For Healthcare professionals and other decision-makers

How to choose AI: A multistakeholder perspective on the curation process

24th May 2023

Intelligent Health UK

PP-CALA-GB-0203 May 2023

Calantic™ Digital Solutions

Disclosures

- This talk is sponsored by Bayer AG.
- Calantic™ Digital Solutions by Bayer is an AI Platform technology offering for Radiology. Availability varies between countries and regions. Please contact your local Bayer representative for further information.
- Further information on our product website at www.calantic.com
- **Adverse events should be reported.** Reporting forms and information can be found at https://mhra.gov.uk/yellowcard or search for MHRA Yellow Card in Google Play or Apple App Store. Adverse events should also be reported to Bayer plc. Tel.: 0118 206 3500, Fax.: 0118 206 3703, Email: pvuk@bayer.com

Housekeeping

Interactive session, so please ask questions during the session – there will be plenty of opportunities

We will ensure we keep to time throughout the meeting

We will be using internet-based voting technology at the start of the meeting – please have your phones at the ready

We will be completing workmats later in the session

Agenda

Time	Agenda	Lead
11.40	Objectives and introduction to the workshop	Juan Gutierrez Alliende
11.45	Interactive session: Audience insights into challenges and unmet needs in introducing AI applications	All/Bayer
12.00	Interactive session: Breast cancer screening workflow – addressing unmet needs using a curated application offering	All/Bayer
12.35	Final summary and close	Juan Gutierrez Alliende

Workshop presenters

Name	Function
Bayer workshop lead/moderator	
Juan Gutiérrez Alliende	Medical Advisor Lead
Bayer facilitators	
Joana Reis	Global Medical Affairs
Imran Siddiqui	Medical Advisor

Meeting objectives

- Gather participant feedback regarding the unmet need and challenges that must be considered for successful curation.
- Demonstrate the importance and benefits of a robust, consistent, and scalable curated approach to applications for future AI adoption.
- Show how a curated Radiology AI platform offering could allow the selection of a fully validated application as part of a diagnostic workflow.

Ever increasing pressure on healthcare is threatening the sustainability of radiology departments and patient care in **Europe**

GREATER COMPLEXITY

5x

Increase

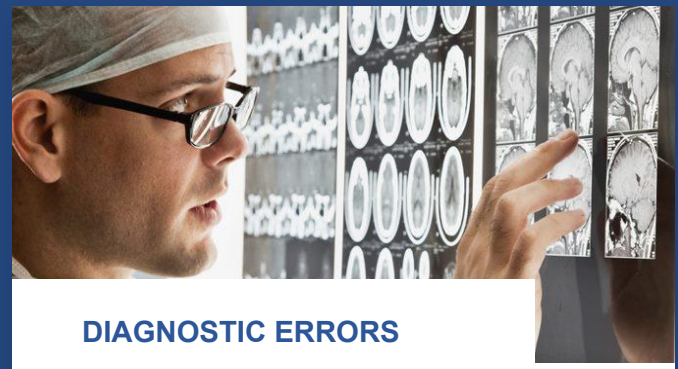
In the number of images produced per scan.[1]

RADIOLOGY DEPARTMENTS PUSHED TO THEIR LIMITS

46%

Radiologists

reporting signs of burn-out.[2]



DIAGNOSTIC ERRORS

~40m

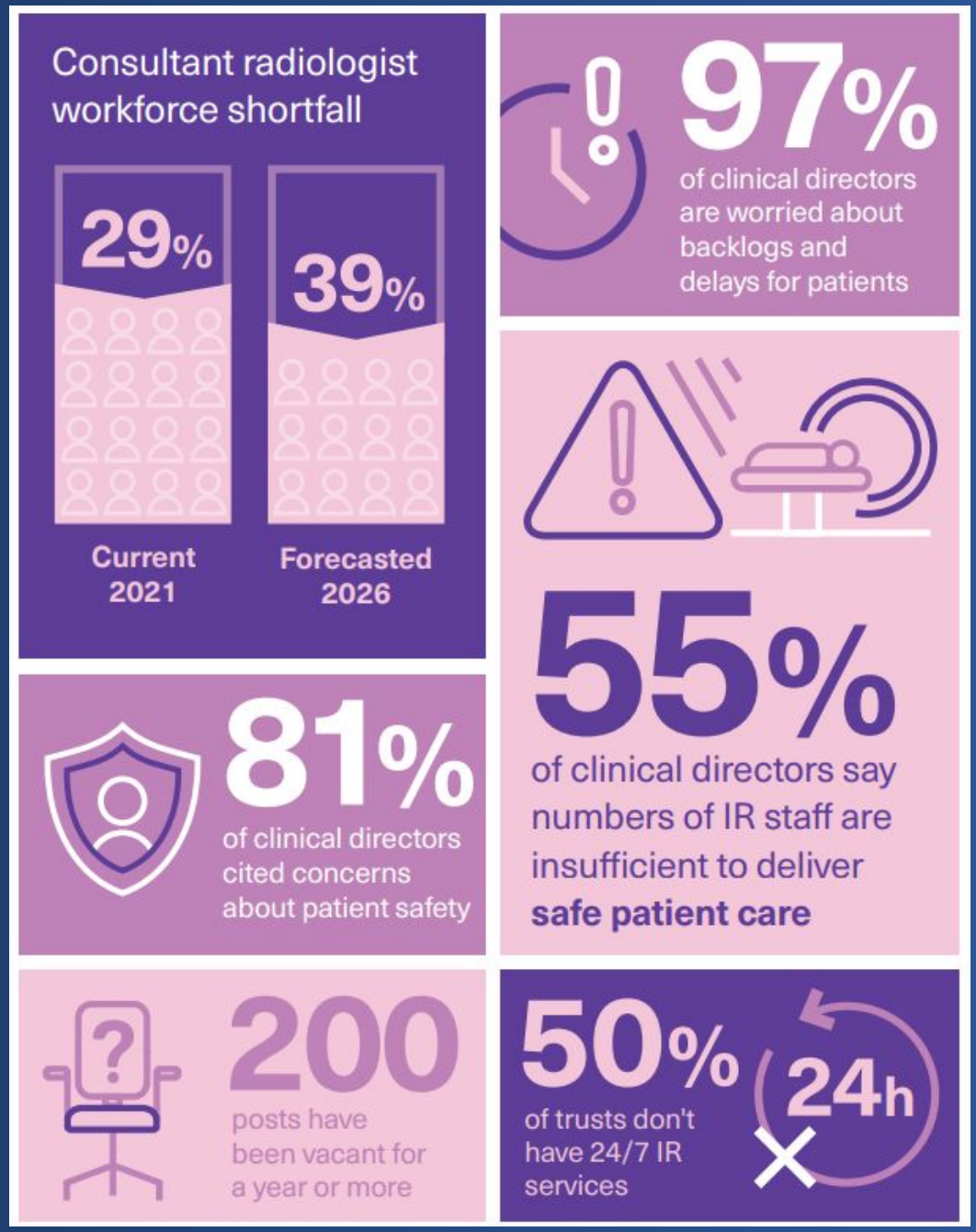
Diagnostic Errors

per year worldwide.[3]

1) McDonald RJ, Schwartz KM, Eckel LJ et al (2015) “The Effects of Changes in utilisation and Technological Advancements of Cross-Sectional Imaging on Radiologist Workload”, Academic Radiology, Volume 22, Issue 9, Pages 1191-1198.
2) Medscape Radiologist Lifestyle, Happiness & Burnout Report (2020). URL https://www.medscape.com/slideshow/2020-lifestyle-radiologist-6012479 [Accessed 03/02/2023].
3) Itri JN, Tappouri RR, McEachern RO et al (2018) “Fundamentals of Diagnostic Error in Imaging” , Radiographic, Volume 38, Issue 6, 1845-1865.

The UK is facing a radiology capacity challenge

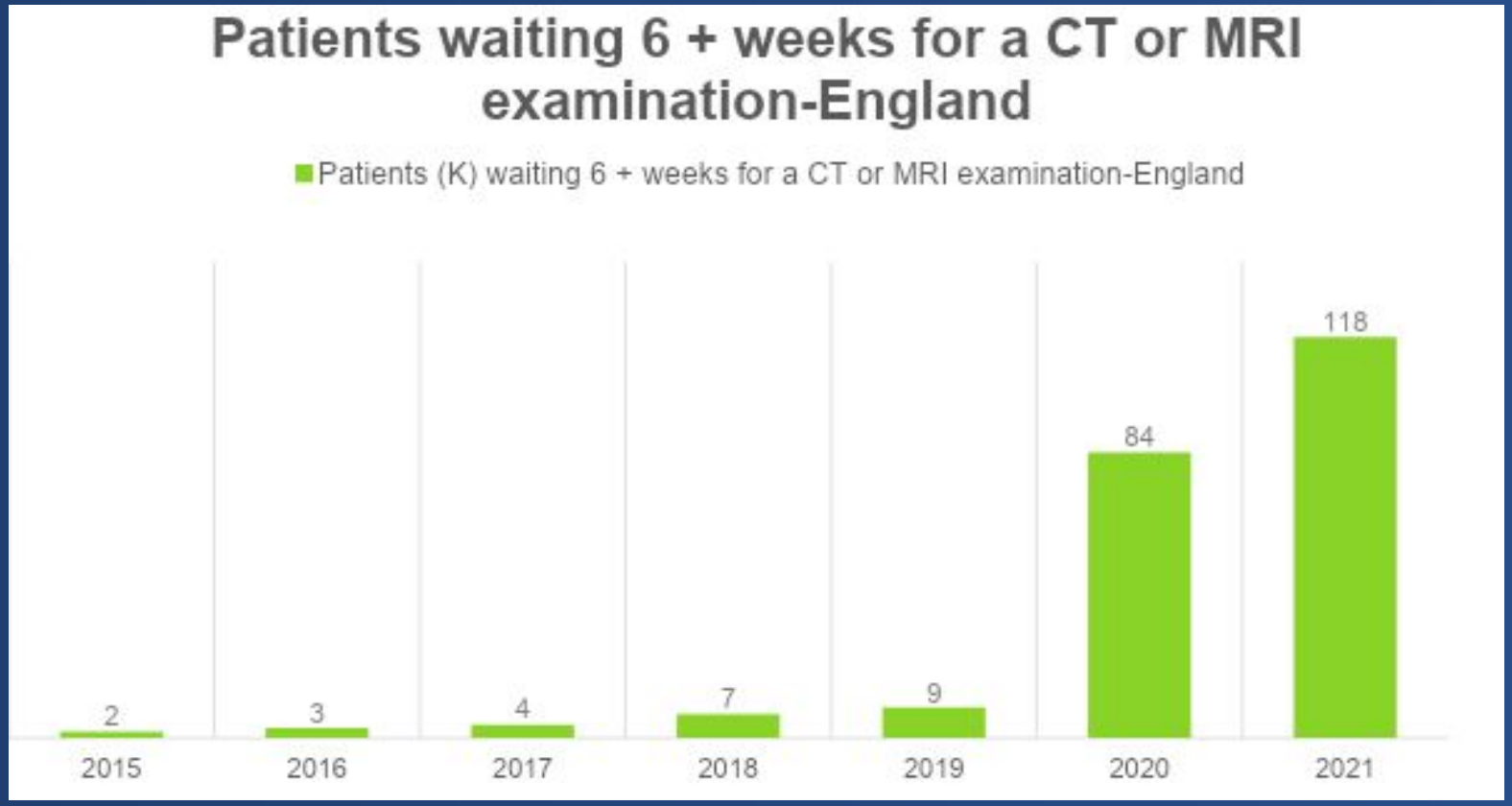
- Demographic transformation is increasing the pressure on healthcare systems.
- Stagnating number of trained radiologists available:
  - The Royal College of Radiologists projected a shortfall of 39% by 2026.[1]



1) 2021 Clinical radiology census report (2021), https://www.rcr.ac.uk/sites/default/files/clinical_radiology_census_report_2021.pdf [Accessed 02/05/2023].

Royal College of Radiologists

UK Workforce Census **2021 report**



representing just over

25%

of all those awaiting imaging[2]

* Graph based on the information obtained in references.[1,2]

1. https://www.rcr.ac.uk/system/files/publication/field_publication_files/clinical-radiology-uk-workforce-census-2020-report.pdf [Accessed 02/05/2023].
2. https://www.rcr.ac.uk/sites/default/files/clinical_radiology_census_report_2021.pdf [Accessed 02/05/2023].

Interactive session: Audience insights into challenges and unmet needs in selecting AI applications

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Mentimeter access

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Question 1: Please confirm your speciality

Please select 1 answer

1. Radiologist
2. Clinician
3. Scientist
4. Hospital head/executive
5. Industry
6. Payor
7. Other

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Question 2: How many AI applications do you currently use in your centre?

Please select 1 answer

1. 0
2. 1–5
3. 5–10
4. >10
5. Not applicable

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Exponential rise in available AI technologies

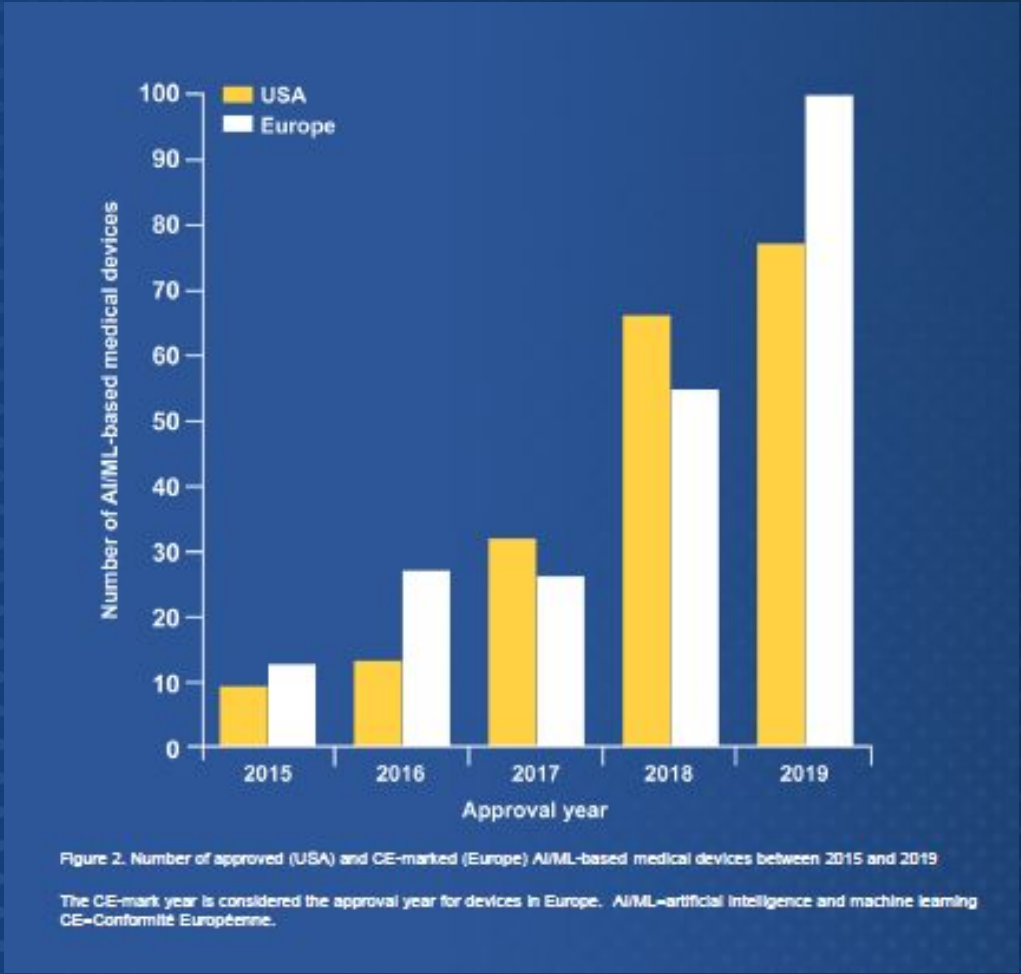
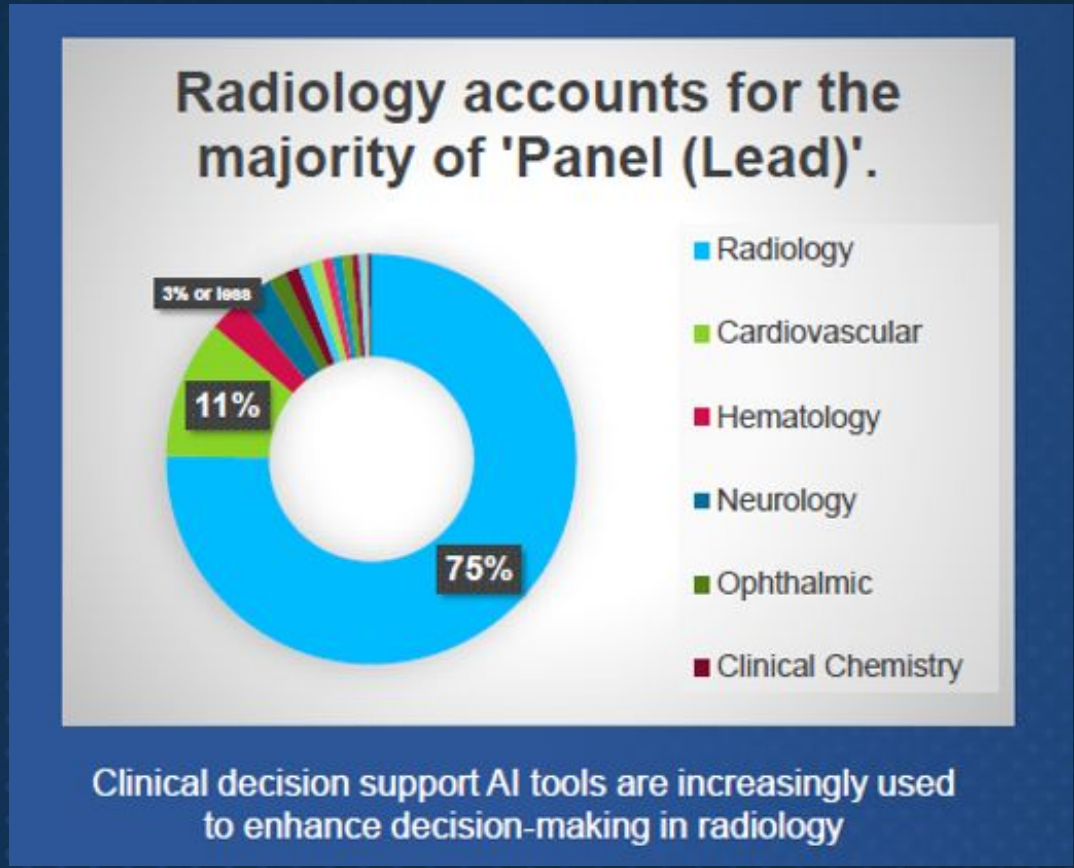


Figure 2. Number of approved (USA) and CE-marked (Europe) AI/ML-based medical devices between 2015 and 2019

The CE-mark year is considered the approval year for devices in Europe. AI/ML=artificial intelligence and machine learning CE=Conformité Européenne.



Available online: https://www.globenewswire.com/news-release/2020/ 02/26/1990679/0/en/Artificial-Intelligence-in-Medical-Imaging-Market-Report-2019-CAGR-of-36-89-By-Offering-Technology-Deployment-Type-Application-Leading-Players-BenevolentAI-OrCam-Babylon- Freenome-I.html [Accessed 26/04/2023].
Data puvblished Oct5, 2022- FDA Center for Digital Health, https://fda.gov/medical-devices/software-medical-device-samb/artificial-intelligence-and-machine-learning-aiml-enable-medical-devices?utm_source=FDALinkedin#resources.

Question 3: Does your centre currently use a deployment platform of AI applications?

Please select 1 answer

1. Yes
2. No
3. Not applicable

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Question 4: Which of the following features would you consider when choosing an AI application to incorporate into the patient workflow?

Please select all that apply

1. Indications
2. Validation & performance
3. Available evidence
4. Reimbursement status
5. Workflow integration
6. Ease of use & user interface
7. Cost

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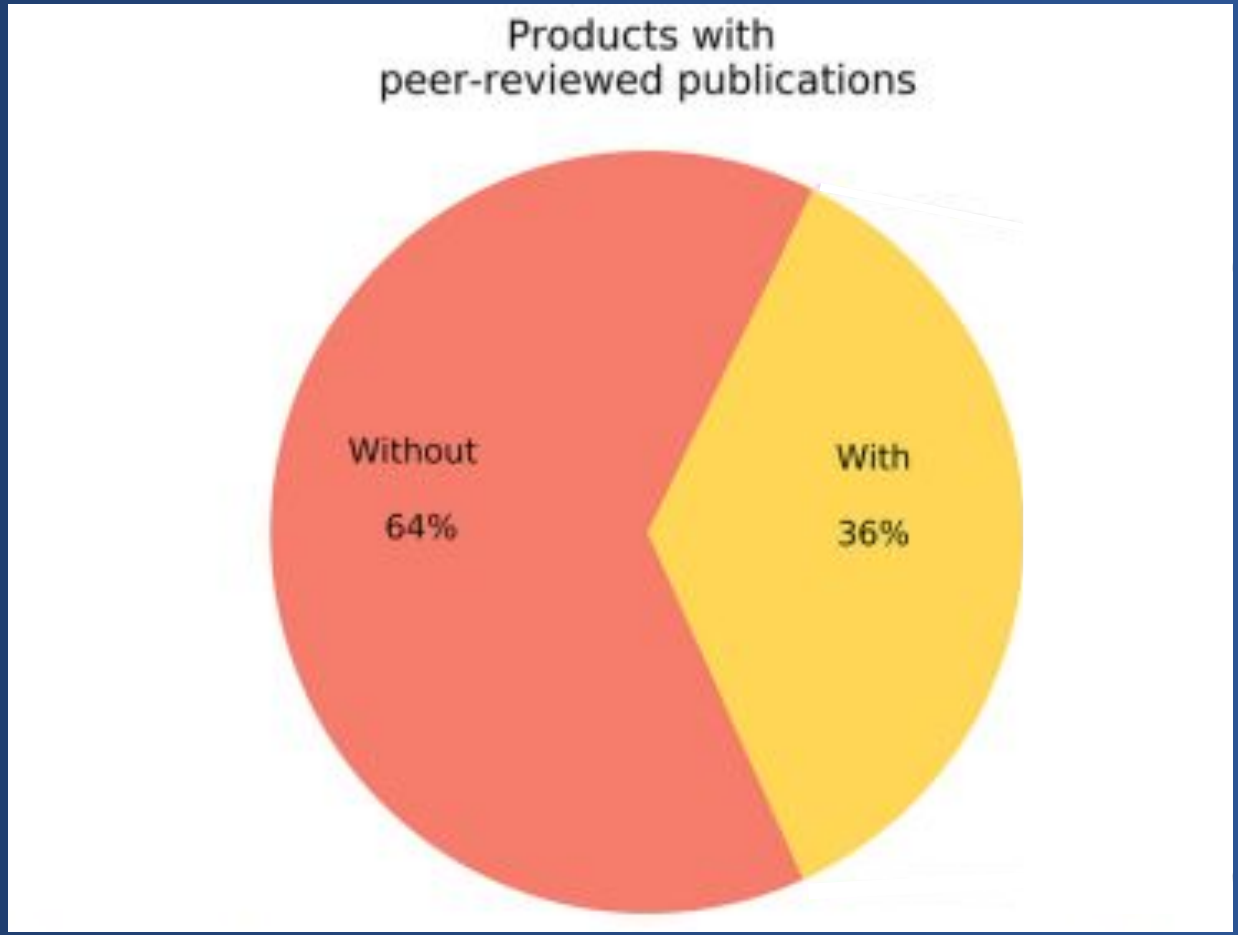
Clinical evidence

High-quality evidence used to determine AI performance contributes to **confidence in** and **implementation**.[1.]

Robust evidence of improved human decision-making when using AI systems is still lacking [2].

A review of 100 CE-marked AI products from 54 different vendors [3].

- 64% no peer-reviewed evidence of its efficacy.
- 18% had evidence level 3 or higher



1. Understanding healthcare workers' confidence in AI https://digital-transformation.hee.nhs.uk/binaries/content/assets/digital-transformation/dart-ed/understandingconfidenceinai-may22.pdf [Accessed 03/05/2023]
2. Vasey B, Novak A, Ather S, Ibrahim M, McCulloch P. DECIDE-AI: a new reporting guideline and its relevance to artificial intelligence studies in radiology. Clin Radiol. 2023 Feb;78(2):130-136. doi: 10.1016/j.crad.2022.09.131. PMID: 36639172.
3. Van Leeuwen KG, Schalekamp S, Rutten MJCM, van Ginneken B, de Rooij M. Artificial intelligence in radiology: 100 commercially available products and their scientific evidence. Eur Radiol. 2021 Jun;31(6):3797-3804. doi: 10.1007/s00330-021-07892-z. Epub 2021 Apr 15. PMID: 33856519; PMCID: PMC8128724.

Question 5: When new applications have been introduced into an institution, what have been the main challenges?

Please select all that apply

1. IT integration/implementation
2. Workflow integration
3. Performance validation
4. Post-deployment analysis & monitoring

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Question 6: Based on your own understanding (or best guess), how long do you think it would take for a centre to integrate a new AI application for use internally?

Please select 1 answer

1. Less than 1 month
2. 1–3 months
3. 6–12 months
4. More than 12 months

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Why Curation?

From Customer perspective

AI becomes more relevant for me, however, I do not completely trust in the apps performance and specific features, and we do not have the time & expertise to investigate all the options.

From Bayer perspective

Building on 150 years as established pharma company together with extensive expertise in radiology, Bayer Radiology is perfectly placed to differentiate based on robust curation.

Question 7: Does your place of work regularly review newly approved applications to ensure you have the most appropriate ones available for use?

Please select 1 answer

1. Yes
2. No
3. Don’t know
4. Not applicable

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Question 8: What do you think are the main challenges to the widespread adoption of AI?

Please select all that apply

1. Cost/unknown or insufficient ROI
2. Performance concerns/metrics (lack of sufficient clinical evidence)
3. Complexity of or uncertainty about workflow integration
4. Technology is too new/not standard practice
5. No perceived need

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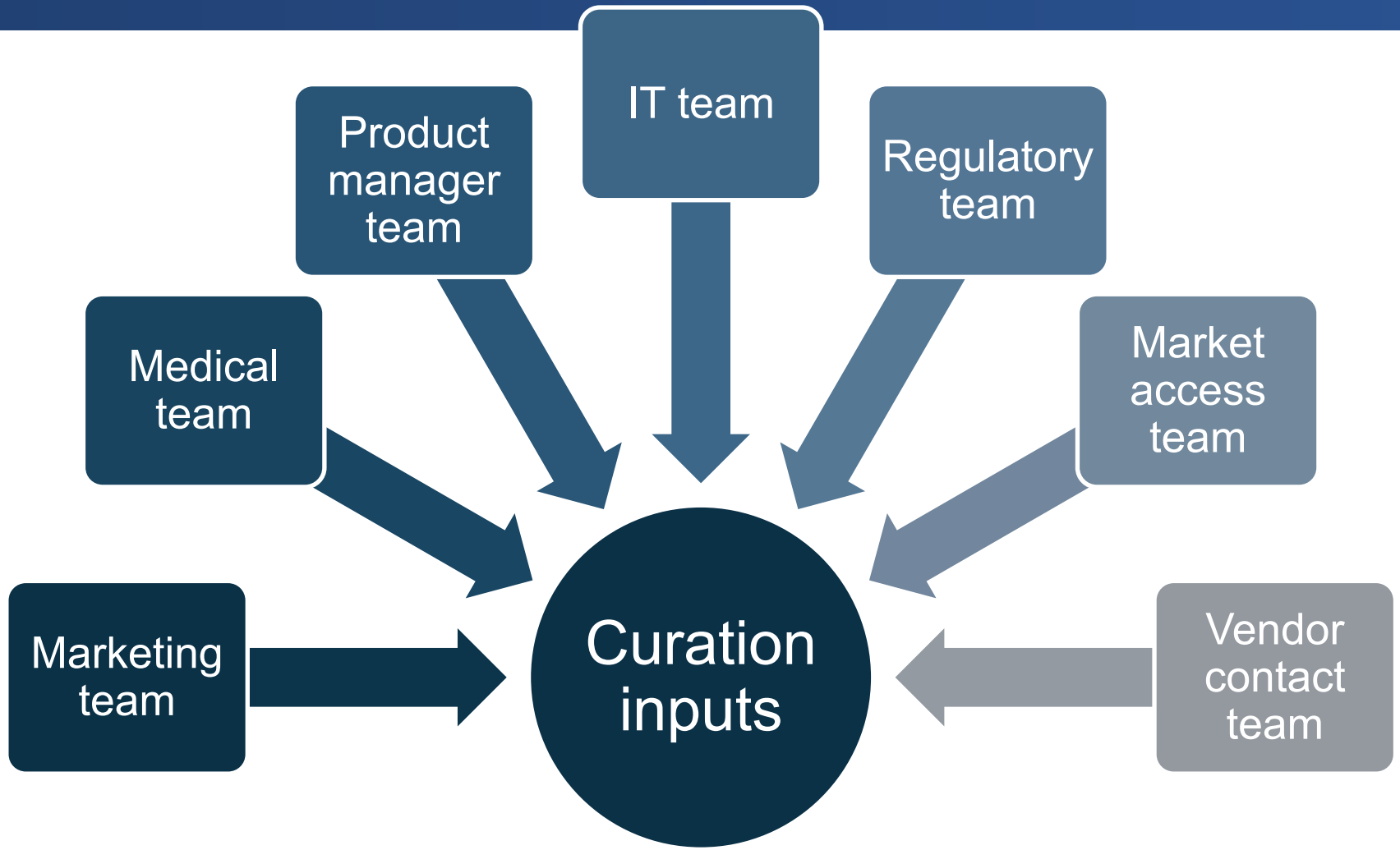
How do we do curation?

Multiple teams' involvement…



How do we do curation?

What does the process look like…

Prioritise Pathology
(Organ/indication if multi organ service line)

- Review incidence
- Review prevalence
- Clinical outcomes

Map Patient Imaging Workflow

- Identify pain points
- Identify potential leverage points
- Bayer internal diseases experts as input source

Prioritise Customer Pain Points

- Understand regional requirements & clinical differences

Identify & Evaluate Potential Solutions (apps)

- Initial clinical utility (including evidence)
- Geographic fit (value and regulatory clearance)
- Effort (regulations & technology)
- Workflow fit

In-depth analysis (some apps)

- Competitive analysis
- In-deep clinical utility assessment
- Workflow integration assessment
- Package readout

Interactive Session: Breast cancer screening workflow – addressing unmet needs using a curated application offering

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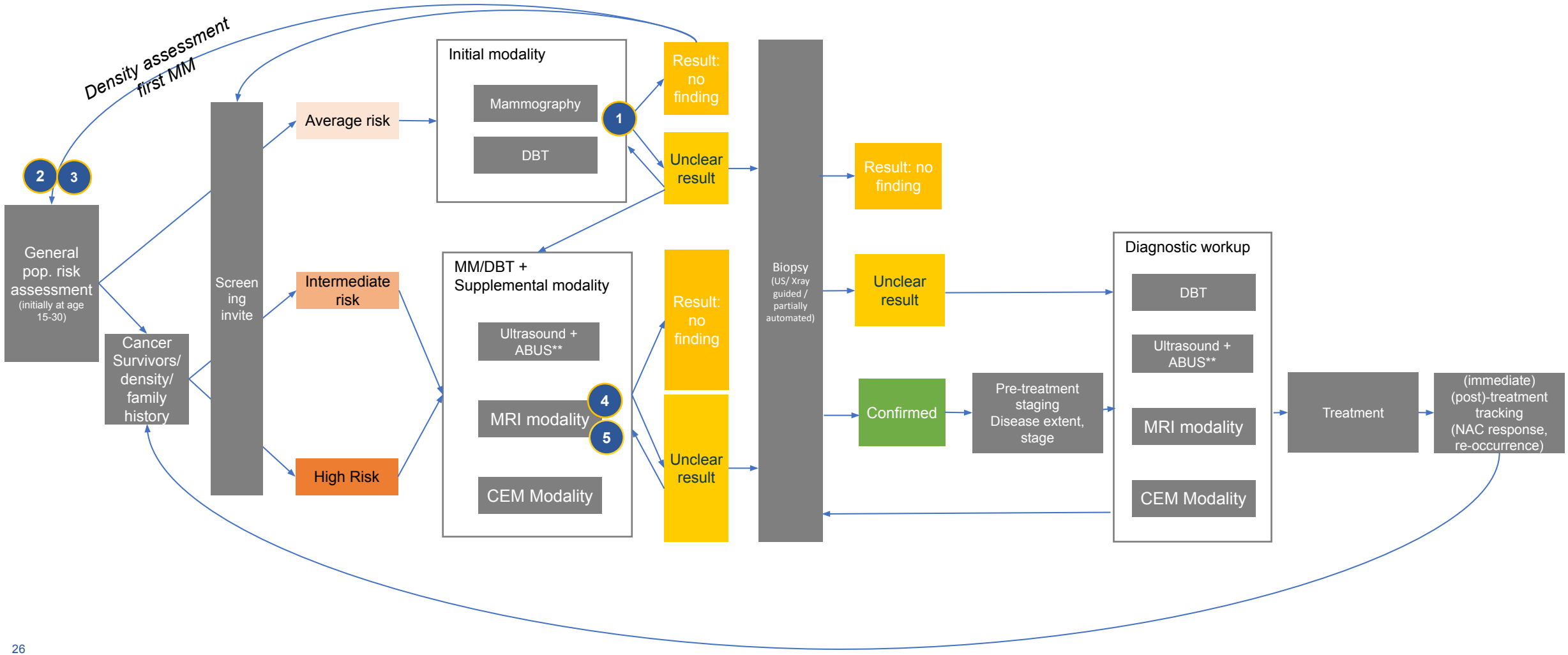
We identified pain points in the breast imaging workflow



We further articulated these pain points and adapted (the value proposition) for the various regional inputs

01

Screening

Some countries require double reading (EU) which has huge workload implications. Also chance for diagnostic errors, high recall rates in MM & DBT.

02

SCR + Risk Assessment

Identifying and managing high-risk patients is challenging for suites as the risk factors are complex and it is burdensome to build quantitative analysis.

03

Density Assessment

Subjectivity of density assessment, new laws for mandatory reporting (US), not following clinical guidelines due to lack of knowledge and lack of mandatory reporting (EU).

04

MRI Reading

High false positive rates & workload, reading MRI is time consuming.

05

MRI Scanning

Scan time takes too long/ capacity issues hindering uptake & reimbursement, movement artifacts.

Interactive Session

Instructions

- Divide into groups.
- Review several potential applications for incorporation into your workplace.
  - Identify one to select for inclusion.
  - Discuss the challenges which may be faced integrating the chosen application into your workplace.
  - Provide any thoughts or feedback either directly on the workmat or on the post-it notes provided.

Session to be completed at **12:35** (time reminder will be provided).

Lesion assessment

Application 1	
Description	The product could be used to improve radiologist interpretation of 2D and 3D mammography as a concurrent reading tool for the detection and characterisation of abnormalities.
Imaging modality	2D and 3D.
Target patient population	Asymptomatic women.
Intended use	Recognise suspicious calcifications and soft tissue lesions (including densities, masses, architectural distortions, and asymmetries).
Intended change in treatment	The algorithm is intended to identify high-risk breast lesions quickly, enabling earlier detection, earlier treatment to improve screening outcomes.
Care setting	Screening.
Regulatory	UKCA and CE mark.
Evidence	Four retrospective peer-review-articles, one clinical trial.
Other information	Vendor-neutral, on-prem, on-cloud installation.

Application 2	
Description	Utilising this product as a simultaneous reading tool for detecting abnormalities, could potentially enhance radiologists' interpretation of 2D and 3D mammography.
Imaging modality	2D and 3D.
Target patient population	Symptomatic and asymptomatic women.
Intended use	Recognise suspicious soft tissue lesions (including densities, masses, architectural distortions, and asymmetries).
Intended change in treatment	The algorithm aims to rapidly detect high-risk breast lesions, facilitating timely identification, treatment, and ultimately improving the chances of survival.
Care setting	Screening and diagnosis.
Regulatory	UKCA and CE mark.
Evidence	Two retrospective studies and two clinical trial for asymptomatic patients, and one retrospective study for Symptomatic patients.
Other information	Implementation on OEM A and B, on-prem, on-cloud.

Application 3	
Description	The product could be used for malignancy detection, calcification detection, certainty scoring, case scoring. Built on deep-learning and artificial intelligence technology the product aid radiologists in addressing the challenges of reading tomosynthesis.
Imaging modality	3D.
Target patient population	Asymptomatic women.
Intended use	Identifying both harmful soft tissue densities and calcifications indicative of malignancy.
Intended change in treatment	High-risk breast lesions identification, for earlier detection, and treatment.
Care setting	Screening.
Regulatory approval	FDA, UKCA and CE mark.
Evidence	Three retrospective peer-review articles, one clinical trial.
Other information	Vendor-neutral, on-cloud installation.

Lesion assessment

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Lesion assessment

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Lesion assessment

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Regulatory approval	FDA, UKCA and CE mark.
Evidence	Three retrospective peer-review articles, one clinical trial.
Other information	Vendor-neutral, on-cloud installation.

Breast screening app curation | Part I – Lesion assessment

You have been asked to review 3 lesion assessment applications for potential incorporation into your workplace

Which one of the applications would you integrate into your workplace and why?	In your opinion, what further information do you need to curate an application?	What challenges do you foresee in implementing the chosen application?

Density assessment

Application 1	
Description	The product AI-based algorithm calculates volumetric breast density, fibroglandular tissue volume, and breast volume, and assigns a density grade used by the radiologist to assess breast density.
Imaging modality	Digital mammography and digital breast tomosynthesis.
Target patient population	Screening population (asymptomatic women) and outpatient care.
Intended use	Automatic assessment of the volumetric breast density helping to differentiate women in a continuous scale of breast density in a score correlated to the BI-RADS (5th edition) density categories.
Intended change in treatment	Women triaged for additional breast screening.
Care setting	Outpatient care and/or Screening setting.
Regulatory	UKCA marking, CE mark, FDA approved.
Evidence	10 retrospective studies, 5 clinical trials.
Other information	Vendor-neutral, on-prem installation, on-cloud installation.

Application 2	
Description	AI-based algorithm to provide accurate and consistent density estimates from standard digital mammograms. It is a breast density assessment solution.
Imaging modality	Digital mammograms.
Target patient population	Screening population (asymptomatic women) and outpatient care.
Intended use	The application automatically analyses “for presentation” 2D digital mammograms to assess breast tissue composition, generating breast density group information for the patient (BI-RADS A+B as fatty and BI-RADS C+D as dense) in accordance with the American College of Radiology’s Breast Imaging Reporting and Data System (BI-RADS) density classification scale
Intended change in treatment	Provide complementary information on breast density.
Care setting	Outpatient care and/or Screening setting.
Regulatory	UKCA marking, CE mark.
Evidence	6 retrospective studies.
Other information	Vendor-neutral, on-prem installation, on-cloud installation.

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Intended change in treatment	Provide complementary information on breast density.
Care setting	Outpatient care and/or Screening setting.
Regulatory	UKCA marking, CE mark.
Evidence	6 retrospective studies.
Other information	Vendor-neutral, on-prem installation, on-cloud installation.

Breast screening app curation | Part II – Density assessment

You have been asked to review two density assessment applications for potential incorporation into your workplace.

Which one of the applications would you integrate into your workplace and why?	In your opinion, what further information do you need to curate an application?	What challenges do you foresee in implementing the chosen application?

Final summary and close

Juan Gutierrez Alliende

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Artificial Intelligence holds the potential to help address some of these challenges, and thereby…

address operational inefficiencies,[1]

optimise patient journeys,[2]

provide the tools to help you focus on patient outcomes.[3]

1) *Ranschaert E, Topff L, Pianykh O, (2021) "Optimization of Radiology Workflow with Artificial Intelligence" Radiologic Clinics of North America, Volume 59, Issue 6, 955-966.*
2) *Blezek DJ, Olson-Williams L, Missert A et al (2021) "AI integration in the Clinical Workflow" Journal of Digital Imaging, Volume 34, Issue 1, 1435-1446.*
3) *Wichmann JL, Willemink MJ, De Cecco CN (2020) "Artificial Intelligence and Machine Learning in Radiology: Current State and Considerations for Routine Clinical Implementation" Investigate Radiology, Volume 55, Issue 9, 619-627.*

Curated AI application benefits

- Curation process is a complex and time-consuming process that requires a significant amount of resources and in which multiple experts with different specialties participate.
- It has the potential to:
  - Improved efficiency
  - Quality assurance
  - Tailored offer
  - Integration and interoperability
  - Regulatory compliance
  - Expert support

Thank you

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