Εφαρμογές Τεχνητής Νοημοσύνης στην Υγεία: Προκλήσεις και Προοπτικές

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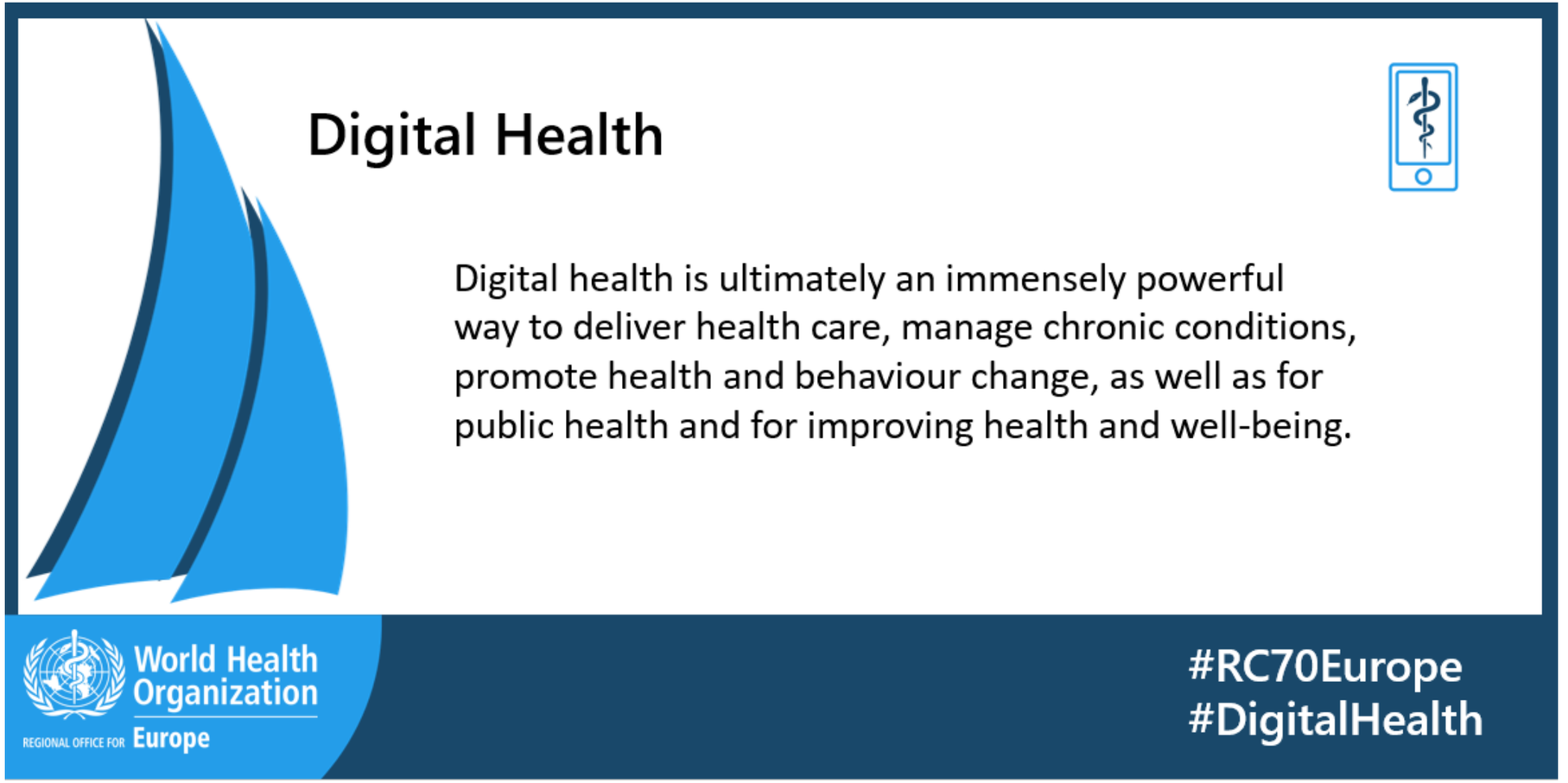
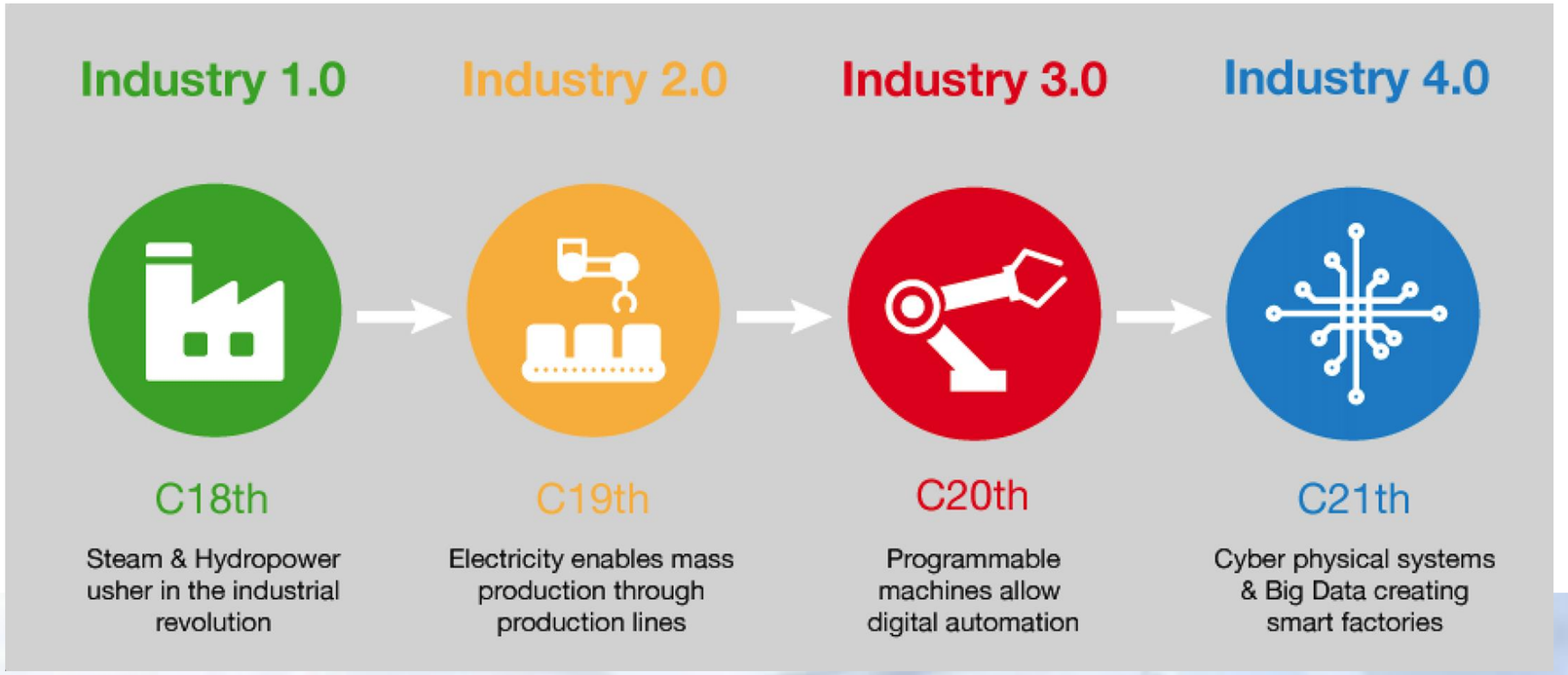
Ακαδημαϊκός Υπότροφος Ψηφιακής Υγείας,
Τμήμα Ιατρικής, ΠΘ

ΠΑΝΕΠΙΣΤΗΜΙΟ
ΘΕΣΣΑΛΙΑΣ

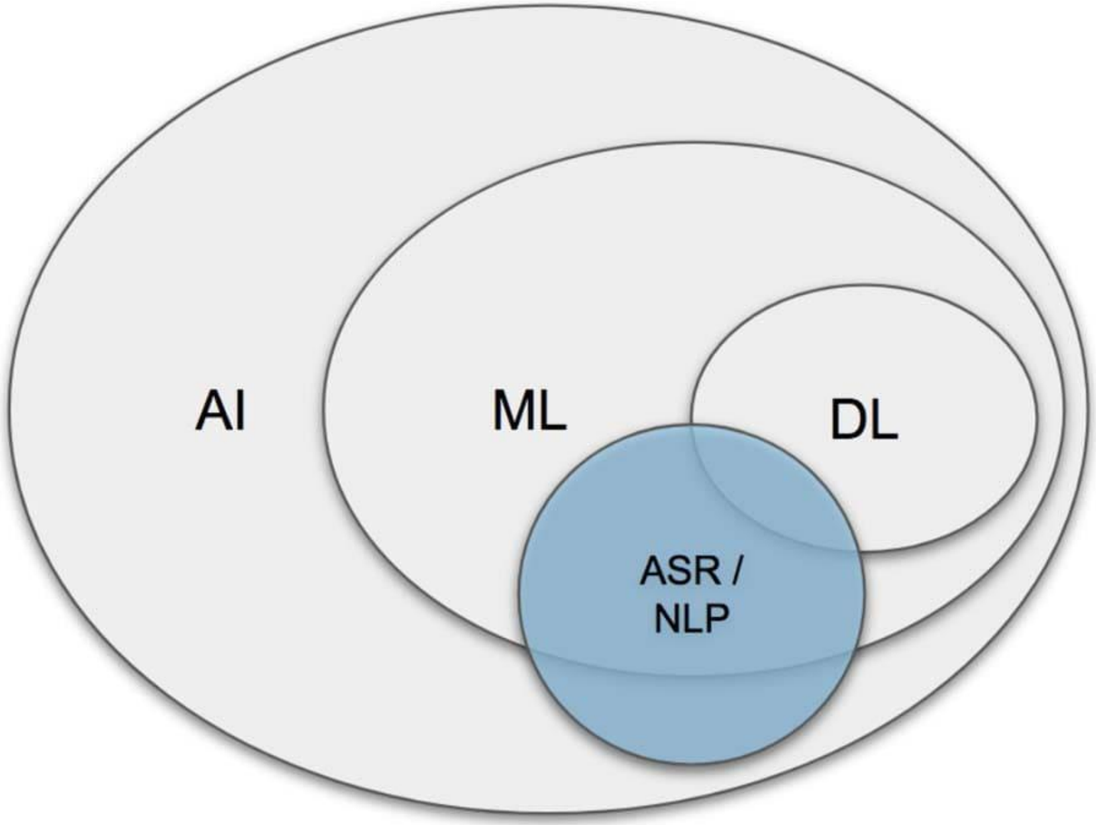
ΨΗΦΙΑΚΗ ΥΓΕΙΑ



4η Βιομηχανική Επανάσταση στην ΥΓΕΙΑ: IoT, Big Data, AI -Robots, 5G



AI



Artificial Intelligence (AI)

Machine Learning (ML)

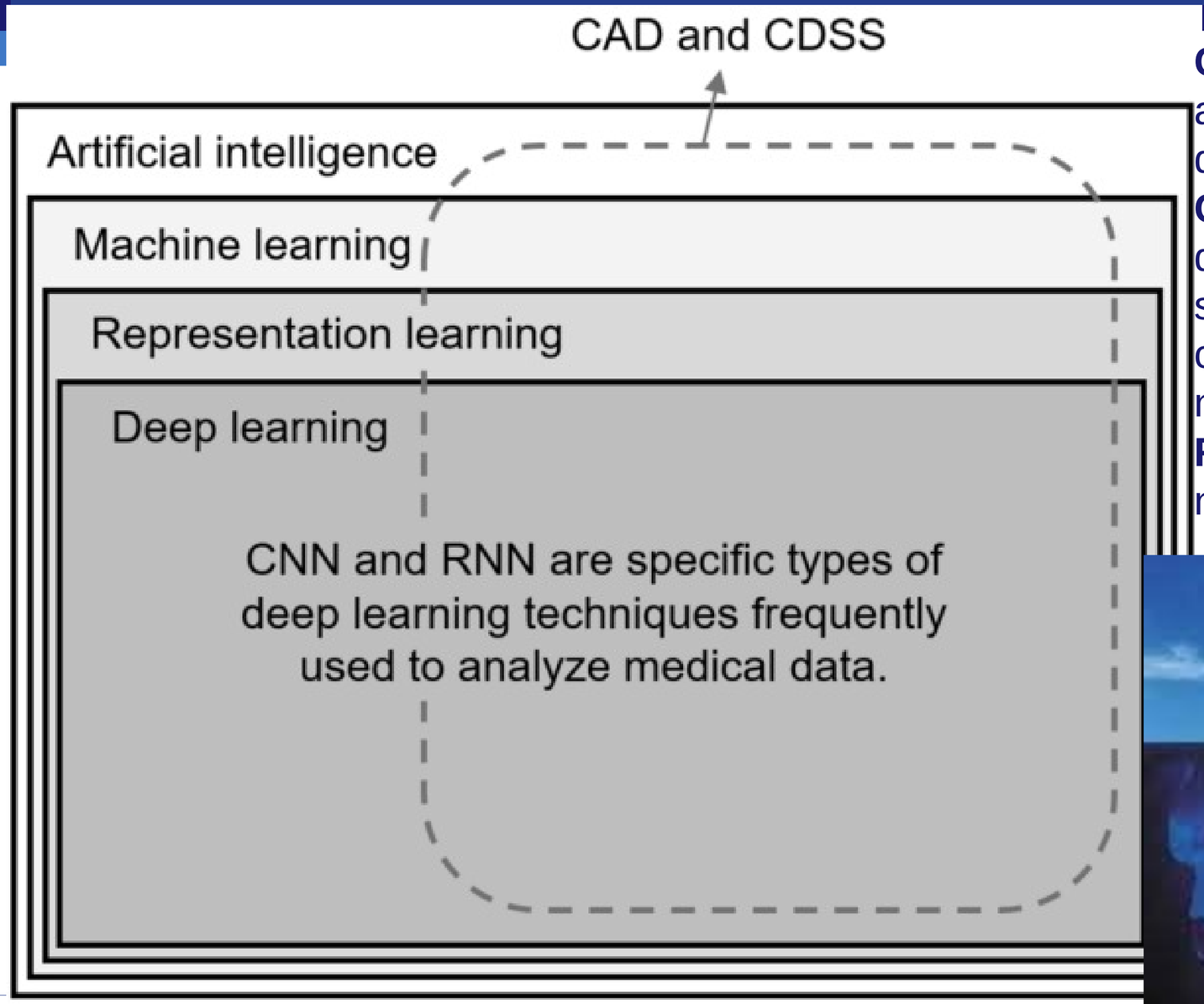
Deep Learning (DL)

Artificial Neural Networks (ANN)

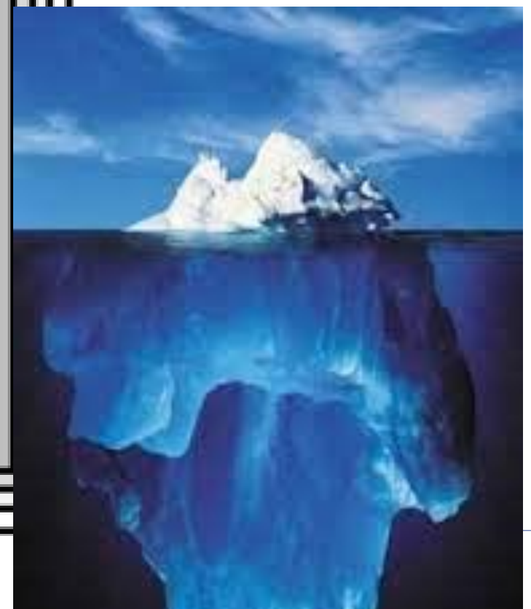
Natural Language Processing (NLP)

Automated Speech Recognition (ASR)

CAD and CDSS are the most common types of software tools in the application of AI in medicine.



CAD = computer-aided detection/diagnosis; **CDSS**= clinical decision support system; **CNN** = convolutional neural network; **RNN** = recurrent neural network.



ReferenceJ Educ Eval Health Prof. 2019; 16: 18.

3 Types of Artificial Intelligence

Artificial Narrow Intelligence (ANI)

Stage-1

Machine Learning

- Specialises in one area and solves one problem


Siri


Alexa


Cortana

Artificial General Intelligence (AGI)

Stage-2

Machine Intelligence

- Refers to a computer that is as smart as a human across the board

Artificial Super Intelligence (ASI)

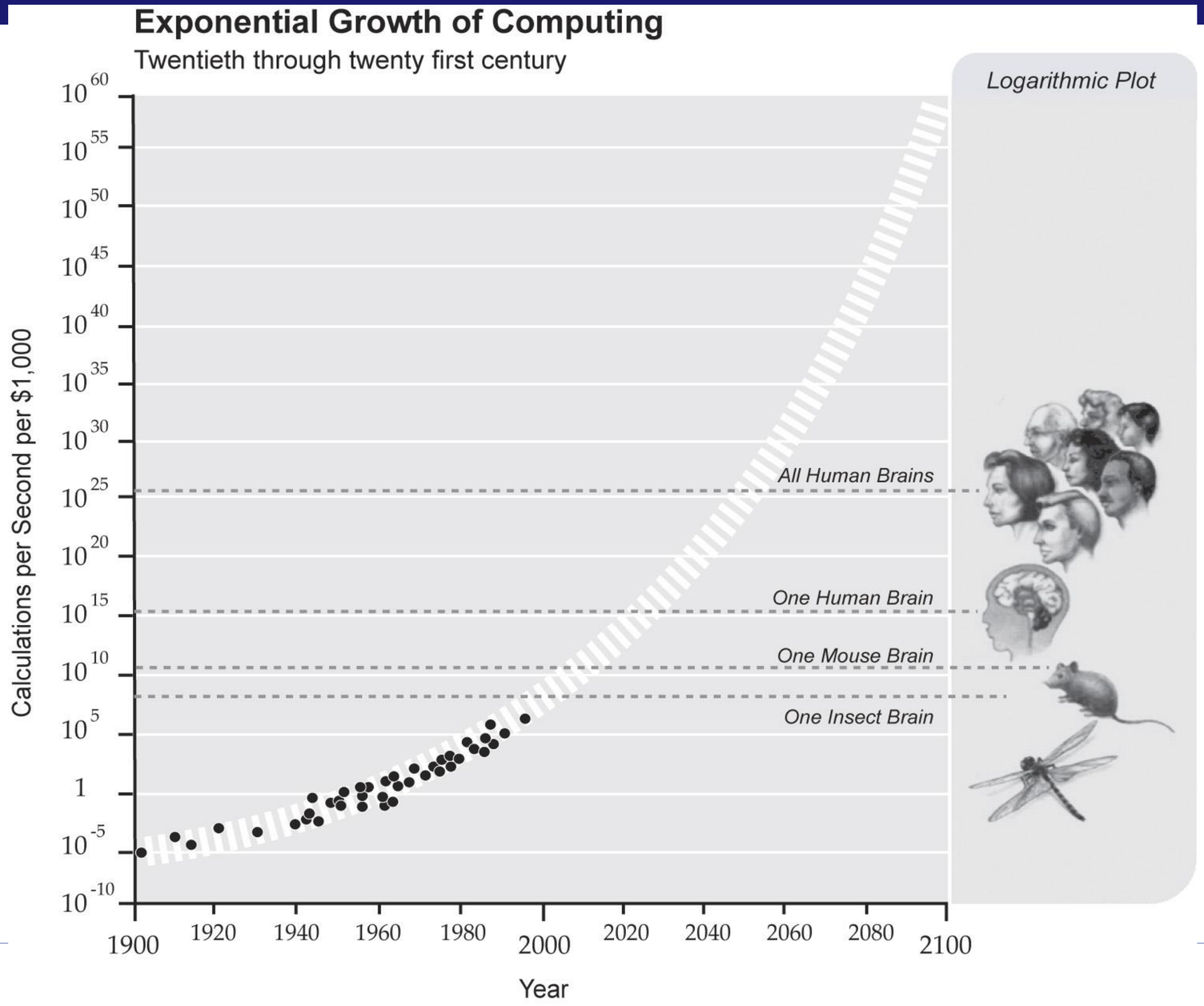
Stage-3

Machine Consciousness

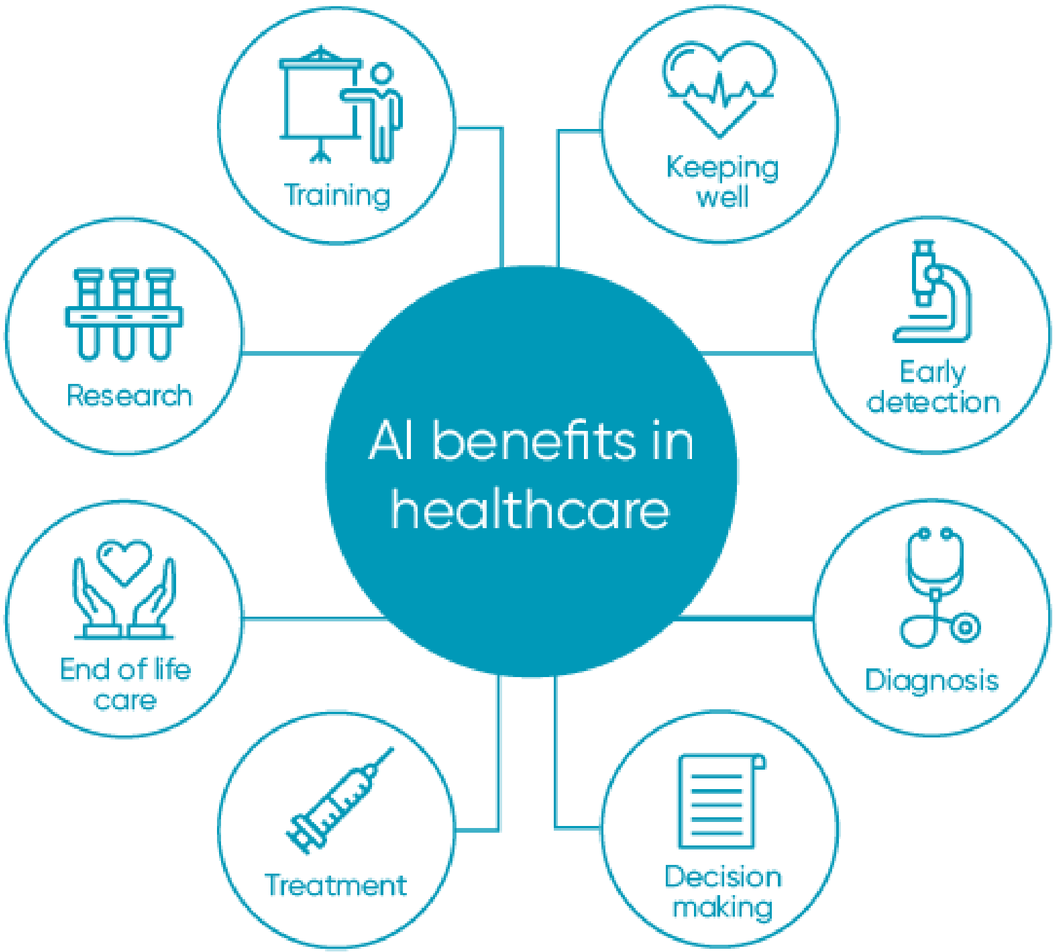
- An intellect that is much smarter than the best human brains in practically every field

Ref: What is Artificial Intelligence? By Vaishali Advani -Jul 15, 2020 greatlearning blog

Singularity point

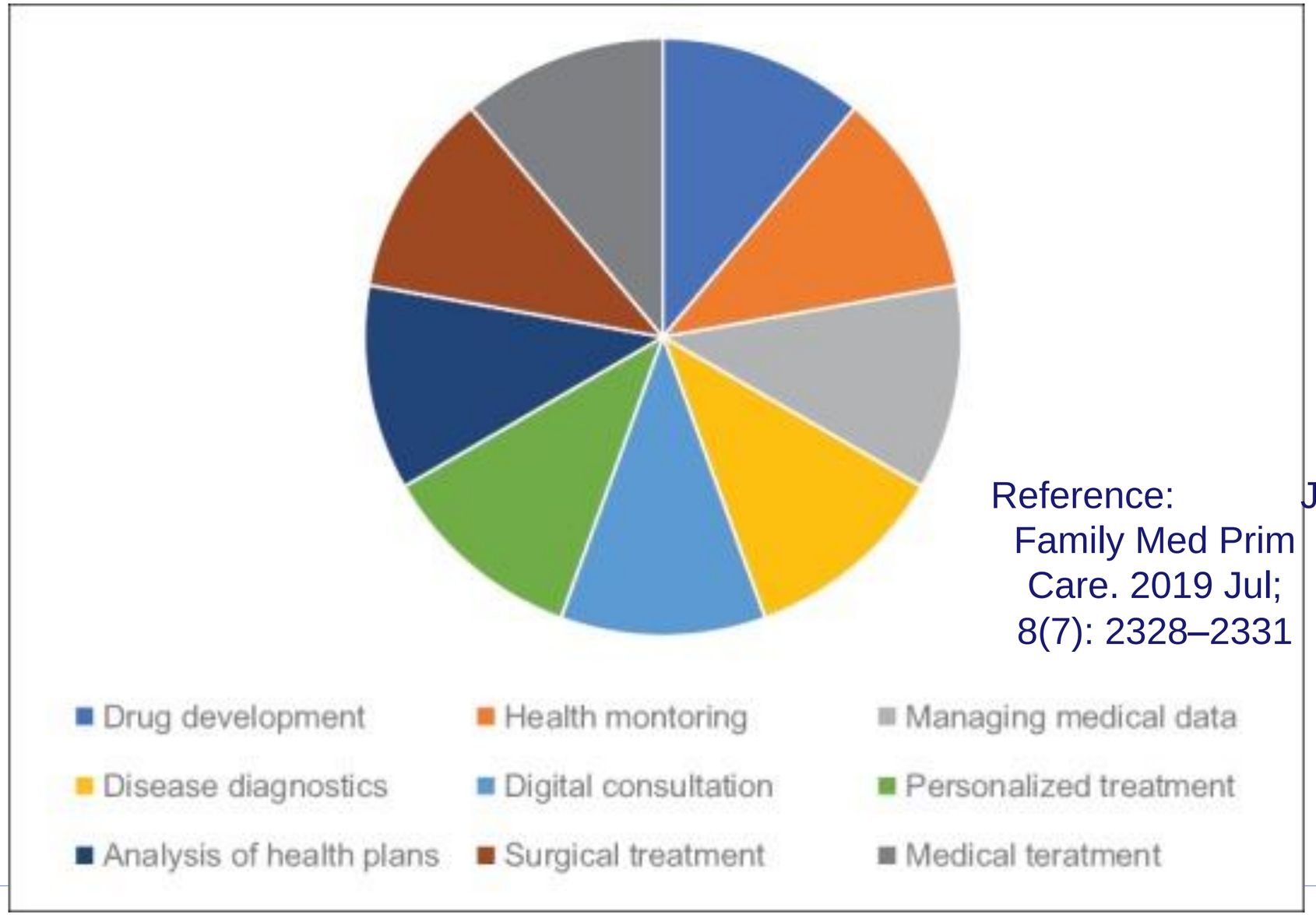


AI Benefits in HealthCare



https://www.ideagen.com/

Applications of artificial intelligence in health care



Reference: J Family Med Prim Care. 2019 Jul; 8(7): 2328–2331

ML specification in clinical decision making

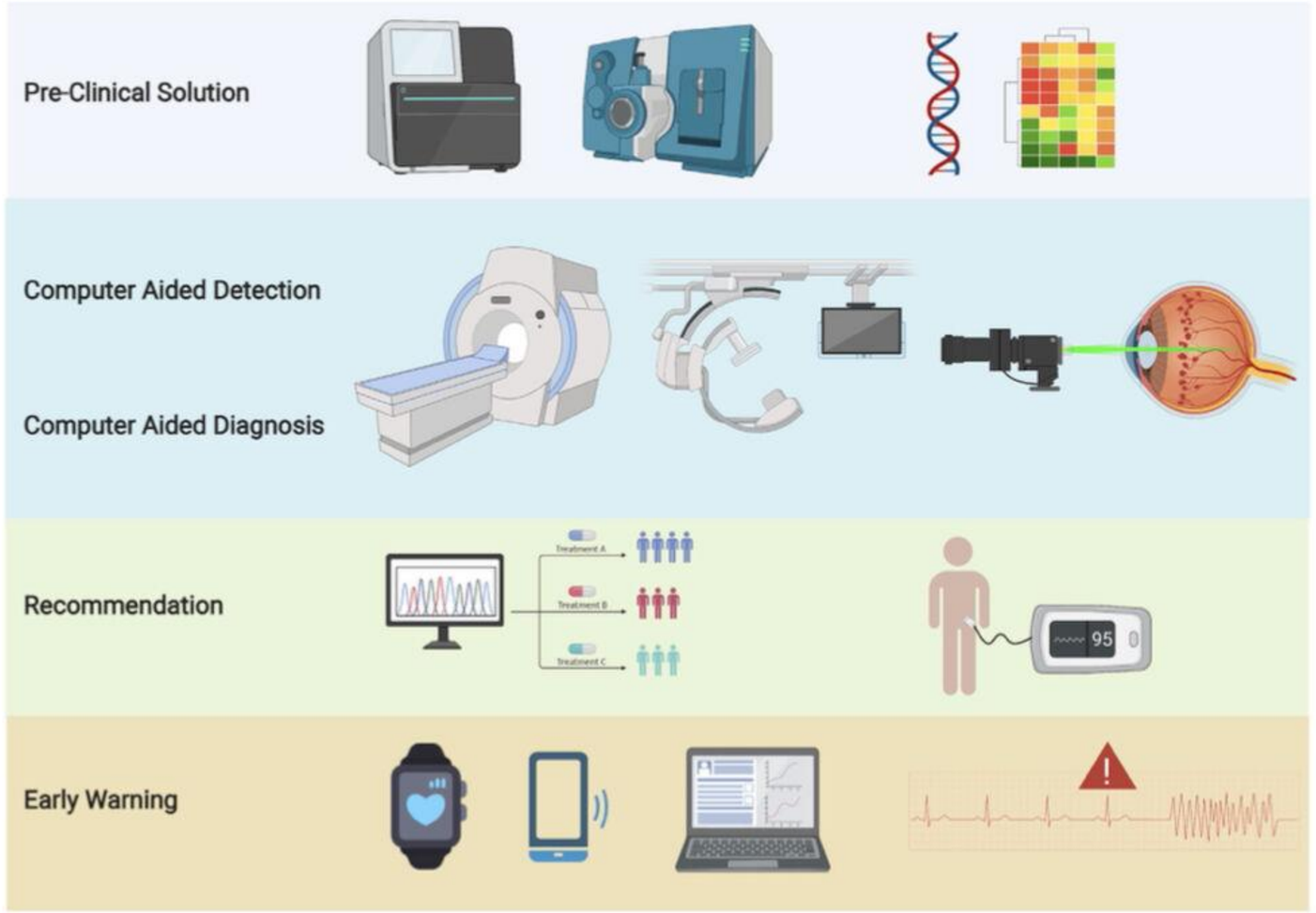
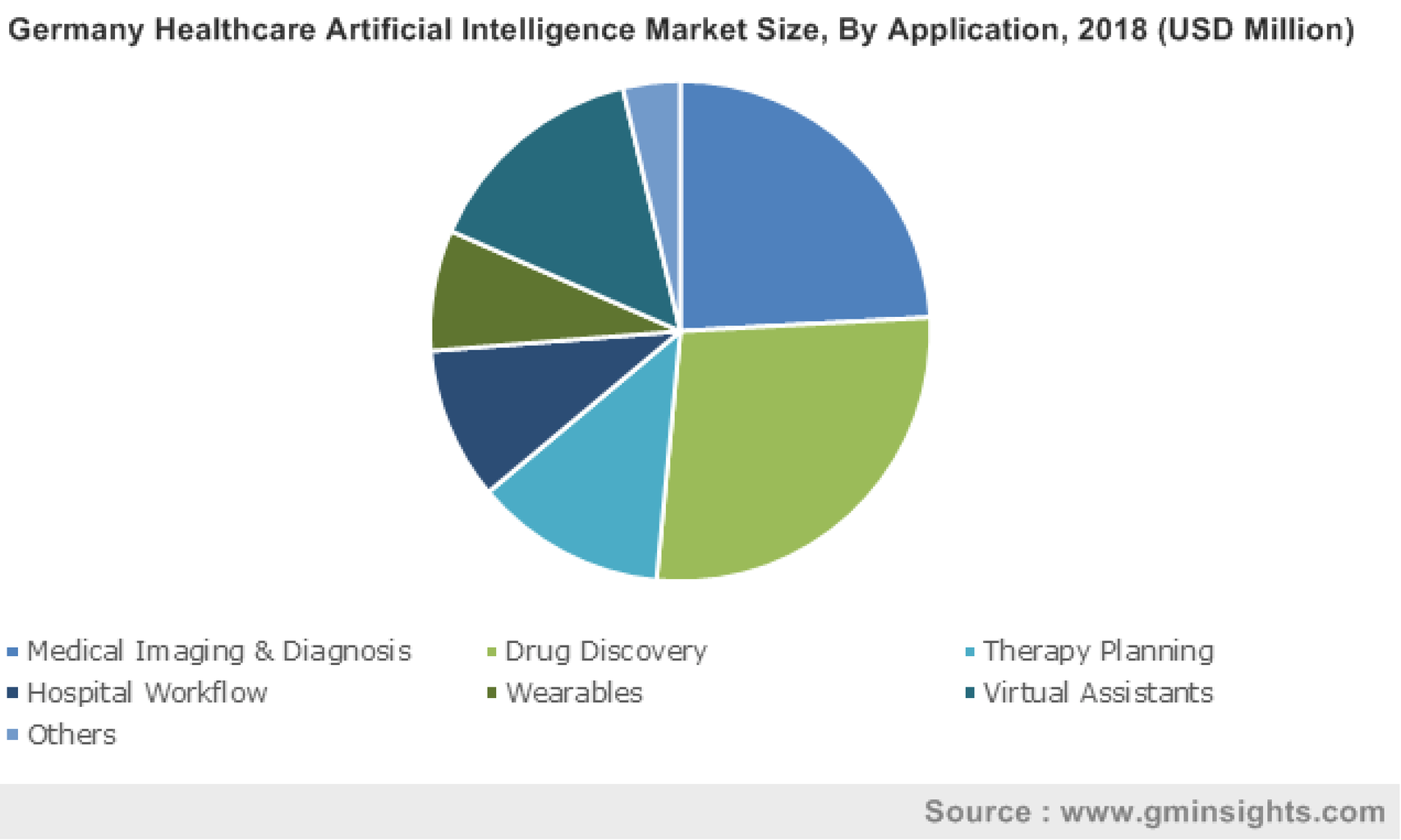


Figure 1. Graphical representation of ML specifications in clinical decision making

From top to bottom: DNA and metabolome sequencing devices for biomarker discovery for pre-clinical solutions; image acquisition techniques for CAD, such as magnet resonance imaging, X-ray, and retinal photography; precision medicine drug recommendation systems and a smart insulin recommendation pump; smart wearables and electronic health record surveillance providing early warning.

https://doi.org/10.1016/j.medj.2021.04.006

Use of various AI Healthcare applications varies



Ref : Global Market Insights. Healthcare Artificial Intelligence Market Share Growth Report 2019-2025

U.S. Healthcare Artificial Intelligence Market Size, By Application, 2013-2024 (USD Million)

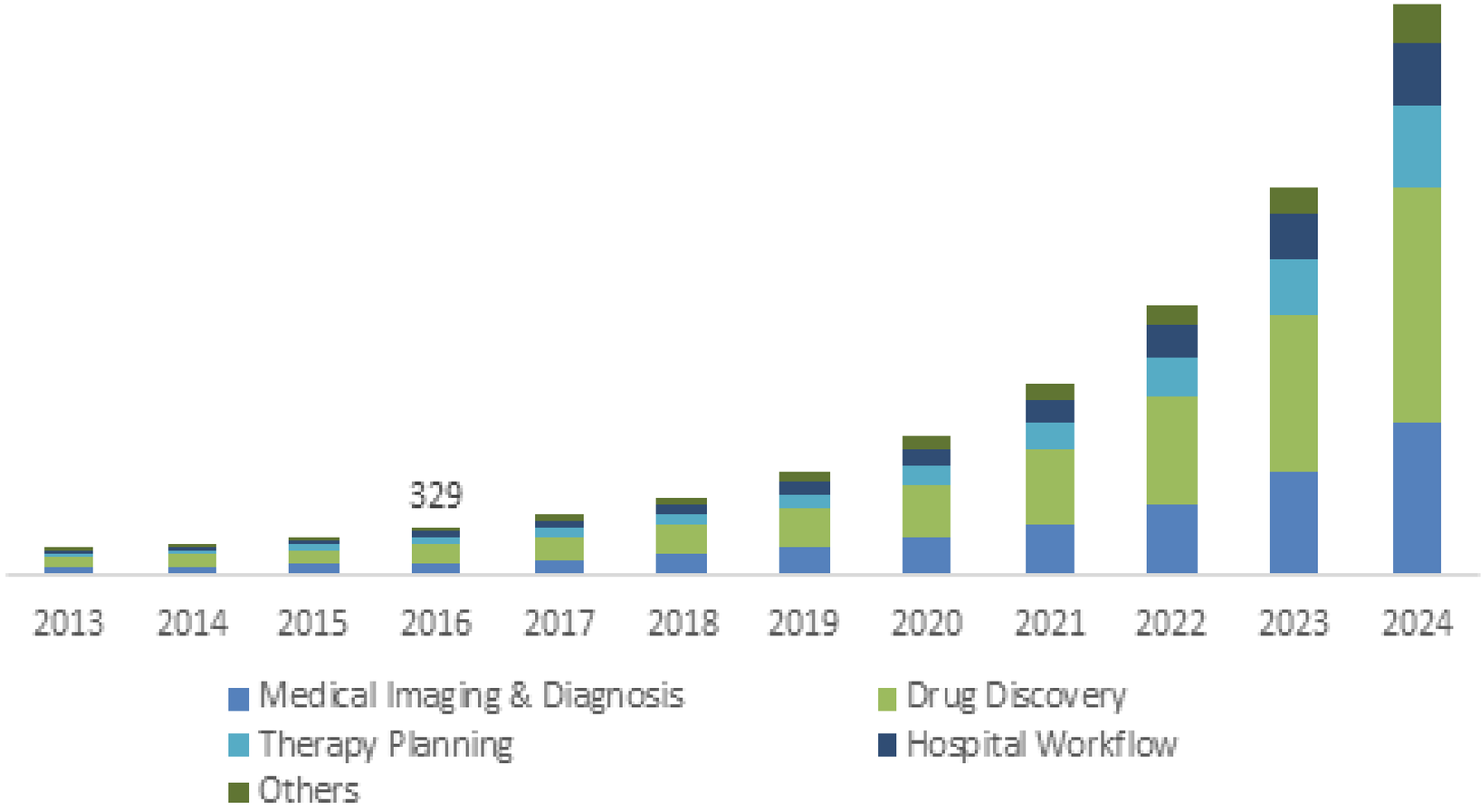
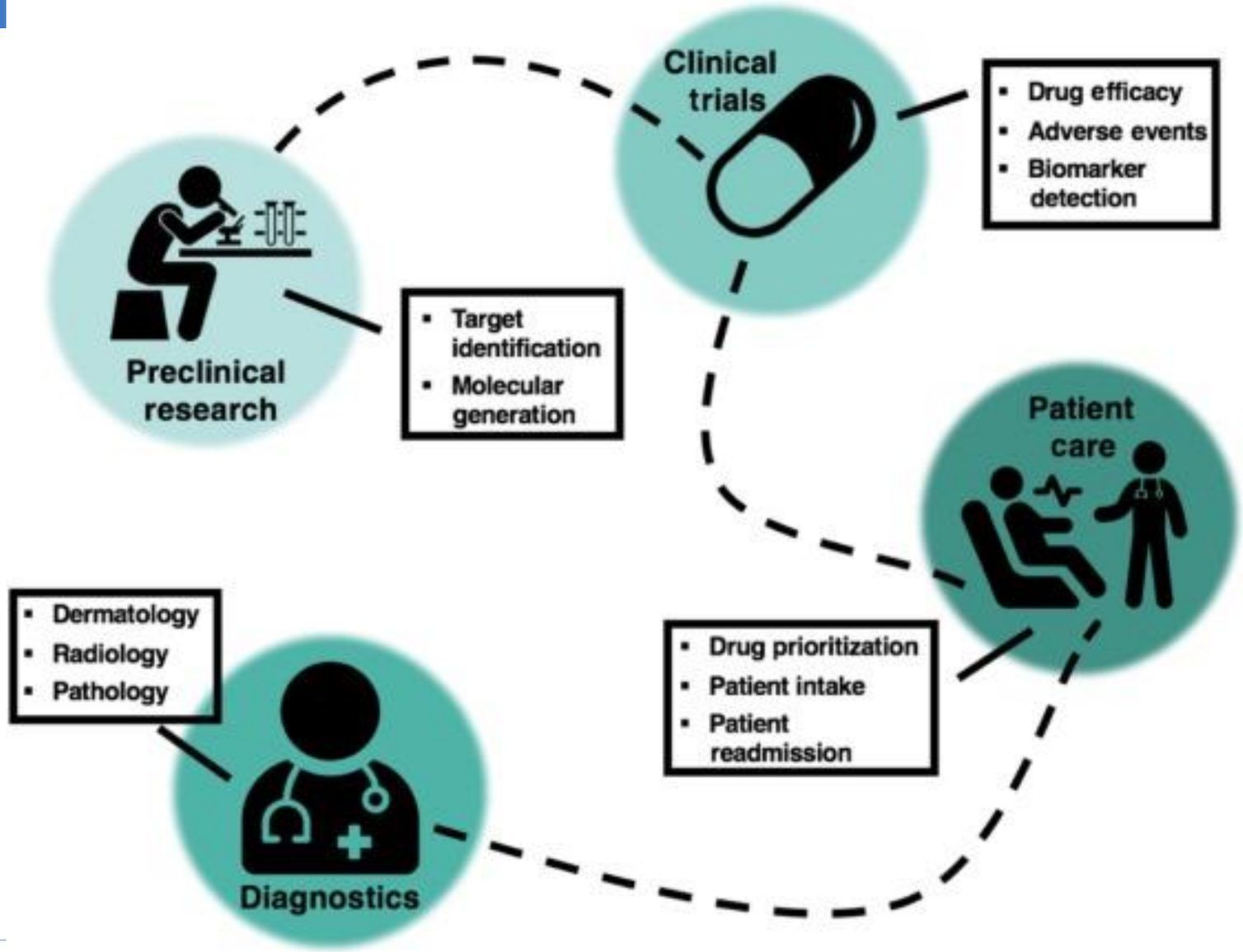


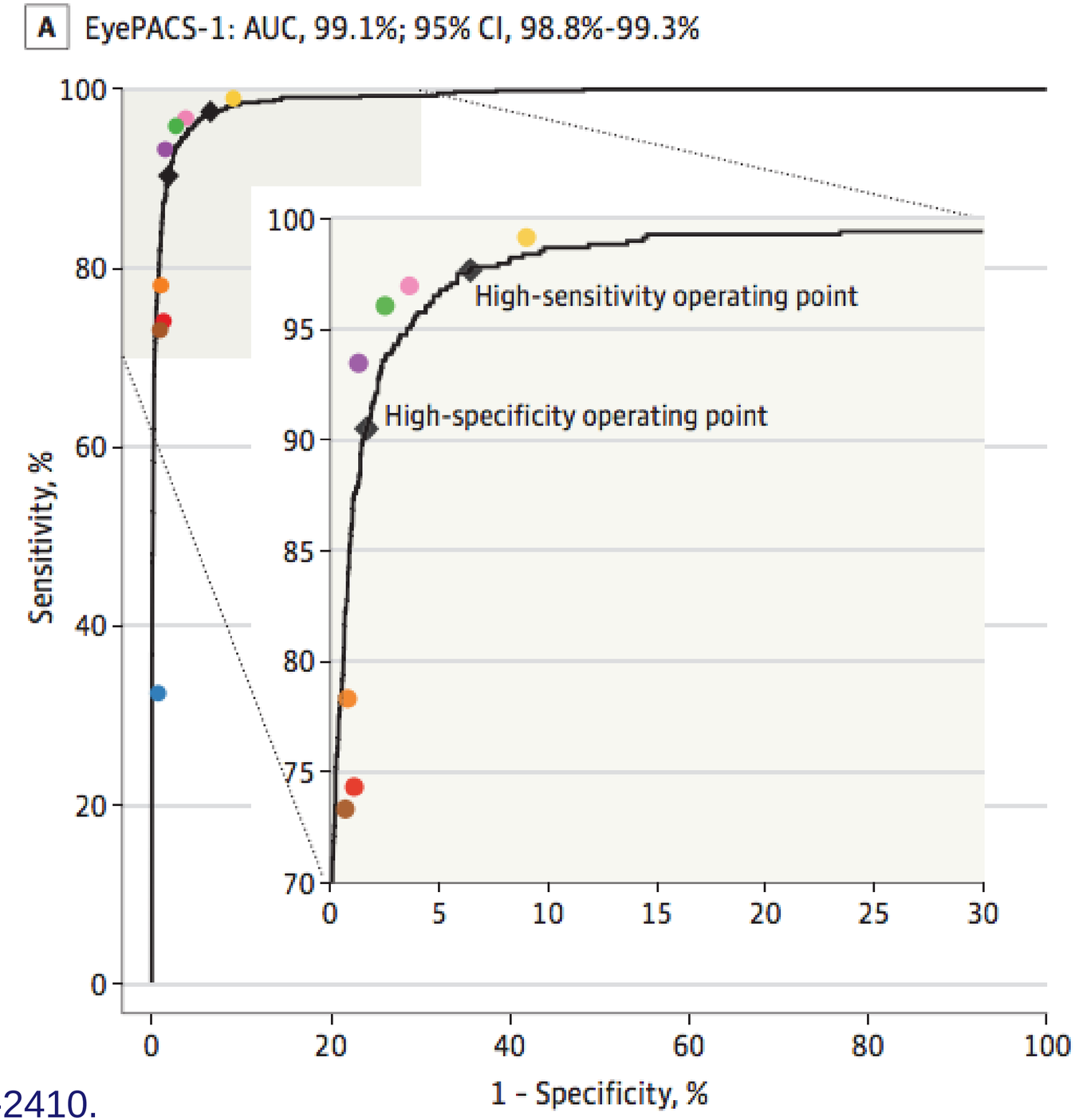
Photo Credit:: Global Market Insights. Healthcare Artificial Intelligence Market Share Growth Report 2019-2025

Artificial Intelligence (AI) Applications within the Healthcare Landscape.



Trends in Pharmacological Sciences

Google AI



Performance of the algorithm (black curve) & eight ophthalmologists (colored dots) for the presence of referable diabetic retinopathy (moderate or worse diabetic retinopathy or referable diabetic macular edema) on a validation set consisting of 9963 images. The black diamonds on the graph correspond to the sensitivity and specificity of the algorithm at the high sensitivity and high specificity operating points.

JAMA. 2016;316(22):2402-2410.

AI in routine health care

Artificial intelligence / Machine learning

Google's medical AI was super accurate in a lab. Real life was a different story.

If AI is really going to make a difference to patients we need to know how it works when real humans get their hands on it, in real situations.

MIT Technology Review

AI based Medical Devices

FDA NEWS RELEASE

FDA permits marketing of artificial intelligence-based device to detect certain diabetes-related eye problems

For Immediate Release:

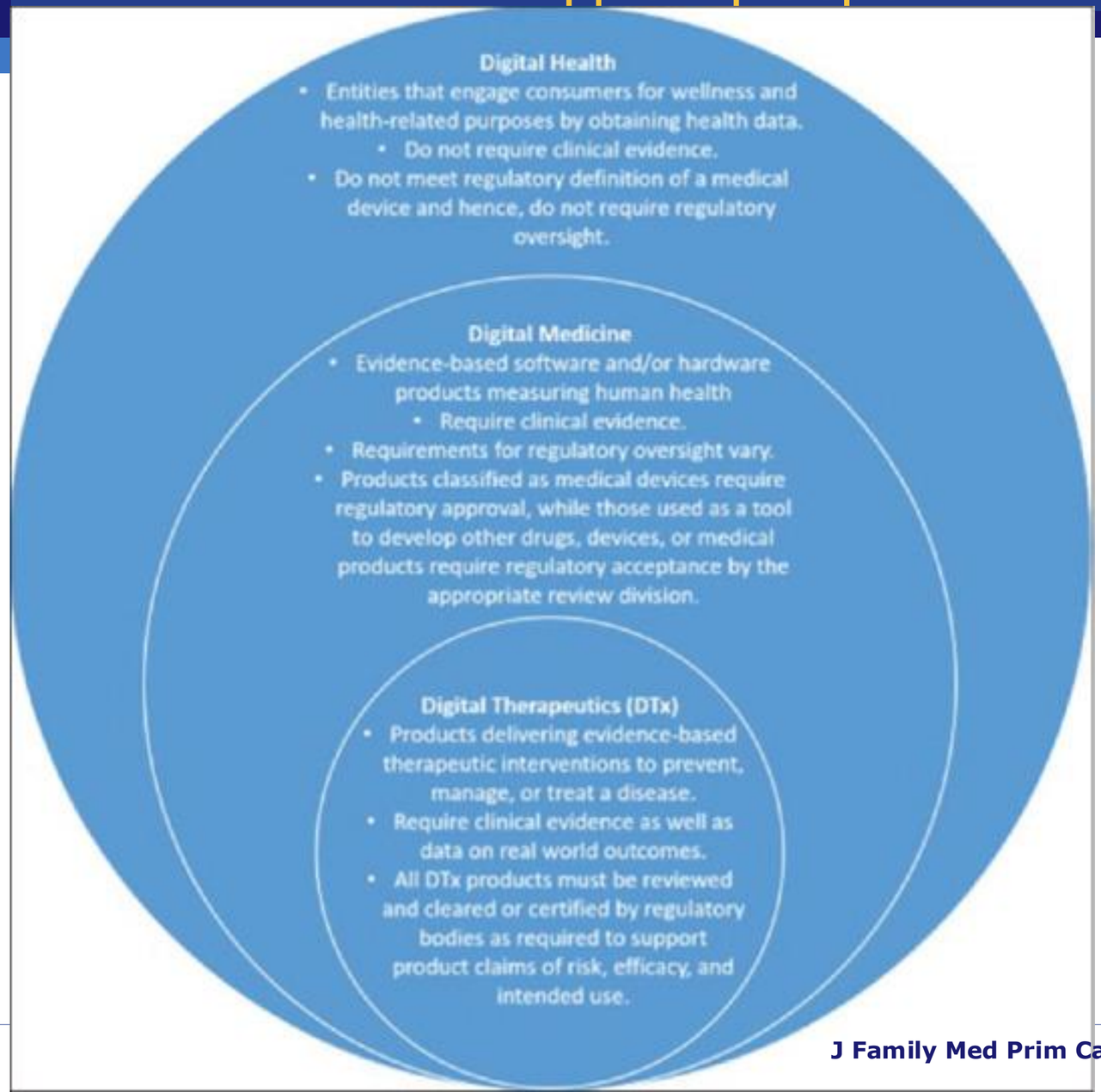
April 11, 2018

FDA U.S. FOOD & DRUG ADMINISTRATION

An AI diagnostic system that detects signs of diabetic retinopathy in retinal images

- Proven to be effective in real-world clinical workflows
- Results in less than a minute - no human grader
- Clinically validated with high sensitivity and specificity

Ψηφιακή Υγεία-Ψηφιακή Ιατρική-Ψηφιακή Θεραπευτική



Εφαρμογές Ψηφιακής Υγείας: Δεν χρήζουν πιστοποίησης

Εφαρμογές Ψηφιακής Ιατρικής: Χρήζουν πιστοποίησης πχ CE ή MDR Class I

Εφαρμογές Ψηφιακής Θεραπευτικής: Χρήζουν πιστοποίησης MDR Class IIa, IIb, III

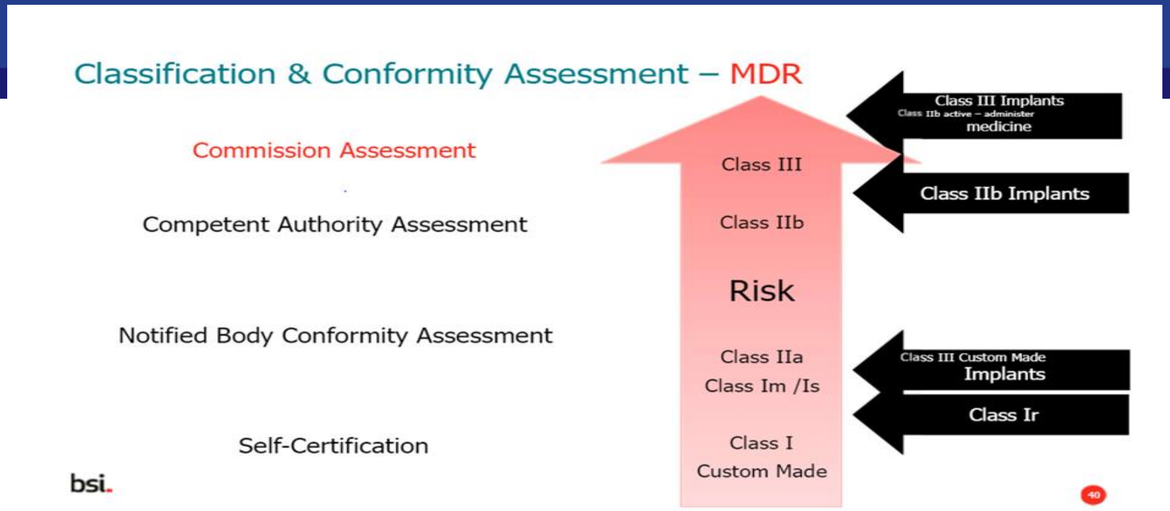
J Family Med Prim Care . 2020 May 31;9(5):2207-2213

Ψηφιακή Θεραπευτική (Digital therapeutics-Dtx)

Dtx στη διεθνή βιβλιογραφία, είναι ένα υποσύνολο της ψηφιακής υγείας, που αφορά τεκμηριωμένες θεραπευτικές παρεμβάσεις που βασίζονται σε υψηλής ποιότητας, πιστοποιημένα προγράμματα λογισμικού για την πρόληψη, τη διαχείριση ή τη θεραπεία μιας ασθένειας.

Οι καινότομες αυτές εφαρμογές νέων τεχνολογιών στην υγεία, έχουν προοπτικές αλλά και προκλήσεις και χρήζουν εισαγωγής ενός ΡΥΘΜΙΣΤΙΚΟΥ ΚΑΙ ΝΟΜΙΚΟΥ ΠΛΑΙΣΙΟΥ ΨΗΦΙΑΚΗΣ ΥΓΕΙΑΣ.

Classification of Medical Device Software (MDSW)



Rule 11 of MDR Annex VIII

"**Software** intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class **IIa**, except if such decisions have an impact that may cause:

— death or an irreversible deterioration of a person's state of health, in which case it is in **class III**; or

— a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as **class IIb**.

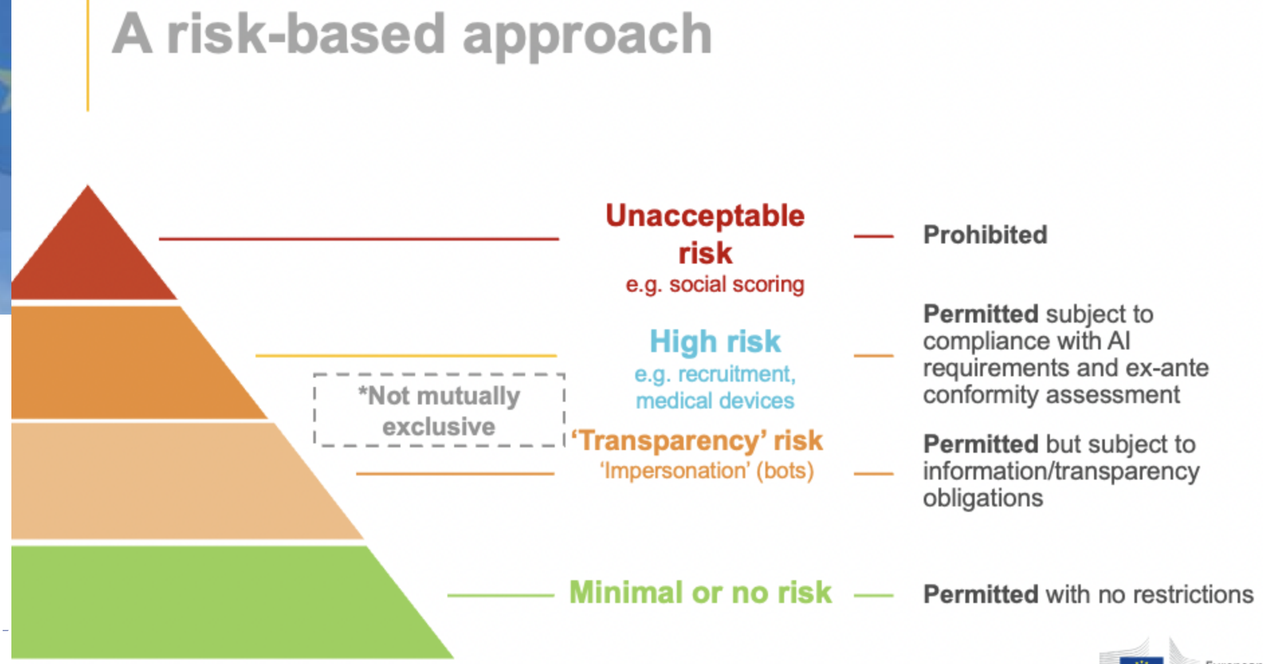
Software intended to monitor physiological processes is classified as **class IIa**, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as **class IIb**.

All other software is classified as **class I**."

Proposed AI HealthCare Regulatory Framework (EU)

Article 43 (3) **AIAct** manages overlap and conformity, providing that where AI systems that are devices or are part of a device can be assessed under the MDR or IVDR conformity assessment procedure.

The AIA is not yet clear about the result of conformity assessment under overlapping assessment and how this will be reflected in a final declaration of conformity. The result under the AIA would be an EU technical documentation certificate (article 44 AIA) which seems to be complementary to an MDR / IVDR certificate



Οι εφαρμογές ψηφιακής θεραπευτικής υπάγονται στα Ιατροτεχνολογικά προϊοντα

Όσες εφαρμογές προορίζονται για ιατρική χρήση, θα πρέπει να πληρούν, σε ότι αφορά την ΕΕ, τις διατάξεις του **Medical Devices Directive,** που αντικαστάθηκε από 26/5/2021 από τον **Medical Devices Regulation**.

Στην Ελλάδα, αρμόδιος φορέας (Notified Body) είναι το ΕΚΑΠΤΥ (Εθνικό Κέντρο Αξιολόγησης της Ποιότητας και Τεχνολογίας στην Υγεία -Ε.Κ.Α.Π.Τ.Υ. Α.Ε.) www.ekapty.gr που λειτουργεί ως ανεξάρτητος Φορέας Πιστοποίησης Συστημάτων Ποιότητας και Προϊόντων, εποπτευόμενος από το Υπουργείο Υγείας.

Οι εφαρμογές **mobile health**, είναι ένα μόνο τμήματα του γενικότερου συνόλου, της εργαλείων της **Ψηφιακή Θεραπευτικής (Digital therapeutics-Dtx)**.

Stages of Medical Devices Trials vs Phases of Pharma Trials

Pharmaceuticals			Medical Devices		
Phase	**Subjects**	**Purpose**	**Stage**	**Subjects**	**Purpose**
0 Pilot / Exploratory	10 - 15	• Test a very small (subtherapeutic) dose of a new drug to study its effects & how it works in the human body. • Not all drugs will undergo this phase.	Pilot / Early Feasibility / First-in-Human	10 - 30	• Small study to collect preliminary safety & device performance data in humans. • Guides device modifications &/or future study design.
I Safety & Toxicity	10 - 100	• True first-in-human study to test safety & toxicity, usually in healthy humans.	Traditional Feasibility	20 - 30	• Assess safety & efficacy of the near-final or final device design in patients. • Guides the design of the pivotal study.
II Safety & Efficacy	100's	• Assess efficacy & safety in patients.			
III Clinical Effectiveness	100's – 1000's	• Confirm clinical efficacy, safety & adverse events. • Compare the new drug to standard care or a commonly used drug.	Pivotal	100's	• Large study to confirm clinical efficacy, safety & risks. • Statistically driven.
IV Post-Market / Surveillance	1000's	• Monitor long term effectiveness & safety in the general population.	Post-Market	1000's	• Monitor long term effectiveness, safety & usage in the general population.

European Radiology (2021) 31:3797–3804
https://doi.org/10.1007/s00330-021-07892-z

IMAGING INFORMATICS AND ARTIFICIAL INTELLIGENCE

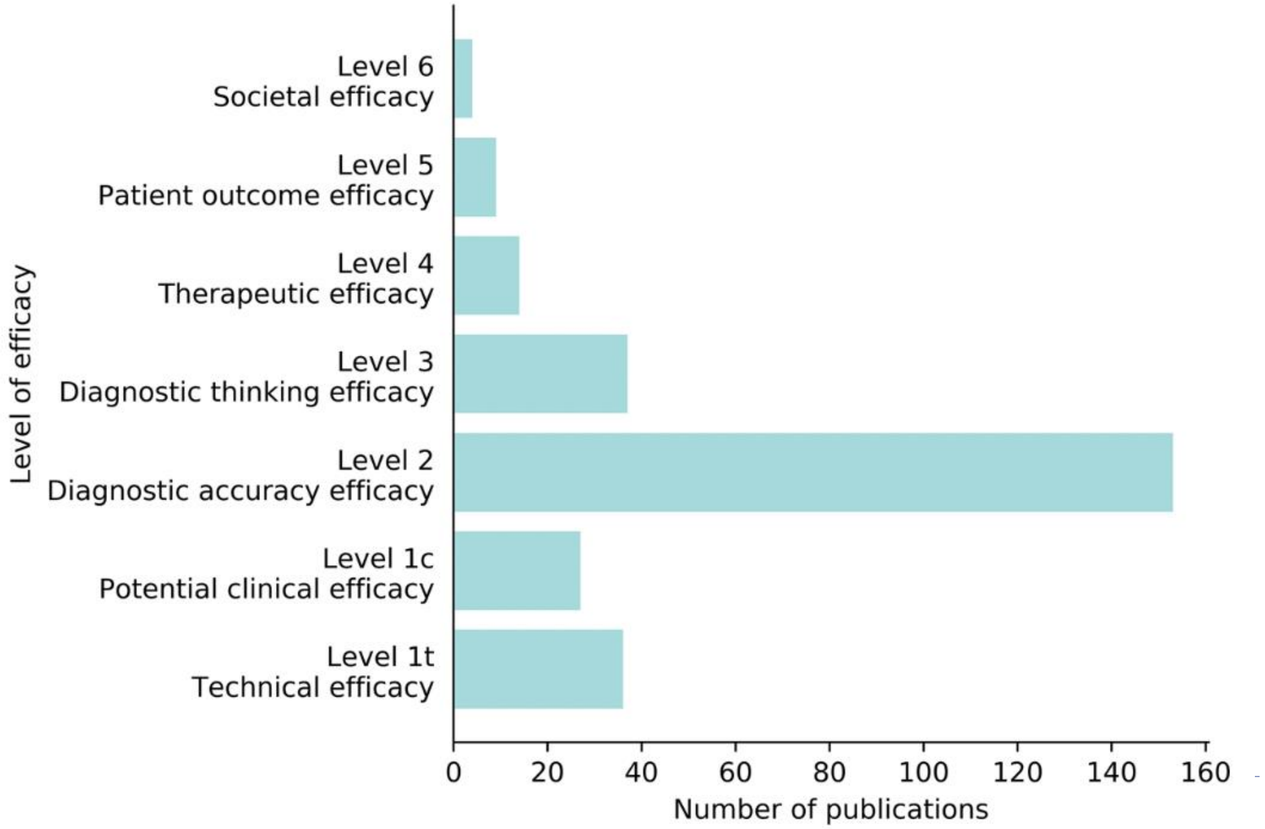
Artificial intelligence in radiology: 100 commercially available products and their scientific evidence

Kicky G. van Leeuwen [1] · Steven Schalekamp [1] · Matthieu J. C. M. Rutten [1,2] · Bram van Ginneken [1] · Maarten de Rooij [1]

Received: 19 November 2020 / Revised: 4 February 2021 / Accepted: 15 March 2021 / Published online: 15 April 2021

Key Points:

- Artificial intelligence in radiology is still in its infancy even though already 100 CE-marked AI products are commercially available.
- Only 36 out of100 products have peer-reviewed evidence ofwhich most studies demonstrate lower levels of efficacy.
- There is a wide variety in deployment strategies, pricing models, and CE marking class of AI products for radiology.



Review

Role of Artificial Intelligence Applications in Real-Life Clinical Practice: Systematic Review

Jiamin Yin[1*], BA; Kee Yuan Ngiam[2*], MBBS; Hock Hai Teo[1*], PhD

[1]Department of Information Systems and Analytics, School of Computing, National University of Singapore, Singapore, Singapore

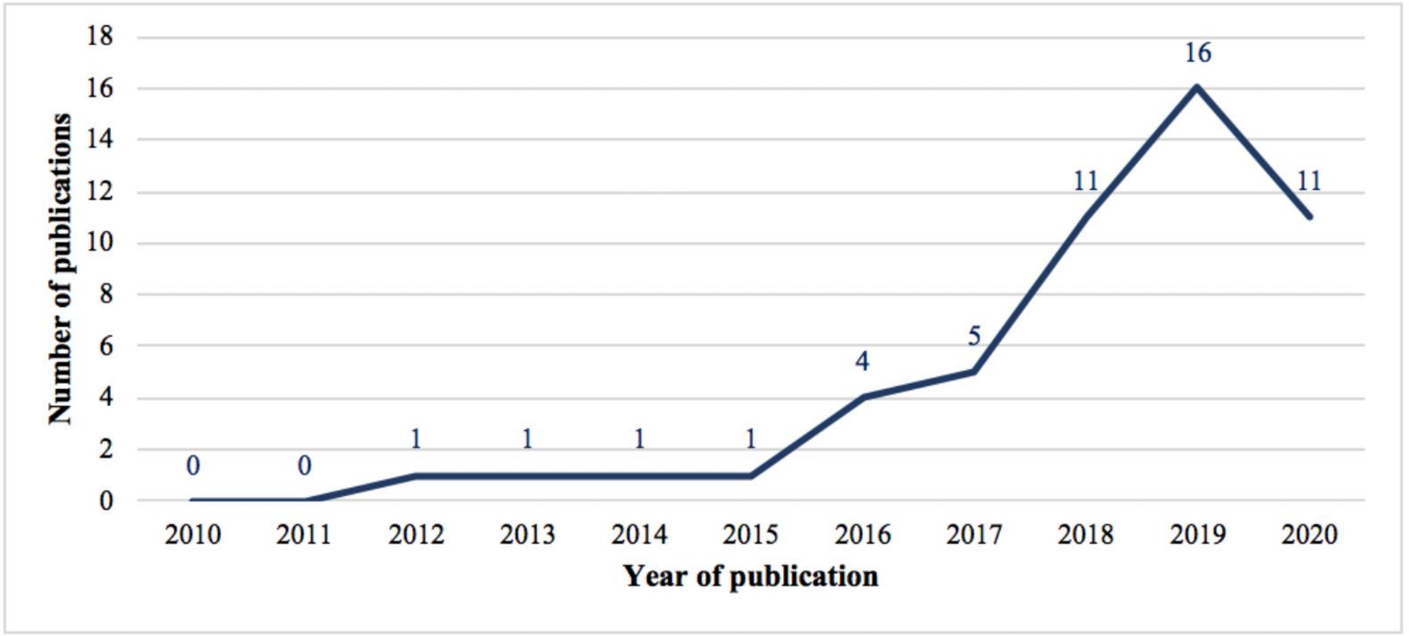
[2]Department of Surgery, National University Hospital, Singapore, Singapore

[*]all authors contributed equally

Results: We identified 51 relevant studies that reported the implementation and evaluation of AI applications in clinical practice, of which 13 adopted a randomized controlled trial design and eight adopted an experimental design

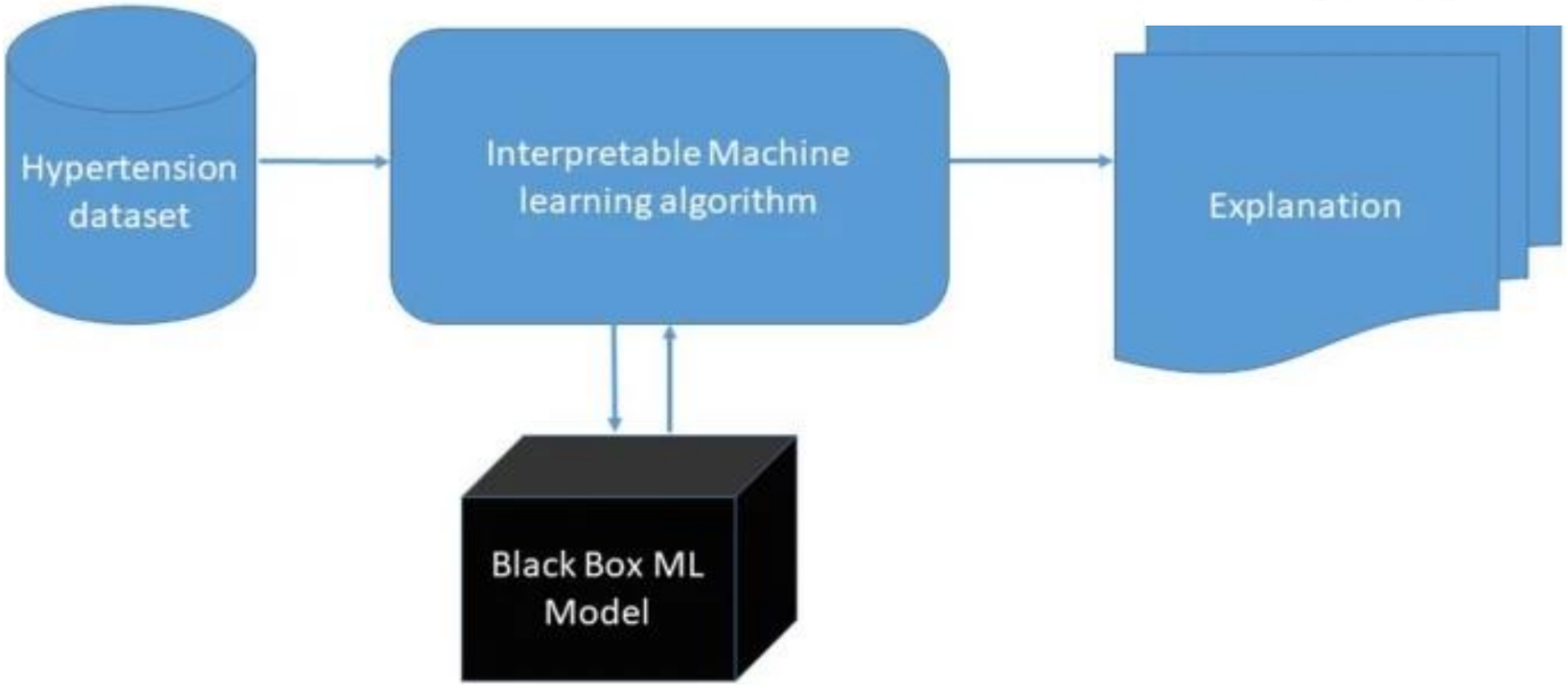
Conclusions: This review indicates that research on the clinical implementation of AI applications is still at an early stage despite the great potential. More research needs to assess the benefits and challenges associated with clinical AI applications through a more rigorous methodology.
(J

Figure 2. Distribution of the included articles from 2010 to 2020.



Interpretable Machine Learning in Healthcare (XAI)

Interpretability process of black box machine learning algorithms



POLICY FORUM | TECHNOLOGY AND REGULATION

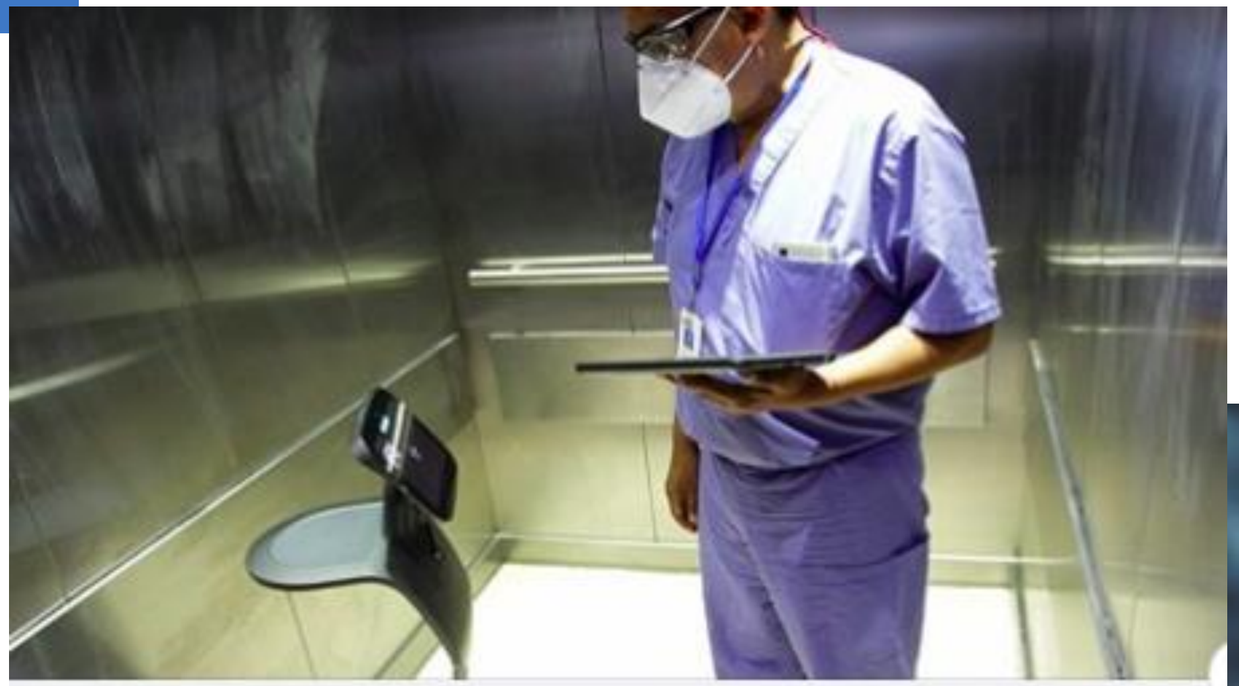
Beware explanations from AI in health care

Boris Babic[1,2,3], Sara Gerke[4,5], Theodoros Evgeniou[6], I. Glenn Cohen[5,7]
+ See all authors and affiliations

Science 16 Jul 2021:
Vol. 373, Issue 6552, pp. 284-286
DOI: 10.1126/science.abg1834

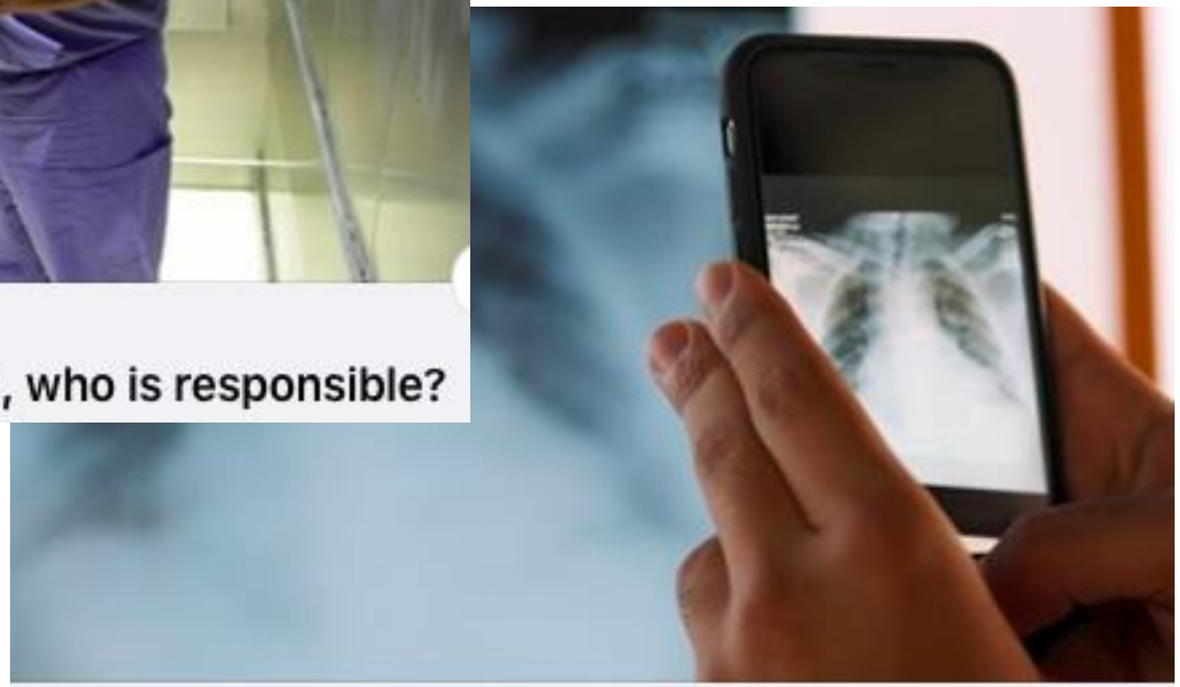
Reference: BMC Med Inform Decis Mak 19, 146 (2019).

AI in HealthCare Challenges



QZ.COM

When AI in healthcare goes wrong, who is responsible?



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The Geographic Bias in Medical AI Tools

Artificial Intelligence

Is the field of study

Machine Learning

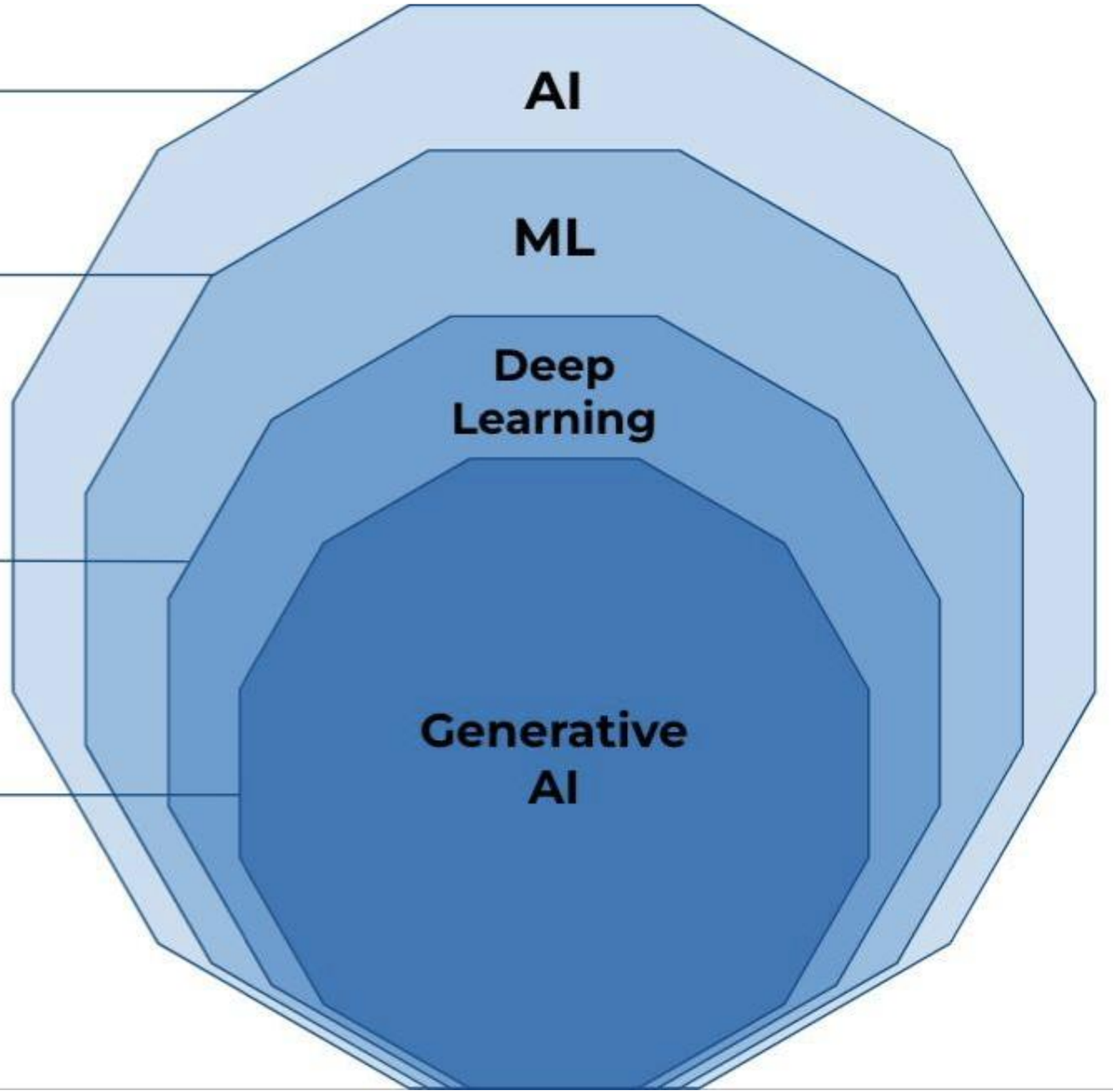
Is a branch of AI that focus on the creation of intelligent machines that learn from data. Another very well know branch inside AI is **Optimization**.

Deep Learning

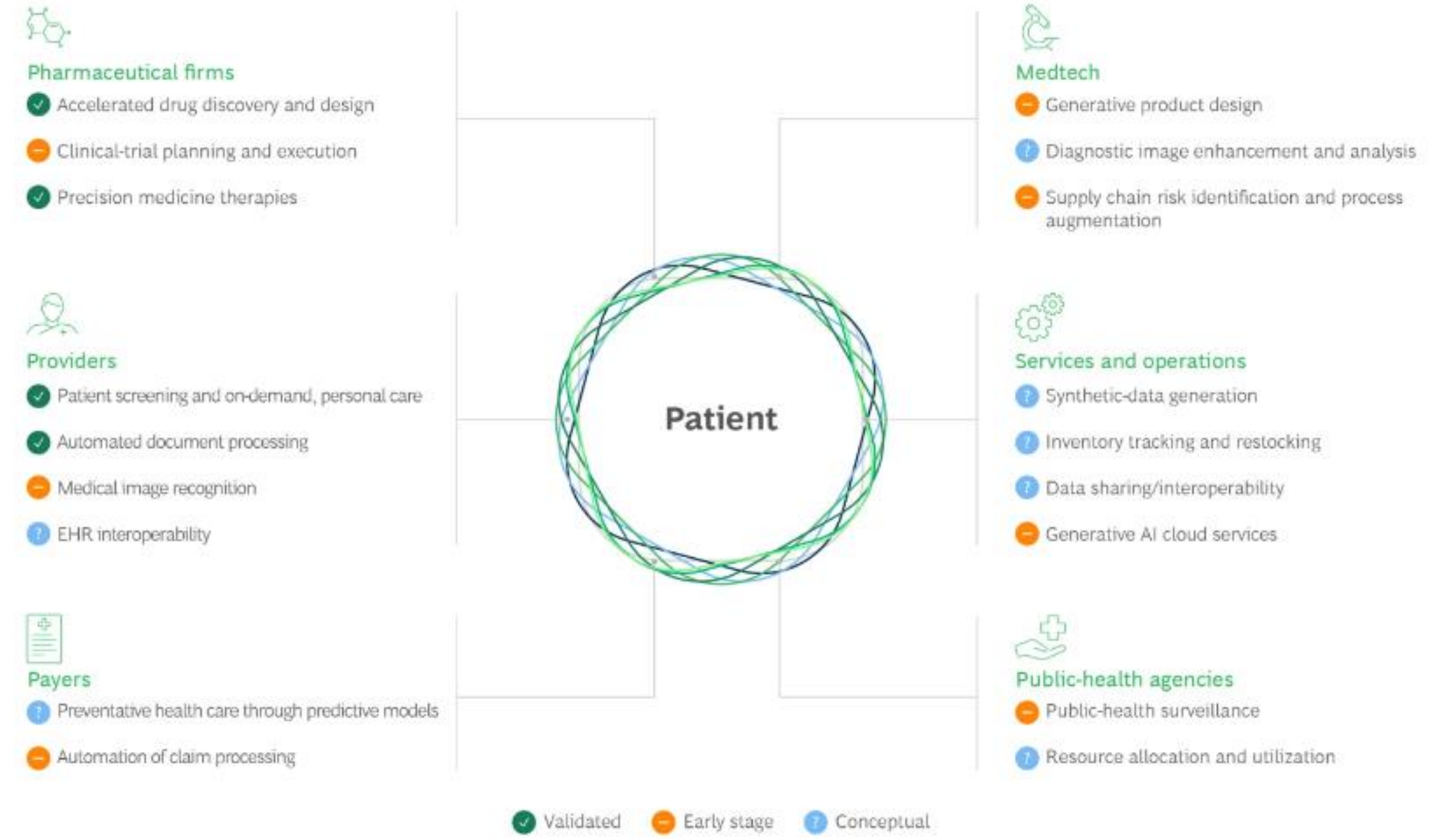
Is a subset of Machine Learning methods, based on **Artificial Neural Networks.**
Examples: CNNs, RNNs

Generative AI

A type of ANNs that generate data that is similar to the data it was trained on.
Examples: GANs, LLMs

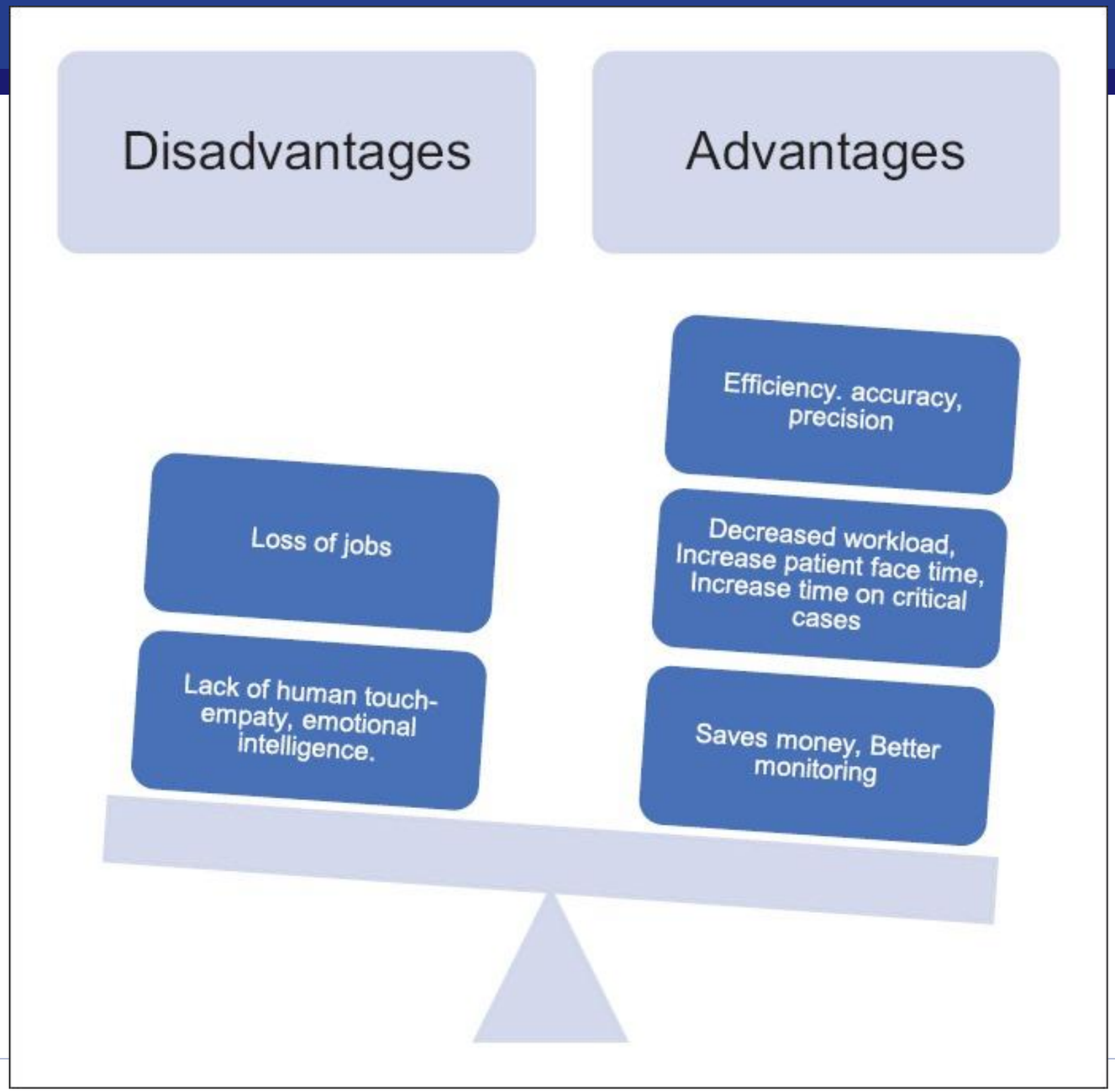


Generative AI Has Potential Use Cases Across All Health Care Segments



Source: BCG analysis.

Advantages and disadvantages of artificial intelligence in medicine

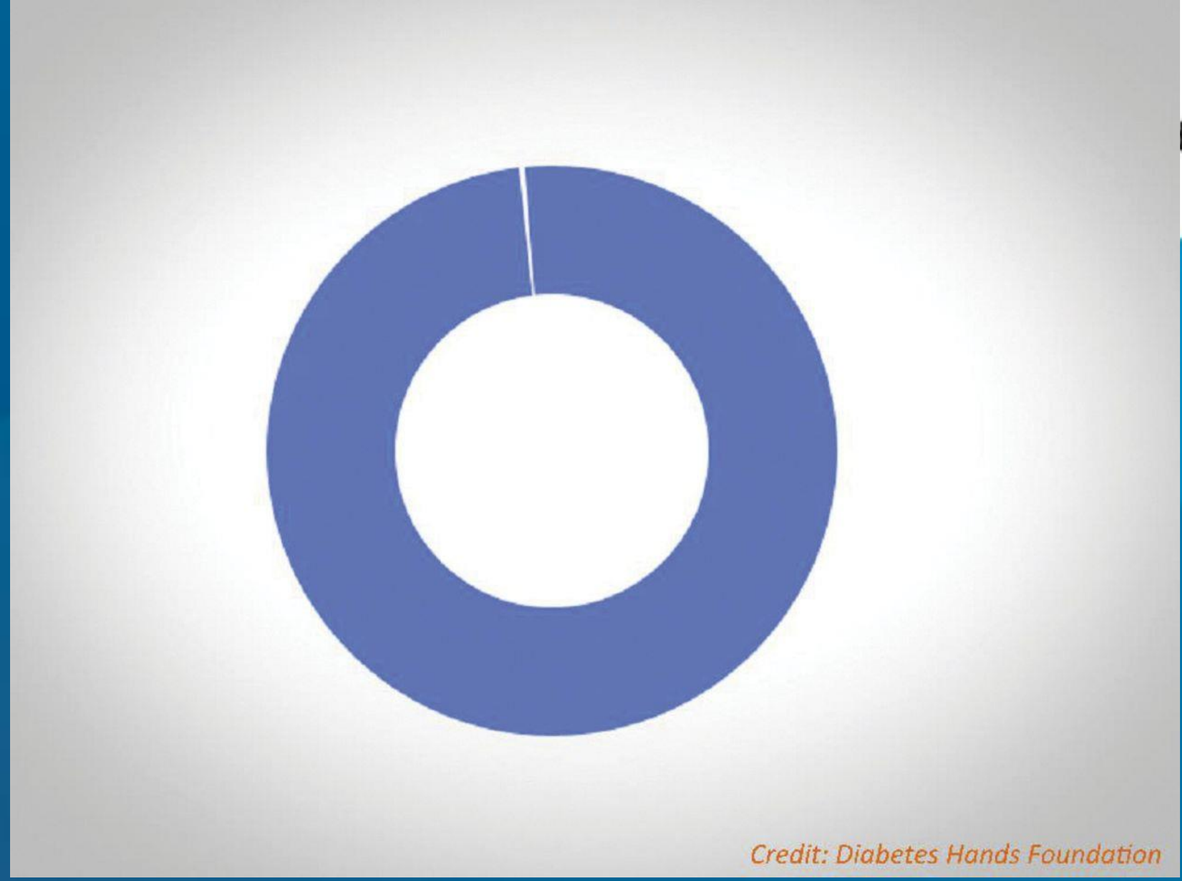


Reference: J Family Med Prim Care. 2019 Jul; 8(7): 2328–2331

AI and Clinical Research and Innovation

- Transparent Reporting of a multivariable prediction model for Individual Prognosis Or Diagnosis (TRIPOD) Statement **-AI**
- Consolidated Standards of Reporting Trials (CONSORT) Statement**-AI**
- Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) Statement **–AI**
- DECIDE-**AI**: new reporting guidelines to bridge the development-to-implementation gap in clinical artificial intelligence
- Developing specific reporting guidelines for diagnostic accuracy studies assessing AI interventions: The STARD-**AI** Steering Group
- Assessment of Diagnostic Accuracy Studies (QUADAS) **-AI**

Image illustrating the relationship between the time spent self-managing diabetes (blue) and time spent with a health care provider (white).



Digital Health could help the patient empowerment and coaching.

David G. Marrero Diabetes Spectr 2016;29:54-57

Treatment of Diabetes in Older Adults: An Endocrine Society* Clinical Practice Guideline

Derek LeRoith ✉, Geert Jan Biessels, Susan S Braithwaite, Felipe F Casanueva, Boris Draznin, Jeffrey B Halter, Irl B Hirsch, Marie E McDonnell, Mark E Molitch, M Hassan Murad ... Show more

The Journal of Clinical Endocrinology & Metabolism, Volume 104, Issue 5, May 2019,

Overall Health Category		Group 1: Good Health	Group 2: Intermediate Health	Group 3: Poor Health
Patient characteristics		No comorbidities **or** 1-2 non-diabetes chronic illnesses* **and** No ADL[c] impairments and ≤1 IADL impairment	3 or more non-diabetes chronic illnesses* **and/or** Any one of the following: mild cognitive impairment or early dementia; ≥2 IADL impairments	Any **one** of the following: End-stage medical condition(s)**; Moderate to severe dementia; ≥2 ADL impairments; Residence in a long-term nursing facility
		Reasonable glucose target ranges and HbA1c by group		
		Shared decision-making: individualized goal may be lower or higher		
Use of drugs that may cause hypoglycemia (e.g., insulin, sulfonylurea, glinides)	No	Fasting: 90-130 mg/dL Bedtime: 90-150 mg/dL <7.5%	Fasting: 90-150 mg/dL Bedtime: 100-180 mg/dL <8%	Fasting: 100-180 mg/dL Bedtime: 110-200 mg/dL <8.5%[v]
	Yes[b]	Fasting: 90-150 mg/dL Bedtime: 100-180 mg/dL ≥7.0 and <7.5%	Fasting: 100-150 mg/dL Bedtime: 150-180 mg/dL ≥7.5 and <8.0%	Fasting: 100-180 mg/dL Bedtime: 150-250 mg/dL ≥8.0 and <8.5%[v]

MANAGEMENT OF DIABETES IS MORE CHALLENGING FOR THE ELDERLY PATIENTS WITH COMORBIDITIES

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement N° 857223

Greek Deployment Site : (Central Greece) Use Case 3

USE CASE 3– Diabetes: predictive modelling of glycaemic status

- Greek PS Coordinator: Dr Kostas Votis (CERTH/ITI)
- PI : Assist. Prof. Alexandra Bargiota (UTH)
- Central Greece Pilot Coordinator : Dr George E. Dafoulas (UTH & Cities) Net)

«ΜΕΛΕΤΗ ΑΞΙΟΛΟΓΗΣΗΣ ΑΛΓΟΡΙΘΜΟΥ ΜΗΧΑΝΙΚΗΣ ΜΑΘΗΣΗ ΓΙΑ ΤΗ ΓΛΥΚΑΙΜΙΚΗ ΡΥΘΜΙΣΗ ΜΕΣΩ ΜΕΤΡΗΣΕΩΝ ΣΥΣΤΗΜΑΤΟΣ ΣΥΝΕΧΟΥΣ ΥΠΟΔΟΡΙΑΣ ΚΑΤΑΓΡΑΦΗΣ ΓΛΥΚΟΖΗΣ (CGM) ΣΕ ΠΡΑΓΜΑΤΙΚΟ ΧΡΟΝΟ ΣΕ ΑΣΘΕΝΕΙΣ >=65 ετών ΜΕ ΣΑΚΧΑΡΩΔΗ ΔΙΑΒΗΤΗ ΤΥΠΟΥ 2 ΚΑΙ ΣΥΝΝΟΣΗΡΟΤΗΤΕΣ».

ΨΗΦΙΑΚΗ ΥΓΕΙΑ : ΠΡΟΚΛΗΣΕΙΣ

From pilots to routine care deployment….

Κλινικά Πρωτόκολλα

Προστασία Δεδομένων (GDPR)

Cybersecurity/Κυβερνοασφάλεια

CE/DOC MDR –Ιατροτεχνολογικό προϊόν?

Διασφάλιση ασφάλειας ασθενή-χρήστη

Διαλειτουργικότητα

Ρυθμιστικό και Νομικό Πλαίσιο

Κόστος /Αποτέλεσμα - ασφαλιστική κάλυψη

ΥΛΙΚΟΕΠΑΓΡΥΠΝΗΣΗ

Κάρτα Αναφοράς Περιστατικών Χρηστών Ιατροτεχνολογικών Προϊόντων

Σχετ.: ΦΕΚ 2197Β/2-10-2009, ΦΕΚ 2198Β/2-10-2009, ΦΕΚ 1060Β/10-8-2001

Προς: *(Στοιχεία επικοινωνίας κατασκευαστή στην Ελλάδα)*	**Κοινοποίηση:** ΕΘΝΙΚΟΣ ΟΡΓΑΝΙΣΜΟΣ ΦΑΡΜΑΚΩΝ Τμήμα Ανεπιθύμητων Ενεργειών Τομέας Υλικοεπαγρύπνησης Λ. Μεσογείων 284 Τ.Κ. 155.62, Χολαργός - ΑΘΗΝΑ Τηλ.: 210-6507528 Fax: 210-6549585

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Χορηγούνται Μόρια Συνεχιζόμενης Ιατρικής Εκπαίδευσης (CME) από τον Π.Ι.Σ.

30 Μαΐου - 1 Ιουνίου 2025

Αθήνα

Ξενοδοχείο Amalia

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