DeepRadiology

REDEFINING MEDICAL PRACTICE THROUGH ARTIFICIAL INTELLIGENCE ™

Something amazing is coming.....

KEEP ME UPDATED

CAREERS

Tartalom

- Miért én vagyok az előadó?
- Mit nevezek mesterséges intelligenciának?
- Dotcomlufi vagy valóság?
- Jogi-etikai-szabályozási dilemmák
- „Sehallselát Dömötör buta volt, mint hat ökör” avagy AI-ember interakció
- Tipikus AI hibák

Viktor Gál MD., Ph.D.
Presenter

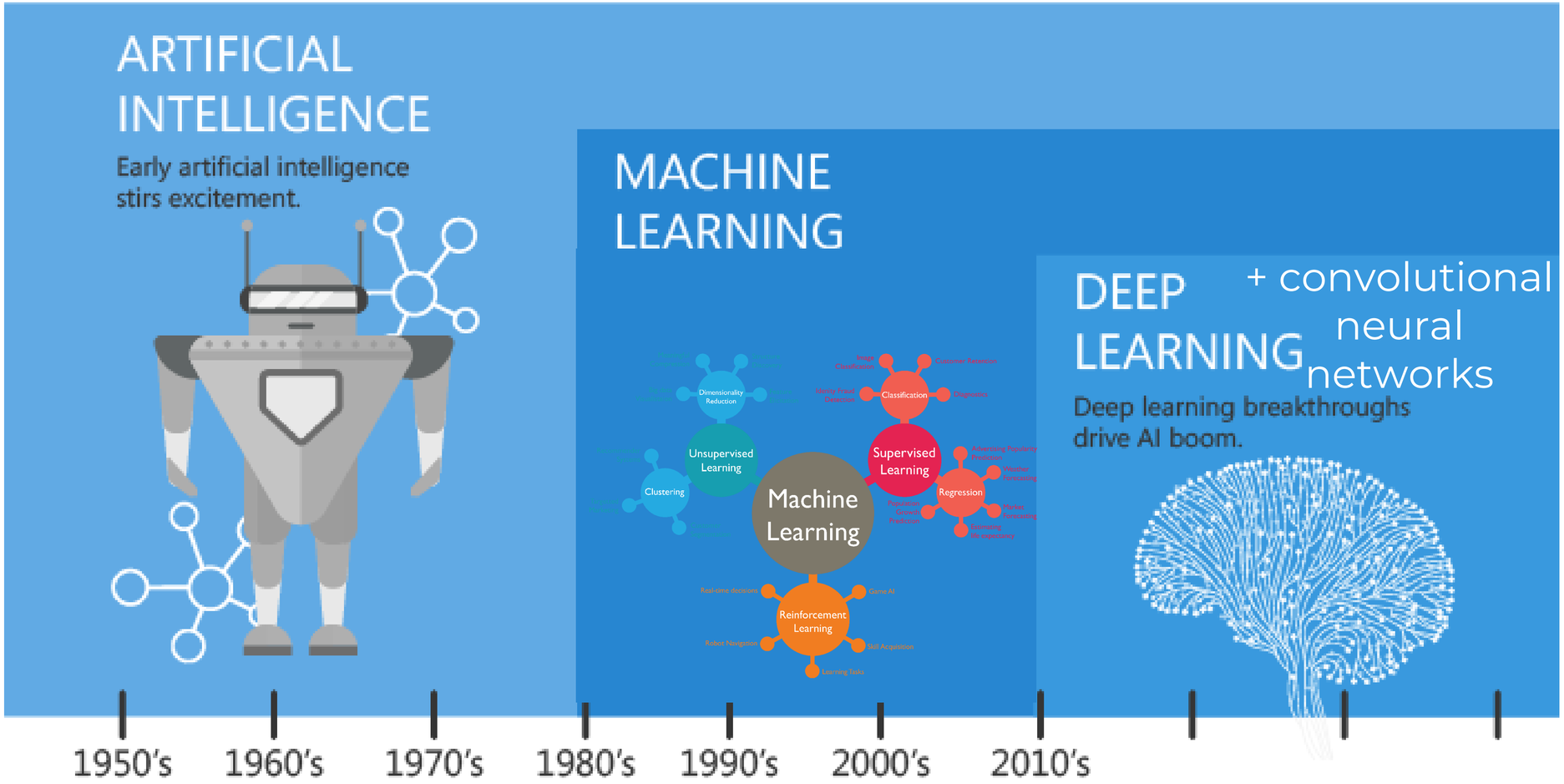
Disclosure

Radiologist/researcher specialized in MSK and neuro MRI (Semmelweis University & Research Centre for Natural Sciences)

CEO of ORTHOPRED startup, MSK MRI diagnostics automation

Afib, owner/user of a Kardia

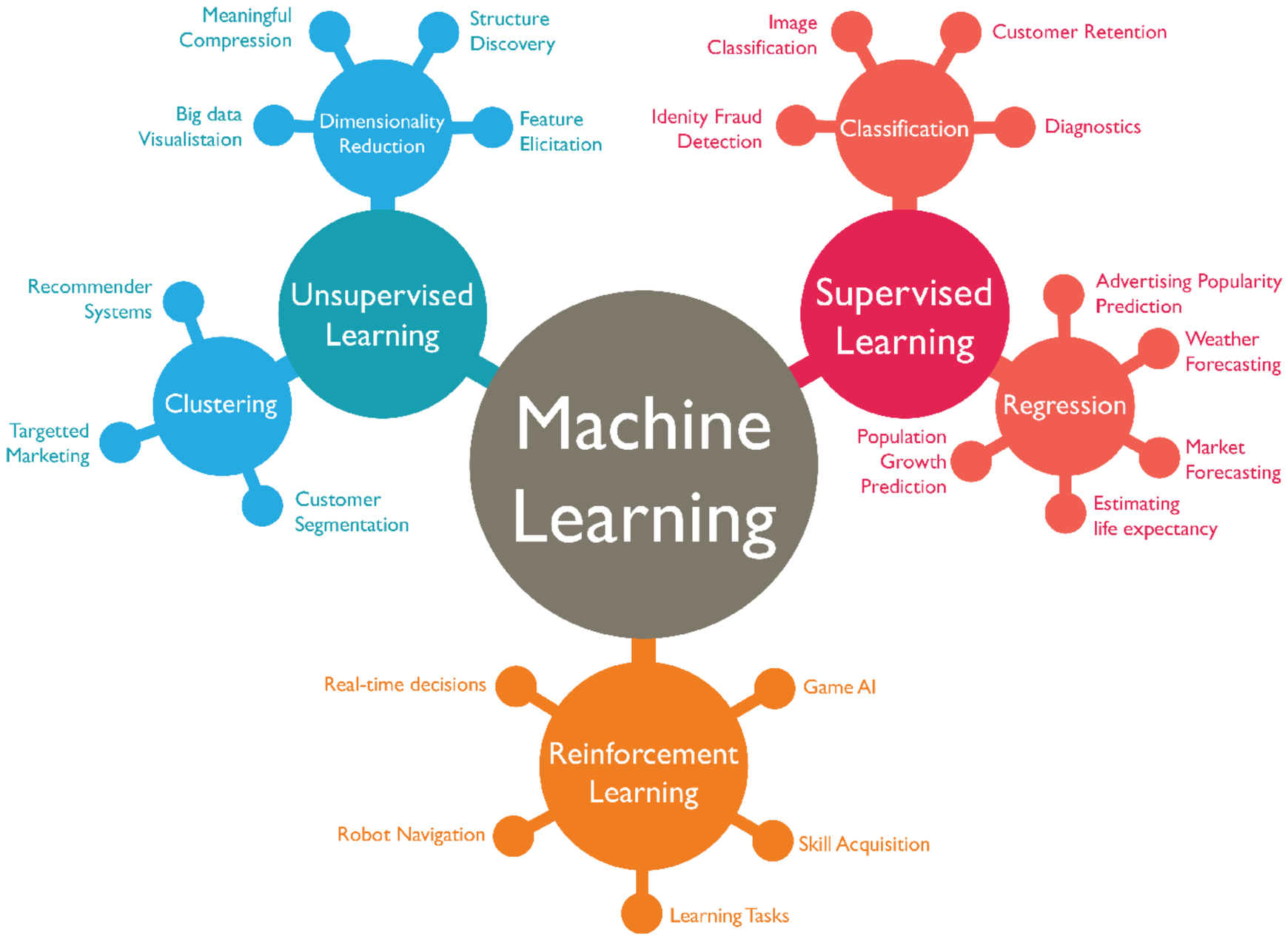
ARTIFICIAL INTELLIGENCE: DEFINITION?

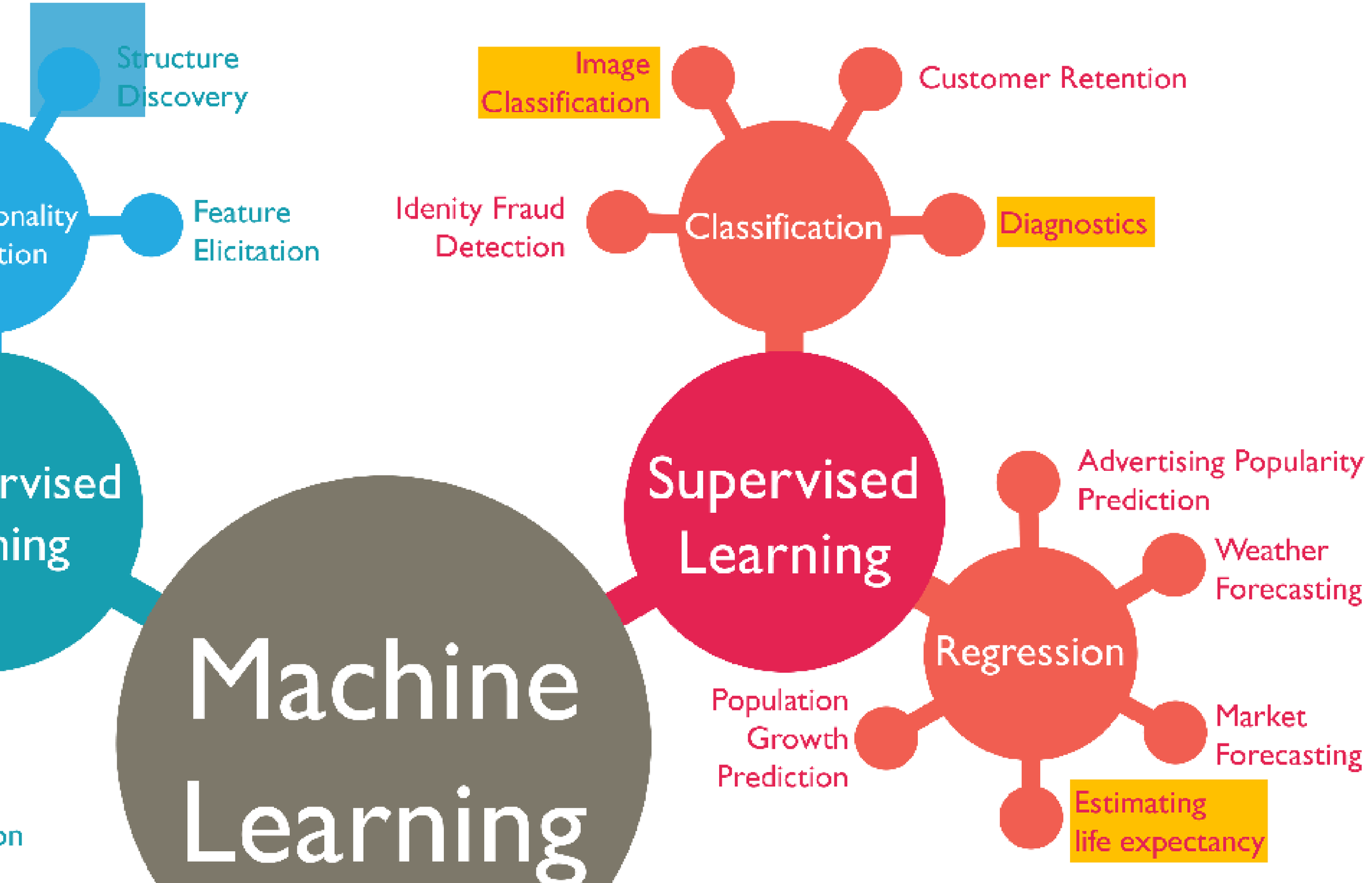


Since an early flush of optimism in the 1950's, smaller subsets of artificial intelligence - first machine learning, then deep learning, a subset of machine learning - have created ever larger disruptions.

Posted on March 29, 2018 By Tanmoy Ray

https://www.stoodnt.com/blog/ann-neural-networks-deep-learning-machine-learning-artificial-intelligence-differences/


Machine Learning
Unsupervised Learning
Dimensionality Reduction
Meaningful Compression
Structure Discovery
Big data Visualistaion
Feature Elicitation
Clustering
Recommender Systems
Targetted Marketing
Customer Segmentation
Supervised Learning
Classification
Image Classification
Customer Retention
Idenity Fraud Detection
Diagnostics
Regression
Advertising Popularity Prediction
Weather Forecasting
Population Growth Prediction
Market Forecasting
Estimating life expectancy
Reinforcement Learning
Real-time decisions
Game AI
Robot Navigation
Skill Acquisition
Learning Tasks


Structure
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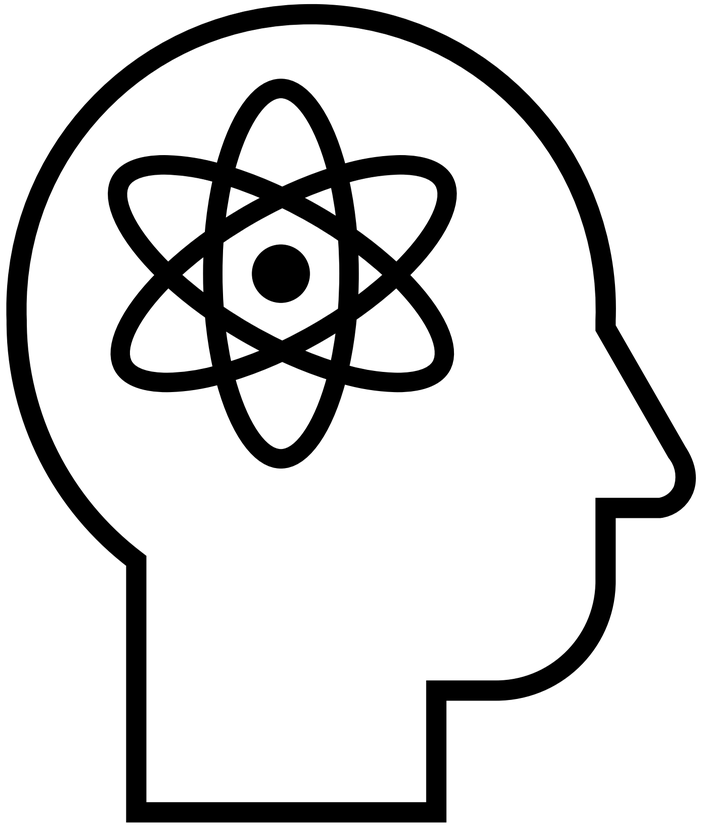
Supervised
Learning
Image
Classification
Customer Retention
Idenity Fraud
Detection
Classification
Diagnostics
Advertising Popularity
Prediction
Weather
Forecasting
Regression
Population
Growth
Prediction
Market
Forecasting
Estimating
life expectancy

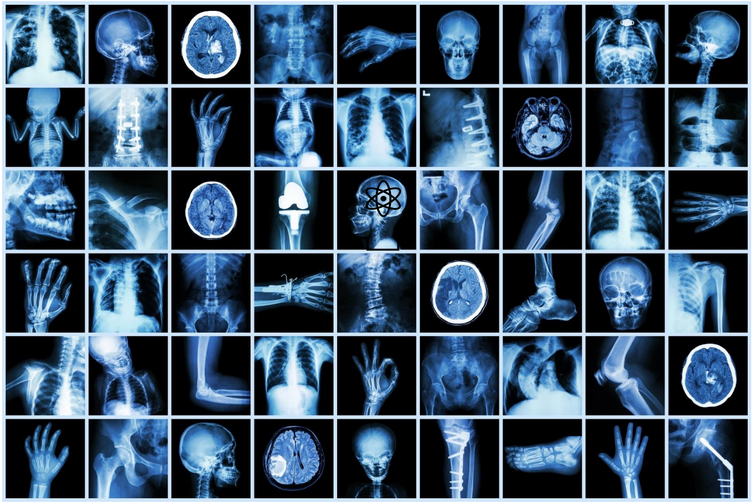
IS IT REVOLUTIONARY? REQUIREMENTS?



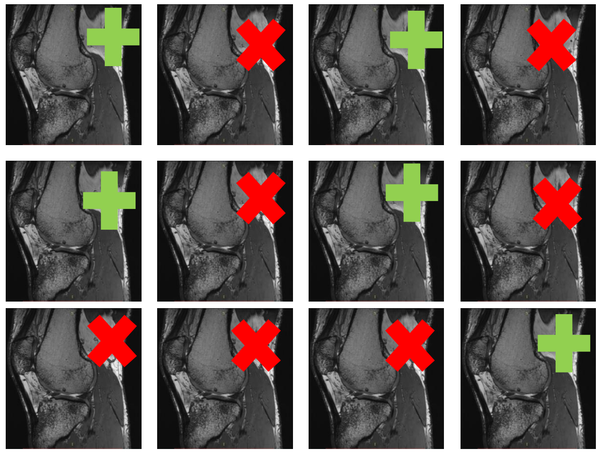
IS REVOLUTIONARY? REQUIREMENTS?

Digitalization

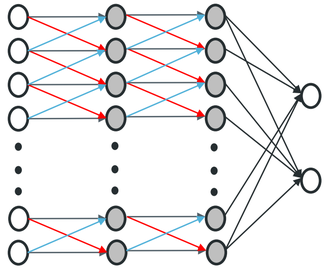
Hardware



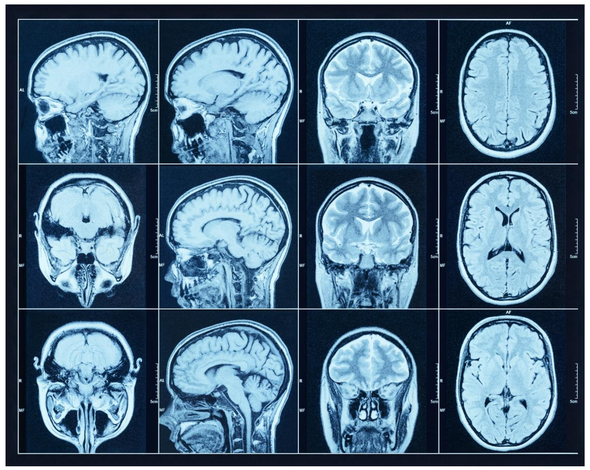
Big database



Standard annotation

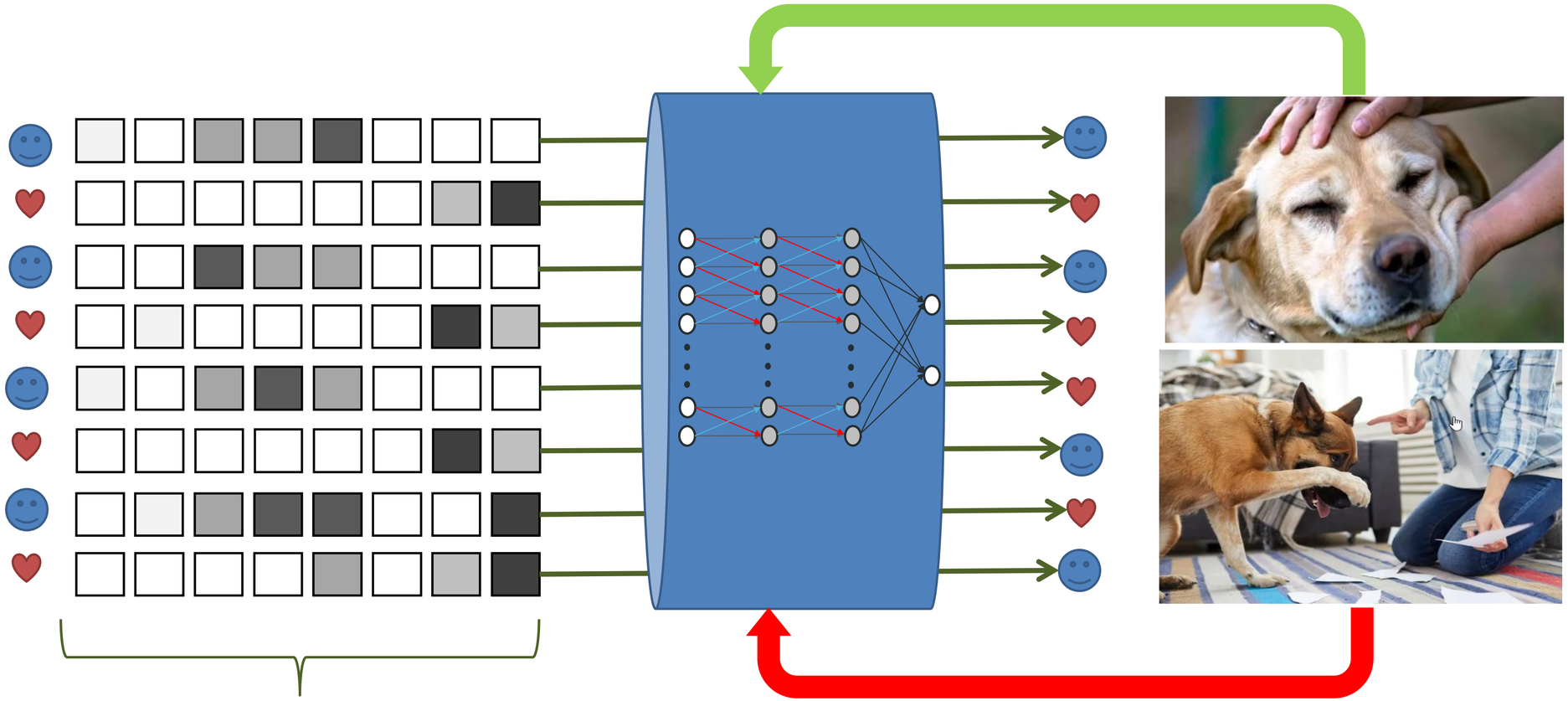


„Off the shelf” algorithms



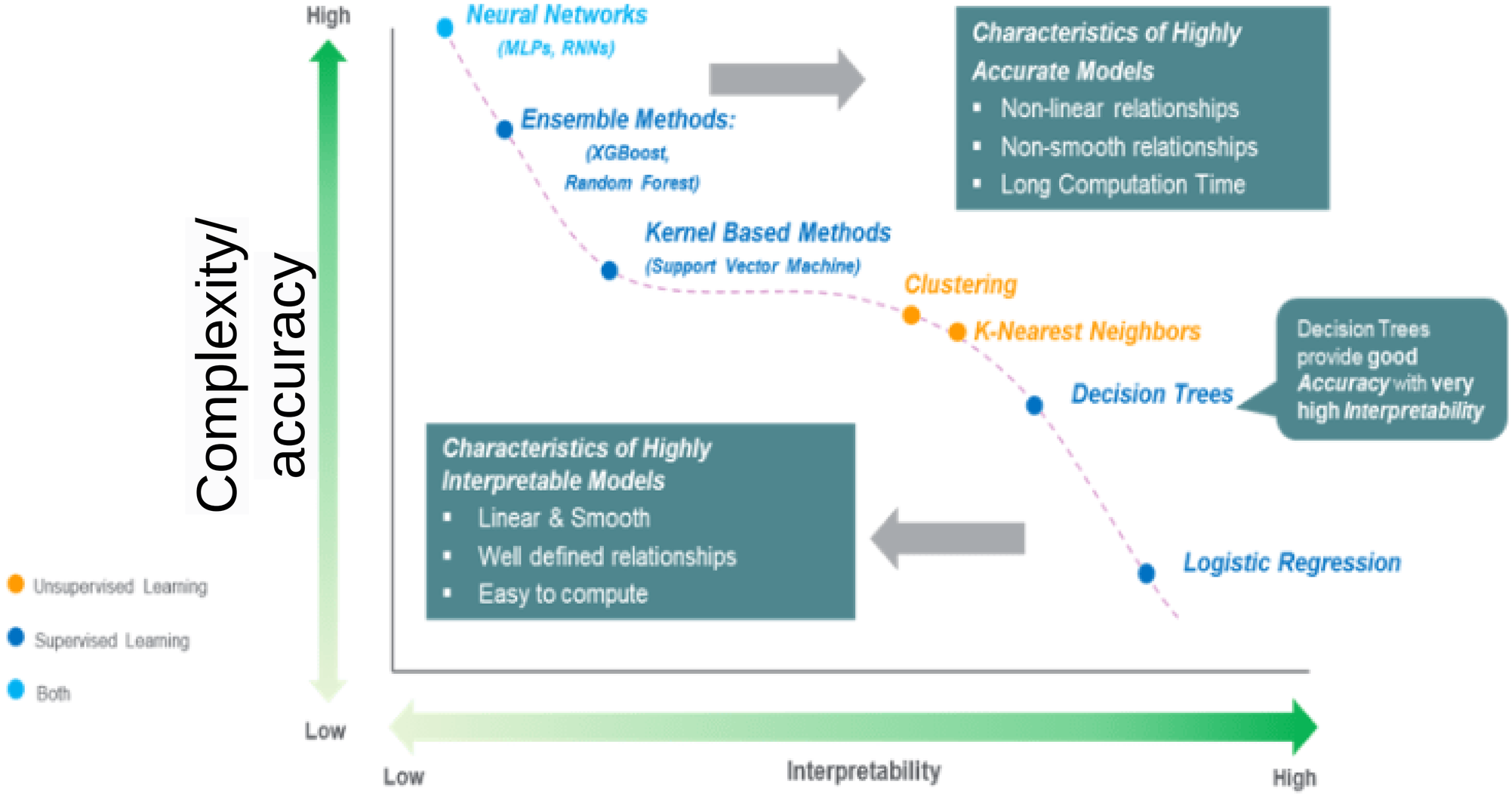
Standard protocol

SUPERVISED LEARNING OF NEURAL NETWORKS: CLASSIFICATION



Features: **raw** vs. „hand made”

PERFORMANCE / INTERPRETABILITY



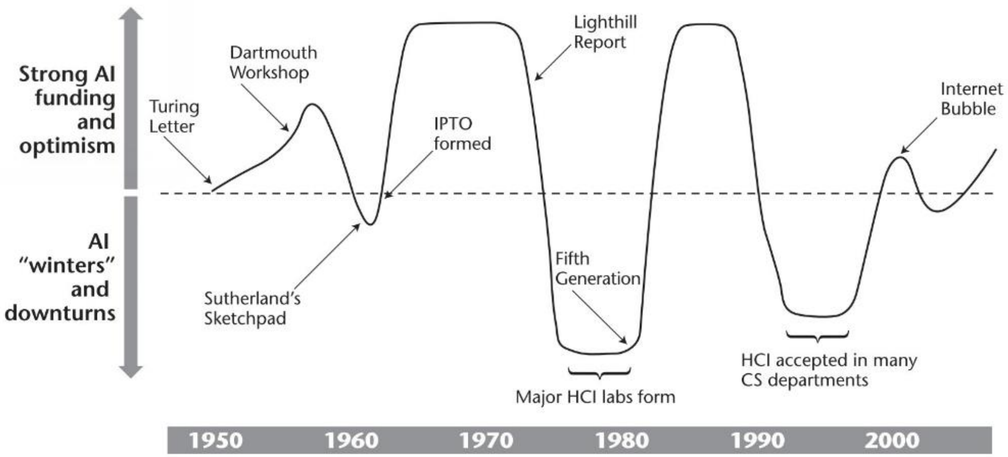
http://datascienceninja.com/2019/07/01/the-balance-accuracy-vs-interpretability/ **Sharayu Rane on July 1, 2019**

VERY BRIEF History OF Artificial Intelligence

1956 Dartmouth Conference: birth of the definiton/notion of AI

1974-2011 3x „**AI winter**” period with hype in between

1998 Yann LeCun (Facebook) Convolutional Neural Network (hand-written postal code reading)



Grudin, J. (2009)
AI and HCI: Two fields divided by a common focus.

Frankish, K. & Ramsey, W.M. (2017)
The Cambridge Handbook of Artificial Intelligence.

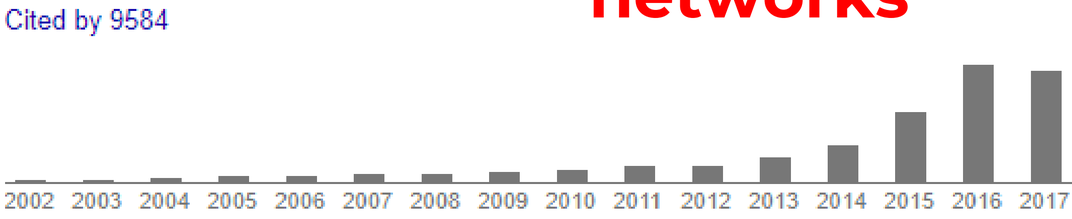
Non-deep learning

AlexNet (2012) Geoffrey Hinton(Google): ImageNet contest winner(15.4 vs 26.2% error rate)

GoogLeNet (2015)

Microsoft ResNet (2015) 3.6% error rate (better than human)

Deep learning+ convolutional neural networks



AI TARGETS

Big data problems

Big Data Analysis, exploration of statistical correlations beyond human capacity

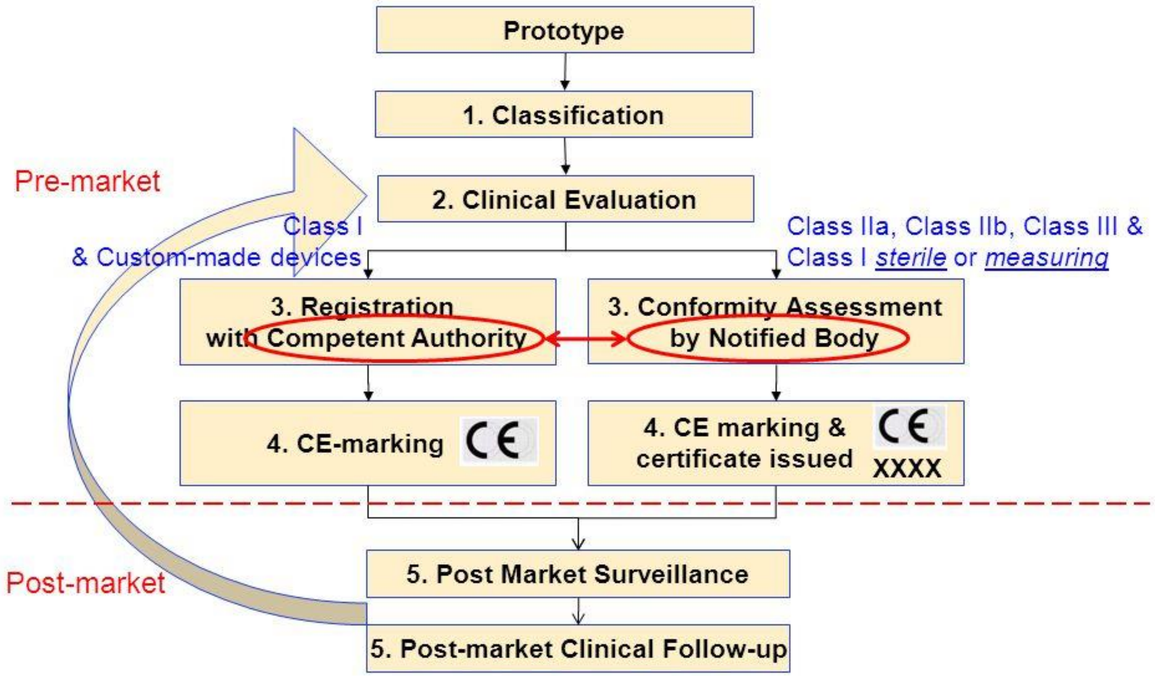
HR problems/reliability

- **Risk of misdiagnosis ↓**
- **Precision ↑**
- **Speed ↑**
- Exam planning, **triage, report acceleration, second opinion, screening**

CE: REGULATORY PROC

Lifecycle of Medical Device

IRISH MEDICINES BOARD



EMERGO

Europe
The Regulatory Process for Medical Devices

MDR Process
Effective early 2020

Starting in early 2020, medical devices must comply with the Medical Device Regulation (MDR) in order to obtain CE Marking certification.

Appoint a "Person Responsible" for regulatory compliance.
Determine classification of your device using Annex VII (Classification Criteria) of the MDR.

Class I Self-certified	Class I Sterile, measuring or reusable surgical	Class IIa	Class IIb	Class III
Implement QMS but Annex VIII compliance not required.	Implement a Quality Management System (QMS) in accordance with Annex VIII of the MDR. Most companies apply the EN ISO 13485 standard to achieve compliance. Your QMS must include Clinical Evaluation, Post Market Surveillance (PMS) and Post Market Clinical Follow-up (PMCF) plans. Make arrangements with suppliers about unannounced Notified Body audits.			
Prepare CE Technical File with CER according to Annex II.	In accordance with Annex II, prepare a CE Technical File or Design Dossier (Class III*) providing information about your device and its intended use plus testing reports, Clinical Evaluation Report (CER), risk management plan, IFU, labeling and more. Obtain a Unique Device Identifier (UDI) for your device.			
Appoint an Authorized Representative (EC REP) located in the EU who is qualified to handle regulatory issues. Place your EC REP name and address on device label. Obtain a Single Registration Number from EUDAMED.				
No Notified Body audit of QMS or Technical File.	Your QMS and Technical File or Design Dossier must be audited by a Notified Body, a third party accredited by a European Competent Authority to audit quality management systems and products.			
	You will be issued a CE Marking certificate for your device and an ISO 13485 certificate for your facility following successful completion of your Notified Body audit. ISO 13485 certification must be renewed every year. CE Marking certificates are typically valid for 3 years, but are reviewed during your annual ISO 13485 surveillance audit.			
Prepare a Declaration of Conformity, a legally binding document prepared by the manufacturer stating that the device is in compliance with the MDR. You may now affix the CE Marking.				
Register the device and its Unique Device Identifier (UDI) in the EUDAMED database. UDI must be on label.				
CE certificates do not expire. Clinical evaluation must be kept updated.	You will be audited by a Notified Body each year to ensure ongoing compliance with the MDR. Failure to pass the audit will invalidate your CE Marking certificate. Your must perform Clinical Evaluation, PMS and PMCF activities to maintain certification.			

* All devices require will require clinical data. Most of these data should refer to the subject device. Clinical studies are required for Class IIb and III implants. Existing clinical data may be acceptable. Clinical trials in Europe must be pre-approved by a European Competent Authority.

This is a simplified overview of the process. Your Notified Body may choose to audit your submission and request more documents, which will add time to your approval.

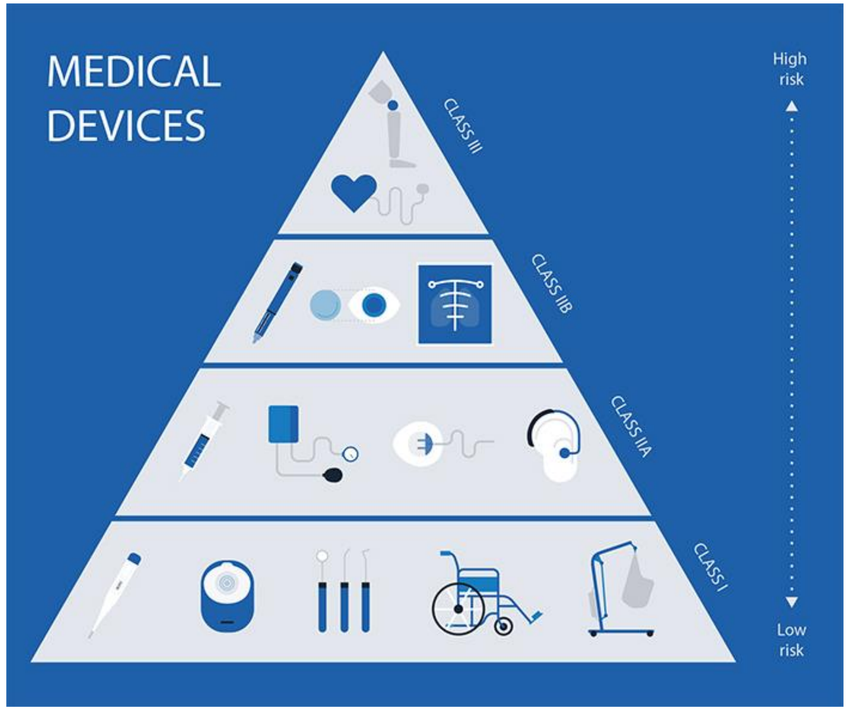
EmergoGroup.com/europe

CE CERTIFICATION: CLASSES

- 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**.
- MDD vs **MDR**: European Medical Device Directives (soon to be replaced by the Medical Device Regulation)

CE CERTIFICATION: CLASSES

State of Healthcare situation or patient condition		Significance of Information provided by the MDSW to a healthcare situation related to diagnosis/therapy		
		High Treat or diagnose *~ IMDRF 5.1.1*	**Medium** Drives clinical management *~ IMDRF 5.1.2*	**Low** Informs clinical management *(everything else)*
	Critical situation or patient condition *~ IMDRF 5.2.1*	**Class III** *Category IV.i*	**Class IIb** *Category III.i*	**Class IIa** *Category II.i*
	Serious situation or patient condition *~ IMDRF 5.2.2*	**Class IIb** *Category III.ii*	**Class IIa** *Category II.ii*	**Class IIa** *Category I.ii*
	Non-serious situation or patient condition *(everything else)*	**Class IIa** *Category II.iii*	**Class IIa** *Category I.iii*	**Class IIa** *Category I.i*



https://towardsdatascience.com/how-to-get-clinical-ai-tech-approved-by-regulators-fa16dfa1983b

FDA APPROVAL SUBMISSION TYPES

510(K) SUBMISSION

Each person who wants to market in the U.S., a Class I, II, and III device intended for human use, for which a Premarket Approval (PMA) is not required, must submit a 510(k) submission to FDA
to demonstrate that the device to be marketed is at least **as safe and effective (substantially equivalent) to a legally marketed device that is not subject to PMA**. Submitters must support their substantial equivalency claims.

PMA

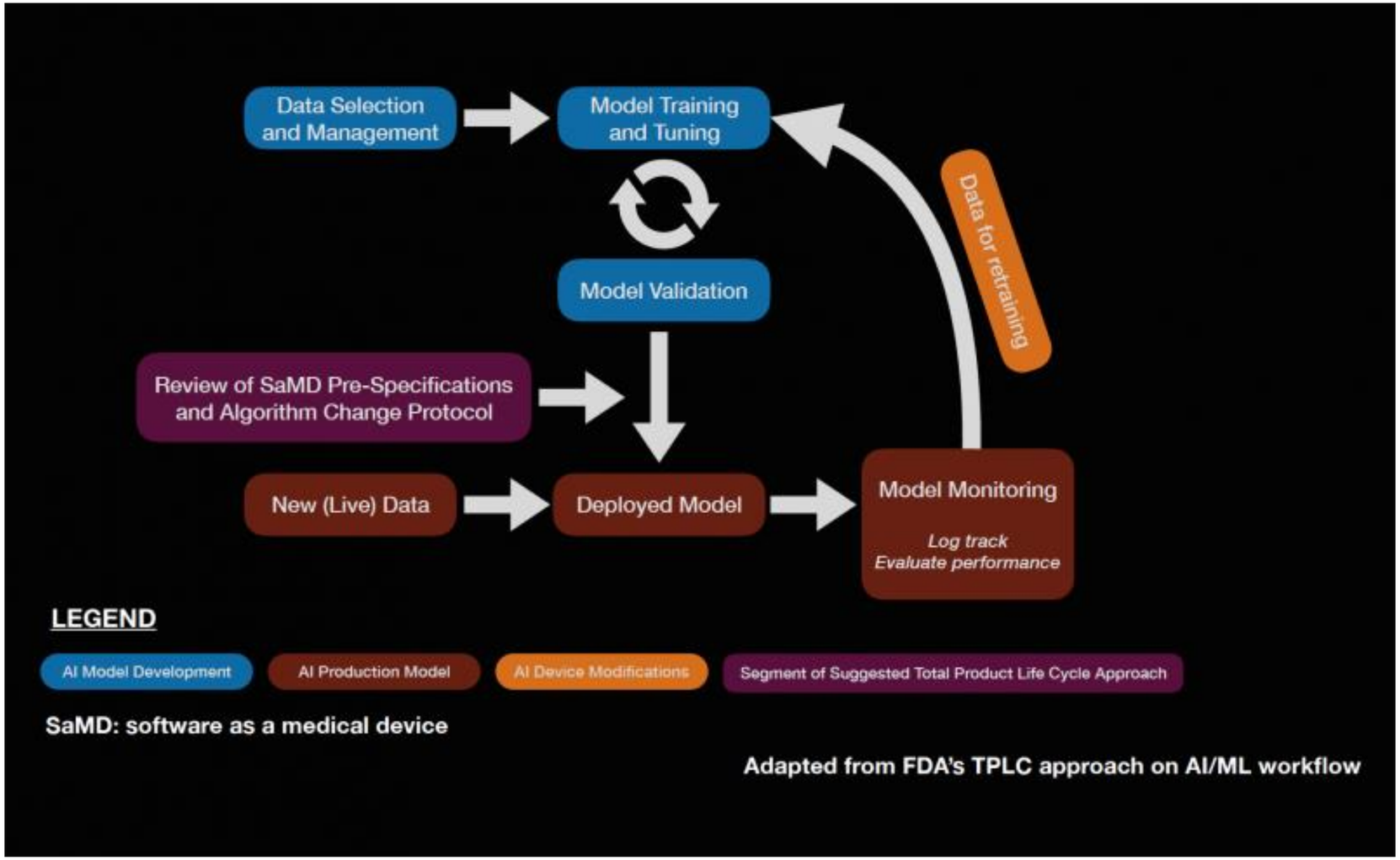
Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of **Class III** medical devices, and the **most stringent** of the device marketing applications. Class III devices are those that **support or sustain human life**, are of substantial importance in preventing impairment of human health, or which **present a potential, unreasonable risk of illness or injury**. General and special controls alone are insufficient to assure the safety and effectiveness of Class III devices. PMA applications will include technical sections, usually divided into non-clinical laboratory studies and clinical investigations. PMA approval typically requires a facility inspection.

DE NOVO

The de novo pathway for device marketing rights was added to address **novel devices of low to moderate risk that do not have a valid predicate device**. Upon successful review of a de novo submission, FDA **creates a classification for the device**, a regulation if necessary, and identifies any special controls required for future premarket submissions of substantially equivalent devices. PRE-SUBMISSIONS (PRE-SUBS)
Pre-submissions are made to the FDA in order to request FDA feedback. Pre-subs are used for various reasons including meeting requests, to study risk determination, for submission issues, and for FDA feedback to specific questions related to a pending submission or protocol. The main purpose of the Pre-Sub Program (previously known as the Pre-IDE Program) is to provide the opportunity for a sponsor to obtain FDA feedback prior to an intended submission of an IDE or marketing application. The Pre-Sub Program can also provide a mechanism for the Agency to provide advice to sponsors who are developing protocols for clinical studies for which an IDE would not be required, such as studies of non-significant risk (NSR) devices or for clinical studies conducted outside of the U.S. to support future U.S. marketing applications. Consequently, the Pre-Sub program can provide an efficient path from device concept to market while facilitating the agency’s goal of fostering the development of new medical devices.

TPLC adaptive algorithms require a total product lifecycle (TPLC) regulatory approach vs. „locked algorithm”

TPLC FDA

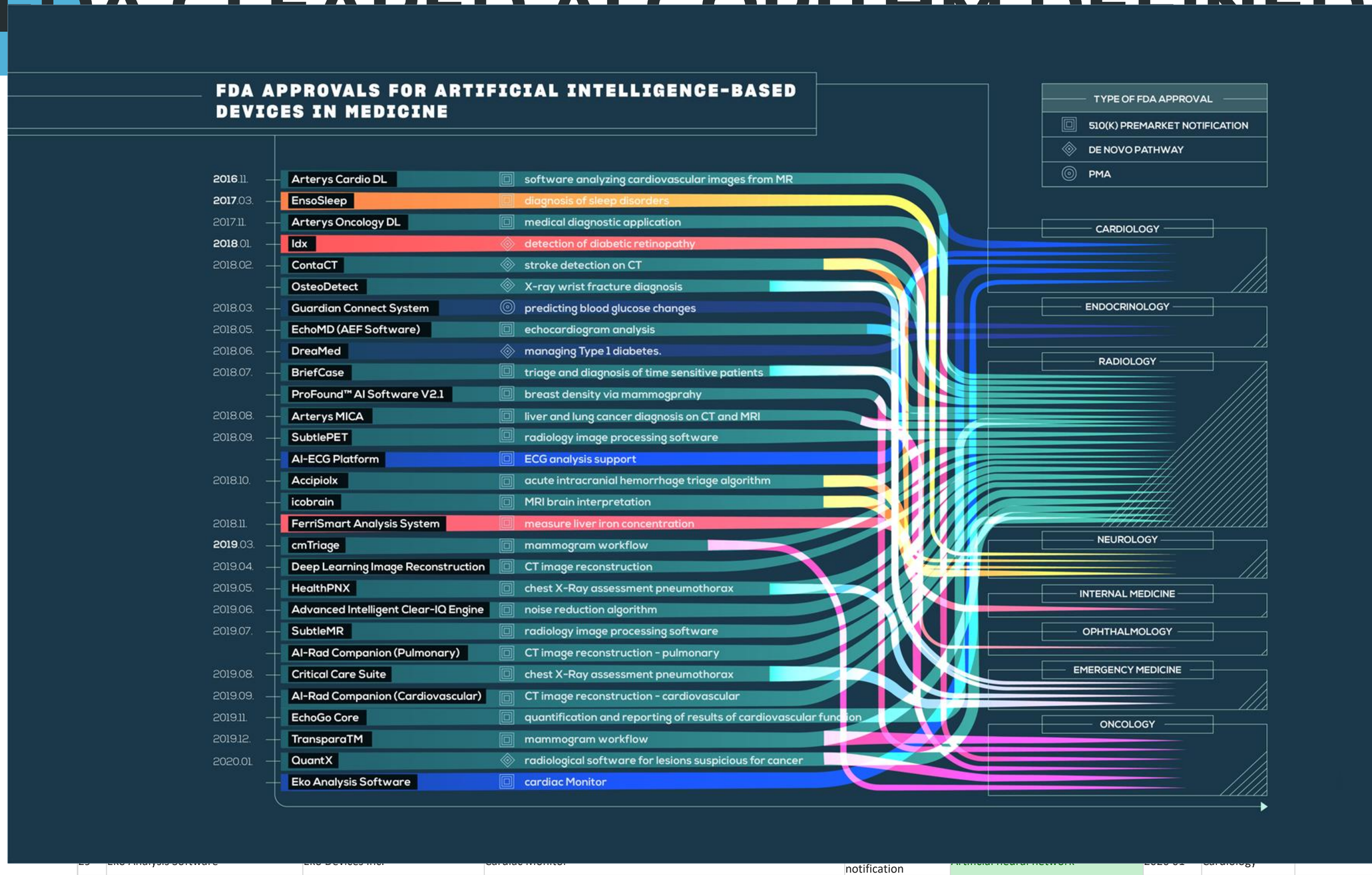

Data Selection and Management
Model Training and Tuning
Model Validation
Review of SaMD Pre-Specifications and Algorithm Change Protocol
New (Live) Data
Deployed Model
Model Monitoring
Log track
Evaluate performance
Data for retraining
LEGEND
AI Model Development
AI Production Model
AI Device Modifications
Segment of Suggested Total Product Life Cycle Approach
SaMD: software as a medical device
Adapted from FDA's TPLC approach on AI/ML workflow

FDA APPROVED AI SOFTWARES

https://medicalfuturist.com/fda-approved-ai-based-algorithms/

(Click to sort Ascending)	(Click to sort Ascending)	(Click to sort Ascending)	(Click to sort Ascending)	(Click to sort Ascending)	(Click to sort Ascending)	(Click to sort Ascending)	(Click to sort Ascending)	(Click to sort Ascending)
Arterys Cardio DL	Arterys Inc	software analyzing cardiovascular images from MR	510(k) premarket notification	deep learning		2016 11	Radiology	Cardiology
EnsoSleep	EnsoData, Inc	diagnosis of sleep disorders	510(k) premarket notification	automated algorithm		2017 03	Neurology	
Arterys Oncology DL	Arterys Inc	medical diagnostic application	510(k) premarket notification	deep learning		2017 11	Radiology	Oncology
Idx	IDx LLC	detection of diabetic retinopathy	de novo pathway	A.I.		2018 01	Ophthalmology	
ContaCT	Viz.AI	stroke detection on CT	de novo pathway	A.I.		2018 02	Radiology	Neurology
OsteoDetect	Imagen Technologies, Inc.	X-ray wrist fracture diagnosis	de novo pathway	deep learning		2018 02	Radiology	Emergency medicine
Guardian Connect System	Medtronic	predicting blood glucose changes	PMA	A.I.		2018 03	Endocrinology	
EchoMD Automated Ejection Fraction Software	Bay Labs, Inc.	echocardiogram analysis	510(k) premarket notification	machine learning		2018 05	Radiology	Cardiology
DreaMed	DreaMed Diabetes, Ltd	managing Type 1 diabetes.	de novo pathway	A.I.		2018 06	Endocrinology	
LungQ	Thirona Corporation	Quantitative analysis of chest CT scans	PMA	Not available	https://bit.ly/2EkHTCM	2018 06	Radiology	Pulmonology
BriefCase	Aidoc Medical, Ltd.	triage and diagnosis of time sensitive patients	510(k) premarket notification	deep learning		2018 07	Radiology	Emergency medicine
ProFound™ AI Software V2.1	iCAD, Inc	breast density via mammogprahy	510(k) premarket notification	deep learning		2018 07	Radiology	Oncology
SubtlePET	Subtle Medical, Inc	radiology image processing software	510(k) premarket notification	deep neural network-based algorithm		2018 09	Radiology	
Arterys MICA	Arterys Inc	Liver and lung cancer diagnosis on CT and MRI	510(k) premarket notification	A.I.		2018 08	Radiology	Oncology
AI-ECG Platform	Shenzhen Carewell	ECG analysis support	510(k) premarket	AI-ECG		2018 09	Cardiology	

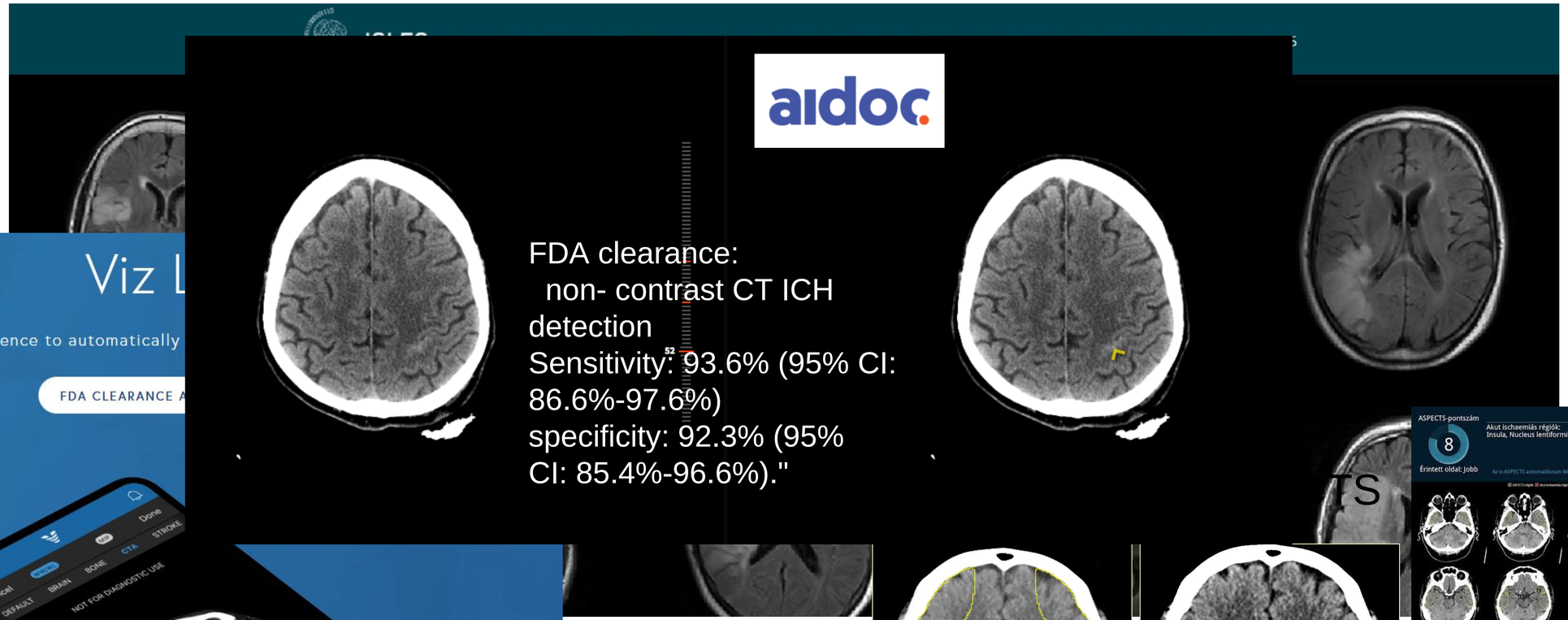
FDA CLEARED AI ALGORITHM DEFINED

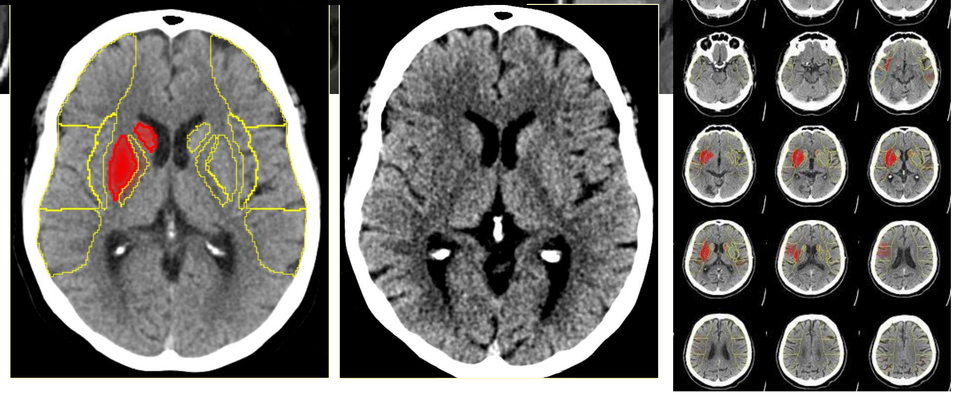


•S Benjamens, P Dhunnoo & B. Meskó
npj Digital Medicine **volume 3**, Article number: 118 (2020)

Cranial AI

STROKE





Köszönet: Martos János 2018

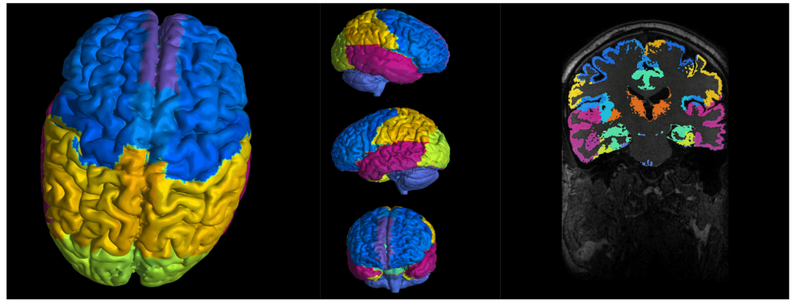
SEGMENTATION/VOLUMETRY

quibim QUantitative Imaging Biomarkers Medicine

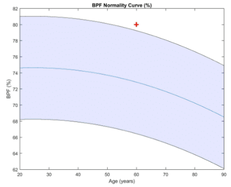
http://quibim.com
info@quibim.com

Brain
Volumetry

Imaging Center	ERESCANER H U POLITECNI…	Patient Name	Glioblas
Modality	MR	Patient ID	
Study Description	RM111 - RM CEREBRAL	Patient Sex	M
Study Date	16/03/2016	Birthdate	



Brain Parenchyma Fraction (%)	80.02



	Absolute Volume (mL)	Relative Volume (% of ICV)
Gray Matter	759.70	41.82
White Matter	693.73	38.19
CSF	362.87	19.97

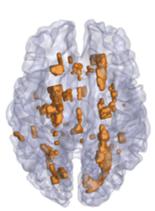
	Absolute Volume (mL)		Relative Volume (% of ICV)	
	Right	Left	Right	Left
Hippocampus	5.58	4.63	0.30	0.25
Frontal	55.13	57.04	3.03	3.14
Amygdala	1.89	1.20	0.10	0.06
Temporal	61.67	43.08	3.39	2.37
Precentral	9.12	9.10	0.50	0.50
Cerebellum	51.11	50.45	2.81	2.77

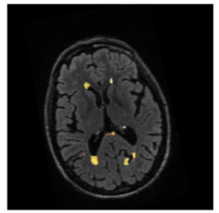
quibim QUantitative Imaging Biomarkers Medicine

http://www.quibim.com
info@quibim.com

Brain
Longitudinal MS Lesions

Imaging Center		Patient Name	
Modality	MR	Patient ID	
Study Description		Patient Sex	
Study Date		Birthdate	



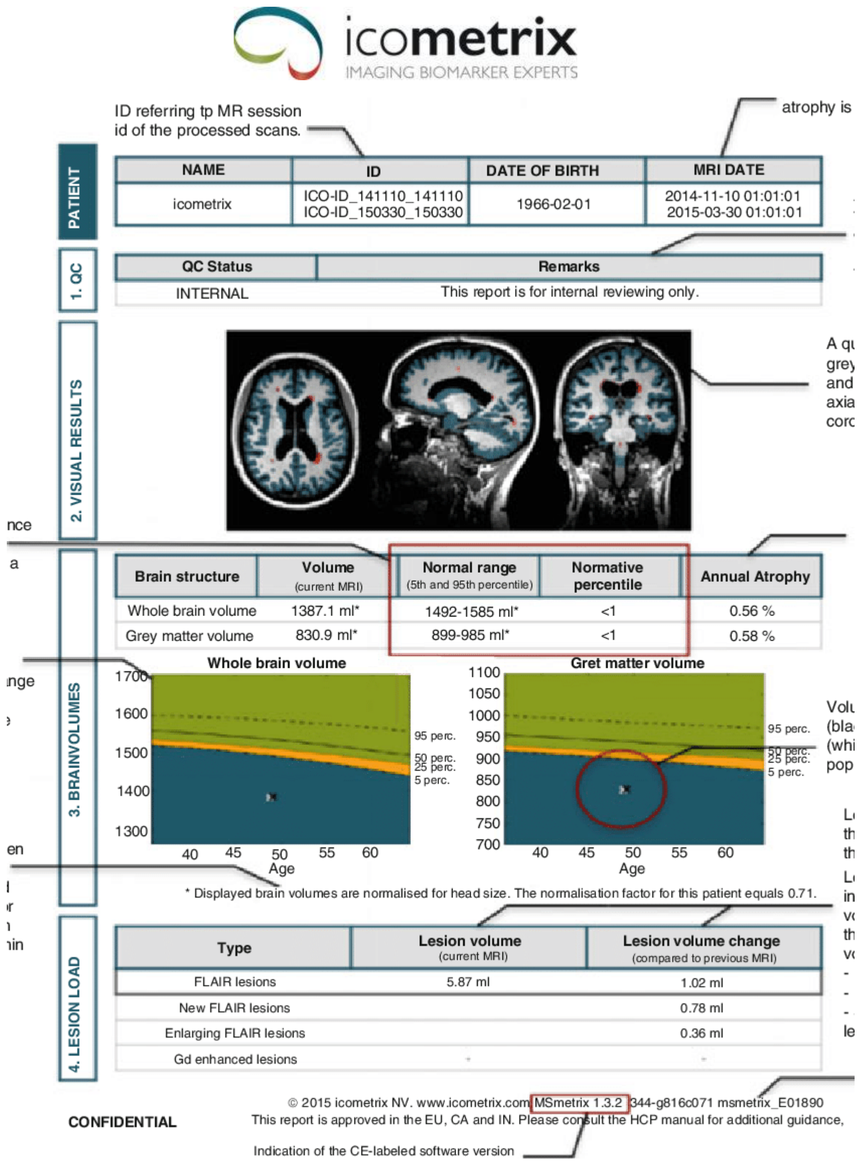


Basal Lesion (Disappearing)
Basal and Follow-up Lesion (Stable)
Follow-up Lesion (New)

Lesion Study				
	Basal		Follow-up	
Flair Lesions	Significant Lesion Count	44	Significant Lesion Count	51
	Total Lesion Volume [mL]	15.87	Total Lesion Volume [mL]	17.07
	Dominant Lesion Volume [mL]	6.37	Dominant Lesion Volume [mL]	8.50
	Dominant Relative Lesion Volume [%]	40.14	Dominant Relative Lesion Volume [%]	49.79
	Brain Parenchyma Fraction (BPF) [%]	0.77	Brain Parenchyma Fraction (BPF) [%]	0.77
Texture Biomarkers	Minimum Kurtosis	1.62	Minimum Kurtosis	1.27
	Mean Kurtosis	3.25	Mean Kurtosis	3.31
	Mean Entropy	1.55	Mean Entropy	1.39
	Maximum Entropy	3.13	Maximum Entropy	2.99

Longitudinal Analysis			
New Significant Lesion Count	7	Change of Brain Parenchyma Fraction (BPF) [%]	0.09
Percentage of Estimated Brain Volume Change per Year (PBVC/y) [%]	0.40	Change of Minimum Kurtosis [%]	-21.31
Percentage of Estimated Brain Lesion Volume Change (PBLC) [%]	7.54	Change of Mean Kurtosis [%]	1.82
Annualized Rate of Brain Volume Loss (ARBVL) [%]	0.40	Change of Mean Entropy [%]	-10.66
New Flair Lesions [mL]	0.94	Change of Maximum Entropy [%]	-4.62
Enlarging Flair Lesions [mL]	3.95	Volume of Lesion Decrease [mL]	2.91

SEGMENTATION /VOLUMETRY



icometrix
IMAGING BIOMARKER EXPERTS

ID referring tp MR session id of the processed scans.

atrophy is

PATIENT

NAME	ID	DATE OF BIRTH	MRI DATE
icometrix	ICO-ID_141110_141110 ICO-ID_150330_150330	1966-02-01	2014-11-10 01:01:01 2015-03-30 01:01:01

1. QC

QC Status	Remarks
INTERNAL	This report is for internal reviewing only.

2. VISUAL RESULTS

A qu grey and axia corc

3. BRAINVOLUMES

Brain structure	Volume (current MRI)	Normal range (5th and 95th percentile)	Normative percentile	Annual Atrophy
Whole brain volume	1387.1 ml*	1492-1585 ml*	<1	0.56 %
Grey matter volume	830.9 ml*	899-985 ml*	<1	0.58 %

Whole brain volume

1700 1600 1500 1400 1300

95 perc.
50 perc.
25 perc.
5 perc.

40 45 50 55 60
Age

Gret matter volume

1100 1050 1000 950 900 850 800 750 700

95 perc.
50 perc.
25 perc.
5 perc.

40 45 50 55 60
Age

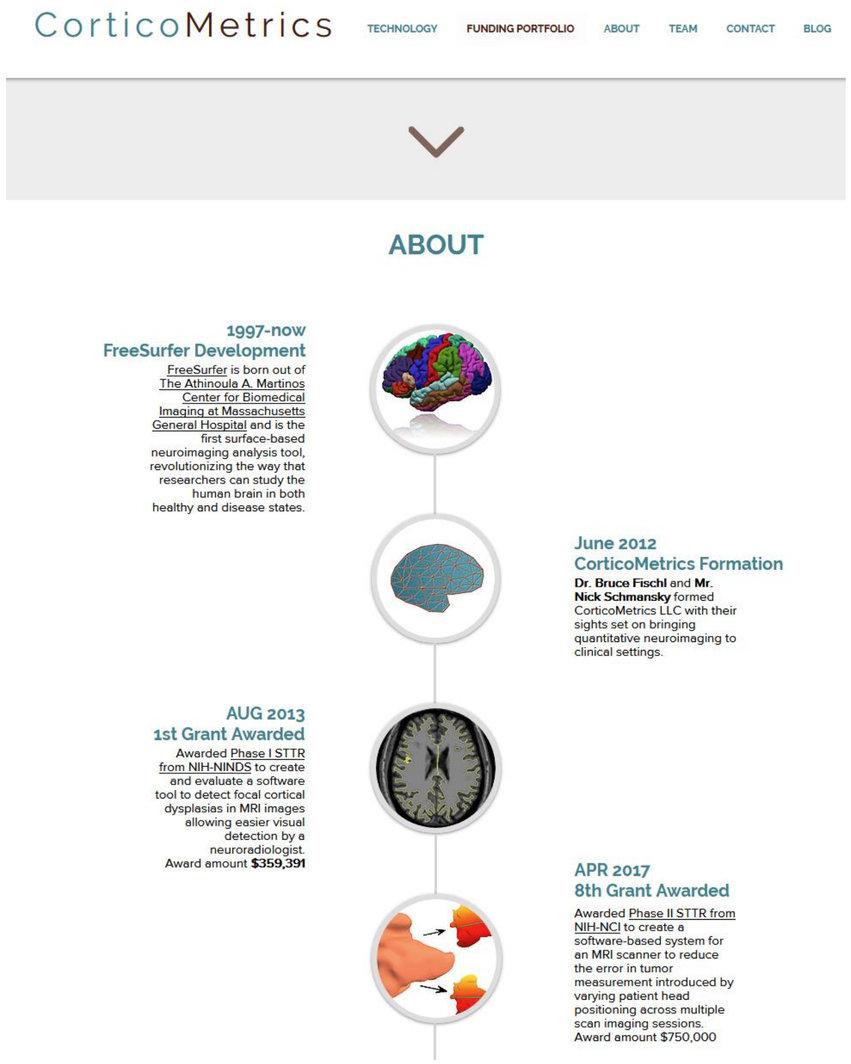
* Displayed brain volumes are normalised for head size. The normalisation factor for this patient equals 0.71.

4. LESION LOAD

Type	Lesion volume (current MRI)	Lesion volume change (compared to previous MRI)
FLAIR lesions	5.87 ml	1.02 ml
New FLAIR lesions		0.78 ml
Enlarging FLAIR lesions		0.36 ml
Gd enhanced lesions		

CONFIDENTIAL

Indication of the CE-labeled software version



CorticoMetrics

TECHNOLOGY | FUNDING PORTFOLIO | ABOUT | TEAM | CONTACT | BLOG

ABOUT

1997-now
FreeSurfer Development

FreeSurfer is born out of The Athinoula A. Martinos Center for Biomedical Imaging at Massachusetts General Hospital and is the first surface-based neuroimaging analysis tool, revolutionizing the way that researchers can study the human brain in both healthy and disease states.

June 2012
CorticoMetrics Formation

Dr. Bruce Fischl and **Mr. Nick Schmansky** formed CorticoMetrics LLC with their sights set on bringing quantitative neuroimaging to clinical settings.

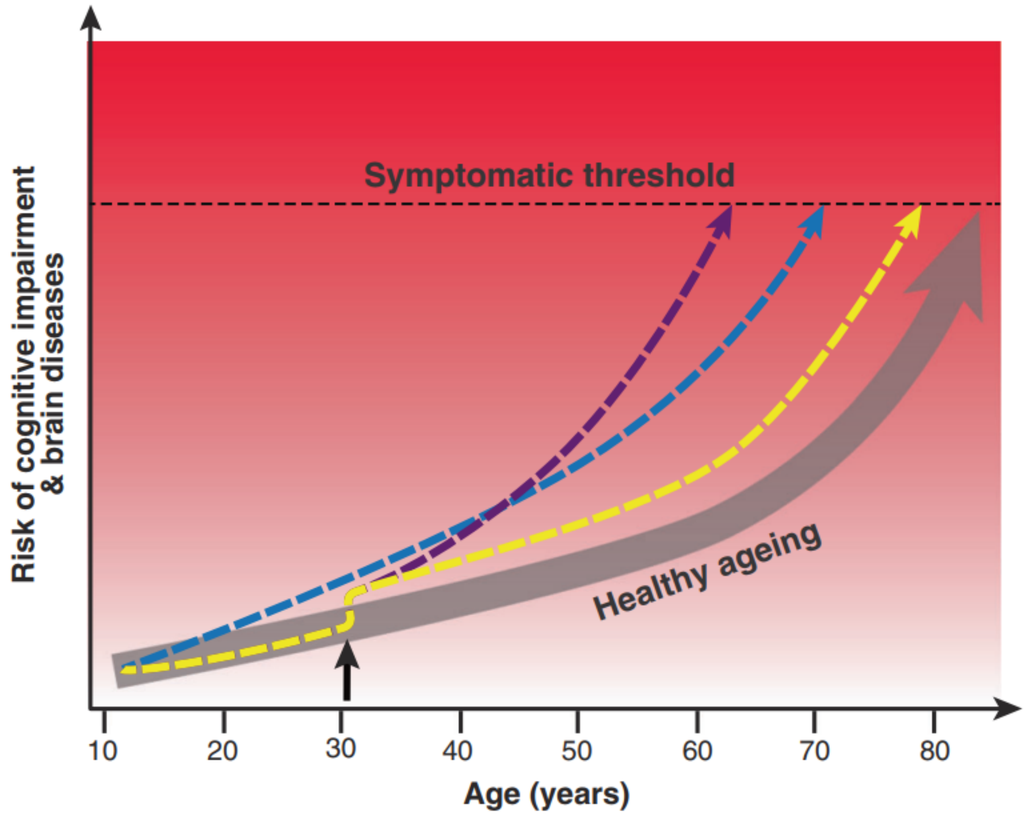
AUG 2013
1st Grant Awarded

Awarded Phase I STTR from NIH-NINDS to create and evaluate a software tool to detect focal cortical dysplasias in MRI images allowing easier visual detection by a neuroradiologist. Award amount **$359,391**

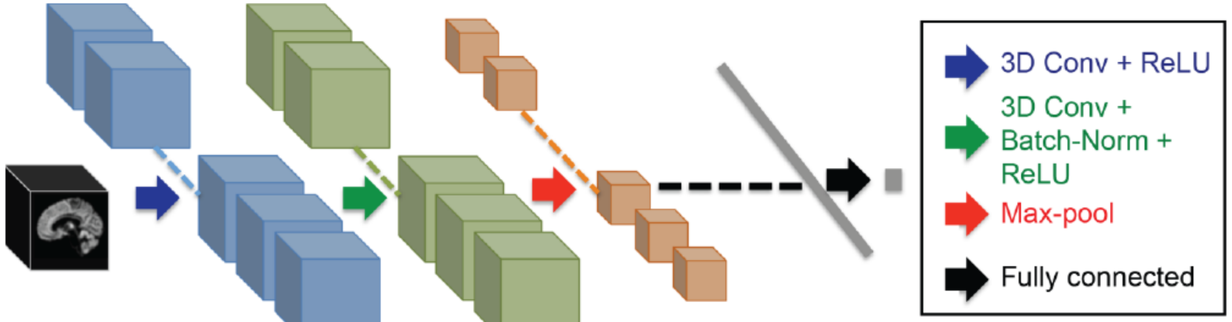
APR 2017
8th Grant Awarded

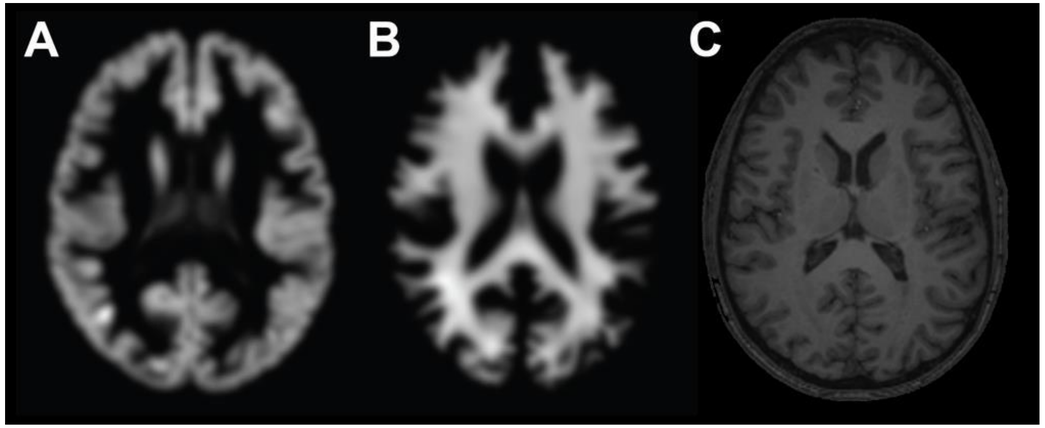
Awarded Phase II STTR from NIH-NCI to create a software-based system for an MRI scanner to reduce the error in tumor measurement introduced by varying patient head positioning across multiple scan imaging sessions. Award amount $750,000

PREDICTING BRAIN AGE: EARLY DIAGNOSTICS OF ALZHEIMER?



Cole et al., 2018, *Mol Psych*





Cole et al. Neuroimage. 2017

Chest/Mammo XRAY/ CT AI

CHEST XRAY ANALYSIS

OXIPIT

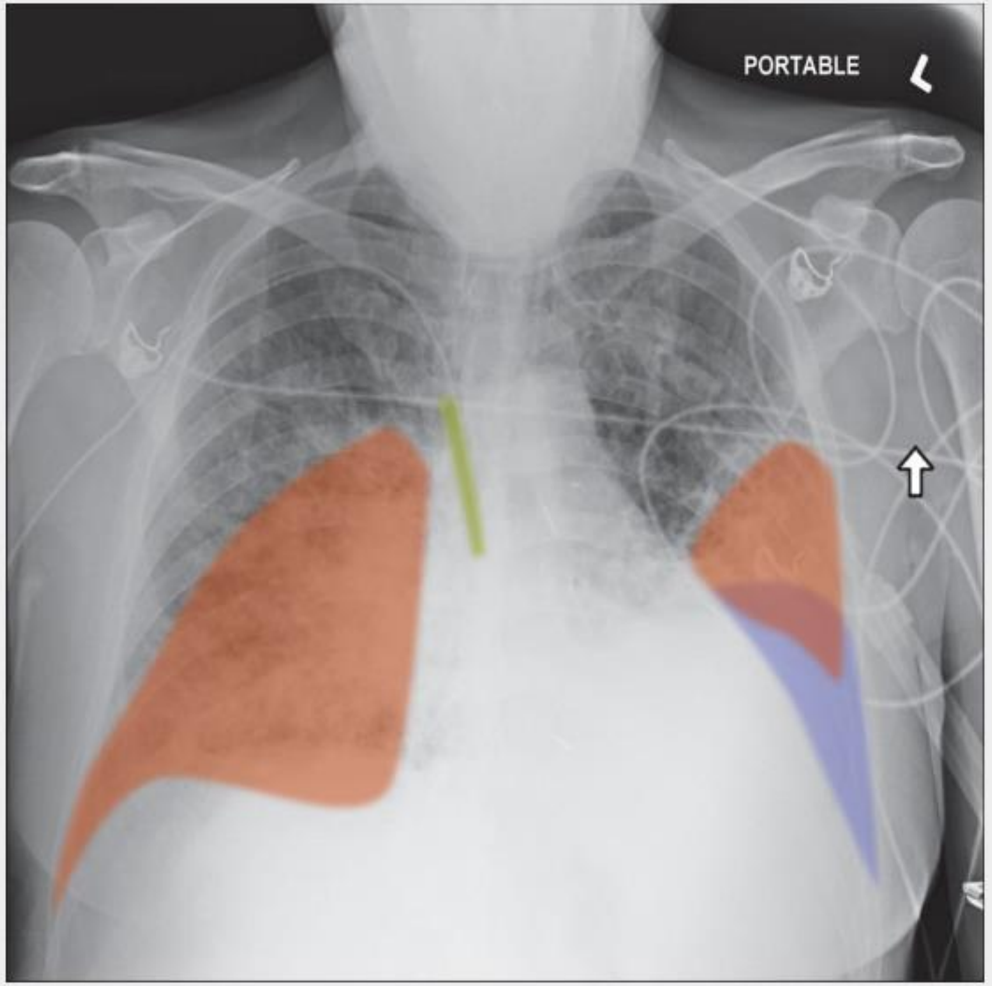
Example results

Findings

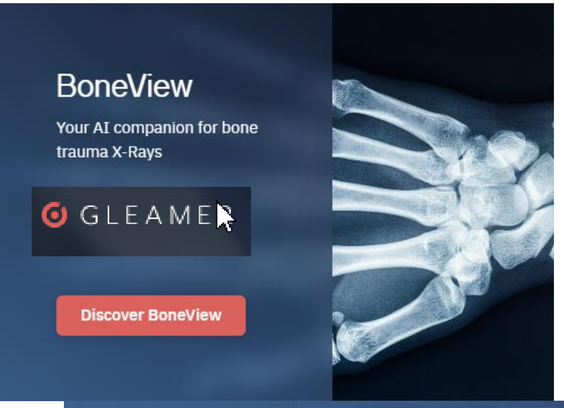
- There is volume loss in both lungs. Ill defined opacities are present bilaterally.
- A left sided pleural effusion is seen filling the costophrenic sulcus.
- The hilar area is enlarged.
- The mediastinum is within normal limits.
- Central venous cathether is observed with tip at the superior vena cava.

Impression

Bilateral consolidation. Left pleural effusion.



FRACTURE DETECTION- EXTREMITIES XRAY



External validation of a commercially available deep learning algorithm for fracture detection in children

Diagnostic and Interventional Imaging
Volume 103, Issue 3, March 2022, Pages 151-159

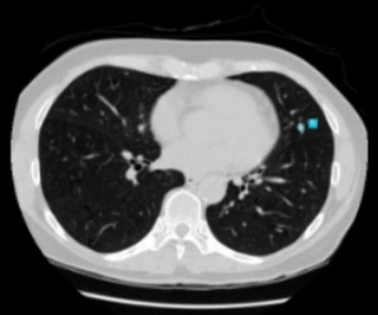
LUNG NODULE CLASSIFICATION

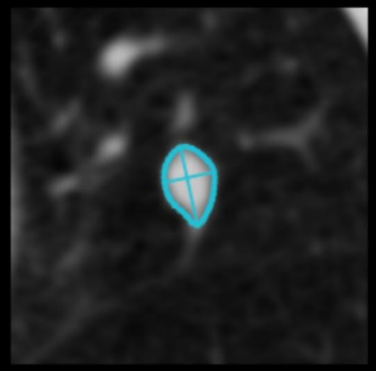
Nodule: 1
Slice: 141
Composition: Solid

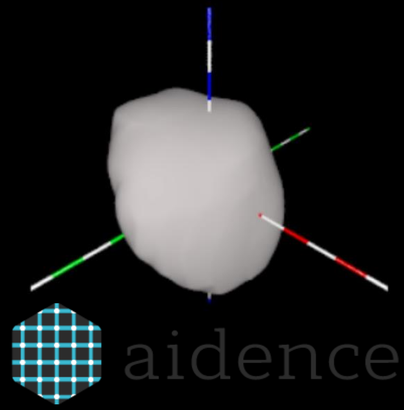
Growth: 138%
VDT: 292 days
VDT CI: (264, 325)

Current study: 02-01-2001

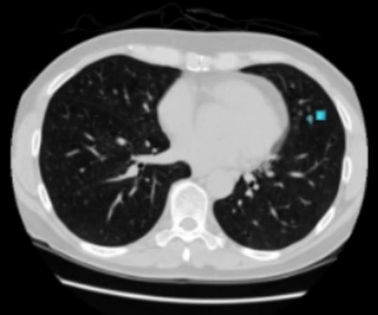
	Diameter (mm)	Volume (mm³)	Volume CI
Current	9x6 (8)	233	(223, 244)
Prior	6x4 (5)	98	(90, 106)

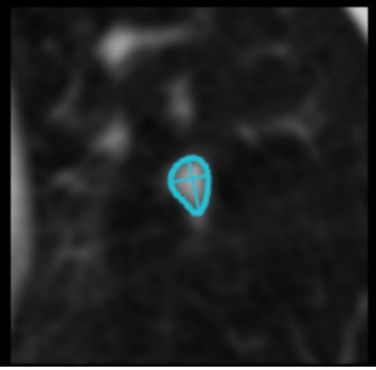


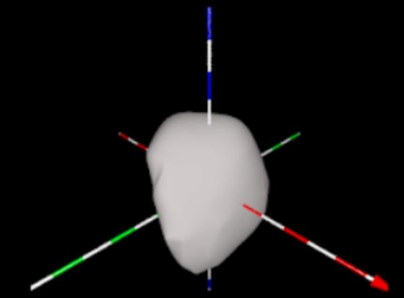


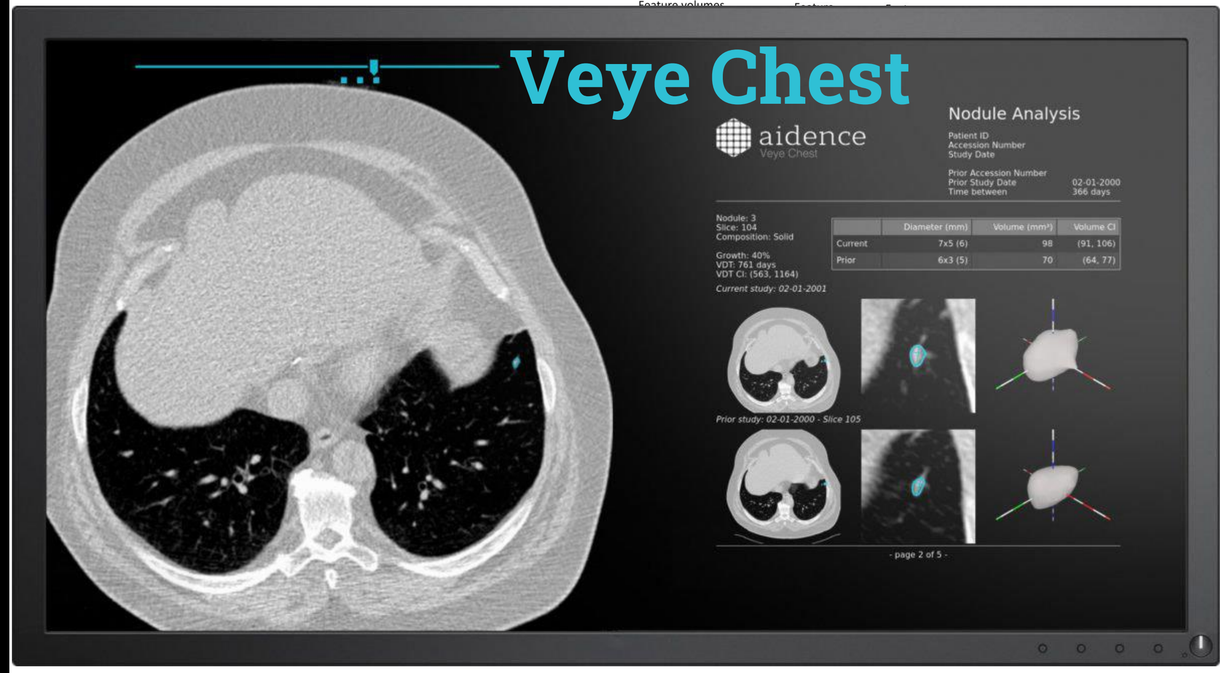


Prior study: 02-01-2000 - Slice 146

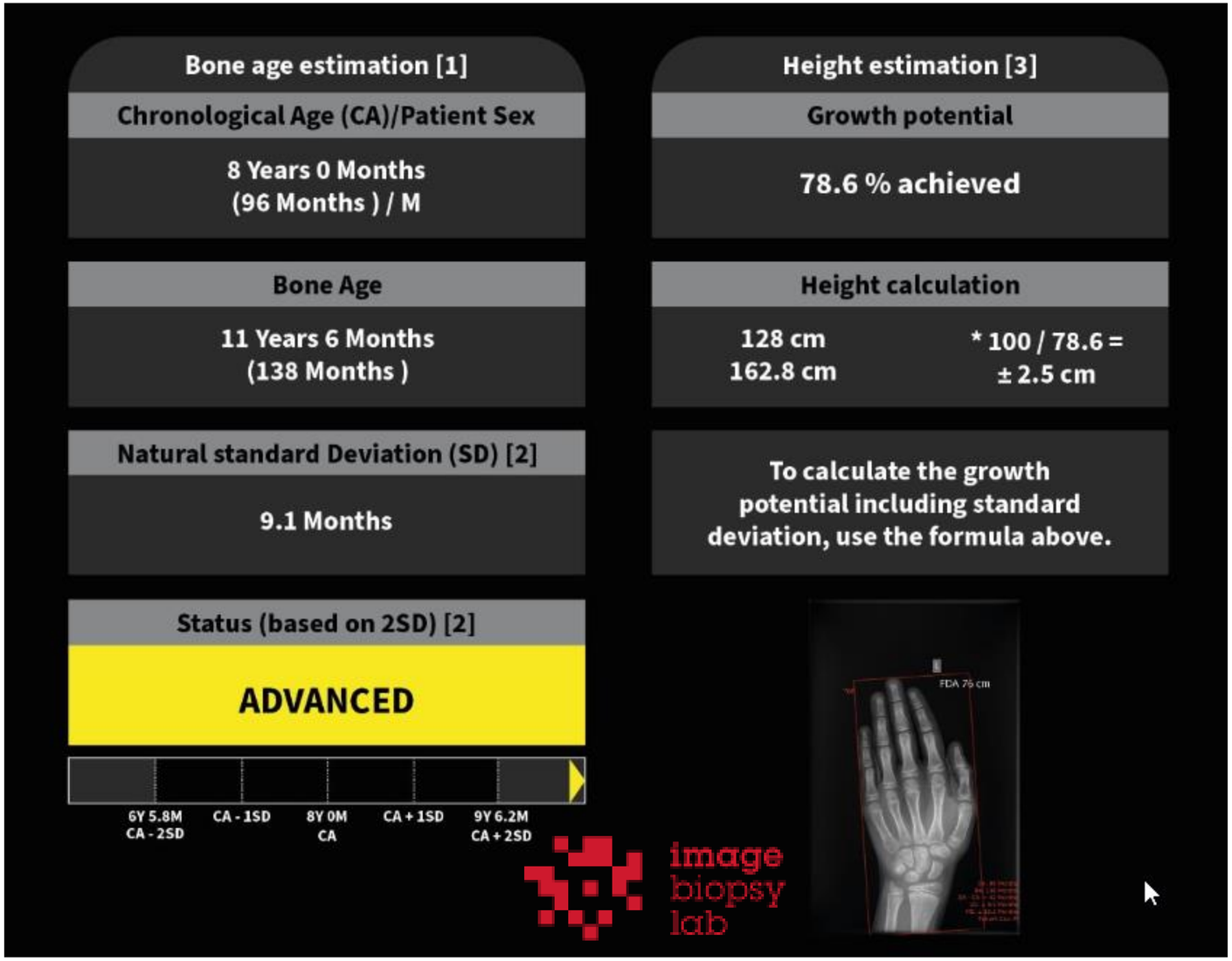








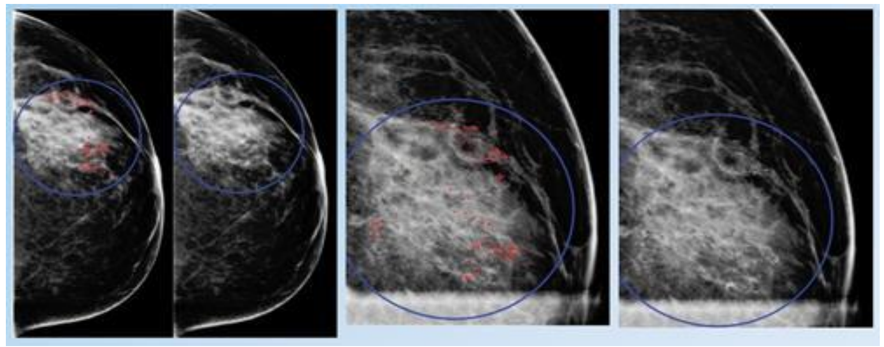
BONE AGE ASSESSMENT

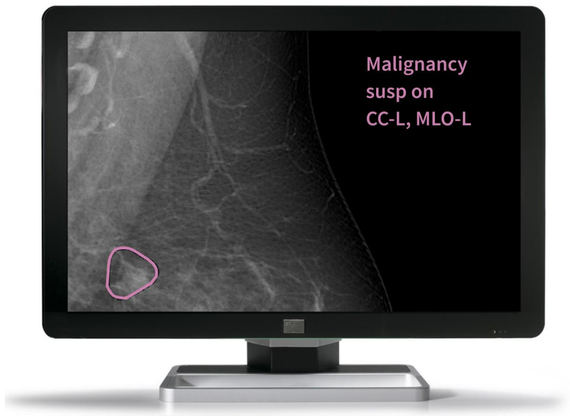


BoneXpert

Greulich & Pyle ±4.3 months mean absolute deviation
adult height estimation according to Bailey and Pineau ±2.5 cm

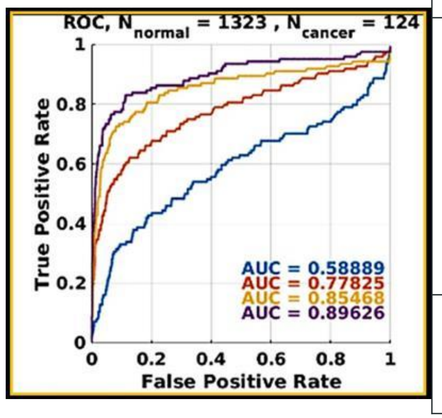
CAD OUTPERFORMING MAMMOGRAPHERS?





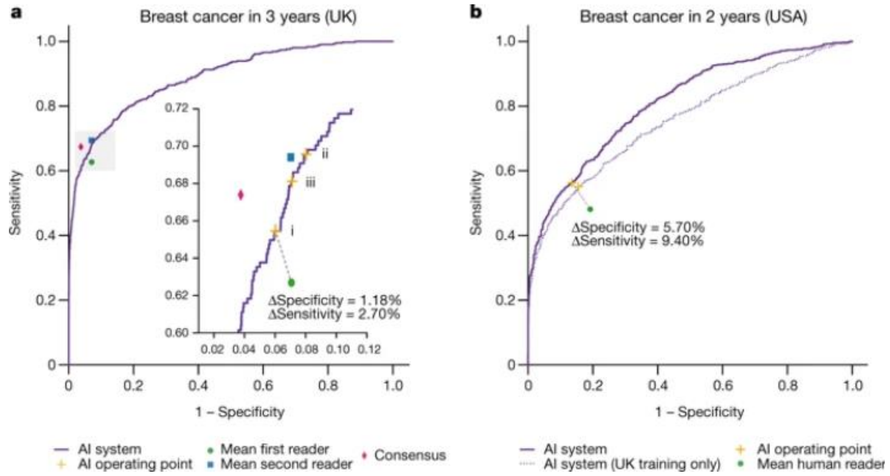
KHEIRON
MEDICAL TECHNOLOGIES

Mia™
CE



Performance of CAD software vs. radiologists by false-positive rates			
	Radiologists	**CAD software (at 100% sensitivity threshold for cancer detection)**	**Potential reduction in breast biopsies from use of CAD software**
Academic radiology department	**80%**	**35%**	**57%**

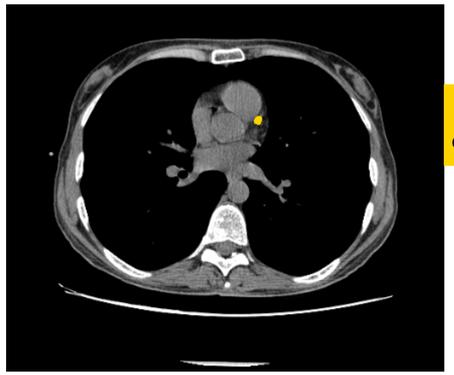
Alyssa Watanabe of the University of Southern California (USC) Keck School of Medicine, ECR 2017



McKinney, S. M. *et al. Nature* **577**, 89–94 (2020).

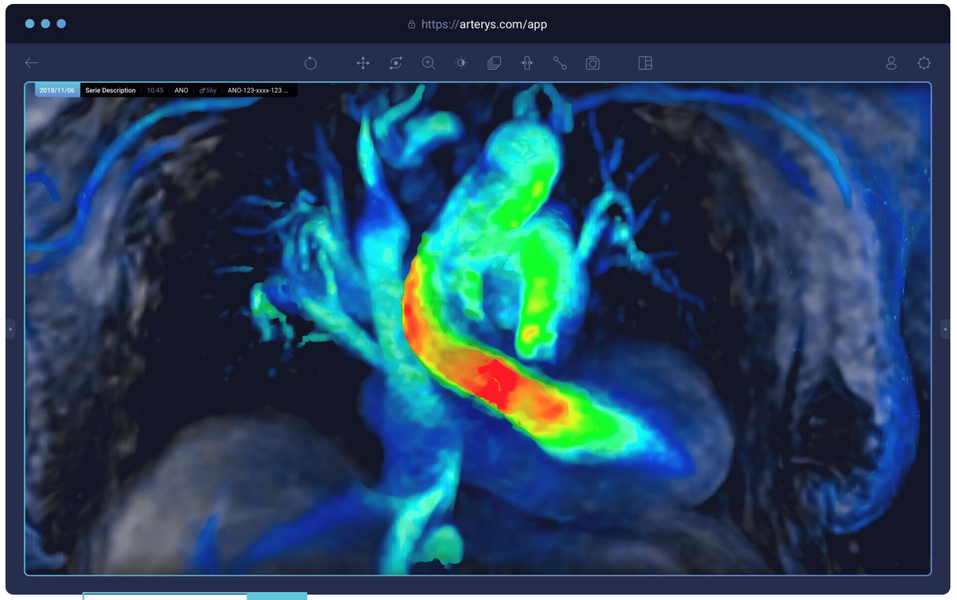
AI in CARDIOLOGY

CARDIAC IMAGING: PLANNING, 4D FLOW, CA++ SCORE



zebra MEDICAL.VISION

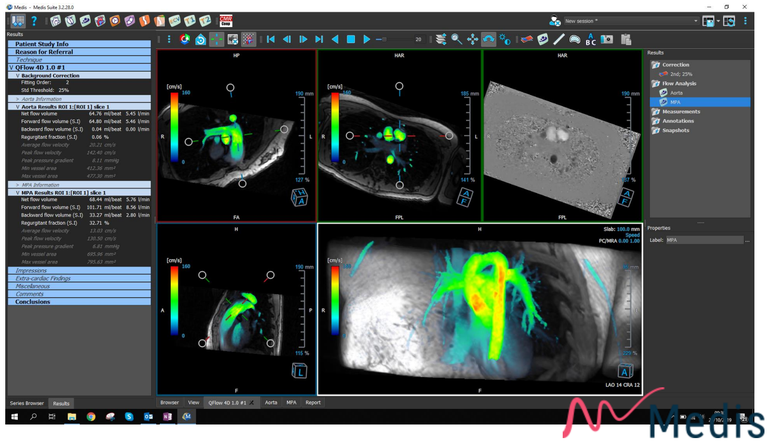
Calcium score, FDA cleared



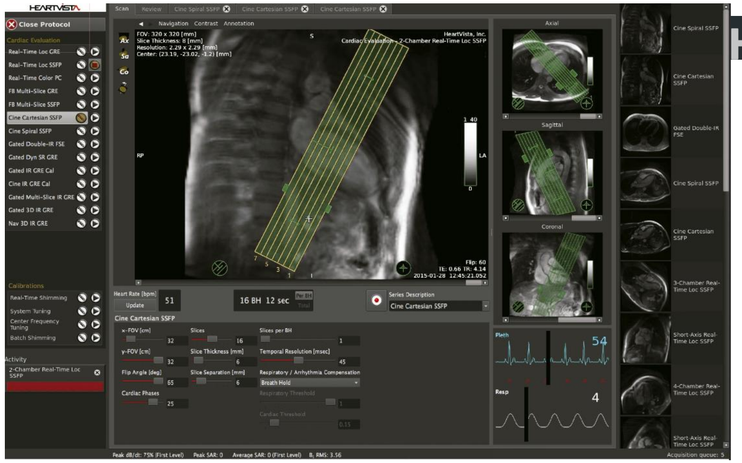
CARDIO AI
ARTERYS

4D Flow (FDA approved)

4D Flow (FDA approved)



Medis

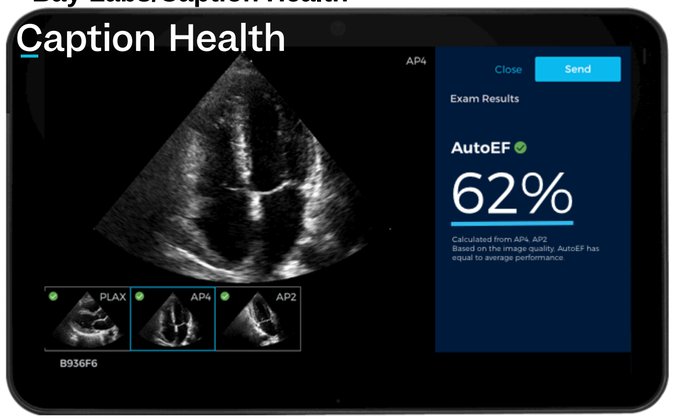


HEARTVISTA

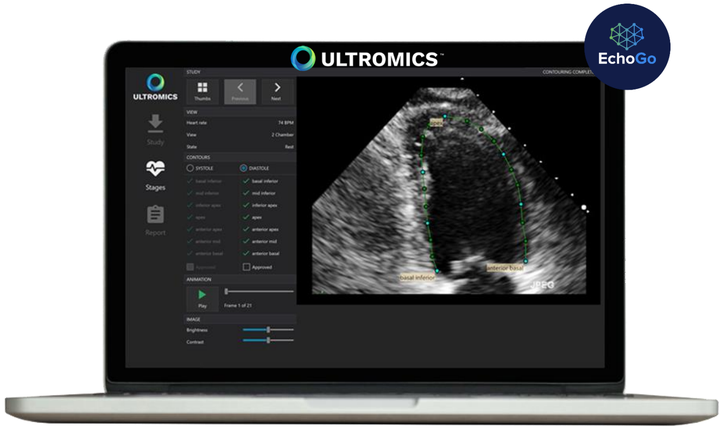
OneCLick (FDA approved)

CARDIAC SEGMENTATION/ CONTOUR DETECTION: EF /STRAIN/VOLUMETRY ASSESSMENT

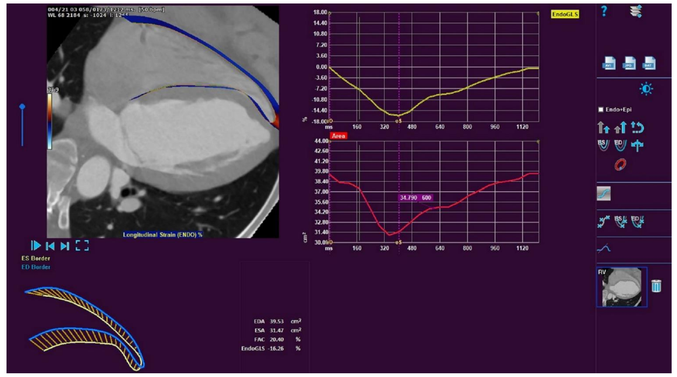
Bay Labs/Caption Health



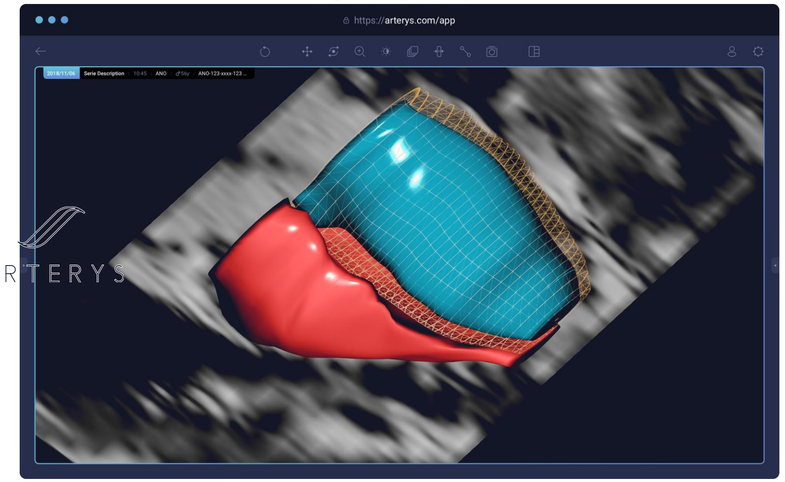
Echo: AI contour, EF, FDA cleared



Echo: AI contour, EF, strain FDA cleared

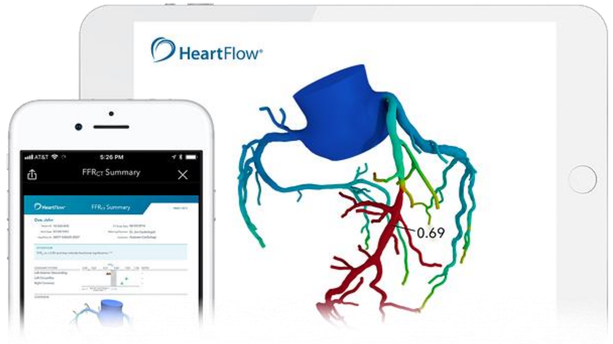


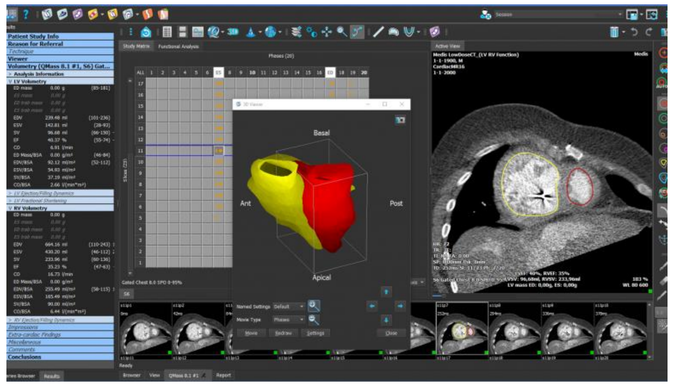
CT strain (Research)



2D SSFP and 3D Cine LV/RV segmentation(FDA)

HeartFlow FFR_{CT} Analysis

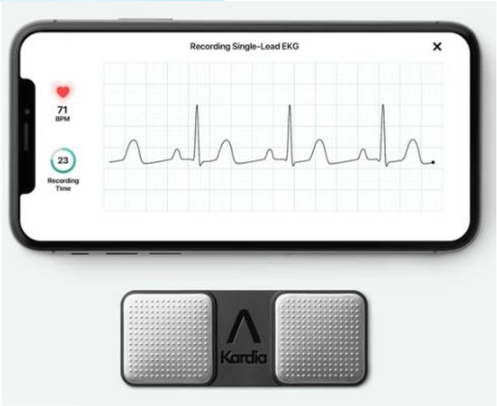


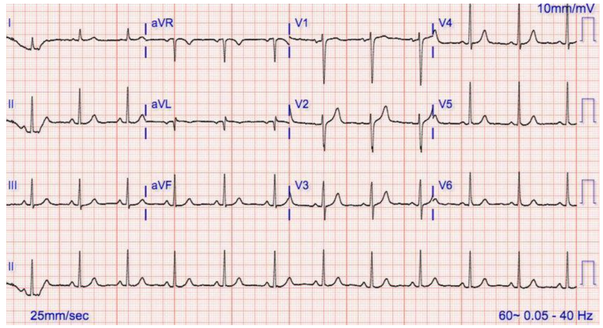


Medis

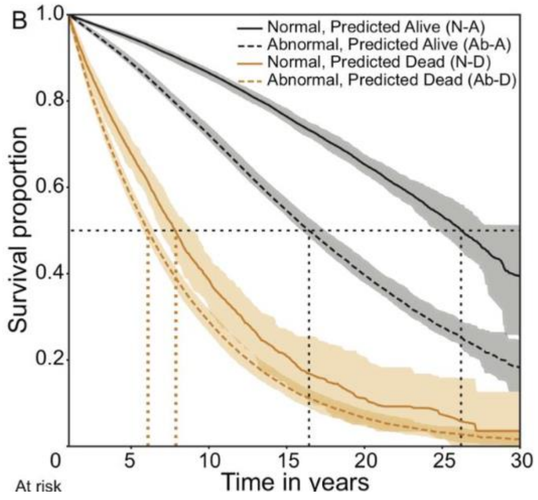
CT contour (FDA cleared)

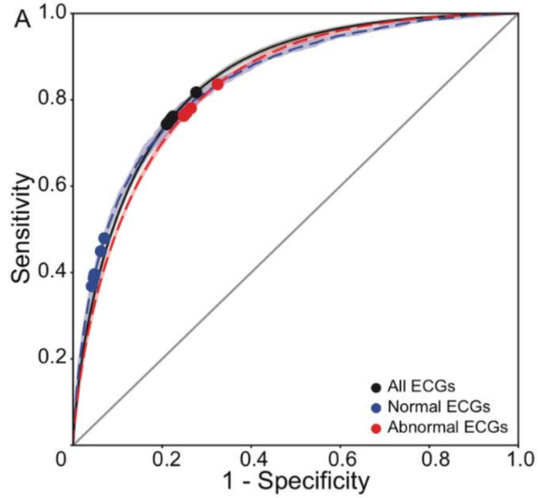
ECG: AFIB DETECTION, ARRYTHMIA/ DEATH PREDICITON





Predicting 1-year all-cause mortality: 0.830 (AUC)



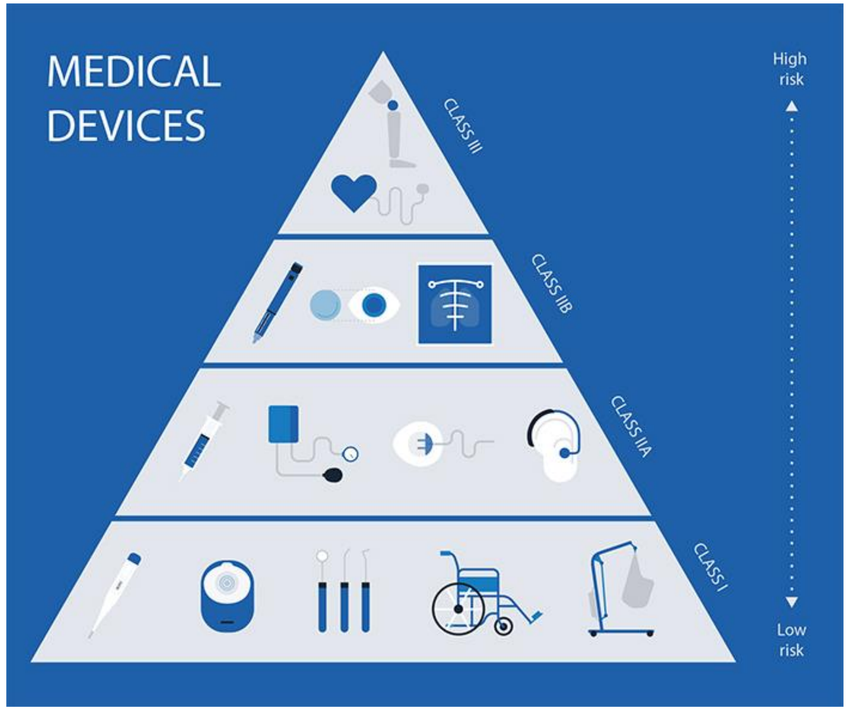


Raghunath et al, Nature Medicine 2020

Ethical issues, regulations

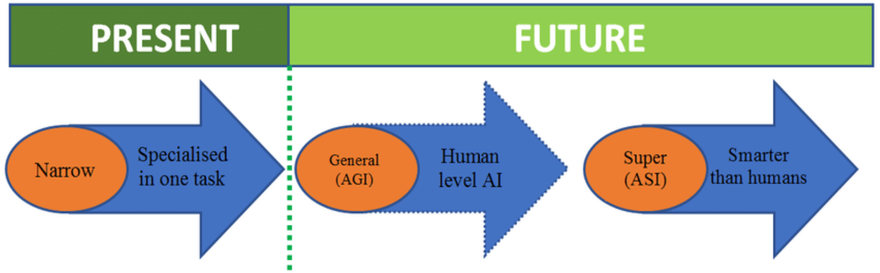
CE CERTIFICATION: CLASSES

State of Healthcare situation or patient condition		Significance of Information provided by the MDSW to a healthcare situation related to diagnosis/therapy		
		High Treat or diagnose *~ IMDRF 5.1.1*	**Medium** Drives clinical management *~ IMDRF 5.1.2*	**Low** Informs clinical management *(everything else)*
	Critical situation or patient condition *~ IMDRF 5.2.1*	**Class III** *Category IV.i*	**Class IIb** *Category III.i*	**Class IIa** *Category II.i*
	Serious situation or patient condition *~ IMDRF 5.2.2*	**Class IIb** *Category III.ii*	**Class IIa** *Category II.ii*	**Class IIa** *Category I.ii*
	Non-serious situation or patient condition *(everything else)*	**Class IIa** *Category II.iii*	**Class IIa** *Category I.iii*	**Class IIa** *Category I.i*

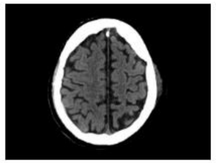


https://towardsdatascience.com/how-to-get-clinical-ai-tech-approved-by-regulators-fa16dfa1983b

NARROW AI: LIMITATIONS

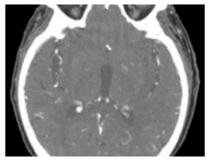


Class IIa: diagnostic **support**



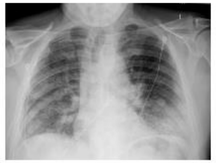
Intracranial Hemorrhage

510(k) Triage and notification software indicated for use in the analysis of non-enhanced head CT images; flags and communicates suspected positive findings of pathologies in head CT images, namely Intracranial Hemorrhage (ICH).



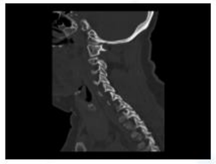
Vessel Occlusion

510(k) Triage and notification software indicated for use in the analysis of head CTA images; flags and communicates suspected positive findings of Vessel Occlusion.



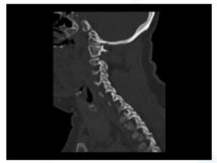
Pneumothorax

510(k) Triage and notification software indicated for use in the analysis of Chest X-Ray images; flags and communicates Pneumothorax (Ptx).



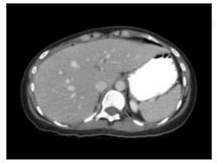
Acute C-Spine Fractures

510(k) Triage and notification software indicated for use in the analysis of cervical spine CT images; flags and communicates suspected positive findings of linear lucencies in the cervical spine bone in patterns compatible with fractures.



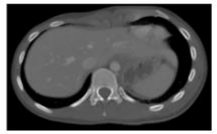
Acute C-Spine Fractures

510(k) Triage and notification software indicated for use in the analysis of cervical spine CT images; flags and communicates suspected positive findings of linear lucencies in the cervical spine bone in patterns compatible with fractures.



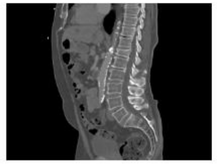
Intra-Abdominal Free Gas

510(k) Triage and notification software indicated for use in the analysis of abdomen CT images; flags and communicates suspected positive cases of Intra- Abdominal Free Gas (IFG).



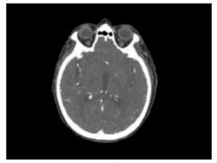
Rib Fractures

510(k) Triage and notification software indicated for use in the analysis of chest CTs (with or without contrast); flags and communicates suspected cases of three or more acute Rib fracture (RibFx) pathologies.



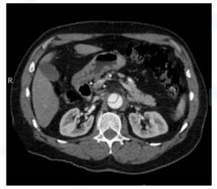
Vertebral Compression Fractures

510(k) Triage and notification software indicated for use in the analysis of chest and abdominal CT images; flags and communicates suspected positive cases of Vertebral Compression Fractures (VCFx) findings.



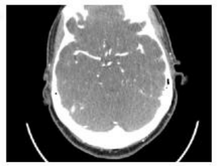
M1 Large Vessel Occlusions

510(k) Triage and notification software indicated for use in the analysis of head CTA images; flags and communicates suspected positive findings of M1 Large Vessel Occlusion (M1 LVO).



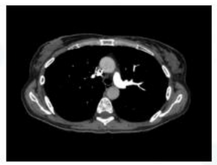
Aortic Dissection

510(k) Triage and notification software indicated for use in the analysis of CT exams with contrast that includes the chest; flags and communicates suspected positive findings of Aortic Dissection.



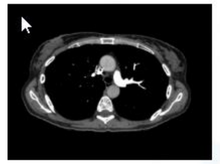
Brain Aneurysm

510(k) Triage and notification software indicated for use in the analysis of Head CTA images; flags and communicates Brain Aneurysm (BA).



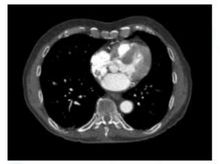
Pulmonary Embolism

510(k) Triage and notification software indicated for use in the analysis of CTPA images; flags and communicates Pulmonary Embolism (PE).



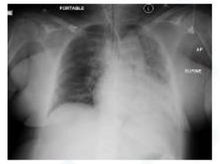
Pulmonary Embolism

510(k) Triage and notification software indicated for use in the analysis of CTPA images; flags and communicates Pulmonary Embolism (PE).



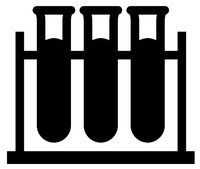
Incidental PE

510(k) Triage and notification software indicated for use in the analysis of CT images (not dedicated CTPA protocol) ; flags and communicates incidental Pulmonary Embolism (PE).



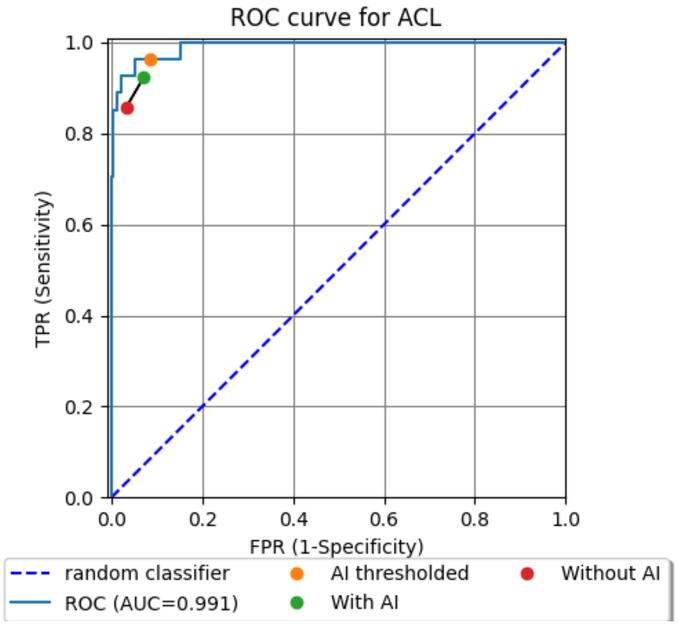
Malpositioned Endotracheal Tubes (ETT)

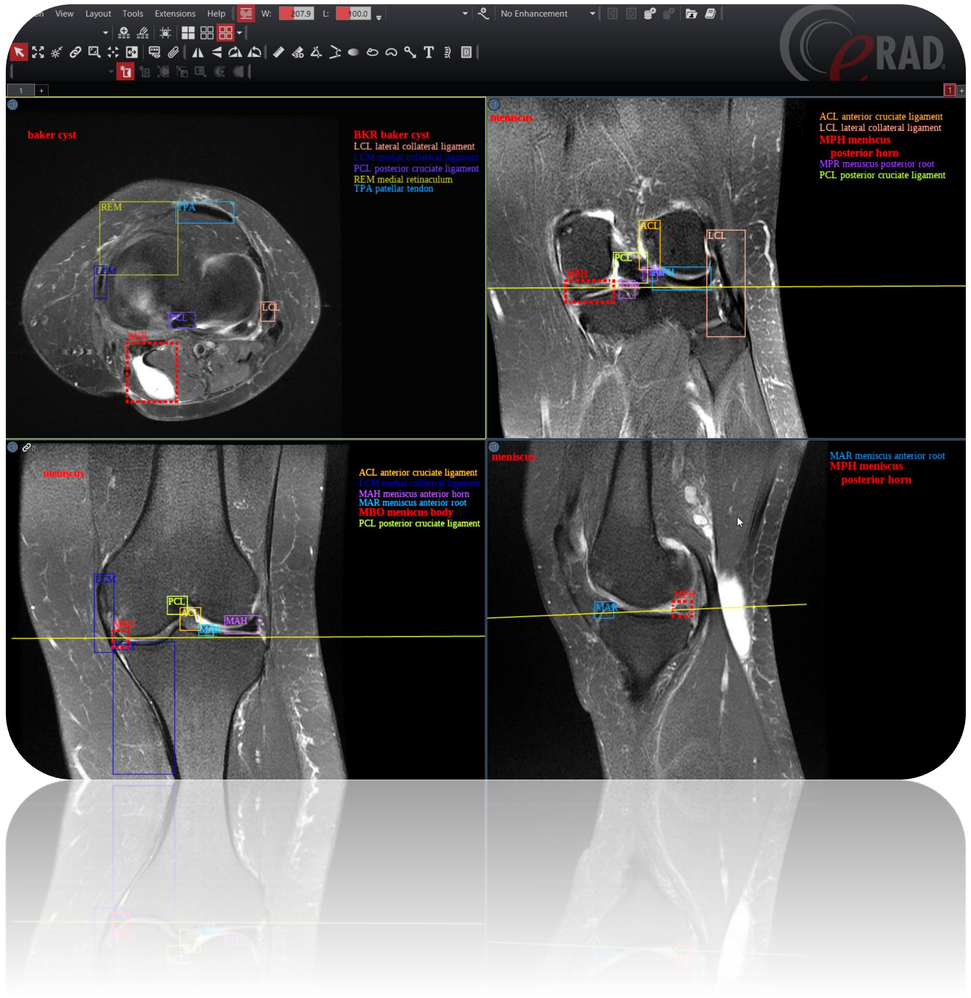
510(k) Triage and notification software indicated for use in the analysis of Frontal Chest X-Ray images; flags and communicates suspected positive cases of vertically malpositioned endotracheal tube (ETT) in relation to the carina.

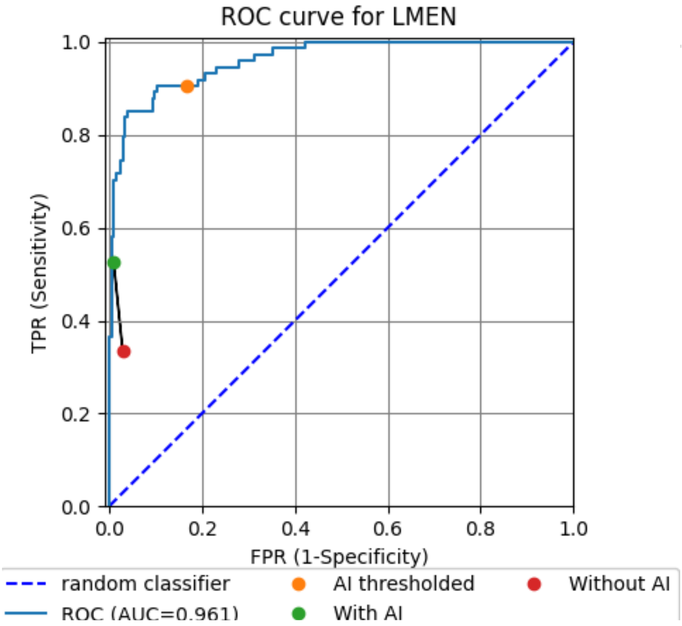


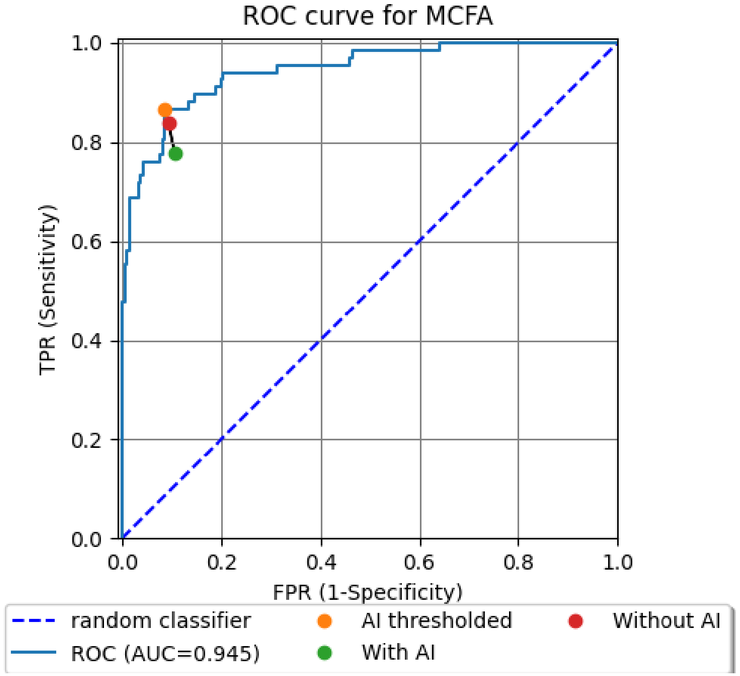
Na, K, Cr

AI-HUMAN INTERACTION

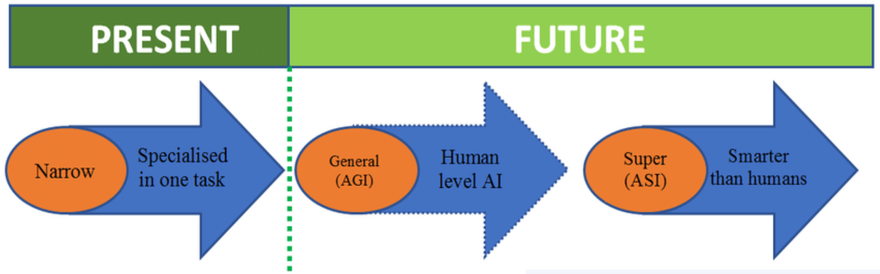




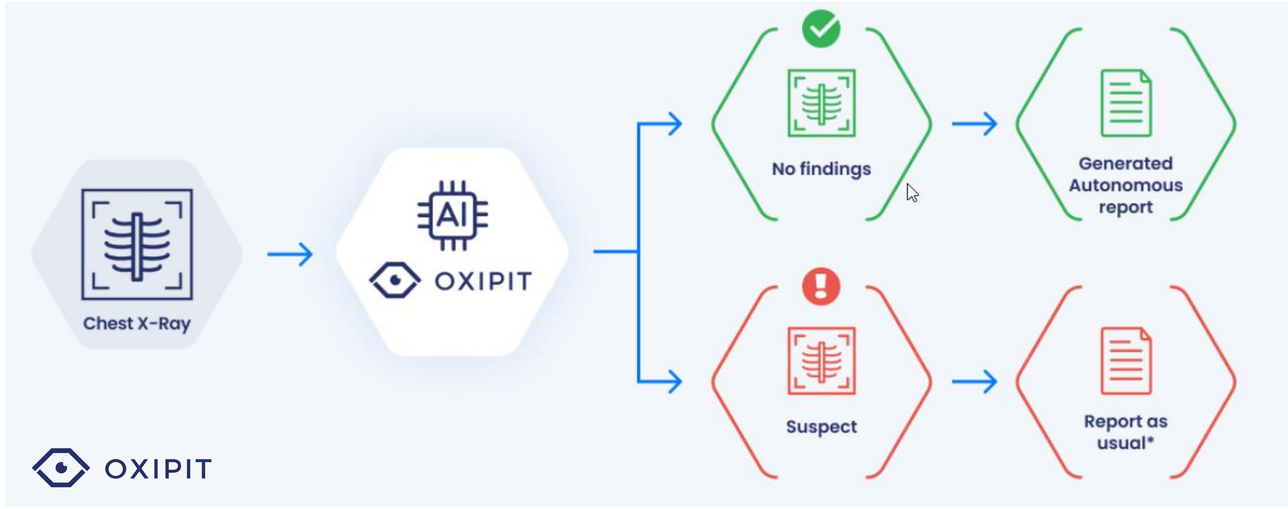


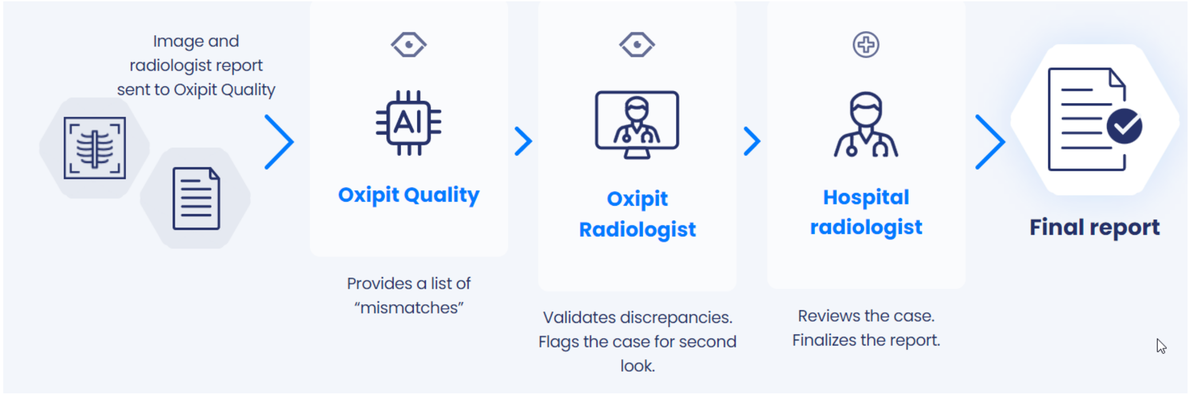


GENERAL AI: RESPONSIBILITY?



Class IIb: autonomous



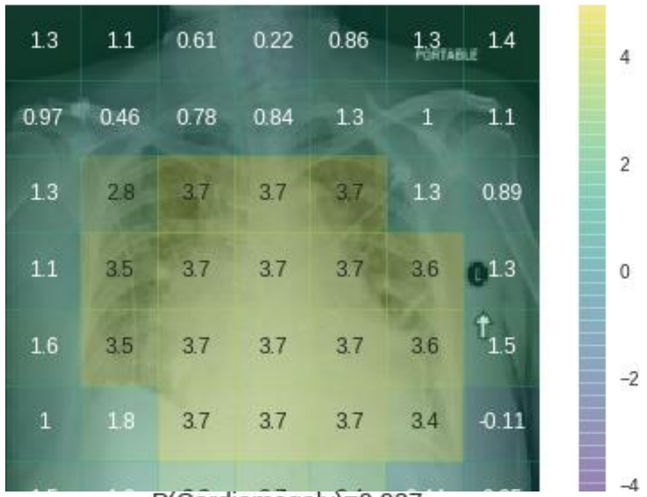


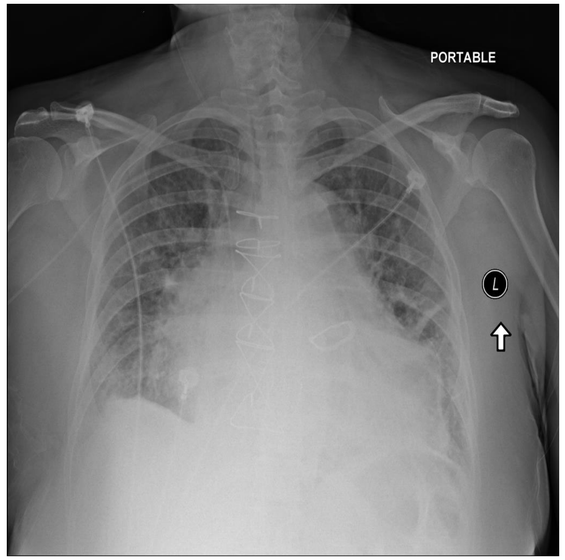
Who signs the report?

AI mistakes

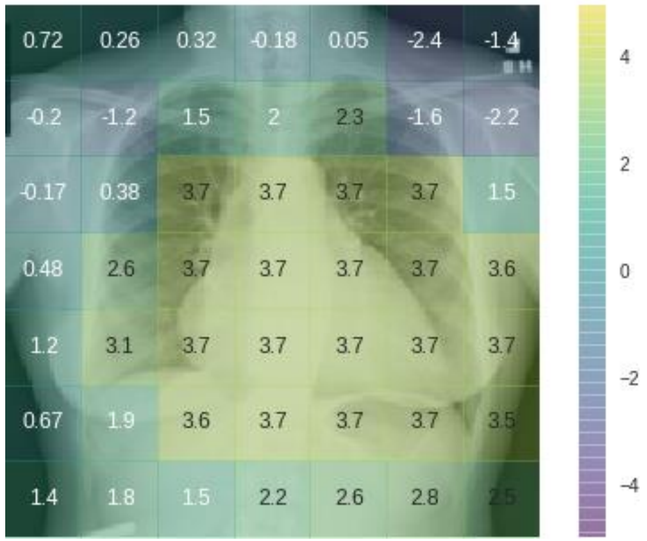
TYPICAL AI MISTAKES

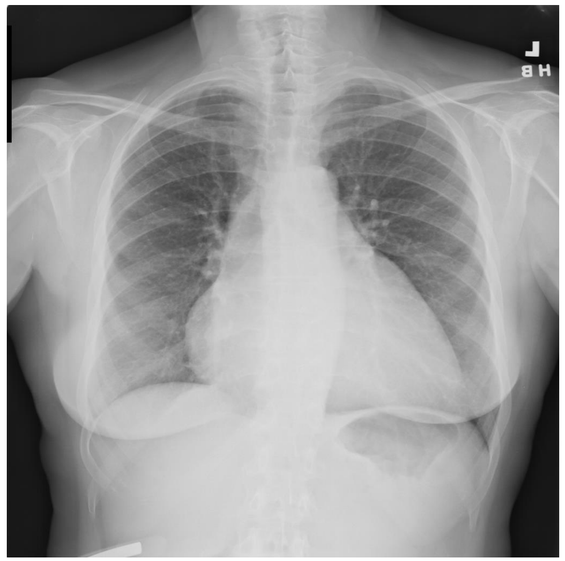
P(Cardiomegaly)=0.752





P(Cardiomegaly)=0.937





Zech et al. PLOS Medicine 2018

CONCLUSION

ML can surpass human level performance in certain, **narrowly defined** areas (narrow AI)

- Diagnostic/imaging reports **accelerated, precision** improved (segmentation, ECG)
- Correlation/regression information exploration (prediction, age assessment)
- Requirements: big database, standardized protocols, unified annotation

Ethical issues:

- low cost vs. narrow solution
- Responsibility?

Thank you for your attention!