Breast Tomosynthesis (DBT), conventional ultrasound, Automated Breast Ultrasound (ABUS) and Magnetic Resonance Imaging (MRI).

Recent examples of this change are evident in several markets. In the USA, it has now become mandatory in 38 states to notify women of their breast density after a mammogram, with many health systems going much further in terms of informing women about the potential impact of breast density on the effectiveness of different imaging types in both screening and diagnosis. In Europe, MRI is also being offered as an addition to conventional 2D mammography for high risk patients in some countries, namely Austria and Italy and is also being assessed for use elsewhere. Moreover, as awareness of risk-based adaptive imaging for breast cancer diagnosis increases, use of ultrasound and MRI will also rise.

Large-scale clinical studies are also assessing the potential of personalised breast imaging, especially assessing adaptive diagnostic pathways for "high risk" patients. Some of the most high profile studies include MyPeBS (1) (targeting 85,000 participants across five European countries), WISDOM (2) (targeting 100,000 participants, risk-based screening approach based on genomics and breast density, with highest risk receiving mammogram and MRI in the USA) and the DENSE trial (3) (30,000 participants, focus on supplemental use of MRI for women with extremely dense breasts, Netherlands).

1. **MyPeBS:** mypebs.eu/
2. **WISDOM:** wisdom.secure.force.com/portal/
3. **DENSE:** www.juliuscenter.com/dense/nl-nl/welkom/welkom

The wider use of different hardware and software used in "adaptive" breast cancer detection and diagnosis provides an opportunity to improve care standards for healthcare providers. This technology is also more widely available on the market today. Below, we have provided a summary of most commonly used imaging modalities in use for breast cancer detection and diagnosis today.

Technology	Screening/diagnosis	Maturity of use	Assessment
2D Digital mammography (2D FFDM)	Both; most common screening modality worldwide; also used heavily in diagnostics follow up.	Mature; widespread adoption in almost all mature healthcare markets; partial adoption in emerging markets.	Most commonly used in screening, widely established as clinical "standard" for diagnosis. Proven limitations in sensitivity for women in higher breast density categories.
3D Digital breast tomosynthesis (DBT)	Both; still nascent in screening but increasingly common in diagnosis; emerging variations (compound view, "HD" tomosynthesis emerging.	Increasingly common in mature healthcare markets for diagnosis; screening uptake still nascent.	Growing evidence of improved sensitivity and specificity over 2D mammography, especially in higher breast densities. Longer reading times common seen as barrier.
Conventional ultrasound (US Diag.)	Predominantly used for diagnosis and/or biopsy.	Widespread in diagnosis; limited adoption in screening.	Commonly used in diagnostic follow up and for biopsy guidance; lack of reproducibility of results seen as restrictive. Highly dependent on user training and interpretation.
Automated Breast Ultrasound (ABUS)	Targeted as supplemental option to mammography in screening.	Adoption relatively slow; growing support in regions with high proportion of population with dense breasts, especially Asia Pacific markets.	Offers reproducibility over conventional ultrasound and growing evidence to support accuracy above 2D mammography in high breast density women.
MRI	Diagnosis; screening in a few select countries.	Increasingly common in "high-risk" patients as part of diagnosis; under consideration in many markets.	Gold standard; growing sup-port for more widespread use, especially in high risk women. Cost and availability of MRI main barrier.

Chart 1 Market Size and Forecast - Breast imaging modalities ($ Revenues)
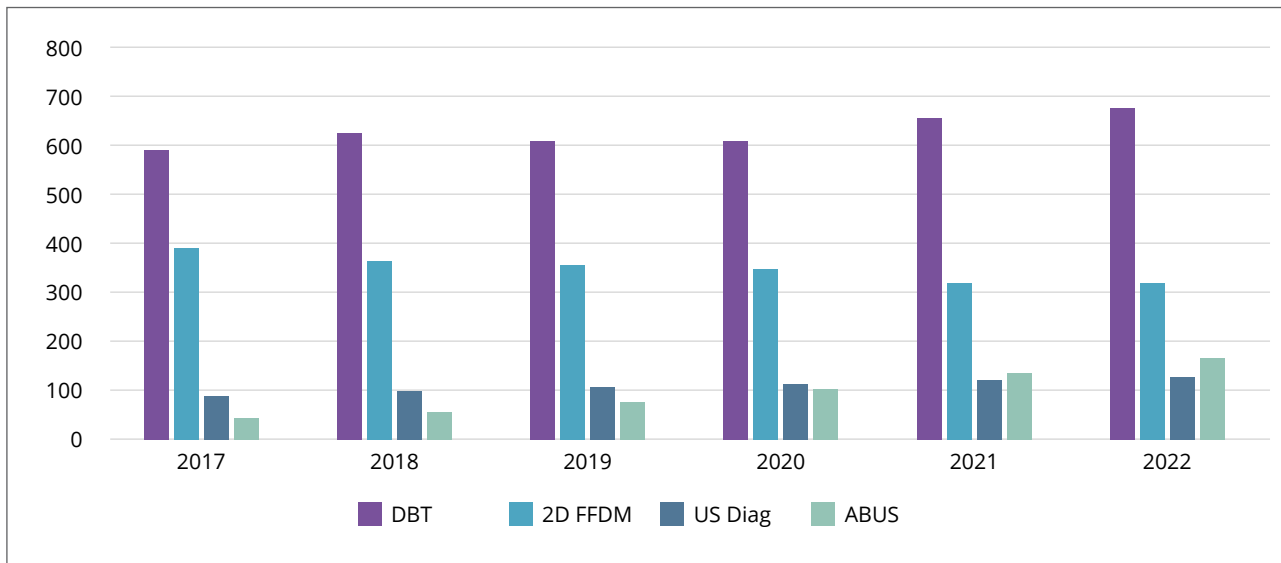
As these figures demonstrate, the range of imaging hardware in use or under assessment for use in breast detection and diagnosis today is expanding and increasingly complex. Health providers are consequently under pressure evolve and adapt their diagnostic pathways to meet these new standards of care and to remain competitive versus their peers.

Emergence of AI for breast imaging is revitalizing CAD

It is not just imaging hardware that is also drastically changing the breast imaging sector – the growing availability of dedicated software, much of it using artificial intelligence (AI), is also rapidly changing the diagnosis and detection of breast cancer.
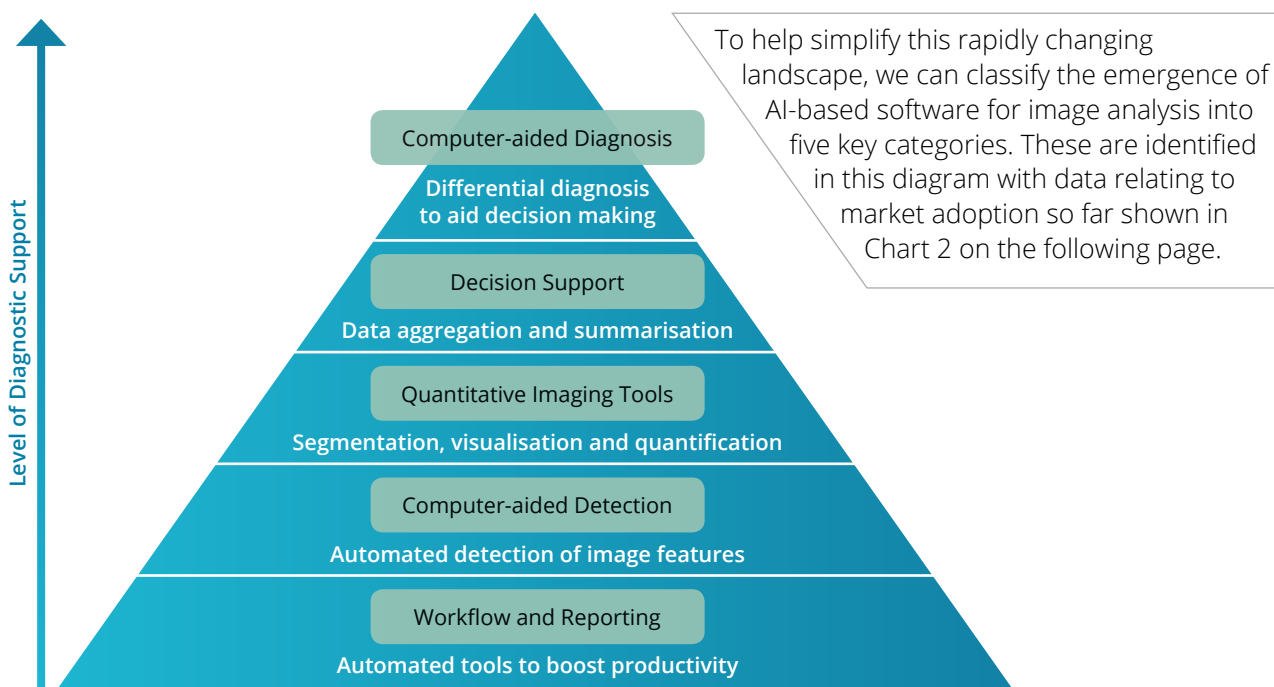

Level of Diagnostic Support

Computer-aided Diagnosis
Differential diagnosis to aid decision making

Decision Support
Data aggregation and summarisation

Quantitative Imaging Tools
Segmentation, visualisation and quantification

Computer-aided Detection
Automated detection of image features

Workflow and Reporting
Automated tools to boost productivity

To help simplify this rapidly changing landscape, we can classify the emergence of AI-based software for image analysis into five key categories. These are identified in this diagram with data relating to market adoption so far shown in Chart 2 on the following page.

Chart 2 AI-based breast image analysis - Product category - world   Revenue forecast ($m)

Legend:
- Computer-aided detection (CADe)
- Quantitative imaging tools
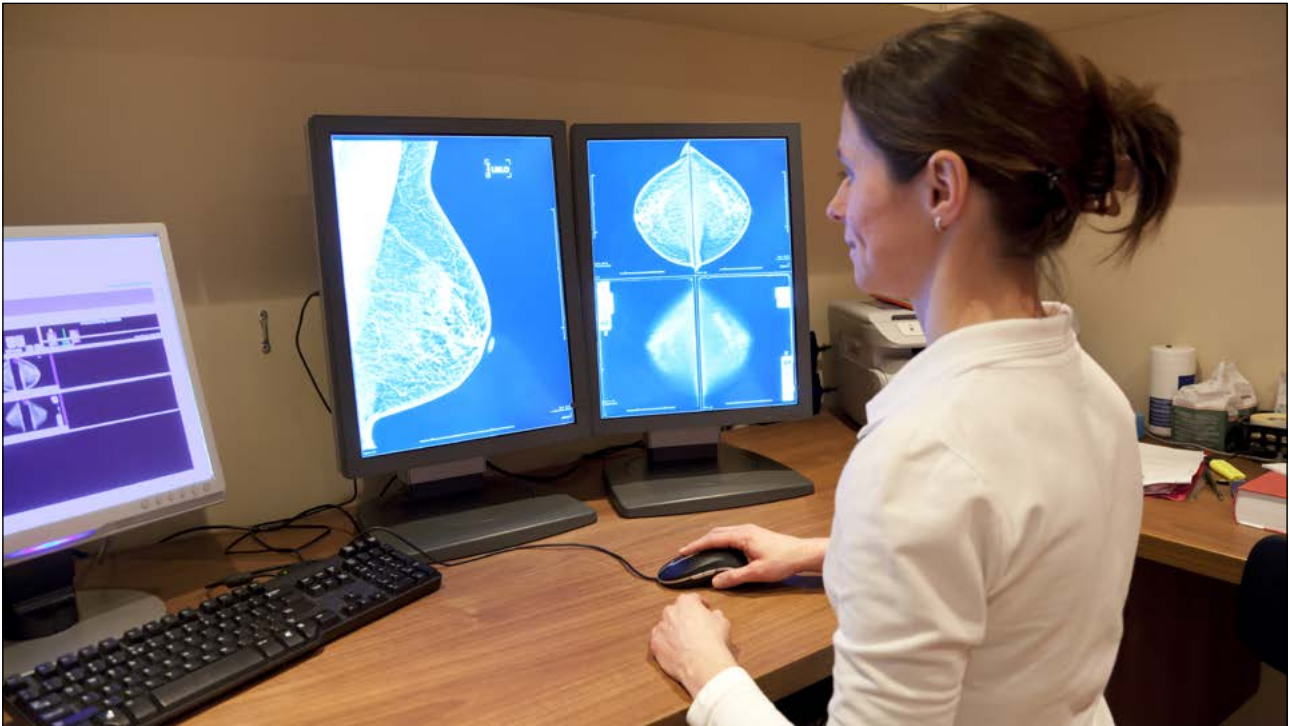- Design support tools
- Computer-aided diagnosis (CADx)
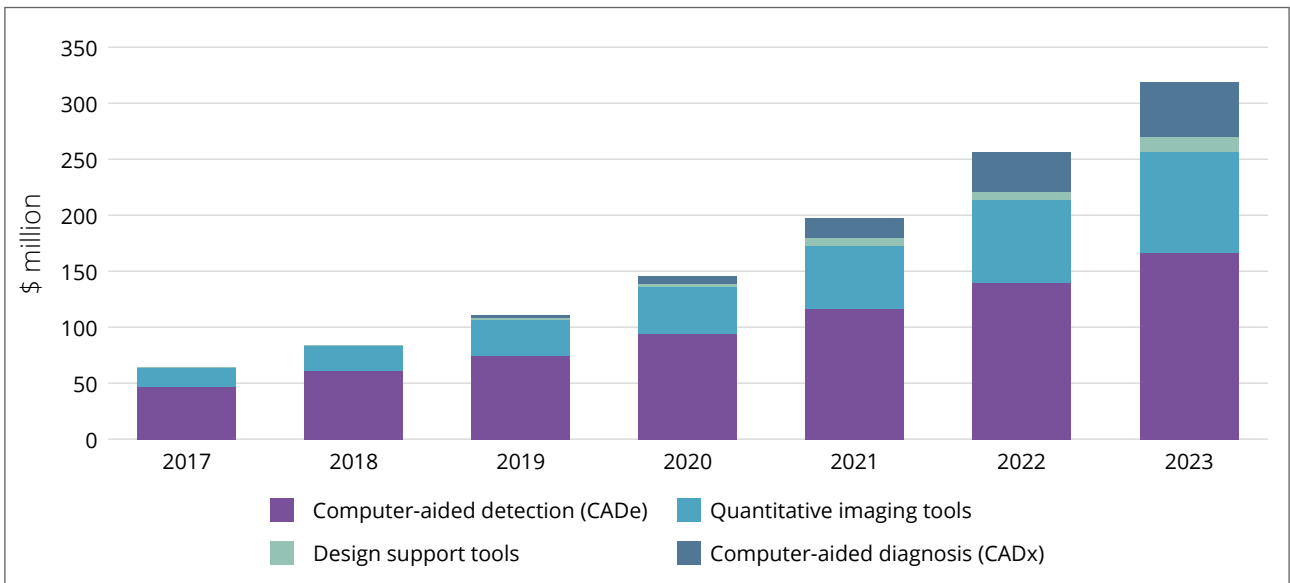
As the data on this page shows, there is already an established market for AI-based breast image analysis software, predominantly in the US. In fact, most breast imaging centres in the US already use some form of breast cancer detection software. However, the market has largely failed to take-off outside of the US, mainly due to the limitations of early generation AI-based products. That is poised to change following the introduction of solutions with improved detection accuracy. Use of new artificial intelligence techniques has sparked renewed investment and research into breast software, both in the US and internationally.

Healthcare providers who had previously dismissed Computed Aided Detection (CAD) are now taking a second look; in our recent analysis, we forecast traditional CADe spending will more than triple worldwide by 2023. Moreover, the trend from full-field digital mammography (FFDM) to digital breast tomosynthesis (DBT) is driving new investment in

* Some non-AI quantitative imaging tools, e.g. perfusion analysis, have transitioned to mainstream

** Breast CADe has transitioned to mainstream in the US, but not in other regions
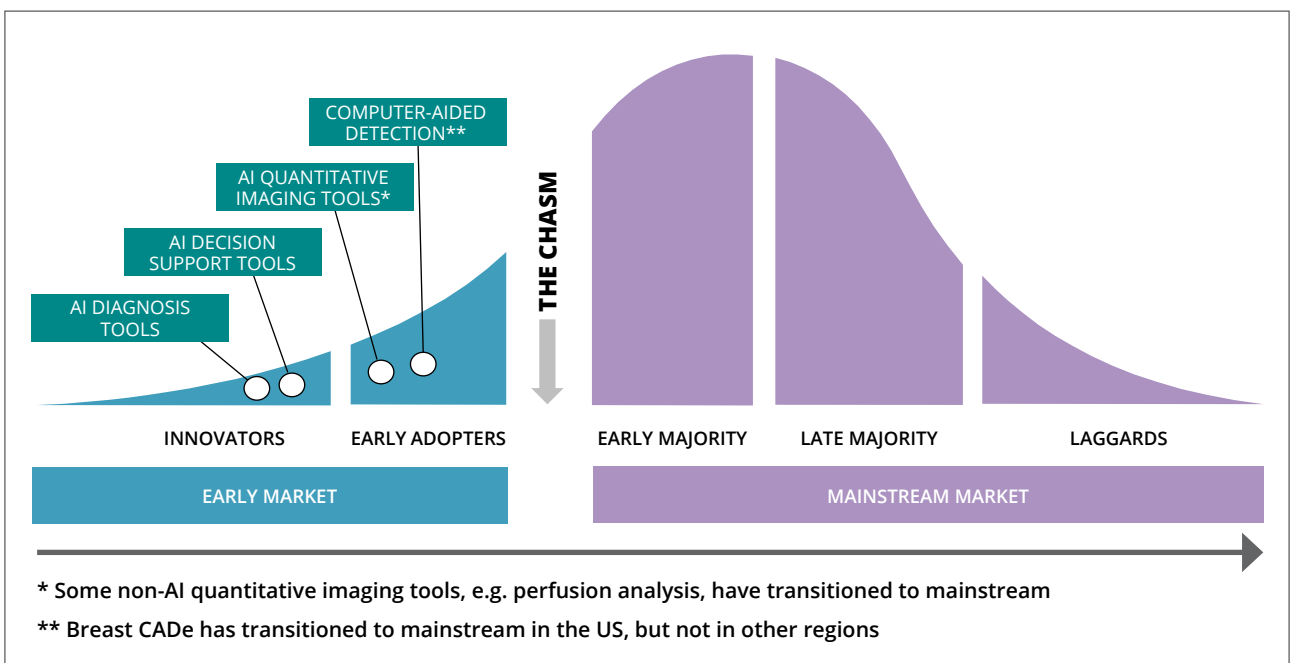
breast cancer detection software. Breast cancer detection software is mostly used as a second-read tool today. However, as the detection accuracy of the latest generation of deep learning products continues to improve, alongside the introduction of advanced functionalities such as predictive scoring for the likelihood of malignancy, the argument for using detection software for the primary read is getting stronger.

Soon we will also see a greater role for software in the diagnostic process, namely decision support and automated diagnosis tools. These tools will provide the radiologist with additional information to aid in diagnostic decision making, such as a predictive score for the likelihood of malignancy at suspicious locations, based on calcification and soft tissue findings. Products with this capability are already entering the market and as shown in Figure 1 are predicted to see significant uptake in the coming years, though it will be some time before they are in widespread use.

For healthcare providers, the rapid expansion in the number of breast detection software tools, many of which are from new start-up ventures, can be daunting. These tools also create challenges for integration, with many existing imaging IT platforms or traditional PACS systems unable to seamlessly embed this growing selection of tools

within their platforms. At the same time, with the expanded range of imaging hardware available, the task of integrating software solutions for different modalities from different vendors into an integrated platform has become far harder.

Broader health IT trends influencing health providers

Healthcare providers are also experiencing broad changes, both in terms of their organisations and the models of care being provided. Consolidation into larger networks has been the prevalent trend in many countries in recent years; amalgamation of breast imaging services across these networks has created interoperability and content exchange issues. This is worsened if proprietary hardware or software is being used at some breast imaging sites. Care models are also changing, driven by a changing reimbursement model focused on care outcomes and multidisciplinary care. This re-organisation and reform of healthcare systems further complicates adoption of more personalised and adaptive breast imaging services. Above all, it also places a high priority on breast imaging informatics solutions that are scalable, accessible and allow native integration and interfacing with a broad range of systems, hardware, software and tools.

The challenges presented by breast imaging

Integrating new technology and supporting multidisciplinary care teams use of diverse diagnostic information in breast diagnosis and detection is often overlooked by healthcare providers when planning for new informatics implementations. Some of the most common challenges from an interoperability, operational and access perspective have been outlined in the column on the right fo this page.

Considerations for breast imaging IT strategy

So how should healthcare providers address these challenges?

The process of planning and implementing an IT strategy to support breast imaging services is dependent on a multitude of factors. The type of healthcare provider and variety of diagnostic stakeholders that require access are big influences. Existing imaging IT, hardware and other enterprise software such as Electronic Medical Records (EMR), are also big factors. Therefore, every implementation is slightly different and unique to the needs of each provider.

When deciding on potential strategies for IT platform implementation, there are two common approaches; a customised combination of standalone IT software and tools, or selection of a more centralised, single IT platform from a single vendor. Both approaches have benefits and trade-offs for each health organisation. However, given the broader context of consolidated healthcare systems and growing demand for multi-disciplinary care in breast detection and diagnosis, we see growing evidence favouring centralised imaging IT platforms with an enterprise imaging strategy.

Benefits of enterprise imaging for breast imaging IT

Adoption of an enterprise imaging strategy to support management of medical imaging and associated clinical content has rapidly

INTEROPERABILITY

- A wider variety of modalities used for breast imaging increases likelihood of multi-vendor soft-ware and imaging equipment at a single provider

- Greater diversity of images, views and tools required, especially new AI-based software

- Proprietary viewing software and dedicated workstations can lead to "lock-in" of essential data

- Challenging integration with other imaging IT diagnostic and operational software

- Growing need for integration with local, regional and national patient record systems to access broader patient history within the diagnostic reading viewer.

OPERATIONAL

- Longer reading times for DBT and ultrasound scans compared to conventional mammography

- More complex and diverse reporting requirements

- Need for collaborative tools to support multidisciplinary care team care pathways

- Declining availability of reporting resources

- Increased bandwidth and performance capabilities required to handle DBT images.

ACCESS

- Need for users to switch between different workstations (physical or virtual) or open external applications

- Wider access requirements across a broader clinical stakeholder team

- Growing use of outpatient breast imaging services and co-ordination between outpatient and acute care settings

- Enterprise Imaging solutions to offer a single platform to manage all imaging.

progressed in recent years. Many healthcare providers have already taken initials steps towards this harmonised platform-based approach, especially in core radiology services. This initial centralised imaging and workflow platform in radiology also offers a unique opportunity for extension to cover breast detection and diagnosis. Consolidation into a single platform has numerous benefits for many stakeholders in the breast imaging diagnostic pathway. We see the most prominent outlined in the table below:

While there are some nuanced benefits for using a customised selection of best of breed breast imaging IT for some specialist and advanced users (such as academic research tools), the complex and customised integration required often incurs significant cost in terms of funding and time. Moreover, with the progression of adaptive imaging pathways, clinical co-ordination

and centralisation of healthcare IT, integration of a multi-vendor, standalone best-of-breed strategy can be complex and costly.

In comparison, a centralised enterprise imaging approach should require far less customised integration. It also offers a critical benefit: freedom for the user in terms of access to a wide variety of detection and diagnostic tools. Given that breast imaging is evolving, users increasingly want flexibility to use a broader range of tools and imaging hardware, something difficult to implement with a best-of-breed strategy. Moreover, an enterprise imaging strategy allows far better integration with the clinical patient records from across the health network. This allows physicians to not only improve the quality of their diagnoses, but also track the longitudinal progress of their patients, collaborating with multi-disciplinary colleagues and making interventions where necessary.

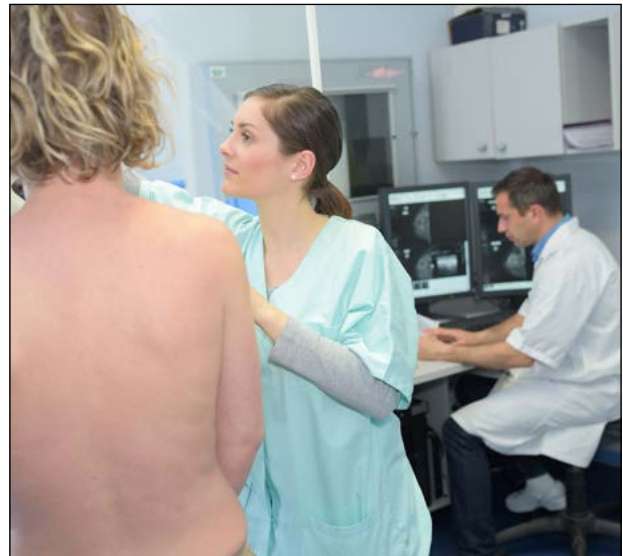| For the user/physician:	For administrators and IT managers:
Access and viewing of all breast imaging studies, priors and report history	Improved workflow and efficiency across network of breast imaging sites and central management of all breast imaging services on single platform
Multitude of dedicated breast imaging tools, including protocols and viewing specialism for all breast imaging studies (e.g. DBT slabbing and scrolling, graphical annotation	Native ingestion of data from all types of imaging modalities in a standard-based, vendor-neutral manner: 2D FFDM, DBT (normal, compound and High definition), ABUS, Conventional ultrasound and MRI
Remote access for off-site reading (especially important for clinic and mobile mammography operations)	Integration support and ongoing updates of integration with a range of common software tools for CADe, BI-RADS, breast density analysis
Clinical collaboration tools supporting cross-discipline communication between health provider sites and clinical teams	Central platform provides basis for analytics and intelligence on breast imaging operations, offering opportunity for optimisation and maximising ROI
Single workstation and viewer for all breast imaging applications, including CAD, BI-RADS scoring applications and breast density analysis	Support for curation and integration of emerging AI-based tools with core platform, especially for growing range quantitative measurement and decision support
Native embedded workflow, task list and seamless links to providers dictation and reporting solution	Improved security and reduced risk for "back-door" cyber-attack with managed schedule of up-dates for single platform versus multiple standalone systems and legacy software applications
Integration with broader clinical records and electronic health record.	Improved interoperability image exchange for sharing patient imaging data between core stake-holders in the care network.

Summary and conclusion

Choosing the right solution and vendor partner to support an enterprise imaging strategy is a critical decision. It can also have widespread impact on a range of diagnostic services. In terms of breast imaging detection and diagnosis, the platform selected should ultimately enable users the freedom to use a wide variety of different imaging hardware, detection software and decision support tools. When assessing the capability of vendors to support adaptive breast imaging, we believe the following factors are most important:

- Track record of multi-site breast imaging EI implementations

- Mature breast imaging tools including recent technology developments (HD DBT etc.)

- Centralised platform-based approach for core operational and viewing

- Modular approach to additional value -add services (analytics, BI)

- Flexibility in terms of architecture (on-premise, hybrid or cloud offerings)

- Can act as long-term partner in terms of service, support, training and security

- Clear development roadmap for ongoing integration of new technology, especially AI-based diagnostic tools.

Breast cancer diagnosis continues to evolve. An abundance of new technology and clinical research is emerging that is re-shaping diagnostic practices to establish new standard of breast care. However, healthcare providers are having to navigate this transition in context of consolidating health systems, changing reimbursement and declining physician resources. Moreover, many health providers still view mammography as a silo from the rest of medical imaging.

A robust enterprise imaging platform can integrate mammography and other breast technologies into the full imaging service line, enabling a complete medical imaging record for patients and physicians from many different clinical groups. Some providers have already embarked on the journey of shaping their enterprise imaging strategy, but few have included breast imaging so far. Unifying and consolidating imaging data and content into a single enterprise imaging solution can provide a robust foundation for breast cancer diagnosis. Moreover, by utilising the initial investment made in the enterprise imaging platform for breast imaging services, healthcare providers can also save significant money in terms of hardware, software and services compared to stand-alone solutions and the many challenges of integration.

Healthcare providers assessing enterprise imaging should thoroughly scrutinise vendor offerings to ensure that the selected platform can empower users with the freedom to use a wide variety of different breast-specific hardware, software and AI-based tools. While no vendor today can offer full seamless integration for every diagnostic tool available "out of the box", healthcare organisations should look for vendor solutions that can offer native integration for commonly used breast diagnostic tools, seamless interfacing and curation of broader patient information from the patient record, and a broad service and support offering.

At Signify Research we are passionately curious about Healthcare Technology and we strive to deliver the most robust market data and insights, to help our customers make the right strategic decisions. We blend primary data collected from in-depth interviews with technology vendors and healthcare professionals, to provide a balanced and complete view of the market trends.

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