

심혈관질환에서 인공지능 소프트웨어

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College of Medicine
Dong-Ju Choi, MD. PhD



[illegible]

Introduction



US FDA Medical Device



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Medical Devices



Coronavirus (COVID-19) and Medical Devices

Learn more about devices such as diagnostic tests, ventilators, and personal protective equipment (PPE)—including surgical masks, face shields, respirators, gowns, and gloves.

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US FDA Digital Health



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About the Digital Health Center of Excellence

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What is Digital Health?



Our goal: Empower stakeholders to advance health care by fostering responsible and high-quality digital health innovation.

US FDA (SaMD) Software as a Medical Device

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Software as a Medical Device (SaMD)

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Software as a Medical Device (SaMD)

Artificial Intelligence and Machine Learning in Software as a Medical Device

What are examples of Software as a Medical Device?

Global Approach to Software as a Medical Device

As technology continues to advance all facets of health care, software has become an important part of all products, integrated widely into digital platforms that serve both medical and non-medical purposes. Software, which on its own is a medical device – Software as a Medical Device – is one of three types of software related to medical devices. The other two types of software related to medical devices include software that is integral to a medical device (Software in a medical device) and software used in the manufacture or maintenance of a medical device.


What is Software as a Medical Device?

The term [Software as a Medical Device](#) is defined by the [International Medical Device Regulators Forum \(IMDRF\)](#) as “software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.”

Use of Software as a Medical Device is continuing to increase. It can be used across a broad range of technology platforms, including medical device platforms, commercial “off-the-shelf” platforms, and virtual networks, to name a few. Such software was previously referred to by industry, international regulators, and health care providers as “standalone software,” “medical device software,” and/or “health software,” and can sometimes be confused with other types of software.

How are Regulators Addressing the Challenges with Software as a Medical Device?

US FDA (AI/ML SaMD) AI/ML Software as a Medical Device

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Software as a Medical Device (SaMD)

Artificial Intelligence and Machine Learning in Software as a Medical Device

What are examples of Software as a Medical Device?


Global Approach to Software as a Medical Device

Artificial Intelligence and Machine Learning (AI/ML) Software as a Medical Device Action Plan

The U.S. Food and Drug Administration (FDA) issued the “Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan” from the Center for Devices and Radiological Health’s Digital Health Center of Excellence.

The Action Plan is a direct response to stakeholder feedback to the April 2019 discussion paper, “Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning-Based Software as a Medical Device” and outlines five actions the FDA intends to take.

[Download Action Plan \(PDF - 747 KB\)](#)



Content current as of: 01/12/2021

Regulated Product(s) Medical Devices





Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan

January 2021



AI/ML SOFTWARE AS A MEDICAL DEVICE ACTION PLAN

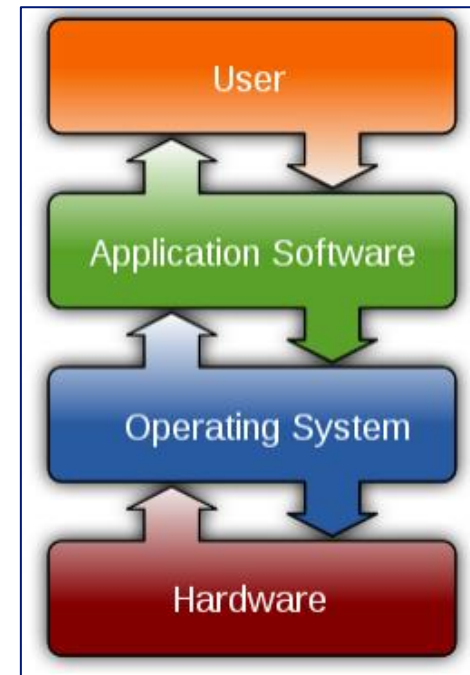
1. Tailored Regulatory Framework for AI/ML-based SaMD
2. Good Machine Learning Practice (GMLP)
3. Patient-Centered Approach Incorporating Transparency to Users
4. Regulatory Science Methods Related to Algorithm Bias & Robustness
5. Real-World Performance (RWP)

What we heard: Stakeholders described the need for clarity on Real-World Performance (RWP) monitoring for AI/ML software.

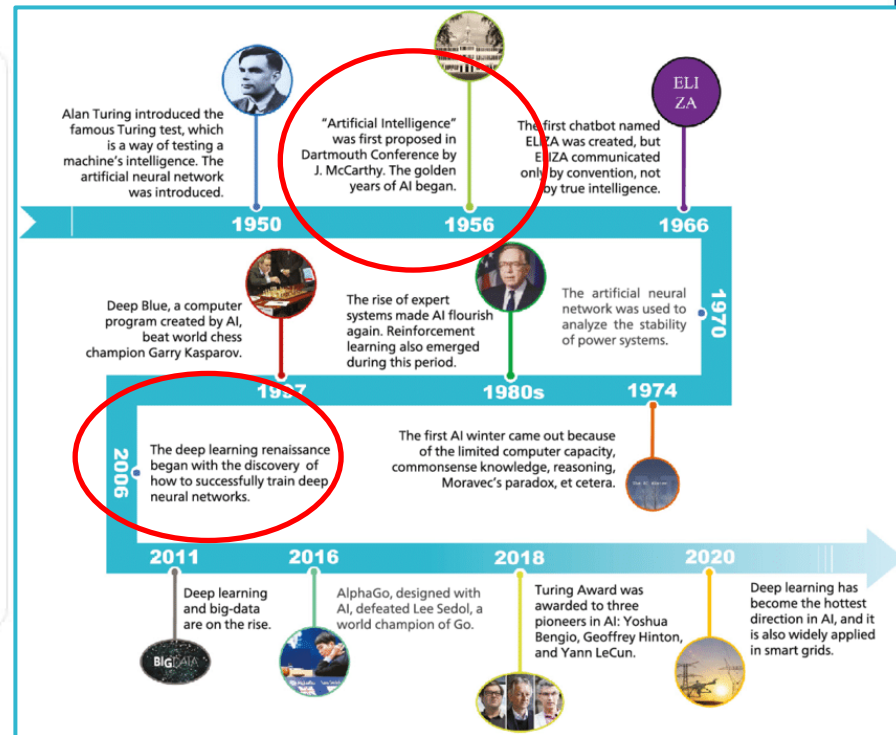
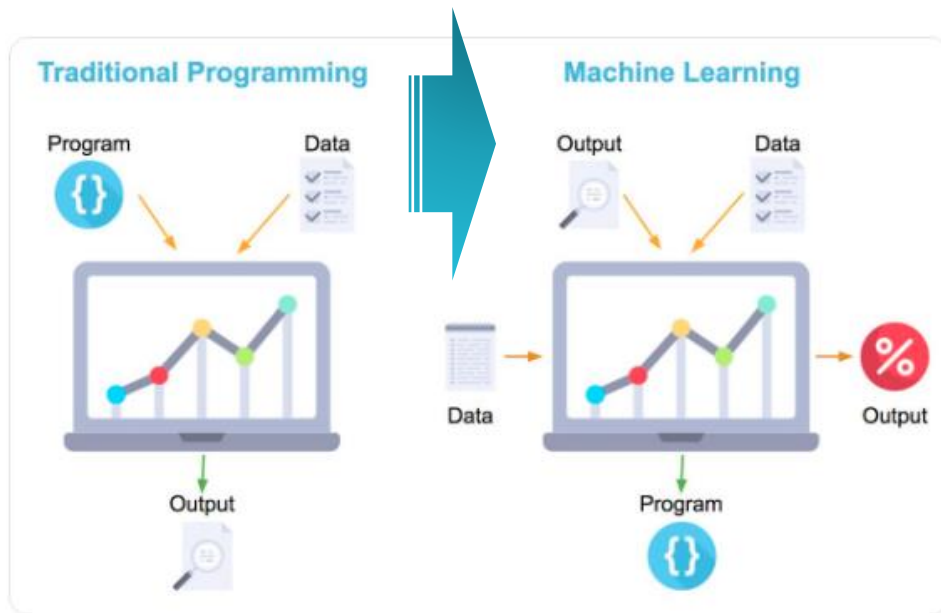
What we'll do: Work with stakeholders who are piloting the RWP process for AI/ML-based SaMD



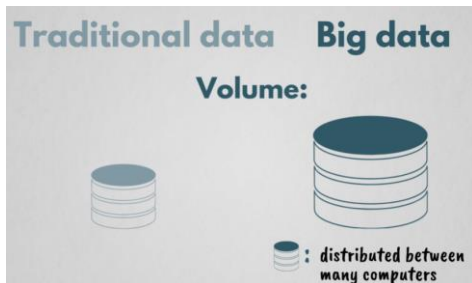
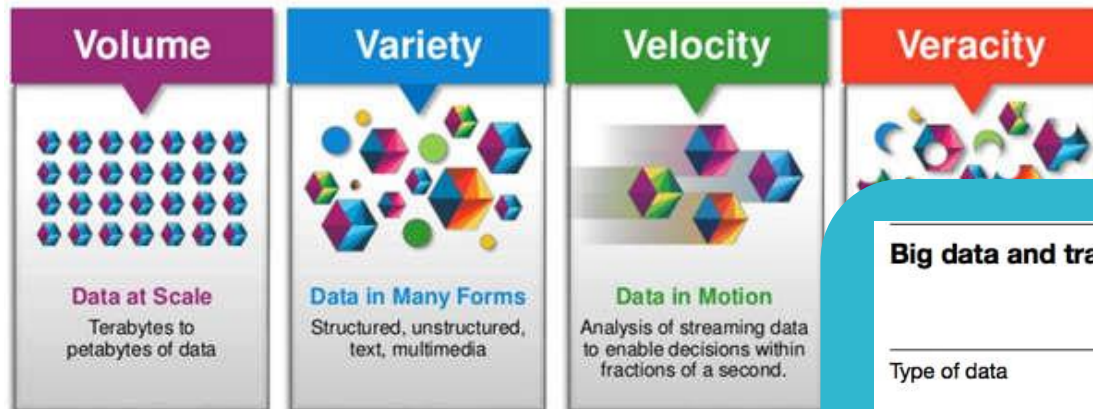
Software is a collection of instructions and **data** that tell computer how to work, including computer programs, libraries, and related non-executable **data**, such as online documentation or digital media.



Software(traditional) vs. AI Software



Traditional Data vs. Big Data

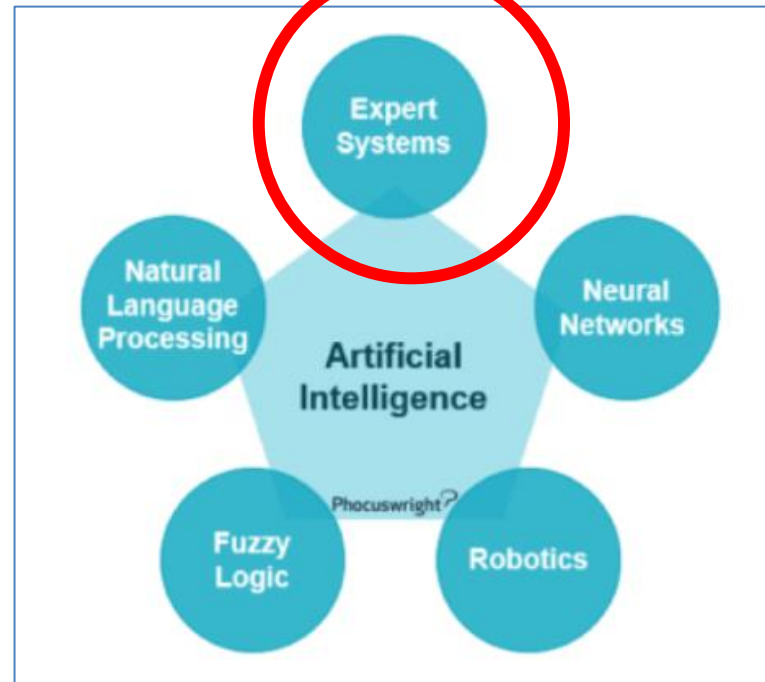
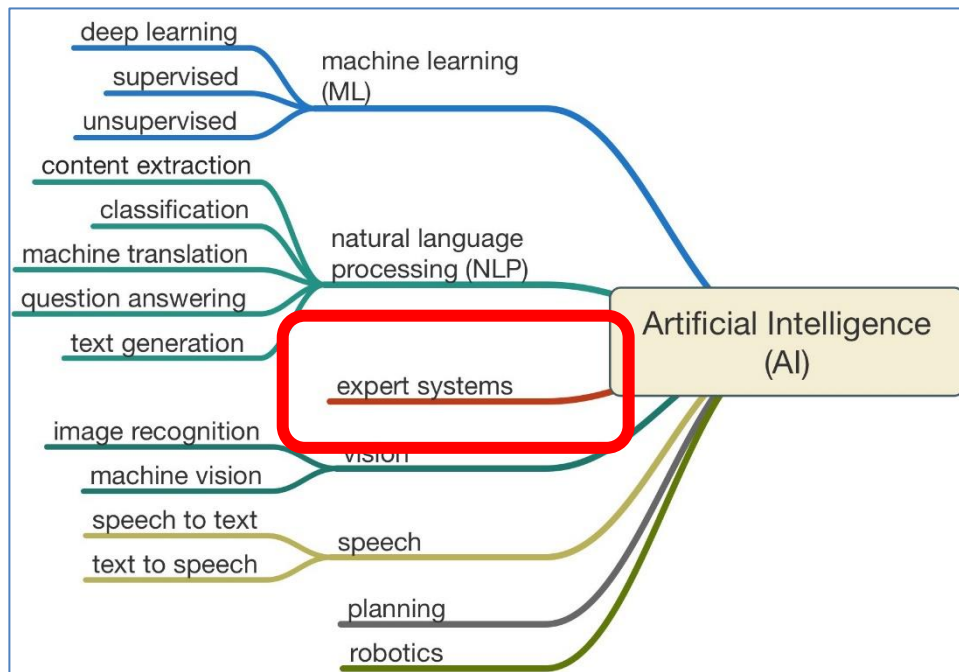


Big data and traditional analytics

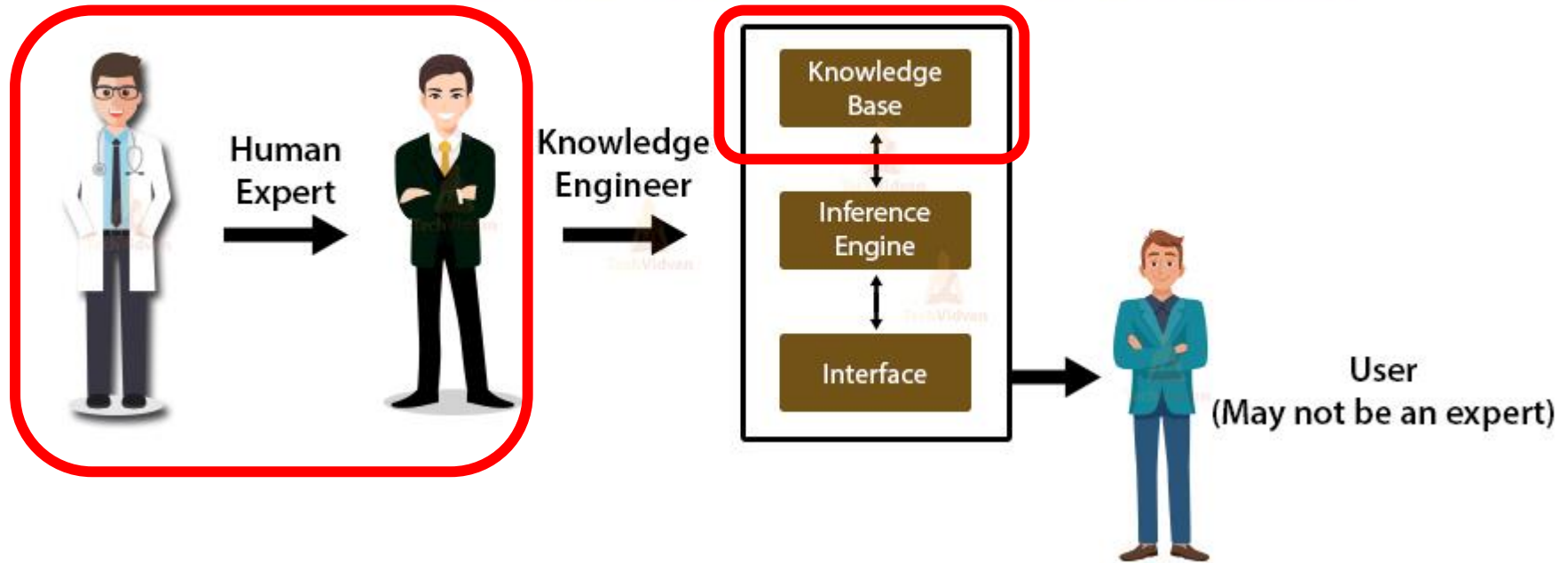
	Big data	Traditional analytics
Type of data	Unstructured formats	Formatted in rows and columns
Volume of data	100 terabytes to petabytes	Tens of terabytes or less
Flow of data	Constant flow of data	Static pool of data
Analysis methods	Machine learning	Hypothesis-based
Primary purpose	Data-based products	Internal decision support and services



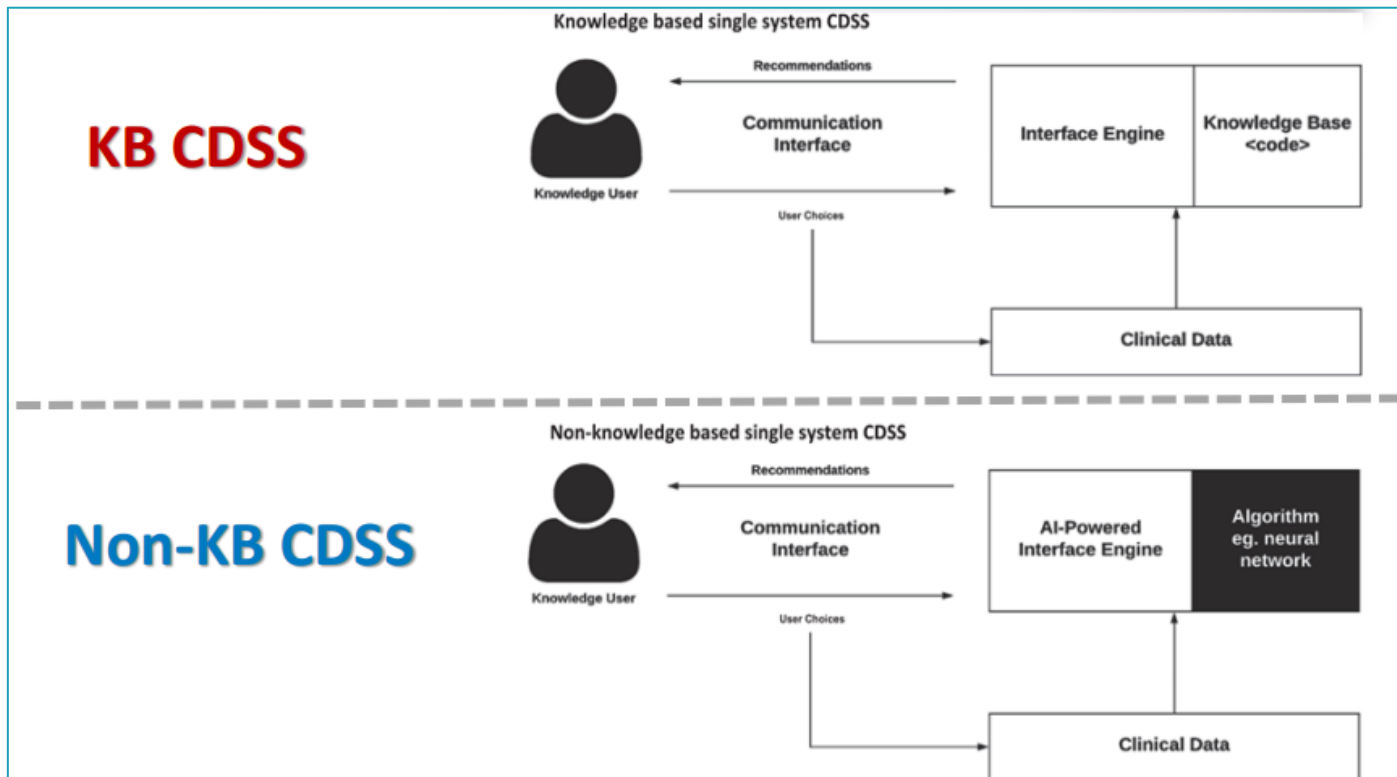
Artificial Intelligence.....?



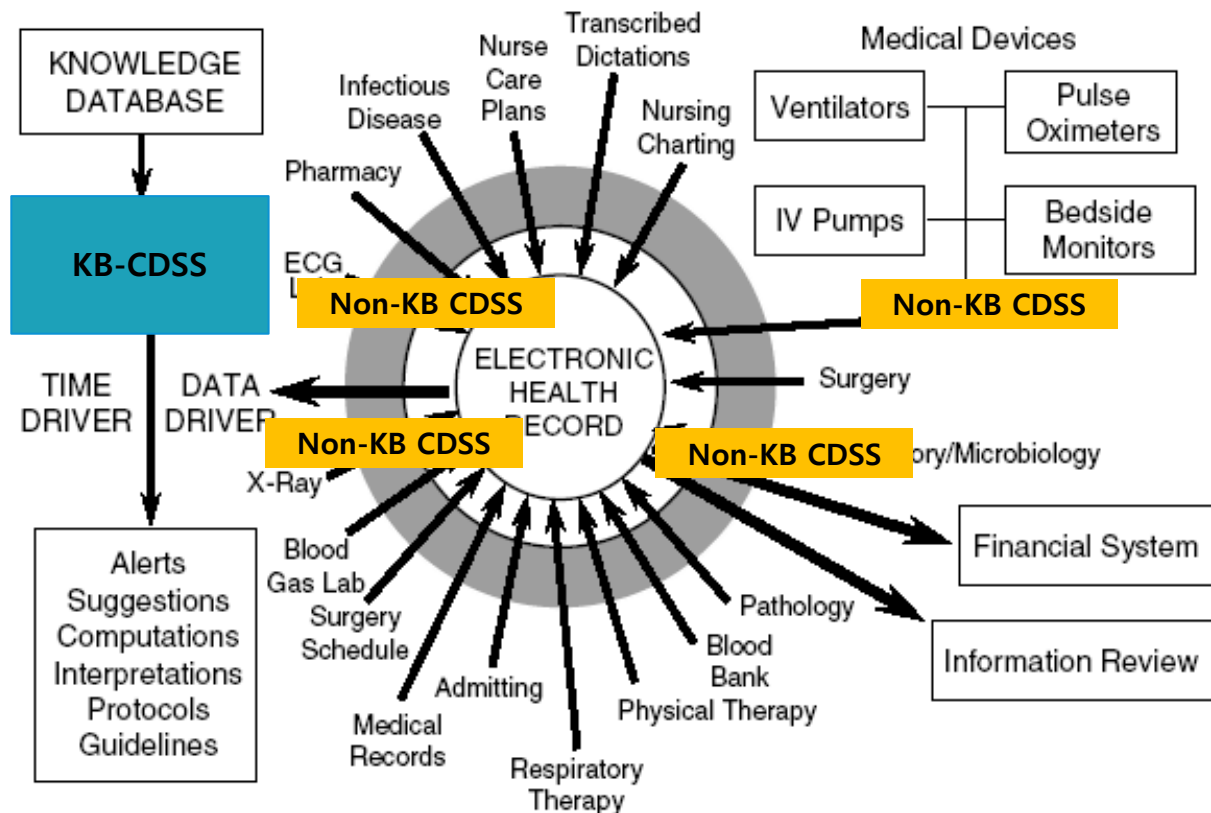
Components of Expert Systems in AI

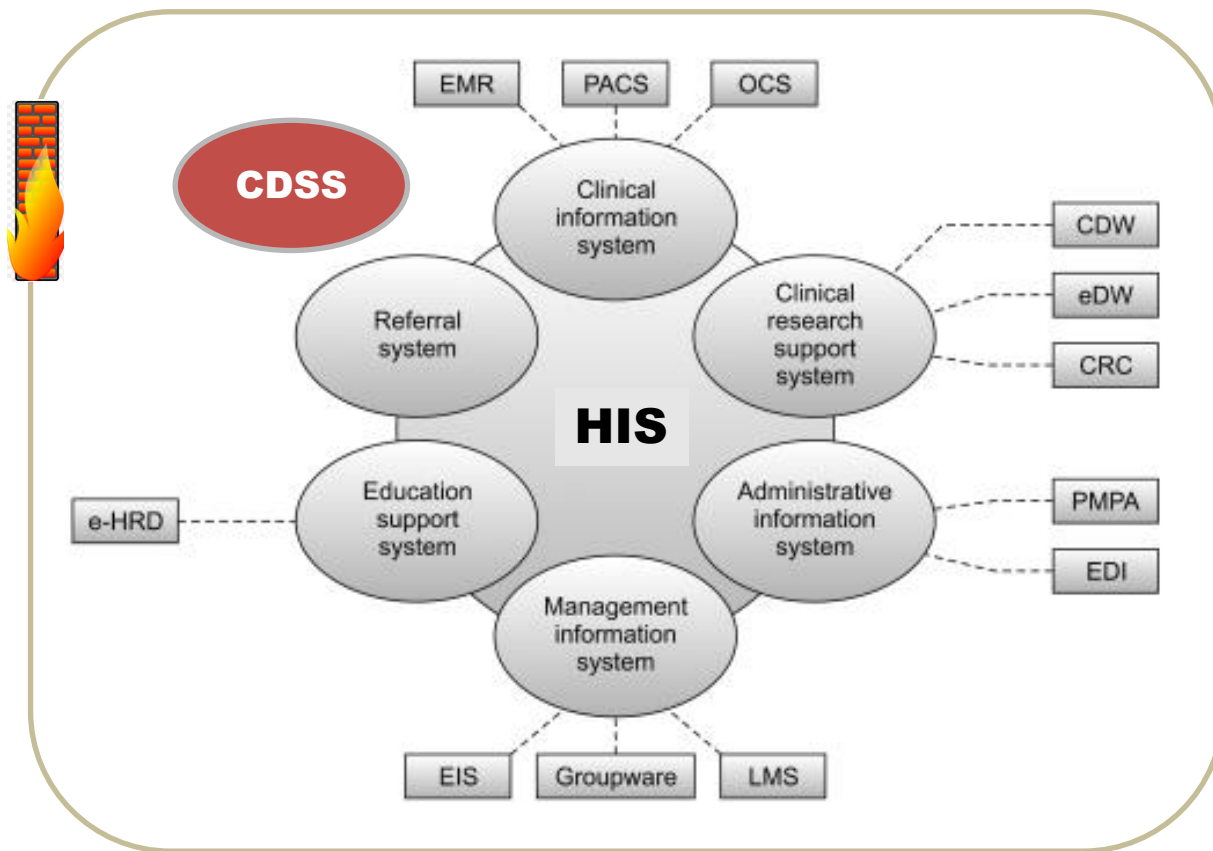


CDSS(Clinical Decision Supporting System)



CDSS(Clinical Decision Supporting System)





#속보 #메타버스 가보자고 #배터리 분할 #갤럭시 버즈2

영상

기업 "14개월 만에 숙원 풀었다"...데이터3법 본회의 통과

유진상 기자 차현아 기자

입력 2020.01.09 21:45

데이터 경제 활성화를 위해 정부가 추진하는 데이터3법(개인정보보호법, 신용정보법, 정보통신망법 등 일명 개·망·신법)이 본회의를 통과했다. 업계가 강력하게 통과를 요청해 왔던 숙원이 해결됐다. 법안이 발의된지 1년 2개월만이다. 이에 따라 4차 산업혁명 관련 산업이 대거 수혜를 볼 수 있을 전망이다.

#이-

김정
자원
오토
비결
윤종
양재
"누구
최종

데이터 3법 '가명정보' 결합전문기관 늘린다

발행일 : 2021.07.28 18:00

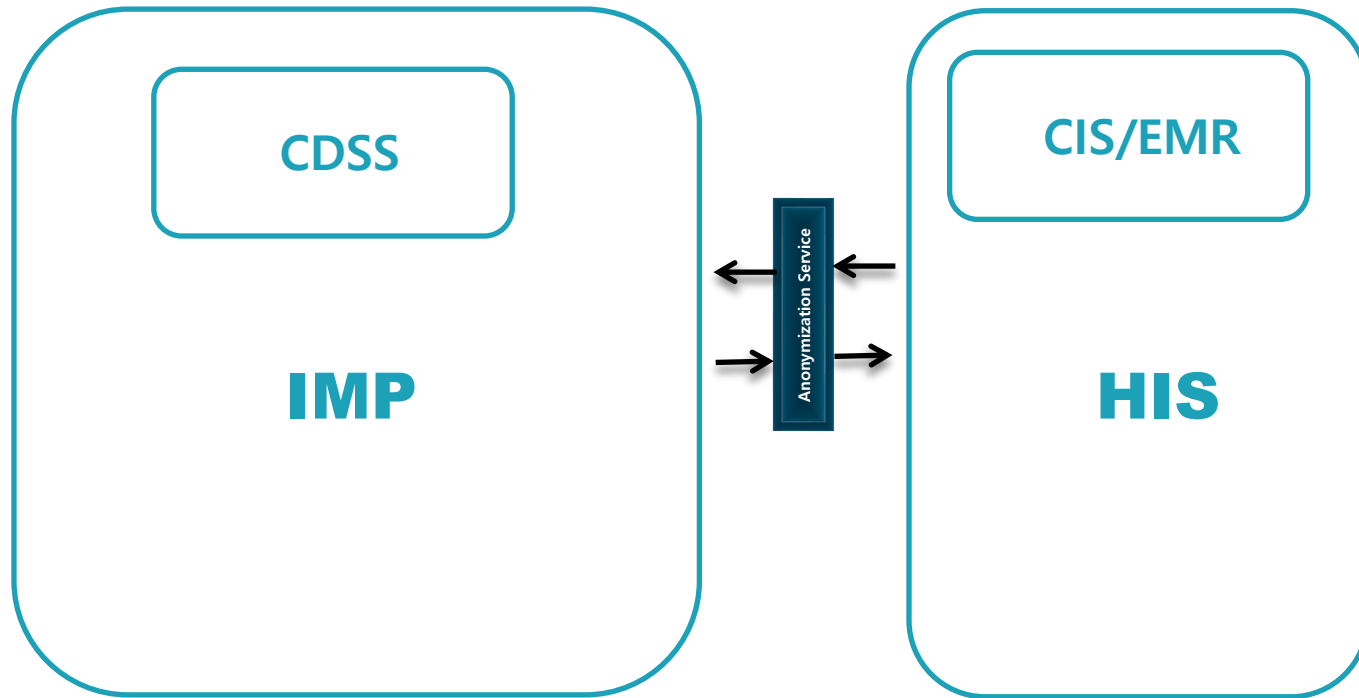


▶ 빗더미에 벼랑 끝 내몰린 중년층.. 이것으로 걱정 해결!

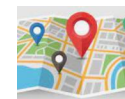
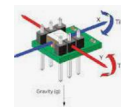
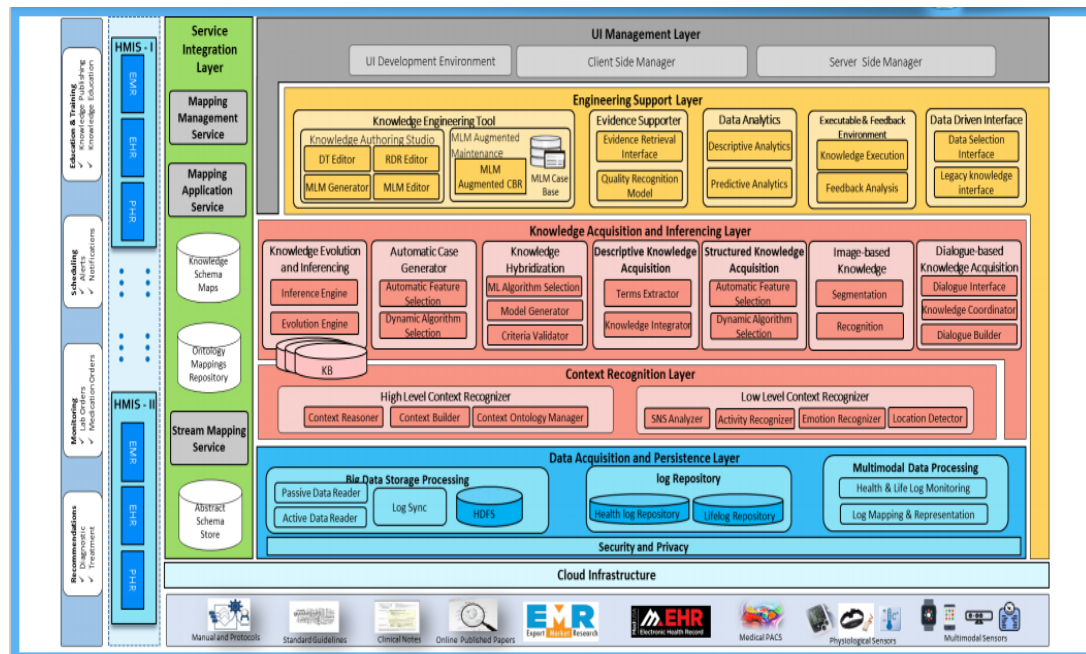
김부겸 총리, 지원센터 개소식 참석
올해 27곳으로 작년비 3배 확충
결합 기간은 기존보다 절반 단축
기관 역할도 결합 전 단계로 강화



IMP(Intelligent Medical Platform) vs. CDSS



IMP(Intelligent Medical Platform)



HIS



AI-CDSS in Hospital Setting

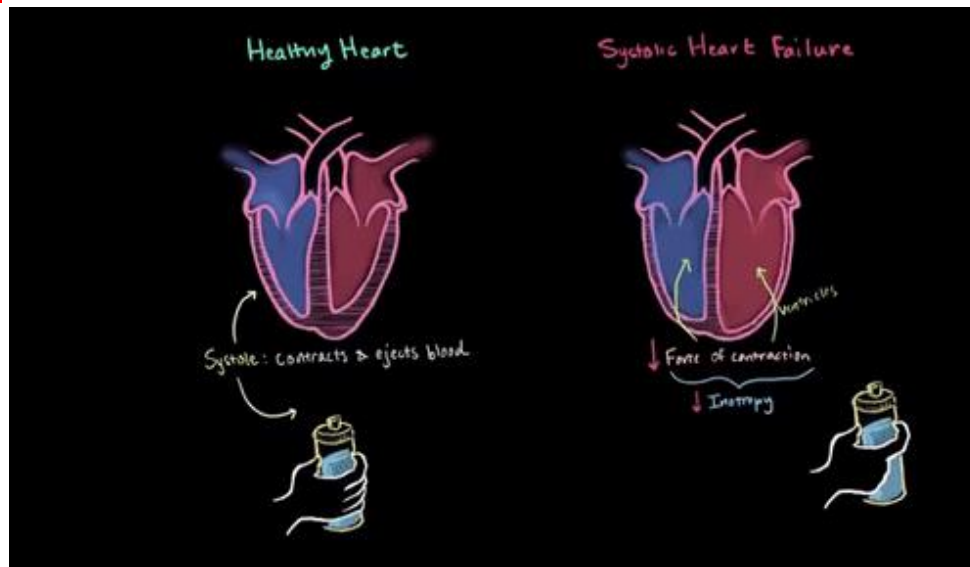


Heart Failure

심부전



Poor memory
Shortness of breath
Dry cough
Chest pain
Heart pounding or racing
Swollen abdomen
Loss of appetite
Cold hands
Swollen lower legs
Swollen ankles
Cold feet



ARTICLE OPEN



Artificial intelligence for the diagnosis of heart failure

Dong-Ju Choi^{1,3} , Jin Joo Park^{1,3} , Taqdir Ali² and Sungyoung Lee² 

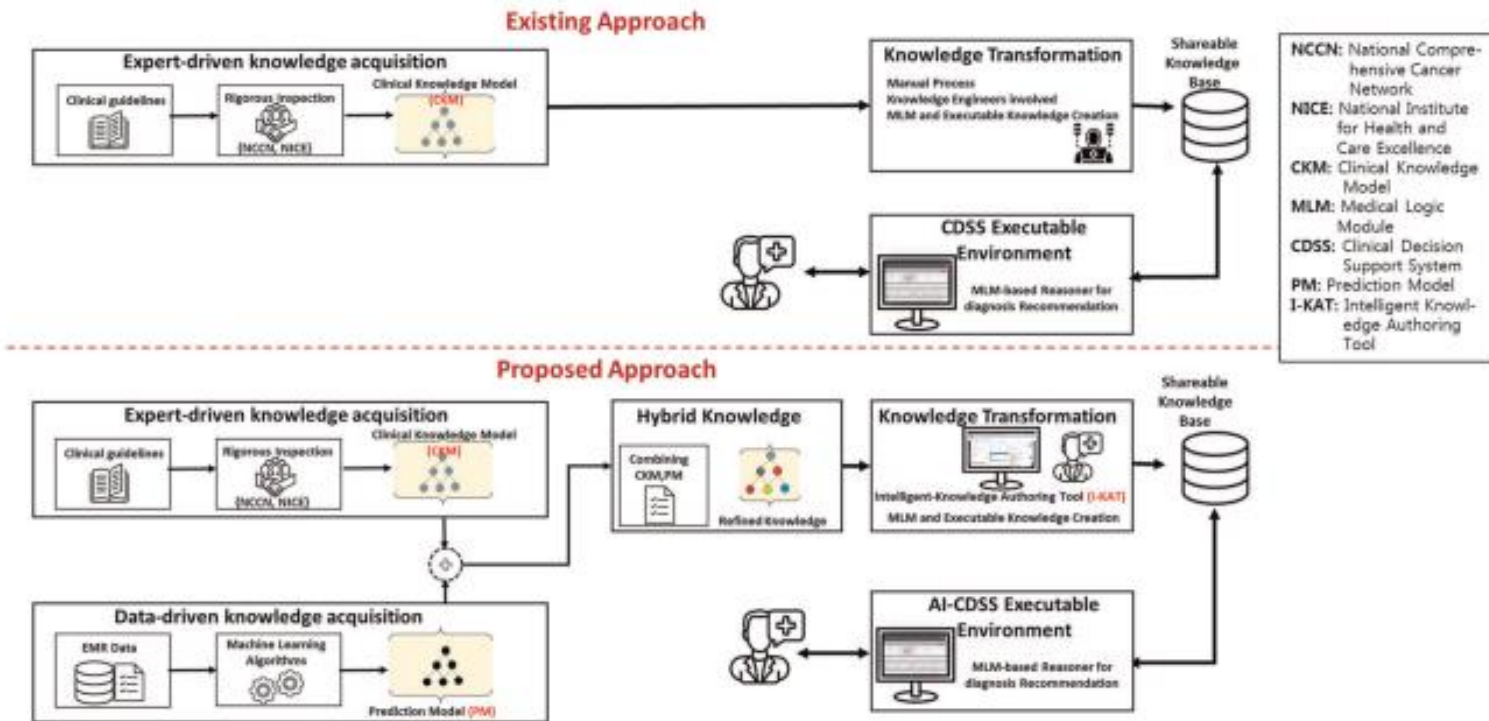
The diagnosis of heart failure can be difficult, even for heart failure specialists. Artificial Intelligence–Clinical Decision Support System (AI-CDSS) has the potential to assist physicians in heart failure diagnosis. The aim of this work was to evaluate the diagnostic accuracy of an AI-CDSS for heart failure. AI-CDSS for cardiology was developed with a hybrid (expert-driven and machine-learning-driven) approach of knowledge acquisition to evolve the knowledge base with heart failure diagnosis. A retrospective cohort of 1198 patients with and without heart failure was used for the development of AI-CDSS (training dataset, $n = 600$) and to test the performance (test dataset, $n = 598$). A prospective clinical pilot study of 97 patients with dyspnea was used to assess the diagnostic accuracy of AI-CDSS compared with that of non-heart failure specialists. The concordance rate between AI-CDSS and heart failure specialists was evaluated. In retrospective cohort, the concordance rate was 98.3% in the test dataset. The concordance rate for patients with heart failure with reduced ejection fraction, heart failure with mid-range ejection fraction, heart failure with preserved ejection fraction, and no heart failure was 100%, 100%, 99.6%, and 91.7%, respectively. In a prospective pilot study of 97 patients presenting with dyspnea to the outpatient clinic, 44% had heart failure. The concordance rate between AI-CDSS and heart failure specialists was 98%, whereas that between non-heart failure specialists and heart failure specialists was 76%. In conclusion, AI-CDSS showed a high diagnostic accuracy for heart failure. Therefore, AI-CDSS may be useful for the diagnosis of heart failure, especially when heart failure specialists are not available.

npj Digital Medicine (2020)3:54; <https://doi.org/10.1038/s41746-020-0261-3>



Heart Failure Silo in IMP

(Hybrid Knowledge-base Expert system CDSS)



Heart Failure Silo in IMP

Stage 1: Knowledge Acquisition



Cardiology Guideline

B Taking help from published guideline

A Physician experience and heuristics



Physician

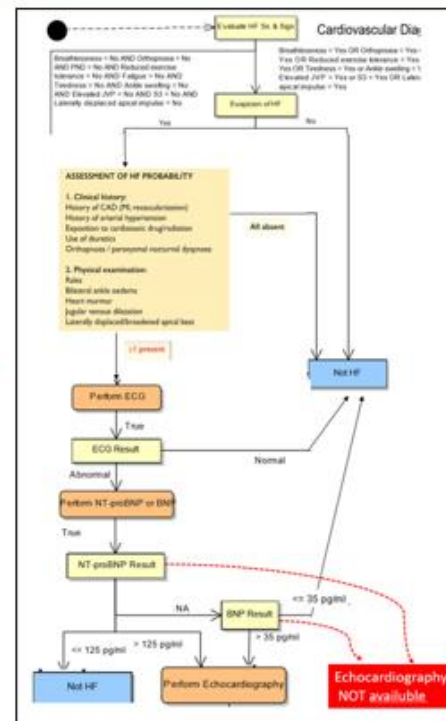
A + **B** + **C**



심장센터 eCRF

C Real practice with existing systems

Data

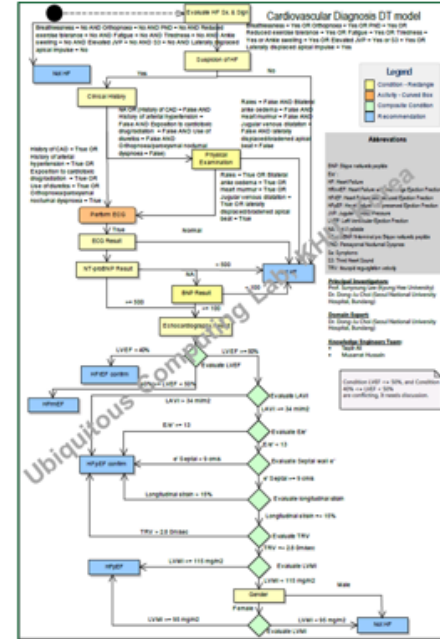


Heart Failure Silo in IMP

Stage 1: Knowledge Acquisition: 14 attributes

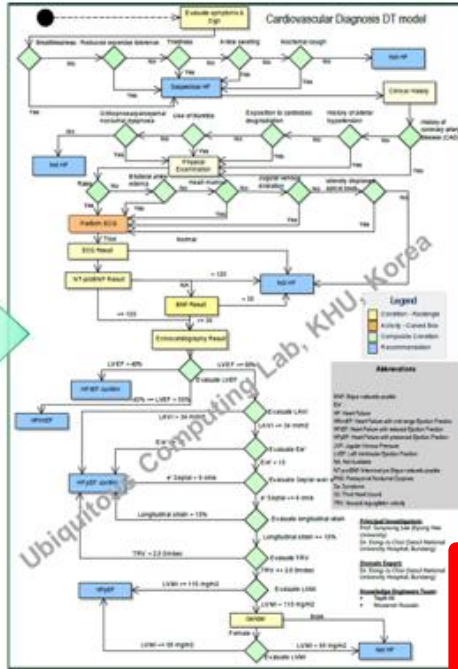
S. No.	Attribute Name	Attribute Description
1	Signs & Symptoms	Patient has some sign and symptom like, breathlessness, exercise tolerance, tiredness, ankle swelling, and nocturnal cough.
2	Clinical History	It checks the patient history such as coronary artery disease (CAD), arterial hypertension, exposition to cardio toxic drug/radiation, use of diuretics, orthopnea.
3	Physical Examination	In this category, physicians check rales, bilateral ankle edema, heart murmur, jugular venous dilatation, laterally displaced apical beat.
4	ECG Result	Noninvasive test to check how fast the heart beats, it may be normal or abnormal.
5	BNP Result	B-type natriuretic peptide (BNP) blood test measures the levels of the BNP hormone in patients' blood.
6	NT-proBNP Result	N-terminal pro-B-type natriuretic peptide level
7	Left Ventricular Ejection Fraction (LVEF)	It finds total amount of blood in the left ventricle is pumped out with each heartbeat.
8	Left Atrial Volume Index (LAVI)	Measure to evaluate the LA size
9	E/e'	Measure to evaluate the diastolic function
10	e' Septal	Measure to evaluate the diastolic function
11	Longitudinal strain	Measure to evaluate myocardial contractility
12	Tricuspid Regurgitation Velocity (TRV)	TRV has been shown to correlate with pulmonary artery systolic pressure (PASP) at rest (1–3) and with exercise (3–7).
13	Left Ventricular Mass Index (LVMI)	Measure to evaluate the LV size
14	Gender	The state of being male or female





Stage 3: Knowledge Rules Creation (Expert-Driven)

Decision Tree



Intelligent Knowledge Authoring Tool (I-KAT)



Total Rules: 1309
Total Patient Data : 300
Initial Accuracy : 90%

Production Rules

Rule #	RuleTitle	SymptomsAndSigns	ClinicalHistory	PhysicalExam	ECG	NTproBNP	BNP	LVEF
1	CardiovascularRule-1	0	-	-	-	-	-	-
2	CardiovascularRule-2	1	-	-	-	-	-	-
3	CardiovascularRule-3	1	0	-	-	-	-	-
4	CardiovascularRule-4	1	1	0	-	-	-	-
5	CardiovascularRule-5	1	1	1	0	-	-	-
6	CardiovascularRule-6	1	1	1	1	<125	-	-
7	CardiovascularRule-7	1	1	1	1	1	<35	-
8	CardiovascularRule-8	1	1	1	1	1	>=35	<40
9	CardiovascularRule-9	1	1	1	1	1	>=35	[]39 & 50
10	CardiovascularRule-10	1	1	1	1	1	>=35	>=50
11	CardiovascularRule-11	1	1	1	1	1	>=35	>=50
12	CardiovascularRule-12	1	1	1	1	1	>=35	>=50
13	CardiovascularRule-13	1	1	1	1	1	>=35	>=50
14	CardiovascularRule-14	1	1	1	1	1	>=35	>=50
15	CardiovascularRule-15	1	1	1	1	1	>=35	>=50
16	CardiovascularRule-16	1	1	1	1	1	>=35	>=50
17	CardiovascularRule-17	1	1	1	1	1	>=35	>=50
18	CardiovascularRule-18	1	1	1	1	1	>=35	>=50
19	CardiovascularRule-19	1	1	1	1	>=125	-	<40
20	CardiovascularRule-20	1	1	1	>=125	-	-	[]39 & 50
21	CardiovascularRule-21	1	1	1	1	>=125	-	>=50
22	CardiovascularRule-22	1	1	1	>=125	-	-	>=50
23	CardiovascularRule-23	1	1	1	1	>=125	-	>=50
24	CardiovascularRule-24	1	1	1	>=125	-	-	>=50

LAMI	Te	septal	lateral	basal	strain	TRV	LVM	Gender	Diagnosis	Recommendation	Test/Referral/Spec
									Not HF		Cardio_D_1
									Suspicious HF		Cardio_D_2
									Not HF		Cardio_D_3
									Not HF		Cardio_D_4
									Not HF		Cardio_D_5
									Not HF		Cardio_D_6
									Not HF		Cardio_D_7
									HFpEF confirm		Cardio_D_8
									HFmEF		Cardio_D_9
									HF pEF confirm		Cardio_D_10
									HF pEF confirm		Cardio_D_11
									HF pEF confirm		Cardio_D_12
									HF pEF confirm		Cardio_D_13
									HF pEF confirm		Cardio_D_14
									HFpEF		Cardio_D_15
									Male Not HF		Cardio_D_16
									Female Not HF		Cardio_D_17
									Female HFpEF		Cardio_D_18
									HFpEF confirm		Cardio_D_19
									HFmEF		Cardio_D_20

Heart Failure Silo in IMP

Stage 4: 2nd Knowledge Modeling (Data-Driven)

Contributing Factors:

(Heart Failure Diagnosis)

Patient Dataset: 1000



EMR/HMIS

ID	Age	Gender	Symptoms & Sign (If 1 or more=1, NO=0)	Clinical History (If 1 or more=1, NO=0)	Physical Exam (If 1 or more=1, NO=0)	ECG (normal=0, abnormal=1)	NT-proBNP	BNP	LVEF	LAVI	LVMI	E/e'	e' septal	TRV	Longitudinal strain(GLS)
10611919	79	M	1	0	0	0	185.3			17		7.38	6.1	2.5	
11066473	63	M	1	1	0	0	209			39	62.01	8.31	6.74		
11264619	41	F	0	0	0	0	327.8		61.54	23.67	83.4	6.1	10.82	14.5	
13401793	82	M	1	0	0	1	185.4		60.98		90.96	6.54	8.1		19.3
15072850	82	M		1	1	0		177.2	55		54.78	5.32	9.4		
16805356	71	M	1	0	1	1	380.2		52.94		102.4	5.89	10.7	2.5	16.6
18411764	26	M	1	1	0	1	203.4		65.75	18.08	86.07	5.08	11.8		12
20659893	83	F	1	1	1	0	156.2		60.56	33.09	82.15	11.25	4.8	2.6	
26190107	78	F	1	0	0	0	201.6		56.1	31.54	83.92	10.44	4.5	2.6	18
26289425	34	F	1	1	0	1	1447.6		55.56	33.56	67.11	7.89	12.3	2.3	
27645097	84	M	1	1	0	0	164.6		62.5	33.89	95.64	12.24	6.7	2.8	
27691432	68	M	1	0	0	0	321.6		65.38		65.57	6.87	8.3	2.7	20.3

Machine Learning Algorithms

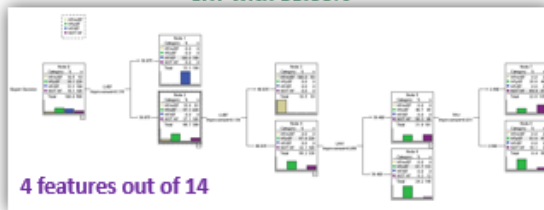


Black box Algorithms

- Naïve Bayes = 77%
- Generalized Linear Model = 74%
- Deep Learning = 80%

White box Algorithms

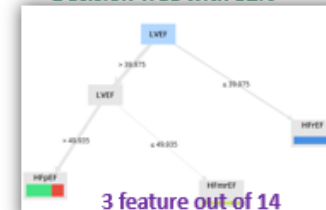
CRT with 88.55%



Random Forest with 86%



Decision Tree with 82%



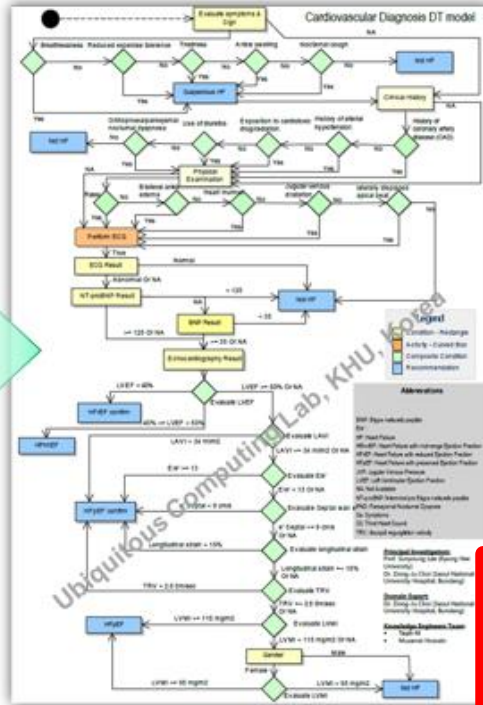
Heart Failure Silo in IMP

Stage 5: Knowledge Rules Creation (Data + Expert-Driven)



Medical Experts

Decision Tree

Intelligent Knowledge
Authoring Tool (I-KAT)

Production Rules

Rule #	RuleTitle	Symptoms/Signs	ClinicalHistory	PhysicalExam	ECG	NTproBNP	BNP	LVEF
1	CardiovascularRule-1	0	-	-	-	-	-	-
2	CardiovascularRule-2	1	-	-	-	-	-	-
3	CardiovascularRule-3	1	0	-	-	-	-	-
4	CardiovascularRule-4	1	1	0	-	-	-	-
5	CardiovascularRule-5	1	1	1	0	-	-	-
6	CardiovascularRule-6	1	1	1	1	< 125	-	-
7	CardiovascularRule-7	1	1	1	1	1	-	< 35
8	CardiovascularRule-8	1	1	1	1	1	-	>= 35 < 40
9	CardiovascularRule-9	1	1	1	1	1	-	>= 35 ([] 39 & 50
10	CardiovascularRule-10	1	1	1	1	1	-	>= 35 >= 50
11	CardiovascularRule-11	1	1	1	1	1	-	>= 35 >= 50
12	CardiovascularRule-12	1	1	1	1	1	-	>= 35 >= 50
13	CardiovascularRule-13	1	1	1	1	1	-	>= 35 >= 50
14	CardiovascularRule-14	1	1	1	1	1	-	>= 35 >= 50
15	CardiovascularRule-15	1	1	1	1	1	-	>= 35 >= 50
16	CardiovascularRule-16	1	1	1	1	1	-	>= 35 >= 50
17	CardiovascularRule-17	1	1	1	1	1	-	>= 35 >= 50
18	CardiovascularRule-18	1	1	1	1	1	-	>= 35 >= 50
19	CardiovascularRule-19	1	1	1	1	1	>= 125	< 40
20	CardiovascularRule-20	1	1	1	1	>= 125	-	([] 39 & 50
21	CardiovascularRule-21	1	1	1	1	>= 125	-	>= 50
22	CardiovascularRule-22	1	1	1	1	>= 125	-	>= 50
23	CardiovascularRule-23	1	1	1	1	>= 125	-	>= 50
24	CardiovascularRule-24	1	1	1	1	>= 125	-	>= 50

LAI	Te	Septal	LongitudinalStrain	TVV	LVM	Gender	DiagnosisRecommendation	TrueReferencePath
1	Not HF						Cardio_D_1	
2	Suspicious HF						Cardio_D_2	
3	Not HF						Cardio_D_3	
4	Not HF						Cardio_D_4	
5	Not HF						Cardio_D_5	
6	Not HF						Cardio_D_6	
7	Not HF						Cardio_D_7	
8	HFpEF confirm						Cardio_D_8	
9	HFmEF						Cardio_D_9	
10	HF pEF confirm						Cardio_D_10	
11	HF pEF confirm						Cardio_D_11	
12	HF pEF confirm						Cardio_D_12	
13	HF pEF confirm						Cardio_D_13	
14	HF pEF confirm						Cardio_D_14	
15	HFpEF						Cardio_D_15	
16	Not HF					Male	Cardio_D_16	
17	Not HF					Female	Cardio_D_17	
18	HFpEF					Female	Cardio_D_18	
19	HFpEF confirm						Cardio_D_19	
20	HFmEF						Cardio_D_20	

Total Rules: 15409
Total Patient Data : 600
Final Accuracy : 98.3%

Heart Failure Silo in IMP

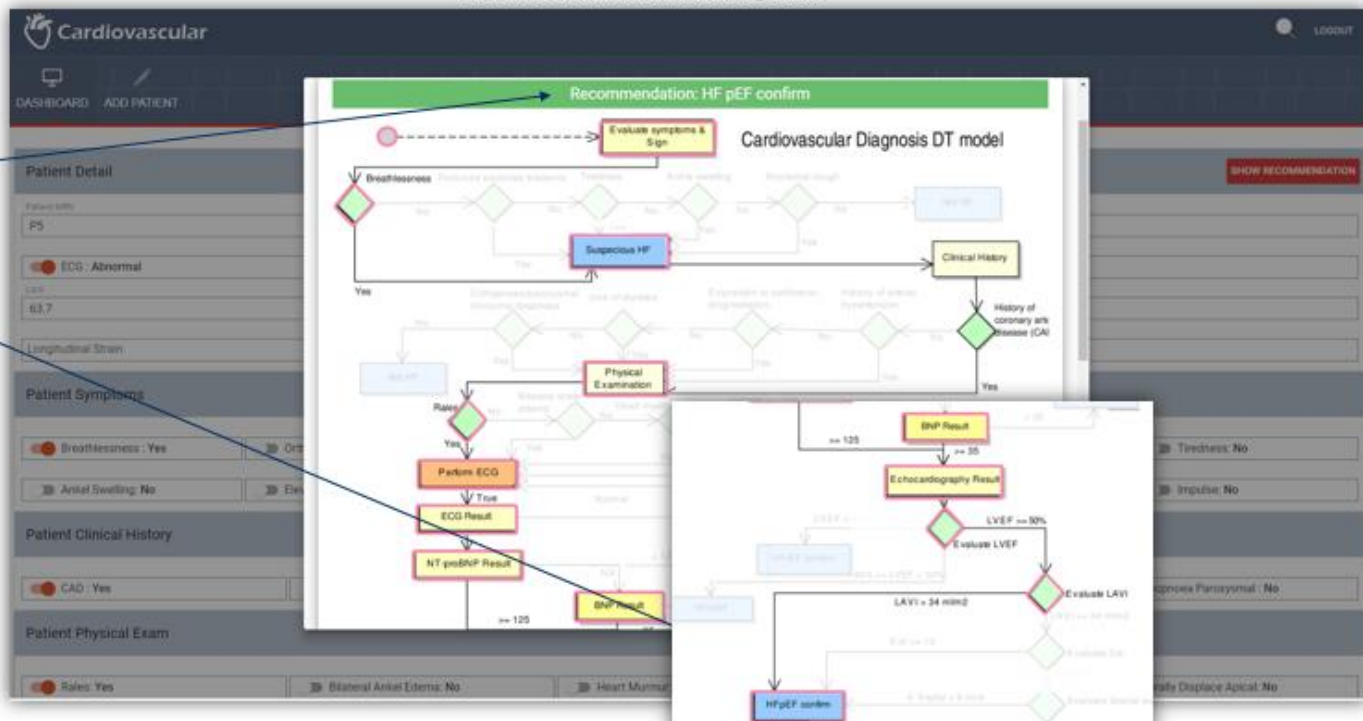
Stage 6: Implementation

Login Screen: Only authorized physicians can be logged in to the system

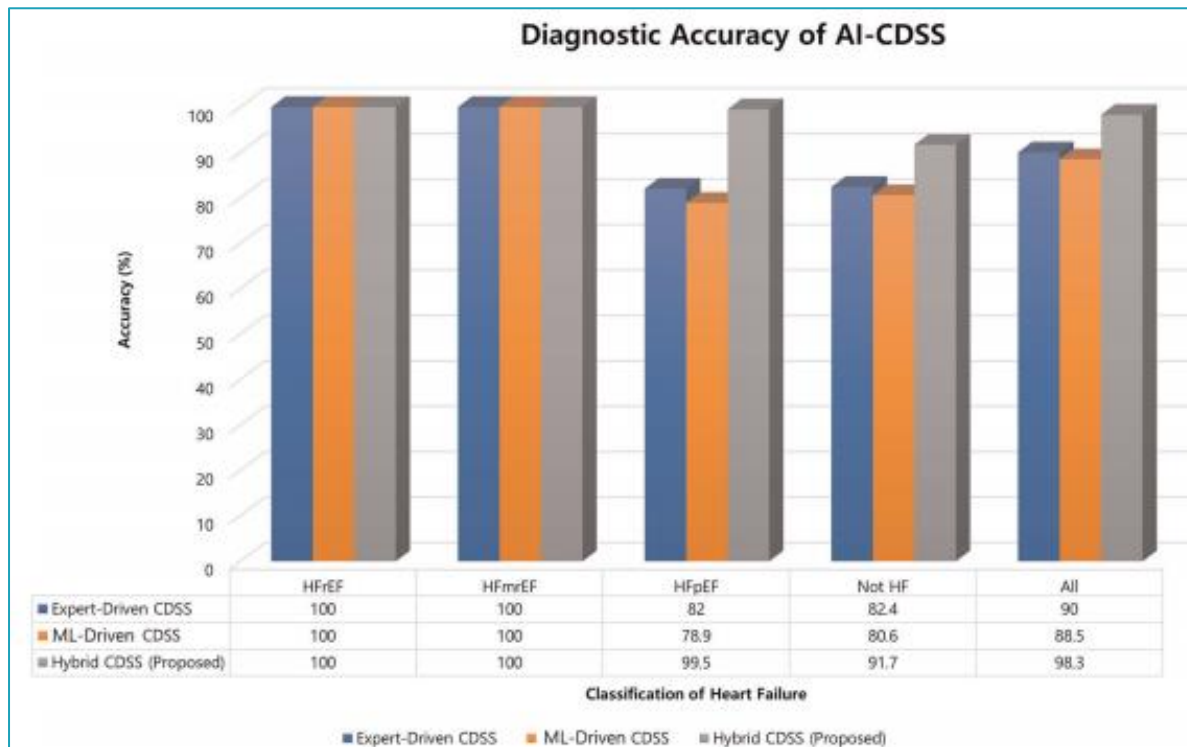
CDSS Intervention: Shows the recommendation of a patient based on patient profile and symptoms
The decision comes from knowledge base

Final
Decision

Knowledge
Rule
triggered



Validation of AI-CDSS: retrospective test set



HUMAN Intelligence

ARTIFICIAL Intelligence

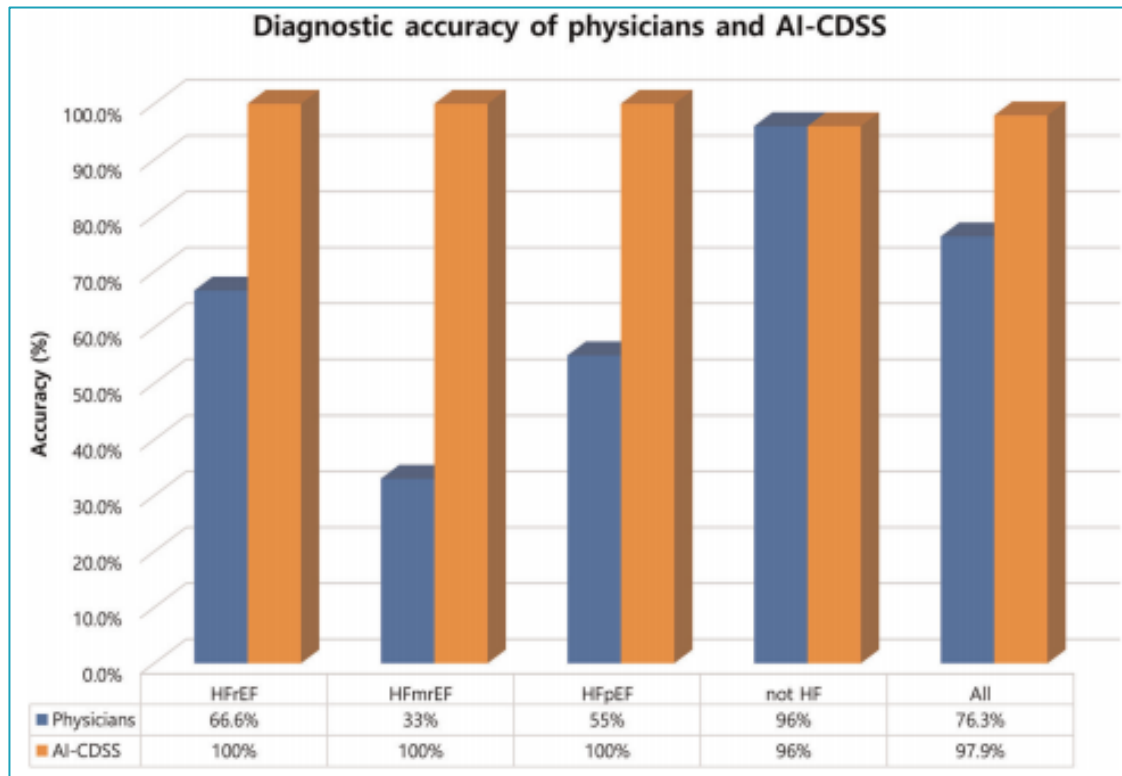


Pilot Study

연구계획서 제목	심부전 진단용 인공지능 플랫폼의 유용성에 대한 연구 (Clinical application of Artificial Intelligence Platform for the Diagnosis of Heart Failure)
연구목적	호흡곤란이 주소인 환자에서 심부전 진단에 대한 인공지능 플랫폼의 유용성 평가를 하고자 함.
연구 설계	A prospective, single arm, single-center, pilot study
연구 예상 기간	12 개월
연구대상자수	전체 100명
연구대상	호흡곤란 환자
시험 약	해당 사항 없음
용법 및 용량	해당 사항 없음
주요 선정기준	<ol style="list-style-type: none"> 만 19 세 이상, 80세 미만의 남·녀 호흡곤란을 주소로 외래를 방문한 환자 첫 번째 방문에서 심전도, NT-proBNP(or BNP) 및 심초음파를 시행한 환자 본 임상연구에 참여할 것을 자발적으로 서면 동의한 자
주요 선정 제외 기준	<ol style="list-style-type: none"> 중증의 호흡곤란으로 입원치료가 필요한 환자 의사소통이 어려운 환자
목표대상자수 산정	100명
유효성 평가 기준	<ol style="list-style-type: none"> 1. 일차 연구목표: Diagnostic accuracy of clinical decision support system (CDSS) to diagnose heart failure. 2. 이차 연구목표 CDSS의 진단 정확도에 영향을 미치는 요소



Physician vs AI-CDSS



Heart Failure Silo in IMP

Physician vs AI-CDSS

Patients with dyspnea



Physician



76%

AI-CDSS



Expert driven
Data driven
Hybrid approach



98%



Diagnostic
accuracy
for heart
failure
diagnosis:

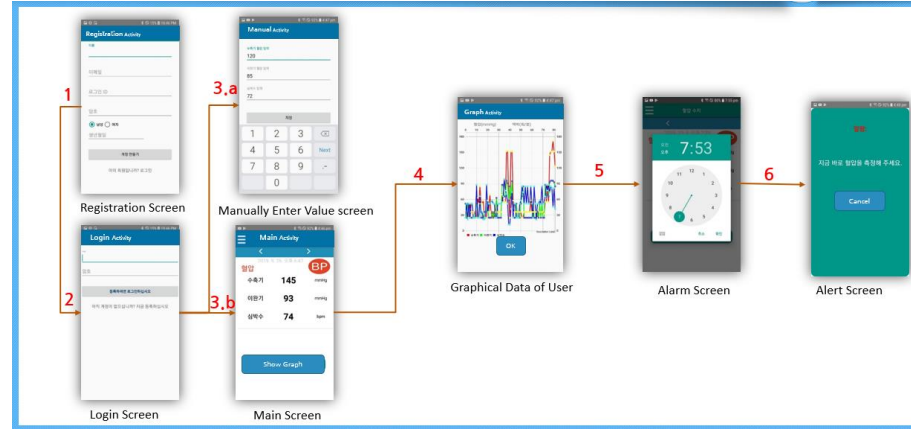


AI-CDSS in Home Care Setting

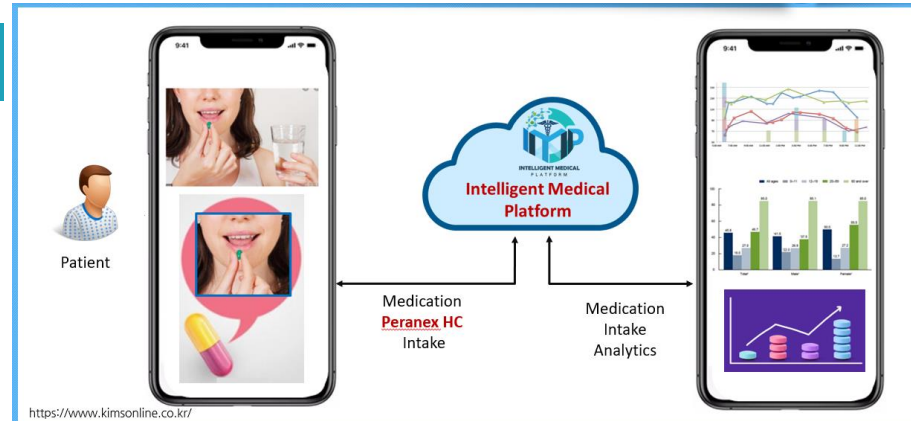


AI-Patient Monitoring and Management App.(AI-PAMM)

Monitoring



Management





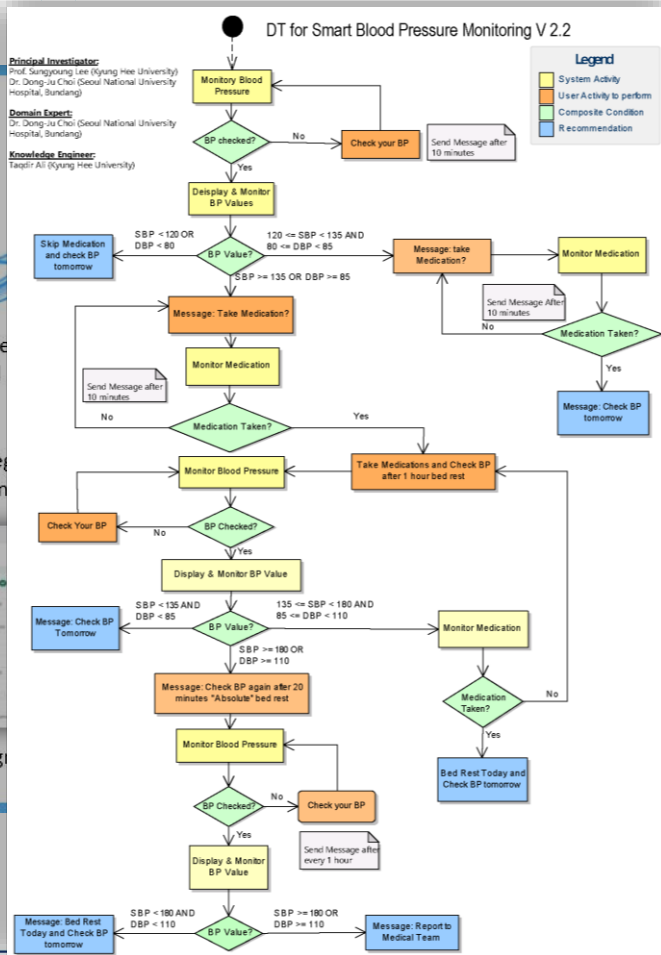
1

Physician develops
monitoring rules and

2 Inter
mon



Vital Sig



remotely

2 Hypertension monitoring API send
information to server



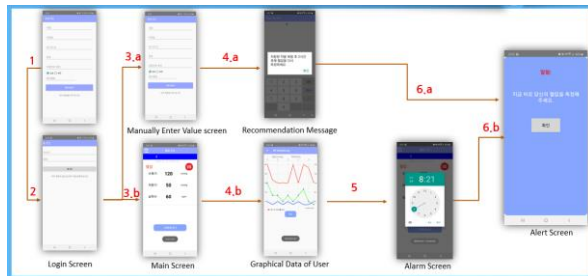
1 Patient Checking Blood
Pressure



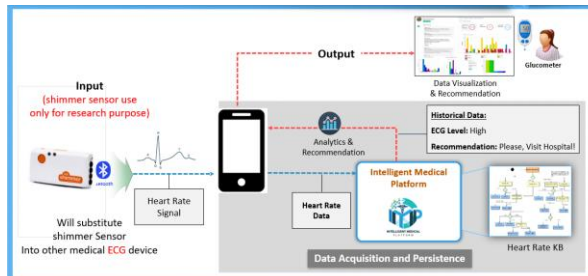
and suggestion to the patient



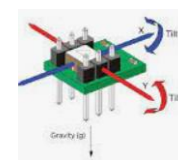
Blood Pressure



ECG



Behavior



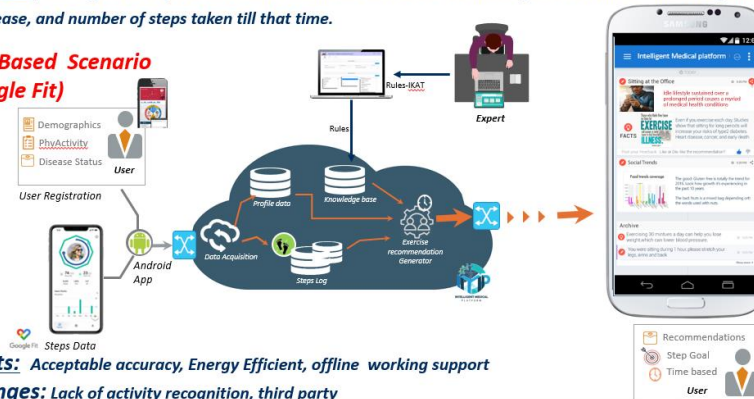
그 외의 접속 가능한 wearable devices..... PPG, Impedance, Bwt...



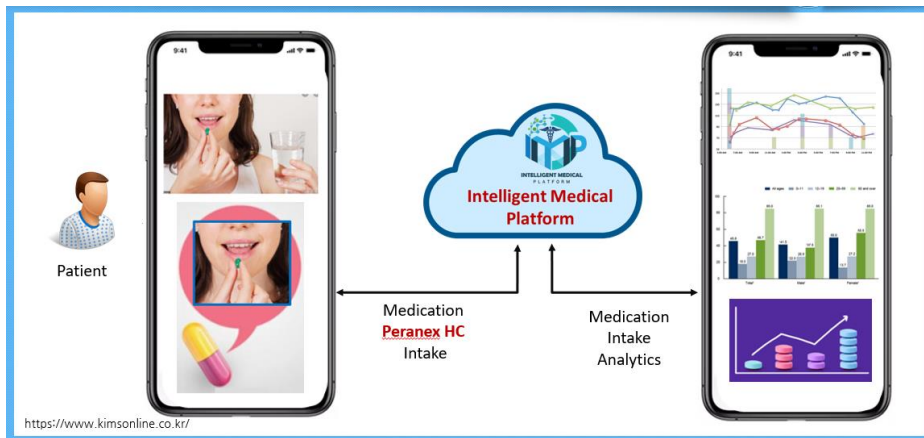
Behavior

Objective: Identify user Steps status and recommend exercise on the basis of context where context depends on age, disease, and number of steps taken till that time.

Step Based Scenario (Google Fit)



Adherence



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HRPP SOP ver3.2_2018.06.01/e-IRB(rev) 2018.09.20

심의결과통보서

IRB No.	B-1904/532-301	제출경로	분당서울대학교병원	
연구 과제명	(국문)	자가인식 앱 피드백 시스템을 통한 edoxaban 약물 순응도 향상 연구: 무작위대조군연구		
	(영문)	Self-awareness of drug adherence to edoxaban using an automatic app, feedback system: a randomized controlled study		
	Protocol No.	Adhere_App	Version No.	2.0

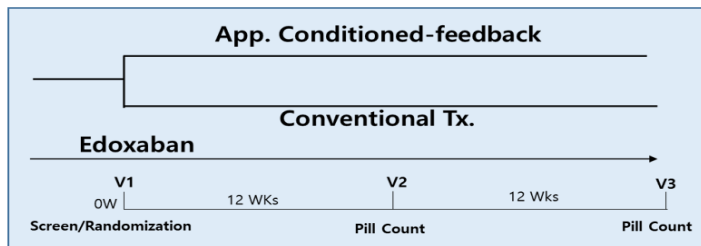
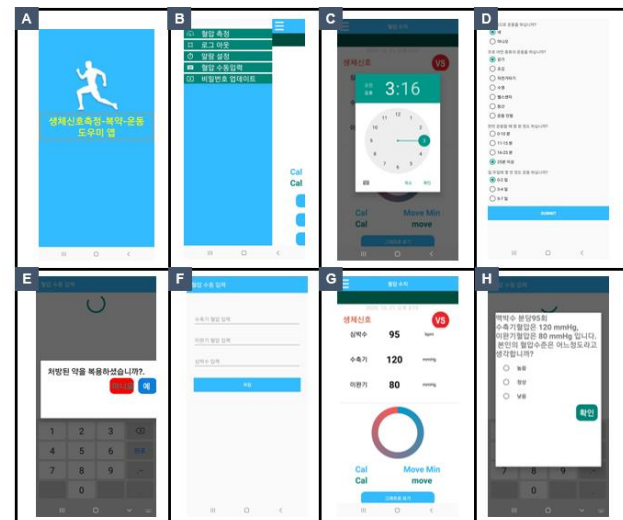
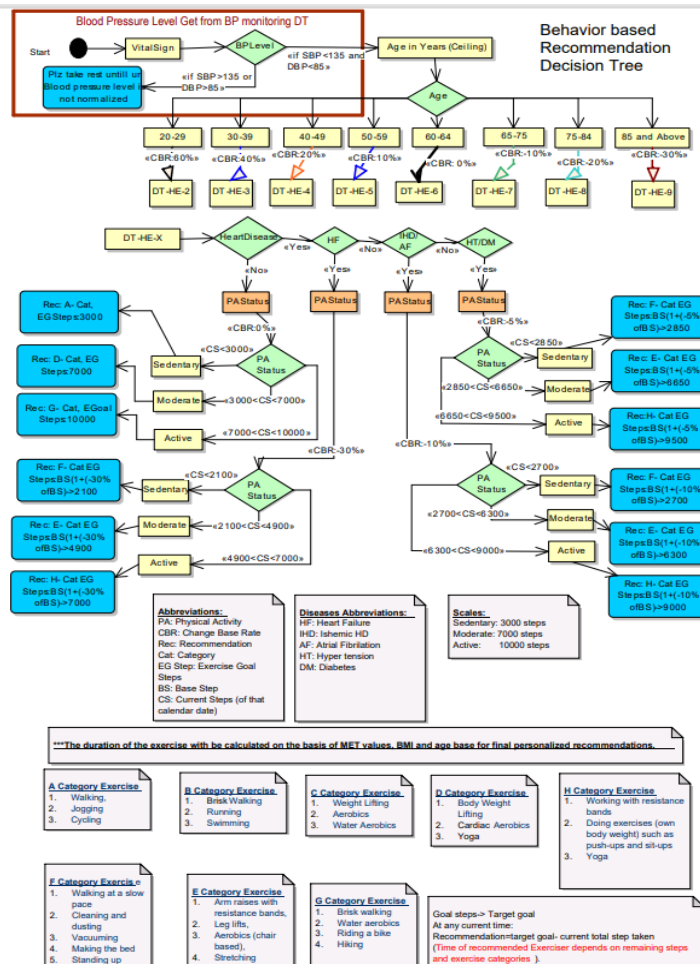


Figure 3





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26-Jul-2021

Dear Dr. Kim:

Your manuscript entitled "Rationale, Design, and Efficacy of a Smartphone Application for Improving Self-Awareness of Adherence to Edoxaban Treatment: A Randomized Controlled Study (Adhere App)" being given full consideration for publication in [BMJ Open](#).

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Rationale, Design, and Efficacy of a Smartphone Application for Improving Self-Awareness of Adherence to Edoxaban Treatment: A Randomized Controlled Study (Adhere App)¹

In-Cheol Kim¹, Ji-Hyun Lee², Dong-Ju Choi², Sung-Ji Park³, Ju-Hee Lee⁴, Sang Min Park⁵, Mina Kim⁶, Hack-Iyoung Kim⁷, Sunki Lee⁸, In-Jae Kim⁹, Seounghoon Choi¹⁰, Jaehun Bang¹¹, Bilal Ali¹¹, Musarrat Hussain¹¹, Tagdir Ali¹¹, and Sungyoung Lee¹¹¹



CDSS(Clinical Decision Supporting System)

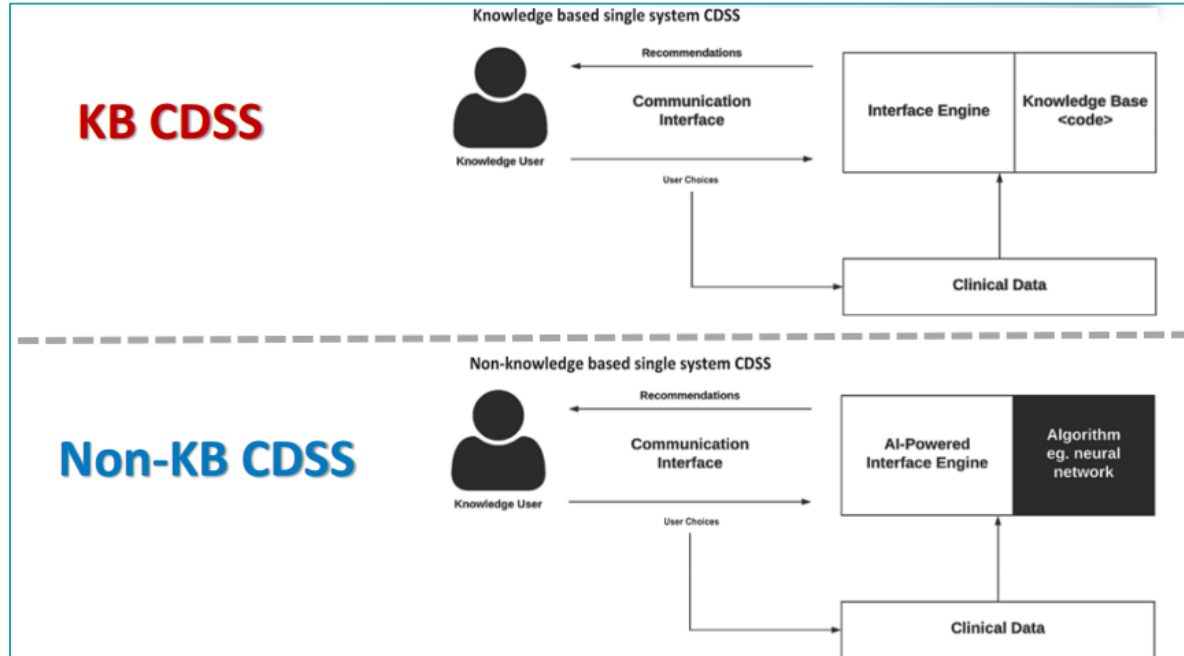
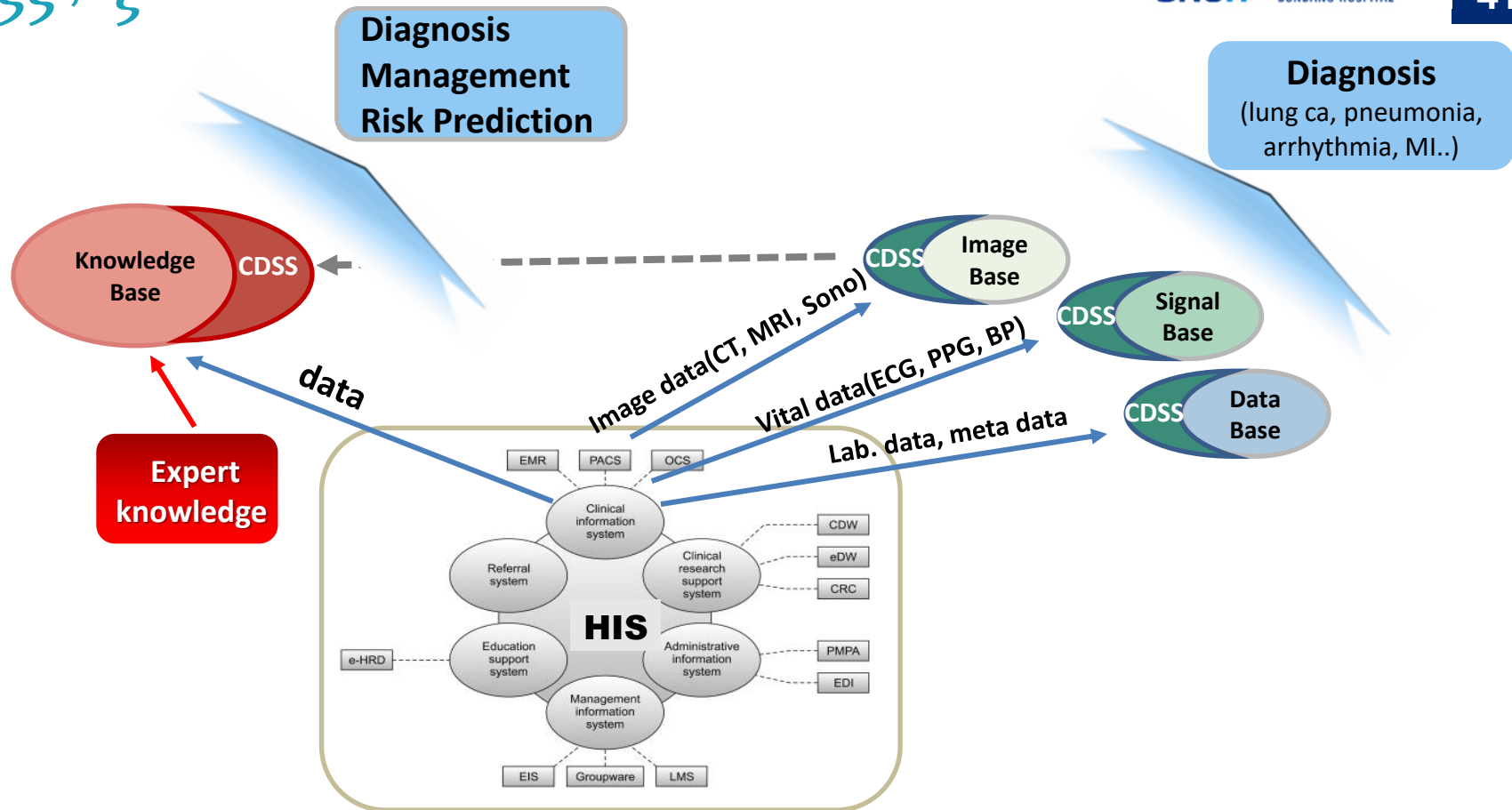


Image Based CDSS

Signal Based CDSS

Data Based CDSS





- 1. AI-CDSS may be useful for the diagnosis of HF, especially when HF specialists are not available in hospital setting.**
- 2. AI-CDSS may be also useful for the monitoring and managements of chronic disease in usual life setting.**
- 3. It is necessary to devise ways in which many kinds of AI-CDSS and SaMD can be used complementary to or fused with each other.**
- 4. Methods that can smoothly link HIS and CDSS is essential.**

