Overview : Korea Medical Device program

Staying relevant in the 4th industrial Revolution
- Digital Health & Regulatory Approaches

Head of Quality & Regulatory
Health Technology, Philips Korea

Jaryeong Shin

July 3, 2018

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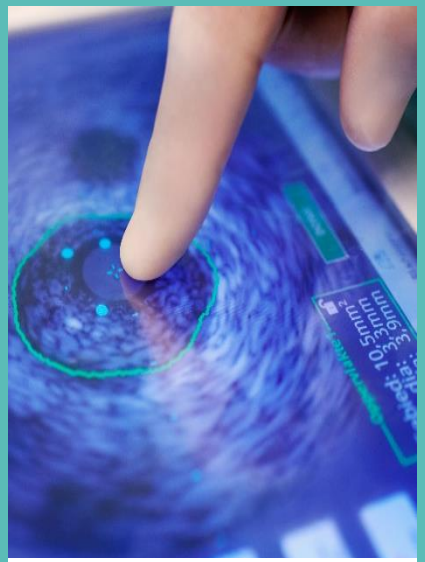
Four profound trends are shaping the future of health technology

- **Global resource constraints**

- **Aging populations and the rise of chronic illnesses**

- **Increasing consumer engagement**



- **Digitization**

Agenda

I. Overview : Korea Medical Device program (software focus)

II. MFDS's new regulatory initiatives to drive Digital Health

III. Business trend : Innovation in Digital Health

IV. Considerations

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I. Overview : Korea Medical Device program (software focus)

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Medical Device Software Regulation/Guidelines

Guideline ID	Title of Guideline	Latest Published/ Revised Date	Description
고시 제2018-10호	의료기기 허가 신고 심사 등에 관한 규정	2018-02-27	Medical Device Registrations, Technical Documentations
안내서-0612-02	의료기기 소프트웨어 허가심사 가이드라인	2018-06-15	Software Requirements for Medical Device Registration
안내서-0804-01	빅데이터 및 인공지능(AI) 기술이 적용된 의료기기의 허가·심사 가이드라인	2017-11-22	Software Requirements for Big Data and AI (Artificial intelligence) Medical Device Registration
To be released	의료기기의 사이버 보안 허가 심사 가이드라인	To be released	Cyber Security for Medical Device Registration
지침서-2015-5-006	의료기기와 개인용 건강관리(웰니스) 제품 판단기준	2015-07-10	Wellness Devices
안내서-2015-5-105	휴대형의료영상전송장치 소프트웨어 허가심사 가이드라인	2015-02-27	Requirements for Mobile PACS Registration
안내서-2015-5-107	의료영상전송장치 소프트웨어 기술문서 작성을 위한 가이드라인	2015-02-27	Requirements for PACS Registration
안내서-2013-5-006	모바일 의료용 앱 안전관리 지침	2013-12-31	Mobile Medical Apps
안내서-0095-01	의료기기 소프트웨어 밸리데이션 가이드라인	2007-01-01	Medical Device Software Validation

Medical Device vs Wellness Device

General principle for determination criteria :

The wellness device shall be identified by the intended use of the device and the potential hazards which are included in the device

Medical Device

A device like any instrument, machine, contrivance, or material which is intended to be used for human beings or animals by itself or combination with others

- For the purpose of diagnosis, therapy, alleviation, treatment, or prevention of the illness
- For the purpose of diagnosis, therapy, alleviation, or compensation of the injury or disability
- For the purpose of test, replacement, or modification of the structure or functions of the body
- For the purpose of control of the conception

Wellness Device

A device like any instrument, machine, contrivance, material, software, or application which is intended to be used for human beings by itself or combination with others

- For the purpose of maintaining or improving of the general healthy condition or activity
- For the purpose of inducing of the healthy life style or habit
- For the purpose of supporting self management for **chronic disease**

Chronic disease: Cardiac disorder, Hypertension, Hypotension, Diabetes, …

Reference: Wellness device scope announced by MFDS in 2015

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Medical Device Software?

Software is an embedded or integral part of the final medical device
SiMD = Software in Medical Device

Software is itself a medical device (software only device)
SaMD = Software as Medical Device

Reference: 안내서 0612-02 의료기기 소프트웨어 허가심사 가이드라인
Software Requirements for Medical Device Registrations

Medical Device Classifications

KMDN (Korea Medical Devices Nomenclatures)

		Examples; Software related (not limited to below)
Class I	Slight-risk medical devices	imager for medical use
Class II	Low potential risk medical devices	CT, MRI, XR, Mammo, SPECT, PET, PET-CT, PACS (hardware/software- or **software only),** software workstations (hardware/software-or **software only),** patient monitors, fetal monitors, central monitors, Telemetry systems, Patient monitoring modules, Pulse Oximeters, Ultrasound systems (except cardiovascular use, echocardiograph, echoencephalograph), Ultrasound transducers
Class III	<30 days blood contact medical devices and/or High potential risk medical devices	Ultrasound imaging sys. (cardiovascular use, echocardiograph, echoencephalograph), Ultrasound transducers for vascular surgical use, Defibrillators (under 360J), Fluorography (Fluoroscopic X-ray, Angiographic X-ray), software workstations (software imaging analyzer- or **software only**)
Class IV	>30 days blood contact medical devices and/or High potential risk medical devices	Ultrasound transducers for neural surgical use, Defibrillators(over 360J)

What is required for Registration ?

(Class II and the higher)

Technical Fil Rqmts since 2007

- *Software Structure (Architecture) and Main Functions, Algorithm*
- *Software Name, Version*
- *Software Operating Environment*
- *Software Instructions for Use, incl. User-Interface pictures, Function Descriptions*

<Required Document Appendices>

- Software Requirement Specification
- Software Architecture Specification
- Software Design Document
- Software Verification & Validation Plan
- Software Verification & Validation Report (SW V&V Report)

Technical File Rqmts from July 2015

- *Software Structure (Architecture) and Main Functions, ~~Algorithm*~~*
- *Software Name, Version*
- *Software Operating Environment (SaMD only)*
- *Software Instructions for Use, incl. User-Interface pictures, Function Descriptions*

<Required Document Appendices>

- *Software Compliance Summary Report [Appendix 13*. MFDS SW Report Form]*
- *Software Verification & Validation Report (SW V&V Report)*

Referenced to International Standards
- IEC62304 Software Life-Cycle Management*
- IEC60601-1 ED3 PEMS Requirements.

**) Appendix 13 from MFDS Notification of Medical Device Registrations, Technical Documentations*

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MFDS SW Report Form

Software Compliance Summary Report [Appendix 13. MFDS SW Report Form]*

Referenced to IEC 62304 SW LCM

- *Software Type (SiMD or SaMD)*
- *Software Functional Characteristics*
- *Software Safety Classification*
- *Software Development*
  - *- Plan*
  - *- Requirement Analysis*
  - *- Implementation*
  - *- Verification & Validation*
  - *- Release*
- *Software Maintenance & problem Solving*
- *Software Risk Management*
- *Software Configuration Management*

SW LCM shall be controlled within QMS

Software Compliance Summary Report

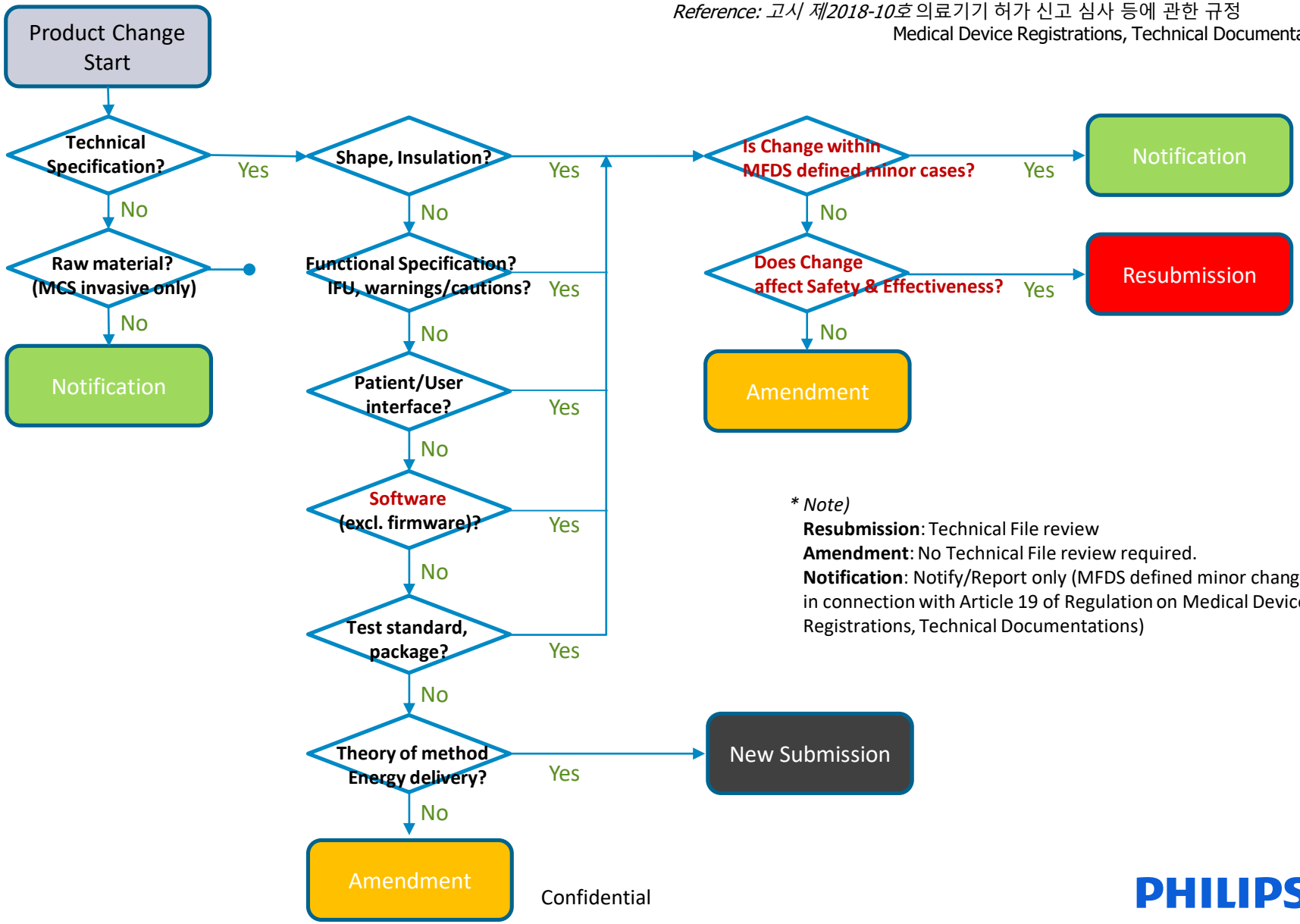
Model name		Software name/version	
Software type	□ Software is an embedded or integral part of the final medical device □ Software is itself a medical device (software only device)		
Software functional characteristics	□ control □ diagnosis □ data receiving * Multiple selection is possible	□ measurement □ data conversion □ display	□ analysis □ data transmission □ miscellaneous
Software safety classification	□ A	□ B	□ C
Software operating environment			
Software development	Software development plan		
	Software requirement analysis		
	Software implementation		
	Software verification & validation		
	Software release		
Software maintenance process and problem solving			
Software risk management			
Software configuration management			

**) Appendix 13 from MFDS Notification of Medical Device Registrations, Technical Documentations*

***) SW LCM = IEC62304 Software Life-Cycle Management*

Regulatory path for Change : Decision Tree

Reference: 고시 제2018-10호 의료기기 허가 신고 심사 등에 관한 규정
Medical Device Registrations, Technical Documentations



** Note)*
Resubmission: Technical File review
Amendment: No Technical File review required.
Notification: Notify/Report only (MFDS defined minor changes, in connection with Article 19 of Regulation on Medical Device Registrations, Technical Documentations)

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Regulatory path for Change : Timeline

Type	Description	Official Review cycle	*Examples (not limited to below)*
Resubmission	Technical File review required	42 working days	✓ Major software change ✓ New function added
Amendment	No Technical File review	10 working days	✓ Minor software change (no new function) other than MFDS defined Notification cases under regulation
Notification	Notify/Report only (Self-Declaration)	Immediately	✓ UI change (w/o safety & effectiveness) ✓ Minor bug fixes (to reflect registered specification)

Challenge to Industry

- *Frequent change of Software as a result of* ***Constant improvement***

Regulatory review for changes

- Users need to use ***the Latest and Greatest version of software***

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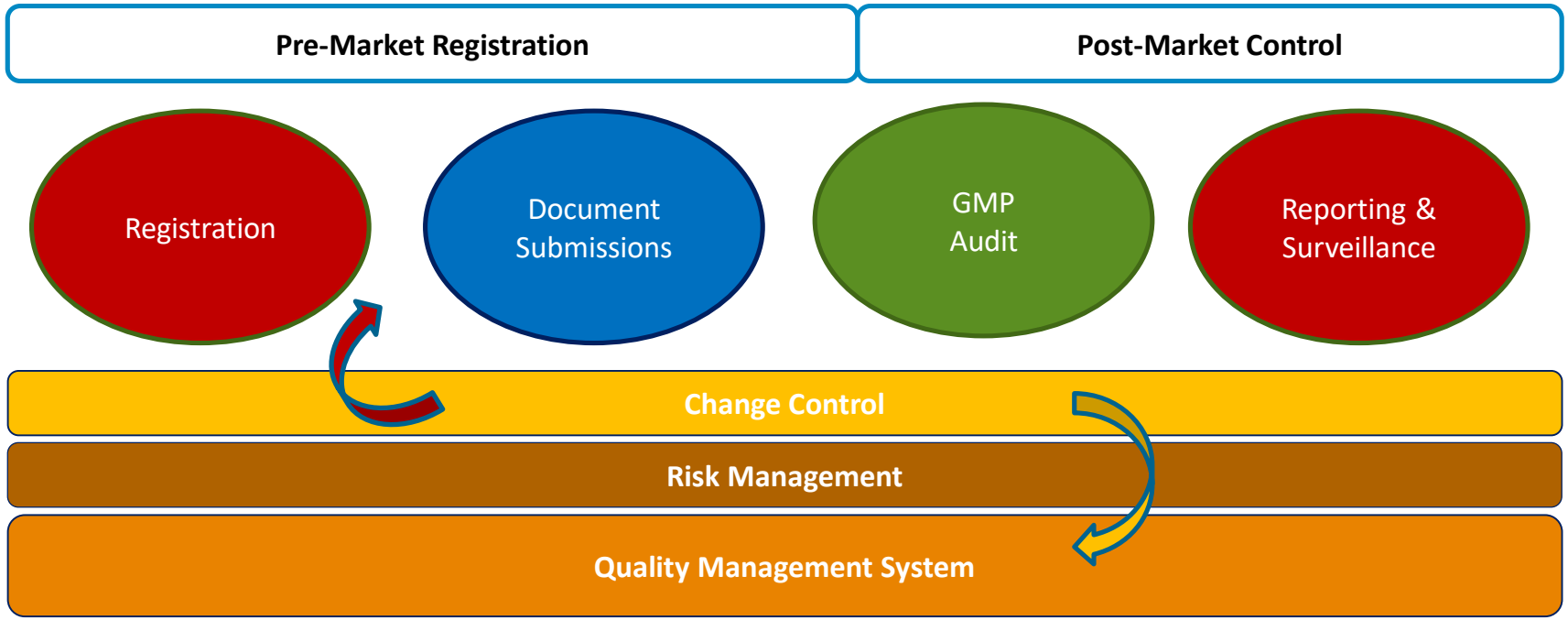
Recent change : Software version filing

As of 15 June 2018, the guideline "Software Requirements for Medical Device Registration" is revised & released by MFDS:

- ***MFDS allows the company to file software version as 1.2.x,*** *for example. 'x' means that multiple numbers acceptable.*
- *However, 3rd digit in this example must not be triggering safety and effectiveness change* ***but only bug fixes****.*
- ***This is accepted only when a manufacturer provides a documented software version control process within software configuration management in QMS as an evidence.***



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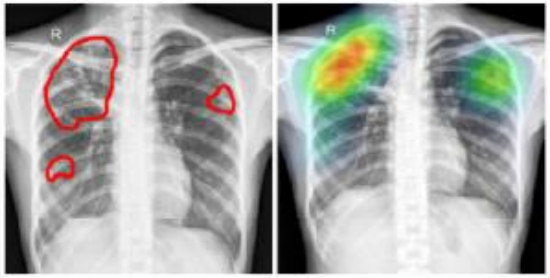
Software Requirements for Big Data and AI (Artificial intelligence) Medical Device Registration

폐결절 영상분석 SW(㈜루닛)

환자의 폐 영상에 결절의 위치와 가능성을 표시



골 연령 판단 SW(㈜뷰노)

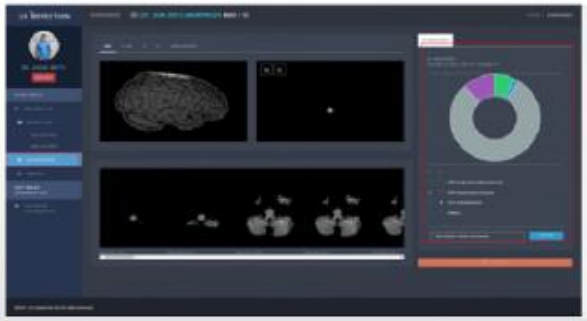
손 X-레이 사진을 이용하여 뼈의 나이(연령)를 분석

Watson for Oncology(IBM)

환자에 적합한 치료방법을 분석하여 의료진에게 제공

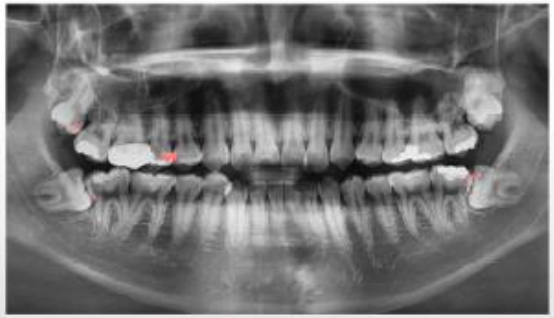
뇌경색 진단SW(㈜JLK인스펙션)

뇌MRI영상, 임상자료를 이용한 **뇌경색 병변 검출 및 유형분류**



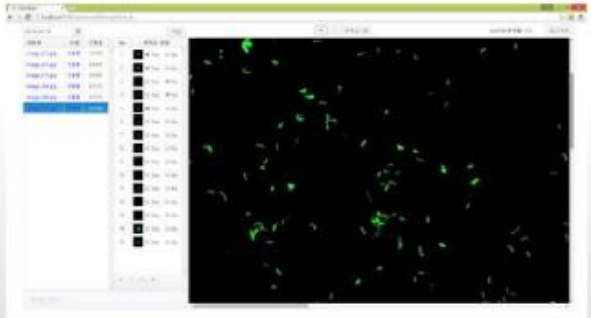
치아 우식 판별보조 SW(㈜바텍)

치아 엑스레이 사진을 이용하여 **충치를 판별**



결핵 진단SW(인스페이스)

결핵균 영상을 이용한 **결핵 진단 보조**



Pictures sourced from MFDS presentation for 2018 Medical Device Regulatory policy (dated Mar 2018)

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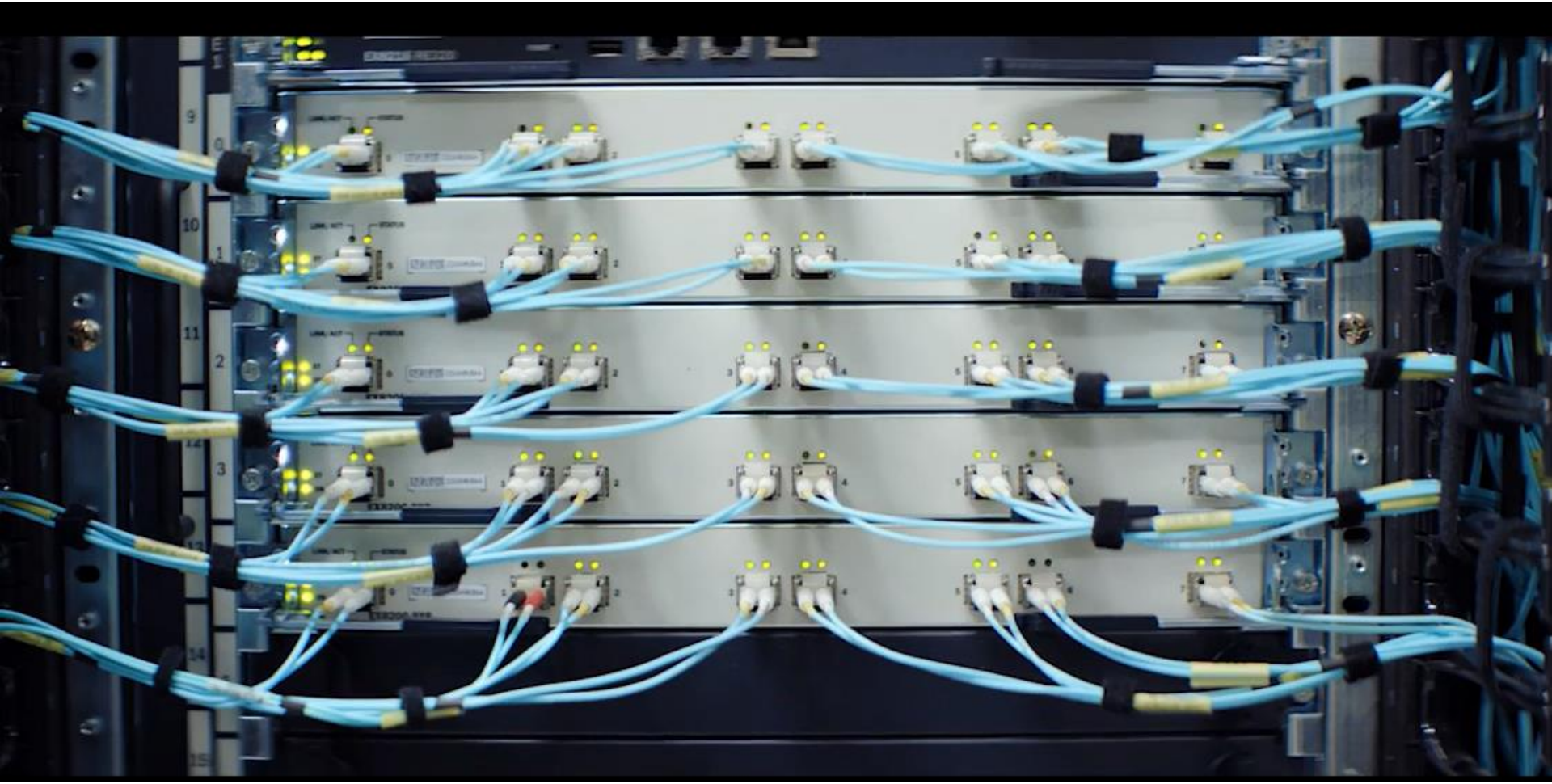
Cyber Security
for Medical Device Registration



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Real World Data &
Real World Evidence

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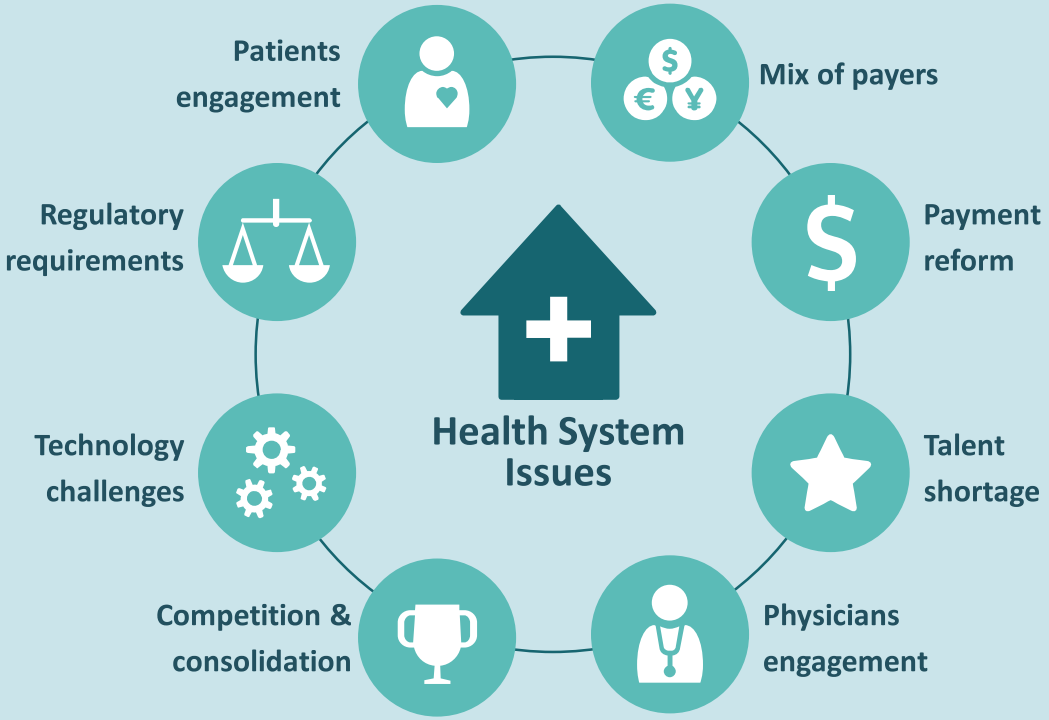
Global Health Systems are facing many challenges…

and are looking for solutions…



- Lower cost of care to offset lower reimbursement
- High quality of care
- Payer mix shift and consolidation
- System and IT integration to provide total care
- Talent attraction and retention
- Physician engagement
- Change management

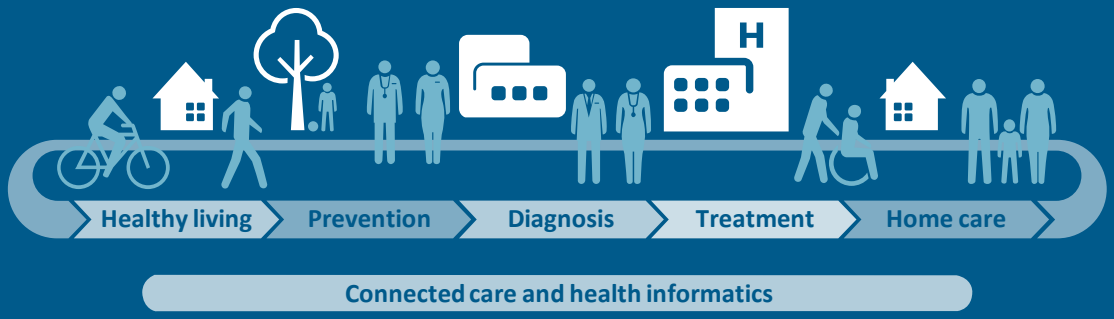
+

Unique Health Systems in Korea

- 95% private and non-profit hospitals
- Gov. controls reimburse. Policy
- Super aging population with multi chronic disease

Ready to take on the healthcare challenge

At Philips, we take a holistic view of people's health journeys, starting with healthy living and prevention, precision diagnosis and personalized treatment, through to care in the home – where the cycle to healthy living begins again.



Feeding the innovation pipeline

around

10%

R&D investments as a % of sales

~60% software focus in R&D work

~11,500

R&D professionals around the globe

47,800

design rights

62,000 patent rights

Opportunities for AI across health continuum

Clinical decision support

AI combines large amounts of medical data to generate more holistic view of patients to support clinicians' decision making process.

Population health management

Predictive insights in patient populations helps healthcare providers to take preventative action, reduce risks, and save costs.

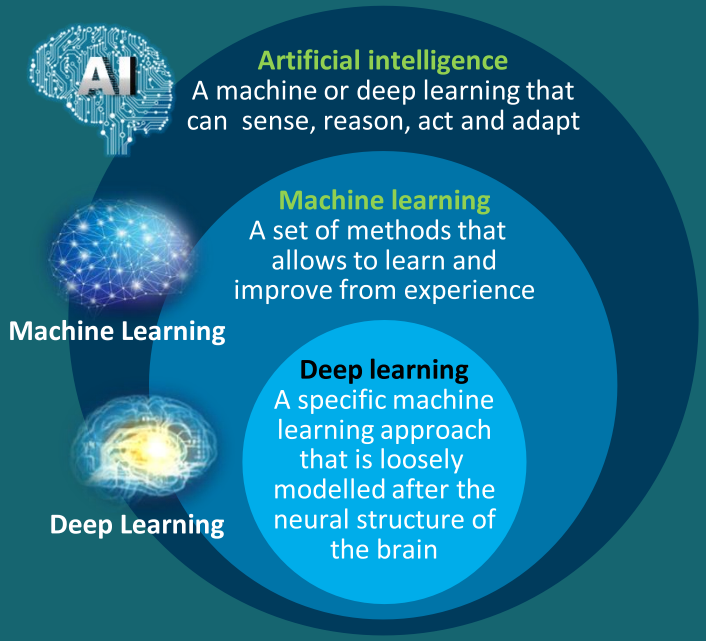
Operational optimization

Supports clinicians to optimize workflows such as planning, procedure and selecting the right exam for the right patient

Empowering patients

As AI gets embedded into solutions for home care and healthy living, this will enables people to take control over their own health.

Philips AI is Adaptive Intelligence



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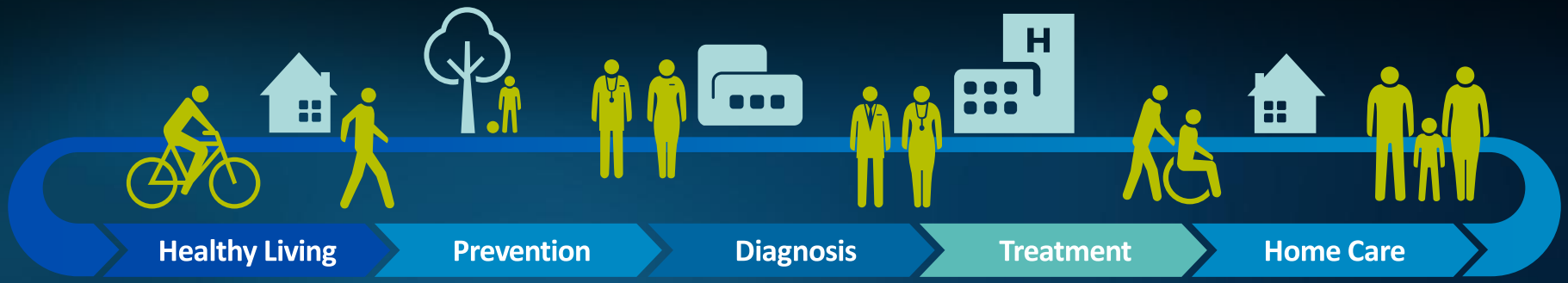
Adaptive Intelligence

Philips AI (Adaptive Intelligence) supports healthcare professionals to deliver higher care quality with enhanced clinical outcome and increased operational efficiency

Big data is gathered from multi vendors and brands

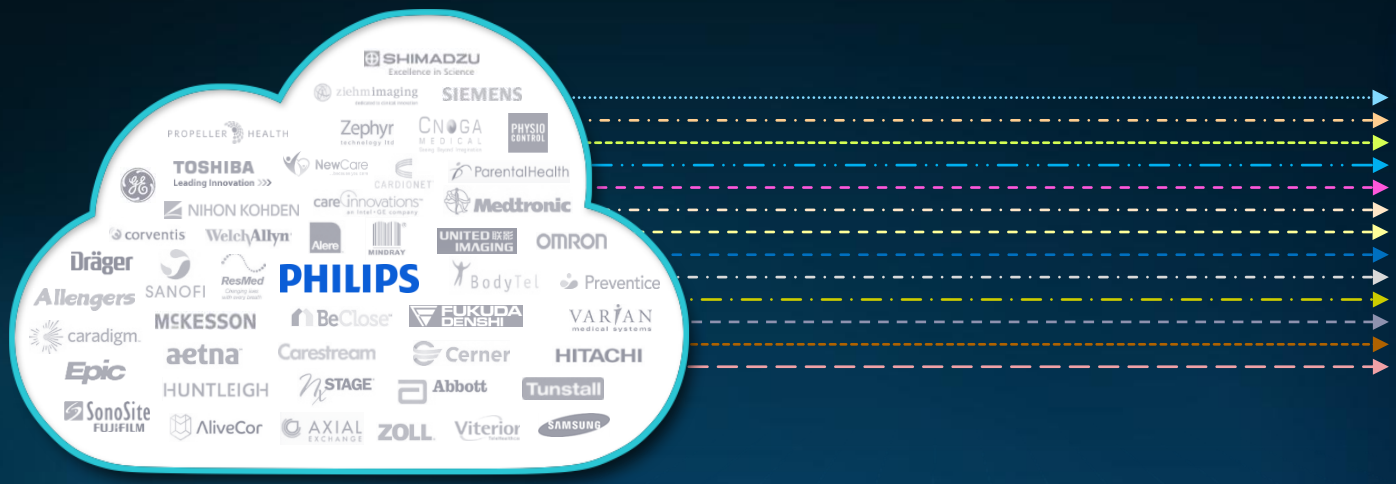


Wide (Longitudinal) Data
Continuous monitoring over time

Deep Data
More detailed info than ever before

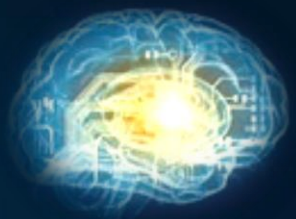
Dense Data
Big data pattern recognition

Big data is gathered from multi vendors and brands : un-filtered and un-unified data, difficult to connect with AI



BIG DATA
from
Multi Vendors/Brands

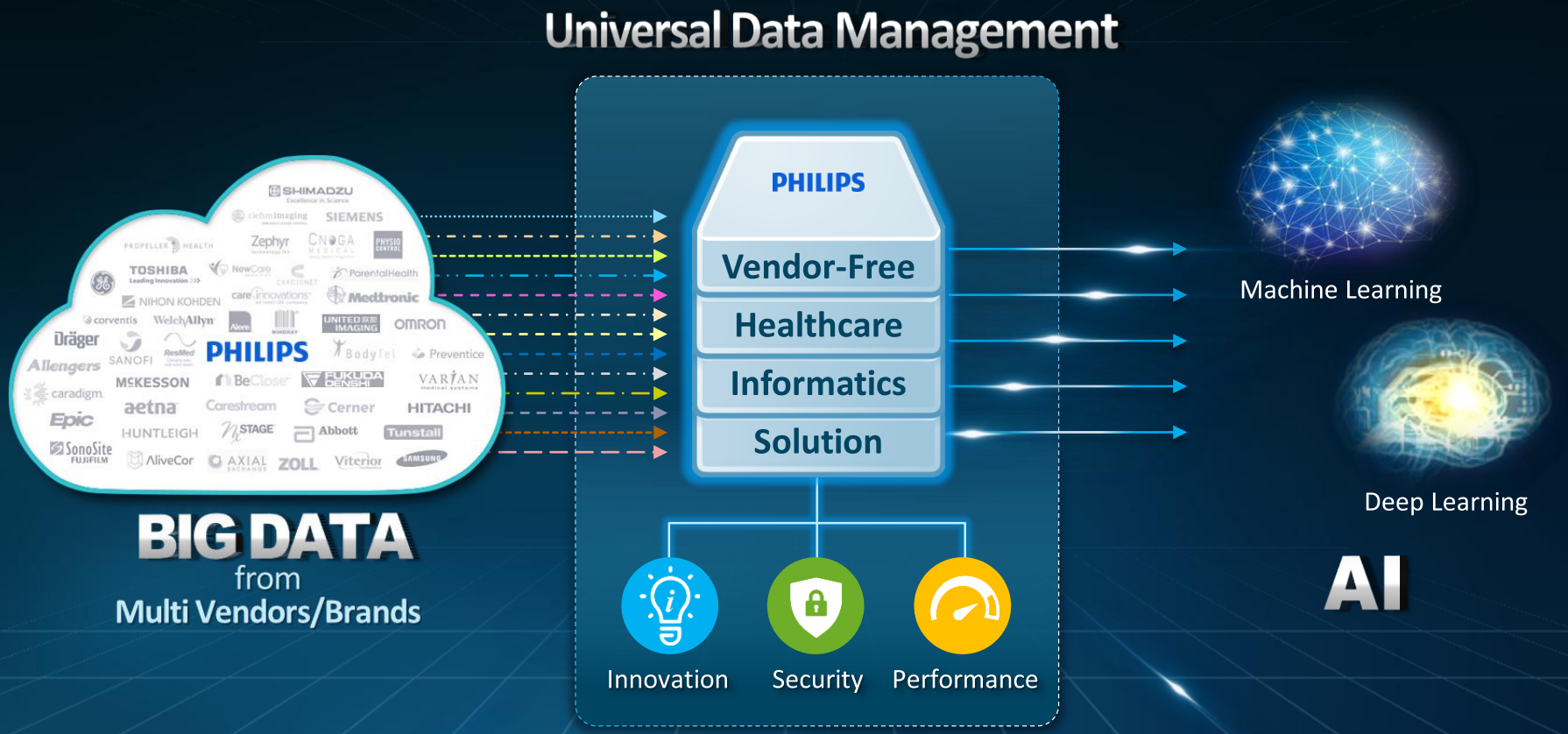
Machine Learning



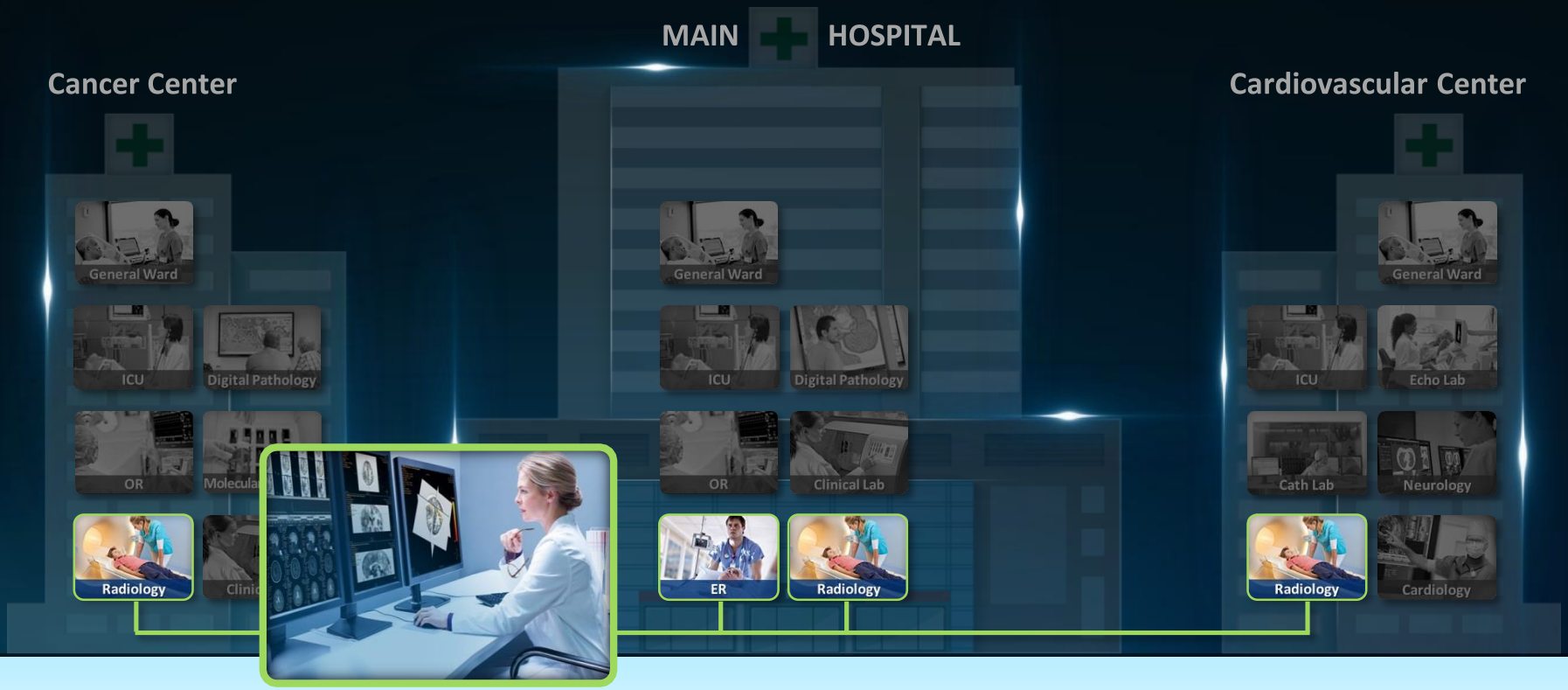
Deep Learning

AI

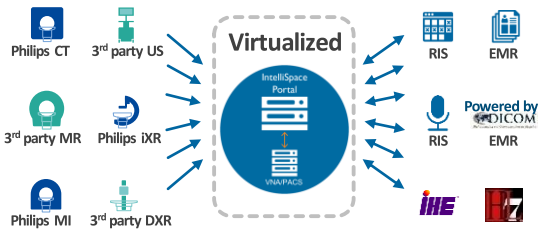
Philips provides vendor-free solutions and helps universal data management for smart hospital



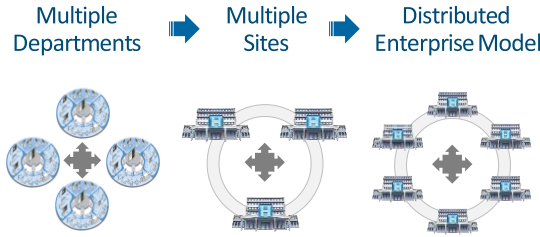
Smart Hospital: **Connected Advanced Visualization**



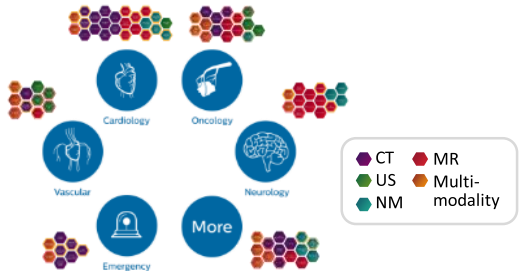
Multi-Modality / Multi-Vendor



Multi-Access



Clinical Decision Support Applications

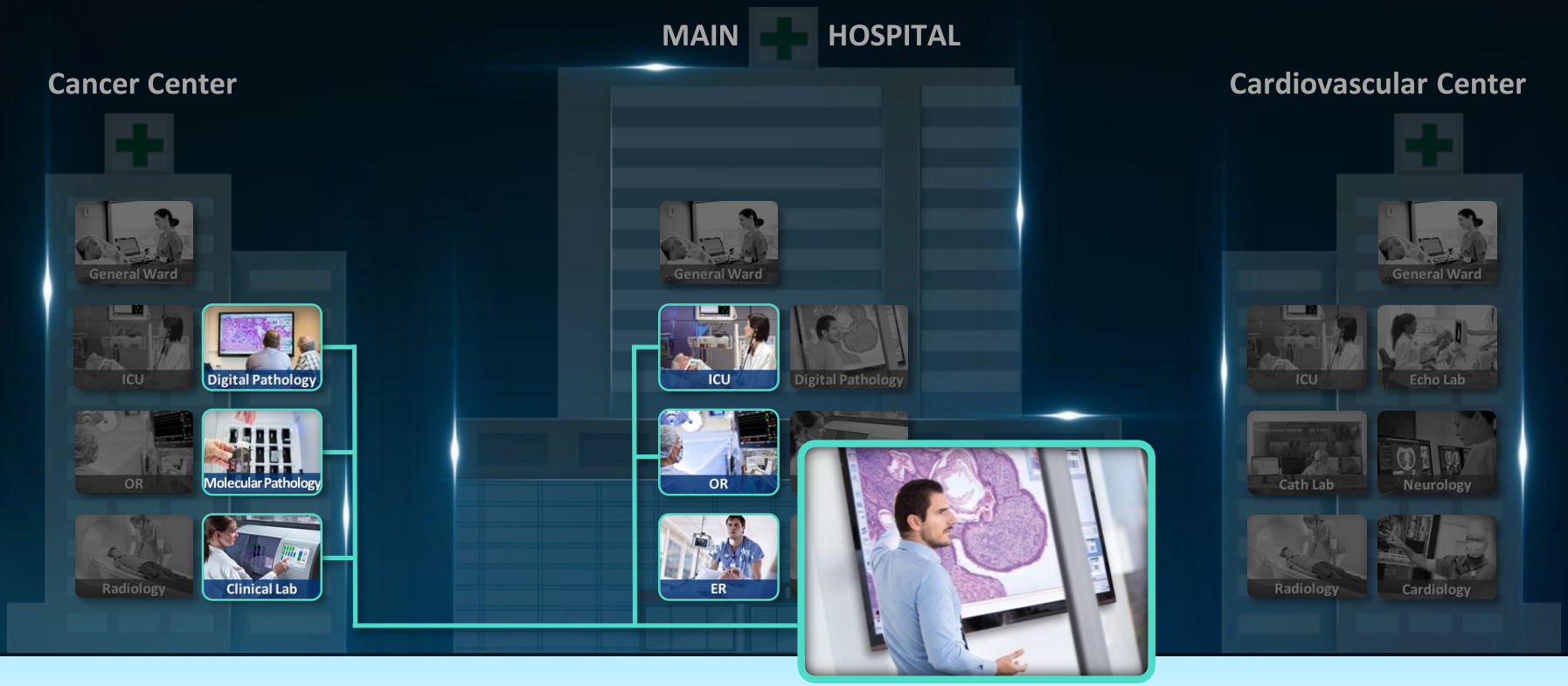


Smart Hospital: **Connected Monitoring Solution**

AI Development using DWC in 2018

- Cardiac arrest early detection
- Enhanced sepsis early detection
- Probability of re-admission

Smart Hospital: **Digital Pathology Solution**



Ultra Fast Scanner

Designed for routine use in high volume labs and integrated pathology networks.

Image Management System

To improve the efficiency and effectiveness of your pathology lab.

Pathologist Suite

Designed to get pathologists through cases as fast as possible.

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Considerations

Needs are ;

1. Regulatory Paradigm shift to be relevant in Digital Health

2. Streamlined regulatory process to support patient's Faster access to Innovative Health Technology across the regulations

For sustainable Healthcare system in 4th Industrial Revolution, the ***reliable partnership*** between the regulator and industry is needed more than ever.

Recent publication for reference :
: Deciding when to file for Medical Device Software Change

Contains Nonbinding Recommendations

Deciding When to Submit a 510(k) for a Software Change to an Existing Device

Guidance for Industry and Food and Drug Administration Staff

Document issued on October 25, 2017.

The draft of this document was issued on August 8, 2016.

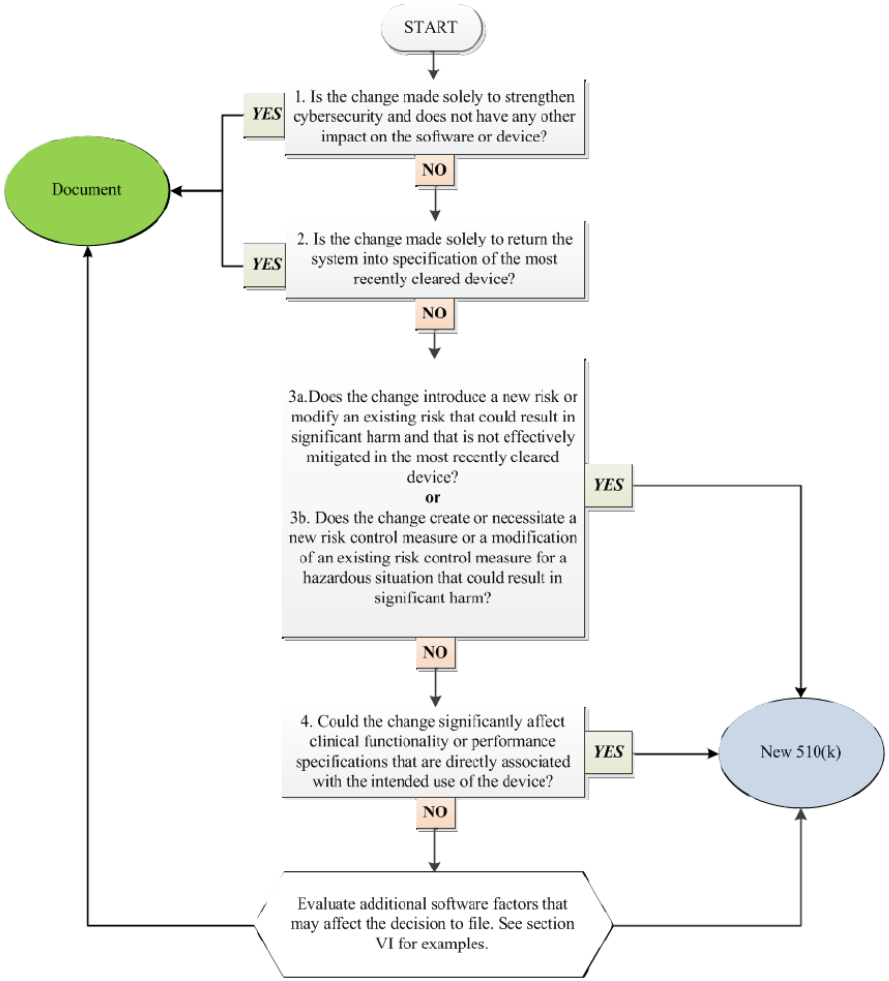
For questions about this document, contact (CDRH) Linda Ricci, Office of Device Evaluation, 301-796-6325, Linda.Ricci@fda.hhs.gov.

For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach and Development (OCOD), by calling 1-800-835-4709 or 240-402-8010.

FDA U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Service
Food and Drug Administratio

Center for Devices and Radiological Healt
Center for Biologics Evaluation and Researc



This flowchart is not intended to be used as a 'stand-alone' document and should only be considered in conjunction with the accompanying text in the guideline.

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