산업계의 글로벌 규제조화 활동

IMDRF/AIMD WG/N67

2022-09-02

㈜휴톰 박현배

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안녕하세요?

주요 약력

- IMDRF AIMD(Artificial Intelligence Medical Devices) Working Group & 국내운영추진단 부팀장
- IMDRF SaMD(Software as a Medical Devices) Working Group & 국내운영추진단 위원

現 ㈜휴톰 RA/QA Team Leader

前 ㈜뷰노 품질책임자

산업계의 글로벌 규제조화 활동

CLINICAL DIAGNOSTICS

HEALTHCARE DECISION MAKERS & INFLUENCERS

Patient & Family Support

Patients make decisions in consultation with their doctors. But are influenced by their loved ones to seek more information and sometimes are encouraged to seek medical advice in the first place. Patients and their support groups play a strong role in healthcare decision making.

Doctors & Medical Groups

Doctors directly make and strongly influence medical decisions for their patients. However, medical groups often act in concert to provide improved patient outcomes and share learnings across the practice.

Clinical Practice Setting Bodies

Large clinical practice setting bodies such as the National Comprehensive Cancer Network serve to provide collective best practices among (for example) urologists as they seek to screen prostate cancer. These bodies strongly influence healthcare decisions.

Payors (Insurance)

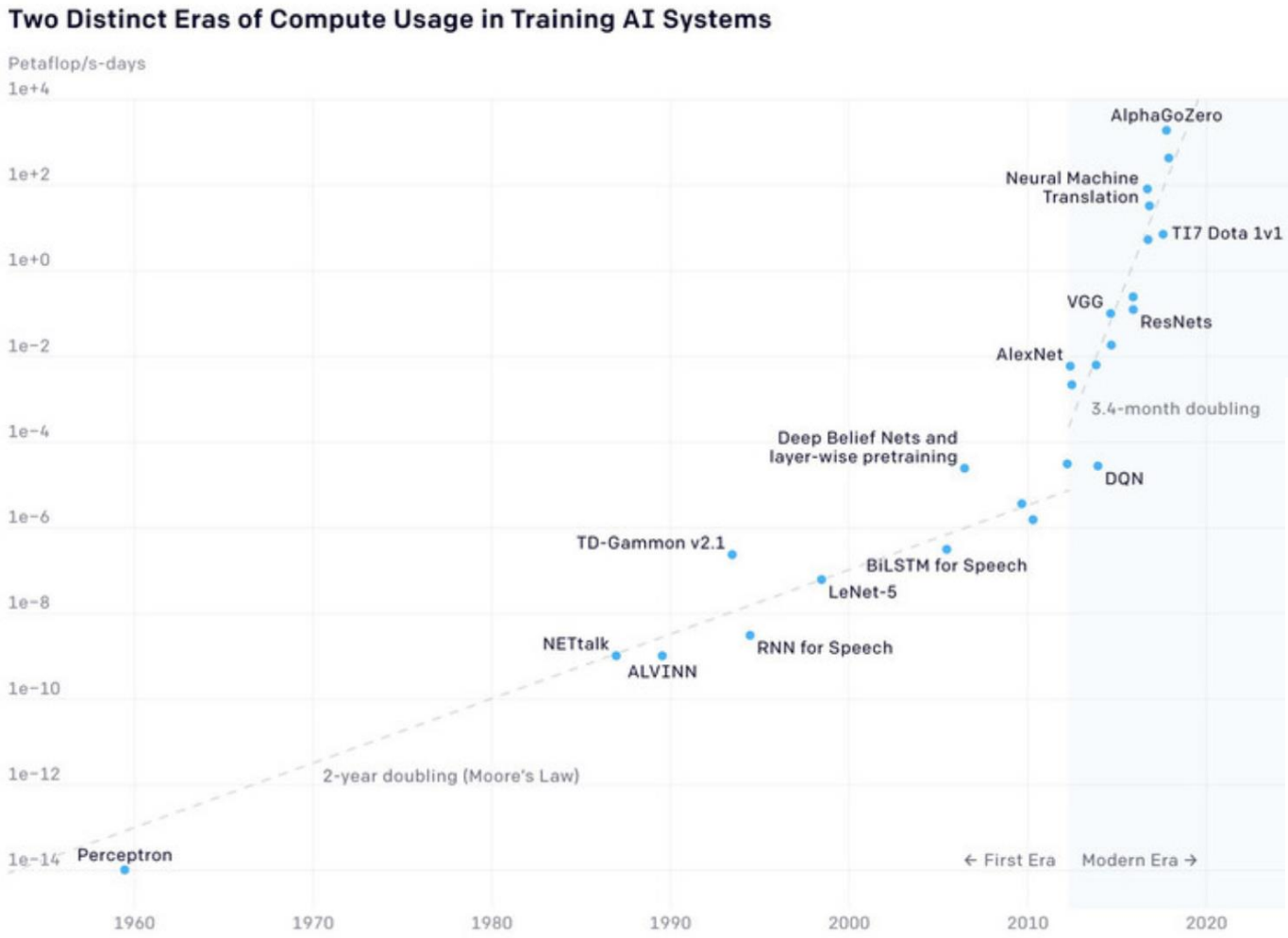
Insurance companies are another strong influence in the healthcare decision making process. If patients are unable to afford medication, procedures or medical devices because they are not covered or don't offer great coverage - patents may not seek the medical solution they need.

Regulatory Bodies

Regulatory bodies set standards for how drugs and medical devices should behave and what should happen when it performs outside expectations. Regulatory bodies influence both payors and doctors in their decision making process.

MKA Insights

기술의 성장 속도 VS 규제의 변화 속도



전문성 결여 지적에 칼뽑은 식약처...심사 인력 대거 채용

최선 기자 | 발행날짜: 2019-10-11 05:45:57

의약품 심사 40명, 의료기기 47명 충원안 국회에 제시
국회도 인력 충원 통한 전문성 강화 공감대

[메디칼타임즈=최선 기자] 의약품 허가 심사와 사후 관리 부실로 뭇매를 맞은 식품의약품안전처가 대거 신규 인력 채용에 나선다.

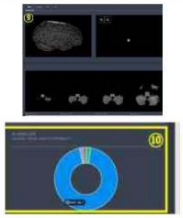
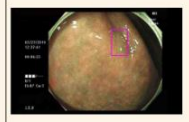
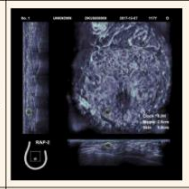
국정감사에서 비판받은 추적관리, 시판 후 부작용 보고 등 의약품 관련 이슈들이 주로 전문 인력 부족에서 비롯됐다는 점에서 충원을 통한 해외 기관 의존도 낮추기가 성공할 지도 관심사다.

10일 식약처에 따르면 식약처는 정부안으로 심사인력을 최대 87명 신규 충원하는 방안을 국회에 제출한 것으로 확인됐다.

산업계의 글로벌 규제조화 활동

MFDS: + 101

[표 63] 최근 5년간('17~'21) 허가·인증된 인공지능(AI) 기반 의료기기 세부현황[5)]

연번	업체명	품목명 (등급)	허가번호 (허가일자)	사용목적	제품외형
1	㈜뷰노	의료영상 분석장치 소프트웨어(2)	제허 18-360호 ('18.5.16)	Greulich-Pyle (GP) 방식의 골연령 모델을 기반으로 환자의 좌측 손 X-ray 영상에 대한 골연령을 분석하여 의료인이 환자의 골연령을 판단하는 것을 지원하기 위한 목적의 소프트웨어	
2	㈜제이엘케이 인스펙션	의료영상 진단보조 소프트웨어(3)	제허 18-573호 ('18.8.14)	환자의 뇌 Magnetic Resonance(MR) 영상자료와 임상자료를 바탕으로 뇌경색(허혈성 뇌졸중)의 유형 분류 진단을 자동으로 진행하여 의료진의 뇌경색 진단결정을 보조하는데 사용하는 소프트웨어	
99	㈜엔도아이	내시경영상 검출·진단 보조 소프트웨어 (2)	제인 21-5073호 ('21.12.28)	대장 내시경 영상 내에서 정상과 다른 이상 부위를 검출한 후 윤곽선, 색상 또는 지시선 등으로 표시하거나 질병의 유무, 질병의 중증도 또는 질병의 상태 등에 대한 가능성 정도를 자동으로 표시하여 의료인의 진단결정을 보조하는데 사용하는 소프트웨이	
100	모니터코퍼레이션 ㈜	2등급초음파 영상검출·진단보조 소프트웨어 (2)	제인 21-5077호 ('21.12.29)	의료영상 내에서 정상과 다른 이상 부위를 검출한 후 색상 또는 지시선 등으로 표시하여 의료인의 진단 결정을 보조하는 데 사용하는 소프트웨어	
101	에이치디엑스 ㈜	의료영상분석 소프트웨어 (2)	수인 21-4567호 ('21.12.06)	흉부, 상복부 또는 두경부 CT 영상에서 장기를 부위별로 분할하여 제공하는 소프트웨어(결과를 검토하고 편집하기 위한 사용자 인터페이스를 제공하지 않음)	

FDA: + 130

* 2015~2020년 말 기준

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

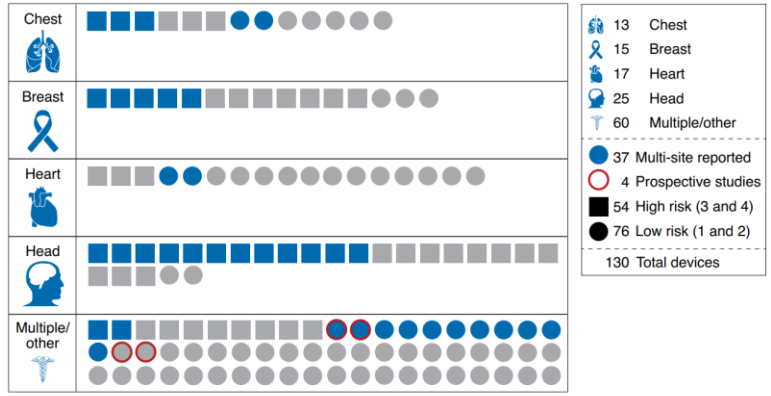


Fig. 1 | Breakdown of 130 FDA-approved medical AI devices by body area. Devices are categorized by risk level (square, high risk; circle, low risk). Blue indicates that a multi-site evaluation was reported; otherwise, symbols are gray. Red outline indicates a prospective study (key, right margin). Numbers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

산업계의 글로벌 규제조화 활동

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

2017. 11.

식품의약품안전처
식품의약품안전평가원
의료기기심사부 첨단의료기기과

인공지능 의료기기의 허가·심사 가이드라인(민원인 안내서)

2022. 5. 12.

식품의약품안전처
식품의약품안전평가원
의 료 기 기 심 사 부

[전문가협의체 위원]

소속	직위	성명	비고
삼성서울병원	교수	장동경	학계
세브란스병원	교수	김광준	
서울대학교병원	교수	박창민	
분당서울대학교병원	교수	박상준	
서울성모병원	교수	김헌성	
서울아산병원	교수	서준범	
아주대학교	교수	박래웅	
연세대학교	교수	유선국	
성균관대학교	교수	신수용	
경희대학교	교수	이승룡	
공주대학교	교수	최대선	
가천대학교	교수	이강윤	
서울대학교	교수	박영석	
카이스트	교수	유회준	
(주)라이프시맨틱스	대표	송승재	산업계
(주)카이랩	대표	배인호	
(주)루닛	이사	장민홍	
(주)루닛	이사	이정인	
(주)뷰노	이사	김현준	
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(주)디지털 헬스케어 파트너스	대표	최윤섭	
삼성전자(주)	차장	김철신	
삼성메디슨(주)	수석	김동환	
한국디지털병원 수출사업협동조합	상무이사	김태형	조합

산업계의 글로벌 규제조화 활동

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HOME > AI INDUSTRY > 의료·헬스케어

식약처, 인공지능 의료기기 국제 기준 개발착수... 국내 AI의료기기 전문가협의체 구성

정한영 기자 | 승인 2020.09.10 21:51

이미지:본지

IMDRF International Medical Device Regulators Forum

Artificial Intelligence Medical Device(AIMD) 16th Meeting

2021.07.08.

Ministry of Food & Drug Safety, South Korea

Schedule (proposal)

Month	Sun	Mon	Tue	Wed	Thu	Fri	Sat
	27	28	29	30	1	2	3
7 (Jul)	4	5	6	7	8 (AIMD Meeting) - Review the written comments (meeting frequency will be discussed depends on the situations and the amount of the comments)	9	10
	11	12	13	14	15 (AIMD Meeting)	16	17
	18	19	20	21	22 (AIMD Meeting)	23	24
	25	26	27	28	29 (AIMD Meeting)	30	31
8 (Aug)	1	2 - Submit the Final WD to MC	3	4	5	6	7

IMDRF International Medical Device Regulators Forum

MLMD Definitions Task Force

2021-04-29 update

Mr David Wotton
Therapeutic Goods Administration, Australia

Local VS Global Model Change

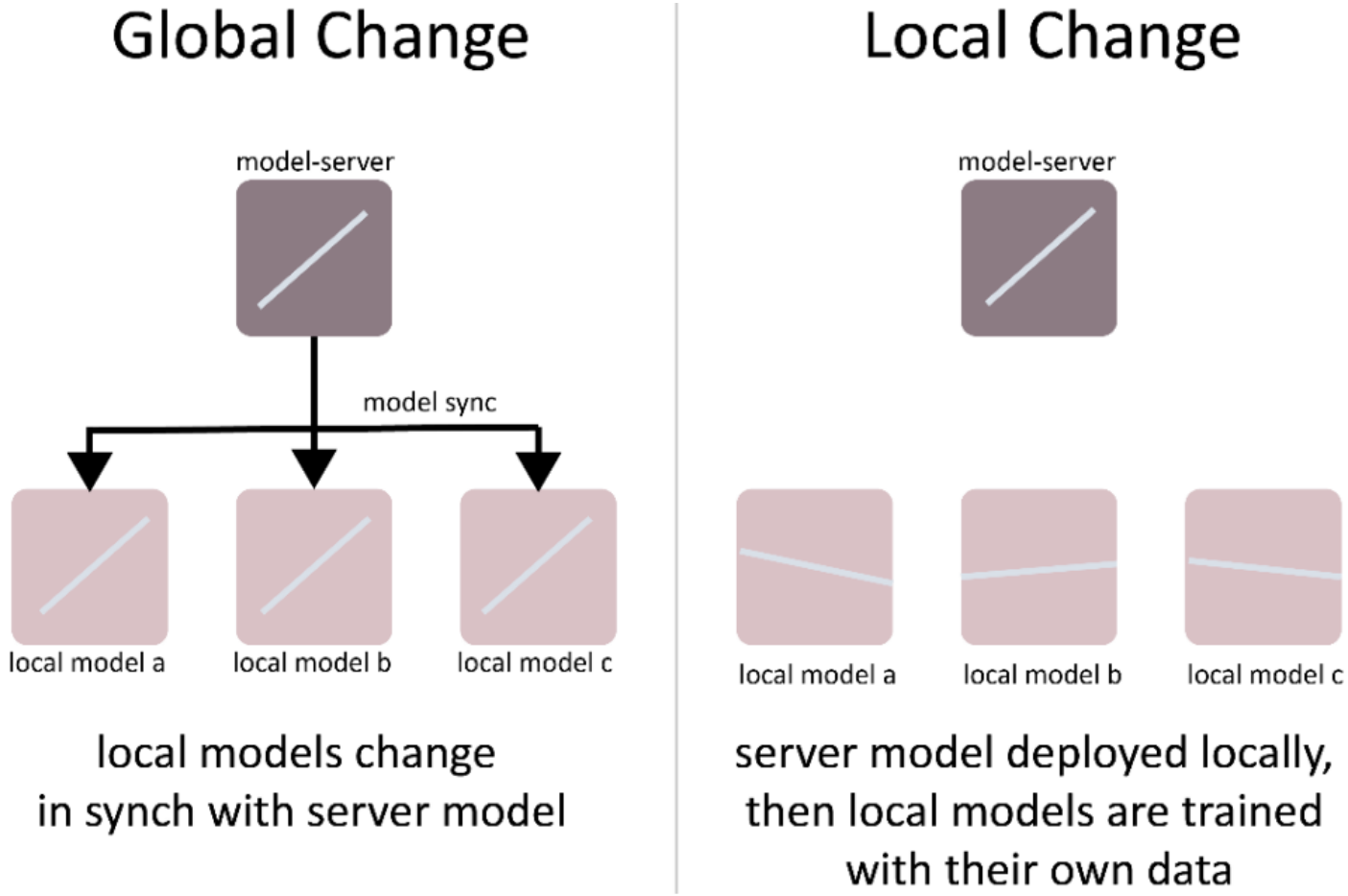


Figure 1 Global and local model change

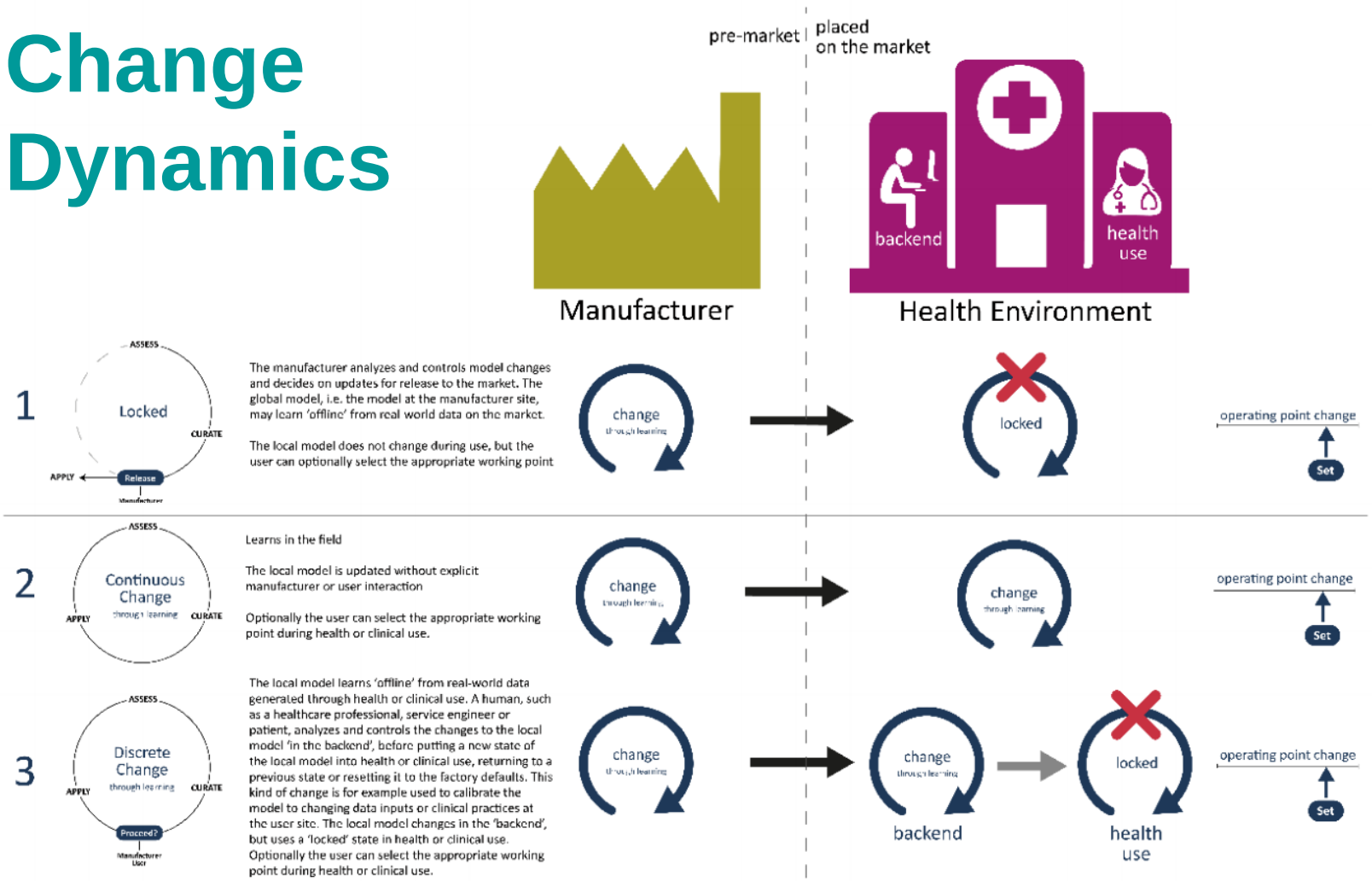


Figure 3 Illustration of locked, continuous and discrete change in relation to placement on the market.

Intentional user-initiated substantive change

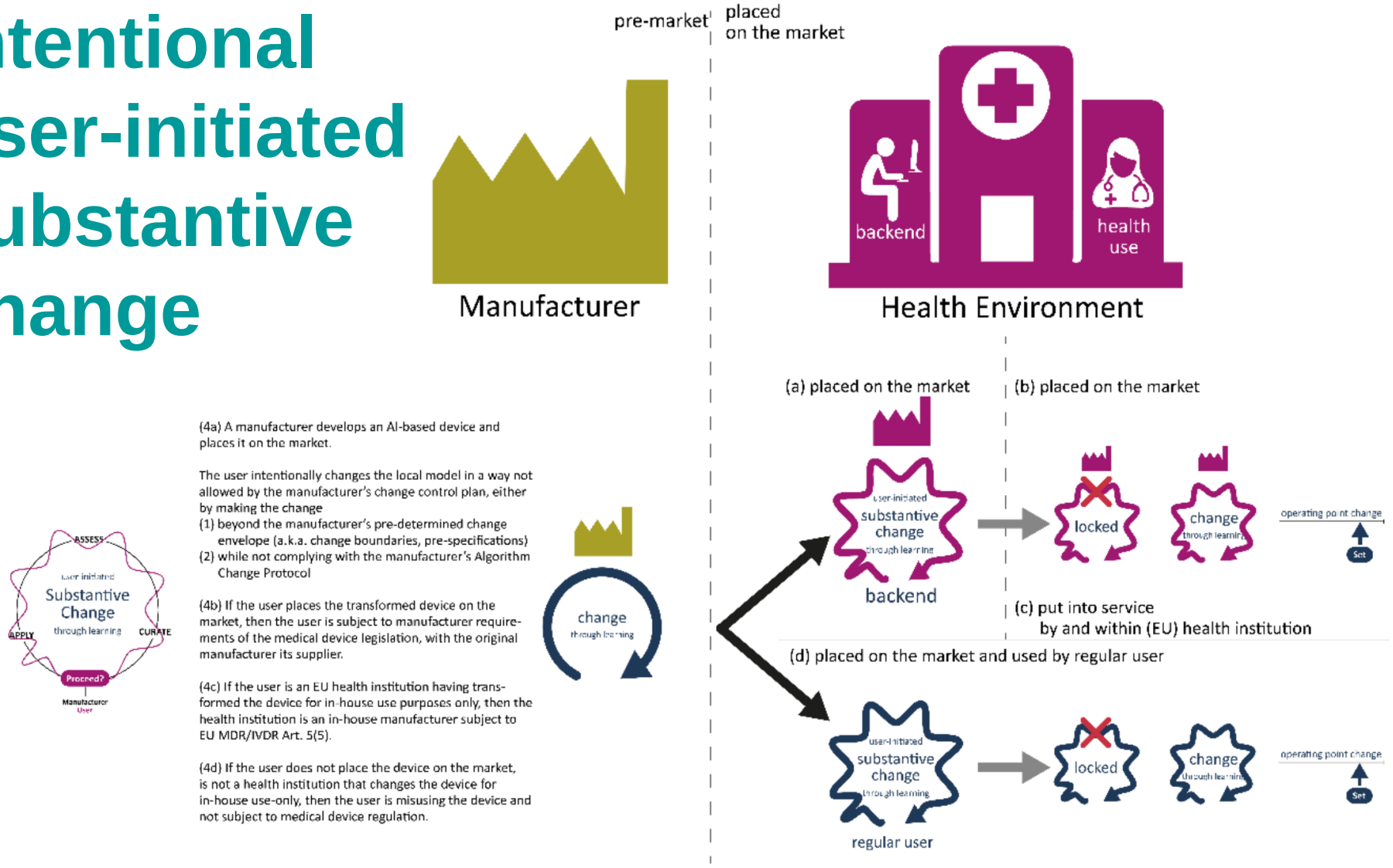
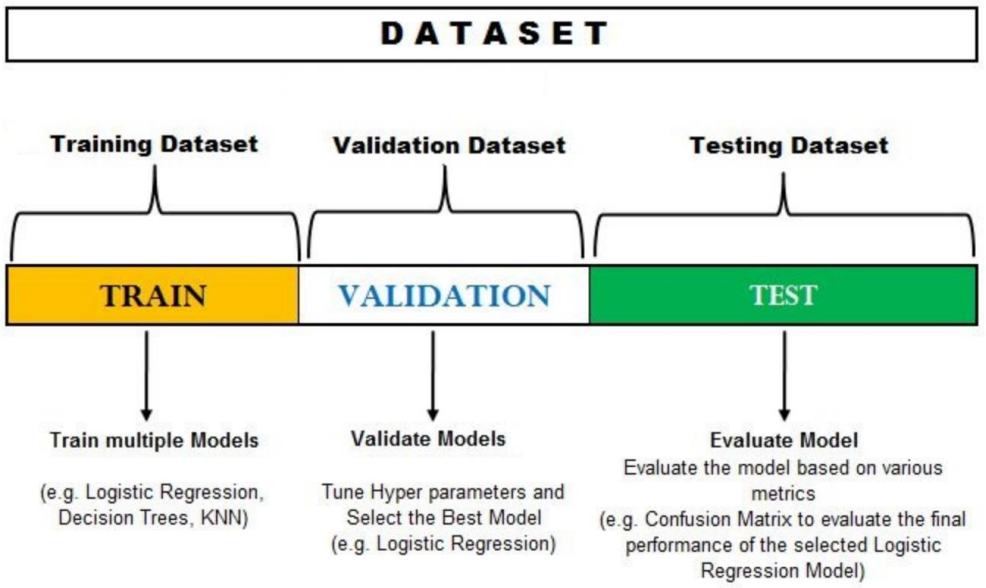


Figure 4 Illustration of substantive change initiated by the user. The user is either another manufacturer (4b), an EU-based health institution (4c) or a regular user (4d).

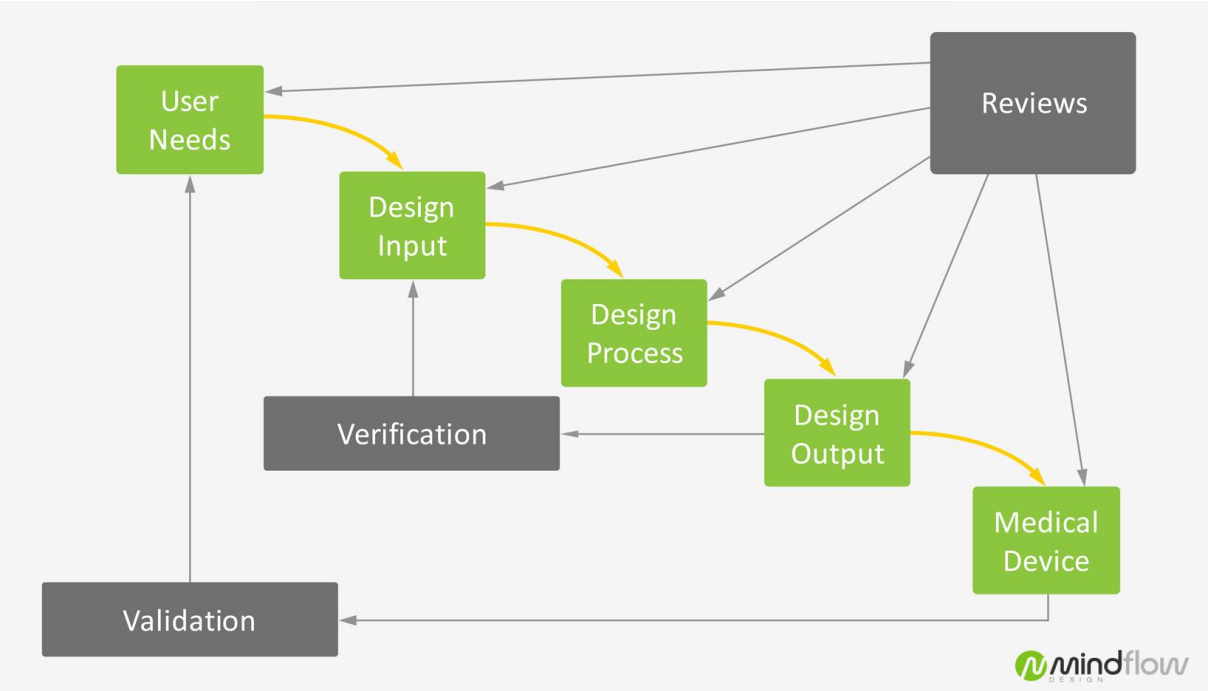
VALIDATION

ML Model Development



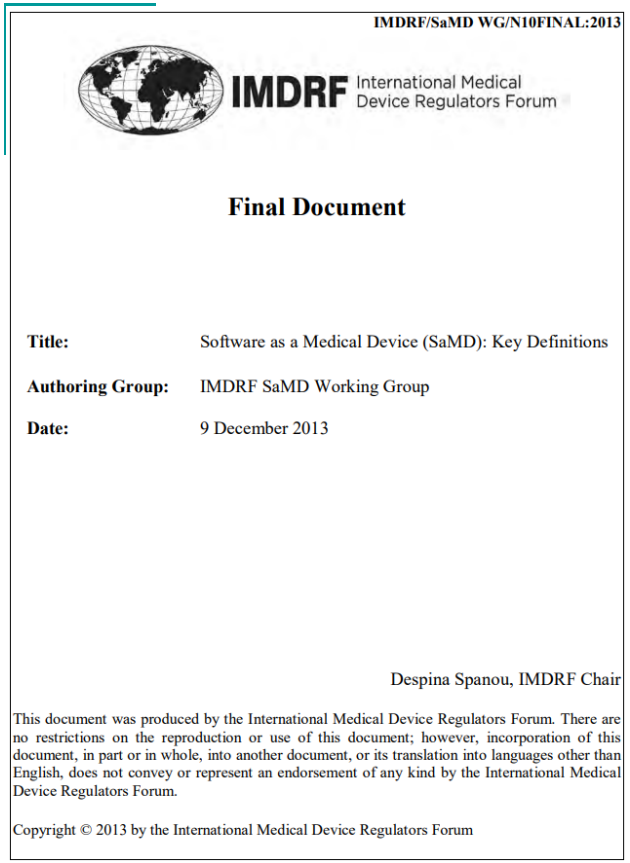
Data Curation or Model Tuning

Medical Devices Development



객관적인 증거의 검사 및 제공의 확인

IMDRF SaMD Working Group



IMDRF/SaMD WG/N10FINAL:2013

IMDRF International Medical Device Regulators Forum

Final Document

Title: Software as a Medical Device (SaMD): Key Definitions

Authoring Group: IMDRF SaMD Working Group

Date: 9 December 2013

Despina Spanou, IMDRF Chair

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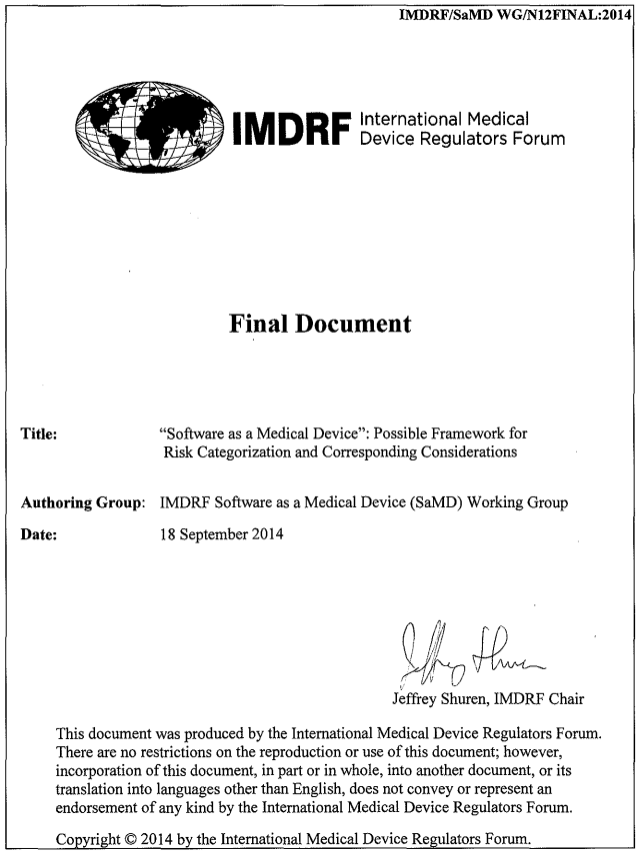

IMDRF/SaMD WG/N12FINAL:2014

IMDRF International Medical Device Regulators Forum

Final Document

Title: "Software as a Medical Device": Possible Framework for Risk Categorization and Corresponding Considerations

Authoring Group: IMDRF Software as a Medical Device (SaMD) Working Group

Date: 18 September 2014

Jeffrey Shuren, IMDRF Chair

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IMDRF/SaMD WG/N23 FINAL: 2015

IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

International Medical Device Regulators Forum

Title: Software as a Medical Device (SaMD): Application of Quality Management System

Authoring Group: IMDRF SaMD Working Group

Date: 2 October 2015

Toshiyoshi Tominaga, IMDRF Chair

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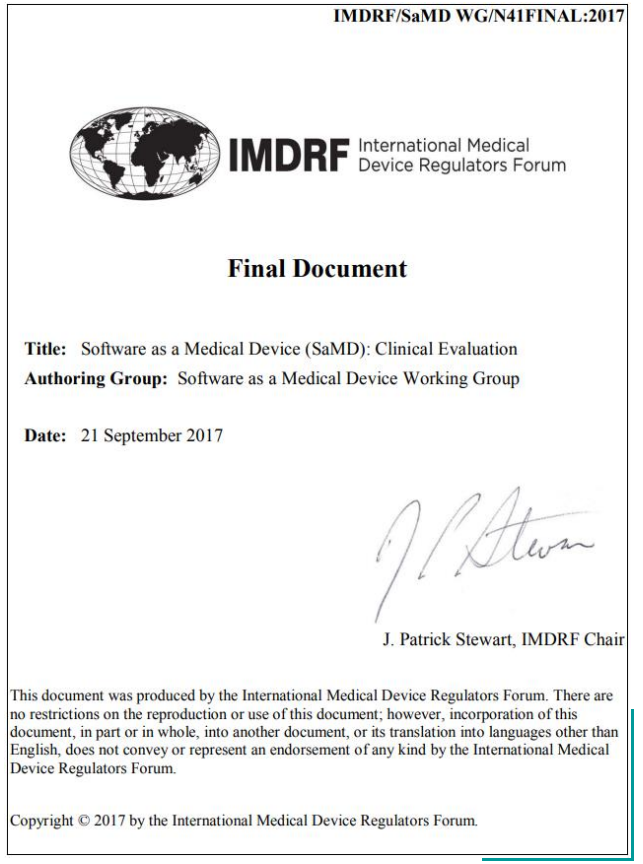

IMDRF/SaMD WG/N41FINAL:2017

IMDRF International Medical Device Regulators Forum

Final Document

Title: Software as a Medical Device (SaMD): Clinical Evaluation

Authoring Group: Software as a Medical Device Working Group

Date: 21 September 2017

J. Patrick Stewart, IMDRF Chair

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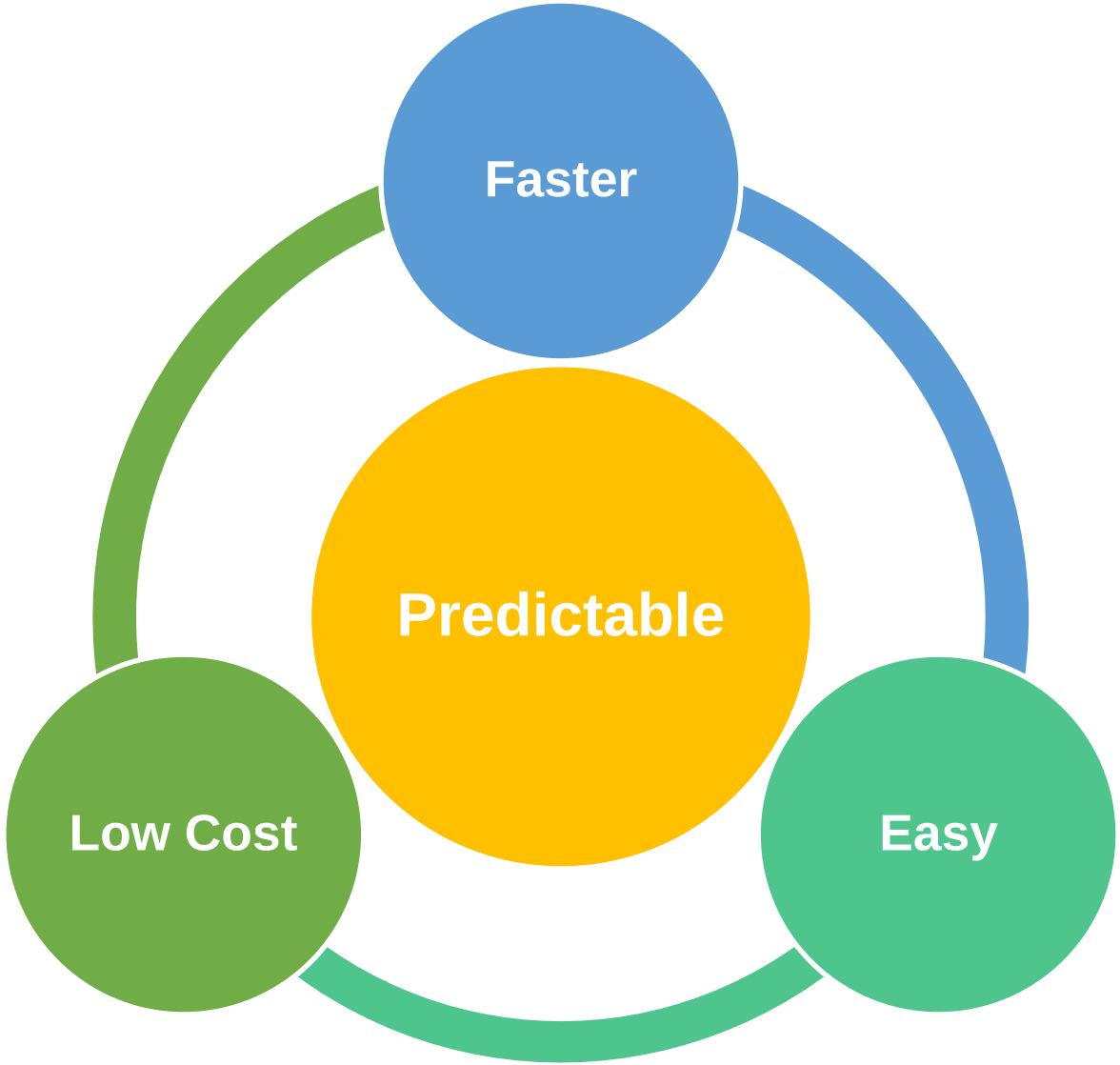
Healthcare Regulatory Strategy



Thank you

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