Artificial Intelligence Technologies and Their Applications in Healthcare Settings

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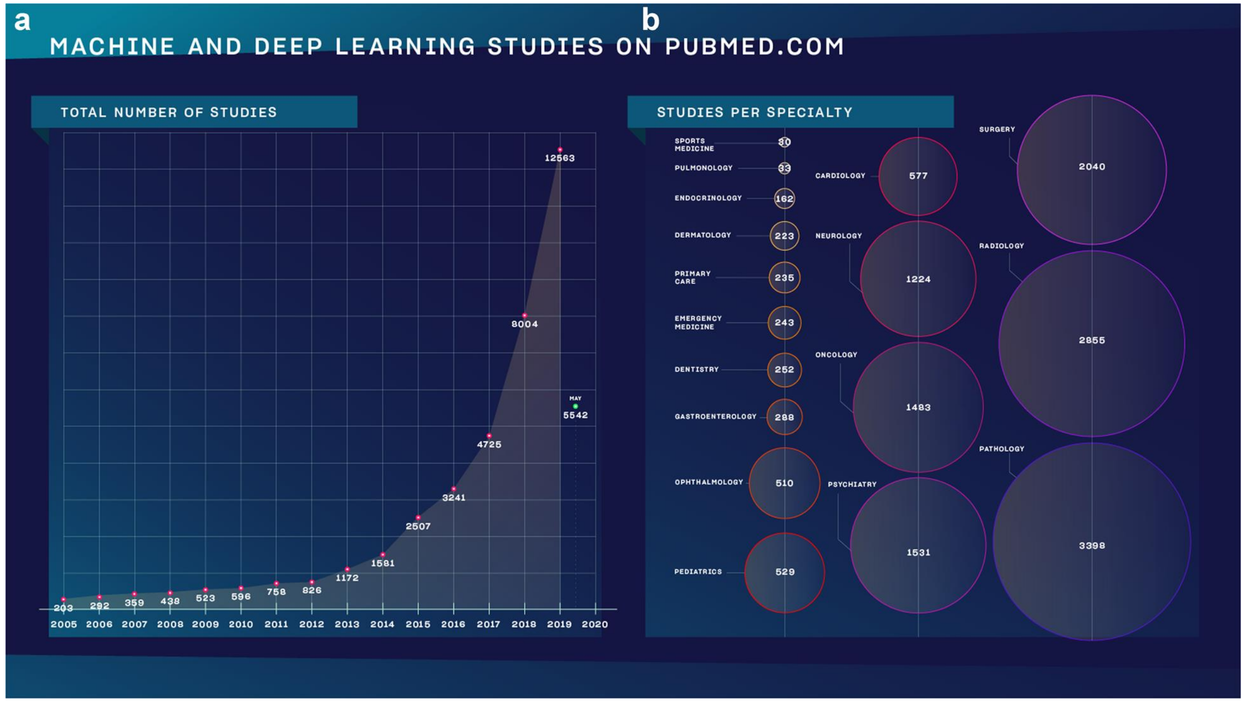
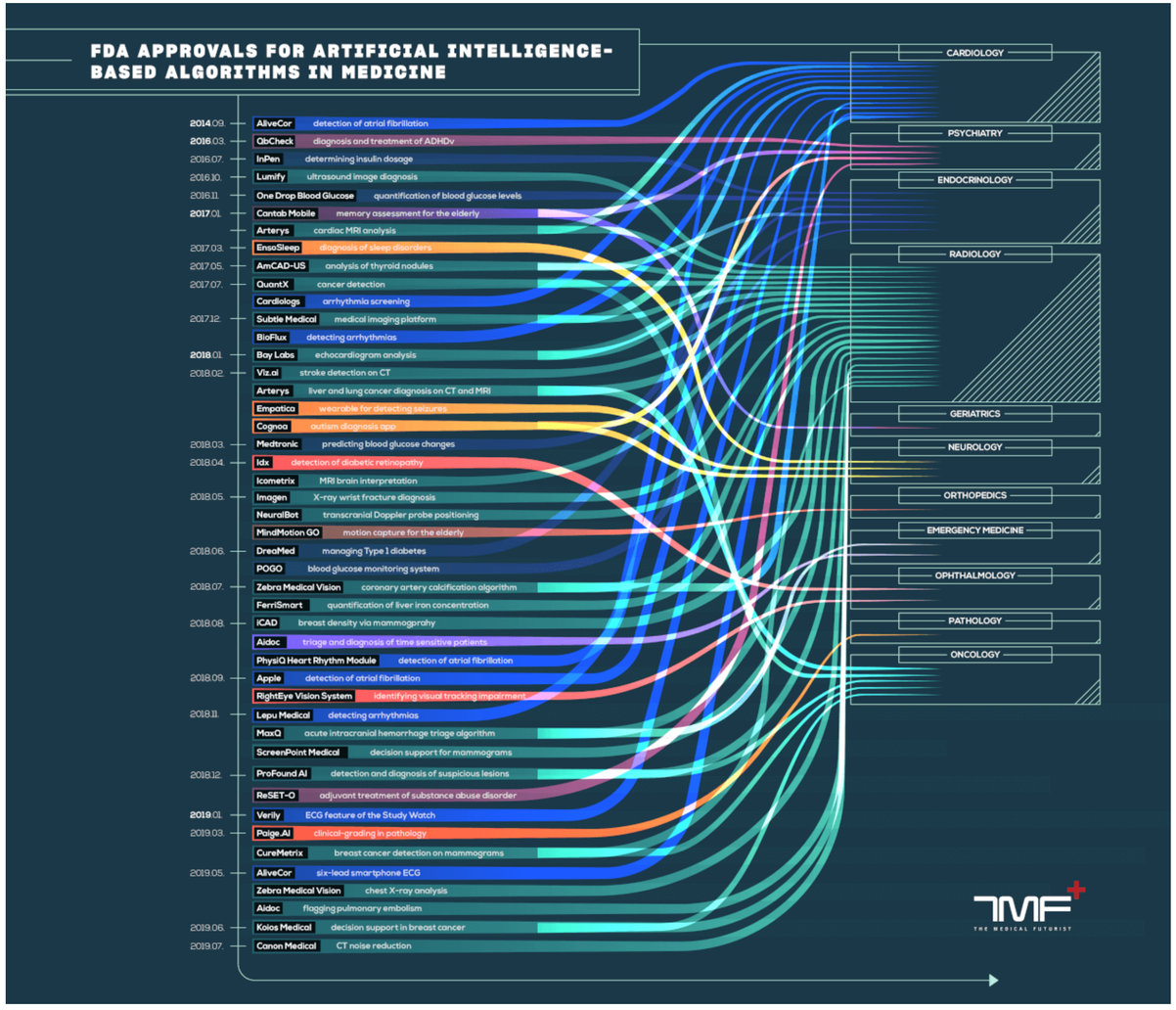
IMDRF International Medical Device Regulators Forum | Australia 2022

SUNG KYUN KWAN UNIVERSITY(SKKU)

SAIHST Samsung Advanced Institute for Health Sciences & Technology, SKKU

- **Explosion of Medical AI Research**





Source : Bertalan Meskó et. al., npj Digital Medicine(2020), The Medical Futurist(2019)

- ## First FDA Approved AI SaMD in 2017

Guidance for Industry and Food and Drug Administration Staff

Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data - Premarket Notification [510(k)] Submissions

Document issued on: July 3, 2012

The draft of this document was issued on October 21, 2009.

For questions regarding this guidance document contact Nicholas Petrick (OSEL) at 301-796-2563, or by e-mail at Nicholas.Petrick@fda.hhs.gov; or Mary Pastel (OIVD) at 301-796-6887 or by e-mail at Mary.Pastel@fda.hhs.gov.

Center for Devices and Radiological Health
CDRH

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Division of Imaging and Applied Mathematics
Office of Science and Engineering Laboratories
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

Arterys Receives FDA Clearance For The First Zero-Footprint Medical Imaging Analytics Cloud Software With Deep Learning For Cardiac MRI

USA - English

ARTERYS

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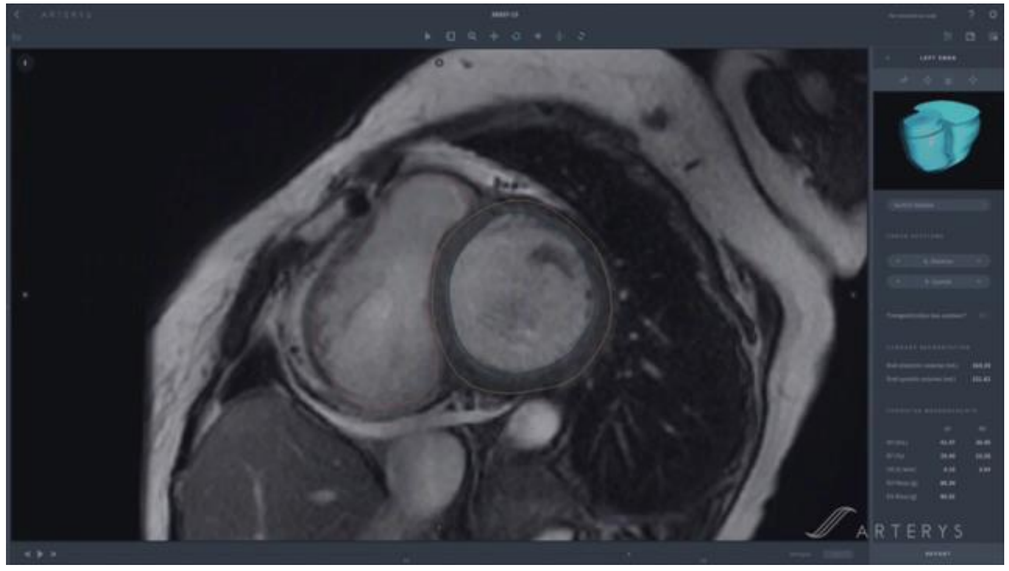


- ## Regulatory Authorized Medical AI

How medical AI devices are evaluated: limitations and recommendations from an analysis of FDA approvals

A comprehensive overview of medical AI devices approved by the US Food and Drug Administration sheds new light on limitations of the evaluation process that can mask vulnerabilities of devices when they are deployed on patients.

Eric Wu, Kevin Wu, Roxana Daneshjou, David Ouyang, Daniel E. Ho and James Zou

Medical artificial-intelligence (AI) algorithms are being increasingly proposed for the assessment and care of patients. Although the academic community has started to develop reporting guidelines for AI clinical trials[1–3], there are no established best practices for evaluating commercially available algorithms to ensure their reliability and safety. The path to safe and robust clinical AI requires that important regulatory questions be addressed. Are medical devices able to demonstrate performance that can be generalized to the entire intended population? Are commonly faced shortcomings of AI (overfitting to training data, vulnerability to data shifts, and bias against underrepresented patient subgroups) adequately quantified and addressed?

In the USA, the US Food and Drug Administration (FDA) is responsible for approving commercially marketed medical

Fig. 1 | Breakdown of 130 FDA-approved medical AI devices by body area. Devices are categorized by risk level (square, high risk; circle, low risk). Blue indicates that a multi-site evaluation was reported; otherwise, symbols are gray. Red outline indicates a prospective study (key, right margin). Numbers in key indicate the number of devices with each characteristic.

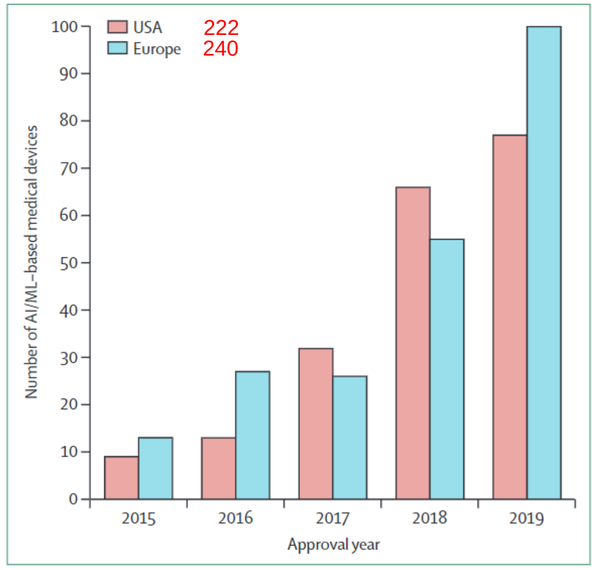
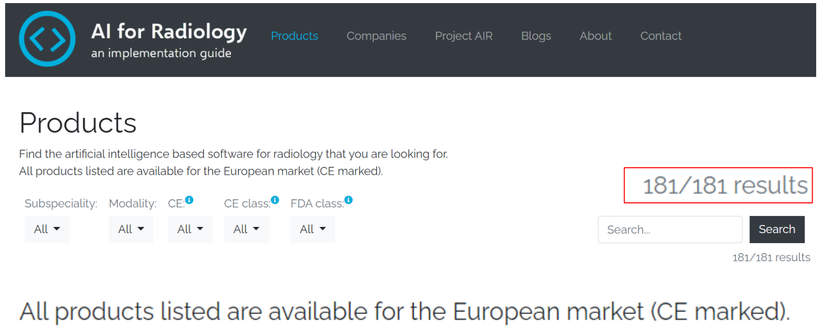


Figure 2: **Number of approved (USA) and CE-marked (Europe) AI/ML-based medical devices between 2015 and 2019**
The CE-mark year is considered the approval year for devices in Europe. AI/ML=artificial intelligence and machine learning. CE=*Conformité Européenne*.



All products listed are available for the European market (CE marked).

Source : Eric Wu et. al., Nature Medicine(2021), Urs JMuehlematter et. al., Lancet Digital Health(202)

- ## Regulatory Authorized Medical AI

Original Research

FDA-regulated AI Algorithms: Trends, Strengths, and Gaps of Validation Studies

Shadi Ebrahimian, MD, Mannudeep K. Kalra, MD, Sheela Agarwal, MD, Bernardo C. Bizzo, MD, Mona Elkholy, MS, Christoph Wald, MD, Bibb Allen, MD, Keith J. Dreyer, DO, PhD

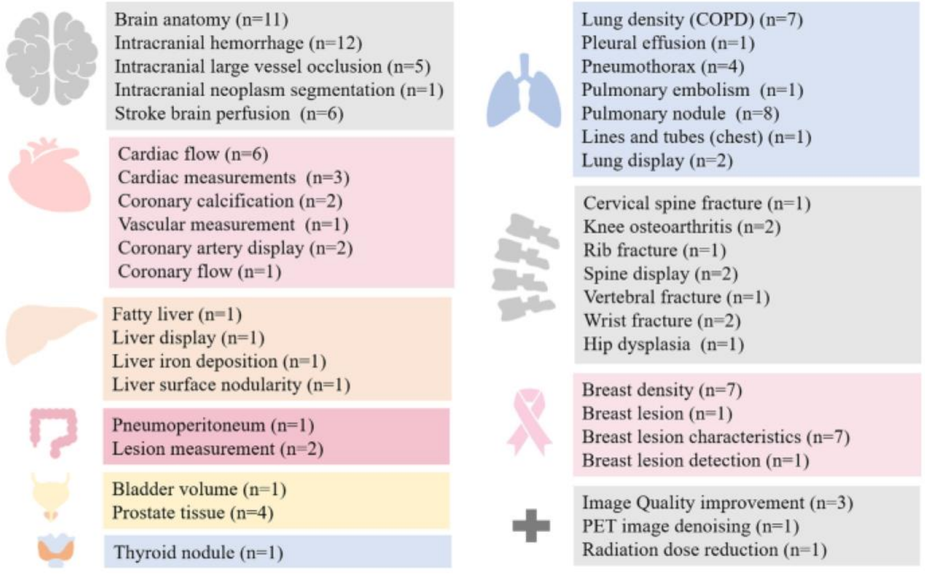


Figure 2. Summary of specific target findings evaluated by the FDA-regulated AI/ML algorithms. AI/ML, artificial intelligence/machine learning; FDA, Food and Drug Administration.

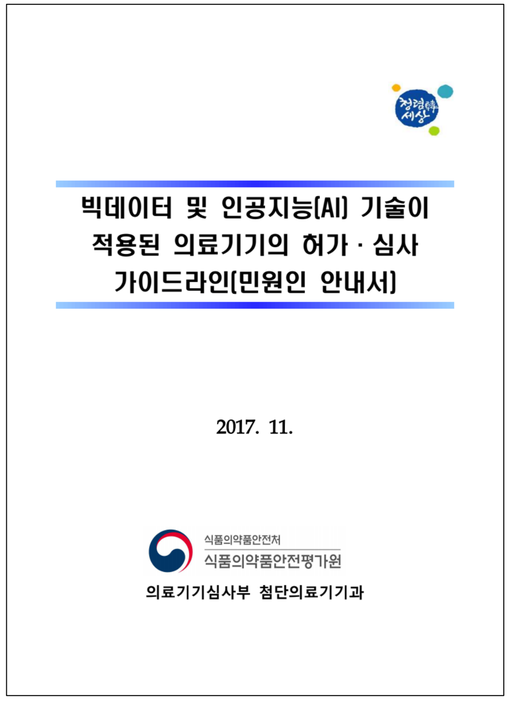
TABLE 1. Summary of FDA Regulated Software Across Different Function, CAD, and AI Groups. Some Algorithms Performed More Than One Functions. (NA- not applicable for non-AI-based software)

Factors		FDA-regulated Software (Whether AI/ML-based)	
		Yes	No
Functions	Characterization	13	1
	Detection	43	0
	Improvement	6	0
	Quantification	64	7
	Segmentation	16	1
	Visualization	13	4
CAD category	CADt	27	0
	CAD	5	0
	CADx	4	0
	CADe/x	7	0
	IPQ	59	7
	Unclassified	16	2
AI categories	AI-De	18	NA
	AI-Im	3	NA
	AI-Pr	26	NA
	AI-Q	46	NA
	AI-S	5	NA
	AI-Cx	11	NA
	AI-V	6	NA
	Unclassified	25	NA

AI/ML, artificial intelligence/machine learning; AI-Im, improvement; AI-Pr, prioritization; AI-Q, quantification; AI-S, segmentation; AI-V, visualization; CAD, computer-aided; CADe/x, detection/diagnosis; CADt, triage; CADx, diagnosis; FDA, Food and Drug Administration; IPQ, image processing/quantification.

Source : Shadi et. al., *Academic Radiology(2022)*

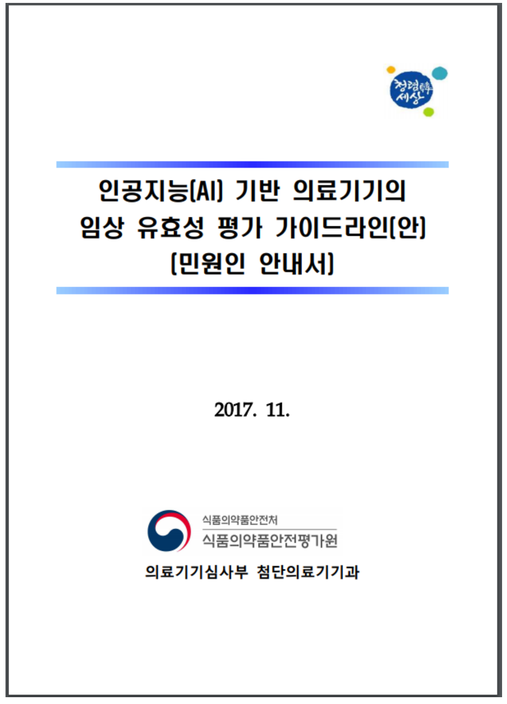
- **First MFDS Approved AI SaMD in 2018**



빅데이터 및 인공지능(AI) 기술이 적용된 의료기기의 허가·심사 가이드라인(민원인 안내서)

2017. 11.

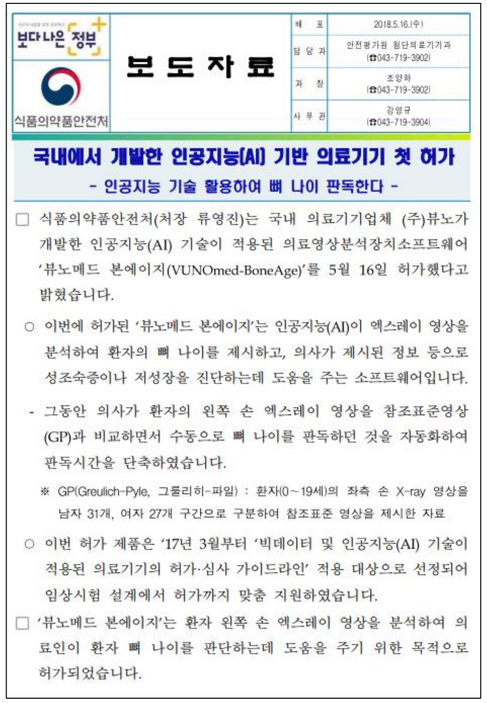
식품의약품안전처
식품의약품안전평가원
의료기기심사부 첨단의료기기과



인공지능(AI) 기반 의료기기의 임상 유효성 평가 가이드라인(안) (민원인 안내서)

2017. 11.

식품의약품안전처
식품의약품안전평가원
의료기기심사부 첨단의료기기과



보다 나은 정부

보 도 자 료

배 포	2018.5.16.(수)
담 당 과	안전평가원 첨단의료기기과 (☎043-719-3902)
과 장	조양하 (☎043-719-3902)
사 무 관	강영구 (☎043-719-3904)

식품의약품안전처

국내에서 개발한 인공지능(AI) 기반 의료기기 첫 허가

- 인공지능 기술 활용하여 뼈 나이 판독한다 -

□ 식품의약품안전처(처장 류영진)는 국내 의료기기업체 (주)뷰노가 개발한 인공지능(AI) 기술이 적용된 의료영상분석장치소프트웨어 '뷰노메드 본에이지(VUNOmed-BoneAge)'를 5월 16일 허가했다고 밝혔습니다.

○ 이번에 허가된 '뷰노메드 본에이지'는 인공지능(AI)이 엑스레이 영상을 분석하여 환자의 뼈 나이를 제시하고, 의사가 제시된 정보 등으로 성조숙증이나 저성장을 진단하는데 도움을 주는 소프트웨어입니다.

- 그동안 의사가 환자의 왼쪽 손 엑스레이 영상을 참조표준영상(GP)과 비교하면서 수동으로 뼈 나이를 판독하던 것을 자동화하여 판독시간을 단축하였습니다.

※ GP(Greulich-Pyle, 그룰리히-파일) : 환자(0~19세)의 좌측 손 X-ray 영상을 남자 31개, 여자 27개 구간으로 구분하여 참조표준 영상을 제시한 자료

○ 이번 허가 제품은 '17년 3월부터 '빅데이터 및 인공지능(AI) 기술이 적용된 의료기기의 허가·심사 가이드라인' 적용 대상으로 선정되어 임상시험 설계에서 허가까지 맞춤 지원하였습니다.

□ '뷰노메드 본에이지'는 환자 왼쪽 손 엑스레이 영상을 분석하여 의료인이 환자 뼈 나이를 판단하는데 도움을 주기 위한 목적으로 허가되었습니다.

"인공지능이 뼈 나이 판독" 국내 개발 'AI 의료기기' 첫 허가

[중앙일보] 입력 2018.05.16 11:00

성조숙증에 걸리면 여성호르몬이 과다 분비돼 뼈가 비정상적으로 빨리 자란다. 이 병에 걸린 4세 여아(오른쪽 사진)의 손목 근처 손바닥뼈가 7개로 정상 여아(작은 사진)보다 3개나 많고 크다. 뼈나이로는 7세에 해당한다. 뼈나이가 빠르면 나중에 키가 덜 자란다.

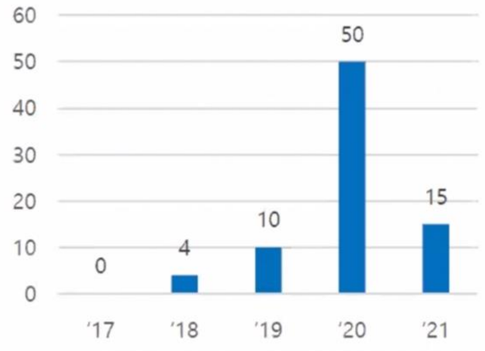
식품의약품안전처는 국내 의료기기업체 (주)뷰노가 개발한 인공지능(AI) 기술이 적용된 의료영상분석장치 소프트웨어 '뷰노메드 본에이지(VUNOmed-BoneAge)'를 16일 허가했다고 밝혔다.

Medical AI is Nothing New

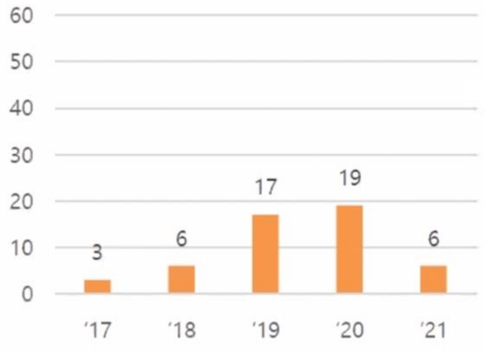
인공지능 의료기기 허가 및 임상시험계획승인 현황('21.8월)

구 분	'17	'18	'19	'20	'21	계
허 가	0	4	10	50	15	**79**
임 상	3	6	17	19	6	**51**

<연도별 허가(건)>



<연도별 임상시험계획승인(건)>



적응증

- ✓ 골연령
- ✓ 뇌경색
- ✓ 폐 결절
- ✓ 흉부 비정상 부위
- ✓ 유방암
- ✓ 폐질환
- ✓ 요추 압박골절
- ✓ 대장 이상 부위
- ✓ 전립선암
- ✓ 부정맥
- ✓ 뇌동맥류
- ✓ 당뇨병성망막병증
- ✓ 황반변성
- ✓ 녹내장
- ✓ 기억장애형 경도인지장애
- ✓ 알츠하이머
- ✓ 신경퇴행성 파킨슨증
- ✓ 관상동맥죽상경화증

입력 2021.06.23 06:30 | 수정 2021.07.13 11:54

안전평가원에 따르면 지난 2017년 인공지능(AI) 가이드라인을 식약처가 선제적으로 마련함으로써 당시 AI 의료기기 허가 0건에서, 현재 75건이 허가됐고, 제조업체는 27개소로 늘어났다. 또 일부 업체는 코스닥 상장 등 국내 스타트 기업이 세계적인 인공지능 의료기기 대표기업으로 성장중이다.

Source : 식약처(2020, 2021)

Product Portfolio | VUNO Med Product Overview

VUNO Med® - Chest X-Ray™

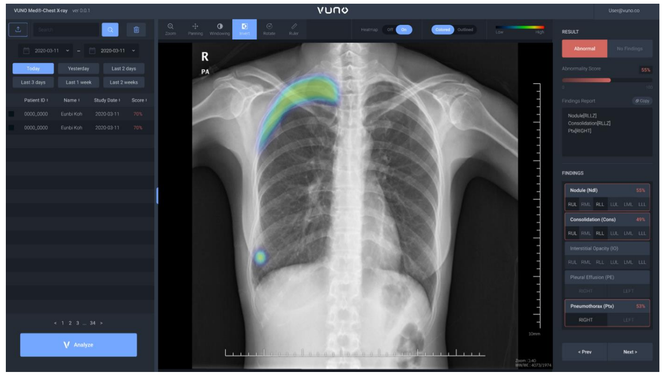
Solution Overview

- AI-based diagnostic support system for abnormalities in Chest X-Rays
- Detects five critical thoracic findings*
- Displays abnormality areas and abnormality scores (%)
- Used 100% CT confirmed images taken with imaging equipment from 15^{+} global vendors
- 0.985 AUROC per-image, 0.943 JAFROC FOM per-lesion

* Nodule/Mass, Consolidation, Interstitial Opacity, Pleural Effusion, Pneumothorax

User Interface

Ministry of Food and Drug Safety CE 2195



Upcoming Updates

- Additional Thoracic Abnormal Findings (11)

Nodule/Mass, Consolidation, Interstitial Opacity, Pleural Effusion, Pneumothorax, Atelectasis, Calcification, Rib Fracture, Mediastinal Widening, Pneumoperitoneum, Cardiomegaly

- Disease Diagnosis (2)
- Trained on +100K images

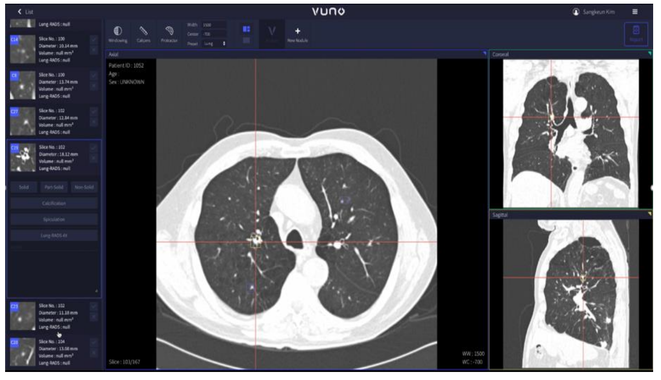
VUNO Med® - LungCT AI™

Solution Overview

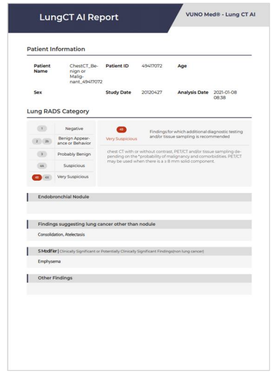
- AI-based detection solution for pulmonary nodules in chest CT scans with nodule RADS score and malignancy prediction capabilities
- Detects nodules between 4mm ~ 30mm within 1 minute with high sensitivity
- Provides volumetric data of nodules and data on the types of nodules
- Provides baseline scans and follow-up data for nodule growth assessment (Can match the scans pixel to pixel)

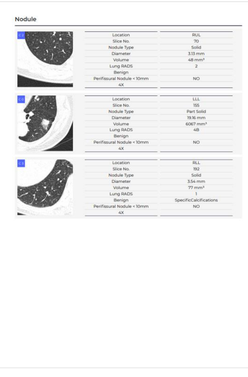
User Interface

Ministry of Food and Drug Safety CE 2195 pmda



Report





Product Portfolio | VUNO Med Product Overview

VUNO Med® - BoneAge™

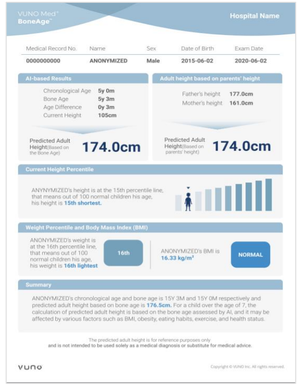
Solution Overview

- Korea’s 1st AI-based medical device approved by MFDS
- Assesses the skeletal age of a child and compares it against his chronological age
- Enhances clinical efficiency by improving reading time and accuracy
- Deep-learning based automatic Bone Age Assessment software that supports both GP and TW3 methods
- Provides a comprehensive patient report including growth charts and expected adult height using actual age, current height and gender
- Used 50,000+ images collected from Korea and US to ensure stable performance across races

User Interface

Ministry of Food and Drug Safety CE 2195 Pmda

Report



VUNO Med® - DeepBrain™

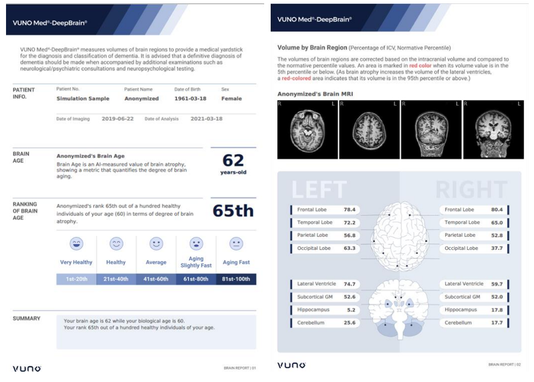
Solution Overview

- Deep-learning based brain parcellation for the quantification of brain atrophy and diagnosis of neurodegenerative diseases
- Segments the brain into over 100 parts to provide information of brain atrophy
- Provides volumetric information on areas, cortical thickness data of cortex area from 0mm, ICV ratio, and WMH (White Matter Hyperintensities) associated with degenerative brain diseases
- A comprehensive report with atrophy information in comparison with normal group
- Processing time is less than 1 minute per case

User Interface

Ministry of Food and Drug Safety CE 2195

Report



Product Portfolio | VUNO Med Product Overview

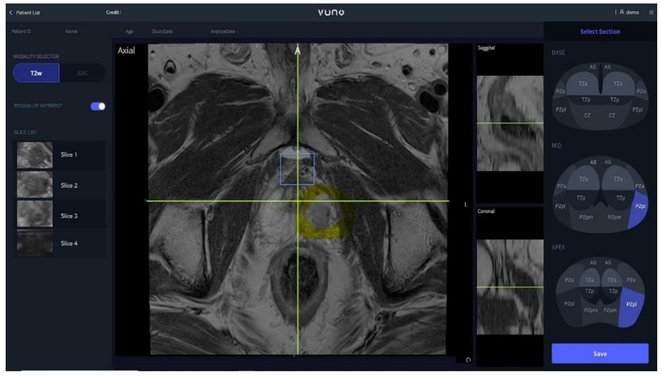
VUNO Med® - PROMISE-I

Solution Overview

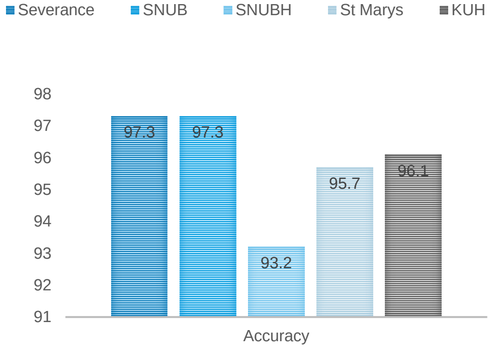
- AI-based image analysis solution that automatically analyzes associated regions for prostate cancer in MR images
- Consistency rate above 90% compared to radiologists
- Solution is intended to help medical professionals diagnose prostate cancer and determine the target biopsy areas

User Interface

Ministry of Food and Drug Safety



Clinical Validation



VUNO Med® - FundusAI™

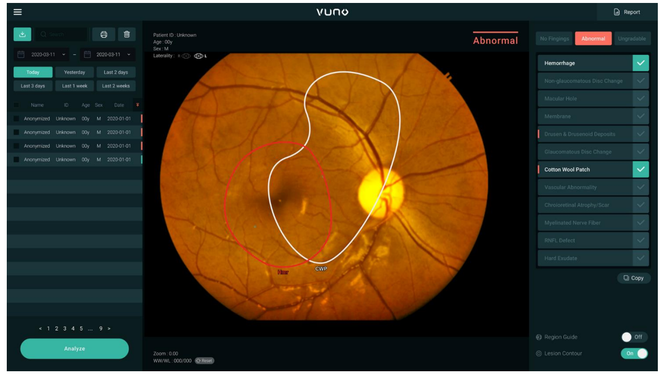
Solution Overview

- Korea's 1st "Breakthrough medical device" and non-radiology AI medical software obtained Class III approval
- Detects and locates 12 fundus abnormalities associated with retinal disease within 2 seconds
- Adjust the sensitivity of each findings based on clinical needs: Low (75%), Mid (85%), High (95%)
- Trained on 103,262 fundus images with 57 Ophthalmologists participated in the research 1
  - 16 Retina specialists, 9 Glaucoma specialists, 3 Corneal specialists1
- Report provided to patient for further consultation

User Interface

Ministry of Food and Drug Safety

CE 2195



Report

SAIHST Samsung Advanced Institute for Health Sciences & Technology, SKKU

SUNG KYUN KWAN UNIVERSITY(SKKU)

Product Portfolio | VUNO Med Product Overview

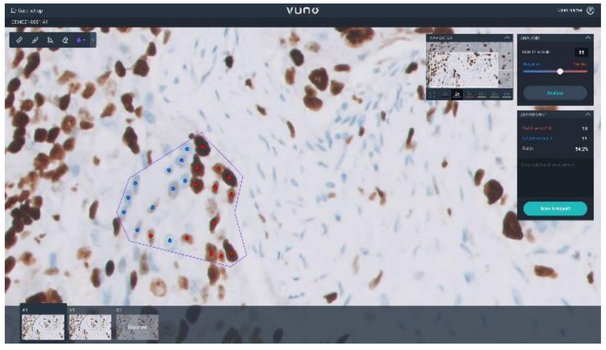
VUNO Med® - PathQuant

Solution Overview

- Provides the number and ratio of cells expressed in immunohisto-chemistry(IHC), which is widely used for the diagnosis of various types of cancer, for biomarker analysis which shortens the reading time and provides consistent quality analysis
- Accuracy above 90 percent in detecting cells compared to that of clinical pathologists

User Interface

Ministry of Food and Drug Safety



Clinical Validation

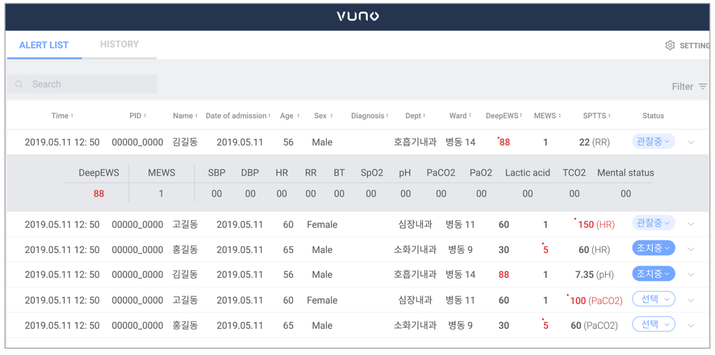
VUNO Med® - DeepCARS

Solution Overview

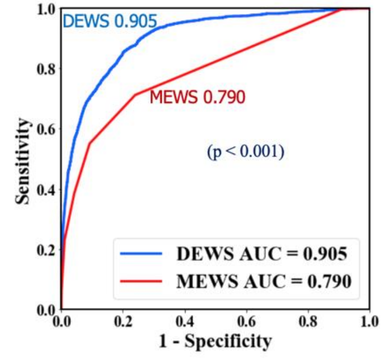
- VUNO Med DeepCARS™ measures and predicts the real-time risk of cardiac arrest of patients in the general wards through 4 vital sign (blood pressure, HR, respiratory rate, body temperature) observation, and provides a risk score from zero to 100.
- The first AI-based SaMD waived for new health technology track in Korea

User Interface

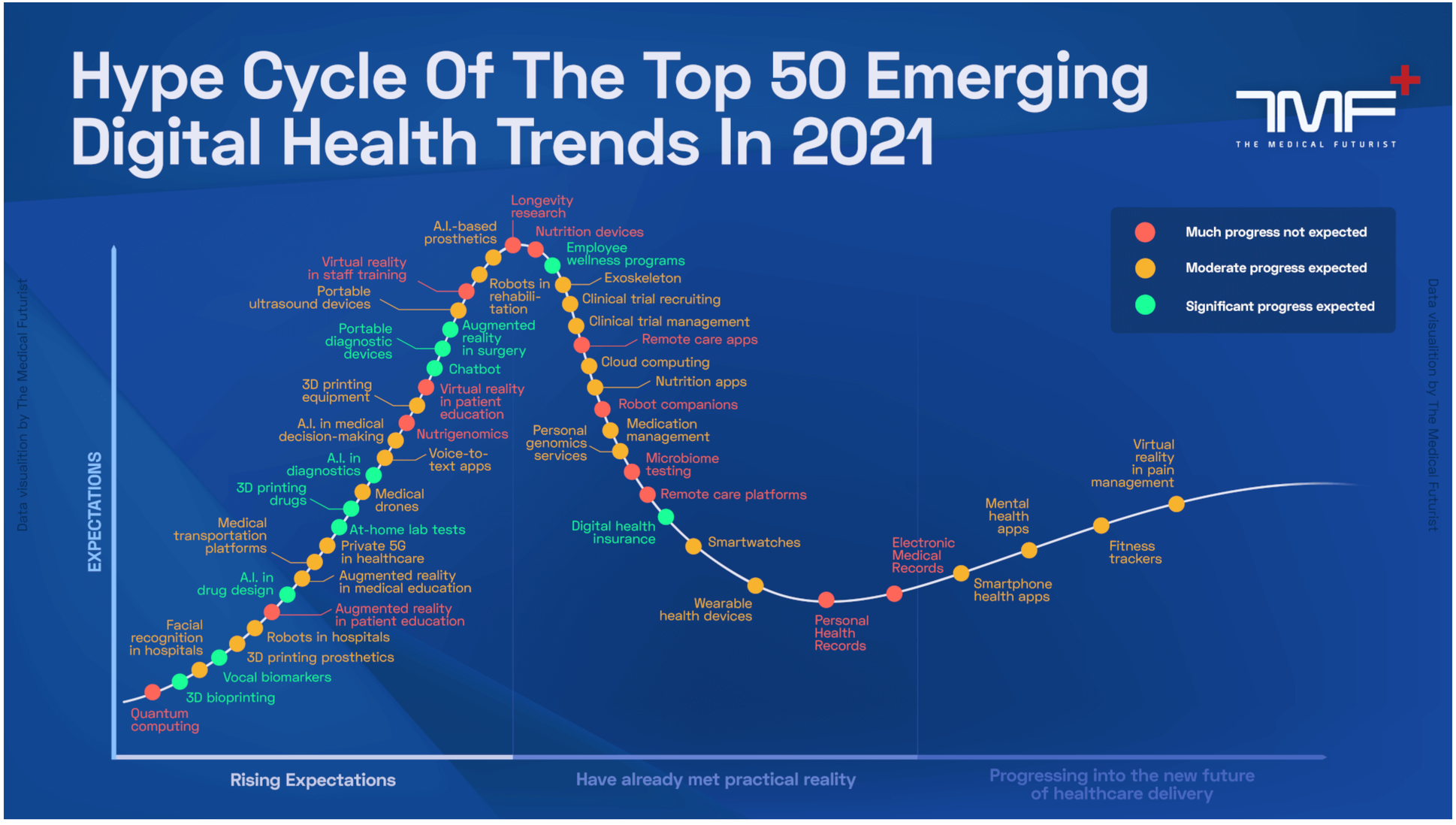
Ministry of Food and Drug Safety



Clinical Validation

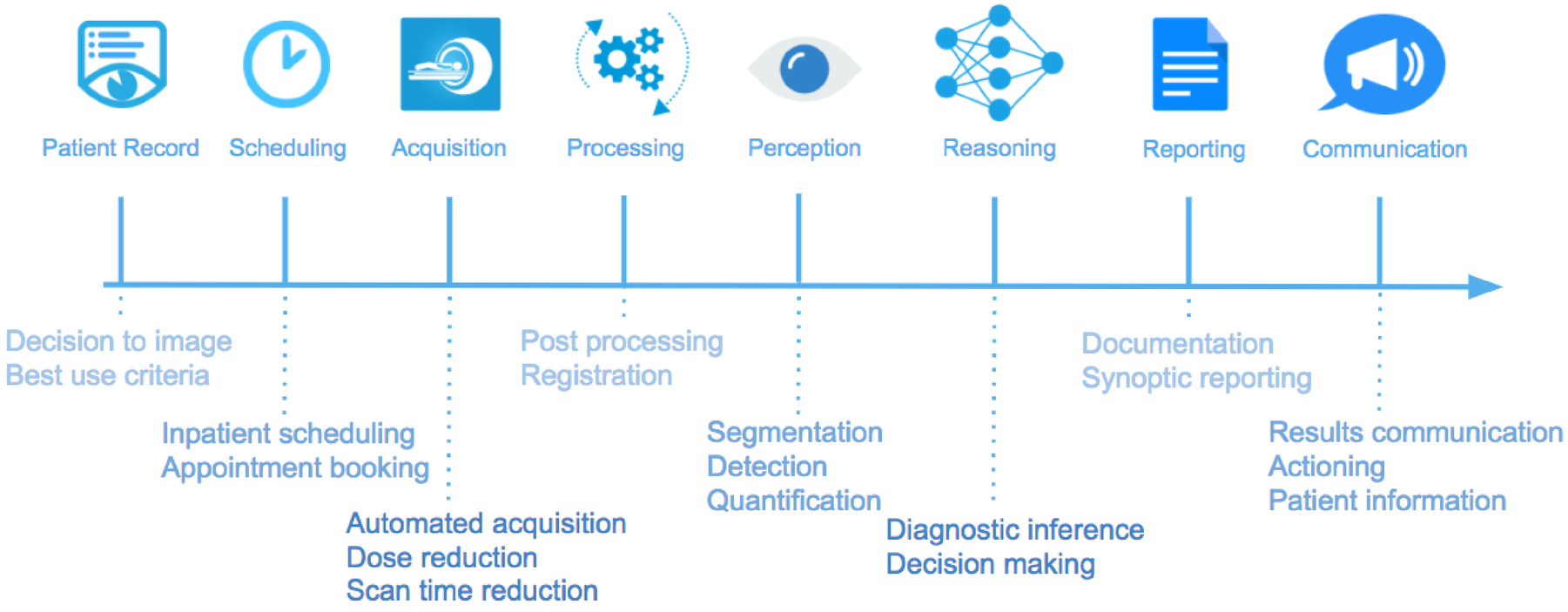


Hype Cycle of Emerging Digital Health Trends



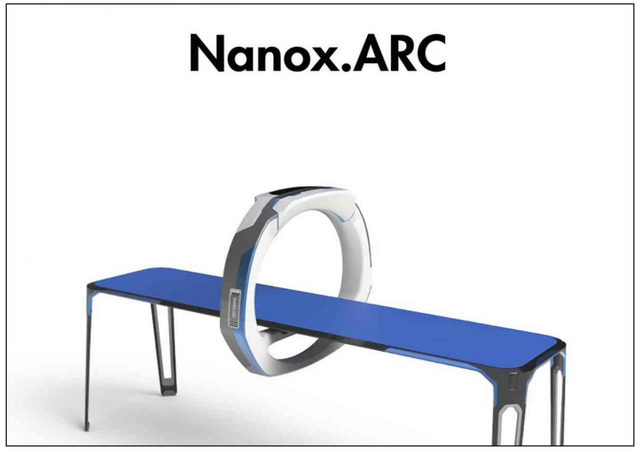
Source : The Medical Futurist (2021)

Diagnostic Imaging Workflow



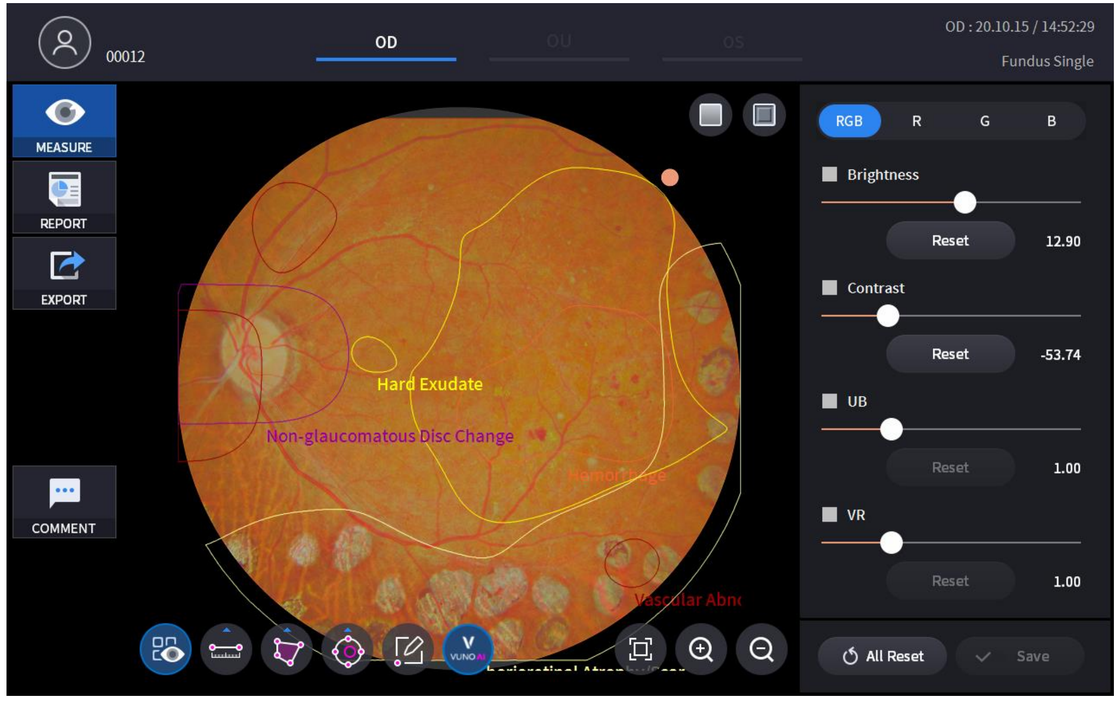
Source : Hugh Harvey(2018)

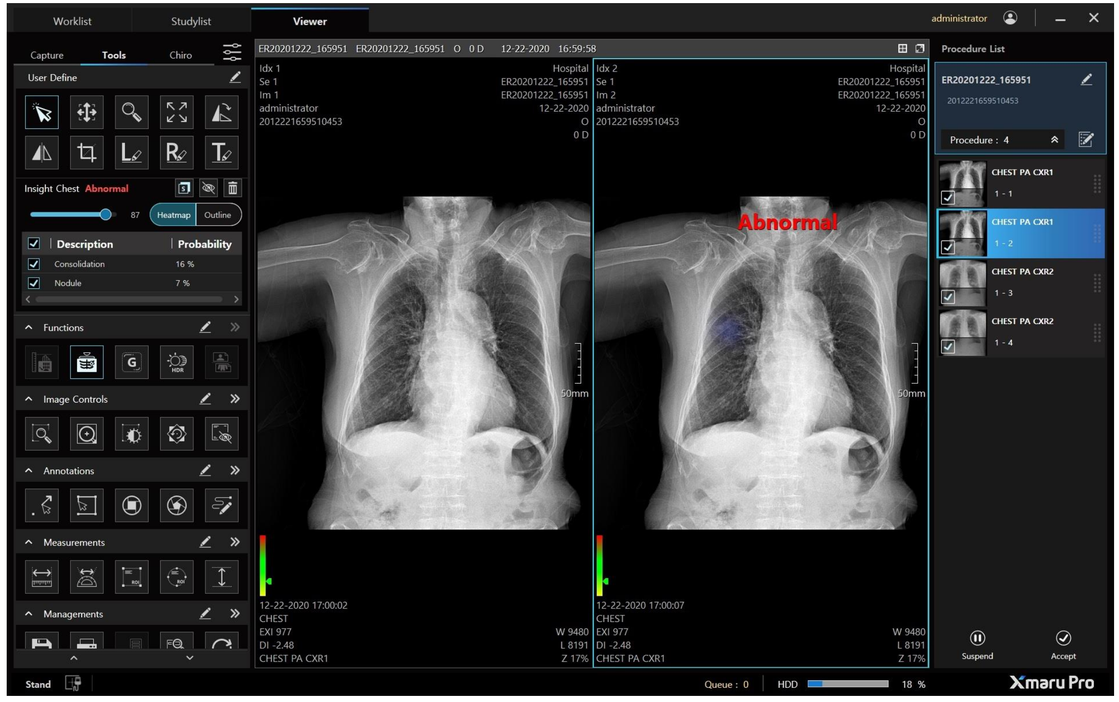
▪ Cheaper, Connected, and AI-Enabled Medical Devices



Source : Butterfly, Hyperfine, Tesseract, Nanox (2021)

▪ Making Existing Medical Devices Smarter using AI





Source : VUNO, Huvits, Rayence (2021)

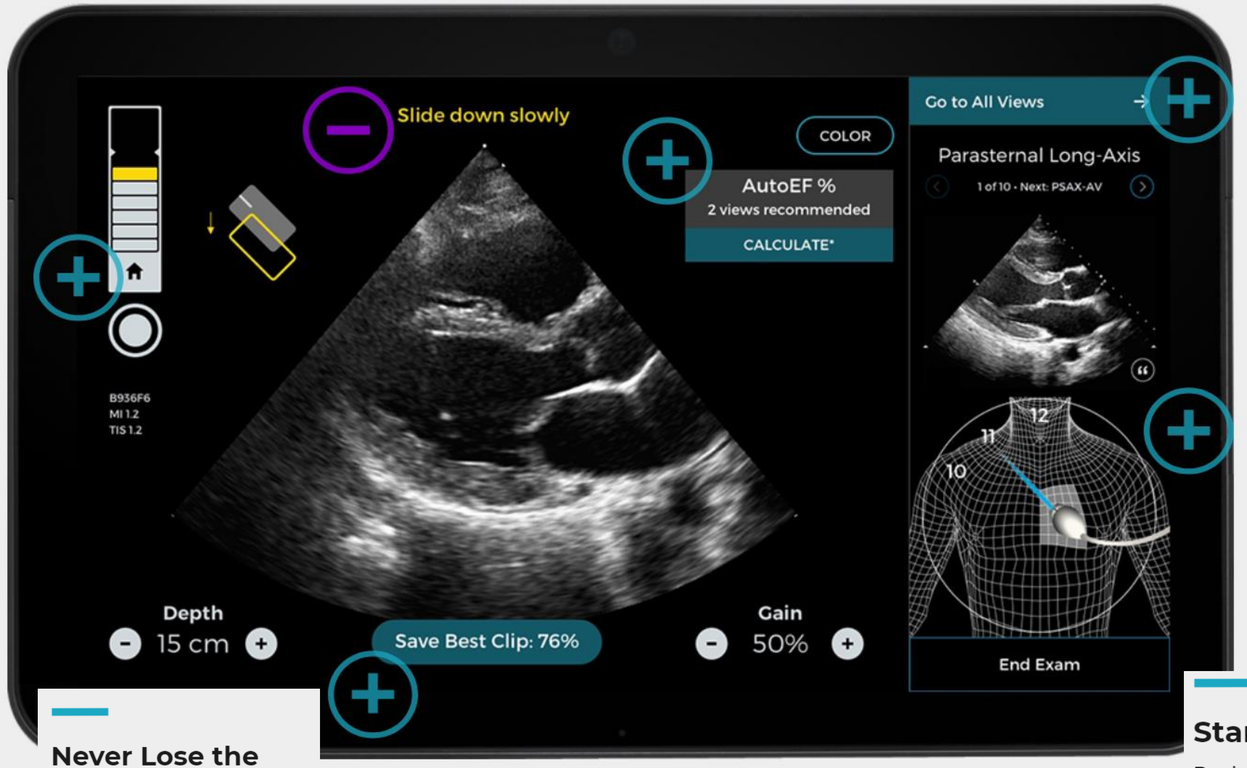
Making Imaging Acquisition Smarter with Quality

Scan with Confidence

Caption AI emulates the expertise of a sonographer by providing real-time guidance that prompts users to make specific transducer movements to optimize and capture a diagnostic-quality ultrasound image.

Capture with Quality

The Quality Meter shows users in real time how close they are to capturing a diagnostic-quality ultrasound image. The meter rises as the user gets closer to the optimal view, turning green when the image is deemed diagnostic. AutoCapture then records the clip, hands-free.



Never Lose the Best

Caption AI continuously keeps track of the best images seen during each scanning session so the best image from each view is automatically captured. Users have the freedom to explore each view with the reassurance that they can always access the best two-second clip seen during their scan at the touch of a button.

Automate Interpretation

Caption AI automatically calculates ejection fraction while scanning from any combination of up to three cardiac views commonly acquired at the point of care: apical 4-chamber (AP4), apical 2-chamber (AP2), and—an industry first—parasternal long-axis (PLAX). It's as quick as a visual assessment, with comparable performance to an expert.

Scan your Way

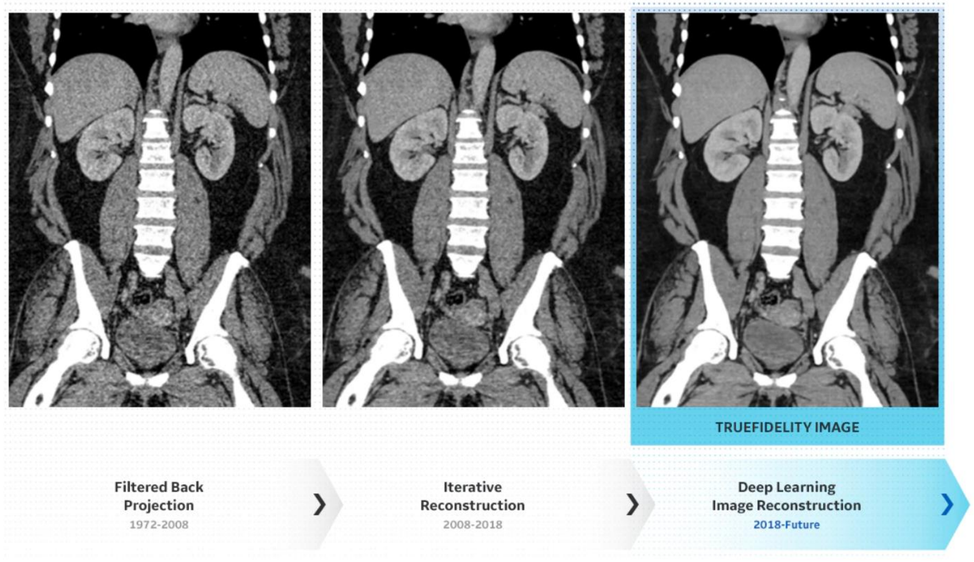
Caption AI gives users the flexibility to create and follow a customizable indication-based or workflow-based protocol of ultrasound views. While scanning, users can easily skip to the view they need.

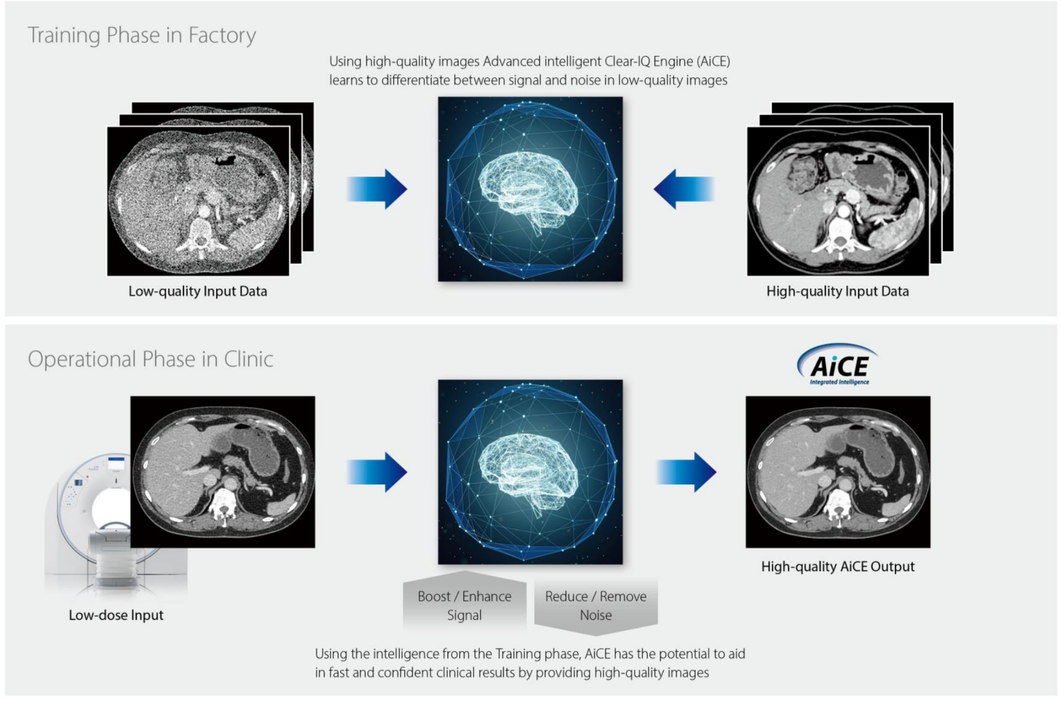
Start Smart

Begin every exam with a probe positioning diagram indicating where to place the ultrasound transducer. A reference image provides a visual example of what to look for while scanning.

Source : Caption Health(2021)

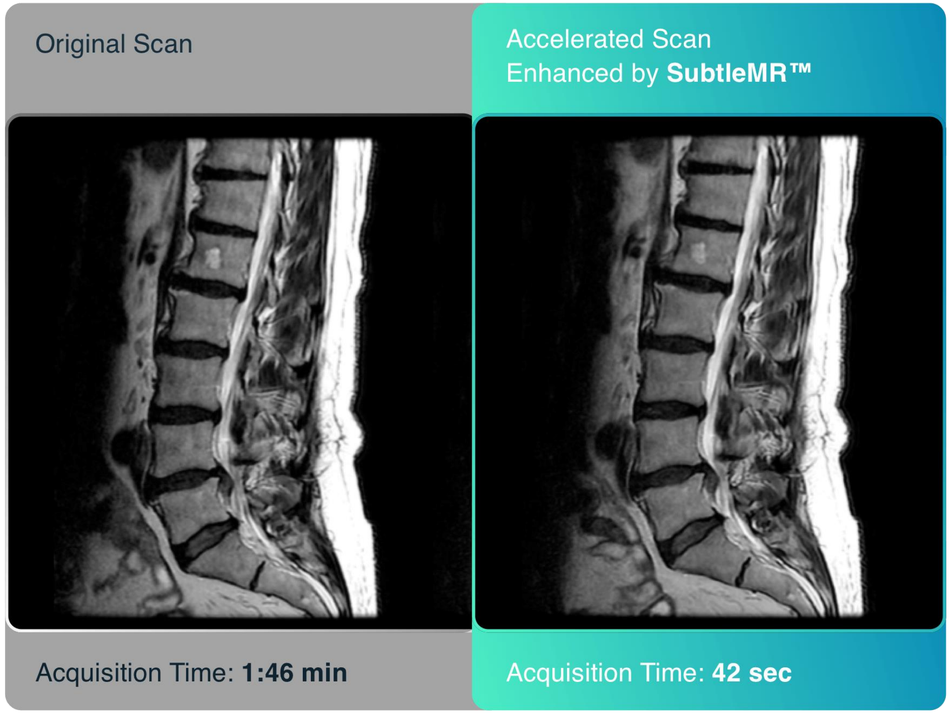
▪ Making Existing Medical Devices Faster or Safer using AI

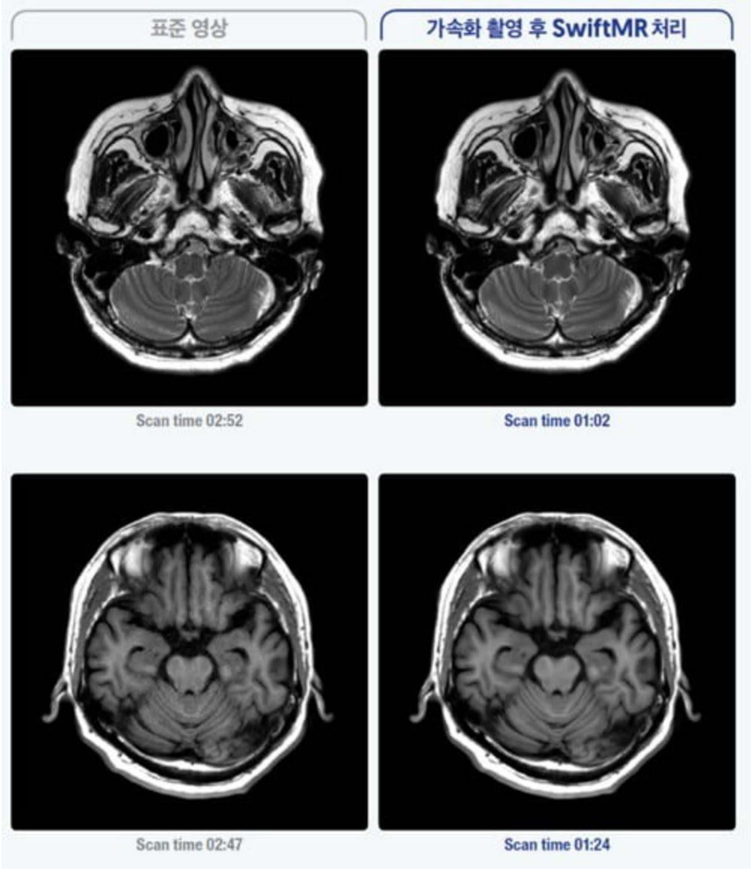




Source : GE, Cannon(2021)

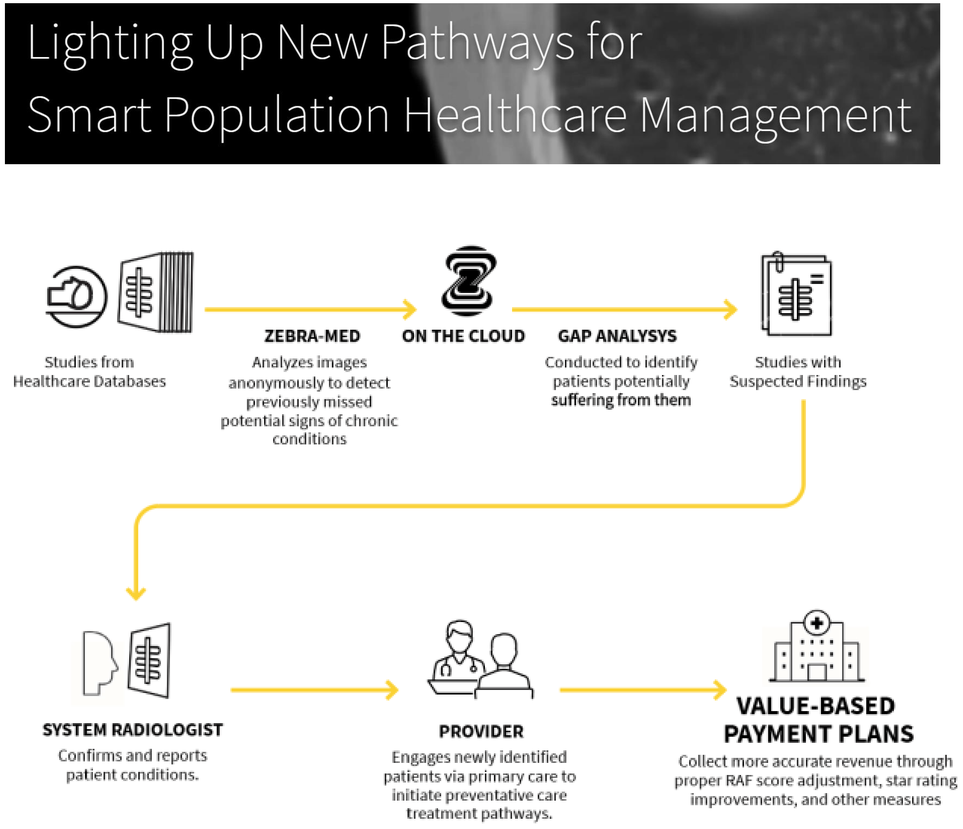
▪ Making Existing Medical Devices Faster or Safer using AI





Source : Subtle Medical, AIRS Medical(2021)

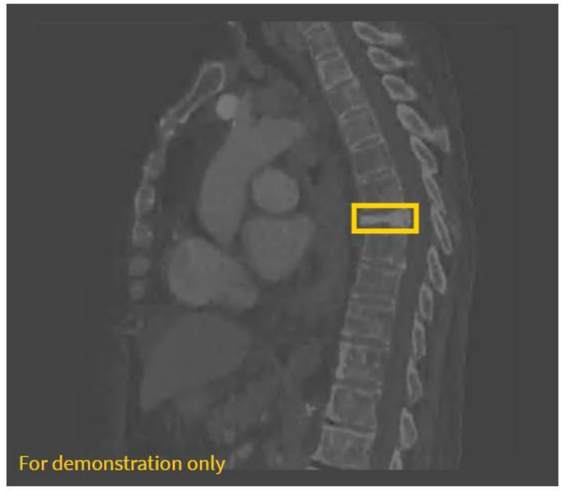
▪ Medical AI for Population Health



In a landmark approval, the American Medical Association (AMA) issued a specific CPT code for AI based automatic analysis of VCFs, an early sign of osteoporosis. This is an important step in proper risk-adjustment of populations towards widespread preventative care, and a game changer in the long term management of this terrible disease.

*Effective January 1, 2022.

*The CPT is named "Cat III-Assistive Augmented Intelligence Analysis," and defined as "Accepted addition of code 0X36T to report an automated analysis of an existing computed tomography study for vertebral fractures."

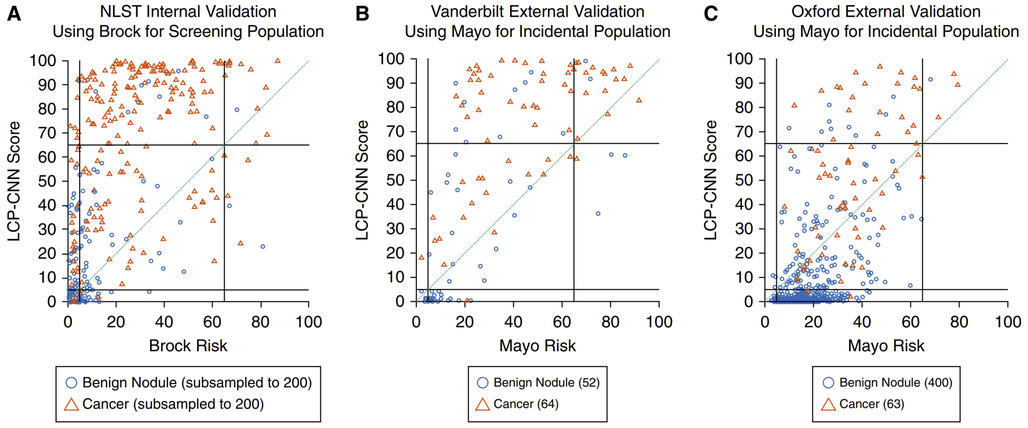


Source : Zebra Medical Vision(2021)

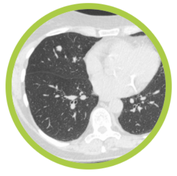
Medical AI for Cancer Risk Stratification

PRESS RELEASE: CMS assigns new technology payment classification for Optellum's Lung Cancer Prediction score

Rhiannon Lassiter - June 28, 2022 - Media / News and PR / Regulatory



How to compute the score for one or more nodules of interest

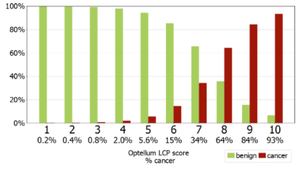


Patient scan

The CT and any prior scans are automatically uploaded in Virtual Nodule Clinic.

Identify nodule

Easily review any available CT and mark the nodule(s) of interest.



Optellum Lung Cancer Prediction score

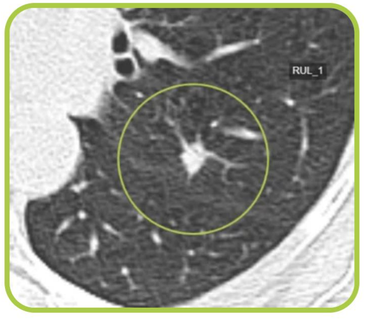
Within seconds, the Optellum Lung Cancer Prediction analyzes the 3D image region around the nodule to compute the score.

Optimal clinical decisions

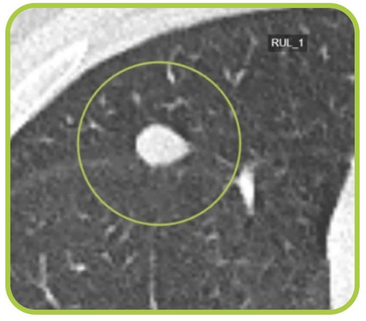
With the support of the Optellum LCP score, make the optimal clinical management decision for the patient.

Optellum LCP Score

INTERPRETATION



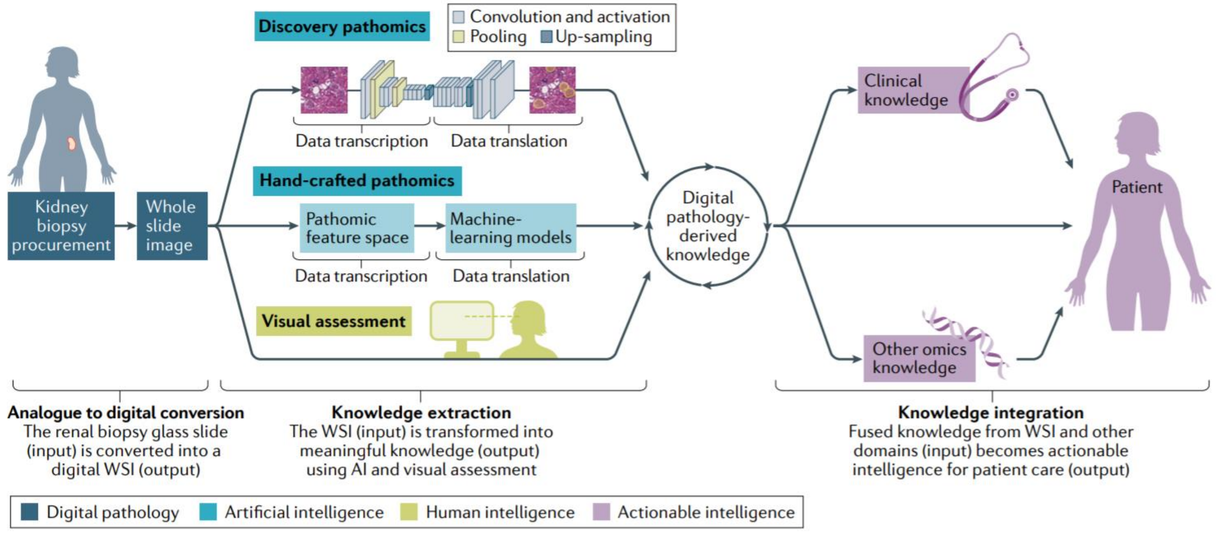
Optellum LCP score 9 = 84% risk of cancer

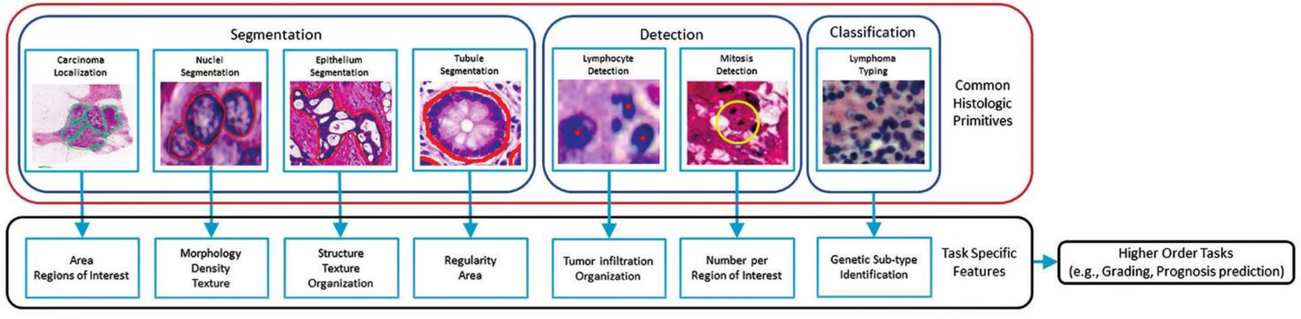


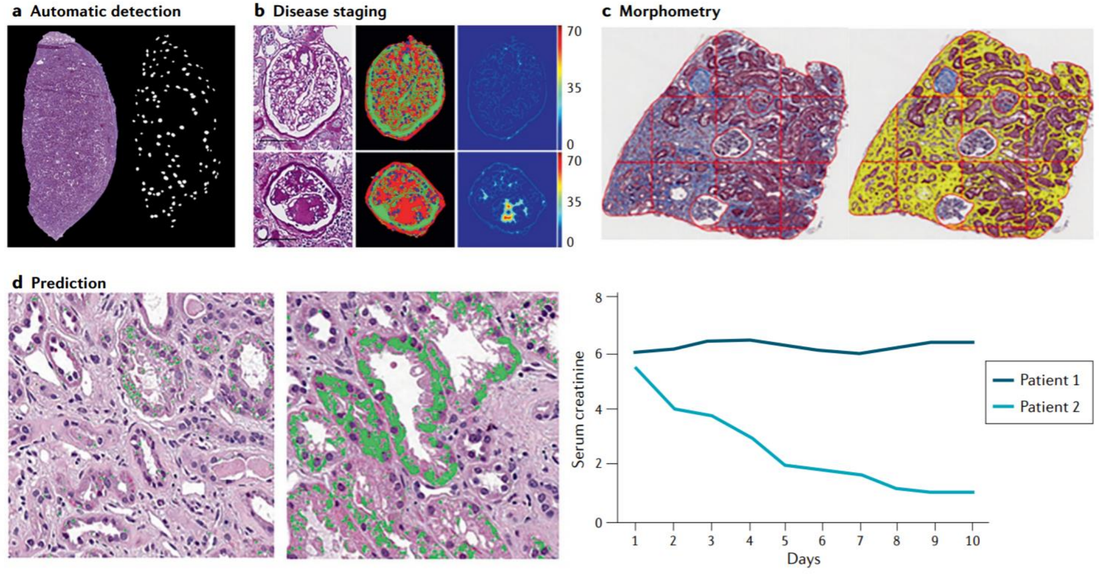
Optellum LCP score 1 = 0.2% risk of cancer

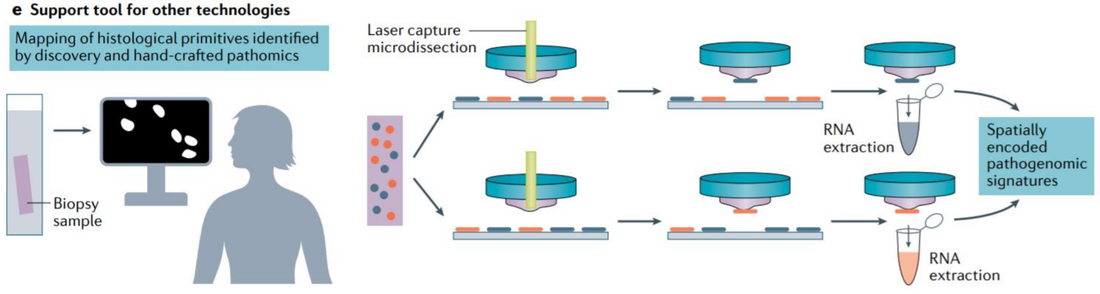
Source : Optellum(2022)

Digital Pathology Workflow with Advanced Analytics



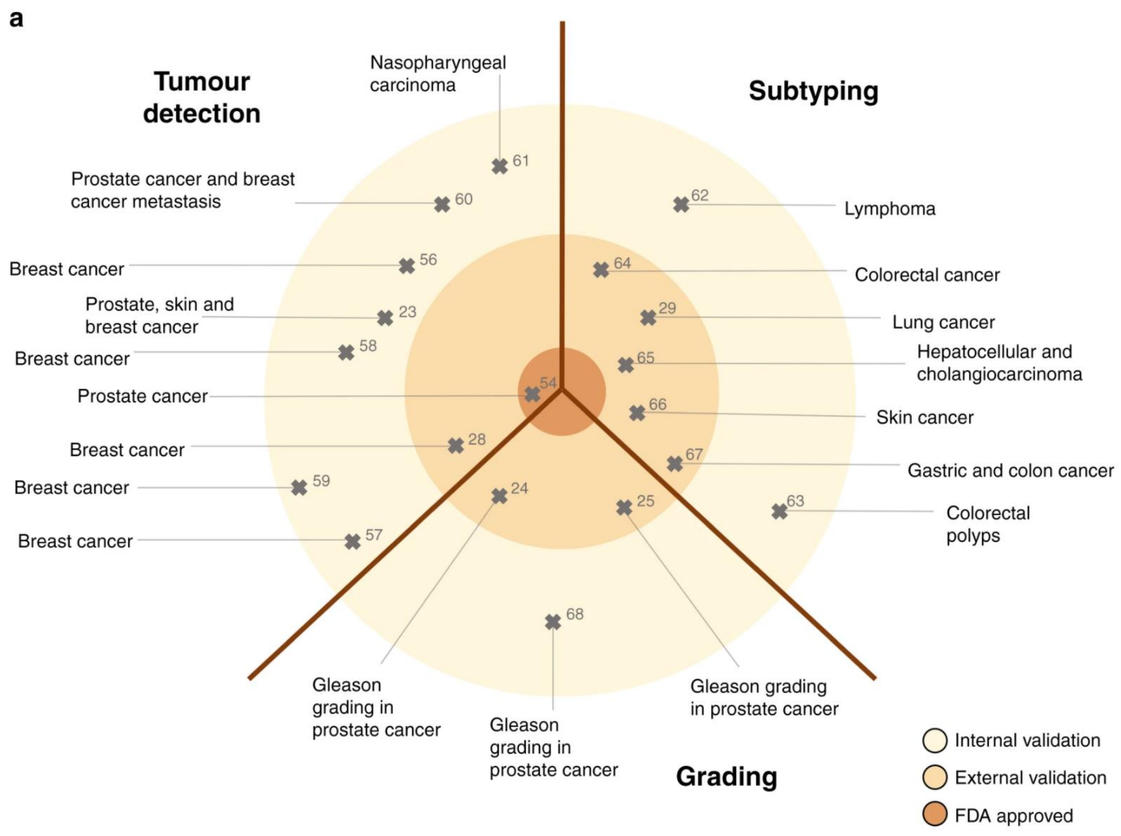


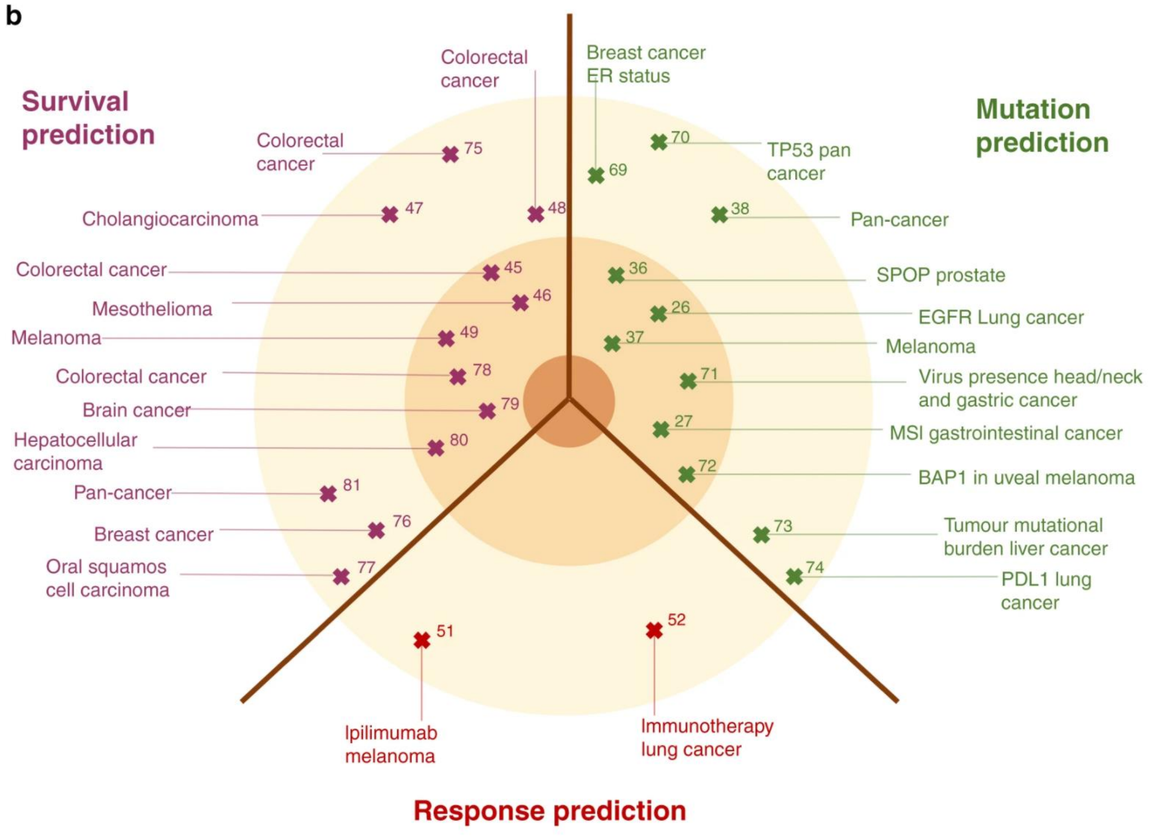




Source : Laura Barisoni et. al., *Precision Medicine in Nephrology,* 2020,
Andrew Janowczyk et. al., *Journal of Pathology Informatics*, 2015

Clinical applications of basic and advanced deep-learning (DL) image analysis in histopathology.





Source : Amelie Echle et. al., *British Journal of Cancer,* 2020

Regulatory Approved/Certified Solutions for Precision Pathology

FDA NEWS RELEASE

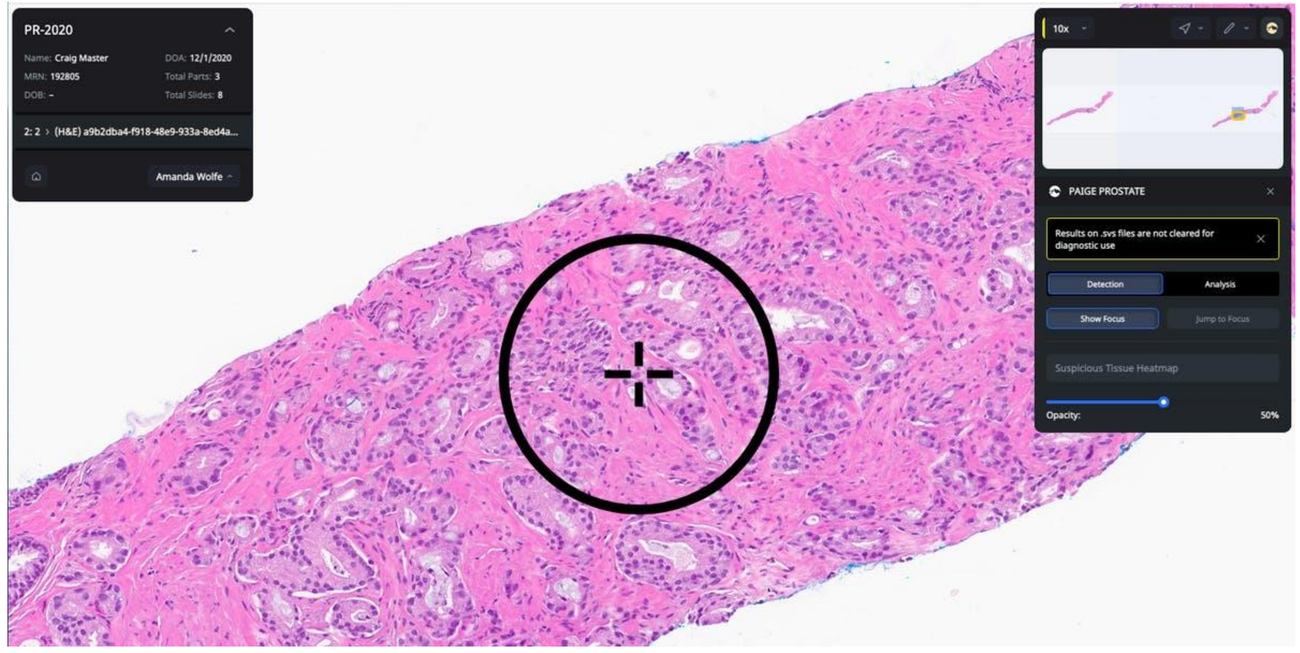
FDA Authorizes Software that Can Help Identify Prostate Cancer

Share Tweet Linkedin Email Print

For Immediate Release: September 21, 2021

Today, the U.S. Food and Drug Administration authorized marketing of software to assist medical professionals who examine body tissues (pathologists) in the detection of areas that are suspicious for cancer as an adjunct (supplement) to the review of digitally-scanned slide images from prostate biopsies (tissue removed from the body). The software, called Paige Prostate, is the first artificial intelligence (AI)-based software designed to identify an area of interest on the prostate biopsy image with the highest likelihood of harboring cancer so it can be reviewed further by the pathologist if the area of concern has not been identified on initial review.

"Pathologists examine biopsies of tissue suspected for diseases, such as prostate cancer, every day. Identifying areas of concern on the biopsy image can help pathologists make a diagnosis that informs the appropriate treatment," said Tim Stenzel, M.D., Ph.D., director of the Office of In Vitro Diagnostics and Radiological Health in the FDA's Center for Devices and Radiological Health. "The authorization of this AI-based software can help increase the number of identified prostate biopsy samples with cancerous tissue, which can ultimately save lives."



Source : paige.ai, FDA(2021)

Regulatory Approved/Certified Solutions for Precision Pathology

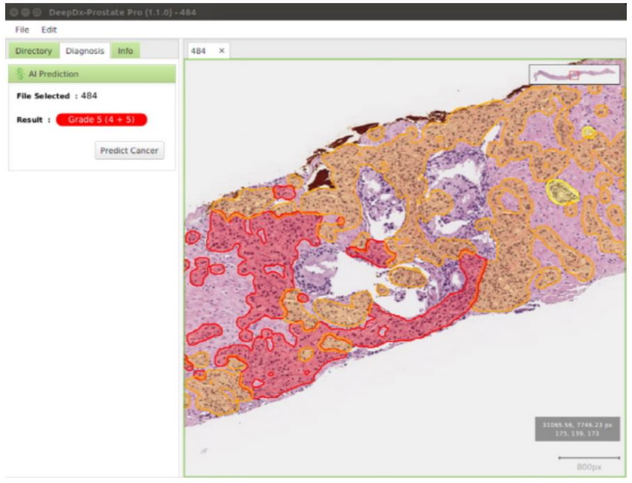
딥바이오, AI 전립선암 진단 보조 솔루션 식약처 허가

이인복 기자 | 발행날짜: 2021-11-18 09:50:29

가

전립선암의 중증도 구분을 보조하는 소프트웨어 세계 첫 사례

[메디칼타임즈=이인복 기자]

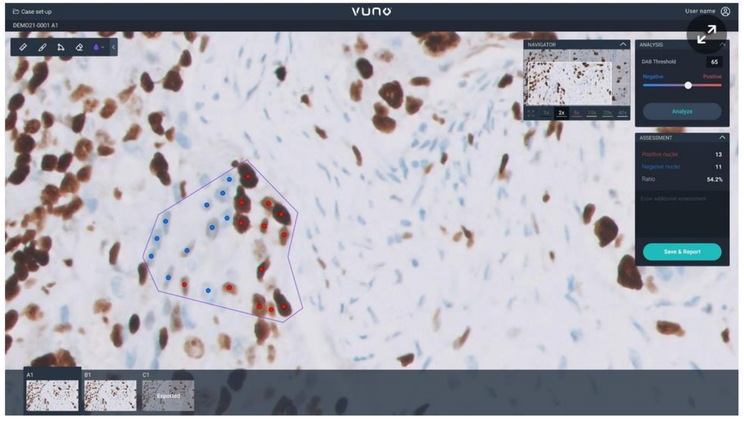


뷰노, 디지털 병리 분석 AI 솔루션 식약처 인증

김혜인 기자 | 입력 2021.06.25 06:00 | 수정 2021.06.25 06:25 | 댓글 0

"뷰노메드 패스퀀트, 발현 바이오마커 자동 정량화로 분석 시간 단축"

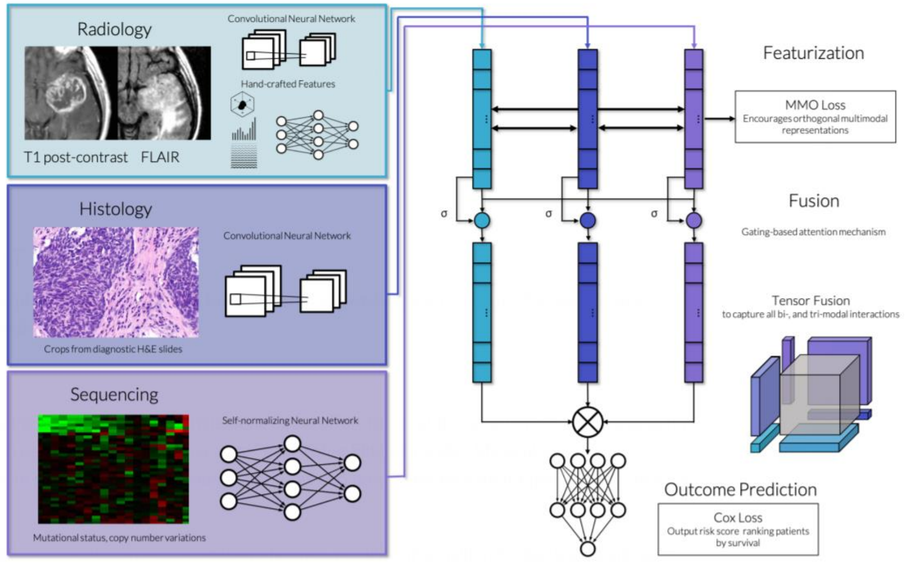
뷰노는 인공지능(AI) 기반 디지털 병리 분석 솔루션 '뷰노메드 패스퀀트(VUNO Med-PathQuant)'가 식품의약품안전처 인증을 획득했다고 지난 24일 밝혔다.

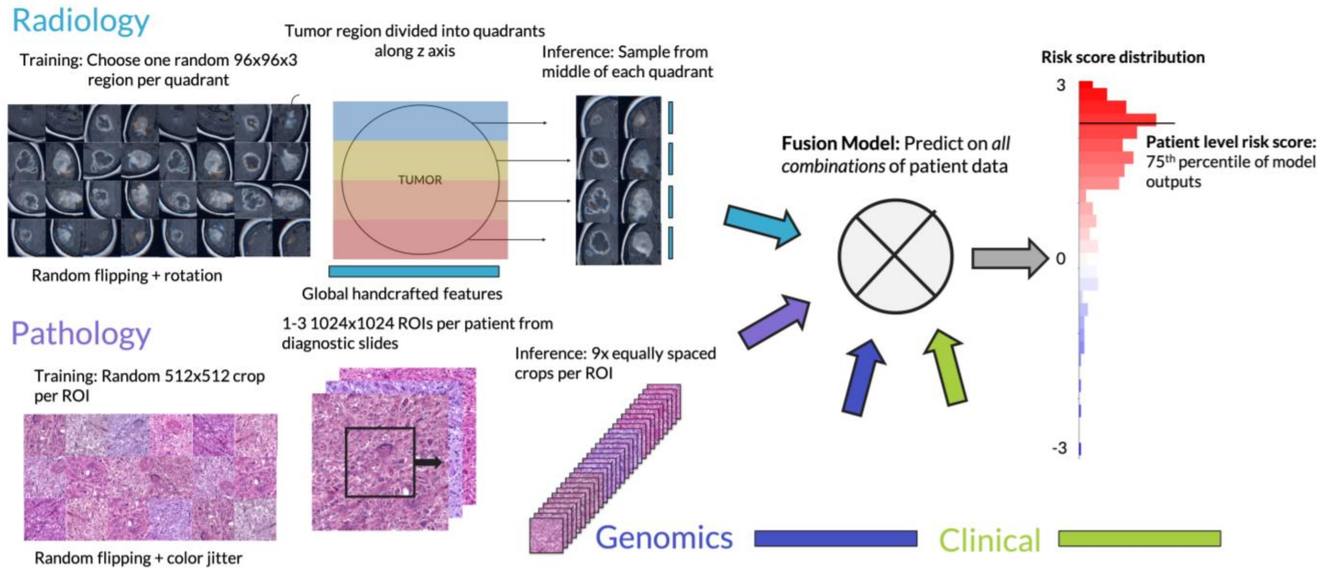


뷰노메드 패스퀀트 스크린샷.

Source : 식약처(2020), 청년의사(2021), FDA(2021)

- **Toward Integrated/Predictive Modeling using Multi-modal/Multi-omic Data**





Source : Nathaniel Braman et. al., MICCAI (2021)

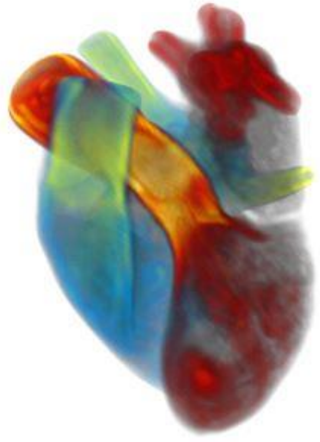
- **Enhanced diagnosis and personalized treatments through virtual testing and optimization of treatment prior to the actual delivery using digital twin of patient**

RESEARCH ARTICLE

Towards Personalized Cardiology: Multi-Scale Modeling of the Failing Heart

Elham Kayvanpour[1,2☯], Tommaso Mansi[3☯], Farbod Sedaghat-Hamedani[1,2☯], Ali Amr[1,2], Dominik Neumann[3], Bogdan Georgescu[3], Philipp Seegerer[3], Ali Kamen[3], Jan Haas[1,2], Karen S. Frese[1,2], Maria Irawati[1], Emil Wirsz[4], Vanessa King[5], Sebastian Buss[1], Derliz Mereles[1], Edgar Zitron[1], Andreas Keller[6,7], Hugo A. Katus[1,2,8], Dorin Comaniciu[3], Benjamin Meder[1,2,8]*

1 Department of Medicine III, University of Heidelberg, Heidelberg, Germany, **2** DZHK (German Centre for Cardiovascular Research), Heidelberg, Germany, **3** Siemens Corporation, Corporate Technology, Imaging and Computer Vision, Princeton, New Jersey, United States of America, **4** Siemens AG, Corporate Technology, Erlangen, Germany, **5** Siemens Corporation, Corporate Technology, Sensor Technologies, Princeton, New Jersey, United States of America, **6** Biomarker Discovery Center Heidelberg, Heidelberg, Germany, **7** Department of Human Genetics, Saarland University, Homburg, Germany, **8** Klaus Tschira Institute for Computational Cardiology, Heidelberg, Germany



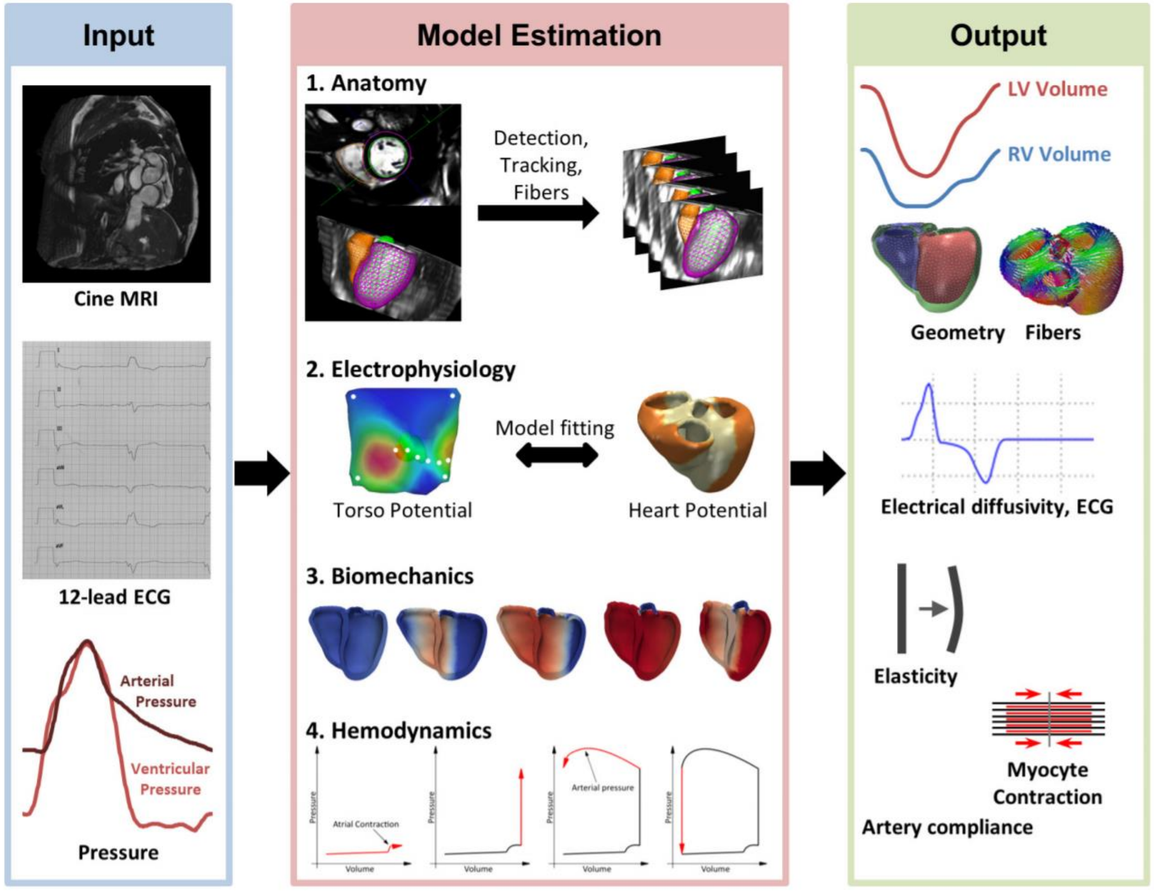
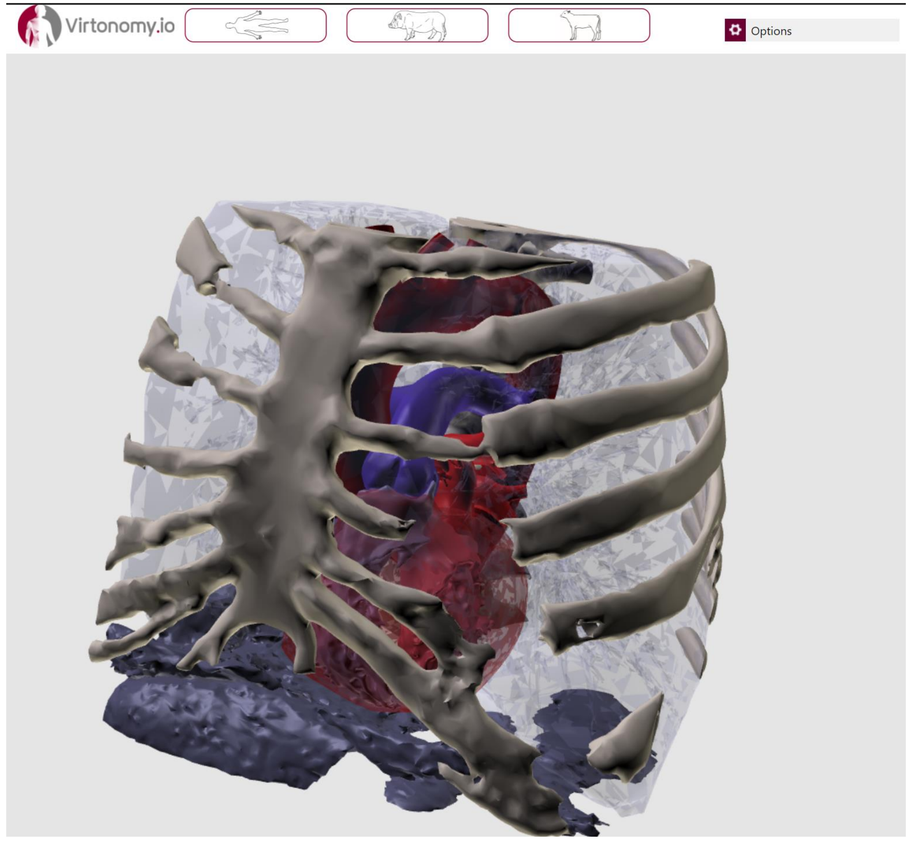


Fig 1. Overview of the modeling pipeline, from clinical data (input) to multi-scale, multi-physics cardiac models (output).

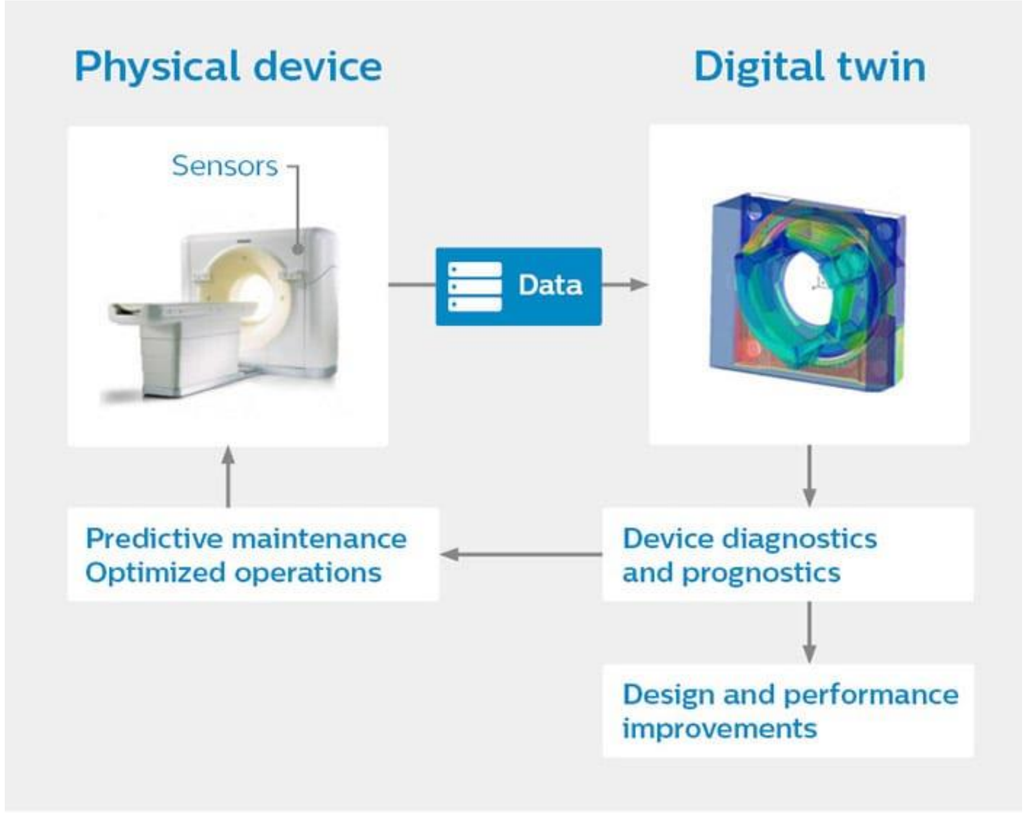
Source : Elham Kayvanpour et. al., Plos One(2015)

- **v-Patients by Virtonomy is a library of common variations to help medical equipment makers test conduct studies on how these variations may affect the performance and safety of new devices**



Source : Virtonomy.io(2021)

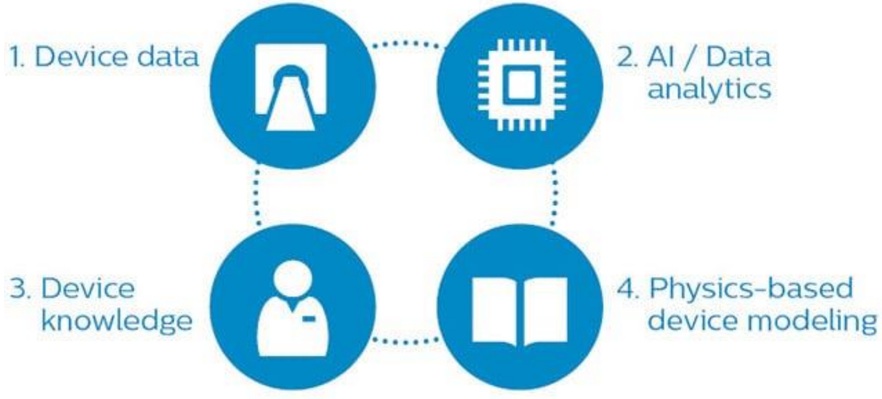
- **Identify maintenance needs before they arise using a virtual representation of a device**



> The challenge is to identify potential problems before they occur, so you can schedule maintenance at a time when the equipment is not in use.

> By running simulations on virtual prototypes of the device, we were able to perform tests that would have taken months and several iterations if we had to build physical prototypes first.

The four components of a digital twin of a device



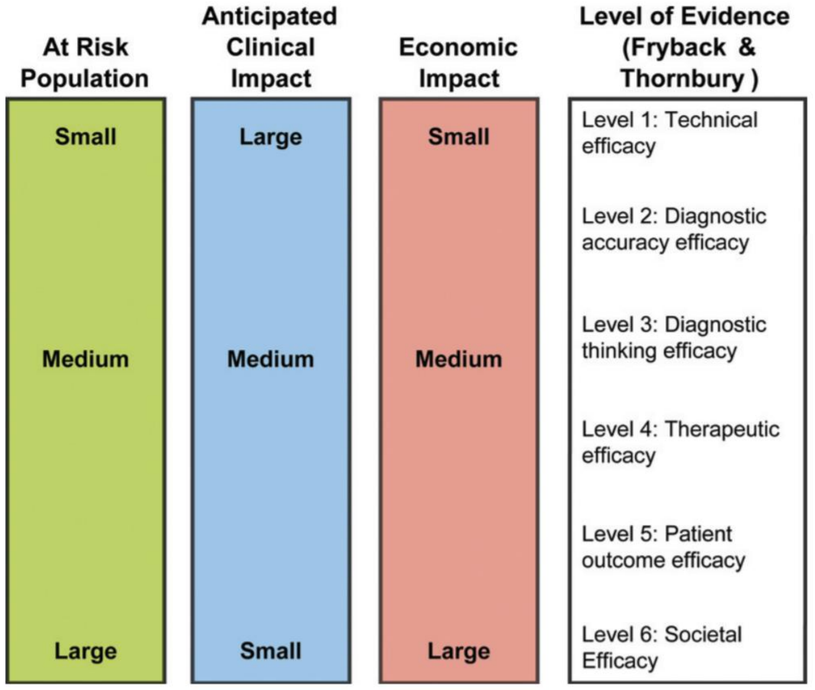
Source : Philips(2018)

- **Virtual hospital models help to plan the beds, schedules of staff, and operating rooms to maximize the care to patients while keeping a check on the costs**

Source : GE Healthcare(2017),

- Level of Evidences for New Diagnostic Technology

Source : RAS LLS(2019)



Dimensions of an evidence strategy.

Six Levels of Efficacy and Challenges for Comparative Effectiveness Research

Level of Efficacy	Examples of Endpoints for Each Level of Efficacy
Level 1: technical efficacy	Imaging resolution
Level 2: diagnostic accuracy efficacy	Test sensitivity/specificity
Level 3: diagnostic thinking efficacy	Pre- and posttest changes in subjectively determined outcome
Level 4: therapeutic efficacy	Effects of diagnostic on choice of therapy
Level 5: patient outcome efficacy	Value of test information including measures of morbidity, mortality, and QALYs
Level 6: societal efficacy	Cost-benefit and cost-effectiveness from the societal perspective

Source.—Reference 8.

Source : G.Scott Gazelle et. al., Radiology(2011)

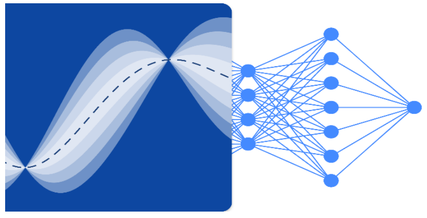
Conclusion

Future Direction in AIMD/Digital Healthcare

Convergent/Translational Medical Device/Digital Healthcare Research

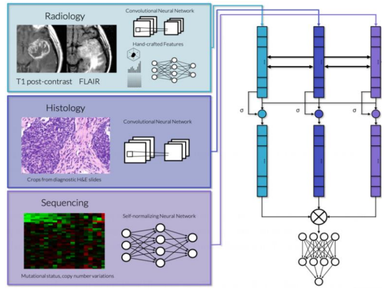
Trustworthy SaMD

- Explainable Prediction
- Uncertainty Quantification
- Calibrated Output
- Fairness/Bias Awareness



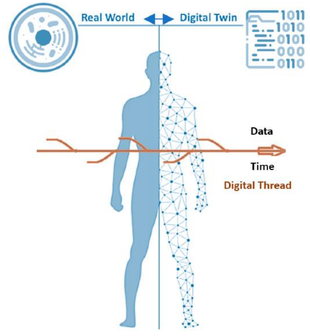
Integrative Medicine

- Multi-modal Fusion
- Multi-omics Approach
- Prognostic Biomarker
- Therapeutic Support



Virtualized Medicine

- Virtualized Patient
- Virtualized Devices
- Virtualized Hospital
- Virtualized Treatment



Medical/Healthcare Data

- Medical Image
- Electronic Medical Records
- Genomic Data
- Patient Generated Health Data

Data-driven Analytics

- Nonlinear Optimization
- Data Mining
- Machine/Deep Learning
- Artificial Intelligence

Thank you!

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E khwanjung@skku.edu