Artificial Intelligence (AI): Application in the Hospital, its Technology and Benefits

November 11, 2019
Eunkyung Jung
Regulatory Affair Specialist & Medical Writer

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“ View the Invisible, Know the Unknown ”

We deliver an AI-based diagnostic platform that can support physicians to make more accurate diagnoses and democratize the quality of care in a more quantitative and objective manner.

SAVE RESOURCE

INCREASE EFFICIENCY

IMPROVE OUTCOME

40+
KR/PCT/US Patents

3
MFDS Approvals /CE Certification

20+
Academic Publications

Our technology, VUNO Med® Solutions

Radiology
(CT/X-ray/MRI)

- **3** MFDS Approvals
- **1** CE Designation (First in Korea)
- **3** FDA/CE Initiation

Biosignals
(ECG/EEG/Speech)

- **1** Product Completion (Non-medical device)
- **1** MFDS Initiation

Pathology
(Digital pathology slides)

- **1** Product Completed MFDS/CE Preparation

EMR
(EMR/EHR)

- **1** MFDS Initiation

Sound scientific evidence

ARTICLE IN PRESS

AMERICAN ACADEMY OF OPHTHALMOLOGY®

Development and Validation of Deep Learning Models for Screening Multiple Abnormal Findings in Retinal Fundus Images

Jaemin Son, MSc,[1,*] Joo Young Shin, MD, MSc,[2,*] Hoon Dong Kim, MD, MSc,[3] Kyu-Hwan Jung, PhD,[1] Kyu Hyung Park, MD, PhD,[4] Sang Jun Park, MD, MSc[4]

Purpose: To develop and evaluate deep learning models that screen multiple abnormal findings in retinal fundus images.

Design: Cross-sectional study.

Participants: For the development and testing of deep learning models, 309 786 readings from 103 262 images were used. Two additional external datasets (the Indian Diabetic Retinopathy Image Dataset and e-ophtha) were used for testing. A third external dataset (Messidor) was used for comparison of the models with human experts.

M ...pital Retin... ...eoul Natio... ...ton- woo... ...cular abno... ...with their...

M ...and spec... ...the perfo...

R ...% to 99.9... ...ious findi... ...sted in the Indian Diabetic Retinopathy Image Dataset and e-ophtha dataset were 94.7% to 98.0%. The model demonstrated a performance that rivaled that of human experts, especially in the detection of hemorrhage, hard exudate, membrane, macular hole, myelinated nerve fiber, and glaucomatous disc change.

Conclusions: Our deep learning algorithms with region guidance showed reliable performance for detection of multiple findings in macula-centered retinal fundus images. These interpretable, as well as reliable, classification outputs open the possibility for clinical use as an automated screening system for retinal fundus images. *Ophthalmology 2019;■:1–10 © 2019 by the American Academy of Ophthalmology. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).*

Supplemental material available at www.aaojournal.org.

Macula-centered retinal fundus images may be used for screening potential vision-threatening conditions, including diabetic retinopathy (DR),[1–3] age-related macular degeneration (AMD), and glaucoma.[4] To maximize accessibility and mitigate cost, automatic algorithms have been developed in the past decade to streamline the process for the diagnosis of DR[5,6] and glaucoma.[7–9] Recently, deep neural networks[10] have revolutionized the field of medical image analysis, and the diagnoses of DR, AMD, and possible glaucoma with these deep learning algorithms have demonstrated discriminative abilities comparable with those of ophthalmologists.[11–20] However, because a diverse spectrum of abnormal findings and diseases can be found on fundus examination, a deep learning algorithm that identifies multiple disease conditions may be more ideal for clinical application. Also, these deep learning algorithms do not reveal how the decisions are made for the diagnoses, limiting interpretation of the outputs of these algorithms and discouraging potential clinical use. Ophthalmologists usually determine diagnoses in retinal fundus images by observing certain findings (e.g., hemorrhage, exudate, cotton-wool patches, etc.) that are associated commonly with the diagnosis (e.g., DR, glaucoma, etc.). This stepwise process is not embedded explicitly in deep learning algorithms that are trained in an end-to-end manner to generate outputs regarding diagnoses directly from an input image.

https://doi.org/10.1016/j.ophtha.2019.05.029
ISSN 0161-6420/19

Computerized Bone Age Estimation Using Deep Learning–Based Program: Evaluation of the Accuracy and Efficiency

Jeong Rye Kim[1]
Woo Hyun Shim[1]
Hee Mang Yoon[1]
Sang Hyup Hong[1]
Jin Seong Lee[1]
Young Ah Cho[1]
Sangki Kim[2]

OBJECTIVE. The purpose of this study is to evaluate the accuracy and efficiency of a new automatic software system for bone age assessment and to validate its feasibility in clinical practice.

MATERIALS AND METHODS. A Greulich-Pyle method–based deep-learning technique was used to develop the automatic software system for bone age determination. Using this software, bone age was estimated from left-hand radiographs of 200 patients (3–17 years old) using first-rank bone age (software only), computer-assisted bone age (two radiologists with software assistance), and Greulich-Pyle atlas–assisted bone age (two radiologists with

AJR American Journal of Roentgenology Diagnostic Imaging and Related Sciences

DOI:10.2214/AJR.17.18224

J. R. Kim and W. H. Shim contributed equally to this work.

Received March 12, 2017; accepted after revision July 7, 2017.

S. Kim is employed by Vuno, Inc., which created the deep learning–based automatic software system for bone age determination. J. R. Kim, W. H. Shim, H. M. Yoon, S. H. Hong, J. S. Lee, and Y. A. Cho are employed by Asan Medical Center, which holds patent rights for the deep learning–based automatic software system for bone age assessment.

[1]Department of Radiology and Research Institute of Radiology, Asan Medical Center, University of Ulsan College of Medicine, 88 Olympic-ro 43-gil, Songpa-gu, Seoul 05505, South Korea. Address correspondence to H. M. Yoon (esporihm@gmail.com).

Supplemental Data
Available online at www.ajronline.org.

AJR 2017; 209:1–7

0361–803X/17/2096–1

Bone age estimation is crucial for developmental status determinations and ultimate height predictions in the pediatric population, particularly for patients with growth disorders and endocrine abnormalities [1]. Two major left-hand wrist radiograph-based methods for bone age estimation are currently used: the Greulich-Pyle [2] and Tanner-Whitehouse [3] methods. The former is much more frequently used in clinical practice. Greulich-Pyle–based bone age estimation is performed by comparing a patient's left-hand radiograph to standard radiographs in the Greulich-Pyle atlas, which comprises a simple comparison of multiple images, can be repetitive and time consuming and is thus sometimes burdensome to radiologists. Moreover, the accuracy depends on the radiologist's experience and tends to be subjective.

Since 1992, concerns regarding interobserver variability in manual bone age estimation [4] have led to the establishment of several automatic computerized methods for bone age estimation, including computer-assisted skeletal age scores, computer-aided skeletal maturation assessment systems, and BoneXpert (Visiana) [5–14]. BoneXpert was developed according to traditional machine-learning techniques and has been shown to have a good performance for patients of various ethnicities and in various clinical settings [10–14]. The deep-learning technique is an improvement in artificial neural network [15]. An algorithm to program itself by learning from the images given a large dataset of labeled examples, thus removing the need to specify rules [15].

Deep-learning techniques permit higher levels of abstraction and improved predictions from data. Deep-learning techniques

American Heart Association | American Stroke Association

An Algorithm Based on Deep Learning for Predicting In-Hospital Cardiac Arrest

Joon-myoung Kwon, MD;* Youngnam Lee, MS;* Yeha Lee, PhD; Seungwoo Lee, BS; Jinsik Park, MD, PhD

Background—In-hospital cardiac arrest is a major burden to public health, which affects patient safety. Although traditional track-and-trigger systems are used to predict cardiac arrest early, they have limitations, with low sensitivity and high false-alarm rates. We propose a deep learning–based early warning system that shows higher performance than the existing track-and-trigger systems.

Methods and Results—This retrospective cohort study reviewed patients who were admitted to 2 hospitals from June 2010 to July 2017. A total of 52 131 patients were included. Specifically, a recurrent neural network was trained using data from June 2010 to January 2017. The result was tested using the data from February to July 2017. The primary outcome was cardiac arrest, and the secondary outcome was death without attempted resuscitation. As comparative measures, we used the area under the receiver operating characteristic curve (AUROC), the area under the precision–recall curve (AUPRC), and the net reclassification index. Furthermore, we evaluated sensitivity while varying the number of alarms. The deep learning–based early warning system (AUROC:

JAHA Journal of the American Heart Association

In-hospital cardiac arrest is a major burden to public health, which affects patient safety.[1–3] More than a half of cardiac arrests result from respiratory failure or hypovolemic shock, and 80% of patients with cardiac arrest show signs of deterioration in the 8 hours before cardiac arrest.[4–9] However, 209 000 in-hospital cardiac arrests occur in the United States each year, and the survival discharge rate for patients with cardiac arrest is <20% worldwide.[10,11] Rapid response systems (RRSs) have been introduced in many hospitals to detect cardiac arrest using the track-and-trigger system (TTS).[12,13]

Two types of TTS are used in RRSs. For the single-parameter TTS (SPTTS), cardiac arrest is predicted if any single vital sign (eg, heart rate [HR], blood pressure) is out of the normal range.[14] The aggregated weighted TTS calculates a weighted score for each vital sign and then finds patients with cardiac arrest based on the sum of these scores.[15] The modified early warning score (MEWS) is one of the most widely used approaches among all aggregated weighted TTSs (Table 1)[16]; however, traditional TTSs including MEWS have limitations, with low sensitivity or high false-alarm rates.[14,15,17] Sensitivity and false-alarm rate interact: Increased sensitivity creates higher false-alarm rates and vice versa.

Current RRSs suffer from low sensitivity or a high false-alarm rate. An RRS was used for only 30% of patients before unplanned intensive care unit admission and was not used for 22.8% of patients, even if they met the criteria.[18,19]

From the Departments of Emergency Medicine, Yonsei University College of Medicine, Seoul, Korea (J.K.); Cardiology (J.P.), Medicine (S.J.), Gachon University Gil Medical Center, Incheon, Korea; VUNO, Seoul, Korea (Youngnam L., Yeha L., Seungwoo L.).

*Dr Kwon and Mr Youngnam Lee contributed equally to this study.

Correspondence to Joon-myoung Kwon, MD, Department of Emergency Medicine, Gachon University Gil Medical Center, Gachon University Gil Hospital, 20, Gyeyangmunhwa-ro, Gyeyang-gu, Incheon 21080, Korea. E-mail: ...

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DOI: 10.1161/JAHA.118.008678

And a recently accepted article in European Radiology

Contents

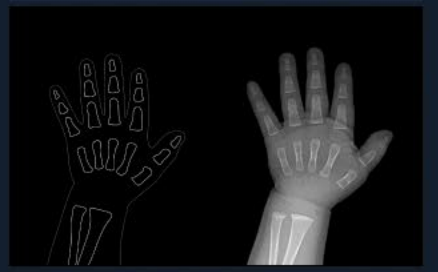
Credit :934

VUNO

sisobus@vuno.co

References | Male (#31)

0y0m



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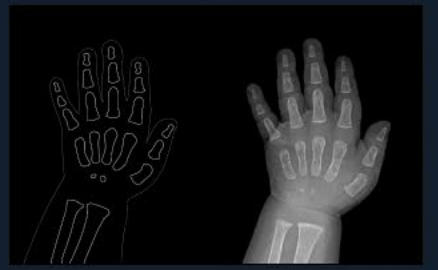

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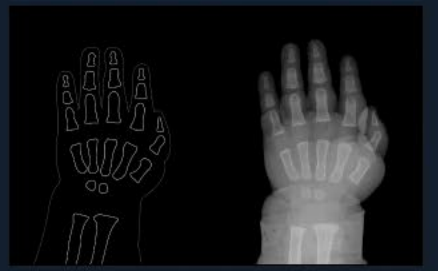


0y9m

Please note that performance depends on image format.

Open file

Attention Map

Result

Analyze

Save

Clear

VUNO Med® – BoneAge (Class II: Analyser, medical Image, software)

- **First AI device in Korea**
- Automates bone age assessment of children
- Supports doctors to assess skeletal maturity
- Reduces reading time
- Improves accuracy

Recent product approval: Before approval

Before VUNO Med® - BoneAge

With VUNO Med® - BoneAge

Photos courtesy of Medifornews, Newsis

Recent product approval: Approval timeline for 3 years

2016

- **Jan** — GMP documentation, Product Prototype
- **May** — First TCF
- **Jun** — Product Classification (Processing period: 10 D)
- **Nov** — Performance Test Completion
- **Dec** — KGMP Certification

2017

- **Apr** — Site, PI Selection
- **Jun** — Site, Vendor Contract
- **Jul** — Protocol Submission, Processing period: 30 D
- **Sep** — Protocol Approval
- **Oct to Dec** — Study Conduction
- **Dec** — Study Completion, Database Lock

2018

- **Jan** — Clinical Study Report
- **Feb** — New Device Application, Processing period: 80 D
- **Apr** — Business License
- **May** — Product Approval, Health Insurance Review, Processing period: 30 D
- **Jun to Nov** — ISO 13485:2016 preparation
- **Nov** — ISO 13485:2016 Certification, CE Marking

Corrective/preventive actions from customer feedback

“I’d like to pay per case.”	Provide cloud-based service model
“I like the report, and my patients like report.”	Make better report
“It’s better than me.”	Expand training set, upgrade performance
“It’s not like me.”	Expand training set, upgrade performance
“Why two hands images don’t work?”	Make CAD find one hand

And more importantly…

Quality management activities
Including software version control, training dataset management

VUNO Med® – BoneAge is ACTIVELY, clinically used by ≥ 50 hospitals, for ≥ thousands of children in Korea.

Standalone Package

- Direct sales with own viewer, mainly used in tertiary hospitals
- Hospital-level adoption for newly formed hospitals

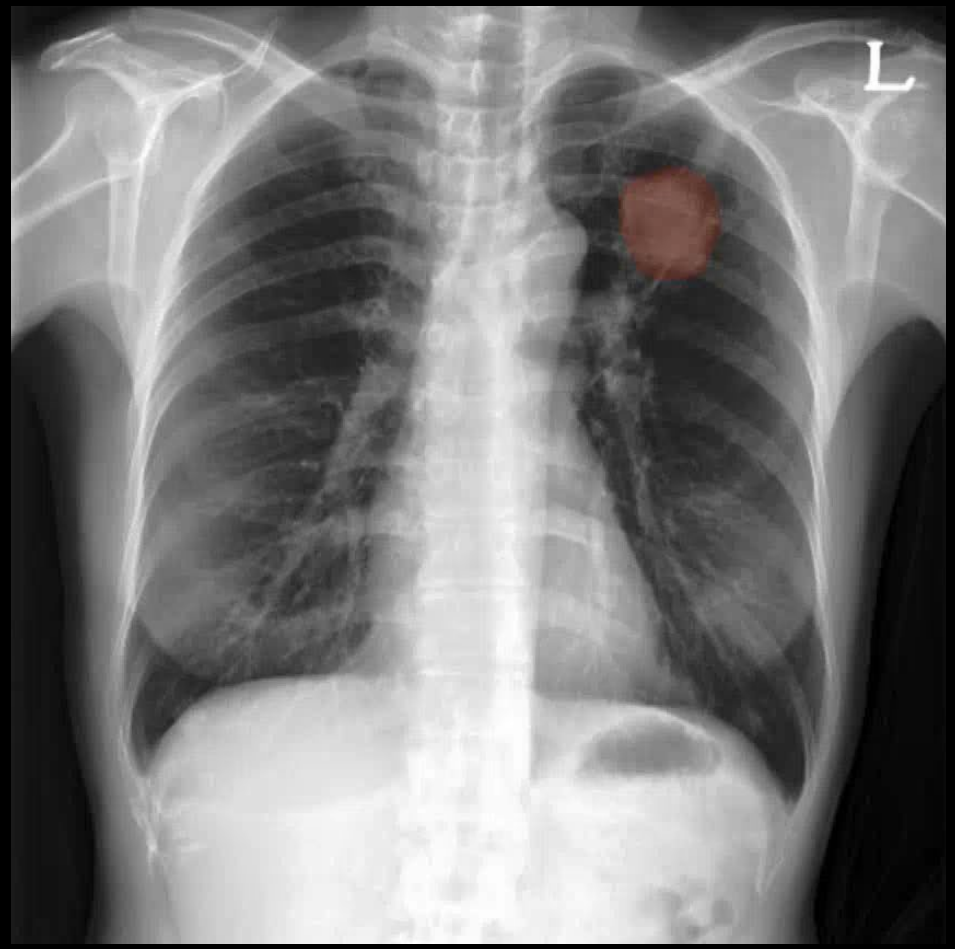
Cloud Service

- Easy access
- Pay per diagnosis (First and only in Korea)
- High repeat purchase rate
- Actively using in real world

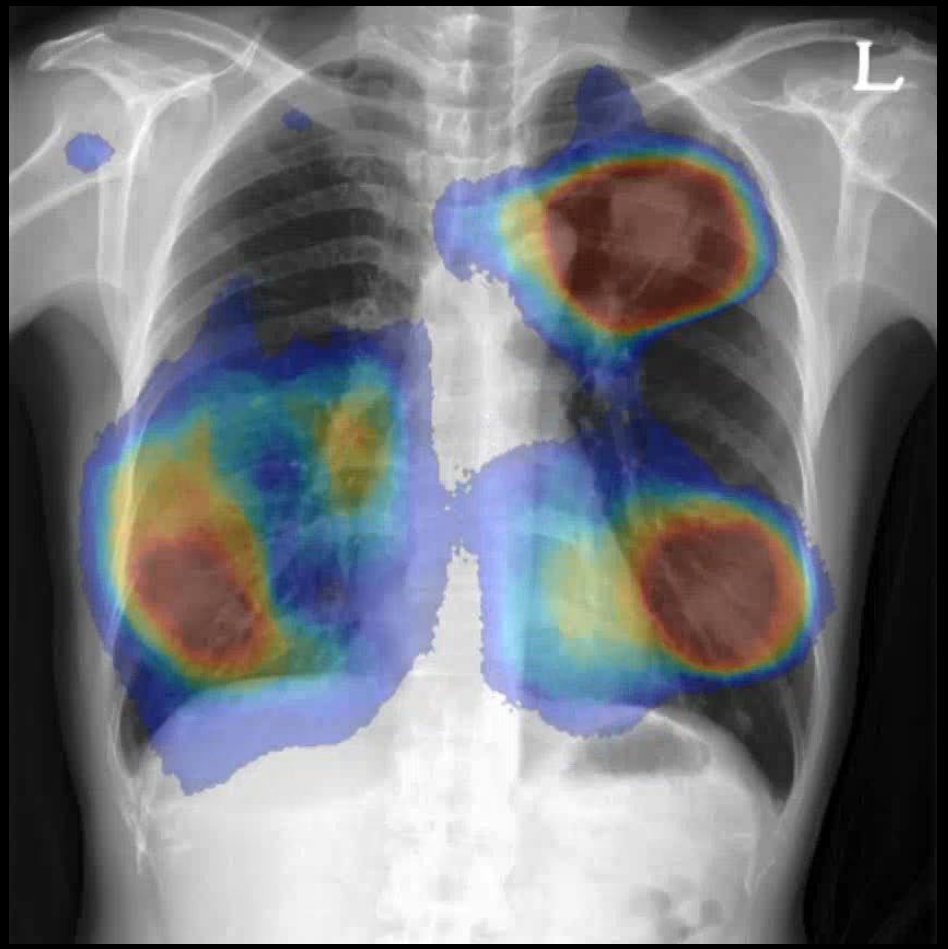
Integrated Engine

- Integrated with PACS
- SaaS based model for PACS companies
- Research-friendly

VUNO Med® – Chest X-ray



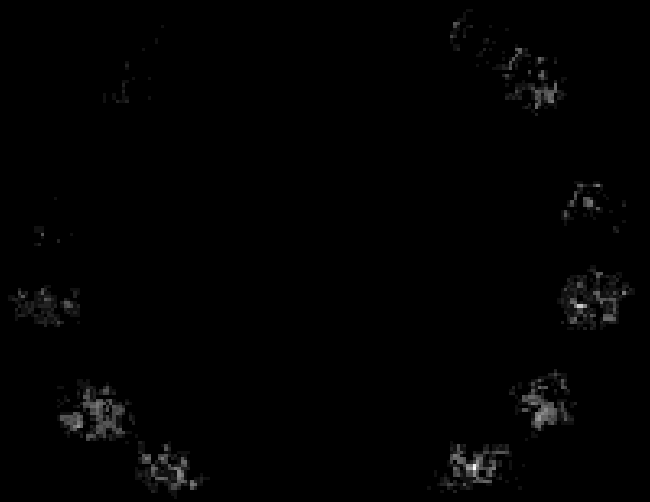
Reference Standard



Prediction

VUNO Med® – DeepBrain

Reference Standard



Prediction

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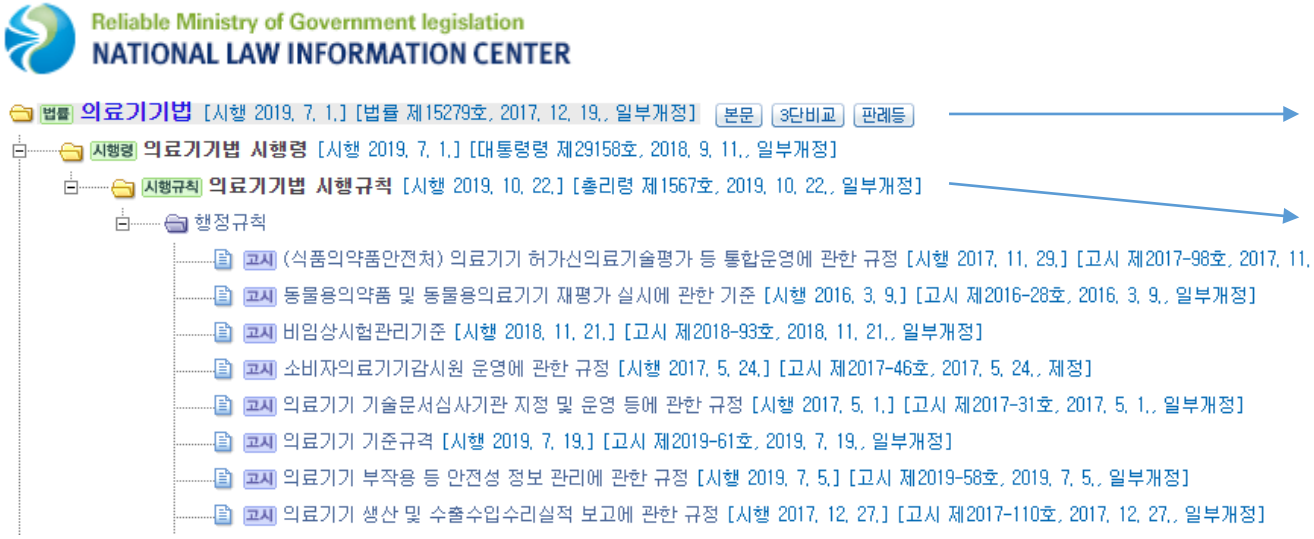
Regulatory information: Regulations



Medical Device Act

MFDS Notifications:

- Regulation on Medical Device Approval · Report ·Review, Etc
- Korea Good Manufacturing Practices
- Standards and Specifications
- Korea Good Clinical Practices

When applied to VUNO Med Solutions

Attached table from MFDS Notification

Product category		1	2	3	4-A	4-B	4-C	4-D	4-E	4-F	4-G	5	6	7
		Comparison Table on Equivalent Product	**Purpose**	**Mechanism of Action**	**Electricity**	**Radiation**	**Electro magnetic Wave**	**Biological**	**Performance**	**Physical /Chemical**	**Safety**	**Clinical**	**Discover of Development**	**Use in Foreign Countries**
1. Novel	**A. Different purpose of use**	O	O	**X**	**O**	△	**O**	**X**	O	X	X	**O**	O	**O**
	B. Different mechanism of action		X	O	O	△	O	X	O	X	X	**O**	O	O
	C. Different raw materials		X	X	X							X	X	X
2. Enhanced	D. Different performance	O	X	X	X	X	X	X	O	X	X	△	X	X
	E. Different test specification		X	X	O	△	O	X	X	X	X	X	X	X
	F. Different method of use		X	X	X							△	O	O
3. Equivalent			X	X	X							X	X	X

Regulatory information: Practical Guidelines

Ministry of Food and Drug Safety

제목 | 의료기기

전체 140건, 현재페이지 1/14

이식형심장충격기용전극 기술문서 작성을 위한 가이드라인(민원인 안내서)
고시번호 | 안내서-0570-03 조회수 | 305

이식형심장박동기전극 기술문서 작성을 위한 가이드라인(민원인 안내서)
고시번호 | 안내서-0969-01 조회수 | 239

펼치기

140 의료기기 소프트웨어 허가심사 가이드라인(민원인 안내서) [개정]
고시번호 | 안내서-2019-0612-03 조회수 | 1323
의료기기 소프트웨어 허가심사 가이드라인(민원인 안내서) 개정본.pdf

139 체외진단용 의료기기에 관한 민원 해설서(민원인 안내서)[개정]
고시번호 | 안내서-0652-03 조회수 | 780
체외진단용 의료기기에 관한 민원 해설서_개정.pdf

138 체외진단용 의료기기 변경허가 관련 민원인 안내서[개정]
고시번호 | 안내서-0937-02 조회수 | 392
체외진단용 의료기기 변경 허가 관련 민원인 안내서(개정).pdf

137 차세대염기서열분석(NGS) 체외진단용 의료기기의 성능평가 가이드라인(민원인안내서)[개정]
고시번호 | 안내서-0658-02 조회수 | 209
차세대염기서열분석(NGS) 체외진단용 의료기기의 성능평가 가이드라인(민원인안내서)_ 개정.pdf

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

Guideline on Clinical Evaluation of AI-based Device

식품의약품안전처 식품의약품안전평가원
의료기기심사부 첨단의료기기과

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

Approval Guideline for Big Data or AI-based Device

식품의약품안전처 식품의약품안전평가원
의료기기심사부 첨단의료기기과

Regulatory information: International standards (translated in KOR)

NIDS 한국의료기기안전정보원
National Institute of Medical Device Safety Information

소프트웨어 검색

품목코드, 품목명, 분류, 규격으로 검색 하실 수 있습니다.

번호	품목	분류	규격
10	A90060.01 유헬스케어 전자청진기	IEC	헬스소프트웨어 제품 안전성 일반 요구사항 제정
9	A90050.01 유헬스케어 산소포화도 측정기	IEC	헬스소프트웨어 제품 안전성 일반 요구사항 제정
		ISO	보건의료정보-개인건강기기 통신-산소포화도 측정기 제정
8	A90040.01 유헬스케어 혈당측정기	IEC	헬스소프트웨어 제품 안전성 일반 요구사항 제정
		ISO	보건의료정보-개인 건강 기기 통신-혈당측정기 제정
		중국(GB)	체외진단용측정시스템 자가측정용혈당검측시스템 공통기... 제정
		중국가이던스(CFDA)	혈당측정기에 대한 중국 가이던스 제정
7	A90030.01 유헬스케어 혈압계	IEC	헬스소프트웨어 제품 안전성 일반 요구사항 제정
		ISO	보건의료정보-개인 건강 기기 통신-혈압계 제정
6	A90020.01 유헬스케어 진단지원시스템	IEC	헬스소프트웨어 제품 안전성 일반 요구사항 제정
5	A90010.02 2등급 유헬스케어 게이트웨이	IEC	헬스소프트웨어 제품 안전성 일반 요구사항 제정
4	A90010.01 1등급 유헬스케어 게이트웨이	IEC	헬스소프트웨어 제품 안전성 일반 요구사항 제정
3	A26430.03 의료영상전송장치소프트웨어	중국가이던스(CFDA)	의료영상전송장치소프트웨어 등록기술심사 지도원칙 제정
2	A26430.07 휴대형 의료영상 전송장치 소프트웨어	미국(FDA가이던스)	모바일 의료용 애플리케이션 제정
1	A 기구·기계	ISO	호흡 가스 모니터의 기본안전 및 필수성능에 관한 ... 제정
		ISO	인체공학 Part 303 : 전자 영상 장비 전문... 제정
		ISO	인체공학 Part 411 : 신체적 입력기기의 설... 제정
		중국(YY)	의료기기소프트웨어 소프트웨어 생존주기 과정 가이드... 제정

Software as a Medical Device (SAMD): Clinical Evaluation

Guidance for Industry and

Software as a Medical Device (SAMD): Clinical Evaluation – Guidance for Industry and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. The words require or requirements used in this document do not reflect

NIDS 의료기기로서 소프트웨어(SaMD): 임상 평가

의료기기로서 소프트웨어(SaMD): 임상 평가
산업 및 식품의약국 담당자를 위한 지침

문서 발행일: 2017년 12월 8일

본 문서의 초안 발행일: 2016년 10월 14일

본 문서에 대한 질문은 센터 사무소장(Office of the Center Director, 전화: 301-796-6900) 또는 디지털 보건 프로그램(Digital Health Program, 이메일: digitalhealth@fda.hhs.gov)으로 문의한다.

FDA U.S. FOOD & DRUG ADMINISTRATION

미국 보건복지부
식품의약국(FDA) 의료기기 및 방사선 건강 센터
(Center for Devices and Radiological Health)

NIDS 의료기기로서 소프트웨어(SaMD): 임상 평가

의료기기로서 소프트웨어(SaMD): 임상 평가 – 산업 및 식품의약국 담당자를 위한 산업 및 식품의약국 담당자를 위한 지침

본 지침은 이 주제에 대한 식품의약국(FDA 또는 당국)의 현재 입장을 제시한 것으로, 이는 어느 누구에게도 권리를 생성하지 않으며 FDA나 공공에 대한 구속력을 갖지 않는다. 본 문서에 사용된 요구되다 또는 요건이라는 단어는 FDA 규제 요건을 의미하지 않으며, 업계 및 FDA 담당자를 위한 고려사항을 나타낼 뿐이다. 대체 방법이 해당 법령 및 규정 요건에 부합하는 경우 대체 방법을 사용할 수 있다. 대체 방법에 대해 논의하려면 제목 페이지에 명시된 본 지침을 담당하는 FDA 담당자 또는 사무국에 연락한다.

FDA 서문

IMDRF는 세계 각국의 의료기기 규제 담당자들이 국제 의료기기 규제의 조화와 통합을 촉진하기 위해 모인 자발적인 그룹이다. IMDRF 관리 위원회(IMDRF Management Committee: IMDRF MC)는 SaMD의 규제 틀을 개발하고 전세계 규제 담당자들이 해당 관할권에 적용할 수 있는 통합 원칙을 개발하기 위해 SaMD 작업 그룹(WG)을 인가하였다.
본 IMDRF 문서는 IMDRF MC에 의해 만장일치로 승인되었다. IMDRF 활동에 대한 자세한 내용은 http://www.imdrf.org/index.asp를 참조한다.

본 지침은 IMDRF에 의해 합의된 국제 통합 원칙을 채택한다. FDA의 이러한 원칙 채택은 규제 관리에 대한 FDA의 특정 규제 접근법 및 예상안의 추가 개발 시 FDA에 초기 틀을 제공한다. 본 지침은 특정 규제 상황에 적용할 수 있는 권장사항을 FDA 담당자와 업계에 제공하거나 현행 규제 제출 관련 사항을 포함한 현 규제 예상안을 수정하지 않는다. 본 문서에 사용된 요구되다 또는 요건이라는 단어는 FDA 규제 요건을 의미하지 않으며, 업계 및 FDA 담당자를 위한 고려사항을 나타낼 뿐이다. FDA는 본 지침의 원칙을 SaMD 및 디지털 건강 기술에 대한 규제 접근법 개발 시 고려하고자 한다. 본 지침의 원칙을 바탕으로 규제 접근법을 개발 시, 기관은 공공 의견 제출의 기회를 제공하는 등의 공론 절차를 따르고자 한다. FDA 지침 문서로서 IMDRF 문서의 FDA 채택에 대한 자세한 정보는 https://www.fda.gov/MedicalDevices/InternationalPrograms/IMDRF/default.htm을 참조한다.

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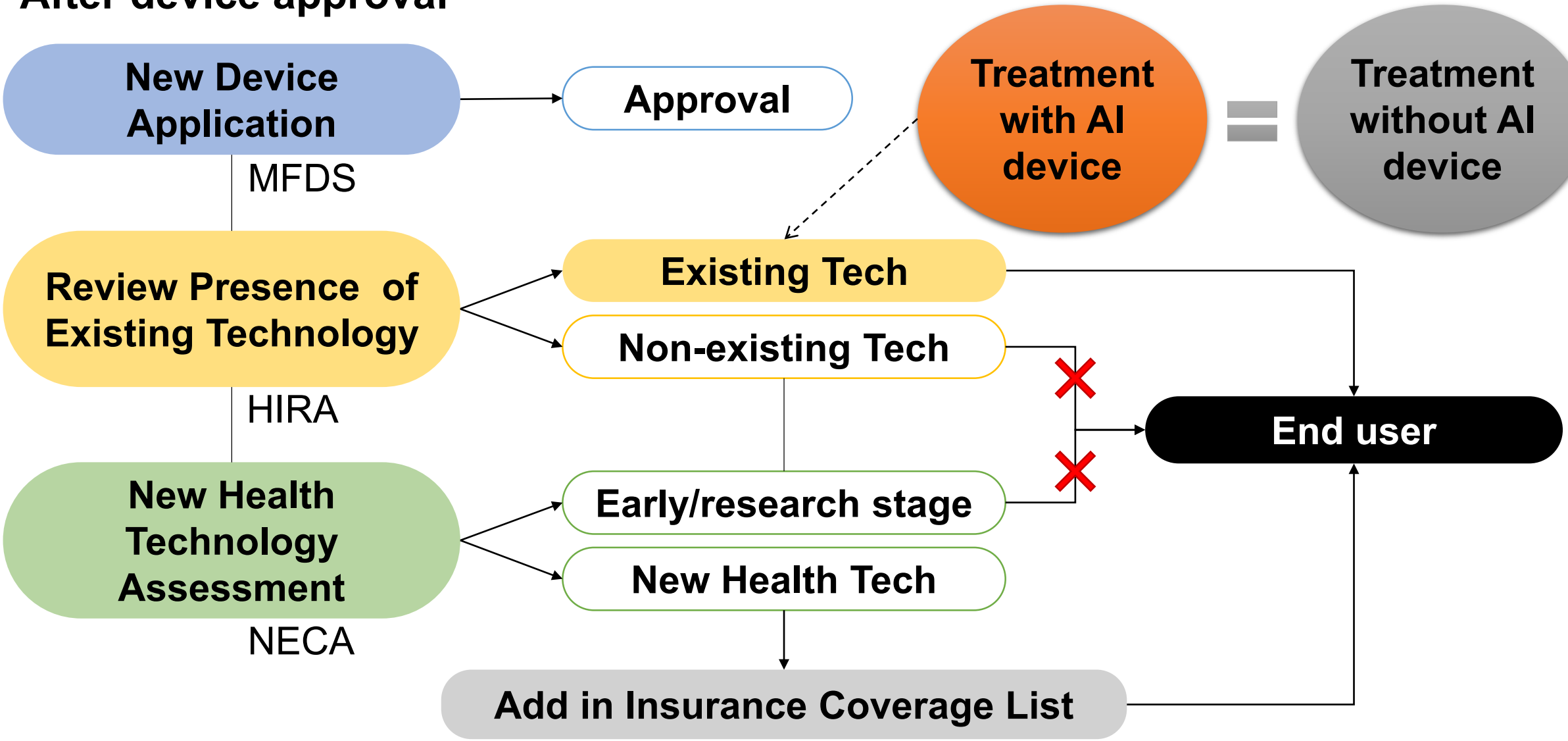
After device approval



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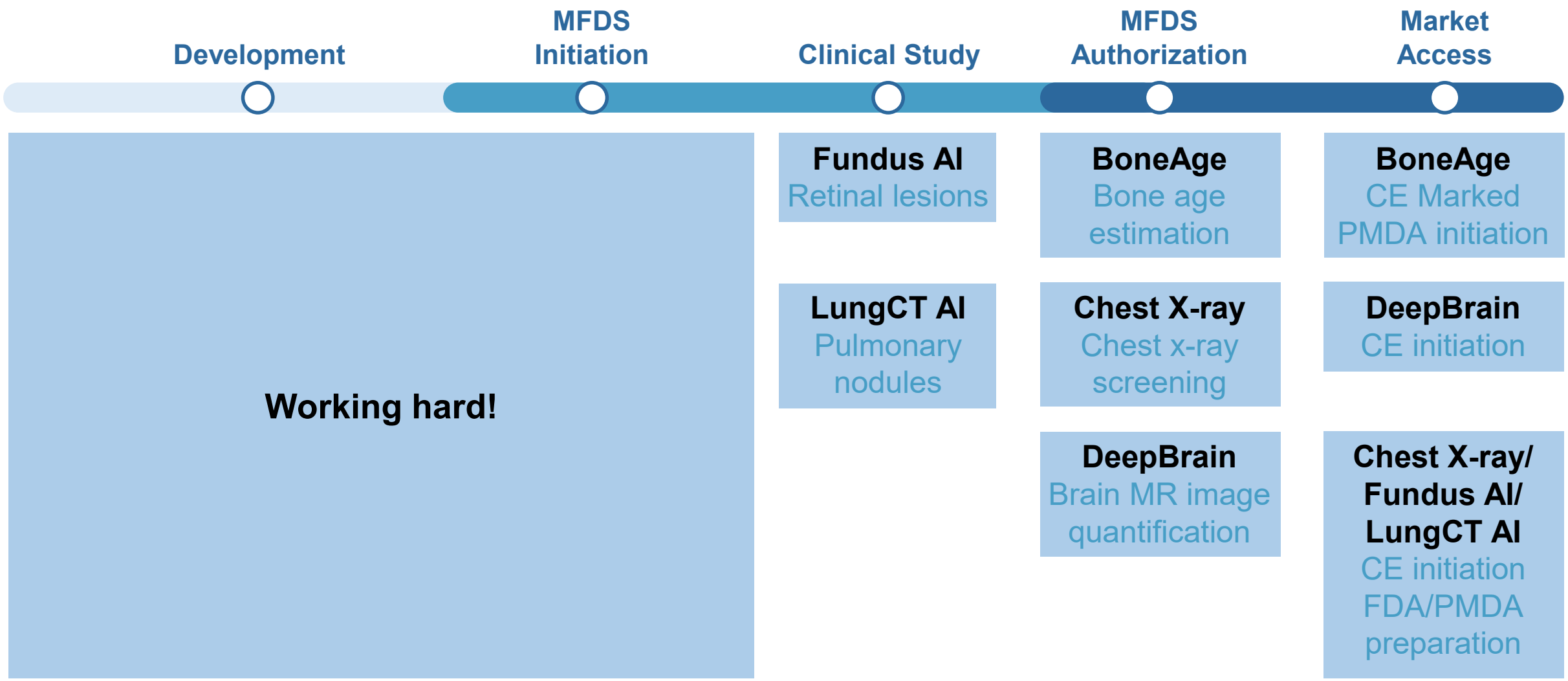

AI Software in Korea: A lot more in near future

No	Product code	Class	Indication	Status	Date
1	**Medical Image Analysis SW**	**2**	**Bone age estimation**	**Approved**	**2018-05-16**
2	Computer-aided diagnosis SW	3	Brain infarction	Approved	2018-08-14
3	Computer-aided detection SW	2	Pulmonary nodule	Approved	2018-08-14
4	**Medical Image Analysis SW**	**2**	**Brain MR image quantification**	**Certified**	**2019-06-24**
5	Computer-aided diagnosis SW	3	Breast cancer	Approved	2019-07-29
6	**Computer-aided detection SW**	**2**	**Chest radiography screening**	**Approved**	**2019-08-20**
7	Computer-aided detection SW	2	Lumbar compression fracture	Approved	2019-08-20
8	Medical Image Analysis SW	2	Chest CT image quantification	Certified	2019-10-02
9			Colonoscopy image quantification	Certified	2019-10-04
10			Gastroscopy image quantification	Certified	2019-10-04
11	Computer-aided detection SW	2	Chest radiography screening	Approved	2019-10-21
12	Medical Image Analysis SW	2	Bone age estimation	Clinical study ongoing	
13	Computer-aided detection SW	2	Pulmonary nodule		
14			Major pulmonary diseases		
15			Fundus photograph screening		
16	Computer-aided diagnosis SW	3	Prostate cancer		
17			Fundus photograph diagnosis		
18			Cerebral aneurysm		
19			Cerebral hemorrhage		
20			Glaucoma		

Special Thanks to 식품의약품안전처 NIDS 한국의료기기안전정보원 National Institute of Medical Device Safety Information AHWP ASIAN HARMONIZATION WORKING PARTY

Thank you for your attention ☺

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