KEYNOTE Real-world implementation: AI in Radiology

JUAN GUTIÉRREZ ALLIENDE

Medical Lead EMEA Digital Solution Business, Radiology

Bayer

Real-world implementation: AI in Radiology

Juan Gutiérrez Alliende, MD

Intelligent Health UK,, 24 May 2023, London, UK

Calantic™ Digital Solutions

PP-CALA-GB-0195 May 2023

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

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

GREATER COMPLEXITY

5x

Increase

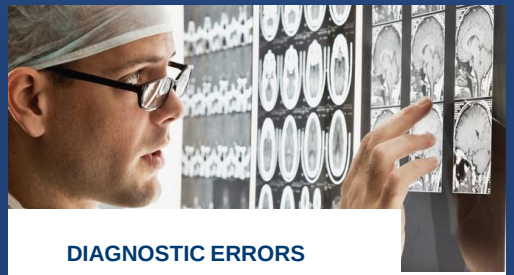
In the number of images produced per scan[1]

RADIOLOGY DEPARTMENTS PUSHED TO THEIR LIMITS

46%

Radiologists

reporting signs of burn-out [2]



DIAGNOSTIC ERRORS

~40m

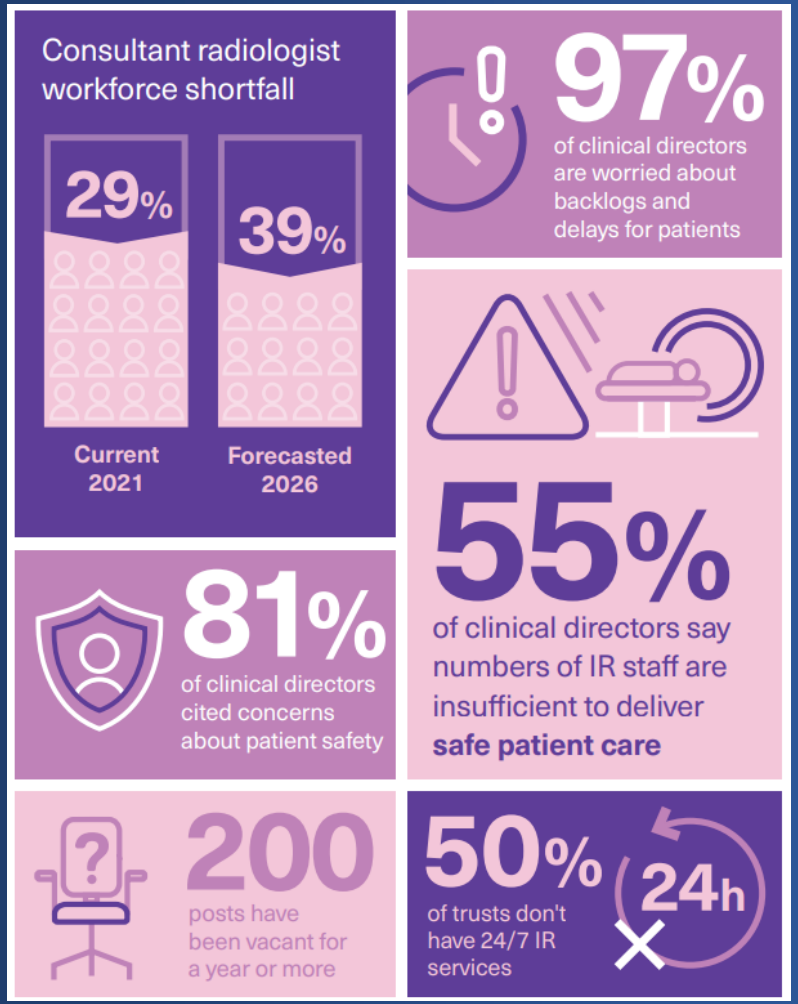
Diagnostic Errors

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*

Europe has a looming radiology capacity challenge

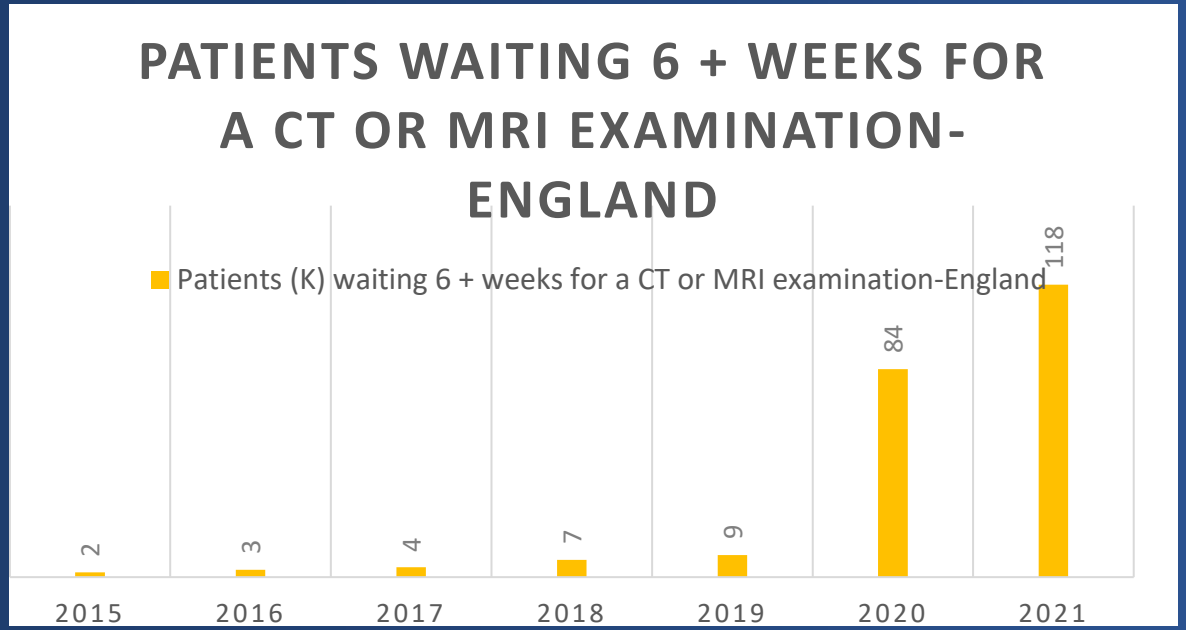
- Demographic transformation is increasing the pressure on healthcare systems.
- Stagnating number of trained radiologists available:
  - The Royal College of Radiologists projected a shortfall of 39% by 2026 [1].



1) 2021 Clinical radiology census report (2021) https://www.rcr.ac.uk/sites/default/files/clinical_radiology_census_report_2021.pdf [Accessed02/05/2023].

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].

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

- Address operational inefficiencies[1],
- optimise patient journeys[2],
- potentially improve 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*

Despite technology advancements, inefficiencies along the overall radiology workflow persist

Modality Selection & Scheduling

Patient set-up & injection

Image Acquisition

Worklist prioritisation

Reading

Diagnosis & Reporting

Administration & Analytics

Results Communication

Treatment Planning & Execution

Planning | **Scan room** | **Reading room** | **Administration** | **Treatment room**

- Patient did not attend,
- Patient set-up & communication,
- Sub-optimal image quality.

- Time-consuming, repetitive tasks (e.g., normal vs. abnormal, image segmentation, measurements),
- Diagnostic errors (e.g., errors of omission),
- Variability and subjectivity in image interpretation
- Departmental inefficiencies (e.g., caseload management, assessment of staff & equipment utilisation).

- Fragmented patient data sources,
- Communication of results,
- Preparation of multidisciplinary (tumour) boards.

Exponential rise in available AI technologies

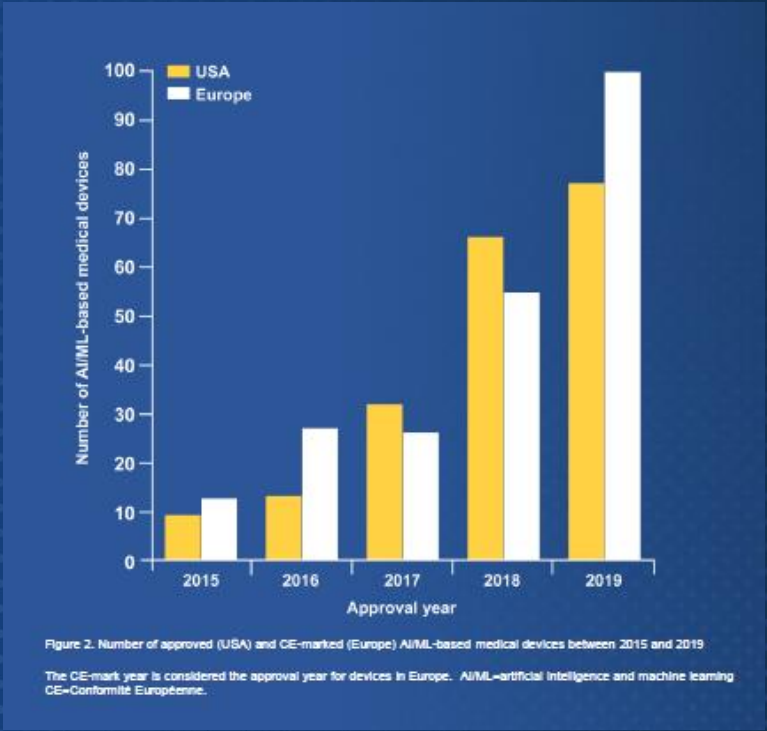


Figure 2. Number of approved (USA) and CE-marked (Europe) AI/ML-based medical devices between 2015 and 2019

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

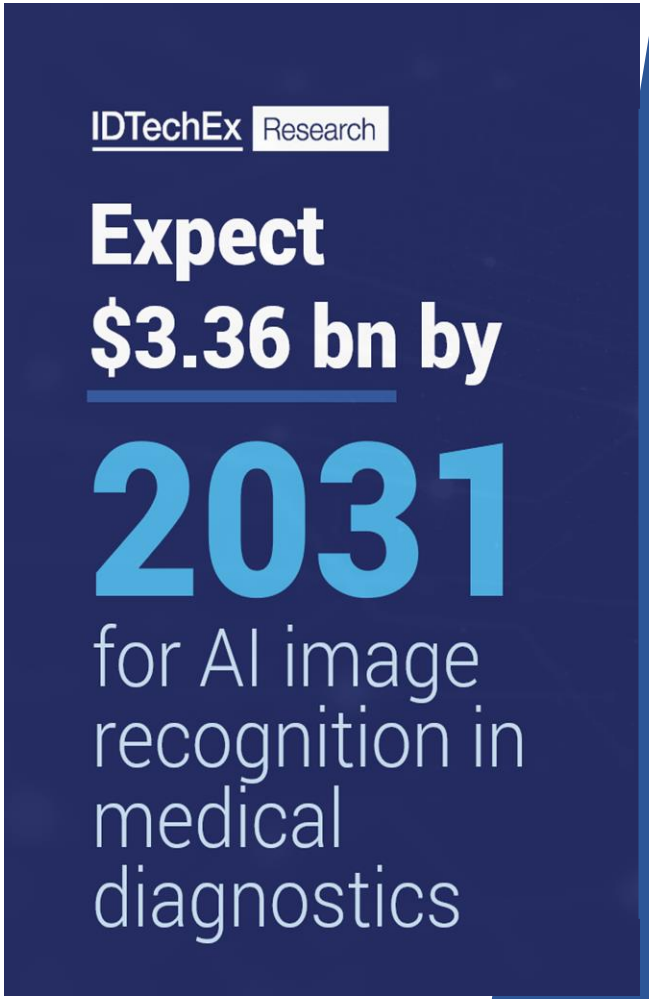
- Certified AI technologies are rising exponentially[1]
- Now **over 200** AI applications with CE certification for Radiology[2]
- Recent estimates predict a more than 10-fold growth in the market for artificial intelligence (AI) in medical imaging over the next decade[3]

1) Muehlematter U, Daniore P & Vokinger K. (2021). Approval of artificial intelligence and machine learning-based medical devices in the USA and Europe (2015–20): a comparative analysis. The Lancet Digital Health. 3. 10.1016/S2589-7500(20)30292-2.
2) Available online: https://grand-challenge.org/aiforradiology/ [Accessed 23/08/2022]
3) 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]

Funding of AI

- Total investment in AI companies between 2014 and 2019 → **1.17 billion USD** (1)
- Between 2019 and 2020, private investment in AI companies increase by **9,3%** (2)
- By 2030, investment in medical images AI base solutions is expected to exceed

…3 billion USD (3)



1. Alexander A, Jiang A, Ferreira C, Zurkiya D. An Intelligent Future for Medical Imaging: A Market Outlook on Artificial Intelligence for Medical Imaging. J Am Coll Radiol. 2020 Jan;17(1 Pt B):165-170. doi: 10.1016/j.jacr.2019.07.019. PMID: 31918875.
2. Artificial Intelligence Index Report 2021 https://aiindex.stanford.edu/wp-content/uploads/2021/11/2021-AI-Index-Report_Master.pdf [Accessed 02/05/2023]
3. Tsao, D. N. (2020). AI in medical diagnostics 2020- 2030: Image recognition, players, clinical applications, forecasts: IDTechEx. https://www.idtechex.com/en/researchreport/ ai-in-medical-diagnostics-2020-2030-imagerecognition- players-clinical-applications-forecasts/766 [Accessed 02/05/2023].

Deployment of algorithms is not commensurat with their Development ...Why [1]

- The deployment is being hindered by **several complex and interrelated issues** lowering the likelihood of AI-based solutions being adopted [2]
- There is a **lack of trust** in AI-based solutions by key stakeholders such as regulators, healthcare professionals and patients [2, 3]

1. Leiner T, Bennink E & Mol C et al. (2021). Bringing AI to the clinic: blueprint for a vendor-neutral AI deployment infrastructure. Insights into Imaging. 12. 10.1186/s13244-020-00931-1.
2. Esmaeilzadeh P. Use of AI-based tools for healthcare purposes: a survey study from consumers' perspectives. BMC Med Inform Decis Mak. 2020 Jul 22;20(1):170. doi: 10.1186/s12911-020-01191-1. PMID: 32698869; PMCID: PMC7376886
3. Richardson, J. P., Smith, C., Curtis, S., Watson, S., Zhu, X., Barry, B., & Sharp, R. R. (2021). Patient apprehensions about the use of artificial intelligence in healthcare. NPJ Digital Medicine, 4(1), 140. https://doi.org/10.1038/s41746-021-00509-1

2020 ACR survey

Prevalence and Attitudes Toward the Use of AI in Clinical Practice:

- 33,5% → using AI
- 66,5% → not using AI

AI Performance in Clinical Practice:

- 94.3% → “inconsistent performance of AI”
- 5.7% → indicated AI “always works”

AI satisfaction

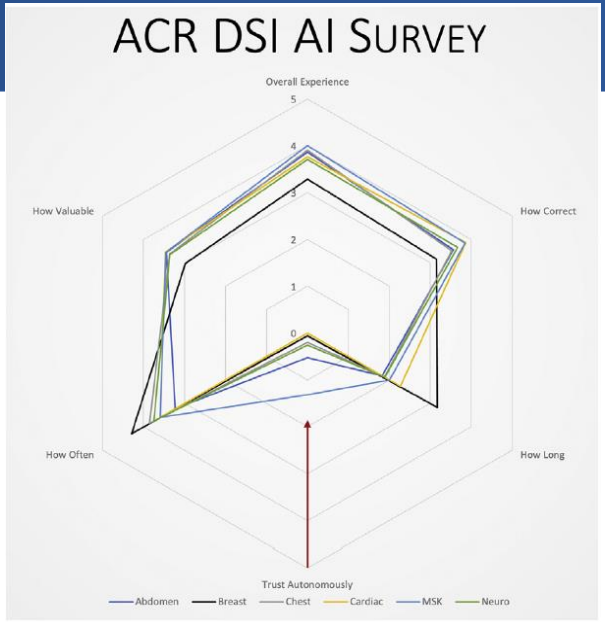


Fig. 3. AI satisfaction. The spider plot indicates an overall positive opinion of AI among respondents. However, few trust AI to perform autonomous interpretations (arrow). AI = artificial intelligence; DSI = Data Science Institute; MSK = musculoskeletal radiology; Neuro = neuroradiology.

Allen B, Agarwal S, Coombs L, Wald C, Dreyer K. 2020 ACR Data Science Institute Artificial Intelligence Survey. J Am Coll Radiol. 2021 Aug;18(8):1153-1159. doi: 10.1016/j.jacr.2021.04.002. Epub 2021 Apr 20. PMID: 33891859.

Implementation of AI

Standardization
- Generalisability
- Clinical use cases
- Scientific evidence
- Interpretability

Governance
- Regulatory framework
- Data protection
- Liability

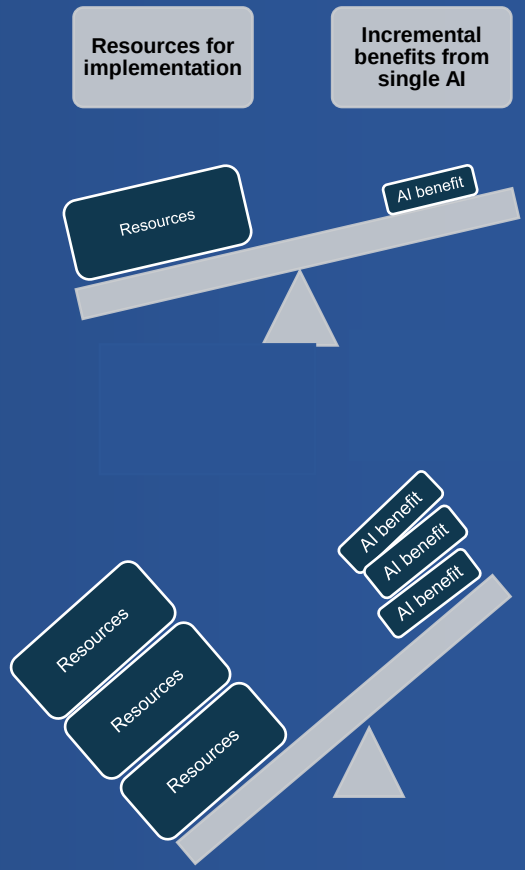
Economics
- ROI
- Product selection

Education
- End users
- Patients

IT
- Integrability
- Scalability
- Resources
  - Human
  - Hardware/softw

The scalability challenge

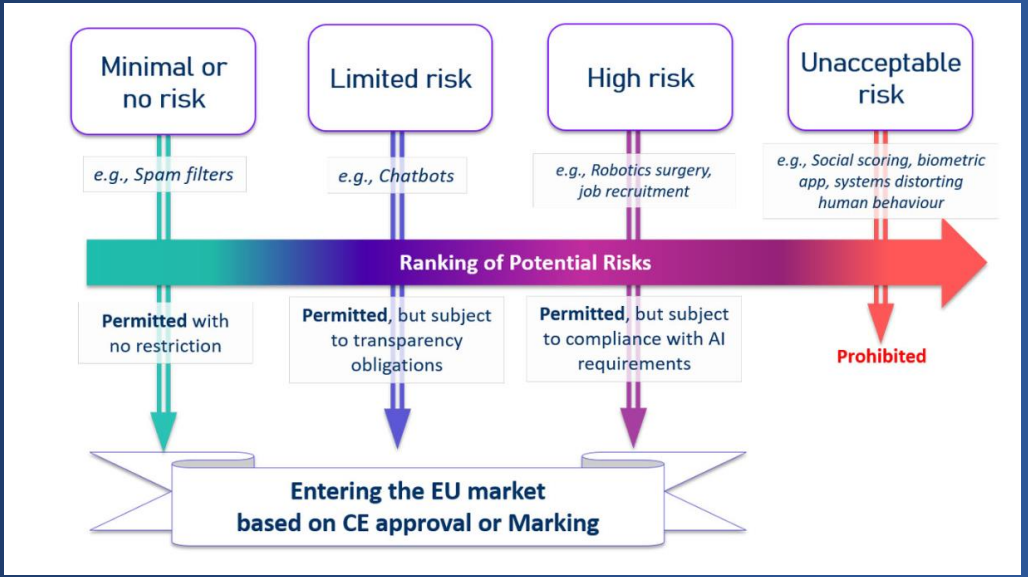
- Adoption is a balance between the incremental benefits of AI and the resources required to **implement** and **maintain** the technology.
- Generally, many AI models have a very specific intended purpose with potentially small incremental benefits.
- Implementation is resource intensive.
- **Scalability strategy** is not routinely considered during implementation.
- Stand-alone point solutions (single AI) implementation are unmanageable[1].



1) Leiner T, Bennink E & Mol C et al. (2021). Bringing AI to the clinic: blueprint for a vendor-neutral AI deployment infrastructure. Insights into Imaging. 12. 10.1186/s13244-020-00931-1.

Artificial Intelligence Act proposal

- Strengthening rules around data quality, transparency, human oversight and accountability.
- Address ethical questions and implementation challenges.
- Provide AI developers, deployers and users with clear requirements and obligations and reduce financial burdens for business.
- Strengthen Europe's position as a global hub of excellence in AI from the lab to the market.



A regulated pathway for Artificial Intelligence in Medical Imaging: https://www.procancer-i.eu/newsletter-2/a-regulated-pathway-for-artificial-intelligence-in-medical-imaging/ [Accessed 02/05/2023]

Software and AI as a Medical Device program (SaMD/AIaMD)

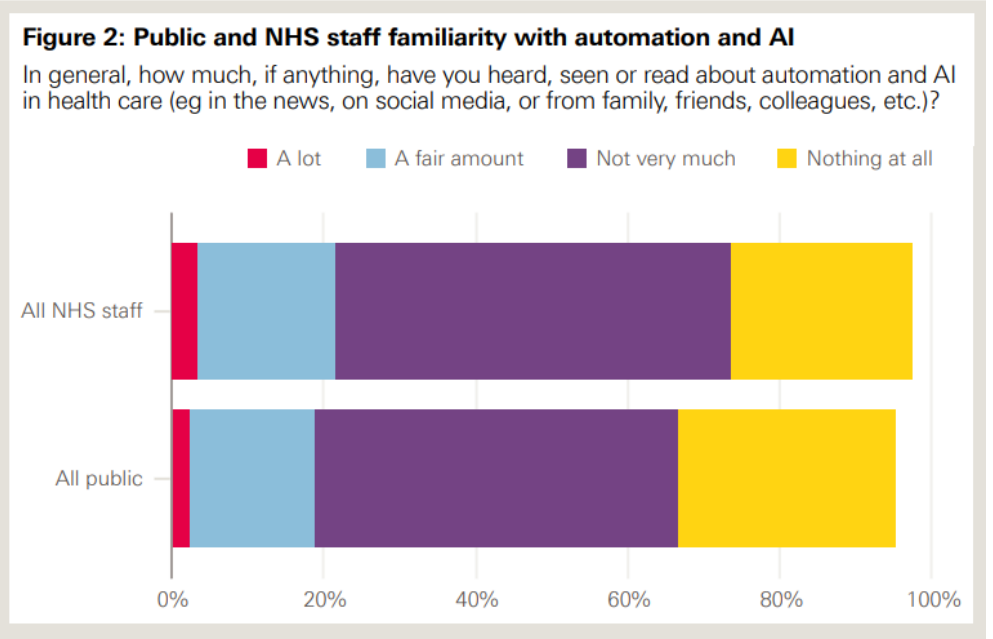
Aims to support the **adoption** of medical devices and AI in the UK market and ensure **responsible innovation**, providing a regulatory framework focused on **patients and public safety.**

- Qualification and intended purpose.
- Classification based on risk.
- “airlock process” to generate real-world evidence.
- Clear Premarket requirements.
- Stronger Post market surveillance and monitoring.
- SaMD/AIaMD cybersecurity
- AI rigor
- AI interpretability
- Adaptative AI change management

1. MHRA, Software and AI as a Medical Device Change Programme – Roadmap. Oct 2022. Available online: https://www.gov.uk/government/publications/software-and-ai-as-a-medical-device-change-programme/software-and-ai-as-a-medical-device-changeprogramme- roadmap#work-packages [Accessed 02/05/2023]
2. Image: https://www.rolandberger.com/en/Insights/Publications/Artificial-intelligence-and-regulations-for-machines.html [Accessed 02/05/2023]

Education for Healthcare Professionals

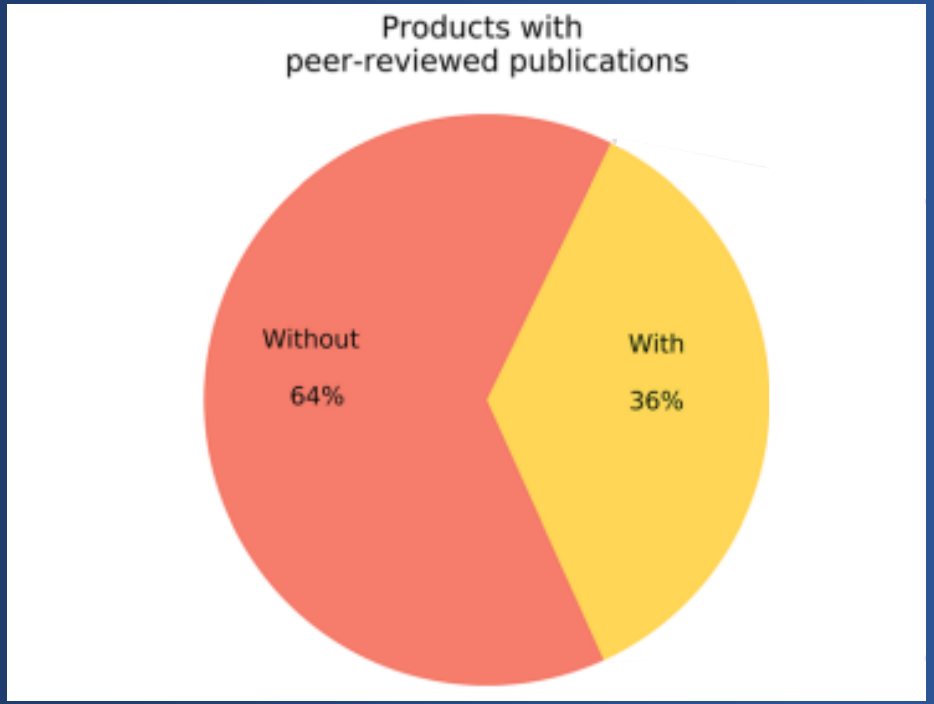
- Most healthcare workers lack direct experience with AI technologies.
  - A 2020 survey found that three-quarters of respondents knows "**not very much**" or "**nothing**" about AI [1]
- Education in AI is critical in the successful implementation, as it can improve HCPs [2,3]:
  - Skills and attitudes toward AI
  - Increased **acceptance** and willingness to use AI in clinical practice



1. Hardie T, Horton T, Willis M, Warburton W. Switched on. How Do We Get the Best out of Automation and AI in Health Care? 2021. doi:10.37829/HF-2021-I03
2. van der Vaart, R., Drossaert, C. H., de Heus, M., Taal, E., & van de Laar, M. A. (2020). Measuring actual eHealth literacy among patients with rheumatic diseases: a qualitative analysis of problems encountered using Health 1.0 and Health 2.0 applications. Journal of Medical Internet Research, 22(9), e17568.
3. Topol, E. J. (2019). High-performance medicine: the convergence of human and artificial intelligence. Nature Medicine, 25(1), 44-56.

Clinical evidence

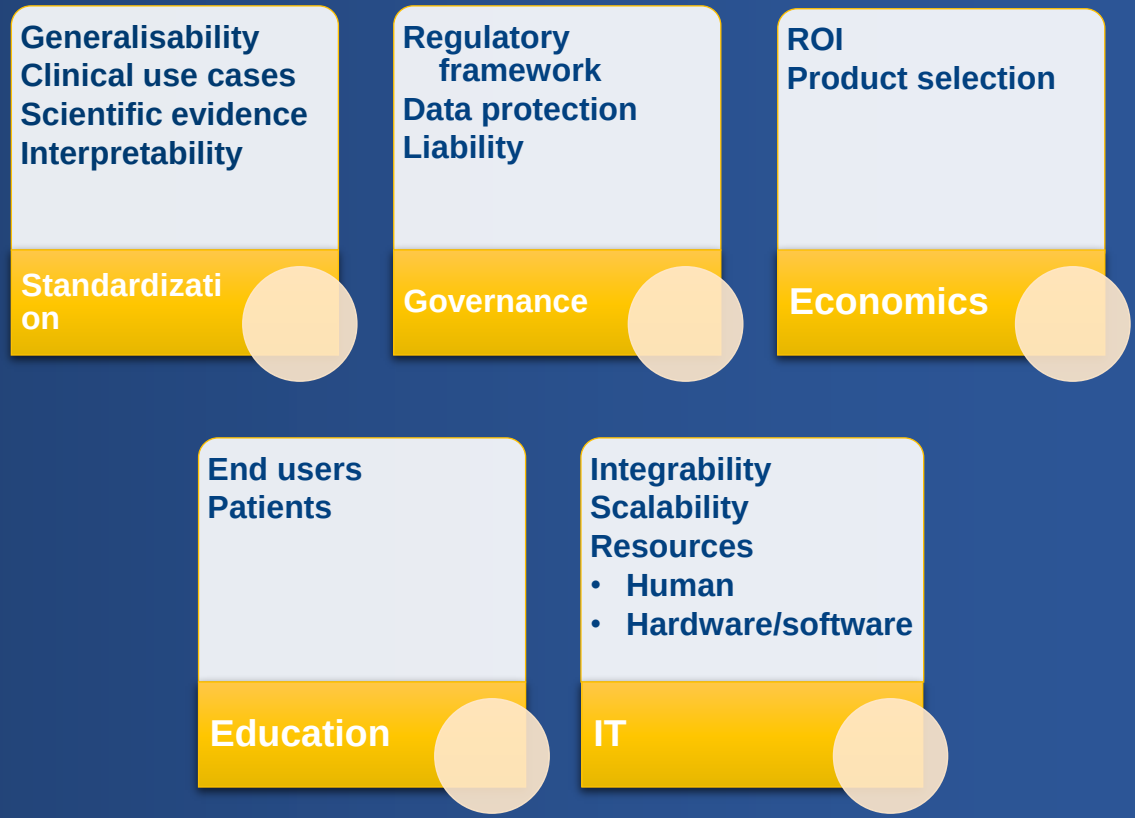
- High-quality evidence used to determine AI performance contributes to **confidence in** and **implementation**.[1.]
- Robust evidence of improved human decision-making when using AI systems is still lacking [2].
- A review of 100 CE-marked AI products from 54 different vendors [3].
  - 64% no peer-reviewed 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.

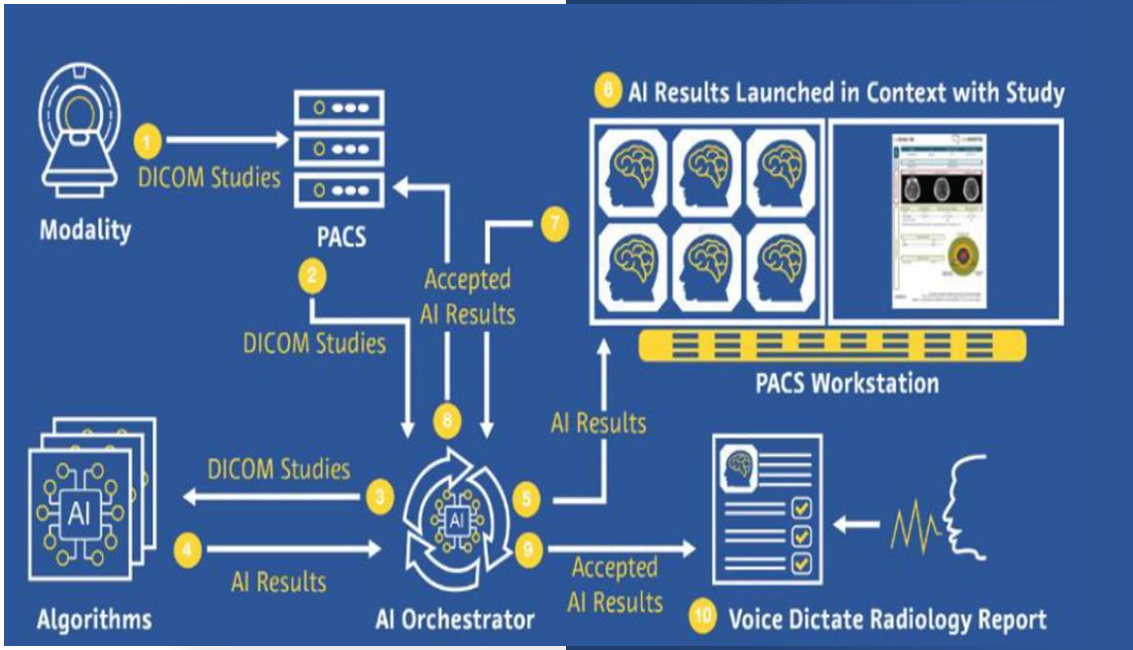
While some will require large-scale actions, others....

…. can be faced with available tools, such as **platform technology**.



What is Platform technology

- Technology infrastructure integrated into the native IT infrastructure of a radiology department (PACS / RIS).
- Enables the communication of imaging data into the native infrastructure and multiple deployed AI models.
- Provides an interface for user interaction with AI results.



The power of platform technology

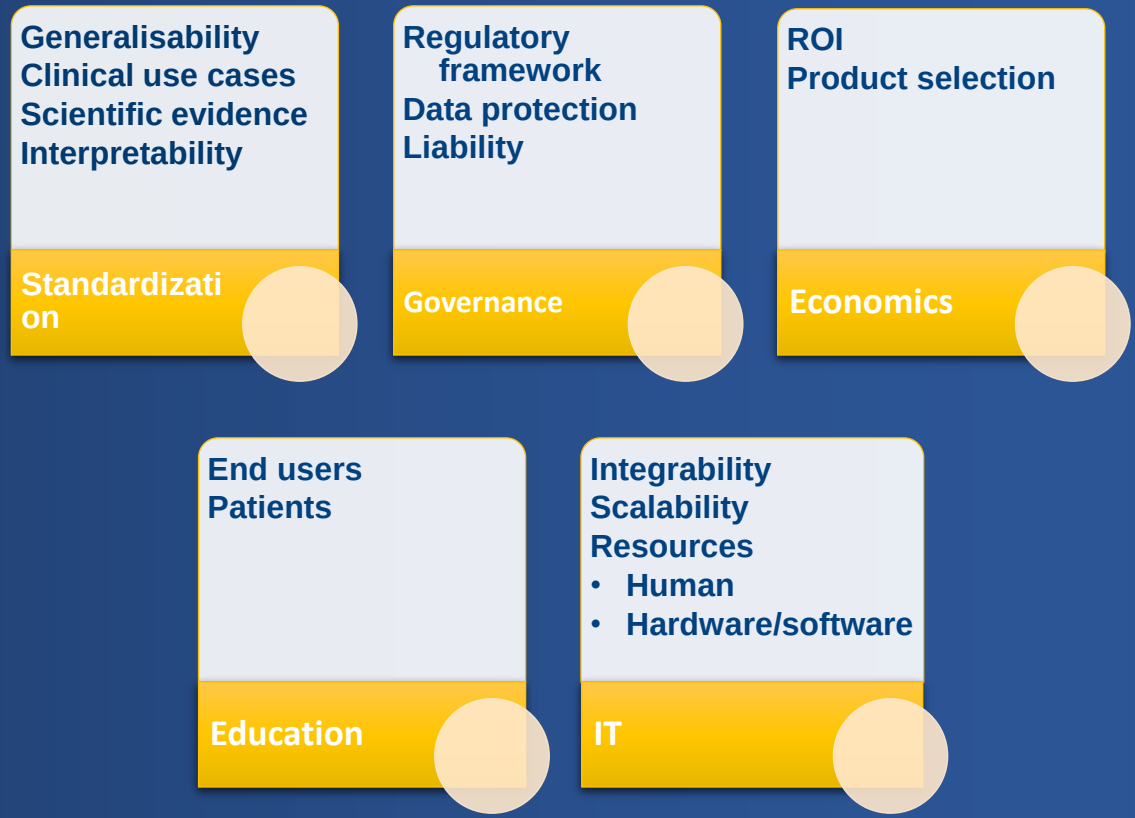
- One-off integration
- Vendor neutral infrastructure with scalable architecture for the future
- Local validation of datasets is possible
- “Try-before-you-buy” prior to committing to an application
- Application-level analytics for quality assurance

The power of platform technology

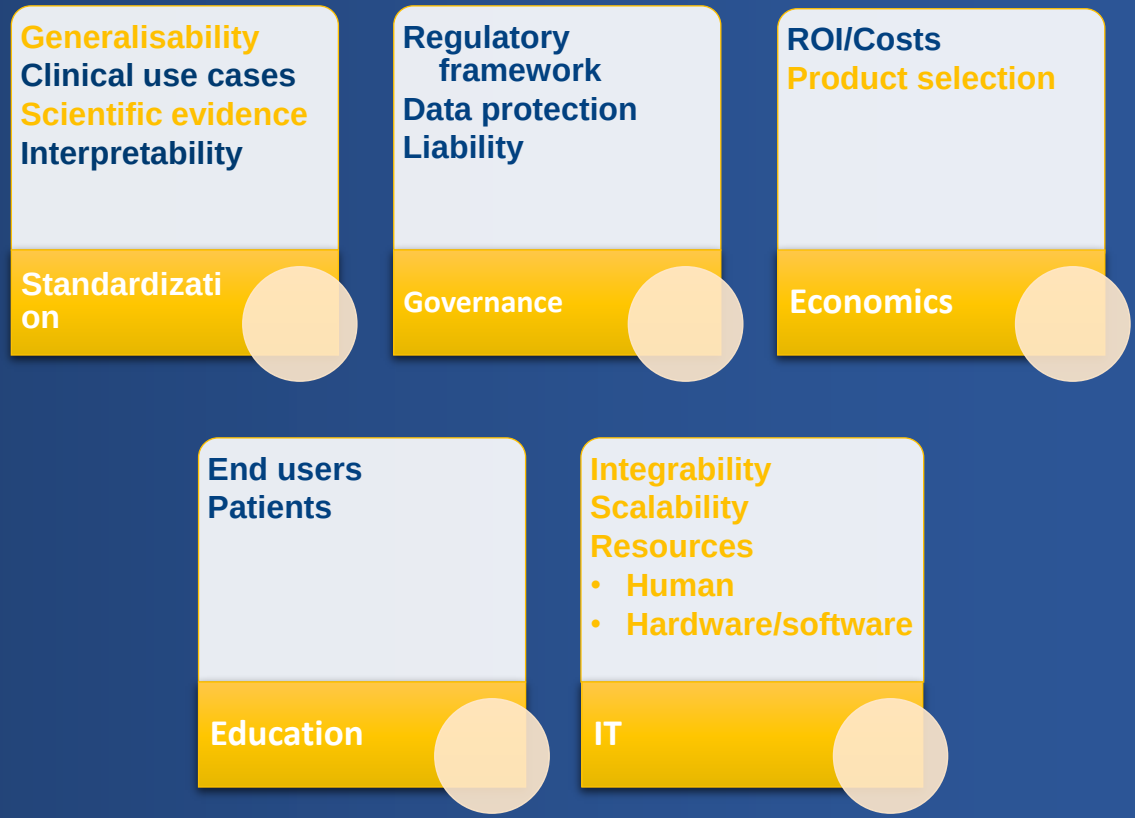
- Generation of Real-World Evidence
- Triggered Automation, Cascade workflows[1] and Ensebling of AI models
- Versioning control[1]
- Platform for local departments to leverage their own data with capability of deployment

1) Leiner T, Bennink E & Mol C et al. (2021). Bringing AI to the clinic: blueprint for a vendor-neutral AI deployment infrastructure. Insights into Imaging. 12. 10.1186/s13244-020-00931-1.

Implementation of AI



Implementation of AI



AI Culture – Keys to success

- Implementation can support or derail the strategic and clinical advantages of the organizations' AI adoption
- AI implementation as a service rather than just a technology
- Understand, in detail, the landscape in which you are operating in
- Focus on the needs of the customer and the AI users
- AI deployment is not all-or-nothing
- Human-in-the-loop AI
- AI adoption is a journey that each stakeholder should enjoy being part of

Figure 1: LTX 2022, highlights from our executive survey: The path to AI Maturity. Available Online at https://www.lxt.ai/blog/highlights-from-our-executive-survey-the-path-to-ai-maturity/ [Accessed 23/08/2022]

Summary

- AI holds the potential to help improve many challenges radiology departments will face in the upcoming years.
- The regulatory landscape is evolving to support and maintain safe and effective implementation.
- Strategy for AI implementation is a key factor for success and must consider scalability.
- There are several key advantages of AI platform deployment compared to single AI application integration.
- Platform technology has the potential to create a sustainable AI ecosystem and help to address the clinical, regulatory, and quality requirements of AI deployment in healthcare.
- The education of the end user will be decisive in adopting the technology.

Thank You

INTELLIGENT HEALTH UK 2023

Breaking down the barriers between tech and healthcare