

15<sup>th</sup> Biennial Symposium of the International Society for Strategic

**IS**<sup>®</sup>**R** 

Studies in Radiology

IS3R 2023

Berlin/Germany August 24–26, 2023

# HOW CLOSE ARE COMPREHENSIVE AI SOLUTIONS?



# Jacob Sosna, MD

Hadassah Hebrew University Medical Center

Jerusalem, Israel





## DISCLOSURES

0

• FUNDER HIGH-RAD

# Al will replace ALL physicians

#### **#SARELGAURMD**



## PROF. GEOFFREY HINTON-2016



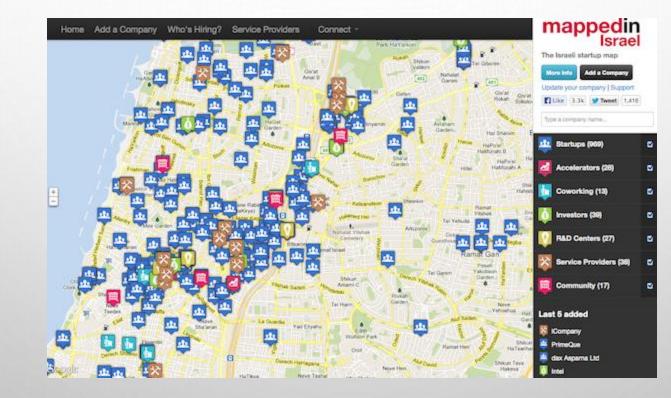
Geoffrey Hinton

"I think that if you work as a radiologist, you are like Wile E. Coyote in the cartoon. You're already over the edge of the cliff, but you haven't yet looked down. There's no ground underneath. People should stop training radiologists now. It's just completely obvious that in five years deep learning is going to do better than radiologists."

Nov 24, 2016



## **START-UP MAP OF TEL AVIV**



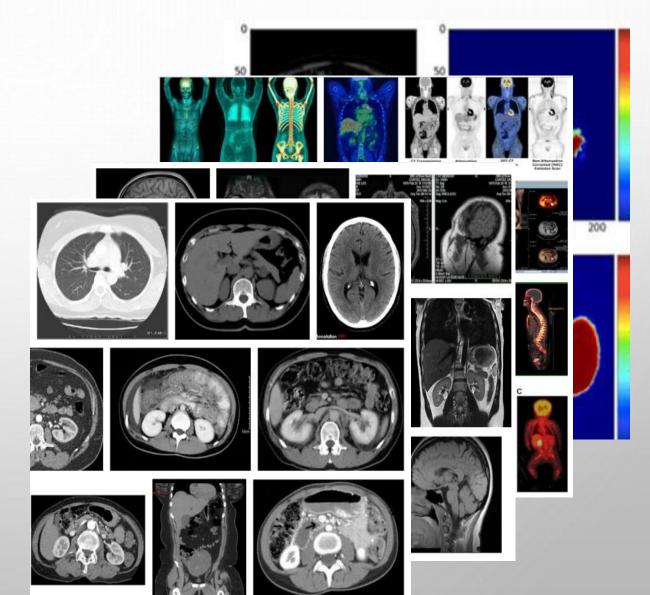


#### **Israel Al**



## THE INFORMATION AGE

- USA:
  - X-RAY 250 M
  - CT 82 M
  - MRI 39 M



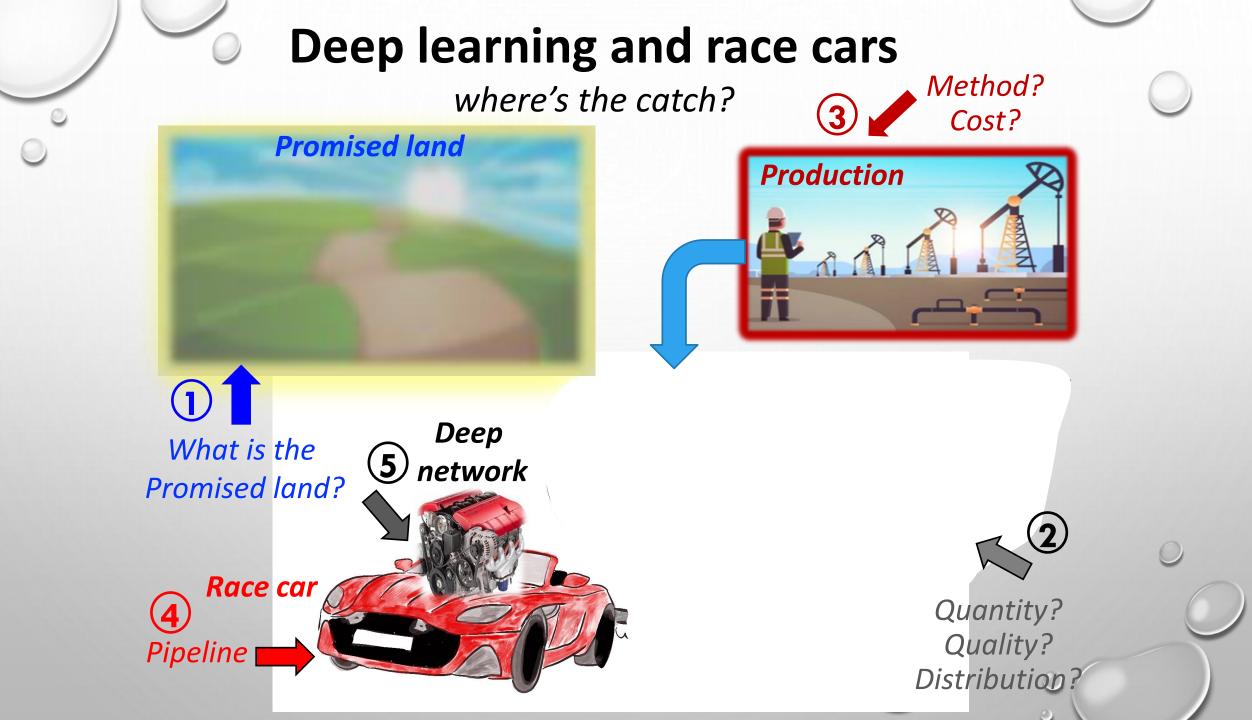
HTTP://WWW.IMVINFO.COM/INDEX.ASPX?SEC=DEF

## **Radiology and Al**

#### Trends and needs

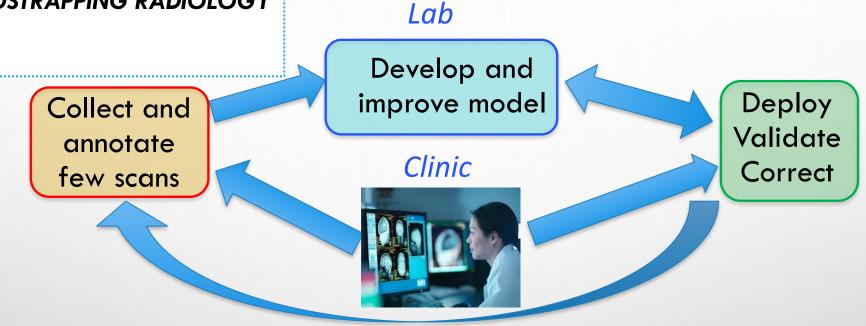
- Increase in the clinical load: more than 40% in the last 5 years
  - Worldwide ~100M comparative studies
- Continued growth in the number of patients
- Shortage of radiologists
- Unprecedented pressure to find automatic solutions to support the radiologists

#### $\rightarrow$ Boost the need for AI solutions



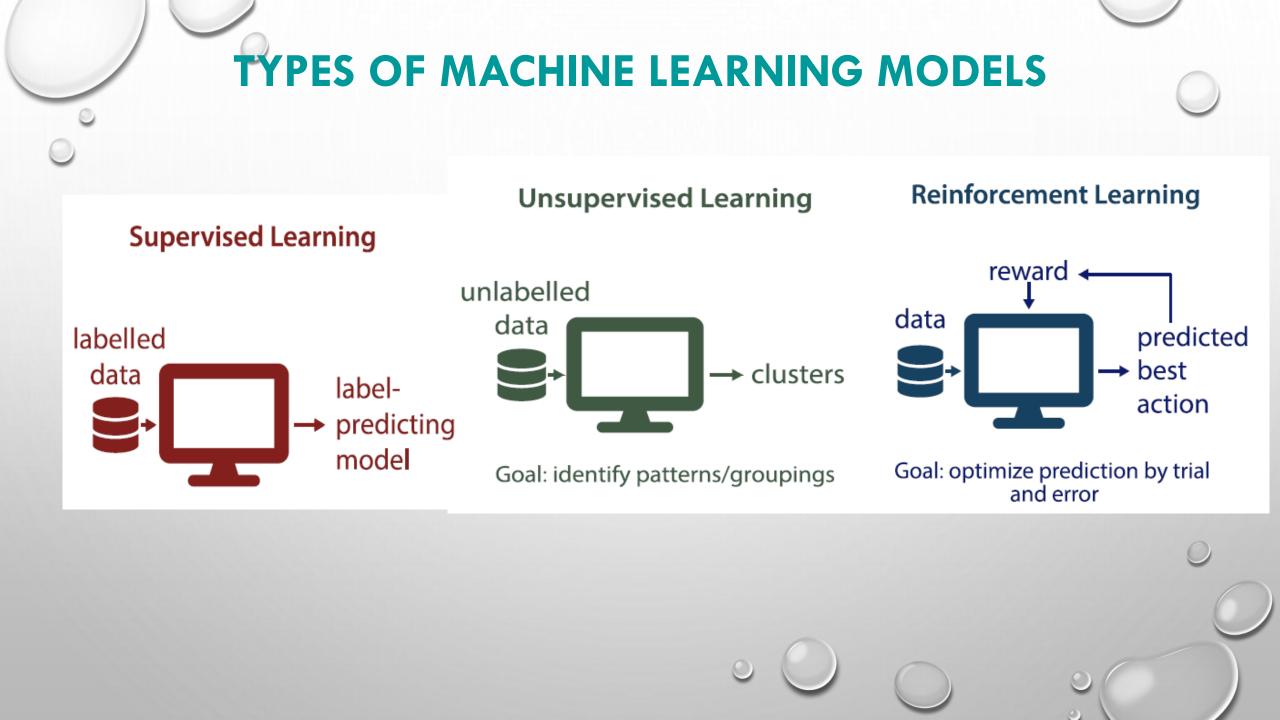
# RADIOLOGIST (HI) IN THE LOOP WORKFLOW

#### BOOSTRAPPING RADIOLOGY



#### Goals

- Provide useful results as soon as possible
- Optimize radiologist time budget
- Improve deep learning model
- Handle rare and out-of-distribution cases



## Al in Radiology: overview and evidence

#### **Primary Market**

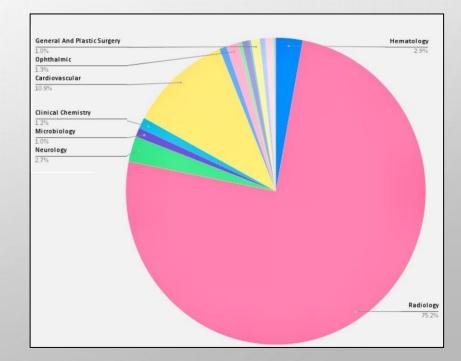
- 211 Al-based companies with 591 FDA-cleared applications; most of the products are a single-point solution for a single finding.
- 448 of the approved devices are within radiology and cardiology

>75% are in **radiology/oncology**: 391 devices

> 11% are in **cardiology**: 57 devices

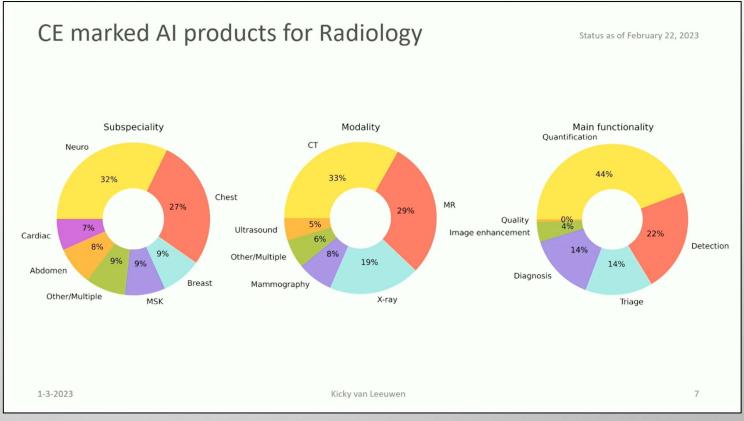
> 3% are in **hematology:** 15 devices

> 3% are in **neurology**: 14 devices



## Al for Radiology: overview and evidence

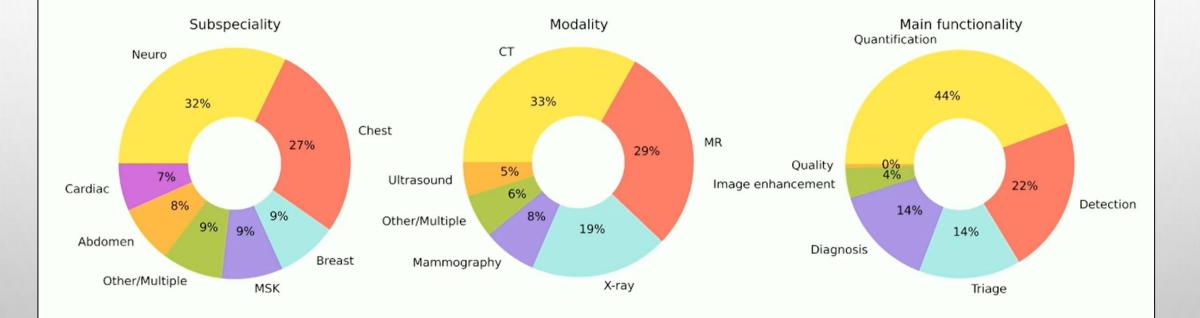
- <u>Subspecialty</u>: 32% in Neuroradiology, 27% are in Chest, 9% in breast, 9% in MSK (bone), 9% in multiple, 8% in Abdoman, and 7% in cardiac
- <u>Modality:</u> 33% in CT, 29% in MR, 19% in X-ray, 8% in mammography, 5% in Ultrasound and 6% in others
- Main Functionality: 44%
   quantitative, 22% detection,
   14% in Triage, 14% in
   Diagnostic and 4% in others



Shifting from single-point solutions to multiple-point solutions

#### CE marked AI products for Radiology

Status as of February 22, 2023



1-3-2023

Kicky van Leeuwen

Value Proposition of Food and Drug Administration (FDA)-Approved Artificial Intelligence (AI) Algorithms for Neuroimaging JACR, August 11<sup>th</sup>, 2023

#### https://doi.org/10.1016/j.jacr.2023.06.03

- A total of 59 AI neuroimaging algorithms were cleared by the FDA between May 2008 and August 2022
- Most of these algorithms (24/59) were compatible with noncontrast CT, 21 with MRI, nine with CT perfusion, eight with CT angiography, three with MR perfusion, and two with PET
- Six algorithms were compatible with multiple imaging techniques.
- The following are the advertised value proposition for these algorithms:
  - Improved quality of care (38/55, 69.1%)
  - •Saving user time (24/55, 43.6%)
  - •Decreased costs (9/55, 15.7%)
  - •Increased revenue (6/55, 10.9%)

Value Proposition of Food and Drug Administration (FDA)-Approved Artificial Intelligence (AI) Algorithms for Neuroimaging JACR, August 11<sup>th</sup>, 2023

ust 11,2023DOEhttps://doi.org/10.1016/j.jacr.2023.06.03

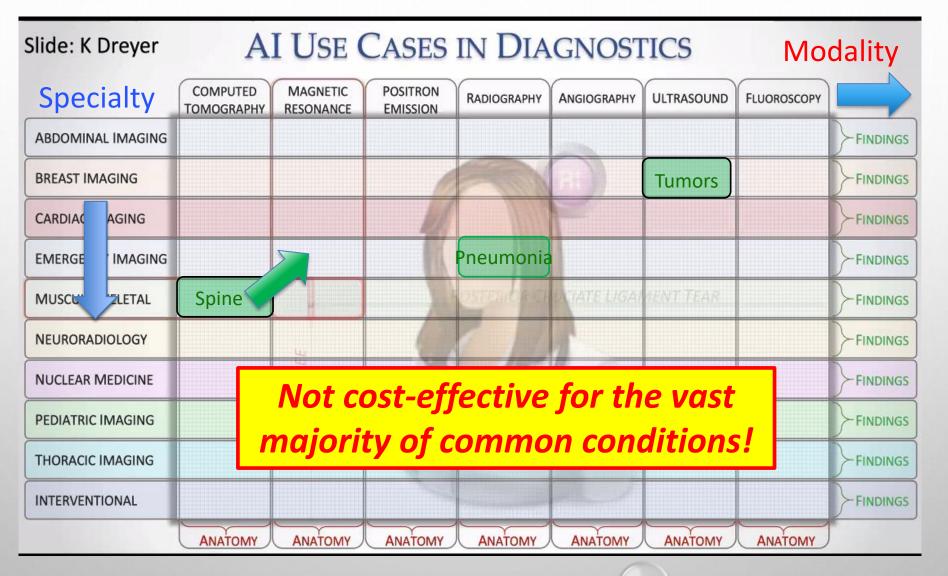
Take-Home Points:

1. A majority of the FDA- cleared AI algorithms approved for neuroimaging are related to the detection or quantification of stroke.

 Most of the algorithms in this study focus on a single clinical problem with binary outcome.

3. The most widely advertised value proposition was improved quality of care.

### NARROW AI – LONG TIME AND HIGH COSTS!



\* Transfer learning, one-shot image classification, GANs to date have shown limited effectiveness for medical image classification tasks

#### 96 AI companies building the next generation of radiology tech

#### **Diagnostic imaging**

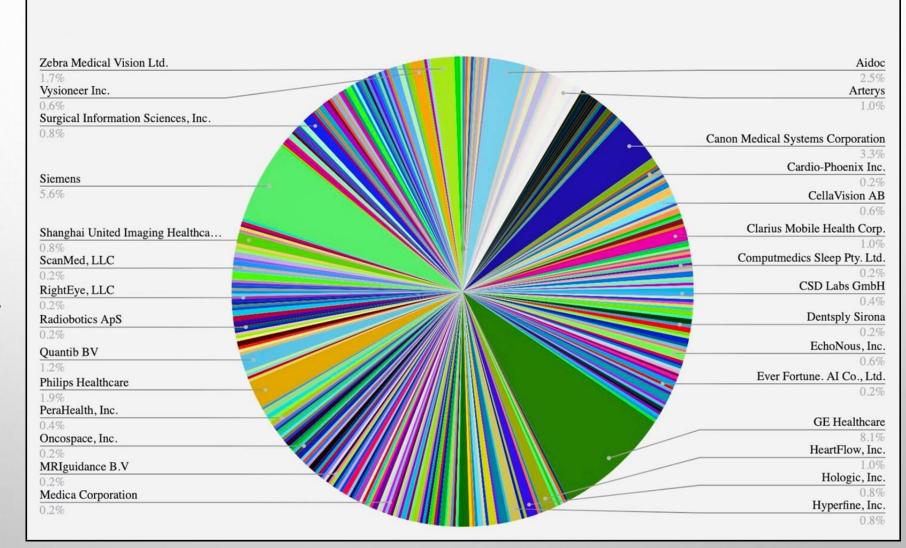


And Address

20NS

#### The AI market

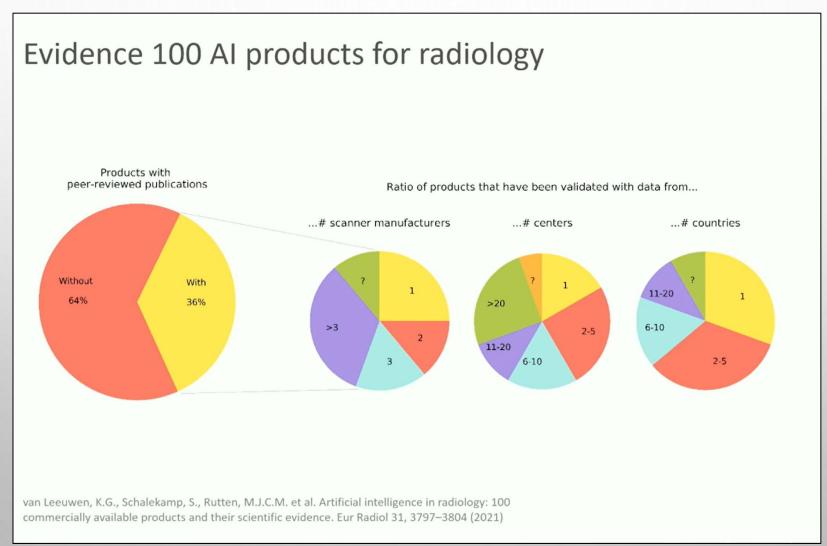
The map of the current landscape of commercially available Al companies by market share



#### The AI platforms hold the most significant market share

#### Supportive clinical publications

• 64% of the companies don't have supportive clinical publications.



## **Restraints and Challenges**

- The FDA regulations concerning AI products are constantly changing, i.e., "Moving Target."
- The European Regulation for CE & MDR demands more substantial clinical evidence and focuses on real-world performance

# Al consolidator platforms

Is consolidation of products a comprehensive solution?

## Al consolidator platforms

- Companies have been doing so by opening their AI platform to other companies and/or developing multiple applications, i.e., offering a multifinding solution
- 27 Al consolidator platforms for Al: Nuance, Blackford, SH, Incepto, Medica:, Sectra, Fufifilm, TCM, Philips, Siemens, AstraZeneca, CTS, DeepPC, etc.
- Companies also pushed to get multiple FDA Clearances to extend their offering. For example, GE has 42 devices cleared, Siemens 29, Canon 17, Aidoc 13, Philips 10, Zebra (acquired by Nanox Vision) 9, Quantib 7 and Viz.ai 6

## Al consolidator platforms (n=27)

Al Platform	PACS/RIS vendor	OEM	Al vendor	Other
Blackford Platform (Blackford Analysis [Bayer])	Al Connect (Wellbeing Software)	Automation Platform (Canon Medical Systems)	Aidoc aiOS (Aidoc)	Change Healthcare Marketplace (Change Healthcare)
CARPL (CARPL.AI)	Intelerad AI Hub and Odyssey (Intelerad)	Digital marketplace, syngo.via (Siemens Healthineers)	<b>Arterys</b> (Arterys [Tempus])	Imaging AI Orchestrator/Marketplace (IBM)
deepcOS (deepc)	Medimsight AI marketplace (Medimsight)	<b>Fujifilm REiLI</b> (Fujifilm)		Softway Medical (Softway Medical)
FOLIO platform (Incepto)	<b>RUBEE for Al</b> (Agfa Healthcare)	<b>GE Edison</b> (GE Healthcare)	Postprocessing platform	Precision Imaging Network (Nuance)
Myrian (Intrasense)	Sectra Amplifier Store (Sectra)	Philips AI Manager (Philips Healthcare)	Alma Health Platform (Alma Health Platform)	Calantic Digital Solutions (Bayer Pharmaceuticals)
<b>Private Al Hub</b> (Ferrum Health)	<b>Telepaxx</b> (TELEPAXX)		Eureka Clinical AI (TeraRecon)	
	Visage AI Accelerator (Visage Imaging)			

## Al consolidator platforms (n=27)

- Blackford (Bayer) 80 apps across 30 partner vendors
- Arterys 19 apps for radiology from 11 vendors
- Incepto 22 apps for radiology; offered by modality, department and organ
   QURE.ai PARTNERS
- DeepPC- 35 apps from over 20 partners
- Medica:;
- Sectra;
- Fufifilm;
- TCM;
- Philips;

- Siemens;
- AstraZeneca;
- CTS;
- SH;
  - Nuance;



### Al consolidator platform at the ECR 2023



The AI platforms offer a variety of apps without a common ground or focus

# Al consolidator platforms

Is consolidation of products a comprehensive solution?

• NO

# **Merging and Acquisition**

Is M&A a comprehensive solution?

#### **M&A activity**

Acquisitions



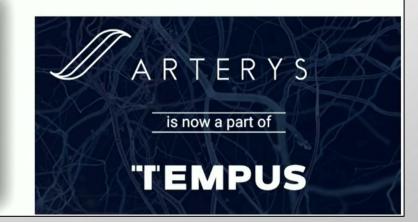
# Blackford announces our acquisition by Bayer

Aidence and Quantib acquired by RadNet American diagnostic imaging services company RadNet acquired the Dutch AI vendors Aidence (lung CT) and Quantib (prostate, neuro). This should build upon RadNet's AI division which already includes breast AI after an earlier acquisition of DeepHealth. So far it seems like not much is going to change for current customers. This acquisition is not the first in the medical imaging AI field, and probably won't be the last.

NEWS | August 11, 2021

#### Nanox to acquire Zebra Medical Vision for \$200m

Nanox will leverage the team, innovative AI technology and Cloud expertise of Zebra-Med to develop a med-tech firm.



#### **Changing market segments**

#### Shift of focus

MaxQ discontinues Accipio Al software as firm switches gears By Erik L. Ridley, AuntMinnie.com staff writer

January 13, 2022 -- Artificial intelligence (AI) software developer MaxQ is switching gears, discontinuing its Accipio line of software for detection and triage of intracranial hemorrhage (ICH) and ending its involvement in the development of image analysis-based AI applications.

Founded in 2014, Enlitic continues to innovate the way artificial intelligence is utilized in healthcare, shifting focus from diagnostics to workflow. Partnerships with the Department of Defense, Konica Minolta, TMC (a Unilabs company), as well as some of the largest diagnostic reading groups in the world give momentum continuing into 2022 with the debut of Curie<sup>TM</sup>, an enterprise platform that utilizes human, artificial, and real-world intelligence to create an evidence-based solution for healthcare information.

"This is the first time Lunit's AI has been officially integrated into an insurance underwriting process, and this proves that our solutions can also bring value to workflows outside of hospital sottings," said Brandon Sun, CEO of Lunit. "We are excited to expand the reach of our AI-powered software and become the driving force of digital innovation in the global insurance market."

#### **Shifting to Pharmaceutical**

#### Shift of focus

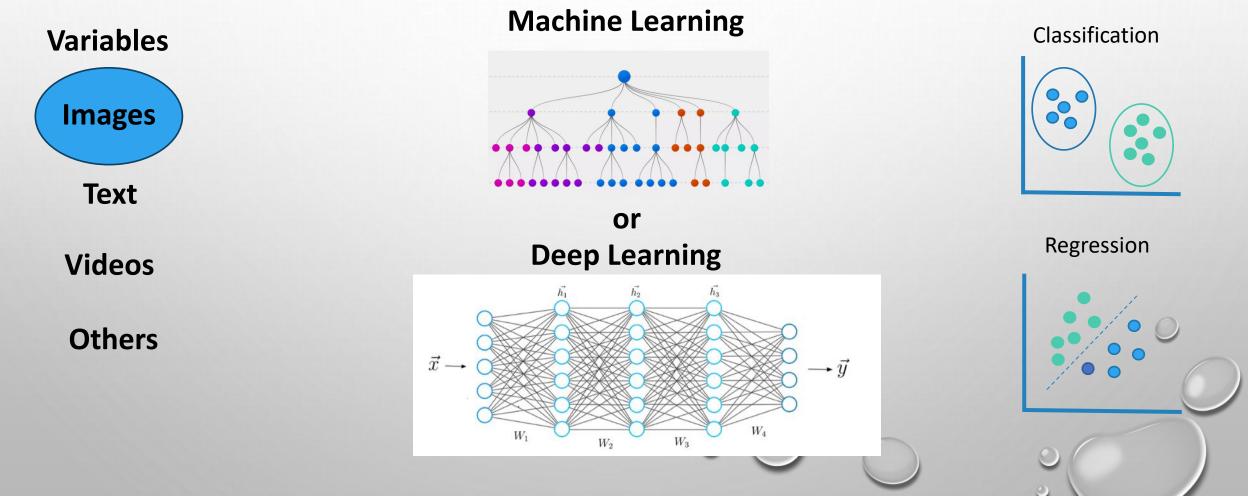
- contextflow partners with clinical data company Medexprim: The partnership is specifically aimed at indicating treatment effectiveness and predict disease progression in non-small cell lung cancer. This collaboration highlights the growing trend of AI vendors, in this case <u>contextflow</u>, expanding their reach into the pharmaceutical and clinical research industries, broadening their customer base.
  - VIDA moving to pharma: VIDA announced a partnership with RAYUS Radiology, an American provider of advanced diagnostic and interventional radiology, to onboard more than 150 locations as clinical trial imaging sites. <u>VIDA</u> originally focused on patient care with their lung AI VIDA Insights. But with the launch of the VIDA Lung Intelligence services last May, their focus seems to have completely shifted to biomarker analysis for pharma. Together with Thirona and Quibim forming another type of Ai-vendors.

# **Merging and Acquisition**

# Is M&A a comprehensive solution? NO

# THE GENERAL PARADIGM OF MACHINE LEARNING

#### Input Data Training of Model (e.g. decision tree/neural network) Application



# What is a comprehensive solution?

EXAMINATION: CHEST (PA AND LAT)

\_\_\_\_ year old woman with ?pleural effusion // ?pleural effusion INDICATION:

TECHNIQUE: Chest PA and lateral

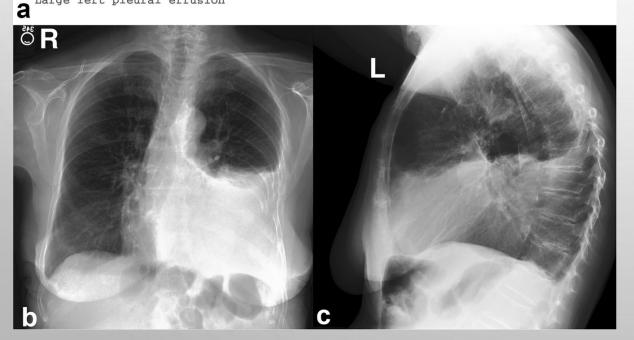
COMPARISON:

FINDINGS:

Cardiac size cannot be evaluated. Large left pleural effusion is new. Small right effusion is new. The upper lungs are clear. Right lower lobe opacities are better seen in prior CT. There is no pneumothorax. There are mild degenerative changes in the thoracic spine

#### IMPRESSION:

Large left pleural effusion



- Clinical information
- Comparison
- PA+Lat
- Most of these do not exist in current products

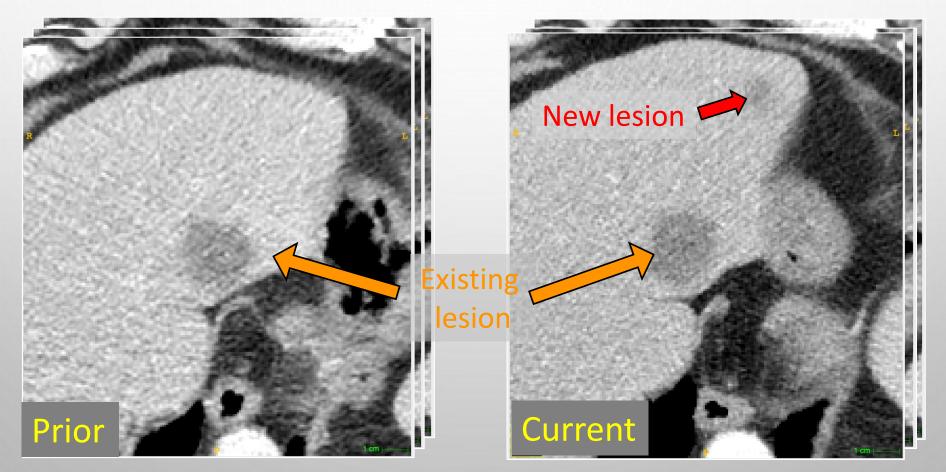
Johnson, A.E.W., Pollard, T.J., Berkowitz, S.J. et al. MIMIC-CXR, a de-identified publicly available database of chest radiographs with free-text reports. Sci Data 6, 317 (2019).

### **Comprehensive Solutions**

- Replicating radiologists knowledge process
  - Clinical data for understanding significance of findings
  - Multiple modalities
  - Multiple time points
  - Incorporating other studies (echocardiography, bronchoscopy)
  - Pathological and genetic data
  - Al for image reconstruction

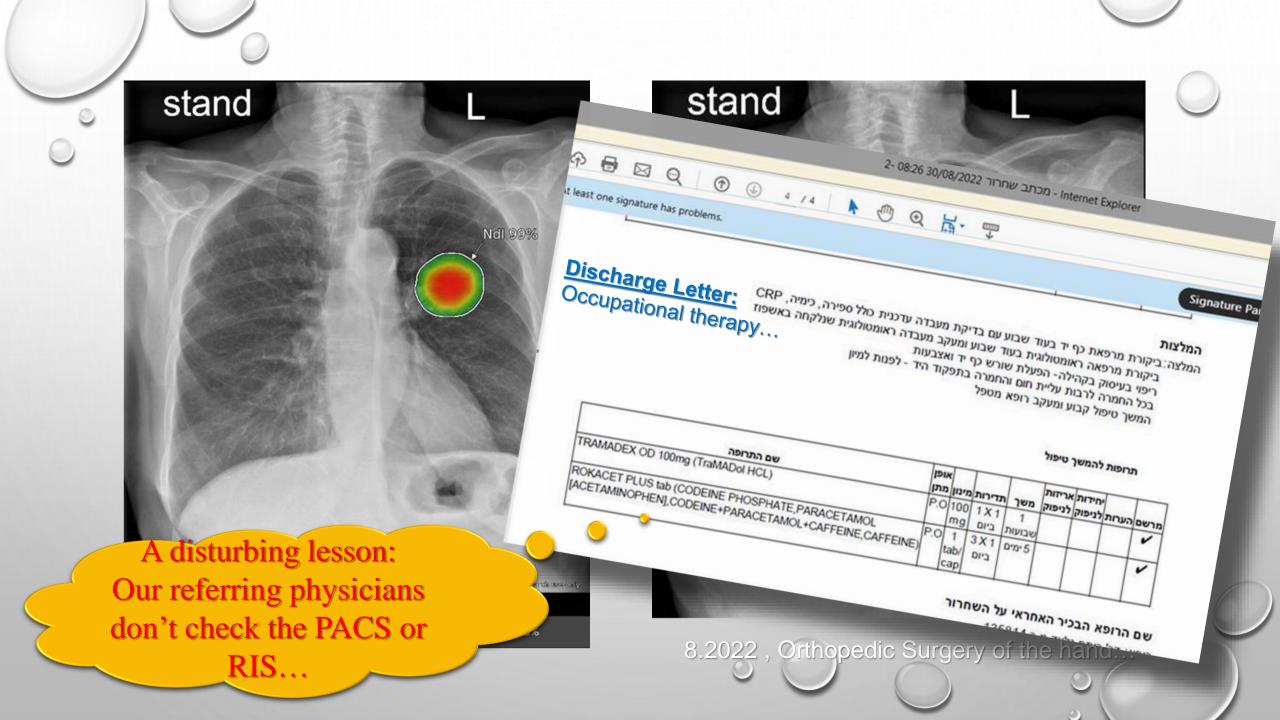
#### **RADIOLOGICAL LESIONS FOLLOW-UP**

- Measure lesion changes over time
- Relative change between consecutive scans is what matters
- Lesion change type: existing, new, disappeared



#### WORKFLOW INTEGRATION

COURTESY PROF. ELI KONEN



#### IMPLEMENTATION OF AI FOR CHEST XR IN ISRAEL

#### Our main concern is the undetected nodules...

Asked for excel of all detected "nodules" Iist of 17,000 accession numbers...

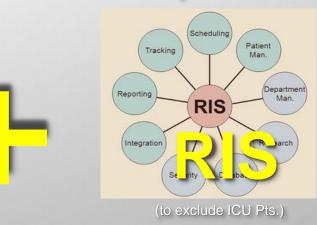
Help for IT < Exclusion criteria:</p>

Oncological Pts.
 Active in recent year

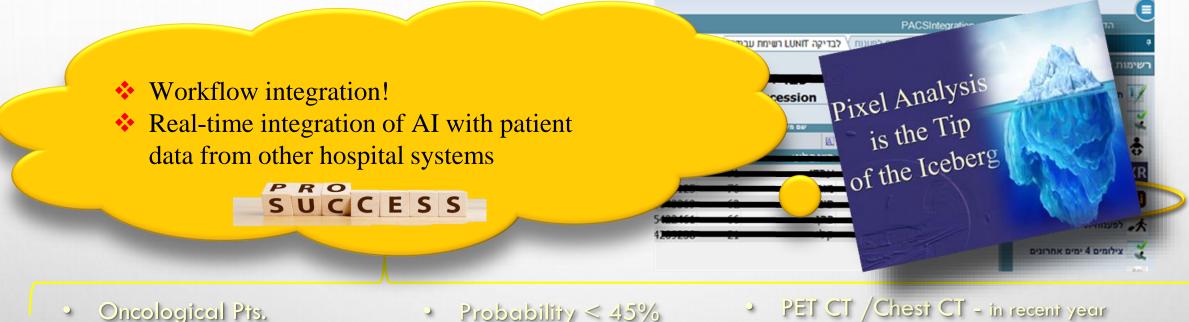


(Oncology Pts. are marked in the EMR)

- PET CT /Chest CT in recent year
- >2 chest x-rays in recent week (ICU)



#### IMPLEMENTATION OF AI FOR CHEST XR IN ISRAEL



Oncological Pts.
 Probability < 45%</li>
 PET CT / Chest CT - in recent year
 Active in recent year
 Active in recent year
 Probability < 45%</li>
 PET CT / Chest CT - in recent year
 >2 chest x-rays - in recent week (ICU)

5-10 "new" / unknown suspected nodule / day

#### **Current state**

The market is fragmented and with multiple low hanging fruit solutions

Al platforms offer a variety of apps without a common ground or focus

The AI market is currently shifting from point solutions to multifindings solution

Real comprehensive solutions are lacking

The demand for quantitative imaging biomarkers information is on the rise

# Al will replace ALL physicians

#### **#SARELGAURMD**



### RADIOLOGISTS USING AI WILL REPLACE RADIOLOGISTS NOT USING IT

#### HOPEFULLY WITHIN 10 YEARS

## RADIOLOGISTS USING COMPREHENSIVE AI SOULTIONS WILL REPLACE RADIOLOGISTS NOT USING IT





15<sup>th</sup> Biennial Symposium of the International Society for Strategic

**IS**<sup>®</sup>**R** 

Studies in Radiology

IS3R 2023

Berlin/Germany August 24–26, 2023