

El invierno de la **INTELIGENCIA ARTIFICIAL**



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Hospital Universitario Bellvitge



SIN CONFLICTOS DE INTERÉS

Aunque estoy disponible....





OBJETIVO

Visión crítica/personal sobre INTELIGENCIA ARTIFICIAL en RADIOLOGÍA



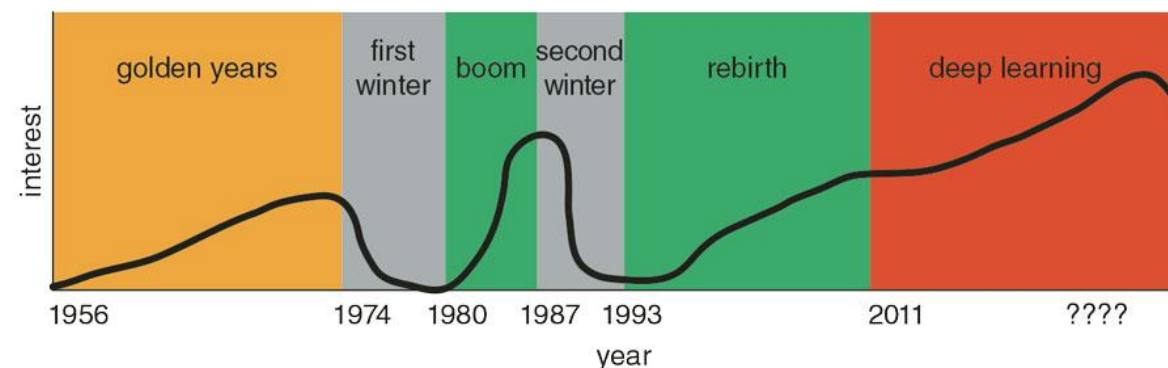
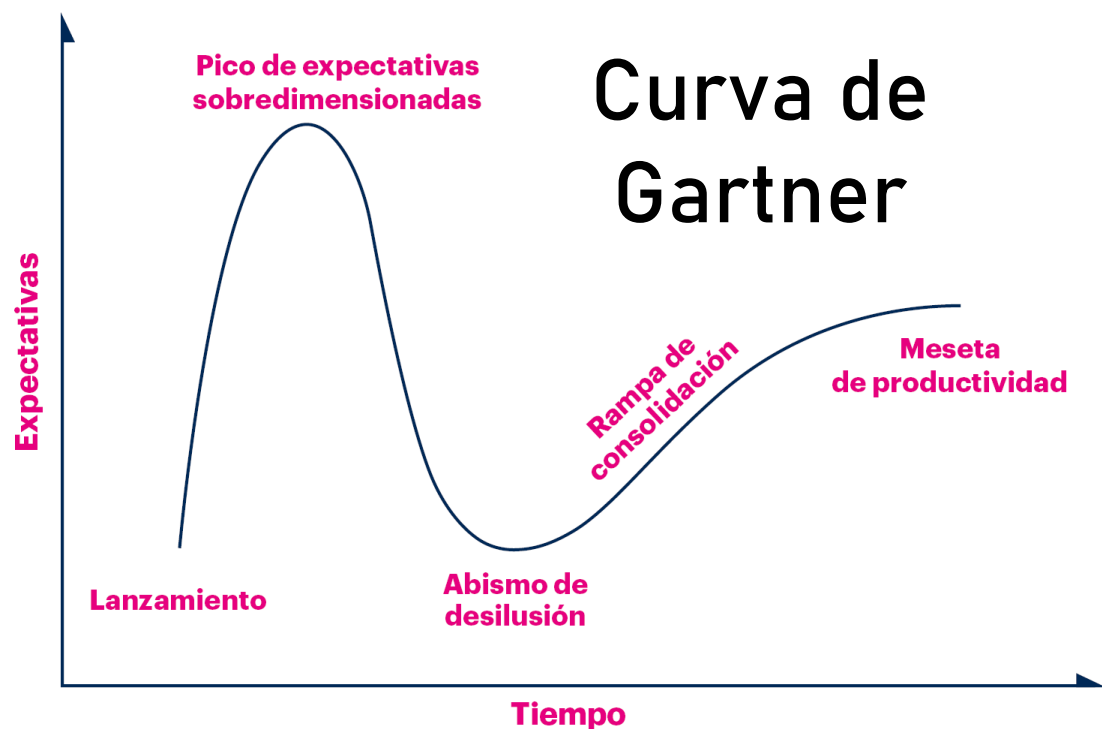


CONCLUSION

Necesitamos una visión crítica/personal sobre
INTELIGENCIA ARTIFICIAL en RADIOLOGÍA
de cada uno de vosotros...



En la historia de la inteligencia artificial, un invierno de IA es un período de financiación e interés reducidos en la investigación de la inteligencia artificial.



El traje nuevo del emperador (Cuento de Hans Christian Andersen 1837)





Reunión Anual
SOCIEDAD ESPAÑOLA DE
NEURORRADIOLOGÍA

SAN SEBASTIÁN

7 - 9 de noviembre de 2024



The New York Times

Opinion

OP-ED CONTRIBUTOR

The Ivory Tower Can't Keep Ignoring Tech

By Cathy O'Neil

Nov. 14, 2017





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The Ivory Tower Can't Keep Ignoring Tech

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FOMO

Fear Of Missing Out

A high-contrast, black and white photograph of a person walking across a large, dark, polished floor. The person is seen from the side, walking away from the viewer towards the right. They are wearing a dark coat and light-colored pants. A long, dark shadow is cast on the floor behind them. The floor is highly reflective, showing bright, diagonal streaks of light that create a sense of depth and movement. The overall atmosphere is mysterious and dramatic.

UNA NOCHE EN LA TIERRA

Cuando la A.I. significa Algunos Indios

'Amazon Fresh' permitía a los clientes comprar sin pasar por caja. Ahora se discute si el secreto de la fórmula estaba en la sofisticada tecnología de la que alardeaba o en el millar de indios que vigilaban las compras a distancia.

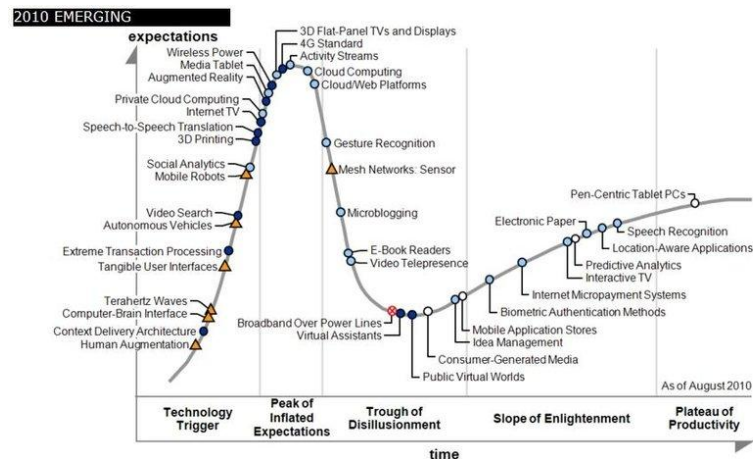
FOMO
Fear Of Missing Out



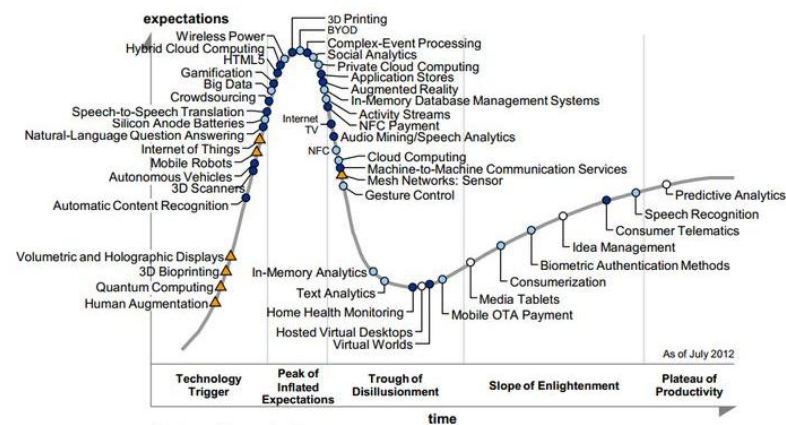
Curva de Gartner



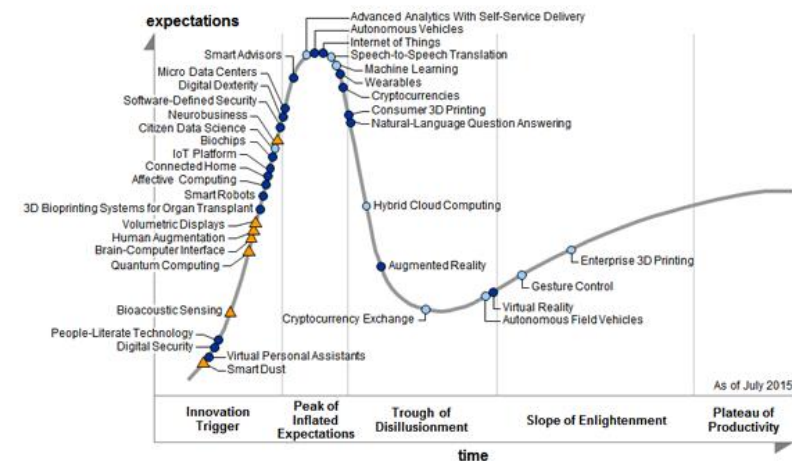
2010



2012



2014



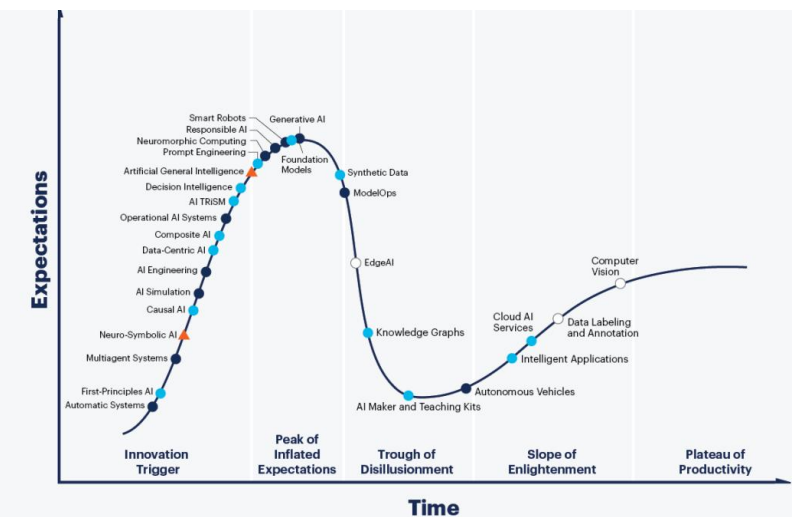
2016



2020



2023



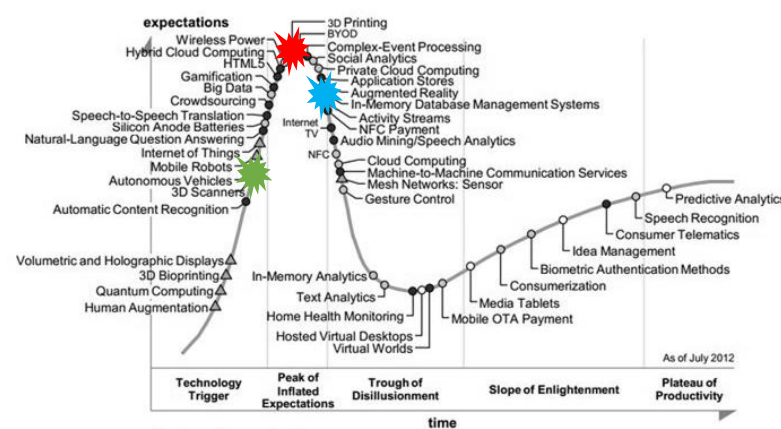
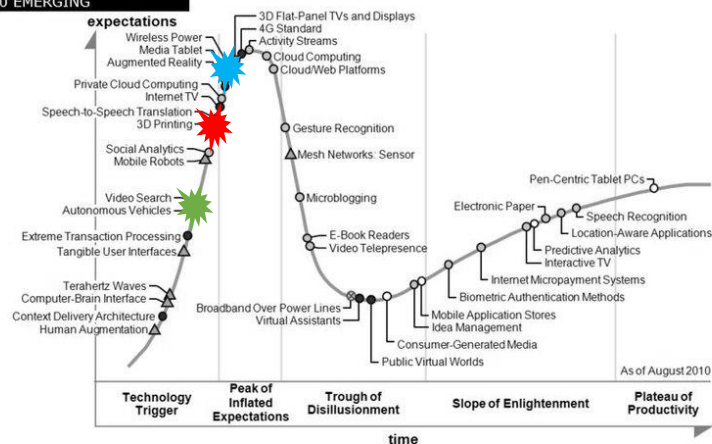


2010

2012

2014

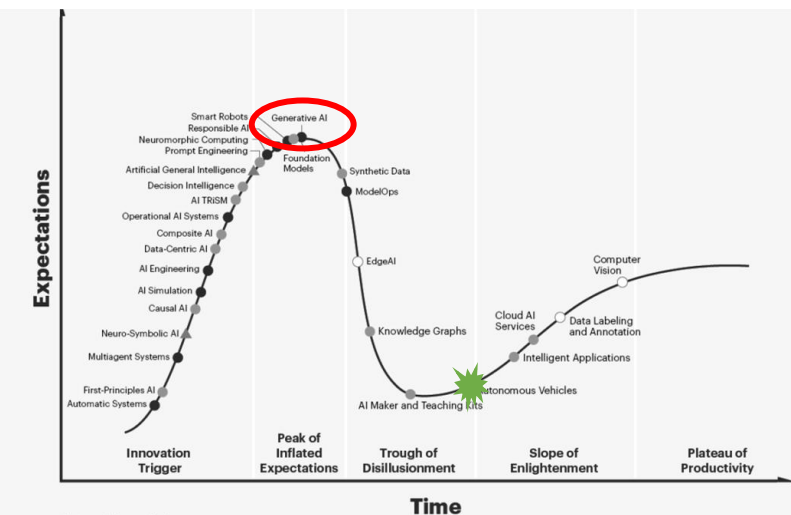
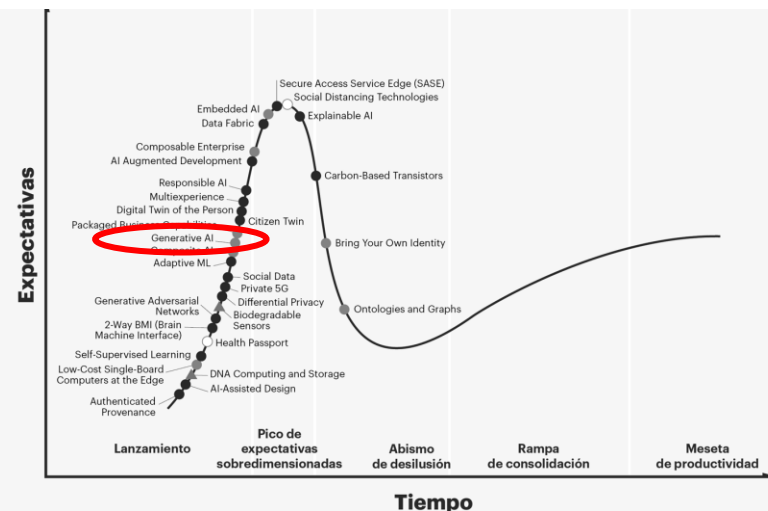
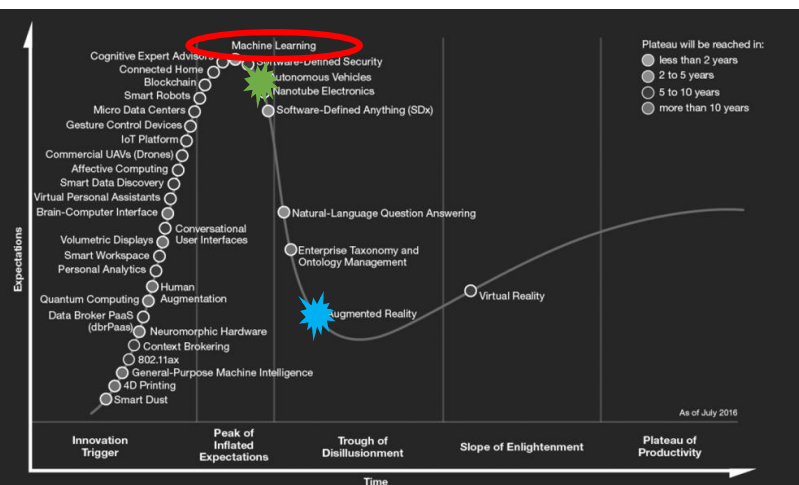
2010 EMERGING



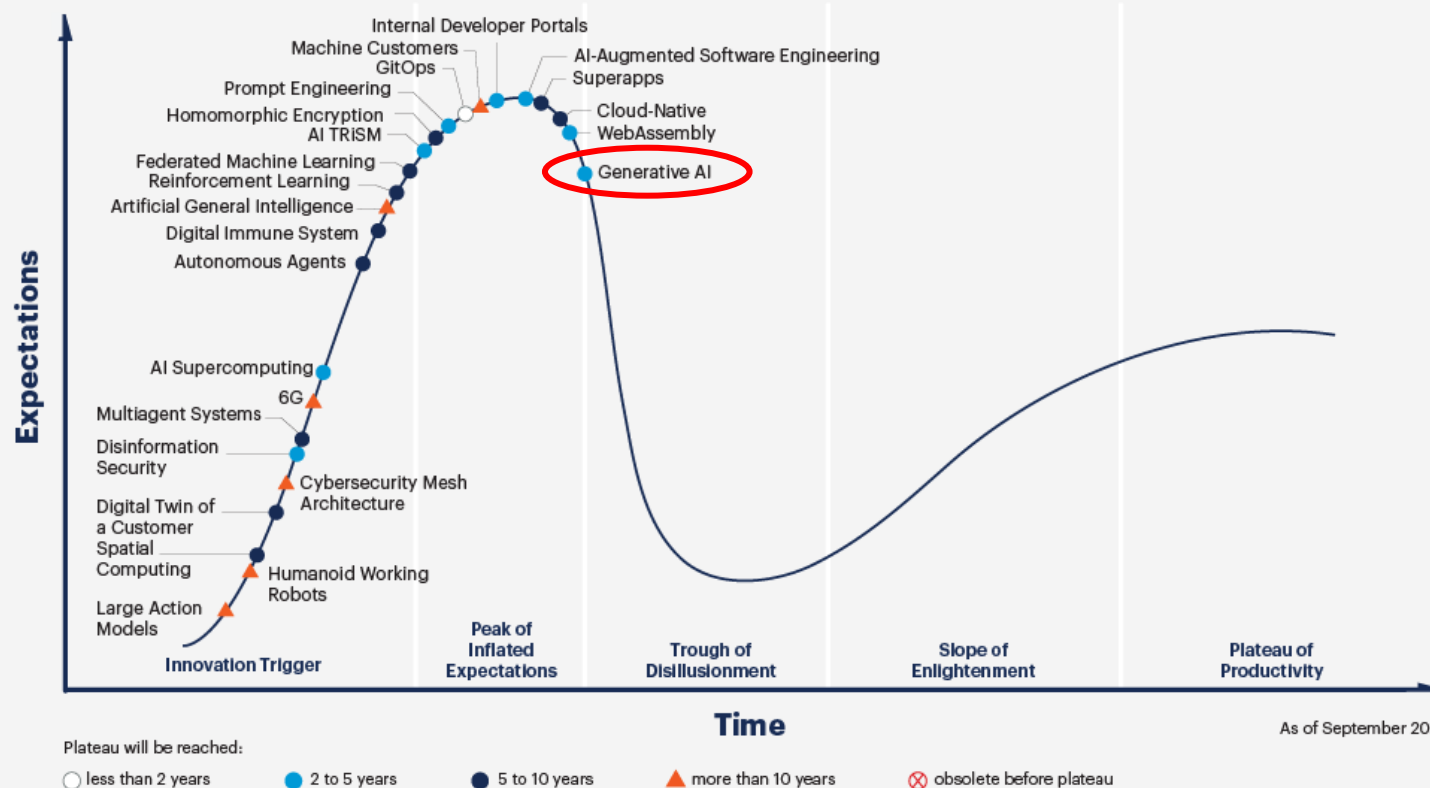
2016

2020

2023



Hype Cycle for Emerging Technologies, 2024



Source: Gartner
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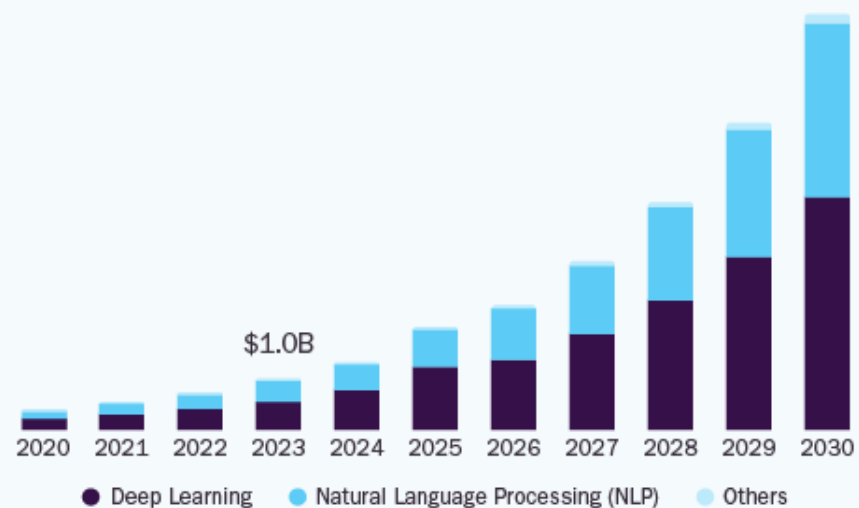
Gartner





AI In Medical Imaging Market Size

by Technology, 2020 - 2030 (USD Billion)



34.8%

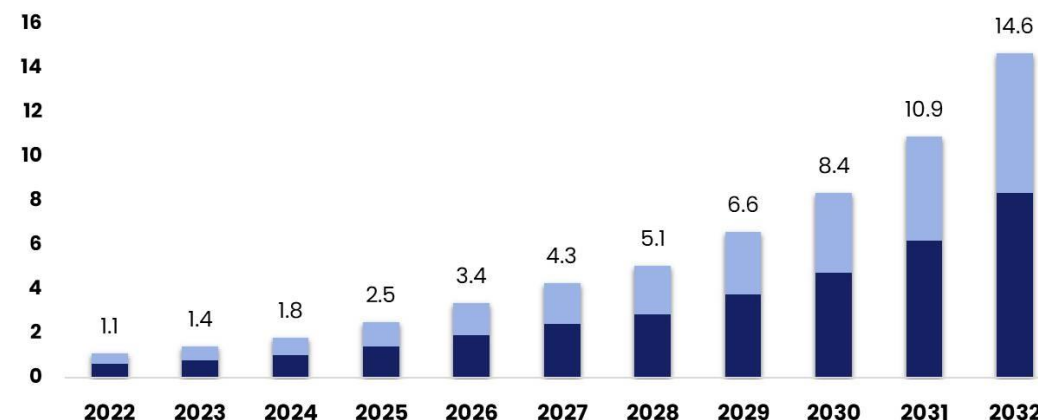
Global Market CAGR,
2024 - 2030

Source:
www.grandviewresearch.com

Artificial Intelligence (AI) In Radiology Market

Size By Solution Type, 2022-2032 (USD Billion)

■ AI Software ■ AI Hardware



The Market will Grow
At the CAGR of:

30.4%

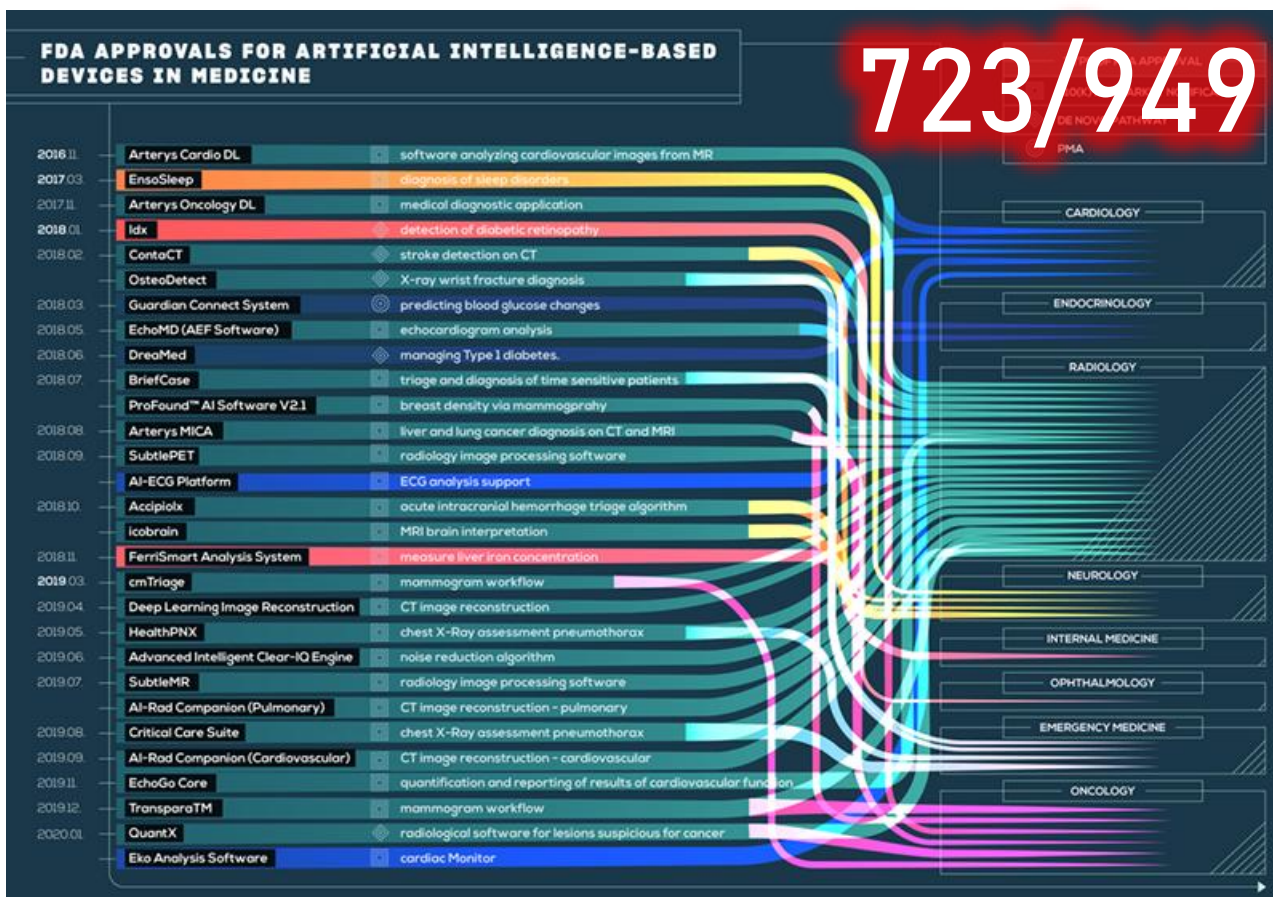
The forecasted market
size for 2032 in USD

\$14.6B

 **MarketResearch**
WIDE RANGE OF GLOBAL MARKET REPORTS



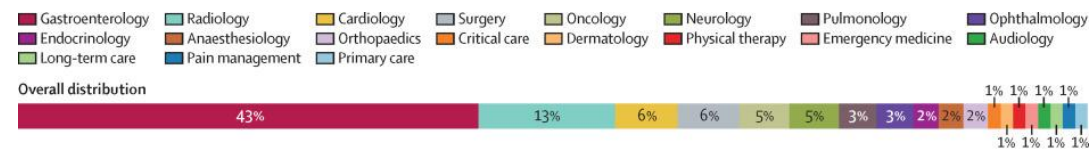
Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices



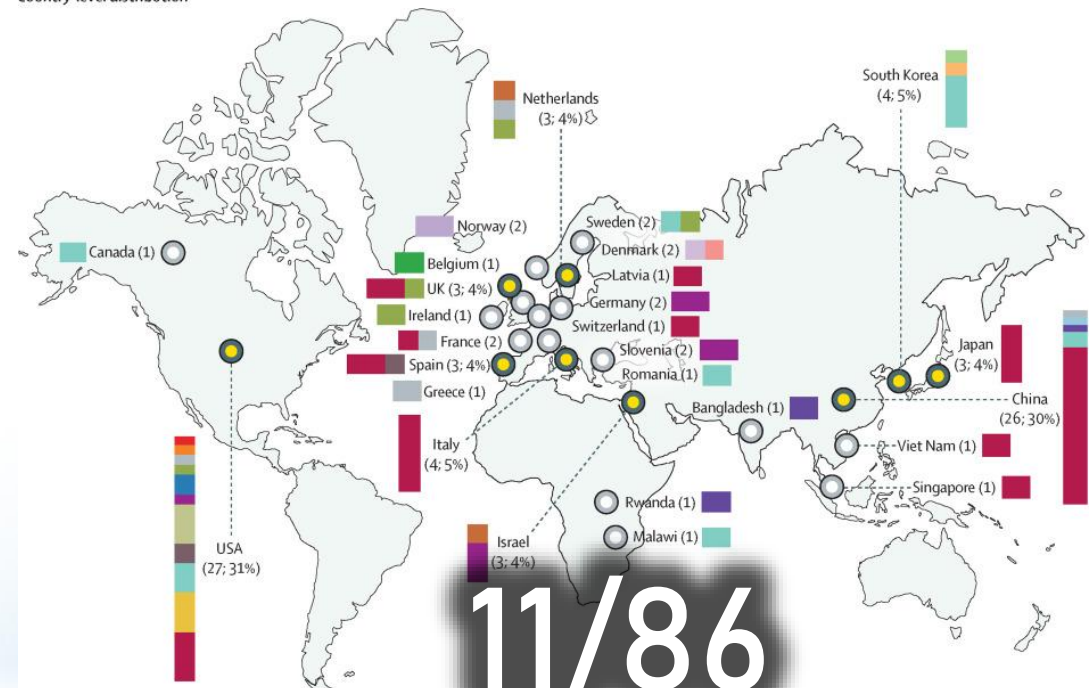
Randomised controlled trials evaluating artificial intelligence in clinical practice: a scoping review

Ryan Han, Julián N Acosta, Zahra Shakeri, John P A Ioannidis, Eric J Topol*, Pranav Rajpurkar*

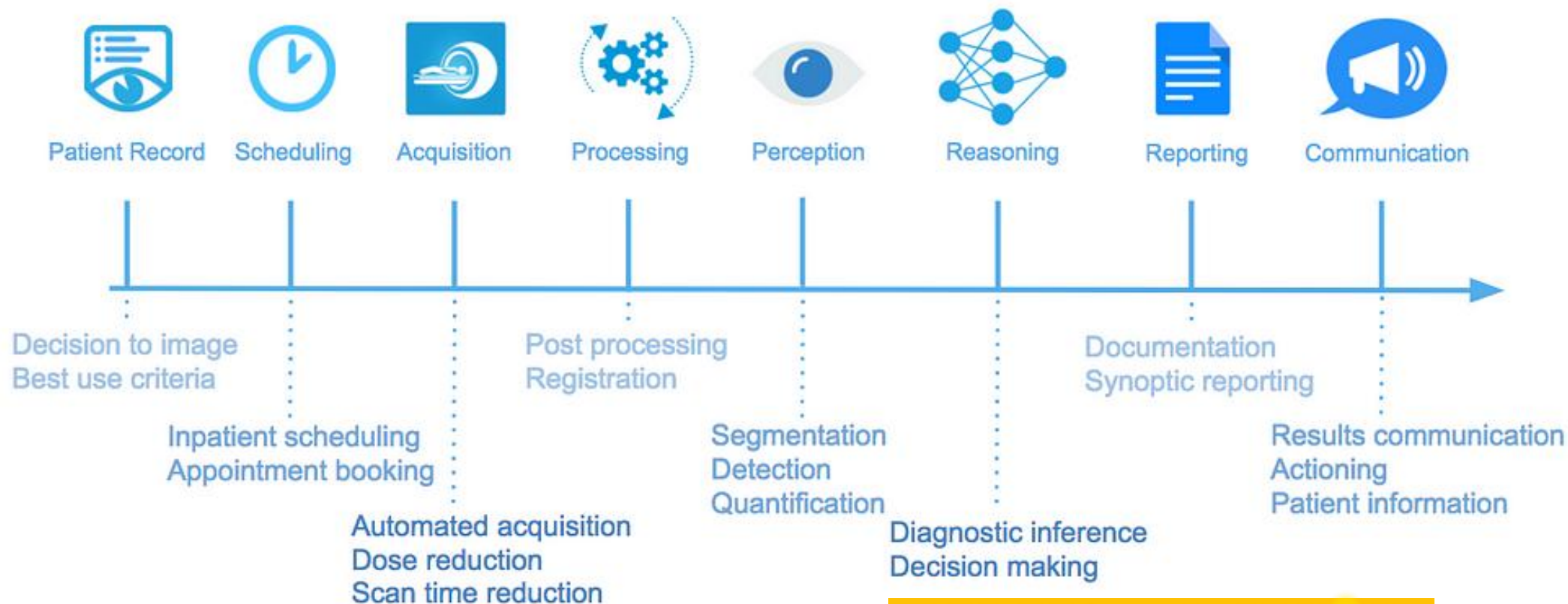
Lancet Digit Health 2024; 6: e367-73



Country-level distribution



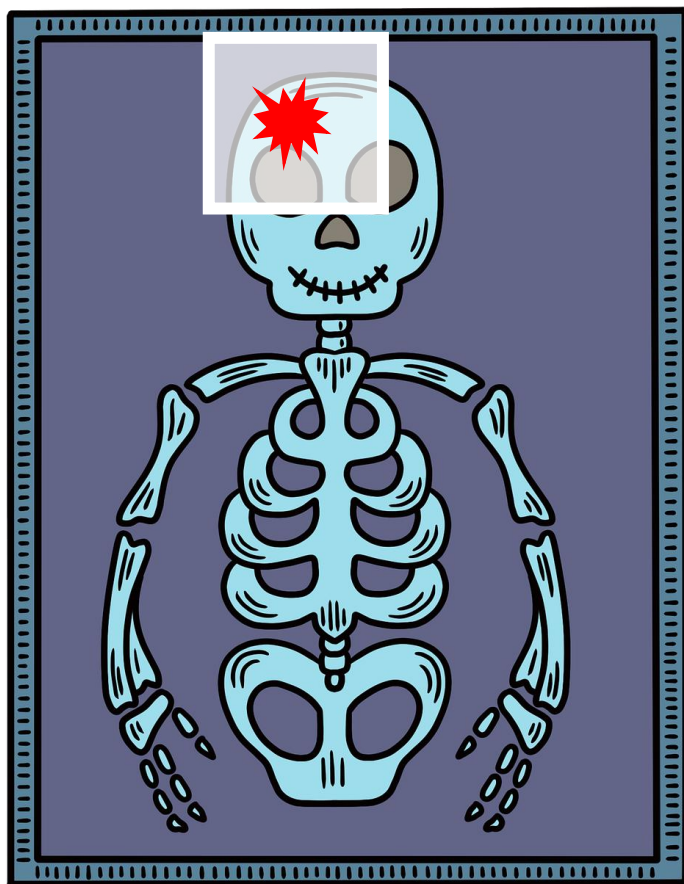
DETECCIÓN



CARACTERIZACIÓN

Simplified schematic of the diagnostic radiology workflow, with examples of where AI systems can be implemented.
Image copyright @drhughharvey.

DETECCIÓN



Definición valores de Sensibilidad (VPN) / Especificidad

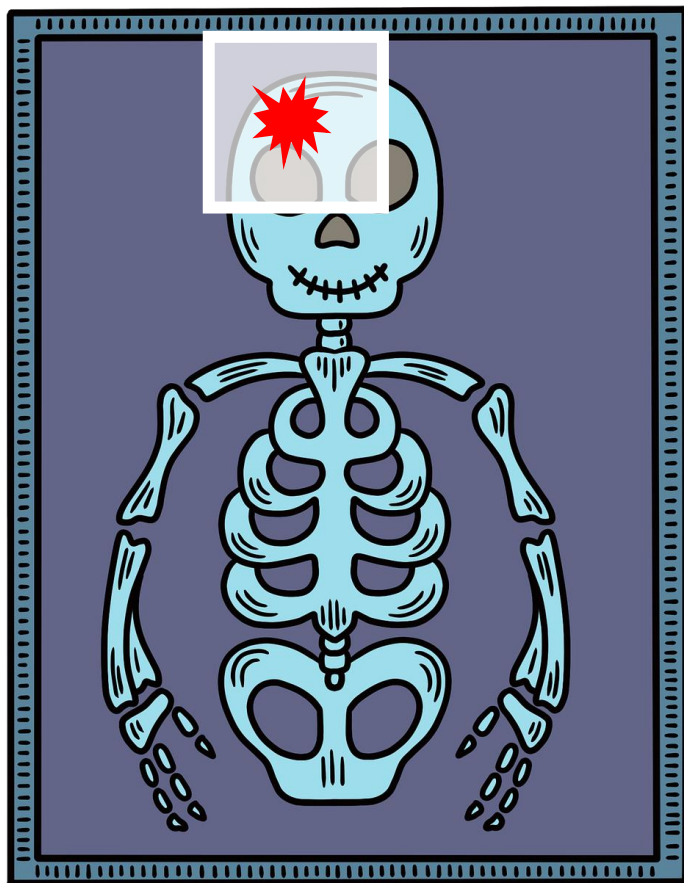
Emitir una predicción con una determinada seguridad

Todos los hallazgos representados de forma balanceada

Estudios Randomizados de implementación



DETECCIÓN



European Radiology (2023) 33:8263–8269
<https://doi.org/10.1007/s00330-023-09747-1>

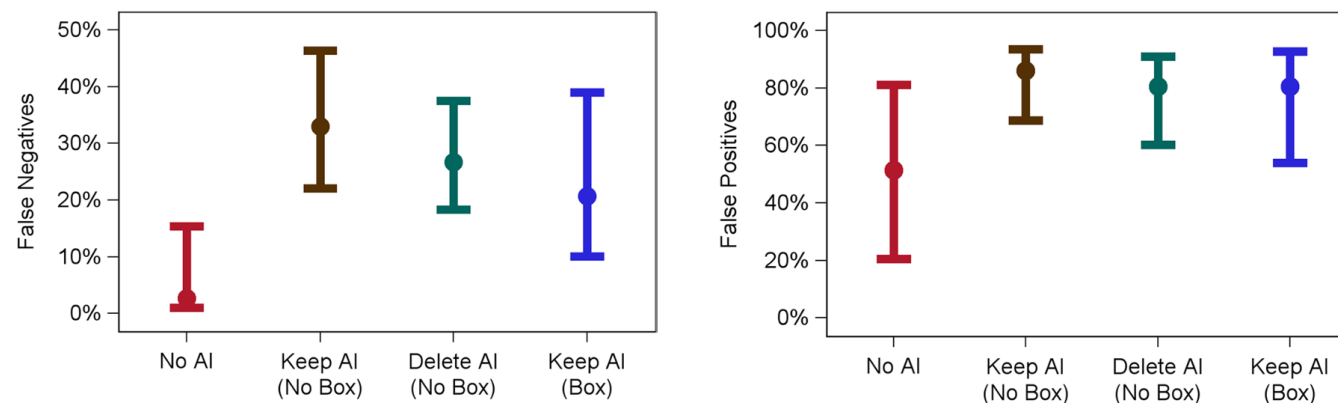
European Radiology
 EUROPEAN SOCIETY
OF RADIOLOGY



CHEST

Can incorrect artificial intelligence (AI) results impact radiologists, and if so, what can we do about it? A multi-reader pilot study of lung cancer detection with chest radiography

Michael H. Bernstein^{1,2,3}  · Michael K. Atalay^{1,3} · Elizabeth H. Dibble¹ · Aaron W. P. Maxwell^{1,3} · Adib R. Karam¹ · Saurabh Agarwal¹ · Robert C. Ward¹ · Terrance T. Healey¹ · Grayson L. Baird^{1,2,3}



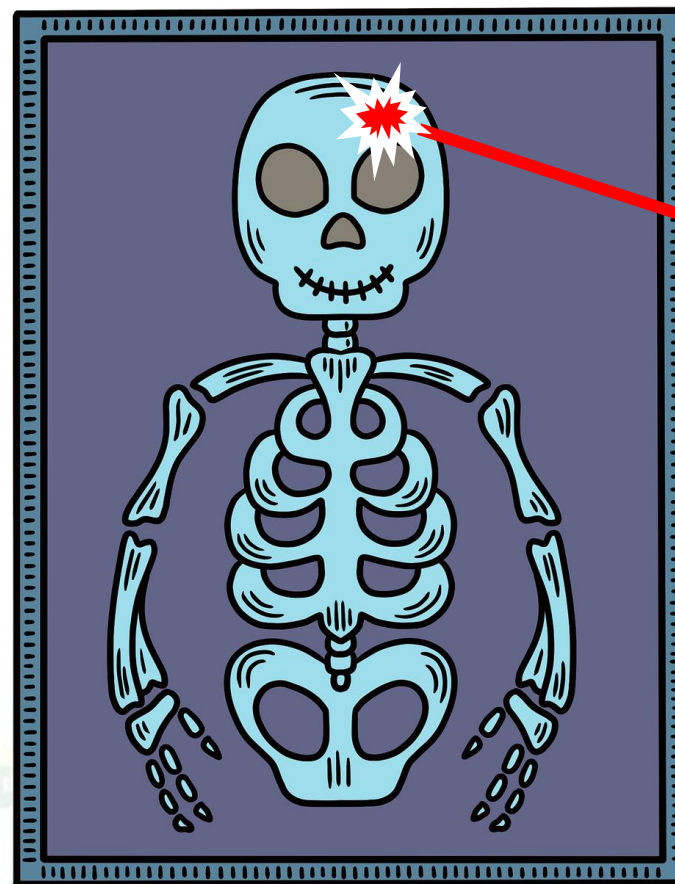
CARACTERIZACIÓN

Definición valores de Especificidad (VPP)

Emitir una predicción con una determinada seguridad

Alta completitud de los datos

Estudios Randomizados de implementación



Glioblastoma

IDH MUTADO

MGMT +

1p/19q co-deletion

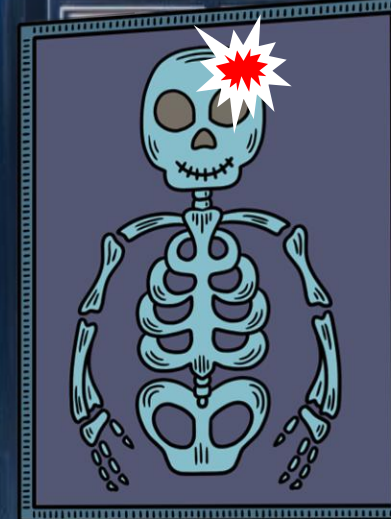
MEDICINA PERSONALIZADA

Glioblastoma

IDH MUTADO

MGMT +

1p/19q co-deletion



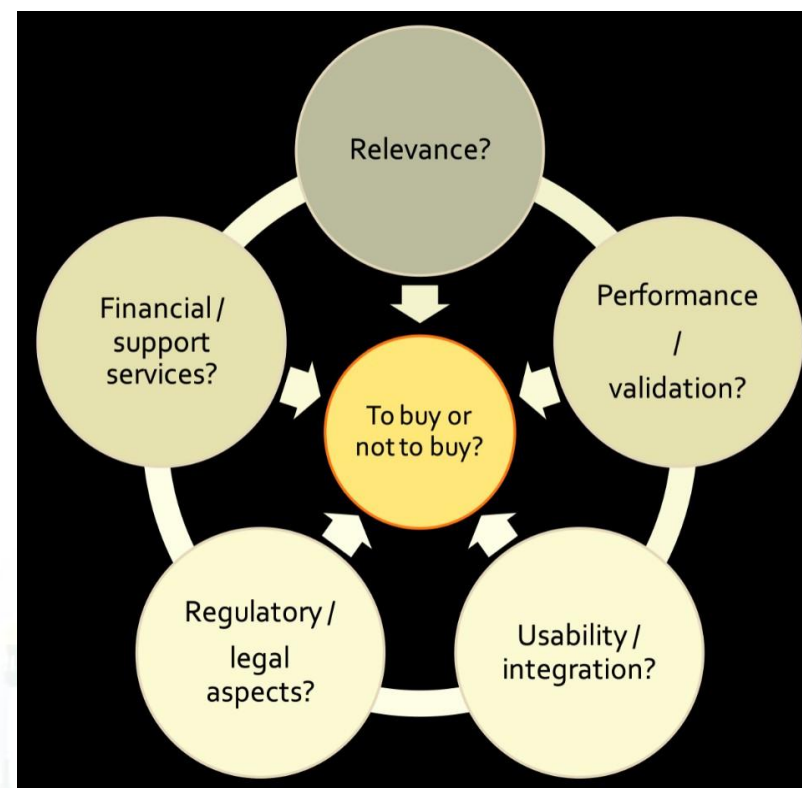
To buy or not to buy—evaluating commercial AI solutions in radiology (the ECLAIR guidelines)

Patrick Omoumi¹  • Alexis Ducarouge² • Antoine Tournier² • Hugh Harvey³ • Charles E. Kahn Jr⁴ • Fanny Louvet-de Verchère⁵ • Daniel Pinto Dos Santos⁶ • Tobias Kober⁷ • Jonas Richiardi¹

Table 1 Checklist of points to consider when assessing a commercial AI solution in radiology

1. Relevance	1.1. What problem is the application intended to solve, and who is the application designed for? Define the scope of application; end-users; research vs. clinical use; usage as double reader, triage, other; outputs (diagnosis, prognosis, quantitative data, other); indications and contra-indications 1.2. What are the potential benefits, and for whom? Consider benefits for patients, radiologists/referring clinicians, institution, society 1.3. What are the risks associated with the use of the AI system? Consider risks of misdiagnosis (including legal costs), of negative impact on workflow, of negative impact on quality of training
2. Performance and validation	2.1. Are the algorithm's design specifications clear? Check robustness to variability of acquisition parameters; identify features (radiomics) or network architecture (deep learning) used 2.2. How was the algorithm trained? Assess population characteristics and acquisition techniques used, labeling process, confounding factors, and operating point selection 2.3. How has performance been evaluated? Check proper partitioning of training/validation/testing data, representativeness and open availability of data. Assess human benchmarks, application scope during evaluation, source of clinical validation 2.4. Have the developers identified and accounted for potential sources of bias in their algorithm? Assess training data collection, bias evaluation, stratification analyses 2.5. Is the algorithm fixed or adapting as new data comes in? Check whether user feedback is incorporated, if regulatory approval is maintained, and if results are comparable with previous versions. *
3. Usability and integration	3.1. How can the application be integrated into your clinical workflow? Consider integration with your information technology (IT) platform, check for compliance with ISO usability standards, consider issues related to practical management of the software 3.2. How exactly does the application impact the workflow? Identify modifications to bring to your current workflow, identify roles in the new workflow (physicians and non-physicians) 3.3. What are the requirements in terms of information technology (IT) infrastructure? Consider on-premise vs. cloud solutions. Identify requirements in terms of hardware and network performance, consider network security issues 3.4. Interoperability - How can the data be exported for research and other purposes? Check whether the export formats are suitable 3.5. Will the data be accessible to non-radiologists (referring physicians, patients)? Check whether the form of the output is suitable for communication with patients/referring physicians 3.6. Are the AI model's results interpretable? Check whether and which interpretability tools (i.e. visualization) are used
4. Regulatory and legal aspects	4.1. Does the AI application comply with the local medical device regulations? Check whether the manufacturer obtained regulatory approval from the country where the application will be used (CE, FDA, UKCA, MDSAP, or other local guidance), and for which risk class 4.2. Does the AI application comply with the data protection regulations? Check whether the manufacturer complies with local data protection regulations and provides contractual clauses protecting patient's data
5. Financial and support services considerations	5.1. What is the licensing model? Assess one-time fee vs. subscription models, total costs, scalability 5.2. How are user training and follow-up handled? Check whether training sessions are included and at which conditions further training can be obtained 5.3. How is the maintenance of the product ensured? Check whether regular maintenance is included, assess the procedure during downtime and for repair 5.4. How will potential malfunctions or erroneous results be handled? Assess the procedure in the event of malfunction and post market surveillance and follow-up

* Note that at the time of writing of these guidelines, no adaptive AI application exists on the market.



1.1. What problem is the application intended to solve, and who is the application designed for?

Define the scope of application; end-users; research vs. clinical use; usage as double reader, triage, other; outputs (diagnosis, prognosis, quantitative data, other), indications and contra-indications

1.2. What are the potential benefits, and for whom?

Consider benefits for patients, radiologists/referring clinicians, institution, society

1.3. What are the risks associated with the use of the AI system?

Consider risks of misdiagnosis (including legal costs), of negative impact on workflow, of negative impact on quality of training

5.1. What is the licensing model?

Assess one-time fee vs. subscription models, total costs, scalability

5.2. How are user training and follow-up handled?

Check whether training sessions are included and at which conditions further training can be obtained

5.3. How is the maintenance of the product ensured?

Check whether regular maintenance is included, assess the procedure during downtime and for repair

5.4. How will potential malfunctions or erroneous results be handled?

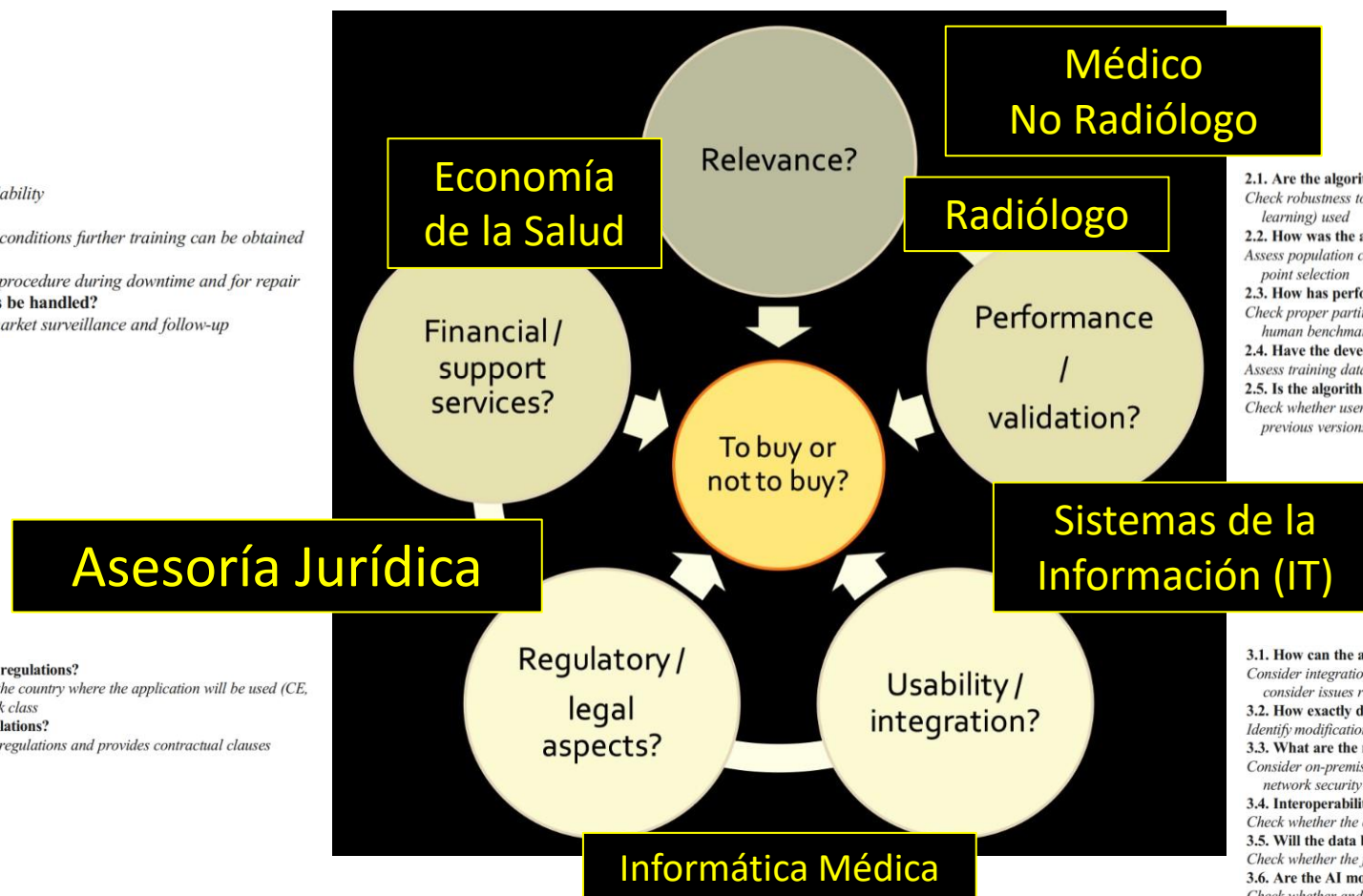
Assess the procedure in the event of malfunction and post market surveillance and follow-up

4.1. Does the AI application comply with the local medical device regulations?

Check whether the manufacturer obtained regulatory approval from the country where the application will be used (CE, FDA, UKCA, MDSAP, or other local guidance), and for which risk class

4.2. Does the AI application comply with the data protection regulations?

Check whether the manufacturer complies with local data protection regulations and provides contractual clauses protecting patient's data



2.1. Are the algorithm's design specifications clear?

Check robustness to variability of acquisition parameters; identify features (radiomics) or network architecture (deep learning) used

2.2. How was the algorithm trained?

Assess population characteristics and acquisition techniques used, labeling process, confounding factors, and operating point selection

2.3. How has performance been evaluated?

Check proper partitioning of training/validation/testing data, representativeness and open availability of data. Assess human benchmarks, application scope during evaluation, source of clinical validation

2.4. Have the developers identified and accounted for potential sources of bias in their algorithm?

Assess training data collection, bias evaluation, stratification analyses

2.5. Is the algorithm fixed or adapting as new data comes in?

Check whether user feedback is incorporated, if regulatory approval is maintained, and if results are comparable with previous versions. *

3.1. How can the application be integrated into your clinical workflow?

Consider integration with your information technology (IT) platform, check for compliance with ISO usability standards, consider issues related to practical management of the software

3.2. How exactly does the application impact the workflow?

Identify modifications to bring to your current workflow, identify roles in the new workflow (physicians and non-physicians)

3.3. What are the requirements in terms of information technology (IT) infrastructure?

Consider on-premise vs. cloud solutions. Identify requirements in terms of hardware and network performance, consider network security issues

3.4. Interoperability - How can the data be exported for research and other purposes?

Check whether the export formats are suitable

Check whether the form of the output is suitable for communication with patients/referring physicians

Check whether and which interpretability tools (i.e. visualization) are used

To buy or not to buy—evaluating commercial AI solutions in radiology (the ECLAIR guidelines)

Patrick Omoumi¹  • Alexis Ducaro
Fanny Louvet-de Verchère⁵ • Danie

Table 2 Top 10 questions to con

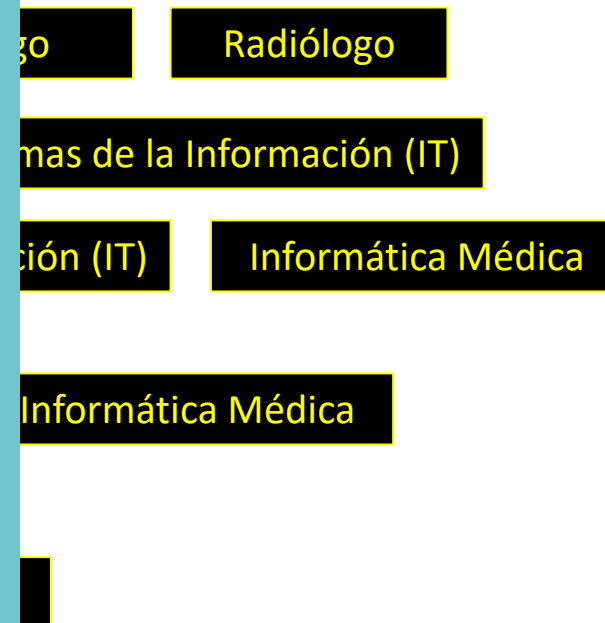
1. What problem is the application application designed for?
2. What are the potential benefits a
3. Has the algorithm been rigorous
4. How can the application be integ is the solution interoperable with
5. What are the IT infrastructure re
6. Does the application conform to data protection regulations of the regulation does it conform to?
7. Have return on investment (RoI
8. How is the maintenance of the p
9. How are user training and follow
10. How will potential malfunction

¿Se puede integrar?

¿Cumple la regulación?

¿Es ético?

¿Es coste-eficaz?







ACTUALIZACIÓN

La regulación legal de la inteligencia artificial en la Unión Europea: guía práctica para radiólogos

Á. Morales Santos^{a,*}, S. Lojo Lendoiro^b, M. Rovira Cañellas^c y P. Valdés Solís^d

Nivel de Riesgo	Clasificación	Descripción o posible efecto adverso
Alto Riesgo	III	• Muerte • O deterioro irreversible del estado de salud
Riesgo Medio - alto	IIb	• Grave deterioro del estado de salud • O un intervencionismo quirúrgico
Riesgo Medio	Ila	• Brinde información que se utilice para tomar decisiones con fines diagnósticos o terapéuticos




Nota: considerar el peor escenario posible: sin tener en cuenta su probabilidad

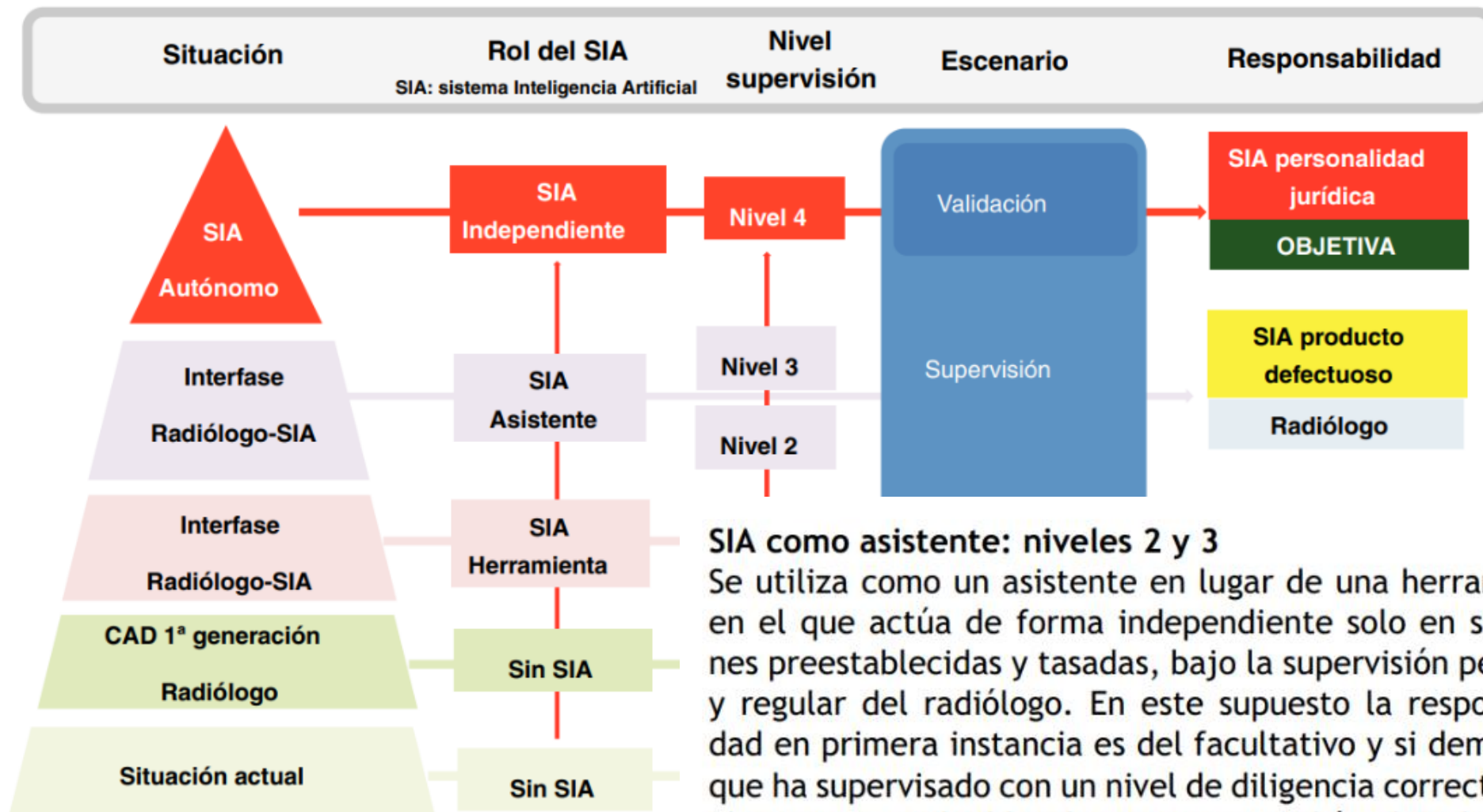
Figura 2 Clasificación niveles de riesgo de los SIA como producto sanitario.

En la actualidad la **Ley-IA-UE no contempla** la posibilidad que los **SIA de alto riesgo sean autónomos**.

Por tanto, la **no supervisión por parte del radiólogo** sería una **conducta ilegal**.

El rol de la **supervisión** debe ser **desplegado durante todo el ciclo de vida en el que pueda actuar el radiólogo**: entrenamiento, validación, revisión, corrección y verificación de resultados.





SIA como asistente: niveles 2 y 3

Se utiliza como un asistente en lugar de una herramienta, en el que actúa de forma independiente solo en situaciones preestablecidas y tasadas, bajo la supervisión periódica y regular del radiólogo. En este supuesto la responsabilidad en primera instancia es del facultativo y si demostrara que ha supervisado con un nivel de diligencia correcto y que el error es atribuible al sistema se podría abrir la vía de responsabilidad por productos defectuosos⁵⁰.

Figura 7 Conexión de los niveles



ERROR por COMISIÓN-ACCIÓN

S.I.A. emite una recomendación CORRECTA de:	HALLAZGO REAL	RADIÓLOGO	INFORMA	RESPONSABILIDAD RADIÓLOGO	COMENTARIO ACTUACIÓN del RADIÓLOGO
Verdadero +	Patológico	ACEPTA	Patología	NO	✓ Actuación correcta
		NO ACEPTA	Normal	SI	■ No acepta la recomendación, discrepa del SIA. ■ Modifica activamente su propuesta ■ Debe justificar en el informe la discrepancia
Verdadero -	No Patológico	NO ACEPTA	Patología	SI	■ Prueba documental (SIA como testigo experto)
		ACEPTA	Normal	NO	✓ Actuación correcta

ERROR por OMISIÓN

S.I.A emite una recomendación INCORRECTA de:	HALLAZGO REAL	RADIÓLOGO	INFORMA	RESPONSABILIDAD RADIÓLOGO	ACTUACION del RADIÓLOGO
Falso +	No Patológico	NO ACEPTA	Normal	NO	✓ Actuación correcta
		ACEPTA	Patología	SI	■ No corrige el error - Supervisa el estudio
Falso -	Patológico	ACEPTA	Normal	SI	
		NO ACEPTA	Patología	NO	✓ Actuación correcta

ERROR por COMISIÓN por OMISIÓN ☒ puede generar responsabilidad penal

S.I.A. emite una recomendación INCORRECTA de:	HALLAZGO REAL	RADIÓLOGO	INFORMA	RESPONSABILIDAD RADIÓLOGO	COMENTARIO
Falso -	Patológico	ACEPTA	Normal	SI	■ El radiólogo no corrige el error ■ No supervisión ■ Violación de la obligación legal de supervisión

Figura 8 Escenarios riesgo legal error diagnóstico del binomio radiólogo-SIA.



ERROR por COMISIÓN-ACCIÓN					
S.I.A. emite una recomendación CORRECTA de:	HALLAZGO REAL	RADIOLOGO	INFORMA	RESPONSABILIDAD RADIÓLOGO	COMENTARIO ACTUACION del RADIOLOGO
Verdadero +	Patológico	ACEPTA	Patología	NO	√ Actuación correcta
		NO ACEPTA	Normal	SI	■ No acepta la recomendación, discrepa del SIA. ■ Modifica activamente su propuesta ■ Debe justificar en el informe la discrepancia
Verdadero -	No Patológico	NO ACEPTA	Patología	SI	■ Prueba documental (SIA como testigo experto)
		ACEPTA	Normal	NO	√ Actuación correcta
ERROR por OMISIÓN					
S.I.A emite una recomendación INCORRECTA de:	HALLAZGO REAL	RADIÓLOGO	INFORMA	RESPONSABILIDAD RADIÓLOGO	ACTUACION del RADIÓLOGO
Falso +	No Patológico	NO ACEPTA	Normal	NO	√ Actuación correcta
		ACEPTA	Patología	SI	■ No corrige el error - Supervisa el estudio
Falso -	Patológico	ACEPTA	Normal	SI	
		NO ACEPTA	Patología	NO	√ Actuación correcta
ERROR por COMISIÓN por OMISIÓN ☒ puede generar responsabilidad penal					
S.I.A. emite una recomendación INCORRECTA de:	HALLAZGO REAL	RADIÓLOGO	INFORMA	RESPONSABILIDAD RADIÓLOGO	COMENTARIO
Falso -	Patológico	ACEPTA	Normal	SI	■ El radiólogo no corrige el error ■ No supervisión ■ Violación de la obligación legal de supervisión

Figura 8 Escenarios riesgo legal error diagnóstico del binomio radiólogo-SIA.



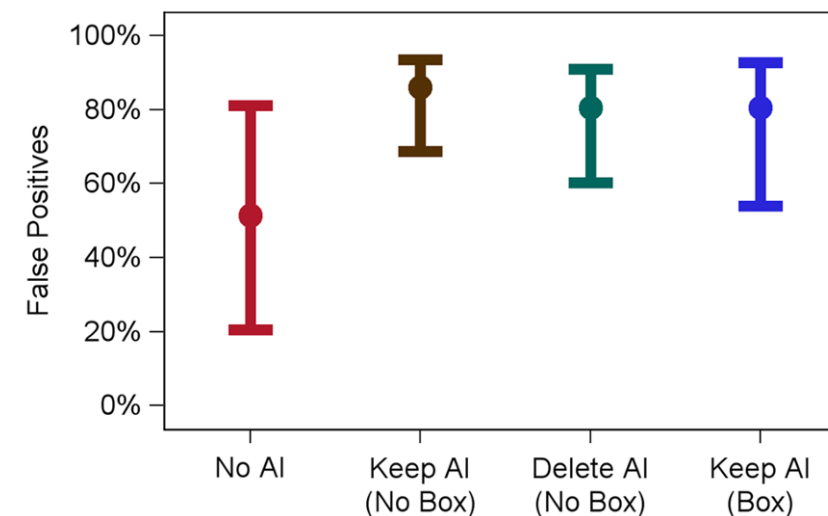
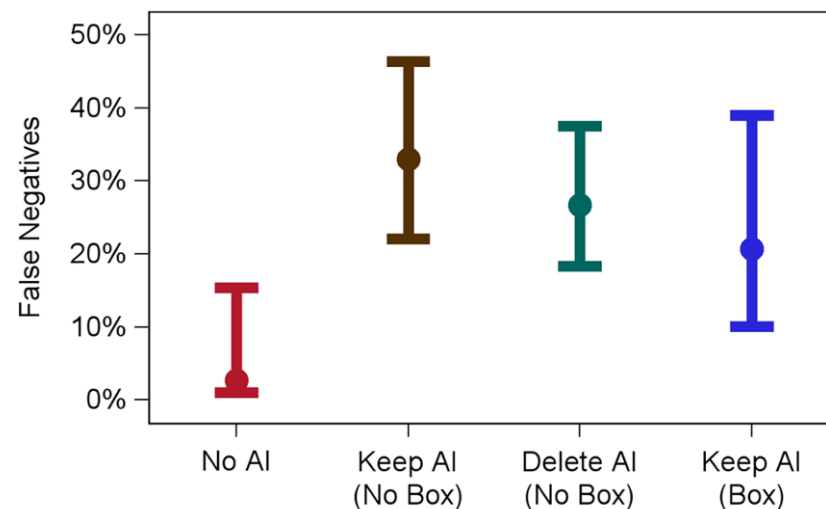


European Radiology (2023) 33:8263–8269
<https://doi.org/10.1007/s00330-023-09747-1>

CHEST

Can incorrect artificial intelligence (AI) results impact radiologists, and if so, what can we do about it? A multi-reader pilot study of lung cancer detection with chest radiography

Michael H. Bernstein^{1,2,3} · Michael K. Atalay^{1,3} · Elizabeth H. Dibble¹ · Aaron W. P. Maxwell^{1,3} · Adib R. Karam¹ · Saurabh Agarwal¹ · Robert C. Ward¹ · Terrance T. Healey¹ · Grayson L. Baird^{1,2,3}



Radiology:Artificial Intelligence

Assistive AI in Lung Cancer Screening: A Retrospective Multinational Study in the United States and Japan

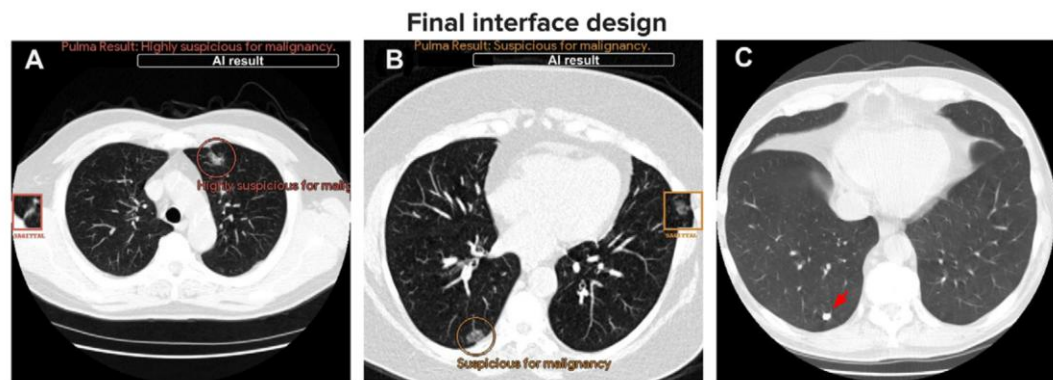


Table 2: Level of Suspicion–based Area Under the Receiver Operating Characteristic Curve Results

Study	U.S.-based Reader Study	Japan-based Reader Study
Average assisted LoS AUC	0.72 (0.66, 0.77)	0.96 (0.93, 0.97)
Average unassisted LoS AUC	0.70 (0.64, 0.75)	0.93 (0.91, 0.96)
Delta	0.025 (0.001, 0.045) <i>P</i> = .02	0.025 (-0.035, 0.081) <i>P</i> = .18
Stand-alone AI model AUC	0.75 (0.70, 0.81)	0.89 (0.78, 0.97)

Note.—Unless otherwise noted, data are the areas under the receiver operating characteristic curve (AUC) or the deltas with 95% CIs in parentheses. AI = artificial intelligence, LoS = level of suspicion.

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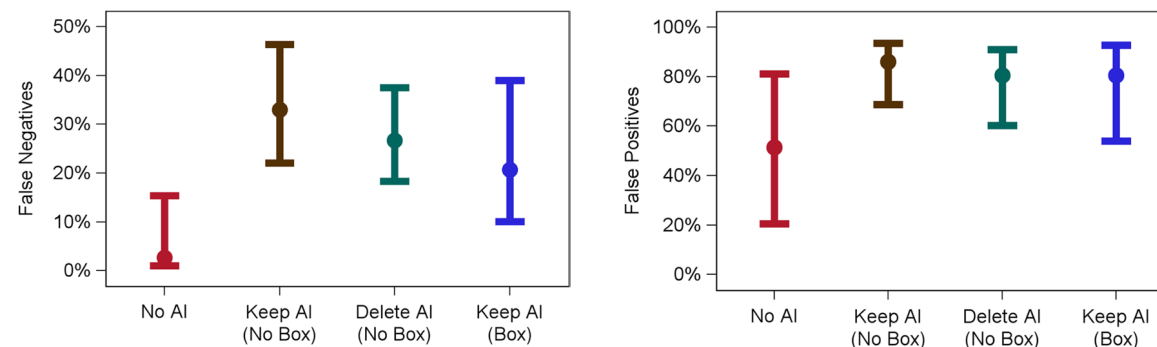
European Radiology
 ESIR European Society of Radiology

CHEST



Can incorrect artificial intelligence (AI) results impact radiologists, and if so, what can we do about it? A multi-reader pilot study of lung cancer detection with chest radiography

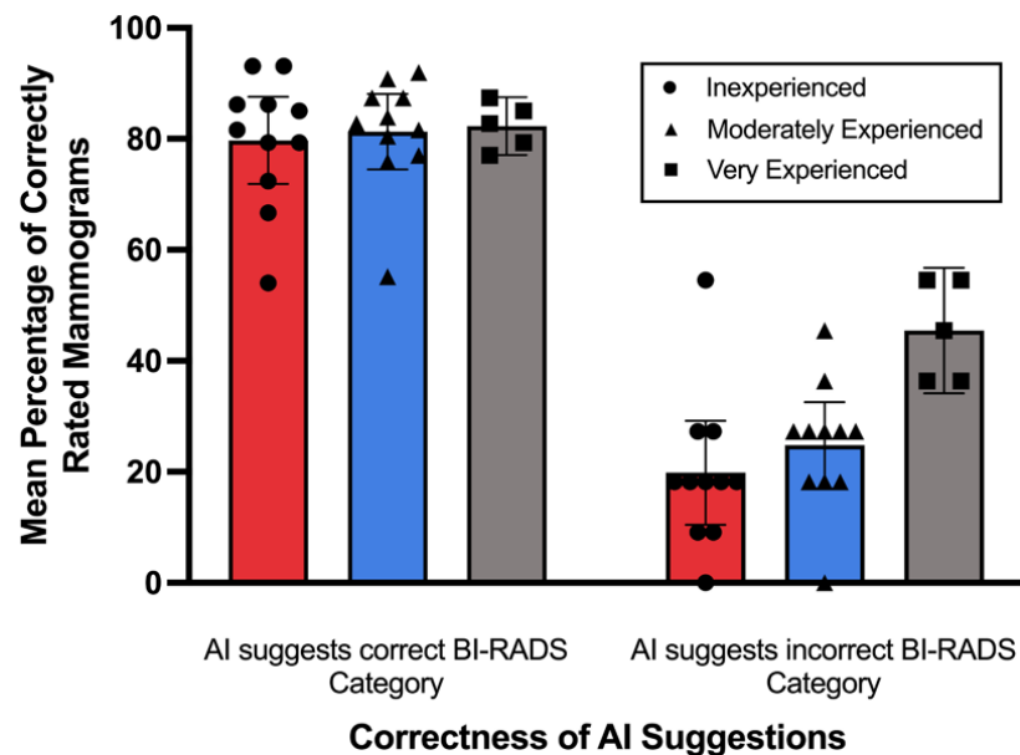
Michael H. Bernstein^{1,2,3} · Michael K. Atalay^{1,3} · Elizabeth H. Dibble¹ · Aaron W. P. Maxwell^{1,3} · Adib R. Karam¹ · Saurabh Agarwal¹ · Robert C. Ward¹ · Terrance T. Healey¹ · Grayson L. Baird^{1,2,3}



Automation Bias in Mammography: The Impact of Artificial Intelligence BI-RADS Suggestions on Reader Performance

Thomas Dratsch, MD* • Xue Chen, MD* • Mohammad Rezazade Mebrizi, PhD • Roman Kloeckner, MD •
Aline Mähringer-Kunz, MD • Michael Püsken, MD • Bettina Baeßler, MD • Stephanie Sauer, MD •
David Maintz, MD • Daniel Pinto dos Santos, MD

Radiology 2023; 307(4):e222176

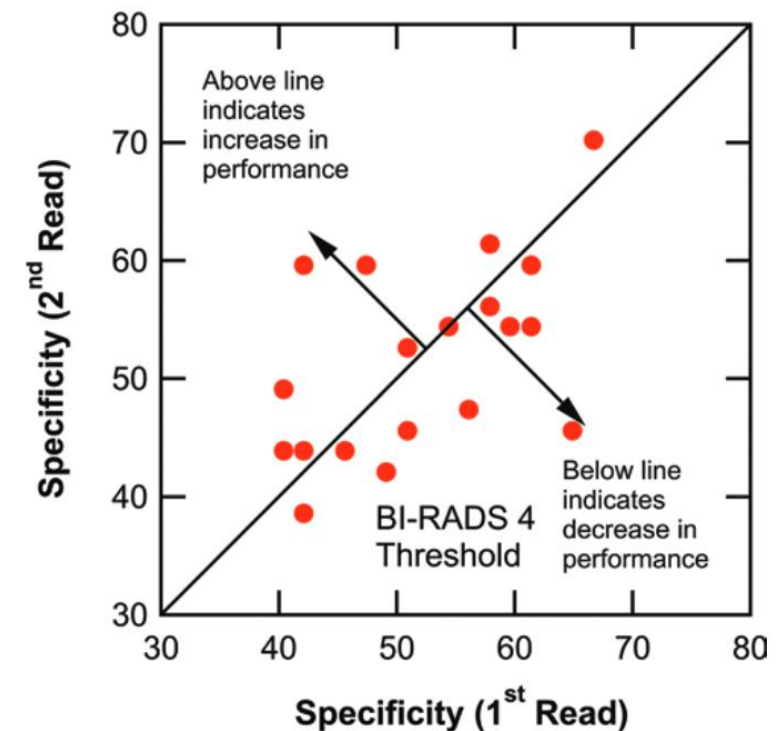
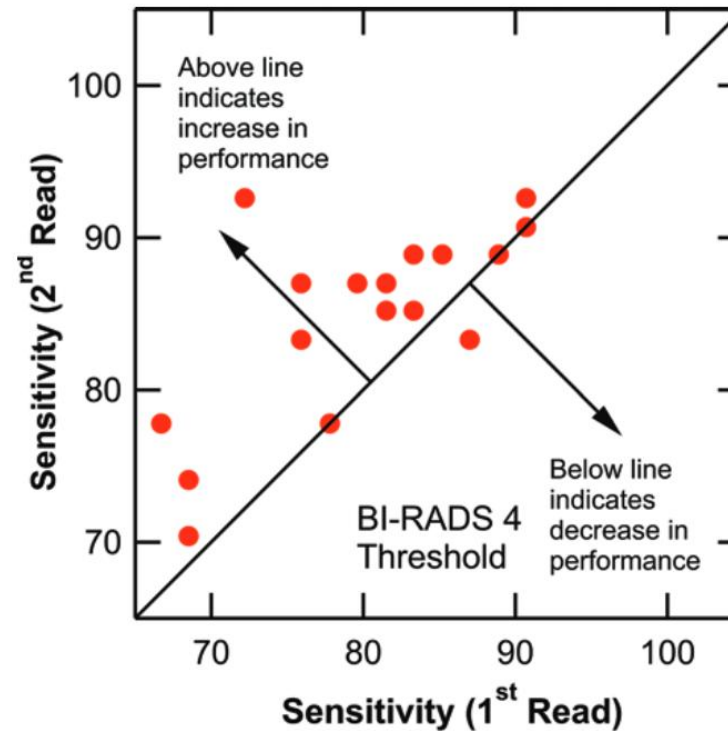


Artificial Intelligence Applied to Breast MRI for Improved Diagnosis

Radiology 2021; 298:38–46

Yulei Jiang, PhD • Alexandra V. Edwards, MA • Gillian M. Newstead, MD

The purpose of this retrospective reader study was to compare radiologist performance in the task of distinguishing cancers from noncancers on breast MRI scans.





CONCLUSION

Necesitamos una visión crítica/personal sobre
INTELIGENCIA ARTIFICIAL en RADIOLOGÍA
de cada uno de vosotros...



A wide-angle photograph of a coastal landscape. In the foreground, the turquoise sea meets a sandy beach. The water is clear, showing the seabed. In the background, there are large, brown, rocky cliffs under a blue sky with some clouds.

SIN CONFLICTOS DE INTERÉS

Sigo disponible....

Parque Natural de Cabo de Gata-Níjar (Almería)