



IMDRF
International Medical Device
Regulators Forum

EU2023
EUROPEAN UNION
Chair



European
Commission

European
Union

PMS for AI Medical Devices

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March 28. 2023



OVERVIEW

Company Introduction

Product Overview

Worldwide registration status

PMS for AI Medical Devices

Key actions for PMS

How to conduct

AI Software

Continuous Learning Capabilities

Performance in Real World Setting

03

04

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07

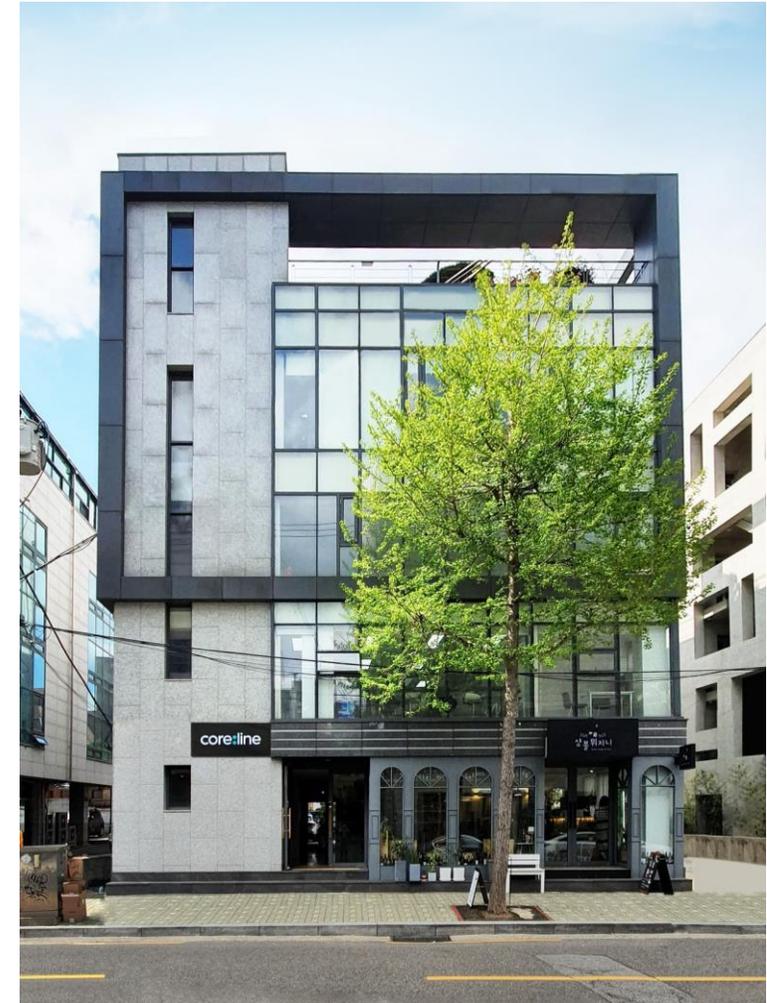
07

08

11

11

14



Company Introduction

➤ Leading large scale AI deployment

K-LUCAS

Korea

300 hospitals
(50 sites on Cloud based)



4 ITLR

EU, Nelson+

8 screening sites
in 5 countries
Full cloud operation



HANSE

Germany

3 Medical Center
Hybrid operation
(Cloud+ On-premise)



ILSP

Italy

8 IRCCS
4 Instituto Tumori
+6 University Hospitals
& Hospital Agencies

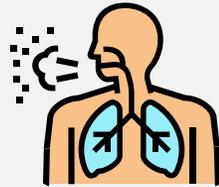


➤ Product Overview – Clinical Products

aview:LCS



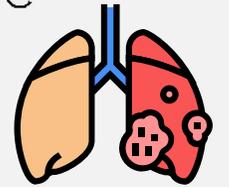
aview:COPD



aview:CAC

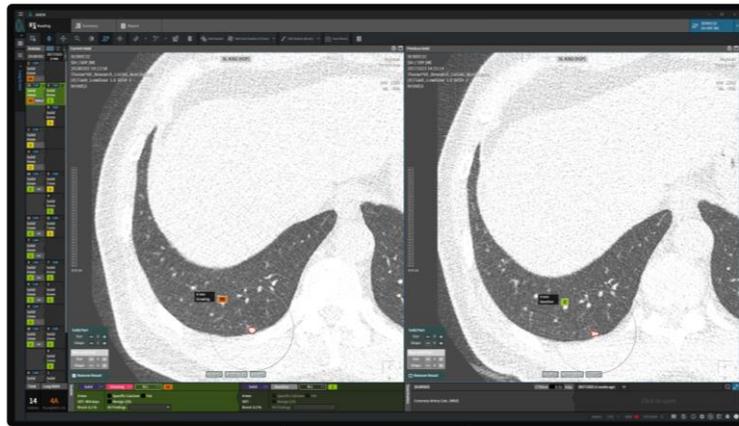


aview:
Lung Texture



Clinical products I

aview:LCS



Key Features

1. Nodule CAD Sensitivity: 0.97, Specificity: 0.7644
2. F/up Mode(Automatic Nodule Matching)
3. Lung RADS(1.0/1.1)
4. Volumetric measurement & Volume Doubling Time(VDT)
5. Brock Score calculation
6. EUPS compliance

aview:COPD

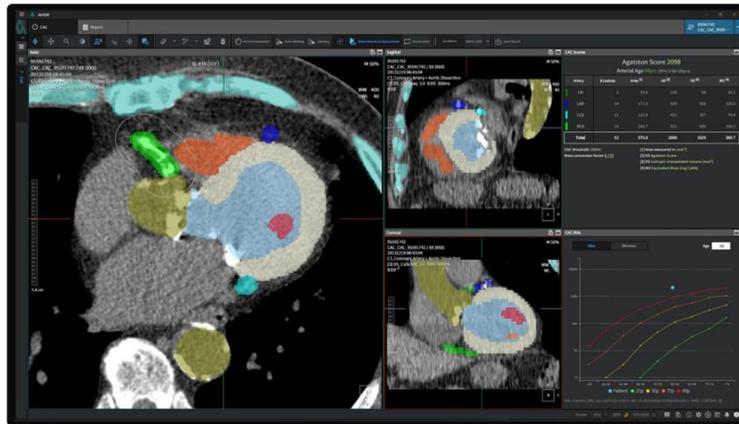


Key Features

1. Fully automated processing
2. Phenotyping
 - Emphysema
 - Airway
 - Fissure Integrity
 - Vessel

Clinical products II

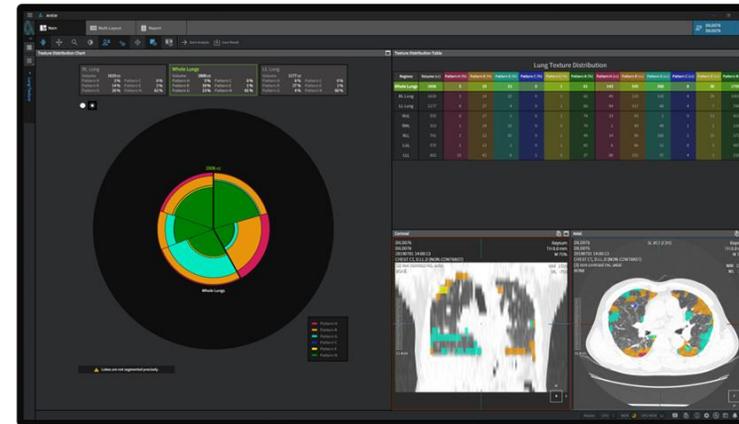
aview:CAC Non-Enhanced CTs



Key Features

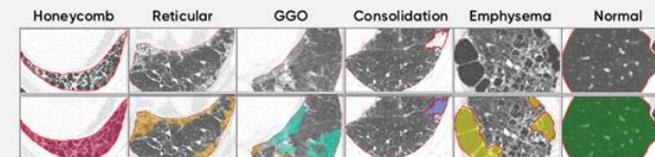
1. Fully Automated and Fast
2. Scores on each Vessel
3. Agatston, Volume and Mass Score

aview:Lung Texture



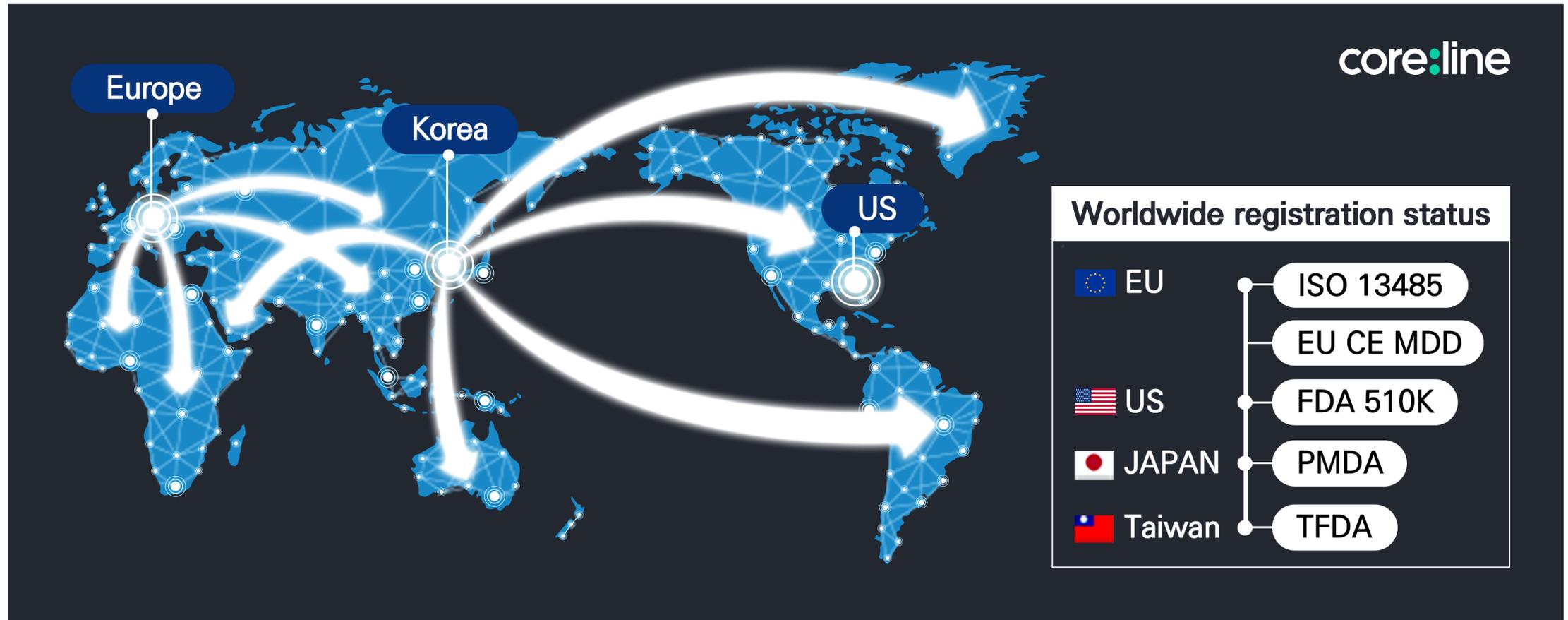
Key Features

1. Fully Automated using AI
2. Lung/Lobe segmentation based on AI
3. 6 Patterns Classification



Company Introduction

> Worldwide registration status



PMS for AI Medical Devices

➤ Key actions for PMS

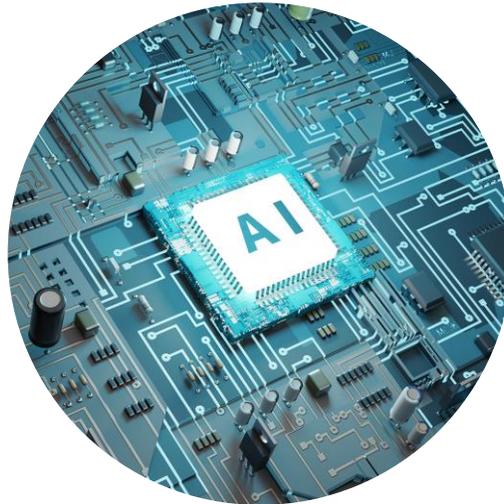
- ✓ **Vigilance Analysis**
 - **Real world Data analysis**
 - Comply with regulatory requirements
 - Safety and effectiveness
- ✓ **Literature search**
- ✓ **Cybersecurity information sharing networks searching**

PMS for AI Medical Devices

> How to conduct



01
Develop PMS plan



02
Implement the plan



03
Generate PMS
report based on the
findings

PMS for AI Medical Devices

> PMS Plan

- ✓ Collecting and analyzing data
- ✓ Following up on collected complaint
- ✓ Communicating information to regulators and users
- ✓ Taking corrective actions on devices
- ✓ Producing a PMCF (Post-Market Clinical Following-up) plan or a rationale for why PMCF is not required

PMS for AI Medical Devices

> Reporting

Region	Report Type	Details
US	Periodic Adverse Drug Experience Report (PADER/PAER)	Required by FDA
EU	Post-Market Surveillance Report (PMSR)	Required for low-risk Class I devices
	Periodic Safety Update Report (PSUR)	Required for Class IIa, Class IIb, and Class III devices
Korea	Report on production and export performance of medical devices	Reported annually
	Report on supply history of medical devices	Reported annually

AI Software

> Continuous Learning Capabilities



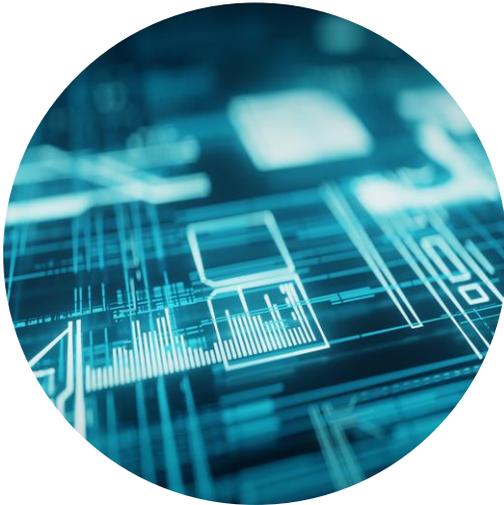
Pre-market assessment is no longer sufficient



Control the learning process and respective changes

AI Software

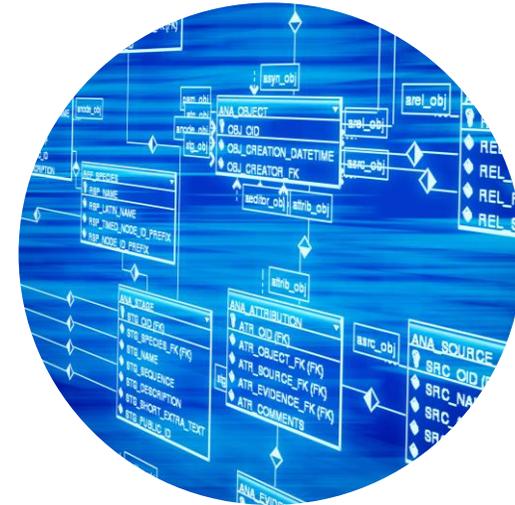
➤ Change Notification



Addition or reduction of input data type to generate the same output



Output results based on the approved input parameters (including changes for interpretation)



Approved workflow

AI Software

> Change Notification related to a continuous learning algorithm



Exclusion/inclusion criteria for input data



Defined boundaries

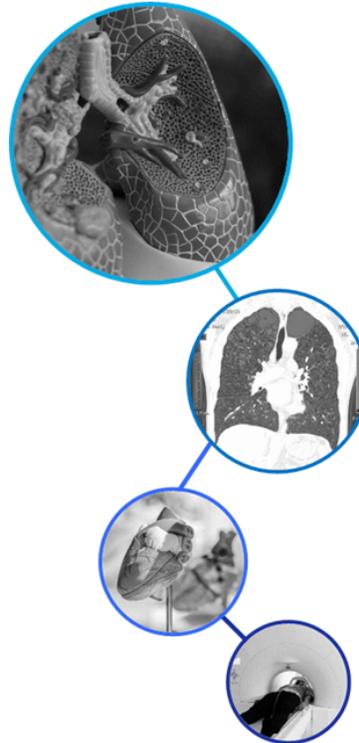


Baseline performance specifications

AI Software

> Performance in Real World Setting

- ✓ High quality machine learning from private datasets
- ✓ But, limited learning data

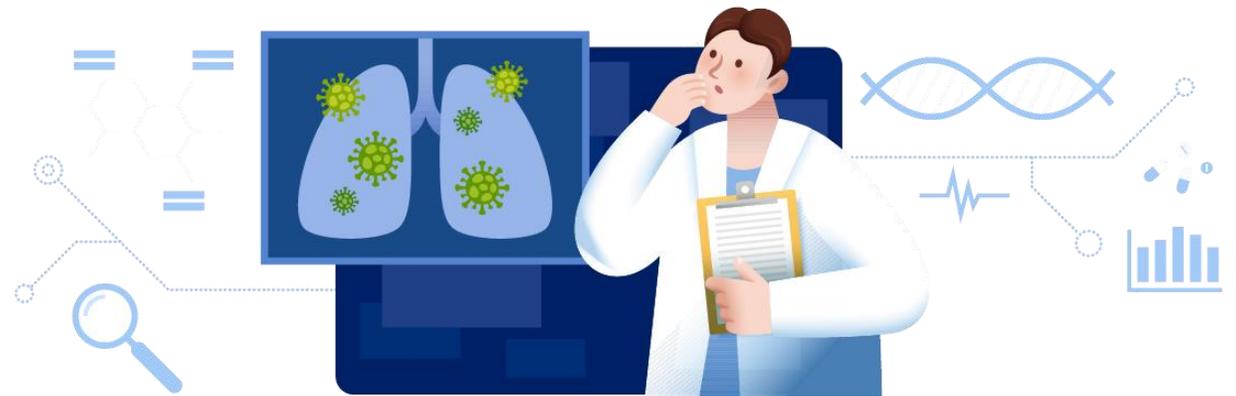


NELSON Dutch-Belgian Lung Cancer Screening Trial	<ul style="list-style-type: none">• Lung Cancer Screening• CT dataset
UKLS UK Lung Screening Trial	<ul style="list-style-type: none">• Lung Cancer Screening• CT dataset 3,000 cases
Russian LS Moscow Lung Screen Trial	<ul style="list-style-type: none">• Lung Cancer Screening• CT dataset 2,000 cases
SNUH 서울대학교병원, Collecting	<ul style="list-style-type: none">• 흉복부 전이암• CT dataset 12,200 cases
Russian LS (Korean Obstructive Lung Disease Cohort)	<ul style="list-style-type: none">• 17개 병원• 흉부 CT dataset 477 cases
ILD Project (10개 병원, Collecting)	<ul style="list-style-type: none">• 8개 병원• ILD CT dataset 762 cases
ROBINSKA (Risk Or Benefit IN Screening for Cardiovascular Diseases)	<ul style="list-style-type: none">• Coronary Artery Calcification• CT dataset (2,000 cases)
Dr. Answer (서울아산병원, 분당서울대병원, 신촌세브란스병원)	<ul style="list-style-type: none">• Coronary Artery Calcification• CT dataset (8,000 cases)
RT-ACS Project (신촌세브란스병원, 서울아산병원, Collecting)	<ul style="list-style-type: none">• 방사선종양치료 계획 Multi-Contouring• CT dataset 800 cases (목표)

AI Software

> Performance in Real World Setting

- ✔ Different setting from pre-market assessment
 - Different Data set
 - Uncontrolled clinical environment



Performance Evaluation for Real World Setting



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THANK YOU / QUESTIONS

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